Immediate implant based breast reconstruction using the TIGR® Matrix

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Introduction

Background

The use of acellular dermal or synthetic matrices has improved the functional and cosmetic outcome of implant based breast reconstruction. The new materials provide additional tissue for implant coverage (comparable to an internal supportive bra) and allow reconstruction of larger breast volumes, a more pronounced ptosis and control of the inframammary fold. However, there are major concerns related to the higher complications rates associated with the use of matrices resulting in reconstruction failure, the lack of prospective studies and long-time follow-up. Moreover, it still remains unclear, which of the acellular dermal, synthetic or biological matrices currently flooding the market meet the reconstruction requirements best. The ideal matrix should be ready to use (without long lasting washing procedures), mouldable, but still mechanically stable, should not cause allergic, immunologic or toxic reactions and should be rapidly integrated into the tissue. More, the costs of the matrix will become a major factor for most hospitals and insurance companies in the future.

The TIGR® Matrix

The TIGR® Matrix Surgical Mesh (TIGR® Matrix) (Novus Scientific AB, Sweden) is a 100% synthetic mesh knitted from 2 fibres with different degradation characteristics (Fig. 1a,b). Whereas fibre 1 (copolymer of polyglycolide, polylactide and trimethylene carbonate) is mechanically stable for 2 weeks and resorbed after 4 months, fibre 2 (copolymer of polylactide and trimethylene carbonate) is mechanically stable for 6-9 months and should be fully resorbed after 3 years. 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”). For it is composed of different fibres with different degradation characteristics it does not lose its strength at once but changes its mechanical stability gradually over time with a strong support in the initial wound healing phase and then becoming increasingly mechanically compliant during the integration phase. It therefore provides a pressure adapted support and should hold the weight of the implant until a sufficient “own tissue bra” exists.

Patients

Between April 2013 and October 2014 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 (Novus Scientific). Indications for mastectomy were breast cancer (n=29) and BRCA 1 or 2 mutations (n=8). Patients with post mastectomy radiation treatment planned were excluded from immediate reconstruction. However, there were 2 patients with a history of previous breast conservation surgery and radiation, as well as in 2 patients post mastectomy radiation was suggested postoperatively for involved lymph nodes or due to the total tumour size exceeding 5cm.
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 inframammary fold from the thoracic wall and medially up to a height corresponding to the nipple position. The implant was inserted under the muscle and covered in the inferior pole (Fig. 2a,b) or only laterally (Fig. 2c,d) with a 15x10 cm (20x30 cm) TIGR® Matrix, 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 postoperative 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 hours. A supportive bra with a superior pole strap was suggested postoperatively for 6 to 8 weeks.

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

Results

Postoperative treatment:
Six patients underwent neoadjuvant chemotherapy due to tumour biology or tumour size and revealed an incomplete pathological remission. Seven patients had post mastectomy chemotherapy, 11 endocrine treatment, in 5 patients no further treatment was suggested. Two patients had post mastectomy radiation and this was due to a total tumour size >5 cm or positive axillary lymph nodes.

Postoperative complications:
Postoperative complications largely depend on the definition of a complication and the time followed up the patient after surgery. Whereas postoperative puncture of a seroma is not always reported as complication drainage for evacuation of a seroma is suggested to be one. Following removal of the drain 7 patients had 1-6 punctures for seroma. This was also due to the decision of the surgeon for an early puncture rather than to wait for a complication caused by seroma. In a prior study we showed that the amount and duration of drainage in patients with TIGR® Matrix reconstruction is lower when compared to acellular dermal matrices (Fig. 3).

One patient had fluid secretion through the incision in the inframammary 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.

Postoperative cosmetic result
The cosmetic outcome / patient satisfaction with the cosmetic result was rated on a scale from 1 (worse result) to 10 (excellent result) by both the patients and the surgeon and was a mean of 9.1 (patients) and 8.3 (surgeons) (Fig. 4,5,6,7).
Postoperative oncological result

After a median follow-up of 10 months (mean 10.4 months, range 3-20) there were no local or distant recurrences. Six patients underwent contralateral reduction mammoplasty for symmetrisation 6 months after mastectomy, one patient had a contralateral delayed implant reconstruction, another patient underwent remodelling with lipofilling, in one patient a contralateral mastectomy and immediate reconstruction was done with a TIGR® Matrix, but for the postoperative follow up was only one month the patient was not included in the survey.

Macroscopic and histological analysis

Macroscopic and histologic examination of biopsies obtained at the time of nipple reconstruction 3, 6 or 12 months after surgery showed a good integration of the matrix (Fig. 8,9,10).

Comments

- The TIGR® Matrix is composed of 2 fibres with different degradation time. 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 stability of the mesh in the initial healing phase is crucial that the implant does not exert pressure on the mastectomy flaps before healing has occurred. Therefore the mesh should be adequately fixed with sutures to diminish the weight load of the implant on the vulnerable mastectomy flaps.

- Postoperative complications largely are related to patient selection and poor surgical technique rather than the type of mesh used for reconstruction. 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 is for every matrix reconstruction) is a poor soft tissue coverage after mastectomy with the blood supply of the mastectomy flaps in doubt. In these instances the mesh may not be integrated but causes wound complications followed by implant exposure and reconstruction failure.

- The costs for TIGR® Matrix are lower compared to similar matrices or meshes. The mesh is available in sizes of 15x10cm and 30x20cm (which may be used for bilateral reconstructions and can be cut in the desired size without the risk of unravelling.

- The TIGR® Matrix meets all the requirements for an ideal matrix (Table 1).

- The long-time outcome of the matrix with respect to capsular contracture rate is not known yet. Two patients with a radiation prior to reconstruction and 2 patients with a post mastectomy radiation had no radiation associated complications and a good cosmetic result, but the follow-up was too short to draw further conclusions.
**Figures**

Fig. 1 a,b: The TIGR® Matrix consists of two different fibres (a). Following degradation (removal) of fibre 1 the mesh loses its rigidity and becomes more pliable (b).

Fig. 2 a-d: Implantation of the mesh. The mesh either covers the implant in the complete inferior pole after the pectoralis major muscle fibres have been dissected off the thoracic wall (2 a,b) or only laterally between the pectoralis muscle and the serratus anterior fascia after “dual plane” dissection (2 c,d).
Fig. 3: The amount and time of drainage was lower in patients with TIGR® Matrix assisted implant breast reconstruction compared to acellular dermal matrices.

Fig. 4 a-d: The 54 year old patient underwent skin-sparing mastectomy for multicentric carcinoma of the right breast (a,b). Immediate implant reconstruction with a TIGR® matrix covering the implant in the inferior pole was performed (a,b). Postoperative view following adaption reduction of the left breast and nipple-areola reconstruction shows an excellent cosmetic result (c,d).
Fig. 5 a-d: A 42 year old patient underwent neoadjuvant chemotherapy for breast cancer in the upper inner quadrant of the left breast (a,b). Following partial clinical remission a bilateral nipple-sparing mastectomy was done with immediate reconstruction with implants and a TIGR® Matrix. The late postoperative result showed a good cosmetic result (c,d).
Fig. 6 a-d: The 45 year old patient had a nipple-sparing mastectomy for a cancer of the right breast. Preoperative (a,b) and postoperative view (c,d) after implant based reconstruction with a TIGR® Matrix.
Fig. 7 a-d: 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 (a,b). 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 R matrix. Compared to the expander / implant reconstruction of the right breast the left breast revealed a better cosmetic result with a more pronounced ptosis (c,d).
Fig. 8 a-d: Macroscopic (a,b) and microscopic (c,d) view of TIGR® Matrix 3 months after reconstruction. The mesh is integrated into connective tissue, showing neo-vessel formation, fibroblasts and phagocytic cells.
Fig. 9 a-d: Macroscopic (a,b) and microscopic (c,d) view of TIGR® Matrix 6 months after reconstruction.
Fig. 10 a-f: Macroscopic (a,b) and microscopic (c,d,e,f) view of T TIGR® Matrix matrix 12 months after reconstruction. Remnants of the matrix are incorporated within connective tissue.
Table 1: The TIGR® Matrix meets most of the requirements for an ideal matrix.

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<tr>
<th>Requirement</th>
<th>Rating</th>
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<tr>
<td>Internal supportive bra</td>
<td>+++</td>
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<tr>
<td>Allows some ptosis</td>
<td>++</td>
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<tr>
<td>Replacement of thinned / missed tissue</td>
<td>?</td>
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<tr>
<td>Non allergic, immunologic, toxic</td>
<td>+++</td>
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<tr>
<td>Durability, but mechanical stable</td>
<td>+++</td>
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<tr>
<td>Mouldable, pliable, soft</td>
<td>+++</td>
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<tr>
<td>Ready for use, sterile</td>
<td>+++</td>
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<tr>
<td>Easy to handle</td>
<td>+++</td>
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<tr>
<td>Rapid and good integration (high porosity)</td>
<td>++</td>
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<tr>
<td>Use in radiation, infection</td>
<td>?</td>
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<tr>
<td>Low complication rate</td>
<td>++</td>
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<td>Low capsular contracture rate</td>
<td>?</td>
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<tr>
<td>Moderate cost</td>
<td>+++</td>
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<tr>
<td>Personal experience</td>
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