ÖSSUR
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i-Digits® Quantum 4-Site System

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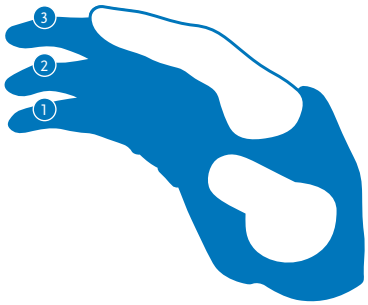
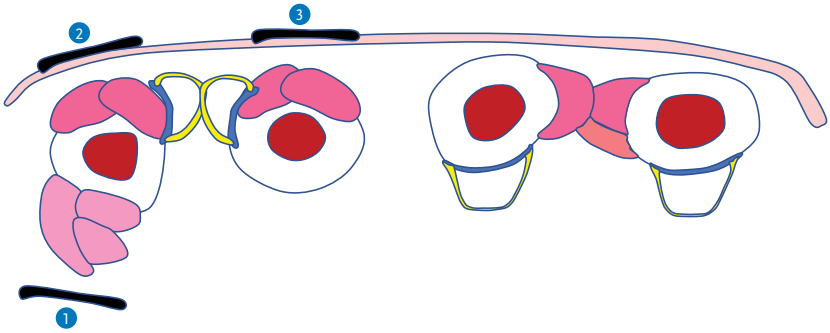
Whitepaper



Myoelectric control for hand prostheses is an ever-evolving field. A feature which is frequently requested by end-users is the ability to move each digit independently[1]. The combination of the Starfish procedure and the i-Digits Quantum 4-Site System aims to bring this enhanced control method to end-users.

Challenges



There are approximately 2 million individuals with amputations living in America[2], with roughly 20,000 new cases of upper limb loss and amputations per year[3]. While upper limb amputations account for roughly a third of all limb loss, amputations at the wrist and distal account for 90% of all upper limb amputations[3]. The prescription of prostheses to fit these individuals has been limited by available hardware, knowledge, limited experience with upper limb amputations, and complicated surgical presentations[4]. Innovations in surgical techniques and advances in technology continue to emerge in response to these challenges and in support of the functional goals of this user group.

Modern Approach

In a survey, hand surgeons expressed a lack of experience with partial hand prosthetic options[5], and yet surgical techniques continue to be developed to help combat limitations in prosthetic hardware, address after-effects of amputation, and unlock new options of prosthesis control. Targeted muscle reinnervation (TMR) has been offered to proximal upper limb amputees for some time[6] and has been shown to increase control options for myoelectric prosthesis[7]. Regenerative peripheral nerve interface (RPNI) from University of Michigan[8], developed separately from TMR, has been shown to provide similar promising effects. At the partial hand level, the Starfish procedure has been introduced by surgeons at the OrthoCarolina Hand Center to allow for clean, independent, easily accessible surface EMG for the independent control of prosthetic digits[9].

Traditional control of an upper limb prosthesis for a partial hand amputation involves two-site control, typically utilizing the thenar and hypothenar muscles in the hand. This allows the user to either open or close the digits of the prosthesis. **The Starfish procedure provides a prosthesis user with an intuitive way to operate their digits independently, while at the same time providing the prosthetist with control sites that are easy to utilize.** The Starfish surgical procedure involves taking the interosseous muscles and transposing them to the dorsum of the hand. Then, to help provide an isolated signal, the flexor tendon sheath and the volar plate are elevated and rotated to create a buffer between individual interosseous muscles. After healing, the patient can flex the corresponding finger to generate a myoelectric signal. That myoelectric signal can be used to control a prosthetic digit, with the appropriate hardware[8].

i-Digits Quantum Conventional

The i-Digits is an externally powered partial hand prosthesis with individual articulating digits. The system may include a manually rotatable thumb as necessary. The prosthesis has compliant grip, where each digit can conform to the shape of an object for stable grasp. For gripping delicate objects, proportional control is available and variable grip allows for an increase in grip force, both at the user's discretion. Pre-programmed grips are available to the user based on their goals. A flexible wrist connection connects the battery pack to the prosthesis which helps maintain wrist range of motion (ROM).

i-Digits have been shown to reduce functional deficits in individuals with partial hand amputation[9]. In performing the Southampton Hand Assessment Procedure (SHAP) with an i-Digits prosthesis users demonstrated significant improvement[10,11]. Using the Patient Specific Functional Scale (PSFS), which identifies tasks that are both important and difficult to complete, users of an i-Digits prosthesis demonstrated significant improvement in the top 5 goals in individuals with partial hand amputation[10].

i-Digits Quantum 4-Site System

Working closely with the surgeons at the OrthoCarolina Hand Center, Össur has developed the appropriate hardware to give partial hand patients independent control of their prosthetic digits. The discrete control system provides up to 4 channel independent control of the i-Digits system. Combining the control sites provided by the Starfish procedure with discrete control allow the user to manipulate each prosthetic digit either independently or in conjunction with each other and any intact anatomy. This combination provides quick, intuitive control of the prosthesis with which the patient can assume a variety of grips and hand positions directly.

Data shows that the Starfish surgical procedure paired with multi-site prosthesis controll delivers:[11] high satisfaction rates with appearance, grasp, release, and overall function; improved functional activities including self-grooming, work, recreation, meal preparation and eating; a higher percentage of patients returning to employment; and improved scores on the Disabilities of the Arm, Shoulder, and Hand (DASH) outcome measure.

Combining the Starfish procedure with i-Digits Quantum 4-Site System... provides quick, intuitive control of the prosthesis with which the patient can assume a variety of grips and hand positions directly.

Conclusion

Use of the i-Digits Quantum 4-Site System in conjunction with the Starfish procedure allows for even more distinct, independent control due to the separation and availability of muscle sites in the dorsum of the hand. An initial case study (n=3) of this treatment combination has shown improved functional outcomes in all administered outcome measures, including the SHAP dexterity assessment, and the user-specific goals assessed under the PSFS. Over a training period followed by several weeks of home use patients scored highly in user satisfaction and adaptation to the device as compared to previously used prosthetic devices[12].

References

1. Cordella F, Ciancio AL, Sacchetti R, Davalli A, Cutti AG, Guglielmelli E and Zollo L (2016) Literature Review on Needs of Upper Limb Prosthesis Users. Front. Neurosci. 10:209. doi: 10.3389/fnins.2016.00209
2. Ziegler-Graham, K., MacKenzie, E., Ephraim, P., Travison, T., & Brookmeyer, R. (2008). Estimating the prevalence of limb loss in the United States: 2005 to 2050. Arch Phys Med aRehabil, 89, 422-429.
3. Dillingham, T., & MacKenzie, E. (2002). Limb amputation and limb deficiency: epidemiology and recent trends in the United States. Southern Medical Journal, 95, 875-883
4. V. G. van Heijningen and A. Underhill, "User experiences of digital prostheses in daily functioning in people with an amputation of thumb or finger," Journal of Hand Therapy, Feb. 2022, doi: 10.1016/j.jht.2022.01.002.
5. Graham, E. M., Baschuk, C. M., Atkins, D. J., Hutchinson, L., Duncan, C. C., & Mendenhall, S. D. (2022). Hand Surgeons' Understanding of Partial Hand Prostheses: Results of a National Survey Study. HAND
6. Hijjawi JB, Kuiken TA, Lipschutz RD, Miller LA, Stubblefield KA, Dumanian GA. Improved myoelectric prosthesis control accomplished using multiple nerve transfers. Plast Reconstr Surg. 2006;118:1573–1578
7. Urbanchek MG, Kung TA, Frost CM, Martin DC, Larkin LM, Wollstein A, Cederna PS, Development of a regenerative peripheral nerve interface for control of a neuroprosthetic limb. Biomed. Res. Int. 2016, 1–8 (2016)
8. Gaston, R. G., Bracey, J. W., Tait, M. A., & Loeffler, B. J. (2019). A novel muscle transfer for independent digital control of a myoelectric prosthesis: the Starfish procedure. The Journal of Hand Surgery, 44(2), 163
9. Wanamaker, A. B., Whelan, L. R., Farley, J., & Chaudhari, A. M. (2019). Biomechanical analysis of users of multi-articulating externally powered prostheses with and without their device. Prosthetics and Orthotics International, 43(6), 618-628.
10. Whelan, L. R., & Farley, J. (2018). Functional outcomes with externally powered partial hand prostheses. JPO: Journal of Prosthetics and Orthotics, 30(2), 69-73
11. Nord, KM et al. Outcomes of the Starfish Procedure using Muscle Transfer for Independent Digital Control of a Myoelectric Prosthesis, and Gaston, RG et al., A Novel Muscle Transfer for Independent Digital Control of a Myoelectric Prosthesis: The Starfish Procedure (Jun 13, 2018).
12. Serbin, R. et. al. (2024). Enhancing Prosthetic Outcomes in Partial Hand Amputees: A Case Series on the Starfish Procedure and Four-Site Myoelectric Prostheses [Manuscript submitted for publication]. Department of Orthopaedic Surgery, Atrium Health Musculoskeletal Institute, Charlotte, NC