Advances in Amputation
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From the Editor

Welcome to the JNLCP for Spring 2020, Advances in Amputation.

Several of our authors in this issue say that amputation is a life-changing event, and so it is. We think of amputation so often as a post-traumatic event, inflicted by a major crush— or even a shark bite (Surf, 2011). Vascular disease, largely related to diabetes, causes 54% of the 185,000 amputations in the US. Trauma accounts for about 45%, and malignancy is a minor factor at about 2% (Amputation Coalition, n.d.). Limb absence can also be congenital. Finally, coronavirus has proved to cause coagulopathies; limb loss related to this is beginning to show up in the statistics (Tang et al., 2020).

Like many of us perhaps you’ve only ever seen sockets to hold leg prostheses in place. Take a look at osseointegration in action. How about the latest in targeted muscle innervation for an upper extremity prosthesis that goes far beyond the older muscle-powered prostheses we’ve seen for years? Imagine a hand prosthetic that can grasp something as softly and gently as your own hand...and support a free-climber on the climb up a cliff. The historical background and new technologies our authors share here offer the nurse life care planner excellent perspectives from experienced clinicians, technologists, physicians, and nurse life care planners. You’ll find your practice enriched by their experience.

You can also search online for many solutions complementing the high-tech things we have here. There are a growing number of cottage-industry solutions to congenital losses. See a few advances in homemade 3-D printing (e-NABLE, 2020) and even Lego bricks (Tech News, 2019).

It’s been hard for me to write this editor’s note as business-as-usual when so much is going on around the world. The metaphors of the earth shifting beneath us, sailing on uncharted waters, that unanchored up-in-the-air feeling...we all struggle to find the words to help us relate the events of this terrible time to something familiar.

I know you’ve seen some version of this sentence more than once lately: As I write this, our world is changing forever. It came to me that it feels as if we’ve suffered an amputation of sorts, too—a loss of something that felt solid, supported us all our lives, and can never really be replaced. Some of it’s from acute trauma: the sudden overwhelming by a contagious disease; some of the effects are the consequences of preexisting conditions: poverty, pollution, inequality, prejudice, and fear.

What will provide the functional capacity for easy movement in crowds and public transportation, children’s hugs and kisses, the support of work? I guess that remains to be seen. Personally, I’d love to be around in a generation or so to see the accounts that historians will write. Think of the possibilities: epidemiological, medical, nursing, surely. Then social, psychological, education, public health, political, economic; art, drama and music, literature, communication; sports; sociology, family and childrearing, memoirs, spiritual and religious practices, charity; energy use, food supply, ... so many genres will look at what we’ve lost. Meanwhile we also can take many opportunities to discover what’s really important. What prosthetics will we develop and learn to rely on? Those are the advances I want to see.

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The Best Years of Our Lives, 1946


e-NABLE (2020) http://enablingthefuture.org/lend-a-hand/


Information for Authors

AANLCP® invites interested nurses and allied professionals to submit article queries or manuscripts that educate and inform the Nurse Life Care Planner about current clinical practice methods, professional development, and the promotion of Nurse Life Care Planning. Submitted material must be original. Manuscripts and queries may be addressed to the Editor. Authors should use the following guidelines for articles to be considered for publication. Please note capitalization of Nurse Life Care Plan, Planning, etc.

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- Submit only original manuscript not under consideration by other publications
- Put the title and page number in a header on each page (using the Header feature in Word)
- Place author name, contact information, and article title on a separate title page
- Use APA style (Publication Manual of the American Psychological Assoc. current edition)

Art, Figures, Links
- All photos, figures, and artwork must be in JPG or PDF format (JPG preferred for photos).
- Line art must have a minimum resolution of 1000 dpi, halftone art (photos) a minimum of 300 dpi, and combination art (line/tone) a minimum of 500 dpi.
- Each table, figure, photo, or art must be submitted as a separate file, labeled to match its reference in text, with credits if needed (e.g., Table 1, Common nursing diagnoses in SCI; Figure 3, Time to endpoints by intervention, American Cancer Society, 2019). Graphic elements embedded in a word processing document cannot be used.
- Live links are encouraged. Please include the full URL for each.

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Manuscript Review Process
Submitted articles are peer reviewed by Nurse Life Care Planners with diverse backgrounds in life care planning, case management, rehabilitation, and nursing. Acceptance is based on manuscript content, originality, suitability for the intended audience, relevance to Nurse Life Care Planning, and quality of the submitted material. If you would like to review articles for this journal, please contact the Editor.

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I hope everyone is healthy and weathering the COVID-19 and social distancing well. During this crazy and quickly changing time, I wish everyone the best. I would like to thank all our members who are still actively working in patient care and those who have found their own ways to give back.

As some have learned at the conference Kim Kushner made the tough decision to stepdown as President of the AANLCP, and so the Executive Board felt it was in the best interest of the Association I move back into the position as President. I look forward to working with the Executive Board and our members as we work through our next adventure.

We were able to sneak our 2020 Expand Your Horizons Conference in right before everything shutdown, and what a conference it was! The current situation makes it feel even more special in retrospect. The setting was in beautiful San Diego and our weather was perfect. Our Conference Committee worked very hard all year and brought together a wonderful conference and a marvelous group of speakers. I would like to thank our conference committee Cochairs Jenn Craigmyle and Kelly Campbell, and their team: Barbara Greenfield, Kelly Ehrhardt, Amy MacKenzie, Brenda Boston, and Laura Maycock for all their hard work and dedication.

The “First -Time Attendee, Newly Certified, and Student” social on Thursday was a big hit and well-attended. We met new friends and colleagues and toasted marshmallows over a cozy fire. The traditional Friday “Welcome Reception” also had a great turnout. I don’t know if I’ve ever been to a hotel with staff more accommodating and pleasant. There was a caricature artist, and I hope everyone has their caricature proudly displayed in their office. The harbor cruise featured a wonderful dinner, and we saw people dancing and singing with heretofore unknown talent!

This year I had the pleasure of awarding the well-deserved Ambassador Award to Barbara Bates in absentia. She has worked very tirelessly for the AANLCP and the CNLCP for many years. Thank you, Barbara! I looked forward to presenting the Distinguished Service Award to Victoria Powell for weeks, and stalked her husband for the first half of the conference to make sure he was present. He wasn’t aware that she was winning the award – because she was presenting the same award to me! Unbeknownst to us both, the Executive Board fooled us into having both of us on the stage at the same time. When Victoria walked on stage and reached under the podium, I had no idea what was going on. One thing I do know, I am honored to share the Distinguished Service Award with Victoria.

Kay Hairston was the winner of Find A Codes’ free one-year subscription, congratulations.

I would also like to send out a great big “THANK YOU” to all of our conference sponsors and vendors. They are the ones who support us throughout the conference and the year.

Please, feel free to reach out to me if you have any questions, comments, or suggestions. I appreciate them all.

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Ms. Pettengill has over 32 years of experience as an RN, working in the hospital setting in geriatrics, pediatrics, telemetry, and orthopedics. For the last 29 years she has been a case manager for work related injuries and illnesses. Ms. Pettengill has extensive experience with catastrophic injuries and in 2004 became certified as a Nurse Life Care Planner. Ms. Pettengill became a Medicare Set Aside Consultant Certified in 2005 and began writing MSAs. She currently works per diem for a local home health agency to keep her hands-on clinical skills current, working with patients over the continuum of care including high tech pediatric patients. She has been a member of AANLCP since 2004, often working on the conference committee. She served as the CNLCP® Certification Board Secretary from 2007 to 2018.

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Corey Pettengill BS is a graduate student from Eastern Michigan University studying Orthotics and Prosthetics. He graduated Cum Laude from the University of Vermont last year with his bachelors in biology. He is passionate about helping patients with their rehabilitation needs and is excited to begin practicing. He recently began working with a company which manufactures cranial orthosis. He is scheduled to graduate from EMU spring 2021. In his spare time, Corey enjoys rock climbing, hiking, and drumming.

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Michele Nielsen Cook

Michele Nielsen Cook has been an RN since the 1970s, a medical case manager and vocational counselor since the 1980s, and a life care planner (CLCP and CNLCP) since the 1990s, primarily in Oregon and the Pacific Northwest. She has been owner and operator of Medical Vocational Planning for several decades, growing it into six offices and thirty employees, until working solely seemed more ‘workable.’ With her son joining her as a Certified Rehabilitation Counselor (CRC) this summer, she is growing her company to prepare for the future. She can be contacted at michelejcook18@gmail.com.

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Aislinn Wyatt has master’s degree in education from Notre Dame and a master’s in prosthetics and orthotics from the University of Washington. She is a licensed and certified prosthetist/orthotist and has worked as a clinician in both the private and public sectors.
When planning long-term care for an amputee, the NLCP should realize that a good portion of future costs are for prosthetics and related supplies. Over the past 10 to 15 years, there have been incredible advancements in prosthetics. While technological advancements so far have come in the devices themselves, there is also increased research in sockets and liners. This article defines prosthetic component terms and serves as a basis for following articles, where many photos can be found.

**Lower Extremity**

*Components:* Socket, suspension system, pylon, foot.

Sockets must be well made to provide control over the prosthesis, prevent skin irritation, and increase comfort. The prosthetist custom-designs it to fit the amputee’s unique residual limb. There are multiple design options.

A silicone suction socket incorporates a silicone liner with a suspension sleeve and a supportive carbon fiber frame on the outer aspect.

A vacuum-assisted socket has a liner, a suspension sleeve, and an air evacuation pump. A vacuum between the liner and the socket wall holds the prosthesis snugly in place. A vacuum-assisted socket is used with a vacuum suspension system.
A dynamic suction socket has a thin, bioelastic socket with a supportive outer frame of carbon fiber. This type of socket allows residual limb muscle fibers to fire freely within the socket, allowing for muscle strengthening. Lastly, dynamic sockets are designed with panels that can be adjusted for fit.

The prosthettist makes a plaster cast or model of the residual limb from which to fabricate a test (evaluation) socket with a special transparent material. This allows the prosthettist to evaluate areas of pressure that can then be marked up and refit. An amputee may go through several test sockets over several weeks before a definitive socket is made. The practitioner must work not only on the socket’s alignment to allow for strength, flexibility, and fit. Creating a prosthesis is highly individualized. A component that works for one person may not be appropriate for the next.

Some amputees prefer cosmetic socket covers made of PVC or silicone to look like the natural limb, and others use spandex or Lycra sleeves. They can be applied during the laminating process so the pattern is adhered to the socket itself. Similarly, the amputee can bring in meaningful graphics or emblems to apply to the socket before laminating. Another option is a customizable fairing that snaps over the prosthesis itself. Other decorative options are custom painting or airbrushing like that used on motorcycles or automobiles.

Underneath the socket is typically a liner fits over the residual limb and acts as a cushioning barrier between the socket and the skin to increase comfort.

Because weight fluctuates daily and even over hours in a single day, the amputee must be able to manage the residual limb differences easily. One way to manage volume changes is with prosthetic socks. Prosthetic socks are usually worn over the liner to manage residual volume changes of the residual limb. Socks come in different materials and thicknesses (plies). Prosthetic socks should be replaced every six to twelve months and replaced when they look stretched or frayed. The prosthettist should always document the number of socks or plies the amputee is wearing at rechecks; an increased number indicates the need for socket replacement.

Suspension systems hold the prosthesis to the residual limb.

A sleeve suspension is simple and easy to use. It is made of a stretchy fabric, much like wet suit material, worn over the outside of the socket and extends onto the bare skin of the residual limb where it adheres. This seals the top of theocket to prevent air from entering or exiting the socket. The sleeve includes a valve that releases air as the amputee walks. Even a pinhole leak in the suspension sleeve can eliminate the suction effect resulting in the immediate need for a replacement sleeve.

**NURSING DIAGNOSES TO CONSIDER**

*NANDA-I 2018-2020*

1. Risk for activity intolerance, Domain 4, Class 4
2. Risk for falls, Domain 11, Class 2
3. Risk for impaired skin integrity, Domain 11, Class 2
4. Risk for activity Intolerance, Domain 4, Class 4

Another common suspension system is the *pin suspension*. This suspension uses a similar liner, but it has a locking pin that extends from the posterior aspect of the liner to the posterior part of the socket. The wearer dons the liner and then the prosthesis, entering the pin into the lock which keeps the prosthesis from falling off. Unlike the suspension socket, the liner is worn under the socket rather than on top of it. Most wearers think that the pin suspension feels securely attached, but pistoning of the tissues in and out of the socket can be a problem.

Suction or vacuum suspension uses subatmospheric pressure to suspend the residual limb within the socket. These require more maintenance than other suspension systems and can feel very hot in the summer. However, they help residual volume constant and makes the limb feel lighter to the wearer.

Prosthetic knee joints are also custom-fit to the wearer’s needs. A single axis knee is a moves only in one axis. They are durable and reliable, but only move at one speed. These are appropriate for above-knee amputees to utilize their prosthesis primarily to transfer.

A polycentric knee (also called four-bar) has multiple axes. It is more versatile, but also limits walking speed. Some four-bar knees incorporate a hydraulic swing control to allow changes in walking speed. A hydraulic knee allows for the adjustment of walking speed through air or liquid hydraulics within the joint. These are typically used by more active individuals, but they can be heavy and require more maintenance.

A microprocessor knee has sensors in the joint to adjust function in real time via an onboard computer or microprocessor. This controls the speed and the ease in which the knee reacts while the amputee is walking. These are best known for their control for stumble and fall and lower energy demands for the wearer. However, they depend on battery life, have higher initial and repair costs, and can require more maintenance.

The *pylon* is a metal pipe between the socket and the prosthetic foot, attached with a variable adapter. A foot shell that resembles a naturally-biological foot is designed to protect the prosthetic foot and to fill out the user’s shoe.
We create a world of possibilities for people with limb loss or limb difference through the highest quality and most accessible care and customized orthotic and prosthetic solutions. One by one, we listen to challenges, collaborate with partners, lead through innovation, and apply our expertise to help move lives forward. Learn more at HangerClinic.com.
Prosthetic feet and ankles are the final components. There are over 250 prosthetic feet available. The solid ankle cushioned heel (SACH) foot is the most basic, with no moving parts and a soft heel to absorb impact. These are typically provided on the first prosthesis or for people who walk very little. A single axis foot has one joint that allows the foot to move up and down. It provides for stability. A multi-axis foot allows the foot to move up and down and side to side and is appropriate for those who would need more foot movement for activities such as walking on uneven ground, hiking, golfing, and other recreational activities.

A dynamic response foot absorbs energy when it touches the ground and releases it as the foot leaves the ground. It has a full-length plate that provides a sense of push-off for increased balance and more natural gait.

Combined knee and ankle systems
Microprocessors first came on the market used in knee joints. Knee-ankle systems now use a combination of hydraulic and microprocessor control, and they coordinate the knee and ankle function to provide more stability and increasingly difficult walking surfaces such as uneven ground, inclines, declines and loose gravel. These combination microprocessor units are typically recommended for the more active individuals with above-knee amputations. However, they must be coordinated, and it would void the warranty if you used a microprocessor knee from one company and a microprocessor ankle from another.

Upper Extremity
As with a lower-extremity prosthesis, a socket fits over the residual limb with a suspension sleeve to hold it in place. Other elements can include a control system, some terminal end device (to replace the hand), and a wrist unit. An above-elbow amputee would also include an elbow joint, and a shoulder disarticulation or above could also contain a shoulder joint.

There are many design options. A functional cosmetic or aesthetic prosthesis is generally worn for cosmetic purposes and looks like the biological missing limb. But there is no active control and limited functional capabilities. It may not require a harness.

Body-powered devices use cables and harness systems. Such a device is activated by using the shoulder to pull the cable that activates the terminal end device (hand, hook, or prehensor) to open and close.

These are typically used with a harness system such as the figure 8 or figure 9 harness. Figure 8 harnesses wrap around both shoulders and look like the number 8 turned on its side. Figure 9 harnesses wrap around only one shoulder. Type of harness is determined by the level of amputation and recipient preference. These body-powered devices are lighter, easy to operate, easy to repair, and have low initial cost, but they do appear very mechanical and require a certain range of motion of the residual limb.

Myoelectric prosthetic devices use battery power coupled with muscle activity. Skin electrodes detect signals from muscle movement to control the operation, speed, and direction of the prosthesis. A myoelectric prosthesis provides

The Limb Loss and Preservation Registry is housed at Mayo Clinic and funded by the National Institutes of Health (NIH). NIH and the Department of Defense aim to establish the number of people in the United States living with limb loss and to provide insight on their challenges and needs. The Limb Loss and Preservation Registry promises to collect data that will improve prevention, treatment and rehabilitation efforts for this population.

Data collected includes amputations and hospitalizations, details on prosthetic fittings, providers of prostheses, and patient-reported outcomes. Eventually objective data will be collected on patient functioning. Mayo is developing analytical tools to provide data dashboards and statistical reporting.

Find the registry at http://www.mayo.edu/research/labs/motion-analysis/research/limb-loss-preservation-registry or contact the registry staff at limblosspreservationregistry@gmail.com
Component replacement

Each prosthetic component has a usable lifespan. The history of replacement of the prosthetic wearer is a good indicator for future estimates. The following are general lifespan recommendations are for the adult user. Pediatric amputees will have much different replacement needs due to growth and activity.

According to the Amputee Coalition, prosthetic liners should last six to twelve months and be replaced if they are stretched out or become thin. Prosthetic socks should last up to twelve months, but should be replaced at any time when stretched or frayed. Suspension sleeve lifespan varies due to user activity, and should be replaced when they can no longer provide suspension or if they are torn or stretched out.

Upper limb harnesses should be replaced when frayed, have broken straps or fasteners, or if they become torn. They need to be checked annually, but their lifespan varies. Prosthetic sockets must be replaced with significant weight loss or gain or for any loss of skin integrity. Initially the prosthetic provider will modify the fit of the prosthetic socket with pads, moleskin, heat, windows, and other such techniques.

This article defines prosthetic component terms and serves as a basis for following articles, where many photos can be found.

Activity-specific devices

These can be body powered, myoelectric, or hybrid and can be customized for a single specific recreational or vocational activity.

Activity-specific terminal end devices are available for a multitude of recreational activities. One might utilize a swim fin, for example, a cup-shaped ball thrower, a clamp for weight lifting or wielding a golf club or tennis racquet, or even specialized attachments for technical rock-climbing. In addition, there are activity-specific end devices for tasks such as hammers, spatulas, saws, etc.

Another consideration for the upper limb user is cables for body-powered users and gloves for those with cosmetic restoration.

Prosthetic feet, knees, and terminal devices should be replaced every five years or sooner if they have failure or significant change in activity level.

Current research

Advances in all areas of prosthetic design are in the works across the nation. While this article addresses the elements of a prosthesis and typical componentry, NLCPs will soon see many advances.

While there have been improvements in prosthetic design since the wars in Iraq and Afghanistan, a prosthesis is only as good as the interface between the prosthesis and the residual limb. An ill-fitting socket will render even the most advanced prosthesis unusable. Today research is focused on sockets, liners, various suspension systems, and increasing sensory feedback.
University of Texas at Dallas researchers are working on electronic whiskers as a potential for electronic human skin (The O&P Edge September 2018) to provide sensation feedback from the prosthetic to the user. These are not yet commercially available.

Prosthetic hands rely on electrodes placed on the skin to receive signals from the underlying muscles. The electrodes then deliver limited and somewhat unreliable signals to allow gross movements of the prosthetic hand.

Chalmers University in Sweden has also implanted an osseoneuromuscular device to control a hand prosthesis. Titanium implants in the ulna and radius transmit signals from and to electrodes in nerves and muscles above the level of the amputation to give the recipient sensation from and muscle control of a hand prosthesis. Because it provides tactile sensations, it is the first clinically viable, dexterous, and sentient prosthetic hand usable outside of a lab setting (The O & P Edge, March 2019).

A group in Massachusetts is developing wireless sensors to improve prosthetic device function for those with upper-limb amputations and osseointegration. There is no place to locate wires with an osseointegration because there is no socket; they plan to create wireless sensors.

Just a few of the many products being studied and released to interface between the residual limb and the prosthesis itself:

- Nano-skin
- self-healing recyclable e-skin
- socket-less sockets
- click-adjustable sockets
- breathable liners
- heat storing liners
- volume control sockets

The NLCP can look forward to these and other developments to provide safety, function, and quality of life for amputees.
 KNOW YOUR PROSTHETIST

April Pettengill, RN, CRRN, CDMS, CNLCP, MSCC
Corey Pettengill BS

Abstract:
The specialty of orthotics and prosthetics (O&P) has evolved historically much like nursing, medicine, and life care planning. And similar to these professions, prosthettists, orthotists, and pedorthotists come from many different levels of education, certification, and competence. Life care planners need to be able to understand what makes a certified provider the best choice. How do we know the people providing care are qualified? What kind of training do they have, are they licensed or certified? What do they need to do to keep their credentials? And more importantly, why do we care?

History of Prosthetics in Short

According to the Amputee Coalition of America (ACA), artificial limbs were around long before written word. The Aztec god Tezcatlipoca can be seen in Aztec hieroglyphics with an obsidian limb after losing his foot while fighting the Earth Monster. Queen Vishpala lost her leg in battle and was given an iron leg sometime before 1800 BCE. This was memorialized in an Indian poem. An Egyptian noblewoman’s mummy was found with a prosthetic toe that scientists believe dates back sometime between 1064 to 664 BCE. In the early part of the Middle Ages, sea battle survivors with amputations were often fitted with a scrap of wood, and knights with basic iron limbs. Ambrose Pare considered the father of the modern prosthetic, developed the first hinged knee prosthetic for a French king in the 1500s (Amputee Coalition, 2019).

True prosthetic advancements waited until more modern times. One of the forerunners was Joseph E. Hanger, an engineering student at Washington College who enlisted in the Civil War in 1861. Two days later, he was hit by a cannonball and underwent a field amputation, the first amputee of the Civil War. Upon returning home he began working on a replacement leg using whiskey barrel staves. This
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became known as the “Hanger leg” (Hanger Inc., 2020). The Civil War resulted in over 60,000 men who had amputated limbs requiring a prosthetic. This birthed the cottage industry of limb replacement. The people who were creating these replacement limbs were called “fitters.” The fitters were typically technically-skilled metal workers or woodworkers.

In 1888, Albert Winkley (The Winkley Artificial Limb Company) developed the “slip socket” to reduce friction by adding a piece of leather around the stump. At this time there was no regulation and information on how to create limbs was passed down from fitter to fitter, with many like Hanger and Winkley forming companies of their own: the Salem Leg Company, Ohio Willow Wood (founded by train brakeman and double amputee William Arborgast and still in existence today), The D.W. Dorrance Company (known for its arm prostheses), and Fillauer Company (a pharmacy that now offered artificial limbs) to name a few. (The American Orthotic & Prosthetic Association, 2020).

The History of Certification

In 1917, the Surgeon General of America and the US Government called together a group of fitters and artificial limb manufacturers. They discussed the importance of specific training and knowledge for those who were providing limbs to consumers. This led to the creation of the Artificial Limb Makers of America (ALMA) organization. The ALMA began to write scholarly papers and had a newsletter to spread information regarding artificial limbs. They developed a code of ethics and held annual and regional meetings. Eventually the smaller shops closed or were purchased by larger companies. After World War II, the Veterans Administration (VA) also joined the push for quality care of all kinds. They wanted those who were making the limbs to have a minimal education to better ensure patients were treated properly. (Hovorka et al., 2002).

ALMA’s early attempts to provide education and research began the foundation for educational requirements. Their efforts led to the inception of the American Board of Certification for the Orthotic and Prosthetic Appliance Industry in September 1948. The ABCOPAI was founded by Chester E. Hadden, CPO, three orthopedic surgeons, and three O&P practitioners. In an effort to standardize the knowledge base, the leaders determined that the certified individual would have to pass an exam and would be designated Certified Orthotists and Certified Prosthetists rather than “fitters” (American Board for Certification in Orthotics, Prosthetics & Pedorthics, 2020).

The first exam was given in 1951 with 51 people certified in the first year. In 1952, a 6-week program supported by the VA, and coordinated by the National Academy of Sciences was started at the University of California at Los Angeles. Additional programs were started at New York University, and Northwestern University. In 1959, they amended the name, dropping the terms “appliance industry” and adopting the title of the American Board of Certification for Orthotics and Prosthetics, Inc (ABCOP or ABC).

In the 1970s, the ABC leaders determined there was a need for further standardization of the minimum education qualifications to sit for the exam: a high school diploma, a 6-week course, and minimal practical experience. In 1973, the ABC revised the requirements to include a minimum of an associates degree in prosthetics and orthotics. By 1976, three specialized courses were added.

The American Academy of Orthotists and Prosthetists was founded in 1970 to provide education for the certified, state-licensed practitioners and assistants. Referred to as The Academy, they provide support, host an annual national educational conference, and offer other educational opportunities. In 1986, the ABC raised the level of education to require a bachelors in O&P. A few years later the National Commission on Orthotics and Prosthetics Education (NCOPE) spun off the ABC. Their responsibility was to oversee the education providers to ensure they were providing the minimum level of education for the candidates, and developed a post-


By 1992 the bachelor’s degree became the minimal requirement to sit for the exam. However due to lack of educational funding to establish appropriate degree program, the ABC allowed people with associate degrees to sit for the exam as late as 1997 (Horovka et al., 2002).

Due to the continued lack of availability of bachelors programs, in 1984 a competing organization, the Board of Certification/Accreditation (BOC) began to provide certification for orthotists and, in 1996, for prosthetics certification, both based on practical hours rather than education (Board of Certification/Accreditation, 2020). They required 1000 hours of documented patient care to sit for the exam. Continuing education and renewal requirements included 75 credits every 5 years broken down into 20% business and 80% scientific credits (Board of Certification/Accreditation, 2020). In July 2016, the BOC decided to cease offering new orthotic and prosthetic certifications. They have continued to support those with the certification and allowed for renewal (Board of Certification/Accreditation, 2016).

The Current Requirements for O&P education

As prosthetics and bracing became more complicated, the certifying bodies wanted to move to a masters level education. Some colleges couldn’t provide a masters program as they lacked masters-educated professors. Georgia Tech opened the first Master’s program followed by Eastern Michigan University and the University of Connecticut. By 2012, all programs for O&P were master’s level programs. Starting in 2020, CPO candidates must have a Masters in Prosthetics and Orthotics.

There are 12 NCOPE-accredited Master
of Prosthetics and Orthotics programs in the United States (Georgia Tech is no longer accepting students). Candidates must complete a full time, 12 month residency program per discipline (orthotics or prosthetics) or 18 month combined residency (orthotics and prosthetics) in an NCOPE-accredited facility. The residency supervisor is required to have three years of certified practice and coursework to become a resident mentor. (National Commission on Orthotic and Prosthetic Education, 2018).

Certifications
The ABC also provides licensing for states where that is a requirement. Currently only 15 states require licenses to practice O&P. Even certification is not required in all of the states to practice O&P (American Board for Certification in Orthotics, Prosthetics & Pedorthics, 2020). This means that in the rest of the states anyone can call themselves a prosthetist, fit patients for braces, orthotics, and prosthetics not having received the education or proven they have the knowledge by passing the national exams. However, many insurances or federally funded programs will only pay for devices that were fitted and provided by certified or licensed professionals. (See State Licensure map)

So why does all of this matter?
Prosthetics are highly individualized. There is no such thing as an “off-the-shelf” prosthetic. Components are put together from many suppliers and companies and require a trained clinician to ensure everything is as it should be. By using CPOs, we can ensure that the pricing is accurate and the product is appropriate for the individual. (See Berry, p. 21, ed.)

As prosthetics are custom fitted, Medicare does not regulate the components themselves. This allows the CPO to put together the best device for the patient and not be forced into putting specific items together. Education helps make up for some of the lack of regulation that permits the CPO the discretion to properly create unique solutions. However, the prosthetist must have the education and understanding of body mechanics, and anatomy to avoid harmful outcomes. The market will generally support good products and practitioners. Educated individuals will understand the merit behind longer lasting, better quality devices and want to provide high quality care to maintain their position in the field, are less concerned with profit margins, and understand the concept of doing well by doing good. Certification is the only true way to tell if an individual has the proper education and understanding.

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ABC is the only current certifying organization.

Medicare supplier standards help ensure some level of accountability to individuals (University of Michigan, 2014). Not all fraud is detected by Medicare and certainly it is not detected immediately. In April 2019, the Department of Justice announced a huge fraud scheme involving prescriptions for back, knee, leg, shoulder, and wrist braces that were not medically necessary (The O&P EDGE, 2019). Fraudulent braces present a huge risk of injury and likely more money for insurance to cover damages. It is important to recognize situations which may put clients at risk of fraud, educate them on key warning signs, and use legitimate prosthetic and orthotic practitioners to prevent these sorts of fraudulent actions (Lake, 2019).

**Take-aways:**

**Identify good O&P professionals.**

1. Make sure they are ABC certified. Look for the CPO, CO, or CP credential. This will also ensure they are following under the ABC code of conduct. Those with a BOC certification will also likely provide good quality care, however over time their certifications will become dated due to lack of new BOC certification. MPO or MSPO means that they have acquired a masters degree in the field of prosthetics and orthotics, an indication of quality.

2. Clinics and practitioners can specialize in different areas, such as just prosthetics or just pediatrics. Knowing if a practitioner has a specialty may help decide if they are right for your client.

3. Consider client convenience. Many clients will have issues with mobility or limited resources; devices will often need adjustments. Clinician accessibility is important and must be weighed alongside the quality of the care they will be able to provide.

4. Good communication is important. Ensure the client is able to work well with the practitioner. While this can be hard to predict beforehand, the ways practitioners handle communication and promote patient participation in care can be an indicator of the level of care they may provide.

It is important to note that there are many factors affecting patient care at any given time. It is important for the Nurse Life Care Planner to have a frank discussion with the prosthetist to make sure they understand we need

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**Certifications and requirements (American Board for Certification in Orthotics, Prosthetics & Pedorthics, 2020; National Commission on Orthotic and Prosthetic Education, 2018)**

<table>
<thead>
<tr>
<th>Certification</th>
<th>Min. Education</th>
<th>Min. Practice</th>
<th>Examination</th>
<th>Recertification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certified Orthotist and Prosthetist (CPO)</td>
<td>Master’s degree</td>
<td></td>
<td>Written, practical, and patient management exams for both O and P</td>
<td>100 credits/5 years</td>
</tr>
<tr>
<td>Certified Orthotist (CO)</td>
<td>Master’s degree</td>
<td></td>
<td>Written, practical, and patient management exam</td>
<td>75 credits/5 years</td>
</tr>
<tr>
<td>Certified Prosthetist (CP)</td>
<td>Master’s degree</td>
<td></td>
<td>Written, practical, and patient management exam</td>
<td>75 credits/5 years</td>
</tr>
<tr>
<td>O&amp;P Assistant (COPA)</td>
<td>High school, additional specific coursework</td>
<td>1900 hours residency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>O&amp;P Technician (COPT)</td>
<td>Assoc. degree</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pedorthist (C. Ped)</td>
<td>High school</td>
<td>1000 hours experience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthotic Fitter (COF), Mastectomy Fitter (CMF), Certified Therapeutic Shoe Fitter (CTSF)</td>
<td>Variable education and licenses in similar allied health professions</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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prices, replacement timeframes, and supplies based not on insurance or collateral payment sources, but based upon what is best for the patient. Quality practitioners will try their best to provide good products and treatments, but are strongly conditioned to consider insurance constraints; those with better insurance will get better devices. When putting together the life care plan, it is important to ask the practitioner about better components, or upgrading where appropriate without regard to collateral sources.

Life care planners must work collaboratively with prosthetists and orthotists to ensure the highest quality care for our clients. This means recognizing the field’s complicated history and culmination of the progressive educational efforts resulting in high quality practitioners. Additionally, knowing some general methods for distinguishing prosthetics and orthotics practitioners who have education and experience in the field from those who do not will help ensure the highest quality care for our clients.

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Board of Certification/Accreditation. (2020). Our History. BOC. https://www.bocusa.org/about/history/


Expert Consult:
Prosthetic Criteria and Considerations for Life Care Planning

Dale Berry, CP, FAAOP, LP

Providing for prosthetics in a life care plan, Life Care Planners commonly use clinical care procedures and prices from the billing record. Unfortunately, although this sounds logical and reasonable, using past prosthetic services and invoice history can and often will be indefensible for future prosthetic cost, design and replacement cycle. In part, this is because the timeline and deadline to provide an accurate life care plan may not be compatible with the patient having reached maximum medical improvement (Meier, Choppa, and Johnson, 2013).

Projecting future costs related to the prosthesis can be predicted accurately. However, this requires integrating prosthetic assessment history with clinical practice guidelines, standards of care, current and potential functional level assessment while applying fair market value of current technologies.

Prosthetic Rehabilitation
The primary challenge is that life care plans are commonly produced within 1-3 years of the initial injury. But patient treatment process, needs, and requirements for an individual vary considerably between post-surgical rehabilitative intervention (Esquinazi, 2004) and long-term services: prosthetic care and related expenses for the first 18-36 months (early care) after amputation are significantly different compared to long term prosthetic care. Understanding the differences between the clinical care and billing records is key.
The 3 primary differences between early rehabilitation and lifetime care are

1. Rehabilitative care vs. long-term care
2. Contract pricing vs. fair market value
3. Benefits coverage vs. medically necessary care

**Rehabilitative care vs. long term care**
Immediately following amputation, the patient is understandably faced with a life changing transition. Aside from the emotional, psychological and social challenges of missing a limb, there are some very specific physiological issues that must be clinically addressed when providing a prosthesis (Ulger et al., 2018). Post-surgical physical conditions create specific and unique clinical and billing occurrences during early rehabilitation that should not be continued in long term care.

The primary post-surgical issue for prosthetic fitting is significant post-surgical edema. This increases the size and shape of the residual limb. Although compression therapy will help over time, a significant contributor to edema reduction is movement and exercise to stimulate vascular and lymphatic return. This can be achieved by wearing a prosthesis.

The patient’s residual limb will be sensitive, muscles and joints are painful, and the patient will need to learn how to walk with a prosthetic device. One clinical option for early rehabilitation is to provide an Immediate Post-Operative Prosthesis, or IPOP to allow for early ambulation and rehabilitation; this also contributes to vascular return and edema reduction (Samuelson, Andrews, and Hauddek, 2017). This style of prosthesis is specifically intended for immediate post-surgical care, and its costs and services should not be duplicated for long term care.

The next rehabilitation stage may include a preparatory prosthesis, somewhat self-explanatory. Its purpose is to prepare the residual limb for full weight bearing, reduce post-surgical edema, and provide a basic prosthetic design to enable the patient to learn to walk (for the lower limb amputee) or use a hand or terminal device (for the upper extremity amputee).

Wearing a preparatory prosthesis will predictably decrease residual limb edema to the point where the socket will no longer fit properly, requiring replacement. A replacement socket can be custom designed and attached to the existing components, effectively providing what may seem like a new prosthesis. Although replacement sockets are used for long term care and should be included in a life care plan, replacement frequency in early rehabilitation is much higher than in long term care.

The socket replacement cycle during post-surgical care is very short: in initial rehabilitation the socket may need to be replaced as frequently as once every 3-6 months. However, once the residual limb has fully matured, with the post-surgical edema expelled and the muscles atrophied, a prosthetic socket has a normal life span of up to 24-30 months.

---

**FIGURE 1 - Reasonable replacement times for components in amputation rehabilitation.**

<table>
<thead>
<tr>
<th>Device</th>
<th>IPOP</th>
<th>Preparatory</th>
<th>Socket Replacement</th>
<th>Definitive Prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fair Market Value (FMV)</td>
<td>$4,959</td>
<td>$15,616</td>
<td>$12,318</td>
<td>$40,583</td>
</tr>
<tr>
<td>Reasonable Useful Life (RUL)</td>
<td>1-2 Months</td>
<td>6-18 Months</td>
<td>6-30 Months</td>
<td>5 years</td>
</tr>
</tbody>
</table>
Both the preparatory prosthesis and IPOP are very simple in design and meant for short term use. Costs related to prosthetic devices used during rehabilitation are typically less than prostheses designed for long term wear. Therefore, any costs related to IPOP, preparatory prosthesis, or high frequency of replacement sockets are not relevant to long term cost projections.

**Contract pricing vs. fair market value**

Discount and contract rates heavily influence the prosthetic industry. There are three major pricing profiles: Medicare, contract, and fair market value. The price of any style prosthesis can vary significantly depending on patient location and payor source.

Clinical care and billing records can have a significant effect on the price of the prosthesis depending upon insurance benefits or network: for example, pricing of the same transtibial prosthesis can vary by over $8,200. (Figure 2)

The ultimate determinant is the industry standard, the L-Code system. The Center for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) identifies each prosthetic element with a specific four-digit L-Code; each code has a specific reimbursement. Medicare provides a sustainable, fair, and reasonable reimbursement in the United States, because on average, 50% of prosthetic industry patient volume and revenue base consists of patients who are Medicare beneficiaries (Hanger Clinic, 2017).

This matters because each prosthetic provider entity is owned and operated by either a private or public corporation. Antitrust regulations prevent companies from setting or fixing price levels as a group or industry, so each prosthetic provider must establish line item pricing for each code, commonly referred to as usual and customary (U&C), manufacturer suggested retail price (MSRP) or fair market value (FMV), based upon personal preference, experience and competitive market conditions. The fair market value for prosthetic providers is commonly set between 20% to 30% above Medicare pricing.

Each L-Code can have up to twelve different reimbursement levels depending upon the service location. The lowest reimbursement level is referred to as the Medicare floor; the highest, the Medicare ceiling.

For example, the 2019 Medicare reimbursement for the microprocessor L5973 foot has a floor to ceiling variance of $2,317.53 based solely upon where the patient receives the care: (Figure 3). Therefore, the expected fair market value consumer price for this will be between $20,728 (20% > Medicare average reimbursement) to $22,793.90 (30% > Medicare average reimbursement).

The NLCP should closely evaluate any invoice history for prosthetics to determine the level of contract discounting applied. Failure to do so can have a negative impact on future plan projections.

**Benefits coverage vs. medically necessary care**

While insurance and other collateral sources are not considerations in most life care planning cost projections, it’s useful to understand the significant role insurance has in treatment decisions and billing history. An individual may select an economical insurance plan with limited or no

---

**FIGURE 2 - Pricing variations depending on payor source.**

<table>
<thead>
<tr>
<th>Private Insurance In Network Pricing</th>
<th>Medicare Floor</th>
<th>Medicare Average</th>
<th>Medicare Ceiling</th>
<th>Fair Market Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$11,824.68</td>
<td>$13,911.39</td>
<td>$17,391.83</td>
<td>$20,872.26</td>
<td>$21,913.70</td>
</tr>
</tbody>
</table>
coverage for prosthetics, which is reasonable considering that traumatic amputation is obviously unforeseeable. However, once the amputation has occurred, the patient is now challenged with limited benefits with access to only basic or restricted care options.

An individual with amputation of the arm above the elbow may meet all medically necessary criteria for an advanced myoelectric prosthesis. However, if the insurance policy at the time of the accident only covers basic services, the benefit will provide only for a body-powered prosthesis with harness and hook. Past billing and clinical care history for this patient would indicate a prosthesis with a fair market value of $17,000, consistent with what the patient’s benefit coverage at the time.

However, that cost projection using only past billing and history would result in a gross underestimation, because medical records and supporting documentation could establish and validate that medically appropriate and necessary care would be a myoelectric prosthesis with a fair market value of $76,000 per device. (Figure 4)

Two individuals of the same age with identical insurance benefits from one insurance company could have different coverage based upon the cause of amputation. The Aetna medical policy states that a microprocessor knee can be medically necessary when the amputation is “from a non-vascular cause” (Aetna, 2019).

Therefore, a life care plan for Patient “A” with limb loss caused by a motor vehicle accident would be covered for a microprocessor knee. Patient “B” whose limb loss was related to vascular surgical malpractice would not.

These two very similar cases reveal why reviewing their past medical files and billing should logically be the same but are not. Prostheses for these two patients with the exact same insurance policy and exact same amputation level would look similar to the untrained eye, and both provide the same basic function is so much that they both enable the patient

There are three major pricing profiles: Medicare, contract, and fair market value. The price of any style prosthesis can vary significantly depending on patient location and payor source.
FIGURE 4 - FMV (past billing) vs. medical necessity for arm prosthetic, representative example.

<table>
<thead>
<tr>
<th>Basic Body Powered Prosthesis with suspension harness and hook</th>
<th>Self-Suspending Myoelectric Prosthesis with Bionic Hand</th>
</tr>
</thead>
<tbody>
<tr>
<td>$17,765 Fair Market Value</td>
<td>$76,430 Fair Market Value</td>
</tr>
</tbody>
</table>

It is critical for the NLCP to recognize limited service options due to benefit coverage restrictions for past care; these collateral sources must not apply to life care plan projections for medically necessary and appropriate future care.

to walk. But the two prosthesis contain very different knee components.

Patient “A” invoice history would include an advanced microprocessor computerized knee that provides optimum stability at a value of $42,385 per prosthesis, while Patient “B” invoice history would have a basic mechanical knee at a value of only $17,456 per prosthesis. (Figure 5)

Be aware that past clinical care and billing history can be heavily influenced by insurance contract limitations and policy language which can limit access to medically necessary and reasonable technologies during rehabilitation. It is critical for the NLCP to recognize limited service options due to benefit coverage restrictions for past care; these collateral sources must not apply to life care plan projections for medically necessary and appropriate future care.

Functional level

Prosthesis style, model, and type decisions are primarily based on potential functional abilities as measured by the industry standard Functional K Level. This validates medical necessity and directly affects cost (Table 1).

Prosthetic services and components are considered reasonable and necessary, according to Social Security Act § 1862(a)(1)(A) provisions. For an individual with a lower limb amputation, prosthetic devices are determined medically necessary when a qualified health care professional evaluates and documents that an individual “will reach or maintain a defined functional state within a reasonable period of time and is motivated to ambulate” (CMS, n.d.).

Potential functional ability is based on the prosthetist’s and treating physician’s reasonable expectations, considering factors including, but not limited to the individual’s past-history (including prior prosthetic use if applicable), current condition: status of the residual limb and the nature of other medical problems combined with the individual’s desire to walk.

Functional level validates the best possible activity level of the prosthetic wearer, and the technology needed to achieve optimal functional level in activities of daily living. The cost of technology is directly proportional to functional level.

For a prosthetic foot, the fair market value for a K1 foot ranges from $304 to $415; a K2 foot component ranges from
$304 to $543. A person who can use a K3 foot is looking at a much wider range, $961 to $22,752 for just the foot component. For prosthetic knees the range is even greater: a simple functional K1 knee can cost as little as $448 and a functional level K3/K4 waterproof microprocessor knee component has a fair market value of over $70,000.

An individual’s functional level is a key factor in planning, especially if the mechanism of injury for the amputation caused other injuries and co-morbidities that might negatively impact the functional K Level. It is not uncommon for an individual to be classified as K1 or K2 for the first post-injury year to eventually progress to functional level K3 or K4 over time. When preparing a life care plan for an individual with a lower limb amputation, past, present and future functional K Level must be taken into consideration to ensure an appropriate and accurate projection. There are no functional standards or restrictions for individuals with an upper limb amputation.

Activities and protheses
The primary function of a prosthesis to provide comfort and function and enable the individual to accomplish expected activities of daily living (ADL) that match the individual’s functional K Level. An ADL prosthesis has components and technology for features enabling the wearer to access a community environment consistent with functional level and day-to-day routine tasks.

An ADL prosthesis may not be able to accommodate appropriate function, durability, comfort, or cosmetics for functional K3 or K4 (and select K2) individuals. These individuals need will meet medical necessity for activity prosthesis. Evidence based clinical practice guidelines (VA and DOD, 2008 and 2017) identify the clinical efficacy of specialized prosthetic limbs that are “specifically focused on certain functional tasks” (VA, DOD, n.d.).

Specialty prostheses enable participation in vocational, social or personal activities that would be restricted with the limitations of the ADL. The NLCP should assess whether the individual has work, recreational, or specialized activities that require specialized or unique design features.

It would be uncommon for an activity prosthesis to appear in the record while the residual limb is undergoing stabilization and the individual is still in the rehabilitation phase. After 36 months, few if any prosthetic wearers will have a history of owning an activity prosthesis, largely because most insurance carriers only provide benefits for one prosthesis at a time. Although the patient may not have had a special activity prosthesis in the past, the NLCP should consider providing for one in the plan based upon functional level, avocational activities, and lifestyle.

FIGURE 5 - Different allowed benefit by cause of limb loss, representative example.
### Reasonable useful life

A prosthesis (CFR, 414.202) is classified by Medicare as durable medical equipment prosthetics orthotics and supplies (DMEPOS) (CFR 424.57). Government regulatory standards for the replacement of a prosthetic device stipulate that a prosthesis that has been in continuous use (CFR, 414.230) has a reasonable useful lifetime (RUL) of no less than 5 years (CFR, 414.210).

The “no less than 5-year” time frame for lower limb prosthesis is supported by peer reviewed published studies. A retrospective study (Narang, 1982) of 14,400 prosthetic wearers over a 25-year time period established the average life of a prosthesis is about 5 years. Although this large study is over 40 years old, a smaller 1992 clinical study (Nair, 2008) following 173 lower limb prosthetic wearers over a 10-year period indicated that transfemoral amputees in this study on an average needed one new prosthesis every 10 years while transtibial amputees needed a new prosthesis every 7 years. A more current study (O’Keeffe, 2019) determined that prostheses may last for 5 to 7 years with intermittent requirement for consumables replacement, e.g., socks, straps, and liners.

Reasonable useful life of a prosthesis can be negatively affected by, but not limited to the following: (Local Coverage Articles, n.d.):

- A change in the physiological condition of the patient
- Irreparable wear of the device or a part of the device
- The condition of the device, or if part of the device requires repairs and the cost of such repairs would be more than 60% of the cost of a replacement device, or of the part being replaced.

When calculating the average reasonable useful life of a prosthesis over a patient's lifetime, it is appropriate to use a replacement cycle of 5 years (Hachisuka, Nakamura, et al., 2001) while realizing that extenuating circumstances can reduce or extend the life of a specific prosthesis.

Due to normal and expected changes in the residual limb, the prosthetic socket may lose appropriate fit and function making the prosthesis unusable, even though the prosthetic components (knee, foot, ankle) are still functional and appropriate. In this event the prosthetic socket can be replaced and secured to the existing functional prosthetic.

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Components. Included with the replacement socket are the required consumable items (e.g., liners, socks) and required maintenance to the components. It is reasonable to include a replacement socket at the half-life of the prosthesis to accommodate physiological change in the size and shape of the residual limb.

Supplies and maintenance

There are predictable supplies and maintenance for a prosthesis wearer. With the most common prosthetic designs, liners and socks worn next to the skin over an extended period can cause hygiene issues related to sweat and bacteria (Hachisuka, Nakamura, et al., 2001), requiring annual replacement.

A common shortcut approach to calculate supplies and maintenance is to apply a yearly amount based upon a percentage of the total cost of the prosthesis (MacKenzie, Jones, Bosse, et al., 2007). But there is no clinical, scientific, medical or published peer reviewed evidence to support or validate this for any configuration of user, equipment, K level, or supply quality.

Supplies and maintenance can be estimated accurately for key prosthetic elements. Consumable items and their life cycle can be clearly identified and priced. Most prosthetic components have a full manufacturer’s warranty up to 3 years with some up to 5 years, during which time allowance for replacement is not reasonable. It is reasonable to include a 2-3 hours of clinical support for maintenance and follow-up for miscellaneous services and care.

There is no need for supplies and maintenance expense for the years that a new prosthesis or replacement socket are being provided, as the prosthesis and replacement socket includes liners, socks, maintenance and follow-up care.

A 5-year cycle for a prosthesis will therefore include one (1) Prosthesis, one (1) Replacement Socket and three (3) incidents for Supplies and Maintenance (Figure 6).

Conclusion

In a life care plan for an individual that has undergone an amputation, prosthesis costs will often be a significant, if not the largest, line item. Although historical and current prosthetic records contain valuable information to establish the style, type, and cost of prosthesis the patient has had in the past or is currently wearing, these records cannot be solely relied upon to produce accurate future cost projections.

They do, however, provide the basis to create an accurate and defendable long-term prediction of prosthetic costs: historical information. This provides the foundation to corroborate functional level to establish appropriate and medically necessary care and technology. Past billing records can however, be useful to help identify specific HCPCS L-codes; this will assist in calculating current fair market value. The NLCP must consider key factors related to current prosthetic clinical practice guidelines, coding, billing practices, and regulatory standards to develop a life care plan for an individual suffering from limb loss.

FIGURE 6 - 5-year cycle for replacement items, representative example.

<table>
<thead>
<tr>
<th>New Prosthesis</th>
<th>Supplies &amp; Maintenance</th>
<th>Supplies &amp; Maintenance</th>
<th>Replacement Socket</th>
<th>Supplies &amp; Maintenance</th>
<th>New Prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>2021</td>
<td>2022</td>
<td>2023</td>
<td>2024</td>
<td>2025</td>
</tr>
</tbody>
</table>
# TABLE 1. Functional ambulation levels (K-Levels)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>K0</strong> Level 0</td>
<td>Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.</td>
</tr>
<tr>
<td><strong>K1</strong> Level 1</td>
<td>Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.</td>
</tr>
<tr>
<td><strong>K2</strong> Level 2</td>
<td>Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.</td>
</tr>
<tr>
<td><strong>K3</strong> Level 3</td>
<td>Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.</td>
</tr>
<tr>
<td><strong>K4</strong> Level 4</td>
<td>Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.</td>
</tr>
</tbody>
</table>

Sources: Centers for Medicare & Medicaid Services, Local Coverage Determination (LCD): Lower Limb Prostheses (L33787) United Health Care, Prosthetic Devices, Specialized, Microprocessor Or Myoelectric Limbs, Guideline Number CS104.I, Effective Date December 1, 2018

# REFERENCES

- Centers for Medicare & Medicaid Services (CMS) (n.d.), Local Coverage Determination (LCD): Lower Limb Prostheses (L33787)
- Code of Federal Regulations (CFR), Title 42. Public Health, Chapter IV Section § 414.202
- Ibid., § 424.57
- Ibid., § 414.230
- Ibid., § 414.210 (f) (1)
- Hanger Clinic 2017 Annual Report, Securities and Exchange Commission, Form 10-K.
- Local Coverage Article (n.d.) Lower Limb Prostheses - Policy Article (A52496)
REFERENCES


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Abstract

Limb amputation is a catastrophic event that affects every aspect of the individuals’ life. For some amputees, conventional socket-type prostheses fail to provide needed mobility and independence. Osseointegration prosthesis (OIP) or bone-anchored prosthesis bypasses the need for a socket by connecting the bone to the prosthesis via a surgically implanted titanium implant. Indications, complications, and life care planning considerations are addressed.

Introduction

Limb loss is a devastating event that negatively affects functional, physical, emotional, psychological, and socioeconomic well-being. Amputation occurs with industrial, civilian, and military trauma; peripheral vascular disease (PVD); diabetes; burns; infections (such as osteomyelitis); and congenital and acquired limb deficiencies and deformities (Chung et al., 2020, Maldonado et al., 2016).

PVD and diabetes account for nearly 200,000 nontraumatic amputations annually (Pasquina, et al., 2015). In 2014, 108,000 diabetics were hospitalized for lower extremity amputations (CDC, 2017). Between 2009-2015, nontraumatic amputations increased by 50%, affecting 4.6 out of 1,000
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adults with diabetes. Significantly, this increase affected younger adults between ages of 18-44 and middle-aged adults between 45-64 years of age (Geiss et al., 2019).

According to the Operation Iraqi Freedom report, 50% of all amputations are upper extremity and combat-related, although recently this has decreased to less than 20% because of improvements in protective equipment (Chung et al., 2020).

Prostheses: Osseointegration

Properly fitting prostheses improve balance, gait, walking time and distance, and ADLs; poorly fitting prostheses can cause pain, stress, skin irritation, and wounds. The prosthetic socket plays the central role in fit and requires numerous fittings to ensure optimal functionality (Aydin et al., 2018; Pasquina et al., 2015). Some amputees have significant difficulty achieving proper fit in a socket type prosthesis, putting them at risk for complications and increased dependence. Osseointegration prostheses (OIP) eliminate need for a socket by providing a direct connection between the bone in the residual limb and a prosthetic limb. Osseointegration (OI) is a percutaneous implant system with a direct skeletal attachment. This improves control of the prostheses, increases range of motion, comfort, endurance, proprioception, and quality of life (Thesleff et al., 2017; Herbert et al., 2017). Nevertheless, given the inherent risk factors, osseointegration is reserved for those who have tried and failed socket ambulation for at least two years before pursuing OI (Personal communication with Dr. McGough, January 14th, 2020). At last one expert believes OI will become standard of care, although more clinical trials are needed (personal communication with Dr. Forsberg on January 28, 2020).

Brief historical overview

Dr. Per-Ingvar Branemark (5/3/1929-12/20/2014) a Swedish orthopedic surgeon and researcher accidentally stumbled upon osseointegration while studying microcellular blood flow in the mammals in the 1950s (https://www.britannica.com/biography/Per-Ingvar-Branemark; Personal communication with Kurt Collier, CPO and VP of Prosthetics at Integrum, January 15, 2020).

Dr. Branemark inserted a funnel-like titanium fixture in a rabbit femur. After completing the study, he tried to extract it only to find it had become embedded in the bone, with no signs of rejection (https://en.wikipedia.org/wiki/Per-Ingvar_Branemark; Personal communication with Kurt Collier, CPO and VP of Prosthetics at Integrum, January 15, 2020). Several years later, he used titanium implants to repair cleft palates in Swedish children, and again found that the titanium implant was osseointegrated, merged with the bone, with no signs of rejection. In 1990 Drs. P.I. Branemark and B. Rydevik performed the first trans-femoral osseointegration implant surgery in Gothenburg Sweden (Collier, 2020).

Osseointegration implant systems

Although there are currently several osseointegration implants available internationally (see Thesleff et al., 2017), this article will focus on two of the most common implant systems used in the United States at this time, osseointegration prostheses for rehabilitation of amputees (OPRA) and osseointegrated prosthetic limb (OPL). It is noteworthy to mention the percutaneous osseointegrated prosthesis (POP) developed by the VA scientists in Salt Lake City USA. The POP is provided for above knee amputation and includes an “endoprosthetic stem implanted into the bone and a post that connects to the stem and exits through the skin” (https://www.research.va.gov/Events/research_fair/Research_Fair_Highlights21.pdf). POP involves a two-stage surgery. An early feasibility study in 2015 for individuals 18 years of age and older by George E. Wahlen began at the Department of Veterans Affairs Medical Center in Utah; however, no updated information is available at this time (Thesleff et al., 2016; https://clinicaltrials.gov/ct2/show/NCT02720159).

Osseointegrated prosthetic limb (OPL) was first used in Australia in 2013, and is intended for transfemoral or transtibial amputations. The two designs include OPL-A and OPL-B. As with other implants in this category, OPL has undergone changes based on clinical feedback (Thesleff et al., 2017). The OPL is a press-fit system that can be implanted either in one or two stages, but is most commonly done in one. Weightbearing can begin in a few days, progressing to using two crutches for six weeks, then one crutch for six weeks, followed by full weight bearing. It may take 3-6 months to achieve full weight bearing (Holmes, 2020).
**OPRA - Osseointegration prostheses for rehabilitation of amputees**

Osseointegration prosthesis for rehabilitation of amputees (OPRA) is FDA-approved for transfemoral amputations through a humanitarian device exemption (HDE). Although OPRA is also available for above- and below-elbow and finger/thumb amputations, these are reserved for clinical trials until the transfemoral implants receive full market approval. At the time of this writing, they are used at several hospitals, including Walter Reed Medical Center (Collier, 2020).

The OPRA (see Figure 1) consists of 3 parts (https://integrum.se/opra-implant-system/are-you-a-potential-candidate/transfemoral-above-knee-amputations/):

- **Fixture**: the anchoring device implanted inside the individual’s bone
- **Abutment**: a connection protruding from the skin attached to the fixture
- **Abutment screw**: a titanium alloy screw that secures abutment to the fixture

Once OPRA is implanted in the intermedullary canal of the bone, the skin at the end distal part of the femur is flapped directly over the bone and may heal and form scar tissue. Scar tissue healing is superior to scab healing and poses less of a risk of infection. (Collier, 2020). The OPRA system is implanted in two stages. In the first stage, the osseointegrated device is implanted and healing may proceed for 3-6 months. In the second stage, the abutment is threaded into the fixture that attaches to the prosthetic limb. After the second surgery, for the next 2-6 months, the individual can gradually progress to full weight bearing. The entire process may take between 8-12 months (Holmes, 2020).

**Common outcomes**

Recipients often report the following:

- Improved range of motion
- Decreased risk of ulceration and pain due to pressure due to socket free prosthetic attachment
- Stable connection
- Effortless attachment and detachment of prosthesis
- Improved osseoperception
- Can be worn for extended periods of time
- Reduced phantom pain
Clinical Studies
A follow-up study by Tsikandylakis et al. (2014) examined transhumeral OI implant survival, adverse events, OI revisions, and bone remodeling in 18 subjects, 20% of all individuals evaluated for transhumeral OI at Sahlgrenska University Hospital in Sweden. The inclusion criteria for this study were (Tsikandylakis et al., 2014):

- Transhumeral amputation due to trauma or malignant tumor
- Difficulty using or wearing socket prosthesis
- Short residual limb
- Compliant patients

In 16 of the 18, implant survival rates were 83% at two years and 80% at five years. Three implants failed, with two primary and one revised implant removed due to loosening. One implant was removed secondary to contralateral shoulder arthritis and arthrodesis. Of 43 total adverse events, 21 (49%) were mild, 16 (37%) moderate, and 6 (14%) severe. Superficial infections were successfully treated with oral antibiotics with complete recovery. Deep implant infections occur in the intramedullary canal around the OI implant, causing pain, swelling, and positive bacterial cultures and may require surgical intervention (Table 1). (Tsikandylakis et al., 2014).

Herbert et al. (2017) reviewed 14 clinical outcome studies between 2003-2017. The most common complications were soft tissue infections and stoma irritation, but some studies reported minor incidence of deep bone infections (Herbert et al., 2017) (Table 2). The most common pathogens involved were coagulase-negative staphylococci and Staphylococcus aureus, but Enterococcus faecalis were also seen (Tillander et al., 2017). Persistent resistant infections are one of the main reasons for implant extraction. Risk factors for related joint infections include diabetes, rheumatoid arthritis, end-stage kidney disease, undernourishment, impaired immune response, wound infection, and presence of S. aureus in the nasal passages (Tillander et al., 2017).

Perhaps the most serious complication is osteomyelitis. A study by Tillander et al. (2017) of 96 patients with 102 intramedullary implants reveals that implant-associated osteomyelitis was diagnosed in 16 out of 90 patients with femoral OI implants, a 10-year cumulative risk of 20%. Ten implants were removed due to osteomyelitis, a 10-year cumulative risk of 9%. The median time from implantation to osteomyelitis was 2.6 years (range 0.3-13.8 years). Table 3 demonstrates long-term risks of osteomyelitis. The author stipulates that although the results to a higher long-term risk of osteomyelitis, newly adopted standards for implants, surgical, and rehabilitation protocols may mitigate the risk of infection and osteomyelitis.

Readers are encouraged to research further clinical trials at clinicaltrials.gov using key words

- Osseointegration
- Bone-anchored prosthesis
- Neuro-prosthesis

There is an e-OPRA Implant System for Lower Limb Amputees study recruiting subjects, a study identifier NCT03720171.

Representative institutions’ experiences
The Center for the Intrepid
In 2013, the VA started the first human OIP study in living bone (research.va.gov). As of 2019, sixty transfemoral amputees had osseointegration surgery at the Walter Reed Medical Center in Texas, most with a placement of an intermedullary rod in the residual femur, followed by threading of an abutment into the implant in about 8 weeks (Lipe, 2019). OIPs are reserved for individuals with a significant difficulty using conventional prostheses due to discomfort, pain, infection, skin breakdown, tissue scarring, poor fit, sweating and other factors.

All prosthetics are fabricated directly at the affiliated Department of Prosthetics at the Center For the Intrepid (CFI). CFI prosthetists can make any needed adjustments on the spot during rehabilitation. The most common complication is superficial skin infection, usually treated with oral antibiotics. To date, no other serious complications, such as deep bone infections, implant rejection, bone or implant fractures have been observed (Lipe, 2019).
Holmes Prosthetic Center
In 2014, the owner of Holmes Prosthetic Center in Houston TX traveled to Australia to get hands-on experience in working with osseointegration prostheses. Their protocol is initial follow-up every few weeks as weight bearing increases, for alignment and knee programming. If there are no issues or complications, future routine follow-up is every 6 months. The Holmes Prosthetic Center provides osseointegration prostheses for upper and lower limbs. However, there are few upper extremity prosthesis so far. The cost ranges between $30,000-$110,000 per leg (Holmes, 2020).

Eschen Prosthetics New York City
The Hospital for Special Surgery in New York City NY provides osseointegration surgery for upper and lower extremity amputees. Prostheses are provided by Eschen Prosthetics and Orthotics. The prosthetist becomes involved immediately after the surgery. A weight-loading pilon is placed immediately after surgery and the individual may stand on the following day. The physician and physical therapist collaborate on a highly individualized weight-loading protocol that depends on bone strength and several other factors. The loading weight usually starts at twenty pounds and is gradually increased by five pounds every other day. When successful loading exceeds body weight, the prosthesis can be connected to the implant.

After a four week follow up, the frequency of visits depends on individual need. OIP provides increased adduction and abduction range of motion in the hip as compared to a conventional socket prosthesis. Individuals using the OIP can feel the ground when they walk; sensory input to the brain is facilitated each time a step is taken (Harris, 2020).

Considerations for Nurse Life Care Planners
Lack of or limited standards of practice, standardized coding, and pricing information (and perhaps some resistance in the medical and the rehabilitative communities to implement procedures and products with limited safety parameters) may present challenges to the NLCP. These challenges can be mitigated if the NLCP refers to the standards of practice for the NLCPs. Specifically, Standard 13, Collaboration states, “The nurse life care planner collaborates with healthcare consumers, healthcare providers, and others, in the conduct of practice.” (AANLCP, 2015)

Asking the right questions before surgery will provide the building blocks for a strong LCP foundation. For the surgeon:

• What type of OI implant surgery will be performed, one- or two-stage?
• What are the possible risks?

• How long is the surgery?
• How long is the postoperative recovery, healing process, and wound care?
• If two- stage surgery is performed, what is the anticipated time interval between stages?
• Can regular prosthetics be worn while the individual is awaiting the second surgery?
• What is the cost of the surgery?
• What are the frequency and costs of OI implant failure and revision?
• What is the frequency of implant-related infections (superficial, osteomyelitis)?
• What is the frequency of implant extraction for severe infection?
• What is the frequency of abutment replacement? What is the cost?
• How often does mechanical loosening occur and what is the treatment?
• What is the life expectancy of the OI implant?
• How often is surgical follow up and for how long?
• When can weightbearing be initiated?

For orthopedist and the PM&R physician (not all-inclusive):
• What is the frequency and duration of follow-up?
• What is the frequency of infection? Mild, moderate, severe?
• If osteomyelitis is suspected, clinical diagnostic tests and treatments?
• How long is the course of antibiotic therapy, oral or IV? Frequency and duration?
• How often does infection occur?
• What minimizes risk of infection?
• What radiologic, hematologic, tissue cultures, histologic analysis, invasive testing is needed and how often?
• How soon after surgery does physical therapy start?
• Frequency and duration of physical therapy?
• What are the billing codes and costs?
• Is osteoporosis possible due to bone resorption?
• What blood work is recommended for monitoring?
• Any supplements or meds recommended to mitigate osteoporosis?
For the healthcare consumer: Ask about desires, needs, and current challenges with a socket is critical (circumstances permitting) as part of your comprehensive nursing assessment. A thorough review of medical, rehabilitative, and other records may reveal that the socket type prosthesis has been a considerable hardship for the past two years, meeting criteria for considering OIP. Common problems include:

- Discomfort and pain
- Persistent skin infections and skin breakdown of the residual limb
- A short residual limb and a poor fitting prosthesis
- Residual limb size changes
- Soft tissue scarring
- Large surface area of skin grafting
- Socket stability issues
- Limited capacity for free movement of the prosthetic limb

**Coding and costing**

Identifying specific codes may be challenging for both planners and therapists. At this time, the DME coding used for OPRA AXOR is DME:5999 unlisted. There are a limited number of prosthetists working with OIP because of difficulty billing for the services. Also seek codes from physicians and other team members. See sidebar for commonly used codes.

**Conclusion**

Limb amputation is a catastrophic event that affects every aspect of the individual’s life. A prosthesis that does not provide adequate support during ambulation causes pain, suffering, and limits independence. For some amputees, conventional socket-type prostheses fail to provide needed mobility and independence. Osseointegration prosthesis (OIP) or bone-anchored prosthesis bypasses the need for a socket by connecting the bone to the prosthesis via a surgically implanted titanium implant.

One of the most common and concerning complications is infection. Each patient may expect at least 1 infection every 2-3 years. Although most infections are superficial, some occur deeply in the bone around the implant and may require extraction of the implant if oral or IV antibiotics fail. Osteomyelitis may require extensive treatment and hospitalization. Nevertheless, for some amputees, OI prostheses provide improved movement, resolution of problems experienced with conventional prosthesis, improved functional mobility, and community reintegration. Key players include the amputee, surgical team, orthopedist, prosthetist, physical therapist, PM&R physician, and scientists involved in ongoing technology development. OI prostheses may become a standard of care in the future. However, more clinical trials and effective mitigation of adverse events are needed. The reader is encouraged to keep abreast of new and updated information on the topic of osseointegration prostheses.

<table>
<thead>
<tr>
<th>COMMON CPT CODES FOR OSSEOINTEGRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STAGE 1</strong></td>
</tr>
<tr>
<td>20902  Bone graft, major or large</td>
</tr>
<tr>
<td>27599  Unlisted procedure, femur or knee</td>
</tr>
<tr>
<td>27596  Transfemoral amputation, reamputation</td>
</tr>
<tr>
<td>15832  Excision, excessive skin and subcutaneous tissue, thigh</td>
</tr>
<tr>
<td>64774  Excision, neuroma</td>
</tr>
<tr>
<td>24930  Transhumeral amputation, reamputation</td>
</tr>
<tr>
<td>24931  Transhumeral amputation, reamputation, with implant</td>
</tr>
<tr>
<td>15836  Excision, excessive skin and subcutaneous tissue, arm</td>
</tr>
<tr>
<td><strong>STAGE 2</strong></td>
</tr>
<tr>
<td>27596  Transfemoral amputation, reamputation</td>
</tr>
<tr>
<td>24930  Transhumeral amputation, reamputation</td>
</tr>
<tr>
<td>24931  Transhumeral amputation, reamputation, with implant</td>
</tr>
<tr>
<td>64774  Excision, neuroma, cutaneous</td>
</tr>
<tr>
<td>64784  Excision, neuroma, major peripheral nerve</td>
</tr>
<tr>
<td>15002  Sure prep or creation of recipient site by excision of open wound</td>
</tr>
<tr>
<td>15200  Full-thickness graft, free, closure of donor site, trunk, 20 sq cm or less</td>
</tr>
<tr>
<td>13121  Repair, complex, arm or leg, 2.6-7.5 cm</td>
</tr>
<tr>
<td>13122  Repair, complex, arm or leg, add’l 5 cm or less</td>
</tr>
</tbody>
</table>

Amputation Osseointegration Resources

https://www.amputee-coalition.org/inmotion_online/inmotion-29-05-web/40/  
https://tricare.mil/mtf/WalterReed/Health-Services/M_S/Osseointegration/Osseointegration-FAQs  
Brand new fact sheet https://www.amputee-coalition.org/resources/osseointegration-an-overview/
In transcutaneous osseointegration, a metallic prosthesis is implanted in the bone of an amputated limb, generally a femur, but occasionally a tibia or humerus. The bone grows into or onto the prosthesis, resulting in a permanent implant. This implant exits the skin via a stoma and then attaches directly to the prosthetic limb. There are several advantages when comparing OIP to the conventional prosthesis.

The first and the most important is that the patient no longer uses a socket. Skin complications are very common with socket prostheses, and socket ambulation is considerably less comfortable than with OIP. Socket ambulation is also prohibitively difficult in patients with short residual limbs. OI may provide better function in these individuals.

Osseointegration also allows osseoperception, the sense of where the prosthetic foot is in space and on the ground. Socket amputors generally must look at the prosthetic foot each time they step upon it. After OI these patients have a strong sense of where the foot is, how hard it has been struck upon the ground, and even what sort of a surface is below the foot (concrete versus carpet, for example).

Procedure, complications, recovery, candidates, contraindications

Most OI patients are a part of a surgical research protocol. Osseointegration can be performed in one or two stages. With a one-stage procedure, the device is implanted and exteriorized (brought through a stoma) simultaneously. Theoretically, this procedure carries a higher risk of infection, but also eliminates one surgery. In a two-stage plan, the device is implanted and exteriorized three to six months later.

The risk of infection is between 5%-20%, given that a foreign body is permanently penetrating the skin, although deep bone infections are much rarer. Drainage, irritation, swelling and other skin issues are common at the stomal site. Amputees do experience falls and given that the OI amputees are often much more active than the socket amputees, there may be a higher risk of bone and device fractures.

Recovery time is measured in months to years depending upon the implant. Some individuals are ready for weight bearing in 1-3 months, while others may require between 6-12 months. The patients begin limited weight bearing, but generally are walking between 3-6 months. The therapy is extensive as patients relearn how to walk and try to eliminate circumductive or Trendelenberg gait habits formed with a socket ambulation.

Ideal candidates include superstar athletes and those who can barely ambulate with socket prosthesis. Extremely active amputees generally have better bone and muscle quality and rehabilitate faster and achieve more. Interestingly, amputees who are not good socket ambulators also show dramatic improvement. Specifically, those with short residual limbs and with very large thighs walk substantially better without socket prosthesis. The OIP can be used in any population, except in skeletally immature children.

Contraindications include active infection, insufficient bone or soft tissue stock, and behavioral or psychological problems. Since problems with the stoma and the device are expected, those who cannot follow medical advice, catastrophize, or seek multiple medical options are not appropriate candidates for OIP.
Table 1. Adverse events for OI implants in trans-humeral amputees (Tsikandylakis et al., 2014).

<table>
<thead>
<tr>
<th>Adverse Event (AE)</th>
<th>Definitions</th>
<th>Number/%</th>
<th>Treatment/Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial infection at the implant insertion site</td>
<td>Signs of infection and positive cultures from skin/abutment junction</td>
<td>35% or 15 infections of AE 2 years -19% (3 out of 16) 5 years- 38% (5 of 13)  Staphylococcus aureus most prevalent organism</td>
<td>Surgical revision of integumentary insertion area; local, mechanical debridement; local or oral antibiotics (2-6 weeks) stabilization of soft tissue.</td>
</tr>
<tr>
<td>Skin reaction at the insertion site</td>
<td>Color changes, serous discharge, presence of a granulation ring</td>
<td>19% of AE (8 patients) 2 year -38% (6 of 16) 5 year- 62% (8 of 13)</td>
<td>Clinical observation, nonsurgical cleansing, chemical cauterization (AgNO3)</td>
</tr>
<tr>
<td>Deep implant infection</td>
<td>Infection in the intramedullary canal with clinical signs of infection and positive intramedullary bacterial cultures</td>
<td>1 patient 3.5 years after first surgery. Dx: Osteomyelitis with positive cultures for E.coli</td>
<td>Oral antibiotics x 3 months with complete resolution of infection and full us of the OI prosthesis</td>
</tr>
<tr>
<td>Incomplete distal fracture at first surgery</td>
<td>Fracture or erosion of the distal cortical bone during surgery</td>
<td>19% (8 fractures) of AE 44% (8 of 18 patients)</td>
<td>Six fractures required no treatment; 1 fracture required autologous bone transplantation; 1 treated with modified passive rehabilitation between the 1st and the second surgery.</td>
</tr>
<tr>
<td>Defect of the bony canal at 2nd surgery</td>
<td>Limited loss of the bony canal due to drilling</td>
<td>3 out of 18</td>
<td>Bone healed spontaneously and uneventfully</td>
</tr>
<tr>
<td>Partial skin flap necrosis</td>
<td>Inadequate viability of the skin flap at the implant insertion site</td>
<td>3 out of 18</td>
<td>Healed in 2-4 weeks following skin debridement and oral antibiotics</td>
</tr>
<tr>
<td>Endosteal bone resorption</td>
<td>Loss of bone due to bone resorption in the endosteum</td>
<td>Observed in 3 implants at 2 and at 5 year follow up.</td>
<td></td>
</tr>
<tr>
<td>Distal bone resorption</td>
<td>Resorption in the distal bone leading to exposure of the fixture</td>
<td>Observed 1 at 2 years and 2 x at 5 year follow up without exposing the OI fixture.</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2. OI Complications in lower limb amputations (Herbert et al., 2017).

<table>
<thead>
<tr>
<th>Study</th>
<th>Infections</th>
<th>Other complications</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hagberg (2009)</td>
<td>2 superficial infections treated with antibiotics.</td>
<td>a. 20/100 patients had implant removed, b. 11/20 implant removed permanently. c. 4/100 with OI implant did not use the prosthetic limb due to phantom pain, osteomyelitis, or issues with contralateral limb</td>
<td>37 patients-17 had no complications or minor complications 2 out of 4 patients that had explantation underwent successful re-implantation</td>
</tr>
<tr>
<td>Aschoff (2010)</td>
<td>1 patient experienced deep intermedullary infection and required explantation of the OI implant.</td>
<td>20/37 patients experienced at least 1 revision of the OI implant. 14/37 patients had minor revisions of the stoma 4 patients experienced removal of the implant: a. 1 due to intermedullary infection b. 2 due to soft tissue problems c. 1 due to implant failure 7 years after surgery</td>
<td></td>
</tr>
<tr>
<td>Tillander (2010).</td>
<td>a. 2/39 patients experienced infection 3 month after OI b. 7/39 patients experienced implant infections at 3 year follow up All treated with oral antibiotics</td>
<td>1 implant removed due to mechanical loosening 1 abutment removed due to chronic skin infection</td>
<td></td>
</tr>
<tr>
<td>Branemark (2014)</td>
<td>Superficial skin infection 28/51 patients experienced superficial infection 41 times. 39 patients experienced serious infections 4/51 patients experienced deep infection during a 2 year period</td>
<td>46/51 patients experienced at least 1 complication, total 101 complications. 1. Implant removal-4 patients 2. Fractures- 5 patients (vertebral compression, ipsilateral hip, below elbow 3. Episodic pain during rehab-5 patients 4. Mechanical abutment complications-4 patients, replaced with no long-term effect</td>
<td>No implant fractures reported</td>
</tr>
<tr>
<td>Al Muderis (2016)</td>
<td>29/86 patients experienced infection: a. 25 /29 had low grade soft tissue infections. 23 were treated with oral and 1 treated with parenteral antibiotics b. 4/29 had high grade soft tissue infection required surgical intervention</td>
<td>26 patients had at least one complication excluding infection: a. 17 had stoma hyper granulation b. 14 had soft tissue problems c. 3 had proximal femoral fracture d. 1 required implant replacement due to poor OI e. 2 had implant breakage</td>
<td>31 out of 86 patients did not experience any complications or adverse events. 26 did not develop infection</td>
</tr>
</tbody>
</table>
### Table 2. OI Complications in lower limb amputations (Herbert et al., 2017) Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Infections</th>
<th>Other complications</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al Muderis (2017)</td>
<td>15/22 patients experienced minor infections.</td>
<td>6/22 had elective soft tissue refashioning</td>
<td>No revision surgeries, fractures, or implant failures report in this group</td>
</tr>
<tr>
<td></td>
<td>12 treated with oral antibiotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 required IV antibiotics</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 3. Long-term risk of osteomyelitis (Tillander et al., 2017)

<table>
<thead>
<tr>
<th>Diagnosis of Osteomyelitis</th>
<th>Interventions/treatments</th>
<th>Comments</th>
<th>Use of prostheses</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 patients (16 implants)</td>
<td>4 patients osteomyelitis resolved with prolonged antibiotics without extracting implant.</td>
<td>6 out of 10 implant extractions occurred 4-102 months (median 25 months) post OI implant insertion</td>
<td>2/16 patients were unable to use their prostheses during treatment for osteomyelitis</td>
</tr>
<tr>
<td>10 patients and 102 implants</td>
<td>10 patients had extraction of the implant secondary to osteomyelitis.</td>
<td></td>
<td>6/16 had moderately restricted prostheses use</td>
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<tr>
<td>10 year estimated risk of 20%</td>
<td>10 year risk of implant extraction due to infection is 9%</td>
<td></td>
<td>2/16 were able to fully use their prostheses</td>
</tr>
<tr>
<td>5/34 short stumps (15%)</td>
<td>Mean time for diagnosis of osteitis is 125.5 months; range is 64-192 months.</td>
<td></td>
<td>6 patients could not be assessed because they were in early rehabilitation</td>
</tr>
<tr>
<td>10/60 in normal &amp; long stumps (17%)</td>
<td>Treated with short course of oral antibiotics, mean number of treatments 21.5; range 10-30</td>
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<tr>
<td>6 patients out of 96 did not have definitive diagnosis, but had osteitis before 5 year follow up (8% risk at 10 years of implant use)</td>
<td>Mean time for diagnosis of osteitis is 125.5 months; range is 64-192 months.</td>
<td></td>
<td>3/6 patients with osteitis were able to use their prostheses to full extent, while the other 3/6 patients had moderate restriction in prostheses use.</td>
</tr>
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Abstract
Powered upper extremity orthoses may become a part of our nurse life care plans for evaluatees from infancy with obstetrical injuries to adulthood for a variety of conditions including stroke, spinal cord injury, motor vehicle accidents resulting in nerve injury, multiple sclerosis and amyotrophic lateral sclerosis (Shoemaker 2018).

Introduction
Obstetric brachial plexus palsy (OBPP) and obstetric brachial plexus injury (OBPI) occur for a variety of reasons, and adults can develop upper extremity paresis from illnesses and injuries mentioned above. At birth, the incidence of OBPP is as high as four per 1,000 births where medical care is not good, and one to three in 1,000 births in locations with good obstetric care (Erel 2008). About 70% of affected infants obtain function within four to six months (Serac 2013).

Contractures of the elbow often occur. Significant range of motion compromise may benefit from surgical and non-surgical (i.e., elbow extension orthotics) treatment. This article discusses external motorized orthoses for adolescents and adults.
Background

Upper extremity prosthetics were first used in 1915 (Childress, 1985). Powered upper extremity orthotics are robotic arm and hand braces designed to help restore function to weak or paralyzed upper extremities.

Upper extremity exoskeletons

“The main function of an upper extremity exoskeleton is human power augmentation for manipulation of heavy and bulky objects.” (Kazerooni, n.d.); “for every forty pounds of weight from an object, a worker might support only four pounds while the device supports the remaining 36 pounds.” The user can sense the weight of the load and modify movements accordingly. The elbow motor lift capacity at the hand depends on the user’s forearm length, tone, biceps strength (if any), weight of forearm, etc.

Someone without upper extremity limitation can also use this technology with intelligent assist devices (IAD), simple upper extremity enhancers, to significantly decrease back injuries from lifting.

There have been many kinds of upper extremity exoskeleton systems described over the years, among them:

- electrically actuated upper extremity robotic exoskeleton systems (Kiguchi et al., 2003; Gopura et al., 2009)
- anthropometric powered exoskeleton systems (Perry et al., 2007)
- hand rehabilitation exoskeleton and data glove (Yamaura et al., 2009)
- pneumatically actuated exoskeleton systems (Yamaura et al., 2009)
- biometric orthoses (Yamaura et al., 2009)
- “muscle suit” are additional systems (Gopura et al., 2009)
- Functional evaluations: lifting a laundry basket, drinking from a cup, turning on lights, and bringing an eating utensil to the mouth

After casting for fabrication, each received an individually fitted and programmed exoskeleton. They had occupational therapy with a therapist with expertise using the device. Patient A was able to increase elbow flexion by ten degrees and extension by fifty degrees. Patient B did not increase flexion with the device but did increase extension by thirty-five degrees. Ultimately, they demonstrated improved function both in and outside their homes using the powered orthosis.

Coding and Costing

Consider the following:

- Brachial plexus specialist – CPT 99214
- Orthopedic surgeon to evaluate shoulder joint deformity – CPT 99215
- Physical medicine and rehabilitation – CPT 99244
- Psychologist/Counselor, especially at times of challenges in self-perception (entering adolescence, consideration of parenthood, etc.)
- Physical therapy
- Occupational therapy
- Social skills support, computer interface, functional behavior analysis and implementation
- Surgery
  - (Modified quad surgery – ‘mod quad’ – latissimus dorsi muscle transfer, teres major muscle transfer, subscapularis muscle release, and axillary nerve decompression and neurolysis – CPT 23397, 23410, 23406, 64708
  - for common deformities of the shoulder such as internal rotation contracture, limitations of elevation and external rotation – CPT 23397, 23415, 23405, 23929

The MyoPro by Myomo was originally developed at MIT with Harvard Medical School. According to their website, “The motorized device works by reading the faint nerve signals (myoelectric signals) from the surface of the skin then activating small motors to move the arm and hand as the user intends.”

General contraindications to this device include “high tone, contractures severely limiting range of motion (ROM), lack of detectable EMG signal, cognitive deficits, shoulder dislocation, pain during joint ROM, and lacking motivation and support system. Each individual is evaluated and thus other contraindications may present” (personal correspondence, Oddie). The Myomo device on the market currently is for individuals 12 years old and older. A pediatric model is in development and was scheduled for release in 2020 but its launch has been delayed because of the COVID-19 outbreak.

Shoemaker (2018) describes two cases using the MyoPro device. Both Patient A, a 67-year-old man, and Patient B, a 61-year-old man, were affected on their right (dominant) sides by stroke. Evaluations included:

- Therapy consultation
- Passive and active range of motion measurements
- Electromyography of the wrist flexors, biceps, and triceps
- Disabilities of the Arm Shoulder and Hand (DASH) survey (see also Treadwell et al., page XXX, Ed.)
• Post-operative medications
• Imaging
• Aids for grooming, dressing
• Bluetooth-compatible devices for the size of the.evaluee
• Weighted leather strap to keep books open
• Driving evaluation
• Steering knob for a vehicle
• Kitchen and craft vise
• Vocational/avocational evaluation, site development, placement, monitoring

According to BioTuesdays, the average selling price of this powered orthotic device (they do not use the word ‘exoskeleton’ when billing) is $13,400; the actual cost may be $85,000. Two batteries are required, one in use and one to charge. Additional equipment includes the charger, harness, and lining materials.

• L3904 – wrist hand finger orthosis, external powered, electric, custom-fabricated

“There is no separate payment for batteries and/or battery charges billed concurrently with a powered base item.”

• If not billed concurrently, batteries (L7360, L7364, L7349) are reimbursed by CMS from $227 to $530.
• The charger (L7362, L7368), if not billed concurrently, is reimbursed from $250 to $603.

(Please see Berry for more information on costing, page 21, Ed.).

Replacement

The product warranty for the MyoPro is three years. This product has not been on the market long enough to have accurate replacement data for replacement. It is likely comparable to replacements for all upper extremity prostheses – about five years. (Also refer to Berry, page 21, Ed.)

Conclusion

Prior to this technology, adolescents and adults could not be fully functional because of range of motion deficits. A powered orthosis makes many pursuits possible. Nurse life care planners need to continue to be abreast of developments. What a pleasure it is to be able to share with our adult clients who are depressed because of what they have lost. Fyodor Dostoevsky said, “To live without hope is to cease to live.” We have every reason to offer hope to so many people.
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OTHER RESOURCES

January 2020 DMEPOS (Prosthetics, Orthotics and Supplies) Fee Schedule


Targeted muscle reinnervation (TMR) is a complex surgical procedure for high-level amputees that takes nerves previously dedicated to hand, wrist, or elbow motion and implants them into adjacent muscles, dramatically amplifying the nerve signals. The goal is to provide users “thought control” of a myoelectric prosthesis.

TMR reroutes the four upper arm nerves to the pectoral muscles of the chest to provide intuitive control of a prosthesis. Targeted sensory reinnervation (TSR) reroutes the sensory nerves along the upper arm nerves of TMR that provide cutaneous sensory feedback. This allows the prosthesis wearer some cutaneous feedback.

Traditional myoelectric prostheses give three degrees of freedom: elbow flexion and extension, wrist rotation, and grasp/release of hand or terminal device. TMR surgery creates additional EMG sites which are controlled with intuitive muscle contractions to enhance prosthesis functional use.

The procedure has been performed at medical centers nationwide, including the San Antonio Military Medical Center and Walter Reed National Military Medical Center. An exciting development is the promising response for pain treatment for those with neuroma. Recent research in the areas of secondary and primary TMR aims to optimize efficacy and efficiency and demonstrates potential for establishing a new standard of care for amputees [https://www.ncbi.nlm.nih.gov/pubmed/28831329].

**Procedure description and evaluation**

As a brief anatomy refresher, the brachial plexus exits the cervical spine from C5 to T1 and lies underneath the clavicle, where it branches off into the various peripheral nerve branches in the arm; median, ulnar, axillary and radial nerves. (Fig. 1, Brachial plexus anatomy) When the arm is amputated, those nerves are severed. However our brain does not know the limb is missing (resulting in phantom sensation) and continues to send nerve signals proximally. The functions of TMR are

- reroute these four nerves from the brachial plexus pectoralis muscle
- collect patterns of signals from the nerves and muscles to control a myoelectric prosthesis

**Who is the ideal candidate for TMR?**

The ideal TMR surgery candidate has had an above-the-elbow amputation. (Because of growth factors the surgery is currently limited to those over 14 years of age but this may change with further developments.) There are also minimum weight requirements. There must be enough pectoralis tissue to allow room for the surgical implantation of the nerves into the muscle. For obvious reasons, the candidate must not also have any nerve degeneration or damage. Congenital limb loss patients are not currently considered appropriate for this procedure.

TMR has actually become a standard recommendation for those with high upper limb loss. One thing to keep in mind is the amputation does not have to be new.
TMR process

The surgeon determines whether the patient meets criteria for the technology by examination and records review when the initial debridements are taking place (for a traumatic loss). The next step is getting medical and financial clearance. With traditional health insurance, this last takes between two weeks and six months. The surgery itself is about an eight-hour procedure due to the number of nerves affected and the dissection of each, and involves a two-day hospital stay.

Then the hard part begins: the waiting. Nerves grow at a rate of one millimeter per day on average and nothing more can proceed until adequate regeneration occurs. It is usually about six months before determining whether there are any successful muscle contractions. During this postop wait time, the amputee begins prosthetic fittings and occupational therapy training.

TMR has actually become a standard recommendation for those with high upper limb loss. One thing to keep in mind is the amputation does not have to be new.

Pattern Recognition

“Traditional myoelectrics are like listening to a concert and trying to decipher if the string section is louder than the brass section. Pattern recognition is like hearing what piece of music the orchestra is playing.”

In a traditional myoelectric prosthesis, there are two electrodes; one located on the inner arm surface and one on the outer arm. The patient thinks of the movement required to flex and extend the wrist; which results in muscle contraction then picked up by the electrodes and the prosthesis responds.

But our limbs are not limited by a single muscle to move, hold, or otherwise control our movements; when we move our arms or hands, multiple muscles work together. Each contributing muscle contract produces an electrical signature and this combination of signals generates a unique detectable concert pattern. When one reaches to retrieve an object, many muscle fasciculations and various contractions in differing intensity occur.

Pattern recognition had been used in the lab for years and first used in clinical practice in 2014. Modern microelectronics sense these contraction patterns from the skin surface and associates them with that concert of muscle activity. Instead of getting one signal at a time, multiple electrodes sense the series of contractions that make up the movement. The electrodes, now spread over a wide area, are recognizing these fine movements and picks up the pattern because the various signals are repeated. When the prosthesis learns the patterns, it becomes more intuitive.

Training for myoelectric prosthesis used to take hours tethered to a program on a computer, but with pattern recognition's microcontroller included in the prosthetic limb, it only takes a few minutes to train and is dependent upon how much time you want to spend on perfecting the control of the arm. This is because adding pattern recognition to prostheses eliminated mode switching (on/off, flex/extend), and allow modulations from gentle to strong contractions in the prosthesis. Contrast this to previous focus on having the patient work to increase muscle contraction intensity before fitting a prosthesis. When training for pattern recognition, we do the opposite; we do not want artificially high muscle contraction. Rather, the instruction is to tell the brain to perform the movement as if there was a fully intact limb, with normally small and large movements.

For the wearer, pattern recognition increases intuition. Contractions can be light and recalibration for light and strong effort is quick and simple. Wearers can recalibrate with a touch of a button, and most recalibrate each morning. For the O&P practitioner, there is less required muscle testing, and less need for electrode adjustment (Fig 1). Donning and doffing the prosthesis is much more forgiving because this no longer requires one specific spot for one specific electrode.
Pattern Recognition Charges
Pattern recognition is an add-on to the total cost of the prosthesis. There is a dongle which is required and unless this dongle is lost, it should be a one-time cost for the life of the prosthesis. Currently pattern recognition does not have its own Medicare billing code so L7499 is used for all associated components. Billing consists of the system itself as well as a signal conditioner and the calibration platform.

In this case study, the initial amputation charges were $40,000. The TMR surgery was an additional $27,500. Follow up exams were required at $137 to $204 per session and therapy at $111 per session. The prosthesis, including pattern recognition was $190,000.

TMR in the future
TMR has opened up many options for future innovation. Thumb control; specifically abduction and adduction are being studied. Wrist supination is expected to be included in the future. Research is being developed to enhance the signals recorded by the electrodes and to eliminate crosstalk from other muscles. A humeral rotator is being studied to improve elbow function. Currently the military is working on osseointegration for the transhumeral patient coupled with pattern recognition. Additional research is being conducted on TMR in transtibial patients for pain control.

Current concerns are the lack of real estate in the pectoral muscles to provide enough locations for sensors, electrodes, wires and other electronics carry out their functions. This has spawned other hypothesis for study such as the design of very small capsules which could be inserted into the muscle and allow more room for electronics.

Fig. 1 Sensors in place for TMR prosthesis.
Coming!
Fall 2021

Core Curriculum for Nurse Life Care Planning
2nd edition
Mr. S was a 49-year-old truck driver who was involved in a rollover tractor trailer accident on July 31st. He was found outside of the truck and with his left arm completely under the cab. After a very prolonged extrication he went to the local trauma center where he underwent a shoulder disarticulation amputation, eventually followed by several debridements and a surgical flap. On August 7th he underwent TMR surgery.

Complicating factors:

- Mrs. S was disabled from a traumatic brain injury a year before her husband’s injury. She had some cognitive deficits and walked with a cane. Her ability to provide care for his wound VAC or understand his treatments were limited.
- Mr. S lacked reliable transportation, resulting in delays in treatment and therapy.
- TMR surgery was relatively new. Lack of knowledgeable occupational therapists caused additional delays and reliance on out of state providers.
- Mr. S was obese which complicated fitting of the shoulder harness.
- Chronic wound infections resulted in additional surgery which changed the residual musculature and required a new socket.

Mr. S was left with reasonable scars. Scarring is always a concern in amputation cases. Any cleft of hollow in the scar can be a breeding ground for fungus, threatening the health of the residual limb.

Creating the test socket

A test socket is a socket made of clear acrylic so the practitioner can see if there are any areas of blanching that indicate pressure points (Fig. 1). Typically, a practitioner will plan for one to two test sockets for each new prosthesis. Because this was a shoulder disarticulation case, the socket had to completely cover the shoulder girdle in order to provide support for the lever mechanism used to lift the prosthetic arm away from the body. The more joints that are missing, the more difficult this is.

Before the test socket was placed, small stickers with electrodes were used to test his output before they were made into the socket itself (Fig. 2). A pattern recognition program by CoApt shows the user a computer animated arm, and the user is asked to mimic the motions made by the animated arm, such as opening and closing the hand, flexing and extending the elbow, and so forth. The electrodes pick up the signals from the residual muscles, showing the practitioner where the signals are strongest, optimal electrode placement, and how many electrodes indicate activation for a given particular motion. These practice electrodes then are embedded into the test socket to see if this array will give the desired control (Fig. 3)

Alignment is next. The socket is to be lined up with the spine (Fig. 4). Mr. S’s body habitus makes it appear it is off, but the goal is to put the weight over the shoulder and hip, down to the foot. The next is color matching, but colors are limited without customization. Custom matched silicone gloves and coverings can be made to include freckles, wrinkles, veins, age spot and hair to look much more natural, but this comes at an increased cost for fabrication and upkeep.

Prosthesis Delivery

The socket portion is made in-house, and the componentry comes from the manufacturer. In this particular case Mr. S was provided with a Bebionic hand and a hybrid Utah
elbow from Motion Control (Fig.5). A switch was placed on the front of the socket which includes a cord. When Mr. S pulls the cord, the shoulder is allowed to swing free. When locked the shoulder remains in one place and he can use the myoelectric control to flex and extend the elbow and wrist.

Mr. S enjoyed playing recreational league softball. At the time of his TMR surgery, Mr. S intended to be able to play softball again. He was super positive throughout this whole ordeal and never battled depression or loss of purpose. His wife, though disabled, was a positive influence on him throughout. However the one time he broke down was when he realized the prosthesis shoulder joint was manual and he was not going to be able to reach up to catch a ball. His providers discussed a famous one-armed professional baseball player, Pete Gray, and how he could play ball, but it would look different than it did prior to his injury. He did get a bat, started practicing, and was able to hit the ball. He also enjoyed playing disc golf and was able to continue playing with a few adjustments for balance.

Training
As with all upper limb loss, occupational therapy has to be an integral part of rehabilitation. In Mr. S’s case it was impossible to find someone locally with any knowledge of TMR surgery rehabilitation. An occupational therapist in Houston with a private consulting company was called in to assist. Utilizing the best in telecommunication, she showed Mr. S the exercises he was to practice. She also communicated with a local provider to act as continued support.

Telecommunication worked very well and was also utilized by CoApt and the prosthetist office. The prosthetist’s office was outfitted with multiple large screen monitors and cameras so that full range of motion could be assessed remotely alongside a video of the practitioner in the remote location.

The Nemesis
The nemesis in this particular case was a tiny spot that refused to heal. It was determined he had developed a fistula. Mr. S had a total of three procedures to close it. The first two were small in-office procedures; the third was a more extensive surgical excision. This changed Mr. S’s anatomy, resulting in the need for a new socket.

Body Powered Prosthesis
Normally a patient with an upper extremity loss would be expected to initially have a body-powered device. His goal was to be fully operational with the myoelectric prosthesis before delivering a body powered device. One reason to provide for a body powered device is for use when a myoelectric prosthesis is in for repairs. However, Mr. S had a non-dominant arm loss, is fully functional without a prosthesis, and does not depend on it to function on a daily basis. He has never desired a body powered prosthesis.

Mr. S wears his prosthesis all day. He has low dexterity for retrieving small items. He has continued working with pain management for pain and sleep.

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<tr>
<th>Table 1. L Codes for Upper Extremity Prostheses</th>
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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.

![Quick-DASH Scores based on 5 subjects](image)

*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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Supporting Certified Life Care Planners with Prosthetic Life Cost Projections™.

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612-810-1100
For 14 years, ANS has worked tirelessly to build powerful partnerships within the workers’ compensation, medical provider, and legal communities. The Clinical Nurse Consultants on our team offer a personalized approach, that starts with giving each and every case the time, attention, and respect it deserves—and ends with giving patients, adjusters, and physicians results they feel good about.

ANS currently offers four unique solutions, including a pharmacy intervention program—which has played a significant role in reducing opioid usage in injured workers—as well as Medicare Set-Aside, medical cost projection, and nurse expert services.

ANS partners with AANLCP and has been a proud supporting member for more than 15 years.
LOOKING AHEAD

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November  Durable Medical Equipment

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May  The Business of NLCP
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