



## Clinical Literature Synopsis

# “IMMEDIATE IMPLANT RECONSTRUCTION USING ABSORBABLE TIGR MESH AFTER NIPPLE-SPARING MASTECTOMY”

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## BACKGROUND & METHODS

### Nipple-Sparing Mastectomy (NSM)

NSM with immediate implant reconstruction is an increasingly popular technique for treatment of breast cancer and risk reducing surgery – in general with low rates of complications and good cosmetic outcomes.

### Limitations with current meshes used in implant reconstructions

#### ADM (animal acellular dermal matrices)

Increased risk of infection, seroma formation and implant loss. High costs.

#### Synthetic meshes including polypropylene, Ultrapro and Vicryl

Promising results in small series with regard to infection and implant loss rates, but additional disadvantages such as lack of incorporation into the body's own tissues with non-absorbable mesh, possible higher capsular contracture rates and possible poorer outcomes in the setting of radiotherapy.

### Absorbable Synthetic Meshes – TIGR<sup>®</sup> Matrix

Increasing interest in the use of longer-term absorbable synthetic meshes in breast reconstruction, such as **TIGR<sup>®</sup> Matrix** which has shown fewer overall complications (29% versus 36%) and lower implant loss rates (4.9% versus 22%) vs biological meshes. These previous studies with TIGR Matrix have been in conjunction with Skin-Sparing Mastectomy-use (SSM), ie up to now limited data for its use in NSM.

**Concern with NSM:** higher overall complication rates compared to SSM mainly related to risk of nipple necrosis.

### Aim of this study

Evaluate outcomes following use of TIGR Matrix in the context of NSM, compared with SSM, with immediate implant reconstruction.

**Table 1**  
Surgical characteristics of included procedures

| Mastectomy type     | Number (%) |
|---------------------|------------|
| Nipple-sparing      | 43 (26)    |
| Skin-sparing        | 121 (74)   |
| Reconstruction type |            |
| Tissue expander     | 44 (27)    |
| Direct-to-implant   | 120 (73)   |

### Methods

Retrospective review of a prospectively maintained database of 164 skin and nipple-sparing mastectomies with immediate implant reconstruction using TIGR Matrix.

Data was analysed with regard to patient demographics, indications for surgery, surgical procedure, complication rates and locoregional recurrence rates.

Complete muscle coverage techniques for implant or tissue expander insertion were not routinely used, due to the increased pain and poorer lower pole projection associated with this technique. Prepectoral implant reconstructions were also not performed.

TIGR Matrix has subsequently been used for prepectoral reconstruction but it is out of the scope of this study.

## MAIN RESULTS & KEY TAKEAWAYS

### Main Results

No differences in outcomes between the NSM and SSM groups except for a higher incidence of skin or nipple necrosis in the NSM group (12% vs 2%). All these cases were superficial only and all were successfully managed conservatively.

56% of the NSM cohort had risk-reducing surgery, compared with 9% of the SSM cohort – supporting the increased popularity of NSM for risk reducing surgery due to good cosmetic outcomes and low nipple loss rate.

Equally low rates of infection (NSM 9%, SSM 11%) and implant loss rates (NSM 9%, SSM 6%) in both groups.

Results regarding radiotherapy are limited as only four patients in the NSM group underwent radiotherapy. The NSM cohort included smokers and ex-smokers, in similar proportions to those undergoing SSM, without an increase in complication rate.

Single-stage reconstruction was performed in 73% of the total cohort and in 84% of the NSM patients.

### Key Takeaways

Previous reports have shown low infective complication rates with TIGR Matrix in SSM, with infection rates of 1.7–10% and implant loss rates of 3.6–6.7%. This study supports those findings, with low complication rates in the SSM group (infection rate 11%, implant loss rate 6%).

In addition - in this first study to report on the use of TIGR Matrix in consecutive NSM cases with immediate implant reconstruction – TIGR Matrix shows equally low complication rates in the NSM setting with infection rates of 9%, implant loss rate of 9% and no nipple loss.

Patients selected for NSM in the study had significantly smaller breast volumes than patients undergoing SSM - showing that NSM is not a suitable procedure for all patients, as better cosmetic results are achieved in patients with smaller, non-ptotic breasts. The study confirms that a high rate of single-stage reconstructions can be achieved with the use of TIGR Matrix following NSM in small to moderate volume breasts.

**Table 4**  
Surgical outcomes in Nipple-Sparing Mastectomy (NSM) versus Skin-Sparing Mastectomy (SSM) groups; NSM patients were more likely to experience skin or nipple necrosis but all cases in this cohort were managed conservatively

|                               | NSM (43) | SSM (121) |
|-------------------------------|----------|-----------|
| <b>Infection</b>              | 4 (9%)   | 13 (11%)  |
| <b>Skin/nipple ischaemia*</b> | 5 (12%)  | 3 (2%)    |
| <b>Superficial</b>            | 5        | 3         |
| <b>Full-thickness</b>         | 0        | 0         |
| <b>Haematoma</b>              | 0        | 1 (1%)    |
| <b>Implant loss</b>           | 4 (9%)   | 7 (6%)    |
| <b>Capsular contracture</b>   | 1 (2%)   | 8 (6%)    |

NSM with immediate implant-based reconstruction using TIGR Matrix is a safe and effective procedure, relatively low-cost alternative, with comparable outcomes to SSM and to NSM using other forms of mesh. TIGR Matrix allows single stage reconstruction to be performed post NSM with a low complication rate.

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.