EVALUATING THE BIOMECHANICAL EFFICACY OF AN ORTHOPEDIC IMPLANT IN AN IN-VIVO RABBIT MODEL

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INTRODUCTION

Our lab has developed an orthopedic implant for individuals who have suffered a C5-C8 spinal cord injury. The implant, when used in tendon-transfer surgery, improves hand function by modifying the transmission of forces. The implant is passive and creates a differential (swiveling) mechanism which enables the distribution of movement from one muscle across multiple output tendons, even as the fingers driven by the output tendons adapt to external contact constraints during grasping [1]. As with any implant, there will be a foreign body response. This foreign body response could encapsulate the implant, tendons, and surrounding tissues in scar tissue. This in turn may limit the implant's functionality. To determine our implant's efficacy in the presence of a foreign body response, we conducted a three-week live animal survival trial, implanting the implant between tendons I/II and III/IV of the extensor digitorum communis (EDC) tendon bundle of the New Zealand white rabbit with varying suture protocols [2]. Prior work had shown one suture loop per implant suture hole to be unreliable, with the suture failing in previous trials. Following the implantation period, we validated the efficacy of the implant-tendon construct to create differential action by comparing it against the non-implanted contralateral leg.

METHODS

A pilot study was conducted with n=2 rabbits implanted with the implant. For rabbit 1, the implant was secured to tendons with one suture loop through each available suture hole on the implant. Rabbit 2 had two suture loops through each of the suture holes. The rabbits were implanted for three weeks. Throughout the first week, the rabbits had bandage changes daily and were maintained in their cages. During the second week, the rabbits no longer received bandages and were allowed some time daily to move about in a larger pen. In the third week, the rabbits participated in daily passive range of motion exercises and continued to exercise in the larger pen. Following euthanasia, a biomechanical test was performed using a custom test bed to quantify the efficacy of the implant (Figure 1). The test bed measures force and displacement of the EDC tendons for translational and rotational movements. Translational movement was achieved using springs on both distal tendon bundles while weight was applied proximally to the EDC muscle with a preload of 0.57 N then in the following increments: five 0.2 N, three 0.5 N, three 1.0 N, and one 2.0 N. Rotational movement was achieved using a spring on just one tendon bundle and again applying weight proximally with a preload of 0.57 N then in the following increments: five 0.2 N, three 0.5 N, and two 1.0 N. Three trials were conducted each for translation and rotation for the implanted and contralateral limb of each rabbit. Data from the implanted leg was then compared to the contralateral.

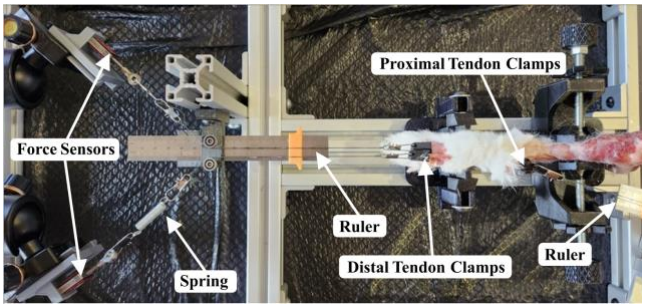

Figure 1: Biomechanical test bed used to quantify the efficacy of the implant with key features labeled. Test bed is currently shown in the rotation configuration, with a spring on one distal tendon pair.

RESULTS AND DISCUSSION

Results from the pilot study found that the implant had remained secured to the EDC tendons successfully and fibrosis had formed around the implant site in both rabbits. The amount of fibrosis was seen to be larger in rabbit 2, with the increase in suture eliciting a larger foreign body response. For rabbits 1 and 2, there was no significant difference in the force to create movement between the implanted and contralateral leg. For rabbit 1, the force ratio between tendon bundles I/II and III/IV was found to be 37% higher in the implanted case until 1 N of added weight and 26% higher overall across all weight increments. This shows that the implant increased the force balance between the tendon bundles during rotation. In rabbit 1, the implanted case was found to have an 113% improvement in the differential action between tendon bundles. For rabbit 2, the force ratio between the tendon bundles was negligible and the implanted case was found to have a 19% improvement in the differential action between tendon bundles. This difference in rabbit 2 was likely due to the increased foreign body response inhibiting implant functionality.

SIGNIFICANCE

These preclinical trials continue to advance the development of an orthopedic implant that will allow for improved hand function for individuals experiencing C5-C8 spinal cord injuries. This work develops the New Zealand white rabbit model for research applications, specifically with tendons. Additionally, this work expands on rehabilitation practices and surgical methods in the rabbit model.

REFERENCES

[1] Mardula KL, et al. *HAND*. 2015;10(1):116-122.
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