Innovations in Pediatric Prosthetics

Michelle J. Hall, MS, CPO[1]; Rosanna L. Wustrack, MD[2]; Donald R. Cummings, BS, CP[3]; Richard I. Welling Jr., MSPO, CPO[4]; Mary K. Kaleta, PT, DPT, PCS[1]; Kevin D. Koenig Jr., MPO[1]; Jennifer C. Laine, MD[1,5]; Sara J. Morgan, PhD, CPO[1]

[1]Gillette Children's Specialty Healthcare, St. Paul, MN; [2]University of California San Francisco Department of Orthopaedic Surgery, San Francisco, CA; [3]Scottish Rite for Children, Dallas, TX; [4]Children's Healthcare of Atlanta, Atlanta, GA; [5]University of Minnesota Department of Orthopaedic Surgery, Minneapolis, MN

Abstract: The pediatric patient with limb differences continues to provide unique challenges and demands appropriate, pediatric-specific innovation. Not only do children test the current technology with their size, weight, and potential growth but also with their chosen activities, energy-level and drive to explore varied environments. This article explores the recent advances within the broader realm of prosthetics, primarily based on research in adult patients. It identifies technologies that have already been translated to pediatric populations and points out areas for potential pediatric applications. This review highlights numerous needs and gaps in the currently available resources and tools for these patients, including surgical techniques, prosthetic componentry, and rehabilitation strategies. Further innovation and research are needed for pediatric patients to maximize their functional potential while using a prosthesis.

Key Concepts:
- For adults living with limb differences, innovative surgical techniques have improved function and decreased phantom limb pain. The effects of such techniques are not yet well understood in the pediatric population.
- Smaller, lighterweight, and more durable prosthetic components are still needed for upper and lower limb pediatric prostheses.
- Advances in virtual reality and video games have creatively improved therapeutic interventions for children using prostheses.

Introduction

In 2005, an estimated 1.6 million persons were living with the loss of a limb in the United States.[1] Children, 18 years and under, accounted for 1.6% of the total with an estimated 25,000 children living with limb loss.[1] Congenital limb deficiency, trauma, and cancer diagnoses are the main indications for amputation in children. McLarney and colleagues used a database of commercially insured children to estimate the rates of major lower extremity limb loss. They found a prevalence of 38.5 cases per 100,000 per year between 2009-2015.[2] Congenital limb absence or difference accounted for 84% of the cases, followed by trauma at 13.5%.[2] Although this diagnosis may initially be devastating to the family, with care from the multidisciplinary medical team, these children tend to do well.

Children are some of the most active prosthesis users, often requiring pediatric-specific prosthetic components to engage in a variety of high-level activities. Over the past decade, prosthetic options for pediatric prosthetic limb users have expanded. Improved prosthetic design and technology have allowed for not only daily use but also sport and activity-specific uses. Some of the advanced prosthetic technologies that evolved for adults may also be applicable to adolescents and teenagers. Children with amputations have helped identify a number of activity limitations and mobility restrictions that could be addressed, in part, through the advancement in prosthetic design and technology.[3]

This is the second article in a *JPOSNA* two-part series. The first, "Essentials of Pediatric Prosthetics" *(JPOSNA Volume 2, Number 3)* provides orthopaedists with a general overview for providing care and prescribing prostheses for the child with limb differences.[4] The aim of this second narrative review is to provide an overview of recent advancements in care and design options for pediatric prosthesis users. The purpose of this article is to keep orthopaedic surgeons up to date with technology so they may advise families of children with limb differences and prescribe prostheses accordingly. This article also identifies several areas where advancements in prosthetic technology and care are needed; this may alert manufacturers and researchers to these clinical needs. Readers should have a basic understanding of pediatric prosthetics prior to reading this article and may wish to first review the previous article.[4]

Surgical Advances

Phantom & Limb Pain

The incidence of phantom limb pain (PLP) in children is poorly understood. The few studies evaluating PLP prevalence among children and adolescents report wide ranges. Occurrence of pediatric PLP varies from 3.7-90%, and variance in rates may relate to clinical factors such as etiology of limb loss.[5] While the rates tend to decrease over time, some children may still experience PLP one year after surgery.[5] Amputees also report pain at or around the distal end of the amputated limb. This is termed residual limb pain and is thought to be due, in part, to neuroma formation at the end of the cut nerves. The incidence of painful neuroma formation and residual limb pain in adults varies widely depending on the study but was reported at 67.7% in a cross-sectional survey performed through the Amputee Coalition.[6] Data on residual limb pain in pediatric patients is limited.

Both targeted muscle reinnervation (TMR) and regenerative peripheral nerve interface (RPNI) were initially developed to control upper limb neuroprosthetic devices (see *Upper Limb Prosthetics* below); however, it was observed that adult patients reported less limb pain following these procedures. As a result, TMR and RPNI have gained popularity to prevent and treat both PLP and neuroma-related pain. For TMR, transected sensory and mixed motor nerves are transferred to nearby redundant motor branches allowing the severed nerves to grow in an organized fashion rather than form a neuroma. This can be done at the time of index amputation or in a staged fashion. A prospective randomized control study on adults showed improvement in PLP and residual limb pain at one year in the TMR cohort compared to those with cut nerves buried into muscle.[7] Similar improvement was noted at one year in a prospective cohort of patients treated with TMR for PLP and residual limb pain.[8] RPNI involves grafting free autologous skeletal muscle to the cuts ends of sensory and mixed motor nerves (Figure 1). This appears to prevent neuroma formation similar to TMR. These techniques have not been routinely used for children and adolescents but are low morbidity and have the potential to improve postoperative pain in this population. Further prospective studies should focus on these interventions for PLP and neuroma-related pain in children and adolescents.

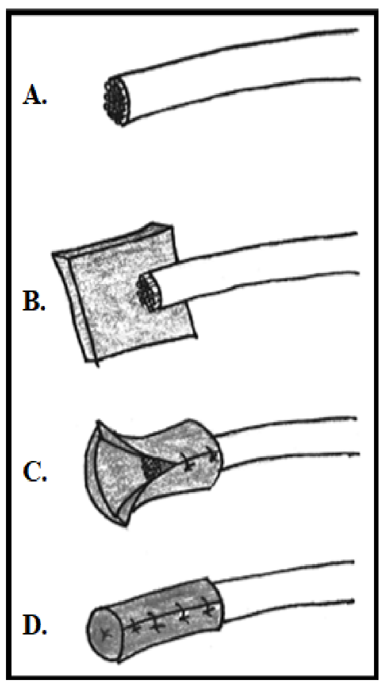

Figure 1. Surgical Technique for RPNI
A. Cut nerve end;
B. The cut nerve is implanted onto a muscle graft of 2x1x0.5cm to3x1.5x1cm depending on the size of the nerve. The nerve end is secured to the muscle with 2-3 6.0 nonabsorbable monofilament sutures from the epineural-to-epimysial stitches;
C, D. The muscle graft is wrapped over the never end and sutured to itself.

Bone Anchored Prostheses (BAP)

BAP allows for direct connection of the prosthesis to the skeleton, thereby eliminating the need for a traditional socket and improving osseoperception. Several studies among adults with transfemoral amputations have shown improved prosthetic satisfaction, sitting comfort, mobility and reduced cost of energy while walking with BAP.[9,10] Several different implant systems are available globally; however, the OPRA™ Implant System (Integrum, Sweden) is currently the only system FDA approved for use in adults at the transfemoral level and available with humanitarian exemption for transhumeral amputees (Figure 2). Other designs have been used in the U.S. on a custom or experimental basis. The OPRA™ implant consists of an osseointegrated, titanium intramedullary screw that connects to an abutment which is brought through the skin. A prosthetic arm or leg can then be attached to the abutment. The enhanced-OPRA (e-OPRA) system is currently under investigation in a small trial of adults. It is designed to enable bidirectional communication between implanted neuromuscular electrodes and the external prosthesis to create volitional motor control and sensory feedback. These electrodes can directly communicate with an artificial limb controller using advanced algorithms and neural stimulation paradigms to provide the bidirectional feedback.[11]

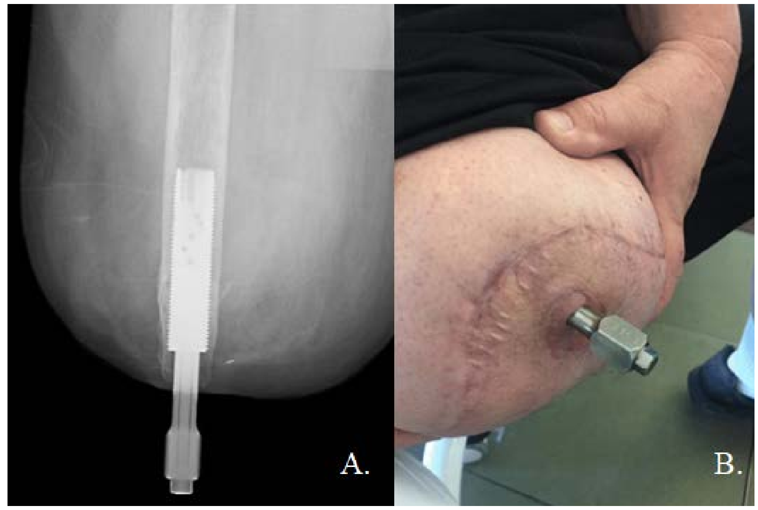

Figure 2. Osseointegration
A. Radiograph of the osseointegrated OPRA implant.
B. Clinical photo demonstrating the abutment coming through the skin for attachment to the prosthesis. (Photos courtesy of Richard J. O'Donnell, MD, University of California San Francisco Department of Orthopaedic Surgery, San Francisco, CA)

While most studies across the various available implants demonstrate improved quality of life with BAP, there remains a high infection rate.[10,12-14] The feasibility of BAPs in growing children is unknown due to the risk of osseous overgrowth and implant infection. However, osseointegration can similarly be used to improve prosthesis use and function in skeletally mature adolescents with limb differences; this population should be considered for future clinical trials with BAP.

Agonist-Antagonist Myoneural Interfaces (AMI)

AMI is a surgical construct to create mechanoreceptor-proprioceptive signal to the central nervous system (CNS). The tendons from antagonizing muscles are sutured together so that contraction of one muscle causes stretch of the other. With AMI activation, a natural proprioceptive response is generated from mechanoreceptors within each muscle which is interpreted by the CNS as sensation of joint position, speed, and torque associated with movements of the phantom limb. Clites and colleagues described the new "Ewing" amputation as the incorporation of AMI into the transtibial residuum of three patients; this technique could improve bidirectional neural control of lower limb bionic prostheses.[15] While this technique is still experimental, it could allow for more complex lower limb motions and a higher activity level for children with lower limb loss.

End Bearing Residuum

The Ertl procedure is the creation of a tibiofibular bone synostosis to create an intentionally weight-bearing residuum at the time of transtibial amputation.[16] Proponents cite lack of "scissoring" of the residual tibia and fibula, plus end weight-bearing as means to increase weight tolerant surfaces within the socket and improve walking ability. To date, data are mixed when the Ertl procedure is compared to the standard Burgess amputation. A prospective randomized trial, the Transtibial Amputation Outcomes Study (TAOS), comparing the Ertl to the standard Burgess technique for individuals 18 and older following trauma has completed data collection with results expected to be published in 2021.[17,18] This study should provide guidance and indications for the Ertl versus Burgess procedures in adult patients.

In the pediatric population, the Ertl procedure has been used by some to aid prosthetic fitting and prevent residual limb boney overgrowth. Data is limited, and results have been mixed.[19,20] Firth and colleagues treated four patients with the Ertl procedure. One of the four cases required revision for stump overgrowth. The authors concluded that the Ertl procedure "may serve as one of the options for treatment of trans-tibial amputations in older children."[19] More research is needed to determine the efficacy of the Ertl procedure in children.

Upper Limb Prosthetics

Modern Pediatric Designs

Upper limb differences require great understanding and experience by the prosthetic team for their treatment. Limitations in both activities of daily living (ADLs), such as dressing and tying shoes, and in physical activities, such as playing sports or music, can leave the child feeling isolated. The design of a prosthesis is often modified to help the child overcome a specific limitation, rather than a general design for all activities. Additionally, cosmesis can be a significant concern for children, especially as they reach adolescence.

Upper limb prostheses were traditionally made with an exoskeletal design, which provided both limb shape and strength. Similar to lower limb prostheses, manufacturers have developed components that allow for endoskeletal designs in upper limb pediatric prostheses. These tend to be lighterweight and adjustable. The use of a foam cover and glove can make the prosthesis more cosmetically appealing to some children. This design may be less durable, so exoskeletal design may still be preferred in younger children.

Socket advances have sought to improve patient comfort while improving control of the terminal device. Rolled

Figure 3. Myoelectric Multi-articulating Hand
Multi-articulating hands allow teens to use many different grips, beyond a traditional three-jaw chuck, which allow greater task variability as seen here.

silicone allows for custom, intimately fitting, flexible inner sockets. These are used with a rigid outer frame to provide control of the terminal device. Other companies have created a "socketless socket," where the traditional socket is replaced by struts and straps to provide an adjustable, open interface for increased comfort; this is limited to use in teens and adults at this time.

Cosmesis plays a considerable role in upper limb prosthetic design. A child who was comfortable with their limb difference in elementary school may find themselves uncomfortable answering questions about their limb when they reach middle or high school. These adolescents and teens may opt for a high definition non-articulating prosthesis that intimately matches their intact arm's skin tone, nail length, etc. These prostheses are more fragile than a typical prosthesis and require greater care but may boost the child's confidence.

Technological Advances

Perhaps the greatest advance in upper limb prosthetics recently is the incorporation of multi-articulating hands that mimic normal hand movement, including multiple grips and gestures (Figure 3). Traditional myoelectric prostheses are limited to a three-jaw chuck grip pattern,

Figure 4. Prosthetic Locking Liner
With the availability of smaller prefabricated liners and lock mechanisms, this is now a suspension option for children's prostheses.

but these new hands provide precision index pinch, lateral pinch, and numerous other patterns in addition to three-jaw chuck.[21] A user can switch between grips in several ways: myoelectric signal, limb movement, selection button on the prosthesis, or a smartphone app.

TMR and RPNI were developed to improve myoelectric prosthetic control in the upper limb. Using numerous electrodes in the socket, both techniques serve to amplify the signals from the muscle to improve prosthetic control. This amplification translates into smoother and more intuitive motion of the prosthetic elbow and hand. These signals are then combined with machine learning algorithms to provide real-time control of an advanced robotic prosthetic hand.[22] While TMR and RPNI have been successfully used for over 100 adults with upper limb amputations, they have not been used for or studied in children or adolescents with proximal upper limb differences.[23] Children and adolescents have increased potential compared to adults for cortical remodeling and adaptation. For these reasons, Zuo and colleagues argue that children and adolescents with bilateral proximal upper limb amputations and select adolescents with unilateral proximal upper limb amputations should be considered for TMR.[24] More research needs to be done on the use of pattern recognition technology for children.

Much media attention has been given to 3D printed prostheses for children. Although these may appear to be a low-cost option for families, they often lack the intimate fit and durability of a traditional prosthesis.[25,26] This may lead to greater rejection and breakage. Under the guidance of a prosthetist, 3D-printed devices may fit a niche where traditional components do not exist for a small child with a limb difference. Provision of 3D printed prostheses without the guidance of a prosthetist is generally not recommended for most patients with upper limb loss. In the future, as this technology evolves, it may become a more viable option.

Lower Limb Prosthetics

Modern Pediatric Designs

Most prosthetic manufacturers and suppliers offer a selection of pediatric-sized endoskeletal pylons, adapters, feet, knees, and liners. These pediatric components are welcomed by prosthetists, who perhaps 20 years ago were limited to only exoskeletal prostheses and Solid Ankle Cushion Heel (SACH) feet for children. Modular components included in a child's endoskeletal prosthesis can be interchanged, re-aligned, and adjusted for growth. However, pediatric modular components also have weight and activity limits that occasionally cause the pairing of an adult-sized foot with a pediatric knee for a child's prosthesis. Use of both pediatric and adult components on a single prosthesis is easily addressed in most situations with pediatric-to-adult modular adapters. The availability of modern modular pediatric components facilitates prosthetic individualization for each child.

Custom or prefabricated gel liners now exist in pediatric sizes for use with small locking pins, shuttle locks, or valves (Figure 4). These have been commonly used for adults for decades, but only recently have been manufactured specifically for pediatric patients. One growth-friendly feature of gel liners is that the initial socket can be fit with a thicker liner and later changed to a thinner one as the child grows. If combined with a flexible thermoplastic inner socket and an outer frame, the socket may fit comfortably for several years. This all depends on how quickly the child is growing.

For partial foot limb differences, and possibly Symes or Boyd levels, an alternative to the soft silicone or foam "toe-filler" is an orthosis-like design with a dynamic carbon posterior strut. Like a floor-reaction ankle-foot orthosis, the residual foot is supported in a padded lower section with an extended carbon foot plate. A posterior composite strut is attached to the upper section, enclosing the proximal tibia. This design extends the toe lever to help "restore" the functional foot length and shift forces away from pressure sensitive areas on the residual limb. The energy storage and return properties of this design may also restore the gait rockers, improve efficiency, stride length, and speed in running. The prosthetist can switch posterior struts to adjust the stiffness and optimize energy return and gait mechanics for individuals. Although research in this area is solely focused on adults, early anecdotal clinical experience indicates that it may be promising for pediatrics.[27]

Technological Advances

Although well-established, the SACH foot is no longer the standard of practice for active children and adolescents. Prosthetic feet for children are now available in flexible fiberglass or carbon fiber energy storage and return (ESAR) feet, thus supporting the highly active lifestyle of most children with lower limb differences. Feet that are multiaxial and dynamic in function are now specifically made for the smaller and lighter child who is also highly active. A child in the early adolescent phase may require an adult-sized prosthetic foot (usually size 22–23cm length) to match the shoe size of their contralateral foot, but their body weight is significantly below the lowest threshold for which the foot is designed. Thus, they may have to go a year or two wearing a foot that is too stiff for them. Gaps exist in the development of prosthetic feet for adolescent children.

A relatively new posterior-mounted carbon fiber blade with a heel module and foot shell enables children with long transtibial or Symes amputations to be fitted with an ESAR foot, whereas they did not have the clearance for traditional ESARs mounted at the distal socket. One version includes a slot in the carbon pylon to allow lengthening as the child grows (Figure 5).[28] Uniquely, this foot also enables the prosthetist to switch out the heel plate for a longer one and to then use a bigger foot

Figure 5. Crossover ESAR Foot
This style of prosthetic foot allows children with longer lower limbs to utilize the spring of the energy-storing foot.

shell to match the child's growing contralateral foot. This design has been termed a "crossover" foot because it is appropriate for daily use at home and school but is also dynamic enough for many sports. This is particularly true for sports like basketball, tennis, or volleyball that require quick pivots, stops, and turns where having a heel is a benefit. Contrast this to a traditional "J-shaped" running blade that does not incorporate a heel component and is often better suited for straightforward running and sprinting. This is just one example of a recent innovation that addresses the unique needs of the highly active and growing child.

Currently, many children use separate daily and activity-specific prostheses. For active adults or teens, there are now several "quick-disconnect" couplers that enable them to quickly switch between a walking and a running foot (Figure 6). Currently, no such lower extremity component is commercially available for children. Now that more pediatric modular components and multiple types of knees and feet exist, a pediatric quick-disconnect adapter may reduce the need for separate prostheses.

For longer amputations such as a Symes or Boyd level in children, there is often limited space for a prosthetic foot to be included without adding a lift to the sound side. Although surgical growth modulation solves this when the child is older, early on, the prosthetist may be challenged to fit a prosthetic foot in the available space. A gap still exists in appropriate, pediatric-sized, low-profile feet, but it has improved. Newer low-profile pediatric feet or foot plates may partially meet this need; however, durability and the cosmetic appearance of these options are still lacking.

Children with amputations or limb differences through or above the knee can now be fitted with a prosthetic knee relatively early, even while still crawling.[29,30] Multiple pediatric-sized knees can be used as soon as the child and family are ready for them, but there is still not an ideally designed infant-sized knee for transitioning from crawling to walking. After moving through the toddler phase, children generally progress to faster walking and running. At this point, a fluid-controlled knee is an ideal component to facilitate variable cadence up to and including running. There are a few pediatric hydraulic or pneumatic knees that also have the enhanced stability provided in a polycentric design. These are generally sized for 7-14 year olds, but there is not a good hydraulic knee for younger, smaller children who nevertheless walk and run. Pediatric knees usually are limited to 100 pounds of body weight. On occasion, these knees will break when used by a highly active child nearing the knee's upper weight limit. At that point, the only option is to switch the child to an adult-sized knee, which may be overly bulky or heavy until the child grows into it. There is a need for lightweight, durable knees for highly active adolescents.

Microprocessor knees are thought to improve stability, safety, and gait quality in adults with transfemoral amputation. These knees can also be used successfully by adolescents, though there are several potential limitations. Many microprocessor knees are not durable and have limited water and dirt tolerance, challenging their use with highly active adolescents. Additionally, these knees are often too large and/or heavy for adolescents and children. A good candidate for microprocessor technology would be an adolescent with bilateral amputations who has potential for unlimited community ambulation (K-level 3). Patients with bilateral amputations may benefit from the enhanced stability and control that microprocessor knees provide on stairs, inclines, and uneven terrain.

Figure 6. Quick Disconnect Adapter
This adapter allows the teen to switch between a daily and sports-specific prosthetic foot at their choosing.

Therapeutic Advances & Gaps

It is not uncommon for individuals to reject an upper limb prosthesis due to operating difficulties and limited tactile feedback. Therefore, the therapist's responsibility is to provide training to optimize the use of the prosthesis. Recent studies and clinical experiences have demonstrated the effectiveness of video games and virtual reality systems in increasing the individual's motivation for prosthetic training as well as increased skill in using the prosthesis (Figure 7).[31,32]

Combining virtual reality platforms with action observation supports improved prosthetic control by the individual.[33] Action observation refers to "the phenomenon in which observing the behavior of another person produces the same neural activity as that performed by oneself".[33] Preliminary work by Yoshimura et al. suggests action observation was improved with virtual reality training, which may improve prosthetic control.

Key areas for improvement in the realm of upper limb prosthetic rehabilitation include greater tools to improve tactile and vibratory input. Increasing a child's ability to determine and modify their grasp using their upper limb prosthesis can improve the child's independence in the home and in educational environments. Tools providing a variety of sensory feedback can assist with advancing the child's ability to discern different grasps with their

Figure 7. Virtual Training
Motivation of children may be increased with the incorporation of video games or virtual reality activities. These activities require the children to shift weight on their leg prostheses or move their arm prostheses to play the games.

prosthesis. This could be integrated into the virtual reality applications for advanced training.

For children with lower limb prostheses, video games can optimize rehabilitation, specifically focusing on balance control. For example, using the Nintendo Wii gaming system (Redmond, WA), an individual stands on a platform to interface with their virtual avatar (Figure 7). In this manner, the gaming system is utilized as a fun, interactive, motivating tool and serves to improve an individual's awareness of weight distribution through the prosthesis. Advances in lower limb prosthetic rehabilitation are needed for progressing children's ability to participate in age-appropriate gross motor skills such as running, climbing, jumping, and skipping.

Conclusion

Over the past decade, major advancements have been made in surgical techniques, prosthetic design, and rehabilitation strategies for adults with amputations. While some recent prosthetic innovations have been extended to pediatric applications, most have not yet reached pediatric patients and their families. Further, many pediatric prosthetic components are simply adaptations of adult versions rather than innovations designed from the start for pediatric patients. Parents and families may see examples of prosthetic components designed for adults and feel that their child is perhaps missing out on impressive technology. Future research and innovation are needed to improve pediatric-specific options and optimize multidisciplinary care for pediatric patients with limb loss or difference.

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