A Microbiologic Comparison of Acellular Dermal Matrices as an Aseptic Reconstructive Material

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Background: Over the last 10 years, the use of acellular dermal matrix (ADM) in breast reconstructive surgery has gained popularity. Unfortunately, 3 recent meta-analyses have demonstrated an increased risk of infection when used for breast reconstruction (1-3). This may be due to the fact that some ADM products are actually not sterile, but instead are "aseptically processed."

Methods: In order to test the sterility of ADM products, five separate 2x4cm samples of 14 different brands of ADM (Table 1) were sterilely cut into 1x1 cm pieces and placed in liquid culture media for aerobic/anaerobic bacteria, acid-fast bacilli (AFB), and fungi. Standard culture media was incubated for 3 weeks and AFB for 6 weeks. The Biomerieux Vitek 2 system was used to identify organisms from positive cultures. Separate samples of the ADMs were fixed, processed for paraffin embedding, and used for fluorescent in situ hybridization (FISH) using a universal bacterial DNA probe EUB338 to detect any presence of bacterial DNA on the ADMs. FISH slides were evaluated with confocal microscopy. Differences were tested with the Mann-Whitney U test with $p<0.05$ considered significant.

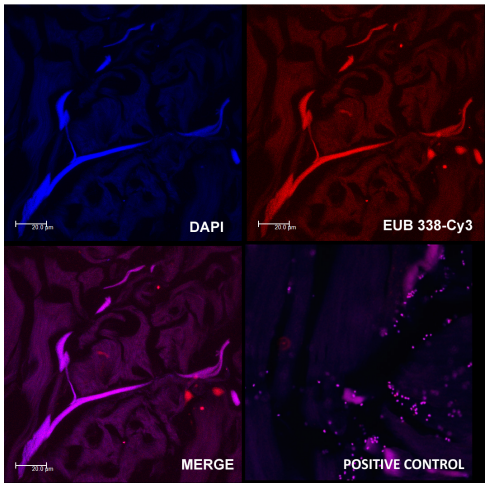
Table 1: Acellular Dermal Matrix Properties and Sterility Comparison

Product	Company	Source	Sterile?	Method of Sterilization	Positive Cultures	No. bacteria/HPF
*Alloderm (freeze-dried)	Lifecell	Human	No	Aseptically processed	Yes, Bacillus Sp.	6.25
*Alloderm (ready to use)	Lifecell	Human	Yes	Electron beam irradiation (low dose)	Yes, Staph Warneri	2
*AlloMax	Bard (Davol)	Human	Yes	Tutoplast® process, gamma irradiation (low dose)	No	2.25
DermACELL	Lifenet	Human	Yes	Gamma irradiation	No	4.75
*DermaMatrix	Synthes/MTF	Human	No	Aseptically processed	Yes, Staph Epi	2.75
Flex HD	Ehicon/MTF	Human	No	Aseptically processed	Yes, Staph Warneri	3
*Flex HD Pliable	Ehicon/MTF	Human	No	Aseptically processed	No	2.5
Integra (dermal regenerative template)	Integra	Bovine/Shark	Yes	Gamma irradiation	No	0
Permacol	Covidien	Porcine	Yes	Gamma irradiation	Yes, Staph Warneri, Staph Epi	NA
PriMatrix	TEI Biosciences	Fetal Bovine	Yes	Ethylene oxide, silver ions	No	1.5
Repriza	Promethian Life Sciences	Human	Yes	Gamma irradiation	No	1
Strattice	Lifecell	Porcine	Yes	Electron beam irradiation	No	1
SurgiMend PRS	TEI Biosciences	Fetal Bovine	Yes	Ethylene oxide	Yes, Staph Warneri, Staph Epi	1
XCM Biologic	Synthes	Porcine	Yes	Gamma irradiation	Yes, Staph Warneri, Bacillus sp.	1.5

* Denotes most commonly used types in breast reconstruction. MTF: Musculoskeletal Transplant Foundation, HPF: high powered field, NA: not yet analyzed

Results: The following ADMs had positive cultures (cxs): AlloDerm, AlloDerm RTU, Permacol, DermaMatrix, XCM biologic, Flex HD, and SurgiMend (all were either Bacillus sp., Staph Warneri, or Staph Epidermidis, 1-2 CFU only). Of the positive cxs, 4 were from terminally sterilized ADMs, and 3 were from aseptically processed ADMs. Results of FISH demonstrated traces of bacterial DNA on all matrices except for Integra (Table 1, Figure 1). Number of bacteria per high power field (HPF) on FISH ranged from 0 (Integra) to 13 (AlloDerm) with an average of 2.3. There were more bacteria per HPF in the aseptically processed group compared to the sterile group, although this did not reach significance (3.6 vs 1.9, p= 0.09).

Figure 1: FISH Confocal Images of AlloDerm®



Conclusion: Standard culture techniques of both sterile and aseptically processed ADMs yielded an equal amount of positive cultures, all of which were standard skin flora and were likely contaminants from the culture process. FISH analysis demonstrated evidence of prior bacterial contamination on all ADMs with the exception of Integra. Whether these findings are correlated with clinical infections remains to be studied.

References:

1. Kim JY, Davila AA, Persing S, Connor CM, Jovanovic B, Khan SA, Fine N, Rawlani V. A meta-analysis of human acellular dermis and submuscular tissue expander breast reconstruction. Plast Reconstr Surg. 2012 Jan;129(1):28-41.
2. Ho G, Nguyen TJ, Shahabi A, Hwang BH, Chan LS, Wong AK. A systematic review and meta-analysis of complications associated with acellular dermal matrix-assisted breast reconstruction. Ann Plast Surg. 2012 Apr;68(4):346-56.
3. Hoppe IC, Yueh JH, Wei CH, Ahuja NK, Patel PP, Datiashvili RO. Complications following expander/implant breast reconstruction utilizing acellular dermal matrix: a systematic review and meta-analysis. Eplasty. 2011;11:e40.

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