
COMPARISON TESTING OF TENDON REPAIR AUGMENTATION GRAFT MATERIALS LOAD-TO-FAILURE AND EVALUATION OF FAILURE PATTERNS

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INTRODUCTION

Reliable repair of damaged or severed tendons (e.g., massive rotator cuff tears) poses a significant clinical challenge for the orthopaedic surgeon resulting in a reported failure rate of between 20 and 57%.¹⁻³ The development of novel implantable biomaterials, improved sutures, and new surgical techniques to achieve more consistent fixation has targeted enhancement of the overall success rate in recent years. One critical property of reinforcement membranes is adequate strength to support anatomical forces and fixation devices. The purpose of this study was to determine the reliability of a specific test method designed to simulate forces imparted by sutures to commercially available soft tissue augmentation grafts.

METHODS

Allograft and xenograft materials of different origins were selected as follows: Acellular human dermis (GRAFTJACKET[®] Matrix, Wright), porcine-derived material (RESTORE[®] Graft, DePuy Orthopedics), cross-linked, porcine-derived material (CUFFPATCH[®] Graft, Arthrotek, and ZCR[®] Graft, Zimmer), bovine-derived Type 1 collagen (TISSUEMEND[®] Graft, Stryker Orthopaedics), and cross-linked, equine-derived material (OrthADAPT[®] FX Graft, Pegasus Biologics). The size of each specimen was 2cm x 5cm.

Specimens were hydrated according to the package insert immediately prior to testing. In horizontal mattress fashion sutures (#2 FIBERWIRE[®] Sutures, Arthrex) were passed through the membranes using a custom template engineered to simulate clinically relevant positioning and provide reproducibility (5mm from the edge and 5mm width from center to center). Suture ends were affixed to a tubular guide controlling for length and distance of the knot on each test specimen. The bottom ½ of the sample was held in the lower pneumatic jaws at a maximum compressive pressure of 300 psi to prevent slippage. The tied suture loop was placed on an “S” hook which was suspended from the Instron 1321 upper crosshead **FIGURE 1**. This allowed freedom for the suture to orient in the vertical plane without restriction. The suture was pulled at a distraction rate of 12.5mm/sec with a 1000kg load cell until failure.^{4,5}

FIGURE 1 |

Standard Methodology

- Instron 1321
- 1000 kg load cell
- 12.5 mm/sec distraction⁴
- “S” hook for knotted looped suture
- Horizontal suture
- #2 FIBERWIRE[®] sutures
- Suture placement template
- Pneumatic jaws clamp tissue



FIGURE 1 | Illustration of the test apparatus for the Instron 1321.

RESULTS

The modes of failure and the average force to failure (N) are presented in **FIGURE 2** and **FIGURE 3**. The observed failure mode of suture pull-through occurred via four distinct patterns: (1) Isthmus pull-out (2) Side pull-out (3) End pull-out and (4) Implant tear. Tear patterns tended to vary by implant type.

CONCLUSION

Failure mode differed between implant types, suggesting that suture method for each implant should be considered independently prior to utilization. For example, our tests suggest that the TISSUEMEND® Graft, CUFFPATCH® Graft, and OrthADAPT® FX Graft should have sutures placed across a wider distance in the horizontal mattress to minimize pull-through.

REFERENCES

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This study was supported in part by a grant from Wright Medical Technology, Inc., Arlington, TN, U.S.A.

PARTICIPATING SURGEONS

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ORTHADAPT® FX is a registered mark of Pegasus Biologics.
RESTORE® is a registered mark of DePuy Orthopedics.
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| | ISTHMUS PULLOUT | SIDE PULLOUT | END PULLOUT | IMPLANT TEAR | SUTURE BREAK |
|-----------------------|-----------------|--------------|-------------|--------------|--------------|
| CUFFPATCH® GRAFT | 6 | | 1 | | |
| GRAFTJACKET® MATRIX | 3 | 2 | 10 | | 2 |
| ORTHADAPT® FX GRAFT** | 6 | | 2 | | |
| RESTORE® GRAFT | 2 | | 4 | | |
| TISSUEMEND® 1.1 GRAFT | 4 | 2 | | | |
| TISSUEMEND® 1.2 GRAFT | 5 | | | 1 | |
| ZCR® GRAFT | 2(3*) | 3(3*) | | | |

FIGURE 2 | Variation of failure mode by implant type.⁵
*Both failure modes occurred in same 3 tests.⁵

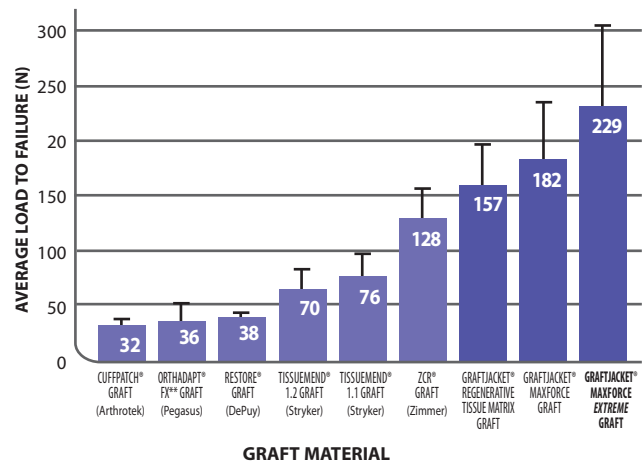


FIGURE 3 | Overall failure force of commercially available implants measured in Newton's force.⁵

**Data on file, not included in the peer reviewed publication. In total, 8 specimens were tested. Four of the specimens tested at a distraction rate of 12.5mm/min were included in this analysis due to comparable results.

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