

Initial results of the use of TIGR® Matrix *Surgical Mesh* for prosthetic breast reconstruction and secondary procedures following prosthetic breast reconstruction or breast augmentation.

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Background

Implant based breast reconstruction is an attractive option for women undergoing mastectomy who are lacking tissue required for autologous reconstruction or have concerns related to donor site morbidities. Immediate reconstruction has a particular advantage as it gives a positive psychological contribution to the patient.

Immediate breast reconstruction with expanders originally involved the total muscle coverage technique including the pectoralis major, serratus anterior and the anterior fascia of the rectus muscle. Complete muscle coverage was necessary in order to protect the implant from exposure but the rigidity of the muscle may restrict inferior pole expansion which can result in a high-riding implant and an ill-defined infra-mammary fold.

With improved techniques and increased patient demands, skin sparing and nipple sparing procedures have gained popularity and this has increased the need for plastic surgeons skilled in producing aesthetically pleasing results with small incisions and as few procedures as possible. Despite the refinement of primary surgical techniques and the introduction of new prosthetic materials, complications such as reconstructive failure or implant dislocations are common after prosthetic breast reconstructions.

The use of acellular dermal matrices (ADM) to provide reinforcement to the muscle and to provide supplemental tissue coverage between the released muscle and the infra-mammary fold has been popularized and showed good initial results. However, recently published evidence show an increased rate of complications following the use of ADM, in particular seromas, infections and failure of vascularization (1, 2). Concerns have also been raised related to the high variation of mechanical characteristics of some ADMs and that this may contribute to asymmetric results over time (3).

Breast augmentation is one of the most common aesthetic operations performed in the world. As over 1'500'000 breast augmentations are performed yearly world-wide (4) and 15-30% of these require a reoperation within five years, there is a great need for further development of surgical techniques to correct these complications.

Acellular dermal matrices have been used in corrective surgery (5, 6) but recent evidence suggests that acellular dermal matrices are generally associated with a high complication rate (7) and other options could therefore prove more efficient.

In this paper we describe our results using a long-term absorbable synthetic matrix, TIGR® Matrix, as a temporary reinforcement when treating these complications.

About TIGR® Matrix *Surgical Mesh*

TIGR® Matrix is the world's first long-term resorbable synthetic mesh product. It is indicated for reinforcement of soft tissue where weakness exists and is manufactured from two different synthetic resorbable fibers. TIGR® Matrix has high strength during the first 6 months following implantation, and is completely degraded and resorbed after approximately 3 years. TIGR® Matrix is manufactured from the well known and proven materials glycolide, lactide and trimethylene carbonate which degrade through hydrolysis and are cleared from the host tissue through normal metabolic pathways.

TIGR® Matrix is now being used as an alternative to ADM in order to aid in correction of breast implant complications such as bottoming-out, and as an adjunct in mastopexy surgery. The knitted structure of TIGR® Matrix allows for easy handling and fixation while being strong and flexible. As shown in preclinical trials, TIGR® Matrix is rapidly vascularized and has a transient inflammatory response, and over time, TIGR® Matrix was replaced by well-organized connective tissue (8).

Since its market introduction in 2010 TIGR® Matrix has been used in a variety of plastic and general surgical procedures where soft tissue reinforcement is required and has shown excellent results and performance with a minimum of complications (9).

Procedures and results

A total of 11 primary reconstructions and 51 secondary surgical procedures were performed using TIGR® Matrix. 30 procedures were revisions of breast reconstructions, 12 revisions of augmentation and 1 mastopexy revision. Reasons for surgery included:

- Capsular contracture
- Elevation or reconstruction of infra-mammary fold
- Implant removal or replacement
- Asymmetric primary results
- Scar revision
- Implant repositioning

There were also a number of patients where TIGR® Matrix was used in a primary aesthetic procedure, mainly for mastopexy. For these procedures it was decided that additional reinforcement was needed because of existing tissue weakness and that using a reinforcing matrix would produce a more durable and aesthetically superior result.

table 1

| Procedures | Nr of patients | Nr of breasts |
|---|----------------|---------------|
| Primary reconstruction | 11 | 19 |
| Revision reconstruction | 30 | 51 |
| Augmentation/Mastopexy revision | 13 | 26 |
| Augmentation and Augmentation Mastopexy | 3 | 6 |
| Mastopexy | 5 | 10 |
| TOTAL | 62 | 112 |

Perioperative findings included two failed ADM grafts (2 patients) that required removal as they were fragmented or not integrated at all. Both of these patients had received prior radiation. The biologic material implanted in earlier procedures at different centers in their primary reconstruction was found to be non-integrated and ineffective. The ADM grafts were thus removed and TIGR® Matrix was used successfully to replace the ADM instead.

All procedures (table 1) were performed without any complications during surgery.

9 patients had a history of radiation and thin skin flaps resulting in a slower healing and incorporation of the mesh implant. These patients were also found to have very thin skin flaps that required extra attention during the surgical procedure. Other characteristics of the patient population can be found in table 2.

table 2

| Characteristics | |
|--------------------------------------|--------------|
| Average follow-up (months) [min-max] | 5.1 [0.2-17] |
| Average age | 54 |
| Nr of patients with prior radiation | 9 (14.5%) |
| Nr of smokers | 4 (6.5%) |

Patients were seen in the clinic at regular interval following surgery. Average follow-up time was 5 months, ranging from 0.2-17 months. The complications observed are shown in table 3.

Complications not accounted for in the table, include 11 cases of asymmetry or mild asymmetry that in 6 cases required a corrective procedure at a later stage. Infection complications were noted early in the series and lead to a new routine when placing the drains, using longer subcutaneous tunnels and a longer draining period. These corrective actions dramatically reduced events of infections for the later half of the patient series.

table 3

| Complication | Nr of breasts w complications | % (of total breasts) | Requiring intervention |
|----------------------------|-------------------------------|----------------------|------------------------|
| Flap necrosis | 2 | 1.8 | 2 |
| Seroma | 2 | 1.8 | 2 |
| Infection/extrusion | 4 | 3.6 | 4 |
| Relapse of IMF/Malposition | 2 | 1.8 | 2 |
| Rippling | 2 | 1.8 | 1 |

References

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Conclusion

This limited data set shows that TIGR® Matrix has great potential as temporary reinforcement in patients undergoing breast reconstruction or breast surgery revisions.

By providing means to reinforce the fixation of the pectoralis major to the chest wall or to re-define and support the inframammary fold, TIGR® Matrix adds significant value and can help achieve superior clinical results.

Dr. Becker has been in plastic surgery practice since 1981 and is certified by the American Board of Plastic Surgery. Dr. Becker received his medical degree from the University of Witwatersand, Johannesburg, South Africa, and completed his plastic surgery residency at the Medical College of Virginia. He is a member of many regional and national medical societies including the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Reconstructive Surgeons, American College of Surgeons and the Royal College of Surgeons - Edinburgh. He also has an academic affiliation to the Voluntary Faculty - Cleveland Clinic Florida.

Certifications & Professional Recognition

American Board of Plastic Surgery, 1981
Royal College of Surgeons, Edinburgh, Scotland, 1976

Academic Background

Undergraduate:
University of Witwatersand Johannesburg, South Africa, 1971
Medical:
University of Witwatersand, Johannesburg, South Africa, 1966-1971
Plastic Surgery:
Medical College of Virginia, Richmond, Virginia, 1978-1980
University of Witwatersand, Johannesburg, South Africa 1976-1978
Residency:
Fellow of the Royal College of Surgeons, Edinburgh, Scotland, 1976

Medical Devices Developed

Mentor Becker® Adjustable Breast Implant
Adjustable Saline Implant Spectrum®
Adjustable Gel Implant Spectra®
Becker Liposuction Cannula®

Societies, Memberships and Affiliations

American Society of Plastic Surgeons, Fellow, 1996
Hon. Member, Association of Plastic & Reconstructive Surgeons of Southern Africa
American Society of Plastic Surgeons
American Society for Aesthetic Plastic Surgery
American Medical Association
Lipoplasty Society of North America
Florida Society of Plastic Surgeons
Palm Beach County Medical Society
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