Development of prosthetic knee joint technologies for children and youth with above-knee amputations

De ontwikkeling van knieprothesen voor kinderen en jeugdigen met bovenbeen amputaties

door

Jan Andrysek

Development of prosthetic knee joint technologies for children and youth with above-knee amputations
Thesis, Utrecht University, The Netherlands
ISBN-9789039350423

The studies presented in this thesis were financially supported by grants from Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Heffernan/Co-Steel Innovation Scholarship, Bloorview Childrens Hospital Foundation, and Ontario Rehabilitation Technology Consortium.

Printed by: U of T Press, Canada
Cover design & Lay-out: Vanda Andrysek

Development of prosthetic knee joint technologies for children and youth with above-knee amputations

De ontwikkeling van knieprothesen voor kinderen en jeugdigen met bovenbeen amputaties
(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht
op gezag van de rector magnificus, prof.dr. J.C. Stoof,
ingevolge het besluit van het college voor promoties
in het openbaar te verdedigen op
dinsdag 30 juni 2009 des middags te 11.45 uur

door

Jan Andrysek
geboren op 18 December 1973 te Vitkov, Tsjechie

Promotoren:
Prof. dr. P.J.M Helders, Universiteit Utrecht
Prof. dr. C. Macarthur, University of Toronto

Contents

1 Introduction

Lower-limb prosthetic technologies play a significant role in the rehabilitation of children and youth with limb absence or loss (further referred to as limb loss, limb deficiency or amputation), primarily through the appropriation of functional mobility, which in turn facilitates a more typical biopsychosocial development. Proximal limb deficiencies involving the loss of the knee joint are especially detrimental because replacement of associated functions using artificial means is particularly challenging. In contrast to the technological advancements seen in adult above-knee prosthetics that promote a plurality of gait and mobility improvements, initiatives addressing the prosthetic needs of children have not yielded equivalent progress. This is a likely symptom of the challenging technical and functional requirements, and also perhaps the niche commercial market for this population. Nevertheless, attention to the rehabilitative needs of children represents an important undertaking, and a necessary societal investment for the future.

Children with lower-limb amputation

Children with limb deficiencies comprise about 5% of all lower-limb amputees.[1] They are categorized as either congenital (in utero limb reductions) or acquired (postperinatal amputations); about 70% of children and adolescents will present with congenital deficiencies, the remaining 30% with acquired amputations due to trauma (motor vehicle accidents, burns, lawn-mower accidents) or disease (cancer).[2,3] The etiology of congenital limb deficiencies is not well established, although genetic, environmental, and maternal diseases and complications of pregnancy are defined in the minority of cases.[4-6] Congenital limb defects occur at an approximate rate of 0.3 to 1.0 per 1000 live births of which the prevalence of lower-limb deficiencies is marginally less than upper-limb deficiencies.[4,7-9] Of children with lower-limb deficiencies, over half are at the below-knee level, and close to 40% are at the above-knee level, which can be further subdivided into proximal femoral focal deficiency (PFFD), transfemoral and knee disarticulations.[1,3,10] Apart from ongoing improvements in prenatal screenings to diagnose fetal anomalies, prevention is problematic due to the diversity and limited understanding of etiology.

Dealing with the physical challenges of lower limb loss typically entails two distinct steps, surgery and prosthetic fitting. The two main goals of surgery are to remove the traumatized or diseased portion of a limb and reconstruction to promote healing and create a functional residuum. In the case of congenital limb deficiencies, surgery is required primarily for the latter reason, so as to increase the potential likelihood of a successful prosthetic fitting. The prescription and fitting of prostheses to children takes careful consideration of numerous factors including the cognitive maturity and physical status of the individual. Since the degree of disability increases with more proximal levels of amputation and especially the loss of major joints, individuals with through- and above-knee amputations typically face greater challenges in their rehabilitation. Biomechanical deviations associated with inadequate proximal joint musculature, unstable joints, malrotation, and limb length differences, can further augment the challenges of fitting children who have congenital limb deficiencies.[5]

For children with congenital limb deficiencies, prosthetic fitting can start as early as 9 to 16 months of age, as the child starts to pull him or herself up. The standard approach is that children with acquired amputations should be fitted with a prosthesis as soon as physically possible. Because individual cases may greatly vary, a clinic team should ascertain when the child is physically, intellectually, and emotionally ready for prosthetic and surgical interventions. Generally accepted guidelines outlining specific developmental milestones exist for the prescription and fitting of various prosthetic technologies.[5,10,11] Once initially fitted, children require a new lower-limb prosthesis annually up to the age of 5 years, bi-annually from 5 to 12 years and once every 3 to 4 years thereafter because of wear and tear as well as physical changes related to growth (prosthetic length, socket fit).[12,13] As children develop physically and emotionally, they become candidates for more advanced and efficacious prosthetic components, such as articulating prosthetic knee joints and energy storing foot components, thus further facilitating function and development.[1]

Children with lower limb loss perform very well in physical activities, and prosthetic components play an important role. As a result many advocate the fitting of more advanced prosthetic components at earlier ages. In fact, 95% of children with limb loss are functional walkers (mean walking distance of at least 5km per day) and 93% partake in physical programs at school.[3,10] Another study found that 85% of young amputees became independent walkers without requiring handheld walking aids and 62% actively participated in recreation with peers.[6] The most important outcomes of lower-limb prosthetic rehabilitation relate to mobility and physical activity.[14] Vannah et al[3] reported a survey of 258 children, finding that walking was the first priory for 34% of children with lower-limb amputations, and playing sports for 20%. Comfort, which is primarily associated with socket fit, was a priority for 28% and appearance for only 8%. Once a child realizes that the prosthesis is a means for achieving functional mobility and higher levels of physical activity, there is a high level of acceptance and utilization.[3] This in turn enables the child to achieve high degrees of personal, developmental and recreational autonomy.

Prosthetic technologies

Technological advancements in prosthetic systems continue to play a key role in the rehabilitation of individuals with lower-limb amputations and limb-deficiencies. Once surgical intervention, prosthetic fitting, and physical therapy and training have all been applied, it is primarily the functional symbiosis of the biological (human) and artificial (prostheses) systems that facilitate a successful rehabilitative outcome. Despite their various technical and performance limitations, lower-limb prostheses prescribed for children tend to be highly utilized, with 9 out of 10 children using their limbs for more than 9 hours per day, and an overall rejection or abandonment rate of only 1%.[3,10]

Prostheses for individuals with amputations above the knee are referred to as transfemoral or above-knee prostheses. Knee disarticulation patients (transection between the tibial and femoral condyles) are also missing the functional aspects of the knee, but their prostheses are typically termed knee disarticulation prostheses; the main difference is associated with provisions to manage the long residual limb to ensure that the thigh and shank segments are proportional to the intact limb. As both amputation types require a knee joint as part of their prosthesis, the term above-knee or transfemoral is used here to include knee disarticulations.

A transfemoral prosthesis is comprised of a socket and suspension as a means for interfacing and securing the prosthesis to the residuum, a knee joint, and a foot component, assembled (in the case of typical endoskeletal systems) using pylons and connectors. All of these components contribute toward a comfortable and well-functioning prosthesis. The socket fit and suspension influence comfort, proprioception, load-bearing capability and control of the prosthetic limb.[15] The knee joint facilitates controlled articulation for activities such as sitting, kneeling or the swing-phase of walking, and plays a major role in stability during weight-bearing.[16,17] The foot component can enhance stability, a smooth rollover and progression of the shank, as well as comfort.[18-20] It is the setup, interaction and alignment of all these components that contribute to a successful prosthetic treatment (figure 1.1).

The knee is the largest and one of the most complex joints in the human body and a key facilitator of functional and efficient mobility. Replacing its function using artificial systems is proving very difficult; thus during amputation surgery, whenever possible, effort is taken to preserve the anatomical knee joint.[5,21] When this is not achievable, the patient will ultimately need to rely on an artificial substitute.

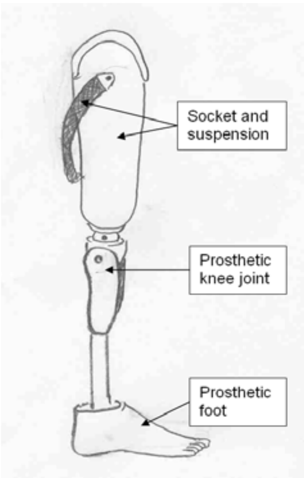


Figure 1.1: Typical composition of an above-knee prosthesis

The knee joint

The primary concern of prosthetic knee joint function is the means for controlling its articulation; in general terms, when load is placed on the prosthetic limb, the knee control should resist flexing during gait (stance-phase control), and the rest of the time it should facilitate smooth flexion and extension at the knee (swing-phase control). As a consequence of certain technical limitations (limited densities of power sources and excessive size and weight of actuators), prosthetic knee joint control is conventionally achieved using passive systems such as dampers, brakes, locks and linkage mechanisms. This approach is highly effective during level and downhill walking, but due to the absence of active torque, it impedes standing up, walking up inclines and stairs, and running.

The basis for enumerating and classifying existing prosthetic knee joint designs includes defining the means of articulation (mono or polycentric) and the types of swing-phase and stance-phase controls that are employed.[17,22] A brief overview is provided below.

Mono versus polycentric:

Akin to a simple hinge, the single-axis knee facilitates monocentric articulation that is centered circa the ‘would be’ anatomical location of the knee. Without provision of supplementary stance control, this type of prosthetic mechanism, through alignment and voluntary control of hip musculature, provides limited stability during stance. A more stable alignment can be achieved by shifting the knee axis posterior of a virtual line extending between the hip and ankle, but this negatively affects the swing-phase foot clearance and the ability to bend the knee during the pre-swing of gait.[23] (figure 1.2).

Although substantially more complex, the polycentric mechanism (usually a four- or six-bar linkage) addresses the abovementioned issues. With a center of rotation that relocates as a function of knee angle, the polycentric knee mechanism enhances stability via a posterior (and proximal) center of rotation when the knee is extended, and a more anterior one as the knee is flexed. Mechanical adjustments of the linkages in these knees allow the stability characteristics to be programmed to correspond with patient needs.[24-28]

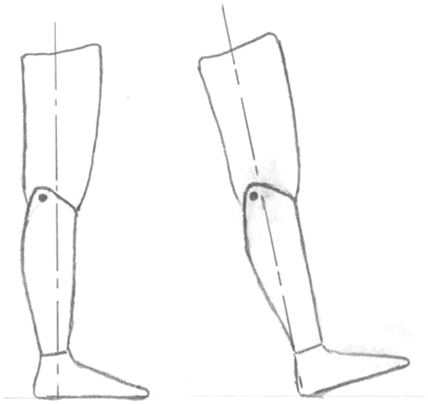


Figure 1.2: left – knee joint axis is aligned just posterior of weight-bearing line (load line vector), causing the knee joint to be stable during standing and mid stance-phase; right – during loading response (initial stance-phase of gait) due to heel-strike loading, the load line vector is located more posterior to the knee joint thus potentially decreasing instability.

Stance-phase control:

Stance stability is delivered by an internal torque that is generated in response to an external flexion moment that would otherwise cause the knee joint to flex. This is conventionally achieved using locks, linkages, friction (brakes), and dampers (hydraulic fluid). Various strategies exist by which the specific stance control mechanism can be activated, usually in response to some feature of the weight-bearing load passing through the prosthesis.

Swing-phase control:

When not under weight bearing, control of knee flexion and extension is of primary importance during the swing-phase of gait. Friction and fluid-based dampers are commonly used to improve temporal and kinematic symmetry and reduce excessive heel-rise during mid-swing and impact at terminal swing, often seen at higher walking speeds. Friction control generally works well for slower walking speeds, while fluid-based systems can accommodate a range of walking speeds. Many modern prosthetic knees for adults use microcontrollers and signals from sensors (load transducers, electrogoniometers) to apply the appropriate damping levels to control stance and swing phases.

Paediatric prosthetic knee systems

From the 1950s onward, prosthetic knee joints for adults significantly improved, primarily because of the application of hydraulic damping and, more recently, microprocessors. The application of these technologies in paediatric prostheses, however, remains impractical because of size and weight constraints and issues relating to usage and durability.[5p790] Existing paediatric knees are of the following varieties:

1) Single-axis: To provide some stability, this type of knee is aligned with a knee axis that is posterior of the thigh-ankle line. An extension assist (a spring biased in extension) helps to keep the knee extended during weight acceptance.

2) Single-axis with manual lock: same as above, but the knee can be locked for extra stability. When locked, gait is with a permanently extended knee joint.

3) Polycentric (four-bar): As described above, this type of mechanism is inherently more stable than single-axis knees.

4) Polycentric (six-bar): This mechanism toggles into a locked state to provide enhanced stability over four-bar knees and stance flexion.

Most commonly, paediatric prosthetic knee joint components employ friction-based swing-phase control.

As children approach adolescence and size and weight constraints are less challenging, more advanced control mechanisms become accessible. But the challenge concerning young children is the provision of compact and lightweight knee mechanisms that provide effective stance- and swing-phase control.[16]

Outcome measures in prosthetics

The successful execution of the development process yielding improvements in the desired aspect(s) of product performance requires an intimate understanding of the design problems that are being addressed, as well as final outcomes desired, which often precipitates further design revisions and improvements. Along the design process continuum (i.e. problem identification and design conceptualization, and prototype evaluation), a multitude of outcome measures have been developed and deployed in prosthetic rehabilitation[29], aiming to provide information, either through indirect measurement of patient performance or patient and/or care-giver reports, on patients' wellbeing and functioning. These outcome measures have been summarized as part of three recent systematic reviews for adults and a number of studies specific to children.

Most recently, in a ten-year literature review of lower-limb prosthetic outcome measures, Condie et al.[29] identified 40 articles of which 28 were included in their analysis. Categorization of the articles revealed three main areas of outcome measurement, including mobility, general function and quality of life. In an earlier ten-year review of lower-limb rehabilitation by Geertzen et al.[30], 24 of 104 searched articles were analyzed and categorized into those relating to 'general aspects of rehabilitation' (N=6), 'functional outcomes' (N=9), 'predictive factors' (N=6), 'phantom pain' (N=2), and 'skin problems' (N=1). Finally, a systematic review examining the effects of prosthetic components on the functioning of lower-limb amputees[31] found 356 articles of which 40 met the authors' outlined inclusion criteria. Of these 27 used gait related outcome measures including spatiotemporal and kinematic parameters, 15 used oxygen uptake, 2 used heart rate, and one the Borg scale to measure aspects of physical exertion.[31] The above reviews cross all ages, but studies focusing on children with limb-loss similarly address the broad spectrum of biomechanical, functional status and health-related quality of life measures.[3,10,18,32-36]

Reliable and validated measures (biomechanical, functional, quality of life) spanning the breadth of human health and wellbeing are an essential part of research and clinical practice. However, at the initial stages of device development and evaluation, biomechanical and in particular functional measures provide the greatest usefulness and applicability, as they more directly map to the physical features of the device, allowing the designer to ascertain the advantages, drawbacks and necessary improvements to the design. As such, gait related biomechanical and physiological measures are pivotal in the early stages of the development and evaluation of prosthetic technologies.

Gait and gait assessments in prosthetics

Level ground walking comprises a significant part of mobility, making its measurement (spatiotemporal, kinematic and kinetic characteristics and efficiency) an important facet of many prosthetic studies.[31] It has been well documented that the gait of individuals with above-knee prostheses is slower, more energy expending, and that it presents various gait deviations and compensations when compared to able-bodied gait.[37-40] In this regard, the development of new prosthetic technologies is typically directed to ameliorate these deficiencies.

The primary participants of empirical studies are adults, likely because most technological advancements are initially developed for this group rather than children. The most notable recent advancement in prosthetic knee joint technologies is the application of microprocessor-based swing- and stance-phase control, which has spurred numerous research initiatives to help establish empirical evidence of the benefits. Findings to date indicate that these new technologies facilitate more normal gait characteristics[41-43], lower energy expenditure[44-49] and cognitive demand during walking[50,51], decreased falls[51,52], and increased physical activity.[49,53] Moreover, crossover studies[54] report increases in gait speeds with higher-end knee components, although these are still well below that of able-bodied individuals. A trend toward increasing gait speeds in above-knee amputee adults is also apparent when examining the 'self-selected' walking speeds reported in published research (figure 1.3), related to technological advancements.

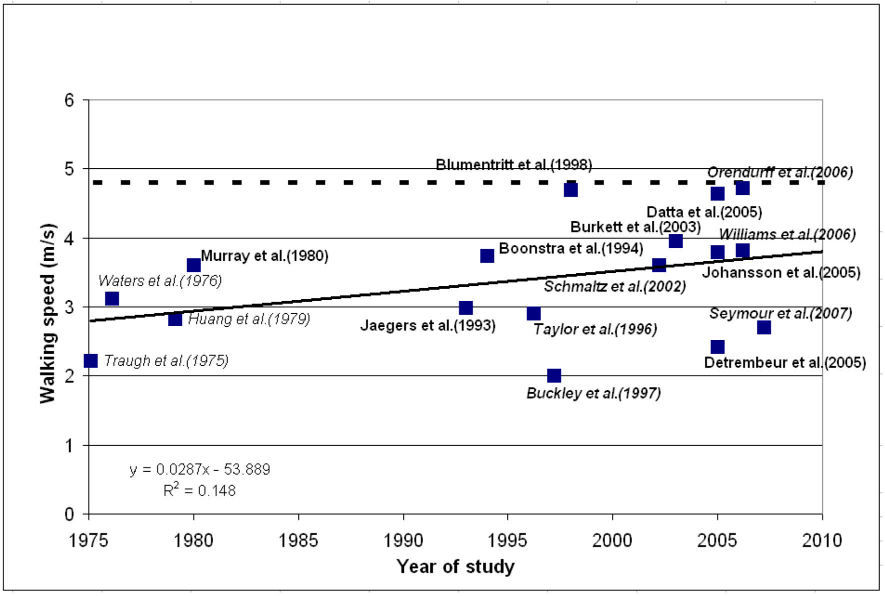


Figure 1.3: Gait studies publishing self-selected walking speeds of active, adult above-knee amputees (vascular amputees excluded).[37,41,43-46,49,50,54-62] Data labels that are **bolded** represent studies where gait velocities were obtained during over-ground gait analysis. Data labels that are *italicized* represent studies where gait velocities were obtained during oxygen uptake measurements. Data labels that are ***italicized and bolded*** represent studies where gait velocities were obtained during oxygen uptake measurements on a treadmill. Varying experimental procedures are likely confounding factors and the resulting variability in self-selected walking speeds across studies. Self-selected walking speed of adult able-bodied individuals is shown by a dashed line.

In comparison, advancements in paediatric prosthetic knee technologies have been relatively minor, as has the undertaking of evaluative studies.[35,63-66] Similar to adults, paediatric above-knee amputee gait is substantially (about 30%) slower than age-matched able-bodied children and despite a number of design improvements since the early 1990s, this has remained relatively constant (table 1.1). One of the main improvements has been the provision of stance-phase control through polycentric knee joints, which makes it possible for young children to be fitted with an articulating knee joint. While stance-phase controlled articulating knee joints have not been shown to increase walking speed in children when compared to a locked knee, major gait and mobility improvements are evident.[35] Providing swing-phase knee flexion not only improves prosthetic knee kinematics but helps to eliminate compensatory gait deviations such as hip abduction and pelvic rotation to provide a more typical gait pattern[1,35,38,67], thus relieving potential long-term complications such as chronic back-pain[67] and joint degeneration.[68,69]

Table 1.1: Gait studies involving children with above-knee amputations.

Study	**Knee types**	**No. and description of subjects**	**Mean age (range or +/-1 S.D.)**	**Walking speed m/s (+/-1 S.D.)**
Hoy et al. (1982) /Zernicke (1985)	Friction knee	5 unilateral	11.3 (+/- 2) years	1.01 (+/- 0.16) m/s
Hoy et al. (1985)	Friction – some 4-bar	5 unilateral	10.5 (7.9-12.8) years	1.05 (+/- (0.09) m/s
Wilk et al. (1999)	4-bar, 6-bar, single-axis	7 unilateral	4.1 (2.4-6.9) years	0.96 m/s
Andrysek et al. (2007)	6-bar, one 4-bar	6 total 3-unilateral 3-bilateral (AK/BK)	10.8 (7-13) years	0.99 (+/- 0.08) m/s

Note: The Hoy and Zernicke studies published on the same data.

In addition to stance-phase control to achieve normalized gait patterns, prosthetic knee joints should also posses other gait-enhancing functional features. For example, during stance-phase (loading response and mid-stance), the knee should be ‘locked’ except to allow 10-15 degrees of controlled knee flexion, referred to as stance-flexion, which has been associated with more natural kinematics, better shock absorption and reduction of rise of center of gravity.[17,70,71] In terminal stance, the stance-phase control mechanism should deactivate to provide minimal resistance to flexion, thus allowing pre-swing-phase flexion to occur.[17,26] During the swing-phase, knee control plays an important role in mid-swing to limit heel-rise, and then again in terminal swing to decelerate the shank for a smooth and safe transition into stance. Poor control of the prosthetic limb during the swing-phase can adversely affect foot-clearance, thus increasing the potential for tripping.[71] (figure 1.4)

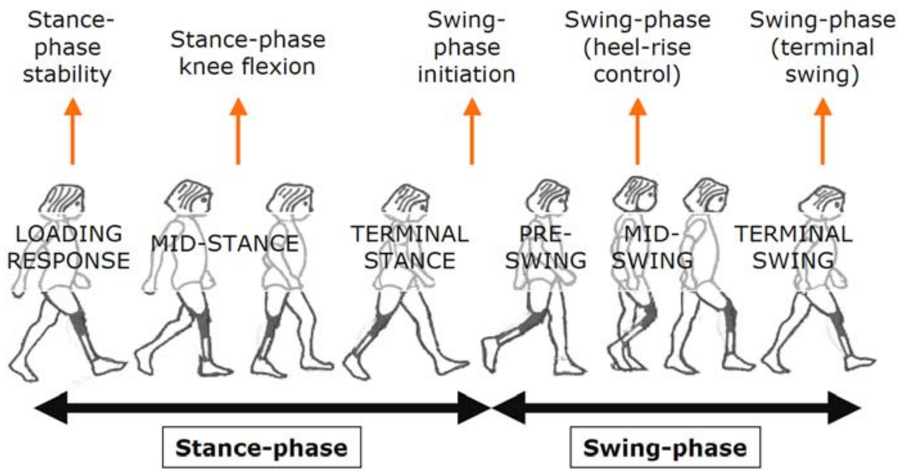


Figure 1.4: Components of the gait cycle.

In summary, due primarily to weight and size constraints, to date no single paediatric knee joint provides all of the above-mentioned functions.[16] Prosthetic knee joints for small children can be especially ineffectual, seldom fulfilling elementary stance- and/or swing-phase requirements. It was the focus of this thesis to research, develop and evaluate new stance- and swing-phase control approaches for use in prostheses for children.

Thesis outline

Mobility and participation in physical activity is of primary importance for children with limb absence or loss. A prosthetic knee joint is an essential facilitator of this, providing controlled articulation to enable sitting, standing, and natural, safe and efficient movements during mobility. Despite recent and notable improvements for adult above-knee amputees, prosthetic knee joints for children and youth provide only very basic functions. For this thesis, structured design processes and empirically-driven biomechanical models were used to aid the design and development of novel knee control systems intended to improve elements of functionality, while quantitative gait analysis and self-report measures were employed to assess functional outcomes.

Chapter two is an examination of the design considerations for selecting the type of prosthetic knee joint mechanism. In this chapter, we explore the important functional requirements of paediatric prosthetic knees and evaluate common and theoretical mechanisms in terms of their function. We establish a basis for configuring a simple single-axis mechanism to provide the advantageous functions of more complex, multi-linkage mechanisms. The important elements of stance-phase control function are established. In chapter three, a novel stance-phase mechanism is presented and evaluated as part of a crossover design field trial utilizing a self-report measure. The results of long-term field-testing are also reported. The focus of chapter four was to establish guidelines for obtaining reliable intra-session measures of impaired gait using quantitative techniques. These findings provided the basis for the quantitative gait assessments performed in chapter five by allowing us to compare the gait performance of the new prosthetic knee design to conventional high-end paediatric knee joint technologies. Chapter six examines the other aspect of prosthetic knee joint control, namely swing-phase control. A unique technical solution is presented that circumvents some of the problems of conventional fluid-based swing-phase controllers. In chapter seven, the performance of a prototype of the new swing-phase control mechanism is evaluated during gait, involving a sample of young individuals with above-knee amputations. The final chapter provides a discussion and summary of this work and its broader implications, including application to other patient populations.

References

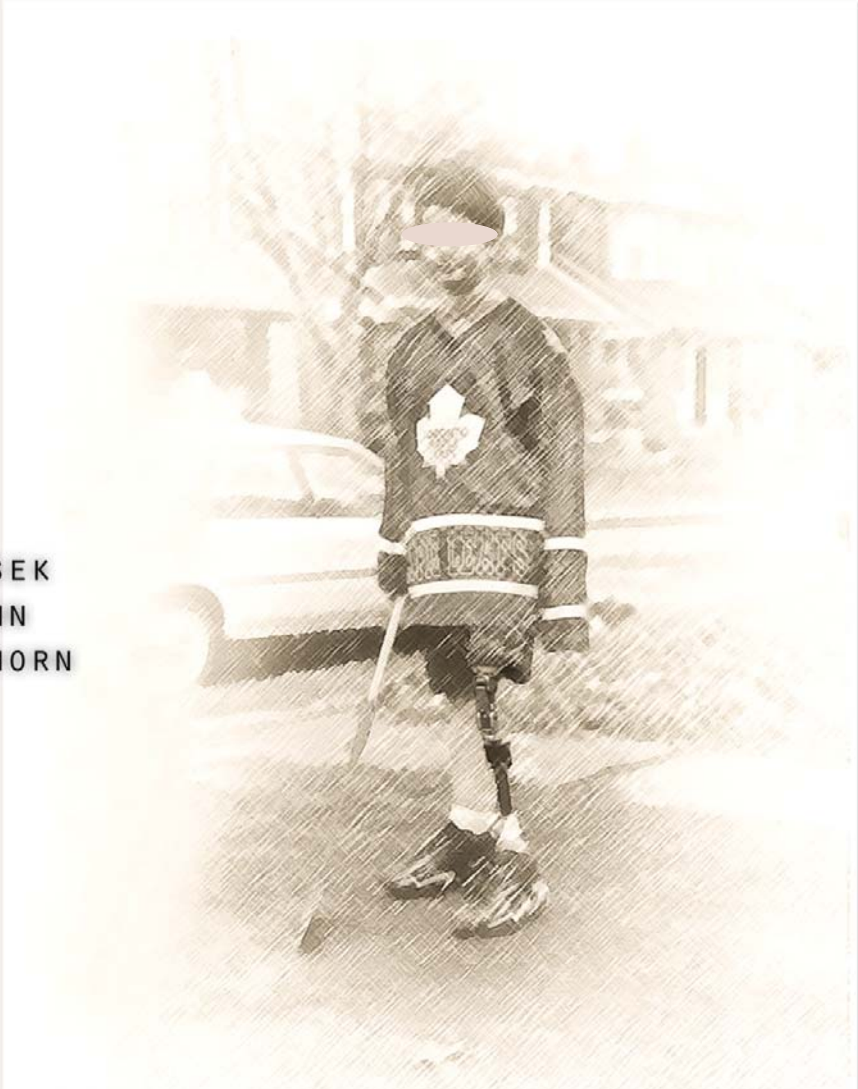
1. Pitkin MR. Effects of design variants in lower-limb prostheses on gait synergy. JPO 1997; 9: 113-22.
2. Krebs DE, Edelstein JE, Thornby MA. Prosthetic management of children with limb deficiencies. Phys Ther 1991; 71: 920-34.
3. Vannah WM, Davids JR, Drvaric DM, Setoguchi Y, Oxley BJ. A survey of function in children with lower limb deficiencies. Prosthet Orthot Int 1999; 23: 239-44.
4. McGuirk CK, Westgate MN, Holmes LB. Limb deficiencies in newborn infants. Pediatrics 2001; 108: E64.
5. Atlas of limb prosthetics: surgical, prosthetic, and rehabilitation principles. 2nd ed. Rosemont, IL: American Academy of Orthopedic Surgeons; 2004.
6. Sener G, Yigiter K, Bayar K, Erbahceci F. Effectiveness of prosthetic rehabilitation of children with limb deficiencies present at birth. Prosthet Orthot Int 1999; 23: 130-4.
7. Dillingham TR, Pezzin LE, Mackenzie EJ. Limb amputation and limb deficiency: epidemiology and recent trends in the United States. South Med J 2002; 95: 875-83.
8. Froster UG, Baird PA. Congenital defects of lower limbs and associated malformations: a population based study. Am J Med Genet 1993; 45: 60-4.
9. Kallen B, Rahmani TM, Winberg J. Infants with congenital limb reduction registered in the Swedish Register of Congenital Malformations. Teratology 1984; 29: 73-85.
10. Boonstra AM, Rijnders LJ, Groothoff JW, Eisma WH. Children with congenital deficiencies or acquired amputations of the lower limbs: functional aspects. Prosthet Orthot Int 2000; 24: 19-27.
11. Jain S. Rehabilitation in limb deficiency. 2. The pediatric amputee. Arch Phys Med Rehabil 1996; 77: S9-13.
12. Nelson VS, Flood KM, Bryant PR, Huang ME, Pasquina PF, Roberts TL. Limb deficiency and prosthetic management. 1. Decision making in prosthetic prescription and management. Arch Phys Med Rehabil 2006; 87: S3-S9.
13. Lambert CN. Amputation surgery in the child. Orthop Clin North Am 1972;3:473-82.
14. Wenz W, Wenz D, Doderlein L. Rehabilitation program for children and adolescents with limb defects or amputations of the lower extremity. Rehabilitation (Stuttg) 1998; 37: 134-9.
15. Kapp SL. Transfemoral socket design and suspension options. Phys Med Rehabil Clin N Am 2000; 11: 569-83.
16. Cummings D. The missing link in pediatric prosthetic knees. Biomechanics 1997; 4: 163-8.
17. Michael JW. Modern prosthetic knee mechanisms. Clin Orthop Relat Res 1999; 361: 39-47.
18. Colborne GR, Naumann S, Longmuir PE, Berbrayer D. Analysis of mechanical and metabolic factors in the gait of congenital below knee amputees. A comparison of the SACH and Seattle feet. Am J Phys Med Rehabil 1992; 71: 272-8.
19. Graham LE, Datta D, Heller B, Howitt J, Pros D. A comparative study of conventional and energy-storing prosthetic feet in high-functioning transfemoral amputees. Arch Phys Med Rehabil 2007; 88: 801-6.
20. Boonstra AM, Fidler V, Spits GM, Tuil P, Hof AL. Comparison of gait using a Multiflex foot versus a Quantum foot in knee disarticulation amputees. Prosthet Orthot Int 1993; 17: 90-4.
21. Krajbich JI. Lower-limb deficiencies and amputations in children. J Am Acad Orthop Surg 1998; 6: 358-67.

22. Balaraman V, Singh YP. Enumeration of human knee prostheses - an overview. Biomed Sci Instrum 1995; 31: 263-8.
23. Seroussi RE, Gitter A, Czerniecki JM, Weaver K. Mechanical work adaptations of above-knee amputee ambulation. Arch Phys Med Rehabil 1996; 77: 1209-14.
24. Breakey JW, Marquette SH. Beyond the four-bar knee. JPO 1998; 10: 77-80.
25. Cappozzo A, Leo T, Cortesi SS. A polycentric knee-ankle mechanism for above-knee prostheses. J Biomech 1980; 13: 231-9.
26. de Vries J. Conventional 4-bar linkage knee mechanisms: a strength-weakness analysis. J Rehabil Res Dev 1995; 32: 36-42.
27. Öberg K. Knee mechanisms for through-knee prostheses. Prosthet Orthot Int 1983; 7: 107-12.
28. Radcliffe CW. Four-bar linkage prosthetic knee mechanisms: kinematics, alignment and prescription criteria. Prosthet Orthot Int 1994; 18: 159-73.
29. Condie ME, Scott H, Treweek S. Lower limb prosthetic outcome measures: a review of the literature 1995 to 2005. JPO 2006; 18(1S): 13-45.
30. Geertzen JH, Martina JD, Rietman HS. Lower limb amputation. Part 2: Rehabilitation - a 10 year literature review. Prosthet Orthot Int 2001; 25: 14-20.
31. van der LH, Hofstad CJ, Geurts AC, Postema K, Geertzen JH, van LJ. A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. J Rehabil Res Dev 2004; 41: 555-70.
32. Pruitt SD, Varni JW, Seid M, Setoguchi Y. Prosthesis satisfaction outcome measurement in pediatric limb deficiency. Arch Phys Med Rehabil 1997; 78: 750-4.
33. Pruitt SD, Seid M, Varni JW, Setoguchi Y. Toddlers with limb deficiency: conceptual basis and initial application of a functional status outcome measure. Arch Phys Med Rehabil 1999; 80: 819-24.
34. Loder RT, Herring JA. Disarticulation of the knee in children. A functional assessment. J Bone Joint Surg Am 1987; 69: 1155-60.
35. Wilk B, Karol, L Halliday S, Cummings D, Haideri N, Stepheson J. Transition to an articulating knee prosthesis in pediatric amputees. JPO 1999;11:69-74.
36. Engsberg JR, Lee AG, Tedford KG, Harder JA. Normative ground reaction force data for able-bodied and below-knee-amputee children during walking. J Pediatr Orthop 1993; 13: 169-73.
37. Waters RL, Mulroy S. The energy expenditure of normal and pathologic gait. Gait Posture 1999;9:207-31.
38. Mensch G, Ellis P. Physical therapy management of lower extremity amputations. Rockville, MD: Aspen Publishers; 1986.
39. Goujon-Pillet H, Sapin E, Fode P, Lavaste F. Three-dimensional motions of trunk and pelvis during transfemoral amputee gait. Arch Phys Med Rehabil 2008;89:87-94.
40. Nolan L, Wit A, Dudzinski K, Lees A, Lake M, Wychowanski M. Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees. Gait Posture 2003; 17: 142-51.
41. Schmalz T, Blumentritt S, Jarasch R. Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. Gait Posture 2002; 16: 255-63.
42. Segal AD, Orendurff MS, Klute GK et al. Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. J Rehabil Res Dev 2006; 43: 857-70.
43. Seymour R, Engbretson B, Kott K et al. Comparison between the C-leg microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic

knees: a preliminary study of energy expenditure, obstacle course performance, and quality of life survey. Prosthet Orthot Int 2007; 31: 51-61.
44. Buckley JG, Spence WD, Solomonidis SE. Energy cost of walking: comparison of "intelligent prosthesis" with conventional mechanism. Arch Phys Med Rehabil 1997; 78: 330-3.
45. Taylor MB, Clark E, Offord EA, Baxter C. A comparison of energy expenditure by a high level trans-femoral amputee using the Intelligent Prosthesis and conventionally damped prosthetic limbs. Prosthet Orthot Int 1996; 20: 116-21.
46. Datta D, Heller B, Howitt J. A comparative evaluation of oxygen consumption and gait pattern in amputees using Intelligent Prostheses and conventionally damped knee swing-phase control. Clin Rehabil 2005; 19: 398-403.
47. Chin T, Sawamura S, Shiba R et al. Effect of an Intelligent Prosthesis (IP) on the walking ability of young transfemoral amputees: comparison of IP users with able-bodied people. Am J Phys Med Rehabil 2003; 82: 447-51.
48. Heller BW, Datta D, Howitt J. A pilot study comparing the cognitive demand of walking for transfemoral amputees using the Intelligent Prosthesis with that using conventionally damped knees. Clin Rehabil 2000; 14: 518-22.
49. Orendurff MS, Segal AD, Klute GK, McDowell ML, Pecoraro JA, Czerniecki JM. Gait efficiency using the C-Leg. J Rehabil Res Dev 2006; 43: 239-46.
50. Williams RM, Turner AP, Orendurff M et al. Does having a computerized prosthetic knee influence cognitive performance during amputee walking? Arch Phys Med Rehabil 2006; 87: 989-94.
51. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. Arch Phys Med Rehabil 2007; 88: 207-17.
52. Kahle JT, Highsmith MJ, Hubbard SL. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. J Rehabil Res Dev 2008; 45: 1-14.
53. Kaufman KR, Levine JA, Brey RH, McCrady SK, Padgett DJ, Joyner MJ. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Arch Phys Med Rehabil 2008; 89: 1380-5.
54. Johansson JL, Sherrill DM, Riley PO, Bonato P, Herr H. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil 2005; 84: 563-75.
55. Traugh GH, Corcoran PJ, Reyes RL. Energy expenditure of ambulation in patients with above-knee amputations. Arch Phys Med Rehabil 1975;56:67-71.
56. Huang CT, Jackson JR, Moore NB et al. Amputation: energy cost of ambulation. Arch Phys Med Rehabil 1979; 60: 18-24.
57. Murray MP, Sepic SB, Gardner GM, Mollinger LA. Gait patterns of above-knee amputees using constant-friction knee components. Bull Prosthet Res 1980; 17: 35-45.
58. Jaegers SM, Vos LD, Rispens P, Hof AL. The relationship between comfortable and most metabolically efficient walking speed in persons with unilateral above-knee amputation. Arch Phys Med Rehabil 1993; 74: 521-5.
59. Boonstra AM, Schrama J, Fidler V, Eisma WH. The gait of unilateral transfemoral amputees. Scand J Rehabil Med 1994; 26: 217-23.
60. Blumentritt S, Scherer HW, Michael JW, Schmalz T. Transfemoral amputees walking on a rotary hydraulic prosthetic knee mechanism: a preliminary report. JPO 1998; 10: 61-70.

61. Burkett B, Smeathers J, Barker T. Walking and running inter-limb asymmetry for Paralympic trans-femoral amputees, a biomechanical analysis. Prosthet Orthot Int 2003; 27: 36-47.
62. Detrembleur C, Vanmarsenille JM, De Cuyper F, Dierick F. Relationship between energy cost, gait speed, vertical displacement of centre of body mass and efficiency of pendulum-like mechanism in unilateral amputee gait. Gait Posture 2005; 21: 333-40.
63. Hicks R, Tashman S, Cary JM, Altman RF, Gage JR. Swing phase control with knee friction in juvenile amputees. J Orthop Res 1985; 3: 198-201.
64. Hoy MG, Whiting WC, Zernicke RF. Stride kinematics and knee joint kinetics of child amputee gait. Arch Phys Med Rehabil 1982; 63: 74-82.
65. Zernicke RF, Hoy MG, Whiting WC. Ground reaction forces and center of pressure patterns in the gait of children with amputation: preliminary report. Arch Phys Med Rehabil 1985; 66: 736-41.
66. Andrysek J, Redekop S, Naumann S. Preliminary evaluation of an automatically stance-phase controlled pediatric prosthetic knee joint using quantitative gait analysis. Arch Phys Med Rehabil 2007; 88: 464-70.
67. Stam HJ, Dommisse AM, Bussmann HJ. Prevalence of low back pain after transfemoral amputation related to physical activity and other prosthesis-related parameters. Disabil Rehabil 2004; 26: 794-7.
68. Royer T, Koenig M. Joint loading and bone mineral density in persons with unilateral, trans-tibial amputation. Clin Biomech (Bristol, Avon) 2005; 20: 1119-25.
69. Royer TD, Wasilewski CA. Hip and knee frontal plane moments in persons with unilateral, trans-tibial amputation. Gait Posture 2006; 23: 303-6.
70. Blumentritt S, Scherer H, Wellershaus U, Michael J. Design principles, biomechanical data and clinical experience with a polycentric knee offering controlled stance phase knee flexion: a preliminary report. JPO 1997; 9: 18-24.
71. Gard, SA. Use of quantitative gait analysis for the evaluation of prosthetic walking performance. JPO 2006;18(1S): 93-104.

2 Design characteristics of paediatric prosthetic knees



J. Andrysek
S. Naumann
W.L. Cleghorn

IEEE Trans Neural Syst Rehabil Eng 2004; 12: 369-78

Abstract

Objective: To determine important knee joint functional requirements (FRs) and examine whether, and in what configuration, a single-axis knee mechanism can satisfy the design parameters (DPs) associated with these important FRs.

Methods: Children and their parents provided subjective opinions of the relative importance of FRs for prosthetic knee joints. Relationships were drawn between these FRs and deductions were made regarding the importance of associated DPs. Passive kinematic models were developed for five knees including four- and six-bar knees corresponding to two commercially available components, and for three configurations of a single-axis knee. Stance-phase control, specifically stability after heel-strike and swing-phase initiation at push-off, and toe-clearance were modeled.

Results: FRs related to comfort, fatigue, stability, and falling were found to be of high importance, while sitting appearance and adequate knee flexion were of low importance. A single-axis knee joint configuration can satisfy highly important DPs including swing-phase initiation and toe-clearance comparably to four- and six-bar knees.

Conclusions: The results suggest that a single-axis knee design incorporating stance-phase control will mutually satisfy the identified set of highly and moderately important FRs.

Introduction

A variety of prosthetic knee joint designs exist, generally classified by the type of articulation they provide and the means of controlling the articulation.[1] Articulation can be single-axis or polycentric. The control of the articulation is differentiated predominantly on the basis of the gait phase (i.e. swing or stance). Stance-phase control, helping to keep the leg from buckling when loaded, can be achieved in several ways including the alignment of prosthetic components, manual locks, weight-activated stance mechanisms, mechanical friction, fluid resistance, and polycentric mechanisms. Many knee joints incorporate a combination of these. Swing-phase control influences toe-clearance and the degree of knee flexion, and can be implemented using mechanical friction, pneumatic or hydraulic mechanisms or a combination of these. In many cases, energy-storing components such as springs are also used to complement swing-phase control.

The simplest prosthetic knee joint design is a single hinge. The stability of the knee, which tends to be most critical just after heel-strike when the load line originates at the rear of the foot, is largely influenced by the anterior/posterior placement of the prosthetic knee axis with reference to the weight-bearing line. Axis placement is in part inherent in the design of the prosthesis and in part modifiable by the prosthetist through prosthetic alignment. Greater stability during early stance-phase is achieved through posterior placement of the knee axis; however, this also results in increased stability at terminal stance-phase, which makes it more difficult to initiate swing-phase.[2] In addition, a more posterior placement of the knee axis decreases toe-clearance during the swing-phase.[3] Axis location also influences maximum knee flexion angle and the sitting appearance via the length of the thigh portion. The relationships of knee axis placement on the aforementioned design parameters (DPs) are summarized in table 2.1.

Table 2.1: Relationships between the DPs and the placement of the knee axis.

DP	Move axis posteriorly	Move axis anteriorly
Stance-phase stability	More stable but more difficult initiation of swing-phase	Less stable but easier initiation of swing-phase
Toe-clearance	Less toe-clearance	More toe-clearance
Maximum knee flexion angle	Increased	Decreased
Thigh portion length	Thigh may appear too long	Thigh less likely to appear long

Polycentric knee joint designs typically have instantaneous centers of rotation at full knee extension that are posteriorly and proximally located in relation to the anatomical knee axis. These designs provide better knee stabilization during heel-strike without adversely affecting swing-phase initiation and toe-clearance. Numerous publications describe the beneficial features of polycentric knees.[4-9] Additionally, polycentric knees generally provide greater maximum knee flexion. They also decrease the thigh portion length of the prosthesis for a more natural sitting appearance for amputees with long residual limbs, including those with knee disarticulations. For the amputee, better knee control and increased toe-clearance may translate into more comfortable and less fatiguing gait and a decrease in the number of falls.[10]

We have identified eleven knees as being suitable for children that are summarized in table 2.2. The 3R38 from (Otto Bock Healthcare GmbH), shown in figure 2.1a, is a small single-axis joint that is prescribed for very small children. For stability, the prosthetic alignment with this knee must be such that the knee axis is placed posterior of the weight bearing line. For the purpose of static alignment, a line joining the ankle and hip joints (also known as the TKA line) when viewed sagittally is used. For additional safety and to help facilitate the child’s transition to an articulating prosthesis, the knee offers an optional manual lock (3R39). The TK-1C1 (Teh Lin Prosthetic & Orthopaedic Co.) is a larger, higher capacity single-axis knee that also offers a manual lock. The remainder of paediatric knee joints is larger and more suitable for older children. The 3R65 (Otto Bock Healthcare GmbH) is a single-axis knee with the only hydraulic swing-phase control for children.

Four-bar linkage knees make up the majority of paediatric knees (figure 2.1c,e-i,k). Through design and different linkage geometries, these knees provide varying levels of stability, which for some units can be further adjusted by the prosthetist to fit the client's need. Certain features, such as foot rotation (3R66) and pneumatic swing-phase control (TK-4P0C - DAW), provide additional benefits to the child amputee. A six-bar linkage knee for children, the Total Knee Junior (Össur hf.), also falls within the category of polycentric knees (figure 2.1d). The additional linkages augment stability during weight-bearing so that the knee locks securely in extension during early stance-phase while at the same time allowing for a slight amount of controlled flexion to absorb some of the impact force and provide a more natural gait.[11-13] Due to these added benefits, this knee joint has gained in popularity with many users in recent years.

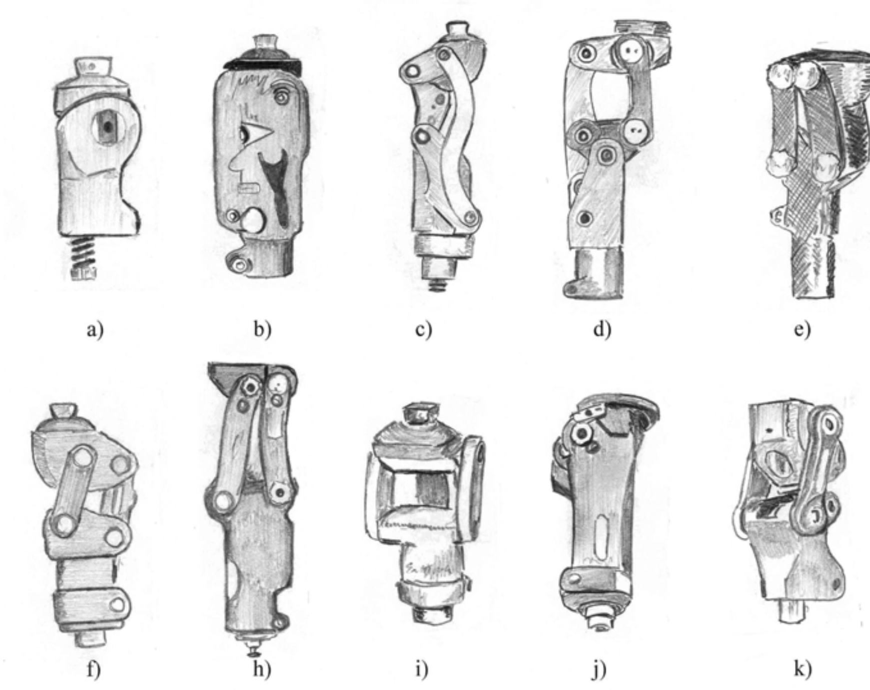


Figure 2.1: Endoskeletal paediatric knees currently on the market: (a) 3R38; (b) 3R65; (c) 3R66; (d) Total Knee Junior; (e) Children's Transfemoral Prosthesis; (f) MightyMite; (h) TK-4P0C; (i) Child's Play knee (SSK610); (j) TK-1C1; (k) 1M12.

Table 2.2: Paediatric knees currently on the market. Data were obtained by various methods including direct measurement, company literature and by contacting company representatives. Lengths are measured from the top of the knee (thigh connector excluded) to the bottom of the pylon connector. N/A ≡ data not available.

Manufacrer	Model	Type	Max. knee flexion (°)	Mass (g)	Length (mm)	Max. User weight (kg)
Otto Bock HealthCare GmbH. Duderstadt, Germany	a) 3R38 b) 3R65 c) 3R66	Single-axis Hydraulic 4-bar & rotator	150 135 165	130 350 255	64 119 120	35 45 35
Össur hf. Reykjavik, Iceland	d) Total Knee Jr	6-bar & stance flexion	145	340	146	45
Chas. A. Blatchford & Sons Ltd, Hampshire, United Kingdom	e) Children's Transfemoral Prosthesis	4-bar	130	333	107	60
Fillauer Inc./ Hosmer Dorrance Corp. Chattanooga, TN, United States	f) MightyMite	4-bar	130	290	108	60
DAW Industries San Diego, CA, United States	g) 4-bar h) TK-4P0C	4-bar friction 4-bar pneumatic	160 160	340 369	N/A 165	54 54
Seattle Systems Inc. Poulsbo, WA, United States	i) Child's Play knee (SSK610)	4-bar knee	140	281	115	36
Teh Lin Prosthetic & Orthopaedic Co., Taipei, Taiwan	j) TK-1C1	Single axis with lock	N/A	311	112	50
Proteor Group Cedex, France	k) 1M12	4-bar friction	135	323	94	55

Functional aspects of prosthetic knees

Stance-phase Knee Control:

Stance-phase control, characterized in general by the provision of a knee "locking" moment during early stance-phase (just after heel-strike), should not impede the initiation of knee flexion during transition into the swing-phase. Whether using polycentric or single-axis knees, knee stability is achieved through a specific placement of the knee axis and the effort to flex the knee prior to toe-off can be characterized by the hip flexion moment that must be generated by the amputee’s hip musculature to make the leg bend. Where stability is achieved through alternative means such as weight-activated locks, the knee cannot be flexed unless most of the prosthesis is unloaded. Since during normal gait the leg does become significantly flexed prior to toe-off, weight-activated locks generally result in abnormal gait.

A load line diagram can be applied to both single-axis and polycentric knees in describing the stability characteristics of a prosthesis.[9] This method results in some inaccuracies, since it neglects the weight and inertial contributions, however, these errors are estimated to be less than 10%.[14] These errors increase with increased walking speed.[15] For the purpose of a relative comparison of different knee joints, however, the static analysis provides a simplified, yet effective means of assessing the stability characteristics post heel-strike and the ease of initiating flexion just prior to toe-off.

Toe-clearance:

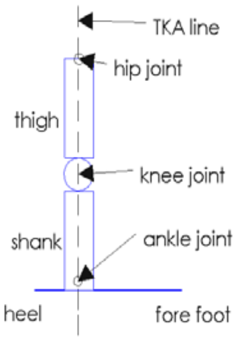
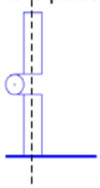
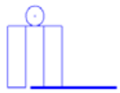
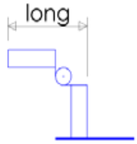
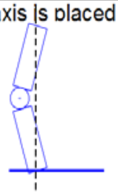
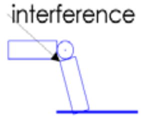
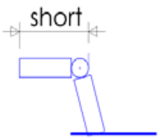
Adequate toe-clearance decreases the likelihood of tripping and/or the need for the amputee to initiate compensatory actions such as vaulting or circumducting during gait.[16] Toe-clearance is in part dependent on the trajectory of the lower-limb during the swing-phase, defined by the knee and hip kinematics in relation to the ground. The trajectory is a function of a series of well-orchestrated alterations of passive and active moments at the knee, provided to a degree by a swing-phase control mechanism, the amputee’s hip musculature, and the inertial properties of the prosthetic limb. A secondary influence on toe-clearance is the shortening/lengthening of the limb as described in table 2.1 for single-axis knees.

Adequate Knee Flexion:

Maximum knee flexion can affect many activities. At least 90º of flexion is needed to sit, although 120º should be considered a necessary minimum. For children, additional maximum knee flexion enhances functionality greatly and allows such activities as playing on the floor. Therefore, a paediatric knee with maximum knee flexion of 150º or more is desirable.

Although maximum knee flexion is highly dependent on the specific knee design, generalizations can be inferred about the influence of axis location on maximum knee flexion. In general, placing the axis posteriorly by a shift (approximately 1cm), as in for example the 3R65 or 3R38 (Otto Bock Healthcare GmbH), helps to increase maximum knee flexion. Posterior alignment of the knee axis via a rotation allows for reduced maximum knee flexion. The effects vary and are summarized in table 2.3.

Table 2.3: Effect of single-axis knee placement in the sagittal plane on sitting appearance and maximum knee flexion. Effect varies depending on whether axis placement is by a shift (translation) or a rotation of the knee joint axis.

	Method of knee axis placement	**Knee flexion**	**Sitting appearance**
	Knee axis is placed posteric 	More maximum knee flexion 	Less natural: 
	Knee axis is placed posteric ROTAT 	Less maximum knee flexion 	More natural 

Sitting Appearance:

Placement of the knee at the anatomical position gives the appearance of symmetry between the intact and prosthetic legs during sitting for unilateral amputees. That is, the thigh and shank portions of the prosthesis are the appropriate lengths when the prosthesis is flexed at 90º. In some cases where the amputee has a long residual limb, this may be more difficult to achieve. In general a posterior placement of the knee axis will increase the length of the thigh portion as seen in table 2.3.

Objectives

The three objectives of this study were to: measure the importance of DPs relating specifically to paediatric polycentric and single-axis knees, evaluate the degree to which each of these knees satisfied relevant DPs, and make suggestions as to the future state and directions of prosthetics developments in paediatric prosthetic knees.

Methodology

The study was composed of two parts. Part one involved determining the set of most important DPs. Potential users were given questionnaires and asked to rate the importance of a set of functional requirements (FRs) relating to prosthetic knee joints. FRs were then related to DPs based on expert input. The second part composed of a quantitative evaluation of the most important DPs using models developed for several knee joint designs including a 4-bar knee (3R66), 6-bar knee (Total Knee Junior), and three versions of a single-axis knee. Values for DPs determined for the 4 and 6-bar knee joints were set as the benchmarks when comparing the results of the single-axis knee joints. DPs for the single-axis knee joints were categorized as either meeting the benchmark (DP satisfied), satisfying the DP but not meeting the benchmark (DP partially satisfied), and not satisfying the DP (DP not satisfied).

PART 1 – Determining importance ratings of DPs

Questionnaires were administered to a total of 5 subjects, 7 to 9 years in age (mean = 8.2 years). Subject information is presented in table 2.4. All had an above-knee amputation and were wearing an above-knee prosthesis on a daily basis. The cause of amputation for all subjects was congenital. Four of the subjects had a proximal femoral focal deficiency (PFFD).

Among children the prevalence of congenital over acquired amputations is about 2 to 1 with the majority of congenital cases being diagnosed as PFFD. [17,18] Three of the five subjects wore a Total Knee Junior (Össur hf.), one wore the 3R66 (Otto Bock Healthcare GmbH), and one had a single-axis exoskeletal unit (manufacturer unknown).

Table 2.4: Subject information.

Subject	**Sex**	**Age (yrs.)**	**Knee type**	**Condition**
1 (S1)	M	9	Total Knee Junior	Congenital – PFFD
2 (S2)	M	8	Total Knee Junior	Congenital – PFFD
3 (S3)	F	8	3R66	Congenital
4 (S4)	F	9	Total Knee Junior	Congenital – PFFD
5 (S5)	M	7	Single axis	Congenital – PFFD

Through consultations with prosthetists, therapists, and engineering staff within the Centre, sets of FRs and DPs were defined. FRs are defined as the user's needs and DPs the means for addressing these needs. FRs consisted of comfort, fatigue, secure/stable feeling, less tripping, adequate knee flexion and sitting appearance. It should be noted that the knee component does not solely influence the comfort and fatigue, but that it does so in association with the remainder of the prosthesis. The knee partially affects comfort in that better stance-phase control, requiring lower moments to be generated at the hip, reduces the magnitude of forces between the socket and stump thus increasing comfort. Lower moments also decrease muscle fatigue.

DPs consisted of stance-phase stability, swing-phase initiation, thigh portion length and maximum knee flexion angle. Both stance-phase stability and swing-phase initiation are quantified as a moment at the hip. Toe-clearance is measured as the lengthening/shortening of the leg as the knee is flexed. For details relating to the set of DPs see table 2.5. Relationships among them were defined as shown in table 2.6 using a matrix format commonly utilized through Quality Function Deployment (QFD).[19-21] A set of questions based on the defined FRs and a questionnaire, suitable for young children, were then developed. A Likert scale with four anchoring responses of not important, important, very important and very, very important, was used to record responses. Scientific and ethical clearance was obtained before commencing with the questionnaires. Responses were then recorded as a percentage of the entire scale with the rating of 'not important' corresponding to 0% and "very, very important" to 100%. Means and standard deviations were calculated for the five subjects.

Results, specifically the importance ratings of DPs, were used to help determine a focus for the modeling of DPs. An emphasis was placed on the modeling of DPs with high relative importance for the purpose of comparing different knee joint designs.

Table 2.5: DPs used for evaluating knee joints and units for measuring them.

DPs	Measurement	Units
Stance-phase stability	Moment at the hip joint required to stabilize the knee after heel-strike	Nm
Swing-phase initiation	Moment at the hip joint required to flex the knee prior to toe-off	Nm
Toe-clearance	Length of prosthesis in varying degrees of knee flexion	cm
Thigh portion length	Distance from center of hip joint to knee cap while sitting	cm
Maximum knee flexion angle	Angle between thigh and shank when knee joint is maximally flexed	ºs

Table 2.6: Relationships between FRs and DPs; '*' related; '**' strongly related.

DPs / FRs	Stance-phase stability	Swing-phase initiation	Toe-clearance	Thigh portion length	Max. knee flexion angle
Comfort	*	*	*		
Fatigue	*	*	*		
Secure Stable Feeling	**				
Less Tripping			*		
Sitting Appearance				**	
Adequate knee flexion					**

PART 2 - Modeling DPs (prosthetic knee models)

Passive kinematic models were developed for five knee types including three single-axis prostheses and two commercially available polycentric knees as described below. The knee models are shown in figure 2.2 and include the thigh, shank, and foot of the prosthesis.

Single-axis:

Neutral alignment (NA) – a hypothetical single-axis setup whereby the greater trochanter, knee axis, and ankle are collinear providing a marginally stable static alignment. In this setup, the knee axis is too far anterior, and without any supplementary locking mechanism, most amputees would find it difficult to keep the prosthesis extended during heel-strike (figure 2.2a).

Stable alignment (SA) – the knee joint is 2cm posterior of the TKA line. In prosthetic practice such an alignment will provide some stance-phase stability during heel-strike loading (figure 2.2b).

Concept alignment (CA) – this setup, as with the neutral alignment setup, is unstable during heel-strike. However, it is proposed here since it offers a means of mutually satisfying the DPs of swing-phase initiation, toe-clearance, maximum knee flexion angle, and thigh portion length (figure 2.2c).

Polycentric:

4-bar knee (3R66) – dimensions taken directly from a prosthetic component and manufacturer's recommended alignment was used (figure 2.2d).

6-bar knee (Total Knee Junior) – dimensions taken directly from a prosthetic component and manufacturer's recommended alignment was used (figure 2.2e).

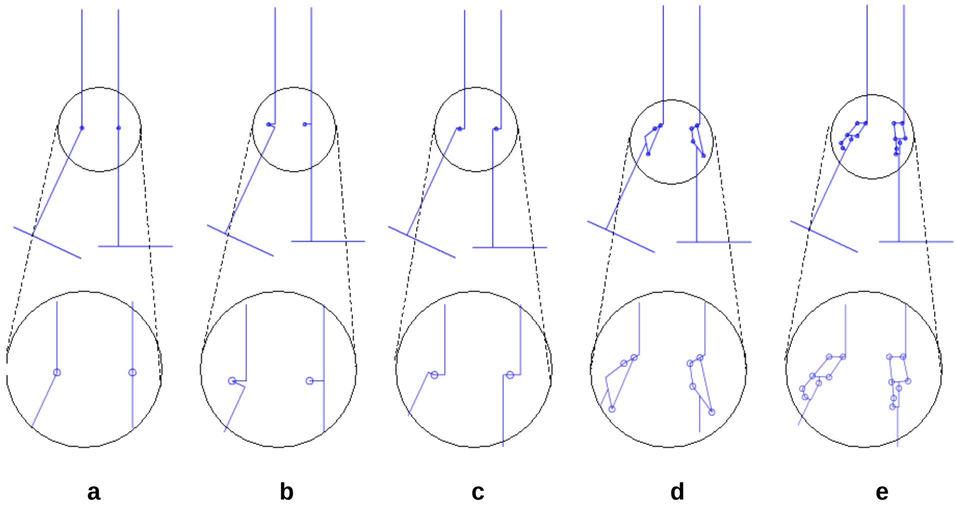


Figure 2.2: Knee joint types analyzed shown in slightly flexed and fully extended positions with enlargement of the knee mechanism shown below. Rotational axes are depicted as circles and lines represent linkages. Thigh, shank and foot portions are shown as lines. (a) Neutral Alignment – NA; (b) Stable Alignment – SA; (c) Concept Alignment – CA; (d) Four-bar knee - 3R66; and (e) Six-bar knee - Total Knee Junior.

PART 2 - Modeling DPs (stance-phase control models)

Stance-phase control is assessed under two extreme conditions. The first corresponds to heel-strike and the acceptance of weight at the initiation of the stance-phase. At this point, the amputee requires the knee to remain extended for support but the knee is typically least stable. The second point occurs near the termination of stance-phase just prior to toe-off and the onset of the swing-phase. The amputee must initiate knee flexion despite the highly stable loading of the prosthesis resulting from the ground reaction forces located at the forefoot. At this point of the gait cycle, the amputee must use the hip flexion musculature around the hip joint of the stump to initiate knee flexion. Load lines are used to represent the equivalent single force vector that results at these two points of the gait cycle. The concept of using “load lines” for analyzing control of prosthetic knees is described in detail by Radcliffe.[9] In figure 2.3, diagrams b) and c) illustrate how knee control is analyzed for single-axis knees and polycentric knee, respectively. Post heel-strike, the load line must pass through or anterior of the knee axis in order for the knee to remain extended. In figure 2.3b), the load line passes through the knee joint axis, representing marginal knee stability, and anterior of the hip joint. The moment at the hip is a product of the perpendicular distance (moment arm) from the load line to the hip joint (D_{heel}), and the magnitude of the ground reaction force at the foot which is approximately equal to the amputee's weight for walking. If we assume that the ground reaction forces during the stance-phase are the same across all types of knees, it is possible to compare hip moments in terms of the moment arms D_{heel} and D_{toe}. In this way a comparison of knee stability after heel-strike and ease of knee flexion initiation prior to toe-off can be made across different knees.

In figure 2.3, the dimensions of the hypothetical prostheses were made to correspond to a 50th percentile 10-year-old child, male or female.[22] For the analysis of stance-phase stability, the location of ground reaction forces acting on the foot were as in figure 2.3b, and are based on published results.[23]

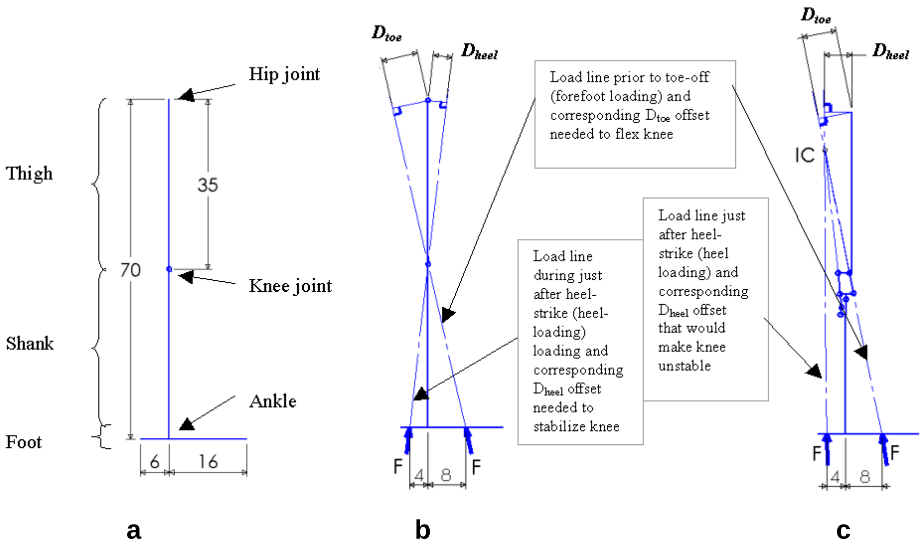


Figure 2.3: Modeled prostheses – dimensions are in centimeters: (a) leg dimensions for models; (b) stance-phase model for a single-axis knee showing load lines resulting from heel loading (during heel-strike) and forefoot loading (prior to toe-off); (c) stance-phase model for a polycentric knee showing load lines resulting from heel loading (during heel-strike) and forefoot loading (prior to toe-off) and passing through the instantaneous center (IC) of rotation.

PART 2 - Modeling DPs (toe and heel-clearances)

Halfway through swing-through to full extension, the toe is nearest to the ground, and just prior to full extension, the heel is in closest proximity to the ground. A flexion angle of 30° from the vertical was set for the hip, which corresponds to the hip kinematics of above-knee amputees for the last 25% of the gait cycle. During this time, as the hip remains at approximately 30°, the knee extends from its maximum flexed position of approximately 60° to full extension.[24-26] For each knee type, the maximum distances between the toe and hip (L_{maxToe}) and heel and hip ($L_{maxHeel}$) were determined, corresponding to the maximum lengthening of the prostheses. The corresponding knee flexion angles, at which the maximal lengthening occurs, were also recorded and shown as α and β in figure 2.4.

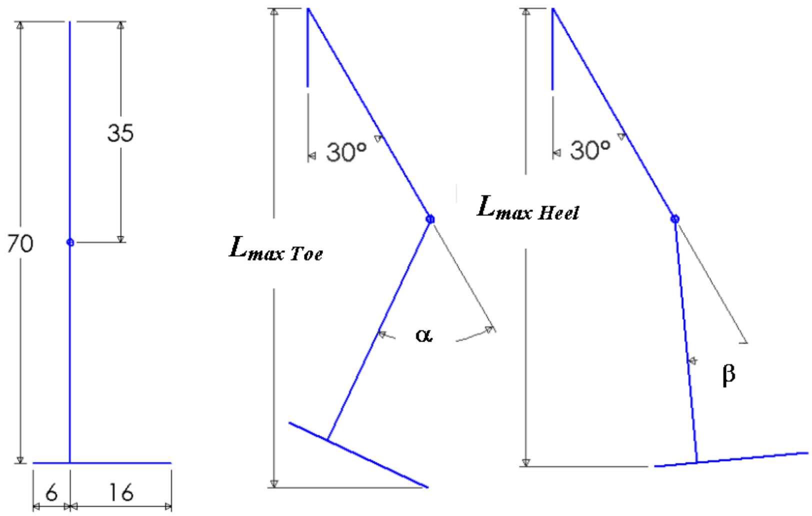


Figure 2.4: Toe and heel-clearance measurements: (a) leg dimensions for model; (b) maximum lengthening at toe (L_{maxToe}) at 30° hip flexion; (c) maximum lengthening at heel ($L_{max\ Heel}$) at 30° hip flexion.

Results

Importance ratings for FRs

FR score means and standard deviations for each subject are presented in table 2.7.

Table 2.7: Importance rating percentages for 5 subjects labeled S1 through S5 (ratings are out of 100).

Functional Requirement	S1	S2	S3	S4	S5	Mean	S.D.
Fatigue	57	99	98	100	87	88	18
Comfort	61	100	91	85	94	86	15
Less Tripping	83	91	85	93	68	84	10
Secure Stable Feeling	86	95	79	66	73	80	12
Adequate Knee Flexion	33	55	37	10	62	39	21
Sitting Appearance	14	36	92	11	17	34	34

Stance-phase control

The moment arms at the hip for the two loading conditions and five knees are presented in table 2.8. Flexion moments are positive, while extension moments are negative.

Table 2.8: D_{toe} and D_{heel} values as defined in figure 2.3 are the moment arms at the hip joint and are representative of the net hip moments.

Knee joint	D_{toe} (cm)	D_{heel} (cm)
Neutral alignment (NA)	7.8	-4.0
Stable alignment (SA)	12.1	0
Concept alignment (CA)	8.3	-3.5
4-bar (3R66)	8.6	5.0
6-bar (Total Knee Junior)	7.4	5.9

Toe and heel-clearance

Table 2.9 and table 2.10 contain the results of the toe- and heel-clearance models.

Table 2.9: Values of maximum lengthening of prostheses as determined by the model; L_{maxToe}, for toe-clearance, $L_{maxHeel}$ for heel-clearance and the difference ($L_{max\ Toe}$ -$L_{max\ Heel}$).

Knee joint	L_{maxToe} (cm)	$L_{maxHeel}$ (cm)	$L_{max\ Toe}$ -$L_{max\ Heel}$ (cm)
Neutral alignment (NA)	68.8	65.8	3.0
Stable alignment (SA)	70.7	66.6	4.1
Concept alignment (CA)	69.1	66.8	2.3
4-bar (3R66)	68.8	66.7	2.1
6-bar (Total Knee Junior)	69.1	66.8	2.3

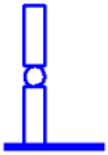
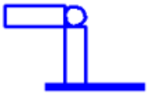
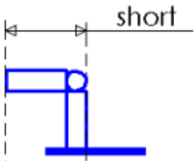
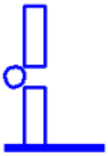
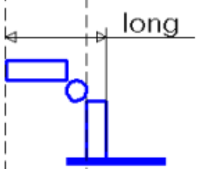
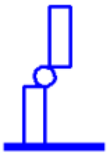
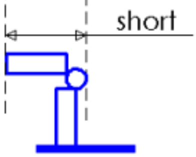
Table 2.10: The knee flexion angles at which the maximum lengthening occurs; α for toe-clearance and β for heel-clearance

Knee joint	α (°)	β(°)
Neutral alignment (NA)	55	20
Stable alignment (SA)	57	23
Concept alignment (CA)	53	19
4-bar (3R66)	54	18
6-bar (Total Knee Junior)	53	18

Thigh portion length and maximum knee flexion angle

No quantitative measurements were made for thigh portion length and maximum knee flexion angle since the values of these parameters are design dependent. The following diagrams provide a qualitative illustration of these (table 2.11). The NA single-axis knee provides good sitting appearance for amputees with long residual limbs by decreasing the length of the thigh portion. It does not however allow for large knee flexion angles since the thigh and shank portions are more likely to interfere. The SA single-axis knee provides increased maximum flexion angles but also increases the length of the thigh portion resulting in a less desirable sitting appearance. The CA single-axis knee provides good sitting appearance by keeping the thigh portion short at 90º of knee flexion and also allows for large maximum knee flexion angles.

Table 2.11: The NA, SA and CA single-axis knee joints illustrating the general characterization of thigh portion length and maximum knee flexion angle.

Knee type	Knee Extended	Knee Flexion	Thigh portion length
NA single-axis knee			
SA single-axis knee			
CA single-axis knee			

Discussion

Information obtained from the questionnaires suggests that FRs associated with comfort, fatigue, stability, and tripping were regarded as highly important, while adequate knee flexion and sitting appearance were of moderate importance. Despite the relatively high standard deviations for adequate knee flexion and sitting appearance, these two FRs are significantly different from the remainder of the FRs. The high standard deviations may be attributed to other factors that influence the child's perception of the level of importance that are not necessarily related to the knee joint. For example, a child with a long residual limb will tend to rate the importance of sitting appearance more highly.

The high importance DPs, based on the relationships defined in table 2.6, include stance-phase stability, swing-phase initiation and toe-clearance. Thigh portion length and maximum knee flexion angle were moderately important. One potential bias in the results may be attributed to the fact that four of the five subjects were diagnosed with PFFD, which can make controlling a prosthesis more difficult, and therefore could reflect a greater need for stance-phase control, as well as toe-clearance. Despite this bias, the values correspond well to the findings obtained for adult amputees.[27]

The DPs, stance-phase stability, swing-phase initiation and toe-clearance, were chosen for further analysis because of their relative high importance. Also, whereas the analyses of thigh portion lengths and maximum knee flexion angles are dependent on the specific design of the knee, the analysis of these high importance DPs is not.

Heel-strike stability is measured in terms of the hip flexion moment required to make the leg stable or unstable. The moments are specified in relative terms as D_{heel}. The actual moment can be derived by multiplying the D_{heel} value by the magnitude of the ground reaction force during early stance. From table 2.8, the D_{heel} values are 5.9cm and 5.0cm for the Total Knee Junior and 3R66 knee, respectively. A single-axis knee, with a posterior placement of the knee axis, provides marginal stability (D_{heel} = 0cm). In this case, the amputee will most likely use his/her hip muscles to ensure that the leg remains extended. Alignment of single-axis knees, possessing the neutral (NA) and concept (CA) alignments are inherently unstable, and generally would not be prescribed without some additional form of stance-phase control.

The ease for the user to initiate flexion at toe-off is specified as D_{toe}. From table 2.8, with the exception of the SA single-axis knee, all other knees require approximately the same hip flexion moments, with D_{toe} values ranging from 7.4cm for the Total Knee Junior to 8.6cm for the 3R66. The SA single-axis knee requires about 1.5 times more hip muscle force, with a

D_{toe} of 12.1cm. Smaller values of D_{toe} translate into lower hip muscle forces for initiating flexion just prior to toe-off.

From table 2.9, L_{maxToe} values (the maximum vertical lengthening of the prosthesis measured to the toe) for NA, CA, 3R66 and Total Knee Junior are comparable and within 3 mm of each other. In addition, the knee flexion angles at this maximum vertical lengthening are nearly equal across the knees. However, a lengthening of nearly 20mm occurs with the SA single-axis knee. This is likely to have an adverse effect on gait comfort and efficiency, and increase the probability of tripping and/or requiring compensating gait deviations. $L_{maxHeel}$, the maximum vertical lengthening of the prosthesis measured to the heel, is nearly equivalent for all knees, with the exception of the NA single-axis knee, which shortens by approximately 10mm over the other four knees. Although the L_{maxToe} value on average (across all the knees) is over 27mm longer than $L_{maxHeel,}$, it is important to consider both of these points of the gait cycle when analyzing foot-clearance because of the additional effect of the fall and rise of the center-of-mass during the gait cycle, and, more precisely, that of the hip or greater trochanter on the amputated side. $L_{maxHeel}$ and L_{maxToe} occur at about 80 and 95 percent of the gait cycle, respectively, during which time the hip goes through a vertical displacement downward of between 20 to 30mm during normal walking.[11] As such, inadequate clearance of the heel can cause the heel of the foot to strike the ground before the leg has fully extended, which will prevent the action of stance-phase control, resulting in buckling of the prosthetic leg.

Summarizing the above results, DPs of high importance, including swing-phase initiation and toe-clearance, are satisfied near equally by NA, CA, 3R66 and the Total Knee Junior, although only 3R66 and the Total Knee Junior satisfy the DP relating to stance-phase stability. Any design of NA or CA will require an additional means of satisfying this DP. The SA single-axis knee is a compromise among all the DPs, providing marginal stance-phase stability at the expense of more difficult swing-phase initiation and decreased toe-clearance. NA and CA both have potential for good sitting appearance, however of these, CA is likely to allow for greater maximum knee flexion.

Table 2.12 is a qualitative summary of the above results. With the four- and six-bar knee as the benchmark technologies for providing satisfactory knee joint function, the single-axis designs (NA, SA and CA) all fall short of fully satisfying all of the DPs. The SA single-axis knee only partially satisfies four of the five DPs and therefore is prescribed mainly to small children where there are size and weight constraints. The CA single-axis knee *with stance-phase control* is shown in table 2.12, and is being proposed subsequent to this investigation as a light and less complex knee joint to four- and six-bar knees, to best satisfy the proposed FRs.

Conclusions

Research into prosthetic devices is ongoing, driven by the need for devices that are increasingly more functional. Until recently, the supply of prosthetic components for the paediatric population was limited to simple single-axis knees with limited performance. The introduction of paediatric polycentric knees by several manufacturers has provided children with above-knee amputations with better control during stance without compromising important functional requirements relating to swing-phase toe-clearance, adequate knee flexion and sitting appearance. An alternative approach for achieving the mutual satisfaction of highly and moderately important FRs for a single-axis knee design has been demonstrated. The proposed single-axis configuration, incorporating stance-phase control could ultimately result in a highly functional, yet less complex, prosthetic knee joint.

Table 2.12: Values for DPs determined for the four- and six-bar knee joints are used as benchmarks when comparing the results of the single-axis knee joints. DPs for the single-axis knee joints were categorized as meeting the set benchmark (DP fully satisfied) ‘+’, not meeting the benchmark but still satisfying the DP (DP partially satisfied) ‘0’, and not satisfying the DP (DP not satisfied) ‘-‘.

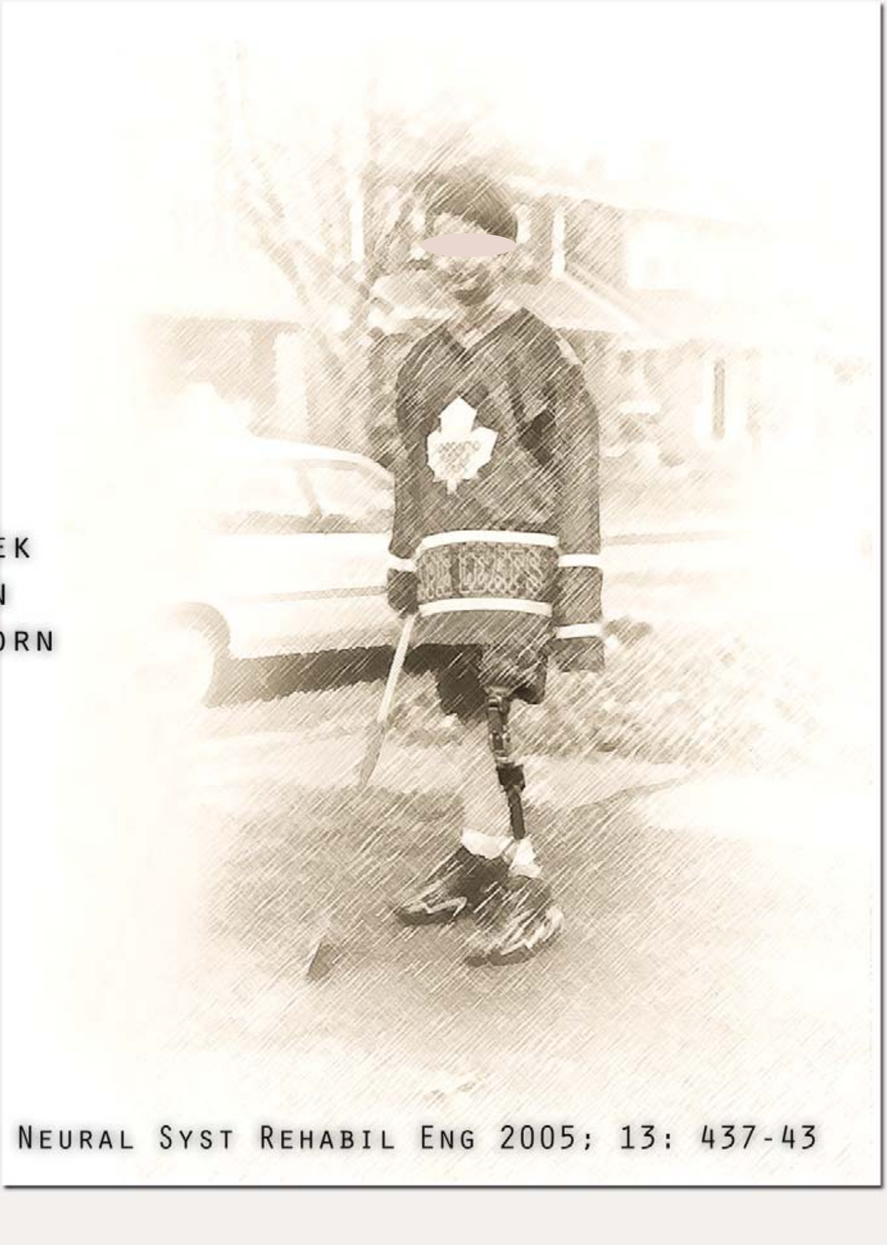
Knee joint	Stance-phase stability	Swing-phase initiation	Toe-clearance	Thigh portion length	Maximum knee flexion angle
Neutral alignment (NA)	-	+	+	+	-
Stable alignment (SA)	0	0	0	0	+
Concept alignment (CA)	-	+	+	+	+
CA with stance control	+	+	+	+	+
4-bar (3R66)	+	+	+	+	+
6-bar (Total Knee Jr)	+	+	+	+	+

References

1. Balaraman V, Singh YP. Enumeration of human knee prostheses - an overview. Biomed Sci Instrum 1995; 31: 263-8.
2. Yang L, Solomonidis SE, Spence WD, Paul JP. The influence of limb alignment on the gait of above-knee amputees. J Biomech 1991; 24: 981-97.
3. van de Veen, P. G. An investigation of design criteria of modular endoskeletal lower limb prosthetics [dissertation]. Twente, the Netherlands: University of Twente; 1989.
4. Breakey JW, Marquette SH. Beyond the four-bar knee. JPO 1998; 10: 77-80.
5. Cappozzo A, Leo T, Cortesi SS. A polycentric knee-ankle mechanism for above-knee prostheses. J Biomech 1980;13:231-9.
6. Greene MP. Four bar linkage knee analysis. Orth and Prosth 1983; 37: 15-24.
7. de Vries J. Conventional 4-bar linkage knee mechanisms: a strength-weakness analysis. J Rehabil Res Dev 1995; 32: 36-42.
8. Öberg K. Knee mechanisms for through-knee prostheses. Prosthet Orthot Int 1983; 7: 107-12.
9. Radcliffe CW. Four-bar linkage prosthetic knee mechanisms: kinematics, alignment and prescription criteria. Prosthet Orthot Int 1994; 18: 159-73.
10. Seroussi RE, Gitter A, Czerniecki JM, Weaver K. Mechanical work adaptations of above-knee amputee ambulation. Arch Phys Med Rehabil 1996; 77: 1209-14.
11. Gard SA, Childress DS. The influence of stance-phase knee flexion on the vertical displacement of the trunk during normal walking. Arch Phys Med Rehabil 1999;80:26-32.
12. Inman VT, Ralston HJ, Todd F. Human Walking. Baltimore, MD: Williams and Wilkins; 1981.
13. Lafortune MA, Hennig EM, Lake MJ. Dominant role of interface over knee angle for cushioning impact loading and regulating initial leg stiffness. J Biomech 1996; 29: 1523-9.
14. Cappozzo A, Figura F, Leo T, and Merchetti M. Biomechanical evaluation of above-knee prostheses. Biomechanics V-A, Baltimore, MD; University Park Press; 1976: 366-372.
15. Wells RP. The projection of the ground reaction force as a predictor of internal joint moments. Bull Prosthet Res 1981; 10-35: 15-9.
16. Mensch G, Ellis P. Physical therapy management of lower extremity amputations. Rockville, MD: Aspen Publishers; 1986.
17. Boonstra AM, Rijnders LJ, Groothoff JW, Eisma WH. Children with congenital deficiencies or acquired amputations of the lower limbs: functional aspects. Prosthet Orthot Int 2000; 24: 19-27.
18. Krebs DE, Fishman S. Characteristics of the child amputee population. J Pediatr Orthop 1984; 4: 89-95.
19. Bossert JL. Quality Function Deployment. Milwaukee, WI: ASQC; 1991.
20. Jacques GE, Ryan S, Naumann S, Milner M, Cleghorn WL. Application of quality function deployment in rehabilitation engineering. IEEE Trans Rehabil Eng 1994; 2: 158-64.
21. Revelle JB, Moran JW, Cox CA. The QFD handbook. New York, NY: John Willey & Sons; 1998.
22. Anthropometry of infants, children and youth to age 18 for product design safety. National Institute of Standards and Technology; 1977 [Online] http://ovrt.nist.gov/projects/anthrokids.

23. Zernicke RF, Hoy MG, Whiting WC. Ground reaction forces and center of pressure patterns in the gait of children with amputation: preliminary report. Arch Phys Med Rehabil 1985; 66: 736-41.
24. Jaegers SM, Arendzen JH, de Jongh HJ. Prosthetic gait of unilateral transfemoral amputees: a kinematic study. Arch Phys Med Rehabil 1995; 76: 736-43.
25. Laassel EM, Loslever P, Angue JC. Patterns of relations between lower limb angle excursions during normal gait. J Biomed Eng 1992; 14: 313-20.
26. Ounpuu S, Gage JR, Davis RB. Three-dimensional lower extremity joint kinetics in normal pediatric gait. J Pediatr Orthop 1991; 11: 341-9.
27. Postema K, Hermens HJ, de Vries J, Koopman HF, Eisma WH. Energy storage and release of prosthetic feet. Part 1: Biomechanical analysis related to user benefits. Prosthet Orthot Int 1997; 21: 17-27.

3 Design and quantitative evaluation of a stance-phase controlled prosthetic knee joint for children



J. Andrysek
S. Naumann
W.L. Cleghorn

IEEE Trans Neural Syst Rehabil Eng 2005; 13: 437-43

Abstract

Objectives: The aims of this study were to demonstrate a theoretical basis for the design of a stance-phase controlled paediatric prosthetic knee joint, clinically test prototypes of the knee, and use a questionnaire to evaluate its performance.

Methods: Biomechanical models were used to analyze the stance-phase control characteristics of the proposed knee, and those of three other commonly prescribed paediatric knee joint mechanisms, which were also the conventional knee joints used by the six participants of this study (mean age 10.8 years). A questionnaire pertaining to stance-phase control was designed and administered twice to each child; once for the evaluation of the prototype knee joint and once for the conventional knee joint.

Results: Stance-phase modeling results indicated decreased zones of instability for the new knee as compared to other paediatric knee joints. Questionnaire results revealed a decrease in the frequency of falls with the prototype compared to other knees, especially in highly active children. The children also reported worrying less about the knee collapsing during walking. No differences were evident for stance-phase stability during running, walking on uneven terrain, ambulating up and down stairs and inclines, fatigue and types of activities performed.

Conclusions: A new knee joint has been developed and demonstrated to improve stance-phase stability for the children in this study.

Introduction

Most commercially available prosthetic knee joint components for children with above-knee (AK) and through-knee (TK) amputations utilize four- and six-bar linkages. These knees allow for better stance-phase control than simple single-axis knees, specifically by decreasing knee flexion tendency during heel-strike and mid-stance while allowing free flexion at toe-off.[1-3]

The importance of stance-phase stability is highly rated by amputees.[1,4] But despite the advancements in knee joint stance-phase control, children with AK and TK amputations do occasionally fall. The cause of falls can be attributed to one of two situations. The first is a knee that does not fully extend prior to weight bearing, such as in the case that the child stubs his/her toe or trips, or if the knee extension resistance is set too high. This situation may also occur from inadequate extension assist, whereby the knee extends, but then rebounds into a flexed position prior to weight acceptance. The second situation is a knee that is fully extended during weight acceptance, but does not remain extended, and therefore becomes unstable. A new knee joint design is presented here and hypothesized to provide better stability by 1) ensuring that once the knee is fully extended during swing it remains so until weight acceptance and 2) decreasing the extent of conditions that can make the knee unstable during weight bearing.

The knee is based on a new type of stance-phase mechanism described in the subsequent sections (figure 3.1). The knee is under 12 cm in length, weighs 320g, flexes to 160°, and has a weight-bearing capacity of 60kg. The knee design was based on the identification and modeling of important design parameters including stance-phase control, foot-clearance, maximum knee flexion, and thigh length for sitting appearance. A single-axis configuration was established to concurrently satisfy the aforementioned design parameters to benchmark levels set by four- and six-bar linkage knees.[1] As an extension of this previous work, this study focused on the analysis and evaluation of the new stance-phase control mechanism. The aims of this work were to demonstrate a theoretical basis for the design of a stance-phase controlled prosthetic knee joint, clinically test prototypes of the knee, and use a questionnaire to evaluate its effectiveness.

Figure 3.1: Prototype knee joint.

Background

Stance-phase controller

The basis for the prototype knee is a latch that engages/disengages to lock/unlock the knee depending on the moment created at a control axis (figure 3.2). During gait, the knee becomes locked at the end of the swing-phase when the knee fully extends. Locking or latch engagement is facilitated by a lock (latch) spring. The latch remains engaged as the prosthesis accepts weight and is secured in position as a result of prosthetic loading that creates a flexion moment at the control axis. This occurs at heel loading of the foot. As the weight transfers over to the forefoot, the latch disengages allowing the knee to freely flex by the application of a small, naturally occurring hip flexion moment.

Augmented stance-phase control is preferred for children with very short residual limbs, or with congenital amputations and unstable hip joints. However, it can also benefit highly active children that are inclined to ambulate over inconsistent and uneven terrain.

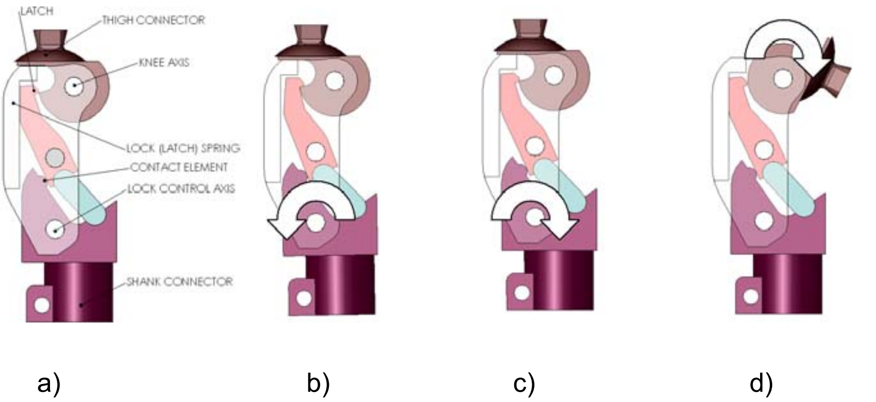


Figure 3.2: (a) Prototype knee; (b) lock engaged as a result of lock (latch) spring and/or flexion moment created at the control axis; (c) lock disengaged due to extension moment generated at the control axis; (d) knee joint shown flexed due to a flexion moment at the main knee axis.

Methodology

Knee instability diagrams

The knee instability diagrams provide an effective means for assessing and illustrating knee joint stance-phase characteristics. Similar approaches have been used with single-axis and four-bar knees.[5,6] A variation of these techniques applicable to more complex dual axes systems such as a six-bar knee is described here. It was used to analyze the stability characteristics of several different commercially available paediatric prosthetic knees.

Stability is a function of the line of action of loads placed on the prosthesis, referred to as the load line vector. For the knees analyzed here, stability is dependent on the orientation of the load line vector with respect to certain knee joint axes here forth referred to as the 'stability-affecting axis'.

For the knees with two stability-affecting axes, including the prototype knee and the six-bar knee, the analysis is performed by determining the zones taken up by the following:

1) All the load line vectors originating at the toe, creating a flexion moment at the main knee axis and an extension moment at the control axis (figure 3.3a).

2) All the load line vectors passing through the main knee axis, not exceeding the toe-load boundary on the plantar foot and creating an extension moment at the control axis (figure 3.3b).

3) All the load line vectors passing through the control axis, not exceeding the toe-load boundary on the plantar foot and creating a flexion moment at the main knee axis (figure 3.3c).

The union of any two of the three determined zones of instability provides the overall zone of instability (figure 3.3d). It is of interest to note that because the knees are always stable under rear-foot loading, the heel-load boundary is excluded from the analysis.

For knees with only one stability-affecting axis, including single-axis and four-bar linkage knees, the analysis is performed by determining the zones taken up by the following:

1) Load line vectors originating at the toe and creating a flexion moment at the main knee axis.

2) Load line vectors originating at the heel and creating a flexion moment at the main knee axis.

3) Load line vectors passing through the main knee axis and in between the toe and heel-load boundaries .

Again, the overall zone of instability is the union of any two of the three determined zones of instability.

The overall zone of instability diagram depicts the stability characteristics of a specific knee joint prosthesis. Load lines originating from the foot that pass exclusively through the zone of instability represent a loading of the prosthesis that will cause knee instability. Load lines passing outside of the zone of instability to any extent represent a stable situation.

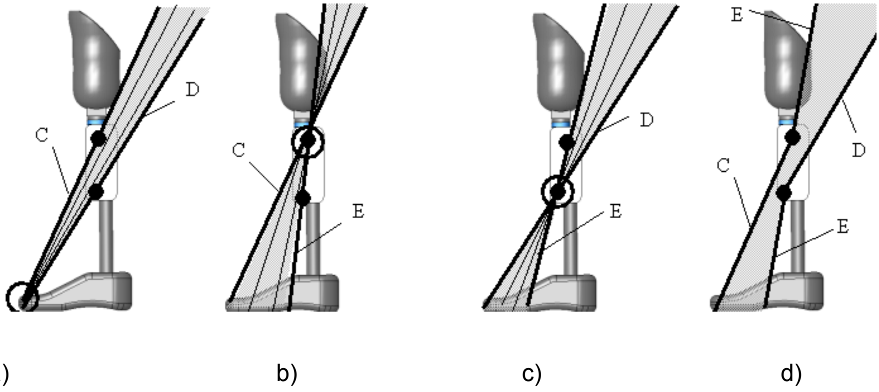


Figure 3.3: Knee stability analysis for a knee joint with two stability-affecting axes. Boundary load line vector represented as thick line and other instability creating load line vectors as thinner lines. The shaded area represents all the possible instability causing load line vectors: (a) vectors originating from toe-load boundary (labeled 'C & D'); (b) about main knee axis (labeled 'C & E'); c) about the control axis (labeled 'D & E') and (d) the overall zone of instability.

Paediatric knees studied

Four knee types including the prototype knee were modeled using the zones of instability method (see table 3.1). Approximations of knee-axis locations were based on measurements taken from actual components. Passive kinematic models were developed and implemented in SolidWorks CAD software. In the case of the 4-and 6-bar knees, relevant secondary instantaneous centers of rotation were determined using the Kennedy–Aronhold theorem.[7]

Subjects

Six children with AK amputations were recruited for this study from three prosthetic clinics. The children met the following inclusion criteria: 1) they were between 7 and 13 years old at the time of initial data collection, 2) amputations were performed at least two years ago, and 3) the prosthetic components had optimal fit as determined by the child's prosthetist.

Subject characteristics are summarized in table 3.2. Ethical clearance was received from the Institution's Research Ethics committee.

Table 3.1: Paediatric knee components used in zones of instability analysis.

Knee Type	Specific component modeled (if applicable)
Single-axis	generic
4-bar	3R66 Otto Bock HealthCare GmbH. Max-Näder-Straße, 15D-37115 Duderstadt, Germany
6-bar	Total knee Junior (Össur hf. Grjothals 5, 110 Reykjavik, Iceland).
Prototype	New design

Since children were already familiarized with their conventional knee joints and because of the considerable functional differences among the knees, no attempts were made to blind the children or prosthetists. Also, two of the six children preferred not to use cosmetic covers making concealment of the knee joints difficult.

Table 3.2: Subject characteristics

	Description	Amputation cause	Extent of amputation	Stump length	Conventional knee
S1	Male – 12 years old	Congenital	Unilateral	>50% SLTL	Total knee Junior (Össur)
S2	Female – 11 years old	Congenital	Unilateral	>50% SLTL	Total knee Junior (Össur)
S3	Male – 12 years old	Acquired	Unilateral	<50% SLTL	Total knee Junior (Össur)
S4	Female – 7 years old	Congenital	Bi-lateral (AK/BK)	>50% SLTL	3R66 (Otto Bock)
S5	Female – 10 years old	Acquired	Bi-lateral (AK/BK)	>50% SLTL	Total knee Junior (Össur)

SLTL – Sound Limb Thigh Length

Prostheses

Prototype knee joints were fabricated in-house and one prototype was mechanically tested for structural integrity using the ISO 10328 standard (structural testing of lower-limb prostheses) as a guide. Accelerated cyclic testing was used to evaluate stance-phase mechanism reliability. For two of the children, entirely new prostheses were fabricated for the prototype knees, matching the components (socket, pylons, feet, etc.) and alignment of their conventional prostheses. These were the first two children to be field-testing the prototype knees, so they continued to have access to their conventional prostheses as backups. For the remaining four participants, knees were exchanged in the existing prostheses.

Questionnaire

Questionnaires evaluating lower-limb prosthetic function have been used extensively in the past for adult populations[4,8-11] and paediatric populations.[2,12] These questionnaires address numerous factors such as appearance, fatigue, stability, fit, discomfort and pain, types of activities, and physical environments, but not stance-phase control specifically.

A questionnaire to evaluate the effectiveness of the stance-phase control mechanism was developed with the aid of professionals, including therapists, prosthetists and engineers, working in this field. The questionnaire consisted of 15 questions that were grouped into five categories labeled “general”, “walk,” “run,” “uneven ground,” and “inclines and stairs.” All questions, with the exception of question 3, were close-ended. The majority of questions were answered using a five-point Likert scale. Other questions were answered with a yes/no or by selecting an appropriate response from a supplied list. The questions are presented in table 3.3. The Wilcoxon Signed Ranks Test was applied.

Protocol

Each child was given the questionnaire twice; once for the conventional knee joint and once for the prototype knee. All children wore each of the knees for a minimum of four weeks prior to answering the questionnaire. Care was taken to test the knees under similar circumstances. Both knees were tested either during the school year or during summer holidays. The children were given the option to answer the questionnaires by themselves or with their parent(s).

Table 3.3: Questions and response options.

Category	Questions	Response options
GENERAL	**Q1**: Types of activities performed:	1. Walk fast; 2. Walk fast & jog; 3. Walk fast, jog & run
	Q2: In certain situations does the knee give out from under you?	Yes/No
	Q3: How often does the knee give out:	H = Hour; D=Day; W=Week, M=Month (i.e. twice per day = 2/D)
WALK	**Q4**: When you are walking, does your knee ever collapse on you?	Yes/No
	Q5: When you are walking do you worry about whether your knee will collapse on you?	5 Point Scale (0: Not at all – 5: All the time)
	Q6: When you walk for a longer time, how tired do you feel?	5 Point Scale (0: Not at all – 5: Very tired)
RUN	**Q7**: In the last four weeks has your knee collapsed on you while running?	Yes/No
	Q8: When you are running do you worry about whether your knee will collapse on you?	5 Point Scale (0: Not at all – 5: All the time)
UNEVEN GROUND	**Q9**: When you encounter uneven (rough) ground, do you:	1. Continue as normal, 2. Avoid it, 3. Move slowly/cautiously
	Q10: How stable is your prosthesis on uneven ground?	5 Point Scale (0: Very Stable – 5: Unstable)
	Q11: Over uneven (rough) ground, do you worry about tripping?	5 Point Scale (0: Not at all – 5: All the time)
INCLINES AND STAIRS	**Q12**: Rate the difficulty of walking up a hill or ramp	5 Point Scale (0: Easy – 5: Very difficult)
	Q13: Rate the difficulty of walking down a hill or ramp	5 Point Scale (0: Easy – 5: Very difficult)
	Q14: Rate the difficulty of walking up stairs	5 Point Scale (0: Easy – 5: Very difficult)
	Q15: Knee preference	1. Conventional; 2. Prototype

Results

Knee stability for different knee joints

The zones of instability for the single-axis, four-bar, six-bar and prototype knees are presented in figure 3.4. The prototype has a fixed control axis depicted as a solid circle. The position of the control axis of the six-bar knee varies and is depicted as a hollow circle. In the locked mode, the six-bar knee may be flexed several degrees. This feature acts to provide stance-flexion. It also causes the control axis to travel in the proximal direction thus decreasing the zone of instability and making the knee more stable. The prototype knee has the same stance-flexion feature, but since the control axis is fixed, the zone of instability remains relatively unchanged during stance flexion.

Questionnaire

Questionnaire results are presented in table 3.4. Question 4 responses were recalculated from the original responses.

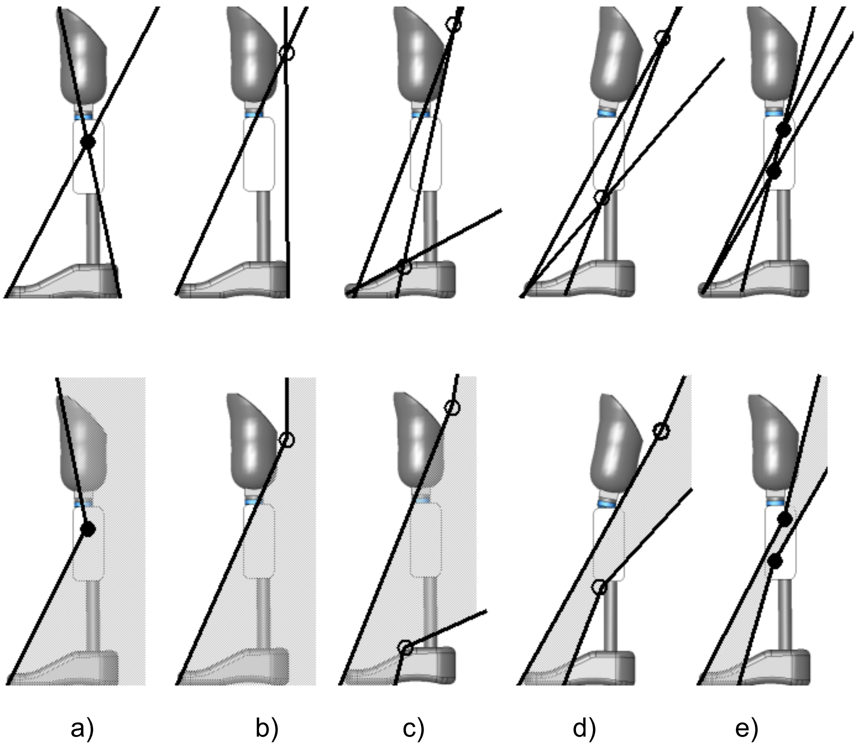


Figure 3.4: Top diagrams show the boundary load lines for each knee and bottom diagrams the resultant zones of instability. Knee joints depicted are: a) single-axis; b) four-bar knee; c) six-bar knee; d) six-bar knee during stance-flexion; and e) prototype knee. Axes that are instantaneous centers are shown as hollow circles and physical or fixed axes are solid circles.

Table 3.4: Responses to questionnaire including median (CONV ≡ Prosthesis with conventional knee joint; PROT≡ Prosthesis with prototype knee joint).

	Questions	Knee Type	S1	S2	S3	S4	S5	S6	Med -ian
GENERAL	**Q1**: Types of activities performed: 1. Walk fast; 2. Walk fast & Jog; 3. Walk fast, jog & run	CONV	3	2	1	3	3	1	-
		PROT	3	2	1	3	3	1	-
	Q2: In certain situations does the knee give out from under you?	CONV	Y	Y	Y	Y	Y	Y	-
		PROT	Y	N	N	N	Y	N	-
	Q3: How often does the knee give out: (specified as # of times per month)	CONV	90	30	4	60	30	1	30
		PROT	4	0	0	0	1	0	1
WALK	**Q4**: When you are walking, does your knee ever collapse on you?	CONV	Y	Y	Y	Y	Y	Y	-
		PROT	Y	N	N	N	N	N	-
	Q5: When walking do you worry about whether your knee will collapse on you? (0: Not at all – 5: All the time)	CONV	4	5	3	4	3	0	3.5
		PROT	3	0	0	0	1	1	0.5
	Q6: When you walk for a longer time, how tired do you feel? (0: Not at all – 5: Very tired)	CONV	4	4	4	5	3	1	4
		PROT	3	1	2.5	4	2	2	2.25
RUN	**Q7**: In the last four weeks has your knee collapsed on you while running?	CONV	Y	Y	*	N	Y	*	-
		PROT	Y	N	*	N	N	*	-
	Q8: When running do you worry about whether your knee will collapse on you? (0: Not at all – 5: All the time)	CONV	5	4	*	0	3	*	3.5
		PROT	2	0	*	0	2	*	1
UEVEN GROUND	**Q9**: When you move to uneven (rough) ground, do you: 1. Continue as normal, 2. Avoid, 3. Move slowly/cautiously	CONV	3	3	3	3	3	3	-
		PROT	3	1	3	3	3	1	-
	Q10: How stable is your prosthesis on uneven (rough) ground? (0: Very Stable – 5: Unstable	CONV	5	3	3	1	1	2	2.5
		PROT	4	1	1	4	3	5	3.5
	Q11: Over uneven (rough) ground, do you worry about tripping? (0: Not at all – 5: All the time)	CONV	4	5	4	3	3	3	3.5
		PROT	3	3	5	3	2	3	3
INCLINES AND STAIRS	**Q12**: Rate the difficulty of walking up a hill or ramp (0: Easy – 5: Very difficult)	CONV	5	3	4	0	5	0	3.5
		PROT	0	2	2	0	4	0	1
	Q13: Rate the difficulty of walking down a hill or ramp (0: Easy – 5: Very difficult)	CONV	3	2	2	3	0	2	2
		PROT	0	1	1	0	2	1	1
	Q14: Rate the difficulty of walking up stairs (0: Easy – 5: Very difficult)	CONV	0	2	4	0	4	2	2
		PROT	0	1	2	0	1	2	1

	Q15: Knee preference 1. Conventional; 2. Prototype		2	2	2	2	2	2	-

* data not available since children did not jog or run

Discussion

Instability zone modeling

Figure 3.4 shows the instability zone diagrams for several types of knees. These results may change slightly depending on the specific knee joint in question. For example, the four-bar knee depicted in figure 3.4b has a proximally located instantaneous center (IC) of rotation, while some four-bar knees have ICs of rotation that are more distally located on the thigh. For these knees the zones of instability fall between those of figures 3.4a and b. In other words, the four-bar knee has stance-phase properties that more closely resemble those of a single-axis knee joint.

The single-axis knee joint has the largest zones of instability, followed by the four-bar linkage knee, the six-bar knee, and the prototype knee. This enhanced stance-phase control of four-bar knees in comparison to single-axis knees is well documented.[5,13,14] With the narrow zone of instability of the prototype knee, knee flexion will only occur with a load line that originates at the forefoot and has a slight anterior to posterior tilt. This loading condition occurs naturally just prior to toe-off as the amputee applies a small hip flexion moment. The six-bar knee with a larger zone of instability can be flexed under a larger array of loading conditions, but is generally stable during heel loading regardless of the hip moment.

A control axis placed distal and anterior of the main flexion axis had been previously explored in designs utilizing frictional brakes capable of locking the knee under flexion.[15,16] Some of our earlier research focused on this control strategy in order to address knee instability attributed to load acceptance during knee flexion. In essence, a flexion moment at the control axis applies through the specific mechanical system a flexion resisting moment at the knee axis via the frictional brake. However, a moment can only be generated at the control axis if the knee is locked in the first place. At the instance that the prosthesis becomes loaded, the brake is in an indeterminate state. The zone of stability without the initial determination of the brake state is unpredictable, and dependent on the sensitivity of the brake. A highly sensitive brake will ensure a locked knee at heel-strike, thus giving a tight zone of instability (figure 3.4d). But this may also cause the knee to inadvertently lock up during swing. An insensitive brake will behave like a single-axis knee (figure 3.4a). With the prototype knee, the status of the lock is determined prior to loading, since the knee locks upon full extension, and therefore, a tight zone of instability is achieved. Furthermore, as there is only one locking position, the lock will not be inadvertently activated during the swing-phase.

Questionnaire

Data from the questionnaires supported the hypothesis that decreased zones of instability can facilitate more reliable stance-phase stability. All six children experienced an improvement in stance-phase stability with the prototype knee. All six children reported that their conventional knees became unstable at least once during the 4-week testing period. In comparison, only two of the six children wearing the prototype reported knee instability. The median number of monthly occurrences of knees giving out were 30 and 1 for the conventional and prototype knees, respectively ($p<0.03$). The children with the prototype knee also reported that they had minimal worries about falling during walking, scoring (0.5/5) versus (3.5/5) for the conventional knee joints ($p<0.06$).

All children felt that the knees could be more stable on uneven terrain and had moderately high worries about tripping. Most children indicated that while ambulating over uneven terrain they tended to be more cautious, regardless of the type of knee joint. Reported levels of fatigue between the knees were insignificantly different, although slightly lower for the prototype knee. This suggests that the added stance-phase stability does not adversely affect gait efficiency although additional studies are needed.

The children’s activity levels remained unchanged with the different knees as evidenced in responses to the questionnaires. The children that were able to run and jog reported much greater decreases in incidents of falls than less active children. Highly active children reported falling 1-3 times per day with their conventional prostheses while less active children fell 1-4 times per month (table 3.5). Based on observations by the authors, prosthetists, therapist, and parents of the children, the children's gait did not exhibit any adverse characteristics from the increased stance-phase stability. After some initial modifications to the locking mechanism to increase its sensitivity, all children were able to control lock disengagement with ease and without observable compensatory movements.

Table 3.5: Relationship between activity level and number of falls.

Subject Group	# of falls/month Conventional knees	# of falls/month Prototype
Persons that walk only	1-4	0
Persons that walk and jog	30	0
Persons that walk, jog and run	30-90	0-4

Long-term testing

All six children reported that they preferred the prototype knees. Upon the completion of the study the children were given the option of keeping the prototype knee joint or reverting to their conventional knees. Five of the six children continued wearing the prototype knees and at the time of publication had been wearing them for 14 months on average (3-21 months). Subject 1 stopped wearing the prototype because he was fitted with an adult prosthesis that he preferred. One child (Subject 5), despite reporting a preference for the prototype knee, later expressed that she felt indifferent about the knees, and wore the conventional knee. She has recently switched back to using the prototype knee.

The knees have functioned reliably for all the children. For the less active children, no maintenance has been required. For the active children, the extension bumpers were replaced about every six months. In addition, the contact element depicted in figure 3.2a showed higher than normal wear after six months for one child. Originally, some of the knees showed considerable wear on the lock, but through material selection and a slight modification of the design, wear on the latch has been minimized. To date, no additional deformations, failures, or excessive wear of parts have otherwise been observed.

Limitations

Although typical to this type of research[17-19], one limitation of this study was the small sample size studied. Challenges associated with the recruitment of suitable participants and the costs associated with the provision of testing prostheses are often inhibitive of larger studies. Another limitation of the study relates to the questionnaire, which does not entirely disassociate the reason that a child falls. Questions 2-4 inquire about the knee giving out, but the interpretation of this may be taken to include causes such as tripping. Additional questions to identify the number of falls specific to each cause would help to better identify the origins of falls.

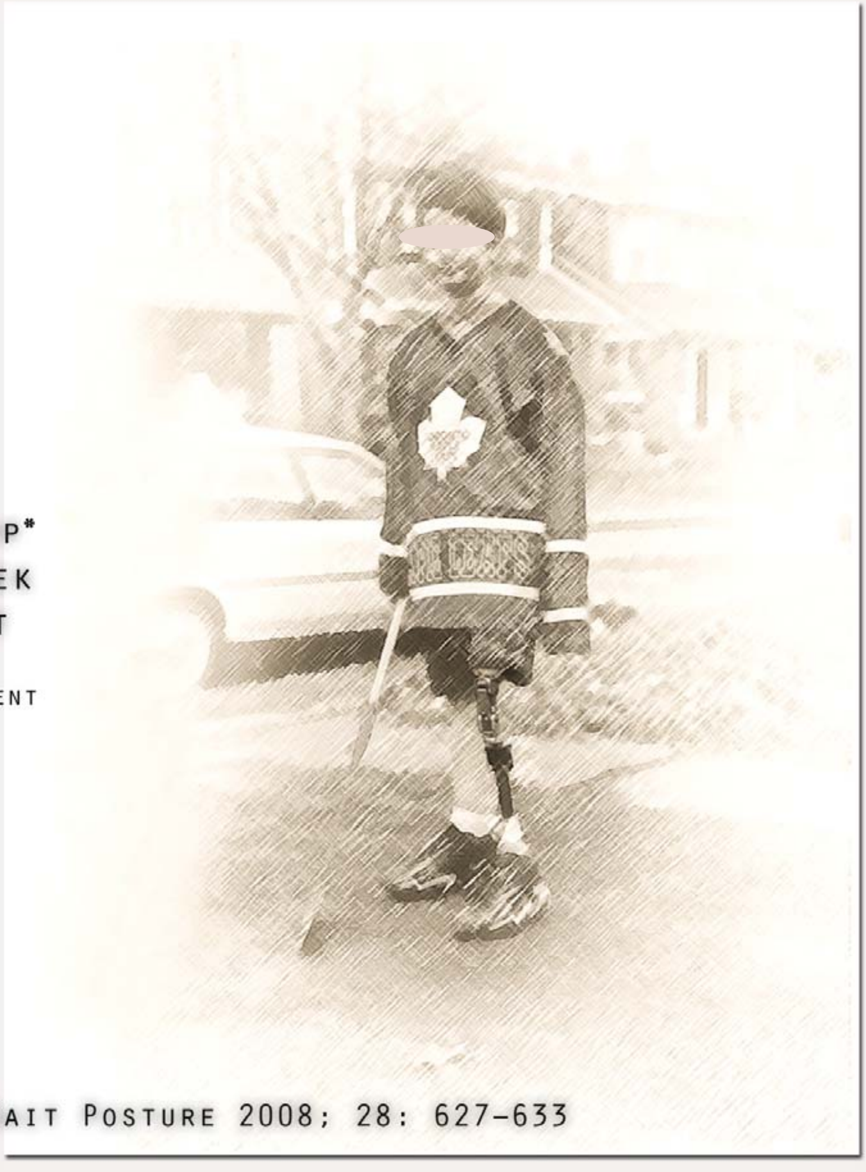
Conclusions

The provision of stance-phase stability is an essential function of prosthetic knees. A stability-modeling technique was presented, which unlike previous techniques, allows for modeling of knee joint mechanisms with dual stability-affecting axes. Today's commercially-available paediatric prosthetic knee joints are highly innovative and provide superior stability for children with amputations when compared to technologies available a decade or two ago. Despite these advancements, many children still experience occasional falls which can be attributed to knee joint instability. To combat this, a unique knee mechanism aimed at limiting the conditions under which instability occurs was developed and tested. Significant decreases in falls were observed. Consistent with the trend in the paediatric market toward more stable knee joints, the children in this study showed a preference for this knee. This was evidenced not only in the questionnaire responses, but also through long-term clinical testing.

References

1. Andrysek J, Naumann S, Cleghorn W. Design characteristics of pediatric prosthetic knees. IEEE Trans Neural Syst Rehabil Eng 2004; 12: 369-78.
2. Boonstra AM, Rijnders LJ, Groothoff JW, Eisma WH. Children with congenital deficiencies or acquired amputations of the lower limbs: functional aspects. Prosthet Orthot Int 2000; 24: 19-27.
3. Cummings D. The missing link in pediatric prosthetic knees. Biomechanics 1997; 4: 163-8.
4. Postema K, Hermens HJ, de Vries J, Koopman HF, Eisma WH. Energy storage and release of prosthetic feet. Part 1: Biomechanical analysis related to user benefits. Prosthet Orthot Int 1997; 21: 17-27.
5. Radcliffe CW. Four-bar linkage prosthetic knee mechanisms: kinematics, alignment and prescription criteria. Prosthet Orthot Int 1994; 18: 159-73.
6. Öberg K. Knee mechanisms for through-knee prostheses. Prosthet Orthot Int 1983; 7: 107-12.
7. Uicker JJ. Theory of machines and mechanims. UK: Oxford University Press; 2003.
8. Datta D, Howitt J. Conventional versus microchip controlled pneumatic swing phase control for trans-femoral amputees: user's verdict. Prosthet Orthot Int 1998; 22: 129-35.
9. Legro MW, Reiber GD, Smith DG, del Aguila M, Larsen J, Boone D. Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. Arch Phys Med Rehabil 1998; 79: 931-8.
10. Jensen JS, Raab W. Clinical field-testing of ATLAS prosthetic system for trans-femoral amputees. Prosthet Orthot Int 2003; 27: 55-62.
11. Grise MC, Gauthier-Gagnon C, Martineau GG. Prosthetic profile of people with lower extremity amputation: conception and design of a follow-up questionnaire. Arch Phys Med Rehabil 1993; 74: 862-70.
12. Vannah WM, Davids JR, Drvaric DM, Setoguchi Y, Oxley BJ. A survey of function in children with lower limb deficiencies. Prosthet Orthot Int 1999; 23: 239-44.
13. Breakey JW, Marquette SH. Beyond the four-bar knee. JPO 1998; 10: 77-80.
14. de Vries J. Conventional 4-bar linkage knee mechanisms: a strength-weakness analysis. J Rehabil Res Dev 1995; 32: 36-42.
15. Radcliffe CW. Design of prosthetic and orthotic devices and biomechanical studies of locomotion. Bull.Prosthet.Res - VA RER&DS Programs 1977; 141-149: 1977.
16. Radcliffe CW. Design of prosthetic and orthotic devices and biomechanical studies of locomotion. Bull.Prosthet.Res - and other VA Research Programs 1979; 87-95.
17. Hicks R, Tashman S, Cary JM, Altman RF, Gage JR. Swing phase control with knee friction in juvenile amputees. J Orthop Res 1985; 3: 198-201.
18. Hoy MG, Whiting WC, Zernicke RF. Stride kinematics and knee joint kinetics of child amputee gait. Arch Phys Med Rehabil 1982; 63: 74-82.
19. Zernicke RF, Hoy MG, Whiting WC. Ground reaction forces and center of pressure patterns in the gait of children with amputation: preliminary report. Arch Phys Med Rehabil 1985; 66: 736-41.

4 Single-session reliability of discrete gait parameters in ambulatory children with cerebral palsy based on GMFCS level



S. Redekop*
J. Andrysek
V. Wright

*Graduate student

Gait Posture 2008; 28: 627-633

Abstract

Objective: To evaluate the intra-session reliability of discrete gait parameters in ambulatory children with varying levels of mobility impairment.

Methods: The single session reliability of 28 discrete spatiotemporal and kinematic variables was evaluated from computerized gait analysis (CGA) in 33 ambulatory children with cerebral palsy (CP), subcategorized according to Gross Motor Function Classification System (GMFCS) Levels I (n=11), II (n=12) and III (n=10). Nineteen boys and fourteen girls participated, mean age = 8y 1m (SD = 3y 0m). Intra-class correlation coefficients (ICCs) estimated reliability and the number of strides required to obtain an ICC of at least 0.90 was determined.

Results: The reliability of discrete gait parameters was dependent upon GMFCS Level, with children in GMFCS Level I exhibiting the highest reliability (ICC range=0.70-0.96). GMFCS Levels II and III had lower levels of reliability with ICC values varying from 0.54-0.95 and 0.45-0.98, respectively. With the exclusion of pelvis range of motion, an average of four strides provided a reliability estimate of at least 0.90 for GMFCS Level I, while six strides were needed for children in Levels II and III.

Conclusions: On the basis of the intra-session reliability results from the present study, further work is recommended to examine the test-retest reliability of these gait parameters in children with CP.

Introduction

Computerized gait analysis (CGA) has become increasingly popular in the assessment of gait in individuals with motor impairments. In the analysis of children with cerebral palsy (CP) it has been shown to be more accurate in detecting and defining gait deviations than visual assessment.[1-3] As a result, CGA has been used extensively in the evaluation of complex gait abnormalities and in assessing the effect of interventions in these children.[4-10]

As with other biological measures, parameters measured during gait analysis are influenced by intra-subject variability as well as measurement error related to the measurement instrument. Consequently, data collected from one stride of gait may not be representative of an individual's performance and could by chance reflect an atypical pattern. Accordingly, sampling a number of repetitions has been recommended in order to decrease the variability that exists between strides of gait.[11,12] In the evaluation of walking and running in healthy adults it has been shown that at least three gait strides should be examined to obtain reliable measures.[12,13]

Despite CGA's widespread use in the evaluation of children with CP, no studies have investigated the number of strides needed to obtain a stable measure of gait parameters in this population. Many CGA studies have assumed that one stride can be used to adequately represent an individual's gait characteristics[5,6,14], while others have used the average of two to six strides.[4,15,16]

Several studies have evaluated the reliability of kinematic and kinetic gait data in children with CP.[17,18] These studies measured the similarity between kinematic and kinetic waveforms within and between days. Using the Coefficient of Multiple Correlation (CMC), it was found that intra-subject repeatability between waveforms was better for able-bodied children than for children with CP. Although informative, these studies fail to report the reliability of discrete gait parameters, such as maximum knee flexion, which are required to evaluate the complex gait patterns in these children. Discrete gait parameters are obtained by extracting clinically relevant features of the continuous curves. The appeal and widespread application of this approach is attributed to the fact that discrete parameters are easier to interpret, compare and analyze than waveforms. Although these clinically relevant discrete parameters have been extensively used for children with CP,[4,15,16] their repeatability in CGA remains unexplored.

Due to the wide variation of movement patterns in children with CP, evaluative studies often group participants in clinically meaningful ways in an attempt to decrease sample heterogeneity, for example by using the Gross Motor Functional Classification Scale (GMFCS).[19] It has been shown that gait parameters measured using CGA are associated with the child's overall motor function, as defined by the GMFCS.[15] However it is unclear whether the reliability of gait measures captured by CGA differs depending on the levels of motor function of the child, i.e., the GMFCS Level.

Thus, in reference to children with CP, the main objectives of this study were to determine 1) how many strides must be averaged to obtain a reliable measure of commonly-used, clinically-relevant discrete gait parameters, and 2) whether the functional level of the child, based on the GMFCS, affects the reliability of these gait parameters.

Methods

A single-session, repeated measures reliability study was conducted with a convenience sample of ambulatory children with CP.

Participants

The 33 children who participated varied in age from 4 to 14 years. Their characteristics are summarized in table 4.1. Eleven of the participants were in GMFCS Level I (eight males, three females), 12 were in GMFCS Level II (four males, eight females) and 10 were in Level III (seven males, three females). All children were community ambulators. The majority of participants used lower-limb orthoses regularly, but the gait trials in this study were performed in the barefoot walking condition. Six of the 10 children in GMFCS level III walked with a walker, while the others used canes. Exclusion criteria included botulinum toxin A injections in the lower limbs within the last three months, and any orthopaedic or neurosurgery in the lower extremities in the previous six months. Prior to participation all procedures were explained to the child and his/her parent or guardian, and informed written consent was obtained as approved by the research ethics board at our facility.

Table 4.1: Participants' characteristics.

GMFCS level	Diagnosis	Age (y) Mean (SD)	Height (m) Mean (SD)	Mass (kg) Mean (SD)
I (N=11)	1 spastic triplegia 2 spastic diplegia 8 hemiplegia (7 left; 1 right)	7.0 (3.1)	126.0 (17.1)	28.3 (11.5)
II (N=12)	10 spastic diplegia 2 hemiplegia (2 left)	8.2 (2.4)	126.2 (16.2)	30.9 (13.2)
III (N=10)	10 spastic diplegia	10.0 (3.3)	133 (18.8)	33.3 (14.6)

Instrumentation

All data were collected in the Human Movement Laboratory at our facility. Three-dimensional gait data were captured at 120Hz using the Vicon MX system with seven infrared cameras[a]. The cameras encompassed a 10m walkway. Data were processed to determine spatiotemporal and kinematic parameters using BodyBuilder software[a].

Procedure

Participants wore spandex shorts and tank tops to minimize marker movement artifact. Reflective markers (14mm spheres) were placed at anatomical landmarks on the lower extremities (anterior superior iliac spines, sacrum, lateral thigh, lateral femoral condyle, lateral tibia, lateral ankle malleolus, posterior calcaneous, 5th metatarsal head and the midpoint between the base of the 1st and 5th metatarsals). Markers were placed on the medial femoral condyle and the medial ankle malleolus for static captures only. Participants were instructed to walk barefoot along the 10m walkway at their regular, self-selected walking speed. Four complete passes were collected for each subject. For a pass to be considered complete, we required that markers were not obstructed so as to permit their accurate 3-dimensional reconstruction.

Reflective markers were manually identified using Vicon Workstation[a]. Local dynamic and bone-embedded coordinate systems were defined for the feet, shanks, thighs and pelvis. All trajectories were filtered using a generalized cross-validated spline technique.[20]

Data analysis

Twenty-eight discrete gait measures were selected for analysis from those commonly used in clinical outcome studies done on this population (table 4.2).[4,15,16] Custom-written Matlab[b] programs were used to extract the discrete parameters from relevant features of kinematic curves. The mean and standard deviation (SD) of all variables were summarized across eight strides and subcategorized according to GMFCS levels. Patterns of differences among GMFCS Levels were considered for a subset of five parameters using a one-way analysis of variance (ANOVA) with a Tukey post hoc test. The parameters tested were: velocity, mean pelvic tilt, hip range of motion (ROM), knee angle at initial contact (IC) and ankle ROM. Inferential tests were not conducted on all parameters due to the small subgroup sample sizes (Type II error issue) and multiple correlated variables (Type I error issue).

The reliability analysis was done using eight repeated measures of each discrete parameter for each subject (table 4.3). In order to obtain the data from eight strides of gait while minimizing the likelihood of fatigue, variables were extracted from two consecutive mid-walk strides for each of the four gait passes.

Data were analyzed unilaterally; for the children with hemiplegia data were analyzed for the affected limb, whereas the side of the body was arbitrarily chosen for the children with spastic diplegia. Reliability was estimated using the interclass correlation ($ICC_{2,1}$)[21] method (equation 4.1), which is a well-established analytical technique for investigating the reliability of biological measures.[12,22,23]

$$ICC_{2,1} = \frac{MS_B - MS_E}{MS_B + (k-1)MS_E + k(MS_R - MS_E)/n} \tag{4.1}$$

where MS_B, MS_R, and MS_E are the mean squares of the 2-way analysis of variance, n is the number of subjects, and k is the number of strides.

The 95% confidence interval (CI) for each of the ICCs was also computed. Mean ICC values of 0.90 and above were used for each reliability analysis, in order to ensure that the lower bounds of the 95% confidence intervals were at least 0.75, which has been used as a threshold in other reliability studies.[24]

The ICC coupled with the Spearman Brown formula for stepped-up reliability facilitated the calculation of the number of strides (*k*) necessary to obtain a stable measure based on a desired level of reliability (research objective 1). This method has been previously used to calculate the intra-session reliability in the study of postural control measures in the elderly, and is described by the following formula.[22,23]

$$k = \frac{R^*(1-R)}{R(1-R^*)} \tag{4.2}$$

where R^* is the desired reliability level and R is the reliability of a single measure calculated using equation 4.1.

The second objective of this study was to determine whether the variability of discrete gait parameters is dependent upon the child's GMFCS level, i.e., the gait-related functional ability of the child. The standard error of measurement (SEM) was used to assess the magnitude of variability for each parameter within GMFCS levels and to ascertain if the overall variability differed between groups. The formula SEM = $s_x\sqrt{(1-r_x)}$ was used, where s_x is the standard deviation of the set of observed data across subjects and r_x is the reliability, calculated by the ICC method. SEM values presented in table 4.4 were calculated using the appropriate number of strides averaged to achieve an ICC of at least 0.90. Applied to sets of observed data, it gives an estimate of the heterogeneity within groups.

The data were analyzed using SPSS version 15.0 for Windows[c].

Results

The mean and SD of all variables summarized across eight strides are presented in table 4.2. In terms of spatiotemporal variables, children in GMFCS Level I had greater self-selected velocities and higher cadences than children in Levels II or III, although the differences were not statistically significant ($p>0.05$). Defining clear patterns of difference across GMFCS levels for joint kinematics was difficult as large variability (SD) was measured within groups, reflecting the diverse pattern of motor involvement in this condition. Results of the statistical analysis are shown in table 4.2. Significant differences were found for knee flexion at IC and ankle ROM for Level III when compared to Levels I and II, whereas no differences were found for hip ROM.

Table 4.3 shows the reliability of gait variables for when a single stride is considered. Results are presented within each GMFCS Level. In general, good to high levels of repeatability (ICCs $\geq$ 0.70) were observed for gait parameters for all functional levels. The exceptions were pelvis ROM and ankle ROM for GMFCS Levels II and III, as well as hip adduction at IC and maximum knee flexion for GMFCS Level II. In addition, the lower limit of the CIs achieved the targeted threshold of 0.75 for 66 of the 114 ICCs calculated (57%), and between 0.70 and 0.75 for another 16 of the ICCs. GMFCS Level I scores were the most reliable, with ICCs varying from 0.70 – 0.96. GMFCS Levels II and III had lower levels of reliability with ICC values varying from 0.54 - 0.95 and 0.45 - 0.98, respectively.

The number of strides (*k*) required to achieve a reliability greater than or equal to 0.90 is also shown in table 4.3. To encompass all collected gait parameters, four strides are required for children in GMFCS Level I. However, with the exclusion of pelvis ROM and maximum hip internal rotation, three strides would be sufficient to achieve an ICC of 0.90. In GMFCS Levels II and III, the number of strides required varied between one and six for all variables except pelvis ROM. For the pelvis ROM, eight strides were needed in Level II, whereas an estimated 11 strides were needed for Level III to obtain a reliability coefficient of at least 0.90.

The measurement variability within each GMFCS level, as reflected by the SEM, is shown in table 4.4 when the recommended number of strides was considered. In general, SEM values were comparable across functional levels with a mean difference of 1.08º (range: 0.09º – 2.92º) across kinematic gait parameters. The SEM for the pelvic ROM for GMFCS Level III could not be calculated, as the appropriate level of reliability was not achieved with eight strides.

Discussion

There is lack of consensus regarding the number of strides needed to obtain a stable measure of gait parameters in the CP populations. Knowledge of the minimum number of strides required in a single testing session is important to consider as it would ensure that children are not subjected to an unnecessarily lengthy evaluation. This is particularly relevant for children in younger age groups who may vary in their levels of cooperation, and for children with inefficient gait patterns who may tire easily, i.e., those in GMFCS Level III. Furthermore, within-session reliability is of importance in applications where gait analysis results from a single session are used for clinical decision-making (i.e. orthopedic surgery).[8,10]

This study provides evidence that the gait of children with GMFCS Level I is stable enough such that a reliable estimation for all studied gait parameters may be obtained from an average of four strides, i.e., two passes with two strides captured per pass. Greater variability was seen in the gait patterns of children with GMFCS Levels II and III where an average of six strides, i.e., three passes with two strides captured per pass, was needed to obtain the same level of reliability for all parameters, excluding pelvis ROM.

Table 4.2: Mean and standard deviation (in brackets) values for gait parameters taken across 8 strides for 3 GMFCS levels. Unless otherwise specified all units are in degrees. *Note:* IC = initial contact; Max = maximum; Min = minimum.

	Parameter	**GMFCS I**	**GMFCS II**	**GMFCS III**
	[a]Velocity (m/s)	0.9 (0.2)	0.8 (0.3)	0.8 (0.3)
	Stride Length (m)	0.8 (0.2)	0.8 (0.2)	0.8 (0.2)
	Cadence (steps/min)	131.0 (30.0)	119.0 (23.0)	117.0 (23.0)
PELVIS	Min up obliquity angle	-2.2 (5.1)	-4.6 (3.5)	-2.6 (4.6)
	Max up obliquity angle	4.3 (4.8)	4.9 (3.9)	4.6 (4.5)
	[a, b] Mean pelvic tilt	5.2 (5.9)	8.4 (8.3)	15.7 (7.0)
	Pelvis range of motion (ROM)	8.2 (2.9)	10.3 (2.6)	8.5 (1.6)
HIP	Max Internal Rotation	-0.5 (10.2)	7.6 (9.9)	5.8 (9.0)
	Min Internal Rotation	-18.0 (9.8)	-15.0 (9.0)	-9.0 (8.8)
	Max Up Obliquity Stance	4.0 (4.8)	4.6 (4.1)	4.1 (4.4)
	Max Hip Adduction	6.8 (4.9)	6.4 (5.8)	15.1 (14.6)
	Min Hip Adduction @ IC	-4.2 (9.2)	-7.4 (5.4)	-10.2 (12.4)
	Min Hip Adduction Swing	-16.5 (11.6)	-20.1 (10.8)	-23.1 (17.9)
	Max Hip Int Rotation	24.7 (9.8)	22.5 (16.8)	32.5 (16.6)
	Min Hip Int Rotation	1.5 (7.2)	-6.6 (11.3)	3.7 (27.9)
	Min Hip Flexion	-9.9 (13.8)	-7.8 (9.0)	2.6 (12.3)
	Hip Flexion IC	30.5 (9.1)	33.3 (14.5)	48.3 (9.2)
	[a]Hip ROM	47.5 (12.3)	49.3 (9.8)	52.9 (11.0)
KNEE	Max Knee Flexion	61.0 (10.5)	62.0 (10.0)	63.5 (10.5)
	Min Knee Flexion	8.1 (9.2)	7.1 (14.9)	24.4 (12.3)
	[a, b, c] Knee Flexion @ IC	25.1 (9.4)	34.2 (9.7)	45.4 (11.7)
	Min Knee Flexion in Stance	8.3 (9.6)	7.3 (15.2)	24.4 (12.3)
	Knee ROM	52.9 (13.1)	54.9 (17.3)	39.2 (12.5)
ANKLE	Max Ankle Dorsiflexion	9.3 (12.8)	15.5 (9.3)	17.1 (6.7)
	Min Ankle Dorsiflexion	-11.0 (10.7)	-6.1 (12.4)	-14.3 (15.3)
	Ankle Dorsiflexion IC	-2.7 (9.4)	5.0 (7.5)	4.4 (6.4)
	[a, b, c] Ankle ROM	20.2 (7.4)	21.6 (8.2)	31.4 (10.2)
	Min Ankle Dorsiflex. Swing	-10.7 (10.9)	-5.3 (12.9)	-11.9 (15.8)

[a] Variables for which inferential analysis was performed among GMFCS levels
[b] Indicates a significant difference between Level I and Level III ($p \leq 0.05$)
[c] Indicates a significant difference between Level II and Level III ($p \leq 0.05$)

Table 4.3: Calculated reliability of a single trial and the number of strides (*k*) to be averaged to obtain a reliability level of at least 0.90, subcategorized based on GMFCS Level. Reliability estimates ≥0.90 are in bolded text.

	Parameter	GMFCS Level 1			GMFCS Level 2			GMFCS Level 3		
		ICC	95% CI	N.S.	ICC	95% CI	N.S.	ICC	95% CI	N.S.
	Velocity (m/s)	0.76	(0.57, 0.91)	3	0.83	(0.70, 0.93)	2	0.83	(0.68, 0.95)	2
	Stride Length (m)	0.83	(0.68, 0.94)	2	0.84	(0.72, 0.94)	2	0.88	(0.76, 0.96)	2
	Cadence (steps/min)	0.84	(0.70, 0.95)	2	0.76	(0.59, 0.90)	3	0.74	(0.54, 0.91)	4
PELVIS	Min up obliquity angle	**0.91**	(0.83, 0.97)	1	0.83	(0.68, 0.94)	2	**0.93**	(0.84, 0.98)	1
	Max up obliquity angle	**0.90**	(0.81, 0.96)	2	0.85	(0.71, 0.94)	2	0.86	(0.73, 0.96)	2
	Mean pelvic tilt	0.85	(0.73, 0.94)	2	**0.96**	(0.91, 0.99)	1	**0.95**	(0.88, 0.98)	1
	Pelvis range of motion	0.70	(0.52, 0.87)	4	0.54	(0.33, 0.79)	8	0.45	(0.22, 0.76)	11
	Max Internal Rotation	0.85	0.73,0.94)	2	0.83	(0.69, 0.94)	2	0.75	(0.55, 0.91)	3
	Min Internal Rotation	0.85	(0.72, 0.94)	2	0.73	(0.55, 0.89)	4	0.71	(0.50, 0.90)	4
	Max Up Obliq. Stance	0.88	(0.79, 0.95)	2	0.84	(0.70, 0.94)	2	0.83	(0.68, 0.95)	2
HIP	Max Hip Adduction	0.85	(0.73, 0.94)	2	0.79	(0.62, 0.92)	3	**0.97**	(0.93, 0.99)	1
	Min Hip Adduction @ IC	0.82	(0.68, 0.92)	3	0.63	(0.42, 0.84)	6	**0.92**	(0.84, 0.98)	1
	Min Hip Adduct. Swing	**0.90**	(0.81, 0.96)	2	0.75	(0.57, 0.90)	3	**0.95**	(0.89, 0.99)	1
	Max Hip Int Rotation	0.75	(0.58, 0.89)	4	0.88	(0.78, 0.96)	2	**0.94**	(0.88, 0.98)	1
	Min Hip Int Rotation	0.81	(0.67, 0.92)	3	**0.90**	(0.80, 0.96)	2	**0.98**	(0.95, 0.99)	1
	Min Hip Flexion	**0.96**	(0.92, 0.99)	1	0.81	(0.66, 0.93)	3	**0.93**	(0.85, 0.98)	1
	Hip Flexion IC	0.81	(0.68, 0.92)	3	**0.95**	(0.89, 0.98)	1	0.87	(0.73, 0.96)	2
	Hip ROM	0.77	(0.62, 0.90)	3	0.71	(0.52, 0.88)	4	0.86	(0.73, 0.96)	2
KNEE	Max Knee Flexion	**0.90**	(0.81, 0.96)	2	0.61	(0.40, 0.83)	6	0.85	(0.70, 0.95)	2
	Min Knee Flexion	0.91	(0.82, 0.96)	1	0.89	(0.80, 0.96)	2	0.93	(0.85, 0.98)	1
	Knee Flexion @ IC	0.85	(0.73, 0.94)	2	0.84	(0.70, 0.94)	2	0.93	(0.86, 0.98)	1
	Min Knee Flex. Stance	0.90	(0.82, 0.96)	1	0.88	(0.77, 0.96)	2	0.93	(0.85, 0.98)	1
	Knee ROM	0.90	(0.82, 0.96)	1	0.80	(0.64, 0.92)	3	0.82	(0.66, 0.94)	2
ANKLE	Max Ankle Dorsiflexion	0.89	(0.80, 0.96)	2	0.87	(0.76, 0.95)	2	0.87	(0.75, 0.96)	2
	Min Ankle Dorsiflex.	**0.94**	(0.89, 0.98)	1	0.85	(0.71, 0.94)	2	0.81	(0.64, 0.94)	3
	Ankle Dorsiflexion IC	**0.90**	(0.82, 0.96)	1	0.77	(0.60, 0.91)	3	0.88	(0.76, 0.96)	2
	Ankle ROM	0.87	(0.76, 0.95)	2	0.64	(0.43, 0.85)	6	0.64	(0.42, 0.87)	6
	Min Ankle Dorsiflex. Sw.	**0.94**	(0.89, 0.98)	1	0.85	(0.71, 0.94)	2	0.84	(0.68, 0.95)	2

N.S. ≡ Number of strides for ICC ≥ 0.90

Table 4.4: SEM values of spatiotemporal and kinematic measures. Unless otherwise stated SEM is expressed in degrees. *Number of strides averaged to obtain an ICC ≥ 0.90.

	Parameter	GMFCS level 1		GMFCS level 2		GMFCS level 3		
		Strides*	SEM	Strides*	SEM	Strides*	SEM	Difference SEM
	Velocity (m/s)	3	0.08	2	0.08	2	0.10	0.02
	Stride Length (m)	2	0.05	2	0.07	2	0.07	0.02
	Cadence (steps/min)	2	11.19	3	8.34	4	8.01	3.18
PELVIS	Min up obliquity angle	1	1.52	2	1.00	1	1.25	0.52
	Max up obliquity angle	2	1.17	2	0.87	2	1.30	0.43
	Mean pelvic tilt	2	1.57	1	1.69	1	1.62	0.12
	Pelvis ROM	4	0.71	8	0.80	11	NA	0.09
HIP	Max Internal Rotation	2	3.96	2	2.51	3	2.92	1.45
	Min Internal Rotation	2	3.90	4	3.01	4	2.64	1.26
	Max Up Obliquity Stance	2	1.19	2	1.10	2	1.74	0.64
	Max Hip Adduction	2	1.70	3	1.33	1	2.65	1.32
	Min Hip Adduction @ IC	3	3.06	6	1.65	1	3.46	1.81
	Min Hip Adduction Swing	2	2.60	3	3.68	1	3.93	1.33
	Max Hip Int Rotation	4	1.95	2	4.88	1	3.92	2.92
	Min Hip Int Rotation	3	2.16	2	2.26	1	4.04	1.88
	Min Hip Flexion	1	2.73	3	2.73	1	3.29	0.57
	Hip Flexion IC	3	1.58	1	3.39	2	2.75	1.82
	Hip ROM	3	3.01	4	3.21	2	2.22	0.99
KNEE	Max Knee Flexion	2	2.96	6	3.24	2	3.11	0.28
	Min Knee Flexion	1	2.81	2	3.69	1	3.31	0.88
	Knee Flexion @ IC	2	2.49	2	2.50	1	3.01	0.52
	Min Knee Flexion in Stance	1	3.01	2	3.76	1	3.31	0.75
	Knee ROM	1	4.08	3	4.28	2	3.67	0.61
ANKLE	Max Ankle Dorsiflexion	2	2.57	2	2.71	2	2.17	0.54
	Min Ankle Dorsiflexion	1	2.59	2	1.84	3	3.92	2.08
	Ankle Dorsiflexion IC	1	2.90	3	1.34	2	1.52	1.56
	Ankle ROM	2	2.19	6	2.51	6	2.88	0.69
	Min Ankle Dorsiflexion Swg	1	2.60	2	1.92	2	3.78	1.86

Pelvic ROM was the most unreliable gait parameter across functional groups. For the GMFCS Levels II and III, the averages of eight and 11 strides, respectively, were needed to obtain a stable measure. The variability of this parameter may be due, in part, to increased forward trunk lean and associated pelvic tilt during single-limb stance phase[25] that was observed in the data. This is a common compensatory mechanism in children with CP that is used to aid the forward progression of the body's centre of gravity, believed to involve the hip extensors and flexors and their associated spasticity and/or tightness.[25]

As part of the second objective to examine and compare reliability among GMFCS levels, the error for each functional group was examined using SEM. SEM values were comparable across GMFCS levels, with a maximum difference that was less than three degrees for all measured kinematic parameters. These values were considered to be sufficiently small to permit the subsequent comparison of ICC values between functional groups. As discussed above, children in GMFCS Levels II and III exhibited greater variability in their gait patterns overall than those in Level I. From a measurement perspective, this means that more strides are needed to obtain a stable representation of gait when compared to children in Level I.

Statistical analysis of mean score among GMFCS Levels (table 4.2) fitted with our hypotheses as far as the impact of the underlying spasticity and range of motion restriction on gait patterns (e.g., the angle of knee flexion at IC became progressively large from GMFCS Level I through Level III). This result provides an indication of the validity of CGA as conducted in our movement lab. For other parameters in which patterns of difference in scores among GMFCS levels were not evident, this may have been due to the fact that differences in mean values were small in comparison to the variability within groups (SD). This wide variability within GMFCS Levels may be attributed, in part, to the clinically 'ideal' walking environment presented during CGA. Since CGA evaluates short-distance walking over a flat surface and allows rest periods, it is unlikely to test the maximal functional capabilities of ambulatory children with CP that form the basis of the child's classification within the GMFCS. As a result, CGA studies that consider results according to GMFCS Levels may fail to identify score differences that have been observed under more functionally demanding tasks, such as the six-minute fast walk test.[26] There are several existing classifications of gait deviations in children with CP[27] that may be more sensitive to underlying differences among children, however they have not had high clinical use as the majority of published research studies that use CGA as an outcome classify children according to GMFCS levels.[9, 27]

Limitations

The present study did not evaluate the reliability of kinetic parameters since the use of walking aids prevented the collection of kinetic data for the participants in GMFCS Level III. However, these have been found to be more stable than the kinematic parameters in typically developing and CP children.[17] Furthermore, measurement bias that can be estimated using the Bland-Altman method could not be assessed in the current study as only one visit was analyzed.

Based on our protocol, two strides per pass were used for the analysis. This reduced the number of passes required to obtain eight strides, which was felt to increase cooperation and minimize the likelihood of fatigue. The impact of using a combination of intra-pass and inter-pass strides was assessed from a sub-reliability analysis on 16 children (6GMFCS level I, 6GMFCS level II, 4 GMFCS level III). For each child we obtained 4 gait strides within a single pass and 1 gait stride from four separate passes. The required number of strides was calculated using an ICC of 0.9. Excluding pelvis ROM, on average 0.46 (0.76) more strides were needed when using only inter-pass strides (unpublished work). Thus the mean underestimation for the current study lies between 0 and 0.46 of a stride, which was felt to be acceptable particularly due to the stringent ICC of 0.9 that was used.

Conclusions

In this study, the reliability of discrete gait parameters was presented for ambulatory children with CP, grouped according to GMFCS Levels. The reliability of gait parameters was dependent upon mobility level, with children in GMFCS Level I exhibiting the lowest within-session variability in their gait patterns. With the exclusion of pelvic ROM, an average of four strides provided a reliability estimate of at least 0.9 for GMFCS Level I, while six strides were necessary for children in GMFCS Levels II and III. This finding provides information that will facilitate optimized measurement of reliable gait parameters in future CGA studies.

Using the results from the present study as a guideline for the number of strides required, further work should examine the test-retest reliability of discrete gait parameters in children with CP. This would give an indication of the day-to-day reliability of the phenomenon and would facilitate the calculation of the minimal change that is detectable over a given time period and thus provide an empirically driven interpretation of gait results from rehabilitation intervention studies.

References

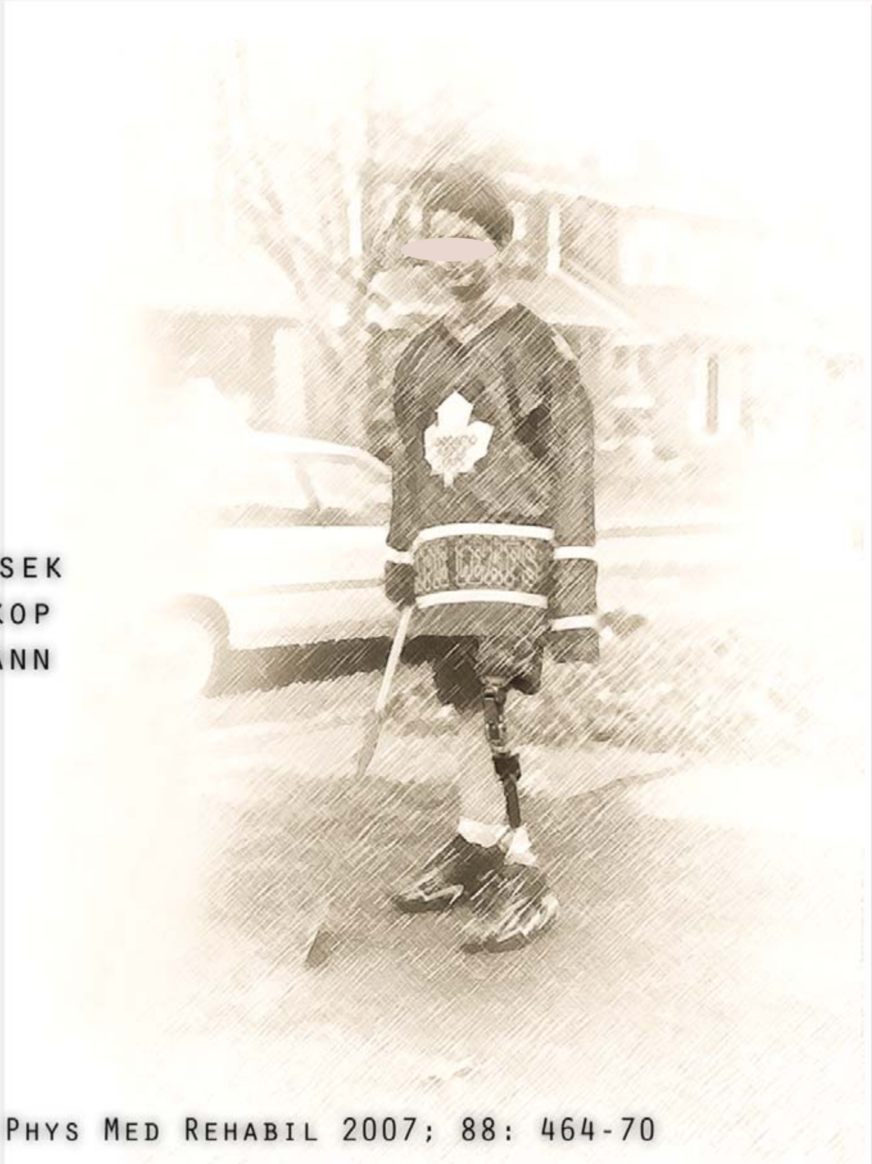
1. Krebs DE, Edelstein JE, Fishman S. Reliability of observational kinematic gait analysis. Phys Ther 1985; 65: 1027-33.
2. Eastlack ME, Arvidson J, Snydner-Mackler L, Danoff, JV, McGarvey CL. Interrater reliability of videotaped observational gait analysis assessments. Phys Ther 1991; 71: 465-72.
3. Mackey AH, Lobb GL, Walt SE, Stott NS. Reliability and validity of the observational gait scale in children with spastic diplegia. Dev Med Child Neurol 2003; 45: 4-11.
4. Galli M, Cimolin V, Valente M, Crivellini M, Ialongo T, Albertini G. Computerized gait analysis of Botulinum Toxin treatment in children with cerebral palsy. Disability and Rehabilitation 2007; 29: 659-664.
5. Arnold AS, Liu MQ, Schwartz MH, Ounpuu S, Delp S. The role of estimating muscle-tendon lengths and velocities of the hamstrings in the evaluation and treatment of crouch gait. Gait Posture 2005; 23: 273-81.
6. Rodda JM, Graham HK, Nattrass GR, Galea MP, Baker R, Wolfe R. Correction of severe crouch gait in patients with spastic diplegia with use of multilevel orthopaedic surgery. J Bone Joint Surg 2006; 88: 2653-64.
7. Sutherland DH, Santi MS, Abel MF. Treatment of stiff-knee gait in cerebral palsy: a comparison by gait analysis of distal rectus femoris transfer versus proximal rectus release. J Pediatr Orthop 1990; 10: 433-441.
8. Gage JR. Gait analysis: an essential tool in the treatment of cerebral palsy. Clin Orthop 1993; 288: 126-34.
9. Abel MF, Damiano DL, Gilgannon M, Carmines D, Kang HG, Bennett BC, Laws ER. Biomechanical changes in gait following selective dorsal rhizotomy. J Neurosurg (Pediatrics 2) 2005; 102: 157-162.
10. DeLuca PA. Gait analysis in the treatment of the ambulatory child with cerebral palsy. Clin Orthop 1991; 264: 65-75.
11. Bates BT, De Vita P, Kinoshita H. 83. Biomechanical aspects of sport shoes and playing surfaces. Calgary, Alberta: University Press; 1983; 191-198.
12. Diss CE. The reliability of kinetic and kinematic variables used to analyse normal running gait. Gait Posture 2001;14: 98-103.
13. Winter DA. Kinematic and kinetic patterns in human gait: Variability and compensating effects. Hum Mov Sci 1984; 3: 51-76.
14. Ounpuu S, DeLuca P, Davis R, Romness M. Long-term effects of femoral derotation osteotomies: An evaluation using three-dimensional gait analysis. J Pediat Orthop 2002; 22: 139-45.
15. Damiano DL, Abel MF. Relation of gait analysis to gross motor function in cerebral palsy. Dev Med Child Neurol 1996; 38: 389-396.
16. Corry IS, Cosgrove AP, Duffy CM, Taylor TC, Graham HK. Botulinum toxin in hamstring spasticity. Gait Posture 1999; 10: 206-210
17. Steinwender G, Saraph V, Scheiber S, Zwick EB, Uitz C, Hackl K. Intrasubject repeatability of gait analysis data in normal and spastic children. Clin Biomech 2000; 15: 134-9.
18. Mackey A, Walt SE, Lobb GA, Stott S. Reliability of upper and lower limb three-dimensional kinematics in children with hemiplegia. Gait Posture 2005; 22: 1-9.
19. Palisano R, Rosenbaum P, Walter S, Russell D, Wood E, Galuppi B. Development and reliability of a system to classify gross motor function in children with cerebral palsy. Dev Med Child Neurol 1997; 39: 214-223.
20. Woltring HJ. A Fortran package for generalized cross-validatory spline smoothing and differentiation. Adv Eng Software 1986; 8: 104-13.

21. Shrout P, Fleiss JL. Intraclass Correlations: uses in assessing rater reliability. Psychol Bull 1979; 86: 420-428.
22. Com'veau H, Hebert R, Prince F, Raiche M. Intrasession reliability of the center of pressure minus center of mass variable of postural control in the healthy elderly. Arch Phys Med Rehabil 2000; 81: 45-8.
23. Lafond D, Corriveau H, Hebert R, Prince F. Intrasession reliability of center of pressure measures of postural steadiness in healthy elderly people. Arch Phys Med Rehabil 2004; 85: 896-901.
24. Monaghan K, Delahunt E, Caulfield B. Increasing the number of gait trial recordings maximizes intra-rater reliability of the CODA motion analysis system. Gait Posture 2007; 25: 303-315.
25. Gage J. The Treatment of Gait Problems in Cerebral Palsy. London, UK: Mac Keith Press; 2005.
26. Thompson P, Beath T, Bell J, Jacobson G, Phair T, Salbach N, and Wright V. (in press) Test-retest reliability of the 10-metre fast walk test and 6-minute walk test in ambulatory school-aged children with cerebral palsy. Dev Med Child Neurol
27. Lee JH, Sung IY Yoo JY. Therapeutic effects of strengthening exercise on gait function of cerebral palsy. Disabil Rehab 2007; 11: 1-6.

Suppliers

a) Vicon Peak**,** Oxford, UK.
b) The Mathworks, IncNatick, MA, USA.
c) SPSS Inc, Chicago, Il, USA.

5 Preliminary evaluation of an automatically stance-phase controlled paediatric prosthetic knee joint using quantitative gait analysis



J. Andrysek
S. Redekop
S. Naumann

Arch Phys Med Rehabil 2007; 88: 464-70

Abstract

Objectives: To evaluate the effects on gait of a new paediatric prosthetic knee joint using an automatic stance-phase lock (ASPL), shown previously to help prevent falls, and to propose future design considerations and prosthetic alignments.

Methods: In a crossover case-series study design temporal, kinematic and kinetic gait parameters were measured for 3 children with unilateral above-knee amputations and 3 children with bilateral above-knee or below-knee amputations, in a human movement laboratory.

Results: Spatiotemporal parameters indicated higher gait velocities with the ASPL knee joint for the children with unilateral amputations. The increased speed, as expected, was associated with increased temporal inter-limb asymmetry, joint moments and powers, and excessive prosthetic knee range of motion in swing. A trend toward increased pelvic motions was observed with the ASPL knee when compared to conventional knees.

Conclusions: The biomechanical performance of the single-axis ASPL knee joint was shown to be comparable to more complex polycentric paediatric prosthetic knee joint technologies worn by the children in this study.

Introduction

It has been demonstrated that providing a young child with an above-knee or through-knee amputation with an articulating knee joint promotes the development of a more normalized gait pattern.[1] By the age of 5 years, most children will have been transitioned from their solid-knee prostheses, or prostheses with manually locking knees, to an articulating joint. About a dozen different articulating paediatric prosthetic knee joints are available commercially, the majority of which utilize polycentric mechanisms.[2,3] Compared with conventional single-axis designs, polycentric knee joints help to enhance stance-phase stability, increase toe-clearance and may be more aesthetically fitted to children with long residual limbs.[4,5]

Due to the posterior loading of the prosthetic foot, stance-phase stability is most critical during early stance phase. However, the condition for a stable knee joint develops during late swing phase, at which point it is essential that the knee joint fully extends and continues to remain extended. Regardless of the prosthetic knee joint type, single-axis or polycentric, weight acceptance onto a flexed knee diminishes prosthetic stability. Therefore, it is during weight acceptance that persons with amputations are highly susceptible to falls.

To address the limitations of conventional paediatric stance-phase control mechanisms, we proposed and pursued the development and testing of a unique new prosthetic knee joint mechanism. The basis of the design is a lock that automatically engages when the knee fully extends during late swing-phase (figure 5.1). This prevents the shank from inadvertently rebounding into flexion prior to weight bearing. Furthermore, the knee is locked prior to weight bearing, and not as a result of weight bearing. Therefore, during heel loading it is essentially impossible to unlock the knee. Toe loading deactivates the lock thus facilitating the initiation of knee flexion.

Details of the knee joint design and the results of a preliminary evaluation of its effectiveness are described elsewhere.[6] A questionnaire-based study found that use of the knee joint significantly reduced the frequency of falls in children with lower-limb deficiencies, from a median of one incident per day, to 1 incident per month, when compared to polycentric-based knee joints. Furthermore, children reported feeling more confident during walking and did not perceive significant changes in fatigue levels during walking. The range of activities that the children could and chose to perform did not change, nor did their levels of perceived difficulty.

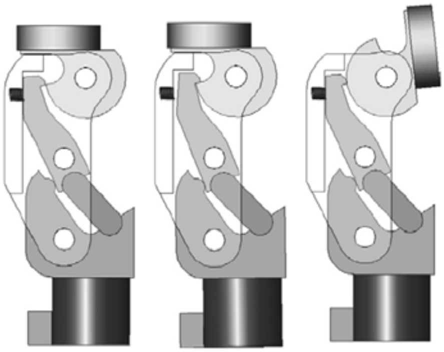


Figure 5.1: ASPL knee joint mechanism shown unlocked (left) and locked (middle) and in 90° of knee flexion (right).

The knee joint design is based on a single-axis configuration that was optimized to meet certain design criteria.[2] Specifically, the knee joint axis was placed in a more anterior location than is customary for single-axis knees, which utilize a posterior placement of the knee axis to help knee joint stabilization in early stance phase. The anterior placement of the axis decreases the moment at the knee joint in late stance as the forefoot is loaded, allowing for a more effortless initiation of knee flexion.[7,8] This decreased muscular effort at the affected hip joint, ultimately results in a more efficient and less laborious gait.[9]

The anterior placement of the knee joint was further optimized to increase swing-phase foot clearance, thus decreasing the chance tripping and/or the need for compensatory actions such as hip hiking.[2,10] Modeling was applied, and revealed that the single-axis design could be used to achieve levels of ease of knee flexion initiation and foot clearance, comparable to polycentric knee joints.

The goal of this study was to undertake a comprehensive biomechanical analysis of gait so to evaluate the performance of the automatic stance-phase lock (ASPL) technology in comparison to conventional paediatric knee joint components, to determine design features that may be improved, and to suggest prosthetic alignment options. A secondary goal of this study was to obtain kinetic measures of gait, currently not found in published literature.

Methods

Participants

A convenience sample of 6 children with lower-limb deficiencies participated in this study. The children were between 7 and 13 years old (mean age, 10.8y). Three of the children had unilateral above-knee amputations and 3 had bilateral above-knee and below-knee amputations. The children were considered good community ambulators and used their prostheses on a daily basis. None of the children used gait aids. The children were fitted with their conventional prostheses, which included a polycentric knee joint, at least 2 years prior to the study. To ensure adequate familiarization, the children wore the prostheses with the respective knee joints for a minimum of 4 weeks prior to gait data collection.[11] The order of the knees was assigned randomly, resulting in subjects 1, 2, and 4 wearing the conventional knee first. The characteristics describing the subject group are presented in table 5.1. Ethics clearance was received from the research ethics committee and informed consent obtained from the participants. For both conventional and ASPL knees, original fitting and alignment of prostheses were performed by the same qualified prosthetists. Prior to each trial, the alignment and prosthetic function were checked and adjusted by a prosthetist to establish optimal prosthetic function.

For a supplementary comparison, gait data were also collected for 15 able-bodied children of ages between 7 and 11 years (mean age, 9.5y), comprising the reference group.

Table 5.1: Amputee participant characteristics and types of prostheses used.

Subjects	Sex	Age (y)	Height (cm)	Mass (kg)	Congenital or age at amputation	Knee Unit	Foot Unit*
Unilateral group							
Child 1	M	12	155	52.0	Congenital	Total Knee Jr[e]	SpringLite[f]
Child 2	M	12	147	45.0	7y	Total Knee Jr[e]	Seattle[g]
Child 3	F	11	135	53.0	Congenital	Total Knee Jr[e]	Seattle[g]
Bilateral group							
Child 4	F	7	126	30.5	Congenital	3R66[f]	Seattle[g]
Child 5	F	10	139	34.5	Congenital	Total Knee Jr[e]	TruPer[h]
Child 6	F	13	149	37.5	4y	Total Knee Jr[e]	TruPer[h]

Abbreviations: F, female; M, male. *For the bilateral group the same foot component was used on both limbs.

Instrumentation and procedure

Gait analysis was conducted using a 7-camera data capture system[a] sampling at 60Hz. Participants donned tight fitting shorts. Reflective markers were placed on the heads of the first and fifth metatarsals, midpoint between the base of the first and fifth metatarsal, and posterior calcaneus. Markers were also placed on the lateral ankle malleolus, lower anterior shank, head of the fibula, lower anterior thigh, lateral thigh, greater trochanter, anterior superior iliac spine, and sacrum to define the shank, thigh and pelvis segments. Three additional markers (medial malleolus, lateral and medial condyles of the femur) were placed to define the body-embedded coordinate systems and joint centers for a neutral standing static frame.

Ground reaction forces were recorded with 2 offset force platforms[b,c]. These were located at the center of the walkway. Data were sampled at 240Hz on a computer.

Local-dynamic and bone-embedded coordinate systems were defined for the feet, shanks, thighs, and pelvis. Coordinate data were passed through a low-pass 6Hz digital Butterworth filter and custom-defined programs were used to process data. Segment rotations were defined using an existing mathematical Euler sequence of coronal, followed by transverse and then sagittal plane rotations.[12] Joint moments and powers were normalized to body mass.

Gait trials were performed along a 10-meter walkway. Children were instructed to walk at their regular, self-selected walking speeds. For the able-bodied children, trials were repeated until at least 5 complete trials were obtained. For the children with amputations, 5 complete trials per side were obtained. For a complete trial, it was required that markers were not obstructed allowing for their accurate 3-dimensional reconstruction, and that complete forceplate data from at least 1 forceplate were collected. To minimize the effects of fatigue, the children took short breaks between trials. In addition, children had their gait recorded from the sagittal and frontal planes using standard video recording equipment.

Data and statistical analysis

To facilitate the comparative analysis of kinematic and kinetic parameters, relevant defining points were extracted from the curves. The extraction process was automated using custom peak detection software, and the results were visually checked for accuracy. For each subject, median values of the 5 trials were reported separately for each limb, as applicable.

The data for each subject were further analyzed for significant intra-subject differences using a statistically-based approach previously applied to the evaluation of prosthetic feet.[13] We chose a similar approach, but due to the small sample size, we chose to apply a more conservative non-parametric test based on Bates et al.[14] The nonparametric Mann-Whitney *U* test was applied using SPSS[d] statistical analysis software. Conservatively, a *p* value of 0.01 was chosen.

The analysis was applied to the 2 sets of 5 trials (for the ASPL and conventional knees) for each parameter, separately for the above-knee and contralateral limbs. It is important to note that the results of this analysis were not intended to give means for inferring the effects of interventions, in this case the 2 knees joints, on populations, but rather as an instrument to determine possible intervention-dependent trends within groups.

Results

Spatiotemporal, kinematic, and kinetic data are presented in figures 5.2 through 5.5. A summary of those results including statistical analysis is presented in tables 5.2, 5.3, and 5.4. Tables 5.2 through 5.4 summarize the trends across subject groups which are divided into "all subjects," the children with unilateral amputations (subjects 1–3) and children with bilateral amputations (subjects 4–6).

Median values for spatiotemporal data, including velocity, cadence, and stride length, are presented in figure 5.2. As seen in figure 5.2A, subjects 2 and 3 walked faster with the ASPL knee joint when compared with their conventional components ($p<0.01$), and 2 others showed a trend toward faster gait. Two of the 6 children demonstrated a trend toward slower walking speed with the ASPL knee joint. All 3 children with unilateral amputations showed a trend or walked faster with the ASPL knee joint.

The children with unilateral amputations walked with longer stride lengths in order to achieve faster walking speed with the ASPL knees (see figure 5.2, table 5.3). There was no trend for cadence. For the bilateral group no trends were apparent for walking velocity or stride length, but cadence slightly decreased with the ASPL knees (see figure 5.2, table 5.4). The asymmetry index was calculated as the ratio of above-knee side-stance phase percentage of gait cycle to intact or below-knee side-stance phase percentage of gait cycle.[15] An asymmetry index of 1 signifies perfect symmetry. Across all subjects, a larger asymmetry index for the ASPL knee was indicative of longer above-knee swing time. For subjects 1, 2, 3, and 5 this resulted in greater asymmetry. For subjects 4 and 6 symmetry was improved with the ASPL knee (see figure 5.2D).

All subjects exhibited higher above-knee knee ranges of motion (ROMs) for the ASPL knee, indicating a greater ROM at the knee during the swing phase (see figure 5.3). Increased ROMs were also evident for the ASPL knee at the pelvis. This included greater pelvic rotation for the children with unilateral amputations and greater pelvic obliquity ROMs for children with bilateral amputations. For this latter group, reduced below-knee side knee ROMs were also observed.

For the children with unilateral amputations, kinetic measures indicated increased power generation and absorption on the intact side for the ASPL knees when compared with the conventional knees. This was accompanied by an increased intact-side dorsiflexion moment at the ankle for the ASPL knee (see figure 5.4, 5.5; table 5.3).

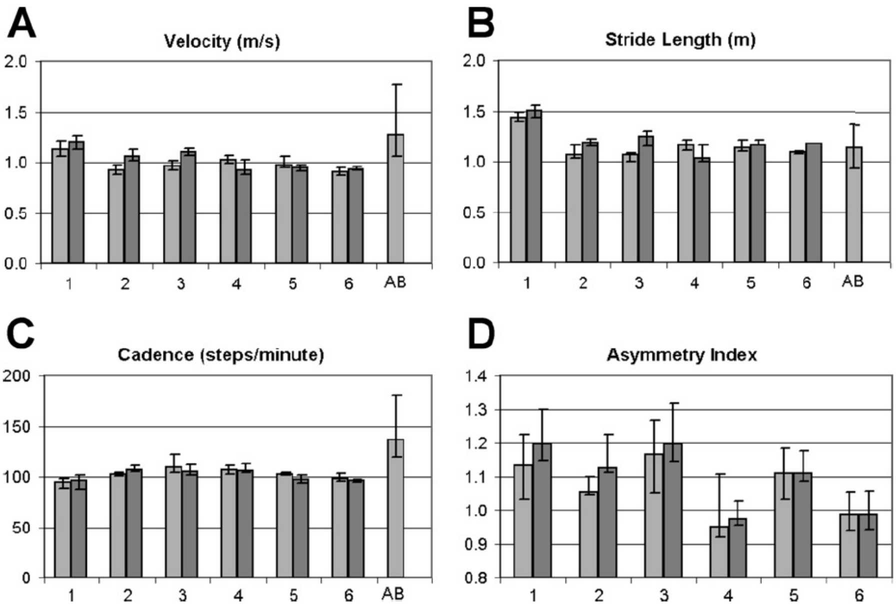


Figure 5.2: Spatiotemporal measures for: (A) velocity; (B) stride length; (C) cadence; and (D) asymmetry index. NOTE. Median values are presented, with error bars indicating ranges. Reference group is labeled (AB). The subject numbers on the abscissa correspond to those in table 5.1. Legend: Light bars indicate conventional knees and darker bars ASPL knees.

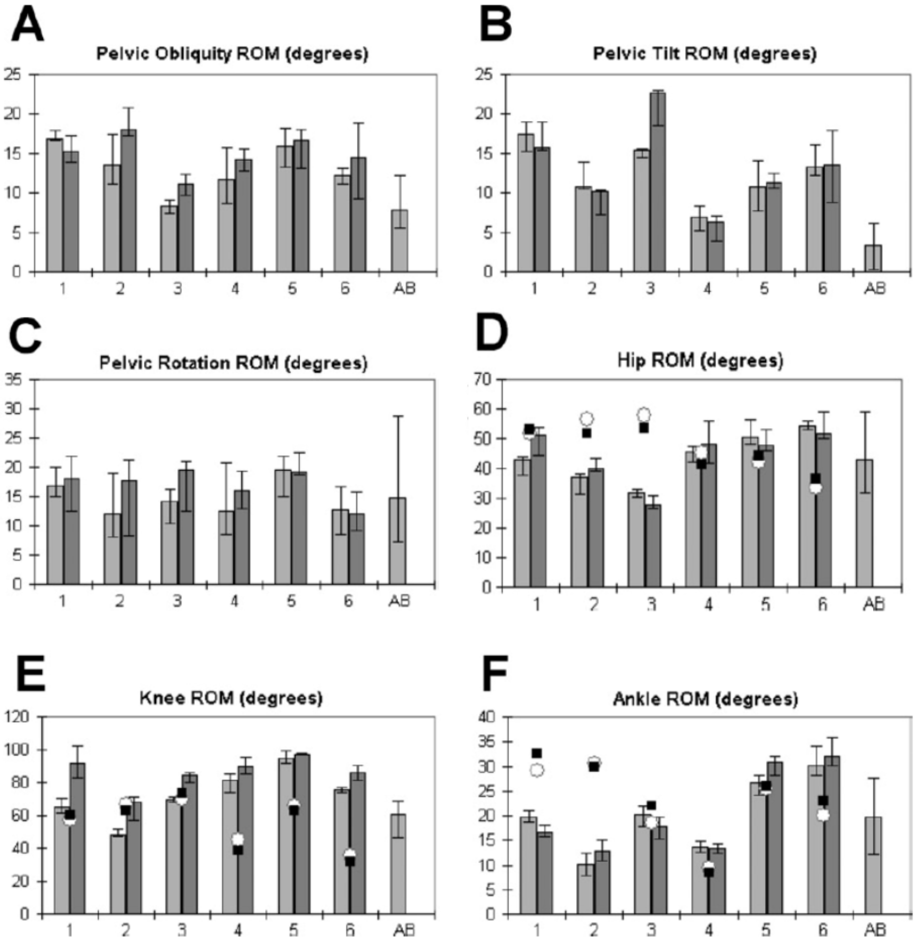


Figure 5.3: Kinematics for: (A) pelvic obliquity ROM; (B) pelvic tilt ROM; (C) pelvic rotation ROM; (D) hip ROM; (E) knee ROM and (F) ankle ROM. NOTE. Median values are presented, with error bars indicating ranges. Hollow circles and dark squares comprise the intact and below-knee side data for the conventional and ASPL knees, respectively. For clarity, ranges (error bars) are omitted on the intact and below-knee sides. For the reference group (AB), medians and ranges are reported. The subject numbers on the abscissa correspond to those in table 5.1. Legend: Light bars indicate conventional knees and darker bars ASPL knees.

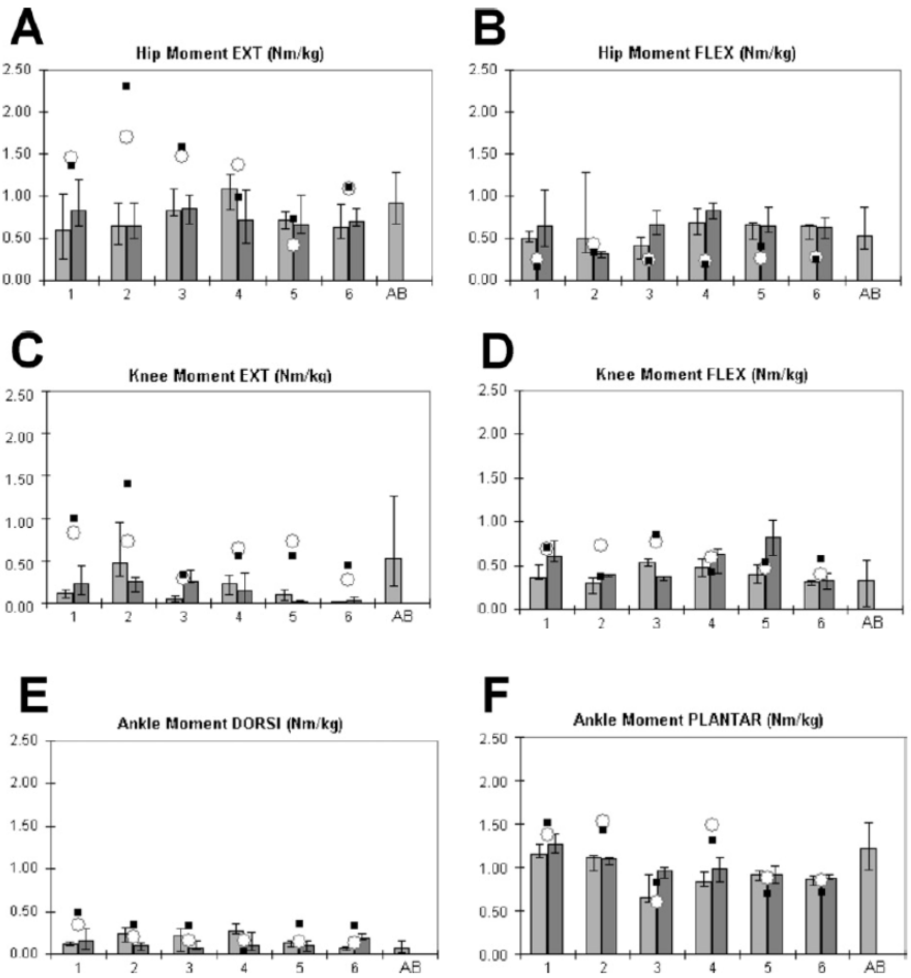


Figure 5.4: Internal joint moments for: (A) hip moment extension; (B) hip moment flexion; (C) knee moment extension; (D) knee moment flexion; (E) ankle moment dorsiflexion; and (F) ankle moment plantarflexion. NOTE. Median values are presented, with error bars indicating ranges. Hollow circles and dark squares comprise the intact and below-knee side data for the conventional and ASPL knees, respectively. For clarity, ranges (error bars) are omitted on the intact and below-knee sides. For the reference group, medians and ranges are reported. The subject numbers on the abscissa correspond to those in table 5.1. Abbreviations: DORSI, dorsiflexion; EXT, extension; FLEX, flexion; PLANTAR, plantarflexion. Legend: Light bars indicate conventional knees and darker bars ASPL knees.

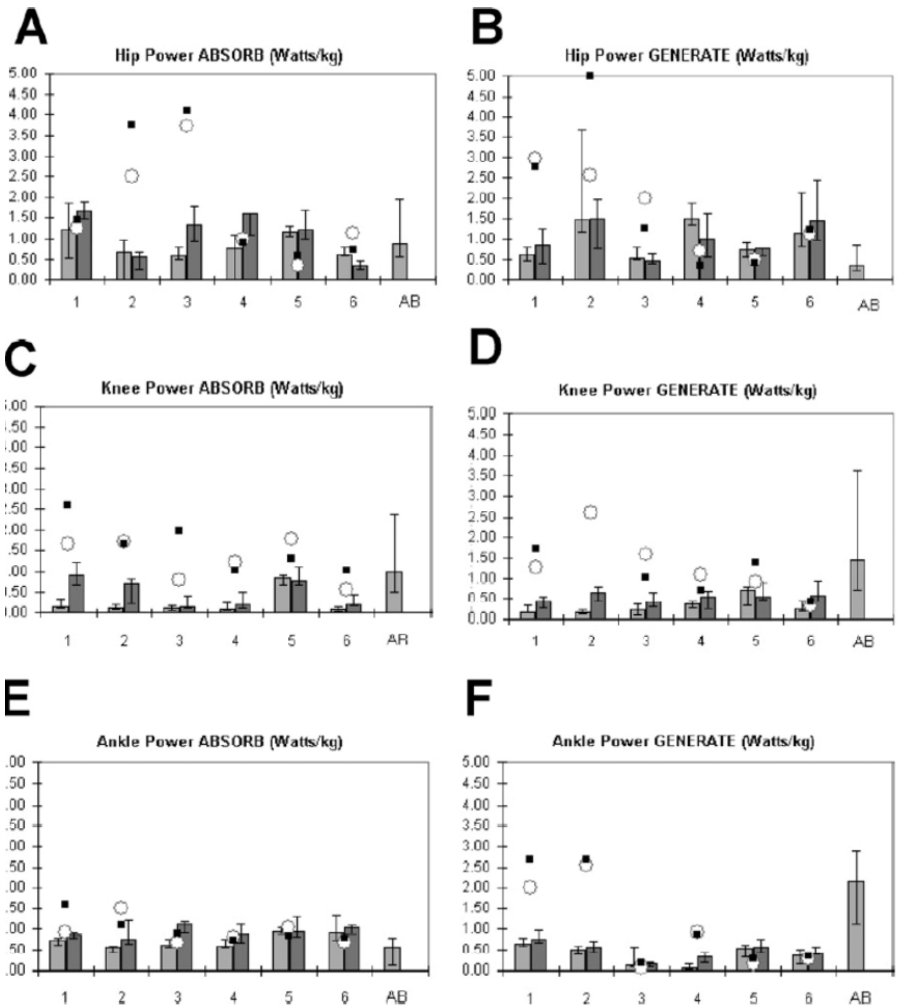


Figure 5.5: Joint powers for: (A) hip power absorption; (B) hip power generation; (C) knee power absorption; (D) knee power generation; (E) ankle power absorption; and (F) ankle power generation. NOTE. Median values are presented, with error bars indicating ranges. Hollow circles and dark squares comprise the intact and below-knee side data for the conventional and ASPL knees, respectively. For clarity, ranges (error bars) are omitted on the intact and_below-knee sides. For the reference group, the median and ranges for the group are provided. The subject numbers on the abscissa correspond to those in table 5.1. Abbreviations: ABSORB, power absorption; GENERATE, power generation. Legend: Light bars indicate conventional knees and darker bars ASPL knees.

Table 5.2: Statistical comparison of conventional and ASPL knees with parameters that show a trend across all subjects.

Gait Parameters	**Subjects**					
	1	2	3	4	5	6
Asymmetry index	0.075*	0.009*	0.806*	0.175*	0.754*	0.806*
Above-knee side						
Knee ROM	**0.009***	**0.009***	**0.009***	0.016*	0.602*	0.014*

NOTE. Values are *p* values. Boldface indicates *p*<0.01. *The subject's gait parameter value for the ASPL knee joint was higher than for the conventional knee joint.

Table 5.3: Statistical comparison of conventional and ASPL knees with parameters that show a trend for the children with unilateral amputations.

Gait Parameters	**Subjects**		
	1	2	3
Velocity	0.175*	**0.009***	**0.009***
Stride length	0.117*	**0.009***	0.016*
Pelvic rotation ROM	0.602*	0.175*	0.175*
Above-knee side			
Knee power generation	0.016*	0.014*	0.028*
Knee power absorption	**0.009***	0.014*	0.117*
Ankle power absorption	0.028*	0.014*	**0.009***
Intact Limb			
Hip flexion moment	0.251	0.806	0.465
Knee extension moment	0.047*	0.027*	0.465*
Ankle dorsiflexion moment	0.076*	0.142*	0.028*
Hip power absorption	0.251*	0.086*	0.347*
Ankle power generation	0.117*	0.806*	0.016*
Ankle power absorption	0.076*	0.014*	**0.009***

NOTE. Values are *p* values. Boldface indicates *p*<0.01. *The subject's gait parameter value for the ASPL knee joint was higher than for the conventional knee joint.

Table 5.4: Statistical comparison of conventional and ASPL knees with parameters that show a trend for the children with unilateral amputations.

Gait Parameters	**Subjects**		
	4	5	6
Cadence	0.754	**0.009**	0.176
Pelvic obliquity ROM	0.257*	0.754*	1.00*
Above-knee side			
Knee flexion moment	0.076*	0.016*	0.806*
Below-knee side			
Ankle plantarflexion moment	0.047	0.117	0.221

NOTE. Values are *p* values. Boldface indicates *p*<0.01. *The subject's gait parameter value for the ASPL knee joint was higher than for the conventional knee.

Discussion

This study compared the spatiotemporal, kinematic, and kinetic gait variables of 6 children wearing the ASPL and conventional knee joints. A case-series design was applied in consideration of the diverse gait patterns observed among the limb-deficient children in this study. This is a trait associated with above-knee amputee gait that is expounded in this study due to the heterogeneous nature of the group. The children varied in age, sex, levels of amputation, and in the types of prosthetic components they used. Three of the children had secondary limb deficiencies, and subject 3 used an ankle-foot orthosis on her intact limb.

Although gait data were collected 3-dimensionally, the majority of parameters presented here were limited to the sagittal plane. This approach is effective in describing prosthetic gait, as the majority of gait deviations occur in this plane.[16-18] The exception includes the kinematic data for the pelvis, where pelvic obliquity was used as an indicator of hip hiking.[19]

The subject group data well matched those reported by other studies. The spatiotemporal parameters measured presented here were in close agreement with those reported elsewhere.[20-22] Wilk et al,[1] however, reported similar walking speeds but much higher cadences. These differences may be attributed to the fact that the prosthetic knees used in their study had cadence responsive swing-phase control.

Comparison of ASPL and conventional knees

Spatiotemporal and kinematic parameters:

For the children with unilateral amputations the trend toward faster walking speed is a positive one. It is a preliminary indication that the ASPL knee joint may by effective in restoring, and possibly improving user function during gait, however more testing is required before these results can be generalized to the larger population. Furthermore, the trend does not extend to the children with bilateral amputations.

The higher ASPL than conventional knee asymmetry index is indicative of longer swing time with the ASPL knee joint. As expected this increased swing time is accompanied by increased and higher than normal above-knee–side knee ROMs for the ASPL knee. Both ASPL and conventional knee joints used in this study utilized simple friction-based swing phase controls, which were not designed to adapt to changes in walking speed. The greatest ASPL and conventional differences in temporal asymmetry and above-knee-side knee ROMs were seen for the children with unilateral amputations (p<0.01). This is expected, because these children walked considerably faster with the ASPL knees as compared with their conventional knees (p<0.01 for subjects 2 and 3). As part of future work it is important to consider applying cadence-responsive swing-phase control to the ASPL knee joint to allow for more normal gait characteristics over a range of walking speeds.[18,23-25]

Pelvic obliquity is an important indicator of the compensatory action of hip hiking which commonly prevails in above-knee prosthetic gait.[19] Hip hiking may be attributed to prostheses that are too long or provide insufficient foot clearance during the swing phase.[26] In this study, 5 of the 6 children exhibited a trend toward increased pelvic obliquity ROMs with ASPL, although only subject 3 showed a significant difference (p<0.01). Although it is possible that these were due to slight length discrepancies between the conventional and ASPL prostheses, as set up by the prosthetists, the trend may be evidence of the beneficial shortening of the polycentric knees during swing phase.[4,5] Future work will focus on increasing the anterior placement of the ASPL knee axis. This is a relatively simple modification performed by aligning the knee joint in slight flexion, but one that was not utilized in this study.

Kinetics:

One of the goals was to evaluate the muscular effort at the hip joint of the prosthetic side during stance phase. No trends were evident in either group that would suggest greater muscular effort with the ASPL knee joint. All of the knees that were tested were designed to be stable in early stance phase regardless of the internally applied hip moment. Therefore, differences in the peak hip extension moments between the ASPL and conventional knees were not expected. The above-knee side peak hip flexion moment associated with the knee flexion initiation in late stance also did not reveal any consistent differences between the conventional and ASPL knees. Two of the children did however have higher moments (p<0.01), and therefore the effects of alternate alignment strategies (i.e., relative anterior placement of knee axis) should be examined as part of future work.

The majority of intact side peak moments and powers for the children with unilateral amputations were higher with the ASPL knee than with the conventional knees. This is likely due to the faster walking speed that the children chose. The reason for faster gait is therefore not likely due to increased component efficiency. This is consistent with previous work,[6] in which children did not report any differences in perceived fatigue when comparing the ASPL and conventional knees.

Future work

Analysis of maximal stance-phase power generation and absorption for the hip, knee, and ankle joints did not reveal any notable differences in mechanical work adaptations between components. This suggests that the components have similar biomechanical characteristics, and require comparable muscular effort to control. However, a metabolic analysis of gait should be undertaken to further compare gait efficiency.

Future work will also aim to evaluate the effects of a more anterior placement of the knee axis in the ASPL knee joint to further enhance foot clearance. This anterior shift of the axis is easily obtained through alignment by introducing a slight amount of flexion at the knee during stance phase. The effects of this on the reduction of above-knee side hip flexion moments will also be evaluated.

Last, work is ongoing to accessorize the knee joint with a fluid-based swing-phase control mechanism. This will help to limit excessive swing-phase knee flexion ROMs as well as swing times for greater temporal symmetry at higher walking speeds.

Study limitations

A limitation of this study is the sample size and the diversity of the group studied. A larger sample is needed in order to more effectively draw out differences between components. A further limitation is that data for each component were collected during a single session and therefore does not account for day-to-day variations in gait. For able-bodied children, Steinwender et al[27] found between-day coefficients of variation for velocity, cadence, and stride length, of 8.0(2.3)%, 5.7(1.6)%, and 6.2(3.0)%, respectively. Assuming that prosthetic gait is susceptible to similar levels of day-to-day variability, one would except that differences, for example, the trend toward faster ASPL versus conventional knee velocities found for the unilateral group, would be reproducible, because a mean increase of 10.5% in velocity for the ASPL was measured for subjects 1, 2, and 3.

Conclusions

This study is important because it provides a preliminary biomechanical evaluation of a new type of stance-phase controlled knee joint shown in previous work to reduce the frequency of falls for children with above-knee amputations. For the 6 children who participated in this study, the biomechanical performance of the ASPL knee joint was shown to be comparable to conventional polycentric prosthetic knee joints. This is a positive result as it suggests that the benefits of more complex polycentric knee joint mechanisms can be realized via simpler single-axis designs. The results also suggest that the stance-phase control strategy that is effective in reducing falls, does not adversely affect the biomechanics of gait. However, replication of our study by others would help to support the generalizability of these outcomes. The goals of future work are to develop a cadence-responsive swing-phase controller to improve temporal symmetry and limit the excessive swing-phase knee flexion ROMs at faster gait speeds. Alternative knee axis alignments will also be tested to further increase foot clearance and ease of knee joint flexion initiation in late stance.

References

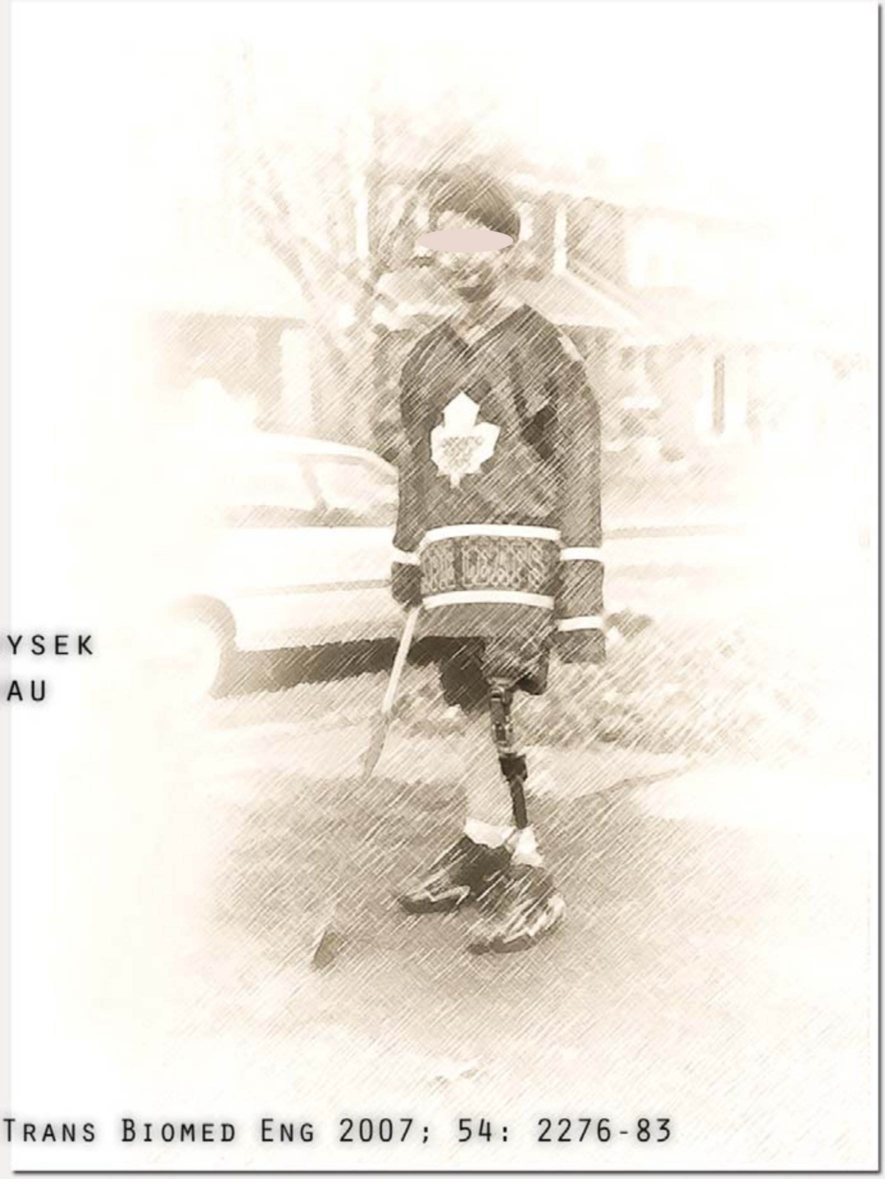
1. Wilk B, Karol, L Halliday S, Cummings D, Haideri N, Stepheson J. Transition to an articulating knee prosthesis in pediatric amputees. JPO 1999; 11: 69-74.
2. Andrysek J, Naumann S, Cleghorn W. Design characteristics of pediatric prosthetic knees. IEEE Trans Neural Syst Rehabil Eng 2004; 12: 369-378.
3. Cummings D. The missing link in pediatric prosthetic knees. Biomechanics 1997; 4: 163-8.
4. Breakey JW, Marquette SH. Beyond the four-bar knee. JPO 1998; 10: 77-80.
5. Radcliffe CW. Four-bar linkage prosthetic knee mechanisms: kinematics, alignment and prescription criteria. Prosthet Orthot Int 1994; 18: 159-73.
6. Andrysek J, Naumann S, Cleghorn W. Design and quantitative evaluation of a stance-phase controlled prosthetic knee joint for children. IEEE Trans Neural Syst Rehabil Eng 2005; 13: 437-43.
7. Schneider K, Hart T, Zernicke R, Setoguchi Y, Oppenhaim W. Dynamics of below-knee child amputee gait: SACH foot versus FLEX foot. J Biomech 1993; 26: 1191-204.
8. Schmalz T, Blumentritt S, Jarasch R. Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. Gait Posture 2002; 16: 255-63.
9.Johansson JL, Sherrill DM, Riley PO, Bonato P, Herr H. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil 2005; 84: 563-75.
10. van de Veen, P. G. An investigation of design criteria of modular endoskeletal lower limb prosthetics [Dissertation]. Twente, the Netherlands: University of Twente; 1989.
11. English RD, Hubbard WA, McElroy GK. Establishment of consistent gait after fitting of new components. J Rehabil Res Dev 1995; 32: 32-35.
12. Apkarian J, Naumann S, Cairns B. A three-dimensional kinematic and dynamic model of the lower limb. J Biomech 1989; 22: 143-55.
13. van der Linden ML, Solomonidis SE, Spence WD, Li N, Paul JP. A methodology for studying the effects of various types of prosthetic feet on the biomechanics of trans-femoral amputee gait. J Biomech 1999; 32: 877-89.
14. Bates B, James R, Dufek J. Single subject analysis. In: Stergiou N, editor. Innovative analysis of human movement. Champaign: Human Kinetics; 2004: 3-28.
15. Burkett B, Smeathers J, Barker T. Walking and running inter-limb asymmetry for Paralympic trans-femoral amputees, a biomechanical analysis. Prosthet Orthot Int 2003; 27: 36-47.
16. Perry J, Burnfield JM, Newsam CJ, Conley P. Energy expenditure and gait characteristics of a bilateral amputee walking with C-leg prostheses compared with stubby and conventional articulating prostheses. Arch Phys Med Rehabil 2004; 85: 1711-7.
17. Seroussi RE, Gitter A, Czerniecki JM, Weaver K. Mechanical work adaptations of above-knee amputee ambulation. Arch Phys Med Rehabil 1996; 77: 1209-14.
18. Jaegers SM, Arendzen JH, de Jongh HJ. Prosthetic gait of unilateral transfemoral amputees: a kinematic study. Arch Phys Med Rehabil 1995; 76: 736-43.
19. Michaud SB, Gard SA, Childress DS. A preliminary investigation of pelvic obliquity patterns during gait in persons with transtibial and transfemoral amputation. J Rehabil Res Dev 2000; 37: 1-10.
20. Zernicke RF, Hoy MG, Whiting WC. Ground reaction forces and center of pressure patterns in the gait of children with amputation: preliminary report. Arch Phys Med Rehabil 1985; 66: 736-41.

21. Hoy MG, Whiting WC, Zernicke RF. Stride kinematics and knee joint kinetics of child amputee gait. Arch Phys Med Rehabil 1982; 63: 74-82.
22. Hicks R, Tashman S, Cary JM, Altman RF, Gage JR. Swing phase control with knee friction in juvenile amputees. J Orthop Res 1985; 3: 198-201.
23. Nolan L, Wit A, Dudzinski K, Lees A, Lake M, Wychowanski M. Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees. Gait Posture 2003; 17: 142-51.
24. Murray MP, Sepic SB, Gardner GM, Mollinger LA. Gait patterns of above-knee amputees using constant-friction knee components. Bull Prosthet Res 1980; 17: 35-45.
25. James U, Öberg K. Prosthetic gait pattern in unilateral above-knee amputees. Scand J Rehabil Med 1973; 5: 35-50.
26. Mensch G, Ellis PE. Physical therapy management of lower extremity amputations. Rockville: Aspen; 1986.
27. Steinwender G, Saraph V, Scheiber S, Zwick EB, Uitz C, Hackl K. Intra subject repeatability of gait analysis data in normal and spastic children. Clin Biomech (Bristol, Avon) 2000; 15: 134-9.

Suppliers and supplies

a. Vicon 370; Vicon Peak, Oxford, UK.
b. Kistler 9261; Kistler Instrumente AG, Winterthur, Switzerland.
c. Bertec 4060; Bertec Corp, Columbus, OH.
d. SPSS Inc, Chicago, IL.
e. Össur hf, Reykjavik, Iceland.
f. Otto Bock HealthCare GmbH, Duderstadt, Germany.
g. Seattle Limb Systems, Poulsbo, WA.
h. College Park Industries, Fraser, MI.

6 An electromechanical swing-phase controlled prosthetic knee joint for conversion of physiological energy to electrical energy: Feasibility study



J. Andrysek
G. Chau

IEEE Trans Biomed Eng 2007; 54: 2276-83

Abstract

Objective: Microprocessor-controlled prostheses facilitate a more natural and efficient gait for individuals with above-knee amputations by continually adjusting the level of swing-phase damping. One caveat associated with these technologies is that the user must charge the on-board batteries on a daily basis. It is therefore the aim of this study to examine the feasibility of using an electromechanical system to provide prosthetic swing-phase damping and concomitantly the function of converting physiological energy that is normally dissipated during the swing-phase, to electrical energy.

Methods: Gait data from a single subject and data from a kinematic simulator were used to develop an empirical model.

Results: The results indicate that a DC motor-based damper can replicate peak-damping torques during gait to accuracies between 84.9% and 100%, on average across gait conditions. The potential for generating electricity was realized for three of the four tested conditions with power generation ranging from 0.20W to 0.54W.

Conclusions: The findings in this study indicate that an electromagnetic system has appropriate characteristics for use in swing-phase control and also has the potential to recover energy under particular conditions.

Introduction

For able-bodied gait, control at the knee joint during the swing-phase is based almost entirely on passive damping. During the swing-phase passive moments first limit heel-rise as the knee joint flexes and then slow the shank down as the knee joint fully extends.[1] For persons with above-knee amputations this has led to the successful implementation of energy dissipating swing-phase control knee mechanisms. Historically, these controllers have utilized mechanical friction, hydraulic and pneumatic-based dampers, and more recently microprocessor control to augment the performance, improve gait efficiency[2-4], increase smoothness, and reduce gait deviations.[5]

Microprocessor-based knee joint prostheses use feedback control and unlike conventional technologies adjust to a broader range of gait conditions. They work by continually gathering temporal, kinematic and/or kinetic data, which are used to modulate the knee damping levels. High capacity energy cells such as lithium-ion batteries provide power to the sensors, microprocessor and damper-controlling actuators. The energy cells require daily charging, which is a caveat of all currently available microprocessor-based technologies.

The main objective of this study was to evaluate the function of an electromagnetic motor as a passive swing-phase controller. Specifically, the goal was to evaluate and compare the damping characteristics of the electromagnetic motor to current state-of-the-art fluid based systems. The secondary goal of this study was to examine the feasibility of utilizing the electromagnetic motor to convert physiological energy to electrical energy for recharging on-board batteries, thus combating the aforementioned drawback. Mechanisms that generate electrical power ‘parasitically’ during walking are receiving considerable attention on other fronts, predominantly targeting the elimination of batteries in wearable electronic devices, such as cell phones. In contrast to the implementation proposed here, the devices use piezoelectric materials and electromagnetic generators, implanted in shoes, to generate energy during loading.[6,7] While it was the goal here to determine whether energy could be converted and specifically under what conditions, it remains the focus of future work to establish whether the levels of energy recovery are adequate to eliminate the need to charge on-board batteries altogether. Hence, it is the eventual goal of this initiative to develop a self-energizing microprocessor-based swing-phase control mechanism for use in above-knee prostheses.

Background

The fundamental components of the proposed system comprise of a geared direct current (DC) brushed motor functioning as a damper and a generator. The basic equations describing a DC generator are

$$V_T = E_A - I_A R_A \qquad (6.1)$$

$$E_A = k\Phi\omega \qquad (6.2)$$

$$\tau = k\Phi I_A \qquad (6.3)$$

where V_T is the voltage across the motor terminals, E_A the internally generated voltage, I_A the armature current, R_A the armature resistance, k the motor constant, Φ the magnetic flux, ω the rotor speed, and τ the rotor torque.

Equation 6.4 is obtained by substituting equations 6.2 and 6.3 into equation 6.1. The expression is then simplified and constant terms are consolidated so that $a = k\Phi$ and $b = R_A/k\Phi$, thus yielding equation 6.5.[8] Based on equation 6.5 it is apparent that for a given value of V_T, motor torque (τ) is positively proportional to motor speed (ω). This velocity dependent torque characteristic, similar to that of traditional fluid-based dampers, provides the basis for swing-phase control. Furthermore, the amount of generated current that is redirected back into the motor, represented by V_T, gives means for controlling the swing-phase damping levels (τ). For example, the maximum damping (τ) is possible when a short circuit is produced at the motor terminal (i.e. V_T=0). The aforementioned description can be illustrated by plotting ω and τ in equation 6.5, whereby the slope is defined by b/a and the y intercept is V_T/a.

$$k\Phi\omega = V_T + \tau R_A / k\Phi \qquad (6.4)$$

$$a\omega = V_T + b\tau \qquad (6.5)$$

Methodology

Feasibility of swing-phase knee damping - overview

The following protocols were applied in evaluating the feasibility of utilizing a geared motor for swing-phase control. First, using camera-based gait analysis, sagittal plane kinematic data (knee joint angles and angular velocities) were measured for a single subject wearing conventional fluid-based prosthetic knee joint components. These data were applied to a kinematic simulator in order to replicate the behaviour of the prosthetic knee joint components, so that their damping characteristics could be measured. Secondly, the damping characteristics were measured for a specifically selected geared motor. Damping characteristics were measured over a range of speeds and damping levels. The latter was adjusted by changing the amount of current flow back to the motor, or in effect V_T. These data were then used in an empirical model to predict the damping response of the geared motor during gait, and facilitate a comparative analysis with the conventional knee joints.

Feasibility of generating current to charge batteries - overview

The protocol for determining energy recovery for walking required one additional experiment. The amount of recovered energy is dependent on motor speed (angular velocity) and damping level (i.e. amount of generated current redirected back into the motor). Current that is not redirected back into the motor is used to charge the batteries. Therefore, the relationships between charging current, angular velocity and damping levels were established and an empirical model was applied to estimate the levels of energy recovery during gait.

Subject

Gait analysis involved a 15-year old male with a unilateral above-knee amputation. His regular prosthesis comprised of an energy storing foot[a], a polycentric knee joint with hydraulic swing-phase control[b] (HYD), and carbon fiber socket with belt suspension. The swing-phase damper was optimally set for both regular and fast walking speeds, as determined by a qualified prosthetist.

Gait analysis

The gait analysis was conducted using a seven-camera VICON 370[c] data capture system sampling at 60Hz. The subject donned tight fitting shorts. Reflective markers were placed on the heads of the first and fifth metatarsals, midpoint between the base of the first and fifth metatarsal, and posterior calcaneous, the lateral ankle malleolus, lower anterior shank, head of the fibula, lower anterior thigh, lateral thigh, greater trochanter, anterior superior iliac spine, and sacrum to define the foot, shank, thigh and pelvis segments. Three additional markers (medial malleolus, lateral and medial condyles of the femur) were placed to define the body-embedded coordinate systems and joint centres for a neutral standing static frame.

Coordinate data were passed through a low-pass 6Hz digital Butterworth filter and custom-defined programs were used to process data. Segment rotations were defined using an existing mathematical Euler sequence of coronal, followed by transverse and then sagittal plane rotations.[9]

Data collection was performed over two sessions. During the first session, data were collected with the subject's regular prosthesis, which comprised of the knee joint with hydraulic swing-phase control (HYD). Gait trials were performed along a 10-meter walkway. The subject was instructed to walk at his regular, self-selected (SS) walking speed and then at his fast walking (FW) speed. At the end of session 1, the knee joint in the subject's prosthesis was exchanged for a single-axis knee with pneumatic (PN) swing-phase control. Swing-phase control was optimally adjusted by a prosthetist. After one week of accustomization the subject returned to the gait laboratory and data were collected with the pneumatic knee joint. At the end of the session the pneumatic swing-phase controller was disabled and walking data were collected at both self-selected and fast walking speeds.

Experimental setup

A kinematic simulator was developed (figure 6.1). It comprised of an electric wheelchair motor to drive the knee joints and subsequently the geared motor, an optical encoder and converter[d], and a torque sensor[e] to record position and torque, respectively. The simulator was designed to provide drive at constant velocity (direct drive) and sinusoidal drive using a linkage system. The linkage system facilitated the adjustment of wave amplitude. Period was adjusted by varying the speed of the drive motor. Data from the kinematic simulator were acquired using the NI 6025-E data acquisition board[f], Measurement Studio software[f], and a custom written program in Visual Basic.NET[g]. Position and torque were sampled at 25Hz and imported into an Excel worksheet for post analysis. Position data were differentiated once for angular velocities and twice for angular accelerations.

Electromagnetic generator

The selection of the geared motor involved the consideration of a number of parameters including maximum rated speed, maximum rated torque, rated voltage, overall size and overall weight. A 12V DC brushed motor (Series 2338[h]) and planetary gear head with 159:1 gear ratio (Series 30/1[h]) were purchased. With its compact size (30mm in diameter and 89mm in length) and low weight (270 grams), this motor gear head combination is suitable for application to prosthetics.

Electronic circuit

The circuit that was developed for bench testing is shown in figure 6.2. A F-MOS FET[i] (K3G44) was used to modulate the current flow between the geared motor and Nickel-Metal Hydride batteries [j] (1.2V per cell and 860mAh capacity), or in effect V_T. This was achieved by changing the MOS FET gait voltage (V_{GSS}). The amount of charging current was measured using ammeters A1 and A2.

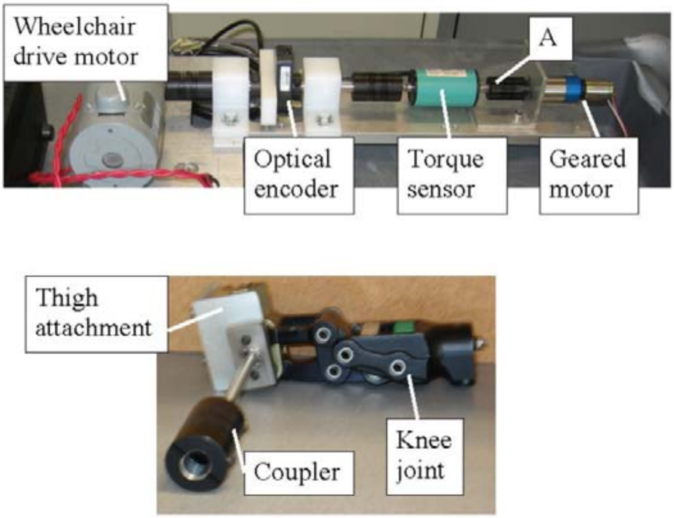


Figure 6.1: Kinematic simulator used in bench tests (constant velocity drive shown). Top: Setup used for geared motor tests. Bottom: Custom adaptor developed to attach to the upper (thigh) connector of each of the two prosthetic knees. The adaptor comprised of a shaft that aligns coincidentally with the knee joint axis and a flexible coupler to attach at point labeled ‘A’ in top figure.

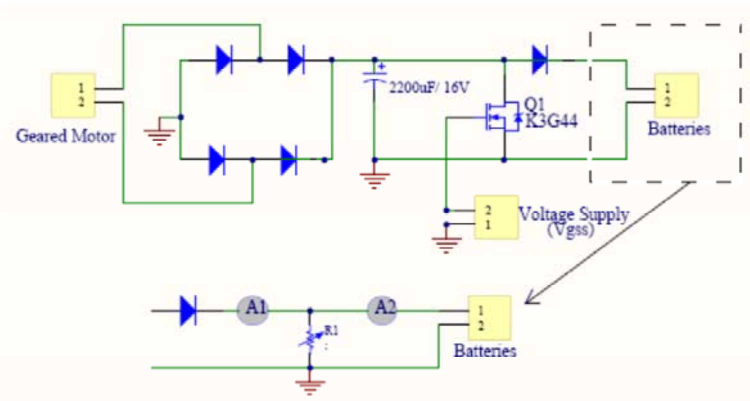


Figure 6.2: Circuit used in bench testing. V_{GSS} represents the MOS FET gait voltage used to modulate the amount of generated current that is redirected back into the motor. The amount of charging current was measured using ammeters A1 and A2.

Damping profiles of fluid-based prosthetic knees - experiment 1

The kinematic simulator was set up for sinusoidal drive. A custom adaptor was developed to attach to the upper (thigh) connector of each of the two prosthetic knees. The adaptor comprised of a shaft that was aligned coincidentally with the knee joint axis (figure 6.1). In the case of the polycentric knee joint where no single axis of rotation exists, the adaptor axis was aligned with the proximal, anterior axis. During testing, the bottom (shank) portion was securely clamped to the bench top and the adaptor shaft coupled to the simulator drive shaft. A flexible coupler was used to compensate for initial misalignment and dynamic misalignment from the polycentric motion of the hydraulic knee joint.

The amplitude and period of the sinusoidal drive were adjusted to match the subject's swing-phase knee kinematics, as measured in the gait lab. This process was repeated for the two walking speeds and two knees. Torques and positions were sampled.

Damping limits of geared motor - experiment 2

The kinematic simulator was set up for constant velocity drive. The geared motor was driven at velocities ranging from 100º/sec to 450º/sec in increments of 50º/sec. This process was then repeated once with the motor terminals connected together (short circuit, V_T =0), and twice more with the geared motor connected to the electronic circuit, as shown in figure 6.2. First, F-MOS FET gate voltage (V_{GSS}) was set to zero, and then to 5V. For each condition torque data were sampled and averaged.

Damping control with geared motor - experiment 3

The kinematic simulator was set up for constant velocity drive and geared motor connected to the circuit. The geared motor was driven at 100 º/s up to 450º/s in increments of 50º/s. V_{GSS} was varied in 0.1V increments between 0 and 5.0V. For each condition position and torque data were sampled and averaged. The effective range of V_{GSS} was determined (3.7 to 4.4V).

Current for charging batteries - experiment 4

The kinematic simulator was set up for constant velocity drive and the geared motor was connected to the circuit. A variable resister (*R1*) was used to load the circuit to drain the batteries. Two ammeters (*A1* and *A2*) were applied to measure current (figure 6.2). With V_{GSS} = 0V, the resistor was adjusted to draw 50mA (*A1*). The motor speed was increased until the generated current (*A2*) was also 50mA. The motor speed was recorded. This was then repeated for current values up to 500mA in increments of 50mA and V_{GSS} from 3.7V to 4.4V, in 0.1V increments.

Results

The spatiotemporal data from the gait analysis are presented in table 6.1. The sagittal-plane knee kinematics are shown in figure 6.3a and b.

The measured knee torques from experiment 1 for the two fluid-based knees are presented in figure 6.3c. With the exception of the hydraulic knee joint during fast walking the torques produced were similar for all conditions. During flexion and extension peak torques of approximately 2Nm were measured. The hydraulic knee during fast walking produced a knee extension torque in excess of 3Nm. Figure 6.3d exemplifies the comparison of the knee angles and angular velocities measured in the gait lab and those produced in the kinematic simulator. From experiment 2, the geared motor under open circuit conditions produced a constant torque of less than 0.2Nm, for angular velocities below 350º/s. The short-circuit test produced torques proportional to angular velocity that were in excess of 3.5Nm at 300º/s (figure 6.4a). From experiment 3 with the circuit the range of torques was reduced. The lower boundary (V_{GSS}=0V) remained about the same initially and then at 208 º/s steadily increased. At the top end (V_{GSS} = 5.0V), the torque was slightly reduced from the maximum established in experiment 2 (figures 6.4a and b).

Based on experiment 4, charging of batteries was possible for angular velocities in excess of 208º/s, for V_{GSS}= 0 (figure 6.4c). For V_{GSS}>4.0V, charging was not possible because current could not be produced without exceeding the maximum rated speeds of the motor and gear head.

Table 6.1: Spatiotemporal measures.

		Velocity (m/s)	Stride Length (m)	Cadence (steps/s)	Stance-phase % of gait cycle	
					Prosthetic	Intact
No swing-phase control	SS	1.15	1.51	1.52	54.9	66.0
	FW	1.39	1.64	1.69	56.4	63.5
Pneumatic	SS	1.12	1.38	1.62	57.2	65.7
	FW	1.37	1.62	1.70	56.4	62.5
Hydraulic	SS	1.05	1.43	1.46	56.1	64.0
	FW	1.43	1.68	1.70	*	*

*Intact side data were not obtained for fast walking with hydraulic knee due to an insufficient capture volume. SS ≡ Self selected walking speed. FW ≡ Fast walking speed.

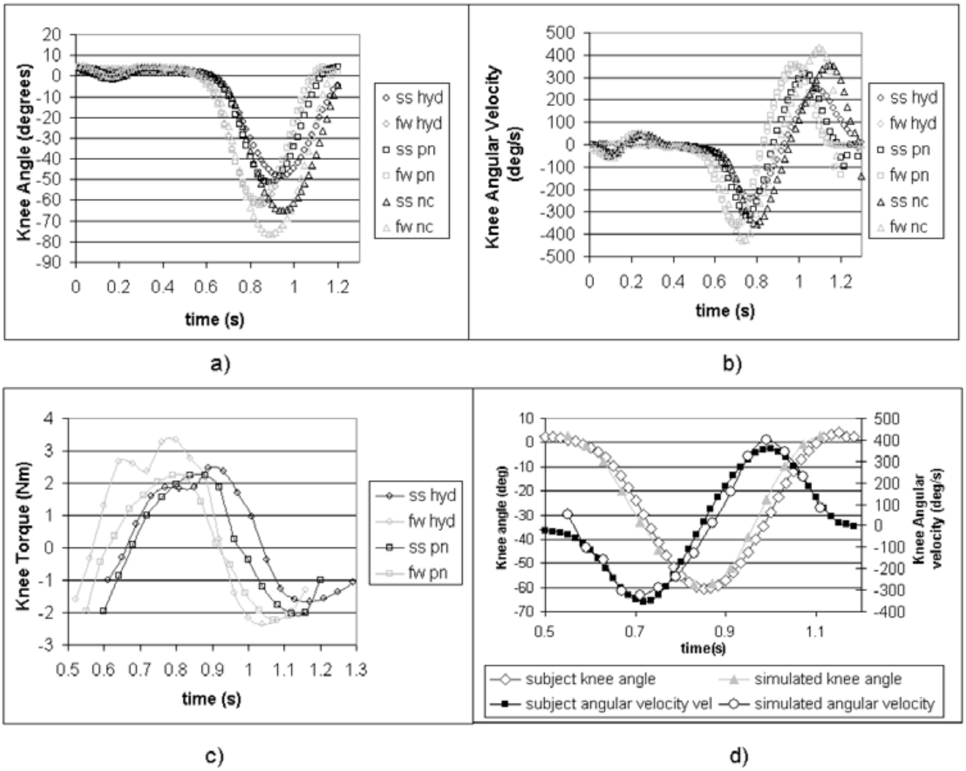


Figure 6.3. (a) Angle, (b) knee angular velocity gait data, and (c) torque data for the fluid-based knee joints; (d) exemplified knee angle and angular velocity data for actual (gait lab) and simulated (bench tests) for SS speed with the hydraulic damper.

Swing-phase knee damping - gait model

The data from experiment 3 (figure 6.4b) were applied to the subject's gait kinematics and the passive knee torques as determined in experiment 2. For each point of the gait cycle, the angular velocities were matched and V_{GSS} determined so as to provide the desired damping level (i.e. to match the fluid-based knees). Linear interpolation was applied for in-between values of V_{GSS} and values for angular velocities that were between negative 100º/s and 100º/s (figure 6.5).

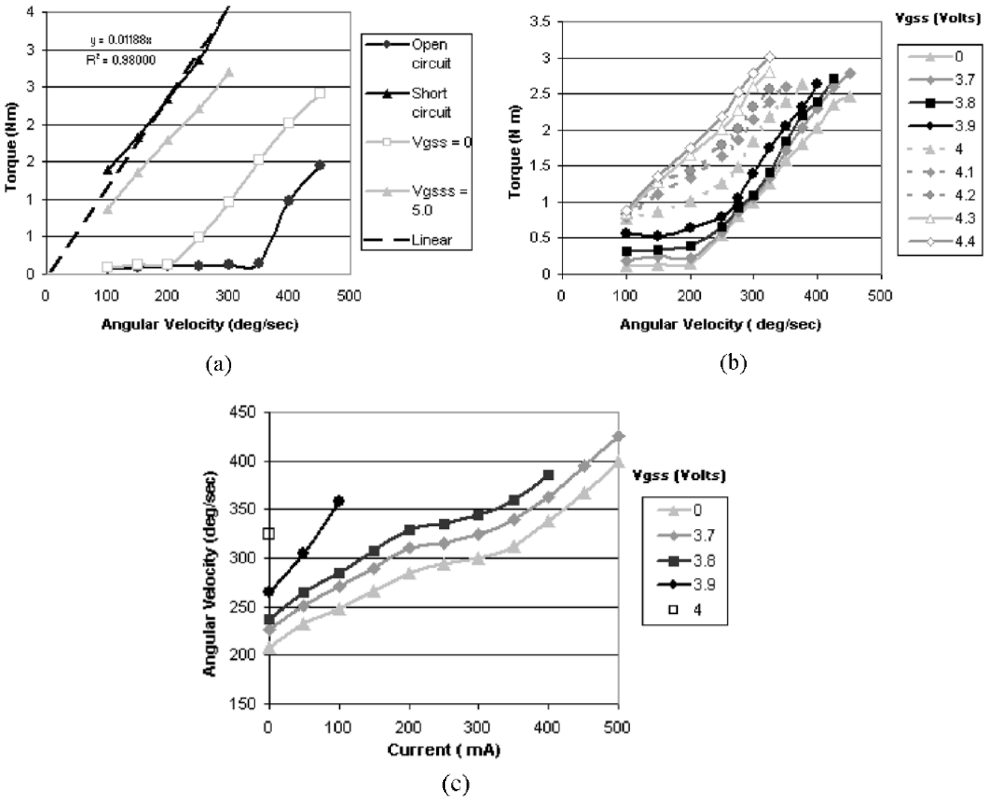


Figure 6.4: Geared motor: (a) damping limits; (b) damping control; and (c) charging current.

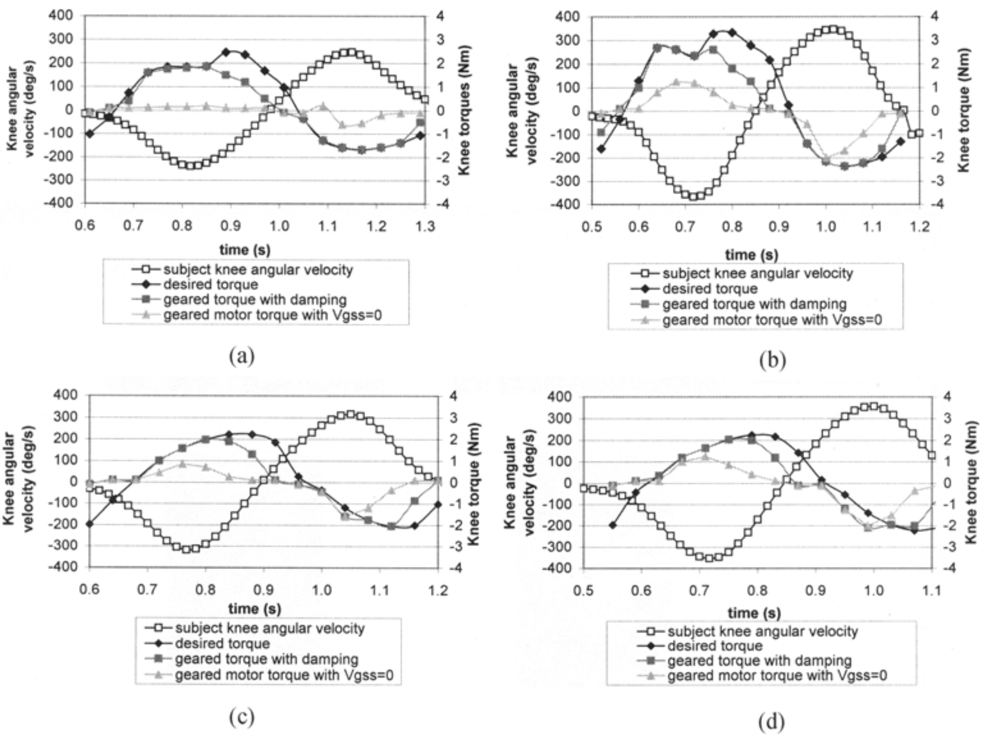


Figure 6.5: Comparison of geared motor torque (modeled for V_{GSS} = 0 and with optimal damping) with desired torque (fluid-based dampers): (a) SS walking speed with hydraulic; (b) FW with hydraulic; (c) SS walking speed with pneumatic; and (d) FW with pneumatic.

Two attributes of the data in figure 6.5 are summarized in table 6.2. The first is the ability of the geared motor to produce the necessary peak damping torque. For each condition, the peak flexion torque corresponds to the maxima seen in figure 6.5 and the peak extension torque the minima. The ratios between the geared motor and conventional knees for each global maxima and minima are presented as percentages, calculated by dividing motor torque by conventional knee joint torque. On average, over the four conditions, the geared motor produced 84.0% of the desired peak flexion torque and 98.7% of the peak extension torque (table 6.2).

The second part of the analysis is a comparison of the entire torque curves. The RMS error, representing the overall differences between the geared motor and conventional knee joint torque curves, was calculated using all of the data points comprising the torque curves. This was repeated for all four conditions. These values ranged from 0.59Nm for the hydraulic knee joint at the self-selected walking speed to 0.84Nm for the pneumatic knee joint during fast walking.

Table 6.2: Summary of geared motor swing-phase control results

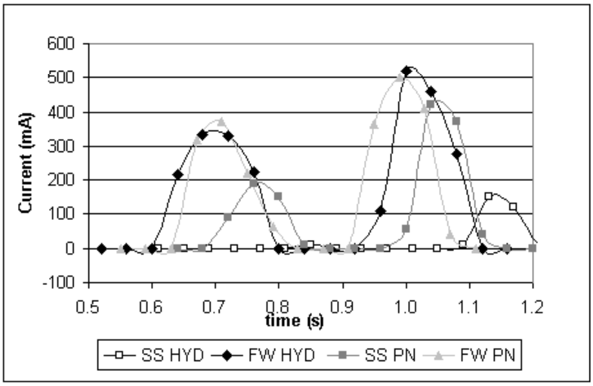
Parameter	**Hydraulic**		**Pneumatic**		**Ave-rage**
	SS	**FW**	**SS**	**FW**	
Peak flexion torque (Nm)	1.9	2.7	2.0	2.0	2.1
Difference in peak flexion torque (%)	75.9	80.5	89.0	90.5	84.0
Peak extension torque (Nm)	1.7	2.4	2.0	2.1	2.0
Difference in peak ext. torque (%)	100.0	100.0	100.0	94.7	98.7
RMS error (Nm)	0.59	0.84	0.72	0.82	0.74

Charging current - gait model

Data from experiment 4 were used to model charging current. For each point of the gait cycle the angular velocities and V_{GSS}, as determined above, were used along with data of figure 6.4c. The results are presented in figure 6.6 and summarized in table 6.3.

Table 6.3: Summary of charging analysis results.

Parameter	**Hydraulic**		**Pneumatic**		**Average**
	SS	**FW**	**SS**	**FW**	
Pmax (Watts)	0.47	8.01	4.53	5.37	4.60
P1 (Watts)	0.00	0.21	0.20	0.54	0.24
P2 (Watts)	0.10	0.87	0.50	0.92	0.60
P3 (Watts)	0.57	3.28	1.95	3.39	2.30
P1/Pmax (%)	0.00	2.64	4.47	10.06	4.29
P2/Pmax (%)	2.47	10.88	10.96	17.07	10.34
P2/P3 (%)	17.20	26.56	25.45	26.99	24.05



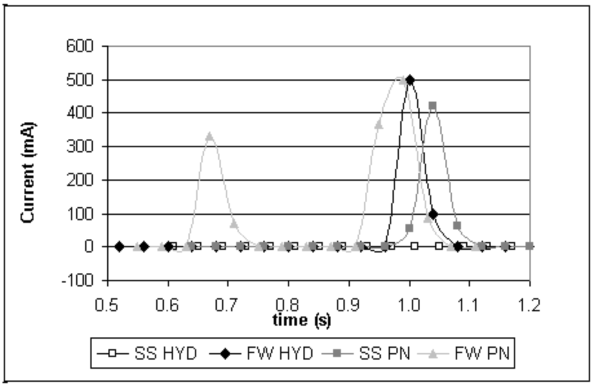


Figure 6.6: Model-based current for charging batteries: (a) for V_{GSS} = 0 and (b) with swing-phase damping.

The average swing-phase power absorbed by the fluid-based dampers was 4.6W (table 6.3). This power (*Pmax*) is potentially available for charging the batteries. It is calculated as the product of the knee angular velocities and torques. The efficiency of energy recovery (*P1*) is about 4.3% of *Pmax* as based on the average predicted current and a 6-volt circuit (5 batteries at 1.2V each). The losses are attributed to three factors. First, there are losses associated with the motor and gears that convert mechanical energy to electrical energy. The 2338-series motor with the 30/1 gear head is specified by the manufacturer to be 60% efficient. Secondly, some energy is lost because it is redirected back to the motor to provide swing-phase damping, where it is dissipated in the form of heat. This can be determined by calculating the power (*P2*) when V_{GSS} = 0. As before, the power is based on the current produced for a 6-volt circuit. On average about 10.3% of *Pmax* is converted to electrical energy, as compared to 4.3% when swing-phase damping is provided. Finally, losses occur because charging current is only produced for angular velocities above 208º/sec. The energy lost for velocities below 208º/s is estimated by dividing *P2* by *P3* (the average product of the gear motor torques and knee angular velocities for $V_{GSS} = 0$). On average, only 24% of the energy is utilized.

Discussion

The concept of an energy recovering prostheses was previously explored, although always in the context of entirely mechanical systems.[10,11] The preliminary work presented here pertains to the development of an energy-recovery system to minimize the daily maintenance requirements associated with microprocessor-controlled prostheses. At the same time, and in contrast to conventional approaches that utilize fluids, the work explores the application of a geared motor for swing-phase damping.

In this study, gait analysis provided the kinematic data used to model the function of the proposed swing-phase controller. In order to eliminate the errors associated with estimation of kinetics by inverse dynamic methods, which stem in large part by limited accuracy in estimating the inertial properties of prostheses, measurements of torque were obtained directly.[1] Patil *et al.*[12] and Zarrugh & Radcliffe[13] used direct measurement of chamber pressures in pneumatic swing-phase controllers to determine the damping torques during walking. Their protocol presented a challenge here, since one of the knee joints was a commercial unit and could not easily accommodate pressure transducers. Hence an alternative protocol was applied whereby kinematic data were initially collected in a gait lab, and kinetic data subsequently measured using a kinematic simulator.

For simplicity, the gait model assumed that passive torque was exclusively a function of angular velocity, and therefore the effects of inertial properties of the rotor and gears motor were assumed to be negligible. This assumption was tested by driving the geared motor in a sinusoidal motion at 1.25Hz and amplitude of 65º, closely corresponding to the swing-phase kinematics of our subject at his self-selected walking speed. The output torque was measured. Torque was also predicted using the equation of the fitted curve for the upper boundary of damping (figure 6.4a). Predicted and actual torque profiles are presented in figure 6.7. Differences between the curves are small, and as predicted, mainly attributed to the effect of angular accelerations which are also plotted for comparison.

Swing-phase damping

From figures 6.4a and b, it is evident that the relationship between the damping torque and angular velocity is positively proportional. This underpinning characteristic of the electromagnetic motor makes its application in prosthetic swing-phase control viable and useful. Subsequently, the effectiveness of damping is in large part a function of the specific design parameters of the system, including the size and type of motor, gear head ratios and electronic circuitry. These parameters may be optimized with subsequent design iterations of the system, and are likely to lead to further improvements in swing-phase control.

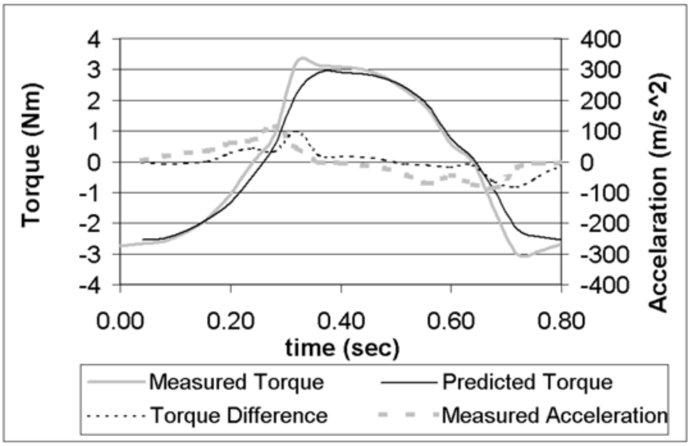


Figure 6.7: Predicted versus measured torque for a sinusoidal input.

With the current system, on average the geared motor produced 84.0% of the desired peak flexion torque and 98.7% of the peak extension torque (table 6.2). In all cases, the torques closely matched the desired values during initial knee flexion and also during initial knee extension (figure 6.5). The geared motor was, however, not able to produce torques to match those of the pneumatic and hydraulic knees in the later stages of knee flexion and again knee extension, resulting in a mean RMS error of 0.74Nm across the four testing conditions. This appears to be in large part attributed to the fact that the timing of the peak torques produced by the fluid-based prosthetic knees is delayed and not matched to the peak angular velocity. This may be due to a system delay in the pressurization of the cylinder chambers, although it is not entirely clear whether this delayed onset of the peak torque is a favourable characteristic, and whether the proposed system should attempt to mimic it. In the case that it is a desired characteristic, a geared motor capable of producing higher torques at lower speeds would be needed. The 3242 series motor and 32/3 series planetary gear head[h] are rated for 6.5Nm. The overall mass of 435g is still reasonable for prosthetic applications.

The peak flexion and extension moments measured were somewhat lower than those reported in other studies of 5 to 10Nm.[12,13] There are two possible explanations for this. First, the prosthesis used by our subject incorporated lightweight composite materials (foot and shank), unlike the prostheses described in the other two studies. Secondly, the prosthesis used in this study was fabricated for an adolescent and would therefore be lighter than the adult prostheses used in the other two studies. This further supports the previous conclusion that a higher capacity geared motor, for example the 3242 series may be required.

Energy recovery

The potential for generating electricity was realized for three of the four conditions with power generation ranging from 0.20W to 0.54W. Walking with the hydraulic-based knee joint at the self-selected speed did not produce a charging current, hence *P1*= 0W. This was likely a consequence of the subject's slower walking speed with the hydraulic than with both the pneumatic swing-phase damper and when no swing-phase damping was applied (table 6.1). The slower velocity was associated with a lower cadence and knee flexion angle (figure 6.3a), all contributing factors to the low knee angular velocities and lack of charging current. For healthy adult amputees, walking speeds in excess of 1.1m/s are common.[14-16] Slower speeds, such as the one measured for the SS HYD condition, tend to be associated with the gait of elderly patients and the use of low-level components such as mechanical friction swing-phase control.[17,18] Therefore, the slower walking speed for this condition may be indicative of inadequate knee joint function, and possibly ill-tuned swing-phase controller, despite taken efforts. Furthermore, providing a healthy active amputee with effective swing-phase control, which is the goal of this initiative, should facilitate higher self-selected walking speeds (i.e. >1.1m/s), and consequently adequate energy recovery.

Moreover, in order to facilitate charging at lower angular velocities, and possibly slower walking speeds, one of two system design modifications are possible. The first is to select a motor with a higher speed constant. For example an 18V version of the geared motor used here has a speed constant that is about 1/3 lower. This would reduce the minimum charging velocity from 208º/s to 131º/s. Conversely, decreasing the number of batteries will lower the charging potential. Tests with 4 cells (4.8V) resulted in a minimum charging velocity of 161º/s.

Whether enough energy is recovered to keep the batteries charged depends on a number of factors, which affect the balance between power generation and power consumption. One factor is the design of the control system, including microcontroller and sensors. Microcontrollers are becoming evermore powerful and efficient and that is helping to pave the way for a self-energizing prosthetic system. The second factor relates to user habits and the speed and distance that the user walks each day. Employing power saving strategies in the prosthesis to limit control of the knee to the swing phase (and putting the system into standby mode otherwise) will help to facilitate a balance between generation and consumption.

Limitations

Although it is a limitation of this study that the work was performed on a single subject, care was taken to ensure that the subject's gait was representative of normal trans-femoral amputee gait. Relevant gait parameters including walking speed, cadence, stride length, and prosthetic knee flexion were compared to other published data.[14-18] Furthermore, the adopted protocol aimed at testing both a pneumatic and hydraulic damper was in part applied to account for inter-subject variability that is attributed to the use of different prosthetic systems.

Conclusions

The findings in this study suggest that a geared motor has appropriate characteristics for use in swing-phase control. Above all, this includes the velocity dependent response of the output torque. This approach has another potential benefit and that is to reduce the daily need to recharge batteries in microprocessor-controlled prostheses. The results in this study support the feasibility of this approach as it relates to both swing-phase damping and charging of batteries, and this sets the foundation for future work.

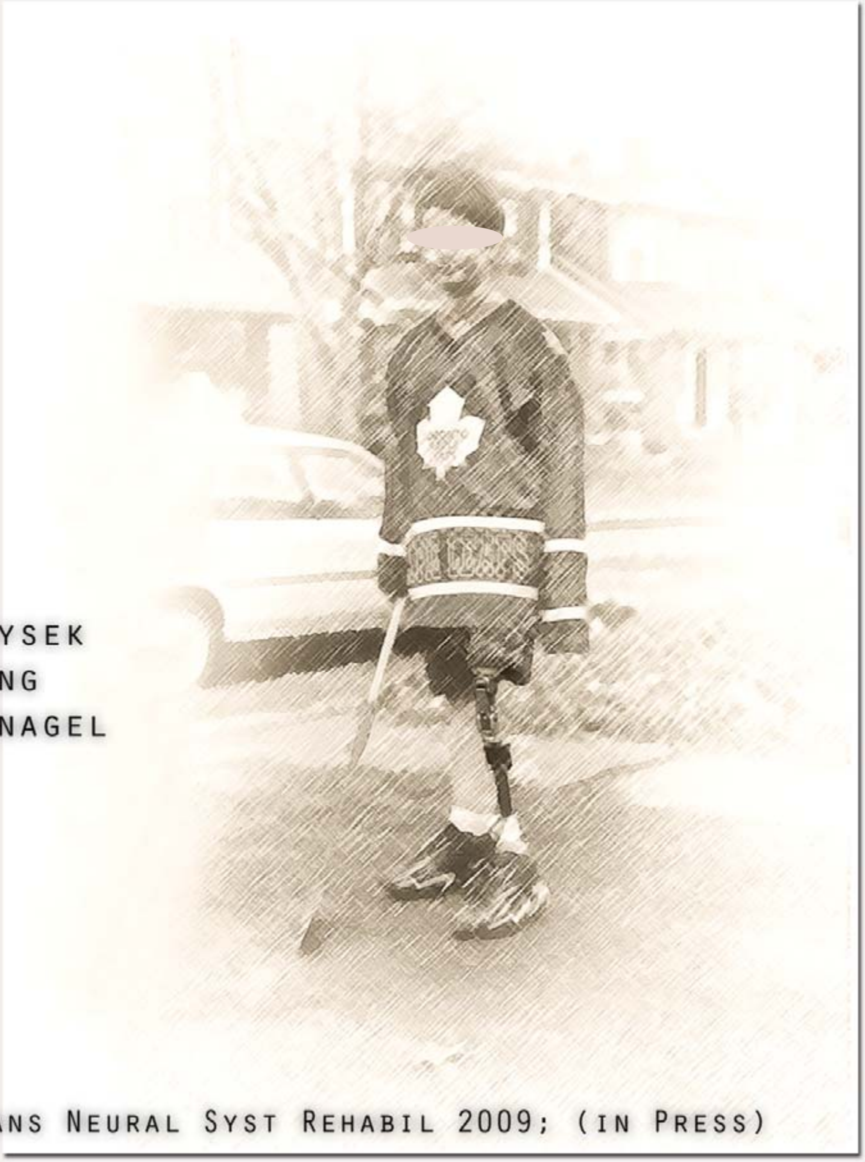
References

1. Whittle MW. Gait Analysis: an introduction. 3rd ed. Oxford: Butterworth-Heinemann; 2002.
2. Buckley JG, Spence WD, Solomonidis SE. Energy cost of walking: comparison of "intelligent prosthesis" with conventional mechanism. Arch Phys Med Rehabil 1997; 78: 330-3.
3. Johansson JL, Sherrill DM, Riley PO, Bonato P, Herr H. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil 2005; 84: 563-75.
4. Taylor MB, Clark E, Offord EA, Baxter C. A comparison of energy expenditure by a high level trans-femoral amputee using the Intelligent Prosthesis and conventionally damped prosthetic limbs. Prosthet Orthot Int 1996; 20: 116-21.
5. Heller BW, Datta D, Howitt J. A pilot study comparing the cognitive demand of walking for transfemoral amputees using the Intelligent Prosthesis with that using conventionally damped knees. Clin Rehabil 2000; 14: 518-22.
6. Hayashida J. Unobtrusive integration of magnetic generator systems in common footwear [dissertation], MIT MECH. Eng. Dept and MIT Media Lab: Massachussets Institute of Technology; 2000.
7. Kymisis J, Kendall C, Parasido J, Gershenfeld N. Parasitic power harvesting in shoes. Proc 2nd IEEE Int Conf Wearable Comput (ISWC): 1998; 132-9.
8. Rorabaugh B. Mechanical Devices for the Electronics Experimenter. New York, NY: TAB Books – McGraw-Hill; 1995.
9. Apkarian J, Naumann S, Cairns B. A three-dimensional kinematic and dynamic model of the lower limb. J Biomech 1989; 22: 143-55.
10. Farber BS, Jacobson JS. An above-knee prosthesis with a system of energy recovery: a technical note. J Rehabil Res Dev 1995; 32: 337-48.
11. Seliktar R. Self energized power system for above knee prostheses. J Biomech 1971; 4: 431-5.
12. Patil KM, Chakraborty JK. Analysis of a new polycentric above-knee prosthesis with a pneumatic swing phase control. J Biomech 1991; 24: 223-33.
13. Zarrugh MY, Radcliffe CW. Simulation of swing phase dynamics in above-knee prostheses. J Biomech 1976; 9: 283-92.
14. Blumentritt S, Scherer HW, Michael JW, Schmalz T. Transfemoral amputees walking on a rotary hydraulic prosthetic knee mechanism: a preliminary report. JPO 1998; 10: 61-70.
15. Seroussi RE, Gitter A, Czerniecki JM, Weaver K. Mechanical work adaptations of above-knee amputee ambulation. Arch Phys Med Rehabil 1996; 77: 1209-14.
16. van der Linden ML, Solomonidis SE, Spence WD, Li N, Paul JP. A methodology for studying the effects of various types of prosthetic feet on the biomechanics of trans-femoral amputee gait. J Biomech 1999; 32: 877-89.
17. Boonstra AM, Schrama JM, Eisma WH, Hof AL, Fidler V. Gait analysis of transfemoral amputee patients using prostheses with two different knee joints. Arch Phys Med Rehabil 1996; 77: 515-20.
18. Jaegers SM, Arendzen JH, de Jongh HJ. Prosthetic gait of unilateral transfemoral amputees: a kinematic study Arch. Phys Med Rehabil 1995; 76: 736-743.

Suppliers and supplies

a. SpringLite foot, Otto Bock HealthCare GmbH., Duderstadt, Germany
b. Total knee 2100, Össur hf., Reykjavik, Iceland.
c. Vicon Peak, Oxford, United Kingdom.
d. E6S – EDAC, US Digital Inc., Washington, US
e. Model 8645 7.5Nm, A-tech instruments Ltd., Scarborough, Ontario, Canada
f. National Instruments, National Instruments, TX, USA
g. Microsoft Corp.,
h. MicroMo (Faulhaber Group) Electronics Inc., Clearwater, Florida, US
i. Sanyo Canada Inc.
j. Panasonic Corp.

7 Evaluation of a Prosthetic Swing-Phase Controller with Electrical Power Generation



J. Andrysek
T. Liang
B. Steinnagel

IEEE Trans Neural Syst Rehabil 2009; (in Press)

Abstract

Objective: The objective of this study was to evaluate the gait performance and charging capabilities of the DC motor-base swing-phase controller.

Methods: Three adolescents with above-knee amputations walked with a prototype of the new swing-phase controlled knee joint and temporal, kinematic and kinetic gait parameters were measured under a variety of damping conditions.

Results: Gait parameters including cadence and knee angle symmetry were found to be acceptable when knee damping was adapted for each participant. Across the three subjects and two walking speeds, between 0.57 and 1.57W of electrical power was produced.

Conclusions: These results indicate that this technology may be utilized for prosthetic swing-phase control and ultimately may alleviate the need for manually charging of microprocessor-based prostheses.

Introduction

An increasing portion of lower-limb prosthetic systems employ electronics to enhance overall function. Microprocessor knee joints that sense and react to changing gait and environmental conditions are becoming an integral part of today's prosthetic rehabilitation services. While the clinical benefits associated with these technologies are increasingly evident[1-6], their main caveats include increased size, weight and cost due to increased system complexity, and the limited working time associated with a finite battery life.

During walking, the knee joint performs predominantly negative work[7,8]; hence the main reason for the widespread application of passive damping or braking mechanisms within prosthetic knee joints.[9,10] During the swing-phase of above-knee amputee gait, dampers limit the amount of heel-rise during knee flexion, and then gradually decelerate the shank prior to full knee extension, ultimately controlling the motion and timing of the limb to facilitate gait that is efficient, comfortable, aesthetic and safe.[9,11] While existing damping mechanisms dissipate this mechanical energy primarily in the form of heat, the energy can be converted to electrical energy to supply power to microprocessor-based prosthetic systems, therefore eliminating the need to manually charge batteries.

In our previous work, we examined the feasibility of using a system comprising of a geared direct current (DC) motor and electronics to provide damping at knee joint, and concomitantly the generation of electrical energy.[12] Figure 7.1, derived from these experiments, exemplifies the characteristics of the damping and generating functions of the proposed system.

A desired trait of the system is that torque is velocity dependent and increases linearly with faster speeds. Furthermore, by varying the electrical load on the system, torque can be controlled at a given speed. These two inherent characteristics of DC motors make their application as variable dampers feasible. Low damping levels are achieved by limiting the influence of electrical loads, for example by disconnecting the motor from the circuit and batteries. Conversely, maximum damping levels are achieved by short-circuiting the motor (i.e. connecting together the motor terminals). In our system this is accomplished using a MOSFET (metal–oxide–semiconductor field-effect transistor) and a relay switch. No electrical energy is generated for the aforementioned minimum and maximum damping conditions, however, the intermediary damping conditions produce functional levels of electrical power generation, (since a portion of the current is directed to the batteries, using the MOSFET and/or relay) with maximum power generation occurring when all current is directed to the batteries. With increasing driving speed of the motor, higher current and voltage are produced, and therefore more power is generated. Conversely, when the motor is driven at a lower speed, the current does not overcome the potential of the batteries, and therefore charging of the batteries does not occur.

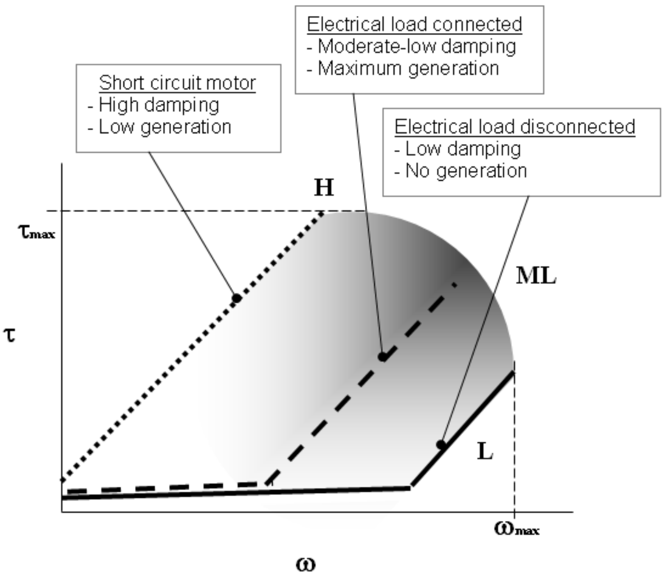


Figure 7.1: The damping and generating characteristics of the proposed system. Torque (τ) is shown as a function of angular velocity (ω). Darker (shaded) regions indicate higher levels of electrical power generation.

The biomechanical generation of electricity has previously been evaluated in shoe-based systems, backpacks and more recently with a knee brace.[13-18] The common goal of these devices has been to efficiently convert mechanically energy to electrical energy, without being obtrusive or requiring the user to do extra work. The concept here is similar in that damping levels are varied in real-time to optimize gait characteristics, with electrical power generation being the useful by-product. In a previous study utilizing a kinematic simulator, we determined that a geared DC motor of practical size and weight could be used for prosthetic swing-phase control and the concurrent production of electrical power. To gain further insight into these initial findings, it was the aim of this study to evaluate 1) the swing-phase control function of the technology, and 2) the potential to generate electrical power.

Methods

Overview

A geared DC brushed motor was mechanically integrated into an existing prosthetic knee joint and a PC-based control and data acquisition system to vary damping levels in real-time and to record relevant system and gait parameters was developed. Testing was performed with three individuals with above-knee amputations.

Mechanical integration

A commercially-available DC brushed motor (Model 2342S0118CR)[a] was attached to an existing single-axis prosthetic knee joint, such that flexing/extending motions of the knee joint could be transmitted to drive the motor (figure 7.2). The motor was provided with a 66:1 gear head (series 30/1)[a], and the final transmission gear stage applied a further 2:1 ratio using spur gears, for a final 132:1 increase in speeds in the motor. A torque cell (model QWFK-8M)[b] was directly coupled to the knee axis, and a 10k Ohm potentiometer (SP2800 series)[c] for knee position sensing at a supplementary axis was coupled by a spur gear. The single-axis knee joint, to which the motor and sensors were attached, provided stance-phase control (i.e. automatic stance-phase lock); this mechanism locks the knee from early to mid-stance, and therefore does not affect swing-phase function[19]; see figure 7.2. The prototype knee (knee component only) weighed just over 1.1kg, which is comparable to microprocessor knees such as the C-leg from Otto Bock (1.15kg) and Rheo knee (1.63kg) from Össur.

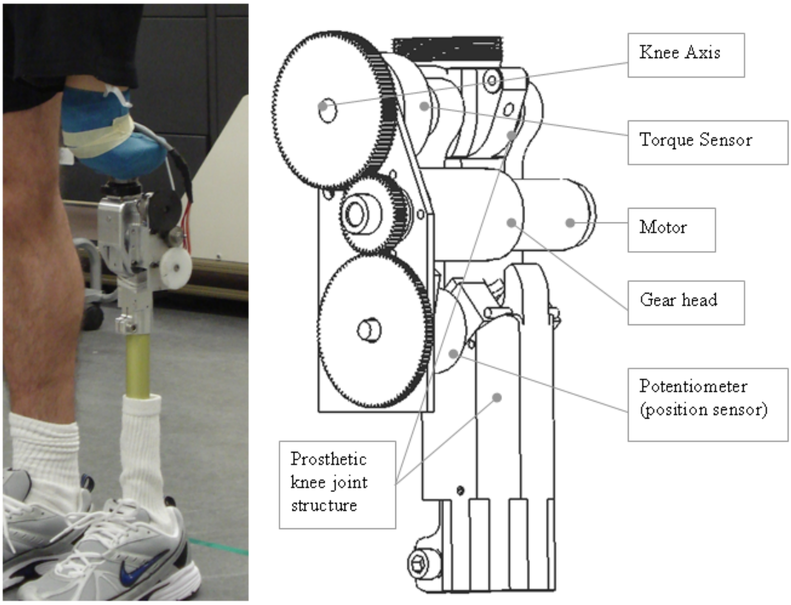


Figure 7.2: Mechanical setup: (right) schematic of prototype knee joint; (left) prototype prosthesis worn by subject.

Control and data acquisition system

The components of the control system included a data acquisition card (NI 6031-E)[d] and a custom written program in Labview 7.1[d] sampling at 100Hz. The generator/damping control circuit was similar to that used before[12], but a relay switch was added to the circuit in addition to the MOSFET to extend the range of damping control to include lower torques, or in effect to disconnect the load (i.e. batteries) from the motor. The MOSFET gate voltage and relay input voltage (here forth referred to as the control signal or control voltage) was supplied by an analog output channel. Knee flexion and extension angle, angular velocity (derived from the position signal) and torque were measured and recorded. An electrogoniometer[e] was applied to the intact limb to measure knee angles.

The control algorithm comprised of a simple feedback system utilizing the position and angular velocity data for input, and outputting control signals to vary damping levels. Control signals were established to provide evenly distributed levels of damping as specified in table 7.1. The knee flexion and extension cycles were controlled independently (based on angular velocity) and damping levels were set to correspond to knee angles, thus resulting in damping profiles such as those shown in figure 7.3 for the adapted damping condition. The adapted damping (AD) condition was one, where the damping profile was adjusted heuristically based on gait observation and feedback from the participant.

Subjects

Participants included three males with above-knee amputations. Subject 1 was 17 years old, 177cm tall and weighed 73kg. Subject 2 was 26 year-old, 175cm tall and weighed 60kg. Subject 3 was 15 years old, 178cm tall and weighed 55kg. All subjects were experienced prosthetic users, and had worn their prosthesis for at least 10 years. The participants had high-end hydraulic swing-phase controlled knee joints as part of their conventional prostheses (Models 2100 and 2000)[f].

Testing

Testing was performed over a single session in a gait laboratory setting. The subject donned the prosthesis with the prototype knee joint and prosthetic alignment was confirmed by a prosthetist. The subject walked back and forth in 10m passes and the damping characteristics of the knee joint were adjusted within the control program. For each damping condition, the subject was given several passes for acclimation before data were collected. The subject was informed about what changes in damping to expect before attempting to walk. Testing was done at the subject's comfortable walking (CW) and fast walking (FW) speeds.

Four damping settings were applied. These included no damping (ND), maximum charging (MC), maximum damping (MD), and adapted damping (AD) (table 7.1). For the first three conditions, the control signals were a constant 0, 3.4, and 5V, respectively (figure 7.3). For the adapted damping condition, the damping profile was adjusted heuristically based on gait observation and feedback from the participant. This is a common procedure used by prosthetists to adapt a particular swing-phase controller to the patient's gait requirements (usually at the time of prosthetic fitting).

Data collection for conventional knee joint

A tri-axial accelerometer (Model #: MMA7261QT)[g] was placed on the prosthetic shank of the participant's conventional prosthetic limb, and data were sampled using a data acquisition board (NI 6212)[d] and mini laptop (ASUS EEE PC laptop)[h]. Vertical accelerations were used to identify heel-strikes, and cadence was calculated for the CW and FW speeds.

Table 7.1: Control voltages and corresponding damping levels and electrical power generation levels. Status of electronics was also described.

Control voltage	Damping level	Generating condition	Specification
5V	High (H)	Very low	MOSFET is ON and used to short-circuit motor
4.1V	Medium High (MH)	Low	Some current is directed to batteries and some to motor
3.8V	Medium (M)	Medium	
3.4V	Medium Low (ML)	Maximum	MOSFET is OFF and all current directed to batteries
0V	Low (L)	None	Relay is opened to disconnect electrical load

Evaluation criteria and data Analysis

For each condition, data from three consecutive strides as defined by the peak prosthetic knee flexion angles were averaged. Cadence and knee angle symmetry were the primary outcome measures used to assess gait and swing-phase performance. Cadence was calculated from stride times. Maximum and minimum values for knee angles were manually extracted. A symmetry index was calculated for the knee angles by taking the prosthetic limb peak knee angle minus the intact limb peak knee angle, divided by the mean of the two peak knee angles, multiplied by 100%. Mechanical powers were calculated as the product of angular velocity and torque. Electrical powers were calculated as the product of battery voltage and battery current. Mean values for mechanical and electrical powers were determined for one stride of gait. Mechanical and electrical energy was calculated from the powers. Efficiency of power generation was calculated as the electrical energy divided by the mechanical energy, and expressed as percentages. Finally, during earlier testing it became apparent that a delay existed in the onset of damping (i.e. torque), therefore, we also examined the delays in the system.

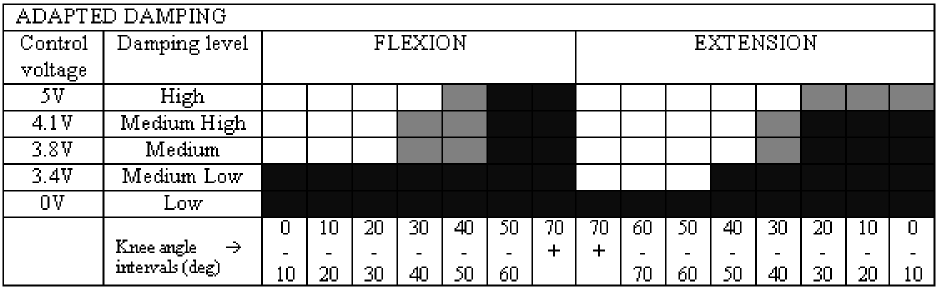


Figure 7.3: Damping profiles for the AD conditions. Knee angle intervals are shown along the bottom for flexion and extension cycles. Blocks shaded black represent the control voltages used for subjects 3, and blocks shaded black plus blocks shaded grey represent the control voltages used for subjects 1 and 2 (i.e. same control voltages were used for subjects 1 and 2).

Results

The control voltages for the ND, MG and MD conditions were determined prior to testing, while the control voltages for the AD condition were determined during testing with the feedback of the participants. Interestingly, subject 2 preferred the same settings as subject 1, and therefore the settings in figure 7.3 were applied to both subjects. Subject 3, in general, preferred lower torque settings.

Gait and power generation data for each of the three subjects are presented in table 7.2. Figure 7.4 presents the means for the three subjects, two walking conditions and four swing-phase control conditions. As shown by the higher cadence, on average the subjects walked fastest with the AD setting. At the CW speed, mean cadence (one standard deviation shown in brackets) for the AD setting was 1.52(0.04) steps/s compared to 1.40(0.07) to 1.51(0.03) steps/s with the other three settings and 1.50(0.05) steps/s with the participants' conventional knee joints. At the FW speed, mean cadence for the AD setting was 1.67(0.02) steps/s compared to 1.56(0.04) to 1.66(0.08) steps/s with the other three settings and 1.73(0.02) steps/s with the participants' conventional knee joints.

The ND condition, which resulted in slowest walking speeds, also resulted in excessively high prosthetic side heel-rise shown by peak knee flexion angles (table 7.2). The symmetry index illustrates this further (figure 7.4). Positive values of the symmetry index, as seen for the ND setting, indicate greater prosthetic than intact side peak knee flexion angles, and a negative symmetry index, as seen for the MD setting, represents over-damping on the prosthetic side. The ND condition produced greatest asymmetries of up to 27.4(7.3)% on average across both walking speeds. The AD setting resulted in greatest symmetry with an average symmetry index across both walking speeds of -5.4(9.0) %.

As seen in table 7.2, mechanical power absorption is closely related to knee torques, in this case the peak knee torques during knee flexion and extension are presented. Mean mechanical power absorption at the knee ranged from 1.18(0.35)W for the ND condition to 10.11(1.57)W for the MD condition. Evaluated for the MG setting, on average 2.07(0.19)W and 3.04(0.11)W of electrical power was generated for the CW and FW speeds, respectively (figure 7.4). The ratio of energy converted to electrical energy was a very consistent 36.7(0.4)% and 35.1(0.6)%, for the CW and FW speeds, respectively. The AD setting produced slightly less than half the power of the MG setting, or on average between 0.89(0.41)W and 1.36(0.29)W, for CW and FW respectively. Power generation efficiency was reduced to 18.9(4.4)% and 18.1(2.7)% for CW and FW, respectively.

Table 7.2: Gait and power generation values for the three subjects.

		Comfortable Walking					Fast walking			
		ND	MG	MD	AD		ND	MG	MD	AD
Cadence (steps/s)	S1	1.41	1.53	1.58	1.47		1.54	1.70	1.69	1.69
	S2	1.33	1.53	1.34	1.53		1.53	1.70	1.55	1.68
	S3	1.47	1.48	1.43	1.55		1.60	1.57	1.57	1.64
Peak pros. knee angle (°)	S1	78.1	63.1	49.5	52.1		90.1	72.9	61.4	62.5
	S2	75.6	65.1	49.0	54.7		84.4	70.4	58.3	62.4
	S3	82.4	72.9	60.5	67.2		85.1	78.0	66.5	70.5
Peak intact knee angle (°)	S1	63.3	63.0	63.9	63.9		61.1	63.6	61.9	64.7
	S2	56.7	58.7	58.6	61.2		60.8	61.8	61.9	61.8
	S3	68.0	66.5	65.1	68.9		66.4	68.9	70.5	67.6
Symmetry Index (%)	S1	20.9	0.1	-25.4	-20.4		38.4	13.6	-0.8	-3.5
	S2	28.7	10.3	-18.0	-11.1		32.6	13.0	-6.1	0.9
	S3	19.2	9.1	-7.4	-2.4		24.7	12.5	-5.7	4.2
Mean mechanical power (W)	S1	1.10	5.06	7.09	4.11		1.79	8.97	11.2	6.67
	S2	0.88	5.64	4.94	5.21		1.56	8.78	8.30	8.09
	S3	1.57	6.19	7.48	6.32		1.9	8.2	10.9	7.6
Mean Electrical power (W)	S1	-0.01	1.88	0.02	0.57		-0.01	3.15	0.18	1.03
	S2	-0.01	2.07	0.03	0.75		-0.01	3.03	0.22	1.47
	S3	0.00	2.26	0.17	1.36		0.00	2.93	0.33	1.57
Mechanical energy (J)	S1	4.7	19.8	26.9	16.8		7.0	31.6	39.6	23.7
	S2	4.0	22.1	22.2	20.4		6.1	30.9	32.2	28.9
	S3	6.4	25.0	31.4	24.5		7.0	31.3	41.5	27.6
Electrical energy (J)	S1	0.0	7.4	0.1	2.3		0.0	11.1	0.7	3.7
	S2	0.0	8.1	0.1	3.0		0.0	10.7	0.9	5.2
	S3	0.0	9.1	0.7	5.2		0.0	11.2	1.3	5.7
Power generation efficiency (%)	S1	-0.7	37.2	0.2	13.8		-0.4	35.1	1.6	15.4
	S2	0.0	36.5	2.3	21.5		-0.4	34.5	2.6	18.1
	S3	0.0	36.5	2.3	21.5		0.0	35.8	3.1	20.8

Figures 7.5 (a-d) exemplify one stride of walking at the CW speed for subject 1, showing the intact and prosthetic knee flexion angles, damping torques, and derived mechanical power absorption. Figure 7.6 exemplifies the power generation parameters for the MG and AD settings. These graphs

clearly depict the changes in torques and power generation stemming from the application of different settings. Specifically, compared to the other conditions, the AD condition produced high damping just prior to full knee extension, a desired characteristic for eliminating terminal swing-impact. Another point of interest is the nature of power generation, which is highly transient, occurring in two bursts, one in flexion and one in extension.

Based on the control signal and damping torque data as exemplified in figure 7.6, a delay of approximately 0.050s was found between the control voltage and the measured increase in torque. For CW and FW this resulted in a maximum delay of torque onset of about 15º and 20º, respectively. Unlike the former, a decrease in damping torque occurred without a delay.

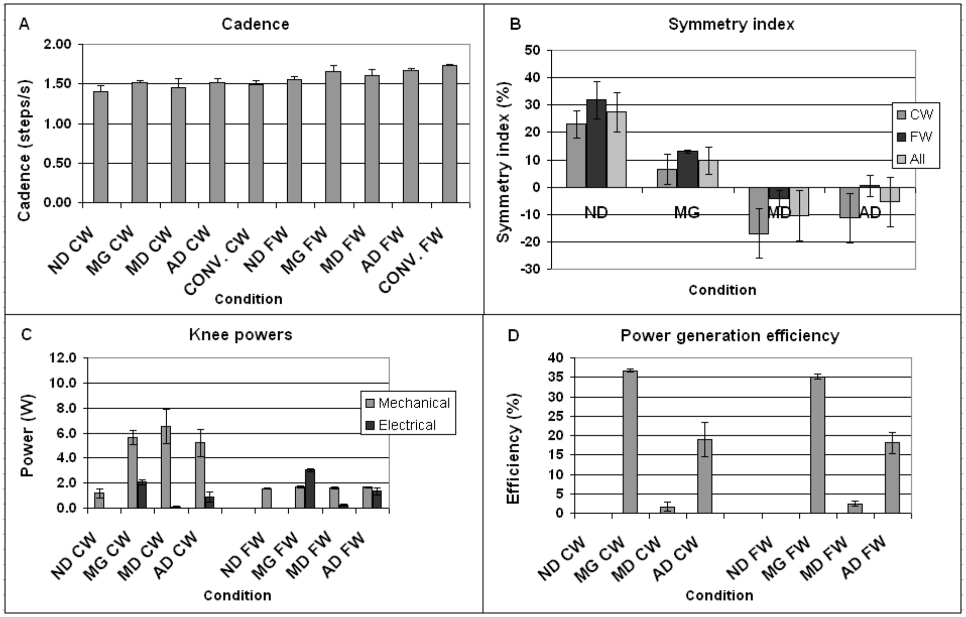


Figure 7.4: (A) Cadence; (B) Symmetry index; (C) Knee powers; Power generation efficiency. Mean values and one standard deviation (error bars) for the three subjects. Abbreviations for conditions refer to combinations of damping setting and walking speed; for example ND CW refers to the no damping setting and comfortable walking speed. In the legend of figure B, 'All' refers to the mean and standard deviation of all damping conditions and walking speed across subjects.

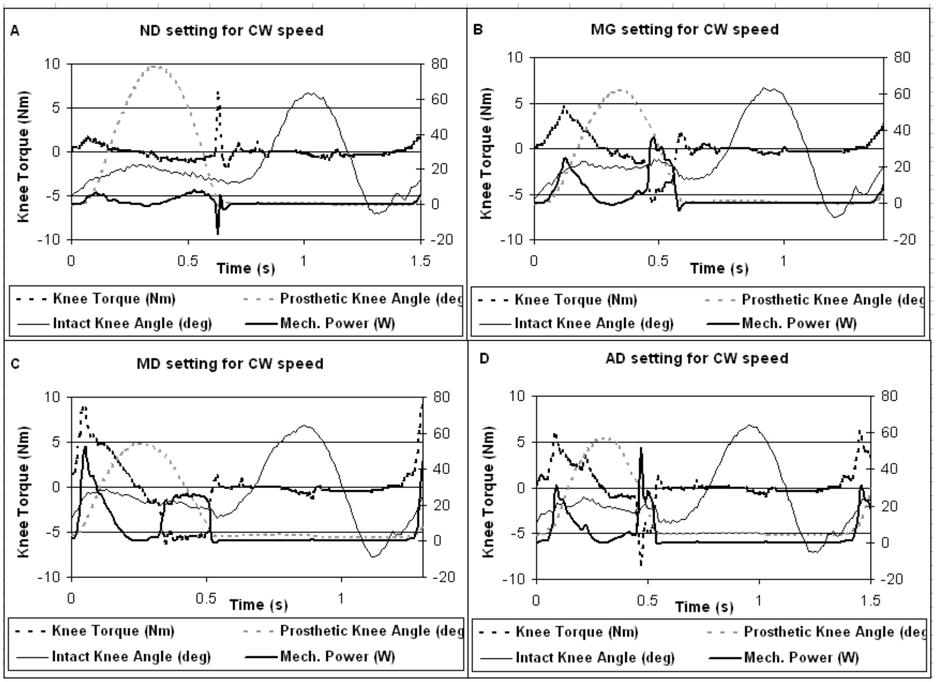


Figure 7.5: Mechanical power, prosthetic and intact limb knee angles, and prosthetic knee torques shown for one stride for subject 1 for the comfortable walking speed for the four damping conditions. Knee torque values shown on primary y-axis and all other parameters shown on the secondary y-axis.

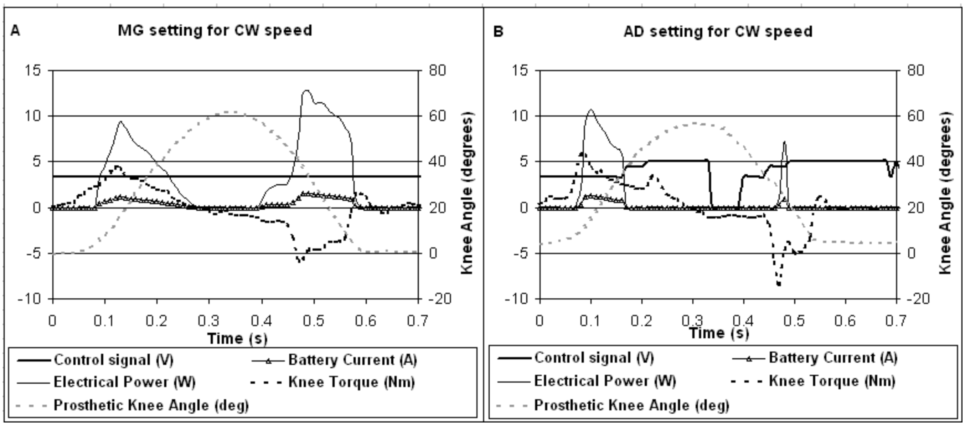


Figure 7.6: Control voltage, battery current, electrical power generation, knee torques and knee angles shown during swing-phase for (A) MG and (B) AD conditions. Knee angle values are shown on the secondary y-axis.

Discussion

This work presents a preliminary evaluation of a new type of swing-phase controller with power generating capabilities. To examine the swing-phase control characteristics, we evaluated several temporal and kinematic gait parameters. From figure 7.4, as expected the ND setting for all subjects resulted in slower gait (lower cadence). This setting would be representative of a low-end prosthetic knee joint without swing-phase control. These types of devices are commonly prescribed for less active individuals. In contrast, the AD setting resulted in the highest cadences that were on par with the subjects' conventional prosthetic knee joints. Some of the differences in walking speeds between the AD setting and conventional knees may be attributed to limited acclimation time with the prototype knee.

Kinematic asymmetry at the knee was greatest for the ND setting during FW, and the MD setting for CW. In the former case insufficient damping resulted in excessive prosthetic knee flexion, and in the latter over-damping resulted in insufficient knee flexion. The AD setting provided high symmetry during FW and acceptable symmetry during CW. For the CW speed, lower damping levels during swing-phase knee flexion would have produced higher symmetry. Although it was not in the scope of this study, further work should focus on developing a higher-level control algorithm capable of modulating gait at different walking speeds. The algorithms may not only be designed to optimize gait characteristics, but concomitantly maximize power generation.

The MG setting presents the optimal condition for generating electrical energy. From figure 7.4, just over 1/3 of mechanical energy was converted into electrical energy. Based on figures 7.5 and 7.6 the energy was generated during both knee flexion and knee extension phases. The AD setting, which not only provided near ideal damping characteristics, also produced substantial power generation, mainly during knee flexion (figure 7.6). Specifically, this setting produced slightly less than half the power of the MG setting, or on average between 0.89(0.41)W and 1.36(0.29)W, for CW and FW respectively. Donelan et al.[13], using a specially designed energy harvesting knee brace reported the production of 2.4W of electricity per leg in able-bodied males. Differences in the physical properties of the prosthetic and human legs account for the difference in power generation between this study and theirs, namely the fact that human limbs weigh several times more than prosthetic limbs, which would result in greater braking torques and mechanical energy dissipation. The values obtained here are higher than those previously derived theoretically; this is due to the use of a more powerful motor in this study.[12]

While the system delay of 0.050s for the onset of damping did not present a problem in these experiments because it was compensated for in the damping setting (figure 7.3), the same might not be the case for higher-level feedback systems where more robust control is needed. Further work is needed to determine the source of the delay so that it can be reduced.

Finally, while this technology has the potential to eventually benefit individuals with amputations, it is important to point out several design considerations. First, in contrast to hydraulic based dampers which can serve both functions of stance and swing-phase control alternatively by switching between low and very high levels of damping, extending the capacity of the geared motor to provide damping torques needed for stance-phase stability is likely impractical and would result in an excessively large and heavy knee joint. Therefore, with this technology, consideration must be given for the provision of some form of auxiliary control during the stance-phase. Secondly, the gears and motor produce a distinct sound that may be a potential nuisance to some users. Lastly, further work is needed to evaluate the long-term function, durability and reliability of the mechanical components and specifically gears, as well as the application of higher-level control algorithms, and their effect on gait and power generation.

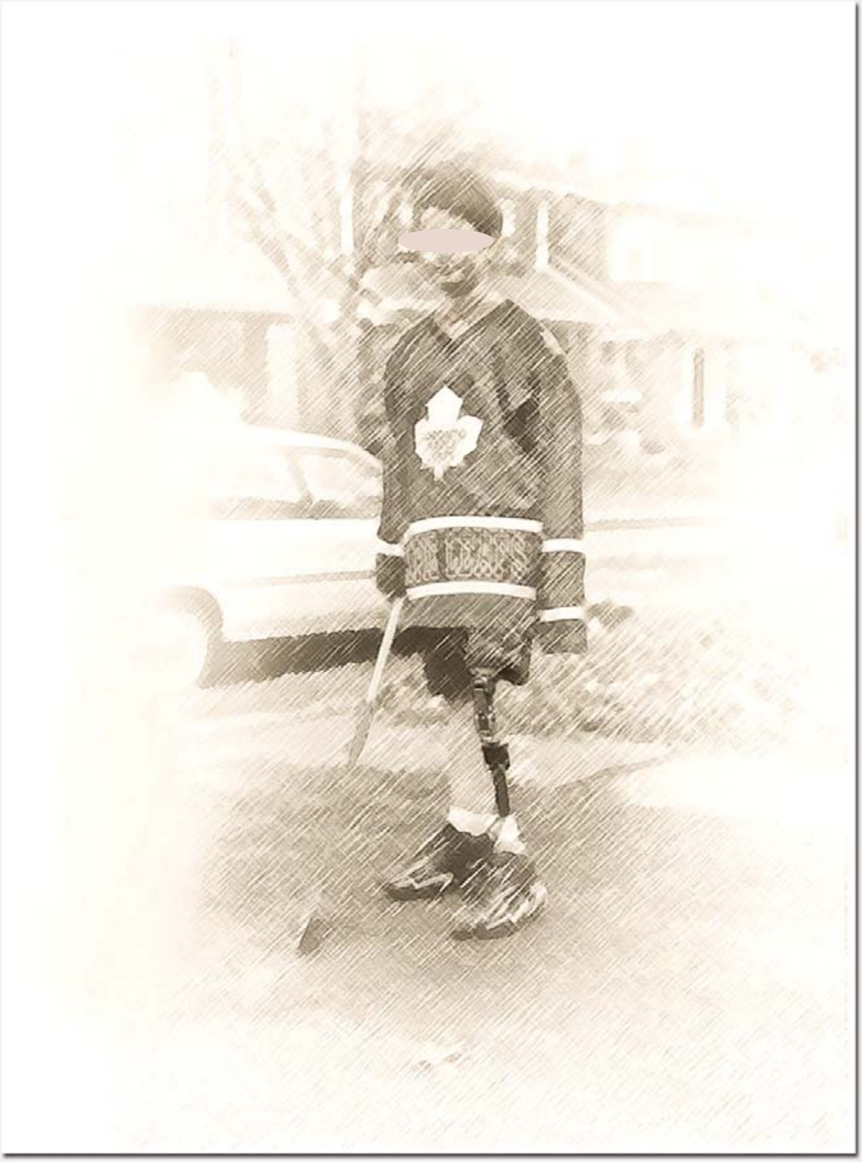
References

1. Chin T, Sawamura S, Shiba R et al. Effect of an Intelligent Prosthesis (IP) on the walking ability of young transfemoral amputees: comparison of IP users with able-bodied people. Am J Phys Med Rehabil 2003; 82: 447-51.
2. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. Arch Phys Med Rehabil 2007; 88: 207-17.
3. Johansson JL, Sherrill DM, Riley PO, Bonato P, Herr H. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil 2005; 84: 563-75.
4. Kaufman KR, Levine JA, Brey RH, McCrady SK, Padgett DJ, Joyner MJ. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Arch Phys Med Rehabil 2008; 89: 1380-5.
5. Segal AD, Orendurff MS, Klute GK et al. Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. J Rehabil Res Dev 2006; 43: 857-70.
6. Wetz HH, Hafkemeyer U, Drerup B. The influence of the C-leg knee-shin system from the Otto Bock Company in the care of above-knee amputees. A clinical-biomechanical study to define indications. Orthopade 2005; 34: 298, 300-298, 309.
7. Harris GF, Smith P. Human motion analysis - current application and future directions. New York: IEEE Press; 1996.
8. Whittle MW. Gait Analysis: an introduction. 3rd ed. Oxford: Butterworth-Heinemann; 2002.
9. Atlas of Limb Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles. Rosemont, IL: American Academy of Orthopedic Surgeons; 1992.
10. Lim PA. Advances in prosthetics: a clinical perspective. Phys Med Rehabil: State Art Rev 1997; 11: 13-38.
11. Pezzin LE, Dillingham TR, Mackenzie EJ, Ephraim P, Rossbach P. Use and satisfaction with prosthetic limb devices and related services. Arch Phys Med Rehabil 2004; 85: 723-9.
12. Andrysek J, Chau G. An electromechanical swing-phase-controlled prosthetic knee joint for conversion of physiological energy to electrical energy: feasibility study. IEEE Trans Biomed Eng 2007; 54: 2276-83.
13. Donelan JM, Li Q, Naing V, Hoffer JA, Weber DJ, Kuo AD. Biomechanical energy harvesting: generating electricity during walking with minimal user effort. Science 2008; 319: 807-10.
14. Hayashida J. Unobtrusive integration of magnetic generator systems in common footwear [dissertation], MIT MECH. Eng. Dept and MIT Media Lab, Massachussets Institute of Technology, US; 2000.
15. Kuo AD. Biophysics. Harvesting energy by improving the economy of human walking. Science 2005; 309: 1686-7.
16. Kymisis J, Kendall C, Parasido J, Gershenfeld N. Parasitic power harvesting in shoes. In: Proc 2nd IEEE Int Conf Wearable Comput (ISWC) 1998;132-9.
17. Rome LC, Flynn L, Goldman EM, Yoo TD. Generating electricity while walking with loads. Science 2005; 309: 1725-8.
18. Rome LC, Flynn L, Yoo TD. Biomechanics: rubber bands reduce the cost of carrying loads. Nature 2006; 444: 1023-4.
19. Andrysek J, Naumann S, Cleghorn W. Design and quantitative evaluation of a stance-phase controlled prosthetic knee joint for children. IEEE Transactions on Neural Systems and Rehabilitation Engineering 2005; 13: 437-43.

Suppliers

a. MicroMo (Faulhaber Group) Electronics Inc., Clearwater, Florida, US
b. Advanced Mechanical Technology Inc., MA, USA
c. Novotechnik, Southborough, MA, USA
d. National Instruments, TX, USA
e. Biometrics Ltd., Gwent, UK
f. Össur hf., Reykjavik, Iceland
g. Motorola Semiconductor, Austin, TX, USA
h. AsusTek Computer Inc.

8 Summary and General Discussion



Summary

The design of prosthetic components requires consideration of the functional benefits as well as detrimental factors such as weight, bulk, cost, and maintenance requirements. In paediatric prosthetics this is especially true as children and youth are typically more physically active and demand more function from their prostheses than adults do. However, they also require that the prosthetic components be compact, lightweight, and highly durable. As such, the provision of effective prosthetic knee joint components for children and adolescents remains a challenge, one that was the primary focus of this thesis.

With a number of important functional advantages over single-axis configurations[1-6], four and six-bar linkages comprise the most commonly utilized paediatric prosthetic knee joint mechanisms.[6,7] These mechanisms, however, inherently result in prosthetic knee joints that are larger, heavier and more complex.[7] In this context, the focus of **chapter 2** was to examine whether, and in what form, a simple single-axis joint can be made to function as effectively as four- and six-bar linkage mechanisms. In this study a sample of children were surveyed on the important aspects of prosthetic knee function. Using a standardized design approach referred to as Quality Function Deployment[8-10], these functions and child preferences were translated into performance features of the design. Using passive kinematic models, the highly rated physical design features, including stance-phase stability, swing-phase initiation, and foot-clearance were evaluated for several commercially available prosthetic knee joint components, and benchmarks established. Various single-axis configurations were then comparatively evaluated and a preferred one was proposed.

The optimal single-axis configuration is based on an axis placement that is effectively anterior of the weight-bearing line. This configuration is advantageous in terms of increased foot clearance and ease of knee flexion initiation in terminal stance-phase. Compared to a conventional alignment-stabilized single-axis knee joint, the proposed single-axis configuration increases foot-clearance by 20mm, which is on par with four- and six-bar linkage knees. For the child, the functional advantage is a lower probability of tripping[11,12], and/or reduced compensatory gait deviations.[13] A further advantage of the proposed knee-axis configuration is reduction in muscular

effort required to bend the knee in late stance-phase by 50% when compared to an alignment stabilized single-axis configuration.[6,14] Again, this functional advantage of the proposed single-axis configuration is comparable to four- and six-bar knees.

The children's perceived ratings of functional requirements were in close agreement with adult studies[15] outlining the importance of stability and other stability-related features. Moreover, the findings implied that a single-axis mechanism could be configured to meet important functional requirements as long as supplementary provisions were made for stance-phase control. This established an important basis for the design and development of a new prosthetic knee joint that strived to provide greater functionality, via simpler means, and in a more compact form, thus potentially addressing a number of longstanding clinical and technical drawbacks of existing paediatric prosthetic knee joints.

In chapter 3, the design of the prosthetic knee joint was advanced with a primary focus on the stance-phase control mechanism, the necessity of which was established in the chapter 2. In this chapter, a novel stance-phase strategy and mechanism were presented. A new modeling approach was developed to facilitate biomechanical analysis of this mechanism, and other dual-control-axis stance-phase mechanisms, such as six-bar linkage knees. Based on the functional features of this new knee joint and the biomechanical analysis of its stability, it was hypothesized that the new knee would be more stable than four- and six-bar paediatric prosthetic knee joints. In a crossover case-series design, six children were surveyed after wearing the new knee and either a four- or six-bar linkage knee (their conventional components) to evaluate the relative performance of the new stance-phase mechanism during common mobility tasks. A longitudinal follow-up was performed and user preferences noted.

Conventionally, stance-phase control mechanisms facilitate a stable or locked knee joint in response to a specific stance-phase loading pattern. Major deviations from this pattern can lead to poor knee stabilization resulting in a stumble or fall.[5] To alleviate this drawback, our stance-phase mechanism defaults to a locked knee upon knee extension with knee destabilization, as is desired in latter stance, occurring as a result of a specific loading pattern that is particular to that part of the gait cycle (figure

8.1). In this way, the new knee has a greater propensity to remain stable during early and mid-stance of gait. A further advantage of our knee is, as it fully extends, it automatically locks in full knee extension and remains locked until and during load acceptance. In contrast, four- and six-bar knees can rebound back into a flexed position during terminal swing unless other measures such as extension bias springs are incorporated. With these two stance-phase stability-enhancing characteristics, the expectation was for an improvement in one or more aspects of mobility, to be revealed via the self-report questionnaire.

As posited, the questionnaire data revealed greater reliability in stance-phase stability, with a significant decrease ($p<0.03$) in the incidence of falls.[16] The median number of reported monthly occurrences of knees giving out were 30 and 1, for the conventional (4 and 6-bar knees) and the new knees, respectively. The children with the new knee also reported minimal concerns during walking. The stability enhancements did not significantly alter the fear and/or caution when walking on uneven surfaces, nor the perceived level of fatigue during ambulation. All of the children indicated on the questionnaire that they preferred the new knee to their conventional knees. Upon the completion of the study, the children were presented with the option of keeping the new knee or reverting to their conventional knees. Five of the six children continued wearing the new knee, for 14 months on average (3-21 months).

While a paucity of literature exists pertaining to falls in the paediatric amputee populations, clinical practice suggests that a child's ability to control knee joint articulation to prevent falls is an important aspect of prosthetic prescription.[17] Falls, including those occurring during walking and running, are the leading cause of unintentional injury in able-bodied children [18,19], and in elderly adults with lower-limb amputations.[20,21] While falls in young children are considered a part of normal development of the locomotor system, one of the goals of prosthetic management should be to minimize their incidence. As such, the preliminary findings relating to the reductions in frequencies of falls, associated with the new knee, were highly encouraging.

In chapters 2 and 3, unique and novel design features addressing important gait functions relating to stance-phase stability, stance flexion initiation, and toe clearance were presented. The objective of chapter 5 was to evaluate the effects of these design features on gait. Gait assessments comprise the most commonly applied outcome measures in lower-limb prosthetics[22], providing a direct measurement of important aspects of biomechanical and mobility functions. Chapter 4 is an important prerequisite to chapter 5, addressing methodological issues of gait parameter measurement reliability.

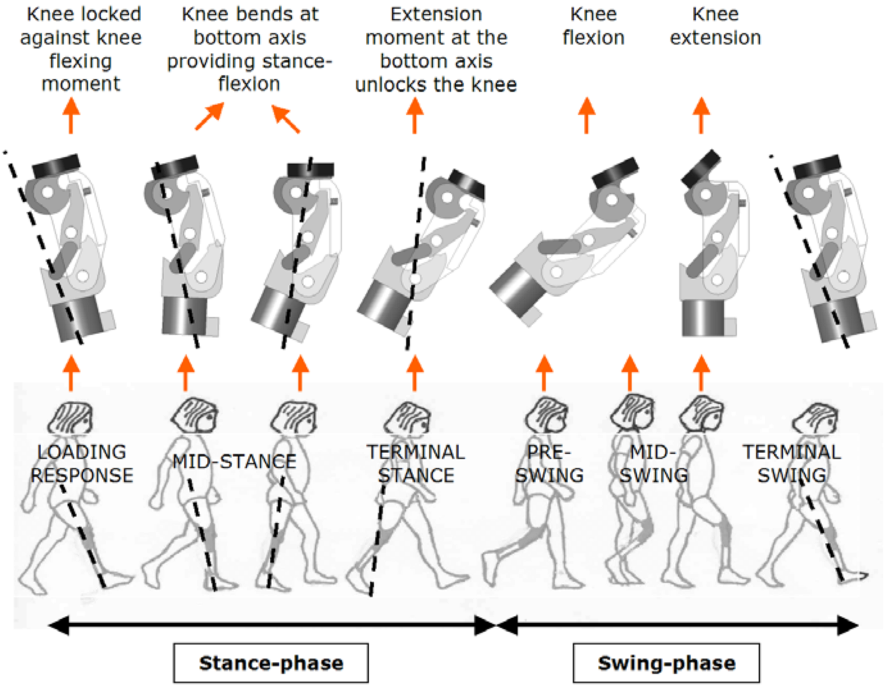


Figure 8.1: Knee function during gait. Dashed lines represent load vectors. When the load vector is behind the top axis (knee axis), then a knee flexion moment is generated tending to bend the knee. A load vector anterior of the knee axis keeps the knee joint extended. Moments generated around the bottom axis (or control axis) operate the lock. When the load vector is behind the control axis, the knee lock is being forced into a locked position. When it is in front, the lock is being disengaged.

In chapter 4, we examined the intra-subject variability of common spatiotemporal and kinematic gait parameters from quantitative gait analysis of children with mobility impairments stratified across three levels. There was a paucity of published data and a lack of consensus on the number of repeating strides of gait that should be used during gait analysis, to ensure that a stable representation of the measures was obtained. For example, previous studies involving amputees used from one gait cycle (stride) up to 12 strides[23-28] to make inferences about intervention-related changes in gait. Data may not be reliable if based on too few strides; conversely, collecting many strides to get a stable representation of gait can be challenging and at times impractical, especially when dealing with small children. In this regard, it was important to establish criteria for the minimal number of repeated intra-session measures that provide a reliable representation of gait.

The work of chapter 4 involved a group of ambulatory children with cerebral palsy, sub-categorized according to the Gross Motor Function Classification System. The advantage of studying children with CP was twofold: 1) availability of a larger population base giving access to an adequate sample size for this type of study; 2) stratification of children into homogeneous groups by their levels of impairment, allowing us to assess gait parameter reliability across varying levels of gross motor function. Findings indicated that 4 to 6 strides provide reliable estimates of spatiotemporal and kinematic gait parameters across a broad range of gross motor functional levels, ranging from children capable of walking without limitations and exhibiting only minor gait deviations (Level 1) to children requiring the use of handheld mobility devices such as canes and walkers (Level III). As such, the findings in chapter 4 can be generalized to other paediatric patient populations, including children with above-knee amputations; this methodological resolution was applied to the evaluation of the new knee joint presented in chapter 5.

The aim of **chapter 5** was to evaluate the effects of the new knee joint on gait and to propose future design considerations. The significant finding in this study was an overall increase in the self-selected walking speed of the unilateral amputees, both when directly compared to the four- and six-bar knees used in this study and those reported in literature.[17,29,30] (figure 8.2) The increased walking speed for the unilateral amputees was associated with increased joint support moments and powers, an expected result given the correlation of these gait parameters.[31] These results suggested that mechanical work adaptations, for example, the hip flexion torque required to initiate prosthetic side pre-swing knee joint flexion associated with the new knee were comparable to four- and six-bar linkage knees. This was a positive finding considering that increased joint moments may potentially lead to joint degeneration.[32,33]

In chapter 3, non-significant differences were reported between the different knees in terms of subjective ratings of fatigue.[16] Because the increase in walking speed was associated with increased joint moments and powers, which are typically associated with greater energy expenditure[36], it did not seem plausible that the new knee joint facilitated more energy efficient gait. However, future work should investigate the metabolic cost associated with the new knee. This work should, however, be initiated only after all known and outstanding design considerations have been applied to achieve optimal performance; one of these includes swing-phase control.

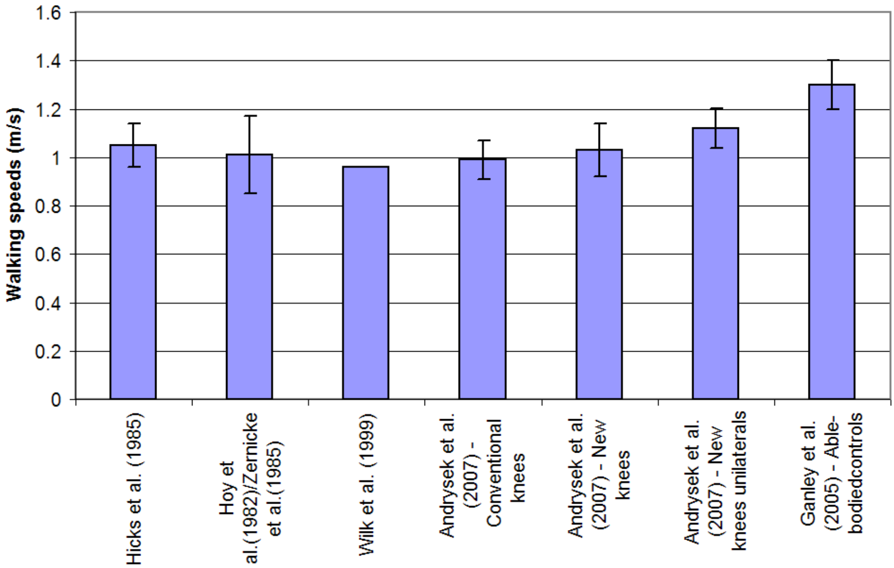


Figure 8.2: Average self-selected gait speeds from published studies involving children with above-knee amputations. One standard deviation shown by error bars, except for Wilk et al., where none was reported. For Andrysek et al. (2007)[34] data are presented for the children's conventional knee joint, the new knee and the new knee excluding the children with bilateral amputations. Able-bodied controls were obtained from Ganley et al. (2005).[35]

Conventional swing-phase control mechanisms are friction or fluid-based (hydraulic and pneumatic), the latter facilitating greater functionality[37] but resulting in greater technical complexity, component size and weight, and maintenance requirements.[7,38] As such, utilization of fluid-based swing-phase mechanisms in paediatric prosthetics has been limited. The new knee joint in this study provided simple friction control, the limitations of which were exhibited (especially in children with unilateral amputations) via pronounced spatiotemporal and kinematic asymmetries with increased walking velocities, most notably prolonged prosthetic side swing-times and excessive heel-rise. The remainder of the studies in this thesis explored an innovative and novel approach for swing-phase damping, possessing a number of potential functional and physical advantages when compared to conventional technologies.

Chapter 6 explored the unique application of a geared DC motor for use in swing-phase control; the distinctive features of this technology provided the opportunity for a cadence-responsive and adaptable swing-phase damping. In this work, empirically-based biomechanical models were used to ascertain the feasibility of using a DC brushed motor in prosthetic swing-phase damping control applications. This was done by comparing the gait-based damping characteristics of the DC brushed motor to conventional hydraulic and pneumatic systems across several gait conditions. The results indicated that a DC motor-based damper can replicate peak-damping torques during gait to accuracies between 84.9% and 100%, on average across gait conditions. However, we showed that these can be further improved by optimizing the system's configuration to perform analogously to highly-functional, fluid-based systems.[39] The eventual goal is to exceed the performance of these conventional systems.

In **chapter 7** these improvements were applied to a prototype that was developed and evaluated with a group of young active individuals with above-knee amputations. Temporal, kinematic and kinetic gait parameters and power generation performance were evaluated for self-selected and fast walking speeds for four damping settings including no damping, maximum damping, damping that provided maximum power generation, and adapted damping. For the adapted damping condition, the damping profile was adjusted heuristically based on gait observation and feedback from the participants.

Gait parameters including cadence and knee angle symmetry were found to be acceptable when knee damping was adapted for each participant. As expected the adapted damping condition resulted in the least pronounced gait deviations, while producing between 0.57 and 1.57W of electrical power, which is adequate to power a microprocessor-based prosthetic controller. One limitation of our testing approach was that we had used a single adapted damping setting for both self-selected and fast walking gait speeds. As such we did not fully utilize the beneficial features of this technology, namely the system's ability to automatically adjust to changing gait conditions. It is highly plausible that had we applied different damping profiles individually during self-selected and fast-walking trials, the gait characteristics would have further improved. As such, future adaptations will include the development of more sophisticated algorithms to automatically adapt to changing gait patterns.

With the proliferation of microprocessor-based prosthetics, the DC-motor technology holds other potentially significant advantages. Existing microprocessor fluid-based prosthetic knee joint technologies utilize complex actuated valves to adjust damping properties.[40] In contrast, DC motor damping levels are affected by the strength of the magnetic field and simply altered by using electronic components such as a MOSFET. Hence, the potential for a simple, inexpensive adaptable prosthetic swing-phase damper exists. A subsequent advantage of this approach is the opportunity to use the DC motor to generate electrical energy during portions of the gait cycle made feasible because of the predominantly eccentric muscle activity during the swing-phase of gait, which results in overall negative work.[41] In these high-end knees, this energy can ultimately be used by the onboard microprocessor, thus eliminating the need for large and heavy battery packs, and extending the operating range so that external charging needs be performed less frequently (figure 8.3). It is the consolidated advantages of these features that will hopefully make the development of smaller and lighter microprocessor-based prosthetics a reality. Such compact, light-weight alternatives are particularly appealing for paediatric prosthetic applications.

The development of the swing-phase controller as presented in chapter 6 was preliminary, and no attempts have been made to integrate the prototype swing-phase controller into the stance-phase controlled knee joint (described in chapters 2,3&5) at this time. In fact, it is quite plausible that the DC motor technology might only be suitable for use in prosthetic knee joints designed specifically for older children. Nevertheless, the technology holds promise that active youth will benefit from high-end microprocessor prosthetic technologies, to date designed only for adults.[25,42-54]

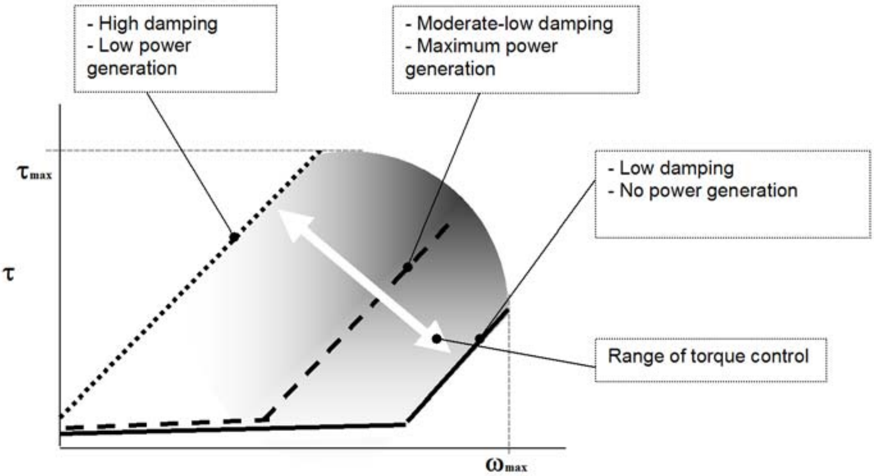


Figure 8.3: The damping and generating characteristics of the DC motor-based swing-phase controller system. Torque (τ) is shown as a function of angular velocity (ω). Darker (shaded) regions indicate higher levels of electrical power generation.

Much of the work presented in this thesis focused on addressing the shortcomings of existing prosthetic knee joints for children and youth with lower limb loss. The initial chapter identified the importance of stance-phase related design features, preparing the foundation for the development of a unique prosthetic stance-phase controller. The result was a prosthetic knee joint that provided more reliable stance-phase stability and was associated with reduced self-reported falls. Furthermore, we showed that this enhanced stance-phase stability was obtained without adversely affecting gait characteristics when compared to existing prosthetic knee joints. Validation of the functional advantages associated with the knee was shown by the children's self-reported preference for the new knee. The new knee joint can potentially deliver these benefits to young children because of its small size and lightness (table 8.1). The recommended age for fitting articulating prosthetic knee joints is 3-4 years. This is the age that children become capable of controlling knee articulation[38] and physically have adequate space to accommodate the larger size of these joints in their prosthetic shanks.[7] One additional benefit of our knee is its weight capacity of up to 60kg allowing it to be prescribed to older children and small adults. This is desirable from a commercialization perspective.

Table 8.1: Physical characteristics of knee joints tested.

	Overall length	Mass of knee	Weight capacity
Andrysek knee	11.2cm	320g	60kg
Four-bar knee	12.0cm	255g	35kg
Six-bar knee	14.6cm	340g	45kg

Novel approaches to prosthetic development

Recently, the first tissue engineered trachea was successfully transplanted into a human patient, as well as an in vitro demonstration of engineered beating heart tissue with blood vessels. The emerging and rapidly growing field of regenerative medicine[55] holds promise that one day a lost limb may be re-grown with all its physical and functional elements. However, the lower limb is an immensely complex architecture of tissues with specialized functions. For the time being, advancements in the areas of biomedical engineering and robotic systems will play a pivotal role in extending the performance of existing devices to more closely match the biological limb (table 8.2).

One primary limitation of existing prosthetic limbs is that they are not, and do not function as, extensions of the human body, and that effectively all of the major tissues (bone, muscle, skin, nerve) and their respective functions are terminated at the residuum. Because of this, tasks involving weight bearing, motor control, and sensing are all significantly compromised. For example, conventional prosthetic systems rely on the physical and structural interaction of the socket and the soft tissues surrounding the bone to transmit loads from the prosthesis to the residuum and effectively the skeletal structure. However, the soft tissues of the residuum are not (by nature) intended to serve this purpose, resulting in patient discomfort, skin breakdowns, and poor limb control. The termination of sensory signals at the residuum also poses major limitations, including the patient's inability to gauge the status of the prosthesis. Poor proprioception further exacerbates the problem. With less feedback as to the location and orientation of the prosthesis in space, and in relation to the ground, individuals with prosthesis are more likely to stub or catch the toe of their prosthesis during the swing-phase, potentially resulting in a stumble or fall. When the biological limb inadvertently comes in contact with the ground, active musculature assists in the reestablishment of balance to prevent a fall; however, this is not the case for conventional prosthetic systems, which are mainly passive in nature. It is the consolidation of these elements that need to be adequately addressed to better serve the prosthetic needs of patients in the future.

Osseointegration

Osseointegration, whereby a prosthesis is directly anchored to the living bone of the residual limb has been shown to be an excellent alternative for amputees experiencing complications or limitations in using conventional prosthetic socket technologies. Direct attachment to the bone increases control of the limb, eliminates pain and perspiration issues associated with sockets, decreases perception of weight, and improves osseoperception.[56] Although still perceived as investigational interventions, osseointegrated prostheses are associated with positive clinical outcomes such as increased prosthetic use, mobility, and quality of life in adults.[57,58] Disadvantages of this technology include the risk of deep-infections although the incidence of these adverse events are being reduced with improving treatment procedures.

Sensory feedback and motor control

Tapping into the nervous system is being investigated as a means for sensory feedback and for imposing controlling signals in prosthetic devices. The most commonly utilized and least invasive techniques include surface electromyography; these techniques show great promise in lower-limb prosthetics in terms of provision of a multiplicity of reliable and independent signals that may be acquired and used in controlling common mobility tasks.[59] Improvements to this technique, via decreased cross-talk from adjacent muscle groups and thus increased reliability of signals, are implantable electrodes that can be implanted into residual muscles.[60] Other techniques such as targeted re-innervations whereby severed nerves are surgically directed to re-innervate new muscles and skin sites, offer means and the opportunities for restoration of sensory feedback.[61] More recent developments in neuroprosthetics are aspiring to tap into the nervous system at the cortical level, thus bypassing the peripheral nervous system. Multi-electrode arrays are implanted in the motor cortex of the brain to sense the activities within that part of the brain associated with the desired movements. As with the previous techniques, these signals or intents are then supplied to control the movements of the prosthesis. Providing a multitude of signals in a reliable, real-time and concurrent fashion, offers the opportunity to go beyond passive reactive prosthetic systems, to systems resembling active human limbs.

Artificial muscles

Transcending conventional passive systems is essential if greater prosthetic functionality is to be realized. For example, climbing stairs or a hill, sitting up or running all necessitate concentric muscle activity, and therefore prosthetic knee actuation (table 8.2). However, mimicking muscle activity in lower limb prosthetics requires powerful actuators and high-density energy storage means, and any gains procured by conventional technologies have thus far been negated by the added weight of the prosthetic systems. Electroactive polymer materials with functional similarity to biological muscles hold great potential in prosthetic applications, as do other innovations such as the McKibben Artificial Muscle pneumatic actuator[62]. High density energy storage, such as Lithium Ion batteries, and conservation techniques such as energy reabsorption[39] are helping to make the utilization of actuators in lower-limb prosthetics a reality.

Ultimately, the convergence of innovations in biomedical engineering, robotics and informatics, may help to blend the interface between machine and human systems to facilitate the development of more human-like prosthesis. The clinical benefits of these emerging technologies are not likely to be witnessed in the short term, especially in paediatric prosthetics.

Table 8.2: Comparison of functions of biological limb and state-of-the-art prosthetic systems available today.

HUMAN LEG:	PROSTHETIC LEG:
-Stand -Sit -Walk -Kneel -Walk on uneven terrain -Walk at different speeds -Recover from a stumble -Run -Ascend/descend stairs -Adjust for shoe type -Jump -Sit up -Swim -Kick -Leap -Crouch -Crawl -Push off -Climb -Peddle -Skate -Ski -Dance -Hop -Twirl -Spin -And an -Incredible -Many -Things ...	-Stand -Sit -Walk -Kneel -Walk on uneven terrain* -Walk at different speeds* -Recover from a stumble* * high-end devices only facilitate these functions

Future research

Developing prosthetic components for children requires unique solutions that incorporate simplicity, durability and reliability, while supporting the typically active lifestyles of children. These requirements are echoed when considering the unmet needs of other amputee patient populations; specifically children and adults with above-knee amputations living in developing countries.

An estimated 3 to 4 million lower-limb amputees reside in developing countries, the majority of whom are young and active individuals, whose limb loss is primarily a result of traumatic injury due to armed conflict, landmines, and accidents.[63,64] In stark contrast to the technological advancements in developed countries, prosthetic technologies in developing countries are typically crude devices providing meager function. Given that many individuals are reliant on physical labour for their livelihoods, enabling functional mobility via effective and functional prosthetic intervention is an important socioeconomic consideration. Despite ongoing efforts by various organizations to address this need, there continues to be a paucity of appropriate prosthetic technologies. These technologies should facilitate high-level activity, have durability and reliability under harsh conditions (water, sand, extreme temperatures), be simple, easily maintained, culturally acceptable and most importantly low-cost.[64]

These design requirements have been challenging, especially in terms of above-knee prosthetic function. Consequently, the most utilized prosthetic knee joint mechanism has been the manually locking knee joint, which in industrialized nations is predominantly prescribed to very-low functioning elderly patients.[65] While desirably stable in the locked mode during stance, the knee remains in full extension during the swing-phase resulting in major gait deviations and compensations; the long-term ramifications of which include musculoskeletal problems.[32,33,66] The alternative is a free hinge (usually aligned to provide some stability) but this does not appear to be functionally adequate. The majority of young and active individuals in developing countries reportedly prefer to use the knee in the locked mode[67], likely in part due to the increased demands of keeping the knee stable on uneven and rough surfaces. Nevertheless, alignment stabilized single-axis knee joints with optional manual locks prevail as the most commonly prescribed devices in developing countries[63,68,69], presumably because of a lack of other options. One recent attempt utilized a redesigned version of a commonly used friction-based stance-phase control mechanism typically used in developed countries with geriatric patients. These types of devices were shown to be unreliable in stance-phase locking after only 6 months of use in 65% (22/34) cases.[70] Other approaches have utilized more complex mechanisms such as four-bar linkage knees, while employing certain cost reducing measures such as the decentralization of manufacturing and fabrication, such that the knees are entirely constructed by prosthetists/ technicians in clinics of developing countries.[71]

While such approaches are important to the goal of procuring affordable prosthetics in developing nations, it is clear that the development of innovative technologies is an integral part of this process. From a historical perspective, consolidation of state-of-the-art technologies (hydraulics, microprocessors) into high-end prosthetic appliances for use in developed countries is more common than the development of technologically simple devices capable of appropriate and acceptable performance, for developing countries. Limited commercial opportunities is the main issue. In developing countries these are due to a lack of health-care funding, while for children in developed countries it is the niche commercial market. In both circumstances, the result is slow technological progress. It is the goal of Bloorview in our future work to address these issues.[72]

Last, informed care goes hand in hand with the development of prosthetic devices. In this thesis, preliminary work is presented towards the evaluation of several new technologies. As part of future work, a broader range of outcome measures will be applied to gain greater insight into the potential advantages and disadvantages of these technologies on the health and well being of these children. For instance, energy expenditure studies are widely used in rehabilitation research as functional outcome measures in both adults[25,45-49] and children[73-76] with lower-limb amputations, as they provide an important insight into the efficiency of mobility. Self-report questionnaires also measure function, patient satisfaction, quality of life and other important aspects relating to patient well-being.[77-84] Extensive evaluative studies are required once interventions have, as far as possible, been finalized. In the case of prosthetic components this may be when they enter the market.

Conclusions

In summary, lower-limb loss poses a major limitation on mobility and therefore a significant personal and societal burden. While the provision of prostheses is an effective part of rehabilitation, existing prosthetic knee joint technologies for children possess major functional and physical limitations. Addressing these limitations is challenging and requires not only innovative research into the fundamentals of amputee gait biomechanics, but also novel technical approaches capable of producing highly functional, yet technically simple solutions. Such devices may not only improve the wellbeing of children with amputations, but also individuals in developing countries.

References

1. Breakey JW, Marquette SH. Beyond the four-bar knee. JPO 1998; 10: 77-80.
2. Cappozzo A, Leo T, Cortesi SS. A polycentric knee-ankle mechanism for above-knee prostheses. J Biomech 1980; 13: 231-9.
3. de Vries J. Conventional 4-bar linkage knee mechanisms: a strength-weakness analysis. J Rehabil Res Dev 1995; 32: 36-42.
4. Öberg K. Knee mechanisms for through-knee prostheses. Prosthet Orthot Int 1983; 7: 107-12.
5. Radcliffe CW. Four-bar linkage prosthetic knee mechanisms: kinematics, alignment and prescription criteria. Prosthet Orthot Int 1994; 18: 159-73.
6. Andrysek J, Naumann S, Cleghorn W. Design characteristics of pediatric prosthetic knees. IEEE Trans Neural Syst Rehabil Eng 2004; 12: 369-78.
7. Cummings D. The missing link in pediatric prosthetic knees. Biomechanics 1997; 4: 163-8.
8. Bossert JL. Quality Function Deployment. Milwaukee, WI: ASQC; 1991.
9. Revelle JB, Moran JW, Cox CA. The QFD handbook. New York, USA: John Willey & Sons; 1998.
10. Jacques GE, Ryan S, Naumann S, Milner M, Cleghorn WL. Appplication of quality function deployment in rehabilitation engineering. IEEE Trans Rehabil Eng 1994; 2: 158-64.
11. van de Veen, P. G. An investigation of design criteria of modular endoskeletal lower limb prosthetics [dissertation]. Twente, the Netherlands: University of Twente; 1989.
12. Gard, SA. use of quantitative gait analysis for the evaluation of prosthetic walking performance. JPO 2006; 18(1S): 93-104.
13. Mensch G, Ellis P. Physical therapy management of lower extremity amputations. Rockville, MD: Aspen Publishers; 1986.
14. Yang L, Solomonidis SE, Spence WD, Paul JP. The influence of limb alignment on the gait of above-knee amputees. J Biomech 1991; 24: 981-97.
15. Postema K, Hermens HJ, de Vries J, Koopman HF, Eisma WH. Energy storage and release of prosthetic feet. Part 2: Subjective ratings of 2 energy storing and 2 conventional feet, user choice of foot and deciding factor. Prosthet Orthot Int 1997; 21: 28-34.
16. Andrysek J, Naumann S, Cleghorn W. Design and quantitative evaluation of a stance-phase controlled prosthetic knee joint for children. IEEE Transactions on Neural Systems and Rehabilitation Engineering 2005; 13: 437-43.
17. Wilk B, Karol, L Halliday S, Cummings D, Haideri N, Stepheson J. Transition to an articulating knee prosthesis in pediatric amputees. JPO 1999; 11: 69-74.
18. Britton JW. Kids can't fly: preventing fall injuries in children. WMJ 2005; 104: 33-6.
19. Spencer MT, Baron BJ, Sinert R, Mahmoud G, Punzalan C, Tintinalli A. Necessity of hospital admission for pediatric minor head injury. Am J Emerg Med 2003; 21: 111-4.
20. Miller WC, Speechley M, Deathe B. The prevalence and risk factors of falling and fear of falling among lower extremity amputees. Arch Phys Med Rehabil 2001; 82: 1031-7.
21. Miller WC, Deathe AB. A prospective study examining balance confidence among individuals with lower limb amputation. Disabil Rehabil 2004; 26: 875-81.
22. van der LH, Hofstad CJ, Geurts AC, Postema K, Geertzen JH, van LJ. A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. J Rehabil Res Dev 2004; 41: 555-70.

23. Goujon-Pillet H, Sapin E, Fode P, Lavaste F. Three-dimensional motions of trunk and pelvis during transfemoral amputee gait. Arch Phys Med Rehabil 2008; 89: 87-94.
24. Michaud SB, Gard SA, Childress DS. A preliminary investigation of pelvic obliquity patterns during gait in persons with transtibial and transfemoral amputation. J Rehabil Res Dev 2000; 37: 1-10.
25. Datta D, Heller B, Howitt J. A comparative evaluation of oxygen consumption and gait pattern in amputees using Intelligent Prostheses and conventionally damped knee swing-phase control. Clin Rehabil 2005; 19: 398-403.
26. Graham LE, Datta D, Heller B, Howitt J, Pros D. A comparative study of conventional and energy-storing prosthetic feet in high-functioning transfemoral amputees. Arch Phys Med Rehabil 2007; 88: 801-6.
27. Jaegers SM, Arendzen JH, de Jongh HJ. Prosthetic gait of unilateral transfemoral amputees: a kinematic study. Arch Phys Med Rehabil 1995; 76: 736-43.
28. MacFarlane PA, Nielsen DH, Shurr D. Mechanical gait analysis of transfemoral amputees: SACH foot versus the Flex-Foot. JPO 1997; 9: 144-151.
29. Hoy MG, Whiting WC, Zernicke RF. Stride kinematics and knee joint kinetics of child amputee gait. Arch Phys Med Rehabil 1982; 63: 74-82.
30. Hicks R, Tashman S, Cary JM, Altman RF, Gage JR. Swing phase control with knee friction in juvenile amputees. J Orthop Res 1985; 3: 198-201.
31. Lelas JL, Merriman GJ, Riley PO, Kerrigan DC. Predicting peak kinematic and kinetic parameters from gait speed. Gait Posture 2003; 17: 106-12.
32. Royer T, Koenig M. Joint loading and bone mineral density in persons with unilateral, trans-tibial amputation. Clin Biomech (Bristol, Avon) 2005; 20: 1119-25.
33. Royer TD, Wasilewski CA. Hip and knee frontal plane moments in persons with unilateral, trans-tibial amputation. Gait Posture 2006; 23: 303-6.
34. Andrysek J, Redekop S, Naumann S. Preliminary evaluation of an automatically stance-phase controlled paediatric prosthetic knee joint using quantitative gait analysis. Arch Phys Med Rehabil 2007; 88: 464-470.
35. Ganley KJ, Powers CM. Gait kinematics and kinetics of 7-year-old children: a comparison to adults using age-specific anthropometric data. Gait Posture 2005; 21: 141-5.
36. Umberger BR, Martin PE. Mechanical power and efficiency of level walking with different stride rates. J Exp Biol 2007; 210: 3255-65.
37. Nelson VS, Flood KM, Bryant PR, Huang ME, Pasquina PF, Roberts TL. Limb deficiency and prosthetic management. 1. Decision making in prosthetic prescription and management. Arch Phys Med Rehabil 2006; 87: S3-S9.
38. Jain S. Rehabilitation in limb deficiency. 2. The pediatric amputee. Arch Phys Med Rehabil 1996; 77: S9-13.
39. Andrysek J, Chau G. An electromechanical swing-phase-controlled prosthetic knee joint for conversion of physiological energy to electrical energy: feasibility study. IEEE Trans Biomed Eng 2007; 54: 2276-83.
40. Michael JW. Modern prosthetic knee mechanisms. Clin Orthop Relat Res 1999; 39-47.
41. Whittle MW. Gait Analysis: an introduction. 2nd ed. Oxford, UK: Butterworth-Heinemann; 2002.
42. Schmalz T, Blumentritt S, Jarasch R. Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. Gait Posture 2002; 16: 255-63.
43. Segal AD, Orendurff MS, Klute GK et al. Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. J Rehabil Res Dev 2006; 43: 857-70.

44. Seymour R, Engbretson B, Kott K et al. Comparison between the C-leg microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: a preliminary study of energy expenditure, obstacle course performance, and quality of life survey. Prosthet Orthot Int 2007; 31: 51-61.
45. Buckley JG, Spence WD, Solomonidis SE. Energy cost of walking: comparison of "intelligent prosthesis" with conventional mechanism. Arch Phys Med Rehabil 1997; 78: 330-3.
46. Taylor MB, Clark E, Offord EA, Baxter C. A comparison of energy expenditure by a high level trans-femoral amputee using the Intelligent Prosthesis and conventionally damped prosthetic limbs. Prosthet Orthot Int 1996; 20: 116-21.
47. Chin T, Sawamura S, Shiba R et al. Effect of an Intelligent Prosthesis (IP) on the walking ability of young transfemoral amputees: comparison of IP users with able-bodied people. Am J Phys Med Rehabil 2003; 82: 447-51.
48. Heller BW, Datta D, Howitt J. A pilot study comparing the cognitive demand of walking for transfemoral amputees using the Intelligent Prosthesis with that using conventionally damped knees. Clin Rehabil 2000; 14: 518-22.
49. Orendurff MS, Segal AD, Klute GK, McDowell ML, Pecoraro JA, Czerniecki JM. Gait efficiency using the C-Leg. J Rehabil Res Dev 2006; 43: 239-46.
50. Williams RM, Turner AP, Orendurff M et al. Does having a computerized prosthetic knee influence cognitive performance during amputee walking? Arch Phys Med Rehabil 2006; 87: 989-94.
51. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. Arch Phys Med Rehabil 2007; 88: 207-17.
52. Kahle JT, Highsmith MJ, Hubbard SL. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. J Rehabil Res Dev 2008; 45: 1-14.
53. Kaufman KR, Levine JA, Brey RH, McCrady SK, Padgett DJ, Joyner MJ. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Arch Phys Med Rehabil 2008; 89: 1380-5.
54. Johansson JL, Sherrill DM, Riley PO, Bonato P, Herr H. A Clinical Comparison of Variable-Damping and Mechanically Passive Prosthetic Knee Devices. Am J Phys Med Rehabil 2005; 84: 563-75.
55. Viola J, Bhavya L, Oran G. The emergence of tissue engineering as a research field. Arlington, VA: The National Science Foundation; 2003 [Online] http://www.nsf.gov/pubs/2004/nsf0450/start.htm.
56. Fairley M. Osseointegration: In the Wave of the Future? O&P Edge; 2006 [Online] http://www.oandp.com/articles/2006-09_03.asp.
57. Hagberg K, Branemark R, Gunterberg B, Rydevik B. Osseointegrated trans-femoral amputation prostheses: prospective results of general and condition-specific quality of life in 18 patients at 2-year follow-up. Prosthet Orthot Int 2008; 32: 29-41.
58. Staubach KH, Grundei H. The first osseointegrated percutaneous prosthesis anchor for above-knee amputees. Biomed Tech (Berl) 2001; 46: 355-61.
59. Huang H, Kuiken TA, Lipschutz RD. A strategy for identifying locomotion modes using surface electromyography. IEEE Trans Biomed Eng 2009; 56: 65-73.
60. Weir RF, Troyk, PR, DeMichele G, Kerns, D. Implantable EMG sensor (IMES) for improved myoelectric control. In: Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics: Vancouver, Canada; 2007; 223.
61. Schultz AE, Marasco PD, Kuiken TA. Vibrotactile detection thresholds for chest skin of amputees following targeted reinnervation surgery. Brain Res 2009; 1251: 121-9.

62. Hannaford B, Winters JM, Chou CP, Marbot PH. The anthroform biorobotic arm: a system for the study of spinal circuits. Ann Biomed Eng 1995; 23: 399-408.
63. Day HJ. A review of the consensus conference on appropriate prosthetic technology in developing countries. Prosthet Orthot Int 1996; 20: 15-23.
64. Cummings D. Prosthetics in the developing world: a review of the literature. Prosthet Orthot Int 1996; 20: 51-60.
65. Devlin M, Sinclair LB, Colman D, Parsons J, Nizio H, Campbell JE. Patient preference and gait efficiency in a geriatric population with transfemoral amputation using a free-swinging versus a locked prosthetic knee joint. Arch Phys Med Rehabil 2002; 83: 246-9.
66. Stam HJ, Dommisse AM, Bussmann HJ. Prevalence of low back pain after transfemoral amputation related to physical activity and other prosthesis-related parameters. Disabil Rehabil 2004; 26: 794-7.
67. Jensen JS, Raab W. Clinical field testing of trans-femoral prosthetic technologies: resin-wood and ICRC-polypropylene. Prosthet Orthot Int 2004; 28: 141-51.
68. Jensen JS, Craig JG, Mtalo LB, Zelaya CM. Clinical field follow-up of high density polyethylene (HDPE)-Jaipur prosthetic technology for trans-femoral amputees. Prosthet Orthot Int 2004; 28: 152-66.
69. Prosthetic component manufacturing in Vietnam. Prosthetic Outreach Foundation; 2009 [Online] http://www.pofsea.org/VNknee.htm.
70. Jensen JS, Raab W. Clinical field-testing of ATLAS prosthetic system for trans-femoral amputees. Prosthet Orthot Int 2003; 27: 55-62.
71. Uncrippling the world. LEGS Program - LeTourneau University, TX, US; 2009 [Online] http://www.legsresearch.org/people.html.
72. Andrysek J, Steinnagel B, Redekop S. Pilot testing of an automatic stance-phase lock in a low-cost prosthesis. 16th Biennial 2008 CAPO Convention "Meeting in the Middle": Winnipeg, Canada; 2008.
73. van der Windt DA, Pieterson I, van der Eijken JW, Hollander AP, Dahmen R, De Jong BA. Energy expenditure during walking in subjects with tibial rotationplasty, above-knee amputation, or hip disarticulation. Arch Phys Med Rehabil 1992; 73: 1174-80.
74. Loder RT, Herring JA. Disarticulation of the knee in children. A functional assessment. J Bone Joint Surg Am 1987; 69: 1155-60.
75. Colborne GR, Naumann S, Longmuir PE, Berbrayer D. Analysis of mechanical and metabolic factors in the gait of congenital below knee amputees. A comparison of the SACH and Seattle feet. Am J Phys Med Rehabil 1992; 71: 272-8.
76. Engsberg JR, Herbert LM, Grimston SK, Fung TS, Harder JA. Relation among indices of effort and oxygen uptake in below-knee amputee and able-bodied children. Arch Phys Med Rehabil 1994; 75: 1335-41.
77. Pruitt SD, Varni JW, Setoguchi Y. Functional status in children with limb deficiency: development and initial validation of an outcome measure. Arch Phys Med Rehabil 1996; 77: 1233-8.
78. Pruitt SD, Seid M, Varni JW, Setoguchi Y. Toddlers with limb deficiency: conceptual basis and initial application of a functional status outcome measure. Arch Phys Med Rehabil 1999; 80: 819-24.
79. Pruitt SD, Varni JW, Seid M, Setoguchi Y. Prosthesis satisfaction outcome measurement in pediatric limb deficiency. Arch Phys Med Rehabil 1997; 78: 750-4.
80. Pruitt SD, Varni JW, Seid M, Setoguchi Y. Functional status in limb deficiency: development of an outcome measure for preschool children. Arch Phys Med Rehabil 1998; 79: 405-11.

81. Callaghan BG, Condie ME. A post-discharge quality of life outcome measure for lower limb amputees: test-retest reliability and construct validity. Clin Rehabil 2003; 17: 858-64.
82. Demet K, Martinet N, Guillemin F, Paysant J, Andre JM. Health related quality of life and related factors in 539 persons with amputation of upper and lower limb. Disabil Rehabil 2003; 25: 480-6.
83. Gallagher P, Maclachlan M. The Trinity Amputation and Prosthesis Experience Scales and quality of life in people with lower-limb amputation. Arch Phys Med Rehabil 2004; 85: 730-6.
84. Legro MW, Reiber GD, Smith DG, del Aguila M, Larsen J, Boone D. Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. Arch Phys Med Rehabil 1998; 79: 931-8.

Dutch Summary
(Nederlandse samenvatting)

Het ontwerpen van prothetische componenten vereist aandacht zowel voor de functionele voordelen als voor de schadelijke factoren zoals gewicht, omvang, kosten en onderhoudsvereisten. Dit geldt vooral voor kinderprothesen, omdat kinderen en jonge volwassenen van nature meer fysieke activiteit ontwikkelen en hun prothesen zwaarder belasten dan volwassenen. Daarnaast dienen de prothetische componenten in deze leeftijdsgroep compact, licht en zeer slijtvast te zijn. In het licht daarvan blijft de voorziening van effectieve componenten voor knieprothesen voor kinderen en adolescenten, het primaire accent van dit proefschrift, een uitdaging.

Vanwege een aantal belangrijke functionele voordelen boven één-assige configuraties, worden vier- en zes-stangige verbindingen het meest frequent toegepast bij knieprothesemechanismen in de kindergeneeskunde. Met deze mechanismen ontkomt men echter niet aan een knieprotheseconstructie die groter, zwaarder en meer complex is. In deze context kwam de nadruk in **hoofdstuk 2** op onderzoek of, en in welke vorm, een eenvoudige één-assige gewrichtsconstructie even effectief kan functioneren als vier- en zes-stangige verbindingsmechanismen. In deze studie werd een groep kinderen onderzocht met betrekking tot de belangrijke aspecten van knieprothesefunctie. Uitgaande van een gestandaardiseerd ontwerp werden deze functies en voorkeuren van kinderen vertaald naar prestatiekenmerken van het ontwerp. Met behulp van passieve kinematische modellen werden de als hoogwaardig geachte fysieke ontwerpkenmerken, waaronder stabiliteit van de sta-fase, aanzet van de zwaaifase en voetafwikkeling geëvalueerd met betrekking tot verschillende commercieel beschikbare componenten voor knieprothesen en werden standaarden vastgesteld. Daarna werden diverse één-assige configuraties met elkaar vergeleken en een voorkeursexemplaar voorgesteld.

De voorgestelde configuratie heeft voordelen in de zin van toegenomen voetafwikkeling en gemakkelijke knieflexie-aanzet in de terminale sta-fase. Een toegenomen voetafwikkeling resulteert in een verminderde kans op struikelen en/of een vermindering van compensatoire gangspoorafwijkingen in vergelijking met een voor gangspoor gestabiliseerde één-assige configuratie. De bevindingen duidden erop dat een één-assig mechanisme in een zodanige vorm zou kunnen worden gefabriceerd dat het aan belangrijke functionele eisen zou kunnen voldoen wanneer aanvullende maatregelen zouden worden genomen voor controle over de sta-fase. Hiermee werd een belangrijke basis gelegd voor het ontwerp en de ontwikkeling van een nieuwe knieprothese met inherente competentie voor verbeterde functionaliteit, met eenvoudiger middelen en met een compactere vorm, waardoor mogelijk een aantal allang bestaande klinische en technische nadelen van knieprothesen voor kinderen zouden kunnen worden verbeterd.

In hoofdstuk 3 werd het ontwerp van de knieprothese uitgebreid, met als primair accent verbetering van het controlemechanisme voor de sta-fase. In dit hoofdstuk werd een nieuwe sta-fasestrategie en -mechanisme gepresenteerd. Er werd een nieuwe benadering ontwikkeld voor de modellering om biomechanische analyse van dit mechanisme en andere tweevoudige controle-as sta-fasemechanismen, zoals 6-stangige knieverbindingen, te vergemakkelijken. Uitgaande van de functionele eigenschappen van dit nieuwe kniegewricht en de biomechanische analyse van de stabiliteit ervan ontstond er een verwachting dat de nieuwe knie stabieler zou zijn dan vier- en zes-stangige knieprothesen voor kinderen. In een cross-over ‘case-series’ opzet, werden kinderen onderzocht na het dragen van de nieuwe knieprothese en ofwel een vier- ofwel een zes-stangige knieverbinding om de relatieve prestaties van het nieuwe sta-fasemechanisme te evalueren.

Met gebruikelijke knieprothesen, maken sta-fasecontrolemechanismen een stabiel of vastgezet kniegewricht los als reactie op een specifiek sta-fasebelastingspatroon. Aanzienlijke afwijkingen van dit patroon kunnen leiden tot destabilisatie van de knie met struikelen of vallen tot gevolg. Met ons sta-fasemechanisme wordt dit nadeel beperkt door terugkeer naar de standaardwaarde (dat wil zeggen een vastgezette knie) tijdens extensie van de knie met destabilisatie van de knie dat nodig is bij het eindstadium van staan, en optreedt als gevolg van een specifiek belastingspatroon dat behoort bij dat gedeelte van de loopcyclus. Op deze manier heeft de nieuwe knie een grotere neiging om stabiel te blijven tijdens de vroege en middelste loopstand. Een ander voordeel van onze knie is dat deze bij volledige extensie automatisch vastgezet wordt in de volledige extensiefase van de knie en vastgezet blijft tot aan en tijdens belading. Met deze twee sta-fase stabiliteitvergrotende eigenschappen ontstond bij ons een verwachting van een verbetering van een of meer aspecten van de mobiliteit, die tot uiting zou komen via de zelfgerapporteerde enquête.

Zoals wij veronderstelden, lieten de gegevens van de vragenlijstenquête meer betrouwbaarheid in de stabiliteit van de sta-fase zien, met een significante vermindering ($p<0,03$) in de incidentie van vallen. Het mediane aantal gerapporteerde maandelijkse voorvallen van defect raken van de knieën waren respectievelijk 30 en 1, voor de conventionele (vier- en zes-stangige knieën) en de nieuwe knieën. Alle kinderen gaven op de vragenlijst aan dat zij de voorkeur gaven aan de nieuwe knie in plaats van hun conventionele knieën. Vijf van de zes kinderen bleven de nieuwe knie gebruiken (in plaats van hun conventionele knieën) gedurende gemiddeld 14 maanden (3-21 maanden).

Hoewel er zeer weinig literatuur is over vallen in de populaties van geamputeerde kinderen, wijst de klinische praktijk erop dat het vermogen van een kind om scharnieren van het kniegewricht te beheersen teneinde vallen te voorkomen een belangrijk aspect is bij het voorschrijven van prothesen. Vallen, inclusief vallen tijdens wandelen en rennen, is de belangrijkste oorzaak van onbedoeld letsel bij gezonde kinderen en ouderen met onderbeenamputaties. Bij jonge kinderen wordt vallen weliswaar als een deel van de normale ontwikkeling van het bewegingsapparaat beschouwd, maar het zou een van de doelen van onderhoud van prothesen moeten zijn om de incidentie van vallen te minimaliseren. In het licht daarvan waren de voorlopige bevindingen met betrekking tot de reducties van de frequenties van vallen, gerelateerd aan de nieuwe knie, zeer bemoedigend.

In hoofdstukken 2 en 3 werden unieke en nieuwe ontwerpaspecten gepresenteerd die betrekking hebben op belangrijke loopfuncties. Het doel van hoofdstuk 5 was evaluatie van de effecten van deze ontwerpaspecten op de gang. Beoordelingen van de gang behoren tot de meest frequent toegepaste uitkomstmaten bij prothetische geneeskunde van het been en voorzien in een directe meting van belangrijke aspecten van de biomechanische- en bewegingsfunctie. Hoofdstuk 4 bevat belangrijke informatie die onontbeerlijk is voor een goed begrip van hoofdstuk 5 en behandelt methodologische vraagstukken over de betrouwbaarheid van metingen van parameters van de gang.

In hoofdstuk 4 onderzochten wij de intraproefpersoon-variabiliteit van bekende parameters voor ruimte en tijd en kinematische gang verkregen uit kwantitatieve analyse van de gang van kinderen met variabele niveaus van mobiliteitsbeperking. Er was een gebrek aan gepubliceerde gegevens en een tekort aan consensus met betrekking tot het aantal herhaalde stappen van de gang die tijdens analyse van de gang zouden moeten worden gebruikt om zeker te weten dat een stabiele weergave van de metingen verkregen was. Gegevens zouden onbetrouwbaar kunnen zijn als deze zijn gebaseerd op onvoldoende stappen; het verzamelen van veel stappen voor een stabiele weergave van de gang kan echter veel moeite kosten en soms onpraktisch zijn, vooral bij kleine kinderen. In dit opzicht was het van belang om criteria vast te stellen met betrekking tot het minimale aantal herhaalde metingen tijdens de sessies die een betrouwbare weergave verschaffen van de gang.

Hoofdstuk 4 bevat ook verwerkte gegevens van een groep ambulante kinderen met cerebrale parese, die behoorden tot een subcategorie op grond van de ‘Gross Motor Function Classification System’. Onderzoek bij kinderen met CP had een tweevoudig voordeel: 1) beschikbaarheid over een grotere populatiedatabase die toegang gaf tot een afdoende steekproefgrootte voor dit studietype; 2) stratificatie van kinderen naar homogene groepen op grond van hun niveaus van beperking, waardoor wij in staat waren om de betrouwbaarheid van de parameters van de gang te beoordelen op variabele niveaus van de totale motorische functie. De bevindingen wezen erop dat 4 tot 6 stappen betrouwbare schattingen van parameters voor ruimte en tijd en kinematische gang verschaffen over een breed gebied van motorische functieniveaus, variërend van kinderen die zonder beperkingen kunnen lopen en slechts kleine afwijkingen van de gang hebben tot kinderen die niet zonder hulpmiddelen voor de mobiliteit kunnen zoals wandelstokken en looprekken. In het licht daarvan, kunnen de bevindingen in hoofdstuk 4 gegeneraliseerd worden naar andere kindergeneeskundige patiëntenpopulaties, inclusief kinderen met amputaties boven de knie; deze methodologische beslissing werd toegepast bij de evaluatie van het nieuwe kniegewricht dat in hoofdstuk 5 werd gepresenteerd.

Het doel van **hoofdstuk 5** was de effecten van het nieuwe kniegewricht op de gang te evalueren en overwegingen voor een toekomstig ontwerp voor te stellen. De belangrijke bevinding in deze studie was een algemene toename van de zelfgekozen wandelsnelheid van de kinderen met een eenzijdige amputatie, zowel bij een directe vergelijking met de vier- en zes-stangige knieën die in dit onderzoek werden gebruikt als met die welke in de literatuur worden vermeld. De toegenomen wandelsnelheid van de kinderen met een eenzijdige amputatie vertoonde een verband met toegenomen steunmomenten en steunkrachten voor het gewricht, wat een verwacht resultaat was op grond van de correlatie van deze parameters voor de gang. Deze resultaten duidden erop dat mechanische werkaanpassingen, zoals het heupflexiekoppel dat nodig is voor de aanzet van de prothetische 'side pre-swing' flexie van het kniegewricht dat gerelateerd is aan de nieuwe knie, vergelijkbaar waren met vier- en zes-stangige verbindingsknieën. Dit was een positieve bevinding als men bedenkt dat toegenomen gewrichtsmomenten kunnen leiden tot gewrichtsdegeneratie. Parameters voor ruimte en tijd en kinematische parameters brachten echter toegenomen asymmetrieën aan het licht die gerelateerd waren aan de nieuwe knie, wat een behoefte aan modificaties van het ontwerp van de zwaaifasecontrole doet vermoeden.

Conventionele zwaaifasecontrolemechanismen zijn op wrijving of vloeistof gebaseerd, waarbij laatstgenoemde de functionaliteit bevordert maar leidt tot een meer complexe techniek, een toename van de grootte en het gewicht van componenten, en hogere eisen qua onderhoud. In het licht daarvan is gebruik van op vloeistof gebaseerde zwaaifasemechanismen in kinderprothesen beperkt. Het nieuwe kniegewricht in deze studie voorzag in een eenvoudige beheersing van de wrijving, terwijl de beperkingen hiervan tot uiting kwamen (vooral bij kinderen met eenzijdige amputaties) via uitgesproken asymmetrieën in tijd en ruimte en kinematische asymmetrieën bij toegenomen wandelsnelheden, waarvan langere 'side swing'-tijden en buitensporige verhoging van de hak van de prothese het meest opvielen. De overige studies in dit proefschrift onderzochten een innovatieve en nieuwe benadering van zwaaifasedemping, met een aantal mogelijke functionele en fysieke voordelen in vergelijking met conventionele technieken.

Hoofdstuk 6 beschrijft een onderzoek van de unieke toepassing van een gelijkstroommotor met versnelling voor gebruik bij de beheersing van de zwaaifase; de kenmerkende eigenschappen van deze techniek verschaften de gelegenheid voor een cadansgevoelige en adapteerbare zwaaifasedemping. In dit onderzoek werden op empirie gebaseerde biomechanische modellen gebruikt om de haalbaarheid van het gebruik van een gelijkstroommotor met contactborstels voor beheersing van de zwaaifasedemping bij toepassingen in prothesen na te gaan. Dit werd uitgevoerd door vergelijking van de op de gang gebaseerde dempingeigenschappen van de gelijkstroommotor met contactborstels met conventionele hydraulische en pneumatische systemen in verschillende omstandigheden van de gang. De resultaten wezen erop dat een op een gelijkstroommotor gebaseerde demper piekdempende koppels kan reproduceren tijdens de gang tot nauwkeurigheden die gemiddeld tussen 84,9% en 100% liggen, in verschillende omstandigheden van de gang. Wij hebben echter aangetoond dat deze nog verbeterd kunnen worden door optimalisatie van de configuratie van het systeem zodat het prestaties kan leveren die analoog zijn met hoogfunctionele, op vloeistof gebaseerde systemen. Het uiteindelijke doel is de prestaties van deze conventionele systemen te overtreffen.

Hoofdstuk 7 beschrijft de ontwikkeling van een prototype van het zwaaifasecontrolemechanisme en een evaluatie ervan met hulp van drie actieve adolescenten en jonge volwassenen met amputaties boven de knie in verschillende omstandigheden van demping en gangsnelheden. De prestaties van gang en krachtontwikkeling werden beoordeeld met geselecteerde parameters van tijd, en kinematische en kinetische parameters. Parameters van de gang, inclusief cadans en kniehoeksymmetrie, bleken acceptabel als kniedemping voor elke deelnemer werd aangepast. Door de drie proefpersonen en twee wandelsnelheden, werd tussen de 0,57 en 1,57W elektrisch vermogen geproduceerd. Deze resultaten geven aan dat deze techniek gebruikt kan worden voor beheersing van de zwaaifase van prothesen en mogelijk op den duur de behoefte aan manueel opladen van op microprocessoren gebaseerde prothesen zou kunnen verminderen. De geconsolideerde voordelen van deze eigenschappen bezitten misschien de potentie om de ontwikkeling van kleinere en lichtere op microprocessoren gebaseerde prothesen te verwerkelijken. Zulke compacte, lichtgewicht alternatieven zijn vooral aantrekkelijk voor toepassingen in kinderprothesen.

Hoofdstuk 8 geeft een overzicht van alle voorgaande hoofdstukken en beschrijft de bijdrage van het onderzoek aan de ontwikkeling van moderne knieprothesetechnieken voor kinderen. Lopend en toekomstig onderzoek behelst bevordering van de ontwikkeling van de zwaai- en stafasetechnieken om uiteindelijk ook te voorzien in de behoeften van andere patiëntenpopulaties.

Acknowledgements

First and foremost, there are my parents, who through risk and self-sacrifice provided us with the opportunities that only Canada offers, fleeing the old country with two suitcases, two preteen kids, and starting a new life essentially from scratch. Somehow they found the resources to put two kids through University, through two degrees each, excluding this PhD, to make it possible for me to arrive at this point. Thank you.

I would like to thank Dr. Colin Macarthur for recognizing my potential to be a productive scientist, and to always be highly encouraging and supportive of my research and development work. It has been, and continues to be an incredible experience, to be able to pursue the development of unique prosthetic and orthotic solutions for individuals around the world. I would like to thank both Dr. Macarthur and Dr. Paul Helders for making it possible for me to pursue this Doctoral degree, which was a main missing piece in my research endeavors. I am grateful for their incredible support and guidance throughout the process.

Before Dr. Macarthur, there was Dr. Steve Naumann, whom I would like to thank for introducing me to the research world, and for providing me the opportunity to develop some of my earliest ideas into working devices, thus encouraging me to pursue this area of research further.

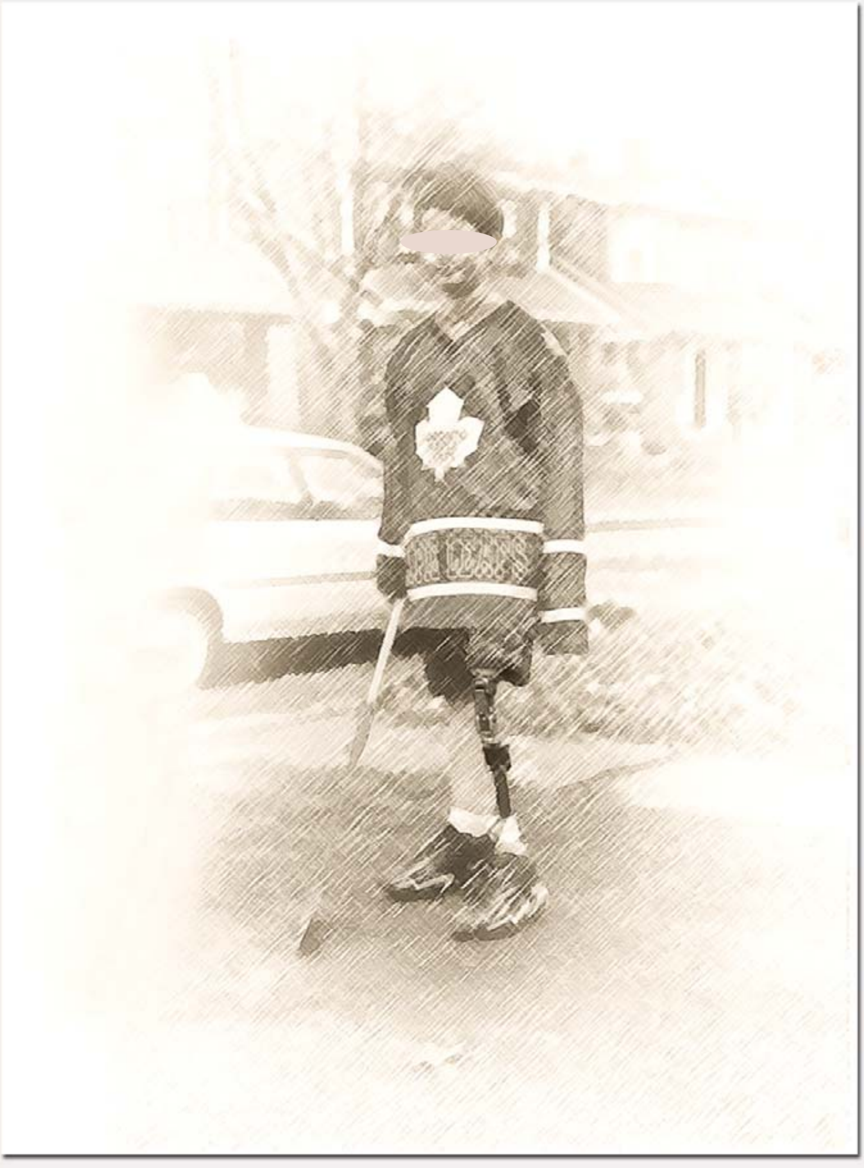
This work would not have been possible without the contributions of many of my colleagues, some who are listed as co-authors, and others who are not, but have played important roles in the research, development and commercialization of the prosthetic technologies presented here. For the fear of omitting names, I will keep this a general acknowledgement. Your contributions to this work are greatly appreciated.

I am thankful that Dr. Macarthur and Dr. Helders held us to the tight time lines for the completion of this thesis, thus minimizing the opportunities for procrastination. Being part of team Canada, which included my colleagues Steve Ryan and Patty Rigby, made the process a lot more pleasant. Thank you both for your support and help.

Last but not least, I would like to thank my wife Vanda for designing the cover and chapter pages, and helping with some of the formatting, but even more importantly keeping the little ones occupied in the evenings so that I

could have time to work on this thesis. She always believed there would be the opportunity for me to get my doctorate, and has always been incredibly supportive of my work.

List of publications



Journal

Andrysek J, Liang T, Steinnagel B. Evaluation of a prosthetic swing-phase controller with electrical power generation. IEEE Trans Neural Syst Rehab Eng 2008; in-press.

Redekop S, Andrysek J, Wright V. Single-session reliability of discrete gait parameters in ambulatory children with cerebral palsy based on GMFCS level. Gait Posture 2008; 28(4): 627-33.

Andrysek J, Redekop S, Matsui N, Kooy J, Hubbard S. A method to measure the accuracy of loads in knee-ankle-foot orthoses using conventional gait analysis, applied to persons with poliomyelitis. Arch Phys Med Rehabil 2008; 89(7): 1372-9.

Andrysek J, Chau G. A self-energizing electromechanical swing-phase controlled knee joint prostheses: Feasibility study. IEEE Trans Biomed Eng 2007; 54(12): 2276-83.

Andrysek J, Redekop S, Naumann S. Preliminary evaluation of an automatically stance-phase controlled pediatric prosthetic knee joint using quantitative gait analysis. Arch Phys Med Rehabil. 2007; 88: 464-70.

Andrysek J, Naumann S, Cleghorn W. Design and quantitative evaluation of a stance-phase controlled prosthetic knee joint for children. IEEE Trans Neural Syst Rehab Eng 2005; 13(4): 369-78.

Andrysek J, Naumann S, Cleghorn W. Design characteristics of paediatric prosthetic knees. IEEE Trans Neural Syst Rehab Eng 2004; 12(4): 368-78.

Otto E, Semotok C, Andrysek J, Basir O. An intelligent diabetes software prototype: Predicting blood glucose levels and recommending regimen. Diabet Tech Therap 2000; 2(4): 569-76.

Conference proceedings & abstracts

Andrysek J, Redekop S, Matsui N, Kooy J, Hubbard S. Errors associated with gait laboratory measurements of orthotic knee joint moments. ACRM-ASNR Joint Educational Conference, (pE17)October 15-19, 2008.

Harrison D, Andrysek J, Cleghorn W. Design of a low-cost, stance-phase prosthetic knee. PACE Global Annual Forum - “Collaboration for Innovation”, Detroit, MI, July 28-August 02, 2008.

Andrysek J, Steinnagel B. Redekop S. Johnson B. Pilot testing of an automatic stance-phase lock in a low-cost prosthesis. 16th Biennial 2008 CAPO Convention “Meeting in the Middle. Winnipeg, MB, June 18-21, 2008.

Andrysek J. New developments in stance-phase control. Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics, (p545), Vancouver, BC, July 29-August 3, 2007.

Andrysek J, Chau G. Preliminary investigation of a non-fluid-based swing-phase damping mechanism for above-knee prostheses. Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics, (p546), Vancouver, BC, July 29-August 3, 2007.

Zabjek K, Redekop S, Andrysek J. Optimization of full body kinematic models for the assessment of paediatric gait and postural stability. 30th Canadian Medical and Biological Engineering Conference: Improving Medical Device Usability, (p286) Toronto, ON, June 16-19, 2007.

Andrysek J, Kinematic versus kinetic strategies in prosthetic stance-phase control. 30th Canadian Medical and Biological Engineering Conference: Improving Medical Device Usability, Toronto, ON, June 16-19, 2007.

Andrysek J, Stance-phase control means for prosthesis. 30th Canadian Medical and Biological Engineering Conference: Improving Medical Device Usability (p259), Toronto, ON, June 16-19, 2007.

Andrysek J, Redekop S. Terminal swing noise attenuation in prostheses. 30th Canadian Medical and Biological Engineering Conference: Improving Medical Device Usability, (p261) Toronto, ON, June 16-19, 2007.

Andrysek J, Redekop S, Zabjek K. Biomechanical analysis of running gait of two types of prosthetic knee joints. 1st Joint ESMAC - GCMAS Meeting (JEGM06) Amsterdam, the Netherlands, September 28-30, 2006.

Andrysek J, Redekop S. Biomechanics of paediatric running gait: single-axis versus polycentric knee joints. 14th Biennial Conference for the Canadian Society for Biomechanics. (p39) Waterloo, ON, August 16-19, 2006.

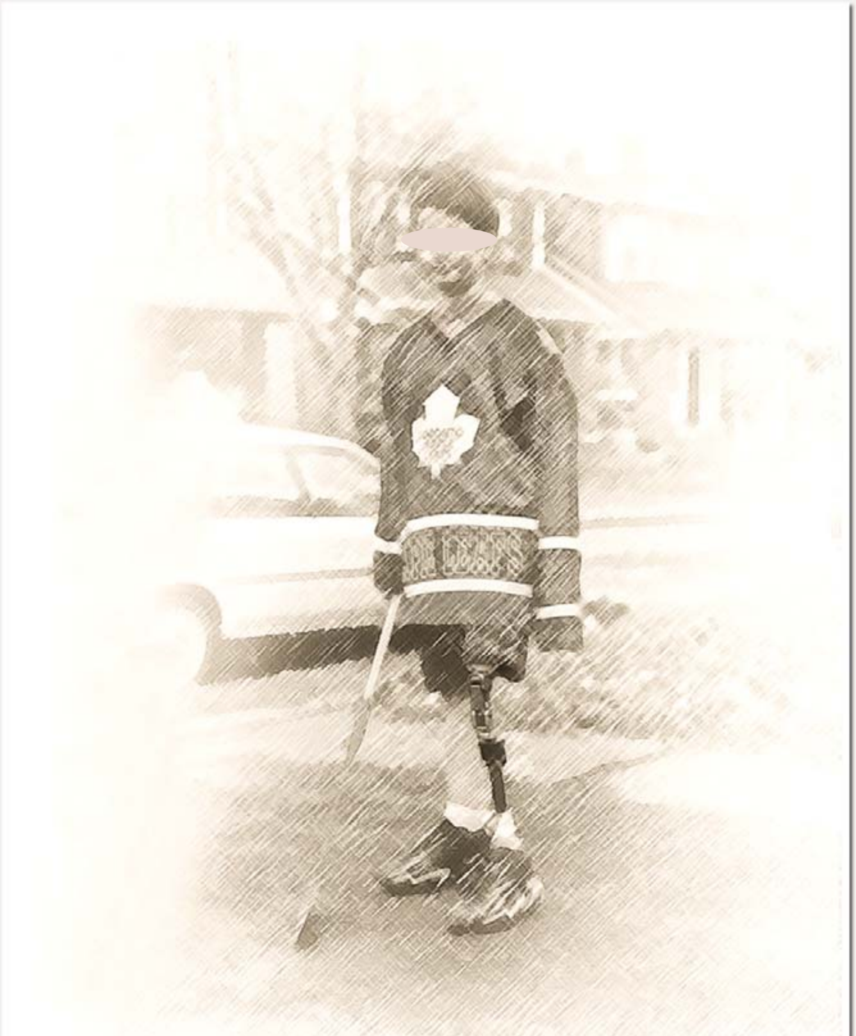
Andrysek J, Redekop S, Hubbard S, Naumann S, Cleghorn W. Design and testing of a new stance-phase controlled prosthetic knee joint. CAPO 2006 Convention: Boomers – Coming of Age. Kelowna, BC, August 16-19, 2006.

Andrysek J, Naumann S, Cleghorn W. Development and clinical testing of a new stance-phase controller for paediatric prosthetic knee joints. Association of Children's Prosthetic - Orthotic Clinics Annual Meeting, Orlando, FL, March 16-19, 2005.

Andrysek J, Naumann S, Cleghorn W, Linh Le N. Evaluation of a cam/roller mechanism for swing-phase control in paediatric prostheses. Association of Children's Prosthetic - Orthotic Clinics Annual Meeting, Banff, AB, March 24-27, 2004.

Andrysek J, Naumann S, Cleghorn W. Design of a paediatric prosthetic knee. Proceedings of the 26th Canadian Medical and Biological Engineering Society Conference (p16), Halifax, NS, 2000.

Curriculum Vitae



Jan Andrysek graduated with a B.Sc. (honors) degree in Biological Engineering form the University of Guelph in the year 1998, and a M.A.Sc. degree in Biomedical/Mechanical and Industrial Engineering from the University of Toronto in the year 2000. As part of a two-year scholarship in part funded by NSERC and in part by Heffernan/Co-Steel, Jan worked as a research engineer on the development of prosthetic technologies at the University of Toronto and Bloorview Kids Rehab (at that time Bloorview MacMillan Children's Center) until the year 2002. His work continued with CIHR funding until the year 2004, when Jan was promoted to Scientist at Bloorview Kids Rehab where his research focus now relates to the development of prosthetic and orthotic technologies, gait and mobility analysis, and biomechanical modeling. Jan is the holder of several patents and the recipient of the Clifford Chadderton Award for Prosthetics and Orthotics Research presented at the 2007 ISPO World congress. In addition, Jan has successfully licensed the knee joint developed here, to an international prosthetic/orthotic manufacturing company. Since 2004, Jan has published in peer-reviewed articles (N=7), as conference proceedings (N=9), conference abstracts (N=5), and invited presentations (N=2). In addition, he has successfully obtained numerous research grants to support his work (N=16). Jan is a registered Professional Engineer in the province of Ontario.