

# Prosthesis satisfaction in lower limb amputees

## A systematic review of associated factors and questionnaires

Erwin C. Baars, MD<sup>a,\*</sup>, Ernst Schrier, MSc<sup>b</sup>, Pieter U. Dijkstra, PhD<sup>b,c</sup>, Jan H.B. Geertzen, MD, PhD<sup>b</sup>

### Abstract

**Background:** Factors influencing patient satisfaction with a transtibial prosthesis have been studied fragmentarily. The aims of this systematic review were to review the literature regarding factors of influence on patient satisfaction with a transtibial prosthesis, to report satisfaction scores, to present an overview of questionnaires used to assess satisfaction and examine how these questionnaires operationalize satisfaction.

**Methods:** A literature search was performed in PubMed, Embase, PsycInfo, CINAHL, Cochrane, and Web of Knowledge databases up to February 2018 to identify relevant studies.

**Results:** Twelve of 1832 studies met the inclusion criteria. Sample sizes ranged from 14 to 581 participants, mean age ranged from 18 to 70 years, and time since amputation ranged from 3 to 39 years. Seven questionnaires assessed different aspects of satisfaction. Patient satisfaction was influenced by appearance, properties, fit, and use of the prosthesis, as well as aspects of the residual limb. These influencing factors were not relevant for all amputee patients and were related to gender, etiology, liner use, and level of amputation. No single factor was found to significantly influence satisfaction or dissatisfaction. Significant associations were found between satisfaction and gender, etiology, liner use, and level of amputation.

**Conclusion:** Relevance of certain factors for satisfaction was related to specific amputee patient groups. Questionnaires assessing satisfaction use different operationalizations, making comparisons between studies difficult.

**Abbreviations:** OEF= Operation Enduring Freedom, OIF= Operation Iraqi Freedom, PEQ= Prosthesis Evaluation Questionnaire, SATPRO= Satisfaction with Prosthesis Questionnaire, SCS= Socket Fit Comfort Score, SPU= Survey for Prosthetic Use, TAPES= Trinity Amputation and Prosthesis Experience Scales, VAS= visual analogue scale.

**Keywords:** amputation, prosthesis fitting, questionnaires, satisfaction

### 1. Introduction

Regaining mobility is an important rehabilitation objective for patients with a transtibial amputation. Satisfaction with the prosthesis plays a key role in regaining mobility and is important for optimizing use of the prosthesis, preventing rejection, and increasing compliance with the medical regimen.<sup>[1,2]</sup> Forty percent to 60% of amputee patients are not satisfied with their prostheses.<sup>[3,4]</sup> Fifty-seven percent are dissatisfied with the

comfort of their prostheses, and over 50% report pain while using their prostheses.<sup>[3,4]</sup> Rejection of the prosthesis can be seen as the ultimate expression of dissatisfaction with the prosthesis and occurs in up to 31% cases of prostheses prescribed to armed forces service members with lower limb amputations, mainly as a result of technical problems (e.g., “too much fuss” during use and the prosthesis being “too heavy”).<sup>[5]</sup> These findings make (dis)satisfaction with transtibial prostheses a highly relevant issue in lower limb amputee care.<sup>[4,5]</sup>

Patient satisfaction is a key indicator of the quality of care. It plays an important role in the evaluation of outcomes of health care services and management of the health care budget.<sup>[1,2,6–8]</sup> Numerous theories and models of patient satisfaction exist, including “the value expectancy model,” “the disconfirmation theory,” “the attribution theory,” and “the need theory.”<sup>[6,8]</sup> Satisfaction is defined in different ways, for example, “an emotional or affective evaluation of the service based on cognitive processes which were shaped by expectations”; “a congruence of expectations and actual experiences of a health service”; and “an overall evaluation of different aspects of a health service.”<sup>[6]</sup> In summary, patient satisfaction entails matching patients’ experiences with their expectations.

The various questionnaires assessing satisfaction with the prosthesis operationalize satisfaction differently. For example, the Trinity Amputation and Prosthesis Experience Scales (TAPES) assesses satisfaction using a 5-point scale that comprises questions on “color,” “noise,” “shape,” “appearance,” “weight,” “usefulness,” “reliability,” “fit,” “comfort,” and “overall satisfaction.”<sup>[9,10]</sup> The Prosthesis Evaluation Questionnaire (PEQ) uses 2 visual analogue scales to assess overall satisfaction and satisfaction with walking with the prosthesis during the previous 4 weeks.<sup>[11]</sup>

Editor: Jianxun Ding.

ECB and ES contributed equally to this work.

Funding/support: No funding was provided. The authors received no financial benefits in relation to this study.

The material in our study has not been previously published or presented.

The author (s) of this work have nothing to disclose.

There is no conflict of interest regarding the manuscript.

<sup>a</sup> Vogellanden, Center for Rehabilitation, Zwolle, <sup>b</sup> Department of Rehabilitation Medicine, Center for Rehabilitation, <sup>c</sup> Department of Oral and Maxillofacial Surgery, University Medical Center Groningen, University of Groningen, Groningen, the Netherlands.

\* Correspondence: Erwin C. Baars, Vogellanden, Center for Rehabilitation, Hyacinthstraat 66a, 8001 BB Zwolle, the Netherlands (e-mail: e.c.t.baars@vogellanden.nl).

Copyright © 2018 the Author(s). Published by Wolters Kluwer Health, Inc. This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

Medicine (2018) 97:39(e12296)

Received: 5 June 2018 / Accepted: 16 August 2018

<http://dx.doi.org/10.1097/MD.00000000000012296>

In this review, prosthesis satisfaction is viewed as a multidimensional and dynamic construct. Prosthesis satisfaction is the patient's subjective and emotional evaluation of (aspects of) the prosthesis that is influenced by the appearance, properties, fit, and use of the prosthesis, as well as aspects of the residual limb. Emotions regarding the prosthesis are also influenced by the patient's psychological state, for example, depression and anxiety; psychological factors; and person-related characteristics, such as prior experiences, coping, expectations, general values, beliefs, perceptions, and social context.<sup>[6,7]</sup> Hence, satisfaction with the prosthesis (or prosthesis components) is a biopsychosocial construct that is influenced by all of the aforementioned factors.<sup>[1,2,6,7]</sup>

Recently, a systematic review analyzed patients' experiences, including satisfaction, with transtibial prosthetic liners.<sup>[11]</sup> This review has several limitations. First, half of the included studies had small sample sizes ( $\leq 10$ ). Second, most of the included studies used author-designed questionnaires, some of which were based on the PEQ. Third, satisfaction was not studied in all of the included studies. Fourth, in several studies, patients' experiences with liners were assessed with test prostheses instead of definitive prostheses. Finally, in 2 studies, the same population was researched.<sup>[12,13]</sup>

Given that prosthesis satisfaction is not only interpreted differently by researchers<sup>[1,2,6]</sup> but also operationalized differently in questionnaires, it is difficult to compare results of studies on prosthesis satisfaction. A comprehensive overview of factors that influence satisfaction with the prosthesis is currently missing. Such an overview will help clinicians to systematically assess these factors and target them to improve outcomes.

This systematic review aims to identify factors of influence on patient satisfaction with a definitive transtibial prosthesis, report satisfaction scores, present an overview of questionnaires used to assess satisfaction with the prosthesis, and examine how these questionnaires operationalize satisfaction.

## 2. Methods

This study is reported in accordance with the PRISMA guidelines. Ethical approval is not required for this is a systematic review of previously published studies.

### 2.1. Search strategy

Six databases (PubMed, Embase, PsycInfo, CINAHL, Cochrane, and Web of Knowledge) were searched from their inception to February 2018. The search strategy used for PubMed was based on terms related to lower limb prosthesis, including "lower limb," "leg," "artificial limb," and "prosthesis"; and patient satisfaction, including "patient satisfaction," "acceptance," "rejection," "satisfaction," and "dissatisfaction." Excluded were the terms "endoprosthesis," "arthroplasty," "graft," "implant," and "breast." With the aid of an information specialist, the search strategy for MEDLINE was designed: (leg OR lower limb) AND (prosthesis OR artificial limb) AND (patient satisfaction OR accept\* OR reject\* OR satisf\* OR dissatisf\*) NOT (endoprosthesis OR implant OR graft OR bypass OR breast). The search strategy was adapted for each of the databases accordingly.

### 2.2. Study selection

Studies were collected in a RefWorks database and duplicates (publications listed more than once) were removed. Two

observers (JG, EB) independently assessed the titles and abstracts of the studies identified in the databases.

Inclusion criteria were as follows: a questionnaire was used to assess patient satisfaction with a definitive prosthesis; the transtibial amputation level was studied, or, in case of mixed samples, separate data were presented on transtibial amputee patients; age of (part of) the study population was  $> 18$  years and separate data were presented on this group; sample size was  $> 10$ ; and studies were published in English, Dutch, or German.

Excluded were studies of interim or test prostheses, congress abstracts with no full text available, and all types of reviews. After title and abstract assessment, observer agreement was calculated (Cohen Kappa and absolute agreement), and discrepancies in assessments were discussed between observers until consensus was reached. Full text studies included in the first round were assessed independently for inclusion and exclusion criteria by the same observers (JG, EB) and recorded on a predesigned form. Next, a consensus meeting took place to discuss the recorded studies. Double publications (studies using the same study population) were removed. Reference lists of included studies were checked for any relevant studies not identified in the database searches. The full text of these studies was assessed and interobserver agreement was calculated.

The methodological quality of included studies was assessed independently by 2 authors (ES, EB) by means of a checklist based on the Methodology Checklist for Cross-Sectional/ Prevalence Studies of the Agency for Healthcare Research and Quality.<sup>[14]</sup> For longitudinal studies, additional criteria from the Methodological Index of Non-Randomized Studies (Minors check list) were assessed.<sup>[15]</sup> When relevant data were missing or a mixed group of amputee patients was described in the study and no separate data on transtibial amputee patients were presented, we contacted the corresponding authors with the request to provide these data.

Factors associated with prosthesis satisfaction were extracted independently by 2 observers (ES, EB) and recorded on a predesigned form. These factors were categorized into 5 satisfaction domains: appearance of the prosthesis, properties of the prosthesis, fit of the prosthesis, use of the prosthesis, and aspects of the residual limb.

### 2.3. Questionnaires

Two observers (ES, a rehabilitation psychologist with 17 years of experience in rehabilitation care, and EB, a physiatrist with 18 years of experience in amputee patient care) independently analyzed the questionnaires used in the studies regarding questions or combinations of questions that assessed prosthesis satisfaction. Questions that asked the patient to subjectively or emotionally evaluate the appearance and properties of the prosthesis or its fit and use were labeled as satisfaction questions. For example, the question "Rate how your prosthesis looks," with answering possibilities on a visual analogue scale anchored by "terrible/excellent," was labeled as a satisfaction question. If responses to a question were endorsed on a numerical scale, for example, "How many prostheses wore out?," this question was not labeled as a satisfaction question. Discrepancies in assessment of questions were discussed until consensus was reached.

## 3. Results

### 3.1. Search

A total of 1832 unique studies were identified for assessment after removal of duplicates from the search results. Thirteen studies

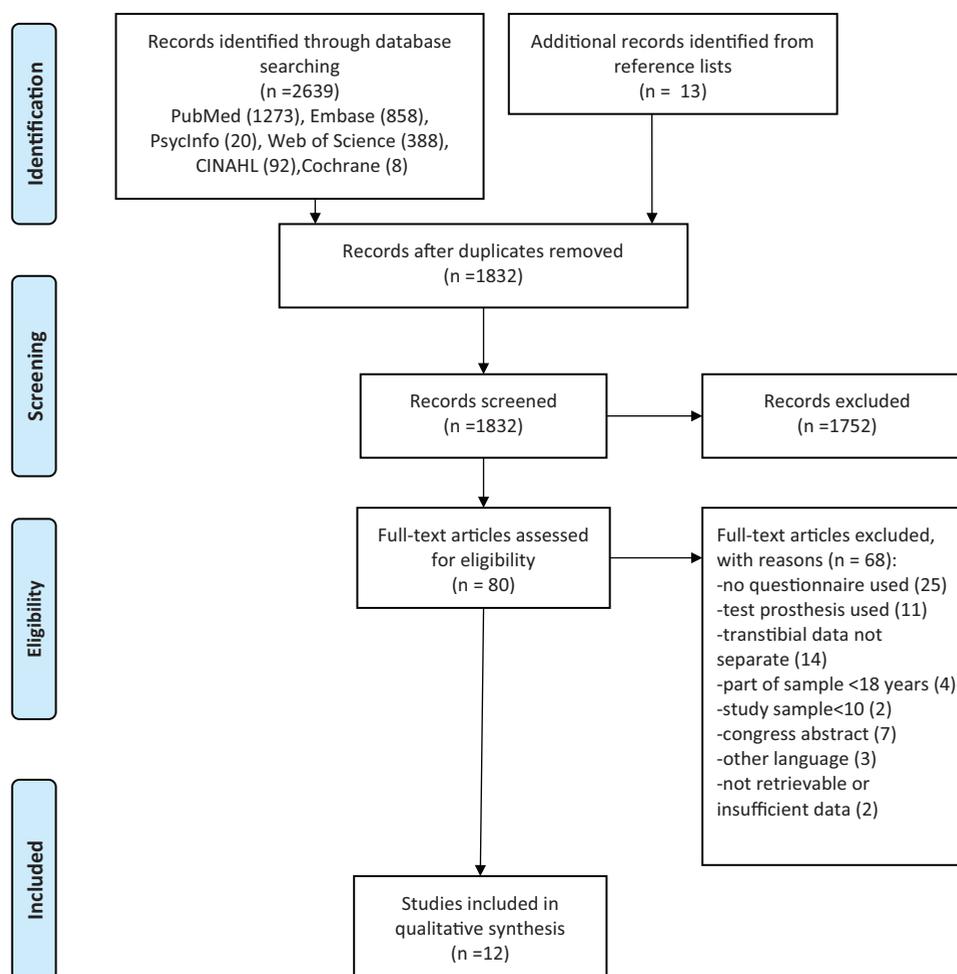


Figure 1. Flow chart of paper assessment.

were identified from the reference lists of the included studies (Fig. 1). Cohen Kappa as a measure for interobserver agreement for title and abstract assessment was 0.793, absolute agreement 98%. Eighty studies remained after the first assessment and full text of these studies was retrieved, in addition to the full text of studies identified from the reference lists. Sixty-seven studies were excluded (Fig. 1).<sup>[10,13,16–76]</sup> The assessment resulted in the final inclusion of 12 studies (Fig. 1).<sup>[1,3–5,77–84]</sup> Cohen Kappa as a measure for interobserver agreement of the full text assessment and selection was 0.39 (absolute agreement 67%).

### 3.2. Study descriptions and quality assessment

Most studies had a cross-sectional design. Two had a longitudinal design.<sup>[79,84]</sup> Sample sizes varied from 14 to 581 participants, age ranged from 18 to 70 years, and 60% to 100% was male. Participants were recruited from prosthetic centers, amputee patient groups, hospitals, medical services for armed forces service members, and registered charities (Table 1).<sup>[1,3–5,77–83]</sup> One of the contacted authors responded to our request for additional data on transtibial amputee patients.<sup>[84]</sup>

Quality criteria that were met for ranging from 6 out of 10 to 10 out of 10 (Table 2). The longitudinal studies<sup>[79,84]</sup> met 2 and 3 of the 8 additional Minors criteria (Table 2).

### 3.3. Overall satisfaction

Overall satisfaction with the prosthesis was analyzed in 5 studies.<sup>[3,77,78,82,84]</sup> Van de Weg and van der Windt<sup>[78]</sup> compared 2 overall satisfaction scores between groups of patients with different types of liners and found no significant differences between these patients.

A regression analysis demonstrated that male gender, paid work, a nonvascular reason for amputation, and a longer period of time since amputation were associated with somewhat higher satisfaction scores. Ali et al<sup>[77]</sup> analyzed satisfaction with liners and found significantly higher overall satisfaction scores for Seal-in liner users. Berke et al<sup>[3]</sup> reported mean overall satisfaction scores (range 0–10) in veterans and service members who lost limbs in the Vietnam conflict (7.3) or in the Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) conflicts (7.5). Harness and Pinzur<sup>[82]</sup> found overall satisfaction to be associated with “appearance” ( $r=0.44$ ), “residual limb health” ( $r=0.44$ ), “less pain” ( $r=0.40$ ), “ability to ambulate” ( $r=0.66$ ), and “ability to make transfers” ( $r=0.36$ ). Giesberts et al<sup>[84]</sup> analyzed satisfaction with the modular socket system in a longitudinal study using an overall prosthesis evaluation score, ranging from 0 to 10, with 0 equaling “not at all satisfied” and 10 equaling “very satisfied.”

**Table 1**  
**Summary of participant characteristics from studies analyzing factors influencing patient satisfaction with transtibial prosthesis.**

Study	Country	Recruitment	% Men (N)	TT (%)	Mean age ± sd, y	Reason for amputation (%); level of amputation	TSA, PU, mm/y	HPU	Employment (%)	Questionnaire
Dillingham et al [4]	USA	Hospital	87% (78)	51%	33 ± 11*	100% trauma; TF, TT, KD, A, F	TSA: 8 ± 3 y	nr	nr	Author-designed questionnaire
Harness and Pinzur [82]	USA	Hospital	77% (60)	100%	66 ± 1	100% vascular; TT	PU: range 6–180 mm	nr	nr	PEQ
Van de Weg and van der Windt [79]	NL	Limb fitting center	60% (220)	100%	62 ± 18	38% vascular 42% trauma 20% other; TT	PU: mean 17 ± 16 y	93% >6	27%	PEQ based
Berke et al [3]	USA	Aimed forces service members; W OIF, OEF	100% (298)	75%	61	100% trauma; UL, TF, TT, F	TSA: mean 39 y	nr	79%	SPU
Galley et al [5]	USA	Aimed forces service members; W OIF, OEF	97% (283)	56%	29	100% trauma; HD, IF, KD, TT, A, F	TSA: mean 38 ± 5 y	nr	54%	SPU
Kark et al [1]	Australia	Amputee group	100% (178)	58%	61 ± 3	100% trauma; HD, IF, KD, TT, A, F	TSA: mean 3 ± 1 y	nr	80%	PEQ
Ali et al [77]	Malaysia	Medical/engineering research center	98% (172)	54%	29 ± 6	15% vascular 85% trauma; TF, TT	TSA: 19 ± 34 y	nr	nr	PEQ based
Webster et al [79]	USA	Department of Veterans Affairs medical centers, hospital, trauma center	100% (243)	100%	44 ± 6	100% trauma; TT	PU: 22 ± 6 y	12 ± 3	nr	PEQ based
Cairns et al [83]	UK	Members of Murray Foundation, a registered charity in Scotland	100% (87)	60%	62 ± 9	100% vascular; TF, TT	nr	nr	15%	TAPES
Samtner et al [81]	Spain	Limb fitting center, rehabilitation center	69% (153)	67%	78% between 45 and 70 y	18% vascular, 15% diabetes	PU: ≤ 9 to 69 y	≤ 8 to ≥ 12	nr	Author designed questionnaire
Sinah et al [90]	NL	Limb fitting center, rehabilitation center	88% (16)	100%	65 ± 10	33% trauma 34% other; TF, KD, TT, HD, PF	PU: ≥ 6 mm	nr	nr	SATPRO
Giesberts et al [84]	Indonesia	Database limb fitting center	88% (368)	76%	43 ± 15	16% vascular/diabetes 76% trauma 8% other; TF, KD, TT	TSA: 13 ± 10 y PU: 11 ± 9 y	10 ± 4	59%	TAPES
			79% (11/14)	100%	37 ± 10	13% (2/15) vascular 87% (13/15) trauma	TSA 12 ± 12 PU: 12 y (range 75 d–35 y)	10: 13.2 ± 4.2	nr	SCS PEQ Overall prosthesis satisfaction score (0–10)

A = ankle; F = (partial) foot; HD = hip disarticulation; HPU = hours of prosthesis use per day; KD = knee disarticulation; mm = months; nr = data not reported; NL = Netherlands; OIF/OEF = Veterans of Operation Iraqi Freedom/Operation Enduring Freedom; PEQ = Prosthesis Evaluation Questionnaire; PU = prosthesis use; SATPRO = Satisfaction with Prosthesis Questionnaire; SCS = Socket Fit Comfort Score; SPU = Survey for Prosthetic Use; to = fitting with modular socket system; TAPES = Trinity Amputation and Prosthesis Experience Scales; TF = transfemoral; TSA = time since amputation; TT = transtibial; UK = United Kingdom; UL = upper limb; USA = United States of America; WV = Vietnam veterans.

\* Age at time of amputation.

**Table 2**  
Study quality assessment.

Quality criteria	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Dillingham et al <sup>[4]</sup>	+	+	+	+	+	+	-	+	+	+	-	+								
Harnes and Pinzur 2001 <sup>[82]</sup>	+	+	+	-	+	+	+	-	-	-	-	-								
Van de Weg and van der Windt <sup>[78]</sup>	+	+	-	-	-	-	+	+	+	+	+	+								
Berke et al <sup>[3]</sup>	+	+	-	+	+	+	+	+	+	+	-	-								
Gailey et al <sup>[5]</sup>	+	+	+	+	+	+	+	-	+	-	-	-								
Kark et al <sup>[1]</sup>	+	+	+	-	+	+	+	-	+	+	-	-								
Ali et al <sup>[77]</sup>	+	+	-	-	+	+	+	-	-	-	-	+								
Cairns et al <sup>[83]</sup>	+	+	-	-	+	+	-	-	+	+	-	+								
Samitier et al <sup>[81]</sup>	+	+	+	-	+	-	+	-	+	-	-	-								
Sinah et al <sup>[80]</sup>	+	+	+	+	-	+	+	+	-	+	-	-								
Webster et al <sup>[79]</sup>	+	+	+	+	+	-	+	+	+	+	-	-	+	+	-	-	-	-	-	+
Giesberts et al <sup>[84]</sup>	+	+	+	-	+	-	+	+	-	-	-	-	+	+	-	-	-	-	-	-
Sum	12	12	8	4	11	9	10	5	9	6	1	5	2	2	0	0	0	0	0	1

1. Is the source of information reported? 2. Were inclusion criteria reported? 3. Were exclusion criteria reported? 4. Was the time frame of recruitment reported? 5. Was the recruitment setting reported? 6. Were subjects consecutively recruited or population based? 7. Has the questionnaire been tested for measurement properties/unbiased assessment of study endpoints? 8. Have participants been excluded from analysis? 9. Has confounding been assessed and controlled for, (subgroups analysis of multi variate analysis)? 10. Were missing data reported? 11. Were missing data imputed? 12. Was response rate reported? 13. Was there prospective collection of data? 14. Was the follow-up period appropriate to the study aim? 15. Was the loss to follow up less than 5%? 16. Was there prospective calculation of study size? 17. Was there an adequate control group? 18. Were there contemporary groups? 19. Was there baseline equivalence of groups? 20. Was there adequate statistical analysis? \*

\*Criteria for longitudinal studies.

Mean visual analogue scale (VAS) scores (range 0–10) for overall satisfaction ranged from 6.9<sup>[77]</sup> to 7.7,<sup>[84]</sup> and mean overall satisfaction sum scores (range 0–21) ranged from 11.0 to 12.0.<sup>[78]</sup> Mean overall satisfaction with liners (range 0–100) ranged from 63.1 for polyethylene liners to 83.1 for Seal-in liners.<sup>[77]</sup>

### 3.4. Appearance

Several studies described the percentage of patients satisfied with the appearance of their prostheses or reported satisfaction scores regarding appearance.<sup>[4,77,78,82,84]</sup> Harness and Pinzur<sup>[82]</sup> found a positive association between overall satisfaction and appearance of the prosthesis ( $r=0.44$ ). Two studies compared different prosthesis liners in relation to satisfaction with appearance.<sup>[77,78]</sup> Van de Weg and van der Windt<sup>[78]</sup> found no significant differences regarding satisfaction with appearance of the prosthesis (“looks”) between users of different liners. Ali et al<sup>[77]</sup> found that patient satisfaction with appearance of the prosthesis was highest for Seal-in liner users. The operationalization of satisfaction with appearance of the prosthesis included the factors “appearance,” “color,” “touch/feel,” “look (s),” “cosmetics,” and “shape.”<sup>[4,77,78,82–84]</sup> Giesberts et al<sup>[84]</sup> found no change in satisfaction with appearance over time using the PEQ, in patients using the modular socket system.

The PEQ was applied in 3 studies and uses an appearance scale to assess satisfaction.<sup>[1,82,84]</sup> This scale includes 5 questions: 1 on appearance of the prosthesis, 2 on damage done to clothing or prosthesis cover, and 2 on freedom in choice of clothing and shoes. PEQ-based questionnaires were used in 2 studies. One study included a question on cosmetic satisfaction with the prosthesis, a concept closely related to appearance, while the other study included a question on satisfaction with appearance.<sup>[77,78]</sup> The TAPES, used in 2 studies, includes 1 question regarding satisfaction with appearance.<sup>[79,80]</sup> This question is part of its Aesthetic Satisfaction Subscale. The other 2 questions of this subscale assess satisfaction with the shape and color of the prosthesis. In the Survey for Prosthetic Use (SPU), used in 2 studies, appearance is not assessed.<sup>[3,5]</sup> The Satisfaction with

Prosthesis Questionnaire (SATPRO) was used in 1 study and includes 15 questions, 1 of which assesses satisfaction with the look of the prosthesis.<sup>[81]</sup> Two studies used author-designed questionnaires. Dillingham et al<sup>[4]</sup> used 1 question to assess satisfaction with the appearance of the prosthesis. Cairns et al<sup>[83]</sup> included a subscale on the aesthetics of the prosthesis, another concept closely related to appearance. This subscale includes 3 questions assessing “color,” “shape,” and “feel/touch” of the prosthesis.

### 3.5. Properties of the prosthesis

Satisfaction with properties of the prosthesis was reported in 7 studies.<sup>[3–5,79,80,83,84]</sup> Sinha et al<sup>[80]</sup> found that satisfaction with the weight of the prosthesis was significantly higher in transtibial amputee patients than in transfemoral amputee patients. Webster et al<sup>[79]</sup> found significantly lower levels of functional satisfaction in transtibial amputee patients than in transmetatarsal amputee patients. No significant differences in satisfaction with functional and physical properties of the prosthesis were found between Vietnam veterans and OIF or OEF veterans in the study of Berke et al.<sup>[3]</sup> Another study found a prosthesis rejection rate of 18% in Vietnam veterans and 31% in OIF or OEF veterans.<sup>[5]</sup> The operationalization of satisfaction with functional and physical properties of the prosthesis included the factors “weight,” “smell,” “noise,” “being waterproof,” “durability,” “reliability,” “usefulness,” “easy to clean,” “ease of use,” “works well regardless of the weather”, “limitations imposed on clothing,” “shoe choice (height and style),” “damage done to clothing,” and “interaction of prosthesis cover with clothing and joint movement.”<sup>[3–5,79,80,83,84]</sup>

Giesberts et al<sup>[84]</sup> found a nonsignificant decline in PEQ scores over time when assessing satisfaction with sounds of the prosthesis. The PEQ includes 2 questions on satisfaction with properties of the prosthesis.<sup>[1,82]</sup> These questions assess the patients’ rating of “prosthesis weight” and “squeaking, clicking or belching sounds” made by the prosthesis. Two PEQ-based questionnaires also included satisfaction questions assessing the properties “sound” and “smell” of the prosthesis.<sup>[77,78]</sup> The

Functional Satisfaction Subscale of the TAPES includes 3 questions on satisfaction with “weight,” “usefulness,” and “reliability” of the prosthesis.<sup>[79,80]</sup> The SPU has a satisfaction section with 3 questions on satisfaction with “smell,” “sound,” and “weight” of the prosthesis and a dissatisfaction section with questions on “lack of reliability” and “lack of functionality” of the prosthesis.<sup>[3,5]</sup> In the SATPRO, 4 of the 15 questions concern properties of the prosthesis. The scores on these questions are not analyzed on item level.<sup>[81]</sup> An author-designed questionnaire included 3 questions on factors affecting satisfaction with the cosmetic properties of prosthesis: “durability,” “being waterproof,” and “easy to clean.”<sup>[83]</sup>

### 3.6. Fit

Dillingham et al<sup>[4]</sup> reported on satisfaction with the fit and comfort of the prosthesis without using a between-group comparison. Other studies that examined the fit of the prosthesis did perform between-group comparisons of war veterans and included the variables employment, gender, marital status, reasons for amputation, years since amputation, and mobility level. Three of 4 studies found no significant differences between groups.<sup>[3,78,81]</sup> Ali et al<sup>[77]</sup> found that the type of liner significantly influenced patient satisfaction with the fit of the prosthesis. Satisfaction with prosthesis fit and suspension was highest in Seal-in liner users, and satisfaction with prosthesis donning and doffing was highest in users of polyethylene foam liners.<sup>[77]</sup> The operationalization of satisfaction with fit included the factors “comfort,” “fit,” “donning and doffing,” “suspension,” “pistoning,” “rotation,” and “socket fit.”<sup>[3,4,77,78,81,84]</sup>

Giesberts et al<sup>[84]</sup> found a significant decline ( $P=.027$ ) in satisfaction with comfort and pain over time using the Socket Fit Comfort Score (SCS) in patients using the modular socket system. The Utility Scale of the PEQ includes 2 questions on satisfaction with the fit and comfort of the prosthesis; the latter is a concept closely related to fit.<sup>[1,82]</sup> In a PEQ-based questionnaire, 1 question was used to measure satisfaction with fit (“comfort to wear”).<sup>[78]</sup> The TAPES has incorporated “fit” and “comfort” into 3 questions on prosthesis properties in a subscale assessing satisfaction.<sup>[79,80]</sup> The SPU includes 1 satisfaction question on “fit.”<sup>[3,5]</sup> The SATPRO also includes 1 question on satisfaction with the comfort of the prosthesis.<sup>[81]</sup> The SCS assesses satisfaction with socket comfort while sitting, standing and walking, using a scale ranging from 0 to 10, with 0 being “most uncomfortable socket you can imagine” to 10 the “most comfortable socket fit.”<sup>[84]</sup>

### 3.7. Aspects of the residual limb

Berke et al<sup>[3]</sup> compared differences in satisfaction with the prosthesis between 3 groups of veterans with limb loss. It was found that Vietnam veterans had significantly less skin problems of the residual limb than OIF or OEF veterans, which positively affected their satisfaction with the prosthesis. Another study found overall satisfaction to be associated with residual limb health and less pain in the residual limb ( $r=0.4$ ).<sup>[82]</sup> Giesberts et al<sup>[84]</sup> found a nonsignificant decline in residual limb health using the PEQ in patients using the modular socket system. The operationalization of satisfaction with the residual limb included the factors “sweating/perspiration,” “wounds,” “irritation,” “blisters,” “pimples,” “skin rash,” “swelling,” “pain,” and “phantom pain.”<sup>[1,3–5,79,80,82]</sup>

The PEQ includes a Residual Limb Health Scale containing 6 questions and a total of 10 questions on pain, 3 of which specifically assess pain in the residual limb.<sup>[1,82,84]</sup> Questionnaires based on the PEQ included several questions on different aspects of the residual limb that influence satisfaction, such as “sweating,” “wounds,” “irritation,” “smell,” and “pain.”<sup>[77,78]</sup> The TAPES includes 1 question on residual limb pain.<sup>[79,80]</sup>

The SPU includes 3 questions on aspects of the residual limb that impact satisfaction; these include “pain,” “skin problems,” and “sweating.”<sup>[3,5]</sup> An author-designed questionnaire included questions on “skin irritation,” “wounds,” “perspiration,” and “pain.”<sup>[4]</sup>

### 3.8. Use of the prosthesis

In 2 studies, differences between groups regarding satisfaction with prosthesis use were analyzed.<sup>[77,78]</sup> Users of polyethylene foam inserts were more satisfied than users of silicon liners or polyurethane liners while sitting or while walking on uneven terrain.<sup>[78]</sup> Users of Seal-in liners were more satisfied while “sitting,” “walking,” “walking on uneven terrain,” and “walking on stairs” than users of silicone liners with a shuttle lock or polyethylene foam liners.<sup>[77]</sup> Harness and Pinzur<sup>[82]</sup> analyzed factors associated with satisfaction with prosthesis use. Satisfaction with use was associated with the “ability to ambulate” and the “ability to transfer.” Giesberts et al<sup>[84]</sup> found no significant change in ambulation or prosthesis utility over time in patients fitted with the modular socket system. Another study found that satisfaction with walking with the prosthesis was higher in transtibial amputee patients than in transfemoral amputee patients.<sup>[1]</sup> The operationalization of satisfaction with use included satisfaction with “sitting,” “walking,” “walking on uneven terrain,” “walking up and down stairs,” “ease of use,” “daily use,” and performance-based measures.<sup>[1,4,77,78,82–84]</sup>

The Ambulation Scale of the PEQ includes 8 questions, 1 of which assesses satisfaction while walking down the stairs.<sup>[1,82,84]</sup> The PEQ-based questionnaires included questions on satisfaction with prosthesis use in different circumstances, including “sitting,” “walking,” “climbing stairs,” and “walking on uneven terrain.”<sup>[77,78]</sup> In the SATPRO, 2 of the 15 questions assess satisfaction with prosthesis use.<sup>[81]</sup> An author-designed questionnaire assessed satisfaction with a question on “hours of prosthesis use.”<sup>[4]</sup>

## 4. Discussion

### 4.1. Study aim

The analysis of the included studies revealed that a considerable number of transtibial amputee patients were not satisfied with their prostheses or aspects of their prostheses. Satisfaction with the prosthesis is a multidimensional construct that is affected by various factors. In the included studies, several factors were found to influence satisfaction and dissatisfaction and the use of different operationalizations of satisfaction in the questionnaires makes comparison of outcomes between studies impossible.

### 4.2. Participants

Participants assessed in the included studies were predominantly physically active males who had undergone a traumatic amputation and who had a wide range in age and time since amputation.<sup>[1,3–5,77–84]</sup> In some studies, participant characteristics

**Table 3**  
**Satisfaction scores and factors related to satisfaction grouped in 5 domains.**

Ref. year	Statistics	Questionnaire comparison	Appearance	Properties	Fit	Residual limb	Use
Dillingham et al [4]	Scale mean range: 0–100	Author designed	Appearance: 58.1	Weight: 58.1	Comfort: 43.2		Ease of use: 60.8
Harness and Pinzur [82]	Scale mean (sd), range: 0–100	PEQ	Appearance: 73.3 (2.4)			Residual limb health: 79.7 (2.3)	Ambulation: 55.3 (3.1) Transfer: 64.6 (2.9)
	Regression analyses	Associations with overall satisfaction	Appearance: $r = 0.44^*$			Residual limb health: $r = 0.44^*$	Ability to ambulate: $r = 0.66^*$
Van de Weg and van der Windt [78]	Percentage (%) satisfied Chi square?	PEQ based Satisfied with liner Comparison of 3 liners: PEFI/SL/ PUL	Looks: 67%/68%/66%		Fit: 69%/ 64%/ 68% Donning and doffing: 79%/ 77%/ 78%		Sitting: 88%/ 62%/ 59%* Walking: 70%/ 60%/ 54% Walking uneven terrain: 46%/ 25%/ 39%* Stairs: 54%/ 51%/ 45%
	Mean (sd), range: 0–10 ANOVA Mean (sd) range: 0–21 ANOVA	Overall satisfaction score 7.3 (1.0)/ 7.0 (2.1)/ 6.9 (1.9) Satisfaction sum score 12.0 (3.9)/ 11.3 (5.0)/ 11.0 (5.0) Males were more satisfied than females ( $b = 2.6^*$ ). Working amputee patients were more satisfied than non- working ( $b = 1.6^*$ ). Vascular amputee patients were less satisfied than other amputee patients ( $b = -1.7^*$ ). Patients amputated less than 10 years ago were less satisfied than patients with a more longstanding amputation ( $b = -1.9$ )					
Berke et al [83]	Percentage satisfied with prosthesis Chi-square	SPU Comparison: W/ (OIF, OEF) Overall satisfaction 7.3/7.5 (range 0–10)		Weight: 95%/94% Noise: 40%/48% Smell: 33%/39% Mechanical Waterproof Rejection: 18%/ 31%	Fit: 91%/82% Socket comfort and fit: 76%/73%	Skin problems: 52%/72%* Sweating: 70%/57%	
Gailey et al [85]	Percentage of devices rejected	SPU Comparison W/(OIF, OEF)					
Kark et al [1]	Point-biserial correlation	PEQ					Walking: Transfemoral amputee patients were less satisfied than trans-tibial amputee patients: $r_{10} = 0.50^*$
Ali et al [77]	Mean VAS (range 0–100) ANOVA	PEQ-based Satisfaction with liners Comparison: SLS/PFL/ SIL Overall satisfaction 75.9/ 63.1/ 83.1	Cosmetic 69.1/73.3/83.1*		Fit: 79.6/64.8/ 87.1* Donning/doffing: 71.4/79.7/57.2 Suspension: 81.7/ 55.2/93.7		Walking: 72.8/65.2/ 84.7 Uneven-walking: 63.9/ 54.1/ 77.9 Climbing stairs: 68.8/ 60.8/80.6* Sitting: 68.8/76.4/ 79.4
Webster et al [79]	Mean scores	TAPES mean Functional scale range (5–25)		Functional satisfaction was lower in trans-tibial amputee patients (17.8) than in transmetatarsal patients (21.4)			

(continued)

**Table 3**  
(continued).

Ref. year	Statistics	Questionnaire comparison	Appearance	Properties	Fit	Residual limb	Use
Cairns et al. <sup>[83]</sup>	Percentage of wearers reporting neutral or dissatisfied opinion	Author designed Satisfaction with cosmetics	Color: 59% Shape: 49% Touch: 57%	Waterproof quality: 61% Ability to keep clean: 64% Durability: 45%			Fit under clothing: 45% Natural bending of cosmesis: 58% Influence on prosthetic joint movement: 43%
Samtlier et al. <sup>[81]</sup>	Mean (range 15–60) <i>t</i> test	SATPRO: satisfied with suspension system Comparison: MFCL-2/ MFCL-3		Weight: Transfemoral amputee patients were less satisfied with weight than transtibial patients $b = -0.399^*$	Without VASS: 30.5/25.7 With VASS: 26.5/ 28.4		
Sinah et al. <sup>[80]</sup>	Regression analyses	TAPES		Sounds score PEQ $t1:93$ $t2:81$	Comfort SCS: $t1:7.3 \pm 1.5$ $t2:7.0 \pm 1.3$	Residual limb health score PEQ $t1:79$ $t2:78$	Utility score PEQ: $t1:75$ $t2:74$ Ambulation score PEQ: $t1:74$ $t2:73$
Giesberts et al. <sup>[84]</sup>		SCS (range 0–10), PEQ	Appearance score PEQ $t1:81$ $t2:84$				

*b* = regression coefficient; MFCL = Medicare Functional Classification Level; *n.s.* = not significant; OIF/ORF = veterans of Operation Iraqi Freedom/Operation Enduring Freedom; PEQ = Prosthesis Evaluation Questionnaire; PFL = polyethylene foam liner; PUL = polyurethane liner; *r* = correlation coefficient;  $r_{pb}$  = point biserial correlation coefficient; SATPRO = Satisfaction with Prosthesis Questionnaire; SCS = Socket Fit Comfort Score; SIL = Seal-in liner; SL = silicone liner with shuttle lock; SO-scale = sound scale; SPU = Survey for Prosthetic Use;  $t1$  = 1–3 months post fitting with modular socket system;  $t2$  = 4–6 months post fitting with modular socket system; TAPES = Trinity Amputation and Prosthesis Experience Scales; VAS = visual analog scale; VASS = vacuum-assisted socket system; W = Vietnam veterans.  
\*  $P < .05$ .

were correlated. Armed forces service members, for example, were almost exclusively 30- to 60-year-old males who were employed, had undergone traumatic amputations, and used their prostheses many hours per day.<sup>[3,4]</sup> Female amputee patients were underrepresented and outcome regarding appearance, comfort, and use of the prosthesis was not given separately for women.<sup>[1,3–5,78,80–84]</sup>

#### 4.3. Overall satisfaction

Five studies assessed overall satisfaction with the prosthesis, which is the least specific evaluation of satisfaction.<sup>[3,77,78,82,84]</sup> Overall satisfaction scores give no insight into the specific aspects of satisfaction and offer no directions for improvement. The operationalization of overall satisfaction was associated with “appearance of the prosthesis” “residual limb health,” “experiencing less pain,” and “being able to ambulate and make transfers.”<sup>[3,77,78,82]</sup> The scores on overall satisfaction suggest that there is considerable room for improvement (Table 3).

#### 4.4. Appearance of the prosthesis

The use of the words “appearance,” “look (s),” “cosmetics,” and “aesthetics” in the questionnaires refer to the operationalization of appearance of the prosthesis and illustrates why it is difficult to draw comparisons between study outcomes. These words are similar in nature, for they all refer to the outward form/appearance of the prosthesis, but subtle semantic differences are nevertheless present. “Appearance” is the more neutral option, whereas “looks” and “aesthetics” refer to the appreciation of the appearance of the prosthesis. “Cosmetics,” in turn, can also refer to the enhancement of the (normal) appearance. These words are not interchangeable, and differences in meaning may result in different interpretations of questions regarding appearance, thereby influencing the outcomes of the questionnaires.

The difference in the number of questions used in the scales of the questionnaires also makes it difficult to compare outcomes. The number of questions on satisfaction with appearance, for example, varied from 1 question in the SATPRO, 3 questions in the TAPES, and 5 questions in the PEQ, all with different scale ranges (Table 4). In addition, while most questionnaires assess satisfaction, only 1 assesses dissatisfaction with “reliability” and “functionality” of the prosthesis (SPU).<sup>[81]</sup> The low satisfaction scores on appearance of the prosthesis indicate that there is also room for (considerable) improvement (Table 3).

#### 4.5. Properties of the prosthesis

One study reported on rejection rates of the prosthesis of 18% of Vietnam veterans and 31% of OIF/OEF veterans, predominantly because of dissatisfaction with properties of the prosthesis.<sup>[5]</sup> One study reported an increase of satisfaction with appearance and a decrease in satisfaction with sounds and utility of the prosthesis and a decrease of residual limb health over time.<sup>[84]</sup> In another study, the mean satisfaction score regarding weight of the prosthesis was 58.1 (range 0–100).<sup>[4]</sup> Amputee patients with a more proximal amputation were less satisfied with the function and weight of the prosthesis than amputee patients with a more distal amputation, and transfemoral amputee patients were less satisfied while walking with the prosthesis than transtibial amputee patients.<sup>[1,79,81]</sup> As mentioned above, satisfaction in the domains “residual limb health” and “prosthesis use” is related to overall satisfaction.<sup>[82]</sup>

Again, considerable improvement is possible in these domains.

**Table 4**

**Assessment of satisfaction questions in questionnaires.**

Questionnaire	Domain, question	Single question or scale from guideline	Answer possibilities, 0 question number	SQ <sup>1</sup>	SQ <sup>2</sup>
TAPES-R Please tick the box that represents the extent to which you are satisfied or dissatisfied with each of the different aspects of your prosthesis mentioned below:	Subscale aesthetic satisfaction 1. Color (2. Shape 3. Appearance Subscale Functional satisfaction 4. Weight 5. Usefulness. 6. Reliability 7. Fit 8. Comfort Overall satisfaction	Scale 3 items Scale 5 items	3-point scale: 1. Not satisfied 2. Satisfied 3. Very satisfied		
TAPES-R Please circle the number (0–10) that best describes how satisfied you are with your prosthesis?	Overall satisfaction	Question	Scale: 0 (not at all satisfied) to 10 (very satisfied)		
SATPRO For each question, please circle the number that best describes your satisfaction with your prosthesis.	1. My prosthesis is <b>comfortable</b> . 2. When I am in the presence of people other than my family, I <b>am at ease</b> wearing my prosthesis. 3. My prosthesis is easy to clean. 4. My prosthesis <b>works well</b> regardless of the weather. 5. My prosthesis is <b>easy</b> to put on. 6. There are chances that I will hurt myself with my prosthesis. 7. <b>I find it easy</b> to move with my prosthesis. 8. The repairs/adjustments to my prosthesis are done in reasonable time. 9. My prosthesis will last me a long time. 10. When I wear my prosthesis, <b>I can accomplish more</b> things than without it. 11. I am <b>satisfied</b> with the look of my prosthesis. 12. <b>I find it easy</b> to use my prosthesis with or without a walker/cane. 13. <b>It was easy</b> to understand how to use my prosthesis. 14. My prosthesis causes me physical pain or <b>discomfort</b> . 15. In general, I am <b>satisfied</b> with my prosthesis. 1A. Rate <b>how happy</b> you have been with your current prosthesis. 16A. Rate <b>how satisfied</b> you have been with your	No guideline	4-point scale for all items: 1. Totally agree 2. Rather agree 3. Rather disagree 4. Totally disagree	6 8 9 10 12	
PEQ Satisfaction questions (over the past four weeks)		Three single questions	Visual analogue scale anchored with “extremely unhappy/ extremely happy” (1A)		

(continued)

**Table 4**  
(continued).

Questionnaire	Domain, question	Single question or scale from guideline	Answer possibilities, 0 question number	sq <sup>1</sup>	sq <sup>2</sup>
PEQ	16B. Rate how satisfied you have been with how you are walking.	Scale 2 questions	visual analogue scale anchored with: "extremely dissatisfied/ extremely satisfied" (16A, 16B)		16C
PEQ	16C. Rate how satisfied you have been with how things have worked out since your amputation.	Scale 2 questions	Visual analogue scale anchored with "extremely dissatisfied/ extremely satisfied" (16C)		
PEQ	1B. Rate the fit of your prosthesis.	Scale 8 questions	Visual analogue scale anchored with "terrible/ excellent" (1B, 1C, 1D, 2E, 2)		1B 1C 1D
PEQ	1C. Rate the weight of your prosthesis.		visual analogue scale anchored with: "worst possible/best possible" (2H)		2E 2H 2I
PEQ	1D. Rate your comfort while standing when using your prosthesis.		visual analogue scale anchored with: "completely exhausting/ not at all" (2G)		
PEQ	2E. Rate your comfort while sitting when using your prosthesis.				
PEQ	2G. Rate how much energy it took to use your prosthesis for as long as you needed it.				
PEQ	2H. Rate the feel (such as the temperature and texture) of the prosthesis (sock, liner, socket) on your residual limb (stump).				
PEQ	2I. Rate the ease of putting on (donning) your prosthesis.				
PEQ	3J. Rate how your prosthesis has looked.	Scale 5 questions	Visual analogue scale anchored with: "terrible/excellent" (3J)		3J 4O 4P
PEQ	4O. Rate your ability to wear the shoes (different height, styles) you prefer.		visual analogue scale anchored with: "cannot/ no problem" (4O)		
PEQ	4P. Rate how limited your choice of clothing was because of your prosthesis		visual analogue scale anchored with: "worst possible/not at all" (4P)		
PEQ	3L. If it made any sounds in the past four weeks, rate how bothersome these sounds were to you.	Scale 2 questions	Visual analogue scale anchored with: "extremely bothersome/ not at all" (3L)		3L 4P
PEQ	4R. Rate how smelly your prosthesis was at its worst.	Scale 6 questions	Visual analogue scale anchored with: "extremely bothersome/ not at all" (5T, 5U, 5V)		4R 5T 5U 5V
PEQ	5T. Rate any rash (es) that you got on your residual limb.		visual analogue scale anchored with: "extremely smelly/not at all" (4F)		
PEQ	5U. Rate any ingrown hairs (pimples) that were on your residual limb				
PEQ	5V. Rate any blisters or sores that you got on your residual limb				
PEQ	6C. How bothersome were these sensations in your phantom limb		Visual analogue scale anchored with "all the time/never" (6C)		6C 7G 8J
PEQ	7G. In the past 4 wks, how bothersome was the pain in your phantom limb		extremely bothersome/extremely mild" (7G); "extremely bothersome/not at all" (8J)		

(continued)

**Table 4**  
**(continued).**

Questionnaire	Domain, question	Single question or scale from guideline	Answer possibilities, 0 question number	sq <sup>1</sup>	sq <sup>2</sup>
PEQ Ambulation scale	8J. How <b>bothersome</b> was the pain in your residual limb? 13D. Rate <b>how you felt</b> about being able to walk down stairs when using your prosthesis.		Visual analogue scale anchored with: "cannot/no problem"(13D)		13D
PEQ Group 5 The following section asks about your satisfaction with particular situations given that you have an amputation. Prosthetic care questions	17E How <b>satisfied</b> are you with the person who fit your current prosthesis 17F. How <b>satisfied</b> are you with the training you have received on using your current prosthesis? 17G. Overall, how <b>satisfied</b> are you with <b>the gait</b> and prosthetic training you have received since your amputation. 19F. How <b>bothersome</b> is it when you sweat a lot inside your prosthesis (in the sock, liner, socket)? 20G. How <b>bothersome</b> to you is swelling in your residual limb (stump)? 20I. How <b>bothersome</b> is it to see people looking at you and your prostheses?	Three single questions about prosthetic care	Visual analogue scale anchored with: "extremely dissatisfied/extremely satisfied" (17E, 17F, 17G)		17E 17F 17G
PEQ Importance questions			Visual analogue scale anchored with "extremely bothersome/not at all"(19F,20G,20I)		19F 20G 20I
SPU section #7 Prosthetic satisfaction		No guideline		7.1a 7.1b	
7.1 For prosthetics that wore out (type: electronic, body-powered/mechanical, sports/specialty)	a. How <b>many</b> prosthetics wore out? b. On average, <b>how often</b> have you had to replace your prosthesis?		7.1: amount 7.2b: 4 different timeframes (less than yearly, every 1–2 y, every 3–5 y, every 6+ y)		
SPU #7	a. How <b>many</b> were there? b. In general, what was the major reason why you stopped using each type of prosthesis?	No guideline	7.2: amount 7.2b: check all the boxes that apply (14 items)	7.2a 7.2b	
SPU #7	a. My prosthesis <b>fits well</b> . b. The weight of my prosthesis is <b>manageable</b> . c. My prosthesis is <b>pain-free</b> to wear. d. My prosthesis is <b>easy to put on</b> . e. I am <b>bothered</b> with skin problems. f. I am <b>bothered</b> by noises from my prosthesis. g. I am <b>bothered</b> with smells from my h. I am <b>satisfied</b> with my prosthesis. i. I can cope with my prosthesis. j. I have adjusted to life with a prosthesis. k. I am interested in trying a different type of	No guideline	Select 1 box: Strongly agree Agree Disagree Strongly disagree (all items)	7.3i 7.3j 7.3k 7.3l 7.3m 7.3n 7.3o 7.3p 7.3q 7.3r	

(continued)

**Table 4**  
(continued).

Questionnaire	Domain, question	Single question or scale from guideline	Answer possibilities, 0 question number	SQ <sup>1</sup>	SQ <sup>2</sup>	
SPU #7 7.4 Prosthetic service	prosthesis on a trial basis.					
	l. I want to change this current prosthesis to another type.					
	m. I usually receive an appointment with my prosthetist within a reasonable amount of time (initial or repeat visits).					
	n. I am satisfied with the training I initially received on how to use my prosthesis.					
	o. I am satisfied with the training I received on how to maintain my prosthesis.					
	p. I was fully informed about prosthetic equipment choices.					
	q. I receive adequate information on new types of prostheses on a regular basis					
	r. I had a role in choosing my prosthesis.					
	s. I am <b>happy</b> with the comfort and fit of my socket.					
	t. I am <b>bothered</b> with sweating inside my socket.					
	u. I cannot wear my prosthesis because my <b>socket fits poorly</b> .		No guideline		7.4a	
	a. In the last 5 y, did you feel that you were able to get a repair when you needed one?			Yes/no (7.4.a, 7.4b)	7.4b	
	b. In the last 5 y, did you feel that you were able to get a replacement when you needed one?			Check one of the 5 possibilities: 1–14 d, 2–4 wk, up to 2 mo, over 2 mo, but less than 6 mo, over 6 mo (7.4c, 7.4d)	7.4c	
	c. For your last prosthesis, how long did it take to get a new replacement (from when your physician placed the order until your new prosthesis was ready for the initial fitting)?				7.4d	
d. How long do you think it should take to get a new replacement?						

SQ<sup>1</sup> is Satisfaction question (SQ) according to the questionnaire guide lines, but we doubt that it is a SQ. SQ<sup>2</sup> is not a satisfaction question (SQ) according to the questionnaire guide lines, but we consider it a SQ.

#### 4.6. Prosthesis use

The PEQ assesses prosthesis use in different circumstances because of their possible influence on satisfaction. A person might be perfectly satisfied with the prosthesis while sitting but dissatisfied with the same prosthesis while walking on uneven terrain.<sup>[1,82]</sup> Thus, satisfaction is also related to the kind of activity a person wants to do. Although most questionnaires include questions on prosthesis use, for instance regarding the distance walked, they do not include questions that measure the level of satisfaction with this particular distance.

#### 4.7. Questionnaires

The reviewed studies used existing questionnaires, parts of existing questionnaires, adapted questionnaires, and author-designed questionnaires to measure prosthesis satisfaction. Various operationalizations were used in the questionnaires to assess aspects of satisfaction with a transtibial prosthesis. The reasons for choosing a particular operationalization were not explained in the questionnaire guidelines or discussed in the studies (Table 4). Furthermore, it was sometimes difficult to determine whether the questions assessed satisfaction or another construct. The following question illustrates this difficulty: “Over the past four weeks, rate how you felt about being able to walk down stairs when using your prosthesis.” Answering possibilities were on a VAS anchored by “cannot” and “no problem” (PEQ 13D).<sup>[1,82]</sup> Because the answer indicates the patient’s subjective/emotional evaluation of walking, this was considered to be a satisfaction question concerning prosthesis use.

All factors that influence satisfaction were categorized into 5 different domains: appearance, properties, fit, residual limb, and use. The residual limb was mentioned in only 3 studies, despite the fact that it affects satisfaction with the prosthesis. Comparison of study outcomes was difficult due to different operationalizations of satisfaction in the questionnaires, differences in the phrasing of questions and choice of words, and differences in study objectives (Tables 3 and 4). In addition, the time frame studied also influences outcomes and was only evaluated in the PEQ (Table 4).

#### 4.8. Prosthesis satisfaction

The findings of this review indicate that it is important for researchers studying prosthesis satisfaction to motivate the use of a specific operationalization and preferably cover all factors and domains influencing satisfaction (Table 4). This review provides an overview of factors that affect prosthesis satisfaction and can help researchers assess satisfaction during history taking, clinical examination, and prosthesis evaluation. At the same time, satisfaction is a subjective/emotional evaluation influenced by psychosocial factors that might change and vary over time. To enable research synthesis of prosthesis satisfaction in meta-analyses, researchers should be aware of the different operationalizations used in the questionnaires, for these impede comparisons of outcomes and calculation of effect sizes across studies.

#### 4.9. Limitations of this review

The review was limited by the quality of the studies identified for inclusion. Many studies were excluded because they lacked specific data on transtibial amputee patients. In addition, only 1 author answered our request for additional data. We also

excluded studies because of language restrictions and retrieval problems, thereby possibly excluding potential relevant studies. Studies included mainly employed males with traumatic amputations, which limits generalizability of findings to amputee patients with other characteristics. Patients were recruited from specific sources, which also limited generalizability. Finally, the diversity in questionnaires used and the different operationalizations of prosthesis satisfaction made pooling of quantitative data in a meta-analysis impossible.

#### 4.10. Implications for future research

Ideally, prosthesis satisfaction should be systematically evaluated by means of an assessment of all known factors influencing satisfaction. The choice of a specific operationalization and questionnaire should be motivated. Furthermore, future research should take into account that prosthesis satisfaction is an emotional evaluation that is best assessed during a specific time frame, thereby respecting the dynamic aspects of satisfaction. Adhering to these principles will enhance comparability of future studies assessing prosthesis satisfaction and make meta-analysis and pooling of data possible.

### 5. Conclusion

Factors influencing patient satisfaction with a transtibial prosthesis are diverse and include appearance and properties (functional and physical) of the prosthesis, fit of the prosthesis, functional use of the prosthesis, and aspects of the residual limb. Relevance of certain factors seems to be related to specific amputee groups. Questionnaires assessing patient satisfaction use different operationalizations, making comparisons between outcomes of questionnaires impossible.

#### Author contributions

**Writing – original draft:** Erwin Baars, Ernst Schrier, Pieter Dijkstra, Jan Geertzen.

**Writing – review & editing:** Erwin Baars.

**Methodology:** Pieter Dijkstra.

#### References

- [1] Kark L, Simmons A. Patient satisfaction following lower-limb amputation: the role of gait deviation. *Prosthet Orthot Int* 2011;35: 225–33.
- [2] MohdHawari N, Jawaid M, MdTahir P, et al. Case study: survey of patient satisfaction with prosthesis quality and design among below-knee prosthetic leg socket users. *Disabil Rehabil Assist Technol* 2017;10: 868–74.
- [3] Berke GM, Ferguson J, Milani JR, et al. Comparison of satisfaction with current prosthetic care in veterans and service members from Vietnam and OIF/OEF conflicts with major traumatic limb loss. *J Rehabil Res Dev* 2010;47:361–71.
- [4] Dillingham TR, Pezzin LE, MacKenzie EJ, et al. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study. *Am J Phys Med Rehabil* 2001;80:563–71.
- [5] Gailey R, McFarland LV, Cooper RA, et al. Unilateral lower-limb loss: prosthetic device use and functional outcomes in servicemembers from Vietnam war and OIF/OEF conflicts. *J Rehabil Res Dev* 2010;47: 317–31.
- [6] Batbaatar E, Dorjdagva J, Luvsannyam A, et al. Conceptualisation of patient satisfaction: a systematic narrative literature review. *Perspect Public Health* 2015;135:243–50.
- [7] Batbaatar E, Dorjdagva J, Luvsannyam A, et al. Determinants of patient satisfaction: a systematic review. *Perspect Public Health* 2017;137: 89–101.

- [8] Hills R, Dip TP, Kitchen S. Toward a theory of patient satisfaction with physiotherapy: exploring the concept of satisfaction. *Physiother Theory and Pract* 2007;23:243–54.
- [9] Gallagher P, Franchignoni F, Giordano A, et al. Trinity amputation and prosthesis experience scales: a psychometric assessment using classical test theory and rasch analysis. *Am J Phys Med Rehabil* 2010;89:487–96.
- [10] Gallagher P, MacLachlan M. Development and psychometric evaluation of the Trinity Amputation and Prosthesis Experience Scales (TAPES). *Rehabil Psychol* 2000;45:130–54.
- [11] Richardson A, Dillon MP. User experience of transtibial prosthetic liners: a systematic review. *Prosthet Orthot Int* 2016;1:6–18.
- [12] Gholizadeh H, Abu Osman NA, Eshraghi A, et al. Evaluation of new suspension system for limb prosthetics. *Biomed Eng Online* 2014;10:1.
- [13] Gholizadeh H, Abu Osman NA, Eshraghi A, et al. The effects of suction and pin/lock suspension systems on transtibial amputees' gait performance. *PLoS One* 2014;9:e945201-9.
- [14] Zeng X, Zhang Y, Kwong JS, et al. The methodological quality assessment tools for preclinical and clinical studies, systematic review and meta-analysis, and clinical practice guideline: a systematic review. *J Evid Based Med* 2015;8:2–10.
- [15] Slim K, Nini E, Forestier D, et al. Methodological index for non-randomized studies (minors): development and validation of a new instrument. *ANZ J Surg* 2003;73:712–6.
- [16] Alaranta H, Lempinen VM, Haavisto E, et al. Subjective benefits of energy storing prostheses. *Prosthet Orthot Int* 1994;18:92–7.
- [17] Åström I, Stenström A. Effect on gait and socket comfort in unilateral trans-tibial amputees after exchange to a polyurethane concept. *Prosthet Orthot Int* 2004;28:28–36.
- [18] Boutwell E, Stine R, Hansen A, et al. Effect of prosthetic gel liner thickness on gait biomechanics and pressure distribution within the transtibial socket. *J Rehabil Res Dev* 2012;49:227–40.
- [19] Datta D, Harris I, Heller B, et al. Gait, cost and time implications for changing from PTB to ICEX sockets. *Prosthet Orthot Int* 2004;28:115–20.
- [20] Datta D, Vaidya SK, Howitt J, et al. Outcome of fitting an ICEROSS prosthesis: views of trans-tibial amputees. *Prosthet Orthot Int* 1996;20:111–5.
- [21] Dudkiewicz J, Pisarenko B, Herman A, et al. Satisfaction rates amongst elderly amputees provided with a static prosthetic foot. *Disabil Rehabil* 2011;33:1963–7.
- [22] Arwert HJ, Van Doorn-Loogman MH, Koning J, et al. Residual-limb quality and functional mobility 1 year after transtibial amputation caused by vascular insufficiency. *J Rehabil Res Dev* 2007;44:717–22.
- [23] Atherton R, Robertson N. Psychological adjustment to lower limb amputation amongst prosthesis users. *Disabil Rehabil* 2006;28:1201–9.
- [24] Chadderton HC. Consumer concerns in prosthetics. *Prosthet Orthot Int* 1983;7:15–6.
- [25] Chen MC, Lee SS, Hsieh YL, et al. Influencing factors of outcome after lower-limb amputation: a five-year review in a plastic surgical department. *Ann Plast Surg* 2008;61:314–8.
- [26] Coffey L, Gallagher P, Desmond D. A prospective study of the importance of life goal characteristics and goal adjustment capacities in longer term psychosocial adjustment to lower limb amputation. *Clin Rehabil* 2014;28:196–205.
- [27] Dajpratham P, Tantiramai S, Lukkapihonchut P, et al. Factors associated with vocational reintegration among the Thai lower limb amputees. *J Med Assoc Thailand* 2008;91:234–9.
- [28] Deans SA, McFadyen AK, Rowe PJ. Physical activity and quality of life: a study of a lower-limb amputee population. *Prosthet Orthot Int* 2008;32:186–200.
- [29] Gallagher P, MacLachlan M. Evaluating a written emotional disclosure homework intervention for lower-limb amputees. *Arch Phys Med Rehabil* 2002;83:1464–6.
- [30] Gauthier-Gagnon C, Grise M, Potvin D. Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. *Arch Phys Med Rehabil* 1999;80:706–13.
- [31] Kegel B, Carpenter ML, Burgess EM. A survey of lower-limb amputees: prostheses, phantom sensations, and psychosocial aspects. *Bull Prosthet Res* 1977;10:43–60.
- [32] Legro MW, Reiber GD, Smith DG, et al. Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. *Arch Phys Med Rehabil* 1998;79:931–8.
- [33] Sapp L, Little CE. Functional outcomes in a lower limb amputee population. *Prosthet Orthot Int* 1995;19:92–6.
- [34] Van der Linde H, Hofstad CJ, Geertzen JH, et al. From satisfaction to expectation: the patient's perspective in lower limb prosthetic care. *Disabil Rehabil* 2007;29:1049–55.
- [35] Magnusson L, Ramstrand N, Fransson EI, et al. Mobility and satisfaction with lower-limb prosthesis and orthoses among users in Sierra Leone: a cross-sectional study. *J Rehabil Med* 2014;46:438–46.
- [36] Jarl G, Heinemann AW, Lindner HY, et al. Cross-cultural validity and differential item functioning of the orthotics and prosthetics users' survey with Swedish and United States users of lower-limb prosthesis. *Arch Phys Med Rehabil* 2015;96:1615–26.
- [37] Raschke SU, Orendurff MS, Mattie JL, et al. Biomechanical characteristics, patient preference and activity level with different prosthetic feet: a randomized double-blind trial with laboratory and community testing. *J Biomech* 2015;48:146–52.
- [38] Sinha R, van den Heuvel WJ, Arokiasamy P, et al. Influence of adjustments to amputation and artificial limb on quality of life in patients following lower limb amputation. *Int J Rehabil Res* 2014;37:74–9.
- [39] Mohd Hawari N, Jawaid M, Md Tahir P, et al. Case study: survey of patient satisfaction with prosthesis quality and design among below-knee prosthetic leg socket users. *Disabil Rehabil Assist Technol* 2017;12:868–78.
- [40] Ali S, Abu Osman NA, Eshraghi A, et al. Interface pressure in transtibial socket during ascent and descent on stairs and its effect on patient satisfaction. *Clin Biomech* 2013;28:994–9.
- [41] Coleman KL, Boone DA, Laing LS, et al. Quantification of prosthetic outcomes: elastomeric gel liner with locking pin suspension versus polyethylene foam liner with neoprene sleeve suspension. *J Rehabil Res Dev* 2004;41:591–602.
- [42] Gholizadeh H, Abu Osman NA, Eshraghi A, et al. Transtibial prosthetic suspension: less pistoning versus easy donning and doffing. *J Rehabil Res Dev* 2012;49:1321–30.
- [43] Hachisuka K, Dozono K, Ogata H, et al. Total surface bearing below-knee prosthesis: advantages, disadvantages, and clinical implications. *Arch Phys Med Rehabil* 1998;79:783–9.
- [44] Selles RW, Janssens PJ, Jongenengel CD, et al. A randomized controlled trial comparing functional outcome and cost efficiency of a total surface-bearing socket versus a conventional patellar tendon-bearing socket in transtibial amputees. *Arch Phys Med Rehabil* 2005;86:154–61.
- [45] Eshraghi A, Abu Osman NA, Karimi MT, et al. Quantitative and qualitative comparison of a new prosthetic suspension system with two existing suspension systems for lower limb amputees. *Am J Phys Med Rehabil* 2012;91:1028–38.
- [46] Horne CE, Neil JA. Quality of life in patients with prosthetic legs: a comparison study. *JPO* 2009;21:154–9.
- [47] Boldingh EJ, Van Pijkeren T, Wijkman DW. A study on the value of the modified KBM prosthesis compared with other types of prosthesis. *Prosthet Orthot Int* 1985;9:79–82.
- [48] Ali A, Abu Osman NA, Abd Razak NA, et al. The effect of dermo and Seal-in X5 prosthetic liners on pressure distributions and reported satisfaction during ramp ambulation in persons with transtibial limb loss. *Eur J Phys Rehabil Med* 2015;159:31–7.
- [49] Morgan SJ, McDonald CL, Halsne EG, et al. Laboratory- and community-based health outcomes in people with transtibial amputation using crossover and energy-storing prosthetic feet: a randomized crossover trial. *PLoS One* 2018;13:e0189652.
- [50] Desmond D, Gallagher P, Henderson-Slater D, et al. Pain and psychosocial adjustment to lower limb amputation amongst prosthesis users. *Prosthet Orthot Int* 2008;32:244–52.
- [51] Gunawardena NS, Seneviratne RA, Athauda T. Prosthetic outcome of unilateral lower limb amputee soldiers in two districts of Sri Lanka. *JPO* 2004;16:123–9.
- [52] Akarsu S, Tekin L, Safaz I, et al. Quality of life and functionality after lower limb amputations: comparison between uni- vs. bilateral amputee patients. *Prosthet Orthot Int* 2013;37:9–13.
- [53] Coffey L, Gallagher P, Horgan O, et al. Psychosocial adjustment to diabetes-related lower limb amputation. *Diabet Med* 2009;26:1063–7.
- [54] Bilodeau S, Hebert R, Desrosiers J. Lower limb prosthesis utilization by elderly amputees. *Prosthet Orthot Int* 2000;24:126–32.
- [55] Murray C, Fox J. Body image and prosthesis satisfaction in the lower limb amputee. *Disabil Rehabil* 2002;24:925–31.
- [56] Karmarkar AM, Collins DM, Wichman T, et al. Prosthesis and wheelchair use in veterans with lower-limb amputation. *J Rehabil Res Dev* 2009;46:567–76.
- [57] Legro MW, Reiber G, Del Aguila MD, et al. Issues of importance reported by persons with lower limb amputations and prostheses. *J Rehabil Res Dev* 1999;36:155–63.
- [58] Zidarov D, Swaine B, Gauthier-Gagnon C. Quality of life of persons with lower-limb amputation during rehabilitation and at 3-month follow-up. *Arch Phys Med Rehabil* 2009;90:634–45.

- [59] Fisher K, Hanspal R. Body image and patients with amputations: does the prosthesis maintain the balance? *Int J Rehabil Res* 1998;21:355–63.
- [60] Matsen SL, Malchow D, Matsen FA. Correlations with patients' perspectives of the result of lower-extremity amputation. *J Bone Joint Surg Am* 2000;82-A:1089–95.
- [61] Pezzin LE, Dillingham TR, Mackenzie EJ, et al. Use and satisfaction with prosthetic limb devices and related services. *Arch Phys Med Rehabil* 2004;85:723–9.
- [62] Roth EV, Pezzin LE, McGinley EL, et al. Prosthesis use and satisfaction among persons with dysvascular lower limb amputations across postacute care discharge settings. *PM R* 2014;6:1128–36.
- [63] Buijk CA. Use and usefulness of lower limb prostheses. *Int J Rehabil Res* 1988;11:361–7.
- [64] Christ O, Jokisch M, Preller J, et al. User-centered prosthetic development: comprehension of amputees' needs. *Conf Proc IEEE Eng Med Biol Soc* 2012;2012:1929–32.
- [65] Gallagher P, Maclachlan M. Adjustment to an artificial limb: a qualitative perspective. *J Health Psychol* 2001;6:85–100.
- [66] Durmus D, Safaz I, Adigüzel E, et al. The relationship between prosthesis use, phantom pain and psychiatric symptoms in male traumatic limb amputees. *Compr Psychiatry* 2015;59:45–53.
- [67] Moustapha A, Sagawa Junior Y, Watelain E, et al. Epidemiological cross-sectional survey of outcome in lower-limb amputees in the Nord-Pas de Calais region. *Ann Phys Rehabil Med* 2010;53:e22.
- [68] Safari MR, Tafti N, Aminian G. Socket interface pressure and amputee reported outcomes for comfortable and uncomfortable conditions of patellar tendon bearing socket: a pilot study. *Assist Technol* 2015;27:24–31.
- [69] Kuret Z, Burger H. Quality of life in lower limb amputees. *Prosth Orthot Int* 2015;39: suppl 1 (434).
- [70] Magnusson L. Variables associated with patients' satisfaction with low cost technology prosthetic and orthotic devices and service delivery in Malawi and Sierra Leone. *Prosth Orthot Int* 2015;39: suppl 1 (76).
- [71] Posada AM, Lugo LH, Plata JA, et al. Patients' perspectives on lower limb amputation outcomes. *Prosth Orthot Int* 2015;39: suppl 1 (230).
- [72] Kangkasomboon T, Assarut N, Sakaew T, et al. Self-image and attitude on prosthetic cosmetic cover in lower limb amputee in Thailand. *Prosth Orthot Int* 2015;39(suppl 1):549–50.
- [73] Vazvani HG, Yahyavi E, Eshraghi A, et al. Clinical assessment of a new prosthetic suspension system. *Prosth Orthot Int* 2015;39: [Epub ahead of print].
- [74] Vance RL, Gallagher P, O'Keeffe F, et al. The impact of cognition on physical and psychosocial outcomes at discharge from a lower limb prosthetic rehabilitation programme. *Prosth Orthot Int* 2015;39: suppl 1 (545).
- [75] Migaou Miled H, Ben Brahim H, HadjHassine Y, et al. Tunisian lower limb amputees and satisfaction towards their prosthesis: about 74 cases. *Ann Phys Rehabil Med* 2016;59S:e31–2.
- [76] Christ O, Beckerle P, Rinderknecht S, et al. Usability, satisfaction and appearance while using lower limb prostheses: implications for the future. *Neurosci Lett* 2011;500:e50.
- [77] Ali S, Abu Osman NA, Naqshbandi MM, et al. Qualitative study of prosthetic suspension systems on transtibial amputees' satisfaction and perceived problems with their prosthetic devices. *Arch Phys Med Rehabil* 2012;93:1919–23.
- [78] van de Weg FB, van der Windt DAWM. A questionnaire survey of the effect of different interface types on patient satisfaction and perceived problems among trans-tibial amputees. *Prosthet Orthot Int* 2005;29:231–9.
- [79] Webster JB, Hakimi KN, Williams RM, et al. Prosthetic fitting, use, and satisfaction following lower-limb amputation: a prospective study. *J Rehabil Res Dev* 2012;49:1493–504.
- [80] Sinha R, van den Heuvel WJ, Arokiasamy P. Adjustments to amputation and an artificial limb in lower limb amputees. *Prosthet Orthot Int* 2014;38:115–21.
- [81] Samitier CB, Guirao L, Costea M, et al. The benefits of using a vacuum-assisted socket system to improve balance and gait in elderly transtibial amputees. *Prosthet Orthot Int* 2016;40:83–8.
- [82] Harness N, Pinzur MS. Health related quality of life in patients with dysvascular transtibial amputation. *Clin Orthop Relat Res* 2001;383:204–7.
- [83] Cairns N, Murray K, Corney J, et al. Satisfaction with cosmesis and priorities for cosmesis design reported by lower limb amputees in the United Kingdom: instrument development and results. *Prosthet Orthot Int* 2014;38:467–73.
- [84] Giesberts B, Ennion L, Hjelmstrom O, et al. The modular socket system in a rural setting in Indonesia. *Prosthet Orthot Int* [Epub ahead of print].