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MECHANICAL PROPERTIES OF PUREGRAFT ESSENCE ACELLULAR DERMAL MATRIX

Ultimate Tensile Strength, Ball Burst Strength, and Suture Pullout Strength

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ABSTRACT

Acellular Dermal Matrices have been used successfully in a large number of surgical applications to support soft tissue compromised by disease or injury. Puregraft Essence Acellular Dermal Matrix (ADM) is the latest Human ADM to be made commercially available and the aim of this study was to conduct a comparative analysis of its performance vs. existing commercially available product. Using industry standard strength testing techniques, Puregraft Essence ADM has shown to be comparable or superior per mm thickness to other well-known and proven commercially available Acellular Dermal Matrices currently in use.

INTRODUCTION

Puregraft Essence Acellular Dermal Matrix (ADM) is a product of donated human tissue obtained from accredited U.S. tissue banks that undergoes strict processing procedures. All tissues used in the development of Puregraft Essence product have been rigorously screened and tested, processed to remove donor cells, and terminally sterilized to a sterility assurance level (SAL) of 10^{-6}, which is the standard of sterility for surgical implants. These proprietary processing steps preserve the integrity of the extracellular matrix proteins, resulting in a strong acellular dermal matrix.

Puregraft Essence ADM comes pre-hydrated, stored in a dual-layer packaging system which preserves the sterility and integrity of the product for up to two years when stored at room temperature. Puregraft Essence comes in a variety of ready-to-use sizes. The 0.8mm nominal thickness strikes the perfect balance between strength and pliability.

Puregraft Essence ADM has been rigorously tested to ensure that its properties are acceptable to serve in a variety of surgical applications.

METHODS

Materials

The testing described in this paper was carried out using the Puregraft Essence product, nominal thickness 0.8mm, with basement membrane (Figure 1). Samples were processed and sterilized according to production specifications. Samples were non-perforated.

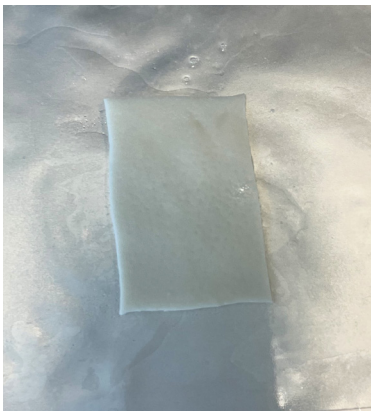

Figure 1: Sterile Puregraft Essence product (0.8mm nominal thickness, basement membrane)

Test Methods

Ultimate Tensile Strength

Testing was performed in accordance with ASTM D638-10, Standard Test Method for Tensile Properties of Plastics. Five (5) samples were cut to a dogbone shape per the standard (Figure 2). Each sample was fixed within the jaws of a force gauge with movable jaws (test fixture) (Figure 3). A tensile force was applied to each sample by moving the upper jaw of the test fixture at a rate of 10 mm/min per the standard. Failure was defined as the point at which a fast drop in tensile force was recorded by the test fixture. The Ultimate Tensile Strength was defined as the maximum tensile force recorded by the fixture, divided by the cross-sectional area of the test sample. Ultimate Tensile Strength is reported in units of Megapascals (MPa), or N/mm2.

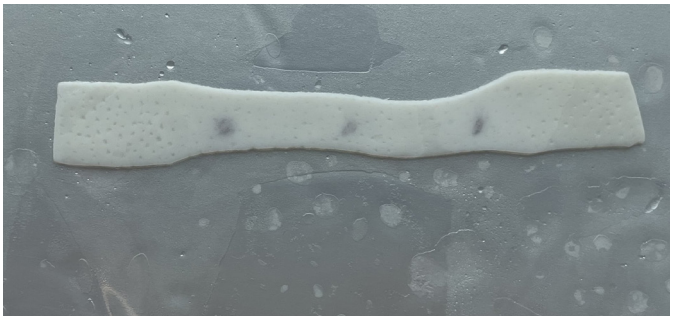

Figure 2: Essence sample cut to dogbone shape per ASTM D638-10

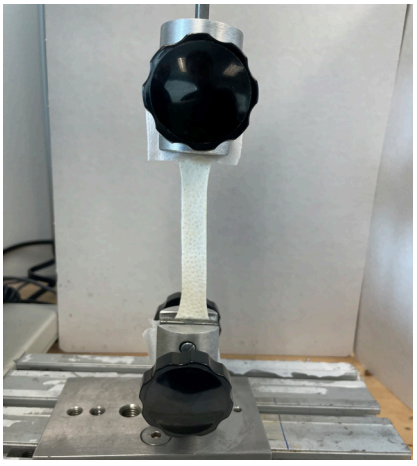

Figure 3: Puregraft Essence fixed within jaws of Ultimate Tensile Strength test fixture

Ball Burst Strength

Testing was performed in accordance with ASTM D3787-07, Standard Test Method for Bursting Strength of Textiles (Constant-Rate-of-Traverse (CRT) Ball Burst Test). Five (5) samples were punched out to fit on the Ball Burst test fixture (Figure 4). Each sample was fixed within a Ball Burst test fixture per the standard (Figure 5). A polished steel ball was driven into the test sample at a rate of 305 mm/min per the standard. Failure was defined as the point at which a fast drop in compressive force was recorded by the test fixture. The Ball Burst Force was defined as the maximum compressive force recorded by the fixture, and is reported in Newtons (N). Ball Burst Strength is calculated as the maximum compressive force recorded by the fixture, divided by the travel of the steel ball into the test sample region. Ball Burst Strength is reported in units of N/cm.

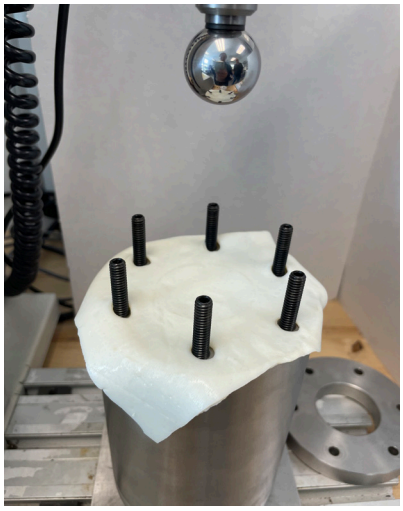

Figure 4: Puregraft Essence with holes punched out sitting on Ball Burst test fixture

Figure 5: Puregraft Essence fixed within Ball Burst test fixture

Suture Pullout Strength

Five (5) samples were cut such that they could be clamped in the lower jaw of the test fixture as described in the **Ultimate Tensile Strength** section. Each sample was fixed in the lower jaw of the test fixture. A length of Arthrex FiberWire Suture (Size 2) was threaded through each sample and looped around the upper jaw of the test fixture (Figure 6). A tensile force was applied to each sample by moving the upper jaw of the test fixture at a rate of 20 mm/min. Failure was defined as the point at which the suture is pulled out from the sample. Suture Pullout Strength is reported in units of N.

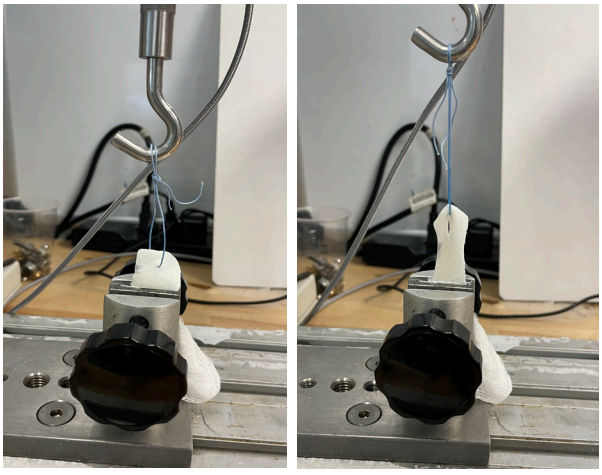

Figure 6: Puregraft Essence sample set up for Suture Pullout Strength test, before and while being pulled

RESULTS

Ultimate Tensile Strength

Puregraft Essence was found to have an Ultimate Tensile Strength of 17 ± 4.8 Mpa (Figure 7). This strength is comparable to that of other commercially available ADM products on the market (Figure 8) and significantly stronger than some of its Xenograft counterparts that are used to support some of the most demanding clinical indications such as hernia repair (Figures 12 & 13) (Deeken, 2012). The average load to failure for Puregraft Essence was 154 ± 38.5 N.

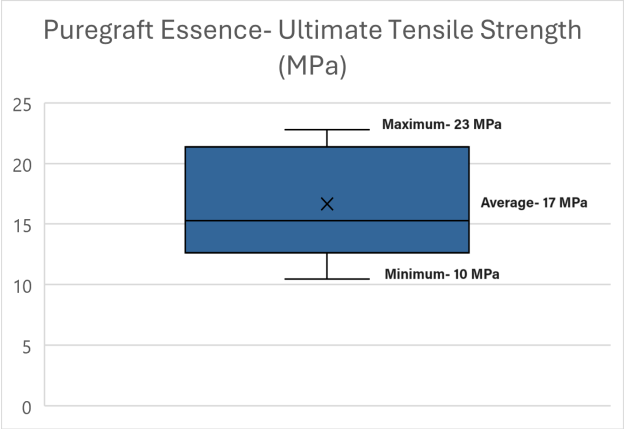

Figure 7: Ultimate Tensile Strength of PG Essence Samples

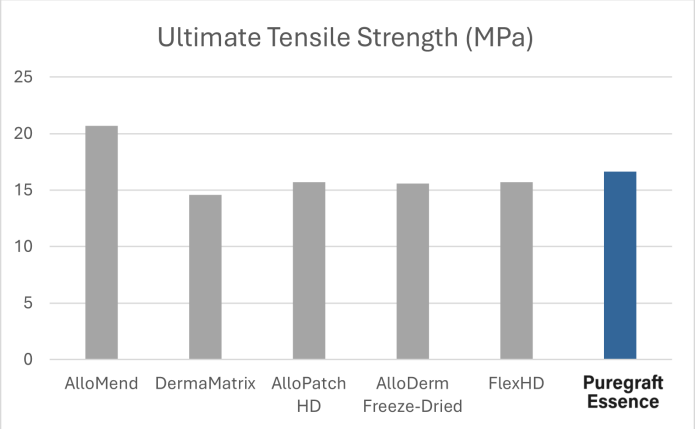

Figure 8: Ultimate Tensile Strength of Competitor ADM Products

Ball Burst Strength

Puregraft Essence was found to have a Ball Burst Force of 1228.0 ± 137.5 N (Figure 9) and a Ball Burst Strength of 635.0 ± 109.0 N/cm (Figure 10), which is a magnitude higher than is needed for abdominal wall reconstruction which is approximately 32N/cm (Zhu, 2015).

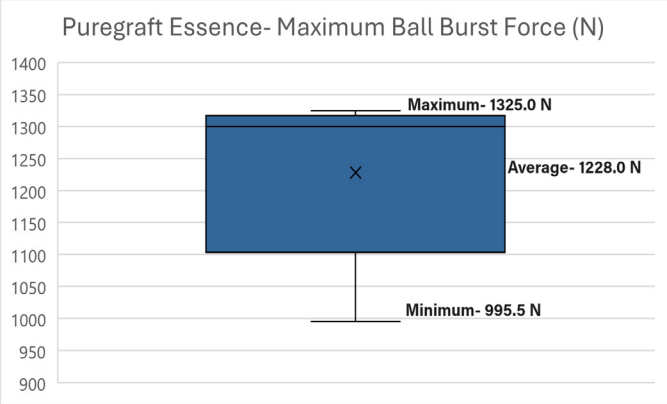

Figure 9: Ball Bull Burst Force of Puregraft Essence

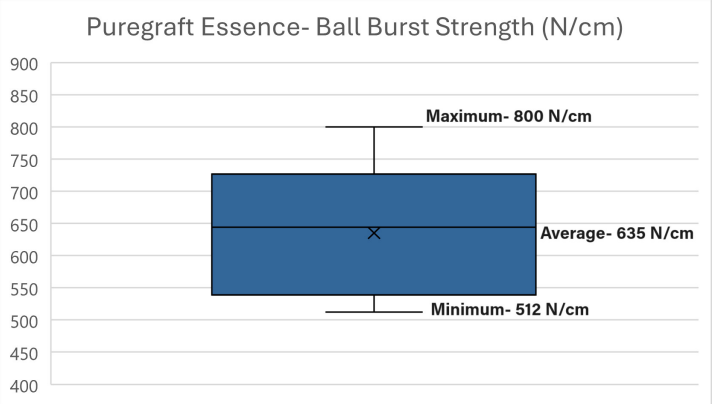

Figure 10: Ball Bull Burst Strength of Puregraft Essence

Suture Pullout Strength

Puregraft Essence was found to have a Suture Pullout Strength of 73.6 ± 27.3 N (Figure 11). This shows that Puregraft Essence is stronger than a 2.0 permanent polypropylene suture (Rashid, 2007) meaning that at the extreme, the suture would be more likely to fail before the tissue. In most cases where a flat sheet acellular dermal matrix would be used, Puregraft Essence would exceed all requirements for a secure placement.

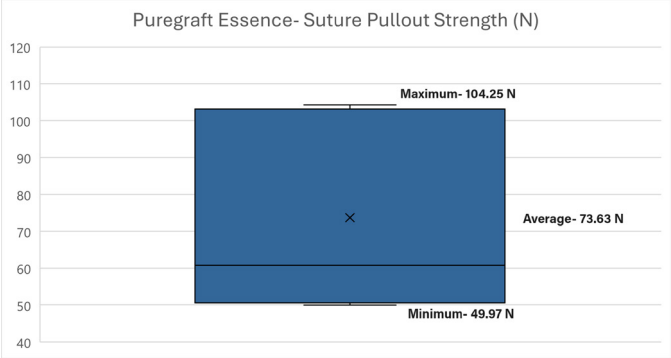

Figure 11: Suture Pullout Strength of Puregraft Essence

Results Summary

Overall, the data on the Puregraft Essence shows it has the strength characteristics needed to support pressures generally required for abdominal wall reconstruction even though Human ADM's are not generally used for that application due to other bio-molecular characteristics. In some cases, the Puregraft Essence even outperformed its thicker Xenograft counterparts (Deeken, 2012) (Figure 12 & 13). Knowing that Puregraft Essence has this strength profile shows that it can be used in a wide range of soft tissue support indications.

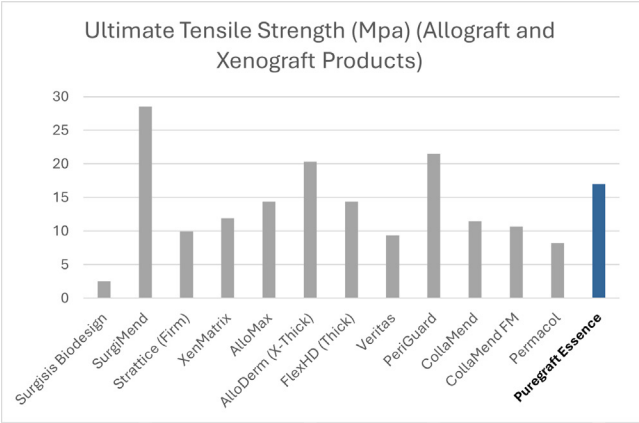

Figure 12. Ultimate Tensile Strength of Published Competitor Allograft and Xenograft ADM Products

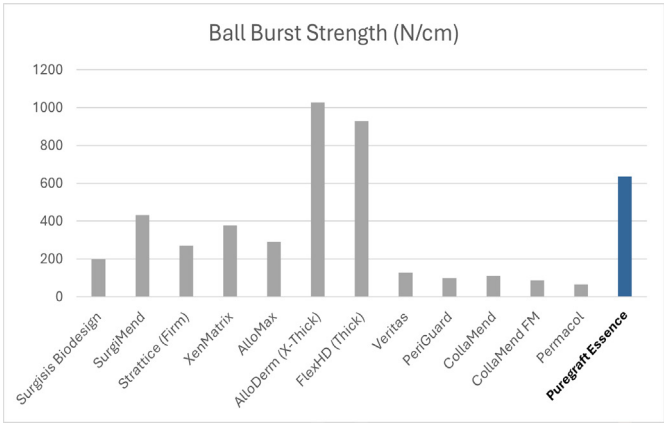

Figure 13. Ball Burst of Published Competitor Allograft and Xenograft ADM Products

DISCUSSION

Extracellular Tissue Matrices (ECM's) is a generic term used for tissue products regardless of origin (Allograft or Xenograft) or tissue type (Dermis, Pericardium, Cornea etc). Extracellular Tissue Matrices are used in several clinical indications, with a large amount of clinical data supporting its use and the benefits attributed by its regenerative properties. The researched clinical indications range from Tympanoplasty where the ECM is under very little biomechanical stress to large ventral hernia where there can be a huge demand placed on the matrix.

With this level of differentiation, no one ECM can serve all clinical indications and leads to several different design characteristics having to be considered, from tissue source and type to what thickness and shape the tissue needs to be to better serve the patient and the surgeon for the clinical indication in which it is used. With the advantage of having over 25 years of market hindsight paired with experienced surgeon input, the design of Puregraft Essence is focused on increasing the safety profile of the tissue while optimizing strength and handling characteristics.

Puregraft Essence is a terminally sterilized Acellular Dermal Matrix derived from Human Cadaveric Dermis. The human tissue is processed gently to remove donor cells but to not cause any damage to the collagen matrix with the aim of tissue compatibility to support the patients intrinsic regeneration and remodeling healing process. Being terminally sterilized to a Sterility Assurance Level (SAL) 10^{-6} is a major safety characteristic associated with all implantable medical devices, but not all tissue products. The decision to opt for this level of sterility was with the sole aim of reducing the risk of implant-associated infections, which despite rigorous donor screening, has been documented with other aseptically produced tissue products as recently as 2021 (Schwarz, 2022) and 2023 (Aziyo, 2023).

Puregraft Essence is stored pre-hydrated in sterile water. Being pre-hydrated enables Puregraft Essence to be ready to use out of the package and may help reduce OR and anesthesia time compared to dehydrated or preserved tissue products, which can either have long rehydration times or require multiple washes to reduce the preservatives out of the tissue.

With tissue thickness being the main determining factor in strength, the thickness of the matrix has a negative effect on the pliability and some evidence suggests that the thicker the ADM placed into the patient, the higher the risk of complications such as seroma and infection (Rose et al, 2016). After rigorous testing, the thickness of 0.8mm was determined to give the optimal strength and handling characteristics, while still being one of the thinnest commercially available ADM's on the market. This consistent thickness reduces the ADM volume in comparison to competitor products, which may also reduce complications clinically.

The final strength consideration in the Puregraft Essence design is the addition of perforations. Early clinical data (Osoria et al, 2014) showed that the addition of perforations increased the rate of cellular invasion without decreasing tensile strength. The data also suggests that the perforations allow for a reduction in seroma and infection (Osoria, 2014).

As stated, every characteristic must be considered when developing a tissue to optimize a patient's recovery. Puregraft Essence has shown that a product can be both strong, and pliable, which are desirable characteristics for any tissue in a surgeon's toolbox.

CONCLUSION

Using industry standard strength testing techniques, Puregraft Essence Acellular Dermal Matrix has been shown to be comparable or superior to other well-known and proven Acellular Dermal Matrices that are commercially available . These favorable biomechanical characteristics combined with superior safety features such as being terminally sterile, consistent 0.8mm thickness, and pre-hydrated, making Puregraft Essence an ideal Acellular Dermal Matrix for a wide range of clinical applications where soft tissue support or augmentation is needed.

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