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ORIGINAL ARTICLE
Reconstructive

Patient-reported Outcome Measures following Traumatic Lower Extremity Amputation: A Systematic Review and Meta-analysis

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Background: Outcomes after traumatic major lower extremity amputation (MLEA) have focused on surgical complications, despite the life-altering impact on patients. With advances in the surgical management of MLEA, a heightened need for consistent reporting of patient-centered outcomes (PCO) remains. This meta-analysis assesses articles for the prevalence and methods of PCO reporting among traumatic MLEA studies.

Methods: An electronic database search was completed using Ovid MEDLINE for studies published between 2000 and 2020. Studies were included that reported any outcome of traumatic MLEA. Weighted means of outcomes were calculated when data were available. The prevalence of PCO was assessed in the categories of physical function, quality of life (QOL), psychosocial, and pain. Trends in PCO reporting were analyzed using Pearson's chi-squared test and analysis of variance when appropriate.

Results: In total, 7001 studies were screened, yielding 156 articles for inclusion. PCO were evaluated in 94 (60.3%) studies; 83 (53.2%) reported physical function and mobility outcomes, 33 (21.2%) reported QOL and satisfaction measures, 38 (24.4%) reported psychosocial data, and 43 (27.6%) reported pain outcomes. There was no change in prevalence of PCO reporting when comparing 5-year intervals between 2000 and 2020 ($P = 0.557$).

Conclusions: Optimization of function and QOL following traumatic MLEA has become a cornerstone of surgical success; however, only 60% of studies report PCO, with no trend over the last two decades suggesting improvement. As healthcare progresses toward patient-centered care, this inconsistent means of reporting PCO calls for improved inclusion and standardization of instruments to assess function, QOL, and other patient-focused measures. *(Plast Reconstr Surg Glob Open 2021;9:e3920; doi: 10.1097/GOX.0000000000003920; Published online 11 November 2021.)*

INTRODUCTION

Major lower extremity amputation (MLEA) is often the best option for risk modification and overall health outcomes following severe trauma.[1] Although many advances have been made in the surgical management of MLEA following trauma, most research in this field focuses on medical outcomes, such as surgical complications, re-amputation rates, and resulting health issues.[2,3] Recently, there has been a push across all fields of medicine to incorporate patient-centered outcomes (PCO) into clinical research to augment medical decision making. PCO are defined as outcomes important to patient decision making, often describing functional status, satisfaction, and quality of life (QOL).[4,5] In 2010, the Patient-Centered Outcome Research Institute was approved by congress as part of the Affordable Care Act to fund research for increased patient-centered endpoints.[6]

Despite this emphasis on improving patient-centered care, there is insufficient research that evaluates PCO after MLEA, including functional capabilities, QOL, mental health status, and chronic pain.[6] Further, the PCO research that does exist lacks cohesiveness and

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Received for publication September 10, 2021; accepted September 10, 2021.

Presented at ASPS Plastic Surgery The Meeting, Atlanta, Georgia, Oct 29–Nov 1, 2021

DOI: 10.1097/GOX.0000000000003920

Disclosure: *The authors have no financial interest in relation to the content of this article.*

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standardization, with few measures specific to lower extremity trauma and amputation.[7,8] Validated patient-reported outcome measures (PROMs) that assess multiple aspects of treatment outcomes, such as the Short Form Survey-36 and the Sickness Impact Profile (SIP), are frequently used in this patient population[9,10]; however, QOL PROM scales specific to patients after traumatic MLEA are rare, prohibiting assessment of the success of treatment options to meet specific needs, values, and expectations of the traumatic amputation patient.[11]

Standardized collection and reporting of patient-centered functional and QOL outcomes following amputation is critical for advancing surgical techniques, comprehensively assessing outcomes, and improving patient expectations and joint medical decision making.[6,11,12] To better understand the prevalence and methods of PCO reported following traumatic MLEA, this study performs a systematic review of articles published between 2000 and 2020 and applies a meta-analysis to assess trends. Improved understanding of PCO research in this population will contribute to the overarching objective in healthcare to incorporate patient-centered data into shared decision making, accounting for patient values and goals and improving outcomes.

METHODS

Search Strategy

A systematic review and meta-analysis were performed, adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines, with the goal of identifying all peer-reviewed studies of traumatic-origin MLEA published between January 2000 and November 2020. An electronic database search using Ovid MEDLINE was performed to identify relevant articles. Medical Subject Headings terms and keywords included in this search we re limb salvage, leg injuries, lower extremity trauma, wounds and injuries, trauma, traumatic; traumatic amputation, major lower extremity amputation, below knee amputation, through knee amputation, above knee amputation, transtibial amputation, transfemoral amputation, lower extremity amputation.

Study Identification

Abstracts and titles from this search were initially screened independently for relevance by two reviewers (ART, WR). If the decision to include an article was not unanimous, a third reviewer (KGK) was consulted until consensus was determined. Included studies then underwent full-text review. Studies that met all inclusion criteria were included in the review and meta-analysis.

Articles were included in this study that reported data on lower extremity amputations if more than 80% of the amputations were "major," defined as above knee- (AKA), below-knee (BKA), or through-knee (TKA) amputation. Similarly, more than 80% of amputations in each study had traumatic etiology; studies were excluded if they reported more than 20% oncologic resections or chronic wound-associated amputations, or if they included upper extremity amputations. Studies could report any outcome, including complication rates, biomechanical data, QOL measures, or functional results. Case reports describing two or more patients were included if they met other inclusion criteria. All articles in the final analysis were in English language and published in peer-reviewed journals.

Study Quality Assessment

The Newcastle-Ottawa Scale for cohort studies was applied to assess the quality and possible biases of each article by a single reviewer (ART). The "most important" factor for assessment of comparability between groups in our review was the level of amputation. An additional star for comparability was awarded to any study design that controlled for at least one confounding factor.

Data Extraction and Statistical Analysis

Article information, including study design, publication year, military population, amputation level and laterality, and cohort size, was collected. All outcomes were recorded, and when data were available, weighted means and SDs were calculated. The inclusion of PCO was analyzed qualitatively and quantitatively by four categories: (1) physical function and mobility, (2) QOL and satisfaction, (3) psychosocial, and (4) pain outcomes. Temporal trends in the reporting of PCO were assessed. Univariate analyses with Pearson's chi-squared test compared the inclusion of PCO between study categories of patient populations, amputation levels, and amputation laterality. Bivariate analysis with one-way analysis of variance compared PCO by studies in 5-year time intervals. Statistical analysis was performed using STATA, v.15 (StataCorp, College Station, Tex.) with significance defined as a P value less than 0.05.

RESULTS

The literature search initially yielded 7001 articles. After the title and abstract screen, 370 articles remained to undergo full-text review, with 156 articles meeting inclusion criteria for data synthesis (Fig. 1). Assessment of study quality using the Newcastle-Ottawa Scale found all studies met a minimum score of six out of nine stars, designating study quality as "good" or higher as defined by the Agency for Healthcare Research and Quality standards.

Among all 156 studies included in the final review, data from 12,486 patients who underwent MLEA were collected. Study characteristics are outlined in Supplemental Digital Content 1. (**See table, Supplemental Digital Content 1,** which displays the studies included. **http://links.lww.com/PRSGO/B832**.) An estimated 140 studies (89.7%) were retrospective, and the average cohort size was 80 patients. In total, 123 studies reported only unilateral amputations, six studies reported bilateral amputations, and 27 studies reported data on both. Most studies reported data on only BKA or AKA patients, 62 and 26 studies respectively; the remaining 68 reported a mix of data from individuals who underwent BKA, TKA, or AKA. Further, 58 articles analyzed military patient populations, whereas the rest focused on civilian amputees.

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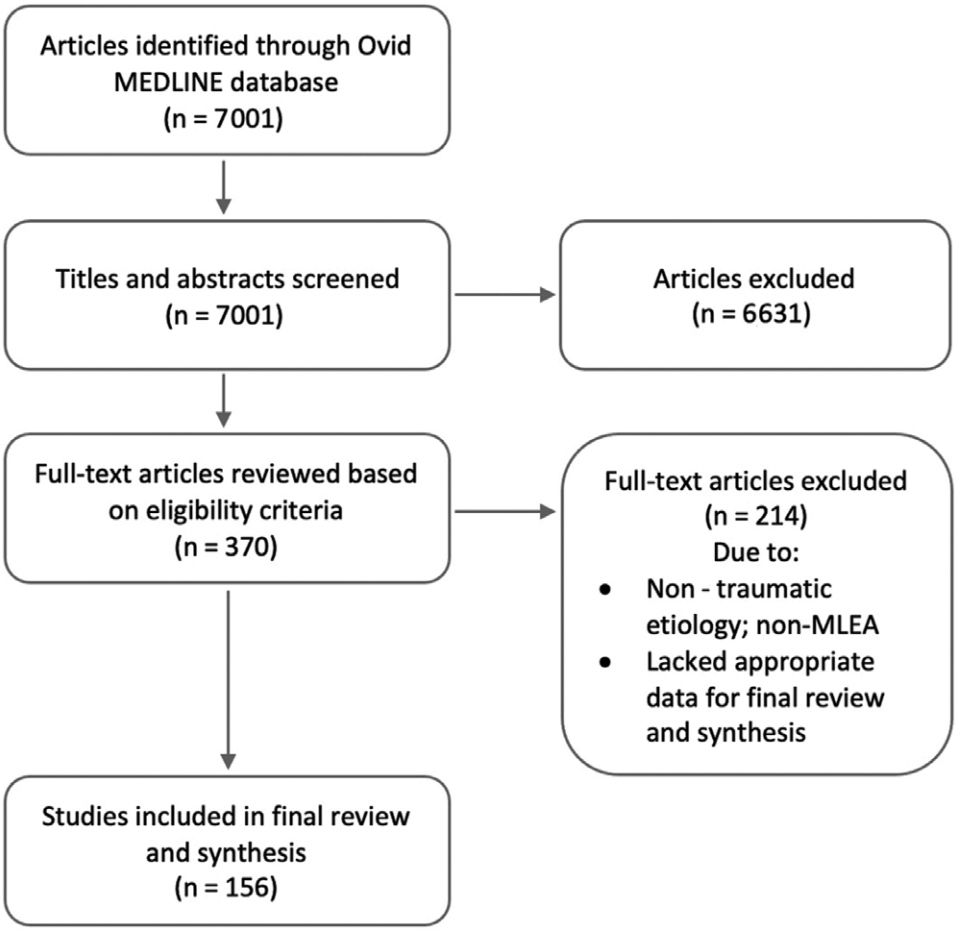

Fig. 1. Flowchart demonstrating the search strategy and article selection process for inclusion in systematic review and meta-analysis according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Analysis of all outcomes in the included articles revealed that 129 (82.7%) studies reported clinical-centered outcomes, including surgical outcomes, complication rates, long-term health outcomes, and biomechanical assessments. In contrast, only 94 (60.3%) studies report PCO. Figure 2 displays the categories of PCO reported among articles; 83 (53.2%) report physical function and mobility outcomes, 33 (21.2%) report QOL and satisfaction measures, 38 (24.4%) report psychosocial effects, and 43 (27.6%) report pain outcomes.

Clinical-centered Outcomes

Of the 129 studies that reported clinical-centered outcomes, 58 (37.2%) reported biomechanical assessments, including kinematic and temporospatial measures, 44 (28.2%) described surgical outcomes or complication rates, 36 (23.1%) reported long-term health outcomes, 33 (21.2%) reported physiologic and metabolic changes, nine (5.8%) reported neurological changes, and only three (1.9%) reported mortality rates after amputation.

The most commonly reported complication after major amputation was infection or abscess by 23 studies, with a weighted rate of 24.4% (Table 1). Other frequently described complication rates were neuroma (20.0%), heterotopic ossification (16.4%), and ulceration (8.7%) (Table 1). The average reoperation rate after amputation was 48.8%, as reported by 14 studies. An estimated 58 studies described kinematic and temporospatial assessments of amputees, often with prosthesis use. These metrics included gait speed, step length, muscle forces, and joint angles. The long-term health outcomes described by 33 studies included chronic back pain and arthritis that developed after amputation.

PCO: Physical Function and Mobility

A total of 83 studies reported outcomes related to physical function and mobility; 38 (24.4%) described measures of functional status, 57 (36.5%) reported ambulatory rates, and 30 (19.2%) described prosthesis use (Fig. 2).

Functional status reported was measured through ability to participate in sports, activity and functional scales, and activities of daily living (ADLs) (Table 2). Sports involvement was described by three studies with an average rate of 48.62% of amputees.[13–15] The Day Activity Scale was used by three studies, with an average score of 29.98 corresponding to high physical activity level.[16–18] The Medicare Functional Classification Level, used in four studies, classified most amputees at a K3 level

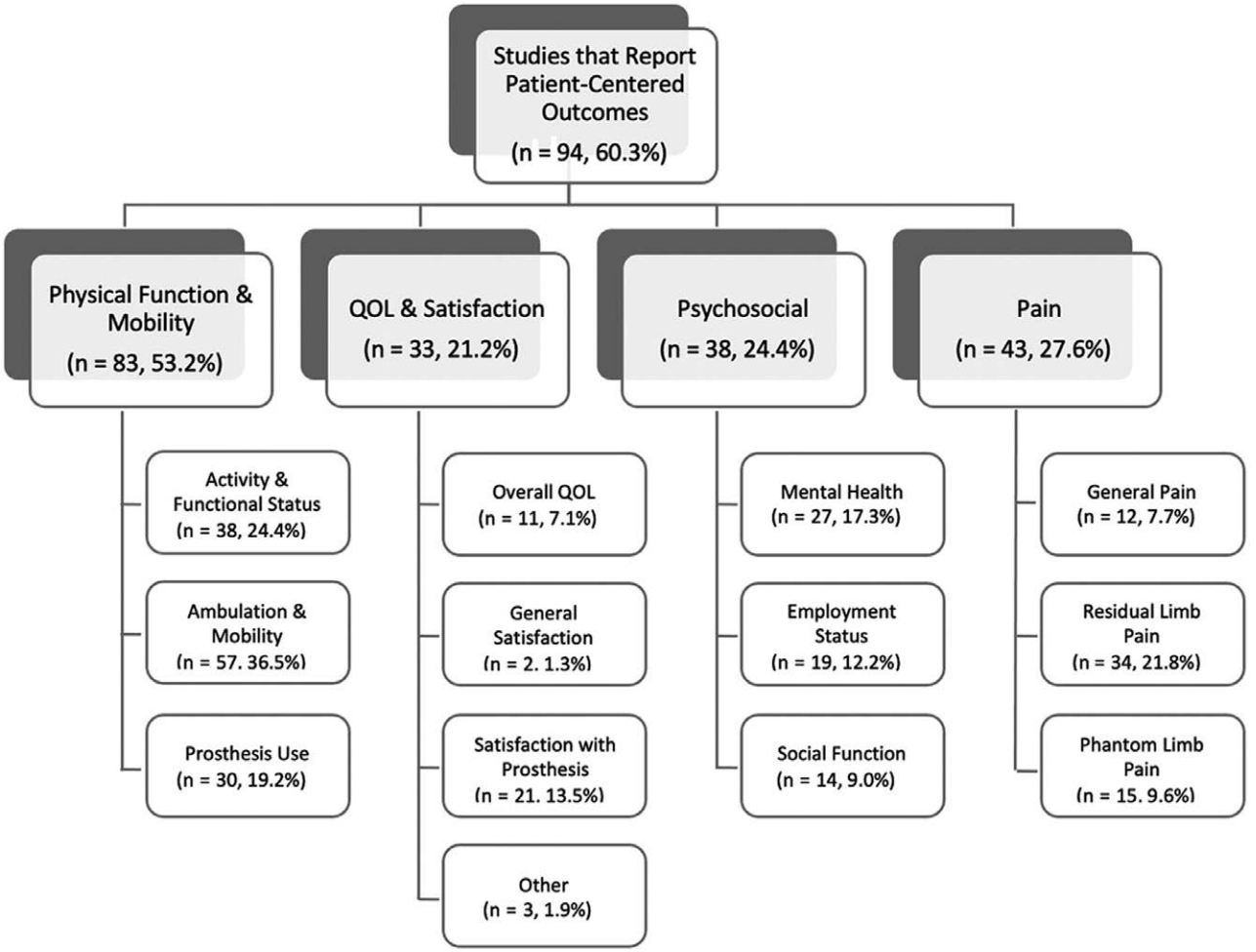

Fig. 2. Flowchart of studies that report PCO, divided into categories and subcategories of physical function and mobility, QOL and satisfaction, psychosocial, and pain.

indicating unlimited community ambulation with ability to use a prosthesis.[14,19–21] ADLs, reported in two studies, displayed an average of 40.4% of amputees able to independently complete basic ADLs.[22,23] Likewise, various subscores of multidimensional scales, including the 36-Item Short Form Survey (SF-36), Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29), and SIP, were used by 20 studies to describe functional status.

Table 1. Amputation Complication Rates

Complication	No. Studies (No. Patients)	Weighted Complication Rate
Infection or abscess	23 (1883)	24.4%
Neuroma	16 (1475)	20.0%
Heterotopic ossification	11 (1084)	16.4%
Ulceration	11 (1239)	8.7%
Stump skin issues	7 (397)	26.2%
Delayed healing	4 (171)	39.2%
Flap necrosis	4 (69)	4.3%
Flap loss or failure	4 (55)	10.9%
Osteomyelitis	2 (57)	5.3%
Bleeding or hemorrhage	2 (54)	5.6%
Skin graft loss	1 (6)	16.7%

Ambulation and mobility are described in Table 2. An estimated 20 studies reported ambulatory rate, with an average rate of 90.97%. The average time to ambulation was 3.68 months among 187 patients.[24,25] A general Ambulation Level was reported by two studies that scored patients from 1 to 7, corresponding to "cannot walk" and "high impact activities," respectively; 64.9% scored at or below a Level 4.[26,27] The Special Interest Group in Amputee Medicine Mobility Grade was also used by two studies, with over half of patients scoring a grade E or F corresponding to occasional walking aid use.[15,28] Other studies included the Harold Wood Stanmore Ambulation Assessment,[29,30] the Lower Extremity Functional Scale,[31] and the Ambulation Grade.[32] More than 20 articles included physical tests, such as the 6 Minute Walk Test and the Timed Up and Go, to measure mobility status.[9,33] Additional measures of ambulation and mobility status included running ability,[34,35] sit-to-stand transitions,[36] and falls or accidents during mobility.[13]

Prosthesis use was commonly reported as a means of assessing mobility (Table 2). Average daily prosthesis use, from 20 articles, was 12.24 hours/day. Eleven studies also described time from amputation to prosthesis use as an

Table 2. Physical Function and Mobility Outcomes

	No. Studies (No. Patients)	Weighted Outcome
Activity and functional status		
Physical activity level		
Sports participation	3 (399)	194 (48.62%)
Day Activity Scale (mean ± SD)	3 (27)	28.98 ± 2.86
Functional status		
Medicare Functional Classification Level		
K0	3 (363)	0 (0%)
K1	3 (363)	0 (0%)
K2	3 (363)	77 (21.21%)
K3	3 (363)	232 (63.91%)
K4	3 (363)	54 (14.88%)
Mean K sore (mean ± SD)	1 (17)	2.89 ± 0.93
ADLs, % independent	2 (256)	103 (40.38%)
Ambulation and mobility		
Ambulation assistance devices		
% Requiring assistive device	11 (803)	489 (60.90%)
Mobility & ambulatory scales		
Ambulation level		
Level 1-2 (cannot walk)	2 (57)	18 (31.58%)
Level 3 (household walker)	2 (57)	6 (10.53%)
Level 4 (community walker)	2 (57)	13 (22.81%)
Level 5 (can walk with varying speeds)	2 (57)	9 (15.79%)
Level 6 (low impact activities)	2 (57)	5 (8.77%)
Level 7 (high impact activities)	2 (57)	6 (10.53%)
Harold Wood Stanmore Ambulation Assessment		
Nonambulatory	2 (277)	3 (1.08%)
Household ambulatory	2 (277)	8 (2.89%)
Community ambulatory	2 (277)	263 (94.95%)
SIGAM Mobility Grade		
A (not using limb)	2 (137)	3 (2.19%)
B (transfers/short distances)	2 (137)	8 (5.84%)
C (walks indoor with aid)	2 (137)	17 (12.41%)
D (walks outdoors with aid)	2 (137)	37 (27.01%)
E (occasional walking aid use)	2 (137)	13 (9.49%)
F (walk anywhere without aid)	2 (137)	59 (43.07%)
Ambulation rate		
Ambulation rate	20 (1164)	1059 (90.97%)
Time to ambulation, mo (mean ± SD)	2 (187)	3.68 ± 0.73
Prosthesis use		
Daily prosthesis use, h/d (mean ± SD)	20 (1877)	12.24 ± 1.90
Time to prosthesis use, mo (mean ± SD)	11 (341)	4.23 ± 1.74

SIGAM, Special Interest Group in Amputee Medicine

average of 4.23 months. Patient prosthesis use was reported by two studies,[37,38] and Li et al used the Houghton Scale to assess patient perspective of their own prosthesis usage.[21]

PCO: QOL and Satisfaction

QOL and satisfaction after major amputation was investigated by 33 (21.2%) studies, with the majority of these articles reporting satisfaction with prosthesis (21 studies, 13.5%); 11 (7.1%) studies examined overall QOL, two (1.3%) reported general satisfaction, and three (1.9%) reported other measures of QOL and satisfaction (Fig. 2).

Various questionnaires and surveys were used to assess overall QOL (Table 3). The Questionnaire for Persons with a Transfemoral Amputation was used by three studies, with an average QOL score of 76.71 out of 100.[33,39] Two studies reported a QOL rating, and more than half of patients reported their QOL to be good, fair, or poor; only 42.5% reported their QOL to be excellent or very good.[26,27,40] QOL was also reported by studies in the SIP and EuroQol Questionnaire (EQ-5D).[10,41–45]

Satisfaction with prosthesis was the most commonly reported QOL or satisfaction metric (Table 3). Various

Table 3. QOL and Satisfaction Outcomes

	No. Studies (No. Patients)	Weighted Outcome
Overall QOL		
Questionnaire for Persons with a Transfemoral Amputation	2 (59)	76.71 ± 10.66
QOL rating		
Excellent or very good	3 (407)	173 (42.51%)
Good, fair, or poor	3 (407)	233 (57.49%)
Satisfaction with prosthesis		
Satisfaction score (0–10)	2 (593)	7.33 ± 0.55
Satisfaction rating		
Dissatisfied	8 (911)	88 (9.66%)
Neither satisfied nor dissatisfied	8 (911)	21 (2.31%)
Satisfied	8 (911)	788 (86.50%)

scales were used, including the Trinity Amputation and Prosthesis Experience Scales (TAPES) by three studies[9,21,46] and Prosthesis Evaluation Questionnaire (PEQ) by eight.[20,35,47–52] Average overall prosthesis satisfaction score was found to be 7.3 on a scale of 10.[19,40] Eight studies had patients rate their prosthesis satisfaction; 86.5% of patients reported that they were satisfied.[17,19,25,28–30,37,40,53,54]

General satisfaction was described by two studies in subscales of the PROMIS-29 and AAOS LLQ.[51,55] Additional QOL and satisfaction reports were in the forms of sexual satisfaction and satisfaction with body image. Em et al reported an overall satisfaction with sexual performance after amputation to be 5.6 out of 10.[56] Gozaydinoglu et al implemented the Amputee Body Image Scale, and Poljak-Guberina et al described overall satisfaction rates with cosmetic outcomes.[46,54]

PCO: Psychosocial

Psychological and social parameters were assessed by 38 (24.4%) articles; these outcomes included mental health (27 studies, 17.3%), employment status (19 articles, 12.2%), and social function (14 studies, 9.0%) (Fig. 2).

Mental health outcomes were analyzed by 29 studies (Table 4). Assorted scales and indices were used including the Beck Depression and Anxiety Indices,[9,56,57] EQ-5D,[44] Patient Health Questionnaire-9,[23] General Anxiety Disorder-7,[23] Short General Health Questionnaire-12 (GHQ-12),[28] and Symptom Checklist-90-Revised (Scl-90-R).[58] The average prevalence of depression and posttraumatic stress disorder among amputees was found to be 19.1% and 31.1%, respectively.[13,26,28,32,40,56,59–62]

Table 4. Psychosocial Outcomes

	No. Studies (No. Patients)	Weighted Outcome
Mental health		
Scales and indices		
Beck Depression Index	3 (181)	13.45 ± 7.55
Beck Anxiety Index	2 (131)	11.95 ± 5.40
Psychiatric disorders		
Depression	7 (1048)	200 (19.08%)
PTSD	9 (1212)	377 (31.11%)
Anxiety	2 (196)	26 (13.27%)
Substance use disorder	3 (552)	22 (3.99%)
Any diagnosis	4 (583)	261 (44.77%)
Employment status		
Employment rate	17 (2048)	1257 (61.38%)

PTSD, post-traumatic stress disorder.

Employment rate was reported by 17 studies, with an average of 61.4% of amputees returning to work (Table 4). Ebrahimzadeh et al reported whether amputees had to change their occupation,[62] and two studies reported whether patients returned to active military duty.[60,63] Adjustment and social function after major extremity amputation was reported by 14 articles, predominantly using social subscales of multidimensional surveys. In total, 10 studies used the SF-36,[9,10,13,35,51,56,64–67] one used the TAPES,[46] and four used the SIP.[10,42,43,68]

PCO: Pain

Less than one third of studies assessed pain in amputees (Fig. 2). A total of 12 (7.7%) studies reported general body pain, 34 (21.8%) reported residual limb pain, and 15 (9.6%) reported phantom limb pain (PLP) measures. General body pain scores were reported through sub-scales of the PROMIS-29 and SF-36 surveys by 12 studies.

Reports of RLP and PLP consisted of prevalence rates and intensity scores (Table 5). Based on data from 21 studies, 44.2% of amputees experienced RLP. The average intensity score of RLP was determined to be 3.27 out of 10. Likewise, 12 studies reported the prevalence of PLP to be 50.6%, and four of these articles reported an average intensity score of 5.13 out of 10.[21,57,64,69]

Patient-reported Outcome Measures

Multidimensional PROMs that assess numerous classifications of PCO were used by 27 articles (Table 6). Used most frequently, the SF-36 was implemented in 14 studies to assess outcomes within the Physical Component Scale (PCS) and the Mental Component Scale and eight sub-scores.[9] The average PCS score as reported by seven studies was 46.63 out of 100, where scores higher than 50 indicated better QOL.[10,33,35,56,66,70,71] The average Mental Component Scale score as reported by five studies was 47.92.[10,35,56,71,72] The average physical functioning sub-score was 60.45, social functioning sub-score was 78.36, and mental health sub-score was 65.84.[9,10,13,35,51,56,64,65,67]

Other frequently used PROMs included the PEQ, SIP, and TAPES (Table 6). The PEQ was used in eight studies to assess prosthesis function, mobility, psychosocial experiences, and general well-being (Table 6).[20,35,47–52] Overall usefulness of prosthesis was rated to be an average of 73.9 out of 100.[35,48–51] Mobility was rated an average score of 75.1, and overall well-being scored a mean of 83.1.[35,48–51] Four studies integrated the SIP in the domains of physical, psychosocial, and independence outcomes, where a score of 0 indicated no dysfunction and 100 indicated complete dysfunction.[10,41–43] Average physical and psychosocial domain scores were 11.65 and 8.84, respectively.[10,41–43] TAPES focused on psychosocial adaptation, activity, and prosthesis satisfaction in three studies.[9,21,46] Average psychosocial score was 58.0 on a scale of 5–75, activity restriction score was 16.2 on a scale of 12–36, and prosthetic satisfaction was 39.8 on a scale of 10–50.[9,21,46] Less commonly included PROMs were the PROMIS-29, AAOS LLQ, and EQ-5D measures (Table 6). The EQ-5D self-reported measures of mobility, self-care, pain, and mental health.[44,45]

Table 5. Pain Outcomes

	No. Studies (No. Patients)	Weighted Outcome
Residual limb pain		
RLP prevalence	21 (1615)	713 (44.15%)
Pain score (0–10)	17 (1144)	3.27 ± 1.37
PLP		
PLP prevalence	12 (1264)	639 (50.55%)
Pain score (0–10)	4 (101)	5.13 ± 1.33

Table 6. Patient-reported Outcome Measures

PROM Scale	No. Studies (No. Patients)	Weighted Score
SF-36		
General health	9 (623)	64.53 ± 7.27
Physical functioning	9 (623)	60.45 ± 10.19
Role limitations due to physical function	10 (701)	50.09 ± 9.91
Social functioning	9 (623)	78.36 ± 4.31
Vitality/energy	9 (623)	62.11 ± 6.59
Bodily pain	11 (739)	63.10 ± 8.93
Mental health	9 (623)	65.84 ± 8.08
Role limitations due to emotional health	9 (623)	60.27 ± 11.66
PCS	7 (332)	46.63 ± 5.63
Mental Component Scale	5 (196)	47.92 ± 6.29
Total score	1 (271)	59.00 ± 5.00
Sickness Impact Profile		
Overall score	4 (177)	13.20 ± 4.81
Physical domain	4 (177)	11.65 ± 5.01
Body care and movement	2 (58)	11.38 ± 6.30
Ambulation	2 (58)	33.78 ± 11.23
Mobility	2 (58)	13.72 ± 6.78
Sleep and rest	2 (58)	22.28 ± 10.16
Psychosocial domain	4 (177)	8.84 ± 3.85
Emotional behavior	2 (58)	10.27 ± 6.20
Social interaction	2 (58)	12.17 ± 7.64
Alertness behavior	2 (58)	8.43 ± 6.88
Communication	2 (58)	1.77 ± 1.79
Independent dimension		
Household management	2 (58)	21.25 ± 8.77
Work	2 (58)	50.88 ± 15.96
Eating	2 (58)	2.35 ± 2.28
PEQ		
Prosthesis function		
Usefulness	5 (179)	73.89 ± 3.20
Residual limb health	4 (168)	61.30 ± 25.06
Appearance	3 (101)	73.77 ± 5.23
Sounds	4 (112)	61.33 ± 5.76
Mobility		
Ambulation	5 (179)	75.07 ± 6.45
Psychosocial experience		
Perceived responses	4 (112)	90.10 ± 2.86
Social burden	2 (73)	83.42 ± 7.05
Frustration	5 (179)	70.67 ± 8.26
Well-being	5 (179)	83.09 ± 6.20
TAPES		
Psychosocial adjustment	3 (107)	58.00 ± 3.28
Activity restriction	3 (107)	16.22 ± 3.41
Prosthetic satisfaction	3 (107)	39.82 ± 3.71
PROMIS-29		
Physical function	1 (604)	44.53
Satisfaction with social roles	1 (604)	49.9
Pain interference	1 (604)	54.1
Depression	1 (604)	48.4
Fatigue	1 (604)	47.5
Sleep disturbance	1 (604)	49.1
Anxiety	1 (604)	48.6
American Academy of Orthopaedic Surgeons Lower Limb Questionnaire Score	1 (28)	88.25 ± 1.62

Trends in Reporting PCO

Univariate statistical analysis compared the prevalence of PCO reporting based on study characteristics (Table 7). Studies that included data from military amputee populations reported PCO at a higher frequency than studies on nonmilitary amputees, trending toward significance (70.7% versus 55.1%, $P = 0.054$). There was no difference in the frequency of PCO reporting between studies that reported outcomes of all BKA patients or all AKA patients (50.0% versus 59.7%, $P = 0.403$). Studies that reported data on all bilateral amputees reported PCO at a significantly higher rate of 100.0% when compared with only 56.9% in studies that reported all unilateral amputees ($P = 0.036$).

To compare the reporting of PCO over time, bivariate analysis was performed between 5-year time intervals of articles published between 2000 and 2020 (Table 8). The frequency of studies that reported PCO during each 5-year interval ranged between 59.2% and 66.7%; no significant difference was found between each time interval ($P = 0.557$). Figure 3 depicts patterns in the overall reporting of PCO and among subcategories of PCO between 2000 and 2020. There was no discernible trend in changes of PCO reporting during this 20-year time period.

DISCUSSION

This study demonstrates a significant paucity in research between clinical-centered outcomes and PCO; in the last two decades only 60% of articles that report outcomes of traumatic MLEA include any form of PCO in their analysis. This gap is widened further when taking into account specific patient-reported outcomes, such as functional capabilities, QOL, and psychosocial measures, which are only reported in 53%, 21%, and 24% of articles, respectively. Although previous reviews have explored PCO reporting after MLEA, this study is the first to highlight the prevalence and details of the discrepancy in PCO documentation in this patient population.[73]

The extensive variety and inconsistency of approaches to measure PCO revealed by this meta-analysis made it difficult to compare traumatic amputee populations by etiology. More than 45 unique measurements, ratings, and scales were implemented by the included studies to assess physical function and mobility of amputees alone. Nearly 40 other measurements were used to reflect the impact of traumatic amputations on QOL, psychosocial, and pain outcomes. Despite the useful data provided by each PCO metric, comparing surgical strategies or recovery methods using these disparate measurements is a challenge. Further, we revealed that despite global pushes in healthcare research to incorporate and emphasize PROMs, there has been no trend in PCO inclusion in the last 20 years to suggest improvement. Though many factors may contribute to this finding, the lack of a standardized tool to measure PCO among traumatic amputees likely plays a significant role.

Table 7. PCO by Categories

	Total Arrticles	Studies with PCO	*P*
Patient population			
Military	58	41 (70.69%)	0.054
Nonmilitary	98	54 (55.10%)	
Amputation level			
All BKA	26	13 (50.00%)	0.403
All AKA	62	37 (59.68%)	
Laterality			
All unilateral	123	70 (56.91%)	**0.036**
All bilateral	6	6 (100.00%)	

Bold indicates significance level. Significance is defined as $p > 0.05$.

Table 8. PCO by 5-year Intervals

5-Year Interval	No. Studies	Studies with PCO	*P*
2000–2005	21	14 (66.67%)	0.557
2006–2010	36	22 (61.11%)	
2011–2015	50	30 (60.00%)	
2016–2020	49	29 (59.18%)	

The traumatic amputee population has higher rates of anxiety and depression than the general population, warranting a closer assessment of overall well-being and daily function.[74] Studies have shown that patient satisfaction after lower extremity amputation is highly correlated with physical function in combination with psychological distress factors, such as depression and ability to return to work.[75] O'Toole et al found that these factors were more predictive of satisfaction than injury severity or specific treatment itself.[75] Unfortunately, postamputation care does not often focus on psychosocial or QOL interventions. Archer et al found that 85% of individuals after traumatic lower extremity injury reported an unmet need for at least one service, including vocational and mental health services.[76] Engaging these highly comorbid patients with patient-centered surgical and recovery plans specifically adapted for traumatic amputees may address these health disparities and care limitations, leading to improved long-term outcomes.[77,78]

A standardized set of PROMs individualized to the needs of the traumatic MLEA population is critical for clinical and patient-centered improvement. Presently, no traumatic amputee-specific QOL metric has been used that allows us to analyze the experiences distinct to this patient population.[11] Many functional scales and instruments used in these studies are not designed for the traumatic amputation population and thus may not elucidate small changes in outcomes reliably.[79] Measurements overly specific to patients, such as military or amputation level-specific metrics, included in some articles lacks generalizability to larger populations of traumatic amputees.[78] On the contrary, the use of standardized scales and PROMs intended for the general population such as the SF-36, or nontraumatic amputees such as the PEQ is not tailored to the specific needs and values of this patient population.[10,47] Although some provide some reliable data, such as associations of higher phantom pain severity with SF-36 scores for physical function and PCS, others may not reflect true differences from baseline function and QOL.[79,80]

Multiple scales specific to lower extremity surgical outcomes exist, such as the Lower Extremity Functional Scale and the Locomotor Capabilities Index.[7,79,81] Instruments specific to traumatic injury, such as the Toronto Extremity

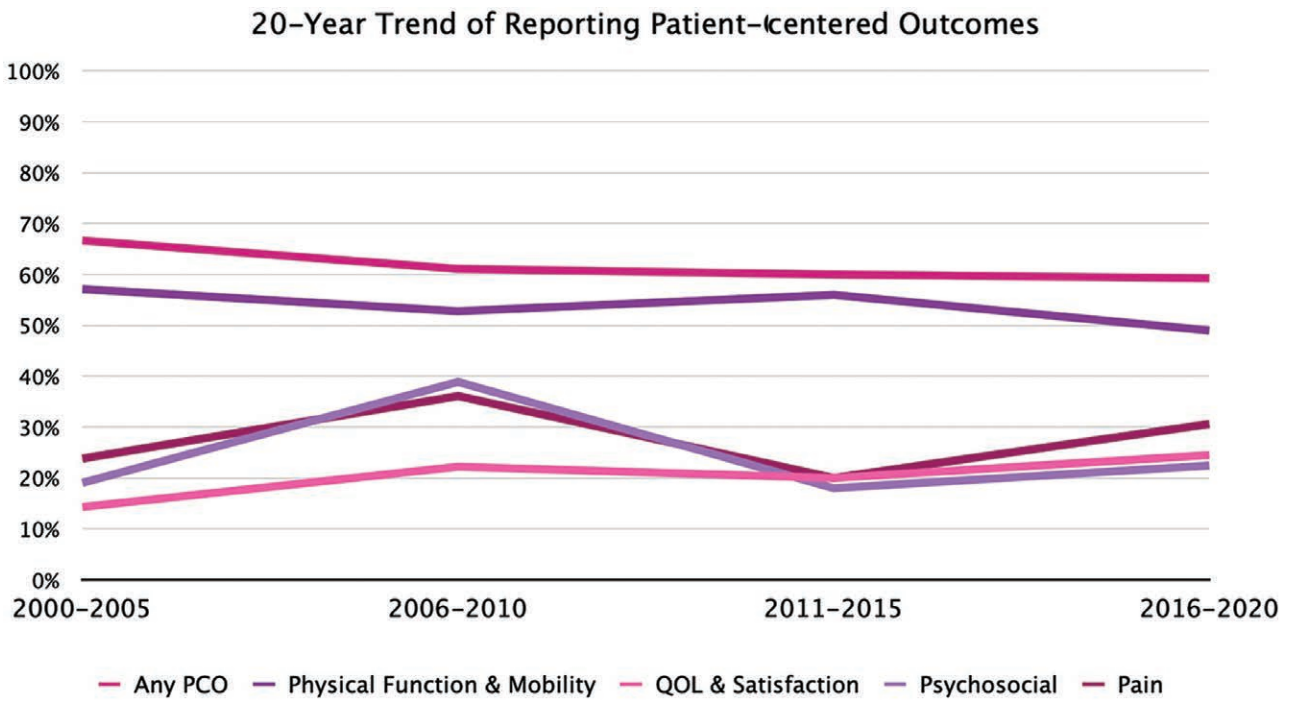

Fig. 3. Graph of trends in reporting PCO between 2000 and 2020 in 5-year intervals.

Salvage Score,[79] and to lower extremity amputations, such as the TAPES and the Prosthetic Mobility Questionnaire, have also been developed.[9,82] However, instruments targeting the unique intersect of traumatic MLEA populations have yet to be implemented. Our meta-analysis calls for the creation of more PCO instruments, such as the LIMB-Q currently under development, customized to both lower extremity and traumatic amputees to guide management.

This meta-analysis and systematic review is limited in several ways. Many articles included for analysis were retrospective in nature, which has inherent biases. This study investigated the general reporting rates of PCOs; the individual significance of specific variables regarding patient well-being and patient-defined amputation success was not determined due to the heterogeneity of patient populations and means of data reporting. The subjective nature of PCO data is a large limiting factor in its analysis, considering the personalized responses and long-term follow up of subjects. Further research will be necessary into the relative significance of each PCO on amputation and patient success, advantageous mechanism of collecting and reporting this data, and suitable methods to include PCO in medical decision-making for traumatic amputations.

CONCLUSIONS

Despite an emphasis on patient QOL and functional capabilities as important factors to assess after traumatic lower extremity amputation, only 60% of studies in the past two decades report PCO, with no trends in increasing prevalence over time. The inconsistency of measures and scales used to examine PCO precludes providers and patients from having a comprehensive understanding of outcomes after MLEA. As healthcare continues to progress toward patient-centered care, our study calls for improved inclusion and standardization of measures to assess functional capabilities, QOL, satisfaction, and other patient-valued measures among traumatic lower extremity amputees.

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REFERENCES

1. Pinzur MS. Outcomes-oriented amputation surgery. *Plast Reconstr Surg.* 2011;127 (Suppl 1):241S–247S.
2. Tevis SE, Kennedy GD. Postoperative complications and implications on patient-centered outcomes. *J Surg Res.* 2013;181:106–113.
3. Sheehan TP, Gondo GC. Impact of limb loss in the United States. *Phys Med Rehabil Clin N Am.* 2014;25:9–28.
4. Werner RM, Greenfield S, Fung C, et al. Measuring quality of care in patients with multiple clinical conditions: summary of a conference conducted by the Society of General Internal Medicine. *J Gen Intern Med.* 2007;22:1206–1211.
5. FDA Guidance for Industry. Patient-reported outcome measures: use in medical product development to support labeling claims. December 2009. Available at https://www.fda.gov/media/77832/download. 2009. Accessed April 6, 2021.
6. Washington AE, Lipstein SH. The Patient-Centered Outcomes Research Institute–promoting better information, decisions, and health. *N Engl J Med.* 2011;365:e31.
7. Mundy LR, Grier AJ, Weissler EH, et al. Patient-reported outcome instruments in lower extremity trauma: a systematic review of the literature. *Plast Reconstr Surg Glob Open.* 2019;7:e2218.

8. Kim KG, Tirrell AR, Dekker PK, et al. The need to improve patient-centered outcome reporting following lower extremity flap reconstruction: a systematic review and meta-analysis. *J Reconstr Microsurg.* 2021;37:764-773.
9. Atiç R, Aydın A. Comparison of the demographic and clinical characteristics, functional status and quality of life of lower extremity amputees to identify the reason for undergoing amputation. *J Back Musculoskelet Rehabil.* 2018;31:973–979.
10. van der Merwe L, Birkholtz F, Tetsworth K, et al. Functional and psychological outcomes of delayed lower limb amputation following failed lower limb reconstruction. *Injury.* 2016;47:1756–1760.
11. Bernatchez J, Mayo A, Kayssi A. The epidemiology of lower extremity amputations, strategies for amputation prevention, and the importance of patient-centered care. *Semin Vasc Surg.* 2021;34:54–58.
12. Ho AL, Klassen AF, Cano S, et al. Optimizing patient-centered care in breast reconstruction: the importance of preoperative information and patient-physician communication. *Plast Reconstr Surg.* 2013;132:212e–220e.
13. Ebrahimzadeh MH, Moradi A, Khorasani MR, et al. Long-term clinical outcomes of war-related bilateral lower extremities amputations. *Injury.* 2015;46:275–281.
14. Kesikburun S, Köroğlu Ö, Yaşar E, et al. Comparison of intact knee cartilage thickness in patients with traumatic lower extremity amputation and nonimpaired individuals. *Am J Phys Med Rehabil.* 2015;94:602–608.
15. Struyf PA, van Heugten CM, Hitters MW, et al. The prevalence of osteoarthritis of the intact hip and knee among traumatic leg amputees. *Arch Phys Med Rehabil.* 2009;90:440–446.
16. Lin-Chan SJ, Bilodeau M, Yack HJ, et al. The force-driven harmonic oscillator model for energy-efficient locomotion in individuals with transtibial amputation. *Hum Mov Sci.* 2004;22:611–630.
17. Molina-Rueda F, Molero-Sánchez A, Alguacil-Diego IM, et al. Weight symmetry and latency scores for unexpected surface perturbations in subjects with traumatic and vascular unilateral transtibial amputation. *PM R.* 2016;8:235–240.
18. Toumi A, Smart R, Elie D, et al. Contribution of Achilles tendon mechanical properties to torque steadiness in persons with transfemoral amputation. *Prosthet Orthot Int.* 2021;45:170–177.
19. Ali S, Abu Osman NA, Naqshbandi MM, et al. Qualitative study of prosthetic suspension systems on transtibial amputees' satisfaction and perceived problems with their prosthetic devices. *Arch Phys Med Rehabil.* 2012;93:1919–1923.
20. Gholizadeh H, Abu Osman NA, Eshraghi A, et al. Satisfaction and problems experienced with transfemoral suspension systems: a comparison between common suction socket and seal-in liner. *Arch Phys Med Rehabil.* 2013;94:1584–1589.
21. Li WS, Chan SY, Chau WW, et al. Mobility, prosthesis use and health-related quality of life of bilateral lower limb amputees from the 2008 Sichuan earthquake. *Prosthet Orthot Int.* 2019;43:104–111.
22. Devan H, Tumilty S, Smith C. Physical activity and lower-back pain in persons with traumatic transfemoral amputation: a national cross-sectional survey. *J Rehabil Res Dev.* 2012;49:1457–1466.
23. Ladlow P, Phillip R, Coppack R, et al. Influence of immediate and delayed lower-limb amputation compared with lower-limb salvage on functional and mental health outcomes post-rehabilitation in the U.K. military. *J Bone Joint Surg Am.* 2016;98:1996–2005.
24. Flint JH, Wade AM, Stocker DJ, et al. Bone mineral density loss after combat-related lower extremity amputation. *J Orthop Trauma.* 2014;28:238–244.
25. Ostojić L, Ostojić Z, Rupcić E, et al. Intermediate rehabilitation outcome in below-knee amputations: descriptive study comparing war-related with other causes of amputation. *Croat Med J.* 2001;42:535–538.
26. Dougherty PJ, McFarland LV, Smith DG, et al. Combat-incurred bilateral transfemoral limb loss: a comparison of the Vietnam War to the wars in Afghanistan and Iraq. *J Trauma Acute Care Surg.* 2012;73:1590–1595.
27. Dougherty PJ, McFarland LV, Smith DG, et al. Bilateral transfemoral/transtibial amputations due to battle injuries: a comparison of Vietnam veterans with Iraq and Afghanistan servicemembers. *Clin Orthop Relat Res.* 2014;472:3010–3016.
28. Graham L, Parke RC, Paterson MC, et al. A study of the physical rehabilitation and psychological state of patients who sustained limb loss as a result of terrorist activity in Northern Ireland 1969–2003. *Disabil Rehabil.* 2006;28:797–801.
29. Steen Jensen J, Nilsen R, Thanh NH, et al. Clinical field testing of polyurethane feet for trans-tibial amputees in tropical low-income countries. *Prosthet Orthot Int.* 2006;30:182–194.
30. Steen Jensen J, Nilsen R, Zeffer J, et al. Clinical field testing of vulcanized rubber feet for trans-tibial amputees in tropical low-income countries. *Prosthet Orthot Int.* 2006;30:195–212.
31. Schnall BL, Chen YT, Bell EM, et al. Functional outcomes of service members with bilateral transfemoral and knee disarticulation amputations resulting from trauma. *Mil Med.* 2016;181(S4):55–60.
32. Osmani-Vllasolli T, Hundozi H, Orovcanec N, et al. Rehabilitation outcome following war-related transtibial amputation in Kosovo. *Prosthet Orthot Int.* 2014;38:211–217.
33. Muderis MA, Lu W, Glatt V, et al. Two-stage osseointegrated reconstruction of post-traumatic unilateral transfemoral amputees. *Mil Med.* 2018;183 (Suppl_1):496–502.
34. Spahn K, Wyatt MP, Stewart JM, et al. Do gait and functional parameters change after transtibial amputation following attempted limb preservation in a military population? *Clin Orthop Relat Res.* 2019;477:829–835.
35. Keeling JJ, Shawen SB, Forsberg JA, et al. Comparison of functional outcomes following bridge synostosis with non-bone-bridging transtibial combat-related amputations. *J Bone Joint Surg Am.* 2013;95:888–893.
36. Bussmann JB, Schrauwen HJ, Stam HJ. Daily physical activity and heart rate response in people with a unilateral traumatic transtibial amputation. *Arch Phys Med Rehabil.* 2008;89:430–434.
37. Laferrier JZ, McFarland LV, Boninger ML, et al. Wheeled mobility: factors influencing mobility and assistive technology in veterans and servicemembers with major traumatic limb loss from Vietnam war and OIF/OEF conflicts. *J Rehabil Res Dev.* 2010;47:349–360.
38. Williams ZF, Bools LM, Adams A, et al. Early versus delayed amputation in the setting of severe lower extremity trauma. *Am Surg.* 2015;81:564–568.
39. van de Meent H, Hopman MT, Frölke JP. Walking ability and quality of life in subjects with transfemoral amputation: a comparison of osseointegration with socket prostheses. *Arch Phys Med Rehabil.* 2013;94:2174–2178.
40. Gailey R, McFarland LV, Cooper RA, et al. Unilateral lower-limb loss: prosthetic device use and functional outcomes in servicemembers from Vietnam war and OIF/OEF conflicts. *J Rehabil Res Dev.* 2010;47:317–331.
41. MacKenzie EJ, Bosse MJ, Castillo RC, et al. Functional outcomes following trauma-related lower-extremity amputation. *J Bone Joint Surg Am.* 2004;86:1636–1645.
42. Taylor BC, French B, Poka A, et al. Osteomyoplastic and traditional transtibial amputations in the trauma patient: perioperative comparisons and outcomes. *Orthopedics.* 2010;33:390.
43. Taylor BC, Poka A, French BG, et al. Gritti-stokes amputations in the trauma patient: clinical comparisons and subjective outcomes. *J Bone Joint Surg Am.* 2012;94:602–608.
44. Giannoudis PV, Harwood PJ, Kontakis G, et al. Long-term quality of life in trauma patients following the full spectrum of tibial

injury (fasciotomy, closed fracture, grade IIIB/IIIC open fracture and amputation). *Injury.* 2009;40:213–219.
45. Jayakaran P, Perry M, Hale L. Comparison of self-reported physical activity levels and quality of life between individuals with dysvascular and non-dysvascular below-knee amputation: a cross-sectional study. *Disabil Health J.* 2019;12:235–241.
46. Gozaydinoglu S, Hosbay Z, Durmaz H. Body image perception, compliance with a prosthesis and cognitive performance in transfemoral amputees. *Acta Orthop Traumatol Turc.* 2019;53:221–225.
47. Dakhil N, Evin M, Llari M, et al. Is skin pressure a relevant factor for socket assessment in patients with lower limb amputation? *Technol Health Care.* 2019;27:669–677.
48. Ferris AE, Aldridge JM, Rábago CA, et al. Evaluation of a powered ankle-foot prosthetic system during walking. *Arch Phys Med Rehabil.* 2012;93:1911–1918.
49. Mahon CE, Pruziner AL, Hendershot BD, et al. Gait and functional outcomes for young, active males with traumatic unilateral transfemoral limb loss. *Mil Med.* 2017;182:e1913–e1923.
50. Pinzur MS, Beck J, Himes R, et al. Distal tibiofibular bone-bridging in transtibial amputation. *J Bone Joint Surg Am.* 2008;90:2682–2687.
51. Polfer EM, Hoyt BW, Bevevino AJ, et al. Knee disarticulations versus transfemoral amputations: functional outcomes. *J Orthop Trauma.* 2019;33:308–311.
52. Esposito ER, Rodriguez KM, Ràbago CA, et al. Does unilateral transtibial amputation lead to greater metabolic demand during walking? *J Rehabil Res Dev.* 2014;51:1287–1296.
53. Hagberg K. Bone-anchored prostheses in patients with traumatic bilateral transfemoral amputations: rehabilitation description and outcome in 12 cases treated with the OPRA implant system. *Disabil Rehabil Assist Technol.* 2019;14:346–353.
54. Poljak-Guberina R, Zivković O, Muljacić A, et al. The amputees and quality of life. *Coll Antropol.* 2005;29:603–609.
55. Amtmann D, Morgan SJ, Kim J, et al. Health-related profiles of people with lower limb loss. *Arch Phys Med Rehabil.* 2015;96:1474–1483.
56. Em S, Karakoc M, Sariyildiz MA, et al. Assessment of sexual function and quality of life in patients with lower limb amputations. *J Back Musculoskelet Rehabil.* 2019;32:277–285.
57. Münger M, Pinto CB, Pacheco-Barrios K, et al. Protective and risk factors for phantom limb pain and residual limb pain severity. *Pain Pract.* 2020;20:578–587.
58. Kapidžić-Duraković S, Karabegović A, Halilbegovic E, et al. Check list of symptoms SCL-90-R at persons with extremities amputations. *Bosn J Basic Med Sci.* 2006;6:58–61.
59. Ebrahimzadeh MH, Hariri S. Long-term outcomes of unilateral transtibial amputations. *Mil Med.* 2009;174:593–597.
60. Gailey RS, Gaunaurd IA, Raya MA, et al. Development and reliability testing of the comprehensive high-level activity mobility predictor (CHAMP) in male servicemembers with traumatic lower-limb loss. *J Rehabil Res Dev.* 2013;50:905–918.
61. Tennent DJ, Polfer EM, Sgromolo NM, et al. Characterization of disability following traumatic through knee and transfemoral amputations. *Injury.* 2018;49:1193–1196.
62. Ebrahimzadeh MH, Fattahi AS. Long-term clinical outcomes of Iranian veterans with unilateral transfemoral amputation. *Disabil Rehabil.* 2009;31:1873–1877.
63. Gailey RS, Scoville C, Gaunaurd IA, et al. Construct validity of comprehensive high-level activity mobility predictor (CHAMP) for male servicemembers with traumatic lower-limb loss. *J Rehabil Res Dev.* 2013;50:919–930.
64. Dahl E, Cohen SP. Perineural injection of etanercept as a treatment for postamputation pain. *Clin J Pain.* 2008;24:172–175.
65. Dougherty PJ. Transtibial amputees from the Vietnam War. Twenty-eight-year follow-up. *J Bone Joint Surg Am.* 2001;83:383–389.
66. Pezzin LE, Dillingham TR, MacKenzie EJ. Rehabilitation and the long-term outcomes of persons with trauma-related amputations. *Arch Phys Med Rehabil.* 2000;81:292–300.
67. Tekin L, Safaz Y, Göktepe AS, et al. Comparison of quality of life and functionality in patients with traumatic unilateral below knee amputation and salvage surgery. *Prosthet Orthot Int.* 2009;33:17–24.
68. Mackenzie EJ, Rivara FP, Jurkovich GJ, et al. The impact of trauma-center care on functional outcomes following major lower-limb trauma. *J Bone Joint Surg Am.* 2008;90:101–109.
69. Schwenkreis P, Pleger B, Cornelius B, et al. Reorganization in the ipsilateral motor cortex of patients with lower limb amputation. *Neurosci Lett.* 2003;349:187–190.
70. Bennet PM, Sergeant ID, Midwinter MJ, et al. Medium-term outcomes in British military amputees. *Bone Joint J.* 2013;95B:224–229.
71. Talbot LA, Brede E, Metter EJ. Effects of adding neuromuscular electrical stimulation to traditional military amputee rehabilitation. *Mil Med.* 2017;182:e1528–e1535.
72. Matsumoto ME, Czerniecki JM, Shakir A, et al. The relationship between lumbar lordosis angle and low back pain in individuals with transfemoral amputation. *Prosthet Orthot Int.* 2019;43:227–232.
73. Penn-Barwell JG. Outcomes in lower limb amputation following trauma: a systematic review and meta-analysis. *Injury.* 2011;42:1474–1479.
74. Mckechnie PS, John A. Anxiety and depression following traumatic limb amputation: a systematic review. *Injury.* 2014;45:1859–1866.
75. O'Toole RV, Castillo RC, Pollak AN, et al; LEAP Study Group. Determinants of patient satisfaction after severe lower-extremity injuries. *J Bone Joint Surg Am.* 2008;90:1206–1211.
76. Archer KR, Castillo RC, MacKenzie EJ, et al; LEAP Study Group. Perceived need and unmet need for vocational, mental health, and other support services after severe lower-extremity trauma. *Arch Phys Med Rehabil.* 2010;91:774–780.
77. Poitras ME, Maltais ME, Bestard-Denommé L, et al. What are the effective elements in patient-centered and multimorbidity care? A scoping review. *BMC Health Serv Res.* 2018;18:446.
78. Vyas KS, Johnson K, Mardini S. The role of patient-centered outcomes research in plastic surgery. *Ann Plast Surg.* 2016;77:585–586.
79. Mundy LR, Klassen A, Grier J, et al. Development of a patient-reported outcome instrument for patients with severe lower extremity trauma (LIMB-Q): protocol for a multiphase mixed methods study. *JMIR Res Protoc.* 2019;8:e14397.
80. Rahimi A, Mousavi B, Soroush M, et al. Pain and health-related quality of life in war veterans with bilateral lower limb amputations. *Trauma Mon.* 2012;17:282–286.
81. Binkley JM, Stratford PW, Lott SA, et al. The lower extremity functional scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. *Phys Ther.* 1999;79:371–383.
82. Gallagher P, MacLachlan M. Development and psychometric evaluation of the trinity amputation and prosthesis experience scales (TAPES). *Rehabil Psychol.* 2000;45:130-154.