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ARTICLE



How to measure success in lower extremity reconstruction, which outcome measurements do we use a systematic review and metanalysis

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ABSTRACT

Different factors have to be considered and weighted in the treatment algorithm of lower extremity reconstruction. A combination of both clinicians' and patients' perspectives is necessary to provide a conclusive picture. Currently, there aren't any standardized and validated measurement data sets for lower extremity reconstructions. This makes it necessary to identify the relevant domains. We, therefore, performed a systematic review and metanalysis of outcome measurements and evaluated their ability to measure outcomes after lower extremity reconstruction. A systematic review and metanalysis according to the 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses' protocol were performed for studies reporting at least one structured outcome measurement of lower extremity reconstruction. Both Patient (PROMs)- and Clinician reported outcome measurements (CROMs) were analyzed. Of the 2827 identified articles, 102 were included in the final analysis. In total 86 outcome measurements were identified, 34 CROMs, 44 PROMs and 8 (9.3%) outcome measurements that have elements of both. Twenty-four measure functional outcome, 3 pain, 10 sensations and proprioception, 9 quality of life, 8 satisfaction with the result, 5 measure the aesthetic outcome, 6 contours and flap stability and 21 contain multidomain elements. A multitude of different outcome measurements is currently used in lower extremity reconstruction. So far, no consensus has been reached on what to measure and how. Validation and standardization of both PROMs and CROMs in plastic surgery is needed to improve the outcome of our patients, better meet their needs and expectations and eventually optimize extremity reconstruction by enabling a direct comparison of studies' results.

ARTICLE HISTORY

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Introduction

The reconstruction of complex tissue loss in the lower extremity is often challenging. Many different factors have to be considered and weighted in the treatment algorithm, with the best possible functional recovery of the limb as the ultimate goal. Clinical results however are not enough anymore to describe treatment results, in fact, a lot more is necessary to really understand patients' needs with the overall goal to improve outcomes. Lower extremity reconstruction is complex as it often has to address multiple components, both bone and soft tissues. Different outcome measurement tools were developed to assess this complexity but are not able to describe the outcome both for the point of view of the clinician and that of the patient [1]. Surgical outcomes focused on complications and function from the physician's viewpoint provide valuable information but do not provide a complete picture. To this end, as in other areas of healthcare, the patient-reported outcomes have become an integral part of assessing the quality and efficacy of care delivered [2]. Only a combination of both clinicians' and patients' perspectives can help to provide a conclusive picture of the outcome. Currently, however there aren't any standardized and validated measurement data sets for lower extremity reconstruction. Therefore, it is

necessary to start from the foundation and identify the domains which are really relevant for the different stakeholders, first of all, patients and surgeons. An additional challenge is the small size of study cohorts in reconstructive plastic surgery that leads in many cases to studies with a relative low level of evidence. This is also the reason why physicians rarely have sufficiently reliable data about expected results and potential complications that can be easily explained to non-experts with misunderstandings and eventually unmet patients' expectations as a consequence [3]. Some surgeons have tried to address this lack of evidence by creating their own outcome measurement tools, which furthermore increases the difficulty to compare study outcomes and makes apparent the necessity to build a minimal data set. Choosing the appropriate outcome measurements is crucial to understand the patient's needs and accordingly choose the right treatment. Also, it is pivotal to plan and to carry out studies, to enable comparison between similar studies and finally to draw conclusions with a clinical impact as inappropriate outcome measurements can generate misleading results [4]. For these reasons, we decided to perform a systematic review and metanalysis of the outcome measurements currently available (PROMs and CROMs) and to

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evaluate their effectiveness to measure outcomes after lower extremity reconstruction.

Materials and methods

Overview

A systematic review was carried out to identify any studies reporting PROMs and CROMs to assess the results of lower extremity reconstructions. Title and abstract screening, full-text review and data extraction were handled independently by two reviewers (ISB and FEZ), and disagreements at any stage were resolved by discussion and consensus. Persisting disagreements were resolved by discussion with a third reviewer (MC). We followed the Preferred Reporting Items for Systematic Reviews (PRISMA) protocol [5]. This review was registered on PROSPERO (www.crd.york.ac.uk/prospéro, Record ID: 42021219425).

Search strategy

The PubMed/MEDLINE, EMBASE, Cochrane and Web of Science database were searched to identify eligible articles. The search strategy included combinations of the following terms: lower extremity; reconstruction; leg; lower limb; foot; knee; tight; heel; toe; tibia; flap and microsurgery (see Table S1, [Supplementary Material](#)). Word variations and exploded medical subject headings were searched for whenever feasible. Additionally, reference lists were hand-searched to identify further studies of interest. The last systematic search was conducted on 27th November 2020.

Study selection

Only in-vivo clinical studies enrolling adults over sixteen were considered. As a small number of controlled trials was anticipated, prospective and retrospective single-arm cohort studies and case series of more than five individuals were also included. Inclusion criteria were studies on patients with flap-based soft tissue reconstruction of the lower extremity and at least one outcome measurement, whether functional, sensation and proprioception, pain sensation, aesthetic, patient satisfaction or overall quality of life and whether a CROM or PROM. Flap survival itself and complications were not considered as outcome measurements. Questionnaires and scores, created by authors for a specific study, often an assembly of various clinician and patient-reported outcome measurements, were considered and listed as a separate outcome measurement.

Exclusion criteria were: all animal studies, studies reporting only on outcomes of bone flaps without soft tissue transfer, studies where outcome measurements were used only to analyze flap donor-site outcome. Furthermore, articles older than 10 years or not in English were excluded. Exact cohort duplicates were excluded, although we did include updates of previously published cohorts with a sample size increase of at least 50%. We report our review process in the flow diagram following the four stages of the PRISMA statement ([Figure 1](#)) [5,6].

Data extraction and quality assessment

We extracted the following information, if available, from all included publications: study design and year of publication, country of study conduction, number of patients, mean age, gender distribution, flap type, indication, defect size, donor site, recipient site, number of outcome measurements and follow up time. To assess the identified outcome measurements we described each

outcome measure qualitatively and extracted the following data for each of them if available: outcome measure type (PROM, CROM), mode of administration, assessment requirements, range of scores and instrument validity. We defined outcome measure validity according to the consensus-based standards for the selection of health measurement instruments (COSMIN) guidelines [7,8]. Validity refers to the degree to which an instrument measurements the outcome that it is meant to measure, content validity (relevancy, comprehensiveness and comprehensibility), construct validity (including structural validity, hypotheses testing and cross-cultural validity\measurement invariance) and criterion validity are different components [7,8].

Results

Our search resulted in 4630 studies, 1575 were found in Pubmed/MEDLINE, 1362 studies in EMBASE, 51 studies were found in the Cochrane database and 1642 in Web of science. After the removal of duplicates, the titles and abstracts of 2827 studies were manually screened. Eventually, 102 studies from 23 different countries, referring to 86 different outcome measurements were included [1,9–109]. The review process is shown in [Figure 1](#) and an overview of included studies is given in [Table 1](#).

The included studies reported on lower extremity reconstruction with any of the following flaps, either free or pedicled: anterolateral thigh (ALT), gracilis, latissimus dorsi, anterior serratus, gastrocnemius, sural, medial plantar, tibial, fibula, deep inferior epigastric perforator (DIEP), superficial circumflex iliac artery perforator (SCIP), parascapular, scapular and radial forearm. Forty-three (42.2%) studies reported on outcomes of free flaps, 38 (37.3%) on pedicled flaps outcomes and 14 (13.7%) report outcomes of both. In 7 (6.9%) studies the flap type was not reported. Mean follow-up in the studies assessed ranged from 12 to 80 months.

Thirty-four (39.5%) identified outcome measurements are CROMs and 44 (51.1%) are PROMs.

Eight outcome measurements were a combination of CROMs and PROMs. The function of the reconstructed extremity was measured with 16 different CROMs and 8 PROMs. The aesthetic outcome was measured with 3 CROMs and 2 PROMs, sensation and proprioception with 9 clinician-reported instruments and one PROM and pain with 3 PROMs. The general quality of life was assessed with 9 PROMs and satisfaction with 8 PROMs. Thirteen PROMs consisted of elements from multiple domains. However, many measurements were not performed according to uniform and standardized protocols and instructions given to participants, test protocols and analysis of results profoundly varied across studies for many identified measurements. An overview of all outcome measurements and their brief description and characteristics is listed in [Table 2](#).

Validated CROMs

The most frequently applied validated CROM was the static two-point discrimination (s2PD) test ($n = 18$ publications; 17.6%) with a cumulative number of 464 reported subjects. Other frequent applied CROMs were the Semmes–Weinstein monofilament (SWM) test ($n = 11$ publications; 10.8%; $n = 271$ patients) and Range of Motion (ROM) ($n = 15$ publications; 14.8%, $n = 587$ patients). For the full list refer to [Table 2](#).

Validated PROMs

The most frequently applied validated PROM was the Lower Extremity Functional Scale 15 (LEFS) ($n = 13$ publications; 12.7%)

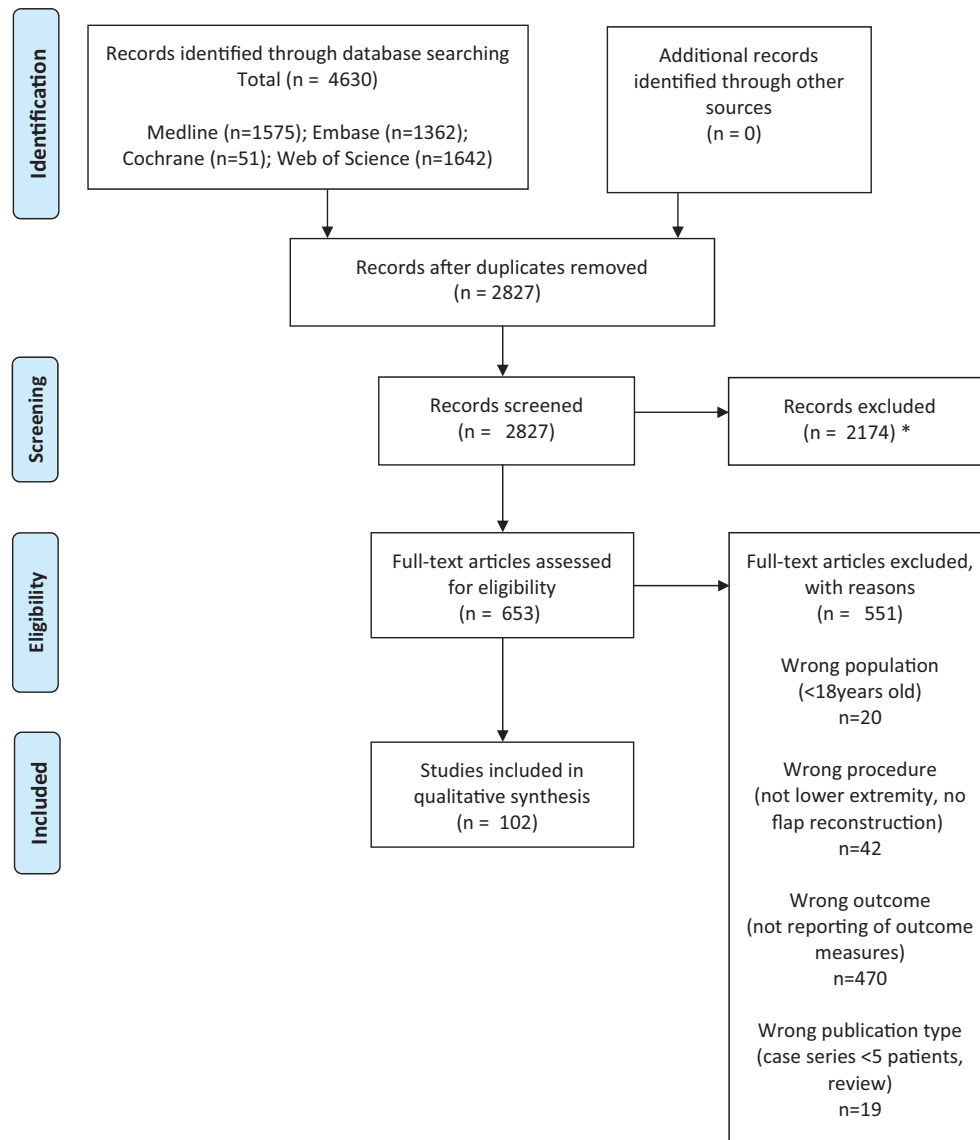


Figure 1. Flow chart of the reviewing process.

with a cumulative number of 859 reported subjects. Other frequent applied PROMs were the 36-Item Short-Form Health Survey ($n = 12$ publications; 11.8%) with 420 reported subjects and the visual analogue pain scale (VAS) ($n = 8$ publications; 7.8%), $n = 135$ patients). For the full list refer to Table 2.

Non-validated outcome measurements

Seventeen patient-reported questionnaires and scores, 25 CROMs and 5 clinician- and patient-reported outcome measurements were found, that are not currently validated for lower extremity reconstruction. Non-validated questionnaires individually assembled for a specific study sometimes based on or a combination of other validated outcome measurements were frequently found in the literature (Table 3).

Discussion

Reconstruction of complex defects of the lower limb using free or pedicled flaps is a routine procedure [110]. Evidence on these complex procedures however is scarce [111]. In order to compare outcomes it is essential to rely on defined outcome measurements [112]. The goal of this systematic review was thus to

identify the most commonly used outcome measurements in lower limb reconstruction to aid clinicians with the choice of appropriate outcome measurements to best follow up their patients with the overall goal to improve patients' outcomes. Our review yielded several noteworthy findings.

Our review showed that there is a wide variety of outcome measurements currently in use, more than 60. This makes it difficult to compare outcomes among different studies. The most frequently used outcome measurements are those that have been in use over the last decades (s2PD, SWM and ROM) and are not exclusively used in lower extremity reconstruction [113,114]. The CROM which is most frequently used in studies is the static two-point discrimination (s2PD) test, used in 16 of the included publications with a cumulative number of 274 reported subjects. Range of motion ROM Testing was only used in 13 publications but with a cumulative population of 417.

Secondly, the majority of outcome measurements used were CROMs (38%). To realistically describe the outcome a combination of different types of outcome measurements is needed to capture at the same time the surgical result and the complications [115]. Well-known clinician-reported outcome measurements are amongst others flap survival, donor- and recipient-site complications, range

Table 1. Overview over included studies and population characteristics.

Study	Outcome measure (N)	Population			Reconstruction characteristics				Instrument administration		
		N	Age [years] Mean ± SD	Male gender [%]	Flap type	Free or pedicled	Indication	Donor site	Recipient site (N)	Setting	Country
Abula et al. 2020 [17]	1	14	35.5 ± NA	57.1	Adipofacial; fasciocutaneous; neurocutaneous	Free	Trauma	ALT, LDF, SNF, PTAPF	Tibia	Ambulant	China
Akdag et al. 2018 [18]	1	8	NA	87.5	Fasciocutaneous	Free	Trauma; burn; infection	DIEP	Feet, ankle	Ambulant	Turkey
Al-Himdani et al. 2020 [19]	2	29	44.0 ± NA	62	Adipofacial; fasciocutaneous	Pedicled; free	Trauma; infection; burn	MSAP; ALT	Foot; ankle; knee; leg	Ambulant	UK
As'adi et al. 2017 [103]	3	51	32.0 ± 2.9	89.8	Fasciocutaneous	Pedicled	Burn	Sural	NA	Ambulant	Iran
Bhullar et al. 2020 [20]	4	40	NA	77.5	NA	Pedicled; free	Trauma	NA	Tibia, ankle	Ambulant	UK
Bigdeli et al. 2019 [21]	2	29	49.6 ± 16.6	79.3	Fasciocutaneous; adipofacial; muscular	NA	Trauma; infection; tumor; burn	ALT, LDF, SNF, PTAPF; sural; gracilis; vastus lateralis	NA	Ambulant	Germany
Brunetti et al. 2020 [22]	1	58	NA	NA	NA	Pedicled	NA	NA	NA	Ambulant	Italy
Buono et al. 2018 [23]	5	24	NA	75	Muscular; fasciocutaneous	Free	Osteomyelitis	LDF; serratus anterior; ALT; lateral arm; thoracodorsal; radial forearm	Tibia	Ambulant	CH
Cang et al. 2020 [24]	3	29	NA	62	Fasciocutaneous	Pedicled	Tumor; trauma; ulcer; burn	Medial plantar	Lower leg, heel, forefoot	Ambulant	China
Cherubino et al. 2020 [25]	1	13	NA	NA	Fasciocutaneous	Free	Trauma, burn	ALT	Lower leg	Ambulant	Italy
Chou et al. 2018 [26]	4	24	NA	79.2	Fasciocutaneous; muscular	Free	Ulcer; trauma; infection; tumor	ALT; LDF; medial sural; gracilis; vactus lateralis	Heel, calcaneal, Achilles tendon	Ambulant	Taiwan
Corten et al. 2013 [27]	3	24	NA	58.3	Muscular	Pedicled	Infection	Gastrocnemius	Knee	Ambulant	Belgium, Canada
Dai et al. 2013 [28]	2	92	36.52 ± NA	81.5	Neurocutaneous	Pedicled	Trauma, osteomyelitis, Ulcer, deformity	Sural	Lower leg; ankle; heel	Ambulant	China
Dai et al. 2013 [29]	3	70	46 ± NA	60	Neurocutaneous	Pedicled	Trauma, osteomyelitis	Saphenus	NA	Ambulant	China
DeFazio et al. 2014 [30]	9	6	NA	66.7	Fasciocutaneous	Free	Infection, trauma	ALT	Achilles tendon	Ambulant	US
Demiralp et al. 2014 [31]	3	21	38.4 ± 3.04	NA	Musculocutaneous	Free	Trauma	Rectus abdominis; LDF	Foot	Ambulant	Turkey
Di Summa et al. 2019 [32]	5	13	NA	NA	Fasciocutaneous	Free	Tumor, trauma, infection; burn	ALT	Knee; ankle	Ambulant	CH
Dong et al. 2014 [33]	2	20	28 ± NA	60	NA	Pedicled	Trauma, infection	NA	Feet, lower leg	Ambulant	China
Doukas et al. 2013 [34]	3	126	NA	97	NA	NA	Trauma, infection	NA	NA	Ambulant	US
Egeler et al. 2018 [35]	2	108	53 ± 15	74.1	Muscle	Free	Trauma; ulcer; infection; osteomyelitis	LDF; gracilis	NA	ambulant	NL
Ehrl et al. 2019 [36]	7	25	50 ± 21.8	60	Fasciocutaneous	Free	Trauma, infection	ALT	Achilles tendon	Ambulant	Germany
Elgohary et al. 2019 [37]	2	25	34.3 ± 10.4	60	Fasciocutaneous	Free	Trauma; ulcer; tumor	Radial forearm; ALT	Heel	Ambulant	Egypt

(continued)

Table 1. Continued.

Study	Outcome measure (N)	Population			Reconstruction characteristics				Instrument administration			Follow-up time [month] Mean ± SD
		N	Age [years] Mean ± SD	Male gender [%]	Flap type	Free or pedicled	Indication	Donor site	Recipient site (N)	Setting	Country	
Ellington et al. 2013 [38]	6	27	NA	NA	NA	Free	Trauma	NA	Foot; ankle	Ambulant	US	NA
Falola et al. 2018 [39]	1	39	55.2 ± 15.1	76.9	NA	NA	Ulcer	NA	Foot; ankle, leg; thigh	Ambulant	US	36.0 ± 16.0
Fischer et al. 2018 [109]	2	32	NA	NA	Fasciocutaneous; Adipocutaneous	Free	NA	ALT	NA	Ambulant	Germany	NA
Fu et al. 2013 [40]	3	11	32 ± NA	72.7	Fasciocutaneous	Pedicled	Trauma	Lateral tarsal	Forefoot; toe; distal metatarsal	Ambulant	China	13.0 ± NA
Gill et al. 2013 [41]	3	18	35 ± NA	61	Muscle	Free	Trauma	LDF; gracilis, rectus abdominis	NA	Ambulant	UK	NA
Goil et al. 2020 [42]	3	67	NA	70.1	Adipofacial	NA	Trauma	Sural	Heel; ankle	Ambulant	India	12 ± NA
Grauberger et al. 2020 [43]	1	43	47.3 ± NA	65	Muscle; fasciocutaneous	Free	Trauma, ulcer, infection, tumor	Gracilis; LDF; ALT	Dorsum of foot	Ambulant	NA	NA
Grinsell et al. 2012 [44]	3	17	NA	NA	Musculocutaneous	Free; pedicled	Tumor	NA	Achilles tendon; heel	Ambulant	Australia	17.9 ± NA
Gu et al. 2013 [13]	2	24	NA	79.2	Neurocutaneous	Pedicled	Trauma, ulcer, tumor, malformation	Sural	Foot; ankle; heel, lateral malleolus, lower leg	Ambulant	China	NA
Gu et al. 2017 [45]	4	11	NA	90.9	Fasciocutaneous	Pedicled	Trauma; infection; tumor	Medial plantar	Heel	Ambulant	China	19.6 ± NA
Halim et al. 2015 [46]	2	10	19.8 ± NA	70	Osteocutaneous	Free	Tumor	Fibula	Tibia; femur	Ambulant	Malaysia	63.0 ± NA
Heidekruger et al. 2019 [1]	7	89	NA	74.2	Muscle; fasciocutaneous; Muscular	Free	Trauma; ulcer, infection, tumor	ALT; gracilis	Foot	Ambulant	Germany	51.2 ± 19.2
Houdek et al. 2018 [47]	1	83	65 ± NA	42	Muscular	Pedicled	Infection	Gastrocnemius	Knee	ambulant	US	NA
Izadi et al. 2012 [48]	1	42	NA	NA	Fasciocutaneous	Free	Trauma, ulcer	Subscapular	NA	Ambulant	UK	NA
Jandali et al. 2018 [49]	2	22	59 ± NA	68	Fasciocutaneous	Pedicled	Trauma, ulcer	Medial sural	Foot; ankle	Ambulant	Germany	12
Jeon et al. 2011 [50]	2	11	NA	36.4	Fasciocutaneous	Free	Trauma; burn; infection	DIAP; thoracodorsal	NA	Ambulant	Korea	29.7 ± NA
Jeon et al. 2013 [51]	1	40	47.8 ± NA	60	Fasciocutaneous	Free	Tumor; trauma; ulcer	Thoracodorsal	Foot	Ambulant	Korea	20.4 ± NA
Jiga et al. 2020 [52]	1	18	NA	72	Muscular	Free	Trauma; ulcer	Vastus lateralis	Heel; foot	Ambulant	Germany	6.0 ± NA
Kapoor et al. 2018 [53]	1	139	NA	NA	Muscular, cutaneous	Free; pedicled	Tumor	NA	NA	Ambulant	US	NA
Kask et al. 2019 [54]	1	6	NA	NA	Fasciocutaneous; muscular;	Free; pedicled	Tumor	ALT; LDF; tensor fascia latae; sartorius	Tibia; ankle	Ambulant	Finland	NA
Khai Lluen et al. 2017 [55]	2	7	41.7 ± NA	42.9	Adipofacial; fasciocutaneous; musculocutaneous	Free; pedicled	Trauma; ulcer tumor	LDF; serratus anterior; medial plantar; sural	Heel	Ambulant	Malaysia	NA
Khan et al. 2012 [56]	2	20	44.5 ± NA	85	Fasciocutaneous	Free	Osteomyelitis	Radial forearm	Tibia	Ambulant	UK	NA
Kim et al. 2017 [108]	1	8	NA	37.5	NA	Pedicled	Infection, tumor	NA	Lower leg, thigh	Ambulant	Korea	11.7 ± NA
Klinkenberg et al. 2013 [104]	2	38	NA	NA	Fasciocutaneous	Free	NA	ALT; lateral arm; parascapular	NA	Ambulant	Germany	NA
Kneser et al. 2011 [57]	3	52	NA	NA	Cutaneous Muscular	Pedicled	Trauma; osteomyelitis; tumor; ulcer	Peroneus brevis; sural	Lower leg, Achilles; ankle; heel; forefoot	Ambulant	Germany	NA
Kotsougiani et al. 2018 [58]	2	389	NA	77.6	Muscular; fasciocutaneous	Free	Trauma; infection; tumor; burn; ulcer; vascular insufficiency	ALT; LDF; gracilis; lateral arm flap; parascapular; rectus abdominis	Lower leg; feet; ankle; knee; thigh	Ambulant	Germany	NA
(continued)												

(continued)

Table 1. Continued.

Study	Outcome measure (N)	Population			Reconstruction characteristics				Instrument administration			
		N	Age [years] Mean ± SD	Male gender [%]	Flap type	Free or pedicled	Indication	Donor site	Recipient site (N)	Setting	Country	Follow-up time [month] Mean ± SD
Kwasnicki et al. 2015 [59]	2	20	38.3	90	NA	Free; pedicled	NA	NA	NA	Ambulant	UK	NA
Lee et al. 2012 [61]	1	24	46.7	70.8	Fasciocutaneous	Free	Trauma; ulcer; tumor	ALT	Heel, foot, knee	Ambulant	Korea	NA
Lee et al. 2016 [60]	3	25	51.7 ± 14.7	88	Fasciocutaneous	Pedicled	Infection; burn; trauma	Sural	lower leg; heel; foot	Ambulant	Korea	NA
Lin et al. 2020 [62]	2	12	NA	75	Fasciocutaneous	Pedicled	Trauma; ulcer	Tibial	Ankle, heel	Ambulant	China	NA
Liu et al. 2020 [63]	2	5	33.8 ± NA	60	Neurocutaneous	Pedicled	Trauma; deformity	Foot dorsal	Foot	Ambulant	China	15.8 ± NA
Lofstrand et al. 2018 [106]	1	17	29.5 ± NA	64.7	Fasciocutaneous	Free	Trauma; tumor; ulcer	Medial plantar	Heel; forefoot	Ambulant	Sweden	59.3 ± 51.3
Lu et al. 2014 [64]	4	19	41.3 ± NA	68.4	Fasciomyocutaneous	Pedicled	Trauma	Sural	Heel	Ambulant	China	14.1 ± NA
Lu et al. 2016 [87]	2	11	NA	63.6	Adipofacial	Free	Trauma	Sural	NA	Ambulant	China	15.3 ± NA
Lu et al. 2019 [65]	2	29	57.3 ± NA	62	Adipofacial; fasciocutaneous	Free	Ulcer	ALT; LDF; vastus lateralis; radial forearm	Ankle; Heel; Achilles tendon; forefoot	Ambulant	US	NA
Luo et al. 2020 [66]	2	227	NA	79.2	Fasciocutaneous	Pedicled	Trauma, ulcer, tumor; osteomyelitis	Tibia; peroneal	Foot	Ambulant	China	12.4 ± NA
Luo et al. 2020 [16]	1	17	NA	87	Fasciocutaneous	Pedicled	osteomyelitis	Peroneal	Ankle	Ambulant	China	28.4 ± NA
Mahmoud et al. 2017 [88]	3	30	38.9 ± NA	80	Fasciocutaneous	Pedicled	Osteomyelitis	Sural; Medial Plantar	Heel; ankle; Achilles tendon	Ambulant	Egypt	13.2 ± NA
Maruccia et al. 2017 [67]	4	22	NA	NA	Fasciocutaneous	Free	Trauma; ulcer; tumor	ALT	Foot	Ambulant	Italy	NA
Meyer-Marcotty et al. 2012 [68]	2	23	48 ± NA	82.6	Adipofacial; fasciocutaneous; muscular	Free	Trauma; ulcer	Suralis; LDF; ALT parascapular; serratus anterior; radialis	Foot plantar	Ambulant	Germany	46.6 ± NA
Mojallal et al. 2011 [12]	2	28	NA	64.3	Adipofacial	Pedicled	Trauma; burn	Sural	Heel; foot	Ambulant	US	NA
Myung et al. 2017 [94]	3	30	NA	86.8	Fasciocutaneous	Free	Trauma; ulcer; tumor	Iliacal; ALT, thoracodorsal artery	Foot	Ambulant	Korea	13 ± NA
Nanda et al. 2018 [69]	2	21	NA	90.5	Adipofacial	Pedicled	Trauma; burn; infection	Posterior/anterior tibial	Mid/lower leg; ankle	Ambulant	India	NA
Oh et al. 2011 [70]	2	20	31.5 ± NA	50	Fasciocutaneous	Free; pedicled	Trauma; tumor	Medial plantar	Heel; forefoot	Ambulant	Korea	19.9 ± NA
Olivan et al. 2015 [71]	5	25	56 ± 13.55	56	Fasciocutaneous	Free	Trauma; tumor	ALT	Foot	Ambulant	Brazil	12
Ovaska et al. 2014 [72]	8	56	57 ± NA	50	Muscular	Pedicled	Infection	Peroneus brevis	Ankle	Ambulant	Finland, Canada	52 ± NA
Pappalardo et al. 2016 [107]	2	20	48.5 ± NA	70	Fasciocutaneous	Free	Trauma; tumor; ulcer	ALT	Heel; foot	Ambulant	Taiwan	24 ± NA
Patel et al. 2014 [73]	2	57	58.8 ± NA	NA	NA	NA	NA	NA	NA	Ambulant	US	NA
Philandrianos et al. 2018 [74]	2	47	38.2 ± NA	NA	Fasciocutaneous; muscular	Free	Trauma	ALT; LDF	Tibia; ankle	Ambulant	France	NA
Potoschnig et al. 2013 [11]	2	9	NA	NA	Osteofasciocutaneous	Free	NA	Fibula	Tibia	Ambulant	Germany	NA
Qing et al. 2018 [75]	3	15	40.7 ± NA	80	Fasciocutaneous	Pedicled	Ulcer; trauma	ALT	Ankle, heel, foot	Ambulant	China	24.46 ± NA
Rajkumar et al. 2020 [10]	1	47	37 ± NA	95.7	Fasciocutaneous	Pedicled	Ulcer; trauma	Posterior/anterior tibial; peroneal	Foot; ankle	Ambulant	India	NA
Repo et al. 2016 [76]	5	13	NA	100	Osteocutaneous; osteomusculocutaneous	Free	Trauma	Iliac bone	Foot, ankle	Ambulant	Finnland	NA

(continued)

Table 1. Continued.

Study	Outcome measure			Population		Reconstruction characteristics					Instrument administration		
	(N)	N	Age [years] Mean ± SD	Male gender [%]	Flap type	Free or pedicled	Indication	Donor site	Recipient site (N)	Setting	Country	Follow-up time [month] Mean ± SD	
Repo et al. 2016 [77]	3	16	NA	87.5	Muscle; musculocutaneous	NA	Trauma	NA	Tibia	Ambulant	Finland	6.6 years	
Riccio et al. 2019 [9]	3	9	NA	77	Muscle	Pedicled	Trauma	Soleus	Lower leg	Ambulant	Italy	NA	
Rothenberger et al. 2019 [78]	1	26	49 ± 16	76.9	Myocutaneous; fasciocutaneous; muscle	NA	Trauma	ALT; LDF; gracilis	NA	Ambulant	Germany	12	
Rounds et al. 2019 [102]	1	30	NA	86.7	Adipofacial; fasciocutaneous; muscular	Free; pedicled	Trauma	Gastrocnemius; soleus; rectus abdominis; ALT; LDF; gracilis	NA	Ambulant	US	NA	
Sapino et al. 2019 [105]	8	9	62 ± 5.7	55.5	Musculocutaneous; fasciocutaneous	Free; pedicled	Tumor; infection	ALT	Patella	Ambulant	Italy, UK, CH	30 ± 6	
Schmidt et al. 2012 [80]	5	148	NA	65.5	Adipofacial; fasciocutaneous	Pedicled	Trauma; tumor; ulcer	Sural	Pretibial; heel; Achilles tendon; ankle	Ambulant	Germany	NA	
Schmidt et al. 2019 [79]	1	81	NA	NA	Adipofacial; fasciocutaneous	Free; pedicled	NA	Sural; ALT	NA	Ambulant	Germany	NA	
Seyidova et al. 2020 [81]	1	83	NA	78.3	Fasciocutaneous muscle	Free	Trauma, tumor	LDF; gracilis; serratus; tensor fascia lata; ALT; radial forearm; lateral arm; MS	Ankle; knee	Ambulant	UK	NA	
Sofiadelis et al. 2012 [82]	1	103	NA	NA	Fasciocutaneous; muscular	Free	Trauma	scapula LDF; rectus abdominis; gracilis; serratus anterior; Radial forearm;	NA	Ambulant	Australia	NA	
Song et al. 2016 [83]	1	5	NA	100	Fasciocutaneous; Muscular	Pedicled	Trauma, deformity	Medial plantar, LDF	Heel, foot, ankle, leg, toes	Ambulant	China	NA	
Soni et al. 2012 [84]	1	9	NA	NA	Muscular	Free; pedicled	Trauma	Gastrocnemius; tibialis	NA	Ambulant	UK	60 ± NA	
Soons et al. 2015 [85]	3	7	43.0 ± NA	85.7	Chimeric (tendon/ fasciocutaneous)	Free	Trauma	posterior; LDF Radial forearm; ALT	Achilles tendon	Ambulant	NL	32.3 ± NA	
Struckmann et al. 2014 [86]	10	21	NA	71.4	Fasciocutaneous adipocutaneous muscle myofasciocutan	Free; pedicled	Trauma, ulcer	ALT; sural; gracilis flap; lateral arm; LDF; medial plantar; parascapular	Foot	Ambulant	Germany	32.4 ± NA	
Suh et al. 2017 [89]	2	59	62.5 ± NA	56	Fasciocutaneous	Free	Tumor	ALT, SCIP; SGAP; PIAP; UMT	Foot; ankle	Ambulant	Korea	NA	
Tan et al. 2015 [90]	3	7	NA	57.1	Neurocutaneous	Pedicled	Trauma; tumor; ulcer; deformity	Sural	Heel; ankle; foot	Ambulant	Turkey	NA	
Tekin et al. 2013 [91]	7	9	26.7 ± NA	100	Muscular	Free	Trauma	NA	Heel	Ambulant	Turkey	51.6 ± NA	
Theil et al. 2020 [92]	1	43	NA	42	Muscular	Pedicled	Infection	Gastrocnemius	Knee	Ambulant	Germany	NA	
Trevatt et al. 2014 [93]	1	8	53.2 ± NA	NA	Fasciocutaneous	Free; pedicled	NA	Foot plantar	Heel; ankle	Ambulant	UK; Pakistan	NA	
Unluer et al. 2018 [14]	2	31	52.0 ± NA	90.3	Muscular	Pedicled	Trauma	Hemiseous	Lower leg	Ambulant	UK; UAE	NA	
Vallier et al. 2012 [95]	3	14	43.0 ± NA	71.4	Osteocutaneous	Pedicled	Trauma; burn	Posterior tibial	Foot, ankle	ambulant	US	60.2 ± NA	
Wang et al. 2015 [96]	3	8	NA	75	Cutaneous	Pedicled	Ulcer; tumor, trauma	Calcaneal	Heel	Ambulant	China	NA	
(continued)													

(continued)

Table 1. Continued.

Study	Population			Reconstruction characteristics				Instrument administration		
	Outcome measure (N)	Age [years] Mean $\pm$ SD	Male gender [%]	Flap type	Free or pedicled	Indication	Donor site	Recipient site (N)	Setting	Country
Yang et al. 2013 [97]	2	15	80	Adipofacial	Pedicled	Osteomyelitis	Sural	Calcaneus; tibia	Ambulant	China
Yang et al. 2013 [15]	1	51	84.3	Fasciocutaneous; osteoseptocutaneous, ossear	Free	Trauma	ALT; fibula	Tibia	Ambulant	China
Zhang et al. 2016 [98]	3	16	75	Fasciocutaneous	Pedicled	Burn; trauma	Medial plantar hallucal artery	Foot	Ambulant	China
Zheng et al. 2016 [100]	1	26	73.1	Adipofacial	Pedicled	Trauma; ulcer	Sural	Heel; ankle	Ambulant	China
Zheng et al. 2019 [99]	2	7	100	Chimeric	Free	Trauma	ALT	NA	Ambulant	China
Zhong et al. 2015 [101]	3	5	20	Neurocutan	Pedicled	Deformity	Sural	Foot, ankle	Ambulant	China

ATF: anterolateral thigh flap; CH: Switzerland; DIEP: deep inferior epigastric perforator flap; LDF: latissimus dorsi flap; MSAPF: medial sural artery perforator flap; NA: no answer; NL: Netherlands; PIAP: posterior interosseous artery perforator flap; PTAPF: posterior tibial artery perforator flap; SCIP: superficial circumflex iliac artery perforator flap; SD: standard deviation; SGAP: superior gluteal artery perforator flap; SNF: sural neurocutaneous flaps; UAE: United Arab Emirates; UK: United Kingdom; UMT: upper medial thigh perforator flap; US: United States.

Table 2. Overview over the characteristic of the included outcome measures.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
Functional Consistence/stability	Ambulation/weight-bearing capacity	364	11 [14,42,71,82,91,102,12,13,94,96,105]	Ambulation is categorized based on walking capability (different categorizations, definitions), defined as good, mild, or bad depending on the level of assistance needed [71].	Yes/no Good/bad	None	Non-validated
	Chen classification	20	2 [32,99]	The Chen classification globally estimates the effectiveness of reconstructions [128].	None	None	Non-validated
	Energy Expenditure Index (EEI)	9	1 [91]	Four different parameters are measured with a sensor: walking on a treadmill (0° incline and 5° incline) with a 1.5-km/h velocity and a 3 km/h velocity for 5 min.	None	Vmax 29 C sensor	Non-validated
	Functional rating (Mahmoud et al. 2017)	30	1 [88]	Functional outcomes graded from excellent (flap survival and walking without aids or special shoes) to the poor (alternative reconstructive procedure required) [88].	Poor/excellent	None	Non-validated
	Heel-rise-test/toe walking	219	4 [9,30,72,80]	To assess calf muscle strength. Variations exist: rising on the toes with one leg as many times as possible or walk on the toes.	None	None or a metronome	Non-validated
	Insole-pedobarographic gait analysis	53	3 [9,68,86]	Plantar foot pressure distribution and dynamic parameters such as step length and step cadence is measured and symmetry is analysed in comparison with the healthy side. Analyses are performed barefoot with the attachment of soles.	None	Pressure sensors and software	Non-validated

(continued)

Table 2. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
Ilizarov functional criteria	Ilizarov functional criteria	14	1 [17]	Functional criteria: significant limp, equinus rigidity of the ankle, soft-tissue dystrophy (skin hypersensitivity, insensitivity, decubitus), pain and inactivity [129].	Poor/excellent	None	Non-validated
	Muscle strength and endurance	90	5 [14,32,44,85,105]	Muscle strength is scored from M0 to M5 (M5 = full strength, M0 = paralysis). Variations exist, also with using measuring devices [130]. The result can also be presented as a mean strength of the operated lower limb/mean strength of the non-operated lower limb $\times$ 100%.	M0–M5	None or dynamometer	Non-validated
	Posture	9	1 [9]	Parameters, such as medialateral and anteroposterior excursion, sway path, mean velocity and mean distance are measured [131].	None	Sensor/convert-er/software	Non-validated
	Range of motion	587	15 [1,26,28,30,32,33,38,44,57,67,72,80,85,101,105]	Range of motion (ROM) is measured with a goniometer and measurements of the reconstructed site are compared with those of the unaffected side for calculation of deficit and rating of the result. Depending on the location of the reconstructed site different movement angles are measured. Total active motion (TAM) or passive range of motion can be measured.	Good/poor	Goniometer	Non-validated
	The Freiburg Ankle Scoring System (FASS)	9	1 [91]	Evaluation of ankle function.	0–100	None	Non-validated
	The Maryland Foot Score (MFS)	5	1 [83]	Functional evaluation specific to foot and ankle function, based on walked distance, foot/ankle stability, support aids, limp, shoes, stairs; terrain, cosmesis, range of motion [132].	0–100	None	Non-validated
	Weber score	21	1 [86]	Evaluations of the taloribial joint function in 6 dimensions, including radiologic changes, pain, activity, walking ability and active range of motion. A low score indicates better functionality [133].	None	None	VFOI
	Time to ambulation	268	10 [24,26,38,46,56,65,73,76,88,89]	Time between the reconstructive procedure until walking without aids. Alternatively duration of wheelchair use.	None	None	Non-validated
	Time to preinjury activity/return to work	57	3 [26,30,38]	Time between the reconstructive procedure until return to work or return to normal activity.	None	None	Non-validated
	Walking test	55	4 [38,91,95,101]	Subjects walk at a regular walking rhythm, different versions available (100-feet (30.5-m) timed walking test; 6 min/10 min walking test (6MWT) (10MWT)).	None	Chronometer	VFOI
Circumference measurement	Circumference measurement	299	6 [30,57,72,80,85,94]	The discrepancy of circumference between the operated site and the contralateral healthy site is measured.	None	Measuring tape	Non-validated
	Flap contour, adherence and consistency	598	17 [1,27,31,43,61,65,68,40,72,73,81,68,87,95,107,102,62]	Flap contour is rated from good (no adjustment to closed shoes needed) to bad (unable to wear closed shoes) [71]. Alternatively, consistency was evaluated based on photos of the flap, categorized as normal, adherent to underlying structures, bulky [72].	Good – Bad	None	Non-validated

(continued)

Table 2. Continued.

Domain	Outcome measure	Population	Studies <i>n</i> (ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
Aesthetic	Flap Stability (F5)	138	4 [30,71,72,103]	F5 good (no fissures, wounds, lateral movement of flap) mild (occasional fissures/wounds), bad if these problems appear repeatedly [71].	Good – Poor	None	Non-validated
	Flap Shifting	21	1 [86]	Assessed with a suture under the flap. The flap is moved transversely and sagittally distance between the marking and suture measured (shift of >0.5 cm = pathologic) [86].	>0.5 cm	Vicryl	Non-validated
	Scoring system (Zhang et al.)	20	1 [33]	Assessment of five aspects: flap healing, sensation, shape, temperature and donor site scar [134].	0–10	None	Non-validated
	Venous congestion	554	16 [10,13,19,20,24,28,29,46,60,69,70,74,88,96,103,105]	Monitoring of venous congestion according to the modified flap swelling scale [10] or observation of skin color change.	0–IV	Ultrasound/none	Non-validated
	Flap appearance (Maruccia et al. 2017)	22	1 [67]	Parameters: overall appearance, color match, texture match, donor-recipient tissue interface, hairiness, final scar location and development of skin contractures.	0–5 each	None	Non-validated
	Strasser's objective grading system	11	1 [50]	Photographic evaluation based on malposition, distortion, asymmetry, contour deformity and scarring of the flap [135].	0–15	None	Non-validated
Sensation	The Vancouver Scar Scale	126	4 [1,21,36,86]	Evaluation of aesthetic outcome based on pigmentation, scar height, elasticity perfusion, each ranked separately and added up [136].	0–3/0–5	Questionnaire	Validated
	Hot and cold sensitivity test/thermal sensation	49	3 [23,86,90]	Testing of thermal sensation with e.g. metal stick [90]. The results are considered positive in the case of 2 correct responses [86].	Pos./Neg.	Metal stick	VFOI
	Moving one-point test (1 PM)	25	1 [71]	Measures cutaneous sensory threshold [71] (see 1 PS)	None	Pressure-specified sensory device	Non-validated
	Neuronal conduction	7	1 [90]	Nerve conduction measurement according to the guidelines of the American Association of Electrodiagnostic Medicine [137].	None	Electro-myogram equipment	VFOI
	Pinprick test	24	1 [23]	Testing the actual ability to feel a pinprick and the ability to determine the difference between sharp and dull [138].	Yes/no	Sharp device	
	(toothpick;neurotip) Semmes-Weinstein Monofilament (SWM) test	VFOI 271	11 [1,29,30,45,55,64,75,78,87,96,105]	Measurements start with a thicker monofilament, continue at a distance of 0.5 cm with the next thinner monofilament until no perception can be felt. The total anesthetic area is measured [139].	None	Semmes-Weinstein Monofilament	Validated
	Sensitivity testing with light stimulation	103	3 [101,12,23,103]	Sensitivity to touch. Variations exist, sensibility grading can be made according to the British Medical Research Council.	Yes/no	None	Non-validated

(continued)

Table 2. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
PROM Functional	Static one-point test (1 PS)	25	1 [71]	Measures cutaneous sensory threshold (minimum intensity of stimulus required to generate a sensation response) [71].	None	Pressure-specified sensory device	Non-validated
	Static two-point discrimination (s2PD)	464	18 [13,23,29,37,40,45, 62,70,75,80,86,90, 93,97,99,105–107]	Shortest distance between 2 points patient can perceive as being touched with 2 versus 1 point, smaller distance correlates with improved nerve function. Sensory recovery good, if discrimination attains 80% of values in the corresponding area. Analysis of deep sensory perception.	Good/poor	Paperclip etc	VFOI
	Tuning fork vibration test at 128 Hz	119	3 [1,64,87]	Analysis of deep sensory perception.	None	Tuning fork	VFOI
	Foot and Ankle Disability Index (FADI)	21	1 [31]	A 34-item questionnaire, rated with Likert scales and divided into two subscales: the Foot and Ankle Disability Index (26 items) and the Foot and Ankle Disability Index Sport (8 items) [140,141].	FADI 0–104 Sport 0–32	Questionnaire	Validated
	The Frequency Intensity Time (FIT) Index	29	2 [76,77]	Evaluation of the level of physical activity, factors frequency per week, intensity and length of activity are multiplied [142].	0–100	Questionnaire	VFOI
	The Foot Function Index (FFI)	60	4 [18,37,45,98]	A 23-item questionnaire (alternative versions with 17 items), the impact of foot function in three dimensions (pain, disability, activity restrictions), high scores correlate with more pain and disability [143].	0–10 (each)	Questionnaire	Validated
	The Lower Extremity Functional Scale (LEFS)	859	13 [25,32,35, 39,44,53,58,65, 77,86,97,104,109]	Twenty function-related questions; higher scores represent better function [144].	0–80	Questionnaire	Validated
	The Olerud–Molander Ankle score (OMA)	56	1 [72]	A self-administered questionnaire with nine different items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports, work/activities of daily living [145].	0–100	Questionnaire	Validated
	The Paffenbarger Physical Activity Questionnaire	126	1 [34]	Eight-item questionnaire measuring participation in sports/leisure activities. Each activity is rated according to the Compendium of Physical Activities with energy expenditure expressed as metabolic equivalents (METs) [146,147].	0–5	Questionnaire	Validated
	The Toronto Extremity Salvage Score (TESS)	6	1 [54]	Measures activity limitations in everyday activities such as working, dressing and driving a car with 30 questions [148].	0–100	Questionnaire	Non-validated
Aesthetic	Visual Analog Foot and Ankle Scale Questionnaire	72	2 [76,89]	Twenty questions, which can be categorized in three subgroups (pain; function; other complaints) [149,150].	0–100	Questionnaire	Non-validated
	(Seyidova et al. 2020)	83	1 [81]	Questionnaire about satisfaction with color, contour, texture, scar, the bulkiness of flap, similarity to other side, the overall appearance of the flap and the donor-site.	0–5	Questionnaire	Non-validated

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Table 2. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
	Visual Analog Aesthetic Scale	76	4 [24,45,69,75]	Ten-centimeter line used as a visual assessment tool for satisfaction with aesthetic result; centimeters on the line correspond to the aesthetic outcome. [45,151,152]	0–1	Visual scale	VFOI
Pain	Numerical Pain Rating Scale	145	2 [1,72]	The Numerical Rating Scale (NRS) is a numeric segmented version of the Visual Analogue Scale VAS (ranging from 0 to 5, 10, 20 or 100) [153].	0–5/100	None	validated
	The Chronic Pain Grade (CPG) scale	126	1 [34]	A questionnaire measuring the severity of chronic pain, pain intensity, disability score and disability points can be derived and result in an overall grading [154,155].	Grade I–IV	Questionnaire	Validated
	Visual analogue pain scale	135	8 [32,38,60,63,64,86,91,98]	Ten-centimeter lines used as a self-reported visual assessment tool for pain perception, centimeters on the line correspond to pain intensity [151,152].	0–10	Visual scale	VFOI
Sensation	Cold intolerance severity score questionnaire	16	1 [98]	A self-administered Cold Intolerance Severity Score questionnaire [156].	0–100	Questionnaire	Validated
Quality of life	Bavarian plastic surgery questionnaire (Schmidt et al. 2019)	81	1 [79]	An assembly out of 4 well-established health care scores (short form health survey-12 [157], the Dresden Body Image Score-35, the Patient Health Questionnaire (PHQ)-4, a questionnaire focusing on joint function [X-SMFAI] and additional questions addressing social and work life [79].		Questionnaire	Non-validated
	Body Image Quality of Life Inventory (BIQLI)	21	1 [31]	A 7-point response format ranging from very negative (–3) to very positive (+3) effects of body image on 19 life domains [158].	–3 to +3	Questionnaire	Validated
	Questions on life satisfaction (FLZM)	9	1 [11]	Assessment of general and health-related quality of life with 2 8-item modules: 'General Life Satisfaction' and 'Satisfaction with Health' [159,160].	NA	Questionnaire	Validated
	The 36-item short-form health survey	420	12 [1,21,30,31,35,36,49,59,86,91,104,109]	The SF-36 evaluates the patient's self-reported quality of life. Questions are categorized in 8 subgroups: physical function, role functioning (physical), role functioning (emotional), vitality, mental health, social functioning, body pain and general health. Each category provides a separate score and, further composite scores such as physical, mental and overall scores are derived [161].		Questionnaire	Validated
	The 12-item short-form health survey	81	2 [27,73]	The SF-12 questionnaire is an adapted version of the SF-36 and consist of 12 questions observing physical health (PCS) and mental health (MCS) [162,163].		Questionnaire	Validated
	The 15D questionnaire	85	3 [72,76,77]	The 15D questionnaire evaluates the quality of life in physical, mental and social well-being dimensions. A difference ≥ 0.015 in the 15D score is estimated to be clinically significant and the difference is experienced by patients [164].	0–1	Questionnaire	Validated

(continued)

Table 2. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
	The EuroQol-5D (EQ-5D)	49	2 [84,20]	The EuroQol-5D is evaluating a patient's quality of life and consists of five dimensions (EQ-5D self-classifier: mobility; self-care; pain/discomfort; usual activities; anxiety/depression) and a Visual Analog Scale (EQ VAS). A set of standard demographic questions is optional [165].	0–100	Questionnaire	Validated
	The EQ Visual Analogue Scale (EQ-VAS)	40	1 [20]	The EuroQol Visual Analogue Scale (a 10 cm/100 mm long horizontal or vertical line) is used as a self-reported visual assessment tool for quality of life.	0–100	Visual scale	Validated
	The Sickness Impact Profile (SIP)	59	3 [38,41,95]	A 136-question-based assessment of the consequences of sickness on physical and psychosocial health. Walking, mobility, body care and movement, social interaction, alertness, emotional behavior, communication, sleep, eating, work, home management and recreation are evaluated [166].	0–100	Questionnaire	Validated
Satisfaction	Questionnaire (Khan et al. 2012)	20	1 [56]	A 7-item multiple-choice questionnaire assesses patient satisfaction with functional and aesthetic outcome [56].	Yes/no	Questionnaire	Non-validated
	Questionnaire (Grauberg et al. 2020)	43	1 [43]	A phone-based questionnaire capturing functional, aesthetic outcome appearance and satisfaction utilized a Likert scale ranging from 1 to 5.	1–5 each	Questionnaire	Non-validated
	Questionnaire (Jeon et al. 2013)	40	1 [51]	Five questions evaluate: Foot pain at rest, daily activities, overall satisfaction, donor site satisfaction and willingness to recommend the operation [51].		Questionnaire	Non-validated
	Questionnaire (Jeon et al. 2011)	11	1 [50]	Five questions evaluate: Color, softness, operative-site contour, overall satisfaction and willingness to recommend the operation [50].		Questionnaire	Non-validated
	Questionnaire (Brunetti et al. 2020)	58	1 [22]	Patients rate functional and aesthetic outcomes on a 5-point Likert considering mobility impairments and sensitivity loss and aesthetic satisfaction [22].	0–5	Linkert scale	Non-validated
Multi-domain	Reconstruction outcome scales (Boyden et al.)	253	2 [66,100]	A subjective self-assessment using a 4-point scale	–1 to 2	None	Non-validated
	Satisfaction scale (Kim et al. 2017)	8	1 [108]	Patients are asked about overall satisfaction with the procedure.	Yes/no	None	Non-validated
	Satisfaction overall (Luo et al. 2020)	244	2 [16,66]	A 42-item questionnaire with five separate subscales (Pain, Other Symptoms, Activities of Daily Living, Sport and Recreation Function, Foot- and Ankle-Related Quality of Life). Answers are given on Linkert scales for each item [168].	0–100	Questionnaire	Validated
	Foot and Ankle Outcome Score (FAOS)	52	1 [57]				
	Questionnaire (Gill et al.)	18	1 [41]	A questionnaire assessing the donor and transfer sites for aesthetic, functional and sensory outcomes and complications		Questionnaire	Non-validated

(continued)

Table 2. Continued.

Domain	Outcome measure	Population	Studies <i>n</i> (ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
	Questionnaire (Gail et al.)	67	1 [42]	Patients rate their satisfaction with the procedure, the aesthetic outcome of the donor site and return to work on a scale of 1–10 [42].	1–10	Questionnaire	Non-validated
	Questionnaire (Kotsougiani et al. 2018)	389	1 [58]	Patient's general and cosmetic (scarring, symmetry and naked/dressed appearance) satisfaction is assessed with Likert scales (score, 0–4) [58].	0–4 each max. 16	Questionnaire	Non-validated
	Questionnaire (Philandrianos et al. 2018)	47	1 [74]	Donor site and recipient site are evaluated, questions regarding functional outcome (pain, loss of strength, diminution of movement, footwear are answered with 'yes' or 'no' answer). Aesthetic outcome was rated with a numeric score of 0–10, additionally, circumference difference between legs is measured.		Questionnaire	Non-validated
	Questionnaire (Potoschnig et al. 2013)	9	1 [11]	Evaluation of demographic and socioeconomic status, postoperative complications, including pain, swelling, intolerance of weather variation and limitation by working or in private life.	NA	Questionnaire	Non-validated
	The back-specific Oswestry Disability Index (ODI)	13	1 [76]	Ten-item questionnaire evaluating lifting, pain, personal care, sitting, sex life, sleeping, social life, standing, traveling and walking [169].	0–5 each	Questionnaire	Validated
	The Chinese Manchester foot pain and disability index	5	1 [63]	A 17-item questionnaire with three domains: physical limitation, personal appearance and pain [170].	0–3	Questionnaire	Validated
	The (modified) Enneking score	93	3 [19,48,67]	Validated functional score recording pain, function, emotional acceptance, support, walking and gait [171,172].	0–5 each	Questionnaire	Validated
	The Flap Outcome Questionnaire (FOQ)	40	1 [20]	A 11-item questionnaire assessing functional ability, daily living, symptom control, aesthetic appeal, overall flap rating and quality of life.		Questionnaire	Non-validated
	The Oxford Knee Score	43	1 [92]	A disease-specific 12-item questionnaire divided into individual assessments of pain and function [173]	0–48	Questionnaire	Validated
	The Short Musculoskeletal Function Assessment (SMFA) questionnaire	140	2 [34,95]	A questionnaire summarizing dysfunction in four domains (mobility, arm/hand function, daily activities, emotional status), ten categories within MFA: mobility, hand and fine motor, household, self-care, sleep and rest, leisure and recreation, family relationships, cognition and thinking, emotional adjustment and adaptation, employment [174].	0–100	Questionnaire	Validated
	The Western Ontario and MacMaster Universities osteoarthritis index (WOMAC)	42	2 [27,41]	A questionnaire measuring pain, stiffness and function in the hip and knee [175].		Questionnaire	Validated

(continued)

Table 2. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
CROM/ PROM	Hamlyn mobility score (HMS)	20	1 [59]	A psychometric evaluation of a sensor-based mobility score. An activity protocol, while wearing an ear-worn accelerometer, with (performance scores from 0 to 5) includes for a 6-minute walk, timed up and down stairs and timed up-and-go tests. Additionally, four questions regarding the use of mobility aids, work and leisure activities, satisfaction with walking and pain were assessed [59].	0–5	Test protocol, accelerometer and questionnaire	Validated
	Johner–Wruhs evaluation criteria	51	1 [15]	Criteria include bony nonunion, osteomyelitis and amputation; neurovascular disturbances; deformity; pain; gait and daily activities [176].	Poor/excellent	Questionnaire	Non-validated
	Questionnaire (Ehrl et al. 2019)	25	1 [36]	The questionnaire inquires about wound healing complications, shoe provision, satisfaction with the treatment and pain scores according to the Numerical Rating Scale at rest and during activity. Objectively, the range of motion of the ankle, Thompson (manual compression of the triceps surae muscle; passive dorsal extension in the ankle is a positive result), monofilament and tuning fork (128 Hz) tests are performed. The Vancouver Scar Scale was also included.	None	Questionnaire, monofilament, tuning fork	Non-validated
	Questionnaire (Lee et al. 2012)	24	1 [61]	Functional and cosmetic outcomes are assessed by the physician and patient. Walking in a straight line, walk up 12 steps and put on socks and shoes on [61].	0–4	Questionnaire	Non-validated
	Questionnaire (Sapino et al. 2019)	9	1 [105]	General appearance, shape, color and texture are evaluated on a combined numerical scale performed by both the patient and the clinician.	0–20	Questionnaire	Non-validated
	Questionnaire (Buono et al. 2018)	24	1 [23]	Tissue thickness, texture and aesthetic appearance (e.g. relief, color match, symmetry with healthy side) are assessed by the patient and clinician.		Questionnaire	Non-validated
	The American Orthopedic Foot and Ankle Society Scoring System (AOFAS)	64	5 [30,40,49,52,55]	The AOFAS includes 4 different scores, each related to a specified anatomic region (1) the ankle/hindfoot, (2) the midfoot, (3) the hallux metatarsophalangeal/interphalangeal and (4) the metatarsophalangeal/interphalangeal region. Patient-reported questions about pain, activity, functional limitations and footwear and examiner-reported data about alignment, gait and motion are included within 3 subscales [177].	0–100	Questionnaire	VFOI

(continued)

Table 2. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
	The Knee Society Score (KSS)	116	3 [27,47,105]	The objective knee score evaluates alignment, ligament stability and ROM, along with deductions for flexion contracture or extensor lag. A subjective VAS score of pain, walking, as well as patient satisfaction, functional activities and patients expectations are also included [178,179].	0–100 per section	Test protocol and VAS	Validated
AOFAS: The American Orthopedic Foot and Ankle Society Scoring System; BIQLI: Body Image Quality of Life Inventory; ClinROM: clinician-reported outcome measures; CPG: Chronic Pain Grade Scale; EEI: Energy Expenditure Index; EQ-VAS: EQ Visual Analogue Scale; FADI: Foot and Ankle Disability Index; FASS: Freiburg Ankle Scoring System; FAOS: Foot and Ankle Outcome Score; FFI: Foot Function Index; FIT: Frequency Intensity Time Index; FOQ: Flap Outcome Questionnaire; FS: flap stability; HMS: Hamlyn Mobility Score; KSS: The Knee Society Score; LEFS: lower extremity functional scale; METS: metabolic equivalents; MFS: Maryland Foot Score; NRS: Numerical Rating Scale; ODI: The back-specific Oswestry disability index; OMA: Olerud-Molander Ankle score; PHQ: the Patient Health Questionnaire; PROM: patient-reported outcome measure; ROM: Range of motion; SF-12: The 12-Item Short-Form Health Survey; SF-36: The 36-Item Short-Form Health Survey; SMFA: The Short Musculoskeletal Function Assessment; SIP: Sickness Impact Profile; SWMT: Semmes-Weinstein Monofilament Test; s1PS: Static One-Point Test; s2PD: Static Two-Point Discrimination; TAM: Total Active Motion; TESS: Toronto Extremity Salvage Score; VFOI: Validated For Other Intentions; VAS: Visual Analogue Scale; WOMAC: The Western Ontario and MacMaster Universities Osteoarthritis Index; 6MWT: 6 min Walking Test; 10MWT: 10 Min Walking Test; 1PM: Moving One-Point Test; CROM: clinician-reported outcome measurements; PROM: patient-reported outcome measure.							

of motion, grip and pinch strength, ability to bear weight, sensation, length of surgery and length of hospital stay [116,117]. They are used in determining cost-effectiveness and quality assurance [118].

Additionally to CROMS different PROMs were used in 31 studies. The importance of PROMs steadily increases and new PROMs are currently being developed [119,120]. PROMs allow surgeons and researchers to quantify otherwise intangible outcomes like form, function and quality of life from a patient's perspective [121]. PROMs can be deployed across the patient care journey, to support diagnosis, disease severity determination, referral pathways, treatment decision-making and post-operative care [119]. To address the discrepancy between the patient's expectations and the clinicians definition of a successful procedure PROMs are crucial [119]. The most commonly used PROM was the Lower Extremity Functional Scale, a self-report condition-specific measurement that yields reliable and valid results and is appropriate for use as a clinical and research tool [118]. The fact that despite its introduction only in 1999, it has already been used to rate results of 793 patients illustrates the growing appreciation for this tool and more generally the growing awareness for the importance of PROMs use.

Certain outcome measurements (e.g. Vancouver Scar Scale) can be used as PROMs and CROMs. A comparison of the rating of outcomes shows that clinicians tend to overrate outcomes compared to patients [122]. CROMs are well accepted by patients and show high reliability [123]. It is argued whether PROM results are more challenging to interpret than objective CROMs due to a higher inter- and intraobserver variability and subjective PROM scoring for cultural and other individual reasons [124].

Most studies included only a smaller number of patients and are retrospective, demonstrating a need for larger studies, ideally prospective and with some sort of reliable comparison (randomized, matched pairs, or similar). Many advances in outcome research have been achieved in the past two decades enabled by new information technologies, data sharing and collaborative efforts but the need for improvement in outcome measurement methodology used in plastic surgery research remains urgent [125,126].

There is a tendency toward self-created scores, which are often used without validation and/or cultural adaptation. Some authors also assembled their own questionnaire using parts of already existing outcome measurements [1,79]. We advocate for the use of validated scores only and hopefully for an internationally recognized standard set that could be used for all studies and make outcomes comparable across the world. This is true not only for CROMs but also for PROMs. Pusic et al. showed in a systematic review the increasing importance of validated PROMs, the group found that only few PROMs (in this case used in breast surgery studies), were validated and had evidence to support their use [127]. Validation and standardization of PROMs but also CROMs in plastic surgery is needed [127].

Our review shows that there isn't any accepted 'gold standard' in outcome measurements in lower extremity reconstructions, neither what to measure, nor how or when. In particular, the most striking finding is that there isn't any agreement about which domains are important and relevant for clinicians and patients, that should be included in the analysis. This is the first step for every reliable analysis and we are convinced that an expert group should identify these domains together with the instruments to measure them and, not less important, the time points when to perform the measurements. based on the literature no single 'gold standard' for outcome measurements in lower extremity

Table 3. Overview over the characteristic of the included non-validated outcome measures and outcome measures validated for other intentions.

Domain	Outcome measure	Population	Studies <i>n</i> (ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
GROM Functional	Ambulation/weight-bearing capacity	364	11 [14,42,71,82,91,102,12,13,94,96,105]	Ambulation categorized based on walking capability (different categorizations, definitions), defined as good, mild or bad depending on the level of assistance needed [71]. The Chen classification globally estimates the effectiveness of reconstructions [128].	Yes/no Good/bad	None	Non-validated
	Chen classification	20	2 [32,99]	Four different parameters are measured with a sensor: walking on a treadmill (0° incline and 5° incline) with a 1.5-km/h velocity and a 3 km/h velocity for 5 min. Functional outcomes graded from excellent (flap survival and walking without aids or special shoes) to the poor (an alternative reconstructive procedure required) [88]	None	Vmax 29 C sensor	Non-validated
	Energy Expenditure Index (EEI)	9	1 [91]	Functional outcomes graded from excellent (flap survival and walking without aids or special shoes) to the poor (an alternative reconstructive procedure required) [88]	None	None	Non-validated
	Functional rating (Mahmoud et al. 2017)	30	1 [88]	To assess calf muscle strength. Variations exist: rising on the toes with one leg as many times as possible or walk on the toes.	None	None or a metronome	Non-validated
	Heel-rise-test/ Toe walking	219	4 [9,30,72,80]	Plantar foot pressure distribution and length and step cadence is measured and symmetry is analysed in comparison with the healthy side. Analyses are performed barefoot with the attachment of soles.	None	Pressure sensors and software	Non-validated
Consistence/stability	Insole-pedobarographic gait analysis	53	3 [9,68,86]	Functional criteria: significant limp, equinus rigidity of the ankle, soft-tissue dystrophy (skin hypersensitivity, insensitivity, ¹²⁹ decubitus), pain and inactivity. Muscle strength is scored from M0 to M5 (M5 = full strength, M0 = paralysis). Variations exist, also with using measuring devices [130]. The result can also be presented as a mean strength of the operated lower limb/mean strength of the non-operated lower limb $\times$ 100%.	Poor/excellent	None	Non-validated
	Ilizarov functional criteria	14	1 [17]	Parameters, such as mediolateral and anteroposterior excursion, sway path, mean velocity and mean distance are measured [131].	None	Sensor/convert-er/software	Non-validated
	Muscle strength and endurance	90	5 [14,32,44,85,105]	Range of motion (ROM) is measured with a goniometer and measurements of the reconstructed site are compared	Good/poor	Goniometer	Non-validated
	Posture	9	1 [9]				
	Range of motion	587	15 [1,26,28,30,32,33,38,44,57,67,72,80,85,101,105]				

(continued)

Table 3. Continued.

Domain	Outcome measure	Population	Studies <i>n</i> (ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
	The Freiburg Ankle Scoring System (FASS) The Maryland Foot Score (MFS)	9	1 [91]	with those of the unaffected side for calculation of deficit and rating of the result. Depending on the location of the reconstructed site different movement angles are measured. Total active motion (TAM) or passive range of motion can be measured.	0–100	None	Non-validated
		5	1 [83]	Evaluation of ankle function. Functional evaluation specific to foot and ankle function, based on walked distance, foot/ankle stability, support aids, limp, shoes, stairs, terrain, cosmesis, range of motion [132].	0–100	None	Non-validated
	Weber score	21	1 [86]	Evaluations of the talotibial joint function in 6 dimensions, including radiologic changes, pain, activity, walking ability and active range of motion. A low score indicates better functionality [133].	None	None	VFOI
	Time to ambulation	268	10 [24,26,38,46,56,65,73,76,88,89]	Time between the reconstructive procedure until walking without aids. Alternatively duration of wheelchair use.	None	None	Non-validated
	Time to preinjury activity/return to work	57	3 [26,30,38]	Time between the reconstructive procedure until return to work or return to normal activity.	None	None	Non-validated
	Walking test	55	4 [38,91,95,101]	Subjects walk at a regular walking rhythm, different versions available (100-feet (30.5-m) timed walking test; 6 min/10 min walking test (6MWT) (10MWT)).	None	Chronometer	VFOI
	Circumference measurement	299	6 [30,57,72,80,85,94]	The discrepancy of circumference between the operated site and the contralateral healthy site is measured.	None	Measuring tape	Non-validated
	Flap contour, adherence and consistency	598	17 [27,1,31,43,61,65,68,40,72,73,81,68,87,95,107,102,62]	Flap contour is rated from good (no adjustment to closed shoes needed) to bad (unable to wear closed shoes) [71]. Alternatively, consistency was evaluated based on photos of the flap, categorized as normal, adherent to underlying structures, bulky [72].	Good – Bad	None	Non-validated
	Flap Stability (FS)	138	4 [30,71,72,103]	FS good (no fissures, wounds, lateral movement of flap) mild (occasional fissures/wounds), bad if these problems appear repeatedly [71].	Good – Poor	None	Non-validated
	Flap Shifting	21	1 [86]	Assessed with a suture under the flap. The flap is moved transversely and sagittally distance between the marking and suture	>0.5 cm	Vicryl	Non-validated

(continued)

Table 3. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
Aesthetic	Scoring system (Zhang et al.)	20	1 [33]	measured (shift of >0.5 cm = pathologic) [86]. Assessment of five aspects: flap healing, sensation, shape, temperature and donor site scar [134].	0–10	None	Non-validated
	Venous congestion	554	16 [10,13,19,20,24,28,29,46,60,69,70,74,88,96,103,105]	Monitoring of venous congestion according to the modified flap swelling scale [10] or observation of skin color change.	0–IV	Ultrasound/ None	Non-validated
	Flap appearance (Maruccia et al. 2017)	22	1 [67]	Parameters: overall appearance, color match, texture match, donor-recipient tissue interface, hairiness, final scar location and development of skin contractures.	0–5 each	None	Non-validated
	Strasser's objective grading system	11	1 [50]	photographic evaluation based on malposition, distortion, asymmetry, contour deformity and scarring of the flap [135].	0–15	None	Non-validated
Sensation	Hot and cold sensitivity test/thermal sensation	49	3 [23,86,90]	Testing of thermal sensation with e.g. metal stick [90]. The results are considered positive in the case of 2 correct responses [86].	Pos./ Neg.	Metal stick	VFOI
	Moving one-point test (1 PM)	25	1 [71]	Measures cutaneous sensory threshold [71] (see 1 PS)	None	Pressure Specified Sensory Device	Non-validated
	Neuronal conduction	7	1 [90]	Nerve conduction measurement according to the guidelines of the American Association of Electrodiagnostic Medicine [137].	None	Electro-myogram equipment	VFOI
	Pinprick test	24	1 [23]	Testing the actual ability to feel a pinprick and the ability to determine the difference between sharp and dull [138].	Yes/no	Sharp device (toothpick,neurotip)	VFOI
PROM Functional	Sensitivity testing with light stimulation	103	3 [12,23,103]	Sensitivity to touch. Variations exist, sensibility grading can be made according to the British Medical Research Council.	Yes/no	None	Non-validated
	Static one-point test (1 PS)	25	1 [71]	Measures cutaneous sensory threshold (minimum intensity of stimulus required to generate a sensation response) [71].	None	Pressure-specified sensory device	Non-validated
	Static two-point discrimination (s2PD)	464	18 [13,23,29,37,40,45,62,70,75,80,86,90,93,97,99,105–107]	Shortest distance between 2 points patient can perceive as being touched with 2 versus 1 point, smaller distance correlates with improved nerve function. Sensory recovery good, if discrimination attains 80% of values in the corresponding area.	Good/poor	Paperclip etc	VFOI
	Tuning fork vibration test at 128 Hz	119	3 [1,64,87]	Analysis of deep sensory perception.	None	Tuning fork	VFOI
PROM Functional	The frequency intensity time (FIT) index	29	2 [76,77]	Evaluation of the level of physical activity, factors frequency per week, intensity and length of activity are multiplied [142].	0–100	Questionnaire	VFOI

(continued)

Table 3. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
Aesthetic	Visual analog foot and ankle scale questionnaire	72	2 [76,89]	Twenty questions, which can be categorized in three subgroups (pain; function; other complaints) [149,150].	0–100	Questionnaire	Non-validated
	Questionnaire (Seyidova et al. 2020)	83	1 [81]	Questionnaire about satisfaction with color, contour, texture, scar, the bulkiness of flap, similarity to other side, the overall appearance of the flap and the donor-site.	0–5	Questionnaire	Non-validated
	Visual analog aesthetic scale	76	4 [24,45,69,75]	Ten centimeter line used as a visual assessment tool for satisfaction with aesthetic results, centimeters on the line correspond to aesthetic outcome [45,151,152].	0–1	Visual scale	VFOI
Pain	Visual analogue pain scale	135	8 [32,38,60,63,64,86,91,98]	Ten centimeter line used as a self-reported visual assessment tool for pain perception, centimeters on the line corresponds to pain intensity [151,152].	0–10	Visual scale	VFOI
Quality of Life	Bavarian plastic surgery questionnaire (Schmidt et al. 2019)	81	1 [79]	An assembly out of 4 well-established health care scores (short form health survey-12 [157], the Dresden Body Image Score-35, the Patient Health Questionnaire (PHQ)-4, a questionnaire focusing on joint function [X-SMFA]) and additional questions addressing social and work life [79].		Questionnaire	Non-validated
Satisfaction	Questionnaire (Khan et al. 2012)	20	1 [56]	A 7-item multiple-choice questionnaire assesses patient satisfaction with functional and aesthetic outcomes [56].	Yes/no	Questionnaire	Non-validated
	Questionnaire (Grauberger et al. 2020)	43	1 [43]	A phone-based questionnaire capturing functional, aesthetic outcome appearance and satisfaction utilized a Likert scale ranging from 1 to 5.	1–5 each	Questionnaire	Non-validated
	Questionnaire (Jeon et al. 2013)	40	1 [51]	Five questions evaluate Foot pain at rest, daily activities, overall satisfaction, donor site satisfaction and willingness to recommend the operation [51].		Questionnaire	Non-validated
	Questionnaire (Jeon et al. 2011)	11	1 [50]	Five questions evaluate color, softness, operative-site contour, overall satisfaction and willingness to recommend the operation [50].		Questionnaire	Non-validated
	Questionnaire (Brunetti et al. 2020)	58	1 [22]	Patients rate functional and aesthetic outcomes on a 5-point Likert considering mobility impairments and sensitivity loss and aesthetic satisfaction [22].	0–5	Linkert scale	Non-validated
	Reconstruction outcome scales Boyden et al. Satisfaction scale (Kim et al. 2017)	253 8	2 [66,100] 1 [108]	A subjective self-assessment using a 4-point scale	–1 to 2	None	Non- validated Non-validated

(continued)

Table 3. Continued.

Domain	Outcome measure	Population	Studies n(ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
Multi-Domain	Satisfaction overall (Luo et al. 2020)	244	2 [16,66]	Patients are asked about overall satisfaction with the procedure.	Yes/no	None	Non-validated
	Questionnaire (Gill et al.)	18	1 [41]	A questionnaire assessing the donor and transfer sites for aesthetic, functional and sensory outcomes and complications		Questionnaire	Non-validated
	Questionnaire (Goi et al.)	67	1 [42]	Patients rate their satisfaction with the procedure, the aesthetic outcome of the donor site and return to work on a scale of 1–10 [42].	1–10	Questionnaire	Non-validated
	Questionnaire (Kotsouglani et al. 2018)	389	1 [58]	Patient's general and cosmetic (scarring, symmetry and naked/dressed appearance) satisfaction is assessed with Likert scales (score, 0–4) [58].	0–4 each max. 16	Questionnaire	Non-validated
	Questionnaire (Philandrianos et al. 2018)	47	1 [74]	Donor site and recipient site are evaluated, questions regarding functional outcome (pain, loss of strength, diminution of movement, footwear are answered with 'yes' or 'no' answer). Aesthetic outcome was rated with an numeric score of 0–10, additionally circumference difference between legs is measured.		Questionnaire	Non-validated
CROM/ PROM	Questionnaire (Potoschnig et al. 2013)	9	1 [11]	Evaluation of demographic and socioeconomic status, postoperative complications, including pain, swelling, intolerance of weather variation and limitation by working or in private life.	NA	Questionnaire	Non-validated
	The Flap Outcome Questionnaire (FOQ)	40	1 [20]	A 11-item questionnaire assessing functional ability, daily living, symptom control, aesthetic appeal, overall flap rating and quality of life.		Questionnaire	Non-validated
	Johner–Wruhs evaluation criteria	51	1 [15]	Criteria include: bony nonunion, osteomyelitis and amputation; neurovascular disturbances; deformity; pain; gait and daily activities [176].	Poor/excellent	Questionnaire	Non-validated
	Questionnaire (Ehrl et al. 2019)	25	1 [36]	The questionnaire inquiries about wound healing complications, shoe provision, satisfaction with the treatment and pain scores according to the Numerical Rating Scale at rest and during activity. Objectively, the range of motion of the ankle, Thompson (manual compression of the triceps surae muscle; passive dorsal extension in the ankle is a positive result),	None	Questionnaire, monofilament, tuning fork	Non-validated

(continued)

Table 3. Continued.

Domain	Outcome measure	Population	Studies <i>n</i> (ref)	Brief description of outcome measure	Range of scale	Requirements	Validation
	Questionnaire (Lee et al. 2012)	24	1 [61]	monofilament and tuning fork (128 Hz) tests are performed. The Vancouver Scar Scale was also included.	0–4	Questionnaire	Non-validated
	Questionnaire (Sapino et al. 2019)	9	1 [105]	Functional and cosmetic outcomes are assessed by the physician and patient. Walking in a straight line, walk up 12 steps and put on socks and shoes on [61].	0–20	Questionnaire	Non-validated
	Questionnaire (Buono et al. 2018)	24	1 [23]	General appearance, shape, color and texture are evaluated on a combined numerical scale performed by both the patient and the clinician.		Questionnaire	Non-validated
	The American Orthopedic Foot and Ankle Society Scoring System (AOFAS)	64	5 [30,40,49,52,55]	Tissue thickness, texture and aesthetic appearance (e.g. relief, color match, symmetry with healthy side) are assessed by patient and clinician. The AOFAS includes 4 different scores, each related to a specified anatomic region (1) the ankle/hindfoot, (2) the midfoot, (3) the hallux metatarsophalangeal/interphalangeal and (4) the metatarsophalangeal/interphalangeal region. Patient-reported questions about pain, activity, functional limitations and footwear, and examiner-reported data about alignment, gait and motion are included within 3 subscales [177].	0–100	Questionnaire	VFOI

AOFAS: The American Orthopedic Foot and Ankle Society Scoring System; BIQLI: Body Image Quality of Life Inventory; ClinROM: clinician-reported outcome measures; CPG: Chronic Pain Grade Scale; EEI: Energy Expenditure Index; EQ-VAS: EQ Visual Analogue Scale; FADI: Foot and Ankle Disability Index; FASS: Freiburg ankle scoring system; FAOS: Foot and Ankle Outcome Score; FFI: Foot Function Index; FIT: Frequency Intensity Time Index; FOQ: Flap Outcome Questionnaire; FS: Flap Stability; HMS: Hamlyn Mobility Score; KSS: The Knee Society Score; LEFS: Lower Extremity Functional Scale; METS: metabolic equivalents; MFS: Maryland Foot Score; NRS: Numerical Rating Scale; ODI: The back-specific Oswestry disability index; OMA: Olerud-Molander Ankle score; PHQ: the Patient Health Questionnaire; PROM: patient-reported outcome measure; ROM: Range of motion; SF-12: The 12-Item Short-Form Health Survey; SF-36: The 36-Item Short-Form Health Survey; SMFA: The Short Musculoskeletal Function Assessment; SIP: Sickness Impact Profile; SWMT: Semmes-Weinstein Monofilament Test; s1PS: Static One-Point Test; s2PD: Static Two-Point Discrimination; TAM: Total Active Motion; TESS: Toronto Extremity Salvage Score; VFOI: Validated For Other Intentions; VAS: Visual Analogue Scale; WOMAC: The Western Ontario and MacMaster Universities Osteoarthritis Index; 6MWT: 6 min walking test; 10MWT: 10 min walking test; 1 PM: Moving One-Point Test.

reconstruction exists regarding which outcome measurement should be used or how the outcome measurement should be assessed and analyzed exactly [126]. To optimize surgical treatment and rehabilitation in extremity reconstruction it is crucial to record and evaluate standardized outcomes. The identification of the relevant domains should then become the basis for the establishment of outcomes registries.

Our systematic review only evaluated studies within the last 10 years. This time interval was found to be representative of extremity reconstruction in its current form. Additionally, older studies would have been unlikely to use PROMs but it is possible that relevant outcome measures, that might be considered less 'popular' these days could have been missed using this time interval.

Also, some of the excluded papers (small series, non-structured outcome) might have analyzed interesting aspects, relevant to patients and clinicians, but in a way that prevents comparison. This study combines data from a wide range of lower extremity defects and reconstructions and lists the outcome measures used overall. Indeed for clinical application sub-analysis of certain groups might be more intuitive for analysis rather than as a whole. This need however could not be satisfactorily addressed due to the heterogeneous nature of most publications assessed.

Conclusion

A big number of different outcome measurements is currently used in lower extremity reconstruction and while there are many different measurements, there is no validation study exploring the needs of the patients. We, therefore, advocate for international action to address this shortcoming. The literature shows that, unlike in other fields of medicine, no consensus has been reached on what to measure and how. We need to analysis the relevant domains and need to put them through validation studies. There is a need for registries that will allow for studies with significant cohort sizes. This has to be done in order to improve results and put the needs of our patients first.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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