TIGR® matrix

Clinical Literature Synopsis

"TIGR® Matrix SURGICAL MESH – A TWO-YEAR FOLLOW-UP STUDY AND COMPLICATION ANALYSIS IN 65 IMMEDIATE BREAST RECONSTRUCTIONS"

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BACKGROUND & METHODS

Acellular Dermal Matrices (ADM) vs TIGR® Matrix in implant based breast reconstructions

Acellular dermal matrices (ADM)

It has become increasingly popular to use matrices, such as ADMs, in implant-based breast reconstruction. Perceived advantages of ADMs include better definition and control of the limitations of the implant pocket and the inframammary fold, enablement of a dual plane technique, giving a more naturally shaped lower breast pole and diminishing the need for lower polemuscular coverage and therefore extensive muscle dissection. ADMs might also decrease the risk of capsule formation.

The drawback of ADMs is a potential increased risk for complications, including infection, seroma formation, mastectomy flap necrosis and loss of implant. In addition, the ADMs are afflicted with non-negligible costs.

TIGR® Matrix

To lower the cost and to avoid implanting biological material, the use of synthetic meshes has been proposed.

TIGR Matrix is a synthetic long-term absorbable mesh. It is macroporous and knitted from two types of fibers: a fast-degrading copolymer and a slow-degrading copolymer. The slow-degrading part of the mesh keeps its strength for 6–9 months and is completely resorbed after about three years, whereas the fast-degrading part gives extra strength during the healing phase and gradually absorbs, making the mesh softer and more flexible and stretchable, during the first four months. Both parts of the mesh are degraded by hydrolysis into small molecules that are excreted from the body.

The cost of TIGR Matrix is about one third of the cost of ADM.

This is the first study examining TIGR Matrix in a larger series of immediate breast reconstruction.

Aim of this study

The main aim was to examine short-term complications (<30 d) following breast reconstruction with TIGR Matrix in combination with a tissue expander or an implant. The secondary aim was to examine predictors for complications.

Methods

All consecutive patients operated on with breast reconstruction with TIGR Matrix and tissue expanders (TEs) or permanent implant were prospectively included.

Exclusion criteria were ongoing smoking, BMI (kg/m2)>30, planned postoperative radiation, and inability to leave informed consent.

Either nipple-sparing (NSM) or skin-sparing (SSM) mastectomy was performed.

A retropectoral pocket was created and a TIGR Matrix was sutured in place to the inferior border of the pectoral muscle superiorly, the chest inferiorly and to the serratus fascia laterally, using 2–0 Maxon.

An anatomical TE or a permanent anatomical silicone implant (direct-to implant (DTI)) was placed into a retropectoral pocket. one subcutaneous and one submuscular drain was used for each breast and kept until drain volume was less than 30 ml/24h.

MAIN RESULTS & KEY TAKEAWAYS

Main Results

Fifteen breasts (23%) were affected by complications within 30 d: four (6.2%) major complications and eleven (17%) minor complications. The major complications included two implant losses and one pulmonary embolism (PE).

The implant losses were due to wound dehiscence with exposure of the TE in one case and infection in the other case. The PE occurred despite prophylactic anticoagulation in a patient with anaortic valve replacement and an atrial fibrillation.

All patients, but one, have had their TEs exchanged for a permanent implant. During the operation TIGR Matrix meshes were visually well integrated in all cases but one.

Table 1 Details about the patients and the reconstructions.

		Total (patients=49)
Age (years)		46.0 45.6 (9.4) (26.6–71.0)
Weight (kg)		65.0 64.0 (8.4) (49.0–84.0)
BMI (kg/m^2)		23.2 23.1 (2.6) (17.9–28.4)
Smoking	Yes No	0 49 (100.0%)
Bleeding (ml)		177.8 100.0 (231.9) (20.0–1450.0)
Follow-up time (months)		23.6 23 (6.1) (17–34) Total (breasts=65)
Indication	BRCA1 BRCA2 DCIS[a] Invasive cancer Increased risk[b]	27 (41.5%) 4 (6.2%) 13 (20.0%) 6 (9.2%) 15 (23.1%)
Type of mastectomy	Nipple sparing Skin sparing	57 (87.7%) 8 (12.3%)
Incision	Submammary fold Wise pattern Lateral Vertical Horizontal	39 (61.9%) 11 (17.5%) 8 (12.7%) 3 (4.8%) 2 (3.2%)
Postoperative radiation		0 (0%)[d]
Preoperative radiation	No Yes[c]	58 (89.2%) 7 (10.8%)
Resectionweight (g)		264.4 255.0 (140.5) (50.0–660.0) n=62
Type of implant	Expander Permanent[e]	60 (92.3%) 5 (7.7%)
Peroperative expander fill (ml)	Expander 0 ml Expander>0 ml Filled volume (ml)	2 (3.5%) 53 (93.0%) 142.2 (78.8) 140.0 (20.0–350.0) n=53

Smoking was an exclusion criteria and could not be investigated in this material.

Four minor surgical complications occurred after 30 d (minimum follow-up 17 months). There were no implant losses. In addition, minor aesthetic corrections, such as dog-ear resection, were performed in 10 breasts.

Predictors for a complication were age over 51 years, BMI over 24.5 kg/m2, large resectionweight, and the need for a wise pattern excision of skin.

Key Takeaways

The implant loss rate of 3.1% seen in this study is similar to that of other studies on reconstruction with both biological and synthetic matrices.
Previous reports of complications with matrices have stated seroma formation in up to 15% of cases and infection in up to 30%. In light of this, the seroma frequency of 3.1% and infection rate of 1.5% in this study have to be considered low and speaking against an increased risk with TIGR Matrix.

Risk factors for short-term complications in implant based reconstruction with TIGR Matrix seem to be similar to those with reconstruction with other forms of matrices.

Breast reconstruction with a tissue expander and TIGR Matrix can be performed with a low complication rate. The majority of the problems encountered after 30 days were minor aesthetic shortcomings. Further studies are needed to investigate the long-term complication rate, capsule formation and aesthetic result.

Table 2 Complications within 30 d.

Major complications	**Total**	**4 (6.2%)**
Breast-related (4.6%)	**Implant loss**	**2 (3.1)**
Other (1.5%)	Pulmonary embolism Reoperation due to Hematoma	1 (1.5%) 1 (1.5%)
Minor complications	**Total**	**11 (17%)**
	Epidermolysis[a] **Hematoma[a]** **'Red breast'** **Seroma** **Minimal wound rupture[a]** **Partial necrosisa** **Wound infection[a]**	**3 (4.6)** **1 (1.5%)** **2 (3.1)** **2 (3.1)** **1 (1.5%)** **1 (1.5%)** **1 (1.5%)**

TIGR® Matrix Surgical Mesh is a resorbable surgical implant. It is made from two different synthetic polymer fibers that are knitted together to form a matrix. TIGR Matrix is characterized by long-term resorption and a dual stage degradation design that follows the natural wound healing and remodeling stages, this will allow the body to withstand the stresses after the matrix has been absorbed. The new connective tissue can then offer a long-term support. The result is a surgical mesh that is easy to use for a variety of reconstructive surgery applications where a balance between mechanical support and degradation time is needed. TIGR Matrix is made from materials that have been in clinical use since the 1970's and the product is supported by a growing body of peer-reviewed clinical evidence.

TIGR® Matrix Surgical Mesh is intended for use in reinforcement of soft tissue where weakness exists in procedures involving repair of indirect inguinal hernias and ventral hernias, in prophylactic use to reinforce the midline suture, and in reconstructive breast surgery for both prepectoral and submuscular surgical procedures.

Caution: Read instructions for use which accompany the product for indications, contraindications, warnings and precautions.
TIGR® Matrix Surgical Mesh received 510(k) clearance by the FDA in 2010 and carries the CE-mark since 2011.

CE 2797