A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis

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Abstract—A correct prosthetic prescription can be derived from adapting the functional benefits of a prosthesis to the functional needs of the prosthetic user. For adequate matching, the functional abilities of the amputees are of value, as well as the technical and functional aspects of the various prosthetic components. No clear clinical consensus seems to be given on the precise prescription criteria. To obtain information about different prosthetic components and daily functioning of amputees with a prosthesis, we performed a systematic literature search. The quality of the studies was assessed with the use of predetermined methodological criteria. Out of 356 potentially relevant studies, 40 studies eventually qualified for final methodological analysis and review. Four satisfied all the criteria and were classified as A-level studies, 26 as B-level, and 10 studies as C-level studies. Despite a huge amount of literature, our formal clinical knowledge had considerable gaps concerning the effects of different prosthetic components and their mechanical characteristics on human functioning with a lower-limb prosthesis. Therefore, with regard to prosthetic guideline development, we must still largely rely on clinical consensus among experts. The integration of knowledge from research with the expert opinion of clinical professionals and the opinions and wishes of consumers can form a solid base for a procedure on guideline development for prosthetic prescription.

Key words: artificial limbs, biomechanical parameters, human functioning, lower-limb amputation, physiological parameters, prosthesis, prosthetic foot, prosthetic knee, prosthetic prescription, prosthetic suspension, socket, stump, systematic review.

INTRODUCTION

Prosthetic prescription for patients with lower-limb amputation is primarily based on empirical knowledge. Many options are available for different prosthetic components; however, prescription criteria are based mainly on subjective experiences of physicians, therapists, and prosthetists [1,2]. On the other hand, third-party payers frequently require justification for purchasing costly prostheses [2]. Also, clarity for the customer is required since quality of care is becoming more important. In the ideal situation, prosthetic prescription is based on adjusting the mechanical characteristics of a prosthesis to the functional needs of the prosthetic user [3], yet no clinical guidelines seem to be available for this use.

The development of scientifically based clinical guidelines is a way of making health care more consistent and efficient and diminishes the gap between what clinicians do and what scientific evidence supports. A systematic

literature review is the first step in clinical guideline development. It may also highlight knowledge gaps in the existing evidence [4]. To our knowledge, no scientifically based guidelines for lower-limb prosthetic prescription exist. Also, no consensus seems to exist among different professionals with regard to the criteria for selecting prosthetic components related to the functional abilities and needs of patients. In this perspective, the Dutch Health Care Insurance Board (CVZ) has initiated a national project to develop clinical guidelines for lower-limb prosthetic prescription to obtain consensus among clinicians, manufacturers, and insurance companies in the Netherlands. The first step is to extract as much scientifically based knowledge from the literature as possible. In this respect, two types of studies can be distinguished: (1) clinical studies focusing on motor performance or daily functioning with a lower-limb prosthesis and (2) technical studies focusing on the mechanical characteristics of prosthetic components without specifically human functioning. In view of prosthetic guideline development, only studies addressing motor performance and human functioning with a lower-limb prosthesis are considered relevant. Hence, this review will be restricted to these clinically oriented studies.

METHOD

Procedure

We performed a systematic search using the Medline database (from 1966), Current Contents (from 1996), The Cochrane Database (2001 issue), and Psyclit (from 1971) until February 2001. A combination of the following key words and their synonyms was used: lower-limb prosthesis, lower-limb amputation, prosthetic prescription, prosthetic foot, prosthetic knee, prosthetic suspension, stump, socket, and physiological and biomechanical parameters. Also we checked the references from the retrieved articles and (systematic) reviews to extend the search.

Based on their abstracts, studies were further considered when:

1. The papers were written in the English, German, or Dutch languages.

2. The study design was either a randomized controlled trial (RCT), a cohort study, or a case-controlled study, allowing at least some control of confounding factors.

3. The study investigated patients with a transfemoral, through-knee, or transtibial amputation.

4. The study used subjective findings, activities of daily living measures, and/or functional characteristics of human stance or gait (spatio-temporal, physiological, kinematic, kinetic, or electromyographic [EMG] parameters) as outcome variables.

5. The study evaluated specific components of the prosthesis.

6. The goal of the study was to provide insight into the effects of different prosthetic components on human functioning with a lower-limb prosthesis.

Methodological Criteria

After this abstract-based selection of relevant studies, we assessed the methodological quality of each article using a checklist of 13 predetermined criteria. This checklist was based on the integration of two existing criteria lists for quality assessment [5,6], which were originally developed to evaluate randomized controlled trials (see **Appendix**, which can be found in the online version only [7,8]). Some criteria were adapted for nonrandomized controlled trials. Each criterion was scored at two levels: invalid/no "0" and valid/yes "1." If a criterion was not applicable, it was scored "0." Two reviewers (HL and CH) independently analyzed the studies. If the reviewers found a discrepancy, they achieved consensus in the second instance.

For this review, the included studies were required to sufficiently control for selection and measurement bias. Studies were classified as—

• A-level studies: Studies with a total score of at least 11 points or more, including 6 points out of the A- and B-criteria, including a positive score for blinded outcome assessment (criterion B7) and timing of the measurement (criterion B8).

• B-level studies: Studies with a total score between 6 and 10 points, including a positive score for timing of the measurement (criterion B8).

• C-level studies: Studies with a total score of at least 6 points out of the A- and B-criteria with an invalid score on criteria B7 and B8.

Therefore, only the studies in which the total score of the A- and B-criteria was at least 6 out of a possible 9 points were used in the best-evidence synthesis.

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RESULTS

Selection of Studies

Out of 356 potentially relevant studies on lower-limb prosthetic functioning, we selected 64 studies based on their abstracts (see the **Figure** for the selection algorithm according to the QUOROM statement [9]). References from the retrieved studies and (systematic) reviews yielded 72 more papers. We similarly assessed the abstracts of these 72 studies, selecting 17 additional studies and fulfilling the preliminary selection criteria. Most of the studies that did not meet these criteria were either uncontrolled case series or case reports (criterion A1) or their primary purpose was not related to human functioning with a prosthesis (criterion B6). For instance, many articles focused only on amputation techniques or on the technical possibilities of early prosthetic fitting. Hence, we methodologically assessed the full texts of 81 selected studies using the checklist of 13 criteria just mentioned [1–3,10–87]. Based on these assessments, 40 studies received an A-, B- or C-level classification and were included for final review (**Tables 1** and **2**). An important reason for excluding the 41 other studies was that the selection of the study sample was so poorly described that the results could not be reliably interpreted from a clinical perspective.

No classical RCTs were identified, yet all included studies used crossover designs that allowed sufficient control for confounding. Four papers were classified "A-level studies" [17,18,67,68], twenty-six "B-level studies" [2,3, 13,16,20,22,23,27,30,36,37,42,44–46,55–58,61,66,69,71, 77,81,83], whereas ten studies were classified "C-level studies" [1,15,35,39,52–54,59,63,76]. The main difference between the A- and B-level studies was a negative score on the "blinded assessment" (criterion B7). Indeed, only Postema et al. [67,68], Boonstra et al. [17,18], and Gailey et al. [35] (C-level study) reported that their subjects were blinded to the intervention. Seven studies applied no randomization of the sequence of interventions [2,20,42,46, 52,61,71] and, therefore, had a negative score on criterion A4. Of the other studies, only Postema et al. described which randomization procedure was applied [67,68]. The randomization was done with the aid of a dice, and the code was broken only after the entire trial had been completed. Seven articles scored negatively for functional homogeneity [16–18,22,23,30,81]. Based on the provided subject characteristics, the study sample could be concluded to be considerably heterogeneous for activity level, which was not accounted for by a stratified analysis.

In some studies, the prosthetic components, other than the component investigated, were not kept constant, resulting in a "0" on criterion B6 [1,15,39,44,55,56,61,63,76]. In eight studies on prosthetic mass [35,39,52–54,59,63,76] and the Board's study on prosthetic socket design [15], the subjects were not allowed sufficient time to adapt to the intervention, so they received a negative B8 score. Eight studies did not indicate possible dropouts [1,3,16,30,52, 53,76,81]. Insufficient information was available about how many subjects were eventually subjected to the intervention. Therefore, this study received a negative score on criterion C10. In six studies, the authors failed to provide adequate measures of variability, even though such data were necessary to interpret the results [1,13,15, 63,71,81].

Selected Study Results

The selected studies on functioning with a lower-limb prosthesis allowed a division in four categories based on their focus of attention: effects of different (1) prosthetic feet, (2) prosthetic knees, (3) prosthetic sockets, and (4) prosthetic mass. The prosthetic foot was the focus of investigation in 28 studies [1–3,13,16,20,22,23,30,36,44, 45,52,53,55–58,63,66–69,71,76,77,81,83]. The main clinical findings are shown in **Table 3**. The prosthetic knee was the focus in five studies [17,18,42,46,61], the prosthetic socket in one study [15], and prosthetic mass in six studies [25,35,37,39,54,59], with the main clinical findings in **Table 4**.

As dependent variables, time-distance parameters are probably the most easily obtainable objective data for evaluating changes in a patient's gait performance [88]. From a clinical point of view, such parameters are also readily interpretable. Hence, many of the included studies focused primarily on these parameters as well as on kinematic variables [1–3,13,15,16,22,30,36,37,39,45,52, 53,56,57,59,61,63,66–68,71,76,77,81,83]. Fifteen studies used oxygen uptake [13,17,20,25,35,44,45,52,54,58,59, 63,76,81,83], and two studies assessed heart rate [46,63]. To evaluate the difficulty of walking, 1 study used the Borg scale [56], 2 studies evaluated patient satisfaction [20,67], and 21 studies used walking speed to investigate differences between specific prosthetic components [1,2,13,16,20,22,25,39,46,52–54,61,63,66,68,69,71,76, 77,81].
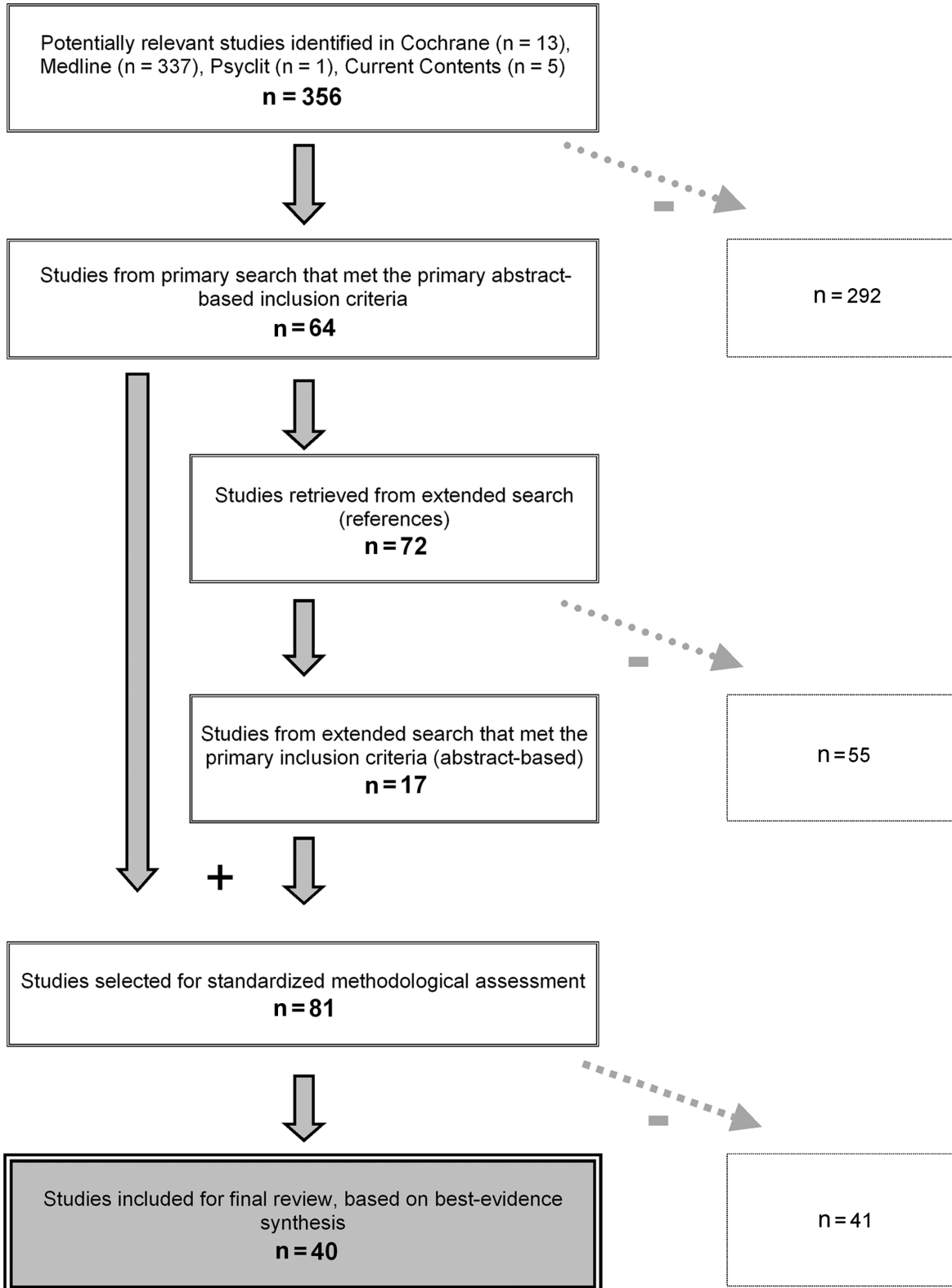
Figure.
Selection algorithm.

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Table 1.
Assessment of methodological aspects of reviewed studies on prosthetic feet.[*]

Author	Parameters	Subjects (Reason & Level of Amputation, & Age [yr] [Range or Mean ± SD])	Selection					Intervention						Statistical Validity				Total Score	Level of Evidence
			A1	A2	A3	A4	A	B5	B6	B7	B8	B9	B	C10	C11	C13	C		
Barth et al. [13]	Walking speed, step length, cadence, $\dot{V}O_2$ (mL/kg/min, mL/kg/m), joint motion (°), time-related variables	3 traumatic TT, 39 ± 10; 3 vascular TT, 64 ± 5	1	1	1	1	4	1	1	0	1	1	4	1	0	0	1	8	B
Boonstra et al. [16]	Walking speed, joint motion (°), time-related variables	9 TT, 20–70	1	0	1	0	2	1	1	0	1	1	4	0	1	1	2	8	B
Casillas et al. [20]	$\dot{V}O_2$ (mL/kg/min, mL/kg/m), satisfaction (0–100), walking speed	12 traumatic TT, 50 ± 14; 12 vascular TT, 73 ± 7	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B
Cortes et al. [3]	Kinetic, kinematic, and time-related variables	8 traumatic TT, 19–49	1	1	1	1	4	1	1	0	1	1	4	0	1	1	2	10	B
Culham et al. [22]	Walking speed, stride length, cadence, time-related variables, knee motion (°)	10 TT (9 vascular, 1 traumatic), 32–79	1	0	1	1	3	1	1	0	1	1	4	1	1	1	3	10	B
Culham et al. [23]	Electromyographic (EMG) activity of vastus lateralis and medial hamstrings, bilaterally	10 TT (9 vascular, 1 traumatic), 32–79	1	0	1	1	3	1	1	0	1	1	4	1	1	1	3	10	B
Doane & Holt [30]	Center of mass displacement and velocity, joint motion (°), time-related variables	8 TT, 55–67	1	0	1	0	2	1	1	0	1	1	4	0	1	1	2	8	B
Gitter et al. [36]	Joint muscle power output (W)	5 traumatic TT, 20–50	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Goh et al. [1]	Walking speed, time-related variables	6 TT, 53 ± 9; 5 TF, 48 ± 11	1	1	1	0	3	1	0	0	1	1	3	0	1	0	1	7	C
Hsu et al. [44]	$\dot{V}O_2$ (mL/kg/min, mL/kg/m)	5 TT, 27–36	1	1	1	1	4	1	0	0	1	1	3	1	1	1	3	10	B
Huang et al. [45]	$\dot{V}O_2$ (mL/kg/min), joint motion (°)	8 traumatic TT, 30 ± 6; 8 vascular TT, 63 ± 5	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Lehmann et al. [52]	$\dot{V}O_2$ (mL/kg/m), walking speed, GRFs (N/kg), joint motion (°)	9 TT, 21–53	1	1	1	0	3	1	1	0	0	1	3	0	1	1	2	8	C
Lehmann et al. [53]	Metabolic rate (cal/kg/min, cal/kg/m), walking speed, GRFs (N/kg), joint motion (°)	10 TT, 21–36	1	1	1	1	4	1	1	0	0	1	3	0	1	1	2	10	C
MacFarlane et al. [56]	Borg scale (0–20 scale)	7 traumatic TT, 19–49	1	1	1	1	4	1	0	0	1	1	3	1	1	1	3	10	B
MacFarlane et al. [55]	Linear and temporal and gait symmetry variables	7 traumatic TT, 19–49	1	1	1	1	4	1	0	0	1	1	3	1	1	1	3	10	B
MacFarlane et al. [58]	Linear and temporal and gait symmetry variables	5 traumatic TF, 37 ± 5	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
MacFarlane et al. [57]	$\dot{V}O_2$ (mL/kg/min, mL/kg/m)	5 traumatic TF, 37 ± 5	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Menard et al. [2]	GRFs (N/kg), walking speed	8 traumatic TT, 31–51	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B

Table 1. (Continued)
Assessment of methodological aspects of reviewed studies on prosthetic feet.[*]

Author	Parameters	Subjects (Reason & Level of Amputation, & Age [yr] [Range or Mean ± SD])	Selection					Intervention						Statistical Validity				Total Score	Level of Evidence
			A1	A2	A3	A4	A	B5	B6	B7	B8	B9	B	C10	C11	C13	C		
Nielsen et al. [63]	Walking speed, $\dot{V}O_2$ (mL/kg/min, mL/kg/m), heart rate	7 traumatic TT, 27 ± 7	1	1	1	1	4	1	0	0	0	1	2	1	0	0	1	7	C
Perry et al. [66]	Walking speed, cadence, joint motion (°), and velocities (rad/s)	10 vascular TT, 49–72	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Postema et al. [67]	Preference (0–10 scale)	10 traumatic/oncologic TT, 34–66	1	1	1	1	4	1	1	1	1	1	5	1	1	1	3	12	A
Postema et al. [68]	Walking speed, cadence, joint motion, GRFs, energy absorption	10 traumatic/oncologic TT, 34–66	1	1	1	1	4	1	1	1	1	1	5	1	1	1	3	12	A
Powers et al. [69]	Walking speed, stride length, cadence, GRFs (% body weight), ankle motion (°)	10 traumatic TT, 22–72	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Rao et al. [71]	Walking speed; stride length (m); cadence, foot, shank, and thigh velocities (rad/s)	9 vascular TT, 62 ± 7	1	1	1	0	3	1	1	0	1	1	4	1	1	0	2	9	B
Schmalz et al. [76]	Walking speed, stride length, $\dot{V}O_2$ (mL/kg/m)	8 traumatic TT, 17–70	1	1	1	1	4	1	0	0	0	1	2	0	1	1	2	8	C
Snyder et al. [77]	Walking speed, stride length, cadence, GRFs (N/kg), ankle and knee motion (°)	7 vascular TT, 45–70	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Torburn et al. [81]	Walking speed, cadence, stride length, EMG, $\dot{V}O_2$ (mL/kg/min, mL/kg/m), joint motion (°)	5 TT (3 traumatic, 2 dysvascular), 43–58	1	0	1	1	3	1	1	0	1	1	4	0	1	0	1	8	B
Torburn et al. [83]	$\dot{V}O_2$ (mL/kg/min, mL/kg/m), walking speed, stride length, cadence	10 traumatic TT, 51 ± 6, 7 vascular TT, 62 ± 8	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B

[*]See main text "Methods" section for explanation of criteria and symbols and see reference section for references.
Note: Criterion C12 (intention-to-treat) is not mentioned in this table, because this criterion was not applicable in all final-selected studies.
GRF = ground reaction force
TT = transtibial
TF = transfemoral
$\dot{V}O_2$ = oxygen uptake

Many different comparisons were made. Furthermore, differences in selected and presented outcome parameters among studies investigating the same prosthetic components did not allow a true meta-analysis of the results. Hence, we decided to focus our review on the consistency of clinical findings across studies on the same topic. In the case of inconsistency, methodological quality was used for final interpretation.

Studies on Prosthetic Feet

One A-level study [67], fifteen B-level studies [2,3,13,16,20,22,30,56,57,66,69,71,77,81,83], and five C-level studies used time-distance parameters to compare different types of prosthetic feet [1,52,53,63,76]. In general, few discriminative effects were found. For instance, in most studies the self-selected (comfortable) walking speed was not influenced by the type of prosthetic foot in

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Table 2.
Assessment of methodological aspects of reviewed studies on prosthetic knee, prosthetic socket, and prosthetic mass.[*]

Author	Parameters	Subjects (Reason & Level of Amputation, & Age [yr] [Range])	Selection					Intervention						Statistical Validity				Total Score	Level of Evidence
			A1	A2	A3	A4	A	B5	B6	B7	B8	B9	B	C10	C11	C13	C		
Board et al. [15]	Stump volume (mL), pistoning (cm), step length, stance duration	11 traumatic TT, 32–64	1	1	1	1	4	1	0	0	0	1	2	1	1	0	2	8	C
Boonstra et al. [17]	$\dot{V}O_2$ (mL/kg/min, mL/kg/m), preference	28 traumatic/oncologic TF, 15–63	1	0	1	1	3	1	1	1	1	1	5	1	1	1	3	11	A
Boonstra et al. [18]	Walking distance, ease of walking, temporal variables, goniometry	28 traumatic/oncologic TF, 15–63	1	0	1	1	3	1	1	1	1	1	5	1	1	1	3	11	A
Czerniecki et al. [27]	$\dot{V}O_2$ (mL/kg/m), walking speed	8 traumatic/oncologic TF, 30–44	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Gailey et al. 35]	$\dot{V}O_2$ (mL/kg/min)	10 traumatic/oncologic TT, 24–52	1	1	1	1	4	1	1	1	0	1	4	1	1	1	3	11	C
Gitter et al. [37]	Muscle power output (W), joint power output (W)	8 traumatic/oncologic TF, 30–44	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Hale [39]	Walking speed, joint motion	6 traumatic/oncologic TF, 22–61	1	1	1	1	4	1	0	0	0	1	2	1	1	1	3	9	C
Heller et al. [42]	Sway velocities (mm/s)	10 traumatic/oncologic TF, 38	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B
Isakov et al. [46]	Heart rate, walking speed	14 vascular TF, 50–75	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B
Lehmann et al. [54]	Self-selected walking speed, $\dot{V}O_2$ (mL/kg/m)	15 TT, 18–70	1	1	1	1	4	1	1	0	0	0	2	1	1	1	3	9	C
Mattes et al. [59]	$\dot{V}O_2$ (J/s), step length, swing time, stance time	6 traumatic/oncologic TF, 18–50	1	1	1	1	4	1	1	0	0	1	3	1	1	1	3	10	C
Murray et al. [61]	Walking speed, stride length, cadence, temporal components of gait	7 traumatic TF, 33–46	1	1	1	0	3	1	0	0	1	1	3	1	1	1	3	9	B

[*]See main text "Methods" section for explanation of criteria and symbols, and see reference section for references.
Note: Criterion C12 (intention-to-treat) is not mentioned in this table, because this criterion was not applicable in all final-selected studies.
GRF = ground reaction force
TT = transtibial
TF = transfemoral
$\dot{V}O_2$ = oxygen uptake

traumatic [2,3,13,56,67,76,81,83] or vascular transtibial amputees [13,22,66,71,81,83], and traumatic transfemoral amputees [57]. A few exceptions, however, were found. Compared to the SACH (Solid Ankle Cushion Heel) foot, three B-level studies found a higher self-selected walking speed with a prototype energy-storing foot in traumatic transtibial amputees [20] and with the Flex-Foot in traumatic [69] and vascular transtibial amputees [77]. Casillas et al. explained their results by the higher bioenergetic efficiency level the subjects experienced while walking with the prototype energy-storing foot [20]. Powers et al. and Snyder et al. both explained the observed difference in walking speed by the greater stride length with the Flex-Foot compared to the SACH foot [69,77], while cadence remained constant. Two studies reported a change in cadence. MacFarlane et al. found a lower cadence when individuals walked with the Flex-Foot compared to the SACH foot in combination with a greater stride length for the Flex-Foot [56]. Because of a trade-off effect, no differences were found in walking speed. Torburn et al. found a greater cadence for the Carbon Copy II foot compared with the Flex-Foot and SACH foot [81]. A possible explanation for the slightly different study results may be found in the differences in

Table 3.
Main clinical findings of reviewed studies on prosthetic feet.[*]

Author	Intervention	Outcome	Level of Evidence
Barth et al. [13]	SACH foot, SAFE II, Seattle Lightfoot, Quantum, Carbon Copy II, Flex-Walk	Traumatic amputees: significantly shorter sound limb when wearing Flex-Walk and SAFE II; however, when wearing SACH, they had significantly longer sound-limb step length. Total group: with SACH foot, they had less dorsiflexion; with Flex-Walk, greater dorsiflexion than sound limb; with wearing Carbon Copy II and Quantum, greater sound limb acceptance forces. No significant differences in energy cost among prosthetic feet.	B
Boonstra et al. [16]	Multiflex, Quantum	No differences in walking speed, plantar-dorsiflexion range of motion (ROM), knee joint ROM, hip flexion-extension ROM. Quantum foot: longer swing phase on prosthetic side, step time longer, inversion-eversion angle was 2.1° larger, adduction-abduction ROM was 3.1° larger.	B
Casillas et al. [20]	SACH foot, energy-storing foot (prototype)	For traumatic amputees with energy-storing foot: free walking speed was higher, $\dot{V}O_2$ (per meter) was lower, more significant as speed increased. Higher satisfaction rating when amputees walked with energy-storing foot. No differences found for vascular patients.	B
Cortes et al. [3]	SACH foot, Single Axis, Greissinger, Dynamic foot	Similar behavior for SACH and Dynamic feet (nonarticulated mechanism) on one hand and for Single Axis and Greissinger (articulated mechanism) on other hand.	B
Culham et al. [22]	SACH foot, Single Axis	No differences in walking speed, cadence, stride length, gait cycle duration, mean peak stance phase flexion of prosthetic and contralateral limb. Angle of peak swing flexion was 46.37° ± 9.60° with SACH and differed significantly from Single Axis (41.34° ± 7.44°) in prosthetic limb; for contralateral limb, following angles were found: 51.35° ± 4.12° and 47.71° ± 7.10°.	B
Culham et al. [23]	SACH foot, Single Axis	No differences of activity patterns of quadriceps in sound limb. SACH foot: peak quadriceps activity occurred later (30%) in stance phase of prosthetic limb than Single Axis foot (30%). SACH foot: hamstrings of prosthetic limb were active throughout early- and midstance phase, and peak activity occurred at 30% of gait cycle; with Single Axis foot, two peaks of hamstrings activity were observed (at 10% and 60%).	B
Doane and Holt [30]	SACH foot, Single Axis	No differences in velocity of center of mass. SACH foot: ankle angle of prosthetic leg during foot-flat was less than with Single Axis foot (–5.4 ± 2.1° and –11.9 ± 3.0°, respectively).	B
Gitter et al. [36]	SACH foot, Seattle Foot, Flex-Foot	Seattle and Flex-Foot: increase in energy absorption and release during push-off, but no differences in pattern or magnitude of knee and hip power outputs compared to SACH foot.	B
Goh et al. [1]	SACH foot, uniaxial foot	No differences in walking speed. SACH foot: period of heel-strike to foot-flat of prosthetic leg took twice as long as that of uniaxial foot for transtibial and transfemoral amputees (44.5% vs. 22.4% and 33.7% vs. 20.4%, respectively). Transtibial and transfemoral showed an average difference of 7.5° and 5.0°, respectively, in ankle angle during early-stance phase. No differences in GRFs for transtibial amputees. Vertical GRF on prosthetic side for transfemoral amputees showed differences in its loading pattern: SACH foot has two-peak loading pattern, uniaxial a three-peak loading pattern.	C
Hsu et al. [44]	SACH foot, Flex-Foot, Re-Flex VSP	Improvements of Re-Flex VSP vs. Flex-Foot and SACH foot: energy cost—walking 5% and running 11%, gait efficiency—walking 6% and running 9%. No differences between Flex-Foot and SACH foot.	B
Huang et al. [45]	SACH foot, Single Axis, Multiple Axis	No differences in energy consumption. SACH foot: good late-stance stability, limited dorsiflexion. Multiple Axis foot: less late-stance stability, more late-stance dorsiflexion. Ankle joint degree of freedom is an important factor for comfort; Multiple Axis most comfortable.	B
Lehmann et al. [52]	SACH foot, Seattle Foot, Flex-Foot	No differences in walking speed, and metabolic efficiency during walking and running. Flex-Foot: longest midstance phase, greatest ankle angle range, and greater forward movement of center of pressure.	C
Lehmann et al. [53]	SACH foot, Seattle Foot	No differences in walking speed and in metabolic efficiency during walking and running. Seattle Foot: longer midstance phase, push-off phase was shorter, ankle ROM during stance was greater (20.2° vs. 9.8°), maximal dorsiflexion moment was greater (97.5 Nm vs. 84.3 Nm), knee ROM during stance was greater (43.2° vs. 34.3°), knee ROM during swing was greater (66.0° vs. 62.1°).	C
MacFarlane et al. [56]	Conventional foot, Flex-Foot	Walking with conventional foot was more difficult across all grade and speed conditions.	B
MacFarlane et al. [55]	Conventional foot, Flex-Foot	No differences in walking speed. Flex-Foot: stride length increased (134.3 cm compared to 129.8 cm) and cadence decreased; single support time increased, allowing larger, more normal steps with uninvolved leg, which means decrease of cadence, reflected by increase in cycle time (124.3 for Flex-Foot and 122.2 for conventional foot).	B

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Table 3. (Continued)
Main clinical findings of reviewed studies on prosthetic feet.[*]

Author	Intervention	Outcome	Level of Evidence
MacFarlane et al. [58]	SACH foot, Flex-Foot	No differences in stride length. Flex-Foot: more symmetrical late-stance phase and decrease in physiological requirement of walking.	B
MacFarlane et al. [57]	SACH foot, Flex-Foot	Flex-Foot: lower exercise intensity, lower energy cost, and more efficient gait in range of walking speeds.	B
Menard et al. [2]	Seattle Foot, Flex-Foot	No differences in walking speed. In symmetry, Flex-Foot more closely matched intact side overall than Seattle Foot.	B
Nielsen et al. [63]	SACH foot, Flex-Foot	SACH foot: at walking speeds of 2.5 mph and above, energy cost was higher and relative exercise intensity was higher; at walking speeds of 2.5 mph and above, energy cost per meter was higher.	C
Perry et al. [66]	Single Axis, Seattle Lite, Flex-Foot	No differences in walking speed, stride length, and cadence. Time of peak knee flexion was significantly later than normal for Seattle, Single Axis, and Flex-Foot. Seattle and Flex-Foot: less plantar flexion than Single Axis foot. Single Axis foot: no intrinsic restraint to control plantar flexion or dorsal flexion.	B
Postema et al. [67]	Two conventional (Otto Bock Multi Axial and Otto Bock Lager) and two energy-storing prosthetic feet (Otto Bock Dynamic Pro and Hangar Quantum)	None of prosthetic feet favored by subjects. Score of one conventional foot (Otto Bock Lager) was statistically lower than scores for other feet.	A
Postema et al. [68]	Two conventional and two energy-storing prosthetic feet	No differences in walking speed or cadence. ROM at ankle with Otto Bock Lager (conventional foot) were greater. Increase in late-stance dorsiflexion results in increase of knee flexion moment and decrease in knee stability.	A
Powers et al. [69]	Flex-Foot, Carbon Copy II, Seattle, Quantum, SACH foot	No differences in cadence. Flex-Foot: walking speed (although not significantly) and stride length were greater compared to SACH and Quantum (1.50 m vs. 1.44 m and 1.44 m). Flex-Foot: greater dorsiflexion compared to Carbon Copy II, Seattle, Quantum, and SACH foot.	B
Rao et al. [71]	Single Axis, Seattle Lite, Flex-Foot	No differences in walking velocities, stride characteristics, cadence, mean shank velocity curves, and mean thigh velocity patterns. Single-Axis: uncontrolled foot and shank mobility. Flex-Foot and Seattle Lite: restricted mobility.	B
Schmalz et al. [76]	Otto Bock 1S71, Otto Bock 1D10, Otto Bock 1D25, Otto Bock 1C40, Flex Walk II	No differences in walking speed, stride length, and energy consumption at 4.0 km/h. Otto Bock 1S71: higher energy consumption at 4.8 km/h and smaller plantar flexion moment immediately after heel contact. 1C40 and Flex Walk II produced higher maximum dorsiflexion moments during toe-off.	C
Snyder et al. [77]	Flex-Foot, Carbon Copy II, Seattle Lite, Quantum, SACH foot	Flex-Foot: free walking velocity was greater compared to SACH foot; stride length was greater than SACH (1.35 m vs. 1.25 m), Carbon Copy II, and Seattle Lite foot. No differences in cadence. Flex-Foot and Quantum: greater terminal stance dorsiflexion than Seattle, Carbon Copy II, and SACH. Flex-Foot: greater dorsiflexion means greater tibial advancement and results in greater stride length.	B
Torburn et al. [81]	Flex-Foot, Carbon Copy II, Seattle, STEN, SACH foot	No differences in walking speed, stride length, phasing of activity of muscles tested, and energy cost. Carbon Copy II: greater cadence than SACH or Flex-Foot (102 vs. 98). Flex-Foot: greater dorsiflexion (19.8° ± 3.3° vs. 13° ± 4.2°), greater maximum dorsiflexion torque occurring at ankle joint during stance (19.9° ± 7.5° vs. 10.4° ± 2.0°), more rapid rate of progression of center of pressure during single-limb support.	B
Torburn et al. [83]	SACH foot, Carbon Copy II, Seattle Lite, Quantum, Flex-Foot	No differences in energy consumption. Energy rate of traumatic group greater than dysvascular group. No difference in walking speed, stride length, and cadence.	B

[*]See main text reference section for references. $\dot{V}O_2$ = oxygen uptake

the selection of the study groups. In two B-level studies, MacFarlane et al. reported a more symmetrical gait pattern with the Flex-Foot compared to a SACH foot in both transtibial and transfemoral amputees related to symmetrization of the late stance and late swing phase durations in particular [56,57].

Some studies investigated joint motion as an outcome parameter [13,16,22,45,52,53,66,67,69,77,81]. In the A-level study by Postema et al. [67], the range of motion (ROM) at the ankle during the stance phase of a single-axis conventional foot was greater than the same ROM of two energy-storing feet. This result could readily

Table 4.
Main clinical findings of reviewed studies on prosthetic knee, prosthetic socket, and prosthetic mass.[*]

Author	Intervention	Outcome	Level of Evidence
Knee			
Boonstra et al. [17]	Mechanical swing phase control (Otto Bock) and pneumatic swing phase control (Tehlin knee)	Six patients preferred Otto Bock 3R20 because bending Tehlin knee was very easy, which gave an unsafe feeling; Nineteen patients preferred Tehlin knee because they walked more easily and/or faster. Walking with Tehlin knee required more energy.	A
Boonstra et al. [18]	Mechanical swing phase control (Otto Bock) and pneumatic swing phase control (Tehlin knee)	Normal speed: walk faster and more comfortably with Tehlin knee. Fast walking is easier with Tehlin knee. Tehlin knee: duration of swing phase of prosthetic side is greater, stride time is greater, hip range of motion (ROM) is not different, knee ROM is smaller, and 10° flexion duration is shorter.	A
Heller et al. [42]	Conventional knee unit vs. Intelligent Prosthesis knee unit	Gait using Intelligent Prosthesis was not less cognitively demanding then using conventional knee mechanism. Total sway during gait was significantly less for Intelligent Prosthesis than for conventional prosthesis.	B
Isakov et al. [46]	Prosthesis with an open-knee mechanism versus a locked-knee mechanism	Locked-knee mechanism enabled a higher walking speed with a lower heart rate increase than open-knee.	B
Murray et al. [61]	Hydraulic knee (HK) and constant friction knee component (CFC)	At slow speed: no differences in velocity, cadence, or stride length. Free-speed and fast walking: increase in cadence and walking speed with HK. More asymmetry in stance phases and swing phases with CFC.	B
Socket			
Board et al. [15]	30 min walk under vacuum condition and normal condition	With vacuum stump, volume increased 3.7% and in normal condition, volume decreased 6.5%. Both step length and stance durations were more symmetrical with vacuum.	C
Mass			
Czerniecki et al. [27]	Three load conditions: 0 kg, 0.68 kg, 1.34 kg of extra mass	No differences in self-selected walking speeds and metabolic cost.	B
Gailey et al. [35]	Three load conditions: 0 g, 454 g, 907 g of extra mass	No differences in metabolic cost.	C
Gitter et al. [37]	Three load conditions: 0 kg, 0.68 kg, 1.34 kg of extra mass	No differences in timing or duration of stance and swing phase, but there was a combined increase in hip flexor muscle contraction work and mechanical energy transfer across hip joint.	B
Hale [39]	Three load conditions: 0%, 75%, 100% of subject's sound shank mass (1.33–3.37 kg)	No differences in walking speed, stride length, stride time, and swing time. Increase in prosthetic mass: decreased knee flexion and prolonged knee extension.	C
Lehmann et al. [54]	Proximal center of mass location versus distal center of mass location, prosthesis weights of 42% to 70% of normal-limb weight	Proximal center of mass location produced a more efficient gait. Weight change from 42% to 70% of normal had no significant effect.	C
Mattes et al. [59]	Three load conditions: 0%, 50%, 100% of subject's sound shank mass (0.85–1.70 kg)	No differences in step length and symmetry in step length. Prosthetic limb swing time increased as its mass and moment of inertia were increased, whereas that for intact limb was relatively unaffected by inertial manipulation of prosthetic limb. Energy cost of walking increased significantly as inertial properties of prosthetic limb and intact limbs became more similar because of prosthetic limb loading.	C

[*]See main text reference section for references.

be related to the mechanical characteristics of the different feet, i.e., the presence or absence of an ankle axis in the frontal plane. The presence of an ankle axis allowed greater early-stance plantar flexion immediately after heel contact [66,67]. Furthermore, the energy-storing Flex-Foot showed a greater late-stance dorsiflexion compared with the conventional SACH foot in three B-level studies [69,77,81] and two C-level studies [52,76] on traumatic and vascular transtibial amputees. The fact that the Flex-Foot resulted in a greater stride length indicates a greater tibial advancement as a result of increased dorsiflexion [77].

Nine B-level studies assessed oxygen consumption [13,20,44,45,52,58,76,81,83]. In three studies with traumatic transtibial amputees, oxygen consumption per distance traveled was slightly lower with a prototype

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energy-storing foot [20] or with the Flex-Foot [58,63] than with the SACH foot. In the study of Hsu et al. with nonvascular amputees, oxygen consumption was lower with the Re-Flex VSP compared with the SACH and Flex-Foot [44]. However, in the other six studies no such beneficial effect of energy-storing feet was found [13,45,52,76,81,83]. This discrepancy in results, however, is hardly clinically significant and may again be related to differences in the selection of the study groups.

As for patient satisfaction, the only A-level study concluded that no specific prosthetic foot was consistently favored over another type of foot by traumatic transtibial amputees [68]. Yet, in one B-level study, the prototype energy-storing foot scored a higher satisfaction rate than the SACH foot in traumatic transtibial amputees [20]. Another B-level study concluded that walking with the SACH foot was perceived to be more difficult than walking with the Flex-Foot [56]. However, since the prosthetic users were not blinded in the latter two studies, these results should be interpreted with caution.

Studies on Prosthetic Knees

Each of the five studies on prosthetic knees made different comparisons (**Table 4**). The A-level study of Boonstra et al. concluded that a Tehlin knee with a pneumatical swing phase controller resulted in a more comfortable and faster walking performance during normal and fast walking compared to a knee with a mechanical swing phase control, i.e., Otto Bock 3R20 (results from questionnaires) [18]. This result was explained by a shorter swing phase duration of the prosthetic leg caused by an impeded knee flexion. However, energy expenditure at 3 km/h was somewhat higher with the pneumatically controlled knee [17]. Apparently, the preference of the amputees in favor of the Tehlin knee was not related to lower energy costs. Similar results were found in two B-level studies. Heller et al. found that a conventional knee unit resulted in greater total frontal plane excursion of the head compared to the Intelligent Prosthetic knee (a microprocessor-controlled prosthesis) [42], whereas Murray et al. found more symmetry in both stance- and swing-phase duration and a higher comfortable and fast walking speed for a prosthesis with a hydraulic knee compared to a prosthesis with a constant-friction knee in traumatic transfemoral amputees [61]. Apparently, these results indicate that a more advanced mode of control of the prosthetic knee movement during the swing phase can lead to more gait symmetry and speed than simply applying constant fric-

tion or force to the knee, particular in active prosthetic users. The improvements in the smoothness of walking are most likely related to the restraining effect of the hydraulic or pneumatic component at the beginning and the end of the prosthetic swing phase, allowing more normal weight acceptance at the beginning of the prosthetic stance phase and easier weight transfer at the end of prosthetic stance phase [61]. On the other hand, the B-level study of Isakov et al. [46] concluded that a Mauch S-N-S hydraulic knee prosthesis with a locked knee may enable vascular patients to adopt a higher walking speed compared to an unlocked open-knee unit. This finding should be interpreted in view of the fact that their study sample was characterized by an older age (50–70 years) and a lower activity level (i.e., vascular amputees with additional health problems, such as diabetes mellitus, hypertension, heart failure, and myocardial infarction) compared to the studies of Boonstra et al. [17,18] and Heller et al. [42].

Study on Prosthetic Socket

Board et al.'s C-level study investigated the effect of prosthetic socket type on time-distance parameters in transtibial amputees [15] (**Table 4**). More symmetrical step length and stance duration and less stump volume loss were observed with a vacuum total surface-bearing suction socket compared to a normal total surface-bearing suction socket. This result can be explained by the assumption that a vacuum socket provides a better fitting of the stump tissues and a better "total skin" contact, allowing more mechanical and sensory control over the prosthetic leg. The subjects reported that their prosthetic limb was held more firmly with the vacuum socket and that their stump pistoned less within the socket during walking. Because of the better fit, the amputees spent more time on their prosthetic limb and felt more confident of the control over and position of their prosthesis. The methodological quality of this study was poor, however, because the other prosthetic components were not kept constant with the different sockets. Also the time to adapt to the prosthetic change was relatively short, i.e., subjects were familiarized with the intervention for only 15 minutes. Therefore, the results of this study should be interpreted with caution.

Studies on Prosthetic Mass

The six studies on prosthetic mass (**Table 4**) did not reveal any influence of mass on the efficiency or

kinematics of gait, with one exception. Lehmann's C-level study showed that a more proximal center of mass location produced a more efficient gait in traumatic transtibial amputees [54]. Although Selles et al. reviewed a slightly different selection of studies on this specific topic, their conclusion is more or less the same [89]. More specifically, they concluded that inertial loading of the modern lightweight lower-limb prosthesis has no beneficial effect on the amputee's gait pattern or energy expenditure.

DISCUSSION

Limited unbiased information can currently be obtained from studies on the effects of different prosthetic components on human functioning with a lower-limb prosthesis for evidence-based prosthetic prescription. Only four A-level studies were identified, two on prosthetic feet and two on prosthetic knees.

Some evidence suggests that energy-storing feet such as the Flex-Foot result in a comfortable walking speed and stride length that are about 7 to 13 percent higher than with a conventional SACH foot in both traumatic and vascular transtibial amputees [20,69,77]. This difference is probably related to an amputee's having slightly lower oxygen consumption while walking with an energy-storing foot [20,58]. Possibly, such feet also facilitate the symmetry of gait [57]. These considerations seem important, particularly for the active prosthetic user. On the other hand, prosthetic feet with an ankle axis in the frontal plane, such as the single-axis Lager foot (Otto Bock), mimic the normal roll-off motion of the ankle-foot complex in the sagittal plane, allowing an early foot-flat position and concomitant early-stance-phase stability. Some researchers believe that especially the more inactive prosthetic users may benefit from an early foot-flat mechanism to facilitate weight transfer onto their prosthesis [1,66,67]. According to Perry et al., the stability of timely foot-flat support with limited knee flexion requires a greater arc of functionally restrained plantar flexion [66]. Also, uphill and downhill walking may be easier with a wide ROM at the prosthetic ankle joint [58]. A single-axis foot, however, may offer relatively little late-stance stability because of an unrestrained dorsiflexion [66]. In this respect, the Flex-Foot and the SACH foot provide more stability during the late-stance phase [45] and may be preferable to patients who tend toward a short prosthetic stance phase. Hence, indivi-

dual considerations related to intended use and activity level remain important with respect to the definitive choice of the prosthetic foot. One should note that in the reviewed studies, dorsiflexion is also used for the prosthetic feet that have rigid ankles. This can be confusing because they do not truly dorsiflex, but bend. Therefore, pseudo-dorsiflexion could be more appropriate when one is discussing the properties of rigid ankles.

As for the prosthetic knee in transfemoral amputees, one can conclude that a prosthesis with an advanced mode of swing-phase control, either by a pneumatic or a hydraulic knee unit, is somewhat superior to a prosthetic knee that only provides a constant force or friction. Especially active prosthetic users may profit from the advanced characteristics of swing-phase controllers, such as the Tehlin knee, in terms of gait symmetry and comfortable walking speed [42,61]. These beneficial effects cannot readily be explained on the basis of energy expenditure. On the other hand, the typical geriatric vascular patient may still profit from the stance-phase stability that is provided by a conventional locked-knee unit [46]. To what extent prosthetic knees with stance-phase stabilizers such as the Intelligent Prosthetic Knee should be prescribed to these or other patients based on its functional benefits has to be further supported by clinical evidence. Hence, again, individual considerations must ultimately determine the choice and prescription of the prosthetic knee.

With regard to the prosthetic socket used by transtibial amputees, firm conclusions cannot be drawn from the literature. It is, nevertheless, plausible from a clinical perspective that a vacuum (total-surface bearing) socket assures a better skin contact than a normal suction or suspension socket and, thus, a better control over the prosthetic limb [14]. Within certain limits, prosthetic mass does not seem to influence the gait pattern or efficiency in lower-limb amputees. However, there is some evidence that a proximal center of mass location results in a slightly more efficient gait than a distal distribution of prosthetic mass [54].

Functional outcomes should be assessed for various aspects of mobility, such as making transfers, maintaining balance, walking level, climbing stairs, negotiating ramps and obstacles, changing walking speed, etc. Most studies reviewed in this paper assessed walking on a treadmill (at self-selected walking speeds), probably for reasons of technical and practical convenience. Indeed, Mulder et al. already pointed out that the vast majority of clinical studies

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on human walking have used rather standardized gait assessment protocols with limited "ecological validity" [90]. Although perhaps less analytic, modern systems for ambulatory monitoring of human activity [91] can provide objective and valid data about (changes in) human motor behavior during prolonged periods of hours or days in a much more ecologically valid way. First, subjective assessments of comfort, stability, and efficiency should certainly be used more when blinding of the prosthetic users can be assured. Second, the effects of different prosthetic feet should also be evaluated in patients with, for example, a through-knee or transfemoral amputation because generalizing results from transtibial amputees to these higher levels of amputation may be invalid. Last, more research is needed into the effects of prosthetic knees with stance-phase stabilizers as well as into the functional effects of different prosthetic sockets in through-knee and transfemoral amputees.

Therefore, with regard to prosthetic guideline development, we must still largely rely on clinical consensus among experts. In a formal consensus procedure, different sources of evidence are needed.

CONCLUSION

Our formal clinical knowledge has considerable gaps concerning the (beneficial) effects of different prosthetic components on human functioning with a lower-limb prosthesis. For future research, functional comparisons between different prosthetic components should be categorized according to the level of activity of the amputee and the intended use of the prosthesis. Such an approach would better acknowledge the importance of individual needs and abilities that guide clinical decision-making in daily practice. The integration of knowledge from research with the expert opinion of clinical professionals and the opinions and wishes of consumers can form a solid base for a procedure on guideline development for prosthetic prescription.

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