01.01.16 Mechanical Stretching Devices

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DISCLAIMER/INSTRUCTIONS FOR USE

Related Policies:

- None

Summary

Description

The use of mechanical stretching devices is designed to provide a prolonged stretch to joints that have reduced range of motion (ROM) secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders. The objective of stretch therapy is to improve ROM without compromising the stability and quality of the connective tissue and joint.

Summary of Evidence

Low-Load Prolonged-Duration Stretch (LLPS) Devices (Dynamic Splinting Devices)

For individuals who have functional limitations in range of motion (ROM) who receive low-load prolonged-duration stretch (LLPS) devices (dynamic splinting devices) and physical therapy (PT) for persistent joint stiffness or contractures secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders of the knee, elbow, wrist, finger, toe (hallux limitus of the great toe), shoulder and ankle the evidence includes systematic reviews, randomized controlled trials (RCTs), nonrandomized and observational studies. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life (QOL). There is limited evidence that use of dynamic LLPS devices for rehabilitation of joints, knee, elbow, wrist, finger and toe (hallux limitus of the great toe) may relieve joint stiffness, increase active range of motion (AROM) and decrease pain in the treatment of compliant patients. However, study limitations included small sample sizes and short follow-up timeframes of 12-months or less. Studies of dynamic LLPS devices for rehabilitation of shoulder and ankle have not yet demonstrated similar potential benefits. Further high-quality comparative RCTs to include larger sample sizes and longer follow-up are needed to further evaluate whether LLPS mechanical stretching device improves functional outcomes compared to alternative treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. However, even though there is limited peer-reviewed scientific evidence regarding the effectiveness of LLPS (dynamic splinting) devices in individuals with joint stiffness or contractures secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders of the knee, elbow, wrist, finger and toe (hallux limitus of the great toe) for carefully selected individuals, the use of LLPS (dynamic splinting) devices is widely consider to be in accordance with generally accepted standards of medical practice in the United States by orthopedists as well as physical and occupational therapists for selected populations. Therefore, in carefully selected individuals the use of LLPS (dynamic splinting) devices will be considered medically necessary when the criteria below are met, see Policy.

For individuals who have functional limitations in ROM who receive LLPS (dynamic splinting) devices for improved spasticity outcomes in individuals following neurological insults such as stroke, multiple sclerosis (MS), cerebral palsy (CP); or neurological trauma [such as brain injury [BI], spinal cord injury (SCI)], the evidence includes a systematic review (Khan et. al. 2017). Relevant outcomes include symptoms, change in disease status, functional outcomes, and QOL. In the systematic review which evaluated the evidence regarding the effectiveness of non-pharmacological interventions which included (stretching, passive movements, dynamic splinting) the findings of this review indicated there was low quality evidence regarding the effectiveness of dynamic splinting in the treatment of spasticity in the elbow related to stroke and use of this device in the other neurological conditions. Therefore, the evidence remains unclear regarding the use of LLPS (dynamic splinting) for the treatment of spasticity related to various neurological conditions. Additional studies are needed to build the evidence regarding the effectiveness of these devices for this indication which should include comparative RCTs to other mechanical stretching devices such as static progressive devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Static Progressive Stretch Devices

For individuals who have functional limitations in ROM who receive static progressive stretch devices and physical therapy, the evidence includes RCTs, a systematic review, and case series. Relevant outcomes include symptoms, change in disease status, functional outcomes, and QOL. Three RCTs have evaluated static progressive stretch devices but comparators in each differed (PT, a dynamic splint, and a serial stretch device). The evidence on static progressive stretch devices does not currently support an improvement in pain and function with static progressive stretch compared to alternative treatments. One RCT found greater improvements in ROM and Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores with serial stretch devices for the knee compared with static progressive stretch devices. Another RCT evaluating static progressive stretch for shoulder adhesive capsulitis found significant differences in shoulder ROM compared with PT alone at the end of 4 weeks of treatment, with no difference in pain and function. A trial reported results of 34 participants with adhesive capsulitis that compared static progressive stretch to physical therapy alone or the combination of stretch and physical therapy. Although significant improvements with static stretching were found compared with placebo in terms of range of motion, differences between groups were generally similar. A fourth RCT found comparable improvements in most outcomes for the static progressive stretch device compared with dynamic splinting, and a systematic review of case reports and series found similar clinical efficacy for increasing elbow range of motion between static progressive stretch devices and dynamic splints. Dynamic splints are used for 8 to 24 hours per day while static progressive stretch devices require several 30-minute sessions. It is not known whether patient compliance is higher with static progressive stretch devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Serial Stretch Devices

For individuals who have functional limitations in ROM who receive serial stretch devices and PT, the evidence includes an RCT and observational studies. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life. The best evidence consists of serial stretching with ERMI devices used to treat knee ROM. One small RCT and a larger retrospective comparative study have reported that high intensity stretching with ERMI devices improved ROM more than lower intensity stretching devices in individuals who were post-injury or surgery. Other available data consist of retrospective case series that have demonstrated improved ROM in individuals whose range had plateaued with PT. The clinical significance of gains in this surrogate outcome measure is unclear. Further high-quality comparative trials are needed to determine whether these patient-controlled devices improve functional outcomes better than alternative treatments and identify the patient populations that might benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable

OBJECTIVE

The objective of this evidence review is to evaluate whether mechanical stretching devices (e.g., static progressive stretch, low-load prolonged-duration stretch (dynamic splinting) or serial stretch) improve health outcomes in individuals with a decreased ROM.

PRIOR APPROVAL

Not applicable.

POLICY

Low-Load Prolonged-Duration Stretch (LLPS) Devices (Dynamic Splinting Devices)

Low-load prolonged-duration stretch (LLPS) devices (dynamic splinting devices) may be considered **medically necessary** for use on the knee, elbow, wrist, or finger in any of the following clinical settings:

A. As an addition to physical or occupational therapy in the subacute injury or post-operative period (greater than or equal to 3 weeks but less than or equal to 4 months after injury or surgery) in individuals with signs and symptoms of persistent joint stiffness or contracture:
    a. For an initial period of up to 4 months; **and**
    b. If the individual shows improvement after the initial period, thereafter for as long as improvement can continue to be demonstrated; **Or**
B. In the subacute injury or post-operative period (greater than or equal to 3 weeks but less than or equal to 4 months after injury or surgery) in an individual whose limited range of motion poses a meaningful (as judged by the physician) functional limitation, **AND** who has not responded to other therapy (including physical or occupational therapy);
    a. For an initial period of up to 4 months; **and**
    b. If the individual shows improvement after the initial period, thereafter for as long as improvement can continue to be demonstrated; **Or**
C. In the acute post-operative period for individuals who have undergone additional surgery to improve the range of motion of a previously affected joint:
    a. For an initial period of up to 4 months; **and**
    b. If the individual shows improvement after the initial period, thereafter for as long as improvement can continue to be demonstrated; **Or**
D. For individuals unable to benefit from standard physical or occupational therapy modalities because of an inability to exercise:
    a. For an initial period of up to 4 months; **and**
    b. If the individual shows improvement after the initial period, thereafter for as long as improvement can continue to be demonstrated.

Persistent Joint Stiffness of the Hallux Limitus (Great Toe)

Low-load prolonged-duration stretch (LLPS) devices (dynamic splinting devices) may be considered **medically necessary** for the treatment of persistent joint stiffness of the hallux limitus (i.e., degenerative pathology in the first metatarsophalangeal joint or the great toe) following bunionectomy or cheilectomy when provided within two months after surgery.

No Improvement after 4 Months of Use

If there is no significant improvement after 4 months of use low-load prolonged-duration stretch (LLPS) devices (dynamic splinting devices) for the above medically necessary indications, this will be considered **not medically necessary** under any circumstance, including but not limited to individuals unable to benefit from standard physical or occupational therapy modalities because of an inability to exercise.

Investigational

Low-load prolonged-duration stretch (LLPS) devices (dynamic splinting devices) including, but not limited to the following is considered **investigational** because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Knee, elbow, wrist, or finger not meeting the above criteria
- Persistent joint stiffness of the hallux limitus (i.e., degenerative pathology in the first metatarsophalangeal joint or the great toe) not meeting the above criteria
- For the treatment of the shoulder and ankle
- For the treatment of conditions related to chronic joint stiffness or chronic fixed contractures caused by the following:
    - Cerebral palsy
    - Long term lack of motion in the joint
    - Neuromuscular disease
    - Plantar fasciitis
    - Rheumatoid arthritis
    - Stroke

Static Progressive Stretch Devices

Static progressive stretch devices including, but not limited to the following are considered **investigational** for all indications because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Joint Active Systems (JAS) Splints
    - JAS Elbow
    - JAS Shoulder
    - JAS Ankle
    - JAS Knee
    - JAS Wrist
    - JAS Pronation/Supination
    - JAS EZ Turnbuckle Finger Orthosis

- Stat-A-Dyne and Static-Pro (elbow, knee, wrist)

Serial Stretch Devices (E1399)

Serial stretch devices including but not limited to the following are considered **investigational** for all indications because evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- ERMI Knee Extensionator
- ERMI Knee/Ankle Flexionator
- ERMI Shoulder Flexionator
- ERMI MPJ Extensionator
- ERMI Elbow Extensionator II

POLICY GUIDELINES

Required Documentation

Medical records documenting the following, when applicable:

- Current prescription from physician.
- Physician office notes that indicate the following:
  - The affected joint;
  - The date of injury/surgery;
  - Previous treatment attempted; and
  - Treatment plan, including proposed duration of use.

Coding

See the Codes table for details.

BACKGROUND

Range of Motion Impairments

Loss of full ROM occurs in a significant proportion of individuals following surgical procedures around a joint. The most common cause of severe postoperative motion loss is the development of intra-articular or extra-articular arthrofibrosis. Arthrofibrosis, characterized by periarticular fibrosis and bands of scar tissue, is described as a painful loss of end range of motion compared with the normal contralateral side. Loss of ROM can lead to impairments to including, but not limited to the following walking, sitting, lifting, rising from a chair and navigating stairs.

Treatment

Treatment of arthrofibrosis may include physical therapy, manipulation under anesthesia, arthroscopic or open lysis of adhesions, or revision surgery. Conservative treatment typically consists of postoperative physical therapy with pressure stretching techniques and home exercises. When rehabilitation has failed, serial casting, static braces, or dynamic splints that provide low-load prolonged stretch may be used. Dynamic splints use spring loading or elastic bands to provide low-intensity tension (less than that exerted by a physical therapist) and are designed to be worn over relatively long periods (ie, 6 to 8 hours or overnight). The efficacy of a stretching regimen to permanently remodel tissue is considered to be a function of the intensity, length of the session, number of sessions per day, and number of days per week that stretching is performed.

Several types of mechanical stretching devices are available for extension or flexion of shoulder, elbow, wrist, fingers, knee, ankle, and toes. Mechanical stretching devices include static progressive stretch, low-load prolonged-duration stretch (LLPS) (also referred to as dynamic splinting), and serial stretch devices. In most cases, mechanical stretching devices are used as an adjunct treatment to physical therapy and/or exercise.

- **Low-Load Prolonged-Duration Stretch (LLPS) Devices (Dynamic Splinting Devices):** Low-load prolonged-duration stretch (LLPS) (also known as dynamic splinting devices) permit active and passive motion (elastic traction) within a limited range. LLPS devices maintain a set level of tension by incorporated springs and are designed to provide a low load, prolonged stretch to joints that have reduced ROM. Most of these devices are adjustable tension-controlled units that provide a continuous dynamic stretch while patients are asleep or at rest. Commonly time of use is continuously for 6 – 12 hours, which can be at night or can be two three-hour sessions during the day for less than four months. Examples of this type of device include, but are not limited to:
  - Dynasplint System® (Dynasplint Systems, Inc., Severna Park, MD)
  - Ultraflex (Ultraflex Systems, Pottstown, PA)

  - Pro-glide™ Dynamic ROM devices (DeRoyal®, Powell, TN)
  - Advance Dynamic ROM® devices (Empi, St. Paul, MN)

- **Static Progressive Stretch (SPS) Devices:** SPS stretch devices (also known as bi-directional SPS devices) hold the joint in a set position but allow for manual modification of the joint angle (inelastic traction). This device provides low-to-moderate intensity stretching with a crank or rachet that progressively increases the stretch within each session. Examples of this type of device include, but are not limited to:
  - Joint Active Systems (JAS) splints (Joint Active Systems, Inc., Effington, IL)
    - JAS Elbow
    - JAS Shoulder
    - JAS Ankle
    - JAS Knee
    - JAS Wrist
    - JAS Pronation/Supination
  - Stat-A-DYNE and Static-Pro® (elbow, knee, wrist) (DeRoyal Industries, Inc.)

- **Patient-Actuated Serial Stretch (PASS) Devices:** PASS devices use hydraulics to alternate between periods of higher intensity stretch and relaxation. Examples of this type of device include, but are not limited to:
  - ERMI Knee Extensionator® (ERMI, Inc., Atlanta, GA)
  - ERMI Knee/Ankle Flexionator® (ERMI, Inc., Atlanta, GA)
  - ERMI Shoulder Flexionator® (ERMI, Inc., Atlanta, GA)
  - ERMI MPJ Extensionator® (ERMI, Inc., Atlanta, GA)
  - ERMI Elbow Extensionator® II (ERMI, Inc., Atlanta, GA)

Regulatory Status

The U.S. Food and Drug Administration (FDA) has determined that devices classified as "Exerciser, Non-Measuring" are considered Class I devices and exempt from 510(k) requirements. This classification does not require submission of clinical data on efficacy, only notification to the FDA prior to marketing. FDA product code: ION

RATIONALE

This evidence review was created in March 2009 with searches of the PubMed database. The most recent literature update was performed through June 2025.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Mechanical Stretching Devices

Low-Load Prolonged-Duration Stretch (LLPS) Devices (Dynamic Splinting Devices)

Clinical Context and Therapy Purpose

The purpose of low-load prolonged-duration stretch (LPPS) devices (dynamic splinting devices) in individuals who have functional limitations in ROM is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with functional limitations in joint ROM after injury or surgery to include limitations in joint ROM due to spasticity following neurological insult.

Interventions

Low-load prolonged-duration stretch (LPPS) devices (dynamic splinting devices) are designed to provide a low load, prolonged stretch to joints that have reduced ROM. Most of these devices are adjustable tension-controlled units that provide a continuous dynamic stretch while individuals are asleep or at rest. Commonly time of use is continuously for 6 – 12 hours, which can be at night or can be two three-hour sessions during the day. For devices that provide low-load prolonged-duration stretch see Background.

Comparators

Conservative treatment typically consists of postoperative physical therapy with pressure stretching techniques and home exercises. When rehabilitation has failed, serial casting, static braces, or stretching devices static progressive or serial stretch.

Outcomes

Improvement in functional outcomes and joint ROM.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Limited Range of Motion in Individuals following a Neurological Insult

Systematic Reviews

Khan et al. (2017) evaluated the evidence from published systematic reviews of clinical trials for effectiveness of non-pharmacological interventions for improved spasticity outcomes. Spasticity is common following neurological insults such as stroke, multiple sclerosis (MS), cerebral palsy (CP); or neurological trauma [such as brain injury, spinal cord injury (SCI)]. Physical impairments from spasticity [restricted joint range of movement (ROM), loss of dexterity, abnormal limb posture] can lead to progressive functional limitation [mobility, transfers, activities of daily living (ADLs)] and impact quality of life (QOL). The inclusion criteria were systematic reviews/meta-analyses that evaluated and defined non-pharmacological interventions (uni- and/or multi-disciplinary) aimed at reducing spasticity; reported a systematic electronic search of literature for a defined period; reviews conducted in adult population (≥ 18 years) and published in English. Also, systematic review/meta-analysis evaluating non-pharmacological interventions after concomitant pharmacological/surgical interventions were included. Overall 18 systematic review/meta-analyses: 4 published in the Cochrane Library database and 14 published in other academic journals were included. These reviews were conducted in various neurological cohorts: stroke (6), one each in multiple sclerosis (MS) brain injury SCI, and mixed or other neurological condition (9). Non-pharmacologic interventions used in the treatment of spasticity include physical interventions (stretching, passive movements, dynamic splinting); transcutaneous electric nerve stimulation (TENS); transcranial direct current stimulation (tDCS); shock wave; vibratory stimulation (whole body vibration); electromyography biofeedback; repetitive transcranial magnetic stimulation (TMS); therapeutic ultrasound; acupuncture; orthotics (splints, casts), thermotherapy, cryotherapy and others. The findings indicated though a broad range of non-pharmacological approaches in the treatment of spasticity in different neurological cohorts, high-quality evidence for effectiveness of these modalities is limited. Low quality evidence included the use of dynamic elbow splinting in stroke and other neurological conditions. The authors concluded “Despite the range of non-pharmacological interventions in use, evidence for many is still unclear. More research is needed to build evidence for types of non-pharmacological therapy components, modalities, duration and setting of therapy. Future research should focus on interventions that can be integrated into MD programs to develop effective care-pathways and long-term functional outcomes.”

Limited Range of Motion in individuals following Surgery or Injury

Systematic Reviews

In a Hayes Health Technology Assessment (May 2022) reviewers evaluated the safety and effectiveness of low-load prolonged duration stretch (LLPS), static progressive stretch (SPS) and patient-actuated serial stretch (PASS) mechanical stretching devices to restore range of motion (ROM) for the treatment of joint contractures in individuals due to injury with or without surgical repair which varied by indication treated and had insufficient response to prior management with reduced range of motion (ROM) and impaired function in the effected joint (finger, hand, wrist, elbow, shoulder, knee, great toe). Reviewers searched PubMed and Embase from 1993 to April 18, 2018 and included 23 studies (10 RCTs, 12 observational studies and 1 case series) with sample sizes 21-192. All study participants were adults with a contracture of various joint(s) which resulted from fracture, extensor injury, burns, total knee arthroplasty [TKA], cruciate ligament repair, shoulder capsulitis or hallux limitus. Mechanical stretching device therapy in addition to standard physical therapy (PT) compared to standard PT (active mobilization, manual stretching), splinting and botulinum toxin) were utilized. Outcome measures were range of motion (ROM), function, pain, patient assessment, strength and complications with follow-up 4-weeks to 12-months. The best available evidence was related to LLPS and finger contracture for extensor injury and repair, that included 5 RCTs with longest follow-up of 6-months which found no incremental benefit in clinical outcomes (ROM, total active motion [TAM], hand function and grip strength) over standard of care. For any other type of mechanical stretching devices for the treatment of contractures of the knee, wrist, hand, elbow, shoulder or great toe regardless of indication or etiology, and device type there were only 1-2 studies each available with longest follow-up of 12-months. Each of the two studies presented conflicting outcome findings (ROM and pain). Overall, mechanical stretching devices appear to be safe, no major safety issues were reported. The overall evidence was considered very-low to low quality due to the paucity of the evidence based on the small number of available studies and the inability to replicate findings. The current evidence does not establish benefit over standard treatment such as PT with static splinting.

Sameem et al. (2011) conducted a systematic review to evaluate which rehabilitation protocol yielded the best outcomes with respect to range of motion (ROM) and grip strength in extensor zones V-VIII of the hand after surgical repair of the extensor tendons. A total of 17 articles were included in the final analysis. Seven studies evaluated static splinting, 12 studies evaluated dynamic splinting, and four studies evaluated early active splinting. Static splinting yielded "excellent/good" results ranging from 63% (minimum) to 100% (maximum) on the total active motion (TAM) classification scheme and TAM ranging from 185° (minimum) to 258° (maximum) across zones V-VIII. Dynamic splinting studies demonstrated a percentage of "excellent/good" results ranging from 81% (minimum) and 100% (maximum) and TAM ranging from 214° (minimum) and 261° (maximum). Early active splinting studies showed "excellent/good" results ranging from 81% (minimum) and 100% (maximum). Only one study evaluated TAM in zones V-VIII, which ranged from 160° (minimum) and 165° (maximum) when using two different early active modalities. The authors concluded “The available level 3 evidence suggests better outcomes when using dynamic splinting over static splinting. Additional studies comparing dynamic and early active motion protocols are needed before a conclusive recommendation can be made.”

Randomized Controlled Trial

We identified an additional RCT by Plaass et al (2022) that was not included in the above summarized systematic reviews. Reviewers performed a prospective randomized single-center study to evaluate the clinical and radiological effect on hallus valgus (HV) utilizing dynamic splinting. The inclusion criteria were symptomatic HV and the potential to wear the dynamic splint for at least 3 months. The patients were randomly assigned in a 1:1 ratio to either treatment using a HV orthosis (dynamic splinting) or no treatment. The assessment of radiological outcomes was observer blinded. Weight bearing anterior-posterior and lateral foot x-rays were performed for diagnosis and at follow-up. A total of 70 patients were initially randomized and of these 36 were assigned to the intervention group, During the study period 15 patients did not complete the study. In both groups 6 patients declined to further participate due to personal reasons. In the control group one patient did not undergo a follow-up x-ray for the primary outcome evaluation and two patients declined to further participate in the study due to the inability to handle the questionnaires. Therefore, 26 patients were in in the control group and 29 patients were in the intervention group (i.e., treatment group with dynamic splinting). All patients in the treatment group received a controlled dynamic stretch device (halluxsan) and were instructed to set the device such that there was no pain but a perceptible traction. The subjects wore the brace during their rest time for as long as tolerated. The following clinical parameters were documented: MTP 1 range of motion (ROM), metatarsalgia and any lesser toe deformities. The following were also utilized in the evaluation the American Orthopedic Foot and Ankle Society – Hallux Metatarsophalangeal Interphalangeal Scale (AOFAS), the Short Form-36 (SF-36), Foot and Ankle Outcome Score (FAOS), and a Numeric Rating Scale (NRS) for pain. The intervention group was asked to judge the splint comfort based on a 10-point Likert scale. The difference of change between the treatment and control group was the primary outcome. Change in HVA was defined as the follow- up value minus the baseline value and a difference from baseline of 5º was judged as relevant. There was not a significant change in the MTP 1 ROM, AOFAS, and SF-36 mental or physical score during follow-up. Changes in the FAOS for symptoms, quality of life and activities of daily living and sports showed no significant difference, Pain scores at rest and while starting walking showed no significant difference, however, a significance difference was found regarding pain during walking and running (p = 0.039; p = 0.0072) and strong trend regarding the pain subscale of the FAOS score (p = 0.170) was observed, which showed a significant difference between groups at follow-up (p = 0.027). All patients in the intervention group used the splint during the entire study period. Most of the patients wore the splint between 2-4 hours per day (63.3%, 15/23), while 13.6% (3/23) wore it for a shorter time and 22.6% (5/23) for longer. A total of 43.5% (10/23) in the intervention group reported no or slight pain (NRS 0-2) while wearing the splint, while 30.4% (7/23) reported moderate pain (NRS 3-6) and 13% (3/23) reported severe pain (NRS >7). Based on the radiographic results baseline and follow-up showed no significant difference between the HVA (hallux valgus angle) and IMA (intermetatarsal 1-2 angle): HVA (p = 0.378; p = 0.358; p = 0.784) and IMA (p = 0.368; p = 0.484; p = 0.948). During the 12-week follow-up only one (4%, 1/25) patient in the intervention group observed a subjective deterioration in the HV position, but three (12%, 3/25) observed a slight improvement in the HV-position after wearing the splint. However, in the control group 29% (8/28) observed a deterioration in the HV position and only 7% (2/28) observed an improvement. Regarding reduction in pain 16% (4/25) of the patients in the intervention group and 7% (8/28) in the control group experienced a reduction in HV pain, and 12% (3/25) and 43% (12/28) experienced an increase. Limitations of this study included the relatively short treatment period and the pronounced HV position. The authors concluded “The current study shows that the treatment of patients with symptomatic HV using a dynamic splint can reduce pain, delay subjective deterioration of the toe position and is well accepted by patients.”

Noncomparative, Nonrandomized Studies

Rives et. al. (1992) reported the results of a prospective, non-randomized noncomparative study in which a total of 23 proximal interphalangeal joints that were severely contracted (approximately 45 degrees) as a result of Dupuytren's disease and underwent operative correction and 6 months of dynamic extension splinting. Proximal interphalangeal joint extension was measured preoperatively and postoperatively at 3-month intervals for 1 year and at 6-month intervals thereafter. Mean follow-up was 2 years (minimum, 1 year). Overall, at 2 years, 44% improvement in proximal interphalangeal joint extension was noted. Mean improvement of 59% in proximal interphalangeal joint extension was noted in the participants who complied with the postoperative dynamic extension splinting program. The individuals who were noncompliant demonstrated a 25% improvement in proximal interphalangeal joint extension. The difference in values between participants who were compliant and those who were not was statistically significant. Other factors such as the severity of contracture, the digit involved, and the necessity for capsular release were not significantly related to outcome. The authors concluded “This study suggests that soft tissue responds to continuous dynamic extension stresses and can be remodeled over time.”

Observational Study

Nuismer et. al (1997) in a retrospective chart review evaluated a convenience sample of subjects at multiple sites using low-load prolonged stretch (LLPS) orthoses for contracture management. The records of 17 participants from skilled nursing facilities, hand clinics, and hospitals were reviewed. There was a total of 18 contractures (2 wrists, 12 elbows, 4 knee) secondary to neurological and orthopedic causes. The chart review focused on participant demographic information, range of motion (ROM), functional outcomes, and wear schedules. The authors found that the use of LLPS orthoses significantly increased ROM for the whole sample, mean 28.61 degrees (range, -10-66, p<0.001), which in turn significantly improved the participants' functional outcomes. When the sample was divided into two pathology groups to compare a predominately geriatric population with neurological pathologies to a somewhat younger population with a history of musculoskeletal pathology, both groups showed a significant gain in ROM with the use of the LLPS orthoses. The authors concluded "The use of LLPS orthoses for contracture management can mediate the losses in ROM and function that occur with joint contractures."

Section Summary: Low-Load Prolonged-Duration Stretch Devices (Dynamic Splinting Devices)

Systematic reviews, RCTs, noncomparative nonrandomized and observational studies have evaluated low-load prolonged-duration stretch (LLPS) (dynamic splinting) devices when utilized to relieve persistent joint stiffness or contractures secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders of the knee, elbow, wrist, finger, toe (hallux limitus of the great toe) shoulder and ankle. There is limited evidence that use of dynamic LLPS devices for rehabilitation of joints, knee, elbow, wrist, finger and toe (hallux limitus of the great toe) may relieve joint stiffness, increase active range of motion (AROM) and decrease pain in the treatment of compliant patients. However, study limitations included small sample sizes and short follow-up timeframes of 12 months or less. Studies of dynamic LLPS devices for rehabilitation of shoulder and ankle have not yet demonstrated similar potential benefits. Further high-quality comparative RCTs to include larger sample sizes and longer follow-up are needed to further evaluate whether LLPS improves functional outcomes compared to alternative treatments. This technology is widely utilized by orthopedists as well as physical and occupational therapists for selected populations.

In a systematic review Khan et. al. (2017) evaluated the evidence regarding the effectiveness of non-pharmacological interventions for improved spasticity outcomes in individuals following neurological insults such as stroke, multiple sclerosis (MS), cerebral palsy (CP); or neurological trauma [such as brain injury [BI], spinal cord injury (SCI)]. Non-pharmacologic interventions used in the treatment of spasticity included physical interventions (stretching, passive movements, dynamic splinting). The findings of this review indicated there was low quality evidence regarding the effectiveness of dynamic splinting in the treatment of spasticity in the elbow related to stroke and use of this splinting in the other neurological conditions. Therefore, the evidence remains unclear regarding the use of LLPS (dynamic splinting) for the treatment of spasticity related to various neurological conditions and additional studies are needed to build the evidence regarding the effectiveness of these devices for this indication which should include comparative RCTs to other mechanical stretching devices such as static progressive devices.

Static Progressive Stretch Devices

Clinical Context and Therapy Purpose

The purpose of static progressive devices in individuals who have functional limitations in ROM is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with functional limitations in joint ROM after injury or surgery.

Interventions

Static progressive stretch devices provide a low- to moderate-intensity force to hold a joint at its end range and gradually increase the stretch. In contrast to the long periods of low-intensity stretch provided by dynamic splinting devices, patient-controlled serial stretch and static progressive stretch devices are designed to be used for 15 to 30 minutes, in up to 8 sessions per day. Static progressive stretch devices are available for the knee, shoulder, ankle, wrist, and for pronation and supination. Individuals are typically instructed to use them for 30 minutes, 3 times a day. During each session, individuals adjust their device by turning a ratchet or turnbuckle to the maximum tolerated position of end-range stretch. Each position is held for several minutes to allow for tissue relaxation to occur, and the device is then advanced to a new position of stretch. It is proposed that the systems unload the joint to reduce joint surface pressures during the stretch. For devices that provide static progressive stretch see Background.

Comparators

Conservative treatment typically consists of postoperative physical therapy (PT) with pressure stretching techniques and home exercises. When rehabilitation has failed, serial casting, static braces, or dynamic splints that provide low-load prolonged stretch may be used. Dynamic splints use spring loading or elastic bands to provide low-intensity tension (less than that exerted by a physical therapist) and are designed to be worn over relatively long periods (i.e., 6 to 8 hours or overnight).

Outcomes

Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint ROM is an intermediate outcome. According to the knee examination form developed by the International Knee Documentation Committee (2000), an extension deficit of 6° to 10° or a flexion deficit of 16° to 25° when compared with the noninvolved knee is categorized “abnormal,” and an extension deficit of more than 10° or a flexion deficit of more than 25° when compared with the noninvolved knee is categorized “severely abnormal.”

For the elbow, normal range of motion is suggested to be 100° of flexion (range, 30° to 130°). The mean shoulder range of motion for activities of daily living has been described as 121° flexion, 46° extension, 128° of shoulder abduction, 116° of shoulder cross-body abduction, 90° of external rotation with abduction of 59°, and 102° of internal rotation with 0° of abduction. Functional range of motion for the wrist is considered to be 38° of wrist flexion and 40° of wrist extension. For the knee, 110° of flexion is an appropriate goal for activities of daily living such as stair climbing and sitting in a chair.

Functional outcome measures include the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) for the hip and knee, and Disabilities of the Arm Shoulder and Hand questionnaire (DASH) for the upper limb. The DASH is a 30-item questionnaire on symptoms and functional activities (5 levels ranging from a range of motion of no difficulty to unable to perform), which calculates a score ranging from 0 (no disability) to 100 (most severe disability).

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Four RCTs evaluating JAS devices in the knee, shoulder and elbow were identified. Characteristics and outcomes for the RCTs are reported in Table 1. and described in greater detail below.

Table 1. Summary Characteristics of RCTs using Static Progressive Stretch Devices to Treat Restricted Range of Motion

Author	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
SS (ERMI Flexionater/Extensionater) device vs. SPS device						
Papotto and Mills (2012)	U.S.	1	NR	20 patients >65 y with arthrofibrosis after TKA	HIS (Knee Flexionater) for 5-10 min followed by 5-10 min recovery for 20-30 min a session, totaling 60 min/d	LIS (Static-Pro Knee); increase in force every 5 min for 30 min, 3 times/d
SPS device vs. PT						
Ibrahim et al (2012, 2014,) Hussein et al (2015)	U.S.	NR	2007-2010	60 patients with shoulder adhesive capsulitis	PT plus SPS: one 30-min session/d (wk 1), two 30-min sessions/d (wks 2-3), three 30-min sessions/d (wk 4)	PT
Teytelbaum et al (2024)	U.S.	1	2019-2022	34 patients with shoulder adhesive capsulitis	PT (2-3 times weekly) + HIS HIS 60 min/day divided into 10 minutes on followed by 10 minutes of rest then 10 more minutes on (repeated twice daily)	PT alone (three 60 minute sessions/week)
SPS device vs. dynamic splint						

Author	Countries	Sites	Dates	Participants	Interventions	
Lindenhovius et al (2012)	U.S.	1	2003-2008	66 patients with posttraumatic elbow stiffness	SPS device (Joint Active Systems), for three 30-min sessions/d, to improvement plateau	Dynamic splints, 6-8 h/d continuously, to improvement plateau

ERMI: End Range of Motion Improvement; HIS: high-intensity stretch; LIS: low-intensity stretch; NR: not reported; PT: physical therapy; RCT: randomized controlled trial; SPS: static progressive stretch; SS: serial stretch; TKA: total knee arthroplasty.

Knee

Randomized Controlled Trials

Papotto and Mills (2012) reported on a small (N=20) RCT that compared high-intensity serial stretch with lower intensity static progressive stretch devices for home therapy in patients who had undergone total knee arthroplasty. High-intensity stretch was performed with the End Range of Motion Improvement (ERMI) Knee/Ankle Flexionater. Patients in this high-intensity stretch group were instructed to stretch at an intensity that mimicked the intensity provided by their physical therapists during outpatient sessions and to use the device in 20- to 30-minute sessions, for a total of 60 minutes per day. The lower intensity stretch group used a static progressive stretch device (Static-Pro Knee), which consists of a brace secured to the upper and lower leg with cuffs and straps. These patients were instructed to use the Static-Pro Knee in three 30-minute sessions each day, increasing the force applied to the joint every 5 minutes. After an average of 7 weeks of treatment, patients treated with ERMI reported significantly greater improvement in knee flexion, change in range of motion, and WOMAC scores compared with the static progressive stretch patients (Table 2).

Table 2. Summary Results of RCTs Using Static Progressive Stretch Devices to Treat Restricted Knee Range of Motion

	After 7 Weeks of Treatment		
Study	**Knee Flexion >110°**	**Change in ROM**	**Change in WOMAC Scores**
Papotto and Mills (2012)			
HIS	91%	29.9°	25.6
LIS	22%	17.0°	12.4
p	<.001	.001	.048

HIS: high-intensity stretch; LIS: low-intensity stretch; RCT: randomized controlled trial; ROM: range of motion; WOMAC: Western Ontario and McMaster University Osteoarthritis Index.

Case Series

Several case series on JAS devices have been published by a group of investigators that include Bonutti (stockholder in Joint Active Systems), McGrath, Ulrich, and Mont. Bonutti et al (2008) reported on a series of 41 patients with refractory knee stiffness who used a static progressive stretch (JAS) device after failing physical therapy. Patients in this study had a total range of motion of less than 90° or a flexion contracture that impaired quality of life. Twenty-five patients had previously undergone manipulation under anesthesia. After a mean of 9 weeks of use (range, 3 to 27 weeks), mean range of motion increased by 33° (range, 0° to 85°), with mean final extension of -6° and flexion of 108°. Outcomes were comparable to those reported with other nonoperative treatments; however, improvements occurred in shorter treatment times with the static progressive stretch device.

Shoulder

Randomized Controlled Trials

Ibrahim et al (2012) published an evaluator blinded RCT of 60 patients with shoulder adhesive capsulitis randomized to 4 weeks of treatment with a static progressive stretch (JAS) device plus physical therapy compared with physical therapy alone. Ibrahim et al (2014) and Hussein et al (2015) provided additional follow-up at 1 and 2 years. The trial was independently funded, with devices provided by Joint Active Systems. Patients were evaluated for range of motion, functional outcomes with the DASH questionnaire, and the visual analog scale for pain. Improvements in range of motion were statistically greater with the static progressive stretch device than with physical therapy alone (Table 3), but this did not translate into a difference in pain and function at 4 weeks or in pain at 2 years. As noted above, the mean shoulder range of motion for activities of daily living has been described as 128° of shoulder abduction and 90° of external rotation with abduction of 59°. Final DASH scores were 2.5 in the static progressive stretch group compared with 36.2 in the control group (p<.001). It is unclear why functional limitations would increase in the control group over 2 years when adhesive capsulitis is generally a self-limiting condition. Authors reported that there were no losses to follow-up over 2 years. A limitation of the study is that the comparator of physical therapy alone was not provided with the same duration as physical therapy plus static progressive stretch (Tables 4 and 5). Use of an active comparator such as dynamic splinting would provide greater certainty on the effectiveness of this technology.

Teytelbaum et al (2024) published an evaluator-blind (treating surgeon) RCT of 34 patients with adhesive capsulitis in the US. Patients were randomized to 1 of 3 groups: home high-intensity stretch device alone, physical therapy alone, or the combination of both treatments. Patients were followed for at least 12 months. Shoulder range of motion was the primary outcome and all planes of motion improved from baseline in each treatment group. Tables 3 through 5 summarize the results and limitations of the study.

Table 3. Summary Results of RCTs Using Static Progressive Stretch Devices to Treat Restricted Shoulder Range of Motion

	After 4 Weeks of Treatment					Mean at 2-year Follow-Up				
Study	**VAS (SD)**	**DASH (SD)**	**Active Abduction in degrees (SD)**	**Passive Abduction in degrees (SD)**	**External Rotation in degrees (SD)**	**VAS**	**DASH Scores (Range)**	**Active Abduction in degrees (SD)**	**Passive Abduction in degrees (SD)**	**External Rotation in degrees (SD)**
Ibrahim et al (2012, 2014,) Hussein et al (2015)										
static progressive stretch + PT	1.10 (0.92)	5.25 (7.144)	141.93 (12.22)	162.50 (11.48)	73.17 (6.37	1.17 (0.91)	2.53 (3.89)	176.71 (3.80)	177.50 (3.11)	86.63 (3.01)

PT	0.83 (0.79)	15.27 (4.51)	114.27 (16.22)	136.13 (14.32)	51.93 (7.34)	1.70 (1.29)	36.24 (26.28)	101.37 (15.34)	148.37 (18.59)	49.67 (13.52)
Diff (95% CI)	0.27 (-0.57 to 1.10)	-10.03 (-21.5 to 1.44)	27.67 (20.12 to 35.21)	26.37 (17.23 to 35.50)	21.23 (16.27 to 26.19)	-0.53 (-1.37 to 0.31)	-33.71 (-45.19 to - 22.24)	75.34 (67.79 to 82.89)	29.13 (20.00 to 38.27)	49.67 (13.52)
p	>.05	>.05	<.001	<.001	<.001	>.05	<.001	<.001	<.001	<.001
	Forward Flexion in degrees,mean (SD)	**Abduction in degrees, mean (SD)**	**External Rotation in degrees, mean (SD)**	**Internal Rotation in degrees, mean (SD)**	**SST scores, mean (SD)**	**ASES Painmean (SD)**	**ASES Function, mean (SD)**	**ASES Total, mean (SD)**		
Teytelbaum et al (2024)[a]										
HIS	70.0 (32.0)	100.0 (32.0)	50.0 (39.7)	4.3 (2.1)	7.5 (2.6)	28.3 (16.4)	(29.6 (9.0)	57.9 (20.1)		
PT	47.5 (25.5)	57.8 (28.4)	30.0 (18.3)	3.3 (2.2)	6.8 (3.6)	23.3 (10.0)	25.2 (15.8)	49.1 (24.6)		
Combination	67.3 (35.8)	68.6 (25.9)	56.4 (22.0)	3.9 (1.3)	7.8 (2.6)	32.3 (12.9)	27.9 (10.9)	60.2 (20.1)		
p		.003 (HIS vs PT)								

ASES, American Shoulder and Elbow Surgeons; CI: confidence interval; DASH: Disabilities of the Arm Shoulder and Hand questionnaire; HIS: high-intensity stretch; PT: physical therapy; RCT: randomized controlled trial; SD: standard deviation; SST: simple shoulder test; VAS: visual analog scale.
[a]Results presented as change from baseline to final follow-up (at least 12-months)

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Ibrahim et al (2012, 2014,) Hussein et al (2015)			3. In this study, the treatment was given in addition to standard physical therapy.		
Teytelbaum et al (2024)				3. No safety reporting; 5. Small differences between groups without discussion of clinical significance	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ibrahim et al (2012, 2014,) Hussein et al (2015)		1. Patients were not blinded to treatment, although assessors of the range of motion measurements were.	2. Hussein et al (2015) did not report that this was the same study as Ibrahim et al (2012).			
Teytelbaum et al (2024)		1., 2. Only surgeon was blind			3. Unclear if clinically important difference	3., 4. Few between group comparisons reported; no confidence intervals

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Elbow

Randomized Controlled Trials

Lindenhovius et al (2012) reported on results of a range of motion RCT that compared static progressive stretch using a JAS device to dynamic splinting in 66 patients with posttraumatic elbow stiffness. Patients included had lost more than 30° in flexion or extension after an elbow injury or surgery and had failed to improve for at least 4 weeks with regular stretching exercises. The evaluation was conducted by an investigator not involved in the care of the patients but who did not appear to have been blinded. Ten percent of patients in the dynamic splinting cohort asked for a change in treatment due to discomfort with the splint. Follow-up at 12 months was available for 80% of patients in the static progressive stretch group and 68% of patients in the splinting group, potentially reflecting lower patient satisfaction with dynamic splinting. Improvements were comparable between the groups in most outcomes (flexion-extension arc, flexion, forearm rotation), except for DASH scores (significantly better in the static progressive stretch group at 6 months but equivalent at 12 months) and flexion contracture (equivalent at 6 months but significantly better in the splinting group at 12 months; Table 6). Statistical analysis was intention-to-treat but did not account for repeated measures or baseline covariates. Range of motion was similar between groups at all time points.

Table 6. Summary Results of RCTs Using Static Progressive Stretch Devices to Treat Restricted Elbow Range of Motion

	Mean at 6-Month Follow-Up

Study	Flexion Arc (Range)	Change in DASH Scores (Range)
Lindenhovius et al (2012)		
static progressive stretch	91° (50°-140°)	25 (3-50)
DS	93° (15°-130°)	32 (5-83)
p	.80	<.05

DASH: Disabilities of the Arm Shoulder and Hand questionnaire; DS: dynamic splinting; RCT: randomized controlled trial.

Case Series

Ulrich et al (2010) reported on the use of a static progressive stretch (JAS) elbow device in 37 patients. Patients with deficits in flexion or extension had undergone at least 6 weeks of exercise with at least 2 weeks of minimal motion gain (<5°). After 1 to 3 daily, 30-minute sessions for a mean treatment time of 10 weeks (range, 2 to 23 weeks), mean range of motion increased by 26° (range, 2° to 60°) to a final range of motion of 107° (range, 70° to 140°). Results were compared with the literature on other upper extremity stretch devices (e.g., splints), which achieved similar success rates (81% to 88%) with 6 to 10 hours of daily wear over 6 to 10 months.

Systematic Reviews

A systematic review by Muller et al (2013) compared the effectiveness of dynamic splint, static splint, or static progressive stretch in patients with posttraumatic or postoperative elbow stiffness. They included 13 case series and case reports (N=247 patients; range, 1 to 37 patients). Mean duration from the incident to the start of treatment was 6.9 months. The greatest increase in range of motion was obtained with dynamic splints (46°), followed by static progressive stretch devices (40°), and static splints (34°). These differences were statistically significant (p<.001) but might not be clinically significant. None of the selected studies assessed patient compliance, which is potentially affected by the duration of wear and comfort of the device. This systematic review was limited by the inclusion of low-quality studies, including case reports.

Forearm Rotation

Case Series

McGrath et al (2009) reported on a series of 38 consecutive patients with limitations in forearm rotation who had plateaued with physical therapy. Treatment with a static progressive stretch (JAS) pronation/supination device began at an average of 21 weeks (range, 6 to 75 weeks) after the upper-extremity injury. At the start of treatment, mean range of motion was 96° (range, 20° to 150°). After an average of 12 weeks of treatment (range, 3 to 57 weeks), mean range of motion increased to 138° (range, 70° to 180°).

Wrist

Case Series

McGrath et al (2008) also reported on the use of a static progressive stretch (JAS) wrist device in 47 consecutive patients with posttraumatic or postsurgical wrist stiffness. All patients' range of motion had plateaued (67°; range, 18° to 114°) after a mean of 12 weeks of physical therapy (range, 6 to 28 weeks) and was not expected to improve with standard therapeutic modalities. After a mean of 10 weeks of static progressive stretch treatment (range, 4 to 26 weeks), range of motion increased to 101° (range, 60° to 156°).

Lucado et al (2008) retrospectively reviewed 25 patients with distal radius fractures who had been treated with a JAS Flexion/Extension device or JAS forearm Pronation/Supination device at their institutions. The mean time from injury to the initiation of treatment with a static progressive stretch device was 94 days (range, 48 to 188 days), and duration of use was 75 days (range, 14 to 160 days). There were significant improvements in range of motion and DASH scores. The median DASH score improved from 43 to 19 (on a scale from 100 to 0) after static progressive stretch therapy.

Section Summary: Static Progressive Stretch Devices

Four RCTs have evaluated static progressive stretch devices but comparators in each differed (e.g., PT, a dynamic splint, and serial stretch device). The evidence on static progressive stretch devices does not currently support an improvement in pain and function with static progressive stretch compared to alternative treatments such as dynamic splinting. One RCT found greater improvements in range of motion and WOMAC scores with serial stretch devices for the knee compared with static progressive stretch devices. Another RCT evaluating static progressive stretch for shoulder adhesive capsulitis found significant differences in shoulder range of motion compared with physical therapy alone at the end of 4 weeks of treatment, with no difference in pain and function at this time point. At longer follow-up, the physical therapy group showed a decline in function. Use of an active comparator would provide greater certainty on the effectiveness of this technology. A small trial in adhesive capsulitis compared static progressive stretch to physical therapy alone or the combination of stretch and physical therapy. Although significant improvements with static stretching were found compared with static stretch in terms of range of motion, differences between groups were generally small. Another RCT found comparable improvements in most outcomes for the static progressive stretch device compared with dynamic splinting, and a systematic review of case reports and series found similar clinical efficacy for increasing elbow range of motion between static progressive stretch devices and dynamic splints. Dynamic splints are used for 8 to 24 hours per day while static progressive stretch devices require several 30-minute sessions. It is not known whether patient compliance would be higher with the static progressive stretch devices resulting in an improvement in clinical outcomes.

Serial Stretch Devices

Clinical Context and Therapy Purpose

The purpose of serial stretch devices in individuals who have functional limitations in ROM is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with functional limitations in joint ROM after injury or surgery.

Interventions

Serial stretch devices (e.g., ERMI) use hydraulics to alternate between periods of higher intensity stretch and relaxation. See also Background.

Comparators

Conservative treatment typically consists of postoperative PT with pressure stretching techniques and home exercises. When rehabilitation has failed, serial casting, static braces, or dynamic splints that provide low-load prolonged stretch may be used. Dynamic splints use spring loading or elastic bands to provide low-intensity tension (less than that exerted by a physical therapist) and are designed to be worn over relatively long periods (i.e., 6 to 8 hours or overnight).

Outcomes

Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint ROM is an intermediate outcome. According to the knee examination form developed by the International Knee Documentation Committee (2000), an extension deficit of 6° to 10° or a flexion deficit of 16° to 25° when compared with the noninvolved knee is categorized “abnormal,” and an extension deficit of more than 10° or a flexion deficit of more than 25° when compared with the noninvolved knee is categorized “severely abnormal.” Range of motion thresholds in joints other than the knee are noted above.

Functional outcome measures include the WOMAC for the hip and knee and DASH for the upper limb.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Knee

Randomized Controlled Trials

The small RCT by Papotto and Mills (2012; described above) compared a serial stretch (ERMI Knee/Ankle Flexionater) device with a static progressive stretch (Static-Pro) device for home therapy in 20 patients who had undergone total knee arthroplasty. After an average of 7 weeks of therapy, treatment with the serial stretch device resulted in a 29.9° gain in motion compared with 17.0° with the static progressive stretch ($p<.001$). Knee flexion of 110° or more was obtained in 91% of the serial stretch group compared with 22% of the static progressive stretch group ($p<.001$). Improvement on the 100-point

WOMAC was significantly greater in the serial stretch group (25.6) than in the static progressive stretch group (12.4; p=.048) (Table 2).

Nonrandomized Comparative Studies

Stephenson et al (2010) reported on an industry-funded retrospective comparative study of high-intensity stretch devices, low-intensity stretch devices, and no devices, based on claims data for 60,359 patients who had a diagnosis of arthrofibrosis following knee injury or surgery. There were 143 patients who used a high-intensity stretch device, 607 who used a low-intensity stretch device, and 59,609 who did not use any stretching device. To make the groups comparable in terms of severity, the lower intensity stretch and no device patients were required to have a diagnosis relating to osteoarthrosis, ankyloses, contracture/fracture, or stiffness in the lower leg. After controlling for baseline differences in the type of knee surgery and musculoskeletal disease, the high-intensity stretch group had significantly lower rates of rehospitalization than low-intensity stretch and no device patients. Significantly more patients with no device (47.4%) had a subsequent knee event within 6 months after the index surgery compared with high-intensity (24.5%) or low-intensity (22.2%) stretch patients.

Uncontrolled Trials

A frequently cited study was reported by Branch et al (2003; Branch was medical director at ERMI). Patients (N=34) in this prospective series who did not have full knee range of motion after 6 weeks of physical therapy were prescribed a serial stretch (ERMI Knee/Ankle Flexionater) device. The 2 patients in the study who had a range of motion greater than 115° at the start of therapy regained full range of motion. Of the 6 patients with a range of motion between 90° and 115° at the start of therapy, 5 regained full range of motion; and of the 16 patients with a range of motion between 60° and 90° at the start of therapy, 13 regained full range of motion. For the 10 patients who began mechanical therapy with a range of motion between 0° and 60°, only 4 regained full range of motion but this group regained the most range of motion (mean, 79°) of the 4 groups. With functional range of motion defined as 115° or more, 31 (91%) of the 34 patients met this goal, and the improvement in range of motion for the entire group was highly significant. A retrospective review from this group found that passive knee extension deficits that had plateaued with physical therapy decreased range of motion 10.5° to 2.0° with the ERMI Knee Extensionater.

Shoulder

Case Series

An industry-funded retrospective series (2011) with 36 patients was identified; it evaluated a serial stretch (ERMI Shoulder Flexionater) device. Patients with adhesive capsulitis who had failed 6 weeks of physical therapy (glenohumeral abduction and external rotation not equal to the opposite uninvolved limb) were treated with the serial stretch device in combination with continued physical therapy. Patients were instructed to perform 6 daily, 10-minute sessions of end-range stretching at home, using an intensity that was uncomfortable but not painful. Blinded evaluation at the end of treatment found that range of motion of the involved limb equaled that of the opposite limb. Scores on the American Shoulder and Elbow Society Standardized Shoulder Assessment Form showed significant improvement ($p<.05$), and patients with greater pain at baseline had the greatest improvement in American Shoulder and Elbow Society scores (gain of 50 points of 100 total).

Section Summary: Serial Stretch Devices

The evidence includes a small RCT and a larger retrospective comparative study that reported high intensity stretching using serial stretch (ERMI) devices improved range of motion more than lower intensity stretching devices in patients who were post-injury or surgery. Other available data consist of retrospective case series demonstrating improvements in range of motion among patients whose range had plateaued with physical therapy. The clinical significance of gains in this surrogate outcome measure is unclear.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

- No guidelines or statements were identified.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	None	
HCPCS		
	E1800	Dynamic adjustable elbow extension and flexion device, includes soft interface material
	E1801	Static progressive stretch/patient actualized serial stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
	E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface material
	E1803	Dynamic adjustable elbow extension only device, includes soft interface material
	E1804	Dynamic adjustable elbow flexion only device, includes soft interface material
	E1805	Dynamic adjustable wrist extension and flexion device, includes soft interface material
	E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
	E1807	Dynamic adjustable wrist extension only device, includes soft interface material
	E1808	Dynamic adjustable wrist flexion only device, includes soft interface material
	E1810	Dynamic adjustable knee extension and flexion device, includes soft interface material
	E1811	Static progressive stretch/patient actualized serial stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
	E1812	Dynamic knee, extension/flexion device with active resistance control
	E1813	Dynamic adjustable knee extension only device, includes soft interface material

Codes	Number	Description
	E1814	Dynamic adjustable knee flexion only device, includes soft interface material
	E1815	Dynamic adjustable ankle extension and flexion device, includes soft interface material
	E1816	Static progressive stretch/patient actualized serial stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
	E1818	Static progressive stretch/patient actualized serial stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories
	E1821	Replacement soft interface material/cuffs for bi-directional static progressive stretch device
	E1822	Dynamic adjustable ankle extension only device, includes soft interface material
	E1823	Dynamic adjustable ankle flexion only device, includes soft interface material
	E1825	Dynamic adjustable finger extension and flexion device, includes soft interface material
	E1826	Dynamic adjustable finger extension only device, includes soft interface material
	E1827	Dynamic adjustable finger flexion only device, includes soft interface material
	E1828	Dynamic adjustable toe extension only device, includes soft interface material
	E1829	Dynamic adjustable toe flexion only device, includes soft interface material
	E1830	Dynamic adjustable toe extension and flexion device, includes soft interface material
	E1831	Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
	E1832	Static Progressive stretch finger device, extension and/or flexion with or without range of motion adjustment, includes all components and accessories
	E1840	Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material

Codes	Number	Description
	E1841	Static progressive stretch/patient actualized serial stretch shoulder device, with or without range of motion adjustment, includes all components and accessories
	E1399	Durable medical equipment, miscellaneous
Type of Service	DME	
Place of Service	Outpatient/Home	

POLICY HISTORY

Date	Action	Action
June 2025	Annual Review	Policy Renewed
May 2024	Annual Review	Policy Renewed
May 2023	Annual Review	Policy Renewed
January 2023	Annual Review	Policy Revised
January 2022	Annual Review	Policy Revised
January 2021	Annual Review	Policy Revised
January 2020	Annual Review	Policy Revised
January 2019	Annual Review	Policy Revised
January 2018	Annual Review	Policy Revised
January 2017	Annual Review	Policy Revised
January 2016	Annual Review	Policy Revised
January 2015	Annual Review	Policy Revised
February 2014	Annual Review	Policy Revised
February 2013	Annual Review	Policy Revised
February 2012	Annual Review	Policy Revised

Date	Action	Action
October 2011	Annual Review	Policy Renewed
August 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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