Prosthetic Knee Prescription Protocol for Infants

C. Fitting MPO (fchantel@med.umich.edu)
University of Michigan Orthotics and Prosthetics Center
Creation date: March 2020, Reassessment date: February 2021

Clinical Question: For infants with knee disarticulation (KD) or transfemoral (TF) limb loss or absence, does an early provision of an articulated prosthetic knee improve crawling and walking compared to a knee locked in full extension?

Background: Independent mobility is important for the growth and development of children with KD or TF limb loss or absence. These young patients were historically fit with a locked knee prosthesis in order to increase stability as they begin to pull to stand and eventually to walk, and an articulating knee was not to be provided until the child was able to walk proficiently with the locked knee prosthesis[1]. Recent research has sought to explore the efficacy of the Early Knee Protocol, a program that provides children with an articulating knee prosthesis as their first full-length device[2]. This protocol challenges the historical paradigm, arguing that the children are able to normalize knee motion with an articulating knee, resulting in a more natural, efficient gait while crawling and walking. The protocols will need to be assessed with considerations both for crawling and walking during motor development. Though it is the current standard of some practices, evidence supporting the provision of a locked knee prosthesis to children is lacking[3]. Comparisons of locked knee and articulating knee devices for crawling and recently walking infants have informed debate on the success of the two treatment options. This CAT provides evidence on the value of the Early Knee Protocol by exploring crawling and walking kinematics, gait abnormalities, and general prosthetic acceptance by children using locked and articulating knee prostheses.

Search Strategy:
Databases Searched: PubMed, CINAHL, Web of Science
Search Terms: [(artificial limb[MeSH terms) OR (prosthesis OR prostheses OR prosthetic OR "artificial limb")] AND (infant* OR pediatric OR child) AND (transfemoral OR above knee)
Eligibility Criteria: original research, peer-reviewed, published, English

Synthesis of Results: Five studies[1,3-6] explored the effect of an articulating knee prosthesis on gait kinematics compared to a locked knee prosthesis in a total of 29 pediatric patients with KD or TF limb loss or absence. Two articles[3-4] reported different outcomes using the same 5 subjects. One study[5] was a case report, one[6] was a cross-sectional design, and three[1,3-4] were before and after experimental designs, including the two studies[1,3] that assessed the same participants. The studies reported improved crawling and walking kinematics[1,3-4] with decreased gait deviations[3-6] and a more natural gait pattern[1,3-6] when using the articulating knee prosthesis. Because of the nature of the research and participants, studies were limited in sample size and did not generally include blinding, randomization, or control groups. Two of the studies[1,3] that used gait laboratory data reported incomplete data and a need for multiple trials due to the small markers necessary for infant subjects. One study reported differences in age groups between the Early Knee and Traditional knee protocol groups that may have directly influenced results[6]. Additionally, four of the studies were conducted by the same principal investigators at the same location[1,3-4,6]. All but one of the subjects included in the studies had congenital amputations, which may have influenced the outcomes of the chosen protocol[1,3-6]. The case study[5] differed from the other four articles in that it did not use objective measures of data, but rather relied on parent and prosthetist perception of the infant's attitudes and function. There was some evidence for greater acceptance of an articulating knee prosthesis in the case study[5] as well, which was not assessed in other studies.

Clinical Message: An articulating knee prosthesis is likely to improve crawling and walking ambulation for infants with TF or KD limb loss or absence, giving them a more kinematic, efficient, and natural gait. Current evidence is lacking in quality due to the constraints of conducting this research, however, all studies reported gait improvements in articulating compared to locked knee prostheses. Specific improvements included quicker crawling velocity and cadence[4], a step-through crawling pattern[4], decreased gait abnormalities in crawling[1,4], greater peak knee flexion in crawling[1], decreased gait deviations in walking[3,6], and greater peak knee flexion in walking[3].

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	Beachler 2008[5]	**Geil 2010[4]**	**Geil 2013[1]**	**Geil 2014[3]**	**Geil 2020[6]**
Study Objective	Evaluate functional mobility and prosthetic acceptance in an infant with a transfemoral amputation using crawling, locked knee, and articulating knee prostheses.	Assess crawling kinematics in infants with transfemoral amputations using articulating and locked knee prostheses.	Assess peak knee flexion and compensatory movements in crawling in infants with transfemoral or knee disarticulation amputations using articulating and locked knee prostheses.	Assess gait kinematics and deviations in children using articulating and locked knee prostheses.	Evaluate gait kinematics in children using the traditional knee and early knee protocols compared to children without amputation or limb deficiency.
Population	Number of subjects: 1 Age at final observation: 20 months Sex: male Etiology: amputation Level of amputation: transfemoral Side: right	Number of subjects: 5 Ages: 13-23 months Sex: 2 males, 3 females Etiology: amputation, absence Level of amputation: knee disarticulation or transfemoral Side: 4 right, 1 left	Number of subjects: 5 Ages: 13-23 months Sex: 2 males, 3 females Etiology: amputation, absence Level of amputation: knee disarticulation or transfemoral Side: 4 right, 1 left	Number of subjects: 7 Ages: 18-92 months Sex: 3 males, 4 females Etiology: amputation, absence Level of amputation: knee disarticulation or transfemoral Side: 5 right, 2 left	Number of subjects: 16 Ages: 12-60 months Sex: 7 males, 9 females Etiology: amputation, absence, none Level of amputation: knee disarticulation or transfemoral Side: 6 right, 4 left
Recruitment Source	Not stated	Children's Healthcare of Atlanta Limb Deficiency Center	Children's Healthcare of Atlanta Limb Deficiency Center	Not stated	Children's Healthcare of Atlanta, Georgia State University, Shriners Hospital for Children in Shreveport, LA

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Inclusion Criteria	Not stated	Healthy, daily prosthesis use, receipt of the prosthesis <2 weeks prior, no PT or training in their prosthesis, able to transition from sit to quadruped with prosthesis, able to crawl 10m without stopping	Healthy, daily prosthesis use, receipt of the prosthesis <2 weeks prior, no PT or training in their prosthesis, able to transition from sit to quadruped with prosthesis, able to crawl 10m without stopping	Unilateral knee disarticulation or transfemoral amputation, no older than 7 years old, able to walk safely without an assistive device, previous treatment per the Early Knee Protocol	Children with limb loss: used prosthesis daily, did not use assistive devices, used the same knee protocol since the time of their first prosthesis
Exclusion Criteria	Not stated	Children already walking, children with neuromuscular conditions, bilateral lower limb deficiency, longitudinal femur deficiencies, upper limb involvement, or orthopedic impairment	Children already walking, children with neuromuscular conditions, bilateral lower limb deficiency, longitudinal femur deficiencies, upper limb involvement, or orthopedic impairment	Not stated	Not stated
Intervention	Crawling prosthesis Full length prosthesis with articulating knee	Full length prosthesis with articulating knee	Full length prosthesis with articulating knee	Full length prosthesis with articulating knee	Full length prosthesis with articulating knee
Comparison	Full length prosthesis with locked knee	Full length prosthesis with locked knee	Full length prosthesis with locked knee	Full length prosthesis with locked knee	Full length prosthesis with locked knee
Outcomes	Subjective observation of the infant's functional mobility and acceptance of each prosthesis	Crawling kinematics: velocity, cadence, crawling pattern	Crawling kinematics: peak knee flexion, hip abduction and adduction, trunk movement	Walking kinematics: peak knee flexion in swing phase, gait abnormalities in swing phase	Walking speed, cadence, step length knee flexion, pelvic obliquity, thigh abduction, heel height

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Study Design	Case study	Before and after experimental design	Before and after experimental design	Before and after experimental design	Independent measures study
Methodology	○ Crawling prosthesis delivered at 11 months ○ Full length prosthesis with locked knee delivered at 14 months ○ Full length prosthesis with articulating knee delivered at 18 months	○ Motion analysis with 10 markers ○ Crawled along 10m pathway ○ 5 trials completed in each condition ○ Successful trial defined as the child completing three crawling cycles along the 10m path	○ Motion analysis with 10 markers ○ Crawled along 10m pathway ○ 5 trials completed in each condition ○ Successful trial defined as the child completing three crawling cycles along the 10m path	○ Motion analysis ○ Walked along 10m pathway ○ 3 trials completed in each condition	○ Motion analysis ○ Walked along 10m pathway ○ 10 trials completed for each participant
Key Findings	○ Infant crawled easily once fit with the crawling prosthesis with increased functional mobility ○ Subject did not accept the locked knee prosthesis and preferred to continue using the crawling prosthesis ○ Child accepted the articulating knee prosthesis and was able to ambulate independently after two months of use	○ Articulating knee prosthesis led to quicker velocity and cadence ○ Articulating knee prosthesis led to a step-through crawling pattern ○ Locked knee prosthesis led to a step-to crawling pattern	○ Average peak knee flexion in the articulating knee condition was 97.8°, significantly greater than flexion in the locked knee condition (25.3°). ○ Prosthetic knee flexion was lower than anatomical knee flexion in both conditions with greater differences seen in the locked knee condition	○ Average peak knee flexion in the articulating knee condition was 70.4° ○ Statistically significant increase in circumduction deviation in locked condition ○ Increase in hip hiking in locked condition in 6/7 subjects	○ Children in the early knee and control groups walking with increased speed as age increased ○ 12 clearance adaptation were noted in the traditional knee group, 6 in the early knee group ○ All children in the early knee group flexed the prosthetic knee in swing

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Other Considerations	The transition from the crawling prosthesis to an articulating knee prosthesis appeared to be more natural than to a locked knee prosthesis	Children were given a non-standardized accommodation period to each prosthesis	More hip abduction seen on prosthetic side for 4/5 children, more prominent in locked knee condition	Average peak knee flexion in subjects exceeded that of typically developing children (70.4° vs 52°)	Children in the early knee group maintained knee stability throughout the clinical trials
Limitations	○ Case report with one subject ○ Results may not be generalizable ○ Potential maturation effect ○ No objective measures were included ○ Used parent and prosthetist interpretation of child's opinions	○ Difficult to track small markers ○ No standardized accommodation time ○ Multiple attempts necessary to achieve a successful trial ○ No blinding ○ No randomization ○ No control population	○ Missing data from obscured markers in some trials ○ Crawling pattern variability between and within subjects ○ Small sample size ○ No blinding ○ No randomization ○ No control population	○ Results not compared with children not treated with the Early Knee Protocol ○ Wide variability in age range of children developing motor skills ○ Small sample size ○ No blinding ○ No randomization ○ No control population	○ Prosthetic designs to accommodate PFFD may affect results for children with this etiology ○ Children in the early knee group generally older than in the traditional knee group ○ Small sample size ○ No randomization
Clinical Utility	Infant functional mobility may increase with use of an articulating knee rather than a locked knee prosthesis and lead to better rates of acceptance of the prosthesis.	An articulating knee prosthesis allows the infant quicker crawling velocity and cadence and a more normal crawling pattern.	An articulating knee prosthesis allows the infant to crawl with greater peak knee flexion and decreased compensatory movement of the hip and trunk, more closely mirroring crawling kinematics of normally developing peers.	When walking, children fit with the Early Knee Protocol appear to have improved gait kinematics and decreased gait deviations.	When walking, children fit with the Early Knee Protocol appear to have less gait adaptations than children fit with the Traditional Knee Protocol, as compared to typically developing children without amputation.

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