

DICTAMEN PERICIAL ESPECIALIDAD DE CIRUGÍA DE MAMA

Se lleva a cabo el presente dictamen pericial a solicitud de COMPENSAR EPS para ser aportado dentro del proceso de responsabilidad civil adelantado en su contra bajo el radicado 11001310301520190050300 y que cursa ante el Juzgado 15 Civil del Circuito de Bogotá D.C.

Identificación del perito

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A. Estudios realizados

Pregrado: Universidad de la Sabana

Posgrado:

- Cirugía General Unisanitas
- Mastología Universidad CES

B. Metodología

Para llevar a cabo el presente dictamen pericial se procedió a una lectura y estudio de las historias clínicas de la usuaria Carmen Adriana González Mesa identificada con cédula de ciudadanía 51604199, sumado a la revisión y conocimiento de artículos científicos, protocolos y guías médicas relacionadas.

C. Respuestas al cuestionario

A continuación procederé a dar respuesta a las siguientes preguntas formuladas por COMPENSAR EPS:

1. Explicará el perito especialista en términos de común entendimiento ¿en qué consiste el carcinoma ductal infiltrante de seno padecido por la señora CARMEN ADRIANA GONZÁLEZ MESA?

La señora Carmen presentó en 2013 un cáncer o tumor maligno de mama derecha de tipo ductal, es decir que proviene de los conductos mamarios y el cual es el subtipo más frecuente; al diagnóstico se encontró una masa de más de 5cm, sin compromiso de los ganglios axilares, ni compromiso a distancia de otros órganos; por lo cual fue clasificado como un cT3N0M0 estadio IIB, que corresponde a un estadio intermedio de la enfermedad que va de I a IV. Además, presentaba un subtipo her2 positivo con receptores hormonales positivos bajos que permite guiar el tratamiento específico del tumor diagnosticado.

2. Explicará el profesional especializado en términos de común entendimiento ¿en qué consiste la reconstrucción mamaria?

Existen varias modalidades de reconstrucción mamaria en cáncer de mama: la inmediata que se realiza en el mismo tiempo quirúrgico del manejo del cáncer, inmediata diferida la cual se realiza unos pocos días después del manejo quirúrgico del cáncer y la diferida, la cual se realiza meses después del manejo del tumor inicial. La paciente Carmen tuvo un manejo con reconstrucción de la mama en dos tiempos en el cual en el primer tiempo quirúrgico se operó en conjunto con mastología el cáncer de mama y se realizó un colgajo local en la mama y colocación de prótesis expansora por parte de cirugía plástica. Se esperaba un segundo tiempo quirúrgico luego de la expansión mamaria progresiva, donde se cambiaba por prótesis definitiva, el cual tuvo cambio de plan quirúrgico debido a complicaciones locales del expansor no atribuibles a la conducta médica.

3. Teniendo en cuenta el contexto de la paciente CARMEN ADRIANA GONZÁLEZ MESA aclarará el perito experto ¿estaba indicado el proceso de reconstrucción mamaria para este caso? Por favor, justifique su respuesta.

Teniendo en cuenta que la paciente Carmen es una paciente joven, de 52 años al momento del diagnóstico, con un cáncer de mama que por su tamaño inicial presenta mala relación seno/tumor (es decir el tumor es muy grande para ser resecado con cirugía conservadora, con margen de seguridad y obtener un adecuado resultado estético); considero que el abordaje de reconstrucción en dos tiempos, que se realizó en la paciente que fue el adecuado, ya que provee los mejores resultados, teniendo en cuenta un adecuado tratamiento del cáncer y beneficios en estética oncológica desde la cirugía inicial.

4. Informará el perito especialista ¿cuáles son los riesgos inherentes al tratamiento reconstructivo de seno instaurado en la paciente CARMEN ADRIANA GONZÁLEZ MESA?

Existen múltiples riesgos al realizar el tratamiento reconstructivo en dos tiempos; se debe tener en cuenta que desde el momento inicial se explica al paciente que requiere mínimo dos intervenciones quirúrgicas y un aumento en el tiempo quirúrgico en la cirugía inicial que puede aumentar los riesgos inherentes la anestesia y la cirugía. Entre ellos los más importantes asociados a la anestesia son: paro cardiorrespiratorio, trombosis venosa, accidente cerebrovascular, infarto cardíaco, alergia a medicamentos, náuseas, vómito. Además, al tener una reconstrucción con prótesis tiene riesgos asociados a la cirugía como infección, sangrado, seromas o colecciones de líquido, necrosis de los colgajos (pérdida de los colgajos de piel y tejido mamario por disminución de la suplencia de sangre a los mismos), granulomas de cuerpo extraño, contractura capsular, ruptura del expansor o del implante mamario definitivo y alteración de la apariencia estética de la mama.

El riesgo de cualquier complicación desde menores hasta mayores esta descrito aproximadamente en un 30% en este tipo de intervenciones, pero se asocia principalmente a infecciones de sitio operatorio, seromas y hematomas. La tasa de pérdida del implante reportada es de alrededor de 10%, que es mucho menor a las tasas de contractura capsular que oscilan alrededor de 40%. Algunas de las complicaciones

requieren reintervenciones subsecuentes; lo cual aumento los riesgos quirúrgicos progresivamente y la fibrosis de los tejidos especialmente en pacientes sometidas a radioterapia durante el manejo del cáncer.

5. Aclarará el profesional especializado ¿a qué se refiere el hallazgo de “neoseno con contractura II-II” documentado en la historia clínica de la atención brindada a CARMEN ADRIANA GONZÁLEZ MESA el 8 de agosto de 2014?

La contractura capsular es el proceso en el cual la cápsula de tejido fibrótico que se forma normalmente alrededor de una prótesis mamaria, por ser un cuerpo extraño, forma un endurecimiento progresivo que genera deformidad y posterior dolor. La clasificación de BAKER es la forma del médico de evaluar el grado de contractura capsular de una prótesis y según eso definir el manejo. Va desde el grado 1 donde el paciente no tiene síntomas, no hay cambios en el tamaño, forma o textura de la mama, grado 2 con alteraciones estéticas menores dada por mayor firmeza al tacto del tejido, grado 3 donde las alteraciones estéticas son obvias con mayor redondez del seno, alteración de la forma del pezón, pero no hay mucho dolor y el grado 4 donde el seno ya es muy rígido, existe una alteración evidente en la forma del seno y aumenta el dolor de forma importante.

Según lo reportado en la historia clínica de cirugía plástica el 08/08/14 la señora Carmen presentaba alteración en el neoseno o seno reconstruido dado por deformidad clasificada como BAKER 2-3; este hallazgo es esperado dada la radioterapia adyuvante reciente que completó en 20/julio/14 y el cual como se plasma en la historia no generó contraindicación para el inicio de la expansión mamaria. La radioterapia es un tratamiento oncológico que tiene como efecto secundario la fibrosis de los tejidos; este varía de paciente a paciente; pero, en senos reconstruidos aumenta el grado de contractura capsular al compararlo con paciente reconstruidas que no requieren este manejo adyuvante.

6. Manifestará el perito experto si, de acuerdo con la revisión en literatura y el análisis de la historia clínica ¿estaba contraindicada la realización de mamografía en el seno derecho de la paciente CARMEN ADRIANA GONZÁLEZ MESA dada la presencia de expansor mamario?

No existe hasta la actualidad ninguna evidencia en la literatura, que la mamografía este contraindicada en pacientes con expansor mamario; por el contrario, existen múltiples estudios que avalan este estudio como uno seguro para el diagnóstico y seguimiento de pacientes con prótesis mamarias tanto expansoras como definitivas. Las tasas reportadas de complicaciones por mamografías son cercanas al 1% y se asocian a dolor secundario al procedimiento y no existe al momento una relación causal entre la mamografía y la ruptura de prótesis mamarias reportada en la literatura. Por lo tanto, no estaba contraindicada la realización de mamografía en el seno derecho reconstruido de la paciente Carmen.

7. Conceptuará el perito especialista si ¿los antecedentes propios de la paciente CARMEN ADRIANA GONZÁLEZ MESA, tales como la realización de mamoplastia de reducción previa y radioterapia, aumentaron el riesgo de complicaciones en el proceso de reconstrucción mamaria?

En el caso de la Señora Carmen existen varios factores de riesgo que aumentaron el riesgo de complicaciones en el proceso de reconstrucción, entre ellos: la mamoplastia de reducción previa, la radioterapia y las múltiples intervenciones quirúrgicas en el seno; que aumentan progresivamente la fibrosis que es el tejido cicatricial, que a su vez aumenta el riesgo de mala cicatrización de los tejidos; la contractura capsular, el dolor crónico secundario y la deformidad. Además, está el hecho de la abdominoplastia previa de la paciente que la hace no candidata a otros tipos de reconstrucción con tejido autólogo que al no requerir necesariamente prótesis podrían haber disminuido el riesgo de complicaciones secundarias a las mismas. Por otra parte, la mala adherencia a su manejo de hipertensión de base también altera la microvasculatura en todo el cuerpo y, por tanto, la cicatrización de cualquier reintervención. Todo esto aumentando el riesgo de complicaciones asociadas a los procedimientos subsecuentes a los que tuvo que ser sometida para lograr un resultado tanto oncológico como estético adecuado.

8. Haciendo uso de su conocimiento en la materia y conforme al análisis de la historia clínica de CARMEN ADRIANA GONZÁLEZ MESA, determinará el profesional especializado si ¿es posible atribuir indubitadamente la ruptura del expansor mamario a la mamografía practicada a la paciente el 9 de agosto de 2014 en ASISTIR SALUD?

La mamografía como se ha demostrado es un estudio diagnóstico seguro en pacientes con prótesis mamarias, en el caso de la señora Carmen no existen indicios clínicos o paraclínicos que permitan atribuir la ruptura del expansor mamario a la mamografía realizada el 9 de agosto de 2014. En primer lugar en la descripción del examen y en una ecografía de mama posterior del 26/08/14 no se evidencian complicaciones inherentes a la prótesis, no hay signos imagenológicos de ruptura del expansor y en segundo lugar tenemos múltiples valoraciones médicas de medicina general, medicina interna, oncología y cirugía plástica hasta el 30 de octubre de 2014, donde no existe pérdida de volumen de la mama reconstruida; el cual es el primer signo clínico de ruptura de la prótesis mamaria expansora la cual es insuflada con solución salina, y en caso de una ruptura presenta fuga inmediata hacia los tejidos circundantes y absorción del líquido por tejido adyacente. Es a partir del 14/11/14 donde se sospecha ruptura del expansor mamario, por pérdida de volumen luego de una sesión de expansión.

9. Indicará el perito experto ¿si para el momento en que se inició el proceso de expansión en la paciente CARMEN ADRIANA GONZÁLEZ MESA se advirtió alguna anomalía con el expansor mamario que desaconsejara su realización?

El proceso de expansión mamario se inició más de un mes luego de completar la radioterapia, la cual terminó el 20/06/14 y se dio orden de inicio de expansión el 8/08/14. Este orden secuencial de cirugía con reconstrucción con expansor, en el cual intraoperatorio se hace una expansión parcial según tolerancia de los tejidos; posterior radioterapia adyuvante y al finalizar la radioterapia inicio de proceso de expansión ambulatoria; es el manejo usual en pacientes con este tipo de reconstrucción. Trata de obtener el mayor volumen mamario posible, con la seguridad de una expansión progresiva de los tejidos que se encuentran en proceso de cicatrización dada la cirugía reciente y radioterapia posterior. En el

momento de inicio de la expansión mamaria, no existía ninguna anomalía clínica que lo contraindicara o desaconsejara su realización.

10. Explicará el perito especializado si ¿el examen de ecografía mamaria cuenta con sensibilidad para establecer la ruptura de un expansor mamario?

La ecografía de mama es el mejor examen para descartar una ruptura de una prótesis mamaria. La capacidad diagnóstica de la ecografía en ruptura mamaria esta reportada cercana a un 95%, con sensibilidad del 75 al 96% y especificidad del 88 al 95%; su capacidad diagnóstica es comparable con la resonancia magnética, pero con los beneficios de menor irradiación y menor duración del examen. Incluso se ha reportado una mejor capacidad diagnóstica de compromiso por infiltración de silicona a nivel de ganglios axilares de la ecografía vs la resonancia magnética. Logra diferenciar con alta veracidad un verdadero negativo de una ruptura de prótesis.

11. Conceptuará el perito especialista si ¿en la ecografía mamaria practicada el 26 de agosto de 2014 a CARMEN ADRIANA GONZÁLEZ MESA se documentó alguna alteración relacionada con el expansor mamario?

En la ecografía mamaria del 26/08/14 realizada de control a la señora Carmen no se evidencia ruptura de prótesis mamaria, no se observó ninguna particularidad en la reconstrucción; además de no encontrar signos sugestivos de recidiva tumoral.

12. Valiéndose de la historia clínica, manifestará el profesional especializado ¿a partir de qué momento se estableció que el expansor mamario implantado a la paciente CARMEN ADRIANA GONZÁLEZ MESA presentaba ruptura?

Acorde con la información de la historia clínica, en sesión de expansión del 30/10/14 la paciente describe sensación de pérdida de volumen mamario, en ese momento la profesional tratante inicia expansión lenta más frecuente para evaluar posible desuflación y se deja control clínico. Dicho control se llevó a cabo el 13/11/14 evidenciando una pérdida del volumen mamario a pesar de insuflación con solución salina; se decide suspender proceso de expansión e inician posteriormente trámites para segunda intervención quirúrgica con el fin de continuar con el proceso reconstructivo.

13. Haciendo acopio de su conocimiento técnico, lo descrito por la literatura y previo examen de la historia clínica de CARMEN ADRIANA GONZÁLEZ MESA, explicará el perito experto ¿de haberse sospechado la ruptura del expansor mamario previamente a la consulta del 13 de noviembre de 2014, se hubiera dado continuidad al proceso de expansión?

En caso de evidencia de ruptura del expansor mamario, no existe ningún beneficio en continuar insuflación del mismo; la inyección de solución salina adicional en el expansor, se perdería al salir de la

prótesis rota y difundirse de forma segura en el tejido circundante, sin lograr su objetivo que es el aumento progresivo de volumen de la mama y expansión del colgajo local. Es por esto que desde el 13/11/2014 se suspende la expansión mamaria y se pasa a un nuevo plan quirúrgico con el fin de completar el proceso de reconstrucción mamaria.

14. Conceptuará el perito experto si ¿es posible atribuir la ruptura del expansor mamario a alguna conducta médica desplegada por alguno de los profesionales que atendió a CARMEN ADRIANA GONZÁLEZ MESA? Por favor, explique su respuesta.

La causa específica de la ruptura de un expansor mamario es casi imposible de establecer, debido a que existen múltiples factores que pueden estar asociados a una ruptura de un implante, entre ellos la edad del paciente, las comorbilidades, la técnica quirúrgica, el tipo de implante utilizado, el volumen total infiltrado, el daño de la válvula del dispositivo. No obstante, en el caso de la señora Carmen lo que es claro, es que el volumen con el que fue insuflado hasta el momento de la ruptura del expansor era menor al que se tenía como meta antes de realizar un cambio por prótesis definitivo y que hasta el 13/11/2014 no se tenía ninguna evidencia clínica o imagenológica de ruptura del mismo. Es por lo tanto lógico, considerar que no existe evidencia que la pérdida de la prótesis expansora fuera causada por alguna conducta médica dentro del marco del manejo oncológico y de comorbilidades de la paciente en mención.

15. Indicará el perito especialista si ¿la contractura del neoseno es secundaria a la ruptura del expansor o si por el contrario corresponde a condiciones idiosincráticas de la paciente?

La ruptura de una prótesis expansora no es causa demostrada de contractura capsular; existen en cambio, múltiples factores que se asocian en este caso a la presencia de contractura capsular, la cual como se evidencia en la historia clínica fue progresiva hasta un grado severo. Los principales son: las cirugías previas y subsecuentes de la paciente que aumentan progresivamente el riesgo de fibrosis, el tener un cuerpo extraño en el seno como lo es la prótesis mamaria que aumenta el grado de fibrosis y esto sumado a la radioterapia que recibió durante su manejo oncológico si son factores de riesgo demostrados de riesgo de contractura capsular.

16. Informará el perito si, conforme a la revisión documental adelantada ¿se le informaron a la paciente CARMEN ADRIANA GONZÁLEZ MESA los riesgos propios de la cirugía de reconstrucción con colgajo dorsal ancho y prótesis estilo 410?

La cirugía de reconstrucción con colgajo dorsal ancho fue realizada el 18/07/16. Como se evidencia en el consentimiento informado ese día le fueron informados los posibles riesgos y complicaciones como infección, sangrado, seroma, lesión de órganos o tejidos vecinos, lesión vascular y/o neurológica, recuperación lenta de funciones corporales, cicatriz, reintervenciones, entre otros. En constancia este documento fue firmado por la paciente y un testigo.

17. Previa revisión de la historia clínica, haciendo acopio de su conocimiento técnico y lo descrito por la literatura científica, explicará el profesional especializado si ¿considera usted que el tratamiento brindado a CARMEN ADRIANA GONZÁLEZ MESA y la reconstrucción mamaria que como parte de esta se le practicó, fueron acordes a la *lex artis ad hoc*?

De acuerdo con la revisión de la historia clínica y sumado a mis conocimientos como mastóloga, considero que el cáncer de la señora Carmen de subtipo ductal infiltrante grado 2, T3N0M0 estadio IIB con subtipo her2 luminal. Recibió un manejo oncológico completo, satisfactorio y acorde a las guía internacionales de práctica clínica y evidencia que se tenía en el momento del manejo. La secuencia de quimioterapia neoadyuvante dado el compromiso localmente avanzado, con posterior mastectomía con vaciamiento axilar con reconstrucción inmediata en dos tiempos, posterior radioterapia y hormonoterapia adyuvantes; considero era un manejo acorde con la edad, expectativas funcionales y estéticas y comorbilidades de la paciente.

18. Indicará el perito experto si ¿de acuerdo con la revisión por usted realizada es posible concluir que la fluctuación en el control de la hipertensión de la paciente CARMEN ADRIANA GONZÁLEZ MESA sea consecuencia de la ruptura del expansor y/o de las intervenciones quirúrgicas subsiguientes?

Una de las comorbilidades importantes de la señora Carmen durante todo el proceso fue la hipertensión arterial; la cual es considerada de difícil manejo y especialmente complicada de manejar, dada la pobre adherencia a su tratamiento que es evidenciada a lo largo de la historia clínica. La paciente recibió múltiples medicamentos antihipertensivos incluyendo losartán, verapamilo, hidroclorotiazida, nifedipino, metoprolol con baja adherencia y baja respuesta al manejo. Sin embargo, no existe ninguna evidencia científica que el mal control de la tensión arterial sea secundario a una ruptura de prótesis expansora o de una reintervención quirúrgica; es más asociado a factores como aumento de consumo de sal y mala adherencia al manejo médico instaurado, la cual si se refleja en la historia clínica.

19. Explicará ¿qué es el “dolor neurítico” descrito en la historia clínica de la paciente CARMEN ADRIANA GONZÁLEZ MESA y cómo fue manejado?

El dolor neurítico o neuropático en paciente oncológicos es resultado de múltiples factores; la infiltración tumoral de tejidos blando, huesos o nervios lo puede causar de forma inicial; sin embargo, tras el manejo existen factores que lo pueden incrementar como cirugías y reintervenciones posteriores, quimioterapia, radioterapia, entre otros. Se caracteriza por dolor agudo persistente asociado a parestesias, disestesias y su manejo es multimodal incluyendo, manejo farmacológico y no farmacológico. En el caso de la señora Carmen el manejo fue integral recibió manejo multimodal con medicamentos como acetaminofén, diclofenaco, tramadol, paracetamol, amitriptilina, pregabalina, codeína inclusive se ofreció bloqueo paravertebral el cual no aceptó y tuvo una reintervención sobre la cicatriz del colgajo dorsal el 12/03/18 por neuroma dorsal persistente. La respuesta y tolerancia a este manejo fue variable e inconstante; sin embargo, se ofrecieron todas las posibilidades terapéuticas disponibles para la mejoría del dolor.

20. Conceptuará el perito especialista si ¿es posible afirmar que el carcinoma ductal infiltrante de seno padecido por la señora CARMEN ADRIANA GONZÁLEZ MESA fue tratado con éxito?

Acorde con el registro en la historia clínica la señora Carmen cuyo tumor fue diagnosticado en abril/13 y recibió manejo oncológico oportuno, integral y multimodal. Tuvo una respuesta satisfactoria con remisión total hasta el 2018 evidenciado clínica e imagenológicamente.

21. ¿Hay conexión entre la ruptura del expansor mamario y el dolor neurítico? De acuerdo con la historia clínica existen otras condiciones asociadas a dicho dolor neurítico?

No existe una evidencia científica actual de causalidad de dolor neurítico con una ruptura de prótesis mamaria; existen otros factores asociados como la presencia de un cáncer mamario, la intervención quirúrgica inicial y reintervenciones subsecuentes, quimioterapia y radioterapia, entre otros. Cada uno de los factores puede aumentar el dolor neuropático ya instaurado por el cáncer de mama.

D. Conclusiones:

La paciente Carmen quien fue diagnosticada en 2013 con un cáncer de mama localmente avanzado, tuvo una atención oportuna e integral, recibiendo manejo neoadyuvante con quimioterapia, posterior mastectomía + vaciamiento axilar con reconstrucción inmediata en dos tiempos y posterior radioterapia y hormonoterapia. El resultado de manejo del cáncer hasta el momento final de la historia clínica revisado fue satisfactorio, con remisión completa de la enfermedad. Durante el curso de la reconstrucción mamaria, la paciente presentó ruptura de la prótesis expansora, que no fue secundaria a la realización de la mamografía de seguimiento realizada el 9 de agosto de 2014 o a otro manejo oncológico recibido en el curso de su enfermedad. Posteriormente, presentó complicaciones asociadas al manejo reconstructivo como reintervenciones, contractura capsular severa y dolor crónico neuropático de difícil manejo; las cuales fueron manejadas de forma oportuna e integral por sus médicos tratantes, incluyendo manejo médico, reintervenciones quirúrgicas y seguimiento estricto.

E. Consideraciones

Manifiesto que no me encuentro incurso en algunas de las causales establecidas en el artículo 50 del C.G.P. y que actualmente no tengo un vínculo con Compensar EPS.

En el presente dictamen no he utilizado métodos, experimentos o investigaciones diferentes a las usadas habitualmente en el desarrollo de mi ejercicio profesional o de dictámenes periciales rendidos en otras oportunidades.

A la fecha he realizado o participado en las siguientes publicaciones:

- Presentación del póster “Patología mamaria benigna en hombres, más allá de la ginecomastia”. En el IX Congreso Nacional de Mastología del 9 al 12 de noviembre de 2022.
- Presentación del póster “Recurrencia de carcinoma de mama In Situ, experiencia en dos instituciones de alta complejidad”. En el VIII Congreso Nacional de Mastología del 13 al 16 de noviembre de 2019.
- Publicación del artículo “Supervivencia global de pacientes con cáncer de mama manejadas en la unidad de mastología de un centro de alta complejidad en Colombia. Un seguimiento a cinco años.” Publicado 31 mayo 2019 en la Revista de Senología y Patología Mamaria.
- Presentación del trabajo “Manejo mínimamente invasivo de una estenosis aórtica: disfunción de una prótesis de Edwards Sapiens” en modalidad de presentación oral en el “44º Congreso Nacional Avances en Cirugía - Simposio Nacional del Residente Quirúrgico” del 14 al 17 de agosto de 2018.
- Presentación del trabajo “Incidencia de hernias internas posteriores a gastrectomía laparoscópica en Clínica Universitaria Colombia” en modalidad de poster en el “44º Congreso Nacional Avances en Cirugía - Simposio Nacional del Residente Quirúrgico” del 14 al 17 de agosto de 2018.
- Coautora del capítulo “Páncreas ectópico” del libro “Tratado de Pancreatología” realizado por la Asociación Colombiana de Gastroenterología publicado en 2015, editorial Panamericana.

A la fecha no he rendido dictamen pericial en ningún proceso judicial. Tampoco he sido designada en procesos anteriores o en curso por parte de COMPENSAR EPS o su apoderada.

F. Bibliografía

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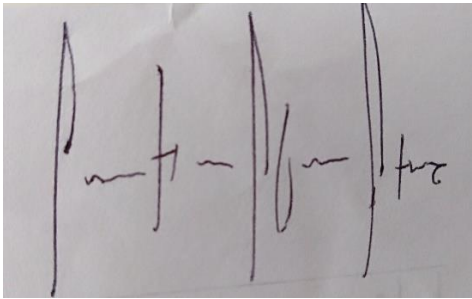
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G. Anexos

Hoja de Vida

Diplomas y títulos académicos



Dra. Camila Higuera Clavijo
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PERFIL PROFESIONAL

Soy Mastóloga de la Universidad CES de Medellín. Poseo experiencia en el área clínica y quirúrgica. Me he desempeñado en áreas como consulta externa y cirugía programada. Tengo gran capacidad de trabajo en equipo, se crear un ambiente de trabajo ameno y eficiente. La organización es, además, parte esencial de mi forma de trabajo. Soy una persona madura, responsable y con gran energía para trabajar.

EDUCACIÓN FORMAL

- Universidad CES, subespecialización en Mastología, enero de 2021 a 15 diciembre 2022.
- Universidad CES, Diplomado en Docencia universitaria, agosto 2022.
- Fundación Universitaria Sanitas, Especialización en Cirugía General, febrero 2015 a marzo 2019.
- Universidad de la Sabana, Facultad de Medicina, Médico general con énfasis en bioingeniería. Enero de 2003 a diciembre 2010.

ESTUDIOS ADICIONALES

- Participación en el curso “dolor y cuidados paliativos” realizado el 19 de septiembre de 2023 con intensidad horaria de 20 horas.

- Centro internacional de entrenamiento en emergencias, “Curso soporte vital avanzado (ACLS)” realizado el 21 de diciembre de 2022 con intensidad horaria de 48 horas.
- Participación en el “IX Congreso Nacional de Mastología” del 9 al 12 de noviembre del 2022.
- Participación en el “XXI Congreso colombiano de cáncer” del 11 al 13 de agosto 2022, con una intensidad horaria de 24 horas.
- Participación en el “Curso virtual masterclass en cáncer de mama” de marzo a julio del 2022, con una intensidad horaria de 30 horas.
- Participación en el “47 congreso semana quirúrgica nacional” del 12 – 15 de noviembre 2021.
- Participación en la “VII jornada de ética” Clínica Colsanitas el 22 de octubre del 2021 con una intensidad horaria de 6 horas.
- Participación en el “VIII Congreso Nacional de Mastología” del 13 al 16 de noviembre de 2019.
- Participación en el “Congreso Internacional Innovación, Tecnología y Humanización para el control del cáncer” realizado por el Instituto Nacional de Cancerología del 27 al 30 de agosto de 2019.
- Participación en el “45 Congreso Semana Quirúrgica Nacional” del 18 al 21 de agosto de 2019.
- Participación en el “44 Congreso Nacional avances en cirugía y 31 Congreso Panamericano de trauma” del 14 al 17 de agosto de 2018.
- Participación en el “VII Congreso Nacional de Mastología” del 16 al 18 de noviembre de 2017.
- Realización del curso “Terapia Nutricional Total” el 23 de septiembre de 2017, con una intensidad horaria de 36 horas.
- Participación en la “IV Jornada de Ética Clínica Universitaria Colombia” el 22 de septiembre de 2017 con una intensidad horaria de 5 horas.
- Participación en el “2 Congreso Internacional de Cirugía y 1 Simposio de Cirugía Pediátrica” los días 18 y 19 de mayo de 2017, con intensidad horaria de 16 horas.
- Participación en el “II simposio de nutrición Colsanitas” el 19 de mayo de 2017 con intensidad horaria de 4 horas.
- Realización en el curso virtual de “Detección temprana de cáncer de mama” el 1 de septiembre de 2016 con una intensidad horaria de 40 horas.
- Participación en el “42 Congreso Nacional Avances en cirugía” agosto 23 a 26 de 2016.
- Participación en el “XXX congreso anual Hacia la nutrición integral” del 19 al 21 de mayo de 2016.
- Participación en el “41º Congreso Nacional Avances en Cirugía José Feliz Patiño Restrepo” del 11 al 14 de agosto de 2015.
- Participación en el “I congreso internacional de cirugía” del 21 al 23 de mayo de 2015 con intensidad horaria de 20 horas.

PUBLICACIONES

- Presentación del póster “Patología mamaria benigna en hombres, más allá de la ginecomastia”. En el IX Congreso Nacional de Mastología del 9 al 12 de noviembre de 2022.
- Presentación del póster “Recurrencia de carcinoma de mama In Situ, experiencia en dos instituciones de alta complejidad”. En el VIII Congreso Nacional de Mastología del 13 al 16 de noviembre de 2019.
- Publicación del artículo "Supervivencia global de pacientes con cáncer de mama manejadas en la unidad de mastología de un centro de alta complejidad en Colombia. Un seguimiento a cinco años." Publicado 31 mayo 2019 en la Revista de Senología y Patología Mamaria.
- Presentación del trabajo “Manejo mínimamente invasivo de una estenosis aórtica: disfunción de una prótesis de Edwards Sapiens” en modalidad de presentación oral en el “44º Congreso Nacional Avances en Cirugía - Simposio Nacional del Residente Quirúrgico” del 14 al 17 de agosto de 2018.
- Presentación del trabajo “Incidencia de hernias internas posteriores a gastrectomía laparoscópica en Clínica Universitaria Colombia” en modalidad de poster en el “44º Congreso Nacional Avances en Cirugía - Simposio Nacional del Residente Quirúrgico” del 14 al 17 de agosto de 2018.
- Coautora del capítulo “Páncreas ectópico” del libro “Tratado de Pancreatología” realizado por la Asociación Colombiana de Gastroenterología publicado en 2015, editorial Panamericana.

IDIOMAS

- University of Cambridge, “Certificate in Advanced English Council of Europe level C1 – Grade B”, Vigente desde Diciembre 2011 hasta la actualidad.
- Embassy CES – Study Group Australia, “General English program with a recognition award for outstanding performance”, Nivel alcanzado: Avanzado, intensidad de 36 semanas, realizado del 3 de enero al 9 de septiembre de 2011.
- Embassy CES – Study Group Australia, “Cambridge exam preparation course for FCE (First Certificate English)”, Nivel alcanzado: avanzado, intensidad de 12 semanas, Realizado del 21 de marzo al 10 de junio de 2011.
- Embassy CES – Study Group Australia, “Cambridge exam preparation course for CAE (Cambridge Advanced English) with recognition award for outstanding performance” Nivel alcanzado: avanzado, intensidad de 12 semanas, Realizado del 12 de septiembre al 2 de diciembre del 2011.

EXPERIENCIA LABORAL

ONCOSAPIENS

Me desempeño como mastóloga desde enero de 2023 hasta la actualidad en clínica vida e Incodol en áreas de consulta externa y cirugía; manejando tanto patología benigna, como maligna de la mama.

Jefe inmediato: Dr. Fernando Herazo – Teléfono: 3146554752

MEDICÁNCER

Me desempeño como mastóloga desde junio del 2023 hasta la actualidad en medicáncer en área de consulta externa; manejando tanto patología benigna, como maligna de la mama.

Jefe inmediato: Dr. Miguel Ángel Barrios– Teléfono: 3006173363

CLÍNICA SANTA MARIA DEL LAGO

Me desempeñé como cirujana general desde Julio de 2019 hasta diciembre de 2020 en áreas de hospitalización, urgencias y salas de cirugía.

Jefe inmediato: Dra. Hernández - Teléfono: 3002135941

HOSPITAL DE ENGATIVÁ

Me desempeñé como cirujana general desde febrero hasta noviembre de 2020 en áreas de hospitalización, urgencias y salas de cirugía.

Jefe inmediato: Dr. Monsalve - Teléfono: 3187758293

CLÍNICA CHÍA

Me desempeñé como cirujana general desde octubre de 2019 hasta septiembre de 2020; en áreas de hospitalización, consulta externa, urgencias y salas de cirugía.

Jefe inmediato: Dr. Araujo - Teléfono: 3144709886

CLÍNICA COLSUBSIDIO

Me desempeñé como cirujana general desde octubre hasta diciembre de 2019 en áreas de hospitalización, consulta externa, urgencias y salas de cirugía.

Jefe inmediato: Dr. Bolívar - Teléfono: 3006170181

CLÍNICA PARTENON

Me desempeñé como cirujana general desde febrero de 2019 hasta mayo de 2019; en áreas de hospitalización, urgencias y salas de cirugía.

Jefe inmediato: Dr. Higuera - Teléfono: 3167444541

HOSPITAL DE SUBA II NIVEL

Me desempeñé como médico hospitalario del área cirugía desde agosto hasta diciembre de 2014 en áreas de hospitalización y salas de cirugía.

Jefe inmediato: Jefe Yalena - Teléfono: 3104770016

HOSPITAL PABLO VI BOSA

Me desempeñé como médico de urgencias desde marzo del 2013 hasta enero de 2014.

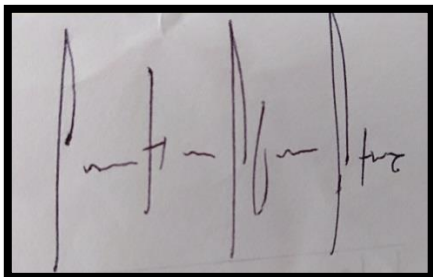
Jefe inmediato: Dra Harvy Neuta – Líder de urgencias Teléfono: 7799800

HOSPITAL SAN JOSÉ EL COCUY

Me desempeñé como médico rural desde enero 2012 hasta enero 2013.

Jefe inmediato: Dr. Harvy Silva – Gerente del hospital Teléfono: 3112633910

Camila Higuera Clavijo
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A handwritten signature in dark ink, appearing to read 'Camila Higuera Clavijo', enclosed within a black rectangular border.



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LE CONFIERE EL TÍTULO DE

Especialista en Mastología

EN TESTIMONIO DE ELLO FIRMA Y REFRENDA EL PRESENTE DIPLOMA
CON LOS RESPECTIVOS SELLOS. EXPEDIDO EN MEDELLÍN - ANTIOQUIA
A LOS 15 DÍAS DEL MES DE DICIEMBRE DE 2022

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Universidad CES

Patricia Chejne Fayad
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Decana Medicina
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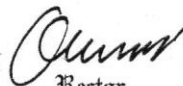
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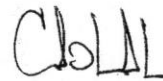
cursó y aprobó los estudios y cumplió los demás requisitos
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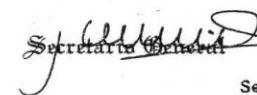
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Dado en el Campus Universitario de Chía, a los 14 días del mes de Diciembre de 2010.


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Rectoría


Decano


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Secretaria General

Personería jurídica otorgada por la
resolución 130 de Enero 14 de 1980,
Ministerio de Educación Nacional.

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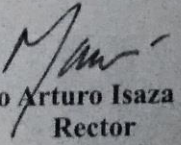
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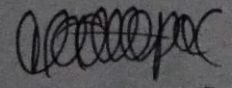
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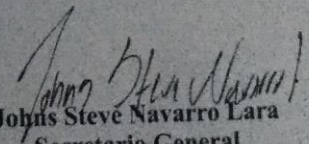
Cumplió los requisitos académicos exigidos para optar al grado de especialista, le confiere el título de

Especialista en Cirugía General

En testimonio de ello se firma y refrenda con los respectivos sellos el presente Diploma en Bogotá D.C. a los siete (07) días del mes de marzo del año dos mil diecinueve (2019)


Mario Arturo Isaza Ruget
Rector


Natalia Restrepo Centeno
Decana


John Steve Navarro Lara
Secretario General

Medellín, abril 12 de 2023

A QUIEN INTERESE

Fernando Herazo Maya, mayor de edad e identificado con cédula de ciudadanía 73.146.094 y quien actúa como Representante Legal de ONCOSAPIENS SAS.

CERTIFICA QUE

MARIA CAMILA HIGUERA CLAVJO, mayor de edad e identificado con cédula de ciudadanía 1020722947, labora con ONCOSAPIENS desde el 1 de ENERO de 2023, mediante un contrato de prestación de servicios.

La Doctora **María Camilia Higuera Clavijo**, devenga en promedio la suma de VEINTE MILLONES DE PESOS (\$ 20.000.000) mensualmente

Cualquier informacion adicional podrá ser solicitada a través nuestro contacto celular 3206482040 o al email: fherazo@oncosapiens.com

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Complications in Post-Mastectomy Immediate Breast Reconstruction: A Ten-Year Analysis of Outcomes

C.K. Mak Joanna, Ava Kwong



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Title Page

(ORIGINAL ARTICLE)

Title

Complications in Post-Mastectomy Immediate Breast Reconstruction: A Ten-Year Analysis of Outcomes

Running Title:

Ten Year Analysis of Complications in Post-Mastectomy Immediate Breast Reconstruction

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Word Count: 1752

Funding of research: None

Conflict of interest: None from all authors

Author's contribution statement:

J. Mak: Literature search, review, analysis and manuscript

A. Kwong: Manuscript preparation, supervision and final editing

Disclaimers

Abstract of this manuscript was presented at World Congress of Surgery 2019, Krakow, Poland.

Full publication of this paper has never been submitted for publication elsewhere.

Micro-abstract:

Breast reconstruction offers cosmetic and psychological advantages for women who choose to have a mastectomy. This study aims to evaluate the complications of the various options in 243 immediate breast reconstruction procedures. Re-operative complication rate was low at 6.6%. Diabetes mellitus, obesity and a free pedicle autologous reconstruction were identified as risk factors for complications.

Abstract:

Introduction: Immediate breast reconstruction offers cosmetic and psychological advantages post-mastectomy. There are various options of reconstruction and this study aims to evaluate the associated complications.

Methods: This is a single center retrospective study analyzing data from January 1st, 2008 to December 31st, 2017 for immediate breast reconstruction procedures post-mastectomy performed at an academic breast unit. Procedures included expander and implant insertion, latissimus dorsi (LD), pedicle transverse rectus abdominis musculocutaneous (pTRAM), free TRAM (fTRAM) and deep inferior epigastric perforator (DIEP). Complications and re-operative complications (defined as those requiring a reoperation within the first 30-day period), and associated risk factors were investigated using separate logistic regressions and odds ratios (OR) were calculated.

Results: A total of 243 post-mastectomy immediate breast reconstruction procedures and complications rates were analyzed. The overall complication rate was 27.6%, comprising mainly of reconstruction-specific complications such as post-TRAM hernia or bulges, fat necrosis and implant capsular contracture and leakage. The rate of re-operative complications was relatively low at 6.6%. The flap failure rate was similar between expander/implant reconstruction and autologous reconstruction methods at 3.3% and 5.6% respectively ($p=0.60$). Logistic regression identified significantly higher risks associated with diabetes mellitus (OR 5.21, $p=0.022$), obesity (OR 5.80, $p=0.016$) and free pedicle autologous reconstruction (OR 3.975, $p=0.046$) for re-operative complications.

Conclusion: Different methods of immediate breast reconstruction post-mastectomy are feasible and safe. However, patient variables and procedure choice should be taken into consideration when counseling patients on reconstructive options as they are strong predictors for postoperative complications.

Keywords: Breast cancer; complications; immediate breast reconstruction; mastectomy

Manuscript

Introduction

Breast cancer is the leading cancer for women worldwide and in Hong Kong, data has shown that one in 15 women are diagnosed with breast cancer before the age of 75 years.¹ For women who choose to have a mastectomy, breast reconstruction offers psychological and cosmetic advantages.² Advancement in surgical techniques for autologous flaps and breast prostheses have widened the options for post-mastectomy reconstruction.

In the Western populations, the reported rates of postmastectomy reconstruction range from 17% to as high as 60%.^{3,4} On the contrary, reconstruction rates in Asia are much lower, ranging from 2.6% to 18%, although the general trend has indicated this is also on the rise.⁵⁻⁷ According to the Hong Kong Hospital Authority's "10th Report of the Surgical Outcome Monitoring and Improvement Program", the rate of breast reconstruction post-mastectomy in Hong Kong's public hospitals is 11% [8], with the absolute number of breast reconstructions almost doubling within the past 10 years.⁸

Immediate breast reconstruction has been proven to be oncologically safe,⁹ although it is associated with increased operative complications when compared to mastectomy alone.¹⁰ The types of reconstruction include implant and autologous tissue reconstruction, or a combination of both. Each method of reconstruction has its own risks and benefits profile and the decision for the type of reconstruction should be individualized. The decision making remains a challenge and it should be an informed decision between the surgeon and patient based upon the assessment of risks. This study aims to evaluate the complications of the various common options of immediate breast reconstruction and identify the associated risk factors.

Methods

This is a single center retrospective study analyzing data from January 1st, 2008 to December 31st, 2017 for immediate breast reconstruction procedures post-mastectomy performed at an academic breast unit. Reconstruction was performed immediately after mastectomy during the same operation. Procedures included expander and implant insertion, latissimus dorsi (LD), pedicle transverse rectus abdominis musculocutaneous (pTRAM), free TRAM (fTRAM), deep inferior epigastric perforator (DIEP) and transverse upper gracilis (TUG) flap reconstruction. Clinical variables included procedure type, laterality (uni- vs. bilateral procedures), smoking status, body mass index (BMI), lymph node management (SLNB or axillary dissection), any chemotherapy, irradiation and medical comorbidities such as diabetes mellitus (DM) and hypertension were evaluated. Tumour characteristics including tumor size and lymph node number was assessed. Obesity was defined as having a BMI greater than 25. A complication was defined as any adverse event occurring post-operatively. A re-operative complication was defined as those requiring reoperation within the initial 30-day post-operative period.

All statistical analyses were performed on SPSS 22.0 (SPSS Inc, Chicago, IL). Categorical variables were analysed by chi-squared test and continuous variables with Student *t* test where appropriate. A multivariate logistic regressions and odds ratios (OR) were calculated in order to determine risk factors associated with postoperative complications. Statistical significance was set at 0.05.

Results

Data from 243 patients were included in the analysis. The median age of the cohort was 45.4 ($\pm$ 8.1) and the average BMI was 23 ($\pm$ 3.6). The median follow-up period was 46 months. Patient and tumor characteristics are summarized in Table 1. There were 30 implant-based reconstructions (12.3%). Implant based reconstructions consisted of purely implant reconstruction as well as a mixed type of LD and implant. Autologous reconstructions consisted of latissimus dorsi flaps or abdominal based flaps. There were 58 LD flaps (23.9%), 131 pTRAM flaps (53.9%), 17 free TRAM flaps (7.0%) and 7 DIEP flaps (2.9%).

Overall complication rate was 27.6% (Table 2). This comprised mostly of the non-acute, reconstruction-specific complications including fat necrosis, abdominal bulge or hernia, implant capsular contracture and implant leakage or displacement (Table 3). The re-operative complication rate was 6.6%, which mainly consisted of flap necrosis. The flap necrosis rate was 4.5%. No statistical difference was demonstrated in the rate of flap necrosis, nipple necrosis, wound dehiscence, hematoma formation, skin flap necrosis and seroma formation between implant-based and autologous-based reconstructions. There was no 30-day operative mortality. Table 4 outlines the risk factors associated with the complications.

Multivariate logistic regression showed that the only risk factor for overall complication was an autologous based reconstruction (odds ratio [OR] 2.24, confidence interval [CI] 1.087-5.387, $P=0.03$). This is illustrated in Table 5. Diabetes mellitus (OR 5.21, CI 1.34-47.28, $P=0.022$) and obesity (OR 5.80, CI 1.28-10.05, $P=0.016$) are independent factors associated with re-operative complications. A free-flap reconstruction was also a risk factor for postoperative major complication (OR 3.98, CI 0.08-0.98, $P=0.046$). Obesity (OR 4.43, CI 1.11-16.59, $P=0.035$) and free flap reconstruction (OR 4.67, CI 0.04-0.86, $P=0.031$) were associated with flap necrosis. The results are shown in Table 6.

Discussion

In Hong Kong, the incidence of breast cancer is rising annually, with the latest reported incidence being over 4100 cases in 2016.¹ This reflects on the need for the development of a comprehensive surgical plan. Breast reconstruction offers significant quality of life benefits post-mastectomy that are both psychological and physical.² Despite accounting for the patient's body habitus, age, medical comorbidities, availability of donor sites, prior irradiation, women are faced with a plethora of surgical options regarding breast reconstruction. Choosing the best operation requires weighing the benefits against the risks of each procedure to formulate an individualized decision. Reliable data on complication rates would be needed to assess the risks of the various methods.

Interestingly, in our cohort, we have found that there was a preference for autologous tissue rather than implant-based reconstructions. This contrasted with the Mastectomy Reconstruction Outcomes Consortium (MROC) study results, with data mainly from America, where it was predominantly implant based reconstruction.^{11,12} Multiple factors would influence this including patient preferences, cultural differences between Asian and Western populations, differences between healthcare systems, as well as surgeon factors and preferences. For example, in Hong Kong, within the public hospital setting, breast implants are self-financed items, which are paid for by the patients, whereas autologous reconstructions do not come with additional costs or fees. On the contrary, the American healthcare system is primarily private insurance based. The cost of implant based reconstruction is lower than autologous reconstruction regarding hospitalization and operation fees, as a result, patients may be more inclined to choose the more economical option.

This was a single center, retrospective study conducted at a tertiary academic unit. In the current literature, there is a paucity of Asian studies published examining post-mastectomy breast reconstruction complications. This is one of the few studies examining Chinese patients. Our overall complication rate was 27.6%, which is relatively high, but is comparable to the 2-year complication rate published by the MROC group of 32.9%.¹² The overall complications

comprised largely of fat necrosis and abdominal hernias or bulges at the donor site. Implant specific complications include capsular contracture, leakage, deflation and rupture. Using the Baker classification of breast contracture, this study included and consisted of those with grading II to IV. The rate of contracture was 40 percent, affecting twelve patients. However, on closer inspection, all twelve patients were Baker class II, which meant they had minimal breast symptoms and cosmesis was satisfactory. Multivariate logistic regression demonstrated autologous tissue based reconstruction as the sole clinical risk factor for overall complications. Autologous tissue based flaps have known donor site complications, pedicled transverse rectus abdominis muscle (pTRAM) flaps especially, have been shown to be associated with abdominal bulging and hernias in up to 63 percent and 18 percent of patients.¹³⁻¹⁵

Among the clinical variables included in the regression models, two showed significant effects on major complications. Obese patients were found to have greater risks for major complications, re-operation and flap necrosis. This finding echoes pre-existing literature that have demonstrated significant associations between obesity and postoperative complications for both implant-based and autologous tissue reconstructions.^{16,17} One systemic review of autologous flap reconstruction suggested that muscle-conserving abdominal flaps may have an advantage in reducing morbidity in obese patients, and may be considered the surgical option of choice.¹⁷ Theoretically, patients should undergo weight reduction prior to mastectomy and reconstruction for a better outcome; however, the feasibility is questionable since weight reduction can be a lengthy process and should not interfere with the timing of surgery.

Not surprisingly, diabetes mellitus was associated with greater risks for major complications and re-operation. Similar to obesity, the association between diabetes and postoperative complications for breast reconstruction has been established in literature. Nonetheless, there appears to be a more established association between diabetes and implant-based reconstruction, with a heightened risk of wound healing complications, compared to a less defined association between diabetics and autologous-flap based reconstructions.^{18,19} There have been reports suggesting delayed breast reconstruction after the mastectomy decreased postoperative morbidity in diabetics.²⁰

In the current study, smoking was not identified as a risk factor for post-operative complications although statistical significance may not have been achieved due to the few numbers of active smokers in the patient population.

Previous investigations have shown that current smokers are at an increased risk for post-reconstruction flap and donor site complications.^{21,22} Smoking cessation for even a short duration of four weeks was found to decrease total post-operative complications.²³

This analysis did not find any significant effects by chemotherapy on complications in breast reconstruction, which confirms the findings in literature of previous studies.^{24,25} On the contrary, studies have shown that irradiation during and following reconstruction was associated with higher complication rates compared to non-irradiated reconstructions although this analysis did not find any significant effect.^{11,12} Literature has shown that outcomes of autologous tissue reconstructions performed better than implant-based reconstructions in the setting of postmastectomy radiation therapy.²⁶⁻²⁹

In the literature, bilateral reconstructions are associated with greater risks for complications.^{11,12} This cohort failed to demonstrate any associations although the calculated p value was low, it was not statistically significant, which partly, may be explained by a small case number of bilateral reconstructions. This information would be relevant to patients with bilateral breast cancers, as well as those high-risk genetic carrier patients seeking prophylactic mastectomies, with or without unilateral breast cancers.

The retrospective nature and non-randomized nature of this study has the limitation for possible selection bias. A randomized controlled trial would better control the potential confounding factors; however, this would be difficult as surgeons and patients have their own preferences for the procedure type, and ultimately, the decision would be the patient's choice.

In conclusion, risk factors associated with post-mastectomy breast reconstruction complications for breast cancer include obesity and diabetes mellitus. Adverse events did not lead to reconstruction failure, and successful reconstruction was achieved in majority of the patients. Women undergoing reconstruction after mastectomy should demonstrate a comprehensive understanding on the risks and benefits during the consent process to aid the decision of a suitable reconstructive option.

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Table 1: Clinical characteristics by reconstruction type

Characteristic	Total (n=243)	Implant (n=30)	Flap (n=213)	p value
Age (years) [†]	45.4 ± 8.1	39.2 ± 7.1	46.3 ± 7.9	<0.001
BMI (kg/m ²) [†]	23.0 ± 3.6	23.2 ± 5.8	23.0 ± 3.3	0.782
Diabetes mellitus	6 (2.5)	5 (2.5)	1 (3.3)	0.745
Smoking history	28 (11.5)	8 (26.7)	20 (9.4)	0.014
Hypertension	26 (6.6)	0 (0)	16 (7.5)	0.120
Laterality				
Unilateral	226 (93)	21 (70)	205 (96.2)	<0.001
Bilateral	17 (7)	9 (30)	8 (3.8)	
Tumor size (mm) [†]	21.8 (0 to 300)	14.3 (0 to 80)	22.8 (0 to 300)	0.157
Total number positive LN [§]	11.2 ± 8.3	6.5 ± 6.3	11.9 ± 8.3	0.001
Axillary Surgery				0.028
SLNB	86 (35.4)	16 (53.3)	70 (32.9)	
AD	157 (64.6)	14 (46.7)	143 (67.1)	
Chemotherapy- During and/or after	153 (63)	14 (46.7)	139 (65.3)	0.048
Neoadjuvant	76 (31.3)	6 (20)	70 (32.9)	0.155
Adjuvant	84 (34.6)	8 (26.7)	76 (35.7)	0.331
Radiation	111 (45.7)	7 (23.3)	104 (48.8)	0.009

Statistically significant values ($p < 0.05$) are given in bold.

BMI body mass index, SLNB sentinel lymph node biopsy, AD axillary dissection

*There were 7 patient who received neoadjuvant and adjuvant chemotherapy.

[†]Mean with range are presented for age, BMI, tumor size and total number of axillary LNs.

Table 2: Post-operative complication rate by reconstruction type

	Total (n=243)	Flap (n=213)	Implant (n=30)	p value
Overall complications	67 (27.6)	52 (24.4)	15 (50)	0.003
Re-operative complications	16 (6.6)	14 (6.6)	2 (6.7)	0.985

Statistically significant values ($p < 0.05$) are given in bold

Table 3: Breast and Donor site: Type of Complication by Reconstruction Type

	Total (n=243)	Implant (n=30)	Flap (n=213)	p value
<i>Re-operative Complication</i>				
Flap necrosis	11 (4.5)	1 (3.3)	10 (4.7)	0.737
Nipple necrosis	2 (0.8)	1 (3.3)	1 (0.5)	0.104
Wound dehiscence	2 (0.8)	0 (0)	2 (0.9)	0.594
Hematoma	1 (0.4)	0 (0)	1 (0.5)	0.901
<i>Overall complications</i>				
Mastectomy skin flap necrosis	1 (0.4)	0 (0)	1 (0.5)	0.701
Seroma	2 (0.8)	0 (0)	2 (0.9)	0.594
<i>Reconstruction-Type Specific Complication</i>				
Capsular contracture	12 (4.9)	12 (40)	-	<0.001
Implant leak/rupture/deflation	1 (0.4)	1 (3.3)	-	0.008

Chronic fat necrosis	12 (4.9)	-	12 (5.6)*	0.182
Abdominal wall bulge, or hernia	22 (9.1)	-	22 (10.3)*	0.065

Statistically significant values ($p < 0.05$) are given in bold

*All of these patients received an abdominal flap

Table 4. Clinical characteristics for risk factors associated with complications and re-operative complications

	Overall Complications (%)	<i>p</i> value	Re-operative complications (%)	<i>p</i> value
Age >65	0 (0)	0.427	0 (0)	0.706
Current Smoker	7 (10.4)	0.977	2 (13.3)	0.661
Hypertension	4 (6.0)	0.812	1 (12.5)	0.231
Diabetes mellitus	2 (3.0)	0.749	14 (87.5)	0.007
Obesity	20 (29.9)	0.066	8 (50)	0.011
Laterality (ref: unilateral)				
Bilateral	8 (11.9)	0.062	3 (18.8)	0.057
Axillary Surgery (with reference to SLNB)				
AD	39 (58.2)	0.198	12 (75)	0.368
Reconstruction type (ref: implant)				

Autologous Tissue	52 (77.6)	0.003	14 (87.5)	0.985
Type of Autologous Tissue reconstruction (Ref: Pedicle)				
Free flap	7 (13.5)	0.565	4 (28.6)	0.035
Chemotherapy- before and/or after	37 (55.2)	0.123	7 (44.8)	0.565
Radiotherapy	25 (37.3)	0.873	8 (57.1)	0.873

Statistically significant values ($p < 0.05$) are given in bold

SLNB sentinel lymph node biopsy, AD axillary dissection

Table 5. Multivariate logistic regression for overall complications

	Odds ratio	95% CI	<i>p</i> value
Reconstruction type (ref: Implant)			
Autologous Tissue Flap	2.242	1.087-5.387	0.030

Statistically significant values ($p < 0.05$) are given in bold

Table 6. Multivariate logistic regression for re-operative complications

	Odds ratio	95% CI	<i>p</i> value
Diabetes mellitus	5.213	1.341-47.284	0.022

Obesity	5.798	1.267-10.049	0.016
Type of Autologous Tissue reconstruction (Ref: Pedicle)			
Free Flap	3.975	0.081-0.979	0.046

Statistically significant values ($p < 0.05$) are given in bold

Surgeon-Controlled Comparison of Direct-to-Implant and 2-Stage Tissue Expander–Implant Immediate Breast Reconstruction Outcomes

Vitali Azouz, MD, Stephen Lopez, MD, and Douglas S. Wagner, MD

Background: Current literature comparing outcomes of immediate breast reconstruction using direct-to-implant (DTI) single-stage and 2-stage tissue expanders (TEs) is conflicting. This study compared overall outcomes and determined predictive patient factors associated with higher complication rates.

Methods: After institutional review board approval, a retrospective cohort study of consecutive patients who underwent immediate breast reconstruction from 2010 to 2014 at a single hospital was performed. Demographic data and complications were recorded and compared using univariate analysis. Infection was defined as any patient receiving antibiotics beyond the expected postoperative course or restarting antibiotics for a suspected infection.

Results: Seventy-nine breasts (50 patients) underwent immediate breast reconstruction using tissue expansion, and 117 breasts (69 patients) underwent immediate breast reconstruction using the DTI technique. Overall complications, infection rate, and rate of aesthetic revisions were higher in the TE group compared with the DTI group. There was no difference in rates of seroma, hematoma, and mastectomy skin flap necrosis between the 2 groups. Infectious complications were significantly higher in patients with body mass index of greater than 30 who underwent TE-based reconstruction than those who underwent DTI-based reconstruction.

Conclusions: Single-stage DTI immediate breast reconstruction has less overall complications than 2-stage TE-based immediate reconstruction. Direct-to-implant immediate breast reconstruction may provide favorable outcomes in patients with body mass index of greater than 30.

Key Words: immediate breast reconstruction, tissue expanders, direct-to-implant, 2-stage breast reconstruction, single-stage breast reconstruction, infection, postoperative complications, implant-based breast reconstruction

(*Ann Plast Surg* 2017;00: 00–00)

As the incidence of mastectomy increases owing to advances in genetic screening, imaging technology, breast cancer incidence, and patient preference, the rates of breast reconstruction have risen accordingly. From 2000 to 2015, breast reconstructions have increased by 35% in the United States, with most of breast reconstructions performed being implant based.¹ The techniques of implant-based immediate breast reconstruction, including 2-stage tissue expanders (TEs) and direct-to-implant (DTI) placement, are well described and widely practiced.² Currently, TEs are the preferred choice of reconstruction representing 72.6% of breast reconstruction performed in 2015.¹ Direct-to-implant, however, presents opportunities for improvement. The single-stage

nature of the operation bypasses both the expansion period and secondary implant placement procedure, a process requiring several months to achieve final reconstruction.³ Direct-to-implant using acellular dermal matrix has also been shown to be more cost-effective than TE.⁴ For these reasons, DTI has become increasingly popular over the past decade.⁵ Although recent studies have compared aesthetic outcomes and complication rates between TE and DTI, the literature is conflicting.

The goal of this study is to compare overall outcomes, in regards to complication and aesthetic revision rates, of TE versus DTI immediate breast reconstruction in a single surgeon's experience. In addition, this study seeks to determine which patient factors may be associated with higher complication and revision rates, as a predictive factor to be used in patient selection.

METHODS

After institutional review board approval, a retrospective analysis of patients who underwent immediate breast reconstruction with either tissue expansion or direct-to-implant technique at Summa Health Hospital, Akron, Ohio, from 2010 to 2014 was performed. This cohort represented consecutive patients from a single plastic surgeon at a single institution. Patients who underwent delayed breast reconstruction were excluded from this study. Mastectomies were performed by 1 of 5 established general surgeons on staff at our institution. From 2010 to 2012, the plastic surgeon predominately performed immediate breast reconstruction using TEs. From 2012 to 2014, the plastic surgeon changed his practice to predominately perform immediate breast reconstruction using the direct-to-implant technique. For both cohorts, the plastic surgeon developed a subpectoral pocket for the prosthesis by elevating the pectoralis major and suturing perforated AlloDerm RTU (LifeCell Corporation, Branchburg, NJ) as an inferolateral sling as described in the literature. Two 7-mm axiomed drains, 1 in the subcutaneous plane and 1 deep to the AlloDerm were placed. Prostheses were placed using the no-touch technique with an introducer sleeve. Triple antibiotic irrigation was used in nearly all cases. For the 2-staged group, Deraspan low pole plus full height textured surface TEs (Surgical Specialty Products Inc, Victor, Mont) were used with an initial fill volume of 120 to 600 mL. For the single-staged group, 250 mL to 800 mL smooth round silicone gel implants (Mentor Corporation, Santa Barbara, Calif) were used. The type of implants and acellular dermal matrix used during this time period was consistent during the study period. Postoperatively, patients were followed up weekly for the first month and once every 3 months for a year. Drains were placed only during the initial reconstruction and not during the implant exchanged. Prophylactic antibiotics were continued until drains were removed. Drains were removed when the daily output was less than 25 mL/d, which on average was no longer than 2 weeks.

Demographic data obtained retrospectively for patients in the TE and DTI groups included the following: body mass index, age, smoking status, diabetes, preoperative and postoperative radiation, preoperative and postoperative chemotherapy, previous breast surgeries, and mastectomy type. Overall complications including infection, mastectomy skin necrosis, fat necrosis, implant loss, delayed wound healing, hematoma, seroma, capsular contracture, and subsequent aesthetic revisions were

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recorded. To allow for comparison with current literature, we elected to use a single breast as a unit of analysis.

In this study, infection was defined as any patient receiving antibiotics beyond the expected postoperative course or restarting antibiotics for erythema or suspected infection. Infections occurring before and after 30 postoperative days from the initial reconstruction were recorded. Seroma was defined as any fluid collection that developed after drain removal. This included fluid collections that were aspirated and those that did not require aspiration. Mastectomy skin flap necrosis was defined as any tissue ischemic changes that occurred from partial thick to full thickness whether debrided or not. Capsular contracture was defined as Baker contracture classification grades III and IV.⁶ Aesthetic revisions were determined by the plastic surgeon and were defined as the following subsequent procedures: dog-ear revision, scar revisions, fat grafting, revisions for asymmetry, and size change.

Using SPSS v21.0 software, statistical analysis was performed using Student *t* test for numeric data and either Pearson χ^2 or Fisher exact test for categorical data. Univariate analysis was used to identify and calculate odds ratios with 95% confidence intervals. A value of $P \leq 0.05$ was considered statistically significant.

RESULTS

One hundred ninety-six breasts (119 patients) met the selection criteria for our study. Seventy-nine breasts (50 patients) underwent immediate breast reconstruction using tissue expansion. Thirteen breasts (8 patients) were performed after the primary surgeon shifted his practice. Five patients (9 breasts) underwent planned TE reconstruction owing to significant preoperative asymmetry and inadequate soft tissue coverage. Two patients (4 breasts) were converted intraoperatively from planned DTI to TE owing to ischemic mastectomy skin flaps. Of the 13 breasts that underwent TE reconstruction during the DTI era, 3 breasts had complications. Two breasts were treated with oral antibiotics for infection, and 1 breast developed a seroma. One hundred seventeen breasts (69 patients) underwent immediate breast reconstruction using the direct-to-implant technique. Most patients in our study had stage 0 cancer or underwent prophylactic mastectomy ($n = 196$, 69.9%; Fig. 1). The mean follow-up for our cohorts was 14.7 months. The mean patient body mass index (BMI) was 27.1, and mean patient age was 49 years old. Approximately two thirds of patients underwent bilateral reconstruction (66.4%), and one third underwent unilateral reconstruction (33.3%) (Table 1). Demographic parameters were similar between both cohorts. The only parameter that differed was the mastectomy type. The TE group had a greater number of skin-sparing mastectomies

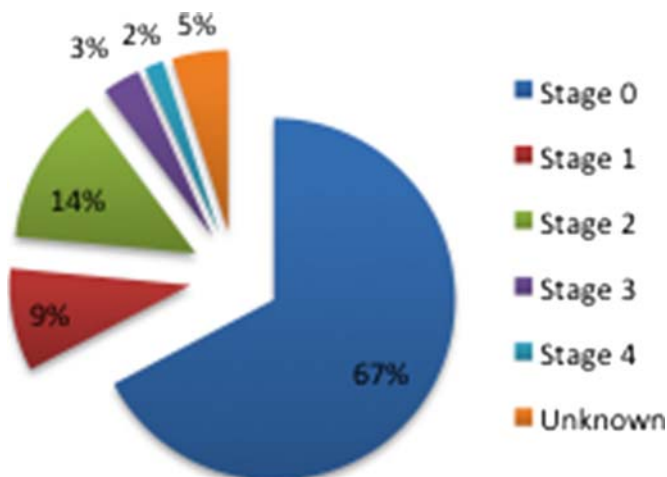


FIGURE 1. Cancer stage.

TABLE 1. Overall Patient Characteristics (per Patient)

Characteristic	All Patients (N = 119)
Unilateral reconstruction	40 (33.6%)
Bilateral reconstruction	79 (66.4%)
BMI, mean $\pm$ SD, kg/m ²	27.1 $\pm$ 5.69
Min–Max	16.8–43.4
Current smoker	21 (17.6%)
Previous smoker	2 (1.7%)
PVD	1 (0.8%)
DM	7 (5.9%)
Cancer stage	
Stage 0	80 (67.2%)
Stage 1	11 (9.2%)
Stage 2	16 (13.4%)
Stage 3	4 (3.4%)
Stage 4	2 (1.7%)
Unknown	6 (5.0%)

DM, diabetes mellitus; PVD, peripheral vascular disease.

(SSMs) and fewer nipple-sparing mastectomies (NSMs) compared with the DTI group (Table 2).

Statistical comparison showed a significant increase in overall complications for patients in the TE group (40.5%) versus the direct-to-implant group (28.2%) ($P = 0.037$). Infection rates were shown to be significantly higher in the TE group (34.2% vs 13.7%, $P = 0.0022$) (Table 3). Most of infections occurred within the first 30 days for both cohorts (TE, 83%; DTI, 81%). The TE group had a higher rate of aesthetic revisions compared with the DTI group; however, this was not statistically significant (52.9% vs 38.5%, $P = 0.055$). There was no difference in rates of seroma, hematoma, and mastectomy skin flap necrosis between the 2 groups (Table 3). There was no difference in infection rates among patients who underwent bilateral versus unilateral breast reconstruction in the DTI group ($P = 1.00$). However, patients in the TE group who underwent unilateral breast reconstruction were more likely to experience a postoperative infection compared with those undergoing bilateral reconstruction ($P < .002$). Further demographic stratification showed higher complication rates in each group with patients with BMI of greater than 30 ($P < 0.005$), smoking (within 3 months of reconstruction; $P < 0.041$), and postoperative radiation ($P < 0.027$). In the TE cohort, patients with BMI of greater than 30 experienced more overall complications than those in the DTI cohort ($P < 0.005$). Current smokers in the TE group had more overall complications than those in the DTI group ($P = 0.041$). In addition, patients who received postreconstructive radiation in the TE group experienced more complications than those in the DTI group ($P = 0.029$) (Table 4).

DISCUSSION

Current literature comparing outcomes between TE and direct-to-implant immediate breast reconstruction is conflicting. A meta-analysis by Basta et al³ found significantly greater incidence of flap necrosis, reoperation, and implant loss in DTI compared with TE. However, no significant difference was found between the 2 with respect to seroma, hematoma, contracture, or infection.³ Roostaieian et al⁷ reported no significant difference in overall complication rate, revision rate, or aesthetic outcomes. In addition, the authors reported fewer office visits and less reconstructive time with DTI compared with TE.⁷ The goal of our study was to directly compare TE and direct-to-implant immediate breast reconstruction outcomes and determine predictive patient risk factors.

TABLE 2. Demographics and Patient Characteristics (per Surgery)

Characteristic	All Breast	Reconstruction Method		P*
	Reconstructions (N = 196)	TE (n = 79)	DTI (n = 117)	
BMI, mean $\pm$ SD, kg/m ²	27.1 $\pm$ 5.69	26.2 $\pm$ 4.81	27.6 $\pm$ 6.16	0.081
Current smoker	32 (16.3%)	17 (21.5%)	15 (12.8%)	0.106
Radiation				
Before reconstruction	4 (2.0%)	2 (2.5%)	2 (1.7%)	0.825
After reconstruction	9 (4.6%)	3 (3.8%)	6 (5.1%)	0.615
Chemotherapy				
Before reconstruction	32 (16.3%)	15 (19.0%)	17 (14.5%)	0.408
After reconstruction	35 (17.9%)	14 (17.7%)	21 (17.9%)	0.968
Endocrine therapy				
Before reconstruction	6 (3.1%)	3 (3.8%)	3 (2.6%)	0.546
After reconstruction	12 (6.1%)	7 (8.9%)	5 (4.3%)	0.189
Prior breast surgery of any kind	63 (32.1%)	21 (26.6%)	42 (35.9%)	0.197
Prior lumpectomy	20 (10.2%)	10 (12.7%)	10 (8.5%)	0.319
Mastectomy type				<0.001
SSM	150 (76.5%)	70 (88.6%)	80 (68.4%)	
NSM	39 (19.9%)	5 (6.3%)	34 (29.1%)	
Radical	0	0	0	
MRM	7 (3.6%)	4 (5.1%)	3 (2.6%)	

*The *P* values were calculated via independent samples Student *t* test for numeric data and Pearson χ^2 or Fisher exact tests for categorical data depending on cell sample size distribution.

MRM, modified radial mastectomy.

TABLE 3. Complications by Method

Complication	All Breast	Reconstruction Method		P*	OR (95% CI)
	Reconstructions (N = 196)	TE (n = 79)	DTI (n = 117)		
Reconstruction with complication	65 (33.2%)	32 (40.5%)	33 (28.2%)	0.037	0.577 (0.316, 1.055)
Complication by mastectomy type					
SSM	48 (32.0%)	27 (38.6%)	21 (26.3%)	0.107	
NSM	13 (33.3%)	3 (60.0%)	10 (29.4%)	0.310	
MRM	4 (57.1%)	2 (50.0%)	2 (66.7%)	1.000	
Implant loss	10 (5.1%)	4 (5.1%)	6 (5.1%)	1.000	
Total flap loss	0	0	0	NA	
Partial flap loss	0	0	0	NA	
Infection	40 (20.4%)	24 (30.3%)	16 (13.6%)	0.004	0.363 (0.178, 0.740)
Fat necrosis	2 (1.0%)	1 (1.3%)	1 (0.9%)	0.758	
Mastectomy skin necrosis	26 (13.3%)	10 (12.7%)	16 (13.7%)	0.916	
Wound healing delayed	9 (4.6%)	6 (7.6%)	3 (2.6%)	0.124	
Hematoma	1 (0.5%)	1 (1.3%)	0	0.202	
Seroma	26 (13.3%)	13 (16.5%)	13 (11.1%)	0.279	
Capsular contracture	6 (3.1%)	2 (2.5%)	4 (3.4%)	1.000	
Implant malposition	0	0	0	NA	
Implant exposure (loss)	7 (3.6%)	5 (6.3%)	2 (1.7%)	0.120	
Implant deflation	0	0	0	NA	

Odds ratio are expressed relative to direct implant method for complications with *P* < 0.05.

*The *P* values were calculated via Pearson χ^2 or Fisher exact tests for categorical data depending on cell sample size distribution.

CI, confidence interval; MRM, modified radial mastectomy; NA, not applicable; OR, odds ratio.

TABLE 4. Stratified Complications by Method and Characteristics

Complication	All Breast	Reconstruction Method		<i>P</i> *	OR (95% CI)
	Reconstructions (N = 196)	TE (n = 79)	DTI (n = 117)		
Any complication					
BMI (>30 kg/m ²)	15	8 (66.7%)	7 (19.4%)	0.002	0.121 (0.028, 0.518)
BMI (≤30 kg/m ²)	50	24 (35.8%)	26 (32.1%)	0.634	
Current smoker	17	10 (58.8%)	7 (46.7%)	0.723	
Pre-RTX	1	1 (50%)	0	1.000	
Prechemo	8	4 (26.7%)	4 (23.5%)	1.000	
Post-RTX	5	3 (100%)	2 (33.3%)	0.167	
Postchemo	13	6 (42.9%)	7 (33.3%)	0.568	
Infection					
BMI (>30 kg/m ²)	12	8 (66.7%)	4 (11.1%)	<0.001	0.063 (0.013, 0.306)
BMI (≤30 kg/m ²)	28	16 (23.9%)	12 (14.8%)	0.161	
Current smoker	8	5 (29.4%)	3 (20.0%)	0.691	
Pre-RTX	1	1 (50%)	0	1.000	
Prechemo	5	4 (26.7%)	1 (5.9%)	0.161	
Post-RTX	2	2 (66.7%)	0	0.083	
Postchemo	7	4 (28.6%)	3 (14.3%)	0.401	

Odds ratio are expressed relative to direct implant method for complications with $P < 0.05$.

*The P values were calculated via Pearson χ^2 or Fisher exact tests for categorical data depending on cell sample size distribution.

CI, confidence interval; OR, odds ratio; RTX, radiation therapy.

Similar to recent studies, our study showed no difference in the rates of seroma formation, implant loss, mastectomy skin necrosis, hematoma, capsular contracture, or wound healing delay between our 2 groups.^{7–9} Our study also reflects the increasing incidence of NSM performed for breast cancer as our DTI cohort had significantly more NSMs and less SSMs than our TE group.^{10–14} Interestingly, we found that our TE group had a significantly higher overall complication rate than our DTI group. Although our complication rates appear to be higher than those published, which ranges from 0.2% to 52%,^{3,5,7–9,15–25} our results reflect a broader definition of postoperative complications. In our study, we defined infection as any instance where antibiotics were restarted for any clinical signs of infection or continued after drains had been removed, whereas most studies fail to define infection. We used this expansive definition to be as inclusive as possible to capture the true rate of postoperative infection, which we found to be significantly higher in our TE cohort.

Our results suggest that immediate breast reconstruction using TEs has a higher rate of infection than previously believed. One possible reason, as noted by Avraham et al,²⁶ is that patients who undergo immediate breast reconstruction for a therapeutic indication are at a higher risk of developing infection than those who undergo breast reconstruction after prophylactic mastectomy. Whereas most of our patients underwent prophylactic mastectomy, our TE cohort had a greater percentage of patients who underwent therapeutic breast reconstruction. Another possibility is that patients who undergo immediate breast reconstruction using TEs frequently require lengthy reconstruction period involving multiple expansions and revisions to achieve symmetry, whereas those who undergo single-stage reconstruction may achieve symmetry and satisfaction earlier. This may explain our finding that patients who underwent unilateral TE placement were more likely to experience postoperative infection as compared with bilateral TE placement. As some authors have shown, the prevalence of infection is greater during the expansion period than after the silicone implant is placed.^{27–29} This finding is congruent with our study because infections in our TE

cohort only occurred while the TE was still in place and not after the TE was exchanged for a permanent implant. Possible reasons for these findings include contamination during percutaneous expansion, temporary ischemia with each expansion, skin envelope thinning with each expansion, larger breast envelope dead space leading to seroma, and need for additional operations.

When we further evaluated our data to determine predictive patient risk factors for complications, we found that patients with BMI of greater than 30 were more likely to experience postoperative complications with TE versus DTI immediate breast reconstruction. Furthermore, patients with BMI of greater than 30 were more likely to have an infectious complication when undergoing TE versus DTI. Our finding agrees with the literature consensus that patients with BMI of greater than 30 are more likely to experience postoperative complications overall^{28,30–32} and that infection is the main complication in this high-risk patient population. Although some studies support using TEs in obese patients because it may place less initial tension on the mastectomy skin flaps and it affords a planned second procedure for revisions,^{9,33,34} our study suggests that obese patients have better outcomes if they undergo DTI reconstruction. However, in cases where soft tissue coverage is inadequate or mastectomy skin flaps are found to be ischemic intraoperatively, TE reconstruction should be used to prevent complications and possible implant loss.

As many authors report, DTI immediate breast reconstruction provides increased satisfaction, decreased healthcare costs, decreased exposure to anesthesia, increased psychological well-being, shorter overall reconstructive time and recovery, and excellent aesthetic results.^{7–9,33,35} Patients in our TE cohort had similar aesthetic revision rates as our DTI cohort, a finding consistent with the literature.^{8,34} Direct-to-implant provides comparable aesthetic results with fewer complications even in obese patients and should be offered in patients with BMI of greater than 30.

Although our study was limited by a small number of patients who received radiation, our results are congruent with the literature

because irradiated patients developed complications at a much higher rate than those patients who were not irradiated.^{36–39} By having a single surgeon at a single institution exclusively perform all the reconstructions, technique variability was limited. As the mean follow-up in our study was 14.7 months, we may have missed delayed complications such as capsular contracture, which some authors argue occurs primarily within the first 2 postoperative years.³⁹ Finally, our study was limited by its retrospective nature and cohort size. Additional prospective research with a larger cohort is needed to further substantiate our findings.

CONCLUSIONS

Single-stage direct-to-implant immediate breast reconstruction has less overall complications than 2-stage TE-based reconstruction and provides favorable outcomes in patients with BMI of greater than 30.

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Reconstructive Trends After Tissue-Expander Loss in Breast Reconstruction

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Purpose: Tissue-expander breast reconstruction (TEBR) is a common method of reconstruction after mastectomy but may result in complications that may necessitate removal. Although complications in TEBR have been well studied, there is a paucity of data regarding outcomes after tissue-expander loss. In this study, we examine the eventual reconstructive pathways and associated factors of patients who required tissue-expander removal after infection.

Methods: This retrospective study examines patients undergoing breast reconstruction at a single institution. Patients included underwent mastectomy, immediate TEBR, and subsequent tissue-expander loss. Patients who underwent autologous reconstruction after mastectomy or had successful TEBR were excluded. Patients were followed for an average of 7 years, with a minimum of 2 years and a maximum of 13 years.

Results: A total of 674 TEBR patients were initially screened, of which 60 patients (8.9%) required tissue-expander removal because of infection or skin necrosis. Thirty-one of these patients (group 1) did not complete reconstruction after initial tissue-expander loss, whereas the remaining 29 patients (group 2) underwent either TEBR or autologous reconstruction after tissue-expander loss. Group 1 had a significantly higher mean body mass index than group 2 (32.61 ± 8.88 vs 28.69 ± 5.84 ; $P = 0.049$) and also lived further away from our institution than group 2 ($P = 0.052$), which trended toward significance. There were otherwise no significant differences in demographics between the 2 groups.

Among the 29 patients in group 2, 18 patients underwent a second TEBR (group 2a), and 11 patients underwent autologous reconstruction (group 2b). Patients in group 2b had a significantly greater mean number of complication related admissions (1.11 ± 0.323 vs 1.55 ± 0.688 ; $P = 0.029$) and also had higher occurrence of postmastectomy radiation therapy (16.7% vs 45.5%; $P = 0.092$), although this was not significant. There were otherwise no differences between the 2 groups.

Conclusion: Our data demonstrate the trends in breast reconstruction decision making after initial tissue-expander loss. This study elucidates the factors associated with patients who undergo different reconstructive options. Further work is needed to delineate the specific reasons between the decision to pursue different reconstructive pathways among a larger cohort of patients.

Key Words: breast reconstruction, tissue expander, infection, reconstructive failure (Ann Plast Surg 2022;88: S170–S173)

Breast cancer is a widely pervasively disease, affecting 1 in 8 women with more than 270,000 new cases of invasive breast cancer reported in 2020 in the United States alone.¹ The Women's Health and Cancer Rights Act of 1998 mandates insurance coverage of reconstruction

after mastectomy, procedures of the contralateral breast to attain symmetry, and subsequent revisions due to complication, thus giving patients the right to reconstruction after mastectomy. Tissue-expander breast reconstruction (TEBR) is one of the most common methods of reconstruction, with more than 80,000 such procedures done in the United States in 2020.² This 2-stage method of reconstruction consisting of initial tissue-expander placement followed by exchange for permanent prostheses has been considered a safe and effective method of reconstruction and has seen a rising demand over the past 2 decades.^{3,4} With this increased demand, there has also been an increase in the study of complications after surgery and the factors that contribute to them. Reported complication rates for TEBR have ranged from 20% to 50%, whereas risk factors for complications include age, body mass index (BMI), and smoking status, to name only a few.⁵

Reoperation rates in TEBR have often been cited at approximately 10%^{6–9} and are due to conditions such as expander infection, skin necrosis, wound dehiscence, and hematoma. Patients who undergo reoperation and require tissue-expander removal have the option to undergo a second TEBR procedure, autologous reconstruction, or opt out of further reconstruction. Although complications of TEBR have been extensively studied, there is a dearth of data regarding eventual patient outcomes after these complications. This study examines the trends in decision making after tissue-expander removal, factors contributing to decision making, and safety of second tissue-expander versus autologous reconstruction.

METHODS

An institutional review board–approved retrospective study using the prospectively collected REDCap database of patients from a single institution was performed. All patients who underwent unilateral or bilateral and therapeutic or prophylactic mastectomy followed by immediate tissue expander–based reconstruction from 2001 to 2018 were included in this study. All included patients had submuscular placement of a breast tissue expander. Patients who underwent delayed reconstruction or underwent autologous reconstruction immediately after mastectomy were excluded. Further inclusion criteria limited this study to patients who experienced tissue-expander loss, defined in our study as removal of the expander without immediate replacement or transition from implant-based reconstruction to autologous reconstruction due to complication. Patients were followed for an average of 7 years, with a minimum 2-year follow-up and a maximum of 13 years.

Differences in demographics and complications between patient cohorts were analyzed via independent t test and χ^2 analysis. Nonparametric data were compared via Mann-Whitney U test. All P values were 2 sided, and statistical significance was set to $P < 0.05$. Statistical analysis was performed using SPSS v.27.

RESULTS

A total of 674 TEBR were initially screened, of which 60 patients (8.9%) required tissue-expander removal. Most of these patients had infection as the primary cause of expander removal, whereas several patients had secondary complications as well; 3 patients had skin necrosis as the primary cause of expander loss (Table 1). Of these 60

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TABLE 1. Complications in Patients Who Underwent Tissue-Expander Removal

Complication	No. Patients (%)
Infection	57 (95)
Skin necrosis	15 (25)
Wound dehiscence	17 (28)
Hematoma	3 (5)

patients, 31 patients (group 1; 51.7%) did not undergo another attempt at breast reconstruction at our institution, whereas 29 (group 2; 48.3%) did. Demographic comparison group 1 and group 2 showed a higher BMI in the former but did not otherwise show any other significant differences (Table 2). Of note, 46 patients of the total 60 examined (76.7%) were Caucasian, of which 26 patients completed reconstruction. Of the total 60 patients, 6 (10%) were Black or Hispanic, of which 0% completed reconstruction, and 2 patients (3.3%) were Asian, of which 1 completed reconstruction, whereas the other patient did not. Further comparison between these 2 groups did not reveal significant differences in time from initial TEBR to infection or number of admissions. Patients who did not undergo secondary reconstruction lived further away from our institution than patients who did undergo reconstruction after TEBR failure, which approached significance (Table 3).

Of the 29 patients who underwent secondary reconstruction, 18 underwent a second TEBR (group 2a), whereas 11 underwent autolo-

TABLE 2. Demographic Comparison of Patients Who Did Not Undergo Reconstruction (Group 1) Versus Patients Who Did Undergo Reconstruction (Group 2) After Initial TEBR Failure

	Group 1: No Reconstruction (n = 31)	Group 2: Reconstruction (n = 29)	P
Patient demographics, mean $\pm$ SD			
Age, y	54.6 $\pm$ 21.0	50.6 $\pm$ 8.4	0.344
BMI, kg/m ²	32.6 $\pm$ 8.9	28.7 $\pm$ 5.8	0.049
Race, % (n)			
Caucasian	64.5% (20)	89.7% (26)	0.117
Black/African American	9.7% (3)	0.0% (0)	
Hispanic or Latino	9.7% (3)	0.0% (0)	
Asian	3.2% (1)	3.4% (1)	
Not reported	12.9% (4)	6.9% (2)	
Smoking status, % (n)			
Never	54.8% (17)	65.5% (19)	0.257
Quit	29.0% (9)	31.0% (9)	
Current	16.1% (5)	3.4% (1)	
Comorbidities, % (n)			
DM2	22.6% (7)	17.2% (5)	0.605
HTN	48.4% (15)	27.6% (8)	0.098
Chemotherapy, % (n)			
Preoperative	25.8% (8)	10.3% (3)	0.122
Postoperative	22.6% (7)	31.0% (9)	0.459
Radiation therapy, % (n)			
Preoperative	22.6% (7)	10.3% (3)	0.204
Postoperative	12.9% (4)	27.6% (8)	0.155

Boldface indicates statistical significance with *P* value < 0.05.

DM2, diabetes mellitus 2; HTN, hypertension.

TABLE 3. Time to Infection, Number of Admissions, and Distance From Patient to Institution

	Group 1: No Reconstruction (n = 31)	Group 2: Reconstruction (n = 29)	P
Initial TEBR to infection time, mean number of days $\pm$ SD	65.9 $\pm$ 66.5	69.5 $\pm$ 75.9	0.848
Admissions, mean $\pm$ SD	1.32 $\pm$ 0.541	1.28 $\pm$ 0.528	0.736
Distance, median miles	34.27	25.59	0.052

gous reconstruction (group 2b) (Table 4). Of the latter group, 4 patients underwent reconstruction using deep inferior epigastric perforator flaps, 3 patients underwent reconstruction using latissimus dorsi flaps, 3 patients underwent reconstruction using free transverse rectus abdominus musculocutaneous flaps, and 1 patient underwent a free transverse rectus abdominus musculocutaneous flap, one for reconstruction of 1 breast and deep inferior epigastric perforator flap for reconstruction of the contralateral breast. Demographic comparison of group 2a versus 2b revealed higher rates of postmastectomy radiation in the latter group, which approached significance. Further comparison did not reveal differences in time from initial TEBR to infection or time to secondary reconstruction after failed TEBR in either group. Group 2b had significantly higher admissions due to complications, which included infection and wound dehiscence of the donor site (Table 5).

DISCUSSION

Tissue-expander breast reconstruction is a widely performed and well-studied procedure that provides patients a return to normalcy after mastectomy. Given the occurrence of complication after initial expander placement, it is important for surgeons and patients to consider the options available for a safe continuation of reconstruction. In the instance of implant infection, the reported cause of the majority of implant failure in previously published work and our data,^{8,10} the decision between medical management, reoperation with implant salvage, or implant removal must be made.

A prospective cohort study conducted by Viola et al¹¹ found a tissue-expander salvage rate of 73% (19 of 26 patients) with antibiotics alone using a same-day multidisciplinary clinic outpatient protocol and found factors such as temperature at initial presentation, time to infection, and bacterial speciation from periprosthetic fluid to be significant factors associated with explantation of the tissue expander. Other authors have also identified age, BMI, and white blood cell count as predictors of complication requiring implant removal during stage I of reconstruction.¹² Traditional methods of salvage include oral or intravenous antibiotics, capsulectomy, debridement, and implant replacement, although newer methods of implant salvage such as the use of antibiotic-impregnated polymethylmethacrylate plates are also under investigation.^{13,14}

However, salvage of the implant may not always be an option. Spear et al¹⁵ stratified the potential for implant salvage by infection severity, finding increased severity with threat of implant exposure, gross purulence, or lack of soft tissue coverage options to be associated with lower chance of safe implant salvage. In a 2013 study, Reish et al¹⁶ examined 1241 immediate implant-based breast reconstruction patients and found a 5.1% infection rate, of which 25.3% recovered with intravenous antibiotics alone, whereas the remainder required reoperation. Of the 56 patients in the study's patient cohort who underwent explantation of the implant, the majority underwent a secondary implant-based reconstruction successfully. A recent study by Poppler et al¹⁰ further demonstrated the safety of a secondary implant-based reconstruction after initial tissue-expander failure, with 79% of their patient cohort having successful reconstruction at the time of final follow-up despite earlier explantation.

TABLE 4. Demographic Comparison of Patients Who Underwent a Second TEBR After Initial TEBR Failure (Group 2a) Versus Patients Who Underwent Autologous Reconstruction After Initial TEBR Failure (Group 2b)

	Group 2a: TEBR (n = 18)	Group 2b: Autologous (n = 11)	P
Patient demographics			
Age, y	50.9 ± 9.5	50.0 ± 6.6	0.775
BMI, kg/m ²	28.4 ± 6.0	29.2 ± 5.8	0.715
Smoking status, % (n)			
Never	72.2% (13)	54.5% (6)	0.346
Quit	27.8% (5)	36.4% (4)	
Current	0.0% (0)	9.1% (1)	
Comorbidities, % (n)			
DM2	16.7% (3)	18.2% (2)	0.917
HTN	27.8% (5)	27.3% (3)	0.976
Chemotherapy, % (n)			
Preoperative	5.6% (1)	18.2% (2)	0.279
Postoperative	27.8% (5)	36.4% (4)	0.628
Radiation therapy, % (n)			
Preoperative	11.1% (2)	9.1% (1)	0.862
Postoperative	16.7% (3)	45.5% (5)	0.092

In our patient cohort, 674 patients were initially screened, and the 60 patients who underwent tissue-expander explantation were included. In analysis outside the scope of this work, we found that an additional 49 patients had clinical evidence of infection and were treated with oral or intravenous antibiotics, thus undergoing successful salvage of the tissue expander. Thus, the overall infection rate at our institution among patients from 2001 to 2018 was 16.2% (109 patients of 674 total) with a salvage rate of 45.0% (49 patients of 109 total).

We further analyzed the 60 patients who required tissue-expander removal. Most of these patients had clinical infection with implant exposure and elevated white blood cell count upon presentation. A slight majority of patients who underwent tissue-expander failure did not undergo further reconstruction, and we found distance to our institution to be one of the most significant factors that could affect this. Indeed, previous work by Roughton et al¹⁷ found distance to their surgeon to be an independent factor determining likelihood of reconstruction after initial mastectomy in North Carolina, with women living 10 to 20 miles away from their nearest surgeon having 22% lower odds and women living greater than 20 miles away having 27% lower odds of undergoing reconstruction. Furthermore, this study and a 2003 study by Alderman et al¹⁸ found that non-Caucasian minorities were less likely to undergo reconstruction after mastectomy. Although limited in

TABLE 5. Differences Between Patients Undergoing Secondary TEBR Versus Secondary Autologous Reconstruction

	Group 2a: TEBR (n = 18)	Group 2b: Autologous (n = 11)	P
Initial TEBR to infection time	68.1 ± 84.7	71.7 ± 62.8	0.904
Complication related admissions	1.1 ± 0.323	1.6 ± 0.688	0.029
Time to stage 2	505.3 ± 156.9	489.4 ± 208.0	0.816

Boldface indicates statistical significance with P value < 0.05.

representation in our study cohort, it is striking that none of the 6 African American or Hispanic patients who underwent tissue-expander removal chose to undergo further reconstruction, suggesting a similarity in trends between immediate reconstruction after mastectomy and secondary reconstruction after explantation. Although causation for this trend is unclear, it highlights the need for plastic surgeons to properly educate patients regarding options after tissue-expander failure and address clinical safety and financial concerns the patient may have.

Further comparison of patients who underwent a second tissue expander-based reconstruction versus an autologous tissue reconstruction after tissue-expander removal revealed an increased number of complication-related admissions in the latter group. Previous work has found autologous reconstruction to be a viable option with improved cosmesis after failed initial TEBR, although the procedure may be complicated by issues such as vessel scarring due to radiation after tissue-expander placement.^{19–21} Our patient cohort revealed a higher incidence of postmastectomy radiation in patients undergoing autologous reconstruction after failed TEBR, and reasons for readmission included infection and skin necrosis, without any incidence of flap failure.

In conclusion, our research has found that a significant proportion of women do not undergo further reconstruction after initial TEBR failure, and this may be especially prevalent within minority populations and in patients who lived further away from our institution. Of the patients who did undergo further reconstruction, both a second TEBR and autologous reconstruction are safe options, although the latter may experience more complication as a result of confounders such as postmastectomy radiation. Our study is limited by patient sample size and its retrospective nature. Going forward, it would be useful to survey patients who did not continue reconstruction after initial failure and determine the reasoning behind their decision.

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Tissue Expander Complications Do Not Preclude A Second Successful Implant Based Breast Reconstruction

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Abstract

Background: Implant based breast reconstruction is the most common method of breast reconstruction in the United States but the outcomes of subsequent implant based reconstruction after a tissue expander (TE) complication are rarely studied. The purpose of this study is to determine the long term incidence of implant loss in patients with a previous TE complication.

Methods: This is a retrospective review of the long term outcomes of all patients with TE complications at a large academic medical center from 2003–2013. Patients with subsequent TE or implant complications were compared to those with no further complications to assess risk factors for additional complications, or reconstructive failure.

Results: One hundred sixty-two women were included in this study. The mean follow up was 8.3 ± 3.1 years. Forty-eight women (30%) went on to have a second TE or implant placed. They did not differ from women who went on to autologous reconstruction or no further reconstruction. Of these, 34 women (71%) had no further complications, and 38 women (79%) had a successful implant based reconstruction at final follow-up. There were no patient or surgical factors significantly associated with a second complication or implant loss.

Conclusions: Following TE complications, it is reasonable to offer women a second attempt at tissue expansion and implant placement. This study demonstrates that long term success rates are high and there are no definitive patient or surgical factors that preclude a second attempt at implant based breast reconstruction.

INTRODUCTION

Implant based breast reconstruction is the most common method of breast reconstruction in the United States. In 2016, nearly 89,000 breast reconstructions with implants were performed.¹ In their meta-analysis of complication rates after breast reconstruction, Tsoi et al. found that 5.4% of tissue expander (TE) or implant reconstructions resulted in reconstructive failure, and that on average 9.4% of women have an infection, 7.4% have a hematoma or seroma, and 4.9% have skin flap necrosis.² Two large cohort studies report overall complication rates for two stage TE/implant based reconstructions as high as 20–

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50%.^{3,4} Although the perioperative risk factors contributing to failure of implant-based reconstruction are widely known, the ultimate success rate of subsequent implant reconstruction in patients who experience a complication or loss of their TE remains unclear.⁵⁻⁷

In a retrospective study of 54 patients who had a TE complication and went on to implant placement, Adkison et al. suggest that patients with a TE complication are 3 times more likely to have a subsequent complication and 9 times more likely to lose their prosthesis.⁶ However, Spear, et al. report that 12 of 13 (92%) patients had a successful reconstruction nearly two years after implant placement in spite of having a previous TE complication.⁵ Similarly, Halvorson, et al. showed that 8 of 9 (89%) were able to keep an implant, although 2 patients developed late contracture.⁸ These studies are small, retrospective case series with short durations of follow-up and minimal bias analysis.⁹ Consequently, few recommendations exist for how best to manage or counsel a patient that experiences a complication of their TE but still desires implant-based reconstruction.

The study reviews a single center's 10-year experience with TE complications and subsequent implant-based breast reconstruction. Our aim was to determine the incidence of implant loss after TE complications and identify factors for implant-based reconstructive success or failure following complications. Secondary analyses also describe the causes of TE complications in this patient series and culture results among women with infections.

METHODS

Study Sample

Following IRB approval (201308013), data were retrospectively collected from the medical record. All patients who underwent mastectomy and breast reconstruction with TE placement from February 2003 to May 2013 at the Siteman Cancer Center in St. Louis, Missouri were retrospectively identified using the physician billing database of Washington University School of Medicine in St. Louis. Patients that had mastectomy and TE placement but did not experience a subsequent complication were then excluded from further study.

Study Design

Our primary analysis compared patients who did or did not have a complication of their permanent implant after having a complication with their TE. The primary outcome was removal of the permanent implant. Patient and surgical factors were compared between patients who did or did not have a second complication using univariate and multivariate logistic regression. Cancer, radiation therapy, and complication laterality were taken into account in all analyses as a complication associated with radiation of the right TE would not necessarily have any bearing on a left sided permanent implant complication.

As patients offered a permanent implant without autologous tissue flap were subject to surgeon selection bias, we first characterize the patients in our primary analysis with demographic analysis of all patients included in the study. We call this "patient selection analysis." For this analysis, patients were divided into three categories: autologous reconstruction (women who had any autologous flap with or without implant placement),

implant only reconstruction (women who had an implant placed without a flap), and no further reconstruction. Patient and surgical factors were compared between groups. Finally, we perform a secondary analysis of the TE complications experienced by all women included in this study. We call this “complications analysis.” This analysis is intended to further characterize the population of women in this study, allowing readers to decide if our results are generalizable to their patient population.

Patient and surgical factors considered important for analysis included patient age at the time of reconstruction, body mass index (BMI), diabetes mellitus (DM), and smoking status (i.e. never, prior, and current). Clinical and surgical information included laterality of the breast reconstruction, laterality of complications, acellular dermal matrix (ADM) use, chemotherapy, post-mastectomy radiotherapy, premature TE removal, permanent implant removal, and duration of reconstructive follow-up. When applicable, the time from mastectomy to radiotherapy, from mastectomy to delayed TE placement, and from TE placement to implant exchange were recorded. For premature explantation of the TE or implant, the time period from device placement to removal and reason for removal were noted. Infection was defined as resumption of oral antibiotics after routine postoperative administration, readmission for intravenous antibiotics and/or explantation. The decision to admit for intravenous antibiotics was based on surgeon preference that included consideration of failure to improve on oral antibiotics, fever, pitting edema of the skin, social support, and travel distance. Mastectomy skin flap necrosis was defined as full thickness skin loss requiring intervention, hematoma as bleeding requiring reoperation, seroma as fluid collection requiring drainage, and capsular contracture as a documented Baker Grade III or IV that required operative intervention with capsulectomy.

Reconstructive technique

Chemotherapy and radiation therapy was administered per the recommendations of the medical and radiation oncologists. For patients who received neoadjuvant chemotherapy, mastectomy was delayed at least 4 weeks from the last chemotherapy treatment. Patients received a single dose of prophylactic IV antibiotics within one hour prior to incision for all surgeries. At the time of initial breast reconstruction, the TE was placed beneath the pectoralis major, serratus anterior, and rectus fascia, or beneath the pectoralis major muscle and ADM. TEs were filled with a variable volume at the time of insertion and further expansion commenced 3–4 weeks after surgery in the absence of wound healing delays or infection. Tissue expansion was completed prior to radiotherapy in all cases except patients who had delayed reconstruction. At the time of TE exchange to permanent implant, capsulotomy or capsulectomy was always performed. Two drains were always placed at the time of TE placement and zero or one drain placed at implant exchange. Patients with a drain were always kept on prophylactic oral antibiotics, either cephalexin, trimethoprim-sulfamethoxazole, or doxycycline, until it was removed.

Statistical Analysis

Categorical variables were compared between groups using Pearson’s chi-squared, the Mann-Whitney U test, or Kruskal-Wallis H-test. One-way analysis of variance or the t-test were used to compare groups when variables were continuous and normally distributed. A

Post-hoc Tukey correction was used when more than two groups were compared. Logistic regression models evaluated associations between patient and surgical factors and implant failure accounting for breast laterality, confounding factors such as timing of reconstruction, ADM use, and patient variables selected based on literature review. Confounders were selected based on literature review and removed from the model in a backwards step-wise manner based on significance within the model or a change of the beta for TE removal cause of more than 10%.¹⁰ Statistical analyses were performed using SPSS 23 software (IBM, Chicago, IL, USA) with significance set at $p < 0.05$.

RESULTS

Patient Characteristics

951 women received 1453 TEs (502 bilateral, 449 unilateral) between 2003 and 2013. One hundred seventy-eight (19%) women had a complication of their TE, or had their TE removed before completing reconstruction. Nine (1%) women that requested their TEs be removed and 5 (0.5%) women that had cancer progression requiring premature TE removal were excluded from analysis. Two women (0.2%) were lost to follow-up before final reconstruction but after TE removal and excluded from analysis. The complication rate among patients decreased significantly over the study period from 37% (95% CI: 0.31–0.43) among the first quartile to 23% (95% CI: 0.17–0.29) among the final quartile ($p < 0.05$).

One hundred sixty-two (17%) women were included in this study (Figure 1). Mean follow-up duration among these women was 8.3 ± 3.1 years (range 4.0 – 14.0 years). One hundred forty-eight women (91%) had a TE complication in one breast and 14 women (9%) had a TE complication in both breasts.

Following TE complications, 48 women (30%) went on to have a second TE or implant placed (Figure 2), 47 women (29%) went on to an autologous reconstruction (Figure 3), and 67 women (41%) had no further reconstruction. Twenty-seven women (17%) in the autologous reconstruction group had an implant along with a latissimus flap. None experienced further complications with their implant. Twenty women (12%) had an autologous reconstruction without implant. Autologous flaps employed included pedicled latissimus dorsi, pedicled transverse rectus abdominis muscle (TRAM) flaps, muscle sparing TRAMs, deep inferior epigastric perforator (DIEP) and superficial inferior epigastric artery (SIEA) flaps.

Among the 162 women included in this study, 149 (92%) underwent immediate TE placement and 13 women (8%) underwent delayed TE placement. The median time to TE placement in patients with delayed placement was 122 days (IQR: 71–465, range 14–2199). Women who had delayed TE insertion were significantly more likely to have had adjuvant chemotherapy ($p < 0.01$) than women with immediate TE insertion. Their other demographic characteristics, cancer details, and comorbidities did not differ significantly.

The first case of ADM use among patients included in this study occurred in 2004. After 2005, only 2 cases were performed without using ADM. Patients with ADM were more likely to smoke than those without ADM (38% v. 16%, respectively; $p < 0.01$) and to have a

shorter duration of follow-up (7.1 v. 11.7 years, respectively; $p < 0.01$). There were no other significant differences in age, BMI, comorbidities, time to completion of reconstruction, or likelihood of permanent implant loss among patients with, or without ADM.

Patient Selection Analysis

Following tissue expander complications, selected patients were offered another attempt at implant-based reconstruction. No significant differences were seen between patients who went on to repeated alloplastic reconstruction, autologous reconstruction, and no further reconstruction (Table 1). However, patients offered a second attempt at implant based reconstruction were marginally less likely to have had radiation ($p = 0.06$). The median time to implant placement after initial tissue expander placement was 316 days [IQR: 203–534].

Permanent Implant Outcomes following Tissue Expander Infection

Fourteen of 48 women (29%) who had an implant placed subsequently had an implant complication requiring removal. The median time to implant removal was 48 days [IQR: 33–277, range: 8–3817]. Four of these women (8%) eventually had another implant placed without further complication; in total, 38 of 48 women (79%) completed their reconstruction with a permanent implant. Three women (6%) went on to have an autologous reconstruction. The remaining 7 women (15%) underwent no further reconstruction. (Figure 4). Among women who went on to have an implant placed, age, race, BMI, diabetes mellitus (DM), smoking status, stage, radiation status, chemotherapy status, ADM use, the cause for TE removal, and cultures at time of TE removal did not make a significant difference for final success of implant reconstruction in univariate and multivariate logistic regression (See Appendix, Supplemental Digital Content 1, which shows the Univariate associations of patient and surgical variables with premature removal of a permanent implant, INSERT HYPER LINK).

The most common cause for implant removal was infection (5 patients (34%)), followed by wound dehiscence/exposure (4 patients (29%)). Mastectomy flap necrosis, capsular contracture, malposition, and pain each resulted in removal of implant(s) in one patient (7% each patient). One further patient (7%) requested implant removal without pathologic cause. In all but one case, the side of TE complication was the same as the side of the implant complication.

Tissue Expander Complications

Among the 162 women included in this study, 150 (93%) required TE explantation. Twelve (7%) women were placed on intravenous (IV) antibiotics for cellulitis and subsequently had their TE exchanged for an implant without needing a premature TE explantation. Seventy-six (47%) women were placed on intravenous antibiotics for cellulitis prior to having their TE explanted. The most common cause of TE explant was infection (85 women [52%]), followed by mastectomy flap necrosis, implant exposure or wound dehiscence, implant leak, deflation or rupture, seroma, pain, hematoma, and capsular contracture (Table 2). The median time to IV antibiotics for breast cellulitis was 38 days (IQR: 25–87, range: 5–938). The median time to TE removal was 59 days (IQR: 28–145, range: 4–940).

Fifty-eight of 85 women (68%) required explant of their infected TE a median of 2 days (IQR: 1 – 3) after starting IV antibiotics. Fourteen women (16%) initially responded to IV antibiotics followed by 15.5 days (IQR: 8.5 – 23.8) of PO antibiotics but still required TE removal a median of 57 days (IQR: 25–55, range 12–278) after beginning antibiotics. The remaining 12 women (14%) did not require TE removal prior to implant exchange. The median duration of antibiotic treatment among women who responded to antibiotics was 4 days (IQR: 2.5 – 10.0) of IV antibiotics followed by 12 days (IQR: 1.8 – 18.0) of PO antibiotics. Infection was the most common reason for TE removal among all women, regardless of whether they were treated with IV antibiotics and regardless of if their cellulitis responded to antibiotics.

Among the 12 women whose infections resolved on antibiotics and whose TEs did not require premature removal, 8 of 12 (66%) had a successful implant-based reconstruction without further complications. Two women (17%) had a successful autologous reconstruction. Only one woman (8%) required subsequent removal of her implant for infection. Notably, her infection was *Methicillin resistant Staphylococcus aureus* (MRSA) and never fully resolved prior to implant exchange (Table 3).

Cultures from 82 patients were sent (81 at time of TE removal, 1 in a patient who only received IV antibiotics). Cultures in 29 patients had no growth. Methicillin sensitive *Staphylococcus aureus* (MSSA) was the most common bacterial isolate (32 of 82 cultures (39%)). *Pseudomonas aeruginosa* was the second most common isolate (6 cultures (7%)) (Table 4).

DISCUSSION

This study of outcomes of implant based reconstruction following a TE complication demonstrates that implant based reconstruction is still successful in most women (38 of 48, 79%). Among the subgroup of women whose infection resolved without the need for tissue expander explantation and went on to prosthetic reconstruction, eight of nine (89%) recovered without further infectious complications. Our analysis failed to show any significant predictors of implant failure. This suggests that it is reasonable to offer a second try at alloplastic reconstruction to women who are not candidates for, or wish to avoid, autologous reconstruction.

These results confirm the findings of prior studies and provide a larger cohort than any prior series.^{5,6,8} Unlike prior studies, our analysis also accounts for laterality, improving the accuracy of analysis. While our success rate was lower than prior series, our period of follow up was much longer (minimum follow-up of 4 years and mean follow-up of 8 years) and therefore likely catches late complications that were missed in prior studies. Moreover, unlike the works of Spear or Halvorson,^{5,8} our results support the prior work of Adkinson, et al.⁶ that suggests that patients who experience a TE complication are at three times the risk of permanent implant complication, and nine times more likely to have definitive implant loss. Our reconstructive failure rate of 21% among these women was higher than historically reported rates of 0.7 – 7.1% but our results make intuitive sense.^{2,11,12} Consequently,

patients considering alloplastic reconstruction after TE complications should be informed of the increased risk of failure.

Our results do not support the findings of Adkinson, et al. that tobacco use and radiation therapy were associated with increased risk of complications in this population.⁶ These results are not exactly comparable because Adkinson, et al consider all TE patients rather than just those with complications and they do not parse out those who have had a TE, versus an implant, or versus a TE then implant complication. Moreover, the methodology of their analysis was not fully described and did not mention correcting for multiple comparisons. Therefore, we would still consider offering a second attempt at implant-based reconstruction to women who smoke or who have undergone ipsilateral radiation therapy, though we would certainly counsel them to stop smoking. Our series does not control for factors like soft tissue laxity, donor site adequacy, and patient willingness to consider an autologous flap and is therefore subject to significant bias. We routinely encourage patients with poor quality skin or severe radiation damage to have an autologous reconstruction with or without implants. Our acceptable results with a second attempt at prosthetic reconstruction, then, may be largely attributable to favorable patient selection and not generalizable to all patients with a failed prosthesis.

We no longer routinely keep our patients with drains on antibiotic prophylaxis although this practice remains common.^{13–17} Prophylactic antibiotics, when used, should cover methicillin sensitive *Staphylococcus aureus* as well as *Pseudomonas*, the two most common isolates in this case series and two of the most common isolates in Halvorson's series.⁸ It should also cover methicillin resistant *Staphylococcus*, coagulase negative *Staphylococcus*, *Streptococcus* and *Enterobacter*. For our practice, doxycycline is a well-tolerated, inexpensive, and broadly effective antibiotic to limit these breast-implant associated infections.¹⁸

This study had limitations. The primary limitation is the retrospective case series design which precluded a comparison group and limited the granularity of some data. While this study is the largest series of its type to date, it is still fairly small (48 patients with the intervention of interest) and the likelihood of type II error (missing a true difference or association) is high. This study included multiple surgeons, making it more broadly generalizable but also introducing additional variability that may mask associations. This study also spanned 2003 – 2013, a period that saw the popularization of the use of acellular dermal matrices (ADM) in breast reconstruction. We stopped analyzing patients with index primary TE after 2013 to ensure a longer follow-up period; however, this may have limited the applicability of our results to current surgical practice. Future, prospective studies that better control for patient and surgical variables are warranted to determine if factors like smoking, radiation therapy, complication type (infection, mastectomy flap necrosis, etc.) should dissuade further attempts at breast reconstruction with an implant.

CONCLUSIONS

Following TE complications, it is reasonable to offer women a second attempt at tissue expansion and implant placement. These data suggest that long term success rates are around

79%. No patient or surgical factors clearly demonstrated increased risk for a second complication. Despite this, good surgical technique and judgement is recommended with particular attention paid to infection prophylaxis. Women should be counseled that although the chance of success is high, the fact that they have had a complication increases their long term risk of failure by a factor of at least three. In light of this, every attempt should be made to limit patient risk factors by stopping smoking, weight loss, proper nutrition, and tight control of comorbidities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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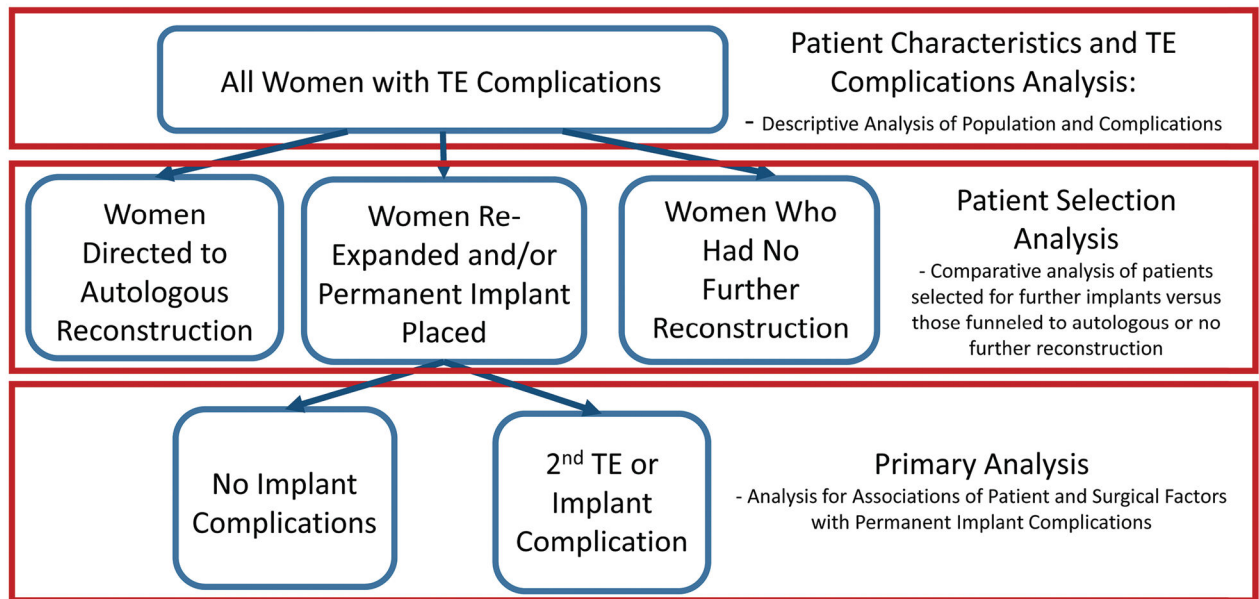


Figure 1:
Study Design and Statistical Analyses
TE = tissue expander



Figure 2:

Patient with bilateral failed tissue expanders successfully reconstructed with second episode of tissue expanders followed by implants. **A.** Preoperative frontal view prior to skin-sparing mastectomies. **B.** Preoperative oblique view prior to mastectomies. **C.** Frontal view of tissue expanders explanted on both sides following skin-sparing mastectomies, immediate subpectoral tissue expanders with acellular dermal matrix slings, and subsequent infection 67 days later. **D.** Oblique view of tissue expanders explanted on the both sides. **E.** Frontal view three years following bilateral tissue expanders followed by silicone smooth round breast implants and nipple-areola reconstructions to salvage failed tissue expander

reconstructions. **F.** Oblique view three years following bilateral tissue expanders followed by implant exchanges and nipple-areola reconstructions.

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Figure 3.

Patient with failed tissue expander reconstructed with autologous flap. **A.** Preoperative frontal view prior to mastectomies. **B.** Preoperative oblique view prior to mastectomies. **C.** Frontal view of tissue expander explanted on the left side following radiation therapy. Right sided tissue expander remains. **D.** Oblique view of tissue expander explanted on the left side following radiation therapy. **E.** Frontal view two years following deep inferior epigastric artery perforator (DIEP) flap performed on left to salvage failed tissue expander reconstruction. Implant exchange on right and bilateral nipple-areola reconstructions also

performed. **F.** Oblique view two years following DIEP flap (left), implant exchange (right) and bilateral nipple-areola reconstructions.

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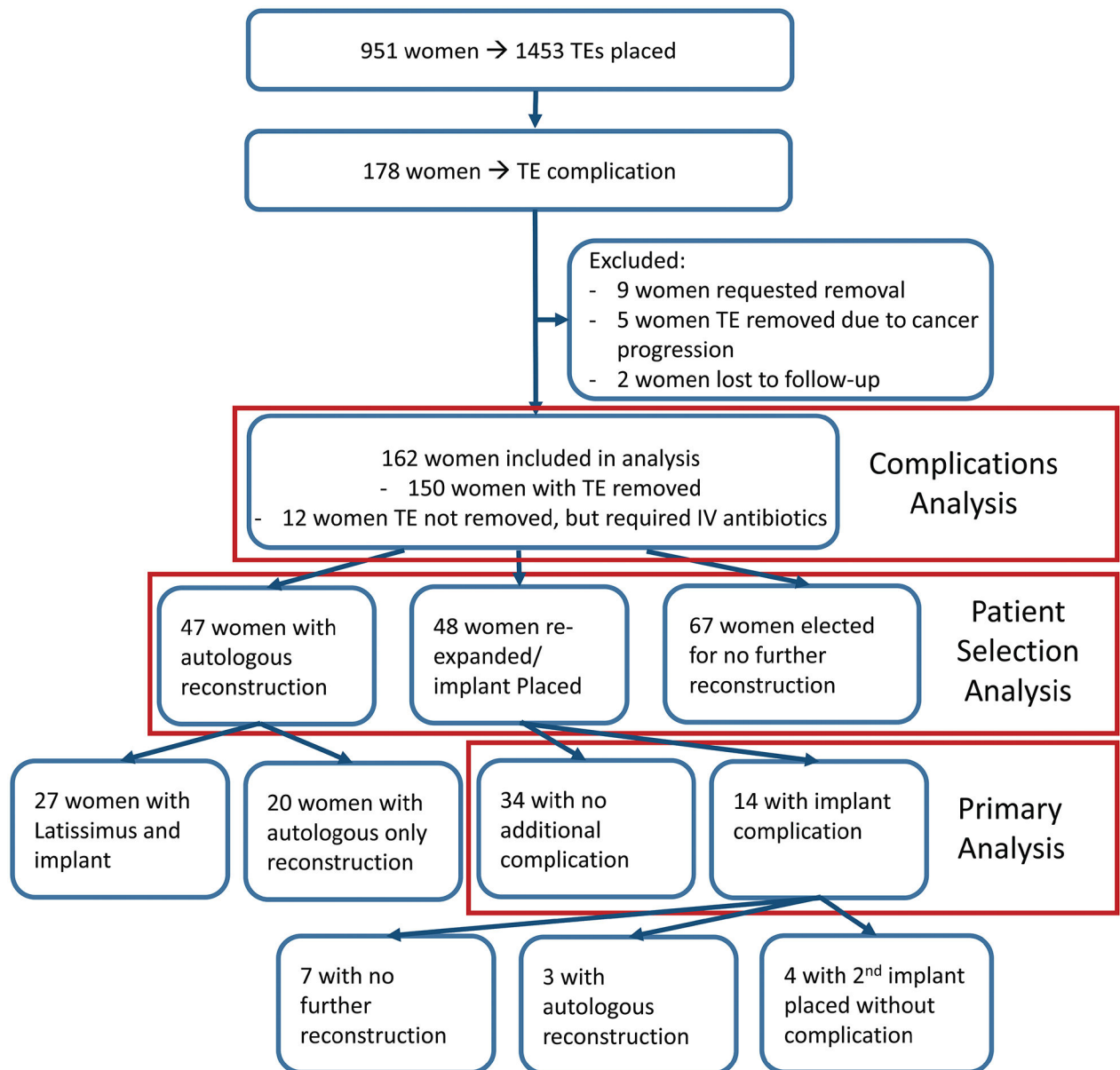


Figure 4:
Patient Inclusion and Outcomes Flowsheet
TE = tissue expander

Table 1:

Comparison of Patient Characteristics by Reconstructive Pathway after TE Complication

	Autologous Reconstruction n(%), Mean $\pm$ SD	Implant Placed n(%), Mean $\pm$ SD	No Reconstruction n(%), Mean $\pm$ SD	p value
Number of Patients	47 (100%)	48 (100%)	67 (100%)	NA
Age (Years)	47 $\pm$ 10	50 $\pm$ 12	50 $\pm$ 10	NS
Race	White – 36 (77%) Black – 11 (23%)	46 (96%) 2 (4%)	52 (78%) 15 (22%)	NS
Body Mass Index (BMI)	30 $\pm$ 6	30 $\pm$ 6	31 $\pm$ 8	NS
Delayed TE Placement	2 (4%)	3 (6%)	8 (12%)	NS
Clinical Stage	Stage 0–1 – 13 (29%) Stage 2 – 12 (27%) Stage 3 – 10 (22%) Stage 4 – 10 (22%)	20 (53%) 7 (18%) 2 (5%) 9 (24%)	20 (30%) 18 (27%) 23 (34%) 6 (9%)	NS
Adjuvant Radiation	None – 20 (43%) Post TE – 26 (55%) Pre TE – 1 (2%)	28 (74%) 10 (26%) 0 (0%)	41 (61%) 25 (37%) 1 (25%)	NS
Chemotherapy	None – 11 (23%) NeoAdj. – 15 (32%) Adjuvant – 21 (45%)	14 (33%) 12 (29%) 16 (38%)	12 (18%) 14 (21%) 41 (61%)	NS
Diabetes Mellitus	4 (9%)	3 (6%)	9 (13%)	NS
Smoking Status	Never – 18 (38%) Prior – 13 (28%) 16 (34%)	25 (52%) 10 (21%) 13 (27%)	26 (39%) 17 (25%) 24 (36%)	NS
Acellular Dermal Matrix	39 (83%)	38 (79%)	49 (73%)	NS
IV Antibiotics Given	27 (57%)	19 (40%)	38 (57%)	NS
Follow-up (Years)	8 $\pm$ 3	8 $\pm$ 3	9 $\pm$ 3	NS

Bold text indicates significant differences. TE = Tissue Expander; NA = Not applicable; NS = Not Significant; NeoAdj. = Neo-Adjuvant; IV = Intravenous

Table 2:**Causes for Tissue Expander Removal**

Cause	Number of Patients (% of study population)	% of all patients with TEs (n=951)
Infection	86 (52%)	9%
Mastectomy flap necrosis	19 (12%)	2%
TE exposure or wound dehiscence	18 (11%)	2%
TE leak, deflation, or rupture	18 (11%)	2%
Seroma	5 (3%)	0.5%
Pain	3 (2%)	0.3%
Hematoma	2 (1%)	0.2%
Capsular contracture	1 (0.5%)	0.1%
Patient requested removal	9 (Excluded)	1%
Cancer Progression	5 (Excluded)	0.5%

Table 3:

Patients with Salvaged Tissue Expanders after Infection

Patient Number	Bacterium	Antibiotic(s)	Duration in days and Route (IV vs PO)	Final Outcome	Comments
1	Unknown	Vancomycin	10 IV 15 PO	No Recon	Patient chose no further reconstruction and TE was removed after resolution of infection
2	Unknown	Vancomycin; Cefepime; Clindamycin	5 IV PO Unknown	Implant	No further complications
3	Unknown	Vancomycin; Piperacillin& Tazobactam; Trimethoprim & Sulfamethoxazole	2 IV PO Unknown	Implant	No further complications
4	Unknown	Vancomycin; Cefepime	14 IV	Autologous	Implant under latissimus flap
5	Pseudomonas	Gentamycin	11 IV	Implant	No further complications
6	Unknown	Levaquin; Piperacillin& Tazobactam; Amoxicillin, Clavulanate	4 IV PO Unknown	Implant	No further complications
7	Unknown	Vancomycin; Trimethoprim & Sulfamethoxazole; Keflex	10 IV 7 PO	Implant	Seroma pocket drained at time of first infection. Had two episodes of cellulitis managed with antibiotics prior to implant exchange. After exchange, no further complications.
8	Unknown	Vancomycin; Piperacillin& Tazobactam; Trimethoprim & Sulfamethoxazole	4 IV 10 PO	Autologous	Underwent bilateral DIEP flaps due to poor quality skin following radiation therapy.
9	Unknown	Vancomycin; Piperacillin& Tazobactam; Trimethoprim & Sulfamethoxazole	4 IV 19 PO	Implant	No further complications
10	MRSA	Linezolid; Trimethoprim & Sulfamethoxazole	0 IV 81 PO	No Recon	Implant removed after infection presented, erythema never fully resolved prior to implant exchange
11	Unknown	Vancomycin; Cefepime; Clindamycin; Ciprofloxacin	2 IV PO Unknown	Implant	No further complications
12	Unknown	Vancomycin; Doxycycline	4 IV 14 PO	Implant	Seroma pocket opened at time of infection. No further complications

Table 4:

Tissue Expander Infection Culture Results

Species	# Of Cultures (%)
No Growth	29 (35%)
Methicillin Sensitive <i>Staphylococcus aureus</i>	32 (39%)
Methicillin Resistant <i>Staphylococcus aureus</i>	4 (5%)
Other Gram (+) Bacteria (<i>Streptococcus</i> , <i>Corynebacterium</i>)	2 (2%)
<i>Pseudomonas aeruginosa</i>	6 (7%)
Other Gram (–) Bacteria (<i>Enterococcus faecalis</i> , <i>Peptostreptococcus</i>)	2 (2%)
Anaerobic Species (<i>Propionibacterium</i> , <i>Proteus mirabilis</i>)	2 (2%)
<i>Candida</i> Species	1 (1%)
Multiple bacterial species	4 (5%)

[Original]

Effect of Breast Reconstruction on Breast Cancer Therapy

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Abstract : Few studies have examined the effect of immediate breast reconstruction (IBR) on the overall progression of breast cancer therapy. This study examines the effect of IBR on the breast cancer therapy. 142 patients underwent mastectomy in our department (With IBR group, n=17; Without IBR group, n=125). We examined the number of days from diagnosis to surgery, operation time, length of postoperative stay, number of days from surgery to postoperative therapy, and complications in patients with or without breast reconstruction and by type of reconstruction. In the IBR group, the operation time was longer ($P<0.001$), postoperative hospital stay was longer when adjusted for multivariate analysis ($P=0.008$), and complications were significantly more common ($P<0.001$), but there was no significant difference when limited to grade ≥ 3 complications. There was no difference until the start of postoperative treatment. The results reveal that IBR requires coordination between the surgical and operating room staff, and does not affect the transition to postoperative treatment but does affect an increased incidence of minor complications and length of postoperative stay.

Keywords : breast cancer, immediate breast reconstruction.

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Introduction

The incidence of breast cancer is increasing worldwide, affecting one in nine women in Japan [1]. Although breast-conserving surgery is becoming more widespread, approximately 40% of women undergo mastectomy [2]. Immediate breast reconstruction (IBR) improves the quality of life by reducing the body image changes and negative psychological effects of mastectomy [3–5]. However, breast reconstruction requires the placement of implants in the body and procedures not directly related to cancer treatment such as the removal

of the vastus lateralis and rectus abdominis [4]. Breast cancer also affects relatively more people aged <40 , and the number of patients increases rapidly from their late 30s [6, 7].

The amount of time and effort that can be spent on treatment varies among individuals. In Japan, breast surgeons often manage the entire treatment of breast cancer, from diagnosis to surgery and drug therapy, and when breast reconstruction is performed, the surgical schedule must be coordinated first with plastic surgery. Although many studies have discussed the effectiveness, evaluation, and safety of breast recon-

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struction [3, 8–14], few have examined the overall time from diagnosis to surgery and the start of postoperative therapy. The increased complications are also extremely burdensome to patients. We considered these factors to be important for patients when deciding on breast reconstruction. Therefore, we retrospectively evaluated the effect of breast reconstruction on patients with breast cancer who underwent mastectomy.

Materials and Methods

Patients

In this study, we examined patients who underwent unilateral mastectomy ($\pm$ axillary manipulation) with or without IBR.

The study population was comprised of 164 patients who underwent mastectomy at the Second Department of Surgery, School of Medicine, University of Occu-

pational and Environmental Health Japan, between January 2017 and November 2021. Patients who underwent simultaneous bilateral breast cancer surgery, simultaneous surgery with non-breast cancer surgery, and two cases of male breast cancer, were excluded. Finally, 142 cases were included in the study (Figure 1). One group of patients underwent IBR at the time of mastectomy (With IBR group), whereas the other group underwent mastectomy without breast reconstruction (Without IBR group). The With IBR group consisted of 7 cases with implants and 7 with latissimus dorsi musculocutaneous (LDM) flap breast reconstruction, and 3 with deep inferior epigastric perforator (DIEP) flap reconstruction.

This study was approved by the ethics committee of the University of Occupational and Environmental Health (No. UOEHCRB20-109). The patients were informed verbally and in writing regarding the purpose of the study, and their consent was obtained. If direct

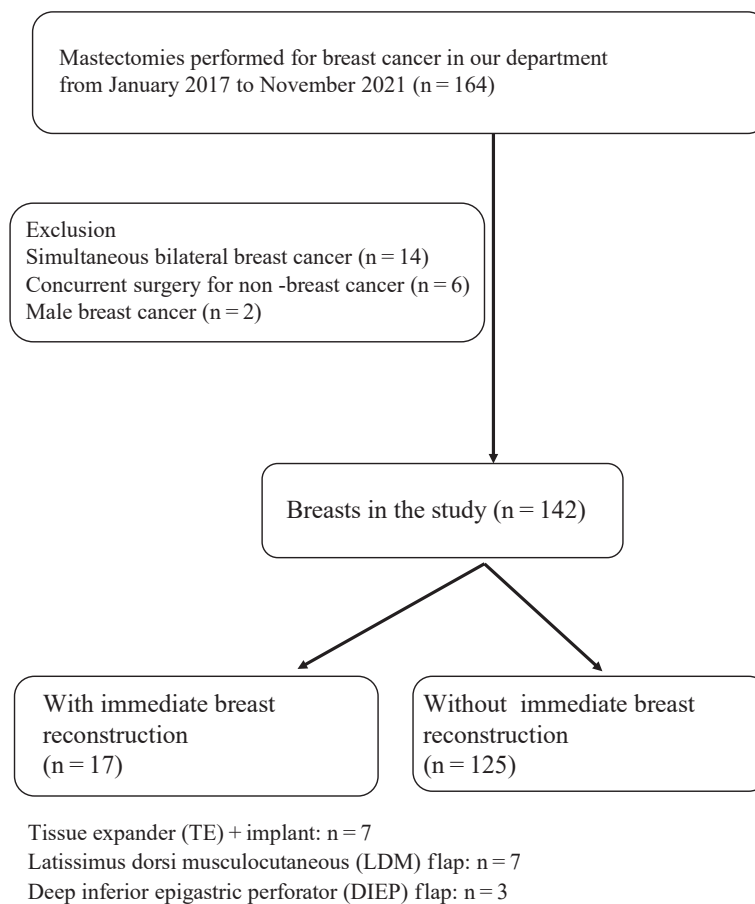


Figure 1. Study flow diagram.

consent could not be obtained, information about the conduct of the research was made public, and the alternative to refuse participation was given.

Course of breast cancer from diagnosis to surgery

Diagnoses were made on an outpatient basis by echo-guided needle biopsy. Some patients who were referred to us had already been diagnosed with breast cancer by a previous physician. Patients who may have been referred for mastectomy asked if they wished to have breast reconstruction once diagnosed with breast cancer, and those who wished to have breast reconstruction were referred to a plastic surgeon in the same hospital at a later date.

Surgical procedures

All patients underwent mastectomy. A sentinel node biopsy was performed in cases of cN0, and axillary lymph node dissection was added if there were metastases in the sentinel nodes. Sentinel node biopsy was sometimes omitted for ductal carcinoma in situ mastectomy or for stage IV mastectomy for local control. Breast reconstruction was indicated based on the patient's choice. However, according to the regulations of the Japanese Society of Breast Oncoplastic Surgery, breast reconstruction with implants was performed only in patients who had a preoperative diagnosis of stage $\leq$ II and no skin invasion, chest wall invasion, or advanced lymph node metastasis. In all cases, reconstruction with implants was performed after tissue expansion by a tissue expander (TE), followed by implant replacement. After mastectomy, the patients were directly transferred to the plastic surgery department for breast reconstruction surgery.

Study Design

The following data were collected from the electronic medical records: basic characteristics, cancer characteristics, and treatment course (outpatient records, hospitalization records, surgical records, and preoperative and postoperative treatment). The number of days from diagnosis to surgery, operation time, length of postoperative stay, number of days from surgery to postoperative therapy, and complications with or without IBR were evaluated. For patients who were diagnosed with breast cancer and had been referred by

a previous physician, the number of days from the first visit to surgery was used as the duration until surgery. Reconstructive cases with implants were examined at the time of initial mastectomy + TE insertion, not at the time of implant replacement. Surgical complications were evaluated according to the Japan Clinical Oncology Group postoperative complication criteria [15].

Statistical analysis

To assess the differences between the two groups, the Chi-square test was used to analyze categorical variables, whereas the Mann–Whitney test was used for continuous variables. The nonparametric K-sample test on the equality of medians was used for items with significant differences among the four groups. Univariate and multivariate regression analyses were performed to examine the association of IBR with the number of days from diagnosis to surgery, operation time, length of postoperative stay, number of days from surgery to postoperative care, and complications. The multivariate analysis was adjusted for age, BMI, smoking, diabetes mellitus (DM), and axillary lymph node dissection (Ax). We chose age, BMI, smoking, DM, and Ax as factors that clinically influence breast cancer therapy and complications based on previous evidence and our clinical judgment [16, 17]. Odds ratios (ORs) for complications associated with the reconstruction type were estimated by univariate and multivariate logistic regressions. Statistical analyses were performed using STATA version 17 (Stata Corp LLC, Texas), and statistical significance was set at $P < 0.05$.

Results

The baseline characteristics of the patients are shown in Table 1. The operation time was predominantly longer in the With IBR group ($P < 0.001$). The median operation times for the implant group, LDM flap group, and DIEP flap group were 231 (207–251), 455 (372–582) min, and 551 (518–716) min, respectively. No difference was found in the number of days from diagnosis to surgery, number of days from surgery to postoperative therapy, and postoperative hospital stay (Table 2). Table 3 compares the number of days from diagnosis to surgery, surgery time, days

Table 1. Patient characteristics

	Without IBR group (n = 125)	With IBR group (n = 17)
Age (mean $\pm$ SD)	65.0 $\pm$ 12.1	48.4 $\pm$ 8.6
Range	(40–87)	(29–63)
Body mass index (mean $\pm$ SD) kg/m ²	23.9 $\pm$ 4.5	22.8 $\pm$ 3.5
Range	(14.5–38.8)	(16.3–29.5)
	n (%)	n (%)
Stage at diagnosis		
0	20 (16)	6 (35)
I	44 (35)	9 (53)
II	44 (35)	1 (6)
III	13 (10)	1 (6)
IV	4 (3)	0 (0)
Subtype		
Luminal A	68 (54)	12 (71)
Luminal B	19 (15)	2 (12)
Luminal B HER2	12 (10)	1 (6)
HER2	7 (6)	1 (6)
TNBC	19 (15)	1 (6)
Neoadjuvant chemotherapy		
Yes	14 (11)	2 (12)
Postoperative treatment		
Yes	97 (78)	11 (65)
Axillary lymph node dissection		
Yes	41 (33)	3 (18)
Diabetes		
Yes	24 (19)	0 (0)
Smoking		
Yes	32 (26)	6 (35)
Type of reconstruction		
No reconstruction	125 (100)	0 (0)
Implant	0 (0)	7 (42)
Latissimus dorsi musculocutaneous (LDM) flap	0 (0)	7 (42)
Deep inferior epigastric perforator (DIEP) flap	0 (0)	3 (18)

SD: standard deviation, LDM: latissimus dorsi musculocutaneous, DIEP: deep inferior epigastric perforator.

from surgery to postoperative care, and length of hospital stay after surgery for the group without IBR and the group with IBR, then the group without IBR and

the type of breast reconstruction, respectively. The univariate analysis showed no significant difference in the implant group when compared with the Without IBR group; however, after adjustment for age, BMI, axillary lymph node dissection, smoking, and diabetes mellitus, the time taken for the surgery in the implant group was significantly longer than that in the Without IBR group. Another multivariate analysis showed that length of postoperative hospital stay differed between the With and Without IBR groups, and, among those with reconstruction, it was particularly prolonged in the LDM and DIEP groups (Table 3). The overall complication rate was significantly higher in the With IBR group than in the Without IBR group; however, no difference was found in grade ≥ 3 complications (Table 4,5). The main cause of increased complications in With IBR group was implant (Table 4). Most of the complications in cases with additional breast reconstruction were skin necrosis/flap necrosis (Table 5).

Discussion

The main results of this study showed that the addition of IBR at the time of mastectomy increased and the number of complications, but grade ≥ 3 complications remained the same and did not delay the start of postoperative therapy. The operation time was longer in the IBR group, with the autologous tissue group in particular contributing to a longer operation time and longer postoperative hospital stay. The operation time was also longer for all procedures, especially for reconstruction using autologous tissue.

No difference was found in the time from diagnosis to surgery because we have full-time breast surgeons and plastic surgeons on staff, making it easy to consult with them as soon as the patient wishes to undergo breast reconstruction, and we can provide both implant and autologous tissue reconstruction at the same hospital. Since not many patients have requested breast reconstruction in our department, we can respond to those who do wish to undergo breast reconstruction as soon as possible. If the number of patients who wish to undergo breast reconstruction increases in our department in the future, the results may be different, but because Japanese insurance coverage for implants is limited to early-stage breast cancer of stage $\leq$ II, preop-

Table 2. Impact of breast reconstruction on breast cancer treatment.

	Without IBR	With IBR	Reconstruction method			<i>P</i> (non-IBR vs. IBR)	<i>P</i> (comparison of four groups)
			Implant	LDM flap	DIEP flap		
N	125	17	7	7	3		
Number of days from diagnosis to surgery (days)	42 (31–59)	67 (38–79)	74 (31–84)	47 (22–202)	67 (60–79)	0.117	0.176
Median (IQR)							
Operation time (minutes)	196 (166–233)	372 (248–518)	231 (207–251)	455 (372–582)	551 (518–716)	<0.001	<0.001
Number of days from surgery to postoperative therapy (days)	55 (39–74)	56 (43–81)	55 (33–144)	52 (43–81)	56 (56–56)	0.714	0.934
Length of postoperative hospital stay (days)	12 (10–14)	15 (10–17)	10 (8–12)	15 (15–16)	18 (17–18)	0.212	0.007
Complications	22 (17)	10 (59)	5 (71)	5 (71)	0 (0)	<0.001	<0.001

IBR: immediate breast reconstruction, DIEP: deep inferior epigastric perforator, IQR: interquartile range, LDM: latissimus dorsi musculocutaneous, SD: standard deviation.

Table 3. Effect of immediate breast reconstruction on breast cancer therapy considering age, BMI, smoking, and axillary lymph node dissection

		Univariate model			<i>P</i>	Multivariate model			<i>P</i>
		Coefficient	95% CI			Coefficient	95% CI		
Number of days from diagnosis to surgery	Without IBR								
	With IBR	−6.30	−83.92	71.33	0.873	−2.44	−86.32	81.44	0.954
Operation time	Without IBR								
	With IBR	194.48	155.94	233.02	<0.001	207.59	169.63	245.54	<0.001
Number of days from surgery to postoperative therapy	Without IBR								
	With IBR	7.70	−18.79	34.18	0.566	14.44	−15.18	44.05	0.336
Length of postoperative hospital stay	Without IBR								
	With IBR	0.75	−1.78	3.28	0.558	3.50	0.95	6.06	0.008
Number of days from diagnosis to surgery	Without IBR								
	Implant	−20.00	−137.40	97.41	0.737	9.31	−109.63	128.25	0.877
	LDM flap	9.86	−107.54	127.26	0.868	5.13	−119.83	130.08	0.935
	DIEP flap	−12.04	−188.62	164.53	0.893	−44.09	−219.38	131.21	0.620
Operation time	Without IBR								
	Implant	30.47	−13.19	74.12	0.170	55.98	17.96	93.99	0.004
	LDM flap	273.33	229.67	316.98	<0.001	288.50	248.58	328.41	<0.001
	DIEP flap	393.18	327.52	458.85	<0.001	392.35	336.32	448.38	<0.001
Number of days from surgery to postoperative therapy	Without IBR								
	Implant	14.23	−32.93	61.39	0.551	16.10	−32.93	65.14	0.516
	LDM flap	6.90	−26.94	40.74	0.687	15.09	−22.42	52.60	0.427
	DIEP flap	−7.10	−87.96	73.75	0.862	5.48	−78.28	89.24	0.897
Length of postoperative hospital stay	Without IBR								
	Implant	−2.04	−5.80	1.73	0.286	0.85	−2.72	4.41	0.640
	LDM flap	1.82	−1.95	5.58	0.341	5.20	1.45	8.94	0.007
	DIEP flap	4.77	−0.89	10.43	0.098	6.19	0.93	11.45	0.021

Age, BMI, smoking, and axillary lymph node dissection were included in the multivariate logistic regression model. BMI: body mass index, CI: confidence interval, DIEP: deep inferior epigastric perforator. IBR: immediate breast reconstruction, LDM: latissimus dorsi musculocutaneous.

Table 4. Odds ratio of complications related to immediate breast reconstruction

	Univariate model				Multivariate model			
	OR	95% CI		<i>P</i>	OR	95% CI		<i>P</i>
Without IBR	reference				reference			
With IBR	6.69	2.29	19.50	<0.001	11.79	3.11	44.65	<0.001
Without IBR	reference				reference			
Implant	11.70	2.13	64.28	0.005	22.96	3.48	151.30	0.001
LDM flap+DIEP flap	4.68	1.25	17.57	0.022	7.28	1.48	35.87	0.015

Age, BMI, smoking, and axillary lymph node dissection were included in the multivariate logistic regression model. BMI: body mass index, IBR: immediate breast reconstruction, DIEP: deep inferior epigastric perforator, IBR: immediate breast reconstruction, LDM: latissimus dorsi musculocutaneous.

Table 5. Complications according to grade

Complications	Without IBR group (n=125)	With IBR group (n=17)	<i>P</i>
Any grade n (%)			
All complications	22 (18)	10 (59)	0.001
Wound infection	8 (6.4)	1 (5.9)	0.707
Skin necrosis/flap necrosis	10 (8)	9 (52.9)	<0.001
Postoperative hemorrhage	3 (2.4)	0 (0)	0.680
Wound dehiscence	1 (0.8)	0 (0)	0.880
Grade≥3 n (%)			
All complications	8 (6.4)	3 (18)	0.128
Wound infection	0	1 (5.9)	0.12
Skin necrosis/flap necrosis	6 (4.8)	2 (11.8)	0.245
Postoperative hemorrhage	2 (1.6)	0 (0)	0.774
Wound dehiscence	0 (0)	0 (0)	—

IBR: immediate breast reconstruction.

erative drug therapy is often introduced for advanced breast cancer [12], and breast reconstruction after pre-operative chemotherapy is also being performed [13, 14], patients may not be adversely affected even if additional breast reconstruction delays the surgery.

The operation time was significantly longer in the With IBR group than in the Without IBR group. Reconstruction with autologous tissue usually requires longer operation time than reconstruction with prostheses, and among autologous tissue, procedures that require microscopic anastomosis of flap vessels, such as the DIEP flap, are more difficult and require a relatively longer operation time [18–20]. A prolonged

operation time increases postoperative complications and involves increased surgical staff labor and operating room management, so the importance of communication among surgical staff has been noted [21]. Cooperation is needed to shorten the operation time, such as the prompt transition from breast surgery to plastic surgery and smooth positional changes through cooperation among surgical staff.

A critical path has been introduced for breast cancer surgery, and patients are usually admitted to the hospital 1–2 days preoperatively. In the case of mastectomy, the hospital stay is 7–10 days postoperatively. In our hospital, a drain is placed after mastectomy, and

the patient is discharged from the hospital only after drain removal. The drain is removed when the drainage volume is ≤ 40 ml per day. Factors that influence drain removal include high BMI, axillary lymph node dissection, comorbidities, old age, and preoperative chemotherapy [22, 23]. It has been pointed out that microsurgical breast reconstruction requires longer postoperative hospital stay as well as longer operating time compared to implant-based reconstruction [24]. When adjusted for multivariate analysis in this study, length of postoperative stay was longer in the With IBR group, especially with the LDM and DIEP flap group (Table 3).

Concerns have been raised about the negative effect of IBR on oncologic outcomes, and the effect on postoperative therapy has been widely reported. Although postoperative treatment does not appear to be delayed enough to be clinically problematic [25–27], concerns have been raised about complications that delay adjuvant therapy for autologous reconstruction, especially with the transverse rectus abdominus myocutaneous (TRAM) flap [28]. In this study, no significant difference was found in the time to postoperative therapy between the With IBR group and the Without IBR group (Table 2). When performing breast reconstruction, in addition to the usual complications associated with overall surgery, such as seroma, bleeding, hematoma, skin necrosis and infection, complications ischemia/necrosis/loss, other complications may also occur, such as fat necrosis, implant capsular contracture, implant failure, exposure, or malposition related to breast reconstruction [16]. Reports of complications after IBR vary (10–59%) [24, 29–31], but in this study, complications of any grades were 59%, and complications of Grade ≥ 3 were 18% (Table 5). The risk of complications seems to vary with the type of IBR [29]. Risk factors for breast reconstruction include autologous tissue, general health condition, obesity, smoking, and diabetes [17, 29]. In pulmonary embolism, a serious side effect of abdominal flaps, BMI and BRCA gene mutations have been cited as risk factors [32]. One report indicated that reconstruction with implant was associated with more complications than reconstruction with autologous tissue [33], and another study reported no particular difference in complications between reconstruction with implant and that

with autologous tissue [34]. In this study, both implant and autologous tissue breast reconstruction were factors for increased complications compared to cases without breast reconstruction (Table 4). Although they did not affect postoperative therapy, the increased number of complications is a burden on the patient. Special care should be taken to explain the procedure of breast reconstruction to patients who are at risk for complications.

Limitations

The limitations of the study should be discussed. First, this study was not a randomized controlled trial (RCT), so the influence of unobserved confounding factors cannot be excluded. However, it is not possible to conduct a RCT because the choice of reconstruction and procedure depends on the patient's clinical stage, financial situation, and preferences. Second, the sample size was small, giving a wide confidence interval in the statistical estimation. However, we believe that the present study gives a certain view, even with reference to conservative values of the confidence intervals. Third, this study is based on cases collected at a single hospital. Since there are differences between hospitals not only in patient demographics but also in surgical procedures and postoperative management methods, a large-scale analysis at multiple hospitals would be desirable for generalization.

Conclusions

Breast reconstruction, especially reconstruction using autologous tissue, requires a longer operation time, necessitating adjustments when scheduling surgery. In addition, patients should be fully informed that while there are few serious complications associated with breast reconstruction that would affect postoperative therapy, there is an increased risk of minor complications, and patients who choose reconstruction with autologous tissue may have a longer postoperative hospital stay.

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Conflict of Interest

None

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ARTICLE OPEN



Clinical Studies

A nationwide study of breast reconstruction after mastectomy in patients with breast cancer receiving postmastectomy radiotherapy: comparison of complications according to radiotherapy fractionation and reconstruction procedures

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BACKGROUND: We examined the patterns of breast reconstruction postmastectomy in breast cancer patients undergoing postmastectomy radiotherapy (PMRT) and compared complications based on radiotherapy fractionation and reconstruction procedures.

METHODS: Using National Health Insurance Service (NHIS) data (2015–2020), we analysed 4669 breast cancer patients with PMRT and reconstruction. Using propensity matching, cohorts for hypofractionated fractionation (HF) and conventional fractionation (CF) were created, adjusting for relevant factors and identifying grade ≥ 3 complications.

RESULT: Of 4,669 patients, 30.6% underwent HF and 69.4% CF. The use of HF has increased from 19.4% in 2015 to 41.0% in 2020. Immediate autologous (32.9%) and delayed two-stage implant reconstruction (33.9%) were common. Complication rates for immediate ($N = 1286$) and delayed two-stage ($N = 784$) reconstruction were similar between HF and CF groups (5.1% vs. 5.4%, $P = 0.803$, and 10.5% vs. 10.7%, $P = 0.856$, respectively) with median follow-ups of 2.5 and 2.6 years. HF showed no increased risk of complications across reconstruction methods.

CONCLUSION: A nationwide cohort study revealed no significant difference in complication rates between the HF and CF groups, indicating HF for reconstructed breasts is comparable to CF. However, consultation regarding the fractionation for reconstructed breast cancer patients may still be necessary.

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INTRODUCTION

The escalating incidence of breast cancer has led to a corresponding rise in the number of breast cancer patients opting for breast reconstruction. This trend is particularly evident in South Korea, where breast reconstruction surgery following mastectomy gained coverage under the National Health Insurance Service (NHIS) in April 2015. Consequently, the rate of breast reconstruction cases in South Korea rose from 19.4% in 2015 to 53.4% in 2018 [1]. Similarly, the number of patients requiring postmastectomy radiotherapy (PMRT) is also expected to increase, given that PMRT is administered to one-third of breast cancer patients [2]. Despite the growing number of patients undergoing breast reconstruction and PMRT, the question of determining the optimal approach for patients receiving PMRT remains unsolved.

PMRT is associated with reconstruction-related complications and negatively impacts patients' satisfaction. According to the

Mastectomy Reconstruction Outcomes Consortium (MROC), PMRT significantly elevated the risk of complications by 2.6 times higher in patients with implant-based reconstructions compared to those who did not receive PMRT [3]. Likewise, irradiated autologous flaps exhibited a stronger association with fat necrosis and revision surgery compared to unirradiated flaps [4]. Patients with implant reconstruction and PMRT reported the lowest satisfaction levels [3]. These findings highlight the importance of finding strategies to minimise reconstruction-related complications.

Breast reconstruction is a multifaceted procedure that encompasses a variety of options, making it difficult to reach a consensus on the integration of reconstruction and PMRT. There are several approaches for breast reconstruction in terms of timing and materials. The timing of reconstruction can be classified as immediate, delayed, or a combination of both (delayed two-stage) [5]. In delayed two-stage reconstruction, known as delayed-

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immediate, a tissue expander is placed immediately with mastectomy, and it is exchanged for the implant or autologous tissues later [6]. Reconstruction materials can be either implants or autologous tissue such as fat or muscle, each with its unique advantages and drawback. While autologous flaps exhibit greater tolerance to irradiation compared to implants, not all patients are eligible for autologous reconstruction.

The advancements in radiation techniques have also added to the complexity of PMRT in reconstructed breasts. One of the major changes is the adoption of hypofractionation in breast cancer radiotherapy. By delivering a higher dose per fraction, HF can reduce treatment duration. Apart from convenience, HF has demonstrated comparable oncological outcomes to conventional fractions while exhibiting similar or even superior toxicity results [7–10]. However, these studies excluded patients with breast reconstruction. Consequently, the use of hypofractionation for reconstructed breasts remains controversial. For instance, the ESTRO guideline recommends adopting hypofractionation regardless of any oncoplastic surgery, while the ASTRO guideline does not yet endorse it [11, 12].

Therefore, we conducted a nationwide study to examine the current practices in breast reconstruction with PMRT following the implementation of insurance reimbursement in 2015. In addition, we compared the complication rates associated with hypofractionation and conventional fractionated PMRT. Ultimately, this study aimed to provide comprehensive nationwide data on breast reconstruction approaches and evidence for the comparable safety of HF for patients undergoing breast reconstruction.

MATERIALS AND METHODS

Data sources and study population

In South Korea, medical services in South Korea are covered by the NHIS, so it harbours large datasets of healthcare utilisation on a nationwide scale. It can provide demographic information, death information, and medical services utilisations at outpatient clinics as well as admissions. For research purposes, any researcher with ethical approval from the institutional review board can request the database. The personal information is deidentified, and analysis can be performed by using the International Statistical Classification of Diseases and 10th revision (ICD-10), and a procedure or operation code.

The study was approved by the Seoul National University Hospital's Institutional Review Board (Number 2204-067-1315). The need for informed consent was waived due to the use of pseudonymized data. We requested a customised NHISS database of Korean female breast cancer patients who underwent mastectomy and postmastectomy radiation therapy (PMRT) between 2015 and 2020. The operational codes used for this study are listed in Supplementary Table 1. The study period was between 2015 and 2021. This period was chosen to capture the impact of the reimbursement for breast reconstruction, which began in 2015. Among the 58,028 women with mastectomy and radiation therapy for breast cancer (ICD-10; C50) between 2015 and 2020, we initially excluded no history of reconstruction ($n = 6020$) (Supplementary Fig. S1). Next, we excluded patients with multiple mastectomies ($n = 925$), time interval longer than 1 year between mastectomy and PMRT ($n = 7950$), and PMRT number less than 14 or greater than 35 ($n = 38,464$).

Finally, there were 4669 patients eligible for a pattern of care analysis.

Definitions

PMRT was administered following mastectomy surgery. Information on fraction size or number was unavailable in the database; therefore, the number of claim codes for radiation treatment, including chest wall and tumour bed boost irradiation, was considered to represent the fraction number. Only claim codes recorded up to three months from the initial PMRT date were counted. Using the survey result of the pattern of care study conducted by the Korean Radiation Oncology Group, we divided fractionation groups as follows [2]. Conventional fractionation (CF) was defined as 25–35 radiation treatments, assuming a total dose of at least 45–50 Gy in 1.8–2.0 Gy fractions. Conversely, hypofractionation (HF) was defined as 14 to 24 radiation treatments, assuming a total dose of 40–42.5 Gy in fractions greater than 2 Gy.

Breast reconstruction can be classified based on the reconstruction material and timing. Autologous breast reconstruction utilises tissue from the patient's own body, such as latissimus dorsi (LD), transverse rectus abdominis musculocutaneous (TRAM), or deep inferior epigastric artery perforator (DIEP). Implant-based involves the placement of breast implants either a tissue expander (TE) or direct-to-implant (DTI). Regarding the timing of reconstruction, immediate reconstruction is performed on the same day as mastectomy or before the initiation of PMRT. Delayed reconstruction consisted of two types of reconstruction: one-stage and two-stage delayed reconstruction. One-stage delayed reconstruction involves reconstruction surgery after the completion of PMRT, while two-stage delayed reconstruction involves tissue expander insertion followed by PMRT and final definitive reconstruction.

The primary outcome of this study was the incidence of reconstruction-related complications requiring surgery following PMRT. Only surgeries performed by the Department of Plastic Surgery were considered complication events. We employed the operational codes for breast capsulectomy (breast capsulorrhaphy, capsulotomy, capsular flap), debridement, and skin graft. Capsulectomy performed on the day of final reconstruction was not considered a complication. Capsular contracture referred to capsulectomy performed exclusively in patients with implants. The capsular contracture was limited to patients requiring surgical intervention, because the specific procedure code for breast capsulectomy assigned by the national standard code was available. Wound complication was defined as an adverse event necessitating surgical debridement and skin graft. Patients with delayed two-stage complications were excluded if they lacked a final reconstruction history or complication history.

Statistical analysis

Basic descriptive statistics were used to examine the practice pattern trend in PMRT and breast reconstruction. The cohort was divided based on the timing of breast reconstruction (immediate vs. two-stage delayed reconstruction), and the toxicity outcomes between CF and HF were compared. Baseline characteristics between CF and HF were evaluated using t-tests and chi-square tests for continuous and categorical variables, respectively. To adjust the baseline characteristics between two fractionated regimens, a 1:1 greedy nearest propensity matching method was implemented in PSMATCH (SAS version 9.4) with a caliper of 0.2. Adjusted covariates included age, hypertension, diabetes, reconstruction material, IMRT, year of PMRT, and bolus. A standardised mean difference (SMD) of 0.2 was set as the cut-off value between the groups.

Crude complication rates between the two fractionation groups were compared using chi-squared tests. To account for the difference in the follow-up duration, a competing risk analysis for complications was performed, with death as the competing risk. Cox regression model was employed to identify variables associated with complications. Variables with a P value < 0.1 in univariate analysis were included in the multivariate analysis. The follow-up duration was defined as the time interval between the first date of PMRT and the date of the complication event, death, or the last visit. Categorical variables were represented as proportions with percentages. Continuous variables were expressed as medians with range. Data processing and statistical analyses were performed by Statistical Analysis System (SAS) version 9.4 (SAS Institute, Cary, NC, USA) and Stata version 15.0 (StataCorp, College Station, TX).

RESULTS

Practice patterns of postmastectomy radiotherapy and breast reconstruction

A significant increase in the utilisation of breast reconstruction and PMRT was observed, with the number of patients undergoing these procedures rising from 341 in 2015 to 962 in 2020. Among 4,669 breast cancer patients who received PMRT and reconstruction between 2015 and 2020, implants were employed in 59.2% of the cases (Fig. 1a). Within the realm of autologous reconstruction, TRAM flaps were the most prevalent choice (38.5%), followed by DIEP (37.6%) and LD (23.9%) (Fig. 1b). Immediate reconstruction was the most frequently performed timing strategy, accounting for 55.4% of patients. Delayed two-stage reconstruction was utilised in 36.0% of patients, followed by delayed one-stage reconstruction in 8.6% of patients (Fig. 1c). When considering both

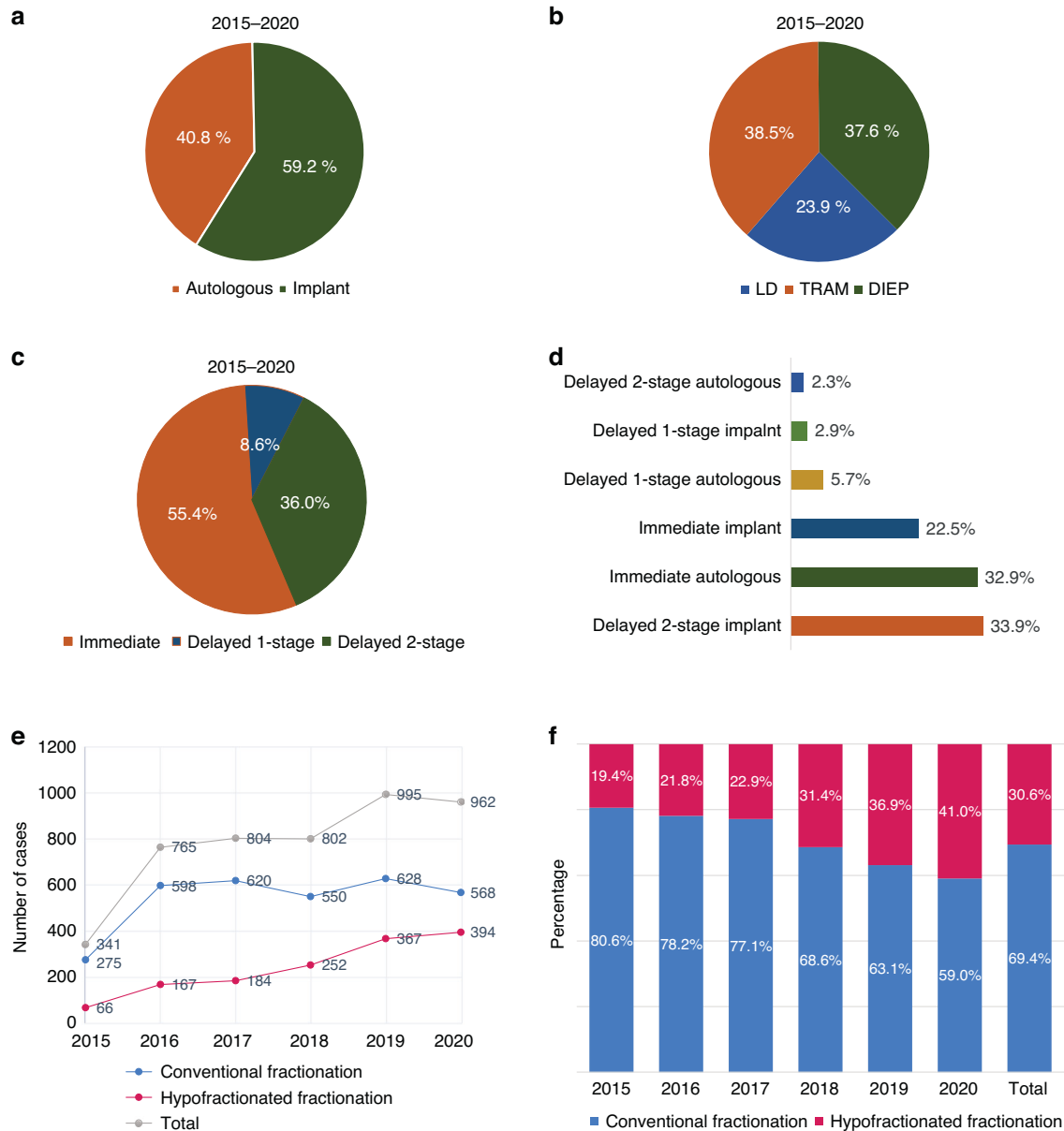


Fig. 1 Types of breast reconstruction and fractionations in patients with postmastectomy radiotherapy (PMRT) between 2015 and 2020. **a** Rate of implant and autologous-based reconstructions. **b** Materials used for autologous reconstruction. **c** Types of breast reconstructions by timing. **d** Breast reconstruction by timing and material. **e** Rate of conventional fractionation and hypofractionated fractionation. **f** The yearly trend of fractionation for reconstructed breasts between 2015 and 2020. LD lattissimus dorsi, TRAM transverse rectus abdominis musculocutaneous, DIEP deep inferior epigastric artery perforator

reconstruction materials and timing, delayed two-stage implant reconstruction was the most common procedure, performed in 33.9% of the cohort. Immediate autologous reconstruction and immediate implant reconstruction followed with respective frequencies of 32.9% and 22.5% (Fig. 1d). Regarding fractionation, 69.4% of the cohort received conventional fractionation (CF), while 30.6% underwent hypofractionation (HF). Notably, a gradual increase in the use of HF was observed, with the proportion of patients receiving HF rising from 19.4% (66 cases) in 2015 to 41.0% (394 cases) in 2020 (Fig. 1e, f).

Immediate breast reconstruction: baseline characteristics and complication incidence rate

A total of 2436 patients with immediate reconstruction were eligible for the complication analysis. Prior to propensity

matching, there were 1793 patients in the CF group and 643 patients in the HF group. Table 1 summarises the baseline characteristics of the immediate reconstruction cohort before and after matching. In the unmatched cohort, HF was associated with recent year of PMRT, IMRT technique, and shorter follow-up periods. The proportion of implant use was marginally higher in the CF group. Significantly more patients in the CF group received bolus treatment. Following 1:1 matching, all variables except PMRT fraction number were well-balanced. The median PMRT fraction number of CF and HF patients was 28 and 17, respectively.

The matched cohort analysis revealed comparable follow-up durations between the CF and HF groups. Both groups had a median follow-up of 2.5 years, with a range of 0.3–5.9 years. During a median follow-up duration of 2.5 years, the complication rates were 5.4% in CF and 5.1% in HF ($P = 0.803$). The complication

Table 1. Baseline characteristics of the immediate reconstruction cohort before and after propensity matching.

	Before 1:1 matching			After 1:1 matching		
	CF	HF	SMD	CF	HF	SMD
Characteristics	N = 1793	N = 643		N = 643	N = 643	
Year						
2018–2020	998 (55.7)	484 (75.3)	0.397	473 (73.6)	484 (75.3)	0.050
2015–2017	795 (44.4)	159 (24.7)		170 (26.4)	159 (24.7)	
Age						
>45	963 (53.7)	352 (54.7)	0.022	351 (54.6)	352 (54.7)	0.009
≤45	830 (46.3)	291 (45.3)		292 (25.4)	291 (45.3)	
Hypertension						
Yes	450 (25.1)	153 (23.8)	−0.063	159 (24.7)	153 (23.8)	−0.058
No	1343 (74.9)	490 (76.2)		484 (75.3)	490 (76.2)	
Diabetes						
Yes	549 (30.6)	186 (28.9)	−0.071	187 (29.1)	186 (28.9)	−0.022
No	1244 (69.4)	457 (71.7)		643 (70.9)	457 (71.7)	
Fraction number	28 (25–35)	17 (15–24)	−3.612	28 (25–35)	17 (15–24)	−3.517
IMRT						
Yes	471 (26.2)	453 (70.5)	0.972	453 (70.5)	453 (70.5)	0
No	1322 (73.7)	190 (29.5)		190 (29.5)	190 (29.5)	
Bolus						
Yes	540 (30.1)	147 (22.9)	−0.190	146 (22.7)	147 (22.9)	0.003
No	1253 (69.9)	496 (77.1)		497 (77.3)	496 (77.1)	
Reconstruction material						
Implant	751 (41.9)	243 (37.8)	−0.025	268 (41.7)	243 (37.8)	−0.021
Autologous	1042 (58.1)	400 (62.2)		375 (58.3)	400 (62.2)	
Median follow-up (year)	3.3 (0.3–6.6)	2.5 (0.3–5.9)	−0.357	2.5 (0.3–5.9)	2.5 (0.3–5.9)	−0.041

CF conventional fractionation, HF hypofractionated fractionation, SMD standardised mean difference, IMRT intensity modulating radiotherapy, mo months.

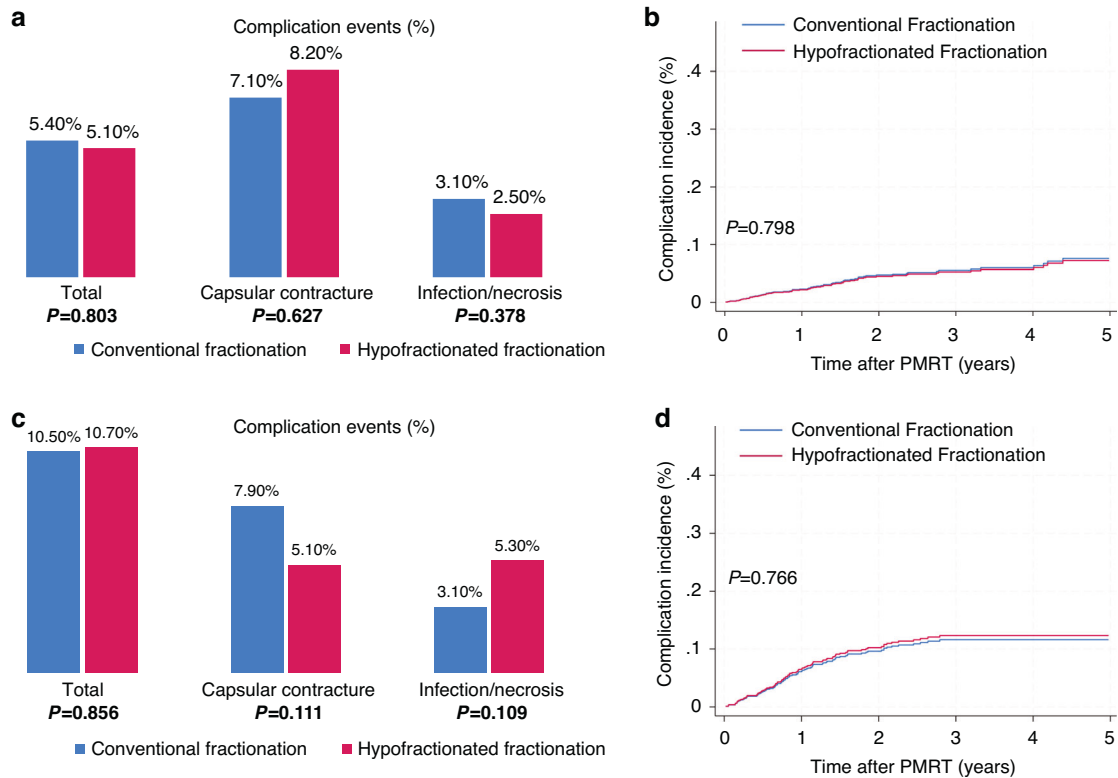


Fig. 2 Complications events and incidence according to fractionation and reconstruction timing. **a** Complication events in the matched immediate reconstruction cohort (N = 1286). **b** Cumulative incidence in the matched immediate reconstruction cohort (N = 1286). **c** Complication events in the matched two-stage delayed reconstruction cohort (N = 784). **d** Cumulative incidence in the matched two-stage delayed reconstruction cohort (N = 784).

Table 2. Cox regression proportional hazards model for complication in the immediate reconstruction cohort after matching (N = 1286).

Characteristics	Univariate	Multivariate	
		Hazard ratio (95% CI)	P
Year	2018–2020 (vs. 2015–2017)	1.06 (0.66–1.71)	0.784
Age	>45 (vs. ≤45)	1.03 (0.63–1.65)	0.913
Hypertension	Yes (vs. no)	1.89 (0.97–1.75)	0.062
Diabetes	Yes (vs. no)	1.06 (0.63–1.78)	0.833
Fractionation	HF (vs. CF)	1.01 (0.67–1.53)	0.832
IMRT	Yes (vs. no)	1.16 (0.74–1.80)	0.520
Bolus	Yes (vs. no)	1.24 (0.78–1.95)	0.361
Reconstruction material	Implant (vs. autologous)	2.70 (1.76–4.14)	<0.001
		2.65 (1.72–4.07)	<0.001

HF hypofractionated fractionation, CF conventional fractionation, IMRT intensity modulating radiotherapy, mo months.

incidence was not significantly different between two groups (Fig. 2a). Capsular contracture was the most common severe complication, occurring 7.1% in CF and 8.2% in HF ($P = 0.627$). The wound complications requiring debridement and skin graft were observed in 3.1% in CF and 2.5% in HF ($P = 0.378$). Figure 2b illustrates the cumulative incidence of complications, and the curves of the two fractionation groups did not differ from each other ($P = 0.798$). Similarly, there was no difference in complication incidence in the unmatched cohort as well (Supplementary Fig. S2A). In the matched cohort, implant-based immediate reconstruction was the only prognostic factor significantly associated with complications (hazard ratio (HR) 2.65, confidence interval (CI) 1.72–4.07, $P < 0.001$, Table 2). However, HF, IMRT, and bolus were not identified as significant factors.

Delayed two-stage breast reconstruction: baseline characteristics and complication incidence rate

In a retrospective analysis of 1347 patients undergoing delayed two-stage breast reconstruction, comprising 782 in the CF group and 565 in the HF group, the baseline characteristics of the unmatched and matched cohorts were compared (Table 3). Like the immediate breast reconstruction cohort, discrepancies were observed in the year of treatment, fraction number, intensity-modulated radiotherapy (IMRT) utilisation, bolus administration, and follow-up duration. The differences in the baseline characteristics were similar to the immediate cohort. Following propensity matching, the variables, except PMRT fraction number, were balanced between in the two groups. The median PMRT fraction number of CF and HF was 28 and 17, respectively. Unlike the

Table 3. Baseline characteristics of the delayed two-stage reconstruction cohort before and after propensity matching.

	Before 1:1 matching			After 1:1 matching		
	CF	HF	SMD	CF	HF	SMD
Characteristics	N = 782	N = 565		N = 392	N = 392	
Year						
2018–2020	500 (63.9)	415 (73.5)	0.399	288 (73.5)	295 (75.3)	0.109
2015–2017	282 (36.1)	150 (26.5)		104 (26.5)	97 (24.7)	
Age						
>45	387 (49.5)	278 (49.2)	−0.022	188 (48.0)	200 (51.0)	0.090
≤45	395 (50.5)	287(50.8)		204 (52.0)	192 (49.0)	
Hypertension						
Yes	173 (22.1)	121 (21.4)	0.063	84 (21.4)	82 (20.9)	−0.058
No	609 (77.9)	444 (78.6)		308 (78.6)	310 (79.1)	
Diabetes						
Yes	176 (22.5)	145 (25.7)	0.071	87 (22.2)	103 (26.3)	0.109
No	606 (77.5)	420 (74.3)		305 (77.8)	289 (73.7)	
Fraction number	28 (25–35)	17 (15–24)	−4.504	28 (25–35)	17 (15–24)	−4.426
IMRT						
Yes	260 (33.2)	428 (75.8)	1.009	251 (64.0)	256 (65.3)	0.043
No	522 (66.8)	137 (24.2)		141 (36.0)	136 (34.7)	
Bolus						
Yes	262 (33.5)	127 (22.5)	−0.337	114 (29.1)	101 (25.8)	−0.199
No	520 (66.4)	438 (77.5)		278 (70.9)	291 (74.2)	
Reconstruction material						
Implant	723 (92.5)	532 (94.2)	0.165	369 (94.1)	372 (94.9)	0.091
Autologous	59 (7.5)	33 (5.8)		23 (5.9)	20 (5.1)	
Median follow-up (year)	3.2 (0.9–6.4)	2.6 (0.4–6.3)	−0.269	2.8 (0.9–6.1)	2.6 (0.6–6.0)	−0.126

CF conventional fractionation, HF hypofractionated fractionation, SMD standardised mean difference, IMRT intensity modulating radiotherapy.

immediate reconstruction cohort, implants were predominately used as the final reconstruction material. The median interval between PMRT and final reconstruction was 258 days (range 31–985 days).

The matched cohort had a median follow-up duration of 2.6 years (0.6–6.1 years), with the CF group at 2.8 years (0.9–6.1 years) and the HF group at 2.6 years (0.6–6.0 years). The overall incidence of complication did not differ significantly between the groups (CF: 10.5% and HF: 10.7%, $P = 0.856$) (Fig. 2c). Capsular contracture occurred in 7.9% and 5.1% in CF and HF, respectively ($P = 0.111$). Similarly, the wound complication rates did not differ significantly between the two groups (CF: 3.1% and HF: 5.3%, $P = 0.109$). Furthermore, the cumulative complication incidence did not differ between the two groups ($P = 0.766$) (Fig. 2d). This was also consistent in the unmatched group was observed as well (Supplementary Fig. S2B). Univariate and multivariate analyses revealed hypertension (HR 2.42, CI 1.39–3.5, $P = 0.002$) and diabetes (HR 2.36, CI 1.36–4.01, $P = 0.002$) to be significantly associated with an increased risk of complications (Table 4). Except for patients' comorbidities, the factors related to radiation or reconstruction did not increase the risk of complications. Neither the use of bolus nor the time interval between PMRT and definitive surgery demonstrated prognostic significance.

DISCUSSION

This study represents the first population-based national cohort study to investigate the pattern of care and complications among patients with breast reconstruction and PMRT between 2015 and 2020. Despite the increasing number of breast reconstructions,

uncertainties persist regarding the timing and materials employed in the context of PMRT. Moreover, with advancements in radiation technology, hypofractionation has emerged as a replacement for conventional fractionation in breast cancer treatment. However, despite several randomised prospective studies, the impact and safety of hypofractionation under breast reconstruction setting was not well studied. Here, we utilised the big data from the National Health Insurance Service and reported the current status of breast reconstruction and PMRT in the South Korean population and showed comparable complication rates regardless of fractional regimens.

Our nationwide cohort study revealed that immediate reconstruction (55.4%) was the most preferred approach, followed by delayed two-stage reconstruction (36.0%). Within immediate reconstruction, autologous tissues were preferentially selected over implants. This finding aligns with the concerns regarding the elevated complications risk associated with implants compared to autologous tissue in an immediate reconstruction setting. Despite these concerns, implants remained a population choice, probably due to the shorter surgery time, faster recovery, and no donor site morbidity. Delayed two-stage reconstruction with implants was also commonly performed in our cohort. This approach is endorsed by the NCCN, as the immediate implant placement carries an increased incidence of capsular contracture, malposition, and poor cosmesis [13]. However, delayed reconstruction using autologous tissue was rarely chosen compared to the immediate reconstruction setting.

We found comparable toxicity between CF and HF in the immediate reconstruction cohort [14]. Globally, a limited number of studies have investigated the use of HF in reconstructed

Table 4. Cox regression proportional hazards model for complication in the delayed two-stage reconstruction cohort after matching ($N = 784$).

Characteristics	Univariate	Multivariate			
		Hazard ratio (95% CI)	P	Hazard ratio (95% CI)	P
Year	2018–2020 (vs. 2015–2017)	1.08 (0.68–1.69)	0.736		
Age	>45 (vs. ≤45)	1.02 (0.95–1.01)	0.190		
Hypertension	Yes (vs. no)	1.75 (1.10–2.76)	0.016	2.42 (1.39–3.50)	0.002
Diabetes	Yes (vs. no)	2.10 (1.37–3.23)	0.001	2.36 (1.36–4.01)	0.002
Fractionation	HF (vs. CF)	1.05 (0.69–1.61)	0.793		
IMRT	Yes (vs. no)	0.75 (0.49–1.15)	0.196		
Bolus	Yes (vs. no)	1.25 (0.82–1.91)	0.290		
Reconstruction material	Implant (vs. autologous)	1.14 (0.45–2.88)	0.779		
Interval between PMRT and definitive surgery	10 mo (vs. ≤10 mo)	0.99 (0.99–1.00)	0.141		

HF hypofractionated fractionation, CF conventional fractionation, IMRT intensity modulating radiotherapy, mo months.

breasts, with heterogeneity in fractionation regimen and complication rates. Another cohort study conducted in Brazil examined the safety of hypofractionated PMRT (2.65–2.67 Gy/fraction) in reconstructed breasts. Among 35 patients who underwent implant-based immediate reconstruction, capsular contracture developed in 11.4% [14]. In contrast, a U.S. Phase II trial reported an incidence of severe complications of 35% in 43 patients receiving a dose of 36.63 Gy in 11 fractions with a daily fraction size of 3.33 Gy [15].

Beyond compatibility between fractionation regimens, our study identified several associated risk factors for reconstruction-related complications. Implant usage emerged as the sole significant prognostic factor for complications. This aligns with existing knowledge regarding the increased susceptibility of implants to radiation-induced complications. Despite the elevated risk of adverse effects such as capsular contracture associated with implants, their popularity persists due to cost-effectiveness and broader eligibility compared to autologous tissues. Consequently, further advancements in implant-based reconstruction and radiation techniques are paramount to enhancing reconstruction outcomes. While bolus application has been shown to increase toxicity in reconstructed breasts, our study did not identify a significant association between bolus usage and complication risk. This discrepancy may arise from the application of different bolus definitions in our study and the prior literature. Bolus is more likely to induce skin-related toxicity, whereas our study focused primarily on complications requiring surgical interventions [16]. However, de Sousa et al. reported an increased risk of infection (HR 10.3, CI 1.7–61.8), and reconstruction failure (HR 13.89, CI 2.24–85.98) in patients undergoing two-stage reconstructions when bolus was applied daily [17]. In contrast, alternate-day bolus usage was not associated with complication risk. Therefore, it is still important that the decision to use bolus for PMRT should be individualised considering the benefits and the risks.

A recent prospective randomised trial, the Radiation Fractionation on Patient Outcomes After Breast REConstruction (FABREC) study, found no significant differences in oncologic outcomes or chest wall toxicity between conventional fractionation and hypofractionation in 400 patients with immediate implant-based reconstructions [18]. The FABREC trial also reported improved quality of life in patients over 45 years old, along with reduced treatment breaks and financial toxicity in the HF group. Another pivotal study, RT CHARM (ALLIANCE A221505), is currently underway and includes both immediate and delayed reconstruction. Its results are eagerly anticipated, as they will provide valuable data on the safety of hypofractionation in the reconstruction setting.

Addressing the role of acellular dermal matrix (ADM) in immediate implant-based breast reconstruction is vital due to its widespread use and potential impact on complications. ADM is a biomaterial processed to remove cellular components while preserving extracellular matrix structure. Until now, the effect of ADM on patients undergoing PMRT is not well defined, but a few retrospective studies suggested a protective role in irradiated patients [19–21]. However, our study could not directly identify its actual usage because it has not been reimbursed by the government. A multi-institutional data from the South Korea Radiation Oncology Group indicated its prevalence, with over 50% utilisation in breast reconstruction and PMRT between 2015 and 2016 [22]. Considering the contemporary reliance on ADM in breast reconstruction practices, it may be reasonable to assume its significant incorporation in our study population, especially since ADM is routinely integrated into implant-based reconstruction protocols at our institution.

In addition to ADM usage, it is also important to understand the dosimetric planning and target delineation in our population. While the specific planning protocols may vary among hospitals in South Korea, it seems to follow the general principle [23]. For the hypofractionation scheme, at least 95% planning target volume was required to be covered by 95% of the prescribed dose, and the maximum point dose (D max) was limited to below 105–107%. Organ-at-risk constraints ensured that the volume of the ipsilateral lung receiving 5 Gy (V5) and 20 Gy (V20) did not surpass 45% and 20%, respectively. The mean dose to the heart was maintained below 3 Gy and 5 Gy for right-sided tumours and left-sided tumours, respectively. The most commonly utilised RT techniques were forward IMRT (field-in-field) followed by VMAT and 3D conformal, according to a multi-institutional retrospective study conducted in South Korea [22]. In terms of target delineation, it seems that there is no specific preference between RTOG and ESTRO guidelines among radiation oncologists in South Korea [23]. Also, some institutions adopted new ESTRO-ACROP target delineation guideline which allows excluding implants from the clinical target volume [24, 25]. As there is no information on dosimetry planning and target delineations, it will be critical to interpret our results with caution.

Our study has several limitations. In our study, we excluded patients who received fewer than 14 or more than 35 fractions of radiotherapy, which could have arisen from various causes such as multiple treatment courses, treatment for metastatic lesions, or unconventional fractionation regimens. Furthermore, there may have been discrepancies between the actual number of fractions delivered and the number billed due to variations in billing practices and treatment principles across institutions. While it is

challenging to derive precise radiation fractionation details from such a large-scale dataset, we believe existence of a significant difference in radiation fractions between the HF and CF groups presented, which is supported by several factors: First, the trend of increasing HF adoption in Korea since 2015 aligns with the observed pattern in our study [26]. Second, a separate analysis by Kim et al. using individual patient ($N = 393$) revealed comparable major breast complication rates (12.0% vs. 12.3%) following immediate reconstruction for both HF and CF groups [27]. While we recognise the inherent limitations of the nationwide database [28], we believe our study serves as a valuable step towards establishing a more robust and verifiable method for radiation fractionation assessment within national databases. Accurately filtering out such complexities from large datasets proved exceedingly challenging, necessitating an exclusion approach to maintain cohort homogeneity. Although this resulted in a reduced sample size, the enhanced treatment homogeneity within the cohort enabled us to draw more meaningful conclusions from our analysis. The radiation field or site could not be identified in the national database. Our definition of complications was limited to major events requiring capsulectomy, wound debridement, or skin graft by plastic surgeons. Other complications requiring only medical treatment were not included. Furthermore, the relatively short follow-up duration in some patients may have resulted in the failure to capture adverse events. Therefore, it is necessary to approach the interpretation of our findings with caution.

CONCLUSION

This nationwide study, the first to examine trends and complications in breast cancer patients undergoing both reconstruction and PMRT, revealed a moderate increase in the adoption of HF. Importantly, the major complication rates remained comparable between HF and CF, irrespective of the timing of reconstruction. Nevertheless, ongoing prospective trials on fractionation hold promise for further optimising PMRT strategies in this setting.

DATA AVAILABILITY

Any researcher with an approved IRB can request a customised database to the National Health Insurance Data Sharing Service (<https://nhiss.nhis.or.kr/>). Upon approval, all raw data were only accessible from "Data analysis room" located within the National Health Insurance Service (NHIS-2022-1-675).

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AUTHOR CONTRIBUTIONS

Study concept and design: BSJ. Acquisition of the data: HR and BSJ. Analysis and interpretation of data: HR and BSJ. Drafting of the manuscript: HR and BSJ. Statistical analysis: HR and BSJ. Manuscript review and approval: KHS, JHC and BSJ. Obtained funding: KHS, JHC and BSJ. Study supervision: KHS, JHC and BSJ. All authors read and approved the submitted version of the manuscript.

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COMPETING INTERESTS

The authors declare no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was performed in accordance with the Declaration of Helsinki. This study was approved by the Institutional Review Board of the Seoul National University Hospital (IRB Number 2204-067-1315). The need for informed consent was waived because the data was anonymized.

CONSENT FOR PUBLICATION

Not applicable.

ADDITIONAL INFORMATION

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Prepectoral Direct-to-Implant versus Staged Tissue Expander Breast Reconstruction: A Comparison of Complications

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Background: Direct-to-implant (DTI) reconstruction has multiple advantages over a staged tissue expander (TE) approach. However, its use may be limited by concerns of increased complications. This study is the largest series to date comparing postoperative outcomes for DTI versus TE reconstruction in the prepectoral plane.

Methods: The authors retrospectively reviewed 348 patients who underwent 536 total immediate, prepectoral implant-based breast reconstructions between January of 2018 and December of 2021. The authors compared the presence of risk factors and the rate of six separate complications between patients who underwent DTI versus TE reconstruction up to 1 year after surgery.

Results: Of 348 patients, 147 (42%) and 201 (58%) underwent TE and DTI reconstruction ($P = 0.1813$), respectively. The overall infection rate was 16.4% ($n = 57$). DTI patients had a significantly greater incidence of wounds ($P < 0.0001$), including minor ($P < 0.0011$) and major wounds ($P < 0.0053$). Significantly greater mastectomy resection weights were found for DTI patients who experienced any complication ($P < 0.0076$), postoperative wounds ($P < 0.0001$), and major wounds specifically ($P < 0.0035$). Compared with medium-thickness acellular dermal matrix (ADM), extra thick ADM was associated with significantly increased rates of infection ($P < 0.0408$) and wounds ($P < 0.0001$). **Conclusions:** Prepectoral DTI reconstruction in patients with adequate flap perfusion may have complication rates comparable to staged TE reconstruction, apart from a higher incidence of postoperative wounds. Greater mastectomy resection weights and thickness of ADM may specifically contribute to infection and wound-healing complications. Prepectoral DTI reconstruction is encouraged in the patients with adequate flap perfusion and moderate to low mastectomy resection weights who desire comparable or smaller implant volumes. (*Plast. Reconstr. Surg.* 154: 224e, 2024.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

Shortly after the introduction of silicone implants in the 1960s, subcutaneous implant placement for reconstruction was abandoned by the plastic surgery community

because of high reported rates of complications and poor aesthetic outcomes.¹⁻³ The subpectoral space quickly became the predominant plane for implant-based breast reconstruction, dominating plastic surgery practice for decades to follow.^{4,5}

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Recent advancements in conservative mastectomy techniques, simplified approaches to fat grafting, and the use of commercially available bioprosthetic meshes, or acellular dermal matrix (ADM) specifically, have eliminated many of the original concerns previously attributed to subcutaneous breast implant placement.^{4,6–8} Collectively, these improvements have enhanced aesthetic outcomes and decreased patient morbidity for prepectoral reconstruction, leading to its reemergence as a viable reconstructive technique in recent years.⁹

Two-stage reconstruction with tissue expanders (TE) followed by replacement with a saline or silicone implant is the most frequent method of implant-based breast reconstruction in the United States.^{10–12} In addition to being both reliable and safe, staged TE reconstruction provides more precise control over the pocket and anatomical placement of the implant.¹⁰ However, a disadvantage to staged TE reconstruction is the requirement to undergo serial expansions, reported to be uncomfortable, burdensome, and time-consuming to patients.^{7,13,14} In addition to avoiding the risks associated with anesthesia in a second planned surgery, single-stage or direct-to-implant (DTI) reconstruction avoids the requirements of frequent tissue expansion, demonstrating improved overall patient comfort and satisfaction.

The recent resurgence of prepectoral breast reconstruction has left a gap in the literature regarding the safety and complication profile of DTI reconstruction performed in this plane. Most existing studies comparing DTI versus staged TE reconstruction are limited by their inability to differentiate between patients who underwent prepectoral and subpectoral implant placement.^{10,15,16} Remaining studies that focus on prepectoral reconstruction are either small, retrospective, or fail to compare outcomes between patients who underwent single-stage DTI and two-stage TE reconstruction.^{4,9,17–24} The purpose of this study is to fill this gap by comparing risk factors and postoperative complications between patients who undergo immediate DTI and staged TE reconstruction in the prepectoral plane.

PATIENTS AND METHODS

Following institutional review board approval, the authors retrospectively reviewed cases of immediate, prepectoral implant-based breast reconstruction performed by one of four plastic surgeons between January of 2018 and December of 2021. Patients who underwent autologous, subpectoral, or delayed reconstruction were

excluded. Patient-specific factors, including demographics, medical comorbidities, and cancer treatments, were collected from electronic patient charts. Specific surgical factors considered for analysis were mastectomy type, mastectomy resection weights (averaged if bilateral), final implant volumes (on the cancer side, averaged if bilateral), ADM thickness, and type of reconstruction (DTI or TE).

The surgeons performing the mastectomy portion of the procedure were distributed evenly between cohorts. At our institution, the most frequent pattern of skin incision is a transverse elliptical pattern at the inframammary fold. All plastic surgeons use 16 × 20 perforated AlloDerm Select Tissue Matrix (Lifecell Corp., Branchburg, NJ) in one of three available thicknesses: medium (1.6 ± 0.4 mm), thick (2.4 ± 0.4 mm), or extra thick (3.4 ± 0.6 mm). Three of the surgeons wrap the ADM around the implant or expander before placement anterior to the pectoralis muscle, whereas one surgeon sutures the ADM to the anterior chest wall (pectoralis muscle) in a way that creates a pocket for the implant. The decision to proceed with DTI reconstruction is a uniform practice among our plastic surgeons that is made intraoperatively following a thorough clinical evaluation of flap quality. A SPY imaging system (Stryker Corp., Fort Myers, FL) is used in a small number of cases. DTI reconstruction is selected for most patients desiring comparable or smaller implant volumes that are deemed to have adequate mastectomy flap thickness and perfusion. Patients are commonly discharged with two drains per side of reconstruction.

Evaluation of clinic notes, emergency room visits, and subsequent operative procedures determined whether each patient experienced one of the following complications: hematoma, seroma, minor infection (resolved with oral antibiotics), major infection (intravenous antibiotics or surgery), minor wounds (≤1 × 1 cm), major wounds (>1 × 1 cm), and mastectomy flap necrosis. Rates of reoperation for a complication and surgical implant removal were subsequently determined. Once separated based on DTI versus staged TE reconstruction, specific patient factors, surgical factors, and complication rates were compared between the two cohorts. Patients were then subdivided further according to the complications that they experienced, and the frequency of patient- and surgical-related factors was reassessed.

Microsoft Excel (Microsoft Corp., Redmond, WA) was used to identify significant differences between cohorts by conducting a one-tailed *t*

Table 1. Patient Demographics, Medical Comorbidities, and Surgical Factors by Type of Reconstruction

Characteristic	All Patients	Reconstructive Method		<i>P</i>
		DTI	TE	
No.	348	201	147	
Demographics/comorbidities				
Age, yr	51.9 ± 10.7	52.7 ± 11.1	50.8 ± 10.1	<0.0457 ^a
BMI, kg/m ²	27.1 ± 5.6	27.6 ± 5.6	26.4 ± 5.5	<0.0308 ^a
Active smoker	20 (6%)	11 (5%)	9 (6%)	0.7937
Diabetes mellitus	17 (5%)	10 (5%)	7 (5%)	0.9304
Neoadjuvant chemotherapy	127 (36%)	71 (35%)	56 (38%)	0.5766
Adjuvant chemotherapy	94 (27%)	62 (31%)	32 (22%)	0.0618
Adjuvant radiation therapy	105 (30%)	58 (29%)	47 (32%)	0.5356
Surgical factors				
Final implant size, cc	508.9 ± 139.5	481.6 ± 130.2	549.8 ± 143.1	<0.0001 ^a
Mastectomy resection, g	639.1 ± 325.6	656.8 ± 321.7	590.9 ± 331.4	0.0821
ADM thickness				
Medium	87 (28%)	22 (11%)	65 (56%)	<0.0001 ^a
Thick	77 (25%)	55 (29%)	22 (19%)	0.0573
Extra thick	144 (47%)	115 (60%)	29 (25%)	<0.0001 ^a
Mastectomy ^b				
SSM	203 (60%)	116 (58%)	87 (64%)	0.3370
NSM	97 (29%)	61 (31%)	36 (26%)	0.3844
Other ^c	38 (11%)	22 (11%)	14 (10%)	0.8076

BMI, body mass index.

^aStatistically significant.^bMost patients at our institution have a transverse elliptical incision in the inframammary fold.^cOther refers to either skin-reducing mastectomy or modified radical mastectomy, or a mix of SSM and NSM in bilateral cases.

test for continuous variables and a chi-squared or Fisher exact test for categorical variables. Significance was set to a 95% confidence interval with a value of $P < 0.05$.

RESULTS

Retrospective review identified 348 patients who underwent 536 total immediate, prepectoral breast reconstructions over the 4-year timespan. Average patient age was 51.9 ± 10.7 years, and body mass index was 27.1 ± 5.6 kg/m². Forty-two percent of patients ($n = 147$) underwent staged TE reconstruction and 58% ($n = 201$) underwent DTI reconstruction. There was no significant difference between patients who underwent bilateral versus unilateral reconstruction according to the type of reconstruction ($P = 0.1813$). Both age (52.7 years versus 50.8 years; $P < 0.0457$) and body mass index (BMI) (27.6 kg/m² versus 26.4 kg/m²; $P < 0.0308$) were significantly greater in the DTI cohort, whereas final implant size was significantly greater in patients who underwent TE reconstruction (549.8 cc versus 481.6 cc; $P < 0.0001$) (Table 1).

Complications

Forty-one percent of all patients ($n = 141$) had a complication, 37% ($n = 52$) of whom

experienced two or more complications (Table 2). Forty-five percent of patients with a complication ($n = 63$) underwent reoperation, and 34% ($n = 47$) required implant removal. Major wounds ($n = 61$) were most frequent, observed significantly more than hematoma ($n = 18$; $P < 0.0001$), seroma ($n = 25$; $P < 0.0001$), minor infection ($n = 25$; $P < 0.0001$), major infection ($n = 40$; $P < 0.0238$), and minor wounds ($n = 39$; $P < 0.0174$). Patients with medium-thickness ADM had significantly fewer overall complications than patients with either thick (29.2% versus 53.2%; $P < 0.0013$) or extra thick ADM (29.2% versus 50.3%; $P < 0.0011$) (Table 3 and Fig. 1).

The incidence of any complication was significantly greater in patients who underwent DTI versus TE reconstruction (49.8% versus 27.9%; $P < 0.0001$). This remained true whether stratified by type of mastectomy, either skin-sparing mastectomy (SSM) ($P < 0.0101$) or nipple-sparing mastectomy (NSM) ($P < 0.0354$) (Table 4). In general, patients who experienced a complication had significantly greater mastectomy resection weights than patients without a complication (713 g versus 549 g; $P < 0.0008$). This remained significant in patients who underwent DTI reconstruction only (711 g versus 596 g; $P < 0.0077$) but not TE reconstruction (719 g versus 580 g; $P = 0.0600$). Patients with mastectomy resection weights greater than

Table 2. Incidence of Complications by Type of Reconstructive Method

	Reconstructive Method			<i>P</i>
	All Patients	DTI	TE	
No.	348	201	147	
All complications	141 (41%)	100 (50%)	41 (28%)	<0.0001 ^a
Hematoma	18 (5%)	9 (4%)	9 (6%)	0.4938
Seroma	25 (7%)	17 (8%)	8 (5%)	0.2819
Infection	57 (16%)	34 (17%)	23 (16%)	0.7520
Major infection	40 (12%)	24 (12%)	16 (11%)	0.7603
Minor infection	25 (7%)	12 (6%)	13 (9%)	0.3052
Postoperative wounds	91 (26%)	68 (34%)	23 (16%)	<0.0001 ^a
Major wounds	61 (17.5%)	45 (22%)	16 (11%)	<0.0053 ^a
Minor wounds	39 (11%)	32 (16%)	7 (5%)	<0.0011 ^a
Reoperation	74 (21%)	38 (19%)	36 (24%)	0.2086
Implant removal	49 (33%)	30 (15%)	19 (13%)	0.5962

^aStatistically significant.**Table 3. Incidence of Complications Stratified by ADM Thickness**

	ADM Thickness		
	Medium	Thick	Extra Thick (%)
No.	90	75	144
All complications	29.2% ^{a,b}	53.3% ^a	50.3% ^b
Hematoma	7.6%	12.8%	7.8%
Seroma	4.5%	8.0%	9.0%
Infection	10.0% ^a	16.0%	20.1% ^b
Postoperative wounds	12.2% ^{a,b}	33.3% ^a	35.4% ^b

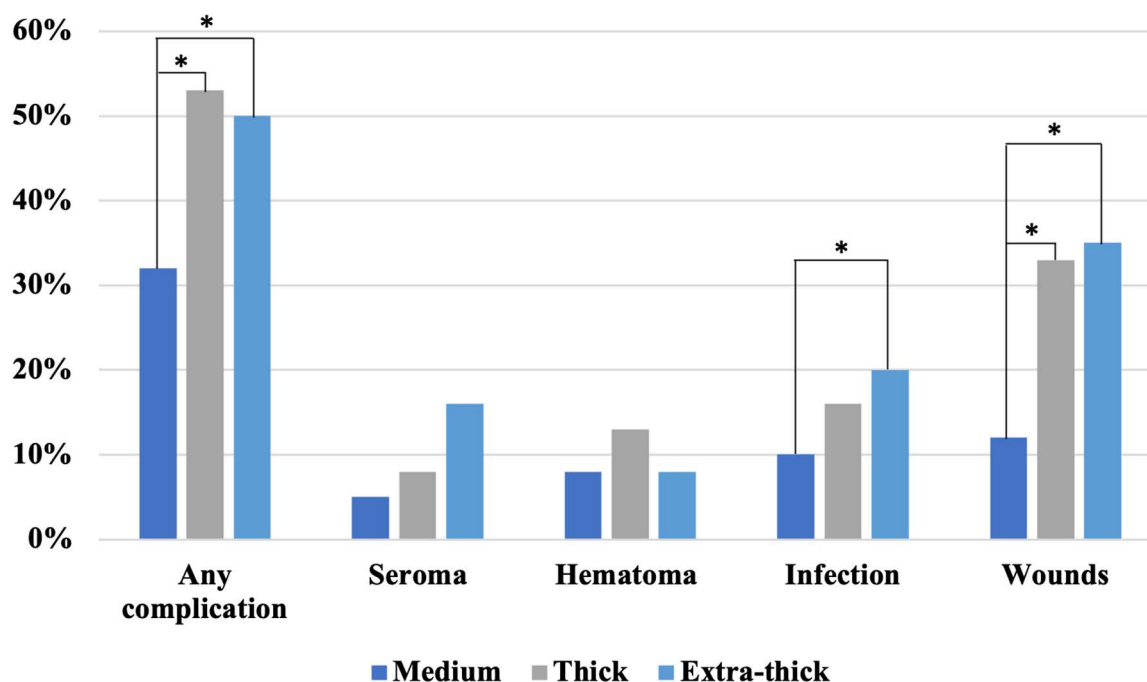
^aIndicates significance difference between medium-thickness ADM and thick ADM.^bIndicates significance difference between medium-thickness ADM and extra thick ADM.**Fig. 1.** Proportion of patients with each postoperative complication based on thickness of acellular dermal matrix received.

Table 4. Complications between Patients Who Underwent Skin-Sparing or Nipple-Sparing Mastectomy According to Type of Reconstruction Performed

	All Patients	Reconstructive Method		<i>P</i>
		DTI	TE	
No.	348	201	147	
Any complication				
SSM	39.2%	46.6%	29.2%	<0.0101 ^a
NSM	39.5%	47.5%	25.7%	<0.0354 ^a
<i>P</i>	0.9515	0.9412	0.6968	
Seroma				
SSM	8.8%	10.3%	6.8%	0.3791
NSM	6.2%	8.2%	2.8%	0.4073
<i>P</i>	0.4298	0.6448	0.06721	
Hematoma				
SSM	5.4%	4.3%	6.9%	0.5347
NSM	6.2%	6.6%	5.6%	1.000
<i>P</i>	0.7932	0.4973	1.000	
Infection				
SSM	22.0%	23.4%	20.5%	0.7245
NSM	16.9%	17.3%	16.1%	0.9067
<i>P</i>	0.4233	0.4836	0.6644	
Wounds				
SSM	20.5%	24.1%	15.7%	0.1393
NSM	28.9%	37.7%	13.9%	<0.0124 ^a
<i>P</i>	0.1702	0.0582	0.7951	

^aStatistically significant.

or equal to 600 g, specifically, had a significantly higher incidence of complications than patients with weights less than 600 g (54% versus 36%; $P < 0.0055$), including when separated based on DTI reconstruction (59% versus 45%; $P < 0.0486$). Final implant sizes greater than or equal to 600 cc were associated with significantly more complications in both the DTI ($P < 0.0009$) and TE reconstruction cohorts ($P < 0.0016$).

Hematoma and Seroma

Eighteen patients (5%) developed a hematoma. Eleven of these patients (61%) required reoperation for a complication, and 7 (39%) underwent implant removal. Twenty-five patients (7%) developed a seroma. Twelve (48%) patients ($n = 12$) required reoperation for a complication, with 8 cases (32%) resulting in implant removal. No significant differences were noted in the incidence of hematoma (6.1% versus 4.5%; $P = 0.4938$) or seroma among patients who underwent DTI versus TE reconstruction (6.1% versus 4.5%; $P = 0.2819$).

Infection

Total infection rate was 16.4% ($n = 57$). Of these patients, 17 had minor infections (30%), 32 had major infections (56%), and 8 had separate incidences of both minor and major infections (14%). Sixty-three percent of patients with

an infection ($n = 36$) required reoperation for a complication, and 58% ($n = 33$) underwent implant removal. Patients with extra thick ADM had a significantly greater incidence of infection compared with patients with medium-thickness ADM (20.1% versus 10.0%; $P < 0.0408$), although no difference was observed between medium and thick ADM (20.1% versus 16.0%; $P < 0.5737$).

The incidence of infection did not differ significantly according to whether the patient underwent DTI or TE reconstruction (16.9% versus 15.6%; $P = 0.7520$). Rates of reoperation and implant removal were also comparable ($P > 0.1662$). In the DTI reconstruction cohort specifically, patients who developed an infection had a significantly greater final implant volume than patients without infection (525 cc versus 473 cc; $P < 0.0413$). Implant volume did not significantly impact infection outcomes in the TE cohort (523 cc versus 542 cc; $P = 0.3577$).

Eleven percent of patients in this study experienced a major infection ($n = 40$), 75% of which ($n = 30$) required reoperation for a complication and, ultimately, implant removal. Alternatively, 7% of all patients experienced a minor infection ($n = 25$), with 52% ($n = 15$) requiring reoperation for a complication. There was no significant difference in the incidence of major infection (11.9% versus 10.9%; $P = 0.7603$) or minor infection

(8.8% versus 10.9%; $P = 0.3052$) between patients who underwent DTI or TE reconstruction.

Postoperative Wounds

Of all 348 patients, 91 (26%) had either a major or minor persistent wound that was noted on follow-up examination. A total of 52 patients (57%) had major wounds, 30 (33%) had minor wounds, and 9 (10%) had separate major and minor wounds. In general, the rate of reoperation for a complication in patients with a wound-healing complication was 48% ($n = 43$), whereas 36% ($n = 33$) required implant removal. Medium-thickness ADM was associated with significantly fewer wound-healing complications than both thick (12.2% versus 33.3%; $P < 0.0011$) and extra thick ADM (12.2% versus 35.4%; $P < 0.0001$).

The proportion of patients who developed a wound complication was significantly greater for DTI compared with staged TE reconstruction (33.8% versus 15.6%; $P < 0.0001$). This remained true when stratifying by patients who received NSM ($P < 0.0124$) but not SSM ($P < 0.1393$). Patients with DTI reconstruction and a wound-healing complication had significantly more reoperations than the patients with wounds in the staged TE reconstruction cohort (69.6% versus 39.8%; $P < 0.0132$), whereas implant loss approached significance (52.2% versus 30.9%; $P = 0.0664$). Significantly greater mastectomy resection weights were also found in patients who experienced major or minor wounds compared with patients without wound-healing complications in general (743 g versus 590 g; $P < 0.0012$) and in the DTI reconstruction cohort specifically (739 g versus 601 g; $P < 0.0058$), but not in patients who underwent staged TE reconstruction (777 g versus 566 g; $P = 0.0654$). Mastectomy resection weight cutoff values greater than or equal to 600 g were associated with a significantly increased incidence of postoperative wounds in all patients (37.7% versus 22.3%; $P < 0.0075$) and in patients who underwent DTI reconstruction specifically (42.7% versus 28.1%; $P < 0.0381$). Meanwhile, final implant size did not have a significant impact on the incidence of wound-healing complications in either the DTI reconstruction cohort (485 cc versus 480 cc; $P = 0.4021$) or the staged TE reconstruction cohort (535 cc versus 540 cc; $P = 0.3972$).

Of the patients evaluated in this study, 61 (17.5%) experienced major wounds. Sixty-four percent ($n = 39$) and 52% ($n = 32$) of these patients required reoperation and implant removal. Patients with major wounds, compared with those

without, had a significantly greater BMI (28.3 kg/m² versus 26.9 kg/m²; $P < 0.0488$). The incidence of major wounds was significantly greater for DTI versus staged TE reconstruction (22.4% versus 10.9%; $P < 0.0053$). Compared with patients without wound healing sequelae, patients who developed major wounds had significantly greater mastectomy resection weights in general (775 g versus 589 g; $P < 0.0013$), and in the DTI reconstruction cohort specifically (780 g versus 601 g; $P < 0.0035$). Alternatively, minor wounds were experienced by 39 patients (11%). Compared with major wounds, patients who experienced minor wounds required reoperation (63.9% versus 20.5%) and implant removal (52.5% versus 10.3%) significantly less often ($P < 0.0001$). The incidence of minor wounds was significantly greater for DTI versus staged TE reconstruction (15.9% versus 4.8%; $P < 0.0011$).

DISCUSSION

This study is one the largest to compare risk factors and complication rates among patients who undergo DTI and staged TE reconstruction in the prepectoral plane. First attempted in the 1960s when modified radical mastectomies were the mainstay of treatment, prepectoral or subcutaneous implant-based reconstruction led to high rates of mastectomy flap necrosis, delayed wound healing, and implant extrusion.^{1-4,23} Advancements in both mastectomy and reconstruction techniques have led to improved wound healing outcomes over time. However, postoperative wounds are still a relatively common complication of breast reconstruction and a source of delay in patients requiring treatment with adjuvant therapy.^{10,25}

Compared with the patients in our study who underwent TE reconstruction, those who underwent DTI reconstruction had approximately twice the rate of major wounds and three times the rate of minor wounds. One benefit to staged TE reconstruction is the ability to perform progressive, controlled expansion of the prosthesis to decrease tension placed on a thin mastectomy flap.^{26,27} Theoretically, prepectoral DTI reconstruction places greater tension on the overlying skin and subcutaneous tissue with initial implant placement, predisposing the patient to incisional dehiscence.^{10,28,29} Excess tension can also impair vascular perfusion in the mastectomy flap and place the patient at high risk of flap necrosis.^{30,31} It is for these reasons that many plastic surgeons reserve DTI reconstruction for patients with generous skin envelopes who desire comparable or

smaller implant volumes.³¹ However, our study demonstrated that final implant volume alone did not lead to significantly greater wound-healing complications in patients who received DTI reconstruction, a finding that is consistent with previous literature.^{32,33}

As opposed to final implant volume, greater mastectomy resection weights significantly increased the incidence of wound-healing complications in patients with DTI reconstruction. Previous studies, including a prospective randomized trial, have similarly found mastectomy resection weight to be independently associated with increased reconstructive complications.^{32–34} Mastectomy procedures interrupt the axial perfusion of the overlying breast skin, leaving the flap dependent on random pattern perfusion from the subdermal plexus.³⁵ Assuming a positive correlation between the resection weight and volume, it may be that patients with larger mastectomy resection weights have a greater skin envelope surface area with a longer distance from the perforating vessels that supply a given subdermal plexus and thus have an increased risk of compromised vascular supply.^{27,34,36,37} Consequently, impaired microcirculation and oxygenation predispose the patients with larger breasts to wound healing and infection-related sequelae. It is possible that mastectomy resection weight alone does not impact perfusion enough to influence reconstructive outcomes, as no significant relationship was identified for the patients who underwent staged TE reconstruction. Rather, it may be the combination of immediate insertion of implants in DTI reconstruction with large mastectomy resection weights that surpasses the threshold to significantly affect perfusion in the mastectomy flap.

BMI was previously a major concern in immediate prepectoral breast reconstruction given that mammary hypertrophy and skin flap redundancy can predispose patients to insufficient flap perfusion.^{4,26,32} However, recent literature suggests that BMI alone should not be a contraindication to immediate prepectoral reconstruction.^{18,38,39} Our study found BMI to not have a significant impact on complication rates between patients who underwent DTI and staged TE reconstruction. Assuming adequate perfusion, redundant tissue in obese patients can be deepithelialized for additional device coverage or preserved to reduce tension placed on the mastectomy flap with direct implant insertion.³⁸ Rather than BMI, studies are increasingly emphasizing meticulous intraoperative assessment of mastectomy flap vascularity as the single strongest predictor of reconstructive

outcomes.^{1,4} In patients determined to not have adequate mastectomy flap perfusion, a staged TE approach can be applied. Adequate flap perfusion may also be important to consider when determining candidacy for NSM, as nipple-areola complex necrosis is a frequent complication.⁴⁰ The patients in our study who underwent NSM with DTI reconstruction were found to have significantly more wound-healing complications than the patients who underwent TE reconstruction, a difference that was not observed in the SSM cohort.

ADM revolutionized prepectoral breast reconstruction through its ability to provide a barrier of support between an implant and a relatively thin mastectomy flap.^{6,23} Despite its widespread use in prepectoral reconstruction, several studies have associated ADM with increased rates of various complications such as seroma, infection, and reconstructive failure.^{6,10,41,42} However, few articles have effectively assessed for differences in complication rates according to ADM thickness specifically.^{43,44} Rose et al. found that patients with thicker ADM had a greater but not significant incidence of seroma, infection, skin necrosis, and reintervention.⁴³ Alternatively, Hong and Kim found no significant relationship between ADM thickness and complication rates.⁴⁴ Patients with thicker ADM in our study experienced a greater incidence of infection, postoperative wounds, and overall complications. Thicker ADM likely requires more time to integrate into native tissue and thus delays revascularization and oxygenation.^{45,46} Delayed revascularization then places the patient at risk for complications, including infection, delayed wound healing, and integrative failure.^{46–49} Variations of ADM, such as porous and meshed versions, may accelerate the integrative process and decrease this risk.^{50,51} Therefore, the increased support provided by thicker variations of ADM may not outweigh the potential for greater complication rates.

The retrospective design of this study limited our ability to control the selection process for DTI reconstruction. Therefore, specific patient risk factors, such as flap thickness or perfusion, likely influenced a patient's candidacy for this procedure. Conducting a large, prospective, randomized study would better prevent selection bias and provide better evidence to support the conclusions of this study. Another limitation of this study is the inability to account for certain surgical variables (ie, mastectomy resection weight) in every patient because of inconsistencies in the information recorded on operative and clinic documents. To expand on the conclusions presented in this report, future studies should assess the influence of skin incision patterns

and evaluate the incidence of mastectomy flap necrosis separately from major wounds. Because the outcomes were analyzed across four individual plastic surgeons and multiple breast surgeons, some degree of intraoperative variability in technique is expected. However, our institution's division of plastic surgery is currently undergoing a quality improvement project to standardize aspects of preoperative, intraoperative, and postoperative care. The division has also recently implemented the use of negative-pressure wound therapy with instillation and dwell for prosthesis salvage, although it is not a standardized practice at this time.

CONCLUSIONS

Rates of most complications were comparable for prepectoral DTI and TE reconstruction, apart from a greater incidence of postoperative wounds in the DTI reconstruction cohort. Extra thick ADM in all patients, in addition to larger mastectomy resection weights and undergoing an NSM in patients with DTI reconstruction, were associated with greater incidences of infection and wound-healing complications. Therefore, the authors encourage prepectoral DTI reconstruction with medium or thick ADM in patients with adequate flap perfusion, moderate to low mastectomy resection weights, and comparable or smaller desired implant volumes.

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DISCLOSURE

The authors have no financial disclosures or conflicts of interest to report.

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Feasibility of Contrast-Enhanced Mammography in Women with Breast Implants

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Abstract

Contrast-enhanced mammography (CEM) may provide an alternative to magnetic resonance imaging as a diagnostic exam in women with known or suspected breast cancer or as a screening exam in women at increased risk of breast cancer. Women with breast augmentation, either for oncologic or cosmetic reasons, may fall into this increased risk population and need safe and effective screening and diagnostic imaging tools. Here, we present our clinical practice data in order to demonstrate the feasibility of CEM in women with breast implants. An institutional review board-approved, Health Insurance Portability and Accountability Act-compliant, retrospective review of our tertiary cancer center's database yielded 104 women with breast implants who underwent 198 CEM exams from November 2014 to March 2020. All 198/198 (100%) exams were successfully completed in 104 women. Exam indications included: 174/198 (88%) screening due to increased risk, 10/198 (5%) to evaluate a palpable abnormality, 9/198 (<5%) to evaluate disease extent following neoadjuvant chemotherapy for a known breast malignancy, and 5/198 (<3%) for a 6-month follow-up. 97/104 (93%) women had dense breasts. Routine and implant-displaced low-energy views were obtained with contrast-enhanced images obtained on displaced views for all patients. 197/198 (99.5%) exams yielded no complications. In one exam, the patient experienced mild vasovagal symptoms following the administration of contrast. In conclusion, it is feasible to utilize CEM in both diagnostic and screening capacities in women with breast implants.

Keywords

contrast-enhanced mammography; breast implants; screening; high-risk screening

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Introduction

Contrast-enhanced mammography (CEM) is gaining a foothold within both diagnostic and screening breast imaging settings. CEM allows for the evaluation of not only anatomic information but also the functional information of enhancing neovascularity, akin to contrast-enhanced breast magnetic resonance imaging (MRI).

Early research into CEM focused primarily on the diagnostic setting, with an emphasis on its use for the diagnostic evaluation of screen-detected abnormalities¹ and abnormal clinical findings.² Diagnostic evaluation by CEM was then expanded to include those patients with a known diagnosis of cancer requiring preoperative staging assessment as well as those receiving systemic neoadjuvant chemotherapy.³

Once the role of CEM in the diagnostic setting was more clearly delineated, investigators began to explore the role of CEM in the screening setting. Early investigations focused on screening in increased risk populations, including women at intermediate risk (15%–19% lifetime risk) and women at high risk ($\geq 20\%$ lifetime risk). Women at high risk include those with deleterious gene mutations and their untested first-degree relatives, women with a strong family history of breast cancer, women with a history of chest irradiation between 10 and 30 years of age, and women with dense breasts and a personal history of breast cancer or a personal history of pre-menopausal breast cancer. Researchers found that CEM had an improved sensitivity over standard digital mammography (87.3% vs. 50%) while still maintaining an acceptable positive predictive value.⁴ In women with both intermediate risk and dense breast tissue, Sorin et al. found that CEM had an improved sensitivity in detecting breast cancer when compared with standard mammography (90.5% vs 52.4%), although CEM had a lower specificity (76.1% vs 90.5%).⁵ In women with intermediate risk secondary to a personal history of lobular neoplasia, Hogan et al.⁶ showed that CEM had both high sensitivity and specificity.

While MRI remains the gold standard for high-risk screening, it is expensive, not always readily available, and not always possible in certain individuals (i.e., those with pacemakers or who have severe anxiety/claustrophobia). This has led to further interest in advancing CEM as an alternative technique for screening intermediate- to high-risk women. And while these retrospective studies have shown a potential benefit of CEM over standard mammography, larger-scale, prospective data are needed to confirm the retrospective findings. Of note, a prospective, multicenter American College of Radiology Imaging Network (ACRIN) trial, the “Contrast Enhanced Mammography Imaging Screening Trial (CMIST),” is being planned, which will compare CEM to digital breast tomosynthesis (DBT) in the screening of women at average-to-intermediate risk who have mammographically dense breasts.

A Unique Population: Imaging Women with Breast Implants

As CEM becomes more widely available and its uses more clearly delineated, its applications to particular subgroups need to be assessed. One such subgroup of women is those with breast implants.

Many investigators have looked at the effects of breast implant augmentation on screening mammography, showing an overall decrease in measurable breast tissue in women following breast implant augmentation. The amount of visualized tissue is correlated with the degree of capsular contracture, implant position, preoperative breast size, implant size, and implant type. In addition, women with implants undergo two sets of images – standard views and implant-displaced views – which increases the overall exam dose.

Despite these concerns, a study by Kopans et al. showed no significant difference in recall rates for women with breast implants compared to those without implants or to those with a history of prior breast cancer treatment.⁷ Another study by Kam et al. showed no significant difference in the cancer detection rate for women with implants compared to those without implants.⁸ Thus, both studies support the continued use of screening mammography in women with breast implants.

Women with breast implants can also have additional history which puts them into a greater-than-average risk category for the development of breast cancer, thus necessitating advanced imaging for the screening and diagnosis of breast cancer in this population. Unfortunately, however, women with breast implants have been excluded from some research with CEM, purely due to the presence of their implants. It is in this population that our institution has begun using CEM.

Technique

An institutional review board-approved, Health Insurance Portability and Accountability Act-compliant, retrospective review of our large tertiary cancer center's database yielded 104 women with breast implants who underwent 198 CEM exams from November 2014 to March 2020. The electronic medical record as well as images and radiology reports from the institutional Picture Archiving and Communication System were reviewed for exam indication, technique, and patient characteristics including breast density and implant type, both subjectively assessed by the reporting radiologist at the time of clinical interpretation. Complications related to the CEM exam were also recorded.

All CEM examinations were performed on a dual-energy mammography system (Senographic Essential; GE Medical Systems, Milwaukee, WI). Prior to contrast administration, standard non-displaced craniocaudal and mediolateral oblique views were obtained for each breast. Then, each patient received Iohexol (Omnipaque 350; GE Healthcare) at a dose of 1.5 ml/kg via intravenous power injection at a rate of 3 ml/s up to a maximum dose of 150 ml. Once contrast injection was completed, a delay of approximately 2.5 min occurred so the patient could be positioned for the CEM portion of the exam. Implant-displaced craniocaudal and mediolateral oblique views of each breast were then obtained. Each view was imaged with two almost simultaneous exposures, a low energy exposure (26–30 kVp) and a high energy exposure (45–49 kVp), in order to straddle the K-edge of iodine. The low-energy images served as the equivalent of a 2D full-field digital mammogram. Iodine images recombined the low and high-energy images by using a proprietary algorithm to elucidate areas of contrast enhancement.

Clinical Experience

All 198/198 (100%) exams in 104 women were successfully completed: 32/104 (31%) women had saline implants, 70/104 (67%) had silicone implants, and 2/104 (2%) had one saline and one silicone implant. 94/104 (90%) women had subpectoral implants and 10/104 (10%) women had retroglandular implants. 102/198 (52%) exams were bilateral and 96/198 (48%) unilateral. Exam indications included: 174/198 (88%) screening exams due to increased risk, 10/198 (5%) exams for a palpable abnormality, 9/198 (< 5%) exams for evaluation of disease extent following neoadjuvant chemotherapy for a known breast malignancy, and 5/198 (< 3%) exams performed as a 6-month follow-up to a previously abnormal CEM exam. 97/104 (93%) women had dense breasts. 197/198 (99.5%) exams yielded no complications. In one exam, the patient experienced mild vasovagal symptoms following administration of contrast but was able to complete the exam. See Figure 1 for an example of a high-risk screening CEM in a patient with silicone breast implants.

It is current practice at our institution to interpret all CEM exams in real time, thus limiting our ability to calculate a true “call-back” rate in the subgroup of patients who underwent a screening CEM exam. Of the 174 screening CEM exams, 59 patients had a same-day screening ultrasound exam and 11 patients had a same-day diagnostic ultrasound exam for further evaluation of a mammographic finding. No patients underwent concurrent (within one month) screening MRI. When stratified by BI-RADS category, of the 174 screening CEM exams, 19 exams (11%) were given a BI-RADS 0, 3, or 4 category and were recommended for additional imaging and or biopsy. Specifically, 12 (7%) women were recommended to undergo further evaluation of a CEM-only finding with MRI, 3 women were recommended for short interval follow-up based on a non-enhancing mammographic finding, and 2 were recommended for biopsy of non-enhancing calcifications seen on the low-energy mammography images. The additional imaging and/or biopsies in these 19 women did not result in diagnosis of a cancer. Given our relatively small sample size, we were unable to perform statistical analysis of mammography standard benchmarks; however, we hope to report on this data in the future as we evaluate more patients with breast implants.

In the patient sample that was evaluated, only one cancer was found, which was mammographically occult but was detected on a concurrently performed screening breast ultrasound. The same-day CEM exam had marked background parenchymal enhancement obscuring the underlying lesion; however, evaluation of the area was not impacted by the in-situ breast implant.

Lastly, of the 9 exams performed for evaluation of disease extent following neoadjuvant chemotherapy, all had a contrast-enhanced breast MRI performed within a 7-day window. Results of the CEM and MRI exams were concordant in all cases, showing either decreased or resolved malignant enhancement. No additional sites of disease were identified.

Conclusions

CEM is a promising modality for the screening and diagnostic evaluation of breast cancer. The exam is currently being used clinically at our institution for a wide variety

of indications; however, most exams are performed for screening in intermediate risk populations, especially in women with dense breasts. As the uses of CEM continue to expand, we have successfully included women with breast implant augmentation for imaging with CEM. Our cohort of women with breast implants undergoing CEM is small and covers a wide range of indications beyond just screening, which limits our ability to assess parameters such as sensitivity and specificity for cancer detection. Further research and inclusion of these women within our standard practice protocols is necessary to gain a better understanding of the utility of this modality in this specific population.

While the limits of mammography in augmented breasts still exist, including a decrease in measurable/visualized breast tissue and increased mean glandular dose, CEM is technically feasible and may serve as a good alternative for those women at increased risk who cannot undergo screening with MRI.

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Highlights:

- Contrast-enhanced mammography is increasingly being utilized as a screening and diagnostic tool for women at intermediate to high risk of breast cancer.
- Women with breast augmentation present a unique population that require attention and inclusion in screening and diagnostic imaging paradigms.
- Contrast-enhanced mammography is a technically feasible breast imaging exam in women with breast implants.

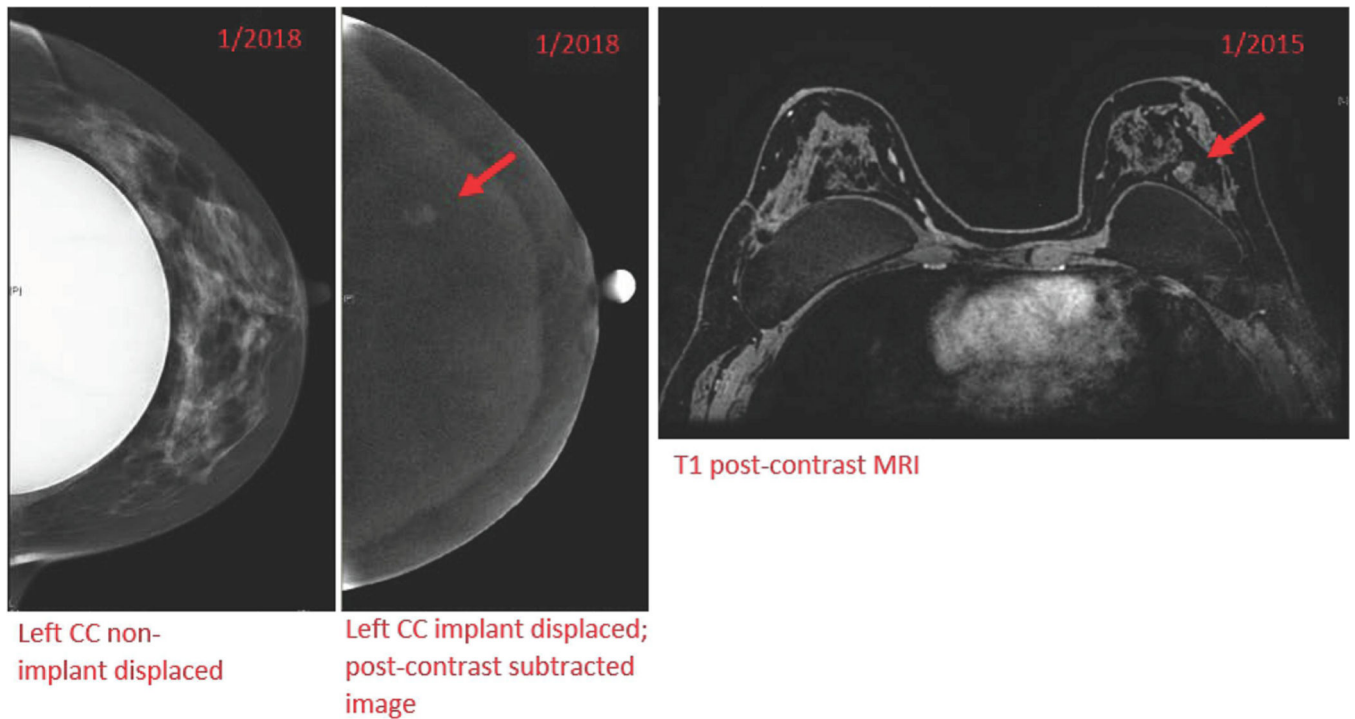


Figure 1.

51-year-old woman in whom CEM was performed for high-risk screening. (A) A subpectoral silicone implant is in place. (B) Post-contrast implant displaced mammography demonstrates a circumscribed enhancing mass, correlating with (C) a stable benign mass on a prior MRI. The mass was assessed as BI-RADS 2.

Accuracy of Ultrasonography in Breast Implant Rupture Diagnosis: Systematic Review and Meta-Analysis

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Background: Breast augmentation is the most common aesthetic operation performed in the United States and worldwide; 1,862,506 breast augmentation procedures were performed in 2018, an increase of 27.6 percent compared to 2014 data.

Methods: In the present study, the authors performed a systematic review to identify the accuracy of ultrasonography for diagnosing breast prosthesis rupture. Studies in which the ultrasound diagnostic test was compared to a surgical finding as a reference standard were reviewed.

Results: As a result, 20 primary studies were included in the analyses, with a total of 1987 patients and 3297 prostheses. The use of ultrasound for diagnosis of breast prosthesis rupture presented the following results: pooled sensitivity, 73.7 percent (95 percent CI, 70.2 to 77.1 percent); pooled specificity, 87.8 percent (95 percent CI, 86.5 to 89.0); area under the receiver operating characteristic curve, 0.7762; diagnostic odds ratio, 11.04 (95 percent CI, 5.79 to 21.08).

Conclusion: This study supports that ultrasound of breast prostheses is an adequate tool in the diagnosis of rupture. (*Plast. Reconstr. Surg.* 148: 939, 2021.)

Breast augmentation is the most common aesthetic operation performed in the United States, reaching 329,914 procedures in 2018, with an increase of 15.2 percent compared to 2014.¹ Worldwide, 1,862,506 breast augmentation procedures were performed in 2018, an increase of 27.6 percent during the same period.² This procedure has been performed on women younger than 34 years in 56.7 percent of cases,² which means that they potentially have many years of life with the prosthesis. The most common indication for breast implants is augmentation, followed by reconstruction, usually after breast cancer treatment.³ In the United States, the silicone smooth prosthesis is used the most, mainly from the following three manufacturers: Sientra (Santa Barbara, Calif.), Mentor (Irvine, Calif.), and Allergan (Irvine, Calif.).^{4,5} In contrast, textured implants are more common in Europe.^{4,5} Silicone-filled, saline-filled, and polyvinylpyrrolidone-hydrogel-filled implants are on the market. Silicone breast implants from the

French manufacturer Poly Implant Prothèse were recalled from the European market after identification that the implants contained non-medical-grade silicone filler. In December of 2011, facing a large increase in the reported rupture rate and a possible cancer risk, in France, it was recommended that explantation of Poly Implant Prothèse devices be considered, regardless of their condition.⁶ Therefore, there has been an increase in explantation procedures in the past decade, which has contributed to the present study.

Besides this specific episode, reoperation for breast implant explantation mainly occurs when women desire an aesthetic change and have signals and symptoms of capsular contracture and implant bleeding or rupture, such as pain, palpable masses, and asymmetry. The leading theory on the pathogenesis of capsular contracture includes the alignment and contraction of fibroblasts within the capsule that forms around a breast implant.⁵ The ruptured implants can be differentiated as “intracapsular” and “extracapsular.”

An intracapsular rupture is defined as a rupture of the implant shell, with an intact inflammatory

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capsule around the implant. By contrast, an extracapsular rupture is defined as a rupture of both structures (shell and capsule).⁷

The rupture can be frequently asymptomatic, as the silicone released by the implant remains confined within the fibrous capsule surrounding the implant itself.⁸ This justifies the importance of diagnostic imaging for predicting the integrity of the prosthetic implant. The U.S. Food and Drug Administration recommends ultrasound or magnetic resonance imaging surveillance of silicone implants 5 to 6 years postoperatively and every 2 years thereafter to assess for integrity/rupture.⁹ Imaging is a financial burden to patients, mainly because a tool such as magnetic resonance imaging is costly, and therefore previous studies have pointed out that an initial assessment with ultrasound is an optimal alternative under economic analysis.¹⁰ The aim of this systematic review is to define whether ultrasound has satisfactory accuracy in the screening of breast implant ruptures, beside the fact that it is an accessible tool.

PATIENTS AND METHODS

The present study performed a systematic review in accordance with a prospective protocol using Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement guidelines.¹¹

Search Strategy

A search strategy was developed using the following terms: “breast implant,” “rupture,” and “ultrasound” as text words and Medical Subject Headings (i.e., MeSH and Emtree). MEDLINE, Embase, Cochrane Library, Insight, and the gray literature (Google Scholar and the British Library) were searched for studies published up to November of 2019. No language restrictions were applied. Reference lists of all available primary studies were reviewed to identify additional relevant citations.

Study Selection

Observational, cross-sectional, and cohort studies were included. The ultrasound diagnostic test was compared to the surgical findings as a reference standard, whereas the exclusion criteria were applied for studies without complete verification by surgery.

Patients

We included women who were screened for prosthesis rupture using ultrasound, before the explantation procedure.

Index Test

The index test was an ultrasound examination of the breasts with prostheses. Positive and negative reads were assigned according to findings predefined by the radiologists, such as low-level internal echoes, stepladder sign (i.e., a series of horizontal echogenic straight or curvilinear lines traversing the interior of the implant), snowstorm appearance (i.e., highly echogenic pattern of scattered and reverberating echoes with a well-defined anterior margin and loss of posterior detail),¹² and the discontinuity of envelope and echogenic noise.

Reference Standard

The reference test was the examination of breast prosthesis during surgery using the PICA mnemonic: P, population (women with mammary prostheses); I, index test (ultrasound of breasts); C, comparison (breast surgery findings); and O, outcome (breast implant rupture).

Data Extraction

Two reviewers (M.L.R.U. and A.C.M.L.) independently screened the abstracts relating them to the study inclusion criteria. The screening process was conducted in Rayyan QCRI (Rayyan Systems, Inc., Cambridge, Mass.).

Assessment of Methodologic Quality

Methodologic quality assessment of studies for diagnostic accuracy was performed according to criteria from the Quality Assessment of Diagnostic Accuracy Studies. These criteria assess the quality of included studies in terms of risk of bias and concerns regarding applicability over four domains.¹³

Statistical Analysis

A 2×2 contingency table was constructed for each selected study. Rates were calculated as true-positive, false-positive, true-negative, and false-negative. When any cell containing “0” was present in the contingency table, 0.5 was added to all cells in all studies to facilitate calculations. Dichotomization of the contingency tables was performed as follows: (1) index test (cited findings suggesting intracapsular or extracapsular rupture) and (2) reference test (visible and touchable findings of intracapsular or extracapsular rupture during surgery).

For all studies, we calculated the true-positive rate (sensitivity), specificity, false-positive rate ($1 - \text{specificity}$), and the diagnostic odds ratio. The

diagnostic odds ratio, which relates to different combinations of sensitivity and specificity, was calculated as follows: $[\text{sensitivity}/(1 - \text{specificity})]/[(1 - \text{sensitivity})/\text{specificity}]$.¹⁴ A diagnostic odds ratio greater than 1 indicated that the assay had discriminative power. The diagnostic odds ratio describes the odds of the positive test results in participants with disease compared to the odds of positive test results in those without disease. Bivariate analysis was used to calculate pooled estimates of sensitivity, specificity, and diagnostic odds ratio with 95 percent confidence intervals for summary estimates.¹⁵

To analyze the accuracy of ultrasound, the area under the curve was calculated from the hierarchical summary receiver-operating characteristic curves. Area under the curve values greater than or equal to 0.5, 0.75, 0.93, and 0.97 were considered to represent fair, good, very good, and excellent accuracy, respectively.¹⁶

Heterogeneity of both sensitivity and specificity across the studies was tested using chi-square analysis, with a chi-square value of $p < 0.05$ considered heterogeneous. As an alternative method to

explore heterogeneity, the I^2 index was also used. The I^2 index presents the percentage of total variation across studies attributable to heterogeneity rather than chance; I^2 values of 75 percent or greater were considered substantial heterogeneity.¹⁵ The meta-analysis was performed using Metadisc 1.4 and Review Manager (RevMan) version 5.3 software.^{17,18}

RESULTS

Study Identification and Eligibility

Among the 261 studies identified from electronic database searches and reference lists, we excluded 234 published studies through title and abstract screening (Fig. 1). Twenty-four full-text studies were then retrieved. Of those, 11 studies were excluded after further scrutiny. A complete list of excluded studies is available from the authors.

Study Descriptions

Twenty primary studies were included^{7,19–37} in analyses. A total of 1987 patients and 3297

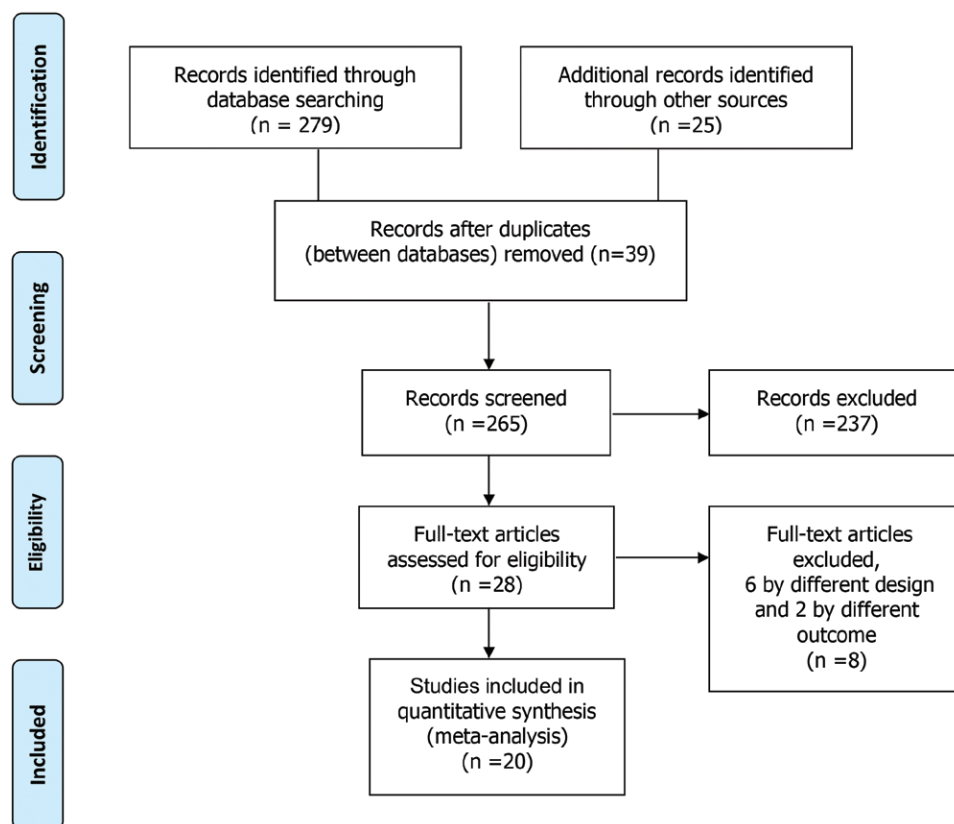


Fig. 1. Search strategy. (From Moher D, Liberati A, Tetzlaff J, Altman DG. The PRISMA group. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Med* 2009;6:e1000097. For more information, visit www.prisma-statement.org.)

prostheses met the criteria for inclusion and were analyzed. The main characteristics of the included studies are listed in Table 1. Table 2 shows the sum contingency table. The contingency tables per study may be requested from the authors.

Quality Assessment

The Quality Assessment of Diagnostic Accuracy Studies 2 was performed considering the following categories: selection of patients, index and reference test, and flow and timing (Fig. 2). Regarding selection, five studies did not clarify the process and were considered an “unclear” risk of bias.^{21,26,28,29,35} For the index and reference test, most studies did not mention blinding of the radiologists and operations and were classified as “unclear.” Therefore, the “concern” with these items was considered “low,” as all prostheses were explanted and observed out of the bodies. For flow and timing, most studies did not cite the interval between the index and referenced tests, and in one, the interval was considered inadequate because it was from 6 to 12 months.⁷

Characteristics of Included Studies

Different ultrasound equipment was used by the institutions where the studies were performed. Machines with a 5- to 17-MHz transducer and from different manufacturers were used. Three studies did not show information about the equipment.^{29,30,32} Criteria that suggest prosthesis rupture were previously defined and were very similar between them. Most of them included patients with complaints; only three included asymptomatic people, for breast reconstruction after cancer and aesthetic augmentation,^{7,34,35} and three included Poly Implant Prothèse preventive explantation.^{29,31,32} One study did not specify the indications of explantation.

Regarding the position of implants, for five surgery teams, subglandular prosthesis prevailed,^{23,24,27,28,35} and eight studies did not provide information regarding prosthesis position.^{21,25,26,29,30,33,34,36} Complete data regarding these topics, patient age, the age of prosthesis removed, and prosthesis composition are listed in Table 1.

Accuracy of Ultrasound

The use of ultrasound for diagnosis of breast prosthesis rupture presented the following results: pooled sensitivity, 73.7 percent (95 percent CI, 70.2 to 77.1 percent); pooled specificity, 87.8 percent (95 percent CI, 86.5 to 89.0); area under the receiver operating characteristic curve, 0.7762; and diagnostic odds ratio, 11.04 (95 percent CI,

5.79 to 21.08). The data and sum contingency table of ultrasound, identified in this systematic review, are discriminated in Table 2.

Sensitivity Analysis

We considered the importance of describing the results divided by material of prosthesis and indication for surgery; however, no studies discriminated results with these specifications. Instead, we discerned by studies published in the past decade, with the hypothesis that the accuracy of ultrasound gets better with new equipment and trained professionals. The performances of before and after 2010 publications were as follows: pooled sensitivity, 67.6 percent (95 percent CI, 62.2 to 72.7 percent) and 79.5 percent (95 percent CI, 74.8 to 83.7 percent); pooled specificity, 77.2 percent (95 percent CI, 73.3 to 80.7) and 90.3 percent (95 percent CI, 89.0 to 91.6 percent); area under the receiver operating characteristic curve, 0.7251 and 0.9289; and diagnostic odds ratio, 6.141 (95 percent CI, 3.205 to 11.765) and 35.86 (95 percent CI, 12.48 to 102.99), respectively (Fig. 3).

We performed an analysis discriminating by prosthesis position: “majority subglandular” and “majority retropectoral.” The “retropectoral” sample showed the best result but only included recent studies, which is probably the reason for achieving a better performance and does not allow us to confirm any difference.

Heterogeneity

Great heterogeneity in sensitivity and specificity was found between studies. This could be explained by the difference in equipment and different frequencies of symptoms in each population, in addition to the difference in materials. As the *Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy* makes clear, heterogeneity is common in diagnostic test accuracy reviews.³⁸ According to this source, “computing separate I^2 statistics for sensitivity and specificity fails to account for variation explained by threshold effects, and the correlation of sensitivity and specificity, and will overestimate the degree of heterogeneity observed.”³⁸

As this study stands up in forest plots, we performed the analyses excluding the results of Liston et al., and only with this exclusion I^2 we got 91.4 percent to 82.1 percent for specificity. Discriminating by before and after the year 2010, I^2 was 15.6 percent and 74.9 percent for sensitivity and 89.2 percent to 88.5 percent for specificity, respectively.

Table 1. Characteristics of Included Studies

Authors, Year	Country	Inclusion Criteria	No. of Patients	Age of Patients (Range) (yr)	Prosthesis Composition or Brand	Position of Implants	Age of Implant (Range) (yr)	No. of Implants Removed	No. of Intact	No. of Rupture
Ahn et al., 1994	United States	Pain, flattening of the implants, and palpable masses	29	46 (31–72)	Silicone gel	NA	13 (6–19)	57	36	21
Beckman et al., 1999	The Netherlands	Pain, capsular contracture, breast deformity or symptoms of autoimmune disease, and aesthetic complaints	18	47 (25–71)	Silicone gel	NA	16 (4–22)	35	19	16
Berg et al., 1993	United States	Signs and symptoms of prosthesis contracture or rupture	33	NA	Silastic I and polyurethane-covered silicone	NA	NA	56	38	18
Caskey et al., 1994	United States	Pain, flattening of the implants, and palpable masses	31	46.5 (31–68)	Silicone gel	93% subglandular, 7% retropectoral	13.9	59	37	22
Chung et al., 1996	United States	Signs and symptoms of prosthesis contracture or rupture and systemic symptoms such as arthralgias, myalgias, chronic fatigue, and memory loss	98	NA	Silicone gel	64% subglandular, 36% retropectoral	NA	192	130	62
DeBruhl et al., 1993	United States	Signs and symptoms of prosthesis contracture or rupture and symptoms of autoimmune disease	75	46 (31–72)	Silicone gel	63.1% subglandular, 36.8% retropectoral	NA	57	37	20
Di Benedetto et al., 2008	Italy	Not specified	63	51 (24–71)	NA	NA	7.8 (4–25)	82	26	56
Everson et al., 1994	United States	Signs and symptoms of prosthesis contracture or rupture and joint swelling	32	(29–63)	Silicone gel	NA	NA	74	39	22
Hold et al., 2012	United Kingdom	Signs and symptoms of prosthesis contracture or rupture	14	NA	Silicone gel	77% subglandular, 23% retropectoral	9.5 (1–24)	22	10	12
Ikeda et al., 1999	United States	Signs and symptoms of prosthesis contracture or rupture and rheumatologic or serologic abnormalities	16	45 (30–71)	Silicone and silicone/saline	64% subglandular, 36% retropectoral	12 (3–25)	31	13	18
Leckenby et al., 2016	United Kingdom	PIP preventive explantation	455	NA	PIP	NA	6.3 (0.1–16.8)	875	765	109
Liston et al., 1994	United Kingdom	Signs and symptoms of prosthesis contracture or rupture and implant-induced anxiety	30	39.7 (25–60)	98% silicone gel, 2% saline	NA	NA	43	31	13
Mennie et al., 2014	United Kingdom	PIP preventive explantation	192	44 (25–76)	PIP	41% subglandular, 59% retropectoral	8.7 (6–15)	384	304	80
Oulhaj et al., 2013	France	PIP preventive explantation or signs and symptoms of prosthesis contracture or rupture	455	42.8 (31–55)	PIP	46.7% subglandular, 53.3% retropectoral	6	828	764	64
Reynolds et al., 1994	United States	Signs and symptoms of prosthesis contracture or rupture; patients with desire to have their implants removed or replaced for saline prostheses	13	48.9 (37–63)	Silicone gel	NA	12 (7–22)	24	11	13
Rietjens et al., 2014	Brazil	Postmastectomy reconstruction	101	50 (25–73)	Silicone gel	NA	4.75 (0.5–13.6)	107	75	32
Scaranelo et al., 2004	Brazil	Asymptomatic (unsatisfied or hardening of breast)	44	NA	Silicone gel	78.3% subglandular, 21.7% retropectoral	11.9	72	52	25
Stachs et al., 2015	Germany	Signs and symptoms of prosthesis contracture or rupture and asymptomatic for augmentation (30%)	7	39 (23–65)	Silicone gel and PIP	NA	6 (1–14)	13	8	5
Stivala et al., 2017	France	Breast reconstruction and aesthetic augmentation	175	54 (21–81)	Allergan and Sebbin	100% retropectoral	(0–40)	242	207	35
Venta et al., 1996	United States	Breast reconstruction and aesthetic augmentation	106	45 (28–67)	Silicone gel	75% subglandular, 25% retropectoral	10.8 (1–21)	53	39	14

NA, not available; PIP, Poly Implant Prothèse.

Table 2. Accuracy of Ultrasound for Detection of Breast Prosthesis Rupture*

Test	Ultrasound Total (95% CI) (%)	Ultrasound until 2009 (95% CI) (%)	Ultrasound after 2010 (95% CI) (%)
Sensitivity	73.7 (70.2–77.1)	67.6 (62.2–72.7)	79.5 (74.8–83.7)
Specificity	87.8 (86.5–89.0)	77.2 (73.3–80.7)	90.3 (89.0–91.6)
DOR	11.04 (5.79–21.08)	6.14 (3.20–11.76)	35.86 (12.48–102.99)
AUC	0.7762	0.7251	0.9289
TP	483	215	268
FP	322	116	206
FN	172	103	69
TN	2320	392	1928
No.	3297	826	2471
Studies included	20	13	7

DOR, diagnostic odds ratio; AUC, area under the curve; TP, true-positive; FP, false-positive; FN, false-negative; TN, true-negative.

*Reference standard: surgery. Comparison of ultrasound pooled vs. studies published in 2009 and before vs. studies published in 2010 and after.

DISCUSSION

The present study is the largest systematic review with meta-analysis focusing in accuracy of ultrasound in diagnostic of breast implant rupture, based on the more accurate reference standard: surgical findings. Although we do discuss screening too, it is important to clarify the difference between a diagnostic and a screening tool, and that most primary studies have a target population of patients with complaints, making it not possible to synthesize data about screening. As a general rule, screening tests have high sensitivity as the most important feature, with the aim of not dismissing a “sick” person. In contrast, a diagnostic test must have a high specificity, to identify whether a person, previously screened or with a complaint, is sick. Ultrasonography proved to have a high specificity, suggesting that if this tool indicates a suspected ruptured implant, it is extremely likely to be ruptured.³⁹

There is some discordance about the necessity of screening an asymptomatic person with breast prosthesis. Although some institutions recommend ultrasonography or magnetic resonance imaging surveillance of silicone implants 3 to 6 years postoperatively and every 2 years thereafter to assess for integrity/rupture,^{9,40} there is no evidence-based recommendation about imaging for asymptomatic patients (any age, any implant).¹² Rupture of saline implants is often clinically evident, as there is a change in breast contour, and it does not represent a health risk. Regarding silicone implants, women followed prospectively with untreated ruptured implants do not appear to have an elevated health risk.⁴¹ In the case of asymptomatic women, screening has a potential harm (including patient anxiety, cost, and unnecessary surgery), and an elective removal of a ruptured

silicone gel breast implant would probably not be necessary.^{12,41}

Actually, the U.S. Food and Drug Administration itself published in an advisory panel, “noting the current scientific data and recommendations for [magnetic resonance imaging] screening for silent rupture and questioning whether much was gained by this recommendation. There is a concern expressed about cost to patients and mentioned, false-positive findings and whether information about a silent rupture would change practice (such as decisions about removal of the device).”⁹

Furthermore, for women aged 40 years and older, mammography/digital breast tomosynthesis is used as a breast cancer screening tool and can evaluate prosthesis integrity too.¹² As a diagnostic tool, mammography would not be used as a first choice, because it fails to detect the more common intracapsular ruptures, thus exhibiting a low sensitivity in the detection of implant failure. In addition, the examination can be painful, especially in the presence of capsular contracture, and it exposes the patient to radiation therapy.⁴² When comparing costs, using the national Medicare Global Diagnostic Service Fee, from the United Kingdom, bilateral magnetic resonance imaging is 9.7 times more expensive than a screening mammogram and 8.2 times than a breast ultrasound examination.⁴² Chung et al. performed a study using American fees and concluded the “strategy of screening symptomatic women with ultrasound to be optimal and economical.”¹⁰ Besides the economic benefits, ultrasound is a more available and painless tool, that does not expose the patient to radiation.

One previous systematic review approach on this topic, by Song et al. in 2011, compared magnetic resonance imaging and ultrasound in the diagnosis of silicone gel implant failure: it

	Risk of Bias				Applicability Concerns		
	Patient Selection	Index Test	Reference Standard	Flow and Timing	Patient Selection	Index Test	Reference Standard
Ahn et al., 1994	+	+	+	+	+	+	+
Beekman et al., 1999	+	+	+	+	+	+	+
Berg et al., 1993	?	+	+	+	?	+	+
Caskey et al., 1994	+	+	+	+	+	+	+
Chung et al., 1996	+	+	+	+	+	+	+
DeBruhl et al., 1993	+	+	+	+	+	+	+
Di Benedetto et al., 2008	+	+	+	+	+	+	+
Everson et al., 1994	?	+	+	+	?	+	+
Hold et al., 2012	+	+	+	+	+	+	+
Ikeda et al., 1999	?	+	+	+	?	+	+
Leckenby et al., 2016	?	+	+	+	?	+	+
Liston et al., 1994	+	+	+	+	+	+	+
Mennie et al., 2014	+	+	+	+	+	+	+
Oulharj et al., 2013	+	+	+	+	+	+	+
Reynolds et al., 1994	+	+	+	+	+	+	+
Rietjens et al., 2014	+	+	+	+	+	+	+
Scaranelo et al., 2004	?	+	+	+	?	+	+
Stachs et al., 2015	+	+	+	+	+	+	+
Stivala et al., 2017	+	+	+	-	+	+	+
Venta et al., 1996	+	+	+	+	+	+	+

High
Unclear
Low

Fig. 2. Methodologic quality summary.

included five studies that evaluated only ultrasound and eight that examined both magnetic resonance imaging and ultrasound, adding up to 13 studies in the ultrasound group.⁴³ Results were shown discriminated by subgroups and the values here are the ones from the largest analysis, which included 11 studies (“defined index test criteria”). Comparing the review by Song et al. and the present study, the results were as follows:

sensitivity, 60.0 percent (95 percent CI, 52.0 to 68.0 percent) and 73.7 percent (95 percent CI, 70.2 to 77.1 percent); and specificity, 75.0 percent (95 percent CI, 66.0 to 83.0 percent) and 87.8 percent (95 percent CI, 86.5 to 89.0 percent), respectively. The better performance indicated in the present study, besides the large difference in performance between studies from before and after the year 2010, may be a reflection of recent

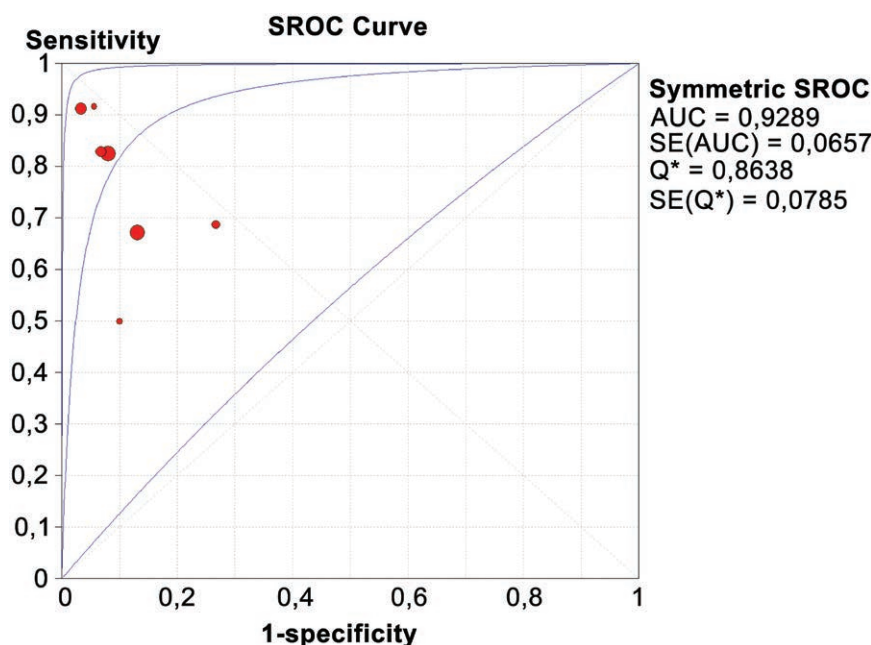


Fig. 3. Summary receiver operating characteristic (SROC) curve of studies published after 2010. AUC, area under the receiver operating characteristic curve.

advancements in ultrasound technology that have led to the development of high-resolution devices, because the older review included only two and ours included nine studies from the past two decades. With regard to weaknesses of this systematic review, the primary studies included in this systematic review had a lack of discrimination based on results by material of prosthesis and indication for surgery, which kept us from performing more specific analyses.

CONCLUSION

This study supports the belief that ultrasound of breast prostheses is an adequate tool for the diagnosis of rupture.

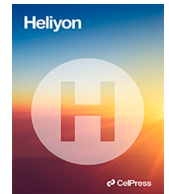
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Research article

Ultrasound versus MRI for evaluation of silicone leakage from silicone breast implants

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ABSTRACT

Background: Implant ruptures and gel bleed are not uncommon among women with silicone breast implants. While magnetic resonance imaging (MRI) is traditionally considered the gold standard diagnostic modality, recent studies suggest ultrasound might be an acceptable alternative. This study compares the efficacy of ultrasound and MRI in assessing implant integrity.

Methods: Women with silicone breast implants underwent a breast and axillary ultrasound and MRI on the same day. All tests were assessed by experienced radiologists. The accuracy, sensitivity, and specificity of ultrasound and MRI for implant rupture detection and silicone depositions in axillary lymph nodes were evaluated.

Findings: A total of 104 women participated in the study. The accuracy, sensitivity, and specificity of ultrasound for detecting implant ruptures compared to MRI were 96 %, 95 %, and 96 %, respectively. MRI demonstrated significantly lower sensitivity (44 %) for detecting silicone depositions in axillary lymph nodes compared to ultrasound. A significant association was observed between the presence of enlarged axillary lymph nodes and/or axillary pain and the detection of silicone depositions in axillary lymph nodes on ultrasound ($\chi^2(1, N = 104) = 5.1, p = 0.024$). Six women exhibited silicone depositions in axillary lymph nodes despite having intact first-pair implants, indicative of gel bleed.

Interpretation: Ultrasound is nearly as effective as MRI for detecting breast implant ruptures and is superior for detecting silicone depositions in axillary lymph nodes. We therefore recommend initiating radiological examination in women with breast implants with a breast and axillary ultrasound, proceeding to MRI only if the ultrasound is inconclusive. The prevalence of gel bleed is understudied and its potential adverse health effects might be underestimated. Further research is needed to explore its potential association with development of systemic symptoms.

1. Introduction

Breast augmentation surgery using silicone breast implants is the most commonly performed aesthetic plastic surgery procedure

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worldwide. Almost 2 million breast augmentation surgeries are performed annually worldwide, a number that is only rising [1]. While most women probably do not develop health complaints, local complications are not uncommon and include capsular contraction, breast pain, and implant ruptures. Most implant ruptures are intracapsular (around three-fourths) and the remaining one-fourth are extracapsular [2]. Notably, the 10-year rupture rate of implants is between 10 and 15 % after breast augmentation and between 20 and 25 % after breast reconstruction [2–8].

Implant ruptures are deemed clinically significant due to the recommended removal of affected implants, with the US Food and Drug Administration (FDA) cautioning that removing silicone gel after an implant rupture can be challenging [9]. However, the phenomenon of ‘gel bleed’, wherein silicone particles migrate from implants into the body, remains insufficiently studied [10]. Gel bleed is most commonly demonstrated by presence of silicone depositions in axillary lymph nodes, as silicone particles are thought to spread mainly through the lymphatic system. It is assumed that, even in the absence of an implant rupture, gel bleed can occur in substantial amounts [11].

Mammography, ultrasound, and MRI are the most commonly used breast imaging options. MRI, with its high sensitivity and specificity, is currently considered to be the gold standard for the diagnostic assessment of silicone breast implants. Nonetheless, MRI is costly, has limited availability, and is not suitable for patients with claustrophobia. Additionally, ultrasound is commonly used for the assessment of breast implants. However, the sensitivity and specificity of ultrasound for implant rupture assessments can vary substantially as they are dependent on the experience of the radiologist [12]. Importantly, many radiologists clinically acknowledge ultrasound to be a good modality for assessment of silicone depositions in axillary lymph nodes. One study, with histopathological confirmation of silicone-containing lymph nodes as the gold standard, found that the sensitivity of ultrasound for detecting silicone depositions in axillary lymph nodes was substantially higher than MRI (87.5 % and 20 %, respectively) [13]. Nevertheless, research on this topic is surprisingly scarce as the presence of silicone depositions in axillary lymph nodes is often deemed clinically insignificant.

However, there is a subset of women with silicone breast implants who report systemic symptoms which they attribute to their breast implants. This is referred to as Breast Implant Illness (BII). BII encompasses a variety of symptoms including extreme fatigue, myalgia, arthralgia, morning stiffness, night sweats, and cognitive symptoms such as memory loss [14]. Although the exact pathophysiology of BII is unknown, it is hypothesized that the symptoms are caused by an immune response to the leakage of silicone particles. In this regard, presence of silicone depositions as an indicator of this leakage could be clinically relevant.

More than a decade ago, a specialized silicone outpatient clinic was founded at the Amsterdam University Medical Center, the

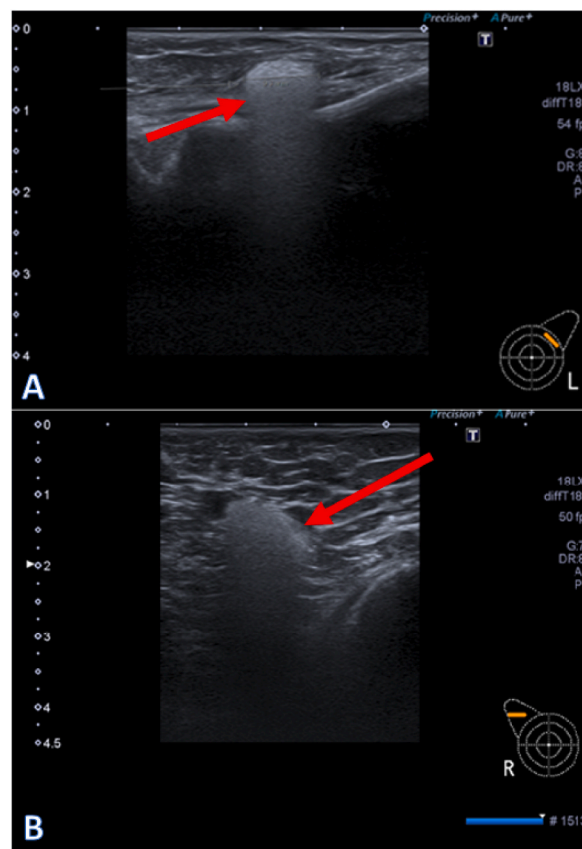


Fig. 1. Ultrasound of silicone depositions. **A.** Ultrasound of the left breast showing a silicone deposition. **B.** Ultrasound showing a lymph node with evident snowstorm sign in the right axilla, indicating silicone depositions.

Netherlands, to assess women with suspected silicone-associated health complaints. A recently published cohort study from this clinic observed that 75 % of women with a suspicion of BII also reported local symptoms [15]. These include stabbing pain and severe itch deep in the breasts and axillaries, often accompanied by axillary lymphadenopathy. The prevalence of local symptoms in this study population decreased significantly from 75 % to 34 % after surgical removal of the implants. In addition, the systemic symptoms the women experienced subsided in 2 out of 3 women after surgical removal of the implants [15]. Based on these clinical findings and previous studies, local and systemic symptoms seem to be associated. Given that gel bleed may be associated with development of systemic symptoms, early and simple detection of silicone leakage may be essential in diagnosing BII in women with breast implants [16].

Therefore, in the current study, we aim to investigate the most effective imaging technique for assessing implant integrity in this patient population, specifically focusing on implant ruptures and signs of gel bleed through presence of silicone depositions in axillary lymph nodes.

2. Methods

Women who visited the specialized silicone outpatient clinic of Amsterdam UMC, location VUmc, with suspected BII in 2021–2022 were eligible for inclusion. All radiological tests were performed at Amsterdam UMC. Women who had undergone radiological implant assessment at another clinic during the previous year were not included in this study.

Patients were notified at presentation that their clinical information may be used for research purposes with the aim of improving care and developing a national care pathway for these patients and verbal informed consent was obtained. The study was reviewed by the ethical review board of the Amsterdam UMC, VU University Medical Center Amsterdam (reference number: 2022.0617). It was determined that the Medical Research Involving Human Subjects Act did not apply to this study, and the necessity for written informed consent was waived. The Netherlands Society of Internal Medicine, Netherlands Society of Plastic Surgeons, and the patient-associations were closely involved during the inception and the continuation of this out-patient clinic.

A breast MRI and ultrasound were preferably performed on the same day. The ultrasound of both implants (if applicable) and bilateral axillary lymph nodes were conducted with special interest in the so-called ‘snowstorm phenomenon’ in the breast and axilla, indicating silicone depositions in the lymph nodes (Fig. 1A and B). This snowstorm phenomenon has been validated by multiple studies with histopathological confirmation [13,17–19]. Given the observed high sensitivity and specificity of ultrasound in these studies for silicone detection in axillary lymph nodes, we regarded ultrasound as the gold standard in the current study for the assessment of silicone depositions in axillary lymph nodes. In addition, the implants were accessed by ultrasound for integrity and inhomogeneity and reported as intact, intracapsular rupture, extracapsular rupture, or suspicion of a rupture. As MRI is considered the gold standard for the assessment of implant ruptures, all ultrasounds were performed before the MRI was evaluated. While the MRI and ultrasound were not necessarily evaluated by the same radiologists, all radiological tests were conducted by radiologists specialized in breast radiology. The breast MRI protocol consists of a 3 d T2 Spair series with a sagittal reconstruction, a silicone suppressed series (silicone low), and a water suppressed series (silicone high). According to the breast silicone protocol, the integrity of the implants was scored as intact, internal degradation (water droplets), an intracapsular rupture (keyhole, teardrop, capsular sign, and linguini sign), or an extracapsular rupture [20]. The ultrasound and MRI images were evaluated independently. To increase the accuracy of the results, all ultrasound images with a suspicion of silicone depositions in axillary lymph nodes were reviewed a second time by one experienced radiologist for confirmation.

Statistical analyses were performed using IBM SPSS Statistics (version 28.0; IBM Corp., Armonk, N.Y.). Spearman correlations and chi-square tests were used for comparison of data. Data are shown as mean [SD] in case of normally distributed data and as median

Table 1
Baseline characteristics.

Total	N = 104
Age in years	47.3 (±11.8)
Pair of implants	
1st pair of implants	72 (69 %)
2nd pair of implants	21 (20 %)
3rd pair of implants	8 (8 %)
≥4th pair of implants	3 (3 %)
Implant brand	
Known implant brand (i.e., Allergan, Eurosilicone, Mentor)	70 (67 %)
Unknown brand	34 (33 %)
Reason for implants	
Cosmetic	94 (90 %)
Reconstructive	10 (10 %)
Age of current implants in years	13.0 [8.0–17.0]
Total implantation duration in years	16.0 [10.3–23.8]
Reported history of ruptured implants	
Yes	12 (11 %)
No	86 (83 %)
Unknown	6 (6 %)

Data are presented as number (percentage), median [IQR] or mean (±SD).

[IQR] in case of non-normally distributed data. The sensitivity and specificity of detecting implant ruptures and silicone depositions in axillary lymph nodes with ultrasound and MRI were calculated. Therefrom, the accuracy was calculated, representing the proportion of true positive results (both true positive and true negative) in the selected population. A p-value of <0.05 was considered statistically significant.

3. Results

In total, 105 women underwent radiologic assessment with MRI and ultrasound. After second analysis, one woman was excluded for not meeting the study criteria since the MRI images were evaluated before the ultrasound images. Baseline characteristics of the 104 remaining women are shown in Table 1.

Most women came to the clinic with their first pair of implants (69 %), with a median implantation time of thirteen years. The majority had breast implants because of cosmetic reasons (90 %). Twelve women were certain they had had ruptured implants in the past, while six women were unsure whether their previous implants had ruptured or not. Almost two-thirds of women reported their implant brand (67 %), while 34 women did not know from which brand their implants were (33 %). Three women presented with a single breast implant and 101 women presented with bilateral implantation, resulting in a total of 205 assessed implants. Local symptoms were reported by 69 women (66 %), consisting of breast pain or intense itching of the breasts, capsular contraction, or pain in the armpits.

3.1. Implant ruptures

In total, 20 women showed one or two ruptured implants on radiological imaging (Fig. 2A and B). Of the 103 right-sided implants, 13 showed a rupture on MRI, which were all also detected by ultrasound. Of the 102 left-sided implants, twelve showed a rupture on MRI. Of these, eleven ruptures were also detected by ultrasound. The radiologist had a suspicion of a rupture of nine breast implants in eight women (one bilateral) during echography, which could not be confirmed by MRI. This resulted in a high specificity (95 %) and sensitivity (96 %) of ultrasound for the detection of implant rupture, in comparison to the gold standard MRI (Table 2). In addition, accuracy was equally high (95 %). The duration of implantation of the current implants was correlated with the presence of an implant rupture ($r_s = 0.257, p = 0.009$). No correlation was found between implant ruptures and the presence of local symptoms, such as breast pain ($r_s = -0.106, p = 0.287$).

3.2. Axillary silicone depositions

In addition, we compared the axillary lymph nodes on ultrasound and MRI. As previously stated, ultrasound is considered the

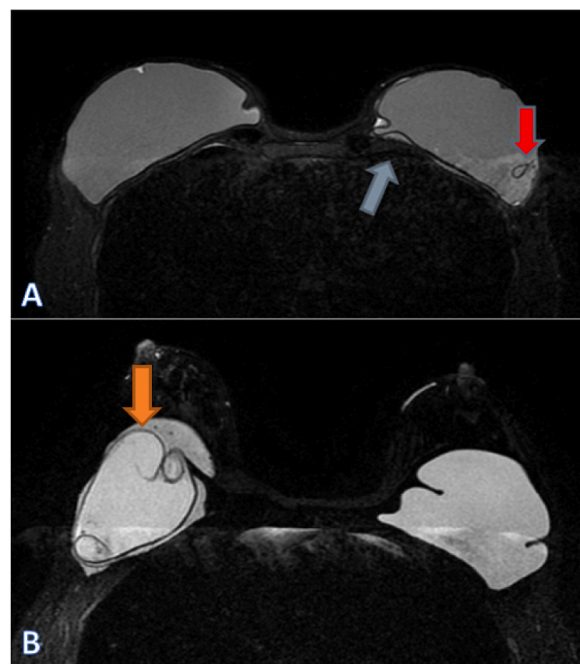


Fig. 2. Breast MRI's with silicone breast implants. **A.** Blue arrow shows a subcapsular line, the red arrow points to a teardrop sign. Both are indicative of an intracapsular implant rupture. **B.** Axial MRI silicone suppressed image showing an inhomogeneous implant and internal degradation with linguini sign of the left breast (orange arrow), confirming an intracapsular rupture.

Table 2

Sensitivity, specificity, and accuracy of ultrasound in comparison to gold standard MRI for the detection of implant ruptures.

US	MRI		
	Implant rupture +	Implant rupture -	
Implant rupture +	25	9	
Implant rupture -	1	170	
	Sensitivity 96 % (80–100 %)	Specificity 95 % (91–98 %)	Accuracy 95 % (91–98 %)

Data are presented in percentages with 95 % confidence intervals. US: ultrasound. MRI: magnetic resonance imaging.

primary modality for the detection of silicone depositions in axillary lymph nodes. MRI indeed demonstrated a lower sensitivity compared to ultrasound for the detection of silicone depositions in the axillary lymph nodes, as shown in Table 3 (sensitivity 44 %, 95 % CI 25–65 %). No silicone depositions were seen on MRI that were not detected by ultrasound (specificity 100 %, 95 % CI 98–100 %). Fig. 1 shows examples of the typical snowstorm sign. Additionally, the MRI showed enlarged axillary lymph nodes but without a silicone signal in twenty women. In six of them, the ultrasound revealed an evident snowstorm sign, thus indicating silicone depositions. A significant association was observed between presence of enlarged axillary lymph nodes, pain, or intense itching in the armpits and the detection of axillary silicone depositions on ultrasound (χ^2 (1, N = 104) = 5.1, p = 0.024).

3.3. Gel bleed

In six women who had their first pair of implants and showed no signs of implant rupture, ultrasound detected silicone depositions in their axillary lymph nodes. This was confirmed by an evident silicone signal on MRI in the same axillary lymph nodes in five out of six women. The duration of their implant placement ranged from 8 to 22 years, with an average of 15.3 years. Subsequently, five out of six women had their implants surgically removed and reported that the shells of all explanted breast implants appeared intact postoperatively.

4. Discussion

This study compared the use of ultrasound to MRI for the detection of implant ruptures and silicone depositions in axillary lymph nodes among women with silicone breast implants. We observed a high sensitivity, specificity, and accuracy of ultrasound for the detection of implant ruptures in comparison to gold standard MRI. In addition, ultrasound was superior to MRI for the detection of silicone depositions in axillary lymph nodes. We found an association between the presence of enlarged axillary lymph nodes or axillary pain and the detection of silicone depositions in axillary lymph nodes on ultrasound. Lastly, we observed six women with a first pair of implants without signs of rupture who showed evident signs of silicone depositions in axillary lymph nodes, indicative of gel bleed from the implants.

While the number of breast augmentation surgeries worldwide is increasing, there is currently no consensus regarding the management of systemic complications associated with silicone breast implants. The FDA recommends the first periodic radiologic implant screening 5–6 years postoperatively, and every 2–3 years thereafter [21]. However, adherence to these recommendations is low, with one US study reporting only 5.9 % compliance among their study population [22]. Recently, the FDA updated its guidelines, now suggesting ultrasound as an acceptable alternative for screening asymptomatic patients [23]. Nevertheless, MRI is considered as the gold standard for breast implant assessment in most other countries. The high sensitivity and specificity of gold standard MRI for establishing implant ruptures have been described in multiple earlier studies [24–26]. In our current study, in comparison to MRI, ultrasound showed only one missed rupture and there was a suspicion of a rupture in nine implants that was not confirmed by MRI. Based on these results, we recommend to initially perform an ultrasound in women with breast implants for the detection of implant ruptures and to only consider performing a MRI if the ultrasound is inconclusive. Importantly, performing an ultrasound instead of the MRI is more cost-effective and often easier available, making it accessible for wider adoption in clinical practice.

For decades, some women with breast implants have consequently reported development of systemic symptoms [15,27–29]. The exact pathophysiology remains unclear; however, an immune response to gel bleed has been proposed to play a role [10]. Surprisingly little research has been conducted into the occurrence of gel bleed or the supposed mechanism behind it. Currently, there are no well-defined criteria for establishing gel bleed and we found no studies that investigated the prevalence of gel bleed in women with

Table 3

Sensitivity, specificity, and accuracy of MRI in comparison to ultrasound for the detection of silicone depositions in axillary lymph nodes.

MRI	US		
	Axillary silicone +	Axillary silicone -	
Axillary silicone +	12	0	
Axillary silicone -	15	178	
	Sensitivity 44 % (25–65 %)	Specificity 100 % (98–100 %)	Accuracy 93 % (88–96 %)

Data are presented in percentages with 95 % confidence intervals. US: ultrasound. MRI: magnetic resonance imaging.

breast implants. Most likely, this is because gel bleed or even implant ruptures are generally not considered health risks. However, given the consistent reports of women with breast implants and unexplained systemic symptoms, this assumption is at least questionable and deserves more attention in scientific research. Knowledge about potential health risks of silicone leakage through either implant ruptures or gel bleed is currently lacking. This calls for more research into the quantification and possible adverse effects of silicone leakage in the body.

We noticed silicone depositions in axillary lymph nodes with ultrasound as a sign of gel bleed in six women with their first pair of intact implants. In five of these women, the silicone depositions were also seen on MRI images with a silicone signal in the corresponding lymph nodes. Of the five women who underwent implant removal afterwards, none reported an implant shell rupture postoperatively. This supports the hypothesis that accumulation of silicone in lymph nodes can occur in the absence of an implant rupture [11]. While it is often assumed that gel bleed is caused by the silicone gel bleeding through the shell, several observations indicate it might actually be the shell itself that deteriorates. One case report describes a woman with saline breast implants and histopathologically proven silicone depositions in cervical lymph nodes, suggesting these were derived from the silicone shell of the saline implants [30]. Another case report describes a woman with sarcoidosis, in which histopathology with a Laser Raman microprobe analysis revealed the axillary lymph nodes contained silicone structures that are exclusively found in the shell of the implants [31]. These observations support the hypothesis that shell deterioration at least contributes to the accumulation of silicone depositions at distant sites. The prevalence of gel bleed is understudied, most likely underreported and its potential adverse health effects might therefore be underestimated. Given the consistent local and systemic symptoms that some women with breast implants report, further research is needed to investigate a possible association between gel bleed and development of systemic symptoms. In light of the above, the difference in sensitivity for the detection of silicone depositions in axillary lymph nodes on MRI and ultrasound should not be underestimated. Especially in women with silicone breast implants who report local symptoms such as breast or axillary pain or axillary lumps, gel bleed might be indicative of an association with the implants. In this patient group, ultrasound should be the modality of choice for the evaluation of implant status. In particular, the axillary lymph nodes should be part of the standard assessment.

We believe our study contributes to optimizing the clinical care pathway for women with silicone breast implants who report local and systemic symptoms. In addition, it contributes to the limited knowledge on gel bleed and might stimulate more research into its potential adverse health effects. However, this study has several limitations that need to be addressed. The relatively small sample size and selection of patients used for this study (i.e., women with breast implants who report systemic symptoms) may limit our ability to extend our results to the general population of all women with breast implants. Secondly, all ultrasounds were performed by experienced radiologists who specialize in breast diagnostics. The high sensitivity and specificity of ultrasound observed in this study might not be applicable to all radiologists in general.

In conclusion, our results indicate ultrasound is an effective, cheap, and accessible diagnostic modality for evaluating silicone breast implant status. In addition, ultrasound proves to be the modality of choice for diagnosing silicone depositions in axillary lymph nodes as an indication of gel bleed. Therefore, we recommend initiating the radiological examination of breast implants with an ultrasound of both breasts and axillae, and only performing a MRI if the ultrasound results are inconclusive. We highlight the importance of further research into the possible association between gel bleed and development of systemic symptoms in women with silicone breast implants.

Data availability statement

Data will be made available on request.

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CRediT authorship contribution statement

Karlinde A. Spit: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Siham Azahaf:** Writing – review & editing, Validation, Methodology. **Christel J.M. de Blok:** Writing – review & editing, Supervision, Methodology. **Katya M. Duvivier:** Writing – review & editing, Investigation, Data curation, Conceptualization. **Oliver T. Wiebenga:** Writing – review & editing, Investigation, Data curation, Conceptualization. **Prabath W.B. Nanayakkara:** Writing – review & editing, Supervision, Project administration, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Risk factors for capsular contracture after breast reconstruction with tissue expanders and silicone implants in nonirradiated patients

A retrospective observational cohort study

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Abstract

Breast reconstruction surgery with tissue expanders and silicone implants is widely performed; however, risk factors for late complications such as capsular contracture have not been fully investigated despite their high prevalence. We investigated the association between expander and implant positions and the development of capsular contracture in patients who underwent breast reconstruction surgery over 10 years previously. In this retrospective observational study, we analyzed 239 patients, among whom 69 (28.9%) had developed capsular contracture of Baker Classification grade II or higher. The position of the expander was classified into six categories based on the inferior margin of the healthy breast. The position of the implant was defined as an upward movement from the position of the expander and was classified into three categories based on the inferior margin of the breast at the time of expander insertion. Using multivariate logistic regression analysis, we assessed whether the misalignment of the expander and silicone implant positions affected capsular contracture development. Both expander and implant positions were significantly different between the groups. The odds ratios, adjusted for confounding variables, were 3.4 and 5.2 for an expander position of 1 and 2 lateral fingers upward, respectively, and 4.8 and 45.4 for a silicone implant position of 2 and 3 lateral fingers upward, respectively. We identified malposition of expanders and silicone implants as risk factors for developing capsular contracture. Correct insertion and adequate dilatation of the expander in the correct position could reduce the risk for capsular contracture.

Keywords: breast neoplasms, contracture, dilatation, mammoplasty, risk factors, tissue expansion devices

1. Introduction

Breast reconstruction surgery with tissue expanders and silicone implants has long been the primary option due to the low level of invasiveness and excellent cosmetic properties.^[1] However, early complications of prosthetic breast reconstruction include infection, hematomas, and necrosis due to poor circulation, and late complications such as capsular contracture and rupture have also been reported.^[2] In particular, capsular contracture might occur when the skin stretched by the expander shrinks over a long period of time, which not only affects cosmetic properties but also the physical functions of the breast. Baker classification Grade IV would impose a physical burden, such as pain, a twitching sensation, and dyskinesia, which would warrant capsule resection and revision surgery.^[3] The prevalence of capsular contracture 10 years after surgery is as high as 23.7%, and measures designed at reducing risk for capsular contracture may be recommended.^[4] Therefore, high-risk patient populations that are prone to developing capsular

contracture need to be identified in order to initiate preventive measures.

Infection, inflammation, blood species, and irradiation have been reported as risk factors for capsular contracture.^[5] However, in the authors' experience, capsular contracture often develops within 10 years of reconstruction for certain conditions, which the risk factors identified in previous studies have not been sufficient to explain. Because capsular contracture, which is stimulated by an immune response to foreign materials in the body, is common in irradiation, infection, and hematoma patients, the enhancement of the foreign body reaction by external stimulation may be a risk.^[6] In addition, the authors have experienced an increase in capsular contracture over a long period of time when the expander is improperly positioned. However, the association between expander positional abnormalities and the development of capsular contracture is unclear, as this was not discussed in the paper by Cordeiro et al, which followed patients for a long time after surgery (mean follow-up of 36.7 months).^[7]

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The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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Therefore, in this study, we investigated the association between the expander and implant positions and the development of capsular contracture in patients who underwent breast reconstruction surgery over 10 years previously.

2. Patients and Methods

2.1. Research design

This was a retrospective observational study using patient medical records at a clinic for breast reconstruction with implants in Tokyo, Japan. This clinic was selected as one of the facilities in Japan that perform a great number of tissue expander/implant breast reconstructions. Data were collected in March, 2019.

2.2. Participants

We included patients who had undergone breast reconstruction with implants (both the expander and the silicone implant are inserted under the pectoralis major muscle), for whom at least 10 years had passed from silicone implant insertion to the date of investigation, and who visited the clinic once a year. We excluded patients who had been irradiated, and those in whom an expander other than that made by Allergan® had been inserted. A total of 264 patients were assessed for eligibility and 25 patients were excluded according to the criteria (implant year <10 years: eight patients, expander used other than that made by Allergan®: three patients, and irradiated: 14 patients). All eligible 239 patients were included in this study.

2.3. Outcome measure

The degree of capsular contracture was assessed by the plastic surgeon according to the Baker Classification.^[3] The severity of capsular contracture was assessed at 10 years after implant placement, and a Baker Classification of grade II or higher was considered to indicate capsular contracture.

2.4. Independent variables

The position of the expander was classified into one of the following six categories based on the inferior margin of the healthy breast: symmetry, 1 lateral finger upward, 2 lateral fingers upward, 1 lateral finger downward, 2 lateral fingers downward, and outside. The position of the implant was defined as an upward movement from the position of the expander and was classified into one of the following three categories based on the inferior margin of the breast at the time of expander insertion: (I) 1 lateral finger upward, (II) 2 lateral fingers upward, and (III) 3 lateral fingers upward.

2.5. Confounding variables

Age, number of years after implant, timing of reconstruction (delayed or immediate), type of papillary surgery, healthy lateral breast surgery, presence of complications during expander insertion, early complications (i.e., reoperation), volume of expander (mL), and volume of implant (mL) were recorded.^[8] As all the patients were advised to perform massage by themselves, so this variable was not collected.

2.6. Statistical analysis

Patients were divided into two groups based on the occurrence of capsular contracture and attributes were compared between the groups by a *t* test or a χ^2 -squared test. Whether the misalignment of the expander and silicone implant positions affected the development of capsular contracture was examined by multivariate logistic regression analysis, adjusting for confounding

variables. Missing values were ignored in multivariate logistic regression ($N = 9$). For excluding the potential bias for the interaction in positions between silicone implants and expanders, subgroup analysis of only those with abnormal expander position (category: 1) was conducted. All statistical analyses were conducted using STATA (STATA Corp LP, College Station, TX).

2.7. Ethical considerations

Since this study used reviewed medical chart data as a retrospective observational study, written informed consent from the participants was unnecessary. An announcement regarding the study and the option for participants to opt out was posted on the website of our clinic. The study protocol was approved by the Ethics Committee of the Breast Surgery Clinic, Tokyo, Japan, which included external reviewers.

3. Results

Of the 239 patients, 69 (28.9%) developed capsular contracture. Among 69 cases, there were three grade II capsular contracture cases and 66 grade III cases according to Baker Classification.^[3] There were no grade IV cases in the study population. Table 1 reports descriptive statistics for each variable according to the presence or absence of capsular contracture. Mean years after implant insertion was 12.0 years among those without capsular contracture and 12.2 years among those with ($P = .334$). The position of the expander and the position of the implant were significantly different between the groups ($P < .001$, $P < .001$, respectively).

Table 2 shows the results of a logistic regression analysis in which variables that may be risk factors for capsular contracture were included. The odds ratios, adjusted for age, timing of reconstruction, implant volume, and time since implant placement, were 3.4 for an expander position of 1 lateral finger upward, 5.2 for an expander position of 2 lateral fingers upward, 4.8 for a silicone implant position of II, and 45.4 for a silicone implant position of III. Expander positions of 2 lateral fingers downward and outside were omitted in this analysis because of the small number of samples. To exclude the potential bias for the interaction in positions between silicone implants and expanders, subgroup analysis of only those with abnormal expander positions (category: 1) was conducted. Table 3 represents the results of subgroup analysis. The adjusted odds ratios for a silicone implant position were 4.2 for II and 18.6 for III.

Images of typical capsular contracture and a silicone implant within the capsule are shown in Figure 1. Within the capsular contracture (Fig. 1A), the implant was intact but crushed and the shape was unrestored (Fig. 1B). Figures 2 and 3 show the clinical course of, respectively, delayed and immediate cases with capsular contracture. Figure 4 captures the long-term observation of a patient who did not develop capsular contracture and whose expander and implant were properly aligned.

4. Discussion

This study examined risk factors for the development of capsular contracture in patients who could be followed for more than 10 years and for whom the implant replacement was performed by one plastic surgeon, with a focus on the location of the expander and the implant. An abnormal upward position of the expander and an upward misalignment of the implant site were extracted as risk factors. The occurrence of capsular contracture, despite capsular incision or capsular excision at the time of silicone implant insertion in order to achieve symmetry, suggests that even if the position of the silicone implant is temporarily corrected, it moves upward over time and capsular contracture occurs. It is noteworthy that one might argue that it is the contracture which moves the implant up. Further study is

Table 1**Baseline characteristics.**

	Without capsular contracture (N = 170)		With capsular contracture (N = 69)		P value
	N	%	N	%	
	Mean	SD	Mean	SD	
Age	48.1	0.7	50.7	1.1	.050
Years after implant insertion	12.0	1.6	12.2	1.7	.334
Timing					
Immediate	60	68.2	28	31.8	.453
Delayed	110	72.8	41	27.2	
Expander position					
Symmetry	124	81.0	29	19.0	<.001
1 upward	16	40.0	24	60.0	
2 upward	7	38.9	11	61.1	
1 downward	19	90.5	2	9.5	
2 downward	4	100.0	0	0.0	
Outside	0	0.0	3	100.0	
Nipple plasty (N = 169)					
None	8	66.7	4	33.3	.265
NAG	20	55.6	16	44.4	
NASC flap	0	0.0	1	100.0	
NG	99	75.6	32	24.4	
NSM	21	75.0	7	25.0	
Star flap	17	68.0	8	32.0	
Star flap + NG	1	100.0	0	0.0	
Tattoo	3	75.0	1	25.0	
Implant position (N = 169)					
I	126	88.7	16	11.3	<.001
II	40	55.6	32	44.4	
III	3	12.5	21	87.5	
Complication					
No	162	72.6	61	27.4	.054
Yes	8	50.0	8	50.0	
Reoperation					
No	141	74.2	49	25.8	.038
Yes	29	59.2	20	40.8	

NAG = nipple areola graft, NASC = nipple areola sub-cutaneous flap, NG = nipple graft, NSM = nipple-sparing mastectomy, SD = standard deviation.

Table 2**Related factors for capsular contracture.**

Variables	Crude odds ratio	95% CI (Lower)	95% CI (Upper)	P value	Adjusted odds ratio	95% CI (Lower)	95% CI (Upper)	P value
Expander position (ref: symmetry)								
1 upward	6.4	3.0	13.6	<.001	3.4	1.4	8.5	.008
2 upward	6.7	2.4	18.8	<.001	5.2	1.5	17.4	.008
1 downward	0.5	0.1	2.0	.301	0.9	0.2	4.3	.861
Implant position (ref: I)								
II	6.3	3.1	12.7	<.001	4.8	2.2	10.5	<.001
III	55.1	14.8	205.7	<.001	45.4	10.6	193.7	<.001
Age	1.0	1.0	1.1	.051	1.1	1.0	1.1	.015
Implant volume	1.0	1.0	1.0	.591	1.0	1.0	1.0	.939
Timing (ref: immediate)	0.8	0.4	1.4	.443	1.2	0.5	2.6	.706
Years after implant insertion	1.1	0.9	1.3	.332	0.9	0.8	1.2	.619

needed for concluding the causal relationship between the mal-position of implants and occurrence of capsular contracture.

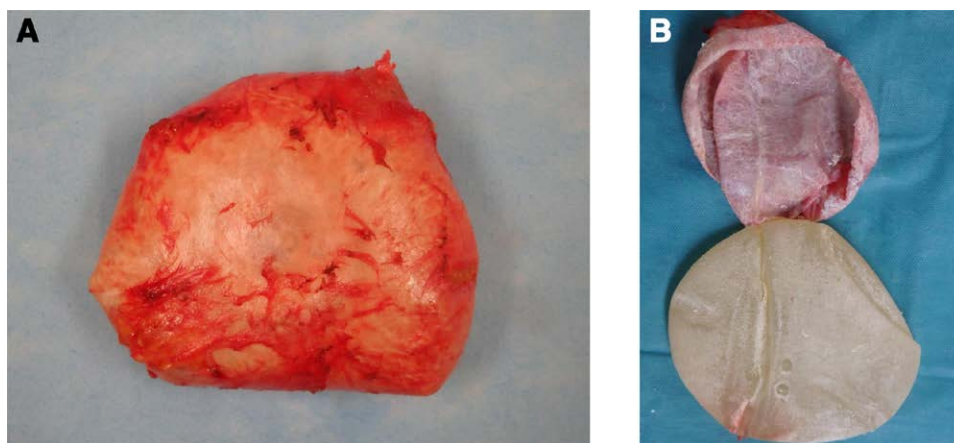
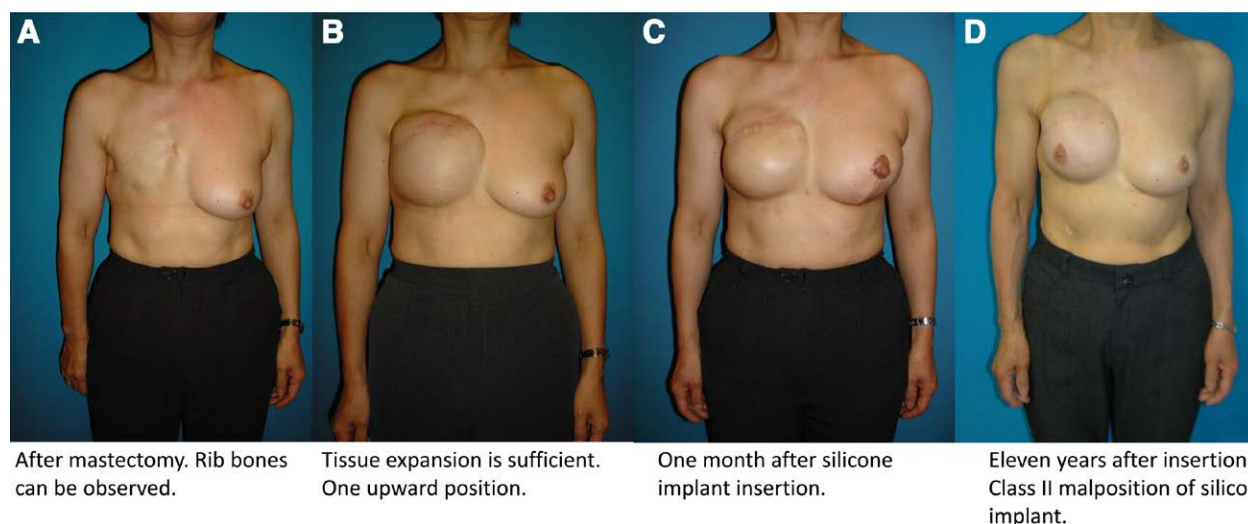
The more the expander was tilted upward, the higher the risk of film contracture. Since the expander is also a foreign body, the first capsule (virgin capsule) is formed for the individual shortly after insertion. The position remains displaced and stretched to form an envelope. The breast shape is most full at the bottom of the breast, otherwise known as the lower pole. The implant itself does not have the ability to stretch the skin. If the skin is inadequately expanded the implant may be displaced upward, even when the capsule is incised and dissected inferiorly. Alternatively, the dissected area where the elastic fibers are

stretched but not fully extended may shrink, leading to contraction. Therefore, the risk of capsular contracture is expected to be reduced when the elastic fibers are sufficiently stretched so as to become fully extended.^[9]

In the present study, possible risk factors were collected such as implant volume, timing, and years after implant insertion, however they were not considered as risk factors among the study participants.^[10,11] This may be due to the difference in the definition of outcome measure. In our study participants, we included minimal to severe capsular contracture as an outcome, and we did not find any cases representing severe contracture: majority of the cases were with moderate capsular contracture.

Table 3**A subgroup analysis among patients with normal expander position.**

Variables	Adjusted odds ratio	95% CI (Lower)	95% CI (Upper)	P value
Implant position (ref: I)				
II	4.2	1.6	11.0	.004
III	18.6	3.7	93.0	<.001
Age	1.0	1.0	1.1	.160
Implant volume	1.0	1.0	1.0	.621
Timing (ref: immediate)	0.8	0.3	2.3	.724
Years after implant insertion	1.0	0.7	1.3	.995

**Figure 1.** Confirmation of capsular contracture 15 years after implant insertion. (A) Gross appearance of capsule contracture. (B) Silicone implant.**Figure 2.** Delayed case with upward displacement of the tissue expander. (A) After mastectomy. Rib bones can be observed. (B) Tissue expansion is sufficient. The expander is in 1 lateral finger upward position. (C) 1 month after silicone implant insertion. (D) 11 years after insertion. Class II malposition of silicone implant.

4.1. Clinical implications

Reconstruction with a tissue expander and implant is especially suitable for Japanese patients, many of whom prefer not to have a new scar elsewhere on the body. When performing breast reconstruction with implants, many plastic surgeons give importance to implant selection, but we show that the most important consideration is that the correct expander is inserted in the correct position. If the expander is inserted in the correct position and sufficient extension of the skin in that area is achieved, a less contractile envelope will be formed and the probability that capsular contracture occurs over time decreases. In other words, forcing the implant into the skin in a location where the skin is not stretched

should be avoided. Given the high risk of capsular contracture, even if the position of the implant is later corrected, re-expanding with an expander after resection of capsular contracture is necessary to prevent recurrence of capsular contracture.

Recently, because of breast implant-associated anaplastic large cell lymphoma, textured expanders and implants are no longer used and are being replaced with products with a smooth surface. This makes them prone to positional abnormalities and raises concerns about the possibility of more patients with capsular contracture in the long term. Now more than ever, sufficient skin expansion in the correct position at the time of expander insertion is required.

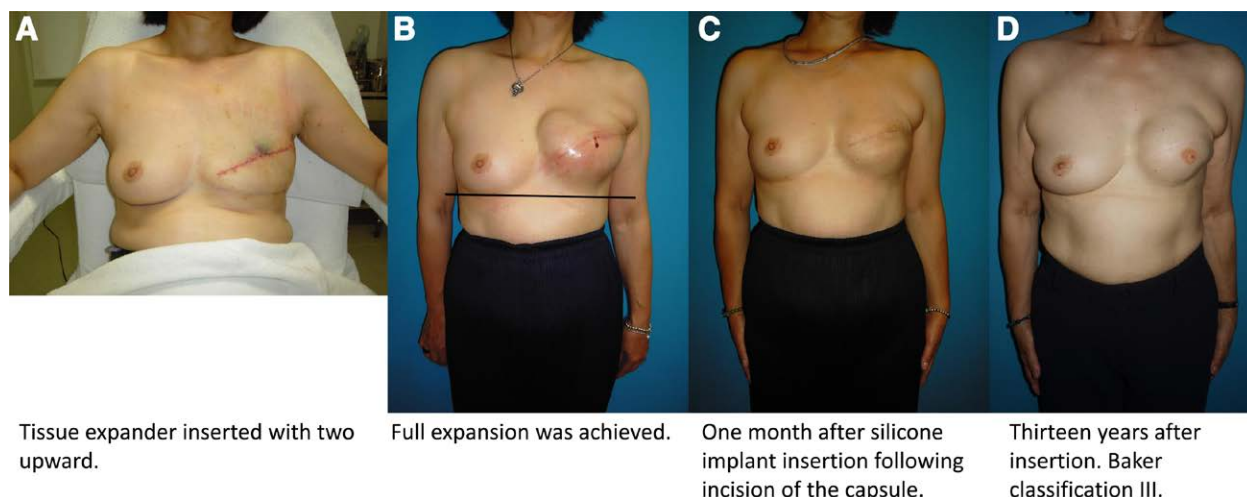


Figure 3. Immediate case with upward displacement of tissue expander. (A) Tissue expander inserted in 2 lateral finger upward position. (B) Full expansion is achieved. (C) 1 month after silicone implant insertion following incision of the capsule. (D) 13 years after insertion. Baker Classification grade III.

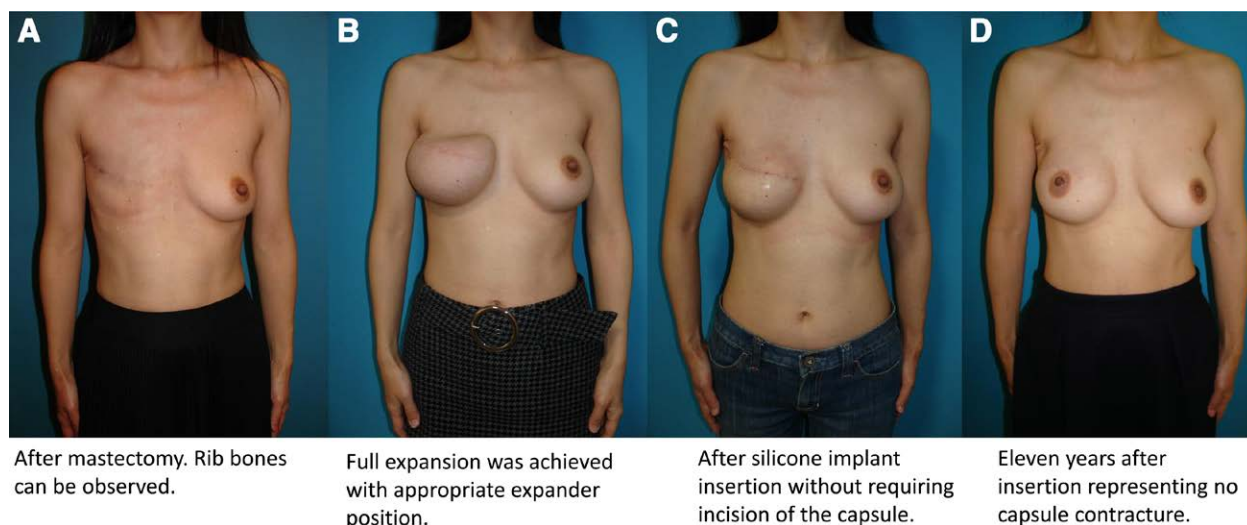


Figure 4. Delayed case without displacement of tissue expander. (A) After mastectomy. Rib bones can be observed. (B) Full expansion is achieved with appropriate expander position. (C) After silicone implant insertion without requiring incision of the capsule. (D) 11 years after insertion demonstrating no capsular contracture.

4.2. Limitations

As a single-center study, caution is advised when generalizing from these results. However, because of the uniformity of the plastic surgeon's procedures, we were able to identify the risk factors for capsular contracture as expander and implant malposition. There may be a sampling bias, as certain categories of patients did not visit the outpatient clinic; for example, those without complications (including capsular contracture) and those who died or were receiving breast cancer treatment. This study did not include pre-pectoral placement, therefore the value would be improved by examining both pre-pectoral and retro-pectoral patients in the future.

5. Conclusion

Malposition of expanders and silicone implants were identified as risk factors for developing capsular contracture, a late complication of breast reconstruction in non-irradiated patients. The odds ratios, adjusted for confounding variables, were 3.4 and 5.2 for an expander position of 1 and 2 lateral

fingers upward, respectively, and 4.8 and 45.4 for a silicone implant position of 2 and 3 lateral fingers upward, respectively. Our finding that correct positioning and adequate expansion of the expander might reduce the occurrence of capsular contracture.

Author contributions

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Supervision: Hiromi Sanada.

Writing – original draft: Gojiro Nakagami.

Writing – review & editing: Yoshiko Iwahira, Gojiro Nakagami, Hiromi Sanada.

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The Baker Classification for Capsular Contracture in Breast Implant Surgery Is Unreliable as a Diagnostic Tool

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Background: Breast implants are frequently used in cosmetic and reconstructive breast surgery. Capsular contracture, the most common long-term complication, is usually graded using the Baker classification. Despite its widespread use, the reliability of the Baker classification has never been established. The aim of this study was to determine the interobserver reliability and agreement of the Baker classification.

Methods: Sixty women who had undergone cosmetic breast augmentation were included. They were examined independently by two plastic surgeons from an observer pool. The Baker score was determined, along with firmness, dislocation, symmetry, and pain using four-point scales. Patients were asked to complete the BREAST-Q postaugmentation module. The interobserver reliability and agreement were calculated for all variables with a quadratic weighted kappa.

Results: The interobserver reliability of the Baker classification was poor (kappa, 0.55; 95 percent CI, 0.37 to 0.72). Interobserver reliability of the clinical parameters firmness (0.64; 95 percent CI, 0.49 to 0.79), dislocation (0.49; 95 percent CI, 0.26 to 0.73), and symmetry (0.61; 95 percent CI, 0.34 to 0.88) was also poor. Pain scores seemed more reliable (0.72; 95 percent CI, 0.56 to 0.89); however, most patients had no pain. The interobserver agreement for the Baker score was 48 percent; in 43 percent, the observers differed one category; and in 12 percent, the difference was more than one category.

Conclusions: Interobserver reliability and observer agreement of the Baker classification for capsular contracture were poor. Consensus about how to adequately rate the symptoms of capsular complaints is lacking. A more reliable method of measurement or description is needed, especially for scientific research purposes, to assess the long-term problems associated with breast implants. (*Plast. Reconstr. Surg.* 146: 956, 2020.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Diagnostic, IV.

Breast augmentation using implants is one of the most frequently performed cosmetic operations. Furthermore, the method of breast reconstruction used most is implant-based.

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In The Netherlands, approximately 3.3 percent of women have breast implants. Between 2015 and 2017, approximately 11 of the 60,000 inserted breast implants, or 25 percent of the procedures, were for reconstructive purposes in The Netherlands. Capsular contracture is reported as a common long-term complication associated with breast implants and is usually the primary reason for reoperation.¹ Reported incidences range from 0.6 to 17.4 percent for primary augmentation and 21.1 to 47.7 percent for breast reconstruction.² In addition, revision surgery in both groups is

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Table 1. Baker Classification of Capsular Contracture after Augmentation Mammoplasty*

Class	Description
I	Breast absolutely natural; no one could tell breast was augmented
II	Minimal contracture; I can tell surgery was performed, but patient has no complaint
III	Moderate contracture; patient feels some firmness
IV	Severe contracture; obvious just from observation

*From Baker JL Jr. Augmentation mammoplasty. In: Owsley JQ Jr, Peterson RA, eds. *Symposium on Aesthetic Surgery of the Breast*. St. Louis: Mosby; 1978:256–263.

reported to result in a higher incidence of capsular contracture.²

After implantation of any implant, a host response is evoked, resulting in the formation of a fibrotic capsule around the prosthesis. This is part of a normal foreign body response. Normally, the fibrous tissue remains thin and supple, and most patients do not experience any complaints. However, in an adverse course, the capsule may thicken, tighten, or even contract. The type of implant, surgical technique, low-grade infection, and postoperative radiotherapy are factors described to be associated with capsular problems.² Clinically, these capsular changes can cause hardening of the breast or even deformation and may result in implant dislocation and asymmetry of the breasts. Some patients may experience tenderness or pain. The symptoms can occur in isolation or in any combination. In addition, they can present at various time points after surgery and can progress at different rates. In other words, the presentation of capsular-related complaints is very heterogeneous.

With the increasing popularity of breast implants over recent decades, the number of patients with complaints attributed to pathologic changes in the fibrous capsule has increased progressively. In the medical literature, the concept of “capsular contracture” is used as a generic term for the collation of capsule-related complaints. With the recognition of these capsular problems related to breast implants, attempts were made to classify capsular contracture with regard to the severity of the symptoms. In 1978, Baker introduced a clinical classification of capsular contracture for the first time. His original classification is still the most widely used and generally accepted.³ It uses a four-point scale ranging from grade I (natural) to grade IV (severe contracture) (Table 1). Notably, the scale does not specify how this contracture presents. The classification was later modified by Spear and Baker to accommodate for the reconstructed breast by adding

Table 2. Baker Classification of Capsular Contracture*

Grade	Description
1	Grade 1 capsular contracture is asymptomatic (producing or showing no symptoms). The formation of scar tissue around the implant does not interfere with the size, shape, or texture of the breasts. The breasts appear natural and remain soft to the touch.
2	Grade 2 capsular contracture usually presents itself with only minor cosmetic symptoms. The breasts will usually appear normal in shape but feel somewhat firm to the touch.
3	Grade 3 capsular contracture presents itself with obvious cosmetic symptoms. The breasts will be firm to the touch and appear abnormal (e.g., they will be overly round and hard-looking, and the nipples may be misshapen. However, this grade of capsular contraction often does not cause much (if any) pain.
4	Like grade 3 capsular contracture, grade 4 capsular contracture causes the breasts to become hard and misshapen. Patients with grade 4 capsular contracture also experience breast soreness; their breasts will often be tender and painful to the touch.

*From Tehrani K. What is capsular contracture and how can it be treated? Available at: <https://www.plasticsurgery.org/news/blog/what-is-capsular-contraction-and-how-can-it-be-treated>. Accessed July 23, 2019.

sublevels IA and IB.⁴ The Baker score is used in research settings to report incidence rates of capsular contracture in studies on the performance of implants or surgical techniques,^{5–7} and it is used in more fundamental research in which clinical data (e.g., Baker scores) are correlated with biomedical data (e.g., histology, immunologic data).⁸ The classification is frequently used for clinical diagnoses in individual patients. In The Netherlands, reimbursement even depends on this classification; the capsular contracture should be classified as severe with a Baker grade IV score to obtain (partial) reimbursement by the health insurers for surgical treatment. Pain is one of the factors deemed necessary for this reimbursement. Although pain was not originally included in the Baker classification, pain has found its way into various versions of the Baker classification published in journals and online (Tables 2 through 4). It is unclear when pain exactly appeared in the classification. Because pain can be found in multiple versions of the Baker classification, it seems that many authors consider pain to be essential to grade capsular contracture. Nevertheless, it is remarkable that so many different versions of one classification exist.

Despite of its wide use, the reliability of the Baker classification has not yet been established. The aim of this study, therefore, was to determine

T2-T4

Table 3. Baker Classification*

Grade	Description
I	Soft
II	Minimal, implant palpable, not visible
III	Moderate, palpable, and visible
IV	Severe, hard, painful with distortion

*From Hodges A. *A-Z of Plastic Surgery*. Oxford: Oxford University Press; 2008. 10.1093/acref/9780199546572.001.0001.

the reliability of the Baker classification by determining the interobserver reliability and observer agreement of the Baker classification. In addition, the interobserver reliability of rating the separate clinical symptoms associated with capsular contracture was determined.

PATIENTS AND METHODS

Study Population

This was a cross-sectional, observational, multicenter study. Women who had undergone breast augmentation surgery more than 5 years before inclusion and without a history of breast malignancy were eligible to participate in this study. The protocol was approved by the institutional review board at each study center. All patients provided written informed consent. The study was performed in accordance with the Declaration of Helsinki and guidelines for Good Clinical Practice.

Study Procedure

Eligible patients were recruited by means of two routes: (1) patients who underwent breast augmentation more than 5 years previously were identified from the hospital records and invited by phone to partake, and (2) eligible patients who visited the outpatient clinic visit for complaints related to the breast implant were asked to participate. After providing informed consent, patients were invited to the outpatient clinic.

Seven plastic surgeons with ample experience in breast surgery and who use the Baker classification in daily practice were asked to participate in the observer pool. Plastic surgeons were handed out the official Baker classification on paper and were instructed to classify capsular contracture as they would do in clinical practice. At the clinic, the patient's breasts were examined independently by two surgeons from the pool of observers. Breasts were scored according to the Baker classification and separately scored for the symptoms associated with capsular contracture. Patients were also asked to complete a questionnaire pertaining to

Table 4. Baker Classified Capsular Contracture*

Grade	Description
I	The augmented breast feels as soft as an unoperated one
II	Minimal—implant palpable, but not visible
III	Moderate—implant easily palpable, and it (or distortion from it) is visible
IV	Severe—the breast is hard, tender, painful, and cold; distortion is often marked

*From Richards A, Dafydd H. *Key Notes on Plastic Surgery*. Chichester, UK: Wiley; 2014. 10.1002/9781118757017

the postaugmentation quality of life, the Dutch version of the BREAST-Q postaugmentation module. The BREAST-Q is a comprehensive patient-reported outcome measure, which evaluates satisfaction with breasts and impact on quality of life. It includes questions about symptoms, appearance, and satisfaction. It specifically asks for visible and sensible complaints about softness of the implants and pain.

Outcomes

The main outcome was the Baker classification for capsular contraction (Table 1). Additional outcomes were (a) firmness of the breast, (b) dislocation of the implant, (c) pain, and (d) symmetry. Each of these outcomes was scored using a four-point Likert scale for the left and right breasts separately, except for (d) symmetry, which was scored comparing both breasts. For each of these measures, the interobserver reliability and the observer agreements were determined. A summed score of the items a + b + c was used to test the intraobserver validity by correlating the Baker score with this summed score. Additional outcomes were demographic data (i.e., age; date of augmentation; and, if applicable, revision surgery and implant type and size) and patient-reported outcomes (BREAST-Q post-augmentation module).

Statistical Analysis

A minimal sample size of 50 patients was estimated. This was based on a repeated measurement with two independent observers and a desired 95 percent confidence interval of 0.1 for an intraclass correlation coefficient of 0.8.⁹ To establish a safe margin, a target sample size of 60 participants was decided on. Descriptive statistics were used for all variables. Interobserver reliability was determined by calculating the weighted kappa scores for the Baker classification and the individual clinical parameters using a quadratic weighting with VassarStats (Richard Lowry, Poughkeepsie, N.Y.)

Table 5. Patient Characteristics

Characteristic	Value (%)
No. of patients	60
Mean age $\pm$ SD, yr	49 $\pm$ 11
Type of prosthesis	
Silicone	55 (92)
Other (monobloc)	5 (8)
Mean size $\pm$ SD, cc*	307 $\pm$ 88
One-side augmentation	3 (1.6)
Revision surgery	21 (35)
More than once	8 (13)

* $n = 44$ (73%).

online statistical software.¹⁰ For the cumulative clinical parameter scores, the intraclass correlation coefficient based on one-way analysis of variance was calculated.¹¹ Observer agreement was calculated for all parameters, which were rated using a four-point scale. To correlate observer and patient opinion, Pearson correlation coefficients were calculated between observer scores (Baker score and the summed item score) and patient-reported outcome measures (BREAST-Q postaugmentation module domains and question 1H which specifically asks for symmetry). All statistics were calculated using IBM SPSS Version 22.0 (IBM Corp., Armonk, N.Y.).

RESULTS

Patient Characteristics

Between 2017 and 2018, 60 patients were included in this cross-sectional study. Relevant

patient characteristics are listed in Table 5. Nearly all [$n = 55$ (92 percent)] patients had received some type of silicone implant; the others had received monobloc implants, with a silicone shell and hydrogel filling. Sixteen patients (27 percent) did not know what their implant size was. Three women had undergone one-side augmentation; symmetry was not evaluated in those cases. Of all patients, 35 percent had already undergone revision surgery, 13 percent more than once (Table 5).

Baker Score and Separate Symptom Scores

An overview of the distribution of all scored parameters on the four-point Likert scales used is given in Figure 1. Baker score, firmness, dislocation, and pain were scored per breast, whereas symmetry was scored based on both. For all parameters, data are skewed, with a higher prevalence for lower symptomatic values. This was especially true for pain, which was scored 166 times as I (no pain) and only six times as IV (much pain).

Interobserver Agreement and Reliability and Intraobserver Validity

Interobserver reliability and observer agreement are presented in Table 6 for all parameters. For the Baker score, the interobserver reliability is rather low ($\kappa = 0.55$). The observer agreement is also low, with the same score given in only 48 percent of breasts. In 41 percent of cases,

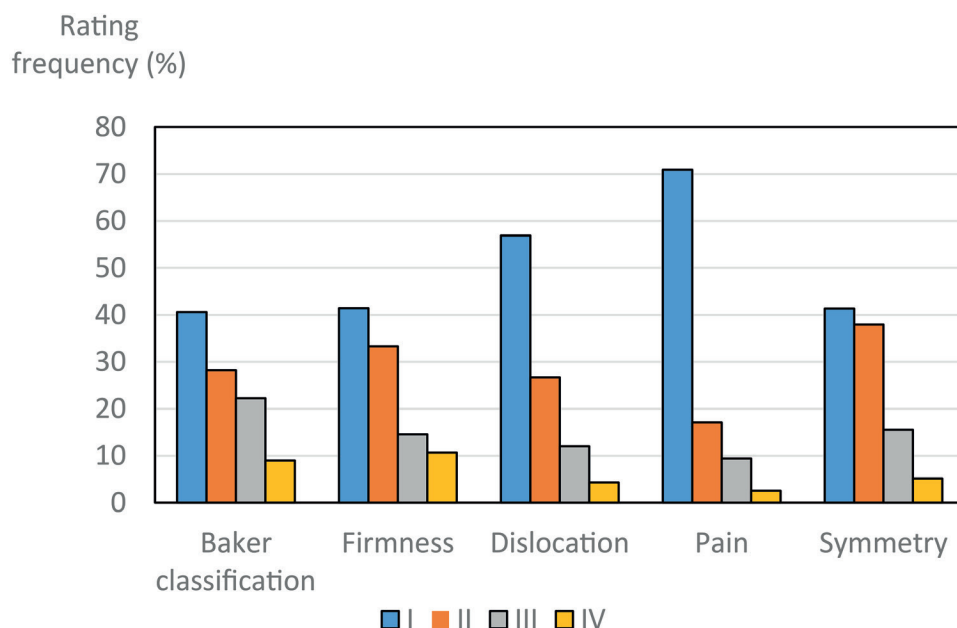


Fig. 1. Distribution of scored characteristics by all observers. Each breast was scored for all parameters except symmetry, which was based on both breasts. It shows a skewed distribution toward fewer symptoms for most women.

Table 6. Interobserver Reliability and Observer Agreement*

	Interobserver Reliability		Observer Agreement (%)	Observer Agreement ± 1 (%)
	Kappa [†]	95% CI		
Baker	0.55	0.37–0.72	48	89
a) Firmness	0.64	0.4–0.79	55	92
b) Dislocation	0.49	0.2–0.73	61	91
c) Pain	0.72	0.5–0.89	75	97
Symmetry	0.61	0.3–0.88	52	97
Summed item score (a + b + c)	0.72 [‡]	0.62–0.80 [‡]		

*Observer agreement indicates the percentage of cases in which observers rate equally, observer agreement ± 1 indicates the percentage of cases in which there is maximally one-level difference between observers.

[†]All kappa values were calculated using quadratic weighting.

[‡]Intraclass correlation coefficient.

observers differ by one category, whereas in 11 percent of cases they differ by two or more categories. Similar outcomes are found for the individual symptoms. The highest agreement is met when rating pain. However, it should be noted that, in 64 percent of cases, this agreement was reached on having no pain (scoring 1 by both observers). From the BREAST-Q, domains 1 (Satisfaction with Breasts) and 5 (Physical Well-being) correlated weakly to moderately with the given Baker scores and the cumulative clinical parameter score (Pearson r between 0.295 and 0.393) (Table 7). The symmetry parameter correlated weakly (Pearson $r = -0.223$) with question 1H of the BREAST-Q, which specifically asks the patient to evaluate the symmetry of her breasts. There was a good correlation between the cumulative scores and the Baker score given by the same observer (Pearson $r = 0.84$), indicating that the intraobserver rating of capsular contracture is consistent.

DISCUSSION

This study aimed to assess the interobserver reliability of the Baker classification for capsular contracture, a well-established tool for grading capsular contracture in clinical practice and in

research. We found that the interobserver reliability was quite poor, as was the interobserver agreement. In the majority of cases, the given Baker classification differed between the two observers and, in 11 percent, by more than one level.

The diverse presentation of (local) problems associated with breast implants is well known by all plastic surgeons dealing with these implants. Most of these problems are collectively referred to as capsular contracture and graded using the Baker classification. Although widely accepted, the Baker classification is inconsistently defined in both reference works and in scientific literature.^{2,12–14} Several other methods and classifications have been proposed over the years. All, excluding applantation tonometry, are four-point Likert scales similar to the Baker classification, with similar generic descriptions.^{15–18} The reliability of these classifications has not been assessed, nor have they gained broad support. Applantation tonometry is used in various studies to evaluate breast softness or hardness and could be used to measure that one aspect of capsular-related complaints more reliably. It has gained limited use in daily clinical practice and has been described as unreliable when comparing differently shaped implants, which would severely limit its use in daily clinical practice.^{19,20}

It may be expected that grading the severity of problems with a very diverse presentation, on a single ordinal scale, poses a challenge. This was shown to be the case. To address this challenge, plastic surgeons in this study were also asked to separately grade the main symptoms associated with capsular contracture: firmness, dislocation pain, and asymmetry. Remarkably, rating these specific symptoms by plastic surgeons also proved unreliable. Although there is a notion among plastic surgeons of the concept of capsular contracture and its symptoms, these ideas do not seem to match. Within the individual surgeon, a consistent rating of symptoms and the Baker score exists, but between surgeons, it seems that no consensus

Table 7. Correlation of Baker Score with the BREAST-Q*

	BREAST-Q Domain		
	1 (p)	5 (p)	1H (p)
Baker score	–0.295	–0.368	
(average all observers)	(0.001)	(0.000)	
Cumulative score	–0.393	–0.324	
(average all observers)	(0.000)	(0.000)	
Symmetry			–0.223
(average all observers)			(0.017)

*Pearson correlation coefficients with p value between Baker and cumulative clinical parameter scores given and BREAST-Q domains 1 (Satisfaction with Breasts) and 5 (Physical Well-being), and between the observed symmetry and question 1H of the BREAST-Q, which specifically asks for symmetry.

exists on what “firmness” or “dislocation” exactly are, or when either of those symptoms is mild, severe, or normal. To categorize these symptoms reliably, we need to reach consensus on the interpretation of symptoms. This may be achieved by describing these symptoms in more detail. We propose to describe the symptoms of (local) breast implant–related complaints separately, using a more qualitative approach. We suggest that using more qualitative descriptions will result in clearer communication and better comparability.

This qualitative approach should include and discriminate between physical findings such as firmness, dislocation, and symmetry and experienced symptoms such as pain or tenderness. We propose to refer to these complaints as “breast implant–related complaints.” We purposefully use the term breast implant–related complaints because the presence of actual capsular abnormalities can be established only by operating on the breast.

To improve the assessment of implant-related complaints, it is important to bear in mind the purpose of the classification. The Baker classification is broadly used for two main purposes: clinical and scientific. First and foremost, it is used by health care professionals in clinical practice (i.e., to assess capsular complaints in individual patients, decide whether intervention surgery is necessary, and exchange this information between colleagues). A clearer definition of symptoms may be helpful, especially with regard to communication between health care professionals. Nevertheless, intervention remains a very personal preference for both patient and surgeon and depends on many factors. Therefore, we propose to refrain from labeling a certain grade as an indication for surgery.

Second, the Baker classification is used in scientific research. Many studies aim to compare different surgical methods or implant materials in breast implant procedures with regard to their long-term complication rate. When the measurement of capsular contracture is unreliable, this poses a major problem. For this purpose, a more reliable way of describing the presence and severity of the collation of problems associated with capsular contracture is warranted. Our expectation is that better definitions and more consensus on how these symptoms are described and classified will improve reliability. Future exploratory studies are necessary to prove this. For scientific research, in particular, it is necessary that each study describes the classification they used to conduct their research in detail and to use multiple observers.

The main reason why the Baker classification has become so popular is probably because it is

simple. In creating a new method of classifying breast implant–related complaints, a choice will have to be made between a more simple, clinical oriented classification, or a more extensive, descriptive classification. In both cases, a clear consensus and instructions are needed to improve reliability. The more descriptive measure will probably be more complex, needing more training and consensus to achieve good reproducibility. The latter could, therefore, be less applicable in daily clinical practice.

This study has several strengths and limitations. In this study, no extensive instruction on grading using the Baker classification was given beforehand. All participating surgeons were familiar with the classification and use it in daily practice. In the study setup, it was decided to conduct the scoring as it is being performed in normal practice. Surgeons will have used the classification as they have been taught, possibly influenced by their personal experience since then. Providing extensive instructions might therefore improve the agreement. Not all grades of the Baker classification were equally represented in the population. In our population, women with no/few symptoms were overrepresented. Although this is a representation of the prevalence of capsular contracture, for the sake of assessing reliability, a less skewed distribution might have been preferable. Each patient was rated by two observers from a pool of seven observers. Therefore, we cannot assess whether systematic differences existed between the observers. In contrast, multiple observers mimic clinical practice, and the results are more representative of all plastic surgeons than if only two observers had rated all patients.

CONCLUSIONS

The interobserver reliability of the Baker classification for capsular contracture is poor. Although there is a general notion of what capsular complaints are (i.e., dislocation, firmness, asymmetry, and pain), individual plastic surgeons have different interpretations about what these symptoms entail and how to grade their severity. A more reliable method of measurement or description is needed, especially for scientific research purposes.

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Predictors for Implant Rupture in Two-Stage Tissue Expander-Based Breast Reconstruction: A Retrospective Cohort Study

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ABSTRACT

Background. Two-stage tissue expander/implant-based method has been used predominantly for breast reconstruction. Implant rupture is one of the bothersome complications, inducing additional morbidity including reoperation. The present study aimed to identify the independent factors associated with development of implant rupture.

Patients and Methods. Patients who underwent immediate two-stage prosthetic breast reconstruction between 2010 and 2016 were reviewed. Inserted implants were followed up using magnetic resonance imaging every 2 years and/or ultrasound/computed tomography scans every 6 or 12 months that were conducted for cancer surveillance. Associations of perioperative and intraoperative variables with the development of implant rupture were evaluated.

Results. In total, 797 cases (744 patients) were analyzed. During a median follow-up of 43 months after second-stage operation, implant rupture was identified in 22 cases. The 5-year cumulative incidence was 3.1%. Multivariable analyses showed that the interval between the first- and second-stage operations was inversely associated with the risk of implant rupture. Maximal discrimination was observed at the interval of 6.5 months. Cases with an interval ≤ 6 months were associated with higher risks for

implant rupture than those with ≥ 7 months, after adjusting for other variables. Type of implant was associated with the development of implant rupture, showing that using two kinds of fourth-generation implant (Allergan Biocell textured round and Allergan smooth round implants) was associated with a significantly increased risk of implant rupture compared with that of Mentor MemoryShape implants (fifth-generation implant).

Conclusion. Several operation-related variables appear to be associated with implant rupture in two-stage prosthetic reconstruction.

Since its invention in 1961 and first use in augmentation mammoplasty in 1962,¹ silicone breast implant has evolved considerably in terms of its reliability and stability, with great advances in technology for manufacturing. Thanks to those constant efforts, prosthetic breast reconstruction using silicone implants has become the predominant modality for reconstruction in breast cancer patients nowadays.²

Diverse kinds of implant-associated complications can develop following two-stage prosthetic reconstruction. Development of rupture of inserted implant is one of the most bothersome ones. Ruptured silicone implant can cause a broad spectrum of adverse outcomes, from minor ones including subtle changes in breast shape in cases with intracapsular rupture to relatively major ones including lymphadenopathy, formation of granuloma, or even systemic symptoms in those with extracapsular rupture.^{3–5} Consequently, development of implant rupture could degrade overall cosmesis and patient satisfaction, and requires additional operation for implant removal or exchange, which can increase patient morbidity.

So far, there have been several studies published investigating any predictors for implant rupture. Most of them failed to identify them,^{3,6–8} and suggested that external forces or trauma might induce implant shell fatigue and subsequently contribute to implant rupture. However, these presumptions have not been supported by solid clinical evidence yet. One of the main drawbacks of anecdotal studies is that they contain heterogeneous study population including patients of augmentation mammoplasty and those of breast reconstruction, in which cases of one-stage direct-to-implant reconstruction and those of two-staged tissue expander-based reconstruction were both included. These study populations could have significant heterogeneity in terms of baseline characteristics, intraoperative circumstances, and postoperative course, which could act as significant confounders. Besides, a majority of studies were driven by manufacturers, which might make it difficult to exclude possibility of conflict of interests.

Two-staged tissue expander/implant-based method consists of multiple steps, including first-stage operation of tissue expander insertion, postoperative tissue expansion, and second-stage operation of implant exchange. A considerable number of patients received adjuvant radiotherapy, chemotherapy, or hormone therapy for cancer treatments. We hypothesize that some of those factors related to intraoperative surgical procedures or postoperative course are associated with the development of implant rupture in two-stage prosthetic reconstruction.

The present study was undertaken to evaluate incidence of rupture of silicone implant following immediate two-stage prosthetic breast reconstruction and to investigate potential association of several patient- and operation-related variables with the development of implant rupture.

PATIENTS AND METHODS

Based on a prospectively maintained database of our department, patients with breast cancer who underwent immediate two-staged tissue expander/silicone implant reconstruction following total mastectomy between 2010 and 2016 and completed both stages (first and second stages) of reconstructive operations were identified. Patients undergoing one-stage direct-to-implant reconstruction, those using combination methods with implant and autologous flaps together, and those undergoing delayed reconstruction were excluded to reduce heterogeneity of the study population. This study was conducted with approval of the institutional review board of our institution.

Data Collection and Outcome Measure

Patient and operation-related (total mastectomy, first- and second-stage reconstructive operations) characteristics were retrieved from the preexisting database, which was prospectively updated monthly by ancillary doctors. Data regarding postoperative course, including interval between the stages, and oncologic treatments were also gathered.

The outcome of interest was development of implant rupture. In our institution, patients whose breasts were reconstructed with silicone implants were educated to be examined with breast magnetic resonance imaging (MRI) every 2 years, because it was established that breast MRI had the highest specificity and sensitivity to detect the rupture of breast implant.^{9,10} Also, for postoperative regular cancer surveillance, which was conducted by general surgeons in most cases, breast cancer patients were checked up with breast ultrasound every 6 (for invasive cancer) or 12 months (for noninvasive cancer) for postoperative 5 years at least. In patients with advanced tumor, chest computed tomography scan was also examined annually. If any indication of implant rupture was detected on imaging work-ups, mostly on breast ultrasound, the patients were referred to plastic surgeons for more detailed evaluation. Then, all consulted patients were checked by plastic surgeons with physical examination and breast MRI. If implant rupture was confirmed or suspected in the tests, the patient was scheduled to undergo elective operation for implant removal or exchange under consideration of their schedule of oncologic treatment and general health condition. Time to implant rupture was assessed, which was defined as the date of second-stage operation (exchange to implant) to that of implant rupture confirmed on breast MRI.

Statistical Analysis

Cases with implant rupture and those without it were compared in terms of patient- and operation-related variables. Pearson's χ^2 test or Fisher's exact test was used for analyzing categorical variables, and Student's *t*-test or Mann–Whitney test for continuous variables. Kaplan–Meier analysis was conducted to generate curves of implant rupture-free duration and to compare according to each categorical variable with log-rank test. To evaluate independent impacts of those variables on the development of implant rupture, univariable and multivariable Cox regression analyses were conducted, which determined hazard ratios (HRs) and the corresponding 95% confidence intervals (CIs). Variables showing a *p*-value < 0.15 on univariable analyses were involved in the multivariable analyses. A *p*-value less than 0.05 was deemed to be significant. All statistical analyses were performed with

Statistical Package for the Social Sciences software version 20 (IBM Corporation, Armonk, NY, the USA).

Results

An initial screening identified 827 cases (790 patients) undergoing immediate two-stage prosthetic reconstruction. Of these, a total of 744 patients representing 797 cases were included in the final analysis. There were 53 patients with bilateral reconstruction. Mean age was 43.6 years (range 18–66 years), and mean body mass index (BMI) was 22.0 kg/m² (range, 15.1–33.7 kg/m²). Median follow-up periods from total mastectomy and first-stage operation and from second-stage operation were 53.0 and 43.0 months, respectively. Median interval between the first- and second-stage operations was 10 months. All patients used silicone-filled implant, and there was no case using saline-filled one. Textured implants were used more frequently than smooth ones (60.8% versus 39.2%), and shaped implants more than round ones (54.0% versus 46.0%). With regard to the specific products of implant used, Mentor MemoryShape Contour Profile Gel implants were the most popularly used (41.3%), followed by Allergan Smooth Round Gel (28.9%), Allergan Natrelle 410 Anatomical Gel (11.4%), Mentor MemoryGel (18.5%), Allergan Textured Round Gel (5.4%), and others (Table 1).

During the follow-up period, implant rupture was detected in 22 cases (3.0%). Of these, only one patient complained of change in shape of a reconstructed breast before the rupture was diagnosed, and the other patients did not present any signs or symptoms related to the inserted breast before the rupture was detected. On preoperative MRI, one case presented a sign implying both intra- and extracapsular rupture, and the other 21 cases showed sign of intracapsular rupture only. All patients showing a sign of implant rupture on breast MRI were confirmed to have ruptured implant on operation of implant removal/exchange. The 2-year and 5-year cumulative incidence was 0.3% and 3.1%, respectively. Median interval from second-stage operation to implant rupture was 51.5 months (range, 12–110 months). Table 2 presents results of comparison of

patient- and operation-related characteristics between cases with implant rupture and those without it. Patient demographics and first-stage operation-related characteristics were generally similar, except for the rate of acellular dermal matrix (ADM) use. With regard to the second-stage operation-related characteristics, type of implant used, either by manufacturer or by specific profiles, and the rate of conducting balancing procedure differed significantly. Interval between the first- and second-stage operations was also significantly different, that is, significantly shorter in cases with implant rupture.

In Kaplan–Meier analyses, no categorical variables showed significant differences in implant rupture-free duration, including reconstruction surgeon, ADM use, tissue expander type, mastectomy type, implant type (by manufacturer and by specific product), balancing procedure, adjuvant radiotherapy, chemotherapy, and hormone therapy. Although cases using Allergan round textured implants showed a higher cumulative incidence of implant rupture than those using other products, the differences were not statistically significant (Fig. 1). To adjust for potential learning curve effect, cases were categorized into two groups according to the time of second-stage operation: cases undergoing the operation between 2010 and 2014 and those between 2015 and 2018. Still the rate of implant rupture did not differ significantly between the two groups.

Univariable and Multivariable Analyses for Identifying Predictors of Implant Rupture

Interval between the First- and Second-Stage Operation On univariable analysis, interval between the staged operations showed marginally significant association with the development of implant rupture ($p = 0.052$). That is, cases having elongated intervals between the stages had lower risk for implant rupture, compared with those having shorter intervals (HR 0.849, 95% CI 0.720–1.001). This association was more prominent on subsequent multivariable analysis (HR 0.815, 95% CI 0.674–0.985, $p = 0.034$) (Table 3).

TABLE 1 Specific kinds of silicone implant used

Manufacturer	Texture and shape (product)	Case no.
Mentor	Textured shaped (MemoryShape)	329 (41.3%)
	Smooth round (MemoryGel)	61 (18.5%)
Allergan	Textured shaped (Natrelle 410 Anatomical Gel)	91 (11.4%)
	Textured round (Biocell textured styles 110, 115, and 120)	43 (5.4%)
	Smooth round (style 10, 40, and 45)	230 (28.9%)
Bellagel	Smooth round	40 (5.0%)
	Textured shaped	3 (0.4%)

TABLE 2 Baseline characteristics of overall study population

Characteristics	Overall (<i>n</i> = 797)	Cases with rupture (<i>n</i> = 22)	Cases with no rupture (<i>n</i> = 775)	<i>p</i> -value
<i>Patient-related</i>				
Age at second-stage operation (years)	43.6 (± 7.4)	44.5 (± 5.5)	43.5 (± 7.3)	0.487
BMI at second-stage operation (kg/m ²)	22.0 (± 2.8)	22.1 (± 3.7)	22.0 (± 2.8)	0.722
Diabetes	8	0	8 (100.0%)	0.632
Hypertension	31	1 (3.2%)	30 (96.8%)	0.872
Active smoking	21	0	21 (100.0%)	0.434
<i>First stage operation-related</i>				
Type of mastectomy				0.695
NSM	259	8 (3.1%)	251 (96.9%)	
Non-NSM	538	14 (2.6%)	524 (97.4%)	
Mastectomy weight	352.4 (± 173.7)	311.5 (± 208.5)	353.6 (± 172.6)	0.064
<i>Type of tissue expander</i>				
Siltex microtextured	658	19 (2.9%)	639 (97.1%)	0.633
Biocell macrotextured	139	3 (2.2%)	136 (97.8%)	
Size of tissue expander	389.5 (± 91.8)	386.4 (± 94.1)	389.6 (± 91.8)	0.836
<i>ADM</i>				
Use	470	7 (1.5%)	463 (98.5%)	0.008
No use	326	15 (4.6%)	311 (95.4%)	
Initial inflation volume	146.9 (± 96.5)	140.2 (± 76.5)	147.1 (± 97.0)	0.867
<i>Second stage operation-related</i>				
Size of implant	330.4 (± 103.1)	318.3 (± 110.0)	330.7 (± 103.0)	0.649
<i>Type of implant</i>				
Manufacturer				< 0.001
Mentor	390	2 (0.5%)	388 (99.5%)	
Allergan	364	19 (5.2%)	345 (94.8%)	
Bellagel	43	1 (2.3%)	42 (97.7%)	
Product				< 0.001
Mentor textured shaped	329	1 (0.3%)	328 (99.7%)	
Mentor smooth round	61	1 (1.6%)	60 (98.4%)	
Allergan textured shaped	91	3 (3.3%)	88 (96.7%)	
Allergan textured round	43	8 (18.6%)	35 (81.4%)	
Allergan smooth round	230	8 (3.5%)	222 (96.5%)	
Bellagel textured shaped	3	0	3 (100.0%)	
Bellagel smooth round	40	1 (2.5%)	39 (97.5%)	
Balancing procedure (contral.)				0.028
Augmentation	172	10 (5.8%)	162 (94.2%)	
Mastopexy	15	1 (6.7%)	14 (93.3%)	
Reduction	16	0	16 (100.0%)	
Adjuvant radiotherapy	121	1 (0.8%)	120 (99.2%)	0.159
Neoadjuvant chemotherapy	37	0	37 (100.0%)	0.294
Adjuvant chemotherapy	315	6 (1.9%)	309 (98.1%)	0.233
Hormone therapy	643	20 (3.1%)	623 (96.9%)	0.218
Tamoxifen administration	602	21 (3.5%)	581 (96.5%)	0.028
Interval between first and second stage*	10.0	6.0	10.0	< 0.001

*Median

BMI body mass index, NSM nipple-sparing mastectomy, ADM acellular dermal matrix, contral. contralateral

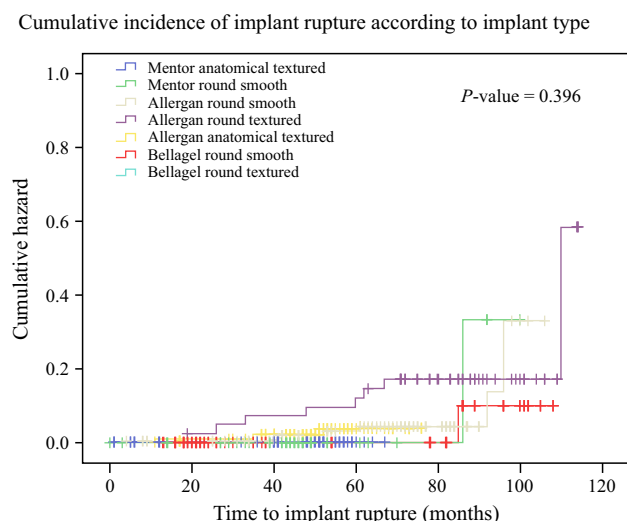


FIG. 1 Kaplan–Meier analysis to compare a cumulative incidence of implant rupture according to the implant type. There were no statistically significant differences by implant type

To identify any threshold value of the interval, which could have the greatest discrimination in the rate of implant rupture, receiver operating characteristic (ROC) curve analysis was conducted. Maximal statistical significance was achieved with an interval of 6.5 months, showing an area under the curve (AUC) of 0.772 ($p < 0.001$) (Fig. 1 online supplement). Figure 2 depicts the incidence rate of implant rupture according to interval between the stages. Based on these results, cases were categorized into two groups by the interval of 6.5 months: 124 cases with interval ≤ 6 months and 673 cases ≥ 7 months. On Kaplan–Meier analysis, the implant rupture-free duration was significantly different between two groups ($p = 0.006$) (Fig. 3). Multivariable analysis demonstrated that cases with interval between the stages ≤ 6 months were associated with significantly higher risks for implant rupture than those with ≥ 7 months (HR 4.145, 95% CI 1.355–12.677, $p = 0.013$).

The interval between the stages could be affected considerably by schedule of adjuvant therapies, considering that the second-stage operation was usually conducted after completion of those treatments in the authors' institution. To reduce related potential confounding effects, further analyses were preceded with excluding cases receiving adjuvant treatment, which led to 442 cases remaining. Similar results to those presented above were obtained, with multivariable analysis showing that the interval between the stages both as a continuous variable (adjusted p -value = 0.013, HR 0.700, 95% CI 0.527–0.929) and as a categorical variable (≤ 6 months and ≥ 7 months) (adjusted p -value = 0.027, HR 5.152, 95% CI 1.200–22.113) had significant associations with the development of implant rupture.

Implant Type Cases using Mentor MemoryShape implants served as reference in the following analyses, which were used most predominantly in the study population. Univariable Cox regression analysis showed that the risk of implant rupture was significantly different according to the type of implant used. Specifically, use of Allergan Biocell textured round implant was associated with a significantly increased risk of implant rupture compared with that of Mentor MemoryShape implants ($p = 0.037$, HR 10.520, 95% CI 1.150–96.242). This association remained significant after adjusting for other variables (HR 18.86, 95% CI 1.712–207.890, $p = 0.016$). Besides, cases using Allergan smooth round implant also showed a significantly increased risk of implant rupture in the multivariable analyses (HR 13.257, 95% CI 1.463–120.127, $p = 0.022$). No other variables, including use of ADM, conducting balancing procedure in the contralateral breast, and hormone therapy, influenced the outcomes significantly.

The two types of implant that showed significant association with the occurrence of implant rupture, Allergan smooth round and Allergan textured round implants, were the so-called fourth-generation non-form-stable implant. Therefore, further analysis was conducted categorized by the generation of implant: 334 cases using non-form-stable implant (fourth generation) and 420 using form-stable implant (fifth generation). Cases using Bellagel implant were not included in this analysis. As a result, on multivariable Cox regression analysis, use of fourth-generation implant was associated with a significantly increased risk of rupture compared with that of the fifth-generation one after adjusting for other variables (HR 3.793, 95% CI 1.064–13.526, $p = 0.040$).

Subgroup Analysis According to Implant Type (Generation) and Interval Between the Stages Subgroup analyses were conducted to evaluate whether influence of interval between the stages could differ according to the implant type (generation). Of 334 cases using non-form-stable implant (fourth generation), 49 (14.7%) had an interval between the stages ≤ 6 months and 285 (85.3%) had an interval ≥ 7 months. On Kaplan–Meier analysis, the rupture-free duration was significantly different between the two groups ($p = 0.014$). On multivariable analysis for this subgroup, similar to the overall study population, cases with an interval ≤ 6 months showed a significantly elevated risk of implant rupture compared with those with ≥ 7 months (HR 6.823, 95% CI 1.536–30.301, $p = 0.012$). Specific kinds of implant were not associated with implant rupture ($p = 0.504$).

In 420 cases using form-stable implant (fifth generation), there were 70 (16.7%) cases with an interval ≤ 6 months and 350 (83.3%) with ≥ 7 months. The two groups

TABLE 3 Univariable and multivariable analyses for predictors of implant rupture

Variables	Univariable		Multivariable	
	<i>p</i> -Value	HR (95% CI)	<i>p</i> -Value	HR (95% CI)
<i>Patient-related</i>				
Age	0.586	1.017 (0.958–1.080)		
BMI	0.367	1.071 (0.923–1.244)		
Diabetes	0.732	0.048 (0–)		
Hypertension	0.523	1.931 (0.256–14.564)		
Active smoking	0.648	0.048 (0–)		
<i>Reconstructive surgeons</i>				
Surgeon A	Ref.			
Surgeon B	0.232	2.016 (0.639–6.365)		
Surgeon C	0.218	2.263 (0.728–7.033)		
Surgeon D	0.885	0.848 (0.091–7.892)		
<i>First stage operation-related</i>				
<i>Type of mastectomy</i>				
Non-NSM	Ref.			
NSM	0.706	0.839 (0.338–2.087)		
Mastectomy weight	0.880	1.000 (0.997–1.002)		
<i>Type of tissue expander</i>				
Siltex microtextured	Ref.			
Biocell macrotextured	0.226	2.252 (0.605–8.382)		
Size of tissue expander	0.895	1.000 (0.995–1.006)		
Use of ADM	0.615	0.771 (0.280–2.124)		
Initial inflation volume	0.983	1.000 (0.995–1.005)		
<i>Second stage operation-related</i>				
<i>Operation period</i>				
Period 1	Ref.		Ref.	
Period 2	0.942	0.957 (0.291–3.143)	0.074	3.403 (0.889–13.034)
Size of implant	0.709	0.999 (0.994–1.004)		
<i>Type of implant</i>				
Mentor textured shaped	Ref.		Ref.	
Mentor smooth round	0.276	4.701 (0.291–76.045)	0.264	5.005 (0.296–84.563)
Allergan textured shaped	0.099	5.928 (0.715–49.188)	0.088	7.659 (0.736–79.658)
Allergan textured round	0.037	10.520 (1.150–96.242)	0.016	18.867 (1.712–207.890)
Allergan smooth round	0.137	5.675 (0.575–56.011)	0.022	13.257 (1.463–120.127)
Bellagel textured shaped	0.416	3.272 (0.188–57.075)	0.160	8.308 (0.435–158.718)
Bellagel smooth round	0.990	0 (0–)	0.989	0.002 (0–)
<i>Balancing procedure</i>				
Augmentation	0.277	1.649 (0.669–4.061)		
Mastopexy	0.269	3.195 (0.408–25.041)		
Reduction	0.983	0 (0–)		
Adjuvant radiotherapy	0.648	0.623 (0.082–4.754)		
Neoadjuvant chemotherapy	0.600	0.047 (0–)		
Adjuvant chemotherapy	0.237	0.564 (0.219–1.456)		
Hormone therapy	0.193	2.633 (0.612–11.325)		
<i>Interval between stages</i>				
As a continuous variable	0.052	0.849 (0.720–1.001)	0.034	0.815 (0.674–0.985)
As a categorical variable				
≥ 7 months	Ref.		Ref.	

Table 3 (continued)

Variables	Univariable		Multivariable	
	<i>p</i> -Value	HR (95% CI)	<i>p</i> -Value	HR (95% CI)
≤ 6 months	0.023	2.796 (1.150–6.797)	0.013	4.145 (1.355–12.677)

Variables showing $p < 0.15$ on univariable analyses were included in the multivariable analyses

HR hazard ratio, CI confidence intervals

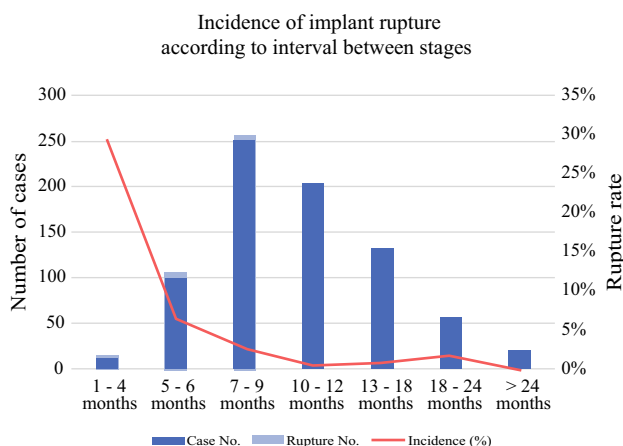


FIG. 2 Incidence of implant rupture according to the interval between the first- and the second-stage operation

Cumulative incidence of implant according to interval between the stages

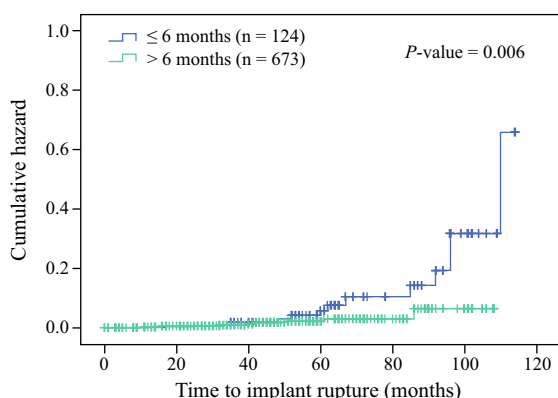


FIG. 3 Kaplan-Meier analysis to compare a cumulative incidence of implant rupture according to the interval between the stages ≤ 6 months or > 6 months. Cases with an interval ≤ 6 months showed a significantly higher cumulative incidence of implant rupture, compared with those with > 6 months

showed similar cumulative incidence on Kaplan-Meier analysis ($p = 0.941$). On multivariable analysis, the interval between the stages did not have a significant influence on the development of implant rupture ($p = 0.635$).

DISCUSSION

Despite prevalence of two-stage tissue expander/implant breast reconstruction, there have been few studies investigating risk factors of implant rupture with a focus on cases using this modality exclusively. The present study assessed cumulative incidence of implant rupture following two-stage tissue expander/implant breast reconstruction, with approximately 800 cases having relatively homogeneous characteristics for a considerable follow-up period. In addition, we evaluated potential association of dozens of patient-, operation-, and postoperative oncologic treatment-related variables with the development of implant rupture and found some factors might be associated with increased risks of rupture.

In the current study, patients of breast reconstruction using silicone implants were examined with regular check-up using diverse imaging modalities for the purpose of cancer surveillance and implant status assessment. Breast MRI, which has shown the highest sensitivity and specificity for detection of implant rupture, up to over 90%, was recommended to be checked every 2 years regularly. Also, during the interval of MRI examination, breast ultrasound and/or chest computed tomography was performed repeatedly. Although those examinations do not show sensitivity and specificity as high as breast MRI, regular and repetitive check-ups could reduce the probability of missing a ruptured implant. Besides, medical costs for the majority of those examinations for breast cancer patients were covered by national insurance for 5 years after diagnosis of breast cancer in our country. Therefore, most patients were followed up with appropriate examinations during this period at least, which might reduce a risk of underestimation of implant rupture despite the retrospective study design. In the present study, the 5-year cumulative incidence of rupture was approximately 3%, which was comparable to that of previous studies¹¹⁻¹⁷ (Table 4).

Interestingly, we found that having a short interval between the first- and second-stage operation was associated with an increased risk for implant rupture regardless of other variables. In our institution, the second-stage operation was usually scheduled to be conducted within 1 year

TABLE 4 Brief summary of previous studies regarding 6 years cumulative incidence of implant rupture by implant type and procedures

Implant type	6-Year cumulative incidence of implant rupture (%)			
	Primary augmentation	Revision augmentation	Primary reconstruction	Revision reconstruction
Allergan round (smooth and textured) ¹¹	5.5	2.3	9.3	–
Allergan textured shaped ¹²	5.0	5.0	7.5	14.3
Mentor round (smooth and textured) ¹³	1.1	11.6	3.8	5.9
Mentor textured shaped ¹⁴	2.1	2.9	1.5	0

after the first-stage operation, considering the schedule of adjunct oncologic treatments, patient desire, and operating room availability. A similar association was observed after restricting analyses to individuals not receiving any oncologic treatments. The exact mechanism for this finding could not be clearly elucidated from the current clinical study. One possible explanation could be an increased association with the stretch-back phenomenon of expanded tissue. Liu et al. demonstrated in their experimental study that in vivo skin tension and immediate stretch-back ratio could be decreased with elongating expansion maintenance time.¹⁸ That is, having a short maintenance period of tissue expander could induce relatively strong skin tension and stretch-back forces compared with having a long maintenance period. It is likely that, in cases with shorter maintenance period of tissue expander, increased skin tension for stretch-back could put slight but constant pressure on the underlying implant, which might lead to implant rupture in the long run.

Notable was that type of implant was significantly associated with the development of rupture. In particular, cases using two kinds of fourth-generation implant (Allergan textured round and Allergan smooth round) showed a significantly higher risk than those using Mentor MemoryShape implant. Similar results were shown in previous core studies, as shown in Table 4. Seigle-Murandi et al. reported similar results in their 12-year retrospective cohort study.¹⁷ In their study, Allergan style 110 implant (Biocell textured) showed the highest estimated risks of removal for implant rupture, up to 33% by postoperative 3000 days, followed by Allergan CUI with 9% and Allergan 410 implant with 6%.

Compared with the fifth-generation ones, the fourth-generation implants are known to have lesser form stability. The two Allergan round products (textured and smooth) were known to have the least stiffness of form stability compared with other products.^{12,19} It is likely that implants with lesser form stability might be more vulnerable to external force and pressure from surrounding tissue compared with those with more form stability, and might have a higher risk of folding. This folding might result in constant fatigue of implant shell,^{20,21} eventually leading to

an elevated risk of rupture.²² This hypothesis could be further supported by the findings of subgroup analysis. In cases using the fourth-generation implants, the interval between the stages was an independent predictor of rupture, showing an increasing risk of rupture in patients with shorter interval, while this association disappeared in those using the fifth-generation ones. This might suggest that the fourth-generation implants with lesser form stability might be more vulnerable to external force like stretch-back phenomenon compared with the fifth-generation ones with more form stability. It is likely that form stability might be associated with vulnerability of implant to external force from adjacent tissue including surrounding capsule and overlying expanded skins, which might influence a risk of implant rupture eventually. Further experimental and clinical studies are required for obtain more solid conclusions.

Potential medicolegal aspects regarding the development of implant rupture could be important and be worth of mentioning. Misdiagnosis of implant rupture could lead to unnecessary reoperation for removal or exchange of implant, which may be encountered not infrequently.²³ If the development of implant rupture is suspected on physical examination or other imaging modalities, like ultrasound, it may be recommended to check the implant status in more detail once again with MRI before determining to conduct exploratory operations. Also notable was the finding of the current study that a majority of cases with implant rupture development were asymptomatic before diagnosis. This suggests the need for regular postoperative check-up to evaluate status of inserted implants, or detect potentially silent rupture in patients undergoing implant-based breast reconstruction. It may be mandatory for reconstructive surgeons to educate patients on the necessity of long-term postoperative follow-up and to recommend them to have regular examinations using imaging modalities.

A number of limitations of this study need to be mentioned. A retrospective study design could contain a risk of underestimation of the event, although a majority of patients were followed up with imaging modality in the regular schedule mentioned above. The median follow-up

period of 43 months would not be sufficient for evaluating incidence of implant rupture. Further studies with longer follow-up period would be necessary. Finally, our study population had relatively low BMI and included a small number of obese patients compared with other populations including Western, which may make it difficult to generalize our findings.

CONCLUSIONS

The findings of the current retrospective cohort study suggest that the interval between the first- and second-stage operations and type of silicone implant used might be associated with the development of implant rupture in cases of two-stage tissue expander/implant breast reconstruction. Having a shorter interval between the stages and using non-form-stable Allergan smooth and textured round implants could be associated with an increased risk of implant rupture. This could have clinical significance in that those factors could be determined by reconstruction surgeons, which suggests that the risk of implant rupture could be somewhat reduced by managing some preoperative and operative factors. This information might be helpful not only in patient counseling, preoperative planning, and intraoperative decision-making, but also in future advances in implant manufacturing. Of course, further larger-sized prospective studies with longer follow-up period would be required to verify these results.

DISCLOSURE None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

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Reconstrucción mamaria inmediata con expansores tisulares

Immediate breast reconstruction with tissue expanders

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RESUMEN

Introducción: La reconstrucción mamaria postmastectomía es la forma habitual en nuestro país. En el Instituto de Oncología se realizan en la actualidad con sistematicidad de manera inmediata para disminuir el impacto psicológico de la mastectomía.

Objetivo: Evaluar el comportamiento de la reconstrucción mamaria inmediata con el uso de expansores tisulares.

Métodos: Se realizó un estudio observacional, descriptivo, retrospectivo y longitudinal, en pacientes ingresadas en el Instituto Nacional de Oncología y Radiología con criterios de reconstrucción mamaria inmediata con expansores tisulares, en el periodo comprendido entre octubre de 2015 a diciembre de 2018. El universo estuvo conformado por 51 paciente siendo la muestra 43.

Resultados: Predominó la reconstrucción en mujeres entre 40 y 49 de color de la piel blanca. La mayoría con hábitos tóxicos de fumadoras. Se realizó como técnica quirúrgica la reconstrucción inmediata con expansión tisular, fue el más utilizado el anatómico. Las principales complicaciones estuvieron relacionadas con la radioterapia y hábitos tóxicos.

Conclusiones: Todas las mujeres se reconstruyeron con expansor tisular, de forma inmediata, con bajo índice de complicaciones.

Palabras clave: reconstrucción mamaria inmediata; mastectomía; expansores tisulares.

ABSTRACT

Introduction: Postmastectomy breast reconstruction is the usual way in our country. At the Oncology Institute they are currently performed systematically immediately to lessen the psychological impact of mastectomy.

Objective: To evaluate the behavior of immediate breast reconstruction with the use of tissue expanders.

Methods: An observational, descriptive, retrospective and longitudinal study was carried out in patients admitted to the National Institute of Oncology and Radiology with criteria for immediate breast reconstruction with tissue expanders, in the period from October 2015 to December 2018. The universe it was made up of 51 patients, sample 43.

Results: Reconstruction predominated in women between 40 and 49 of white skin color. Most with toxic smoking habits. Immediate reconstruction with tissue expansion was performed as a surgical technique, anatomical was the most used. The main complications were related to radiation therapy and toxic habits.

Conclusions: All the women were reconstructed with a tissue expander, immediately, with a low rate of complications.

Key words: immediate breast reconstruction; mastectomy; tissue expanders.

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Introducción

El cáncer de mama, constituye el tumor más frecuente en la mujer adulta y representa del 20 % - 25 % de los tumores malignos del sexo femenino.⁽¹⁾

La expansión tisular se ha convertido en una técnica clásica para la reconstrucción mamaria desde que se introdujo por *Radovan* a finales de los 70 e inicio de los 80, se le atribuye ser el pionero en comenzar la utilización de expansores tisulares.⁽²⁾ La reconstrucción mamaria moderna ha sido favorecida por varios avances. La tendencia a técnicas de mastectomía menos agresivas, que facilitan la cobertura cutánea, la introducción y progreso de los implantes mamarios de silicona, la colocación

submuscular de implantes, la técnica de expansión tisular y grandes avances en el conocimiento anatómico de los diversos colgajos disponibles.⁽³⁾ En Cuba se comenzó la reconstrucción mamaria en la década de los años ochenta en los Servicios de Cirugía Plástica de los hospitales "Hermanos Ameijeiras" y "General Calixto García" también se realizó reconstrucciones mamarias en el Instituto Nacional de Oncología y Radiobiología (INOR), por *Carrillo y Rodríguez* en 1998, y se les colocó implantes mamarios.⁽⁴⁾ Posteriormente se continuó estudios, publicados en el año 2013 y 2014 en el INOR en pacientes con reconstrucción mamaria por patología mamaria, así como, 96 casos estudiados con reconstrucción mamaria postmastectomía.^(5,6) La mayoría de las reconstrucciones se hacían postmastectomías, luego de concluidos tratamientos de quimioterapia y radioterapia. En los últimos años, se han realizado reconstrucciones inmediatas en equipo multidisciplinarios con los cirujanos mastólogos dedicados a la mama. En el mismo acto quirúrgico, con este trabajo evaluamos el comportamiento de la reconstrucción con el expansor tisular de forma inmediata.

Métodos

Se realizó un estudio observacional, descriptivo, retrospectivo y longitudinal, en el INOR, con criterios de reconstrucción mamaria inmediata, con expansores tisulares en el periodo comprendido de octubre de 2015 a diciembre de 2018. El universo fue de 51 pacientes y la muestra quedó conformada por 43 pacientes, con la previa solicitud de su consentimiento informado. Los criterios de inclusión fueron las pacientes con edad entre 20 y 59 años, que manifestaron su disposición a participar en la investigación, con criterios de reconstrucción mamaria inmediata. La fuente de recolección de datos fueron las historias clínicas.

Procedimientos quirúrgicos y descripción de las técnicas empleadas en el estudio

Se ejecutó el marcaje a 1 cm por debajo del surco submamario, indicándose la posición del expansor, Luego de la mastectomía, se creó un bolsillo submuscular, por el borde externo del músculo pectoral mayor y se realizó una disección medial e inferior del bolsillo para colocar el expansor. Para dar cobertura total del mismo, fue necesario unir

al borde externo del pectoral mayor con los músculos serratos. Se colocaron expansores lisos o texturizado anatómico o redondo, siempre de válvula a distancia. Se dejó drenajes por contrabertura. La expansión tisular se inició 21 días después de la cirugía con infiltraciones semanales de un 10 % de la capacidad total del expansor hasta, alcanzar un 150 % de su volumen. Una vez alcanzado el volumen máximo, se dejó un periodo de 1-3 meses antes de sustituir el expansor por la prótesis mamaria definitiva. De 1-3 meses más tarde, se realizó la reconstrucción del complejo areola-pezón (CAP) y la cirugía de la mama contralateral para simetrización, cuando así lo desearon las pacientes.

Resultados

La tabla 1 muestra la distribución de pacientes según grupos de edades y color de piel. Puede observarse que, predominó el grupo etario entre 40 - 49 años de edad con un 39,5 %, seguido del grupo entre 30 - 39 años con un 32,6 %. Incidió con mayor frecuencia, el color de piel blanca con 81,3 % y 16,4 % respectivamente.

Tabla 1- Distribución de pacientes según grupos de edades y color de piel

Grupo Etario (n= 43)	Blanca		Mestiza		Negra		Total	%
	n	%	n	%	n	%		
20-29 años	1	2,3	1	2,3	0	0	2	4,7
30-39 años	12	27,9	1	2,3	1	2,3	14	32,5
40-49 años	15	34,8	2	4,7	0	0	17	39,5
50 -59 años	7	16,2	3	6,9	0	0	10	23,3
Total	35	81,3	7	16,4	1	2,3	43	100

Fuente: Historias clínicas archivo INOR.

En la tabla 2 se muestra la distribución de pacientes según a técnica quirúrgica empleada, donde la mastectomía radical modificada representó el 76,7 %, seguido de la mastectomía subcutánea 23,3 % respectivamente. Además, incidió la utilización de expansores anatómicos representando el 81,3 % de la muestra estudiada seguido de los redondos 18,6 % respectivamente.

Tabla 2- Distribución de pacientes según técnica quirúrgica y tipo de expansor

Técnica Quirúrgica (n=43)	Tipo de expansor tisular				Total	%
	Anatómico		Redondo			
	n	%		%		
Mastectomia Radical Modificada	29	67,4	4	9,3	33	76,7
Mastectomia subcutánea	6	13,9	4	9,3	10	23,3
Total	35	81,3	8	18,6	43	100

Fuente: Historias clínicas archivo INOR.

En la tabla 3 se observa la distribución de pacientes según, las complicaciones presentadas en relación con los hábitos tóxicos y la radioterapia, donde se evidenció que de la muestra estudiada el 60,4 % no presentó complicaciones, pues solo 6,9 % de las pacientes presentaron contractura capsular y extrusión del expansor, que estuvo en relación con el tratamiento radioterapéutico.

Tabla 3- Distribución de pacientes según complicaciones en relación con los hábitos tóxicos y radioterapia

Complicaciones (n=43)	Hábitos tóxicos					Radioterapia	%
	Cigarrillo		Si	no	%		
	n	%	n	n			
Contractura capsular	0	0	3	0	6,9	3	6,9
Dehiscencia	2	4,7	0	0	0	2	4,7
Epidermólisis	2	4,7	0	0	0	2	4,7
Extrusión del expansor	0	0	3	0	6,9	3	6,9
Hematoma	3	6,9	0	0	0	3	6,9
Infección de la herida	1	2,3	0	0	0	1	2,3
Seroma	2	4,7	0	1	2,3	3	6,9
Sin complicaciones	19	44,1	7	0	16,3	26	60,4
Total	29	67,3	13	1	32,4	43	100

Fuente: Historias clínicas archivo INOR.

Discusión

Las técnicas modernas permiten opciones de reconstrucción postmastectomía encaminadas a mejorar la calidad de vida de las pacientes. Según estudios *Houssami N.*⁽⁷⁾ muestra que la gran mayoría de las tasas de incidencia del cáncer de mama aumentan exponencialmente con la edad, el 75 % de todos los cánceres invasivos aparecen en la población a partir de los 55 años, siendo este resultado diferente al obtenido en la investigación realizada, y muestra que el 39,5 % de las pacientes predomina el grupo etario de 40-49 años. En un estudio realizado en Cuba por *Sánchez L.*⁽⁶⁾ predominaron las que tenían entre 40 - 49 años (46, para 46,0 %), seguidas de las de 30 - 39 y las de más de 60 años (20,0 %, respectivamente) siendo similar al nuestro.

En este estudio la mayoría de las pacientes eran de color de piel blanca representado 81,4%, coincidió con el realizado por *Olier G.*⁽⁸⁾ que muestra 68,8 % de sus casos prevalece el color piel blanca en pacientes con cáncer de mama inflamatorio en período post-menopáusico. Lo anterior, se explica porque se ha comprobado el papel de los oncogenes en el inicio de la malignización celular y la aparición de esta neoplasia que es frecuente en estas pacientes.

En esta investigación el 67,3 % presentaron hábitos tóxicos de fumadoras, y coincide con literatura revisada que plantea, que el tabaquismo por el efecto vasoconstrictor directo, a nivel de la piel, e indirecto, de inhibición del flujo capilar por liberación de catecolaminas mediado por la nicotina, produce aumento en las necrosis de los colgajos de la mastectomía y trastornos vasculares varios en las técnicas con tejido autólogo.⁽⁹⁾ A pesar de esto, las complicaciones fueron escasas. En relación con la técnica quirúrgica la mastectomía radical modificada representó el 76,7 % de las pacientes seguido de la mastectomía subcutánea 23,3 %. Otras publicaciones⁽¹⁰⁾ muestran que la mastectomía radical modificada sigue siendo un procedimiento habitual en algunos centros hospitalarios e incluso con la mastectomía parcial, aproximadamente entre el 10 y el 30 % de las pacientes están insatisfechas con los resultados estéticos obtenidos.⁽¹⁰⁾ En nuestro estudio aunque se les realizó mastectomía, se beneficiaron por la colocación del expansor de forma inmediata. Otros estudios plantean que la mastectomía subcutánea pudiera indicarse en casos de mamas con lesiones proliferativas, muy fibronodulares y en casos de antecedentes familiares de cáncer de mama. Este estudio se relaciona con la

investigación, pues las mastectomías subcutáneas se realizaron en pacientes con enfermedad fibronodular y pacientes con microcalcificaciones patológicas.⁽¹¹⁾

En el 81,3 % de las pacientes de la investigación realizada se utiliza expansor anatómico, coincidiéndose con otros estudios⁽¹²⁾ que describen, las prótesis expansiva en la cirugía reconstructiva, en la actualidad tienen más aceptación las anatómicas o en gota de agua, puesto que la mayor repartición en el polo inferior le confieren proyección y volumen más natural. En la publicación de *Gutiérrez*, los expansores utilizados en todos los casos fueron biodimensionales texturizados con válvula integrada. No contándose con estos en la investigación realizada.⁽¹⁰⁾ En relación con la radioterapia, la temática es contradictoria en muchas investigaciones. En nuestro instituto en la actualidad se realiza el ganglio centinela que es un valor predictivo para la reconstrucción inmediata e incluso para, la realización de la radioterapia. No se excluye totalmente que para la reconstrucción mamaria inmediata con expansor no debe recibir radioterapia. Es conocido los efectos de sobre este proceso de expansión, pero en este estudio las complicaciones fueron mínimas y además, hoy en día se pueden mejorar estos problemas con la lipotransferencia de grasa.⁽¹³⁾ Colocada en el paso de cambio de expansor por implante definitivo o previo a la expansión, los casos se valoran en un equipo multidisciplinario (oncólogos, cirujanos plásticos y radioterapeutas). En el estudio de *Nordenskjöld*⁽¹⁴⁾ dentro de las combinaciones de tratamiento predominó la de quimioterapia, cirugía y radioterapia (63,2 %). La radioterapia como único tratamiento y la radioterapia más cirugía se empleó en tanto, en uno como en el otro, en 15,8 % de los casos, que coincidió con nuestra investigación.

En este estudio fueron mínimas las complicaciones, a pesar, que varias pacientes fueron irradiadas. Las principales complicaciones presentadas fueron, contractura capsular 3 (6,9 %) y extrusión del expansor 3 (6,9 %) seguido del hematoma 3 (6,9 %) y seroma 3 (6,9 %) que estuvo presente en pacientes fumadoras y no recibieron tratamiento con radioterapia. La doctora *Martí*⁽¹⁵⁾ plantea que la reconstrucción mamaria inmediata es más económica y ahorra sufrimiento psicológico a las pacientes; sin embargo, los tratamientos adyuvantes secundarios al tratamiento quirúrgico del carcinoma mamario como la quimioterapia y sobre todo la radioterapia, deben solaparse con las complicaciones o riesgos propios del postoperatorio. Además, la reconstrucción con prótesis presenta un índice no despreciable de complicaciones con la radioterapia postoperatoria, que a veces

no estaba dentro del plan inicial, pero que se hace necesaria cuando el informe anatómo-patológico definitivo altera esta previsión de tratamiento.

El cáncer de mama es más frecuente en el grupo etario de 40-49 años. Se logró realizar la reconstrucción inmediata en todas las pacientes, mejorándose la calidad de vida.

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Conflicto de intereses

Los autores declaran que no existe conflicto de intereses.

Contribuciones de los autores

Lenia Sánchez Wals: Investigador Principal. Realizó todas las cirugías reconstructivas.

Yandy Leng Rabaza: Residente cuyo tema es su tesis de terminación de residencia. Ayudó como primer ayudante en la cirugía reconstructiva y en la recogida y procesamiento de la información.

Luis Eduardo Martín Rodríguez: Es el cirujano del grupo de mastología que realizó la cirugía oncológica de la mama.

Diego Darío García Torres: Ayudó en el procesamiento y recogida de la información, así como en la búsqueda bibliográfica.

Reconstrucción mamaria con el uso expansores tisulares

Breast reconstruction with the use of tissue expanders

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RESUMEN

Introducción: La reconstrucción mamaria por cáncer, mediante la técnica de expansión tisular es una técnica que proporciona piel de color, textura y sensibilidad naturales.

Objetivo: Caracterizar la reconstrucción mamaria con el uso de expansores tisulares en el Instituto Nacional de Oncología y Radiobiología de Cuba.

Método: Se realizó un estudio retrospectivo y longitudinal en el Servicio de Cirugía Reconstructiva del Instituto Nacional de Oncología y Radiobiología de Cuba del 2013 al 2017. La muestra de 93 pacientes se seleccionó de forma consecutiva del universo de pacientes. El análisis estadístico incluyó las pruebas de Chi-cuadrado, estimación de la razón de momios y regresión logística binaria, con nivel de significación $p \leq 0,05$.

Resultados: Predominó la reconstrucción en mujeres con un promedio de edad de 45,7 años, [IC95% (43,8-47,5) y desviación estándar 9.0]. La quimioterapia se

administró a 74 pacientes y la radioterapia a 41. La reconstrucción diferida se realizó en el 51,6 % de las cirugías, y en el 72,0 % no se presentaron complicaciones. El cáncer en estadio III y el uso de quimioterapia y radioterapia neoadyuvante mostraron riesgo con significación estadística para las complicaciones posquirúrgicas.

Conclusiones: La reconstrucción mamaria mediante el uso de expansores tisulares presentó características demográficas y clínicas similares a las descritas previamente en la población cubana y el resto del mundo, aunque con peculiaridades desde el punto de vista onco-reconstructivo. La realización de la cirugía reconstructiva inmediata luego de la radioterapia neoadyuvante resultó en un mayor riesgo de complicaciones.

Palabras clave: reconstrucción mamaria; expansor tisular; cáncer de mama.

ABSTRACT

Introduction: Breast reconstruction for cancer, using the tissue expansion technique, is a technique that provides skin of natural color, texture and sensitivity.

Objective: To characterize breast reconstruction with the use of tissue expanders at the National Institute of Oncology and Radiobiology of Cuba.

Method: A retrospective and longitudinal study was carried out in the Reconstructive Surgery Service of the National Institute of Oncology and Radiobiology of Cuba from 2013 to 2017. The sample of 93 patients was selected consecutively from the universe of patients. Statistical analysis included Chi-square tests, estimation of the odds ratio and binary logistic regression, with a significance level of $p \leq 0.05$.

Results: Reconstruction predominated in women with an average age of 45.7 years, [95% CI (43.8-47.5) and standard deviation 9.0]. Chemotherapy was administered to 74 patients and radiotherapy to 41. Delayed reconstruction was performed in 51.6% of the surgeries, and in 72.0% there were no complications. Stage III cancer and the use of neoadjuvant chemotherapy and radiotherapy showed a statistically significant risk for postoperative complications.

Conclusions: Breast reconstruction by using tissue expanders presented demographic and clinical characteristics similar to those previously described in the Cuban population and the rest of the world, although with peculiarities from the onco-reconstructive point of view. Performing immediate reconstructive surgery after neoadjuvant radiation therapy resulted in an increased risk of complications.

Key words: breast reconstruction; tissue expander; breast cancer.

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Introducción

La técnica de expansión tisular se basa en la habilidad del tejido vivo de aumentar su área como respuesta a la presión ejercida por una masa que aumenta en volumen y en el principio de que el tejido blando responde a las fuerzas internas y externas para cambiar su forma y tamaño.⁽¹⁾

El objetivo de la expansión tisular radica en lograr el desarrollo de un área donadora de tejido con características similares a donde está el defecto en cuanto a textura, color, grosor y sensibilidad, y que permita la reconstrucción con cicatriz única poco evidente y preservando estéticamente el sitio donador.⁽²⁾

Las reconstrucciones mamarias en el país se realizan a pacientes con una edad media de 43 años, lo que pone de manifiesto que se afecta la población joven. Estas evidencias son de especial importancia para garantizar una organización de los servicios de salud que brinde la posibilidad de satisfacer las necesidades sentidas de las mujeres cubanas.⁽³⁾

Aunque no todas las técnicas disponibles a nivel mundial pueden aplicarse en Cuba, por los recursos médicos necesarios para su ejecución, a las pacientes se les ofrecen soluciones reconstructivas satisfactorias que incluyen la reconstrucción mamaria a través de la expansión tisular.⁽⁴⁾

Existen variables demográficas, oncológicas y reconstructivas que se han abordado poco en las investigaciones nacionales, por lo que se realizó una investigación que permitiera caracterizar la reconstrucción mamaria mediante la expansión tisular en el Instituto Nacional de Oncología y Radiobiología (INOR).

Métodos

Se realizó un estudio descriptivo-analítico, retrospectivo y longitudinal, que incluyó 93 pacientes de toda Cuba a las que se les realizó una reconstrucción mamaria con el uso de expansores tisulares entre enero de 2013 y diciembre de 2017 en el Servicio de Cirugía Reconstructiva del INOR. La muestra resultó en 93 pacientes, seleccionadas de forma consecutiva, que cumplieron con los criterios de inclusión para realizarles el procedimiento de reconstrucción. Los datos se obtuvieron de las historias clínicas y las variables analizadas fueron: la edad al momento de la reconstrucción, el estadio clínico, tipo de cirugía oncológica, uso de quimioterapia y radioterapia, momento de la reconstrucción mamaria, ocurrencia de complicaciones y tiempo transcurrido hasta la reconstrucción.

Los resultados se presentan en tablas de contingencia. Se aplicó el test de Chi-cuadrado, la estimación de razón de momios y el análisis de regresión logística binaria. Se fijó un nivel de significación estadística $p \leq 0,05$.

Criterios de inclusión

Pacientes con criterios de reconstrucción mamaria inmediata o diferida con expansor tisular, que manifestaron su disposición a participar en la investigación y cumplieron el tratamiento oncológico en los casos diferidos, con exámenes de extensión negativos.

Criterios de exclusión

Pacientes que no cumplieron al menos uno de los criterios de inclusión o que el diagnóstico fue de una patología benigna.

Planificación preoperatoria

Se les realizó un examen físico general y mamario, con exámenes de extensión estables. Se le entregó el modelo de consentimiento informado y se tomaron las fotos preoperatorias con vistas frontales, laterales y oblicuas, con previa autorización de las pacientes.

Técnica quirúrgica

Se diseñó la situación del nuevo surco submamario. El bolsillo se situó hasta 1 cm por debajo del surco submamario de la mama contralateral. Tras la mastectomía conservadora de piel o radical modificada, se realizó una inspección de los colgajos cutáneos remanente, así como de la hemostasia. Se creó un bolsillo submuscular, elevándose el borde lateral del pectoral mayor y realizándose una disección medial e inferior del bolsillo para colocar el expansor tisular. Para una mejor cobertura se suturó el músculo pectoral mayor con el músculo serrato anterior. Se colocó un expansor tisular texturizado anatómico o redondo con válvula a distancia, según disponibilidad. Se dejó un drenaje cerrado en axila en el sitio de la disección ganglionar y otro en la región mamaria; ambos se sacaron por la contra-abertura y se suturaron a la pared torácica con nylon 3-0. El cierre se hizo por planos y se vendó con apósitos. Los drenajes se retiraron en un promedio de 7 a 15 días.

La expansión tisular se inició en el quirófano con 20 o 30 ml de azul de metileno para comprobar el expansor con su sistema colector y para, en caso de ruptura o desconexión, comprobar por la orina de la paciente un posible cambio de color verde-azul. Luego se continuó la infiltración 21 días después de la cirugía, con infiltraciones semanales de un 10 % de la capacidad total del expansor hasta alcanzar un 150 % de su volumen. Una vez alcanzado el volumen máximo, se dejó un periodo de 1 a 3 meses antes de sustituir el expansor por la prótesis mamaria definitiva. De 1 a 3 meses más tarde, se realizó la reconstrucción del complejo areola-pezones y la cirugía de la mama contralateral para simetrización, cuando así lo desearon las pacientes.

Aspectos éticos

La investigación contó con la aprobación del Servicio de Cirugía Reconstructiva y del Comité de Ética Médica del INOR y se realizó de acuerdo con la última revisión de la Declaración de Helsinki, que establece los principios éticos para las investigaciones médicas en seres humanos.⁽⁵⁾

Resultados

La edad promedio fue de 45,7 años, con una desviación estándar de $\pm 9,1$ años. El grupo de edad más frecuente correspondió a 40 - 49 años (N = 41, 44,1 %), seguido por el grupo de 50 - 59 años (N = 26, 28 %). Las pacientes fueron diagnosticadas con predominio de los estadios clínicos II y III, que mostraron igual frecuencia (N = 33, 35,5 %). La mama afectada fue similar en frecuencia respecto al lado derecho e izquierdo (N = 44, 47,3 %) vs (N = 43, 46,2 %), respectivamente. Seis pacientes tuvieron un cáncer bilateral (6,5 %), (Tabla 1).

Tabla 1- Características demográficas y clínicas de las pacientes. Uso de expansores tisulares. INOR 2013-2017

Características	N (%)
Edad (Media $\pm$ DE)	45,7 $\pm$ 9,1
<i>Grupos de edad</i>	
< 20	1 (1,1)
20-29	2 (2,2)
30-39	17 (18,3)
40-49	41 (44,1)
50-59	26 (28,0)
> 59	6 (6,5)
<i>Estadio clínico</i>	
I	19 (20,4)
II	33 (35,5)
III	33 (35,5)
Desconocido	8 (8,6)
<i>Mama afectada</i>	
Derecha	44 (47,3)
Izquierda	43 (46,2)
Bilateral	6 (6,5)
Total	93 (100,0)

Fuente: Historia clínica.

*DE: Desviación estándar.

La quimioterapia se indicó en 74 pacientes (79,6 %), con mayor frecuencia de uso en el escenario adyuvante (N = 56, 60,2 %). Hubo asociación entre el uso de la quimioterapia según el estadio clínico, en cumplimiento de las Guías Oncológicas ($p = 0,000$). En el uso de la radioterapia no se estableció asociación con el estadio clínico ($p = 0,185$), con mayor frecuencia de pacientes sin este tipo de tratamiento loco-regional (N = 52, 55,9 %) (Tabla 2).

La mastectomía de *Madden* el proceder quirúrgico más practicado (N = 72, 77,4 %), con predominio en los estadios clínicos II y III (N = 25, 34,7 %), en cada uno. No existió diferencia con significación estadística ($p = 0,551$) entre la cirugía oncológica y el estadio clínico. A 45 pacientes se les realizó una reconstrucción inmediata (48,4 %); en este grupo fue predominante las que se les realizó una cirugía onco reconstructiva (N = 17, 100,0 %). La reconstrucción inmediata se realizó con mayor frecuencia en el estadio III (N = 24, 72,7 %), mientras que la diferida se practicó más en pacientes en estadio tempranos I y II (N = 11, 57,9 % y N = 21, 63,6 %), respectivamente. Hubo asociación entre el momento de la reconstrucción con el estadio clínico ($p = 0,003$). La técnica más empleada en la reconstrucción de la mama contralateral diferida fue la Mastopexia-Mastoplastia (N = 24, 63,2 %). No se realizó cirugía de la mama contralateral en 28 pacientes (30,1 %), de las cuales 17 fueron reconstruidas de forma inmediata. No hubo diferencia con significación estadística ($p = 0,522$). El estadio clínico III se asoció con mayor riesgo de complicaciones, con significación estadística ($p = 0,007$) (Tabla 2).

Tabla 2- Distribución del tratamiento oncoespecífico y de la cirugía reconstructiva según estadio clínico. Uso de expansores tisulares. INOR 2013-2017

Tratamiento oncoespecífico	Estadio Clínico				Total	p
	I	II	III	Descon.*		
Quimioterapia	N (%)	N (%)	N (%)	N (%)	N (%)	
No	5 (26,3)	9 (47,4)	0 (0,0)	5 (26,3)	19 (20,4)	0,000
Adyuvante	13 (23,2)	22 (39,3)	19 (33,9)	2 (3,6)	56 (60,2)	
Neoadyuvante	1 (5,6)	2 (11,1)	14 (77,8)	1 (5,6)	18 (19,4)	
Radioterapia						
No	13 (25,0)	21 (40,4)	12 (23,1)	6 (11,5)	52 (55,9)	0,185
Adyuvante	5 (13,9)	11 (30,0)	18 (50,0)	2 (5,6)	36 (38,7)	
Neoadyuvante	1 (20,0)	1 (20,0)	3 (60,0)	0 (0,0)	5 (5,4)	
Cirugía oncológica						
Onco-reconstruct.	2 (11,9)	6 (35,3)	8 (47,1)	1 (5,9)	17 (18,3)	0,551
Cuadrantectomía	2 (66,7)	1 (33,3)	0 (0,0)	0 (0,0)	3 (3,2)	
M. clásica	0 (0,0)	1 (0,0)	0 (0,0)	0 (0,0)	1 (1,1)	
M. de Madden	15 (20,8)	25 (34,7)	25 (34,7)	7 (9,7)	72 (77,4)	
Uso expansor						0,003
Inmediato	8 (17,8)	12 (26,7)	24 (53,3)	1 (2,2)	45 (48,3)	
Diferido	11 (22,9)	21 (43,8)	9 (18,8)	7 (14,6)	48 (51,7)	
Cirugía Mama Contralateral						
Mastopexia	9 (23,7)	15 (39,5)	9 (23,7)	5 (13,2)	38 (40,8)	0,522
C. Ahorradora de piel	3 (21,4)	5 (35,7)	5 (35,7)	1 (7,1)	14 (15,0)	
Con expansor	3 (33,3)	3 (33,3)	3 (33,3)	0 (0,0)	9 (9,7)	
Con implante	0 (0,0)	2 (50,0)	1 (25,0)	1 (25,0)	4 (4,3)	
No realizado	4 (14,3)	8 (28,6)	15 (53,6)	1 (3,6)	28 (30,2)	
Complicaciones						
Si	3 (11,5)	7 (26,9)	16 (61,5)	0 (0,0)	26 (27,9)	0,007
No	16 (23,9)	26 (38,9)	17 (25,4)	8 (11,9)	67 (72,1)	
Total	19 (20,4)	33 (35,5)	33 (35,5)	8 (8,6)	93 (100,0)	

Fuente: Historia clínica.

*Desconocido, p según Test de Chi-cuadrado, M: Mastectomía.

C: Cirugía.

En 26 pacientes hubo complicaciones (27,9 %); las más frecuentes fueron la infección del sitio quirúrgico (N = 9, 9,7 %), la extrusión y rotura del expansor y extrusión del implante (N = 6, 6,5 % y N = 4, 4,3 %), respectivamente. El 72,0 % de las pacientes no tuvo complicaciones. La reconstrucción inmediata tuvo mayor frecuencia de complicaciones (N = 15, 57,7 %), aunque no hubo riesgo con significación estadística entre el tipo de complicaciones y el momento de reconstrucción (Tabla 3).

Tabla 3- Distribución del tipo de complicación según el momento de la reconstrucción.
 Uso de expansores tisulares. INOR 2013-2017

Complicaciones	Momento de la reconstrucción		Total	OR IC 95 %
	Diferido	Inmediato		
Ninguna	37 (55,2)	30 (44,8)	67 (72,0)	1,68 [0,67- 4,19]
Infección local	3 (33,3)	6 (66,7)	9 (9,7)	0,43 [0,10- 1,54]
Extrusión del expansor	3 (50,0)	3 (50,0)	6 (6,5)	0,93 [0,17- 4,88]
Expansor roto	1 (25,0)	3 (75,0)	4 (4,3)	0,29 [0,03- 2,90]
Extrusión de implante	3 (75,0)	1 (25,0)	4 (4,3)	2,93 [0,29- 29,0]
Contractura capsular	1 (100,0)	0	1 (1,1)	1,87 [0,16- 21,4]*
Dehiscencia de sutura	0 (0,0)	1 (100,0)	1 (1,1)	0,48 [0,04- 5,47]*
Rotura tramo colector de válvula	0 (0,0)	1 (100,0)	1 (1,1)	0,48 [0,04- 5,47]*
Total	48 (51,6)	48 (48,4)	93 (100,0)	

Fuente: Historia clínica.

OR: Odds Ratio

IC: Intervalo de confianza del 95 %.

* Corrección de Haldane-Anscombe.

No se estableció riesgo entre el tratamiento con quimioterapia y las complicaciones según el momento de reconstrucción; sin embargo, en general, el tratamiento neoadyuvante con quimioterapia se asoció con mayor frecuencia de complicaciones (3,62 [1,23-10,64]). En las pacientes que recibieron radioterapia el riesgo fue mayor respecto al uso de la quimioterapia (12,0 [31,27-113,15] vs 3,62 [1,23-10,64]). Hubo asociación entre las complicaciones y el tratamiento con radioterapia neoadyuvante en las reconstrucciones inmediatas (Chi-cuadrado =

8,83, $p = 0,012$), y se identificó como el subgrupo de mayor riesgo (12,0 [31,27-113,15) (Tabla 4).

Tabla 4. Distribución del tratamiento onco-específico y las complicaciones, estratificadas por momento de la reconstrucción. Uso de expansores tisulares. INOR 2013-2017

Momento Reconstrucción	Tratamiento oncoespecífico		COMPLICACIONES		Total	OR IC 95 %
			NO	SI		
Inmediata	QT	No	6 (85,7)	1 (14,3)	7 (15,6)	0,051 [0,00-0,48]
		Adyuvante	18 (72,0)	7 (28,0)	25 (55,5)	0,58 [0,14-2,03]
		Neoadyuvante	6 (48,6)	7 (53,8)	13 (28,9)	3,50 [0,90-13,53]
		Subtotal	30 (66,7)	15 (33,3)	45 (100,0)	1,68 [0,67-4,20]
Diferida		No	12 (100,0)	0 (0,0)	12 (25,0)	0,17 [0,02-1,43]*
		Adyuvante	22 (71,0)	9 (29,0)	31 (64,6)	3,07 [0,57-16,24]
		Neoadyuvante	3 (60,0)	2 (40,0)	5 (10,4)	2,51 [0,36-17,42]
		Subtotal	37 (77,1)	11 (22,9)	48 (100,0)	0,59 [0,24-1,45]
Ambos momentos		No	18 (94,7)	1 (5,3)	19 (20,4)	0,10 [0,01-0,86]
		Adyuvante	40 (71,4)	16 (28,6)	56 (60,2)	1,08 [0,43-2,73]
		Neoadyuvante	9 (50,0)	9 (50,0)	18 (19,4)	3,62 [1,23-10,64]
Total			67 (72,0)	26 (28,0)	93 (100,0)	
Inmediata	RT	No	15 (75,0)	5 (25,0)	20 (44,4)	0,5 [0,13-1,8]
		Adyuvante	15 (71,4)	6 (28,6)	21 (46,7)	0,7 [0,15-2,07]
		Neoadyuvante	0 (0,0)	4 (100,0)	4 (8,9)	12,5 [1,32-119,47]*
		Subtotal	30 (66,7)	15 (33,3)	45 (100,0)	1,68 [0,67-4,20]
Diferida		No	27 (84,4)	5 (15,6)	32 (66,7)	0,31 [0,08-1,24]
		Adyuvante	9 (60,0)	6 (40,0)	15 (31,3)	3,73 [0,92-15,21]
		Neoadyuvante	1 (100,0)	0 (0,0)	1 (2,1)	1,68 [0,14-20,34]*
		Subtotal	37 (77,1)	11 (22,9)	48 (100,0)	0,59 [0,24-1,48]
Ambos momentos		No	42 (80,8)	10 (19,2)	52 (55,9)	0,37 [0,15-0,94]
		Adyuvante	24 (66,7)	12 (33,3)	36 (38,7)	1,54 [0,61-3,84]
		Neoadyuvante	1 (20,0)	4 (80,0)	5 (5,4)	12,0 [31,27-113,15]
Total			67 (72,0)	26 (28,0)	93 (100,0)	

OR: Odds Ratio-

IC: Intervalo de confianza del 95 %.

QT: Quimioterapia. RT: Radioterapia.

*Corrección de Haldane-Anscombe.

El análisis de regresión logística entre el tiempo transcurrido desde la cirugía oncológica hasta la reconstrucción no mostró relación con significación estadística ($p = 0,253$, $RR = 0,988$, IC 95 % [0,968-1,09]).

Discusión

En cuanto a la edad, estos resultados son similares a los que se encontraron en el estudio de *Sánchez* y otros, en los que predominaron las pacientes entre 40 y 49 años, que representaron el 48,9 % de la muestra.⁽⁶⁾

La sociedad norteamericana de cirujanos plásticos reportó para 2018 una distribución por edades similar de las mujeres que recibieron una reconstrucción mamaria por cualquier técnica.⁽⁷⁾ La principal diferencia estuvo en que en los EE.UU. el grupo entre los 30 y 39 años fue menor y representó el 11,8 % del total, lo que pudo estar relacionado con que los programas la detección del cáncer en Cuba identifican las pacientes a edades tempranas.

Según el momento de la reconstrucción, que puede ser inmediata o diferida, *Sánchez* y otros encontraron previamente que entre el 2008 y el 2012 predominó la reconstrucción diferida en el 74,0 % de todas las pacientes.⁽⁶⁾ Estas diferencias con el período 2013 al 2017 apuntan a que se sucedieron cambios de paradigmas en cuanto a los tiempos de reconstrucción, toda vez que se demostró que la reconstrucción inmediata era oncológicamente segura.

Estos resultados también pudieron deberse a que la introducción de las cirugías conservadoras de piel, que permiten la reconstrucción inmediata con buenos resultados, a diferencia de los casos tratados con mastectomías en que las técnicas diferidas suelen traer algunas complicaciones.

En Venezuela el grupo de *Giuseppe* realizó un 69,9 % de las reconstrucciones de forma inmediata.⁽⁸⁾ Los hallazgos de la presente investigación también contrastan con los de *Sergesketter* y otros quienes encontraron en los EE.UU., que la reconstrucción inmediata fue solo el 21,8 %, ⁽⁹⁾ que según *Gibreel* ha ido en aumento en ese país en los mayores de 50 años.⁽¹⁰⁾

Como parte del tratamiento oncológico neoadyuvante y adyuvante del cáncer de mama, las pacientes se tratan con QTP y RTP. Estos resultados coinciden

parcialmente con los de *Sánchez* y otros quienes encontraron que recibió QTP adyuvante el 74,0 % de la muestra, sin embargo, a diferencia de la presente investigación, la radioterapia (RTP) previa a la reconstrucción se aplicó al 64,5 % de las pacientes.⁽⁶⁾

La importancia de esta información radica en que las pacientes que no tuvieran criterios de RTP fueron tributarias a la reconstrucción mamaria con expansión tisular, que constituyen el universo de estudio de la presente investigación. Este tipo de reconstrucción es de elección en estos casos y es un procedimiento de menor complejidad, porque no moviliza colgajos miocutáneos.⁽⁶⁾

Por otra parte, la administración de RTP preoperatoria con la QTP neoadyuvante, aunque en la presente investigación se aplicó a un grupo reducido de pacientes, se puede reducir los tiempos para completar el tratamiento y facilitar una mejor accesibilidad a la reconstrucción mamaria. Lo anterior se demostró por el grupo de *O' Halloran* en Irlanda en un estudio entre el 2010 y el 2016.⁽¹¹⁾

No se encontró un OR que evidenciara diferencias estadísticamente significativas en las frecuencias de complicaciones entre los grupos de pacientes que recibieron la reconstrucción mediante expansores tisulares de forma inmediata o diferida.

Estos resultados coinciden con los reportes del grupo de *Sánchez*, que encontró además un 70 % de las pacientes sin complicaciones⁽⁶⁾ y con los que reportó *Giuseppe* en Venezuela, siendo la complicación más frecuente en este estudio suramericano la formación de contractura capsular sintomática.⁽⁸⁾

Cuando se analizó la medida del efecto de todas las variables del estudio para presentar complicaciones solo tuvo un OR estadísticamente significativo (OR = 4,59, Intervalo de confianza [1,77; 12,50]), el presentar un cáncer en estadio III, como factor de riesgo para las complicaciones posquirúrgicas de la reconstrucción mamaria mediante el uso de expansores tisulares. No se encontraron variables que fueran factores de riesgo ni protectores para fallecer.

No obstante lo anterior, un OR estadísticamente significativo no necesariamente es biológica o clínicamente relevante, y viceversa;⁽¹²⁾ por lo que no puede afirmarse sobre la base de los hallazgos de la presente investigación que presentar un cáncer en estadio III tenga una relación de causalidad con respecto a presentar complicaciones posquirúrgicas de la reconstrucción mamaria.

El hallazgo de que el momento de la reconstrucción no incrementó el riesgo de complicaciones coincide con *Svee* y otros, que evidenciaron en Suecia en el 2018, que la reconstrucción diferida no ofrecía riesgo con respecto a las reconstrucciones inmediatas;⁽¹³⁾ a diferencia de *Sheckter* y otros reportaron en los EE.UU. que para las pacientes que recibían implantes, la reconstrucción diferida sí reducían los indicadores de seguridad.⁽¹⁴⁾

El efecto del tratamiento oncoespecífico en las complicaciones de la reconstrucción de la mama operada con expansores tisulares ha sido estudiado por muchos autores. La introducción de la técnica de fotones con aceleradores lineales, en años más recientes, han logrado disminuir los efectos adversos de la radioterapia.⁽¹⁵⁾

La reconstrucción mamaria mediante el uso de expansores tisulares en el Instituto Nacional de Oncología y Radiobiología presentó características similares a las descritas previamente en la población cubana y el resto del mundo, aunque con peculiaridades desde el punto de vista onco-reconstructivo. No se identificaron factores de riesgo para el fallecimiento. Las pacientes con cáncer en estadio III presentaron un incremento del riesgo de las complicaciones posquirúrgicas de la reconstrucción mamaria mediante el uso de expansores tisulares.

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Conflicto de intereses

Los autores declaran que no existe conflicto de intereses.

Contribuciones de los autores

Lenia Sánchez Wals: Cirujana principal de los casos que se les realizó la reconstrucción mamaria con expansores tisulares.

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Ramón de Jesús Roperó Toirac: Procesamiento Estadístico.



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FACULTAD DE MEDICINA HUMANA

ESCUELA DE POST-GRADO

Complicaciones en los pacientes con expansores tisulares en el HNERM

TRABAJO DE INVESTIGACIÓN

Para optar el Título de Especialista en Cirugía Plástica

AUTOR

Marco Aurelio Gil Malca Pérez

LIMA – PERÚ
2014

COMPLICACIONES EN LOS PACIENTES CON EXPANSORES TISULARES EN EL HNERM.

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Trabajo de Investigación para obtener el título de especialista en cirugía plástica en la UNMSM.

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DEDICATORIAS:

A Yavhé, por que mi historia está bien hecha

A Noemí, Melanie y Kenny, amores de mi vida.

A la memoria de Oscar Manuel y Sheshita, siempre los recordaré con cariño.

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RESUMEN

Introducción: Las complicaciones de los expansores tisulares aumentan la tasa de morbimortalidad y la estancia hospitalaria, los cuales incrementan los costos totales de los mismos, no hay estudios nacionales al respecto.

Materiales y métodos: Se realizó un estudio retrospectivo, revisándose 31 historias clínicas de pacientes adultos en quienes se colocó expansores tisulares entre el 1 de junio del 2001 hasta el 31 de mayo del 2011. Obteniéndose las variables: Edad, sexo, lugar de colocación del expansor, tiempo operatorio, días de hospitalización, presencia y tipo de complicación, reoperaciones.

Resultados: Sexo que predomina el femenino (22 casos), más frecuente entre los 21 y 50 años. La mayoría se colocaron en el torax (41.93%). Se encontró 7 (22.6%) de complicaciones, la mayoría extrusión del expansor en 4 casos, seguidos por ruptura del expansor, dehiscencia de la herida y extrusión del conducto de relleno, con un caso cada uno. Todos los pacientes fueron rehospitalizados y se resolvieron las complicaciones. El tiempo de hospitalización fue entre 4 y 7 días. La tasa de complicaciones es similar a la reportada en la literatura mundial.

PALABRAS CLAVES: Expansores tisulares, Complicaciones, Estancia hospitalaria.

ABSTRACT

Introduction: Complications of tissue expanders increase the rate of mortality and hospital stay, which increase the total costs of the same, there are no national studies on the issue.

Materials and methods: A retrospective study, reviewing medical records of 31 adult patients in whom tissue expanders between June 1, 2001 was placed until May 31, 2011 give the variables. Age, sex, location of placement expander, operative time, length of stay, presence and type of complications, reoperations.

Results: Gender female predominant (22 cases), more frequent between 21 and 50. Most were placed in the thorax (41.93%). It was found 7 (22.6%) of complications, most expander extrusion in 4 cases, followed by cleavage of the expander, and dehiscencia wound filler pipe extrusion, with one case each. All patients were rehospitalized and complications were resolved. Hospitalization time was between 4 and 7 days. The complication rate is similar to that reported in the literature.

KEYWORDS: Tissue Expanders, complications, hospital stay.

INTRODUCION

La expansión tisular es un proceso basado en la capacidad de respuesta de los tejidos a un estímulo mecánico, con la finalidad de aumentar el área de dichos tejidos y poder realizar cirugías reconstructivas más funcionales y estéticas. Los expansores tisulares varían en su textura pueden ser lisos o microtexturizados, pueden variar además en sus formas, tamaños y volúmenes, siendo el cirujano el responsable de escoger el expansor más adecuado para cada caso, de acuerdo a la localización, tamaño y características del tejido a reparar (1), existen diferentes tipos de válvulas, siendo las de localización remotas las que se usan en el Hospital Nacional Edgardo Rebagliati Martins (HNERM). La primera expansión de piel fue reportada en 1957 por Neumann (2), quien usó un balón de globo como expansor para reconstruir un defecto por trauma en el pabellón auricular.

Sin embargo, el uso de los expansores tisulares en cirugía reconstructiva no está exento de complicaciones, y estas incrementan en relación directa los costos de su uso. Las complicaciones, además de aumentar la morbilidad de nuestros pacientes, incrementan la estancia hospitalaria, el uso de antibióticos, las rehospitalizaciones, y en los casos más severos obligan a las reoperaciones y la remoción de los expansores tisulares. Las complicaciones más frecuentes son del sitio quirúrgico (infecciosas, hematomas, seromas, necrosis de piel y exposición del expansor), dolor, neuropraxia. Las infecciones pueden ser menores, que requieren tratamiento con antibióticos y curaciones tópicas hasta complicaciones mayores que amerita la remoción del expansor tisular.

No se encontraron estudios nacionales, que nos permitieran comparar si las tasas de complicaciones en los pacientes con expansores tisulares son equiparables a los reportados en la literatura médica mundial. Crosby (3), refiere un incremento de 1.15 veces en las complicaciones por cada 10% de volumen de los expansores tisulares mamarios llenados. También B  cher (4), encontr   en un estudio de expansores en ni  os una tasa de 3.8% de infecciones serias y de 11.4% de infecciones menores. Asimismo Liu (3), si bien no son expansores tisulares; sin embargo, reporta una tasa de remoci  n de implantes mamarios de 2.4% por infecci  n. Existen reportes de casos de salvamento de expansores tisulares expuestos (5).

MATERIAL Y METODOS

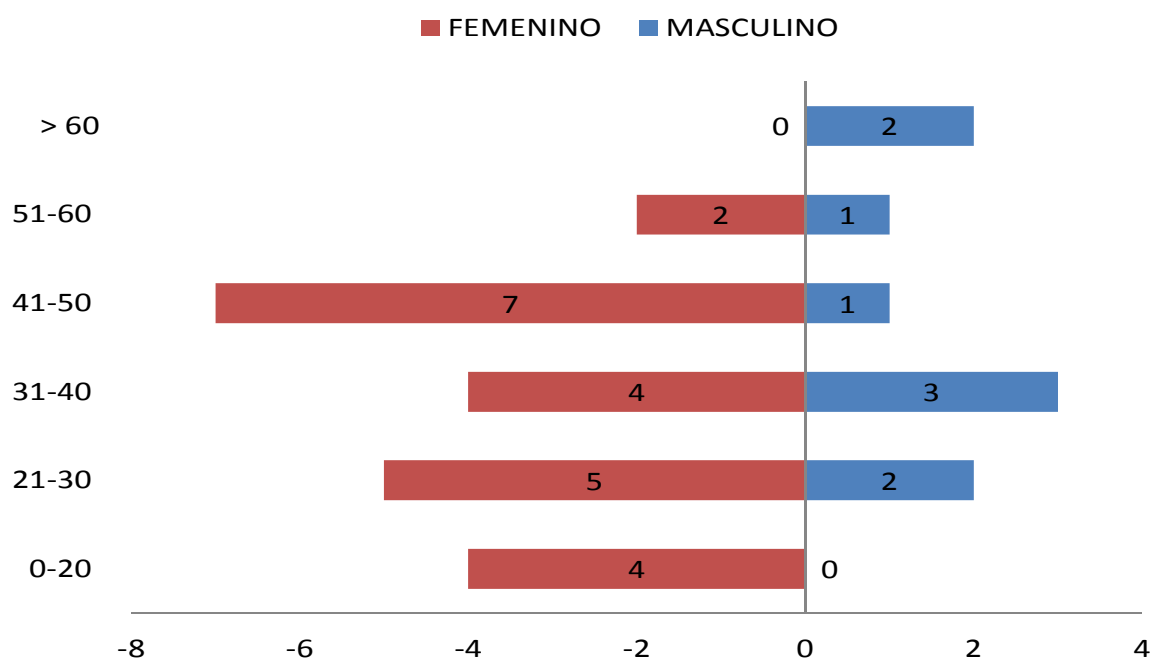
En este estudio retrospectivo se revisaron 33 historias clínicas de pacientes adultos operados para colocación de expansores tisulares en el servicio de cirugía plástica del Hospital Nacional Edgardo RebagliatiMartins, entre el 1 de junio del 2001 y el 31 de mayo del 2011. De las 33 historias clínicas se descartaron 2 por ausencia de datos claros de la evolución de los pacientes.

Se evaluaron las siguientes variables: Edad, sexo, lugar de colocación del expansor, tiempo operatorio, días de hospitalización, presencia y tipo de complicación, reoperaciones.

RESULTADOS

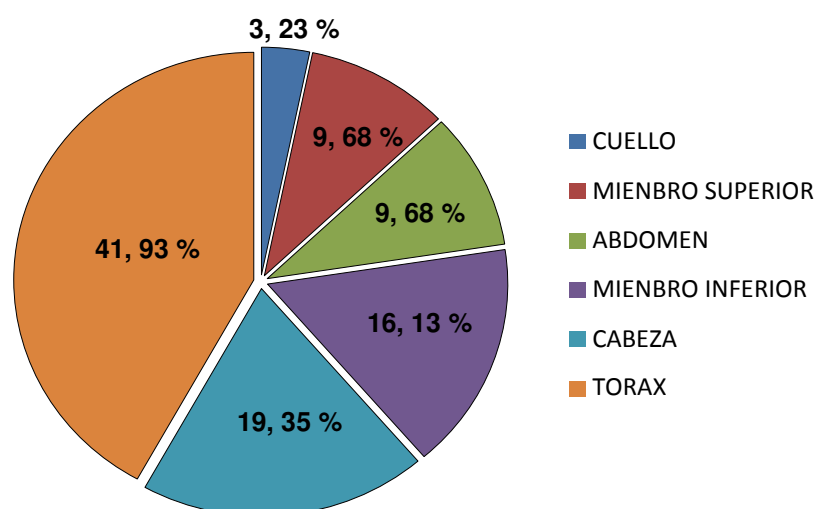
Tres pacientes fueron menores de 20 años, 6 estuvieron en el rango de 21 a 30 años, siete de 31 a 40 años, 8 de 41 a 50 años, cinco de 51 a 60 años y dos pacientes fueron mayores de 60 años. Nueve pacientes fueron masculinos y veintidós femeninos.

Grafico N° 1. Número de pacientes por sexo según grupo etario



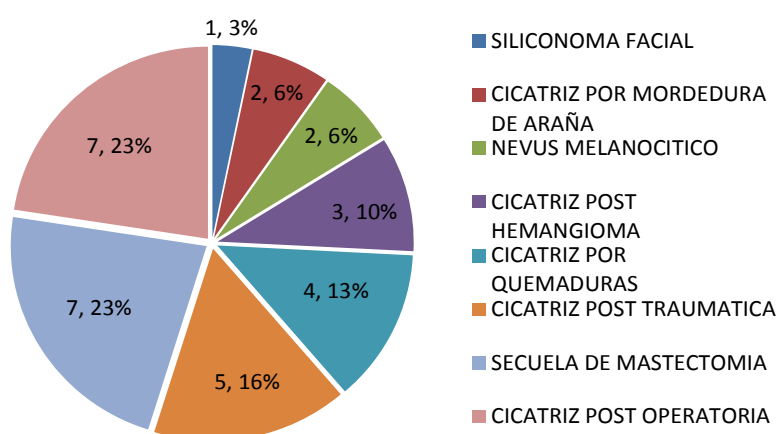
La localización más frecuente de la colocación del expansor tisular fue en torax con 13 casos, seguido por cabeza en 6 pacientes y en miembro inferior en 5. En abdomen y miembro superior en 3 casos cada uno. Y en un paciente se le colocó en la región cervical.

Gráfico N°2: Porcentaje de colocaciones según sitio operatorio



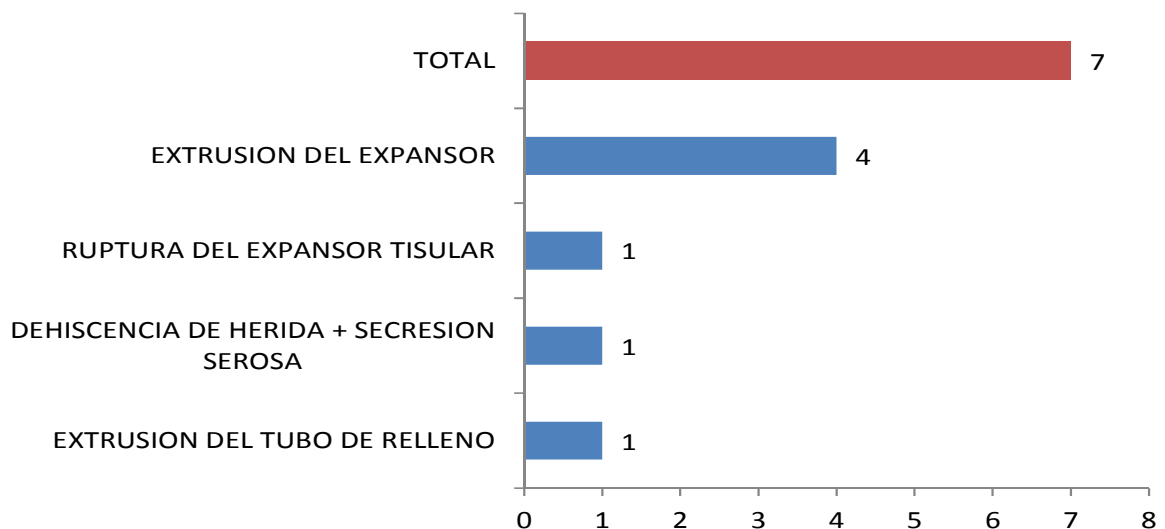
Los diagnósticos de ingreso mas frecuentes para colocación de expansores tisulares fueron secuela de mastectomía y cicatriz postoperatoria con 7 pacientes cada uno, seguidos por cicatrices postrauma y por quemaduras con 5 y 4 casos respectivamente. Cicatriz post tratamiento de hemangomas en 3 pacientes, 2 ingresaron por nevus melanocítico y el mismo número por cicatriz por mordedura de araña, solamente se encontró un caso de siliconoma facial.

Gráfico N°4: Porcentaje de colocaciones según el diagnostico



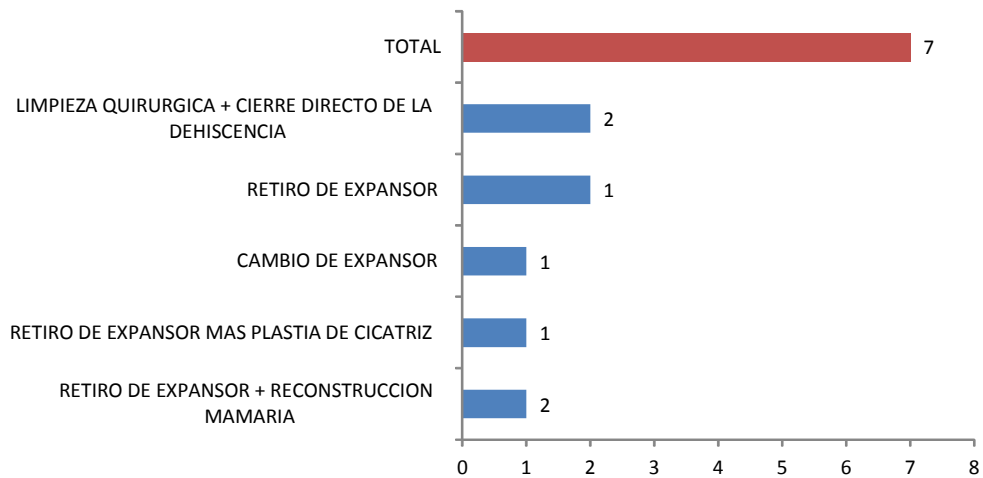
Se encontraron siete (22.6%) complicaciones en los 31 casos, la mayoría extrusión del expansor con cuatro (57,14%) casos; y con uno (14.19%) las siguientes complicaciones extrusión del expansor tisular, ruptura del expansor tisular, dehiscencia de herida con secreción serosa y extrusión del conducto de relleno. Tres de las complicaciones fueron en pacientes con antecedentes de mastectomía dos con extrusión del expansor y un caso de dehiscencia de herida con secreción serosa.

Gráfico N°5: Número y tipo de complicaciones



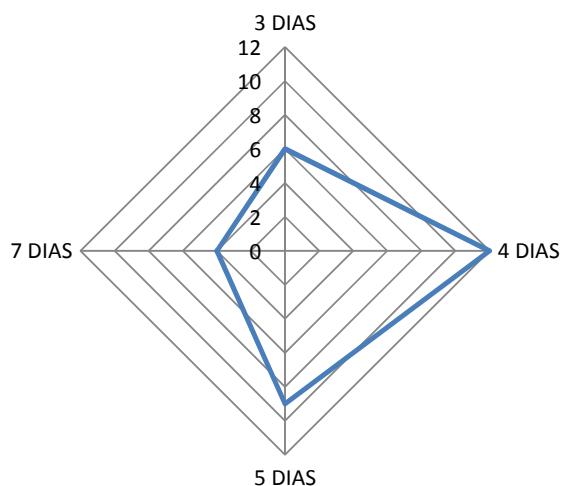
Todos los pacientes que presentaron complicaciones fueron rehospitalizados para su tratamiento, en cuatro casos se les retiró el expansor, en tres de los cuales se les realizó tratamiento definitivo en el mismo acto quirúrgico. A una paciente se le cambió el expansor y en dos casos se manejó conservadoramente con limpieza quirúrgica y cierre de la herida.

Gráfico N°7: Número de colocaciones según tratamiento



El mayor número de pacientes se hospitalizó 4 días, en 12 casos; seguido por 5 pacientes con nueve días; 6 casos con 3 días, y el resto con 7 días; fueron suspendido y reprogramados 3 pacientes. El promedio del tiempo operatorio fue 95 minutos con un rango de un rango de 70 a 120 minutos.

Gráfico N°6: Tiempo de hospitalización de los pacientes con expansores tisulares



CASOS CLINICOS

Caso 1: Paciente mujer de 21 años con cicatriz facial, se le puso un expansor tisular en la región facial, presentando la extrusión del tubo de relleno del expansor. Se realizó retiro del expansor y plastía de la cicatriz.



Caso 3: Paciente mujer de 47 años con antecedente de mastectomía derecha y radioterapia por cáncer de mama, presentó extrusión por dehiscencia de la herida con secreción serosa. Se le realizó retiro del expansor. Y se programó en una semana para reconstrucción mamaria.



Caso 4: Paciente mujer de 50 años, con antecedente de mastectomía derecha, se le coloca expansor tisular, presentando exposición del expansor, se le realizó limpieza quirúrgica y cierre de la herida.



Caso 2: Mujer de 43 años con antecedente de mastectomía izquierda y radioterapia por cáncer de mama, se le colocó expansor tisular, presentando extrusión del expansor. El tratamiento consistió en retiro del expansor y reconstrucción mamaria con colgajo TRAM ipsilateral.



Caso 5: Paciente varón de 33 años con cicatriz en antebrazo derecho, a quien se le coloca expansor tisular en el antebrazo, a las 72 horas postoperatorio presenta signos inflamatorios y secreción serosa, que responde a tratamiento antibiótico y es dado de alta a los 7 días del postoperatorio.



DISCUSION

Hay predominio del sexo femenino sobre el masculino, esto se debe a que una de las indicaciones más frecuentes de colocación de expansores tisulares fue secuela de mastectomía. Desde hace varios años, se viene colocando expansores tisulares previo a la reconstrucción mamaria con TRAM, con resultados estéticos más favorables (6). La localización más frecuente del expansor tisular en este estudio es en tórax, similar a lo reportado por Dotan (7).

La tasa de complicaciones del 22.6%, encontrado en los pacientes adultos con expansores tisulares en el HNERM, es similar a la reportada en la literatura mundial (8,9,10,11); Elshahat (12), refiere mayores complicaciones y pérdida de los expansores tisulares colocados en las extremidades (30 % y 15 % respectivamente), que en aquellos colocados en otras partes del cuerpo (10% y 2.5%). En nuestro estudio la localización más frecuente de las complicaciones fue la mama 3 (42.86%). En 4 de nuestros pacientes fue necesario retirar los expansores, con tratamiento definitivo en tres pacientes, perdiéndose un expansor, en otro caso se cambió el expansor tisular, lo cual representa una pérdida de 2 (6.45%) de los expansores utilizados.

En las siete pacientes con secuela de mastectomía en quienes se utilizó expansores tisulares, cuatro tenían antecedentes de radioterapia, en ellas, tres presentaron complicaciones. Existen estudios (13,14) que demuestran que la tasa de complicaciones aumenta a más del doble en aquellas pacientes con expansores tisulares, quienes recibieron radioterapia posterior a la mastectomía, aparentemente por aumento de la fibrosis y debilitamiento de los tejidos irradiados (15). Yanko (16), encontró

mayores complicaciones en expansores anatómicos, y en aquellos con válvula incorporada también fueron mayores que en los expansores con válvulas remotas.

Toronto (17), reporta que la colocación endoscópica de los expansores tisulares reduce la tasa de complicaciones, el tiempo operatorio y el tiempo del llenado del expansor. En el HNERM no se realiza procedimientos endoscópicos para la colocación de expansores tisulares. El tiempo operatorio fue mayor en las primeras cirugías, la cual ha ido disminuyendo hasta 70 minutos en los últimos procedimientos quirúrgicos.

La extrusión de los expansores y del conducto de la válvula son las complicaciones más frecuentes en nuestros casos, la literatura mundial reporta resultados variables, siendo en algunos casos la extrusión la más frecuente y en segundo lugar las infecciones, y otros reportan a estas últimas como las más frecuentes. Todos nuestros pacientes recibieron antibiótico profiláctico.

Si bien, no encontramos estudios sobre estancia hospitalaria, es importante tener en cuenta que en nuestro estudio los pacientes se encuentren hospitalizados entre 4 y 7 días, cuando una cirugía electiva como es la colocación del expansor tisular, debe ser dado de alta a las 24 horas del post operatorio, y en sólo 3 casos se suspendieron y reprogramaron los pacientes, más aún si sabemos que todas las complicaciones fueron detectadas en los controles ambulatorios de consultorio de cirugía plástica. Una estancia mayor aumenta los costos hospitalarios.

CONCLUSIONES

1. La tasa de complicaciones es similar a la reportada en la literatura mundial.
2. La estancia hospitalaria es prolongada, siendo esta cirugía un procedimiento electivo.
3. El tiempo operatorio ha disminuido con la experiencia en la colocación de los expansores tisulares.
4. En todos los casos de complicaciones se realizaron el tratamiento definitivo o el rescate del expansor o el recambio del mismo, sólo en un caso se retiró el expansor y se reprogramó el tratamiento definitivo en una semana.

RECOMENDACIONES

1. Si se decide colocar expansor tisular previa a la reconstrucción mamaria, se debe elegir a las pacientes sin antecedente de radioterapia.
2. Dar a las 24 horas del post operatorio en la mayoría de los casos por ser una cirugía electiva.

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Reconstrucción mamaria con expansor tisular e implante. Indicaciones y experiencia en 24 casos

Breast reconstruction with tissue expander. Indications and experience in 24 cases



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Resumen

En la actualidad, la reconstrucción mamaria forma parte integral del tratamiento del cáncer de mama; la selección de la paciente es crítica para obtener resultados satisfactorios. El presente trabajo recoge nuestra experiencia en reconstrucción mamaria con expansión tisular e implantes, haciendo hincapié en la selección de las pacientes candidatas a este método reconstructivo.

Revisamos las reconstrucciones mamarias realizadas en un período comprendido entre los años 1998 y 2008 por la misma cirujana, analizando factores como tipo de mastectomía, edad, tiempo de la reconstrucción (inmediata o diferida), causa de la mastectomía, tipo de expansor y prótesis utilizados, complicaciones y satisfacción de las pacientes. En todas excepto en una, la reconstrucción se realizó en dos tiempos operatorios; durante el primero se hizo la colocación del expansor tisular y en el segundo, el cambio por la prótesis mamaria definitiva.

Se realizaron un total de 24 reconstrucciones mamarias en 19 pacientes en el período de 10 años revisado, 14 unilaterales y 5 bilaterales. Las complicaciones presentadas en este grupo de pacientes fueron del 16,6%. El seguimiento de las pacientes fue de 2 a 10 años. Solamente en 1 caso de cuadrantectomía, se realizó la reconstrucción de forma diferida por antecedente de radioterapia (4,1%). En nuestra opinión, la reconstrucción mamaria con expansor tisular e implante es un procedimiento seguro, reproducible y con bajo índice de complicaciones, sin el inconveniente añadido de ocasionar morbilidad en el área donante.

Palabras clave Reconstrucción mamaria,
Expansión tisular, Prótesis mamaria.

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Abstract

Nowadays, breast reconstruction is part of breast carcinoma treatment; patient's selection plays an important role in satisfactory results. The present paper reports our experience in breast reconstruction with tissue expander/implant and emphasizes the importance of choosing the candidates for this method of reconstruction

We review the breast reconstructions realized in a 10 year period (1998-2008) by the same surgeon. We analyzed factors like type of mastectomy, age, time of the reconstruction (immediate or delayed), etiology, tissue expander and implant used complications and patients' satisfaction. All the patients except one underwent breast reconstruction in two stages, first sub-muscular tissue expander, and second reconstruction replacement of tissue expander with implant.

A total of 24 breast were reconstructed in 19 patients using tissue expander/ implant in a 10 years period, 14 unilateral and 5 bilateral.

In terms of complications, they were present in 16,6% cases. The follow up period was between 2 and 10 years. There was only 1 patient with previous quadrantectomy who received radiotherapy (4,1%).

In our opinion, breast reconstruction with tissue expander/ implant remains a safe and reliable method with minimal complications and without morbidity at the donor site.

Key words Breast reconstruction,
Tissue expander, Breast implant.

Numerical Code 5214-52141

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Introducción

En la actualidad, la reconstrucción mamaria forma parte integral del tratamiento del cáncer de mama, y en este proceso, la selección de la paciente es crítica para obtener resultados exitosos. Se necesita una cobertura estable y bien vascularizada para lograr resultados aceptables y de larga duración. La reconstrucción mamaria con expansor tisular e implante es una opción atractiva para muchas mujeres por la ausencia de secuelas en el área donante presentes cuando se realizan reconstrucciones con colgajos, y porque facilita una pronta recuperación. Es importante que las pacientes candidatas a este tipo de reconstrucción hayan sido sometidas a una biopsia diagnóstica previa que normará el criterio oncológico en cuanto a la posibilidad de radiación postmastectomía.

Las indicaciones para llevar a cabo este tipo de reconstrucción mamaria son:

1. Tejidos blandos suficientes y bien vascularizados para cubrir el expansor.
2. Músculo pectoral conservado durante la mastectomía.
3. Cubierta cutánea que no haya sido radiada previamente y que no vaya a ser radiada en el postoperatorio.
4. Aceptación por parte de la paciente.
5. Disponibilidad de citas frecuentes para llevar a cabo el proceso de expansión tisular.

La reconstrucción mamaria con implantes está contraindicada cuando la cubierta cutánea es inadecuada, lo que puede ser secundario a biopsias previas o a enfermedad local avanzada que requiera gran resección de piel durante la mastectomía. La radioterapia previa es una contraindicación relativa para reconstrucción con implante, por presentar un alto índice de exposición protésica y contractura capsular (1-4).

Material y método

Se estudiaron las reconstrucciones mamarias realizadas en el período comprendido entre 1998 y 2008 por la misma cirujana, analizando factores como: tipo de mastectomía realizada, edad de las pacientes, tiempo de la reconstrucción (inmediata o diferida), causa de la mastectomía, tipo de expansor y prótesis utilizados, complicaciones sufridas y satisfacción por parte de las pacientes.

Se emplearon para las reconstrucciones mamarias expansores tisulares biodimensionales texturizados con válvula integrada redondos (133 MV Mc Ghan® Medical Corporation, Sta. Barbara, California, EE.UU.), con capacidad de 250 a 400 cc. y una media de llenado de 311,3 cc. Empleamos también 22 prótesis de gel de silicón texturizadas y 2 de solución salina (todas marca Mc Ghan®) con volúmenes de 120 a 440 cc. y una media de 302,5 cc. En todas las pacientes excepto en 1, la reconstrucción se realizó en dos tiempos quirúrgicos; durante el primero se llevó a cabo la colocación del expansor tisular y en el se-

gundo, el recambio por la prótesis mamaria definitiva (Tabla I).

Técnica Quirúrgica:

Reconstrucción inmediata. Tras la mastectomía, se realiza una adecuada inspección de los colgajos cutáneos remanentes así como de la hemostasia. En los casos de pacientes con poco volumen y con una adecuada cubierta cutánea es posible colocar una prótesis mamaria en forma inmediata. Se crea un bolsillo submuscular, elevando el borde lateral del pectoral mayor y realizando una disección medial e inferior del bolsillo para colocar el expansor tisular. Para una cobertura total del mismo, puede usarse el pectoral menor y los músculos serratos para la cobertura lateral. El borde inferior puede cubrirse con un colgajo de músculo recto anterior o con el colgajo cutáneo siempre y cuando éste tenga un grosor adecuado. Colocamos un expansor tisular texturizado anatómico con válvula integrada. Dejamos un drenaje cerrado en axila en el sitio de la disección ganglionar, y otro en la región mamaria; ambos se sacan por contrabertura y se suturan a la pared torácica con nylon 3-0. El cierre se hace por planos y dejamos un vendaje con apósitos. Los drenajes se retiran en un promedio de 7 a 15 días. La expansión tisular se inicia 1 mes después de la cirugía con infiltraciones semanales de un 10% de la capacidad total del expansor hasta alcanzar un 150 % de su volumen. Una vez alcanzado el volumen máximo, se deja un periodo de 3 meses antes de sustituir el expansor por la prótesis mamaria definitiva. Tres meses más tarde, se realiza la reconstrucción del complejo areola-pezones (CAP) y la cirugía de la mama contralateral para simetrización, cuando así lo desean las pacientes.

Reconstrucción diferida. La tendencia actual se encamina hacia la reconstrucción mamaria inmediata, pero en aquellos casos en los que por preferencia del oncólogo o de la paciente no se hace así, la reconstrucción puede llevarse a cabo en cualquier momento pero, preferentemente, una vez pasado el periodo de quimioterapia para disminuir la morbilidad asociada a la inmunosupresión secundaria a la misma. Sin embargo, es posible realizar la expansión tisular durante el período de administración de la quimioterapia sin que se incremente dicha morbilidad. El abordaje final será el mismo, e incluso en este momento, se puede aprovechar para retirar el catéter de la quimioterapia en caso de que haya concluido la misma.

Sea cual sea el tiempo de la reconstrucción, el segundo procedimiento quirúrgico permite precisar el sitio del surco submamario definitivo; realizar una capsulotomía para liberar los tejidos blandos proporcionando una mayor proyección y ptosis natural a la nueva mama; así como reevaluar la altura y el ancho de la mama para lograr una mayor simetría con la mama contralateral; y desde luego, en este tiempo quirúrgico, se puede llevar a cabo también el procedimiento de simetrización de la mama contralateral.

Reconstrucción del CPA. La reconstrucción del pezón se realizó mediante colgajos locales para pezón en 6 casos o injerto libre de hemipezón contralateral en 2 casos (aquellos unilaterales con pezón contralateral grande). La reconstrucción de la areola se realizó con injerto de piel de espesor total tomado de la superficie interna del muslo en 5 casos y con tatuaje en 3 casos.

Complicaciones Inmediatas.

Necrosis del colgajo cutáneo: especialmente en fumadoras o cuando los colgajos de la mastectomía se han tallado demasiado delgados. Si los colgajos se encuentran pobremente irrigados durante la cirugía, lo ideal sería resecar dicho tejido hasta encontrar bordes sanos y san-

grantes; así mismo es importante una cobertura del implante con músculo para que en caso de sufrimiento de la piel, no se exponga el expansor (5).

Infección: es infrecuente pero grave, llegando a requerir extracción del expansor o de la prótesis. De forma ideal, el siguiente procedimiento quirúrgico debería diferirse entre 3 y 12 meses.

Exposición del expansor o de la prótesis: frecuentemente es el resultado de haber empleado un volumen excesivo, de la aparición de un hematoma, infección o de no haber tenido en cuenta una cobertura cutánea inadecuada; muy frecuentemente, se produce en pacientes radiadas en las que por la calidad de los tejidos, estaba contraindicado el procedimiento.

Tabla I:
Datos de las pacientes del grupo de estudio

PACIENTE	CIRUGÍA	EXPANSOR	TX ADYUVANTE	COMPLICACIONES	CIRUGÍA	PRÓTESIS
1	MRM	400cc (I)	QUIMIO	EPIDERMOLISIS	I-CAMBIO	395cc
2	MP	300cc (D)	NO	CCB GIV	B-CAMBIO	295cc
3	CUAD MRM	300cc(D) 400cc(I)	QUIMIO+RAD QUIMIO	NO NO	I-CAMBIO D-CAMBIO +T CAP	215cc 440cc
4	MRM	300cc(D)	QUIMIO	NO	D-CAMBIO +REC CAP	340cc
5	MRM	300cc(I)	QUIMIO	NO	I-CAMBIO +REC CAP	330cc
6	MS	300cc(D)	NO	NO	B-CAMBIO +REC CAP	280cc
7	MRM MRM	SS ROTA (I) SS 120cc(I)	QUIMIO QUIMIO	NO MAL POS	I-CAMBIO	120cc
8	MRM	300cc(I)	QUIMIO	NO	I-CAMBIO +REC CAP	310cc
9	MRM	300cc(I)	QUIMIO	NO	I-CAMBIO +T CAP	400cc
10	CUA	300cc(I)	QUIMIO	NO	D-CAMBIO	240cc
11	MRM	300cc(D)	QUIMIO	NO	D-CAMBIO +T-CAP	340cc
12	MRM	300cc(I)	QUIMIO	NO	I-CAMBIO	330cc
13	MRM	300cc(D)	QUIMIO	NO	D-CAMBIO	310cc
14	MRM	400cc(I)	QUIMIO	NO	D-CAMBIO +REC CAP	400cc
15	MP	300cc(I)	NO	NO	B-CAMBIO	310cc
16	MRM	300cc(I)	QUIMIO	NO	I-CAMBIO	310cc
17	MRM	300cc(D)	QUIMIO	NO	D-CAMBIO	395cc
18	CUAD	250cc(I)	QUIMIO	NO	D-CAMBIO	215cc
19	MRM	300cc(D)	QUIMIO	NO	I-CAMBIO	310cc

MRM, mastectomía radical modificada, MP mastectomía profiláctica, CUAD cuadrantectomía, MS mastectomía simple; (I) inmediata, (D) diferida; QUIMIO, quimioterapia, RAD, radioterapia; CCB, contractura capsular bilateral, GIV grado cuatro; I, izquierda, D, derecha, B, bilateral, T tatuaje, CAP, complejo areola pezón, REC, reconstrucción.

Hematoma: se previene mediante una hemostasia cuidadosa. Su presencia obliga a una reintervención temprana para drenaje. Esta complicación puede ser advertida tempranamente cuando se emplean drenajes por sistema cerrado al vacío. Cuando se ha llevado a cabo disección ganglionar en la axila, siempre es conveniente dejar 2 drenajes: 1 en axila y otro en la región mamaria.

Seroma: se observa más frecuentemente cuando se requiere resección ganglionar así como cuando se realizan despegamientos tisulares amplios. Este tipo de complicación puede reducirse con el uso prolongado de drenajes. El drenaje por punción está contraindicado por la posibilidad de perforar el expansor.

Complicaciones tardías:

Contractura capsular: todas las prótesis forman una cápsula a su alrededor que será asintomática e inadvertida, pero que en el caso de alcanzar un grado IV según la clasificación de Baker, requerirá reintervención quirúrgica con capsulotomía o capsulectomía con probable sustitución de la prótesis y en casos persistentes, la reconstrucción mamaria definitiva con tejido autólogo.

Por lo general, existe contractura capsular en el 10% de las pacientes no radiadas y en el 40% de las pacientes radiadas (6).

Rotura de la prótesis: en caso de rotura de la prótesis se presentará una deformidad progresiva de la mama, lo que requiere una reintervención quirúrgica con exploración y sustitución de la misma.

Malposición de la prótesis: esta complicación es más frecuente cuando se realiza la reconstrucción inmediata con prótesis, indicada en pacientes muy delgadas con poco volumen mamario; para evitar el desplazamiento de la prótesis es recomendable poner puntos a la dermis que delimiten el espacio de la disección durante la mastectomía.

Resultados

Se realizaron un total de 24 reconstrucciones mamarias en 19 pacientes en un período de tiempo de 10 años, 14 unilaterales y 5 bilaterales; de éstas últimas, en 4 casos fueron operadas las 2 mamas al mismo tiempo y 1 con una diferencia de 2 años entre la mama izquierda y la mama derecha.

Las edades de las pacientes estuvieron entre los 26 y los 62 años de edad, con una media de 49,37 años (Tabla I).

En cuanto a la etiología de la mastectomía, fue profiláctica en 4 casos (16,6%); por hidradenitis supurativa (enfermedad de Verrnehuil) en 2 casos (8,3%); en 17 por carcinoma mamario que no requirió radioterapia (70,8%) y en 1 caso por carcinoma mamario que recibió radioterapia postmastectomía (4,1%).

La reconstrucción fue inmediata a la mastectomía en 13 casos (54,1%) y diferida en 11 (45,8%).

Los expansores utilizados en todos los casos fueron biodimensionales texturizados con válvula integrada (133 MV Mc Ghan® Medical Corporation, Santa Barbara, California, EEUU).

Hubo 16 pacientes que recibieron quimioterapia de las cuales, 11 fueron reconstruidas en forma inmediata postmastectomía y la expansión se llevó a cabo durante la administración de la quimioterapia.

El período entre la colocación del expansor y el cambio por la prótesis definitiva fue de 6 a 10 meses. Los implantes utilizados fueron de gel de silicona en 22 casos y de solución salina en 2. El seguimiento de las pacientes fue de 2 a 10 años. Solamente hubo 1 caso de cuadrantectomía en el que se realizó la reconstrucción de forma diferida ya que tenía antecedentes de radioterapia en la mama a reconstruir (4,1%).

En cuanto a las complicaciones presentadas en este grupo de pacientes representaron un 16,6% del total,



Fig. 1: Caso 6 Tabla I: mujer 32 años de edad con antecedente de 14 cirugías previas por hidradenitis supurativa de 17 años de evolución. Preoperatorio.



Fig. 2: Postmastectomía simple con resección de complejo areola-pezones (CAP) bilateral.

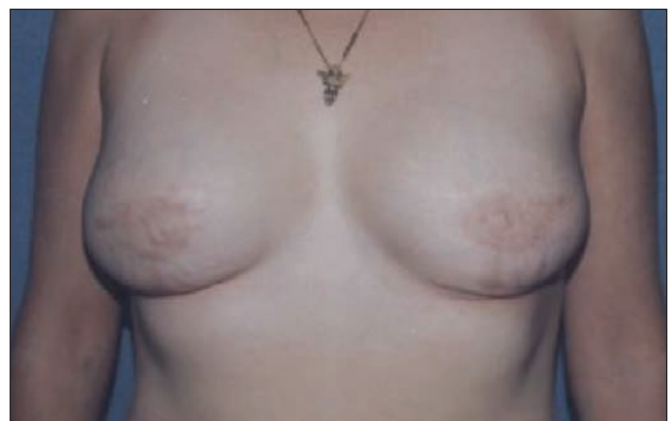


Fig. 3: Imagen a los 7 años de postoperatorio de reconstrucción mamaria con expansor tisular, implante y reconstrucción de CAP.



Fig. 4: Caso 7 Tabla I: mujer de 59 años de edad. Postoperatorio a los 9 años de mastectomía izquierda con reconstrucción inmediata mediante prótesis de solución salina de 120cc. Acude por rotura de la prótesis.



Fig. 5: Postoperatorio tras cambio del implante mamario izquierdo.



Fig. 6: Un año después es sometida a mastectomía radical modificada derecha y reconstrucción inmediata con prótesis de solución salina 120 cc.

siendo: contractura capsular que ameritó retirada de las prótesis y reconstrucción con tejido autólogo en 2 casos (8,3%) mediante un colgajo TRAM pediculado bilateral (paciente 2 de la Tabla I) (7); epidermólisis superficial que se resolvió con tratamiento conservador en 1 caso (4,1%); malposición del implante en 1 caso (4,1%).

En cuanto a la satisfacción por parte de las pacientes con el procedimiento realizado, 1 no estuvo satisfecha (5,2%), 2 estuvieron poco satisfechas (10,5%), 7 satisfechas (36,8%) y 9 manifestaron estar muy satisfechas con los resultados obtenidos (47,3%).

A modo de ejemplo del grupo de estudio, describimos y presentamos en imágenes 4 de los casos tratados en las figuras 1-10.

Discusión

Las técnicas modernas proveen numerosas opciones de reconstrucción postmastectomía encaminadas a mejorar la calidad de vida de las pacientes en comparación con las no sometidas a reconstrucción mamaria (8). Publicaciones recientes proponen la reconstrucción autóloga como un método superior a la reconstrucción mediante expansor tisular e implante mamario definitivo, por presentar resultados estéticos superiores y una mayor duración de los mismos. Sin embargo, hay que tener en cuenta también que la expansión tisular con implantes puede restaurar la forma con una mínima morbilidad (9). Strock presenta un 10,5% de complicaciones entre las que destaca: malposición en una 3,5%, infección en un 4%, ruptura en un 1,8%, extrusión traumática en un 0,6% y contractura capsular en un 0,6% (10). Alderman describe cómo los factores más importantes asociados con un mayor porcentaje de complicaciones fueron el momento de la reconstrucción y el índice de masa corporal de las pacientes, de manera que tanto la reconstrucción inmediata como la obesidad presentaron un mayor número de complicaciones que a su vez fueron de tipo mayor. No se encontraron diferencias significativas en el porcentaje de complicaciones a 2 años entre la reconstrucción hecha con implante y con tejido autólogo o entre la reconstrucción empleando colgajo TRAM pediculado y libre (11). Spears concluye que la reconstrucción protésica es significativamente menos cara y utiliza menos recursos que la alternativa de emplear colgajo TRAM (12). Casado refiere los beneficios de la utilización del colgajo DIEP, señalando en su serie cómo contraindicaciones para la realización del mismo básicamente a la existencia de abdominoplastia previa y los antecedentes de radioterapia adyuvante postreconstrucción inmediata. Sin embargo, aunque son varios los factores a tener en cuenta, finalmente el coste del procedimiento no debería determinar en sí el tipo de reconstrucción a practicar (13).

En el presente trabajo recogimos un 16,6% de complicaciones con seguimiento a largo plazo, porcentaje que consideramos aceptable y que refleja la selección hecha de las pacientes para ser sometidas a este tipo de reconstrucción.

Conclusiones

La reconstrucción mamaria postmastectomía con expansor tisular e implante es un procedimiento seguro, reproducible y con bajo índice de complicaciones.

La administración de quimioterapia durante la expansión no incrementa las complicaciones postoperatorias. La adecuada selección de las pacientes favorece la consecución de resultados satisfactorios.



Fig. 7: Caso 4 Tabla I: mujer de 49 años de edad, postoperatorio de mastectomía radical modificada derecha.



Fig. 9: Caso 3 Tabla I: mujer de 58 años de edad operada de cuadrantectomía mama izquierda con radioterapia postoperatoria 13 años antes. Imagen de preoperatorio de mastectomía derecha.



Fig. 8: Imagen a los 5 años de reconstrucción mamaria diferida con expansor tisular e implante y reconstrucción del CAP.



Fig. 10: Postoperatorio a los 3 años de expansión tisular e implantes bilaterales.

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TRABAJO DE INVESTIGACIÓN



Eficacia del recambio de implantes mamarios y el cambio de plano quirúrgico en el tratamiento de la contractura capsular tipo Baker

Efficacy of the replacement of breast implants and change of surgical plane in the treatment of Baker capsular contracture

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Palabras clave:

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aumento

Key words:

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Los autores de este
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RESUMEN

La contractura capsular es la complicación más común de las mamoplastias de aumento que puede requerir reintervención quirúrgica. El estándar de oro para corregirla es la capsulectomía total, un procedimiento traumático. El objetivo de este trabajo es proponer una técnica quirúrgica para corregir la contractura capsular con recambio de implantes mamarios y cambio de plano quirúrgico. Realizamos un estudio transversal descriptivo de 10 pacientes, con contractura capsular tipo Baker Grados III y IV. Previo a la intervención, todas presentaban distorsión en el implante y en la forma de la mama, firmeza o rigidez palpable, sensación de tensión y endurecimiento, dolor y contractura visible y palpable. Se obtuvieron resultados estéticos favorables y una mejora en bienestar psicológico de las pacientes. Sólo una paciente tuvo recurrencia de la contractura capsular de tipo Baker Grado II y no requirió reintervención. Concluimos que es una alternativa de tratamiento innovadora, menos traumática y que reduce la probabilidad de recurrencia por recolocar el implante en un plano virgen.

ABSTRACT

Capsular contracture is the most common complication of breast augmentation that may require surgical reintervention. The gold standard to correct it is total capsulectomy, a traumatic procedure. The objective of this work is to propose a surgical procedure to correct capsular contracture with replacement of breast implants and change of surgical surface. We carried out a descriptive cross-sectional study of 10 patients, with Baker III and IV Grade capsular contracture. Prior to the surgery, all the patients had distortion in the implant and in the shape of the breast, firmness or palpable rigidity, tension and hardening sensation, pain and visible and palpable contracture. Positive aesthetic results were obtained as well as an improvement in the psychological well-being of the patients. Only one patient had a recurrence of the Baker II Grade capsular contracture and did not require reoperation. We conclude that it is an alternative innovative treatment, less traumatic and one that reduces the likelihood of recurrence by repositioning the implant on a virgin surface.

INTRODUCCIÓN

La mamoplastia de aumento ha tenido una evolución continua desde los años 60 con la introducción de los implantes mamarios y las técnicas empleadas en la actualidad. La colocación de implantes de silicón o de solución salina con propósitos estéticos o reconstructivos se ha vuelto uno de los procedimientos más comunes que realizan los cirujanos plásticos en respuesta al concepto estético de la mama. No existen cánones de belleza establecidos

para la forma y volumen, que varían según la moda, costumbres y gustos.¹⁻⁴ Los implantes mamarios tienen una vida útil limitada, lo que implicaría una nueva cirugía; en promedio, la vida útil esperada es entre 10 y 20 años y está influida por diversos motivos como el tipo de implante, tipo de cirugía realizada, cicatrices, compresión repetitiva excesiva, infecciones, ruptura y otros.⁵⁻⁹ Como todo procedimiento quirúrgico, pueden existir complicaciones como hematoma, seroma, infección, alteración de la sensibilidad del pezón, asimetría, ruptura



del implante y contractura capsular.¹⁰⁻¹⁴ Esta última representa la complicación y resultado adverso más frecuente de la cirugía de mama estética y reconstructiva, que alcanza una incidencia hasta del 59% y es una de las causas más comunes de reintervención quirúrgica postimplantación, especialmente durante el primer año, pero puede ocurrir hasta 10 años después.¹ La forma resultante de la mama, la sensación a la palpación, la simetría de ambas mamas y la consistencia del implante son puntos clave para una cirugía exitosa.² Prevenir la contractura capsular es vital para obtener resultados óptimos, pero, a pesar de que existen varios métodos para reducir la incidencia de su formación, no siempre es posible evitarla.^{5-7,15} Este estudio tiene como objetivo mostrar los resultados obtenidos en el recambio de implantes con cambio de plano quirúrgico en pacientes con contractura capsular grado III y IV.

MATERIAL Y MÉTODO

Realizamos un estudio observacional, descriptivo, transversal y retrospectivo. La información se obtuvo bajo consentimiento informado firmado, a partir de los expedientes clínicos disponibles en el Hospital Angeles de Puebla, de pacientes reintervenidas quirúrgicamente con técnica de cambio de implantes mamarios y de plano quirúrgico, en el periodo de enero de 2008 a diciembre de 2012. Los criterios de inclusión fueron los siguientes: edad entre 17 y 50 años, que tuvieran una sola mamoplastia de aumento previa al estudio (realizada con cualquier técnica), que presentaran contractura capsular grados III o IV de Baker y que, después de intervenidas para corrección de la contractura, siguieran los cuidados médicos indicados y acudieran a seguimiento por dos años. Se excluyeron los expedientes de aquellas pacientes que hubieran sido operadas previamente para corrección de contractura capsular al momento del estudio, con antecedente de cirugía reconstructiva por neoplasia mamaria, con antecedentes de trauma mamario posterior a mamoplastia de aumento o con diagnóstico de dehiscencia o infección postquirúrgica al momento de la corrección. En total, valoramos a 18 pacientes, de las que 10 que cumplían con los criterios mencionados

aceptaron ser incluidas en el estudio. Para la presentación de los resultados utilizamos estadística descriptiva, analizando las siguientes variables: edad, acceso quirúrgico, tipo, marca y forma del implante, volumen del implante, posición del implante, distorsión del implante, distorsión de la forma de la mama, firmeza o rigidez palpable, sensación de tensión de la mama, endurecimiento de la mama, mastalgia espontánea, contractura visible y palpable, grado de contractura capsular, plano quirúrgico previo, bienestar físico, bienestar psicosocial, bienestar sexual, grado de satisfacción personal y postquirúrgico. Todas las pacientes tenían el antecedente de mamoplastia de aumento previa y se reintervinieron con la técnica propuesta para corregir la contractura capsular grado III o IV de Baker. La clasificación de la contractura la realizó el cirujano plástico encargado de las pacientes, por medio de exploración física y ultrasonográfica. Utilizamos hojas de recolección de datos modificadas de las validadas por Pusic y colaboradores,¹⁶ que incluían una serie de 45 preguntas divididas en dos partes: la primera, con 26 preguntas, fue para obtener los datos antes de la cirugía, y la segunda, con 19 preguntas, para recabar información después de la resolución de la contractura capsular. Con las hojas de recolección de datos se evaluaron los datos clínicos y psicológicos de las pacientes antes y después de la cirugía, utilizando una escala del 1 al 10, donde 1 fue la calificación mínima y 10 la máxima. La técnica quirúrgica utilizada consistió en emplear la misma incisión de la mamoplastia de aumento previa, retiro del implante, disección de la cara anterior de la cápsula para rayar con electrocauterio toda la superficie interna de la cápsula y así ayudar a su integración al cuerpo. Posteriormente, se realizó el cambio de plano quirúrgico disecando una nueva bolsa; es decir, si el viejo implante estaba en posición subglandular, se disecó la nueva bolsa en el plano submuscular y, si el implante estaba submuscular, la nueva bolsa quedaría subglandular. Finalmente se colocó el nuevo implante en el plano virgen, con doble esquema de manejo médico, previa aplicación de 1 gramo de ceftazidima o una ampollita de gentamicina, más una ampollita de esteroide de depósito. Este doble esquema se fundamentó en la teoría etiológica más sus-

Cuadro I. Datos de la mamoplastia de aumento previa y de los implantes mamarios que se retiraron.

Paciente	Edad de la paciente (años)	Tipo de incisión quirúrgica	Posición	Forma	Cubierta	Relleno	Volumen (cm ³)	Marca del implante	Diagnóstico preoperatorio
1	28-32	Inframamaria	Subglandular	Redonda	Texturizada	Gel altamente cohesivo	400	COI	Baker III
2	23-27	Periareolar	Subglandular	Redonda	Texturizada	Gel altamente cohesivo	340	Mentor	Baker IV
3	28-32	Inframamaria	Subglandular	Redonda	Texturizada	Gel altamente cohesivo	410	COI	Baker IV
4	33-37	Periareolar	Submuscular	Redonda	Texturizada	Gel altamente cohesivo	350	COI	Baker IV
5	33-37	Periareolar	Submuscular	Redonda	Lisa	Gel altamente cohesivo	280	COI	Baker III
6	23-27	Inframamaria	Subglandular	Redonda	Texturizada	Gel altamente cohesivo	320	Mentor	Baker III
7	28-32	Periareolar	Subglandular	Redonda	Texturizada	Gel altamente cohesivo	340	COI	Baker IV
8	28-32	Periareolar	Subglandular	Redonda	Texturizada	Gel altamente cohesivo	340	Mentor	Baker III
9	28-32	Inframamaria	Subglandular	Redonda	Texturizada	Gel altamente cohesivo	410	PIP	Baker III
10	33-37	Inframamaria	Subglandular	Redonda	Texturizada	Gel altamente cohesivo	410	PIP	Baker III

Cuadro II. Características clínicas de las pacientes incluidas en el estudio antes y después de la corrección de contractura capsular.

Características clínicas	Preoperatorio	Postoperatorio (seis meses después)
Distorsión en implante	5.3	1.6
Distorsión en forma de la mama	6.9	2.1
Firmeza o rigidez palpable	6.3	1.8
Sensación de tensión en mama	6.9	1.3
Endurecimiento de mama	6.8	1.2
Dolor por sí solo	4.8	1.4
Dolor a la palpación	7.2	1.3
Contractura visible	6.4	1.1
Contractura palpable	6.5	1.1
Implante se movió de posición original	3.8	1.4

tentada de la contractura que es la bacteriana. De igual manera, el rayado de la cápsula, en lugar de escindirla, favorece su integración al cuerpo y cicatrización del plano quirúrgico

utilizado.⁹ Los datos obtenidos del expediente clínico se trataron con confidencialidad y veracidad, en apego a la Ley General de Salud en México,¹⁷ y coherente con la Declaración de Helsinki.¹⁸

RESULTADOS

El promedio de edad de las pacientes fue de 30.5 años (rango de 23 a 37) y el promedio de volumen de los implantes retirados fue de 360 mL (rango de 280 a 410 mL). Seis pacientes tenían contractura capsular tipo Baker grado III y cuatro grado IV. La posición original de los implantes era subglandular en ocho pacientes y en dos submuscular. Seis tenían incisión periareolar y cuatro, inframamaria. Ocho tenían implantes redondos con cubierta texturizada rellenos de gel altamente cohesivo, los de una paciente tenían cubierta lisa y los de otra estaban rellenos de silicón (*Cuadros I a III*). Los implantes eran de tres marcas distintas: COI, Mentor y PIP (*Cuadro I*).

Cuadro III. Resultados del examen psicológico practicado a las pacientes incluidas en el estudio antes y después de someterse a la corrección de contractura capsular.

Características psicológicas	Preoperatorio	Postoperatorio (seis meses después)
Bienestar físico	3.2	8.6
Bienestar psicosocial	3.2	9.2
Bienestar sexual	3.6	9.1
Satisfacción con sus mamas	3.4	9.6
Autoconfianza	3.5	9.7
Satisfacción personal	3.4	9.2
Sensación de bienestar	3.3	9.3
Satisfacción con su apariencia	3.2	9.3
Satisfacción con resultado de cirugía	NA	9.2

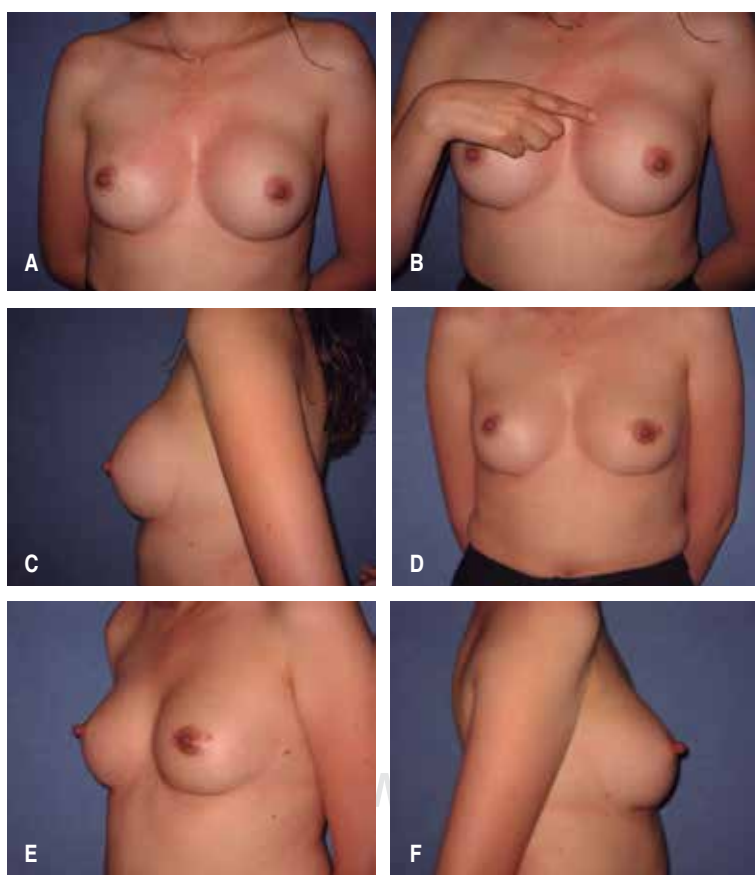


Figura 1. A-C. Paciente con diagnóstico de contractura capsular tipo Baker grado III unilateral izquierda antes de ser reintervenida quirúrgicamente. **D-F.** Paciente después de realizar recambio de implantes mamarios y cambio de plano quirúrgico por incisión periareolar.

Las valoraciones de Pusic las realizó nuestro equipo de trabajo a los seis meses de la cirugía. La valoración postquirúrgica se realizó a la semana de ser intervenidas, posteriormente a los seis meses y seguimiento al año y dos años (*Figuras 1 a 3*). Las valoraciones médicas las realizó el cirujano plástico que operó a las pacientes.

Las características clínicas prevalentes antes de la intervención quirúrgica eran dolor a la palpación, distorsión en la forma, sensación de tensión y endurecimiento de la mama. Después de la cirugía hubo una disminución notoria de todos los síntomas, especialmente en el dolor a la palpación (*Figura 4*). La calificación otorgada por las pacientes en el preoperatorio en cuanto al bienestar psicológico era baja en las variables evaluadas. Esto demostró la inconformidad de las pacientes portadoras de contractura capsular y la alteración en su calidad de vida. Al evaluar a las pacientes en el postoperatorio, la mejora fue significativa (*Figura 5*), especialmente en las variables de autoconfianza y satisfacción con sus mamas. Sólo una paciente tuvo recurrencia, que se clasificó como Baker grado II y no requirió reintervención (*Figura 3 E-H* y *Figura 5*).

DISCUSIÓN

La contractura capsular sigue siendo la complicación número uno, con una prevalencia del 15 al 39% y en algunos reportes hasta del 59%, con más de 50,000 pacientes tratadas anualmente,⁷ y es la razón primaria para una revisión quirúrgica,¹ pudiendo ser tan severa que requiera cirugías adicionales para resolverla, resultando en un gasto extra para las pacientes, un potencial para resultados subóptimos y mayores probabilidades de recurrencia.^{15,19-27}

Existen varios factores que pueden influir en la ocurrencia y el grado de formación capsular. En la actualidad, la mayoría de los cirujanos plásticos e investigadores están de acuerdo en que existen dos principales teorías de formación de la cápsula, que da como resultado la contractura: la teoría bacteriana, que implica la formación de una biopelícula y bacteriemia transitorias, y la teoría de la cicatrización hipertrófica, que involucra la presencia

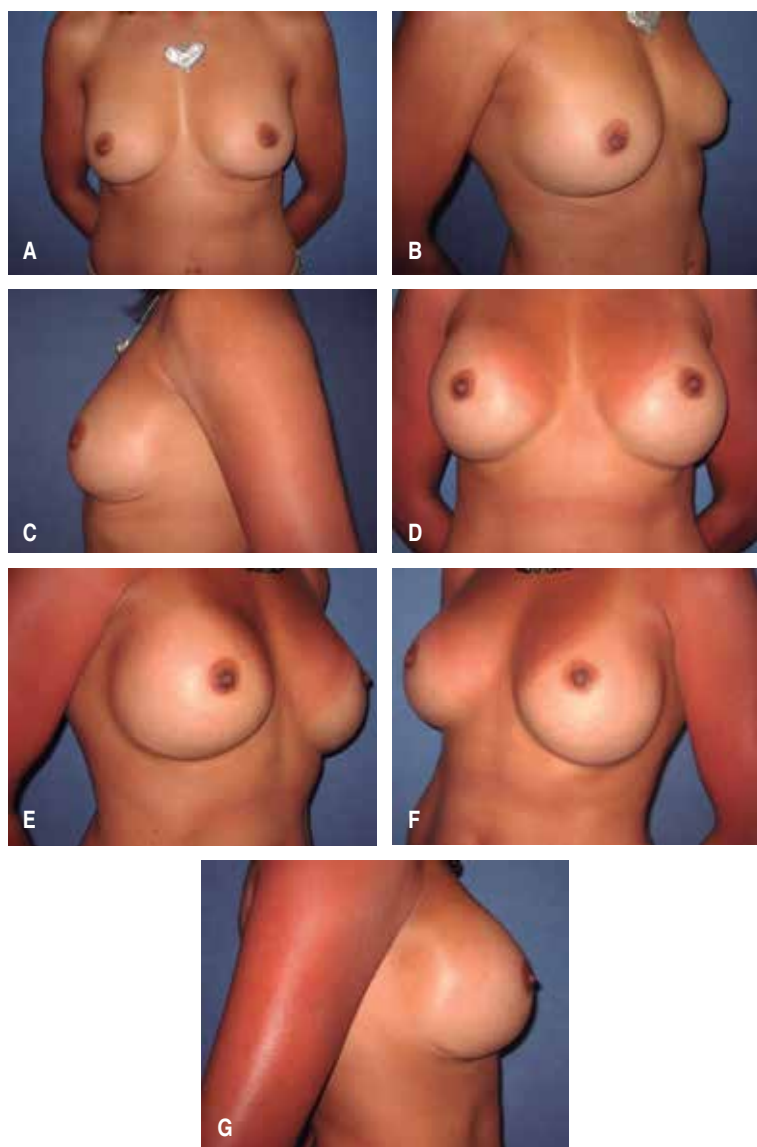


Figura 2. A-C. Paciente con diagnóstico de contractura capsular tipo Baker grado IV bilateral. D-G. Misma paciente después de haber sido intervenida quirúrgicamente con técnica de recambio de implantes y cambio de plano quirúrgico con incisión inframamaria.

de un material no infeccioso como desencadenante de la contractura.⁴⁻⁶ Sin embargo, la etiología sigue siendo un misterio, pero las referencias coinciden en que las causas son infección, sangrado, talco, algodón, seroma y la predisposición a la cicatriz hipertrófica y su fundamento es resultado de un proceso inflamatorio.^{5-7,15}

Para identificar la severidad de la contractura existen dos clasificaciones importantes: la «*Breast Augmentation Classification*» y la clasificación de Baker (*Cuadro IV*).^{7,15} El tiempo adecuado para tratar una contractura capsular, en general, va de seis a nueve meses desde el momento del diagnóstico, ya que en este periodo se alcanza el proceso de homeostasis.³

Existen tres técnicas empleadas de manera regular para este propósito, pero ninguna ofrece resultados satisfactorios al 100% en los reportes. La capsulotomía abierta o incisión de la cápsula sin removerla tiene más del 50% de tasa de recidiva y sus resultados son insatisfactorios, ya que la tensión de la cápsula no será igual en ambas mamas.¹⁵ La capsulectomía total consiste en remover toda la cápsula del implante y recolocarlos, se considera el tratamiento estándar;⁵ sin embargo, en ocasiones la cápsula puede llegar a ser muy gruesa o estar muy adherida al tejido torácico, por lo que en el intento de retirarla se pueden lesionar los músculos intercostales, provocando un neumotórax o pérdida sanguínea importante. Por otro lado, se favorece la infección del material, ya que las biopelículas son extremadamente difíciles de erradicar del elastómero de silicón del implante.⁴ Otra opción es la capsulectomía parcial, más fácil y segura que la capsulectomía total, pero con una mayor tasa de recurrencia,¹ porque la cápsula remanente actúa como nido para el desarrollo de otra contractura capsular, que se considera tejido problema porque se puede colonizar por bacterias.⁵ Por último, el cambio de plano quirúrgico consiste en reubicar un implante mamario de una posición subglandular a una posición submuscular o viceversa.⁵

El objetivo de nuestro trabajo fue demostrar la eficacia de este procedimiento en pacientes con contractura capsular tipo Baker Grado III y IV.

Después de realizar la técnica descrita, se observó una erradicación de contracturas capsulares cercana al 90% en la población estudiada. La excepción fue una paciente, quien durante el seguimiento presentó una recidiva tipo Baker Grado II, que no requirió reintervención. Lo anterior se asemeja a lo reportado por Lesavoy y colaboradores,²¹ en un estudio realizado en 2010 con 36 pacientes, en quienes

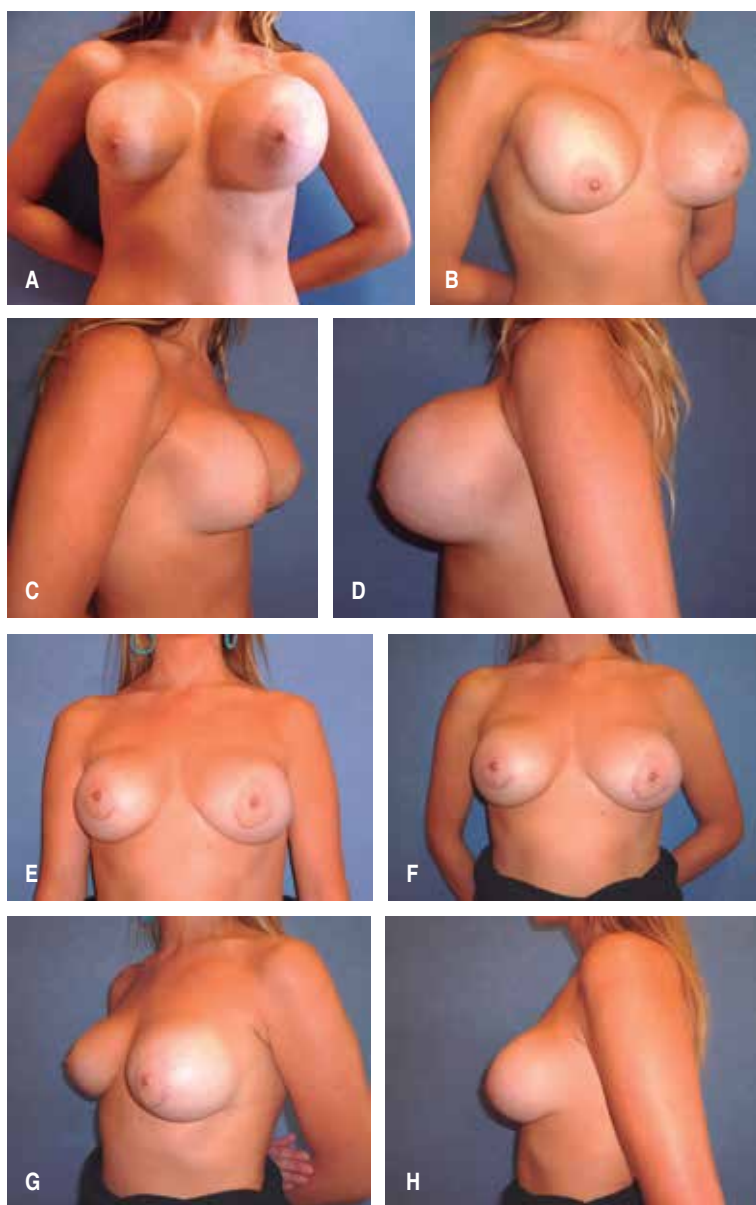
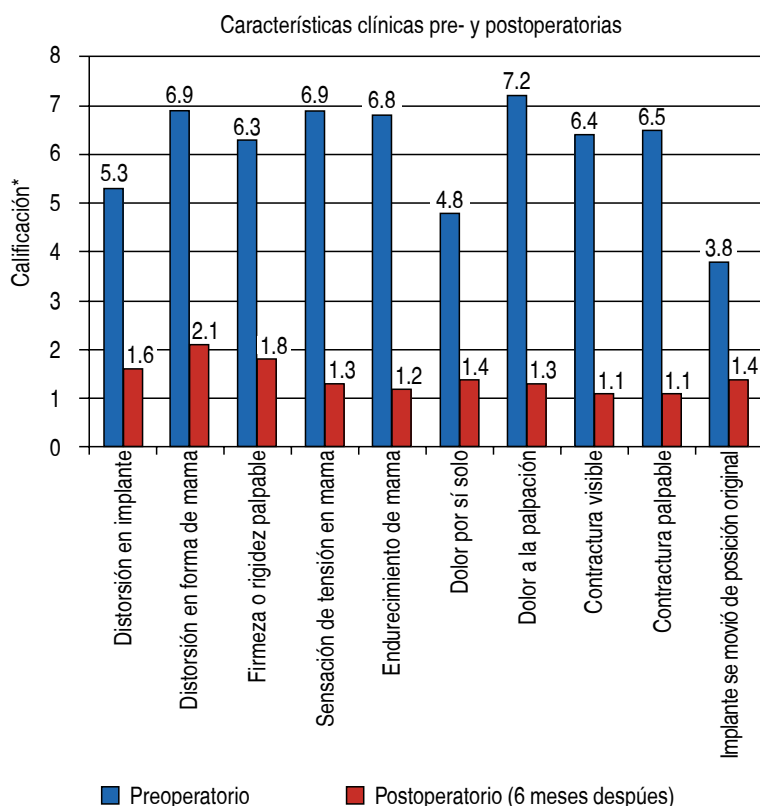


Figura 3. A-D. Paciente con diagnóstico de contractura capsular Baker grado IV bilateral. **E-H.** Paciente con diagnóstico de contractura capsular Baker grado II después de haber sido reintervenida con la técnica quirúrgica propuesta (única paciente con recurrencia).

observaron que, al cambiar de plano quirúrgico para la introducción del nuevo implante mamario se reducían al máximo las complicaciones y la contractura de la cápsula recidivante; sin embargo, es importante mencionar que existe evidencia contrastante. En el año 2000, Collis y Sharpe²² realizaron 100 capsulectomías an-

teriores en 60 pacientes y 99 capsulectomías totales en 100 pacientes, para determinar si el tipo de capsulectomía, anterior o total, afecta en la recurrencia de contractura capsular. Todas las pacientes presentaban contractura capsular subglandular tipo Baker grado III o IV. Ellos observaron recurrencia de contractura en el 50% de las pacientes del grupo de capsulectomías anteriores y 11% de las pacientes del grupo de las capsulectomías totales.

Por otro lado, Castello y colaboradores²⁴ realizaron un estudio similar con 49 pacientes, quienes tenían implantes en planos submuscular y subglandular y fueron corregidas colocándoles nuevos implantes en posición precapsular. En ambos estudios, ninguna de las pacientes presentó recidivas. Esto se puede atribuir a que en su técnica, al igual que en la utilizada en este estudio, se disecciona un plano quirúrgico virgen que disminuye significativamente el grado de recurrencias. La técnica presentada en este trabajo evita nuevas cicatrices externas, ya que se utiliza la misma incisión de la mamoplastia de aumento previa como vía de acceso para retirar el implante y colocar el nuevo. Asimismo, facilita la disección de la cápsula existente, porque sólo se disecciona o se radia la parte anterior, dejando la parte posterior intacta adherida a la pared torácica o al músculo pectoral mayor, según sea el caso; esto con el fin de retirar el implante anterior y poder rayar toda la superficie interior de la cápsula con el objetivo de obtener tejido sano y favorecer su integración al cuerpo y cicatrización del plano quirúrgico. Las características de los implantes también es relevante. En nuestro estudio, nueve pacientes tenían implantes rellenos de gel altamente cohesivo y una de silicón. Esto cobra importancia, ya que el relleno del implante es un factor que puede propiciar la contractura capsular. Si un implante relleno de silicón se llega a perforar, éste se empieza a esparcir dentro de la mama, estimulando la formación de una cápsula como reacción a cuerpo extraño, mientras que si un implante relleno de gel altamente cohesivo se perfora, por su alta cohesividad se mantendrá unido y dentro del implante sin importar la perforación. Con este fundamento se decidió emplear implantes de gel altamente cohesivo en todas las pacientes de este estudio.²



* Calificación otorgada por las pacientes donde 1 representa la mínima y 10 la máxima.

Figura 4. Comparación de características clínicas y calificación otorgada por las pacientes en el pre- y postoperatorio.

En cuanto a las complicaciones, Lee y colaboradores²³ reportaron dos casos de hematoma y tres de reincidencia de contractura tipo Baker grado III, mientras que Castello²⁴ refirió no haber presentado algún caso de recidiva, pero reportó como complicaciones un caso de seroma que requirió exploración quirúrgica y aspiración una semana después de su cirugía y un caso de hematoma que necesitó de evacuación al quinto día del postoperatorio. A diferencia de estos reportes, en nuestro estudio no se documentó ninguna complicación postoperatoria ni temprana ni tardía. El caso de recidiva no requirió reintervención, ya que sólo las de grado III y IV las ameritan.

El tiempo ideal de seguimiento de las pacientes postoperadas por corrección de contractura capsular es de cinco años, con consultas cada seis meses.¹⁵ A las pacientes de nuestro estudio las valoramos a la semana

de intervenidas, a los seis meses y se les dio seguimiento durante 18 a 24 meses. Se ha observado que con un tiempo de seguimiento mínimo de 18 meses con consultas cada seis meses es suficiente, porque si la cápsula se desarrolla nuevamente, lo hará en un tiempo no mayor a un mes.

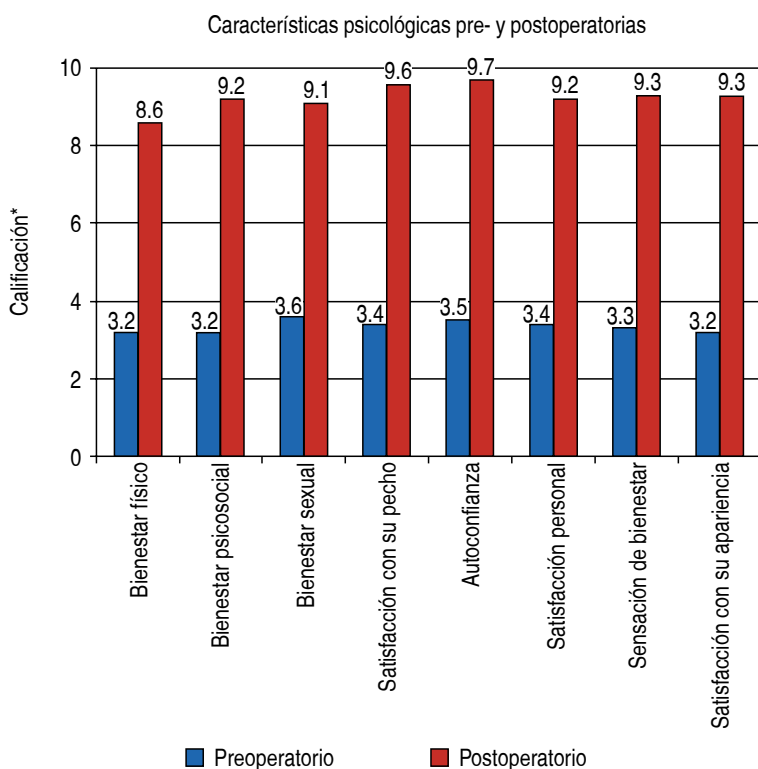
En la encuesta aplicada observamos que el 90% de las pacientes calificó con 9.2 (en una escala del 1 al 10, donde uno representa la mínima y 10 la máxima) y sólo una calificó con ocho (*Cuadro III*). Las cirugías estéticas no sólo mejoran la apariencia, también la autoestima y autoconfianza, y favorecen la calidad de vida de las pacientes. Por este motivo, nuestro equipo realizó una evaluación psicológica que demostró una mejora significativa después de la intervención.

El éxito observado con esta técnica no sólo representa el procedimiento quirúrgico *per se*, también al seguimiento de las medidas básicas, tales como el correcto lavado de manos, uso de guantes libres de talco, cambio de guantes para disecar el nuevo plano, manipulación de los nuevos implantes sólo por una persona, colocación de implantes texturizados rellenos de gel altamente cohesivo, lavado y aplicación de antibióticos y esteroides en la nueva bolsa y tratar de efectuar el menor traumatismo posible a la paciente.^{10,13,15,27} Se considera que el único caso con recidiva se deba al propio sistema inmune de la paciente, ya que con ella se siguieron las mismas medidas; sin embargo, al aplicar la encuesta quedó satisfecha con los resultados obtenidos y la contractura capsular que tenía no era notoria y poco dolorosa (*Figura 3 E-H*).

La mayor limitante del trabajo fue el concepto de belleza distinto entre las pacientes, que se intentó resolver escuchando los intereses individuales. Otra limitante fue el seguimiento de las pacientes durante el tiempo establecido, las pocas pacientes reclutadas y el hecho de seleccionar pacientes con sólo una mamoplastia de aumento previa sin otras intervenciones correctivas.

CONCLUSIÓN

La técnica de recambio de implantes con cambio de plano quirúrgico expuesta en este



* Calificación otorgada por las pacientes donde 1 representa la mínima y 10 la máxima.

Figura 5. Comparación de características psicológicas y calificación otorgada por las pacientes en el pre- y postoperatorio.

Cuadro IV. Clasificación de Baker.²⁸

Grado	Descripción
I	Mama absolutamente natural, nadie podría decir que fue aumentada
II	Contractura mínima, el cirujano puede decir que se realizó una cirugía, pero no tiene alguna queja
III	Contractura moderada, la paciente siente algo de rigidez o firmeza
IV	Contractura severa, obvia a la observación

trabajo es una opción útil, innovadora y efectiva de reintervención quirúrgica, que corrige la contractura capsular tipo Baker grado III y IV y al mismo tiempo reduce la probabilidad de recurrencia de contractura al colocar el nuevo implante en un plano virgen, en comparación con la capsulectomía o capsulotomía, sin necesidad de reducir el tamaño de la nueva prótesis. A su vez, al incidir sobre la misma vía de acceso

previa se obtienen mejores resultados estéticos. Los resultados estéticos y psicológicos de nuestras pacientes fueron satisfactorios. Esta técnica es una buena alternativa para corregir contracturas capsulares con bajas tasas de recidiva.

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