Clinical Practice Guideline: **Upper Extremity Orthoses**

Date of Implementation: **December 20, 2012**

Product: **Specialty**

GUIDELINES

An upper extremity orthotic device is considered medically necessary for patients requiring support, immobilization, and/or stabilization to the upper extremity and are expected to have improved function with the use of the device for the following scenarios:

- To support or substitute for weak muscles (e.g., acute cervical spine injury, brachial plexus injury, peripheral nerve injury, acute sprain or sprain);
- To support or immobilize a pathologic joint (e.g., rheumatoid arthritis, osteoarthritis, tendon pathology [e.g., lateral epicondylitis, de Quervain, trigger finger], compression syndromes [e.g., carpal tunnel or cubital tunnel]) that do not respond to other established treatments;
- To support or immobilize a structure (e.g., trauma, following surgical repair, fractures [e.g., clavicle fracture, acromioclavicular joint sprain]);
- To prevent, correct, or manage contracture or deformity from neurological injury (e.g., traumatic brain injury, stroke), spinal cord injury, peripheral nerve injury, or resulting from disease or immobilization (e.g., post fracture, burns);
- As necessary to allow performance of ADLs (e.g., patients with spinal cord injury).

A custom fitted or custom fabricated orthotic may be medically necessary when an off-the-shelf orthotic is insufficient for the patient's needs when the above medical necessity criteria has been met for an upper extremity orthotic and BOTH of the following criteria are met:

- One or more of the following additional criteria are met:
    - Post-surgical intervention
    - Orthotic requires unique components (e.g., pulleys, rubber bands)
    - Neurologic co-morbidities (e.g., sensory deficit, spasticity)
    - Swelling/Lymphedema comorbidity
    - Multiple-joint involvement
    - Plan of care for serial splinting
    - Orthotic will need frequent modification
    - Skin impairment co-morbidity
- The clinical documentation supports the medical necessity of a custom fitted or custom fabricated orthotic beyond what is necessary for an off-the-shelf orthotic.

Myoelectric powered upper-extremity orthotic devices L3904, e.g., MyoPro® (Myomo, Inc., Boston, MA), are considered unproven due to insufficient literature supporting their use.

When determining the appropriate orthotic for a patient, the practitioner targets the problems in performance of movements or tasks, or identifies a part that requires immobilization, and selects the most appropriate orthotic device. The complexity and medical necessity should be supported in the clinical documentation. The practitioner then fits the device and trains the patient and/or caregivers in its proper use and application. The goal is either to promote indicated immobilization or to assist the patient to function at a higher level by decreasing functional limitations or the risk of further functional limitations.

An orthotic may be prefabricated or custom-fabricated. A *prefabricated* orthotic is one that is manufactured in quantity. Some prefabricated orthotics are supplied as "off-the-shelf" devices that require little to no modification, while others may be designed to be modified for a specific patient's needs. This type of prefabricated orthotic may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom fitted). An orthotic that is assembled from prefabricated components is considered prefabricated.

A *custom* fabricated orthotic is one that is individually made for a specific patient starting with basic materials (e.g., plastic, metal, leather, or cloth) from the patient's individualized measurements. A molded-to-patient model orthotic is a particular type of custom fabricated orthotic in which an impression of the specific body part is made and the impression is then used to make a positive model. The orthotic is molded from the patient-specific model.

A custom fitted or custom fabricated orthotic should only be used when an off-the-shelf orthotic is insufficient to address a patient's goals. The clinical documentation must support the medical necessity of a custom fitted or custom fabricated orthotic beyond what is necessary for an off-the-self orthotic.

Other supporting resources and documentation include the following ASH policies: *Orthotic Training and Evaluation (CPG 152 - S), Casting and Strapping (CPG 145 – S)* and *Strapping and Taping (CPG 143 - S)*.

HCPCS CODES AND DESCRIPTIONS

HCPCS Code	HCPC Code Description
L3650	Shoulder orthosis (SO), figure of eight design abduction restrainer, prefabricated, off-the-shelf

HCPCS Code	HCPC Code Description
L3660	Shoulder orthosis (SO), figure of eight design abduction restrainer, canvas and webbing, prefabricated, off-the-shelf
L3670	Shoulder orthosis (SO), acromio/clavicular (canvas and webbing type), prefabricated, off-the-shelf
L3671	Shoulder orthosis (SO), shoulder joint design, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3674	Shoulder orthosis (SO), abduction positioning (airplane design), thoracic component and support bar, with or without nontorsion joint/turnbuckle, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3675	Shoulder orthosis (SO), vest type abduction restrainer, canvas webbing type or equal, prefabricated, off-the-shelf
L3677	Shoulder orthosis (SO), shoulder joint design, without joints, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3678	Shoulder orthosis (SO), shoulder joint design, without joints, may include soft interface, straps, prefabricated, off-the-shelf
L3702	Elbow orthosis (EO), without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3710	Elbow orthosis (EO), elastic with metal joints, prefabricated, off-the-shelf
L3720	Elbow orthosis (EO), double upright with forearm/arm cuffs, free motion, custom fabricated
L3730	Elbow orthosis (EO), double upright with forearm/arm cuffs, extension/ flexion assist, custom fabricated
L3740	Elbow orthosis (EO), double upright with forearm/arm cuffs, adjustable position lock with active control, custom fabricated
L3760	Elbow orthosis (EO), with adjustable position locking joint(s), prefabricated, item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3762	Elbow orthosis (EO), rigid, without joints, includes soft interface material, prefabricated, off-the-shelf
L3763	Elbow-wrist-hand orthosis (EWHO), rigid, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment

HCPCS Code	HCPC Code Description
L3764	Elbow-wrist-hand orthosis (EWHO), includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3765	Elbow-wrist-hand-finger orthosis (EWHFO), rigid, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3766	Elbow-wrist-hand-finger orthosis (EWHFO), includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3806	Wrist-hand-finger orthosis (WHFO), includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, custom fabricated, includes fitting and adjustment
L3807	Wrist-hand-finger orthosis (WHFO), without joint(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3808	Wrist-hand-finger orthosis (WHFO), rigid without joints, may include soft interface material; straps, custom fabricated, includes fitting and adjustment
L3900	Wrist-hand-finger orthosis (WHFO), dynamic flexor hinge, reciprocal wrist extension/ flexion, finger flexion/extension, wrist or finger driven, custom fabricated
L3901	Wrist-hand-finger orthosis (WHFO), dynamic flexor hinge, reciprocal wrist extension/ flexion, finger flexion/extension, cable driven, custom fabricated
L3905	Wrist-hand-orthosis (WHO), includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3906	Wrist-hand orthosis (WHO), without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3908	Wrist-hand orthosis (WHO), wrist extension control cock-up, non-molded, prefabricated, off-the-shelf
L3912	Hand-finger orthosis (HFO), flexion glove with elastic finger control, prefabricated, off-the-shelf
L3913	Hand-finger orthosis (HFO), without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment

HCPCS Code	HCPC Code Description
L3915	Wrist-hand orthosis (WHO), includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3917	Hand orthosis (HO), metacarpal fracture orthosis, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3919	Hand orthosis (HO), without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3921	Hand-finger orthosis (HFO), includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3923	Hand-finger orthosis (HFO), without joints, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3925	Finger orthosis (FO), proximal interphalangeal (pip)/distal interphalangeal (dip), nontorsion joint/spring, extension/flexion, may include soft interface material, prefabricated, off-the-shelf
L3927	Finger orthosis (FO), proximal interphalangeal (pip)/distal interphalangeal (dip), without joint/spring, extension/flexion (e.g., static or ring type), may include soft interface material, prefabricated, off-the-shelf
L3929	Hand-finger-orthosis (HFO), includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3931	Wrist-hand-finger orthosis (WHFO), includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated, includes fitting and adjustment
L3933	Finger orthosis (FO), without joints, may include soft interface, custom fabricated, includes fitting and adjustment
L3935	Finger orthosis (FO), nontorsion joint, may include soft interface, custom fabricated, includes fitting and adjustment
L3956	Addition of joint to upper extremity orthotic, any material; per joint

HCPCS Code	HCPC Code Description
L3960	Shoulder-elbow-wrist-hand orthosis (SEWHO), abduction positioning, airplane design, prefabricated, includes fitting and adjustment
L3961	Shoulder-elbow-wrist-hand orthosis (SEWHO), shoulder cap design, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3962	Shoulder-elbow-wrist-hand orthosis (SEWHO), abduction positioning, Erb's palsey design, prefabricated, includes fitting and adjustment
L3967	Shoulder-elbow-wrist-hand orthosis (SEWHO), abduction positioning (airplane design), thoracic component and support bar, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3971	Shoulder-elbow-wrist-hand orthosis (SEWHO), shoulder cap design, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3973	Shoulder-elbow-wrist-hand orthosis (SEWHO), abduction positioning (airplane design), thoracic component and support bar, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3975	Shoulder-elbow-wrist-hand-finger orthosis (SEWHO), shoulder cap design, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3976	Shoulder-elbow-wrist-hand-finger orthosis (SEWHO), abduction positioning (airplane design), thoracic component and support bar, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3977	Shoulder-elbow-wrist-hand-finger orthosis (SEWHO), shoulder cap design, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3978	Shoulder-elbow-wrist-hand-finger orthosis (SEWHO), abduction positioning (airplane design), thoracic component and support bar, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3980	Upper extremity fracture orthotic, humeral, prefabricated, includes fitting and adjustment

HCPCS Code	HCPC Code Description
L3982	Upper extremity fracture orthotic, radius/ulnar, prefabricated, includes fitting and adjustment
L3984	Upper extremity fracture orthotic, wrist, prefabricated, includes fitting and adjustment
L3999	Upper limb orthosis, not otherwise specified
L4205	Repair of orthotic device, labor component, per 15 minutes
L4210	Repair of orthotic device, repair or replace minor parts

INTRODUCTION

Non-powered Devices

Non-powered upper limb orthotic devices are most commonly used to treat injuries and disorders of the finger, hand, wrist, elbow, and less often, the shoulder. The devices may be named based on anatomic region (e.g., wrist, hand), by purpose (e.g., correction, restricting motion) or by function (e.g., compensating for deformity, weakness). They can be prefabricated, or custom made. Various types of upper limb orthotic devices are available including but not limited to shoulder orthoses, elbow orthoses, finger orthoses, and elbow-wrist-hand orthoses. These devices can also be classified as either static (e.g., used to prevent deformity, reduce tone, provide stretch), dynamic (e.g., allow restricted motion) or adaptive/functional (e.g., used to compensate for absent function). Static devices are rigid and do not allow motion. They are usually used for fracture management, or treatment of nerve injuries or inflammatory conditions. Dynamic devices do allow some motion and are most often used to treat weak muscles and joint contractures. Adaptive/functional devices are used to assist with function, such as for performance of activities of daily living.

Shoulder orthoses have been marketed under numerous different headings. These include shoulder support braces, shoulder slings, shoulder subluxation orthosis, and shoulder dislocation prevention braces to name a few. The reason for using shoulder supports can be divided into support and immobilization. The support category has been used for recurrent displacements, sports activity and post-stroke subluxation. The immobilization category is used for post-trauma and post-surgery. Many of the shoulder supports are made of elastic materials and are compressive in nature. The claims regarding shoulder supports include reduction in the chance of muscle strain, improved circulation, improved performance, and assistance in efficiency of movement.

The most common conditions for the use of elbow orthoses are epicondylitis, elbow contractures, and neurological disorders. Elbow orthoses or bands that support the forearm are most commonly used for epicondylitis. A review of the literature shows that elbow supports are rarely used as an isolated treatment.

Wrist braces are generally recommended for: 1) support for a sprained wrist or tendonitis, 2) arthritic conditions or hand contractures, and 3) carpal tunnel syndrome (CTS). There is very little research on wrist orthoses and wrist sprains, tendonitis, and arthritic conditions; most of the research involving wrist braces is for carpal tunnel syndrome (CTS). Case studies are the most common methodology for these conditions. Innovative treatments are often the strategy used (Sailer & Lewis, 1995). Most of the bracing used in the athletic field is guided by treatment to return the athlete to play, and not best practice guidelines. Bracing often involves casting and splinting to allow the athletes to return to competition earlier (Singletary & Geissler, 2009). Most of these interventions do not use criteria for return to play as much as they evaluate risk of further or more severe injury.

Finger and hand orthotic devices are most often used post-fracture, post-surgically, or for deformity management. Research has demonstrated positive outcomes for treatment of OA and some deformities as a form of conservative care.

Powered Devices

Myoelectric prostheses use muscle activity from the remaining limb for the control of joint movement. Electromyographic (EMG) signals from the limb stump are detected by surface electrodes, amplified, and then processed by a controller to drive battery-powered motors that move the hand, wrist, or elbow. Although upper arm movement may be slow and limited to one joint at a time, myoelectric control of movement may be considered the most physiologically natural. Myoelectric powered upper-extremity orthotic devices use neurologic sensors, microprocessor units, and electric motors to provide self-initiated movement of the affected upper extremity. One device, the MyoPro® (Myomo, Inc., Boston, MA), is a myoelectric arm orthosis designed to support a weak or deformed arm. It is purported the MyoPro can enable individuals to self-initiate and control movements of a partially paralyzed or weakened arm using their own muscle signals. The device may be used during rehabilitation (as exercise equipment) or as a personal assistive device. Individuals with traumatic brain injury, spinal cord injury, brachial plexus injury, amyotrophic lateral sclerosis, stroke, multiple sclerosis and other upper limb neuromuscular deficits are the targeted candidates for use of the device. According to the manufacture there are three MyoPro 2 models available, all models are myoelectrically controlled by the wearer's own muscle signal. The Motion E features a powered elbow with static rigid wrist support; Motion W has a powered elbow and a multi-articulating wrist, with flexion/extension and supination/pronation; and Motion G offers a powered elbow, a multi-articulating wrist and a powered elbow. According to the United States Food and Drug Administration (FDA), Myomo Inc. received 510(k) approval for the Myomo e100 in 2007 as a Class 2 device, described further as exercise equipment, powered, EMG-triggered. The device is marketed for use by stroke patients undergoing rehabilitation to facilitate stroke rehabilitation by muscle re-education, and/or maintaining or increasing range of motion.

REVIEW OF THE LITERATURE

Published evidence indicates a number of devices are available for a variety of uses and generally supports upper extremity orthoses use for the following indications:

- Support weak or absent muscles (e.g., following cervical spine injury, brachial plexus injury, peripheral nerve injury, sprain, strain;
- Protect and support injured or diseased muscles/joints by limiting motion (e.g., rheumatoid arthritis, osteoarthritis, overuse syndromes [e.g., lateral epicondylitis, cubital tunnel syndrome, carpal tunnel syndrome, de Quervain tenosynovitis, trigger finger], trauma, following surgical repairs, fractures [e.g., acromioclavicular dislocation, clavicle fracture]);
- Prevent contracture or deformity from neurological injury (e.g., brain injury, stroke [i.e., spasticity], spinal cord injury, brachial plexus injury, peripheral nerve injury);
- Correct joint contractures resulting from disease or immobilization (e.g., post fracture, burns);
- Help with performance of ADLs (e.g., patients with spinal cord injuries).

Shoulder Orthoses

Burns and Owens (2010) reviewed the management of shoulder instability in in-season athletes and noted the limited data available to guide treatment of athletes hurt in the middle of the season. Bracing is often a standard option for return to play but it can restrict glenohumeral motion and effect athletic performance.

Buss et al. (2004) followed thirty (30) athletes over a two (2) year period who were treated non-operatively. Nineteen (19) of these athletes have had anterior dislocations and eleven (11) had experienced subluxations. They were treated with physical therapy and with braces, if appropriate. The criteria for deciding what was appropriate was not clear. The athletes were followed for the number of further episodes, additional injuries, and subjective ability to compete. Twenty-six (26) of the athletes were able to complete the season. Ten (10) athletes suffered recurrent instability episodes, and there was an average of 1.4 recurrent instability episodes per athlete. No further injuries were attributable to the original shoulder injury. Sixteen (16) of the athletes underwent surgical stabilization after the season was completed. Reuss et al. (2004) noted possible problem areas with shoulder braces were fit and range of motion restriction. Paterson et al. (2010) completed a systematic review and meta-analysis of the literature on position and duration of immobilization after primary anterior shoulder dislocation. The authors reported that analysis of the best available evidence indicates there is no benefit of conventional sling use for longer than one week in younger patients and bracing in external rotation may provide a clinically important benefit over sling immobilization, but recurrence rates of dislocation were not significantly different. This finding was also noted in a more recent randomized controlled trial by Whelan et al. (2014).

Monk et al. (2015) reviewed the evidence in managing traumatic anterior shoulder instability. Non-operative treatments included slings, bracing and physical therapy. Operative treatments included reconstructions either open or arthroscopically approached. Because this was a scoping review, systematic reviews and randomized controlled trials comparing operative with non-operative treatments and different operative treatments were identified. Results identified that there was limited and weak evidence for the best treatment option.

A Cochrane Review by Ada et al. (2009) looked at supportive devices for preventing and treating subluxation of the shoulder after stroke. Only one (1) trial on shoulder slings met the inclusion criteria. Hurd (1974) examined the effects of a hemi-sling versus no supportive device. Hurd reported that there was no difference between the two (2) groups in subluxation (defined as greater than ten [10] mm) or increasing contracture (defined as more than thirty [30] degrees loss of shoulder external rotation).

There were two (2) observational studies that Ada did not include that seemed to support the use of a sling in stroke patients. They provide an immediate decrease in subluxation. Moodie et al. (1986) showed an immediate eleven (11) degree reduction in subluxation using a Triangular Sling. Brooke et al. (1991) showed a ten (10) degree reduction in subluxation using a Harris Sling.

Parsons et al. (2010) retrospectively evaluated forty-three (43) patients with full thickness rotator cuff tears who underwent a standardized, conservative protocol of sling immobilization for six (6) weeks after repair. Ten (10) patients were considered stiff after surgery. They were compared to the non-stiff group at the end of one (1) year and there was no statistical difference in range of motion (ROM). Repeat MRIs suggested a trend towards a lower retear rate among the stiff patients. Parsons et al. suggested that immobilization may improve the rate of healing.

Kim et al. (2012) compared two (2) groups of patients to see if early passive motion was necessary after arthroscopic rotator cuff repair. Both groups were instructed to wear an abduction brace for four to five (4-5) weeks after surgery and to start shoulder exercise after brace weaning. Fifty-six (56) patients were randomly assigned to a group that began early passive motion three to four (3-4) times per day during the brace wearing stage. Forty-nine (49) patients were assigned to the group that had no passive motion. Outcomes included ROM, VAS, and functional evaluations. There was no statistical difference between the two groups.

Reid et al. (2012) reviewed the literature relating to the conservative management of acromioclavicular joint (ACJ) separations. They identified twenty-four (24) articles to help develop Best Practice Guidelines, but there were no randomized controlled trials (RCTs). They did a narrative review of conservative management, and a shoulder sling was

included. Treatment strategies identified for the initial acute phase were derived from a consensus of retrospective studies. It is clinically accepted that the initial phase broadly includes the use of a sling, analgesics and anti-inflammatory modalities, and exercise at four to six (4-6) weeks post-injury. There were no studies found in the literature that listed objective measures that were used to return an athlete to play. Guidelines were based on clinical experience (Cote et al., 2010).

Nadler and Pauls (2017) sought to determine whether shoulder orthoses prevent or reduce gleno-humeral subluxation and hemiplegic shoulder pain. Eight studies were included, with 186 participants. Findings suggest that applying an orthosis to an already subluxed shoulder immediately reduced vertical subluxation on X-ray, but improvements were not maintained when orthosis was removed. Orthoses with both proximal and distal attachments improved shoulder pain in the majority of stroke patients when worn for four weeks (starting several days or weeks post-stroke). Authors concluded that observational studies suggest that orthoses reduce vertical subluxation whilst in-situ. Available evidence from heterogeneous studies after stroke suggests that orthoses may reduce pain and are well-tolerated with prolonged use.

Elbow Orthoses

Struijs et al. (2001) conducted a systematic review of orthotic devices for tennis elbow. They found seventeen (17) potential titles to include in the analysis. Five (5) of these studies met the eligibility criteria. Four (4) of the studies were a comparison between an orthotic device and a conventional treatment. Two (2) of these studies were a comparison between the orthotic device and corticosteroid injection. One (1) of the studies showed no difference between interventions. Haker (1993) showed significantly better short-term and intermediate-term results with the corticosteroid injection. Three (3) of the studies used the elbow orthotic as an additional treatment and this resulted in short-term results in two (2) of the studies. Erturk et al. (1997) compared use of an orthotic with an injection versus the injection alone. Burton (1988) compared an elbow strap and anti-inflammatory cream versus an anti-inflammatory cream alone, and an elbow strap and manipulation to manipulation alone. Improvement was seen in VAS score. There was no significant difference in maximum grip-strength and pain-free grip strength. The authors concluded that despite elbow supports being a common treatment for tennis elbow, there is no clear evidence for this recommendation.

Hijmans et al. (2004) reviewed the available literature on elbow orthoses and concluded that elbow orthoses cannot be recommended on the basis of scientific evidence because there is no scientific evidence. They reported finding one (1) study on elbow orthosis and contractures (Karachalios et al., 1994) where ROM was the outcome. They included patients secondary to trauma and hemophiliac patients. They reported another study that seemed to indicate static progressive stretching might work (Gelinas et al., 2000). The results on elbow orthosis for epicondylitis were conflicting and this may be due to using

different outcome measurements. Hijmans et al. concluded that: 1) although there was no evidence to prescribe an elbow orthosis, the support did seem to be safe, 2) the immediate effect of epicondylitis bracing seems to be limited, but long-term effects may be seen, 3) it is unknown if bracing at night provides additional benefit. More recently, Veltman et al. (2015) completed a systematic review on static progressive versus dynamic splinting for posttraumatic elbow stiffness. Eight studies (including 232 patients) met the eligibility criteria and were included for data analysis and pooling. Static progressive splinting was evaluated in 160 patients. The average pre-splinting range of motion of all elbows was 72°, which improved by 36° after splinting to an average post-splinting arc of motion of 108°. Dynamic splinting was evaluated in 72 patients with an average pre-splinting range of motion of 63°. The average improvement was 37° to an average post-splinting arc of motion of 100°. The authors concluded that both dynamic and static progressive splinting are good options for the treatment of elbow stiffness.

Struijs et al. (2006) designed a randomized controlled trial to look at the cost effectiveness of a brace, physiotherapy, or both for the treatment of tennis elbow. Outcome measures were success rate, severity of complaints, pain, functional disability, and quality of life. A total of one hundred and eighty (180) patients were evaluated. There were no clinically relevant differences between the groups. Success rate at one (1) month was 89% in the physiotherapy group, 86% in the brace group, and 87% in the combination group.

Johnson et al. (2007) did a systematic review of treatment of lateral epicondylitis. They concluded that: 1) a forearm strap may decrease pain and increase strength short-term, and 2) bracing for up to six (6) weeks may improve a patient's ability to perform daily activities. More recently, Sims et al. (2014) completed a systematic review of randomized controlled trials for the non-surgical treatment of lateral epicondylitis. The following non-surgical techniques were included: corticosteroid injection, injection technique, iontophoresis, botulinum toxin A injection, prolotherapy, platelet-rich plasma or autologous blood injection, bracing, physical therapy, shockwave therapy, or laser therapy. Non-invasive treatment methods such as bracing and physical therapy do not appear to provide a definitive benefit for pain reduction.

Sodhi et al. (2017) compared the protocol and duration of splint use and changes in range of motion outcomes between static progressive and dynamic brace cohorts. Multiple surgical and nonsurgical treatment options exist for patients with elbow stiffness. Many nonsurgical mobilization bracing options have been implemented to increase elbow range of motion. Three of the main bracing options for these patients are turnbuckle, static progressive stretch, and dynamic bracing. The purpose of this study was to review the current literature on turnbuckle, static progressive stretch, and dynamic bracing to provide information for practitioners and patients regarding which brace is more appropriate to use for elbow stiffness. Overall, although all 3 bracing options are available for patients, these studies found that, based on the evaluated metrics, the static progressive brace was a

markedly superior option for patients with elbow stiffness. The time required to wear the static progressive stretch brace was 13 times less than that for the turnbuckle and 5 times less than that for the dynamic devices. Additionally, the high failure rate (10%) and low success rate (29%) of the dynamic brace, compared with the 63% regaining of functional range of motion in the static progressive stretch group, further highlight the benefits of the static progressive stretch brace. Chen et al. (2017) assessed the effectiveness of static progressive orthoses for elbow contracture. Ten clinical trials were included. Significant immediate improvement in the range of motion was reported by all studies, and those effects were still significant at follow-up. No significant difference was shown between static progressive and dynamic orthoses for elbow contracture in one randomized control trial. Authors concluded that current low-quality evidence suggested that static progressive orthoses provided assistance for elbow contracture through improving range of motion. Further research is recommended using high-quality randomized controlled trials.

Wrist/Hand Orthoses

Carpal tunnel syndrome (CTS) is often treated initially with a splint to relieve pressure on the median nerve. There have been a number of trials involving non-surgical treatments for CTS. A Cochrane Review by O'Connor et al. (2003) evaluated non-surgical treatments involving eight hundred and eighty-four (884) people in twenty-one (21) trials. Three of the trials were concerned with splinting, all with a high risk of bias. Overall, there was limited evidence that a) nocturnal hand bracing, b) bracing in extension vs. neutral and c) nocturnal vs. full time splinting are effective or equally effective in improving symptoms and hand function in the short term. One trial that involved fifty-one (51) people showed yoga significantly reducing pain after eight (8) weeks compared to wrist splinting.

Sevim et al. (2004) looked at long term effectiveness of splinting in CTS. They evaluated one hundred and twenty (120) patients with mild and moderate CTS with clinical symptoms and electro-physiologic evidence in a prospective, randomized trial. Sixty (60) patients were instructed to wear splints every night, and there were two (2) groups of thirty (30) patients that received steroid injections. At the end of one (1) year, the splinting provided symptomatic relief and improved sensory and motor nerve conduction velocities. The proximal and distal injections were ineffective.

Gravlee and Van Durme (2007) did a systematic review of brace and splints for musculoskeletal conditions. They concluded that there was limited quality, patient-oriented evidence to support a neutral wrist splint for CTS when used at least four (4) weeks. Wrist splints were most effective when they were worn full-time.

A more recent Cochrane Review completed by Page et al. (2012) reviewed only splinting for CTS. Since the previous review by O'Connor in 2003 that included splinting as a non-surgical intervention, the evidence base for splinting as an intervention for CTS has grown significantly. This review included nineteen (19) studies with 1,190 participants. The

studies involved the following comparisons: 1) splinting versus no treatment, 2) different splint designs, 3) different splint wearing regimens, 4) splint delivered as a single intervention versus another non-surgical intervention, and 5) splint intervention with another non-surgical intervention. The authors concluded that there is limited evidence that a splint worn at night is more effective than no treatment in the short-term. There is insufficient evidence that one splint design or wearing regimen is more effective than another. There is insufficient evidence regarding the use of splints over other non-surgical interventions.

D'Angelo et al. (2015) completed a systematic review to determine the effectiveness of passive physical modalities compared to other interventions, placebo/sham interventions, or no intervention in improving self-rated recovery, functional recovery, clinical outcomes and/or administrative outcomes (e.g., time of disability benefits) in adults and/or children with soft tissue injuries and neuropathies of the wrist and hand. The authors screened 6618 articles and critically appraised 11 studies. Of those, 7 had low risk of bias: 5 addressed carpal tunnel syndrome (CTS) and 2 addressed de Quervain's disease. They found evidence to support the use of various night splints for management of CTS and that in the long term, they are as effective as surgery. They also suggest that a thumb spica may offer short term benefit for the management of de Quervain's disease.

Heales et al. (2020) investigated the immediate effects of forearm and/or wrist orthoses on outcome measures of pain and function in individuals with lateral elbow tendinopathy. The search revealed 1965 studies, of which, seven randomised crossover trials were included. Using the GRADE approach there was low quality evidence revealing a significant decrease in pain during contraction with forearm orthoses compared to a control/placebo condition. Low quality evidence revealed improvements in pain-free grip strength with the use of a forearm orthosis, but not maximal grip strength. Low quality evidence revealed a static wrist orthosis did not improve pain-free grip strength or maximal grip. Authors concluded that there is low quality evidence that forearm orthoses can immediately reduce pain during contraction and improve pain-free grip strength but not maximal grip strength in individuals with lateral elbow tendinopathy. Frye and Geigle (2021) compared prefabricated and custom resting hand splints and establish the feasibility of splinting research for larger scale trials. Thirty-six hands from 19 individuals with cervical spinal cord injury were enrolled during their acute rehabilitation stay. Each eligible hand was randomized to receive a custom or prefabricated resting hand splint for night use. No difference existed in Graded Redefined Assessment of Strength, Sensation and Prehension (GRASSP) outcomes or user preference between custom and prefabricated resting hand splints. Mann-Whitney tests indicated that there was no significant difference in qualitative prehension scores nor quantitative prehension scores between groups. Adherence to the splinting program was high (18 out of 19 participants), and no adverse effects occurred. Four themes emerged from the participant comments: the participants felt splints were helpful in their recovery; they found it challenging to direct their caregivers to help with

the splints; they needed to take ownership for managing their splints; and they wished they received more education on splint rationale. Authors concluded there was no obvious difference in outcome or user preference between prefabricated and custom resting hand splints.

Wouters et al. (2020) described outcomes of nonsurgical treatment for symptomatic thumb carpometacarpal joint (CMC-1) instability. Secondary, to evaluate the conversion rate to surgical treatment. Participants included a consecutive sample of patients with symptomatic CMC-1 instability (*N*=431). All patients received nonsurgical treatment including exercise therapy and an orthosis. Main outcome measures included pain (visual analog scale [VAS], 0-100) and hand function (Michigan Hand Outcomes Questionnaire [MHQ], 0-100) at baseline, 6 weeks, and 3 months. Conversion to surgery was recorded for all patients with a median follow-up of 2.8 years (range, 0.8-6.7y). In this large sample of patients with symptomatic CMC-1 instability, nonsurgical treatment demonstrated clinically relevant improvements in pain and aspects of hand function. Furthermore, after 2.8 years, only 14% of all patients were surgically treated, indicating that nonsurgical treatment is a successful treatment of choice.

McVeigh et al. (2021) reviewed the use of upper-extremity orthoses and casts after injuries to the wrist and hand in the pediatric, adolescent, and young adult population. The common injuries reviewed include pediatric distal radius fractures, scaphoid fractures, metacarpal fractures, mallet fingers, volar plate injuries of the proximal interphalangeal (PIP) joint, and ulnar collateral ligament (UCL) tears of the thumb metacarpophalangeal (MCP) joint. This review included cases of common injuries to the upper extremity, which required orthotic intervention. Immobilization recommendations for nonsurgical pediatric distal radius fractures, nonsurgical metacarpal fractures, mallet fingers, and UCL tears of the thumb MCP include a removable orthosis. Nondisplaced scaphoid fracture orthosis recommendations include initial immobilization in a nonremovable short-arm thumb spica cast. Volar plate injuries of the PIP joint require buddy straps for healing. Authors concluded that the literature demonstrates the effectiveness of removable orthoses in healing, patient satisfaction, and time to return to activity after many common upper-extremity injuries. Removable orthoses should be considered an equal or superior treatment method to cast immobilization, immobilization of additional joints, or longer periods of immobilization.

Alexander et al. (2022) did a systematic review and meta-analysis to determine whether non-robotic dynamic hand orthoses DHOs improve upper limb recovery after stroke in comparison to i) placebo or no intervention and ii) usual care. Authors reviewed 7225 titles and included four studies involving 56 randomized participants, all with a high risk of bias. A positive effect in favor of non-robotic DHOs was observed for two outcomes; upper limb function and dexterity. Authors concluded that the results are encouraging but included

studies were small with high risk of bias meaning there is currently insufficient evidence that non-robotic DHOs improve upper limb recovery after stroke.

Karjalainen et al. (2023) assessed the effects (benefits and harms) of splinting for people with carpal tunnel syndrome (CTS) in a Cochrane Review. Randomised trials were included if the effect of splinting could be isolated from other treatment modalities. The comparisons included splinting versus no active treatment (or placebo), splinting versus another disease-modifying non-surgical treatment, and comparisons of different splint-wearing regimens. Authors excluded studies comparing splinting with surgery or one splint design with another and they excluded participants if they had previously undergone surgical release. Authors included 29 trials randomising 1937 adults with CTS. The trials ranged from 21 to 234 participants, with mean ages between 42 and 60 years. The mean duration of CTS symptoms was seven weeks to five years. Eight studies with 523 hands compared splinting with no active intervention (no treatment, sham-kinesiology tape or sham-laser); 20 studies compared splinting (or splinting delivered along with another non-surgical intervention) with another non-surgical intervention; and three studies compared different splinting regimens (e.g. night-time only versus full time). Trials were generally at high risk of bias for one or more domains, including lack of blinding (all included studies) and lack of information about randomisation or allocation concealment in 23 studies. For the primary comparison, splinting compared to no active treatment, splinting may provide little or no benefits in symptoms in the short term (< 3 months). The mean Boston Carpal Tunnel Questionnaire (BCTQ) Symptom Severity Scale (SSS) (scale 1 to 5, higher is worse; minimal clinically important difference (MCID) 1 point) was 0.37 points better with splint compared with no active treatment. Removing studies with high or unclear risk of bias due to lack of randomisation or allocation concealment supported our conclusion of no important effect. In the long term (> 3 months), there was uncertainty about the effect of splinting on symptoms. Splinting probably does not improve hand function in the short term and may not improve hand function in the long term. In the short term, the mean BCTQ Functional Status Scale (FSS) (1 to 5, higher is worse; MCID 0.7 points) was 0.24 points better with splinting compared with no active treatment. In the long term, the mean BCTQ FSS was 0.25 points better with splinting compared with no active treatment. Night-time splinting may result in a higher rate of overall improvement in the short term. There is uncertainty if splinting decreases referral to surgery. None of the trials reported health-related quality of life. Low-certainty evidence from one study suggests that splinting may have a higher rate of adverse events, which were transient, but the 95% CIs included no effect. Seven of 40 participants (18%) reported adverse effects in the splinting group and 0 of 40 participants (0%) in the no active treatment group. There was low- to moderate-certainty evidence for the other comparisons: splinting may not provide additional benefits in symptoms or hand function when given together with corticosteroid injection (moderate-certainty evidence) or with rehabilitation (low-certainty evidence); nor when compared with corticosteroid (injection or oral; low certainty), exercises (low certainty), kinesiology taping (low certainty), rigid taping (low certainty), platelet-rich

plasma (moderate certainty), or extracorporeal shock wave treatment (moderate certainty). Splinting for 12 weeks may not be better than six weeks, but six months of splinting may be better than six weeks of splinting in improving symptoms and function (low-certainty evidence). Authors concluded that there is insufficient evidence to conclude whether splinting benefits people with CTS. Limited evidence does not exclude small improvements in CTS symptoms and hand function, but they may not be clinically important, and the clinical relevance of small differences with splinting is unclear. Low-certainty evidence suggests that people may have a greater chance of experiencing overall improvement with night-time splints than no treatment. As splinting is a relatively inexpensive intervention with no plausible long-term harms, small effects could justify its use, particularly when patients are not interested in having surgery or injections. It is unclear if a splint is optimally worn full time or at night-time only and whether long-term use is better than short-term use, but low-certainty evidence suggests that the benefits may manifest in the long term.

Powered Orthoses

Evidence in the peer-reviewed published scientific literature evaluating upper limb myoelectric orthoses consists of review articles, observational studies, and few randomized controlled trials with small patient populations, reporting short term outcome. Much of the evidence evaluates use of robotic movement training in a rehabilitation setting as an adjunct to conventional therapies or for exercise training, with limited evidence evaluating use of the myoelectric device in the home setting. Hayes published a Search and Summary report (Hayes, 2018) evaluating use of the MyoPro or similar devices, in general. According to Hayes a search of the literature located few studies consisting of two prospective comparative trials, one prospective uncontrolled study, two case reports and five review articles. The authors concluded there is insufficient evidence to assess safety and/or impact on health outcomes or patient management associated with use of the device for paralysis/paresis following stroke. Although myoelectric powered upper extremity orthotic devices are an evolving technology, additional well-designed, large-scale clinical studies evaluating benefits and harms of this technology after stroke and other neurological injuries are needed to firmly establish safety and clinical efficacy.

In 2013, Page and others published the results of a small randomized controlled trial (RCT) involving 16 subjects with chronic, stable, moderate upper extremity impairment. Subjects were assigned to undergo administered repetitive task-specific practice with or without the use of the Myomo e100 myoelectric upper limb orthosis (n=8 in each group). After the intervention, both groups exhibited nearly identical Fugl-Meyer Assessment of Motor Recovery After Stroke score increases of approximately 2.1 points; the group using the orthotic exhibited larger score changes on all but one of the Canadian Occupational Performance Measure and Stroke Impact Scale subscales, including a 12.5 point increase on the Stroke Impact Scale recovery subscale. The authors concluded that therapist-supervised repetitive task-specific practice integrating the Myomo device is as efficacious

as manual practice in subjects with moderate upper extremity impairment. The generalizability of this study is limited by the small sample size, as well as other methodological issues. Further investigation on the clinical utility and health outcomes is needed.

Willigenburg et al. (2016) conducted an 8-week randomized controlled trial to compare behavioral and kinematic outcomes of post-stroke survivors with moderate upper extremity impairment. The researchers assigned 12 subjects to either the standard treatment of repetitive task-specific practice (*n*=5) or the use of the Myomo e100 myoelectric upper extremity orthotic with repetitive task-specific practice (*n*=7). The individuals who used the myoelectric orthotic scored higher on the Stroke Impact Scale which included self-reported measurements on recovery perceptions (p=0.032) and activities of daily living (p=0.061). The standard treatment group scored higher on kinematic peak hand velocity during the reach-up task (p=0.018). No significant differences between the groups were found on the remaining kinematic outcomes which included elbow extension and shoulder flexion. The researchers concluded the use of the myoelectric orthotic increases the perception of improvement; however, myoelectric orthotics were as effective as the standard manual treatment when evaluating kinematics. Limits of the study include small sample size, stability of treatment issues and short duration. The researchers note that this is the first known study of its kind on portable myoelectric orthotic kinematics and further investigation is needed.

Peters et al. (2017) performed an industry designed and supported observational cohort study to test behavioral outcomes on 18 subjects who had moderate upper extremity impairment following stroke. Each subject performed a series of tests including the Fugl-Meyer Assessment and the Box and Blocks test. The subjects completed the tests in the same order with and without wearing a MyoPro Motion-G myoelectric upper extremity orthotic. The Fugl-Meyer scores were an average of 8.72 points higher ($p<0.0001$) when participants wore the orthotic and the scores exceeded the minimal clinically important difference. In addition, Box and Blocks test scores were higher for the individuals wearing the orthotic ($z=3.42$; $p<0.001$). The researchers found that statistically significant results were demonstrated for many activities including elbow extension, grasping items, finger extension, and manual dexterity. Limitations include a small sample size and a change in study design. The researchers note that this is the first study comparing subjects with or without a myoelectric brace. Well-designed studies with large samples and control groups are needed. Page et al. (2020) sought to determine the efficacy of regimens comprised of: (1) Myomo + repetitive, task-specific practice; (2) repetitive, task-specific practice only; and (3) Myomo only on outcomes for hemiplegic arm. Using a randomized, controlled, single-blinded design, 34 subjects (20 males; mean age 55.8 years), exhibiting chronic, moderate, stable, post-stroke, upper extremity hemiparesis, were included. Participants were randomized to one of the above conditions, and administered treatment for 1 h/day on 3 days/week over an 8-week period. The primary outcome measure was the upper

extremity section of the Fugl-Meyer Impairment Scale (FM); the secondary measurement was the Arm Motor Activity Test (AMAT). The groups exhibited similar score increases of approximately +2 points, resulting in no differences in the amount of change on the FM and AMAT. The results suggest that a therapeutic approach integrating myoelectric bracing yields highly comparable outcomes to those derived from repetitive, task-specific practice-only. Myoelectric bracing could be used as alternative for labor-intensive upper extremity training due to its equivalent efficacy to hands-on manual therapy with moderately impaired stroke survivors.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and expert training, it would be best practice to refer the patient to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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