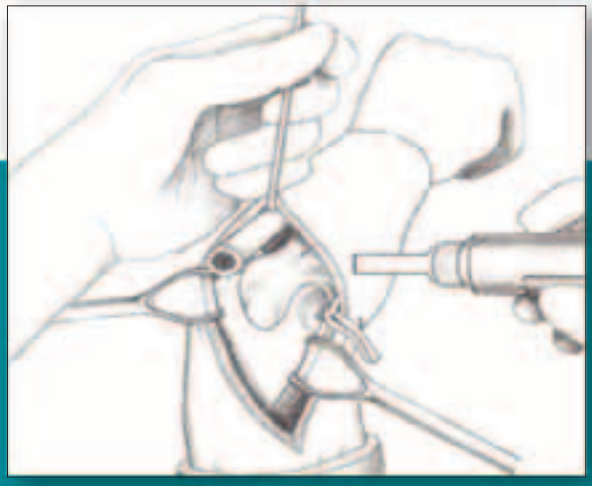
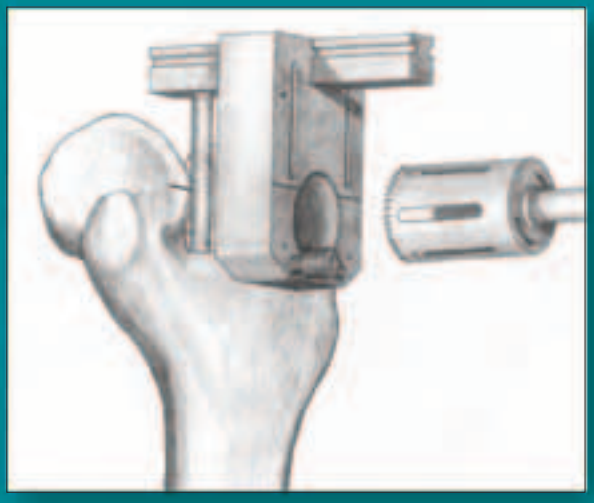
stryker®

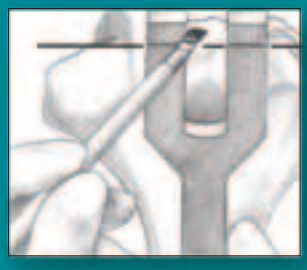
Orthopaedics

Solar® Elbow System
Surgical Protocol

Upper Extremity System







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SOLAR™
UPPER EXTREMITY SYSTEM

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Howmedica Osteonics would like to thank the above surgeons for their assistance in the development of this protocol.

Indications for Elbow Replacement Arthroplasty

1. Rheumatoid Arthritis (RA)

The presence of rheumatic arthritis and a severely damaged elbow joint in patients with pain, loss of function and inability to perform activities of daily living after conservative rheumatologic treatment is a primary indication of total elbow arthroplasty. Many patients can regain the functional activities of daily living through total elbow arthroplasty.

The functional evaluation of the ipsilateral shoulder and wrist is very important. The patient should be able to internally and externally rotate the shoulder, thereby decreasing the torque stresses on the elbow. Some rotation should be achieved if the patient has a stiff, internally rotated shoulder. Otherwise, the rotational loads on the elbow may be excessively high, there by increasing the possibility of implant loosening or fracture. In addition, the wrist and hand should be functional if the maximum benefits of total elbow arthroplasty are to be achieved.

2. Osteoarthritis (OA)

Although osteoarthritis of the elbow is uncommon, certain patients with it may have pain and disabling loss of motion and will benefit from elbow replacement arthroplasty.

3. Post-Traumatic Arthritis (PTA)

Post-traumatic arthritis is an indication for total elbow arthroplasty in selected patients with severe disabling deformity and marked pain, often accompanied by loss of motion. These patients must be carefully screened as they may have excessively high functional demands, which may adversely affect implant performance. These patients must realize that they will need to protect the elbow and will not be able to use it for heavy lifting or impact loading in spite of the fact that they have no pain in the elbow. Youthful patients with post-traumatic arthritis must particularly comprehend these restrictions prior to surgery.

4. Ankylosis of the Elbow

In ankylosis of the elbow resulting from the presence of arthritis, patients may achieve excellent results with a substantial increase in their activities of daily living through total elbow arthroplasty. Replacement arthroplasty of the elbow is particularly useful in patients with bilateral ankylosis. Following surgery, patients should be able to reach their face with their hands and regain the ability to feed and groom themselves. A linked semi-constrained implant is typically required in these cases due to the inadequacy of the ligaments.

5. Acute Intra-articular Fractures

Certain intra-articular elbow fractures are best treated with primary arthroplasty.

Contraindications

Contraindications for total elbow arthroplasty include:

1. Recent sepsis of the elbow joint
2. Charcot Elbow
3. Soft tissue injuries with massive bone and soft tissue loss
4. Neurologic injuries (of biceps, triceps and brachial plexis)
5. Non-compliant patients or patients with unrealistic expectations or goals
6. Obesity

Implant Description

The Howmedica Osteonics Solar™ Total Elbow humeral and ulnar components are manufactured of titanium alloy (Ti-6Al-4V-ELI) with an ultra high molecular weight polyethylene bearing between the two component bearing surfaces. All three sizes of ulnar components are compatible with both of the humeral component sizes. A titanium alloy axle pin fits through the lateral aspect of the humeral component to prevent disassociation of the components. A polyethylene sleeve fits over the axle pin to protect against metal on metal contact in the event of extreme distraction of the device. The axle pin is threaded into the humeral component and torqued in place to secure it. The normal joint compression loads between the humerus and the ulna are transmitted through the polyethylene bearing. Joint loads are not transmitted through the axle pin except under extreme distraction loading. Under these conditions the axle pin acts to resist dislocation and provides the linked, semi-constrained characteristics of the device.

The humeral component is designed to have maximum contact in the epicondylar regions of the humerus where the highest quality bone is present. There are two fins located on the lateral and medial aspects of the humeral stem, which are designed to increase the stability of the component under rotational loads transmitted across the joint.

The ulnar component is designed to restore the normal carrying angle of the elbow. There is also an anterior fin on the ulnar component to help resist the rotational forces placed across the joint.

An anterior offset to the trochlear portion of the humeral components and ulnar components helps to restore the normal center of rotation of the elbow joint. Recreating the center of rotation allows proper soft tissue balancing and restoration of muscle lengths so that loading is balanced and a more normal range of motion is re-established. In order to recreate these relationships, right and left-hand configurations are available.

There are two sizes of humeral components available, standard and large along with three sizes of ulnar components, small, standard and large. All components are fully interchangeable with each other so that any ulnar component will work with any humeral component. This design allows for the greatest possible patient population matching. Long stemmed humeral components are available for revision situations and fractures.

Technique

Pre-operative Planning: The size of the elbow and the medullary anatomy must be determined. Adequate radiographs, including anterior-posterior and lateral views, must be obtained. X-ray templates are then utilized to determine the size of the implant required. The trochlear portion humeral implant is intended to fit within the epicondylar pillars without violating them. If the implant appears to violate this region, a smaller implant should be used. In selecting the ulnar component, make sure that the stem fits adequately and is not oversized, especially in patients with bone deformities as in rheumatoid arthritis. If adequate fit of either component is not possible, then a custom implant may be required.

Surgical Exposure

The patient is placed supine or in a lateral decubitus position. A sterile tourniquet is used in order to gain as much exposure as possible. The arm is positioned over the chest. Regional or general anesthesia is employed (Image 1).

A long, medial curvilinear incision is used with a straight proximal incision that is over the medial border of the triceps and ulnar nerve, crossing the cubital tunnel and then curving across to the proximal third of the ulna (Image 2). Subcutaneous tissues are incised to the fascia layer. The ulnar nerve is found at the cubital tunnel. It is dissected free and is temporarily transposed anteriorly.

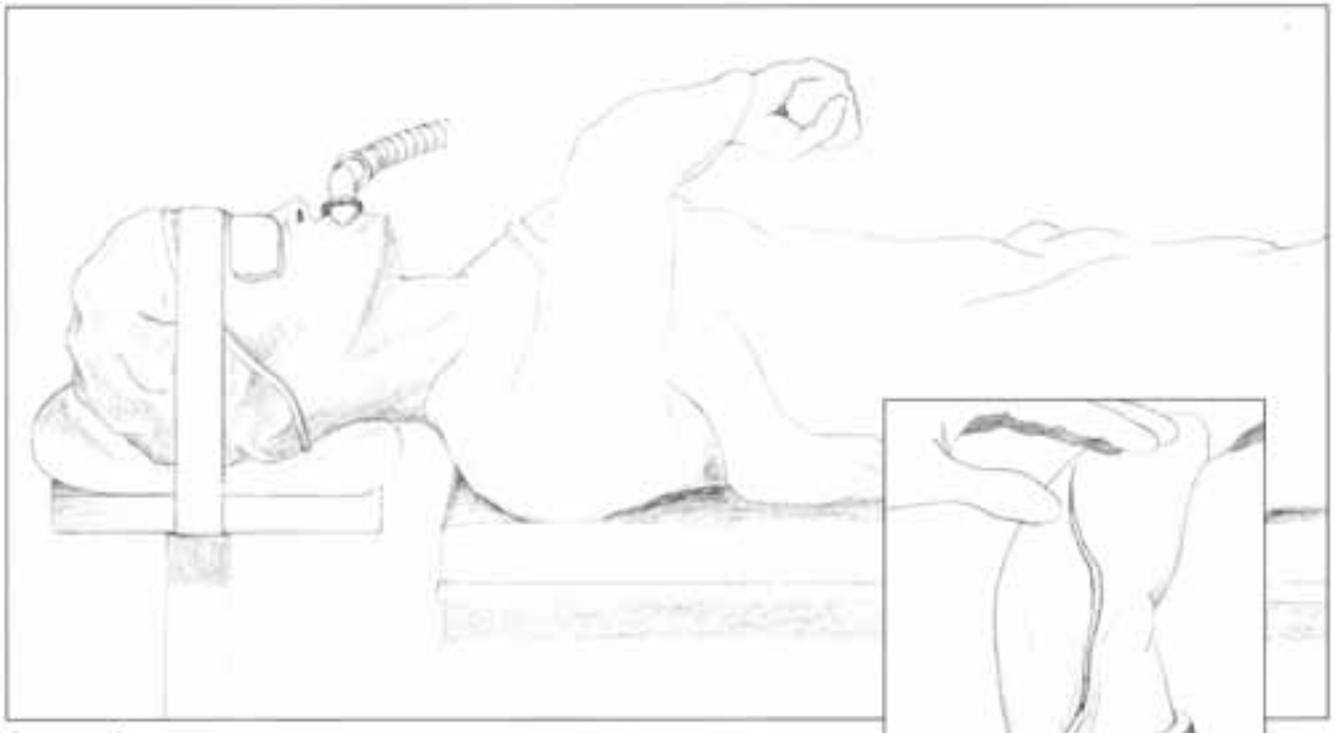

Image 1

Image 2

A Penrose drain is placed around the nerve and a suture is put through the drain to identify and protect the nerve (Image 3). No clamp should be put on the drain as this puts undue tension on the nerve. The nerve is then dissected free several centimeters proximally along the tricep muscle and then distally to where it passes between the two heads of origin of the flexor carpi ulnaris muscle. This allows the nerve to be translocated anteriorly and then protected.

The fascia of the flexor carpi ulnaris is then incised beginning at the proximal and middle third of the ulna and continues down to the place where the ulnar nerve enters the flexor carpi ulnaris. The muscle is left intact and only the epimysium on the fascia is elevated from a medial to lateral direction. The triceps muscle is also released and elevated from medial to lateral taking care to avoid injuring the ulnar nerve, which is within the fibers of the triceps muscle at its proximal aspect. The epimysium of the flexor carpi ulnaris, the insertion of the triceps, and the periosteum of the olecranon must be maintained as one single flap, continuous with the triceps. This entire flap is elevated from medial to lateral to gain access to the joint.

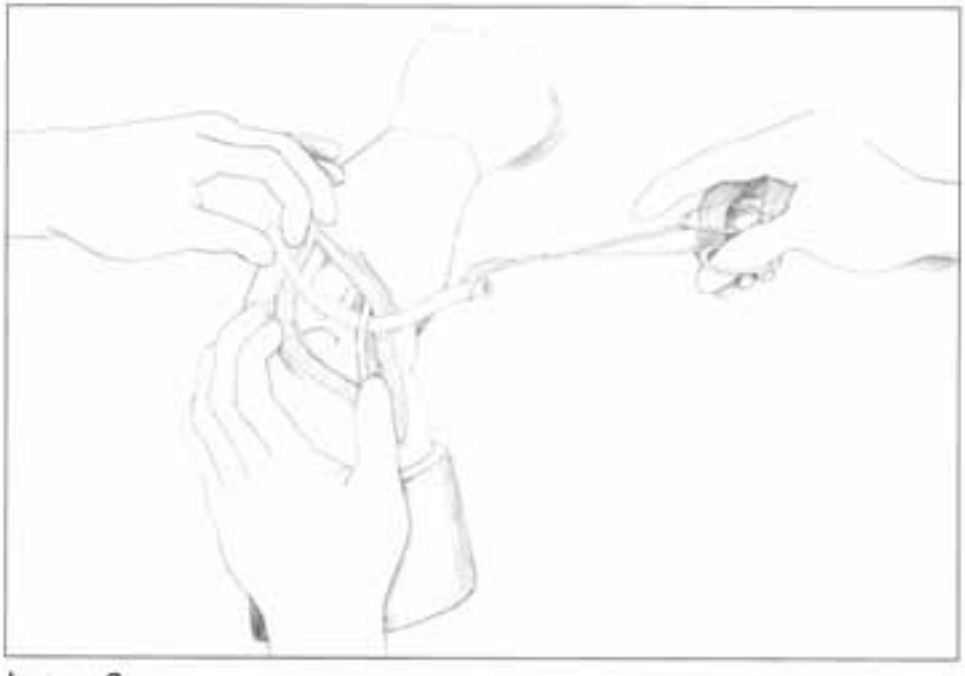

Image 3

This sleeve is further elevated laterally to the lateral epicondyle thereby exposing the radial head. The anconeus muscle is reflected with this incision, and the lateral collateral ligament is reflected from the lateral ulna as the bone is skeletonized to the level of the coronoid.

The capsule and synovium around the radial head are then excised leaving the annular ligament intact. A pair of small Hohmann Retractors are used for exposure of the radius.The radial head can be resected with an oscillating saw at the proximal edge of the annular ligament. Pronating the arm during radial head resection simplifies removal of the radial head. The remaining rough edges of the radius can be rasped or filed smooth.

Full exposure and access to the elbow joint is achieved by resecting the posterior capsule and synovium. This includes carefully releasing the medial collateral ligament from the ulna. The ulnar nerve lies up against the sublime tubercle of the ulna and is vulnerable if not protected (Image 4).

In some instances, especially with long standing elbow contractures, an anterior capsulotomy is required for extension. This capsulotomy is performed using a hemostat behind the capsule as a guide.

Ulnar Preparation

The olecranon is now prepared to be cut. The center of rotation within the semilunar notch must be identified and can be marked with methylene blue (Image 5). A portion of the olecranon usually needs to be removed to allow better access to the ulnar canal for broaching. This can be accomplished

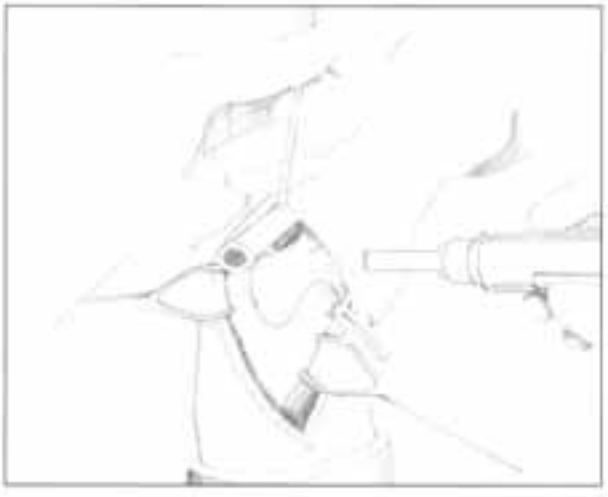

Image 4

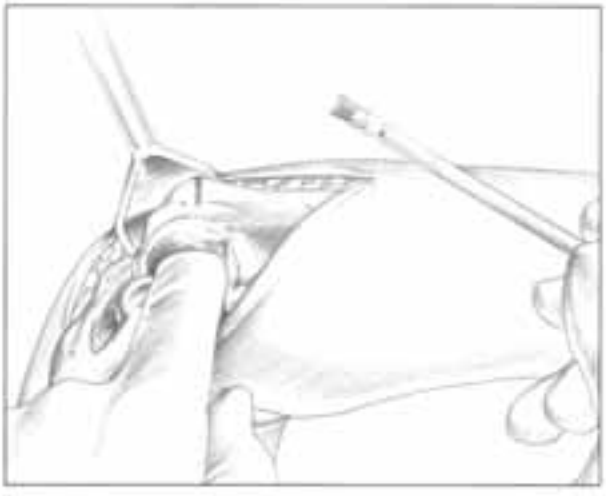

Image 5

by the use of a sagittal saw. A portion of the coronoid process can also be excised at this time to avoid impingement (Image 6).

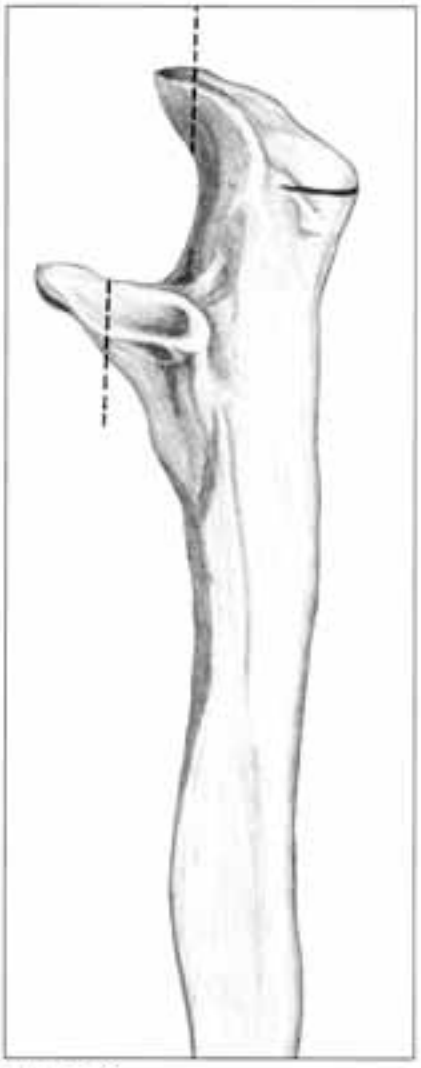

Image 6

The ulna canal is first located at the distal semilunar notch using a high speed burr (Image 7).

Image 7

The starter reamer is then used to open up the canal to accept the ulnar broaches (Image 8). Burr, ream, curette, and broach the ulna carefully to prevent fracture or penetration.

The canal is broached with progressively larger broaches until the final size is reached (Image 9).

Once the final broach/trial has been placed to the appropriate depth restoring the center of rotation, the handle may be removed.

Image 8

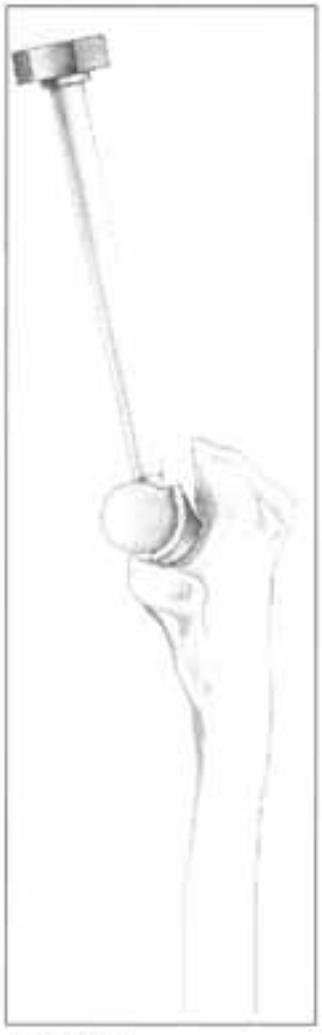

Image 9

Humeral Preparation

The center of rotation (the center of the caputellum and trochlea) is marked using methylene blue (Image 10). This will be the "depth" reference line. The humerus is prepared by first lining up the axis of rotation marks on the initial notch template with the center of rotation reference line. This marked line will also be used for other instrumentation alignment. The notch is then marked within the template. The axis should be oriented in slight internal rotation, as the axis of rotation is slightly internally rotated with respect to the trans epicondylar axis.

Catalog #	Item	Stem Length (mm)
5005-002R	Standard Right Humeral Assembly	79
5005-003R	Large Right Humeral Assembly	89
5005-002L	Standard Left Humeral Assembly	79
5005-003L	Large Left Humeral Assembly	89
5005-012R	Standard Right Long Stem Humeral Assembly	152
5005-013R	Large Right Long Stem Humeral Assembly	152
5005-012L	Standard Left Long Stem Humeral Assembly	152
5005-013L	Large Left Long Stem Humeral Assembly	152
5005-102R	Small Right Ulnar Component	50
5005-202R	Standard Right Ulnar Component	55
5005-302R	Large Right Ulnar Component	63
5005-102L	Small Left Ulnar Component	50
5005-202L	Standard Left Ulnar Component	55
5005-302L	Large Left Ulnar Component	63
5005-203S	Standard Humeral Bearing/Bushing Kit	
5005-303S	Large Humeral Bearing/Bushing Kit	

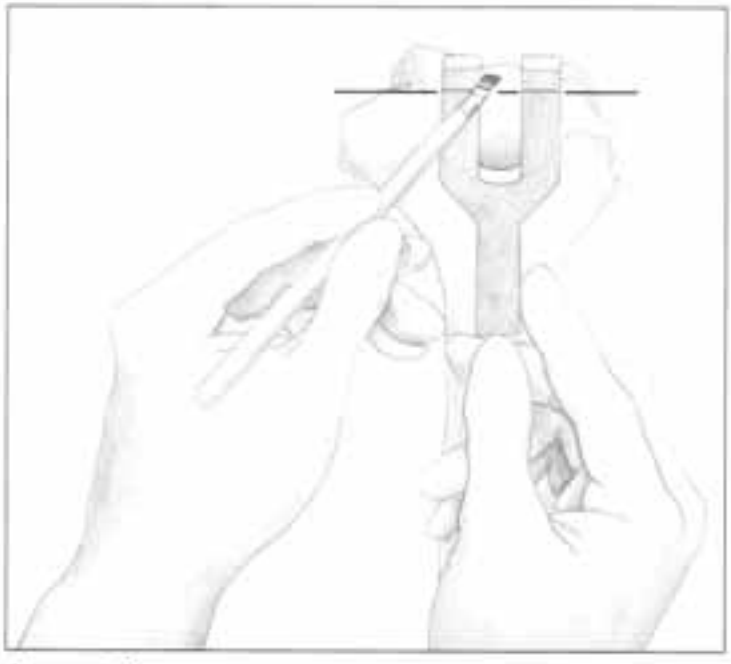

Image 10

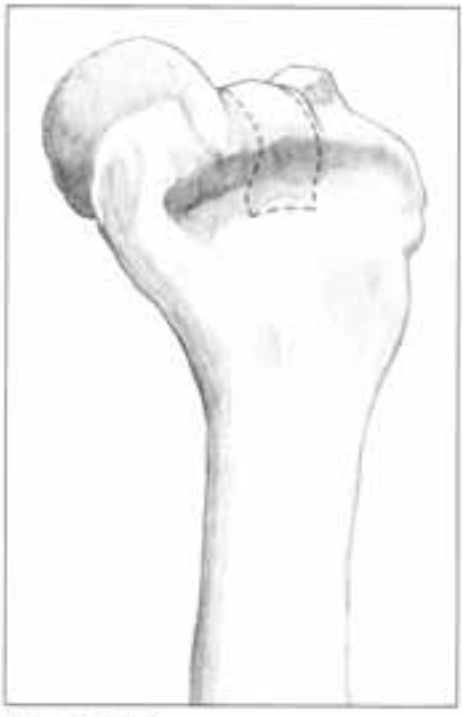

Image 10A

After removing the template, the notch is excised with a sagittal saw (Image 11). Take care to protect the integrity of the epicondylar pillars. The humeral canal is then located using a high-speed burr (Image 11A). The canal is opened up using the starter reamer or a curette, again using care to avoid canal penetration (Image 12). The proper length canal finder is then inserted into the humeral canal (Image13).

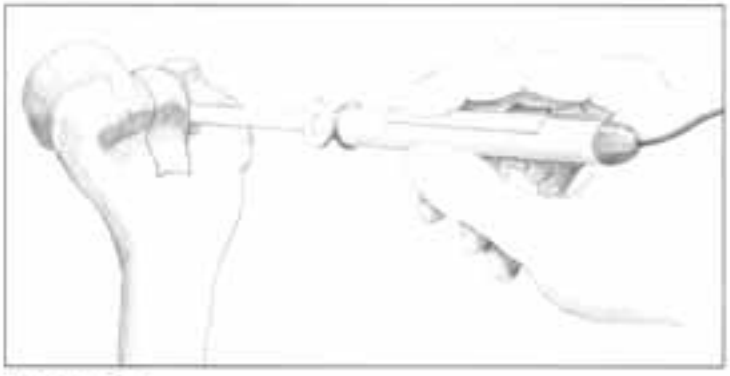

Image 11

Image 12

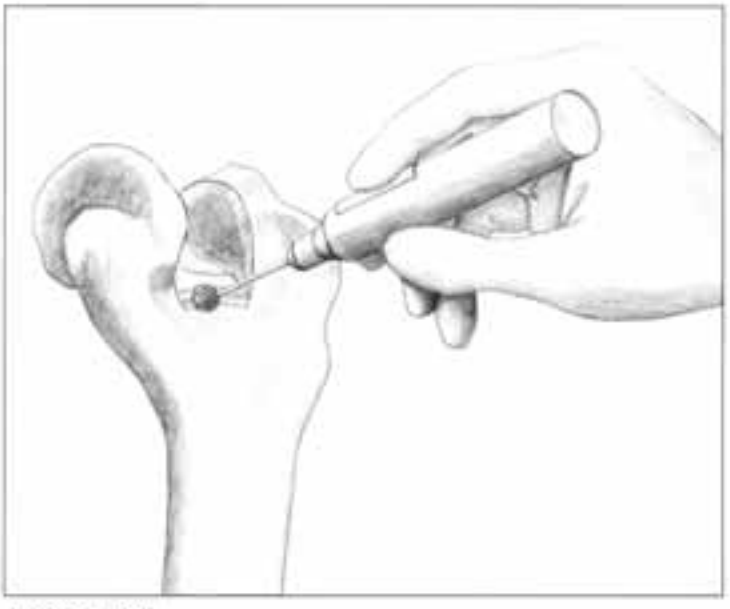

Image 11A

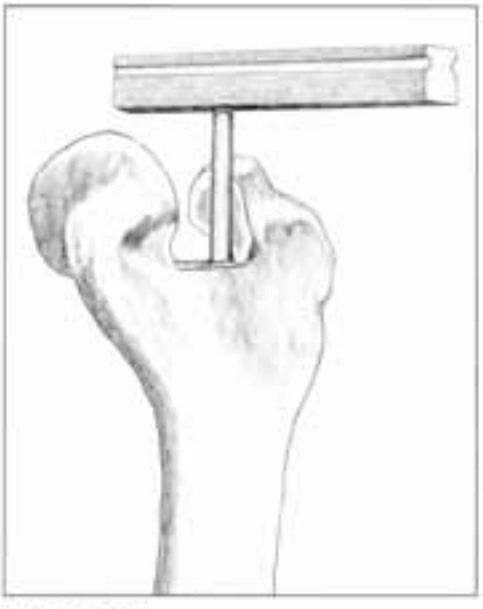

Image 13

The humeral cutting guide is placed over the canal finder for either the standard or the large implant. Align the axis of rotation marks on the jig with the methylene blue axis of rotation reference marks on the humerus (Image 14).

Internal rotation must also be restored as the condyles are slightly internally rotated with respect to the epicondyles. This is achieved by using the adjustment screw to make the face of the cutting guide parallel to the center line of the condyles (Image 15). Once the cutting guide has been positioned, three or four K-wires are placed in the holes provided to secure the guide. The proper sized humeral hole saw (standard or large) on a power drill is inserted into the cutting guide (Image 16). A blunt retractor is used anterior to the humerus to protect the soft tissues.

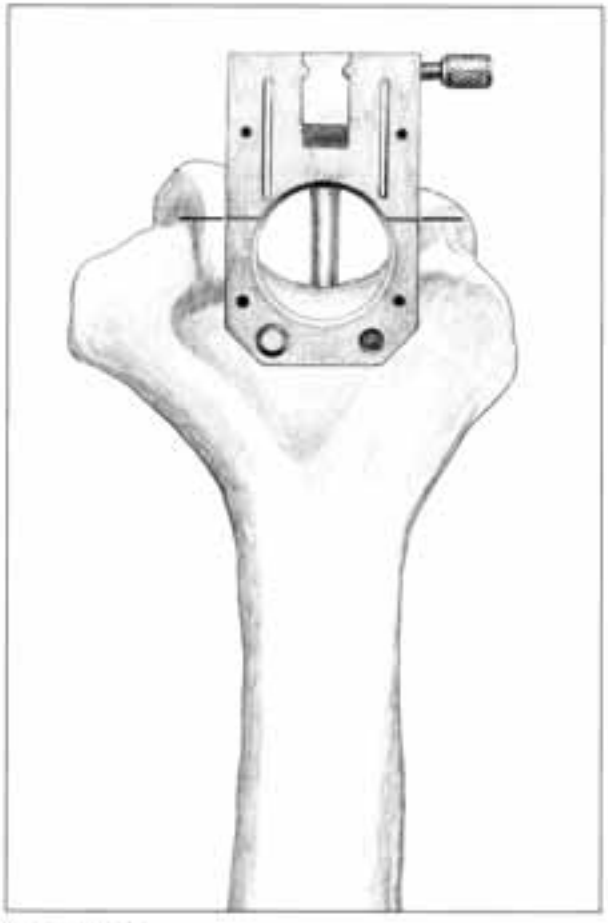

Image 14

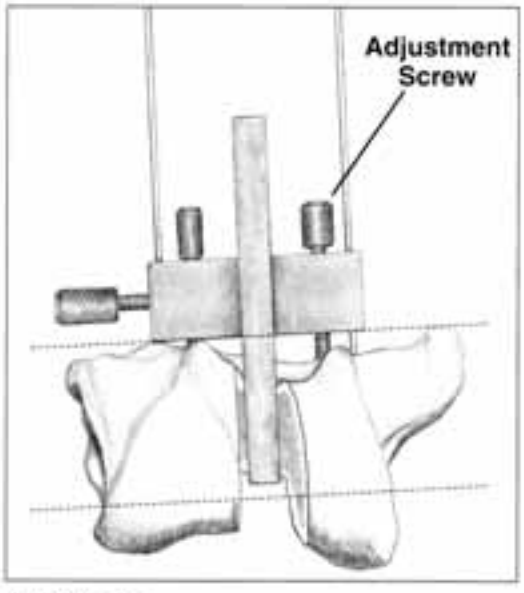

Image 15

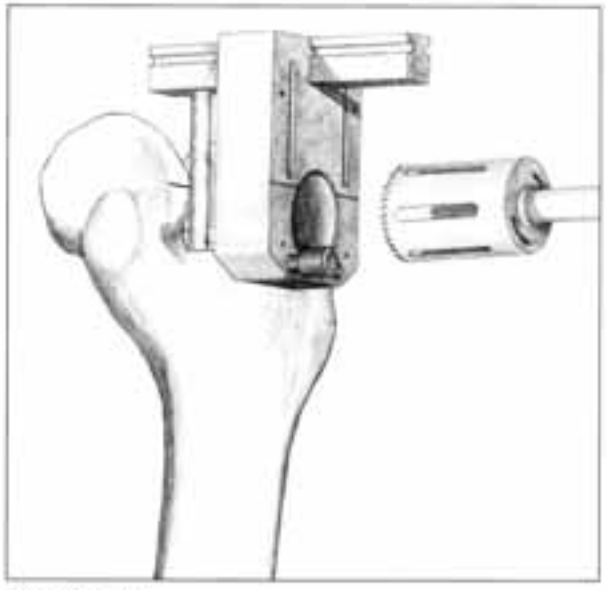

Image 16

The humeral hole is cut half way through proximal humerus (up to the canal finder shaft). The parallel medial and lateral cut can now be made using a narrow sagittal or oscillating saw blade placed through the slots in the cutting guide.

The guide can be removed by sliding it off of the K-wires, and the canal finder is removed. The cutting block can be replaced over the pins and the hole completed (Image 17). Once completed, a "U" shaped cut should exist in the proximal humerus which should precisely match the configuration of the implant size to be used. This "machining" process eliminates tedious burring and yields an exact, secure fit.

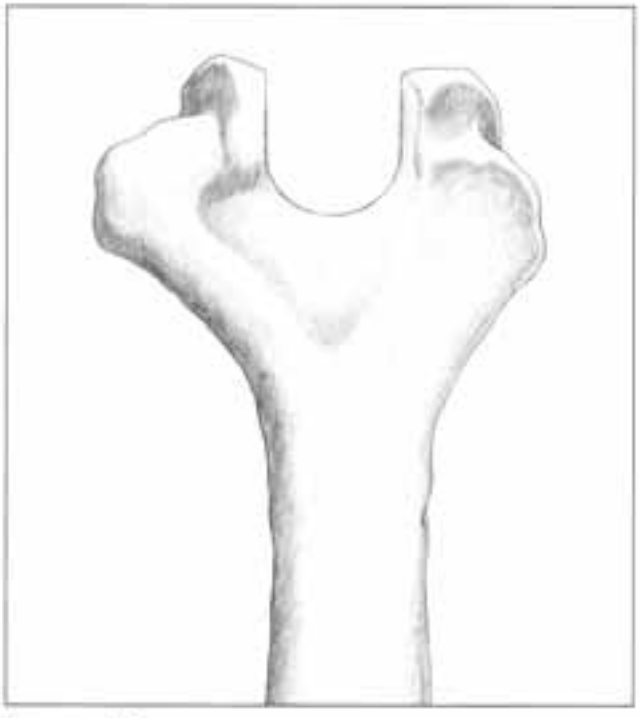

Image 17

The humeral canal is then prepared using sequentially larger broaches until the final size is reached (Image 18). The broach/trial should be completely seated to the bottom of the saw cut preparation to maintain the anatomic axis of rotation. The broach incorporates the lateral fin slots.

Remove the broach handle when the broach/ trial is completely seated in the humerus. The appropriate size trial bearing insert can now be placed on the humeral broach (Image 19 and 19A). The ulnar and humeral components are reduced and secured with gentle thumb pressure while range of motion is tested. Full extension and flexion should be obtainable. If not, the component(s) may need to be more deeply seated, or anterior capsulotomy considered. Assure that there is no impingement on the remaining radius, olecranon, coronoid process, or condyles.

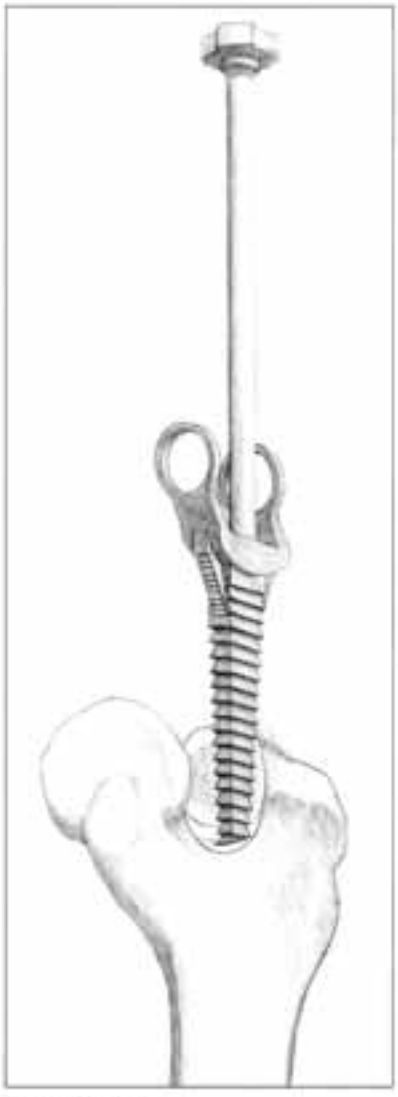

Image 18

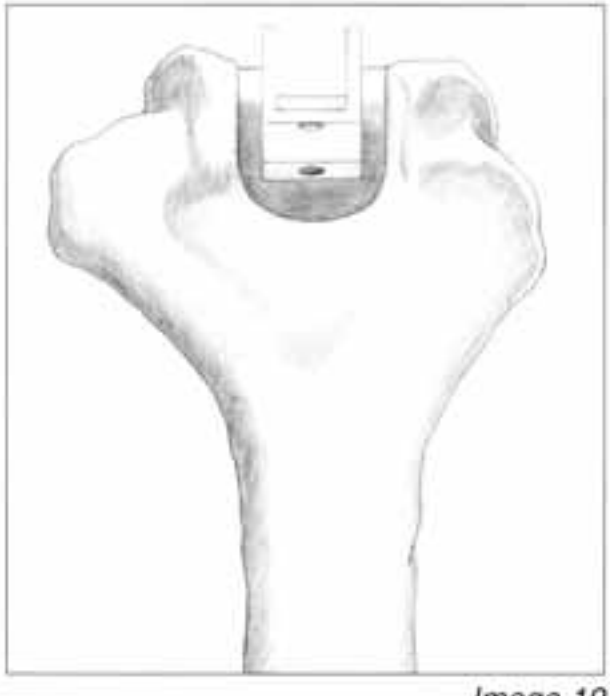

Image 19

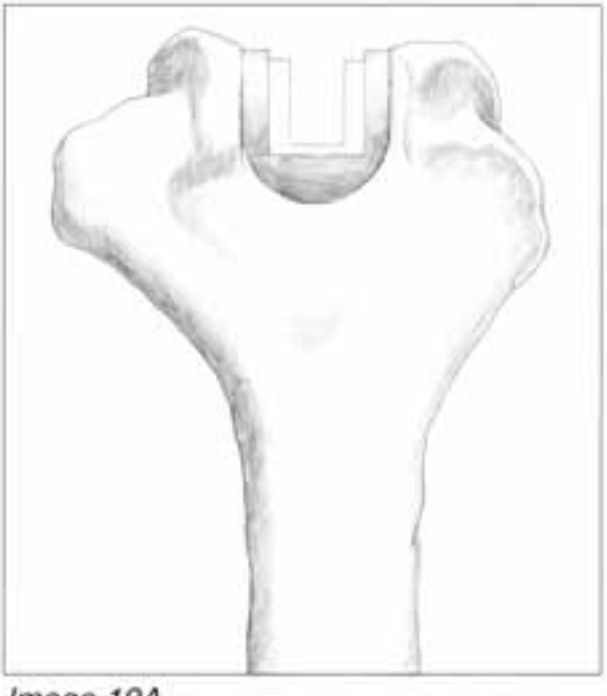

Image 19A

Cementing and Component Installation

Once the components have been fitted satisfactorily, the bone can be prepared for cementing. The ulna and humerus are both cleaned using pulsatile lavage. One batch of rather liquefied bone cement is then mixed. The cement is introduced deeply into the ulna and humerus using a Stryker® cement gun with a modified tip or a syringe. The ulnar and humeral components are inserted making sure that they are placed at the same axis of rotation as the broach/trials. The implants are then gently impacted into place using the impaction instruments provided.

Excess cement is removed. Assure that all cement is removed from the anterior and posterior aspects of the humeral component to allow the bearing surface to fit appropriately. All cement must be kept away from the axle holes.

Axle Pin Drilling

After the cement has hardened, the proper sized out-rigger drill guide (standard or large) for the lateral condyle hole is inserted in the humeral component. A hole is then drilled through the lateral epicondyle (Image 20) using the drill guide.

Alternatively, the hole through the lateral condyle can be drilled with the humeral broach/trial in place prior to cementing the actual implant. If this method is used, care must be taken to insure that when the actual implant is cemented in place that the hole in the lateral condyle lines up exactly with the axle hole in the humeral component.

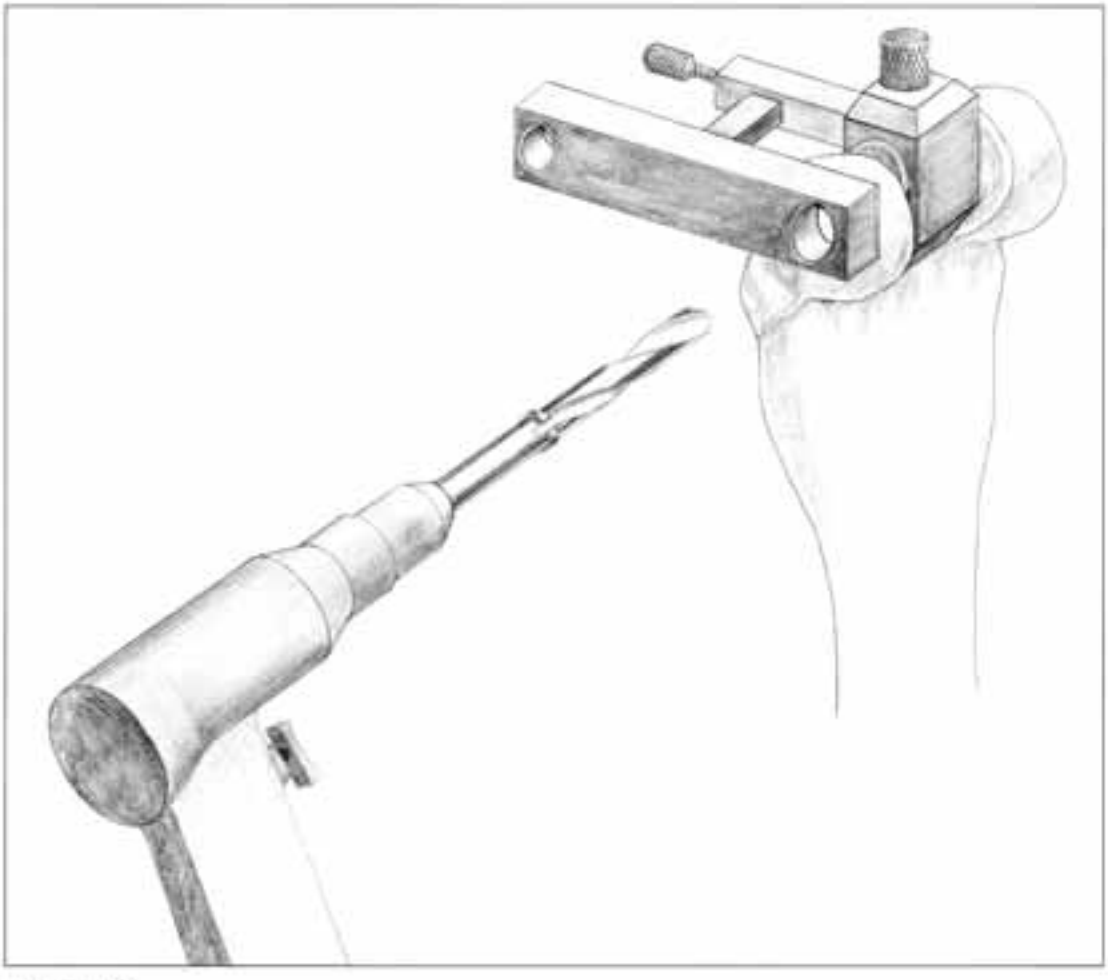

Image 20

Component Assembly and Axle Pin Installation

The polyethylene bearing is placed onto the humeral component and the joint reduced. The axle pin is placed on the torque-limiting screwdriver and can be held captive by giving the axle pin a twist while attaching it. Now slip the polyethylene sleeve bushing over the axle. The axle pin and sleeve bushing assembly can now be inserted into the prosthesis through the hole in the lateral condyle and screwed into the humeral body (Image 21).

Tighten the axle pin until the torque limiting driver snaps audibly and a slip is felt. The axle pin is now locked into position.

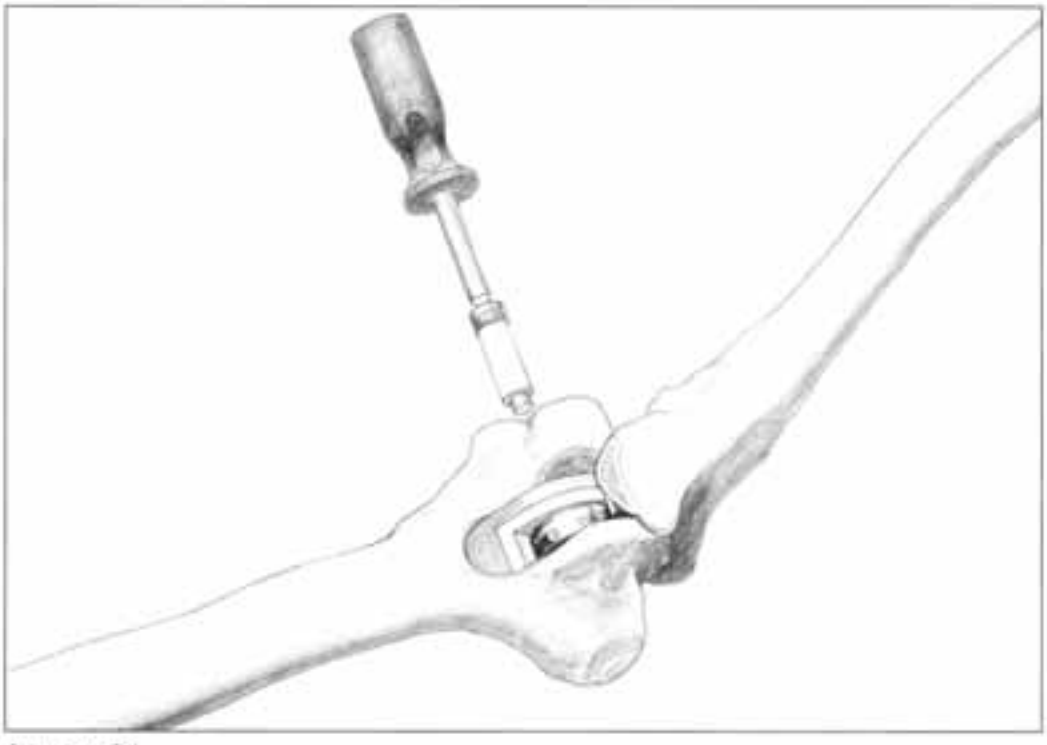

Image 21

If, for any reason, the prosthesis needs to be disassembled, use the same screwdriver to loosen and remove the axle pin and sleeve bushing from the prosthesis. Re-assemble using the same procedure as noted above.

Closure

The wound is generously irrigated and a drain placed under the triceps fascia. The olecranon extending beyond the tip of the ulnar component should be trimmed and contoured to prevent skin pressure sores.

Two or three drill holes are then placed in the olecranon (Image 22), and threaded with #2 permanent sutures for re-attaching the tendon of the triceps to the olecranon process.

The triceps mechanism is then reduced, and the triceps tendon is reattached to the olecranon with the previously placed non-absorbable sutures through bone tunnels (Image 23). Care must be taken in the closure of the fascia of the flexor carpi ulnaris not to compress the ulnar nerve. The ulnar nerve is not routinely transposed, but returned to its natural position. The subcutaneous tissue and skin are then closed. The arm is placed at 45° of extension. A large bulky dressing with an anterior splint is applied.

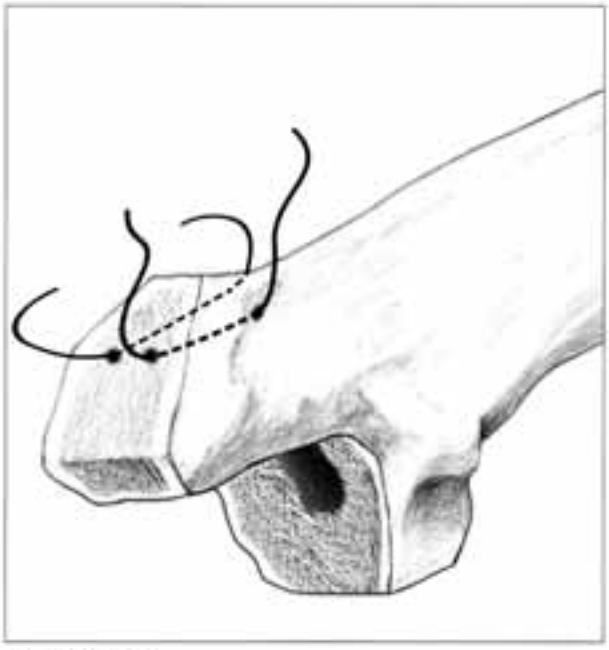

Image 22

Image 23

Postoperative Care

The drain, if used, is removed at 24 hours or when the drainage has stopped. Range of motion exercises are begun under the direction of an occupational therapist. These include active flexion, passive extension, pronation and supination exercises. An adjustable, hinged splint can be used postoperatively so that the elbow can be maintained in either extension or flexion on alternate nights.

Points of Special Note

1. Sizing

The elbow must be properly sized pre-operatively using the radiographic templates. If there are any major bony abnormalities present, a custom implant may be necessary.

2. Surgical

A. The medial epicondyle is usually larger than the lateral epicondyle, so special care must be taken not to make the initial cut too medially. The initial cutting template should be placed to align with the humeral shaft.

B. Do not violate, lever against, or significantly reduce the size of the humerus' "epicondylar pillars"; fracture of the humerus can occur if care is not taken. The epicondylar pillars should be repaired if fractured.

C. Check flexion and extension prior to cementing the components, making sure the edges of the ulna do not impinge. Also be sure that the coronoid process does not impinge. Further trim the bone if this condition exists. Check again before closure.

D. When cementing the humerus, clean all cement from the axle holes. Also make sure that cement is cleaned off the interior, anterior and posterior surfaces so that the humeral polyethylene bearing will fit down easily and completely.

E. Make sure that the axle and polyethylene sleeve bushing are inserted as a unit. The sleeve helps to center the axle during the insertion process. When disassembling the prosthesis, the sleeve bushing must be removed with the torque screwdriver, after the axle is removed; otherwise the prosthesis will not come apart.

Alternate Method for Implantation

An alternate method for implantation of the Solar™ total elbow is as follows: After both the ulna and humerus have been prepared (as previously explained in the protocol) and range of motion has been performed as well as any areas of possible impingement checked, the final implant constructed can be pre-assembled and installed in one piece as follows:

1. First assemble the humeral bearing to the humeral component. The ulnar component is then assembled to the humeral bearing and the axle pin and sleeve bushing inserted into the lateral side of the humeral component.
2. The axle pin is then torqued in place to secure it by using the torque-limiting screwdriver supplied in the instrument set. The total elbow prosthesis is now ready for implantation.
3. Since the assembled elbow prosthesis can be closed to the point where the distal stems of the humeral and ulnar components are parallel to each other, the completed assembly can be inserted as a single unit.
4. The prepared canals are each filled and packed with a single batch of rather liquefied bone cement by using a syringe or similar device.
5. The assembled elbow implant is then inserted and gently impacted into both canals simultaneously being careful that they are both placed at the previous center of rotation.
6. Cement is trimmed before hardening, making sure that cement has not extruded into the bearing area of the device.

Care must be taken to move the implant as little as possible while the cement is hardening.

Cement must be meticulously removed from all aspects of the humeral bearing and ulnar component bearing surfaces. Cement should not be allowed to reach inside the axle pin or sleeve bushing. This could render the device non-functional.

7. The normal closure procedure, as previously explained in this protocol, can now be used.

Total Elbow Prostheses

Description

The Howmedica Osteonics Solar™ Total Elbow Prostheses consist of distal humeral and ulnar components with linking bushings. These components are intended for cemented implantation within the humeral and ulnar preparation.

Materials

- ASTM F-136 Titanium Ti-6Al-4V ELI alloy Elbow humeral and ulnar components.
- ASTM F-648 ultra-high molecular weight Elbow bearing and polyethyene (UHMWPE) bushing.

Indications

- Painful, disabling joint disease of the elbow resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Distal humeral fracture and/or dislocation.
- Revision of previous unsuccessful total elbow replacement, resurfacing or other procedure.
- Clinical management problems where arthrodesis or alternative reconstruction techniques are less likely to achieve satisfactory results.

Contraindictions:

- Any active or suspected latent infection in or about the elbow joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prostheses instability, prostheses fixation failure, or complications in post operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prostheses.
- Skeletal immaturity.
- Patients whose anticipated activities would impose high stresses on the prostheses and its fixation.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of fixation of the device or to failure of the device itself.

Precaution

- Before Clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
- Appropriate selection, placement and fixation of the elbow components are critical factors which affect implant service life. As in the case of all prosthetic implants. Theses components are affected by numerous biologic, biomechanic and other extrinsic factors, thereby limiting the service life and durability of the product. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize its service life.
- Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects.

Utilization and Implantation

- The recommended trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- The Howmedica Osteonics Surgical Protocols provide additional procedural information.

Warning

- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.
- Bearing areas must always be clean and free of debris prior to assembly.
- Contouring and bending of an implant may reduce its fatigue strength and cause failure under load.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.
- Howmedica Osteonics strongly advises against the use of another manufacturer's component with any Howmedica Osteonics total elbow component. Any such use will negate the responsibility of Howmedica Osteonics for the performance of the resulting mixed component implant.
- Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

Adverse Effects

- While the expected life of the total elbow replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of

mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

- Loosening of total elbow components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications, including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fatigue fracture of total elbow prosthesis has occurred in a small percentage of cases.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Serious complication may be associated with any joint replacement. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may necessitate reoperation, arthrodesis of the involved joint and/or amputation of the limb.
- With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondarily, particulate can also be generated by third-body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

Sterilization

- This total elbow component has been sterilized by gamma radiation.
- The packaging of all sterile products should be inspected for flaws in the sterile barrier opening. In the presence of such a flaw, the product must be assumed nonsterile. Special trial prosthesis are available to avoid having to open any aspect of the sterile package prior to component use.
- If the package is opened, but the product is not used, the prosthesis must not be resterilized and must be discarded or returned to the supplier.

CAUTION: Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

WARNING:

THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY IN THE U.S.A.

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