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LITERATURE REVIEW

Transfemoral Prosthesis Suspension Systems

A Systematic Review of the Literature

ABSTRACT

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;93:809–823.

The purpose of this study was to find the scientific evidence pertaining to various transfemoral suspension systems to provide selection criteria for clinicians. To this end, databases of PubMed, Web of Science, and ScienceDirect were explored. The following key words, as well as their combinations and synonyms, were used for the search: *transfemoral prosthesis*, *prosthetic suspension*, *lower limb prosthesis*, *above-knee prosthesis*, *prosthetic liner*, *transfemoral*, and *prosthetic socket*. The study design, research instrument, sampling method, outcome measures, and protocols of articles were reviewed. On the basis of the selection criteria, 16 articles (11 prospective studies and 5 surveys) were reviewed. The main causes of reluctance to prosthesis, aside from energy expenditure, were socket-related problems such as discomfort, perspiration, and skin problems. Osseointegration was a suspension option, yet it is rarely applied because of several drawbacks, such as extended rehabilitation process, risk for fracture, and infection along with excessive cost. In conclusion, no clinical evidence was found as a "standard" system of suspension and socket design for all transfemoral amputees. However, among various suspension systems for transfemoral amputees, the soft insert or double socket was favored by most users in terms of function and comfort.

Key Words: Rehabilitation, Limb Prosthesis, Amputation Stumps, Walking, Review

Prosthetists seek to restore amputees' ability to perform well in activities of daily living by ensuring proper prosthetic fit.[1] Nonuse or limited use of prosthetic devices is a concern for any rehabilitation team. Provision of good prosthesis is the key to successful rehabilitation of persons with amputation. User's mobility, comfort, and satisfaction are associated with socket fit and proper choice of suspension system.[2–6]

The prosthetic socket should mainly stabilize the residual limb in the sagittal and coronal planes; provide body weight support; control the prosthetic knee voluntarily; ensure proper function of muscles; and offer harmony of appearance, function, and comfort, both dynamically and statically.[1,7]

The most common material for transfemoral socket was leather until World War I. Leather was eventually replaced by wood, and the final socket was covered with a cotton sock. Because the wooden sockets did not provide any suction, it was necessary to use bulky suspension accessories, such as a harness.[8] Although the suction socket was introduced in the 1930s, it was not commonly used until the veterans of World War II tried it. The socket was extended distally approximately 5 cm below the distal end of the stump, which was sealed by a valve. The valve ensured air isolation so that the resultant vacuum maintained the stump and the socket in close contact. The suction socket usually causes edema, particularly in long-term use.[8,9] Two main socket designs for the transfemoral prosthesis, the quadrilateral socket[10] and the ischial containment socket,[11] were introduced in the 1950s and the 1980s, respectively. The proximal brim contours differentiate these two designs as follows: in the ischial containment, the ischium and the ischial ramus are inside the socket (medial socket wall), whereas in the quadrilateral socket, the posterior brim lies parallel to the ground and has a wide seat (known as the ischial seat).[12,13] Furthermore, the ischial containment socket can create a bony lock for mediolateral stability and improve the amputee's gait by positioning the femur into adduction.[11,13] An evolution to the ischial containment socket is the ischial-ramal containment socket (also called the Marlo Anatomical Socket [MAS]). In the MAS, developed by Marlo in 1999,[13] the angle of the ischial ramus plays an important role. The medial aspect of the ramus and the ischial tuberosity are encapsulated within the medial aspect of the socket brim, and the medial wall is lowered anteriorly to avoid pressure on the ramus (ascending part).[13]

Clinicians need comprehensive knowledge of socket design and proper suspension systems in accordance with the amputees' needs. Currently, several suspension systems are used with transfemoral prostheses including the hip joint with pelvic band, the Silesian belt, silicone liners with or without a shuttle lock, and suction socket.[14–17] The hip joint with pelvic band and the Silesian belt are usually preferred by geriatric amputees because of the ease of use, and owing to good suspension, it is favored by amputees with a short residual limb.[8,14] Some advantages of the suction suspension are greater use of residual muscles, higher mobility, good cosmetic appearance, and comfort compared with the hip joint with pelvic band and the Silesian belt.[14] However, the suction sockets do not accommodate the fluctuation of the residual limb, which diminishes socket fit and suspension. In addition, in geriatric users, or those with a vascular disease, suction sockets may cause edema at the distal end of the residual limb.[14,18,19] In the 1980s, silicone and polyurethane liners were introduced for lower limb prostheses. These liners are said to decrease shear forces between the socket and the residual limb, to improve suspension, and to control volume fluctuation of the residual limb in transtibial prostheses.[3,19] The roll-on silicone liner offers enhanced suspension, comfort, stability, and cushioning in comparison with the suction sockets and polyethylene foam liners.[20–22] Various techniques are used to couple the liner and the residual limb including the lanyard, distal pin with shuttle lock, vacuum/suction seals, and magnetic lock.[23,24] The Seal-In liner is a new vacuum suspension liner with hypobaric sealing membrane around the silicon liner without any pin and lock or external sleeve,[4,18] which increases the contact surface with the socket wall. The resultant vacuum reduces the rotation, translation, and pistoning movements inside the socket.[4,18]

Bone anchorage is another alternative to the conventional suspension techniques. The concept of osseointegration (OI) was first introduced in 1965 by dentists for dental implant.[25] OI for prostheses was initiated in Sweden in 1990 and has been recently extended to other countries such as the United Kingdom.[8,26] A titanium implant provides the anchorage "by the formation of bony tissue around it without growth of fibrous tissue at the bone-implant interface".[27]

Amputee rehabilitation is influenced by prosthetic components in accordance with the real needs of the individual, which necessitates teamwork and the amputee's enthusiasm to complete the

procedure. Selection criteria for prosthetic suspension systems and socket designs mainly follow the clinician's subjective experience, amputation etiology, the amputee's functional skills, and even the patient's preference[28] (E. Schaffalitzky: *Optimising the Prescription and Use of Lower Limb Prosthetic Technology: A Mixed Methods Approach,* unpublished doctoral thesis, Dublin, 2010). Prosthetic prescription should ideally match the biomechanical characteristics. Therefore, clinical prescription guidelines can help to ensure consistent and efficient prosthetic care. Development of such guideline is partly facilitated through systematic review of literature by highlighting the gaps.[28,30] To date, there is no sound technical guideline or consensus over selection criteria.[28]

Previous studies have performed subjective and objective evaluations of various transfemoral suspension systems. This study aimed to review the literature systematically to develop a guideline for the transfemoral suspension systems. Because the citation number of previously published literature is an indicator of its subsequent recognition and impact in an area of study,[31] the authors were also interested in identifying the number of citations for each article and the journals with more publication in this field.

METHODOLOGY

Search

Relevant research articles were searched through the PubMed, ScienceDirect, and Web of Science databases. The end search date was May 2013. The related

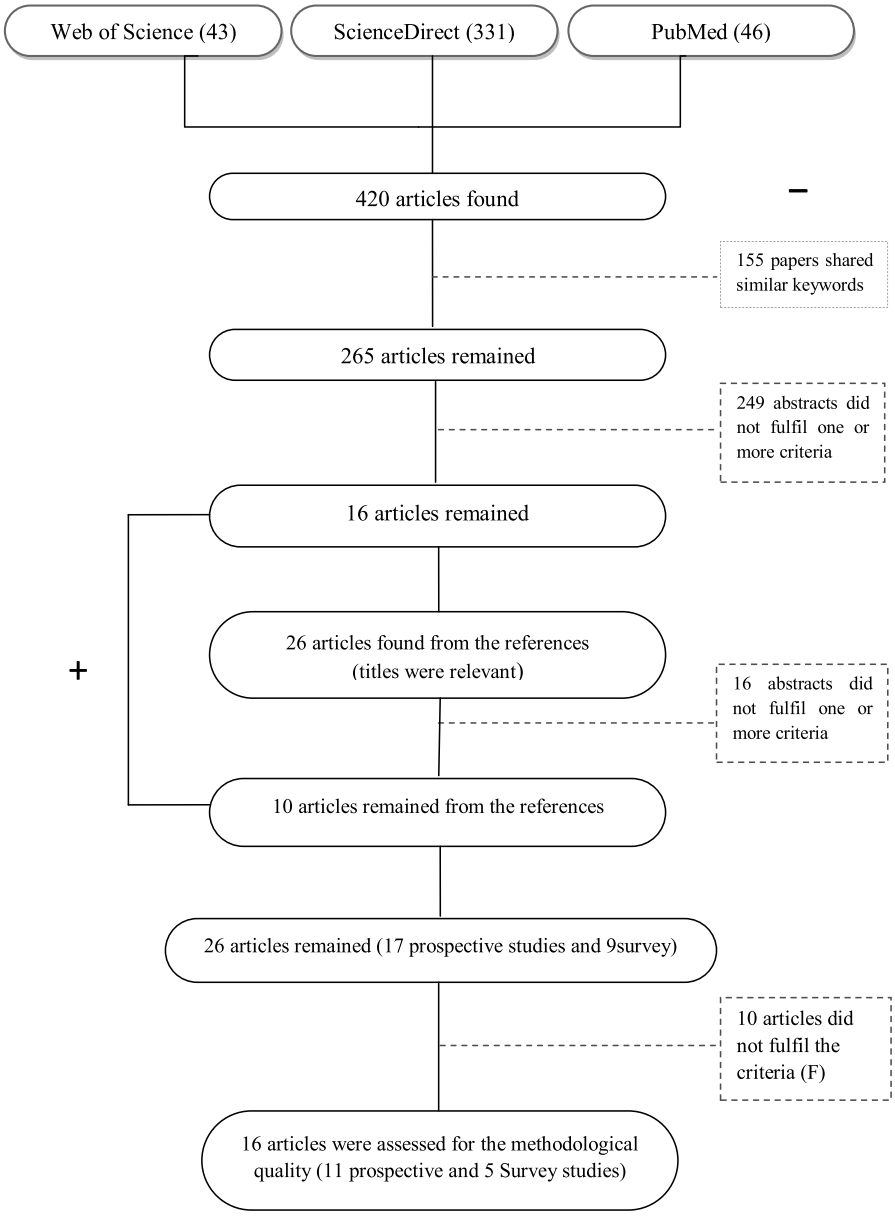

FIGURE 1 *The selection algorithm for this literature review.*

key words as well as their synonyms and combination were applied as follows: *transfemoral prosthesis*, *above-knee prosthesis*, *transfemoral*, *prosthetic liner*, *prosthetic suspension*, *lower limb prosthesis*, and *prosthetic socket*. The references of the resultant articles were also considered.

Criteria

Some systematic criteria were set to facilitate the selection of articles. The studies were included if they evaluated the transfemoral prosthesis suspension system, were written in English, and aimed to provide insights into various suspension systems for transfemoral prosthesis.

The abstract of each article was reviewed to find out the sampling method, design (prospective, retrospective, and case series), outcome measures, research instrument, and protocols.[28] Afterward, two reviewers assessed the article quality separately using a checklist with 12 items. The checklist was based on two available tools for quality assessment, primarily used to assess randomized controlled trials.[32,33] van der Linde et al.[28] adapted the original checklist in their study so that it was also possible to be used for nonrandomized controlled trials.[34] In this study, the same checklist was adopted with a minor change. Because the amputees can easily identify the difference between the suspension systems when they want to wear the prosthesis, blinding is not feasible in studies on suspension systems. Therefore, the authors excluded item B7 regarding blinding from this study (see Appendix; http://links.lww.com/PHM/A72). Thus, the scoring was performed as follows. A criterion was given the score "1" if it was applicable or "0" if not applicable. The articles that successfully controlled the measurement and selection bias were preferred.[28] Finally, the categorization was performed as follows[28]:

- A-level: The articles that gained at least 10 or more points: 6 points from the A and B criteria and a positive score for timing of the measurement (criterion B8) were included in the review.
- B-level: The articles with a total score between 6 and 9, including a positive score for timing of the measurement (criterion B8), were included in the review.
- C-level: The articles with a total score of at least 6 of the A and B criteria with an invalid score on B8, therefore, studies that achieved at least 6 of 9 points for the A and B criteria, were included in the review.[28]

RESULTS

Search Results

From 420 articles, 155 articles were identical among the databases and key words (Fig. 1). From the remaining 265 articles, some were excluded for being case studies, being computational models, or focusing on below-knee or upper limb prosthetics. Another 10 articles were obtained from the references. A total of 26 articles were systematically reviewed, including 9 surveys and 17 prospective studies. Table 1 and Figure 1 present the result of methodological quality evaluation. Ten articles did not achieve A, B, or C levels; nine articles were classified under B level[9,12,18,35–40]; and seven articles obtained A level.[24,41–46] Most of the articles had been published in the journal of *Prosthetics*

TABLE 1 Number of articles based on the journal

Journal Name	No. Articles	Failed	Remained Articles	
			Prospective Study	Survey
Journal of Prosthetics and Orthotics	1	—	1	—
Gait & Posture	1	—	1	—
Annals of Physical and Rehabilitation Medicine	1	—	1	—
Clinical Orthopaedics and Related Research	2	—	2	—
Journal of Pediatric Orthopaedics	1	—	1	—
Upsala Journal of Medical Sciences	1	—	1	—
Journal of Bone & Joint Surgery, British Volume	1	1	—	—
Journal of UOEH	1	1	—	—
American Journal of Physical Medicine & Rehabilitation	2	—	1	1
Clinical Biomechanics	1	1	—	—
Archive of Physical Medicine and Rehabilitation	4	1	—	3
Journal of Rehabilitation Research and development	2	1	1	—
Prosthetics and Orthotics International	8	5	2	1
Total	26	10	11	5

TABLE 2 Prospective and survey studies

Author(s)	Affiliation	Title	Citation (Google Scholar)	Citation (Scopus)	H-index
Erikson and James,[41] 1973	Uppsala University Hospital, Department of Diagnostic Radiology, Uppsala, Sweden	Roentgenological Study of Certain Stump-Socket Relationships in Above-knee Amputees with Special Regard to Tissue Proportions, Socket Fit and Attachment Stability	4	1	14
Fishman et al.,[35] 1987	Weill Cornell Medical College, Department of Obstetrics and Gynecology, New York, United States	Icelandic–Swedish–New York Above-knee Prosthetic Sockets: Pediatric experience	4	1	4
Gottschalk et al.,[12] 1989	University of Texas South Western Medical Center, United States	Does Socket Configuration Influence the Position of the Femur in Above-Knee Amputation?	27	—	8
Flandry et al.,[36] 1989	Hughston Clinic, P.C., Columbus, United States	The Effect of the CAT-CAM Above-Knee Prosthesis on Functional Rehabilitation	19	14	12
Gailey et al.,[37] 1993	US Department of Veteran Affairs, Functional Outcomes Research and Evaluation Center, Miami, United States	The CAT-CAM socket and Quadrilateral Socket: A Comparison of Energy Cost During Ambulation	26	21	6
Trieb et al.,[24] 1999[a]	Klinikum Wels, Department of Orthopaedics, Wels, Austria	Silicone Soft Socket System: Its Effect on the Rehabilitation of Geriatric Patients with Transfemoral Amputations	8	6	23
Dillingham et al.,[38] 2001[a]	University of Pennsylvania, Department of Physical Medicine and Rehabilitation, Philadelphia, United States	Use and Satisfaction with Prosthetic Devices Among Persons with Trauma-Related Amputations: A Long-term Outcome Study	87	66	18
Macchi et al.,[42] 2004	University of Florence, Faculty of Medicine, Florence, Italy	Prosthesis intolerance in Patients with Transfemoral Amputation: A Videocapillaroscopic Study	3	2	14
Hagberg et al.,[43] 2005	Sahlgrenska Academy, Department of Orthopaedics, Gothenburg, Sweden	Socket versus Bone-Anchored Trans-femoral Prostheses: Hip Range of Motion and Sitting Comfort	47	30	10
Dudek et al.,[40] 2005[a]	University of Ottawa, Department of Medicine, Ottawa, Canada	Dermatologic Conditions Associated with Use of a Lower-Extremity Prosthesis	28	19	5
Hagberg et al.,[9] 2008[a]	Sahlgrenska Academy, Department of Orthopaedics, Gothenburg, Sweden	Osseointegrated Trans-femoral Amputation Prostheses: Prospective Results of General and Condition-Specific quality of Life in 18 Patients at 2-Year Follow-up	48	29	10
Hagberg and Brånemark,[39] 2009	Sahlgrenska Academy, Department of Orthopaedics, Gothenburg, Sweden	One hundred Patients Treated with Osseointegrated Transfemoral amputation Prostheses—Rehabilitation Perspective	55	35	10
Tillander et al.,[44] 2010	Göteborg University, Department of Infectious Diseases, Goteborg, Sweden	Osseointegrated Titanium Implants for Limb Prostheses Attachments: Infectious Complications	21	13	1
Klotz et al.,[45] 2011	Centre de médecine physique et de réadaptation de la Tour-de-Gassies, Bruges, France	Influence of Different Types of Sockets on the Range of Motion of the Hip Joint by the Transfemoral Amputee	2	1	1
Tranberg et al.,[46] 2011	Sahlgrenska Academy, Department of Orthopaedics, Gothenburg, Sweden	Improvements in hip- and Pelvic Motion for Patients with Osseointegrated trans-femoral Prostheses	7	3	8
Gholizadeh et al.,[18] 2012[a]	Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, Malaysia	Satisfaction and Problems Experienced with Transfemoral Suspension Systems: A Comparison Between Common Suction Socket and Seal-In Liner	0	0	2

[a]Survey studies.

and Orthotics International. The highest number of citations in Google Scholar was 87 (Table 2) for the article by Dillingham et al.[38] The sample size in the prospective studies ranged from 4 (in Klotz et al.[45]) to 100 subjects (in Hagberg and Brånemark[39]) (Table 3). However, the sample size was 16 (Dillingham et al.[38]) to 159 (Dudek et al.[40]) in the survey studies (Table 4). Most of the participants were unilateral amputees. The main amputation cause was trauma followed by tumor, diabetes, disease, infection, and congenital limb deficiencies (Tables 3 and 4). Sweden and the United States had more relevant publications (6 and 5 articles of 16, respectively).

Lower limb amputees stopped using prosthesis because of not only high energy expenditure but also skin problems, discomfort, and perspiration (Tables 5 and 6). Mostly, the research on transfemoral prosthesis suspension focused on the OI method, the ischial containment socket, and the

TABLE 3 Prospective studies: methodological assessment of reviewed studies on the prosthetic suspension system sorted in ascending order according to the year of publication

	Subject					
Author(s)	Cause of Amputation	Level of Amputation	Sex	Age, Mean (SD)	K-level	Intervention (Prosthetic Suspension)
Erikson and James[41]	Unknown	TF	25 M	42 (12)	K2–K3	Total-contact suction socket of laminated plastic (quadrilateral)
Fishman et al.[35]	Infection, congenital, trauma, sarcoma, arterial puncture	TF	10 (7 M, 3 F)	10.4 (3.9)	Juvenile (5.2–15.6)	ISNY socket (with Silesian bandage or suction) and quadrilateral socket with Silesian bandage or pelvic band[a]
Gottschalk et al.[12]	Trauma, PVD	TF	50 (44 M, 6 F)	17–70 (QL group), 25–60 (IC group)		Ischial containment (CAT-CAM), NSNA, narrow medial-lateral ischial containment socket, and quadrilateral socket (including hard socket or flexible socket)
Flandry et al.[36]	Unknown	TF	5 M	34.4	K2–K3	CAT-CAM and CSS (quadrilateral)
Gailey et al.[37]	Nonvascular pathology	TF	20 M[b]	CAT-CAM, 37.2 (11.3); quadrilateral, 34.6 (9.8); normal, 33.2 (9.5)	K2–K3?	Ischial containment socket (CAT-CAM), CSS (quadrilateral), control group[a]
Macchi et al.[42]	Diabetic and nondiabetic	TF	70 (59 M, 11 F)	69 (5.4)	K2–K3	ISNY socket
Hagberg et al.[43]	Trauma, tumor, other	TF	63 (43 vacuum socket, 20 OI)	51 (11.7), 46 (11.3)	K3	Transfemoral socket prosthesis (CSS, quadrilateral, ischial containment socket) and OI bone-anchored prosthesis
Hagberg and Brånemark[39]	Trauma 67, tumor 21, vascular 3, diabetes 2, infection 7	TF	100 (61 M, 39 F)	43 (12.9)	K2–K3	OI transfemoral prosthesis
Tillander et al.[44]	Trauma or neoplasia	32 TF, 1 TB, 6 upper limb	39 (21 M, 18 F)	49.3	Unknown	OI (TF, TT, upper limb)
Klotz et al.[45]	3 traumatic, 1 vascular	TF	4 M	51	K3	CSS (quadrilateral, ischial containment socket, ischial-ramal containment socket (also called the MAS)
Tranberg et al.[46]	13 traumatic, 4 tumor, 1 infection, 1 arterial embolism	TF	19 (10 F, 9 M)	44.2 (13.7)	K3	OI and TF socket

[a]The authors mentioned other prosthetics components only in two studies: Fishman et al. (different knee joint [hydraulic, polycentric, manual lock, nonarticulated, constant (sliding friction) prosthetic foot: SACH]) and Gailey et al. (prosthetic knee [SA/Hyd, 4 Bar, SA/Pneu, SA/Fric], prosthetic foot [Seattle, Multiflex, SACH, Greissinger]).

[b]Ten subjects wearing ischial containment socket (CAT-CAM) and ten subjects using quadrilateral socket. In addition, they used ten nonamputated subjects as a control group.

[c]Because 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, item B7 regarding blinding was excluded in this study.

F, female; M, male; NSNA, normal shape normal alignment; PVD, peripheral vascular disease; TF, transfemoral; SACH, solid ankle cushion heel; SA/Hyd, single axis hydraulic; SA/Pneu, single axis pneumatic; SA/Friction J, single axis friction joint; 4 Bar, polycentric joint (four bar linkages); QL, quadri lateral; IC, ischial containment; TT, transtibial.

common suction socket (CSS) (quadrilateral). The prosthetic suspension systems used in the prospective studies were as follows (Table 3): the CSS with or without the Silesian bandage, pelvic band, or flexible socket; the Icelandic–Swedish–New York (ISNY) socket with the Silesian bandage or suction; ischial containment socket (contoured adducted trochanter/controlled alignment method [CAT-CAM]), normal shape normal alignment, narrow medial-lateral, and OI bone-anchored prosthesis.

The suspension systems in the retrospective studies were as follows (Table 4): ischial containment socket including the CAT-CAM socket with or without silicone suspension, the CSS with or without strap or silicone suspension (Seal-In liner), and OI.

DISCUSSION

The main objective of this article was to find out the advantages and disadvantages of different

Selection of Patients					Intervention and Assessment						Statistical Validity						
A1	A2	A3	A4	A-Score	B5	B6	B7[c]	B8	B9	B-Score	C10	C11	C12	C13	C-Score	Total Score	Level of Evidence
1	1	1	0	3	1	1	—	1	1	4	1	1	1	1	4	11	A
1	1	0	0	2	1	1	—	1	1	4	0	1	0	1	2	8	B
1	1	0	0	2	1	1	—	1	1	4	0	1	0	1	2	8	B
1	0	1	0	2	1	1	—	1	1	4	0	0	0	1	1	7	B
1	0	0	1	2	1	1	—	1	1	4	0	1	0	1	2	8	B
1	1	0	0	2	1	1	—	1	1	5	1	1	1	1	4	10	A
1	1	0	0	2	1	1	—	1	1	4	1	1	1	1	4	10	A
1	1	0	0	2	1	1	—	1	1	4	1	1	0	1	3	9	B
1	0	1	0	2	1	1	—	1	1	4	1	1	1	1	4	10	A
1	1	1	0	3	1	1	—	1	1	4	1	1	1	1	4	11	A
1	1	1	0	3	1	1	—	1	1	4	1	1	1	0	3	10	A

TABLE 4 Survey studies: methodological assessment of reviewed studies on the prosthetic suspension system sorted in ascending order according to the year of publication

Author(s)	Subject					Intervention (Prosthetic Suspension)
	Cause of Amputation	Level of Amputation	Sex	Age, Mean (SD) or Range	K-level	
Trieb et al.[24]	Unknown	TF	76 (49 men, 27 women)	49–83	K2–K3	CAT-CAM socket with a silicone suspension and without silicone suspension
Dillingham et al.[38]	Trauma (78)	Foot, ankle, transtibial, through-knee, transfemoral	16 TF	Age at time of injury, 32.9 (10.6); time since injury, 7.5 (2.8)	K2–K3	Above-knee prosthesis suspended by strap/other mechanism, suction suspension
Dudek et al.[40]	Trauma, PVD	TF, TT, other	159 (TF)	745 (159 TF)	Unknown	CSS, silicone liner, Silesian belt, others
Hagberg et al.[9]	Trauma (12), tumor (5), arterial embolus (1)	TF	18 (10 F, 8 M)	45	K1–k3	OI
Gholizadeh et al.[18]	Trauma	TF	90 M	47.7 (7)	K2–K3	Seal-In Liner and CSS

[a]Because 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, item B7 regarding blinding was excluded in this study.

F, female; M, male; PVD, peripheral vascular disease; TF, transfemoral; TT, transtibial.

transfemoral suspension systems in articles searched in three main databases, namely, PubMed, Web of Science, and ScienceDirect. The literature indicated that the suspension system and socket design had significant effects on the user's satisfaction, mobility, and comfort.[2,3,14,16,24]

In this study, the number of citations for each article was also checked. The citation number shows how many times an article was taken into account by other researchers. It is dependent on the year of publication. However, some articles could not get a high number of citations even 20 yrs after publication. Compared with the transtibial prosthesis suspension,[3] few studies have explored the transfemoral prosthetic suspension systems, which could be a reason for the low number of citations. Furthermore, 69% of all articles on transfemoral suspension systems were published in the United States and Sweden, which shed light on the type of healthcare system experienced by the study participants in those countries.

Dillingham et al.[38] (2001) inspected satisfaction of lower limb prosthesis users including transfemoral amputees through a retrospective study design. Most of the transfemoral participants had used either strap or suction suspension (CSS). Although they did not investigate the correlation between suspension system and patients' satisfaction, more than 57% of the participants were not satisfied with prostheses.[38] Gholizadeh et al.[18] (2013) reported higher satisfaction and fewer problems with the silicone liner (Seal-In) compared with the CSS in a study on 90 traumatic transfemoral amputees. Only the durability was stated to be inferior to the silicone liner. Besides, the appearance, walking on level and unlevel grounds, and stair negotiation did not demonstrate significant differences between the two systems. The transtibial prosthesis users did not favor the Seal-In liner because of the difficulty of donning and doffing,[47,48] whereas the transfemoral amputees preferred that. It can be attributed to the degree of soft tissue firmness in transfemoral and transtibial residual limbs.

The findings of Gholizadeh et al.[18] (2013) were similar to those of Haberman et al.[49] (1992) and Heim et al.[50] (1997) on transfemoral socket with the silicone liner. They also stated that the silicone liner could enhance the function, comfort, skin protection, cushioning, and quality of the suspension compared with the CSS. Trieb et al.[24] (1999) also compared the ischial containment socket (CAT-CAM) with and without the silicone liner. The findings revealed that the participants could use the silicone liner for a longer period, which can result in improved quality-of-life together with the decreased skin trauma.[24] It is also claimed that the silicone liners cause considerable improvement in the prosthesis function because suspension, cushioning, and skin protection are enhanced.[50] This is similar to the findings of other researchers.[18,49–51] Moreover, a research study showed that discomfort and edema were caused by the CSS.[52] Although Dudek et al.[40] mentioned the type of socket, suspension mechanism, and socket shape, it did not influence the possibility of developing skin problems (such as ulcer, irritation, inclusion cyst, or calluses).

Selection of Patients					Intervention and Assessment						Statistical Validity						
A1	A2	A3	A4	A-Score	B5	B6	B7[a]	B8	B9	B-Score	C10	C11	C12	C13	C-Score	Total Score	Level of Evidence
1	1	1	0	3	1	0	—	1	1	3	1	1	1	1	4	10	A
1	1	0	0	2	1	1	—	1	1	4	1	1	0	1	3	9	B
1	1	0	0	2	1	1	—	1	1	4	1	1	0	1	3	9	B
1	0	1	0	2	1	1	—	1	1	4	0	1	0	1	2	8	B
1	1	0	0	2	1	1	—	1	1	4	1	1	0	1	3	9	B

Koike et al.[51] (1981) introduced a transfemoral double socket (the TC double socket) for individuals with transfemoral amputation. This system yielded satisfactory results, especially for donning and doffing, in comparison with the CSS. It was mainly attributed to the inner socket flexibility that provided constant close contact and decreased the edema.[51] A positive effect of easy donning and doffing has been reported earlier on the user's satisfaction with prosthesis.[18,47–49,53] Transfemoral amputees who use the elastic bandages to reduce the friction during donning the CSS (suction socket without soft insert) find it more difficult compared with the silicone liner.[18] On the other hand, less effort is needed to don the silicone liner in a sitting position; thus, it does not entail balance skills for donning the CSS. A study on 440 transfemoral amputees also supported this and easier donning of a flexible internal socket than the suction socket.[51] In comparison with the CSS, in which suction is created between the skin and socket walls, in the silicone liners (using the Seal-In liner or sleeve), the suction is generated between the soft liner and socket wall. Thus, the soft tissue is protected against the negative pressures applied by the socket. The silicone liner relieves residual limb pain during walking compared with the CSS.[18] That is partly because of the enhanced volume control and skin protection by the coupling between the skin and the liner compared with the suction socket.[18,41] Nevertheless, the durability of the silicone liner is still a concern because it is frequently under tensile and compressive loadings.[18,22,54–56]

The ISNY socket also exhibited results similar to the CSS[35] in adult[57] and juvenile (aged between 5.2 and 15.6 yrs) amputees.[35] The ISNY socket system comprises two parts[57]: a rigid part for weight transfer and a flexible part to support the residual limb tissue. This system can enhance comfort because the socket shape changes on the basis of muscle contraction and improves the gait compared with the CSS (with hard socket wall).[57] The CSS was not a good choice for young amputees because of difficulty in donning.[58] Some clinicians prescribe the CSS for amputees older than 6 yrs, whereas others recommend that after the age of 14 yrs.[8,35] Using the ISNY socket could help younger children in using the suction as suspension system instead of the pelvic or the Silesian band. Nevertheless, the femur angles are identical in both systems. Likewise, when the quadrilateral socket (with the Silesian bandage or the pelvic band) and the ischial containment sockets (with suction as suspension) were compared, the socket configuration did not seem to disturb the femur position within the socket.[12,40] These findings are similar to those of Gottschalk et al.,[12] stating that appropriate surgical procedure for transfemoral amputation has a main role in proper prosthetic comfort and function restoration.[12] However, Flandry et al.[36] and Hachisuka et al.[59] mentioned that the ischial containment socket could improve the amputee's gait by positioning the femur into adduction. Today, the awareness toward the surgical procedures has increased among the surgeons for balancing the abductors and the adductors to enhance the femur position.[8] In addition, similar to the findings

TABLE 5 Prospective studies: main findings from the reviewed studies (prospective) on the prosthetic suspension system

Author(s)	Objective and Parameters	Result (Outcome)	Level of Evidence
Erikson and James[41]	To study the socket fit and the relative movement between the stump bone and socket. examinations concerning soft tissue evaluation in the intact thigh and the stump (without prosthesis), socket fit, and relative movement between the femoral stump and the socket (quadrilateral) were also performed with the patient standing and wearing the prosthesis.	The cross section of residual femoral bone increased somewhat after the amputation as a result of the total reduction in volume of the stump but decreased in relation to the cross section of the intact femur by a mean of approximately 27%. Considerable bone atrophy in the femoral stump. There was total contact between the stump and the socket (suction socket–quadrilateral) in approximately two-fifths of the patients. Of the remaining, different space was noted without bearing weight at the distal end between the stump and socket.	A
Fishman et al.[35]	To compare ISNY and CSS (quadrilateral with Silesian bandage or pelvic band). Positive reaction regarding ISNY: comfort (lighter, less sweating, softer, prefer Silesian bandage to pelvic band, no groin irritation, prefer total suction to Silesian, nonspecific positive comments), function (easier to walk, better gait, easier to run, easier to dance, easier to hop and skip, easier to jump, easier to rise from the floor, easier to doff), cosmetics (less bulky, does not show under the trousers, like to see amputation limb, less noisy, no positive comments), overall (nonspecific comment regarding preferring ISNY socket); negative reaction: comfort (hotter, preferred to wear stockinet), cosmetic (poor frame appearance, poor drape of trousers over socket, unsatisfactory frame color), function (hard socket is safer, more difficult to don)	ISNY socket has improved appearance, function, comfort, and growth adjustability features compared with CSS (quadrilateral with Silesian bandage or pelvic band) in juvenile patients. Using ISNY socket could help the younger children to use suction as their suspension system instead of pelvic band or Silesian band. Nevertheless, femur angles in these 2 systems are similar Seventy percent of the children and their parents indicated better function with ISNY. Sixty percent indicated that appearance of new design, the costs associated with materials, and initial fabrication time are not significantly higher than for CSSs. The ease of socket replacement and adjustments may well significantly reduce the long-term costs of prosthetics care, especially for children.	B
Gottschalk et al.[12]	To determine the position of the residual femur in the above-knee prosthetics socket of various types, to highlight the reasons for malalignment of the residual femur, to recommend methods that can restore the anatomic position of the stump (statically and dynamically)	The anatomic axis of the normal femur was the same in both groups of patients (ischial containment and quadrilateral socket). The position of the residual femur in the quadrilateral sockets varied from 8 to 12 degrees of abduction, whereas in the ischial containment sockets, the femur position varied from 8 to 14 degrees of abduction. The configuration of the socket did not affect the position of the femur in the socket. Although the narrow mediolateral socket concept has some merits, the anatomic alignment of the femoral bone should be achieved by proper myodesis of the adductor muscles at the time of surgery. There was no statistically significant difference in the abduction angles of the amputated femurs between quadrilateral socket and ischial containment socket. The success of the prosthetic fitting, i.e., the optimal restoration of function and comfortable ambulation, depends on the anatomic alignment and dynamic functioning of the transfemoral amputation stump.	B
Flandry et al.[36]	Five rehabilitated unilateral above-knee amputees using CSS (quadrilateral) were converted to ischial containment socket (CAT–CAM) to determine the effect on ambulatory function. (1) Assessment of functional level of ambulation, (2) amputee's subjective assessment by questionnaire, (3) observed gait, (4) femoral shaft adduction angle, (5) observed and instrumented gait analysis, (6) dynamic body torques, and (7) energy cost of walking	The CAT-CAM socket was stated superior by 4 patients. Stability and comfort increased by using CAT-CAM prosthesis. Most gait deviations improved or disappeared. Level of ambulatory independence increased with CAD-CAM compared with quadrilateral socket. Femoral shaft inclination angles improved a mean of 6.5 degrees toward adduction in 4 patients. The compensatory lateral trunk lean in patients with quadrilateral sockets disappeared after conversion. Customary gait velocities were increased, whereas the quantity of oxygen consumed per meter was decreased between 9% up to 50%.	B
Gailey et al.[37]	To compare oxygen uptake and heart rate in 3 different groups (ischial containment socket [CAT-CAM], CSS [quadrilateral], and control group). Means and standard deviations of nonexercise and exercise oxygen uptake and heart rate (during slow speed and fast speed) in 3 groups (CAT-CAM, quadrilateral, and control group) and means and standard deviations of oxygen uptake and heart rate	$\dot{V}o_2$ and heart rate showed significant differences between the control group and the CAT-CAM subjects at the slower speed. The control group and the subjects using the CSS (quadrilateral) socket also showed significantly different differed $\dot{V}O_2$ and HR at the slower pace. More energy expenditure and higher HR were required for faster pace than slower speed. At faster pace, significantly higher energy expenditure was observed in the quadrilateral than the CAT-CAM group. Thus, ambulation at normal pace using the CAT-CAM socket design requires less energy than QUAD socket design. Users of CAT-CAM socket design consumed less energy than those who used a quadrilateral socket. None of the socket designs showed energy advantage at slower pace.	B

Macchi et al.[42]	The aim of this article was to investigate, by videocapillaroscopy, the microcirculation of the skin of the stump in 70 consecutive patients with unilateral transfemoral amputation (prosthesis with an ISNY socket).	Diabetic microangiopathy might be associated with neuropathy and makes the stump skin more susceptible to the prosthesis impact. Prosthesis intolerance is highly associated with the diabetes-like microvascular changes both in nondiabetic and diabetic patients.	A
Hagberg et al.[43]	To report on hip ROM among active prosthesis users, when wearing and not wearing transfemoral socket prosthesis (CSS [quadrilateral] and ischial containment socket) and to compare with individuals rehabilitated with an OI bone-anchored prosthesis. In addition, discomfort when sitting with the prosthesis is reported in both groups. Active hip ROM on the affected hip without wearing the prosthesis and on the contralateral hip for the S group (n = 43) and the OI group (n = 20).	Transfemoral socket (CSS [quadrilateral], and ischial containment socket) significantly reduced the active hip ROM. Discomfort when sitting was common among prosthetic users. The discomfort during sitting increases when hip flexion motion is less than 90. Users of bone-anchored prosthesis (OI) had a normal hip ROM and reported minor discomfort when sitting.	A
Hagberg and Brånemark[39]	To describe the current rehabilitation protocol, OPRA, and to illustrate the overall results. Radiography, registration of complications, hip ROM, walking energy cost, computerized gait analyses, and self-reported HRQOL, the condition-specific assessment by the Q-TFA.	Sixty-eight patients continued using their prostheses (follow-up: 3 mos to 17.5 yrs) and 32 discontinued (4 were deceased, 7 before second surgery, 6 were in initial training, 4 were not using prosthesis, and 11 had the implant removed). Most failures occurred before the OPRA protocol was established. Quality-of-life was improved, and success rate of 94% was achieved at the 2-yr follow-up. OPRA method can make activities of daily life easier for more patients at younger ages. Their patients expressed severe socket-related problems when wearing the prosthesis with suction socket (such as pain, sweating, sitting discomfort, sores and skin irritation, difficulty donning).	B
Tillander et al.[44]	To determine the frequency and describe the presentation of infectious complications with OI and evaluate the bacterial flora at the skin penetration area and its relation to the development of local and implant-related infection. Bacterial colonization and infection at the beginning of the study and at follow-up (possible/probable/definite implant infection, local soft tissue infection in the skin penetration area, superficial colonization without signs of infection)	The incidence of implant infection was 5% at the beginning and 18% at follow-up. Antibiotic treatment healed the infection in 1 patient, and the implant of another patient was removed. However, infectious complications occur in approximately two-fifths of the amputees during a 3-yr period, mostly as local infections in the skin penetration area and more rarely as low-activity implant-associated infections. In superficial and deep cultures, the most common bacteria were *Staphylococcus aureus* and coagulase-negative staphylococci. The titanium implant system caused few infections leading to implant removal or disability.	A
Klotz et al.[45]	To compare the individual influence of different types of socket designs (without a socket, with a CSS [quadrilateral], ischial containment socket, ischial-ramal containment socket [also called the MAS] on the hip's ROM in transfemoral amputees. hip's ROM: flexion, extension, sagittal joint amplitude, abduction, adduction, frontal joint amplitude, global amplitude	The global amplitude of the hip joint was reduced, regardless of the socket type, compared with physiologic conditions without a socket. The ischial-ramal containment socket (MAS) restricted global amplitude of the hip joint less than the other 2 sockets. The 3 studied socket types had a negative impact on the physiologic functioning of the hip joint; however, the ischial-ramal containment socket resulted in the least movement restriction.	A
Tranberg et al.[46]	To compare changes in hip and pelvic kinematics in 19 transfemoral amputees, who were treated with an OI transfemoral prosthesis (comparison between using socket and OI). Hip extension angle during stance phase, hip extension angle of the nonamputee side during stance phase of the sound leg, anterior pelvic tilt angle during stance phase of the prosthetic leg	Hip extension in patients with OI prosthesis increased significantly by 7.38. However, the preoperative anterior pelvic tilt decreased by 4.08. Values for pelvic tilt and hip extension became close to controls. Hip extension and anterior pelvic tilt significantly changed in patients treated with OI. The changes were moderate but in the long-term may have a positive effect on low back biomechanics in reducing the risk for low back pain.	A

HRQOL, health-related quality-of-life; $\dot{V}O_2$, oxygen consumption per unit time; OPRA, Osseointegrated Prostheses for the Rehabilitation of Amputees; ROM, range of motion; QUAD, quadrilateral; S, prosthetic user; Q-TFA, Questionnaire for Persons with a Transfemoral Amputation.

TABLE 6 Survey studies: main findings from the reviewed studies on the prosthetic suspension system

Author(s)	Objective and Parameters	Result (Outcome)	Level of Evidence
Trieb et al.[24]	To compare a CAT-CAM socket with a silicone suspension system (silicone suction sockets) and without silicone suspension.	Patients with the CAT-CAM socket with silicone liner had a significantly greater improvement in traversed distance, and inpatient stay in the rehabilitation center was 5 days less. Furthermore, they had to receive less adjustment (only 21% of them needed adjustment) compared with the amputees using the socket without silicone liner (67% needed adjustment). No significant difference was seen in satisfaction, mean duration of daily use, and the use of assistive devices for gait. Therefore, it is preferable to provide these sockets to geriatric amputee patients rather than CAT-CAM sockets without silicone suspension sleeves. Silicone suction sockets have economic advantages and lead to more gains in ambulation and, therefore, better quality-of-life.	A
Dillingham et al.[38]	To document and examine the use, satisfaction, and problems with prosthesis among traumatic lower limb amputees. Demographic characteristics (sex, education, age at time of injury, time since injury, married at time of injury), clinical characteristics (injury characteristics, mechanism of injury, level of amputation), use and satisfaction with prosthesis (prosthesis use, satisfaction with prosthesis, problems with prosthesis), health services use, insurance coverage, and knowledge about prosthesis (service utilization, knowledge about prosthesis, specific components of prosthesis), problems with residual limb, problems with contralateral limb	Most persons with trauma-related lower limb amputations used a prosthetic device quite intensively, but many were not satisfied with the prosthesis level of comfort. Only 43% of amputees were completely or very well satisfied with the comfort of their devices. These findings highlight the need for further improvements in prosthetic socket fabrication and in the development of interfacing materials that minimize discomfort among amputees.	B
Dudek et al.[40]	To document the incidence of skin problems among lower limb amputees and factors associated with skin problems (with different socket and suspension system). Age, sex, age at amputation, amputation level, reason for amputation, comorbidities, smoking history, occupation, none or single cane, 2 canes, crutches, walker, walking distance, time with current prosthesis, transfemoral socket type, transfemoral suspension, ulcer, irritation, inclusion cyst, callus, verrucous hyperplasia, blister, fungal infection, cellulites	At least 1 skin problem was evident in 337 residual limbs (40.7%). Amputation level, type of walking aid, being employed, and absence of peripheral vascular disease were independently linked to at least 1 skin problem. Risk for developing skin problems in more active amputees is higher.	B
Hagberg et al.[9]	To analyze general and condition-specific HRQOL parameters. SF-36 (PF, RP, BP, GH, VT, SF, RE, and MH. Q-TFA (prosthetic use score, prosthetic mobility score, problem score, and global score)	At follow-up, all the patients except one used the OI prosthesis. Four of the SF-36 scales (PF, RP, body pain, and physical component score) and all 4 Q-TFA scores (prosthetic use, prosthetic mobility, problems, and global health) significantly improved at follow-up indicating better general physical HRQOL, better prosthetic mobility, better global amputation situation, increased prosthetic use, and fewer problems.	B

Gholizadeh et al.[18]	To compare a Seal-In liner with the CSS with regard to patient satisfaction and problems experienced with the prosthesis. Demographic questions such as age, height, weight, amputation side, time since amputation, hours of daily prosthetic use, and activity level. Satisfaction questions: ability to don and doff the prosthesis, perception of prosthetic fit, ability to sit with the prosthesis, ability to walk with the prosthesis, ability to walk on different surfaces, and perception of prosthetic appearance. Problems questions: sweating, skin irritation, wounds, swelling (edema) of the residual limb, pistoning within the socket, unpleasant smell of the prosthesis or residual limb, unwanted sound, pain in the residual limb, and durability of the suspension systems.	Overall, most of the transfemoral amputees were more satisfied with the Seal-In liner than the CSS. If the Seal-In liner durability is increased, it could be a good alternative for transfemoral suspension. Satisfaction showed significant difference in terms of fitting, sitting, and donning and doffing between the Seal-In Liner and the CSS suspension system. However, walking (even and uneven surfaces), cosmetic appearance of the prosthetic devices, and stair negotiation showed no significant differences. The mean overall satisfaction score for the Seal-In liner was higher than for the CSS suspension. The respondents had significantly more problems with the CSS system compared with the Seal-In liner. The CSS caused more difficulties in terms of sweating, wounds, pain, irritation, pistoning, swelling, smell, and sound. Suspension durability of the CSS was significantly higher.	B

BP, bodily pain; GH, general health; HRQOL, health-related quality-of-life; MH, mental health; PF, physical functioning; RE, role functioning from an emotional perspective; RP, role functioning from a physical perspective; SF, social functioning; VT, vitality; Q-TFA, Questionnaire for Persons with a Transfemoral Amputation; SF-36, SF health surveys.

of Gailey et al.,[37] they noticed that oxygen consumption was higher with the CSS (quadrilateral).[36,37]

In another study by Klotz et al.,[45] the hip range of motion was compared among three different systems (CSS with quadrilateral socket, CAT-CAM, and MAS). The three studied socket types had negative impacts on the physiologic functioning of the hip joint; however, the MAS resulted in the least restriction of movement.[45]

Lower limb amputees stop using prosthesis because of not only high energy expenditure but also skin problems, discomfort, and perspiration.[3,13,15,27,38,43,51,60–62] OI was assumed to solve this problem by eliminating the socket. Currently, this technique is mainly performed on transfemoral amputees having problems of short stump, soft tissue scar, skin infection, and volume fluctuation using the conventional sockets.[26,27,39,43,45,63] According to Hagberg et al.,[43] the hip joint range of motion is significantly decreased, whereas discomfort in sitting is increased with the CSS and the ischial containment socket) in comparison with the OI. The OI prosthesis is hoped to enhance the quality-of-life for transfemoral amputees.[39,43] However, there are some unsolved problems in the technique, such as risk for infection and fracture and long process of rehabilitation, and it is not a good option for amputees with higher activity levels. Tillander et al.[44] also reported infectious complications from approximately two-fifths of the amputees during a 3-yr period.

CONCLUSIONS

Transfemoral prosthetic suspension has received less attention in the research compared with transtibial prosthesis. Amputee rehabilitation is challenging because it necessitates teamwork and the amputee's enthusiasm to complete a long and costly procedure. Prosthetic suspension prescription for transfemoral amputees is an open question. Despite the range of clinical and expert opinions, there is little scientific evidence to support the prescription practice. Few studies have performed direct comparisons between suspension systems, and the factors that can influence the outcomes vary greatly (e.g., socket shape, prosthetic components, amputation etiology, limb shape, functional capacity of the patients). In summary, no clinical evidence is available to suggest what kind of transfemoral suspension system has influential effect as a "standard" system for all transfemoral amputees. However, the silicone liner and double socket enhanced the function, comfort, skin protection,

cushioning, and quality of suspension among other different prosthetic suspension systems.

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