International Journal of Surgery 12 (2014) S205–S208

Contents lists available at ScienceDirect

International Journal of Surgery

journal homepage: www.journal-surgery.net

Original research

Acellular bovine pericardium dermal matrix in immediate breast reconstruction after Skin Sparing Mastectomy

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ARTICLE INFO

Article history:
Received 23 March 2014
Accepted 3 May 2014
Available online 22 May 2014

ABSTRACT

Introduction: Mastectomy for breast cancer may bring the patient to develop long term issues concerning the psychological and physical status. Immediate breast reconstruction (IBR) should be considered and proposed by physicians as an integrated procedure in the surgical approach to breast cancer to reduce further surgery. Acellular dermal matrix (ADM) has been used in revision breast reconstruction for fold malposition, capsular contracture and rippling also, showing good outcomes with low risk of complications. Aim of this study was to verify if the known advantages in using ADM for IBR would led to lower rates of seroma formation, infection, skin flap necrosis and overall complication related to the implant.
Methods: We performed a prospective study, including all consecutive patients undergone to IBR with biological graft with ADM between January 2012 and January 2013 at our Institution. Data on major issues of the patients and complications were recorded. All patients underwent to IBR with ADM (Tutomesh) implant with or without fibrin sealant positioning.
Results: A total of 24 patients underwent 28 immediate breast reconstruction with Tutomesh ADM implant. Main postoperative complications included seroma formation in 20.8% (5 pts), infection in 8.3% (2 pts) and hematoma in 4.2% (1 pt). There were any skin flap necrosis in the study. Diabetes was associated in two cases with edema and ecchymosis; hypertension with infection in one case (implant removal) and seroma in one case. First class of obesity (BMI 30–32.7) was associated with seroma in 3 cases, and with infection in one. In patient without fibrin sealant (12 patients – 13 breasts) complications were represented by hematoma (1 pt. 4.2%), infection (1 pt. 4.2%; implant removal) and seroma (4 pts 16.8%).
Conclusions: The use of Tutomesh® bovine pericardium for immediate breast is safe and technically useful. Complications rate is not high, except for seroma formation that can be reduced by the contemporary use of fibrin sealant.

1. Introduction

Mastectomy for breast cancer may bring the patient to develop long term issues concerning the psychological and physical status [1]. Thus, the request for immediate post mastectomy breast reconstruction and the related options for surgical products to replace soft tissues, have simultaneously grown in the last decade [2]. Immediate breast reconstruction (IBR) should be considered and proposed by physicians as an integrated procedure in the surgical approach to breast cancer to reduce further surgery [3]. Skin Sparing Mastectomy (SSM) with IBR has a good impact on quality of life and self-esteem, providing good esthetic outcomes without lowering the local oncological safety [4,5]. IBR after SSM has an acceptable local recurrence rate compared with conventional mastectomy, no evidence of increased postmastectomy pain syndrome (PMPS) compared to mastectomy alone, but the risk of local postoperative complications is still real [6–9]. The advantages in using acellular dermal matrix (ADM) as pectoral extenders versus complete submuscular coverage, include the capability to facilitate to direct implant reconstruction, improve the inframammary and lateral mammary fold definition and decrease rates of capsular contracture. It works as a tissue support, protective against radiation damages and helpful in the correction of secondary breast shape faults [10–13]. It enlarges the surgical devices field offering

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http://dx.doi.org/10.1016/j.ijsu.2014.05.007
1743-9191/

to the patients the opportunity of a complete one stage demolitive/reconstructive operation. ADM has been used in revision breast reconstruction for fold malposition, capsular contracture and rippling also, showing good outcomes with low risk of complications [8,14].

Aim of this study was to verify if the known advantages in using ADM for IBR would led to lower rates of seroma formation, infection, skin flap necrosis and overall complication related to the implant.

2. Methods

We performed a prospective study, including all consecutive patients undergone to IBR with biological graft with ADM between January 2012 and January 2013 at Department of Surgery, Second University of Naples. Patient who underwent breast reconstruction with a biological graft other than Tutomesh® or patient with other type of reconstruction were excluded from the study.

Data on major issues of the patients (age, BMI, surgical features, radio and chemotherapy, comorbidities) were prospectively collected. All complications (seroma, hematoma, infection and need for implant removal) were recorded; ecchymosis and edema were considered minor complications. Preoperative antibiotic short term prophylaxis was used for all the patients (Ceftriaxone 2gr i.v. 1 h before surgery).

The surgical technique utilized for immediate breast reconstruction by a submuscular implant was carried out by suturing the mesh to the inframammary fold, caudal edge of the pectoralis muscle and laterally to the serratus anterior muscle to reach the complete inferior pole coverage, using two meshes when needed. ADM used in our series was a collagene membrane extracted from solvent-preserved bovine pericardium (Tutomesh® by Tutogen – Neunkirchen am Brand – Germany) subject to a multiple step purification process ("Tutoplast Process") and sterilized by gamma irradiation. Tutoplast Process consists of a thorough purification of the tissue and gentle tissue-conserving solvent dehydration [15]. The mesh has a size of 60 × 80 mm.

Fibrin sealant was sprayed between mesh and tissue when needed. A drain was used on all patients.

Statistics were accomplished by the use of dedicated software (SPSS ver 17).

3. Results

A total of 24 patients underwent 28 immediate breast reconstruction with Tutomesh ADM implant over a period of 12 months. Patients characteristics are shown in Table 1. Mean age was 54.0 years (26–70ys); nine patients were smokers; incidence of comorbidities (all under medical control) are depicted in Table 1; chemotherapy was administered postoperatively in 16 cases (75%); 8 patients had chemotherapy before surgery. Fibrin sealant was sprayed between mesh and tissue in 12 patients (15 breasts).

Main postoperative complications included seroma formation in 17.8% (5 pts), infection in 7.1% (2 pts) and hematoma in 3.5% (1 pt). Seroma cases did not require any surgery or implant removal. Hematoma was drained after 24 h from surgery. There were any skin flap necrosis in the study, while ecchymosis were registered in one patient, and edema in one, both of them regressed without any therapy in 14 days. All complications are summarized in Table 2. The mean duration of drain in all patients was 5 days, in 7 cases it was longer; in 5 patients who developed seroma, and in two subject with infection, the mean duration of drain placement was 11 and 10.5 days, respectively. One case of infection regressed promptly with drain and antibiotic therapy (Staphylococcus), the other one required implant removal. The mean duration of follow up was 15.5 months; two patients were lost at the follow up at 5 and 7 months.

Table 1
Patients demographics.

Patient characteristics	Tutomesh® (n = 24, 28 breast)	
Mean age	54,00 years	Var 82,5217; Std Dev. 9,0841
Mean BMI	27,3083	Var 27,3083; Std Dev. 7,5671
Diabetes	12.5% (3 pts)	
Hypertension	37.5% (9 pts)	
Previous Myocardial Infarction	4.2% (1 pt)	
Smokers	37.5% (9 pts)	
Fibrin sealant	50% (12 pts)	
Mean duration of drain	5,1250 (days)	Var12,0272; Std Dev3,4680
Implant removal	4.2% (1 pt)	
Chemotherapy	24 (100%)	AC p 5–20.8%; AT CMF 3–12.5%; Orm. 16–66.7%*
Radiation therapy	0	
Mean follow up	15,5 months	Var 18,6087; Std Dev 4,3138

Comorbidities have been matched with postoperative complications. Diabetes was associated in two cases with edema and ecchymosis; hypertension with infection in one case (implant removal) and seroma in one case. First class of obesity (BMI 30–32.7) was associated with seroma in 3 cases, and with infection in one (no implant removal). Between the nine smoker patients 2 had complications (edema, infection). In the group with fibrin sealant (12 patients – 15 breasts), complications were represented by infection (1 pt. 6.6%), seroma (1 pt. 6.6%), ecchymosis (1 pt. 6.6%) and edema (1 pt. 6.6%).

In patients without fibrin sealant (12 patients – 13 breasts), complications were represented by hematoma (1 pt. 7.7%), infection (1 pt. 7.7%; implant removal) and seroma (4 pts 30.7%). The overall complications rate in the two groups of patients was respectively 13.3% and 46.6%.

4. Discussion

The use of acellular dermal matrix has been adopted by many surgeons in several surgical fields [16–19] when a dermal reinforcement was needed. In reconstructive and revisionary breast surgery ADM use offers several technical advantages (capability to facilitate to direct implant reconstruction, improve the inframammary and lateral mammary fold definition and decrease rates of capsular contracture). The major advantage originating from the three-dimensional acellular collagen structure that operate an inducement to the attraction of fibroblasts and promotion of their replication. Tissue integration of the mesh by reparative processes of fibrosis and angiogenesis follows; three-dimensional collagen structure result as a scaffold for the ingrowth of the patient's own tissue. Thus ADM works as a tissue reinforcement and anatomical folds support. It ensues to be protective against radiation damages

Table 2
Postoperative complications.

Postoperative complications	Tutomesh ® n28 br
Hematoma	1 (4.2%)
Infection	2 (8.3%)
Seroma	5 (20.8%)
S.F. necrosis	0
Ecchymosis	1 (4.2%)
Edema	1 (4.2%)
Total complication by breasts	10 (41.6%)

Table 3
Comparison of complication rates with Veritas and Alloderm.

Postoperative complications	Tutomesh ® no fibrin sealant n13br –12 pts	Tutomesh® + fibrin sealant n15br – 12 pts	Veritas® *n93br* (Mofid et al. 2012) [27]	Alloderm ® *n269br* (Chun et al.2010) [21]
Hematoma	1 (7.7%)	0	2 (2.2%)	6 (2.2%)
Infection	1 (7.7%)	1 (6.6%)	6 (6.65%)	24 (8.9%)
Seroma	4 (30.7%)	1 (6.6%)	7 (7.5%)	38 (14.1%)
S.F. necrosis	0	0	5 (5.54%)	63 (23.4%)
Total complication by breasts	6 (46.1%)	2 (13.3%)	20 (1.5%)	131 (48.7%)

and helpful in the correction of secondary breast shape faults [10–13].

We used an acellular dermal membrane extracted from solvent-preserved bovine pericardium (Tutomesh® by Tutogen – Neunkirchen am Brand – Germany). It is a thin fenestrated bovine pericardium non-crosslinked acellular collagen matrix. Mesh-Perforation intent is to decrease the incidence of seromas, still present in many series [20,21]. Seroma occurrence has reported to be 6.5%, ranging from 0 to 15.4% [22,23]. Our intent was to reduce seroma formation using sprayed fibrin sealant between dissected tissues and dermal matrix to obtain adhesion of the mesh and a synergic stimulus on tissue healing. Human fibrin glue is without any doubt a valuable adjuvant to surgery as a measure against complications. The application of fibrin sealant not only can facilitate the hemostasis but, due to the glue biological properties stimulating fibrosis and angiogenesis, it can also synergize the stimulus promoted by collagen mesh. It reduces secretion from dissected tissues decreasing seroma formation [24]. It is important to not forget the indirect effect fibrin glue has against infection, due to its ability to fill dead space, which might otherwise provide nourishment for bacteria [25,26]. In Table 3 a comparison of complications between the two groups of our series (with or without fibrin sealant) and two studies with different ADM is shown [27]. In our series the all complications rate is lower in the group with fibrin sealant. In the same group seroma and infection rate are lower than in the series with Veritas® or Alloderm®. Obesity represents an important risk factor for the incidence of complications, in particular for seroma formation.

5. Conclusions

The use of Tutomesh® bovine pericardium for immediate breast is safe and technically useful. Complications rate is not high, except for seroma formation that can be reduced by the contemporary use of fibrin sealant. Obesity represents the main comorbidity related to seroma formation. Additional studies are needed to confirm these outcomes.

Ethical approval

Local Board approved the study.

Sources of funding

All Authors have no source of funding.

Author contribution

Adelmo Gubitosi: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript and gave final approval.

Giovanni Docimo: Partecipated substantially in conception and design of the study.

Domenico Parmeggiani: Partecipated substantially in the drafting and editing of the manuscript.

Raffaele Pirozzi: Partecipated substantially in the drafting and editing of the manuscript.

Chiara Vitiello: Partecipated substantially in collecting data.

Pietro Schettino: Partecipated substantially in the analysis and interpretation of data.

Manuela Avellino: Partecipated substantially in collecting data.

Giuseppina Casalino: Partecipated substantially in collecting data.

Maurizio Amato: Partecipated substantially in collecting data.

Roberto Ruggiero: Partecipated substantially in the analysis and interpretation of data.

Ludovico Docimo: Gave final approval.

Conflicts of interest

All Authors have no conflict of interests.

References

[1] C.M. McCarthy, B.J. Mehrara, T. Long, et al., Chest and upper body morbidity following immediate postmastectomy breast reconstruction, Ann. Surg. Oncol. 8 (2013 Nov) 36–44.
[2] E. Kocak, T.W. Nagel, J.H. Hulsen 3rd, et al., Biologic matrices in oncologic breast reconstruction after mastectomy, Expert Rev. Med. Devices 22 (2013 Nov) 165–178.
[3] J. Van Geertruyden, Breast reconstruction with implant, Rev. Med. Brux 34 (4) (2013 Sep) 265–270.
[4] J.L. Trejo-Ochoa, A. Maffuz-Aziz, F.M. Said-Lemus, et al., Impact on quality of life with breast reconstructive surgery after mastectomy for breast cancer, Ginecol. Obstet. Mex. 81 (9) (2013 Sep) 510–518.
[5] A. Agrawal, M. Grewal, D.M. Sibbering, C.A. Courtney, Surgical and oncological outcome after skin-sparing mastectomy and immediate breast reconstruction, Clin. Breast Cancer 13 (6) (2013 Dec) 478–481.
[6] D.R. van Mierlo, T.R. Lopez Penha, R.J. Schipper, et al., No increase of local recurrence rate in breast cancer patients treated with skin-sparing mastectomy followed by immediate breast reconstruction, Breast 22 (6) (2013 Dec) 1166–1170.
[7] J.R. Henderson, A. Tao, C.C. Kirwan, L. Barr, Immediate breast reconstruction does not increase postmastectomy pain, Ann. Surg. Oncol. 14 (2013 Nov) 546–553.
[8] A.W. Peled, R.D. Foster, E.R. Garwood, The effects of acellular dermal matrix in expander-implant breast reconstruction after total skin-sparingmastectomy: results of a prospective practice improvement study, Plast. Reconstr. Surg. 129 (6) (2012 Jun) 901e–908e.
[9] C.A. Salzberg, Focus on technique: one-stage implant-based breast reconstruction, Plast. Reconstr. Surg. 130 (5 Suppl. 2) (2012 Nov) 95S–103S.
[10] J.D. Namnoun, Expander/implant reconstruction with Alloderm recent experience, Plast. Reconstr. Surg. 124 (2009) 387–394.
[11] R.J. Zienowicz, E. Karacaoglu, Implant-based breast reconstruction with allograft, Plast. Reconstr. Surg. 120 (2007) 373–381.
[12] S.L. Spear, P.M. Parikh, E. Reisin, N.G. Menon, Acellular dermis assisted breast reconstruction, Aesth Plast. Surg. 32 (2008) 418–425.
[13] A. Cheng, M. Saint-Cyr, Comparison of different ADM materials in breast surgery, Clin. Plast. Surg. 39 (2) (2012 Apr) 167–175.
[14] S.L. Spear, S.R. Sher, A. Al-Attar, T. Pittman, Applications of acellular dermal matrix in revision breast reconstruction surgery, Plast. Reconstr. Surg. 133 (1) (2014 Jan) 1–10.
[15] Instruction for use. Tutomesh® by Tutogen Medical GmbH an RTI BIOLOGICS Company – Neunkirchen am Brand – Germany.
[16] G.L. Gunnarsson, M. Børsen-Koch, S. Arffmann, Successful breast reconstruction using acellular dermal matrix can be recommended in healthy non-smoking patients, Dan. Med. J. 60 (12) (2013 Dec) A4751.

[17] D.H. Stacey, Use of an acellular regenerative tissue matrix over chronic wounds, Eplasty 13 (2013 Nov 20) e61.
[18] J.M. Kim, S.H. Choi, Healing effect of acellular dermal matrixes for repair of abdominal wall defects in a rat model, In Vivo 27 (6) (2013 Nov-Dec) 755–760.
[19] C. Ahmedbeyli, S. Dirikan İpçi, G. Cakar, B.E. Kuru, S. Yılmaz, Clinical evaluation of coronally advanced flap with or without acellular dermal matrix graft on complete defect coverage for the treatment of multiple gingival recessions with thin tissue biotype, J. Clin. Periodontol. (2013 Dec 4), http://dx.doi.org/10.1111/jcpe.12211.
[20] A.M. Ibrahim, M. Shuster, P.G. Koolen, et al., Analysis of the National Surgical Quality Improvement Program database in 19,100 patients undergoing implant-based breast reconstruction: complication rates with acellular dermal matrix, Plast. Reconstr. Surg. 132 (5) (2013 Nov) 1057–1066.
[21] Y.S. Chun, K. Verma, H. Rosen, et al., Implant-based breast reconstruction using acellular dermal matrix and the risk of postoperative complications, Plast. Reconstr. Surg. 125 (2) (2010 Feb) 429–436.
[22] D.Q. Xue, C. Qian, L. Yang, et al., Risk factors for surgical site infections after breast surgery: a systematic review and meta-analysis, Eur. J. Surg. Oncol. 38 (2012) 375–381.
[23] A.S. Colwell, B. Damjanovic, B. Zahedi, et al., Retrospective review of 331 consecutive immediate single-stage implant reconstructions with acellular dermal matrix: indications, complications, trends, and costs, Plast. Reconstr. Surg. 128 (2011) 1170–1178.
[24] R. Ruggiero, E. Procaccini, S. Gili, et al., New trends on fibrin glue in seroma after axillary lymphadenectomy for breast cancer, G. Chir. 30 (6–7) (2009 Jun-Jul) 306–310.
[25] A. Gubitosi, R. Ruggiero, G. Docimo, A. Esposito, Fibrin sealant in general surgery personal experience and literary review, Ann. Ital. Chir. (2012 Oct 12) [Epub ahead of print], S0003469X12020398.
[26] R. Ruggiero, G. Docimo, A. Gubitosi, et al., Axillary lymphadenectomy for breast cancer and fibrin glue, Ann. Ital. Chir. 85 (2014) 88–92.
[27] M.M. Mofid, M.S. Meininger, M.S. Lacey, Veritas® bovine pericardium for immediate breast reconstruction: a xenograft alternative to acellular dermal matrix products, Eur. J. Plast. Surg. 35 (10) (2012 Oct) 717–722.