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Medical stretching devices are effective in the treatment of knee arthrofibrosis: A systematic review



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ABSTRACT

Aims: This systematic review examines the available evidence on the use of medical stretching devices to treat knee arthrofibrosis, it suggests a focus for future studies addressing limitations in current research and identifies gaps in the published literature to facilitate future works.

Materials and methods: Articles were identified using the Cochrane Library, MEDLINE, PubMed and SCOPUS databases. Articles from peer reviewed journals investigating the effectiveness of medical stretching devices to increase range of movement when treating arthrofibrosis of the knee were included.

Results: A total of 13 studies (558 participants) met the inclusion criteria with the devices falling into the following categories; CPM, load control or displacement control stretching devices. A statistically significant increase in range of movement was demonstrated in CPM, load-control and displacement-control studies ($p < 0.001$). The results show that the stretch doses applied using the CPM, load-control devices were performed over a considerably longer treatment time and involved significantly more additional physiotherapy compared to the displacement-control and patient actuated serial stretching devices.

Conclusion: The systematic review indicates that load-control and displacement-control devices are effective in increasing range of movement in the treatment of knee arthrofibrosis. Displacement-control devices involving patient actuated serial stretching techniques, may be more effective in increasing knee flexion than those utilising static progressive stretch.

The paucity of research in this field indicates that more randomised controlled trials are required to investigate the superiority of the different types of displacement-control stretching devices and which of these would be most effective for use in clinical practice and to compare these with standard physiotherapy treatment.

The translational potential of this article

1. Knee arthrofibrosis is a debilitating condition, current standard treatment has low success rates and is costly to patients and health services.
2. This systematic review indicates that both load control (creep) and displacement control (stress relaxation) home stretching devices are effective in increasing knee range of movement in the treatment of knee arthrofibrosis.
3. Displacement control (stress relaxation) and patient actuated serial stretch type devices may be more appropriate for home use as they

achieve comparable gains in knee range of movement whilst requiring less treatment time by the patient and with limited or no standard physiotherapy treatment.

1. Introduction

Osteoarthritis (OA) is a leading cause of pain and disability among adults [1]; its causes are complex and multifactorial [2]. Total knee replacement (TKR) is commonly performed as part of the management of severe OA, however studies across a number of countries consistently report around 18% of patients are dissatisfied following surgery, with

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one primary reason being arthrofibrosis [3]. Arthrofibrosis is an exaggerated inflammatory response to surgery or injury resulting in extensive scar tissue causing severe pain and loss of range of movement [4]. Basic activities of daily living such as walking, standing up from a chair and climbing stairs are often severely affected [5–8]. Conventional physiotherapy interventions for patients with arthrofibrosis includes passive stretching, joint manipulations and home exercises aimed at increasing the length and density of tissues to achieve plastic deformation enabling the patient to regain knee range of movement (ROM) [9,10]. Unlike elastic deformation where tissue reverts back to its original length once the force is removed, plastic deformation leads to permanent elongation and remodelling of the tissues [11] and is essential if ROM is to be restored (see Fig. 1 illustrating the length tension curve of skeletal soft tissues).

For treatment to be effective soft tissues including some or all of the following: muscles, tendons, ligaments, ECM (scar tissue) and capsules [4] must be stretched every 24 hrs [12,13]; however, public and private healthcare resource limitations rarely allow physiotherapy time to perform effective manual stretching on a daily basis. Moreover, pain and difficulty in performing exercises at home frequently limits patients' progress to achieve plastic deformation [13] with often modest improvements from using physiotherapy alone [14]. Esler et al.'s [15] study reported a mean increase of just 3.1° in a group of patients with arthrofibrosis following TKR, treated with physiotherapy alone. Poor progress results in 5.8% of cases requiring further manipulation under anaesthetic (MUA) as a minimum intervention, and of these 15% also required further surgical intervention including revision surgery [5,16].

Medical stretching devices are increasingly being used to treat patients at home following TKR but none are available as part of the National Health Service in the United Kingdom.

Deformation of tissues can be achieved by applying an external force which can be attained by either applying a constant, prolonged, low load or by displacing the tissues a specific distance. Medical stretching devices fall into two main categories. Load control where a specific, constant, low force is applied across a joint for an extended period of time such as 8–10 hrs and displacement of tissues occurs gradually over time. This is also known as 'creep loading' method. Examples of these load control – creep loading devices include traction therapy and dynamic splints.

Conversely, the second category displacement control devices involve the tissues initially being placed under a large amount of stress, near the end of ROM [11,17]. As tissues accommodate and remodel, resistance to stretch decreases and plastic deformation occurs. Patients regularly increase the displacement a specific amount as discomfort allows. This utilises the biomechanical principles of 'stress-relaxation' by applying progressively increasing constant displacements, this can also be termed static progressive stretch (SPS) [18]. Example devices are Static-Pro, JAS and The ERMI range which includes the Flexionator and Extensionator,

however the latter apply greater loads so have been further split and termed Patient Actuated Serial Stretch (PASS) method devices [19].

There are a number of different nomenclatures used in the published literature [18]. For the purposes of this review to aid clarity of the stretching techniques employed in research studies the term load control - creep (*LC creep*) will be used to define low load, long duration devices. The term displacement control (stress relaxation) (*DCSR*) will be used to define the higher load shorter duration devices. Continuous Passive Motion (CPM) devices do not fall neatly into either *DCSR* or *LC creep* categories but a third category combining elements of both. CPM machines have been used for 25 years to facilitate joint regeneration [20]. The concept of CPM was created by Robert Salter [21] the underlying theory initially being that joint motion would promote healing and degeneration of cartilage but its major clinical use has been to prevent arthrofibrosis in a painless manner that does not create any wound-healing complications following TKR or other surgery [17]. CPM machines enable the joint to be cycled in a slow, passive and controlled manner. The motion is cyclic with a displacement taking place but uses elements of the *LC creep* method as a low level of force is applied and this level is maintained for several hours before it is increased. The literature shows duration of treatment sessions varies from 1.5 to 24 hrs per day [22]. The long treatment time may be a barrier to patient adherence and CPM's are large devices less suitable for use in the home. However less pain is experienced using the CPM whilst *DCSR* involving higher intensity bursts of static stretching maybe more painful for the patient [11]; however this may be better tolerated for a short period than undergoing a state of discomfort for a prolonged period with perhaps less immediate and rewarding results.

A positive outcome of CPM is that patients do experience an initial increase in ROM greater than those not using it. Avoiding stiffness in the early stages minimises the chances of progression to fibrosis of the joint [23]. There may also be psychological benefits as patients feel they are doing something to help them recuperate even when resting. Although many studies have been performed to evaluate the effectiveness of CPM the results are inconsistent and inconclusive because of sample size and heterogeneity of subjects. Meta-analysis of nine randomised controlled trials up to 2014 cast doubt about the effectiveness of CPM devices [24]. They report no significant difference between CPM and non CPM treated patients in terms of ROM and knee extension at six weeks, three months and after six months.

An economic evaluative study found home mechanical therapy devices (*DCSR LC Creep*) resulted in significantly reduced rates of re-operation when compared to standard physiotherapy and they were shown to be economically superior [25]. Three previous descriptive reviews of the devices currently available [11,26,27] have all concluded that medical stretching devices aid increase in ROM. However none of these three reviews were conducted in a systematised approach involving quality assessment, and more published research is available. This systematic review therefore aims to examine the available evidence to facilitate an understanding of different types of devices and their categories. This will enable identification of robust conclusions as to possible effectiveness of these interventions and plans for future works.

This review discusses relevant theories and concepts that underpin the research, including terminology used to define stretching techniques and brings clarity to the appropriate use of these terms [28]. The review suggests a focus for future studies addressing limitations in current research and identifies gaps in the published literature.

1.1. Materials and Methods

This systematic review followed the PRISMA Framework and is registered with PROSPERO Reg no CRD42018115910.

1.2. Search strategy

PubMed, Cochrane Central Register of Controlled Trials, MEDLINE

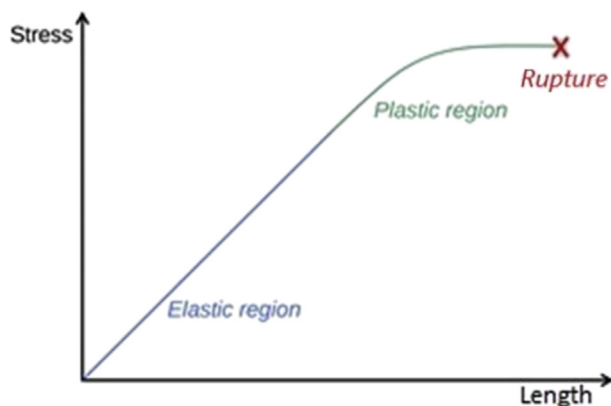


Figure 1. Length tension curve of skeletal soft tissues (Creative Commons 2018, Creative Commons Attribution-ShareAlike 3.0 License.).

and SCOPUS databases were searched with no date limit to identify potentially relevant journal articles. The search was undertaken by two independent reviewers in May 2020. The search performed used the following keywords and subject headings: arthrofibrosis OR stiff* OR contracture* AND range of movement OR range of motion AND knee replacement OR knee arthroplast* OR knee injur* AND stretch* OR static progressive stretch OR stress relaxation OR displacement control OR load control OR creep OR continuous passive motion. See Table 1 for example of search strategy.

1.3. Selection

Articles were selected based on the following inclusion criteria: 1) Patients with knee 'arthrofibrosis, stiffness or contracture' excluding neurology, haematology and non-ambulatory/bedbound patients. 2) Patients receiving treatment for ROM deficit using a medical device for stretching. 3) Articles from peer reviewed journals excluding reviews and case studies/case series. 4) Articles written in English and involving human participants only. A hand search was also conducted reviewing the reference lists of the retrieved papers.

Eligibility assessment was performed independently in an unblinded standardised manner by two reviewers (SA and ZB). Full text screening was required in 33/370 of the articles. Any differences in opinion between reviewers was resolved through a discussion of the full text, a third reviewer (DF) was available for a binding decision if agreement could not be reached, however this was not required.

1.4. Data abstraction, quality assessment and data synthesis

A data extraction sheet (based on the Cochrane Consumers and Communication Review Group's data extraction template for Included

Table 1
MEDLINE search strategy.

PICO	ID	Query
Limited to English	S27	S5 AND S13 AND S19 AND S24
Combined topics	S26	S5 AND S13 AND S19 AND S24
	S25	S5 AND S13 AND S19 AND S24
Population	S24	S20 OR S21 OR S22 OR S23
	S23	(MM "Arthroplasty, Replacement, Knee")
	S22	TI "Knee"
	S21	AB "Knee*"
	S20	TX "Knee*"
Intervention	S19	S14 OR S15 OR S16 OR S17 OR S18
	S18	(MM "Motion Therapy, Continuous Passive")
	S17	(MM "Muscle Stretching Exercises") OR (MM "Nerve Expansion")
	S16	TI "stretch*" OR "static progressive stretch*" OR "stress relaxation" OR "load control" OR "displacement Control" OR "creep"
	S15	AB "stretch*" OR "static progressive stretch*" OR "stress relaxation" OR "load control" OR "displacement Control" OR "creep"
	S14	TX "stretch*" OR "static progressive stretch*" OR "stress relaxation" OR "load control" OR "displacement Control" OR "creep"
Outcome	S13	S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12
	S12	(MM "Range of Motion, Articular+") OR (MM "Arthrometry, Articular")
	S11	TI flexion
	S10	AB flexion
	S9	TX flexion
	S8	TI "range of movement" OR "range of motion"
	S7	AB "range of movement" OR "range of motion"
	S6	TX "range of movement" OR "range of motion"
Problem/population	S5	S1 OR S2 OR S3 OR S4
	S4	(MM "Contracture+")
	S3	TI arthrofibrosis OR stiff* OR Contracture
	S2	AB arthrofibrosis OR stiff* OR Contracture
	S1	TX arthrofibrosis OR stiff* OR Contracture

Studies Version 1.6.2015 [29] was designed and pilot-tested on three randomly selected included studies and refined accordingly. One review author (SA) extracted all the data from the studies and the second author (ZB) checked it against the full-text articles of included studies.

A scoping search revealed a paucity of research investigating the use of medical devices to treat knee stiffness involving a mixture of randomised clinical trials and single arm studies. Therefore to investigate the potential bias at study and outcome level the Downs and Black (1998) [30] quality assessment tools for randomised controlled trials and non-controlled trials was used [31,32].

The small number and heterogeneity of studies render the data unsuitable for synthesis by means of meta-analysis. There are difficulties in quantifying a measure of an 'average effect' across studies due to differences in interventions, comparisons, designs, methods and data reported. Accordingly, the study data (results) is presented in tables, supported by a structured synthesis in accordance with the PRISMA guidelines [33].

2. Results

2.1. Search results

The searching of the databases produced a total of 701 articles which were reduced to 370 after duplicates were removed. 326 articles were excluded after screening their titles and a further 23 after review of their abstracts, leaving 21 relevant articles. Further searches of the articles' reference lists identified 12 additional articles which were reduced to 2 after reading their full text. In total 33 articles were obtained in full text, all of which were written in English. Seven studies did not identify patients as having either stiffness, arthrofibrosis or contracture, six did not involve a medical stretching device, five were not empirical studies, two were case studies, and one involved patients' receiving nerve blocks whilst using the device. A total of 12 articles (13 studies - Seyler et al., 2007 includes two separate trials*) were deemed relevant for inclusion in the review.

See Fig. 2 Flow chart outlining the study selection process.

2.2. Study characteristics

Tables 2–4 provide information regarding the researchers working in the field, their locations, name of the devices used in each study, the stretching technique employed and study characteristics.

Two studies utilised CPM type devices, five studies involved use of a *LC creep* device and six studies involved *DCSR* device. 183 patients were tested in the CPM studies, 184 patients in the *LC creep* studies and 186 in the *DCSR* studies, resulting in 553 patients studied in total. The aetiology of arthrofibrosis in the studies was predominantly following knee replacement, although other aetiologies were included (see Tables 2–4 for details). All 183 patients in the CPM studies had undergone TKR. Of the *LC creep* studies 151 had undergone knee replacement (partial or full) whilst 38 knees had developed arthrofibrosis following another condition. In the *DCSR* studies 102 patients had undergone knee replacement and 84 developed arthrofibrosis following other procedures or pathologies. The quality of the study designs was mixed including two randomised clinical trial studies [17,19], six single arm trials [18,35–39] and five retrospective study designs [9,34a,41,40,34b].

2.3. Dose

The results indicate that the stretch dose applied using the *LC creep* devices were performed over a longer treatment time compared to the *DCSR*; of note a shorter but more flexible dose was prescribed by study [19] using a Patient Actuated Self Stretch (*PASS*) device (see Tables 2–4).

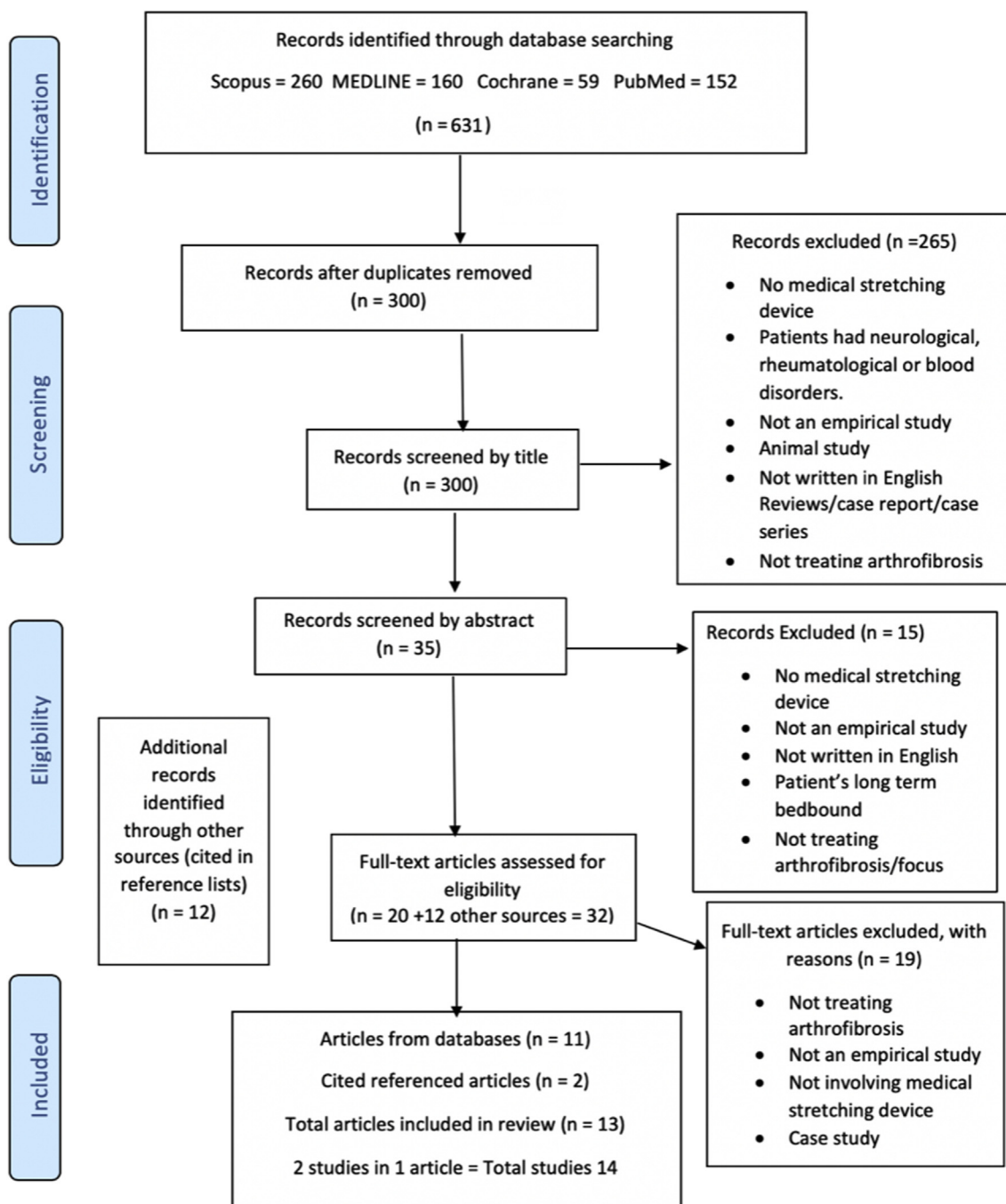


Figure 2. Moher et al. The PRISMA Group (2009): Flow chart of the article selection process in this systematic review.

2.4. Sample demographics

Previous research has found no statistically significant difference in ROM achieved and factors such as age, gender, time from surgery, or time from diagnosis of arthrofibrosis to treatment [18,19,38,39]. The results presented by the included studies support this as any differences between studies was checked and deemed of no significance.

2.5. Risk of bias - Downs and Black quality assessment tool

Presentation of the results of the quality assessment of the studies is shown in Table 5. The methodological quality (scores) across the studies are mixed. Seven out the thirteen studies had a poorer methodology or design scoring between 7 and 14, four of these seven are *LC creep* studies,

two *DCSR* and one *CPM*.

All except one of the *DCSR* studies (34b) scored full marks for the questions relating to the category 'External Validity' (see Table 5) meaning the generalisability of the results to similar populations is strong. However only one of the *LC creep* [41] and one *CPM* study [17] scored full marks in this section, most falling short as studies did not clearly state how participants were recruited, and whether they were representative of the entire population. Some treatments received were not representative of normal treatment, with extended inpatient stays and/or extensive daily physiotherapy provided.

The two clinical trials (studies 17 and 19) by Witvrouw et al. (2013) (*CPM*) and Papotto and Mills (2012) (*DCSR*) achieved high scores of 24/32 and 27/32 respectively fulfilling approximately 80% of the quality assessment tool criteria. Only four criteria were not fulfilled in study 19,

Table 2
Outline of CPM studies included studies.

CPM Studies											
Ref No ^o	Authors, date	Study design	Location	Sample (n)	Name of device	Dosage	Duration	Primary OCM	FU: time	Satisfaction OCM	PT
[37]	Werner (2015)	Single arm trial	US	78 TKR	A CPM machine	Week 1 CMP continuous 22 h per day on none physio days. Outpatient Physio 3 x a week on these days 18 h CPM a day. Week 2: CPM 8 h a day.	2 weeks	ROM: instrument not specified	Y Initial at mean 7.4 weeks. 71/78 participants followed up at 74 weeks	N	Y
[17]	Witvrouw 2013	RCT	Belgium	105 TKR (64 CPM 41 MUA)	Computer controlled motion technology (CPM)	Minimum 1 h 20 min daily (unlimited maximum)	6 weeks	ROM: UG	N	N	Y

FU = follow-up OCM = outcome measure PT = Physiotherapy STR = soft tissue release UG = Universal Goniometer TKR = total knee replacement MUA = Manipulation Under Anaesthetic ROM = range of movement RCT = randomised controlled trial CPM = continuous passive motion

five in study 17.

Long term follow ups were carried out by Ref. [18,35,37,38,40] (see Tables 2–4 for details). All the other studies failed to complete long term follow ups.

Opinions and discussion will focus primarily on the randomised clinical trials and the single arm studies which have been identified to have superior validity, reliability and methodological rigour (>15 points) by the Downs and Black (1998) [30] quality assessment tool.

3. Study results

3.1. Mean change in ROM results

The primary outcome measure in all studies was ROM. A statistically significant increase in ROM was shown in all the groups including 2 CPM studies [17,37] (Table 6), 1 LC creep study [35] (statistical significance was not measured in two further LC creep studies but increases in ROM were over 30°) (Table 7) and 4 DCSR studies [18,19,39,40] (Table 8). The randomised controlled trial using CPM by Witvrouw et al. (2013) [17] treats and measures flexion and extension ROM finding a significant mean ROM increase in flexion of 34.6° +/- 17° following use of the CPM device.

Table 8 sets out the mean increase in ROM of DCSR devices. The DCSR device used in the randomised clinical trial by Papotto and Mills (2012) [19] is the knee Flexionater a variable load/variable position device that uses a hydraulic pump and a quick release mechanism to allow patients to perform dynamic stretching exercises in the home without assistance. The study reports a mean increase in ROM of 29.9° in the high intensity stretch (HIS) DCSR group and 17.0° in the 'low intensity stretch' (LIS) (DCSR) group ($P < 0.00$) but the standard deviation or range within the change in ROM was not provided. The difference in change between groups is 12.9° and therefore fulfils the predetermined minimal clinical important difference stated of 12° or more. However the pooled standard deviations of the change in ROM are not provided. It appears that the HIS (PASS) (DCSR) stretching technique is superior to the LIS (DCSR) technique. This is further supported by Branch et al.'s (2003) study using the same HIS (PASS) device demonstrating the greatest increase in ROM of all the studies in this review attaining a mean of 59.8° (range 23°–104°). Bonutti et al. (2008) [18] (DCSR) report a mean increase in total ROM of 33° (range 0°– 85°) and in flexion 24° (1°– 80°) using the JAS device. Study 38 (Bonutti et al., 2010) reports a median increase in total ROM of 25° (range 8°– 82°), 19° flexion (range, 5°– 80°). There is a noteworthy large variation in increase in ROM between participants. Overall, the results indicate similar increases in ROM using LC creep and DCSR

stretching devices, although as previously highlighted the differences in study methodologies have prevented a formal meta-analysis being performed.

The JAS knee brace was used in Bonutti et al.'s 2008 and 2010 studies [18,38] the device uses static progressive stretch to permanently lengthen shortened connective tissues to regain ROM. A typical stretching session lasts 30 min and sessions are repeated up to three times per day. According to the manufacturer the JAS is designed to stimulate manual therapy. There are no RCT's demonstrating that either the Flexionator or the JAS significantly improved patient outcomes and both are considered experimental and investigational [42].

3.2. Secondary outcome measure: WOMAC- pain, stiffness and physical function

Papotto and Mills (2012) [19] is the only DCSR study to investigate patient reported outcome measures (PROMs), and this study used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC Scale), to assess pain, stiffness and function. The WOMAC is a validated tool and has been recommended for evaluating joint pain and function in total knee replacement patient populations by the National Institutes of Health [43]. All patients in the study by Papotto and Mills (2012) (study 19) demonstrated significant improvement in mean WOMAC Scores, although the high intensity stretch (HIS) group (DCSR) demonstrated significantly greater gains (pre = 54.1, post = 79.7, change = 25.6) than the low intensity stretch (LIS) group (DCSR) (pre = 60.6, post = 73.0, change = 12.4, with the difference between groups $p = 0.048$. Post treatment ROM significantly correlated with post treatment WOMAC scores ($r = 0.53$, $p = 0.02$).

The CPM randomised clinical trial (study 17) by Witvrouw et al. (2013) also used the WOMAC scale. Total scores were recorded and the separate subcategories of pain, stiffness and function. ROM and WOMAC scores were recorded weekly over the 6-week intervention period. In both the CPM device and MUA group a significant mean increase in ROM and WOMAC (total scores and sub scores of pain, stiffness and function) was reported between pre-treatment evaluation and weeks 2 and 6 weeks ($p < 0.05$). No significant difference was found between groups in total or sub scores. However at week 6 the mean function sub-score results were better in the CPM group than the MUA group ($p = 0.065$). Other research has shown substantial decreases in ROM following MUA over time with some requiring repeat MUA or further surgery [44–49]. This initial gain then deterioration in ROM may be explained by an abnormal inflammatory response caused or exacerbated by the sudden breakdown of scar tissue, lack of physiotherapy and or the opportunity to complete

Table 3
Outline of Load Control (LC Creep) included studies.

Load Control (Creep) Studies											
Ref No ^o	Authors, date	Study design	Location	Sample (n)	Name of device	Dosage	Duration	Primary OCM	FU: time	Satisfaction OCM	PT
[9]	Bhave 2005	Retro-spective audit	US	32 TKR (23 Ext) (9 Flex)	Custom knee device (Dynacast PII) different device for extension and flexion.	Ext:30–45 min 3 x a day before physiotherapy 5x a week first few weeks. In some cases used up to 8 h Flex: 30–45 min 2–3 x day plus aggressive physiotherapy (STR, joint mobilisations)	Not specified	ROM: instrument not specified	N	N	Y
[41]	Bhave, 2015	Retro-spective	US	23 patients 27 limbs following femoral lengthening with an internal device for treatment of limb length discrepancy (mean 5.4 cm lengthening performed) Age mean 25 (range 11–58)	Custom knee device (Dynacast PII)	Wear at maximally tolerated tension 6–8 h daily. Use for an additional 2–3 weeks for 1 h, twice a day, even after full extension is achieved, to maintain the correction obtained.	Mean 3.8 weeks mean 7.9 weeks (range 5–11 weeks)	ROM: UG Supine - hip in 10–15 hip flexion.	Initial 3.9 weeks Mean 7.9 weeks	N	Y
[35]	McGrath 2009	Single arm	Belgium	41 TKR	Custom knee device (Dynacast PII)	30–45 min 2–3x a day	Mean 8 weeks, range 6–16 weeks.	ROM: UG	Y At 2 years	Y	Y
[34a]	Seyler 2007 ^(*1)	Retro-spective Multi arm trial	US	79 TKR (78 patients)	Custom knee device	Flex: 30–40 min 2–3x/day Ext: 30–40 min 2–3 x/day	Not specified	ROM: UG	N	N	Y
[36]	Suksathien (2010)	Single arm trial	US	10 participants, 11 knees multiple aetiologies of contracture such as burn scar contractures, intra-articular fractures, septic arthritis, juvenile rheumatoid arthritis, and immobilization 35.2 years old (range 4–66) in the knee contracture group	Splint for knee	Wear the splint as much as possible/ approx. 20 h/day, including night-time. Splint removed every 1–2 h for ROM exercises and hygiene care. Taught to self-adjust the telescopic rod for appropriate force for stretching to the point of discomfort, but not pain, 4 times a day.	Mean 9.2 weeks (range 4–16)	ROM: UG	N	N	N

*1 = Same paper – containing two different studies

FU = follow-up OCM = outcome measure PT = Physiotherapy STR = soft tissue release ACLR = Anterior Cruciate ligament repair PCLR = Posterior Cruciate ligament repair MPFL = Medial patella femoral ligament repair UG = Universal Goniometer TKR = total knee replacement MUA = Manipulation Under Anaesthetic
Ext = extension Flex = Flexion ROM = range of movement RCT = randomised controlled trial

stretching exercises independently at home. This again emphasises the requirement for long-term (>6 months) follow-ups to be incorporated into study designs.

3.3. Patient satisfaction

Acceptability of the devices was investigated in studies [18,35] and [38] using a Likert scale where 0 indicated complete dissatisfaction and 10 indicated total satisfaction. Study [35] (McGrath et al., 2009) reported a mean of 9 points (range 6–10). Study [38] (Bonutti et al., 2010) reported a median score of 9 points and 23/25 patients (92%) were satisfied with the results of treatment with the device reporting a satisfaction score of 6 or more, with only two patients reporting dissatisfaction with the device. Study 18 (Bonutti et al., 2008) found the mean ‘satisfaction’ score was 7.9 points (range 0–10). ‘Three patients reported dissatisfaction with the device. These included a 47-year-old male, a 53 years old

male and 64-year-old female. All three had undergone arthroscopic debridement for knee pain and subsequently had chronic knee stiffness and chronic pain.

4. Discussion

This review has identified that there is a paucity of research conducted in this field, with only thirteen studies identified, which include some research designs that fall lower on the hierarchy of evidence, and are compounded by heterogeneity in study intervention, outcome measure, and follow-up periods. This presents some difficulties in drawing firm conclusions from the available evidence. Of note is that all the studies used the universal goniometer (UG) to measure the primary outcome ROM. Only one of the included studies [35] performed intra and inter-rater testing to ascertain the assessor’s reliability when using the tool. Research indicates the UG may have questionable validity and

Table 4
Outline of Displacement Control (DCSR) included studies.

Displacement Control (DCSR) Studies											
Ref No ^o	Authors Primary	Study design	Location	Sample (n)	Name of device	Dosage	Duration	Primary OCM	FU time	Satisfaction OCM	PT
[38]	Bonutti 2010	Single arm trial	US	25 TKR	JAS Knee Device (Joint Active Systems)	Gentle stretch applied 30 min, every 5 min increase stretch.	Median of 7 wks (range 3–16 weeks).	ROM: UG	N	Y	N
[18]	Bonutti 2008	Single arm trial	US	21 TKR/UKR (of 48 total) 41? 9 ACLR/D, 2 distal femur fracture, 9 following multiple surgeries	JAS Knee Device (Joint Active Systems)	30 min, every 5 min increase stretch. 1st 5 days 1x a day, increased as tolerated - maximum 3x/day	Mean 9 weeks (range 3–27)	ROM: UG	N	Y	N
[39]	Branch 2003	Pro-spective Single arm trial	US	34 patients 14 ACLD 7 Peripatellar injury 4 Fracture 9 Miscellaneous	ERMI Knee/Ankle Flexionater	15 min/session 4–8 times a day. Hold stretch for 5 min followed by 5 min rest (repeated until 15 min elapsed)	ACLD (5wks; 2–12) Peripatellar (8.6wks; 4–16) Fracture (6wks; 4–8) Misc 8.1wks; 3–12)	ROM: UG	N	N	Y
[40]	Dempsey, 2010	Retrospective	United Kingdom	56 24 UKR/TKR, 2 OA, 17 ACLR No specific numbers of: Tibial plateau fracture, ORIF, meniscal surgeries, HTO, open MCL repair	ERMI Knee Extensionater	Six 10-min bouts of end-range stretching per day	3 months	ROM: Not stated	3 months initially. Final mean follow-ups 13.7 ± 11.5 months.	Y	Y
[19]	Papotto 2012	RCT	US	20 TKR (9 LIS 11 HIS)	ERMI Knee/Ankle Flexionater versus the Static Pro	HIS: Multiple times daily, 5–10 min, 10 min recovery. Stretch recovery cycles for 20–30 min. Total 60 min ER stretch/day. LIS: 3 × 30-min sessions/day increase the force every 5 min.	HIS: 6.9 weeks LIS: 7.1 weeks	ROM: UG	N	N	N
[34b]	Seyler 2007 ⁽⁺²⁾	Retrospective Multi arm trial	US	30 TKR (29 patients)	JAS Knee Device (Joint Active Systems)	“As described by Bonutti et al. Bonutti 1994” 30 min every 5 min increase stretch.	Mean 9.4 ± 7.8 weeks	ROM: Not stated	N	N	N

*1 = Same paper – containing two different studies

FU = follow-up OCM = outcome measure PT = Physiotherapy STR = soft tissue release ACLR = anterior cruciate ligament repair ACLD = anterior cruciate deficiency HTO = high tibial osteotomy UG = Universal Goniometer TKR = total knee replacement UKR = Unicompartamental knee replacement MUA = Manipulation Under Anaesthetic ROM = range of movement RCT = randomised controlled trial ORIF = open reduction internal fixation HIS = high intensity stretch LIS = low intensity stretch

reliability especially inter-rater where multiple assessors are involved in measuring the joint. Inter-rater reliability consistently underperforms intra-rater reliability [49,50]. Specific reporting of the intra-rater reliability of the individual tester, the measuring procedure and setting would greatly increase the validity and reliability of the results. Bonutti et al. (2008) [18] and Bonutti et al. (2010) [38] measurements may possess greater reliability as the same physiotherapists recorded and evaluated all ROM measures for each patient. Bonutti et al. (2010) [38] further raises the reliability of their results by confirming two of the papers' authors previously reported inter and intra-rater variability of 3° or less in 100% of cases for knee extension and 95% for knee flexion

cases.

Another key issue arising from the review concerns the ambiguity in defining terms by researchers to describe stretching procedures and devices. This can cause confusion for the reader and hampers a clear understanding of the research actually undertaken.

4.1. Mean ROM increase and implications for clinical practice

The results indicate that DCSR, LC creep and CPM devices improve ROM in patients with knee stiffness.

The mean increase across all the studies using CPM was 33°, in the LC

Table 5
Results of quality assessment tool for *all* studies (downs and black 1998).

	Reference No ^o	CPM studies		Load control studies					Displacement control studies					
		[37]	[17]	[9]	[41]	[35]	[34a]	[36]	[18]	[38]	[35]	[40]	[19]	[34b]
	Primary Authors, date	Werner 2015	Witvrouw 2013	Bhave 2005	Bhave 2015	McGrath 2009	Seyler 2007 (LC)	Suksathien 2010	Bonutti 2008	Bonutti 2010	Branch 2003	Dempsey 2010	Papotto 2012	Seyler 2007 (DCSR)
Reporting	1) Hypothesis clear	no	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	yes
	2) Main outcomes clearly described	no	yes	no	yes	yes	yes	no	yes	yes	yes	yes	yes	yes
	3) Participant characteristics clearly described	yes	yes	no	yes	yes	yes	yes	yes	yes	yes	no	yes	yes
	4) Interventions of interest described	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	5) Distribution of principal confounders in each group described	no	yes	no	no	no	no	no	no	no	no	no	yes	no
	6) Main findings described	yes	yes	yes	yes	yes	yes	yes	yes	no	yes	yes	yes	yes
	7) Provide estimates of random variability in primary OCM data	no	yes	no	no	no	no	no	yes	yes	yes	yes	yes	no
	8) All adverse events lined to intervention reported	no	yes	no	yes	yes	no	yes	yes	yes	yes	no	yes	no
	9) Characteristics of patients lost to follow up described	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	10) Actual probability values reported	yes	yes	no	no	yes	no	no	no	yes	yes	yes	yes	no
External Validity	11) Subjects approached representative of entire population recruited from	no	yes	?	yes	yes	?	?	yes	yes	yes	yes	yes	?
	12) Subjects prepared to participate representative of entire population recruited from	no	yes	?	yes	yes	?	?	yes	yes	yes	yes	yes	?
	13) Staff, places, facilities representative of treatment the majority of patients receive.	yes	yes	?	yes	no	yes	yes	yes	yes	yes	yes	yes	yes
Internal Validity - bias	14) Attempted to blind study subjects	?	no	no	no	no	no	no	no	no	no	no	no	no
	15) Attempted to blind investigator	no	no	no	no	no	no	no	no	no	no	no	no	no
	16) If data dredging' used this is made clear	yes	yes	yes	yes	no	no	yes	yes	yes	?	yes	yes	yes
	17) Do analyses adjust for different lengths of follow up?	?	yes	no	yes	no	no	yes	no	no	yes	no	yes	no
Internal validity - confounding	18) Statistical tests appropriate	yes	yes	no	?	yes	no	no	yes	yes	yes	yes	yes	no
	19) Compliance with intervention reliable	yes	yes	yes	yes	no	yes	no	yes	Yes	yes	yes	yes	yes
	20) Main outcome measure accurate)	?	no	no	?	yes	no	?	yes	yes	?	no	no	no
	21) Were patients in different intervention groups recruited from the same population?	yes	yes	no	yes	no	yes	?	no	no	yes	?	yes	no
		yes	yes	no	yes	no	no	yes	no	no	yes	?	yes	no

(continued on next page)

Table 5 (continued)

Reference No ^o	CPM studies			Load control studies			Displacement control studies							
	[37]	[17]	Witvrouw 2013	[9]	[41]	[35]	[34a]	[36]	[18]	[38]	[35]	[40]	[19]	[34b]
Primary Authors, date	Werner 2015			Bhave 2005	Bhave 2015	McGrath 2009	Seyler 2007	Suksathien 2010	Bonutti 2008	Bonutti 2010	Branch 2003	Dempsey 2010	Papotto 2012	Seyler 2007 (DCSR)
22) Study subjects in different intervention groups?	no	yes		no	no	no	no	no	no	no	no	?	yes	no
23) Study subjects randomised to intervention groups?	no	no		no	no	no	no	no	no	no	no	no	no	no
24) Intervention concealed from patient and staff	?	no		no	no	no	no	no	yes	yes	yes	no	yes	no
25) Adequate adjustment for confounding analysis from which main findings found?	yes	yes		yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
26) Losses to follow up taken into account?	no	yes = 3		no	no	no	no	no	no	no	no	no	yes = 5	no
27) Sufficient power to detect clinically important effect where P < 0.05	12	24		7	16	13	12	10	17	17	19	14	27	10
Total Score														

creep studies 30° and in those using DCSR devices there was a mean increase of 30°. It is important to note all the CPM studies and all but one of the LC creep studies [36] involved frequent additional physiotherapy treatment sessions, whereas only two [39,40] of the DCSR studies involved physiotherapy treatment. It would be expected that regular physiotherapy used in the CPM and LC creep studies would make a positive contribution to increased ROM and is a confounding factor that needs to be considered. Moreover, the CPM and LC creep devices are worn for longer treatment times which can reduce patients' adherence to using the devices [11,27]. Whilst longer treatment times can be supervised in hospital, it is expected patient adherence may suffer in the home setting.

McElroy et al. (2013) comments that CPM devices are cyclic using very short cycles of stretch and relaxation with almost no sustained hold in flexion/extension. They are low intensity applying a low load. McElroy et al. (2011) [11] and Ulrich et al. (2010) [51] indicate that DCSR devices cause tissues to reach plastic deformation more quickly than when applying a creep-based load. When considering results in the two randomised clinical trials Witvrouw et al.'s (2013) [17] study reports an increase in mean flexion of 34.6° which is larger than Papotto and Mills (2012) [19] DCSR study which reports a mean increase of 29.9°. However, Witvrouw et al.'s (2013) [17] study involved daily additional physiotherapy for first two weeks then twice a week for the remaining four weeks, whilst Papotto and Mills (2012) [19] participants received no additional physiotherapy. Conventional non-surgical treatment for arthrofibrosis is aggressive intensive physiotherapy where force is applied to the joint end range to increase ROM. High intensity stretching must be performed daily for plastic deformation to be achieved, the scar tissue broken down and tissues reformed. Physiotherapy in Witvrouw et al.'s study (Witvrouw, Bellemans and Victor, 2013) met these criteria and is likely to have significantly contributed to ROM gained. Furthermore, Witvrouw et al.'s (2013) [17] patients' pre-treatment mean ROM was 50.3° far less than Papotto and Mills (2012) [19] which was 74°. Both factors could have contributed to raising the mean increases in ROM for Witvrouw et al.'s (2013) [17] CPM study.

4.2. Variation in knee ROM

The wide range in ROM increases of individual patients within the same study is observed in many of the studies - see ranges or standard deviations in Tables 6–8. The range can be wide, for example Bonutti et al. (2008) [18] reported a variation increase in ROM of between 4° and 85°. The standard deviations reported by Seyler et al.'s (2007) [34b] results indicate considerable variation in that a proportion of the population had a large increase in extension range (15.5°) whilst the remainder made hardly any improvement (regression by 1°). In Witvrouw et al. (2013) [17] the CPM group's standard deviation (SD ± 17° around a mean of 34.6°) indicate that a proportion of the sample improved by over 45° and another proportion of the sample by less than 20°. This suggests that some patients made considerable gains whereas others may have made none at all. The MUA group's standard deviation (+/- 19.9° around a mean of 23.3°) indicate that a proportion of the sample improved by over 40° and another proportion of the sample by less than 4.

No comment was made by the authors in any of the included studies concerning individuals at extremes of ROM. It seems apparent that in addition to use of the intervention device that other variables are important factors resulting in the wide range of the mean scores and these should be investigated further to identify improvements in clinical practice.

4.3. Secondary outcome measure: WOMAC

The improvements in WOMAC scores recorded in the randomised clinical trials by Papotto and Mills (2012) [19] and Witvrouw et al. (2013) [17] are significant and expressed as means, as is the case with ROM measures. The failure to provide details of the scores of individuals

Table 6
Change in ROM Results CPM devices.

Authors, Primary	CPM STUDIES				
	Mean increase in ROM (°)	Statistically significant	Mean pre/post treatment ROM (°)	Mean total motion (°)	Function (OCM)
Werner 2015 [37]	7.4 weeks mean change in ROM: 31° 7.4 weeks change in flexion: 25 7.4 weeks change in extension 5° at 74 weeks mean change in ROM: 36° at 74 weeks change in flexion: 30° at 74 weeks change in extension: 5°	Change in flexion, extension angles and overall ROM all highly significant at (p < 0.001) Remained highly significant at long term follow up (p < 0.001)	Pre Mean ROM: 80 ± 17.2 Median extension: 5 Median flexion: 90 at 7.4 ± 2.5 weeks: Mean ROM 111 SD 14.2 Median Flexion 115 Median extension 0 at Mean 74 weeks: ROM 116 ± 14 median extension: 0 Median flexion: 120	7.4 weeks mean change in ROM: 31 at 74 weeks mean change in ROM: 36	N
Witvrouw 2013 [17]	LC: Mean flexion increase 34.6° (±17.02°) MUA: Mean flexion increase 23.3° (±19.89°)	Flexion: pre/post intervention both groups sig increase (p < 0.05). Diff between groups not statistically significant (p = 0.067) Extension: No sig difference in MUA group pre/post intervention. Sig diff in CPM extension group pre-treatment to week 6. (p = 0.003 active, p = 0.001 passive)	CPM: Pre 68.5° ± 18.2° MUA: Pre 73.5° ± 15.6° Post measures not stated.	N/A	Y

patients prevents investigation of factors underlying the wide range in degrees of increase in ROM found in Papotto and Mills (2012), Witvrouw et al. (2013) [17], Seyler et al. (2007) [34b] and Bonutti et al. (2008 and 2010) [18,38] studies. Witvrouw et al.'s (2013) [17] study is more informative as it reports on the mean sub scores of pain, stiffness and function in both intervention groups which identifies possible areas which could affect adherence, for example pain, stiffness, function, motivation; yet still presents improvements as means.

The failure in all the studies to investigate further the wide variation in both primary and secondary outcomes is a missed opportunity to inform and improve clinical practice in the treatment of knee arthrofibrosis. Qualitative research focussing on patients' experiences, especially those displaying optimal and suboptimal performances in improvement of ROM may clarify the underlying variables and could inform clinical practice.

4.4. Patient satisfaction and acceptability of the device

There is sparse research covering the acceptability of the devices in these studies and this is recognised by Wanivenhaus' et al. (2015) [52]. Randomised clinical trials by Papotto and Mills (2012) [19] and

Witvrouw et al. (2013) [17] do not formally explore the acceptability of the device to the patients or even make comments on patients' satisfaction or perceptions after using the device. Bonutti et al. (2008 and 2010) [18,38] and McGrath et al. (2009) [35] use a Likert scale where patients score their satisfaction out of 10. The Likert scale offers only the most basic information regarding patients' perceptions.

The failure to consider whether devices are acceptable to patients is a significant omission in the studies, as lower acceptability and comfort of the devices may limit compliance and thereby reduce effectiveness. Bonutti et al. (2008) [18] found the mean satisfaction score was 7.9 points (range 0–10). Three individuals who gained 8°, 17°, and 35° in ROM, respectively, from pre-treatment ROM of (100°, 78°, and 75°) reported satisfaction scores of 1, 2, and 0 points, respectively, however all stated that they continued to have knee pain. The results indicate that two of the patients experiencing pain had limited improvement in their ROM. Pain may result in limited patient adherence and it is possible that lack of progress may have been demotivating resulting in dissatisfaction with the device. However, the third person was performing above (35°) the overall mean ROM increase (33°). It seems likely in this case that continued pain accounted for the extremely low acceptability score of 0. Pain is a significant factor to be taken into account in all aspects of

Table 7
Change in ROM Results for Load Control (LC creep) Devices.

Authors, Primary	LOAD CONTROL (creep) STUDIES				
	Mean increase in ROM(°)	Statistically significant	Mean pre/post treatment ROM (°)	Mean total motion (°)	Function (OCM)
Bhave, 2005 [9]	Extension: <i>Vague</i> Flex: "nearly all achieved increase of 30°"	No stats	N/A	N/A	N
Bhave, 2015 [41]	Not provided and unable to work out based on figures provided.	No stats	Pre: Mean extension 36° (range, 10°–90°). Post Mean 7.9 weeks (range, 5–11 weeks): only 2 of 27 knees (7%) did not achieve <5°.	N/A	N
McGrath, 2009 [35]	Mean extension increase 20.6°	Achieved "full extension (0°) in 42 out of 47 (p < 0.001)"	Pre: 22° (10°–40°) Post: 1.4° (0°–15°)	N/A	Y
Seyler 2007 [30a]	"An overall excellent result was obtained in 71 knees (90%) treated with the custom knee device"	No stats	N/A	N/A	Y
Suksathien, 2010 [36]	Mean extension increase 38.6°	No stats	Pre: mean extension –53.6° (range –30 to –85) Post: mean extension –15° (range 0 to –30)	N/A	N

Table 8
Change in ROM Results *Displacement Control (DCSR)* devices.

Authors	DISPLACEMENT CONTROL (stress relaxation) STUDIES			Function (OCM)	
	Mean increase in ROM(°)	Statistically significant	Mean pre/post treatment ROM(°)		Mean total motion (°)
Bonutti 2010 [38]	Median Total ROM increase 25° (range 8°–82°) Median active flexion 19° (range 5°–80°) Median active extension 7° (range 2°–15°)	Intends to but does not provide answer if statistically significant or not.	Medians Pre: active flexion: 90° (38°–120°) Post: active flexion: 110° (64°–137°) Post active extension: –13° (–21° to –7°) Post active extension: –5° (–14 to 0)	Median total range of motion: pre: 76° (23°–112°) post: 105° (61°–137°)	N
Bonutti 2008 [18]	Mean increase in total ROM 33° (range 0° to 85°) 24° flexion (range 1° to 80°)	p = 0.012 NB Same value given to all. See table p274. Results as a whole (including other aetiologies of stiffness) statistically significant. No specific value for TKRs alone.	Mean Pre extension: 15° (3°–65°) Mean Post extension: 6° (0°–45°) Mean Pre flexion: 84° (30° to 110°) Mean Post flexion: 108° (65° to 135°) p = 0.001	Pre: 69° (21° to 100°) Post: 102° (55° to 130°) p = 0.001	N
Branch 2003 [39]	Mean increase in Flexion 59.8° (range 23°–104°)	The difference between initial ROM and final ROM for entire group is statistically significant at p < 0.000001.	<u>Flexion</u> Mean pre: 70.8 Mean post: 130.6	Not available: only measured 1 direction of movement	N
Dempsey 2010 [40]	<u>Extension</u> Mean increase pre to post: 7.9° Mean increase pre to final FU: 8.5°	Pre to 3 months visit: extension sig improved from 10.5° ± 5.2°–2.6° ± 3.5° (p < 0.001). Extension maintained at the most recent FU (2.0° ± 2.9°), which was sig greater than the initial visit (p < 0.001), but did not differ from the 3 month visit (p = 0.23). Extension gain did not differ between worker's compensation and non-compensation patients (p = 0.56).	<u>Extension</u> Pre: 10.5° ± 5.2° Post: 3 month visit 2.6 ± 3.5 Final FU: 2.0° ± 2.9°	N/A	N
Papotto 2012 [19]	HIS: Mean flexion increase 29.9 LIS: Mean flexion increase 17.0° (p 0.001)	Significant difference between groups at p = 0.001	<u>Flexion</u> HIS: Pre 81.6° ± 7.6 Post: 111.5° ± 6.7° LIS: Pre 84.9° ± 6.3 Post 101.9° ± 6.2	N/A	Y
Seyler's 2007 [34b]	Mean extension increase: 7.4° ± 8.1° Mean flexion increase: 15.1° ± 12.3°	No stats	<u>Total ROM</u> pre: mean of 85.4° ± 22.2° post: mean of 107.9° ± 16.8°	Total increase in flex/ext arc 22.5° ± 16.3° .	N

rehabilitation for TKR [53] including treatment involving medical stretching devices. Stretching tissues in the treatment of arthrofibrosis is a painful process as a degree of tissue damage is necessary to achieve plastic deformation, involving the breakdown of scar tissue followed by remodelling of the tissues, increase in their length and subsequently improved range of movement. Patients need to be informed about this prior to commencement of treatment, however pain associated with the stretching treatment process is rarely mentioned in the studies.

4.5. Dose and additional physiotherapy

Success of a stretching regime to achieve plastic deformation is dependent on the intensity, frequency and duration of the stretch [13], shorter dose duration will require a higher intensity stretch to maximise ROM as in *DCSR*. A low intensity stretch (as in *LC creep*) will require a longer duration to maximise ROM [11,27]. However, it appears although most *LC creep* devices are worn for longer treatment times, they don't necessarily result in a longer treatment duration (based on the number of weeks utilised) (see Tables 2–4). Because of the variation in dose prescription in each study it is also difficult to compare the results across studies. As noted earlier an apparent trend in the research is that CPM and *LC creep* studies involve use of the devices with significant additional physiotherapy whereas *DCSR* studies do not. The additional physiotherapy does not reflect the level available in clinical practice and reduces the external validity of the CPM and *LC creep* studies.

4.6. Ambiguity of terminology used to describe different types of stretching

A problem in the reviewed research is that authors use different terms to describe the stretching principles and procedures employed, creating difficulties for the reader to easily understand the techniques being used and/or compared.

In the studies reviewed *LC creep* stretching/devices are referred to as: 'creep deformation devices', 'creep-based loading', 'low intensity stretch' (LIS), 'low load devices', 'constant load-variable displacement', and 'sustained end range stretch' by different authors. *LC creep* involves application of a constant force to gradually stretch soft tissue and increase joint displacement from its original position [52]. A constant force is applied to the system which is allowed to gradually displace over time [11]. Therefore, *load control (LC creep)* seems the most suitable term. It combines the most scientifically correct term (*load control*) reinforced by the more easily understood term (*creep*).

Displacement control (stress relaxation) (DCSR) is referred to by different researchers as 'static progressive stretch', 'stress relaxation loading', 'low intensity stretching', 'progressive stretching', 'high intensity stretching' (HIS), 'end range motion improvement' (ERMI), and 'patient-actuated serial stretch' (*PASS*). As explained in McElroy et al.'s (2011) [11] review the *stress relaxation* principle is a key feature of *displacement control* which involves an initial large amount of stress (specific deformation across a joint) that decreases over time as the tissue relax. Plastic deformation of soft tissue is achieved through incremental increases in displacement. Therefore, the term *displacement control (stress relaxation) (DCSR)* seems the most appropriate term to use universally as

it combines the most scientifically correct term (*displacement control*) reinforced by the more easily understood term *stress relaxation*. Future researchers in the field of medical stretching devices need to agree on the definition of the terms for stretching techniques utilised to ensure greater clarity for readers.

Branch et al. (2003) [39] recognise three types of ‘stretching protocols’; *LC creep* - ‘Low load prolonged stretch (LLPS) and divide *DCSR* into static progressive stretch (SPS) and patient-actuated serial stretch (*PASS*). They define SPS as involving use of a brace to force the joint into a specific degree of flexion or extension. Once the patient can tolerate moving the joint further into the stretch the angle is increased. Only at the end of the session (recommended 30 min) the load on the joint is removed completely. Conversely during *PASS* patients dynamically stretch their joint into their end of range flexion for 1–5 min; for recovery they release into extension for equal time and the process is repeated for 15 min increasing the joint angle as pain allows. Three *DCSR* studies in this review use *PASS* devices [19,39,40] and the *PASS* devices demonstrated superior gains in ROM of 29% when compared to the SPS based devices (studies 18,34) with mean increases of 33° (flexion 24°) and 25° (flexion 19°) respectively. Further research directly comparing these two different types of stretching devices/protocols should be undertaken.

4.7. Limitations of this review

Although the Downs and Black (1998) [30] tool is recommended by Cochrane as one of two most appropriate tools to assess the quality of non-randomised controlled trial (RCTs) it has received criticism on two counts. 1) it is time consuming to use 2) it requires considerable epidemiological expertise concerning the factors which underlie the assessment of studies [31]. The authors of this review have epidemiological experience and have sought expert opinion on questions where answers were not easily deciphered. A moderate number of the studies were rated as high quality, and this may have led to an overestimation of effect. ROM was the only outcome measure used in seven of the thirteen studies and most studies have neglected to consider patients’ acceptability of the devices.

The heterogeneity of studies identified, does not lend itself to a meta-analysis. Currently there are only two randomised clinical trials investigating this topic. When more are completed with appropriate and comparable designs a meta-analysis will be possible.

5. Conclusion and recommendations

The systematic review indicates that Displacement Control (*DCSR*) devices are effective in increasing ROM in the treatment of knee stiffness. *Load Control (LC creep)* devices are also effective, but this cannot be said with as much confidence as in all of the studies using *LC creep* devices, patients also received additional, extensive physiotherapy treatment which may have contributed to their gains in ROM. Devices involving Patient Actuated Serial Stretching (*PASS*) techniques, may be more effective than static progressive stretch (SPS) devices. *DCSR* and *PASS* devices may be more appropriate for home use as they achieve comparable gains in ROM whilst requiring less treatment time by the patient and no additional physiotherapy. The ‘mid to upper’ quality research comprising some higher-level designs in the hierarchy of evidence supports this conclusion.

This systematic review makes the following recommendations:

1. Further research using randomised controlled trial designs is required to investigate efficacy of home medical stretching devices and longer term follow up of patients in the treatment of arthrofibrosis following TKR (minimum 6 months).
2. Most research using medical stretching devices reports results as mean increases in ROM. However there is a wide variation in the results and experiences of individual patients. Mixed methods research is required to explore underlying factors of patients

achieving successful ROM compared with those with sub-optimal outcomes (eg pain, fear, severity of stiffness, support, motivation and adherence) to inform clinical practice.

3. The variety of terminology used to describe the different types of stretching employed by different devices needs to be clarified and a consensus agreed on the definition of terms. The terms currently used by authors to describe types of stretching are inconsistent, varied and may leave the reader confused. This review suggests that the terms *load control/creep (LC creep)* and *displacement control/stress relaxation (DCSR)* further split into *DCSR- PASS* and *DCSR- SPS* should be used in future research.

Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

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