A novel approach towards the development of an artificial tendon

Introduction: A truly artificial tendon would (1) facilitate secure, durable, load-bearing fixation of prosthetic bones to muscles remaining after limb cancer extirpation and (2) offer a far broader practical scope for tendon-transfer palliation for neurologic deficits. Prior attempts have failed predominantly at the tissue-prosthetic interface, where stress can reach 40,000 mmHg (>5.5 MPa) due to the small force transfer area provided by sutures or staples. Interface necrosis is distressingly common. Whenever immobilizing adhesions do not preclude reliable fundamental different approach is shear-force transfer across interfaces between tissue and the large cumulative lateral area of fine fibers dispersed within the muscle tissue. This is the principle by which plant tendrils hold tenaciously even in very soft soil. Our hypothesis is that a prosthesist of several thousand 12-13 mm diameter polymer fibers inserted as bundles into distal regions of muscles will consistently transfer the load generated by contraction of the muscle and that this bonding strength testing, these interfaces have consistently fallen short. A fundamentally different approach is shear-force transfer across interfaces between tissue and the large cumulative lateral area of fine fibers dispersed within the muscle tissue. This is the principle by which plant tendrils hold tenaciously even in very soft soil. Our hypothesis is that a prosthesis of several thousand 12-13 mm diameter polymer fibers inserted as bundles into distal regions of muscles will consistently transfer the load generated by contraction of the muscle and that this bonding strength testing, these interfaces have consistently fallen short.

Methods: We examined this hypothesis in three different animal models at three different institutions. Each study was approved by the Institutional Animal Care and Use Committee of that institution.

A. A quantitative study of bonding strength in Achilles tendon replacement in 24 rabbits, over 15-90 days, was compared with contralateral polyester cord controls. (University of Cincinnati, Cincinnati, OH). Unspun 12 mm diameter polyester fiber tow in six 4000-4500-fiber bundles (combined cross section ~3 mm2), each swaged into a straight needle, was inserted into the gastrocnemius with exiting fibers contained in a braid. The prosthesis (a simple polyester cord on contralateral side) was used to replace the excised Achilles tendon.

B. Six of devices have been removed from 7 to 62 days with recovery of dogs for adoptive surgery as pets when feasible (n = 5) or euthanasia (n = 1); otherwise, remains at 46 days. Muscle activation and hydraulic energy recovery varied with the iterative development of the device in the primary study of which this coupling was a supporting part. In every instance (7/7) secure coupling was maintained, reliably transmitting muscular energy, whatever the level, to the hydraulic device and all (6/6) explanted have been intact. Strength testing was only done in the initial two specimens and 70 N and 200 N test capacity.

C. In the goat study, one animal was euthanized electively at 35 days (left tension strength, 264 N; right being prepared for histology). A second was euthanized for clinically evident left side coupling separation at 5 days; the right was sent for histology. The 25% failure in pilot animals led us to realize that shortening the muscle-tendon length created excess load. Subsequent procedures carefully avoided this error. No clinical indication of separation or malfunction has been observed in 3 later goats (5 devices), at 24, 25, and 25 days. Testing is scheduled for 5 and 10 weeks post-implantation. Two prostheses tested immediately after implantation had initial interface strengths 173 and 131 N.

Conclusions: These 40 observations in 3 separate animal models are encouraging. In study A (lapine posterior tibial) coupling strength of every specimen exceeded an arbitrary but generous target (15 N/cm2 muscle cross section) with mean score over twice that at every tested period.

The opportunity to test the approach in coupling conditioned, latisimus muscles to a telescemedary hydraulic unit arose when colleagues experienced difficulties with conventional muscle-coupling techniques in assessment of a muscle-energy conversion system. A similar prosthesis, with 6 or 8 bundles of 4500 fibers each were implanted in seven mixed breed 25 to 35 kg dogs, 7-62 days, at the Allegheny-Singer Research Institute. Distal latisimus dorsi muscles were coupled unilaterally and observed until failure of another component (e.g., hydraulic seals, chest-wall fixation of the hydraulic device, etc.) or completion of the prescribed period.

An emulation of muscle fixation to prosthetic bone fixation is underway in 9 semitendinosus muscles of 5 goats (5-24 days the time of abstract submission) at the Ethicon Endo-Surgery Institute. Two eight-bundle (2250 fibers/bundle) devices coupled the semitendinosus muscle in one or both legs of 5 adult goats (total of 9 muscles coupled). This study is intended to assess the device for functionally anchoring muscles to prosthetic replacement bones. A Ti-6Al-4V plate was screwed to the medial tibial shaft and the cord extension of the coupling device secured to it by a smaller compression plate to simulate fixation to a prosthetic replacement bone. Groups are to be assessed at 5 and 10 weeks.

Results: Bonding strength for an artificial tendon must exceed muscle force. A target of 15 N per cm2 greatest cross section was selected from the rather limited data that has been published (1). This yields a minimal target, 43 N for a typical A specimen, and of 60 N for the similar models B and C muscles.

A. Twenty-one were used for bond-strength testing and 3 for histology. Pullout strength at <30 days (n=7), 31-60 days (n=10) and 61-90 days (n=4), and all (n=21) was: 107±58, 111±33, 41±13 and 52±27 for controls.

Differences were statistically significant (1-tailed t-test for paired data; p<0.02 at 10-30 days, p<0.002 at 31-60 days, p<0.001 at 90 days, and p<0.00003 for all). Histology showed 88% of 360 scored sites were weaker ingrowing soft tissue elements than other fibers.

B. Six of devices have been removed from 7 to 62 days with recovery of dogs for adoptive surgery as pets when feasible (n = 5) or euthanasia (n = 1); otherwise, remains at 46 days. Muscle activation and hydraulic energy recovery varied with the iterative development of the device in the primary study of which this coupling was a supporting part. In every instance (7/7) secure coupling was maintained, reliably transmitting muscular energy, whatever the level, to the hydraulic device and all (6/6) explanted have been intact. Strength testing was only done in the initial two specimens and 70 N and 200 N test capacity.

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Similarly, each of the few measurements in studies B (canine latissimus, 2/6 tested to date) and C (caprine semitendinosus, 3/9 tested to date) -- including one as short as 5 days in each group -- has at least doubled those models’ similarly scaled targets. The sole clinical mechanical failure observed was very early (<5 days) in a muscle abnormally shortened (by the full initial tendon length of ~6 cm) in a protocol subsequently judged to be misguided, and revised.

A limitation of these 3 studies is duration (90, 70, and 30 days). Late failures—biologic (e.g., foreign body reaction) or prothetic (e.g., material fatigue)—may occur. While polyester fibers’ history (>45 years) in arterial grafts, the more than adequate stressors tolerated in these studies, and practical potential for still greater stress distribution are reassuring, experimental confirmation of durability is essential. We believe these results warrant longer term observations with both mechanical and histologic examination. Demonstration of durability could prove the device quite useful for orthopaedic limb-salvage reconstruction, broadening the practical scope of tendon-transfer procedures, and a range of new clinical orthopaedic applications.

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Reference: