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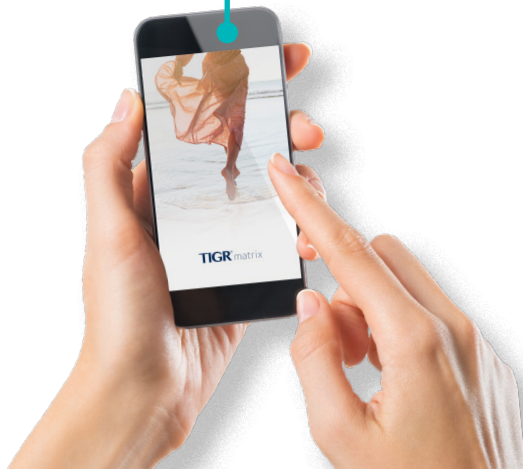


Table of content

1. Are patients most satisfied with a synthetic or a biological mesh in dual-plane immediate breast reconstruction after 5 years? A randomized controlled trial comparing the two meshes in the same patient..... 6
2. Mastectomy and Immediate Breast Reconstruction with Pre-Pectoral or Sub-Pectoral Implant: Assessing Clinical Practice, Post-Surgical Outcomes, Patient’s Satisfaction and Cost..... 8
3. A Retrospective Study Assessing the Outcomes of Immediate Prepectoral and Subpectoral Implant and Mesh-Based Breast Reconstruction 10
4. First-year complications after immediate breast reconstruction with a biological and a synthetic mesh in the same patient: A randomized controlled study 12
5. Drain secretion and seroma formation after immediate breast reconstruction with a biological and a synthetic mesh, respectively: A randomized controlled study 14
6. Prepectoral direct-to-implant breast reconstruction with complete ADM or synthetic mesh coverage – 36-Months follow-up in 200 reconstructed breasts..... 16
7. Comparison of inflammatory response and synovial metaplasia in immediate breast reconstruction with a synthetic and a biological mesh: A randomized controlled clinical trial 18
8. Immediate implant reconstruction using absorbable TIGR® mesh after nipple-sparing mastectomy 20

Table of content, cont.

- 9. TIGR® Matrix surgical mesh – a two-year follow-up study and complication analysis in 65 immediate breast reconstructions.....22
- 10. The Use of TIGR® Matrix in Breast Aesthetic and Reconstructive Surgery : Is a resorbable Synthetic Mesh a Viable Alternative to Acellular Dermal Matrices?24
- 11. De novo experience of resorbable woven mesh in immediate breast reconstruction post-mastectomy26
- 12. Bi-pedicle nipple-sparing mastectomy (modified Letterman technique) and TIGR® mesh-assisted immediate implant reconstruction, in a patient with Cowden syndrome28
- 13. Immediate implant-based breast reconstruction using the TIGR® Matrix.....30
- 14. The Use of Synthetic Mesh in Reconstructive, Revision and Cosmetic Breast Surgery32
- 15. Three-year results from a preclinical implantation study of a long-term resorbable surgical mesh with time-dependent mechanical characteristics.....34

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Are patients most satisfied with a synthetic or a biological mesh in dual-plane immediate breast reconstruction after 5 years? A randomized controlled trial comparing the two meshes in the same patient

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Summary

Biological or synthetic meshes are commonly used in implant-based immediate breast reconstruction (IBR). The aim of this study was to compare patient-reported outcome measurements (PROMs) after IBR with a synthetic mesh and a biological mesh, in a singleblinded randomized controlled trial, using the compared materials in the same patient, thereby eliminating patient-related confounders. Twenty-four patients were recruited, and all patients had a prophylactic bilateral mastectomy and a dual-plane reconstruction using anatomical breast implants.

The patients' two breasts were randomized preoperatively to a biological or a synthetic mesh, using a simple approach with a parallel design. PROMs were measured with BREAST-Q. Twentyone patients answered (88%). Most participants were equally satisfied/dissatisfied with the synthetic and the biological mesh sides regarding size of bra, softness, feel to touch, natural part of body, appearance compared with preoperatively, and palpable wrinkles, and about half of the patients regarding shape of bra, natural appearance, and visible wrinkles. The frequency of capsular contracture rate was zero in both groups at 5 years. One mesh type was not clearly superior to

the other regarding PROMs, but biological and synthetic meshes seem to give rise to different types of reconstructed breasts, and more studies are needed regarding whether knowledge about the effects of different meshes can be used to tailor breast reconstructions to individual patients' wishes. The rate of complications and corrections in the biological mesh breasts was higher, and this must be considered when the type of mesh is chosen.

Conclusions

One mesh type is not generally superior to the other, regarding patient-reported outcomes. Biological and synthetic meshes seem to give rise to different types of reconstructed breasts, and more studies are needed regarding whether knowledge about the effects of different meshes can be used to tailor breast reconstructions to individual patients' wishes. The rate of complications and corrections in the biological mesh breasts is higher, which must be considered when the type of mesh is chosen. □

Mastectomy and Immediate Breast Reconstruction with Pre-Pectoral or Sub-Pectoral Implant: Assessing Clinical Practice, Post-Surgical Outcomes, Patient's Satisfaction and Cost

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Abstract

Immediate breast reconstruction (IBR) rates increase during last years and implant-based reconstruction was the most commonly performed procedure. We examined data collected over 25 months to assess complication rate, duration of surgery, patient's satisfaction and cost, according to pre-pectoral or sub-pectoral implant-IBR.

All patients who received an implant-IBR, from January 2020 to January 2022, were included. Results were compared between pre-pectoral and sub-pectoral implant-IBR in univariate and multivariate analysis.

We performed 316 implant-IBR, 218 sub-pectoral and 98 (31%) pre-pectoral. Pre-pectoral implant-IBR was significantly associated with the year (2021: OR=12.08 and 2022: OR=76.6), the surgeons and type of mastectomy (SSM vs NSM: OR=0.377).

Complications and complications Grade 2-3 rates were 12.9% and 10.1% for sub-pectoral implant-IBR respectively, without significant difference with pre-pectoral implant-IBR: 17.3% and 13.2%. Complications Grade 2-3 were significantly associated with age <50-years (OR=2.27), ASA-2 status (OR=3.63) and cup-size >C (OR=3.08), without difference between pre and sub-pectoral implant-IBR. Durations of surgery were significantly associated with cup-size C and >C (OR=1.72 and 2.80), with senti-

nel lymph-node biopsy and axillary dissection (OR=3.66 and 9.59) and with sub-pectoral implant-IBR (OR=2.088). Median hospitalization stay was 1 day, without difference between pre and sub-pectoral implant-IBR.

Cost of surgery was significantly associated with cup-size > C (OR=2.216) and pre-pectoral implant-IBR (OR=8.02). Bad-medium satisfaction and IBR failure were significantly associated with local recurrence (OR=8.820), post-mastectomy radiotherapy (OR=1.904) and sub-pectoral implant-IBR (OR=2.098).

Conclusion

Complications Grade 2-3 were significantly associated with age <50 years, ASA 2 status and breast cup-size >C, without difference between pre and sub pectoral implant-IBR. Despite a shorter duration of surgery, higher cost was observed for pre-pectoral implant-IBR. More patients achieved bad or medium satisfaction for local recurrence, with PMRT and for sub-pectoral implant-IBR. Pre-pectoral implant-IBR seems to correspond to a reliable, faster technique with equivalent results in terms of complications and better patient satisfaction. To confirm these results, a multicenter study is ongoing.

□

A Retrospective Study Assessing the Outcomes of Immediate Prepectoral and Subpectoral Implant and Mesh-Based Breast Reconstruction

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(1) Introduction

In response to patient concerns about breast cancer recurrence, increased use of breast magnetic resonance imaging and genetic testing, and advancements in breast reconstruction techniques, mastectomy rates have been observed to rise over the last decade. The aim of the study is to compare the outcomes of prepectoral and subpectoral implants and long-term, dual-stage resorbable mesh-based breast reconstructions in mutation carriers (prophylactic surgery) and breast cancer patients.

(2) Patients and methods

This retrospective, two-center study included 170 consecutive patients after 232 procedures: Prepectoral surgery was performed in 156 cases and subpectoral was performed in 76.

(3) Results

Preoperative chemotherapy was associated with more frequent minor late complications ($p < 0.001$), but not major ones ($p = 0.101$), while postoperative chemotherapy was related to more frequent serious ($p = 0.005$) postoperative complications. Postoperative radiotherapy was associated with a higher rate of minor complications (31.03%) than no-radiotherapy (12.21%; $p < 0.001$).

Multivariate logistic regression found complications to be significantly associated with an expander (OR = 4.43), skin-reducing mastectomy (OR = 9.97), therapeutic mastectomy vs. risk-reducing mastectomy (OR = 4.08), and postoperative chemotherapy (OR = 12.89). Patients in whom prepectoral surgeries were performed demonstrated significantly shorter median hospitalization time ($p < 0.001$) and lower minor complication rates (5.77% vs. 26.32% $p < 0.001$), but similar major late complication rates ($p = 0.915$).

(4) Conclusions

Implant-based breast reconstruction with the use of long-term, dual-stage resorbable, synthetic mesh is a safe and effective method of breast restoration, associated with low morbidity and good cosmesis. Nevertheless, prospective, multicenter, and long-term outcome data studies are needed to further evaluate the benefits of such treatments. □

First-year complications after immediate breast reconstruction with a biological and a synthetic mesh in the same patient: A randomized controlled study

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Background

Even though meshes and matrices are widely used in breast reconstruction, there is little high quality scientific evidence for their risks and benefits. The aim of this study was to compare first-year surgical complication rates in implant-based immediate breast reconstruction with a biological mesh with that of a synthetic mesh, in the same patient.

Methods

This study is a clinical, randomized, prospective trial. Patients operated on with bilateral mastectomy and immediate breast reconstruction were randomized to biological mesh on one side and synthetic mesh on the other side.

Results

A total of 48 breasts were randomized. As the synthetically and the biologically reconstructed breasts that were compared belonged to the same woman, systemic factors were exactly the same in the two groups. The most common complication was seroma formation with a frequency of 38% in the biological group and 3.8% in the synthetical group ($p=.011$). A higher frequency of total implant loss could be seen in the biologic mesh group (8.5% vs. 2%), albeit not statistically significant ($p=.083$).

Conclusions

In the same patient, a synthetic mesh seems to yield a lower risk for serious complications, such as implant loss, than a biological mesh. □

Drain secretion and seroma formation after immediate breast reconstruction with a biological and a synthetic mesh, respectively: A randomized controlled study

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Abstract

The aim of this study was to compare seroma production in breast reconstruction with a biological mesh with that of a synthetic mesh, in the same patient. The patients were randomized to biological mesh in one breast and synthetic in the other. Twentyfour breasts were included. The total drain production and the daily drain production were similar in the two groups. After drain removal, there were more seroma aspirations in the biological group. During the exchange to a permanent implant, there was significantly more seroma in the biological group. Seroma formation is different in synthetic and biological meshes.

Results

A total of 24 breasts, in 12 patients, were included. Patient demography and surgical details are presented in Table 1. The total drain production was a median of 579 mL (range 70-1460) in the biological group and 563 mL (range 345-2070) in the synthetic group ($P = .3$). The drains were kept in place for a median of 7.5 days (range 4-14) in the biological group and 8.5 days (range 2-14) in the synthetic group ($P = .9$). The daily drain production was similar in the two groups (Figure 1). After drain removal, there were

no seroma aspirations in the synthetic group and two class III seromas, that is seromas requiring 3 or more aspirations, in the biological group ($P = .157$). There were no TE losses in the synthetic breasts and 1 in the biological breasts. The TE was lost due to infection, following wound edge healing problems. The patient had a total drain production of 980 mL on the biological side and 1245 on the synthetic side and did not require any seroma aspirations. During the exchange to a permanent implant, 11 synthetic mesh breasts had < 1 deciliter seroma and 1 breast > 1 deciliter. In the biological mesh breasts, 1 breast had < 1 deciliter seroma and 10 breasts had > 1 deciliter seroma ($P = .011$). □

Prepectoral direct-to-implant breast reconstruction with complete ADM or synthetic mesh coverage – 36-Months follow-up in 200 reconstructed breasts

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Background

Prepectoral implant placement is an innovative option for breast reconstruction, due to multiple advantages over subpectoral implant placement. The adoption of various ADMs and mesh supports the utilization of the prepectoral technique.

Methods

200 breasts were reconstructed with prepectoral implant placement after nipple-sparing mastectomy in a one-stage direct-to-implant procedure. The implants were completely covered and fixed with porcine ADMs (Strattice™ or Artia™), or with synthetic meshes (TIGR®). The pectoralis major muscle was not detached at all and kept intact entirely.

Results

Minor complications included minimal nipple necrosis without further intervention and complete healing in 14 breasts (7.0%). Major complications comprised implant loss due to skin necrosis and wound infection in 7 breasts (3.5%), and hematoma with revision surgery in 8 breasts (4.0%). At a mean follow-up of 36 months cosmetic results were excellent and good in 180 breasts (90.0%), sufficient in 13 breasts (6.5%) and insufficient in 7 breasts (3.5%). Breast animation defor-

mity and implant displacement could not be observed, while implant rotation was documented in 5 breasts (2.5%). Capsular contractures grade III or IV could not be observed neither in patients with previous radiotherapy nor in patients with radiotherapy to the reconstructed breast.

Conclusions

The single-stage direct-to-implant prepectoral implant placement after NSM with complete coverage of the implant with ADM or synthetic mesh represents a novel and feasible technique for breast reconstruction. This technique provides an alternative to the subpectoral implant placement with excellent cosmetic results avoiding the disadvantages of the subpectoral implant placement. □

Comparison of inflammatory response and synovial metaplasia in immediate breast reconstruction with a synthetic and a biological mesh: a randomized controlled clinical trial

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Abstract

The aim of this study was to compare inflammatory response and synovial metaplasia in implant-based immediate breast reconstruction with a biological mesh (Veritas) with that of a synthetic mesh (TIGR® Matrix Surgical Mesh). We hypothesize that the inflammatory response and formation

of synovial meta-plasia might be different and the rate of capsular contracture therefore different. The patients were recruited from the Gothenburg TIGR®/Veritas Study (ClinicalTrials.gov identifier NCT02985073).

All referrals for bilateral immediate breast reconstruction were assessed for inclusions. During the operation,

the patients were randomized to which sides the biological and the synthetic mesh were going to be applied. During the implant exchange biopsies were taken. Biopsies were taken from 30 breasts in 15 patients. There seem to be more myofibroblast and neovascularization in the biological meshes than in the synthetic and the collagen fibers seem to be aligned in an irregular pattern with both parallel and vertical fibers. In the synthetic meshes, there were more giant cells and foreign body reaction and the collagen fibers were loosely and well aligned, oriented parallel to the surface of the implant. Synovial metaplasia was seen in the majority of both the biological and the synthetic meshes. The histological patterns in early capsules from biological and synthetic meshes vary considerably. Nonetheless, it is unknown what role different cell types have in capsular formation in the long run and there was no difference in clinical capsular contracture at the clinical follow-up in this study.

Results

Biopsies were taken from 30 breasts in 15 patients. All of the cases were prophylactic cases and none of the patients had received radiotherapy. Each patient had one breast operated on with synthetic mesh and one with

biological mesh and at least one biopsy was taken from each side. Median age at the first operation was 35.6 years (min 24.7 and max 58.4 years). Two patients were operated on with Wise-pattern mastectomies and the rest via a sub-mammary incision. The nipple areolar complex was preserved in all cases. Median mastectomy weight was 267.5 grams (min 70 and max 544 grams). Time between mesh insertion and biopsy was a median of 111 days (min 70 and max 145 days). Between the insertion and the biopsy one patient needed a seroma puncture on the side with synthetic mesh. During the operations all meshes were well integrated macroscopically and there was no evidence of clinical infection in any case. In all patients, the seroma formation was more pronounced on the biological side. The clinical follow-up after the implant exchange was a median of 520 days (range 188 to 679 days). All breasts were evaluated as Baker class I or II. □

Immediate implant reconstruction using absorbable TIGR® mesh after nipple-sparing mastectomy

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Background

Nipple-sparing mastectomy with immediate implant reconstruction is an increasingly popular technique for both treatment of breast cancer and risk-reducing surgery, with an evolving body of evidence confirming low complication rates and satisfactory patient outcomes. Immediate implant reconstruction usually requires use of one of many available meshes for complete implant coverage. The aim of this study was to assess outcomes after nipple-sparing mastectomy using synthetic absorbable TIGR® mesh.

Methods

A retrospective review of a prospectively maintained database of 164 skin and nipple-sparing mastectomies with immediate implant reconstruction using TIGR mesh was performed. Data was retrieved and cross-checked with electronic patient records. Data was analysed with regard to patient demographics, indications for surgery, surgical procedure, complication rates and locoregional recurrence rates.

Results

Of 164 implant reconstructions, forty-three were performed after nipple-sparing mastectomy. No differences in outcomes were seen between

the two groups except for a higher incidence of skin or nipple necrosis in the nipple-sparing group (12% versus 2%). There was no nipple loss in this cohort. Infection rate in the nipple-sparing group was 9% versus 11% in the skin-sparing group, with implant loss rates of 9% and 6%, respectively. Mean follow-up was 23.6 months.

Conclusions

Our study has shown that immediate implant reconstruction after nipple-sparing mastectomy using TIGR® mesh is safe and feasible, with low rates of early and medium-term complications.

Level of evidence: Level III, therapeutic study. □

TIGR® Matrix surgical mesh – a two-year follow-up study and complication analysis in 65 immediate breast reconstructions

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Abstract

In recent years, it has become increasingly popular to use matrices, such as acellular dermal matrices, in implant-based breast reconstruction. To lower the cost and to avoid implanting biological material, the use of synthetic meshes has been proposed. This is the first study examining TIGR® Mesh in a larger series of immediate breast reconstruction. The aims of the study were to examine complications and predictors for complications. All consecutive patients operated on with

breast reconstruction with TIGR® Matrix Surgical Mesh and tissue expanders (TEs) or permanent implant between March 2015 and September 2016 in our department were prospectively included. Exclusion criteria were ongoing smoking, BMI (kg/m²) > 30, planned postoperative radiation, and inability to leave informed consent. 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). Predictors for a complication were age over 51 years, BMI over 24.5 kg/m², large resection weight, and the need for a wise pattern excision of skin. 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. In conclusion, breast reconstruction with a TE in combination with TIGR® Matrix Surgical Mesh can be performed with a low complication rate.

Results

During the study period, 65 immediate breast reconstructions with TIGR® mesh were performed in 49 patients, 16 bilateral and 33 unilateral. Details about the patients and operations can be found in Table 1. Fifteen breasts (23%) were affected by complications within 30 d: four (6.2%) major complications and eleven (17%) minor complications (Table 2). The major complications included two implant losses and one pulmonary embolism (PE) and one reoperation due to hematoma in the same patient. 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 an aortic

valve replacement and an atrial fibrillation. The most common minor complication was epidermolysis not requiring revision, which occurred in three cases (4.6%). Risk factors (Table 3) for a complication were age over 51 years (p 1/4 .0081) (Figure 2), BMI over 24.5 kg/m² (p 1/4 .051) (Figure 3), large resection weight (p 1/4 .0026) (Figure 4), and the need for a wise pattern excision of skin (p 1/4 .029) (Figure 3). All patients, but one, have had their TEs exchanged for a permanent implant. During the operation the TIGR meshes were visually well integrated (Figure 5) in all cases but one. Smoking was an exclusion criterion and could not be investigated in this material. A final control was performed in all cases, but two (97%). Minimum follow-up time was 17 months. Four surgical complications occurred after 30 d. Late complications included one case of wound dehiscence treated conservatively, one case of partial areola necrosis treated conservatively, and two cases of capsular contraction, Baker grade II, not requiring correction. There were no implant losses. In addition, minor aesthetic corrections, such as dog-ear resection and lipofilling because of wrinkles, were performed in 10 breasts. □

The Use of TIGR® Matrix in Breast Aesthetic and Reconstructive Surgery : Is a resorbable Synthetic Mesh a Viable Alternative to Acellular Dermal Matrices?

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Introduction

The use of acellular dermal matrices (ADM) and synthetic meshes in breast surgery is gaining popularity in recent years. In implant-based breast reconstruction, complete implant coverage has been the main target of surgeons in order to reduce the risk of implant exposure. The matrices are widely

used in order to facilitate the complete coverage of the prosthesis. In aesthetic breast surgery, ADMs and synthetic meshes can be used as a sling to decrease gravitational changes as well as to strengthen weakened inferior pole tissue, so cosmetic benefits such as stable nipple-areola position and adequate breast projection can be

achieved. The use of these matrices and meshes in both reconstructive and aesthetic breast surgery is promising, especially because the surgical techniques can be used by almost every experienced surgeon and are characterized with a steep but fast learning curve.

Many options are currently available on the market and vary from human cadaveric ADM to fetal bovine-derived ADM, bovine-derived collagen matrix, porcine-derived ADM, and synthetic meshes. ADMs are produced by decellularization of dermal matrix, a process that leaves the extra-cellular scaffold intact. It is within this scaffold that patient's cells repopulate and therefore vascularize the graft. Synthetic meshes are defined as products that are manufactured synthetically. They can be either nonresorbable, partially resorbable, or completely resorbable devices. Concerns regarding the significant cost associated with the biological matrices have been expressed, especially when compared with the synthetic meshes.

It is well documented in the literature that synthetic meshes are viable alternatives to ADMs.¹⁻³

This article documents the authors' experience in the use of a synthetic 100% bioresorbable surgical mesh

(TIGR Matrix, Novus Scientific, Uppsala, Sweden) in breast reconstruction as well as in breast aesthetic surgery.

Summary

TIGR Matrix is an important tool in breast reconstructive surgery as well as in breast aesthetic surgery. The double properties of this mesh, short-term strength and long-term tissue reinforcement, as well as low cost renders this mesh a valuable device for achieving superior results in breast surgery. Moreover, it appears safe, because it is associated with low mesh-complication incidence and explantation rates. □

De novo experience of resorbable woven mesh in immediate breast reconstruction post-mastectomy

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Background

Implant based reconstruction (IBR) is the most common form of breast reconstruction. IBR has advantages: uncomplicated surgery, no donor site and good aesthetic outcome. Disadvantages include infection with implant loss and physical limitation to the size of breast which can be used. Here we describe our initial experience using a resorbable mesh in post mastectomy patients.

Methods

Post mastectomy patients after cancer surgery or for risk reducing surgery were examined over a period of 18 months after undergoing reconstruction surgery with the use of resorbable mesh and implant based reconstruction. Patients were followed for complications including flap necrosis, implant loss, haematoma, seroma and infection rates.

Results

Few major complications were encountered. There were no instances of flap necrosis or haematoma formation. However, 5 reconstructed breasts (n=74, 6.7%) resulted in loss of the implant due to infection. These losses were associated with patients who were current or ex-smokers, or in patients who were undergoing either

radiation or chemotherapy. Minor complications such as superficial wound infections were seen in 8 out of 74 (10%) reconstructed breasts. The overall complication rate was 17.5% or 13 out of 74 reconstructed breasts.

Conclusions

The use of resorbable mesh provides excellent cosmetic outcomes with minimal complications. To avoid complications discretion should be used in patients with risk factors such as smoking and radiation therapy. Level of Evidence: Level IV, therapeutic study. □

Bi-pedicle nipple-sparing mastectomy (modified Letterman technique) and TIGR[®] mesh-assisted immediate implant reconstruction, in a patient with Cowden syndrome

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Abstract

Cowden syndrome, a rare genetic disorder estimated to occur in 1 in 200,000 live births and inherited as an autosomal dominant mutation in PTEN gene, is part of the PTEN hamartoma tumor syndrome. These patients are at risk of breast cancer, as well as cancers of the digestive tract, thyroid,

uterus and ovaries. Often identified by their dentist due to characteristic papillomatosis in the gingival mucosa, they have an estimated lifetime risk of up to 81% of developing breast cancer. This article describes a relatively uncommon procedure of bi-pedicle nipple-sparing mastectomy, a modified Letterman technique, used in the

setting of immediate implant based reconstruction in a patient with Cowden syndrome.

Conclusions

Bi-pedicle nipple-preserving mastectomy for gynaecomastia, a modification of the Letterman technique, has been previously described (3,4). Historically, larger breasted women were offered two-stage procedure of breast reduction followed by skin-sparing mastectomy with reconstruction to achieve a final smaller-sized breast in the setting of risk-reducing mastectomy (5). Safety of skin-sparing mastectomy with ADM-assisted immediate implant reconstruction in patients with small early breast cancers and those with previous breast reduction scars has also been established (5,6). Search of medical literature including PubMed, did not identify use of the modified Letterman approach in the immediate implant reconstruction setting following mastectomy.

Potential pitfalls of nipple loss or necrosis can be circumvented by careful patient selection, avoiding in smokers, diabetics or older patients, careful handling of skin flaps and the pedicle to avoid traction injury and ensuring closure of all wounds without tension. Intraoperatively the pedicle was thinned down to avoid ghosting

effect, which could have potentially compromised vascular supply to the nipple. Special nipple dressings were left undisturbed for a week to minimize risk of wound contamination. The transparent Tegaderm dressing with a window allows visual monitoring of nipple viability by nursing staff in the immediate postoperative period while keeping the wound sealed.

Successful outcome in this case was possible due to coordinated teamwork in a multidisciplinary setting between the specialist breast radiologist, anatomical pathologist, infectious disease specialist, specialist anaesthetist and an oncoplastic breast surgeon. Careful patient selection and education with multiple discussions, detailed information leaflets and close monitoring in the post-operative period by a dedicated breast care nurse is vital. □

Immediate implant-based breast reconstruction using the TIGR[®] Matrix

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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. □

The Use of Synthetic Mesh in Reconstructive, Revision and Cosmetic Breast Surgery

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Background

Recent evidence suggests that the use of acellular dermal matrices in prosthetic breast reconstruction, revision or augmentation may be associated with an increased risk of complications. This article will report the results of a potential alternative, using a new long-term resorbable synthetic matrix in these cases.

Methods

A retrospective study was performed evaluating 11 primary breast reconstructions (19 breasts), 43 secondary reconstructions (77 breasts), 3 augmentation, 7 augmentation mastopexys (6 breasts), and 5 mastopexys (10 breasts) in 62 patients using TIGR® Matrix Surgical Mesh.

Results

Follow-up ranged from 9.4 to 26.1 months with an average follow-up of 16.5 months. The average age was 54 years. The number of patients who had prior radiation was 9 (14.5%). Four patients (6.5%) were smokers. Postoperative breast complications included necrosis of two flaps (1.8%), four infection/extrusions (3.6%), two relapses of inframammary fold/malposition (1.8%), and two with rippling (1.8%). Other complications included six cases of asymmetry that required a

corrective procedure. In a variety of breast surgery cases, very good aesthetic results were achieved.

Conclusion

The long-term absorbable synthetic TIGR® Matrix Surgical Mesh, shows potential when used as temporary reinforcement in patients undergoing breast reconstruction or breast surgery revisions and in primary aesthetic procedures, and it appears to be a viable alternative to the use of acellular dermal matrices. □

Three-year results from a preclinical implantation study of a long-term resorbable surgical mesh with time-dependent mechanical characteristics

Hjort, H.
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Alves, A.
Clermont, G.
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Purpose

The purpose of this study was to evaluate the biocompatibility, local tissue effects and performance of a synthetic long-term resorbable test mesh (TIGR® Matrix Surgical Mesh) compared to a non-resorbable polypropylene control mesh following implantation in a sheep model.

Methods

Full-thickness abdominal wall defects were created in 14 sheep and subsequently repaired using test or control meshes. Sacrifices were made at 4, 9, 15, 24 and 36 months and results in terms of macroscopic observations, histology and collagen analysis are described for 4, 9, 15, 24 and 36 months.

Results

The overall biocompatibility was good, and equivalent in the test and control meshes while the resorbable mesh was characterized by a collagen deposition more similar to native connective tissue and an increased thickness of the integrating tissue. The control polypropylene mesh provoked a typical chronic inflammation persistent over the 36-month study period. As the resorbable test mesh gradually degraded it was replaced by a newly formed collagen matrix with an

increasing ratio of collagen type I/III, indicating a continuous remodeling of the collagen towards a strong connective tissue. After 36 months, the test mesh was fully resorbed and only microscopic implant residues could be found in the tissue.

Conclusions

This study suggests that the concept of a long-term resorbable mesh with time-dependent mechanical characteristics offers new possibilities for soft tissue repair and reinforcement. □

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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.



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