

Risk Factors for Early Failure after Thermal Capsulorrhaphy*

Kyle Anderson,†‡ MD, Russell F. Warren,§ MD, David W. Altchek,§ MD,
Edward V. Craig,§ MD, and Stephen J. O'Brien,§ MD

From the †Center for Athletic Medicine, Henry Ford Health System, Detroit, Michigan, and the §Sports Medicine and Shoulder Service, Hospital for Special Surgery, New York, New York

ABSTRACT

Thermal capsular shrinkage has rapidly become a common procedure for a variety of shoulder conditions usually associated with instability, although clinical data on outcomes are limited. The objective of this study was to identify risk factors for poor outcome after thermal capsulorrhaphy. Of 106 patients who underwent thermal shrinkage, 15 patients with treatment failures were identified. The mean time to failure after the procedure was 6.3 months (range, 1 to 16). Previous operations and multiple recurrent dislocations were associated with poor outcome at a highly significant level. Multidirectional instability and participation in contact sports did not attain statistical significance as risk factors. However, statistical power in these two comparisons was insufficient to exclude them as potential risk factors. A concomitant procedure at the time of thermal capsulorrhaphy was not associated with poor outcome. The data from early treatment failures can be useful in guiding patient selection for thermal capsulorrhaphy. This procedure may be of limited value for patients who have had prior operations or have a history of multiple dislocations. The data also suggest that thermal capsulorrhaphy should be used cautiously in patients with multidirectional instability or in those who are involved in contact sports.

Glenohumeral instability is a common orthopaedic problem, particularly in the young, active population. The term "instability" encompasses a broad spectrum of shoul-

der conditions. Open stabilization procedures have resulted in high success rates in eliminating subsequent dislocations, but they can cause a restriction of important glenohumeral motion.^{4,5,17} This loss of motion can be particularly troublesome for athletes who repeatedly use extremes of glenohumeral motion.³ Arthroscopic procedures are helpful to identify specific lesions and are well suited for treating labral injuries. Their use has generally spared glenohumeral motion, but the results of arthroscopic procedures have not consistently matched the low recurrence rates of open procedures.^{8,22,25} It has been proposed that arthroscopic procedures do not adequately treat capsular injury associated with shoulder instability.⁷

Shrinkage of the shoulder capsule by using thermal energy was developed as an arthroscopic method for treating patients with capsular injury or pathologic laxity. Laser energy was initially used for this application, but use of radiofrequency energy has gained popularity more recently. Currently, thermal shrinkage procedures are being performed at increasing rates, despite the fact that basic science and clinical research data regarding their effects are limited. There is evidence that heating collagenous tissue causes tissue shrinkage through collagen denaturation.^{1,6,27} However, there is also evidence that the biomechanical properties of the tissue deteriorate as the temperature and time of exposure increase.^{19,29} It is not clear how the in vivo healing response affects the biomechanical properties of the tissue in humans. The results of animal experiments suggest that the histologic and biomechanical properties gradually improve over time, but whether they completely return to pretreatment levels is unknown.¹¹

Clinically, thermal treatment or shrinkage is being used for a variety of shoulder problems ranging from microinstability to multidirectional instability. Some surgeons use a thermal device as an adjunct to other arthroscopic procedures, such as labral or biceps-origin repairs (Ref. 18; C. L. Levitz et al., unpublished data, 2000). Others have used this surgical technique for treatment of internal

*Presented at the interim meeting of the AOSSM, Orlando, Florida, March 2000.

‡ Address correspondence and reprint requests to Kyle Anderson, MD, William Clay Ford Center for Athletic Medicine, 6525 Second Avenue, Detroit, MI, 48202.

No author or related institution has received any financial benefit from research in this study.

impingement.^{2,28} Given the broad range of conditions for which it is being used, it is apparent that the indications for use of thermal capsulorrhaphy have not been well defined.

Although the early clinical results for thermal capsulorrhaphy are encouraging, longer follow-up is necessary to evaluate the success of this technology. We propose that currently available data could be useful in refining the indications for thermal capsulorrhaphy and that contraindications for its use could potentially be developed. In particular, an analysis of the records of those patients with a poor outcome could yield valuable information, despite the limited duration of follow-up. The purpose of this investigation was to identify factors associated with failure or poor outcome after thermal capsulorrhaphy.

MATERIALS AND METHODS

We retrospectively reviewed the records of 106 patients who underwent thermal capsulorrhaphy performed with use of a monopolar radiofrequency probe (ORATEC Interventions, Inc., Menlo Park, California) by four experienced shoulder surgeons (RFW, DWA, EVC, SJO) between 1996 and 1999. Patients treated with other forms of thermal energy, such as bipolar radiofrequency or laser, were excluded. The average age of the 78 male and 28 female patients was 26 years (range, 15 to 52). The study population included those patients who had undergone an isolated thermal capsulorrhaphy as well as those who had a thermal treatment as an adjunct to another procedure, such as an arthroscopic labral repair.

Patients who had anterior capsular laxity were treated with anterior heating beginning anteroinferiorly and extending superiorly toward the rotator interval (Fig. 1A). Generally, the areas most difficult to access were treated first. Posterior thermal capsulorrhaphy, for patients who had either isolated posterior instability or posterior instability as a component of multidirectional instability, also began inferiorly and extended superiorly (Fig. 1B). If greater access was necessary inferiorly, an auxiliary posterior portal was used (Fig. 1C). Postoperatively, all patients were treated according to a protocol that involved strict use of a sling immobilizer for the first 4 weeks after surgery. Patients were followed up clinically with a physical examination and were also expected to complete preoperative and postoperative questionnaires for rating the status of their shoulder.¹⁵

In this study, treatment failure was defined as a redislocation, the need for a reoperation, or a L'Insalata shoulder-rating total score of less than 70 points.¹⁵ This score was chosen arbitrarily before data collection was started. Before the study began, the authors also hypothesized six potential risk factors (Table 1). The patients in the study had undergone the following previous shoulder operations: open stabilization (three), arthroscopic Bankart repair (two), arthroscopic repair of a superior labral anterior posterior lesion (two), labral debridement (two), arthroscopic acromioplasty (four), distal clavicle resection (three), and exploration and decompression of the supracapular nerve (one). None of the patients had undergone

previous laser or thermal capsulorrhaphy. Multiple dislocations were defined as more than two recurrences. Sixteen patients participated in contact sports, including hockey, football, rugby, and wrestling. Multidirectional instability was defined as symptomatic instability in two or more directions and presence of a sulcus sign (2+) on examination. Concurrent procedures typically included labral repairs performed arthroscopically. Thirty-eight patients had an arthroscopic repair of the anteroinferior labrum, 4 had a repair of the posterior labrum, and 11 had a stabilization of the superior labrum or biceps origin. There were five arthroscopic subacromial decompressions and one mini-open rotator cuff repair. One patient had a subacromial decompression and mini-open rotator cuff repair in addition to the thermal procedure. Labral debridement without reattachment was not considered an additional procedure.

Age at presentation and its relationship with the likelihood of recurrence has been well documented and was included in this analysis.^{10,12,26} The relationship between treatment failure and time during the course of the study that the procedure was performed was also analyzed with use of the Spearman rank-order correlation to identify any potential "learning-curve" effect.

The relative frequencies of the risk factors were compared between the group of patients with treatment failures and the remainder of the study group. Comparative statistical analysis was performed with use of the chi-square test, the Fisher exact test, or the Mann-Whitney test, where appropriate. Because multiple comparisons were made between these two groups, the significance levels were corrected according to the Bonferroni adjustment. Statistical calculations were performed with use of commercially available software (Sigmatat, SPSS Science, Chicago, Illinois).

RESULTS

From the group of 106 patients who had undergone thermal capsular shrinkage at this institution, 15 patients (14%) met the criteria for failure of treatment as defined earlier. There were nine male patients and six female patients in the failure group. The average age of the entire patient group was 25.9 years (range, 15 to 52), and the average age of the patients in the failure group was 26.7 years (range, 17 to 46). This difference was not statistically significant ($P = 0.56$). The mean time to failure was 6.25 months (range, 1 to 16). The average duration of follow-up for the entire study population was 13 months (range, 5 to 29), and there was no significant difference in follow-up time between the two groups ($P = 0.4$).

Of the 15 patients in the failure group, 4 had had dislocations before treatment and had redislocations after thermal capsulorrhaphy. These patients were subsequently treated with an open stabilization. Two patients had recurrent subluxations; one was treated nonoperatively and the other with a humeral rotation osteotomy. One patient had a concurrent rotator cuff repair and reported persistent weakness on the functional questionnaire. The remaining eight patients had preoperative pain

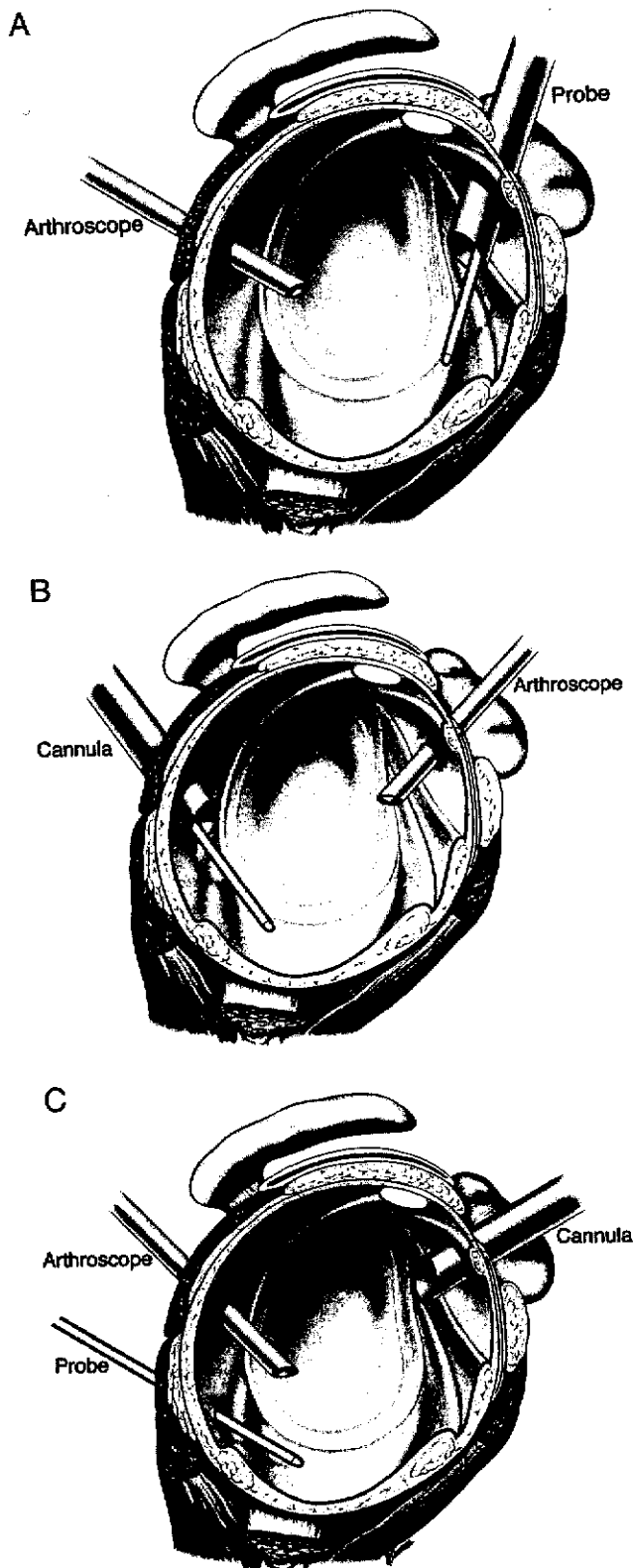


Figure 1. A, anterior capsular laxity was treated by reaching the more difficult access areas first. The thermal treatment began inferiorly along the inferior glenohumeral ligament and extended superiorly toward the rotator interval. B, the arthro-

TABLE 1
Proposed Risk Factors for Failure of Thermal Capsular Shrinkage

1. Previous surgery to the affected shoulder
2. Multiple dislocations before surgery
3. Contact sports participation
4. Multidirectional instability (MDI)
5. Associated injuries (requiring repair and excluding labral debridement)
6. Age at presentation

TABLE 2
Number of Patients with Each Risk Factor (and Frequency) Among Nonfailures and Failures

Proposed risk factor	Nonfailure group (N = 91)	Failure group (N = 15)
Prior surgery	6 (6.5%)	7 (46%) ^a
Multiple dislocations	10 (11%)	8 (53%) ^a
Contact sports	10 (11%)	6 (40%)
Multidirectional instability	4 (4.4%)	3 (20%)
Concurrent procedures	49 (54%)	9 (60%)

^a Significant difference between groups ($P < 0.05$).

or looseness and these symptoms continued after treatment. These patients had a postoperative shoulder rating score of less than 70 points.

Six of the 91 patients from the group without failures had undergone previous surgical procedures to the affected shoulder, whereas 7 of the 15 patients in the failure group had prior operations (Table 2). This frequency of risk factors was significantly different ($P = 0.002$) by chi-square analysis.

A total of 18 patients had a history of multiple dislocations (>2) before their thermal capsulorrhaphy procedure (Table 2). A much higher percentage of the failure group had a history of multiple dislocations before the surgical procedure than did the nonfailure group ($P = 0.006$; $\beta = 0.8$) (Table 2). No patient who had subluxations or microinstability preoperatively went on to have a complete dislocation after the surgical procedure.

After correction for multiple comparisons, the difference between the groups with regard to contact sports participation was not statistically significant ($P = 0.35$) (Table 2). However, the statistical power was insufficient to exclude contact sports participation as an important risk factor ($\beta = 0.7$).

Twenty percent of the failure group had a diagnosis of multidirectional instability, compared with 4.4% of the nonfailure group ($P = 0.14$ before adjustment) (Table 2). Again, this difference was not statistically significant when the P value was adjusted for multiple comparisons

scopic portals were reversed for treatment of the posterior capsule. C, improved access to the inferior capsule was gained by using an auxiliary posterior portal. (Figures reprinted with permission from Anderson K, McCarty EC, Warren RF: Thermal Capsulorrhaphy: Where are we today? *Sports Med Arthroscopy Rev* 7: 117-127, 1999.)

($P = 0.9$). Patients who had a concurrent procedure (labral or biceps origin repairs) at the time of thermal shrinkage were not at an increased risk of failure ($P = 0.9$) (Table 2). In fact, more than half of the patients ($N = 58$) in the study had a concurrent procedure. There was no significant correlation between failure occurrence and the time of the procedure during the study period or the length of follow-up ($P > 0.05$).

DISCUSSION

At the present time, there is little evidence to support the efficacy of thermal capsular procedures. Although studies with sufficient duration of follow-up are lacking, this technology continues to gain popularity at a rate that causes concern. However, existing data could be useful immediately in refining the indications for thermal capsulorrhaphy. By delineating the failures, we can develop contraindications or identify those patients who are at higher risk.

In this study, previous surgical procedures and multiple preoperative dislocations were factors that were present significantly more frequently in the failure group than in the nonfailure patients. Of the 13 patients who had a prior operation, 7 experienced failure of thermal capsulorrhaphy. Prior operations on the affected shoulder was chosen as a potential risk factor because revision procedures have been reported to carry a higher risk of failure.³⁰ Also, the authors hypothesized that scar tissue may have a more limited capacity for shrinkage. Early arthroscopic observations in this series of patients suggested that scar tissue had a less dramatic response to treatment with the thermal probe than did native capsular tissue. As tissue is heated, collagen is changed from a triple-helix to a random coil structure.^{6,27} Intuitively, we can reason that scar tissue, which is less organized than native capsular tissue, has less capacity for shortening. Similarly, retreatment of tissue with the thermal probe may add cumulative damage to tissue without the desired additional shortening.

A patient who has had multiple preoperative dislocations carries a higher risk for the failure of other arthroscopic stabilization procedures.^{13,14,23} In this situation, marked capsular laxity is usually present in addition to labral injuries. The ability to adequately shorten this damaged capsule may be the limiting factor.

Our relatively short-term data also suggest that participation in contact sports and multidirectional instability may be important risk factors for failure. Although these comparisons did not attain statistical significance, there was insufficient power to exclude them as risk factors. As duration of follow-up increases, and if more failures occur among patients with these risk factors, the significance levels may increase.

Participation in contact sports has been suggested as a risk factor for failure in previous reports of shoulder stabilization procedures.^{21,23} The potential of a new traumatic event is of particular concern when the biomechanical properties of the healed capsular tissue have been shown to be diminished. Further research is needed before the advisability of return to contact sports can be determined.

Patients with multidirectional instability have been shown to have a higher risk of failure.^{10,20,30} An unappreciated direction of instability may lead to an inadequate procedure and allow for recurrent instability postoperatively. Data from the present study are not sufficient to determine whether the addition of thermal capsulorrhaphy adequately treats the capsular injury or laxity. The data do suggest that caution is warranted until more data are available on use of this technique in patients who have multidirectional instability. Reports from the literature are inconsistent with regard to the diagnosis of multidirectional instability.^{9,20} In this series, only those patients with frank instability in two or more directions and the presence of a marked sulcus sign were considered to have the condition. It is quite possible that this technique will prove to be very useful for patients with global laxity, who did not meet our definition of multidirectional instability. The primary direction of instability (anterior or posterior) may have an influence on the outcome of these patients. In this study, there were too few patients who had posterior instability (three in the nonfailure group and one in the failure group) to draw valid conclusions as to the likelihood of failure.

Concurrent procedures, such as labral repairs, and age were not significant risk factors for failure in this study. The use of thermal capsulorrhaphy as an adjunct to other procedures, such as arthroscopic labral repair, may prove to be an appropriate use for the technology. Again, further follow-up data should answer this question.

This population represents the first 106 patients treated by these authors; however, there was no correlation between treatment failure and the date of the surgical procedures, which argues against a learning-curve effect. The technique of thermal capsulorrhaphy continues to evolve, with many surgeons becoming less aggressive in terms of the amount of shrinkage created. Initially, complete capsular coverage and even "re-treating" the tissue were recommended. How thoroughly the capsule was treated depended on the surgeon. Many surgeons now advocate "striping" or "dotting" the capsule, leaving a large portion untreated. Theoretically, this allows faster repopulation of fibroblasts, which are killed in the treated areas. Also, the partially treated capsule might retain some of the biomechanical characteristics of untreated capsule, as opposed to the known inferior properties of denatured-collagen tissue. One recent study reported that tissue treated with a grid pattern had superior mechanical properties to tissue treated with complete, "paintbrush" coverage.¹⁶

Another issue that has gained increased attention is early postoperative immobilization to allow for tissue repair without unwanted lengthening.²⁴ We advocate 4 or more weeks of strict immobilization after thermal capsulorrhaphy. Although all of the patients in this study were treated with a sling immobilizer, compliance was not measured. It is possible that some patients may have progressed too rapidly with their postoperative motion and did not allow adequate time for capsular repair or scar formation. Interestingly, despite strict immobilization, no patients in this series had persistent stiffness.

Although early data suggest that many patients benefit from thermal capsulorrhaphy, greater follow-up is necessary. More information can help with patient selection, surgical technique, and postoperative rehabilitation. While we await these studies, early treatment failures have yielded important information that can guide patient selection. Patients who have undergone prior shoulder operations or who have had multiple dislocations appear to be at higher risk of failure after thermal shrinkage operations. At the present time, caution must be exercised when treating patients who participate in collision sports, as well as those with multidirectional instability. Future studies may determine whether thermal modification is most appropriate for patients with microinstability or as an adjunct to arthroscopic stabilization procedures.

REFERENCES

- Allain JC, Le Lous M, Cohen-Solal L, et al: Isometric tensions developed during the hydrothermal swelling of rat skin. *Connect Tissue Res* 7: 127-133, 1980
- Andrews JR, Dugas JR: Diagnosis and treatment of shoulder injuries in the throwing athlete: The role of thermal-assisted capsular shrinkage. *Instr Course Lect* 50: 17-21, 2001
- Bigliani LU, Codd TP, Connor PM, et al: Shoulder motion and laxity in the professional baseball player. *Am J Sports Med* 25: 609-613, 1997
- Bigliani LU, Kurzweil PR, Schwartzbach CC, et al: Inferior capsular shift procedure for anterior-inferior shoulder instability in athletes. *Am J Sports Med* 22: 578-584, 1994
- Cooper RA, Brems JJ: The inferior capsular-shift procedure for multidirectional instability of the shoulder. *J Bone Joint Surg* 74A: 1516-1521, 1992
- Flory PJ, Garrett RR: Phase transition in collagen and gelatin systems. *J Am Chem Soc* 80: 4836-4845, 1958
- Gill TJ, Warren RF, Rockwood CA Jr, et al: Complications of shoulder surgery. *Instr Course Lect* 48: 359-374, 1999
- Grana WA, Buckley PD, Yates CK: Arthroscopic Bankart suture repair. *Am J Sports Med* 21: 348-353, 1993
- Griffin JR, Annunziata CC, Bradley JP: Thermal capsulorrhaphy for instability of the shoulder: Multidirectional and posterior instabilities. *Instr Course Lect* 50: 23-28, 2001
- Hawkins RH, Hawkins RJ: Failed anterior reconstruction for shoulder instability. *J Bone Joint Surg* 67B: 709-714, 1985
- Hecht P, Hayashi K, Lu Y, et al: Monopolar radiofrequency energy effects on joint capsular tissue: Potential treatment for joint instability. An in vivo mechanical, morphological, and biochemical study using an ovine model. *Am J Sports Med* 27: 761-771, 1999
- Hovelius L: Anterior dislocation of the shoulder in teen-agers and young adults. Five-year prognosis. *J Bone Joint Surg* 69A: 393-399, 1987
- Jager A, Kandziora F, Bischof F, et al: Arthroscopic labral reconstruction for anterior shoulder instability. Failure analysis in 187 patients [in German]. *Z Orthop Ihre Grenzgeb* 137: 17-24, 1999
- Koss S, Richmond JC, Woodward JS Jr: Two-to five-year follow-up of arthroscopic Bankart reconstruction using a suture anchor technique. *Am J Sports Med* 25: 809-812, 1997
- L'Insalata JC, Warren RF, Cohen SB, et al: A self-administered questionnaire for assessment of symptoms and function of the shoulder. *J Bone Joint Surg* 79A: 738-748, 1997
- Lu Y, Hayashi K, Edwards RB III, et al: The effect of monopolar radiofrequency treatment pattern on joint capsular healing. In vitro and in vivo studies using an ovine model. *Am J Sports Med* 28: 711-719, 2000
- Lusardi DA, Wirth MA, Wurtz D, et al: Loss of external rotation following anterior capsulorrhaphy of the shoulder. *J Bone Joint Surg* 75A: 1185-1192, 1993
- Mishra DK, Fanton GS: Two year outcome of arthroscopic Bankart repair and electrothermal-assisted capsulorrhaphy for recurrent traumatic anterior shoulder instability. *Arthroscopy* 17: 844-849, 2001
- Naseef GS III, Foster TE, Trauner K, et al: The thermal properties of bovine joint capsule. The basic science of laser- and radiofrequency-induced capsular shrinkage. *Am J Sports Med* 25: 670-674, 1997
- Neer CS II, Foster CR: Inferior capsular shift for involuntary inferior and multidirectional instability of the shoulder. A preliminary report. *J Bone Joint Surg* 62A: 897-908, 1980
- O'Neill DB: Arthroscopic Bankart repair of anterior detachments of the glenoid labrum. A prospective study. *J Bone Joint Surg* 81A: 1357-1366, 1999
- Pagnani MJ, Warren RF, Altchek DW, et al: Arthroscopic shoulder stabilization using transglenoid sutures. A four-year minimum follow-up. *Am J Sports Med* 24: 459-467, 1996
- Roberts SNJ, Taylor DE, Brown JN, et al: Open and arthroscopic techniques for the treatment of traumatic anterior shoulder instability in Australian rules football players. *J Shoulder Elbow Surg* 8: 403-409, 1999
- Schaefer SL, Ciarelli MJ, Arnoczky SP, et al: Tissue shrinkage with the holmium:yttrium aluminum garnet laser. A postoperative assessment of tissue length, stiffness, and structure. *Am J Sports Med* 25: 841-848, 1997
- Speer KP, Warren RF, Pagnani M, et al: An arthroscopic technique for anterior stabilization of the shoulder with a bioabsorbable tack. *J Bone Joint Surg* 78A: 1801-1807, 1996
- Torchia ME, Caspari RB, Asselmeier MA, et al: Arthroscopic transglenoid multiple suture repair: 2 to 8 years results in 150 shoulders. *Arthroscopy* 13: 609-619, 1997
- Verzar F, Nagy IZ: Electron microscopic analysis of thermal collagen denaturation in rat tail tendons. *Gerontologia* 16: 77-82, 1970
- Walch G, Boileau P, Noel E, et al: Impingement of the deep surface of the supraspinatus tendon on the posterosuperior glenoid rim: An arthroscopic study. *J Shoulder Elbow Surg* 1: 238-245, 1992
- Wall MS, Deng XH, Torzilli PA, et al: Thermal modification of collagen. *J Shoulder Elbow Surg* 8: 339-344, 1999
- Zabinski SJ, Callaway GH, Cohen S, et al: Revision shoulder stabilization: 2- to 10-year results. *J Shoulder Elbow Surg* 8: 58-65, 1999