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Implant-based breast reconstruction with Artia™ tissue matrix



Bilal Fakim*, Lyndsey Highton, Ashu Gandhi, Richard Johnson, John Murphy

The Nightingale Centre, Wythenshawe Hospital, Manchester University NHS Foundation Trust, Manchester, UK

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KEYWORDS

Breast reconstruction;
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Summary Background: In 2015, Artia™ (LifeCell, NJ), a new porcine acellular dermal matrix (ADM), was introduced at our unit. As there is lack of clinical studies on its use in breast reconstruction, the purpose of this prospective study was to assess outcome data for patients who underwent Artia™-assisted breast reconstruction. We compared these data with those of other studies of non-human ADMs in widespread use from the literature.

Methods: All consecutive patients who underwent Artia™-assisted breast reconstruction between July 2016 and February 2018 were identified. A prospective database was maintained, including data of patient demographics, type of reconstruction, type of implant, oncological data if applicable, complication rates and adjuvant treatment delays.

Results: Fifty-one patients undergoing 83 implant-based breast reconstructions with Artia™ were included in the study. Of the 83 reconstructions, 62% were performed following risk-reducing mastectomy, 28% following therapeutic mastectomy and 10% for revision procedures. After a mean 276-day follow-up period, the overall complication rate was 10.8%, including 6 breasts (7.2%) developing seromas requiring aspiration, 1 breast developing a haematoma (1.2%) and 2 implant losses (2.4%) in a single patient following neo-adjuvant chemotherapy. There were no cases of wound dehiscence or erythema/red breast syndrome.

Conclusion: This is one of the first studies demonstrating that Artia™-assisted implant-based breast reconstruction is associated with low and acceptable early complication rates. The results are promising and are comparable to our experience using established ADMs, with an implant loss rate of 4.9% across 500 ADM-assisted implant reconstructions.

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Introduction

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* Corresponding author.

E-mail address: bilal.fakim@gmail.com (B. Fakim).

Acellular dermal matrixes (ADM) have revolutionised implant-based breast reconstruction (IBBR) during the last decade or so, facilitating direct-to-implant (DTI) reconstruction, acting as a hammock to allow more natural ptosis and definition of the inframammary fold¹. They have many

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advantages: they can be used in a spectrum of surgeries including both pre-pectoral and sub-pectoral/dual-plane reconstructions and have been reported to reduce the rate of capsular contracture as well as the number of revision surgeries required^{1,2}.

ADMs were historically developed for the treatment of burn injuries, abdominal wall repair and tympanic membrane replacement³. Their use in breast procedures was initially limited to revisional aesthetic surgery before being found to be valuable in breast reconstruction in the early 2000s⁴. In 2010, a US national survey described that more than 50% of the American Society of Plastic Surgeons used ADMs in IBBR then⁵. In addition to potentially being a more cost-efficient surgical option than autologous techniques, ADMs have proved to be very clinically effective over the years^{6,7}.

One of the first ADMs to be used in breast reconstruction was AlloDerm®, a human-derived ADM developed in 2000⁴. However, the restricted availability of human cadaver skin and the associated high costs have limited widespread use⁸. In 2008, Strattice™, a porcine-derived ADM, was launched and has since been a popular choice amongst surgeons. LifeCell Corp. developed its latest ADM, porcine-derived Artia™, in 2015. There is limited clinical experience with this ADM in the literature to date. This study aimed to analyse the use and outcomes of Artia™ in breast reconstruction and draw early conclusions with regard to its effectiveness and safety.

Methods

Study design

All consecutive patients who underwent IBBR with Artia™ at our institution (the Nightingale Centre and Genesis Breast Cancer Prevention Centre, Manchester, UK) were identified, and data were recorded on a prospectively maintained database. The data were collected for patients operated on between July 2016 and February 2018 and included patient demographics; baseline characteristics including BMI, smoking status and diabetes; surgical data; oncological data if applicable; implant type and volume; any delays to adjuvant treatments and complications. The complications were classified as minor and major. Minor complications included those that were managed non-surgically, whereas major complications consisted of those requiring readmission to hospital or unplanned return to theatre. The surgical data included mastectomy type (skin or nipple sparing) and weight; axillary surgery; implant type and volume; unilateral or bilateral reconstruction and type of reconstruction. The data were analysed; the results were recorded and compared with outcome data available from our unit using Strattice™ over the previous nine years and those available in the literature.

Surgical technique

Once the standard mastectomy was performed meticulously identifying the mastectomy plane to ensure skin envelope blood supply is maintained, the mesh was removed from



Figure 1 Artia™ mesh in saline.



Figure 2 Artia™ mesh allowed to soak in saline.

the package using aseptic technique and placed in a sterile saline basin. It was then allowed to soak for a minimum of 2 min. The mesh was then cut and folded as required by the surgeon to fit the surgical site. Following breast implant sizers, definitive implants were then inserted into the pocket. In the patients who had a pre-pectoral reconstruction, the implant were placed over the pectoralis muscle between two sheets of ADM, and these sheets were sutured together anteriorly and secured into the pocket using interrupted sutures at the anatomical boundaries of the breast. In patients who underwent the dual-plane technique, the pectoralis major muscle was raised off the sixth rib inferiorly and dissected medially to the level of the nipple, preserving the pectoralis minor muscle. The implant was placed into the pocket anterior to the rib cage/pectoralis minor muscle, with the pectoralis major muscle draped over the superior aspect of the implant and Artia™ was used to cover the inferior aspect of the implant and sutures placed appropriately to avoid undesirable displacement of the implant. The skin incision was then closed with a tunnelled suction drain in situ (Figures 1-4).

Post-operative management

Following surgery, our patients followed a standard protocol, wherein they were discharged on the same day or the next day with a drain to remain in place for 7 days. Intra-

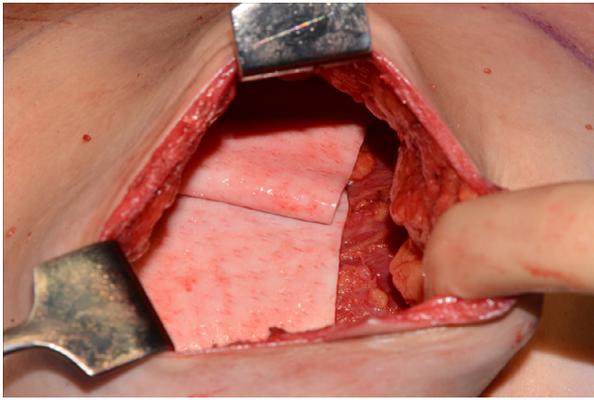


Figure 3 Artia™ in the mastectomy plane.



Figure 4 Two sheets of Artia™ mesh covering an implant.

venous teicoplanin and co-amoxiclav were given on induction, and the patients were discharged with 5 days of oral co-amoxiclav (clarithromycin was substituted if allergic to penicillin). They were reviewed in dressing clinic at 1 week and in out-patient clinic at 2 weeks, 6 weeks, 3 months and 12 months.

Results

Between July 2016 and February 2018, 51 patients underwent a total of 83 immediate breast reconstructions (IBR) with Artia™. The mean age of the patients at the time of surgery was 42.9 years (range: 24-81 years), and the mean BMI was 24.7 kg/m² (range: 18.2-38.7 kg/m²). At the time of surgery, 5 patients (9.8%) were regular smokers and 1 (1.9%) had diabetes. In terms of adjuvant therapy, one patient received adjuvant radiotherapy to 1 breast reconstruction (1.2%), but none had previous chest wall/breast radiotherapy. Three patients (5.9%) had neo-adjuvant chemotherapy, and 5 (9.8%) had adjuvant chemotherapy. None of the patients were found to have had any adjuvant delays. The mean follow-up was 276 days, limiting the evaluation of long-term complications from Artia™.

Of the 83 reconstructions with Artia™, 51 (61.4%) cases were after prophylactic mastectomies, 24 (28.9%) after therapeutic mastectomies and 8 (9.6%) were for revision

Table 1 Patient demographics.

Data	Value
No. of patients	51
No. of breasts	83
Age at time of surgery, years	
- Mean	42.9
- Range	24-81
BMI, kg/m ²	
- Mean	24.7
- Range	18.2-38.7
Smokers, <i>n</i> (% of patients)	5 (9.8%)
Diabetics, <i>n</i> (% of patients)	1 (1.9%)
Radiotherapy, <i>n</i> (% of breasts)	
- Previous	0 (0%)
- Adjuvant	1 (1.2%)
Chemotherapy, <i>n</i> (% of patients)	
- Neoadjuvant	3 (5.9%)
- Adjuvant	5 (9.8%)
Adjuvant delays, <i>n</i> (% of patients)	0 (0%)

procedures. Thirty-two patients (62.7%) had bilateral IBBR, and the remaining 19 (37.3%) had a unilateral procedure. The operative technique was nipple sparing in 48 breasts (57.8%), skin sparing in 23 (27.7%) or skin sparing with immediate nipple reconstruction in 4 (4.8%), excluding the 8 revision procedures. Mean mastectomy weight was 381 g (range: 102-1256 g). The majority of patients, comprising 69 breasts (83.1%), had a single-stage breast reconstruction with an implant, while the remaining 14 (16.9%) had a two-stage reconstruction with tissue expanders (TE). The mean implant volume was 401 cc (range: 125-620 cc).

A total of 24 (28.9%) reconstructions were for oncological reasons. Pathology was invasive ductal carcinoma (IDC) in 17 breasts (70.8%) and ductal carcinoma in situ (DCIS) in 7 (29.2% of tumours). All of the 24 breast reconstructions had axillary surgery: sentinel lymph node biopsy (SLNB) in 17 (70.8%) and axillary node clearance (ANC) in 7 (29.2%) (Tables 1 and 2).

Nine breasts from 8 patients suffered complications, hence increasing the overall complication rate to 10.8%. Minor complications included 6 reconstructions (7.2%), which resulted in seromas requiring aspiration in clinic and 1 haematoma (1.2%). A single patient complained of pain in both reconstructed breasts, which was controlled with regular analgesia. There were no cases of red breast or delayed wound healing. In terms of major complications, one patient, who received neoadjuvant chemotherapy, developed infection and skin necrosis, resulting in bilateral implant failures. This increased the overall explantation rate to 2.4%. At the time of data collection, there had been no reports of capsular contracture and implant malposition. Interestingly, none of the 8 breasts, which received revision surgery with Artia™, developed any complications.

The primary outcome measure in this study was safety (i.e., complication rate). With the overall complication rate of 10.8%, further subgroup analysis found some associations between comorbidity/treatments and complications: out of the 6 patients who developed seromas post-operatively from Artia™, two of them were smokers, a finding in line

Table 2 Outcome data.

Data	Value
Indication for surgery, <i>n</i> (% of breasts)	
- Malignancy	24 (28.9%)
- Risk reducing	51 (61.4%)
- Revision	8 (9.6%)
Surgery, <i>n</i> (% of patients)	
- Unilateral	19 (37.3%)
- Bilateral	32 (62.7%)
Type of reconstruction, <i>n</i> (% of breasts)	
- Nipple sparing	48 (57.8%)
- Skin sparing	23 (27.7%)
- Skin sparing with immediate nipple reconstruction	4 (4.8%)
- Revision procedures	8 (9.6%)
Mastectomy weight, g	
- Mean	381
- Range	102-1256
Implant type, <i>n</i> (% of breasts)	
- TE	14 (16.9%)
- DTI	69 (83.1%)
Implant volume, cc	
- Mean	404
- Range	175-620
Complications, <i>n</i> (% of breasts)	
- Major: skin necrosis leading to reconstruction failure/explantation	2 (2.4%)
- Minor: Seroma	6 (7.2%)
Haematoma	1 (1.2%)

with those reported in studies establishing a link between cigarette smoking and surgical complications.⁹⁻¹¹ Interestingly, no direct relationship was found between high BMI and complications in this study, although only 1 of the 8 patients had a BMI above 30 kg/m². In terms of mastectomy weight, all of the complications were found in breasts weighing more than the mean recorded weight of 381 g in this study.

A total of 9 patients underwent adjuvant therapy: 3 had neoadjuvant chemotherapy, 5 had adjuvant chemotherapy and 1 had adjuvant radiotherapy, which involved a total of 12 breasts undergoing adjuvant therapy. Complications occurred in 3 of the 12 breasts. A single patient, who underwent neoadjuvant chemotherapy, developed infection and skin necrosis, resulting in bilateral implant losses, thereby increasing the overall explantation rate to 2.4%. Another patient who had adjuvant chemotherapy developed a haematoma. However, the remaining 9 breasts did not develop any complication.^{11, 12} Despite the sample of patients having had adjuvant therapy being quite small, the compli-

Table 3 Adjuvant therapy and complication rates.

Therapy	Breasts (<i>n</i>)	Number of breasts with complications
Neoadjuvant chemotherapy	5	2 (single patient)
Adjuvant chemotherapy	6	1
Previous radiotherapy	0	0
Adjuvant radiotherapy	1	0

cation rate was higher (25%) than the overall complication rate of 10.8% (Table 3).

There was no difference in outcomes when comparing skin-sparing and nipple-sparing mastectomies as well as single-stage and two-stage reconstructions. Similarly, out of the 9 breast reconstructions with complications, 5 were performed following therapeutic mastectomies and the remaining 4 were following prophylactic mastectomies; there was thus no difference in complication rates between these two groups. However, it has to be emphasised that this sample is small and a larger cohort of patients would be required to make any definite associations (Figure 5).

Discussion

Since their advent, ADMs have played a crucial role in IBBR. Presently, there are a large number of ADMs available on the market, with varying levels of literature published detailing outcomes such as post-operative complications and patient satisfaction. Because there is currently limited experience with Artia™ reported in the literature, this study aimed to compare Artia™ with two popular non-human ADMs.

Artia™ was devised in 2015 with the help of new processing techniques designed to reduce the components required for an inflammatory response, thus making it similar to human-derived AlloDerm®. For instance, Strattice™ undergoes process-induced alterations in its extracellular matrix. This is known to lead to more inflammation and to affect normal tissue healing and integration¹³. In contrast, the development of Artia™ emphasises on extracellular matrix component preservation with cellular antigen removal. It is terminally sterilised by electron beam irradiation. These new processing techniques have helped to improve the consistency of the material, with an aim of making Artia™ more akin to AlloDerm®. This facilitates handling and preparation in theatre, stimulates fibroblast ingrowth and revascularisation and potentially reduces the risk of complications post-operatively. Artia™ has been reported to being easier to 'drape' than Strattice™ as well as providing a more uniform stretch throughout the mesh. This, together with a better consistency in thickness than that of the other ADMs, makes suturing easier for surgeons^{14,15}. In practice, surgeons have found Artia™ to be more pliable and easier to use than other ADMs. There is no difference in costs, as both Artia™ and Strattice™ cost £1960 per piece. This amounts to no difference in the total cost of surgery to the hospital, as the surgery performed with either ADM is the same. A new full pre-pectoral piece of Artia™ will also soon be released. In contrast to using two meshes for each breast, this new piece

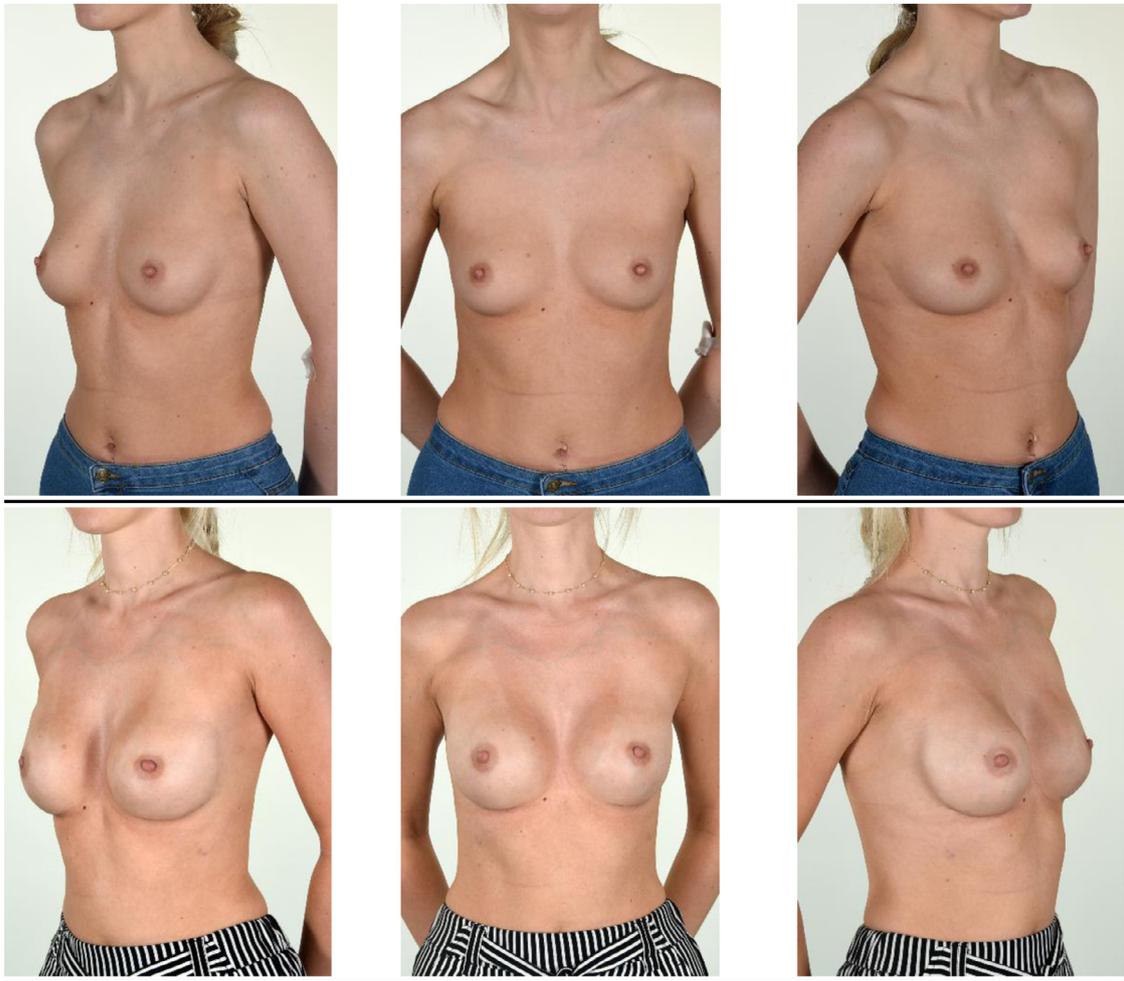


Figure 5 Pre- and post-operative photos from a patient who underwent nipple-sparing mastectomy and subsequent pre-pectoral implant-based breast reconstruction with Artia™ using an infra-mammary fold incision.

should improve the handling of the ADM, decrease the overall costs, decrease operating time and thus lower the overall complication rates.

We have found only two studies in the literature that described the experience with Artia™. Kallaway et al., in their study of 42 cases of IBBR with the mesh, showed quite promising results, with a complication rate as low as 4.8% and only two breasts developing seromas post-operatively¹⁶. Similarly, Wood et al. reported no cases of implant losses when using the ADM after a mean follow-up of 171 days in their study of 17 patients¹⁷.

This study reports early outcomes for 51 patients having 83 Artia™-assisted IBR between July 2016 and February 2018. On analysing the results, it was found that 9 out of the 83 breasts had developed complications, hence resulting in an overall complication rate of 10.8%. The minor complications that occurred in 6 breasts (7.2%) were seromas, and there were no cases of red breast, as described with Strattice™. The seromas were drained in clinic with ultrasound guidance. Bilateral implant losses in a single patient increased the explantation rate to 2.4%, within ABS and BAPRAS national standards^{18,19}.

However, it is important to note that our study had no specific patient selection criteria—all patients who had un-

dergone implant-based breast reconstruction with Artia™ in our unit at the time of data collection were included; resulting in the sample of patients being relatively heterogeneous. It included patients undergoing risk-reducing mastectomies and subsequent reconstructions, those with malignancy as well as some having revision procedures after previous surgery. This could potentially have biased the results and complication rates, as most of the reconstructions (61.4%) were after prophylactic mastectomies. Multiple considerable differences were noted when comparing the group of patients having had risk-reducing mastectomies with the one having had therapeutic mastectomies. The average age of patients who underwent the former was 36.3 years, while that for the latter was 45.3 years. Similarly, adjuvant therapy is linked to higher rates of complications. In the prophylactic mastectomy group, 3 breasts (5.1%) underwent adjuvant therapy; all of them received chemotherapy due to cancer in the contralateral breast. However, 37.5% of the breasts in the therapeutic mastectomy group had adjuvant therapy, automatically making them more prone to complications. Finally, the overall complication rate of 6.8% in patients having had risk-reducing mastectomies was significantly lower than that of 20.8% in the therapeutic mastectomy group. Therefore,

Table 4 Comparison between prophylactic mastectomy and therapeutic mastectomy groups.

Criteria	Prophylactic mastectomy group	Therapeutic mastectomy group
Average age of patients, years	36.3	45.3
Adjuvant therapy, <i>n</i> (% of breasts)	3 (5.1%)	9 (37.5%)
Complications, <i>n</i> (% of breasts)	4 (6.8%)	5 (20.8%)

patients who underwent prophylactic mastectomies and subsequent reconstructions were younger, had less comorbidities and had less adjuvant therapy, which accounted for the lower complication rate. This could have biased the results, especially as the risk-reducing group was larger in our study (Table 4).

It can therefore be concluded that despite the small sample size of this study, the complication rates with Artia™ were low and acceptable. Because there is limited reported experience with Artia™ in the literature, it was not possible to further compare the outcomes with those given in other studies.

Strattice™ comparison

From the iBRA study, Strattice™ is the most commonly used ADM in the UK⁸. Having been on the market for more than 9 years, it has been subject to many clinical studies that have analysed post-operative complications. In 2012, Salzberg et al. conducted a study of 54 patients undergoing a total of 105 reconstructions with the ADM. There were reports of complications in 9 breasts (8.6%), including implant loss and infection in 4 breasts (3.8%), seromas in 2 breasts (1.9%), with 4 breasts requiring explantation. In this study, the complications were observed for an average follow-up period of 3.5 years, which shows the long-term efficacy of Strattice™ in breast reconstruction²⁰. Similarly, a study of pre-pectoral IBR by Highton et al. analysed the outcomes of 106 patients (166 breasts) having had surgery with Strattice™. The overall complication rate was 11.4%, and the reconstruction failure rate was 3%²¹. Therefore, the early results of this study with Artia™ are comparable to the outcomes reported in the aforementioned studies.

However, a study by Dikmans et al. in 2015, from the Netherlands, analysed the use of Strattice™ in IBBR and had less favourable results. It involved 88 patients (*n* = 110 breasts) having either risk-reducing or oncological mastectomies. Their study demonstrated that 78 breasts (70.9%) developed complications following surgery, corresponding to 69 (78.4%) out of the 88 patients. Minor complications comprised seromas, skin necrosis and infections in 58 breasts (52.7%). In terms of major complications, 22.7% of the breasts required further intervention and 11.8% needed an explantation. Dikmans et al. argued that the extremely high complication rates from the study were explained by the limited experience of the surgeons with ADMs as well as the limited availability of ADMs in the Netherlands at the time⁸.

Table 5 Comparison between of ADMs.

ADM	Breasts (<i>n</i>)	Complication rate/%
Artia (this cohort)	83	10.8
Strattice™ (Dikmans)	110	70.9
Strattice™ (Salzberg)	105	8.6
SurgiMend™ (Ohkuma)	95	17.9
SurgiMend™ (Headon)	164	4

SurgiMend™ comparison

In contrast with the porcine-derived Strattice™, Surgimend™ is a bovine-derived ADM¹¹. A study at the John Hopkins Hospital reported on 65 patients undergoing 95 breast reconstructions with Surgimend™. The study concluded that 17 breasts (17.9%) developed complications from the surgery including 13 breasts (13.8%) requiring oral antibiotics for infection and 3 breasts (3.2%) developing haematomas²². A similar study by Headon et al. reviewed the use of SurgiMend™ in 118 patients undergoing 164 IBR. After a mean follow-up period of 21 months, the overall complication rate was 4% including two cases of haematomas and one case of wound dehiscence. Two breasts (1.2%) required explantation due to infection while being on adjuvant chemotherapy. The mean Breast-Q score was 85, and the mean satisfaction score was 9 out of a possible 10²³. This demonstrates that SurgiMend™ is often associated with low complication rates as well as high patient satisfaction with the cosmetic result.

In 2016, Ball et al. compared and analysed the outcomes of 81 patients having surgery with two ADMs - Strattice™ in 30 breasts (25%) and SurgiMend™ in 89 breasts (75%). The study concluded that almost every type of complication was commoner in the group having Strattice™. Despite the rates of revisional surgery required being similar for both groups (6.7%), Strattice™ was associated with higher rates of skin erythema (16.7% versus 4.5%), seroma (10% versus 4.5%) and post-operative haematomas (6.7% versus 1.1%). However, the group of patients having had Strattice™ had been followed up for a longer period of time than the group of patients having had SurgiMend™ (701 days versus 380 days), thus allowing a longer time frame to observe for any complications²⁴.

The studies discussed above consistently show that Surgimend™ is associated with low and acceptable complication rates. They describe overall rates of complication ranging between 4% and 17.9%, within which falls the rate of 10.8% with Artia™ (Table 5).

Conclusion

From this small study, we have demonstrated that use of Artia™ in breast reconstruction is associated with low and acceptable complication rates as well as low rates of revisional surgeries, a finding in line with national guidelines¹⁵. The complication rates were comparable to those obtained from previous studies performed in our unit as well as others mentioned in the literature with well-established ADMs. It is nonetheless important to consider the various risk factors associated with high complication rates when

comparing ADMs¹¹. To date, there is lack of reported experience with Artia™. Despite being on the market for more than two years, surgeons tend to prefer and trust the more commonly used ones. To adequately measure the outcomes of each ADM type and to compare them appropriately, more and larger studies with Artia™ as well as direct comparative studies are required in the future.

The research in this manuscript conforms to the Declaration of Helsinki.

STROBE statement: The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Declaration of Competing Interest Conflict of interest statement

None.

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

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