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ORIGINAL ARTICLE
Breast

Acellular Dermal Matrices in Breast Reconstruction: CARE Trial 5-Year Outcomes Data for More Than 9500 Patients

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Background: Few studies have assessed long-term complications in women undergoing implant-based breast reconstruction with use of an acellular dermal matrix (ADM). This study compared outcomes over 5 years in women undergoing breast reconstruction procedures with and without ADM.
Methods: Complications data in patients enrolled in the prospective Continued Access Reconstruction/Revision Expansion trial were segregated by use of ADM versus no ADM in patients undergoing primary breast reconstruction or revision-reconstruction. Continued Access Reconstruction/Revision Expansion trial evaluated long-term safety and effectiveness of shaped, textured, silicone implants.
Results: Of the 9502 women, 257 had primary (n = 160) or revision-reconstruction ($n = 97$) with ADMs; 9245 had primary (n = 6977) or revision-reconstruction ($n = 2268$) without ADMs. Capsular contracture rates in primary reconstruction were lower with ADM than without at year 5 (3.2% versus 7.4%); rates were similar at year 1 (≤2.4%). Capsular contracture rates in revision-reconstruction were lower with ADM than without at year 5 (1.4% versus 8.9%); rates were similar at year 1 (≤2.5%). Seroma rates were low and sustained for all cohorts throughout the 5 years (≤2.9%). Reoperation rates increased over time in all cohorts, with similar rates between groups (2.4%–47.3% from week 4 to year 5 across cohorts). Other trends over time included lower rates for asymmetry and implant malposition with ADM than without.
Conclusion: These long-term data suggest that the use of ADM in breast reconstruction procedures may provide a benefit in reducing complications, such as capsular contracture, and may sustain low rates of seroma. *(Plast Reconstr Surg Glob Open 2022;10:e4258; doi: 10.1097/GOX.0000000000004258; Published online 14 April 2022.)*

INTRODUCTION

Since 1994, acellular dermal matrices (ADMs) have been employed as soft-tissue replacement devices in many surgical procedures.[1,2] ADMs are biologic mesh-like structures or matrices derived from dermal cells (usually of human, porcine, or bovine origin) and are used in surgical scenarios in which patient tissue deficiencies necessitate cell regeneration and tissue reinforcement.[1,3,4] In implant-based breast reconstruction (IBBR) procedures, ADMs have been used for soft-tissue support to optimize breast volume and shape, help stabilize placement of the implant pocket, reinforce the skin flap, and better define the inframammary fold.[2–5] Further, ADMs are used to recreate landmarks often lost at the time of mastectomy, including the inframammary fold.[2,6] In 2019, 75% of IBBR procedures performed by member surgeons of the American Society of Plastic Surgeons used ADMs, which is 10 percentage points higher than in 2015.[7,8]

Few studies have evaluated long-term complications and outcomes with ADMs in IBBR.[9,10] Published studies with short follow-up periods of about 2 years or less suggest the use of ADMs may be associated with lower rates of capsular contracture but possibly higher rates of seroma, infection, and skin flap necrosis.[9,11–13] However, these results have not been confirmed by observations over longer periods. This study reports 5-year complications data in more than 9500 patients with and without ADM use in patients enrolled in the Continued Access Reconstruction/Revision Expansion (CARE) trial.

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Received for publication October 7, 2021; accepted February 22, 2022.

DOI: 10.1097/GOX.0000000000004258

Disclosure: *WA. Ellsworth IV is a Consultant for AbbVie, Sientra, and Worrell. J. Hammer, L. Luo, and A. Schumacher are employees of Allergan Aesthetics (an AbbVie Company), and may own AbbVie stock. This study was sponsored by Allergan Aesthetics, an AbbVie company, Irvine, California.*

The CARE trial was a 10-year prospective clinical study designed to evaluate the long-term safety and effectiveness of Natrelle 410 breast implants (Allergan Aesthetics, an AbbVie company, Irvine, Calif.) for primary breast reconstruction or revision-reconstruction.[14]

PATIENTS AND METHODS

Analyses were based on data collected from 2003 through 2014 in the CARE trial. This 10-year multicenter trial was conducted in compliance with US Food and Drug Administration requirements. Surgeons certified by the American Board of Plastic Surgery with experience placing silicone-filled implants implanted the devices at their surgical facilities. Each study site obtained approval from the relevant institutional review board before enrolling any patients. All patients provided written informed consent before surgery.

Eligibility

Only patients presenting for primary breast reconstruction or breast implant revision surgery were eligible for this analysis.[14] The accepted indications for primary breast reconstruction were mastectomy due to cancer, genetic predisposition to cancer (prophylactic mastectomy), breast trauma, and asymmetry in the contralateral breast; indications for breast implant revision surgery were previous reconstruction with silicone- or saline-filled breast implants.

Eligible patients were women, aged 18 years or older, with adequate tissue available to cover the implants and willingness to follow all study requirements. Patients were excluded if they had advanced fibrocystic disease considered to be premalignant without accompanying subcutaneous mastectomy, breast cancer without mastectomy, an abscess or infection at the time of enrollment, any disease known to impact wound healing (such as uncontrolled diabetes), tissue characteristics incompatible with implant-based breast reconstruction (such as radiation-related tissue damage or compromised vascularity), any condition that contributed unwarranted surgical risk, psychological characteristics incompatible with the surgical procedure or implant (such as body dysmorphic disorder), or an unwillingness to undergo further surgery for revision if medically required. Patients who were pregnant or nursing were ineligible.

Data Collection

All patients were scheduled for regular monitoring at 1, 2, 3, 5, 7, and 10 years after implantation and were evaluated at any unscheduled visit if an adverse event or complication occurred. Investigators documented the development of local complications and implant-related complications on standardized case report forms at the time of occurrence and reported the complications to the study sponsor. Case report forms captured whether surgical mesh was used in reconstructive procedures without naming specific products. However, American Society of Plastic Surgeons statistical data from the first year ADM use were reported (ie, 2015),[8] coupled with data from studies conducted during the time frame of the CARE trial,[3,4,9–11] suggesting that ADMs were commonly used in breast reconstructions and that Alloderm (Allergan Aesthetics, an AbbVie company, Irvine, Calif.) was the specific ADM product used most often. Data were segregated by primary breast reconstruction or revision-reconstruction cohorts and ADM use within each cohort. Patients remained in the same cohort regardless of subsequent operations.

Takeaways

Question: What are the long-term complications in implant-based breast reconstruction (IBBR) performed with acellular dermal matrix (ADM)?

Findings: A prospective study of long-term data on more than 9500 patients with IBBR demonstrated lower rates of capsular contracture with ADM than without, and low, sustained rates of seroma with and without ADM.

Meaning: Using ADM in breast reconstruction procedures may reduce complications (such as capsular contracture) and sustain low rates of seroma.

Statistical Analyses

The cumulative risks and 95% confidence intervals for the first occurrence of capsular contracture, seroma, reoperation (any breast procedure other than a planned nipple reconstruction), asymmetry, breast infection, hematoma, and implant malposition in patients undergoing primary reconstruction or revision-reconstruction with and without ADM were calculated by Kaplan-Meier methodology for nonstatistical between-group comparisons (SAS version 9.4; SAS Institute, Cary, N.C.). Patient data were censored from Kaplan-Meier analyses if they were lost to follow-up and did not experience the complication. Investigators assessed capsular contracture using the four-point Baker Classification Scale,[15] and capsular contracture was defined by the presence of Baker grades III (moderate) or IV (severe).

RESULTS

Patients

The original CARE study included 9964 patients who underwent primary reconstruction and revision-reconstruction surgeries.[14] This analysis included a total of 9502 patients across four cohorts: (1) primary reconstruction with ADM, (2) primary reconstruction without ADM, (3) revision-reconstruction with ADM, and (4) revision-reconstruction without ADM. Of the 9502 patients, 257 received primary or revision-reconstruction with ADM and 9245 patients received primary or revision reconstruction without ADM (Table 1). At the time of surgery, the median age in the cohorts ranged from 48 to 54 years. Most (73%) patients received primary reconstruction without ADMs. Information on cancer staging, cancer treatment history, and smoking status and history was not collected. Median body mass index was similar between cohorts and ranged from 22.0 to 24.0 kg per m^2. Rates of discontinuation were

Table 1. Baseline Patient Demographics*

	Primary Reconstruction with ADM(*n* = 160)	Primary Reconstruction without ADM(*n* = 6977)	Revision-Reconstruction with ADM(*n* = 97)	Revision-Reconstruction without ADM(*n* = 2268)
Mean (SD) age, y	48.0 (10.6)	49.5 (10.0)	53.7 (10.2)	53.9 (10.0)
Median age, y	48	49	54	54
Median body mass index, kg/m^2	23.1	24.0	22.0	23.6
Reconstruction type, no. (%)				
Unilateral	38 (23.8)	2220 (31.8)	27 (27.8)	786 (34.7)
Bilateral	122 (76.3)	4757 (68.2)	70 (72.2)	1482 (65.3)
Diabetes status, no. (%)				
Yes	8 (5.1)	190 (2.7)	2 (2.1)	43 (1.9)
No	150 (94.9)	6759 (97.3)	94 (97.9)	2217 (98.1)
Reason for reconstruction, no. (%)				
Mastectomy	141 (88.1)	6410 (91.9)	5 (5.2)	114 (5.0)
Prophylactic	85 (53.1)	2973 (42.6)	1 (1.03)	45 (2.0)
Contralateral augmentation	15 (9.4)	504 (7.2)	1 (1.0)	38 (1.7)
Revision	2 (1.3)	36 (0.5)	93 (95.9)	2222 (98.0)
Breast trauma	0 (0)	14 (0.20)	0 (0)	1 (0.04)
Dissatisfaction with breast	0 (0)	3 (0.04)	0 (0)	0 (0)
Ptosis	0 (0)	1 (0.01)	0 (0)	0 (0)

*Some patients did not submit a demographics form.

low and similar between groups through 5 years [ie, 5% (8/160), 4% (4/97), 6% (433/6977), and 7% (153/2268) in the primary reconstruction ADM, revision-reconstruction ADM, primary reconstruction no ADM, and revision-reconstruction no ADM cohorts, respectively]. Loss of patients to follow-up after 5 years precluded meaningful analysis of data up to the planned 10 years of the CARE trial; thus, only 5-year data are presented here. At 10 years, the overall discontinuation rate was 7%, with the greatest discontinuation rate occurring in the revision-reconstruction without ADM group (8.7%).

Capsular Contracture

Rates of capsular contracture were lower in patients with ADM than without ADM in both primary reconstruction and revision-reconstruction (Fig. 1). Although similar at year 1 post-procedure, rates of capsular contracture were lower with ADM than without ADM in patients undergoing primary reconstruction at year 5 (3.2% versus 7.4%; Fig. 1A). Rates of capsular contracture in patients undergoing revision-reconstruction were also lower with ADM than without at year 5 (1.4% versus 8.9%; Fig. 1B), with similar rates at year 1.

Seroma

Low rates of seroma were sustained throughout the trial in all cohorts (≤ 2.9%) and were comparable between groups (Fig. 2). In patients undergoing primary reconstruction (Fig. 2A), seroma rates with ADM initially were slightly higher than rates in the cohort without ADM (eg, 2.8% versus 0.9%, respectively, at 1 year), but the margin of difference between patients with ADM and without ADM subsequently narrowed (2.8% versus 1.6%, respectively, at 5 years). Rates of seroma were similar with and without ADM in patients undergoing revision-reconstruction at all time points (Fig. 2B).

Reoperations

In all cohorts, rates of reoperation increased over time, with similar rates between groups (Fig. 3). Rates of reoperation in patients undergoing primary reconstruction (Fig. 3A) ranged from 7.2% to 38.5% with ADM and 2.4% 37.1% without ADM from 4 weeks to 5 years, respectively. However, these rates remained consistent at years 3, 4, and 5 with ADM, while rates of reoperation continued to increase over time in the cohort without ADM. In patients undergoing revision-reconstruction (Fig. 3B), rates of reoperation ranged from 4.0% to 47.3% with ADM and from 2.5% to 37.0% without ADM from 4 weeks to 5 years, respectively.

Other Complications

Additional analyses showed that rates of complications were low over time in all cohorts for asymmetry, breast infection, hematoma, and implant malposition (Table 2). However, rate comparisons between groups with and without ADM showed some differences; for example, infection rates were higher throughout all time points in primary reconstruction with ADM, but lower in revision reconstruction with ADM.

DISCUSSION

Since its introduction into breast reconstruction practices in 2005, ADM use in IBBR has grown significantly.[6] More than 100,000 IBBR procedures are performed annually in the United States, and American Society of Plastic Surgeons procedural statistics show that the majority of such reconstructions involve use of ADM.[16] Surgeons have found that the use of ADM in IBBR involves benefits such as soft-tissue reinforcement and recreation of breast landmarks often lost during mastectomy.[3,6] Studies also suggest that use of ADM allows for more rapid expansion, better control of implant positioning, and greater lower pole projection.[3,6] The use of ADM has gained more popularity with a recent surgical trend toward performing more direct-to-implant and prepectoral reconstructions, mainly because of advantages, including improved control of implant position and support for overly dissected breast pockets.[17]

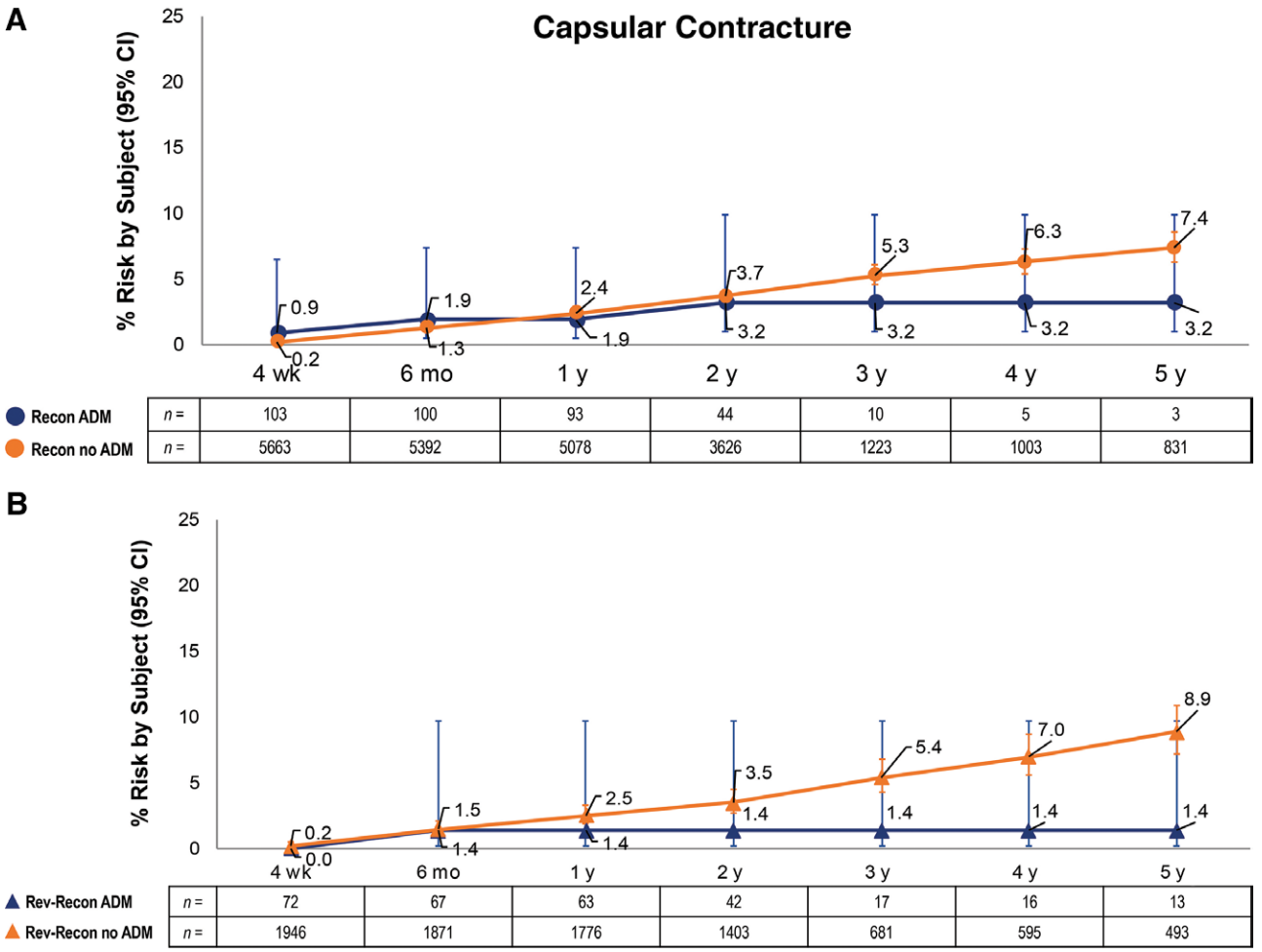

Fig. 1. Capsular contracture. Kaplan-Meier rates of capsular contracture through 5 years following (A) primary reconstruction and (B) revision-reconstruction. n = number of patients remaining.

The literature, however, remains slightly less clear regarding the longer-term complications involving ADM use. Historical reports suggested higher infection and seroma rates associated with ADM use.[9,11,12] These reports have been countered by studies showing similar complication profiles between ADM and nonADM cohorts.[4,18,19] Although some reports have suggested that the use of ADM may curb the complication of capsular contracture, limited population sizes and study durations decrease the strength of the data from such studies.[9,11,20]

To the best of our knowledge, this study represents the largest prospective trial evaluating outcomes in patients undergoing IBBR with and without ADM. This study is unique in that it presents an analysis of long-term data on the potential complications, including capsular contracture in breast reconstruction procedures performed with and without ADM in a large group of patients from a prospective study. Low rates of capsular contracture were observed over time in all cohorts; however, the ADM cohorts had relatively lower rates of capsular contracture at later time points compared with the no ADM cohorts. Low, sustained rates of seroma were observed over time and were comparable between the ADM and no ADM cohorts, particularly in the revision-reconstruction group. Rates of reoperations increased over time in all cohorts, with similar rates between groups. Unlike capsular contracture and seroma, reoperations may have multiple indications and risk factors that increase the chances of occurrence.[21]

These 5-year data lend support to the findings of shorter-term studies evaluating complications with ADM in IBBR.[9,11] A review of six studies of ADM and synthetic mesh use in breast reconstructions, representing a total of 120 patients and 186 reconstructions, found that surgeries performed with ADM or synthetic mesh yielded low rates of short-term complications (ie, over a period of ~2 years or less); for example, there was a 1.2% rate of grade III/IV capsular contracture and a 2.9% rate of seroma over a median of 6–25 months when either ADM or synthetic mesh was utilized.[11] The authors of this review also compared outcomes of procedures performed with ADM versus synthetic mesh; seroma and explantation rates tended to be higher with ADM, whereas rates of minor infections were increased with mesh, hypothetically because of the qualities of synthetic mesh.[11] A multicenter, retrospective study of prepectoral reconstructions performed with

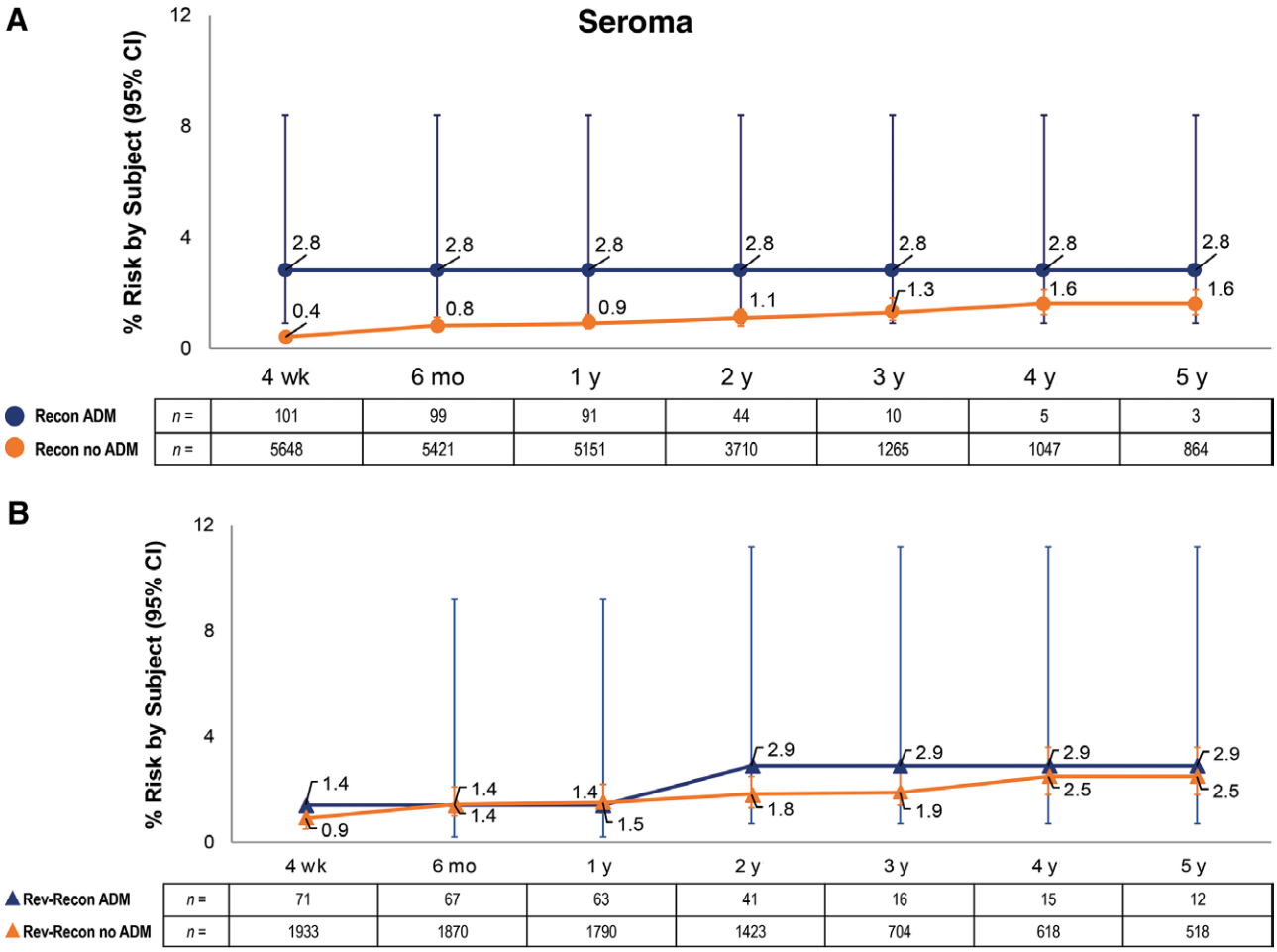

Fig. 2. Kaplan-Meier rates of seroma through 5 years following (A) primary reconstruction and (B) revision-reconstruction. n = number of patients remaining.

porcine-derived ADM, with a mean follow-up period of 22.7 months, found similar rates of capsular contracture (2.1%) at the corresponding time point of the current analysis, but higher rates of seroma (7.7%).[9] In one retrospective study with variable times of follow-up, women who had breast reconstructions using two forms of a human-derived ADM (Alloderm) had higher rates of seroma (8.4% and 9.3%) compared with any time point of the current study, and similar rates of reoperation (9.7% and 22.5%) compared with some time points of the current study.[22] Although these studies provide important clinical information on the complications that may result from the use of ADM in breast reconstruction, they were not designed to make parallel comparisons to breast reconstruction without ADM. A small prospective analysis of breast reconstruction with human-derived or porcine-derived ADM and without ADM, with a 2-year follow-up, found no statistically significant differences between groups in rates of capsular contracture and seroma.[4]

In the current study, there were no consistent trends across cohorts when comparing breast infection rates with and without ADM. Rates of infection were higher with ADM in the primary reconstruction cohort but lower in all other groups. At the same time, all cohorts had incremental increases in infection rates over time through 1, 3, and 5 years, except for the revision reconstruction group with ADM, whose rate remained consistent through all time points. Nevertheless, infection rates were low overall. A meta-analysis comparing complications with human-derived ADM and with no ADM showed an increased risk of infection with ADM, but the reasons for this increase could not be determined.[23]

Limitations

The specific surgical mesh product used in the CARE trial was not recorded, thus prohibiting speculation on the role of ADMs derived from different sources on complication rates. However, Alloderm was likely the most commonly used ADM in this trial.[3,4,9–11] Although statistical significance was not determined in this study and the population sample with ADM was small, the observed trends provide evidence to support the potential role of ADM in reducing the occurrence of capsular contracture in breast reconstruction. The impact of other factors, including patient smoking history, radiation history, cancer staging, and cancer treatment, on the development of complications with or without ADM could not be assessed in this study. Individual biases in reporting outcomes on case

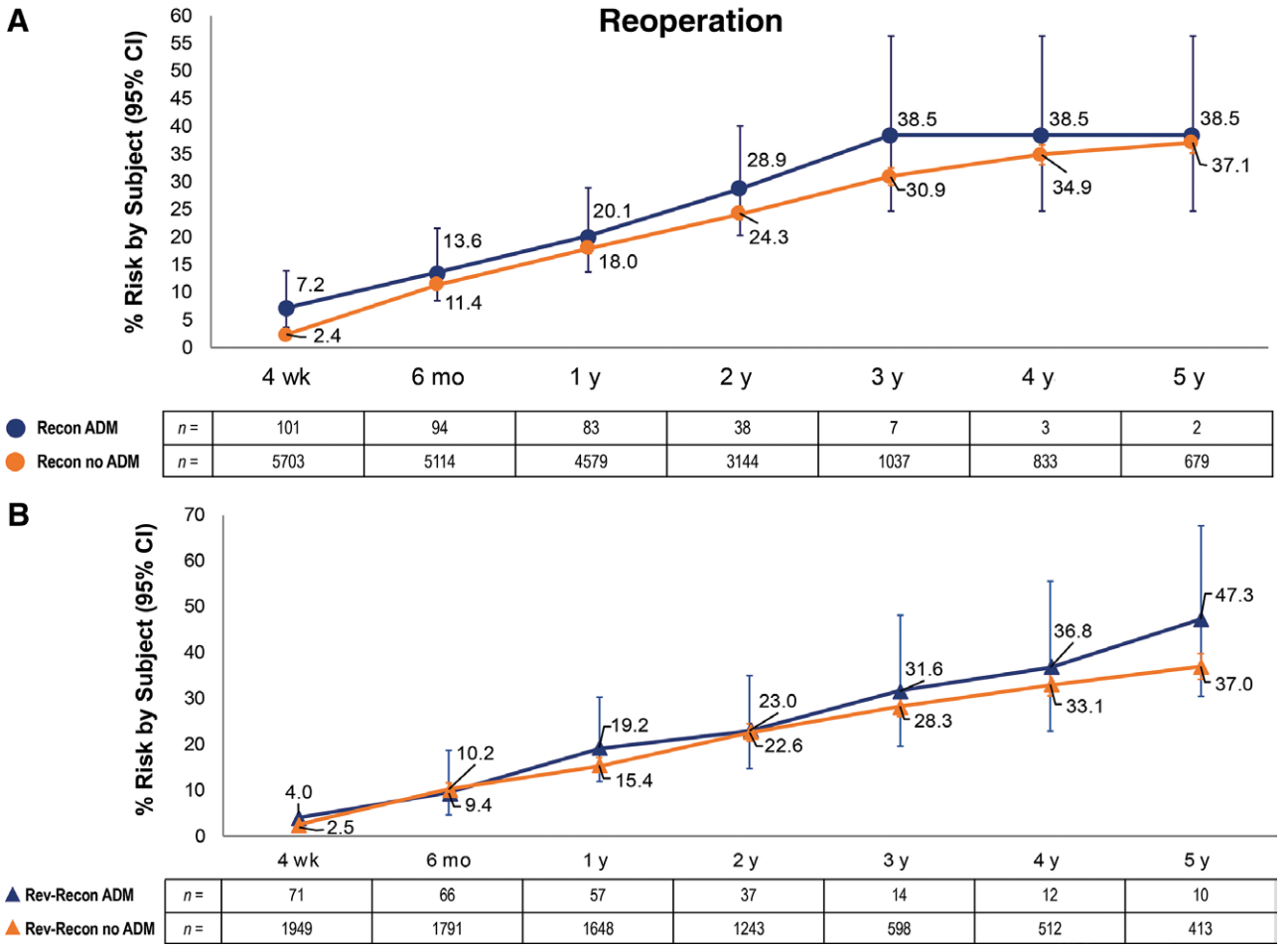

Fig. 3. Kaplan-Meier rates of reoperations through 5 years following (A) primary reconstruction and (B) revision-reconstruction. n = number of patients remaining.

report forms may have been possible and should be considered in the interpretation of the data. The outcomes from this analysis may not be applicable to all implant devices because the implant used in the CARE study (Natrelle 410) is no longer available for use. However, the potential impact of ADM in breast reconstruction remains relevant regardless of implant type.

CONCLUSIONS

Although breast reconstruction techniques and technology continue to evolve, ADM and surgical mesh are becoming more central and critical for surgical success. This prospective study presents long-term data on more than 9500 patients, highlighting outcomes and complication rates of IBBR cohorts with and without ADM. The

Table 2. Kaplan-Meier Risk Rates (95% Confidence Interval) of Asymmetry, Infection, Hematoma, and Malposition

	Primary Reconstruction with ADM(n* = 160)	Primary Reconstruction without ADM(n = 6977)	Revision-Reconstruction with ADM(n = 97)	Revision-Reconstruction without ADM(n = 2268)
Asymmetry				
1 year	2.9 (0.9–8.7)	3.5 (3.0–4.0)	1.4 (0.2–9.6)	2.8 (2.2–3.7)
3 years	4.6 (1.7–12.1)	5.7 (5.0–6.4)	3.7 (0.9–14.3)	4.9 (3.9–6.1)
5 years	4.6 (1.7–12.1)	7.5 (6.5–8.7)	3.7 (0.9–14.3)	6.9 (5.5–8.6)
Breast infection				
1 year	6.7 (3.3–13.6)	3.0 (2.6–3.4)	2.7 (0.7–10.3)	2.9 (2.3–3.8)
3 years	8.5 (4.2–16.7)	3.7 (3.2–4.3)	2.7 (0.7–10.3)	4.5 (3.6–5.6)
5 years	8.5 (4.2–16.7)	4.1 (3.4–4.8)	2.7 (0.7–10.3)	5.5 (4.3–6.9)
Hematoma				
1 year	1.8 (0.5–7.1)	0.5 (0.3–0.7)	1.3 (0.2–8.9)	1.0 (0.7–1.6)
3 years	1.8 (0.5–7.1)	0.5 (0.3–0.7)	1.3 (0.2–8.9)	1.4 (0.9–2.0)
5 years	1.8 (0.5–7.1)	0.6 (0.4–0.9)	1.3 (0.2–8.9)	1.4 (0.9–2.0)
Implant malposition				
1 year	2.9 (0.9–8.8)	1.8 (1.5–2.2)	3.0 (0.7–11.3)	3.0 (2.3–3.8)
3 years	2.9 (0.9–8.8)	3.4 (2.8–4.1)	5.7 (1.8–17.7)	4.9 (3.9–6.1)
5 years	2.9 (0.9–8.8)	4.3 (3.6–5.3)	5.7 (1.8–17.7)	5.7 (4.5–7.1)

*Numbers of patients shown for each cohort reflect the baseline population. Actual numbers of patients at each time point may differ from baseline numbers.

complication of seroma was low and consistent between all cohorts, an important finding. The potential over time for reduced rates of capsular contracture in cohorts treated with ADM is of great interest to the plastic surgeon. Additional long-term studies examining complications in breast reconstruction with and without ADM in IBBRs are warranted.

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ACKNOWLEDGMENTS

Medical writing and editorial assistance was provided to the authors by Regina Kelly, MA, of Peloton Advantage, LLC, an OPEN Health company, Parsippany, NJ. All authors met the ICMJE authorship criteria. Neither honoraria nor payments were made for authorship. The authors thank the patients and their families who participated in this study.

Data Sharing: AbbVie is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual and trial-level data (analysis data sets), as well as other information (e.g., protocols and Clinical Study Reports), as long as the trials are not part of an ongoing or planned regulatory submission. This includes requests for clinical trial data for unlicensed products and indications.

This clinical trial data can be requested by any qualified researchers who engage in rigorous, independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). Data requests can be submitted at any time and the data will be accessible for 12 months, with possible extensions considered. For more information on the process, or to submit a request, visit the following link: https://www.abbvie.com/our-science/clinical-trials/clinical-trials-data-and-information-sharing/data-and-information-sharing-with-qualified-researchers.html.

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