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The efficacy of lower limb orthoses on quality of life, well-being, and participation following stroke: A systematic review

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Abstract

Stroke is the main cause of acquired adult disability globally, with motor impairment affecting 80% of people after stroke. To regain mobility, diminish falls, and improve quality of life (QoL), after a stroke, orthoses are recommended. Most studies, to date, have focused on the positive impact of ankle-foot orthoses on spatial-temporal, kinematic, and kinetic outcomes. The objective of this review is to assess the evidence of the effects of lower-extremity orthoses on perceptions of QoL, psychological well-being, and social participation after stroke. The following databases were used to search the literature: CINAHL, EMBASE, Scopus, and PubMed, between 1990 and 2022. Previous reviews and reference lists were also screened. Information on the trial design, sample characteristics, information of orthoses used, outcome measures, and results were extracted. Critical appraisal was conducted using SIGN guidelines. Ten articles were identified as meeting the inclusion criteria. The effect of orthoses on QoL was inconsistent: 4 articles reported a positive relationship, one found a negative relationship, and 3 did not find any relationship. Six of 7 articles reported a positive relationship between the use of orthoses and psychological well-being and participation, although the level of evidence was low. This literature review has identified a small number of articles addressing the research question. Furthermore, varied study designs, low levels of evidence seen, the variation in follow-up times, and the limited information about the fitting and appropriateness of the orthoses in the studies highlight that more research is needed.

Keywords

quality of life, stroke, orthoses, psychological well-being, participation

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Introduction

Stroke is a brain infarction because of lack of oxygen, caused either by ischemic occlusion or an intracerebral hemorrhage. Stroke is considered to be one of the most severe pathological events, and, with 17 million new cases every year across the world, is the main cause of acquired adult disability around the globe.[1] The consequences of stroke include gait impairments, hemiplegia/hemiparesis, pain, depression, anxiety, and speech problems, with depression and anxiety often being disregarded or underreported.[2,3] These effects have a tremendous impact on individuals' perceptions of quality of life (QoL), psychological well-being, and participation. Considering the incidence of stroke and the increasing number of stroke survivors, it is a priority to understand and identify effective treatments and rehabilitation, so that patients can regain their independence in activities of daily living.[1,2] Lower-limb orthoses are commonly prescribed to people with lower-limb functional loss after a stroke.[4]

Ankle-foot orthoses (AFOs) are known to improve a number of quantitative outcome measures in people with stroke, such as mobility and ambulation,[5,6] gait and energy cost,[7-9] and balance.[5,10] In addition, AFOs have demonstrated other positive qualitative outcomes including level of satisfaction with the orthotic aesthetic, design, and comfort.[11,12] Depending on the severity of the event and on functional loss, foot orthotics and knee-ankle-foot orthotics can also be prescribed and applied, showing also improvements in walking speed, balance, mobility, and other outcomes.[13,14] These devices are commonly produced using thermoplastics, but may also be manufactured using traditional materials such as leather and metal.[13] More recently, composite materials have also been used, which have shown good characteristics such as rigidity, low weight, and efficacy in reducing energy expenditure.[13,15,16] An alternative to AFOs in managing stroke is functional electric stimulation (FES), an external device that uses an electrical current to produce muscle contractions to restore motor function, which has shown equivalent results in walking speed, ambulation, balance, and motor function when compared with AFOs after a stroke.[17,18] As such, FES is considered to meet International Organization for

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Standardization's definition[4] of an orthotic intervention and, therefore, will also be included in this review. In summary, there is good evidence to support orthotic intervention after a stroke; however, this evidence focuses mostly on physical activity measured in a laboratory environment or report measures based on subjective qualitative outcomes.

Orthoses are designed to modify/improve body functions and structure, and, therefore, when considering the International Classification of Functioning, Disability, and Health (ICF), orthoses can potentially play an important role, not only in improving outcomes related to body function and structure but also in increasing activities and participation. Measures such as QoL and psychological well-being are holistic outcome measures, which cover different components of the ICF and offer insights into the user's perception of the impact of the orthosis on a person's day-to-day life.[19] WHO describes QoL as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns."[20] Psychological well-being is an important, inter-related aspect of QoL, also with the potential to be impacted by orthotic intervention.[21] Psychological well-being, under the domain of body function and structures in the ICF, is defined as a state of mental well-being that allows individuals to cope with stresses of life associated with body image and appearance, negative and positive feelings, and self-esteem.[20,22] Participation is a single component of the ICF but is generally overlooked as a suitable outcome measure in studies investigating the efficacy of orthoses after a stroke. It is defined by ICF as "the person's involvement in a life situation, a societal perspective of functioning," which connects with the domains of QoL, social relationships, and environment.[23] All 3 outcomes are affected by stroke and have the potential to be impacted by orthotic intervention.[24]

Quality of life, psychological well-being, and participation are multidimensional concepts that rely on subjective perceptions of a person's well-being, reinforcing the importance of having validated and reliable outcome measures. A systematic review with focus on these outcomes will help to identify evidence gaps that could drive future research, identify method design issues that have limited the utility of previous research, and propose alternatives to improve research. Furthermore, given that no review has previously considered the impact of orthoses on QoL, psychological well-being, and participation after stroke, the aim of this systematic review is to identify outcome measures used to measure QoL, psychological well-being, and participation in persons after stroke and investigate the impact of lower-limb orthotic intervention on QoL, psychological well-being, and participation in persons after stroke.

Methods

Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[25] were used to guide the search strategy and reporting of this systematic review. A systematic electronic database search was performed, using keyword searching between May 2022 to July 2022. The following databases were used: CINAHL, Scopus, EMBASE; and PubMed, between the years 1990 and 2022. Words related to 3 main concepts (condition-related—stroke, outcome-related—QoL, and intervention-related—orthotics) were used in the search and combined using (AND and OR) terms, seen in Table 1. The full search strategy for the different databases is detailed in Appendix 1 (Supplemental Digital Content 1 http://links.lww.com/POI/A267). In addition, a secondary search was conducted, using the reference list of the included articles.

To assess the eligibility of the article, the title and abstract were read, and then, full articles were reviewed by the author and the coauthor independently. Any discrepancies in opinion about the articles meeting inclusion criteria were discussed between the authors, and their inclusion/exclusion was agreed on, allowing full consensus. No automation tools were used in this review. Inclusion criteria were studies with sample size $n > 1$, availability of full text, and articles that related the different terms used for stroke, QoL, and lower-limb orthoses (foot orthotics, AFO, knee-ankle-foot orthotics, and FES). Articles that investigated a range of different conditions were included if it was possible to extract results relating to only stroke conditions. Orthopedic shoes, insoles, and footwear adaptation were included because these were considered to meet the interpretation of orthotic definition by International Organization for Standardization.[4] Studies were included if appropriate outcomes (different domains regarding QoL

Table 1. Concepts used for the search.

Concept condition	Concept outcome	Concept intervention
Stroke	Quality of life	Orthotics
Brain damage	QoL	Orthoses
Hemiplegia	Psychological	Orthos*
Hemiparesis	Depression	Brace
Drop*foot	Appearance	Splint
CVA	Aesthetic	Device
Cerebrovascular accident	Health	Footwear
TBI	Well*Being	Shoes
Traumatic brain injury		FES
		Functional electrical stimulation
		Insole

Abbreviations: CVA, cerebrovascular accident; FES, functional electric stimulation; QoL, quality of life; TBI, traumatic brain injury.

perceptions, psychological well-being, or participation) were clearly defined and assessed using a validated outcome measure.

Studies investigating the use of kinesio tape, or upper-limb orthotics, pilot studies, and studies using qualitative outcomes were removed. Articles were then critically appraised, and levels of evidence were assigned to each publication using the SIGN Critical Appraisal Guidelines.[26] The risk of bias was assessed using the SIGN critical appraisal methodology checklist relevant to the appropriate study design.[27-29] Both authors have accessed the risk of bias independently and, after 3 meetings, achieved consensus of opinion.

Results

Ten studies were included in this review,[30-39] which reported the perceived effects of using an orthotic device on QoL and its domains, psychological well-being, and participation in people with stroke. Results were organized and synthesized according to the outcome measures. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart (Figure 1) details the screening process and inclusion of final selected articles, reviewed.

Outcome measures

In terms of outcome measures, the Stroke-Specific QoL (SS-QoL) questionnaire was used in 3 studies,[31,37,38] the Stroke Impact Scale (SIS) in another 3 articles,[31,34,36] and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) were also used in 3 articles.[32,33,35] Other measures used were the Disability Impact Profile (DIP),[35] Psychosocial Impact of Assistive Devices Scale (PIADS),[30] and Activities-Specific Balance Confidence (ABC) Scale.[39] These outcome measures are described in Table 2.

Overview of studies

A total of 1093 participants were included across all studies. The mean age of all participants was 58 years, excluding 2

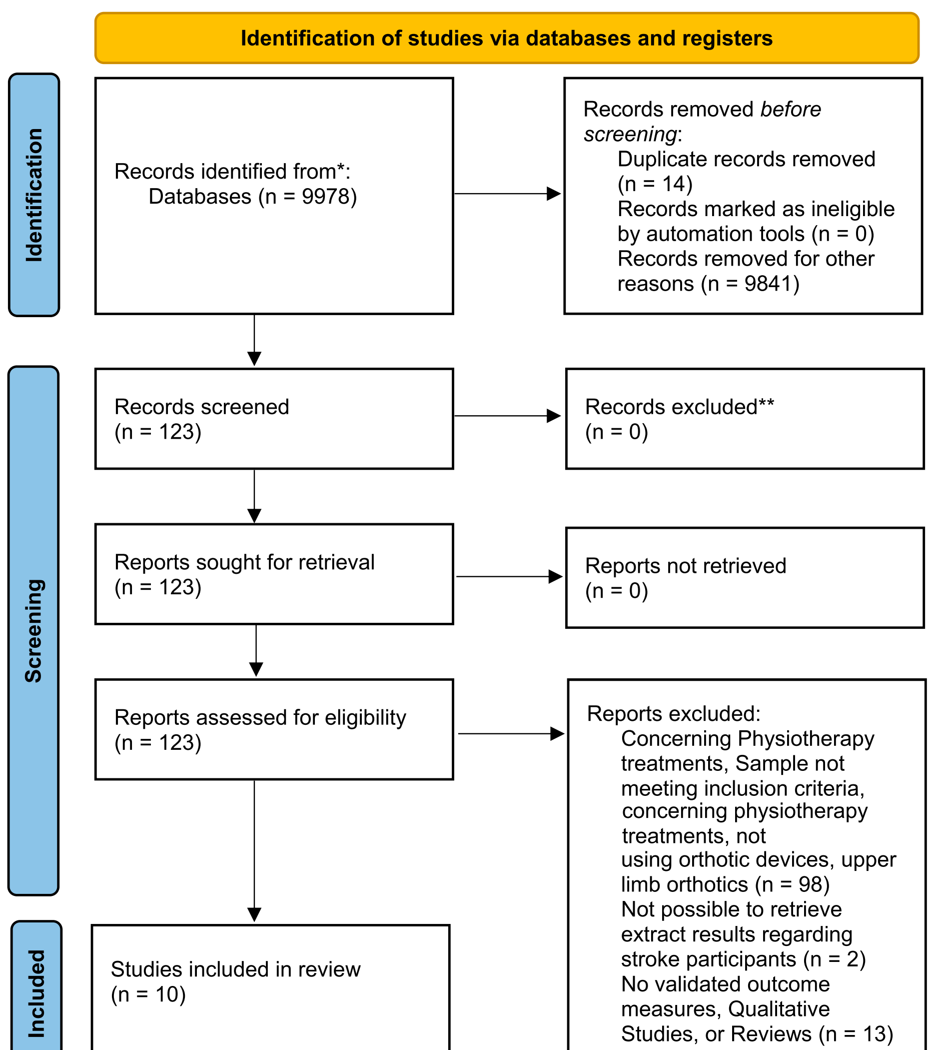

Figure 1. PRISMA chart. PRISMA 2020 flow diagram for new systematic reviews, which included searches of databases and registers only. Based on Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021; 372: n71. doi: 10.1136/bmj.n71. For more information, visit http://www.prisma-statement.org/. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

studies,[32,37] which did not provide this information. Time since stroke was a mean of 59.3 months (with a range between 6.5[33] months and 144 months[39]) excluding 2 articles,[32,37] which did not provide the time since stroke. Four articles reported on FES devices,[30,32,33,36] and 4 articles compared FES orthoses with AFOs.[31,34,35,38] Only one article studied the effects of AFOs only,[39] and one article did not specify which kind of orthoses were used.[37] A data extraction table (Table 3) provides an overview of the included studies.

Critical appraisal

All articles were critically appraised using SIGN,[26] and the following levels were assigned: SIGN level high n = 2;[31,34] SIGN level acceptable n = 5;[33,35,37-39] and SIGN level low n = 3[30,32,36] (Table 4). The low number of articles found resulted in no articles being excluded in this review, even if their quality was low. The 10 articles included 5 randomized control trials, 2 case-control studies, one case series, one case study, and one cross-sectional study. The varying methodologies used across the studies and the wide variation in the risk of bias across the different studies raised the following concerns: nonexistence of randomization,[30,32,36,37,39] convenience sample of participants,[30-33,35-39] lack of clarity on professional role of the personnel applying the devices,[31-38] unclear description about the devices used,[31,34,35,37] sample size,[30,33,35,36,39] and dropout rates.[36,38]

Use of orthoses and QoL perception scores in people after stroke

Overall, 8 articles investigated a possible association between the use of orthoses and QoL perception in people with stroke, as seen in Table 3. Three studies[31,37,38] used the SS-QoL. Bethoux et al[31] and Sheffler et al[38] both compared the use of FES orthoses with AFOs. Sheffler et al[38] reported a time effect for this outcome measure, where the participants under treatments (both FES and AFOs) showed positive significant results over the 36 weeks of the trial ($p = 0.002$). By contrast, Bethoux et al[31] did not find any significant difference in QoL after 6 months of using the SS-QoL for either intervention. In another study[37] using the same outcome measure, which did not specify the orthotic intervention, a negative relationship was found between the use of orthoses and QoL. Participants who did not wear an orthotic device had a higher QoL perception (SS-QoL mean = 83.77 [$p < 0.0001$]), compared with those who did use orthoses (SS-QoL mean = 44.31 [$p < 0.0001$]).[37] The study[37] reported a correlation between the level of severity of the stroke, level of disability, and QoL, indicating that the participants who reported a poorer functional status and

Table 2. Description of outcome measures related to QoL, psychological well-being, and participation founded in the search.

	Outcome measures	No. of items	Dimensions/domains	Scores
QoL overall perception	Medical outcome study SF-36[26-28]	36 items	8 dimensions: physical functioning, role limitations-physical, bodily pain, social functioning, general mental health, role limitations-emotional, vitality, and general health perceptions	Blended score
	DIP[30,31]	39 items	Five domains: mobility, self-care, social activities, communication, and physiological status	From 0 (maximal disability) to 10 (no disability)
	PIADS[33]	26 items	Three areas: competence, adaptability, and self-esteem	Each question can be scored from −3 to 3, where −3 to 0 is negative effect, and 0 to 3 is positive effect
Stroke-Specific QoL Perception Scales	SS-QoL[34,35]	49 items	12 domains: mobility, energy, upper extremity function, work/productivity, mood, self-care, social roles, family roles, vision, language, thinking, and personality	5-point Likert scale
	SIS[36,37]	64 items	8 domains: strength, hand function, ADL/IADL, mobility, communication, emotion, memory and thinking, and participation	5-Point Likert scale
	ABC Scale[39]	16 items	Not applicable	0 (lower level of self-confidence) to 100 (high level of self-confidence)

Abbreviations: ABC, Activities-Specific Balance Confidence; ADL/IADL, Activities of Daily Living/Instrumental Activities of Daily Living; DIP, Disability Impact Profile; PIADS, Psychological Impact of Assistive Devices Scale; QoL, quality of life; SF-36, 36-Item Short-Form Health Survey; SIS, Stroke Impact Scale; SS-QoL, Stroke-Specific Quality of Life Scale.

Table 3. Review results.

Study	Sample size (n)	Time after stroke	Study design	Device	Follow-up	Outcome	Results (mean ± SD)	SIGN level of evidence
Barret and Taylor[30]	21	50.4 months	Case study	FES—ODFS	No follow-up	PIADS	Positive median values of components of PIADS (range of values): competence 1.25 (0.17–2.92); adaptability 1,25 (0.00–3.00); and self-esteem 0.88 (0.13–2.75)	Low
Bethoux et al[31]	495	82.6 months	RCT multicenter	FES—WalkAid® and AFO	6 Months	Combined score of SIS[a], SS-QoL, and individual domains of SIS	Significant improvement in SIS[a] with FES ($p = 0.05$). WA initial 170.0 ± 2.7 to WA 6 months 175.0 ± 2.7	High
Fernandes et al[32]	50	Not identified	Case series	FES	Not specific	SF-36	Significant increase in all domains ($p < 0.05$): physical functioning 21.40 ± 16.38; mental health 14.32 ± 19.79; vitality 14.20 ± 15.06; social functioning 19.0 ± 24.12; role emotional 32.0 ± 40.39; role physical 19.0 ± 38.32; general health 5.94 ± 9.82; and bodily pain 7.66 ± 16.41	Low
Johnson et al[33]	21	6.5 months	RCT	FES—ODFS III	12 weeks	SF-36	No significant results	Acceptable
Kluding et al[34]	197	54.6 months	RCT multicenter	FES—NESS L300 Bioness Inc and AFO	30 weeks	SIS	SIS participation improved in long-term device effect in both groups and together (total sample 7.79 ± 17.83; AFO group 7.09 ± 17.24; FES group 8.48 ± 18.47 ($p < 0.05$) SIS mobility scores improved in the long-term, both groups and together (total sample 5.18 ± 17.78; AFO	High

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Table 3. Review results. (Continued)

Study	Sample size (n)	Time after stroke	Study design	Device	Follow-up	Outcome	Results (mean ± SD)	SIGN level of evidence
							group 3.19 ± 14.30; FES group 7.14 ± 15.04) ($p < 0.05$) and decreased in immediate device effect in the AFO group (−2.63 ± 11.77; $p < 0.05$)	
Kottink et al[35]	29	88.4 months	RCT	FES FML and conventional devices (AFO, shoes, or nothing)	26 weeks	SF-36 and DIP	Significant while comparing FES group with AFO group: SF-36—physical functioning (FES group score change 11.9, and −5.4 in the AFO group [$p < 0.01$]); general health (FES group score change 9.1, and −6.3 in the AFO group [$p < 0.05$]); and PCS-36 (FES group score change 4.1, and −2.6 in the AFO group [$p < 0.01$]). DIP—mobility ($p = 0.006$), self-care ($p = 0.00$), and psychological status ($p = 0.025$). Significant results within the groups were not stated	Acceptable
Laufer et al[36]	24	63.6 months	Case-control	FES—NESS L300 Foot Drop System	1 year	SIS-16	Significant results in: SIS-16 and participation domain in between T1 and T2 and between T1 and T3 ($p < 0.05$) SIS-16: T1 63.6 ± 12.3; T2 72.8 ± 12.9; T3 74.1 ± 12.1 Participation domain: T1 50.2 ± 17.7; T2 62.9 ± 14.9; T3 68.6 ± 16.3	Low

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Table 3. Review results. (Continued)

Study	Sample size (n)	Time after stroke	Study design	Device	Follow-up	Outcome	Results (mean ± SD)	SIGN level of evidence
Ramos-Lima et al[37]	131	Not identified	Cross-sectional study	Not specific	No follow-up	SS-QoL	Patients using orthoses showed SS-QoL mean = 44.31; not using orthoses SS-QoL mean = 83.77; ($p <$ 0.0001)	Acceptable
Sheffler et al[38]	110	44.8 months	RCT	FES—ODFS and Custom PF Stop HAFO	12 weeks	SS-QoL	No significant results regarding the use of orthoses Time effect on SS-QoL between T1 and T2-T4 ($p =$ 0.002)	Acceptable
Zissimopoulos et al[39]	15	144 months	Case-control	AFO[b]	Two study-related visits	ABC Scale	Self-reported balance confidence was significantly greater in conditions with AFO (68.19%) compared with those without (51.62%) ($p \leq$ 0.01)	Acceptable

Abbreviations: ABC, Activities-Specific Balance Confidence; AFO, ankle-foot orthoses; DF, dorsiflexion; DIP, Disability Impact Profile; FES, functional electric stimulation; FML, Finetech Medical Limited; HAFO, Hinged Ankle-Foot Orthoses; ODFS, Odstock Dropped Foot Stimulator; PCS-36, Physical Component Summary; PF, Plantarflexion; PIADS, Psychological Impact of Assistive Devices Scale; RCT, randomized control trial; SF-36, 36-Item Short-Form Health Survey; SIS, Stroke Impact Scale; SIS-16, Stroke Impact Scale 16-Item Version; SS-QoL, Stroke-Specific Quality of Life Scale; WA, WalkAid Device.
[a]Combined score of different domains of SIS, Mobility, Activities of Daily Living and Instrumental Activities of Daily Living, and Social Participation.
[b]AFO nonrigid (posterior leaf-spring; articulated with DF assist; articulated with PF stop; and DF assist or just PF stop).

higher severity of the stroke event had lower QoL scores ($p <$ 0.001).

Three studies[31,34,36] used SIS as an outcome measure (Table 1). Two of these studies[34,36] found positive effects on participants' QoL perceptions. Kluding et al[34] found a significant mean improvement ($p < 0.05$) in the SIS mobility domain after wearing the devices for 30 weeks, in the total sample (SIS mobility mean change = 5.18 ± 14.78). The authors reported significant positive mean change for both AFOs and FES independently in the mobility scores (AFO group: SIS mean change = 3.19 ± 14.30) (FES group: SIS mean change = 7.14 ± 15.04). However, when the device was applied for the first time, a significant negative change in scores was registered in the group wearing AFOs (SIS mobility scores mean change = −2.63 ± 11.77 [$p < 0.05$]). Laufer et al[36] used the SIS short version (SIS-16) in 24 participants using an FES device, Bioness L300 (Ness L300; Bioness Inc). They found a significant increase in the SIS-16 overall score, after use of the device, with the mean values increasing from the baseline to 8 weeks after (SIS mean in T1 63.6 ± 12.3 to SIS mean in T2 72.8 ± 12.9 [$p < 0.05$]) and between the baseline measure and 1 year later (SIS mean in T1 63.6 ± 12.3 to SIS mean in T3 74.1 ± 12.1 [$p < 0.05$]). A third article[31] did not report any significant results in the individual domains of SIS scores. This study combined the domains of Mobility, Activities of Daily Living/Instrumental Activities of Daily Living (ADL/IADL), and Social Participation of SIS and reported a significant increase in this outcome measure scores while using the WalkAid Device (WA) orthosis after 6 months (SIS combined domains mean WA initial 170.0 ± 2.7 to mean WA 6 months 175.0 ± 2.7 [$p = 0.05$]). However, no rationale for combining these scores was provided.

Of the 8 articles measuring QoL perception scores, 3 used the SF-36 outcome measure, and mixed results were seen. Only one article using the SF-36 outcome found a significant positive increase in QoL.[32] This article, a case series of 50 participants, compared the QoL perception scores before and after rehabilitation, while using FES, but did not specify the rehabilitation timeline. Furthermore, insufficient details of the device were provided. The results revealed increased scores in all domains of SF-36 (Table 3). Two other studies[33,35] that used the SF-36[33] to measure QoL did not show any significant increase in QoL. In the study by Johnson et al,[33] in which participants wore an FES Odstock Dropped Foot Stimulator (ODFS) mark III orthosis for 8 weeks, and also received an injection of botulinum toxin A at the beginning of the intervention phase, no significant change was

Table 4. Critical appraisal table.

	Study	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	1.10	Overall assessment	2.2	2.3
RCT	Bethoux et al[31]	Yes	Yes	Yes	No	Yes	Yes	Yes	11.1% and 8.1%	Yes	Yes	High	Yes	Yes
	Johnson et al[33]	Yes	Yes	Yes	No	Yes	Yes	Yes	14%	Yes	NA	Acceptable	Yes	Yes
	Kluding et al[34]	Yes	Yes	Yes	No	Yes	Yes	Yes	18%	Yes	Yes	High	Yes	Yes
	Kottink et al[35]	Yes	Yes	Yes	No	Yes	Yes	Yes	14%	Yes	Yes	Acceptable	Yes	Yes
	Sheffler et al[38]	Yes	Yes	Yes	No	Yes	No	Yes	24%	Yes	NA	Acceptable	Yes	Yes
Case series/ study	Barret and Taylor[30]	Yes	NA	NA	No	NA	NA	Yes	5%	Yes	NA	Low	No	Yes
	Fernandes et al[32]	Yes	NA	NA	Cannot say	NA	NA	Yes	0%	Yes	NA	Low	No	Yes
	Laufer et al[36]	Yes	NA	NA	No	NA	NA	Yes	50%	Yes	NA	Low	No	Yes
	Zissimopoulos et al[39]	Yes	No	NA	No	NA	NA	Yes	0%	Yes	NA	Acceptable	Yes	Yes
Cross-sectional	Ramos-Lima et al[37]	Yes	NA	NA	Cannot say	NA	NA	Yes	NA	Yes	NA	Acceptable	Yes	No

Abbreviations: NA, not applicable; RCT, randomized control trial.
1.1 Clear and appropriate question; 1.2 Treatment group randomized; 1.3 Concealment method used; 1.4 Subjects and investigators blinded; 1.5 Treatment and control at similar at the start of the trial; 1.6 The only difference between groups is the treatment under investigation; 1.7 All relevant outcomes are measured in a standard, valid, and reliable way; 1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?; 1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention-to-treat analysis); 1.10 Where the study is performed at more than one site, results are comparable for all sites; 2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention; and 2.3 Are the results of this study directly applicable to the patient group targeted by this review.

found over time. The second article, by Kottink et al,[35] a randomized control trial including 29 participants, compared FES (Finetech Medical Limited) with AFOs and presented results of the overall health score and the different dimensions of SF-36 over 26 weeks. Kottink et al[35] reported a positive change in QoL scores in all domains for the FES group over time, whereas for the "conventional treatment" group which wore plastic AFOs, a negative change was seen. However, it was not stated if any of these within-group results were significant over 26 weeks. This study[35] also used DIP as an outcome measure, although only presented the results of the comparison between AFOs and FES orthosis.

In summary, a range of different outcome measures were used across 8 studies, which measured QoL perception: SS-QoL (n = 3),[31,37,38] SIS (n = 3),[31,34,36] SF-36 (n = 3),[32,33,35] and DIP (n = 1).[35] Four articles compared AFOs with FES,[31,34,35,38] and the 3 other articles studied the effects of FES only.[32,33,36] Four studies found evidence of improvement of QoL when using an orthosis,[31,32,34,36] one study[37] established a negative correlation between QoL and orthoses, which was related to increased severity of stroke, and 3 other articles did not identify any significant change in QoL scores.[33,35,38] Of the 4 studies that found improvement of QoL,[31,32,34,36] all of them found positive changes while participants used FES devices, but only one study related an increase in QoL with the use of AFOs. Overall, there was a lack of consistency in results. Considering the variable results, the mixed study designs, the different measurement tools, the variation in time points across at which QoL perception was measured in different studies, and limited information regarding the fitting and appropriateness of orthoses in most of the studies, there is currently insufficient evidence that orthotic intervention can increase patient perceptions of QoL after a stroke. However, there was a tendency for FES orthoses to have some positive impact on QoL perception scores, compared with AFOs. The small number of articles investigating AFOs, and the biases detailed above, suggests no definite statements can be made about the effect of FES compared with AFOs on QoL perceptions in people with stroke.

Use of orthoses and psychological well-being perception and participation in people after stroke

Seven articles investigated the relationship between the use of orthoses and the psychological well-being scores and participation in people after stroke (Table 3).[30-32,34-36,39] Three articles used the SIS outcome measure[31,34,36] and presented results for the domains related to psychological well-being and participation. Two articles[34,36] reported a significant positive change in participation scores of SIS for participants using orthoses. Kluding et al[34] found a significant mean improvement after 30 weeks in the SIS participation domain in the total group (7.79 ± 17.83 [$p < 0.05$]), FES group (8.48 ± 18.47 [$p < 0.05$]), and AFO groups (7.09 ± 17.24 [$p < 0.05$][34]). Also, Laufer et al[36] reported an increased perception of the participation domain of SIS for 24 participants using an FES NESS L300 orthosis, between the pretreatment (T1) and 8 weeks after (T2) (T1 50.2 ± 17.7; T2 62.9 ± 14.9 [$p < 0.05$]), and also between T1 and 1-year follow-up (T3) (T1 50.2 ± 17.7; T3 68.6 ± 16.3 [$p < 0.05$]). Bethoux et al[31] did not find any significant change in particular domains regarding psychological well-being or participation, either while using AFOs or FES orthoses.[31] However, they reported a significant increase in the mean values of the participants' perception for a combined score of Mobility, ADL/IADL, and Social Participation of SIS, while using the WalkAid orthosis (SIS combined domains mean WA initial

170.0 ± 2.7 to mean WA 6 months 175.0 ± 2.7 [$p = 0.05$]).[31] No justification for combining the scores was provided.

Two studies[32,35] used the SF-36 outcome measure and presented the results of the specific domains related to psychological well-being. One investigation[32] reported significant increases in mean values for the domains of mental health (14.32 ± 19.79; $p < 0.05$), vitality (14.20 ± 15.06; $p < 0.05$), social functioning (19.0 ± 24.12; $p < 0.05$), and role emotional (32.0 ± 40.39; $p < 0.05$), within the participants. The same outcome measure was used by another study[35] when comparing FES orthosis with the "conventional treatment" (AFOs, shoes, or no device). The overall and specific scores in the different domains were presented, but no significant results were reported either within or between the groups.

Two studies used outcome measures not used by any other authors. Barret and Taylor[30] used the PIADS to measure the possible effects of orthotic devices on people after a stroke, measuring: competence, adaptability, and/or self-esteem. This article investigated the effect of FES ODFS on a group of 21 participants, at one point in time. The authors suggested a possible positive impact of the orthoses on the participants' psychological perception for the 3 domains because they were higher than zero, with median values in competence of 1.25, adaptability of 1.25, and self-esteem of 0.88. Zissimopoulos et al[39] used the ABC Scale, a self-reported balance confidence measure that is used to address self-efficacy, which is one's belief in being able to succeed performing different activities. Fifteen AFO users participated and completed this questionnaire at 2 different appointments. However, the interval between appointments was not specified. In a random order, the individuals were asked to respond to the survey, either considering wearing the AFO, or not wearing it. The results showed significantly greater perceived confidence while using the orthosis (68.19%, $p \leq 0.01$) when compared with not using the orthosis (51.62%, $p \leq 0.01$).

Summarizing the psychological well-being and participation outcomes, 3 articles measured psychological well-being and participation with SIS,[31,34,36] 2 studies used SF-36,[32,35] one article used PIADS,[30] and one used the ABC Scale.[39] Four studies[31,34,35,39] investigated the use of AFOs, and of these, 2[34,39] reported significant changes on psychological well-being and participation scores. Five[30-32,34,35] investigated the use of FES on psychological well-being and participation, and 4 of these studies reported a positive increase overall in related psychological well-being and participation scores. The literature included in this review suggests some evidence that the use of orthoses can have a positive effect on psychological well-being and participation scores in individuals after stroke, although there was more evidence relating to FES compared with AFO for this effect. However, considering the weak SIGN[26] level of evidence and mixed study designs, the lower number of articles found, the variation in follow-up timelines in the different articles or even the lack of reporting of timelines,[40] and the limited information about the fitting process and appropriateness of the chosen orthoses in most studies, the level of evidence found was low.

Discussion

The main objective of this literature review was to identify and appraise peer-reviewed evidence concerning the relationship between orthotic devices and QoL, psychological well-being, and participation, in individuals after a stroke. Ten articles that met inclusion criteria found mixed results and, therefore, limited evidence that orthoses may affect QoL, psychological well-being, and participation in individuals after stroke. The lack of consistency of results suggests that more research is required to investigate the possible effects of orthoses on QoL, psychological well-being, and participation, in people after stroke. This review was composed of randomized controlled trials (n = 5), case-control (n = 2), case series (n = 2), and a cross-sectional study. Different study designs, orthotic interventions, and outcome measures were used, meaning that it was not appropriate to perform a meta-analysis to investigate the research question. Although this review did not find strong supporting evidence, a few important findings warrant further discussion.

Outcome measures

A range of different outcomes were used to measure QoL such as SIS, SF-36, SS-QoL, and DIP. The outcome measure ABC Scale, a self-efficacy measure, was included in this review because these outcome measures look beyond just balance capacity, but also aim to measure self-confidence in one's ability to achieve success in different activities, which relates to the psychological well-being domain.[39] None of the outcome measures provided consistent results. Therefore, it is not possible to recommend a specific outcome to measure QoL while investigating orthoses in this population.

Studies that applied SIS[31,34,36] found a significant positive change in QoL while using orthoses over time. One article[34] found an initial negative correlation between participation scores of SIS when participants were fitted with AFO orthosis, whereas after 30 weeks of using the device, a significant positive correlation was identified. This finding is of note as it potentially indicates that the AFO users might need a habituation/learning period until the participants feel comfortable and safe to use the orthoses.

In the articles that reported a significant positive change in QoL, several concerns were identified in the critical appraisal, providing less confidence in the findings of the studies. One other article[31] found a significant result when using a combination of different domains of SIS, mobility, participation, and ADL/IADL. However, no reason for combining the results in this way was provided, giving cause for concern about the validity of this approach and reliability of the results. SF-36, a generalist QoL-related questionnaire, was used by 3 articles,[32,33,35] and only Fernandes et al reported significant results in a trial. However, the length of follow-up and type of FES devices used were not reported, reducing the quality of evidence. Barret and Taylor[30] studied the effect of FES ODFS on 21 participants but at a one-time point only, with no follow-up, highlighting the difficulty drawing conclusions.

Material and design of orthoses

In this literature review, 8 studies used FES,[30-36,38] and 5 trials investigated the effects of AFOs.[31,34,35,38,39] Of the articles using FES, 3 articles used the ODFS FES system,[30,33,38] 2 used the Bioness L300,[34,36] one used the WalkAid,[31] other applied FML,[35] and one[32] did not specify which kind of FES orthosis was used. The FES orthoses presented in the different articles were generally similar, involving a calf cuff with or without a foot component, but only 2 articles[30,33] indicated the frequency, pulse, and amplitude of the signals used for muscle stimulation. Articles that did not list these specifications of FES[31,32,34-36,38] were at risk of bias because there was a lack of clarity around dosage and optimization of treatment. Furthermore, this research would be challenging to replicate.

The details about the AFOs used in the different articles were insufficient.[41] One of the articles investigating AFOs[35] combined plastic AFOs, shoes, or no treatment, into one group, referring to this as "conventional treatment." The variation in the control group may have impacted the results, not allowing a robust comparison. Two articles[31,39] described variation in design between solid, posterior leaf spring, or hinged AFOs, according to the participant's requirements, but no further details were provided about material choice, thickness of materials, or footwear used. One investigation[38] indicated that the AFO used was a custom-moulded hinged orthoses with a plantarflexion stop, and another one[34] described and specified the precise number of participants using hinged or nonhinged, or prefabricated AFOs, but again, there was a lack of detail on other prescription elements of the AFO. No study specified if composite materials were used in the manufacture of participants' orthoses. Carbon fiber has shown good characteristics such as rigidity, low weight, as also efficacy in reducing energy expenditure and spatiotemporal values.[15,16,40] The lack of inclusion of this material in any of the studies could be due to the increased cost of composite material.[42] However, its inclusion should be considered in future studies.

Similar to a previous review,[41] the lack of details on orthotic design, e.g., material choice, thickness, trimlines, casting angle, and angle of tibial inclination, among others, affected the validity of the reported outcomes because there is no possibility to reproduce the trials in the future, without this information. In addition, the heterogeneity of the prescription across the studies included in this review makes it difficult to draw firm conclusions about possible effects of AFOs on QoL, psychological well-being, and participation.

Eight of 10 articles included in this review used FES orthoses,[30-36,38] which have been shown to address motor impairments after stroke. Traditionally, AFOs were used to address the functional losses seen in the lower limb after a stroke event. However, over the past 20 years, FES devices have gained more popularity.[40] It has been reported that FES devices are preferred to AFOs[17] because they are easy to accommodate in shoes and can improve muscle strength by providing stimulation to weak muscles.[17,43] However, FES provides control during the swing phase in gait and does not impact on gait deviations seen in the stance phase, e.g., mediolateral instability.[44] Functional electric stimulation is a more expensive option compared with thermoplastic AFOs.[44] Functional electric stimulation devices have become more widely available recently and might be considered more attractive by users as they are more technologically advanced, and this could explain why a higher number of publications have investigated FES and QoL, compared with AFOs. Indeed, studies that investigated AFOs only, or compared different AFOs designs, while measuring QoL as an outcome were not identified in the search. This seems an anomaly, given that AFOs have been used for a longer time, and there have been many studies investigating functional and gait outcomes of AFOs. Therefore, there is a need to investigate specifically the influence of different AFO designs on QoL and its related outcomes in people after stroke.

Study design

Because of the small number of articles found, a range of different study designs were included in this review, leading to the inclusion of case series or case-control trials, which provide lower levels of evidence compared with randomized control trials. Two articles with no follow-up were included[30,37] because both used specific outcome measures related to QoL perception on participants using orthoses after stroke. Three studies used sample size calculations,[31,34,38] and 2 achieved the appropriate sample size.[31,34] Seven studies did not provide a sample power calculation and, because of the low numbers in these studies, are likely to be underpowered. This means that the results may not provide sufficient confidence in the reliability of the findings and their application to the wider stroke population. Furthermore, all the samples in the selected trials in this review were recruited by convenience, presenting risk of bias. Studies were included in this review that did not follow blinding procedures during outcomes assessments. Although this is considered a risk of bias according to SIGN guidelines, there are always challenges in blinding assessors and participants to orthotic intervention, because of its visibility, and difficulty in disguising the intervention.

The articles did not measure important variables that might be considered to affect QoL after stroke, including severity of stroke, with the exception of Ramos-Lima et al[37] who found that use of orthoses correlated to a lower QoL score. The authors also reported that a lower QoL was related to a higher level of severity of stroke and a lower level of functionality. Participants might have been provided with the orthotic intervention because of the severity of functional loss, therefore, potentially explaining the lower QoL. This highlights the potential to draw misleading conclusions from research and the complexities of measuring QoL after orthotic intervention. Future studies should seek to incorporate key variables that might impact QoL outcomes, such as severity of stroke, into the study design to control for these variables, and have more confidence in the relationship between the intervention and the measured outcome.

Limitations

The main objective of this study was to understand how QoL perception is affected in individuals after stroke, using orthoses. Given the smaller number of articles identified, the inclusion criteria applied in this review were wider than might be considered ideal, including trials regardless of time after stroke, the type of stroke, level of severity, and/or levels of functioning/mobility. This resulted in a wide range of different outcome measures used and different orthotic interventions, leading consequently to a greater heterogeneity of variables, becoming harder to synthetize/summarize results and to draw more specific conclusions.

A limited number of studies that directly measured QoL were identified. This could be because of the extensive and complex concept of QoL, which is often defined in different ways, and QoL may be considered by some practitioners and researchers as of secondary importance. A range of different QoL, psychological well-being, and participation outcomes were included in this review, including generic and/or disease-specific measures. These can be affected by different variables, which in most of the studies were not accounted for, making it difficult to understand the impact of orthoses on people after stroke. In addition, time is a key factor in stroke rehabilitation, and some recovery may occur naturally through time, allowing improvement in outcomes during the rehabilitation process, which may not be attributed solely to orthotic use, as seen in previous studies.[45,46]

Areas for future research

There is a lack of studies investigating the relationship between QoL and the use of orthoses. Further investigation of QoL perception in participants after a stroke using orthotic interventions is required. It would be logical to focus any investigation on the use of AFOs as these are more commonly used, globally compared with FES. The effect of different AFO variables on QoL, such as different designs, materials, and fine-tuning of the AFO, should also be investigated. Quantification of usage of the orthoses and habituation procedures should also be reviewed and detailed in future investigations. More randomized controlled trials are needed with the use of range of different validated instruments with proven reliability. Psychological debility is a major challenge in individuals after a stroke: Depression has a prevalence of 30% in this population, with the number increasing to 50% at some point in the longer term.[3] This state of depression has a relation to the deconstruction of body image, damaged self-esteem, dysfunction, and disability, which, in turn, can exacerbate the existing physical impairments. A need for understanding how the use of orthoses can impact body image and self-esteem, and its relationship with depression is an important area for future research. Also, there is a need for researchers to measure and account for other variables while measuring the effects of orthotic interventions, which can have an impact on QoL and psychological well-being.

Conclusion

This review found insufficient levels of evidence that orthotic intervention in people after a stroke can increase their QoL perception, psychological well-being, and participation. There was a tendency for participants using FES to report higher QoL, psychological well-being, and participation scores, compared with AFOs. However, more studies have investigated the relationship between QoL outcomes and FES compared with AFOs, and the critical appraisal process identified concerns across all the included studies, indicating a lack of evidence to support one intervention over the other. Key design information about the orthoses, e.g., material choice, thickness, trimlines, casting angle, angle of tibial inclination, or details about the amplitude of stimulation of the FES device, who applied the devices, training/adaptation period to the device. Therefore, further research is required, through longitudinal studies, with a greater focus on AFOs, using QoL, psychological well-being, and participation outcome measures, which focus on the user experience of orthotic intervention. There is potential to include these measures alongside other investigations of orthotic use after stroke, to further investigate the effects of orthotic intervention on QoL, psychological well-being, and social participation.

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