An Artificial Tendon for the Extensor Mechanism of the Knee

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Introduction
A durable means to fix a forcefully contracting muscle to a bone anchor or any inert prosthesis would meet a serious need in clinical orthopaedics, including orthopaedic oncology, revision arthroplasty, expanded tendon transfer and sports-injury reconstruction. No truly artificial tendons have succeeded. Autogenous bone block techniques have also been explored. We have developed and tested a new approach based on the hypothesis that a low mass, high surface area configuration could transmit physiologic loads by shear, without pressure damage to tissue. Feasibility of a fine fiber interface was foreshadowed by the size dependent tissue-to-prosthetic interface vascularity shown much earlier by Davila and Bruck. The resulting device is the OrthoCoupler™. Conceptually, it is the converse of plant roots in soft soil. Instead of living fibers growing into an inert matrix, bundles of inert fibers are exposed to a living matrix (muscle)—which immediately begins to grow in, intercalating and insinuating itself between and among the polymer fibers. Either of these biomechanical composites exhibits strength which far exceeds that of the soft substrate matrix, be that soil or muscle. Simple placement of fibers in unbraided, needle-drawn bundles has repeatedly been shown to rapidly result 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 have uniformly shown bonding strength greater than the ultimate strength of the muscle itself 4-6. The objective of this study was to evaluate four configurations of the OrthoCoupler™ to replace the extensor mechanism of the knee in goats.

Methods

The OrthoCoupler™ consists of a bundle of a few thousand fine polymer fibers, in this case 12-µm polyester (polyethylene terephthalate, PET) fibers (Milliken & Company, Spartanburg SC), swaged into the heel of a needle. The device (Figure 1) includes 32 fiber bundles, which all together comprise 32 x 3,072 or 98,304 twelve-micron fibers. Looped design of the distal end simplifies bone-plate fixation and greatly reduces potential stress concentration versus clamping or knotting. The intermediate portion is a braided strap. Tissue adhesion to the loops and strap is prevented by impregnating these with silicone (Shin-Etsu Silicone of America, Inc., Akron OH). Two variables were assessed in a 2x2 randomized block design: fiber bundles inserted with needles vs. with barbs and coated vs. uncoated fiber bundles. The devices were implanted in the right leg of 24 goats. Specimens were collected from each operated leg and contralateral unoperated controls both for mechanical testing and histology at 90 days post-surgery.

In Vivo/Mechanical Testing: Four treatment groups were evaluated. Each used 98,304 fibers (total cross-sectional area 1% of muscle). The four groups had: (A) Needle uncoated bundles, (B) Needle coated bundles, (C) Barbed uncoated bundles, (D) Barbed coated bundles. The four groups (n=6 for each) were randomly assigned to connect the quadriceps muscle to the tibia (with a bone plate) in the right hind limb of 24 goats. The University of Cincinnati Institutional Animal Care and Use Committee approved all procedures. At 90 days, specimens from each operated leg and contralateral unoperated control were removed and kept at -80°C until thawing and testing. The bones were potted and specimens mounted in an MTS Insight electromechanical test platform (MTS Corp, Eden Prairie, MN) and loaded at 1 mm/sec while monitoring load and grip-to-grip displacement.

Histology: Sections of 8 specimens (2 from each group) were paraffin embedded, sectioned, and stained with hematoxylin/eosin and Masson’s trichrome.

Statistical analysis: Biomechanical properties were compared using ANOVA.

Results

Mechanical Testing: The fiber bundles pulled out of the quadriceps muscle in the operated legs; in the controls the quadriceps muscle tore and pulled off of the femur. Maximum forces in the operated leg (vs. unoperated control) were 1287.6±122.6 N (vs. 1387±118 N) for group A, 1323.4±144.4 N (vs. 1395.8±76.9 N) for group B, 929.7.0±125.2 N (vs. 1337.4±125.6 N) for group C and 967.7±109.2 N (vs. 1528.3±145.7 N) for group D (mean ± SEM). There were no statistical differences between needle vs. barbed devices (p=0.1) or between coated vs. uncoated fiber bundles (p=0.5). The strength of the OrthoCoupler™ and the control legs were statistically equivalent for the needle device (p=0.6). The maximum forces for the barbed devices were significantly lower than the maximum forces for their controls (p=0.001).

Histology: The four groups all showed plentiful fibroblasts with spindle shaped nuclei surrounded by their abundantly produced collagen (blue on trichrome staining), organized between the individual PET fibers (Figure 2). Multiple scattered small blood vessels containing red blood cells were present. No significant inflammatory reaction was seen.

Discussion

In vivo observations and mechanical testing established adequacy of the coupling. Animals required no external fixation, support, or assistance to ambulate spontaneously and well at 24-48 hours. Based on these results, the configuration selected for ongoing, extended-healing studies was needle coated bundles due to easier implantation and mechanical strength similar to the unoperated leg. We believe this technology may be of value for clinical challenges in orthopaedic oncology, revision arthroplasty, tendon transfer, and sports injuries.

References

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