

Multi-Body Simulation of Various Falling Scenarios for Determining Resulting Loads at the Prosthesis Interface of Transfemoral Amputees with Osseointegrated Fixation

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Received 14 November 2012; accepted 31 January 2013

Published online 13 March 2013 in Wiley Online Library (wileyonlinelibrary.com). DOI 10.1002/jor.22329

ABSTRACT: Conventionally, transfemoral amputees are treated with a shaft prosthesis fitted over the residual limb. To improve the quality of life of such patients, in particular those with complications relating to conventional attachment (e.g., skin irritation, stump ulcers, and poor motor-control with short stumps), osseointegrated prosthesis fixation implants have been developed and implanted in a limited population of patients. To assess possible damage to the implant/prosthesis during falling scenarios, the loads in high-risk situations were estimated using a multi-body simulation of motion. Five falling scenarios were identified and performed by healthy volunteer wearing safety equipment. Kinematic data and ground reaction forces were captured as input for the inverse-dynamics-based simulations, from which the forces and moments at a typical implant-prosthesis interface location were computed. The estimated peak loads in all five scenarios were of a magnitude that could lead to bone fracture. The largest peak force observed was 3274 ± 519 N, with an associated resultant moment of 176 ± 55 Nm on the prosthesis-implant interface. A typical femur is prone to fracture under this load, thus illustrating the need for a safety-release element in osseointegrated prosthesis fixation. © 2013 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. *J Orthop Res* 31:1123–1129, 2013.

Keywords: inverse dynamics; transfemoral amputee; osseointegration; impact; falling

For almost a century, the conventional treatment for individuals with transfemoral amputation has been a prosthesis attached to the residual amputated limb by means of a socket.¹ Despite advances in socket designs and insight to socket-soft tissue interaction, optimal function has not been achieved.² Techniques for the osseointegrated fixation of prostheses have been developed with the aim of improving the quality of life for amputees over that with conventional socket attachment, which is associated with complications ranging from skin irritation to pressure ulcers or a lack of motor-control with relatively short residual limbs.³ The largest number of procedures (>100) has been performed with the Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA) device.^{4,5} Other devices, such as the Intraosseous Transcutaneous Amputation Prosthesis (ITAP)^{6,7} or the Endo-Exo-Femurprosthesis,⁸ are all based on the principles established by Brånemark.⁹ The devices are anchored in the residual femur and protrude through the skin and soft tissue; the prosthesis is then attached to an abutment by conventional means. Clinical results show an improvement in the quality of life, mostly due to increased prosthetic use without an increase in prosthetic related problems.¹⁰

About half of the population with a lower extremity amputation experiences a fall at least once a year.¹¹ Although contemporary osseointegrated prosthetic fixation designs have predetermined breaking points intended to prevent interface damage, a recent study illustrated the risk of skeletal and implant fractures at

the implant-bone interface.¹² To protect this interface, a safety device is utilized that prevents the torsional load exceeding a threshold, but is unaffected by bending moments. This is especially important because test standards demand the knee prosthesis withstand mediolateral-bending moments over 600 Nm.¹³ The possible transfer of these loads to the prosthesis-implant interface cannot be neglected. Although torsional load is regarded as the highest risk,¹⁴ a potential hazard also exists in mechanical loosening by bending moments.³ The periprosthetic fracture risk is considered to be three times the fracture risk of intact bone.¹⁴ Therefore, it is important to define thresholds of forces and bending moments during activities of daily living and during high-risk situations such as falling.

Direct in vivo measurement of the forces and moments acting within the body is generally impossible, with a few limited exceptions. Telemetric implants for total knee, hip, or shoulder arthroplasties have provided useful data, especially regarding loads during daily activities.^{15–19} These data are often used for validation purposes or as benchmark data for the establishment of in vitro testing protocols.

The highly accessible situation of an amputee's prosthetic assembly grants the direct measurement of the forces acting on the interface of a socket or osseointegrated prosthesis fixation implant.^{20–22} However, measuring interface forces in high-risk situations, such as falling, is unethical. An inadvertent observation of a falling motion of an amputee did occur during a gait measurement session; loads and duration of falling and impact were observed, although the motion was affected by the patient supporting herself on a wall.^{23,24} Further studies investigated sideways falls with impact at the hip, with the focus on the amount and distribution of pressure affected by

Grant sponsor: German Federal Ministry of Education and Research; Grant number: BMBF AZ 01EZ0775.

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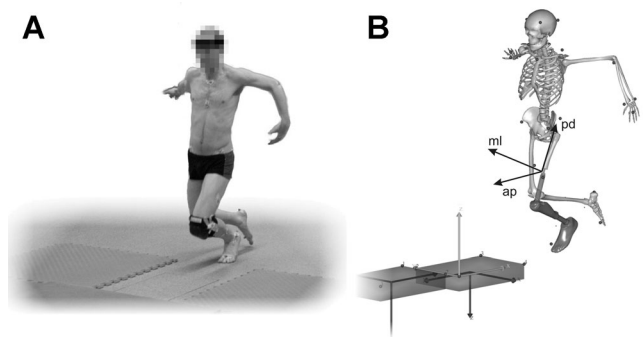


Figure 1. A: Volunteer protected by kneepads falling from gait onto one knee. B: Numerical model of the subject with the coordinate system, where the loads are simulated.

damping materials,^{25–27} but to our knowledge investigations concerning amputees have not been published.

Computational models provide information about forces in the body where these cannot be directly

measured. Thus multi-body simulation methods have been used to compute loading for different biomechanical applications.^{22,28–30} For falls, the simplistic spring-mass-damper models of Robinovitch²⁷ are employed, but to our knowledge high degree of freedom rigid body models have not been utilized to date. We applied such methods to determine estimates of the loads at the interface of osseointegrated fixation and attached prosthesis during falling.

MATERIALS & METHODS

A skeletal model representing a transfemoral amputee (Fig. 1) was driven by kinematic and kinetic data from a healthy subject who mimicked five documented falling scenarios of amputees. The study design was approved by the local ethics committee (No. 710), and the subject provided written consent.

Falling Scenarios

Five falling scenarios, four forward and one backwards, were investigated (Fig. 2). In consultation with the gait lab of Otto

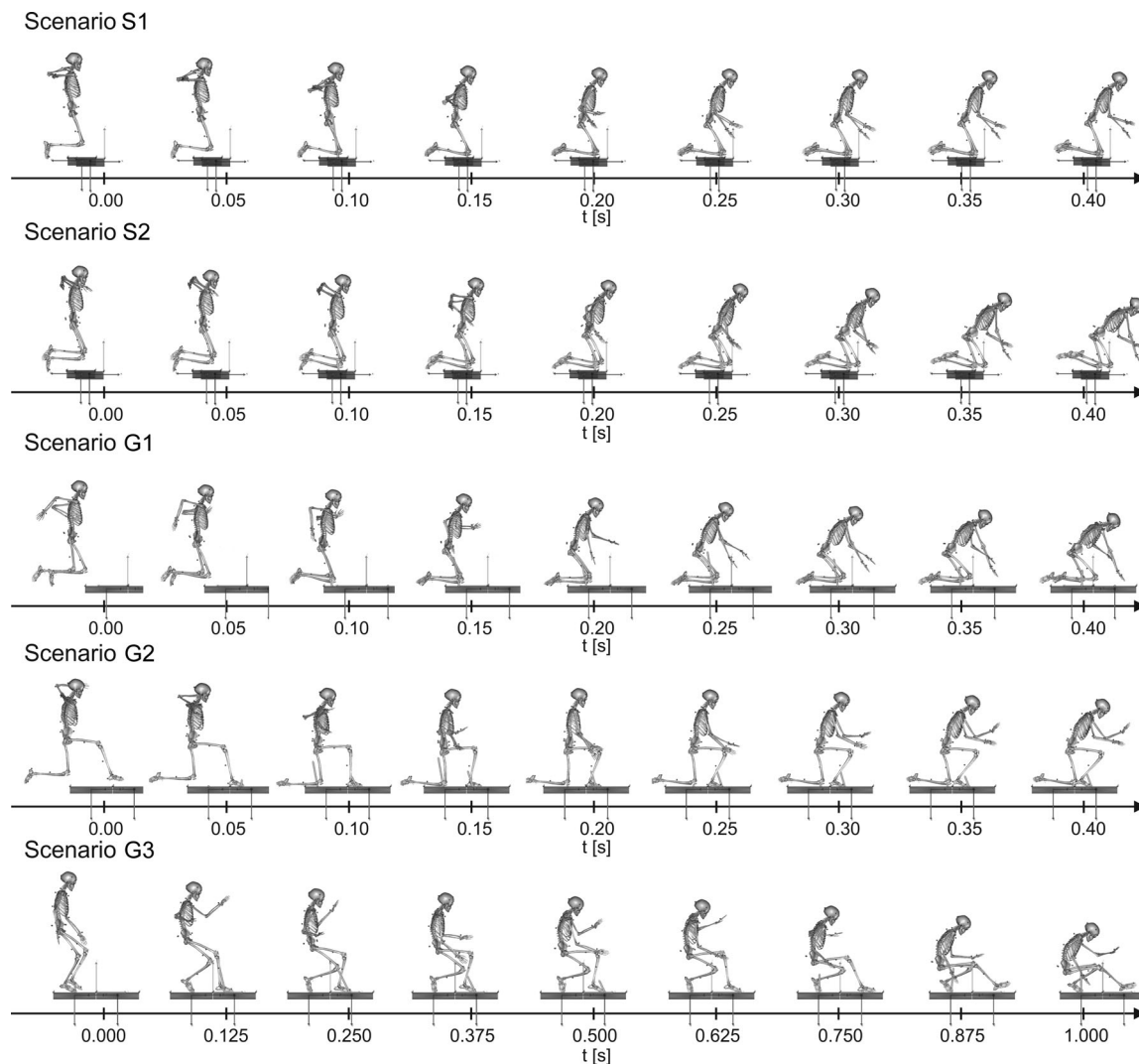


Figure 2. Series of movement during falling and impact of the model in different scenarios. The timeline of each scenario was shifted to adjust the first force peak to 0.1 s. Note the different timescale in scenario G3.

Table 1. The Investigated Falling Scenarios

	S1	S2	G1	G2	G3
Ground contact	Both knees	One knee	One knee	One knee, one foot	Both feet
Initial state	Standing	Standing	Gait	Gait	Gait
Representing	Maximum anticipated load	Maximum anticipated load	Swing phase disruption without support	Swing phase disruption with support	Stepping onto object with subsequent release

Bock HealthCare in Göttingen, Germany, three falling scenarios were identified as typical and frequently occurring in individuals with transfemoral amputation³¹ (Table 1, Scenarios G1, G2, and G3). The first two involve the interruption of the swing phase of the affected leg, for instance by bumping against an obstacle. This causes the prosthesis to remain flexed until heel strike and unlocked, leading to a fall. Scenario G1 represents the case where the amputee is unable to support the fall by the contralateral leg. In scenario G2 the contralateral leg provides additional support. In Scenario G3, the prosthesis disengages stability mode when the hindfoot steps onto an obstacle, leading to uncontrolled knee flexion. The amputee subsequently falls backwards reaching maximum flexion of the prosthesis. In G1 and G2, force was induced by sudden contact of the knee with the ground. G3 was expected to induce loads via maximum knee flexion and resulting unsteady deceleration of the upper body. Video data³¹ recorded at Otto Bock gait lab of the first three scenarios obtained on patients secured by a harness preventing impact was reviewed, and typical movement patterns were identified. Two other scenarios from a stationary standing position were developed to induce high loads and grant high repeatability, with impact on one or both knees (Table 1, Scenarios S1 and S2).

Measurement Protocol

The 5 scenarios were replicated by a healthy volunteer (male, height = 185 cm, body mass = 75 kg), with the aim of mimicking the previously identified movement patterns. Video data were presented to the subject, and exercise trials were conducted until visual agreement with selected scenarios was established. The subject was protected with knee-pads (Oxygen 2, Thailand) to prevent injury. The subject initially touched the ground with one knee (S2 and G1), both knees (S1), or one knee with support of the contralateral foot (G2). G3 was the only backwards-falling scenario and was initiated from the stance phase of gait. The subject's hands were used only at the end of the fall to prevent injuries, and did not have an effect on loading at the time of impact (S1, S2, G1, and G2) or maximum knee flexion (G3). The torso and the arms were free to move. Each scenario was repeated at least 8 times with clean force plate strikes.

The effect of the remaining contact force between foot and ground can be neglected in S1, S2, G1, and G2 because of the inability of the unlocked knee joint to transfer moments. Therefore, it does not affect the region of interest.

The subject's movement patterns were tracked using an optical system (8 Vicon MX-20/MX-40 cameras, Plug-In Gait full body marker model), and ground reaction forces were synchronously measured by two force plates (AMTI BP400600). Kinematic data were acquired at 200 Hz and

filtered with a second order Butterworth low-pass filter (25 Hz). Ground reaction force data were acquired at 1,000 Hz, and also filtered with a second order Butterworth low-pass filter (100 Hz).

Multi-Body Model

A multi-body skeletal model was developed using commercially available software (The AnyBody Modeling System, Version 5.0, AnyBody Technology A/S, Aalborg, Denmark). The model was validated previously by comparing calculated forces and moments with a strain-gauge-based force and moment sensor in six transfemoral amputees during normal gait.³² The model was built from an anthropometric repository and scaled to the subject's height and body mass. It does not contain representations of muscles, as amputee's morphology does not include muscles at the prosthesis-implant interface. The model was driven by the marker trajectories³³ and ground reaction forces applied to the knee at the origin of the resultant force by means of a massless dummy segment. Ground reaction forces during impact from falling are not affected by the subject's muscle activation.²⁷

Forces and moments as determined per the multi-body simulation about the anteroposterior (ap), mediolateral (ml) and proximodistal (pd) axes are reported in the left rigid femur segment 240 mm superior to the knee joint axis (Fig. 1). This location was chosen in consultation with experienced orthopaedic surgeons as representative of the height of above-knee amputations. The remaining segment length is required to provide bicortical implant alignment. The chosen location corresponds to the distal end of a hypothetical implant interface. The time resolution of the simulation was set to 1 ms to resolve adequately the transient effect of falling.

Data Processing

All trials for each scenario were averaged with the force peaks aligned at time = 0.1 s. The duration of the load peak was defined as the time interval in which the load was >50% of the peak load to enable comparisons between scenarios. As a measure of repeatability, the Coefficient of Variation (CV) was determined.

RESULTS

All forwards falling scenarios displayed a distinct force peak, but not the backward falling scenario (Figs. 3 and 4). For S1, falling from a stationary standing position with ground contact on both knees, a mean peak force of 2014 ± 528 N over 11 ± 2 ms was observed (Table 2). For S2, from the same position but with ground contact on one knee, the mean peak force

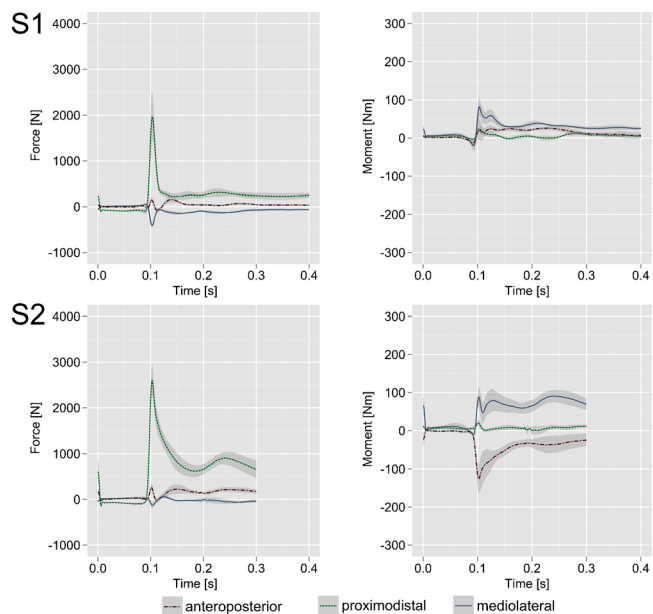


Figure 3. Means and SD of forces (left) and moments (right) 240 mm superior to the knee joint axis (Fig. 1) in falling scenarios S1 (top) and S2 (bottom). Loads in the anteroposterior, proximodistal and mediolateral directions are indicated by red dot-dashed lines, green dashed lines, and solid blue lines, respectively. The timeline of each scenario was shifted to adjust the first force peak to 0.1 s.

was higher (2614 ± 346 N) and the mean duration was longer (35 ± 21 ms).

The largest internal forces in all five scenarios were observed in G1, falling on one knee from normal gait. The mean peak force was 3274 ± 519 N over a loading period of 35 ± 21 ms with a resulting moment of 176 ± 55 Nm over a loading period of 267 ± 150 ms (Fig. 4). The largest component of the resultant force was directed axially along the bone. The mean peak

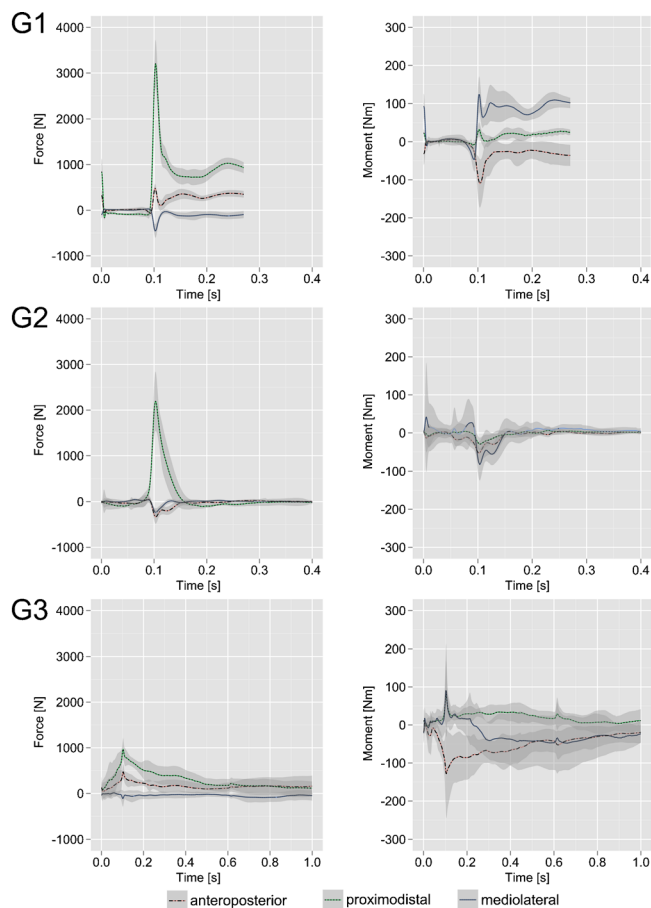


Figure 4. Means and SD of forces (left) and moments (right) 240 mm superior to the knee joint axis (Fig. 1) in falling scenarios G1 (top), G2 (middle) and G3 (bottom). Loads in the anteroposterior, proximodistal, and mediolateral directions are indicated by red dot-dashed lines, green dashed lines, and solid blue lines, respectively. The timeline of each scenario was shifted to adjust the first force peak to 0.1 s.

Table 2. Resultant Peak Forces and Moments 240 mm Superior to the Knee Joint Axis (Fig. 1) and Coefficients of Variation (CV) for Each Scenario

Parameter	S1	S2	G1	G2	G3
Peak resulting force (N)	2014 ± 528	2614 ± 346	3274 ± 519	2234 ± 659	1099 ± 269
Peak resulting force (%BW)	274 ± 72	355 ± 47	445 ± 71	304 ± 90	149 ± 37
Duration (ms)	11 ± 2	35 ± 21	12 ± 1	21 ± 6	n/a
Peak ap force (N)	158 ± 71	259 ± 87	479 ± 97	-333 ± 149	472 ± 166
Peak pd force (N)	1967 ± 531	2596 ± 349	3204 ± 523	2193 ± 650	968 ± 240
Peak ml force (N)	-403 ± 44	-127 ± 66	-455 ± 148	-235 ± 89	-111 ± 180
Peak resulting moment (Nm)	91 ± 28	160 ± 20	176 ± 55	109 ± 37	187 ± 177
Peak resulting moment (%BWm)	12 ± 4	22 ± 3	24 ± 7	15 ± 5	25 ± 24
Duration (ms)	101 ± 176	174 ± 100	267 ± 150	375 ± 388	1222 ± 761
Peak ap moment (Nm)	25 ± 10	-126 ± 37	-110 ± 63	-53 ± 30	-128 ± 117
Peak pd moment (Nm)	23 ± 8	20 ± 8	32 ± 19	-29 ± 17	81 ± 87
Peak ml moment (Nm)	82 ± 26	88 ± 25	124 ± 47	-82 ± 42	90 ± 122
CV of resulting force	0.26	0.13	0.16	0.29	0.24
CV of resulting moment	0.31	0.13	0.31	0.34	0.95

Duration was defined as the time during which the resulting load was above 50% of the resulting peak load.

force for G2 was 2234 ± 659 N with a mean peak moment of 109 ± 37 Nm. The reduced force compared with G1 was due to the support of the contralateral leg.

The lowest peak force of 1099 ± 269 N was observed for the only backwards-falling scenario, G3. Conversely, the largest peak moment, 187 ± 177 Nm, was observed for this scenario.

The highest and lowest reliabilities for the forces were displayed for S2 (CV: 0.13) and G2 (CV: 0.29), respectively. For the moments, the highest and lowest reliabilities were displayed for S2 (CV: 0.13) and G3 (CV: 0.95), respectively (Table 2).

DISCUSSION

We estimated loads at the prosthesis-implant interface for transfemoral amputees with an osseointegrated attachment. Within this investigation, forces and moments were simulated using an inverse dynamics model driven by kinematic data and ground reaction forces measured from a healthy subject mimicking idealized amputee falling scenarios. These results increase our knowledge regarding prosthesis-implant interface loading, which to date was based on sparse scientifically observed and documented amputee falling scenarios.^{23,24} These previous studies reported peak forces of 133%BW and moments of 17% BWm, while our study's highest body-mass-normalized loads and moments were 445%BW (G1) and 25%BWm (G3), respectively. Even with support during the fall (G2), the peak force remained considerably higher than previously reported at 304%BW. Comparisons between such studies are limited by substantial differences among subjects, an undefined amount of support during falling, and the unknown angle of the ground force vector in the data reported by Frossard et al.^{23,24} In a somewhat related study, Magnissalis et al.³⁴ investigated prosthetic loading during kneeling in static hyperflexion and reported bending moments up to 156 Nm about the axis of the knee.

Counter intuitively we found that loads did not double between landing on both knees (S2) compared to landing on one knee (S1), likely due to the prolonged duration of the force peak. In S1, the subject could stabilize himself shortly after impact without any further movement. In S2, velocity was reduced more slowly and over a longer time period (Fig. 2). As expected, loads in G1 were higher than in S2, as the initial state is dynamic in nature, arising out of motion during gait.

The peak loads observed in the five scenarios varied considerably. In G2, the loads were reduced by the subject supporting the fall with his contralateral leg; these results are thus not as reproducible as those in the other scenarios, as the amount of off-loading varied between repetitions. Regarding forces, S2 and G1 displayed a reproducibility in terms of CV close to the inter-step-variance of level walking,³⁵ and thus

can be considered as highly repeatable. Overall reproducibility was worst in G3, where movement patterns are more complex and difficult for the subject to mimic, resulting in highly variable moments. Nevertheless, this scenario is particularly relevant for our target group, as a knee prosthesis has a rigid blocking mechanism at maximum flexion, which may occur during a backwards fall.

Due to the angle of the femur with respect to a vertical axis, the large force also caused considerable moments in S1, S2, and G1. S2 and G1 displayed a large component of the moment around the ap axis, due to the lever arm of the body's center of mass with respect to knee contact in the frontal plane.

Peak loads were, in all scenarios, well above the values observed for level walking of the same subject at a self-selected speed using an identical model (peak forces of 794 ± 64 N and peak moments of 74 ± 7 Nm). Reference data for an osseointegrated subject (male, height = 1.70 m, body mass = 85 kg) directly measured at the attachment during daily activities showed maximum resultant forces of 1018 N and moments of 65 Nm.²⁰

According to the load limits reported in a related study³⁶ of bone failure of osseointegrated prosthesis fixation, our results suggest the possibility of fracture of the affected leg in every investigated scenario. In a numerical simulation of bone-failure, the safety factor against mechanical failure is relatively small, even for level walking.³⁶ Further work is warranted to determine the load magnitudes that will cause damage to the bone-implant interface.

We anticipate the amputation level will substantially influence the magnitude and directions of the resulting internal loads. The utilized model is easily adoptable to perform the necessary calculations. We nevertheless consider reporting these results beyond the scope of the present article.

There are several limitations that must be acknowledged. The energy dissipating properties of the subject's knee-pads must have reduced the forces and moments transferred to the knee. Prosthesis wearers may have a cosmetic cover in place, which also absorbs energy, but this is unlikely to have the same properties as a knee-pad. Simplifying the pad to be a 1.5 cm thick rubber foam device, impact forces would be attenuated by ~8%.³⁷ The pads also allow sliding relative to the floor, thus reducing shear forces. In reality, the shear forces may contribute to the loads considerably. Another obvious limitation is the use of only one subject. Further studies are planned that will focus on the variability of loading among subjects and the dependence of interface loading on amputation level.

As our simulation relies on 3D motion capture data, it is also affected by soft tissue marker errors. However, due to the slender shape of our subject, we consider skin to bone motion only a marginal effect. The low mass of the markers created forces that we suspected

to be responsible for only slight skin deformation. Despite the efforts of the subject to mimic falling scenarios presented to him on video, the conducted scenarios were an approximation to real-life circumstances and present a limitation. Fortunately, transfemoral amputees can often support themselves during falling with various strategies,^{38,39} which has the potential of reducing the ultimate load on the prosthesis structure.

If the potential advantages to some patients from the treatment of transfemoral amputations by means of osseointegrated prosthesis fixations are to be transferred into routine clinical practice, patients must be protected from hazardous loads. Devices to protect the implant-bone interface from torsional loads have been implemented, and potential hazards of bending moments have been reported.^{3,14} For the first time, we report bending moments for cases of unsupported falling that could be relevant for the design of multi-axial safety elements. These findings will be of interest in combination with finite element analysis to determine real stresses in the osseointegrated bone to allow conclusions about location and risk of fracture under high loading situations.

ACKNOWLEDGEMENTS

This study was funded by the German Federal Ministry of Education and Research (BMBF AZ: 01EZ0775). The authors thank the Technical University Berlin and the Otto Bock Healthcare GmbH, Duderstadt, Germany for cooperation in TExoPro, especially Dr. T. Schmalz and M. Bellmann.

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