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ACECONNEX® PRE-SUTURED FASCIA: STRENGTH AND FUNCTIONALITY AFTER LONG-TERM FROZEN STORAGE

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AceConnex® Pre-Sutured Fascia: Strength and Functionality After Long-Term Frozen Storage

INTRODUCTION

Hip arthroscopy is a continuously evolving field, with tremendous advancements in the last decade, especially techniques involving the restoration of labral function in the hip.[1] The use of allograft tissue for the reconstruction or augmentation of the native labrum has demonstrated favorable clinical patient outcomes[2,3], with fascia lata being a preferred allograft due to its superior handling characteristics and ability to achieve a consistent diameter.[4] However, the proper preparation of the sutured fasica lata allograft can be challenging and time consuming. In the operating room, the preparation and suturing of an allograft can take 24 to 45 minutes depending on the tissue type used[5], with longer times experienced for those who are learning the procedure or who perform the reconstructions less frequently.

To address these limitations, a pre-sutured fascia lata allograft has been developed that is accessible off-the-shelf and can be stored frozen for up to two years. The AceConnex Pre-Sutured Fascia device is derived from donated human fascia lata that is rolled into a cylinder and sutured to maintain its shape (**Figure 1**). The device is produced in three trimmable lengths to capture the needs of labral reconstruction and augmentation procedures involving partial or segmental defects (40-60 mm and 60-100 mm) and circumferential defects (60-100 mm and 100-140 mm). Each device contains two regions that can be trimmed to customize the device to fit the specific sizing needs of the patient and surgeon. In addition to the three lengths, each length comes in two different diameters (5.0 mm-5.4 mm and 5.5 mm-6.0 mm).

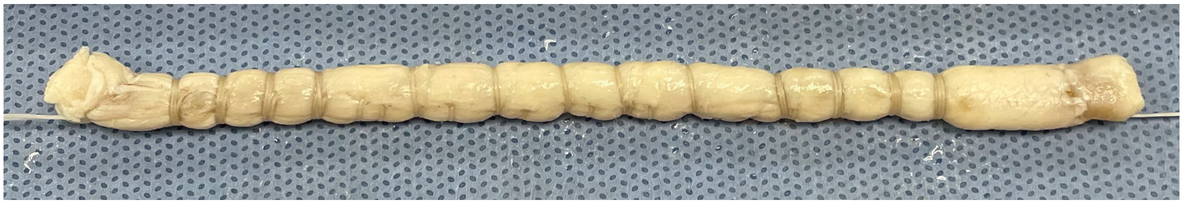

Figure 1. *An example of a 60-100 mm medium AceConnex.*

OBJECTIVE

To ensure AceConnex maintains its tissue strength and functionality, the tensile properties of the device were evaluated after extended shelf life. Extension and elasticity were evaluated using cyclic loading and ultimate tensile testing, and suture retention strength was additionally assessed.

METHODS

Sample Preparation

Samples were prepared for both tensile and suture retention strength testing. All pre-sutured fascia device samples were created from fascia lata tissue recovered from research consented donors. Fascia lata was folded and rolled to a diameter between 5-6 mm and sutured into a tubular shape utilizing size 2-0 Force Fiber® UHMPE surgical suture (Teleflex, Wayne, PA). Pre-sutured fascia devices were sterilized with low-dose electron beam irradiation and stored frozen (-40°C or colder) until use.

Test	Sample Groups	Sample Size	Sterilization Dose	Storage Time	Storage Condition
Cyclic Loading and Tensile Testing	2-Year	30	Nominal (12 kGy)	2 years	-80˚C
	Control	22	Nominal (12 kGy)	< 2 months	-80˚C
	Maximum Sterility Dose	22	Maximum (17 kGy)	1 month	-80˚C
Suture Retention Strength Testing	1-Year	30	Nominal (12 kGy)	1 year	-80˚C
	Control	29	Nominal (12 kGy)	< 6 months	-80˚C

Cyclic Loading and Tensile Testing

Cyclic loading and tensile testing were conducted on an ADMET eXpert 2613 Series Universal Testing Machine with a 100 lb load cell for cyclic loading and a 1000 lb load cell for tensile testing. The gauge length (**Figure 2A**) of all samples was standardized to 3.2 cm by measuring the central region of the device with a steel ruler and marking the edges of the range with a marker to monitor slippage. Extension was recorded as samples were cycled through 600 cycles of progressive loading from 100 cycles of 20-50 N to 100 cycles at 20-300 N, with the upper limit increasing 50 N for each 100 cycles (**Figure 2B**). Samples then underwent tensile testing to calculate tensile modulus and were preloaded to 5 N and then pulled at a rate of 10 mm/min until failure, with failure defined as a 20% drop in force (N).

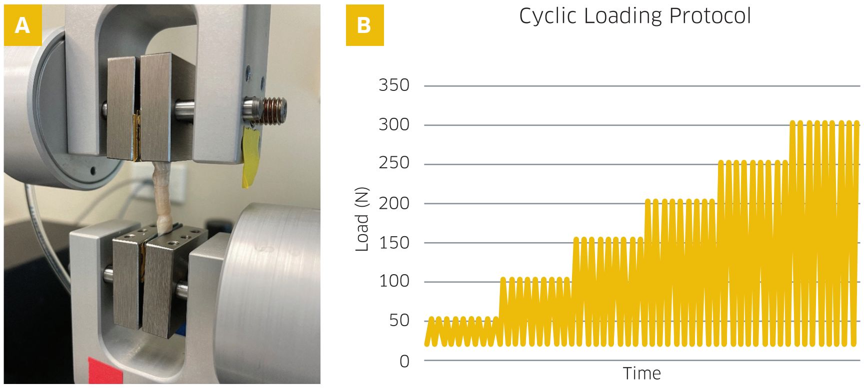

Figure 2. *(A) Sample set up with 3.2 cm gauge length between grips and (B) a representation of cyclic loading protocol (cycle number reduced for visual).*

Suture Retention Strength Testing

Suture retention strength testing was conducted on an ADMET eXpert 2613 Series Universal Testing Machine with a 100 lb load cell, utilizing a custom fixture. The fixture was designed to allow for wrap around anchoring of the sample to the fixture, simulating anchoring to the acetabular rim. Once secured to the testing fixture, a size 2 Force Fiber UHMWPE suture was passed centrally through each sample at a standardized depth of 1 mm (**Figure 3A**). The suture ends were attached to the upper fixture of the testing machine. The gauge length of the test suture loop measured between 4-6 cm. Specimens were monitored for slippage visually during testing by marking the tissue. Samples were tested at a rate of 10 mm/min and failure was defined as a drop of 20% in force (N) (**Figure 3B-D**).

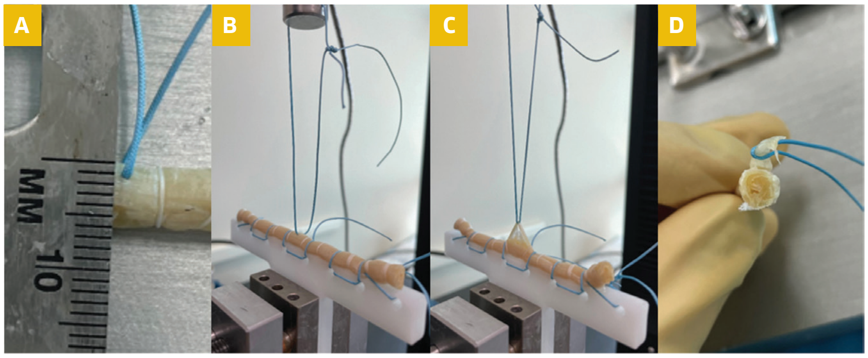

Figure 3. *Example of suture placement on sample (A), sample during testing (B-C), cross section of sample after failure (D).*

RESULTS

Tensile Testing Results

There was no significant difference in mean extension between two-year shelf life, control, and maximum dose samples during cyclic loading (**Figure 4A**). The mean extension at 300 N was 3.32 mm, 3.31 mm, and 3.21 mm for shelf-life, control, and maximum dose samples respectively. Tensile modulus (MPa) was calculated, and no significant difference was found between groups (**Figure 4B**). The stiffness of two-year AceConnex devices measured on average 192.75 (± 24.4) MPa.

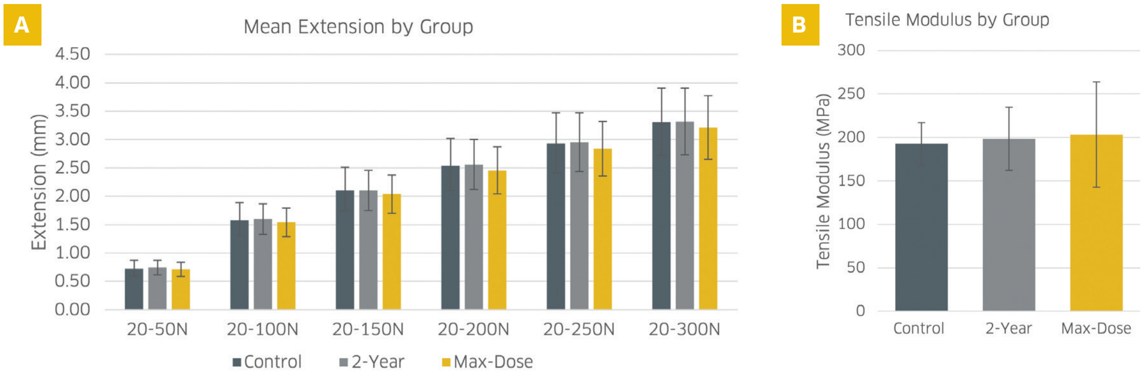

Figure 4. *(A) Mean extension of AceConnex samples by group during cyclic loading (B) tensile modulus of AceConnex samples by group.*

Suture Retention Results

No significant difference was seen in suture retention strength between one-year samples and controls (**Figure 5**). The range of maximum load at failure for all samples was 61.17–221.49 N (13.75–49.79 lbf), with the average at 140.65 N (31.62 lbf).

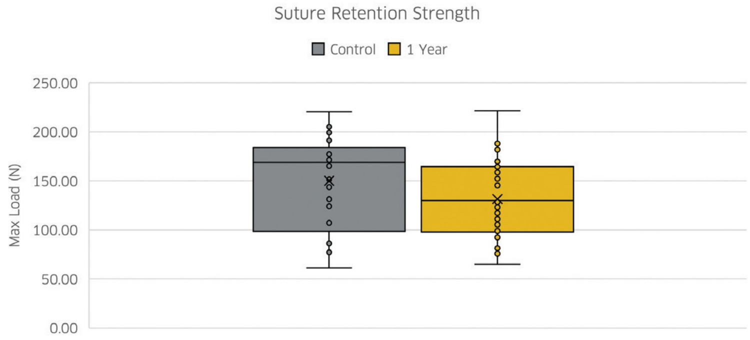

Figure 5. *Suture retention strength (N) for control and one-year shelf life samples.*

DISCUSSION

The tensile modulus of native labrum, reported by Iskiko et al, shows that more degenerative labrum is less stiff than samples considered to be the most similar to normal tissue, 39.61 (±7.9) MPa compared to 151.17 (±61.6) MPa.[6] The stiffness of AceConnex® measured on average 192.75 (± 24.4) MPa, putting it on the higher end of normal labral tissue and making it a good candidate to replace the function of native labral tissue.

Bergmann et al calculated that the average force on the total hip is 1925–2880 N for walking and 2300–3875 N for descending stairs for a person 75–100 kg.[7] The labrum has been shown to support 1–2% of the total load of the hip in normal hips and 4–11% in hips with dysplasia.[8] Taken together, these studies lead to a walking estimate of 38.5–57.6 N of force on the labrum and 46–77.5 N for descending stairs in normal hips. There were no failures of AceConnex devices during cyclic testing up to 300 N, displaying the required strength to resist the forces seen in normal hip mechanics.

CONCLUSION

The results of the cyclic loading and tensile testing paired with the suture retention testing demonstrate that AceConnex Pre-Sutured Fascia devices maintain its tensile strength and elasticity after extended frozen storage. AceConnex maintains the robust strength of fascia lata tissue in a pre-sutured format and is an excellent option for labral reconstruction and augmentation applications.

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1204-TECH [001] - 4/2024