Centre universitaire de santé McGill
McGill University Health Centre

Technology Assessment Unit of the McGill University Health Centre

Clinical efficacy and cost of Allogenic Acellular Dermal Matrix (AADM) in implant-based breast reconstruction of post mastectomy cancer patients

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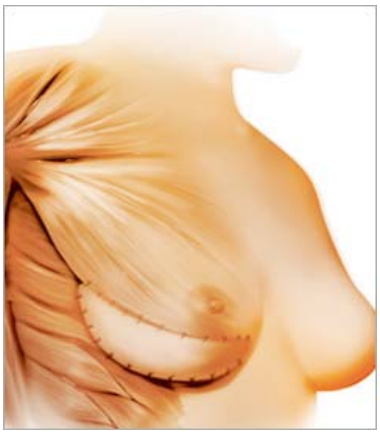

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Report prepared for the Technology Assessment Unit (TAU)

of the McGill University Health Centre (MUHC)

by

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Invitation.

This document was developed to assist decision-making in the McGill University Health Centre. All are welcome to make use of it. However, to help us estimate its impact, it would be deeply appreciated if potential users could inform us whether it : has influenced policy decisions in any way.

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Sommaire

Introduction

La reconstruction du sein après mastectomie peut être réalisée à partir d'implants ou de tissues autogènes. Ce rapport ne concerne que le reconstruction implantaire. L'implantation d'un « *expande*r » suivi d'une prothèse est souvent entravée par l'insuffience de l' enveloppe musculaire, entraînant des complications ou donnant lieu à des résultats esthétiques de piètre qualité. L'utilisation d'une matrice dermique acellulaire et allogénique (AADM) est une approche pouvant permettre d'éviter ces complications et possiblement, de raccourcir le processus de reconstruction.

Objectif

Le but de ce rapport est de réaliser une revue systématique de l'utilisation de l'AADM (de marque AlloDerm ou DermaMatrix) pour la reconstruction du sein suite une mastectomie afin d'évaluer l'innocuité, les avantages pour la santé ainsi que les coûts budgétaires de cette intervention.

Méthode

Nous avons effectué une recherche systématique de la littérature médicale à partir de la bibliothèque Cochrane, de Pubmed, des bases de données Embase et celles portant sur l'évaluation des technologies (INAHTA, CADTH, CRD, AETMIS) sans restriction au niveau de la langue écrite, sur une période s'étendant jusqu'au mois de février 2009. Nous avons également révisé les études mentionnant les risques de complications

esthétiques tardives ainsi que les risques de révision associés. Le taux de révision au CUSM fut estimé conjointement avec le D^r^ Karl Schwarz.

Résultats

Dix études répondant à nos critères d'inclusion furent identifiées. Aucune'était une étude clinique randomisée. Sept études (table 1) portaient sur l'AlloDerm utilisé comme « *expander* » pour la reconstruction mammaire, deux études décrivaient son utilisation dans des contextes cliniques reliees et une étude comparait l'utilisation de l'AlloDerm et du DermaMatrix. La durée moyenne du suivi des études prospectives variait de 8 à 26 mois.

Impacts sur la santé

Taux de complications periopératoires : Ce taux était comparable chez les études utilisant ou non l'AADM.

Nombre d'expansions des tissus : Dans deux études randomisées, ce nombre n'était pas influencé par l'utilisation de l'AADM.

Résultats esthétiques : Une seule étude en faisait mention et soulignait que le sein reconstruit avec l'AADM était presque identique au sein normal non-opéré.

Taux de révision sans l'AADM : Puisque la plupart des révisions font suite à des résultats esthétiques de piètre qualité, le taux de révision reflète mais sous-estime aussi ce nombre d'échecs. Les taux de révision rapportés varient grandement (2.2% à 36%). Selon le D^r^ Schwarz, un taux global de révision de 20% peut être estimé en l'absence de l'AADM.

Taux de révision avec l'AADM : Deux études rapportent un taux identique de 4%. Selon le D^r^ Schwarz, un taux de révision d'environ 5% peut être

estimé suite à des complications tardives entraînant de piètres résultats esthétiques et ce, lors de l'utilisation de l'AADM.

Le Cout

Impact budgétaire : Le coût d'acquisition de l'AADM est d'environ 1 920 $ par procédure chirurgicale. Si l'on estime à 60 par année le nombre de femmes se prévalant de cette technologie (20% procedures bilaterale), l'impact budgétaire total serait de 138 240 $ par année pour le CUSM.

Conclusion

- Il n'existe aucune évidence selon laquelle l'utilisation de l'AADM augmenterait le risque de complications periopératoires.
- l'AADM rapporte un plus faible nombre de révisions avec son utilisation mais aucune évidence solide n'est présentée dans la littérature.
- Selon un membre de notre équipe qui a étudié la technique utilisant l'AADM pour la chirurgie de reconstruction au CUSM, cette approche réduirait la durée de la procédure chirurgicale et se traduirait par de meilleurs résultats esthétiques. Il estime que ceci permettrait d'éviter une révision chirurgicale à 9 femmes (i.e. 15%) parmi les 60 visées (11 procédures) pour une reconstruction mammaire chaque année. Si ces projections s'avèrent exactes, le coût additionnel pour chaque reconstruction mammaire à partir de l'AADM pourrait être réduit.

Recommandations

À la lueur des données précédentes, il est recommandé que cette technologie soit approuvée **d'une façon temporaire** pour 60 cas aux conditions suivantes :

- Pour aider le CUSM à mettre en place une politique interne en regard de cette technologie, le chirurgien concerné devrait maintenir un registre de toutes les reconstructions mammaires faites à partir de l'AADM incluant les facteurs de risque précurseurs de piètres résultats, les complications periopératoires et postopératoires ainsi que tout autre détail pertinent, telles les procédures de révision.
- Une évaluation rétrospective impliquant l'AADM devrait être menée, fondée sur les mêmes critères.
- De plus, le résultat esthétique de chaque intervention impliquant l'utilisation de l'AADM devrait être évalué par au moins 3 intervenants ne faisant pas parti du département de chirurgie plastique.
- Enfin, ce registre des procédures et des évaluations esthétiques devrait être déposé au responsable administratif et au chef du département de chirurgie dans un délai n'excédant pas 18 mois, de façon à statuer sur la poursuite de l'utilisation de l'AADM.

Executive Summary

Background

Restoration of the breast following mastectomy can be performed using either implants or autogenous tissue. This report is concerned only with the former procedure. Implantation of an expander or prosthesis is frequently complicated by lack of a sufficiently large skin-muscle envelope resulting in complications and poor aesthetic outcomes. Use of an Allogenic Acellular Dermal Matrix (AADM) has been suggested as a means to avoid these complications and possibly shorten the reconstructive process.

Objective

The purpose of this report is to carry out a systematic review of the use of AADM (brand names AlloDerm or DermaMatrix) for breast reconstruction following mastectomy with the objective of estimating the safety, health benefit and cost impact of this intervention.

Methods

We performed a systematic search of the medical literature covering the Cochrane library, Pubmed, Embase and health technology databases (INAHTA, CADTH, CRD, AETMIS) in all languages covering the period up to February 2009. We also reviewed studies reporting risk of late aesthetic complications and risk of revision due to them. The revision rate at the MUHC was determined in consultation with Dr. Karl Schwarz.

Results

We found a total of 10 studies, none of which were randomized controlled trials. We found 7 studies (Table 1) on the use of AlloDerm for the purpose of expander-based breast reconstruction, two articles describing its use in other related clinical contexts and one article comparing the use of

AlloDerm to DermaMatrix. The mean duration of follow-up in the prospective studies ranged from roughly 8 to 26 months.

Health outcomes

Perioperative complication rates. In studies with or without use of AADM these were comparable.

Number of tissue expansions. In two controlled studies the number of expansions was uninfluenced by the use of AADM.

Aesthetic results. These were reported in one study. The breast reconstructed with *AADM* was found to be almost identical with the opposite unoperated normal breast.

Revision rate in the absence of AADM use. Since most revisions are undertaken because of poor aesthetic outcome, revision rates reflect but underestimate the frequency of poor aesthetic results. Reported revision rates vary widely (2.2% to 36%). In the opinion of Dr. Schwarz a reasonable estimate of the frequency of revision due to all causes, without use of AADM would be approximately 20%.

Revision rate, with use of AADM. Two studies each report rates of 4%. Dr. Schwarz's estimate of the frequency of revision due to all late complications causing poor aesthetic outcome with use of AADM is approximately 5%.

Cost Issues

Budget impact. The purchase price of AADM is $1,920 per procedure. Based on an estimated 60 women per year (20% bilateral procedures), this would amount to a budget impact of $138,240 per year at the MUHC.

Conclusions

- There is no evidence that use of AADM increases the risk of perioperative complications.
- Its use is reported to be associated with fewer breast revision procedures, but convincing evidence for this is not yet available in peer reviewed literature.
- It is the conviction of a member of our staff who has studied the procedure that use of AADM for breast reconstruction surgery at the MUHC would shorten the surgical procedure and result in superior aesthetic outcomes. He estimates that this would also permit 9 (i.e. 15%) of the projected 60 women (11 procedures) undergoing breast reconstruction each year to avoid breast revision surgery. To the extent that these projections prove to be correct the net incremental cost of each breast reconstruction using AADM could be reduced.

Recommendations

In light of the above it is recommended that this technology receive **temporary** approval for 60 cases on the following **conditions.**

- To assist the MUHC in establishing a permanent policy, the surgeon concerned should be requested to maintain a record of all breast reconstructions in which AADM is used, with documentation of risk factors for poor outcomes, perioperative and post-operative complications, and all other relevant details including subsequent revision procedures.
- A retrospective evaluation of all procedures in which AADM has been used, should also be undertaken, based on the same criteria,

- In addition, the aesthetic outcome of each procedure involving the use of AADM should be formally evaluated by at least 3 individuals who are not members of the Department of Plastic Surgery.
- This record of procedures and aesthetic evaluations should be submitted to the Hospital (the Head of Surgery and the Administrative Director responsible for the Department of Surgery) within 18 months, at which time the decision concerning the continued use of AADM should be made.

Clinical efficacy and cost of Allogenic Acellular Dermal Matrix (AADM) in implant-based breast reconstruction of post mastectomy cancer patients

Background

Restoration of the breast mound following mastectomy can be performed using either implants or autogenous tissue [1]. Implant-based reconstruction is increasingly used as first-line therapy and in the US has been reported to be the treatment of preference in over 60% [1, 2] and 80% [3] of procedures. This type of reconstruction is typically carried out in two stages. In the first stage a tissue expander is placed in the submuscular position below the pectoralis major and serratus anterior muscles at the time of mastectomy. The expander is incrementally inflated with saline over a period of 6 to 8 weeks. Following this, the tissues are allowed to relax and adjust to their new position for a further 4 to 8 weeks. Finally, in the second stage, the tissue expander is replaced by an implant. The following report is concerned only with implant-based reconstruction.

Implant-based reconstruction is complicated by the fact that many candidates have a skin-muscle envelope that is insufficient for expansion. Providing sufficient muscle coverage to breast expanders/implants is a challenge, particularly in thin women and those for whom the pectoralis muscle is damaged or absent [3]. Lack of sufficient coverage can lead to post-reconstruction problems of pain, implant rippling, bottoming-out, symmastia, implant extrusion, implant malposition or capsular contracture

[3, 4]. Recent reports suggest that the frequency of these late complications can be reduced and aesthetic results improved through the use of an allogenic acellular dermal matrix (AADM) sling to provide inferolateral support to the implanted device .[5, 6]. AADM can also be used to restore tissue that has been damaged by radiation, injury or disease [7-9], and there are animal-based studies that suggest that AlloDerm reduces radiation-related inflammation, delays or diminishes pseudo-epithelium formation, and thus may slow progression of capsular fibrosis and competition [10]. However, it has been suggested that the possibility of graft necrosis leading to fibrosis may have hindered enthusiasm for this procedure, although such complications have not been observed clinically [4].

These matrices are created from donated human skin. All cells from the donated skin are removed, with retention of their important biochemical and structural components. Donors are screened for transmissible diseases. Once in position, these acellular matrices are vascularised by the host tissue and are transformed into functional living tissue that resembles its host [11]. Supposedly these acellular matrices lack immunogenic epitopes and therefore, they evade rejection, absorption or extrusion [11] Consequently their use can avoid two common reconstructive problems in these patients; donor-site morbidity and inadequate biomechanically-lasting subcutaneous tissue for reconstruction [12]. There are currently only two recognized brands of AADM, AlloDerm and DermaMatrix. In both cases production complies with FDA human tissue regulations and the procedural guidelines of American Association of Tissue Banks [11, 13] .

For patients undergoing mastectomy for breast cancer, AADM is used in three ways to facilitate breast reconstruction. They provide inferolateral support to the device (expander or prosthesis) during immediate breast reconstruction, and by providing sufficient coverage for the device it is

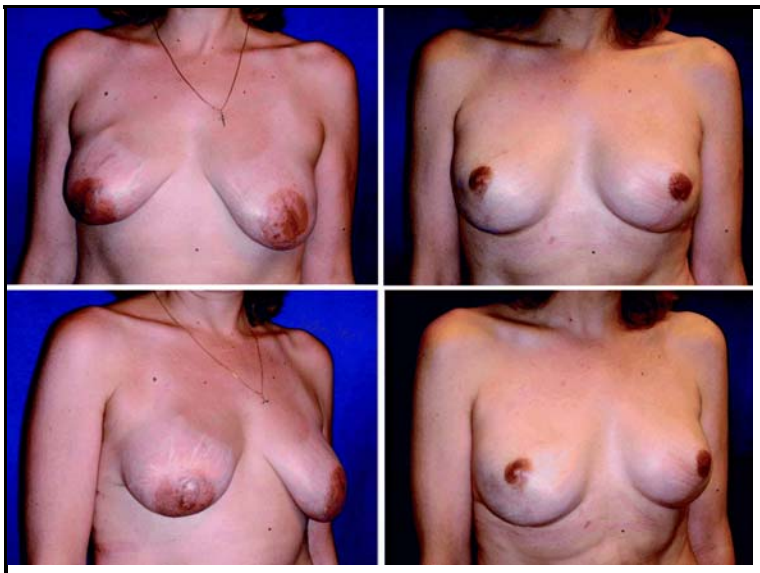

Figure 1a: Before and after picture Comparison

(L**eft**.Bilateral reconstruction . AADM not used . Note inferior displacement of the implants with rippling.

Right. Bilateral reconstruction. AADM was used.)

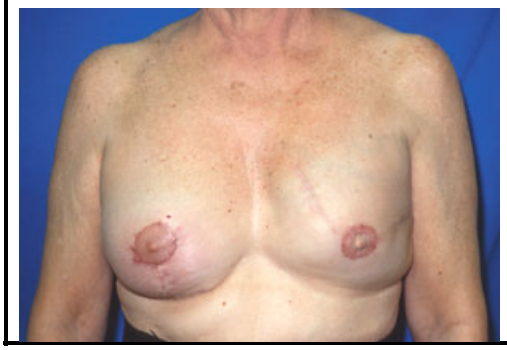

Figure 1b: L Breast constructed using total submuscular technique.Shows the contraction and flattening that could be eliminated with AADM

believed that they allow better and more secure device placement with improved aesthetic outcome and facilitate tissue expansion [3, 14]. In the current report it is only the first use that is considered. They may also be used in revision reconstruction to help camouflage implant rippling.

and to correct implant malposition [4, 15], and finally, they are sometimes utilized in nipple reconstruction [16, 17]. (See Figures 1a and 1b supplied by Doctor K Schwarz).

In addition, placement of the implant/expander normally involves elevation and mobilization of the pectoralis major muscle, and mobilization of portions of the serratus anterior superior and rectus abdominis fascia [18]. Both these procedures can be avoided by use of AADM, which it is suggested will decrease the amount of discomfort experienced by the patient during the tissue expansion phase [3]. For exact details of the surgical technique used to insert the acellular dermal matrix , the original articles should be consulted [2, 3, 5, 8, 14, 16-20].

Methods

A systematic search of the medical literature, including the Cochrane library, Pubmed, Embase and health technology databases (INAHTA, CADTH, CRD, AETMIS) in all languages was performed, covering the period up to February 2009. The search terms used were: ([acellular matrix] OR [acellular dermis] OR [acellular dermal matrix]) AND [breast] AND [reconstruction] AND ([AlloDerm] OR [DermaMatrix]). We selected studies that had a sample size of 20 or more. We extracted information on the study design, study population, efficacy and safety. We also searched for articles reporting revision rate due to serious aesthetic problems that could potentially be corrected by dermal matrix use. We consulted Dr. Karl Schwarz who performs breast reconstruction using AADM at MUHC regarding: i) the risk of revision due to aesthetic problems at the MUHC, ii) the projected decrease in this risk when using acellular dermal matrix, iii)

the operating room (OR) time for reconstruction with or without acellular dermal matrix use, iv) the percentage of unilateral reconstructions, v) the annual number of surgeries. We estimated the potential cost impact of this technology based on the annual number of reconstructions and the percentage of unilateral reconstructions.

Results

We found a total of 10 studies that met our inclusion criteria. We found 7 studies (Table 1) on the use of AlloDerm for the purpose of expander-based breast reconstruction, two articles describing its use in other related clinical contexts and one article comparing the use of AlloDerm to DermaMatrix [2]. The mean duration of follow-up in the prospective studies ranged from roughly 8 to 26 months.

Influence of AADM on tissue expansion time

We found no randomized controlled trials of the efficacy of AADM. One study used a controlled design to compare reconstruction outcomes with and without AlloDerm use[19]. In this retrospective cohort study patients for whom AlloDerm was used were matched 1:1 with patients for whom AlloDerm was not used, for expander size (+/- 100mL), for history of prior irradiation, and for indication for mastectomy (prophylactic/therapeutic). The objective of the study was to evaluate the impact of AlloDerm on the rate of tissue expansions. There was no clinically or statistically significant difference in mean intraoperative expander volume injected (223.8mL AlloDerm vs. 201.1mL non-AlloDerm), mean rate of postoperative expansion (97 mL/injection AlloDerm vs. 95 mL/injection non-AlloDerm), mean number of expansions (5 AlloDerm vs. 6 non-AlloDerm), and average

time to completion of expansion (64 days AlloDerm vs. 60 days non-AlloDerm). The comparison of time to completion in the two groups may be biased because this variable is affected by patient and physician availability.

Another study [2] compared AlloDerm and DermaMatrix use in a retrospective cohort study. This study concluded that there was no difference between the brands of AADM in terms of various measures including intraoperative expander volume, incremental volume of expansion and final expanded volume-to-expander volume to ratio. Thus, use of AADM does not appear to result in any major reduction of the number of doctor's office visits required to complete the expansion.

Influence of use of AADM on perioperative complications

All studies reported the risk of perioperative complications such as infections, seroma or hematoma formation, cellulitis, skin flap necrosis and wound dehiscence (Table 1). Total complication rates were typically less than 10%, which is comparable to the reported risk of such complications in implant-based reconstruction [21]. Two controlled studies concluded that there was no significant difference in the risk of such perioperative complications between the two groups compared (i.e. AlloDerm vs. non-AlloDerm and AlloDerm vs. DermaMatrix) [2, 5]. Thus, there appears to be no evidence of any increased risk of perioperative complications with use of AADM.

Influence of use of AADM on aesthetic result

Only two studies attempted to measure the aesthetic result with AADM [17] It was measured subjectively on a scale ranging from 1 to 10, with 10

being an outstanding result. The study reported an average score of 8.5 (range 4-10) among 31 women. In the study by Spear et al., in women with unilateral reconstructions, both breasts were rated in terms of aesthetic qualities by a blinded panel of physicians on a scale from 0 (poor) to 5 (excellent). On the average it was found that the both breasts received very similar scores.

Since revision operations are almost only undertaken for reasons of poor aesthetic outcome (due to poor placement or migration of the prosthesis) or as a result of one of the long-term complications listed in the introduction, the revision rate will reflect, but under estimate the number of poor aesthetic outcomes. Thus, the health benefits (aesthetic improvement) resulting from use of AADM should be reflected by the extent to which the rate of surgical revision procedures is reduced. To estimate this it is necessary to first estimate the frequency of revision procedures in the absence of use of AADM.

Rate of late complications and revision rates in the absence of AADM use

The reported risk of delayed complications severe enough to require reoperation varies widely. This may be largely due to the fact that the decision to carry out revision depends on the subjective assessment of the physician and the patient [6]. In two substantial implant follow-up studies reported by implant manufacturers the revision rates in the absence of use of acellular matrix were high, 27% and 40.9% [22, 23]. The estimated risk of complications and the risk of revisions due to specific complications reported in five large cohorts of breast reconstruction surgeries is reported

in Table 2. Here, we can see that the risk of late complications such as capsular contracture without the use of AADM ranged from 14% to 36%. However, the overall revision rate due to such complications was much lower, ranging from 1% to 18%. Two studies conducted at university affiliated hospitals reported much lower rates of revision (2.2% [24] and 5% [25]). In the opinion of Dr Schwarz a reasonable estimate of the rate of revision due to all causes, without use of AADM would be approximately 20% (Consistent with opinion of Dr A. Danino).

Rate of late complications and revision rates with use of AADM.

Few studies mention the frequency of late complications or the rates of revision associated with the use of AADM. Salzberg et. al [14] reported two revision cases in their cohort of 49 patients(4%), that required a second surgery . The first was to correct , under local anesthetic, a small fold that was noted as a thickening at the suture line between the pectoralis muscle and AADM graft . The second was a patient who developed full-thickness skin flap necrosis which required secondary closure in the operating room. Spears et. al [5] in their cohort of 43 women (58 breasts) also reported an overall rate of 4% (2/43) revision at 18 months follow-up. Dr. Schwarz's estimate of the frequency of revision due to poor aesthetic outcome of 5% is consistent with this limited evidence.

Cost analysis

The costs for both AlloDerm and DermaMatrix are similar. For a 16X4-cm^2 sheet, AlloDerm is priced at $1976.52, which is comparable to $1920.00 for an equivalent size of DermaMatrix, with no significant difference in their

manipulative properties [2]. It is suggested (Dr K Schwarz) that some 60 women would undergo reconstruction surgeries each year in whom the use of AADM would be required. This would amount to an estimated annual cost of CAN $138,240, assuming 20% of reconstructions are bilateral. If all women requiring implant based surgeries at MUHC needed AADM, this could increase to approximately 100 surgeries or an annual cost of CAN $230, 400 per year. These costs are in addition to the cost of the gel implants, approximately $1500.00 each. Dr. Schwarz estimates that there will be a shorter operating time of 40 minutes per reconstruction when using AADM compared to 1 hour and 15 minutes in the absence of AADM.

Conclusions

Health benefit: Use of AADM may be associated with better aesthetic results and fewer breast revision procedures. However, evidence for this is not yet available from randomized controlled studies. In particular, there is no estimate of the revision rate at the MUHC with or without AADM use. Evidence from two small case series that the revision rate following AADM use is around 5% are consistent with the opinion of our expert, Dr. Karl Schwarz. Further, his estimate that the revision rate without AADM is around 20% is consistent with the opinions of Drs Lessard and Danino. Use of AADM does not appear to increase the risk of perioperative complications or to significantly influence the time required for expansion

Unit cost: In the absence of any effect on operating time or clinical outcome, the purchase price of AADM would be of the order of $1920 per breast reconstruction.

Budget impact: The budget impact resulting from use of these AADM for 72 breast reconstructions in the anticipated 60 patients would then be $138,240 per annum.

Cost effectiveness: Data on long-term efficacy, safety and cost impact of these matrices is required to quantify any benefit or complications that their use may entail with reasonable certainty.

Recommendations

- It is recommended that this technology receive **temporary** approval, for 60 cases, on the following **conditions.**
- To assist the MUHC in establishing a permanent policy, the surgeon concerned should be requested to maintain a record of all breast reconstructions in which AADM is used. It should document all relevant details, including risk factors for poor outcomes such as low BMI and radiation therapy, and should record any subsequent revision procedures.
- In addition, the aesthetic outcome of each procedure involving AADM should be formally evaluated by a panel consisting of 2 to 3 individuals, who are not members of the department of plastic surgery.
- A retrospective evaluation of all procedures in which AADM has been used, should also be undertaken, based on the same criteria,
- This record, with the aesthetic evaluations, should be submitted to the Head of Surgery and the Administrative Director responsible for

the Department of surgery within 18 months, at which time the decision concerning the continued use of AADM should be made.

Table 1: Summary of articles included in the review

Study (Year)	*Procedure*	*Study Design*	*Follow-up (months)*	*Sample size*	*Population*	*Age (years)*	*Complications*
Articles on use of AlloDerm in breast reconstruction in post-mastectomy patients							
Spear et al [5] (2008)	Two-stage breast reconstruction	Prospective cohort study	Mean 25.9 (19.2-35.3)	42	Patients who underwent immediate reconstruction using expanders	Mean 50.3 (Range 36-66)	Infections (6.8%), Partial mastectomy flap loss (3.4%), Seroma (1.7%), capsular contracture (2%)
Preminger et al [19] (2008)	Two-stage breast reconstruction	Matched retrospective cohort	-	45 in each group	Patients who underwent TE/I[a] reconstruction	NA	Seroma (6.7%), Hematoma 6.7%), Cellulitis (2.2%) (compared 4.4%, 0% and 2.2%, respectively in the non-AlloDerm group)
Breuing & Colwell [3] (2007)	Single-stage or two-stage breast reconstruction	Retrospective cohort	Mean 16.1 (6-36)	43 (67 breasts)	Candidates for implant-based reconstruction	Mean 46 (SD 8)	4.4%, 1 implant loss (patient received radiation and experienced extrusion of implant), 2 infections
Zienowicz & Karacaoglu [20] (2007)	Single-stage breast reconstruction	Prospective cohort	Mean 18 (15-24)	24	Post mastectomy breast reconstruction patients	Mean 46.78 (SD 8.31)	6 minor skin flap necrosis
Bindingnavele et al [18] (2007)	Two-stage breast reconstruction	Retrospective case series	Mean 10 (7-21)	41	Patients who underwent staged tissue expansive breast reconstruction	Mean 50 (Range 31-69)	3(7%) seroma formation, 2 (5%)wound infection, 1(2%) hematoma and 1(2%) implant removal
Salzberg [14] (2006)	Single-stage breast reconstruction	Cohort study	Mean 18 (Range 3-52)	49	Good candidates for tissue expander surgery (i.e. those with skin sparing mastectomies, adequate soft-tissue coverage)	NA	No serious complications. 1 recurrence
Margulies et al [17] (2005)	Two-stage breast reconstruction	Retrospective cohort	Mean 7.9	31	Post mastectomy breast reconstruction patients	Mean 46 (Range 26-70)	Total of 18% (4% Infection & flap necrosis , superficial epidermolysis 10%, Loss of nipple-areola complex due to epidermolysis 4%)
Articles on use of AlloDerm in other clinical contexts							
Garramone & Lam [16] (2007)	Nipple reconstruction	Prospective cohort	12	30	Patients who previously had breast reconstruction (14 TRAM[b] flaps and 16 tissue expanded breast mounds)	NA	No infections or wound dehiscence
Glasberg & D'Amico [8] (2006)	Repair of rectus fascia	Cohort study	Mean 18.5 (Range 9-30)	54	Patients who opted for pedicle TRAM flap procedures	49.7 (32-62)	No recurrence of hernia. No infection.. Seroma formation declined from 44% to 17% after improving technique
Article comparing AlloDerm and DermaMatrix							
Becker et al. (ref) (2009)	Two-stage breast reconstruction	Retrospective cohort study	Mean 6.7	30 (25 breasts per group)	Post mastectomy breast reconstruction patients	52.3 (AlloDerm) 49.5 (DermaMatrix)	DermaMatrix group: Seroma 1 (2%), Infection/cellulites 1 (2%)

[a]Tissue Expander/Implant; [b]Transverse Rectus Abdominis Musculocutaneous ; NA : Not available

* 1:1 matching on expander size (+/- 100mL), history of irradiation and indication for mastectomy.

Table 2: Risk of revision due to capsular contracture, implant rippling or implant malposition/extrusion

Author	Sample size	Follow-up	Capsular contracture† n (%)	Implant rippling‡ n (%)	Implant malpostion/extrusion n (%)	Total late Complications n(%)
Studies reporting risk of revision due to specific complications						
McCarthy (2008)	884 patients (1170 reconstructions)	6 months	-	-	7 (0.8%)	7 **(0.8%)**
Mentor (2006)	301* reconstructions (251 patients)	3 years	10* (3.3%)	1 (0.3%)	11* (3.6%)	22 **(7.2%)**
Allergan (2006)	132** reconstructions (98 patients)	4 years	10 (7.5%)	0	14 (10.6%)	24 **(18%)**
Studies reporting risk of specific complications						
Sullivan (2008)	142 reconstructions	6-months to 4 years	45 (31.7%)	-	6 (4.2%)	**51(35.9%)**
Cordeiro (2005)	315 patients (410 reconstructions)	Minimum 1 year (Mean 36.7 months)	74 (18.1%)	27 (6.6%)	-	101**(24.7%)**
Mentor (2006)	251 patients	3 years	8.3%	2.6%	2.9%	**13.8%**
Allergan (2006)	98 patients	4 years	14.1%	6.0%	5.6%	**25.7%**

† Baker grade III/IV when multiple grades reported

‡ Moderate to severe when multiple categories reported

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