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High-Strength, Novel Prosthetic Intervention for Finger Amputees

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LEARNING OBJECTIVES

After completion of this continuing education activity, participants will be able to…

- Describe the characteristics and challenges of the finger amputee population.
- Identify the current prosthetic interventions available for partial-hand amputations.
- Recognize the capabilities and limitations of various prosthetic options.
- Define mass customization.
- Identify the therapist's role in improving outcomes for finger amputees.

High-Strength, Novel Prosthetic Intervention for Finger Amputees

Background

The most common level of traumatic amputation is at the fingers. However, partial-hand (anatomic loss through or distal to the carpals) amputees have been woefully underserved by prosthetic technology despite serious health, financial and social consequences resulting from this type of injury.[1-3] More than 90% of all nonfatal workplace amputations involve the fingers,[4] translating to an estimated 21,000 amputations occurring at work each year.[5] To estimate finger loss outside of work, a study by Conn utilized the National Electronic Injury Surveillance System (a nationally representative sample of 66 US hospital emergency departments) to show that approximately 30,673 non-work-related finger amputations occurred in 2002.[6] The number of traumatic amputations per year increases with population growth.[3] Thus, the numbers noted here can be considered low as of 2019.

The loss of one or more partial or full fingers forever alters the ability to sort mail, play an instrument, return to a vocation or even dress oneself and cut food. Traumatic finger loss is most often caused by machinery, power tools, crushing injuries and stab wounds,[1,7,5] and in the adult population most often happens to men.[6] This injury often affects ability to perform work duties; in one study, 75% of manual laboring men were unable to return to their vocation after their amputation, and 26% left the workforce entirely.[8] Workers Compensation utilizes the *AMA Guides to the Evaluation of Permanent Impairment* to make a determination of whole person impairment based on digit loss.[9] Per the Guides, the hand accounts for 90% of the function of the arm, and an individual with a loss of five digits can experience up to a 54% whole person impairment. Giladi et al found that the Guides correlated well with validated outcome measures concerning

>> **Figure 1. A 26-Year-Old Male After Degloving Accident in Sheet Metal Roller Equipment at Welding Shop**

function and anatomic loss.[10] However, they also found that the Guides fell short in capturing mental health and psychosocial impacts after a disfiguring hand injury, and therefore tended to underestimate true impairment levels.[10]

The restoration of psychosocial wellness is an important consideration in partial hand amputee rehabilitation. When we are in good health, we rarely consider the contribution of our hands to our body image. Not only do they play a fundamental role in activities of daily living, our hands are also highly expressive and deeply important tools for nonverbal communication. Visible disfigurement can cause profound changes to an individual's sense of well-being. Kuret et al describe this injury as a triple threat because it involves "loss of function, loss of sensation and loss of body image."[11] Compounding the challenges for hand amputees are the lack of options for intervention that address both functional and psychosocial needs. This dearth in solutions has resulted in partial hand amputees experiencing greater incidences of PTSD, more pain and a higher likelihood of substance abuse than their peers with more proximal amputations.[12,13] Patients who have undergone trauma to their hand in the work setting are particularly vulnerable to the development of significant anxiety.[14] Because the work setting is often a major source of positive satisfaction and social interaction, the traumatic effect is compounded when this source of self-esteem is lost.[14] In their report examining the relative impact to wellness between levels of upper extremity limb loss, Kearns et al conclude that "Overall, ... clinicians and occupational therapists should be more cognizant of potential psychological differences associated with their patients' level of limb loss. More specifically, individuals with partial hand loss may be more susceptible to greater emotional reactions to their loss and increased psychological distress due to the perception of pain interfering with the work and elevated post-traumatic stress. These factors should be considered in the development and throughout implementation of treatment and rehabilitation."[12]

Advancing Solutions

Although fingers are the primary site for amputation injuries, technology has struggled to find relevant solutions. The combination of a small size and high dexterity and strength requirements presents serious design challenges for replacement digits. The wide range of anatomic presentations post injury also makes it difficult to create generalized solutions. For these reasons, traditional interventions for partial hand amputees have historically been limited to realistic silicone cosmetic restoration. While cosmetic restoration contributes overall to adjustment it adds very little in the way of function and can, in fact, become a hindrance.[11]

In the last 15 years, myoelectric intervention technology has become available to a subset of the population with amputations at the transmetacarpal level. Myoelectric partial hand devices are designed to capture and use electrical signals from contracting muscles to command motorized digits to perform a finite set of hand grasps. While myoelectric devices can assist with activities of daily living (ADLs) in the home very effectively, they currently have limited robustness to environmental conditions outside the home, such as those found on a manual labor job site or in a wood working shop where dust can be an issue. As a result, they are limited in their capacity to return workers to job sites and vocations.

Adjustable fixed opposition posts, such as those made by Point Designs LLC or the Titan Finger by College Park, are another option for transmetacarpal amputees. These systems restore basic grasp and a patient's ability to hold objects. They are physically robust and suitable for many work environments. While they have a finite number of grasp patterns and are not actively driven, they can successfully restore grasping and lifting.

However, at the finger level where the majority of partial hand amputations occur, functional solutions have eluded technologists for years. The size and fine motor function of the fingers require both a robust framework and a highly intimate fit to achieve reasonable prosthetic restoration. Recently, the introduction of a new generation of devices has shifted the paradigm surrounding this age-old problem. Advanced modern manufacturing and materials are allowing the deployment of mass-customization for the first time in history. Companies like Naked Prosthetics, Invisalign® and Adidas are harnessing these technologies to make customized products ranging from prosthetics to varying-density shoe soles. In the mass-customization process, parameters unique to an individual user can be incorporated into the final design of the product. Additive manufacturing allows engineers to create a custom physical product for a fraction of the upfront cost and time required by traditional fabrication methods such as injection molding or machining. These speed and cost reductions make the deployment of complex tailored solutions more affordable and accessible and have opened up exciting new avenues to solving previously intractable problems like functional finger replacement.

Functional Finger Prostheses

Providing appropriate prosthetic devices to finger amputees can enable them to return to the same line of work and maintain financial and physical independence that may otherwise be lost. Naked Prosthetics' individualized devices restore the active grip, pinch and dexterity needed to complete functional tasks both at home and at work.[15] The devices are currently used in welding, auto and woodworking shops, on farms, in construction, by professional musicians and even by competitive athletes. The most common use-times are 12-16 hours per day. Due to their open design, this holds true even in hot environments.

Digit presentation, joint spacing, range of motion and skin sensitivity are just a few parameters that are accounted for in the custom digits. Each device is designed with precision per amputation site. The intimacy of fit combined with the strength of the mechanisms has made Naked Prosthetics' fingers the first commercially successful finger prostheses for amputation distal to the MCP joint. They are created with the working person in mind: robust to almost any environmental condition and designed to withstand rough handling in use. The life expectancy is three to five years under normal wear and tear conditions. There are currently three products to meet the needs of finger amputees: the PIPDriver, MCPDriver and ThumbDriver (Figure 3).

Each device is body-operated by more proximal intact joints; the PIPDriver is driven by an intact PIP, the MCPDriver by an intact MCP and the ThumbDriver is anchored to and driven by both the CMC and MCP joints. The devices work by coupling an intact anatomic joint to an articulating distal prosthetic joint via a four-bar mechanism: when the intact joint moves, so does the distal prosthetic joint (Figure 4). This kinematic coupling allows users to regain dexterity, individual finger control and natural conformation to objects. The structure of the devices is designed with a strength factor of safety above and beyond what the user can reasonably output, ensuring that they will hold up under heavy use. In addition to the dexterity they provide, they are particularly strong in a power hook grip posture. Intuitive motion, dexterity and strength make these prostheses a useful option for individuals with finger amputations.

>> **Figure 2. Four MCPDrivers After a Full Day of Work in an Auto Shop**

The open palm provides breathability and makes it possible to wear the devices in hot environments. They are easy to clean, and the plastic components and soft goods are replaceable.

>> **Figure 3. From Left, the PIPDriver, MCPDriver and ThumbDriver by Naked Prosthetics in Black Carbon**

The Therapist's Role in Improving Outcomes

In upper extremity intervention, clinicians and patients rely on occupational therapists, physical therapists, and certified hand therapists to help users make gains in hand health and in device utilization. While a prosthetist may fit a device, the prosthetics and orthotics field is not prepared to provide the training necessary to ensure their patients are able to achieve full function of their devices. Especially in the case of new technologies, it is imperative that therapists become familiar with them and understand how best to help patients integrate these devices into their lives. For body-driven finger and partial hand prostheses, therapists may develop individualized plans of care that address, but are not limited to, the following factors affecting the patient's functional outcomes:

- Improving the strength and range of motion of the muscles and joints driving the prosthesis. Because these prostheses are body-driven, improving these attributes will directly improve the performance of the prosthesis.
- Decreasing sensitivity, which can limit the patient's tolerance to wearing and using their prosthesis.
- Re-educating and training the patient as to the grip patterns that are possible with each device and how best to use their body and prosthesis to successfully manipulate objects.
- Developing a wearing schedule to slowly increase use and prevent over-use injuries.
- Helping the patient adapt and modify current tools and objects, at home and at work, to function better with the prosthesis.

Naked Prosthetics has seen first-hand the difference in outcomes between patients who go to therapy after obtaining their prostheses versus those who don't. It's because of these experiences and knowing how many factors go into creating successful outcomes that every user is encouraged to pursue therapy prior to, and after receiving the prothesis. The therapist

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plays a vital role in helping finger amputees adapt to their circumstances and to get the most out of the technology provided them.

Outcomes Research

When implementing novel prosthetic technologies, evaluating efficacy and capturing outcomes is essential. The upper extremity prosthetic rejection rate is notoriously high and appears in approximately one of every four adults with upper limb deficiency.[16] To assess the rejection/adoption rate of our devices, Naked Prosthetics performed a phone survey of 102 patients selected at random in 2018. The survey found that 95 patients were still wearing their devices daily after one year's time; the top-stated reason for continued use was functionality of the device. This reflects a significantly higher adoption rate of 93%, as compared to the average 75% for upper limb prostheses.[16]

To assess device performance, Naked Prosthetics encourages its clinical partners to collect the QuickDASH (Disabilities of the Arm, Shoulder, and Hand), a self-reported measure of function, at two times: prior to prosthetic intervention and post-acclimation period. It is typical in prosthetic intervention studies to allow for an acclimation period to ensure the user has grown comfortable with and adapted to the prosthesis. There is no set time, and research varies between one week and several months (if not longer). QuickDASH data were collected internally from five subjects during the course of the ThumbDriver beta rollout in 2017. Figure 6 displays the functional scores along with the subjects' age, occupation, involved digits, prosthetic intervention and wear time. The assessment was administered before prosthetic intervention and eight weeks post-intervention. According to Davidson et al, the average QuickDASH score for able-bodied individuals is 10, and the average partial-hand amputee score is 49.[17] All five users in the beta rollout showed improvement in their functional scores. Of note is that subject 1 and subject 3 had access to hand therapy sessions.

As reported in a case study published in 2019 by Denham et al,[15] an overall increase in both satisfaction and function was observed in a patient utilizing a device by Naked Prosthetics. The study participant gained fine-motor dexterity, gross manual dexterity and grasp. Outcome measures that were employed to substantiate these claims include the Jamar Hand Function Test, the Box and Blocks Test as well as the Minnesota Manual Dexterity Test. In addition to the quantitative improvements, the study participant reported improvements in both completion of daily tasks and ease of recreational activities.

>> Figure 4. Articulation of Distal Prosthetic Joint

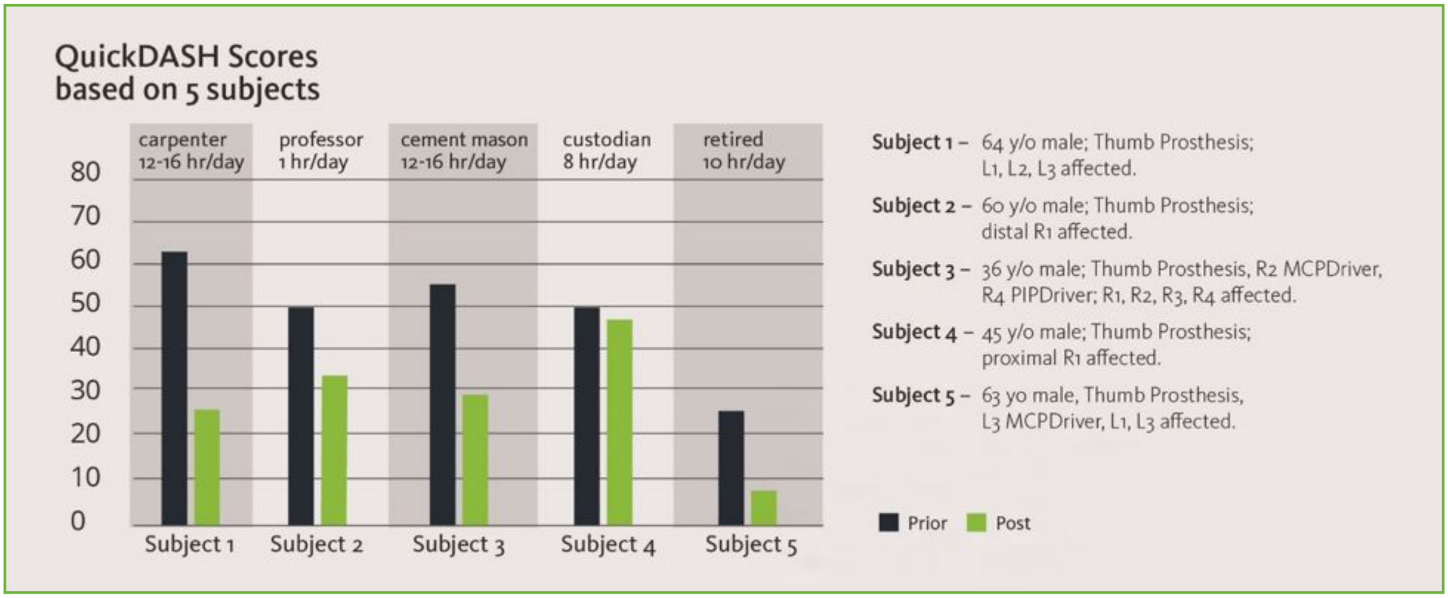
When the intact MCP joint is flexed, the distal prosthetic joint articulates with it, thus providing coupled articulation. Residual first phalanx bone drives the mechanism in the MCPDriver.

Conclusion

Therapists play an integral role in rehabilitating individuals with partial hand amputation. There are more partial hand amputees than almost any other amputation level, and the impacts of this injury can be deceptively profound. Given this, it is important for the hand therapy profession to stay up to date with the needs of the population and the prosthetic technology available. As successful solutions become more mature and accessible, the relationship between clinical prosthetists and therapists can be expected to grow as they work to improve health outcomes for patients.

>> Figure 5. A 38-Year-Old Concrete Finisher Manipulating a Screwdriver Wearing a PIPDriver, MCPDriver and ThumbDriver.

Access to hand therapy allowed this patient to improve joint range of motion, greatly increasing his grasp aperture.



>> **Figure 6. QuickDASH Results for Five Subjects During ThumbDriver Beta Testing**

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