Comparison of CONMED BioBrace® and Artelon FlexBand® for Augmentation of Soft Tissue

CONMED Bioinductive Technologies Research and Development

Objective

Augmentation of soft tissue to reinforce and improve healing has recently gained interest. The purpose of this study was to evaluate and compare the mechanical, morphological and resorption properties of two soft tissue augmentation implants, a reinforced scaffold (BioBrace®, CONMED) and a polycaprolactone-based poly(urethane urea) augmentation device (FlexBand®, Artelon).

The BioBrace® Implant is a highly porous collagen matrix reinforced with bioresorbable poly-L-lactic acid (PLLA) microfilament fibers to provide an open 3-D biologic scaffold with strength.[1] Artelon FlexBand® is a co-polymer of resorbable polycaprolactone (PCL) and non-resorbable poly(urethane urea) (PUUR) made into a knitted textile.[2]

Methods

Mechanical testing was performed via a uniaxial tensile testing setup at physiological conditions (samples were submerged in saline at 37C). Six samples were submerged for 72 hours in saline solution at 37C prior to testing. Mercury intrusion porosimetry was performed to determine implant morphology, measuring porosity, pore surface area, and pore volume of each implant. SEM cross sectional images were also taken at 25X and 100X magnifications. Absorbance was determined by soaking samples in saline solution for 5 minutes and measuring the pre-soak and post-soak weights. A literature search was also performed to compare the resorption times of each device based on the material composition of each device.

Results

Mechanical Testing

Figure 1 below summarizes the maximum load of BioBrace and FlexBand compared to literature values for the native ATFL.[3] BioBrace® and FlexBand® both have similar strength to the native ATFL.

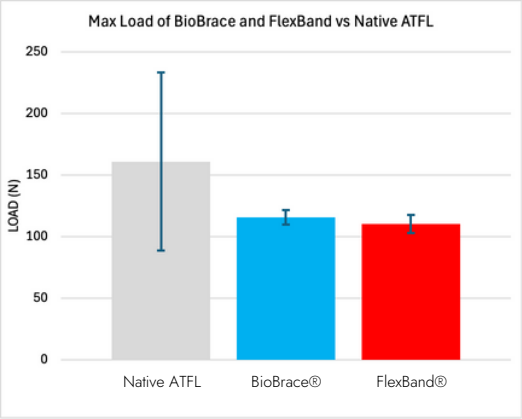

Figure 1: Maximum load of BioBrace and FlexBand compared to the Native ATFL.

Figure 2 below summarizes the stiffness of BioBrace® and FlexBand® compared to literature values for the native ATFL.[3] BioBrace® has similar stiffness to the native ATFL, whereas FlexBand® is ten times less stiff than native ATFL.

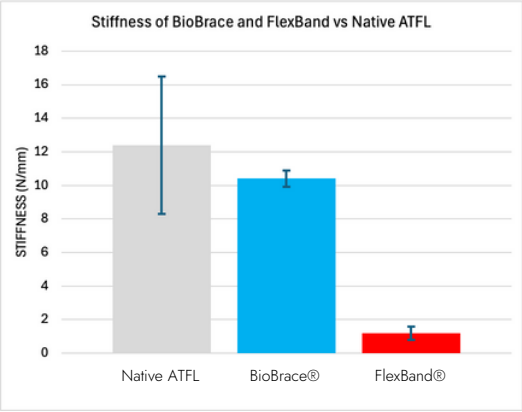

Figure 2: Stiffness of BioBrace® and FlexBand® compared to the native ATFL.

Figure 3 below summarizes the maximum displacement of BioBrace® and FlexBand®. FlexBand® displaces 3.2X the distance as BioBrace®. While not reported by Waldrop et al, the approximate displacement of the native ATFL based on the average maximum load and stiffness is approximately 13mm.[3] The clinical significance is further explained in the discussion below.

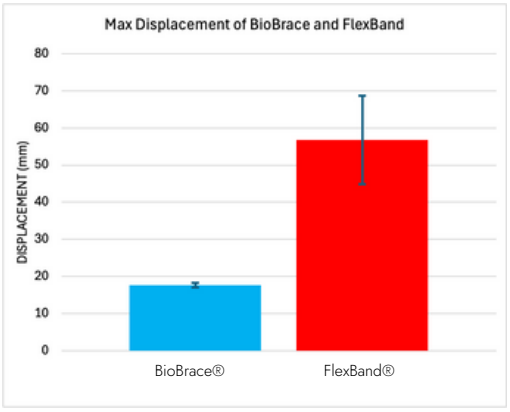

Figure 3: Maximum displacement of BioBrace® and FlexBand®.

Morphology Measurements

Table 1 below summarizes the morphology taking into consideration functional porosity (pores over 10 um in diameter). The BioBrace® has higher overall porosity, >3X more volume for tissue ingrowth and an order of magnitude (>10X) more surface area than FlexBand®.[4]

Parameter	**BioBrace®**	**FlexBand®**
Porosity (%)	80%	66%
Pore Volume (pores >10 um)	2.6 cc/g	0.8 cc/g
Surface Area (pores >10 um)	0.6 m2/g	0.05 m2/g

Table 1: Summary of device morphology.

SEM Imaging

Figure 4 and Figure 5 below show transverse cross sections of each device at 100X magnification and at 25X magnification.

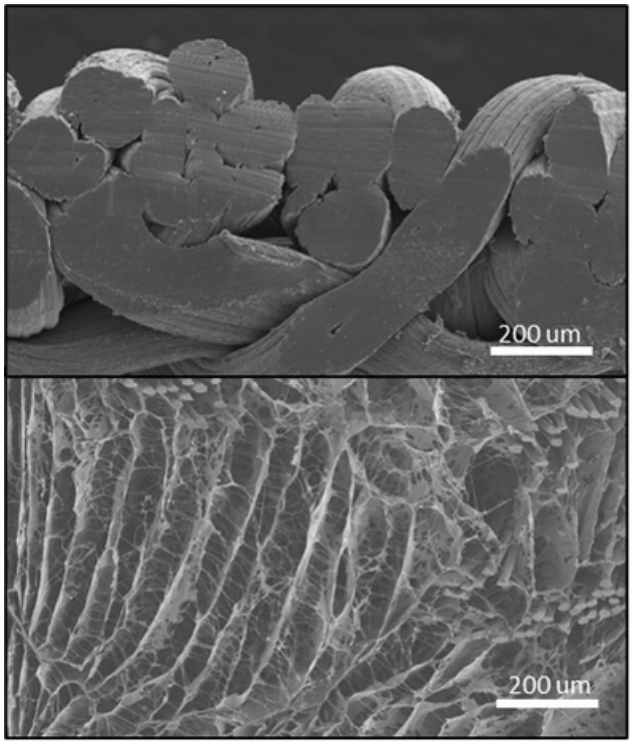

Figure 4: Cross sectional SEM images of FlexBand® (Top) and BioBrace® (Bottom) at 25X.

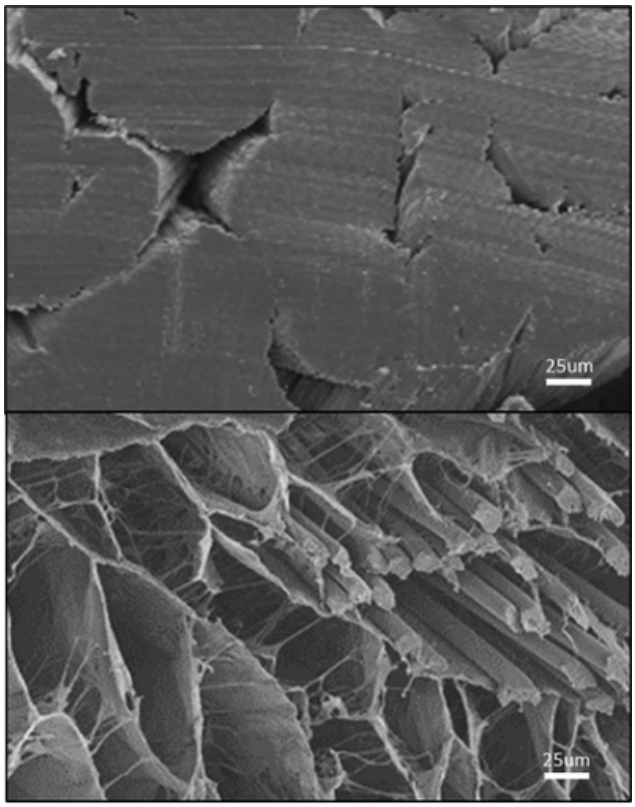

Figure 5: Cross sectional SEM images of FlexBand® (Top) and BioBrace® (Bottom) at 100X.

Absorbance

Figure 4 summarizes the % Absorbance of BioBrace® and FlexBand® after being soaked in saline solution for 5 minutes. Absorbance was calculated by subtracting the pre-soak device weight from the post-soak device weight and dividing the result by the pre-soak device weight. BioBrace® absorbed 370% of its pre-soak device weight in fluid, while FlexBand® absorbed only 70% of its pre-soak device weight in fluid. The devices had similar pre-soak device weights.

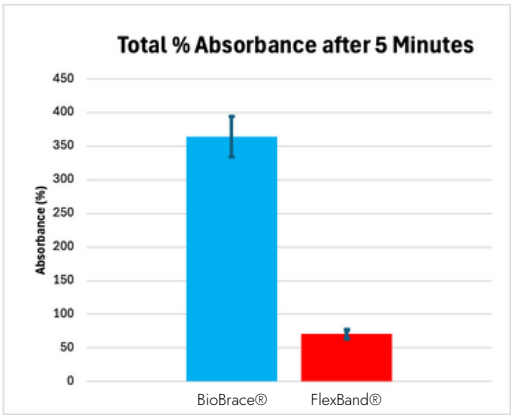

Figure 6: Total % Absorbance of BioBrace® and FlexBand® after being soaked in saline solution.

Material Composition and Resorption

Table 2 below summarizes the material composition and resorption profile of each device based on published data.

Device	Material Composition	Resorption Profile
BioBrace®	Type 1 Collagen Poly-L-Lactic Acid (PLLA) Microfilaments	Type 1 Collagen: 10 Weeks[4] PLLA: 100% strength loss by 156 weeks, fully resorbable[1]
FlexBand®	Polycaprolactone – based Poly-urethane urea (PCL-PUUR)	Device provides 50% strength after 4 years[5] PCL fraction is absorbable, PUUR fraction remains permanently[2,5,6]

Table 2: Summary of resorption properties for each device.

Discussion

BioBrace and FlexBand® have similar strengths to the native ATFL. However, BioBrace® has similar stiffness to the native ATFL whereas FlexBand® is 10 times less stiff then the native ATFL. As a result, FlexBand displaces to an average 57mm compared to BioBrace® at an average of 18mm. The approximate displacement of the native ATFL based on the average maximum load and stiffness reported by Waldrop et al is approximately 13mm.[3] This means that additional strength beyond that displacement is clinically irrelevant. The maximum load of FlexBand is well beyond this clinically relevant distance. While the maximum load of FlexBand® is similar to that of native ATFL, the maximum load value is clinically irrelevant since it occurs at a displacement where the native ATFL has failed. Overall, BioBrace® more closely mimics the biomechanics of the native ATFL and provides sufficient stiffness to reinforce the native ATFL at a clinically relevant displacement.

The morphology measurements of each device revealed that BioBrace has higher porosity, >3X more pore volume for tissue ingrowth and an order of magnitude (>10X) more surface area for cellular attachment versus FlexBand, which results in rapid formation of new host tissue within, below and above the device as demonstrated elsewhere.[1,7,8,9,10] Only functional porosity was considered in the calculation of these different values. Functional porosity is defined as the pore volume and surface area associated with pores with a diameter greater than 10 um. Literature shows fibroblasts, an important cell involved in tissue regenerating and healing, to be between 10-15um in diameter.[11,12,13,14] It has also been reported that no evidence of tissue ingrowth occurred in scaffolds containing pores less than 10um in diameter, and that polymer degradation occurred in some scaffolds with 10-15 um pores before tissue ingrowth was completed.[15,16]

The difference in morphological properties can be visualized with the SEM images in Figures 4 and 5. At the same magnification, BioBrace® shows a significant amount of open space within the highly porous collagen matrix. FlexBand® only consists of large fibers, with open space created only from the gaps in between those fibers. The microfilament fibers within BioBrace® are oriented in the X, Y and Z direction.

This provides height to the scaffold, while allowing the space within the scaffold to be maintained under tension. Furthermore, the spacing of the PLLA microfilament fibers form channels in the direction of device loading, meaning that tissue growth within the scaffold is able to be mechanically loaded throughout the healing process.

The effect of the differences in morphology is further illustrated by the results of the absorbance test. BioBrace absorbed significantly more saline solution versus FlexBand® (370% vs 70%, respectively) after being submerged for 5 minutes. Overall, BioBrace® has a higher capacity for cellular attachment, tissue ingrowth and fluid absorbance than FlexBand®.

In terms of resorption, BioBrace® provides strength for 2 years and then fully resorbs. As some soft tissue injuries take 2 years to heal fully, BioBrace® provides strength throughout the entire healing process. FlexBand® retains 50% of its strength after 4 years, with the non-resorbable fraction of the device remaining permanently.[2,5,6] The material biocompatibility and permanent nature of the co-polymer material may lead to post-operative complications, as there have been cases reported of Artelon removal post-implantation due to swelling and persistent pain in the knee and hand, with some authors recommending against its use.[5,17,18,19,20,21,22] In one case report of an Achilles repair augmented with Artelon, the author suggested that the Artelon material 'may act as a barrier against proper tendon healing.'[23]

Conclusion

The results of this evaluation demonstrated that compared to FlexBand®, BioBrace® has more similar mechanical properties to native tissue and provides clinically relevant strength, higher porosity and pore volume for tissue ingrowth, surface area for cellular attachment, higher fluid absorbance, and is a made of fully resorbable materials.

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