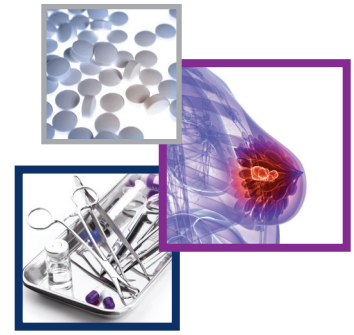
RESEARCH ARTICLE

For reprint orders, please contact: reprints@futuremedicine.com

Breast Cancer Management



Immediate implant-based breast reconstruction using the TIGR® Matrix mesh

Peter Schrenk*

Practice points

- A single-center post-procedure study, the aim was to monitor the safety and performance of TIGR® Matrix in adult patients (>18 years) suitable for immediate implant breast reconstruction following skin-sparing mastectomy.
- The TIGR® Matrix mesh was used in a total of 29 patients undergoing a total of 37 mastectomies and immediate reconstruction.
- Indications for mastectomy were breast cancer (n = 29) and BRCA 1 or 2 mutations (n = 8).
- Cosmetic outcomes, patient satisfaction, complications and oncological outcomes were recorded.
- Early postoperative results showed no adverse reactions to the mesh and a good integration into the tissue.
- The TIGR® Matrix mesh fulfilled many desired characteristics and requirements for a matrix for use in implant-based breast reconstruction.

Background: Different types of acellular dermal, synthetic and biological matrices have been used in connection with immediate implant-based breast reconstruction. **Patients & methods:** A new long-term absorbable surgical matrix, TIGR® Matrix mesh was used in a total of 29 patients undergoing a total of 37 mastectomies and immediate reconstruction. **Results:** Early postoperative results showed no adverse reactions to the mesh and a good integration into the tissue. **Conclusion:** It may therefore constitute an alternative to acellular, dermal or other synthetic matrices currently available.

First draft submitted: 5 January 2016; Accepted for publication: 22 February 2016;
Published online: TBC

The use of acellular dermal or synthetic matrices has improved the functional and cosmetic outcome of implant-based breast reconstruction [1–4]. The new materials provide a scaffold for patient tissue ingrowth and act comparable to an internal supportive bra to provide support for the implant and allow reconstruction of larger breast volumes, a more pronounced ptosis and control of the infra-mammary fold [1–4]. However, there are major concerns related to the higher complication rates associated with the use of matrices resulting in reconstructive failure, the lack of prospective studies and long-time follow-up [5–7].

Moreover, it still remains unclear as to which of the matrices currently flooding the market meet the reconstruction requirements best [8]. The ideal matrix should be ready to use (without prolonged washing procedures), moldable yet mechanically stable, should not cause allergic, immunologic or toxic reactions and should be rapidly integrated into the tissue.

Additionally, the costs of the matrix will become a major factor for most hospitals and insurance companies in the future [3].

KEYWORDS

• immediate implant-based breast reconstruction • long-term absorbable surgical matrix • skin- and nipple-sparing mastectomy • surgical mesh direct breast reconstruction • TIGR Matrix mesh

*Breast Cancer Center, Kepler University Clinic, Linz, Austria; peter.schrenk@liwest.at

Future Medicine part of fsg

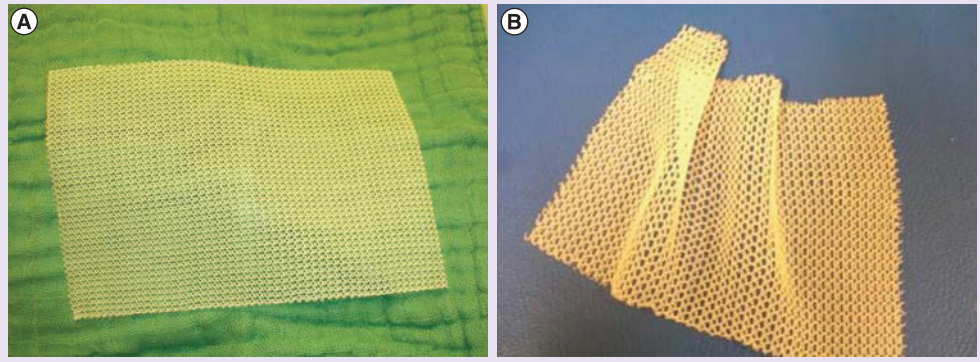


Figure 1. (A) The TIGR® Matrix consists of two different fibers. **(B)** Following degradation (removal) of fiber 1 the mesh loses its rigidity and becomes more pliable.

The TIGR® Matrix mesh

The TIGR® Matrix (Novus Scientific) is a 100% synthetic mesh knitted from 2 fibers with different degradation characteristics (Figure 1A & B). Whereas fiber 1 (copolymer of glycolide, lactide and trimethylene carbonate) is mechanically stable for 2 weeks and resorbed after 4 months, fiber 2 (copolymer of lactide and trimethylene carbonate) is mechanically stable for 6–9 months and should be fully resorbed after 3 years [9]. The advantage of these different degradation times is that the mesh keeps its stability (and gives extra support) during the crucial initial healing phase when pressure of the implant on the already vulnerable mastectomy flaps should be avoided. Contrary to other absorbable meshes, the TIGR® Matrix degrades over a longer period of time than other meshes and in two phases (safety 'back up'). It is composed of different fibers with different degradation characteristics, which means that it does not lose strength at once but changes mechanical stability gradually over time. With a strong support in the initial wound healing phase and becoming increasingly mechanically compliant during the integration phase, the TIGR® Matrix mesh provides a pressure adapted support and should hold the weight of the implant until a sufficient 'own tissue bra' is generated.

Method

In this single-center post-procedure study, the aim was to monitor the safety and performance of TIGR® Matrix in adult patients (>18 years) suitable for immediate implant breast reconstruction following skin-sparing mastectomy. All patients were included between the period of April 2013 and October 2014. The principles

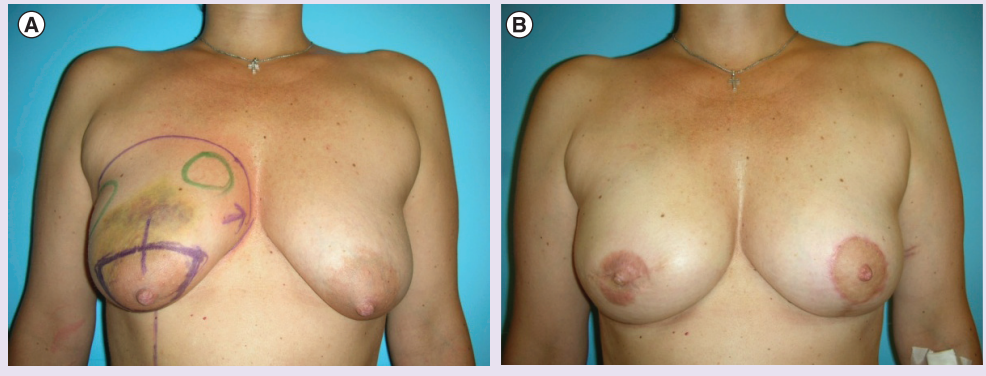


Figure 2. (A) The 54-year-old patient underwent skin-sparing mastectomy for multicentric carcinoma of the right breast. Immediate implant reconstruction with TIGR® Matrix covering the implant in the inferior pole was performed. **(B)** Postoperative view following adaption reduction of the left breast and nipple-areola reconstruction shows an excellent cosmetic result.

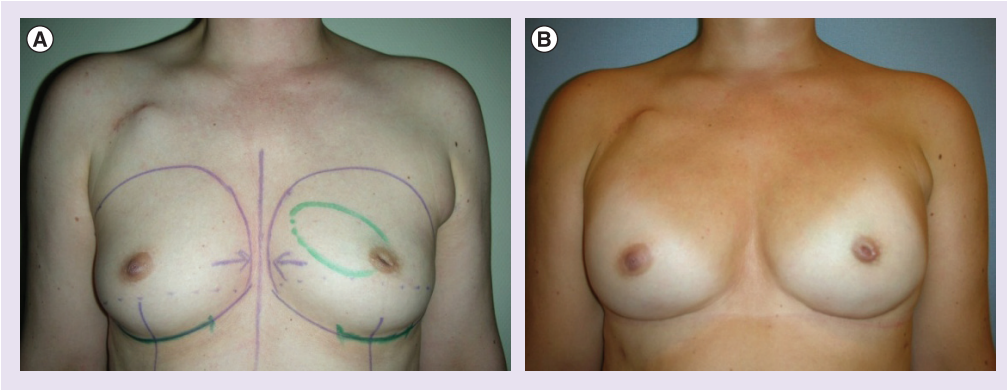


Figure 3. (A) A 42-year-old patient underwent neoadjuvant chemotherapy for breast cancer in the upper inner quadrant of the left breast. Following partial clinical remission, a bilateral nipple-sparing mastectomy was done with immediate reconstruction with implants and a TIGR® Matrix. **(B)** The late postoperative result showed a good cosmetic result.

outlined in the Declaration of Helsinki were strictly followed.

Patients

A total of 29 patients (mean age 46 years, range 25–65 years) underwent a total of 37 mastectomies and immediate reconstruction using an implant and the TIGR® Matrix mesh (Novus Scientific). Indications for mastectomy were breast cancer (n = 29) and BRCA 1 or 2 mutations (n = 8). Six patients underwent neoadjuvant chemotherapy due to tumor biology or tumor size and revealed an incomplete pathological remission. Patients with post-mastectomy radiation treatment planned were excluded from immediate reconstruction. However, there were two patients with a history of previous breast conservation surgery and radiation, as well as in two patients where post-mastectomy radiation was suggested postoperatively for involved lymph nodes or due to the total tumor size exceeding 5 cm.

Surgery

Following nipple-sparing (n = 23) or skin-sparing (n = 14) mastectomy, a submuscular pocket was created with the major pectoralis muscle dissected off its origins in the infra-mammary fold from the thoracic wall and medially up to a height corresponding to the nipple position.

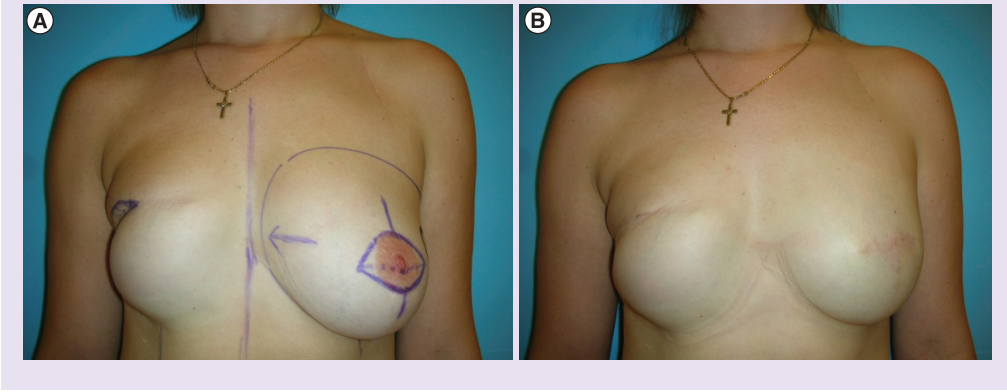


Figure 4. (A) The 29-year-old patient had a history of mastectomy and expander reconstruction for carcinoma of the right breast. Concomitantly a reduction mammoplasty of the left breast was performed. Two years after surgery she was diagnosed with a carcinoma of the left breast and underwent skin-sparing mastectomy and immediate reconstruction with an implant and a TIGR® Matrix. **(B)** Compared to the expander/implant reconstruction of the right breast the left breast revealed a better cosmetic result with a more pronounced ptosis.

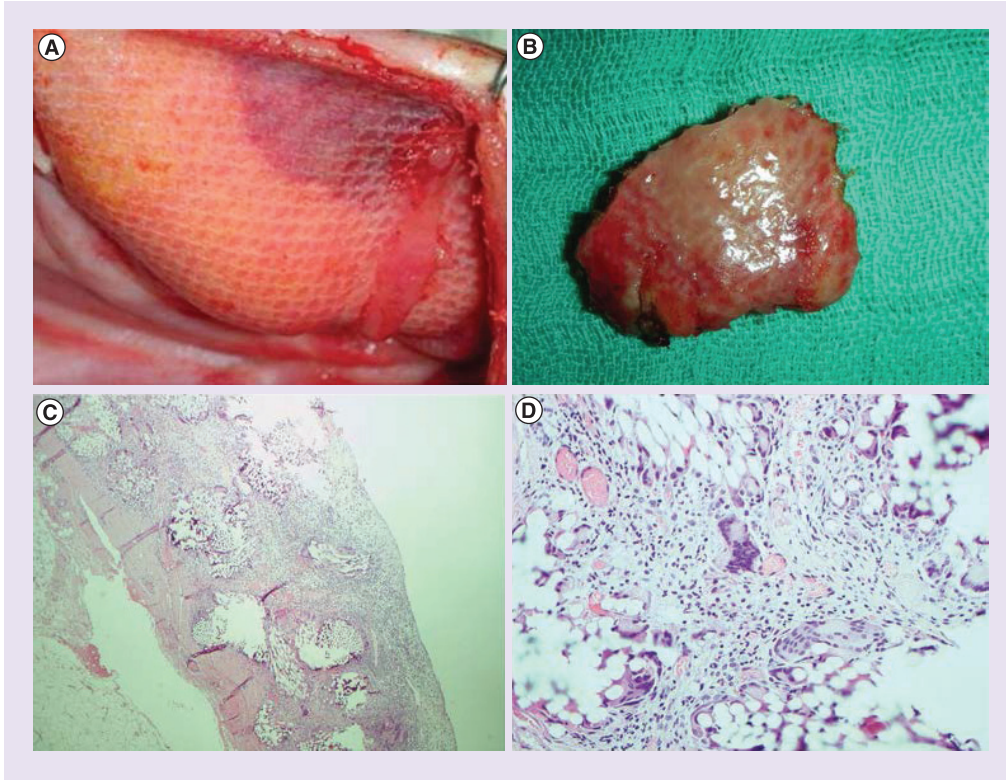


Figure 5. (A & B) Macroscopic and (C & D) microscopic view of TIGR® Matrix 3 months after reconstruction. The mesh is integrated into connective tissue, showing neovessel formation, fibroblasts and phagocytic cells.

The implant was inserted under the muscle and covered in the inferior pole or only laterally with a 15 × 10 cm or 15 × 20 cm (TIGR® mesh, Novus Scientific), which was fixed to the thoracic wall in the inferior pole, cranially to the dissected major pectoralis muscle and laterally to the fascia of the serratus anterior muscle using single 2.0 vicryl sutures (for fixation and positioning of the mesh) and a 2.0 maxon running suture. Positioning of the implant and fixation of the mesh were done in a sitting position.

No peri- or post-operative prophylactic antibiotics were used. Only one drain was used in most patients. The patients were discharged with the drain which was removed in the outpatient clinic, when the drainage was less than 20 cc for 24 h. A supportive bra with a superior pole strap was suggested postoperatively for 6–8 weeks.

Sentinel node biopsy was performed through the mastectomy or a separate axillary incision.

Postoperative treatment

Seven patients underwent postmastectomy chemotherapy, 11 had endocrine treatment, and in 5 patients no further treatment was indicated. Two patients had postmastectomy radiation and this was due to a total tumor size >5 cm or positive axillary lymph nodes.

Postoperative complications

Postoperative complications largely depend upon the definition of a complication and the post-surgical follow-up time for the patient. Whereas postoperative puncture of a seroma is not always reported as a complication, drainage for evacuation of a seroma is suggested to be one. Duration of drainage in our patients was 3–15 days (mean 6.5 days) and was related to our policy to remove the drain when the daily drainage was less than 20 cc. Therefore most patients were released from the hospital with their drainage in place and further treated in the outpatient clinic. Following removal of the drain seven patients had one to six punctures for fluid collection. There was only one seroma which has to be punctured six-times, but no surgical intervention was needed. The puncture of any fluid collection was also due to the decision of the surgeon for an early puncture rather than to wait for a complication caused by seroma and to allow adherence of the tissue to

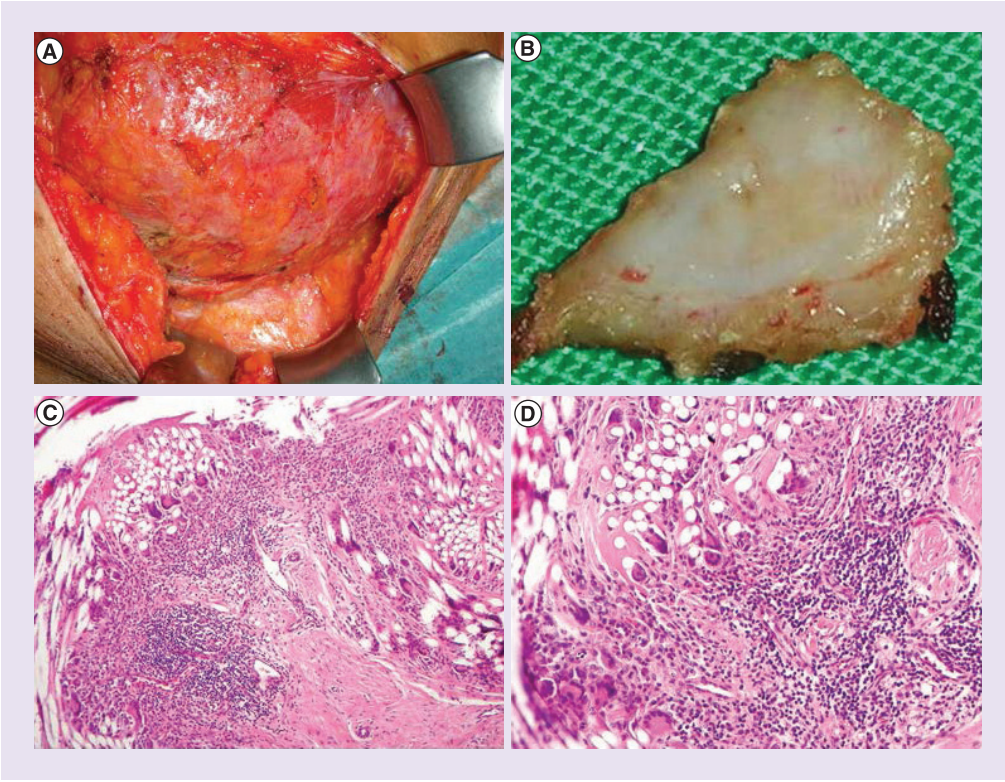


Figure 6. (A & B) Macroscopic and (C & D) microscopic view of TIGR® Matrix 6 months after reconstruction.

the matrix to allow the ingrowth of cells into the matrix.

One patient had fluid secretion through the incision in the infra-mammary fold, which healed spontaneously. One patient showed a wound necrosis of the mastectomy flap 4 weeks after surgery. Conservative treatment failed and due to mesh and implant exposure revision with a latissimus dorsi muscle flap was necessary. This complication was due to the mastectomy or blood supply of the mastectomy flaps but was not related to the TIGR® Matrix mesh.

Postoperative cosmetic result

The cosmetic outcome and patient satisfaction with the cosmetic result was rated on a visual analogue scale from 1 (worse result) to 10 (excellent result) by both the patients and the surgeon each time the patients visited the outpatient clinic. After a median follow-up of 18 months (mean 18.4 months, range 14–32) the postoperative cosmetic result was rated as a mean of 9.1 (patients) and 8.3 (surgeons) **(Figures 2–4)**.

Postoperative oncological result

After a median follow-up of 18 months (mean 18.4 months, range 14–32) there were no local or distant recurrences. Six patients underwent contralateral reduction mammoplasty for symmetrization 6 months after mastectomy, one patient had a contralateral delayed implant reconstruction, another patient underwent remodeling with lipo-filling, and in one patient a contralateral mastectomy and immediate reconstruction was done with a TIGR® mesh, but as the postoperative follow-up was only one month this patient was not included in the survey.

Macroscopic & histological analysis

Macroscopic and histologic examination of biopsies obtained at the time of nipple reconstruction in ten patients 3, 6 or 12 months after surgery showed a good integration of the matrix **(Figures 5–7)**. No surgery was done for treatment of capsular fibrosis yet.

Discussion

The TIGR® Matrix is composed of 2 fibers with different degradation times [9]. This allows a more controlled integration of the matrix with gradual shift/transfer of the implant weight from the matrix to the patient's own soft tissue coverage. The

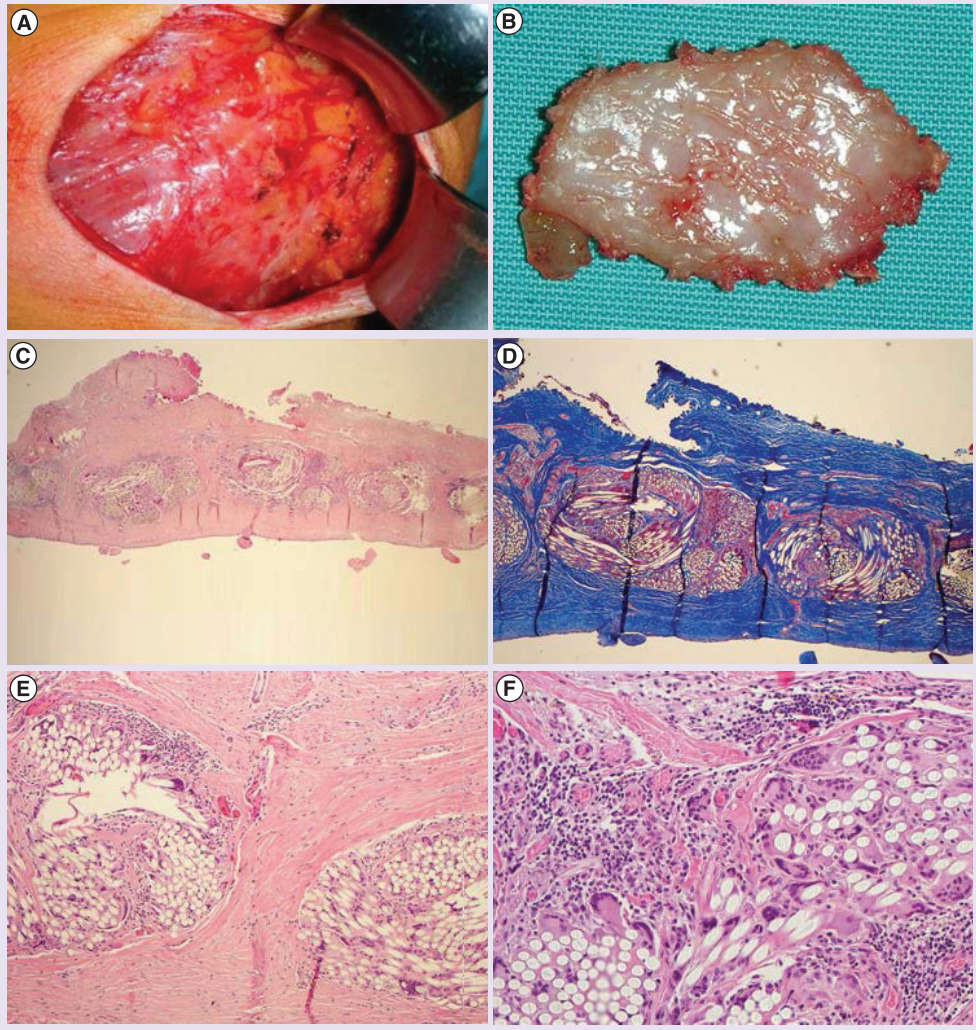


Figure 7. (A &B) Macroscopic and (C–F) microscopic view of TIGR® Matrix 12 months after reconstruction. Remnants of the matrix are incorporated within connective tissue.

stability of the mesh in the initial healing phase is crucial so that the implant does not exert pressure on the mastectomy flaps before healing has occurred. The mesh should therefore be adequately fixed with sutures to diminish the weight load of the implant on the vulnerable mastectomy flaps.

Postoperative complications may be largely related to patient selection and poor surgical technique rather than the type of mesh used for reconstruction but there may be short term differences. In a prior evaluation study, we found that the amount and duration of drainage in patients with TIGR® Matrix reconstruction were lower compared with other acellular dermal matrices **(Figure 8)**. The ideal patients for implant reconstruction with the TIGR® Matrix are patients with a small or medium breast size and no or moderate ptosis. Contraindication (as for every matrix reconstruction) is a poor soft tissue coverage after mastectomy with doubtful blood supply to the mastectomy flaps. In these instances, the mesh may not be integrated but may cause wound complications followed by implant exposure and reconstruction failure.

We have not seen any complications in our patients which may directly be related to the use of neoadjuvant chemotherapy. However, there may be a possible negative impact of chemotherapy (pre- and post-operative) on mesh integration [10]. There are no recommendations regarding the use of antibiotics with respect to synthetic meshes. Our own policy is not to give antibiotics neither intraoperatively nor postoperatively unless there is an infection.

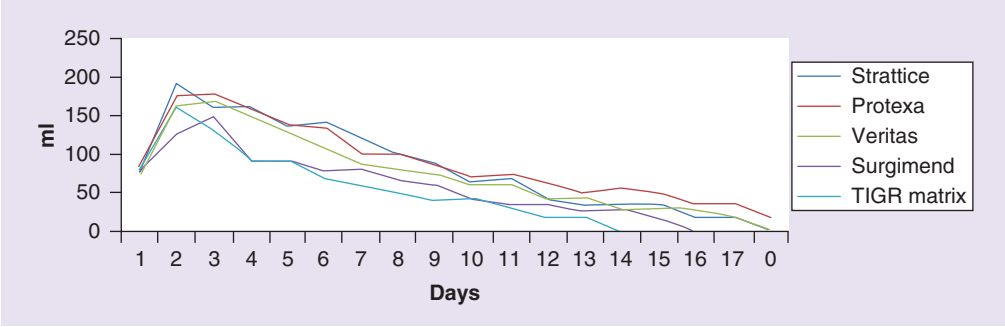


Figure 8. The amount and time of drainage was lower in patients with TIGR® Matrix assisted implant breast reconstruction compared with acellular dermal matrices.

The cost for TIGR® Matrix is lower compared with similar matrices or meshes. The mesh is available in sizes of 10 × 15 cm, 15 × 20 cm and 20 × 30 cm (the largest size may be used for bilateral reconstructions and can be cut to the desired size without the risk of unravelling).

It is important to note that the long-time outcome of the matrix with respect to capsular contracture rate is not yet known.

Two patients with a radiation prior to reconstruction and 2 patients with a postmastectomy radiation had no radiation associated complications and a good cosmetic result, but the follow-up was too short to draw further conclusions.

Conclusion

A new long-term absorbable surgical matrix, TIGR® Matrix mesh was used in a total of 29 patients undergoing a total of 37 mastectomies and immediate reconstruction. Although the follow-up was short the TIGR® Matrix mesh fulfills many desired characteristics and requirements for a matrix for use in implant-based breast reconstruction and is a promising new alternative to acellular, dermal or other synthetic matrices currently available.

Financial & competing interests disclosure

P Schrenk has been a speaker for Novus Scientific. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

The author acknowledges Kris Överby, CMPP for writing assistance for this article. Support for writing assistance came from Novus Scientific.

References

1 Maxwell GP, Gabriel A. Efficacy of acellular dermal matrices in revisionary aesthetic breast surgery: a 6 year experience *Aest. Surg. J.* 33(3), 389–399 (2013).

2 Adetayo OA, Salcedo SE, Bahjiri K, Gupta SC. A meta-analysis of outcomes using acellular dermal matrix in breast and abdominal wall reconstructions: event rates and risk factors predictive of complications. *Ann. Plast. Surg.* doi:10.1097/SAP.0b013e31822afae5 (2011) (Epub ahead of print).

3 Becker H, Lind JG. The use of synthetic mesh in reconstructive, revision and cosmetic breast surgery. *Aesth. Plast. Surg.* 37, 914–921 (2013).

4 Dieterich M, Paepke S, Zwiefel K *et al.* Implant-based breast reconstruction using a titanium-coated polypropylene mesh (Tiloop Bra): a multicenter study of 231 cases. *Plast. Reconstr. Surg.* 132(1), e8–e19 (2013).

5 Hill JL, Wong L, Kemper P, Buseman J, Davenport DL, Vasconez HC. Infectious complications associated with the use of acellular dermal matrix in implant-based bilateral breast reconstruction. *Ann. Plast. Surg.* 68, 432–434 (2012).

6 Ho G, Nguyen TJ, Shahabi A, Hwant BH, Chan LS, Wong AK. A systematic review and meta-analysis of complications associated with acellular dermal matrix-assisted breast reconstruction. *Ann. Plast. Surg.* 68, 346–356 (2012).

7 Wong L, Buseman J, Oldham J. Infectious complications with acellular dermal matrices and breast reconstruction. *Plast. Reconstr. Surg.* 127, 91 (2011).

8 Brooke S, Mesa J, Uluer M *et al.* Complications in tissue expander breast reconstruction: a comparison of Alloderm, Dermamatrix and FlexHD accelular inferior pole dermal slings. *Ann. Plast. Surg.* 69, 347–349 (2012).

9 Hjort H, Mathisen T, Alves A, Clermont G, Boutrand JP. Three-year results from a preclinical implantation study of a long-term resorbable surgical mesh with time-dependent mechanical characteristics. *Hernia* 16, 191–197 (2012).

10 Myckatyn TM, Cavallo JA, Sharma K *et al.* The impact of chemotherapy and radiation on the remodeling of acellular dermal matrices in staged, prosthetic breast reconstruction. *Plast. Reconstr. Surg.* 135(1), e43–e57 (2015).