Biomechanical Testing of Commercially Available Soft-Tissue Augmentation Materials

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Purpose: To evaluate several physical properties and physical dimensions of commercially available soft-tissue augmentation devices. Methods: After 2 × 5-cm strips of several graft materials were hydrated, load elongation, cyclic and permanent displacement, percent elastic displacement, tensile modulus, stiffness, and ultimate load-to-failure strength were determined. With a 5-N preload, 30 cyclic loads between 5 N and 50 N were applied at 12.5 mm/s followed by destructive testing. A vertical stitch suture retention test was also performed. Results: SportMesh (Biomet Sports Medicine, Warsaw, IN) displaced more than any other material (P < .001). GraftJacket MaxForce Extreme (Wright Medical Technology, Arlington, TN) and Allopatch HD 2 (Musculoskeletal Tissue Foundation, Edison, NJ) displaced more than RC Allograft (Arthrex, Naples, FL) (P < .05). Percent elastic deformation did not differ among these materials. OrthAdapt (Pegasus Biologies, Irvine CA) had a higher tensile modulus than RC Allograft, SportMesh, and Allopatch HD 2 (P < .001). Allopatch HD 1 and GraftJacket MaxForce Extreme had a higher tensile modulus than RC Allograft and SportMesh. GraftJacket MaxForce had a higher tensile modulus than RC Allograft (P < .001). GraftJacket MaxForce Extreme stiffness was greater than that of OrthAdapt and SportMesh (P < .001), and GraftJacket MaxForce, RC Allograft, Allopatch HD 1, and Allopatch HD 2 stiffness was greater than that of SportMesh (P < .001). The ultimate strength of GraftJacket MaxForce, GraftJacket MaxForce Extreme, Allopatch HD 1, and Allopatch HD 2 was greater than that of OrthAdapt and SportMesh (P < .05). Acellular human collagen matrix grafts (GraftJacket and Allopatch HD) showed greater suture retention strength than RC Allograft and SportMesh, which were both stronger than OrthAdapt (P < .05). Conclusions: The acellular human collagen matrix grafts showed greater elongation than the cuff tendon allograft (RC Allograft), although SportMesh elongated more than all other materials tested. The tensile modulus, which is “normalized” to eliminate differences in the size of the tissue tested, was greater for the OrthAdapt material than for GraftJacket, Allopatch, RC Allograft, and SportMesh. Suture retention strength was greatest in the acellular human collagen matrix grafts (GraftJacket and Allopatch), whereas both SportMesh and RC Allograft had greater suture retention strength than OrthAdapt. Clinical Relevance: Acellular human collagen matrix grafts (GraftJacket and Allopatch) are stronger after cyclic loading than SportMesh and OrthAdapt and show greater stiffness. Key Words: Scaffold—Tendon graft—Biomechanical test—GraftJacket—OrthAdapt—SportMesh.

Surgical repair of complete and chronic tendon tears frequently involves working with degenerative, frayed tissue, which may be retracted, unable to withstand normal activities, and subject to failure after primary repair.1-3 Augmentation of damaged tendons with grafts may provide additional stability, leading to increased rates of healing.4-7 Tendon augmentation with tissue autografts or tendon transfers is possible but has the disadvantage of donor-site morbidity. Allograft, xenograft, and synthetic materials are currently available for tissue augmentation.5-8-9 Commercially available products may be further classified. Allograft material can be of dermal or tendon origin. Xenografts can be from submucosal, dermal, or pericardial materials; in addition, various synthetic polymers are being developed to fill this role. Some previously available graft materials have been withdrawn from the market. Many factors should be considered

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Supported by grants from Arthrex, Wright Medical Technology, Musculoskeletal Tissue Foundation, Allosource, Pegasus Biologies, and Biomet Sports Medicine. Research was performed at Arthrex. The authors report no conflict of interest.
Received November 29, 2008; accepted May 26, 2009.
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© 2009 by the Arthroscopy Association of North America 0749-8063/09/$36.00/0 doi:10.1016/j.arthro.2009.05.012
when choosing an augmentation graft, including tissue origin, graft processing, cross linking, clinical experience, and physical properties. In addition to providing a scaffold to support tissue remodeling, augmentation supposes a higher load to failure in comparison to frail and injured tissue and allows the grafts to gradually become incorporated into the tendon repair over time, thus avoiding stress shielding.8

The biomechanical properties of tendon augmentation grafts have been studied in the past,10-11 and dermal human allografts (GraftJacket; Wright Medical Technology, Arlington, TN) have been shown to have higher suture retention properties than xenograft materials.12 In vivo animal data support the use of acellular dermal matrix grafts for repair of full-thickness rotator cuff defects.13 In addition to suture retention, information about other physical properties and behavior will help surgeons in the selection and evaluation of tendon augmentation grafts. The hypothesis of this study was that different tissue grafts would show different mechanical properties that would influence their selection as augmentations of different target tendons.

METHODS

Commercially available augmentation tissues were obtained for testing. The materials were removed from their packages at the time of testing and cut into 2-cm-wide and 5-cm-long strips.12 Specimens were hydrated for the recommended interval or rinsed appropriately following the manufacturers' guidelines in normal saline solution before testing. The specimens were kept saturated with saline solution to avoid drying. Submersion in a water bath was not needed to re-create a clinical environment because of the brevity of the test interval. The physical dimensions, including thickness, of all tested materials were recorded.

The load elongation properties after cyclic loading including cyclic displacement and permanent displacement, the percentage of the overall displacement that was "elastic," tensile modulus, stiffness, and ultimate load-to-failure strength were tested on separate 2 × 5-cm strips of the test materials. With an Instron 8871 hydraulic testing machine (Instron, Canton, MA), pressure clamps were used to grip both ends of the prepared tissue strips with a 2-cm gap (Fig 1). A preload of 5 N was applied, and then cyclic loads between 5 N and 50 N were applied for 30 cycles at 12.5 mm/s. Afterward, a final destructive test was performed, also at a distraction rate of 12.5 mm/s. At least 9 separate specimen tests for each material were performed. This was consistent with a prior testing protocol.12

A simple vertical stitch suture retention test was also performed when sufficient test material was available. Allopatch HD 1 (Musculoskeletal Tissue Foundation, Edison, NJ) was not tested because of insufficient materials. A single simple suture of No. 2 FiberWire (Arthrex, Naples, FL) was passed through the distal end of the test material 5 mm from the tissue edge. A simple suture rather than a mattress suture was used because the mattress stitch had previously been tested and recent data have suggested that 2 simple sutures may be more effective in securing tissue than a single mattress suture.14-15 The suture was not tied but was wrapped around a specially designed suture-holding fixator, which mechanically clamped the suture before destructive testing with a test gauge of 30 mm. The tissue end was held firmly in a tissue clamp by an Instron 5544 machine (Fig 2). A single-pull destructive test was conducted with a distraction force applied at 12.5 mm/s. The mode of failure and load to failure were recorded.

The 6 tested materials were the GraftJacket MaxForce and GraftJacket MaxForce Extreme (Wright Medical, Arlington, TN), SportMesh (Biomet Sports Medicine, Warsaw, IN), OrthAdapt (Pegasus Biologies, Irvine, CA), Allopatch HD (2 thicknesses), and the RC Allograft (Arthrex).

The GraftJacket products are acellular dermal matrix allografts produced from human skin by use of
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American Association of Tissue Banks–approved tissues banks. The skin is processed to remove epidermal and dermal cells but preserve collagen types I, III, IV, and VII; elastin; proteoglycans; and fibroblast growth factor. GraftJacket allografts are available in both 5 × 5–cm and 5 × 10–cm sheets and in various average thicknesses. The MaxForce grafts averaged 1.4 mm thick (range, 1.27 to 1.78 mm), and the GraftJacket MaxForce Extreme grafts averaged 2.0 mm thick (range, 1.78 to 2.25 mm). This material required hydration for 15 minutes before testing.

The SportMesh graft is a knitted polyurethane urea fabric made from Artelon fibers (Artimplant AB, Frölunda, Sweden) and distributed by Biomet Sports Medicine. It is available in sheets measuring 4 × 6 cm and is 0.8 mm thick. This is a synthetic material that is sterilized with a dose of 25 kGy of electron beam radiation. Before use, it was soaked in saline solution at room temperature for 5 minutes.

OrthAdapt is an equine pericardium xenograft that is cross linked to add strength and contains 90% type I collagen and 10% type III collagen. It is processed acellular pericardial tissue and not irradiated. The device measures about 0.5 mm thick and comes in 3 × 3–cm or 4 × 5–cm sheets.

Allopatch HD is another acellular human collagen matrix allograft for augmentation of soft-tissue repairs obtained from human fascia lata from the American Association of Tissue Banks. Two thicknesses were used for testing, averaging about 1 mm (range, 0.8 mm to 1.7 mm) and 2 mm (range, 1.8 mm to 2.4 mm) thick. The tested material came in sheets measuring 5 × 5 cm and was packaged in 70% ethanol. It did not need hydration.

The RC Allograft is provided to Arthrex by Allograft Tissue Systems (Bonita Springs, FL) and is a freeze-dried human rotator cuff tendon allograft. After donor screening, the tissue is aseptically recovered and cleansed with the AlloWash (Allograft Tissue Systems) process to reduce or eliminate bacteria, marrow elements, and lipids. The device varies from 2 to 3 mm thick and comes in 2 × 3–cm sheets.

The first endpoint was to measure the material elongation of the clamped test strips occurring during the cyclic loading phase. The initial baseline separation of the clamps was determined after the first cycle. An initial preload of 5 N removed the “slack” from the test construct. The separation of the clamps measured at every 1 of the 30 cycles was recorded and plotted on a graft. The resultant lines had 2 distinct parts. This first part was an upward curving concave line representing the “elastic” section of the curve or the recoverable portion of the tissue stretching. That means that during this part of the tensile loading test, removing the force would allow the tissue to recover to its original length. This was recorded as “cyclic displacement.”

The second portion of the curve was a straight line representing the “plastic deformation” portion of the curve. In this section, even if the load had been removed, the tissue would not have recovered to its original length. This was recorded as “permanent displacement.”

The second endpoint was to determine the percentage of the overall displacement that was elastic. Once the intersection between the elastic and plastic portions of the tissue elongation curve was identified, the percentage of the overall line both represented was calculated. This percentage of the overall displacement represents the recoverable region before permanent (plastic) deformation and can serve as a reference for comparison to that of any specific native tissue. This in turn would suggest how closely the tested augmentation tissue matches the target tissue.

The third endpoint was to measure the tensile modulus of the tissue, which is the resistance of the material to stretching and deformation. The modulus is an intensive property (a physical property of a system that does not depend on the system size or the amount of material in the system). It is a material property normalized for the material’s thickness and gauge.
length (stress over strain). A higher modulus number indicates a greater resistance to stretching, whereas a lower modulus indicates less ability to resist stretching. The modulus of these materials can be compared with the material properties of any reference tissue to judge the suitability of the graft application.

The fourth endpoint was to measure the stiffness of these materials. Stiffness, like the tensile modulus, represents the resistance to stretching, but it is known as an “extensive property” and, as such, is dependent on the specific thickness and gauge length of the material tested. It is a non-normalized resistance to stretching. This means that the same material in different sizes and shapes may have different levels of stiffness (which is a non-normalized physical property).

After completion of the cyclic loading phase, a final destructive test of the entire strip of material was performed. The ultimate load-to-failure strength and mode of failure were recorded. The ultimate load was considered the point when final material failure occurred. The final endpoint determined was suture retention strength performed by use of a single vertical simple stitch.

Statistical analysis was performed with a Kruskal-Wallis 1-way analysis of variance on ranks and an all-pair-wise multiple comparison procedure (Dunn method) to isolate the group or groups that differ from the others. Statistical significance was set at $P < .05$.

RESULTS

The load elongation properties were recorded for all tested materials. The cyclic displacement, which represented the elastic portion of the elongation curve, and the permanent displacement, which is the plastic portion of the elongation curve, are shown in Table 1. Statistical analysis of these showed significant relationships. SportMesh showed significantly greater displacement during cyclic loading than all other graft materials tested ($P < .001$). GrafJacket MaxForce Extreme and Allopatch HD 2 showed greater displacement during cyclic loading than RC Allograft ($P < .05$).

The amount of recoverable stretching (elastic elongation) that a specific material possesses may have clinical implications. To investigate this, the amount of overall stretching represented by the elastic deformation segment ranged from 55% with SportMesh to 65% with OrthAdapt. No statistically significant differences were observed in percent elastic deformation for these materials.

The tensile modulus was determined for these materials (Table 1). Statistical analysis showed that OrthAdapt had a higher tensile modulus than RC Allograft, SportMesh, and Allopatch HD 2 ($P < .001$). Allopatch HD 1 and GrafJacket MaxForce Extreme had a higher tensile modulus than RC Allograft and SportMesh. GrafJacket MaxForce had a higher tensile modulus than RC Allograft ($P < .001$).

Stiffness was determined as well (Table 1). It was found that the stiffness of GrafJacket MaxForce Extreme was greater than that of OrthAdapt and SportMesh ($P < .001$). The stiffness of GrafJacket MaxForce, RC Allograft, Allopatch HD 1, and Allopatch HD 2 was greater than that of SportMesh ($P < .001$).

Ultimate load-to-failure strength testing (Table 1) was performed after the cyclic loading phase was complete. The load-to-failure strength of GrafJacket MaxForce, GrafJacket MaxForce Extreme, Allopatch HD 1, and Allopatch HD 2 was greater than that of OrthAdapt and SportMesh ($P < .05$). Modes of failure are reported in Table 1. Almost every test failed by

| Table 1. Mechanical Properties of Graft Materials Tested |
|---------------------------------|------------------|-----------------|-----------------|-----------------|------------------|------------------|
| Graft Type                      | Cyclic Displacement (mm) | Permanent Displacement (mm) | % Elastic Deformation | Ultimate Load (N) | Stiffness (N/mm) | Modulus (MPa) | Failure Mode   |
| Allopatch HD 1                  | 2.3 ± 0.5          | 1.6 ± 0.4        | 58              | 350 ± 116       | 91.5 ± 11.3     | 73.5 ± 16.5    | 9 tore         |
| Allopatch HD 2                  | 2.9 ± 0.7          | 2.3 ± 0.7        | 57              | 451 ± 135       | 92.5 ± 4.4      | 44.3 ± 6.7     | 10 tore        |
| GrafJacket MaxForce             | 2.6 ± 0.5          | 1.7 ± 0.4        | 60              | 313 ± 111       | 83.3 ± 12.5     | 54.7 ± 11.4    | 10 tore        |
| GrafJacket MaxForce Extreme     | 2.6 ± 0.8          | 2.01 ± 0.7       | 57              | 532 ± 154       | 146.6 ± 38      | 69.0 ± 15.7    | 8 tore, 1 during cycling |
| OrthAdapt                       | 2.4 ± 1.0          | 1.3 ± 0.8        | 65              | 95 ± 30         | 50.6 ± 19.8     | 100.6 ± 36     | 11 tore, 1 during cycling |
| SportMesh                       | 8.4 ± 0.9          | 6.74 ± 0.7       | 55              | 160 ± 8         | 19.6 ± 0.8      | 22.8 ± 2.1     | 10 tore        |
| RC Allograft                    | 1.4 ± 0.2          | 0.81 ± 0.1       | 63              | 208 ± 115       | 79.7 ± 29.1     | 17.5 ± 5.8     | 9 tore         |
midsubstance tearing of the material, although 2 instances of tearing during cycling were observed.

Suture retention strength by use of a single vertical simple stitch was recorded (Fig 3). GraftJacket MaxForce Extreme was stronger than GraftJacket MaxForce, RC Allograft, and OrthAdapt (P < .01). Allopatch HD 2 had greater suture retention strength than RC Allograft, SportMesh, and OrthAdapt (P < .05). GraftJacket MaxForce had greater suture retention strength than RC Allograft and OrthAdapt (P < .05). SportMesh and RC Allograft had greater suture retention strength than OrthAdapt (P < .0001).

DISCUSSION

Biological scaffolds are being used with increasing frequency to reinforce soft-tissue repairs. Although long-term clinical reports of the effectiveness of these biologic scaffolds are currently limited, their mechanical properties can be determined. This study evaluated several physical properties of these commercially available soft-tissue augmentation devices to provide a baseline of mechanical performance that could help determine their most appropriate clinical use.

Tendons become stronger, stiffer, and more resilient with age. If this applies to rotator cuff tendons, it suggests that, with increasing age, the best mechanical profile for a cuff tendon augmentation may also change. Defining the best mechanical profile for a particular tissue’s augmentation graft would also depend on the specific tendon (e.g., Achilles, peroneal, and rotator cuff), the graft’s application (onlay or gap spanning), and the goal (whether to decrease static loads or articular-sided shearing stresses). For instance, articular-sided differential strain in the subscapularis can cause shearing between the tendon layers and may contribute to the propagation of intra-tendinous defects.

After surgical repair, tendons are subjected to cyclic loads during healing and the subsequent rehabilitation. This cyclic testing recorded the elongation properties (both elastic deformation and plastic deformation) of these augmentation grafts. Significant differences did exist in total elongation. SportMesh elongated significantly more than all other materials (P < .001). The thicker dermal and fascia lata grafts (GraftJacket MaxForce Extreme and Allopatch HD 2) showed statistically greater elongation than the rotator cuff tendon allograft (RC Allograft) (P < .05). This shows that different tissue grafts will provide different amounts of stress shielding. These differences in performance in turn may have clinical implications for how much such a graft would contribute to a tendon repair.

All these materials had similar percentages of recoverable elongation (e.g., the percent of overall elongation that was elastic compared with the amount that was plastic deformation). The tensile modulus (or resistance of the material to stretching and deformation) was determined for these materials (Table 1). A higher modulus indicates greater resistance to stretching. Importantly, the modulus calculation is based on the thickness and gauge length of the specimen tested and therefore “normalizes” the different material performances. Consequently, the OrthAdapt material, which is only 0.5 mm thick, had a higher tensile modulus than the 2-mm-thick RC Allograft, the knitted SportMesh fabric, and the 2.0-mm Allopatch HD 2 (P < .001). The other allografts (Allopatch HD 1, GraftJacket MaxForce Extreme, and GraftJacket MaxForce) had a higher tensile modulus than the RC Allograft (P < .001).

The stiffness of a graft, like the tensile modulus, also represents the resistance to stretching. The important difference is that stiffness is not “normalized” to a specific length and width. Instead, it represents the resistance to stretching of the tested graft strip as a whole and will be more representative of the graft performance clinically. This is why the 2-mm-thick GraftJacket MaxForce Extreme showed statistically greater stiffness than the 0.5-mm OrthAdapt (P < .001) whereas OrthAdapt graft had a greater tensile modulus. The dermal and tendon grafts all showed greater stiffness than the SportMesh product (P < .001).

Ultimate load-to-failure strength after cyclic loading showed that the acellular human collagen matrix grafts (different thicknesses of GraftJacket and Allo-
patch HD) were statistically stronger than OrthAdapt and SportMesh (P < .05). The RC Allograft failure load was neither statistically weaker than the acellular human collagen matrix grafts nor statistically stronger than the OrthAdapt or SportMesh.

Suture retention was also evaluated (Fig 3). A simple suture construct was chosen in contrast to a mattress stitch. This accounted for the differences in suture retention strength between this study and the previous study. Limits to the amount of test material available restricted the tissues tested in this manner. The thicker acellular human collagen matrix grafts again showed greater suture retention strengths, with the 2-mm-thick GraftJacket MaxForce Extreme showing the highest failure load and the thinnest graft material (OrthAdapt) showing the lowest (P < .05).

The hypothesis of this study was that different tissue grafts would show different mechanical properties. These differences may influence the preferred choice for different augmentation techniques and for different target tendons. As an example, postoperative protocols may be influenced by different augmentation tissues. Because shoulder abduction significantly reduces the passive loads on a repaired tendon, which otherwise could be significant enough to cause repair failure, the addition of an augmentation may allow earlier abduction.

The weaknesses of this study include the fact that it considered only specifically definable mechanical properties and did not address another clearly important element: the biological enhancement such a graft may contribute to a repair. These data do not address the proper clinical utilization of these materials and whether the preferable augmentation material should be stronger than or more elastic than the target tendon. The effect of stress shielding on an augmented repair was not determined. Whereas some grafts would provide stress shielding in some applications, they might not have in others. This is a "time zero" study, and the data generated cannot be extrapolated to apply throughout the healing and rehabilitation process.

CONCLUSIONS

The acellular human collagen matrix grafts showed greater elongation than the cuff tendon allograft (RC Allograft), although SportMesh elongated more than all other materials tested. The tensile modulus, which is "normalized" to eliminate differences in the size of the tissue tested, was greater for the OrthAdapt material than for GraftJacket, Allopatch, RC Allograft, and SportMesh. Suture retention strength was greatest in the acellular human collagen matrix grafts (GraftJacket and Allopatch), whereas both SportMesh and RC Allograft had greater suture retention strength than OrthAdapt.

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