Design and Quantitative Evaluation of a Stance-Phase Controlled Prosthetic Knee Joint for Children

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***Abstract*—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 efficacy. 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. 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.**

***Index Terms*—Paediatric above-knee amputee, prosthetic knee joint.**

I. 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. Akin to four- and six-bar linkage knees, the new knee design is unstable if it is even slightly flexed during weight-acceptance. The second situation is a knee that is fully extended during weight acceptance, but does not remain extended and, therefore, becomes unstable. The design presented here was hypothesized to provide better stability by 1) ensuring that once the knee is fully extended during swing it remains so until weight bearing and 2) decreasing the extent of conditions that can make the knee unstable during weight bearing.

Fig. 1. Prototype knee joint.

The knee is based on a new type of stance-phase mechanism, described in the subsequent sections (Fig. 1). The knee is under 12 cm in length, weighs 320 g, flexes to 160°, and has a weight-bearing capacity of 45 kg. 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 efficacy.

II. Background

A. 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 (Fig. 2). During gait, the knee becomes locked at

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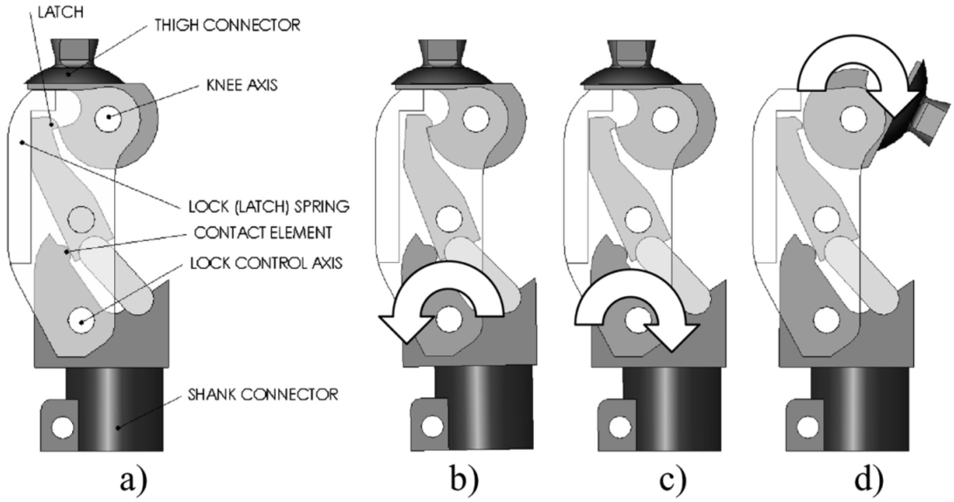

Fig. 2. (a) Prototype knee. (b) Lock engaged as a result of lock (latch) spring and/or flexion moment created at the control axis. (c) Lock disengaged due to extension moment generated at the control axis. (d) Knee joint shown flexed due to a flexion moment at the main knee axis.

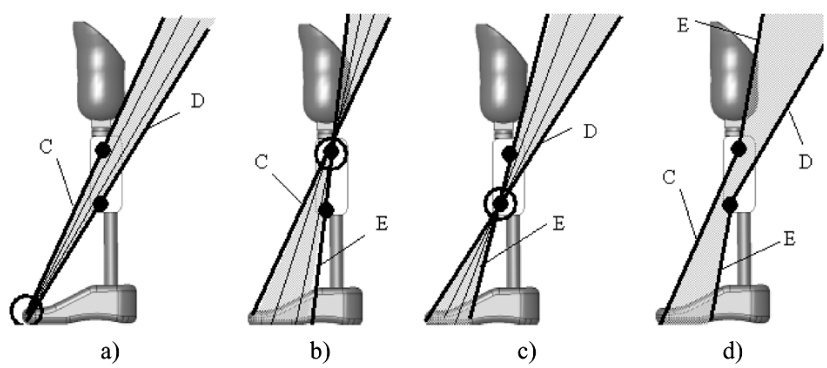

Fig. 3. Knee stability analysis for a knee joint with two stability-affecting axes. Boundary load line vector represented as thick line and other instability creating load line vectors as thinner lines. Shaded area represents all the possible instability causing load line vectors. (a) Vectors originating from toe-load boundary (labeled C and D). (b) About main knee axis (labeled C and E). (c) About the control axis (labeled D and E). (d) Overall zone of instability.

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 occuring 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.

III. Methodology

A. 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 axis 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 axes."

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

TABLE I
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

The union of any two of the three determined zones of instability provides the overall zone of instability [Fig. 3(d)]. 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.

B. Paediatric Knees Studied

Four knee types, including the prototype knee, were modeled using the zones of instability method (see Table I). 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].

C. Subjects

Six children with AK amputations were recruited for this study. The children met the following 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 II. Ethical clearance was received from the Institution's Research Ethics committee.

Since the children were already familiarized with their conventional knee joints and because of the considerable functional differences amongst 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 II
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 hf)
S2	Female – 11 years old	Congenital	Unilateral	>50% SLTL	Total knee Junior (Össur hf)
S3	Male – 12 years old	Acquired	Unilateral	<50% SLTL	Total knee Junior (Össur hf)
S4	Female – 7 years old	Congenital	Bi-lateral (AK/BK)	>50% SLTL	3R66 (Otto Bock Healthcare GmbH)
S5	Female 10 years old	Acquired	Bi-lateral (AK/BK)	>50% SLTL	Total knee Junior (Össur hf)
S6	Female 13 years old	Congenital	Bi-lateral (AK/BK)	>50% SLTL	Total knee Junior (Össur hf)

SLTL – Sound Limb Thigh Length

D. Prostheses

Prototype knee joints were fabricated in-house and one prototype was mechanically tested for structural integrity using the ISO 10 328 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.

E. 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 efficacy 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 III. The Wilcoxon Signed Ranks Test was applied.

F. 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.

TABLE III
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 (rough) 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

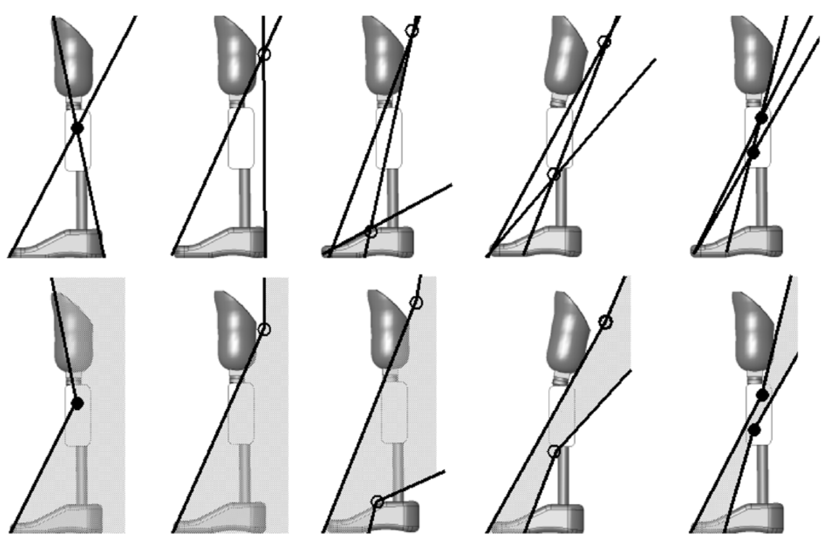

Fig. 4. Top diagrams show the boundary load lines for each knee and bottom diagrams the resultant zones of instability. Knee joints depicted are: (a) single-axis; (b) four-bar knee; (c) six-bar knee; (d) six-bar knee during stance-flexion; and (e) prototype knee. Axes that are instantaneous centers are shown as hollow circles and physical or fixed axes are solid circles.

The children were given the option to answer the questionnaires by themselves or with their parent(s).

IV. RESULTS

A. *Knee Stability for Different Knee Joints*

The zones of instability for the single-axis, four-bar, six-bar and prototype knees are presented in Fig. 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.

TABLE IV
RESPONSES TO QUESTIONNAIRE INCLUDING MEDIAN SCORES (CONV. ≡ PROSTHESIS WITH CONVENTIONAL KNEE JOINT; PROT. ≡ PROSTHESIS WITH PROTOTYPE KNEE JOINT)

	QUESTIONS	KNEE TYPE	S1	S2	S3	S4	S5	S6	Median
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	.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

B. Questionnaire

Questionnaire results are presented in Table IV. Question 4 responses were recalculated from the original responses.

V. DISCUSSION

A. Instability Zone Modeling

Fig. 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 Fig. 4(b) 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 Figs. 4(a) 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, which would 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 instant 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 [Fig. 4(d)]. But this may also cause the knee to inadvertently lockup during swing. An insensitive brake will behave like a single-axis knee [Fig. 4(a)]. 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.

B. Questionnaire

Data from the questionnaires supported the notion 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 four-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 knees 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 did the 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 V). 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 V
RELATIONSHIP BETWEEN ACTIVITY LEVEL AND NUMBER OF FALLS

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

C. Long-Term Testing

All six children reported on the questionnaires 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 have 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 Fig. 2(a) 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.

D. 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.

VI. CONCLUSION

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 trials.

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