Medical Coverage Policy

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Coverage Policy Number 0176

Thermal Shrinkage

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Related Coverage Resources

INSTRUCTIONS FOR USE

Overview

This Coverage Policy addresses thermal shrinkage of a joint capsule, ligament or tendon, intended to reduce capsule laxity and improve joint stability. The procedure employs the use of a radiofrequency probe or laser to deliver nonablative heat to a targeted area. It is hypothesized that heat from the thermal catheter will cause the collagen fibers of the tissue to shrink through collagen denaturation, resulting in a tightening and improved stabilization of the joint capsule or ligaments and tendons.

Coverage Policy

Thermal shrinkage is considered experimental, investigational or unproven for ALL indications, including treatment of a joint capsule, ligament or tendon.

General Background

Thermal shrinkage of the joint capsule (e.g., thermal capsulorrhaphy, thermal capsular shrinkage, arthroscopic thermal capsulorrhaphy, electrothermal arthroscopic capsulorrhaphy [ETAC]) and ligaments or tendons (e.g., electrothermal therapy, radiofrequency thermal shrinkage, thermal shrinkage) has been proposed for use in arthroscopic surgery.

Monopolar radiofrequency probes (single electrode tip and grounding plate) and bipolar radiofrequency probes (two points on the tip of a probe) are used to apply heat to soft tissue. The heat is proposed to ultimately cause the ligament to shrink and shorten by altering the collagen, resulting in tightening of the joint and improved stability. The thermal effect of the energy is dependent on the level of energy, the duration of the application, the nature of the tissues, and the type of device used.

Overall, the reported outcomes of thermal shrinkage have been short-term and consist mainly of decreased tissue trauma at the time of surgery. Published data do not permit strong conclusions regarding the efficacy of thermal shrinkage and impact on improving health outcomes. Complications and failure that may be related to inadequate shrinking or overheating of tissue have been reported in the medical literature. Reported complications have included capsular necrosis, loss of capsular and glenohumeral ligament integrity, nerve damage, and failure leading to recurrent instability.

U.S. Food and Drug Administration (FDA)
Several thermal probe devices used as part of electrosurgical or electrothermal systems have been granted 510(k) approval by the U.S. Food and Drug Administration (FDA) and include but are not limited to: Oratec ORA-50 Electrothermal System and Accessories (Oratec Interventions, Menlo Park, CA), VULCAN® EAS® Electrothermal Arthroscopy System and Accessories (Smith and Nephew, Andover, MA) and VAPR™ TC Electrode (Mitek Products, Norwood, MA). These Class II devices are FDA regulated as electrosurgical cutting and coagulation devices and accessories

Anterior/Posterior Cruciate Ligament (ACL/PCL) Injury
Injuries of the ACL or PCL often result in complete rupture, although in some cases injuries result only in a partial tear or stretching. Depending on the severity of the injury, a person may experience pain, decreased range of motion, and/or some degree of functional impairment. Nonsurgical treatment options may include rest, anti-inflammatory medications, compression, strengthening exercises, and/or physical therapy and cortisone injections. These conservative treatments are frequently used for individuals where there is an incomplete tear or when reconstruction is not desired. For those individuals with complete tears, surgical reconstruction may be the only option.

The standard surgical approach involves the use of allograft or autograft tissue in reconstructing the ligament by way of open arthrotomy or arthroscopy. Thermal shrinkage has been suggested as a treatment modality for individuals with partially intact ACL/PCL ligaments.

Literature Review: Evidence evaluating thermal shrinkage for the treatment of ACL/PCL instability consists of both retrospective and prospective case series (Farng, et al., 2005; Halbrecht, 2005; Indelli, et al., 2003; Carter, et al., 2002) and case reports (Oakes and McAllister, 2003). The published case series involve small patient populations with short-term outcomes and lack of a control group. While some of the studies support improved knee function during the initial post-operative period (Farng, et al., 2005; Halbrecht, 2005; Indelli, et al., 2003), laxity can recur and some of the studies (Halbrecht, 2005; Carter, et al., 2002) have demonstrated greater than 50% failure rates at final follow-up. A recent prospective multicenter clinical trial (n=64) with mid-term follow-up (at least two years for 61 subjects) showed a failure rate for lax grafts of 78.9% and a failure rate for lax native ligaments of 38.1% when subjects underwent thermal shrinkage of the ACL (Smith, et al, 2008). Evidence in the peer-reviewed published scientific literature is insufficient to support the safety and efficacy of thermal shrinkage, and long-term durability of the procedure has not been demonstrated.

Shoulder Instability
Disruption of the glenohumeral ligament (laxity or elongation) may result from trauma or from congenital or developmental weakness and may lead to joint instability. Individuals experience symptoms of aching, heaviness, pain and decreased range of motion. This condition often occurs in individuals who are athletic and in young adults.

Standard treatment consists of conservative therapy, using activity modification, exercises and patient education. For cases that do not respond to treatment, surgical repair may be necessary. The goal of surgery is to re-stabilize the shoulder and maintain full, pain-free range of motion. Surgery consists of inspecting the shoulder joint and repairing, reattaching, or tightening the labrum, ligaments or capsule, with either sutures alone or sutures attached to absorbable tacks or anchors. Although arthroscopic approaches have frequently been performed, there is more concern about the instability recurring after arthroscopic surgery than after open procedures. In some cases, authors propose that the recurrence of instability results from lack of tightening in the stretched-out capsule despite the operative repair. Arthroscopic thermal shrinkage, also referred to as electrothermal arthroscopic capsulorrhaphy (ETAC), has been suggested as a treatment for shoulder instability in cases requiring both tightening of the ligament and reattachment procedures. Reported complications associated with thermal shrinkage of the shoulder include biceps tendon rupture, capsular attenuation, adhesive capsulitis, and axillary neuropathy.

Literature Review: The evidence evaluating thermal shrinkage for treatment of shoulder instability consists of few randomized trials, both retrospective and prospective case series, cohort comparative studies and systematic reviews (Chen, et al, 2016; Jansen, et al., 2012; Engelsma and Williams, 2010; Hawkins, et al., 2007; Massoud, et al., 2007; Miniaci and Codsi, 2006; Park, et al., 2005; Bisson, et al., 2005; Chen, et al., 2005; D'Alessandro, et al., 2004; Miniaci and McBirnie, 2003; Mishra and Fanton, 2001). Several of the studies involve small sample populations evaluating short- to mid-term outcomes. When utilized to treat shoulder ligaments, reported failure rates are generally high and are often related to recurrent instability (Hawkins, et al., 2007; Massoud, et al., 2007; Park, et al, 2005; D'Alessandro, et al., 2004; Miniaci and McBirnie, 2003). When used to treat internal shoulder impingement (n=12) Jansen et al. (2012) reported that at seven year follow-up only 25% of athletes were able to perform at a preoperative sports level. Although short term results in this same group were promising at one and two years, there was significant deterioration at seven years ($p<0.001$). Additionally, Some published reviews indicate that due to unacceptable high failure rates and complications thermal capsulorrhaphy is no longer recommended as a treatment for shoulder instability (Bell, 2010; Bradley and Tejwani, 2010; Johnson and Robinson, 2010; Greiwi and Ahmad, 2010).

Ankle Instability

Arthroscopic shrinkage has also been proposed for treatment of ankle instability, although the medical literature is limited and consists mainly of case series and case reports (de Vries, et al., 2008; Maiotti, et al., 2005; Hyer and Vancourt; 2004). Despite some improvement in mechanical stability and function, these studies evaluate short term outcomes in small patient populations, and the results cannot be generalized. A more recent textbook source indicates the evidence is sparse in the orthopedic literature and does not support thermal capsular shrinkage as treatment for ankle instability (Murphy, 2021). Further well designed clinical trials evaluating long term outcomes are required to support safety and efficacy of the procedure when used to treat ankle instability.

Hip Instability

Thermal modification of the hip capsular tissue has been suggested as a treatment for hip instability. The hip joint capsule consists of collagen tissue, and shrinkage may help stabilize the joint (Philippon, 2001). While limited short-term results appear promising, further long-term, controlled studies are required to support the safety and efficacy of thermal shrinkage for this use.

Hand and Wrist Instability

Thermal energy has been used to treat unstable or loose partial-thickness cartilage defects, meniscal lesions and ligamentous tears of the wrist. Thermal energy has also been proposed for the treatment of scapholunate (SL) instability which describes a wide variety of clinical conditions affecting the scapholunate interosseous ligament of the wrist, including laxity or stretch (Manuel and Moran, 2007). Recently published studies evaluating the role of arthroscopic thermal treatment for wrist and thumb injuries or instability are primarily retrospective in design with small patient populations, and the need for subsequent surgery was not uncommon (Burn, et al., 2020; Helsper, et al., 2020; Wong and Ho, 2019).

One prospective case series (Romero, et al., 2020) (n=20) included patients with symptomatic instability of the SL ligament, alone or with triangular fibrocartilage complex (TFCC) tears, who were treated with electrothermal shrinkage and debridement (where appropriate), followed by placement of a short arm cast for one month. Outcomes were mixed, with a reported overall improvement in grip strength, but continued complaints of pain in

35% of the subjects. Chu and colleagues (2009) studied electrothermal treatment of thumb basal joint instability (n=17) over a minimum two year period. All patients underwent arthroscopic electrothermal treatment of the volar ligaments and joint capsule. At an average follow-up of 41 months pain was improved in all thumbs and the authors reported a significant improvement in thumb pinch strength ($p<0.01$). Limitations of these studies include the small patient populations and lack of a comparator.

While some additional authors have reported improvement in pain after thermal shrinkage (Lee et al., 2012; Garcia-Lopez, et al, 2012; Darlis, et al., 2005) other authors have reported injury to subchondral bone as a result of heat application to the chondral surface (Lu, et al., 2001). Moreover, authors have acknowledged that the potential benefits of thermal shrinkage for wrist instability need to be clarified (DeWal, et al., 2002).

The evidence in the peer-reviewed scientific literature is insufficient to demonstrate safety and efficacy and further, long-term clinical studies are required to support improved patient outcomes when thermal energy is used to treat hand or wrist instability.

Professional Societies/Organizations
The American Academy of Orthopaedic Surgeons (AAOS) provides information regarding thermal capsular shrinkage. According to the AAOS, "Early short-term results with thermal capsulorrhaphy were encouraging, and the procedure rapidly gained in popularity. However, more recent results with patients over a longer follow-up period have shown a much higher failure rate than was first seen. Also, more complications have been reported. As a result, doctors are performing thermal capsular shrinkage less frequently" (AAOS, 2010).

Although it has not been updated, the Washington State Department of Labor and Industries (2003) conducted a technology assessment evaluating histologic studies as well as retrospective and prospective case series of patients who underwent thermal capsulorrhaphy. In summary of their assessment, the committee concluded, "Findings do not substantially show thermal shrinkage's efficacy or effectiveness for the treatment of shoulder instability or anterior cruciate ligament laxity."

Use Outside of the US
No relevant information.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental, Investigational or Unproven when used to report arthroscopy with thermally-induced capsulorrhaphy for any joint capsule, ligament or tendon:

CPT®* Codes	Description
29999	Unlisted procedure, arthroscopy

HCPCS Codes	Description
S2300	Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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