



Kansas City

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Thermal Capsulorrhaphy as a Treatment of Joint Instability

Policy Number: 7.01.82

Last Review: 10/2014

Origination: 11/2006

Next Review: 10/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for thermal capsulorrhaphy. This is considered not medically necessary.

When Policy Topic is covered

Not Applicable.

When Policy Topic is not covered

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

Considerations

The CPT code book specifically directs users to use a non-specific CPT code (29999) to describe thermal capsulorrhaphy. Thus CPT code 29806 (Arthroscopy, shoulder, surgical; capsulorrhaphy) should not be used to describe thermal capsulorrhaphy.

Description of Procedure or Service

Thermal capsulorrhaphy uses thermal energy to restructure collagen in the capsule or ligaments to reduce the capsule size. This procedure has primarily been evaluated for shoulder joint instability but may also be proposed to treat capsular laxity in other joints.

Background

Shoulder instability is a relatively common occurrence, reported in between 2% and 8% of the population. The condition may arise from a single traumatic event (i.e., 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., either 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 modifications or surgical treatment may be considered. Activity modification may be appropriate for patients who can identify a single motion that aggravates instability, such as overhead throwing motions. Surgical treatment may be considered in those who are unwilling to give up specific activities (i.e., related to sports) or when instability occurs frequently or during daily activities.

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 degree of 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. Recent reports of

arthroscopic techniques have described various suturing techniques for tightening the capsule, which require mastery of technically difficult arthroscopic intra-articular knot tying.

Thermal capsulorrhaphy has been proposed as a technically simpler arthroscopic technique for tightening the capsule and ligaments. The technique is based on the observation that the use of nonablative levels of radiofrequency thermal energy can alter the collagen in the glenohumeral ligaments and/or capsule, resulting in their shrinkage and a decrease in capsular volume, both thought to restore capsular tension. Thermal capsulorrhaphy may be used in conjunction with arthroscopic repair of torn ligaments or other structures (i.e., repair of Bankart or superior labrum anterior and posterior [SLAP] lesion). In addition, thermal capsulorrhaphy has also 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. Thermal capsulorrhaphy has also been proposed as a sole arthroscopic treatment. For example, the technique may 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, thermal capsulorrhaphy may be considered in patients with congenital ligamentous laxity, such as Ehlers-Danlos or Marfan's syndrome.

While thermal capsulorrhaphy was initially investigated using laser energy, the use of radiofrequency probes is now more commonly employed. Devices include Oratec ORA-50 Monopolar RF Generator (Oratec Interventions, Menlo Park, CA) and Arthrocare (Arthrocare Corporation, Sunnyvale, CA).

Rationale

At the time this policy was created, there were minimal data published in the peer-reviewed literature regarding the use of thermal capsulorrhaphy, and there were a number of unresolved issues regarding the technique.(1,2) This policy has since been updated on a periodic basis using the MEDLINE database. The most recent update was performed through May 23, 2014. Following is a summary of the key literature to date.

Thermal Capsulorrhaphy of the Shoulder

The evidence on thermal capsulorrhaphy for the shoulder is derived from 1 small randomized controlled trial (RCT) several nonrandomized comparative studies, and 2 large case series with midterm follow-up. Reports of adverse events are also reviewed.

Randomized Controlled Trials: In 2006, a Canadian workgroup reported a multicenter RCT that had been recruiting subjects since 1999.(3) Enrollment was slower than anticipated; 19 patients treated with thermal capsulorrhaphy and 15 subjects treated with surgical repair had completed 2-year follow-up as of publication. This trial is listed as being completed as of March 2012 with an enrollment of 58 patients(4); however, no results of this trial are identified in the published literature.

Nonrandomized Comparative Studies: Levitz et al reported a study of 82 baseball players undergoing arthroscopic surgery for internal impingement in 2001.(5) 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 the capsular laxity. The next 31 patients underwent traditional arthroscopic surgery and also underwent thermal capsulorrhaphy. The main outcome measure was time to return to competition. Among those who did not undergo thermal capsulorrhaphy, 80% returned to competition at a mean time of 7.2 months, with 67% still competing after 30 months. Among those who did undergo thermal capsulorrhaphy, 93% returned to competition at a mean time of 8.4 months, with 90% still competing after 30 months.

Savoie and Field compared the outcomes of patients with multidirectional instability who were treated with either thermal capsulorrhaphy (n=30) or arthroscopic capsular shift (ie, suture repair) (n=26) in

2000.(6) Additional arthroscopic procedures were performed in both groups, as needed. Two patients treated with thermal capsulorrhaphy had an unsatisfactory outcome compared with 3 patients in the suture repair group.

Chen et al reported on 40 patients who underwent combined arthroscopic labral repair and thermal capsulorrhaphy; the results were compared with a historical control group of 32 patients who underwent the same surgery without capsulorrhaphy in 2005.(7) There was no difference in outcomes in the 2 groups, leading the authors to conclude that thermal capsulorrhaphy neither improved nor compromised the results of conventional arthroscopic treatment.

In 2001, Levy et al reported on 90 patients (99 shoulders) with shoulder instability treated with thermal capsulorrhaphy using either radiofrequency (34 patients, 38 shoulders) or laser energy (56 patients, 61 shoulders) and followed up for 23 to 40 months.(8) In the laser-treated group, 59% of the patients considered their shoulder to be "better" or "much better," with a 36.1% failure rate. In the radiofrequency-treated group, 76.9% of patients felt "better" or "much better," with a 23.7% failure rate.

Case Series: D'Alessandro et al published the results of a prospective study of 84 patients who underwent thermal capsulorrhaphy for various indications in 2004.(9) 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 et al reported that the initial wave of enthusiasm for thermal capsulorrhaphy has largely subsided, given the negative results reported by D'Alessandro et al.(10)

Two- to 6-year follow-up was reported on 85 of 100 consecutive patients treated with thermal capsulorrhaphy for glenohumeral instability in 2007.(11) 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, 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 analog scale 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.

Other Joints

Literature on thermal capsulorrhaphy for joints other than the shoulder is limited. One small case series (13 patients) from 2007 reported use of thermal capsulorrhaphy for palmar midcarpal instability.(13) A 2008 publication describes thermal capsulorrhaphy for the parapatellar capsule as controversial.(14)

Adverse Events

In 2007, Good et al conducted a retrospective chart review on patients who had been referred for shoulder stiffness and had developed glenohumeral chondrolysis.(15) Of the 8 patients who had developed glenohumeral chondrolysis after shoulder arthroscopy, 5 had undergone thermal capsulorrhaphy 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 et al identified an additional 10 reported cases of glenohumeral chondrolysis following shoulder arthroscopy in the

English-language literature. 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 thermal capsulorrhaphy is a procedure in which these and other reported risks outweigh any potential benefits."(16)

A 2010 review of shoulder instability in patients with joint hyperlaxity indicates that although initial results with thermal capsulorrhaphy 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.(17) 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 thermal capsulorrhaphy as a failed new technology in sports medicine.(18)

Summary

The literature does not support use of thermal capsulorrhaphy. The few available comparative studies do not support that this procedure is an efficacious treatment for shoulder instability. The case series report a high rate of unsatisfactory results and complications, raising the potential for a net harm. Because of the lack of efficacy and potential for harm, this procedure is considered not medically necessary.

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Billing Coding/Physician Documentation Information

- 29999** Unlisted procedure, arthroscopy
S2300 Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy

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Additional Policy Key Words

N/A

Policy Implementation/Update Information

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| 10/1/06 | New policy. Considered investigational. |
| 10/1/07 | No policy statement changes. |
| 10/1/08 | No policy statement changes. |
| 10/1/09 | No policy statement changes. |
| 10/1/10 | Policy statement changed to not medically necessary. |
| 10/1/11 | No policy statement changes. |
| 10/1/12 | No policy statement changes. |
| 10/1/13 | No policy statement changes. |
| 10/1/14 | No policy statement changes. |
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