

equinox[™]
SHOULDER SYSTEM

ANATOMICAL.
REDEFINED.

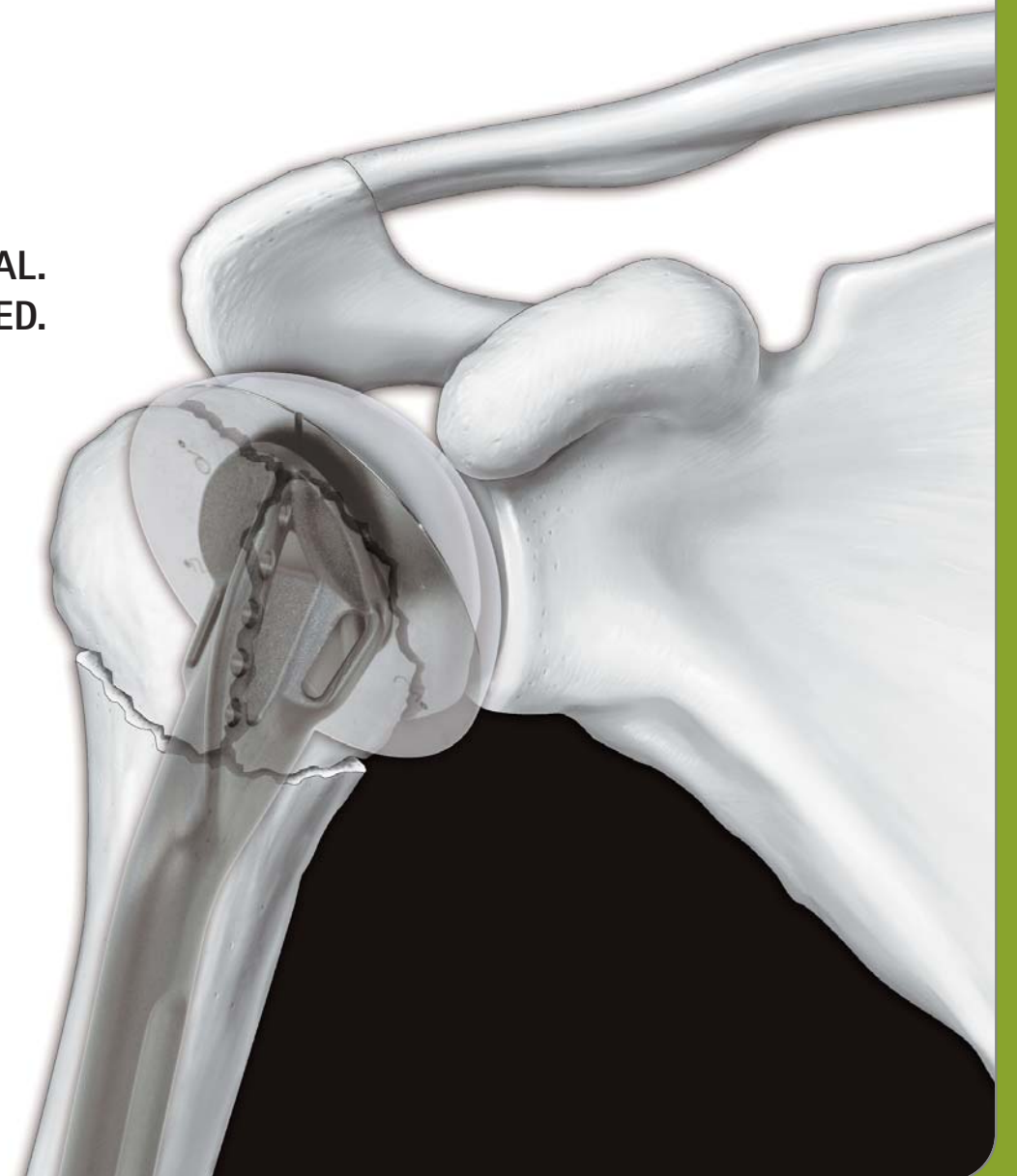




TABLE OF CONTENTS

INTRODUCTION 1

SYSTEM SPECIFICATIONS 2

OVERVIEW TECHNIQUE FOR RIGHT SHOULDER 3

DETAILED OPERATIVE TECHNIQUE 6

SPECIAL CONSIDERATIONS 6

PRE-OPERATIVE EVALUATION 6

PATIENT POSITIONING 6

SURGICAL APPROACH 7

HUMERAL PREPARATION 8

FRACTURE STEM TRIALING 8

 Retroversion when the distal bicipital groove is visible 8

 Retroversion when the distal bicipital groove is not visible 8

 Humeral Stem Height 9

 Tips for Establishing Height Intra-Operatively 9

 Humeral Head Trial 9

TRIAL REDUCTION 10

CEMENTING THE FRACTURE STEM 10

TUBEROSITY FIXATION 11

 Tuberosity Reattachment 11

SUTURING TECHNIQUE FOR RIGHT SHOULDER 12

TYING THE SUTURES 14

FINAL STABLE RECONSTRUCTION 16

POST-OPERATIVE REHABILITATION 17

EQUINOXE IMPLANT SCOPE 18

EQUINOXE INSTRUMENT SCOPE 18

EQUINOXE SHOULDER SYSTEM DESIGN TEAM

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The Equinox Shoulder System redefines "anatomical." The primary stem allows independent adjustability of all four anatomic parameters *in situ*. The fracture stem's offset anterior-lateral fin and asymmetric tuberosity beds define the next generation in complex fracture reconstruction.

INTRODUCTION

Throughout the development process, our team has collaborated on every facet of the Equinox Shoulder System including this surgical technique. We decided to take a comprehensive approach to the technique, discussing the surgery from pre-operative planning to post-operative rehabilitation, since many shoulder replacements are performed by surgeons who may only do two to three per year. Obviously, there are myriad approaches to each step of shoulder arthroplasty and the surgeon should feel free to employ those with which he is most comfortable. The Equinox-specific techniques, though, should be respected to help ensure a safe and successful surgery.

We began the product development process by identifying concerns our team had with shoulder replacements for complex fractures of the proximal humerus. Our goal was to develop solutions to those concerns and we believe the Equinox System significantly improves the surgeon's ability to secure the tuberosities. The asymmetric beds act as a scaffold for the stable reconstruction of the fractured fragments. The offset anterior-lateral fin, when placed in the distal bicipital groove, assists the surgeon in correctly establishing retroversion.

We've decided to offer the surgical technique in two different formats. The first is a high level overview intended as a refresher before surgery or as a guide for the surgeon's support staff. The detailed narrative version is intended for an in-depth understanding of the step-by-step approach that our team has endorsed and should be read at least once before using the Equinox Shoulder System.

We hope that our work, both the technique and the Equinox Shoulder System, will facilitate "A Great Day in the OR" for the surgeon and the staff.

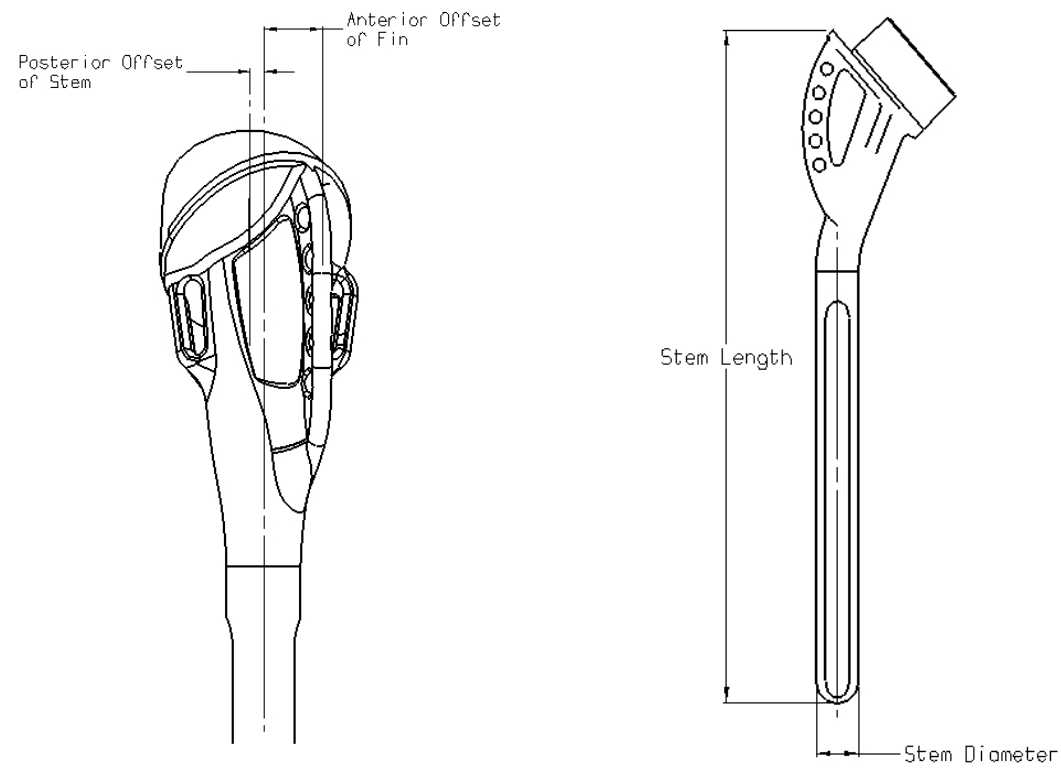
Respectfully,

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SYSTEM SPECIFICATIONS

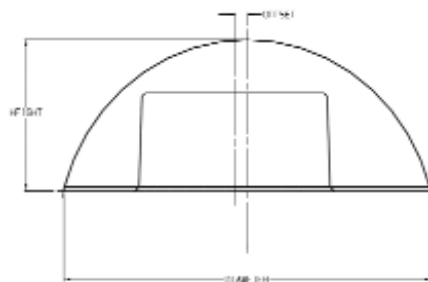


Fracture Stem

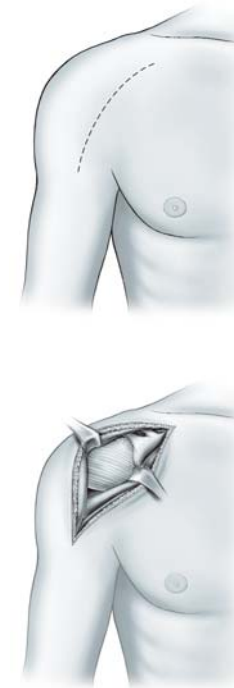
Distal Diameter (mm)	Length (mm)	Sides	Material	Surface Finish			Inherent Posterior Offset (mm)	Anterior Offset of Fin (mm)
				Tuberosity Beds	Remainder of Stem	Suture Holes		
7.0	140	Rights & Lefts	Ti-6Al-4V	16 grade	Satin finish grit blast	Rounded to avoid breakage	1.8	6.0
9.5							1.8	7.5
12.0							1.8	7.5

Humeral Heads

Diameter (mm)	Height (mm)			Offset (mm)	Material
	Short	Tall	Expanded		
38	16	19		0	Co-Cr
41	16	20		0	
44	17	21		1.5	
47	18	22	26	1.5	
50	19	23	27	1.5	
53	20	24	28	1.5	



OVERVIEW TECHNIQUE FOR RIGHT SHOULDER



A. Incision and exposure



B. Reaming the humeral shaft



C. Inserting the trial fracture stem

- Contralateral X-ray with template overlays to approximate height (use fin holes as reference)

- Pull down test — With trial head in place, pull arm distally and the top of the head should be at the top of the glenoid

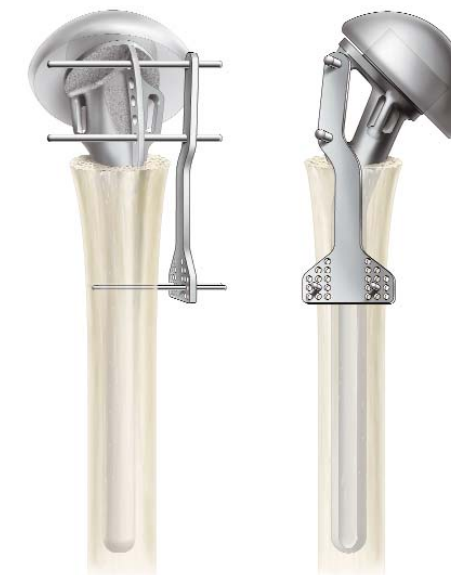
- Finger test — One finger should fit between the greater tuberosity and the acromion

- Piece back the tuberosities to snugly fit under the humeral head

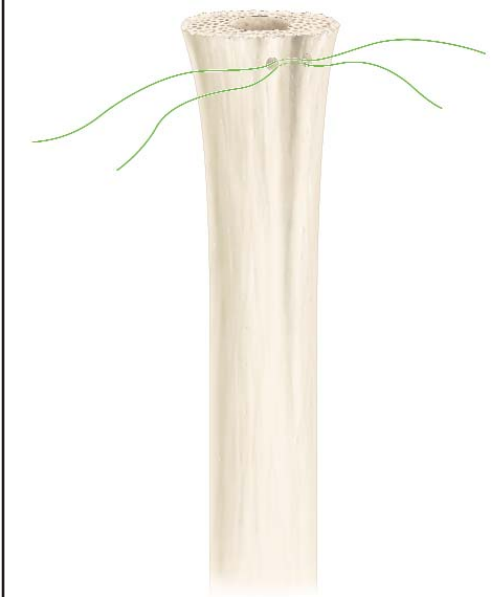
- If medial bone is intact, use as a reference to determine height

- Once height is established, maintain with fracture stem positioning device

D. Establishing/maintaining the height



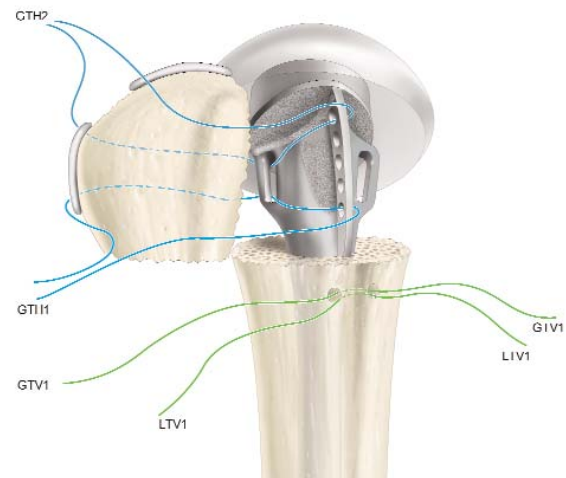
E. Trial reduction



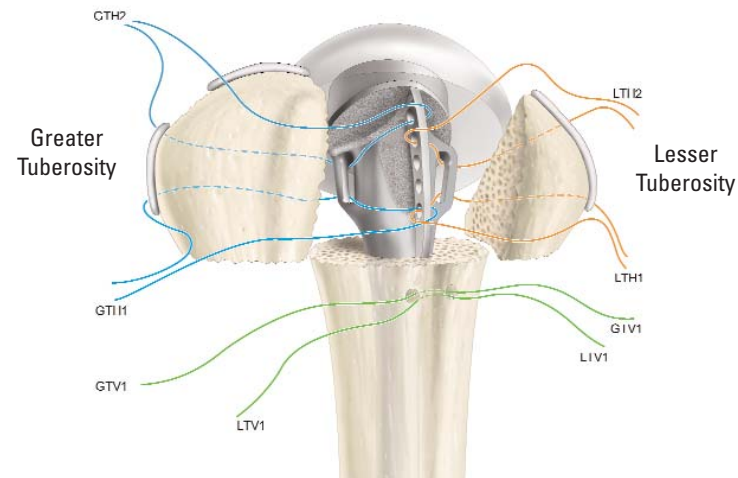
F. Preparing shaft for cement



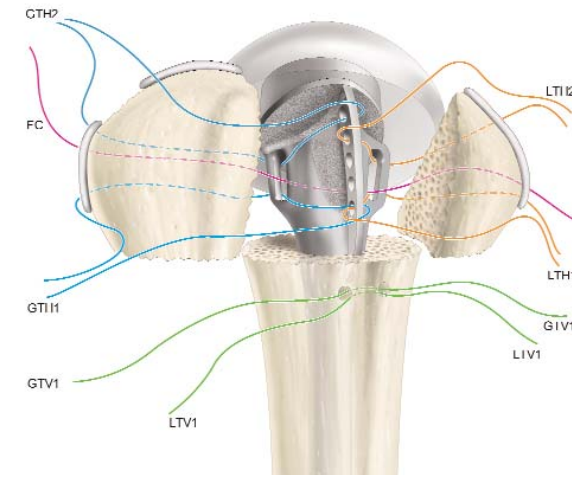
G. Cementing final stem



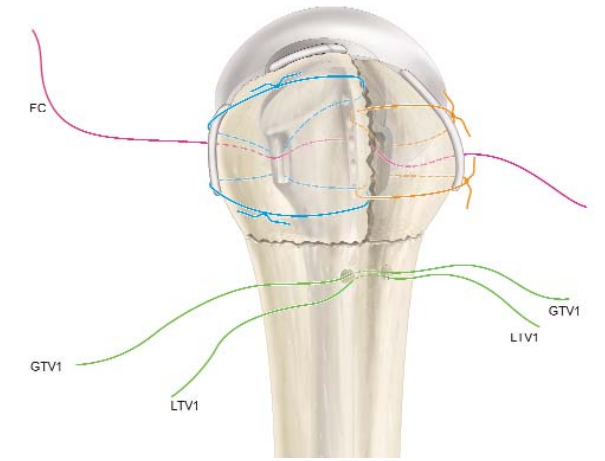
H. Place GT horizontal sutures (GTH)



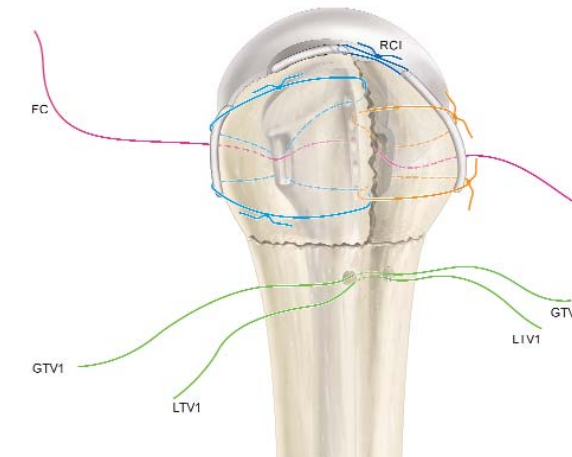
I. Place LT horizontal sutures (LTH)



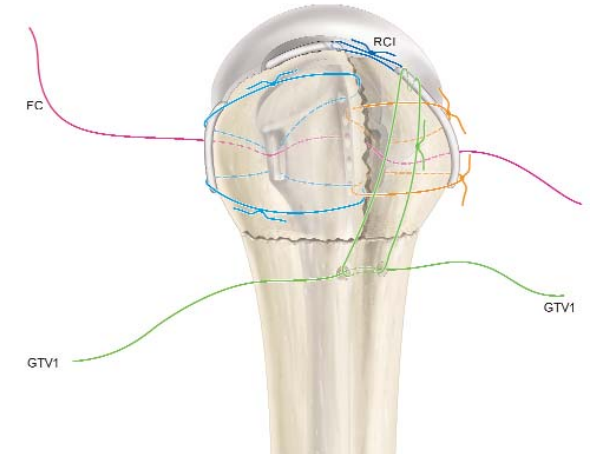
J. Place final cerclage (FC)



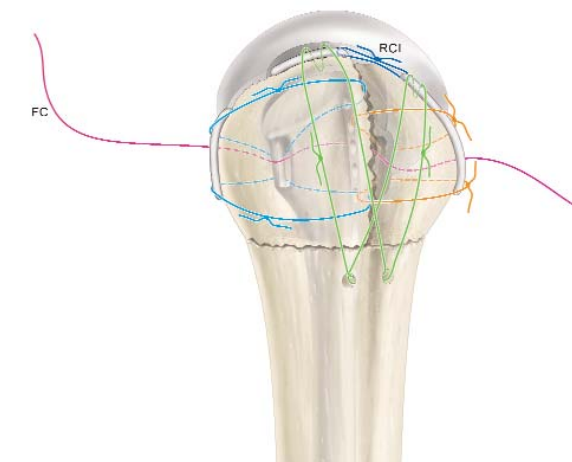
K. Tie horizontal sutures



L. Place and tie cuff interval suture (RCI)



M. Tie LT vertical suture



N. Tie GT vertical suture



O. Tie final cerclage

DETAILED OPERATIVE TECHNIQUE

The Equinoxe™ Fracture Shoulder System is indicated to relieve pain and restore function in skeletally mature individuals with three- and four-part fractures of the proximal humerus and humeral head fracture with displacement of the tuberosities. For a more detailed description of the indications and the listing of contraindications, please refer to the package insert.

Special Considerations

The decision to proceed with proximal humeral replacement should reflect a careful consideration of both injury and patient factors. An important injury factor is the degree of tuberosity displacement; it indicates the degree of soft-tissue injury and is associated with an increased risk of osteonecrosis. The degree of comminution and bone quality are also important factors that may prevent optimal fixation.

Important patient factors include the age and functional needs of the patient. Additionally, the presence of pre-existing functional deficits in the involved extremity must be considered in the decision to proceed with a reconstructive procedure. Patients must be able to participate in a structured post-operative rehabilitative program, which is essential for a successful outcome.

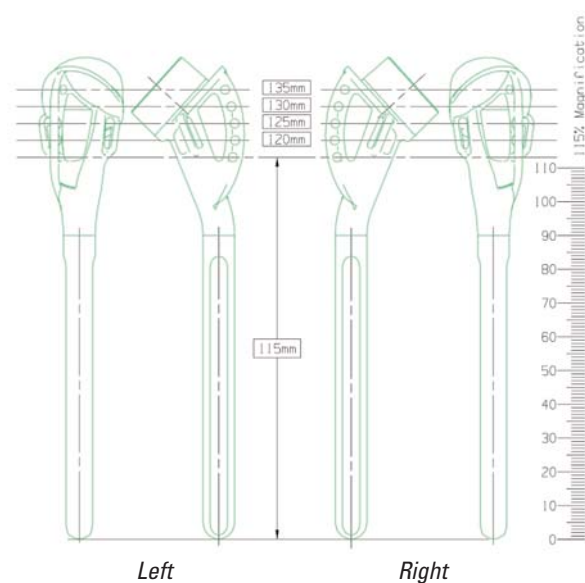


Figure 1
Determining height pre-operatively using
Equinoxe Surgical Templates

A small bolster is placed behind the involved scapula. The patient should be moved to the side of the table so that the upper extremity can be placed into maximum extension without obstruction by the operating table. Alternatively, a captain's chair or similar positioning device can be used for proper patient positioning. The patient should be secured to the operating table to minimize any changes in position intra-operatively. The entire upper extremity should be prepped and draped to allow full mobility during the procedure.

Pre-operative Evaluation

Establishing the appropriate humeral head height and humeral length is a challenge in reconstructing four-part proximal fractures. The most common pre-operative method to evaluate humeral head height in the fractured shoulder is by comparison to the contralateral humerus in an AP radiograph.

Once the appropriate head height is established, mark the AP radiograph with the anticipated location of the humeral head using the Equinoxe surgical templates. (Figure 1) Define the height level of the humeral stem relative to the fracture line. The graduated markings on the template should be used to match those on the stem trial to establish the final height. Additionally, assess the appropriate stem diameter relative to the canal diameter; each stem has a 1mm circumferential cement mantle.

Patient Positioning

The patient should be placed on an operating table in a supine position. The head of the operating table should be elevated approximately 30° in a modified beach chair position. A small

Surgical Approach

A straight deltopectoral incision is made beginning just lateral to the tip of the coracoid process and extending distally and laterally to the insertion of the deltoid. The subcutaneous tissues are divided and medial and lateral flaps are elevated to expose the deeper muscular layers.

The deltopectoral interval is identified by localization of the cephalic vein. The cephalic vein is usually retracted laterally with the deltoid muscle. In some instances the cephalic vein is more easily retracted medially with the pectoralis major. In either case, care should be taken to preserve the cephalic vein throughout the procedure.

The subdeltoid space is mobilized, as is the pectoralis major. The conjoined tendon muscles are identified and the clavipectoral fascia is divided at the medial edge of the conjoined tendon muscles. The fracture hematoma is usually evident after dividing the clavipectoral fascia. The conjoined tendon muscles and the pectoralis major are retracted medially and the deltoid is retracted laterally. This can be most easily accomplished with the use of a self-retaining type of retractor. After the fracture hematoma has been evacuated, the deeper structures can be visualized. The biceps tendon should be identified and tagged with a suture. The biceps tendon provides an orientation to the greater and lesser tuberosities.

The lesser tuberosity is located medial to the biceps tendon and the greater tuberosity is located superiorly and laterally. Each tuberosity should be tagged with a #2 suture for easier mobilization. These sutures should be placed at the tendon insertion site because this is generally the most secure area: placement of the sutures through the tuberosity itself can result in fragmentation. The lesser tuberosity is mobilized and retracted medially while the greater tuberosity is retracted laterally and superiorly to allow visualization of the articular segment. (Figure 2)

In four-part fractures, the articular segment is generally devoid of soft-tissue attachments and is easily removed. The coracoacromial ligament should be identified at its coracoid attachment and followed to its acromial attachment. When possible, preserve the ligament because of its potential contribution to anterior-superior stability.

With the articular segment removed and the tuberosities retracted, the glenoid articular surface should be inspected. In most situations, the articular surface of the glenoid is intact. It should be visualized to confirm the absence of pre-existing degenerative changes or acute injury. The axillary nerve can usually be palpated at the anterior-inferior aspect of the glenoid. Continuity of the axillary nerve can be confirmed by the "tug test" which consists of palpation of the nerve as it comes around the humeral neck on the underside of the deltoid and as it passes inferior to the glenoid. A gentle back and forth "tugging" motion confirms its continuity. At this point the humerus should be placed in extension to expose the proximal portion of the humeral shaft.

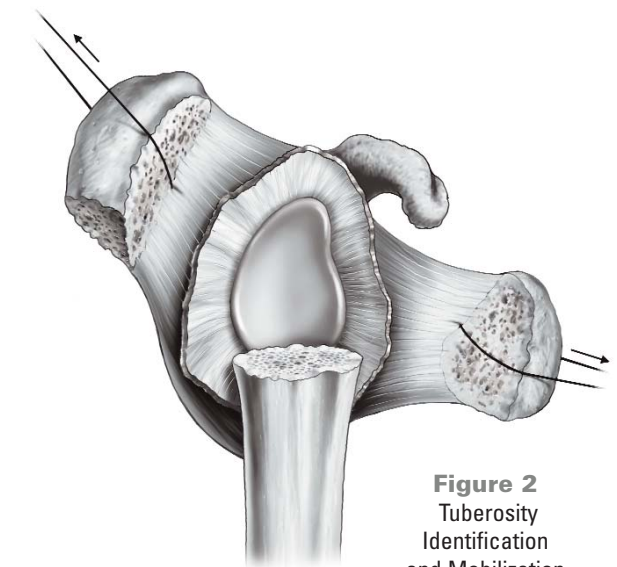


Figure 2
Tuberosity
Identification
and Mobilization

HUMERAL PREPARATION

Sequentially ream the intramedullary canal beginning with the 8mm reamer, until endosteal cortical contact is achieved. (Figure 3) To avoid over reaming, keep in mind the anticipated stem diameter based on pre-operative templating. The canal should be reamed to the depth specified by the laser etching, which corresponds to the height established during the templating.

The use of a cement restrictor is based on personal preference; however, an appropriately sized cement restrictor will improve distribution. If a cement restrictor will be used, it is advantageous to place the cement restrictor in the humeral canal after reaming and before the fracture stem positioning device is attached to the humerus to avoid interference with the K-wires.

Note: Reaming to the 115mm laser mark will ensure adequate depth if desired height was difficult to determine pre-operatively.

Fracture Stem Trialing

Select the trial stem based on the last reamer used. Ensure that the appropriate stem side is chosen (e.g. "Right" or "Left").

Retroversion when the distal portion of bicipital groove is visible

Retroversion is established by aligning the anterior-lateral fin of the trial stem with the posterior aspect of the distal bicipital groove. (Figure 4) Computational analysis of data from our anatomic study of cadaveric humeri demonstrated that placing the fin in the posterior aspect of the distal bicipital groove established retroversion as accurately as the traditional technique of using a pre-selected fixed angle relative to the epicondylar axis.

Retroversion when the distal portion of bicipital groove is not visible

Typically, the distal portion of the bicipital groove is visible but in cases when it is not, the standard technique of retroverting the implant at 20° relative to the forearm should be used. In this case, the surgeon must attach the stem impactor to the trial and screw in the retroversion guide as shown in the figure to the right. By aligning the retroversion guide with the forearm, the stem will be placed in 20° of retroversion. (Figure 5) A mark should be placed on the humeral cortex that corresponds to the anterior-lateral fin of the implant to maintain 20° of retroversion during implantation.



Figure 3
Straight Reamer Scale

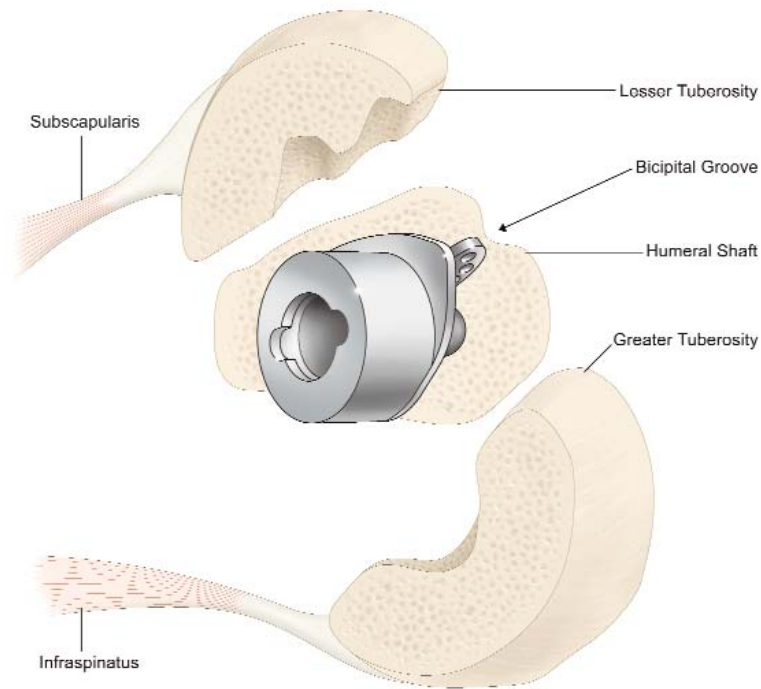


Figure 4
Establish version by aligning the anterior-lateral fin with the distal bicipital groove.

Figure 5
As a visual check of version, the retroversion guide can be aligned with the forearm to place the humeral stem in 20° of retroversion.

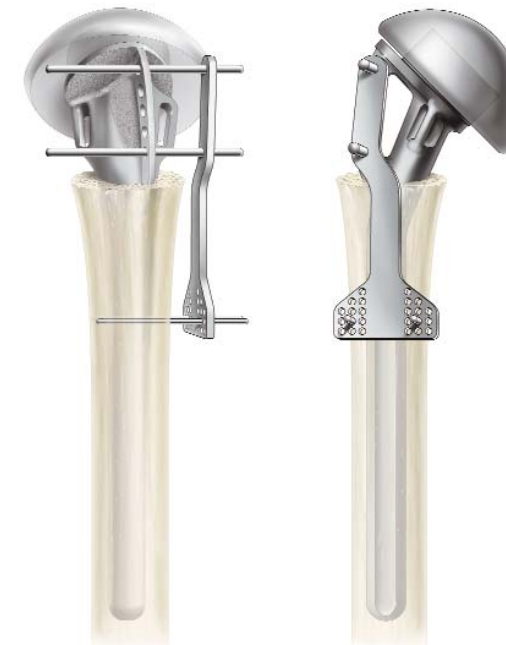


Figure 6
The fracture stem positioning device maintains the surgeon's desired stem height during trial reduction.

Humeral Stem Height

Place the trial stem into the intramedullary canal at the desired height as determined pre-operatively (e.g. templating contralateral shoulder) or based on the surgeon's intra-operative judgment (see "Tips for Establishing Height Intra-operatively"). Select the fracture stem positioning device that corresponds to the size of the stem and slide the two pins through the top and bottom suture holes in the anterior-lateral fin of the stem. Then place two K-wires (0.062mm) into the humeral shaft to stabilize the fracture stem positioning device to the bone. The goal is to secure the K-wires in the cortical bone so choose the widest holes that still align with the humerus. Selecting a middle row allows the surgeon to make +/- 4mm height adjustments during the trial reduction by sliding the fracture stem positioning device off the K-wires and repositioning it.

Tips for Establishing Height Intra-operatively

- **PULL DOWN TEST** — With trial head in place, pull arm distally and the top of the head should be at the top of the glenoid
- **FINGER TEST** — One finger should fit between the greater tuberosity and the acromion
- Piece back the tuberosities to snugly fit under the humeral head
- If there is no medial bone comminution and no metaphyseal bone on the head fragment then the calcar of the humeral stem can be placed directly on this medial bone which will then determine head height.

Humeral Head Trial

As a starting point, choose a humeral head trial based on the size of the patient's anatomic humeral head. The eccentric position of the modular humeral head should be chosen based on the anatomy and/or soft tissue tension as assessed during trial reduction of the tuberosities.

Trial Reduction

Trial reduction is a critical part of the procedure because it defines the parameters needed to obtain a stable construct. After the humeral head is reduced onto the glenoid, the greater and lesser tuberosities are pulled into position. The biceps tendon is allowed to fall between the tuberosities. Traction on the tuberosity sutures not only maintains the tuberosities in position but also provides a more accurate assessment of stability. Self-retaining retractors should be relaxed when assessing soft-tissue tension.

Assessment of posterior, inferior, and anterior stability should be performed by translating the humeral head in each direction. Up to 50% of posterior and inferior translation of the humeral head on the glenoid is acceptable; however, anterior translation should not exceed 25%. If translation is greater, the position of the stem should be re-evaluated to confirm that it has not subsided or rotated within the canal.

Varying the thickness of the modular humeral head provides the ability to optimize stability and range of motion. (Figure 7) If soft-tissue laxity is excessive, a taller humeral head may be needed. Conversely, if soft-tissue tension is excessive, a shorter humeral head is chosen. In either situation, repeat assessment of stability is required to confirm that the proper components and position have been chosen. When the proper position and component size are confirmed, the trial prosthesis should be removed.

Cementing the Fracture Prosthesis

To remove the stem, leave the fracture stem positioning device attached to the humerus and slide the holding pins out of the suture holes in the anterior-lateral fin.

Two drill holes are placed through the humeral cortex into the intramedullary canal. These holes should be placed approximately 1.5 to 2 cm distal to the level of the surgical neck, and adjacent to the bicipital groove. Two #5 non-absorbable sutures are passed through one drill hole into the intramedullary canal and then out through the second drill hole. (Figure 8) These vertical sutures are used for tuberosity fixation. The canal is then irrigated copiously and any loose cancellous bone removed.



Head Diameter (mm)

38 41 44 47 50 53

Height (mm)	Head Diameter (mm)					
	38	41	44	47	50	53
Short	16	16	17	18	19	20
Tall	19	20	21	22	23	24
Expanded				26	27	28

Figure 7
Humeral Head Scope

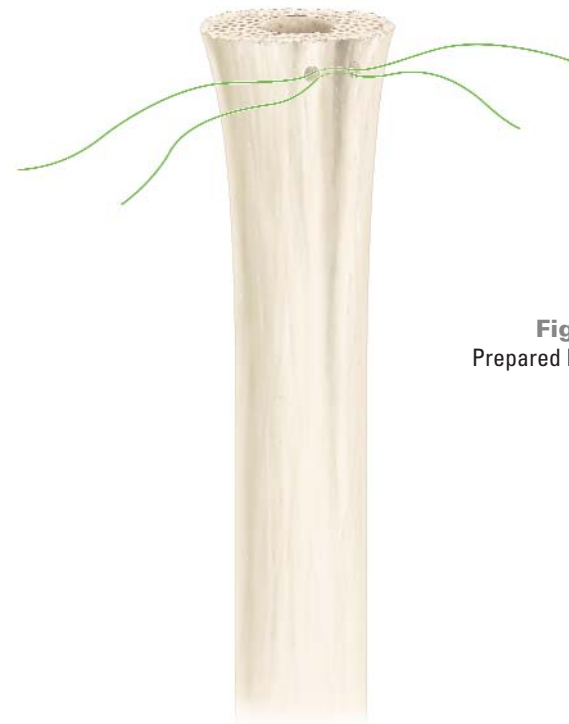


Figure 8
Prepared humerus shaft

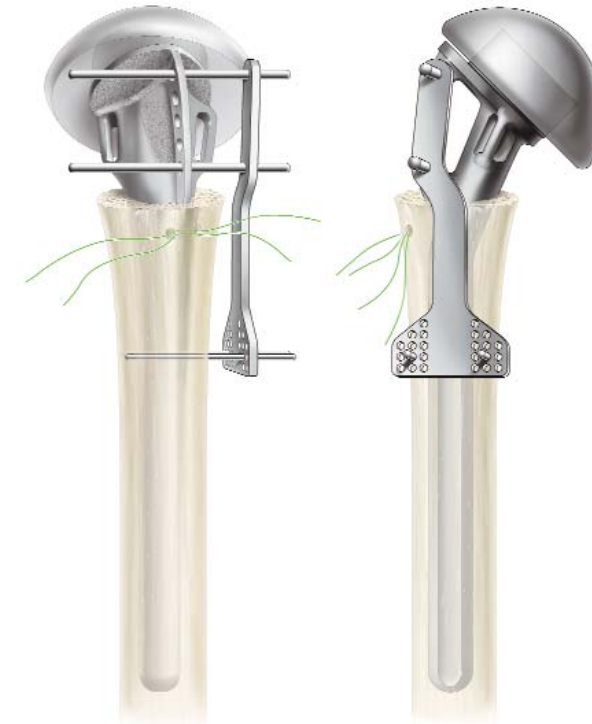


Figure 9

The fracture stem positioning device enables the final prosthesis to be positioned at the same height determined during trialing and maintains the desired height during cement polymerization.

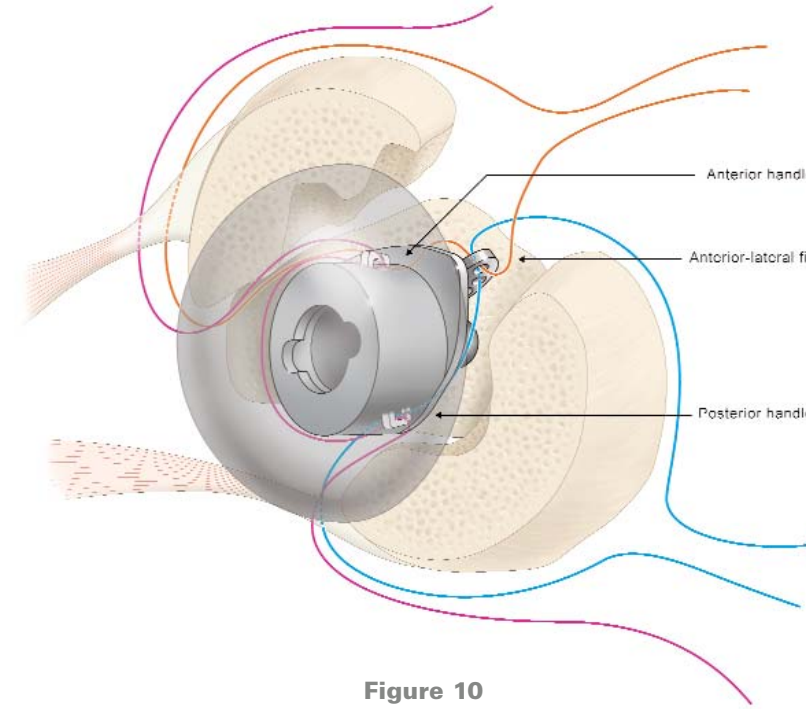


Figure 10
Tuberosity reattachment

Formal cement pressurization is avoided to decrease the possibility of humeral shaft fracture. The intramedullary canal should be packed with a sponge to obtain adequate drying before cementing. Cement is mixed and injected into the canal with a cement gun.

Insert the final prosthesis into the canal and insert the fracture stem positioning device's two holding pins through the top and bottom holes of the stem's anterior-lateral fin. (Figure 9) Ensure the two sutures in the humeral shaft remain mobile and that no cement hardens in the posterior suture handle. This will ensure that the prosthesis is inserted at the same height and version as the trial.

When the cement is hardened, make certain the taper is dry and free of any debris. The final humeral head component is placed on the stem in the same orientation established in the trialing phase. Impact the humeral head using the impactor directly in line with the taper to ensure proper engagement of the Morse taper.

Alternatively, the surgeon may want to pass the sutures through the greater tuberosity then the posterior bar and lateral fin prior to placing the head as this gives easier access.

Tuberosity Fixation

Fixation of the tuberosities to the prosthesis and the shaft is critical to the success of the procedure. Proper tuberosity reattachment and secure fixation will enhance the probability of a successful outcome in terms of pain relief, range of motion, and overall function.

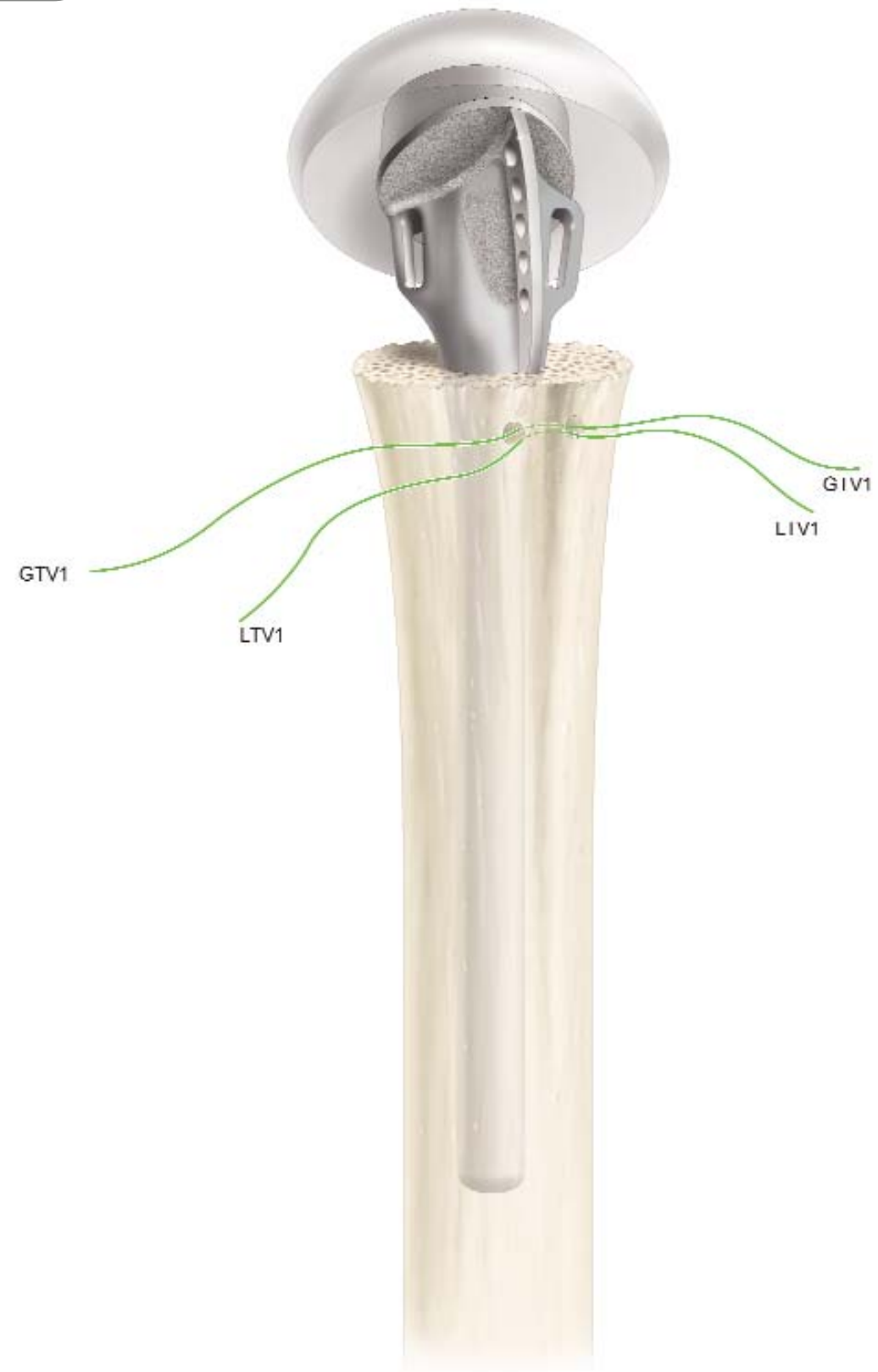
A grafting window is provided in the anterior-lateral fin to allow tuberosity apposition. Apply cancellous bone from the humeral head between the shaft and the tuberosities and between the tuberosities to facilitate healing and a more anatomic reconstruction.

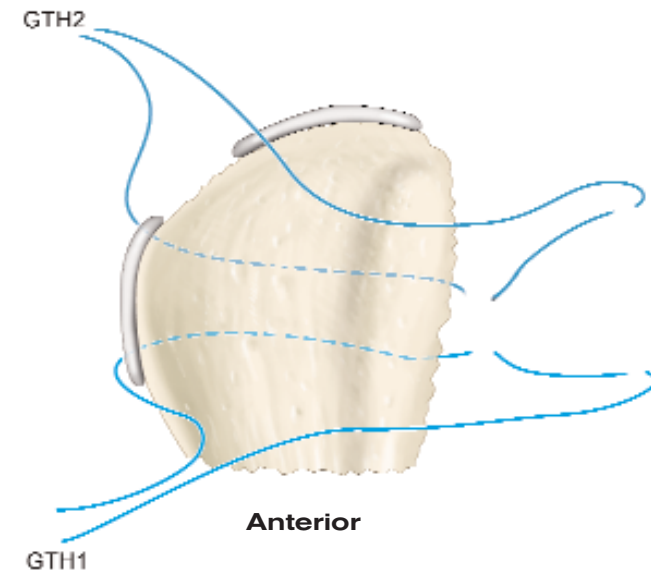
Tuberosity Reattachment

The principles of tuberosity fixation include: (1) two horizontal sutures around each tuberosity to pull the tuberosities to the stem (Figure 10); (2) placement of one longitudinal suture from the shaft to each tuberosity to bring the tuberosities into a position below the prosthetic articular surface and into contact with the humeral shaft; and (3) one final cerclage suture, which cinches the tuberosities together and to the stem for added stability.

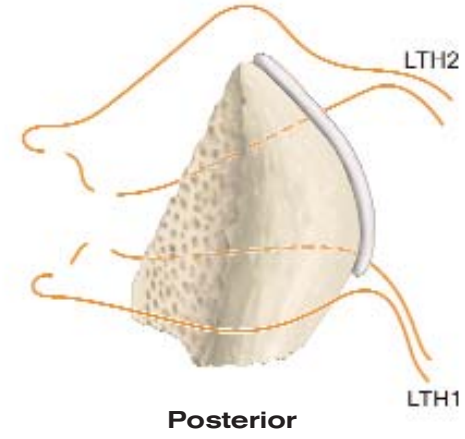
To secure the tuberosities to the stem, we recommend heavy (#5) non-absorbable sutures. Tuberosity reattachment should be performed with the arm in approximately 20 degrees of abduction and neutral flexion.

SUTURING TECHNIQUE
FOR RIGHT SHOULDER

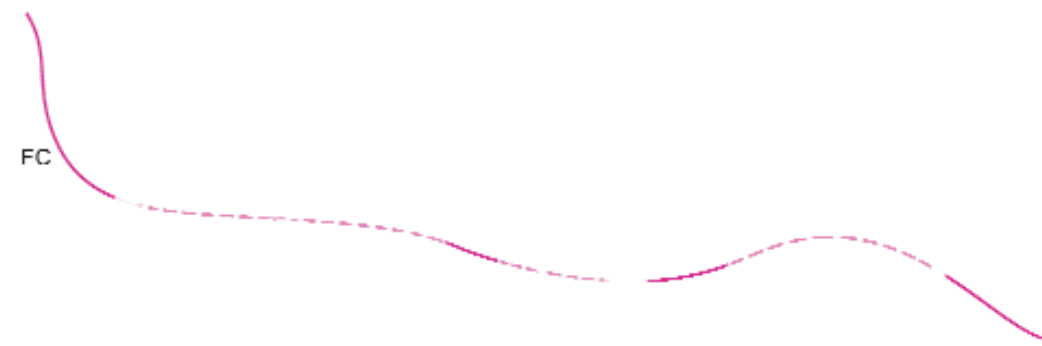




1a: To reattach the greater tuberosity, pass two horizontal sutures between the greater tuberosity and humeral stem. Pass the first suture (First Horizontal suture for the Greater Tuberosity, GTH1) through the lower portion of the infraspinatus tendon where it inserts into the greater tuberosity, through the posterior handle and through an inferior lateral suture hole of the anterior-lateral fin. Pass the second suture (Second Horizontal suture for the Greater Tuberosity, GTH2) through the upper portion of the infraspinatus tendon where it inserts into the greater tuberosity, through the posterior handle and through a superior lateral suture hole of the anterior-lateral fin.



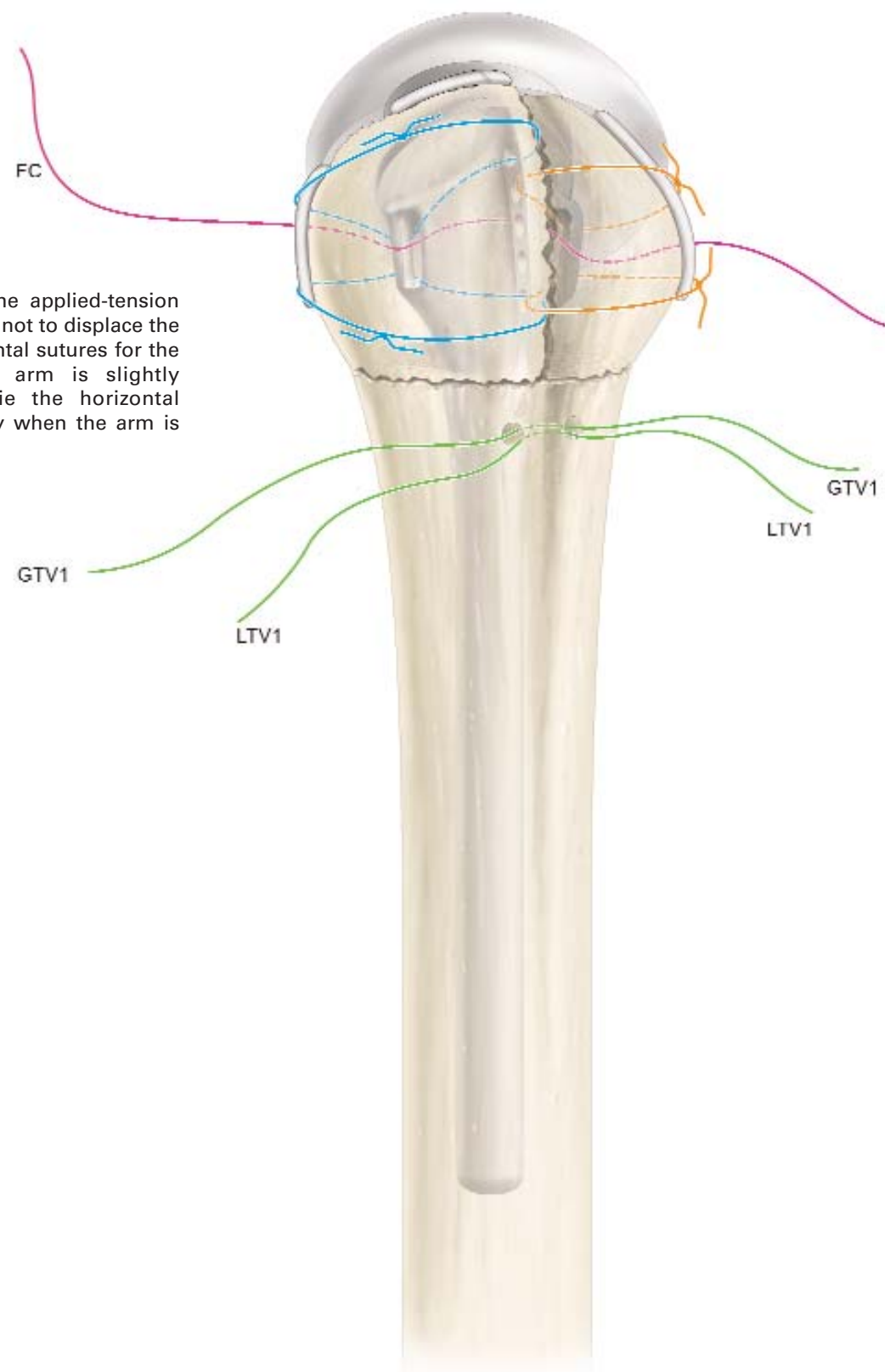
1b: To reattach the lesser tuberosity, pass two horizontal sutures between the lesser tuberosity and the humeral stem. Pass the first suture (First Horizontal suture for the Lesser Tuberosity LTH1) through the lower portion of the subscapularis tendon where it inserts into the lesser tuberosity, through the anterior handle and through an inferior lateral suture hole of the anterior-lateral fin. Pass the second suture (Second Horizontal suture for the Lesser Tuberosity LTH2) through the upper portion of the subscapularis tendon where it inserts into the lesser tuberosity, through the anterior handle and through a superior lateral suture hole of the anterior-lateral fin.



1c: Next, pass the final cerclage (FC) through the middle of the infraspinatus tendon, through the posterior handle and around the medial portion of the stem. Next, pass the final cerclage (FC) through the anterior handle and through the middle of the subscapularis tendon.

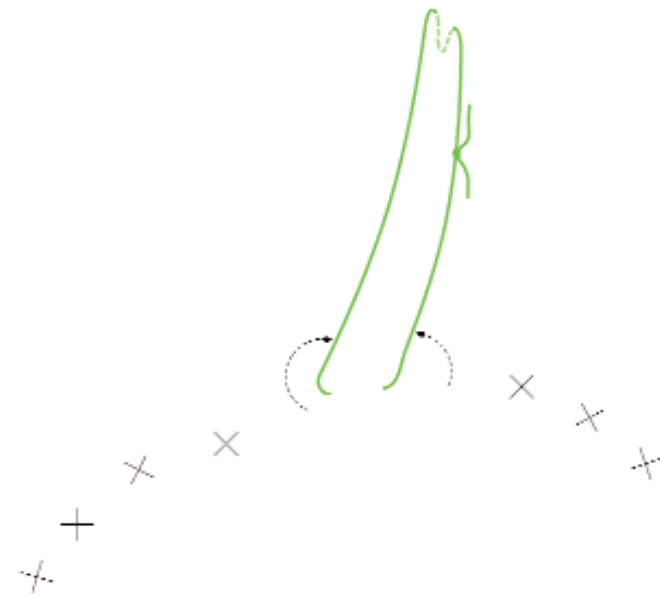
TYING THE SUTURES

2: It is important to balance the applied-tension when tying off each suture so as not to displace the tuberosities. First, tie the horizontal sutures for the greater tuberosity when the arm is slightly externally rotated. Second, tie the horizontal sutures for the lesser tuberosity when the arm is placed in neutral rotation.

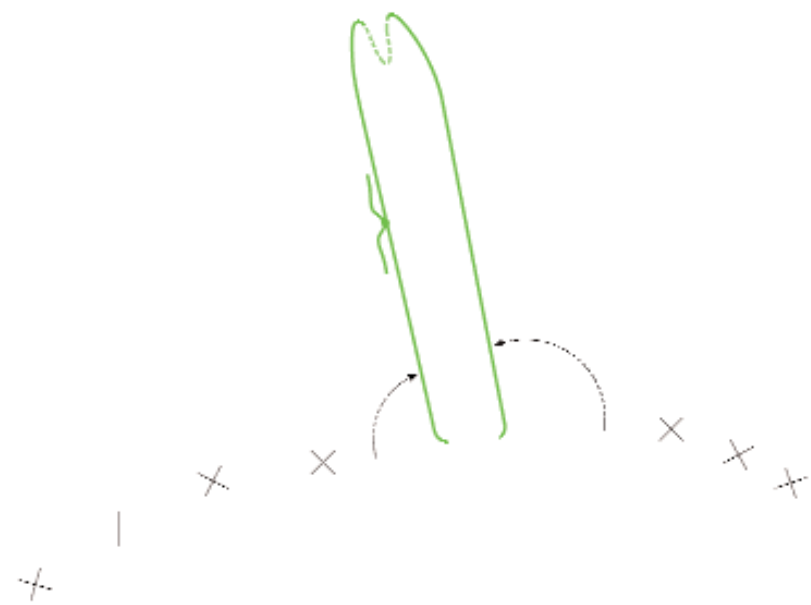




2a: Closure includes repair of the rotator interval with #2 non-absorbable sutures. This repair is performed with the humerus in external rotation to decrease the possibility that rotator interval closure will restrict rotation.



2b: Next, pass and tie the vertical suture (LTV1) through the top upper portion of the subscapularis tendon near the rotator interval where it inserts into the lesser tuberosity.



2c: Finally, pass and tie the vertical suture (GTV1) through the supraspinatus tendon where it inserts into the greater tuberosity.



2d: Once completed, tie the final cerclage.

Final Stable Reconstruction

When the tuberosity fixation is completed, the stability of the fixation should be carefully assessed. Range of motion in forward elevation, external rotation, internal rotation, and abduction should be performed to determine the specific limits of motion that will be allowed in the post-operative rehabilitation program.

Depending on surgeon preference, a drain may be placed deep into the deltopectoral interval and brought out through the skin distally and laterally. The deltopectoral interval is repaired with an absorbable suture, as is the subcutaneous tissue. Skin closure can be performed with either sutures or staples. A sterile dressing is applied and the upper extremity is placed in a sling.

Radiographs in the operating room are strongly recommended. These should include an AP view of the shoulder with the humerus in internal rotation (on the chest) and maximum external rotation as defined by the intra-operative assessment. An axillary view is also obtained. These radiographs provide excellent visualization of the position of the prosthesis as well as the position of the tuberosities.



Post-operative Rehabilitation

It is recommended to initiate the rehabilitation program on the same day as surgery or on post-operative day one. All patients begin active range of motion of the elbow, wrists and hand, and passive range of motion of the shoulder. External rotation should be limited based upon the intra-operative evaluation; internal rotation is allowed to the chest. This is important to avoid any excess stress on the tuberosity repair that could compromise healing.

Exercises are continued for six to eight weeks. Radiographs are obtained approximately two weeks following surgery to confirm the position of the tuberosities. Additional radiographs are obtained at six to eight weeks following surgery to assess the degree of tuberosity healing. If tuberosity healing is sufficient, the sling is discontinued and an active range-of-motion program is begun. The patient is encouraged to use the upper extremity for activities of daily living. Passive range-of-motion is continued with gentle stretching to increase overall range. At eight weeks following surgery, isometric deltoid and internal and external rotator strengthening exercises are begun. Vigorous strengthening exercises are not allowed until active forward elevation of at least 90° is obtained. Most patients can expect continued improvement during the first year following surgery, although most recovery will occur during the first six months.

