

COFIELD² TOTAL SHOULDER SYSTEM



S U R G I C A L T E C H N I Q U E

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Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

PATIENT POSITIONING AND PREPARATION

Place the patient on a standard operating table that is flexed approximately 45° at the waist and 30° at the knees. The patient is moved toward the side of the table of the shoulder to be operated upon so that the lateral aspect of the head is in line with the lateral aspect of the operating table, or a head rest is used. Place a small, folded towel under the scapula. The head is securely positioned, and the trunk is held in place with a chest strap.

Split sheets are useful for the draping procedures. The operative field includes the superior aspect of the shoulder to the base of the neck, the posterior aspect of the shoulder (including the lateral one-third of the scapular spine), and the anterior and lateral chest wall to the nipple line. Drape the limb free, excluding the distal aspect of the limb from the operative field by a sequence of impermeable stockinette, permeable stockinette, and conforming gauze. Cover the exposed skin with plastic drapes, one across the anterior, superior, and posterior aspects of the shoulder girdle and upper arm, and a second drape covering the lateral aspect of the chest wall, the axilla, and the inner aspect of the arm (*Figure 1*).

During the operating procedure, a small Mayo-type stand may be used as an arm rest when the limb is positioned away from the side of the body.



Figure 1



Figure 2

The following is a step-by-step description of the operative technique for total shoulder replacement in a patient with arthritis uncomplicated by rotator cuff tearing or significant bone loss.

SURGICAL APPROACH

1. Anterior approach
2. Develop deltopectoral interval
3. Clear subacromial, subdeltoid, and subconjoined group spaces
4. Incise subscapularis tendon and anterior/inferior shoulder capsule

The anterior skin incision begins over the distal clavicle approximately one and one-half centimeters medial to the acromioclavicular joint. It extends distally, slightly lateral to the coracoid process, and ends just medial to the anterior portion of the deltoid muscle insertion (*Figure 2*).

A small medial skin and subcutaneous flap exposes the deltopectoral interval. Just distal to the clavicle, identify the infraclavicular triangle along the edge of the deltoid muscle. Incise the fascia, extending across the superficial surfaces of the pectoralis major and deltoid muscles along the medial edge of the proximal aspect of the deltoid. Retract this proximal portion of the deltoid laterally. Incise the fascia coursing along the inferior aspect of the pectoralis major and deltoid muscles, along the medial aspect of the upper deltoid. Retract the entire thickness of the deltoid laterally, allowing the cephalic vein to remain in its original position. Continue

dissecting proximally along the medial edge of the deltoid, cauterizing the acromial branches of the thoracoacromial axis. Then proceed distally, incising the thin layers of fascia covering the superficial and deep surfaces of the medial edge of the deltoid muscle. Coagulate any branches of the cephalic vein from the deltoid muscle, and coagulate the deltoid branch of the thoracoacromial axis. Continue the dissection distally as far as the deltoid insertion. For additional exposure, the anterior one-third of the deltoid insertion can be elevated in continuity with the distal periosteum (*Figure 3*).



Figure 3

Incise the extension of the clavicular fascia lateral to the conjoined tendon of the coracobrachialis and short head of the biceps brachii muscles along with the roof of the subdeltoid bursa. Continue the incision upward to the coracoacromial ligament. In many instances, the ligament is left intact. Develop the subacromial space by blunt dissection. Develop the subdeltoid space posteriorly, laterally, and then anteriorly, cauterizing branches joining the anterior and posterior humeral circumflex muscles on the anterolateral aspect of this space. By blunt dissection, develop the space beneath the conjoined tendon group, and palpate the axillary nerve. Place a deltoid retractor (cobra) beneath the deltoid muscle, and place a small knee retractor beneath the conjoined tendon group (*Figure 4*). To obtain additional exposure to the anterior aspect of the shoulder, incise the most cranial centimeter of the pectoralis major tendon near its insertion.



Figure 4

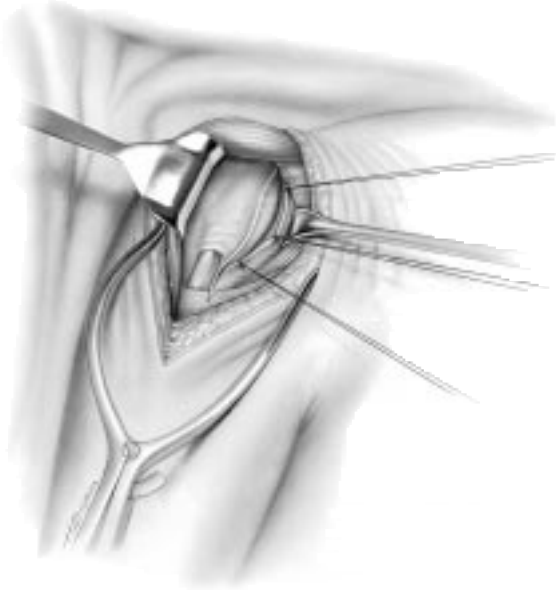


Figure 5

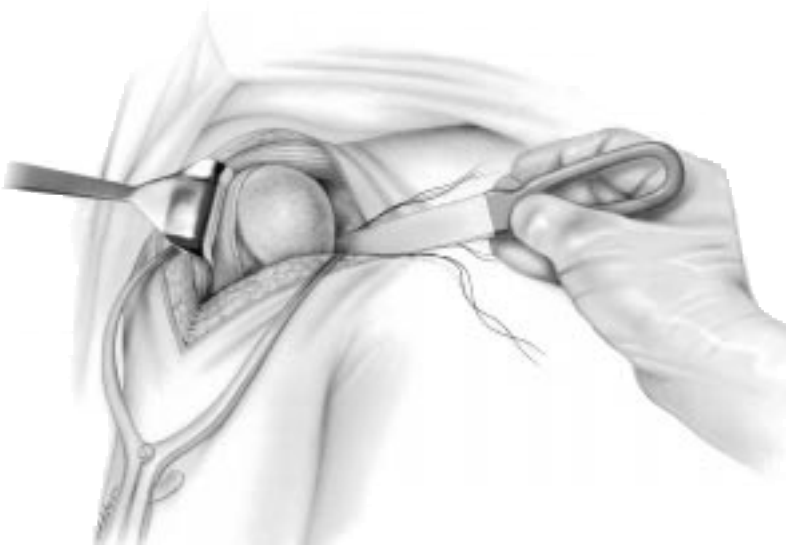


Figure 6

The method of entering the shoulder joint varies according to the amount of anterior shoulder joint contracture. If there is greater than 20° to 30° of external rotation, the joint is entered by dividing the subscapularis through tendon just medial to the anterior shoulder capsule insertion on the humeral head. When there is less external rotation than this, the subscapularis is incised from the bone of the humerus. Begin the arthrotomy by incising the rotator cuff interval area just above or cranial to the superior border of the subscapularis tendon. The vertical part of the arthrotomy incision is then performed according to the parameters outlined above. This incision is continued inferiorly along the anterolateral aspect of the humeral neck exposing the upper portion of the latissimus dorsi (*Figure 5*). The inferior shoulder capsule is then incised to the six o'clock position when there is ample passive movement in elevation. If this movement is limited, the release of the inferior capsule from the humeral neck is continued posteriorly to the four or five o'clock position (in a right shoulder). Great care must be taken to maintain the dissection at the junction between the capsule and bone and to avoid injury to the axillary nerve. A large elevator is then placed in the joint, and the humeral head is subluxated forward (*Figure 6*). This is assisted by arm adduction, extension, and external rotation.

PREPARE HUMERUS

1. Remove osteophytes
2. Prepare humeral canal (diaphysis)
3. Osteotomize humeral head
4. Trim metaphysis
5. Perform trial reduction

To have a clear sense of proximal humeral anatomy, remove the hypertrophic osteophytes that have formed. After this is done, the subchondral plate on the superior aspect of the humeral head is removed, and a bone awl is used to enter the humeral canal. The entry point is typically 1 cm medial to the medial aspect of the junction of the rotator cuff with the humeral head and 1 cm posterior to the groove on the humeral head for the long head of the biceps brachii. These distances will, of course, vary somewhat depending upon the size of the humeral head. By removing the subchondral plate superiorly, it is possible to, with gentleness, direct the bone awl carefully through the head into the humeral canal. The preoperative x-rays will give a good estimation of humeral canal size. Typically, shoulder x-rays are magnified between five and 10 percent. Templates with seven and one-half percent magnification are available to aid in identification of humeral canal size. Humeral canal drills are available in six sizes, varying in 2 mm increments from 6 mm to 16 mm; humeral reamers are available in six sizes from 6 to 16 mm. Typically, one begins preparation of the humeral canal by inserting the 6 mm drill using the T-handle. Progress to larger sizes by inserting progressively larger reamers



Figure 7

until firm resistance is encountered in the humeral diaphysis. This reamer is then left in place, and the T-handle is removed.

The humeral head resection guide is prepared by selecting the degrees of external rotation desired to create with the humeral head osteotomy (*Figure 7 Inset*). Typically, this is 30° or 35°, but it may be reduced to 15° or 20° if there is posterior shoulder joint instability with subluxation. After setting the desired number of degrees, the guide is placed on the humeral reamer, rotated until the rod exiting from the superior aspect of the resection guide is parallel to the forearm, and the cam is then tightened (*Figure 7*). The cutting block on the resection guide is moved to rest adjacent to the humeral head, and the height of the resection is selected so that the osteotomy will be near but slightly above the site of insertion of the rotator cuff into the humeral head. A drill is then placed through the cutting block into the humeral head (*Figure 8*). The head is partially osteotomized with an oscillating saw. The humeral resection guide and intramedullary reamer are removed, and the osteotomy is completed.

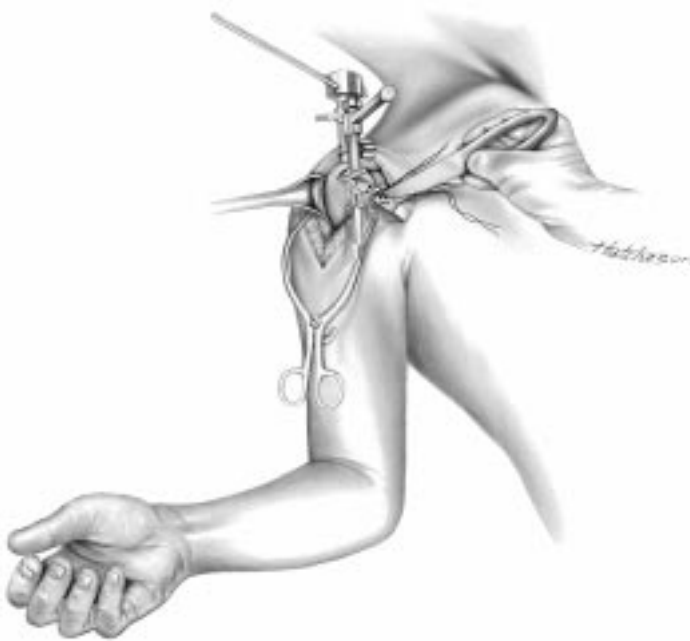


Figure 8

Humeral trials are available in diameters from 6 to 16 mm and progress in 2 mm increments. After creating a slot in the humeral head for the lateral fin of the trial and implant, seat the trial humeral stem using the trial that is 2 mm smaller than the size to which the canal was prepared (*Figure 9*). The plate on the top of the humeral trial must rest flat against the cut metaphyseal surface.

Place the trunnion in the slot of the humeral trial, and select a humeral head trial size based upon the size of the patient, the amount of shoulder capsule laxity, and the amount of bone resected (*Figure 10*). Humeral head trials are available in eight primary sizes, progressing in 2 mm increments from 14x36 mm to 28x50 mm. Two unipolar sizes, 32x54 mm and 36x58 mm, are offered as well. Thus, 10 trial head sizes are available. After placing the trial head on the trial stem, identify metaphyseal bone that extends beyond the rounded portion, and remove this metaphyseal bone, tapering it into the more distal diaphysis.

Perform a trial reduction. Remove the deltoid retractor from beneath the deltoid, and place a medium-sized Richardson retractor under the anterior aspect of the deltoid to retract it, but do not place pressure on the humeral head. Assess the position of the trial humeral head against the glenoid. Ordinarily, it should sit opposite the center of the glenoid — when there is very little glenoid bone erosion. Test the component for translation posteriorly and inferiorly. Typically,

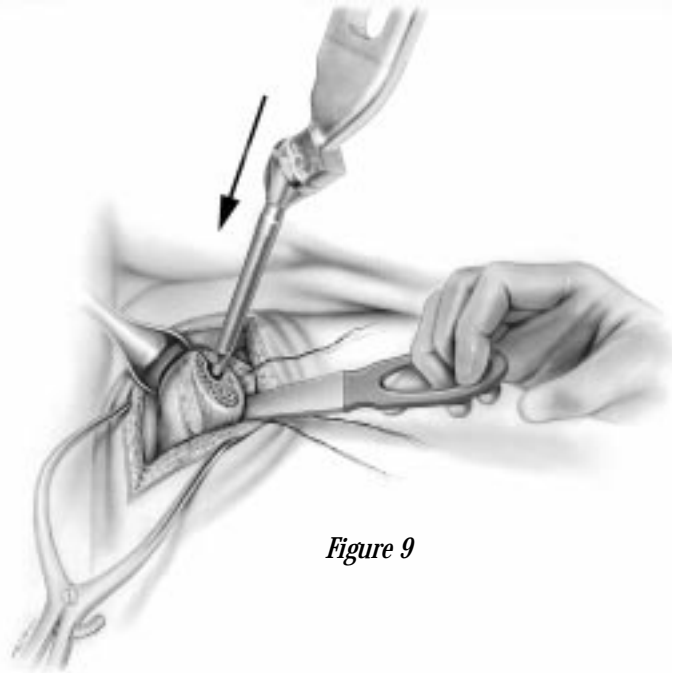


Figure 9

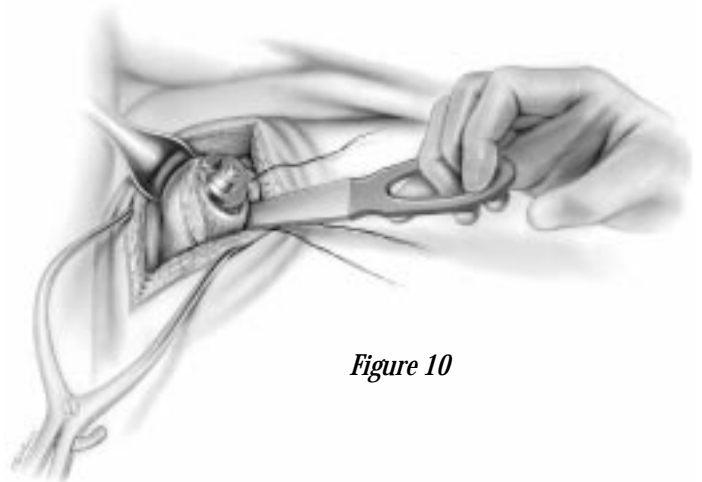


Figure 10

the amount of translation posteriorly that is possible would be one-half the width of the humeral head or less when the arm is in neutral rotation. The amount of translation inferiorly would be one-quarter the width of the humeral head or less when the arm is in 15° to 20° of abduction.

Then assess the range of motion.

Typically, there should be internal rotation to at least 90° and elevation to 150°.

If the elevation is less than this, palpate the attachment of the inferior shoulder capsule on the humeral neck. Some additional inferior humeral capsule may need to be released to allow more full overhead elevation. Redislocate the shoulder and remove the trial humeral head and the trunnion, leaving the trial stem in place.

PREPARE GLENOID AND PLACE COMPONENT

1. Exposure and additional capsule releases
2. Place centering hole
3. Ream glenoid fossa
4. Place peripheral holes
5. Prepare keel slot
6. Sound keel, place trial
7. Prepare bone for cement
8. Place all-polyethylene glenoid component

With the Richardson retractor holding the deltoid laterally, place a bone hook in a firm portion of the humeral metaphysis and retract the proximal humerus laterally. Inspect the joint, remove any loose bodies, and remove hypertrophic synovium from the posterior and inferior aspects of the shoulder joint. Palpate the

posterior shoulder capsule. If it is excessively tight, it may be helpful to release the posterior shoulder capsule along the glenoid rim. However, in most situations, this is not necessary. Remove the bone hook, place the Fukuda-type retractor or the humeral neck retractor on the posterior aspect of the glenoid and gently lever the proximal humerus posteriorly (*Figure 11*). The best position to do this is usually with the humerus in 70° to 90° of abduction and slight flexion.

Additional hypertrophic synovium is then removed from the anterior aspect of the shoulder. If there is a contracture of the anterior aspect of the shoulder, the capsule is then incised anterior-superiorly with the incision continuing inferiorly to the superior band of the inferior glenohumeral ligament. The incision is then directed laterally along this band. An elevator is placed beneath the capsule and subscapularis to free it slightly, and a retractor is then placed in this interval.

With the glenoid exposed, excise soft tissue along the glenoid rim and outline the entire glenoid fossa. All-polyethylene glenoid components come in three sizes: small, medium, and large. Use drill guide 1 to judge the size of the component needed. If the patient is between sizes, it is usually better to choose the smaller size. After selecting the size of glenoid component, use the bone awl to create a site for placing the centering hole. Place drill guide 1 over this site to ascertain correct placement. If not correct, make the minor adjustments to place the centering hole accurately. This is critical to subsequent glenoid preparation.

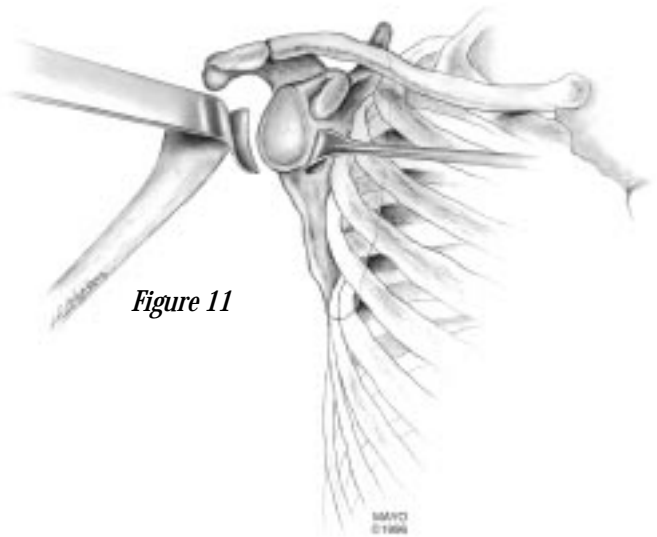


Figure 11

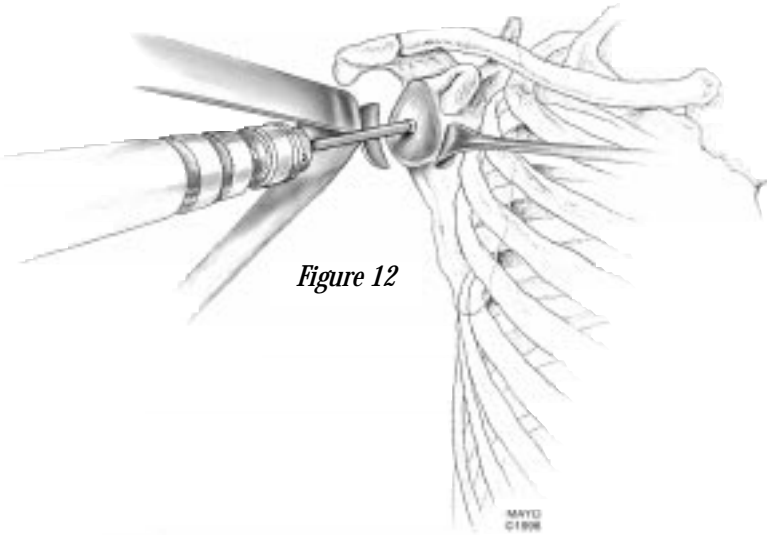


Figure 12

Using drill 1 (longer drill with short drill stop), carefully place the centering hole directing the drill perpendicular to the orientation of the glenoid face selected to create for the glenoid component (*Figure 12*). Proceed very slowly, placing the centering hole, using the drill not only as a cutting instrument but as a guide.

Select the small, medium, or large glenoid fossa reamer, and ream the glenoid surface so a mixture of cortical and cancellous bone is present on the surface (*Figure 13*). Typically, no more than 1 mm of thickness is removed from the anterior and posterior aspects of the glenoid fossa. Superiorly and inferiorly, the depth of reaming may extend to 3 mm or 5 mm.

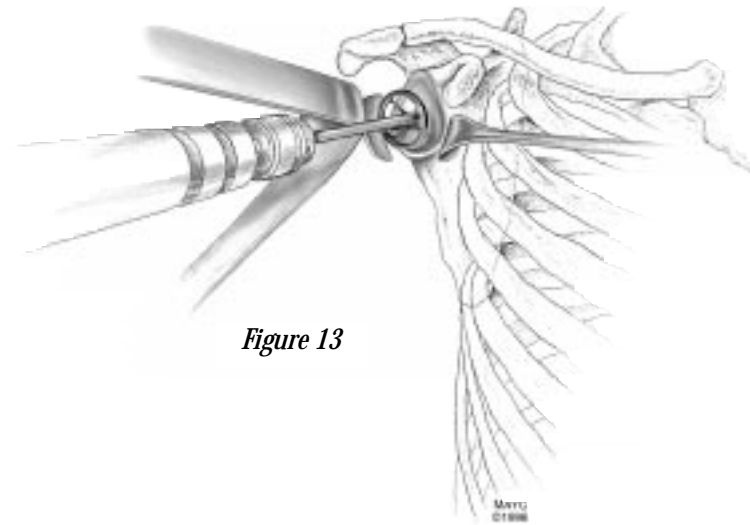


Figure 13

Replace drill guide 1 on the glenoid fossa and place the all-poly drill 2 (large drill with long stop) in the centering hole of drill guide 1 (*Figure 14*). This will secure the drill guide in position. For the all-polyethylene glenoid component, do not seat drill 2 deeper than the previously prepared drill 1 centering hole. Rotate drill guide 1 so that it is in the long axis of the glenoid, and prepare the peripheral holes. Drill one of the peripheral holes using drill 1. Place the glenoid

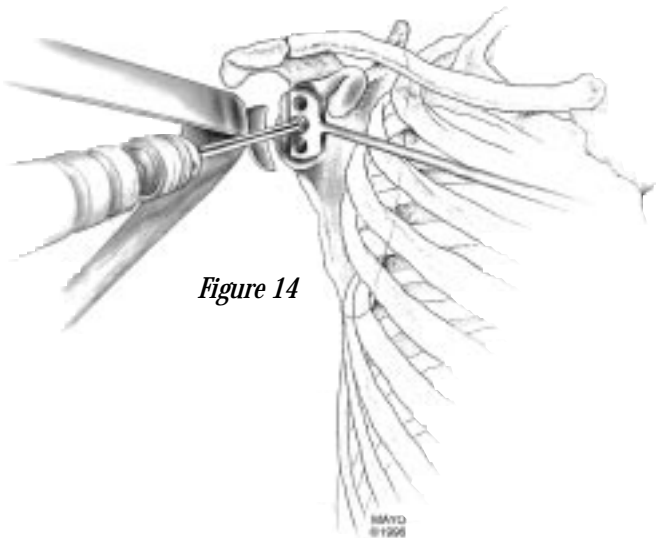


Figure 14

alignment peg in that hole to lock the rotational position, and prepare the second peripheral hole, again with drill 1 (*Figure 15*). Remove the centering drill, the alignment peg, and the drill guide.

Place drill guide 2 such that the superior and inferior flanges of the template lock in the previously prepared peripheral holes. Use the keel cutter to prepare the keel slot (*Figure 16*). Remove template 2. Continue preparation of the keel slot by slowly deepening the slot into the cancellous bone of the humeral neck. This must be done carefully using a burr that is slightly smaller in diameter than the width of the keel slot.

Three keel sizer/rasps, the sizes of the keels for the respectively sized glenoid components, are available to judge the adequacy of keel preparation. When the keel sizer/rasp for the selected glenoid size seats fully, it is removed, and the trial all-polyethylene glenoid component is placed. It should seat flush with the prepared glenoid surface, and, if glenoid slot preparation has been carefully performed, the trial prosthesis should be stable against the glenoid.

Further prepare the bone of the glenoid for cement fixation. Undermine the subchondral plate using the power burr, and roughen any cortical surfaces that remain using a smaller power burr. Use pulsatile lavage to clean the glenoid face and keel slot, and pack the slot repeatedly with gauze sponges.

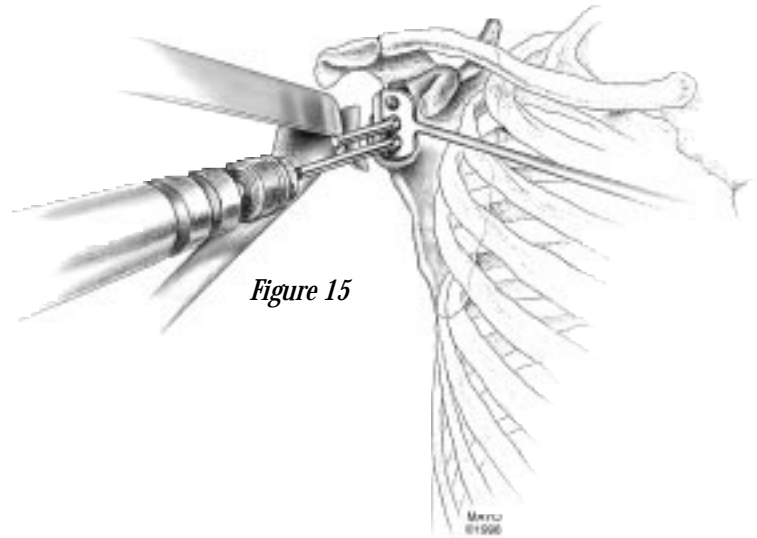


Figure 15

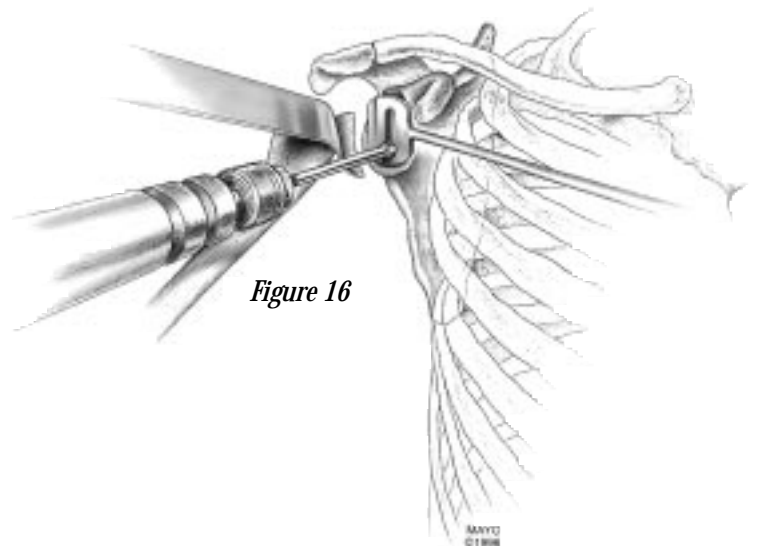


Figure 16

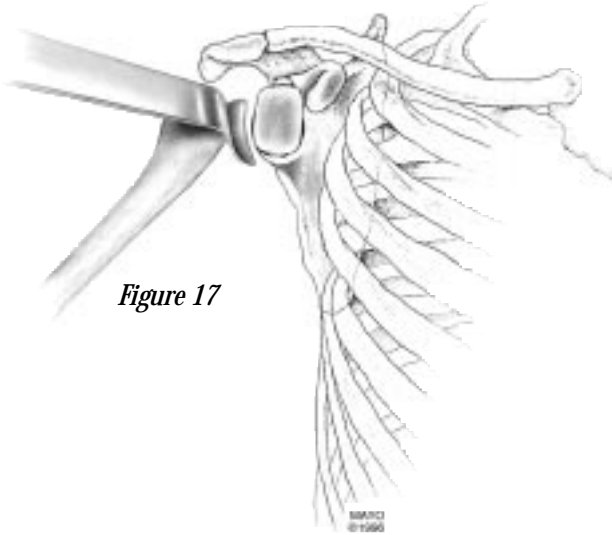


Figure 17

Bone cement is then placed in the keel slot and over the face of the glenoid. It is pressurized into the slot using the surgeon's thumb. Usually, three to four pressurization cycles are used. The all-polyethylene glenoid component is then placed and tapped into position using the impactor (*Figure 17*). Excessive cement is cleaned from around the component, and the cement is allowed to harden.

PLACE HUMERAL COMPONENT

1. Trial reduction(s) with glenoid component in place
2. Cement technique for placing the humeral component

To fix the component with bone cement, utilize a plastic plug placing it at the proper depth in the humeral canal. The canal is cleaned with pulsatile lavage. After drying, bone cement is introduced into the humeral canal with a cement gun. Only a moderate amount of pressurization is done. A humeral stem one size smaller than the diameter to which the canal was prepared is then inserted. After the cement hardens, the humeral head is impacted on the stem (*Figure 18*).

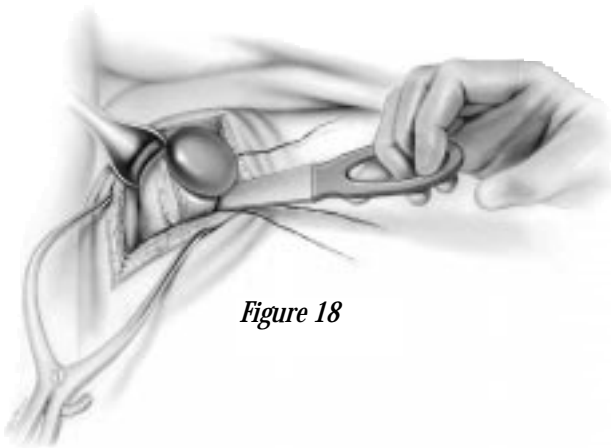


Figure 18

ARTHROTOMY AND WOUND CLOSURE

1. Repair subscapularis and anterior shoulder capsule
2. Assess stability and measure range of motion
3. Close deltopectoral interval and skin

Following joint reduction, light traction is placed on the subscapularis stay sutures. The rotator cuff interval is securely closed, and the subscapularis is either sutured tendon to tendon or tendon to bone (*Figure 19*). If it is planned to suture the subscapularis and anterior shoulder capsule to bone, it is important to place the sutures in the proximal humerus before implanting the humeral component.

After arthrotomy closure, assess stability by passive translation of the humeral head anteriorly, posteriorly, and inferiorly. Typically, the translation will be approximately one-quarter the diameter of the humeral head in any direction with the arm in neutral position. If it is slightly more than this but centers well, the laxity should be of no concern.

Range of motion is then assessed in external rotation, internal rotation, and elevation. These movements are recorded and used to plan the extent of early passive motion that will be allowed.

After lavaging, reassessing the axillary nerve anteriorly and posteriorly, and placing a drain low in the subdeltoid space, the deltopectoral interval is closed. This is followed by skin closure and placement of a dressing.

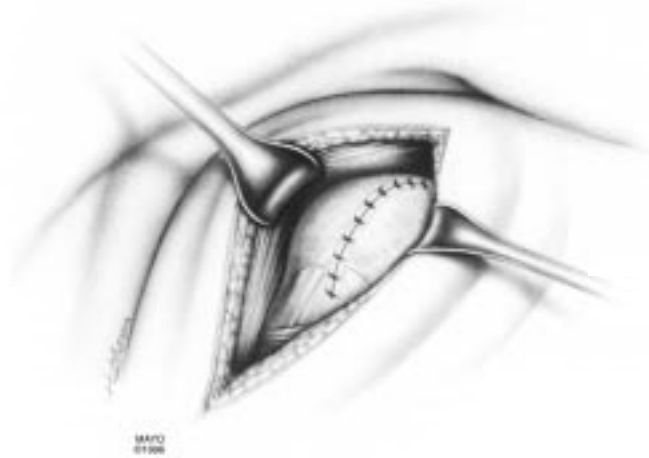


Figure 19

SOFT TISSUE CONTRACTURES

Certain arthritic conditions, especially those associated with prior trauma, have extensive scar formation. A portion of this scar may be excised, but, of necessity, one must leave in place the rotator cuff and much of the shoulder capsule. These structures will have been infiltrated to a greater or lesser degree with scar tissue. As a part of the surgical procedure, in addition to excising unwanted scar, one lyses adhesions within the subacromial-subdeltoid bursa and the glenohumeral joint, resects slightly more bone from the glenoid and humeral surface, and uses thinner components. In addition, a number of different tissue releases can be done about the glenohumeral joint. On the anterior aspect of the shoulder, when there is only moderate limitation of external rotation, the anterior-superior shoulder capsule is incised at the base of the coracoid and along the anterior glenoid rim (*Figure 20*). This segment of the capsule and the overlying subscapularis are then partially freed from the subscapularis fossa using a blunt elevator. Additional mobility of the anterior capsule-subscapularis complex can be obtained by continuing the incision anteriorly just superior to the superior band of the inferior gleno-humeral ligament. This will then separate the anterior capsule from the inferior capsule allowing maximum flexibility of the anterior capsule-subscapularis complex.

An alternative method for releasing an anterior shoulder contracture is to Z-lengthen the subscapularis and anterior

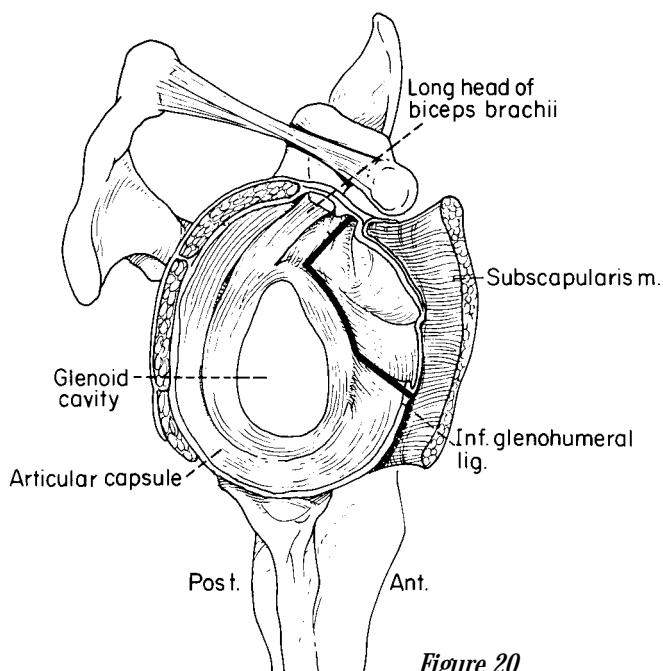


Figure 20

shoulder capsule (*Figure 21*). When performing this technique, one enters the joint through the interval between the supraspinatus and the subscapularis and assesses the thickness of the anterior capsule and subscapularis. If these are near normal in thickness and of adequate quality, Z-lengthening may be done with safety. Unfortunately, a number of patients with contractures, particularly those with rheumatoid arthritis, do not have thick enough tissues to allow Z-lengthening.

Inferior contractures can be released by dividing the anterior-inferior capsule at the humeral neck (*Figure 22*). However, it becomes increasingly difficult to separate the posterior-inferior capsule from the humeral neck because of the proximity to the axillary nerve. Once reaching the seven o'clock position of the inferior capsule attachment to the humeral neck in a right shoulder, it is then safer to carefully direct the incision somewhat posterior-medially to complete the division of the inferior shoulder capsule. In addition, of course, there is often a large amount of scar within the inferior capsule recess, and this can be carefully excised.

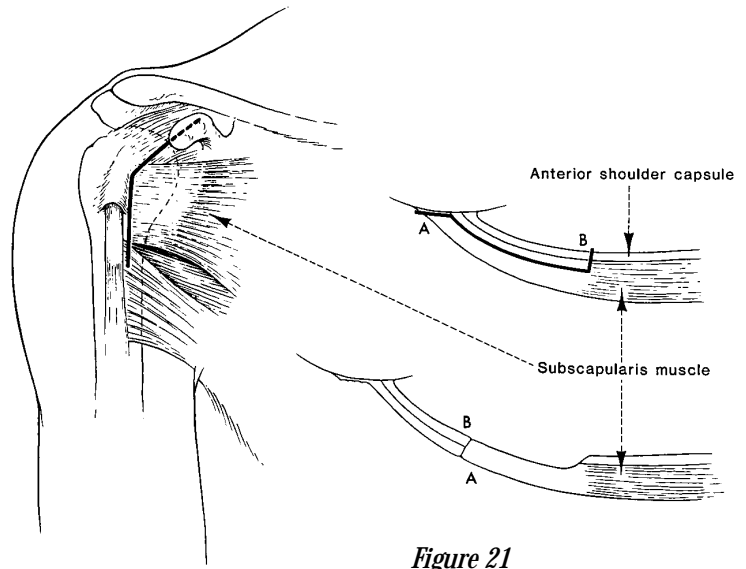


Figure 21

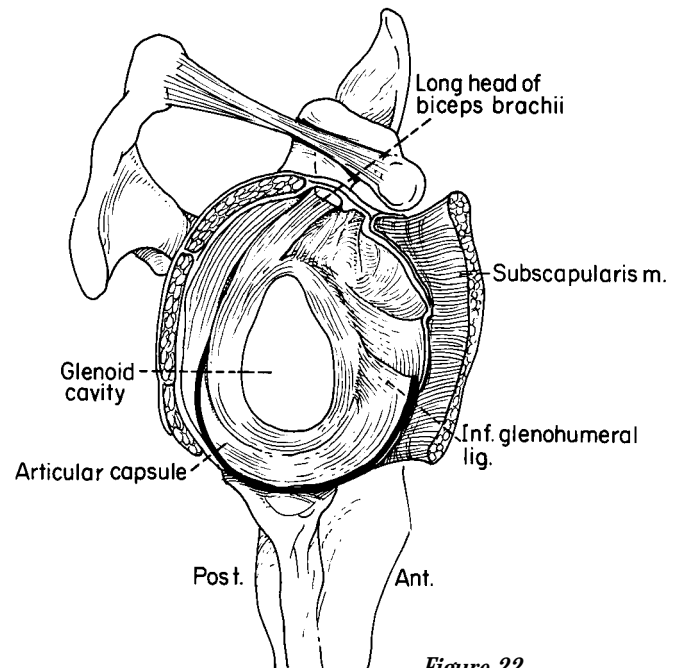


Figure 22

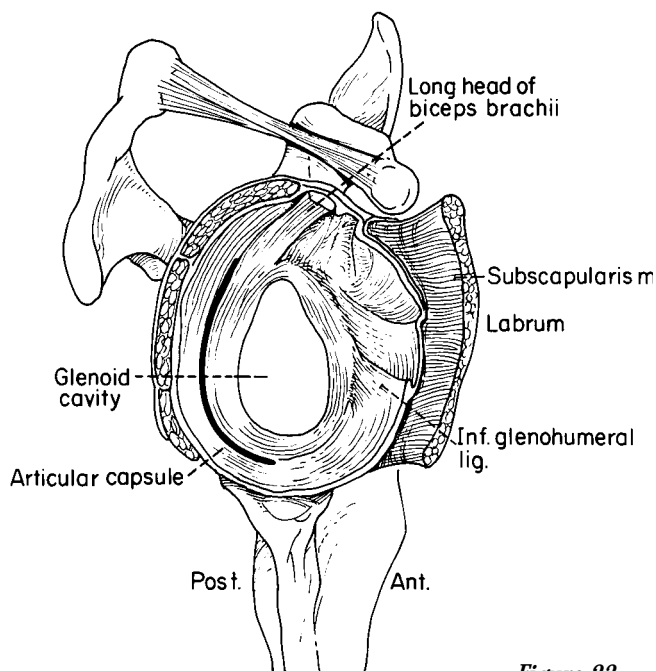


Figure 23

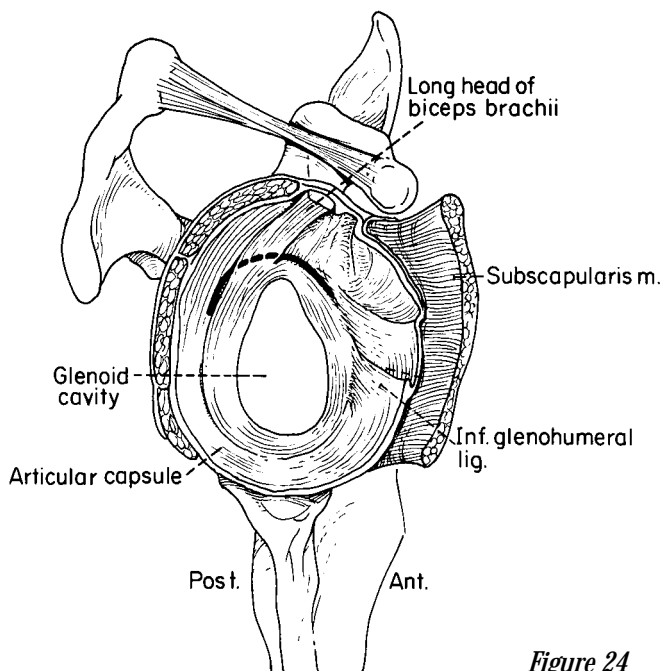


Figure 24

For posterior contractures, the capsule can be released at the glenoid rim similar to the release that was done anteriorly (*Figure 23*).

It is very uncommon for there to be a superior capsule and rotator cuff contracture in the absence of trauma and greater tuberosity displacement medially. However, when superior contractures are present, in addition to lysing the adhesions, in the subacromial region, one can incise the superior capsule at the glenoid rim above the attachment of the labrum and long head of the biceps (*Figure 24*). Remember, one should be careful not to extend this incision too far medially for the suprascapular nerve rests on the undersurface of the supraspinatus and infraspinatus muscles.

GLENOHUMERAL INSTABILITY

Instability of the glenohumeral joint can exist with arthritis as well as in the absence of arthritis. It, in fact, may be compounded following prosthetic arthroplasty. The sizes of the prosthetic components are selected to fill the joint space and supply adequate tension to the shoulder capsule and the rotator cuff. It seems practical to use the supraspinatus tendon and superior shoulder capsule as a guide to the tension needed within the joint and then to match the tension of

the anterior and posterior structures to these. If the superior structures are adequately tensioned with the arm at the side, there will almost never be any tendency for inferior shoulder subluxation. Of course, as an adjunct to this, it is important to maintain arm length.

In addressing anterior shoulder instability during prosthetic arthroplasty, it is important to have adequate volume so that the components seat opposite one another. This may involve lengthening a contracted posterior capsule to prevent anterior subluxation of the humerus on the glenoid. Further measures to treat or avoid anterior instability include preservation of the anterior and anterior-inferior glenohumeral capsule and ligament complex, and removal of less humeral bone anteriorly, either by increasing the height of the bone resection or by increasing the amount of retroversion in the humeral osteotomy. One should avoid glenoid component anteversion and, of course, securely repair and appropriately protect the anterior shoulder structures during and after surgery.

Conversely, in addressing posterior instability, one must be assured the humeral component is seated opposite the glenoid. This is accomplished when the anterior shoulder capsule and subscapularis have adequate length. Additionally, the inferior glenohumeral ligament complex and the posterior capsule and rotator cuff are preserved. One can also remove less humeral

bone by increasing the height of the osteotomy or decreasing the amount of retroversion. Often, as an option in this situation, somewhat thicker components are used. Glenoid retroversion must be eliminated (see below), and a secure anterior repair is necessary to diminish the tendency for posterior subluxation.

As mentioned above, inferior instability is eliminated by preserving or restoring humeral length and by appropriate tensioning the supraspinatus and superior shoulder capsule at the time of surgery. Again, in this situation as in posterior instability, this is usually accomplished by the use of thicker humeral or glenoid components.

Superior shoulder instability is almost always associated with rotator cuff tendon tearing and will be addressed in the section on rotator cuff deficiencies.

BONE DEFICIENCIES

GLENOID

The bone may be qualitatively deficient in osteoporosis or other metabolic bone disease, but often there is also a quantitative deficiency with massive loss of bone substance, wear or fracturing of the peripheral aspect of the glenoid, or central glenoid bone loss. When the central bone loss is relatively small, the defect can usually be eliminated by bone grafting from a portion of the humeral head or the use of a slightly larger amount of methyl-

methacrylate bone cement. If the central deficiency is extreme, it may not be possible to adequately fix a glenoid component, and a humeral head replacement alone may be necessary – or this may be necessary in conjunction with glenoid bone grafting. Deficiencies of the peripheral aspect of the glenoid are most commonly posterior and occur in osteoarthritis. If the humeral subluxation is mild and the amount of asymmetrical erosion is small, one can alter the direction of the humeral osteotomy toward neutral and asymmetrically prepare the glenoid surface, in effect, creating less retrotorsion in the humerus and slightly more retroversion in the glenoid — balancing the joint with tensioning of the posterior shoulder capsule and other surrounding soft tissues. When there is significant subluxation of the humeral head and more than a slight amount of glenoid bone wear (greater than 2 to 4 mm), it will be necessary to consider bone grafting a portion of the humeral head to the deficiency in the glenoid or using the posterior augmented glenoid component. Often, there is an option between these two choices, and, when so, glenoid bone grafting is usually preferred. The graft is carefully prepared and fixed to the glenoid with two small bone screws.

The all-polyethylene lipped offset glenoid component is utilized when there is a small amount of bone wear (as outlined above) and the amount of remaining bone in the glenoid does not

allow one to fully correct the orientation of the glenoid surface by asymmetrical reaming of the subchondral plate.

HUMERUS

Deficiencies of the humerus can be quite extreme, and they have not received the attention they deserve. When there are only metaphyseal deficiencies, these areas of bone loss can be bone grafted or eliminated by the use of additional methylmethacrylate bone cement. As the humeral component has extensive fixation in the diaphysis, elimination of metaphyseal defects by these methods seems safe and practical. When a central metaphyseal defect is combined with a peripheral defect — a defect in the tuberosities — the rotator cuff attachments are compromised. Bone grafting may be needed to deal with this, and, at best, the rotator cuff fixation will be tenuous.

More extensive humeral deficiencies usually occur after severe trauma or after previous prosthetic surgery. There are several available choices, none of which are perfect. One can use the long-stem humeral component to obtain purchase over a greater length of the humeral shaft and supplement this with bone grafting, either autogenous iliac crest bone or allograft. An alternative is the use of a custom humeral component. However, there is not enough information about the treatment of these deficiencies to allow one to develop clear recommendations as to which choice is

better. Probably, however, it is most reasonable to progress from the simple reconstructions to those that are more complex.

ROTATOR CUFF DEFICIENCIES OR TEARING

The rotator cuff is affected to varying degrees in different diagnostic categories. In osteoarthritis, the rotator cuff is usually not torn. When it is torn, the tearing is often small to medium in size, and repair can be done by tendon to tendon closure or by slight transposition of the subscapularis upward (*Figure 24*).

In rheumatoid arthritis, in addition to tearing, there may be thinning and weakening of the entire rotator cuff and capsular structures. These structures may maintain their flexibility, or they may become infiltrated with scar and stiffened. When a rotator cuff tear is present in this diagnostic category, it is typically over the superior part of the joint and associated with upward subluxation and slight medial displacement of the humeral head. Occasionally, the tearing is limited in extent, and tendon to tendon closure is possible. When tears are larger than this, again transposition of the subscapularis and anterior portion of the supraspinatus upward seems to be the most efficacious means of repair. On other occasions, the tearing is nearly transverse near the attachment of the greater tuberosity, and some pedicle advancement can be performed to effect tendon closure without the need for transposition of tissues upward. In rheumatoid arthritis, it is probably rea-

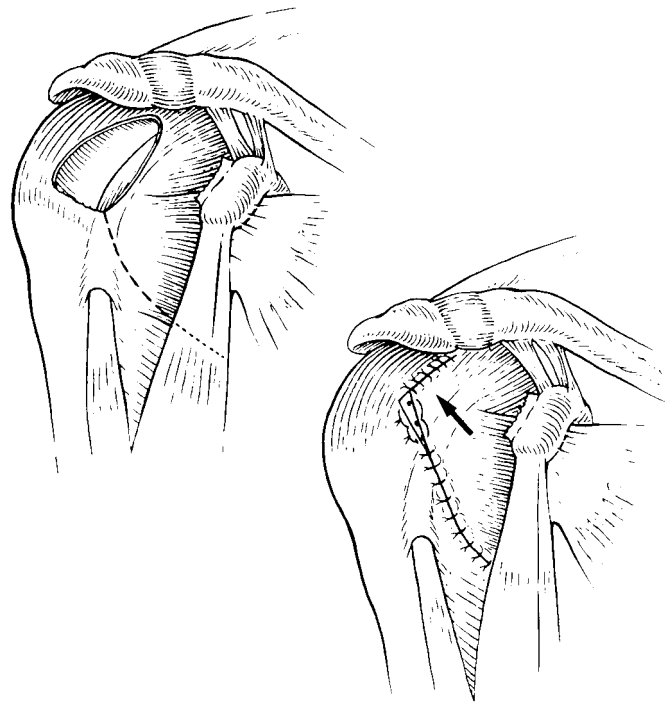


Figure 24

sonable to preserve the coracoacromial arch in order to support these weakened rotator cuff and capsular structures. This includes avoidance of acromioplasty and maintenance of the coracoacromial ligament.

Of course, if there are any irregularities in bone contour on the undersurface of the acromion, these should be smoothed at the time of surgery to avoid, or at least hopefully retard, further damage to the tendon structures.

Severe rotator cuff tear arthropathy may include loss of multiple tissue elements, including the shoulder capsule and rotator cuff. In the presence of such extensive loss, all possible means to deal with these tears may need to be employed, including not only advancement of the tissue laterally but advancement of the anterior and posterior tissues superiorly. In many patients, these deficiencies are extraordinarily large, and when this is combined with substantial glenoid bone loss, it may be wise to use an oversized humeral component and to repair the tissues as best as

possible — tensioning them to maintain joint stability. In this setting, a glenoid component may not be desirable as the humeral head will be in an upwardly subluxated position and create uneven forces across the glenoid, quite likely increasing the frequency of glenoid component loosening. The above approach should be used as seldom as possible for if structures can be returned more closely to their normal anatomical relationships, the outlook for functional recovery will be improved.

POSTOPERATIVE MANAGEMENT

1. Immobilization
2. Rehabilitation

Typically, the arm is placed in a shoulder immobilizer, and when the patient is supine, a small pad is placed behind the lower arm and the elbow so the arm does not fall into extension and stress the arthrotomy repair. The immobilizer is used at night during the first month and much of the time during the day for the first week or two. Following this, a sling is used for the remainder of the first month while the patient is active; while

sitting in a chair, the limb can be free.

Active hand, wrist, and forearm motion exercises are started on the first postoperative day. On the second postoperative day, arrangements are made for instruction of the patient in a passive range of motion program within the limits of the repair, as determined at the time of surgery. This passive motion program is continued during the first month, often in short sessions three times a day, and performed by the relative who has been instructed in the program while the patient is recovering in the hospital. Typically, at three to four weeks, an active assisted pulley program is introduced. At four to six weeks, an active assisted motion program with wand exercises is added, and at this time isometric strengthening is commenced. The isometric strengthening is then converted to elastic strap strengthening at two months. At three months, stretching and additional strengthening are added as needed.



COFIELD² HUMERAL STEMS

Standard Length Humeral Stem Components Chromium Cobalt (ASTM F75)

Implant Cat. No.	Stem Diameter	Stem Length	Trial Cat. No.
7125-9006	6 mm	115 mm	7124-9006
7125-9008	8 mm	145 mm	7124-9008
7125-9010	10 mm	145 mm	7124-9010
7125-9012	12 mm	145 mm	7124-9012
7125-9014	14 mm	145 mm	7124-9014
7125-9016	16 mm	145 mm	7124-9016

* Trial stems are made from stainless steel.



Intermediate Length Humeral Stem Components Chromium Cobalt (ASTM F75)

Implant Cat. No.	Stem Diameter	Stem Length	Trial* Cat. No.
7125-9108	8 mm	195 mm	7124-9108
7125-9110	10 mm	195 mm	7124-9110
7125-9112	12 mm	195 mm	7124-9112
7125-9114	14 mm	195 mm	7124-9114
7125-9116	16 mm	195 mm	7124-9116

* Trial extensions attach to the primary humeral stem trial and are made from stainless steel. The corresponding implant is one piece.



Long Length Humeral Stem Components Chromium Cobalt (ASTM F75)

Implant Cat. No.	Stem Diameter	Stem Length	Trial* Cat. No.
7125-9210	10 mm	245 mm	7124-9210
7125-9212	12 mm	245 mm	7124-9212
7125-9214	14 mm	245 mm	7124-9214
7125-9216	16 mm	245 mm	7124-9216

* Trial extensions attach to the primary humeral stem trial and are made from stainless steel. The corresponding implant is one piece.



COFIELD² HUMERAL HEADS

Primary Humeral Head Components
Chromium Cobalt (ASTM F799)



Implant Cat. No.	Head Height	Head Diameter	Trial Cat. No.
7125-9314	14 mm	36 mm	7124-9314
7125-9316	16 mm	38 mm	7124-9316
7125-9318	18 mm	40 mm	7124-9318
7125-9320	20 mm	42 mm	7124-9320
7125-9322	22 mm	44 mm	7124-9322
7125-9324	24 mm	46 mm	7124-9324
7125-9326	26 mm	48 mm	7124-9326
7125-9328	28 mm	50 mm	7124-9328



Unipolar Humeral Head Components*
Chromium Cobalt (ASTM F799)

Implant Cat. No.	Head Height	Head Diameter	Trial Cat. No.
7125-9332	32 mm	54 mm	7124-9332
7125-9336	36 mm	58 mm	7124-9336

**For use as a hemiarthroplasty only.*

COFIELD² GLENOIDS

Standard All-Poly Glenoid Components UHMWPE (ASTM F648)



Implant Cat. No.	Size	Trial Cat. No.
7125-9501	Small	7124-9501
7125-9502	Medium	7124-9502
7125-9503	Large	7124-9503



+2 mm All-Poly Glenoid Components UHMWPE (ASTM F648)

Implant Cat. No.	Size	Trial Cat. No.
7125-9531	Small	7124-9531
7125-9532	Medium	7124-9532
7125-9533	Large	7124-9533

Lipped All-Poly Glenoid Components UHMWPE (ASTM F648)

Implant Cat. No.	Size	Trial Cat. No.
7125-9521	Small	7124-9521
7125-9522	Medium	7124-9522
7125-9523	Large	7124-9523

Humeral End Cutting Drills

Cat. No.	Size
7124-8806	6 mm
7124-8808	8 mm
7124-8810	10 mm
7124-8812	12 mm
7124-8814	14 mm
7124-8816	16 mm



Humeral Side Cutting Reamers

Cat. No.	Size
7124-8906	6 mm
7124-8908	8 mm
7124-8910	10 mm
7124-8912	12 mm
7124-8914	14 mm
7124-8916	16 mm



T-Handle Quick Connect

Cat. No. 7124-9920



Humeral Resection Guide

Cat. No. 7124-9700



Humeral Implant Impactor/Extractor

Cat. No. 7124-9702



Humeral Trial Impactor/Extractor

Cat. No. 7124-9703



Humeral Head Removal Tool

Cat. No. 7124-9705



Humeral Head Impactor

Cat. No. 7124-9712





Slotted Hammer
Cat. No. 7124-9915



Glenoid Reamer

Cat. No.	Size
7124-9801	Small
7124-9802	Medium
7124-9803	Large



Glenoid Drill Guide 1

Cat. No.	Size
7124-9811	Small
7124-9812	Medium
7124-9813	Large



All-Poly Glenoid Drill Guide 2

Cat. No.	Size
7124-9821	Small
7124-9822	Medium
7124-9823	Large



All-Poly Keel Sizer/Rasps

Cat. No.	Size
7124-9831	Small
7124-9832	Medium
7124-9833	Large



Glenoid Drills

Cat. No.	Description
7124-9835	Glenoid Drill 1
7124-9836	All-Poly Glenoid Drill 2



Glenoid Keel Cutter
Cat. No. 7124-9837



Glenoid Alignment Peg
Cat. No. 11-1030



Glenoid Poly Impactor
Cat. No. 7124-9841

STERILIZATION CASES

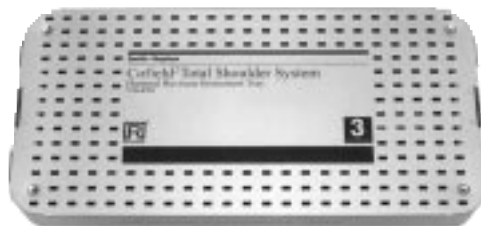
Humeral Preparation Instrument Tray
 Cat. No. 7124-8701



Humeral Trial Instrument Tray
 Cat. No. 7124-8702



Humeral Revision Instrument Tray
 Cat. No. 7124-8703



All-Poly Glenoid Instrument Tray
 Cat. No. 7124-8705



IMPORTANT MEDICAL INFORMATION

Warnings and Precautions

MODULAR PARTIAL AND TOTAL SHOULDER REPLACEMENT INTENDED FOR CEMENTED USE ONLY

IMPORTANT NOTE:

The patient and physician must understand that any of the circumstances listed within the relevant categories below may reduce the chance of a successful outcome, and an increased percentage of risk must be accepted. However, the modular shoulder implant operation can be a successful procedure. Its success rate, however, cannot reach 100 percent, and even in uncomplicated cases, there is some risk.

Humeral components may be utilized for primary fracture treatment in selected cases or combined with the glenoid component for total shoulder replacement.

The goals of total shoulder replacement are to decrease pain, establish adequate mobility, and increase function.

To accomplish these goals, patients who are selected should be those: (1) who have adequate quality and quantity of bone support, particularly in the scapula; (2) who have an intact or repairable rotator cuff mechanism; and (3) who are able and willing to follow their physician's directions, particularly with respect to postoperative care. It is the surgeon's responsibility to evaluate these factors and a variety of patient requirements, select the method of treatment and appropriate devices, and provide proper advice to the patient.

Patients should be cautioned against heavy labor, active sports, or any activity which places heavy or abrupt loads on the implant system.

Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Consideration of bone deformities, condition of the soft tissues, and component placement are critical to minimize a variety of postoperative complications.

DESCRIPTION OF PROSTHESIS

The shoulder prosthesis is a minimally constrained prosthesis for resurfacing the humeral head and, if necessary, the glenoid. The humeral component features fixation holes to facilitate attachment of the tuberosities by means of cobalt chromium wire or heavy non-absorbable sutures. Components also feature porous coating that greatly enhances the implant/cement interface. The glenoid component is stabilized in the cement bed via a keel.

MATERIALS

Humeral heads are cobalt chromium (ASTM F 799 and ISO 5832/12). Humeral stems are cobalt chromium (ASTM F 75 and ISO 5832/4). All polyethylene glenoid components are ultra high molecular weight polyethylene conforming to (ASTM F 648 and ISO 5834/2). Metal backed glenoid components include an UHMWPE insert (ASTM F 648 and ISO 5834/2) with a Ti-6Al-4V (ASTM F 136 and ISO 5832/3) metal back. Cobalt chromium components are porous coated with cobalt chromium beads (ASTM F 74 and ISO 5832/4) and titanium components are porous coated with titanium beads (ASTM F 67 and ISO 5832/2).

The specific component material is listed on the outside carton label.

All implantable devices are for single use.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomenon, in spite of the millions of implants in use.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

The general principles of patient selection and sound surgical judgment apply to proximal humeral replacement and the total shoulder procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft-tissue condition, and component placement are critical to minimize a variety of postoperative complications.

Indications:

Proximal Humeral Prosthesis

1. Complex, acute fractures or fracture-dislocations of the humeral head (e.g., the four-part injuries in the Neer classification, or head-splitting, or head impression fractures).
2. Complex, chronic fractures or fracture-dislocations of the humeral head with malunion, nonunion of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures.
3. Osteo necrosis with intact glenoid cartilage.
4. Selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or who must engage in moderately heavy activities.

Total Shoulder Arthroplasty

Severe destruction of the glenohumeral articular surfaces with intractable chronic pain in rheumatoid arthritis, osteoarthritis, traumatic arthritis, cuff tear arthroplasty, ancient septic arthritis, osteo necrosis with secondary glenoid changes, radiation necrosis, and other failed reconstructive procedures.

Contraindications:

1. Conditions that would eliminate or tend to eliminate adequate implant and/or cement support such as insufficient quantity or quality of bone (particularly glenoid) resulting from conditions such as osteoporosis, trauma, or neoplasia.
2. Recent or active infection.
3. General neurologic conditions or psychiatric conditions which tend to impair a patient's ability or willingness to restrict activities, especially during the healing period.
4. Neuropathic joint.
5. Activity levels which tend to place increased loads on implants not compatible with a successful long term result.
6. Those cases where stabilizing musculature cannot provide stability.

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.

Possible Adverse Effects:

1. Wear of the polyethylene articulating surface of the glenoid component has been reported following total shoulder replacement. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop during the surgical procedure and can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondly, particles can also be generated by third-body wear. Osteolysis may lead to future complications necessitating the removal and replacement of prosthetic components. See Important Physician Information Section for more information.
3. Loosening, bending, separation of all or part of the porous coating, cracking or fracture of humeral or glenoid components is usually attributable to one or more factors included in Contraindications, above, and/or Warnings and Precautions, below. Fatigue fracture of the implant may occur as a result of trauma, strenuous activity, improper alignment, or duration of service. Implants may loosen or migrate due to trauma or loss of fixation.
4. Loosening of components.
5. Dislocations or subluxations.

6. Fractures of humerus or glenoid. Intraoperative fractures are usually associated with revision surgery, deformity, or osteoporosis.
7. Tendon or muscle disruptions, particularly damage to the rotator cuff.
8. Infection, both acute postoperative wound infection and late deep wound sepsis.
9. Neuropathies.
10. Wound problems: Hematoma, delayed wound healing, skin loss.
11. Ectopic bone formation.
12. Although rare, metal sensitivity or allergic reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues may result in histological reactions involving macrophages and fibroblasts.
13. A sudden drop in blood pressure intra-operatively due to the use of bone cement.
14. Periarticular calcification or ossification, with or without impediment to joint mobility.
15. Inadequate range of motion due to improper selection or positioning of components, by humeral impingement, and periarticular calcification.

WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and has a finite expected service life and may need to be replaced in the future.

Loosening, bending, cracking and/or fracture of implants and other complications may result from failure to observe the following warnings and precautions.

Preoperative:

1. Use care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Do not allow the porous surfaces to come in contact with cloth or other fiber releasing materials. Implants and instruments should be protected from corrosive environments such as salt air during storage.
2. An adequate inventory of implant sizes should be available at the time of surgery, including sizes smaller and larger than those expected to be used. Extra implant components are recommended. All packages and implants should be thoroughly inspected prior to surgery for possible damage.
3. Patient conditions and/or predispositions such as addressed in Contraindications, above, should be avoided.
4. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
5. Certain special surgical instruments are required to perform this surgery. Review of the use and handling of these instruments is very important.
6. Surgical technique information is available upon request. The surgeon should be familiar with the technique prior to surgery.

Operative:

1. The correct selection of the implant is important. The appropriate type and size should be fitted to the patient. Improper positioning or inadequate cement support may result in loosening, bending, cracking, or fracture of the component, cement, and/or bone.
2. It is important to have adequate and continuous bone and cement support of the components, particularly the glenoid. Layering of cement and inclusion of air or blood should be avoided.
3. Improper selection, placement, positioning, and fixa-

tion of the implant components may result in unusual stress concentrations and a subsequent reduction in service life of the prosthetic implant.

4. When preparing the bed for the glenoid component, use particular care to preserve a portion of the subchondral bone plate.
5. Revision procedures for previous arthroplasty, etc., are technically demanding and difficult to perform. Errors include misplacement of the incision, inadequate exposure or mobilization, improper positioning of components, or inadequate cement support. Increased operative time, blood loss, and wound hematoma and neuropathies are more likely with revision procedures than with primary surgery.
6. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic. Care should be exercised to prevent fractures.
7. Care should be taken not to scratch, bend, or cut metal components during surgery for the reasons stated in No. 1 of the Preoperative section, above. Once removed from a patient, implants should never be reused, since internal stresses, which are not visible, may lead to early bending or fracture.
8. The modular head must be firmly impacted on the humeral stem component to prevent disassociation. Modular heads and humeral stems should be from the same manufacturer to prevent mismatch of tapers. Taper joints should be free of particulates or blood. Repeated assembly and disassembly of the head to the stem could compromise a critical locking action of the taper joint.
9. During curing of cement, care should be taken to prevent moving implant components. A tight fit of implant to cement and cement to bone is essential to prevent motion which may lead to bone resorption and/or cement cracking.
10. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, extraneous cement, ectopic bone, etc. Foreign particles at the metal-plastic interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to painful or restricted motion. Range of motion should be assessed. During the assessment of the range of motion, it is also important to check the stability of the joint. Insufficient tension in the rotator cuff mechanism can lead to subluxation of the humeral component increasing the risk of loosening of the glenoid component and/or to higher wear rates due to edge loading.
11. An implant should never be reused. While it may appear undamaged, imperfection may exist which would reduce the service life of the implant.

Postoperative:

1. Both postoperative directions and warnings to patients by physicians and postoperative patient care are extremely important. The shoulder is immobilized for two to five days postoperatively. Passive elevation and rotation of the shoulder will help prevent adhesions.
2. Patients should be cautioned against unassisted activity of the shoulder during the first four to six weeks.
3. Use extreme care in patient handling. Support should be provided to the operative arm when moving the patient. While placing the patient on bedpans, changing dressings or clothing, and engaging in similar activities, precautions should be taken to avoid placing any load on the operative extremity.
4. Physical therapy should be carefully monitored using passive motion during the first four to six weeks.
5. Periodic x-rays are recommended for close comparison with postoperative conditions to detect evidence of changes in position, loosening, bending, or cracking of components. Upon evidence of these conditions, the patient should be closely observed, the possibilities of further deterioration evaluated, and the benefits of revision considered.
6. Patients should be cautioned to limit their activities.

IMPORTANT PHYSICIAN INFORMATION

Bone resorption is a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Progressive bone resorption due to reasons other than stress shielding or infection has been termed osteolysis. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by cement, metal, ultra-high molecular weight polyethylene (UHMWPE), and ceramic. Regarding the etiology, it has been hypothesized that particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution, and amount of particulate debris (rate of debris generation). The phagocytic action results in the release of cytokines and intercellular mediators (IL-1, 2, PE2) which encourages osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis for the causes of this phenomenon and potential ways to reduce its occurrence.

Osteolysis may be asymptomatic and, therefore, routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions

which are progressive may necessitate replacement of the prosthetic component(s).

PACKAGING AND LABELING

Shoulder implants are sterilized products and should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, refer to the Resterilization section below.

STERILIZATION

All metal components have been sterilized by a minimum of 25 kilo grays of gamma irradiation. Plastic components have been sterilized by ethylene oxide gas. All components are supplied in protective trays. Inspect packages for punctures or other damage prior to surgery.

RESTERILIZATION

Metal Components

Metal components may be resterilized, if necessary, by steam autoclaving in appropriate protective wrapping after removal of all the original packaging and labeling. Protect prosthesis, particularly mating surfaces, from contact with metal or other hard objects. The following process parameters are recommended for these devices: Prevacuum cycle, 4 minutes at 132°C to 135°C, followed by 20 minutes of drying time.

If porous coated implants are inadvertently contaminated, return the unsoiled prosthesis to Smith & Nephew for resterilization. DO NOT RESTERILIZE porous coated implants. The porous coating requires special cleaning procedures.

Plastic Components

Plastic components may be resterilized by ethylene oxide gas, using the following procedures:

Sterilant	Temperature	Humidity	Maximum Pressure	Concentration	Exposure Time
10% EtO, 90% HCFC	130° F	1300 F	28 psia	550-650 mg/L	120 minutes
10% EtO, 90% HCFC	100° F	40-60%	28 psia	550-650 mg/L	6 hours
100% EtO	131° F	30-60%	10 psia	736 mg/L	80 minutes

Suggested aeration time is 12 hours at 50°C with power aeration. Consult aerator manufacturer for more specific instructions.

INFORMATION

For further information, please contact Customer Service at 1-800-238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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