

# FlexHD Clinical Dossier

## Plastic & Reconstructive Surgery

---

PEER-REVIEWED CLINICAL REFERENCES – PLASTIC SURGERY PAPERS  
AND POSTERS PRESENTED AT MEETINGS – PLASTIC SURGERY CASE  
STUDIES - PLASTIC SURGERY

## PEER-REVIEWED CLINICAL REFERENCES – PLASTIC SURGERY

---

- Chang EI, Liu J. Prospective unbiased experience with three acellular dermal matrices in breast reconstruction. *Journal of Oncologic Surgery*, 2017 Apr 25;[epub ahead of print].
- Sobti N, Liao E. Surgeon Controlled Study and Meta-Analysis Comparing FlexHD and AlloDerm in Immediate Breast Reconstruction Outcomes. *Plast Reconstr Surg*, 138(5):959-967.
- Palaia DA, Arthur KS, Cahan AC, Rosenberg, MH. Incidence of Seromas and Infections Using Fenestrated versus Nonfenestrated Acellular Dermal Matrix in Breast Reconstructions. *Plast Reconstr Surg Global Open* 2015;3:e569
- Vu MM, De Oliveira GS, Mayer KE, Blough JT, Kim JY. A Prospective Study Assessing Complication Rates and Patient-Reported Outcomes in Breast Reconstructions Using a Novel, Deep Dermal Human Acellular Dermal Matrix. *Plast Reconstr Surg Global Open* 2015;3:e585.
- Wilson, Henry B. Early Results Show Reduced Infection Rate Using No-touch Technique for Expander/ADM Breast Reconstruction. *Plast Reconstr Surg Global Open*. 2015 Apr 7;3(3):e317.
- Martin, Jenna B. M.D.; Moore, Ryan B.S.; Paydar, Keyianoosh Z. M.D.; Wirth, Garrett A. M.D., M.S. (2014) Use of Fenestrations in Acellular Dermal Allograft in Two-Stage Tissue Expander/Implant Breast Reconstruction. *Plast Reconstr Surg*, 134(5): 901-904.
- Rosenberg MH, Palaia DA, Cahan AC, Arthur KS, DeLuca-Pytell DM, Bonanno PC. (2014) Breast Reconstruction With or Without Human Acellular Dermal Matrices: A Single-Clinic, Review of Esthetic Outcomes and Risk Factors for Complications. *The Am J Cosm Surg*, 31(1): 7-17.
- Liu D, Mathes D, Neligan P, Chir B, Said H, Louie O. (2014) Comparison of Outcomes Using AlloDerm Versus FlexHD for Implant-Based Breast Reconstruction. *Ann Plast Surg*, 72(5):503-507.
- Seth A, Persing S, Connor C, Davila A, Hirsch E, Fine N, Kim JY. (2013) A Comparative Analysis of Cryopreserved versus Pre-Hydrated Human Acellular Dermal Matrices in Tissue Expander Breast Reconstruction. *Ann Plast Surg*, 70(6): 632-635.
- Brooke S, Mesa J, Uluer M, Michelotti B, Moyer K, Neves RI, Mackay D, Potochny J. (2012) Complications in tissue expander breast reconstruction. A comparison of Alloderm, DermaMatrix, and FlexHD Acellular inferior pole dermal slings. *Ann of Plast Surg*, 69(4): 347-349.
- Seth AK, Hirsch EM, Fine NA, Kim JY. (2012) Utility of acellular dermis- assisted breast reconstruction in the setting of radiation: A comparative analysis. *Plast Reconstr Surg*, 130(4): 750-758.



**PEER-REVIEWED CLINICAL REFERENCES – PLASTIC SURGERY CONT'D**

---

- Rawlani V, Buck DW, Johnson SA, Heyer KS, Kim JY. (2011) Tissue Expander Breast Reconstruction Using Prehydrated Human Acellular Dermis. *Ann Plast Surg*, 66(6):593-7.
- Buck DW, Heyer K, DiBardino D, Bethke K, Kim JY. (2010) Acellular dermis-assisted breast reconstruction with the use of crescentric tissue expansion: a functional cosmetic analysis of 40 consecutive patients. *Aesthet Surg J*, 30(2):194-200.

**Title:** Prospective unbiased experience with three acellular dermal matrices in breast reconstruction

**Author:** Chang, EI , Liu, JCase Report

**Source:** *Journal of Oncologic Surgery*, April 25, 2017 [epub ahead of print]

- Key Takeaways:**
- Comparable complication rates among the three ADMs (FlexHD Pliable, AlloDerm, DermACELL) despite higher rates of smoking and intraoperative fill volumes
  - Shorter time to drain removal for FlexHD and DermACELL (20 days and 15 days, respectively) vs. 26 days for AlloDerm
  - FlexHD was less expensive than AlloDerm (91.5% of the cost of AlloDerm), and less expensive than DermACELL when using breast kits (80.7% the cost of AlloDerm for FlexHD Pliable vs. 83.2% for DermACELL)

## STUDY OBJECTIVE

Prospective study evaluating the complications in tissue expander/implant breast reconstruction for three commercial ADMs: FlexHD Pliable, AlloDerm RTU and DermACELL.

## METHODS

- Prospective study of 47 patients undergoing expander based breast reconstruction between 2014 and 2015
- Eighteen patients (32 breasts) received FlexHD Pliable, 15 patients (22 breasts) received AlloDerm, 14 patients (20 breasts) received DermACELL.
- There were no significant differences in patient demographics or comorbidities.

	AD RTU (22 breasts)	FHD Pliable (32 breasts)	DC (18 breasts)
BMI	24.9 kg/m <sup>2</sup>	25.7 kg/m <sup>2</sup>	25.7 kg/m <sup>2</sup>
IntraOp Fill	180 cc	225 cc	130 cc
Smoking	0%	17%	8%
Radiation	20%	33%	33%

- All ADM used was 8x16 in size and was inset as an inferior sling
- All expanders were placed in the subpectoral position. Expansion began 10-14 days following surgery and continued until the desired size was achieved
- Average follow up was 15.0 months (range: 10.1-33 months)



## RESULTS

- One (2%) FlexHD Pliable patient and one (2%) AlloDerm patient underwent aspiration or drain placement for a seroma following drain removal
- Additional complication rates in Table I, below:

Complication Type	FlexHD Pliable n=32	AlloDerm N=22	DermACELL N=18
Mastectomy Skin Flap Necrosis	2(6%)	1(4.5%)	0
Hematoma	1 (3%)	0	0
Seroma	1 (3%)	1(4.5%)	0
Red Breast	0	0	0
Cellulitis/Infection	0	0	0
Washout/Debridement	0	0	0
Wound Dehiscence	0	0	1(5.6%)
Explantation	0	0	0

## CONCLUSIONS

- Despite higher intraoperative fill volumes, which was noted in the discussion as playing a role in complication rates (“Intraoperative fill can also have a significant role in complications and judicious filling of the expander can likely decrease the risk of complications in expander-implant reconstruction.<sup>16</sup>”) and higher number of patients who smoked, FlexHD Pliable **STILL yielded the same complication rate as the other ADMs and a statistically lower number of days to drain removal** when compared to AlloDerm RTU (20 days for FlexHD Pliable vs. 26 days in AlloDerm RTU).
- The authors present a cost analysis based on pricing at their institution and they found:

AlloDerm was the most expensive of the ADMs. Setting AlloDerm as the reference, FlexHD was 91.5% of the AlloDerm cost and DermACELL was 83.2%. However, when taking into consideration bilateral breast kits from MTF, the pricing per piece becomes 80.7%, the most responsibly priced at this institution.

**Title:** Surgeon controlled study and meta-analysis comparing FlexHD and AlloDerm in immediate breast reconstruction outcomes

**Author:** Sobti N, Liao Eric, MD

**Source:** *Plast Reconstr Surg.* 2016 Nov;138(5):959-967.

**Key Takeaways:**

- **ADM did not influence the infection complication rate.**
- There were no statistically significant differences in incidence of post-operative complications between the FlexHD group compared to the AlloDerm group.

## STUDY OBJECTIVE

Retrospectively assess postoperative complications after immediate breast reconstruction comparing FlexHD Pliable and AlloDerm.

## METHODS

- Retrospective review of 394 breast reconstruction procedures in 233 patients between 2009 and 2015.
- 218 patients underwent mastectomy followed by direct-to-implant breast reconstruction, while 15 patients received tissue expander placement.
- Patient demographics were comparable between the AlloDerm and FlexHD groups, without statistically significant variation in age, body mass index, smoking status or radiation treatment.
- AlloDerm and FlexHD were the ADMs used in the study, with 224 breasts receiving AlloDerm and 170 breasts receiving FlexHD.
  - AlloDerm RTU was used in 68.9% of the AlloDerm cases; freeze dried AlloDerm was used in 31.1% of AlloDerm cases
  - FlexHD Pliable Perforated was used in 80.2% of FlexHD cases; FlexHD Pliable (non-perforated) in 18.8% of FlexHD cases and FlexHD Structural in 0.9% of FlexHD cases.



## RESULTS

---

- The most common post-operative complication across both groups was seroma, with 37 (15.9%) cases overall
  - AlloDerm: 23 (17.4%)
  - FlexHD: 14 (13.9%)
- Other post-operative complications included:
  - Explantation in 6.4% of total cases: 7 (5.3%) AlloDerm cases / 8 (7.9%) FlexHD cases
  - Surgical-site infection in 4.7% of total cases: 6 (4.6%) AlloDerm cases / 5 (5.0%) FlexHD cases
  - Hematoma in 3.9% of total cases: 4 (3.0%) AlloDerm cases / 5 (5.0%) FlexHD cases
  - Delayed wound healing in 5.6% of total cases: 7(5.3%)AlloDerm cases / 6 (5.9%) FlexHD cases
- No statistical difference in infection rate or any other clinical endpoints was observed between AlloDerm and FlexHD in immediate implant-based breast reconstruction
- Patient factors, such as smoking and radiation therapy, and surgeon variables contributing to skin flap quality are more important to breast reconstruction outcomes, than type of ADM used.

**Title:** Incidence of seromas and infections using fenestrated versus nonfenestrated acellular dermal matrix in breast reconstructions

**Author:** Palaia DA , Arthur KS, Cahan AC, Rosenberg, MH

**Source:** *Plast Reconstr Surg Global Open* 2015;3:e569

- Key Takeaways:**
- FlexHD with fenestrations reduces the incidence of seromas without affecting cosmetic results
  - FlexHD may reduce extrusion incidence and improve aesthetic outcomes compared to AlloDerm

## STUDY OBJECTIVE

Retrospectively assess postoperative complications after breast reconstruction with or without fenestrated ADMs

## METHODS

- Retrospective review of 450 breasts in 603 patients between 2006 and 2011
- Patients received immediate reconstruction with expanders and allograft following breast removal with placement of permanent implants following completion of expansion
- Patient demographics were similar between the FlexHD and AlloDerm groups with the exception of mean expander fill size, which was greater in the FlexHD group (540 vs. 513)
- Patient demographics were also similar between fenestrated and nonfenestrated ADM groups with the exception of radiation treatment, which was higher in the fenestrated group (14.1% vs. 5.7%)
- Drains were removed postoperatively at a mean of 6.7 days, based on the drains having achieved a state of removing 30mL or less over the prior 24 hour period
- Postoperative data were collected for at least 6 months after the last stage reconstruction or last-reported complication
- Cosmetic score was blindly evaluated for aesthetics on a scale of 1 to 10 by 2 surgeons and 1 layperson for each patient. The overall cosmetic score was calculated by averaging the 3 raters' assigned scores
- AlloDerm RTM and FlexHD Structural were the ADMs used in the study, with 134 breasts receiving AlloDerm and 316 breasts receiving FlexHD
- A 6x16cm graft was used for both types of ADM, minimizing graft surface area as a variable
- The decision to fenestrate or not was according to the surgeon's discretion; there was no preset determination. 488 (81%) grafts were fenestrated and 115 (19%) were nonfenestrated
- An 11 or 15 scalpel was used to make fenestrations at intervals of approximately 1cm



## RESULTS

---

- There were 77 (13%) cases of seroma overall. However, a significantly higher proportion of patients experienced seroma with nonfenestrated ADM (20%) compared with fenestrated ADM (11%). These results were similar for both ADM types.
- 59 (10%) cases of infection were reported with no statistical difference between ADM type or fenestration status
  - 9% of FlexHD cases reported an infection while 11% of AlloDerm cases reported an infection
  - 9% of fenestrated ADMs reported an infection while 11% of nonfenestrated ADMs reported an infection
- AlloDerm had a significantly higher incidence rate of extrusion (6.2%) compared to FlexHD (1.9%)
- 47 (8%) explantations were reported among all of the breast reconstructions, with no statistically significant differences in ADM or fenestration type
  - 7% of FlexHD reconstructions resulted in an explantation as compared to 9% of AlloDerm reconstructions
  - 8% of fenestrated reconstructions resulted in an explantation as compared to 9% of nonfenestrated reconstructions
- FlexHD trended toward a higher mean cosmetic score (8.7) compared with the AlloDerm group (8.4)
  - The cosmetic score was the same between fenestrated and nonfenestrated groups

**Title:** A prospective study assessing complication rates and patient-reported outcomes in breast reconstructions using a novel, deep dermal human acellular dermal matrix

**Author:** Vu MM, De Oliveira GS, Mayer KE, Blough JT, Kim JY

**Source:** *Plast Reconstr Surg Global Open* 2015;3:e585

- Key Takeaways:**
- FlexHD Pliable yielded acceptably low complication rates and satisfactory patient-reported outcomes
  - Zero infection, seroma, or implant extrusion or malposition reported in the study

## STUDY OBJECTIVE

A prospective study to evaluate surgical and patient-reported outcomes using a deep dermal ADM, FlexHD Pliable

## METHODS

- Prospective observational cohort study of 72 breasts in 41 patients between July 2013 and July 2014
- Patients all underwent immediate 2-stage prosthetic reconstruction after mastectomy
- Patients were excluded if they underwent breast reconstruction after complications from breast augmentation, mastopexy, breast reduction, or breast conservation; had a previously failed reconstruction; underwent autologous breast reconstruction with a tissue expander; had body mass index greater than 40; or had previous radiation treatment
- All patients received a 6x16 cm piece of FlexHD Pliable
- Minimal touch technique was used when handling both FlexHD Pliable and expander
- The average age of the cohort was 46 and average BMI was 26
- Subjective data were gathered using the BREAST-Q questionnaire completed at 2 months postoperatively and 6 months postoperatively
- Ten patients received postoperative XRT



## RESULTS

---

- There were zero cases of infection, seroma or implant extrusion or malposition
- 9 breasts (7 patients) suffered a surgical complication resulting in a 12.5% complication rate
  - Hematoma occurred in two breasts, both requiring reoperation to evacuate them and to replace the tissue expander. Both hematomas resolved without complication
  - The remaining 7 complications were breasts that developed skin flap necrosis, necessitating surgical debridement, and/or tissue expander replacement.
    - 6 resolved without further complication while one ultimately failed reconstruction. This one patient was a prior smoker and was the only complicated breast to have received postoperative XRT
- Of 123 surveys delivered, 120 (97.6%) received a response
- Relative to preoperative scores, BREAST-Q scores at 2-months postoperatively for satisfaction with breasts, psychosocial well being, physical well being, and sexual well being were significantly decreased
- At 6 months, satisfaction with breasts and psychosocial and sexual well being had returned to preoperative values
- 6 month physical well being was correlated with six-month overall satisfaction with surgical outcomes
- Patients who had postoperative SRT were also significantly less satisfied with their breasts and had lower reported sexual well being

**Title:** Early results show reduced infection rate using no-touch technique for expander/ADM breast reconstruction

**Author:** Wilson HB

**Source:** *Plast Reconstr Surg Global Open. 2015 Apr 7;3(3):e317*

- Key Takeaways:**
- The novel, no-touch technique described by Dr. Wilson resulted in a 0% infection and 0% chronic seroma rate in the series of 25 breasts reconstructed with FlexHD Pliable.
  - The combined chronic infection rate for all 36 breasts in the study is 5.5% and chronic seroma is 2.7%.

## STUDY OBJECTIVE

To report a novel technique of tissue expander and acellular dermis placement using no-touch principles with a self-retaining retractor system that holds promise to decrease infectious complications of breast reconstruction.

## METHODS

- Retrospective review comparing the infection rate of the no-touch technique with a baseline comprised of a standard reconstruction technique
- FlexHD Pliable was used in all of the patients in this study
- Number of breasts/patients
  - No-touch technique: 25 breasts/15 patients
  - Standard technique: 16 breasts/10 patients
- The demographics between both groups were comparable
- No-touch technique summary
- All instruments used prior to the reconstruction are removed from the field
- Multiple glove and drape changes throughout the procedure
- After the mastectomy a clear sterile drape is placed and fixed to the patient to cover the exposed skin
- A no-touch retractor system is then utilized during reconstruction to minimize the number of hands inside the surgical field.



## RESULTS

---

- Infection rates
  - No-touch technique: 0%
  - Standard technique: 12.5%
  - Combined: 5.5%
- Seroma rates
  - No-touch technique: 0%
  - Standard technique: 6.2%
  - Combined: 2.7%

**Title:** Use of fenestrations in acellular dermal allograft in two-stage tissue expander/implant breast reconstruction

**Author:** Martin JB, Moore R, Paydar KZ, Wirth GA

**Source:** *Plast Reconstr Surg.* 2014 Nov;134(5):901-4.

- Key Takeaways:**
- Unique, surgeon designed fenestrations in acellular dermal matrix in two stage breast reconstruction leads to improved intraoperative fill volume, decreased number of post operative expansions, increased expansion rate
  - Surgeons also found that there was subjectively less pain, and improved cosmetic outcome

## STUDY OBJECTIVE

Surgeons evaluated the clinical benefits of a uniquely designed, fenestrated, acellular dermal matrix for two-stage breast reconstruction and compared the results to non-fenestrated ADM breast reconstruction.

## METHODS

- Authors created specifically spaced fenestrations in ADM using a novel design. The ADM was sutured to the pectoralis major, laterally to the serratus anterior fascia, and inferiorly to the inframammary fold.
- The midline of the ADM is marked for alignment with the breast midline, leaving slack in the ADM between sutures to allow for immediate expansion.
- The expander is placed in the partial submuscular/allograft pocket and filled using a closed system without pectoralis muscle strain. The skin was closed in a tension-free manner.

## RESULTS

- There were 42 patients (70 breasts) included in the review
  - 6 patients (7 breasts; 5 FlexHD, 2 AlloDerm) received non-fenestrated ADM
  - 36 patients (63 breasts; 6 FlexHD, 12 AlloMax, 45 AlloDerm) received fenestrated ADM
- The total complication rate requiring expander removal was 3 breasts out of 63 within 30 days (4.8%), and 6 breasts of 63 within 90 days (9.5%)
  - 2 out of 45 fenestrated AlloDerm breasts required removal of the expander within 30 days; none additional within 90 days
  - 1 out of 12 fenestrated AlloMax breasts required removal of the expander within 30 days; 2 additional patients (4 breasts) required expander removal within 90 days
  - None of the 6 patients who received fenestrated FlexHD required expander removal within 30 days; and 1 patient (2 breasts) required removal within 90 days

**Title:** Breast reconstruction with or without human acellular dermal matrices: A single clinic, review of esthetic outcomes and risk factors for complications

**Author:** Rosenberg MH, Palaia DA, Cahan AC, Arthur KS, DeLuca-Pytell DM, Bonanno PC

**Source:** *American Journal of Cosmetic Surgery: March 2014, Vol. 31, No. 1, pp. 7-17.*

- Key Takeaways:**
- The use of FlexHD resulted in better aesthetic outcomes than no ADM
  - AlloDerm demonstrated a significantly higher complication rate when compared to no HADM
  - While complication rates with FlexHD trended slightly higher than no HADM, there was no significant difference
  - Both FlexHD and AlloDerm groups exhibited significantly higher perceived esthetic results compared with the no-HADM group

## STUDY OBJECTIVE

Compare the outcomes of ADM vs. non-ADM in breast reconstruction

## METHODS

- Charts were reviewed for all patients undergoing implant-based breast reconstruction at a single clinic from 2006 to 2011 were collected
- Patients were divided into 3 groups: FlexHD, AlloDerm or no ADM
- Reconstruction outcomes reviewed:
  - Infections requiring IV antibiotics
  - Seroma
  - Dehiscence
  - Extrusion
  - Reoperation
  - Aesthetic outcome; evaluated on a scale of 1 to 10



## RESULTS

---

- A total of 650 patient charts (881 breast reconstructions) were analyzed
- The most commonly reported clinical complications in all groups were seroma and infections
  - The FlexHD group had no significant differences in complication rates compared with the no-HADM group
  - The AlloDerm group had an increased adjusted risk of complications compared with the no-HADM group
  - Alloderm had a significantly higher rate of extrusion (implant loss) when compared to FlexHD (6.1% vs 1.8%, respectively; P=.0025)
  - Both FlexHD and AlloDerm groups exhibited significantly higher perceived aesthetic results compared with the no-HADM group (8.22 and 8.02 vs. 6.53, respectively, P < .0001)

**Title:** Comparison of outcomes using AlloDerm vs. FlexHD for implant-based breast reconstruction

**Author:** Liu DZ, Mathes DW, Neligan PC, Said HK, Louie O

**Source:** Ann Plast Surg. 2014 May;72(5):503-7.

- Key Takeaways:**
- FlexHD is safe and useful in immediate, implant based breast reconstruction
  - There were no significant differences in seroma, hematoma, infection, delayed healing or explantation rates when comparing FlexHD to AlloDerm

## STUDY OBJECTIVE

---

Compare the outcomes of ADM vs. non-ADM in breast reconstruction

## METHODS

---

- Charts were reviewed for all patients undergoing implant-based breast reconstruction at a single clinic from 2006 to 2011 were collected
- Patients were divided into 3 groups: FlexHD, AlloDerm or no ADM
- Reconstructions were either single stage or 2 stage with tissue expanders
- ADM size was either 6 cm x 16 cm or 8 cm x 16 cm
- Endpoints: hematoma, seroma, SSI, delayed healing, mastectomy flap necrosis, or loss of implant

## RESULTS

---

- A total of 382 patient charts (547 total breasts) were analyzed
- Multivariate analysis suggests that FlexHD may be a risk factor for implant loss
- There was no significant difference in seroma, hematoma, infection, delayed healing, or explantation rates found between FlexHD and AlloDerm
- Use of ADM resulted in a higher rate of delayed healing and mastectomy flap necrosis compared to no ADM
  - Believed to be related to higher initial expander fill volume that using ADM allows, placing stress on new mastectomy tissue

**Title:** A comparative analysis of cryopreserved vs. prehydrated human acellular dermal matrices in tissue expander breast reconstruction

**Author:** Seth AK, Persing S, Connor CM, Davila A, Hirsch E, Fine NA, Kim JYS

**Source:** *Ann Plast Surg* 2013; 70: 632-635

**Key Takeaways:** FlexHD has a comparable complication profile to AlloDerm for tissue expander breast reconstruction

## STUDY OBJECTIVE

Compare prehydrated human ADM to cryopreserved human ADM for tissue expander breast reconstruction (TEBR)

## METHODS

- Retrospective analysis of TEBR between January 2006 and May 2011 at a single institution
- Reconstructions were performed with insertion of either cryopreserved human ADM (AlloDerm) or prehydrated human ADM (FlexHD) following method previously described by Kim et al.
- The primary outcome was complication rates during stage 1 reconstruction
- Complication rates were subcategorized into flap necrosis, tissue expander migration, infection requiring intervention, hematoma, seroma, exposure/dehiscence of the expander, tissue expander removal and additional reconstruction secondary to a complication

## RESULTS

- Data was from 255 patients, accounting for 369 breast reconstructions
- Mean follow up was 60.6 weeks
- Patients receiving cryopreserved HADM were significantly younger and had a lower BMI
- Total complication rates were 19.1% for cryopreserved HADM and 19.3% for prehydrated HADM
- No differences in rate of flap necrosis, infection, hematoma, seroma, exposure or dehiscence, and the need for salvage autologous reconstruction
- There were no cases of tissue expander migration

**Title:** Complications in tissue expander breast reconstruction

**Author:** Brooke S, Mesa J, Uluer M, Michelotti B, Moyer K, Neves RI, Mackay D, Potochny J

**Source:** *Ann Plast Surg* 2012; 69: 347-349

- Key Takeaways:**
- The use of ADM for tissue expander breast reconstruction has clinical benefits that should be considered despite the risk of complications compared to tissue expander breast reconstruction without ADM
  - There was no significant difference in clinically significant complication rates between FlexHD, AlloDerm and DermaMatrix and no ADM reconstructions
    - FlexHD and DermaMatrix had slightly lower complication rates compared to AlloDerm (n.s.)

## STUDY OBJECTIVE

Compare 3 different types of ADM for tissue expander breast reconstruction (TEBR)

## METHODS

- Retrospective analysis of TEBR between 2000 and 2010 at a single institution
- Reconstructions were classified based on type of ADM used (AlloDerm, DermaMatrix, or FlexHD)
- Clinically significant complications were defined as cellulitis, abscess, seroma, expander leak or puncture, skin necrosis, wound dehiscence, or hematoma requiring intervention and expander removal

## RESULTS

- Data was from 173 patients, accounting for 284 breast reconstructions
- Overall complication rates in the ADM groups were
  - AlloDerm – 22%
  - DermaMatrix – 15%
  - FlexHD – 16%
  - No ADM – 11% (n.s.)
- Infectious complication rates for reconstruction with ADMs compared to no ADM was not significantly different

**Title:** Utility of acellular dermis-assisted breast reconstruction in the setting of radiation: A comparative analysis

**Author:** Seth AK, Hirsch EM, Fine NA, Kim JYS

**Source:** *Plast Reconstr Surg.* 2012 Oct;130(4):750-8.

- Key Takeaways:**
- The use of ADM does not adversely affect complications associated with breast reconstruction
    - FlexHD does not have higher complication rates when compared to AlloDerm
  - The use of ADM may provide advantages specifically in patients undergoing radiation therapy

## STUDY OBJECTIVE

To compare breast reconstructions with and without ADM and evaluate the effect of radiation therapy

## METHODS

- Retrospective analysis of 417 consecutive patients (592 breasts) who underwent a second-stage, permanent implant exchange between January 2006 and October 2008 at a single institution (Northwestern University Medical Center)
- 137 patients (199 breasts) were reconstructed with an ADM, either AlloDerm or FlexHD
- Patients followed a protocol of first stage prosthetic reconstruction, followed by outpatient expansion, post-op radiotherapy if needed, and then second-stage, permanent implant exchange
- Reconstruction with ADM was as follows:
  - The inferior aspect of the ADM was sutured to the inframammary fold and the lateral aspect was sutured to the serratus muscle fascia
  - A tissue expander was placed in the submuscular and subgraft space
  - After the muscle and graft interface was secured and complete expander coverage was obtained, two drains were placed in the inferior space between the mastectomy flap and the graft, and in the axillary and superior subcutaneous planes
  - Drains remained in place until the output was less than 30 ml over 24 hours, typically 7 to 10 days after surgery
  - Serial expansions of the tissue expander were initiated following healing of incisions
  - Second-stage reconstruction was performed with tissue expander to implant exchange
- Mean follow-up for ADM and non-ADM patients was 24.4 +/- 12.7 and 23.2 +/- 8.9 weeks, respectively
- Primary outcome evaluated was complication rates per breast following first stage reconstruction and radiation therapy



## RESULTS

---

- Complication rates, measured both by type and end outcome, were not different between acellular dermis and non-acellular dermis patients
- No differences in complication between FlexHD and AlloDerm was observed
- Age (**> 50 years**), body mass index (**≥30 kg/m<sup>2</sup>**) and smoking were independent risk factors for certain complications
- Post-mastectomy radiation therapy led to a significant increase in total complications (**p = 0.003**), including extrusion (**p = 0.01**) and pain or tightness (**p = 0.0005**) and operative complication rates (**p = 0.004**) in the non-ADM group
- In patients reconstructed with ADM, post-mastectomy radiation therapy did not increase the rate of any complication subtypes, including total complications (**p = 0.14**), extrusion (**p = 1.00**), pain or tightness (**p = 0.10**), operative complications (**p = 0.23**)

**Title:** Tissue expander breast reconstruction using prehydrated acellular dermis

**Author:** Rawlani V, Buck DW, II, Johnson SA, Heyer KS, Kim JYS

**Source:** *Ann Plast Surg.* 2011 Jun;66(6):593-7.

**Key Takeaways:** FlexHD used in tissue expander breast reconstruction showed good incorporation and revascularization with comparable complication rates to other reported studies evaluating ADM

## STUDY OBJECTIVE

Evaluate the use of prehydrated human ADM (PHADM, FlexHD) for tissue expander breast reconstruction

## METHODS

- Retrospective review of 84 patients (121 consecutive breasts) who underwent PHADM-assisted tissue expansion breast reconstruction by a single surgeon
- Reconstruction with PHADM was as follows:
  - 6 cm x 16 cm size PHADM (FlexHD) was secured to the lower pole defect
  - The inferior aspect of the PHADM is sutured to the inframammary fold and the lateral aspect is sutured to the serratus muscle fascia
  - A tissue expander is placed in the submuscular and subgraft space
  - After the muscle and graft interface is secured and complete expander coverage is obtained, two drains are placed in the inferior space between the mastectomy flap and the graft, and in the axillary and superior subcutaneous planes
  - Antibiotic irrigation was used to rinse the operative pocket and the implants
  - The expander is inflated according to degree of skin excess
  - Drains remained in place until the output was less than 30 ml over 24 hours, typically 7 to 10 days after surgery
  - Serial expansions of the tissue expander are initiated following healing of incisions
  - Second-stage reconstruction is performed with tissue expander to implant exchange
- Primary outcome evaluated was complication rates per breast following first stage reconstruction and radiation therapy



## RESULTS

---

- Data was from 173 patients, accounting for 284 breast reconstructions
- Mean follow-up was 44 +/- 26.5 weeks
- Complications occurred in 20 breasts (16.5%)
  - Soft tissue infections – 7.4%
  - Partial flap necroses – 6.6%
  - Seromas – 1.7%
  - Implant exposure – 6.6%
  - Removal of expanders – 9.1%
- Patients receiving radiation showed a trend towards increased complication rates (n.s.)
- Histology from patients who consented at Stage II exchange demonstrated robust revascularization and incorporation of PHADM into native tissue

**Title:** Acellular dermis-assisted breast reconstruction with the use of crescentric tissue expansion: A functional cosmetic analysis of 40 consecutive patients

**Author:** Buck DW, Heyer K, DiBardino D, Bethke K, Kim JYS

**Source:** *Aesthet Surg J.* 2010 Mar;30(2):194-200.

- Key Takeaways:**
- The use of ADM with crescentric tissue expanders resulted in acceptable cosmetic outcomes and complications similar to those previously reported
  - Authors believe complications were not a direct result of the use of ADM

## STUDY OBJECTIVE

Evaluate the use of ADM (PHADM, FlexHD) with crescentric tissue expanders

## METHODS

- Retrospective review of 40 patients who underwent ADM-assisted breast reconstruction with crescentric tissue expansion from 2007 to 2008 by a single surgeon
- Post operative outcome and patient subjective cosmetic scores
- Reconstruction was performed as follows:
  - The pectoralis major muscle was disinserted at the IMF
  - A dermal sling, using either FlexHD or AlloDerm, was created to recreate the IMF
  - A low-profile crescentric expander was placed within the subpectoral pocket and intraoperative expansion was performed

## RESULTS

- Data was from 40, accounting for 58 breast reconstructions
- Mean follow-up was 44 +/- 26.5 weeks
- Overall complication rate was 9%
  - Expander infections – 3%
  - Flap necrosis – 2%
  - Hematoma – 2%
  - Seroma – 2%
- Based on the aesthetic outcomes survey, patients who responded were satisfied with their outcomes

**Title:** Excellent Incorporation of New Acellular Dermal Matrix (ADM) in Challenging Breast Reconstruction Patient Suggests Complications Secondary to Patient Factors and Not the Use of Allograft

**Author:** Wilson, H

**Source:** Poster Presented at Breast Conference Coordinated Care – BC3, Washington DC, February 2014

**Key Takeaways:** This series demonstrates significant reconstructive success in a challenging set of patients utilizing a novel ADM. Visual and histologic assessment of tissue ingrowth into the graft suggests the high rate of complication may be due to patient comorbidities rather than addition of ADM.

## STUDY OBJECTIVE

To assess the clinical performance of FlexHD Pliable in a 10-patient case series

## METHODS

- 10 patients involving 16 breasts had immediate expander-based breast reconstruction with FlexHD Pliable
- At implant exchange the ADM was examined and evaluated for tissue in-growth and biopsied for histological examination

## RESULTS

- All 16 breasts had successful reconstruction
- At expander removal, the FlexHD Pliable showed near-complete visual tissue incorporation in 14 of the 16 breasts (88%)
- 1 breast (6.7%) developed a seroma and 2 breasts (12.5%) developed an infection
- All of the complicated patients had significant comorbidities and an average BMI of 34

## CASE STUDIES - PLASTIC SURGERY

---

- Liao E. (2014) Immediate Direct to Implant Breast Reconstruction Utilizing FlexHD Perforated Pliable Acellular Dermal Matrix. Case Report.

**Title:** Immediate Direct to Implant Breast Reconstruction Utilizing FlexHD Pliable Perforated Acellular Dermal Matrix

**Author:** Liao, E

**Source:** Case Report

**Key Takeaways:** This retrospective review of 12 patients shows that FlexHD Pliable Perforated can effectively be utilized in direct to implant (DI) procedures with minimal complications and great aesthetic results

## STUDY OBJECTIVE

---

To assess the handling and clinical performance of FlexHD Pliable Perforated in a 12-patient direct to implant case series

## METHODS

---

- 12 patients involving 19 breasts underwent immediate breast reconstruction utilizing DI (Direct to Impact) approach
- FlexHD Pliable Perforated and round silicon gel adhesive implants were used along with 2 drains per breast in the subcutaneous plane
- The first drain was removed during the initial visit 1 week after surgery and the second drain was removed during the second visit 2 weeks post-op
- Seroma, infection and reconstruction success were assessed at a 3-month minimum follow up

## RESULTS

---

- All breasts were successfully reconstructed with no infection, implant or wound healing problems
- All drains were removed by the 2-week follow up time-point
- A seroma rate of 5% (1/19) was observed
- The handling of FlexHD Pliable Perforated was scored *Excellent*

## THE USE OF FLEXHD IN BREAST RECONSTRUCTION

### PRE-CLINICAL

---

- Mendenhall, Shaun D. MD; McKenna, Katherine E. BS; Daugherty, Tim MS; Cosenza, Nicole M. MS; Schmucker, Ryan MD; Reichensperger, Joel BS; Koirala, Janak MD; Cederna, Paul S. MD; Neumeister, Michael W. MD. (2014) A Microbiologic Comparison of Acellular Dermal Matrices as an Aseptic Reconstructive Material *Plast Reconstr Surg*, 134(5): 901-904.
- Annor AH, Tang ME, Pui CL, Ebersol GC, Frisella MM, Matthews BD, Deeken CR. (2012) Effect of enzymatic degradation on the mechanical properties of biological scaffold materials. *Surg Endosc*, 26(10): 2767-78.
- Pui CL, Tang ME, Annor AH, Ebersole GC, Frisella MM, Matthews BD, Deeken CR. (2012) Effect of repetitive loading on the mechanical properties of biological scaffold materials. *J Am Coll Surg*, 215(2): 216-28.



## THE USE OF FLEXHD IN BREAST RECONSTRUCTION

## CLINICAL

- Chang EI, Liu J. Prospective unbiased experience with three acellular dermal matrices in breast reconstruction. *Journal of Oncologic Surgery*, 2017 Apr 25;[epub ahead of print].
- Sobti N, Liao E. Surgeon Controlled Study and Meta-Analysis Comparing FlexHD and AlloDerm in Immediate Breast Reconstruction Outcomes. *Plast Reconstr Surg*, 138(5):959-967.
- Wilson, Henry B. Early Results Show Reduced Infection Rate Using No-touch Technique for Expander/ADM Breast Reconstruction. *Plast Reconstr Surg Global Open*. 2015 Apr 7;3(3):e317.
- Palaia DA , Arthur KS, Cahan AC, Rosenberg, MH. Incidence of Seromas and Infections Using Fenestrated versus Nonfenestrated Acellular Dermal Matrix in Breast Reconstructions. *Plast Reconstr Surg Global Open* 2015;3:e569
- Vu MM, De Oliveira GS, Mayer KE, Blough JT, Kim JY. A Prospective Study Assessing Complication Rates and Patient-Reported Outcomes in Breast Reconstructions Using a Novel, Deep Dermal Human Acellular Dermal Matrix. *Plast Reconstr Surg Global Open* 2015;3:e585.
- Martin, Jenna B. M.D.; Moore, Ryan B.S.; Paydar, Keyianoosh Z. M.D.; Wirth, Garrett A. M.D., M.S. (2014) Use of Fenestrations in Acellular Dermal Allograft in Two-Stage Tissue Expander/Implant Breast Reconstruction *Plast Reconstr Surg*, 134(5): 901-904.
- Rosenberg MH, Palaia DA, Cahan AC, Arthur KS, DeLuca-Pytell DM, Bonanno PC. (2014) Breast Reconstruction With or Without Human Acellular Dermal Matrices: A Single-Clinic, Review of Esthetic Outcomes and Risk Factors for Complications. *The Am J Cosm Surg*, 31(1): 7-17.
- Wilson H: Use of ADM in Lower Pole Post Mastectomy Breast Reconstruction: Histology and Aesthetic Outcomes in 16 Patients: A Retrospective Case Series. Presented at BC3 Feb 2014, Washington DC.
- Liu D, Mathes D, Neligan P, Chir B, Said H, Louie O. (2014) Comparison of Outcomes Using AlloDerm Versus FlexHD for Implant-Based Breast Reconstruction. *Ann Plast Surg*, 72(5):503-507.
- Tan, BK: (2013) Pie crusting of acellular dermal matrix may help decrease incidence of seromas in breast Reconstruction. *J Plast Reconstr Aesthet Surg*, 66(11):1629-30
- Seth A, Persing S, Connor C, Davila A, Hirsch E, Fine N, Kim JY. (2013) A Comparative Analysis of Cryopreserved versus Pre-Hydrated Human Acellular Dermal Matrices in Tissue Expander Breast Reconstruction. *Ann Plast Surg*, 70(6): 632-635.
- Michelloti BF, Brooke S, Mesa J, Wilson MZ, Moyer K, Mackay DR, Neves RI, Potochny J. (2013) Analysis of Clinically Significant Seroma Formation in Breast Reconstruction Using Acellular Dermal Grafts. *Ann of Plast Surg*, 71(3): 274-277.



## THE USE OF FLEXHD IN BREAST RECONSTRUCTION

- Maxwell GP, Gabriel A. (2013) Efficacy of Acellular Dermal Matrices in Revisionary Aesthetic Breast Surgery: A 6 Year Experience. *Aesthet Surg J*, 33(3): 389-399.
- Brooke S, Mesa J, Uluer M, Michelotti B, Moyer K, Neves RI, Mackay D, Potochny J. (2012) Complications in tissue expander breast reconstruction. A comparison of Alloderm, DermaMatrix, and FlexHD Acellular inferior pole dermal slings. *Ann of Plast Surg*, 69(4): 347-349.
- Seth AK, Hirsch EM, Fine NA, Kim JY. (2012) Utility of acellular dermis- assisted breast reconstruction in the setting of radiation: A comparative analysis. *Plast Reconstr Surg*, 130(4): 750-758.
- Kim JY, Davila AA, Persing S, Connor CM, Jovanovic B, Khan SA, Fine N, Rawlani. (2012) A Meta-Analysis of Human Acellular Dermis and Submuscular Tissue Expander Breast Reconstruction. *Plast Reconstr Surg*, 129(1): 28-41.
- Cahan A, Palaia D, Rosenberg M, Bonanno P. (2011) The aesthetic mastectomy utilizing a non-nipple sparing portal approach. *Ann Plast Surg*, 66(5): 424-428.
- Rosenberg M, Palaia D, Cahan A, DeChiara S, Arthur K, Petro J, DeLuca-Pytell D, Spanknebel K, Magana R, Bonanno P. (2011) Immediate Single-Stage reconstruction of the Breast Utilizing FlexHD and Implant Following Skin-Sparing Mastectomy. *Am. Journal of Cosmetic Surgery*, 28(3):145-155
- Rawlani V, Buck DW, Johnson SA, Heyer KS, Kim JY. (2011) Tissue Expander Breast Reconstruction Using Prehydrated Human Acellular Dermis. *Ann Plast Surg*, 66(6):593-7.
- Leo K, Louie, O, Neligan PC, Said H. (2010) The Use of AlloDerm Versus FlexHD In Implant Based Breast Reconstruction. *Plast Reconstr Surg*, 125 Supp 6: 142.
- Buck DW 2nd, Heyer K, DiBardino D, Bethke K, Kim JY. (2010) Acellular dermis-assisted breast reconstruction with the use of crescentic tissue expansion: a functional cosmetic analysis of 40 consecutive patients. *Aesthet Surg J*, 30(2):194-200.
- Maxwell GP, Gabriel A. (2009) Use of the acellular dermal matrix in revisionary aesthetic breast surgery. *Aesthet Surg J*, 29(6):485-93.
- Topol BM, Dalton EF, Ponn T, Campbell CJ. (2008) Immediate single-stage breast reconstruction using implants and human acellular dermal tissue matrix with adjustment of the lower pole of the breast to reduce unwanted lift. *Ann Plast Surg*, 61(5):494-9.