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ORIGINAL ARTICLE

Characterizing the macro and micro mechanical properties of scaffolds for rotator cuff repair

Richard D.J. Smith, PhD*, Nasim Zargar, PhD, Cameron P. Brown, PhD, Navraj S. Nagra, MBBS, Stephanie G. Dakin, PhD, Sarah J.B. Snelling, PhD, Osnat Hakimi, PhD, Andrew Carr, DSc

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

Background: Retearing after rotator cuff surgery is a major clinical problem. Numerous scaffolds are being used to try to reduce retear rates. However, few have demonstrated clinical efficacy. We hypothesize that this lack of efficacy is due to insufficient mechanical properties. Therefore, we compared the macro and nano/micro mechanical properties of 7 commercially available scaffolds to those of the human supraspinatus tendons, whose function they seek to restore.

Methods: The clinically approved scaffolds tested were X-Repair, LARS ligament, Poly-Tape, BioFiber, GraftJacket, Permacol, and Conexa. Fresh frozen cadaveric human supraspinatus tendon samples were used. Macro mechanical properties were determined through tensile testing and rheometry. Scanning probe microscopy and scanning electron microscopy were performed to assess properties of materials at the nano/microscale (morphology, Young modulus, loss tangent).

Results: None of the scaffolds tested adequately approximated both the macro and micro mechanical properties of human supraspinatus tendon. Macroscale mechanical properties were insufficient to restore load-bearing function. The best-performing scaffolds on the macroscale (X-Repair, LARS ligament) had poor nano/microscale properties. Scaffolds approximating tendon properties on the nano/microscale (BioFiber, biologic scaffolds) had poor macroscale properties.

Conclusion: Existing scaffolds failed to adequately approximate the mechanical properties of human supraspinatus tendons. Combining the macroscopic mechanical properties of a synthetic scaffold with the micro mechanical properties of biologic scaffold could better achieve this goal. Future work should focus on advancing techniques to create new scaffolds with more desirable mechanical properties. This may help improve outcomes for rotator cuff surgery patients.

Level of evidence: Basic Science Study; Biomechanics

Keywords: Scaffolds; rotator cuff; mechanical properties; biomaterials; supraspinatus tendon; surgical repair

Retearing after surgical rotator cuff repair is a significant clinical problem. Whereas developments in surgical techniques[13,60] have improved clinical outcomes, retear rates have been reported between 11%[39] and 94%,[20] with an average of 39%.[9-11,19-21,34-39,46,59,61,64] Factors positively correlated with rotator cuff retearing include tear size,[8,15,18,28,29,61] patient

For cadaveric specimens, ethical approval was received from Cambridgeshire and Hertfordshire Health Research Authority: Ethics No. 15/EE/0304.

*Reprint requests: Richard D.J. Smith, PhD, The Botnar Research Centre, University of Oxford, Nuffield Orthopaedic Centre, Oxford OX3 7LD, UK.

E-mail address: richard_smith@post.harvard.edu (R.D.J. Smith).

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age,[10,11,15,28,44] and magnitude of fatty infiltration.[23] Patients who retear can have increased pain and reduced function.[21]

In an effort to reduce retear rates, a number of rotator cuff scaffolds have been used. Scaffolds are used to provide mechanical support and also, theoretically, to enhance the native biologic healing processes. Currently, >20 scaffolds are commercially available for surgical rotator cuff repair. These can broadly be categorized into 3 different types: synthetic, biologic, and biosynthetic. Synthetic scaffolds can be absorbable or nonabsorbable, depending on the polymer from which they are made. Examples of synthetic scaffolds include X-Repair (Synthasome, San Diego, CA, USA), LARS ligament (LARS, Arc-sur-Tille, Burgundy, France), Poly-Tape (Xiros plc, Neoligaments, Leeds, UK), and BioFiber (Tornier, Edina, MN, USA). In contrast, biologic scaffolds are derived from decellularized mammalian tissues such as dermis, small intestine submucosa, and fascia lata. Biologic scaffolds can retain proteins from the original tissue that provide instructive cues to host cells.[3,4,58] Examples include GraftJacket (LifeCell, Branchburg, NJ, USA), Permacol (also known as Zimmer Collagen Repair Patch; Tissue Science Laboratories, Aldershot, Hampshire, UK), and Conexa (Tornier). Biosynthetic scaffolds are a combination of synthetic and biologic scaffolds, and BioFiber-CM (Tornier) is a commercially available example.

Even though scaffolds have been commercially available for the past 3 decades, few have demonstrated clinical efficacy in the context of surgical rotator cuff repair. Whereas some clinical studies have yielded promising results,[2,25,47,50] only 2 prospective randomized controlled trials have been conducted,[6,30] one supporting scaffold augmentation,[6] one opposing scaffold use.[30] As currently available scaffolds were not designed for the loading environment of the rotator cuff, this lack of reported efficacy might be explained by the inadequate mechanical properties of commercial scaffolds.

A number of previous studies have investigated the mechanical properties of scaffolds.[1,5,7,14,17] However, no study has directly compared the mechanical properties of scaffolds with those of human supraspinatus tendon, whose function they seek to restore. Furthermore, no previous study has characterized the properties of available scaffolds at the nano/microscale, which may help to understand how scaffolds influence biologic responses.

Hypothesizing that commercially available scaffolds cannot reproduce the mechanical function of the native tissue, we compared the macroscale and nano/microscale mechanical properties of 7 commercially available scaffolds to human supraspinatus tendons.

Materials and methods

Material selection and preparation

Seven different scaffolds were selected for this study (Table I) primarily on the basis of popularity of clinical use. In addition, synthetic, biologic, and biosynthetic scaffolds were selected to represent the 3 main types of scaffold that are currently available (Table I). All scaffolds were prepared according to the manufacturer's instructions. Samples were soaked in phosphate-buffered saline (Sigma-Aldrich, St. Louis, MO, USA) for 5 minutes and then briefly dabbed dry with a paper towel before testing.

Supraspinatus tendons were extracted from 5 fresh frozen human cadaveric specimens aged 60-93 (mean, 76.4) years. Samples included in the study had no macroscopic signs of tissue damage.

Scanning electron microscopy

Two samples measuring 0.5 × 0.5 cm of each scaffold and supraspinatus tendon were prepared for scanning electron microscopy. Samples were fixed in 2.5% glutaraldehyde (Sigma-Aldrich) for 10 minutes. Samples were rinsed twice in deionized water before being dehydrated through a graded ethanol (Sigma-Aldrich) series for 2 minutes at each concentration (40%, 70%, 90%, 95%, 100%). Next, 100 μL of hexamethyldisilazane (Alfa Aesar, Ward Hill, MA, USA) was added to each sample and left for 24 hours. Samples were coated

Table I Information about materials used

Name	Manufacturer	Material	Uncut length × width (mm)	Thickness (mm)
X-Repair	Synthasome (San Diego, CA, USA)	Poly-L-lactic acid	43 × 12	1.39 ± 0.21
LARS ligament	LARS (Arc-sur-Tille, Burgundy, France)	Polyethylene terephthalate	170* × 30*	0.80 ± 0.13
Poly-Tape	Xiros plc, Neoligaments (Leeds, UK)	Polyethylene terephthalate	500 × 40	0.47 ± 0.15
BioFiber	Tornier (Edina, MN, USA)	Poly-4-hydroxybutyrate	50 × 25	1.11 ± 0.19
GraftJacket	LifeCell (Branchburg, NJ, USA)	Human dermis	70 × 40	1.56 ± 0.14
Permacol	Tissue Science Laboratories (Aldershot, Hampshire, UK)	Porcine dermis	50 × 50	1.20 ± 0.16
Conexa	Tornier (Edina, MN, USA)	Porcine dermis	50 × 50	1.36 ± 0.08
Human supraspinatus tendon		Human tendon	—	2.00 ± 0.33

* Represents approximate measurements.