

Veritas in Immediate Implant-based Breast Reconstruction Is Associated with Higher Complications Compared with TiLOOP

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Background: Biologic and synthetic meshes are used in immediate implant-based breast reconstruction for coverage of the lower pole of the implant. This study aimed to compare outcomes of Veritas with TiLOOP bra (TiLOOP group [TG]).

Methods: Retrospective study of skin- and nipple-sparing mastectomies in patients who underwent an implant-based reconstruction using either Veritas or TiLOOP bra between January 2014 and December 2016 was performed.

Results: Thirty-six reconstructions (22 unilateral, 7 bilateral) using the Veritas mesh and 179 breast reconstructions (61 unilateral, 59 bilateral) using TiLOOP bra were identified. The Veritas group (VG) showed a higher rate of postoperative complications compared with the TG (VG = 54% versus TG = 14%, $P < 0.01$), including higher rates of seroma, nonintegration of mesh (VG = 51.4% versus TG = 1.6%, $P < 0.01$), implant rotation (VG = 16.2% versus TG = 1.6%, $P < 0.01$), infection (VG = 18.9% versus TG = 2.1%, $P < 0.01$), and wound breakdown (VG = 10.8% versus TG = 0.5%, $P < 0.01$). The VG also had a higher rate of major interventions (VG = 35.1% versus TG = 7.8%, $P < 0.01$) and minor interventions (VG = 18.9% versus TG = 2.2%, $P < 0.01$) compared with TG, including a higher rate of implant loss and unplanned return to theater.

Conclusions: Veritas mesh was associated with a significantly higher rate of postoperative complications compared with TiLOOP bra. Our data strongly question the safety profile of Veritas in implant-based breast reconstruction. Further studies in this area are warranted. (*Plast Reconstr Surg Glob Open* 2019;7:e2533; doi: [10.1097/GOX.0000000000002533](https://doi.org/10.1097/GOX.0000000000002533); Published online 31 December 2019.)

INTRODUCTION

Breast reconstruction following mastectomy is a potential option for women with breast cancer requiring or choosing a mastectomy for their treatment. The reconstructive options can be broadly classified as autologous or prosthetic/implant based. Implant-based breast reconstructions can be performed as a 2-stage procedure where a tissue expander is later replaced by a permanent gel implant or, if there is adequate skin coverage post mastectomy, as a direct-to-implant (DTI) reconstruction. The

implant can be placed in a subpectoral/dual plane pocket, or subcutaneously in the prepectoral plane. When placed subpectorally, it is now common practice to support the lower pole of the implant with a “mesh” of some type, and if placement is subcutaneous, total coverage of the implant with mesh is desirable. In both subpectoral and subcutaneous placement, control of the implant pocket is essential to minimize the risk of implant erosion and rotation.

A number of products are available for lower pole coverage, ranging from acellular dermal matrices (ADMs) to synthetic meshes, and recently, several ADMs and meshes have been introduced to the Australian market with differing costs, availability, and purported outcomes.^{1,2} The ideal material for use in breast reconstruction should have excellent tensile properties, integrate well with overlying tissue, prevent contracture, and be associated with a low rate of postoperative complications. None of the matrices, either biologic or synthetic, have proven superiority in all these areas.^{1,2}

The 4 breast surgeons at the Westmead Breast Cancer Institute have approximately 10 years of experience each

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Received for publication April 14, 2019; accepted September 10, 2019.

Presented at the Royal Australasian College of Surgeons Annual Meeting in Sydney, Australia, May 8–11, 2018.

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DOI: [10.1097/GOX.0000000000002533](https://doi.org/10.1097/GOX.0000000000002533)

Disclosure: The authors have no financial interest to declare in relation to the content of this article.

in performing implant based reconstruction (IBR) in the setting of skin- and nipple-sparing mastectomy.³ A variety of materials for lower pole coverage have been trialed over this period. At the beginning of the study period, TiLOOP bra had become the preferred product for lower pole support of implants. When Veritas was first introduced to the market, it was promoted as being a biologic agent that would integrate well with human tissue and maintain strength and was thick and pliable. One of perceived potential issues with TiLOOP is that it is very thin and may lead to more visible rippling. It was for these reasons that the surgeons did some cases using the Veritas mesh. Due to a perceived higher rate of postreconstruction complications using Veritas, which were noted during mortality and morbidity meetings, and given the lack of studies comparing biologic materials with synthetic meshes, we conducted a retrospective cohort study comparing the outcomes of immediate implant-based reconstruction using Veritas mesh versus TiLOOP bra from a prospectively maintained dataset.

MATERIALS AND METHODS

Study Design

All patients who underwent skin- or nipple-sparing mastectomy and immediate implant-based breast reconstruction using either TiLOOP bra or Veritas between January 1, 2014, and December 31, 2016, at the Westmead Breast Cancer Institute and associated private hospitals were identified from a prospectively maintained database. The selection of mesh type was at the discretion of the operating surgeon. For patients judged to be potential prepectoral candidates, Veritas was chosen as it was perceived that it was a thicker product and may aid in disguising rippling. Data were supplemented by chart review. All patients were followed for a minimum of 12 months. The study was approved by Western Sydney Local Health District Research Ethics Committee.

Material

TiLOOP bra (PFM Medical, Cologne, Germany) is a monofilament fiber, lightweight, titanized polypropylene mesh used in breast reconstruction with proposed advantages of providing a natural breast feel, high biocompatibility, and the promotion of tissue ingrowth.⁴

Veritas collagen matrix (Baxter Inc., Deerfield, Ill.) is a non-cross-linked biologic acellular matrix derived from bovine pericardium with proposed advantages of faster remodeling, faster incorporation, similar strength to other biologic meshes, and prevention of contraction or stretching post surgery.⁵

Surgical Technique

Mastectomy incisions were made depending on breast size, type of mastectomy, and surgeon's preference, with an incision in the lateral inframammary fold being the most commonly used. In the case of subpectoral/dual plane implant placement, Veritas or TiLOOP bra was used as a lower pole sling attached to the inferior border of the

pectoralis major muscle and the chest wall along the inferolateral border of the breast footprint and any "excess" length of mesh was folded under the implant rather than trimmed along the inframammary crease. In prepectoral reconstructions, the Veritas mesh was cut appropriately, and the 2 resultant pieces were fashioned together as a "wrap" around the implant using a polydioxanone (PDS) suture. The size of Veritas used in the subpectoral/dual plane operation was the same as that used in prepectoral reconstructions (25 cm × 12 cm). An anatomical, high cohesive silicone gel implant was used in all cases. At least 1 drain was routinely placed.

All patients received perioperative intravenous antibiotics. Intraoperative precautions such as minimizing theater traffic, change of gloves before implant insertion, soaking of the implant in 10% betadine/antibiotic solution, and pocket washout before implant insertion were undertaken routinely. Antibiotics were not routinely continued postoperatively.

Outcome Measurements

The primary endpoint was any postoperative mesh or mastectomy-related complication. These included seroma, defined as a persistent fluid collection requiring intervention following the removal of surgical drains, nonintegration of mesh, defined as breakdown of mesh into "soup-like" viscous sterile seroma, implant rotation, defined as movement of the anatomical implant >45 degrees from the breast implant meridian, and pocket infection, defined as clinical evidence of localized breast pocket infection, which was usually accompanied by systemic features requiring prescription of antibiotics or surgical intervention. Unplanned interventions were divided into major and minor interventions; major interventions were defined as complications resulting in an unplanned return to the operating theater (ie, Clavien Dindo classification III⁶). Minor interventions were defined as complications that were treated successfully without surgical interventions including ultrasound-guided drainage or antibiotics (Clavien Dindo classification II or III⁶).

Known potential confounding factors such as smoking, age, diabetes, adjuvant and neoadjuvant chemotherapy, and the use of postmastectomy radiotherapy were analyzed.

Statistics

Descriptive statistics were reported as mean and percentages. Categorical variables were reported as number and percentages, and continuous variables were reported as mean and ranges. Associations between categorical variables were evaluated using chi-square and Fisher's exact test, and *t* test was used for continuous variables. A *P*-value of <0.05 was considered statistically significant. Outcomes were assessed using multivariate linear regression analysis with adjustment for covariates likely to influence outcomes including type of mesh, implant placement, implant volume, age, smoking, diabetes, invasive pathology, neoadjuvant chemotherapy, and adjuvant chemotherapy or radiotherapy. Covariates were included in the multivariate model if their univariate *P*-value was <0.20.

Models were conducted per patient and also per breast. All analyses were performed using the Stata/MP software (v16 for Apple).

RESULTS

Patient and Operative Characteristics

A total of 150 patients met the study inclusion criteria, 120 patients in the TiLOOP group (TG) and 30 patients in the Veritas group (VG). The main indications for surgery were cancer, completion mastectomy, risk reduction, and patient preference. The histopathology results are shown in Table 1. There were no significant differences between groups.

Operative details are described in Table 1. A total of 179 breast reconstructions were performed in the TG, 61 of which were unilateral and 59 bilateral. This was compared with a total of 37 breast procedures in the VG (23 unilateral and 7 bilateral). There were 142 DTI reconstructions (79%) in the TG and 27 DTI reconstructions (73%) in the VG. All the implants were placed in a subpectoral/dual plane pocket in the TG compared with 25 (68%) in the VG, ie, 12 (32%) were placed in a prepectoral pocket. This difference was statistically significant.

There were no statistically significant differences between both groups for risk factors of smoking, age, and diabetes. More patients in the VG received adjuvant treatment with chemotherapy and postmastectomy radiotherapy compared with TG, and these results were statistically significant.

Postoperative Complications

All recorded complications are summarized in Table 2. Overall, the Veritas group (VG) developed a higher rate of complications per breast (54%) compared with the TiLOOP group (14%) ($P < 0.01$). The VG developed a statistically significantly higher rate of nonintegration (VG = 51.4% versus TG = 1.6%, $P < 0.01$), implant rotation (VG = 16.2% versus TG = 1%, $P < 0.01$), infection (VG = 18.9% versus TG = 2.1%, $P < 0.01$), and wound breakdown (VG = 10.8% versus TG = 0.5% $P < 0.01$). The TiLOOP group had a higher rate of flap necrosis (TG = 5.7% versus VG = 0% $P = 0.61$) and hematoma (TG = 1% versus VG = 0% $P = 1$) although this was not statistically significant. The development of skin and or nipple areolar complex ischemia was attributed to the disruption of the subdermal plexus of vessels that supply the overlying skin. In all cases, this was localized and therefore attributed to surgeon error, rather the size of implant used or type of mesh

Table 1. Patients and Surgical Characteristics

	TiLOOP, n (%)	Veritas, n (%)	P
No. patients	120	30	
No. breasts	179	37	
Mean age, y	45 (24–72)	46 (27–70)	N.S.
Smoker	No. patients (n = 120) 6 (5)	No. patients (n = 30) 1 (3.3)	N.S.
Diabetes	7 (5.8)	0 (0)	N.S.
Indications for surgery	No. patients (n = 120)	No. patients (n = 30)	
Cancer	96 (80)	25 (83.3)	N.S.
Risk reducing	24 (20)	5 (16.7)	N.S.
Site of implant	No. patients (n = 120)	No. patients (n = 30)	
Unilateral	61 (51)	23 (77)	N.S.
Bilateral	59 (49)	7 (23)	N.S.
Implant reconstruction	No. breasts (n = 179)	No. breasts (n = 37)	
DTI	142 (79)	27 (73)	N.S.
Staged using tissue expander	37 (21)	10 (27)	N.S.
Mean implant volume, mL	390.32	351.73	N.S.
Placement of implant	No. breasts (n = 179)	No. breasts (n = 37)	
Subpectoral	179 (100)	25 (68)	
Prepectoral	0 (0)	12 (32)	<0.001
NACT	No. patients (n = 120) 9 (7.5)	No. patients (n = 30) 1 (3.3)	N.S.
Radiotherapy	11 (9.2)	8 (26.7)	N.S.
Chemotherapy	26 (21.7)	16 (53.3)	0.001
Histopathology type	No. breasts (n = 179)	No. breasts (n = 37)	
Invasive ca	71 (40)	20 (54)	N.S.
Invasive ductal ca	41 (23)	15 (40)	n/a
Lobular ca	22 (12)	3 (8)	n/a
Papillary	0 (0)	2 (5)	n/a
Others	8 (4)	0 (0)	n/a
DCIS	28 (16)	6 (16)	N.S.
LCIS (incidental)	0 (0)	1 (3)	N.S.
Benign pathology	80 (45)	10 (27)	N.S.
Characteristics of invasive ca	No. invasive cases (n = 71)	No. invasive cases (n = 20)	
Mean size, mm (range)	27.9 (2.5–225)	27.7 (1.5–75)	N.S.
Multifocal	2 (3)	5 (25)	N/A
ER+	50 (70)	15 (75)	N.S.
PR+	40 (56)	13 (65)	N.S.
HER 2+	13 (18)	3 (15)	N.S.
Ki 67, mean (range)	31 (10–80)	31 (5–90)	N.S.

Ca, cancer; DCIS, ductal carcinoma in situ; ER, estrogen receptor; HER 2, human epidermal growth factor receptor 2; LCIS, lobular carcinoma in situ; N/A, not applicable; NACT, neoadjuvant chemotherapy; No, number; N.S., not significant; PR, progesterone receptor.

Table 2. Postoperative Complications

	TiLOOP, n (%) No. Breasts (n = 179)	Veritas, n (%) No. Breasts (n = 37)	P
Seroma/nonintegration	3 (1.7)	19 (51.4)	<0.01
Rotation of implants	2 (1.1)	6 (16.2)	<0.01
Infection	5 (2.8)	7 (18.9)	<0.01
Wound breakdown	1 (0.6)	4 (10.8)	<0.01
Red breast syndrome	0 (0)	1 (2.7)	N.S.
Skin necrosis	9 (5)	0 (0)	N.S.
Nipple necrosis	2 (1.1)	0 (0)	N.S.
Hematoma	1 (0.6)	0 (0)	N.S.
Total complications	23	37	<0.01
Total complications according to breasts	18 (10.1)	20 (54)	<0.01
Total complications according to patients	17 (14.2)	17 (57)	<0.01

No, number; N.S., not significant.

used. In both groups, some patients developed more than 1 complication.

Interventions

There were 14 (7.8%) major interventions in the TG compared with 13 (35.1%) in the VG ($P < 0.01$). Three implant losses were reported in each group (TG = 1.7% versus VG = 8.1%) ($P = 0.05$). A further 11 reconstructions (6.1%) in the TG and 10 reconstructions (27%) in the VG underwent an unplanned return to theater ($P < 0.01$). Of those, 3 breast reconstructions in each group required multiple reoperations with the VeraFlo technique to salvage the implant pocket.⁷

There were 4 (2.2%) minor interventions in the TG compared with 7 (18.9%) in the VG ($P < 0.01$). Six breast reconstructions underwent ultrasound-guided aspiration in the VG compared with none in the TG. One breast reconstruction in the TG required hospital readmission for intravenous antibiotics due to infection.

Confounding Factors

Potential confounding factors identified in this study which were statistically significant were higher rate of adjuvant treatment in the VG and prepectoral placement of implant in the VG (Table 1).

Further analysis was performed on the likelihood of these factors to influence the primary outcomes (Table 3). The plane of implant placement (subpectoral versus prepectoral) was not associated with an increased complication rate (Table 3). Furthermore, when the prepectoral group in the VG was excluded in a subgroup analysis, the complication rate in the subpectoral VG (16/25; 64%) was still statistically significantly higher compared with the TG (18/179; 10%) ($P = 0.001$).

Only 2 factors, adjuvant chemotherapy and type of mesh, were statistically significant. However, a multivariate logistic regression analysis showed that the type of mesh was the only factor directly influencing the primary outcome (Coefficient -0.84, 95% CI -1.03 to -0.66, $P < 0.001$). No other variables were significant either in the per-patient model or in the per-breast model.

DISCUSSION

The use of lower pole sling products has facilitated DTI reconstruction for patients undergoing either skin-

Table 3. Analysis of Factors Influencing Primary Outcomes

Factors	Complication per Patients (n = 34)	No Complications per Patients (n = 116)	P
	Diabetes	1	
Smoking	2	5	N.S.
NACT	3	7	N.S.
Radiotherapy	5	14	N.S.
Chemotherapy	15	27	0.001

Factors	Complication per Breasts (n = 38)	No Complications per Breasts (n = 178)	P
	Prepectoral implant placement	4	
Type of mesh (Veritas)	20	17	<0.0001
DTI	27	142	N.S.
Invasive cancer	21	70	N.S.
Mean implant volume (mL)	393.3	387.4	N.S.

NACT, neoadjuvant chemotherapy; No, number; N.S., not significant.

nipple-sparing mastectomy. To date, there have been limited data on the comparative efficacy of biologic and synthetic meshes, in relation to postoperative complications,^{1,2} with only 1 prospective randomized controlled trial comparing an ADM product with synthetic mesh.⁸ In 2016, Gschwantler-Kaulich et al compared Protexa mesh (ADM) with TiLOOP bra (synthetic mesh) and found that although the overall complication rate was similar in both groups, there was a higher incidence of complications leading to failed reconstructions with implant loss using Protexa.⁸

In our study, we found that the Veritas mesh, a biologic product, had a statistically significantly higher rate of postoperative complications, including seroma, non-integration of the mesh, implant rotation, infection, and wound breakdown compared with TiLOOP, a synthetic mesh. This led to an increased rate of major intervention including implant loss and unplanned return to theater. These findings are similar to several previous literature reviews, which suggested that ADMs are associated with higher postoperative complications, including increased postoperative seroma, infection, and implant loss.^{1,9,10}

Seroma is one of the most common postoperative complications in breast reconstruction, with a reported incidence ranging from 3% to 90%.^{1,11-13} In our study, patients

either presented to clinic with ultrasound confirmed seroma or diagnosed intraoperatively during a takeback to the operating theater. Although some consider that seroma formation is unavoidable following breast reconstruction, a persistent seroma can lead to infection, wound breakdown, skin necrosis, and implant loss.^{11–13} We found that this was true in the VG where the rate of seroma formation (51.4%) was higher compared with the TG (1.7%). Implants with seroma formation also suffered from nonintegration of the mesh, suggesting that the nonintegration of the Veritas may have been contributing to the persistent seromas, and almost half of those developed an infection. Three breast reconstructions ultimately ended with implant loss. At reoperation, eg, for implant rotation, it was not uncommon to find a thick viscous sterile “soup-like seroma” fluid. Interestingly, this is similar to the findings of Mazari et al in their series of 30 reconstructions, in which they describe complete resorption and disappearance of the Veritas mesh resulting in “bottoming out” in 50% of their cases, and a “yellow, gel-like seroma” in the implant cavity.¹⁴ Compared with previous studies, our study demonstrates a higher rate of seroma (0%–7.5%)^{14–16} using Veritas but our rate of seroma development related to TiLOOP bra is lower than previously reported (2.1%–4.8%).^{8,17–20}

Another recognized complication in skin- and nipple-sparing mastectomy is skin envelope flap necrosis.^{1,21,22} Many factors contribute to flap necrosis including patient factors such as smoking, the thickness of the mastectomy skin flap due to surgical technique.^{21,22} In our study, the TG had a higher but nonstatistically significant rate of flap necrosis (5.7%) compared with the VG (0%). However, compared with previous TiLOOP bra studies,^{8,17–19} our rate of flap necrosis was within the reported range (1.4%–7.8%). Having reviewed all cases with skin flap necrosis, it was concluded that in each case the ischemic changes were most likely due to surgical technique and not related to the type of mesh used. In all cases, the surgeon inadvertently thinned out the mastectomy skin flap to point of disruption of the subdermal vascular plexus rendering the overlying skin locally ischemic.

For implant-based reconstruction, the most significant complication for surgeons and patients alike is implant loss, resulting in a flat chest wall. Implant loss is often multifactorial, and significant contributing factors include infection, seroma, and flap necrosis.¹ In our study, the VG had a significantly higher rate of implant loss (8.1%) compared with the TG (1.7%) ($P = 0.05$), despite there being more skin necrosis in the TG group. When reviewed retrospectively, we found that the most common cause for implant loss was postoperative seroma, especially in the VG. This result is reflected in several previous meta-analyses and systematic reviews, which demonstrated that ADM products increase the risk for postoperative seroma, infections, and implant loss.^{9,10}

Risk factors for postoperative complications can be divided into patient factors and surgical factors. Patient factors which have previously been demonstrated to influence postoperative complications in breast reconstruction include age, body mass index, diabetes, smoking status, and neoadjuvant therapy.^{23,24} In our study, there were no

differences between the groups in any of these characteristics, a finding also noted in several previous studies.^{8,15,23,24} Similarly, surgical factors such as indications for surgery, histopathology, characteristics of invasive cancer, and mean implant volume were similar in both groups and when compared with other studies.^{8,15,23,24}

Two potential confounding factors in our study were adjuvant therapy and technique of implant placement. There was a significantly higher rate of adjuvant chemotherapy and radiotherapy in the VG. However, when this potential confounder was adjusted for in multivariate regression analysis, there was no difference between those who had adjuvant chemotherapy and/or radiotherapy and the rate of complications in either groups, and it was concluded that adjuvant therapy was not a significant factor influencing the incidence of postoperative complications in our study. Another significant difference between the groups was the plane of implant placement as all implants in the TG were placed in the subpectoral plane but approximately 30% of the implants in the VG were placed in the prepectoral plane. However, this was not a significant factor in multivariate analysis. Furthermore, when a subgroup analysis was performed excluding the prepectoral implants, the rate of complications in the VG was still significantly higher compared with the TG.

Our study has several limitations. This is a retrospective cohort study with a small number of patients in the VG and a larger number of patients in the TG. Another limitation is that some complications may not be clinically evident. For example, nonintegration and disintegration of Veritas mesh were only recognized in some cases when a patient was returned to the operating room for another reason, eg, for implant malposition, and therefore there is a potential to underestimate its actual incidence. The average follow-up period was only 12 months; therefore, we were unable to measure long-term postoperative complications such as capsular contracture and delayed seroma presentation. Finally, we did not measure the cosmetic outcome and patient’s satisfaction, which are an important measurement of success in breast reconstruction.

CONCLUSIONS

In this single-center, 4-surgeon, retrospective study examining the surgical outcomes of Veritas bovine pericardium mesh compared with TiLOOP bra mesh in implant-based breast reconstruction, we found that postoperative complication rates were higher in the VG. This resulted in higher major intervention rates including unplanned return to theater, as well as a higher implant loss rate.

Our data question the safety of Veritas in the setting of implant-based breast reconstruction. We encourage other surgeons who have experience in the use of Veritas in this setting to review and publish their results.

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