**Load response of an osseointegrated implant used in the
treatment of unilateral transfemoral amputation:
An early implant loosening case study**

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ABSTRACT

Background: Osseointegrated implants for transfemoral amputees facilitate direct load transfer between the prosthetic limb and femur; however, implant loosening is a common complication, and the associated implant-bone loads remain poorly understood. This case study aimed to use patient-specific computational modelling to evaluate bone-implant interface loading during standing and walking in a transfemoral amputee with an osseointegrated implant prior to prosthesis loosening and revision surgery.

Methods: One male transfemoral amputee with an osseointegrated implant was recruited (age: 59-yrs, weight: 83kg) and computed tomography (CT) performed on the residual limb approximately 3 months prior to implant failure. Gait analyses were performed, and the CT images used to develop a finite element model of the patient's implant and surrounding bone. Simulations of static weight bearing, and over-ground walking were then performed.

Findings: During standing, maximum and minimum principal strains in trabecular bone adjacent to the implant were 0.26% and -0.30%, respectively. Strains generated at the instant of contralateral toe-off and contralateral heel strike during walking were substantially higher and resulted in local trabecular bone yielding. Specifically, the maximum and minimum principal strains in the thin layer of trabecular bone surrounding the distal end of the implant were 1.15% and -0.98%, respectively.

Interpretation: Localised yielding of trabecular bone at the interface between the femur and implant in transfemoral amputee osseointegrated prosthesis recipients may present a risk of implant loosening due to periprosthetic bone fracture during walking.

- 1 Rehabilitation exercises should aim to produce implant-bone loading that stimulates bone
- 2 remodelling to provide effective bone conditioning prior to ambulation.

3

1 INTRODUCTION

2 Osseointegrated implants overcome a number of complications associated with
3 traditional socket-fitted prostheses for the treatment of lower limb amputation, including
4 residual limb pain and skin irritation at residual stump-socket interface, which can occur
5 in up to 62% of recipients (Gallagher Malcolm MacLachlan, Pamela, 2001; Hagberg and
6 Brånemark, 2001; Lyon et al., 2000; Mak et al., 2001). Clinical studies have shown that,
7 compared to socket-fitted prostheses, transfemoral osseointegration reduces tissue
8 damage and residual pain (M Al Muderis et al., 2016; Branemark et al., 2001; Sullivan et
9 al., 2003), while improving patient activity levels, and facilitating larger range of hip
10 joint movement (Brånemark et al., 2014; Hagberg et al., 2008, 2005). In two-year
11 follow-up studies by Brånemark et al., 2014 and Hagberg et al., 2008, implant survival
12 rates were 92% in 51 patients and 94% in 18 patients, respectively. Nebergall et al.
13 (2012) used radiostereometric analysis in 51 patients to show no significant implant
14 migration or rotation at ten-year follow-up. In contrast, a systematic review of outcomes
15 of osseointegrated prostheses for transfemoral amputation reported a maximum revision
16 rate of 67%, with osseointegrated implants loosening in up to 6% of patients, and
17 periprosthetic fracture occurring in up to 9% of cases (van Eck and McGough, 2015). In a
18 study of 51 amputees with osseointegrated implants, mechanical failure of the prosthesis
19 was observed in up to 29% of cases (Brånemark et al., 2019), including damage to the
20 abutment and/or abutment screw that forms the connection between the intramedullary
21 stem and the prosthetic lower limb. Failures have also been reported to the intermedullary
22 stem, with four incidents described across 77 patients (Munjed Al Muderis et al., 2016;
23 Zimel et al., 2016).

Transfemoral amputees with osseointegrated implants typically undergo post-operative rehabilitation for up to six months to encourage integration of bone into the implant prior to ambulation (Hagberg and Branemark, 2009). In the first phase of rehabilitation, a controlled loading regime is applied to incrementally stimulate bone mineralization and strength, whilst minimizing risk of implant overloading. Core and limb strengthening exercises are commonly performed in conjunction with axial weight bearing using a short training prosthesis, and static loads of increasing magnitude gradually applied until the amputee is able to support half their bodyweight without significant pain (Al Muderis et al., 2017b; Hagberg et al., 2005; Hagberg and Branemark, 2009). Some protocols also adopt eccentric prosthesis loading exercises to encourage bone growth in directions other than axial (Hagberg and Branemark, 2009). In the second phase of rehabilitation, prosthetic limbs are fitted, and parallel bars and crutches employed to limit load transmission through the entire prosthesis. The patient may repeat the static weight bearing tasks, and progressively introduce different phases of the gait cycle until they are able to ambulate unaided (Leijendekkers et al., 2017). At present, the loading patterns at the bone-implant interface during rehabilitation tasks such as static weight bearing, and normal walking are poorly understood. As a consequence, over-emphasis on functional rehabilitation tasks that under-load the bone in the residual limb may not adequately prepare the patient for the dynamic loads during walking, and may ultimately result early implant loosening or failure (Huiskes et al., 1987; Turner et al., 1986).

Finite element modeling has been used in several studies to investigate stress-strain distributions and long-term remodeling of bone surrounding osseointegrated

transfemoral implants (Helgason et al., 2009; Lee et al., 2008; Stenlund et al., 2017; Tomaszewski et al., 2010). While these previous studies have been used to describe risk of implant failure, implant loading was achieved using a resultant external force and moment applied directly to the prosthesis. However, non-knee-spanning muscles contribute to the linear and angular acceleration of the knee as well as knee joint-contact loading via dynamic coupling (Zajac et al., 2002); replacing the forces of individual muscles by an equivalent knee load may ultimately underestimate prosthesis force response (Blemker et al., 2007; Herzog et al., 2003). The study by Lee et al., 2008 showed distinctive differences in bone-implant interface stresses between weight-bearing and walking; however, the femur did not incorporate subject-specific bone geometry or material properties, which would have significantly altered the magnitude and distribution of the stress predictions.

The objective of this study was twofold. Firstly, to develop a patient-specific multi-body musculoskeletal model of the residual limb of an amputee with an osseointegrated prosthesis in the period before the implant loosened due to a periprosthetic fracture, and secondly, to use this model to evaluate loading patterns at the bone-implant interface during static weight-bearing with both a short training prosthesis and the entire prosthetic limb, as well as walking with the prosthetic limb. The findings of this case study will help in the development of personalised rehabilitation regimens to improve bone-implant integration and minimize early implant loosening.

MATERIALS AND METHODS

Subject recruitment and imaging

One male subject (age: 59 years, weight: 83 kg, height: 1.90 m) with an above-knee amputation due to an automobile accident was recruited 12 months following primary surgery to implant a transfemoral osseointegrated prosthesis. The implant was an Osseointegrated Prosthetic Limb (OPL; Permedica s.p.a, Milan, Italy) with a cross-screw design (M Al Muderis et al., 2016), connected to a Genium microprocessor controlled knee (Otto Bock 3B1), a pylon with in-built torsion adaptor (Otto Bock 2R21) and dynamic response foot (Otto Bock 1C60, size 28 cm) (Figure 1). The subject had no history of previous surgery, osteoarthritis, or pain in the residual or contralateral limb. This study was approved by the University of Melbourne Human Ethics Committee and written-informed consent was obtained.

The subject's residual limb was scanned using computed tomography (CT) (Somaton Definition AS+; Siemens Healthineers, Munich, Germany) with a metal artefact reduction sequence and a voxel size of 0.79 x 0.79 x 0.75 mm. The three-dimensional geometry of the femur and osseointegrated implant was digitally reconstructed from the CT images using commercially available software (Mimics version 21.0; Materialise, Leuven, Belgium). Approximately 14 months post-operatively, the osseointegrated implant failed by periprosthetic fracture leading to loosening of the intramedullary stem in the femoral canal, and the implant was revised to a non-cross-screw design OPL. The position of the revised osseointegrated implant within the intramedullary canal was similar to that of the implant used in the initial surgery, as confirmed by aligning the 3D components obtained in the initial surgery with the 2D projection of the revised components from a frontal-plane x-ray (Figure 2). Since the identical prosthetic limbs were used both prior to and following surgery, it is likely that

1 the positions of the residual limb and hinge axis of the prosthetic knee remained
2 relatively unchanged.

3 **Motion capture experiments**

4 Motion analysis experiments were performed with the subject's revised
5 osseointegrated prosthesis 12 months following the revision surgery. Data collection was
6 performed with the subject standing in a relaxed pose, as well as during over-ground
7 walking at the preferred self-selected speed (Figure 3a). Three-dimensional positions of
8 retro-reflective markers placed on the subject were measured using a 9-camera motion
9 analysis system (Vicon, Oxford Metrics Ltd., UK) sampling at 120 Hz. Ground reaction
10 force data were simultaneously acquired using three instrumented force platforms (AMTI
11 Inc., Watertown, MA) sampling at 1080 Hz. Marker trajectories were filtered using a
12 low-pass, fourth-order Butterworth filter with a cut-off frequency of 10 Hz, while ground
13 reaction force was filtered at 60 Hz using a four-order Butterworth filter.

14 **Computational modeling**

15 A rigid-body musculoskeletal model of the amputee's residual limb prior to
16 prosthesis failure was developed using a subject-specific computational modelling
17 framework (Figure 3b,c). The 12-segment, 23-degree-of-freedom rigid-body model
18 actuated by 76 Hill-type muscle-tendon units was created by scaling a generic
19 musculoskeletal model of an adult to the mass and anthropometry of the patient (Ackland
20 et al., 2012). The 3D geometry of the patient's residual femur was imported into the
21 model, and the distal femur, shank and foot segments replaced with the osseointegrated
22 implant and lower limb. The knee joint was modelled as an ideal hinge, with the external
23 torque of the microprocessor-controlled knee represented by a coordinate (reserve)

1 actuator at the knee. Intact femoral muscles were attached to the residual femur according
2 to the centre of their tendon attachments which were located relative to bony landmarks
3 on the femur using the 3D anatomical atlas software Complete Anatomy (version 5.1.1;
4 3D4Medical, Dublin, Ireland). Surgically reconstructed muscles were re-attached to the
5 distal end of the femur using a myodesis technique and any absent or dysfunctional
6 musculature in the residual limb were removed from the model.

7 The mass and inertial properties of the residual limb segments was determined by
8 representing the associated components using geometric shapes of uniform density. The
9 residual limb above the knee was represented as the frustum of a right circular cone,
10 where the maximum and minimum circumference and height were measured with a
11 measuring tape and a uniform tissue density was assumed of 1.1 g/cm^3 (Smith et al.,
12 2014). The mass, centre-of-mass and mass-moment of inertia components were computed
13 for this geometry using CAD software (Solidworks, Dassault Systems, Paris, France).
14 The combined mass of the knee and pylon segments was measured using digital scales
15 and represented as a solid cylinder with dimensions equal to their maximum
16 circumference and total height, as evaluated using measuring tape. The combined knee
17 and pylon was assigned a constant density for carbon fibre material (1.65 g/cm^3), and the
18 corresponding centre of mass was set at the centre of the cylinder with the mass moment
19 of inertia calculated using standard engineering formula (Eqs 1 and 2). The foot segment
20 was modelled as a triangular prism with its height and width determined using the tape
21 measure. Assuming a uniform density of a carbon fibre material, the centre of mass and
22 mass moments of inertia were computed using the CAD software. The position of the
23 hinge axis on the prosthetic knee was determined by placing two reflective markers

coincident with the rotation axis on the prosthetic limb. The correct positioning of these markers on the axis was verified by examining their 3D measurements recorded by the motion capture system during flexion of the prosthetic limb.

$$I_x = I_y = \frac{1}{12}m(3r^2 + h^2) \quad (1)$$

$$I_z = \frac{1}{2}mr^2 \quad (2)$$

where I is the mass moment of inertia, the subscripts x and y denote the radial directions and z denotes the axial direction, m is the mass, r is the radius, h is the cylinder height.

The musculoskeletal model was used to simulate static weight bearing conditions with a short training prosthesis as well as the prosthetic limb. Simulations of walking were also performed, specifically, four gait events during the stance phase that included ipsilateral heel strike, contralateral toe-off, contralateral heel strike and ipsilateral toe-off (Figure 4). For each simulation, inverse kinematics was applied to the motion capture data. Net internal joint moments were then calculated using inverse dynamics and decomposed into muscle forces using static optimization (Dorn et al., 2012). For static weight bearing with the short training prosthesis, 50% body-weight was applied to both the abutment of the intramedullary stem and to the foot of the intact limb.

A deformable model of the residual limb and implant was developed in a commercial finite element modelling package (Abaqus 2017; Simulia, RI, USA) (Figure 3D). The model was created and output data expressed in the femoral coordinate system, which was located at the centre of the femoral head with the y -axis pointing cranially from the prosthetic knee hinge axis centre to the femoral head centre, the x -axis pointing anteriorly and perpendicular to the plane defined by the y -axis and the prosthetic knee

1 hinge axis, and the z-axis calculated as the cross-product of the x- and y-axes. The three-
2 dimensional geometries of the femoral cortical bone, trabecular bone and implant were
3 meshed using tetrahedron elements using Hypermesh (version 2017.2; Altair
4 Engineering, Michigan, USA).

5 To prevent a stress concentration at the connection between the intramedullary stem
6 and cross-screw, a 0.5 mm fillet was added to the outer edge of the hole on the cross-
7 screw and the mesh density was increased at the interface between the components. The
8 average element size and total number of elements of each component are provided in
9 Table 1. The intramedullary stem and cross-screw were rigidly tied to one another, and
10 the thread on the screw modelled as a uniform 10 mm diameter cylinder. The implant and
11 bone were modelled as linear-elastic solids, with material properties for the implant set to
12 a Ti6Al4V titanium alloy (Al Muderis et al., 2017a), whilst the bone was assigned a
13 heterogeneous apparent bone mineral density (ρ_{app}) with an elastic modulus derived from
14 the CT data (Table 1). The intramedullary stem and the threaded region of the cross-
15 screw were assumed to be completely osseointegrated with the surrounding bone, and
16 these surfaces were tied to prevent relative motion between respective nodes at the
17 contact interfaces. The surface of the femoral head was clamped three-dimensionally to
18 model contact against the acetabulum. This boundary condition was chosen because the
19 resultant hip joint contact force was approximately at the centre of the femoral head,
20 which ensured approximately equivalent boundary condition positions, joint forces and
21 moments with that of the musculoskeletal model. Although this clamped boundary
22 condition would have differed from joint contact in a native joint, this difference was

1 assumed to have only a localised contribution to the femoral stress predictions in the
2 vicinity of the femoral head.

3 For simulations of standing (training prosthesis and entire prosthetic limb) and
4 walking, the rigid-body musculoskeletal model predictions of kinematics, inertial forces,
5 muscle forces and knee joint reaction forces were applied to the finite element model.
6 Twenty-seven muscle forces were included in the model, with each applied across several
7 nodes on the bone in the vicinity of the muscle attachment. The knee-joint reaction force
8 and moment were transmitted to the distal end of the intramedullary stem via a rigid
9 multi-point constraint (MPC). The inertial forces and moments due to linear and angular
10 femoral acceleration were applied at the distal end of the intramedullary stem. Peak von
11 Mises stresses, and maximum and minimum principal strains were calculated for the
12 implant, and femoral trabecular bone and cortical bone in four discrete femoral regions:
13 the femoral neck, intertrochanteric, subtrochanteric and diaphysis (Figure 5). A strain-
14 based failure criterion was used to identify trabecular bone yielding, whereas a stress-
15 based criterion was used to identify cortical yielding/fracture and implant yielding (Table
16 1). To verify model consistency, the hip joint reaction force calculated using the
17 musculoskeletal model was compared to the hip joint-contact force estimated using the
18 finite element model. To evaluate sensitivity of the results to changes in mesh density, the
19 entire FE model mesh density was increased to the highest amount possible
20 (approximately 3.60 million elements) and used to simulate the contralateral toe-off load
21 case (see Supplementary Material). Compared to the nominal mesh density, the stress and
22 strain predictions had an average difference less than 10% for each component, which

1 was considered sufficient to provide reasonable comparisons between the load cases
2 considered in the current study.

3 **RESULTS**

4 The largest muscle contribution to support the residual limb during standing was
5 from adductor brevis, adductor longus, gluteus medius (anterior) and iliacus, with each
6 generating between 62.1 and 248.9 N (Table 2). In comparison, there were greater forces
7 generated by particular hip-spanning muscles during the stance phase of walking, with
8 peak forces greater than 500 N for gluteus maximus, gluteus medius, rectus femoris,
9 iliacus and psoas (Table 2). The resultant force at the abutment of the training prosthesis
10 and knee joint of the lower limb prosthesis were similar during standing (406.7 N and
11 375.6 N, respectively) (Table 2), and each was less than half of the peak knee force
12 during the stance phase of walking (894.8 N at contralateral toe-off). While the training
13 prosthesis produced no external knee joint moment during standing, the resultant knee
14 joint moment for the lower limb prosthesis was 46.2% of the peak observed during stance
15 (41.0 Nm). The maximum linear and angular accelerations calculated for the residual
16 limb centre of mass during the stance phase of walking was 7.6 m/s² and 49.1 rad/s²,
17 respectively (Table 2). The hip joint contact forces predicted by the finite element model
18 were within 5% of those predicted by the rigid-body musculoskeletal model (Table 3).

19 The peak von Mises stress of the intramedullary stem when standing with the
20 training prosthesis and lower limb prosthesis occurred superiorly along the medial edge
21 of its connection with the cross-screw (132.7 MPa and 140.5 MPa, respectively) (Table
22 4) (Figure 6). In contrast, the peak stress on the intramedullary stem increased from 39.8
23 MPa at ipsilateral heel strike to 522.8 MPa at contralateral toe-off, before decreasing to

1 25.6 MPa at ipsilateral toe-off. The peak stresses at the cross-screw when standing with
2 the training or lower limb prosthesis (126.8 MPa and 131.0 MPa, respectively), were
3 much lower than the peak stress incurred during stance in this region (501.8 MPa at
4 contralateral toe-off).

5 For femoral cortical bone, the peak von Mises stress in each region of the femur
6 ranged from 6.1 MPa to 23.2 MPa for the training prosthesis and 10.3 MPa to 41.1 MPa
7 for the lower limb prosthesis during standing (Table 4). During stance, the
8 intertrochanteric region and diaphysis had a peak cortical stress at contralateral toe-off of
9 98.0 MPa and 78.4 MPa, respectively, whilst the femoral neck and subtrochanteric region
10 had a peak stress at contralateral heel-strike of 74.8 MPa and 82.6 MPa, respectively.
11 During walking and standing, the stresses in femoral cortical bone were lower than those
12 of the yield strength of cortical bone (Table 1). The peak stresses in the cortical bone
13 occurred in the vicinity of muscle attachments on the greater and lesser trochanter and at
14 the distal end of the diaphysis, although large stresses were also apparent in the femoral
15 neck for contralateral toe-off and contralateral heel strike (Figure 7).

16 Considering all regions of the femur during standing with the training prosthesis,
17 the trabecular bone had a maximum and minimum principal strain of 0.25% and -0.20%,
18 respectively (Table 4). These strains were slightly greater for the load case with the lower
19 limb prosthesis (0.54% and -0.38%, respectively). During walking, a maximum principal
20 strain of 1.15% was observed in the diaphysis at contralateral heel-strike, while a
21 minimum principal strain of -0.80% occurred in the diaphysis at contralateral toe-off.
22 Strains at or slightly below these maxima were observed in the thin layer of trabecular
23 bone that was present at the interface the implant (Table 4), specifically at the most distal

1 region of the femur (Figure 8). The peak strains during standing did not result in
2 trabecular bone damage, whereas there were localised regions of bone yielding observed
3 during the stance phase of walking (Table 1) (Figure 8).

4 **DISCUSSION**

5 The objective of this case study was to employ patient-specific multi-body
6 musculoskeletal modelling to evaluate the load response of an osseointegrated
7 transfemoral implant prior to its failure due to loosening. This was achieved by
8 quantifying forces, stresses and strains generated during static weight bearing with a
9 training prosthesis and full lower limb prosthesis, as well as during over-ground walking
10 with the lower limb prosthesis. While post-operative static-weight bearing tasks are
11 performed to condition femoral bone prior to ambulation, there is paucity of quantitative
12 data describing resultant loads at the implant-bone interface in osseointegrated
13 transfemoral prostheses. In the present study, the predicted loads during walking may
14 have contributed to failure of the implant-bone fixation after surgery. The findings
15 emphasise the importance of correct prosthesis selection and intraoperative placement, as
16 well as rigorous post-operative rehabilitation prior to ambulation.

17 The osseointegrated implant experienced the largest stresses at the boundary
18 between the intermedullary stem and screw, and the abutment (Figure 6). This finding
19 may be due to the presence of a prominent bending moment, since the length of the stem
20 and diaphysis provide a considerable moment arm of the distally-located forces at knee
21 joint force. Although the stresses at these locations were below the yielding threshold, it
22 is nonetheless suggested that future osseointegrated implant designs mitigate these
23 dynamic bending-generated loads, for example, using alternative implant geometry such

1 as support ribs or radiused edges, or by using less-stiff biomaterials such as 3D printed
2 lattice structures (Chen et al., 2016). Although the locations of the observed peak stresses
3 in the cortical bone tended to occur at the muscle attachments (Figure 7), this result was
4 likely due to the small attachment areas assumed in the finite element model (Polgar et
5 al., 2003). The small attachment regions were applied to achieve the same moment arms
6 of the muscles in the musculoskeletal model which act as point loads. Despite this result,
7 the relatively large stresses observed in the femoral neck during contralateral toe-off and
8 contralateral heel-strike are consistent with studies examining peak stresses in the
9 proximal femur during stance (Martelli et al., 2014; Van Rietbergen et al., 2003).

10 No previous studies have described failures related to the cross-screw, which was
11 the location of the greatest implant stresses in the current study. However, this design is
12 only available in the OPL implant system and is applied to short femurs less than 16 cm
13 in length (Al Muderis et al., 2018), and thus a limited number of individuals have
14 received this implant which inherently restricts the number of patients that would
15 experience potential implant failure. Further, mechanical failures of implanted
16 osseointegrated components without a cross-screw are relatively rare, with only four
17 cases on intramedullary stem failure reported across 77 patients in two studies (M Al
18 Muderis et al., 2016; Zimel et al., 2016). These studies either did not specify the implant
19 failure location or used a considerably different implant design, which prevents a direct
20 comparison to the peak implant stress locations in the current study. Mechanical failure
21 has been reported in the OPRA implant system at the abutment and/or abutment screw
22 that connects to the intramedullary stem and extends out from the bone and skin
23 (Brånemark et al., 2019). Indeed, the peak stress in the intermedullary stem was observed

1 in a similar distal location, external to the bone (163.8 MPa at contralateral toe-off; Table
2 4), which is in close agreement with the stress distributions predicted in the current study.

3 During the single-support phase of stance, the maximum and minimum principal
4 strains for the trabecular bone were sufficient to induce yielding in the femoral neck,
5 intertrochanteric and diaphysis regions (Table 4). In most cases, these were localized to
6 small regions at the interface between the bone and the implant, especially for trabecular
7 bone that appeared to have formed at the distal end of the diaphysis (Figure 8). Localised
8 yielding or microdamage may initiate bone remodeling that potentially strengthens the
9 bone in the vicinity of the implant (Burr et al., 1997; Leucht et al., 2007; Nagaraja et al.,
10 2005). Conversely, excessive yielding may present a risk of periprosthetic bone fracture,
11 or implant migration that may lead to aseptic loosening (Taylor and Prendergast, 2015).
12 The predicted bone yielding sites at the proximal and distal regions of the femur compare
13 well with reported fracture locations associated with osseointegrated implantation where
14 femoral fractures occurred proximal from the implant (Al Muderis et al., 2018; Munjed
15 Al Muderis et al., 2016; Juhnke et al., 2015), or periprosthetic fractures occurred in the
16 proximal or distal region of bone surrounding the implant (McGough et al., 2017; Tyler
17 et al., 2009; Zimel et al., 2016). It is not possible to compare the yielding sites with cases
18 of aseptic loosening, as the initial site of implant loosening has not been reported and
19 cannot easily be determined retrospectively. A comparison between the predicted
20 yielding sites and implant loosening would be well suited to mechanical testing on
21 cadaveric specimens using dynamic imaging techniques such as dual plane fluoroscopy
22 (Tsai et al., 2013), and is recommended in future work.

1 In the present study it was observed that femoral stresses and strains for each of
2 the static weight bearing conditions were much lower than those during walking (Figure
3 8) and were below the thresholds necessary to induce trabecular or cortical bone yielding.
4 Therefore, the standing-based rehabilitation task investigated may be considered
5 inadequate to stimulate bone remodelling to sufficiently condition bone prior to walking.
6 Pre-rehabilitation strategies ought to be developed to gradually introduce bone strains
7 closer to those during walking to promote more extensive bone remodelling, for example
8 sit-to-stand, step-up or squat tasks (Martelli et al., 2014).

9 The results presented in this study are in reasonable agreement with previous
10 finite element analyses of transfemoral osseointegrated implants. The peak stress
11 observed at the distal end of the intermedullary stem at contralateral toe-off (161.7 MPa;
12 Figure 5), was in reasonable agreement with the reported a peak stress of a transfemoral
13 osseointegrated implant of 137 MPa at its distal end during midstance (Xu et al., 2006).
14 Another finite element modeling study of an osseointegrated implant found that the peak
15 von Mises stress of bone surrounding the implant was 8.5 MPa, occurring at late stance
16 (Lee et al., 2008), which is similar to the peak stress observed for this region in the
17 current study of 10.6 MPa at contralateral heel strike. Finally, a previous modelling study
18 predicted a peak von Mises equivalent strain in the diaphysis of an osseointegrated
19 implant of 0.18% (Xu et al., 2016). This was of a similar magnitude to our peak strains
20 predicted in the diaphysis for the training prosthesis (maximum, minimum principal
21 strain: 0.25%, -0.14%) and full lower limb prosthesis during standing (maximum,
22 minimum principal strain: 0.28%, -0.20%). While the peak strains predicted in the current
23 study for stance were much greater, this may be due to the large bending moment

1 generated by the microprocessor-controlled knee (approximately 40 Nm at contralateral
2 toe-off), which was not modeled in the study of Xu et al. (2016).

3 There are limitations of this study that ought to be considered. First, it is unclear
4 whether the regions of low bone density at the bone-implant interface represented the true
5 bone properties or were the consequence of CT artifacts from the metallic implant such as
6 beam hardening, photon starvation or scatter (Pessis et al., 2013). However, a metal
7 artefact reduction algorithm was used to minimise this undesirable effect, though artefact
8 may still affect the CT measurements of bone density close to the implant (Koff et al.,
9 2017; Wellenberg et al., 2018). Second, the tied contact between the implant and bone
10 simulated the case of complete osseointegration of the implant and did not consider the
11 possibility of micro-motion at the bone-implant interface. Third, the thread on the implant
12 was not modeled to avoid stress discontinuities, which may have affected the stress
13 distribution in the vicinity of the bone-implant interface. Finally, due to radiation dosage,
14 a CT scan was not performed following the implant revision surgery; however, the
15 revised implant position was assessed using a frontal-plane x-ray. Comparing the 3D
16 alignment of the initial implant with the 2D projection of the revised implant indicated
17 that the alignment was similar (Figure 2), suggesting the revised implant was press-fit
18 into the intramedullary canal and that its position was not substantially altered in the
19 revision surgery.

20 The present study investigated loading on a transfemoral osseointegrated
21 prosthesis that, after 14 months post-operatively, failed by early loosening and was
22 subsequently revised. By using multi-body musculoskeletal modelling, it was shown that
23 strains at the prosthesis-bone interface during standing were substantially lower than

1 those generated during walking. Localised regions of yielding of trabecular bone in the
2 vicinity of the distal femur were observed during walking, which may ultimately present
3 risk of periprosthetic fracture or implant migration, particularly in cases of insufficient
4 osseointegration and over-emphasis on static weight bearing prior to ambulation.
5 Personalised rehabilitation protocols that target unassisted ambulation ought to involve
6 dynamic tasks that transition the osseointegrated limb between low intensity static
7 weight-bearing and those associated with walking.

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9

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TABLES

Table 1: Material properties, average element size and number of elements used in the finite element model of the transfemoral amputee's residual limb, including osseointegrated prosthesis and femoral cortical and trabecular bone.

Component	Material	Density (g/cm ³)	Elastic modulus (GPa)	Poisson's ratio	Yield limit	Ultimate strength	Average element size (mm)	Number of finite elements
Intramedullary stem	Ti6Al4V ^a	4.4	115	0.33	$\sigma=795$ MPa	$\sigma=860$ MPa	0.37	715,217
Cross-screw	Ti6Al4V ^a	4.4	115	0.33	$\sigma=795$ MPa	$\sigma=860$ MPa	0.23	544,653
Femur	Trabecular bone ^b	0.0-1.0 ^b	0.5-5.7 ^c	0.3	$\epsilon_{Y,comp} = 0.70\%$	N/A	0.85	587,105
					$\epsilon_{Y,tens} = 0.61\%$	N/A		
	Cortical bone ^b	1.0-2.0 ^b	5.7-19.7 ^c	0.3	$\sigma=121.0$ MPa	$\sigma=140.0$ MPa	0.84	119,910

^a Ti6Al4V properties from (Oldani and Dominguez, 2012)

^b Bone densities corresponds to apparent bone mineral density (ρ_{app}) scaled linearly from CT grayscale values to the normal range of femur (Morgan et al., 2003). The threshold for ρ_{app} between trabecular and cortical bone was set as 1.0 g/cm³. Elastic modulus was calculated from apparent bone mineral density using $E=6850\rho_{app}^{1.49}$ (Morgan et al., 2003). The yield strains for trabecular and bone were previously published (Morgan and Keaveny, 2001), as were the yield and ultimate stress for cortical bone (Carter et al., 1981).

Table 2: Magnitudes of the muscle forces (N) calculated using the patient-specific musculoskeletal model and used in the finite element model simulations of over-ground walking and a static standing posture.

Component	Quantity	Gait event					
		Standing: Training prosthesis	Standing: Full lower limb prosthesis	Ipsilateral heel strike	Contralateral toe-off	Contralateral heel strike	Ipsilateral toe-off
Adductor Brevis	Resultant force (N)	70.5	102.5	0.0	0.0	0.0	24.6
Adductor Longus		167.7	248.9	0.0	0.0	0.0	16.9
Adductor Magnus (Superior)		26.9	39.3	0.0	0.0	0.0	21.6
Adductor Magnus (Medial)		9.1	12.4	0.0	0.0	0.0	10.4
Adductor Magnus (Inferior)		37.7	48.2	0.0	0.2	0.0	33.7
Biceps Femoris Long Head		0.0	0.0	16.9	189.2	0.0	39.9
Gemellus		0.0	0.0	0.2	0.2	14.5	0.1
Gluteus Maximus (Superior)		0.0	0.0	49.3	248.9	1.9	0.0
Gluteus Maximus (Medial)		0.0	0.0	96.4	460.8	0.0	0.1
Gluteus Maximus (Inferior)		0.0	0.0	0.4	43.8	0.0	47.5
Gluteus Medius (Anterior)		99.7	101.3	20.6	516.1	101.9	0.0
Gluteus Medius (Medial)		0.0	0.0	52.5	262.1	41.7	0.0
Gluteus Medius (Posterior)		0.0	0.0	99.8	329.2	95.2	0.0
Gluteus Minimus (Anterior)		3.4	3.4	2.4	47.7	23.8	0.0
Gluteus Minimus (Medial)		0.0	0.0	9.1	77.4	28.9	0.0
Gluteus Minimus (Posterior)		0.0	0.0	28.8	137.2	30.6	0.0
Gracilis		4.2	5.9	0.0	0.0	0.0	2.7
Iliacus		62.1	122.1	0.0	0.0	604.6	6.8
Pectineus		13.3	20.0	0.0	0.0	0.1	2.4
Piriformis		0.0	0.0	37.8	185.8	53.2	0.1

Psoas		22.7	73.7	0.0	0.0	723.0	7.5
Quadriceps Femoris		0.0	0.0	4.2	0.0	26.3	2.7
Rectus Femoris		0.0	0.0	26.7	0.0	1011.2	0.2
Sartorius		0.0	0.0	2.5	0.4	20.7	0.2
Semimembranosis		82.5	81.4	1.0	377.6	0.0	42.8
Semitendinosis		11.1	12.7	0.1	20.0	0.0	9.0
Tensor Fasciae Latae		0.0	0.0	8.2	20.8	40.0	0.1
Knee joint	Resultant force (N)	406.7*	375.6	29.7	894.8	647.3	53.3
Knee joint	Resultant moment (Nm)	0.0*	18.9	8.7	41.0	20.5	11.7
Inertia	Angular acceleration resultant (rad/s^2)	0.0	0.0	6.1	12.3	49.1	14.9
Inertia	Linear acceleration resultant (m/s^2)	0.0	0.0	5.0	5.6	7.6	4.1

* Load application point for training condition was at the distal end of the abutment rather than the knee joint.

Table 3: Hip joint reaction force predicted by rigid body and finite element models for training, standing and during the stance phase of walking. The force components are provided in the local hip coordinate system*.

	Standing: Training prosthesis		Standing: Full lower limb prosthesis		Ipsilateral heel strike		Contralateral toe- off		Contralateral heel strike		Ipsilateral toe-off	
	Rigid- body	Finite element	Rigid- body	Finite element	Rigid- body	Finite element	Rigid- body	Finite element	Rigid- body	Finite element	Rigid- body	Finite element
Fx (N)	-192.0	-191.8	-331.7	-331.5	-76.5	-74.5	-731.4	-728.9	-767.8	-767.1	29.1	27.7
Fy (N)	-843.0	-843.4	-992.7	-992.7	-338.1	-340.4	-3215.2	-3213.2	-2884.1	-2882.0	-97.9	-98.3
Fz (N)	187.8	188.1	270.5	269.0	156.8	156.4	903.6	904.3	397.6	393.3	109.4	110.2

* The positive x-direction, y-direction and z-direction is anterior, superior and lateral, respectively.

Table 4: Maximum von Mises stress (MPa) for the osseointegrated prosthesis, and maximum and minimum principal strains for the femoral cortical and trabecular bone. Data are given for standing as well as the stance phase of gait, including heel strike, contralateral toe-off, contralateral heel strike, and toe-off.

Section	Variable	Component	Standing: Training prosthesis	Standing: Full lower limb prosthesis	Ipsilateral heel strike	Contralateral toe-off	Contralateral heel strike	Ipsilateral toe-off
Implant	von Mises stress (MPa)	Intramedullary stem	132.7	140.5	39.8	522.8	475.4	25.6
		Cross-screw	126.8	131.0	39.9	501.8	451.6	11.2
Femoral neck		12.0	13.7	5.4	52.5	74.8	1.6	
Intertrochanteric		18.8	41.1	17.0	98.0	51.4	3.3	
Subtrochanteric		6.1	10.3	4.8	38.2	82.6	4.8	
Diaphysis		23.2	34.7	3.5	78.4	26.0	13.9	
Trabecular bone surrounding implant	Max, Min Principal Strain (%)	All regions of femur	0.22,-0.20	0.26,-0.21	0.12,- 0.12	0.84,-0.80	1.15,-0.74	0.20,-0.12
Trabecular bone	Max, Min Principal Strain (%)	Femoral neck	0.12,-0.20	0.14,-0.21	0.06,- 0.08	0.52,-0.73	0.41,-0.61	0.03,-0.05
		Intertrochanteric	0.25,-0.17	0.54,-0.38	0.11,- 0.13	0.75,-0.79	0.46,-0.62	0.03,-0.03
		Subtrochanteric	0.04,-0.06	0.05,-0.08	0.03,- 0.03	0.21,-0.27	0.40,-0.32	0.07,0.02
		Diaphysis	0.24,-0.14	0.28,-0.20	0.13,- 0.09	0.84,-0.80	1.15, -0.74	0.20,-0.14

FIGURE CAPTIONS

Figure 1: Osseointegrated transfemoral implant modelled in the present study prior to failure by early loosening. The specific regions of the intramedullary stem and cross-screw are indicated, as well as their implanted position in the femur.

Figure 2: Comparison of relative positions of initial osseointegrated implant and femur obtained using CT to the positions of the revised osseointegrated implant and femur obtained using frontal plane X-ray including frontal plane X-ray following the revision surgery, with the 3D geometry of the initial implant and femur aligned to the outline of the femur (a) frontal plane x-ray with segmented outlines indicating the femur (purple), revised implant (green) and the cavity from the removed cross-screw (blue), (b) 3D geometry of initial implant and femur (c), and 2D geometry of femur, revised implant (intramedullary stem) and the cavity from the removed cross-screw (d).

Figure 3: Framework for developing personalised computational model of the residual limb of a transfemoral amputee including over-ground walking experiments performed in a human movement laboratory (a), rigid-body musculoskeletal model of amputee (b), and details of the transfemoral osseointegrated implant, including the intramedullary stem and cross-screw (c), and finite element model of osseointegrated implant and femur (d). Muscle forces are indicated by red arrows. The multi-point constraint (MPC) connection indicated by the blue lines was used to transmit the

knee reaction force (F_{knee}) and moment (M_{knee}) to the prosthesis abutment.

The muscles rectus femoris, sartorius and tensor fasciae latae are omitted for visualization purposes.

Figure 4: Tasks modelled in the present study including standing using a training prosthesis (a), and full lower limb prosthesis (b). Also investigated was the stance phase of gait with the complete lower limb prosthesis including ipsilateral heel strike (c) contralateral toe-off (d) contralateral heel strike (e), and ipsilateral toe-off (f).

Figure 5: Regions of the femur used in the finite element model analysis. These included the femoral neck, intertrochanteric, subtrochanteric and diaphysis.

Figure 6: Von-Mises stress distribution in the osseointegrated implant for each load case. The location of the peak stress for the stem and screw are reported for standing using a training prosthesis (a), and full lower limb prosthesis (b). Stress distributions were also investigated for the stance phase of gait with the complete lower limb prosthesis including ipsilateral heel strike (c) contralateral toe-off (d) contralateral heel strike (e), and ipsilateral toe-off (f).

Figure 7: Von-Mises stress distribution in the femoral cortical bone for each load case. The location of the peak stress for the entire femur is indicated for standing using a training prosthesis (a), and full lower limb prosthesis (b). Stress distributions were also investigated for the stance phase of gait with the complete lower limb prosthesis including ipsilateral heel strike (c)

contralateral toe-off (d) contralateral heel strike (e), and ipsilateral toe-off (f).

Figure 8: The maximum and minimum principal strain (top row and bottom row, respectively) in the trabecular bone surrounding the implant. Regions of bone exceeding the trabecular yield strength are shown in grey. Data are given for standing using a training prosthesis (a), and full lower limb prosthesis (b). Data are also provided for the stance phase of gait with the complete lower limb prosthesis including ipsilateral heel strike (c) contralateral toe-off (d) contralateral heel strike (e), and ipsilateral toe-off (f).

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

Figure 7

Figure 8

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