

Review

Transtibial prosthesis suspension systems: Systematic review of literature

H. Gholizadeh ^{*}, N.A. Abu Osman, A. Eshraghi, S. Ali, N.A. Razak

Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, Malaysia

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ABSTRACT

Background: Today a number of prosthetic suspension systems are available for transtibial amputees. Consideration of an appropriate suspension system can ensure that amputee's functional needs are satisfied. The higher the insight to suspension systems, the easier would be the selection for prosthetists. This review attempted to find scientific evidence pertaining to various transtibial suspension systems to provide selection criteria for clinicians.

Methods: Databases of PubMed, Web of Science, and ScienceDirect were explored to find related articles. Search terms were as follows: "Transtibial prosthesis (32), prosthetic suspension (48), lower limb prosthesis (54), below-knee prosthesis (58), prosthetic liner (20), transtibial (193), and prosthetic socket (111)". Two reviewers separately examined the papers. Study design (case series of five or more subjects, retrospective or prospective), research instrument, sampling method, outcome measures and protocols were reviewed.

Findings: Based on the selection criteria, 22 articles (15 prospective studies, and 7 surveys) remained. Sweat control was found to be a major concern with the available suspension liners. Donning and doffing procedures for soft liners are also problematic for some users, particularly those with upper limb weakness. Moreover, the total surface bearing (TSB) socket with pin/lock system is favored by the majority of amputees.

Interpretation: In summary, no clinical evidence is available to suggest what kind of suspension system could have an influential effect as a "standard" system for all transtibial amputees. However, among various suspension systems for transtibial amputees, the Iceross system was favored by the majority of users in terms of function and comfort.

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1. Introduction

A number of prosthetic suspension systems are available for transtibial amputees. Not only the amputee's functional needs, but also satisfaction with prosthesis should be taken into account when selecting an appropriate suspension system. The clearer the insight into suspension systems, the easier will be the selection for prosthetist (Eshraghi et al., 2012a; Gholizadeh et al., 2012a,b; Schaffalitzky et al., 2012; Zhang et al., 1998).

Non-use or limited use of prosthetic devices is a concern for any rehabilitation team. The provision of a good prosthetic suspension system is the key element in the rehabilitation process of persons with lower limb amputation (Garrison, 2003; Gholizadeh et al., 2012a,b; Kapp, 1999; Nelson et al., 2006; Schaffalitzky et al., 2012; Zhang et al., 1998). Excessive translation, rotation, and vertical movements between residual limb and socket should be prevented through the suspension system (Eshraghi et al., 2012b; Gholizadeh et al., 2011, 2012a,b,d; Klute et al., 2011; Smith et al., 2004). As amputees' statements and research findings suggest, suspension and prosthetic fit are strongly related to functional efficiency and comfort levels (Beil et al., 2002; Gholizadeh et al., 2012a). Walking pattern, residual limb soft tissue and skin, and comfort can be jeopardized by poor suspension (Gholizadeh et al., 2012a,b,d; Papaioannou et al., 2010; Peery et al., 2005; Smith et al., 2004).

The introduction of new designs and materials revolutionized the design of transtibial prostheses after World War II (Sewell et al., 2000). A thigh corset was used as suspension years prior to the introduction of the patellar-tendon bearing (PTB) prosthesis (Radcliffe et al., 1961). The PTB socket quickly became popular, and subsequently, various materials and suspension methods were applied (Sewell et al., 2000). Afterwards, the silicone suction suspension (3S) (Fillauer et al., 1989) and Iceross (Baars and Geertzen, 2005; Kristinsson, 1993) sockets were introduced to the market. These systems were characterized by improved techniques of suspension, total surface bearing (TSB), and hydrostatic loading (Sewell et al., 2000; Staats and Lundt, 1987).

Another popular suspension system in lower limb prostheses is the soft socket or liner that comes with accessories, such as a lock system that bonds to other prosthetic components (Gholizadeh et al., 2012a; Kristinsson, 1993). Although a number of prosthetic suspension systems are available, physicians and prosthetists set selection criteria mainly based on subjective experiences (van der Linde et al., 2004). Ideally, prosthetic prescription should follow the biomechanical characteristics to fulfill the amputees' needs. Clinical prescription guidelines should be provided for prosthetic suspension systems to ensure efficient and consistent health care. A systematic literature review may contribute significantly to the development of such guideline as it can bring knowledge gaps to light (van der Linde et al., 2004; Woolf et al., 1999). To the best of the authors' knowledge, there is no consensus over selection criteria and no sound technical guideline is available (Dasgupta et al., 1997; van der Linde et al., 2004).

* Corresponding author.

E-mail addresses: gholizadeh@um.edu.my, gholizadeh87@yahoo.com (H. Gholizadeh).

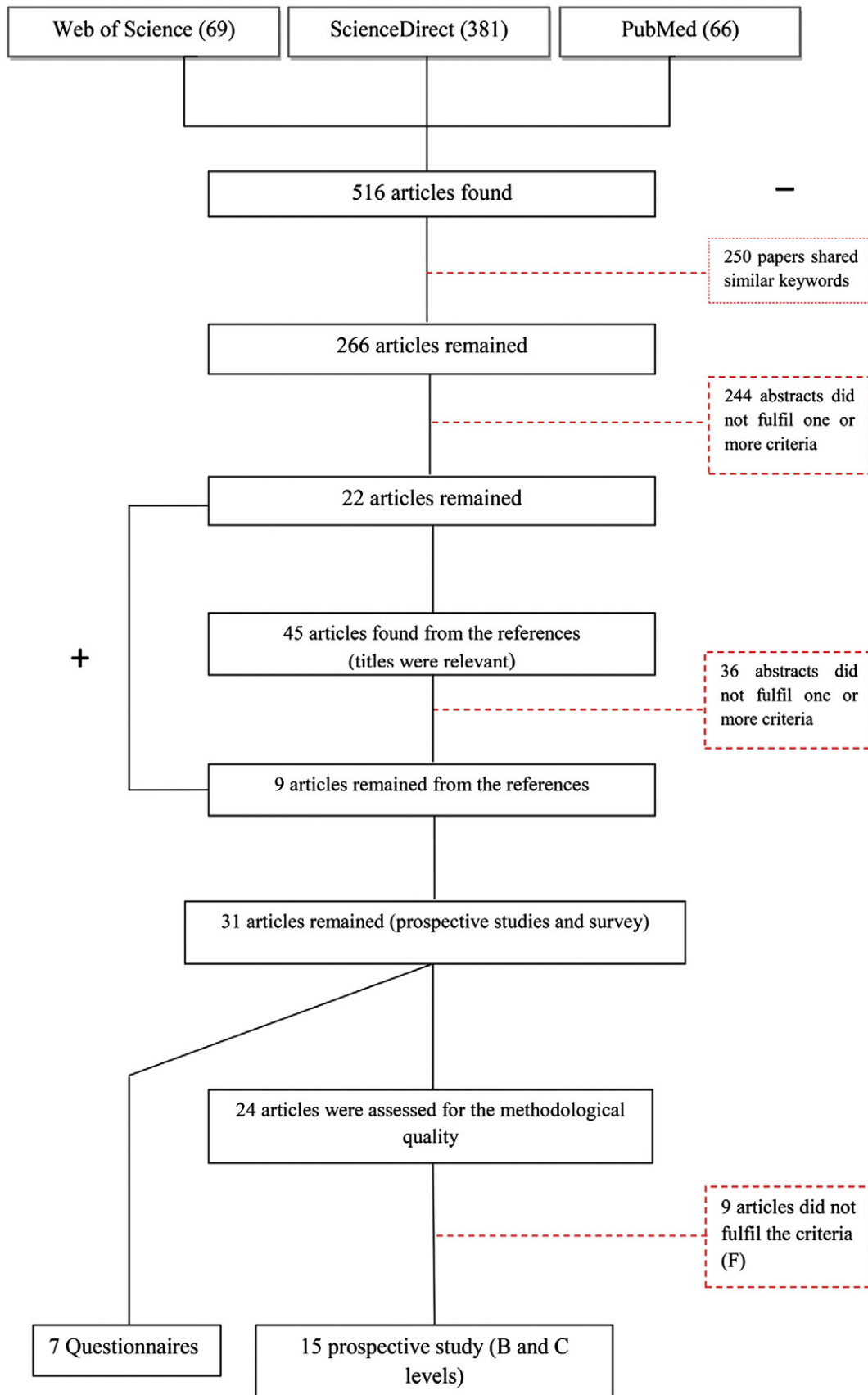


Fig. 1. Selection algorithm for this literature review.

The advantages and disadvantages of various transtibial suspension systems have been examined subjectively and objectively in the literature. This study aimed at reviewing the literature systematically to contribute to the development of a guideline for the current transtibial prosthesis suspension. Furthermore, the number of citations of previously published work is an indicator of its subsequent recognition and impact in an area of study and we were interested to determine the number of citation that each paper received and the journals with more publication in this field.

2. Methods

2.1. Search

Using the Web of Science, ScienceDirect, and PubMed databases, a systematic search was performed to find related research articles. The cut-off date was April 2013. The following keywords, as well as their combinations and synonyms, were used: transtibial prosthesis, prosthetic suspension, lower limb prosthesis, below-knee prosthesis, prosthetic liner, transtibial, and prosthetic socket. Related papers cited in the references were also checked.

2.2. Selection criteria

The systematic criteria were set to facilitate the selection of articles. The studies were included if they evaluated the transtibial prosthesis suspension system, were written in the English language, and aimed to provide insights into various suspension systems for transtibial prosthesis. Study design (case series of five or more subjects, retrospective or prospective), research instrument, sampling method, and outcome measures and protocols were reviewed (van der Linde et al., 2004). Prospective studies were preferred, but well-documented case series were accepted as well.

Subsequent to primary selection based on abstract, the authors assessed the quality of each paper through a 13-element checklist (Appendix A). The checklist was based on two available tools for quality assessment, primarily used to assess randomized controlled trials (van der Linde et al., 2004). Van der Linde et al. adapted the original checklist in their study so that it was also possible to be used for non-randomized controlled trials. In this study, we adopted the same checklist used by Van der Linde et al. with a minor change. As the amputees can easily identify the difference between the suspension systems when they want to wear the prosthesis, it is not feasible to do blinding in studies on suspension systems. Therefore, we excluded the item B7 regarding the blinding in our study (see the Appendix A) (van Tulder et al., 1997; Verhagen et al., 1998). Based on the score levels, a criterion was scored “0” if it is not applicable and “1” if applicable. Two reviewers separately examined the papers. In cases of discrepancy, a second review would be initiated to arrive at a consensus (van der Linde et al., 2004).

The studies were categorized as follows: (van der Linde et al., 2004)

- A-level: Those articles that gained at least 10 or more points; 6 points from the A and B criteria, and a positive score timing of the measurement (criterion B8).
- B-level: Those articles with a total score between 6 and 9, including a positive score for timing of the measurement (criterion B8).
- C-level: Those articles with a total score of at least 6 out of the A- and B-criteria with an invalid score on B8. Studies that achieved at least 6 out of 9 points for the A and B criteria were included in the review.

Finally, to find the number of citations that each paper had received by other researchers, we used the Google scholar databases.

Table 1
Number of papers based on the journal.

Journal name	Number of papers	Failed	Remained papers	
			Prospective study	Survey
Journal of Prosthetics and Orthotics	2	–	0	2
Occupational Medicine	1	1	0	0
American Journal of Physical Medicine & Rehabilitation	1	–	1	0
Medical Engineering & Physics	1	1	0	0
Clinical Biomechanics	3	–	3	0
Archive of Physical Medicine and Rehabilitation	5	–	3	2
Journal of Rehabilitation Research and development	9	5	4	0
Prosthetics and Orthotics International	9	2	4	3
Total	31	9	15	7

3. Results

3.1. Search results

A total of 516 research papers were identified, among which 250 were similar in terms of different keywords and databases (Fig. 1). We assessed the title and abstract of every study. Some of the 266 papers were related to upper limb or above-knee prosthetics, applied computational models, or case study and were thus excluded. In this stage, 22 related papers remained. An additional 45 papers were found from the references, and following the abstract check, only nine papers were found suitable. Finally, 31 papers were selected for this systematic review. Seven out of 31 papers were survey studies (Ali et al., 2012a; Cluitmans et al., 1994; Datta et al., 1996; Ferraro, 2011; Hachisuka et al., 2001; Van de Weg and Van der Windt, 2005; Webster et al., 2009), and the rest of the articles were chosen as basis for the evaluation of the methodological quality (Table 1, Fig. 1). Five articles were classified as A-level (Boutwell et al., 2012; Coleman et al., 2004; Eshraghi et al., 2013; Selles et al., 2005; Yigiter et al., 2002), nine articles were classified as B-level (Ali et al., 2012b; Åström and Stenström, 2004; Brunelli et al., 2013; Eshraghi et al., 2012b; Gholizadeh et al., 2012b,c; Hachisuka et al., 1998; Klute et al., 2011; Wirta et al., 1990) one paper was classified as a C-level (Board et al., 2001), and nine papers

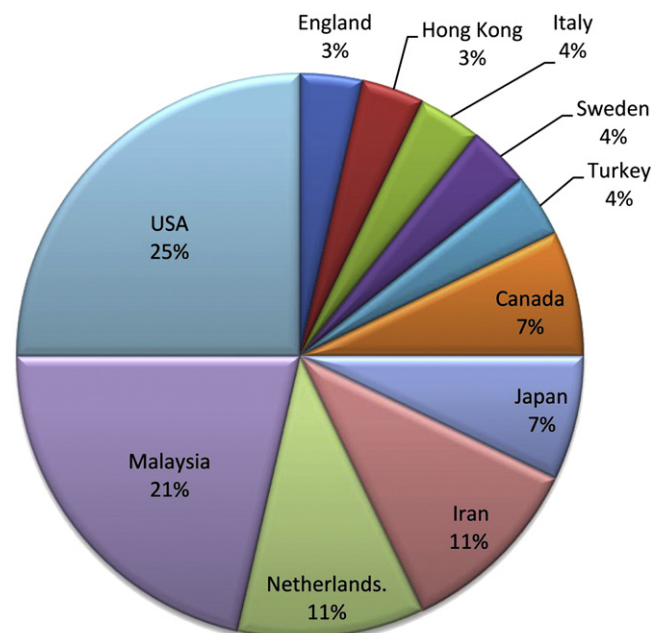


Fig. 2. Number of papers (%) from different countries.

Table 2
Methodological assessment of reviewed studies on the prosthetic suspension system sorted in ascending order according to the year of publication.

Author/s	Journal	Year, page	Times cited ^b	Outcome measures	Subjects (reason, level of amputation, sex, age, activity level)	Selection of patients					Intervention and Assessment					Statistical validity					Total score	Level of evidence	
						A1	A2	A3	A4	A-score	B5	B6	B7 ^c	B8	B9	B-score	C10	C11	C12	C13			C-score
Wirta et al. (1990)	Journal of Rehabilitation Research and development	1990, 385–396	17	Pistoning of stump in socket, knee flexion–extension, harmonic ratios (gait symmetry), subjective responses, suspension discrimination	Cause of amputation? ^a TT, 15 males, 5 females, 49 (23–76), K2–3	1	1	1	0	3	1	1	–	1	1	4	0	1	0	1	2	9	B
Hachisuka et al. (1998)	Archive of Physical Medicine and Rehabilitation	1998, 783–789	29	Donning and doffing, ease of swing, pain during walking, knee flexion and extension, pistoning during walking, skin irritation, perspiration, odor, staining of the socket, appearance and durability of the socket	Trauma 21, diabetic gangrene 4, vascular disease 3, other 4, TT, 27 males, 5 females, 44.5 (16), K? ^a	1	0	1	0	2	1	1	–	1	1	4	0	1	0	1	2	8	B
Board et al. (2001)	Prosthetics and Orthotics International	2001, 202–209	48	Volume changes, pistoning between the bone and socket, gait symmetry, step length, stance duration	Trauma, TT, 11, 45 (32–64), K?	1	1	1	1	4	1	1	–	0	1	3	0	1	0	1	2	9	C
Yigiter et al. (2002)	Prosthetics and Orthotics International	2002, 206–212	18	Balance, socket volume, pistoning, temporal–distance characteristic (step length (cm), stride length (cm), step width (cm)), free cadence (step/min), fast cadence (step/min), walking velocity (cm/s), stride length/lower limb length	Trauma, TT, 13 males, 7 females, 27.8 (7), K2–3	1	1	1	1	4	1	1	–	1	1	4	0	1	0	1	2	10	A
Coleman et al. (2004)	Journal of Rehabilitation Research and development	2004, 591–602	16	PEQ, residual limb volume, step activity, pain, socket comfort, daily ambulatory function, physical changes, subject preference and feedback	Trauma, TT, 10 males, 3 females, 49.4 (9.6), K2–3	1	1	0	1	3	1	1	–	1	1	4	1	1	1	1	4	11	A
Åström and Stenström (2004)	Prosthetics and Orthotics International	2004, 28–36	10	Self-administrated questionnaire, gait symmetry index, temporal and stride variables (speed, step time, single support, step length), kinematics variables (knee extension–flexion–knee load response, knee varus–valgus, knee rotation), interview	Trauma (15), tumor (1), infection (2), diabetes (3), Other (8), TT, 24 males, 5 females, 39 (7–78), K2–3	1	1	0	0	2	1	1	–	1	1	4	0	1	0	1	2	8	B
Selles et al. (2005)	Archive of Physical	2005, 154–161	19	Gait evaluation (walking speed, stride frequency, stride length	Trauma, disease, PVD, TT, 26 (12TSB,	1	1	0	1	3	1	1	–	1	1	4	1	1	1	1	4	11	A

	Medicine and Rehabilitation			(m), swing asymmetry, stride length asymmetry), economic variable [cost, cpo time for delivery (h),CPO time after delivery, delivery time, visits for delivery, visits after delivery, total visits], prosthesis function, activity monitoring, PEQ	14PTB), TSB 67.6 (13.5), PTB 57.9 (15.6), K? ^a																		
Klute et al. (2011)	Archive of Physical Medicine and Rehabilitation	2011, 1570–1574	5	Activity level, residual limb volume before and after a 30-minute treadmill walk, pistoning, and PEQ	Trauma 4, vascular 1, TT, 5, 56(9), K? ^a	1	1	0	1	3	0	1	–	1	1	3	1	0	0	0	1	7	B
Gholizadeh et al. (2012c)	Clinical Biomechanics	2012, 34–39	6	Pistoning between the liner and socket (static positions)	Trauma and diabetes, TT, 6 males, 43 (16.5), K2–3	1	0	1	0	2	1	1	–	1	1	4	0	0	0	1	1	7	B
Boutwell et al. (2012)	Journal of Rehabilitation Research and development	2012, 227–240	2	Skin–liner interface, walking speed (m/s), vertical GRF loading peak (% BW), timing of vertical GRF loading peak (% GC), fore-aft GRF braking peak (% BW), timing of fore-aft GRF braking peak (% GC), stance-phase knee flexion (°), pelvic obliquity ROM (°), questionnaire	Trauma, disease, PVD, TT, 4 males, 7 females, 55.9 (8.9), K? ^a	1	1	0	0	2	1	1	–	1	1	4	1	1	1	1	4	10	A
Gholizadeh et al. (2012b)	Journal of Rehabilitation Research and development	2012, 1321–1330	2	Pistoning between the liner and socket, PEQ	Trauma, diabetes, TT, 10 males, 45.8 (14.4), K2–3	1	0	1	0	2	1	1	–	1	1	4	0	1	0	1	2	8	B
Eshraghi et al. (2012b)	American Journal of Physical Medicine & Rehabilitation	2012, 1028–1038	1	Pistoning between the liner and socket (static positions), PEQ	Trauma, diabetes, TT, 10 males, 42(12.8), K2–3	1	0	1	0	2	1	1	–	1	1	4	0	1	0	1	2	8	B
Ali et al. (2012b)	Clinical Biomechanics	2012, 943–948	0	Skin–liner interface pressure, PEQ	Trauma, diabetes, TT, 7 males, 2 females, 49.3 (15), K2–3–4	1	0	1	0	2	1	1	–	1	1	4	0	0	0	1	1	7	B
Brunelli et al. (2013)	Prosthetics and Orthotics International	2013, 1–9	0	Pistoning (static positions), (level walking and treadmill) (metabolic data), PEQ, Timed Up & Go Test; HSQ; LCI:	Trauma, vascular, infection, TT, 10 males, 44.9 (9.5), K3–4	1	1	0	0	2	1	1	–	1	1	4	0	1	0	1	2	8	B
Eshraghi et al. (2013)	Clinical Biomechanics	2013, 55–60	0	Skin–liner interface pressure	Trauma, diabetes, TT, 9 males, 3 females, 46.8 (12.3), K2–3	1	0	1	0	2	1	1	–	1	1	4	1	1	1	1	4	10	A

TT = transtibial; PEQ = Prosthesis Evaluation Questionnaire; HSQ = Houghton Scale Questionnaire; LCI = Locomotors Capability Index; PVD = Peripheral Vascular Disease; CPO = Certified Prosthetist and Orthotist; TSB = total surface bearing; PTB = patellar tendon bearing; K-level = (K1, 2, 3, 4); BW = Body Weight; GC = Gait Cycle; GRF = Ground Reaction Force.

^a It is not clear (the authors did not mention in the article).

^b Based on Google scholar.

^c As the amputees can easily identify the difference between the suspension systems when they want to wear the prosthesis, it is not feasible to do blinding in studies on suspension systems. Therefore, we excluded the item B7 regarding the blinding in our study.

failed (F). The major distinction between the studies of B and C-levels was the negative score for time to adapt with prosthesis (criterion B8) (van der Linde et al., 2004). The majority of the papers in this literature review were from the United States and Malaysia (Fig. 2).

The highest citation (48) was for Board et al. (2001) published in the journal of Prosthetics and Orthotics International. Six out of 22 papers were published in 2012. The highest number of participants in the prospective studies was 32 (Hachisuka et al., 1998), and the lowest was five (Klute et al., 2011).

The number of subjects used in the survey studies ranged from 13 (Ferraro, 2011) to 243 (Ali et al., 2012a). Although individuals with unilateral and bilateral amputation were included, the participants were mostly unilateral. Trauma was the main cause of amputation; however, tumor, diabetes, disease, infection, and congenital limb deficiencies were also listed (Tables 2, 3, and 4).

Eight out of the 15 prospective studies evaluated the suspension system in terms of vertical movement or pistoning inside the socket, between the soft liner and socket, or between the skin/bone and socket (Board et al., 2001; Brunelli et al., 2013; Eshraghi et al., 2012b; Gholizadeh et al., 2012b,c; Klute et al., 2011; Wirta et al., 1990; Yigiter et al., 2002). A range of imaging methods, including motion analysis system and radiography, was applied to assess the bone/skin/liner position within the prosthetic socket. In some studies, gait was simulated to measure pistoning (Board et al., 2001; Brunelli et al., 2013; Eshraghi et al., 2012b; Gholizadeh et al., 2012c; Yigiter et al., 2002) and in others, suspension was investigated through real gait experiments. The transtibial prostheses used were mainly TSB.

The suspension systems used in the prospective studies are as follows (Table 3):

- TSB socket with pin/lock systems that uses Dermo liner, TEC liner, Alpha liner (3, 6, and 9 mm), elastomeric gel liner, and ICEX system (Manucharian, 2011)
- TSB socket with suction or vacuum system that uses seal-In X5 liner, polyurethane liner, and neoprene sleeve
- TSB socket with magnetic lock system.

PTB and KBM (Selles et al., 2005) sockets that use different suspension system (i.e., Supracondylar, suprapatellar (SCSP), supracondylar (SC), PTB socket with Cuff (PTB/C), PTB socket with waistband and cuff (PTB/WB), PTB socket with figure-of-eight suprapatellar strap (PTB/F8), rubber sleeve (RS), articulated supracondylar wedge (ASCW)).

The Prosthesis Evaluation Questionnaire was the main tool used in the prospective studies. The suspension systems used in the survey studies are as follows (Table 4):

- TSB socket with pin/lock system (i.e., Iceross liner, Fillauer liner, and polyurethane liner)
- TSB socket with suction or vacuum system
- Osseointegration.

4. Discussion

We searched the Web of Science, PubMed, and ScienceDirect databases for relevant papers for studies on transtibial prosthetic suspension systems. Our main intention was to look for the advantages and disadvantages of suspension systems in the literature. Several systems are commonly used for transtibial prostheses, such as TSB socket (i.e., pin/lock, magnetic lock, suction, or vacuum system), and PTB and KBM (Kondylen-Bettung Münster) sockets (i.e., SCSP, SC, Cuff, Waistband, figure of 8 suprapatellar strap, rubber sleeve, and articulated supracondylar wedge) with or without polyethylene soft insert (i.e., Pelite). The studies also revealed the latest developments in osseointegration, which enables the direct connection of the residual limb to prosthetic components.

Google scholar database was used to find the number of citation for each paper as this database covers most peer-reviewed and non-peer reviewed journals compared to other citation indexes (Scopus, and

Web of Science) (Farhadi et al., 2013). This number shows how many times these papers (results) were taken into account by other researchers and it is dependent on the year of publication. Ten out of 22 papers were published between 2011 and 2013 (until April). This may show that research on the transtibial suspension systems has grown recently and could be a reason for receiving less citation. The majority of the papers in this literature review were from the United States and Malaysia based on our criteria used in this systematic review.

Prosthetists need to decide whether a suspension system is suitable or not for various residual limb conditions such as residual limb length, shape (i.e., cylindrical or conical), muscle strength, soft tissue, bony prominence, pain, aspiration of amputee, level of activity, upper limb strength, and amputees' budget. However, no conclusive evidence has been offered that can define clearly which suspension system is the best for transtibial amputees.

4.1. Prospective studies

We did not apply B7 (blinded outcome assessor—Appendix A) for evaluating the studies on suspension systems. It can be attributed to the research design as such design cannot facilitate the conduct of a blind study. When the amputees want to wear the prosthesis, they can easily identify the difference between the suspension systems. This situation could have created respondent bias. However, in other studies on knee joint or foot, performing a blind test was easy (Boonstra et al., 1995, 1996; Postema et al., 1997) and the researcher easily covered the components.

Measurement of pistoning or vertical movement inside the socket is a good indicator of the quality of a suspension system in transtibial prosthesis (Board et al., 2001; Bocobo et al., 1998; Eshraghi et al., 2012b; Gholizadeh et al., 2012a,b,c; Klute et al., 2011; Lilja et al., 1993; Madsen et al., 2000; Newton et al., 1988; Sanders et al., 2006; Stiefel et al., 2009; Street, 2006). Suction or vacuum suspension systems can diminish the displacement of the stump inside the socket, unlike the pin/lock or the use of sleeve (Arndt et al., 2011; Brunelli et al., 2013). Consequently, solidity between the residual limb and socket is increased, and gait asymmetry and skin sores are reduced (Grevsten and Erikson, 1975; Rusaw and Ramstrand, 2011; Sanderson and Martin, 1997). Furthermore, suction or vacuum systems, which employ a Seal-In liner or cushion liner and sleeve can decrease pain at the distal end of the residual limb, specifically for the bony residual limbs (Gholizadeh et al., 2012d). Studies show that amputees have less pain during the stance phase as these liners have a softer distal end compared to the pin/lock system. Moreover, the milking problem (distal tissue stretching) of the pin/lock system is decreased during the swing phase (Beil and Street, 2004; Eshraghi et al., 2012b, 2013). Distal tissue stretching can lead to pain, especially at the cut end of the tibia and along the tibial crest (Krosin, 2004). Vacuum suspension increases the stump volume by 3.7% (Board et al., 2001). Nevertheless, the tasks of donning and doffing are more difficult to perform when suction or vacuum systems are used rather than the pin/lock systems or PTB prosthesis, particularly for older amputees or for those with upper limb problem such as stroke patients (Ali et al., 2012a; Eshraghi et al., 2012b; Gholizadeh et al., 2012b,c,d). Easy donning and doffing are very important in relation to the night time toilet habits of amputees. Moreover, fabricating proper suction and vacuum systems requires more time than that of PTB and TSB with the pin/lock system (Klute et al., 2011). Fewer check sockets and/or less time is required to achieve sufficient fit. Furthermore, proper suction and vacuum systems are not a good choice for amputees who have fluctuation in their stumps.

Compared to the pin/lock system, the new magnetic lock has been shown to partly resolve the milking phenomenon (Eshraghi et al., 2012b). The pistoning measurements reveal values comparable with those of the pin/lock system. However, a suction system with a Seal-In liner causes less pistoning. Prosthetic users preferred the magnetic

Table 3

Main findings from the reviewed studies (prospective) on the prosthetic suspension system.

Author/s	Prosthetic suspension system	Other prosthetic components	Findings	Level of evidence
Wirta et al. (1990).	SCSP, SC, (PTB/C, PTB/WB, PTB/F8, RS), articulated supracondylar wedge ^a	Polyethylene foam liner and SACH foot	Pistoning was correlated poorly with the shape and length of the residual limb. There was no relation between pistoning and walking velocity. Conical residual limbs exhibited less pistoning than cylindrical ones. There was no correlation between the knee flexion–extension deviations with harmonic ratios or pistoning. The longer and the cylindrical-shaped residual limb associated with the higher harmonic ratios.	B
Hachisuka et al. (1998)	PTB, KBM, TSB	Seattle foot or Flex Walker II	Perspiration was not a concern with the Fillauer liner. Iceross increased perspiration in eleven subjects, but it decreased after some weeks or months or usage. The TSB and PTB sockets did not demonstrate difference in vapor penetrability. The majority of below-knee amputees preferred the TSB prosthesis due to higher comfort.	B
Board et al. (2001)	TEC interface systems (urethane liners and suspension sleeves) with one-way valve, TEC interface systems with electric vacuum pump	SACH foot, Flex foot	Approximately 6.5% of the limb volume was lost during walking. However, vacuum resulted in average of 3.7% of volume gain. A higher negative pressure was resulted from the vacuum during the swing phase. Also, the limb and tibia moved axially 4 and 7 mm less, respectively.	C
Yigiter et al. (2002)	PTB and TSB sockets	Dynamic foot	The step length at amputated side showed a decrease in the TSB socket compared to the PTB socket. The amputated side tolerated more weight. The TSB socket also resulted in improved balance that was found to be better than the PTB in both eyes-opened and closed conditions. Performance time was less during walking with TSB socket	A
Coleman et al. (2004)	Alpha® elastomeric gel liner with locking pin suspension versus Pelite liner with neoprene sleeve	–	Pelite™ system was favored over the Alpha® in ambulation. Pain, satisfaction, and comfort showed no differences. Ambulatory intensity profiles showed no significant change.	A
Åström and Stenström (2004)	Polyurethane concept (TEC interface), previous suspension used by the subjects (Iceross, vacuum, and EVA)	–	Twenty out of 29 amputees still used the polyurethane liner after five years. Nineteen participants indicated it to be the best system they had used. The polyurethane liner increased comfort and the physical activity and it remained unchanged for five years.	B
Selles et al. (2005)	ICEX (TSB) versus PTB socket	–	Both ICEX TSB and the PTB socket resulted in similar functional outcomes (ADL, patient satisfaction, and gait characteristics) and equal prosthetic mass. The economic variables were significantly different. The initial fitting process and fabrication of the TSB socket was significantly shorter, but more expensive. Patients' perceptions regarding the sockets did not differ. The PTB group demonstrated a higher activity level of activity at baseline.	A
Klute et al. (2011)	The VASS (custom urethane TEC liner or polyurethane Liner), harmony sleeve, harmony vacuum pump, the pin suspension system (Alpha Spirit, uniform, 6-mm-thick liner with integrated locking pin)	Seattle Light foot	Limb pistoning reduced with the VASS. The participants preferred the pin/lock system and they could take almost half as many steps as pin/lock with the VASS. The pin/lock suspension required fewer check sockets and a shorter time to acquire an adequate fit.	B
Gholizadeh et al. (2012c)	Seal-In X5 liner with valve, Dermo liner with shuttle lock (Icelock).	Talux foot	Significant difference was seen between the two liners. Pistoning with the Seal-In X5 was 71% less than the Dermo liner. Significant difference was also found under different static conditions. The Seal-In liner was more difficult for donning and doffing but the pistoning was less. Two out of 6 subjects preferred the Seal-In liner.	B
Boutwell et al. (2012)	Alpha® gel liners—3 and 9 mm thickness	Otto Bock 1D35 foot	The socket pressure was more uniformly distributed with the thicker gel liner. However, the thicker gel liner did not increase the walking speed. The subjects experienced higher instability while walking with the thicker liner. The loading peak value of the vertical GRF significantly increased with the 9 mm liner. The perceived comfort was increased with the thicker liner and most of the participants preferred that over the thinner liner.	A
Gholizadeh et al. (2012b)	Seal-In X5 liner with valve (Icelock Expulsion Valve 551, Össur) and Dermo liner with shuttle lock (Icelock Clutch 4H 214, Össur)	Talux foot	The Dermo liner showed higher pistoning values than the Seal-In X5 liner throughout the gait cycle ($P < 0.05$). Based on the PEQ, overall patient satisfaction was higher with the Dermo liner. Nevertheless, the Dermo liner caused higher pain and pistoning. The subjects were more satisfied with the socket fit of the Seal-In X5 but it was more difficult to don & doff the liner. No traction was experienced at the end of the liner.	B
Eshraghi et al. (2012b)	Seal-In X5 liner with valve, Dermo liner with shuttle lock (Icelock), Magnetic lock system	Talux foot	The suction system exhibited the lowest pistoning. Similar peak pistoning values were observed for the new magnetic lock and the pin/lock system ($P = 0.086$). Significantly higher satisfaction rates were revealed with the new system in walking, stair negotiation, donning and doffing, uneven walking, and overall satisfaction ($P < 0.05$). Prosthetic suspension was found compatible between all three systems. Fewer problems were reported with the new magnetic lock.	B
Ali et al. (2012b)	Seal-In X5 liner with valve (Icelock Expulsion Valve 551, Össur) and Dermo liner with shuttle lock (Icelock Clutch 4H 214, Össur)	Talux foot	The Dermo liner caused less interface pressure within the socket and less problems were perceived by the subjects. Better suspension was resulted with the Seal-In X5 liner.	B
Brunelli et al. (2013)	Seal-In X5 liner, suction suspension system with sleeve	Springlite foot, styrene gel liner, polyurethane	Pistoning was significantly reduced by the hypobaric Iceross Seal-In® X5. The energy cost of walking and functional mobility showed no statistical changes.	
Eshraghi et al. (2013)	Seal-In X5 liner with valve (Icelock Expulsion Valve 551, Össur) and Dermo liner with shuttle lock (Icelock Clutch 4H 214, Össur), new magnetic lock system	Talux foot	The new magnetic suspension system resulted in reduced pressure within the socket, especially during swing. During stance, all the three systems demonstrated higher peak pressure magnitudes at the anterior socket than the posterior. However, during one gait cycle, even pressure distribution was seen at the medial, lateral and posterior surfaces.	A

^a (SCSP): Supracondylar, suprapatellar; (SC): supracondylar; (PTB/C): PTB socket with cuff; (PTB/WB): PTB socket with waistband and cuff; (PTB/F8): PTB socket with figure-of-eight suprapatellar strap; (RS): Rubber sleeve; (ASCW): articulated supracondylar wedge; (PTB): patellar tendon bearing; (TSB): total surface bearing; (KBM): (Kondylen-Bettung Münster).

Table 4
Main clinical findings of the reviewed studies (survey) on the prosthetic suspension system.

Author/s	Journal	Year, page	Times cited	Outcome measures	Subjects (reason & level of amputation, gender, age, activity level)	Prosthetic suspension	Result (outcome)
Ali et al. (2012a)	Archive of Physical Medicine and Rehabilitation	2012, 1919–1923	0	PEQ (satisfaction) (fitting, donning and doffing, sitting, walking, uneven walking, stair satisfaction, suspension satisfaction, cosmetic, overall satisfaction with prosthesis), problems (sweat, wound, irritation, pistoning, rotation, inflation, smell, sound, pain)	Trauma, TT, 243 males, 44 (6.2), K2–3–4	Seal-In liner, silicone liner with shuttle lock, and Pelite liner	Donning and doffing were easier for those amputees that used the polyethylene and pin/lock liners in comparison to the Seal-In liner. The most durable system was the polyethylene liner. The Seal-In liner demonstrated higher satisfaction parameters than the pin/lock and the polyethylene foam liner. In addition, fewer problems were experienced with the Seal-In liner.
Hachisuka et al. (2001)	Archive of Physical Medicine and Rehabilitation	2001, 1286–1290	16	Hygiene problems (perspiration, eruptions, itching, odor) and explanatory values include TSB use, daily life activity, and washing of limb and prosthetic	Trauma 49, tumor 10 PVD 11, diabetic 12, congenital 1 TT, 65 males, 18 females, 53.4 (14.4), K2–3–4	Iceross (44) 3S (31) Fillauer Silicone Suspension Liner (8)	Males had more problems with perspiration than females. There was direct correlation between the perspiration and hours of use. Skin problems had direct association with age. However, itching and odor became less with age. Active subjects had higher itching problem. Perspiration, itching, odor, and skin breakdown were associated with residual limb hygiene and silicone liner in over 40% of participants with the TSB socket and silicone liner
Van De Weg and Van Der Windt (2005)	Prosthetics and Orthotics International	2005, 231–239	9	PEQ, fit of prosthesis (comfort to wear), ability to don and doff prosthesis, ability to sit with prosthesis, ability to walk with prosthesis, ability to walk on uneven terrain, ability to walk up and down stairs, appearance of prosthesis sweating, wounds/ingrown hairs/blisters, skin irritations, painful stump, swelling stump, unpleasant smells, unwanted sounds	Vascular 83, trauma 93, other (congenital deformities, infection, etc.), 33 unclear 11, TT, 132 males, 88 females, 62.1 (17.5), K? ^a	Pelite, silicone, and polyurethane liners	Some inherent weaknesses of liners first remain to be solved. In developing countries in particular, with high durability and low cost, a prerequisite, PTB or PTB-related prostheses might continue to be the first choice. Most of the literature originates from industrialized nations, which may explain any bias towards technological advances
Christie Ferraro (2011)	Journal of Prosthetics and Orthotics	2011, 78–81	3	ABC scale (stability during activities and the probability of future falls, overall comfort, skin issues, volume fluctuations, ease of knee flexion, perceived pistoning, and activity level)	Reason for amputation?, TT, TF, 13 subjects, age? ^a , K2–3–4	Pin/lock suspension, vacuum suspension	Patients stated decreased pistoning with vacuum systems in comparison to pin/lock suspension. Pin/lock liners caused higher skin problems including blister compared with the vacuum. Blisters may be experienced with vacuum suspension in the case of an air gap or improper fit. The lack of blisters may be taken as evidence that the newer vacuum suspension sockets fit the patients properly. Increased activity levels in some patients wearing vacuum systems.
Datta et al. (1996)	Prosthetics and Orthotics International	1996, 111–115	27	Use of waking aids (indoor–outdoors– rough ground–bad weather), pain, skin breakdown, sweating, comfort (wearing, walking, donning and doffing, maintenance, stair)	Trauma, diabetes, other, TT, 54 subjects, 48.3, K? ^a	Pelite (PTB) and Iceross	Use of the Iceross resulted in significant increase in sweating after the three weeks. But afterwards there was no significant difference between the Iceross and PTB. Participants were more satisfied with the Iceross in terms of comfort in stairs negotiation. But they stated increased sweating, skin rash and itching with the Iceross. However, some reported easier wash of the Iceross.
Cluitmans et al. (1994)	Prosthetics and Orthotics International	1994, 78–83	34	Duration of old prosthesis use, problems with old prosthesis, donning and doffing, ease of maintenance, hygiene, suspension, standing, getting up, walking, necessity of walking aid, walking speed and distances, walking on uneven surfaces, climbing, cycling, getting in and out of the car, and final verdict of patient. Perspiration, itching, soreness, local pressure,	Trauma, vascular, other, TT, male, female, 35–70, K? ^a	Iceross with KBM and PTB sockets	When the suspension system was changed to silicone roll-on socket, the subjects initially complained of itching, more perspiration, and soreness. The participants stated discomfort at the popliteal area when using Iceross. Blisters were also a concern, especially at the proximal edge of the liner. The majority of participants did not indicate any complication for

Table 4 (continued)

Author/s	Journal	Year, page	Times cited	Outcome measures	Subjects (reason & level of amputation, gender, age, activity level)	Prosthetic suspension	Result (outcome)
Webster et al. (2009)	Journal of Prosthetics and Orthotics	2009. 215–222	8	creasing at the back of knee during knee flexion Ambulation distance, use of assistive devices, ability to use prosthesis, employment status, prosthesis for work activities, prosthesis interfering with work, (Advantages) prosthetic function, walking ability, easy and quick attachment, activity level and lifestyle, attachment and suspension, comfort, skin breakdown, risk of infection, potential for limited activity due to failure, (Disadvantages) risk of bone fracture, potential to lose more residual limb, multiple surgeries, presence of percutaneous rod, bent or broken implant, long-term antibiotic use, need to avoid running	Trauma, diabetes, other, TT, TF, 56 transtibial (39 males, 17 females), transfemoral (14 males, 1 female), age (18–65), K? ^a	Osseointegration	donning & doffing. However, a few found it difficult, particularly for quick wear in the middle of night to reach the toilet. Vision-impaired subjects preferred the shuttle lock over the conventional Pelite. The Iceross improved suspension and function significantly. The study found addressing some problems with this new method such as infection problem, failure of implant and extended rehabilitation procedure with the osseointegration will be essential to improve prescription and acceptance of this system by amputees. (Advantages) The subjects who were more satisfied with this new system stated 92% prosthetic function was improved, 88% walking ability, 83% Easy and quick attachment, 79% activity level, 75% decrease pain, 50% less skin problems, 79% better suspension, and 67% improved feeling of the prosthesis. (Disadvantages) The subjects who were not satisfied with osseointegration mentioned: 75% risk of infection increased, 65% potential for limited activity, 35% difficult for running, 50% more antibiotic use, 56% need more operation (surgery), 65% need longer rehabilitation period, 63% increased risk of fractures, 52% implant problem (broken or bent)

TT = transtibial; PEQ = Prosthesis Evaluation Questionnaire; PVD = Peripheral Vascular Disease, TSB = total surface bearing; PTB = patellar tendon bearing; K-level = (K1, 2, 3, 4); ABC = Activity Balance Confidence.

^a It is not clear (the authors did not mention in the article).

lock over the pin/lock and Seal-In liner in terms of donning and doffing (Eshraghi et al., 2013).

This literature review reveals that thicker liners are more comfortable and can distribute the pressure more evenly over residual limbs. However, amputees' instability is increased during walking (Boutwell et al., 2012). The TSB socket allows for higher weight bearing through the use of the amputated leg compared with the PTB socket. In both open- and close-eyed conditions, balance was better as well (Yigiter et al., 2002). Better balance can be associated with overall contact of the TSB socket to the skin, which provides improved proprioception and pressure distribution.

High perspiration is one of the disadvantages of the TSB socket with silicone liner, polyurethane, or TEC liner compared with the PTB socket with Pelite insert due to less ventilation between the skin and the soft liner. Furthermore, amputees with excessive soft tissue at the popliteal fossa find it more difficult to use a sleeve or a silicone liner due to the creasing during knee flexion (Hachisuka et al., 1998, 2001).

Based on the literature, the TSB socket with pin/lock system is favored by the majority of amputees. In our online worldwide survey, the silicone liner with the pin/lock system was the first choice of prosthetists among three different suspension systems, namely, PTB with Pelite soft liner, Iceross with pin/lock, and suction system. Thus far, no clinical evidence is available to prove that the Iceross is the standard system for all transtibial amputees (Datta et al., 1996). As Coleman et al. (2004) and Selles et al. (2005) stated no significant difference could be found in terms of satisfaction, pain, comfort, and functional outcome with the TSB and PTB sockets.

4.2. Survey studies

Ali et al. (2012a) found that donning and doffing are more difficult with the suction system (Seal-In liner) compared to the PTB (with polyethylene soft insert) and Iceross with pin/lock. This finding is similar to that of the prospective studies (Brunelli et al., 2013; Cluitmans et al., 1994; Eshraghi et al., 2012b; Gholizadeh et al., 2012b,c). Furthermore, the polyethylene foam insert was more durable than the silicone liners, which is in accordance with the finding of Van de Weg and Van der Windt in the Netherlands (Van de Weg and Van der Windt, 2005). In developing countries, a suspension system with high durability and low cost should be the first choice of amputees.

Hachisuka et al. (1998) reported that perspiration in prosthesis was less in female amputees than in males. Datta et al. (1996) observed that perspiration increased when using the Iceross but decreased after three weeks. Daily wash of the stump and silicone liner is important to control odor, perspiration, itching, and eruption (Baars and Geertzen, 2005; Hachisuka et al., 2001). Ferraro (2011) found greater vertical movement inside the socket with the pin/lock systems compared to the vacuum suspension. The observation is consistent with that of other studies (Gholizadeh et al., 2012a,b).

5. Conclusion

Methodical assessment, along with knowledge and expertise, can contribute to the selection of a suitable type of prosthesis for an amputee. Based on this literature, measurement of pistoning inside the socket is a good indicator of the quality of a prosthetic suspension system. Suction

systems are capable of diminishing the displacement of the stump inside the socket and decreasing gait asymmetry and pain at the distal end of the residual limb compared to other systems. Nevertheless, the tasks of donning and doffing are more difficult with this system, and it is not a good choice for amputees who have fluctuation in their stumps. This literature review reveals that thicker liners are more comfortable and can distribute the pressure more evenly over residual limb. However, amputees' instability is increased during walking. High perspiration is one of the disadvantages of the TSB socket with silicone liner, polyurethane, or TEC liner compared to the PTB socket with Pelite insert. In developing countries, a suspension system with high durability and low cost (such as Pelite) should be the first choice of amputees. In summary, no clinical support is available to suggest which kind of suspension system could have an influential effect as a "standard" system for all transtibial amputees. However, the TSB socket with pin/lock system (Iceross) was favored by the majority of users. Researchers and manufacturers should give emphasis more on socket fit, durability, donning and doffing procedures, cost, and sweating problem for the design of new prosthetic suspension systems.

Conflict of interest statement

The authors have no conflict of interest.

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Appendix A

Methodological criteria (Van Der Linde et al., 2004)^a.

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			Score ^d
Selection of patients	A1	Adequacy of Description of Inclusion and Exclusion Criteria: This criterion tested whether the patient sample was sufficiently defined with the use of selection criteria: such as age, gender, level of amputation, reason for amputation, activity level of the amputee, time since onset, stump condition, and 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. When the activity level of the patients was not described, sufficient indication of the level of amputation, the reason for amputation, and the age of the subjects were required to globally estimate the activity level of the patients. 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, such as time since onset and time since first walking with the prosthesis. In the case of a within-subjects design, this criterion was scored as "1."	
	A4	Randomization: In group designs, an adequate randomization procedure should have been applied. If the randomization procedure was described and the procedure reasonably excluded bias, this criterion was scored as "1." In within-subjects designs, this criterion was applied to the sequence of interventions ^b .	
Intervention and assessment	B5	Experimental Intervention: The experimental intervention had to be given explicitly in such detail as to make performing a duplicate study as described possible.	
	B6	Cointerventions: This criterion tested whether cointerventions were avoided or were comparable between the study groups.	
	B7 ^c	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. An adequate adaptation period was required.	
Statistical validity	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 standardized protocol.	
	C10	Dropouts: The number of dropouts and the reason for dropping out had to be sufficiently reported. A dropout rate of more than 20% was considered as insufficient.	
	C11	Sample Size: The sample size (<i>n</i>) in relation to the number of independent variables (<i>K</i>) was adequate if the ratio <i>n</i> : <i>K</i> exceeded 10:1.	
	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.	

^aVan Der Linde et al., 2004. 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*, 41, 555–570.).

^bPiantadosi S. Clinical trials as experimental designs. In: Barnett V, Bardley RA, Fisher NI, Hunter S, Kadane JB, Kendall DG, et al., editors. *Clinical trial: a methodological perspective*. New York, Chichester, Weinheim, Brisbane, Singapore, Toronto: John Wiley & Sons, Inc.; 1997. p. 61–105.

^cAs the suspension system is in close contact with the residual limb, and when the amputees want to wear the prosthesis, they can easily identify the difference between the suspension systems. This situation could have created respondent bias. We did not use this item in our review.

^dBased on score levels, a criterion was scored "0" if it is not applicable and "1" if applicable.

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