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## CLINICAL DOSSIER



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## FLEXHD STRUCTURAL IN ABDOMINAL WALL RECONSTRUCTION (AWR)

### PEER-REVIEWED CLINICAL ARTICLES

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**FlexHD<sup>®</sup>**  
**STRUCTURAL**

**PEER-REVIEWED CLINICAL ARTICLES**

**Title:** Evaluating the Impact of Technique and Mesh Type in Complicated Ventral Hernia Repair: A Prospective Randomized Multicenter Controlled Trial

**Author:** Bochicchio GV, Garcia A, Kaufman J, Zhang Q, Horn C, Bochicchio K, Sato B, Reese S, Ilahi O

**Source:** *Journal of the American College of Surgeons*. April 2019.

**Key Takeaways:** Complications post ventral hernia repair are more dependent on repair technique than mesh type used.

## STUDY OBJECTIVE

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First prospective randomized study comparing the outcomes of ventral hernia repair using both different techniques (overlay vs. underlay) and different mesh materials (HADM vs. PADM).

## METHODS

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- 20 patients were evaluated in a prospective randomized study conducted at three centers
  - 30 patients received HADM Structural in an overlay repair procedure
  - 28 patients received HADM Structural in an underlay repair procedure
  - 31 patients received PADM in an overlay repair procedure
  - 31 patients received PADM in an underlay repair procedure
- Mean Patient Age: 60.6 years
- Mean BMI:  $\leq 40$
- History of Hernias: 97.5%
- Average Defect Size:  $\geq 200\text{cm}^2$
- Ventral hernias were repaired using either an anterior component separation with mesh overly, or a posterior component separation with mesh inserted into the retrorectus space or as a sublay if the retrorectus space was not available.
- A training lab was held to standardize procedures and ensure proper technique, and the first case of each site was proctored by the lead investigator.
- Hernia defect was required to be too large for primary closure and component separation was needed to obtain midline closure.



## RESULTS

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- Follow up was conducted at 1-6 weeks, 3 months, 6 months, and 12 months post operatively
- Incidence of recurrence within the first year was 10.8%, with no difference between each of the 4 groups
- Seroma formation was significantly higher in the patients receiving the overlay procedure (26%) than underlay procedure (8.5%), but with no difference between the patients receiving the HADM vs. the PADM
- Surgical site infection rate was significantly higher in the patients receiving the underlay procedure (11.86%) than the overlay procedure (1.64%)
  - While not significant, the lowest SSI (3.45% HADM vs. 9.68% PADM) and infection rate (22.41% HADM vs. 33.87% PADM) was seen in the patients receiving the HADM

**Title:** Complex Ventral Hernia Repair with Acellular Dermal Matrices: Clinical and Quality of Life Outcomes

**Author:** Roth JC, Zachem A, Plymale, MA, Davenport, DL

**Source:** *The American Surgeon*. 2017 Feb 1.

- Key Takeaways:**
- The type of biologic material did not impact hernia outcomes.
  - There is no decrement in Quality of Life one year after hernia repair despite associated morbidity.

## STUDY OBJECTIVE

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Prospectively assess clinical efficacy and Quality of Life (QOL) in patients with complex ventral hernia repairs using FlexHD and Strattice.

## METHODS

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- Prospective review of 35 patients with complex Ventral Hernia Repair (VHR) over three years  
Patient Characteristics:
  - Mean age: 58
  - Mean BMI: 34
  - Life Expectancy of at least 2 years
  - 51% had at least one hernia repair; 23% had two or more repairs
  - 46% of patients had clean (class I) wounds, 3% had clean contaminated (class II), 23% had contaminated (class III) wounds and 24% had dirty/infected (class IV) wounds
  - All patients were candidates for component separation for which approximation of the skin could be achieved
- Patients were analyzed for Surgical Site Infection (SSI), hernia recurrence and QOL at 2-week, 6-week, 6-month, and 1-year time points.
- Mean fascial defect size was 209 sq cm (min 18, max 488)
- Mesh was placed in the retrorectus space in 30 patients (86%), intraperitoneally in 3 patients (9%), as an onlay in 1 patient (3%) and combined retrorectus and onlay in 1 patient (3%)

## RESULTS

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- SSO (Surgical Site Occurrences)
  - 20 patients (**57%**) experienced wound complications.
  - The majority of wound complications (**29%**) were superficial infections
- Hernia Recurrence
  - Overall there were 5 recurrences (**14%**)
    - 3 In the Strattice Group (**17.6%**) vs. 2 in the FlexHD group (**11%**)
- Rate of Seroma
  - 4 Patients (11%) developed a seroma
- Quality of Life
  - None of the patients who came back with hernias underwent additional repairs as the QOL of these patients improved, suggesting that not all recurrences are considered poor outcomes by the patient

**Title:** Complex ventral hernia repair with an acellular dermal matrix and component separation: A case series

**Author:** Garcia A, Baldoni A

**Source:** *Ann Med Surg (Lond)*. 2015 Sep; 4(3): 271–278

**Key Takeaways:** FlexHD Diamond® provides an opportunity to manage and repair complex ventral hernias

## STUDY OBJECTIVE

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Report on the outcomes of FlexHD for complex hernia repair in a small case series

## METHODS

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- Complex ventral hernia repair was performed with intraperitoneal placement of FlexHD Structural or FlexHD Structural Diamond and components separation in 15 patients between July 2011 and September 2012.
- Anterior and posterior component separation was performed with placement of a human acellular dermal mesh. Midline abdominal closure under minimal tension was achieved primarily in all cases.

## RESULTS

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- Mean follow-up was 12.5 +/- 4.5 months
- Mean fascial defect was 282 cm<sup>2</sup>
- 68% had prior abdominal infections
- 53% had at least one failed prior hernia repair

### Post-operative complications

- 2 adverse events (11%) one pulmonary embolism and one post-operative hemorrhage requiring transfusion
- 6 wound-related complications (32%),
- 1 seroma (5%)
- 1 patient with post-operative ileus (5%)
- Operative intervention was not required in any of the cases and most patients made an uneventful recovery.
- At a median 2-year follow-up, three patients had a documented hernia recurrence (16%)
- One patient was deceased due to unrelated causes

**Title:** Effect of acellular human dermis buttress on laparoscopic hiatal hernia repair

**Author:** Ward KC, Costello KP, Baalman S, Pierce RA, Deeken CR, Frisella MM, Brunt ML, Matthews BD

**Source:** *Surg Endosc.* 2015 Aug; 29(8): 2291-7.

**Key Takeaways:** Laparoscopic hiatal hernia repair with FlexHD Structural reinforcement results in improvement of GERD-related symptoms and quality of life without mesh-associated complications

## STUDY OBJECTIVE

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Evaluate the use of ADM for laparoscopic hiatal hernia repair

## METHODS

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- 54 patients were evaluated in a prospective non-randomized study in a single institution
  - 37 patients received repairs with FlexHD Structural
  - 17 patients received repairs with AlloDerm RTM
- Hernias were sliding/Type I (n=14) or paraesophageal/Type III/IV (n=40)
- 4 cm x 7 cm ADM grafts were cut into U-shaped grafts and positioned over the posterior hiatal closure as a buttress
  - Hiatal closure was performed with 3 or 4 #0 Ethibond sutures
  - Graft was anchored with 8-10 #2-0 Ethibond sutures
  - Wedge fundectomy was performed in select patients to obtain an esophageal length of 3 cm or more
  - Standard 360° Nissen fundoplication was performed in all patients over a 54 Fr or 60 Fr bougie
  - Anterior gastropexy was performed in patients with a paraesophageal hernia at the surgeon's discretion
- Barium swallow (BAS) was performed at 6 months and then as needed

## RESULTS

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- 47 patients (87%) completed the BAS at 6 months; each group had 2 recurrences
- At the median follow-up (33 months), there was 18% recurrence in the AlloDerm group and 14% recurrence in the FlexHD group
- Minimal differences were seen in GERD or SF-36 scores between groups
- Repair with FlexHD resulted in significant improvement of GERD symptoms, anti-reflux medication usage, and quality of life

**Title:** Comparison study of acellular dermal matrices in complicated hernia surgery

**Author:** Bochicchio GV, De Castro GP, Bochicchio KM, Weeks J, Rodriguez E, Scalea TM

**Source:** *J Am Coll Surg.* 2013; 217(4):606-13.

**Key Takeaways:** HADM has been shown to perform poorly in complex abdominal wall reconstruction with outcomes such as recurrence (true recurrence) and eventration (functional recurrence). This study was performed to compare the performance of FlexHD Structural to AlloDerm RTM. FlexHD Structural demonstrated fewer recurrences compared to AlloDerm RTM. Bridged repairs should be avoided to minimize recurrences.

## STUDY OBJECTIVE

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Compare the recurrence rate of FlexHD Structural to AlloDerm RTM when used in complex hernia surgery

## METHODS

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- 95 patients were evaluated in a time-interrupted series from 2005 to 2007 and 2008 to 2010
  - 55 patients received repairs with AlloDerm RTM
  - 40 patients received repairs with FlexHD Structural
- Patients were followed for 1 year post surgery and evaluated for hernia recurrence
- Additional outcomes included abdominal laxity, seroma formation and wound or intra-abdominal infection

## RESULTS

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- FlexHD Structural had fewer total recurrences (true and functional) (31%) than AlloDerm RTM (100%)
- When used as an overlay or underlay, FlexHD Structural had a recurrence rate of 15.2%
- Both FlexHD Structural and AlloDerm RTM demonstrate high recurrence when used in a bridged repair
- Wound complication rates were comparable between FlexHD Structural and AlloDerm RTM

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**STRUCTURAL**

**PAPER AND POSTER PRESENTATIONS**

## FlexHD in AWR: Poster Presentation Summary

**Title:** Necrotizing pancreatitis: A unique case of the use of biologic mesh as an onlay in an open abdomen and for reconstruction of the abdominal wall using components separation

**Author:** Dupree D

**Source:** *Poster presented at AWR Summit Meeting, February 2014*

**Key Takeaways:** FlexHD provides an option for surgeons to manage the open abdomen while minimizing risk of additional complications

## STUDY OBJECTIVE

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Surgeon's experience with FlexHD Structural in an open abdomen and for delayed abdominal wall reconstruction

## METHODS

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- Acute pancreatitis was diagnosed preoperatively in a patient with a history of alcoholism
- Decompressive celiotomy with pancreatic debridement and abdominal washout was performed upon initial presentation and the abdomen was left open
- Multiple take backs were performed for further debridement, drainage of abscesses and abdominal washouts
- Subsequently, FlexHD Structural Diamond was placed as an onlay with a wound VAC covering the open abdomen; the abdomen was left open for 8 weeks before placement of a skin graft
- An intermediate skin graft was placed as a bridge to definitive abdominal wall repair 5 months later with FlexHD Structural Diamond placed intra-abdominally as an underlay

## RESULTS

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- The use of FlexHD Structural Diamond as an onlay allowed for intraabdominal fluid collection to be drained while providing a barrier against trauma from multiple dressing changes, which can lead to enterocutaneous fistulae
- Eventually, the abdominal wall was closed primarily with FlexHD Structural Diamond as an underlay with components separation



## FlexHD in AWR: Poster Presentation Summary

**Title:** Retrospective comparative review of multiple meshes for the repair of abdominal wall defects: Our center's experience

**Author:** Kaufman J, Menack M

**Source:** *Poster presented at AWR Meeting, Washington DC, June 2012*

**Key Takeaways:** In situations where conditions prevent placement of synthetic mesh, the authors prefer FlexHD Structural Diamond as their biologic mesh of choice

## STUDY OBJECTIVE

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Review on a single center's experience on the use of various ADMs for complex AWR, including FlexHD Structural, AlloMax, Strattice, Veritas, Bio-A and AlloDerm

## METHODS

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- A retrospective review of all patients that received abdominal wall repairs with mesh in the last 3 years
- All repairs were performed with retrorectus placement of the mesh with bilateral myofascial flaps and selective use of component separation

## RESULTS

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- Of the patients reviewed, 11 patients received biologic mesh
- No recurrences were seen in any of these patients during the 3 year follow up
- One patient died following surgery due to pulmonary embolism
- One patient who received AlloMax, experienced chronic pain and recurrent seroma

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## STRUCTURAL

CASE STUDIES AND WHITE PAPERS

**Title:** **Biologic Mesh Offers Improved Outcomes in High Risk Patients with Recurrent Hernias**

**Author:** Dupree, DJ, Marino, RP.

**Source:** *MTF Biologics White Paper. 2018.*

**Key Takeaways:** Treatment of complex hernias with components separation reinforced with human acellular dermal mesh delivers clinically acceptable short and mid-term results in highly complicated cases.

## STUDY OBJECTIVE

Retrospectively assess clinical efficacy and Quality of Life (QOL) in patients with complex medical histories and large recurrent abdominal hernias using FlexHD Structural Diamond grafts

## METHODS

A retrospective review of 22 patients with extremely complex medical histories and large recurrent abdominal hernias over an average of 21.4 months.

### Patient Demographics

- Mean age: 58.1
- 64% (14 OF 22 patients) had a BMI >30; with 6 patients (27% having a BMI >40)
- All patients had existing comorbidities, including smoking (14 patients; 64%), diabetes (12 patients; 55%), history of cancer (10 patients; 45%), CPD (8 patients; 36%) and Cardiac Disease (7 patients; 32%).
- All patients had prior abdominal surgeries and prior hernia recurrence (22 of 22 patients; 100%)
- 3 of 22 patients (59%) had a history of prior infection
- 13 of 22 patients (59%) presented with VHWG grade 3 or 4 hernias
- Average defect size was 270 cm<sup>2</sup>
- 7 patients (32%) had concomitant procedures performed

Due to the complexity of these cases, the surgical approach is tailored to specific patient situations. However, the following protocol is generally carried out:

Following an initial exploratory laparotomy via a midline incision and dissection of any adhesions, any hernia defects were identified and repaired. Concomitant surgical procedures are performed at this time.

Components separation including release of the external obliques was performed. The abdominal wall was closed primarily and reinforced with large diamond shaped human biologic mesh positioned as an intra-abdominal underlay and secured circumferentially far laterally with 50-70 transfascial sutures (#1 Ethibond, Ethicon, NJ). All tension is front loaded laterally, with no tension on the midline, allowing the fascia to come together with ease.

Two or three 19F drains are inserted; 1-2 subcutaneously; with a third inserted within the retro-rectus space or retroabdominally, depending on the surgical approach and mesh position.

## RESULTS

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Post-operative follow up was performed at one, two and six weeks, and then in six month intervals. Mean follow up was 21.4 months.

20 of the 22 patients were followed more than 30 days. 16 of the 20 patients (80%) had uncomplicated follow up, with no observed hernia recurrence (0%) in any patients.

One patient required reoperation for a small bowel obstruction, unrelated to the hernia repair. At the time of laparotomy, the previously placed FlexHD Diamond graft was inspected and found to be revascularized and well incorporated, with no laxity or hernia recurrence at the repair site.

## CONCLUSION

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Biologic mesh for reinforcement of complex repairs is a viable, safe option in complex cases delivering clinically acceptable short and mid-term results in challenging clinical situations.

**Title:** Repair of recurrent abdominal wall hernia with transversus abdominis muscle release and Ultra Thick FlexHD Diamond

**Author:** Roth JS

**Source:** *Case Report*. 2014.

**Key Takeaways:** Complex abdominal wall repair presents significant challenges in general surgery

FlexHD Diamond provides an opportunity to manage and repair difficult cases such as recurrent hernia in the presence of comorbid conditions.

## STUDY OBJECTIVE

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Report on the use of FlexHD Diamond, Ultra Thick, for the repair of a recurrent abdominal hernia

## METHODS

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- Patient with multiple recurrent hernias and previously failed hernia repairs, prior infection, and skin graft, was diagnosed with an abdominal wall defect that was 14 cm x 22 cm
- Patient underwent laparotomy to excise the skin graft
- Components separation was performed as follows:
  - The anterior rectus sheaths were opened along the medial border of the rectus sheath to expose the medial border of the rectus abdominis muscles
  - The retro-rectus spaces were dissected bilaterally to the border of the rectus abdominis muscle, however, the midline could not be closed
  - A transversus abdominis muscle release was performed by incising the posterior rectus sheath
  - The preperitoneal space was dissected from the overlying muscles laterally into the retroperitoneum
  - Release of the transversus abdominis muscles allowed adequate advancement of the midline fascia
  - FlexHD Diamond was placed in the preperitoneal space and the midline was closed

## RESULTS

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- Abdominal reconstruction was achieved and the patient was discharged 6 days following surgery
- The patient re-presented 9 days following discharge with a superficial wound infection, which was treated locally
- The patient recovered with no additional events

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## STRUCTURAL

PRE-CLINICAL ARTICLES

**Title:** Chemical Sterilization of Allograft Dermal Tissues

**Author:** Phipps A, Vaynshteyn E, Kowalski J, Ngo, MD, Merritt K, Osborne J, Chnari E

**Source:** *Cell Tissue Bank* 2017 Dec;18(4):573-584. DOI 10.1007/S10561-017-9647-0

**Key Takeaways:** MTF's PAAE sterilization process is robust and achieves sterilization of allograft dermal tissue to a SAL 10<sup>-6</sup> without the harmful negative effects of terminal sterilization.

## STUDY OBJECTIVE

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To demonstrate the sterilization capability of a patented process using a proprietary peracetic acid plus ethanol (PAAE) solution used for processing of allograft dermal tissues at MTF while demonstrating minimal structural effect to the sterilized tissue.

## METHODS

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### **Microorganism selection**

Of the six microorganisms identified as most commonly found in transport solution of in-coming dermal tissue over a one year period: *Bacillus subtilis* subsp., *spizizenii* or *Bacillus atrophaeus* (ATCC 6633 or ATCC 9372), *Clostridium sporoges* (ATCC 11437), *Mycobacterium terrae* (ATCC 15755), *Pseudomonas aeruginosa* (ATCC 9027), *Staphylococcus aureus* (ATCC 6538), and *Enterococcus faecium* (AT 700221), *Bacillus subtilis* subsp. was chosen as the test microorganism because it was the most resistant.

*Bacillus subtilis* was identified as the most resistant organism through the Microbial Effectiveness (ME) testing, which was also used to determine the conditions for the Microbial Performance Qualification (MPQ).

\*Please Note: For the purposes of this clinical summary, the methodology of the ME was not detailed.

### **Test Parameters**

The table below shows the conditions under which the validation was performed (Microbial Performance Qualification) vs. the routine conditions under which MTF acellular dermis is processed, as well as the rationale for choosing each condition.

The highlighted entries represent worst- case test conditions.

Parameter	Routine Condition (Actual Current Processing Condition)	Microbial Performance Qualification	Rationale
Material	Decellularized dermal tissue up to 2mm thick	2mm full thickness decellularized dermal tissue	Thick cut full thickness tissue is a challenge to solution permeation
Temperature	Ambient Tem (20-25C)	Ambient Temp (20-25C)	Routine production takes place in ambient temp
Sterilant age	<72 hr	>144 hr	Peracetic acid is known to decrease in potency overtime
Tissue to volume ratio (cm <sup>2</sup> /ml)	0.3cm <sup>2</sup> /ml	0.62cm <sup>2</sup> /ml	Maximizing tissue to volume ratio increases amt of organic load seen by sterilant
Exposure Time	120 min (full cycle)	¼ cycle-30 min	Performed at both ¼ and ½ time to determine robustness
Agitation speed	90 rpm	90 rpm	Agitation speed affects penetration and access of sterilant to tissue
Vaccum (in Hg)	22 in HG	22 in HG	Vacuum facilitates solution penetration through tissue by applying pressure gradient

All studies were conducted by a third-party laboratory facility.

Fifteen dermal tissue sections were inoculated with >10<sup>6</sup> CFU of the most resistant microorganisms, folded in half and interleaved with 5000 cm<sup>2</sup> of dermal tissue in a stainless steel container. The canister was sealed and an 8000-ml aliquot of 144-hr aged PAAE solution added followed by evacuation to 22 in HG. The canister was continuously agitated at an average temperature of 23C for the desired exposure time.

A positive control consisting of inoculated unexposed dermal tissue was assayed for CFU for both the 30min (1/4 cycle) and 60 min (1/2 cycle) exposure tests.

### ***Tensile Strength & Histology***

Tensile strength and histology were performed to examine the effects of the PAAE sterilization process on dermal tissue properties.

Tensile Strength testing was performed by cutting dermal tissue sections and pulling each section in tension at a rate of 50.8mm/min until failure.

Histology was performed obtaining representative micrographs of H&E and IHC staining of unprocessed and PAAE sterilized dermal tissue.



## RESULTS

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No CFU were recovered for either the 30-or 60-minute exposures under the worst-case test parameters. These results demonstrate the attainment of a SAL better than  $10^{-6}$  after the 120-min PAAE exposure used in routine processing.

### ***Tensile Strength***

Average tensile strength of PAAE-sterilized dermal tissues was higher compared with unprocessed dermal tissues,  $15.4 \pm 5.0$  vs.  $11.2 \pm 4.9$  MPa respectively ( $p < 0.0001$ )

### ***Histology***

Histological analysis showed that extracellular matrix components Collagen I, III, vitronectin, elastin and glycosaminoglycans (GAGs) are retained in dermal tissues processed with PAAE. H&E Staining showed that collagen structure was maintained in dermal tissues after PAAE –sterilization indicating minimal effects to the tissue microstructure.

## CONCLUSION

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Validation of a PAAE-based sterilization method (SAL  $10^{-6}$ ) was achieved while demonstrating that its combination with aseptic processing secures the microbiological safety of the allograft dermal tissue, avoiding structural and biochemical damage previously observed with common sterilization methods like ionizing irradiation.

**Title:** A Microbiological and Ultrastructural Comparison of Aseptic versus Sterile Acellular Dermal Matrix as a Reconstructive Material and a Scaffold for Stem Cell Ingrowth

**Author:** Mendenhall, S, Schmucker, R, Daugherty, T, Kottwitz, K, Reichensperger, J, Koirala, J, Cederna, P, Neumeister, M.

**Source:** *Plast Reconstr Surg.* 2017 Jul;140(1):97-108. DOI: 10.1097/PRS.0000000000003448

**Key Takeaways:** Aseptic acellular dermal matrices have more evidence of bacterial DNA compared with sterile acellular dermal matrices, although clinical cultures did not differ between groups. It does not appear terminal sterilization affects stem cell ingrowth, but it may cause damage to the collagen network.

## STUDY OBJECTIVE

To compare aseptically processed and terminally sterilized acellular dermal matrices for differences in the presence of bacterial DNA and living bacteria on the grafts, as well as assess for any damage to the collagen network or negative impact on stem cell ingrowth that may occur with terminal sterilization.

## Methods

Thirteen acellular dermal matrices and Integra Dermal Regeneration Template were tested.

Product	Source	Method of Sterilization	SAL
AlloDerm (Freeze-Dried)	Human	Aseptically Processed	N/A
AlloDerm (Ready to Use)	Human	E-Beam irradiation	10-3
AlloMax	Human	Tutoplast process/gamma irradiation	10-6
DermACELL	Human	Matricell process/gamma irradiation	10-6
DermaMatrix	Human	Aseptically Processed	N/A
FlexHD Structural	Human	Aseptically Processed	N/A*
FlexHD Pliable	Human	Aseptically Processed	N/A*
Integra (Dermal Regen Template)	Bovine/Shark	Gamma irradiation	10-6
Permacol	Porcine	Gamma Irradiation	10-6
PriMatrix	Fetal Bovine	Ethylene Oxide, silver ions	10-6
Repriza	Human	Gamma irradiation	10-6
Strattice	Porcine	E-Beam Irradiation	10-3
Surgimend PRS	Fetal Bovine	Ethylene Oxide	10-6
XCM Biologic	Porcine	Gamma irradiation	10-6

\*The paper does not define a SAL for FlexHD, but we have validated a SAL 10<sup>-6</sup> through in-process sterilization. Manuscript has been accepted for publication and will be available in September in Cell and Tissue Banking.

The following four test methods were applied to five, 1cm x 1cm samples of each of the different ADMs and one, 1cm x 1cm sample of Integra:

#### 1. Fluorescence In Situ Hybridization

- Samples were tested for the presence of bacterial DNA using Fluorescence In Situ Hybridization.

#### 2. Culturing for the Detection of Living Bacteria

After an incubation period of 2 weeks for standard cultures and 6 weeks for mycobacterial cultures, samples were tested for living bacteria.

#### 3. Qualitative Scanning Electron Microscopy

- All ADM samples were scanned with an electron microscope between 100x and 3000x magnification to assess the collagen architecture of the ADMs.
- Integra was excluded from this testing because it is not an acellular dermal matrix
- Samples were then evaluated in a blind manner by three investigators who performed a qualitative assessment using a scale of 1 to 5, with 1 representing perfect visualization of individual collagen fibers and 5 a complete matting together of fibrils for the following:
  - Collagen organization
  - Clumping
  - Fragmentation

#### 4. Stem Cell Seeding

- Adipose-derived stem cells were isolated and counted using trypan blue, then inoculated onto the 1 cm x 1 cm samples of each of the thirteen different ADMs and Integra.
- Cell quantification was then performed on each sample under 20X magnification

## Results

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The following results were obtained for each of the four test methods:

#### 1. Fluorescence In Situ Hybridization

- 8 Aseptic and 18 sterile ADM samples were analyzed
- While the aseptic allograft ADM group demonstrated higher bacterial DNA than the terminally sterilized group (allograft and xenograft), there was no significant difference between the aseptic and terminally sterilized allograft-only ADM group.. (3.4 versus 2.1; p= 0.08)
- Please point out that when you look deep at the data – DermACELL and FlexHD Pliable have nearly the same bacterial DNA (and AlloDerm Freeze dried) by FISH. Interesting in that DermaCell is messaging that it has the LOWEST residual DNA which is why they claim to have no RBS. This suggests no difference between Pliable and DermACELL...and no significant difference between aseptic allograft ADMs and terminally sterilized allograft ADMs.

## 2. Culturing Experiment

- There was a 3.8% positive culture rate (three of 80) for the aseptically processed ADM group and 3.8% positive culture rate (seven of 180) for the sterile matrix group. (P= 0.98)
- Please mention specifically that FlexHD Pliable had NO positive culture growth. . . . Positive cultures were all found to likely represent contaminants from the culturing process because they all had very few colony-forming units and normal skin flora.
- There were no positive cultures for acid fast bacilli or Kin-youn Acid Fast smears after 6 weeks of incubation
- No cultures were positive for fungal growth

## 3. Qualitative Scanning Electron Microscopy

- A lower overall collagen organization score (more distinct collagen network) was demonstrated in the aseptic ADMs compared with the sterile ADMs, which showed more matting/clumping of collagen with less definition (2.6 of 5 vs. 3.6 of 5, respectively).
- Results were nearly identical to the above when only focused on human ADM (2.6 of 5 vs. 3.8 of 5).
- The authors do not show individual material scores, however, one can see that the FlexHD Pliable SEM image demonstrates what appears to be the most individual strands of collagen, the least amount of damage to the matrix.

## 4. Stem Cell Seeding on the Matrices

- Ingrowth varied widely ranging from two to 136 cells per high-power field.
- There was no statistically significant difference between aseptic and sterile matrix groups (p= 0.2)
  - No significant statistical change was appreciated when only human ADMs were analyzed (p= 0.1)

## Conclusions

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Although further clinical and basic science studies are needed, these data indicate that aseptic processing appears to be sufficient to eliminate the vast majority clinically relevant microorganisms and that terminal sterility may actually be detrimental to the collagen network of acellular dermal matrices.

We conclude that the results of this study demonstrate a similar microbiological profile of all acellular dermal matrices, and that surgeon choice of acellular dermal matrix should not be based on terminal sterility alone.

**Title:** Effect of enzymatic degradation on the mechanical properties of biological scaffold materials

**Author:** Annor AH, Tange ME, Pui CL, Ebersole GC, Frisella MM, Matthews BD, Deeken CR

**Source:** *Surg Endosc.* 2012 October; 26 (10): 2767-2778

**Key Takeaways:** FlexHD maintained tensile strength and demonstrated the ability to resist enzymatic degradation following exposure to collagenases in vitro  
AlloMax, Strattice, XenMatrix and Veritas all demonstrated significant loss in tensile strength

## STUDY OBJECTIVE

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Evaluate the effects of in vitro enzymatic exposure on the mechanical properties of biologic scaffolds

## METHODS

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- Nine scaffolds were evaluated, including:
  - Four porcine dermis: Permacol, CollaMend, Strattice, XenMatrix
  - Two human dermis: AlloMax, FlexHD
  - Two bovine pericardium: Veritas, PeriGuard
  - One small intestine submucosa (SIS): Surgisis
- Specimens were hydrated in saline at 37°C and subjected to uniaxial tensile testing to establish baseline properties
- To evaluate the effect of enzymatic exposure, specimens were incubated in collagenase solution for 2, 6, 12, 24 or 30 hours and subjected to uniaxial tensile testing

## RESULTS

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- FlexHD, a non-crosslinked human ADM, demonstrated an improved ability to resist degradation following 30 hours of exposure to collagenase, compared to 6 of the other biologic meshes used in this study, including Strattice, AlloMax, CollaMend, XenMatrix, Surgisis and Veritas
- The only other meshes that demonstrated higher mechanical strength following enzymatic exposure are the 2 crosslinked meshes, Permacol and PeriGuard

**Title:** Effect of repetitive loading on the mechanical properties of biological scaffold materials

**Author:** Pui CL, Tang ME, Annor AH, Ebersole GC, Frisella MM, Matthews BD, Deeken CR

**Source:** *Journal of the American College of Surgeons* 2012 Aug. 215(2): 216-228.

**Key Takeaways:** FlexHD Structural tensile strength increased after repetitive tension testing  
Strattice and AlloMax tensile strength decreased after repetitive tension testing  
The source of the scaffold material, decellularization and sterilization methods may play a greater role in the properties of the scaffold than previously thought

## STUDY OBJECTIVE

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Evaluate the effect of repetitive loading on the biomechanical properties of biologic scaffolds.

## METHODS

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Nine biologic scaffolds were evaluated via standard tensile testing and subjected to 10, 100 and 1000 cycles of repetitive loading. The tension cycle stresses were chosen based on the theoretical calculations of stresses placed on the human abdominal wall.

Scaffolds Evaluated:

- Porcine Dermis
  - Crosslinked: [Permacol](#), [CollaMend](#)
  - Non-crosslinked: [Strattice Firm](#), [XenMatrix](#)
- Human Dermis
  - Non-crosslinked: [FlexHD](#), [AlloMax](#)
- Bovine Pericardium
  - Crosslinked: [PeriGuard](#)
  - Non-crosslinked: [Veritas](#)
- Porcine small intestinal sub-mucosa: [Biodesign Surgisis Hernia Graft](#)

## RESULTS

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- [FlexHD](#), [Permacol](#), and [PeriGuard](#) exhibited a [slight increase](#) in tensile strength with increasing number of cycles
- Tensile strength remained unchanged for [CollaMend](#), [XenMatrix](#), [Veritas](#), and [Surgisis](#) during all cycles
- [Strattice](#) and [AlloMax](#) exhibited [reduced](#) tensile strength with increasing number of cycles

**Title:** Evaluation of human acellular dermis vs. porcine acellular dermis in an in vivo model for incisional hernia repair

**Author:** Ngo M, Aberman H, Hawes ML, Choi B et al.

**Source:** *Cell Tissue Bank* (2011) 12(2):135-45

**Key Takeaways:** Biologics are claimed to perform the same in the setting of abdominal wall reconstruction. This study was performed to compare the performance of HADM to PADM for incisional hernia repair in an animal model.

HADM demonstrated improved performance over PADM at 20 weeks post implantation in terms of post implantation strength and hernia repair success

## STUDY OBJECTIVE

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Compare the performance of HADM to PADM in an in vivo model for incisional hernia repair

## METHODS

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16 New Zealand white rabbits underwent laparotomy with the creation of an abdominal wall hernia. Three weeks later, hernias were repaired with either HADM (FlexHD Structural) or PADM (Strattice Firm). Recurrence (repair success), adhesions, degree of remodeling and tensile strength of the explants were evaluated at 4 and 20 weeks.

## RESULTS

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- HADM demonstrated better repair outcomes than PADM in this model
  - HADM showed improved defect closure (reduction in size of hernia defect) compared to PADM by study conclusion
  - 2 out of 4 rabbits in the PADM group had mesh resorption and significant mesh thinning by the 20 week time point, leaving an unhealed hernia defect
  - HADM possessed an average tensile strength that was 8 times greater than PADM at 20 weeks post implantation

**Title:** A comparison of human and porcine acellularized dermis: Interactions with human fibroblasts In vitro

**Author:** Armour AD, Fish JS, Woodhouse KA, Eng P, Semple JL

**Source:** *Plast Reconstr Surg.* 117: 845, 2006.

**Key Takeaways:** Human dermal matrix was demonstrated to be a better scaffold for human fibroblasts than porcine dermal matrix in vitro

## STUDY OBJECTIVE

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Compare the in vitro performance of human vs. porcine ADM

## METHODS

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Decellularized human and porcine skin were prepared with identical methods and seeded with human fibroblasts for in vitro evaluation of fibroblast behavior.

## RESULTS

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- Fibroblasts infiltrated to a greater degree into human dermis than into porcine dermis. More cells infiltrated into human dermis, and more samples of human dermis showed infiltration of fibroblasts below the surface and cells penetrated deeper into human dermis than into porcine dermis.
- Human fibroblasts adhered equally well to the surfaces of porcine and human acellular dermis
- Fibroblasts proliferated more rapidly on the surface of porcine acellular dermis than on the surface of human acellular dermis



# FlexHD<sup>®</sup>

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**PEER-REVIEWED CLINICAL ARTICLES**

## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**Title:** Evaluation of Modifications to Tissue-Expander Breast Reconstruction, a Quality Improvement Assessment within a Private Practice

**Author:** Wilson, H, Varnadore, A

**Source:** *Annals of Plastic Surgery*. Vol 80, Supplement 6, June 2018.

- Key Takeaways:**
- Rates of complication were similar among all four ADMs analyzed
  - Type of ADM does not affect outcomes to a clinically significant level

### STUDY OBJECTIVE

Compare post-operative outcomes among patients reconstructed pre and post adoption of no-touch technique and deep dermal perforated ADM in a single practice in which all cases were performed by the same plastic surgeon.

### METHODS

- Results of breast reconstruction on 53 patients/87 breasts were analyzed
  - o Historic chart review of outcomes was performed on 29 patients/47 breasts reconstructed pre-adoption of no-touch technique and use of deeper dermal ADM (Pre-2014 Cohort)
  - o Prospective series initiated for 24 patients/40 breasts reconstructed post-adoption of no-touch technique and use of deeper dermal, preperforated ADM (Post -2014 Cohort)
  - o Overall, the majority of reconstructions (86%) were immediate; only 12 (14%) were delayed.

### Comparison of Cohort Characteristics

	ADM	Technique	# of Drains	Post-Operative Abx
<b>Pre-2014 Cohort</b>	AlloDerm Smaller size grafts (avg 54 sq cm +/- 15)	• ADM Sewn to chest wall before placing tissue expander	1	Cephalaxin
<b>Post -2014 Cohort</b>	FlexHD Pliable Perforated Larger Size grafts (avg 132 sq cm +/-22)	• ADM first sewn to inferior aspect of pec major • No touch technique • Change gown after mastectomy; change gloves after each instance of ADM or implant handling	1	Doxycycline

## Postoperative Complications by Breast Reconstructions

Complications	Total (N=87)		Pre-2014 Cohort (N=47)		Post-2014 Cohort (N=40)		P
	n	%	n	%	n	%	
Seroma	3	3.4	1	2.1	2	5.0	0.3459
Infection	4	4.6	2	4.3	2	5.0	0.9999
Flap necrosis	1	1.1	1	2.1	0	0.0	0.9999
Wound dehiscence	2	2.3	2	4.3	0	0.0	0.4975
Hematoma	1	1.1	1	2.1	0	0.0	0.9999
Removal	3	3.4	3	6.4	0	0.0	0.2462
Incomplete graft incorporation	9	10.3	5	10.6	4	10.0	0.9999
Early capsular thickening	11	12.6	11	23.4	0	0.0	0.0006

Rates of seroma, infection, flap necrosis, wound dehiscence, hematoma, removal, incomplete graft incorporation and early capsular thickening were compared in the pre-2014 and post-2014 cohorts.

A lower rate of complications was generally seen in the later cases, although the differences did not reach statistical significance except in the case of early capsular thickening in the inferior pole (7 cases (24.1) in the Pre-2014 cohort vs. 0 (0%) in the Post-2014 cohort). Those cases required capsulectomies in the second stage surgery.

## CONCLUSION

Incorporating a no-touch technique as well as the use of a deep dermal preperforated ADM into our practice has resulted in reduced use of drains, a low rate of perioperative complications and a lower incidence of clinically significant early capsular thickening.

## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**Title:** A Meta-analysis of Studies Comparing Outcomes of Diverse Acellular Dermal Matrices for Implant-Based Breast Reconstruction

**Author:** Lee, KT, Mun, GH

**Source:** *Annals of Plastic Surgery*. 2017 Jul;79(1):115-123. DOI: 10.1097/SAP.0000000000001085.

- Key Takeaways:**
- Rates of complication were similar among all four ADMs analyzed
  - Type of ADM does not affect outcomes to a clinically significant level

### STUDY OBJECTIVE

Meta-analysis of 12 studies (1 prospective study and 11 retrospective studies) to determine if choice of ADM product affects clinical outcomes of breast reconstruction.

Complication rates of three newer-to-market ADMs ; FlexHD, DermaMatrix and Ready-to-Use AlloDerm (RTU AlloDerm), were compared to complication rates for Freeze-Dried AlloDerm (FD AlloDerm), the first introduced and most widely used ADM product.

### METHODS

- Six studies compared the use of FlexHD vs. Freeze-Dried AlloDerm
- Four studies compared the use of DermaMatrix vs. Freeze-Dried AlloDerm
- Four studies compared the use of RTU AlloDerm vs. Freeze-Dried AlloDerm

Outcomes were defined as post-operative complication rates, including infection, seroma, mastectomy flap necrosis, reconstruction failure as well as overall complication rate.

- All ADM used was human allograft
- However, there were differences among the ADMs in processing, storage requirements, need for rehydration prior to use, and sterilization.

### RESULTS

The results of the three comparative groups are outlined below:

#### **FlexHD vs. Freeze-Dried AlloDerm**

- In the six studies comparing the use of FlexHD in 1131 patients vs. Freeze-Dried AlloDerm in 735 patients, three studies demonstrated favorable outcomes for the use of freeze-dried AlloDerm (Liu, Michelotti, Ranganathan), including lower rates of infection, implant extrusion and reconstruction failure, whereas the other three studies (Brooke, Palaia, Seth) showed a trend toward reduced rate of infection in the FlexHD group compared to the freeze-dried AlloDerm group.

**Table I. FlexHD vs. Freeze-Dried AlloDerm**

Studies	Kind of ADM	No. of Cases	Infection	Seroma	Flap Necrosis	Recon Failure	Total Complication
Brooke et al, 2012	FD AlloDerm	49	5 (10.2%)	n/a	n/a	n/a	11 (22.4%)
	FlexHD	62	6 (9.7%)	n/a	n/a	n/a	10 (16.1%)
Liu et al, 2014	FD AlloDerm	165	14 (8.5%)	5 (3.0%)	35 (21.2%)	8 (4.8%)	n/a
	FlexHD	97	14 (14.4%)	3 (3.1%)	18 (18.6%)	8 (8.2%)	n/a
Michelotti et al, 2013	FD AlloDerm	49	n/a	2 (4.1%)	n/a	n/a	n/a
	FlexHD	61	n/a	9 (14.8%)	n/a	n/a	n/a
Palaia et al, 2015	FD AlloDerm	179	20 (11.2%)	25 (14.0%)	n/a	16 (8.9%)	n/a
	FlexHD	424	39 (9.2%)	52 (12.3%)	n/a	31 (7.3%)	n/a
Ranganathan et al, 2015	FD AlloDerm	206	15 (7.3%)	9 (4/4%)	5 (2.4%)	n/a	n/a
	FlexHD	315	51 (16.2%)	9 (2.9%)	13 (4.1%)	n/a	n/a
Set et al, 2013	FD AlloDerm	136	14 (10.3%)	3 (2.2%)	11 (8.1%)	6 (4.4%)	26 (19.1%)
	FlexHD	233	12 (5.2%)	5 (2.1%)	21 (9.0%)	15 (6.4%)	45 (19.3%)
Overall	FD AlloDerm	735	9.3%	6.0%	10.1%	6.3%	20.0%
	FlexHD	1,131	10.8%	6.9%	8.1%	7.2%	18.6%

**DermaMatrix vs. Freeze-Dried AlloDerm**

- In the four studies comparing the use of freeze-dried AlloDerm (175 patients) with DermaMatrix (233 patients), the following results were reported:
  - One Study (Mendenhall ) found similar rates of infection after controlling for obesity, radiotherapy and chemotherapy. Tissue expander loss developed more frequently until 45 days post operatively in the DermaMatrix arm, but the difference disappeared with the passage of time.
  - The pooled risks did not significantly differ between the DermaMatrix and freeze-dried AlloDerm groups, for all outcomes, including infection.

**Table II. DermaMatrix vs. Freeze-Dried AlloDerm**

Studies	Kind of ADM	No. of Cases	Infection	Seroma	Flap Necrosis	Recon Failure	Total Complication
Becker et al, 2009	FD AlloDerm	25	0	0	n/a	n/a	0
	DermaMatrix	25	1 (4.0%)	1 (4.0%)	n/a	n/a	2 (8.0%)
Brooke et al, 2012	FD AlloDerm	49	5 (10.2%)	n/a	n/a	n/a	11 (22.4%)
	DermaMatrix	110	11 (10.0%)	n/a	n/a	n/a	16 (14.5%)
Mendenhall et al, 2015	FD AlloDerm	101	14 (13.9%)	6 (6.1%)	18 (17.8%)	5 (5.0%)	34 (33.6%)
	DermaMatrix	98	16 (16.3%)	3 (3.1%)	21 (21.4%)	11 (11.2%)	38 (38.8%)
Michelotti et al, 2013	FD AlloDerm	49	N/A	2 (4.1%)	n/a	n/a	
	DermaMatrix	110	N/A	6 (5.5%)	n/a	n/a	
Overall	FD AlloDerm	175	10.9%	4.6%	17.8%	5.0%	25.7%
	DermaMatrix	233	12.0%	4.3%	21.4%	11.2%	24.0%

### Ready-to-Use AlloDerm vs. Freeze-Dried AlloDerm

- Four studies compared the use of Ready-to-Use AlloDerm (288 patients) with freeze-dried AlloDerm (304 patients)
  - One study, a retrospective cohort study comparing outcomes in 100 Ready –to-Use AlloDerm patients with 96 freeze-dried AlloDerm patients, found an increased rate of infection in the ready-to-use arm after adjusting for obesity and preoperative chemotherapy. The trend toward higher infection rates was more pronounced in obese patients with a BMI >30, but there was no significant difference in infection rates between the groups in patients with a BMI < 30.
  - A second retrospective study showed higher rates of infection (30% vs. 8%) and reconstruction failure (15% vs. 0%) with ready-to-use AlloDerm compared to freeze-dried AlloDerm in obese patients.

**Table III. Ready-to-Use AlloDerm vs. Freeze-Dried AlloDerm**

Studies	Kind of ADM	No. of Cases	Infection	Seroma	Flap Necrosis	Recon Failure	Total Complication
Buserman et al, 2013	FD AlloDerm RTU AlloDerm	25 29	4 (16.0%) 1 (11.1%)	2 (8.0%) 6 (66.7%)	n/a n/a	n/a n/a	n/a n/a
Lewis et al, 2015	FD AlloDerm RTU AlloDerm	93 74	11 (11.8%) 8 (10.8%)	4 (4.3%) 1 (1.4%)	5 (5.4%) 2 (2.7%)	7 (7.5%) 6 (8.1%)	39 (41.9%) 20 (27.0%)
Weichman et al, 2013	FD AlloDerm RTU AlloDerm	90 105	18 (20.0%) 9 (8.6%)	18(20.0%) 22 (21.0%)	12 (13.3%) 11 (10.5%)	6 (6.7%) 2 (1.9%)	n/a n/a
Yuen et al, 2014	FD AlloDerm RTU AlloDerm	96 100	12 (12.5%) 21 (21.0%)	5(5.2%) 2 (2.0%)	n/a n/a	7 (7.3%) 6 (6.0%)	n/a n/a
Overall	FD AlloDerm RTU AlloDerm	304 288	14.8% 13.5%	9.5% 10.8%	9.3% 7.3%	7.2% 5.0%	41.9% 27.0%

### OVERALL RESULTS

Overall, the meta-analysis demonstrated that AlloDerm RTU, DermaMatrix and FlexHD had risks of post-operative complications similar to Freeze-Dried AlloDerm. This implies that the type of ADM does not affect outcomes to a clinically significant level and that the choice of ADM product can be determined by the surgeon’s preference, considering the relative equivalency of the products.

### CONCLUSION

FlexHD, DermaMatrix, and AlloDerm RTU demonstrated similar rates of complications, including infection, seroma, mastectomy flap necrosis, reconstruction failure to freeze-dried AlloDerm, an ADM with a longer history of use.

## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**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.



## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**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

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- 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

## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**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

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

### METHODS

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- 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

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- 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

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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

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- 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

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- 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

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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

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- 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

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- 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

## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**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

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- 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

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- 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,  $P < .0001$ )

## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**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

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- 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

## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**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

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- 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

## FlexHD in Breast Reconstruction: Peer-Reviewed Clinical Article Summary

**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

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

### METHODS

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- 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

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

## METHODS

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- 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

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- 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

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- 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

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- 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

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- 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



**PAPER AND POSTER PRESENTATIONS**

## FlexHD in Breast Reconstruction: Poster Presentation Summary

**Title:** Excellent Incorporation of New Acellular Dermal Matrix (ADM) in Challenging Breast Reconstruction Patients 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

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

### METHODS

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- 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

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- 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

# FlexHD<sup>®</sup>

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*PLIABLE*

**CASE STUDIES & WHITE PAPERS**

## FlexHD in Breast Reconstruction: Poster Presentation Summary

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

**Author:** Liao, E

**Source:** *Case Report*, 2014.

**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

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

### METHODS

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- 12 patients involving 19 breasts underwent immediate breast reconstruction utilizing DI (Direct to Implant) 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

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- 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*

**ADDITIONAL PUBLISHED  
CLINICAL AND PRE-CLINICAL ARTICLES**

## THE USE OF ADM IN ABDOMINAL WALL RECONSTRUCTION: ADDITIONAL PUBLISHED ARTICLES

### CLINICAL

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- Kaufman J. What is the ideal acellular dermal matrix (ADM) for complex AWR? *Poster presented at: 15th Annual Hernia Repair: American Hernia Society, MARCH 13-16, 2013. Orlando, FL.*
- Garcia A. Clinical use of a newly designed diamond shape biologic mesh improves mesh deployment and decreases OR time and cost. *Poster presented at: 2013 AWR Summit, January 18-20, 2013. Breckenridge, CO.*
- Roth JS, Plymale M, Zachem A, Bower C, Davenport D. Results of a prospective trial comparing a hydrated human acellular dermal matrix and a porcine dermal matrix for complex abdominal wall reconstruction: An interim analysis. *Poster presented at: 2013 AWR Summit, January 18-20, 2013. Breckenridge, CO.*
- Quartey B, Ugochukwu O, Kuehn R, Ospina K. (2012) Incarcerated recurrent Amyand's hernia. *J Emer Trauma Shock, 5 (4): 344-6.*

### PRE-CLINICAL

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- Eberli D, Rodriguez S, Atala A, Yoo J. (2010). In vivo evaluation of acellular human dermis for abdominal wall repair. *J Biomed Mat Res A, 93(4):1527-38.*
- Roth JS, Dexter DD, Lumpkins K, Bochicchio GV. (2009). Hydrated versus freeze-dried human acellular dermal matrix for hernia repair: A comparison in a rabbit model. *Hernia, 13(2):201-7.*
- Freytes, DO, Badylak, SF. Sterilization of Biologic Scaffold Materials. *Encyclopedia of Medical Devices and Instrumentation. Second Edition. 2006.*

## THE USE OF FLEXHD IN BREAST RECONSTRUCTION: ADDITIONAL PUBLISHED ARTICLES

### CLINICAL

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- 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.
- 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
- 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.
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- 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.
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