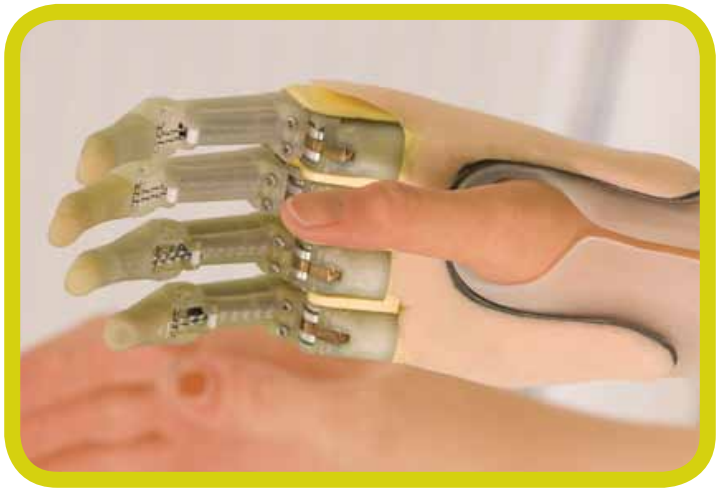
TOUCH BIONICS™
Transforming the Everyday Lives
of Extraordinary People



PRODIGITS™

The Partial Hand Solution

The first electromechanical 'bionic' finger solution for the partial hand amputee.

April 2010

INTRODUCTION

Although externally powered myoelectric prosthetic hands have been available and regarded as "standard practice" for adult and pediatric amputees for decades, for many reasons there has been a total absence of similar technology for the partial hand amputee.

Recent developments in microprocessor size and technology, advancements in battery technology, software development, and smaller motors have finally broken those technological barriers. The result is the unprecedented ability to restore active grasping to persons with either congenital or acquired absence of some or all of their fingers.

Developmental clinical applications of this technology have taken place over the past 2 years, both in the US and the UK, resulting in over 30 fittings of this system. These have included unilateral and bilateral cases, single and/or multiple digital loss, as well as complex congenitally involved and burned hands.

Throughout the process of restoring active grasping to these variously involved patients, each of the component elements were evaluated by a team of clinicians, therapists, technicians and engineers. The results have been revolutionary, innovative and dramatic.

HISTORY

The history of Touch Bionics goes back to a program of work conducted at the Princess Margaret Rose Hospital in Edinburgh from 1963, starting with comprehensive research into developing prosthetic solutions for children affected by Thalidomide. In 1988, work began in earnest on electronic arms, including shoulders, wrists and hands. In 1993, a partial hand system received international publicity and in 1998, major international profile was achieved through the fitting of the world's first electrically powered shoulder.

In 2007, Touch Bionics brought to market the i-LIMB™ Hand, a first-to-market prosthetic device with five individually powered digits for full hand amputees.

THE WORLD'S FIRST BIONIC FINGER

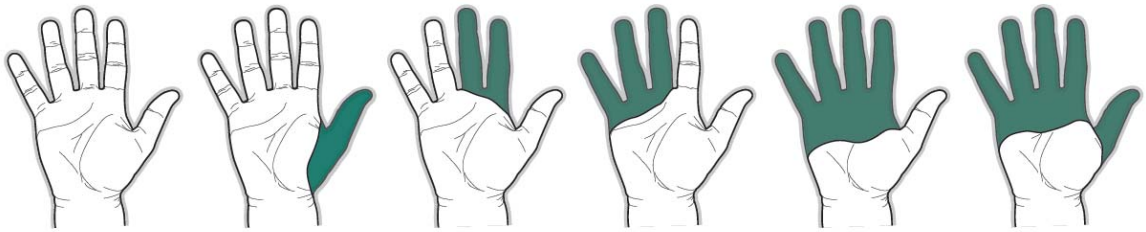
ProDigits™, short for Prosthetic Digits, are the self-contained fingers that are individually powered and controlled to provide new fingers for partial hand patients. The early versions of this solution were tested in November 2000 in studies supported by Nottingham City Hospital in the UK.

The articulating digit underpins much of ProDigits' technical advantage and it is this articulation that provides the biggest benefit to the patient or user. With the ability to bend, touch, pick-up and point – the ProDigits used within an overall prosthesis reflect the function of a natural hand. Commercially available powered solutions have not been available to partial hand amputees in the past.

CANDIDACY

Not having fingers or a thumb to act in opposition to one another makes simple tasks such as holding a fork or a cup difficult and frustrating. Thanks to ProDigits, an expertly built prosthesis rebuilds function and confidence.

Each individually powered ProDigit provides myoelectric control that has never been possible before. Now patients with between 1-5 missing fingers have a solution for what was once a highly debilitating condition.



There are physical criteria that dictate whether ProDigits are appropriate or not – candidates must have 'Amputation at Transmetacarpal Level' or higher of one or more fingers. It is possible to support candidates with a portion of the finger remaining, however, this may affect the aesthetics of the overall prosthesis.

This amputee population is considerable, estimated at around 44,000 patients in the U.S. and 1.2 million worldwide, and until now, these people have had no motor-driven prosthetic solution available to them that offered significant function combined with a favorable aesthetic.

CATEGORIZING HAND DISABILITY

In 1964 a researcher by the name of Swanson developed a system to categorize impairment at each level of finger amputation. A two finger amputation will translate into 20%-40% hand impairment (depending on which fingers are affected) and close to 11%-22% whole person impairment – i.e. overall disability profile, including both physical and psychological metrics. With three fingers this figure changes to between 40%-50% hand impairment and 22%-35% whole person impairment.

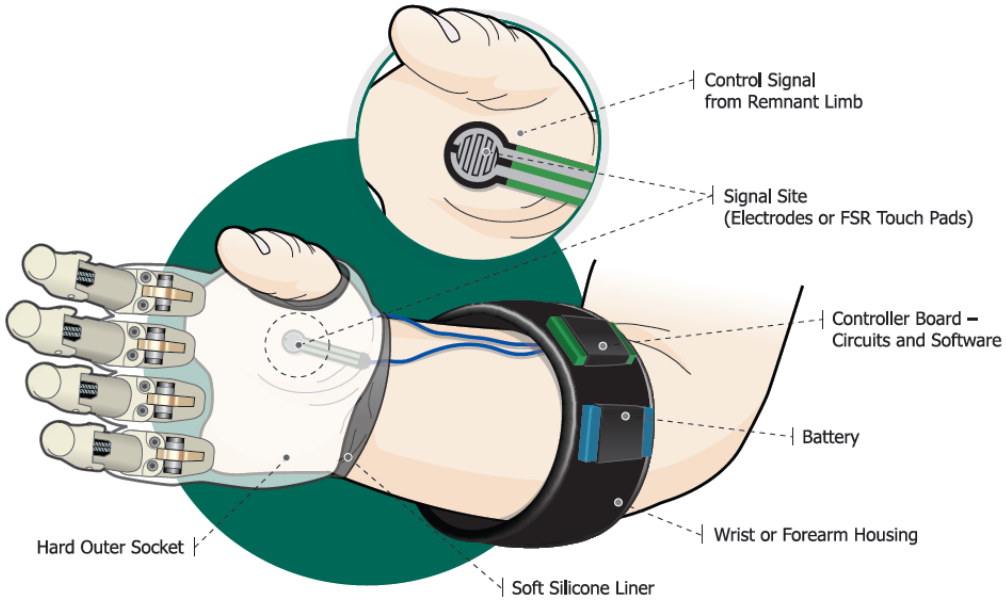
Thumb loss will significantly contribute to the impairment of an individual with digital amputations as the total thumb represents 40% hand impairment. Single ProDigit thumb fittings have demonstrated an excellent return to function.

SOCKET DESIGN AND INTERFACE MATERIALS

Among the many fundamental functions of the hand are proprioception, or the ability to "feel" the apprehended object's temperature and texture, as well as the motions of the wrist, which include flexion, extension, radial and ulnar deviation. Attempts to expose the soft tissue of the hand to allow for proprioception are also made, particularly in the case of bilaterally involved

patients. Teams of rehabilitation specialists, which include a primary role for the Occupational Therapist, make every effort to enable the ProDigits systems to work with, and not inhibit, these natural movements, and designs of prostheses are developed accordingly.

The appropriate clinical approach is rooted in the philosophy associated with the traditional rehabilitation team, which includes the vital roles of PM&R (Physical Medicine and Rehabilitation) Physician, Occupational and/or Certified Hand Therapists, and Prosthetist in the evaluation, design and training of ProDigits prostheses.



All designs make every effort to preserve the critical functional elements of the hand, as well as to protect compromised skin, whether burned, grafted, inelastic or adhered. This is normally accomplished by using multidurometer silicone interface materials, which allows ProDigits users to comfortably wear the sockets without further irritating or damaging the soft tissue of their remnant digits or hands.

The modular nature of each ProDigit and the individually powered motor located within each digit means that the clinician can build a replacement prosthesis that is close to the patient or users missing anatomy. Solutions can be built to match the sound side or any remaining fingers. Thumb solutions can be built using either powered or non-powered options to provide grip opposition.

INPUT/SIGNAL SYSTEMS

All electromechanical prosthetic devices require a method of transferring the user's muscle signal or movement of a remnant part to activate the motion of the device, and create motion in the hand or fingers. Traditionally, myoelectrodes were predominantly used to transfer the patient's muscle contraction to the prosthetic hand.

Although electrodes are regularly used to activate the opening and closing of the fingers of the ProDigits system, the development team expanded the input options to include force sensing resistors (FSR or touch pad) and linear transducers, which allows patients to initiate movement in the fingers even if muscles in the affected area are absent, burned or otherwise unable to generate an electromyographic signal strong enough to create movement (i.e. locating and using the input signal sites further up the forearm).

This allows individual movement of the fingers, sometimes in complex patterns of prehension, including the very important “pinch grip” pattern, which occurs between the thumb and index finger.

CONTROL STRATEGY

Once an acceptable and repeatable signal site and input method is identified and tested, various control strategies are considered and tested, in order to either immediately or sequentially allow the user to intuitively activate the desired motion, whether that motion is flexion (closing of the fingers to grasp an object) of extension (opening of the fingers to release an object), in addition to more complex grasping patterns for specific activities such as activating the index finger only for a pinch grip.

The ProDigits system also allows for non-grasping but very important activities, like finger pointing, which can be used for keyboarding, cell phone or ATM use, as well as “thumbs up” motions normally used as elements of expression by those of us with intact hands.

The practitioner can choose among the various control strategies via Bluetooth connections to the ProDigits System to maximize the functions needed by the user. The Bluetooth controller that forms part of the ProDigits system can control fingers individually and at different speeds. Finer configurations can be managed by the prosthetist via a PC/Laptop using an intuitive GUI (graphic user interface).

POWER

All electromechanical prostheses require stored power, as well as access to charging the batteries, and a method of turning the device off and on. Locating this “hardware” in the device depends on the length of the remnant limb. If the amputation is far enough proximal to the MCP joints, these elements of the device can be integrated into the “palm” of the prosthesis.

If the amputation site is more distal, then the “hardware” must be moved onto the forearm, and housed in as unobtrusive a method as possible, while still providing access for charging the batteries. Battery, controller module and associated wiring have been housed in a number of personalized and functional ways and result from the interaction between the patient and the prosthetist.

FUNCTON AND APPEARANCE

Since the hand and fingers are second only to the face and head as the most visible part of the body – Touch Bionics’ development team has created a choice of two innovative prosthesis

coverings, both of which set new industry benchmarks, meet specific usage objectives and provide a suitable aesthetic to align with the patient's personal preference. Coverings provide a firm grasp and good control of whatever is being held. The silicone base material is a barrier to water and other destructive particles that can damage the electromechanical elements of the system.

For some patients the high-tech clear and black robotic skins offered by the company create a confident and highly functional solution. Others prefer a LIVINGSKIN option – this high definition silicone solution is used to provide a human-like restoration to the combined limb and prosthesis for a comprehensive prosthetic restoration.

With a LIVINGSKIN covering option the silicone provides a surface texture designed to create optimal friction between the powered fingers and the grasped object while, consistent with decades old research related to high utilization of upper extremity prostheses, LIVINGSKIN restores a natural appearance to the prosthesis – eliminating for some the self-consciousness associated with otherwise unnatural appearing prosthetic systems.

The combination of these two covering approaches assures that patients use the ProDigit device both at home and in other social or professional situations.

BENEFITS

The benefits of the ProDigits system to a patient without the ability to grasp any objects are obvious, and relatively easy to identify. What is less obvious as a benefit or, when being considered by a payer or healthcare provider, as a cost saving is the common risk of Overuse Syndrome, also referred to as Repetitive Stress Injuries (RSI), which is associated with unilateral hand loss and excessive use of the intact hand. This commonly results in problems at the wrist, elbow and/or shoulder, and can require medication, therapy and surgery to correct. In the bilaterally involved patient, the benefits of the system are even more obvious.

Vocational and social reengagement is also very important to patients' rehabilitation after a traumatic event. Partial hand injuries are, by their nature, challenging aesthetically and therefore all that can be done to reinstate a patients function and interaction other people within their chosen lifestyle and career is another direct benefit of ProDigits.

Due to the personalized nature of each ProDigits fitting, Touch Bionics is developing a clinical collaborator program in North America that will enable the company to partner with practitioners in order to support patients at a local level. Around the world Touch Bionics has established relationships and distribution channels in over 40 countries to support the roll-out of ProDigits – supported from its Centre of Excellence in Livingston, Scotland, where the company has fit patients from all over the world.

CONCLUSION

Comprehensive treatment of this long neglected population, which includes:

- Careful patient selection
- Pre and post prosthetic Occupational Therapy
- Thoughtful design of the socket, the socket interface and control strategy
- Staged training and follow up and;
- Attention to the aesthetic aspect of the device

Will result in a level of restoration and utilization that is both predictable and unprecedented with the arrival of ProDigits.

While no single prosthetic device can replace the multiple deficits associated with upper extremity limb loss, the goal of returning the partial hand amputee to an optimal level of functional rehabilitation is achieved and monitored by all members of the rehabilitation team.

REFERENCES:

Gambrell, C: Overuse Syndrome and the Unilateral Upper Limb Amputee: Consequences and Prevention. Journal of Prosthetics & Orthotics. 2008: 20; 126- 132.

Lake, C: Experience with Electric Prostheses for the Partial Hand Presentation: an Eight Year Retrospective; Journal of Prosthetics and Orthotics, April 2009, Volume 21, Number 2, 125-130.

Partial-Hand Amputations. Atlas of Limb Prosthetics, Surgical, Prosthetic, And Rehabilitation Principles, American Academy of Orthopaedic Surgeons, Second Edition, Chapter 7, 199-235.

Partial-Hand Amputations. Atlas of Amputations and Limb Deficiencies, Surgical, Prosthetic, and Rehabilitation Principles, American Academy of Orthopaedic Surgeons, Third Edition, Chapter 13, 197-218.

Passero, T, Doolan, K: Aesthetic Prostheses. American Academy of Orthopaedic Surgeons' Atlas of Amputations and Limb Deficiencies Surgical, Prosthetic, and Rehabilitation Principles, 2004: 24; 303-310.

Pillet, J, Mackin, E: Aesthetic Hand Prosthesis: It's Psychological and Functional Potential. Rehabilitation of the Hand and Upper Extremity, 2002, Volume 2; 88; 1461-1472.