Transfemoral Prosthetic Socket Designs: A Review of the Literature

Brodie M (BSc(Hons)); Murray L (BSc(Hons)); McGarry A (PhD)

Department of Biomedical Engineering, University of Strathclyde, Glasgow.

Abstract

Study Design: A literature review.

Introduction: The prosthetic socket is the interface which connects the human body to the artificial limb and allows transmission of body weight and forces for gait. Due to the intimate nature of the transfemoral (TF) socket it is of utmost importance to facilitate optimal comfort and function to the user. The purpose of this review is to provide an overview of the available scientific evidence for a variety of TF socket designs; assess the quality of the literature and to compare the underlying biomechanical principles and the associated advantages/disadvantages of each design.

Methodology: The literature review was conducted in five online databases using Boolean search terms and truncation of relevant keywords. A predetermined methodological criterion was then used to assess the quality of the selected articles.

Results: Socket designs included were: Quadrilateral; Ischial Containment; Marlo Anatomical Socket; Sub-Ischial; High-Fidelity and the Socket-less socket. The selection criteria determined 13 articles suitable for inclusion in this review, all of which are clinical studies.

Conclusion: Based on the chosen search strategy and quality criterion, this review found a limited, low quality evidence base for all included socket designs. Although Ischial Containment attained the highest volume of evidence this socket design was not proven to be superior. The variety of biomechanical features pertaining to each socket design provide several advantages/disadvantages. Recommendations are made for future research.

Abstract word count: 221 words

Key indexing words: transfemoral, socket, interface, biomechanics

Introduction

Transfemoral (or above-knee) amputation (TFA) may be a devastating outcome caused by vascular disease (with or without diabetes), trauma, tumours or infection. TFA involves removing the lower extremity at a level between the knee and hip.[1] In 2015, TFA accounted for almost half (46.4%) of the lower limb amputations in Scotland.[2] Prescribing a prosthesis aims to restore biomechanical function and cosmesis whilst allowing the user to ambulate and maintain independence.[3] Early ambulation is considered to facilitate physiological and psychological advantages.[4]

The transfemoral (TF) prosthesis consists of three main parts; the foot, the knee and the socket coupled with a suspension mechanism. The socket is the structure which accepts and transmits the patient's body weight through the artificial limb. Furthermore, as TFA is a proximal amputation level the socket may encroach on intimate areas of the human body such as the groin, this can then lead to issues with toileting and comfort due to the delicacy of the skin in this region. The socket design should therefore be the main priority to ensure optimal function and comfort.[5] In the most recently published Scottish Physiotherapy Amputee Research Group (SPARG) data TFA's had the highest prosthetic abandonment rate across all levels of amputation with 21.7%.[2] There are numerous reasons for prosthetic abandonment including factors directly associated with the socket such as function, comfort and appearance.[6] Although the most established socket design is Ischial Containment, there is lack of consensus and due to the various options available there is a disparity amongst clinical practice which therefore leads to inequality in patient care.

This review aims to identify the prevalent TF socket designs available and evaluate the corresponding literature. Further aims include: to assess the quality of evidence; to understand the individual biomechanical principles and to compare the associated advantages/disadvantages of each TF socket design. Initially, contemporary designs were explored to establish current practice and design of transfemoral sockets.

Socket Design Concepts

The following TF socket designs were reviewed: Quadrilateral (Quad); Ischial Containment (IC) including the Marlo Anatomical Socket (MAS); Sub-Ischial; High-Fidelity (HiFi) and the Socket-less Socket. Alternative TF designs including the Icelandic-Swedish New-York (ISNY) socket and Scandinavian Flexible Socket (SFS) are acknowledged however these were identified as material and frame variations used in conjunction with other socket designs and biomechanically only serve to add flexibility whilst containing residual soft tissues.[7,8] The Infinite Socket, RevoFit and Willowwood One TF Systems are also recognised as socket adjustment tools and mechanisms designed to improve quality of fit, For that reason they were excluded from this review.[9]

Quadrilateral (Quad) Socket

(a) (b) (c)

Figure 1: Quadrilateral socket shown from a) transverse plane, b) coronal plane posterior view, c) sagittal plane medial view. Image from www.physio-pedia.com (Permission was sought).

The Quad socket, also recognised as Ischial-Bearing, was first described by Radcliffe in the 1950's.[10] Distinguishable features included the horizontal ischial seat; distinctive four walls and narrow anteroposterior/wide mediolateral dimensions (Figure 1). Designed to support the majority of body weight through the ischial tuberosity (IT) with additional hydrostatic loading through gluteal musculature. Radcliffe hypothesised that this would reduce distal pressure and therefore distal oedema.[10] This total contact design utilises differential pressure loading and accommodates dynamic changes in the residuum.[5] High forces are applied to areas of soft tissue, including the femoral triangle which provides the essential counterforce to maintain the IT on the ischial seat. In contrast to this, firm musculature is accommodated via channels created in the socket.[11] Stabilisation of the femur is achieved through angulation of the lateral wall and an accurate mediolateral dimension.[5] The Quad shape can be captured by hand casting or through use of brims such as the Berkeley Brim. This allows the cast to be taken with the patient lying

supine and is therefore a strong indicator for weak/geriatric patients.[12] No additional certifications are required to apply this technique. The Quad design can be used in conjunction with most available suspension methods.

Ischial Containment (IC) Socket

(a) (b) (c)

Figure 2: Ischial Containment socket shown from a) transverse plane, b) coronal plane posterior view, c) sagittal plane medial view. Image from www.physio-pedia.com (Permission was sought).

The IC socket, also known as Ischial-Ramal Containment (IRC), was created to 'solve' the biomechanical faults of the Quad socket. In the 1980's Ivan Long proposed Longs Line: a concept of increasing femoral adduction with the aim to place hip abductor musculature in a more functional position for pelvic stabilisation thus reducing the lateral trunk leaning associated with Quad sockets.[13] Long implemented this technique in the Normal-Shape-Normal-Alignment (NSNA) socket by narrowing the mediolateral dimension and containing the ischium within the socket.[13] John Sabolich further developed this theory and introduced the Contoured Adducted Trochanteric – Controlled Alignment Method (CAT-CAM) socket (Figure 2) which contains the IT and part of the inferior ischio-ramus. A 'bony locking effect' created through a 3-point force system holds the femur in adduction and stabilised the ischium within the socket.[14] Total contact is maintained and weight is transmitted predominately via hydrostatic loading of residual soft tissues with some oblique support from the IT.[15] Sabolich recommended a hands-on instructional course to apply this technique although no additional certifications are required.[14] This socket can be combined with most available suspension methods.

(a) (b) (c)

Figure 3: Marlo Anatomical Socket version 2.0 featuring RevoFit adjustability, socket shown from a) coronal plane anterior view, b) coronal plane posterior view, c) sagittal plane medial view. Images by Marlo Ortiz (Used with permission).

The Marlo Anatomical Socket (MAS), developed by Marlo Ortiz (Ortiz International), may be considered as a variant of IC which fully contains the ischium and ischio-pubic ramus. The enhanced containment of the ischial ramus medially allows the anterior, posterior and medial trimlines to be lowered (Figure 3). Ortiz suggested that this could improve cosmesis in the gluteal region; hip range of motion (ROM); femoral adduction and reduce proximal discomfort.[16,17] The proximal socket is not designed to provide sole weight bearing; this design therefore utilises quasi-hydrostatic loading through soft tissues of the thigh. During shape capture, accurate anatomical measurements are essential to control the horizontal forces which stabilise the socket. As a result, prosthetists are required to attain MAS certification in order to implement this technique correctly.[18] Additionally, most available suspension methods may be used, however auxiliary suspension may inhibit the benefits of lowered trimlines.[16]

Sub-Ischial Socket

(a) (b)

Figure 4: a) NU-FlexSIV socket b) NU-FlexSIV socket highlighting proximal inner socket flexibility. Image by R.J. Garrick/NUPOC (Used with permission).

The Sub-Ischial socket, also known as the *Brimless* socket, has lowered proximal trimlines which are distal to the IT. In the absence of pelvic support this socket also utilises quasi-hydrostatic loading through residual soft tissues. The NU-FlexSIV socket was established by Ryan Caldwell in partnership with Northwestern University Prosthetics-Orthotics Center. It is the first known standardised Sub-Ischial socket technique taught to clinicians. This total contact socket consists of a silicone liner which globally compresses and preloads soft tissues of the thigh; a flexible inner socket extending approximately 25mm below the IT which allows thigh muscles to contract and move with ease; a shorter rigid outer socket, and a sealing sleeve used in conjunction with an elevated vacuum which provides volume stabilisation and allows anchorage to the residual limb (Figure 4).[19] Alternatively, passive suction using a seal-in silicone liner can be used.[20] Benefits associated with the Sub-Ischial socket include reduced sweating proximally; improved hygiene;

increased comfort and hip ROM, and reduced fitting problems.[21] socket prescription indications are for established TF prosthetic users with stable limb volume and well-healed residuum's. The only contraindications were related to the suspension method and not the socket design itself. There is no requirement for specific certification in this socket technique. However, the NU-FlexSIV developers have hosted optional training sessions since 2015 for Certified Prosthetist Orthotist's with 5 years of experience fitting transfemoral sockets.[19]

High-Fidelity (HiFi) Socket

(a) (b)

Figure 5: a) HiFi frame style interface illustrating proximal primary suspension over tissue release areas, secondary pin suspension for active wearer b) The HiFi limb capture and diagnostic process using the High-Fidelity Floor Standing Imager. Image by Randall Alley (Used with permission).

The HiFi socket, also known as Compression/Release Stabilised socket, was developed by Randall Alley (Biodesigns). This design utilises indirect skeletal attachment. An inward force is applied to multiple areas – commonly by four depressions – parallel to the femur. This selectively pre-compresses soft tissues of the thigh and displaces them into adjacent areas designed for release thus allowing intimate capture of femoral movement which aims to reduce motion between the femur and socket wall. Additionally, femoral stabilisation negates the need for ischial support and therefore a Sub-Ischial brim can be incorporated into the socket.[22] Shape capture is achieved via the unique diagnostic tool and casting jig known as the HiFi imager (Figure 5).[23] To effectively apply this technique the prosthetist must be fully trained and certified. The suggested improvements of this design include gait efficiency, balance, hip ROM, comfort and heat dissipation. Most available suspension methods may be used. Additional friction caused by the depressions along with additional suspension is thought to be created through soft tissue bulges reduces the elongation associated with pin suspension.[22]

Socket-less Socket

Figure 6: Martin Bionics Socket-less Socket™. Image by Jay Martin (Used with Permission).

The Socket-less Socket™, created by Jay Martin, CP, FAAOP (MartinBionics.com), is a novel socket design involving various modular components that can be assembled into numerous designs configurations (Figure 6, the cX™ configuration). Weight is transmitted through compliant dynamic socket components which conform to the anatomical shape for maximum comfort. The limb is controlled within the socket by a combination of compliant and semi-compliant socket members, to facilitate control and eliminate painful contact between the distal femur and hard socket.[24] Volume fluctuations are effectively accommodated through user adjustable medium.[25] Advantages include improved heat dissipation, increased hip ROM, reduced socket weight, and many users claim an increase in limb muscle use and hence circulation. Various suspension methods can be used including pin lock, lanyard, suction, vacuum, Velcro, or their unique SharkSkin™ Suspension. Online socket certification can be granted through the Martin Bionics website.[24] However, the perceived benefits of this socket are unsubstantiated and require further investigation.

Methodology

Search Strategy

Relevant research articles were obtained using Boolean searching and truncation of main keywords applied to five online databases (Figure 7). The end search date was March 2019. References of resultant articles were also taken into consideration and via email correspondence, further research was sought from the expert opinions of socket developers including Marlo Ortiz, R.J Garrick, Randall Alley and Jay Martin (April 2019).

Study Selection

The studies were initially refined by title and abstract (Figure 7). Full texts were obtained via the Knowledge Network, PubSage, Science Direct or Google Scholar and then further screened against an inclusion/exclusion criterion (Table 1) to determine eligibility for this review.

Figure 7: Selection Algorithm Flowchart

Table 1: Inclusion/Exclusion Criterion

Quality Assessment

Following the selection process, resultant articles were quality assessed using a predetermined checklist consisting of 12 items (see Appendix A). This checklist is a combination of two quality assessment tools initially created to assess randomised control trials.[26,27] Adaptions by Van der Linde[28] allowed inclusion of non-randomised controlled trials and further alterations by Gholizadeh[29] account for the inability to blind a person with an amputation to the applied socket design/suspension method as differences can be easily identified. Gholizadeh excluded criterion B7, regarding blinding, from the quality assessment checklist. Each criterion of the checklist was scored as either "1" indicating a valid/yes answer or "0" indicating an invalid/no answer. The resultant grades are defined in Table 2.[28]

Table 2: Grades of Evidence[28]

Articles included in this review were required to effectively control selection and measurement bias. However, as no evidence exists to support a minimum time of acclimation to TF sockets, criterion B8 regarding timing of measurement was marked "1" in all articles. Grade C was therefore not applicable to any of the studies. Furthermore, a variety of study designs are included within this review and to allow

for an accurate comparison between articles, a modified version of the Oxford Levels of Evidence was also applied (Table 3)[30,31]:

Table 3: Levels of Evidence[31]

Quality was rated in ascending order both numerically and alphabetically. 1(A) was awarded to the highest quality articles: randomised study designs with appropriate selection bias and methodology. Alternatively, the lowest quality articles: case studies/reports with poor selection bias and methodology attained 4(B).

Results

Overview of Selected Studies

The review process yielded 13 applicable articles (Figure 7). These were quality assessed and essential data was extracted. Each table illustrates the main findings including quality evaluation and PICO (patient/population, intervention, comparator and outcomes). The included articles were all studies published between 1989[32,33] and 2018.[34] All articles, except one which compared variations of IC and tissue loading using the MAS design,[35] compared various socket designs against an IC socket as this was deemed the 'standard of care' design. Of the articles four compared Quad[32,33,36,37]; one compared Quad and MAS[38]; one compared MAS[39]; four compared Sub-Ischial[21,34,40,41] and two compared HiFi.[42,43] No articles were found regarding the Socket-less socket. All tables are therefore ordered firstly by intervention (Quad, MAS, Sub-Ischial, and HiFi) and secondly by year of publication in descending order. The study designs are detailed in Figure 7. Collectively, in terms of quality assessment, five articles achieved level 1,[21,35,37,38,40] four level 2,[32,33,36,39] one level 3[43] and three level 4.[34,41,42] Of these, five papers achieved grade A[32,37,38,40,42] and eight papers obtained grade B (Table 4).[21,33-36,39,41,43] The highest quality paper assessed in terms of study design, selection and measurement bias was by Kahle et al.[40] No evidence was found regarding the Socket-less Socket™ and therefore it was omitted at this stage.

Table 4: Quality Assessment

Individual Socket Designs

Quadrilateral (Quad) Socket

Overall, since the introduction of the Quad socket in the 1950's, five articles have been published between 1989 and 2011 which compare gait biomechanics, metabolic efficiency and comfort levels subjectively.[32,33,36-38] The Quad socket has primarily been compared to IC sockets: with one paper also comparing Quad, IC and MAS collectively. The study designs have included one randomised crossover trial[38]; one randomised controlled trial[37]; one non-randomised crossover trial[33] and two non-randomised controlled trials.[32,36] Overall, quality assessment results include two 1(A)[37,38]; one 2(A)[32] and two 2(B).[33,36] Despite the limited evidence base for the Quad socket, the articles are relatively high quality.

Ischial Containment (IC) Socket

The IC socket has the largest evidence base as it features in all 13 articles. The CAT-CAM design was tested in five articles[21,33,34,40,42]; one article tested the CAT-CAM, NSNA and narrow ML designs[32] whereas the other seven referred to IC generically.

The MAS has only been reported in three articles published between 2011 and 2014.[35,38,39] Of these one compared the MAS to an IC; one article compared MAS to both Quad and IC and one article tested different socket conditions using the MAS design. The study designs included two randomised crossover trials[35,38] and one non-randomised crossover trial.[39] Overall, the quality of evidence included one 1(A)[38]; one 1(B)[35] and one 2(B).[39]

Sub-Ischial Socket

The Sub-Ischial socket has been evaluated in four articles[21,34,40,41] between 2013 and 2018. All articles compared the Sub-Ischial socket to an IC socket. Two articles tested a generic Sub-Ischial socket[21,40] whereas the other two are developing an evidence base for the NU-FlexSIV socket.[34,41] The study designs included two randomised crossover trials[21,40] and two case series.[34,41] The quality of evidence for

the NU-FlexSIV socket is low as both study designs are case series. Overall, the evidence base consists of one 1(A)[40]; one 1(B)[21] and two 4(B).[34,41]

High-Fidelity (HiFi) Socket

The HiFi socket has been reported in two articles[42,43] between 2016 and 2017. Both articles compared HiFi against an IC socket. The study designs were a retrospective cohort study[43] and case study.[42] This yields the lowest quality evidence base amongst the socket designs with one 3(B)[43] and one 4(A).[42]

Overview of Participant Characteristics

Table 5 represents demographic characteristics of participants in the selected studies. Unfortunately, these were heterogeneous and therefore difficult to compare. The sample size ranged from 1[42] to 50.[32] All participants were unilateral; age ranged from 17[32] to 81[35] years. Overall, there were 128 male participants and only 15 female. All papers, except one which included 1 knee disarticulation (KD),[41] included participants of TF level and the most common aetiology was trauma followed by Peripheral Vascular Disease (PVD), tumour or infection. Activity levels of users were omitted from five articles,[32,35-37,41] two of these suggested activities of the participants and as a result K-level was estimated.[37,41] The activity level ranged from K2 to K4. Six articles omitted years since amputation[32-34,38,42,43] and only three articles reported years of prosthetic use.[33,37,43] In addition, residuum length was poorly documented with six articles overlooking this data[32,34,39,41-43] and the other seven varying significantly in data presentation (mean, index range, percentage and ratio) which obscured comparisons. Hip ROM without the socket was only recorded in one article.[38] In addition, other factors such as muscle power were not recorded in any of the articles.

Table 5: Demographic characteristics of participants in selected studies

Overview of Methodology

A wide variety of outcome measures were used in the articles. Due to a disparity in terminology, comparisons were challenging although four overarching topics were identified (Table 6): 10 articles evaluated gait biomechanics[21,32-36,38,40-42]; four measured metabolic efficiency[33,36,37,39]; four utilised physical performance measures[34,40,41,43] and 10 assessed sockets subjectively.[21,33-36,39-43] Table 7 details the most common outcome measures recorded for each comparator. All studies were carried out in a clinic, community or household environment. Socket acclimation time was poorly recorded – seven articles omitted this data[32,35-38,41,43] – and the available data in remaining studies varied greatly, ranging from 0 days to 9 weeks.[34] Five of the 13 articles sufficiently described the clinician's qualifications and additional certifications[21,34,35,40,42]; four described the clinicians as 'experienced'[36-39] and four articles omitted this data completely.[32,33,41,43] Socket suspension methods were recorded in nine articles. Of these three used Common Suction Socket (CSS)[33,35,37]; three operated Vacuum Assisted Suspension (VAS)[21.40,42]; one used both CSS and passive suction[38]; one used both VAS and passive suction[34] and one used both CSS and VAS.[41] Four articles omitted which suspension method was utilised[32,36,39,43] and auxillary suspension was not reported in any of the articles. Ten of the articles listed all the prosthetic componentry used whereas three omitted this data.[32,33,43] Componentry remained constant in all cross-over studies, except two.[34,41] In the controlled trials and cohort studies a diverse range was used. The most common limitations acknowledged within articles were small sample power (1–50) and length of acclimation to socket designs (0 days – 9 weeks).

Table 6: Methodological characteristics of selected studies

Table 7: Comparators and Outcomes Measured Within Articles

Table 8: Main Clinical Findings

Discussion

This review highlights the limited, low quality evidence base pertaining to TF socket designs. All articles aimed to evaluate the variety of biomechanical design features of each socket design and the resultant advantages/disadvantages. This was determined through the ability to maximise gait potential and physical performance, increase metabolic efficiency and improve comfort levels.

Quadrilateral (Quad) Socket

Despite Radcliffe's efforts to introduce biomechanical principles into the prosthetic interface, both Long and Sabolich rejected this design. They suggested that during single limb support, the lack of ischial capture allows the ischium to slide laterally on the horizontal seat as the pelvis stabilises itself. In addition, the wide mediolateral dimension provides insufficient femoral support.[13,14] This would result in greater femoral abduction and subsequent gait deviations including lateral trunk leaning. Shortly after the implementation of IC sockets, Gottschalk et al. investigated this theory and found no significant difference in the abduction angles of 50 TF participants wearing either Quad or IC. Instead they suggested that the amputation technique was the greatest influence to anatomical alignment. Additionally, they recommended myodesis of adductor musculature to the femoral shaft at the time of surgery.[32] However, later research conducted by Hachisuka et al. and Flandry et al. revealed that the femur was indeed more abducted in Quad sockets. Further to this, Flandry et al. noted that lateral trunk leaning had lessened whilst wearing the IC socket.[33,36] The narrow mediolateral dimension and ischial containment have been shown to improve femoral adduction and thus gait biomechanics. Due to the influence of amputation technique, residual femoral length should be recorded in all studies to allow accurate comparison. In cases where a myodesis has been performed, increased femoral length can impact and improve the moment arm for adduction.[1] Klotz et al. then measured global hip ROM in the Quad, IC and MAS design of four participants and found no difference between Quad and IC sockets.[38] Noticeably, in all articles comparing the Quad socket, 'common suction' – where

suction is created directly between skin and socket walls – was the suspension method utilised. This would therefore eliminate any interference from external sources such as rigid pelvic bands and as such highlights the influence of suspension mechanisms.[5]

Gailey et al. investigated metabolic efficiency in 20 TF participants wearing either Quad or IC sockets. Heart Rate (HR) and O2 uptake measurements were taken at two assigned speeds reflecting normal and slow. It was concluded that Quad sockets were less efficient than IC when walking at normal speed (2.5mph).[37] Flandry et al. supported these findings using similar measurements as five participants walked at an unrestricted pace. The results revealed that IC sockets improved oxygen consumption by up to 50% and were therefore more metabolically efficient.[33] Conversely, Hachisuka et al. used a Physiological Cost Index (PCI) calculation and found that IC sockets were not metabolically superior to Quad at the most comfortable speed. Furthermore, he identified that residuum length and lateral force on the amputated side during mid-stance of gait were significant factors for calculating energy cost.[36] As energy cost is directly related to gait, any deviations from normal physiological gait increase energy expenditure and as a result decrease metabolic efficiency.[44] Hachisuka et al. was the only study to contradict the inferior efficiency of the Quad socket and coincidentally was also the only study to utilise a significantly different calculation to determine this. In order to effectively compare metabolic efficiency, both data collection and calculation must be standardised.

Both Hachisuka et al. and Flandry et al. used self-made subjective questionnaires and found that the Quad socket was less comfortable than IC.[33,36] In addition, Hachisuka et al. noted that the greatest discomfort occurred whilst sitting on a chair and during heel off.[36] The IC socket is designed to have a wider anteroposterior dimension providing additional space for the hip flexor muscles to fire at heel off thus allowing improved gait efficiency which could contribute to improved comfort.[14]

Ischial Containment (IC) Socket

The IC socket has been deemed the 'standard of care' and is the most commonly used socket design having overtaken the practice of Quad sockets due to the proposed improvements in gait biomechanics, increased metabolic efficiency and superior comfort levels.[34] Although MAS is a variant of IC, this design offers additional advantages due to improved containment of the ischium and lowered anterior/posterior proximal trimlines. Klotz et al. discovered that the MAS increased global hip ROM when compared to both Quad and IC sockets.[38] This highlighted the effect of proximal trimlines in restricting ROM of the hip joint. Fatone et al. tested the effect of tissue loading and IC on coronal plane stability and gait in six TF participants. Rather than comparing the MAS to alternative sockets, this study tested six different socket conditions: three with IC; three without IC and each with low, medium and high tissue loading. The findings concluded that coronal plane hip moment, lateral trunk lean, step width and walking speed were invariant to changes in the IC and/or tissue loading. This revealed that superior containment of the ischium was not significant in improving gait biomechanics. However, Fatone et al. also reported that the test conditions were measured successively thus acclimations to changes in socket conditions were eliminated.[35] Furthermore, the activity levels of the participants were omitted which introduces potential heterogeneity and obscures comparisons. Activity level can have a fundamental impact on gait biomechanics and metabolic efficiency and should therefore be kept as homogenous as possible within studies.

The lowered posterior proximal trimline also affords the gluteus maximus freedom to fire and function more effectively; this improved muscle function could in turn increase metabolic efficiency.[17] Traballesi et al. measured energy cost of walking (ECW) in both MAS and IC in seven high activity TF participants (K3-K4). ECW was thoroughly measured as HR, O2 uptake, CO2 production, respiratory exchange ratio and walking speed data were collected. Additionally, this study tested the MAS design following a 30 day acclimation period and again after 60 days. The results indicated that the MAS had improved ECW, with significant improvements present after 60 days of acclimation.[39] Not only does this indicate that the MAS is more

metabolically efficient but also suggests that an adequate acclimation period could maximise results.

Subjectively, Fatone et al. utilised the Socket Comfort Score (SCS) and discovered that whilst the ischium was contained, participants reported increased comfort irrespective of tissue loading.[35] Furthermore, Traballesi et al. used the Prosthesis Evaluation Questionnaire – Mobility Section (PEQ-MS) to assess perceived mobility of the MAS in comparison to an IC (CAT-CAM) socket and found a significant improvement when wearing the MAS design.[39] Another suggested benefit of the MAS is improved cosmesis resulting from the lowered proximal trimlines allowing natural contour of the gluteals however no evidence was found to support this.

Sub-Ischial Socket

The distinctive feature of a Sub-Ischial socket is the lowered proximal trimlines and therefore lack of pelvic contact; this offers the advantage of unrestricted hip ROM.[19] The findings of Brown et al. determined that sagittal plane hip motion, noticeably hip extension, had increased whilst walking and climbing stairs.[34] In contrast to this, Fatone et al. found no significant changes in sagittal plane hip motion however this was only recorded whilst walking.[41] Klotz et al. had previously measured hip ROM in Quad, IC and MAS designs and established that neither inhibited ROM required for gait.[38] Therefore, the lowered trimlines could be beneficial for other activities of daily living such as climbing stairs. Fatone et al. also found no significant changes in coronal plane hip moments for either of the subjects[41]; this supported previous findings by Kahle et al. which reported Sub-Ischial socket to be statistically equivalent to IC in all measured coronal hip angles.[21] The femoral alignment in Sub-Ischial sockets was not measured in any of the articles. However, several articles found that the walking base was narrowed and lateral trunk leaning was not present when using these sockets; as the ischium is not controlled this could suggest ischial containment is not essential to achieve optimal femoral adduction.[34,40,41] Further aspects of gait biomechanics were assessed. Kahle et al. found Sub-Ischial socket to be equivalent to IC in most gait and balance outcome measures[40] whilst Fatone et al. reported an improvement in walking speed when wearing the NU-FlexSIV socket.[41]

No evidence was found regarding metabolic efficiency in Sub-Ischial sockets. Consequently, all Sub-Ischial sockets were tested in conjunction with Vacuum Assisted Suspension (VAS). Previous studies and reviews have indicated VAS to be a superior suspension method which may have therefore influenced the performance of these sockets.[45-49] Both Brown et al. and Fatone et al. compared IC sockets using passive suction to NU-FlexSIV sockets with VAS.[34,41] It is unclear whether the outcomes of these studies are due to the socket design or suspension method.

Kahle et al. utilised the PEQ and demonstrated significant subjective improvements in prosthetic related function and quality of life when participants used the Sub-Ischial design.[40] Similar results were found again by Kahle et al. as all subjects reported the Sub-Ischial design to be more comfortable than IC in short-term preference. Furthermore, they discovered significantly lower medial proximal pressure in the Sub-Ischial design which may have contributed to positive subjective scoring.[21] Fatone et al. discovered, using the SCS for both subjects, that the NU-FlexSIV socket was more comfortable.[41] Additionally, Brown et al. also used the SCS and discovered that sitting comfort was improved however walking and running was less comfortable.[34] As the hip abductors are cut during the amputation procedure this biomechanically depletes their ability to stabilise the pelvis and consequently creates an inherent weakness.[1] Therefore, this could suggest that the lowered lateral proximal trimline of the socket may reduce stability around the hip joint and as such the hip abductors would need to overcompensate thus leading to increased muscle fatigue. This could explain the findings of Brown et al. and therefore long-term studies are required to measure muscle performance and assess fatigue levels in Sub-ischial and IC sockets.

High-Fidelity (HiFi) Socket

The HiFi socket incorporates a Sub-Ischial brim and should therefore share the benefits associated with this. In addition, Kahle et al. compared IC against HiFi in a retrospective cohort study of 13 high activity TF participants (K3-K4). Walking speed was the only measurement assessed to determine the walking capacity of participants. The results indicated that the HiFi socket was superior to the IC.[43]

Furthermore, Klenow et al. measured the effects of the HiFi and IC socket on gait in a case study of a 65 year old TF participant where the activity level was similar to the previous study (K3). The findings correlated with the results of Kahle et al. as the patients' self-selected gait velocity had also increased. Additional outcomes included an increase in prosthetic hip adduction and hip extension with reductions in lateral centre of mass deviation during gait.[42] Evidence related to the metabolic efficiency of this socket design was not identified.

In terms of subjective perception, Kahle et al. utilised the Activities-Specific Balance Confidence (ABC) questionnaire to assess perceived balance confidence whilst Klenow et al. used two questionnaires (Owestry v2.0 and WOMAC) to determine perceived disability. The HiFi was found to be superior to IC in both studies.[42,43] There is a lack of standardisation in measurement of subjective perception which precludes comparisons between articles. Consequently, both studies support the suggested benefits of the compression/release technique. However, a low combined sample power of 14 participants significantly limits the generalisability of these findings. Additionally, neither study conducted a randomised trial resulting in a low quality evidence base for this socket design. Furthermore, no long term studies have been conducted to discover if patients can tolerate higher point pressures on the soft tissue. This is a relatively new socket design and requires both specific shape capture tools and certification to implement which makes it less accessible than other designs currently available. As such a more robust high quality evidence base must be established to determine if the additional requirements are justified by this design.

Recommendation for Future Research

To allow effective comparison between studies, the following suggestions have been made. Firstly, sufficient raw data including time since amputation, activity level, residual limb length and prosthetic use should be collected and the demographic characteristics of participants should also be kept as homogenous as possible within studies. The methods used to assess outcome measures should be standardised. Acclimation period plays a vital role in studies comparing socket designs. Therefore, further research must be conducted to establish a sufficient acclimation period, and

this must then be incorporated in future studies. Randomised crossover trials with larger sample sizes are required to establish an evidence base for improved clinical practice. Comparisons between Sub-Ischial socket designs and the HiFi should be conducted to determine the effects of global compression against compression/release. The research must be conducted to establish an evidence base for the Socket-less socket. Finally, a longevity study into effects of sockets designs should be completed to provide greater insight into the long term consequences of these changing designs. In addition to this, there are external critical factors which must be taken into consideration, these include: the impact that the amputation technique may have on position of the femur and the suspension method used.

Conclusions

This review compared the available scientific evidence for prevalent TF socket designs. Limited evidence was revealed, of which, few were high quality studies. The greatest challenge in prosthetic research is the inability to effectively blind a patient to the variables under examination which therefore inhibits a true RCT. Based on this current level of research the socket designs considered were found to have various advantages/disadvantages with no one design proving to be biomechanically superior. Patient preference has been strongly linked to lowered trimlines and may increase compliance. Biomechanical analysis indicated that this in turn improves hip ROM. However, the lack of restriction on the glutes and hamstrings comes at the expense of stability with a patient population already at risk of falling this may be controversial. Ultimately, both the quality and the quantity of prosthetic research must improve to reduce the variance in clinical practice and within patient care.

Acknowledgements

I would like to thank Marlo Ortiz, R.J. Garrick, Randall Alley and Jay Martin for the images and additional information they provided regarding the socket designs.

Declaration of interest

The author reports no conflicts of interest. The authors alone are responsible for the writing of the paper.

References

1. Gottschalk F. Transfemoral amputation: biomechanics and surgery. Clinical Orthopaedics and Related Research®. 1999;361:15-22.
2. Davie-Smith F, Scott H. The Scottish physiotherapy amputee research group (sparg). Physiotherapy. 2015;101:e300-e1.
3. Schuch CM, Pritham CH. Current transfemoral sockets. Clinical orthopaedics and related research. 1999(361):48-54.
4. Esquenazi A, DiGiacomo R. Rehabilitation after amputation. Journal of the American Podiatric Medical Association. 2001;91(1):13-22.
5. Kapp SL. Transfemoral socket design and suspension options. Physical Medicine and Rehabilitation Clinics of North America. 2000;11(3):569-83.
6. Roffman CE, Buchanan J, Allison GT. Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. Journal of physiotherapy. 2014;60(4):224-31.
7. Krebs DE, Tashman S. Kinematic and kinetic comparison of the conventional and ISNY above-knee socket. Clin Prosthet Orthot. 1985;9(3):28-36.
8. Kawamura I, Kawamura J. Some biomechanical evaluations of the ISNY flexible above-knee system with quadrilateral socket. Orthot Prosthet. 1986;40:17-23.
9. Fitzgerald AE, Honicker JL, Chan MD. Dynamic Prosthetic Socket. 2017.
10. Radcliffe CW. Above-knee prosthetics. Prosthetics and Orthotics International. 1977;1(3):146-60.
11. Radcliffe CW. Functional considerations in the fitting of above-knee prostheses: Biomechanics Laboratory, University of California; 1955.
12. Foort J. Socket design for the above-knee amputee. Prosthetics and Orthotics International. 1979;3(2):73-81.

13. Long IA. Normal shape-normal alignment (NSNA) above-knee prosthesis. Clin Prosthet Orthot. 1985;9(4):9-14.
14. Sabolich J. Contoured adducted trachanteric-controlled alignment method (CAT-CAM): Introduction and basic principles. Clin Prosth Orthos. 1985;9:15-26.
15. Pritham CH. Biomechanics and shape of the above-knee socket considered in light of the ischial containment concept. Prosthetics and orthotics international. 1990;14(1):9-21.
16. Muller MD. Transfemoral amputation: prosthetic management. Atlas of Amputation and Limb Deficiencies. 2016;2.
17. Fairley M. MAS Socket: A transfemoral revolution. OandP Edge. 2004;3:6.
18. del Mercado Ortiz RMV. Method of making an anatomical socket. Google Patents; 2013.
19. Fatone S, Caldwell R. Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Prosthetics and Orthotics International. 2017;41(3):237-45.
20. Caldwell R, Fatone S. Technique modifications for a suction suspension version of the Northwestern University Flexible Sub-Ischial Vacuum socket: The Northwestern University Flexible Sub-Ischial Suction socket. Prosthetics and Orthotics International. 2018.
21. Kahle JT, Highsmith MJ. Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: ischial containment versus brimless. J Rehabil Res Dev. 2013;50(9):1241-52.
22. Alley RDCPLP, Williams TWIIIMA, Albuquerque MJCPO, Altobelli DEMD. Prosthetic sockets stabilized by alternating areas of tissue compression and release. Journal of Rehabilitation Research and Development. 2011;48(6):679-96.
23. Alley RD. Adaptable socket system, method, and kit. Google Patents; 2016.
24. Martin JJ. Transfemoral level interface system using compliant members. Google Patents; 2019.
25. Paternò L, Ibrahimi M, Gruppioni E, Menciassi A, Ricotti L. Sockets for limb prostheses: a review of existing technologies and open challenges. IEEE Transactions on Biomedical Engineering. 2018;65(9):1996-2010.

26. van Tulder MW, Assendelft WJJ, Koes BW, Bouter LM, Editorial Board of the Cochrane Collaboration Back Review G. Method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group for spinal disorders. LWW; 1997.
27. Verhagen AP, de Vet HCW, de Bie RA, Kessels AGH, Boers M, Bouter LM, et al. The Delphi list: a criteria list for quality assessment of randomized clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of clinical epidemiology. 1998;51(12):1235-41.
28. van der Linde H, Hofstad CJ, Geurts ACH, Postema K, et al. A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. Journal of Rehabilitation Research and Development. 2004;41(4):555-70.
29. Gholizadeh H, Abu Osman NA, Eshraghi A, Ali S. Transfemoral prosthesis suspension systems: a systematic review of the literature. Am J Phys Med Rehabil. 2014;93(9):809-23.
30. Group OLoEW. " The Oxford 2011 Levels of Evidence." Oxford Centre for Evidence-Based Medicine. http://www cebm net/index aspx? o= 5653. 2011.
31. Ishii LE. Thoughtful Methods to Increase Evidence Levels and Analyze Nonparametric Data. JAMA facial plastic surgery. 2015;17(4):307-8.
32. Gottschalk FA, Kourosh S, Stills M, McClellan B, Roberts J. Does socket configuration influence the position of the femur in above-knee amputation? JPO: Journal of Prosthetics and Orthotics. 1989;2(1):94.
33. Flandry F, Beskin J, Chambers RB, Perry J, Waters RL, Chavez R. The effect of the CAT-CAM above-knee prosthesis on functional rehabilitation. Clinical orthopaedics and related research. 1989(239):249-62.
34. Brown SE, Russell Esposito E, Ikeda AJ, Wilken JM, Fatone S. Evaluation of NU-FlexSIV Socket Performance for Military Service Members with Transfemoral Amputation. US Army Med Dep J. 2018(2-18):38-47.
35. Fatone S, Dillon M, Stine R, Tillges R. Coronal plane socket stability during gait in persons with transfemoral amputation: Pilot study. Journal of Rehabilitation Research and Development. 2014;51(8):1217-28.

36. Hachisuka K, Umezu Y, Ogata H, Ohmine S, Shinkoda K, Arizono H. Subjective evaluations and objective measurements of the ischial-ramal containment prosthesis. Journal of UOEH. 1999;21(2):107-18.
37. Gailey RS, Lawrence D, Burditt C, Spyropoulos P, Newell C, Nash MS. The CAT-CAM socket and quadrilateral socket: A comparison of energy cost during ambulation. Prosthetics and Orthotics International. 1993;17(2):95-100.
38. Klotz R, Colobert B, Botino M, Permentiers I. Influence of different types of sockets on the range of motion of the hip joint by the transfemoral amputee. Annals of Physical and Rehabilitation Medicine. 2011;54(7):399-410.
39. Traballesi M, Delussu AS, Averna T, Pellegrini R, Paradisi F, Brunelli S. Energy cost of walking in transfemoral amputees: Comparison between Marlo Anatomical Socket and Ischial Containment Socket. Gait and Posture. 2011;34(2):270-4.
40. Kahle JT, Highsmith MJ. Transfemoral interfaces with vacuum assisted suspension comparison of gait, balance, and subjective analysis: Ischial containment versus brimless. Gait and Posture. 2014;40(2):315-20.
41. Fatone S, Caldwell R. Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation: Part 2 Description and Preliminary evaluation. Prosthetics and Orthotics International. 2017;41(3):246-50.
42. Klenow TD, Kahle JT, Fedel FJ, Ropp J, Highsmith MJ. Comparative Efficacy of Transfemoral Prosthetic Interfaces: Analysis of Gait and Perceived Disability. JPO: Journal of Prosthetics and Orthotics. 2017;29(3):130-6.
43. Kahle JT, Klenow TD, Sampson WJ, Highsmith MJ. the effect of transfemoral interface design on gait speed and risk of falls. Technol Innov. 2016;18(2-3):167-73.
44. Caldwell LK, Laubach LL, Barrios JA. Effect of specific gait modifications on medial knee loading, metabolic cost and perception of task difficulty. Clinical Biomechanics. 2013;28(6):649-54.
45. Gerschutz MJ, Hayne ML, Colvin JM, Denune JA. Dynamic effectiveness evaluation of elevated vacuum suspension. JPO: Journal of Prosthetics and Orthotics. 2015;27(4):161-5.

46. Gholizadeh H, Lemaire ED, Eshraghi A. The evidence-base for elevated vacuum in lower limb prosthetics: Literature review and professional feedback. Clinical Biomechanics. 2016;37:108-16.
47. Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: a systematic review. Technology & Innovation. 2014;15(4):333-41.
48. Rink C, Wernke MM, Powell HM, Gynawali S, Schroeder RM, Kim JY, et al. Elevated vacuum suspension preserves residual-limb skin health in people with lower-limb amputation: Randomized clinical trial. J Rehabil Res Dev. 2016;53(6):1121-32.
49. Rosenblatt NJ, Ehrhardt T. The effect of vacuum assisted socket suspension on prospective, community-based falls by users of lower limb prostheses. Gait and Posture. 2017;55:100-4.

Appendix A: Methodological Quality Criterion[28]

Selection of Patients – A criteria

- A1 – Adequacy of Description of Inclusion and Exclusion Criteria: This criterion tested whether the participant sample was sufficiently defined. If at least four of the following points are mentioned, this criterion was scored "1":
    - Age, Gender, Level of amputation, Reason for amputation, Activity level of participant, Time since onset, Residuum condition (tissue consistency, length of stump, scar), Comorbidity
- A2 – Functional Homogeneity: The homogeneity of the study sample was assessed for all study designs. In view of clinical guideline development, at least the activity level of the included subjects should be reasonably equal (K-Level). When this is not described, sufficient indication of amputation level, reason for amputation, and age of the participants were required to globally estimate the activity level. If the study sample was heterogeneous, a stratified analysis of the outcome was required to obtain a "1" score
- A3 – Prognostic Comparability: As for group designs, the study groups should be comparable for possible confounding factors (time since onset and time since first walking with the prosthesis). In the case of a within-subjects design, this criterion was scored "1"
- A4 – Randomisation: In group designs, an adequate randomisation procedure should have been applied. If this procedure was described and reasonably excluded bias, this criterion was scored as "1." In within-subjects designs, this criterion was applied to the sequence of interventions[1]

Intervention and Assessment – B criteria

- B5 – Experimental Intervention: The experimental intervention had to be given explicitly in such detail to allow a duplicate study to be performed
- B6 – Cointerventions: This criterion tested whether cointerventions were avoided or were comparable between the study groups (additional procedure)

- B7 – Blinding: In any case, the outcome assessor had to be blinded to the intervention. In many studies investigating prosthetic components, blinding of the patients is always difficult to assure. Therefore, this type of blinding was required only for studies using subjective outcome measures
- B8 – Timing of the Measurement: This criterion pertained to the moment that the outcome was assessed in relation to the time period subjects were given to adapt to the prosthetic change. For this review, there was no adequate acclimation period for TF socket designs; therefore all studies attained "1"
- B9 – Outcome Measures: The outcome parameters should be adequate in relation to the purpose of the study, and they should have been collected with the use of a standardised protocol

Statistical Validity – C criteria

- C10 – Dropouts: The number of dropouts and the reason for dropping out had to be sufficiently reported. This criterion was scored "1" if no dropouts occurred or if they had been sufficiently reported. However, a dropout rate of more than 20% was considered insufficient and therefore scored "0"
- C11 – Sample Size: The sample size (n) in relation to the number of independent variables (K) was adequate if the ratio n:K exceeded 10:1. For this review – number of participants:the intervention
- C12 – Intention to Treat: Intention to treat analysis should be assessed in the case of dropouts
- C13 – Data Presentation: This criterion required that adequate point estimates and measures of variability were presented for the primary outcome measures

1. Piantadosi S. Clinical trials as experimental designs. Clinical Trials. A Methodological Perspective. 1997.

Inclusion Criteria	Exclusion Criteria
Published articles from peer-reviewed journals	Conference papers, white papers, theses or dissertations
Structured reviews, experimental trials, observational studies and surveys	Non-human subjects (material science, finite element studies)
Anything relevant or matches to the aim of research	Specifics on shape capture (CAD-CAM) or manufacture techniques
Transfemoral socket designs (Quad, IC, MAS, Sub-Ischial, HiFi, Socketless)	Specifics on interface pressure measurement or socket alignment
Biomechanics of transfemoral socket designs	Technical notes
History of design development, advantages and disadvantages of socket designs	Transfemoral prosthetics in developing countries
Objective/quantifiable outcome measures used	Osseointegration

Grade of Evidence	Criteria
A	Articles gaining at least 10 points or more: 6 points must be achieved from the A and B criteria (see **appendix A**) and timing of the measurement must have a positive score (criterion B8)
B	Articles with a total score between 6 and 9 points, including a positive score for timing of the measurement (criterion B8)
C	Articles with a total combined score of at least 6 from the A and B criteria (see **appendix A**) with an invalid score on the timing of the measurement (criterion B8)

Level of Evidence	Criteria
1	Randomised Trials
2	Non-Randomised Trials
3	Cohort Studies
4	Case Series/ Case Study
5	Expert Opinion

Author	A1	A2	A3	A4	A-score	B5	B6	B7	B8	B9	B-score	C10	C11	C12	C13	C-score	Total Score	Level of Evidence
Hachisuka et al. 1999 (36)	1	1	0	0	2	1	1	n/a	1	1	4	1	0	1	1	3	**9**	**2 (B)**
Gailey et al. 1993 (37)	1	0	0	1	2	1	1	n/a	1	1	4	1	1	1	1	4	**10**	**1 (A)**
Flandry et al. 1989 (33)	1	0	1	0	2	1	1	n/a	1	1	4	1	0	1	1	3	**9**	**2 (B)**
Gottschalk et al. 1989 (32)	1	1	0	0	2	1	1	n/a	1	1	4	1	1	1	1	4	**10**	**2 (A)**
Klotz et al. 2011 (38)	1	1	1	0	3	1	1	n/a	1	1	4	1	0	1	1	3	**10**	**1 (A)**
Fatone et al. 2014 (35)	1	0	1	1	3	1	0	n/a	1	1	3	1	0	1	1	3	**9**	**1 (B)**
Traballesi et al.2011 (39)	1	0	1	0	2	1	1	n/a	1	1	4	0	0	0	1	1	**7**	**2 (B)**
Brown et al. 2018 (34)	1	1	1	0	3	1	0	n/a	1	1	3	0	0	1	0	1	**7**	**4 (B)**

Author	A1	A2	A3	A4	A-score	B5	B6	B7	B8	B9	B-score	C10	C11	C12	C13	C-score	Total Score	Level of Evidence
Fatone et al. 2017 (41)	1	1	1	0	3	1	0	n/a	1	1	3	1	0	1	1	3	**9**	**4 (B)**
Kahle et al. 2014 (40)	1	0	1	1	3	1	1	n/a	1	1	4	1	1	1	1	4	**11**	**1 (A)**
Kahle et al. 2013 (21)	1	0	1	1	3	1	1	n/a	1	1	4	0	0	0	1	1	**8**	**1 (B)**
Klenow et al. 2017 (42)	1	1	1	0	3	1	1	n/a	1	1	4	1	0	1	1	3	**10**	**4 (A)**
Kahle et al. 2016 (43)	1	0	1	0	2	1	1	n/a	1	1	4	0	1	0	1	2	**8**	**3 (B)**

*A-Score, Selection of Patients; B-Score, Intervention and Assessment; C-Score, Statistical Validity.
Further information on Quality Grading System provided in Appendix A

Author	Population studied (no.)	Age, mean (SD) or [range]	Gender (M:F)	Level	Aetiology	K level	Years since amputation, mean (SD)	Years using prosthesis, mean (SD)	Residuum length, mean (SD)
Hachisuka et al. 1999[36]	12: 6 Quad 6 IRC	Quad: 38.8 (±14.2) IRC: 46.2 (±13.2)	Quad: (5:1) IRC: (6:0)	TF	Quad: 5 Trauma, 1 Atherosclerosis IC: 5 Trauma, 1 Atherosclerosis	Unknown	Quad: 3.9 (±5.6) IRC: 7.7 (±5.5)	Unknown	Ratio: Quad 0.67 (±0.11) IRC 0.7 (±0.14)
Gailey et al. 1993[37]	20: 10 Quad 10 IC	Quad: 34.6 (±9.83) IC: 37.2 (±11.03)	(20:0)	TF	Non-vascular pathology	K2 - K3?	Quad: 15.37 IC: 13.6	Quad 4.6 IC 1.61	Percentage: Quad: 0.61% IC: 0.63%
Flandry et al. 1989[33]	5	34.4	(5:0)	TF	4 Trauma 1 Infection	K2 - K3	Unknown	Quad: 3 months–9 years	Index: 0.40-0.89
Gottschalk et al. 1989[32]	50: 27 Quad 23 IC	[Quad: 17-70] [IC: 25-60]	Quad: (26:1) IC: (18:5)	TF	Quad: 12 Trauma, 15 PVD, IC: 16 Trauma, 7 PVD	Unknown	Unknown	Unknown	Unknown
Klotz et al. 2011[38]	4	51	(4:0)	TF	3 Trauma 1 Vascular	K3	Unknown (at least 5)	Unknown	Range: 22.5-32.5
Fatone et al. 2014[35]	6	[35-81]	(5:1)	TF	5 Trauma 1 Infection	Unknown	Range: 6 - 51	Unknown	Percentage: 32% - 46%

Author	Population studied (no.)	Age, mean (SD) or [range]	Gender (M:F)	Level	Aetiology	K level	Years since amputation, mean (SD)	Years using prosthesis, mean (SD)	Residuum length, mean (SD)
Traballesi et al. 2011[39]	7	33.9 (±9.3)	(6:1)	TF	6 Trauma 1 Sarcoma	K3 - K4	11 (±9.1)	Unknown (at least 5 years)	Unknown
Brown et al. 2018[34]	4	32	(4:0)	TF	Unknown	K4	Unknown	Unknown	Unknown
Fatone et al. 2017[41]	2	TF 29 KD 26	(2:0)	1TF, 1KD	TF Trauma KD Tumour	K3 - K4?	TF 9 KD 15	Unknown	Unknown
Kahle et al. 2014[40]	10	42.9 (±14.7)	(8:2)	TF	7 Trauma 1 Sarcoma 2 PVD	K2 - K4	8.3 (±10.1)	Minimum of 6 months	Percentage: 60.3% (±18.7),
Kahle et al. 2013[21]	9	41.2 (±14.5)	(7:2)	TF	7 Trauma 1 Sarcoma 1 PVD	K2 - K4	9.1 (±10.3)	Minimum of 6 months	Percentage: 57.0% (±16.5)
Klenow et al. 2017[42]	1	65	(1:0)	TF	Trauma	K3	Unknown	Unknown	Unknown
Kahle et al. 2016[43]	13	[26-58]	(11:2)	TF	Unknown	10 K3 3 K4	Unknown	14.4 [3-40]	Unknown

*Quad, Quadrilateral; IRC, Ischial-Ramal Containment; TF, TransFemoral; IC, Ischial Containment; PVD, Peripheral Vascular Disease; KD, Knee Disarticulation.

Author (Study design)	Socket design / Suspension	Comparators	Methods (Tools)	Prosthetist Qualifications/ Certifications	Acclimation
Hachisuka et al. 1999 (non-randomised controlled trial)[36]	**Quad** vs. **IRC** (SFS) / Unknown	Gait Biomechanics Metabolic Efficiency Subjective	• Position of femur – (CT) of every 2cm transverse slice between hip and upper thigh, participant lying supine • Gluteal medial muscle atrophy – areas of bilateral medial muscles measured (image analyser) • Hip adduction angle – (AP X-ray) of pelvis and femur, participant stood on one foot simulating mid-stance • Lateral socket stability – lateral GRF during mid-stance, participants walking at 'most comfortable speed' (walkway with force plate) • PCI calculation = HR at end of 3 min gait minus HR at rest (telemetric ECG) divided by velocity calculated as distance of 3 min gait at most comfortable speed • 6 self-assessment questions for participants and 3 specialist question completed by authors	Unknown 'experienced clinical prosthetist'	Unknown
Gailey et al. 1993 (randomised controlled trial)[37]	**Quad** vs. **IC** / CSS	Metabolic Efficiency	• Participants ambulated for 8 mins at 2 assigned speeds: normal speed 2.5mph and slower speed 1.25mph • HR (vantage performance monitor) and O2 (calibrated Horizon System II Metabolic Measurement Analyser and Hans-Rudolph non-rebreathing value) collected during steady-state ambulation in last 3 mins of each trial	Unknown 'patient wore own prescription sockets made by their own prosthetist'	Unknown

Author (Study design)	Socket design / Suspension	Comparators	Methods (Tools)	Prosthetist Qualifications/ Certifications	Acclimation
Flandry et al. 1989 (non-randomised crossover trial)[33]	**Quad** vs. **IC** (CAT-CAM, 3 acrylic resin, 2 flexible design frame) / CSS	Gait Biomechanics Metabolic Efficiency Subjective	• Converted from Quad socket to CAT-CAM • Position of femur – (AP X-ray) of pelvis and femur whilst free standing • Gait deviations – observation • Stride characteristics and coronal plane body torques – (insole sensors with compression closing switches/skin markers/walkway with force plate) • Cadence, HR and respiratory rates (telemetry equipment), O2 and CO2 gases (modified douglas bag system) collected whilst ambulating at unrestricted pace, data analysis based on last 19th minute of walking • Questionnaire – comfort, balance and stability	Unknown	2 x 2 weeks, 3 x 1 month
Gottschalk et al. 1989 (non-randomised controlled trial)[32]	**Quad**(hard/ flexible sockets) vs. **IC**(CAT-CAM, NSNA and narrow ML IC) / Unknown	Gait Biomechanics	• Position of femur – (AP X-ray) of femurs from hip to knee, anatomical alignment of normal/amputated femur measured on radiograph, length of amputated femur measured from middle of lesser trochanter • Overall socket alignment and angle of socket axis measured from midportion of socket on radiograph at three different levels then angle to the perpendicular measured • An analysis of variance was done, comparing the femur positions in the different sockets	Unknown	Unknown

Author (Study design)	Socket design / Suspension	Comparators	Methods (Tools)	Prosthetist Qualifications/ Certifications	Acclimation
Klotz et al. 2011 (randomised crossover trial)[38]	**Quad** vs. **IC** vs. **MAS** / CSS or Passive Suction	Gait Biomechanics	• Four experimental conditions: without a socket, with Quad socket, IC socket, MAS socket (all tests performed using only the socket no componentry) • Active hip flexion/extension/abduction/adduction tested • Joint amplitudes based on 30 secs of movements (skin markers/Elite system with 12 cameras) • Global amplitude = sum of all ROM	Unknown 'experienced and trained in various techniques'	Unknown
Fatone et al. 2014 (randomised crossover trial)[35]	**MAS** / CSS	Gait Biomechanics Subjective	• Participants walked at self-selected speeds in six randomly assigned IC/tissue loading socket conditions: IC and high; IC and medium; IC and low; no IC and high; no IC and medium; no IC and low • Walking speed, step width, max lateral trunk lean, coronal plane hip moments, trunk kinematics (skin markers/8 camera motion analysis system/walkway with 6 force plates) • SCS after each socket condition	Training from developer Marlo Ortiz through courses provided by the Orthotic and Prosthetic Group of America	Unknown

Author (Study design)	Socket design / Suspension	Comparators	Methods (Tools)	Prosthetist Qualifications/ Certifications	Acclimation
Traballesi et al. 2011 (non-randomised crossover trial)[39]	**IC** vs. **MAS** / Unknown	Metabolic Efficiency Subjective	• Tests performed first with IC then after 30 days of MAS use; last test carried out after 60 days of MAS use • HR, O2, CO2 and respiratory exchange ratio (portable gas analyser/HR monitor) collected whilst ambulating at self-selected speed • Test duration at least 7 mins with data collected during steady-state ambulation in last 2 mins of trial • PEQMS at first and last test	Unknown 'same experienced prosthetist'	30 days and 60 days
Brown et al. 2018 (case series)[34]	**IC** (CAT-CAM) vs. **Sub-Ischial** (NU-FlexSIV) / Passive Suction and VAS	Gait Biomechanics Physical Performance Subjective	• Converted from IC socket to NU-FlexSIV • Walking speed, sagittal hip ROM and maximal hip extension whilst walking over ground and on stairs (skin markers and 26 camera motion capture system) • Socket stability – coronal plane trunk ROM participant walked at a self-selected speed • Limb-socket displacement – (ML digital fluoroscopy) before/after walking on treadmill for 10 mins at standardised speed • 4SST, T-Test, and obstacle course – fastest time recorded of 2/3 repetitions • SCS assessed after accommodation time in each socket	In-person training, multimedia instruction manual and ongoing consultation from NU-FlexSIV socket developers	Ranged between 0 days to 9 weeks

Author (Study design)	Socket design / Suspension	Comparators	Methods (Tools)	Prosthetist Qualifications/ Certifications	Acclimation
Fatone et al. 2017 (case series)[41]	**IC** vs. **Sub-Ischial** (NU-FlexSIV) / CSS and VAS	Gait Biomechanics Physical Performance Subjective	• Converted from IC socket to NU-FlexSIV • Walking speed, step width, lateral trunk lean, sagittal plane hip ROM and coronal plane hip moment (skin markers/8 camera motion system with six force plates) • RSTS, 4SST, and T-Test – fastest time recorded of 2/3 repetitions • SCS assessed after accommodation time in each socket	Unknown	Unknown
Kahle et al. 2014 (randomised crossover trial)[40]	**IC** (CAT-CAM) vs. **Sub-Ischial** / VAS	Gait Biomechanics Physical Performance Subjective	• Two period crossover • Spatiotemporal parameters of gait – participants walked at self-selected speed (GAITRite walkway) • Limits of stability – Biodex balance SD system • 4SST recorded using a stopwatch • PEQ	ABCOP	2 days per socket design
Kahle et al. 2013 (randomised crossover trial)[21]	**IC** (CAT-CAM) vs. **Sub-Ischial** / VAS	Gait Biomechanics Subjective	• Two period crossover • Socket position – vertical/lateral socket movements, and coronal hip angle using (X-rays/fluoroscope) • Skin pressure – (Tekscan F-socket system) • Subjective protocol-specific form	ABCOP, Symmetry TFA VAS systems, Sabolich socket course, Ottobock elevated vacuum socket technology	2 weeks to test sockets initially then 2 days per socket for trials

Author (Study design)	Socket design / Suspension	Comparators	Methods (Tools)	Prosthetist Qualifications/ Certifications	Acclimation
Klenow et al. 2017 (case study)[42]	**IC** (CAT-CAM) vs. **HiFi** / VAS	Gait Biomechanics Subjective	• Spatiotemporal parameters, GRF, Hip ROM (8 camera Vicon Motion Capture system) • Oswestry v2.0 and WOMAC were administered at initial and secondary testing to evaluate perceived disability	ABCOP, Trained to fit HiFi system	30 days
Kahle et al. 2016 (retrospective cohort)[43]	**IC** vs. **HiFi** / Unknown	Physical Performance Subjective	• Gait speed – 2MWT • Risk of falls – ABC questionnaire	Unknown	Unknown (at least 30 days)

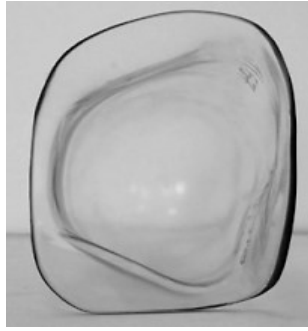
*Quad, Quadrilateral; IRC, Ischial-Ramal Containment; SFS, Scandinavian Flexible Socket; CT, Computed Tomograms; AP, Anteroposterior; GRF, Ground Reaction Force; PCI, Physiological Cost Index; HR, Heart Rate; ECG, Electrocardiograph; Min, minute; IC, Ischial Containment; CSS, Common Suction Socket; mph, miles per hour; O2, Oxygen; CAT-CAM, Contoured Adducted Trochanteric – Controlled Alignment Method; CO2, Carbon Dioxide; NSNA, Normal-Shape-Normal-Alignment; MAS, Marlo Anatomical Socket; ROM, Range of Motion; secs, seconds; PEQMS, Prosthetic Evaluation Questionnaire Mobility Section; VAS, Vacuum Assisted Suspension; 4SST, 4-Square-Step-Test; T-Test, T-Test of Agility; ML, Mediolateral; SCS, Socket Comfort Score; RSTS, Rapid-Sit-To-Stand; PEQ, Prosthetic Evaluation Questionnaire; ABCOP, American board for Certification in Orthotics, Prosthetics, and Pedorthics; TFA, Transfemoral Amputation; HiFi, High-Fidelity; Owestry v2.0, Owestry Low Back Pain Disability Questionnaire v2.0; WOMAC, Western Ontario and McMaster University Osteoarthritis Index; 2MWT, Two-Minute-Walk-Test; ABC, Activity-specific Balance Confidence Scale.

Comparators	Outcomes Measured
Gait Biomechanics	• Spatiotemporal parameters/Stride characteristics[33-35,40-42] • Coronal plane hip moment/ Hip adduction angle/Coronal hip angle/Coronal plane hip abduction torque[21,33,35,36,41] • Range of motion of the hip joint[34,38,41,42] • Socket stability[21,34,36,41] • Position of the femur/Relative femoral shaft inclination[32,33,36] • Limb-socket motion/Vertical movements[21,34] • Ground reaction force[36,42] • Skin pressure[21] • Gluteal medial muscle atrophy [36] • Observational gait analysis for gait deviations[33]
Metabolic Efficiency	• Cadence, HR, Respiratory Rates, O2 uptake and CO2 production[33,39] • HR and O2[37] • Physiological Cost Index[36]
Physical Performance Measures	• 4 Step Square Test[34,40,41] • Agility T-Test[34,41] • 2 Minute Walk Test[43] • Rapid Sit To Stand[41] • Limits of Stability[40] • Obstacle Course[34]
Subjective	• Socket Comfort Score[34,35,41] • Self-made Questionnaire[21,33,36] • Prosthetic Evaluation Questionnaire[34,40] • Prosthetic Evaluation Questionnaire Mobility Section[39] • Activity-specific Balance Scale[43] • Owestry Low Back Pain Disability Questionnaire v2.0[42] • Western Ontario and McMaster University Osteoarthritis Index[42]

*HR, Heart Rate, O2, Oxygen, CO2, Carbon Dioxide

Comparators	Outcomes Measured
Gait Biomechanics	• Spatiotemporal parameters/Stride characteristics[33-35,40-42] • Coronal plane hip moment/ Hip adduction angle/Coronal hip angle/Coronal plane hip abduction torque[21,33,35,36,41] • Range of motion of the hip joint[34,38,41,42] • Socket stability[21,34,36,41] • Position of the femur/Relative femoral shaft inclination[32,33,36] • Limb-socket motion/Vertical movements[21,34] • Ground reaction force[36,42] • Skin pressure[21] • Gluteal medial muscle atrophy [36] • Observational gait analysis for gait deviations[33]
Metabolic Efficiency	• Cadence, HR, Respiratory Rates, O2 uptake and CO2 production[33,39] • HR and O2[37] • Physiological Cost Index[36]
Physical Performance Measures	• 4 Step Square Test[34,40,41] • Agility T-Test[34,41] • 2 Minute Walk Test[43] • Rapid Sit To Stand[41] • Limits of Stability[40] • Obstacle Course[34]
Subjective	• Socket Comfort Score[34,35,41] • Self-made Questionnaire[21,33,36] • Prosthetic Evaluation Questionnaire[34,40] • Prosthetic Evaluation Questionnaire Mobility Section[39] • Activity-specific Balance Scale[43] • Owestry Low Back Pain Disability Questionnaire v2.0[42] • Western Ontario and McMaster University Osteoarthritis Index[42]

*HR, Heart Rate, O2, Oxygen, CO2, Carbon Dioxide




NORTHWESTERN


NORTHWESTERN