The Safety of C-Leg: Biomechanical Tests

Siegmar Blumentritt, PhD, Thomas Schmalz, PhD, Rolf Jarasch, CPO

ABSTRACT

Safe knee function under all real-world conditions is a crucial factor in the prescription of specific prosthetic knee mechanisms. Although many amputees have reported the subjective belief that the electronic C-Leg combines increased function while walking with increased safety, till date there has been little objective evidence to support this claim. This study was designed to identify biomechanical differences that would permit objective evaluation of the relative safety in critical situations of different prosthetic knee joint designs. In the gait laboratory, three experienced amputees wearing a safety harness were tested under conditions that simulated five common real-world situations: walking on even ground, abruptly stopping, abruptly sidestepping, inadvertently stepping onto an object, and tripping when the knee is extending during swing phase. Kinematics and kinetics of three knee joints—the 3C1 (Mauch SNS hydraulic system), 3R80 (rotary hydraulic system), and C-Leg (electronically controlled hydraulic system)—were measured using accepted gait analysis technology (Kistler force plates, VICON system). This study protocol proved to be suitable for defining the potential safety of tested knee joints. The results from instrumented gait analysis were shown to provide an objective reason for knee stability or instability for each individual trial, including the reason for knee collapse. The amputee subjects confirmed that the gait disruption occurring under the tested conditions corresponded closely to critical everyday situations that may lead to fall. Tripping with 3R80 and stepping onto an object with 3C1 results in a significant risk of falling. Because of its biomechanical performance under high-risk conditions, C-Leg seems to be the most suitable design to prevent falls with the prosthesis. (*J Prosthet Orthot.* 2009;21:2–15.)

KEY INDEXING TERMS: lower limb amputee, microprocessor controlled knee, falls, safe knee function, biomechanics

In rehabilitation of leg amputees, the clinical team strives to increase mobility with a prosthesis to the greatest possible extent.[1,2] Indication-based prescription of a prosthetic knee joint requires defining physical capacities and activity range of the patient as well as the rehabilitation goal. The prosthetic knee joint provided determines the technical foundation of amputee's rehabilitation.[3] From a biomechanical perspective, the amputee may receive a knee joint suitable for walking on even ground; one offering shock-absorption during loading response, stability and good function on mild slopes (bouncing system); or one designed for ambulation on uneven terrain and foot-over-foot stair and ramp descent (yielding system). Whichever prosthetic knee joint is selected, it must permit safe locomotion under all conditions that will be encountered.

Many amputees fitted with the C-Leg system (Otto Bock HealthCare GmbH, Duderstadt, Germany) report that this electronic knee joint allows them to move around much more freely than prior mechanical alternatives. Most amputees report that it is no longer necessary to concentrate on the mechanics of walking with the prosthesis. Patients often describe this as "walking without thinking" and ascribe this reduction in mental load to the perceived high degree of safety the C-Leg offers.[4,5]

A number of studies have been published investigating the C-Leg and its electronically controlled stance and swing phase resistances. The biomechanical functions of the C-Leg have been studied by a number of investigators across the globe.[6–17] Comparative clinical observations have been published by Stinus,[4] Köcher,[5] Hauser,[18] Wetz et al.,[12] Drerup et al.,[19] and Hafner et al.[20] Wetz et al.,[12] Swanson et al.,[21] and Bunce et al.[22] reported on the psychosocial dimensions of treatment of transfemoral amputees with a C-Leg. All these publications document improved function with a C-Leg compared with alternative fitting possibilities. Common findings include more responsive swing phase performance over a wider range of cadences, reduced metabolic energy consumption, and a generally enhanced clinical rehabilitation outcome for a high percentage of amputees in different mobility classes.

The authors of the majority of studies ascribe the acceptance of the C-Leg to the increased safety offered to the patient compared with alternative prosthetic knees. However, there is a dearth of objective data confirming the patients' subjective perceptions of increased safety with the C-Leg.

This study reports preliminary results from a novel protocol permitting functional testing of different prosthetic knee joints in critical situations likely to cause an amputee to stumble or fall. This approach permits testing of the

SIEGMAR BLUMENTRITT, PhD, is affiliated with the Department of Research, Otto Bock HealthCare, Duderstadt; and Georg-August-University, Göttingen, Germany.

THOMAS SCHMALZ, is affiliated with the Department of Research, Otto Bock HealthCare, Duderstadt, Germany.

ROLF JARASCH, is affiliated with the Orthopaedic Workshop, Rehabilitation Centre, Göttingen, Germany.

Conflict of interest: Prof. Blumentritt is the head of research department and Dr. Schmalz works for the research department of Otto Bock HealthCare Duderstadt.

Correspondence to: Siegmar Blumentritt, PhD, Otto Bock HealthCare, Department of Research, Max-Näder-Street 15, 37115 Duderstadt, Germany; e-mail: blumentritt@ottobock.de

safety potential of a prosthetic knee in an objective and repeatable manner. The results compare amputee safety with the microprocessor-controlled C-Leg to functional alternatives offering purely mechanical hydraulic yielding (Otto Bock 3R80 rotary hydraulic system and Active Line 3C1 with Mauch SNS hydraulic system).

SAFETY OF TRANSFEMORAL AMPUTEES FITTED WITH PROSTHESIS

Stable static standing with the prosthesis is the foundation for the mobility of each transfemoral amputee. Prostheses allow stable weight bearing during static stance only if the net ground reaction force (GRF) vector acts anterior to the center of rotation of the knee joint, thereby creating an external extension moment that is resisted by the mechanical hyperextension stop. Safe and comfortable weight bearing during two-legged stance depends primarily on alignment of the prosthesis. This applies to any knee mechanism independent of the physical capacities and mobility class of the amputee.

During ambulation, the transfemoral amputee needs a prosthesis offering stable weight bearing during stance phase. It does not matter if he belongs to the group of amputees with a limited mobility level able only to walk indoors or to those with a higher mobility level who are able to walk outdoors without limitation. Dynamic stance phase stability is created by three factors: alignment of the prosthesis, characteristics of prosthetic components (both foot and knee), and the hip moment the patient produces in the sagittal plane during ambulation.[23] Each of these factors is impacted by the mobility class of the amputee.[3] We postulated that three biomechanical factors would be sufficient to assess the clinical safety of prosthetic knees:

1. Knee angle
2. Knee moment
3. Hip moment

A fall is identified by a quickly reducing knee angle dropping to values of 100° and lower, if not a clearly measurable knee flexion moment can be determined at the same time. The value of the flexion moment correlates with the resistance of the joint counteracting flexion (good example: Figure 7, 3R80 high moment, in contrast 3C1 low moment). In addition, the time passing between the end of preceding swing phase and following knee flexion indicates the time of knee flexion in between the stance phase. The hip moment objectifies the amputee's residual limb activities.

As noted previously, the monocentric prosthetic knee is stable under weight bearing only so long as the GRF acts anterior to the mechanical center of rotation and the knee joint is completely extended. Polycentric joints (that are not geometrically locked) are stable under weight bearing so long as the force application line of the GRF runs anterior to the instantaneous center of rotation of the knee. Prosthetic knee joints that provide mechanical stance phase stability—including friction brake mechanisms, manual or geometric locks or stance phase hydraulic resistance—may be stable under weight bearing even when the GRF acts slightly posterior to the center of rotation (Figure 1).

Prosthetic knee joints that resist stance phase knee flexion under load offer more normal biomechanical function than other alternatives. However, for the patient's safety, the stance control mechanism must be activated instantly to

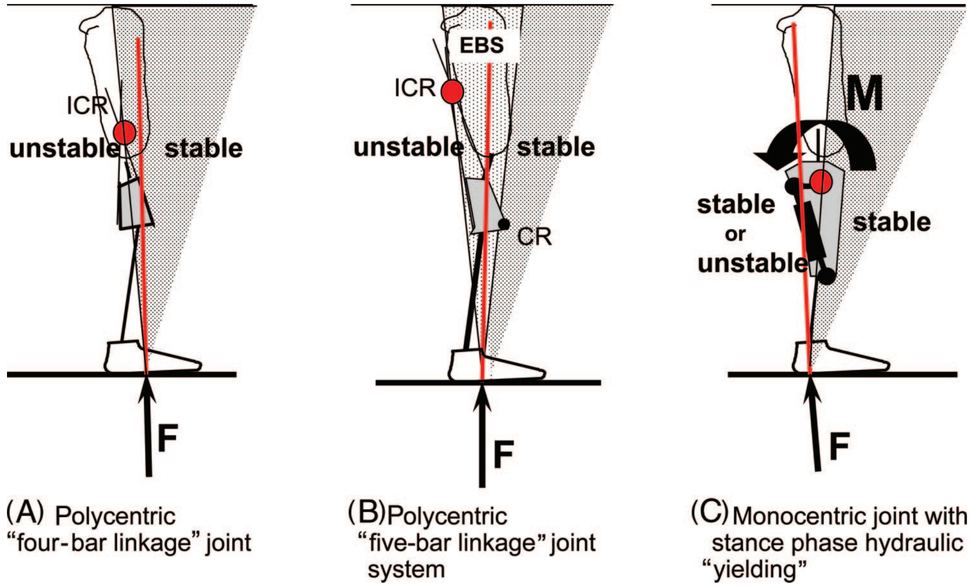

Figure 1. Principles of stance phase knee stability: zone of stability of the prosthetic knee. A, Polycentric "four-bar linkage" joint: stable, if the GRF falls anterior to the ICR; unstable, if it falls posterior. B, Polycentric "five-bar linkage" joint: stable, if the GRF falls anterior to the ICR; unstable, if it falls posterior. Stance flexion occurs if the GRF falls anterior to the ICR but posterior to the mechanical CR. C, Monocentric joint with stance phase hydraulic "yielding" system: stable, if the GRF falls anterior to the center of rotation; stable or unstable, if it falls posterior depending on whether the hydraulic system is in the stance or swing phase control mode.

allow controlled knee flexion (yielding). Equally importantly, the strong flexion resistance that is necessary to provide yielding resistance to knee flexion in stance must be deactivated at the right moment in the gait cycle to permit effortless knee flexion during preswing and swing phase.

Monocentric knee joints with stance phase hydraulic control systems are characterized by two distinctly different magnitudes of knee flexion resistance. In stance phase control mode, knee flexion resistance is very high to provide controlled yielding under full weight bearing. During swing phase control mode, the joint resistances are significantly lower to control the rate of knee flexion and extension while the limb is unweighted. Reliable switching between stance and swing phase control mode is critical for good ambulatory function and for amputee safety. Considering yielding knee joints, three different kinds of mode switching can be defined: extension dependent (Mauch-SNS hydraulic system, CaTech cylinder), load dependent (rotary hydraulic system), and gait phase dependent (sensor-based electronically controlled stance and swing phase). The corresponding switching conditions are summarized in Table 1. Objective measurements of the safety potential of these varying switching strategies have not been described in the literature till date.

METHOD

In an instrumented gait laboratory, amputee subjects were tested under the following real-world situations:

1. Level walking at a self-selected comfortable velocity
2. Stopping abruptly
3. Sidestepping abruptly
4. Stepping onto an obstacle
5. Interruption of knee extension during swing phase (tripping)

The first three activities were tested in random order. This test battery began with the subject walking straightly toward an assistant positioned at the end of the walkway. The assistant flashes hand signals to indicate to the amputee which of the three motions should be performed. The hand signal is given during loading response with the contralateral leg indicating that the amputee should

1. Continue walking in a straight line
2. Stops walking immediately and stand with both feet parallel to one another
3. Sidestep to the nonamputated side

After this test battery, the subject walks at a self-selected comfortable velocity across two force plates (Test 4). Three different objects that are 20 cm long, 2 cm wide and 1–1.5 cm high are placed across the pathway and the amputee is instructed to walk over the obstacles without hesitation. The placement of the objects is systematically varied to ensure that the heel, midfoot, and forefoot strike the object during the test protocol. One obstacle is 1.0 cm thick foam rubber; another is 1.0 cm of foam rubber combined with 0.5 cm cork. The third object is made from 1.5 cm thick rigid polyvinyl chloride (PVC).

The test series concludes by simulating tripping when the shin or foot of the prosthesis bumps something as the knee is extending during swing phase (Test 5). Only the kinematics was measured. The experimenter walks behind the patient holding a very thin cord that is tied to the ankle adapter. As the prosthesis starts to extend during swing phase at any step the patient did not know, the experimenter tugs on the line momentarily to disrupt extension timing. Swing extension is disrupted at different flexion angles to determine the impact on amputee stability.

Throughout all these tests, the amputees are protected from falling by a body harness that glides along a track mounted on the ceiling. The safety harness does not interfere with the amputees' gait (Figure 2).

Motion is measured using the six camera VICON System 460 (Vicon Motion Systems, Oxford, UK). The GRF is measured by two force plates (Kistler Instrumente AG, Winterthur, Switzerland). A reduced set of four passive markers were applied to each subject on the prosthetic and contralateral side in the following locations:

1. Greater trochanter
2. Prosthetic and biological knee center (as defined by Nietert[24])
3. Lateral malleolus
4. Fifth metatarsal head and corresponding location on the prosthetic foot

Kinematic and kinetic data were used to measure knee angle and to calculate sagittal plane moments at the knee and hip, as described previously.[8,25]

PATIENTS

Three subjects with unilateral transfemoral amputations were recruited for this pilot study and agreed to participate

Table 1. Mode switching methods for yielding hydraulic knee joints

Type of mode-switching	Function	
	Disengage stance phase mode	Re-engage stance phase mode
Extension dependent (Mauch SNS, CaTech)	Knee fully extended and knee extension moment and duration >0.1 second	Knee extension movement in swing phase
Load dependent (Otto Bock 3R80 rotary hydraulic system)	Unweighted knee joint or load forefoot with knee fully extended	Weight bearing through knee joint
Gait dependent (Otto Bock Microprocessor-controlled C-Leg system)	Sensor-based gait phase detection	Sensor-based gait phase detection

Figure 2. Safety harness used during all tests.

Table 2. Patients' data

Subject	1	2	3
Sex	m	m	f
Age (yrs)	43	42	25
Mobility class (MOBIS)	4	4	3
Time since amputation (yrs)	26	22	9
Cause of amputation	Trauma	Trauma	Tumor
Mass (kg)	81	85	60
Height (cm)	178	185	161
Length of stump	Long	Average	Long
Stump pain reported	Non	Phantom (rarely)	Non
Foot size (cm)	26	29	25
Walking distance (km/day)	>5	>5	>5

after being informed about the potential risks and benefits. All patients were experienced and successful prosthesis wearers who had previously walked on all tested foot and knee components for an extended period of time. At the time of investigation, all subjects were full-time ambulators on definitive prostheses incorporating the C-Leg system. No amputee had any other disorders or conditions that would interfere with walking and all were classified into mobility classes 3 and 4.[2,26] All subjects were able to walk at least 5 km daily. Table 2 summarizes these patients' demographic data.

Three hydraulic knee joints offering yielding stance control were investigated:

1. Otto Bock 3C1 (Mauch SNS hydraulic system)
2. Otto Bock 3R80 (rotary hydraulic system)
3. Otto Bock C-Leg (microprocessor-controlled system)

The order of testing was randomized. Because all subjects had successfully worn the tested knee joints previously (minimum 18 months), they required approximately 30 minutes of practice until reporting that they had acclimated to each successive knee joint. All patients used the well-fitting socket from their definitive prosthesis and wore the Otto Bock 1C40 C-Walk foot in their customary footwear during the trials. All prostheses were aligned following the manufacturer's instructions and assembled using the Otto Bock LASAR Assembly system. Static alignment was optimized using the Otto Bock LASAR Posture system.[27]

RESULTS

TIME-DISTANCE PARAMETERS

The amputee subjects ambulated at constant mean self-selected walking speed of approximately 1.3 m/s during the tests when they were instructed to stop or step aside, when they stepped onto an obstacle or when swing phase extension of the prosthesis was interrupted.

STOPPING AMBULATION

Figure 3 depicts knee angle and moments at the knee and hip moment typically measured in the prosthetic leg when abruptly stopping ambulation. During the deceleration phase on the prosthesis, significant knee flexion was observed with the 3R80 and moderate knee flexion with the C-Leg. In contrast, the 3C1 does not show significant knee flexion but remains extended until heel strike of the contralateral foot. Stopping with knee flexion by decelerating on the prosthesis is possible only if the stance phase mode remains engaged, which is not the case with the 3C1. Figure 3 shows that an extension moment is acting on the extended knee joint for more than a tenth of a second. The threshold of the 3C1 knee joint was experimentally determined to be 6 Nm, resulting in disengagement of stance control shortly after heel strike (compare with Table 1). This does not allow the amputee to safely decelerate with this prosthetic knee and the risk of falling is significant. Figure 3 also illustrates that the lowest hip moments are produced when decelerating with the C-Leg.

The deceleration process is depicted in Figure 4. The first two right panels show similar positioning of all three knee joints. In the third panel, at heel strike of the contralateral leg, and the fourth panel the different knee flexion angles depicted in Figure 3 can be visualized. The body patterns shown in Figure 4 illustrate that stopping by decelerating with the C-Leg is considerably safer and easier than with the prostheses incorporating the other tested joints.

SIDESTEPPING

Figure 5 summarizes typical moments and knee angles when decelerating on the prosthetic limb and sidestepping. After sidestepping with the contralateral leg has occurred, the contralateral leg strikes the ground adjacent to the force

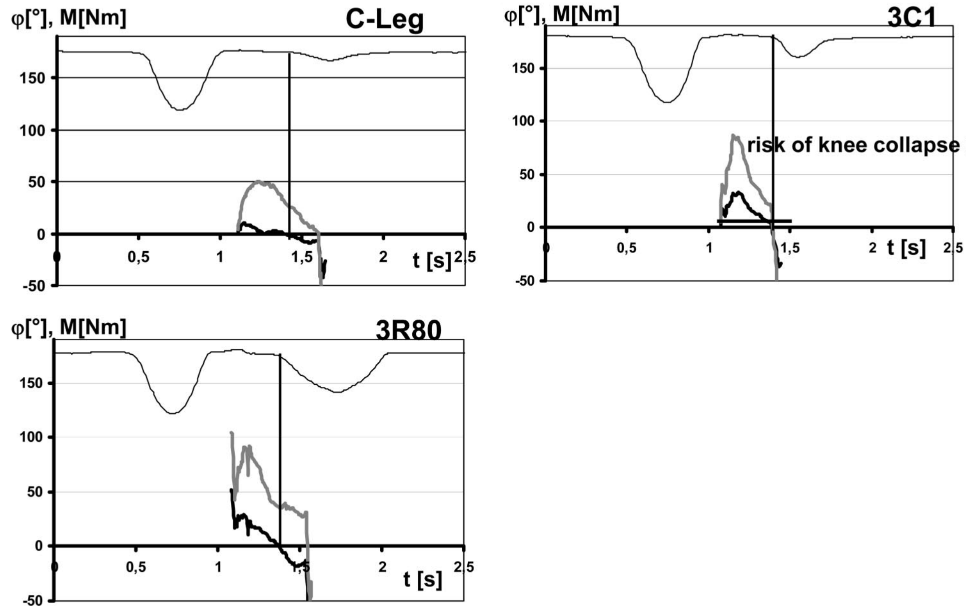

Figure 3. Typical pattern of the ipsilateral knee angle (black thin) and sagittal plane moments at the hip (gray) and knee (black thick), when stopping by decelerating with different hydraulic prosthetic knee joints. The moments of the deceleration step start with heel strike of the prosthetic foot on the force plate and terminate with heel strike of the contralateral foot. The vertical lines mark the transition from a knee extension moment (positive values) to a knee flexion moment (negative values). For the 3C1, the stance disengagement threshold of 6 Nm is indicated by a horizontal line.

plate. Although the movement of the prosthetic knee is similar to that of stopping, the knee extension moments are significantly higher. The only prosthetic knee with an external flexion moment is the C-Leg. Of particular clinical significance, note that the Mauch hydraulic cylinder contained in the 3C1 knee automatically switches into swing phase mode during weight acceptance.

Various phases of the deceleration process are depicted in Figure 6. Note that the sidestepping with the C-Leg is primarily lateral, whereas the other knees result in less effective deceleration so the step is both anterior and lateral. This is illustrated most clearly in the fourth panel, where the differences in step length can be seen. In panels 5 and 6, note that the torso posture is more stable and erect with the C-Leg than with the 3R80 and 3C1.

STEPPING ONTO A FOREIGN OBJECT

When stepping onto a foreign object with the tested knee joints, the stability of the prosthesis and the safety of the amputee differed significantly. Whenever the subjects land on the object with the heel of the shoe, there is a high risk of falling with 3C1 and 3R80. Shortly after contacting the object with the heel, an external knee flexion moment starts acting on the prosthesis. As was the case during deceleration, the initial extension moment under this condition is sufficient in duration and magnitude to disengage the stance stability mode of the Mauch hydraulic system of the 3C1. With the 3R80, the loading after heel strike is not high and fast enough to activate the load-dependent stance control stability required for safe weight acceptance (Figure 7). Only the C-Leg flexes safely under this condition.

If the amputees struck the object with the forefoot, although the pattern of movement was clearly disrupted, none of the prostheses in this study collapsed. All tested joints offered the subjects sufficient stability under this condition. However, the stance stability mode of 3C1 knee joint was disengaged.

If the subject stepped onto the object with the midfoot, the safety potential of the prosthetic knee joints was slightly different. The C-Leg and 3R80 both offered the amputees sufficient stance phase stability under this condition. The 3C1, however, collapsed during some of the trials under this condition.

Figure 8 shows typical results from motion analysis during walking with the 3C1 confirming the risk of knee collapse depending on which portion of the shoe lands on the object. This series of graphs makes it clear that the stance control mode of the Mauch hydraulic system in the 3C1 knee always disengages at heel strike regardless of what portion of the shoe contacts the obstacle. The external knee flexion moment that follows during the single support phase determines whether the knee will collapse, but it depends on the shape and rigidity of objects that the amputee has stepped on (Figure 9). In each instance, these apparently inconsistent results could be explained by close examination of the external moments at the prosthetic knee.

Figure 10 illustrates what occurs when the amputee wearing the 3C1 steps onto a 1.5 cm high foreign object and lands on the midfoot. In most tests, the rigid PVC object caused the

Figure 4. Phases in right-to-left chronological sequence when stopping abruptly with the three tested knees: C-Leg (top), 3R80 (middle), and 3C1 (bottom) at the instant of the hand signal (far right), heel strike of the prosthetic foot (second right), heel strike of the contralateral foot (fourth panel), and static stance (far left). During deceleration the different prosthetic knee angles are indicated in third panel.

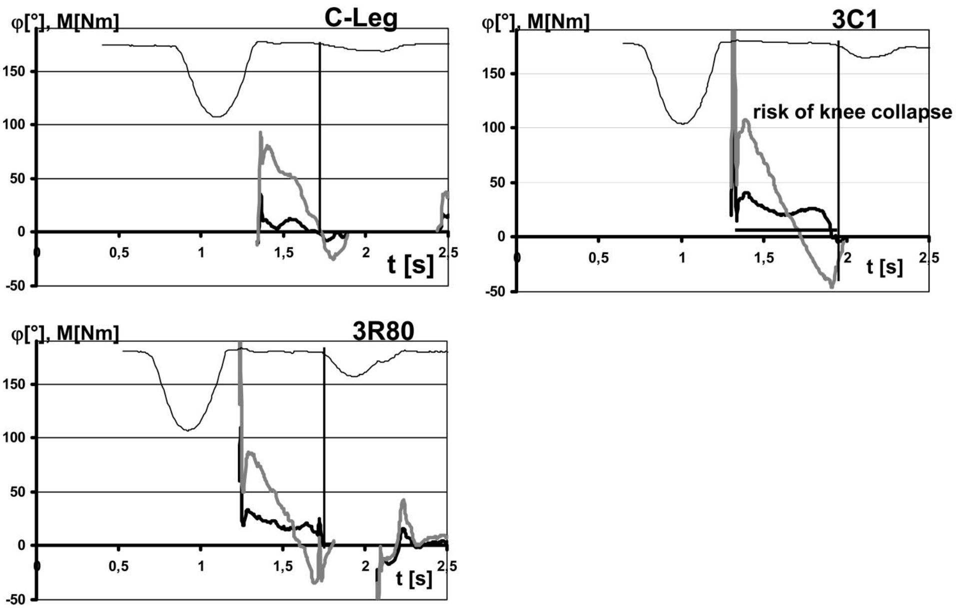

Figure 5. Typical pattern of the prosthetic knee angle (black thin) and sagittal plane moments at the hip (gray) and knee (black thick) when stepping to the side. The moments shown are during stance phase from heel strike to toe-off of the prosthetic foot. The vertical lines indicate the time transition from a knee extension moment (positive values) to a knee flexion moment (negative values). For the 3C1, the threshold of approximately 6 Nm is indicated by the horizontal line.

prosthetic knee to collapse, as shown in the top panels. However, sometimes falling did not occur at midfoot support. In all these cases a delayed onset of the external knee flexion moment was measured, as shown in the middle panels. The lower panels show that the softer rubber and cork object of the same thickness did not result in knee collapse.

INTERRUPTION OF KNEE EXTENSION DURING SWING PHASE [TRIPPING]

Interrupting the normal pattern of knee extension during swing phase simulates the common risk of tripping. Figure 11 shows that the three tested knees behaved differently during this high-risk maneuver. The moment when the experimenter tugged on the cord is indicated for one trial with the 3R80 knee, as is the instant of heel strike on the prosthesis that followed.

After tugging on the cord, the C-Leg reaches full extension most quickly of the tested knees. Even if the knee of the C-Leg remains flexed at heel strike, this prosthetic knee joint can be safely loaded. The 3C1 also continues extending after swing phase disruption but at a slower rate than the C-Leg. This hydraulic stance and swing control knee joint also allows the amputee to load the prosthesis at heel strike. However, the greater the knee flexion angle at the moment the investigator disrupts the motion, the greater the reduction in weight bearing capacity as the amputee recovers from tripping. When swing phase motion is disrupted, the knee angle of the 3R80 does not change significantly. If the 3R80 is flexed at heel strike, it does not offer stable weight bearing and the amputees fall.

SUMMARY OF QUALITATIVE RESULTS

Table 3 summarizes the qualitative results from these investigations, showing that only the C-Leg is safe for amputees under all tested conditions. The Mauch SNS hydraulic system in the 3C1 has the highest risk to the amputee of knee collapse, especially when stepping onto an object. The risk of knee collapse with the 3R80 is greatest after tripping or when the knee is slightly flexed at heel strike, previously published results,[7,16] showing the risk when descending slopes and stairs have been added to this table.

DISCUSSION

In the past 15 years, significant technological advances have been made in the development of highly functional external prosthetic knee joints. More responsive swing phase control and particularly modern stance stability mechanisms have resulted in prosthetic components that more and more closely simulate the kinematics of the biological knee, with some designs permitting controlled knee flexion even under weight bearing conditions. However, the potential for more normal kinematics will only be accepted and used by the amputees if the design of the component provides a high degree of safety. Safe function under real-world conditions is the primary biomechanical requirement of prosthetic knee components for amputees with knee disarticulation, transfemoral, and higher levels of amputation.

Until the mid-1990s, almost only prostheses with the Mauch SNS hydraulic system permitted yielding knee flexion under weight bearing and prescription of these components was commonly restricted to active amputees. Since then,

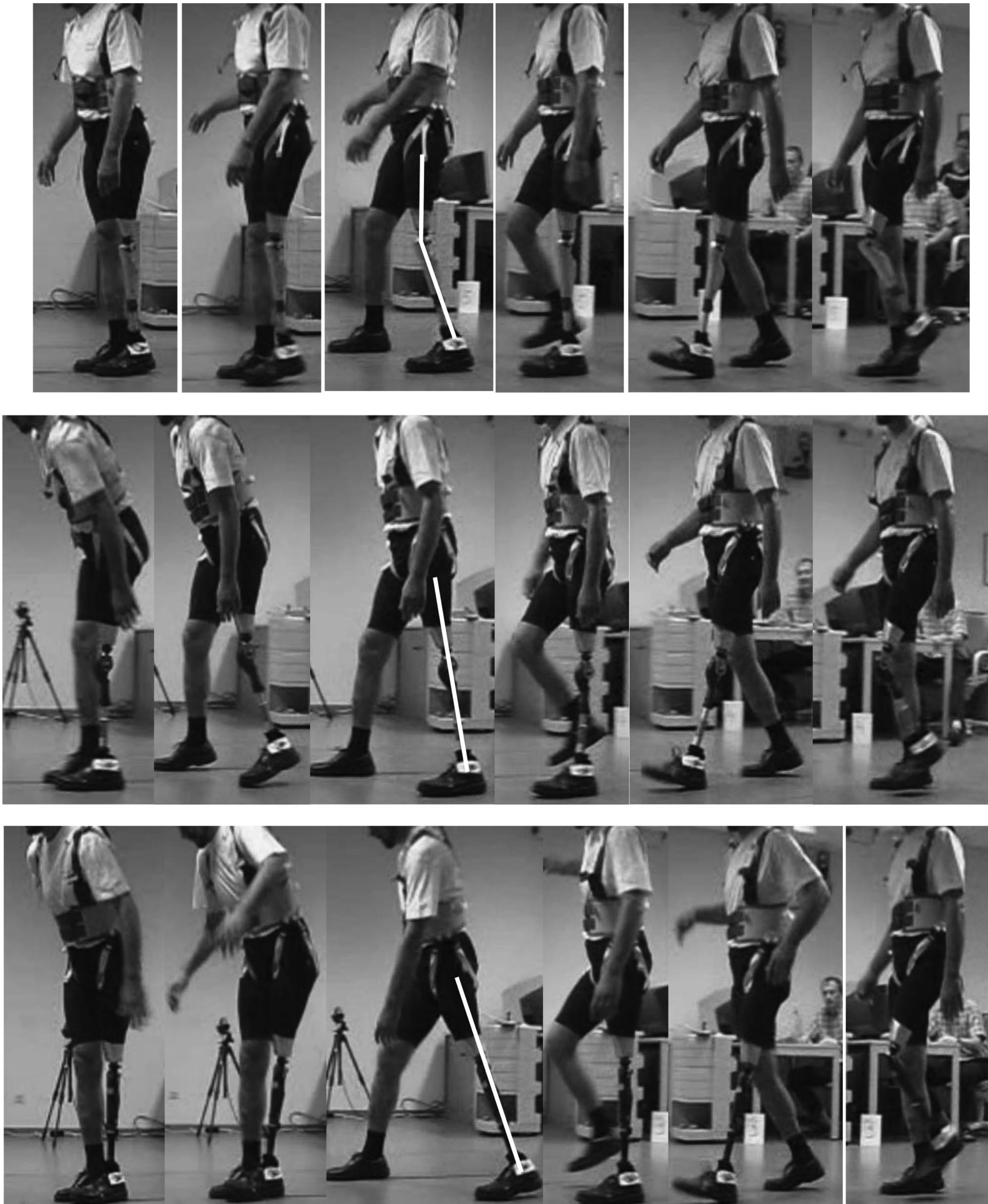

Figure 6. Phases in right-to-left chronological sequence when sidestepping abruptly with the three tested knees: C-Leg (top), 3R80 (middle), and 3C1 (bottom) at the instant of the hand signal (far right), heel strike of the prosthetic foot (second right), midstance of the prosthetic leg (third panel), and static stance (far left). During deceleration the different prosthetic knee angles are indicated in the fourth panel.

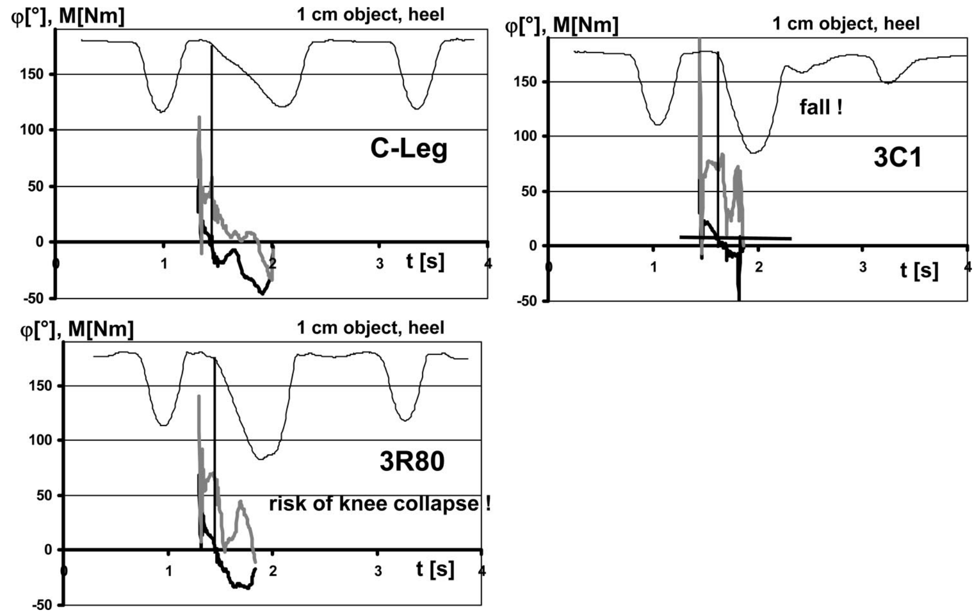

Figure 7. Typical pattern of the prosthetic knee angle (black thin) and sagittal plane moments at the hip (gray) and knee (black thick) when stepping onto a foreign object with the heel of the shoe. The moments shown are during stance phase from heel strike to toe-off of the prosthetic foot. The vertical lines indicate the time transition from a knee extension moment (positive values) to a knee flexion moment (negative values). For the 3C1, the threshold of approximately 6 Nm is indicated by the horizontal line.

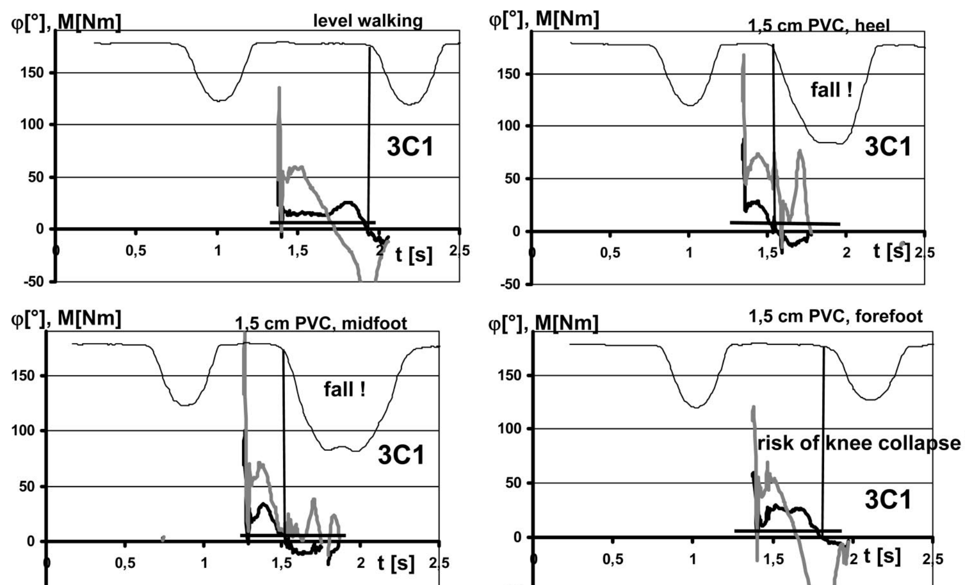

Figure 8. Typical pattern of the 3C1 knee angle (black thin) and sagittal plane moments at the hip (gray) and knee (black thick) during level walking and when stepping onto the 1.5 cm high PVC foreign object with the heel, midfoot, and forefoot. The moments shown are during stance phase from heel strike to toe-off of the prosthetic foot. The vertical lines indicate the time transition from a knee extension moment (positive values) to a knee flexion moment (negative values). The threshold of approximately 6 Nm required to disengage stance stability in the 3C1 is indicated by the horizontal line.

knee mechanism permitting limited knee flexion (bouncing systems) and those that use other biomechanical designs to allow controlled yielding have been developed. Prosthetic knees that permit controlled flexion during loading response have been shown to be of benefit to amputees also of lower activity level.[2,3]

This investigation was designed to simulate critical situations, such as walking on stony or soft ground, in the dark, through the grass, and on ramps and stairs, where the risk of falling is greatest and to objectively measure the potential safety of three commonly prescribed knee joints in such situations.

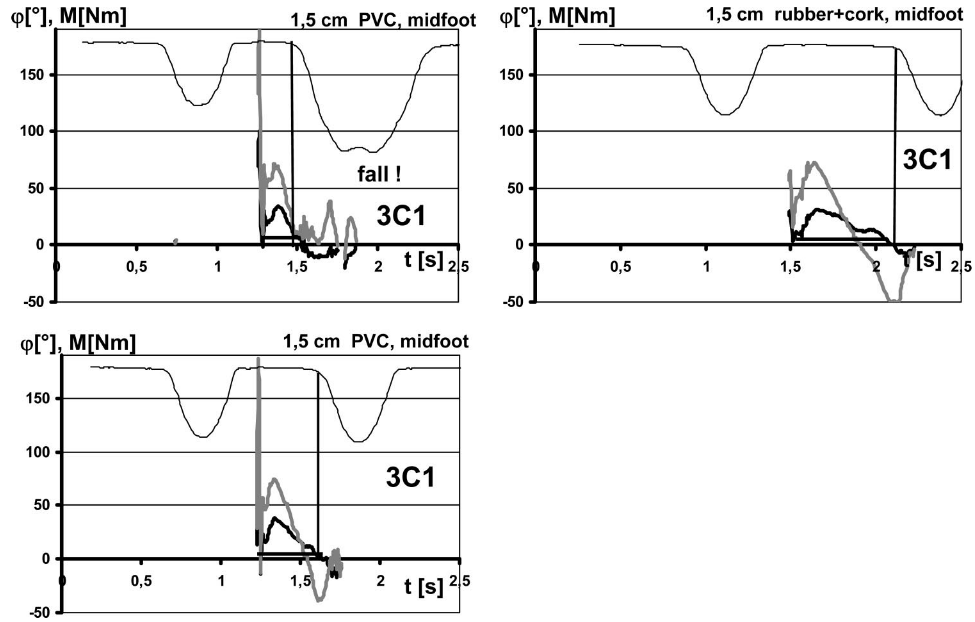

Figure 9. Typical pattern of the 3C1 knee angle (black thin) and sagittal plane moments at the hip (gray) and knee (black thick) during level walking and when stepping onto various 1.5 cm high foreign objects with the midfoot. The moments shown are during stance phase from heel strike to toe-off of the prosthetic foot. The vertical lines indicate the time transition from a knee extension moment (positive values) to a knee flexion moment (negative values). The threshold of approximately 6 Nm required to disengage stance stability in the 3C1 is indicated by the horizontal line.

Reliable and precise switching between stance and swing phase resistance under real-world conditions is critical for amputee safety. The methods used to switch between stance and swing control modes differ considerably depending on the design of the knee component (Table 1). Knee joints that are load dependent or extension dependent are controlled by the muscles of the residual limb. The biomechanical design of these components is generally safe for walking on horizontal and even ground. The amputee must concentrate intently on controlling the prosthesis, however, to negotiate rough terrain or to insure that the prosthesis is always fully extended at heel strike. When walking on uneven ground, on pavement or slopes, the amputee is forced to use more hip power and to increase concentration to safely control the prosthetic knee. Environmental conditions have less effect on knees with load-dependent mode switching than on those with extension-dependent switching. However, the amputee must still concentrate carefully to insure full safety with prosthetic knee joints having load-dependent switching.

The protocols developed for this study proved to be suitable to evaluate the potential safety of prosthetic knee joints. The subjects unanimously confirmed that the situations simulated in the laboratory tests corresponded closely to their daily experience in the real world. Stepping onto the PVC object creates similar effects as walking on cobblestone or when the foot lands on stones or branches. Abrupt stopping and sidestepping are common maneuvers in a pedestrian area. Having the experimenter tug on a cord attached to the ankle of the prosthesis, the amputees describe a feeling like catching the toe on grass or branches during midswing.

These laboratory tests were designed to quantify the biomechanical performance of prosthetic technology in fall avoidance and to differentiate the potential safety of various prosthetic knee designs. Although the test design is not intended to estimate the actual number of falls of any individual amputee, the biomechanical cause for each and every fall that occurred in the laboratory could be clearly identified by the measured parameters. The biomechanical reasons why the prosthetic knee did not collapse could also be clearly shown in each instance. The investigators believe that it is important to clearly understand the biomechanics of each individual incident when a fall occurred under the test conditions, and that the information gathered from each of these critical incidents justifies reporting these preliminary results despite the small number of subjects in the present study.

These laboratory tests confirm the subjective reports by patients that it is difficult, if not impossible, to walk with the Mauch SNS hydraulic system without some risk of falling, even when the amputee is concentrating on the walking process itself. The surprising finding that the Mauch hydraulic system disengages the stance stability mode during loading response may explain this result. If the patient walking with an extension-dependent prosthetic knee strikes an object with the midfoot, the risk of falling is influenced by size and softness of the object. In addition, we would expect that the risk of falling is also influenced by the type of foot (only 1C40 tested) and shoe worn. Our results show that the larger and the more rigid

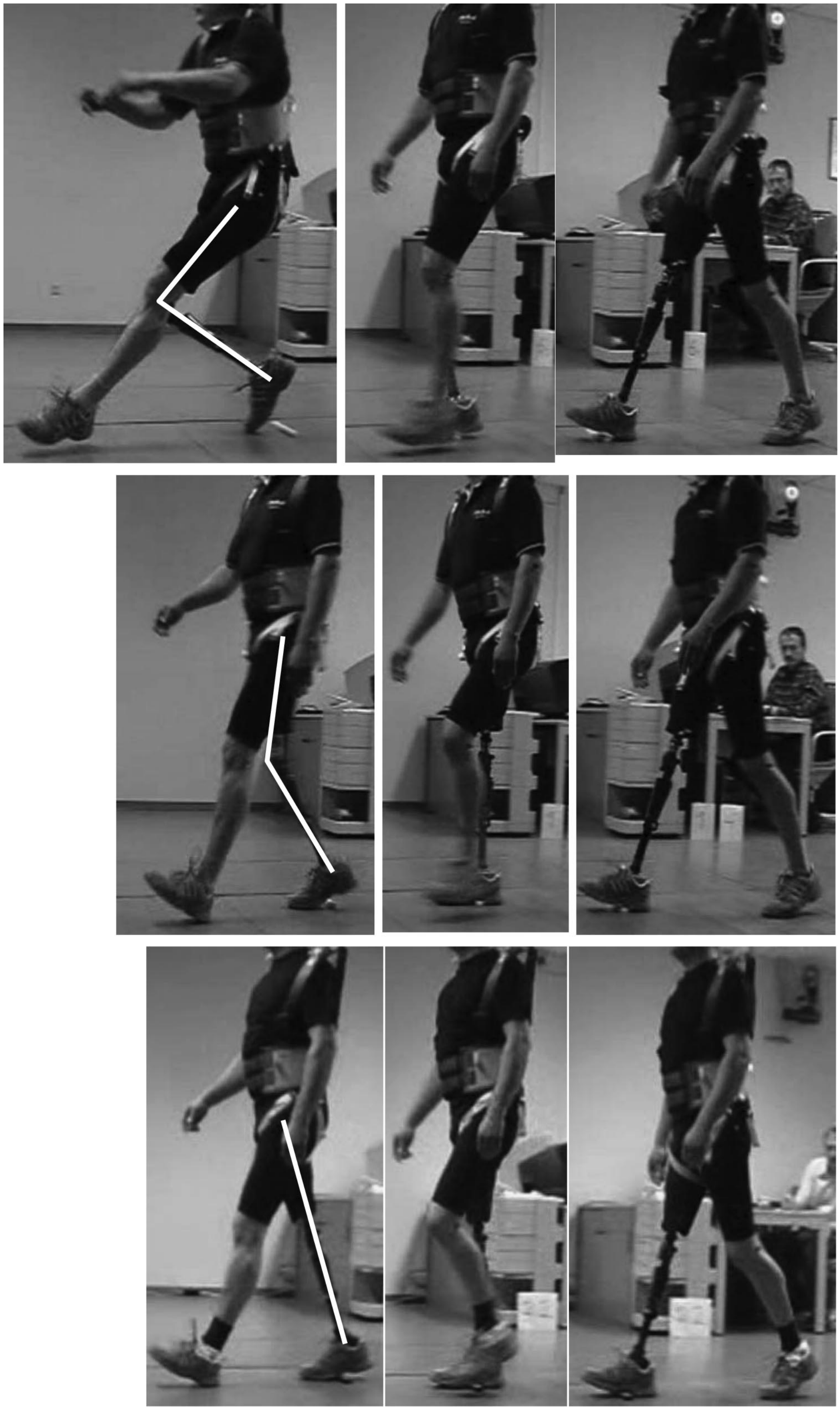

Figure 10. Landing on a 1.5 cm high foreign object with the middle of the shoe while using the 3C1 knee joint; top = 1.5 cm rigid PVC (knee collapse), middle = 1.5 cm rigid PVC (no knee collapse), bottom = 1.5 cm rubber and cork (no knee collapse). Panels in right-to-left chronological sequence illustrate heel strike of the prosthetic foot (right), midstance of the prosthetic leg (middle), and heel strike of contralateral foot (left).

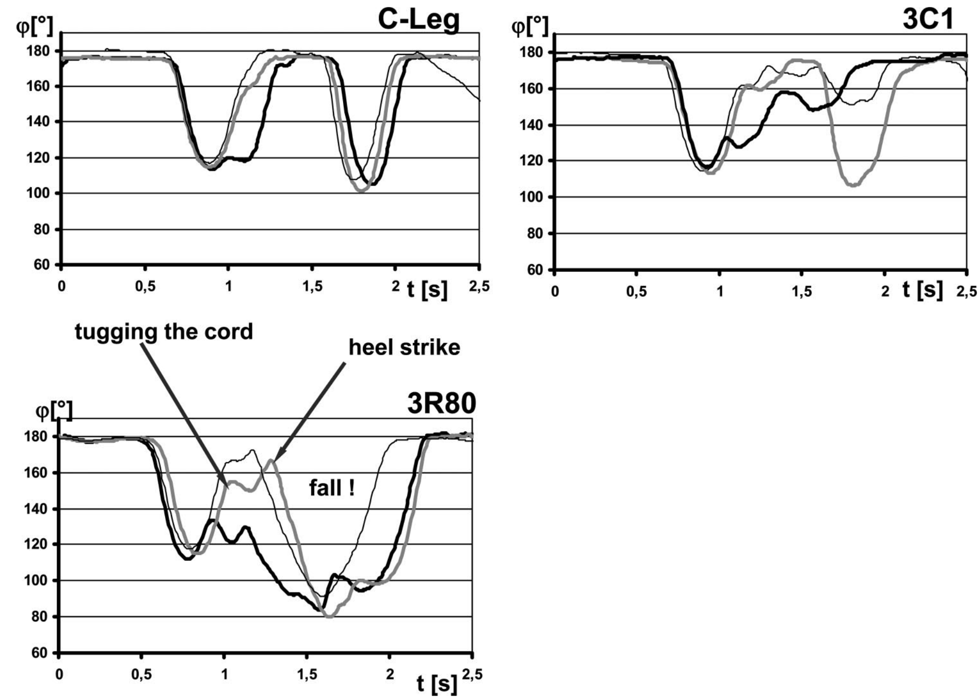

Figure 11. Typical knee motion patterns when tripping during swing phase extension is simulated; the investigator tugs on the cord that disrupts swing extension of the shin at different angles of knee flexion.

Table 3. Qualitative summary of potential safety of tested knee joints in risky situations

Test condition with prosthesis	3C1	3R80	C-Leg
Stopping	Unsafe	(Unsafe)	Safe
Sidestepping	Unsafe	(Unsafe)	Safe
Stepping onto 1.5 cm object with			
Heel	Unsafe	Unsafe	Safe
Midfoot	Unsafe	Safe	Safe
Forefoot	(Unsafe)	Safe	Safe
Tripping by disrupting swing extension	Safe	Unsafe	Safe
Slope descent	(Unsafe)*	(Unsafe)*	Safe
Stair descent	(Unsafe)*	(Unsafe)*	Safe

Unsafe, always fall or a high risk of knee collapse; safe, never collapsed; (unsafe), sometimes collapsed.
*Dependent on hip strength on prosthetic side.

the object, the greater the risk of knee collapse with the Mauch SNS hydraulic knee under this condition.

The C-Leg is unique among the tested components because of its sensor-based detection of motion phase and immediate adjustment of knee flexion resistance based on a software control algorithm. This microprocessor-controlled stance phase function means that ipsilateral hip strength and range of motion can be used in a high degree for balancing, propelling the prosthesis or the user rather than trying to stabilize the knee component.[28] We believe that the functional safety of the C-Leg, under all of the test conditions in this study, provides an objective explanation for the common subjective report from the amputee that walking with the C-Leg requires much less concentration while offering greater safety than alternative designs. This increase in functional, real-world safety may be the reason that prostheses with the C-Leg components have been shown to be more successfully integrated into the patients' body image than prostheses with other knee joints.[12,22] This automated safety may also explain why some highly active amputees comment that they are not controlling the C-Leg in the same way as other prosthetic knees. The biomechanical findings from this study suggest that the automatic stance control of the C-Leg design could provide amputees who are classified as having a lower mobility level the opportunity to perform normal activities of daily living with greater safety.

CONCLUSIONS

Safety of the prosthetic knee is of primary importance in the treatment of transfemoral amputees fitted with prostheses. Falls may lead to significant impairments in amputees' health and quality of life and treatment for this morbidity can markedly increase health care costs. Collapse of the prosthetic knee joint can occur whenever the amputee is suddenly faced with any situation that creates an unanticipated risk of falling. The amputee's reaction time may be inadequate to avoid falling. It is during moments such as these that the safety properties of the prosthetic knee joint are critical if falling and the ensuing risks of injury are to be avoided.

The novel study design presented here permits determination of dynamic safety—the safety the prosthetic knee joints offer during ambulation—making it possible to compare the safety potential of different prosthetic designs. To accurately determine the risk of falling caused by a prosthetic knee joint it was essential during investigations that the amputee could not anticipate the critical situation. Subjects had to be faced with the risk of falling unexpectedly as is typical of falls that occur in amputees' everyday life. This important study criterion should be fulfilled as good as possible. In this study the patients knew that at some point they would be tripped by the experimenter's intervention. Therefore, the situation was not fully unexpected for the amputee.

Knowledge about the real-world fall prevention potential of prosthetic knee joints is one important prescription indication. This biomechanical investigation gives the rehabilitation team objective information necessary to make an appropriate decision about this aspect of prosthetic prescription. Provision of a prosthetic knee component offering adequate safety can not only enhance the outcome for the amputee but also minimizes the legal risk associated with application of inappropriate prosthetic devices.

The results from this study verify that the electronically controlled C-Leg knee joint system significantly reduces amputees' risk of falling and injury compared with mechanical knee joints with Mauch SNS and rotary hydraulics. The probability of falling and fall-related injuries when walking with mechanical knee joints is measurably higher compared with using the C-Leg prosthesis.

ACKNOWLEDGMENTS

The authors acknowledge the valuable contribution of John W. Michael (Georgia Institute of Technology, USA) and Annett Elsner (Otto Bock HealthCare, Research & Development) in preparation of this article.

REFERENCES

1. Baumgartner R, Botta P. Amputationen und Prothesenversorgung der unteren Extremitäten (2. Auflage). Stuttgart: Enke; 1995.
2. Greitmann B, Bork H, Brückner L. Rehabilitation Amputierter. Stuttgart: Gentner; 2002.
3. Blumentritt S. Biomechanische Aspekte zur Indikation von Prothesenkniegelenken. *Orthopädie-Technik* 2004;55:508–521.
4. Stinus H. Biomechanik und Beurteilung des mikroprozessorgesteuerten Exoprothesenkniegelenks C-Leg. *Z Orthop* 2000;138: 278–282.
5. Köcher L. Das Kniegelenksystem C-Leg – klinische Versorgungsstatistik. *Med Orth Tech* 2001;121:129–134.
6. Kastner J, Nimmervoll R, Wagner P. Was kann das C-Leg? – Ganganalytischer Vergleich von C-Leg, 3R45 und 3R80. *Med Orth Tech* 1999;119:131–137.
7. Schmalz T, Blumentritt S, Jarasch R. Leistungsfähigkeit verschiedener Prothesenkniegelenke beim Treppabgehen von Oberschenkelamputierten. *Orthopädie-Technik* 2002;53:586–592.
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;16:255–263.
9. Kristen H, Nimmervoll R. Moderne Prothesen, moderne Passteile. *Med Orth Tech* 2002;122:106–113.
10. 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;85:1711–1717.
11. Willingham LL, Buell NC, Allyn KJ, et al. Measurement of knee center alignment trends in a national sample of established users of the Otto Bock C-Leg microprocessor-controlled knee unit. *JPO* 2004;16:72–75.
12. Wetz HH, Hafkemeyer Wühr UJ, Drerup B. Einfluss des C-Leg-Kniegelenk-Passteiles der Fa. Otto Bock auf die Versorgungsqualität Oberschenkelamputierter. *Orthopäde* 2005;34: 298–319.
13. Johansson JL, Sherrill DM, Riley PO, et al. A clinical comparison of variable-damping and mechanical passive prosthetic knee devices. *Am J Phys Med Rehabil* 2005;84:563–575.
14. Chin T, Machida K, Sawamura S, et al. Comparison of different microprocessor controlled knee joints on the energy consumption during walking in trans-femoral amputees: intelligent knee prosthesis (IP) versus C-Leg. *Prosthet Orthot Int* 2006;30: 73–80.
15. Segal AD, Orendurff MS, Klute GK, et al. Kinematic and kinetic comparison of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. *J Rehabil Res Dev* 2006;43: 857–870.
16. Schmalz T, Blumentritt S, Jarasch R. Biomechanical analysis of stair ambulation in lower limb amputees. *Gait Posture* 2007;25: 267–278.
17. Seymour R, Engbretson B, Kott K, et al. Comparison between the C-Leg microprocessor-controlled prosthetic knee: a preliminary study of energy expenditure, obstacle course performance and quality of life survey. *Prosthet Orthot Int* 2007;31:51–61.
18. Hauser D. Tuberumgreifende Einbettung bei Hüftexartikulationsprothesen. *Orthopädie-Technik* 2005;56:408–411.
19. Drerup B, Bitterle K, Wetz HH, et al. Langzeitergebnisse mit dem C-Leg-Kniegelenksystem – Ergebnisse einer Patientenbefragung. *Med Orth Tech* 2006;126:89–98.
20. Hafner BJ, Willingham LL, Buell NC, et al. Evaluation of function, performance and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. *Arch Phys Med Rehabil* 2007;88:207–217.
21. Swanson E, Stube J, Edman P. Functional body image levels in individuals with transfemoral amputation using the C-Leg. *JPO* 2005;17:80–84.
22. Bunce DJ, Breakey JW. The impact of C-Leg on the physical and psychological adjustment to transfemoral amputation. *J Prosthet Orthot* 2007;19:7–14.

23. Radcliff CW. Four-bar linkage prosthetic knee mechanisms, kinematics, alignment and prescription criteria. *Prosthet Orthot Int* 1994;18:159–173.

24. Nietert M. Das Kniegelenk des Menschen als biomechanisches Problem. *Biomed Tech* 1977;22:13–21.

25. Blumentritt S, Scherer HW, Wellershaus U. Biomechanisch-ganganalytische Bewertung von Prothesenfüßen. *Med Orth Tech* 1994;144:287–292.

26. Schuering HW. Beinprothesen im Hilfsmittelverzeichnis. *Orthopädie-Technik* 2001;51:884–889.

27. Blumentritt S. A new biomechanical method for determination of static prosthetic alignment. *Prosthet Orthot Int* 1997;21:107–113.

28. Kaufman KR, Levine JA, Brye RH, et al. Gait and balance of transfemoral amputees using passive mechanical and microprocessor controlled prosthetic knees. *Gait Posture* 2007;26:489–493.