Estimating Clinical Benefit of a Novel Passive Orthopedic Implant by Relating Objective Measures to Clinical Data

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Introduction

Our group has developed a passive orthopedic implant for use in the ECRL-to-FDP tendon-transfer surgery for high median-ulnar nerve trauma. The implant enables significantly better distribution of the ECRL's excursion across multiple FDP tendons. This in turn enables significantly better grasping capability [1]. Specifically, the implant, by virtue of its passive rotation and translation, enables all four fingers to establish a firm grasp with an object even if they are driven by one muscle. This contrasts with grasping capability enabled by current surgery, where the fingers are coupled and if one finger makes contact the other fingers also stop. The implant's functionality has been validated through biomechanical and cadaver studies, using objective measures such as grip strength and finger kinematics [2,3]. However, since the implant has not yet been validated through a clinical trial, we do not know how the implant will improve the patient's disability. This paper seeks to demonstrate the effectiveness of the implant by using objective measurements of the implant and correlations found from other studies.

Methods

This study was conducted through a literature review of studies that have investigated objective measurement of function and subjective patient satisfaction for a variety of interventions for tetraplegic patients. Results from these studies paired with objective data of the implant's efficacy from our own cadaver experiments were used to predict patient satisfaction with hand function provided by our implant.

Specifically, the implant improves grip strength, stability, and range of motion in a grasping task. These three objective measures are critical to a patient's subjective satisfaction in his/her gripping capability. Specifically, grip strength is the maximum amount of force applied to the object. Grip stability is the ability of the grip to resist disturbance forces in all directions. Range of motion is the total flexion that the fingers can perform in a gripping process. This paper relates the objective and subjective measures using a literature survey.

Results and Discussion

A cadaver study showed that the implant increases maximum gripping strength produced by 32%. Grip strength has been found to be highly correlated with functional activities of the hand such as key pinch [4,5]. The key pinch is used to complete a wide variety of ADLs, such as using a fork, turning a key, and opening a zipper. With this, functional gains in key pinch have been found to be correlated with increased patient satisfaction[4,6].

In terms of grip stability, the implant has been shown to reduce finger slip by 52% after contact with an object and allows fingers to better adapt to objects during the grasping process. Additionally, the implant has been shown to decrease the actuation force requirement to create a full grasp of an object by 45% when compared to the suture-based ECRL-to-FDP tendon transfer surgery, simultaneously improving the domains of grip strength and stability [1].

Dexterity as defined in this paper relates to the ability of individual digits to extend and flex along with the range of motion and accuracy of digits as a whole. In a different study the implant has been shown to provide nearly 170° of differential movement between the index and middle fingers, nearly three times the differentantial movement of 62° provided solely from a suture based tendon transfer surgery [7]. Increases in finger range of motion has been shown to increase overall patient satisfaction. In one study, a 25% increase in finger range of motion postoperatively led to a mean 4.5 point increase in patient satisfaction on the the Canadian Occupational Performance Measurement (COPM) [8]. Scores on categories on the COPM range from 1 to 10, with a higher score indicating greater disability [9].

From these three results, we estimate that the implant will provide a clinically significant improvement in patient satisfaction in post-surgery hand function.

Significance

This work is significant because it estimates the clinically measurable improvement in hand function that a novel orthopedic implant would provide using prior clinical hand function data and laboratory-based objective measurements of the implant's efficacy in improving grip strength and stability and finger range of motion in grasping tasks.

References

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