Frossard, Laurent and Hagberg, Kerstin and Häggström, Eva and Lee Gow, David and Brånemark, Rickard and Pearcy, Mark (2010) *Functional outcome of transfemoral amputees fitted with an osseointegrated fixation : temporal gait characteristics*. Journal of Prosthetics and Orthotics, 22(1). pp. 11-20.

Functional outcome of transfemoral amputees fitted with an osseointegrated fixation: temporal gait characteristics

Laurent Frossard (PhD), Kerstin Hagberg (PhD), Eva Häggström (CPO), David Lee Gow (MSc Rehabilitation), Rickard Brånemark (PhD), Mark Pearcy (PhD)

Laurent Frossard (PhD) is affiliated with the Institute of Health and Biomedical Innovation of the Queensland University of Technology, Brisbane, Australian and the Centre for Health Innovation and Solutions of The University of Queensland, Brisbane, Australia.
Kerstin Hagberg (PhD) is affiliated with the Centre of Orthopaedic Osseointegration of Sahlgrenska University Hospital, Göteborg, Sweden.
Eva Häggström (CPO) and Rickard Brånemark (PhD) are affiliated with the Department of Prosthetics and Orthotics of Sahlgrenska University Hospital, Göteborg, Sweden
David Lee Gow (MSc Rehabilitation) is affiliated with the Caulfield General Medical Centre, Melbourne, Australia
Mark Pearcy (PhD) is affiliated with School of Engineering Systems and the Institute of Health and Biomedical Innovation of the Queensland University of Technology, Brisbane, Australia.

(Manuscript as accepted: Frossard L, Hagberg K, Haggstrom E, Lee Gow D, Brånemark R, Pearcy M. Functional outcome of transfemoral amputees fitted with an osseointegrated fixation: temporal gait characteristics. 2010. Journal of Prosthetics and Orthotics. 22 (1). p 11-20. DOI: 10.1097/JPO.0b013e3181ccc53d)

ABSTRACT

The purpose of this study was to characterise the functional outcome of 12 transfemoral amputees fitted with osseointegrated fixation using temporal gait characteristics. The objectives were (A) to present the cadence, duration of gait cycle, support and swing phases with an emphasis on the stride-to-stride and participant-to-participant variability, and (B) to compare these temporal variables with normative data extracted from the literature focusing on transfemoral amputees fitted with a socket and able-bodied participants. The temporal variables were extracted from the load applied on the residuum during straight level walking, which was collected at 200 Hz by a transducer. A total of 613 strides were assessed. The cadence (46±4 strides/min), the duration of the gait cycle (1.29±0.11 s), support (0.73±0.07 s, 57±3% of CG) and swing (0.56±0.07 s, 43±3% of GC) phases of the participants were 2% quicker, 3%, 6% shorter and 1% longer than transfemoral amputees using a socket as well as 11% slower, 9%, 6% and 13% longer than able-bodied, respectively. All combined, the results indicated that the fitting of an osseointegrated fixation has enabled this group of amputees to restore their locomotion with a highly functional level. Further longitudinal and cross-sectional studies would be required to confirm these outcomes. Nonetheless, the data presented can be used as benchmark for future comparisons. It can also be used as input in generic algorithms using templates of patterns of loading to recognise activities of daily living and to detect falls.

KEYWORDS
Gait; temporal characteristics; transfemoral amputation; osseointegration; functional outcome

1. INTRODUCTION

1.1 OSSEOINTEGRATED FIXATION: SOLUTION FOR TRANSFEMORAL AMPUTATION

Over the last ten years, a few groups have developed innovative surgical methods of attachment of the prosthesis for transfemoral amputees that is based on direct skeletal anchorage. In this case, the socket is replaced by an osseointegrated fixation [1, 2]. One of the most advanced fixations includes an implant, an abutment and a retaining bolt [3-5]. The implant develops a firm biological bonding with the femur, named osseointegration [6-8]. The abutment is connected to the implant, penetrating through the skin, to allow attachment of the external prosthesis.

1.2 BENEFITS OF OSSEOINTEGRATED FIXATION

To date, this technique has been experienced by over 100 transfemoral amputees worldwide mainly scattered in Scandinavia, the UK, Spain and Australia [9]. It has proved to be a successful alternative for amputees who experience complications in using conventional socket-type prostheses due to a short residual limb and soft tissue problems. This technique has contributed to a significant improvement in the quality of life of recipients [10-12]. By definition, the biomechanical benefits of the fixation alone are limited since it does not involve any articulated parts. Nevertheless, the fixation can improve sensory feedback, referred to as osseoperception [7], that might have indirect advantages for locomotion (e.g., foot placement, surface detection, etc). The physical and prosthetic benefits are the most noticeable [11, 13]. The absence of a prosthetic socket can alleviate the skin problems and residual limb pain. It also enables greater hip range of motion and better sitting comfort compared to socket-type prostheses [14]. The prosthetic leg can be attached to and detached from the fixation easily by simply turning a screw.

However, one of the burning issues for clinicians and funding bodies is to determine to what extent these prosthetic benefits are translated into an improvement in functional outcome. By definition, the term “functional outcome” corresponds to the capacity to undertake a wide range of tasks of daily living. Here, this term refers more precisely to the actual capacity of the amputee to use the prosthetic leg and to walk at self-selected pace.

1.3 FUNCTIONAL OUTCOME

So far, studies relying on questionnaires demonstrated that the fixation has increased the capacity of transfemoral amputees to improve their prosthetic activity and walking habits [11, 13]. Other studies described the loading of the fixation during standardised daily activities using patterns, local extrema and impulse [15, 16]. These indicators were essential for engineers designing the fixation but they have limited clinical relevance in relation to functional outcome. One study looking at the load regime during real-world activities of daily living presented some functional outcome indicators but it involved a single participant [17].

1.4 MEASUREMENT OF FUNCTIONAL OUTCOME

The functional outcome of transfemoral amputees can be assessed using a range of spatial and temporal gait characteristics. Some of the clinical indicators commonly acknowledged include the cadence along with the duration of gait cycle, support and swing phases [18-22].

An overview of the resources and comprehensiveness of the output of equipments that are typically used to assess these four variables is presented in

Figure 1 [23-29]. The most comprehensive and resource intensive assessment relies on a 3D motion analysis system synchronised with several force-plates [30]. Alternatively, studies demonstrated that other less resource intensive and equally accurate instruments can be used, including footswitch [31-35], pressure sensors [36], accelerometers and gyroscopes [32, 37], instrumented mats and walkways [30, 31, 38]. Some instruments that can only be used in clinical settings measure a limited number of steps that are only partially representative of the true functional outcome. Other equipments that are portable enabled more realistic measurements [32, 34, 37]. Previous studies focusing on the load applied on the fixation used a portable kinetic recording system based on a transducer and a wireless modem or a data logger [17, 34, 39]. This system enabled the recording of an unlimited number of steps during various activities of daily living [15, 16]. As mentioned above, these studies focused mainly on presenting the load profile over time. Regrettably, the temporal variables of these data sets have yet to be presented.

*** Insert Figure 1 here ***

1.5 PURPOSE AND OBJECTIVES

The purpose of this study was to characterise the functional outcome of transfemoral amputees fitted with an osseointegrated fixation (TFA-OF) using key temporal gait variables. The objectives were:

- To present the cadence, duration of gait cycle, support and swing phases with an emphasis on the stride-to-stride and participant-to-participant variability, and,
- To compare these temporal variables with normative data extracted from the literature focusing on transfemoral amputees fitted with a conventional socket (TFA-SO) and able-bodied participants.

2. METHODS

The raw data used in the study has been published in Lee *et al* (2008) [16] along with a detailed account of methodological aspects associated with the participants (e.g., profile of prosthesis), the apparatus and the procedure. Consequently, only the most relevant information is presented here.

2.1 PARTICIPANTS

A total of three females and nine males unilateral TFA-OF (47.50±9.70 yr, 1.78±0.11 m, 84.27±16.82 kg) participated in this study. Individual and group demographics are presented Table1 (Section A). Each participant was fully rehabilitated, fitted with the fixation for at least one year, was able to walk 200 m independently and weighed less than 110 kg to avoid overloading the transducer. All the participants were active and were classified as a K3 or K4 according to Functional Classification Levels [26]. The research institution's human ethics committee approved this study. The participants provided informed written consent.

2.2 APPARATUS

All participants walked with a prosthesis fitted with a transducer and their usual components [16], including:

- ***Hydraulic knee***: poly cadence responsive (i.e., 9 Total knee), single axis cadence responsive (i.e., 1 Adaptive, 1 C-leg, 1 Mauch Gaitmaster),
- ***Foot***: dynamic foot (i.e., 1 Mercury, 2 C-walk, 1 Carbon Copy, 1 Flexfoot), multi axis foot (i.e., 2 Multiflex, 3 True Step) and single axis foot (i.e., 2 Total concept),
- ***Footwear*** (i.e., 5 Sneakers, 4 Sandals, 3 Leather shoes).

Also, the usual alignment was also replicated to insure ecological assessments.

The raw data were measured using a portable kinetic system with a sampling frequency of 200 Hz. It included a six-channel transducer (Model 45E15A; JR3 Inc, Woodland, CA, USA) mounted between the knee and the fixation and a wireless transmitter (Ricochet Model 21062; Metricom Inc., Los Gatos, CA).

2.3 PROCEDURE

Participants walked under supervision with the instrumented prosthesis for approximately 15 minutes to ensure confidence, safety and comfort. Participants 1 and 2 performed six trials along a 20 m walkway at one site. The other participants performed approximately two trials along a 60 m walkway at another site. All participants walked at self-selected pace. Sufficient rest was given between trials to avoid fatigue.

2.4 DATA ANALYSIS

The load data were processed by a customized Matlab program (Math works, Inc., Natick, MA) according to the following steps:

- ***Step 1: Selection of relevant segment of data***. The first and the last strides recorded for each trial were discarded to ensure that the analysis only included data obtained when participants walked at a uniform pace [39].
- ***Step 2: Determination of gait events***. The graph of the vertical force was used to manually detect

the heel contact and toe-off points with an accuracy of ±0.01 s as determined in previous study [40].

- ***Step 3: Calculation of temporal variables***. The cadence expressed as the number of strides of the prosthetic leg per minute was calculated for each trial. The duration of a gait cycle was determined from heel contact to heel contact and expressed in seconds. The duration of support and swing phases were expressed in seconds and in percentage of the gait cycle.
- ***Step 4: Characterisation of each temporal variable.*** The stride-to-stride analysis providing the variations for a given participant included the mean, standard deviation (SD) and coefficient of variation (COV), defined as the standard deviation divided by the mean. The participant-to-participant analysis providing the variations between participants relied on the same descriptors as well as the median, minimum and maximum values for the group.
- ***Step 5: Comparative analysis***. The normative temporal variables were extracted from the literature focusing on TFA-SO [41-49] and able-bodied participants [50-57]. English publications up to 2008 were selected using mainstream search engines (e.g., PubMed, Medline, Google Scholar) and combinations of keywords such as gait, walking, temporal variable, cadence, gait cycle, support phase, swing phase, transfemoral amputation, above-knee amputation, able-bodied, etc. The publications featuring literature review and/or meta-analyses were purposely excluded to avoid statistical compounding errors [18-22]. The study presented by Frossard *et al* (2008) [17] was also excluded as it provided temporal variables for only one TFA-OF. One data set or more were extracted from each selected study to make sure that normative data matched as closely as possible the group of participants in terms of demographics (i.e., gender, age, height, mass), procedure (i.e., self-selected walking speed) and fitting (i.e., hydraulic knee, foot). Each normative study reported one or more temporal variables [41-57]. Some variables were recalculated based on raw data provided in the article (e.g., cadence in steps per minute/2= cadence in strides per minute], gait cycle time = 120/cadence). The comparisons of the overall results for each group were based on the average. The significance of the differences for the study-to-study comparison was determined using a t-test with $p<.0005$ and $p<.005$ when the number of observations, the mean and the standard deviation were reported.

3. RESULTS

The total number of strides for each participant and for the group is presented in Section B of Table 1. It ranged from 32 to 63 strides, excluding participant 02 who performed only one trial. A total of 613 strides were assessed.

3.1 CHARACTERISATION OF TEMPORAL VARIABLES

The results of the stride-to-stride and participant-to-participant analyses are presented in Section C of Table 1. The individual COV of the cadence, duration of the gait cycle, support and swing phases ranged from 0.007 to 0.042, from 0.016 to 0.081, from 0.026 to 0.089 and from 0.028 to 0.112, respectively. The overall COV of the cadence, duration of the gait cycle, support and swing phases were 0.076, 0.088, 0.089 and 0.125, respectively. The support and swing phases represented 57±3% and 43±3% of the gait cycle, respectively.

*** Insert Table 1 here ***

3.2 COMPARATIVE ANALYSES

An overview of the temporal variables for the three groups is presented in Figure 2, plotting the cadence in relation to the duration of the gait cycle expressed in seconds, and duration of support and swing phases expressed in percentage of gait cycle. Tables 2 and 3 provide the raw data for demographics (Section A), number of samples (Section B) and normative temporal variables (Section C) for the studies focusing on TFA-SO and able-bodied, respectively.

*** Insert Figure 2 here ***

3.2.1 COMPARISON WITH AMPUTEES USING SOCKET

The group of studies focusing on TFA-SO included nine data sets corresponding to a total of 142 participants and 542 observations. Most of the participants were males.

This group of normative studies was 9% younger and 4% lighter. The study-to-study comparison was possible for only three data sets. One normative study was significantly younger. Two were significantly lighter. All the other comparisons, including the one related to the height, were not significant.

The cadence of this group was 2% slower. Only one out of two possible comparisons was significantly quicker. The overall duration of the gait cycle, support and swing phases of this normative group were 3% and 6% shorter, and 1% longer, respectively. The duration of the gait cycle was significantly shorter for five studies and longer for one study out of eight comparisons. The duration of the support phase was significantly shorter for four out of five studies. The duration of the swing phase was significantly shorter for two studies and longer for two studies out of seven comparisons.

3.2.2 COMPARISON WITH ABLE-BODIED PARTICIPANTS

The group of studies focusing on able-bodied included nine studies and 14 data sets corresponding to a total of 258 participants and 1,603 observations. Only three data sets included female participants.

This group of normative studies was 16% younger and 7% lighter. The study-to-study comparison was possible for only two data sets of the same study. One data set involved significantly younger, smaller and lighter females. The other one involved significantly younger males. Both groups had the same height.

The cadence of this group was 11% quicker. All eight possible study-to-study comparisons were significantly quicker. The overall duration of the gait cycle, support and swing phases of this normative group were 9%, 6% and 13% shorter, respectively. The duration of the gait cycle was significantly shorter for seven studies and longer for one study out of eight comparisons. The duration of the support phase was significantly shorter for four studies and longer for one study out of five comparisons. The duration of the swing phase was significantly shorter for five studies out of six comparisons.

*** Insert Table 2 and Table 3 here ***

4. DISCUSSION

4.1 VARIABILITY

Each participant presented a low stride-to-stride variability for the four temporal characteristics. This agrees with previous studies focusing on the magnitude and variability of the loading on fixation during walking and daily activities [15, 16].

Surprisingly, the participant-to-participant variability was lower than expected. For instance, previous study demonstrated that the COV of the peak forces applied on the antero-posterior, medio-lateral and long axes of the fixation during walking were, 0.523, 0.384 and 0.374, respectively [16]. Temporal variables were more consistent than the loading characteristics may be because they are less sensitive to confounders such as the length of the residuum, prosthetic alignment, trunk position, etc.

4.2 FUNCTIONAL OUTCOME

The cadence, the duration of gait cycle and support phases demonstrated that the functional outcome of TFA-OF was either comparable or better than TFA-SO in most studies. The outcome of the comparisons of the duration of the swing phase was more ambivalent. This was due to the fact that the velocity of the leg during the swing depends less on functional outcome and more on the swing control of different types of knee friction systems (i.e., constant friction, variable friction, hydraulic). Overall, the participants were less functional than able-bodied. However, the most functional TFA-OF and the least functional able-bodied were similar.

All combined, the clinical indicators observed in this study revealed that the fitting of an osseointegrated fixation has enabled this group of amputees to restore their locomotion with highly functional level. Further interpretations must be considered carefully giving the limitations of this study.

4.3 LIMITATIONS

4.3.1 GROUP OF ACTIVE PARTICIPANTS

The group of amputees represented approximately 15% of the existing population. The selection of the participants was as random as possible giving the pool and the location worldwide. Nonetheless, the design of the study itself was slightly biased toward recruiting enable and active participants, like any other studies based on several trials of walking. Consequently, finding good functional outcomes was to be expected. Thus, the tangible contribution of this study was to determine to which extent functional outcome was satisfactory.

4.3.2 COMPARISON WITH NORMATIVE STUDIES

In principle, the meta-analysis of normative data extracted from the literature enabled the use of large data sets that have already been validated. However, no studies reported complete demographic and temporal variable data sets. Only 30% of the studies in each group presented three complete temporal variable data sets. Furthermore, a true comparison might be compromised because of the possible multiple use of the same population across several studies from the same authors. This created a potential redundancy in the statistical analysis as the same individual might have been considered several times. Finally, comparisons might be interpreted with care because confounders matched only partially. The height, which is one of the critical confounders, was the same for the three groups. The age and the mass presented small but significant differences. This study included a large female population. More importantly, there were variations in construction of prostheses in terms of components, particularly the knees, and alignments. Other confounders associated with instruments (e.g., footswitch, force-plate, motion analysis), procedure (e.g., accommodation time with experimental leg) and inclusion/exclusion criteria of population (e.g., cause of amputation, level of activity) were not considered [18].

4.4 CONTRIBUTIONS

These limitations do not impinge on three main outcomes of this study. The results presented here can be used to benchmark other cohorts against the most active TFA-OF. The low variability means that temporal variables can be used as default input in generic algorithms using templates of patterns based on timing and magnitude of loading to recognise activities of daily living and to detect falls. Finally, this study confirmed that the portable kinetic system used is a suitable instrument to provide not only engineering (i.e., patterns, local extrema, impulse) but also clinical (i.e., temporal variables) insights into the fitting and usage of the prosthetic leg. The seamlessness of the system enabled the recording of a high number of strides. For instance, this study alone collected approximately 12% more strides than all nine studies in the groups of TFA-SO combined.

4.5 FUTURE STUDIES

The instrument presented here will facilitate longitudinal studies of temporal characteristics of standardised and real-world activities of daily living for a larger cohort of TFA-OF. This will provide a better understanding of the participant-to-participant and activity-to-activity variability. Comparisons of the results from current instruments and the portable kinetic system were outside the scope of this study. However, the possibilities for cross-sectional studies are endless, particularly for the ones allowing reciprocal validation of these instruments (e.g., accuracy), recording complementary clinical indicators such as the temporal variables for the sound leg (e.g., duration of single and double support) and the spatial variables (e.g., step and stride length, walking base) as well as comparisons between prostheses constructions (e.g., hydraulic knee *vs* constant friction).

Both longitudinal and cross-sectional studies will be essential to further establish the functional outcome of TFA-OF in terms of usage of the prosthesis and level of activity. Furthermore, such studies will improve basic knowledge in the areas of rehabilitation, design of components and fitting of prostheses.

5. CONCLUSIONS

This study provided the temporal gait characteristics for a group of 12 transfemoral amputees fitted with an osseointegrated fixation. This was the first attempt to establish to what extent the benefits of this innovative method of attachment of the prosthesis are translated into functional outcome and more particularly walking ability. The results indicated that the fixation enables this group to walk as well or better than other amputees fitted with a socket, although this statement must be understood within the intrinsic limitations of temporal variables and comparisons with data from the literature. Consequently, further longitudinal and cross-sectional studies would be required to confirm these results.

In conclusion, the results presented here are a stepping stone in assessment of true functional outcome of transfemoral amputees fitted with a fixation. However, this study provided key information to clinicians facing the challenge to restore the locomotion of lower limb amputees in the framework of an evidence-based practice.

6. DISCLOSURE OF FUNDING

This study was partially funded by the Australian Research Council Discovery Project (DP0345667), Australian Research Council Linkage Grant (LP0455481), Queensland University of Technology Strategic Link with the Industry and Institute of Health and Biomedical Innovation Advanced Diagnosis in Medical Device Grant.

7. REFERENCES

1. Aschoff H, Grundei H, editors. The Endo- Exo-Femurprosthesis: A new concept of prosthetic rehabilitation engineering following thigh-amputation - Some cases and early results. International Society for Prosthetics and Orthotics 11th World Congress; 2004; Hong Kong.
2. Staubach K, Grundei H. The first osseointegration percutaneous anchor for an exoprosthesis, for routine use in above-knee amputees. *Biomed Technik*. 2001;46:255-61.
3. Brånemark R, Brånemark P-I, Rydevik B, Myers R. Osseointegration in skeletal reconstruction and rehabilitation: A review. *Journal of Rehabilitation Research & Development*. 2001;38(2):175-81.
4. Robinson KP, Brånemark R, Ward D. Chapter 53: Future developments: Osseointegration in transfemoral amputees. In: Smith DG, Michael JW, Bowker JH, editors. *Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic and Rehabilitation Principles - Third Edition*: American Academy of Orthopaedic Surgeons; 2005. p. 673-81.
5. Ward D, Robinson KP. Chapter 24: Osseointegration for the skeletal fixation of limb prostheses in amputation at the trans-femoral level. In: Brånemark P-I, editor. *The osseointegration book - From calvarium to calcaneus*: Quintessenz Verlag - GmbH; 2005. p. 463-75.
6. Pitkin M, Raykhtsaum G, Galibin O, Protasov M. Skin and bone integrated prosthetic pylon: A pilot animal study. *Journal of Rehabilitation Research and Development*. 2006;43(4):573.
7. Brånemark R, Ohrnel LO, Nilsson P, Thomsen P. Biomechanical characterization of osseointegration during healing: an experimental in vivo study in the rat. *Biometerials*. 1997;18:969-78.
8. Brånemark R, Skalak R. An in-vivo method for biomechanical characterization of bone-anchored implant. *Medical Engineering & Physics*. 1998;20:216-9.
9. Hagberg K, Brånemark R. One hundred patients treated with osseointegrated transfemoral amputation prostheses - the rehabilitation perspective. *Journal of Rehabilitation Research & Development*. 2009;In press.
10. Ax E, editor. The personal dimension of innovation: making a personal choice to improve quality of life with innovation. International Society for Prosthetics and Orthotics 11th World Congress; 2004; Hong Kong.
11. Hagberg K, Branemark R, Gunterberg B, Rydevik B. Osseointegrated trans-femoral amputation prostheses: Prospective results of general and condition-specific quality of life in 18 patients at 2-year follow-up. *Prosthetics and Orthotics International*. 2008;32(1):29 - 41.
12. Webster JBMD, Chou TP, Kenly MMD, English MMS, Roberts TLDO, Bloebaum RDP. Perceptions and acceptance of osseointegration among individuals with lower limb amputations: A prospective survey study. *Journal of Prosthetics & Orthotics*. 2009;21(4):215-22.
13. Sullivan J, Uden M, Robinson K, Sooriakumaran S. Rehabilitation of the trans-femoral amputee with an osseointegrated prosthesis: the United Kingdom experience. *Prosthetics and Orthotics International*. 2003;27:114-20.
14. Hagberg K, Haggstrom E, Uden M, Brånemark R. Socket versus bone-anchored trans-femoral prostheses: hip range of motion and sitting comfort. *Prosthetics and Orthotics International*. 2005;29(2):153-63.
15. Lee W, Frossard L, Hagberg K, Haggstrom E, Brånemark R. Kinetics Analysis of Transfemoral Amputees fitted with Osseointegrated Fixation Performing Common Activities of Daily Living. *Clinical Biomechanics*. 2007;22(6):665-73.
16. Lee WC, Frossard LA, Hagberg K, Haggstrom E, Gow DL, Gray S, et al. Magnitude and variability of loading on the osseointegrated implant of transfemoral amputees during walking. *Medical Engineering & Physics*. 2008;30:825-33.
17. Frossard L, Stevenson N, Smeathers J, Häggström E, Hagberg K, Sullivan J, et al. Monitoring of the load regime applied on the osseointegrated fixation of a transfemoral amputee: a tool for evidence-based practice. *Prosthetic and Orthotics International*. 2008;32(1):68-78.
18. Gard S. Use of Quantitative Gait Analysis for the Evaluation of Prosthetic Walking Performance. *Journal of Prosthetics & Orthotics*. 2006;18(6):93-104.
19. Skinner H, Effeney D. Gait analysis in amputees. *American Journal of Physical Medicine*. 1985;64(2):82-9
20. Whittle M. Gait analysis. Second edition ed: Butterworth-Heinemann; 1996.
21. Perry J. Chapter 20: Stride analysis. *Gait analysis - Normal and pathological function*: SLACK Incorporated; 1992. p. 431-41.

22. Whittle MW. Clinical gait analysis: A review. *Human Movement Science*. 1996;15(3):369-87.
23. Gailey RS, Roach KE, Applegate EB, Cho B, Cunniffe B, Licht S, et al. The Amputee Mobility Predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Archives of Physical Medicine and Rehabilitation*. 2002;83(5):613-27.
24. Miller L, McCay JA. Summary and conclusions from the academy's sixth state-of-the-science conference on lower limb prosthetic outcome measures. *Journal of Prosthetics and Orthotics*. 2006;18(6):2-7.
25. Condie E, Scott H, Treweek S. Lower limb prosthetic outcome measures: a review of the literature 1995 to 2005. *Journal of Prosthetics and Orthotics*. 2006;18(6):13-45.
26. Gailey RS. Predictive outcome measures versus functional outcome measures in the lower limb amputee. *Journal of Prosthetics and Orthotics*. 2006;18(6):51-60.
27. Gauthier-Gagnon C, Grisé M-C. Tools to measure outcome of people with a lower limb amputation: Update on the PPA and LCI. *Journal of Prosthetics and Orthotics*. 2006;18(6):61-7.
28. Boone DA, Coleman KL. Use of the Prosthesis Evaluation Questionnaire (PEQ). *Journal of Prosthetics and Orthotics*. 2006;18(6):68-79.
29. Coleman KL, Smith DG, Boone DA, Joseph AW, Del Aguila MA. Step activity monitor: Long-term continuous recording of ambulatory function. *Journal of Rehabilitation Research & Development*. 1999;36(1):8-18.
30. Ghoussayni S, Stevens C, Durham S, Ewins D. Assessment and validation of a simple automated method for the detection of gait events and intervals. *Gait & Posture*. 2004;20(3):266-72.
31. Barker S, Craik R, Freedman W, Herrmann N, Hillstrom H. Accuracy, reliability, and validity of a spatiotemporal gait analysis system. *Medical Engineering & Physics*. 2006;28(5):460-7.
32. Aminian K, Najafi B, Büla C, Leyvraz PF, Robert P. Spatio-temporal parameters of gait measured by an ambulatory system using miniature gyroscopes. *Journal of Biomechanics*. 2002;35(5):689-99.
33. Kyriazis V, Rigas C, Xenakis T. A portable system for the measurement of the temporal parameters of gait. *Prosthetics and Orthotics International*. 2001;25(2):96-101.
34. Holden J, Fernie GR, Soto M. An Assessment of a System to Monitor the Activity of Patients in a Rehabilitation Programme. *Prosthetics and Orthotics International*. 1979;3(2):99-102.
35. Hausdorff JM, Ladin Z, Wei JY. Footswitch system for measurement of the temporal parameters of gait. *Journal of Biomechanics*. 1995;28(3):347-51.
36. Barnett S, Cunningham JL, West S. A Comparison of vertical force and temporal parameters produced by an in-shoe pressure measuring system and a force platform. *Clinical Biomechanics*. 2001;16(4):353-7.
37. Zijlstra W. Assessment of spatio-temporal parameters during unconstrained walking. *European Journal of Applied Physiology*. 2004;92(1):39-44.
38. Lloyd DG, Svensson NL. A technique for the measurement of cadence using walkway vibrations. *Journal of Biomechanics*. 1996;29(12):1643-7.
39. Frossard L, Beck J, Dillon M, Chappell M, Evans JH. Development and Preliminary Testing of a Device for the Direct Measurement of Forces and Moments in the Prosthetic Limb of Transfemoral Amputees During Activities of Daily Living. *Journal of Prosthetics and Orthotics*. 2003;15(4):135-42.
40. Dumas R, Cheze L, Frossard L. Loading applied on prosthetic knee of transfemoral amputee: Comparison of inverse dynamics and direct measurements. *Gait & Posture*. 2009;30(4):560-2.
41. Jaegers SMHJ, Arendzen JH, de Jongh HJ. Prosthetic gait of unilateral transfemoral amputees: A kinematic study. *Archives of Physical Medicine and Rehabilitation*. 1995;76(8):736-43.
42. Macfarlane PAP, Nielsen DHPPT, Shurr DGMAPTCP. Mechanical Gait Analysis of Transfemoral Amputees: SACH Foot Versus the Flex-Foot. *JPO Journal of Prosthetics & Orthotics Fall*. 1997;9(4):144-51.
43. Hale SA. Analysis of the swing phase dynamics and muscular effort of the above-knee amputee for varying prosthetic shank loads. *Prosthetics and Orthotics International*. 1990;14(3):125 - 35.
44. Boonstra AM, Schrama W, Eisma WH, Hof A, Fidler V. Gait analysis of transfemoral amputee patients using prostheses with two different knee joints. *Archives of Physical Medicine and Rehabilitation*. 1996;77:515-20.
45. Murray M, Sepic S, Gardner G, Mollinger L. Gait pattern of above-knee amputees using constant friction knee components. *Bulletin of prosthetics research*. 1980;17(2):35-45.
46. Zuniga E, Leavitt L, Calvert J, Canzoneri J, Peterson C. Gait patterns in above-knee amputees. *Archives of physical medicine and rehabilitation*. 1972;53:373-82.
47. James U, Oberg K. Prosthetic gait pattern in unilateral above-knee amputees. *Scandinavian Journal of Rehabilitation and Medecine*. 1973;5:35-50.
48. Godfrey c, Jousse A, Brett R, Butler J. A comparison of some gait characteristics with six knee joints. *Orthotics and Prosthetics*. 1975;29(3):33-8.
49. Murray M, Mollinger L, Sepic S, Gardner G. Gait patterns in above-knee amputee patients: Hydraulic swing control vs constant-friction knee components. *Archives of Physical Medicine and Rehabilitation*. 1983;64:339-45.
50. Murray M. Gait as total pattern of movement. *American Journal of Physical Medicine*. 1967;46(1):290-333
51. Andriacchi TP, Ogle JA, Galante JO. Walking speed as a basis for normal and abnormal gait measurements. *Journal of Biomechanics*. 1977;10(4):261-8.
52. Murray M, Drought A, Kory R. Walking Patterns of Normal Men. *J Bone Joint Surg Am*. 1964 March 1, 1964;46(2):335-60.
53. Murray M, Kory R, Clarkson B, Sepic S. Comparison of free and fast speed walking patterns of normal men. *American Journal of Physical Medicine*. 1966;45(1):8-24.
54. Kadaba M, Ramakrishnan H, Wootten M, Gainey J, Gorton G, Cochran G. Repeatability of kinematic, kinetic, and electromyographic data in normal adult

gait. *Journal of Orthopaedic Research*. 1989;7(6):849-60.

55. Oberg T, Karsznia A. Basic gait parameters: Reference data for normal subjects, 10-79 years of age. *Journal of Rehabilitation Research & Development*. 1993;30(2):210.
56. Allard P, Lachance R, Aissaoui R, Sadeghi H, Duhaime M. Chapter 15: Able-bodied gait in men and women. In: P. Allard AC, A. Lundberg and C. Vaughan, editor. *Three-dimensional analysis of human locomotion*: Jonh Wiley & Sons; 1997. p. 307-34.
57. Kadaba M, Ramakrishnan H, Wootten M. Measurement of lower extremity kinematics during level walking *Journal of Orthopaedic Research* 1990;8(3):383-92.

8. LIST OF TABLES AND FIGURES

Figure 1. Overview of resources (e.g., time, cost, equipment, space, etc) and comprehensiveness of the output (e.g., range, realism, accuracy, degrees of freedom, etc) of the current instruments used to assess the temporal variables reflecting functional outcome.

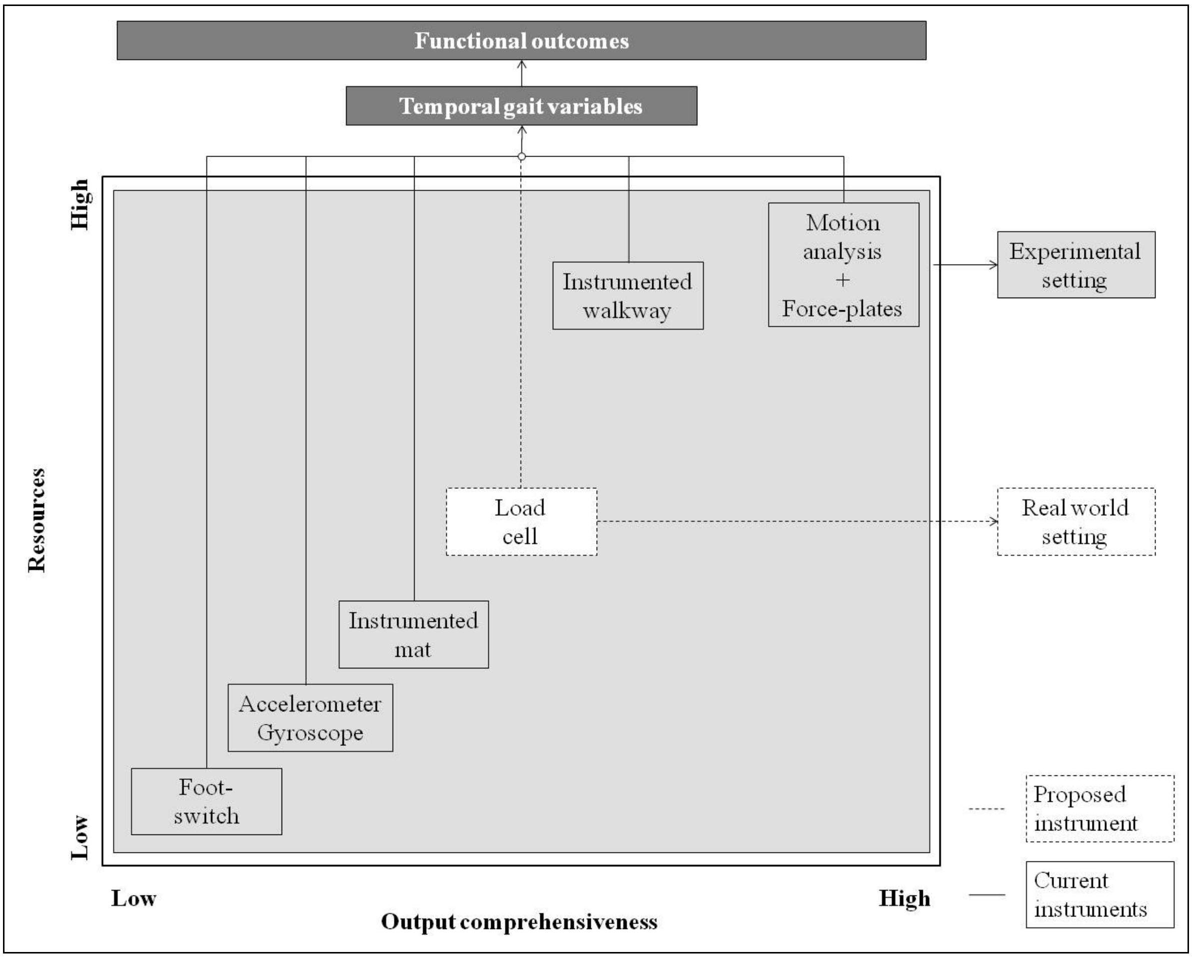

Figure 2. Median and range of the duration of the gait cycle, support and swing phases in relation to the median and range of the cadence for the group of transfemoral amputees fitted with an osseointegrated fixation and socket, and able-bodied participants.

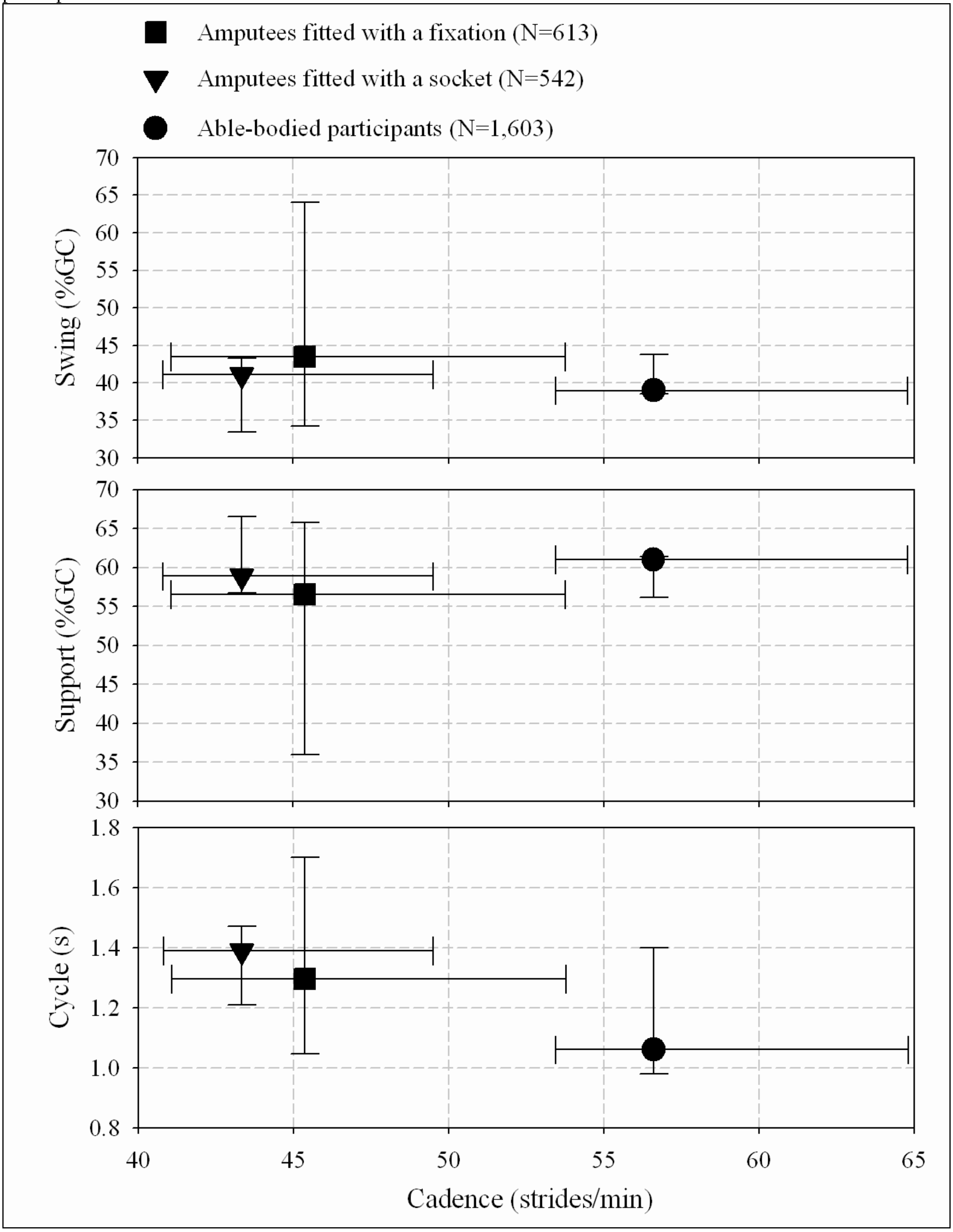

Table 1. Stride-to-stride and participant-to-participant analyses of demographics (Section A), number of samples (Section B) and temporal variables (Section C) for the group of transfemoral amputees fitted with an osseointegrated fixation.

	Section A Demographics				**Section B No of samples**		**Section C Temporal variables**							
							Cadence		**Duration**					
	Gender	**Age**	**Height**	**Mass**	**Trials**	**Oberva-tions**			**Gait cycle**		**Support**		**Swing**	
							Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
	(M/F)	**(yr)**	**(m)**	**(kg)**	**(#)**	**(#)**	**(strides/min)**		**(s)**		**(s)**		**(s)**	
Participant 01	F	39.00	1.71	68.00	6	37	42.74	1.74	1.40	0.07	0.77	0.04	0.63	0.04
Participant 02	M	46.00	1.82	96.10	6	18	45.55	0.63	1.32	0.04	0.70	0.02	0.61	0.02
Participant 03	F	57.00	1.63	61.10	1	32	45.02	-	1.37	0.02	0.76	0.02	0.61	0.02
Participant 04	M	50.00	1.81	74.30	3	56	42.94	0.42	1.40	0.04	0.76	0.03	0.63	0.02
Participant 05	M	59.00	1.89	87.10	2	46	50.80	1.49	1.18	0.04	0.68	0.03	0.51	0.01
Participant 06	M	62.00	1.80	105.00	2	63	42.27	0.72	1.42	0.05	0.82	0.04	0.60	0.02
Participant 07	F	49.00	1.58	53.30	2	57	47.09	0.83	1.28	0.03	0.70	0.04	0.57	0.05
Participant 08	M	41.00	1.77	96.60	2	60	53.42	0.50	1.12	0.05	0.66	0.04	0.46	0.02
Participant 09	M	26.00	1.78	90.00	2	51	45.80	1.36	1.31	0.04	0.73	0.03	0.58	0.02
Participant 10	M	46.00	1.99	99.50	2	54	51.71	0.34	1.16	0.02	0.68	0.02	0.48	0.02
Participant 11	M	50.00	1.82	99.80	2	52	46.16	1.92	1.30	0.10	0.81	0.07	0.50	0.04
Participant 12	M	45.00	1.72	80.40	2	59	45.19	1.21	1.33	0.11	0.72	0.06	0.61	0.07
Median		47.50	1.79	88.55			45.68		1.31		0.73		0.59	
Mean		47.50	1.78	84.27			45.89		1.29		0.73		0.56	
SD		9.70	0.11	16.82			3.48		0.11		0.07		0.07	
Minimum		26.00	1.58	53.30			41.08		1.05		0.46		0.41	
Maximum		62.00	1.99	105.00			53.77		1.70		1.04		0.96	

SD Standard deviation

Table 2. Data sets extracted from studies focusing on transfemoral amputees fitted with a socket: raw data and comparisons for demographics (Section A), number of samples (Section B) and normative temporal variables (Section C).

	Section A Demographics							**Section B No of samples**		**Section C Temporal variables**							
	Gender	**Age**		**Height**		**Mass**		**Participants**	**Obervations**	**Cadence**		**Duration**					
												Gait cycle		**Support**		**Swing**	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**			**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
	(M/F)	**(yr)**		**(m)**		**(kg)**		**(#)**	**(#)**	**(strides/min)**		**(s)**		**(s)**		**(s)**	
Zuniga et al, 1972	M	45.00	-	1.78	-	80.29	-	34	102	-	-	1.43	0.16 **	0.83	0.10 **	0.60	0.06 **
James et al, 1973	M	43.30	12.50 NS	1.77	0.66 NS	69.60	11.70 **	34	170	42.55	-	1.41	0.12 **	0.80	0.08 **	0.61	0.05 **
Godfrey et al, 1975	M	41.00	-	1.79	-	71.00	-	7	21	40.82	-	1.47	0.15 **	0.93	0.02 **	0.54	0.02 NS
Murray et al, 1980	M	41.00	-	1.77	-	79.00	-	10	10	43.50	3.50 NS	1.38	0.11 NS	0.80	0.07 *	0.58	0.06 NS
Murray et al, 1983	M	40.00	-	1.77	-	80.00	-	7	21	49.50	2.00 **	1.21	0.09 **	0.72	0.09 NS	0.49	0.02 **
Hale et al, 1990	M	36.17	13.76 NS	1.74	0.06 NS	63.70	7.92 **	6	18	42.55	-	1.41	0.15 **	0.83	-	0.58	0.06 NS
Jaeger et al, 1995	M	35.70	-	1.85	-	93.00	-	11	33	44.12	-	1.36	0.15 *	0.79	-	0.57	-
Boonstra et al, 1996	-	41.00	-	1.80	-	81.00	-	28	27	43.17	-	1.39	0.12 **	0.93	-	0.47	0.05 **
Macfarlane et al, 1997	M	36.80	5.07 **	1.79	7.34 NS	82.80	14.41 NS	5	140	46.12	-	1.30	-	0.82	-	0.48	-
Median		41.00		1.78		80.00				43.33		1.39		0.82		0.57	
Mean		40.00		1.78		77.82				44.04		1.37		0.83		0.55	
SD		3.21		0.03		8.60				2.67		0.08		0.07		0.05	
Minimum		35.70		1.74		63.70				40.82		1.21		0.72		0.47	
Maximum		45.00		1.85		93.00				49.50		1.47		0.93		0.61	

SD Standard deviation, ** Significantly different (p<.0005), * Significantly different (p<.005), NS Not significantly different, - Not provided

Table 3. Data sets extracted from studies focusing on able-bodied participants: raw data and comparisons for demographics (Section A), number of samples (Section B) and normative temporal variables (Section C).

	Section A Demographics							**Section B No of samples**		**Section C Temporal variables**							
	Gender	**Age**		**Height**		**Mass**		**Participants**	**Obervations**	**Cadence**		**Duration: Gait cycle**		**Duration: Support**		**Duration: Swing**	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**			**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
	(M/F)	**(yr)**		**(m)**		**(kg)**		**(#)**	**(#)**	**(strides/min)**		**(s)**		**(s)**		**(s)**	
Murray et al, 1964	M	43.10	-	1.76	-	73.03	-	12	24	61.00	-	0.98	0.17 **	0.59	0.05 **	0.38	0.03 **
Murray et al, 1964	M	52.70	-	1.76	-	69.40	-	12	24	59.00	-	1.02	0.10 **	0.62	0.07 **	0.40	0.04 **
Murray et al, 1966	M	-	-	-	-	-	-	30	240	56.60	-	1.06	0.09 **	0.65	-	0.41	0.04 **
Murray et al, 1967	M	-	-	-	-	-	-	30	120	56.50	-	1.06	0.09 **	0.65	0.07 **	0.41	0.04 **
Zuniga et al, 1972	M	33.00	-	1.78	-	77.11	-	20	60	-	-	1.40	0.11 **	0.86	0.08 **	0.54	0.04 NS
Andriachhi et al, 1976	-	28.00	-	1.73	-	77.17	-	17	34	56.18	-	1.07	-	0.60	-	0.47	-
Murray et al, 1983	M	38.00	-	1.73	-	74.00	-	2	6	56.50	5.00 **	1.06	0.09 **	0.65	0.07 *	0.41	0.04 **
Kadaba et al, 1989	-	29.00	-	-	-	-	-	40	360	55.80	4.15 **	-	-	-	-	-	-
Kadaba et al, 1990	M	29.00	-	-	-	-	-	28	252	56.00	4.50 **	1.08	0.08 **	0.66	-	0.42	-
Kadaba et al, 1990	F	29.00	-	-	-	-	-	12	108	57.50	4.50 **	1.05	0.08 **	0.64	-	0.41	-
Oberg et al, 1993	M	44.50	-	-	-	-	-	15	150	60.00	3.30 **	-	-	-	-	-	-
Oberg et al, 1993	F	44.50	-	-	-	-	-	15	150	64.80	4.80 **	-	-	-	-	-	-
Allard et al, 1997	M	25.31	4.82 **	1.79	0.06 NS	76.95	11.29 NS	10	30	53.45	3.60 **	-	-	-	-	-	-
Allard et al, 1997	F	20.13	2.20 **	1.67	0.04 **	62.03	5.61 **	15	45	56.75	3.30 **	-	-	-	-	-	-
Median		31.00		1.76		74.00				56.60		1.06		0.65		0.41	
Mean		34.69		1.74		72.81				57.70		1.09		0.66		0.43	
SD		9.74		0.04		5.54				2.89		0.12		0.08		0.05	
Minimum		20.13		1.67		62.03				53.45		0.98		0.59		0.38	
Maximum		52.70		1.79		77.17				64.80		1.40		0.86		0.54	

SD Standard deviation, ** Significantly different (p<.0005), * Significantly different (p<.005), NS Not significantly different, - Not provided