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Medical Policy Manual

Topic: Thermal Capsulorrhaphy as a Treatment of Joint Instability

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Thermal capsulorrhaphy (TC) uses thermal energy to restructure collagen in the joint capsule or ligaments to reduce the capsule size. The technique is based on the observation that the use of nonablative levels of thermal energy can alter the collagen in a ligament and/or capsule, resulting in their shrinkage and a decrease in capsular volume, both thought to restore capsular tension. TC has been proposed as an arthroscopic technique that is technically simpler than surgical arthroscopy for tightening the capsule and ligaments. TC may be used alone or in conjunction with arthroscopic repair of torn ligaments or other structures.

While TC was initially investigated using laser energy, radiofrequency probes are now more commonly used. Devices include Oratec ORA-50 Monopolar RF Generator (Oratec Interventions) and Arthrocare (Arthrocare Corporation).

Thermal Capsulorrhaphy of the Shoulder

Shoulder instability is a relatively common occurrence, reported in 2% to 8% of the population. The condition may arise from a single traumatic event (e.g., subluxation or dislocation), repeated microtrauma, or constitutional ligamentous laxity, resulting in deformation and/or damage in the glenohumeral capsule and ligaments. Shoulder instability may be categorized according to the movement of the humeral head; i.e., as anterior, posterior, inferior, or multidirectional instability.

Multidirectional instability most frequently consists of anterior and inferior subluxation or dislocation. Inferior movement is also classified as multidirectional.

Initial treatment of shoulder subluxation or dislocation is conservative in nature followed by range of motion and strengthening exercises. However, if instability persists either activity modification or surgery may be considered. Surgery consists of inspection of the shoulder joint with repair, reattachment, or tightening of the labrum, ligaments or capsule, performed either with sutures or sutures attached to absorbable tacks or anchors. While arthroscopic approaches have been investigated over the past decade, their success has been controversial due to a higher rate of recurrent instability compared with open techniques, thought to be related in part to the lack of restoration of capsular tension. Reports of arthroscopic techniques have described various suturing techniques for tightening the capsule that require mastery of technically difficult arthroscopic intra-articular knot tying.

TC has been investigated as an arthroscopic treatment of glenohumeral laxity, a common injury among overhead athletes, such as baseball players, resulting in internal impingement of the posterior rotator cuff against the glenoid labrum. Internal impingement is often accompanied by posterior rotator cuff tearing and labral injury. The technique may also be considered in patients with chronic shoulder pain without recognized instability, based on the theory that the pain may be related to occult or microinstability. This diagnosis may be considered when a diagnostic arthroscopy reveals only lax ligaments and is commonly seen among baseball players. Finally, TC may be considered in patients with congenital ligamentous laxity, such as Ehlers-Danlos or Marfan's syndrome.

Thermal Capsulorrhaphy of Other Joints

TC has been proposed as a treatment of anterior cruciate ligament rupture, and for cutting and contouring soft tissue of other joints such as the knee, wrist, ankle, and elbow.

MEDICAL POLICY CRITERIA

Thermal capsulorrhaphy is considered **not medically necessary** as a treatment of joint instability in any joint, including but not limited to the shoulder, knee and elbow.

SCIENTIFIC EVIDENCE[1]

There are minimal data published in the peer-reviewed literature regarding the use of thermal capsulorrhaphy (TC), either as a sole arthroscopic procedure or as an adjunct to other arthroscopic repair of joint lesions. Unresolved issues regarding the technique include the following:[2,3]

- Identifying and quantifying joint laxity
- Optimal temperature and length of exposure to heat
- Variable response of collagen to heat, based on patient age and other factors
- Control of tissue shrinkage (both at the time of surgery and during follow-up as the acute thermal damage heals)
- Effect of potential temperature damage on proprioceptive and position-sensitive nerve endings within the capsule
- Risk of capsular ablation
- Risk of neurologic complications

- Appropriate rehabilitation (i.e., length of immobilization during the healing phase, followed by exercise)

In order to demonstrate safety and efficacy of TC for treatment of joint lesions, evidence from randomized controlled trials comparing TC (alone or as an adjunct procedure) with standard procedures is needed.

Thermal Capsulorrhaphy of the Shoulder

TC as the Sole Arthroscopic Procedure

Randomized Controlled Trials (RCTs)

There are no RCTs comparing TC as the sole arthroscopic procedure with standard procedures for treatment of shoulder joint lesions.

Non-randomized Studies

- Levy and colleagues reported on a case series of 90 patients (99 shoulders) with shoulder instability treated with TC using either radiofrequency (34 patients, 38 shoulders) or laser energy (56 patients, 61 shoulders), and followed for 23 to 40 months.[4] Selection criteria included all of the following: 1) a history of either repetitive microtrauma or a minimal traumatic event leading to recurrent symptoms; 2) clinical examination revealing generalized laxity; and 3) arthroscopic finding of a voluminous capsule with increased joint volume.

  Following diagnostic arthroscopy, TC was the only arthroscopic treatment performed. Outcomes included assessment of pain, stability, mobility, and return to sport or daily activities. In the laser-treated group, 59% of the patients considered their shoulder to be "better" or "much better," while there was a failure rate of 36.1%. In the radiofrequency-treated group, 76.9% of patients felt "better" or "much better," with a 23.7% failure rate. The authors reported that these results matched those of some reported case series of open repair of multidirectional instability, and suggested that due to the minimal morbidity of the arthroscopic approach, thermal shrinkage is a viable alternative to open surgery.

- In 2004, D'Alessandro and colleagues published the results of a prospective study of 84 patients who underwent TC for various indications.[5] With an average follow-up of 38 months, 37% of patients reported unsatisfactory results, based on reports of pain, instability, return to work, and the American Shoulder and Elbow Surgeons Shoulder Assessment score. The authors reported that the high rate of unsatisfactory results was of great concern.

  Levine and colleagues reported that the initial wave of enthusiasm for TC had largely subsided, given the negative results reported by D'Alessandro et al.[6]

- In 2007, Hawkins and colleagues reported 2- to 6- year follow-up results for 85 of 100 consecutive patients treated with TC for glenohumeral instability.[7] Thirty-seven patients (43.5%) were considered to have had a failed procedure, defined as recurrent instability, revision of surgery, and recalcitrant pain or stiffness requiring manipulation. Deterioration of efficacy over time was reported from a series of 12 overhead athletes (volleyball, tennis, baseball, and swimming) who presented with internal impingement at an average age of 27 years (range, 23 to 34). (12) At 2 years after surgery, the modified Rowe score had increased from 45.8 to 90.4; at 7 years postoperatively, the

Rowe score had decreased to 70.4 and visual analogue scale (VAS) score for pain was 4.8. Twenty-five percent of athletes reported that they had returned to their preinjury level of competition, 25% played at a lower level, and 50% had stopped because of their shoulder pain. The authors concluded that this compared unfavorably with the reported 7.5% failure rate when TC was used to supplement suture placation. Subsequently, the authors generally used it only in combination with other surgical procedures.

- A 2010 case series by Engelsma and Willems observed a tendency toward inferior outcomes after TC (n=9) in comparison to capsulorrhaphy by suture (n=3) or labral fixation (n=7) for treatment of posterior shoulder instability.[8]

- In 2012, Jansen and colleagues studied the long-term results of TC in 12 athletes. Patients were evaluated at 1, 2 and 7 years postoperatively and although significant improvement was observed after the second year, only 25% of patients were able to perform sports at a preoperative level. This study is severely limited by sample size, however it does suggest the efficacy of TC in patients with internal shoulder impingement is not sustained over time.[9]

Thermal Capsulorrhaphy Combined with Other Arthroscopic Procedures

Randomized Controlled Trials (RCTs)

There are no RCTs comparing TC as an adjunct arthroscopic procedure with standard procedures alone for treatment of shoulder lesions.

Non-randomized Studies

- Levitz and colleagues reported on a case series of 82 baseball players undergoing arthroscopic surgery for internal impingement.[10] The first 51 patients underwent traditional arthroscopic surgery, consisting of debridement of tears in the rotator cuff and attachment of labral tears. There was no attempt to reduce capsular laxity. The next 31 patients underwent traditional arthroscopic surgery and also underwent TC. The main outcome measure was time to return to competition. Among those who did not undergo TC, 80% returned to competition at a mean time of 7.2 months, with 67% still competing after 30 months. Among those who did undergo TC, 93% returned to competition at a mean time of 8.4 months with 90% still competing after 30 months.

- Mishra and colleagues reported on the 2-year outcomes of 41 athletes with recurrent traumatic anterior dislocations and capsulolabral avulsions who were treated with arthroscopic Bankart repair in conjunction with TC.[11] At a mean of 28 months postoperatively, 38 athletes had returned to their preinjury sport; 3 suffered traumatic redislocations, for a 7% failure rate. The authors concluded that these results are similar to those associated with open surgical repair.

- Savoie and Field compared the outcomes of two different series of patients with multidirectional instability who were treated with either TC (n=30) or arthroscopic capsular shift (i.e., suture repair) (n=26).[12] Additional arthroscopic procedures were performed in both groups, as needed. Two patients treated with TC had an unsatisfactory outcome compared to 3 patients in the suture repair group. The authors concluded that TC is an effective treatment alternative for patients with multidirectional instability.

- Chen and colleagues reported on a case series of 40 patients who underwent combine arthroscopic labral repair and TC; the results were compared with a historical control group of 32 patients who underwent the same surgery without capsulorrhaphy.[13] There was no difference in outcomes in the 2 groups, leading the authors to conclude that capsulorrhaphy neither improved nor compromised the results of conventional arthroscopic treatment.

Adverse Effects

Reports of adverse events related to TC come from non-randomized studies and reviews:

- Good et al. conducted a retrospective chart review on patients who had been referred for shoulder stiffness and had developed glenohumeral chondrolysis.[14] Of the 8 patients who had developed glenohumeral chondrolysis after shoulder arthroscopy, 5 had undergone TC for shoulder instability, and 3 had a thermal procedure with labral repair or synovectomy. The onset was described as early and rapid, with repeat arthroscopy to confirm the diagnosis of chondrolysis and rule out infection at an average of 8 months after the initial shoulder arthroscopy. The mean age of the patients was 23 years (range, 15–39 years). None of the patients had evidence of chondral damage at the index arthroscopy, and none had received postoperative intra-articular pain pumps, a procedure which has also been associated with chondrolysis. The patients required between 1 and 6 procedures after the onset of chondrolysis to manage their pain, including glenoid allograft, humeral head arthroplasty, and total shoulder arthroplasty.

- Good and colleagues identified an additional 10 reported cases of glenohumeral chondrolysis following shoulder arthroscopy in the English-language literature.[15] Five of the 10 cases occurred after the use of gentian violet dye injection into the joint to identify a rotator cuff tear; this technique has since been abandoned. Of the remaining 5 reported cases, 4 involved the use of a thermal device during the procedure. An accompanying editorial by the journal's editors concluded that "pending evidence to the contrary, shoulder TC is a procedure in which these and other reported risks outweigh any potential benefits."

- A review of shoulder instability in patients with joint hyperlaxity indicated that although initial results with TC seemed promising, subsequent studies with longer follow-up showed "unacceptably high rates of failure and postoperative complications", including cases of postoperative axillary nerve palsy and transient deltoid weakness.[16] Abnormal capsular tissue has also been observed in the areas of previous thermal treatment, with either severe thickening or thin, friable deficient capsule.

- In a 2011 review, Virk and Kocher describe TC as a failed new technology in sports medicine.[17]

Thermal Capsulorrhaphy of Other Joints

The literature on TC for joints other than the shoulder is limited. One small case series (13 patients) from 2007 reported use of TC for palmar midcarpal instability.[18] A 2008 publication described TC for the parapatellar capsule as controversial.[19]

Clinical Practice Guidelines

There are no published clinical practice guidelines from U.S. professional societies which address the use of thermal capsulorrhaphy, either alone or in combination with other procedures, for the treatment of instability of any joint.

Summary

Current evidence consistently suggests that thermal capsulorrhaphy (TC) as a treatment of shoulder joint instability is associated with high rates of unsatisfactory results and postoperative complications. For joints other than the shoulder, the evidence is limited and has not demonstrated an improvement in health outcomes. Since the risks appear to outweigh the benefits, TC alone or in combination with other procedures is considered not medically necessary as a treatment of instability in any joint.

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CROSS REFERENCES

Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation, Surgery, Policy No. 118

CODES	NUMBER	DESCRIPTION
CPT	29999	Unlisted procedure, arthroscopy
HCPCS	S2300	Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy