



Muscle sparing one-step reconstruction

SCIENTIFIC EVIDENCE

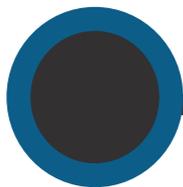
update July 2019



DECO med was established in 1989 in the region of Venice, Italy. As of today, DECO med is the world's only company that provides patented and certified prepectoral implants for post-mastectomy breast reconstruction and has applied for sixteen international patents. What better way to celebrate 30 years as innovation leaders?

*As usual, innovation creates crisis.
When DECO med first invented the new prepectoral
procedure 7 years ago, old ways and the new
procedure stood at opposite poles.
Surgeons were somewhere in between waiting for
clinical evidence.
Some, like pioneers, took the new road.
It is thanks to them that Decomed can offer sturdy
scientific evaluations today.*

2012



First Braxon®
implantation,
Bristol (UK)

2014



pag. 14

Evaluation of a novel breast reconstruction technique using the Braxon® acellular dermal matrix: a new muscle-sparing breast reconstruction.

Berna G., Cawthorn S.J.,
Papaccio G., Balestrieri N.

pag. 15

Evaluation of a novel technique in immediate implant reconstruction with a new shaped acellular matrix graft (Braxon®) placed on the pectoralis muscle in a subcutaneous plane.

Cawthorn S.J., Berna G.

2015



pag. 16

Evaluation of the early post-operative effectiveness of a novel muscle-sparing breast reconstruction technique – Using Braxon (acellular dermal matrix).

Humphries A., Williams S.,
Vidya R., Cawthorn S.J.

pag. 17

No pec touch: A pre-shaped ADM for subcutaneous one-step breast reconstruction.

Berna G., Cawthorn S.J.

2016



pag. 18

Evaluation of the early post-operative effectiveness of a novel muscle-sparing breast reconstruction technique using Braxon® (acellular dermal matrix) – Multicentre European experience.

Vidya R., Cawthorn S.J.

pag. 19

Epipectoral breast reconstruction.

Masia J., Becker H.

2017



pag. 21

Host Integration of an Acellular Dermal Matrix: Braxon® Mesh in Breast Reconstruction.

Iqbal M.F., Bhatnagar A.,
Vidya R.

pag. 23

A Guide to Prepectoral Breast Reconstruction: A New Dimension to Implant-based Breast Reconstruction

Vidya R., Iqbal M.F.

pag. 25

Evaluation of the effectiveness of the prepectoral breast reconstruction with Braxon dermal matrix: First multicenter European report on 100 cases

Vidya R., Masia J.,
Cawthorn S.J., et al

pag. 27

Subcutaneous implant breast reconstruction: Time to reconsider?

Tasoulis M.K., Iqbal M.F.,
Cawthorn S.J., et al

pag. 20

Die vorgeformte porcine Matrix Braxon erste Erfahrungen mit dem innovativem Produkt

Masberg F., Degirmenci S.,
Hornberger M., Mett R.

pag. 22

One-stage breast reconstruction techniques in elderly patients to preserve quality of life.

Maruccia M., Mazzocchi M.,
Dessy L.A., Onesti M.G.

pag. 24

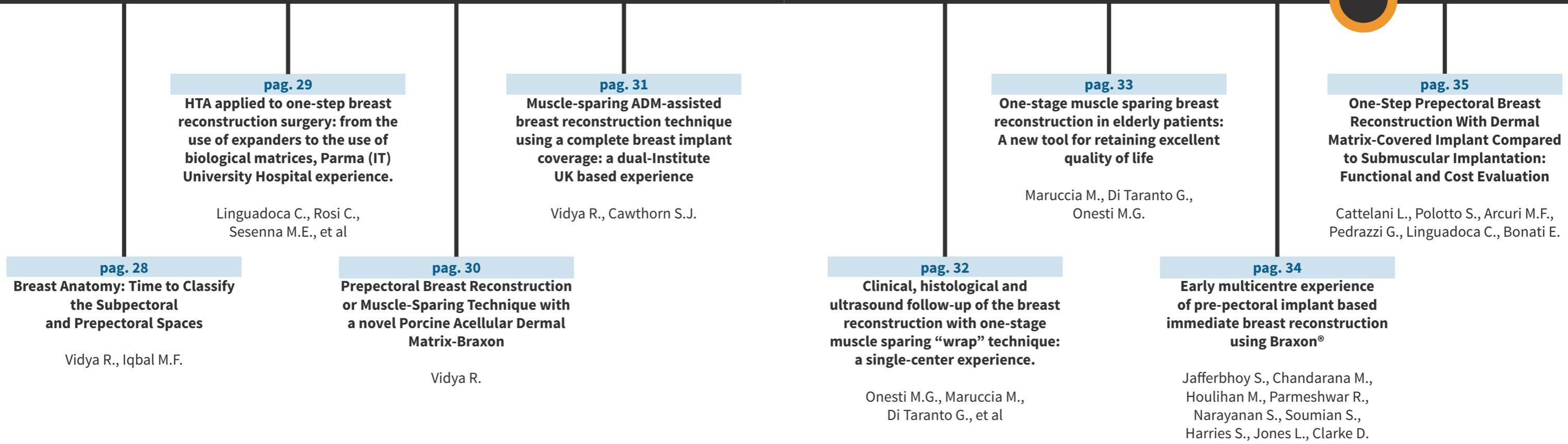
Long term follow-up on prepectoral ADM-assisted breast reconstruction: evidences after 4 years

Berna G., Cawthorn S.J.

pag. 26

Outcome following 150 prepectoral implant based breast reconstruction using Braxon® (ADM): UK experience.

Vidya R., Smith A.H.,
Salem F., et al



pag. 36

Management based on grading of animation deformity following implant-based subpectoral breast reconstruction

Vidya R., Tafazal H., Salem F., Iqbal F.M., Sircar T.

pag. 37

Acellular dermal matrix in implant-based immediate breast reconstructions: a comparison of prepectoral and subpectoral approach.

Chandarana M.N., Jafferbhoy S., Marla S., Soumian S., Narayanan S.

pag. 38

A case of important weight loss after a prepectoral breast reconstruction.

Salgarello M., Barone Adesi L., Mangialardi M.L.

pag. 39

Current evidences on immediate breast reconstruction after mastectomy.

Salgarello M., Visconti G., Barone Adesi L.

pag. 40

Pre-pectoral implant-based immediate breast reconstruction with Braxon Porcine Acellular Dermal Matrix: Is it safe with radiotherapy?

Sewell J., Sharma A., Ficken L., Olsen S., Tillett R., Ferguson D., Ives C., Oliver D.

pag. 41

Evaluation of one hundred prepectoral implant-based reconstructions using Braxon® from a single institution

Chandarana M., Jafferbhoy S., Tan Y., Marla S., Soumian S., Narayanan S.

pag. 42

Prophylactic Bipedicled Nipple Sparing Wise Pattern Mastectomy And Prepectoral Implant/ Adm Breast Reconstruction In Large Ptotic Breasts; Technique And Outcomes

Khalil H., Farooq T., Ashour T., Rhobaye S., Malahias M.

2019



pag. 44

Combination of acellular dermal matrix with a de-epithelialised dermal flap during skin-reducing mastectomy and immediate breast reconstruction.

Kankam H., Hourston G., Forouhi P., Di Candia M., Wishart G.C., Malata C.M.

pag. 43

The Economics of Prepectoral Breast Reconstruction – Comment on.

Cattelani L., Polotto S.

pag. 46

Minimal Pain with Prepectoral Implant-Based Breast Reconstruction.

Vidya R., Green M.

pag. 45

Prepectoral breast reconstruction using the Braxon® porcine acellular dermal matrix: a retrospective study.

Gardani M., Simonacci F., De Sario G., Cattadori F., Raposio E., Palli D.

pag. 47

Outcomes of prepectoral implant-based breast reconstruction with Braxon® acellular dermal matrix—a single-centre experience.

Chandarana M., Soumian S., Jafferbhoy S., Marla S., Narayanan S.

pag. 48

Prepectoral implant-based breast reconstruction: a joint consensus guide from UK, European and USA breast and plastic reconstructive surgeons.

Vidya R., Berna G., Sbitany H., Nahabedian M., Becke H., Reitsamer R., Rancati A., Macmillan D. and Cawthorn S.

pag. 49

Postsurgical Ultrasound Evaluation of Patients with Prosthesis in Acellular Dermal Matrix: Results from Monocentric Experience.

Ballesio L., Casinelli A., Gigli S., Boldrini C., Di Taranto G., Albano A., Onesti M.G.

EVALUATION OF A NOVEL BREAST RECONSTRUCTION TECHNIQUE USING THE BRAXON® ACELLULAR DERMAL MATRIX: A NEW MUSCLE-SPARING BREAST RECONSTRUCTION.

Background

Implant-based breast reconstruction is becoming increasingly popular because of the widespread adoption of acellular dermal matrix (ADM), which allows surgeons to obtain good aesthetic results with fewer operations.

To develop more conservative surgical techniques, a retrospective, three-centre, proof-of-concept study was performed to study the effectiveness of a new, immediate, muscle-sparing breast reconstruction technique using the patented Braxon® ADM, which enables subcutaneous positioning of the breast implant without detaching the pectoralis major.

Methods

Ethics committee of the study coordinating centre approved medical record review on 19 women who underwent muscle-sparing breast reconstruction between November 2012 and January 2014. The first 10 implants were performed using 0.9-mm-thick porcine ADM, with preservatives.

In the subsequent 15 implants, the product was changed to 0.6-mm-thick porcine dry ADM, without preservatives.

Results

Nineteen patients (25 implants) received six bilateral and 13 unilateral muscle-sparing breast reconstructions.

For the first type of ADM used (0.9-mm-thick with preservatives), the rate of implant loss was 12% (n = 3) because of seroma (8%, n = 2) and infection (4%, n = 1). Minor complications, such as seroma (8%, n = 2), occurred when using the 0.6-mm-thick Braxon® ADM and were treated by aspiration. Symmetrical and natural breasts with good shape, ptosis and softness to the touch were obtained.

None of the patients reported experiencing pain.

Conclusions

The preliminary results are encouraging from aesthetic and clinical viewpoints. Further studies are planned to evaluate long-term results.

Berna G., Cawthorn S.J., Papaccio G., Balestrieri N.

ANZ Journal of Surgery - Sep 2014;
doi: 10.1111/ans.12849

EVALUATION OF A NOVEL TECHNIQUE IN IMMEDIATE IMPLANT RECONSTRUCTION WITH A NEW SHAPED ACELLULAR MATRIX GRAFT (BRAXON®) PLACED ON THE PECTORALIS MUSCLE IN A SUBCUTANEOUS PLANE.

Introduction

The traditional sub-pectoral placement of the implant to reduce capsular contraction is now assisted by ADM to achieve better ptosis. Evidence that ADM reduces capsular contraction around implants in subcutaneous planes now exists both in animal models and revisional surgery in breast augmentation.

Methods

We present the first reports of our initial experience of a new ADM assisted fixed volume reconstruction (Braxon®) where the implant wrapped in ADM is placed above the muscle in a subcutaneous plane.

Results

Our preliminary results show reduction in postoperative pain and capsular contraction with good cosmetic outcomes up to one year of follow-up. Early complication due to seroma resulting in implant loss in 2 of 13 have been resolved by a change to thinner ADM (0.6 mm) without preservatives with windows in the ADM behind the implant on the muscle with no further complications (7 reconstructions). Updated experiences will be presented.

Conclusions

Pectoralis preserving one-stage reconstruction with subcutaneous Braxon® appears to offer advantages with less post-operative pain, less contracture and good cosmetic outcomes. The learning curve will tell us if the experience provides the basis for new dimensions in the field of mastectomy and immediate implant-based reconstruction breast surgery.

Cawthorn S.J. and Berna G.

European Journal of Surgical Oncology - May 2014; 40(5): 634;
doi: 10.1016/j.ejso.2014.02.082

EVALUATION OF THE EARLY POST-OPERATIVE EFFECTIVENESS OF A NOVEL MUSCLE-SPARING BREAST RECONSTRUCTION TECHNIQUE – USING BRAXON (ACELLULAR DERMAL MATRIX).

Introduction

We report initial results of a novel muscle-sparing subcutaneous implant breast reconstruction technique using a new Braxon® ADM.

Methods

All patients who underwent muscle-sparing breast reconstruction in 2 breast units in 2014 were included in the study. The Braxon® meshes which comes preshaped completely wraps the implant which is placed on the muscle, without detaching the pectoralis major. It is rehydrated in saline in 10 minutes.

Results

A total of 22 patients underwent mastectomy and Braxon® ADM plus implant reconstruction, 5 bilateral and 17 unilateral: a total of 27 reconstructions. The rate of implant loss was 3.7% (n=1 due to wound breakdown).

Seroma 14% (n=4) and infection 0%. Excellent cosmetic outcomes so far were obtained with a low complication rate. None of the patients reported experiencing pain or the “dancing breast syndrome” at 1 month.

Conclusions

The initial experience appears highly satisfactory. A feasibility study for a randomized trial comparing Braxon® with sub-muscular/ADM implant reconstruction is planned.

Humphries A., Williams S., Vidya R., Cawthorn S.J.

European Journal of Surgical Oncology - Jun 2015; 41(11): S268;
doi: 10.1016/j.ejso.2015.03.200



NO PEC TOUCH: A PRE-SHAPED ADM FOR SUBCUTANEOUS ONE-STEP BREAST RECONSTRUCTION.

Introduction

Implant-based breast reconstruction is becoming increasingly popular because of the widespread adoption of Acellular Dermal Matrix (ADM), which allows good aesthetic results with fewer operations.

A preliminary study was carried out from November 2012 to January 2014, in order to verify the effectiveness of the new immediate muscle-sparing breast reconstruction technique. The patented Braxon, ADM enables subcutaneous positioning of the implant without detaching the pectoralis major muscle.

Between April 2014 and April 2015 another European multicenter study was performed to confirm the preliminary outcomes.

We report the results of the two experiences, from November 2012 to date.

Material & Methods

The muscle-sparing surgical technique involves the use of a pre-shaped porcine ADM which totally wraps the breast implant. The device is positioned in a subcutaneous plane, without detaching the pectoral major muscle. This procedure decreases post-operative complications and betters outcomes.

Results

The preliminary study was carried out on 19 patients (25 implants). Encouraging results were obtained by improving the characteristics of ADM and the surgical technique. The following European multicenter experience on 90 implants reported a reduction of early complications.

Symmetrical and natural breasts with good shape and ptosis were observed. No cases of capsular contracture were detected in both studies.

Conclusions

After more than two years, the muscle-sparing breast reconstruction can be safely proposed as a new option for patients who fit the inclusion criteria.

The use of an ADM for the complete coverage of the implant prevents from capsular contracture. Longer evaluations and histological examinations are planned.

Berna G., Cawthorn S.J.

Journal of Cancer Science & Therapy - Aug 2015;
doi: 10.4172/1948-5956.S1.041



EVALUATION OF THE EARLY POST-OPERATIVE EFFECTIVENESS OF A NOVEL MUSCLE-SPARING BREAST RECONSTRUCTION TECHNIQUE USING BRAXON® (ACELLULAR DERMAL MATRIX) — MULTICENTRE EUROPEAN EXPERIENCE.

Introduction

We report initial results of a prospective audit of novel muscle-sparing subcutaneous implant breast reconstruction technique using a new Braxon® ADM.

This was carried out in UK and Europe.

Methods

All patients who underwent muscle-sparing breast reconstruction since 2014 were included in the study.

The pre-shaped Braxon® ADM completely wraps the implant after rehydration in saline for 5 minutes. The ADM with the implant is placed on the muscle, without detaching the pectoralis major.

Results

A total of 110 patients had Braxon® ADM plus implant reconstruction. 70 patients had unilateral and 20 patients had bilateral procedures. Complication included an implant loss of 1.8%; wound necrosis of 0.9% and 3.6% wound dehiscence. The short-term outcomes have been excellent, with high patient satisfaction, less pain, a more natural shape and a feeling and good cosmetic outcomes.

Conclusions

The initial experience appears highly satisfactory, although long-term follow-up is required.

Vidya R., Cawthorn S.J.

European Journal of Surgical Oncology - May 2016; 42(5): S3;
doi: 10.1016/j.ejso.2016.02.028



EPIPECTORAL BREAST RECONSTRUCTION

Pre pectoral breast reconstruction is gaining more acceptance as the advantages over sub-muscular placement are being recognised

1. No animation deformity
2. Less invasive - no opening of new tissue planes
3. Shorter surgical time -quicker recovery
4. Less post-operative pain -less discomfort
5. No adverse effect on shoulder function.

There are several procedures used for pre pectoral reconstruction

1. Two stage expander to implant
2. Direct to implant reconstruction

Both procedures have disadvantages.

Direct to implant reconstruction is limited to a select group of patients

1. Bulky tissue expanders and implants lead to circulatory concerns
 2. A second stage is required to replace a tissue expander with a gel implant.
- Direct to adjustable implant offers an alternative that can be applied to a wider range of patients. As the adjustable implant can be placed under filled, or even empty, there is less risk of circulatory compromise. The implant is only filled once viable circulation is assured.

The implant offers the possibility of a one stage procedure.

Recent advances in this technique are described:

1. less dependence on full ADM coverage
2. Use of an inferior dermal flaps
3. Thickening of flaps with fat injection
4. Use in radiated patients and suboptimal patients
5. Nipple sparing mastectomy in the large ptotic breast
6. Externalized injection ports

Masia J., Becker H.

London Breast Meeting - Sep 2016



DIE VORGEFORMTE PORCINE MATRIX BRAXON ERSTE ERFAHRUNGEN MIT DEM INNOVATIVEM PRODUKT

Fragestellung

Der Einsatz von azellulären dermalen Matrices im Rahmen der Brustrekonstruktion mit Implantaten hat die Ergebnisse bei der Sofortrekonstruktion der Brust verbessern können. Bisher diente die Gewebematrix als Überbrückung der verbleibenden Lücke zwischen Pectoralimuskel und Unterbrustfalte zur Abdeckung des Implantates und Entlastung der erhalten gebliebenen Brusthaut. Nachgewiesen wurde unter anderem eine Reduktion der Kapselfibrose. Andererseits kann im Zusammenhang mit der verwendeten Matrix das "Red Breast Syndrome" als entzündliche Begleitreaktion beobachtet werden. Mit dem neuen Produkt Braxon steht eine Matrix zur Verfügung, mit der das Implantat nahezu vollständig bedeckt werden kann und eine subpectorale Implantationstechnik vermeidbar wird. Außerdem soll die häufig beobachtete, länger anhaltende Serombildung hierbei deutlich reduziert werden können.

Methodik

Dargestellt wird die Verwendung der vorgeformten porcinen Matrix in Verbindung mit einer Sofortrekonstruktion bei mamillenerhaltender Mastektomie bei inzwischen 10 Jahre zurückliegender kosmetischer Brustaugmentation mit unverändert gutem Langzeitergebnis bei subpectoralem Implantatlager. Vorangegangen war eine neoadjuvante Therapie des invasiv duktales Mammakarzinoms mit Nachweis einer vollständigen Remission.

Ergebnis

Es wurde erneut eine subpectorale Implantation durchgeführt, wodurch sich Abweichungen zum bisher vom Hersteller empfohlenen Vorgehen mit epipectorale Implantationstechnik ergeben. Operationsverlauf und nachfolgender Beobachtungszeitraum boten keine Auffälligkeiten.

Das frühe Operationsergebnis zeigte ein gutes kosmetisches Resultat mit weitgehender Symmetrie zur Gegenseite. Histologisch wurden im Mastektomiepräparat noch regressiv veränderte Reste eines DCIS nachgewiesen.

Schlussfolgerung

Mit der neuen porcinen Matrix steht eine weitere Option zugunsten eines möglichst individuell angepassten Rekonstruktionsverfahrens zur Verfügung, mit der entsprechend der Handhabung intraoperativ Zeit gespart werden kann und ein gutes operatives Frühergebnis zu erreichen ist.

Masberg F., Degirmenci S., Hornberger M., Mett R.

Senologie - Sep 2016;
doi: 10.1055/s-0036-1583406

HOST INTEGRATION OF AN ACELLULAR DERMAL MATRIX: BRAXON MESH IN BREAST RECONSTRUCTION.

Introduction of meshes over the last decade have changed the facet of breast reconstruction. There is an increasing trend of skin sparing mastectomies with implant-based breast reconstruction for therapeutic treatment of breast cancer patients and for risk-reducing surgery in high-risk patients.

Conventionally, a subpectoral implant placement with partial detachment of the pectoralis major muscle is recommended. However, this can be associated with partial muscle injury, resulting in impaired function, breast animation deformity (dancing breast), and postoperative pain.

Breast animation was originally described in submuscular breast augmentation and can be defined as deformity or distortion of the breast that occurs particularly with contraction of the pectoralis major muscle.

Recently a new method of musclesparing technique has been introduced that enables subcutaneous positioning of the breast implant without detaching the pectoralis major. Braxon mesh (Decomed, Venice, Italy) is a natural pre-shaped 0.6 mm thick porcine acellular dermal matrix (ADM) that completely wraps the implant and is placed subcutaneously; its use prevents the need of pectoralis major disinsertion.

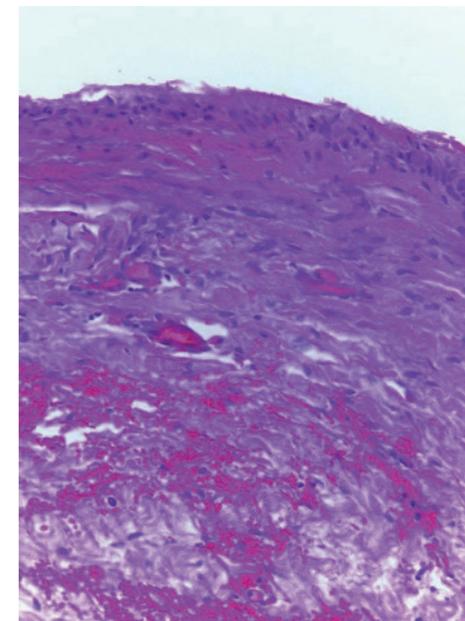
Initial results have shown that good shape, ptosis, and softness are obtained.

The advantages include lack of donor site morbidity, less postoperative pain, and early recovery. We report a case of host integration of Braxon mesh in human tissue.

To date, this is the first report of muscle-sparing mesh-based breast implant reconstruction.

Iqbal F.M., Bhatnagar A., Vidya R.

Clinical Breast Cancer - Dec 2016; 16(6):e209-11
doi: 10.1016/j.clbc.2016.06.009



Sample Braxon Mesh Implants 1 Year After Implantation.

ONE-STAGE BREAST RECONSTRUCTION TECHNIQUES IN ELDERLY PATIENTS TO PRESERVE QUALITY OF LIFE.

Objective

The aim of this study was to review one-stage breast reconstruction techniques performed in elderly patients at our institution to identify the criteria of selection of each in terms of outcomes and quality of life.

Patients and Methods

Patients older than 65 years who underwent one-stage breast reconstruction between January 2004 and July 2014 at our hospital were included. Patients and procedure-related data were collected from the medical records. In particular, patient's age, comorbidities and related ASA physical status, type of one-stage breast reconstruction technique and criteria of selection were analyzed.

Outcomes and results were also evaluated in terms of quality of life using the EORTC QLQ-C30 and -BR23 questionnaires 1 year after surgery.

Results

A total of 840 women underwent breast reconstruction, of whom 138 elderly women received one-stage breast reconstruction. There were 118 cases (85.5%) of monolateral reconstructions and 20 cases (14.5%) of bilateral reconstructions, resulting in 138 breast reconstructions. These were performed with permanent inflatable expanders in the sub-muscular position (Group A, n= 50), with acellular dermal matrix and partial sub-muscular anatomic implant (Group B, n= 50), and with Braxon® acellular dermal matrix and anatomic implant with muscle-sparing technique (Group C, n= 38). The EORTC questionnaires showed the best results in Group C regarding the quality of life.

Conclusions

The elderly population is rapidly increasing, and 50% of all breast cancers occur in women older than 65 years; among them, only 2% undergo breast reconstruction.

A major aspect of breast cancer treatment and subsequent quality of life is the opportunity for a postmastectomy reconstructive surgery.

As survival rates are improving, a larger proportion of patients live with the long-term consequences of their treatment, and breast reconstruction ensures a better quality of life. To increase the reconstruction rates, surgery should be onestage, less invasive as possible, allowing rapid recovery, especially in elderly women, in whom comorbidities are often present with a high anaesthetic risk. Our study highlighted that non skin sparing mastectomy (SSM) and delayed reconstructions should be addressed with Becker implants; immediate reconstructions after SSM should be followed by acellular dermal matrix (ADM) - assisted implant reconstruction, preferring the wrap technique offers a better quality of life in elderly patients.

Maruccia M., Mazzocchi M., Dessy L.A., Onesti M.G.

European Review for Medical and Pharmacological Sciences
Dec 2016; 20(24): 5058-5066
pmid: 28051266

A GUIDE TO PREPECTORAL BREAST RECONSTRUCTION: A NEW DIMENSION TO IMPLANT-BASED BREAST RECONSTRUCTION.

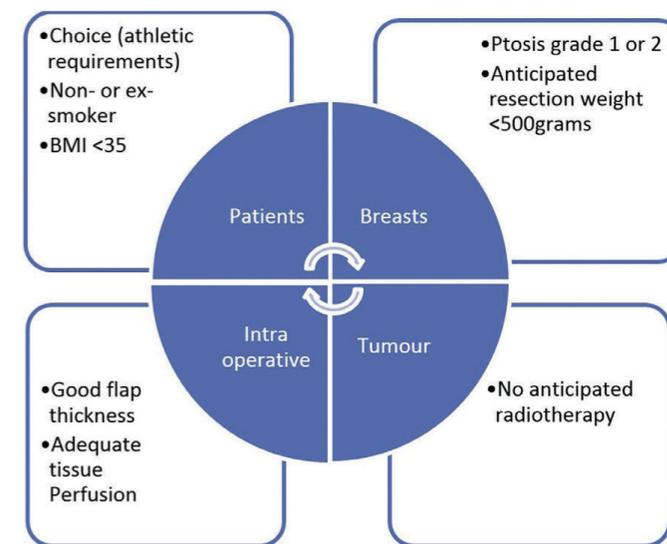
Acellular dermal matrix has revolutionized implantbased breast reconstruction. Breast reconstruction has evolved from the traditional submuscular to the new prepectoral implant based (also known as musclessparing) reconstruction. The new technique is emerging as a highly popular surgery owing to its more minimal approach. We conducted a narrative review to guide prepectoral breast reconstruction, highlighting the technique, the need for appropriate patient selection, and areas for further research. We show that prepectoral breast reconstruction is safe, feasible, and has excellent short-term outcomes (cosmesis and patient satisfaction). Its main advantages are that it avoids animation deformity, prevents shoulder dysfunction, and has a lower incidence of capsular contracture.

Selection for the prepectoral technique is dependent on patient factors (eg, body mass index, lifestyle), breast size, flap assessment, and adjuvant radiotherapy.

Whereas the initial short-term results are promising, long-term outcomes are yet to be reported and is an area that requires further research.

Vidya R., Iqbal F.M.

Clinical Breast Cancer - Jul 2017; 17(4):266-271;
doi: 10.1016/j.clbc.2016.11.009



LONG TERM FOLLOW-UP ON PREPECTORAL ADM-ASSISTED BREAST RECONSTRUCTION: EVIDENCES AFTER 4 YEARS.

Prepectoral implant-based breast reconstruction is on the rise because of the advantages related to preservation of the pectoralis major muscle. Indeed, this reconstructive procedure improves the aesthetic outcomes and the postoperative recovery time, avoiding the risk of breast animation and deformity.

On the other hand, the subcutaneous implant positioning has higher risk of capsular contracture and for this reason, the subpectoral breast reconstruction has been preferred for many years; but the introduction of a preshaped acellular dermal matrix (ADM) which allows a complete implant

coverage led to the onset of the new prepectoral technique, solving the problem of a stiff periprosthetic capsule formation. In fact, the use of ADMs in breast reconstruction has been shown to decrease the capsular contracture formation. Nevertheless, no longterm outcomes have been reported with the use of a pre-shaped ADM for prepectoral breast reconstruction.

The authors present the first ten patients who had a prepectoral ADM-assisted breast reconstruction showing no evidences of capsular contracture after a median follow-up of 4 years.

Berna G., Cawthorn S.J.

European Journal of Plastic Surgery - Feb 2017; 40(3): 255-258;
doi: 10.1007/s00238-017-1285-z

Table 1 Demographic data and long-term outcomes of ten patients who received ADM-assisted prepectoral breast reconstruction

Patient	Age	BMI	Side	Surgery	Implant size (g)	Follow-up (months)	Visible implant	Baker III/IV
1	48	22.6	R, L	NSM	335	50	–	–
2	63	24.2	R	NSM	245	50	–	–
3	62	25.6	R	SSM	335	50	–	–
4	47	20.6	R, L	NSM	280	50	yes	–
5	50	20.9	L	SSM	375	49	–	–
6	54	26.5	L	NSM	320	49	–	–
7	51	19.5	R, L	NSM	335	49	yes	–
8	34	23.8	L	NSM	280	49	–	–
9	58	25.1	R	SSM	320	48	–	–
10	55	22.2	R	NSM	375	48	–	–

R right, L left, NSM nipple-sparing mastectomy, SSM skin-sparing mastectomy

EVALUATION OF THE EFFECTIVENESS OF THE PREPECTORAL BREAST RECONSTRUCTION WITH BRAXON DERMAL MATRIX: FIRST MULTICENTER EUROPEAN REPORT ON 100 CASES.

We report the outcomes of the European prospective study on prepectoral breast reconstruction using preshaped acellular dermal matrix for complete breast implant coverage. Seventy-nine patients were enrolled between April 2014 and August 2015 all over Europe using a single protocol for patient selection and surgical procedure, according to the Association of Breast Surgery and British Association of Plastic Reconstructive and Aesthetic Surgeons joint guidelines for the use of acellular dermal matrix in breast surgery.

The preshaped matrix completely wraps the breast implant, which is placed above the pectoralis major, without detaching the muscle.

A total of 100 prepectoral breast reconstructions with complete implant coverage were performed.

This series, with mean follow-up of 17.9 months, had two cases of implant loss (2.0%) including one necrosis of the nipple and one wound breakdown (1.0% respectively).

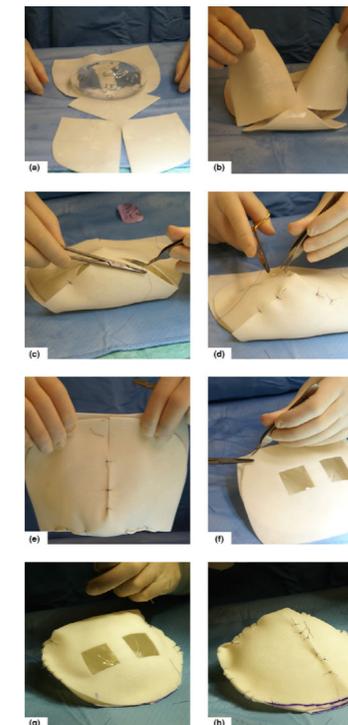
No implant rotations were observed.

Good cosmetic outcomes were obtained with natural movement of the breasts and softness to the touch; none of the patients reported experiencing pain or reduction in the movements of the pectoralis major muscle postoperatively.

The use of preshaped acellular dermal matrix for a complete breast implant coverage in selected patients is safe and gives satisfactory results, both from the aesthetic view point and the low postoperative complication rates. Further studies reporting long-term outcomes are planned.

Vidya R., Masia J., Cawthorn S., Berna G., Bozza F., Gardetto A., Kołacińska A., Dell'Antonia F., Tiengo C., Bassetto F., Caputo G.G., Governa M.

The Breast Journal - Nov 2017; 23(6):670-676;
doi: 10.1111/tbj.12810



OUTCOME FOLLOWING 150 PREPECTORAL IMPLANT BASED BREAST RECONSTRUCTION USING BRAXON® (ADM): UK EXPERIENCE.

Introduction

Prepectoral breast reconstruction is an evolving new technique that is replacing standard submuscular reconstruction. We report the UK experience of a novel muscle-sparing breast reconstruction procedure with a preshaped acellular dermal matrix completely wrapping the breast implant.

Methods

All patients who underwent a muscle-sparing breast reconstruction from Jan 2014 to Sept 2016 were included in the audit and the data was collected from the data base prospectively. All surgeons were mentored for the first five cases. Braxon® is the only dermal matrix, which is pre-shaped and is 0.6 mm thick. The mesh is porcine derived ADM, which totally wraps the implant and is placed prepectorally over the chest wall to form a new breast.

Results

A total of 161 prepectoral breast implant reconstructions were carried out in five centers in the UK with a follow up of 3-3,5 months. 128 were unilateral and 24 were bilateral procedures. The age ranged between 30-76 years (median 56 yrs). The implant sized varied between 120-540 cc (median 360 cc). Complication included hematoma 1,8% (n=3), implant loss 3,7% (n=6), seroma needing aspiration in 11% (n=19) and superficial skin necrosis 1,8% (n=3). The outcomes have been excellent, with high patient satisfaction, less pain, a more natural shape and feeling with good cosmetic outcome.

Conclusions

The Braxon® wrapped-around muscle sparing technique adds a new dimension to implant based breast reconstruction. It eliminates the problem of implant animation and procedure of choice in athletes, active patients who do not want disturbance of their musculoskeletal structure.

Vidya R., Smith A.H., Salem F., Garg N., Dhespande A., Bhaskar P., Sircar T., Cawthorn S.

European Journal of Surgical Oncology - May 2017; 43(5):S1;
doi: 10.1016/j.ejso.2017.01.020

SUBCUTANEOUS IMPLANT BREAST RECONSTRUCTION: TIME TO RECONSIDER?

Improvements in breast surgery techniques such as skin and nipple preserving mastectomy and innovative prosthetics (implants, acellular dermal matrices and meshes) is renewing interest in subcutaneous (prepectoral) implant reconstruction. The aim of this paper is to review the current literature in an attempt to provide a rationale that may support a return to subcutaneous implant placement, so minimising the pain and functional problems resulting from submuscular breast reconstruction.

Tasoulis M.K., Iqbal F.M., Cawthorn S., MacNeill F., Vidya R.

European Journal of Surgical Oncology
Sep 2017; 43(9):1636-1646;
doi: 10.1016/j.ejso.2017.04.008

Comparison of risks and benefits between subcutaneous and submuscular implant breast reconstruction.

Pocket	Benefits	Risks
Subcutaneous	Faster expansion, less post-operative visits Less pain, discomfort Preservation of PMM functionality Less procedure duration Faster recovery No distortion with pectoralis contraction No animation More natural shape Better control of IMF	Increased implant edge visibility and palpability Implant extrusion Increased incidence of capsular contracture without mesh wrap
Submuscular	Decreased implant edge visibility and palpability Decreased risk of capsular contracture Extra soft tissue coverage	Slow expansion, more post-operative visits Impaired PMM functionality More pain/discomfort Increased superior implant dislocation Less control over IMF Increased procedure time Prolonged recovery Lateral implant displacement Breast shape distortion Breast animation

PMM: pectoralis major muscle, IMF: infra-mammary fold.

BREAST ANATOMY: TIME TO CLASSIFY THE SUBPECTORAL AND PREPECTORAL SPACES

Surgical intervention remains the primary treatment modality for most women who develop breast cancer, many of whom require reconstructive surgery.

Recent advances, particularly in implant-based techniques (accounting for 40% of breast reconstructions in the UK and 80% in the USA), devices, and biomaterials (ASoP Surgeons, 2012; Albornoz et al., 2013) have led to increases in both classical techniques (e.g., subpectoral breast reconstruction) and more novel techniques such as prepectoral (musclesparing) reconstruction.

The latter are becoming more popular because the pectoralis major is not detached, so the shoulder dysfunction associated with the classical technique is precluded.

In consequence, better understanding of the anatomy of the prepectoral reconstructive plane is required for successful results.

With this in mind, we describe the subpectoral and the prepectoral spaces, and further describe a novel way of clinically grading the skin flap vascularity.

Vidya R., Iqbal M.F.

Clinical Anatomy - May 2017; 30(4):434-435;
doi: 10.1002/ca.22878

TABLE 1. Novel Grading of Skin Flap Vascularity

Grade	Definition
1	Mastectomy skin flap with good subcutaneous layer throughout
2	Mastectomy skin flap with small patchy areas lacking subcutaneous layer (<1 cm)
3	Mastectomy skin flap with medium to large patchy confluent areas lacking subcutaneous layer (>2 cm)

HTA APPLIED TO ONE-STEP BREAST RECONSTRUCTION SURGERY: FROM THE USE OF EXPANDERS TO THE USE OF BIOLOGICAL MATRICES, PARMA UNIVERSITY HOSPITAL EXPERIENCE.

Introduction

In the last few years, therapeutic alternatives for breast cancer treatment increased dramatically, making breast cancer a curable disease. Considering surgery, skinsparing mastectomy and immediate breast reconstruction represent the most reliable choice. Nevertheless, in case of breast volume larger than 350-400ml, the preparation of a prosthetic pouch solely made by patient's muscles is extremely complex. In those cases, a two-stage reconstruction is mandatory: 1. mastectomy and expander/implant reconstruction; 2. expander/implant replacement with permanent silicone hydrogel implants. The recent availability of acellular dermal matrices (ADMs) made onestep breast reconstruction a feasible procedure even in case of very large breasts. In the light of medical literature data and considering the optimal aesthetic and functional results, the ethical and logistic advantages and the reduction of postoperative pain, the University Hospital of Parma evaluated these new devices. The aims of this study was: 1. to describe the process for ADMs management and utilization two years after their introduction at the University Hospital of Parma; 2. to evaluate economic impact of the new procedure.

Materials and Methods

A multidisciplinary working group was created. Different topics were addressed, such as products selection; definition of treatment eligibility criteria; development of a monitoring sheet (consumption and adherence to indications). To evaluate the financial impacts 2 years after the introduction of the new procedure, the costs related to the new surgical approach have been compared to the two stage standard procedure. Particularly, the total expenditures related to staff and materials, and those related to intermediate services and performances (outpatient visits) have

been considered. The type of examination and performance codes have been evaluated as well.

Results

The analysis of technical sheets, instructions for use, pivotal trials and economic proposals led to the selection of three different ADMs: two animal cell (biologic) membranes (porcine dermal matrix; bovine pericardium) and one silk derived membrane. All of these matrices shared good resistance and tensile strengths, reasonable handling, userfriendliness, tissue inertia. Major inclusion criteria were the followings: breast volume larger than 350 ml, skin flaps viability. Exclusion criteria were obesity, diabetes, smoking history, immune system deficiency, radiotherapy. Since the introduction of the new devices, 58 patients were treated using the one-step procedure (9 cases of bilateral implants). The results of the costs analysis related to the new surgical approach confirmed that, even considering the ADMs massive costs arising, the one-step procedure could lead to a saving of 15% for NHS.

Conclusions

The University Hospital of Parma experience confirmed the published data and constituted a nice example of good clinical practice and evaluation according to HTA methodology.

Paper in Italian

[L'HTA applicato alla ricostruzione mammaria in interventi chirurgici one-step: dall'utilizzo degli espansori all'impiego di matrici biologiche, l'esperienza dell'Azienda Ospedaliero-Universitaria di Parma]

Linguadoca C., Rosi C., Sesenna M.E., Zanardi A., Arcuri M.F., Palli D., Cattelan L.

HTA Focus - Jun 2017;
doi: 10.23753/htafocus2017.01.003

PREPECTORAL BREAST RECONSTRUCTION OR MUSCLE-SPARING TECHNIQUE WITH A NOVEL PORCINE ACELLULAR DERMAL MATRIX - BRAXON®.

Introduction

Implant-based breast reconstruction is on the rise and the use of meshes have facilitated adoption of novel techniques. The disadvantages related to traditional submuscular reconstruction had led to adoption of muscle sparing or prepectoral technique.

Indications and patient selection

It is primarily used in immediate breast reconstruction and in revision surgery. Appropriate selection of patients, tumour biology, and technique are important.

Technique

Braxon 30 × 20 cm (Decomed S.r.l., Venezia, Italy) is the only preshaped porcine-derived ADM matrix that is available. It is 0.6-mm thick, packed dry, and need to be hydrated in saline, so it becomes soft after hydration. It has an anterior flap with a central slit, which when sutured gives the shape. The posterior flap with 2 windows, which is believed, let the seroma fluid out so as to avoid any collection inside the new pocket. The anterior slit and the 2 wings are closed using 2-0 vicryl continuous suture. The desired implant is then placed inside the ADM. A marking pen is used to define the exact size of the matrix that is required to form a wrap around the implant so that the ADM snug the implant and there is no redundant space inside. It is also useful to leave a 2-mm rim around the edges, which will enable easy anchorage to the chest wall. The anterior and posterior edges of the device are sutured together using 2-0 vicryl to form a pocket for the implant. The inferior aspect of Braxon provides the required ptosis and does not require any anchorage.

The lateral space can be closed to improve the shape and reduce any dead space. The new reconstructed ADM implant unit is placed over the

prepectoral space and anchored to the muscle using cardinal sutures at 3, 6, 9, and 12-clock positions using 2-0 vicryl sutures. Other sutures can be placed especially laterally and anteriorly between the matrix and subcutaneous layer before the closure of the skin. All these suture stitches speed up the process of matrix integration and, on the other side, decrease the mechanical stress of the breast implant on the lower pole by suspending the silicone weight. The wound is closed using 3-0 vicryl, and a drain is used.

Outcome

The recent prospective, multicenter study using Braxon in 100 cases (median follow-up, 17.9 months) showed 2% implant loss, 1% wound breakdown, 5% seroma, and 2% haematoma. Problems such as animation deformity and shoulder dysfunction are avoided, and postoperative pain and physiotherapy are minimal due to preservation of chest wall. It appears to be preferred in young, athletic women and in those who prefer to undisturb the chest wall musculature. Patients may develop rippling, which can be corrected by lipomodelling as shown by Becker et al. (6.4%) in his series.

Conclusions

The novel wrap around muscle sparing technique adds a whole new dimension to breast reconstruction.

Vidya R.

Plastic and Reconstructive Surgery - Global Open
Jun 2017; 5(6): e1364;
doi: 10.1097/GOX.0000000000001364

MUSCLE-SPARING ADM-ASSISTED BREAST RECONSTRUCTION TECHNIQUE USING A COMPLETE BREAST IMPLANT COVERAGE: A DUAL-INSTITUTE UK BASED EXPERIENCE.

Introduction

We report our early experience of a novel muscle-sparing breast (prepectoral) reconstruction technique using a preshaped Braxon® mesh (acellular dermal matrix) which completely wraps around the breast implant.

Methods

All patients who underwent prepectoral implant based breast reconstruction between April 2014 to September 2015 were included in the analysis. The dermal matrix Braxon® used is a pre-shaped matrix which forms a complete implant mesh wrap. The new breast created is placed over the chest wall without disturbing the pectoralis musculature.

Results

A total of 51 cases, 42 unilateral and 9 bilateral musclesparing breast reconstructions were carried out. The complications included implant loss 1.7% (n=1) secondary to wound infection, seroma 6.7% (n=4), and superficial wound dehiscence 1.7% (n=1) which was re-sutured without further complication. The median follow-up period was 16.4 (range:8-25) months.

Conclusion

The early experience appears highly satisfactory with a good clinical outcome. The novel prepectoral implant based breast reconstruction using the mesh wrap provides an effective alternative to the more traditional submuscular implant-based technique.

Vidya R., Cawthorn S.J.

Breast Care - Sep 2017; 12(4):251-254;
doi: 10.1159/000464401



CLINICAL, HISTOLOGICAL AND ULTRASOUND FOLLOW-UP OF THE BREAST RECONSTRUCTION WITH ONE-STAGE MUSCLE SPARING “WRAP” TECHNIQUE: A SINGLE-CENTER EXPERIENCE

Background

Prepectoral implant placement and complete coverage with porcine acellular matrix after mastectomy is a new concept in breast surgery presented in few cases in literature.

The aim of this paper is to present our single center experience in one-stage breast reconstruction muscle sparing “wrap” technique by evaluating clinical and aesthetic outcomes, ultrasound and histological examination and patient quality of life.

Methods

From January 2014 to January 2017, 52 patients (40 unilateral, 12 bilateral) underwent to one stage muscle-sparing breast reconstructions with Braxon® acellular dermal matrix and implant. In three patients a surgical biopsy and histological examination with immunohistochemical analysis of the periprosthetic tissue was carried out. All patients underwent breast ultrasound examination and the occurrence of capsular contracture was assessed through the Baker classification and measuring the mammary compliance scores with the Antoon Paar Mammary compliance system. Breast appearance was evaluated with a Visual Analogue Scale (VAS) and in term of quality of life with the EOCRT QLQ C-30 and QLQ BR-23 questionnaires.

Results

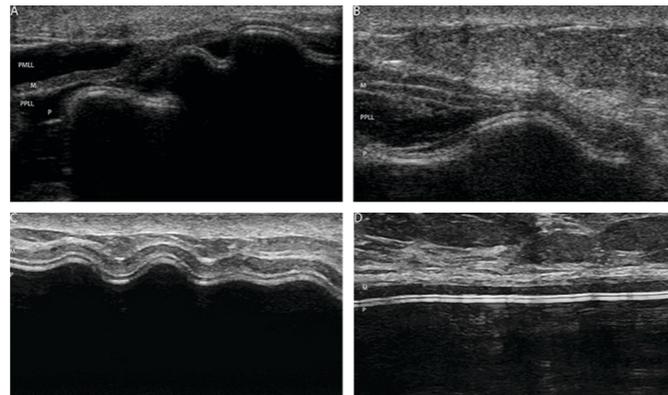
Early and late post-operative complications are reported. Histological and ultrasound evaluation showed a complete integration of the matrix. According to the VAS scale, the EOCRT QLQ C-30 and QLQ BR-23, patients' satisfaction gave high score in terms of quality of life and aesthetic outcomes.

Conclusion

The results of this new surgical technique in selected cases are promising in terms of effectiveness and low rate of post-operative complications, but further longterms evaluations are required.

Onesti M.G., Maruccia M., Di Taranto G., Albano A., Soda G., Ballesio L., Scuderi N.

Journal of Plastic, Reconstructive & Aesthetic Surgery
Nov 2017; 70(11):1527-1536;
doi: 10.1016/j.bjps.2017.06.023



ONE-STAGE MUSCLE SPARING BREAST RECONSTRUCTION IN ELDERLY PATIENTS: A NEW TOOL FOR RETAINING EXCELLENT QUALITY OF LIFE

More than 50% of breast cancer care occurs in elderly but women aged 65 and over generally have lower breast reconstruction (BR) rates.

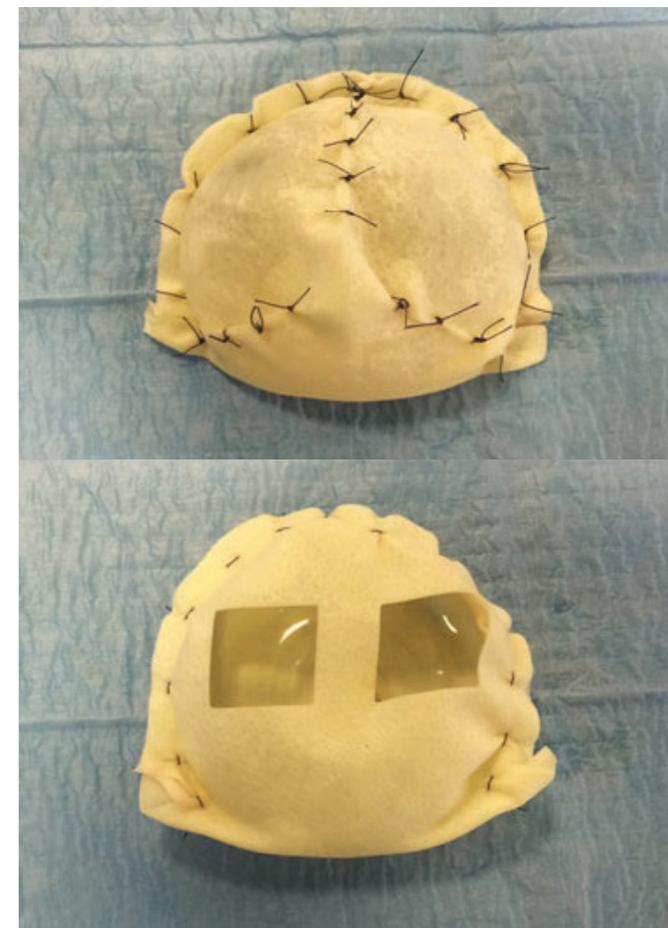
In medical literature, few papers focused on BR in elderly patients and usually the reported techniques are multisteps such as expander-implant reconstruction, local, and free flaps.

We present a one-stage reconstruction technique employed in elderly patients: musclesparing immediate BR with subcutaneous implant and Braxon acellular dermal matrix.

We prove the feasibility and safety of the technique and believe that this new procedure could represent a potential benefit in elderly BR.

Maruccia M., Di Taranto G., Onesti M.G.

The Breast Journal - Mar 2018; 24(2):180-183;
doi: 10.1111/tbj.12860



EARLY MULTICENTRE EXPERIENCE OF PRE-PECTORAL IMPLANT BASED IMMEDIATE BREAST RECONSTRUCTION USING BRAXON®

Background

The last two decades have seen significant changes in surgical management of breast cancer. The offer of immediate breast reconstruction (IBR) following mastectomy is currently standard practice. Skin sparing and nipple sparing mastectomy with implant-based IBR have emerged as oncologically safe treatment options.

Prepectoral implant placement and complete coverage of implant with acellular dermal matrix (ADM) eliminates the need to detach the muscle from underlying chest wall in contrast to the subpectoral technique. We report short-term outcomes of a multicentre study from the United Kingdom (UK) using Braxon® in women having an IBR.

Methods

A prospective study was conducted from December 2015 to October 2016 and included all patients from three breast units in the UK who underwent a mastectomy and an implant-based IBR using Braxon®. The demographic details, co-morbidities, operative details, immediate and delayed complications were recorded.

Specific complications recorded were infection, seroma, unplanned readmission and loss of implant. A comparison was made with complications reported in the National Mastectomy and Reconstruction Audit.

Results

Seventy-eight IBRs were included in the analysis with a median follow-up of 9.98 months. Mean age of the cohort was 50 years with a mean body mass index of 25.7 kg/m². Mean implant volume was 365 cc. The inpatient hospital stay was 1.48 days. About 23% of patients had a seroma, 30% had erythema requiring antibiotics and the explant rate was 10.2 percent. Bilateral reconstructions were significantly associated with implant loss and perioperative complications on univariate analysis.

Conclusion

Our early experience with this novel prepectoral technique using Braxon® has shown it to be an effective technique with complication rates comparable to subpectoral IBR. The advantages of prepectoral implantbased IBR are quicker postoperative recovery and short post-operative hospital stay. Long-term studies are required to assess rippling, post-operative animation, capsular contracture and impact of radiotherapy.

Jafferbhoy S., Chandarana M., Houlihan M., Parmeshwar R., Narayanan S., Soumian S., Harries S., Jones L., Clarke D.

Gland Surgery - Dec 2017; 6(6):682-688;
doi: 10.21037/g.s.2017.07.07

ONE-STEP PREPECTORAL BREAST RECONSTRUCTION WITH DERMAL MATRIX-COVERED IMPLANT COMPARED TO SUBMUSCULAR IMPLANTATION: FUNCTIONAL AND COST EVALUATION

Background

The breast reconstructive subpectoral technique commonly leads to functional consequences. Recently, a new conservative prepectoral breast reconstruction (PPBR) technique was proposed and its surgical safety and aesthetic effectiveness proved. The aim of this prospective nonrandomized study was to compare the functional and economical outcomes of the PPBR procedure versus the subpectoral one.

Patients and methods

From February 2015 to September 2016, 86 patients underwent mastectomy with immediate implant-based reconstruction. Thirty-nine patients were assigned to group 1 and received prepectoral acellular dermal matrix-wrapped implant reconstruction. The remaining 45 patients were assigned to group 2 and received a subpectoral implant or tissue expander. We recorded the operating time, length of hospital stay, analgesic consumption, postoperative pain, upper limb function, esthetic satisfaction, and quality of life. Additional surgical procedures for reconstruction completion or contralateral operation for symmetrization were also recorded.

Results

Compared to group 2 patients, group 1 patients showed less postoperative pain and faster upper limb functional recovery. Patients in group 1 also recorded a lower analgesic consumption and an earlier return to usual work. Moreover, the muscle-sparing technique improved aesthetic outcomes and largely reduced the need for symmetrization.

Conclusion

Immediate breast reconstruction by using prepectoral muscle-sparing acellular dermal matrix-wrapped implant resulted in lower pain intensity

and significant upper limb functional advantages compared to submuscular implant placement. Furthermore, when considering a series of ascertained benefits, PPBR is also economically advantageous, although future studies should better define its cost-effectiveness.

Cattelani L., Polotto S., Arcuri M.F., Pedrazzi G., Linguadoca C., Bonati E.

Clinical Breast Cancer - Dec 2017;
doi: 10.1016/j.clbc.2017.11.015

MANAGEMENT BASED ON GRADING OF ANIMATION DEFORMITY FOLLOWING IMPLANT-BASED SUBPECTORAL BREAST RECONSTRUCTION.

Abstract

Subpectoral breast reconstruction using implants and meshes have been used widely in Europe, the United States and the United Kingdom.

Although this technique has several advantages, animation deformity is a well-documented problem.

We propose a new grading system to classify breast animation in patients undergoing subpectoral implant based breast reconstruction.

We also discuss different techniques to avoid and correct animation deformity.

Vidya R., Tafazal H., Salem F., Iqbal F.M., Sircar T.

Archives of Plastic Surgery - Mar 2018; 45(2):185-190;
doi: 10.5999/aps.2017.01242.

Grade	Definition	Management
1	No visible distortion and displacement of the implant during muscle contraction, both during normal and exercise activity	No action needed
2	Minimal visible distortion with displacement of the implant (Superolaterally) during muscle contraction both in normal and exercise activity, grooving may be seen, unnoticed by patient (Fig. 2)	Offer and discuss intervention
3	Moderate visible distortion during muscle contraction, with displacement of the implant (Superolaterally) during muscle contraction both during normal and exercise activity, often noticed by patient (Fig. 3)	Offer and discuss intervention
4	Severe distortion during muscle contraction with persistent displacement of the implant both in normal and exercise activity, unattractive results disturbing the patient (Fig. 4)	Needs intervention

ACELLULAR DERMAL MATRIX IN IMPLANT-BASED IMMEDIATE BREAST RECONSTRUCTIONS: A COMPARISON OF PREPECTORAL AND SUBPECTORAL APPROACH.

Background

Implant-based immediate breast reconstruction (IBR) is the most common technique for post-mastectomy reconstructions in the United Kingdom (UK). Subpectoral implant placement is the conventional method of reconstruction. Placement of implant in the subcutaneous pocket covered by an acellular dermal matrix (ADM) is a relatively recent approach. We report a comparative analysis of prepectoral versus subpectoral approach for implant based IBR from a single institution in the UK.

Methods

Retrospective analysis from a prospectively maintained data was conducted from January 2015 to May 2017 including all patients who underwent a mastectomy with immediate implant-based IBR in a single breast unit. The demographic details, operative details, immediate and delayed complications were recorded. Specific complications recorded were infection, seroma, unplanned readmission and loss of implant. Factors affecting complication rates and implant loss were analyzed.

Results

One hundred and fifty-four reconstructions were included in the analysis with a median followup of 11.8 months.

Mean age of the cohort was 50 years with a mean BMI of 26.09 kg/m². Major implant-related complication rate was 12.3% with an implant loss rate of 7.8%. Age more than 50 years (P=0.037) and bilateral reconstructions (P=0.0001) had significant impact on complication rate, on multivariate analysis. Patients with bilateral implants had a significantly higher implant loss rate (P=0.0001). Implant loss rates in the prepectoral group (4.2%) and subpectoral group (10.8%) were not statistically significant (P=0.29).

Conclusions

Prepectoral and subpectoral techniques of IBR have comparable outcomes. Studies reporting on long-term outcomes are planned.

Chandarana M.N., Jafferbhoy S., Marla S., Soumian S., Narayanan S.

Gland Surgery - Mar 2018;
doi: 10.21037/gs.2018.03.05

A CASE OF IMPORTANT WEIGHT LOSS AFTER A PREPECTORAL BREAST RECONSTRUCTION.

Abstract

The submuscular implant-based breast reconstruction is the most common reconstructive technique following mastectomy. Recently, subcutaneous implant positioning, together with acellular dermal matrix, has become a promising technique in selected patients.

We present the case of a 42-year-old woman who underwent left nipple-sparing mastectomy with prepectoral acellular dermal matrix (ADM) assisted direct-to-implant (DTI) breast reconstruction and contralateral mastopexy.

The implant was completely wrapped around by Braxon®, a preshaped porcine ADM. A few months after surgery, she experienced a severe weight loss resulting in the aesthetic deterioration of both breasts.

The patient showed a migration of the left implant inferiorly and laterally, and deflation of the contralateral breast. In order to improve the left breast, a lateral capsulectomy was performed to reduce the prepectoral pocket size and lift the implant. Subsequently, a modified donut mastopexy was performed to obtain an upward migration of the nipple-areolar complex.

One of the limiting factors of prosthetic reconstruction, as compared to autologous reconstruction, is the aesthetic deterioration determined by any weight change.

Differently from submuscular implant reconstruction, the prepectoral implant reconstruction follows body changes after weight changes and ageing. In fact, Braxon's integration determines the formation of a capsule adhering to the mastectomy flap which makes the implant more sensible to dermatochalasis.

The greater thickness of the mastectomy flap due to the larger representation of the subcutaneous tissue makes the reconstruction more sensitive to weight changes.

A tailored partial capsulectomy combined with a donut mastopexy can be a solution in these patients after an important weight loss.

Salgarello M., Barone Adesi L., Mangialardi M.L.

European Journal of Plastic Surgery - Apr 2018; 41(5):601-604;
doi: 10.1007/s00238-018-1413-4

CURRENT EVIDENCES ON IMMEDIATE BREAST RECONSTRUCTION AFTER MASTECTOMY.

Abstract

Immediate breast reconstruction after mastectomy is widely used: the introduction of skin sparing and nipple sparing mastectomy (NSM) have broaden the viability of different techniques either prosthetic either autologous one.

In prosthetic reconstruction, expander is in some case still used, even if one stage reconstruction is preferred.

The prosthetic reconstruction is preferred in small breast with minimal/no ptosis and in bilateral cases.

The authors explain the different techniques for direct to implant reconstruction: submuscular-subfascial pocket and use of acellular dermal matrix (ADM) (either in subpectoral either in prepectoral plane).

The autologous reconstruction is preferred in patients with large breast or with previous radiotherapy.

Abdominal flaps are the workhorse because they can provide for large volume flaps and because of the better cosmetic results, even if flaps from areas are available.

Salgarello M., Visconti G., Barone Adesi L.

Translational Cancer Research - Apr 2018; 7(Suppl 3): S339-S350;
doi: 10.21037/tcr.2018.03.40



PRE-PECTORAL IMPLANT-BASED IMMEDIATE BREAST RECONSTRUCTION WITH BRAXON PORCINE ACELLULAR DERMAL MATRIX: IS IT SAFE WITH RADIOTHERAPY?

Introduction

The novel pre-pectoral approach to implant-based reconstruction could improve post-operative pain, shoulder functionality and rate of recovery when compared to the sub-muscular approach. Our questions are: What are the associated complications? Is the reconstruction safe with adjuvant radiotherapy?

Methods

Patients were included in this retrospective cohort study if they had had a Braxon ADM pre-pectoral implant-based reconstruction in the last 13 months at the Royal Devon and Exeter hospital. There were no exclusion criteria.

Results

Twenty-one female patients, 33 to 78 years, underwent Braxon pre-pectoral implant-based reconstruction: three bilateral procedures; 18 unilateral procedures. The length of stay for unilateral or bilateral Braxon procedures was between zero and two nights, with four cases requiring an in-patient stay of less than 24 hours. Three patients underwent re-operations for early complications of haematoma, nipple skin necrosis and wound dehiscence. There was no implant loss but nipple areolar complex necrosis resulted in implant exchange and delayed adjuvant chemotherapy.

Five patients were treated non-operatively for seroma (1), skin necrosis (1), erythema (1) and red breast syndrome (2). Radiotherapy can lead to an increased frequency of complications in reconstructed breasts. In our cohort, four underwent radiotherapy: two patients had no complications; one patient had asymmetry at follow-up that may require further surgery; one patient had wound dehiscence before radiotherapy, however had no further complications.

Conclusion

Data from this cohort demonstrates pre-pectoral implant-based reconstruction with Braxon is safe and effective. It provides low complication rates even with radiotherapy and can be a day-case procedure.

Sewell J., Sharma A., Ficken L., Olsen S., Tillett R., Ferguson D., Ives C., Oliver D.

European Journal of Surgical Oncology - Jun 2018; 44(6):916;
doi: 10.1016/j.ejso.2018.02.239

EVALUATION OF ONE HUNDRED PREPECTORAL IMPLANT-BASED RECONSTRUCTIONS USING BRAXON® FROM A SINGLE INSTITUTION

Introduction

Implant-based immediate breast reconstruction (IBR) is the most common technique for post-mastectomy reconstructions in the United Kingdom (UK). Placement of implant in the subcutaneous pocket covered by an acellular dermal matrix (ADM) is a relatively recent approach. We report on outcomes of 100 prepectoral IBR using Braxon® from a single institution.

Methods

Prospectively maintained database of all patients who underwent a mastectomy and IBR with a prepectoral implant and Braxon from January 2016 to December 2017 in a single breast unit was assessed.

Patient demographics, operative details, immediate and delayed complications were recorded. Factors affecting complication rates were analysed.

Results

One hundred and one reconstructions performed in 88 patients were included in the analysis with a median follow-up of 10 months. The median age of the cohort was 50 years with a mean BMI of 27.56 kg/m².

Mean hospital stay was 1.58 days. 72% of the patients received chemotherapy and 41% patients received adjuvant radiotherapy. Major implant related complication rate was 13.6% with three patients losing implants.

Of the factors analysed for their effect on peri-operative complications, none reached statistical significance on Chi-square test. Invasive cancers [OR: 2.5, 95% CI (0.981-6.371), p ¼ 0.055] and node positive status [OR: 2.58, 95% CI (0.936-7.154), p ¼ 0.067] had a trend towards statistical significance on univariate logistic regression model. None of the factors were significant on multivariate analysis.

Conclusions

Prepectoral implant-based reconstruction using Braxon® has acceptable peri-operative outcomes. Further studies to ascertain long term outcomes need to be conducted.

Chandarana M., Jafferbhoy S., Tan Y., Marla S., Soumian S., Narayanan S.

European Journal of Surgical Oncology
Jun 2018; 44(6): 892-893;
doi: 10.1016/j.ejso.2018.02.138

PROPHYLACTIC BIPEDICLED NIPPLE SPARING WISE PATTERN MASTECTOMY AND PREPECTORAL IMPLANT/ ADM BREAST RECONSTRUCTION IN LARGE PTOTIC BREASTS; TECHNIQUE AND OUTCOMES

Introduction

Nipple sparing mastectomy (NSM) with simultaneous prepectoral direct to implant reconstruction and acellular dermal matrix (ADM) is increasingly offered to patients opting for risk reducing mastectomies.

The recent introduction of prepectoral implant/ADM in the armamentarium of breast reconstruction has proven to reduce pain and animation deformity. Despite this promising method, patients with macromastia and ptotic breasts remain a challenging group to treat. More often they would require secondary corrective procedures and can experience high failure rate and unsatisfactory outcomes. The authors present their experience in utilizing a bipedicled nipple areola complex dermal flap through Wise pattern to achieve a successful NSM with prepectoral implant/ADM (Braxton) as a single stage in patients with large ptotic breasts.

Methods

Patients seeking prophylactic NSM with large ptotic breasts were included in the study between 2016 and 2017. They were offered a single stage wise pattern bipedicled nipple areola complex dermal flap mastectomy and prepectoral implant/ADM breast reconstruction.

The technique and outcomes were recorded.

Results

Sixteen reconstructions were performed in 8 women with median age 32 years (range 27-50) and a median body mass index of 32kg/m² (range 29-35). The resected breast's weight ranged from 750-1300 grams (median 890). All procedures were completed successfully with no failure or nipple areola complex losses during the follow up period (range 3-14 months). All patients reported excellent satisfaction.

Conclusion

The author's results demonstrate that this technique could be safely planned for risk reduction NSM with excellent durable outcomes.

Khalil H., Faroq T., Ashour T., Rhobaye S., Malahias M.

European Journal of Surgical Oncology

Jun 2018; 44(6): 878–879;

doi: 10.1016/j.ejso.2018.02.082

THE ECONOMICS OF PREPECTORAL BREAST RECONSTRUCTION — COMMENT ON.

We read with great interest the article published by Glasberg,¹ and we agree with the potential advantages that prepectoral implant-based acellular dermal matrix-assisted breast reconstruction offers to patients. Moreover, we agree with the invocation of an economic model to evaluate the muscle-sparing technique.

This recent procedure, once its feasibility has been assessed,² necessitates an objective determination regarding hypothetical functional advantages for the patients that can be evaluated by an efficient health insurance system, and a comparison study between the newly adopted surgical method and the traditional subpectoral reconstruction. In fact, according to the European experience, prepectoral implant-based acellular dermal matrix-assisted breast reconstruction may become, for selected patients, a dominant alternative in implant-based breast reconstruction, once its cost-effectiveness is assessed. It must be highlighted that, in our institution, over the past 24 months, prepectoral implant-based acellular dermal matrix-assisted breast reconstruction already represents 52 percent of all implant-based reconstructions.

For these reasons and in agreement with the above-mentioned intentions, we completed recently a single-institution, prospective, clinical study, accepted for publication,⁴ dividing 86 patients into two homogenous groups to compare two immediate implant-based reconstructive approaches (i.e., prepectoral implant-based acellular dermal matrix-assisted breast reconstruction versus the subpectoral method). We evaluated analgesic consumption, upper limb impairment by validated tests (i.e., Brief Pain Inventory Short Form, Constant-Murley Score), and direct intramural costs for each group. We registered meaningful differences in the degree of postoperative pain and upper limb function in favor of the

prepectoral approach. In conclusion, the analysis of hospital direct costs, taking into account the total number of requested operations for each patient, demonstrated the economic superiority of prepectoral implant-based acellular dermal matrix-assisted breast reconstruction versus the subpectoral procedure. Clearly, our results need to be completed through a cost-effectiveness evaluation rating as monetary outcome also the functional and well-being utilities already measured, to have a whole panorama of prepectoral implant-based acellular dermal matrix-assisted breast reconstruction economic analysis.

Cattelani L., Polotto S.

Plastic and Reconstructive Surgery

Sep 2018; 142(3): 415e-417e;

doi: 10.1097/PRS.0000000000004660

COMBINATION OF ACELLULAR DERMAL MATRIX WITH A DE-EPITHELIALISED DERMAL FLAP DURING SKIN-REDUCING MASTECTOMY AND IMMEDIATE BREAST RECONSTRUCTION.

Introduction

Patients with large ptotic breasts undergoing immediate implant-based reconstruction often require skin-reducing mastectomy to optimise the aesthetic outcome. However, healing complications, especially at the resulting inverted T-junction, leading to wound dehiscence, infection, skin necrosis, implant exposure and failed reconstruction have been widely reported. We present an innovative approach for immediate implant-based reconstruction combining porcine- or bovine-derived acellular dermal matrices with a de-epithelialised dermal sling to protect and support the implant, while improving clinical outcomes in this challenging group of patients.

Materials and methods

Demographic, tumour and surgical data were reviewed for patients undergoing Wise pattern (T-scar) skin-reducing mastectomies with immediate implant-based reconstruction combining porcine- or bovine-derived acellular dermal matrices with a de-epithelialised dermal sling.

Results

This technique was successfully employed to reconstruct five large pendulous breasts in four breast cancer patients with a median age of 50.5 years (range 34-61 years) who were not suitable for, or had declined, flap-based reconstruction. The acellular dermal matrices used were SurgiMend®, Strattice™ and Braxon® and the expandable implants were placed in the sub-pectoral (n = 3) and pre-pectoral (n = 1) planes. The technical steps and clinical outcomes are presented. One patient experienced T-junction breakdown overlying the de-epithelialised dermis without implant loss.

Conclusion

The combination of an acellular dermal matrix and a dermal sling provides

a double-layer 'water-proofing' and support for the implants inferiorly, avoiding T-junction breakdown complications, since any dehiscence is on to well-vascularised dermis. Furthermore, the acellular dermal matrix stabilises the implant in the large mastectomy cavity (pocket control). This approach provides a viable option which facilitates mastectomy and immediate implant reconstruction in large-breasted patients.

Kankam H., Hourston G., Forouhi P., Di Candia M., Wishart G.C., Malata C.M.

Annals of The Royal College of Surgeons of England
Aug 2018; e1-e6;
doi: 10.1308/rcsann.2018.0127

PREPECTORAL BREAST RECONSTRUCTION USING THE BRAXON® PORCINE ACELLULAR DERMAL MATRIX: A RETROSPECTIVE STUDY.

Background

Breast cancer is the leading cause of death attributable to cancer among women worldwide. Breast reconstruction has become an integrated part of breast cancer treatment due to long-term psychosexual health factors and its importance to breast cancer survivors. Muscle-sparing techniques using an acellular dermal matrix (ADM) (Braxon; DECO med s.r.l., Venice, Italy) can be considered a possible alternative to immediate reconstruction or two-step reconstruction for patients with medium breasts who want to preserve their natural breast shape.

Methods

We performed a retrospective analysis of reconstructions using a Braxon porcine-derived ADM at the Breast Unit of the University Hospital of Parma and the Breast Unit of Piacenza Hospital from January 2015 to September 2017. The objective was to evaluate the benefits and complications resulting from this technique.

Results

We treated 42 patients and performed a total of 51 muscle-sparing reconstructions using the Braxon porcine-derived ADM. The incidence of cutaneous necrosis was 4% (n=2); the incidence of seroma was 4% (n=2). We had to remove the implants in two cases. Natural and symmetrical breasts with good form, ptosis, and softness were achieved for most patients.

Conclusions

Good results were obtained with a high degree of esthetic and functional satisfaction for the majority of patients. A low rate of early complications compared to that reported in the international literature data was observed.

Gardani M., Simonacci F., De Sario G., Cattadori F., Raposio E., Palli D.

European Journal of Plastic Surgery - Apr 2019; 42: 145;
doi: 10.1007/s00238-018-1455-7



MINIMAL PAIN WITH PREPECTORAL IMPLANT-BASED BREAST RECONSTRUCTION

Dear Editor

We read with great interest the article written by Lanier Steven et al on the “Intraoperative Nerve Blocks Fail to Improve Quality of Recovery after Tissue Expander Breast Reconstruction: A Prospective, Double-Blinded, Randomized, Placebo-Controlled” (1).

It is interesting to note that neither method is superior on comparison.

In the UK we mainly do prepectoral single stage immediate implant based breast reconstruction using a preshaped mesh called Braxon (2). We do not use any nerve blocks and patients only receive local infiltration (20 mls of 0.5% bupivacaine in 200 mls of saline) before incision (presumptive analgesia). Patients receive simple analgesics post operatively and are discharged home same day or the following day (23 hours stay). We have enclosed our breast Q results mainly demonstrating the postoperative pain following surgery (See Figure, Supplemental Digital Content 1, which shows an assessment of post-operative pain following surgery using Breast-Q.

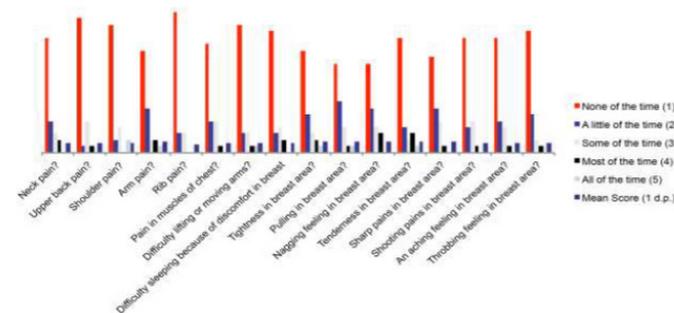
We observed that the majority of the patients (n=50) had very minimal pain and had an early recovery following this technique. This could be attributed to the minimal invasive surgery, lack of chest wall muscle dissection and preservation of normal chest wall anatomy.

Hence we consider that muscle sparing minimally invasive breast reconstruction may be the way forward in selected group of suitable patients.

Vidya R., Green M.

Plastic and Reconstructive Surgery - Jan 2019; 143(1):236e.
doi: 10.1097/PRS.0000000000005135

Pain Assessment



OUTCOMES OF PREPECTORAL IMPLANT-BASED BREAST RECONSTRUCTION WITH BRAXON® ACELLULAR DERMAL MATRIX—A SINGLE-CENTRE EXPERIENCE.

Background

Single-stage direct-to-implant reconstruction is the most common method of reconstruction in the UK after a mastectomy. Prepectoral implant placement with full implant coverage using acellular dermal matrix (ADM) is a relatively new technique. We report on long-term outcomes of prepectoral immediate breast reconstruction (IBR) using Braxon® ADM from a single institution.

Methods

All patients operated for a mastectomy with IBR using Braxon® from January 2016 to March 2018 were included in the study. The demographic details, treatment details and short- and long-term outcomes were evaluated. Factors affecting complication rates were analysed. Patient-reported outcome measures were studied using BREAST-Q questionnaires.

Results

One hundred and sixteen reconstructions performed in 98 patients were included in the study. The median age was 50 years with a mean body mass index of 27.33 kg/m². The median follow-up period was 440 days. The implant-related major complication rate was 17%, with an unplanned readmission rate of 22.4% and a return to theatre rate of 21.4%. Early complications were significantly higher in patients with node-positive disease. Delayed complications were seen in nine patients. The implant loss rate was 4.3%. The mean BREAST-Q scores were 78 for satisfaction with treatment and 64 for satisfaction with breast domains. The outcomes were comparable to reported national data.

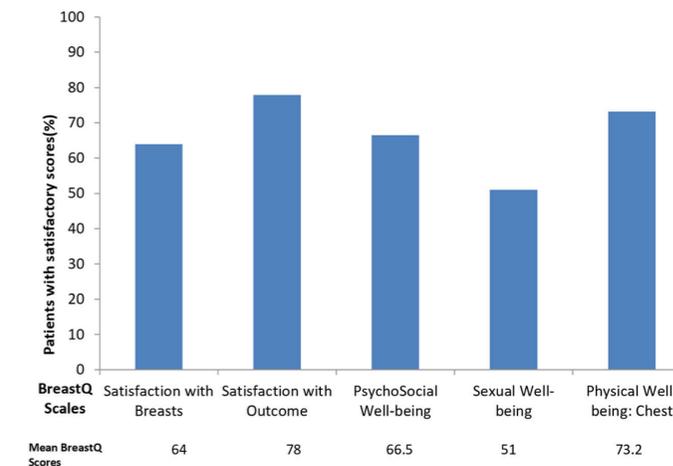
Conclusions

Prepectoral implant-based reconstruction with Braxon has comparable complication rates with good long-term aesthetic and patient-reported

outcomes. Further studies with larger cohort and longer follow-up are needed.

Chandarana M., Soumian S., Jafferbhoy S., Marla S., Narayanan S.

European Journal of Plastic Surgery - Mar 2019; 1-9.
doi: 0.1007/s00238-019-01512-2



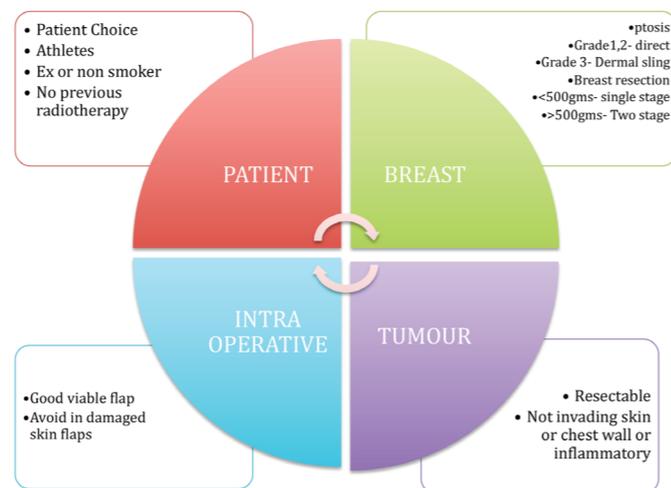
PREPECTORAL IMPLANT-BASED BREAST RECONSTRUCTION: A JOINT CONSENSUS GUIDE FROM UK, EUROPEAN AND USA BREAST AND PLASTIC RECONSTRUCTIVE SURGEONS

Advances in implantable biologic and synthetic products over the last decade have enabled surgeons to replace traditional submuscular implant-based breast reconstruction techniques with a prepectoral or muscle-sparing technique. Prepectoral breast reconstruction is becoming increasingly popular among surgeons and patients due to the preservation of normal chest wall anatomy, with the restoration of body image with minimal morbidity.

In this article, we have described a guide to prepectoral or muscled-saving breast reconstruction with a particular emphasis on patient selection, technique and postoperative outcomes. Hence, a joint consensus guide from UK, European and USA breast and plastic reconstructive surgeons has been agreed, and a crowd-writing method has been adopted to produce this guide.

Vidya R., Berna G., Sbitany H., Nahabedian M., Becke H., Reitsamer R., Rancati A., Macmillan D. and Cawthorn S.

ecancer - May 2019; 13:927;
doi: 10.3332/ecancer.2019.927



POSTSURGICAL ULTRASOUND EVALUATION OF PATIENTS WITH PROSTHESIS IN ACELLULAR DERMAL MATRIX: RESULTS FROM MONOCENTRIC EXPERIENCE

Mastectomy and breast prosthetic reconstruction is the most common surgical treatment for women diagnosed with breast cancer. In the last few years, breast prosthetic augmentation in acellular dermal matrix (ADM) has been introduced. The aim of this study is to present our single-center experience in evaluating the outcome of patients who underwent breast reconstruction in ADM, using ultrasound (US) examination.

US follow-up allows evaluating both normal postoperative findings and changes and potential local complications, demonstrating that ADM is a safe option for women candidates for mastectomy.

Ballesio L., Casinelli A., Gigli S., Boldrini C., Di Taranto G., Albano A., Onesti M.G.

International Journal of Surgical Oncology - Jun 2019;
doi: 10.1155/2019/7437324

TABLE 1: Results of the study, patients.

	T0	T1	T2	T3
<i>Parameters</i>				
Visibility of the membrane	27	22	8	1
Mediolateral membrane folds	18	18	18	18
Periprosthetic fluid	19	10	7	5
Inhomogeneity of soft tissues	20	13	8	3
Liponecrosis	9	10	10	7
<i>Complications</i>				
Seroma	3	3	-	-
Suture granuloma	1	1	-	-
Nipple introflexion	-	-	1	-
Prosthetic infection	1	-	-	-
Residual disease	-	1	-	-



product line



BRAXON®

Braxon® is the unique ADM expressly designed for pre-pectoral breast reconstruction. Its patented shape allows the complete wrapping of the breast implant. No more muscle damages.

NÄTIVE®

Native® is the ultimate ADM expressly designed for breast reconstruction. The thinnest ADM on the market: 0.6mm because the faster it integrates, the better it is.

Equity®

Equity® is the thinnest matrix on the market: 0,4mm. Equine collagen fibers naturally cross-linked. Strength and elasticity for completing the sub-muscular pocket.

ΣGIS®

Egis® is the natural solution for soft tissue repair. Not cross-linked, its high tenacity and robustness allows a secure and lasting protection for abdominal wall defects.

PRESSFIT®

Press-fit® is the ultimate anal fistula plug. Its patented shape prevents rotation and extrusion of the plug. Made of ADM it will be remodelled in self tissue, preventing recurrence.



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ENTITY
IDENTIFIER
FOUNDATION

Rating di
Legalità



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