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Bovine versus Porcine Acellular Dermal Matrix: A Comparison of Mechanical Properties

David M. Adelman, MD, PhD, FACS
Jesse C. Selber, MD, MPH, FACS
Charles E. Butler, MD, FACS

Background: Porcine and bovine acellular dermal matrices (PADM and BADM, respectively) are the most commonly used biologic meshes for ventral hernia repair. A previous study suggests a higher rate of intraoperative device failures using PADM than BADM. We hypothesize that this difference is, in part, related to intrinsic mechanical properties of the matrix substrate and source material. The following study directly compares these 2 matrices to identify any potential differences in mechanical properties that may relate to clinical outcomes.

Methods: Sections of PADM (Strattice; Lifecell, Branchburg, N.J.) and BADM (SurgiMend; TEI Biosciences, Boston, Mass.) were subjected to a series of biomechanical tests, including suture retention, tear strength, and uniaxial tensile strength. Results were collected and compared statistically.

Results: In all parameters, BADM exhibited a superior mechanical strength profile compared with PADM of similar thickness. Increased BADM thickness correlated with increased mechanical strength. In suture tear-through testing with steel wire, failure of the steel wire occurred in the 4-mm-thick BADM, whereas the matrix material failed in all other thicknesses of BADM and PADM.

Conclusions: Before implantation, BADM is inherently stronger than PADM at equivalent thicknesses and considerably stronger at increased thicknesses. These results corroborate clinical data from a previous study in which PADM was associated with a higher intraoperative device failure rate. Although numerous properties of acellular dermal matrix contribute to clinical outcomes, surgeons should consider initial mechanical strength properties when choosing acellular dermal matrices for load-bearing applications such as hernia repair. *(Plast Reconstr Surg Glob Open 2014;2:e155; doi: 10.1097/GOX.0000000000000072; Published online 15 May 2014.)*

Despite being classified together as acellular dermal matrices (ADMs), biologic mesh devices vary widely in both origin and processing. They are derived from numerous sources (human, porcine, bovine, etc.) and tissues (dermis, intestine or bladder submucosa, pericardium, etc.), are decellularized by distinct proprietary methods, and are sterilized by one of several techniques (gamma irradiation, electron beam irradiation, ethylene oxide, etc.).[1,2] The result of this diversity is materials with inherently different biochemistries, mechanical properties,[2] and host responses upon implantation.[3,4] As clinical outcomes in hernia repair can be associated with biomechanical properties, it is reasonable to expect that outcomes might be different for different materials. For example, the use of human acellular dermal matrix has been almost completely abandoned for use

From the Department of Plastic Surgery, The University of Texas, MD Anderson Cancer Center, Houston, Tex.
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in hernia repair due to overwhelming evidence that it leads to unacceptably high rates of hernia recurrence and bulge.[3,5] Despite this, there is a paucity of data that directly compares the initial, preimplant mechanical properties of commercially available ADMs.

A recently published clinical study compared the use of porcine acellular dermal matrix (PADM) and bovine acellular dermal matrix (BADM) in a retrospective cohort of complex abdominal wall reconstructions (AWRs).[6] The study demonstrated a low overall hernia recurrence rate of 3.3% over the approximately 1.8-year mean follow-up, which was similar between the PADM and BADM groups.[6] However, intraoperative device failures (IDFs), characterized by tearing of mesh and suture pulling through mesh, were observed in a number of patients who underwent AWR with PADM (10.1%), whereas none were reported in those with BADM (0%).[6] The goal of this study is to directly compare the mechanical properties of PADM and BADM to help elucidate the contributory role of mesh selection as a potential cause of previously reported device failures in complex AWR.

MATERIALS AND METHODS

The materials evaluated were identical to those used in the previous clinical study[6] and those used clinically at our institution. All materials tested were commercially salable products and within marked expiration dates. These included 3 pieces of PADM (Strattice; Lifecell, Branchburg, N.J.; two 8×8 cm and one 10×10 cm piece) and 3 pieces of BADM (SurgiMend; TEI Biosciences, Boston, Mass.; at 6×12 cm for each thickness). No packages were damaged or adulterated, and temperature sensors were within specifications. Only the "firm" version of PADM was used previously in AWR and was therefore the only version tested in this study. The BADM used in the previous clinical study included several of the commercially available thicknesses (SurgiMend 2.0, 3.0, and 4.0). Because of their availability for clinical use, this range of BADM thickness was tested in the present study. Each matrix was prepared strictly in accordance with the products' instructions for use document. For each test, an $n = 6$ was performed for each matrix (including PADM firm, BADM 2.0, BADM 3.0, and BADM 4.0).

All mechanical strength testing was performed on an Instron tensile testing system (Norwood, Mass.), using a 10-kN load cell and 1-inch pneumatic grips, and data acquired/analyzed by computer. Materials were stretched to failure at a cross-head rate of 300 mm/min, and maximum force before failure was reported in newtons, as a mean ± SD, or in megapascals (MPa) when divided by the original cross-sectional area.

Thickness Testing

Initial thickness and uniformity measurements were taken with a calibrated, digital drop micrometer (Mitutoya, Aurora, Ill.). Uniformity was evaluated by making 5 measurements, including one in each of the 4 corners (approximately 1 cm from each edge) and one at the center of the device. This was repeated for each of 3 hydrated pieces of material and thickness. Additional thickness measurements were made for each individual sample before mechanical testing and reported separately.

Uniaxial Tensile Testing

Uniaxial tensile testing was performed similarly to that described previously[2,7] and following the American Society for Testing and Materials (ASTM) standard D638. Specimens ($n = 6$) for each condition, measuring 1×6 cm with a central section that narrowed to approximately 4 mm forming a "dog-bone" shape (ASTM D638 type V), were uniformly cut with a bench-top press and a steel-rule die. Two specimens were punched from each of 3 sheets of material per condition. The 2 specimens per sheet were punched perpendicular to each other to account for possible anisotropy. Each specimen was clamped and stretched to failure. The strength results were reported as the maximum load at failure in newtons (N); ultimate tensile stress was calculated using the maximum load and the cross-sectional area of the matrix at the central region of the specimen, and Young's modulus of elasticity was calculated from the maximum tangent slope of the stress-strain curve.

Suture Retention Strength Testing

Suture retention strength testing was performed as previously described.[2,7] Specimens ($n = 6$) measuring 2.5×5.1 cm were prepared for each matrix. Stainless steel wire equivalent in diameter to a size 1 suture (0.4 mm diameter, American wire gauge 26) was passed through a tapered hole created with a sharp tapered-point awl, 1 cm from the edge. The material and wire were placed in opposing grips and stressed to failure (suture tore from the material or the wire broke).

Tear Resistance Testing

Tear resistance testing was conducted using a "pant leg" technique similar to that described previously,[2,7] based on ASTM specification D2261-07a, to evaluate the resistance each mesh provides against the propagation of a tear. Specimens for each condition ($n = 6$) were prepared measuring 2.5×7.6 cm. A 2.5-cm slit was cut from the midline of the 2.5-cm edge towards the center of the specimen to form 2

Table 1. Intrasheet Thickness Variability

	Average Thickness (mm) ± SD			
	PADM	BADM 2.0	BADM 3.0	BADM 4.0
Sheet #1	1.72 ± 0.11	2.06 ± 0.05	2.66 ± 0.09	4.40 ± 0.11
Sheet #2	1.66 ± 0.07	2.11 ± 0.06	3.54 ± 0.12	3.53 ± 0.08
Sheet #3	1.63 ± 0.08	1.75 ± 0.16	3.62 ± 0.05	3.81 ± 0.07

tabs. One tab was clamped in the upper grip and one in the lower grip of the tensile testing machine, yielding a 2.5-cm gauge length. Samples were then stretched until complete material failure and the maximum load before failure was reported.

Statistical Analysis

For all mechanical tests, $n = 6$, with 2 specimens taken from each of 3 sheets. One-way analysis of variance was calculated to determine significant differences with Tukey post hoc tests between groups. Differences between the mean of groups were considered significant when $P < 0.05$. A simple linear regression trend line was curve fit in Microsoft Excel where applicable.

RESULTS

Intrasheet Thickness Variability

The variability and uniformity of thickness within each sheet ($n = 3$ separately opened packages greater than or equal to 8 × 8 cm per condition) is summarized in Table 1. The intrasheet SD was low (<10% of mean material thickness) for all of the materials tested.

Uniaxial Tensile Properties

The results of uniaxial testing, summarized in Table 2, demonstrated both similarities and differences under the conditions tested. For BADM and PADM of similar thickness, the ultimate tensile strength (UTS) of BADM was approximately 1.8 times greater than PADM, which was a statistically significant difference ($P < 0.05$), and the physical parameter of UTS significantly increased with increasing material thickness ($P < 0.05$) in the BADM group (Fig. 1). The mean tensile stress and modulus were similar between all materials tested and not statistically different (Fig. 2).

Suture Retention Strength

The mean suture retention strength, summarized in Table 3, increased with increasing material thickness in the BADM group, consistent with the UTS (Fig. 2). For PADM and BADM of similar thickness, BADM required significantly more force for suture pull out than PADM. Despite using stainless steel wire to reduce suture breaking, the steel wire failed before the matrix material itself in 33% of the BADM 3.0 and all of the BADM 4.0 scaffolds.

The break pattern was observed to be visually different between BADM and PADM (Fig. 3). For the thinner BADM, the suture pulled linearly through the scaffold in a direction parallel to the applied force. The PADM scaffolds frequently tore in a lateral or oblique direction, appearing to follow a path of least resistance in a less linear, but highly reproducible manner. In PADM scaffolds, the direction of the tear was frequently not parallel to that of the applied suture force.

Tear Resistance Testing

The PADM mean tear resistance strength was significantly lower than any of the BADM tested regardless of thickness (Table 4). For ADM of similar thickness, the resistance to tearing for BADM was almost twice that of PADM. BADM tear resistance correlated linearly with increasing scaffold thickness (Fig. 4).

DISCUSSION

This study directly compares the in vitro, preimplantation biomechanical properties of the PADM and BADM matrices. The results demonstrate that BADM has significantly higher UTS, suture retention strength, and tear resistance than PADM. In addition, increasing thicknesses of BADM correlated with increased UTS, suture retention strength, and tear resistance. The thickest sheets of BADM had suture retention strength greater than that of 26G wire suture, which failed in every case without tearing the mesh.

Published data suggest that IDFs, specifically tearing of the scaffolds during surgical implantation, may be higher using PADM.[6] It is conceivable that surgeon factors, patient factors, and material factors are all potential contributing causes of device failure,

Table 2. Uniaxial Tensile Properties

	Thickness (mm) ± SD	Maximum Load (N) ± SD	Maximum Stress (MPa) ± SD	Modulus (MPa) ± SD
PADM	1.53 ± 0.16	61.55 ± 15.66	11.76 ± 2.46	49.40 ± 19.17
BADM 2.0	1.64 ± 0.19	108.08* ± 39.43	18.47 ± 5.14	55.68 ± 18.45
BADM 3.0	2.95 ± 0.60	130.24* ± 64.25	12.23 ± 5.37	32.88 ± 14.49
BADM 4.0	3.54 ± 0.59	158.78* ± 39.32	12.84 ± 2.62	31.03 ± 6.35

*Significant difference from all other conditions by 1-way analysis of variance and Tukey post hoc analysis ($P < 0.05$).

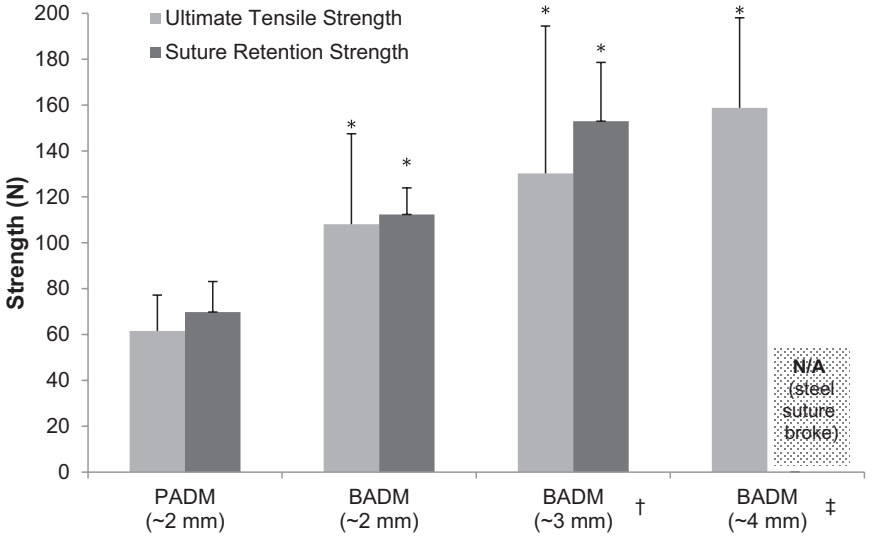

Fig. 1. Ultimate tensile strength and suture retention strength followed similar trends. BADM was statistically significantly ($P < 0.05$) greater for BADM than PADM in both parameters and increased with thickness. *Indicates $P < 0.05$ significant differences of BADM compared with PADM. †Excludes 33% of test samples where steel wire broke first. ‡The steel wire broke in every BADM 4.0 sample, and therefore, suture retention strength could not be calculated.

but only the initial, preimplantation material properties are easily testable in a laboratory environment. The aim of this study was to clearly delineate differences in preimplantation biomechanical properties of PADM and BADM to potentially support a hypothesis for which one material might undergo a medical failure more frequently than the other when used for load-bearing reconstructions such as AWR. Surgeon factors and patient factors, although superficially similar in the retrospective clinical study referred to above, would require a randomized clinical trial to truly understand their predictive contribution to differences in outcomes in PADM and BADM.

The results of this study indicate that there are differences in the inherent mechanical properties of BADM and PADM. The results of standard uniaxial

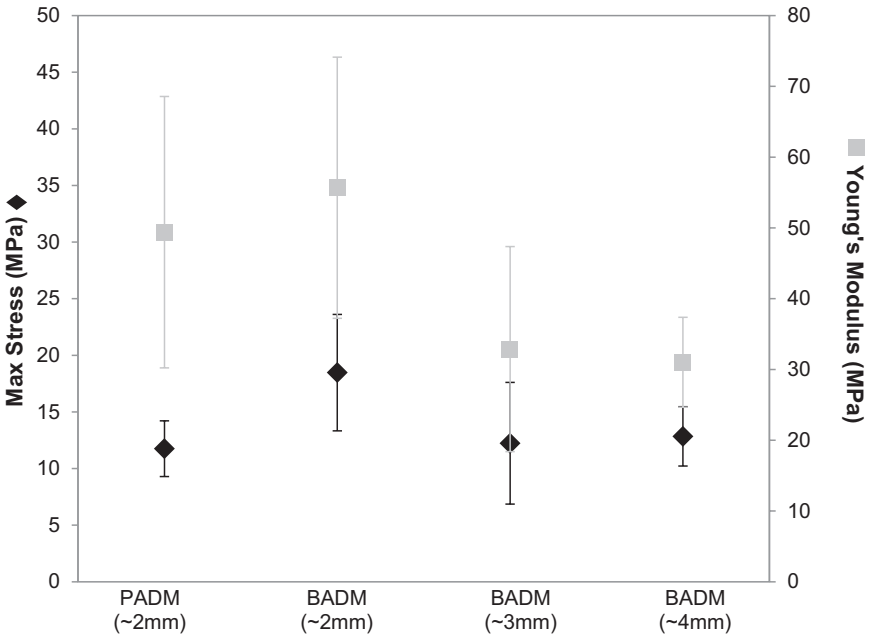

Fig. 2. Tensile stress and stiffness of PADM and BADM by thickness. The average tensile stress and modulus were similar between all materials tested and not statistically different.

Table 3. Suture Retention Strength

	Thickness (mm) ± SD	Maximum Load (N) ± SD
PADM	1.70 ± 0.16	69.81 ± 13.30
BADM 2.0	1.85 ± 0.16	112.36* ± 11.56
BADM 3.0	3.10 ± 0.48	153.02*† ± 25.64
BADM 4.0	3.83 ± 0.35	N/A‡ ± N/A

*Significant difference from all other conditions by 1-way analysis of variance and Tukey post hoc analysis ($P < 0.05$).
†Excludes 2 thickest specimens where stainless steel suture broke.
‡Stainless steel suture broke on all specimens.

tensile testing showed that BADM was significantly stronger than PADM of equivalent thickness and that the strength of BADM increased with thickness. Interestingly, the tensile stress of PADM and BADM ranged from 11.8 to 18.5 MPa, which is similar to that reported for common polypropylene, polyester, and polytetrafluoroethylene synthetic hernia repair meshes.[7] These data suggest that strength alone may not account completely for the IDFs of PADM noted clinically. Additionally, although some anisotropy was noted (data not shown), this difference was not significant and not considered contributory.

Significant differences were noted, however, between PADM and BADM in 2 tests that replicate steps in the clinical use of ADMs in AWR, and these may account for the IDF disparity. In suture retention strength testing, BADM was considerably stronger than PADM of similar thickness, and with the thickness of BADM more commonly used in AWR (approximately 3 or 4 mm thick), the stainless steel wire, equivalent in thickness to a size 1 suture, broke before it tore from the ADM. These data would suggest that suture tearing through a BADM scaffold

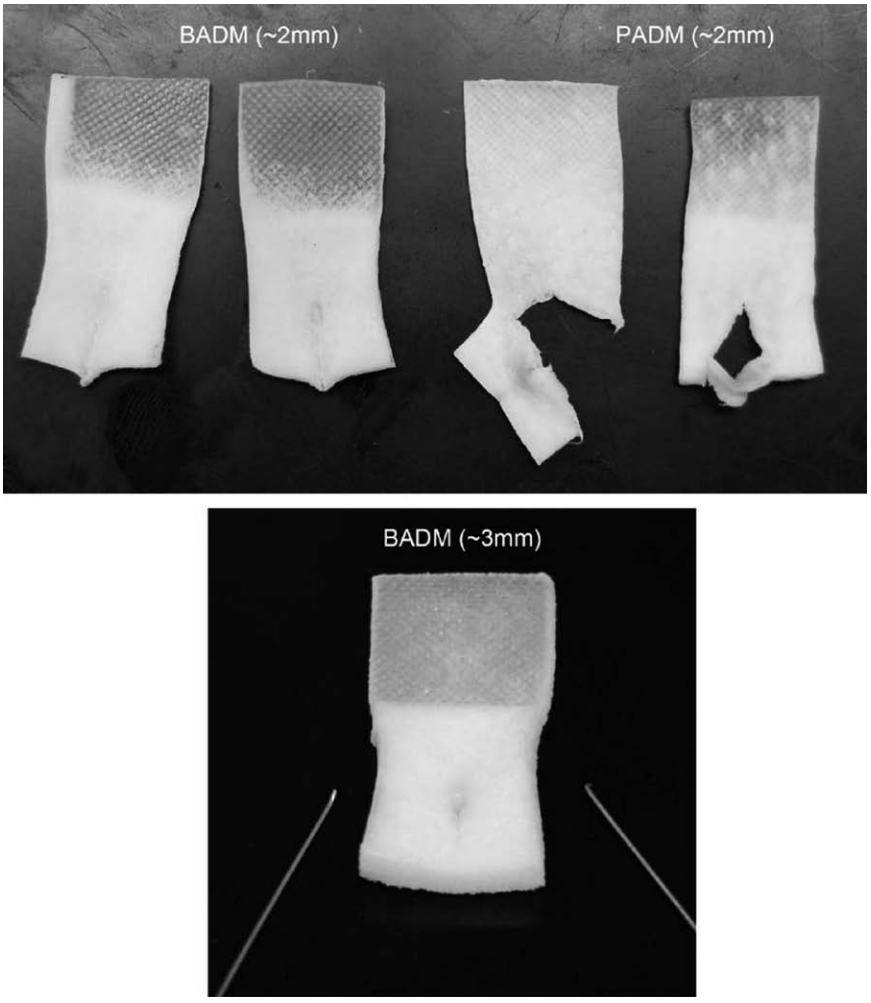

Fig. 3. Images of suture retention testing failure mechanism for BADM and PADM. The stainless steel wire cut through BADM (~2.0 mm) at a high enough force. However, PADM at a much lower force consistently and repeatedly tore obliquely as imaged above. The direction of the pull through was not parallel to that of the suture force applied and seemed as more of a tearing mechanism than a cut. For thicker BADM, the stainless steel suture broke before pulling from the material.

Table 4. Tear Resistance

	Thickness (mm), SD	Maximum Load (N), SD
PADM	1.75 ± 0.14	19.66* ± 3.90
BADM 2.0	1.85 ± 0.27	50.95* ± 11.79
BADM 3.0	3.23 ± 0.54	86.89* ± 15.34
BADM 4.0	3.83 ± 0.32	100.02* ± 14.28

*Significant difference from all other conditions (or between those noted) by 1-way analysis of variance and Tukey post hoc analysis ($P < 0.05$).

under normal and even supraphysiologic tension is unlikely. In contrast, sutures were pulled through the PADM with significantly lower force (half the strength of BADM), and PADM was more likely to tear in directions other than the direction of suture traction. This failure during suture retention strength testing (Fig. 3) seemed to be more of a tearing mechanism, rather than the cutting of the wire through the ADM, as apparent with the thinner versions of BADM. We chose stainless steel wire rather than prolene suture for this study because it is stronger. Prolene breaks before most of the commercially available materials, so it is not very useful in testing tear strength thresholds. The stainless steel wire was a good approximation of the thickness of size 1 Prolene suture, but it could withstand much more force. Similar to the results of suture pull-out testing, significantly less force was needed to propagate a tear in PADM than BADM. The tear resistance test measures the ability of a material to resist propagation of a rip or tear initiated in an area of high stress concentration, such as a cut, nick, suture, or hole. Clinically, these areas may be created during the trimming or shaping of the ADM, during suturing, or when creating an opening in the ADM for an ostomy to pass through. High force situations, either during application or immediately postoperatively (like coughing or vomiting), have the potential to propagate tears leading to IDFs or early hernia recurrence, respectively. The tear resistance strength of PADM was considerably lower than that of BADM and often did not meet the minimum threshold for tear resistance of hernia repair meshes outlined by Deeken et al.[2] In contrast, the tear resistance of BADM was more than twice that of PADM of equivalent thickness and increased with increasing thickness.

Although the exact structural differences between PADM and BADM leading to these outcomes were not evaluated in this study, it is suspected to be due to one or more of the following factors: (1) inherent differences in the collagen fiber architecture of adult porcine dermis as compared with fetal and neonatal bovine dermis, (2) differences in material processing and sterilization, (3) presence of irregularly spaced pores from hair follicles originating in hypodermis of porcine skin, without such pores in BADM (hair follicles instead originate from reticular layer of bovine dermis, not included in BADM). To determine the exact mechanism leading to the results of this study, however, requires further investigation.

Limitations

One possible limitation of this study is that 2 of the authors are consultants for TEI Biosciences. Indeed, our clinical experience with this product has led to both our work with the company and also our

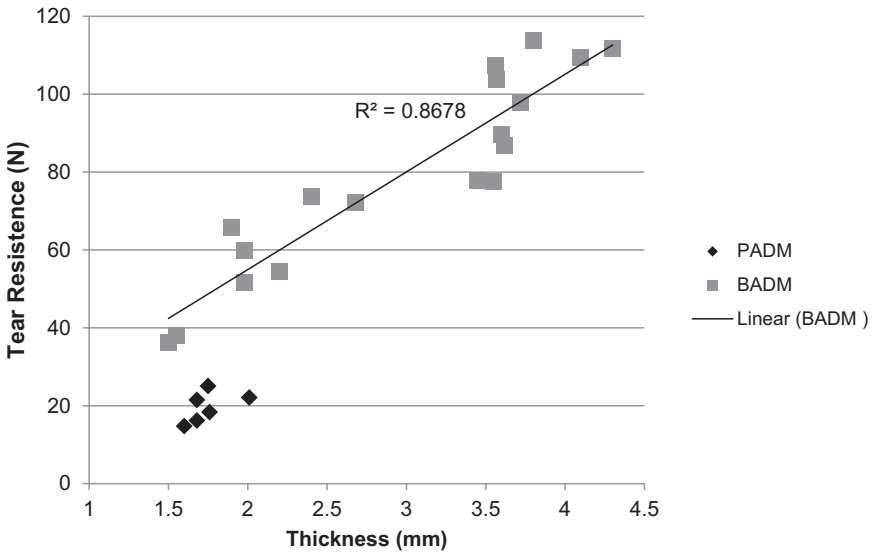

Fig. 4. The tear resistance of BADM was significantly higher ($P < 0.05$) than PADM of equal thickness and the tear resistance increased linearly with increasing BADM thickness.

hypothesis that BADM is a stronger material. We feel that this bias is largely mitigated with this type of investigation for 3 reasons. First, there is very little human involvement in mechanical strength testing. All the physical work is done by the mechanical loader. Second, the endpoint of mechanical failure is obvious and binary. Third, the numerical data of force threshold upon failure are produced by the computer. These data are very resistant to human interpretation and unconscious bias. That said the authors are quite certain that these data are highly reproducible and would be happy to conduct repeated experiments in any environment with appropriate equipment.

An ideal bioprosthetic mesh requires 2 distinct but equally important features: strength of the material to withstand applied forces, both immediately and over time during the remodeling phase, and integration of the material with the host including vascularization and cellular infiltration into the ADM. A limitation of this study is that only one of these features, initial mechanical properties, is evaluated. Additionally, most hernia repairs fail at the musculofascia junction, which changes over time as materials remodel at that interface following implantation.[8] It is important to emphasize that for a complete picture of mesh performance properties, a deeper understanding of the role of acute inflammation, cellular infiltration, neovascularization, and ultimate remodeling of these materials as a function of time is required. This set of in vivo processes, combined with the biomechanical strength of the materials themselves, constitute the multidimensional properties of an ideal mesh and will require further clinical and laboratory study.

CONCLUSIONS

Mechanical strength testing performed in this study definitively demonstrates superior mechanical properties of BADM over PADM, regardless of thickness. These findings may contribute to the previously published observation of higher IDFs in clinical PADM than BADM AWRs.

Jesse C. Selber, MD, MPH, FACS
Department of Plastic Surgery
The University of Texas
MD Anderson Cancer Center
1400 Pressler Street, Unit 1488
Houston, TX 77030
E-mail: jcselber@mdanderson.org

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