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ISSN: 2164-5213 (Print) ISSN: 2164-5280 (Online)

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ISSN Online: 2164-5280 ISSN Print: 2164-5213

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The *Modern Plastic Surgery* (Online at Scientific Research Publishing, <a href="https://www.scirp.org/">https://www.scirp.org/</a>) is published quarterly by Scientific Research Publishing, Inc., USA.

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ISSN Online: 2164-5280 ISSN Print: 2164-5213

### **Breast Reduction Complications**

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How to cite this paper: Alboudi, S., Rahal, A.A., Haidar, I.A. and Alhassanieh, A. (2021) Breast Reduction Complications. *Modern Plastic Surgery*, **11**, 1-5. https://doi.org/10.4236/mps.2021.111001

Received: November 27, 2020 Accepted: December 18, 2020 Published: December 21, 2020

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#### **Abstract**

Background: Breast reduction surgery is increasing in popularity, with so many techniques all around the world, and the community's knowledge of the details of this procedure increases thanks to the Internet and easy access to information, which increases breast reduction reviews for plastic surgery clinics. Reduction mammaplasty is an established and effective technique to treat symptomatic macromastia. Variable rates of complications have been reported, and there is a continued need for better outcome assessment studies. Aim: The purpose of this study was to identify the complications occurred during the first year of breast reduction surgery. Materials and Methods: A prospective study over a 1-year period from October 2018 to October 2019, that included 32 patients who underwent breast reduction surgery using the same technique (inferior pedicle and inverted T scar) in the Department of Plastic Surgery at Al-Mouassat University Hospital, Damascus, Syria. Patients were followed through a whole year after surgery and complications that occurred were recorded. Results: Complications that occurred in 14 patients (43%), and, and were more common in patients with larger breasts and worse symptoms before surgery. The most common complication was delayed wound healing, and it was associated with breast volume before surgery and with smoking. In general, the most relevant factor influencing the incidence of complications was the weight of the resected breast tissue, which is mainly related to the size of the breast before surgery. Conclusion: The weight of the resected breast tissue was the most important factor influencing the occurrence of complications after breast reduction surgery. The most prevalent complication was delayed wound healing and it was associated with the weight of the removed tissue.

#### **Keywords**

Breast Reduction, Complications, Delayed Wound Healing

#### 1. Introduction

Breast reduction surgery is becoming more and more popular in the world, with so many techniques as many as plastic surgeons doing this procedure, but the most used technique is the inferior pedicle with the inverted T scar technique.

Considering that breast reduction has cosmetic and functional indications to relieve patients symptoms, more and more coming as plastic and also reconstructive procedure.

The complications of breast reduction surgery have been studied since 1964, and their increased occurrence has been linked to increased patient's weight and increased quantity of resection [1].

A few studies linked some complications such as seroma and delayed wound healing to the addition of liposuction to surgery [2].

#### 2. Materials and Methods

This was a prospective study over a 1-year period from October 2018 to October 2019, which included 32 patients who underwent breast reduction surgery in the Department of Plastic Surgery at Al-Mouassat University Hospital, Damascus, Syria.

Surgery was performed in all patients using one technique, the inferior pedicle technique, with the inverted T scar.

Patients were followed-up after surgery, and complications that occurred during the follow up period were documented. The complications recorded were: delayed wound healing, infection, hematoma, seroma, fat necrosis, and hypertrophied scars.

The number of complications that occurred in each patient was recorded, and complications rate after surgery was determined by calculating the percentage of patients who had any complication. The association between complications and other variables such as age, smoking and weight was assessed.

All patients who had breast reduction surgery with other techniques like vertical scar breast reduction were excluded from this study, and the patients who were not followed up after surgery were also excluded.

Patients were followed up after surgery and the drains were removed when their daily output reached less than 50 ml. Then patients were seen after 1, 3, 6 months and a year after surgery.

#### 3. Results

32 patients underwent breast reduction surgery using the inferior pedicle technique, with the inverted T scar. All patients were in the reproductive age with a mean age of 37.8 years (range, 23 - 52 years).

The mean BMI was 29.7 kg/m $^2$  (range, 19 - 40 kg/m $^2$ ). The mean weight of single breast resected tissue was 793 gram (range, 140 - 1600 gram).

All surgeries were performed under general anesthesia, and a suction drain was placed in all patients, the mean surgical duration was 151.5 minutes.

Out of 32 patients, 18 had no complications (56.25%), 14 had one or more complication, so the complications rate was 43.75%.

Of the 14 patients with complications 6 had one complication (18.75%), 4 had two complications (12.5%) and 4 had three or more complications (12.5%).

The complications occurred were as follows:

Delayed wound healing in 12 patients (37.5%), hypertrophied scar in 5 patients (15.6%), fat necrosis in 4 patients (12.5%), seroma in 3 patients (9.3%), partial nipple necrosis in 3 patients (9.3%), and infection occurred only in one patient (3.12%) No complete nipple necrosis occurred in any patient.

The most influencing factor in the occurrence of complications was the size of the breast before surgery, and thus the weight of breast tissue removed from each breast.

All delayed wound healing cases were dealt with by conservative methods like daily wound dressings until recovery.

Fat necrosis occurred in 4 patients which were managed conservativly.

Seroma occurred in 3 patients, which we suctioned by simple measures and no reaccumulation of seruma was noticed.

The infection occurred in one patient, and appropriate antibiotics were given according to swab from the wound until total recovery had occurred.

Figure 1 shows Delayed wound healing.

**Table 1** shows the main characteristics of patients with complications and patient without complications.

Patients with one or more complication had a greater body mass index, were more smokers, had a larger resected specimen weight, and suffered of more shoulder grooving due to effect of the brassier.

No difference in mean age was found between the two groups.

**Table 1.** The main characteristics of patients with complications and patient without complications.

| Variable   | Complications | No complications |
|--|---------------|------------------|
| Patients number                                    | 14            | 18               |
| Mean age (years)                                   | 36.7          | 38.5             |
| Mean BMI (kg/m²)                                   | 33.5          | 27.9             |
| Smoking  | 80%           | 55%              |
| Resected specimen<br>weight (gram)                 | 1020          | 580              |
| Shoulder grooving                                  | 71%           | 37.5%            |
| married patients<br>(Only two unmarried patients)  | 100%          | 88%              |
| previous breastfeeding                             | 100%          | 88%              |
| history of breast cancer in first-degree relatives | 0%            | 0%               |



Figure 1. Delayed wound healing.

#### 4. Discussion

In an attempt to reduce complications, smoking should be stopped one month before surgery and two weeks later, and the patient should be advised to lose weight when high BMI is noticed before surgery, and reach a stable weight for at least 6 months before surgery. A meticulous surgical technique with a good understanding of the surgical procedure is essential in an effort to reduce complications

The correlation between resected specimen weight in breast reduction surgery and the increased complications was obvious in this study, as the mean weight of the removed tissue in patients which complications was 1020 g compared to 580 g in patients without complications.

In 1964, Strombeck [1] found an increase in complications rate after breast reduction surgery with the weight of the removed tissue was greater than 500 g from a single breast.

In 2000, Zubowski [3] described the correlation between increased weight of resected tissue from a single breast and increased complications after surgery. Our results are also consistent with the study of Menke *et al.* in 2001 [4].

The increased rate of complications was also associated with the increased body mass index (BMI). Patients with complications after surgery had a mean BMI of 33.5 kg/m<sup>2</sup> compared to 27.9 kg/m<sup>2</sup> in patients without complications. This was also shown by Zubowski [3], but the results of our study are inconsistent with Cunningham study in 2004 [5], which showed no association between increased patient's weight and complications after breast reduction surgery.

The most common complication after breast reduction surgery in our study was delayed wound healing without association with any of other variables, therefore it was linked to the previous risk factors for complications, such as increased weight, excess weight of the removed tissue, and smoking.

Smoking was the most common risk factor in patients with complications, which is logical because the effect of smoking on wound healing and micro perfusion, which was shown by Cunningham [5] in his study published in 2004 as well.

#### 5. Conclusions

The significance of the study results may be affected by the small number of cases included. Complications in this study varied in severity between patients, which should be considered in future studies about the breast reduction surgery complications. The effect of complications severity and number on the patient should be demonstrated.

In addition, it is necessary to study the effect of complications on the aesthetic results of breast reduction surgery.

#### **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

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ISSN Online: 2164-5280 ISSN Print: 2164-5213

# **Keloid of Ears: Recurrence and Its Complications**

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How to cite this paper: Resende, J.H.C., Rodrigues de Souza, A.P., Karoliny de Souza Arruda, E., Soares, G.P., João de Morais Silva, G., Rocha, G.F., Milani, P.M., Obeid, T.C., Cândida de Melo, T. and Brasileiro, E.S.F. (2021) Keloid of Ears: Recurrence and Its Complications. *Modern Plastic Surgery*, 11, 6-13.

https://doi.org/10.4236/mps.2021.111002

Received: November 10, 2020 Accepted: December 22, 2020 Published: December 25, 2020

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#### **Abstract**

In this case report, we present a male patient who arrived at the hospital for the first time at the age of 8 with giant keloids in both ears and diagnosed by the Dermatology and Plastic Surgery as having the "Disease of Jorge Lobo", which is a fungal infection due to the story of the endemic characteristics. After the first surgical intervention, he received guidance from the team for keloids and left the hospital using elastic mesh and a request to change the place where he lived to reduce his contact with the fungi. Fourteen years later, the patient returned to the Plastic Surgery Service having even larger keloids in both ears, twice the size than the first time. We did the second surgical intervention to remove it, but with the patient's commitment that he would correctly comply with the guidelines determined by the surgical team. After finishing all the steps and a post-operative for the case, we observed the satisfaction and the increase of the patient's mood, happier and without the embarrassment of that physical defect.

#### **Keywords**

Keloid, Fibrosis, Disease, Syndrome, Scar, Relapse

#### 1. Introduction

The pathophysiology of keloids shows an immunological reaction against sebaceous secretion in patients affected by the disorder, in the occurrence of these lesions. T lymphocytes are attracted to the site with sebaceous secretion, leading to increased collagen formation and greater proliferation of fibroblasts [1].

The reticular dermis is the basic site of keloid changes. In this place, the colla\*Work performed in partnership with Universidade Alfredo Nasser (UNIFAN) with Clínica Brasil.

gen fibers are formed with nodules that increase in size and are distributed irregularly. The skin of a keloid lesion has a flattened epidermis, without hair, sebaceous and sweat glands [2].

Keloids are disorders of skin repair characterized by excessive accumulation of extracellular matrix produced by fibroblasts and occur when there is not a normal healing process. Studies have shown the increased expression of COXs in keloids, suggesting that the pharmacological block could be used in the treatment [3].

Keloids are a pseudotumor proliferation that extends beyond the edges of the initial wound. It is a smaller keloid, a slightly raised and itchy scar that extends over normal tissue. It is an important keloid, a large, elevated, painful scar that protrudes from normal tissue, developed on extensive surfaces, creating pending tumors [4].

Diagnosed by the patient, it does not require laboratory or imaging exams, and, in a biopsy, we usually observe an increase in collagen and elastic fibers [5]. It is mistaken for hypertrophic scarring due to its similarity in pathology. In this paper, we will report the case of an 8-year-old child [6], male, who had rough, hard, with pruritus, gigantic protruding tumors in both ears, and with an onset report after a sting of an unknown insect. He lived in an endemic area, pond type, humid, and contaminated by waste and with the presence of street animals. This type of keloid is described as the disease of Jorge Lobo [7], as a deep, chronic, granulomatous fungal infection originating from trauma and fungal implantation (paracoccidioides loboi et loboa loboi) in cutaneous and subcutaneous tissues with a keloid aspect (Figure 1). It is also called Lacazione, a disease that could infect humans and animals, such as mycoses. First, we programmed to do Beta-therapy [8], use of compressive meshes, and monthly steroid infiltration (triamcinolone). Three months later (Figure 2), we performed the surgical removal of the giant tumors in the ears, with the hope that if the patient did all the recommendations, the lesion would not recur. In addition to all social problems, the patient was bulling in the city where he lived (Figure 3) [9]. We got free beta-therapy, knitwear, and had follow-up for 30 days until discharge (Figure 4).

Years later, at the age of 22, the same patient returned to the Plastic Surgery Service of the HFSE in Rio de Janeiro, with his head covered by the T-shirt, covering the recurrent keloid in both ears. In this second intervention, we removed almost 1 kg of the operative piece (**Figure 5**) [10]. The postoperative period was considered satisfactory and more energetic measures for the late postoperative period were passed on to the patient's sister, who promised the team to supervise closely and follow the medical guidelines.

All of our operated patients signed the informed consent form from the hospital and the medical team.

#### 2. Case Report

Fourteen years after the first discharge, the patient returns to the hospital with a larger tumor and in the same places. During the physical examination, we found that the keloid of the right ear was smaller than in the left ear. During the second

removal procedure, we removed 350 mg from the right ear and 650 mg from the left ear, the main piece was 36 cm long in the shape of a giant "earring" on the left ear (Figure 6) [11]. To perform the surgical removal, we identified piece by piece of keloid, being very careful to leave the skin on both sides, for the end-to-end raffia with simple stitches, separated and using nylon 4.0. We respect the main anatomical accidents that a normal ear has to make it look as good as possible: Helix, shell, lobe, and tragus (Figure 7) [12]. Given the complexity of the surgery, we considered a few scars at the end of the reconstruction. The larger keloids were found on the edges of the helices of both ears (Figure 8) and the pieces were sent to the Pathology Service, which confirmed the "keloid for an undetermined cause" [13].

In the immediate postoperative period, on the day of surgery, we performed a Beta-therapy session with 700 rds, repeated for 7 days interspersed in each ear [14]. On the fifteenth day, we modeled the lead sheet, which was used for 7 days. On the thirtieth day (Figure 9), before discharge, we made an intradermal infiltration with triamcinolone 10 mg [15], and 1/10,000 saline solution on the edges of both ears. The team followed up the patient for six months, once a month, using elastic semi-compressive mesh and without signs of recurrence [16]. We lost contact with the patient one year after the second surgery due to the change in the city. Five years later, we received a call from the patient and we were happy to know that he was married, with a son, employed, and was not ashamed of the small scars left by the last surgical intervention, which is why we decided to make this publication.

#### 1<sup>st</sup> extirpation:



Figure 1. Preoperative period, face, 8 years old.



Figure 2. Final postoperative period, face, 8 years old.



Figure 3. Preoperative, left side, 8 years old.



Figure 4. Postoperative, left side, 8 years old.



Figure 5. Perioperative—surgical specimen.

#### $2^{nd}$ extirpation:



Figure 6. Preoperative face, recurrent, 22 years old.



**Figure 7.** Post-operative, face, 22 years old and with after 6 months of surgery.



**Figure 8.** Preoperative left side, recurrent, 22 years old.



**Figure 9.** Postoperative, left side, 22 years old and after 6 months of surgery.

#### 3. Discussion

The history of this patient with the disease of Jorge Lobo motivated the team to research more about its causes. Fungal infection to differentiate from a common keloid of the idiopathic cause or by racial problems. What attracted the most attention, in particular, was the volume of tumors and lobular shape without sequence. We also noticed the presence of a pruritus (itch) complaint in the lesions, which is very common in keloids found in other types of scars. Due to their irregular shapes, the lesions did not guide us to a technique of extirpation,

which contributed to define a sequence based on the anatomy of the ear, that is, with many curves. In the first surgeries, at 8 years old, we had no experience with keloids with these characteristics, but, 14 years later, we performed a more severe preoperative and redoubled the post-operative care.

We discussed the possibilities of pre-operative infiltration of triamcinolone or compressive. We opted for beta-therapy in seven sessions immediately after surgery, on the same day, as stipulated by the radiotherapy team. Even so, we prescribed the facial elastic mesh for 12 months, in two stages: 6 months using 24 hours and 6 months using only at night. We monitored the patient for 12 months until he moved to another state in Brazil. Many ideas were presented, but we opted for those we had at that time.

As surgeons, we have had few cases similar to this. There were no cases of keloid in the procedures for placement of earrings or ornaments.

#### 4. Conclusion

During our medical career, this was the biggest keloid we found and we had no idea how we were going to give hope to the patient, nor how to return his anatomically more perfect appearance and with all his anatomical accidents. We thought that, after the first discharge, at 8 years old, we would be away from possible relapses, considering all the possible instructions and warnings that were passed to the child's family, about the possibility of relapses if they did not move away from the endemic area where they lived and about changing habits, such as stop walking barefoot in the contaminated mire, be more careful with hygiene and use elastic mesh. The second time, at the age of 22, we were not so surprised, as we already knew that it could happen again. The giant "earring" shape caused deep embarrassment to the patient, which was the biggest reason for having gone to the hospital with the shirt covering the entire head. Even taking all the precautions we knew about keloids, we knew there would be a recurrence, which would result in a third surgical intervention, which did not happen. For this reason, we think it is a good idea to encourage medical colleagues to always try a second time, even though we know that we may fail. Perhaps the number of prophylactic measures and the patient's move to another less unhealthy location are the causes of the success of this case. There is no conflict of interest due to the care taken by the team to request authorization for publication.

#### **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

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ISSN Online: 2164-5280 ISSN Print: 2164-5213

# Study on the Bidirectional Regulation of Skin Regeneration by Tension

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How to cite this paper: He, W.J., Son, K.M., Fan, F.Q., Fang, Z.Z. and Han, B. (2021) Study on the Bidirectional Regulation of Skin Regeneration by Tension. *Modern Plastic Surgery*, **11**, 14-21. https://doi.org/10.4236/mps.2021.111003

Received: October 21, 2020 Accepted: January 10, 2021 Published: January 13, 2021

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#### **Abstract**

Objective: To explore the related factors of tension on wound skin healing and its solution. Methods: According to the analysis and discussion of 60 trauma patients admitted to the emergency department of our hospital, they were randomly divided into two groups, 30 patients in each group (Observation and control group). The other group was systematically studied for the related factors affecting wound healing and we gave the relevant nursing measures to the control group. Results: The healing rate of the two groups were compared after treatment and nursing. The observation group was better than the control group, and the difference was statistically significant (P < 0.001). Conclusion: Effective reduction of wound tension can induce immune response and have obvious effect on skin repair and regeneration. On the other hand, the prevention and treatment of abnormal hyperplasia and scar were also improved. Avoid other factors affecting wound healing, strengthen postoperative management, reduce scar formation and promote skin regeneration.

#### Keywords

Wound Repair, Tension, Bidirectional Regulation, Organizational Restructuring

#### 1. Introduction

After skin injury, the healing result in regeneration, normal scar tissue repair, hypertrophic scar tissue repair or scar Keloid formation. The role of chemical factors in wound healing has been extensively studied, and although there is an evidence of mechanical forces, the effects are far from well defined. The latest

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progress of the role of mechanical force in skin wound healing was reviewed. Comparison of different species can provide an understanding of the regulators. Interestingly, some findings suggest that tension can induce an immune response, which provides a link between mechanical and chemical forces. Structure and function have been shown to be regulated [1] both chemically and mechanically. The increase of skin tension can lead to abnormal hyperplasia of scar. Although the regeneration ability of human skin after injury is limited, the bidirectional regulation of tension will obviously improve it, thus restoring the whole structure and function of organs.

#### 2. Skin Mechanics

The skin is the largest organ of the human body. It is mechanically very complex tissue. The cuticle (10 - 15  $\mu m$ ), the living epidermis (100 - 150  $\mu m$ ), the dermis (subdivided into papillary and reticular dermis  $\approx 2$  mm) and subcutaneous are present below the skin surface [2]. Although the cuticle is part of the epidermis, it is generally considered as a separate layer due to its specific barrier properties. It is composed of inactive cells, very strong, but flexible and wrinkled. The epidermis is mainly composed of cells that migrate to the skin surface. When cells are closer to the cuticle, they become more keratinized. With age, the ups and downs become smaller and smaller. The dermis is mainly composed of very dense collagen and elastin fiber networks, which dominate the mechanical behavior of the whole skin. The deepest skin layer, subcutaneous or subcutaneous adipose tissue, consists of loose adipose connective tissue. The dermis contains microstructures such as blood vessels, lymphatic vessels, nerve endings, sweat glands, hair follicles and different cell types [3]. People often ignore the influence of different layers on mechanical properties.

#### 2.1. Tension and Immune Response

Tissue contraction is part of normal wound healing. Tension arises during cell-mediated tissue contraction. Fibroblasts (FB) are contractile and because the tissue itself has a certain tension (ability to resist deformation), the FB is subjected to resistance from the surrounding contracting? The force depends on the deformation ability of the extracellular matrix, also known as tissue compliance. The worse the deformation ability of extracellular matrix, the worse the tissue compliance and the greater the corresponding resistance. However, the resistance determines the intracellular tension [4], and mechanical stimulation plays an important role in triggering the interaction between cells and extracellular matrix and producing signals that regulate the phosphorylation of cytokine receptors and cell proliferation. As long as there is mechanical tension in the tissue, cell proliferation and biosynthesis will continue; once tension is alleviated, even if growth factors persist, cells will be transformed into non-proliferative types and begin to degenerate. This result indicates that increased skin wound tension leads to increased scar formation, and can also explain the role of ex-

ogenous pressure in reducing scar contracture. The results showed that the transplantation of full-thickness skin or blade thick skin could affect granulation tissue proliferation to varying degrees and accelerate the rapid completion [5] of FB life cycle. Whether this phenomenon is related to skin graft (especially full thick skin graft) can promote tension relief to some extent.

#### 2.2. Tension and Scar

Scar formation is related to the degree of injury, local inflammation, immune response, skin tension and many other factors. The tension factor is closely related to the degree of scar after healing. It is still a challenging task to reduce the tension and make the incision not only obtain rapid and good healing and not obvious postoperative scar. In recent years, the main purpose of the improved suture technique is to observe the treatment and prevention of pathological scar, that is, hypertrophic scar and keloid, while the degree of tension reduction of subcutaneous suture technique is less. It also involves the evaluation of physiological scar degree and related comparative studies. In recent years, the extension-reducing suture of distal subcutaneous transverse mattress is a kind of peak and method, which can make the tension-reducing incision better. Whether under static tension or periodic dynamic tension, the distal subcutaneous transverse mattress tension-reducing suture is subcutaneous buried vertical mattress suture. Both can effectively maintain the tension-free state of the posterior edge and the adjacent skin on both sides, this suture method can be used in facial scar shaping, which can effectively reduce the tension of the knife-edge, make the cut edge good valgus and alignment, and greatly reduce the dermis suture. Compared with the traditional suture, scar width and POSAS scar scale (Patient and Observer Scar Assessment Scale) score showed that the scar degree was lighter, and itching, pain and other discomfort symptoms were lighter. The degree of scar appearance in the observation group and the control group was observed one week later (Figure 1).

Skin tension is determined by the following factors: 1) the degree of skin tissue defect; 2) the inherent tension of skin tissue and the size of local skin tension are related to skin tension relaxation line [6]. Animal experiments confirmed that with the increase of tension, the width and tension intensity of scar also increased. A relationship between wound tension and scar width confirms to a nonlinear equation [7]. For different parts of the body, skin tension is different. The site of high skin tension often becomes the prone part of pathological scar. Such as keloid often appears in the anterior chest and deltoid muscle and other areas of high skin tension. Studies have shown that FB under tension produces more collagen, and the collagen fibers [8]. And through "Z" shape surgery as far as possible to repair the defective tissue or skin transplantation to alleviate skin tension is one kind.

Treatment: One of the factors of low incidence of hypertrophic scar in the elderly is skin relaxation, low tension and low collagen fiber response.

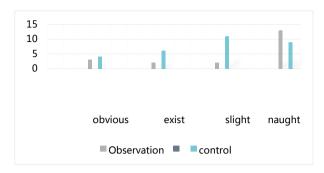


Figure 1. Degree of scar.

Early studies have found that local blood flow disorders caused by pressure can stabilize mast cells, cause tissue hypoxia, and reduce a2\_macroglobulin in local plasma that inhibits collagenase activity. Thus changing collagen metabolism rate, collagen synthesis is reduced, degradation is accelerated, and myofibroblasts (Myofibroblasts, MFB) are degraded, and lysosomal enzymes that can degrade proteoglycan are released, which is beneficial to collagen remodeling [9]. This may be one of the mechanisms by which stress therapy reduces scar formation. To assess postoperative scar formation, an improved version of the modified Vancouver Scar Scale (mVSS) was used, focusing on the size of the scar region (Table 1).

The medical records were evaluated for preoperative and postoperative photographs taken at least one week after surgery. The nonparametric Wilcoxon symbolic rank test was used to analyze the difference of (mVSS) scores before and after operation. All statistical analyses were performed using the SPSS 23.0 version (IBM Corp., Armonk, NY, USA) of the data. Statistical significance is defined as the P < 0.05.

At least a week after surgery, the aesthetic satisfaction of patients was evaluated orally by dealing with the evaluation of wound scar sites (**Table 2**). Presenting the following four questions, full score close to five indicates the higher satisfaction: (Q1) are you satisfied with the postoperative scar at the wound site? (1-5); (Q2) are you satisfied with the postoperative contour of the wound site? (1-5); (Q3) are you satisfied with the wound site after operation? (1-5); And (Q4) are you satisfied with the overall results of the operation? (1-5) Of the 60 patients, 18 patients had a slight scar tendency, 23.33 percent. It is certain that the patient is generally satisfied.

# 3. Effects of Tension and Blood Vessels on Skin Regeneration

As a normal biological process, wound healing is achieved through four precise and highly programmed stages: hemostasis, inflammation, proliferation and remodeling. For successful wound healing, all four stages must be in the correct order and time frame [10], among which the importance of tension can be seen. Many factors interfere with one or more stages of the process, leading to impro-

per or impaired wound healing. This review reviews recent literature on the most important factors affecting skin wound healing as well as underlying cellular and/or molecular mechanisms. Factors discussed include oxygenation, infection, age, sex hormones, tension, diabetes, obesity, drugs, alcoholism, smoking and nutrition.

Table 1. Modified vancouver scar scale.

| Scar characteristics          | Score |
|-------------------------------|-------|
| Vascularity                   |       |
| Normal                        | 0     |
| Pink                          | 1     |
| Red                           | 1     |
| Purple                        | 1     |
| Pigmentation                  |       |
| Normal                        | 0     |
| Hypopigmentation              | 1     |
| Hyperpigmentation             | 1     |
| Pliability                    |       |
| Normal                        | 0     |
| Supple                        | 1     |
| Yielding                      | 1     |
| Firm                          | 0     |
| Ropes                         | 1     |
| Contracture                   | 1     |
| Height (mm)                   |       |
| Flat                          | 0     |
|                               | 1     |
| 2 - 5                         | 2     |
|                               | 0     |
| Depression (cm <sup>2</sup> ) |       |
| Flat                          | 0     |
|                               | 0     |
| 4 - 9                         | 1     |
|                               | 1     |
| Total score                   | 14    |

**Table 2.** Postoperative aesthetic satisfaction scores.

| Patient No. |                 | Satisfaction score |               |                 |              |  |
|-------------|-----------------|--------------------|---------------|-----------------|--------------|--|
|             | Q1              | Q2                 | Q3            | Q4              | Total        |  |
| 1           | 5               | 4                  | 4             | 4               | 17           |  |
| 2           | 5               | 4                  | 4             | 5               | 18           |  |
| 3           | 3               | 5                  | 4             | 3               | 15           |  |
| 4           | 4               | 5                  | 4             | 5               | 18           |  |
| 5           | 5               | 4                  | 5             | 5               | 19           |  |
| 6           | 4               | 3                  | 4             | 3               | 14           |  |
| 7           | 4               | 5                  | 3             | 4               | 16           |  |
| 8           | 5               | 5                  | 4             | 4               | 17           |  |
| Mean ± SD   | $3.87 \pm 0.35$ | $4.37 \pm 0.35$    | $4.00\pm0.03$ | $4.12 \pm 0.45$ | 16.75 ± 1.47 |  |

Higher scores (5 points) indicate greater satisfaction. Q1: Are you satisfied with the postoperative scar at the deformity site? Q2: Are you satisfied with the postoperative contour of the deformity site? Q3: Are you satisfied with the wound site after operation? Q4: Are you satisfied with the overall results of surgery?

Leighton [11] capillary blood flow in dilated flap repair is mainly related to hypoxia and mechanical tension after dilatation. Recent studies have shown that external tension acts on skin tissue and increases the differentiation of skin tissue cells and the proliferation of vascular networks. Mechanical forces affect the development of physiological and pathological tissues and the formation of new blood vessels. At present, many studies have actively explored to know the application of mechanical biological processes to control angiogenesis in living tissues [12]. Under the action of tension, the skin blood vessels will have some morphological changes. The tension produced by tissue dilatation causes sympathetic nerve rupture, that is, desympathetic innervation, which leads to the repositioning and dilatation of hypoxic blood vessels in the tissue. Traffic branches open, capillary alternate opening increased, blood flow speed increased, similar to flap delay phenomenon. Therefore, it can be considered that tissue dilatation is a delayed form of flap, a repeated mechanical dilatation process for the dilated flap, and a continuous hypoxia training process for the flap. Animal experiments have confirmed that the microvascular diameter of the dilated skin increases periodically, and the increase of microvascular density increases linearly in a certain period of time. The ischemia caused by tissue dilatation induces the angiogenesis of the flap (Figure 2).

Vascular reconstruction caused by tension is a complex process, including the synergistic expression of angiogenic factors and receptors, as well as the regulation of oxygen in tissues and the direct effect of mechanical pull on living tissues. Discussion of flap vascular changes caused by dilator dilation [13], Besides observing the vascular diameter and its distribution density, it is mainly the effect of tissue ischemia and hypoxia caused by mechanical tension on vascular changes, and the observation of these changes requires the observation of relevant factors, cell expression and changes through specific detection methods to

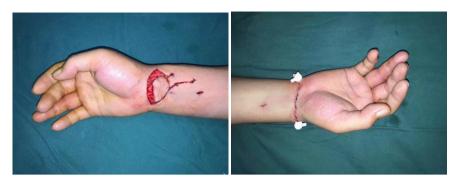


Figure 2. Tension-free suture.

indirectly reflect the changes of blood vessels. At present, the relevant factors are involved in the regulation mechanism of the vascular change process of dilated flap [14], and the results and mechanisms of the interaction need to be further studied. Therefore, we believe that the main direction of this field is to extract more specific angiogenic factors in dilated flaps, which provides a new basis for the mechanism of further dilated flap angiogenesis.

#### 4. Conclusion

Our experience is that the wound tension can affect wound healing. Therefore, in order to ensure good healing of suture wound, it is necessary to minimize suture tension. Previous studies have shown that skin tissue tension around the wound has a significant effect on wound healing. The microtubules and microfilaments of tissue repair cells tend to the direction of local tissue tension line, which affects the direction of wound contraction and cell migration. Reducing tension can not only promote the growth of immune cells, but also promote the regeneration of blood vessels, tissue regeneration accelerates and can also reduce scar formation. Hyperplastic scar is pathological scar caused by excessive synthesis and deposition of collagen [15]. Skin mechanical tension can cause fibroblast proliferation and transformation through various mechanisms, regulate protein excretion, inhibit apoptosis, induce pathological scar formation, and promote its proliferation and expansion. Tension-related therapy, surgical incision design, suture, and skin tensioner, wound tape, pressure treatment can effectively inhibit scar hyperplasia and avoid the occurrence and recurrence of pathological scars and promote skin regeneration.

#### **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

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ISSN Online: 2164-5280 ISSN Print: 2164-5213

# Lessons Learned from Three Different Acellular Dermal Matrices in Direct-to-Implant Breast Reconstruction

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How to cite this paper: Spengler, C., Mett, R., Masberg, F., Vogt, P.M. and Mett, T.R. (2021) Lessons Learned from Three Different Acellular Dermal Matrices in Direct-to-Implant Breast Reconstruction. *Modern Plastic Surgery*, 11, 22-35.

https://doi.org/10.4236/mps.2021.111004

Received: November 25, 2020 Accepted: January 10, 2021 Published: January 13, 2021

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#### **Abstract**

The aim of the study was to show significant differences regarding postoperative complications and outcomes using three different Acellular Dermal Matrices (ADM), namely Epiflex®, Strattice® and Braxon®, in immediate implant-based subjectoral breast reconstruction cases. **Background:** The use of Acellular Dermal Matrices for implant-based breast reconstruction cases continues to evolve. There is a wide variety of products which differ significantly in their biological features. It remains unclear if and how these differences manifest in clinical practice. Methods: 82 cases of primary breast reconstruction in the Department of Plastic and Aesthetic Surgery of HELIOS Clinics Schwerin, Germany between 2010 and 2018 were analyzed. 25 patients received Strattice® acellular dermal matrix (SADM), 22 cases Epiflex® acellular dermal matrix (EADM) and the remaining 35 cases Braxon® acellular dermal matrix (BADM). The mean follow-up was 1.8 years. Cases were analyzed regarding minor or major complications and rate of capsular contracture grade III or IV (Baker Classification). Results: The overall complication rate was 34.1% for all groups (SADM = 40%, EADM = 50%, BADM = 20%, p-value = 0.051). Of all cases, 6 patients underwent implant exchange or secondary autologous reconstruction due to capsular contracture (7.3%). The mean time between revision due to capsular contracture and reconstruction was 35.8  $\pm$ 14.4 months. 50% of patients, who developed capsular contracture, received postoperative radiation. Mean hospitalization time was 8.2 ± 3 days (SADM =  $8 \pm 3.2$  days, EADM =  $10 \pm 2.8$  days, BADM =  $6 \pm 1.3$  days). There were no significant differences between all three groups for demographics, overall complication rate or capsular contracture. However, patients receiving Braxon® matrix showed significantly fewer minor complications (p-value = 0.01). Moreover, patients receiving Braxon® ADM showed a significantly lower time

of hospitalization (p < 0.001). **Conclusion:** No significant differences regarding the overall complication rate were found between the three groups. Different biological features of ADM showed a weak influence on overall results. However, patients receiving Braxon $^{\circ}$  ADM showed significantly lower minor complication rates and hospitalization time. In addition, these matrices showed a trend towards lower capsular contracture rates. The low rate of capsular contracture hints at possible advantages of ADM-use in direct-to-implant cases.

#### **Keywords**

Breast Reconstruction, Acellular Dermal Matrix, ADM, Direct-to-Implant, DTI, Immediate Breast Reconstruction, IBR, Breast Cancer, Skin Sparing Mastectomy, EPIFLEX, Strattice, BRAXON

#### 1. Introduction

There is now widespread application of Acellular Dermal Matrices (ADM) for direct-to-implant (DTI) breast reconstruction. The reasons for this are mainly: 1) artificial elongation of the pectoralis muscle, which limits muscle dissection and surgical trauma and allows for increased initial fill volumes and faster expansion in expander-based cases [1]; 2) provision of an additional protection layer by enhancement of the soft tissue [2]; 3) better control of the inframammary fold and implant migration and the ability to shape the implant pocket, resulting in superior aesthetic outcomes [3] [4]; 4) possibly lower rates of capsular contracture, especially in the case of post-mastectomy radiation therapy (PMRT) [5].

ADMs may be derived from human, porcine or bovine tissue, resulting in different biological features (see **Table 1**). For example, the 1,3-alpha-Gal epitope is a known major xeno-antigen [6] present in porcine matrices. Although drastically reduced by enzymatic cleavage during the manufacturing process, it is not completely eliminated [7]. In line with this, a study by Roessner *et al.* still found residual DNA content on human-derived Epiflex\* ADM [8]. Based on *in vitro* and *in vivo* findings, the host response towards different products may vary [9]. It is yet unknown if and how these experimental findings and different biological properties manifest in clinical practice.

Various studies examine and compare possible complication rates and postoperative results of different ADMs in breast reconstruction [9] [10] [11] [12]. However, these studies vary in terms of patient selection and surgical technique. For example, Paprottka *et al.* included primary or secondary aesthetic breast augmentation cases [13]. Salzberg *et al.* did ADM-assisted reconstruction in prophylactic cases in as much as 68% but did not find significant differences between oncologic and prophylactic cases [13]. To our knowledge, there is no study, which compares Braxon® ADM with other ADM. This study examines the

**Table 1.** Biological features and clinical applications of different ADM products.

| Product name<br>Manufacturer                   | Product specifications and properties   | Indications   |
|--|---|---|
| Strattice®<br>Life Cell Corp,<br>Brachburg, US | Introduced 2008, licensed in Europe and US, porcine-derived, non-crosslinked, undergoes a minimally manipulative manufacturing process with the aim to eliminate the alpha-Gal epitope, thickness 1 - 2 mm provides chemotaxis and suppresses apoptotic induction [37] loses tensile strength significantly in a mouse model between 30 days and 3 months [38] [39] Seems to elicit an intense early immune response in mouse models [40] [41] with later shift to beneficial M2:M1 ratio around day 35 [41] Observed collagen deposition at later time points in mouse models [38] [39] [40] | Breast Reconstruction   |
| Epiflex * DIZG mbH, Berlin, Germany            | Human-skin derived, non crosslinked, thickness >0.3 and >0.8 mm [42] preservation of significant ECM components such as collagen type I, type III, type IV, fibronectin, laminin, vitronectin and hyaluronic acid seem to be preserved after decellularization, small amounts of donor DNA remain   | Breast Reconstruction<br>Hypertrophic Scar Treatment<br>Dermis Replacement<br>Soft Tissue Replacement |
| Braxon®<br>DECO med s.r.l.,<br>Venice, Italy   | pre-shaped, non-crosslinked, 0.6 mm thick, porcine-derived matrix, shows mild fibroblastic reaction and ingrowth of blood vessels after 1 yr in humans [43], no chemical preservatives used during manufacturing process  |   |

outcome of Epiflex\*, Strattice and Braxon\* ADM application in immediate implant-based subspectoral breast reconstruction cases regarding overall minor and major complication rates and the development of capsular contracture.

#### 2. Methods

A retrospective analysis of immediate subjectoral implant-based breast reconstruction cases between 2010 and 2018 in the department of Plastic and Aesthetic Surgery of Helios Clinics Schwerin, Germany was performed using our Hospital Information Software. We scanned for defined OPS procedures and ICD codes. We included all patients who were diagnosed with ductal carcinoma in situ (DCIS), invasive breast cancer and in whom skin-sparing or nipple-sparing mastectomy has been indicated as consented by the interdisciplinary tumor conference of the institution. Furthermore, all patients in whom prophylactic mastectomy has been indicated were included. We included all patients regardless of smoking status, BMI or comorbidities. Patients who underwent prepectoral or delayed reconstruction were excluded from the study. Patients who had partial or full autologous reconstruction (e.g. thoracoepigastric flap or latissimus dorsi flap) before were excluded. In addition, patients who received an ADM during primary or secondary aesthetic breast augmentation were excluded from the analysis. Patients were clustered into the Strattice® (SADM), Epiflex® (EADM) or Braxon® (BADM) group according to the ADM. For detailed description of these matrices see Table 1.

The study was approved by the institutional review board of the University of Rostock, Germany (Registration-Number 2020-0037). Informed consent for the use of data and photographs for scientific purposes was given by each patient. The study is in full accordance with the Helsinki Declaration in its revised 2013 version.

The surgical technique was similar in all cases: After nipple or skin sparing mastectomy via a vertical incision, a limited subjectoral pocket was raised. Im-

plant handling and insertion was done according to the principles given by Deva et al. 2013 [14]. In cases where Strattice\* or Epiflex\* have been used, a suitable piece of matrix was designed and sutured to the retracted pectoralis muscle as an inferolateral hammock for lower pole coverage as described earlier [15]. In cases where Braxon\* matrix has been used, the whole implant was wrapped in matrix and completely covered by it. The inframammary fold was enforced by suturing the hammock down to the chest wall. The excess material of the matrix envelope was sutured down to the chest wall. In all cases, we have used one drain to the subpectoral pocket and one subcutaneous drain. A light pressure dressing was applied. Patients were put to bedrest for 24 hours. Drains were removed as soon as secretion had decreased under 30 ml per day. All cases have been operated by a single author (R.M.) Exemplary pictures of preoperative markings and intra-operative technique are shown in Figure 1.

We analyzed patient charts and data with attention to age, mastectomy weight, implant size, operation time, days of hospitalization and complications. The retrospective endpoints of interest were minor complications such as hematoma, seroma or small-size skin necrosis not requiring revisional surgery, and major complications, defined as implant loss due to skin necrosis, seroma, hematoma or infection. Secondary endpoint was capsular contracture (Baker Classification III or IV) requiring late revisional surgery.

Group homogeneity was tested with either Pearson's Chi Square Test or Kruskal-Wallis Test, as appropriate. We tested statistical significance regarding the defined endpoints using Pearson's Chi Square Test. The significance level was given to a two-sided p-value of smaller than 0.05. Statistical analysis was performed using the latest version of SPSS (IBM Corp., Armonk, New York, USA)

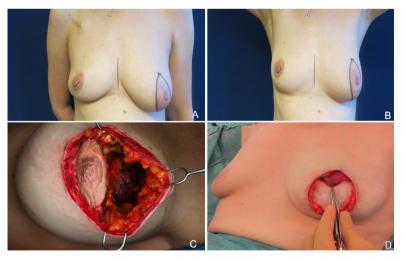


Figure 1. (A) Preoperative markings are shown for a 42-year-old woman with invasive ductal breast cancer of the left breast. (B) The vertical ellipse caudally extends to 2 cm above the inframammary fold. (C) Intraoperative view showing the gland which has been released from the pectoralis major muscle. A minimum of subcutaneous fat is preserved to maximize flap survival. (D) The implant has been wrapped completely in Braxon\* matrix. The upper pole is secured beneath the raised pectoralis flap.

#### 3. Results

The analysis yielded 112 cases, of which 30 cases where excluded for not matching the preset requirements. In total, 82 cases remained, of which 25 cases received Strattice\*, 22 cases Epiflex\* and the remaining 35 cases Braxon\*. Mean follow-up was  $1.8 \pm 1.1$  yrs.

The mean age of all patients was  $50.3 \pm 11.62$  yrs. The leading cause of mastectomy was invasive breast cancer (50%), followed by DCIS (27%) and prophylactic mastectomies (23%). 27% of all patients underwent prior breast conservation therapy. Mean mastectomy weight was  $353 \pm 177$  g and mean implant size has been  $373 \pm 111$  cc. The mean operation duration was  $157 \pm 50$  min. 15 patients have received postmastectomy radiation therapy (PMRT). There were no significant differences between all groups except Follow-Up which was significantly shorter in the BADM group (see **Table 2**).

The overall complication rate was 34.1% for all groups (SADM = 40%, EADM = 50%, BADM = 20%). Although the absolute complication rate of the BADM group is lower than SADM or EADM, there was no significant difference (p-value = 0.051).

Minor complications occurred in 7 cases (8.5%). There were significantly less minor complications in the BADM group vs. EADM (p-value = 0.003). There were no significant differences between SADM vs. EADM or SADM vs. BADM (p-value = 0.158 and 0.089, respectively). In total, we have encountered 21 major complications leading to implant loss (25.6%). There were no significant differences between the three groups regarding major complications (see **Table 3**). The main cause for implant loss was skin necrosis (52.4%), followed by infection (23.8%) and seroma (19%).

Table 2. Summary of demographic and clinical characteristics of different ADM groups.

|                          | SADM            | EADM            | BADM            | Total          | p-Value |
|--------------------------|-----------------|-----------------|-----------------|----------------|---------|
| n                        | 25              | 22              | 35              | 82             |         |
| Age (yrs)                | 49.1 ± 12.7     | 51.1 ± 7.2      | 50.7 ± 13.2     | 50.3 ± 11.6    | 0.651   |
| BMI                      | $22.5 \pm 3.63$ | $22.2 \pm 3.08$ | $22.8 \pm 3.00$ | $22.7 \pm 3.2$ | 0.313   |
| Mastectomy weight (g)    | $342 \pm 188$   | $346 \pm 199$   | $354 \pm 158$   | 353 ± 177      | 0.924   |
| Implant size (cc)        | $348 \pm 131$   | $375 \pm 129$   | $379 \pm 83$    | 373 ± 111      | 0.712   |
| Operation duration (min) | 166 ± 59        | $150\pm40$      | $146\pm48$      | 157 ± 50       | 0.212   |
| Diagnosis                |                 |                 |                 |                |         |
| DCIS                     | 6 (24%)         | 8 (36%)         | 8 (23%)         | 22(27%)        |         |
| Invasive breast cancer   | 15 (60%)        | 9 (41%)         | 17 (48%)        | 41 (50%)       |         |
| Prophylactic             | 4 (16%)         | 5 (23%)         | 10 (29%)        | 19 (23%)       |         |
| Prior BCT                | 9 (36%)         | 5 (23%)         | 8 (23%)         | 22 (27%)       | 0.463   |
| Follow-Up                | 1246 ± 722      | 727 ± 588       | 282 ± 243       | 646 ± 404      | 0.002   |

**Table 3.** Major and minor complications of different ADM used for direct-to-implant breast reconstruction.

|                          | SADM<br>(n = 25) | EADM<br>(n = 22) | BADM<br>(n = 35) | Total<br>(n = 82) | p-Value |
|--------------------------|------------------|------------------|------------------|-------------------|---------|
| Minor Complications      | 2 (8%)           | 5 (22.6%)        | 0 (0%)           | 7 (8.5%)          | 0.011   |
| Seroma                   | 1 (4%)           | 2 (9.1%)         | 0 (0%)           | 3 (3.7%)          | 0.204   |
| Haematoma                | 1 (4%)           | 1 (4.5%)         | 0 (0%)           | 2 (2.4%)          | 0.463   |
| Small Size Skin Necrosis | 0 (0%)           | 2 (9.1%)         | 0 (0%)           | 2 (2.4%)          | 0.061   |
| Implant Loss             | 8 (32%)          | 6 (27.3%)        | 7 (20%)          | 21 (25.6%)        | 0.564   |
| -Skin Necrosis           | 5 (20%)          | 4 (18.2%)        | 2 (5.7%)         | 11 (13.4%)        | 0.206   |
| -Infection               | 3 (12%)          | 0 (0%)           | 2 (5.7%)         | 5 (6.1%)          | 0.317   |
| -Seroma                  | 0 (0%)           | 1 (4.4%)         | 3 (8.6%)         | 4 (4.9%)          | 0.314   |
| -Haematoma               | 0 (0%)           | 1 (4.5%)         | 0 (0%)           | 1 (4.8%)          | 0.257   |
| Overall Complications    | 10 (40%)         | 11 (50%)         | 7 (20%)          | 28 (34.1%)        | 0.051   |
| Capsular Contracture     | 2 (8%)           | 3 (13.5%)        | 1 (2.9%)         | 6 (7.3%)          | 0.31    |

The mean time of hospitalization was  $8.2 \pm 3$  days (SADM =  $8 \pm 3.2$  days, EADM =  $10 \pm 2.8$  days, BADM =  $6 \pm 1.3$  days). Patients of the BADM group had a significantly lower hospitalization time compared to the SADM or EADM group (p < 0.001). There were no significant differences between SADM or EADM patients (p = 0.148).

Of all cases, 6 patients underwent implant exchange or secondary autologous reconstruction due to capsular fibrosis (7.3%). There were no significant differences between the three groups (see **Table 3**). The mean time between reconstruction and revision due to capsular fibrosis was  $35.8 \pm 14.4$  months. 50% of patients with development of capsular contracture received postmastectomy radiation therapy (n = 3).

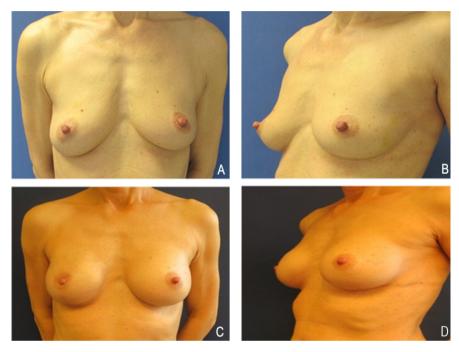
Exemplary postoperative results are given in Figure 2.

#### 4. Discussion

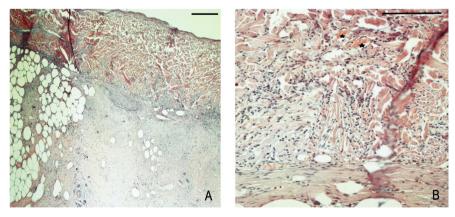
Although the biological properties of ADM are different and numerous experimental and histological studies exist, which show different potential recipient reactions towards ADM, we did not see significant differences between them, clinically. The main reason for implant loss in our study was skin necrosis. While some authors advocate the use of ADM and propose a better perfusion of the skin flap after mastectomy [16], several authors remark that the ADM needs profound perfusion for integration. This might not be the case in critically perfused mastectomy flaps, which ultimately leads to matrix disintegration and possible complications [17] [18] [19] [20]. Rapid integration of ADM is important to avoid complications such as seroma or infection [21]. A study by Kim *et al.* showed that the use of ADM in case of necrotic mastectomy flap led to higher explantation rates, although only with borderline statistical significance [21].

Our own histologic analysis has shown rapid integration of the Braxon® matrix with neo-vascularization, even though we encountered mastectomy flap necrosis (example given in Figure 3).

However, there is no clear data, if and how ADM influences the perfusion of mastectomy flaps. Surgical techniques, like a more radical approach towards mastectomy, might damage the subdermal plexus leading to elevated rates of skin flap necrosis, hence marginalizing the influence of ADM. A study by Rose *et al.* shows that there is a trend towards higher complication rates if thick



**Figure 2.** Postoperative result 6 months after right-sided nipple sparing mastectomy and immediate reconstruction with an Allergan® Style 410 MM 320 cc anatomic implant and Braxon® matrix (A) preoperative anterior view (B) preoperative oblique view (C) postoperative anterior view (D) postoperative oblique view.



**Figure 3.** Histological analysis of a piece of Braxon\* matrix, which was obtained 3 weeks after implantation due to skin necrosis and subsequent implant and matrix removal. (A) Histiocytic infiltration is evident. The bar indicates 500 μm. (B) Early neo-vascularization is visible. The vessels are indicated by asterisks. The bar indicates 100 μm.

(thickness > 1.2 mm) ADM are used [22]. As the thickness of the ADM increases, perfusion and ingrowth of repopulating cells gets more difficult and renders these ADM more prone to failure of integration. This might attribute to the somewhat high complication rate observed in the SADM group, given that the Strattice\* ADM was the thickest of the compared ADM (see **Table 1**).

We have seen significantly fewer minor complications in the BADM group when compared to the EADM group. Furthermore, we have seen a slightly lower rate of implant loss in the BADM group (20%) compared to SADM (32%) or EADM (27.3%), although without reaching statistical significance. Moreover, the time of hospitalization of patients who received Braxon® Matrix was significantly lower when compared to patients who received Strattice® or Epiflex® matrix.

These favorable results might be attributable to the manufacturing process of Braxon\* which is free of chemical preservatives. Vittekova *et al.* showed the different cytotoxic potential of three ADM *in vitro*. Notably, the cytotoxicity of one ADM remained even after multiple washings [23]. Nevertheless, to our knowledge, there are no studies available at the moment comparing Braxon\* and its cytotoxicity with other matrices.

We did not find a significantly lower complication rate for EADM, as has been reported by Paprottka *et al.* In contrary, Glasberg *et al.* reported lower complication rates for Strattice ADM compared to AlloDerm. Furthermore, Eichler *et al.* reported a complication rate of 40.6% for Epiflex ADM and found it to be significantly higher compared to SurgiMend in a study of 127 patients [24]. These findings can be confirmed to some degree with the current data. It could be shown that the group of patients who received Epiflex had the highest overall complication rate, although without reaching statistical significance. The implant materials' mechanical properties influence the incorporation process between the host tissue and the implant. Given that EADM patients presented with the highest rate of seroma formation, the mechanical properties of this matrix might lead to more encapsulation rather than integration. Roessner *et al.* found residual donor DNA content on Epiflex matrices which might elicit a pronounced immune response and force encapsulation. The immunogenicity of residual DNA content on biological scaffolds is well-known [25].

The observed overall complication rate is comparable to current literature, although in the upper range. Salzberg *et al.* report overall complication rates of 3.9% and implant loss rates of 1.3%. However, the range of reported complication rates is wide. In a study comparing outcomes of three different ADMs (human, porcine and bovine), Paprottka *et al.* reported a re-operation rate of 23% of 52 cases. Chun *et al.* reported skin necrosis in 23.9% of 269 ADM-assisted breast reconstruction cases and seroma in 14.1% of their cases. In a study of 121 cases, Rawlani *et al.* report an overall complication rate of 16.5% [26]. Antony *et al.* reported an overall complication rate of 23.6% in their study of 153 cases [27].

In 11 cases (13.4%) we observed severe skin necrosis that led to implant loss. 27% of our patients underwent prior breast conservation therapy which might be a possible cause for an increased number of skin necrosis and surgical side

infections. Nevertheless, the available literature does not support this assumption [28] [29]. Compared to direct-to-implant cases without the use of ADM, the available literature reports overall early complication rates (within 6 months of surgery) of 16% - 42%, which might increase up to 70% in the setting of pre- or postmastectomy radiation therapy and skin necrosis was reported in 7% - 20% of analyzed cases [30] [31].

Regarding capsular contracture, our study showed a rate of 7.3% with no statistically significant differences between the three groups. In a study of 124 cases of breast reconstruction where porcine ADM has been used, 6% of non-irradiated breasts and 13% of irradiated breasts developed capsular contracture III/IV [32]. Salzberg *et al.* reported capsular contracture as low as 0.4%. In a small series with a 4-year follow up on Braxon-assisted reconstruction cases, there was no evidence of capsular contracture [33]. Our study shows the lowest capsular contracture rate in the BADM group. This might be attributable to the total wrapping of the implant compared to the use of Epiflex® and Strattice® as an inferolateral hammock only, which leaves the implant's bottom side as well as the upper pole exposed [34]. However, the BADM group also had the shortest follow-up time.

The total coverage of implants with BRAXON® requires more material compared to the other two groups which makes sound tissue perfusion mandatory. The cost of using ADM is comparable for all three products and is within a 2000 - 2500 US-Dollar range. To our knowledge, there currently is no additional reimbursement for the use of ADM in Germany.

Furthermore, there were no differences in operation duration between the three groups. The Braxon® matrix is pre-shaped, which makes total implant-wrapping easy and takes equal time compared to the inferolateral hammock technique. We did not see any cases of bottoming out. The possibility to suture down the ADM material to the chest wall plays a crucial role in shaping the implant pocket and securing the inferior border. The implant's downward force is disseminated on the virtually tear-resistant ADM rather than to depend on single sutures enforcing the inframammary fold.

The longitudinal character of our study might contain a bias as the experience with ADM use has grown over time and led to better results with the last used Braxon® matrix regardless of the underlying biological properties of the matrix itself. However, the surgeon, who performed the included procedures, is very experienced with skin sparing mastectomies and implant-based immediate breast reconstructions without the use of ADM. As the handling and operative techniques required for successful use of ADM are comprehensible, the influence of poor technique or handling can likely be neglected. A specific patient selection and preoperative decision making might have led to improved results and lower rates of implant loss. Nevertheless, the similar group characteristics (age and BMI) do not support this assumption. While the total wrapping of the implants with Braxon® matrix might explain the lower rates of capsular contracture, which was observed and which might be a bias regarding this endpoint of

the study, it does not explain the lower rate of minor complications. This effect is probably due to the fact that more matrix material also requires better perfusion and mandates more remodeling and integration of an increased amount of material compared to a strip of matrix as with Epiflex® or Strattice®. We have not used intraoperative skin flap monitoring, which might have led to ADM use in cases with critical mastectomy flap perfusion. As mentioned earlier, to our knowledge no studies are available which clearly underline the role of ADM in enhancing or reducing tissue perfusion. This aspect actually underlines the usefulness of intraoperative skin flap monitoring as a matter of controversy. When we encountered severe disruption of flap perfusion intraoperatively, we changed to a delayed procedure or no ADM-use at all. These cases have not been included in our retrospective study. Finally, we acknowledge the concerns regarding the use of Allergan Style 410 implants. Our study included patients from 2010 to 2018. Allergan Style 410 implants have been recalled in 2019 for concerns regarding their potential to induce BIA-ALCL. During the period from 2010 to 2017 there were no studies or guidelines available which recommended against the use of Allergan Style 410 implants. On the contrary, Unger et al. in 2016 and McGuire et al. in 2017 reaffirmed the safety of these implants [35] [36]. Currently, we do not use these implants, and all our patients who have received these products are closely counseled and monitored for any signs of BIA-ALCL.

#### 5. Conclusion

Although our study did not show significant advantages of one specific ADM, it showed a positive tendency towards the use of Braxon® Matrix with lower overall complication rates, and a low rate of capsular contracture. However, the different biological features of the compared ADM might only have marginal influence on clinical outcomes in our study. Low rates of capsular contracture or secondary procedures point out an advantage of ADM-assisted breast reconstruction when compared to implant reconstruction alone. There could be a protective role of ADM with regards to postoperative radiation therapy although further studies are needed to elucidate this promising feature.

#### **Ethical Approval**

The study was approved by the institutional review board of the University of Rostock, Germany (Registration-Number 2020-0037). The study is in full accordance with the Helsinki Declaration in its revised 2013 version.

#### **Informed Consent**

Patients signed informed consent regarding publishing their data and photographs.

#### **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

#### **Role of Authorship**

Dr. Claas Spengler is the responsible and corresponding author of the manuscript. He collected the data, did the statistical analysis, wrote the manuscript and is responsible for the submission process. Dr. Roland Mett is the head physician of the clinic where all cases have been performed. He is the responsible surgeon for all reviewed cases. Dr. Frank Masberg proof-read the manuscript and overviewed the references. He also assisted in taking and processing the shown figures. Prof. Dr. Peter Vogt assisted during planning and conducting the retrospective review, he also proof-read the manuscript. Dr. Tobias Mett is the senior author of the paper. He designed the study, oversaw the data collecting process and assisted in revising and proof-reading the manuscript.

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ISSN: 2164-5213 (Print) ISSN: 2164-5280 (Online)

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