An Artificial Tendon with Durable Muscle Interface

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Introduction: A coupling mechanism that can permanently fix a contracting muscle to an inert prosthesis would meet a serious need in clinical orthopaedics, with applications in orthopaedic oncology, revision arthroplasty, tendon transfer procedures and sports-injury reconstruction[1,2]. No prior truly artificial tendons have succeeded[3]. Others have explored autogenous bone block techniques[4]. We hypothesized that a low-mass, high-surface-area interface could transfer physiologic loads by shear, without pressure-damage to tissue. This hypothesis draws its premise from the size-dependent tissue-to-prosthetic interface vascularity shown much earlier by Davila[5] and Bruck[6]. The resulting device is the OrthoCoupler™.

Simple placement of sufficiently small (12µm) polymer fibers via unorganized, needle-drawn bundles has repetitively been shown to encourage tissue ingrowth, which rapidly results in a stable biomechanical composite structure—with adjacent prosthetic fibers rarely in contact. Predicate studies of similar technology toward muscle harnessing for circulatory power and for tissue-to-tissue coupling (addressing collagen-deficient wounds in general and plastic surgery) have uniformly shown bonding strength greater than the muscle itself[7-10].

Methods:

♦ ***In Vitro Fatigue Testing*:** Forty samples, composed of 18,432 12-micron polyester (PET) fibers each, were fatigue-tested, cycling at 10 load levels (159N, 239N, 250N, 270N, 290N, 310N, 330N, 350N, 370N, and 390N, n=4 each). These iteratively chosen loads range from 30% to 73% of maximum safe single load 531N, which had been determined in pilot work as tensile strength mean (889N) minus two standard deviations (2*179N) for 95% confidence level.

♦ ***In Vivo / Mechanical Testing*:** Semitendinosus tendon was removed bilaterally in eight goats, removing periosteum, and fixing a 316L stainless steel plate to the tibia. Left sides were re-attached with an OrthoCoupler™ of 36,864 fibers (equivalent to two of the *in vitro* specimens). Right sides (controls) were reattached using the Krackow stitch with #5 braided polyester sutures. One animal was lost from fracture at site of bone plate screws at 4 days. In one goat, contralateral control was omitted because of local skin inflammation noted pre-operatively.

At 60-61 days, specimens were removed and kept frozen at -80°C until thawing and testing at the Orthopaedic BioMaterials Laboratory at OSU. Tibial bone plate and pelvic insertion were gripped in an MTS 858 Bionix servohydraulic materials testing frame (MTS Corp, Eden Prairie, MN) and loaded at 1 mm/sec while monitoring load and grip-to-grip displacement.

♦ ***Histology*:** Sections of both experimental and control from 5 animals were paraffin embedded, sectioned, and stained with hematoxylin/eosin and Masson's trichrome.

Results:

♦ ***In Vitro Fatigue Testing***: Of the 40 samples tested to greater than 10^7 cycles, there were no failures in the 32 subjected to ≤ 350N (≤ 65.9% of single-cycle mean tensile strength). One of four failed (i.e., broke) at 370N (at 3.9 million cycles) and four of four failed at 390N (at 6.3±2.7 million cycles, mean ± SD).

♦ ***In Vivo / Mechanical Testing***: Controls pulled out at 120.5±68.3N, whereas the experimental sides held beyond muscle tear at 298±111.3N (mean ± SD). Difference was significant by both Student's t test ($p<0.0003$) and Wilcoxon rank sum test ($p<0.0007$).

♦ ***Histology***: On the experimental side, filaments were described as "widely separated" with the surrounding healing and inflammatory process extending into the interstices. Control sutures had no such interstices, remaining compactly organized.

Conclusions: The *in vitro* fatigue results established mechanical reliability by showing 100% durability to over 10^7 cycles at all stresses up to 350N—extrapolating to 700N for the double-size in vivo device (quantity chosen to occupy between 1% and 2% of the muscle cross-sectional area), almost twelve times the predicted maximal contractile force[11] of this muscle [$15N/cm^2$ x 4 cm^2 maximum cross-section = 60N] and well over twice that muscle's own tear strength of 298N. Testing at 370N showed 75% durability through 10^7 cycles.

In vivo observations, mechanical testing, and histology established adequacy of coupling. Animals required no external fixator to ambulate spontaneously and well at 24-48 hours. Repair strength consistently exceeded passive tensile strength of the intact muscle; i.e. muscle tear strength was in every instance reached with the healed fiber-muscle composite still soundly intact. Histologic observation of fully vascularized integrated tissue encourages us to expect permanently sustained strength in current longer-term studies. We believe this technology may be of value for clinical challenges in orthopaedic oncology, revision arthroplasty, and sports medicine.

References:

1. Beach WR: J Pediatr Orthop 11:731-6, 1991.
2. Nerubay J: Clin. Ortho. & Rel. Res., 229: 143-48, 1988
3. Hunter J: Am Jl Surg. 109:325-38. 1965.
4. Higuera CA: J Orthop Res. 2005 Sep;23(5):1091-9.
5. Davila JC: Ann. NY Acad. Sci. 146:138-47, 1968.
6. Bruck SD: Biomater. Med. Devices Artif. Organs. 1:79-98, 1973.
7. Melvin DB: ASAIO J. 43:M434-M441, 1997.
8. Melvin DB: ASAIO J. 2003 May-Jun;49(3):314-9.
9. Melvin DB: Chapter 11 in Guldner NW, Klapproth P, Jarvis JC (edit), Cardiac Bioassist 2002, Aachen, Shaker Verlag, 2003. Pages 157-166.
10. Trumble DR: ASAIO J. 2002 Jan-Feb;48(1):62-70.
11. Sola OM: J Heart Transplant 9:151-9, 1990.