

NOVEL MECHANICAL FINGER PROSTHESES

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NURSING DIAGNOSES TO CONSIDER NANDA-I 2018-2020

1. Readiness for enhanced self-care Domain 4, Class 5
2. Risk for activity intolerance Domain 4, Class 4
3. Readiness for enhanced self-concept Domain 6, Class 1
4. Readiness for enhanced power, Domain 9, Class 2

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Understanding the Problem

Finger loss is the most prevalent traumatic amputation in the United States and has been historically underserved by functional prosthetic technology. Despite the reality that 94% of upper-limb amputations occur at the digit and metacarpal levels, little in the way of technological development has occurred, leaving working-age people with only cosmetic options after finger loss (1,2,3). Losing 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. The injury is so devastating that in one study, 75% of heavy manual laboring men could not return to their line of work, and 26% left the workforce (4).

Many partial hand and finger amputations occur in workplaces where manual labor is performed. The injuries are caused by machinery, power tools, crushing injuries, and stab wounds (3,5). According to the American Medical Association's Guides to the Evaluation of Permanent Impairment, the hand accounts for 90% of the function of the arm (6); an individual losing five digits can experience up to a 54% whole person impairment.

Given the lack of functional intervention options, not surprisingly, outcomes for partial hand amputees are worse than more proximal arm amputations. Literature shows

that partial hand amputees experience more mental health issues, more pain, and less function than forearm amputees (7). Individuals with the ability to return to work after partial finger loss often rely heavily on their contralateral limb and/or compensatory movement. This leads to overuse injuries, especially to the contralateral limb (8,9). An ideal intervention would not only restore the ability to perform self-care and daily living tasks, but also be robust enough to allow a person to return to work.

Our hands serve many roles. Besides being the most versatile end effectors in the world, they connect us emotionally and socially with others, and express or represent feelings, thoughts, or symbolic aspects of one's self (10). Disfigurement can cause profound changes to an individual's sense of well-being. It can lead to social ostracization, agoraphobia, problems with routine social interactions, and a psychological conflict between body image and what the ego maintains as ideal. Up to 94% of individuals with mutilating hand injuries experience symptoms associated with stress and anxiety disorders, major depression, pain syndromes, and adjustment problems, and these problems do not resolve with time (11). Patients who have undergone trauma to their hand in the work setting seem particularly vulnerable to developing significant anxiety. Additionally, work is often a major source of positive satisfaction and social interaction, so the traumatic effect is compounded when it is lost (11). Consequently, the plan of

care after disfiguring hand injury should include means for restoring psychosocial wellness.

Finding a Solution

Recent advances in technology have provided partial hand patients with functional options for the first time. Myoelectric intervention for transmetacarpal level amputations, for example, first came on the market about 10 years ago. These devices capture signals from muscle bodies to command motorized digits to perform a finite set of hand grasps, all within a physical envelope much smaller than with full hand loss. While these can be life-changing and are a good option for restoration of basic function at the transmetacarpal level, many find they are not as responsive as desired, inappropriate for use in harsh environmental conditions such as a manual labor job site, and cumbersome.

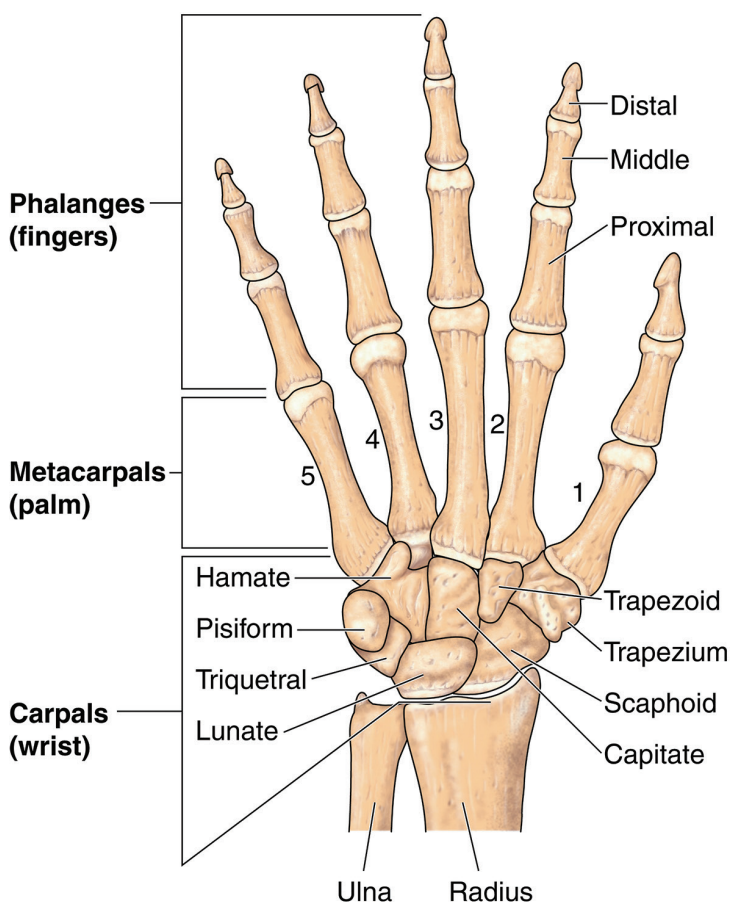
Another transmetacarpal option is the adjustable fixed opposition post, such as those made by Point Designs LLC, or the Titan Finger by College Park. These systems restore basic grasp and a patient's ability to hold objects. They are physically robust and suitable for many work environments. While they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

At the digit level, where 88% of partial hand amputations occur, for decades the only solution has been realistic silicone cosmetic restoration. Recently, a new generation of devices using advanced modern manufacturing and materials allow mass customization for the first time in history. Naked Prosthetics is one company, along with examples like Invisalign® and Adidas, harnessing these new capabilities.

Naked Prosthetics' Solution

Using mass-customization and novel design, Naked Prosthetics' fingers restore natural motion, dexterity, and strength. This company is unique because it has brought together experienced engineers from aerospace, robotics, prosthetics and product development to collaborate with clinicians and patients. Strong focus on engineering design means that the devices are kinematically and structurally optimized to account for both the capabilities of the patient's driving joints and the conditions under which the devices are used. Each device is designed with a safety factor above and beyond the forces the user will see and can be used in virtually any environment.

There are three products available that cover all levels of partial finger amputation: the PIPDriver, the MCPDriver, and the ThumbDriver. Operated by the user through intuitive movement and driven by remaining intact joints, these prostheses require little acclimation restore digit dexterity and hand strength without specialized training. Users report that with time these prostheses feel like parts of their bodies (12,13,14).





Each affected finger receives a custom design to restore digit length, joint spacing, and range of motion, accounting for a user's unique amputation level and joint capability. Beyond the functional design, each has been tested for structural integrity and fatigue life. For example, the PIPDriver design saw over six million high stress real-world cycles on the benchtop before being released to beta testing. Product life expectancy is three to five years with minimal maintenance.

These devices restore the active grip and pinch force needed to complete many functional tasks both at home and at work. When a worker experiences finger loss, the team makes decisions concerning return to the workplace, vocational retraining, and settlements. Providing appropriate prosthetic devices in these cases can mean returning to the same line of work, quickly. They are used in welding, auto and woodworking shops, on farms, in construction, by professional musicians, and even by competitive athletes, each with high physical demands and harsh working environments in careers and hobbies. They are commonly in use 12-16 hours per day even in high temperature environments.

Outcomes Research

Naked Prosthetics supports evidence-based work both inside the company and with external clinical partners. Upper extremity prosthetic rejection rate is notoriously high: about one of every four adults with upper limb deficiency cease use of their arm prostheses within months (9). In 2018, we performed a phone survey of 102 patients selected at random and found that 95 were still wearing these devices daily after one year; the most-often cited reason was its functionality.

To assess device performance, Naked Prosthetics encourages its clinical partners to collect the Quick-DASH (Disability of Arm, Shoulder, and Hand) self-report function, activity, and participation survey before and after fitting. Quick-DASH asks questions about a variety of common manual tasks and the patient's difficulty in performing them. It contains work and hobby assessment modules, and is widely used in upper-extremity impairment assessment to evaluate function. A lower score means improved ability, with 0 representing no impairment. Quick-DASH data were collected internally during the ThumbDriver beta rollout in 2017 and are shown below for all completed subjects. Figure 1 displays the age, occupation, presentation, intervention, wear-time, and Quick-DASH score change before intervention and eight weeks post-intervention. According to Davidson et al. (15), the average Quick-DASH score for able-bodied individuals is 10, and the average partial hand amputee score is 49. All five users showed improvement.

In a case study published in 2019 by Denham et al. (16), the patient expressed satisfaction and function increased using this device, gaining fine motor dexterity, gross manual dexterity, and grasp for daily tasks and recreational activities.

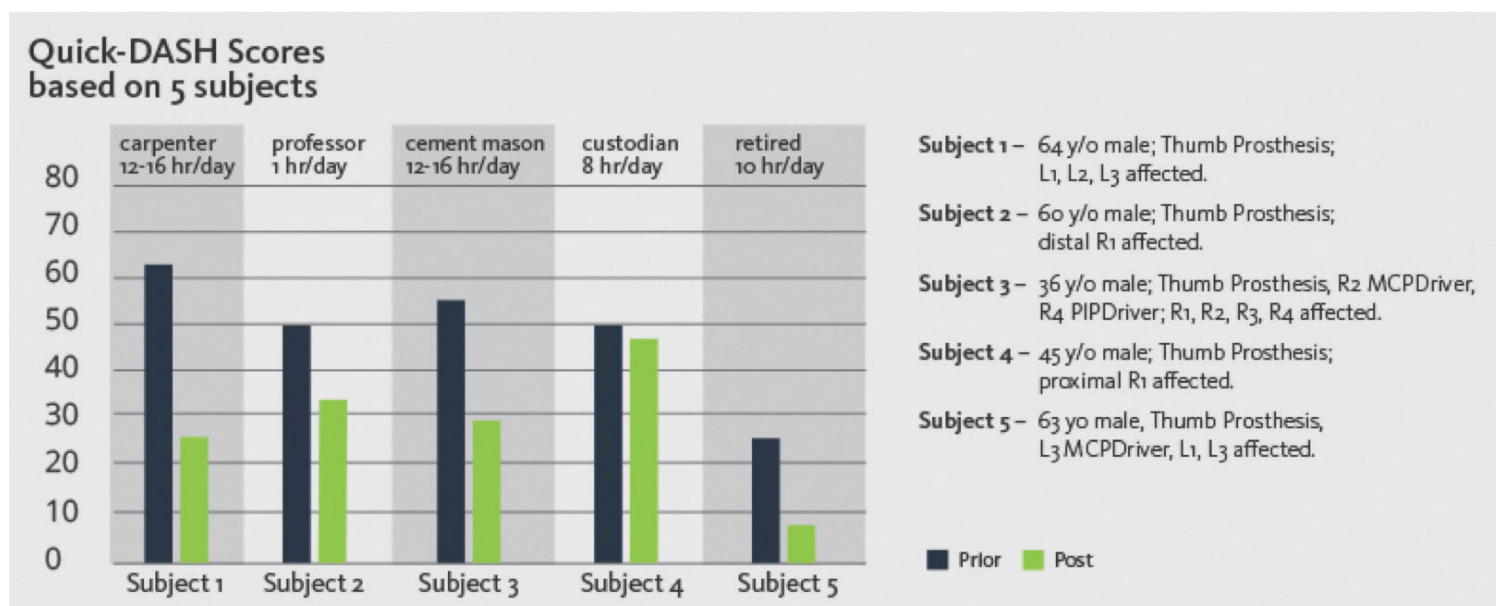


Figure 1. Age, occupation, presentation, intervention, wear-time, and Quick-DASH score change. Higher score indicates more disability.



Outcome measures were measured with the Jamar Hand Function Test, the Box and Blocks Test and the Minnesota Manual Dexterity Test.

Obtaining a Device

Like most prosthetic manufacturers, Naked Prosthetics does not sell directly to the public. A certified prosthetist (CP) helps determine needs and appropriate technical specifications, and takes necessary measurements, images, and molds of the affected hand. Naked Prosthetics fosters strong relationships with clinical practices and is happy to help the NLCP identify a clinic familiar with the technology.

Once the device is fabricated and delivered, the CP will fit the patient, often with advice from the support team via video or phone. After fitting, the recipient should engage with hand therapy to improve outcomes. Day-to-day device maintenance is straightforward: the user simply washes the device as an anatomical hand. It holds up well to harsh chemicals and tough environments. In some cases, users may want to lubricate joints with a basic food-safe oil likely found in their kitchens.

Patients can expect to cosmetically refresh their MCPDrivers and ThumbDrivers at least once per year. This involves purchasing a fairing replacement kit, which can be swapped out by either the recipient or a clinician. Expected yearly maintenance includes the above-mentioned cosmetic refresh,

and potential replacement of minor parts like rings, screws, or wrist straps. Life expectancy of each device is three to five years, and a standard warranty of one year is provided with extended warranties available.

Coding

Only certified prosthetists can bill for these prosthetic devices. Recommended L-coding for all products is L7499, "upper extremity prosthesis, not otherwise specified." Miscellaneous codes do not have attached reimbursement amounts; interested prosthetists can contact the manufacturer for a quote and MSRP based on specific patient needs. Quotes will vary case-by-case due to the custom nature of each device and amputation. Naked Prosthetics provides a reimbursement support packet of material that makes the process easier.

Conclusion

The prevalence of finger and thumb amputations and the significance of these impairments on the lives of patients who experience such injuries warrant a better standard of care. Development of prostheses for this population has been impeded by technical and anatomical challenges, but a new generation of practical, durable, body-driven prosthetic digits can enable care teams to address an unmet need and transform the lives of people who have undergone finger amputation.

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