Load applied on the residuum of individuals with transfemoral amputation fitted with bone-anchored prostheses: A scoping review protocol

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Abstract

This scoping review aims to answer two research questions (1) What is the scope of variables used to describe loading data measured using a portable kinetic recording apparatus (Q1)? (2) What is the range of the loads applied on residuum of individuals with transfemoral amputation fitted with an osseointegrated fixation (Q2)? The objectives of this scoping review are (A) to map the scope of loading variables and (B) to report the range of loads that has been directly measured using a portable kinetic recording apparatus fitted at the distal end of the residuum during rehabilitation exercises, standardized and unscripted activities of daily living, and adverse events. This scoping review will consider studies involving individuals with transfemoral amputation fitted with a bone-anchored prosthesis using screw-type or press-fit osseointegrated fixations. The broad concept examined by this scoping review will relate to kinetics analysis or inner loading of bone-anchored prostheses. More specifically, this review will focus on the concepts associated with extraction and presentation of loading information acquired using direct measurement techniques. This scoping review will consider studies describing at least one characteristic of loading applied to screw-type or press-fit osseointegrated fixations. This scoping review will consider studies relying on measurements conducted in care facilities, experimental settings as well as open environment. This scoping review will consider a broad range of study designs in order to capture the concepts outlined above. The search strategy will aim to find unpublished and published studies.

Keywords

Direct skeletal attachment; Bone-Anchored Prostheses; Loading; Kinetic; Osseointegration; Transfemoral amputation

Review question

The main purpose of this scoping review is to characterize loading information applied on the residuum of individuals with transfemoral amputation fitted with an osseointegrated fixation for bone-anchored prostheses.

The objectives of this scoping review are (A) to map the scope of loading variables and (B) to report the range of magnitude of loads that has been directly

measured using a portable kinetic recording apparatus fitted at the distal end of the residuum during rehabilitation exercises, standardized and unscripted activities of daily living, and adverse events.

The specific review questions are:

- Review Question 1: What is the scope of variables used to describe loading data that has been directly measured using a portable kinetic recording apparatus mounted at the distal end of

the residuum of individuals with transfemoral amputation fitted with an osseointegrated fixation (Q1)?

- Review Question 2: What is the range of magnitude of the loads applied on residuum of individuals with transfemoral amputation fitted with an osseointegrated fixation measured directly with a portable kinetic recording apparatus during rehabilitation exercises, standardized and unscripted activities of daily living, and adverse events (Q2)?

Background

Limitations of socket prostheses

Socket-suspended prostheses are the predominant aid used by individuals with lower limb loss to regain mobility.¹⁻³ Generally, sockets are tedious to attach as a tight fit around the residual limb must be achieved to warrant proper suspension (Figure 1).⁴ This is often challenging for individuals with a short residuum.

In all cases, numerous literature reviews highlighted that sockets present drawbacks mainly due to poor socket-skin interfaces. The compression of the residuum combined with high friction generates discomfort and pain often leading to skin damage (e.g., sweating, ingrown hairs, irritation, blisters, sores, abscesses).⁵⁻⁸ Consequently, these factors limit the individual's ability to use their prosthesis, resulting in shorter wearing duration and reducing their overall level of activity.⁹ Some individuals also experience a restricted range of motion due to the socket, adding to the number of difficulties with the essential prosthetic component. Overall socket prosthetic users tend to be dissatisfied with their prosthesis, highlighting the need for a better method of prosthetic attachment.^{10,11}

Over the past decade, several groups have attempted to alleviate these sockets shortcomings by developing bone-anchored prostheses.¹² In this case, the socket is replaced by an osseointegrated fixation implanted directly in the residual bone (Figure 1).¹³ This method of prosthetic attachment is now commonly accepted as a viable alternative to socket-suspended prostheses, particularly for young and active individuals with nonvascular transfemoral amputation (TFA).¹⁴ Fixations are surgically inserted following a one or two-step procedure depending on treatment protocols.¹⁵⁻²⁴ To date, the most acknowledged surgical procedure relies on fixation with a screw-type design implanted into the residual femur.^{12,15,18-20,25-40} However, implantations of press-fit fixations are currently increasing at a rapid pace.^{17,21,33,40-47} Other devices are currently at various

stages of development, particularly in Europe and the United States.^{13,48-71} All fixations commercially available include a medullar part directly connected to the femur providing a solid union between living bone and device.¹³ Fixations also include a percutaneous part (e.g., abutment, dual cone) with a proximal end inserted into the medullar part and a distal end protruding through the skin to enable external attachment of the prosthesis.^{13,57}

Insert Figure 1 here

Clinical benefits and shortcomings of bone-anchored prostheses

Studies have demonstrated that bone-anchored prostheses have major clinical benefits when compared to socket prostheses (e.g., health-related quality of life, prosthetic use, body image, hip range of motion, sitting comfort, donning and doffing, osseoperception, walking ability) and acceptable safety (e.g., implant stability, infection, breakage of parts).^{18-20,27-29,36,38,73-76} Additionally, this method of attachment allows individuals to participate in a wide range of daily activities for substantial period of time.^{27,32,77-87} Altogether, bone-anchored prostheses significantly enhance quality of life.^{15,18-20,42}

Nonetheless, several concerns with bone-anchored prostheses must be addressed to facilitate broader acceptance.^{14,88} The main current issues relate to lengthy rehabilitation programs, deep and superficial infections, as well as risk of injury and damage of prosthetic components.^{15,16,36,38,44-46,64,72,84,85,89-93}

Need for a better understanding of loading

In principle, these issues could be associated with the loads applied on the fixation during its lifespan, as forces and moments are transferred from the ground up by prosthetic components. Therefore, issues with the fixation could be addressed through the design and optimization of fixation parts and prosthetic componentry.^{90,94} In particular, bone-anchored prostheses should be designed to accept incidental (e.g., fall) or excessive (e.g., running) loading while avoiding potential serious injuries (e.g., peri-prosthetic fracture, hip dislocation, femoral head fracture), and costly component damage (e.g., bending of the percutaneous part).^{27,32,76-79,83-85,95,96} Therefore, an understanding of the actual loads translated to the medullar part by the percutaneous part during rehabilitation and daily activities is a prerequisite to solve these issues.^{27,32,77,79-87}

Loading applied on the fixation and adjunct

joints (e.g., knee, hip) have been assessed relying on typical inverse dynamics equations. Forces and moments were calculated using kinematic data obtained with 3D motion capture combined with dynamic data applied while stepping over up to two force-plates.⁹⁷⁻¹⁰³ Unfortunately, the required experimental setup limited ecological measurements (e.g., limited number of steps, targeting force-plates, use of markers). In addition, calculations might be prone to errors (e.g., determination of inertial characteristics of the prosthetic limb).^{97,98,100,102}

More recently, loads applied on the fixation have been also measured directly using customized and commercial portable kinetic systems featuring a data logger and a multi-axial load transducer mounted between residuum and the prosthetic knee joint.^{27,32,77-80,82-86,95,104,105} This method has a distinct advantage over other techniques, as the three components of forces and moments can be measured directly, providing real-time feedback to patients and clinicians, without the need for extensive computation.¹⁰² These forces and moments have been directly recorded during a wide range of conditions. Indeed, fragmented publications reported various loading characteristics (e.g., pattern, peak values, impulse, loading rate) during either rehabilitation phases, standardized and unscripted daily activities as well as adverse events.

Demand for scoping review to map loading data

Surprisingly, reviews compiling these datasets are yet to be presented to-date. However, systematic description of the recording and analysis methods as well as the compilation of loading data are needed to provide a comprehensive understanding of the mechanical constraints applied on osseointegrated fixations across all conditions. A typical systematic review and eventually a meta-analysis, would be ideal to achieve such comprehensive analysis. However, this type of review is difficult to complete since publications focusing on loading tend to be only explorative.^{27,32,77-82,84-87,95,100,102,104} They report loading values without consideration for the outcome of the intervention (e.g., type of fixation).^{12,13,91,106,107} Consequently, determination of direct treatment effect is not presented.

A scoping review might be a suitable alternative method as loading information could be reported more broadly regardless of treatment effect.^{72,108,109} Characterisation of the loads applied on osseointegrated fixations can be achieved by mapping (A) the scope of variables used to extract loading information and (B) the range of loads

expressed in raw units and percentage of body weight that were reported at different phases of the treatment ranging from rehabilitation to independent activities. Preliminary searches in main databases (e.g., Medline/PubMed, CINAHL, Web of Science, Google Scholar, EMBASE, SCOPUS) revealed no completed or in progress systematic reviews on this topic.

Methods

Inclusion criteria

Participants

This scoping review will consider studies involving individuals with transfemoral amputation fitted with a bone-anchored prosthesis using either screw-type or press-fit osseointegrated fixations.

Concept

The broad concept examined by this scoping review will relate to kinetics analysis or inner loading of bone-anchored prostheses. More specifically, this review will focus on the concepts associated with extraction and presentation of loading information (e.g., patterns, peak values, impulse and loading rate) acquired using direct measurement techniques (e.g., load transducers). This scoping review will consider studies describing at least one these characteristic of loading applied to screw-type and/or press-fit osseointegrated fixations.

Context

This scoping review will consider studies relying on measurements conducted in care facilities (e.g., in or out-patient rehabilitation centers), experimental settings (e.g., motion analysis laboratories) as well as open environment (e.g., home).

Study types

This scoping review will consider a broad range of study designs in order to capture the concepts outlined above, such as:

- Descriptive observational studies including individual case reports, case series, and descriptive cross-sectional studies,
- Analytical observational studies including prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies.

Insert Figure 2 here

Search strategy

Key elements of the search strategy are presented in Figure 2-Section A. The search will be conducted by two reviewers. The search strategy will aim at finding published studies in peer and non-peer reviewed sources. An initial limited search of Medline/Pubmed has been undertaken to identify articles on this topic, followed by analysis of the text words contained in the titles and abstracts, and of the index terms used to describe these articles. This informed the development of the proposed search strategy including tailored keywords and index terms each information source. Furthermore, individual search strategies will be applied for each database, using specific descriptors. A full search strategy is detailed in Appendix I. The reference list of all included studies will be screened for additional studies.

The databases to be searched include:

- Medline/PubMed
- CINAHL
- Web of Science
- Google Scholar
- EMBASE
- SCOPUS
- LILACS
- ProQuest Dissertations
- Theses Global

Only studies published in English since 1990 will be included corresponding to the year of first implantation of an osseointegrated fixation to an individual with a lower limb amputation.¹² The upper date limits will be the date when the search will be conducted.

Data extraction

Key elements of the data extraction are presented in Figure 2-Section B. The data extracted will broadly include information about the concept, context and study methods of significance to the scoping review question (i.e., Q1, Q2), and specific objectives of each reference (e.g., forces and moments applied on the medio-lateral, antero-posterior and long axes of the fixation).

Reference Data Extraction Form

The extraction will be performed using the Reference Data Extraction Form (RDEF) displayed in Appendix II. This form was designed to collect relevant datapoints for a single dataset corresponding to loading information in a single activity (i.e., load bearing exercises, walking with aids, level walking,

standardized daily activities and unscripted activities of daily living, fall). This means that several forms might be used for a given publication depending on the number of activities reported.

This form was also designed to organize the extraction of relevant datapoints within five majors sections as described in Figure 2. The first and last sections focus on reference and appraisal information, respectively. The other sections derive from the PICO process commonly used for evidence-based medicine (i.e., population, intervention, comparator, outcomes).

At this stage, the form presented here included 1,005 datapoints for a single comprehensive dataset. This form was designed to be as exhaustive as possible with the aim to capture the broadest range of information. However, the same variables can be reported in several different ways. For example, the loading data in Section 5.5 could be entered in units for forces (e.g., N) and/or percentage of body weight (e.g., %BW). However, it is more likely that a given publication will focus on limited aspects of a load, creating an incomplete dataset. Also, load data presented only in raw units will be converted to percentage of the body weight and vice-versa when possible, during the data mapping process. Altogether, it has been estimated that a total of 495 datapoints should be sufficient to describe a single basic dataset. So, it is more likely that this draft of RDEF will be modified and revised as necessary during the process of extracting data from each study included. Modifications will be detailed in the full scoping review report.

Two independent reviewers will complete the RDEF including the appraisal. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. Authors of papers might be contacted to request missing or additional data where required.

Reference data

The first section of the RDEF includes 17 (2%) datapoints of comprehensive and basic information focusing on the reference it-self (i.e., data entry, publication, descriptor).

Population data

The second section of the RDEF includes 48 (5%) datapoints of comprehensive and basic information focusing on population. This section aims at describing the group of participants involved in the study including the type of participants, the typical demographics (e.g., gender, age, mass, height, BMI), the amputation information (e.g., age at

amputation, year since amputation, length of residuum) and the cause of amputation.

Intervention data

The third section of the RDEF includes 38 (4%) datapoints of comprehensive and basic information focusing on intervention. This section aims at reporting the attachment (e.g. socket, BAP), the prosthetic components used (e.g., knee unit, ankle/foot unit, protective device, footwear, cosmetic cover), the timeline of the evaluation (e.g., pre-op, post-op, follow-up) and methodology used to record the loading data (e.g., device, software).

Comparator data

The fourth section of the RDEF includes only 5 (0.5%) datapoints of comprehensive and basic information focusing on comparator. This section focuses on the possible alternative datasets that could be reported for comparison purposes involving individuals fitted with socket prosthesis and/or able-bodied participants (e.g., load measurement with inverse dynamics).

Outcome data

The fifth section of the RDEF includes 877 (87%) and 365 (74%) datapoints of comprehensive and basic information focusing on outcomes, respectively. This section focuses on the type of variables extracted (e.g., mean patterns, peak values, loading rate, impulse), the extraction of data (e.g., number of trials and gait cycles), the type of activity (i.e., load bearing exercises, walking with aids, level walking, standardized daily activities and unscripted activities of daily living, fall), the commonly reported spatio-temporal characteristics (e.g., cadence, speed of walking, duration of gait cycle, support and swing phases, length of steps, strides and walking base) and loading data. As described in Figure 2, a strong emphasis will be put on extracting information about loading data (i.e., Q2) including the onset as well as minimum and maximum magnitude in raw units and percentage of the body weight for up to four peaks of forces (F) and moments (M) applied along the anterior-posterior (AP), medial-lateral (ML), and long axes (LG), as well as the resultant (RT) on the fixation. An example of these loading variables applied on an osseointegrated fixation during an average gait cycle is provided in Figure 3.

Insert Figure 3 here

Appraisal data

The appraisal of the methodology used to produce the magnitude of the loads will be critical to

determine the level of evidence while answering Review Question 2. Ultimately, this information will be essential to determine how much the loading data extracted in this review could be deemed reflective and trustworthy (e.g., strength of the recommendations).

The sixth section of the RDEF includes 20 (2%) datapoints of comprehensive and basic information focusing on appraisal. Preliminary analysis of initially identified articles focusing on inner loading of bone-anchored prostheses revealed that appraising their methodological quality might be challenging. Conventional appraisal guidelines (e.g., GRADE, Newcastle-Ottawa Scale, Levels of Evidence for Primary Research Question of Clinical Orthopaedics and Related Research) could only partially evaluate some specific methodological aspects (e.g., selection bias, comprehensiveness).¹¹⁰⁻¹²¹

Consequently, in this review, the methodological quality of the selected studies will be established using a specifically designed Quality Assessment Criteria (QAC). The development of this tool was largely inspired from principles laid in quality assessment guidelines such as the one for Effective Public Health Practice Project (EPHPP).¹²²

The methodological quality of each dataset will be determined by assessing sample size, confounding, instrumentation and comprehensiveness aspects. Each of these four quality aspects will be categorized as weak, moderate or strong according to the appraisal criteria described in Table 1. Some tentative categorization values for appraisal are also suggested in Table 1 based on current knowledge and preliminary analysis. Consequently, these values might be adjusted for the subsequent scoping review.

The appraisal of sample size aspects relates essentially to the number of participants in each dataset. Since 1990, the number of patients treated with screw-type fixations in limited centers worldwide has progressed steadily but slowly to warrant long term patient safety (e.g., observation time). The current population is estimated at 500 individuals worldwide.¹²³⁻¹²⁶ In principle, assessment of the sample size could be based on the number of participants considered in a study reported in percentage of the population worldwide at the time of testing. This information is only reported in limited number of publications. Attempts have been made to monitor the global population on a yearly basis but estimations might lack validity and accuracy.¹²³⁻¹²⁶ Alternatively, the sample size aspects will be appraised against best methodological standards published in the field of prosthetic research. Geil

(2016), conducted a “brief review of the articles published in Journal of Orthotics and Prosthetics (JPO)” and revealed that “primary research studies of human subjects sample size ranged from 3 to 41, with an average [...] of 14.1”.^{127p93} This information was used to make educated choices for categorization of sample size aspects detailed in Table 1.

The appraisal of confounding aspects of a dataset depends on the number of variables reported that could be potentially associated with inner loading data listed in Section 5.5 of RDEF. Typically, these variables are related to the population, the intervention and spatio-temporal characteristics detailed in Sections 2, 3 and 5.4 of RDEF, respectively. The total number of confounders included in the RDEF is 130. However, only 110 basic confounders selected from this exhaustive list was considered in tentative values in Table 1.

The appraisal of the instrumentation aspects of a dataset depends on level of evidence for both the validity and accuracy of the loading data. Here, the validity refers to the acknowledged capacity of the data collection tools used to actually measure inner loading. The accuracy refers to the degree of closeness of measurements of forces and moments expected to be around ± 1 N and ± 1 Nm, respectively. The appraisal of instrumentation aspects will also depends on how these evidences stack against a potential total of eight published validation articles.

The appraisal of comprehensiveness aspects of a dataset depends on the number of inner loading data variables actually reported compared to total expected variables. Typically, these variables are associated with mean patterns, peak values, loading rate and/or impulse. The objectives of this scoping review requires that a particular emphasis will be put on the reporting onset and magnitude of up to four peaks of forces and moments applied on the three axes of the fixation during each gait cycle (Figure 3). The total number of outcomes included in the RDEF is 877. However, only 365 basic outcomes selected from this exhaustive list was deemed sufficient in tentative values in Table 1.

The overall methodological quality of each dataset will be scored based on points accrued for each aspect as detailed in Table 2. A total score between 0 to 3 pts, 4 to 7 pts and 8 to 12 pts classified overall quality of the dataset as weak, moderate and strong, respectively.

Insert Table 1 and Table 2 here

Validation data

The last section of the RDEF includes only

two datapoints reporting if the actual dataset and appraisal information have been sent to and validated by the authors.

Data mapping

Key elements of the data mapping are presented in Figure 2-Section C. The raw data extracted using the RDEF will be collated into a single database enabling the recording, analysis and reporting of all critical information related to the review question. First, the compiled information will be extracted and/or calculated from the raw data and will include, but not be limited to, the maximum and absolute maximum of the load reported.

Then, the compiled data will be grouped in relation to the type of activities (i.e., load bearing exercises, walking with aids, straight level walking, standardized daily activities, unscripted activities of daily living, fall). The compiled data will then be presented in diagrammatic and/or tabular form in a manner aligned to the objective and scope of this scoping review. Tables and charts will report the range of absolute maximum forces and moments on each axis expressed in raw unit and percentage of body weight (Figure 2). A narrative summary will be included to describe how the results related to the reviews objective and question/s.

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To know more

Conflicts of interest

The authors have no conflicts of interest to declare.

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Figure 1. Schematic representation of the residuum (A) of an individual with transfemoral amputation using conventional method of prosthetic attachment relying on socket (B) in contact with the skin or bone-anchored prosthesis (BAP) relying on an osseointegrated fixation (C) including a medullar part (D) inserted into the femur, and percutaneous part (E) protruding the residuum each connecting to the rest of a prosthesis (F).

Figure 2. Overview of the search, data extraction, data mapping the scope of variables and range of loads applied on the residuum of individuals with transfemoral amputation fitted with osseointegrated fixation for bone-anchored prosthesis. LBE: load bearing exercises

Figure 3. Example of minimum and maximum as well as peaks of typical forces and moments applied on osseointegrated fixation during an average gait cycle. (HC: Heel contact, TO: Toe-off, AP: Antero-posterior axis, ML: Medio-lateral axis, LG: Long axis)

Table 1. Specifically designed Quality Assessment Criteria (QAC) for appraisal of four methodological quality aspects of direct measurements of prosthetic inner loading, including appraisal criteria and tentative categorization values

Quality aspects	Strength of data set		
	Weak (1 point)	Moderate (2 points)	Strong (3 points)
Sample size			
Appraisal criteria	Sample size is 50% less than average sample size studies	Sample size is between 50% less and 50% more than average sample size studies	Sample size is 50% more than average sample size studies
Tentative value	Sample size is less than 6 participants included in the analysis	Sample size is between 7 and 21 participants included in the analysis	Sample size is more than 22 participants included in the analysis
Confounders			
Appraisal criteria	Report less than 50% of the total basic confounders	Report between 50% and 80% of total basic confounders	Report greater than 80% of the total basic confounders
Tentative value	Report less than 54 out of 110 basic confounders	Report between 55 and 88 out of 110 basic confounders	Report more than 89 out of 110 basic confounders
Instrumentation			
Appraisal criteria	Limited evidence of validity of data collection tools and accuracy of measurements compared to less than 40% of expected number of validation articles	Satisfactory evidence of validity of data collection tools and accuracy of measurements compared to between 40% and 60% of expected number of validation articles	Strong evidence of validity of data collection tools and accuracy of measurements compared to more than 60% of expected number of validation articles
Tentative value	Limited evidence of validity of data collection tools and accuracy of measurements stacking against less than 2 out of 8 expected number of validation articles	Satisfactory evidence of validity of data collection tools and accuracy of measurements stacking against between 3 and 5 out of 8 expected number of validation articles	Strong evidence of validity of data collection tools and accuracy of measurements stacking against more than 6 out of 8 expected number of validation articles
Comprehensiveness			
Appraisal criteria	Report less than 50% of the total basic outcomes	Report between 50% and 80% of total basic outcomes	Report more than 80% of the total basic outcomes
Tentative value	Report less than 438 out of 877 basic outcomes	Report between 439 and 702 out of 877 basic outcomes	Report more than 703 out of 877 basic outcomes

Table 2. Specifically designed score system to determine overall methodological quality of a dataset based on points accrued following Quality Assessment Criteria (QAC).

Overall score	Overall strength of dataset		
	Weak	Moderate	Strong
	Less than 4 out of 12 pts, corresponding to less than 33% of total points	Between 4 and 7 out of 12 pts, corresponding to between 33% and 60% of total points	More than 7 out of 12 pts, corresponding to more than 60% less than total points

Appendix I: Search Strategy

First, the search strategy to find relevant publications will rely on selection of databases to be searched including, Medline/Pubmed, CINAHL, Web of science, Google Scholar, EMBASE, SCOPUS, LILACS, ProQuest Dissertations and Theses Global.

Then, each database will be searched individually using relevant search syntaxes and combining key MeSH and other database-specific subject terms together with commonly used keywords provided in Table 3. Using these keywords will be paramount giving the proliferation of general terms referring to bone-anchored prosthesis and individual acronyms for each fixation.

MeSH terms	Commonly used keywords
Population	
<ul style="list-style-type: none"> Adult Amputees Humans 	<ul style="list-style-type: none"> Above-the-knee prosthesis Individuals with transfemoral amputation Limb prostheses Prosthetic limb Prosthetics TFA Transfemoral amputees Transfemoral prosthesis Unilateral amputation
Intervention - Fixation	
<ul style="list-style-type: none"> Amputation Amputation stumps Artificial Limbs Bone and bones Implants Lower extremity Orthopedics Osseointegration Prostheses Prosthesis failure Reconstructive surgical procedures Titanium 	<ul style="list-style-type: none"> BAP: Bone-anchorage/anchored prosthesis Direct bone attachment DSA: Direct skeletal attachment EEFP: Endo-exo femoral prosthesis Endo-exo prosthesis ILP: Integral leg prosthesis Implant supported prosthesis Intramedullary attachment Intraosseus fixation/implant/device ITAP: Intraosseous transcutaneous amputation prosthesis OGAAP: Osseointegration Group of Australia Accelerated Protocol OIP: Osseointegrated (femoral) prosthesis OPL : Osseointegrated prosthesis leg OPRA: Osseointegrated Prosthesis for the Rehabilitation of Amputees Osseointegrated percutaneous implant Percutaneous fixation/implant/device POP: Percutaneous osseointegrated prostheses Press-fit Prosthetic pylon SBIP: Skin and Bone Integrated Pylon Screw-type Skeletal attachment Skin-implant bone interface Transcutaneous
Comparators	
<ul style="list-style-type: none"> Able-bodied Control Sound Socket 	<ul style="list-style-type: none"> Socket-suspended prosthesis

Outcomes - Activities

• Activities of Daily Living	• Dynamic load bearing exercises
• Canes	• Load bearing
• Crutches	• Parallel bars
• Gait	• Static load bearing exercises
• Monitoring, ambulatory	• Walking aids
• Rehabilitation	• Walking sticks
• Walking	
• Weight-bearing	
-

Outcomes - Loading data

• Amputation/rehabilitation	• Direct
• Biomechanical Phenomena	• Dynamic
• Biomedical	• Energy
• Engineering/methods	• Finite Element Analysis
• Equipment Design	• Force
• Evidence-Based Medicine	• Force plate
• Prostheses and Implants	• Indirect
• Prosthesis Fitting	• Inner load
• Stress, Mechanical	• iPec
• Transducers	• JR3
• Weight-Bearing	• Kinematic
	• Kinetic
	• Load transducer
	• Model
	• Moment
	• Motion capture
	• Movement
	• Physical
	• Power
	• Scale
	• Semi direct
	• SenseWear
	• Simulation
	• Spatial characteristics
	• Spatio-Temporal characteristics
	• Stress
	• Temporal characteristics
	• Work
-

Appendix II: Draft study details, characteristics, and results extraction instrument/s

Data extraction instrument/s

Reference data extraction form						
Full reference selected					Completion rate	
Reference data and dataset						
Section	Variables	Unit	Information			
1	Reference					
1.1	Data entry					
1.1.1	Publication ID	(#)	x			
1.1.2	Reviewer	(txt)	x			
1.1.3	Date	(dd/mm/yy)	x			
1.2	Publication					
1.2.1	Title	(txt)	x			
1.2.2	Author/s	(txt)	x			
1.2.3	Affiliation	(txt)	x			
1.2.4	Country	(txt)	x			
1.2.5	City of origin	(txt)	x			
1.2.6	Year of publication	(txt)	x			
1.2.7	EndNote Nb	(txt)	x			
1.2.8	Dataset ID	(#)	x			
1.3	Descriptor					
1.3.1	Aims of study	(txt)	x			
1.3.2	Methodology/design	(txt)	x			
1.3.3	Concept/intervention	(txt)	x			
1.3.4	Key findings 1	(txt)	x			
1.3.5	Key findings 2	(txt)	x			
1.3.6	Key findings 3	(txt)	x			
2	Population					
2.1	Participants					
2.1.1	Control	(#)	x			
2.1.2	Symptomatic	(#)	x			
2.1.3	Total	(#)	x			
2.2	Demographic					
			Male		Female	
2.2.1	Gender	(#)	x		x	
			Mean	SD	Min	Max
2.2.2	Age	(yrs)	x	x	x	x
2.2.3	Mass	(kg)	x	x	x	x
2.2.4	Height	(m)	x	x	x	x
2.2.5	BMI	(kg/m2)	x	x	x	x
2.3	Amputation					
			TFA-1		Side	
					Left	Right
2.3.1	Level - LLA	(#)	x		x	x
			Mean	SD	Min	Max
2.3.2	Age at amputation	(yrs)	x	x	x	x
2.3.3	Year since amputation	(yrs)	x	x	x	x

Load applied on the residuum of individuals with transfemoral amputation fitted with bone-anchored prostheses: A scoping review protocol

2.3.4	Length of residuum	(cm)	x	x	x	x
2.3.5	Length of residuum	(%SND)	x	x	x	x
2.4	Cause					
2.4.1	Not specified	(#)	x			
2.4.2	Trauma	(#)	x			
2.4.3	Tumor	(#)	x			
2.4.4	Cardiovascular disease	(#)	x			
2.4.5	Diabetes mellitus	(#)	x			
2.4.6	Infection	(#)	x			
2.4.7	Other	(#)	x			
2.4.8	Total	(#)	x			
3	Intervention					
3.1	Attachment					
			Socket	Fixation	Nb of surgery	
3.1.1	Methods	(Y/N)	x	x	x	
3.2	Prosthetic					
			Type	Brand	Model	
3.2.1	Fixation	(txt)	x	x	x	
3.2.2	Knee unit	(txt)	x	x	x	
3.2.3	Ankle/Foot unit	(txt)	x	x	x	
3.2.4	Protective device	(txt)	x	x	x	
3.2.5	Footwear	(txt)	x	x	x	
3.2.6	Cover	(txt)	x	x	x	
3.3	Evaluation					
			Nb	Pre-op	Post-op	Follow-up
3.3.1	Timeline	(x)	x	x	x	x
3.3.2	Timeline	(mth)	x	x	x	x
3.4	Recording					
3.4.1	Methods					
			Type	Brand	Model	
3.4.1.1	Device 1	(txt)	x	x	x	
3.4.1.2	Device 2	(txt)	x	x	x	
3.4.2	Analysis					
			Type	Brand	Version	
3.4.2.1	Software (txt)	(txt)	x	x	x	
4	Comparator					
4.1	Population					
4.1.1	None	(txt)	x			
4.1.2	BAP	(txt)	x			
4.1.3	ABD	(txt)	x			
4.1.4	Socket	(txt)	x			
4.1.5	Sound limb	(txt)	x			
5	Outcomes					
5.1	Variables extracted					
5.1.1	Mean patterns	(Y/N)	x			
5.1.2	Peak values	(Y/N)	x			
5.1.3	Loading rate	(Y/N)	x			
5.1.4	Impulse	(Y/N)	x			
5.1.5	Other	(Y/N)	x			
5.2	Extraction					
5.2.1	Number of trials	(#)	x			
5.2.2	Number of gait cycles	(#)	x			
5.3	Activity					
5.3.1	Code	(txt)	x			

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5.3.2	Label	(txt)	x							
5.3.3	Description 1	(txt)	x							
5.3.4	Description 2	(txt)	x							
5.3.5	Description 3	(txt)	x							
5.3.6	Compilation	(txt)	x							
5.4	Spatio-Temporal Characteristics									
			Mean	SD	Min	Max				
5.4.1	Cadence	(step/min)	x	x	x	x				
5.4.2	Speed of Walking	(m/s)	x	x	x	x				
5.4.3	Temporal									
5.4.3.1	Duration									
5.4.3.2	Gait cycle	(s)	x	x	x	x				
5.4.3.3	Support phase	(s)	x	x	x	x				
5.4.3.4	Swing phase	(s)	x	x	x	x				
5.4.3.5	Gait cycle	(%CG)	x	x	x	x				
5.4.3.6	Support phase	(%CG)	x	x	x	x				
5.4.3.7	Swing phase	(%CG)	x	x	x	x				
5.4.4	Spatial									
5.4.4.1	Step length	(cm)	x	x	x	x				
5.4.4.2	Stride length	(cm)	x	x	x	x				
5.4.4.3	Walking base	(cm)	x	x	x	x				
5.5	Loading data									
			F AP	F LM	F LG	F RT	MAP	M ML	M LG	M RT
5.5.1	Overall Max - Onset									
5.5.1.1	Mean	(s)	x	x	x	x	x	x	x	x
5.5.1.2	SD	(s)	x	x	x	x	x	x	x	x
5.5.1.3	Min	(s)	x	x	x	x	x	x	x	x
5.5.1.4	Max	(s)	x	x	x	x	x	x	x	x
5.5.1.5	Mean	(%SUP)	x	x	x	x	x	x	x	x
5.5.1.6	SD	(%SUP)	x	x	x	x	x	x	x	x
5.5.1.7	Min	(%SUP)	x	x	x	x	x	x	x	x
5.5.1.8	Max	(%SUP)	x	x	x	x	x	x	x	x
5.5.1.9	Mean	(%GC)	x	x	x	x	x	x	x	x
5.5.1.10	SD	(%GC)	x	x	x	x	x	x	x	x
5.5.1.11	Min	(%GC)	x	x	x	x	x	x	x	x
5.5.1.12	Max	(%GC)	x	x	x	x	x	x	x	x
5.5.2	Overall Max - Magnitude									
5.5.2.1	Mean	(N)	x	x	x	x	x	x	x	x
5.5.2.2	SD	(N)	x	x	x	x	x	x	x	x
5.5.2.3	Min	(N)	x	x	x	x	x	x	x	x
5.5.2.4	Max	(N)	x	x	x	x	x	x	x	x
5.5.2.5	Mean	(%BW)	x	x	x	x	x	x	x	x
5.5.2.6	SD	(%BW)	x	x	x	x	x	x	x	x
5.5.2.7	Min	(%BW)	x	x	x	x	x	x	x	x
5.5.2.8	Max	(%BW)	x	x	x	x	x	x	x	x
5.5.3	Overall Min - Onset									
5.5.3.1	Mean	(s)	x	x	x	x	x	x	x	x
5.5.3.2	SD	(s)	x	x	x	x	x	x	x	x
5.5.3.3	Min	(s)	x	x	x	x	x	x	x	x
5.5.3.4	Max	(s)	x	x	x	x	x	x	x	x
5.5.3.5	Mean	(%SUP)	x	x	x	x	x	x	x	x
5.5.3.6	SD	(%SUP)	x	x	x	x	x	x	x	x
5.5.3.7	Min	(%SUP)	x	x	x	x	x	x	x	x
5.5.3.8	Max	(%SUP)	x	x	x	x	x	x	x	x
5.5.3.9	Mean	(%GC)	x	x	x	x	x	x	x	x

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5.5.3.10	SD	(%GC)	x	x	x	x	x	x	x	x
5.5.3.11	Min	(%GC)	x	x	x	x	x	x	x	x
5.5.3.12	Max	(%GC)	x	x	x	x	x	x	x	x
5.5.4	Overall Min - Magnitude									
5.5.4.1	Mean	(N)	x	x	x	x	x	x	x	x
5.5.4.2	SD	(N)	x	x	x	x	x	x	x	x
5.5.4.3	Min	(N)	x	x	x	x	x	x	x	x
5.5.4.4	Max	(N)	x	x	x	x	x	x	x	x
5.5.4.5	Mean	(%BW)	x	x	x	x	x	x	x	x
5.5.4.6	SD	(%BW)	x	x	x	x	x	x	x	x
5.5.4.7	Min	(%BW)	x	x	x	x	x	x	x	x
5.5.4.8	Max	(%BW)	x	x	x	x	x	x	x	x
5.5.5	Peak 1 - Onset									
5.5.5.1	Mean	(s)	x	x	x	x	x	x	x	x
5.5.5.2	SD	(s)	x	x	x	x	x	x	x	x
5.5.5.3	Min	(s)	x	x	x	x	x	x	x	x
5.5.5.4	Max	(s)	x	x	x	x	x	x	x	x
5.5.5.5	Mean	(%SUP)	x	x	x	x	x	x	x	x
5.5.5.6	SD	(%SUP)	x	x	x	x	x	x	x	x
5.5.5.7	Min	(%SUP)	x	x	x	x	x	x	x	x
5.5.5.8	Max	(%SUP)	x	x	x	x	x	x	x	x
5.5.5.9	Mean	(%GC)	x	x	x	x	x	x	x	x
5.5.5.10	SD	(%GC)	x	x	x	x	x	x	x	x
5.5.5.11	Min	(%GC)	x	x	x	x	x	x	x	x
5.5.5.12	Max	(%GC)	x	x	x	x	x	x	x	x
5.5.6	Peak 1 - Magnitude									
5.5.6.1	Mean	(N)	x	x	x	x	x	x	x	x
5.5.6.2	SD	(N)	x	x	x	x	x	x	x	x
5.5.6.3	Min	(N)	x	x	x	x	x	x	x	x
5.5.6.4	Max	(N)	x	x	x	x	x	x	x	x
5.5.6.5	Mean	(%BW)	x	x	x	x	x	x	x	x
5.5.6.6	SD	(%BW)	x	x	x	x	x	x	x	x
5.5.6.7	Min	(%BW)	x	x	x	x	x	x	x	x
5.5.6.8	Max	(%BW)	x	x	x	x	x	x	x	x
5.5.7	Peak 2 - Onset									
5.5.7.1	Mean	(s)	x	x	x	x	x	x	x	x
5.5.7.2	SD	(s)	x	x	x	x	x	x	x	x
5.5.7.3	Min	(s)	x	x	x	x	x	x	x	x
5.5.7.4	Max	(s)	x	x	x	x	x	x	x	x
5.5.7.5	Mean	(%SUP)	x	x	x	x	x	x	x	x
5.5.7.6	SD	(%SUP)	x	x	x	x	x	x	x	x
5.5.7.7	Min	(%SUP)	x	x	x	x	x	x	x	x
5.5.7.8	Max	(%SUP)	x	x	x	x	x	x	x	x
5.5.7.9	Mean	(%GC)	x	x	x	x	x	x	x	x
5.5.7.10	SD	(%GC)	x	x	x	x	x	x	x	x
5.5.7.11	Min	(%GC)	x	x	x	x	x	x	x	x
5.5.7.12	Max	(%GC)	x	x	x	x	x	x	x	x
5.5.8	Peak 2 - Magnitude									
5.5.8.1	Mean	(N)	x	x	x	x	x	x	x	x
5.5.8.2	SD	(N)	x	x	x	x	x	x	x	x
5.5.8.3	Min	(N)	x	x	x	x	x	x	x	x
5.5.8.4	Max	(N)	x	x	x	x	x	x	x	x
5.5.8.5	Mean	(%BW)	x	x	x	x	x	x	x	x
5.5.8.6	SD	(%BW)	x	x	x	x	x	x	x	x
5.5.8.7	Min	(%BW)	x	x	x	x	x	x	x	x

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5.5.8.8	Max	(%BW)	x	x	x	x	x	x	x	x
5.5.9	Peak 3 - Onset									
5.5.9.1	Mean	(s)		x	x	x	x	x	x	x
5.5.9.2	SD	(s)		x	x	x	x	x	x	x
5.5.9.3	Min	(s)		x	x	x	x	x	x	x
5.5.9.4	Max	(s)		x	x	x	x	x	x	x
5.5.9.5	Mean	(%SUP)		x	x	x	x	x	x	x
5.5.9.6	SD	(%SUP)		x	x	x	x	x	x	x
5.5.9.7	Min	(%SUP)		x	x	x	x	x	x	x
5.5.9.8	Max	(%SUP)		x	x	x	x	x	x	x
5.5.9.9	Mean	(%GC)		x	x	x	x	x	x	x
5.5.9.10	SD	(%GC)		x	x	x	x	x	x	x
5.5.9.11	Min	(%GC)		x	x	x	x	x	x	x
5.5.9.12	Max	(%GC)		x	x	x	x	x	x	x
5.5.10	Peak 3 - Magnitude									
5.5.10.1	Mean	(N)		x	x	x	x	x	x	x
5.5.10.2	SD	(N)		x	x	x	x	x	x	x
5.5.10.3	Min	(N)		x	x	x	x	x	x	x
5.5.10.4	Max	(N)		x	x	x	x	x	x	x
5.5.10.5	Mean	(%BW)		x	x	x	x	x	x	x
5.5.10.6	SD	(%BW)		x	x	x	x	x	x	x
5.5.10.7	Min	(%BW)		x	x	x	x	x	x	x
5.5.10.8	Max	(%BW)		x	x	x	x	x	x	x
5.5.11	Peak 4 - Onset									
5.5.11.1	Mean	(s)			x	x				
5.5.11.2	SD	(s)			x	x				
5.5.11.3	Min	(s)			x	x				
5.5.11.4	Max	(s)			x	x				
5.5.11.5	Mean	(%SUP)			x	x				
5.5.11.6	SD	(%SUP)			x	x				
5.5.11.7	Min	(%SUP)			x	x				
5.5.11.8	Max	(%SUP)			x	x				
5.5.11.9	Mean	(%GC)			x	x				
5.5.11.10	SD	(%GC)			x	x				
5.5.11.11	Min	(%GC)			x	x				
5.5.11.12	Max	(%GC)			x	x				
5.5.12	Peak 4 - Magnitude									
5.5.12.1	Mean	(N)			x	x				
5.5.12.2	SD	(N)			x	x				
5.5.12.3	Min	(N)			x	x				
5.5.12.4	Max	(N)			x	x				
5.5.12.5	Mean	(%BW)			x	x				
5.5.12.6	SD	(%BW)			x	x				
5.5.12.7	Min	(%BW)			x	x				
6	Appraisal									
6.1	Type	(txt)	Quality Assessment Criteria (QAC)							
			Value		Strong		Moderate		Weak	
6.2	Sample Size	(#)	x		x		x		x	
6.3	Confounders	(#)	x		x		x		x	
6.4	Instrumentation	(#)	x		x		x		x	
6.5	Comprehensiveness	(#)	x		x		x		x	
6.6	Overall Outcome	(#)	x		x		x		x	
7	Validation									
7.1	RDEF sent to authors	(yes/no)	x							
7.2	RDEF data validated by authors	(yes/no)	x							

- X : datapoint
- F ML: Force applied on medio-lateral axis of the residuum
- F AP: Force applied on antero-posterior axis of the residuum
- F LG: Force applied on long axis of the residuum
- F RT: Resultant of the force applied on the residuum
- M ML: Moment applied around the medio-lateral axis of the residuum
- M AP: Moment applied around the antero-posterior axis of the residuum
- M LG: Moment applied around the long axis of the residuum
- M RT: Resultant of the moment applied on the residuum
- N: Newton (unit of force)
- Nm: Newton meter (unit of moment)
- %BW: Percentage of the body weight (relative unit of force)
- %BWm: Percentage of the body weight meter (relative unit of moment)