

## Summary

A coupling mechanism that can durably fix a forcefully contracting muscle to a totally inert prosthesis would meet a serious and common need in clinical orthopaedics. We have explored a new approach based on the hypothesis that a low-mass, high-surface configuration designed to transfer force by shear would transfer greater loads, without pressure-damage to tissue, than can be transferred by the interlocking mechanism of sutures or staples. The resulting device is the OrthoCoupler™.

Conceptually, it is the converse of plant roots in soft soil. Instead of living filaments 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 that far exceeds that of the soft substrate matrix, be that soil or muscle.

## The Need

A successful truly artificial tendon would expand effective treatment in at least four important applications—(1) functionality of **prosthetic bones** after cancer extirpation, (2) broadened possibilities for **tendon transfer** procedures, (3) **revision arthroplasty** and (4) **sports injury reconstruction**. None of these four are effectively answered by scaffolds, grafts or any other existing technology. Every one of them could be addressed, were there a truly artificial tendon that could reliably and durably transfer force. As used here, “truly artificial tendon” simply means one that is not only amenable to established engineering bonding/attachment means at prosthetic interfaces distally, but also capable of tenacious biological interface bonding with muscle proximally.

Each of these clinical scenarios has its own particular needs:

1. Rendering complete or segmental **prosthetic bones** (otherwise quite successful for reconstruction after cancer extirpation) actually functional: These metallic replacements for femurs or tibias (for example) must be attached to muscles if the person is to walk. Scaffold-induced neotendons and autografts do not work here: there is nothing living beyond the gap to which the scaffold-induced or autografted tissue can heal. A truly artificial or inert tendon, instead, depends only on straightforward engineering principles for this distal fixation.

Given the necessity for cancer removal, wide-margined operations are necessarily done in spite of limited rehabilitation potential. Several segmental bone prostheses have been developed<sup>1</sup> for upper<sup>2</sup> and lower<sup>3</sup> extremities. If prosthetic femurs are placed, tendons not removed as part of the cancer operation<sup>4</sup> have generally been simply sutured to prosthesis, where they become fixed only to a fibrous envelope—sometimes allowing patients to walk<sup>5</sup>, but with less than normal functionality. Bone block transfer with tendons has had limited success<sup>6 7</sup>. In a particularly ingenious approach, Chao’s laboratory at Johns Hopkins, as recently reported by Higuera, augmented healing with a range of tissue factors—but strength still remained less than half that of controls<sup>1</sup>. Anchoring an inert and truly artificial tendon to an inert bone prosthesis would, on the other hand, be amenable to straightforward mechanical design for minimizing stress concentration and material fatigue.

2. **Extensive muscle re-direction for neurological deficit**: A truly artificial tendon could be made as long or short as desired. Dramatic rehabilitation can sometimes follow the ‘borrowing’ of extensor muscles from a flexor group (or vice versa), reattaching and retraining when natural extensors are devastated by cerebral palsy or peripartum brachial plexus injury.

Imaginative tendon transfer techniques by resourceful pediatric reconstructive orthopaedists have achieved some remarkable results, but are sharply limited by available length. In spastic cerebral palsy, symptoms may be addressed, usually on a highly individualized basis, by such operations as the Green procedure (forearm musculature)<sup>8</sup>. On the other hand, after other procedures such as bilateral posterior adductor transfers to ischium and iliopsoas transfers, late gait analysis is sufficiently discouraging that the procedure has been abandoned by some clinicians<sup>9 10</sup>. Late obstetric brachial plexus palsy in the forearm and hand is another broad-ranging syndrome. It often includes weakness or absence of wrist or metacarpophalangeal or interphalangeal joint extension; weakness or absence of finger flexion; forearm supination, or less commonly pronation contracture, ulnar deviation of the wrist, dislocation of the radial or ulnar head, thumb instability, or sensory disturbance of the hand. Many of the motor manifestations would be treatable if less dysfunctional muscles could be reassigned and

retrained—but traditional tendon transfer operations are only applicable to a minority.<sup>11</sup> The tendons must reach targets with acceptable tension. Often, though, native tendons alone simply are not long enough to do so.

A real artificial tendon could be made any length wished—were a durable load-bearing muscle-end bond achievable. Redirection of muscle forces in these severely disabled children could be far more flexible.

3. **Revision arthroplasty.** Although increases in mean population age and improved artificial joint durability are both almost certain, neither of these competing influences on revision arthroplasty rates are precisely predictable. Most clinicians believe that second and even third and later replacements will become more, not less, common over time. A safe and reliable, muscle re-coupler with near-unlimited potential for design customization may prove extremely useful if these people are to be rehabilitated.
4. Any **sports injury reconstruction** in which a distal muscle to bone reconstruction might improve on current less-than-optimal attempts at direct tendon repair (supraspinatus to humerus for rotator cuff; gastrocnemius to calcaneus for Achilles, for examples). Although only some sports injuries are to tendons, those are among the most frustrating to treat: Achilles, patellar, and pectoralis tendon tears and severe sprains may be amenable to simple prostheses securely anchored in gastrocnemius, quadriceps, and pectoralis muscles, respectively. The ease-of-use of the OrthoCoupler placement has particular potential in sports-medicine usage; minimally invasive placement could be quite straightforward; only the arthroscopically accessible musculotendinous junctions need be exposed.

### The Underlying Bioengineering Problem

Otherwise useful and ingenious prior methods, ranging from autografted and allografted tendons to neotendons generated by ‘scaffolding’, whether with carbon fibers<sup>12 13</sup> that gradually fragment, or absorbable suture material<sup>14, 15</sup>, have never been shown to even approach adequacy for any of these four dilemmas.

Though tendons function simply as tension elements - intuitively inviting trials with cables, ropes, wires and on and on—the quest for an effective artificial tendon has been frustrating and elusive. Hunter<sup>16</sup> reviewed early attempts, dating as early as a century ago. Whenever immobilizing lateral adhesions were sufficiently controlled to actually allow examination of soft-tissue bonding strength and durability, that durability consistently fell short. Even though cords, rods, and cables do work in acute trials<sup>17 18</sup>, connections repeatedly separate after a few days to a few weeks of force transfer.

The underlying difficulty is the prosthetic-tissue interface. Tendons must rely on durably connecting with living tissue that is kept alive by blood flow, and every traditional tissue-fixation means employs interlocking. Across every increment of those bearing surfaces, normal force is transferred. Common examples illustrate the problem: a biceps often generates 50 to 100 N of force and a quadriceps five times that. That range of forces divided by even optimistic projections of cumulative suture bearing areas in the respective tendons yields a compressive stress, or pressure that not uncommonly reaches several thousand mmHg. Forceful muscle contractions pull on those interlocking connections to the point of ischemia (blood-flow compromise). Ischemia, with its induced loss of tissue mechanical integrity, sharply limits the force that can be repetitively transmitted across any given cross-section.

### The OrthoCoupler

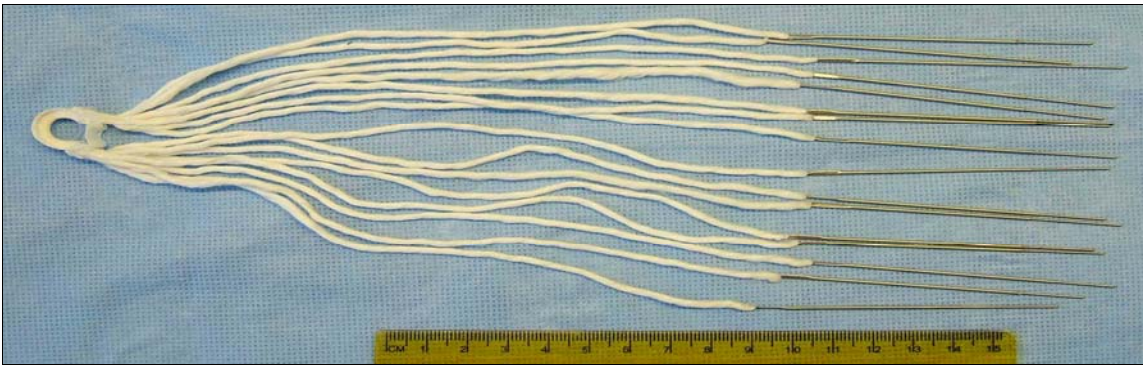
The basic element of the OrthoCoupler™ is a tow (unbraided bundle) of several hundred to a few thousand fine polymer fibers, in this case 2688 12- $\mu$ m polyester (PET) fibers swaged into the heel of a conventional needle (**Figure 1**).

A single OrthoCoupler consists of a number of these tows (to date, 4 to 16 depending on muscle size), with a loop for fixation to prosthesis, and disposable needles for delivery (**Figure 2**).

In one application of the OrthoCoupler, the semitendinosus tendon was removed bilaterally in eight goats. Left sides were reattached with the OrthoCoupler



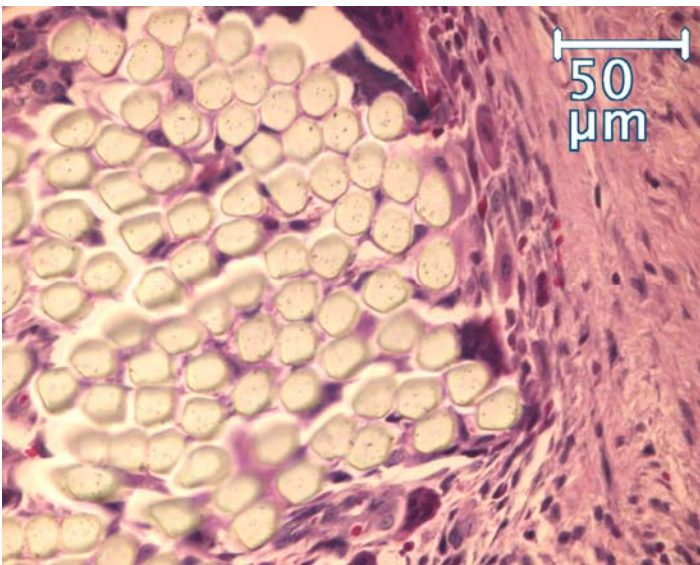
**Figure 1.** Close-up of the FiberSecure, a tow (unbraided bundle) of twelve-micron polyester fibers, converging into the heel of a needle.



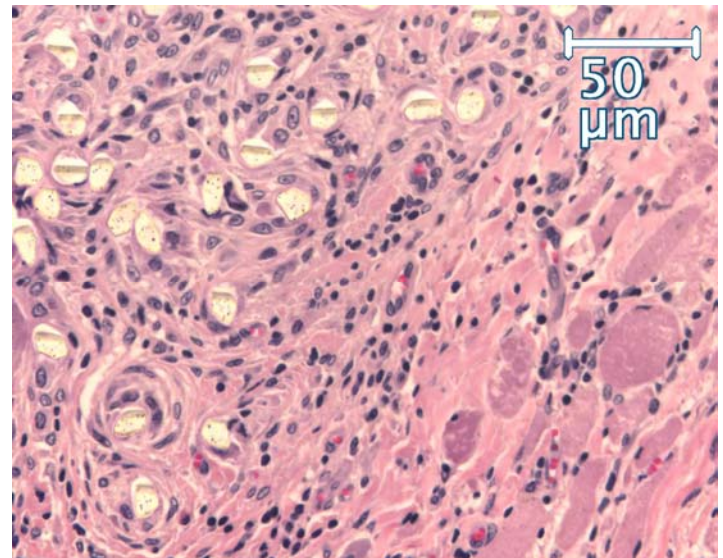
**Figure 2** OrthoCoupler device. Each of the 18,432 fibers from the upper 8 needles continues uninterrupted to the lower 8, thus presenting twice that number (36,864) of fiber-segments for a 35-40 mm long insertion path. Looped design simplifies bone-plate fixation and greatly reduces potential stress concentration.

and right sides were reattached using the Krackow stitch with #5 braided polyester sutures. Suture control pulled out at  $120.5 \pm 68.3$  N, whereas the OrthoCoupler held until muscle tear at  $298 \pm 111.3$ N (mean  $\pm$  SD) at 60 days post-surgery. The fixation strength consistently exceeds the passive tensile strength of the intact muscle. Muscle tear strength was in every instance reached with the fiber-muscle composite produced in healing still soundly intact.

We demonstrated thorough tissue integration by histologic examination of local tissue/fiber interfaces without any suggestion of microencapsulation or compromise of vascularity. Control sutures had no fiber separation, remaining compactly organized (**Figure 3**). The filaments of the OrthoCoupler devices were widely separated with the surrounding healing and inflammatory process extending into the interstices (**Figure 4**).



**Figure 3.** Micrograph of control side with Krackow stitch (the sole suture fragment which was found in a specimen after destructive testing - all others avulsed and tore free)



**Figure 4.** Micrograph of experimental side with OrthoCoupler tow (a random sample - all fiber-containing muscle regions remained intact).

Pilot studies of the most demanding clinical challenge imaginable—replacing the extensor mechanism for the body’s most massive and most powerful muscle, the quadriceps femoris, also succeeded, again in goat trials. After radical removal of the quadriceps tendon, patella and patellar tendon *en bloc*, the cut thigh muscle stumps were re-fixed to tibial bone plates. After healing, they simply could not be pulled out. The Orthocoupler’s tissue-prosthetic interfaces tested (standard Instron device protocols) at 15 to 30 days remained soundly intact through tearing strength of the muscle itself. Those tested at 60 days remained secure to and through fracture of the femur itself.

Each of these results were achieved with very low cumulative mass implants—fiber cross-section in the distal muscle insertions sites never exceeded 2% of the local native muscle cross-section.

Finally, *in vitro* testing has shown the fatigue strength of the fiber bundles themselves (tested to over  $10^7$  cycles) to be over  $168 \text{ N/mm}^2$  (168 MPa), whereas the maximal contraction strength of a muscle is only 0.15 N per  $\text{mm}^2$  of largest cross-sectional area<sup>19</sup>. Since the device-to-muscle size ratio is consistently between 1% and 2%, this provides a safety factor against fatigue of more than 10 (that is,  $1\% * 168 / 0.15 > 10$ ).

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