A PILOT STUDY COMPARING CYCLIC LOADING AND ELONGATION PROPERTIES OF TISSUE AUGMENTATION SCAFFOLDS

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INTRODUCTION

The use of collagen based scaffolds for the reinforcement of tendon repairs has gained interest in recent years due to advances in processing technologies and the clinical need to restore damaged tissues. Scaffold materials vary in terms of origin and processing, and thus exhibit different performance characteristics. Tendons often experience stretch and extension in a wide range of strain rates in the body[1], lending them to exhibit viscoelastic load-elongation behavior with a defined toe region (lengthening of crimped collagen fibers) followed by an elastic region (loading of lengthened fibers). When utilizing a collagen based scaffold for tendon reinforcement, viscoelastic behavior should be considered as it relates biomechanically to the repair construct. A scaffold possessing viscoelastic behavior that closely resemble native tendon may increase mechanical compatibility and load sharing during the healing process and potentially enhance the surgical outcomes. Viscoelastic behavior of collagen based scaffolds for the reinforcement of tendon repairs may be an important factor when considering repair integrity, potential reduction of re-injury and maintaining the normal physical motion of the body[2].

The focus of this pilot study was to evaluate and compare load-elongation viscoelastic behavior of two commercially available collagen based implants. Samples were analyzed for elongation in the toe and elastic regions when subject to a 120N tensile load. Plastic deformation was also evaluated as a result of cyclic loading from 5-120N for 30 cycles. The upper load limit of 120N was chosen because it is clinically relevant to rotator cuff abduction forces and so that consistent loading curves could be generated without specimen slippage from the test grips during cyclic loading.

MATERIALS & METHODS

Commercially available product was obtained for testing and is summarized in Table 1. Four samples each of the OrthADAPT® Bioimplant and GraftJacket® Regenerative Tissue Matrix (RTM) were treated in saline according to the Instructions for Use (IFU) prior to testing. GraftJacket® samples were cut with a scalpel to 4cm x 5cm to match the dimensions of the OrthADAPT® Bioimplant. Specimens were placed centrally in the test grips with a 2cm gauge length and testing was performed in a saline bath at 37°C to simulate a physiological environment. Specimens were subject to cyclic loading (5-120N) at a test speed of 12.5 mm/min for 30 cycles and analyzed for load-elongation following 1 cycle and for permanent deformation following 30 cycles.

Table 1: Summary of Products Tested

COMPANY	PRODUCT	MATERIAL	SIZE	THICKNESS*
Synovis Orthopedic and Woundcare, Inc.	OrthADAPT® Bioimplant	Equine Pericardium	4 cm x 5 cm	>0.5 mm
Wright Medical Technology, Inc.	GraftJacket® Regenerative Tissue Matrix	Human Dermis	5 cm x 5 cm	0.63 mm – 1.40 mm

* As specified by the manufacturer.

RESULTS

The data is reported as mean values in terms of "toe region" elongation and elongation at 120N in Table 2. Upon loading to 120N, the OrthADAPT® Bioimplant exhibited 16% (SD=3%) elongation in the toe region and a total elongation of 32% (SD=6%), whereas the GraftJacket® RTM showed 52% (SD=16%) elongation in the toe region and a total elongation of 76% (SD=32%). Load-elongation curves for each material during the first cycle are shown in Figure 1.

Table 2: Loading-Elongation Behavior of Collagen Based Implants

SPECIMEN	Elongation (%)	
	Toe Region	@ 120N
OrthADAPT® Bioimplant (4cm x 5cm)	16	32
GraftJacket® RTM (cut to 4cm x 5cm)	52	76

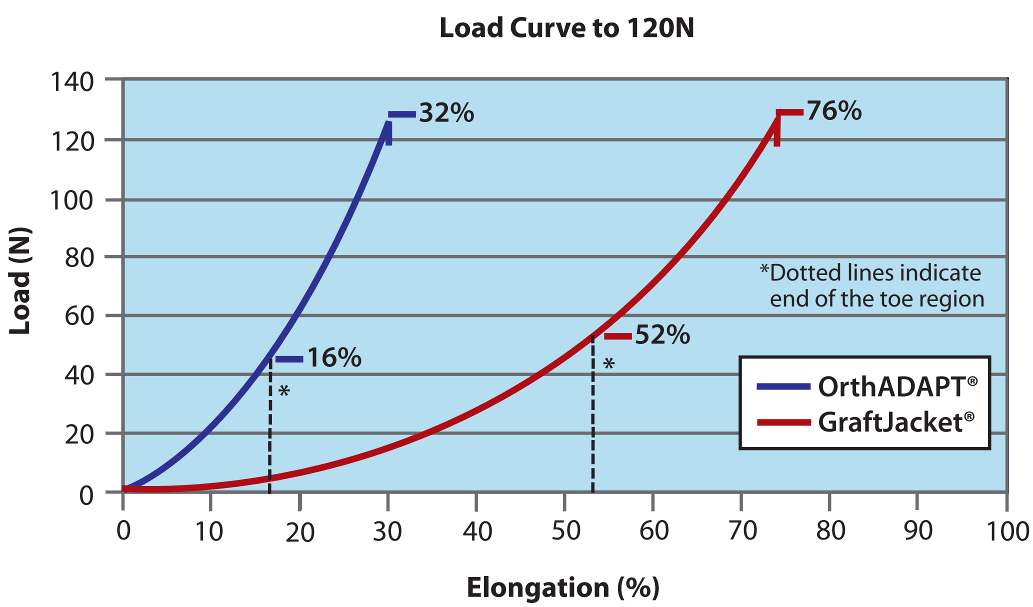

Figure 1: Load-elongation curve comparing the collagen based implants.

The results of the deformation analysis are shown in Table 3. As demonstrated in Figure 2, after 30 cycles (5-120N) the OrthADAPT® Bioimplant showed no permanent deformation while GraftJacket® RTM showed 21% (SD=8%) permanent deformation.

Table 3: Resultant Permanent Deformation Following 30 Cycles (5-120N)

SPECIMEN	% Permanent Deformation @ 120 N after 30 cycles (5-120N)	
	Mean	SD
OrthADAPT® Bioimplant (4cm x 5cm)	0	0
GraftJacket® RTM (cut to 4cm x 5cm)	21	8

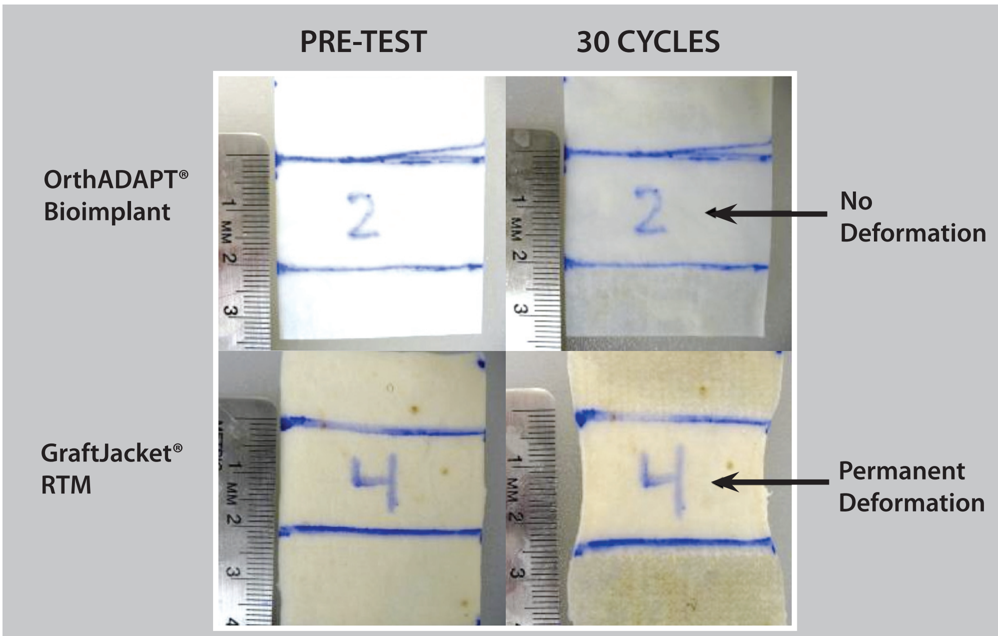

Figure 2: Permanent deformation of GraftJacket® RTM after cyclic loading.

DISCUSSION

The results of this study show that when loaded in tension to 120N, the elongation of the OrthADAPT® Bioimplant (16% toe region, 32% @120N) is significantly less than that of the GraftJacket® RTM (52% toe region, 76% @120N). Elongation of human tendon under load is reported to be up to 2% in the toe region and up to 8-10% in the elastic region before macroscopic failure occurs[5]. Although both implants in this study showed greater elongation than what is reported for human tendon it is clear that the load-elongation behavior of the OrthADAPT® Bioimplant more closely resembles that of the human tendon than the GraftJacket® RTM. The mechanical behavior demonstrated by the OrthADAPT® Bioimplant in this study indicates that the implant can functionally contribute to load sharing in the reinforcement of tendon repairs, whereas the GraftJacket® RTM will undergo significant elongation a functional contribution to the repair is realized.

After cyclic loading (30 cycles @120N) the OrthADAPT® Bioimplant showed no permanent deformation. GraftJacket® RTM showed permanent deformation of 21% in the direction of the applied load. Implants that do not deform under clinical loads and maintain the mechanical integrity and biomechanical function of the repair construct throughout the healing process may be beneficial for the reinforcement of tendon repairs.

It is hypothesized that a collagen based scaffold used to reinforce a tendon repair construct should possess similar viscoelastic behavior as a normal tendon to provide the same function[3]. The viscoelastic behavior of the OrthADAPT® Bioimplant may be more functionally suitable for the reinforcement of tendon repair than the GraftJacket® RTM because its viscoelastic load–elongation behavior more closely resembles that of human tendon.

CONCLUSIONS

- OrthADAPT® Bioimplant samples exhibited significantly less elongation than GraftJacket® RTM samples in both the toe region and total elongation up to a load of 120N.
- OrthADAPT® Bioimplant samples showed no permanent deformation after 30 load cycles (5-120N) whereas GraftJacket® RTM samples showed 21% plastic deformation.
- OrthADAPT® Bioimplant may be more appropriate than GraftJacket® RTM for the reinforcement of tendon repairs due to load-elongation behavior that more closely resembles that of human tendon reported in the literature.

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