

Description

Joint stiffness or contracture may be caused by immobilization following an injury, disease or surgery. A joint contracture is characterized by persistently reduced range of motion as a result of structural changes in muscles, tendons, ligaments, and skin. This decrease in joint mobility occurs when elastic connective tissue is replaced with inelastic fibrous material, resulting in tissue that is resistant to stretching.

Dynamic (spring loaded dynamic, low-load prolonged-duration stretch [LLPS]) splints, bi-directional static progressive stretch [SP] splints and patient-actuated serial stretch [PASS]) devices are intended to stretch joints that have reduced range of motion secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders. These devices are intended to replace or reduce the number of physical therapist-directed sessions by providing frequent and controlled joint mobilization in a hospital or in the patient's home. The goal is to cause permanent elongation of the connective tissue in order to increase range of motion. Mechanical stretching devices are not motorized and may be prefabricated or custom fabricated.

Several types of stretching devices are available and may be classified as follows:

- Dynamic (low-load prolonged-duration stretch [LLPS]) devices – allow resisted active and passive motion (elastic traction) within a restricted range. LLPS devices sustain a set level of tension using integrated springs. Examples of LLPS devices include but are not limited to: Dynasplint System®, EMPI Advance Dynamic ROM®, and LMB Pro-Glide™.
- Bi-directional static progressive (SP) stretch devices - maintain the joint in a set position but permit manual modification of the joint angle and may allow for active motion without resistance (inelastic traction). Examples of this type of device include but are not limited to the Joint Active Systems (JAS) splints (e.g., JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination) and Air Cast.
- Patient-actuated serial stretch (PASS) devices - allow resisted active and passive motion (elastic traction) within a limited range. PASS devices supply a low to high-level load to the joint using pneumatic or hydraulic systems that can be adjusted by the patient. Examples of PASS devices include the ERMI Knee Extensionater®, ERMI Elbow Extensionater®, ERMI Knee/Ankle Flexionater®, and ERMI Shoulder Flexionater®.

Policy

VCHCP considers dynamic (low-load prolonged-duration stretch [LLPS]) devices **Medically Necessary** for use on the knee, elbow, wrist or finger in any of the following clinical settings:

1. As an addition to physical therapy in the sub acute injury or post-operative period (≥ 3 weeks but ≤ 4 months after injury or operation) in patients with signs and symptoms of persistent joint stiffness; OR
2. In the subacute injury or post-operative period (≥ 3 weeks but ≤ 4 months after injury or operation) in an individual (a) whose limited range of motion poses a meaningful (as judged by the physician) functional limitation, AND (b) who has not responded to other therapy (including physical therapy); OR
3. In the acute post-operative period for patients who are undergoing additional surgery to improve the range of motion of a previously affected joint; OR
4. For patients unable to benefit from standard physical therapy modalities because of an inability to exercise. No significant change after four months period is prophylactic use in contractures and is not medically necessary.

VCHCP considers dynamic (low-load prolonged-duration stretch [LLPS]) devices **Investigational/Not Medically Necessary** in the following:

1. Dynamic (low-load prolonged-duration stretch [LLPS]) devices are considered **investigational/not medically necessary** for use in the management of chronic joint stiffness and/or chronic or fixed contractures.
2. .
3. Bi-directional static progressive (SP) stretch devices are considered **investigational/not medically necessary**.
4. Patient-actuated serial stretch (PASS) devices are considered **investigational/not medically necessary**.

Rationale

Dynamic (low-load prolonged-duration stretch [LLPS]) devices

Although there are inadequate data in the published peer reviewed literature to validate the effectiveness of dynamic splinting in improving joint range of motion (ROM), this technology is widely used in the orthopedic and physical therapy communities for selected patient populations. On the basis of national community standards, dynamic splinting may be considered medically necessary in the clinical settings outlined under the Policy section of this document. Due to a lack of scientific evidence demonstrating effectiveness of this technology, it is considered investigational/not medically necessary for use in the management of shoulders, chronic joint stiffness, and/or contractures.

Bi-directional static progressive (SP) stretch devices

Static progressive stretch devices do not have published scientific literature validating

their effectiveness. It is not utilized on the basis of national community standards; research is limited to case reports and small uncontrolled studies. There is no evidence that static progressive stretch devices whose method is similar to manual therapy, significantly improve clinical outcomes. This technology is considered investigational/not medically necessary for use in the management of joint stiffness, or contractures.

Patient-actuated serial stretch (PASS) devices

In 2003 Branch et al. conducted a prospective study to determine the effectiveness of using patient-controlled home mechanical therapy to increase knee ROM in patients with knee contracture. The sample size included 34 patients who had failed to reach full ROM with a 6-week regimen of conventional physical therapy. Patients included those who developed knee contractures following anterior cruciate ligament (ACL) injury (n=14), peripatellar injury (n=7), fracture (n=4), and other, unspecified causes (n=9). These patients used a patient-controlled device (the ERMI Knee/Ankle Flexionater®) four to eight times daily for 15 minutes. The duration of the treatment ranged from two to 12 weeks. Thirty-one (91.2%) of these patients regained functional flexion after 6.7 weeks. Full ROM was regained by 74% of the patients and mean knee flexion progressed from 70.8 degrees to 130.6 degrees. Two patients in this study required surgical manipulation. Conclusions regarding this study are limited by the small sample size and lack of a control group. Furthermore, due to the overall lack of published studies investigating PASS devices, no conclusion can be drawn regarding their efficacy in treating joint stiffness or contractures for any other indication.

Background/Overview:

A joint contracture is characterized by chronically reduced range of motion (ROM) secondary to structural changes in non-bony tissues including muscle, tendons, ligaments, and skin. Prolonged immobilization of joints following surgery or trauma is the most common cause of joint contractures. While immobilization may prevent excess tension to the joint and prevent disruption of the healing of repaired tissues, it can also cause pathologic conditions that contribute to the development of joint contractures. Other causes of joint contractures include spasticity secondary to nerve damage, such as stroke or spinal cord injury and muscle weakness due to muscle, tendon, or ligament disease including paralysis.

Dynamic (low-load prolonged-duration stretch [LLPS]) devices

Most spring loaded dynamic splinting devices are designed to provide a low load, prolonged stretch to joints that have reduced range of motion secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders. 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. Medically necessary wearing time is less than four months. The objective of stretch therapy is to improve range of motion without compromising the stability and quality of the connective tissue and joint. Currently, dynamic splinting

devices are available for but not limited to the elbow, wrist, knee, ankle, and toes. For use in shoulders or any other condition not listed above as medically necessary, there is a lack of scientific evidence regarding its effectiveness.

A number of products are available for patient home use incorporating this technology and include but may not be limited to: Dynasplint® System, EMPI Advance Dynamic ROM®, LMB Pro-Glide™ and Ultraflex®.

Bi-directional static progressive (SP) stretch devices

Bi-directional static progressive stretch devices concept of static progressive stretching applies a different biomechanical principle than the medical necessity criteria mentioned for the spring loaded dynamic splinting devices of low load prolonged stress technique. The static progressive stretch technique, coupled with stress relaxation, a series of incremental increasing displacements is applied to a joint over a period of time, which theoretically causes plastic deformation of the soft tissues, which the brace can maintain. The stretch or force applied is typically increased every few minutes by the patient in order to increase range of motion during the period of brace utilization, thus the area never has time to recover. The period of brace utilization is typically 30 minutes, used 2-3 times a day. The combined principles of static progressive stretch & stress relaxation are utilized in braces from manufacturers that include but may not be limited to: Joint Active Systems (JAS splints) & Air Cast.

Patient-actuated serial stretch (PASS) devices

PASS devices supply a low to high-level load to the joint using pneumatic or hydraulic systems that can be adjusted by the patient. PASS devices are available for the ankle (ERMI Knee/Ankle Flexionater®), elbow (ERMI Elbow Extensionater®), knee (ERMI Knee Extensionater®, ERMI Knee/Ankle Flexionater®), and shoulder (ERMI Shoulder Flexionater®). These devices are custom fitted. Typically a certified ERMI representative develops an individualized treatment protocol and provides training regarding its correct usage.

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