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ORIGINAL ARTICLE

Thermal Shrinkage for Shoulder Instability

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Abstract Thermal capsular shrinkage was popular for the treatment of shoulder instability, despite a paucity of outcomes data in the literature defining the indications for this procedure or supporting its long-term efficacy. The purpose of this study was to perform a clinical evaluation of radiofrequency thermal capsular shrinkage for the treatment of shoulder instability, with a minimum 2-year follow-up. From 1999 to 2001, 101 consecutive patients with mild to moderate shoulder instability underwent shoulder stabilization surgery with thermal capsular shrinkage using a monopolar radiofrequency device. Follow-up included a subjective outcome questionnaire, discussion of pain, instability, and activity level. Mean follow-up was 3.3 years (range 2.0–4.7 years). The thermal capsular shrinkage procedure failed due to instability and/or pain in 31% of shoulders at a mean time of 39 months. In patients with unidirectional anterior instability and those with concomitant labral repair, the procedure proved effective. Patients with multidirectional instability had moderate success. In contrast, four of five patients with isolated posterior instability failed. Thermal capsular shrinkage has been advocated for the treatment of shoulder instability, particularly mild to moderate capsular laxity. The ease of the procedure makes it attractive. However, our retrospective review revealed an overall failure rate of 31% in 80 patients with 2-year minimum follow-up. This mid- to long-term cohort study adds to the literature lacking support for thermal capsulorrhaphy in general, particularly posterior instability.

Keywords shoulder instability · arthroscopic shoulder stabilization · thermal capsulorrhaphy · outcomes

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Each author certifies that his or her institution has approved the reporting of these cases, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participating in the study was obtained.

Level of evidence: Therapeutic Study Level IV. See levels of evidence for a complete description.

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Introduction

Monopolar radiofrequency (RF) thermal capsular shrinkage for stabilization of the shoulder joint was introduced clinically in 1996 and gained considerable popularity for the better part of the next decade. The reported advantages of the thermal procedure over other techniques are that it is technically easy to perform, dissection of the soft tissues and division of the subscapularis is avoided, cosmesis is improved, the complication rate is low, post-operative pain is decreased, and range of motion is easier to restore.

Basic science studies of thermal heating of tissue accumulated as interest in this technology mounted. These studies showed that joint capsular tissue can be shortened by thermal energy at the temperature range of 65°C to 80°C. Thermal energy causes a significant decrease in the mechanical properties of the tissue, collagen denaturation, and cell necrosis. Thermally treated tissue is repaired by remaining fibroblasts and vascular cells, with subsequent improvement of mechanical properties [[4, 28–33, 46, 47, 55, 60, 62, 67, 70, 71, 73–76], [9, 37, 44, 50, 52, 53, 60, 72]]. The shortened tissue stretches with time if subjected to significant loading immediately after surgery [37]. Leaving viable tissue between heat-treated regions (grid or stripe technique) improves the healing process [29, 46, 73]. Loss of afferent sensory stimulation due to the destruction of sensory receptors in the capsule may also play a role in clinical improvement [4]. Volume reduction of the capsule is achieved with arthroscopic capsular plication (average of 19.0%) [35] and thermal capsular shrinkage (26–36%) [35, 49, 72]. However, combined arthroscopic capsular plication with thermal capsular shrinkage (average of 41% reduction) or open inferior capsular shift obtain more volume reduction (43–56%) [49].

Mid- and long-term clinical results of thermal capsular shrinkage of the shoulder are now available, though to date, few prospective, randomized, and controlled studies have been reported [13, 59]. Most studies suggest that the most successful outcomes of this procedure occur in patients with mild instability, unidirectional anterior instability, and thermal procedures in combination with arthroscopic suture or tack repairs of the capsule and/or labrum [3, 13, 14, 18–20, 26, 42, 57, 58, 65, 66]. Outcomes of thermal capsular shrinkage in contact athletes and in shoulders with a history of previous dislocations or multidirectional instability have been less satisfactory than open stabilization procedures [2, 13, 16, 18, 21, 43, 57, 69, 78]. Post-operative rehabilitation program and patient compliance are likely important to outcome [37, 77], but are not well studied. Complications and failings of thermal capsulorrhaphy began gaining attention in 2004 with D'Alessandro's prospective study showing a 31% incidence of failure. Simultaneously, there has been increasing recognition of the post-surgical chondrolysis phenomenon [5, 10, 11, 23, 39, 40, 48, 54, 63, 68]. Other complications such as axillary nerve injury [13, 15, 24, 25, 39, 51, 56, 57, 79] and capsular attenuation [12, 36, 52, 64, 79] mounted in the literature.

We sought to add to the literature with a large mid- to long-term cohort study of the thermal capsular shrinkage procedure of the shoulder. Our aims specifically included assessment of overall success of the procedure and the incidence of complications. We also assessed how patient age, gender, type of sport as well as direction(s) and etiologies of instability affected result. Finally, we studied the effects of concomitant surgical procedures.

Materials and Methods

A retrospective review was conducted at one institution, with institutional review board approval, to identify all thermal capsular shrinkage procedures of the shoulder performed using a monopolar radiofrequency device (ORATEC Interventions, Inc., Menlo Park, CA, USA) before June 1999. During this time, 103 shoulders with mild to moderate shoulder instability (1+ to 2+ in one or more planes) and no prior surgery for stabilization were treated with this procedure by six shoulder surgeons. Instability was defined as translation with load and shift testing as follows: 1+, excessive translation up to the glenoid rim, but no subluxation; 2+, humeral head translates over glenoid rim but reduces spontaneously; and 3+, frank dislocation of humeral head over glenoid rim without spontaneous reduction [1].

Excluded from the study were one patient with a concomitant rotator cuff repair and one with hereditary sensorimotor neuropathy. Demographic information such as age, gender, dominant arm, and primary sport or activity was obtained from the remaining 101 patients.

Of 101 patients eligible for this study with a minimum of 2-year follow-up, detailed data were available on 80 patients with an average of 3.3 years of follow-up (range 2.0–4.7 years). There were 53 males and 27 females in this group, a gender ratio of 3:1. The average age was 25.8 years (range 15–52), with males averaging 25.5 (range 16–41) and females 26.8 (range 15–52). The dominant shoulder was the operated shoulder in 68% of patients.

The chief complaint, history of previous surgery, and the etiology, degree, direction, and frequency of instability were recorded at the time of initial presentation. The chief complaint was pain in 49%, instability in 27%, and pain and instability in 23%. The etiology of instability was acute trauma in 40%, repetitive overhead trauma in 50%, and atraumatic in 10%. Sixty-two percent of patients participated in overhead activities such as throwing, volleyball, tennis, and competitive swimming. Twenty-two percent participated in contact sports such as lacrosse, football, and rugby.

Ten of 80 (12.5%) patients eligible for the study had prior surgery on the affected shoulder: diagnostic arthroscopy (8), distal clavicle resection/coracoclavicular reconstruction (1), and acromioplasty (1). The direction of shoulder instability on the examination under anesthesia was anterior in 53%, posterior in 6.3%, and multidirectional (defined as >1+ instability in two or more directions) in 40%.

Intra-operative shoulder exam under anesthesia, findings at arthroscopy, and all surgical procedures were documented. Associated labral pathology was debrided or repaired as needed at the time of thermal capsular shrinkage. Labral procedures were performed in combination with thermal capsular shrinkage in 59% of patients. In those patients, labral debridement was performed in 20% and labral repair in 39% (Fig. 1). Mean follow-up was 3.3 years (range 2.0–4.7 years). Patients were maintained in sling immobilization for a minimum of 4 weeks post-operatively.

The 101 patients were contacted by phone or e-mail for this study. Follow-up included the L'Insalata subjective outcome questionnaire [38], and an unbiased observer (A.P.T.) asked the patients to describe their pain, shoulder stability, and activity level. Failure of the thermal capsular shrinkage procedure was defined as recurrent instability (frank dislocation or subluxation), unresolved chief complaint, or inability to return to sport/activity/lifestyle at previous level. Patients were followed for a minimum of 2 years or until failure. Mean follow-up was 3.3 years (range 2.0–4.7 years).

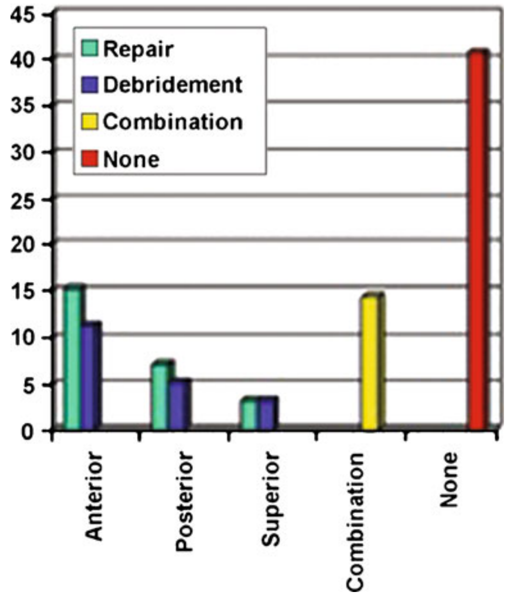

Fig. 1. Labral procedures performed at the time of thermal capsular shrinkage. Numbers expressed as a percent on *Y*-axis

The Kaplan–Meier product-limit method [34] was used to estimate clinical survival of the procedure. Survival curves were compared between groups using the Gehan log-rank test of significance [8]. In addition, paired *t* tests were used to determine if there was any difference between items with two variables. Within-subject analyses of variance with censoring were used to identify differences between items with three variables or more. Alpha level was maintained at 0.05. Statistical software (SPSS 12.0, Chicago, IL, USA) was used to analyze the data.

Results

Thermal capsular shrinkage failed in 31% (25/80 shoulders) at a mean time of 38.9±1.8 months (Fig. 2). One patient had a transient axillary sensory neuropathy that resolved in 6 weeks. There were no other complications.

There was no significant difference between failure rates between genders, as 10 of 27 (37%) females and 15 of 53 (28%) males failed ($p=0.42$). Similarly, age was not found to be a significant factor in outcome as 10 of 35 (29%) of those aged 15–30 failed and 15 of 41 (37%) of those aged 31–52 failed ($p=0.61$). There was no significant difference between chief complaints at presentation, as 13 of 36 (36%) with pain only failed, five of 20 (25%) with instability only failed, and seven of 17 (41%) with pain and instability failed ($p=0.55$).

Past history and etiologies of instability were not significantly different with regard to success of the procedure. Ten of 29 (34.5%) with traumatic shoulder instability failed, two of eight (25%) with atraumatic instability failed, and 12 of 37 (32%) with repetitive overhead activity-related instability failed ($p=0.87$). Throwers, with a failure rate of 35% (eight of 25), did not have a significantly higher incidence of failure than non-throwers with 17 of 49 (32%) failing ($p=0.82$). Contact athletes, with five of 16 (31%) failures, did not have a significantly higher incidence of failure compared with non-contact athletes, in which 20 of 57 (35%) failed ($p=0.77$). History of previous dislocation, including multiple dislocations, was not associated significantly with failure, as five of 19 (26%) failed in the previous dislocation group and 20 of 55 (36%) failed in the no-dislocation group ($p=0.49$). Patients with concomitant labral repair (five of 23) had a 22% failure rate vs.

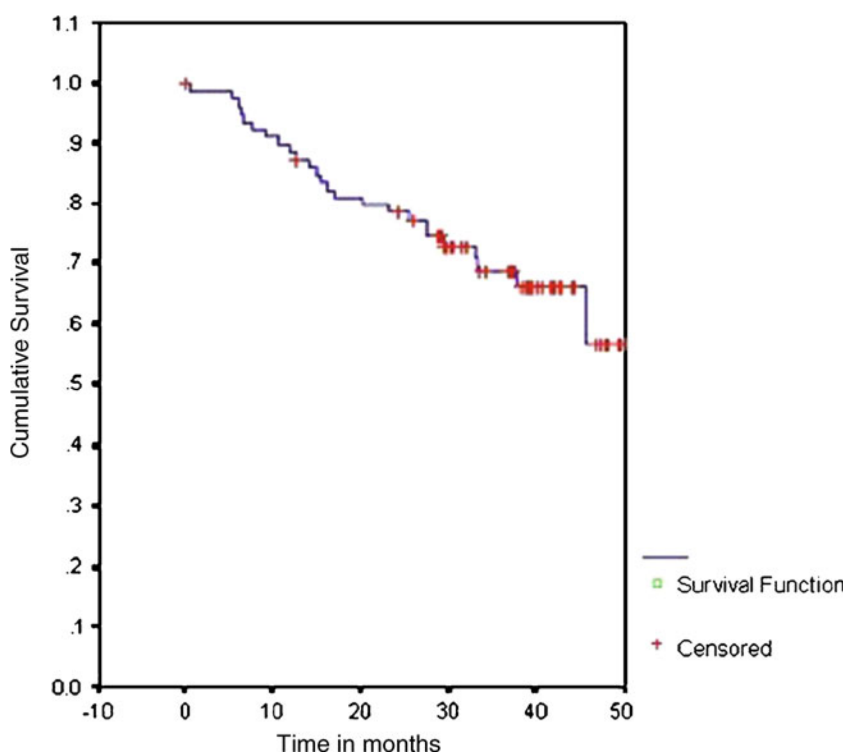

Fig. 2. Kaplan–Meier survival curve demonstrating an overall cohort failure of 31%

those with no repair (20 of 51) with a 39% failure rate. The difference between these two groups approached significance (p=0.07) (Fig. 3). Similarly, the presence of a Bankart lesion, which was usually repaired, approached statistical significance as a factor affecting outcome positively, as only three of 18 (17%) failed in this group, while 22 of 56 (39%) failed in the non-Bankart lesion group (p=0.07).

Only the direction of instability (p=0.04) was predictive of thermal capsular shrinkage failure between groups, as four of five (80%) patients with predominantly posterior instability failed the procedure. In contrast, 14 of 44 (22%) patients with isolated anterior instability and eight of 26 (28%) of those with multidirectional instability failed (Fig. 4). The mode of failure was recurrent instability in 18 of 25 patients. The remaining seven patients failed due to recurrent pain or inability to return to previous level of function. Failure occurred in atraumatic fashion in 17 of 25 (68%) of patients.

Discussion

The purpose of this retrospective review was to determine indications for thermal capsular shrinkage and review risk factors for failures. We sought to stratify results of thermal capsular shrinkage based on patient age, gender, shoulder instability direction(s), degree of instability, etiologies of instability, effects of concomitant surgical procedures, and efficacy in contact and throwing athletes. Our retrospective review of 80 patients with 2- to 5-year follow-up revealed an overall failure rate of 31%. Most patients (18 of 25) who failed the thermal procedure did so due to recurrent instability, but this failure tended to occur in an atraumatic fashion.

The main limitation of our study is the loss of follow-up of 21 of 101 eligible patients, a common challenge in a young, urban population. The use of telephone or e-mail interviews for the most recent follow-up of the patients was also limiting. Specifically, we were unable to gather objective information from physical examinations of shoulder range of motion, strength of the deltoid and rotator cuff musculature, nor shoulder instability signs including apprehension, anterior and posterior translation, and the sulcus sign. In addition, our study was a retrospective cohort analysis, and as such, it was limited by the availability and accuracy of the medical record, subject to selection bias, and there was not a control group.

The overall failure incidence in our study is significantly higher than that reported in early studies [58, 67]. For example, in 2001, a survey of 379 members of the American Shoulder and Elbow Surgeons, the Arthroscopy Association of North America, and the American Orthopaedic Society for Sports Medicine found only an 8.3% rate of recurrent instability with RF thermal capsular shrinkage [79]. However, our incidence of failure is almost identical to that reported by D'Alessandro et al. [13] and Hawkins et al. [27] in their prospective studies.

Our study did not find significant differences in failure rates between items such as gender, young versus middle age, chief complaint, etiology of instability, history of dislocation versus no dislocation, or participation in throwing or contact sports versus who did not participate in those sports. Other authors have found thermal shrinkage to be more beneficial than not in overhead athletes with internal impingement [13, 14, 41, 42, 65, 77]. Further study may

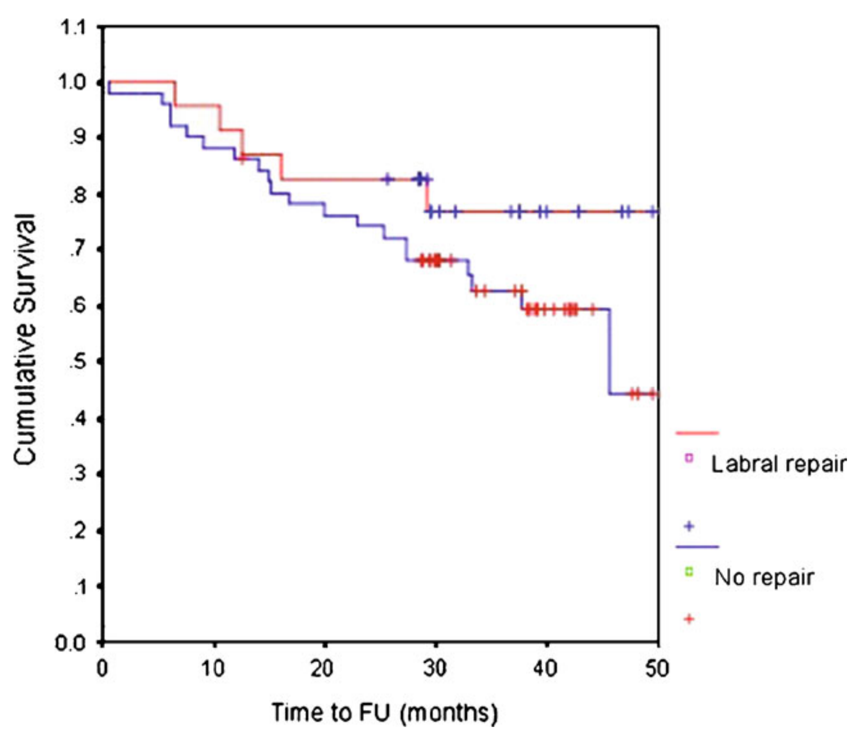

Fig. 3. Kaplan–Meier survival curve demonstrating influence of labral repair on outcome. The difference between the two items is significant (p=0.04)

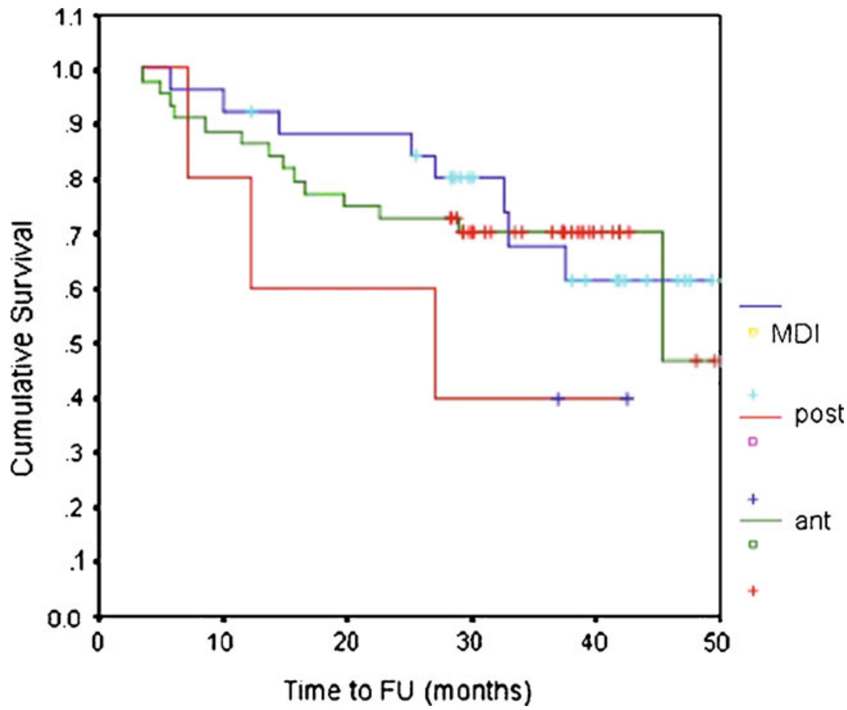

Fig. 4. Kaplan–Meier survival curve demonstrating influence of direction of instability on outcome. Patients with predominantly posterior instability had a significantly higher failure rate (p=0.04)

determine whether thermal shrinkage is ever appropriate for microinstability or used as an adjunct to other stabilization procedures, but in our study with a large number of overhead athletes, the high failure incidence of 32–35% is not acceptable.

Outcomes of thermal capsular shrinkage in contact athletes and in shoulders with a history of previous dislocations have been less satisfactory than open and other arthroscopic stabilization procedures for the most part [2, 13, 16, 21, 43, 61, 65, 69]. Our results for thermal capsular shrinkage in contact athletes were poor with 31% failure, and in shoulders with a history of previous dislocations, 26% failed. Mishra and Fanton are the only authors that report a low incidence of traumatic re-dislocation with thermal capsular shrinkage in contact athletes, comparable to open stabilization [58].

We found a trend toward significance favoring patients with concomitant thermal shrinkage and labral repair (22% failure) versus those without a labral repair (39% failure). This finding is similar to other early results showing enhanced shoulder stability with the thermal capsular shrinkage procedure in combination with other arthroscopic procedures, such as rotator interval closure, labral repair, and arthroscopic capsular shift [3, 19, 20, 26, 42, 58, 65, 66].

There was a significant difference (p=0.04) between directions/type of instability in our study, as patients with isolated anterior instability and those with multidirectional instability fared better than patients with predominantly posterior instability, in whom 80% failed. Other authors have found that the most successful outcomes of this procedure occur in patients with unidirectional anterior instability [3, 13, 19, 20, 26, 42, 58, 66]. Worst outcomes of treatment of posterior instability with this technique have been noted in previous studies by Hawkins [27] and Miniaci [57].

Multidirectional instability (MDI), especially those with generalized ligamentous laxity, presents the greatest challenge in management of shoulder instability. Initially, it was thought that thermal capsular shrinkage would be particularly useful for MDI because of the ability of this procedure to decrease capsular volume globally. Most authors have found an increased risk of failure with thermal capsular shrinkage for treatment of MDI ranging from 24% to 59% [43] [2, 27, 57, 69]. We noted a failure incidence of 28% (eight of 26) for MDI in our series.

Only one complication, a temporary axillary nerve injury, occurred in our series, though subsequently, this complication was noted in two more patients who had surgery after June 1999. This complication has been described previously [13, 17, 21, 24, 39, 51, 57, 79], and intra-operative and cadaver studies showed that heating of the axillary nerve can occur during thermal capsular shrinkage of the shoulder and may potentially reach levels that can damage neural tissue [6, 15, 25]. Additional reported complications of this procedure include severe capsular necrosis and refractory stiffness not typical of suture capsulorrhaphy [7, 21, 52, 57, 64]. Refractory stiffness after thermal shrinkage has not been noted at our institution. Finally, chondrolysis, the most dreaded complication of this procedure, did not occur in our series. However, chondrolysis has been reported with greater frequency as time has passed [5, 10, 11, 23, 39, 40, 48, 54, 63, 68]. Recent studies have highlighted the potential for elevated temperature of the arthroscopic fluid during thermal capsulorrhaphy [22, 23, 45, 53, 68]. It seems that arthroscopic fluid flow/exchange is of paramount importance in keeping the joint temperature low.

In summary, thermal capsular shrinkage as an isolated treatment for instability had an unacceptably high incidence of failure at 31% in our series. When used as an adjunct to labral repair, the failure rate fell to 22%, suggesting that the labral repair was the more important variable. Essentially, no group had a satisfactory outcome. Thermal shrinkage may play some role in addressing difficult areas to access in the capsule, but suture plication is more predictable at this time. Presently, the complications and lack of predictable response of tissue shortening precludes recommending thermal shrinkage for most patients with instability. Our study lends further credence to concerns that results for this procedure have deteriorated over time, especially for conditions that appear to be at more risk to fail, such as multidirectional instability, posterior instability, and in contact athletes.

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