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Arthroscopic Bankart Repair

Experience With an Absorbable, Transfixing Implant

Stephen Fealy, MD; Mark C. Drakos, BA; Answorth A. Allen, MD; and Russell F. Warren, MD

The use of arthroscopic means to address shoulder instability has provided a technically advantageous way to approach Bankart lesions while posing complex questions regarding the specific indications for such an intervention. A successful outcome with arthroscopic Bankart repair is a function of proper surgical indication and patient selection. Several authors have evaluated the causes of failure and reasons for success with the Suretac device. The development of a bioabsorbable repair device at the authors' institution was precipitated by a desire to address and repair Bankart lesions arthroscopically while avoiding the frequent complications associated with the metal staple and the transglenoid suture technique. The Suretac represents the first generation of bioabsorbable transfixing devices. The initial objectives of the Suretac device were to adequately and dynamically tension soft tissue to bone, while providing a bioabsorption profile that mirrored the native healing response. The Suretac device is an appropriate surgical tool for arthroscopically repairing Bankart lesions in a carefully selected patient population.

Treatment of the Bankart lesion has remained a controversial topic since it was first described in 1938.[3] The essential lesion of shoulder instability, as described by Bankart, is thought by many to represent the most common disorder underlying possible causes for shoulder instability.[2,19,31] It represents a detachment of the labrum and its osseous insertion from the anteroinferior glenoid. Reestablishing the structural integrity of the soft tissue to glenoid interface is the paramount objective of the Bankart repair and has an essential role in surgery for shoulder stability. Although the traditional open Bankart repair remains the gold standard in treatment options, continued development of arthroscopic techniques and the development of bioabsorbable implants has made arthroscopy-based procedures for labral detachment the treatment of choice at many centers, including the authors' center.

The advent of arthroscopic means to address shoulder instability has provided a technically advantageous way to approach these lesions while posing complex questions regarding the specific indications for such an intervention. It is clear that a successful outcome with arthroscopic Bankart repair is a function of proper surgical indication. Patient selection is as important if not more important than surgical technique. Research results previously reported indicate that the ideal candidate for arthroscopic Bankart repair is one who has instability attributable to a discrete Bankart lesion without concomitant capsular laxity or in-

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jury.[4,29,30,32,35] These authors report that open Bankart repair is more appropriately indicated for patients in whom there is a need for anterior and/or inferior capsular shift and patients who have generalized capsular laxity in addition to the presence of a discrete Bankart lesion. Open stabilization procedures generally have failure rates less than 10%.[7] Capsular laxity can be addressed easily with open procedures. Conversely, the prospect of treating these injuries with decreased morbidity, pain, recovery time, and improved cosmesis has made arthroscopic Bankart repairs an attractive alternative. There have been several reports that recognize that open techniques can produce a consistent low rate of recurrence, but these authors have observed a loss of motion (particularly external rotation).[6,7,9,11] A slower and less consistent ability to return to contact sports such as football also has been documented.[4,7] This observation calls into consideration the role of arthroscopic over open repair of Bankart lesions for athletes who participate in contact sports. The nature of certain sports, rather than surgical technique, is responsible for recurrence of instability after arthroscopic and open techniques have been used.

Several authors have compared open results with arthroscopic Bankart repair results; the current authors will discuss the outcomes of these studies below. Arthroscopic treatment of the Bankart lesion has been addressed technically with repair using metallic staples, transglenoid sutures, bioabsorbable repair devices, and arthroscopically-placed sutures and knotless anchors. Arthroscopic repair of Bankart lesions, regardless of technique used, has been consistently associated with more benefits than open technique. Patients who undergo arthroscopic Bankart repair experience less surgical morbidity, have better range of motion (ROM), and have quicker return to full function than those who undergo open procedures. However, despite the variety of arthroscopic options to address Bankart lesions, several studies have reported higher rates of failure postoperatively than after open procedures.[1,7,11,21] Initial rates of failure using arthroscopic techniques were consistently higher than those produced using open techniques, although open rates of recurrence have been documented to be as high as 37% in one study.[16]

Development of Suretac

The development of a bioabsorbable repair device at the authors' institution was precipitated by a desire to address and repair Bankart lesions arthroscopically while avoiding the frequent complications associated with the metal staple and the transglenoid suture technique. The Suretac (Acufex Microsurgical; Mansfield, MA) can be placed arthroscopically without an accessory incision and avoids the technical difficulty associated with arthroscopic knot tying. Initially, metallic implants were chosen to achieve the necessary soft tissue to bone fixation arthroscopically. This intervention included the use of screws, staples, pins, and other devices. However, complications arose in the form of loosening, migration, breakage, joint impingement, articular cartilage damage, and incidence of pain caused by the implant. Reports of recurrence of instability after arthroscopic stapling ranged between 3% and 33%.[7] Poor positioning and subsequent movement and fatigue failure of the metallic staple were responsible for the high rates of failures with this device. It is this particular complication that provided the impetus to design biodegradable fixation devices for orthopaedic procedures on the shoulder.[12,28]

Transglenoid sutures seemingly provided an attractive alternative to leaving a permanent device in the shoulder. However, the technique initially required an accessory posterior incision and carried an associated risk of neurovascular injury.[20,26] In addition, the procedure bears a risk of articular cartilage injury because of transscapular drilling. Failure rates of transglenoid suture repair have been reported between 0% and 44%.[7] O'Neil[20] recently reported his experience with arthroscopic Bankart repair using a transglenoid technique in which suture knots were tied posteriorly on the scapular neck and not through

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a separate incision. All patients who were treated had recurrent, unidirectional, anterior instability with an isolated detachment of the labrum. Six patients had a bony Bankart lesion, which was associated with a decreased ROM and strength at a mean of 52 months postoperatively. Ninety-five percent of patients reported a favorable outcome, and two patients who had an American Shoulder and Elbow Surgeons score less than 80 participated in contact football and had reported episodes of subluxation.

The arthroscopic staple and the transglenoid suture technique lacked the properties to provide minimally invasive, yet adequate strength to oppose soft tissue to bone. A new device designed for the specific purpose of limiting morbidity was needed. This device hopefully would provide a similar bioabsorptive profile to that of healing tissue. As the injured tissue reestablished the integrity of its bone interface, it gradually would be absorbed while simultaneously declining in fixation strength in an inverse proportion. This would limit the complications inherent with the permanence of the metallic implant.

Science of the Bioabsorbable Suretac Device

The Suretac fixation device was designed to provide an adequate intervention to address anterior shoulder instability and to overcome the shortcomings of previous modalities. The four primary initial objectives of the implant, as outlined by Speer and Warren[29] included: (1) adequate, initial tissue to bone fixation strength; (2) a bioabsorption profile that mirrors the healing response, providing adequate, dynamic fixation strength; (3) a bioabsorption profile that would not abate the return of motion in the joint; and (4) a bioabsorbable material that is metabolized via normal body functions without having any pyrogenic, antigenic, carcinogenic, mutagenic, or other toxic properties.

Polyglyconate was the material found to adhere most closely to these stringent inclusion criteria. It is a copolymer made up of trimethylene carbonate and glycolic acid in a reaction initiated by diethylene glycol and catalyzed by stannous chloride dihydrate. The chemical formula is indicated below with a ratio approximately 67.5 X and 32.5 Y.

$(CH_2COOCH_2COO)_X$
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$(CH_2CH_2CH_2OCOO)_Y$
Trimethylene Carbonate Moiety

The compound is metabolized by hydrolysis and its byproducts are excreted through normal biologic pathways. It is essential to keep the Suretac device dry and sealed until surgery, because exposure to humidified air may begin the hydrolysis process.

The device loses ¼ of its strength each week, until 4 weeks when the device no longer plays a mechanical role (Fig 1). The tack has a mean bending strength of 23.6 kg at its insertion, 11.6 kg at 2 weeks, 1.2 kg at 3 weeks, 0 at 4 weeks, and 0.0 at 6 weeks. The rate of loss was approximately 4.13 kg/week, reaching 0.0 at 4 weeks.[29] The Suretac is a cannulated tack made of the same material as Maxon sutures (Davis & Geck, Danbury, CT). The head diameter is 6.5 mm; the modified Suretac II has a spiked head undersurface that is 8 mm in diameter (Fig 2). The flat head of the original Suretac allows the device to capture soft tissue and oppose it to bone as it is being inserted. Concentric ribs along the shaft of Suretac improve its ultimate pullout strength, which is 100 N at insertion.

The Suretac provides one point of fixation between soft tissue and the glenoid margin, which compromises the surgeon's ability to use the device to retension the inferior glenohumeral ligament and capsule. A robust and healthy capsulolabral complex is an anatomic necessity to use the Suretac successfully. Comparison of failure strengths between devices used for arthroscopic Bankart repair showed that the Suretac had the lowest initial pullout strength when compared with staples and sutures.[17,27] Early motion after Bankart repairs using the Suretac has been associated with early failure, and motion is restricted for

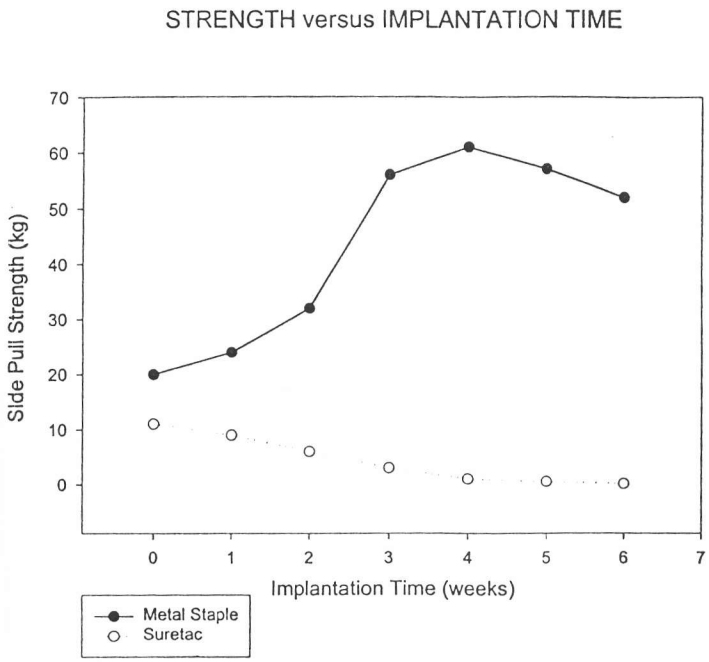
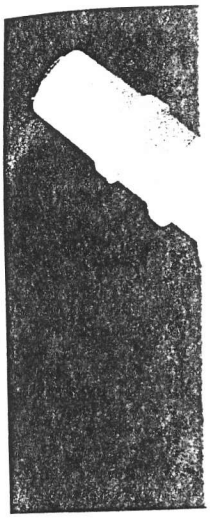


Fig 1. Side pull strength of the bioabsorbable Suretac as a function of time as compared with a metal staple. (Reproduced with permission from KP Speer, RF Warren: Arthroscopic Shoulder Stabilization: A Role for Biodegradable Materials. Clin Orthop 291:67–74, 1993.)



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4 weeks after the procedure at the authors' institution. However, in a pilot study, the Suretac mediated fixation was stronger than the staple and remained so for the duration of the 10-week study.[29] Although the metal staple seemed to hinder repair fibers from reestablishing the soft tissue osseous connection, the Suretac provided no such limitations. The Suretac may take as many as 6 months to be absorbed completely by the body.

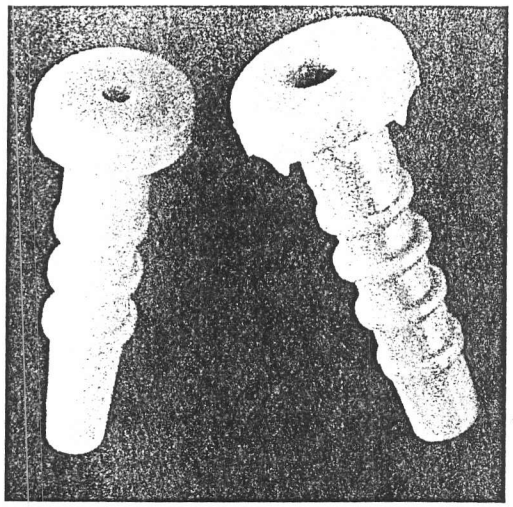

Fig 2. The Suretac device has either a flat or spiked head to grab soft tissues. The head diameter is 6.5 mm for the flat head, and is 8 mm for the spiked Suretac II. (Reprinted with permission from Smith & Nephew, Andover, MA.)

Suture anchors, although technically challenging, recently have provided a means of adequate tissue fixation with minimal risk of injury to surrounding soft tissue structures.[36] However, Shea et al[27] reported that the failures of suture and staple techniques were significantly lower in those with intact labrum-bone complexes.

Surgical Indications: Suretac

Currently, the authors use the Suretac biodegradable device for patients with a Bankart lesion, Type II superior labrum anterior and posterior (SLAP) lesion, or posterior labral separation (Fig 3).[34] The quality of the tissue must be adequate to allow the Suretac device to hold. Capsular laxity, if present, should be treated with other surgical options. Capsular laxity must be addressed either with a superior shift, thermal capsulorraphy, or capsular plication. Patients with multidirectional instability
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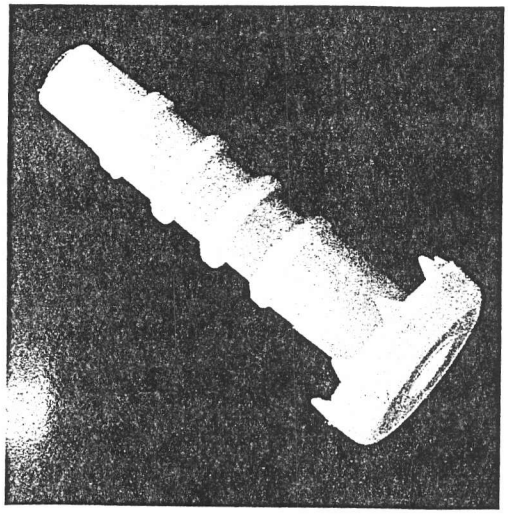

Fig 3. Photograph of Suretac II device. Concentric ribs along the shaft of Suretac improve its ultimate pullout strength. (Reprinted with permission from Smith & Nephew, Andover, MA.)

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...ctional instability are treated with an open capsular shift. The technical aspect of this are similar to using anchors in that capsular tissue may be tensioned appropriately. Anchors, similar to the Suretac, should be placed as low as 4 or 5 o'clock on a right shoulder. Placement of the Suretac and conventional anchors must be directly at the articular margin to avoid failure of the repair. Because of the head on a Suretac, the hole is drilled slightly more medially for an anchor.

Rehabilitation

Protection of the repaired capsulolabral construct is required to avoid recurrence of instability during the initial healing period. A period of 4 weeks with the shoulder in a sling is important. During this period, pendulum exercises are allowed. At 4 weeks, the sling is abandoned, and active motion is initiated under the supervision of a physical therapist. Theraband is used to achieve external and internal rotation, which is begun 4 weeks after surgery. By Week 6, external rotation at 90° is initiated and progressed to a full ROM as tolerated. Weightlifting including forward flexion of the shoulder is allowed at Week 6, and bench pressing may be begun at approximately Weeks 8 to 10. The authors do not allow overhead military presses in patients treated with either arthroscopic or open techniques. Sports usually are resumed by 4 months after surgery.

Using a more refined approach, the authors have found that Bankart lesions repaired with the Suretac device, will heal as readily as Type II SLAP lesions and posterior labral detachments that are repaired with the Suretac.

Complications of the Suretac Device

Recently, Burkart et al[5] reported on four cases of synovitis caused by the Suretac device. Each case of synovitis was associated with recurrence of shoulder instability and failure of the implant. Three of these cases were SLAP repairs whereas the fourth was an arthroscopic Bankart repair. All four patients complained of shoulder pain postoperatively. All four patients had an increase in C-reactive protein and an elevated erythrocyte sedimentation rate. In addition, subsequent arthroscopy revealed a massive synovitis with intraarticular effusion in all four patients. In three of the patients, the Suretac was broken at the head-neck junction of the device and loose fragments had fallen into the joint cavity. Bacterial cultures in all four patients were negative. Histologic evaluation revealed a massive infiltration of phagocytic cells including multinucleated giant cells and histiocytes. Burkart and colleagues[5] observed that the Suretac may be prone to early failure particularly with SLAP tears because of its degradability profile. The current authors also had several cases of synovitis associated with placement of a Suretac for glenohumeral instability (Fig 4). In each case, the patient presented with a diffuse loss of motion and shoulder pain after their index procedure. Symptoms were relieved after arthroscopic debridement and synovectomy.

In the series of Burkhart et al[5] three of 18 patients (22%) with SLAP lesion repairs using the Suretac had foreign body reactions. Other studies have shown significantly lower complication rates with greater statistical power.

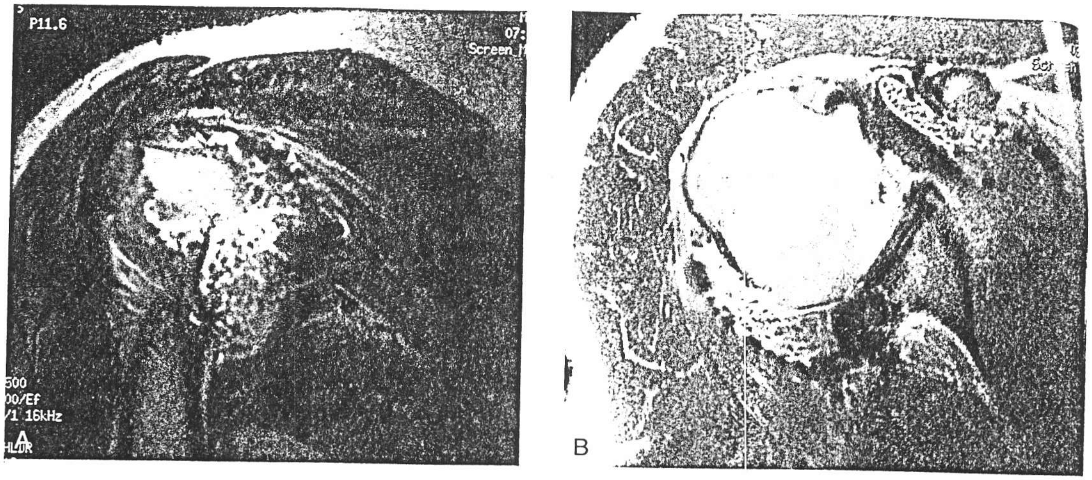

Fig 4A–B. (A) Sagittal oblique and (B) axial MRI scan of a patient who had synovitis develop from placement of the Suretac device 3 weeks after arthroscopic repair of a Bankart lesion. The gross glenohumeral joint effusion with particulate debris can be seen on the sagittal and axial views.

Segmuller et al[24] reported three of 71 cases (4.2%) that showed an adverse reaction to the Suretac at a second arthroscopy. Edwards[8] reported similar findings indicating that five of 100 patients (5%) who were treated with the Suretac device had an adverse reaction to the polyglyconate implant. Three of the reported five failures (60%) were in patients who had SLAP repairs. It was postulated that the early motion played a role in failure of the device.[5] The current authors recommend 4 weeks of immobilization with the shoulder in a sling with daily pendulum exercises when the Suretac is used to repair a SLAP lesion. In a study by Pagnani and Warren[21] 19 of 22 patients (86%) treated with the Suretac device for SLAP lesions reported results of satisfactory or better with the procedure. In addition, 86% presented with no or minimal loss of motion postoperatively. Ninety-one percent of the patients reported a significant improvement in pain after the procedure. None of the patients presented with Suretac synovitis.

Warner et al[32] selected a cohort of patients specifically with arthroscopic Bankart repairs. Only two of 15 patients with recurrent instability after arthroscopic Bankart repairs with the Suretac device had residual polyglyconate polymer debris surrounded by a histiocytic infiltrate. Such a finding could contribute to chronic inflammation at the site of repair more than 6 months after the initial procedure.[32]

Warner and associates[32] made several technical observations regarding their use of the Suretac in a cadaver model, which was embedded in a clear polymer. They created a discrete Bankart lesion arthroscopically in eight shoulders from cadavers and then repaired the lesions using the Suretac. The specimens were dissected to reveal placement of the Suretac relative to the articular margin and scapular neck. They observed four consistent technical errors in their repair of the Bankart lesion: (1) inadequate abrasion of the anterior and inferior juxtaarticular scapular neck; (2) inadequate superior and medial shift of the inferior glenohumeral ligament before placement of the lowest Suretac; (3) medial placement of the Suretac relative to the articular margin (Fig 5); and (4) insufficient capture and compression of capsular tissue by the Suretac device.

Warner et al[32] reported technical difficulty in their ability to adequately abrade the anteroinferior scapular neck inferior to the 4 o'clock position on a right shoulder through a superoanterior arthroscopic portal. The impor-

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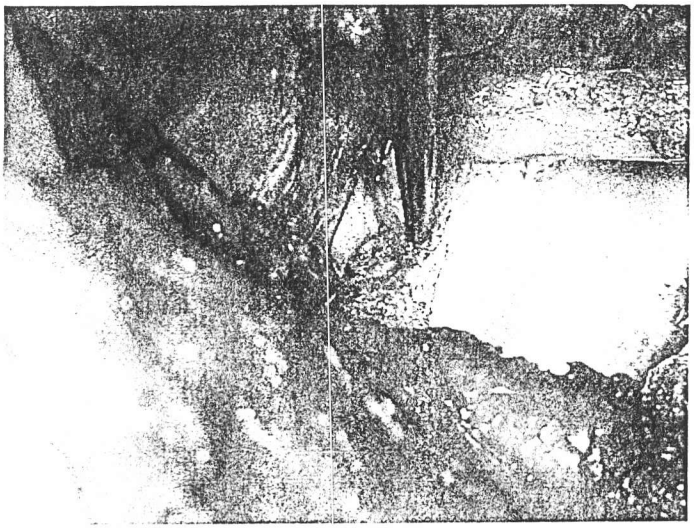

Fig 5. Medial placement of the Suretac or any anchoring device will repair a Bankart lesion at a nonanatomic site and will be directly responsible for clinical failure and recurrence of glenohumeral instability. In this patient, who underwent an open revision anterior shoulder stabilization, the metal anchors were placed medial to the glenoid articular margin (medial to the forceps). The patient had an atraumatic recurrence develop within 1 year of the index procedure.

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Other causes of complications include inadequate numbers of Suretacs, poor technique, chondral injuries, impingement of the humeral head, destruction of the soft tissue, inadequate mobilization of the labrum and inferior glenohumeral ligament during the procedure, and failure to follow an appropriately conservative rehabilitation protocol.[7,13,25]

Suretac: Surgical Technique

As outlined in the product technique guide, the Suretac can be placed arthroscopically with the patient in either the beach chair or lateral decubitus position.[34] The current authors do shoulder arthroscopy with the patient in the beach chair position. Proper placement of the Suretac should follow a step-wise progression: (1) glenoid site preparation: The anterior glenoid margin (immediately adjacent to the glenoid articular cartilage) should be debrided of any soft tissues, and a bleeding anterior margin is prepared to promote soft tissue healing to the margin; (2) drill hole placement: It is important for the surgeon to be aware that there is a tendency for the drill to slide medially along the anterior glenoid neck; a 7-mm cannula is placed into the joint to allow passage of the Suretac insertion instrumentation (Fig 6A); the Suretac drill, guide wire, and drill handle are placed against the labrum and capsule and then advanced into the glenoid at the articular margin (Fig 6B), and it is important to insert the guide wire and drill at an oblique angle to avoid penetrating the glenoid articular cartilage; (3) Suretac placement: The inferior Suretac should be placed first; the Suretac is placed over a guide wire after the drill has been removed (Fig 7).

Outcomes Evaluation of the Suretac Device

The success of the arthroscopic Bankart procedure has been marred by high failure rates, defined as the presence of recurrent instability.[6,11,13] Age, followed by activity level, are

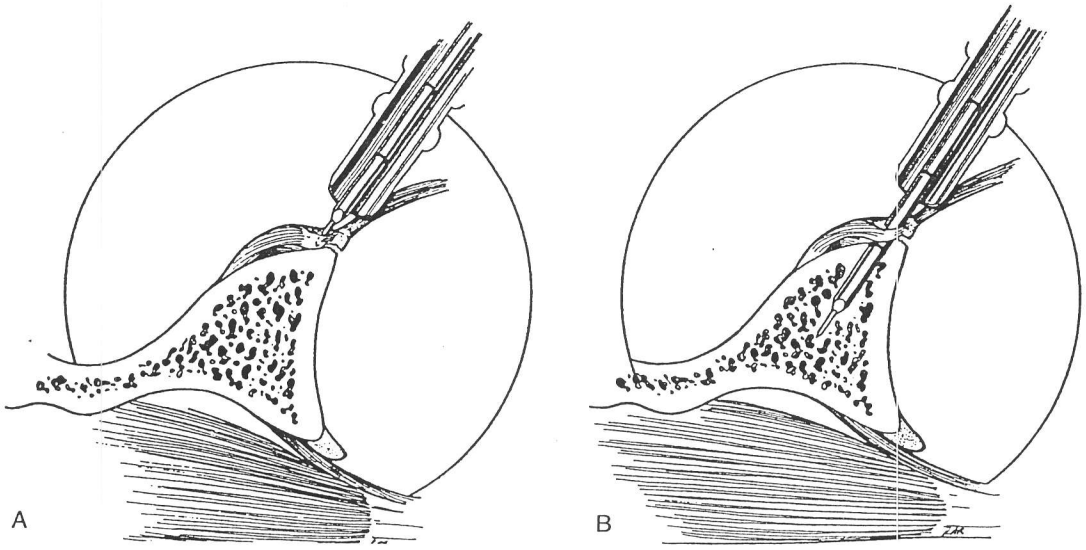

Fig 6A–B. (A) The Suretac insertion instrumentation is brought into the joint through a 7-mm cannula. Care must be taken to avoid medial sliding of the guide pin during insertion. The angle of the glenoid neck, as seen in this axial drawing, predisposes the pin to slide medially, away from the glenoid articular margin. (B) The Suretac drill, guide wire, and drill handle are placed against the labrum and capsule and then advanced into the glenoid at the articular margin. The drill is inserted to the depth of the actual Suretac implant. The drill should be removed, while keeping the guide pin in the glenoid. (Reprinted with permission from Smith & Nephew, Andover, MA).

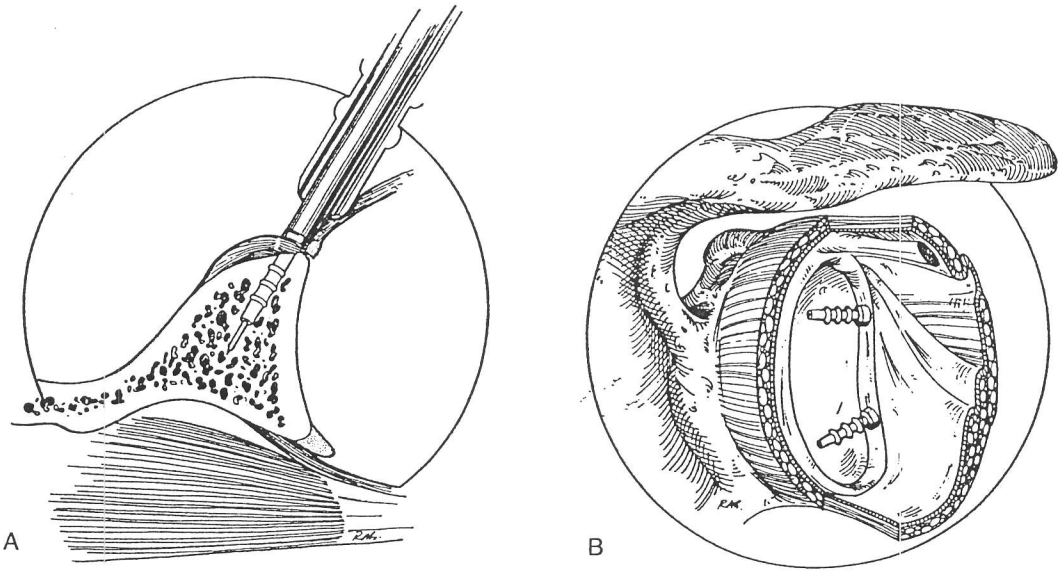

Fig 7A–B. (A) The cannulated Suretac bioabsorbable device is inserted over the guide wire. The head of the device should oppose the capsulolabral complex to the articular margin of the glenoid. (B) Intraarticular view of glenohumeral joint after proper placement of Suretac devices. (Reprinted with permission from Smith & Nephew, Andover, MA).

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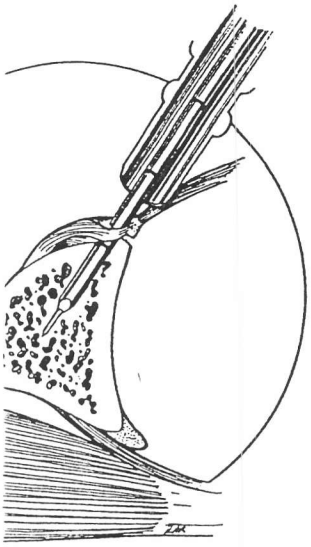

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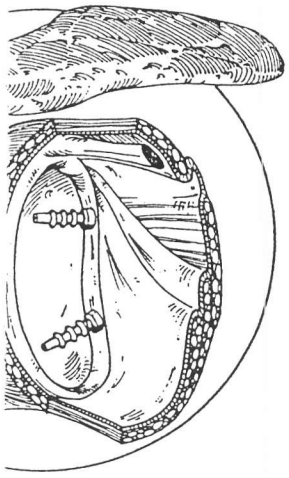

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the two primary predictors of recurrence after stabilization procedures of the shoulder.[18] There is an inverse correlation between age and the incidence of recurrence. The high failure rate of all arthroscopic Bankart repairs seems to be attributable to patient selection rather than the bioabsorbable device. Failure rates can be minimized by selecting patients with anterior shoulder instability attributable to an acute, traumatic event where the patient has a discrete Bankart lesion and a well-developed inferior glenohumeral ligament.

Most recently, Cole and associates[7] evaluated 59 of 63 consecutive patients who underwent either arthroscopic (Suretac) or open repair of a Bankart lesion. Patients included in the study were not randomized, and all had traumatic instability. Patients were divided into two treatment groups based on their examination under anesthesia and disorder identified at surgery. Patients in Group I (N = 39) had only anterior instability with a Bankart lesion during examination under anesthesia and the lesions were repaired arthroscopically with a Suretac. Patients in Group II (N = 24) had anterior and inferior instability during examination under anesthesia, and were treated with an open capsular shift. Clinical failure was defined as recurrent dislocation, subluxation, or presence of apprehension during physical examination. There was no significant difference between groups regarding incidence of failure or any other measured parameter. Twenty-four percent of patients in Group I and 18% of patients in Group II had an unsatisfactory outcome. Good to excellent results were observed in 84% and 91% of Groups I and II patients, respectively. Patients in Group II had a significant loss of forward elevation compared with patients in Group I. Seventy-five percent of patients in both groups returned to their previous level of activity. All cases of recurrent instability were associated with a fall or event during contact sports within the first 2 years postoperatively.

The authors evaluated 52 patients with chronic, anterior instability of the shoulder; 49 of 52 patients had instability develop as a result of a traumatic event. Fifty of 52 patients had a Bankart lesion.[30] At a mean of 42 months postoperatively, 79% of patients were asymptomatic and in 21% of patients, the repair was considered a clinical failure. Seven of the 11 failures occurred atraumatically and in four patients, the repair was considered a clinical failure as a result of a repeat traumatic event involving contact sports. The results of the current study resulted in the development of a more focused indication for use of the Suretac at the authors' institution and a more sensitive appreciation of subtle capsular laxity that may be seen in conjunction with a Bankart lesion. Use of the Suretac was determined to be an inappropriate indication for patients with a Bankart lesion who had a significant capsular injury. The authors observed that use of the Suretac to address Bankart lesions and capsular laxity would result in an unacceptably high rate of clinical failures. The Suretac ideally would be used in patients who suffered anterior instability as a result of a traumatic event, and in those who had a robust and mobile Bankart lesion. Laurencin and colleagues[15] reexamined their arthroscopic Bankart results with the Suretac following optimized indications and found recurrent instability in 10% of 45 patients.

Resch et al,[22] using an inferior transsubscapularis portal to reach the anteroinferior margin of the glenoid, documented a 9% recurrence rate in 98 patients using the Suretac. Of the 318 procedures they did using the Suretac, no complications were reported. Similarly, Karlsson and associates[14] documented a 10% recurrence rate in 82 shoulders that underwent arthroscopic Bankart repair with the Suretac in patients with recurrent, posttraumatic anterior shoulder instability. The average Constant and Rowe score for these patients at an average of 2 years postoperatively was 90 points and 93 points, respectively. No patient had evidence of a loss of motion in any plane at followup. Segmuller et al[24] reported their results in 71 shoulders in which the Suretac was used. The cohort included patients with Bankart lesions, SLAP tears, and

other labral disorders. The recurrence of dislocation in the 31 patients with anteroinferior instability was 3.2%.

Future Directions

The Suretac represents the first generation of bioabsorbable transfixing devices. The future of the Suretac will be determined by clinical results from arthroscopic labral repairs and by complications associated with use of the device. Technically, suture anchors are more difficult to place than implants such as the Suretac. For this reason some clinicians may find the Suretac an appealing alternative.[7,10,11,13,37] However, in the patient with a discrete Bankart lesion without capsular laxity, multiple Suretacs alone can be placed with good results.

The authors have successfully used biodegradable anchors with sutures for several years to address capsular laxity that often is present in conjunction with Bankart lesions. The authors routinely combine Suretac use for Bankart repair with thermal capsulorraphy to address this capsular component. This technique, although preliminary, may be an effective means of surgically treating capsular laxity. Currently, design changes are being considered to provide altered angles of the device for the head to match the glenoid.

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