ARTHROSCOPIC ROTATOR CUFF REPAIR

Normal Rotator Cuff

PDS Suture Marker

Technique

Partial Articular Side

Rotator Cuff Tear

Acromial Spur

CHARLOTTE SHOULDER SYSTEM

Surgical Technique

Diagnostic Arthroscopy

- Standard posterior portal
- · Standard anterior rotator interval portal
- Assess for:
 - Labral pathology
 - Glenohumeral articular cartilage lesions
 - Biceps tendon pathology
 - Capsular integrity
 - Synovitis
- Assess articular surface of the rotator cuff
 - Intact
 - Partial tear
 - Full thickness tear

Arthroscopic Subacromial Decompression +/-Distal Clavicle Excision

- Subacromial portals
 - Posterior (optional for inflow)
 - Posterolateral (scope)
 - Anterolateral (shavers or burrs)
- Prompt acromioplasty—standard technique
- Rasp to palpate and smooth acromium

Arthroscopic Rotator Cuff Repair¹

- Assessment of cuff size/configuration/ arthroscopic reparability
- Cuff mobilization
 - Capsular release(s)
 - Coracohumeral ligament release
 - Greater tuberosity preparation
 - Motorized burr (on reverse) to prepare greater tuberosity
 - Avoid complete decortication/deep trough



Full Thickness Rotator Cuff Tear (Articular Side)





After Acromioplasty

After Debridement

Full Thickness Rotator Cuff Tear (Bursal Side)

Surgical Technique

Suture Anchor Placement

- Percutaneous placement via small incision at lateral border of acromion
- "Dead man's angle" (Figure 1)
- Start with most anterior anchor
- Drill/tap to laser mark depth
- LactoScrew® Suture Anchor placed to laser mark depth
- Assess stability of anchor under direct visualization
- Pull sutures through anterior portal
- Repeat process moving posteriorly as needed
 - 5–7 mm between anchors
 - Avoid suture tangling
- Rotator cuff repair
 - Mini Suture Punch utilized for placement of sutures through cuff (Figure 2)
 - One suture at a time
 - Simple or mattress sutures
 - Avoid suture crossing /tangling with systematic suture management utilizing existing cannula and portals
 - Start posteriorly, working anterior
 - Prepare for knot tying

Figure 1





Figure 2





Mini Suture Punch Suture Passage

Knot Tying³

- Tie sutures with the Nordt[™] Knot Tightener from anterior anchor first utilizing lateral portal (Figure 3)
- First throw: utilize the suture through cuff as the post
- Second throw: two half-hitches, same direction, around post utilizing Nordt[™] Knot Tightner
- Third throw: half-hitch, opposite direction, alternate post (locking the knot)
- Fourth throw: half-hitch, opposite direction, alternate post
- Fifth throw: half-hitch, opposite direction, alternate post
- Cut suture ends 1–2mm above knot
- Pull next suture ends through lateral portal
- Repeat knot tying process
- Assess stability of repair (Figure 4)

Figure 3



Figure 4

- 1. Gartsman GM. Arthroscopic management of rotator cuff disease. J Am Acad Orthop Surg. Jul-Aug; 6(4): 259-66, 1998.
- Gartsman GM; Khan M; Hammerman SM. Arthroscopic repair of full-thickness tears of the rotator cuff. J Bone Joint Surg (A) Jun; 80(6):832-40, 1998.
- 3. Connor PM, Milia M. Arthroscopic knot tying techniques: a critical assessment. *J Arthroscopy*, Submitted for publication, 2000.

Developed in conjunction with Patrick M. Connor, M.D. and Donald F. D'Alessandro, M.D., Charlotte, North Carolina.

Charlotte,[™] LactoScrew[®] and Nordt[™] are trademarks of Arthrotek, Inc.

This brochure is presented to demonstrate the surgical technique utilized by Patrick M. Connor, M.D and Donald F. D'Alessandro, M.D. Arthrotek, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. Arthrotek is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

This material is intended for the Arthrotek Sales Force and surgeons only. It is not intended to be redistributed without the express written consent of Arthrotek.



Assess the Stability of the Repair

Arthrotek, Inc.

A Wholly Owned Subsidiary of Biomet, Inc. 56 East Bell Drive Warsaw, Indiana 46582 USA

ARTHROTEK° SOFT TISSUE ANCHORING DEVICES ATTENTION OPERATING SURGEON

DESCRIPTION

The Arthrotek® Soft Tissue Anchoring Devices are resorbable repair devices used to attach soft tissue to bone. LactoSorb[®] Soft Tissue Screw and Washer and MicroMax[™] Suture Anchor are used with or without a suture LactoSorb[®] L-15 Screw Anchors consist of a screw and head design and are used with a suture. The devices are implanted into a predrilled bone hole and are made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactic/polyglycolic acid copolymer degrades and resorbs in vivo by hydroly-sis to lactic and glycolic acids, which are then metabolized by the body.

MATERIALS

Poly-L-Lactic Acid/Polyglycolic Acid Ultra-High Molecular Weight Polyethylene (UHMWPE) Polyester Polypropylene

INDICATIONS

1. LactoScrew[®] L-15 Screw Anchor (85% PLLA/15% PGA): Shoulder

Bankart repair

SLAP lesion repair Acromio-clavicular separation

Rotator cuff repair

Capsule repair or capsulolabral reconstruction Biceps tenodesis Deltoid repair

Wrist/Hand

Scapholunate ligament reconstruction Ulnar/radial collateral ligament reconstruction

Ankle/Foot

Lateral stabilization

Medial stabilization Achilles tendon repair/reconstruction

Hallux valgus reconstruction

Mid- and forefoot reconstruction Flbow

Tennis elbow repair

Ulnar or radial collateral ligament reconstruction Biceps tendon reconstruction

Knee

- Medial collateral ligament repair Lateral collateral ligament repair Posterior obligue repair
- Joint capsule closure liotibial band tenodesis
- Patellar ligament/tendon repair
- 2. LactoSorb® L-15 Screw and Washer (85% PLLA/15% PGA) and MicroMax[™] Suture Anchor:

Shoulder Indications

Bankart Repair SLAP Lesion Repair Acromio-clavicalur Separation Repair Rotator Cuff Repair Capsule Repair and Capsulolabral Reconstruction Biceps Tenodesis Deltoid Repair

Wrist Indications Scapholunate ligament reconstruction

Elbow Indications Tennis Elbow Repair

Biceps Tendon Reattachment Medial and Lateral Repairs Ulnar or Radial Collateral Ligament Reconstruction

Knee Indications

Extra-Capsular Repair Medial Collateral Ligament Repair Lateral Collateral Ligament Repair Posterior Obligue Ligament Repair Joint Capsule Closure

Iliotibial Band Tenodesis Reconstruction Patellar Ligament/Tendon Repair

Vastus Medialis Obliquus (VMO) Muscle Advancement

LactoSorb[®] L-15 Screw and Washer and MicroMax[™] Suture Anchor are preloaded with suture for use at the discretion of the physician.

CONTRAINDICATIONS

Active infection

2. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

- 3. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections
- 4. Pathologic soft tissue conditions, which would prevent secure fixation.

WARNINGS

01-50-1072

Date: 02/05

Arthrotek[®] internal fixation devices provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy soft tissue or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of incomplete healing. Therefore, it is important that immobilization (use of external support, sling, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's activity level and adherence to weight bearing or load bearing instructions have an affect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and polymeric aspects of the surgical implants.

- 1. Correct selection of the implant is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the device is not designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
- 2. The implants can loosen or be damaged when subjected to increased loading associated with inadequate healing. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
- 3. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important for adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure. 4. Care is to be taken to assure adequate soft tissue fixation at the time of surgery. Failure to achieve
- adequate fixation or improper positioning or placement of the device can contribute to a subsequent undesirable result.
- 5. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
- 6. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of devices can occur if excessive force (torque) is applied while seating. 7
- DO NOT USE if there is loss of sterility of the device.
- 8. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or undamaged containers.
- 9. Ensure contact of tissue to bone when implanting, DO NOT OVERTIGHTEN the screw. Structural damage to the tissue and implant may occur if the screw is overtightened.
- 10. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful soft tissue management. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports that are intended to immobilize the repair site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy tissue, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.
- 11. MicroMax[™] Suture Anchor—Loss of bone fixation may occur if flanged wings are not properly deployed.

PRECAUTIONS

Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Arthrotek recommends that all instruments be regularly inspected for wear and disfigurement.

If device contains MaxBraid[™] suture, refer to manufacturer package insert for further information.

POSSIBLE ADVERSE EFFECTS

- 1. Infection can lead to failure of the procedure.
- Neurovascular injuries can occur due to surgical trauma.
- 3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
- Implantation of foreign materials can result in an inflammatory response or allergic reaction.
- 5. Inadequate healing.
- 6. Pain, discomfort, or abnormal sensation due to the presence of the device.
- 7. Necrosis of the bone or tissue.

STERILITY

CE 0086

Arthrotek* resorbable implants are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date

STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE PRODUCT TO TEMPERATURES GREATER THAN 120°F OR 49°C.

Caution: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician. Authorized Representative: Biomet U.K., Ltd.

Waterton Industrial Estates Bridgend, South Wales CF31 3XA U.K.

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Arthrotek at the contact information provided herein.



P.O. Box 587, Warsaw, IN 46581-0587 • 800.348.9500 ext. 1501 • ©2002, 2006 Arthrotek, Inc. All Rights Reserved web site: www.arthrotek.com • eMail: arthrotek@arthrotek.com

Form No. Y-BMT-961/033106/K INVENTING THE FUTURE OF ARTHROSCOPY