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THE BIOMECHANICAL PROPERTIES OF MESHED ALLOMEND[®] ACELLULAR DERMAL MATRIX: FLUID EGRESS AND SURFACE AREA

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The Biomechanical Properties of Meshed AlloMend[®] Acellular Dermal Matrix: Fluid Egress and Surface Area

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ABSTRACT

Acellular dermal matrix (ADM) tissue can be used to replace or repair integumental soft tissues compromised by disease, injury or surgical procedures. ADM biomaterial typically is commercially available in meshed, perforated or unmodified sheets. Meshing (cutting slits) or perforating (stamping small holes) the graft allows fluid to flow through it (egress) and these modifications also can increase the surface area that remains in contact with the wound bed.

Enhanced fluid egress could reduce the risk of seroma, which is the most common complication reported in breast reconstructions using ADM tissue.¹ Seromas can slow vascular ingrowth and postpone integration of the graft.² Further, increasing the surface area of an ADM graft that comes in contact with the patient's vascularized native tissue may allow for more rapid vascularization and faster patient recovery.³

In this study, the fluid egress properties and respective surface areas of meshed and perforated ADM tissue were compared.



AlloMend ADM Tissue

Introduction

AlloMend ADM (AlloSource[®], Centennial, CO) is produced through a proprietary process of cleaning, rinsing and decellularizing donated human dermal tissue, with significant removal of cellular debris (including DNA and RNA), proteins and antigens.⁴ The process does not require the use of detergents or enzymes, thereby mitigating the possibility of harmful residuals in the tissue. Further, the product has been tested by standard ISO 10993-5 methodology and determined to be non-cytotoxic.

AlloMend ADM tissue undergoes a terminal e-beam sterilization procedure, resulting in a 10-6 Sterility Assurance Level (SAL), meeting the same stringent sterility levels required by the U.S. Food and Drug Administration for implantable biomedical devices.

Because of its terminal sterilization, AlloMend ADM can be stored at room temperature for up to two years. Unlike some other ADM products, AlloMend ADM is pre-hydrated and ready for immediate use without requiring a lengthy rehydration period. The AlloMend ADM proprietary process results in a three-dimensional, collagen-rich, biocompatible, non-cytotoxic matrix that retains its biomechanical properties. This process and the resulting tissue properties help ensure the grafts will be readily accepted by the recipient through subsequent revascularization and cell repopulation. AlloMend ADM is available as both a meshed an unmeshed product. Meshing increases fluid flow out of the surgical site, enhances conformability and increases the surface area of the graft.

The purpose of this study was to quantify and compare the fluid egress properties and the surface area of meshed and perforated ADM tissue.

Materials

This study utilized three different cut patterns for ADM tissues – a 1:1 meshed pattern and two perforation patterns. Perforation Pattern #1 (*Figure 1*) is representative of a commercially available graft, while perforation Pattern #2 (*Figure 2*) approximately doubles the perforation density of Pattern #1.



Figure 1. Perforated Pattern #1, based on a commercially available product. Perforations are 3mm in diameter at a density of 41 perforations per 320 cm² or approximately 0.128 perforations per cm². All dimensions are in centimeters.



Figure 2. Perforated Pattern #2. Perforations are 3mm in diameter at a density of 80 perforations per 320 cm² or approximately 0.25 perforations per cm². All dimensions are in centimeters.

Methods - Analyzing Fluid Egress

Six full thickness ADM tissues from three different donors were processed. From each donor, two samples were prepared with 1:1 meshing, two with Pattern #1 perforations and two with Pattern #2 perforations. Thus, the study utilized 18 total samples, six of each cut pattern. Sample thickness was measured in five locations and recorded.

AlloSource researchers designed a testing device (*Figures 3 and 4*) to measure the fluid egress properties of the 18 tissues – six of each pattern. The ADM samples were placed between two pipe flanges with a valve below and clear pipe above. The pipe was filled with fetal bovine serum (FBS). The valve was opened, allowing fluid to flow through the sample. A camera recorded the amount of time required for the FBS to pass between two lines on the pipe (21.6 cm). Each sample was run in triplicate.



Figure 3. Fluid egress testing device. The pipe was filled to the fill line (left) with FBS and the time was recorded as it passed from Line 1 (middle) to Line 2 (right) for each sample.



Figure 4. Representative photos of meshed (left) and perforated Pattern #1 (right) placed in the fluid egress testing device.

Methods - Determining Surface Area

Meshing or perforating ADM tissue can change its surface area due to the additional area inside the pores. The surface area of these modified ADM samples is calculated based on the length, width and thickness of the graft, as well as accounting for the mesh length or the perforation diameter. SolidWorks was used to visualize each of the three patterns.

The surface area of a perforated ADM graft is reduced when holes are stamped into it, but at the same time, the surface area is increased by the area inside the hole. Therefore, the surface area of a perforated graft can be calculated as follows:

Surface Area = (Original Area) + (# holes) * (perimeter of each hole) * (graft thickness) - (# holes) * (cross sectional area of each hole)

or

Surface Area = (area of top of graft) + (# holes) * (area of inside of hole)

where the "Original Area" refers to the surface area (length x width) of the unperforated graft.

Unlike the perforating process, meshing does not remove any material from the graft. Instead, small lines are cut into the tissue and as the graft is stretched, each line becomes a small pore. Thus, the surface area of a meshed graft is equal to the entire surface area of the top of the graft plus the area inside of the pores. The total surface area of a meshed tissue is calculated as follows:

Surface Area = (Original Area) + (# mesh lines) * (perimeter of mesh hole) * (graft thickness)

where the "Original Area" refers to the surface area (length x width) of the unmeshed graft.

The increase in surface area from either perforating or meshing is:

Percent Increase in Surface Area = (Modified Surface Area – Original Surface Area)

(Original Surface Area) * 100%

Results - Analyzing Fluid Egress

The time required for fluid to pass from line 1 to line 2 of the fluid egress testing device was recorded for each sample in triplicate. The average egress time for each variety of cut tissue was calculated. As seen in Table 1 and Figure 5, there was a significant difference in egress properties across the three patterns (Minitab 17, One-Way ANOVA, p=0.000).

PATTERN	AVERAGE TIME	STANDARD DEVIATION	95% CONFIDENCE INTERVAL
Perforated 1	10.369 seconds	1.598 seconds	(9.189, 11.549)
Perforated 2	6.504 seconds	1.273 seconds	(5.324, 7.683)
Meshed	1.974 seconds	1.157 seconds	(0.795, 3.154)

Table 1. Draining Times for Meshed and Perforated ADM



Figure 5. Average Draining Times for Meshed and Perforated ADM (error bars indicate standard deviation)

A General Linear Model ANOVA indicated that neither donor (p=0.249) nor graft thickness (p=0.914) had a significant impact on the results.

The time required for the FBS to pass through the testing device is inversely proportional to the volumetric flow rate through the graft (i.e. a lower time indicates a higher volumetric flow rate).



Time

In the study, the meshed ADM tissue had an average volumetric flow rate approximately 5.3 times that of the Pattern #1 perforated tissue and approximately 3.3 times the flow rate of the Pattern #2 perforated tissue. Thus, a meshed ADM would seem to significantly improve the fluid egress properties of the graft compared to perforated tissue at either of the two tested perforation densities.

Results - Determining Surface Area

The surface area calculations for each type of cut pattern are noted below. The tissue thickness was assumed to be 1 mm for purpose of this analysis.

MESHING

In a 2x2 cm graft, there are 130 mesh lines. Each mesh line is 1.5 mm long. The calculation for the surface area of a meshed tissue is as follows:



Figure 6. Meshed ADM visualization.

Surface Area = (Original Area) + (# mesh lines) * (perimeter of mesh hole) * (graft thickness)

Surface Area = $(4 \text{ cm}^2) + (130)(2 * 1.5 \text{ mm})(1 \text{ mm})$ Surface Area = $4 \text{ cm}^2 + 3.9 \text{ cm}^2 = 7.9 \text{ cm}^2$ Increase in Surface Area from Meshing = $\frac{7.9 - 4}{4} * 100\% = 97.5\%$

Thus, meshing in a 1:1 pattern nearly doubles the surface area of the graft.

In a 16x20 cm graft, the area of a perforated surface is calculated as follows:

PERFORATION PATTERN #1



Figure 7. Area of the top of the graft with holes removed (left) and area of the inside of each hole (right).

Surface Area = (area of top of graft) + (# holes) * (area of inside of hole)

Surface Area = $317.1018 \text{ cm}^2 + (41 \text{ holes})(0.09424 \text{ cm}^2)$

Surface Area = 320.966 cm^2

Original Graft Area = $(16 \text{ cm})(20 \text{ cm}) = 320 \text{ cm}^2$

Increase in Surface Area from Perforation Pattern $\#1 = \frac{320.966 - 320}{320} * 100\% = 0.3\%$

PERFORATION PATTERN #2



Figure 8. Area of the top of the graft with holes removed (left) and area of the inside of each hole (right).

Surface Area = (area of top of graft) + (# holes) * (area of inside of hole)

Surface Area = 314.34513 cm² + (80)(0.09424 cm²)

Surface Area = 321.884 cm²

Original Graft Area = $(16 \text{ cm})(20 \text{ cm}) = 320 \text{ cm}^2$

Increase in Surface Area from Perforation Pattern #1 = $\frac{321.884 - 320}{320} * 100\% = 0.59\%$

Perforation at these two densities yielded less than a one percent increase in the surface area of the ADM tissue.

Conclusion

This quantitative comparison revealed that meshing ADM tissue significantly improves fluid egress properties and substantially increases the surface area compared to ADM tissue perforated at levels at or beyond those typically available on the market.

Meshing increased the volumetric flow rate by a factor of five compared to perforating with Pattern #1 (approximately 0.128 perforations per cm2) and by a factor of three compared to perforating with Pattern #2 (approximately 0.25 perforations per cm2).

Meshing also nearly doubled the surface area of the graft compared to an unmodified ADM tissue sheet, while perforating at either density increased the surface area less than one percent.

References

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