## **REVIEW ARTICLE**

# Rehabilitation Techniques for Adults Undergoing External Fixation Treatment for Lower Limb Reconstruction:

# A Systematic Review

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#### **A**BSTRACT

**Introduction:** External fixation devices are commonly used in orthopaedic surgery to manage a range of pathologies. In this patient population, there is currently no consensus on optimal rehabilitation techniques. There exists a large variation in practice, with a limited understanding of how these affect treatment outcomes.

Methods: Following Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines, a systematic review was conducted of Allied and Complementary Medicine Database (AMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, PEDro, and COCHRANE databases, grey literature sources and forward and backward searching of included articles. Studies were selected following rigorous screening with predefined inclusion criteria. Data quality was assessed using validated appraisal tools. Articles were synthesised by rehabilitation type and descriptive analysis was subsequently performed.

**Results:** From 1,156 articles identified, 18 were eligible for inclusion. The overall quality was low, with clinical commentaries and case studies being the most common study type. Studies were synthesised by rehabilitation type, the most common themes being gait re-education, strengthening, therapy-assisted, active exercises and weight-bearing exercises.

**Conclusion:** There is a lack of high-quality evidence to support meaningful recommendations and guide rehabilitation practices for this patient cohort. Further research for patients being treated in external fixation, especially related to the potential effects of physical rehabilitation on bone healing, return of strength, mobility and independent function is likely to have transferability within wider orthopaedic populations.

Clinical significance: This systematic review is unable to provide clinical recommendations due to the poor quality of the available literature. However, it is hoped this paper will provide a foundation for further research to improve rehabilitation for patients being treated with external fixation.

**Keywords:** Circular frame, Ex-fix, External fixation, External fixator, Limb reconstruction, Lower limb fracture, Physiotherapy, Rehabilitation, Systematic review.

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#### INTRODUCTION

The use of external fixation devices in orthopaedics has been longstanding with evidence for its use in managing fractures dating back over 2000 years.<sup>1</sup>

Since the beginning of the last century, there have been significant advances in our understanding of the optimal biological and mechanical conditions for bone healing.<sup>2</sup> In the 1940s, Professor GA Ilizarov developed the circular frame and distraction histogenesis.<sup>1</sup> Recent technological advances have led to an expansion of the indications of using external fixator devices to definitively treat a wide range of orthopaedic pathologies.<sup>3</sup> This includes but is not limited to, acquired deformities, nonunions, bone infection, congenital bone defects, osteosarcoma management, as well as acute complex trauma, such as where compromised soft tissues often preclude optimal use of internal devices.<sup>3</sup>

The beneficial role of mobilisation in optimal load bearing and surrounding muscle conditioning towards bone healing, strengthening and remodelling has long been established.<sup>4</sup> Treatment is often prolonged and places a significant physical and psychological burden on patients and their families. For this

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reason, optimal care should be delivered by multidisciplinary limb reconstruction teams including nursing, rehabilitation and psychological support.<sup>5</sup> Targeted input towards this may not only improve bone consolidation and union rates but may also

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#### Table 1: Search strategy

#### Search terms

TI ("lower limb reconstruct\*" or "femoral lengthen\*" or "femur N3 lengthen\*" or "tibial lengthen\*" or "tibia N3 lengthen\*" or "femur\* or "femur\* or "femur\* or "femur\* n3 fracture\*" or "femur\* N3 fracture\*" or "femur\* N3 lengthen\*" or "femur N3 lengthen\*" or "femur\* n3 lengthen\*" or "femur\* n3 fracture\*" or "femur\* n3 fr

#### AND

TI (frame\* or "taylor spatial frame" or ilizarov or "external fixator" or "circular frame") OR AB (frame\* or "taylor spatial frame" or ilizarov or "external fixator" or "circular frame")

#### AND

AND TI AB physiotherapy or physio or rehab\* or "muscle strength\*" or "functional outcome\*" or exercis\* or physical N3 activit\* or "physical therap\*"

#### OR

TI (frame\* or "taylor spatial frame" or ilizarov or "external fixator" or "circular frame") OR AB (frame\* or "taylor spatial frame" or ilizarov or "external fixator" or "circular frame")

#### ANI

AND TI AB physiotherapy or physio or rehab\* or "muscle strength\*" or "functional outcome\*" or exercis\* or physical N3 activit\* or "physical therap\*"

have a positive impact in reducing treatment times, overall health care-related costs, reducing psychological burden and improving functional recovery for the patient. Common complications of circular frame treatment are muscle contractures, pain and pin-site infections, which may be prevented and managed by multidisciplinary interventions.<sup>2</sup>

Despite the important perceived benefits of rehabilitation, there is paucity of evidence in the literature. In 2001, Barker et al. conducted a literature review, identifying one study exploring knee range of motion. Following this, a consensus process produced a detailed rehabilitation pathway guideline for patients being treated in external fixation, from early inpatient postoperative guidelines to outpatient rehabilitation. While this guideline has been invaluable to clinicians working with this population it lacks empirical evidence to support the recommendations. Evidence that is not unfeasible to collect and could prove the need for rehabilitation in this patient population.

More recently, the National Major Trauma Rehabilitation Group (NMTRG) in the United Kingdom (UK), developed a guideline for the assessment and rehabilitation of the major trauma patient.<sup>5</sup> A subcategory of this is lower limb reconstruction and rehabilitation of a patient with external fixation. As with the guidelines produced by Barker et al., <sup>6</sup> this was based on clinician consensus and demonstrates the components of rehabilitation that major trauma centres are providing to this patient population in the UK. However, there is very little novel clinical research to support these components. More than 20 years after the consensus guidelines by Barker et al.,<sup>6</sup> the question of evidence-based rehabilitation for people being treated with external fixation still needs exploring. More recently, a Brazilian scoping review was published, again highlighting the lack of evidence, two decades after Barker et al. <sup>6</sup> This review explored the published literature, as well as mapping available evidence regarding physiotherapy assessment and treatment for patients with proximal and mid-tibial external fixator treatment.8 Whilst this review was systematic, they excluded studies using external fixation for urgent trauma, it did not include any quality appraisal and the authors recommended further research assessing the quality of published evidence. Given the complexity of external fixation treatment, the health care-related costs, and current challenges in resource allocation within the National Health Service in the UK, there is an urgent need for evidence to support rehabilitation.

The aim of this systematic review is to synthesise and critically appraise the rehabilitation evidence for adults undergoing treatment with external fixation.

#### **M**ETHODS

This systematic review was conducted according to the Cochrane Collaboration Guidelines and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. <sup>9,10</sup> The protocol was registered on the International Prospective Register of Systematic Reviews (PROSPERO) database, registration No. 360712.

#### Search Strategy

The search strategy was developed in collaboration with a research librarian (see acknowledgements). The search terms used are shown in Table 1. Filters were applied to include only studies written in the English language, and search terms were searched within the title and abstract.

#### **Information Sources**

The following databases were searched: Allied and Complementary Medicine Database (AMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, PEDro, and COCHRANE from inception to 21 September 2022, and updated on 5 June 2023. Reference lists of included studies, as well as forward searching of included studies, were conducted. To ensure the completeness of data sources, grey literature sources were also searched (British Library, ETHOS, NICE guidelines, Greynet international, BASE, and clinicaltrials.gov). The search results were imported into Rayyan QCRI online software for screening.<sup>11</sup>

#### **Selection Process**

References identified by the literature search were deduplicated in Rayyan QCRI online software and then split into two groups, each reference group was independently screened by two reviewers (KCC and RW; JP and JF). Screening of title, abstract, and full text was completed based on predetermined eligibility criteria described in the following.

Disagreements between pairs were resolved through discussion, reference to the full text and with the additional reviewers (CH, JB and JL), and with a senior reviewer (DC) to confirm relevance for the review. To promote interrater reliability, 50% of



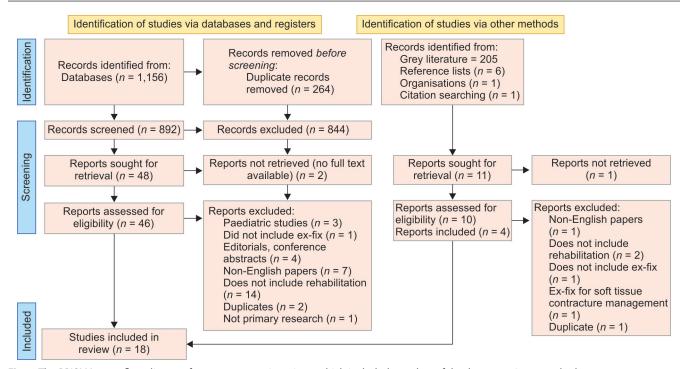


Fig. 1: The PRISMA-2020 flow diagram for new systematic reviews which included searches of databases, registers, and other sources

the final included sample was reviewed by independent senior reviewers (CH, DC and JB).

# **Eligibility Criteria**

Eligible studies were those which included participants who had lower limb trauma (open fracture, soft tissue damage or complex closed fractures), elective lower limb deformity corrective surgery, bone infection surgery, or fracture nonunion and were treated with the use of external fixation. Participants were over the age of 16 years. Only primary research, including clinical commentaries, and case studies were included. Specific exclusion criteria were studies with participants below the age of 16 years, with cancer, who had treatment of the injury with an internal nail, amputation, the use of external fixation for soft tissue contracture management, conference proceedings and papers not written in English.

#### **Data Extraction**

Data from the included studies were extracted independently by pairs of reviewers (KCC and RW; JP and JF) using a data extraction form in Microsoft Excel. Data extracted from the results included information such as country, population, study design, sample size, intervention used, control group, follow-ups, dropout rate and outcome measures used. Each pair of reviewers completed the data extraction for half of the included results. Any discrepancies were resolved by discussion between the reviewers and the senior reviewers, as was in the inclusion process.

#### **Methodological Assessments**

The potential risk of bias was assessed using the Mixed Methods Appraisal Tool (MMAT).<sup>12</sup> This was chosen due to the advantage of being applicable to multiple study designs. Comment and review papers were assessed for potential risk of bias using the Joanna Briggs Critical Appraisal Checklist for Text and Opinion Papers as the MMAT did not include comment or review papers.<sup>13</sup> The potential risk of bias was assessed independently by two pairs of reviewers

(JP and JF; KCC and RW) as described in the data extraction process and disputes resolved by senior reviewers (DC, CH, JB and JL).

The Consensus on Exercise Reporting Template (CERT)<sup>14</sup> supported by the EQUATOR network was used to assess the rigour of reporting. Exercise interventions have traditionally been underreported in the evidence, impacting the reproducibility of the intervention.<sup>14</sup>

#### **Synthesis**

A narrative synthesis was completed due to the heterogeneity of the included studies, the synthesis without meta-analysis (SWiM) guidelines were used to support this process.<sup>15</sup> Studies were synthesised by type of rehabilitation intervention, linking the aims of the systematic review in synthesising the rehabilitation techniques. A preliminary synthesis was undertaken to explore all possible themes of the types of rehabilitation used, these were tabulated and discussed by all authors to identify the main rehabilitation themes.

#### RESULTS

Database searching identified 1,157 references reducing to 892 after duplicates were removed. The grey literature search and forward and backward search identified 213 references. Of all of these, 18 studies met the inclusion and exclusion criteria (Fig. 1). Grey literature searching identified doctoral theses, relevant studies within the theses were published separately and have been included in this review, therefore the theses themselves were not included. A clinical trial protocol was identified on clinicaltrials. gov, and the author was contacted and confirmed the project was presented at a conference as an abstract, however, it was excluded as there was no access to the results. Full details are available on the PRISMA diagram (Fig. 1).

The summary of all studies included in the review is provided in Table 2. A total of 235 participants were included and involved

Tabl	Table 2: Included studies	studies				
No.	Source	Study title	Authors	Date	Study type	Participants
<del>-</del>	Database search	Clinical efficacy of kinesiology taping in reducing oedema of the lower limbs in patients treated with the Ilizarov method-preliminary report.	Dariusz Białoszewski, Weronika Woźniak, Sławomir Zarek	2009	RCT	24 patients with oedema undergoing limb lengthening using an Ilizarov frame
2	Database search	Functional rehabilitation with a foot plate modification for circular external fixation	James A Blair, Johnny G Owens, Joey Saucedo, Joseph R Hsu; Skeletal Trauma Research Consortium (STReC)	2013	Retrospective chart analysis	11 active-duty military male patients undergoing lower-extremity limb salvage enrolled in the return to run pathway
m	Database search	Physical therapy management of patients undergoing limb lengthening by distraction osteogenesis	Debra Branin Coglianese, John E Herzen berg, James A. Coulet	1993	Clinical commentary with two case studies included	1 male patient undergoing limb lengthening following a traumatic injury and 1 female patient with congenital deformity
4	Database search	Physiotherapy for patients with an Ilizarov external fixator: A survey of current practice	KL Barker, M Burns, S Littler	1999	Survey of physiotherapists	Surveys sent to physiotherapists working in centres known to treat patients with external fixation
70	Database search	Physiotherapy in Ilizarov fixation	YM Gan	2003	Clinical commentary informed by non-systematic literature search	Nil as clinical commentary
9	Database search	Reamed intramedullary nailing vs circular frame external fixation for segmental tibial fractures (STIFF-F): A mixed methods feasibility study	Caroline B Hing, Elizabeth Tutton, Toby O Smith, Molly Glaze, Jamie R Law, Jonathan Cook, Melina Dritsaki, Emma Phelps, Cushla Cooper, Alex Trompeter, Michael Pearse, Michael Law and Matthew L Costa	2021	Mixed methods feasibility study: Pilot RCT, qualitative interviews and survey	3 patients recruited to RCT, 19 staff, 4 patients and 9 physiotherapists completed survey/qualitative interview
^	Database search	Rehabilitation of an adult patient with arthrogryposis multiplex congenita treated with an external fixator	Luciana Delboni Taricco and Solange Sumire Aoki	2009	Case study	1 patient, 35-year old female with female with arthrogryposis multiplex congenita
œ	Database search	The Ilizarov procedure: Limb lengthening and its implications	Stephanie Simard, Mary Marchant and Gregory Mencio	1992	Clinical commentary	Nil as clinical commentary
6	Database search	Using consensus techniques to produce clinical guidelines for patients treated with the Ilizarov fixator	K Barker and M Burns	2001	Delphi process	Clinicians with experience of working with Ilizarov fixation
10	Database search	Use of a hinged external knee fixator after surgery for knee dislocation	James P Stannard, Todd M Sheils, Gerald McGwin, David A Volgas, and Jorge E Alonso	2003	Nonrandomised prospective functional outcome study	36 patients with 39 knee dislocations managed with external frames
1	Forward/ backward search	Physiotherapy during Ilizarov fixation	Stuart A Green	1990	Clinical commentary	Nil as clinical commentary
12	Forward/ backward search	Management of open complex tibial plateau fractures by Ilizarov fixator: follow-up of 8.5 years	Abdel-Salam A Ahmed	2019	Rerospective cohort study	27 patients with open tibial fractures
13	Forward/ backward search	Return to running and sports participation after limb salvage	Johnny G Owens, James A Blair, Jeanne C Patzkowski, Ryan V Blanck, Joseph R Hsu, and the STReC	2011	Retrospective cohort study	10 military patients enrolled in the "Return to Run Clinical Pathway"



e.	Table 2: (Contd)						
١. ا	No. Source	Study title	Authors	Date	Date Study type	Participants	
41	Forward/ backward search	Return to duty after integrated orthotic and rehabilitation initiative	James A Blair, Jeanne C Patzkowski, Ryan V Blanck, Johnny G Owens, Joseph R Hsu, STReC	2014	Retrospective cohort study	146 service members enrolled in the Return to Run Clinical Pathway were analysed retrospectively	
15	Grey literature search	NMTRG	NMTRG, UK	2023	Guideline	Nil as clinical guideline	
16	Updated database search	A novel implementation of physiotherapy in a known case of malunited supracondylar fracture of the femur with osteomyelitis managed with ilizarov fixator	Purva S Shahade, Purva H Mundada, Ruchika J Zade, Pratik Phansopkar	2022	Case study	1 × 25-year-old male with osteomyelitis after a road traffic accident, managed in a llizarov external ring fixator	
17	Updated database search	Early-stage physical therapy for a patient with proximal tibial fracture with acute compartment syndrome and neurovascular deficits managed with external fixation complicated by chronic osteomyelitis: A case report	Abhishek Daf, Avanti A Gachake, Palash R Satone, Om C Wadhokar, Pratik Phansopkar	2022	Case study	1 × 32-year-old male with complex lower limb fractures, fasciotomy from road traffic accident, multiple operations and debridements and lizarov fixator	
18	Updated database search	Patient experience from a doctor's perspective: A case report concerning treatment, fracture healing and rehabilitation of multiple complex injuries due to a high energy motor vehicle collision	MA de Ruijter, JA Lucke, JZ Yuan, RJ Derksen	2022	Case study	1 × 35-year-old male doctor (trauma resident) with a lower limb fracture from a road traffic accident managed in an external fixator	

122 physiotherapists through consultation (n=78) or participation in surveys (n=44). The participants' ages ranged from 16 to 72 years and the majority of the participants had experienced trauma (n=233). However, two of the case studies included patients with congenital deformities (n=2).  $^{19,20}$  Of the articles identified, two were randomised control trials (RCTs), four were clinical commentaries, three were retrospective cohort studies, one survey, four were case studies, one Delphi study, one clinical guideline, one retrospective chart analysis and one non-randomised outcome study.  $^{5,6,19-34}$  The date ranges of the included studies were from 1990 to 2022. The clinical commentary papers discussed the surgical technique mainly and in the postoperative care advice had suggested rehabilitation interventions, with some evidence provided, but these were unreproducible.  $^{19,20,23,24}$ 

# **Quality of Exercise Reporting**

The quality of reporting and replicability of rehabilitation interventions from clinical trials is a key part of the critical appraisal process. The CERT tool was used for the interventional and cohort studies. <sup>21,22,26–28,33</sup> Overall, the CERT scores were low. The maximum possible CERT score is 19 and the studies included in this review ranged from one to five. This highlights the lack of transparent and robust intervention reporting throughout the available literature. The most consistent score on the CERT assessment was whether a study had detailed any non-exercise components. In contrast, the poorer reported items were locations of the exercise and whether it was completed in a group or individually. The two studies with the highest CERT scores, with five out of the possible 19 were both observational studies in military populations enrolled in a return to running programme. <sup>26,27</sup>

# Methodological Assessment/Potential Risk of Bias of Included Studies

The mixed methods assessment tool highlighted that the included studies had a high potential risk of bias. Areas of high potential risk of bias were with regard to the study population not being representative of the wider clinical population, such as active military personnel, and accounting for confounders in the analysis. <sup>26,27</sup> Furthermore, it is unclear if the interventions were delivered as planned and if they were adhered to. This demonstrates poor external validity and does not account for confounding variables. The Joanna Briggs risk of bias tool was used to assess commentary papers and found incongruence with the literature, poor clarity if they portrayed both sides of the argument, and if the paper referenced the whole extent of the literature. Considering the results of the risk of bias tools, the findings of the included studies should be interpreted with caution. See Table 3 for a breakdown of this information.

## **Thematic Analysis**

Following the SWiM guidelines, the rehabilitation interventions were categorised into themes based on the type of intervention.<sup>15</sup>

#### **Rehabilitation Themes**

Gait re-education was the most common rehabilitation theme in the included studies, reported in 11 of the 15 studies. <sup>6,19,20,22–25,29,30,32,33</sup> However limited information was provided on the details of this intervention. Strengthening is a key part of rehabilitation after lower limb trauma and was the second most common theme of the interventions, reported in nine out of 15 papers. <sup>6,19,20,23,26,27,31,33,34</sup> However, poor reporting and the low

Table 3: Critical appraisal

Are there clear Do Study identity research all (ID) questions re 2 Yes 3 Yes 7 Yes 8 Yes 10 Yes 11 Yes 12 Yes 13 No 13 No 16 Yes 17 Yes 16 Yes 16 Yes 16 Yes 16 Yes 17 Yes	Do the collected data allow to address the research question?	Are the participants representative of the	Are measurements nts appropriate regarding the hoth the outcome and	Are there	Are the confounders	During the study period, is the intervention	
	Yes	target population?	intervention (or exposure)?	complete outcome data?	accounted for in the design and analysis?	administered (or exposure occurred) as intended?	CERT score/19
		No	No	Yes	No	Unclear	5
	res	No	No	No	No	No	ΑN
	Yes	No	No	No	No	Yes	ΥN
	Yes	No	Yes	Yes	No	Unclear	ΥN
	Yes	No	Yes	No	No	Yes	1
	Yes	Yes	Yes	No	No	Yes	ΥN
	Yes	No	Yes	Yes	No	Yes	1
	No	No	No	No	No	Yes	5
	Yes	No	No	No	٥N	Yes	2
	Yes	No	No	No	٥N	Unclear	Ϋ́
17 Yes	Yes	No	Yes	No	٥N	Unclear	Ϋ́
18 Yes	Yes	No	No	No	٥N	Yes	Ϋ́Z
		MMAT qu	MMAT quantitative descriptive studies				
Are there Do clear research all Study ID questions re	Do the collected data allow to address the research question?	Is the sampling strategy relevant to address the research question?	Is the sample representative of the target population?	Are the measurements appropriate?	Is the risk of nonresponse bias Iow?	Is the statistical analysis appropriate to answer the research question?	
4 Yes	Yes	Yes	Yes	Yes	Yes	Yes	
9 Yes	Yes	Yes	Yes	Yes	Yes	Yes	
		MM	MMAT mixed methods studies				
Are there clear Do research all	Do the collected data allow to address the	Is there an adequate rationale for using a mixed methods design to address the research	Are the different components of the study effectively integrated to answer the	Are the outputs of the integration of qualitative and quantitative components adequately integrated.	Are divergences and inconsistencies between quantitative and qualitative results adequately	Do the different components of the study adhere to the quality criteria of each tradition of the mathode involved?	CEDT scow/10
Yes	Yes	Yes	Yes	Yes	Yes	Unclear	2
		MMAT	MMAT randomised controlled trials				
Are there Do clear research all Study ID questions re	Do the collected data allow to address the research question?	Is randomization appropriately performed?	Are the groups comparable at baseline?	Are there complete outcome data?	Are outcome assessors blinded to the intervention provided?	Did the participants adhere to the assigned intervention?	CERT score/19
1 Yes	Yes	No	Unclear	No	No	No	_



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			Interests of relevant			
Study ID	Source of opinion clear?	Standing in the field?	population central focus?	Position result of an analytical process and logic expressed?	Reference to the extant literature?	Incongruence with literature or sources logically defended?
3	Yes	Yes	Yes	Yes	Yes	Unclear
2	Yes	Yes	Yes	Yes	Yes	Unclear
80	Yes	Yes	Yes	Yes	Yes	Unclear
11	Yes	Yes	Yes	No	No	No

CERT scores of the included articles are challenging as there is limited information regarding repetitions, sets, and frequency. Therefore, many of the exercises reported as strengthening may have not been defined as strengthening exercises under the American College for Sports Medicine guidelines.<sup>35</sup> As reflected by the CERT scores, the majority of the studies reported that strengthening exercises were important but as per gait re-education, provided no further details. The only exception to this was the military studies which provided some information about the exercises which would allow reproduction. 26,27,33 Three of the fifteen studies involved active, high-level rehabilitation interventions such as plyometrics and agility. 26,27,33 Whilst these studies were observational in design and lacked control groups or evaluation of the rehabilitation interventions, they did demonstrate the efficacy of progressive rehabilitation programmes during external fixation treatment, improvements in patient function, and return to running and duty. These are detailed in Figure 2.

#### **Therapist-assisted Treatments**

Physiotherapy has been evolving as a profession and active treatment; for example, exercise, are now commonly the main intervention, especially within lower limb trauma.<sup>33</sup> However. therapist-assisted treatments which are passive in nature are still used as adjuncts which are reflected in the themes. Nine studies reported therapist-assisted interventions which included massage, splinting, joint mobilisations, shockwave and taping.  $^{6,19,21,24,28-30,32,34}$  Of the two RCTs included, one investigated kinesio-tape vs massage to reduce oedema, which, whilst a problem, is not usually the main focus of rehabilitation treatment. 21,22,36 It is worth noting that in line with the poor reporting of exercise interventions, there was limited information regarding the therapist-assisted modalities which would allow reproduction. The frequency, duration and professional delivering this intervention was not reported. Furthermore, the objective measures used were not standardised or validated and did not account for other variables.36

#### **Other Adjuncts**

Other adjuncts reported in seven of the studies were peer support, psychological support, art therapy, wound care, wheelchair badminton, sensory re-education and home visits. 6,20,22,24,30-32 These studies recognised the enormity of the psychological adjustment required whilst being treated in external fixation and delivered or recommended interventions to reflect this. It is well recognised that pin-site infections are a common complication of external fixation and therefore one study, an underpowered RCT, included a wound assessment in a rehabilitation programme. 20,37 Education components for patients being treated with complex procedures such as external fixation are reported in three studies. 20,22,29 Education as a theme encompasses, for example, pinsite care and practical education for external fixation, as well as pain education which is focussed towards long-term pain management strategies. As the majority of patients being treated in external fixation will require several months of treatment, education may be an important part of rehabilitation and will likely require further investigation regarding efficacy, content, frequency and timing. The need for group-based education, psychological services and further social support adjuncts such as vocational rehabilitation is acknowledged in the consensus-based guidelines, however, there is no evidence to support this yet.<sup>5,6</sup> It would be worthwhile for future research to include a return-to-work percentage whilst a patient

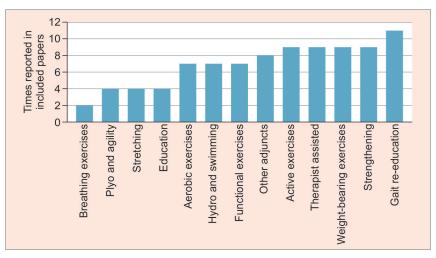


Fig. 2: Rehabilitation intervention themes

is in external fixation within demographics across the UK. Figure 2 gives a breakdown of rehabilitation themes.

#### Discussion

This is the first systematic review of its kind to explore rehabilitation interventions for adult patients undergoing limb reconstruction with external fixation. This review identified studies that used a wide range of research methods and different therapeutic interventions. Whilst a recent scoping review also aimed to explore the evidence, their aims were different from this review, including physiotherapy-related assessments, only exploring proximal and middle third tibial injuries, and not including a quality appraisal. <sup>8</sup>

The studies included in this systematic review are of varying methodological design with a high risk of bias, mainly commentaries, case studies and consensus designs. Clinical  $commentaries\ represent\ the\ lowest\ level\ of\ quality\ on\ the\ evidence$ hierarchy pyramid.<sup>38</sup> While the aim of this review was not to identify the effectiveness of the interventions, there is a lack of robust experimental research into rehabilitation interventions for patients treated with external fixators. A limitation of the many studies included in the review is low external validity. The two studies with the highest CERT scores were both completed in male military populations with average ages of 27.6 and 31.5 years, which are more active than the general population. <sup>26,27</sup> A study of open fractures in UK hospitals in 2021 reported an average age of 45.8 years, with 66.1% males.<sup>39</sup> Whilst this represents patients treated with internal fixation as well, it still provides a useful comparison and shows that the population requiring external fixation may have different demographics to these military studies.

The findings of this systematic review demonstrate the high variability of rehabilitation in practice. It is difficult to establish any level of causality, whether this is due to the variability in research evidence or confounding variables. With such variance, synthesising the available information on rehabilitation techniques for this patient population still remains unclear. The variable nature of rehabilitation interventions could contribute to the lack of high-quality research within this area, as designing high-quality interventional studies is complex when considering multiple confounders from different interventions. In agreement with the wide variation of rehabilitation techniques found in this systematic review, the consensus guidelines by Barker et al.<sup>6</sup> and the NMTRG

consensus clinical guideline on lower limb reconstruction, and the recent scoping review also demonstrate a wide variety of rehabilitation interventions ranging from bed exercises, functional tasks such as sitting to standing, therapy assisted modalities such as taping to return to sports activities such as agility and plyometrics. There are challenges with research on individual rehabilitation interventions as clinical practice often uses a combination of treatments. However, the Medical Research Council's complex intervention framework is one model that can incorporate multiple factors and could be applied to this area. This is especially relevant when considering how appropriate and ethical it is for research studies to deny patients treatments to assess the efficacy of individual rehabilitation techniques.

Confounding the complexity of rehabilitation interventions, although the role of physiotherapists within limb reconstruction has long been advised, their role as specialists in the UK depends on local service provision. The limited provision of specialist roles within this patient cohort is likely to contribute to the lack of research within this area. The Health and Care Professions Council published a diversity report on physiotherapists in 2021 and reported only 3% were employed by higher education institutions in universities or academia. The small cohort of academic physiotherapists is also likely to contribute to the lack of research within rehabilitation for patients being treated with external fixation.

The CERT tool aims to improve reporting and the quality of research in physiotherapy literature.<sup>14</sup> Rehabilitation in clinical practice has a large number of variables. These include the location of delivery (home or gym), delivery style (group or one-to-one), frequency of rehabilitation, and even considering the more complex variable of adherence. All of these factors are extremely important to consider when reporting research for the findings to be clinically relevant or replicable within clinical practice. Due to the low quality of the literature and study designs included in the review, alongside the lack of reporting, this review is unable to draw any conclusions on these factors from the literature. This is evident by the low CERT scores in this review. This issue is not unique to the rehabilitation of patients being treated with external fixation, other areas of rehabilitation such as tendinopathy literature have reported similar concerns.<sup>42</sup> Without thorough reporting, the replicability of the intervention is impacted, influencing practicality and therefore outcomes, as well as clinical interpretation and the translational gap between research and practice. This systematic review documents



the high variability of rehabilitation techniques for patients with external fixation which aims to encourage further research in this area. It is well known that complications within this population are common such as pin-site infections, wire breakages, wire slippages, or metalwork failure.<sup>33</sup> Despite this, the studies included in this review do not report any adverse events, demonstrating positive results bias. This is especially pertinent to consider for future research as there is limited evidence to prove if too little or even too much rehabilitation has a detrimental effect on patients being treated with external fixation, for example, the relationship between aerobic exercise and increased pin-site infections.

This review finds a lack of high-quality interventional trials, in agreement with a Delphi process completed in 2001.6 The NMTRG limb reconstruction clinical consensus guideline attempts to build upon this with more pragmatic detailed criteria.<sup>5</sup> These clinical guideline documents have great value for clinicians with limited experience in this area, as they are populated by expert clinicians across the UK and provide an excellent representation of rehabilitation interventions currently provided in the UK. However, it is important to consider these guidelines are not based on high-level evidence and are based on clinical experience alone, demonstrating a high risk of bias. For example, the NMTRG guidelines recommend twice daily inpatient physiotherapy and increasing the frequency of outpatient physiotherapy whilst a patient is going through adjustments or lengthening, despite the lack of evidence to support this.<sup>5</sup> Whilst physiotherapy services support the recovery of patients, and it is generally assumed that an increase in physiotherapy intervention is beneficial, there is no high-quality evidence that supports this frequency, which is untested in this complex population. Given the current challenges of staffing and resources within the National Health Service (NHS), frequency recommendations need to be clinically effective to provide value for money. Future studies in this area may benefit from including health economics to assess the cost and efficiency of patient pathways.

Another challenge encountered with research on patients being treated with external fixation is the heterogeneity of the population. Even within the trauma patients being treated with external fixation, there may be patients requiring significant orthoplastics intervention including soft tissue coverage, bone transport or bone infection treatment, in comparison to otherwise isolated complex fracture management. External fixation is also used in other orthopaedic problems such as deformity correction and congenital defects; this provides challenges when attempting to consider these patients collectively in one group. Demographic groups provide challenges for other research areas. However, it is especially pertinent when considering a rehabilitation programme; for example, for a 20-year-old patient being treated with external fixation, compared to an 80-year-old patient. Given these challenges, it could be argued that this systematic review should have focussed on a specific area such as trauma; however, this was not feasible due to the paucity of research.

Another challenge identified within this review is the wide variety of terminology to describe limb reconstruction treatment with external fixation. This is something that was especially important to consider in the search strategy and required significant tailoring with support from an expert librarian. For example, limb reconstruction has been described as limb salvage, circular frames have been described as external fixation, external fixators, ex-fix, llizarov frames or brand names, such as Taylor-Spatial frames. This highlights how this area would benefit from more standardised

terms to allow for more systematic search strategies and a thorough assessment of evidence in the future.

Recent developments in external fixation technology, software and surgical interventions, especially the hexapod system have enabled more complex bone correction of limbs that would previously have been amputated. When managing these complex patients, the lack of foundational rehabilitation evidence becomes even more pertinent. Highlighting the need for rehabilitation evidence to guide the management of these patients. One other important consideration in relation to the complexity of this patient cohort is the importance of psychological adjustment of being treated with external fixation. This is discussed in the NMTRG and they advise psychological screening, group education, peer support, and onward referrals. 5 Given the high likelihood of psychological distress in this cohort that comes with aesthetic changes from external fixator treatment, it may be relevant to consider the evidence and the need for group-based interventions and peer-based support. This would be interesting for future studies and health economic evaluation to consider.

There are multiple benefits of optimising rehabilitation input in this population, potentially benefitting clinical, radiological and patient-reported outcomes. The exact role of rehabilitation towards optimising the biological and mechanical environment, although having been recommended has not been adequately evaluated.<sup>5,6</sup> Bone healing and recovery trajectory is guided by Wolff's law, which affects treatment times and prognosis. 4 Whilst it is theorised that weight bearing whilst in external fixation is beneficial, this area lacks practical literature and evidence in terms of bone healing response to loading and rehabilitation whilst in external fixation devices. This guestion of what rehabilitation is required is particularly pertinent to patients undergoing a period of bone transport or deformity correction using external fixation, as it could be theorised these patients may be at higher risk of complications from loading exercises in the early regenerative phase of treatment where strain environment needs to be low. Variations in external fixator constructs can also impact the stability of specific areas of healing; there lacks evidence of whether rehabilitation programmes need to be tailored according to this.43

As previously discussed, the course of treatment is often lengthy for this intervention. The effects of reducing times for both patients and their families as well as for direct healthcare costs need to be established. Furthermore, the impact of these interventions in allowing a faster return to independent mobility and functioning during treatment needs to be established. Finally, the focus of any treatment intervention is the patient. The effect of this rehabilitation process in improving the overall patient experience both from a physical and psychological aspect should be established through employing regular standardised patient reporting outcome scores.

#### Limitations

The articles included in this review are from global sources and therefore there may be challenges when applying this to patients treated within the UK. A limitation of this systematic review is that only papers published in the English language were included due to logistics. The final search terms were decided after strategic search planning with a specialist librarian (see acknowledgements) and grey literature and forward and backward searching was completed to mitigate this risk. It is also accepted that excluding paediatrics is potentially a limitation within this area. However, it was decided that, due to the significant differences in paediatric populations in terms of bone healing, and the local population

served by the authors, the focus would be on the adult population for this systematic review.

#### Conclusion

This systematic review has highlighted the lack of strong evidence to guide towards optimal rehabilitation for patients being treated with external fixation. Whilst this review has been unable to provide any specific recommendations due to the paucity of available research, it highlights the potential benefits and the importance of critically examining how rehabilitation may impact the journey of a patient being treated with external fixation. The findings of this review have also highlighted some of the challenges of research in this area. For example, the heterogeneity and complexity of the population make designing, tailoring and delivering rehabilitation programmes that are individualised and also standardised in a research protocol. There are also ethical and practical considerations when using multiple interventions in practice. It is recommended that future research studies consider these factors, which may make study designs, such as high-quality observational studies, more appropriate in this area as a next step.

#### **Clinical Significance**

Whilst this systematic review has been unable to provide direct clinical recommendations it has highlighted the lack of clinical evidence in this area and challenges to consider in future research. It is hoped that this will be a catalyst for more research in the future. Research in this area also has the potential to provide innovative solutions to challenges in this area within service constraints; for example, research on group-based intervention is likely to provide cost benefits as well as peer and social support in a complex patient cohort. Whilst it has been out of the remit for this review to discuss the cost implications, further research in health economics in relation to high service demands and the high treatment burden for this population is recommended. Finally, further research for patients being treated in external fixation, especially in relation to the potential effects of physical rehabilitation on bone healing, return of strength, mobility and independent function is likely to have transferability within wider orthopaedic populations.

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## **Authors' Contributions**

JP, DC, CH, RW, JF and JB conceived the research synthesis; JP, JF, RW and DC wrote protocol, and database searching was completed by RW and JF. Grey Literature searching was completed by JP. Forwards and backwards searching were completed by JP, JF, RW and KCC. Screening of studies completed by JP, RW, JF and KCC. Disagreements were resolved through discussion and 50% of the final included sample was completed by additional reviewers DC, CH, JB and JL. Updated search completed by JL, RW, and JP. The manuscript was drafted by JP and DC and all authors were involved in manuscript reviewing and editing.

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