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Prepectoral breast reconstruction with TiLoop® Bra Pocket: a single center prospective study

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Abstract. – OBJECTIVE: In the last decades, immediate breast reconstruction (IBR) raised in frequency, and prepectoral positioning of the implant is becoming the trend nowadays. The aim of this paper is to describe our case series in IBR with prepectoral implant placement and complete coverage of it with the TiLoop® Bra titanium-coated polypropylene mesh (TCPM), pre-shaped as a pocket.

PATIENTS AND METHODS: Eighteen women with breast tumors were selected and underwent mono- or bilateral mastectomies and prepectoral IBR with tissue expanders or prostheses. After the prepectoral lodge was ready, the implants were inserted into TiLoop® Bra Pocket meshes and positioned over the pectoralis major muscle fascia. The mean surgical time of their positioning was four minutes.

RESULTS: This preliminary study showed meaningful results in prepectoral IBR with TiLoop® Bra Pocket covering the implants, for we observed a reduction of implant's exposure time and risk of bacterial contamination. Of the 18 patients that underwent this procedure, only three presented complications that resolved in a maximum of four weeks.

CONCLUSIONS: A considering reduction of surgical time in implant positioning was achieved, lowering exposure time and risk of complications as infection.

Key Words:
Immediate breast reconstruction, Prepectoral breast reconstruction, Titanium-coated polypropylene mesh, Breast cancer.

Introduction

According to World Health Organization, breast cancer is the most common malignancy in women worldwide: in 2012 it represented over 25% of new cancer cases diagnosed (excluding non-melanoma skin cancer[1-3]) and its incidence is expected to exceed all cancers by 2020[4].

Recently, Panchal et al[5] pointed out the current trends in post mastectomy breast reconstruction: in 2014 immediate breast reconstruction (IBR) raised to 54% of invasive cancer cases and 63% of ductal carcinoma in situ cases[6], and in 2002 implant-based breast reconstruction surpassed autologous techniques as the most common method performed in USA[7].

Prepectoral positioning of the implant during breast reconstruction was firstly described by Snyderman and Guthrie in 1971[8]. It represented a fundamental advancement in prosthetic breast reconstruction, but it was associated with a high incidence of complications, including mastectomy skin flap necrosis, implant extrusion, capsular contracture, implant visibility, palpability, and rippling.

Subpectoral implant placement offers some advantages: minimal implant visibility, reduced rippling and minimal palpability of implant edges at the upper pole. However, pectoralis major detachment leads to morbidity, animation deformity and postoperative pain[9,10].

The introduction of new devices such as acellular dermal matrix (ADM) or titanium-coated poly propylene mesh (TCPM), gave new revival to prepectoral breast reconstruction[11]. These innovative devices wrap the implant and create a further protective layer for subcutaneous placement. The subcutaneous approach represents a less invasive, easier to perform and time sparing surgical procedure. It is associated with reduced postoperative

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pain and a more natural breast shape with no animation deformity and improved aesthetic result[12,13].

For the first time, we validated a new device in the setting of prepectoral breast reconstruction. In this study we describe a series of 18 patients undergoing IBR with prepectoral implant placement and complete coverage with a titanium-coated polypropylene mesh (TCPM), specifically preshaped as a pocket TiLoop® Bra (TiLoop® Bra, pfm medical, Cologne, Germany).

Patients and Methods

Between August 2017 and January 2018, women that presented breast cancer diagnosis or harboured a genetic predisposition to it (i.e., mutation in BRCA1 or BRCA2 genes), and were undergoing mono- or bilateral mastectomy, were enrolled for this prospective study at our institution Breast Unit Integrata, Livorno, Cecina, Piombino, Elba, Azienda USL Toscana nord ovest, Italy. Main inclusion criteria was suitability for nipple-sparing or skin-sparing mastectomy and immediate heterologous breast reconstruction with prepectoral tissue expander or definitive prosthesis. Other inclusion criteria consisted in body mass index (BMI) between 25 and 35 kg/m^2 and no previous breast surgery. Patients that were used to smoke 20 or more cigarettes per day, were excluded.

Prior to surgery, all patients were evaluated for both autologous or alloplastic breast reconstruction, taking into account patient preference, body habitus, co-morbidities and prior abdominal surgery. Only patients willing to undergo prosthetic breast reconstruction, who refused autologous reconstruction or presenting any contraindication to these procedures, were enrolled in this study. Approval by local Ethics Committee was obtained and all patients provided written informed consent. Our study was performed with respect to the ethical standards of the Declaration of Helsinki, as revised in Tokyo in 2004.

Our surgical technique for prepectoral breast reconstruction with definitive or temporary implants and TiLoop Bra mesh has been previously described[14,15]. Mastectomy was performed through wise pattern, inframammary fold or lateral S-shaped incisions that were shaped on patients' anatomical characteristics (Figure 1). Previously to the incisions, local anaesthetic (Ropivacaine hydrochloride 7.5 mg/dl) was injected long the incision lines. After mammary gland removal, skin flaps were raised in the subdermal plane and evaluated if suitable for prepectoral placement of a definitive prosthesis. When skin coverage was considered too feeble to support pressure and weight of a definitive prosthesis, a tissue expander (Allergan®, Inc., Irvine, CA, USA) was inserted instead. Tissue expanders were filled with sterile saline solution at 30% of their maximum volume before placement, in order to avoid excessive stress over mastectomy flaps. Otherwise, when skin flaps were considered adequate, direct reconstruction with definitive prosthesis (Natrelle 410; Allergan, Inc., Irvine, CA, USA) was the first choice. In each case, a TiLoop® Bra Pocket was briefly soaked in a gentamicin solution, then adjusted around the implant, after confirming with a sizer in case of definitive prosthesis. TCPM pockets are available in two sizes, medium or large. The proper device was chosen according to implant volume for each case. The TCPM pocket, with the implant inside, was then placed in a totally subcutaneous prepectoral position. Cranial, medial and lateral borders of the mesh were secured to the pectoral fascia with absorbable 2-0 interrupted stiches (Vicryl®, Ethicon, Norderstedt, Germany) (Figure 2). Once the prepectoral lodge was ready, surgical time of implant positioning was recorded.

After local anaesthetic injection, one vacuum drain (calibre: 19 Fr) was inserted in the inframammary fold and patients received oral Ceph-

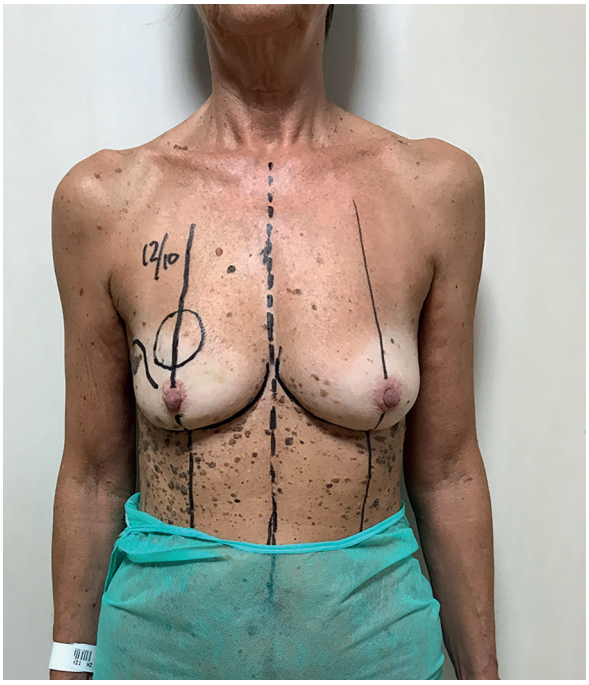

Figure 1. Pre-surgical picture of a patient suffering for tumor of the right breast.

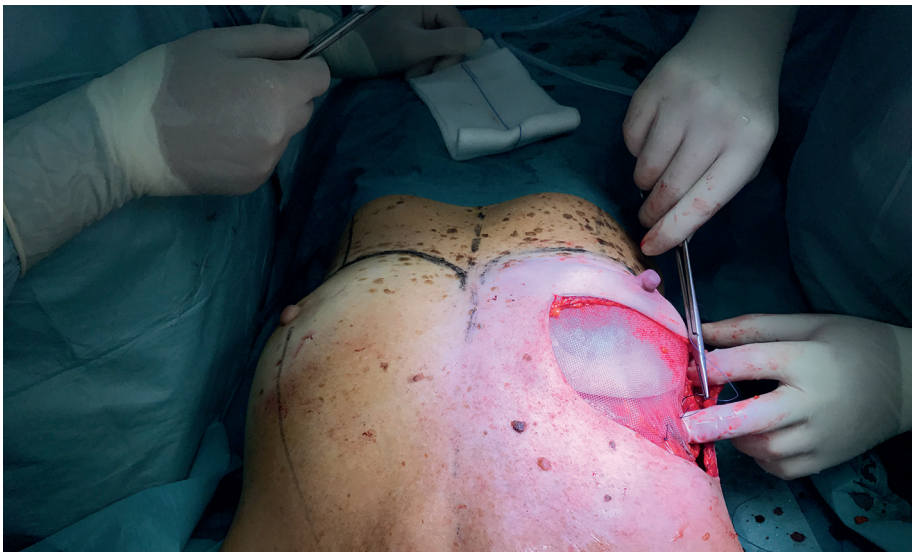

Figure 2. TiLoop® Bra Pocket with the implant inside is placed in a totally subcutaneous prepectoral position. Cranial, medial and lateral borders of the mesh are secured to the muscular fascia.

alosporin class antibiotics until surgical drains were removed. Compressive wound dressing was performed and substituted after 24 hours with post-surgical bra, that was maintained for 60 days. In cases of two-stage reconstruction with a tissue expander, the first postoperative expansion was scheduled three weeks following discharge and two other expansions were performed until reach of the final volume.

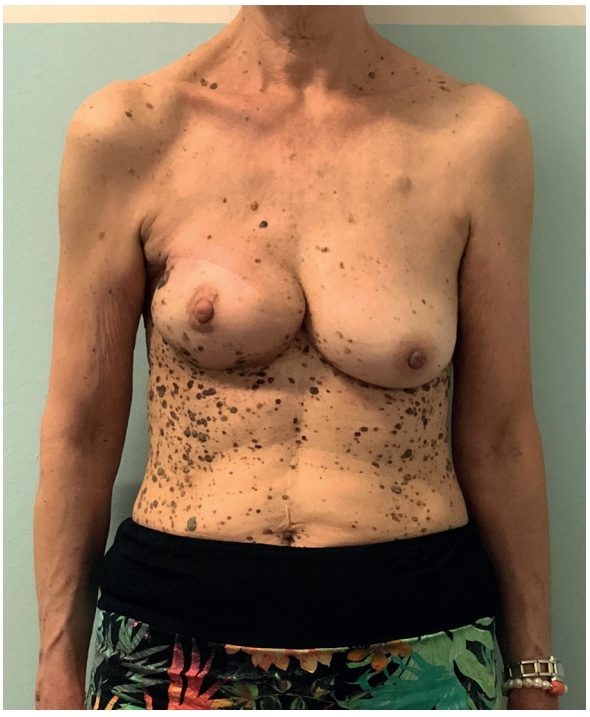

Figure 3. Post-operative picture of the patient, 10 months after surgery.

All of the procedures in both oncological and reconstructive phases were performed by the same surgeons.

Follow-up lasted 11 to 15 months, with an average of 12 months. Patients were evaluated every two weeks for the first two months and every two months thereafter.

Quality of life was assessed with BREAST-Q score. Patients underwent this test one month before mastectomy and six months after definitive prosthesis positioning. Absolute BREAST-Q scores and their changes before and after treatment were analyzed. The Shapiro-Wilk test was used to verify for normal distribution of continuous variables. Consequently, BREAST-Q scores and panel scores were analyzed as continuous variables using the *t*-test. Values of $p < 0.05$ were considered statistically significant.

Surgical complications were classified as those potentially requiring a reoperation, including skin-nipple necrosis, seroma, wound dehiscence, wound infection and hematoma. Their occurrence was used to evaluate secondary outcomes.

Capsular contracture was assessed with the Baker scale during postoperative follow-up.

Results

From August 2017 to January 2018, 18 women were enrolled in this study and data were collected

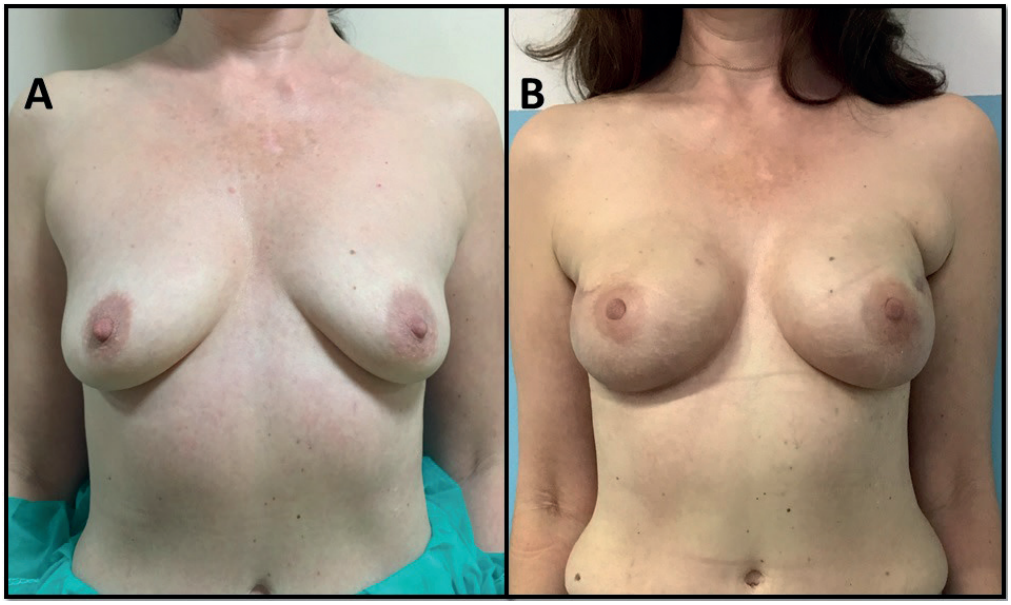

Figure 4. A bilateral breast tumor case: the picture shows pre-surgical time (**A**) and post-operative state (**B**), 30 days after surgery.

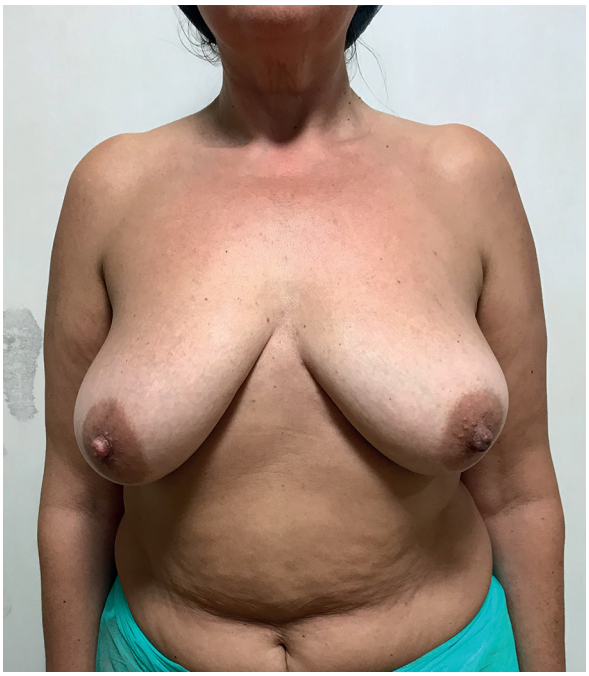

Figure 5. Pre-surgical picture of a case of a monolateral tumor of the left breast.

on their demographics, medical and family history (Table I**)**. Patients' age ranged from 34 to 67 (mean age 52 years) and they presented a mean BMI of 29.2 kg/m^2 (range 25-35 kg/m^2). None of them presented relevant comorbidities but five were light smokers (less than 20 cigarettes per day).

All of them presented breast cancer confirmed by biopsy and were eligible for nipple sparing (seven) or skin sparing (11) mastectomy. Four of the patients had to undergo bilateral mastectomy due to BRCA mutation.

Eighteen tissue expanders (12 in monolateral cases and six in three bilateral cases) and four prostheses (two in monolateral cases and two in a bilateral case) were used for breast reconstruction. Tissue expanders volume ranged from 400 to 600 cc (mean volume 500 cc).

Twenty-two TiLoop® Bra Pocket devices were used: 10 were medium and 12 were large size.

After prepectoral lodge was ready, mean surgical time of implant positioning was four minutes, with a range of three to 10 minutes.

The drain was removed between the fourth and tenth postoperative day (mean value: 6.5 days). Figure 3 shows the postoperative results 10 months after surgery, while Figure 4 shows a bilateral case pre-surgery and 30 days after surgery, respectively. Figure 5 shows a pre-operative picture of a left breast tumor case. The patient underwent a skin-sparing mastectomy and a tissue expander (600 cc volume) with TiLoop® Bra Pocket was positioned subcutaneously. The right contralateral breast underwent a reductive mastoplasty (Figure 6 A). The tissue expander was substituted with a definitive prosthesis, six months after the last expansion (Figure 6 B).

Follow-up lasted from 11 to 15 months, with an average of 12 months.

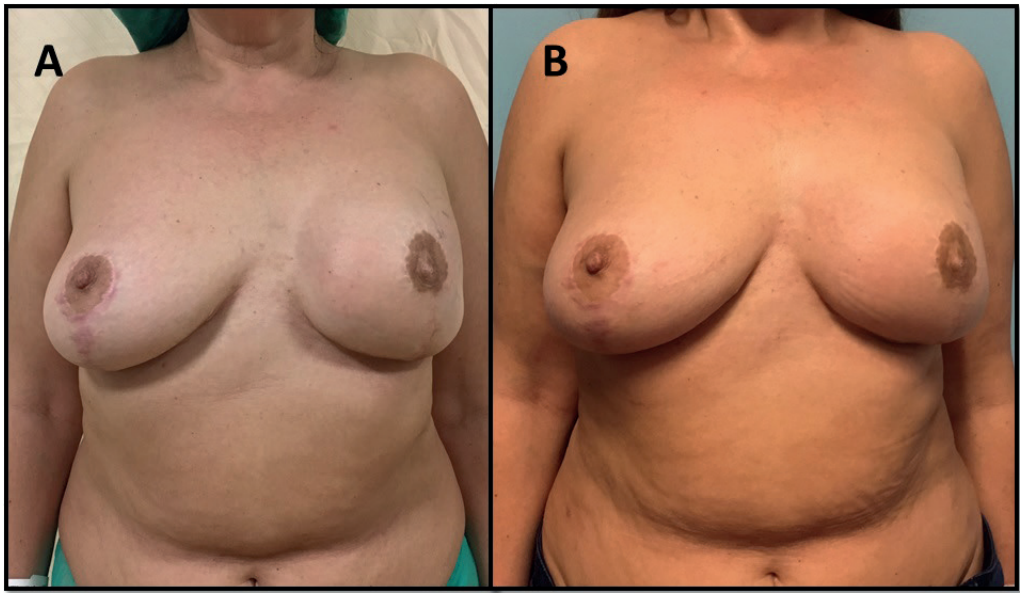

Figure 6. Post-surgical picture of a two-time left breast reconstruction. The patient underwent a skin-sparing mastectomy and a tissue expander (600 cc volume) with TiLoop® Bra Pocket was positioned subcutaneously. The right contralateral breast underwent a reductive mastoplasty (**A**). The tissue expander was substituted with a definitive prosthesis, in the second reconstructive time, six months after the last expansion (**B**).

Health-related quality-of-life was assessed comparing the preoperative and postoperative BREAST-Q scores[16]. Overall Satisfaction with Breasts, Psychosocial Well-being, and Sexual Well-being scores were all significantly increased after surgery ($p < 0.05$).

Complications were recorded in three cases (16.7%). Two patients (11.1%) that underwent breast reconstruction with tissue expanders after monolateral skin sparing and nipple sparing mastectomies, presented seroma that resolved with aspirations performed in outpatient clinic in three and four weeks respectively. The other complication (5.6%) was registered in one of the patients that underwent a monolateral reconstruction with definitive prosthesis: a delay in scarring occurred and resulted in partial thickness wound dehiscence. It was treated with ambulatory wound dressings and resolved in 16 days.

No significant (Baker III to IV grade) capsular contracture was registered.

Discussion

Recently, total mastectomies had increased in rate thanks to various factors such as better detection of multicentric tumors, widespread prophylactic mastectomies in patients with genetic mutations and improved quality of breast reconstruction[17].

IBR is proved to affect positively patients' quality of life, without influencing cancer recurrence or survival[18-23].

Table I. Demographic and anamnestic characteristics of the 18 patients enrolled in the study.

Patients' characteristic	Range of values (mean value) of the 18 patients
Age (years)	34-67 (52)
BMI (kg/m^2)	25-35 (29,2)
Ethnicity	18 Caucasians
Comorbidities	none
Smoking	5 (27.8%) light smokers (< 20 cigarettes per day)
BRCA1 mutation	4 (22.2%)

Implant-based IBR have been performed mostly by submuscular placement of the implant, since Gruber et al[24] and Argenta et al[25] showed its advantages over the prepectoral approach. This procedure is considered superior in improving cosmetic results and reducing some complications rate, but it can lead to animation deformity and early postoperative pain and discomfort due to elevation of pectoralis major muscle[26].

Avoidance of pectoralis major muscle dissection is obtained when the implant is placed subcutaneously. Several studies reported shorter recovery period and major patients' satisfaction when prepectoral reconstruction is assessed[27,28], whereas complication rates between prepectoral and subpectoral techniques appear to be comparable[29].

Despite its advantages, prepectoral breast reconstruction presents some limits in its application, such as the need for subcutaneous thickness major than 1 cm, implant volume lower than 550 mL and risk of implant exposure at the inframammary fold in patients with high degree of breast ptosis[30].

ADM and TCPM opened new horizons in implant-based breast reconstruction, introducing the concept of totally wrapping the prosthesis and bringing back the notion of total prepectoral approach in breast reconstruction. The technique was first described in 2014 and was based on positioning the implant in a subcutaneous pocket, wrapped by a titanium-coated polypropylene mesh[31].

Those devices add coverage to the implants, leading to better results in prepectoral IBR in aesthetic and functional terms, in particular when mastectomy flaps are thin[32-37].

We have previously published our surgical technique for immediate breast reconstruction with implant and TiLoop® mesh[38-44].

Recently, the titanium mesh TiLoop® Bra Pocket has been introduced and approved for surgical use in United Europe, China, and Australia. It is a ready-to-use mesh pocket made of non-resorbable titanised type 1a polypropylene. It covers completely the implant and undergoes prepectoral fixation with cranial, medial and lateral resorbable stitches, in order to prevent dislocation. The upgrade to a pre-shaped mesh was introduced in order to ease the device positioning over the implant and to achieve intraoperative time shortening.

Indeed, synthetic meshes with titanised surface help to achieve a good cell growth and lower levels of scarring, shrinkage and inflammation[45].

Moreover, together with the ADM, they are proven to decreases capsular contracture rate, due to a diminished inflammatory response[46,47]. In this preliminary study, no capsule contracture was registered, but the follow-up period could be too short to adequately address this issue.

Duration of operating time has an adverse influence on wound complication and implant loss[48,49] and TiLoop® Bra does not require any rehydration or long treatment before use with an estimated setting time as low as 3-5 min. The pre-shaped TiLoop® Bra Pocket shortens even more intraoperative time, reducing the time of exposure of implant and mesh, along with the possibility of intraoperative contamination and infections. At least in our case series, TiLoop® Bra Pocket allowed us to spend less than 10 minutes (four minutes on average) to position the implants in prepectoral space previously prepared. The pre-shaped mesh pocket guaranteed a complete cover of the implant and its insertion under the mastectomy flap instantly, reducing TE/prosthesis exposure time and risk of bacterial contamination.

In our small group of patients, no infections of the surgical site occurred and only two patients suffered for seroma[50] and one for delayed scarring.

Conclusions

This preliminary study showed interesting results in prepectoral IBR with the recently introduced TiLoop® Bra Pocket covering the implants. Of the 18 patients that underwent this procedure, only three presented complications that resolved in a maximum of four weeks.

TiLoop® Bra Pocket allowed a considering reduction of surgical time in implant positioning, lowering exposure time and risk of infection.

We wanted to show our caseload and underline the easiness and efficacy of this technique. Nevertheless, we consider that our follow-up is short for drawing conclusion in the setting of implant-related complications and further studies would be useful to validate this new pre-shaped titanised mesh.

Conflicts of interest

The first author has been recently contracted (March 2018) for attending events and workshop as a guest speaker, on an "ad hoc" basis contractor or freelance consultant agreement with pfm medical, TILOOP Bra manufacturing company. The rest of the authors have nothing to disclose. No funding was received for this article.

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