

UNI-Elbow System

Radio-Capitellar Replacement

Operative technique



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This publication sets forth detailed recommended procedures for using Stryker devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multicomponent instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling Instruments and Sizers V15106).

See package insert (Instruction for Use) (V15130) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

For additional information for the rHead System please reference RHD-ST-1 and for rHead Extended Stem System please reference RHD-ST-2

Introduction

The UNI-Elbow System is designed specifically for Uni-Compartmental Arthroplasty of the lateral radial humeral joint. The implant offers an alternative to hemi-arthroplasty of the proximal radial head. The implant is used for the treatment of degenerative joint disorders of the radio-capitellar joint.

The radio capitellum implant component is designed to be used in conjunction with the rHead prosthesis.

The capitellum and the polyethylene component of the radial head assembly articulate against each other in a concave-convex spherical relationship and are anatomically designed for minimal resection. The implants are available in left and right hand configurations, various sizes, and they are modular, meaning that any size capitellum will fit with any size head. In addition, the intuitive instruments utilizing Precise Guidance Technology allow for a simple, easy to follow technique.

The UNI-Elbow implant is fabricated from cobalt chrome. The intramedullary stem is coated with commercially pure titanium plasma spray. The articular surface is highly polished for articulation with the rHead component.



Indications and contraindications

Indications

When UNI-Elbow System is used in a unicompartmental arthroplasty application with a standard or extended stem:

The UNI-Elbow implant is indicated for use in the elbow for reduction or relief of pain and/or improved elbow function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease including osteo-arthritis or traumatic arthritis
- Inflammatory degenerative joint disease including rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments and devices have failed; and
- Treatment of fractures that are unmanageable using other techniques

The UNI-Elbow capitellar implant is intended for cemented use only.

Contraindications

- Inadequate skin, soft tissue, or ligamentous structures
- Insufficient quantity or quality of bone stock
- Muscle deficiency or elbow flexion and extension
- Previous open fracture or infection in or around the joint
- Skeletal immaturity
- Known sensitivity to material used in this device

Warnings and Precautions

Please see package insert for Warnings, Precautions, Adverse Reactions, and other essential product information.

Stryker systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

The safety of UNI-Elbow System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

Operative technique

The initial incision

The patient is placed under a general or a regional anesthesia. The extremity is prepped and draped in the usual sterile fashion. A sterile tourniquet is often a good option. An arm table may be used if the patient is in a supine position or the arm may be brought across the chest.

A classic Kocher skin incision is made identifying the interval between the anconeus and the extensor carpi ulnaris (Fig. 1). The incision extends approximately 6-7cm. The dissection is carried down to the joint capsule. The origin of the anconeus can be released subperiosteally and retracted posteriorly to permit adequate exposure of the capsule.

Capsular exposure

If the elbow is stable, the capsule is exposed by elevating a portion of the extensor carpi ulnaris sufficiently to allow identification of the lateral collateral ligament complex. Alternatively, the extensor carpi ulnaris may be split longitudinally in line with its fibers staying anterior to the attachment of the lateral collateral ligament. The lateral capsule is divided slightly anteriorly to the collateral ligament and the annular ligament and capsule are reflected anteriorly and posteriorly to expose the radial head. A portion of the lateral collateral ligament and anterior capsule can be reflected off the lateral epicondyle and anterior humerus to expose the capitellum. The lateral ulno-humeral ligament must not be disturbed. If the ligament has been disrupted, then the exposure progresses through the site of disruption to expose the radiohumeral joint. The common extensor tendon and elbow joint capsule are retracted as needed to maximize exposure.

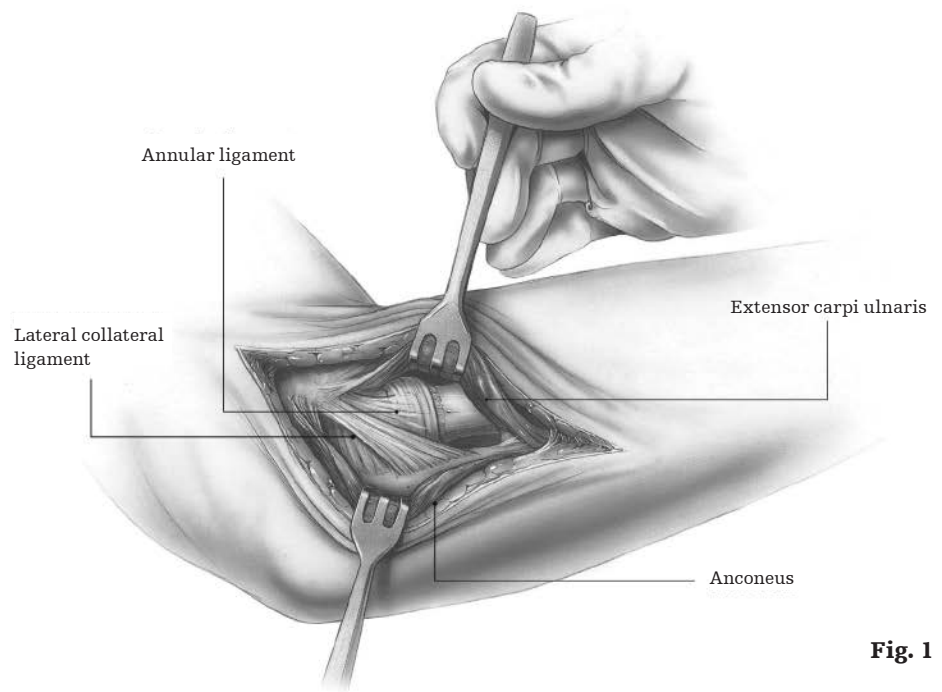


Fig. 1

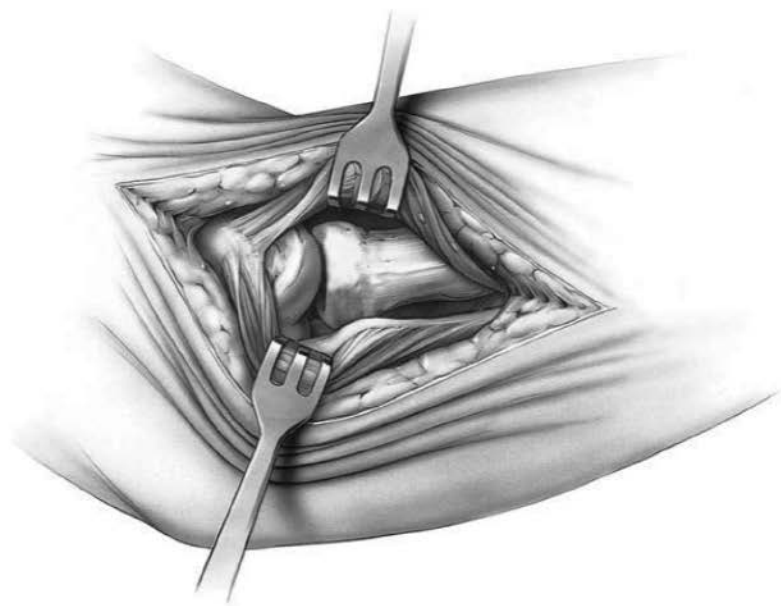


Fig. 2

Note:

To provide additional exposure to the joint space, a preliminary conservative cut can be made to the proximal radius. Once the capitellum has been appropriately prepared and trialed, continue with proper radial head resection and technique.

Operative technique

Axis of rotation locator clamp assembly and K-Wire placement

Assemble the axis of rotation locator clamp by securing the locator cup with the cup bolt and upper arm to the axis bar slot bolt. Then assemble the drill guide to the upper arm and advance the thread half way down (Fig. 3A).

There are two capitellum templates in the instrument set, left and right. Each end of the template is labeled to match the large or small implant. Preoperative planning with the X-Ray template is recommended to assist in the selection of the appropriate sized implant.

Place the center hole of the capitellum template under the drill guide and advance the template until it engages the retaining ring.

The axis of rotation locator clamp is then placed over the elbow with the medial epicondyle resting in the locator Cup (Fig. 3B).

Match the outline of the template with the distal articulating surface of the capitellum. The curvature of the edge of the template should align with the most distal articular surface of the original capitellum. Once alignment is achieved, tighten the drill guide against the lateral epicondyle (Fig. 3C).



Fig. 3A

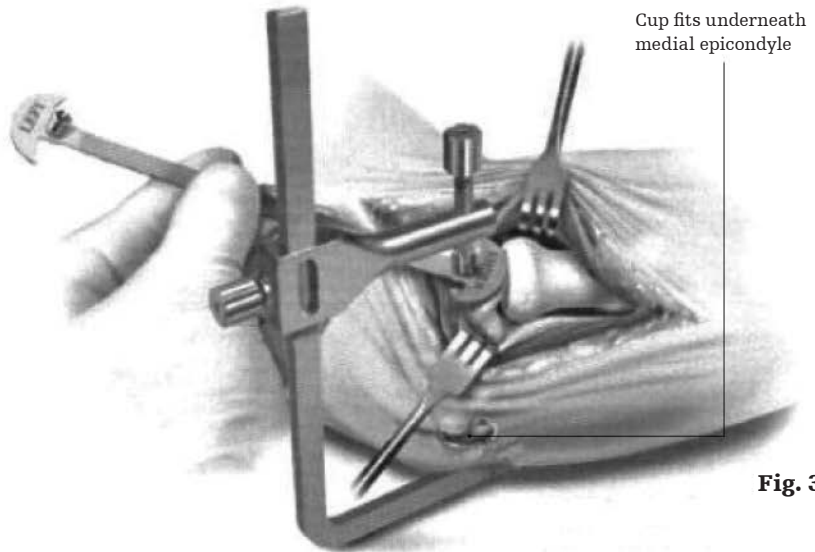


Fig. 3B

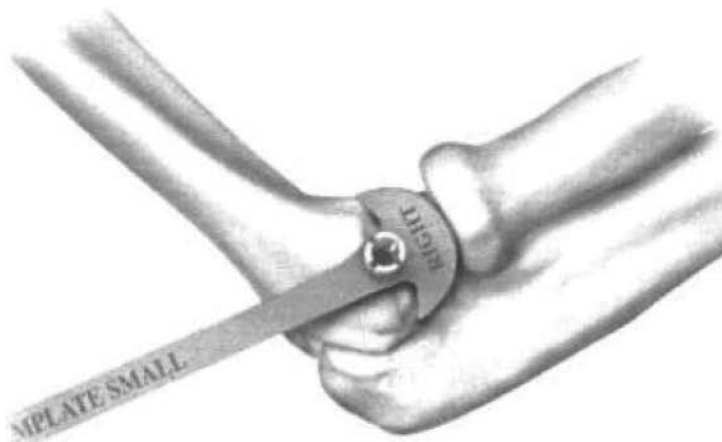


Fig. 3C

Operative technique

Insert a 1.5mm (0.062) K-Wire through the drill guide and advance into the capitellum (Fig. 3D).

The K-Wire should be advanced to the mid-line of the distal humerus when viewed on the A/P plane. Care should be taken not to extend the K-Wire through the medial epicondyle. Leaving the K-Wire in place, remove the axis of rotation locator clamp and template (Fig. 3E).

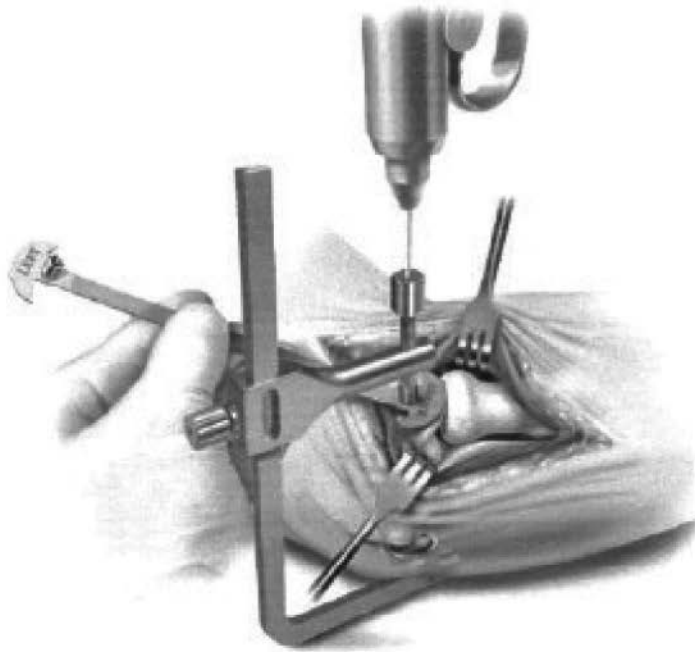


Fig. 3D

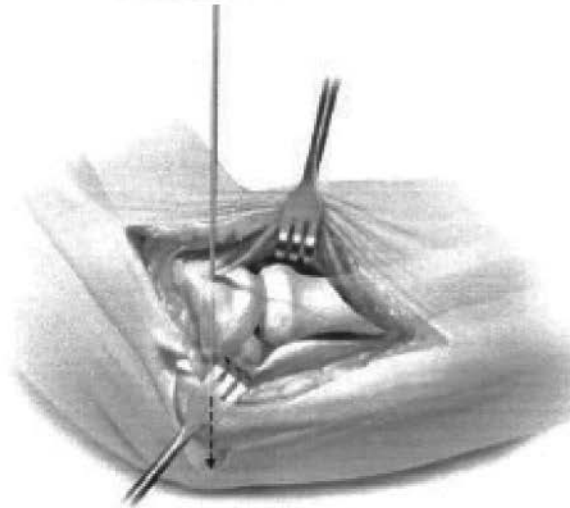


Fig. 3E

Operative technique

Precise guidance technology (PGT) resection guide

There are two resection guides, small and large. Based on capitellum template being used, choose the corresponding resection guide.

Place the PGT resection guide over the K-Wire and slide down until it rests on the capitellum (Fig. 4A). Assemble the resection guide handle to the resection guide and align so it is parallel with the long axis of the humerus (Fig. 4B).

Once proper alignment is achieved, place the second 1.5mm (0.062) K-Wire in the resection guide to secure the orientation. The handle can then be removed. The PGT resection guide has two slots for resection of the capitellum.

The proximal, or posterior, slots represent the actual size of the capitellum implant. The distal, or anterior, slots are off-set by 2mm and would be used when excessive erosion of the capitellum is present. Either both proximal or both distal slots must be used. Mis-matched cutting guide slots cannot be used (Fig. 4C).

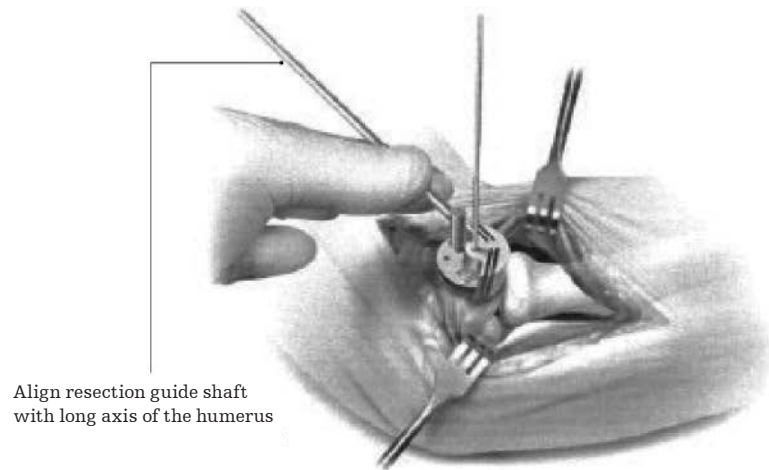


Fig. 4A



Fig. 4B

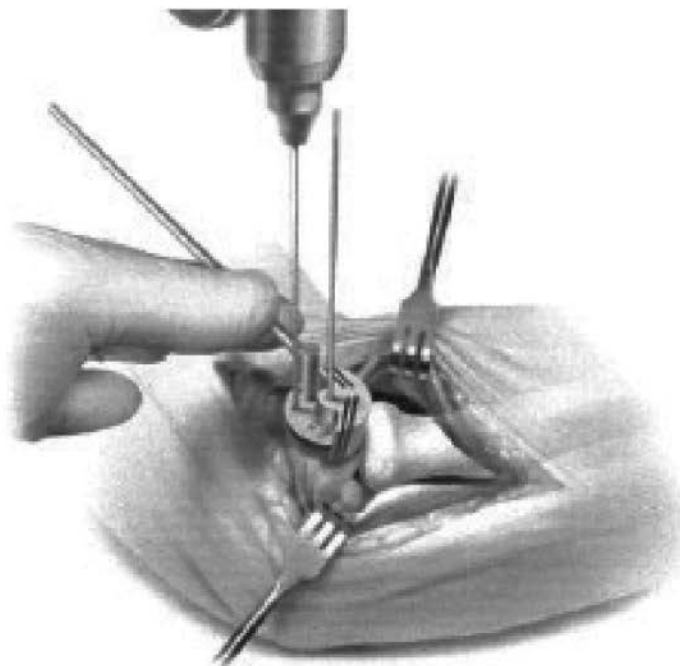


Fig. 4C

Operative technique

Using a sagittal saw, insert the sawblade into the chosen slot in the resection guide. (Fig. 4D).

Perform the transverse and oblique cuts to the deep base of the capitellum.

Important:

The cut should never cross the ridge of the trochlea (Fig. 4E).

Note:

It is helpful to use an osteotome to score the recess of the trochlea. This creates a fracture line when the capitellar head is removed.

Using a small osteotome and rongeur, remove the capitellar head and trim remaining fragments (Fig. 4F - 4H).

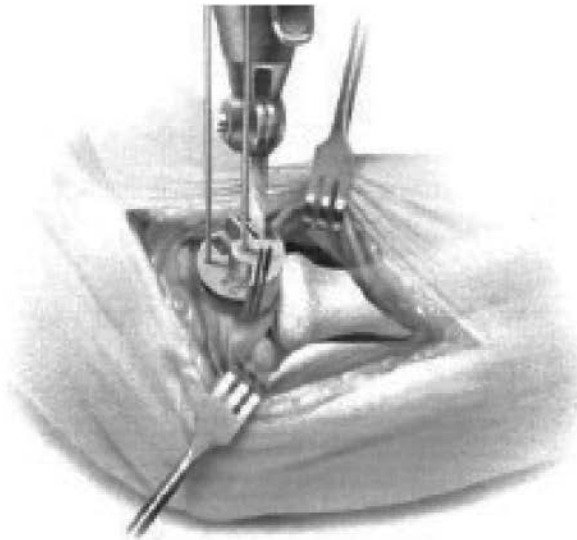


Fig. 4D

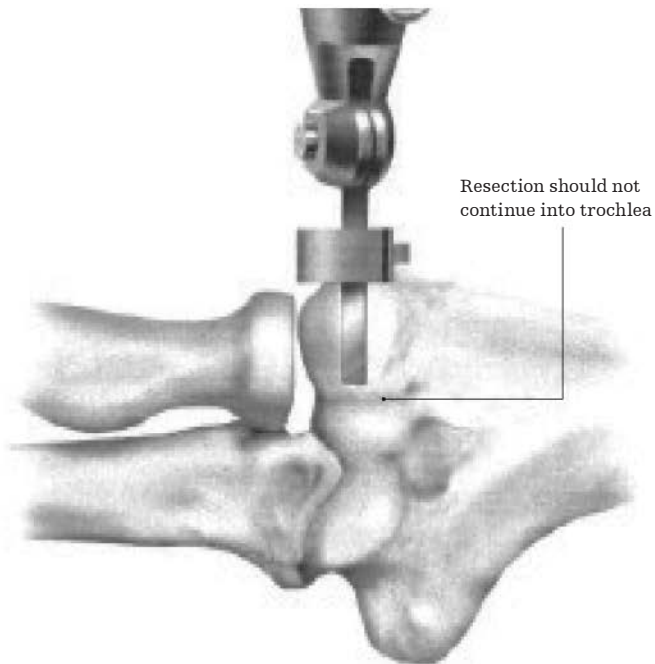


Fig. 4E

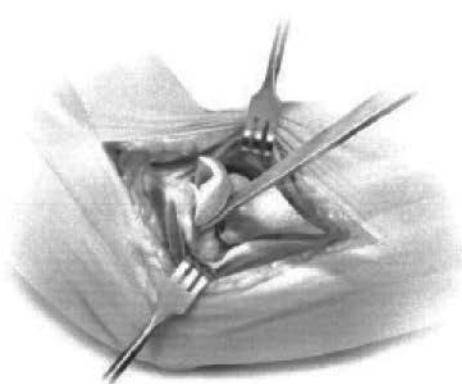


Fig. 4F

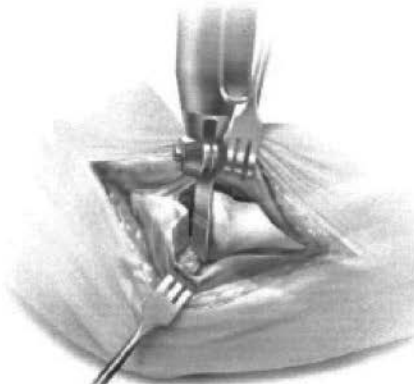


Fig. 4G



Fig. 4H

Operative technique

Capitellum trial

Assemble the capitellum trial handle onto the capitellum trial (Fig. 5A). Place the capitellum trial against the resected humerus (Fig. 5B).

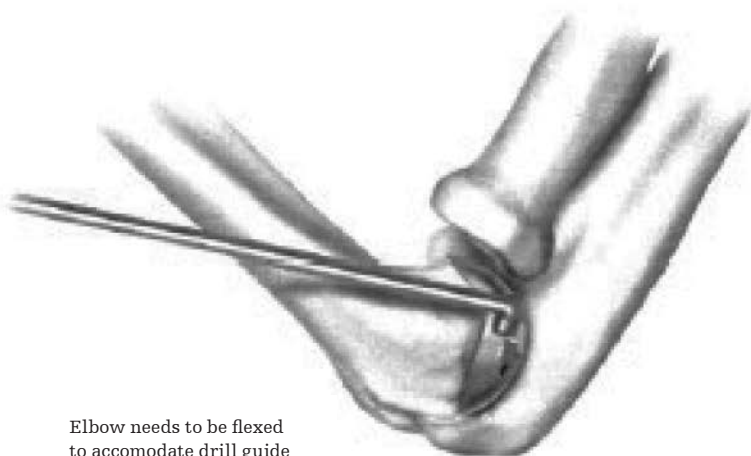
Note:

The handle does not have an orientation reference to the humerus.

First, insert 1.5mm (0.062) K-Wires through the lateral holes and into the distal humerus to firmly secure the trial component. Remove the trial handle and crop the K-Wires at the surface of the trial leaving enough K-Wire exposed to facilitate removal but not allowing the K-Wire to make contact with the radial head. Assess range of motion (Fig. 5C).



Fig. 5A



Elbow needs to be flexed to accomodate drill guide

Fig. 5B

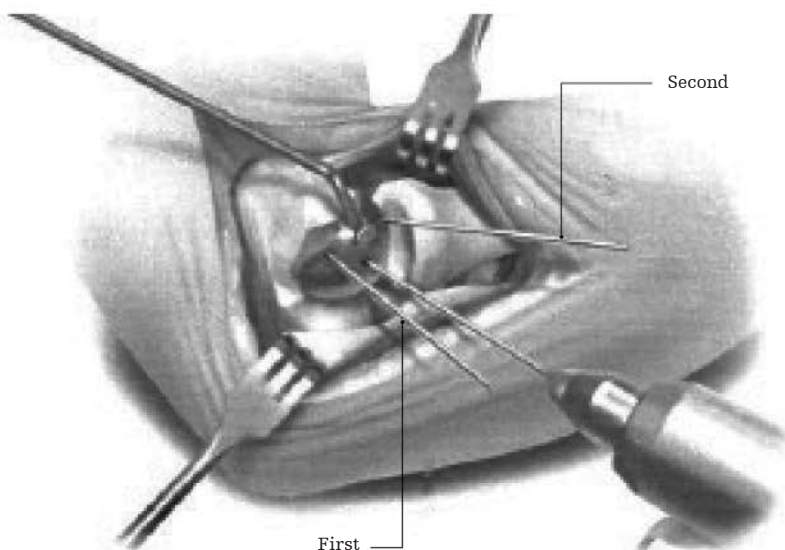


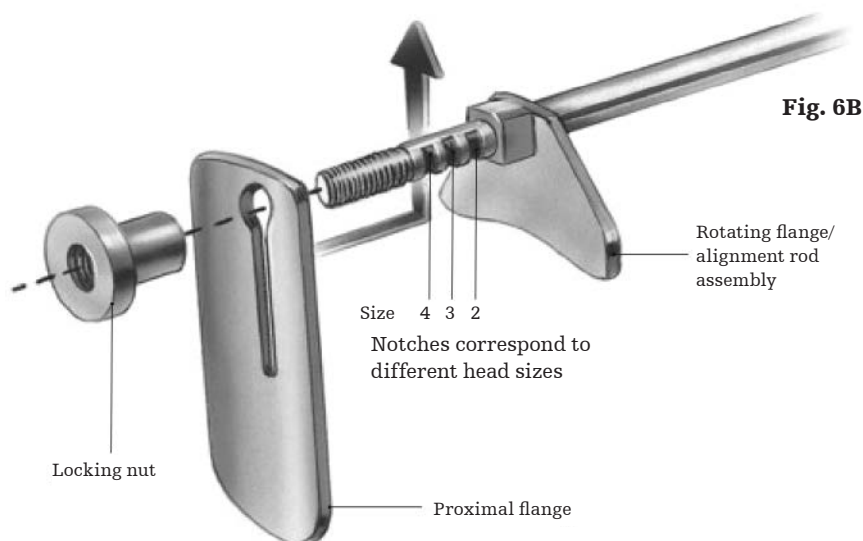
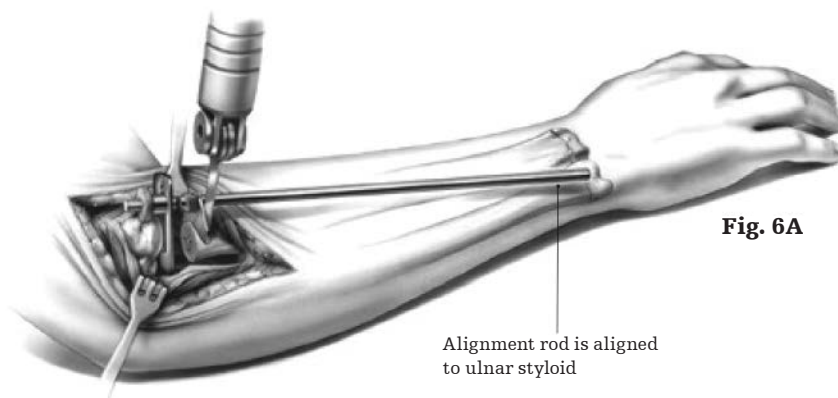
Fig. 5C

Operative technique

Using the radial head resection guide, standard collar

The radial neck cut requires a resection guide. The device is inserted over the capitellum with the axis of the alignment rod oriented over the ulnar styloid (Fig. 6A). This alignment reflects the anatomic axis of forearm rotation. Test forearm rotation with the guide in place to ensure proper alignment. The proximal flange of the guide is placed against the articular surface of the capitellum and the rotating flange/alignment rod assembly is then guided proximally or distally to the desired length of radial shaft resection (Fig. 6B).

Each notch on the threaded portion of the rod corresponds to a different head size. The rotating flange placement direction must be matched to the anticipated radial head implant size and the axis of forearm rotation. Once the desired length has been established, the proximal flange is secured by tightening the locking nut. The guide must be again aligned to the ulnar styloid (the axis of forearm rotation), not the radial shaft.



Operative technique

Using the radial head resection guide, 6mm extended collar

If X-Ray templating is performed, it may become apparent that the fracture incurred by the patient is distally migrated and the standard 2mm rHead stem collar will not restore adequate neck length. For this specific situation the rHead system is also offered in a 6mm extended collar. This 6mm extended collar is intended to be used with distally migrated fractures of the proximal radius.

In addition to a complete set of 6mm extended collar stem trials, a spacer is included for use with the rHead resection guide. This additional spacer is placed over the distal tip of the resection guide with the raised block facing the proximal portion of the resection guide. The spacer is slid proximal until it makes contact with the "rotating flange" (Fig. 6C). The remainder of the technique is unchanged. The addition of this spacer assures that the proper amount of bone is resected for the extended collar implant.

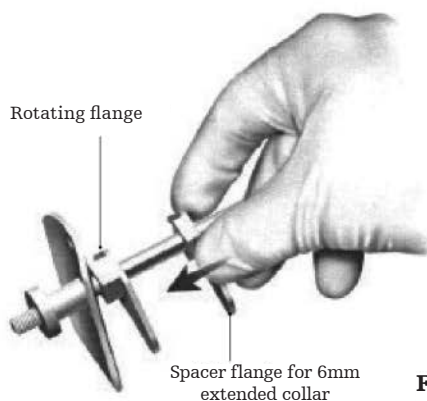


Fig. 6C

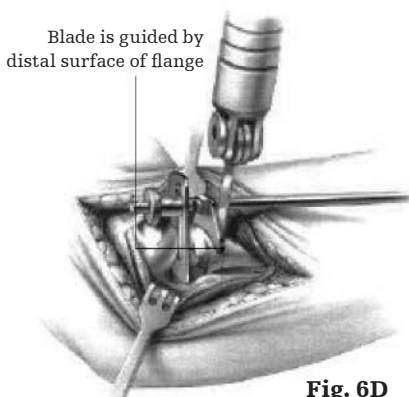


Fig. 6D



Fig. 6E

Resecting the radial head

Using the resection guide, the blade should be guided by the distal surface of the rotating flange (Fig. 6D). During the resection, the forearm is pronated and supinated while the cutting guide is used to align the sawblade perpendicular to the axis of rotation (Fig. 6E). Once initial alignment cuts have been made, the guide is removed and the resection is completed. The distal extent of resection is the minimal amount that is consistent with the restoration of function (Fig. 6F). This includes at least the margin articulating with the ulna at the radial notch.

When the rHead is to be used after radial head resection was previously performed, the guide is employed to "freshen" the resected proximal radius.

If the medullary canal is not obvious after the radius has been recut, it should

be thus identified with a tool such as a curved Kelly or a high speed burr.

In addition, radial length should be restored (axial traction) using a lamina spreader if there is a positive ulnar variance.

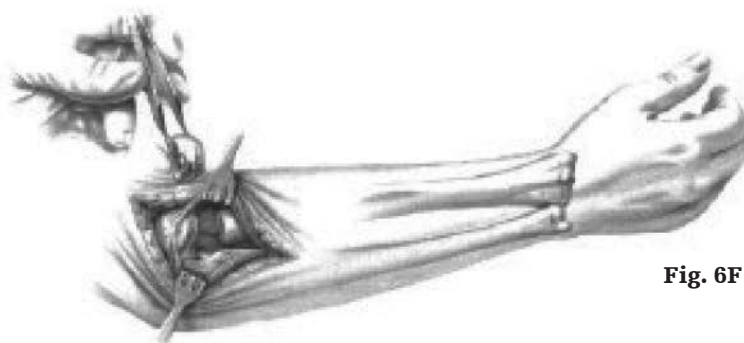


Fig. 6F

Operative technique

Intramedullary preparation, proximal radius

If the elbow is unstable, varus stress and rotation of the forearm into supination allows improved access to the medullary canal. If the elbow is stable but the exposure is not adequate to access the medullary canal, careful reflection of the origin of the collateral ligament from the lateral epicondyle may be necessary to permit subluxation to the medullary canal. The canal can be entered with a pair of curved needle holders or a high speed bone burr so the broaching process can be initiated.

Note:

When using the system with an extended stem, a starter awl is provided in the rHead Extended Stem instrument tray. See RHD-ST-2 for specific instructions related to rHead Extended Stem implantation

The canal is then broached as allowed by the pathologic anatomy of the proximal radius (Fig. 7). Care should be taken not to rotate or twist the broach during the broaching process.

The curve of the broach should be directed away from the bicipital tuberosity and towards the radial styloid (Fig. 7). If the position of the tuberosity cannot be easily assessed, it generally is opposite of the radial styloid. Serial sized broaches are used until the broach fits snugly in the canal at the appropriate depth.

The curve of the broach should be directed towards the radial styloid

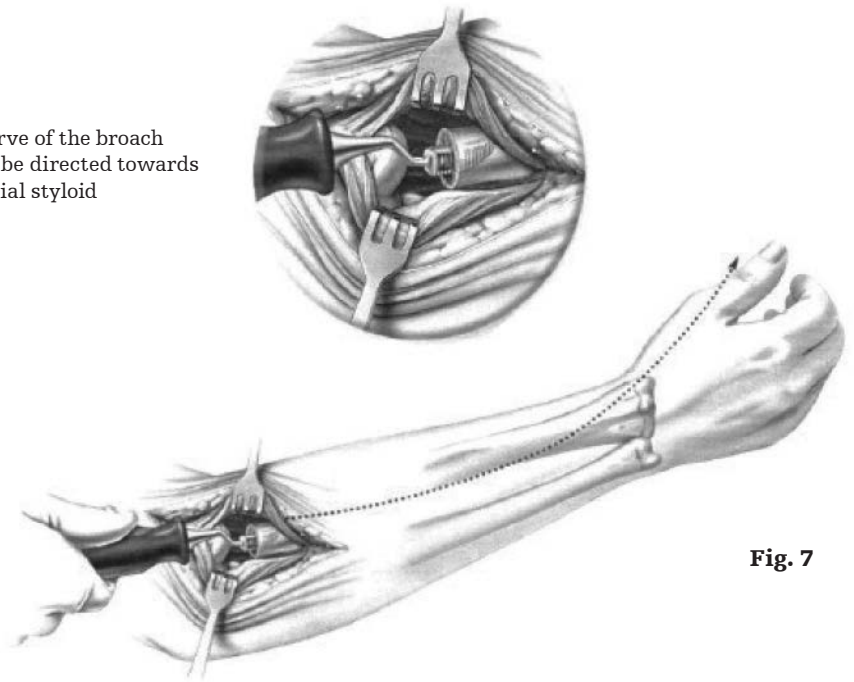


Fig. 7

Operative technique

Trial reduction, proximal radius

The appropriate sized trial stem is inserted in an arc-like fashion, facilitated by the curve of the stem (Fig. 8A, 8B). Assure the collar is flush with the resection.

Use the resected native head to properly determine the head size to be trialed. To avoid overstuffing, if the native head is between two sizes, it is generally preferable to select the smaller rather than the larger size.

The trial head is attached to the trial stem (Fig. 8C), and tracking, both in flexion and extension and forearm rotation, should be carefully assessed. Malalignment of the osteotomy will cause abnormal tracking during flexion / extension and forearm pronation/supination.

Note:

In some instances adequate tracking cannot be attained. In this circumstance the implant should not be used.

Once acceptable alignment has been determined the radial head trials are removed.

Note:

The head and stem trial components are designed to be a “non-locking” lateral or morse taper assembly mechanism.



Fig. 8A

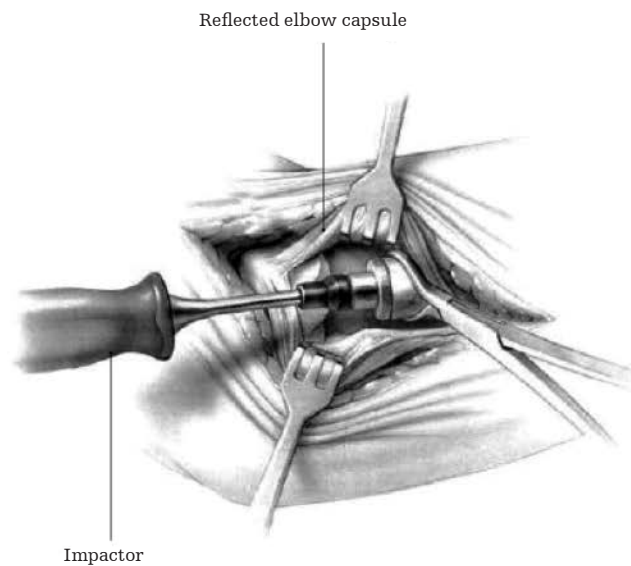


Fig. 8B

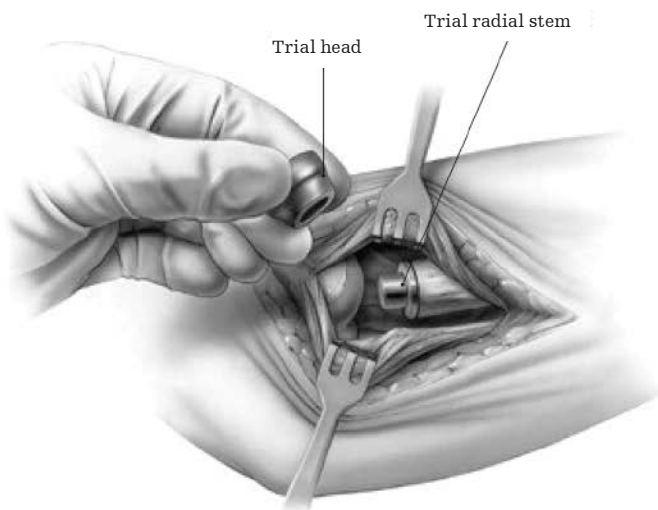


Fig. 8C

Operative technique

Broaching of the distal humerus

Remove the cropped medial K-Wire's. The central K-Wire will remain in situ and act as a drill and broach guide wire.

Remove the lateral K-Wires and slide the capitellum trial off the center K-Wire. The elbow may have to be brought into full flexion to remove the trial (Fig. 9A).

Using the cannulated 3.5mm drill, drill over the center K-Wire to create the broach pilot hole into the distal humerus.

Note:

Care should be taken not to over drill or perforate the posterior cortex of the humerus (Fig. 9B).

Insert broach into the pilot hole and impact. The broach should be advanced until the teeth are at the same level as the capitellum osteotomy. Care should be taken to identify proper alignment and not to over broach the distal humerus (Fig. 9C).

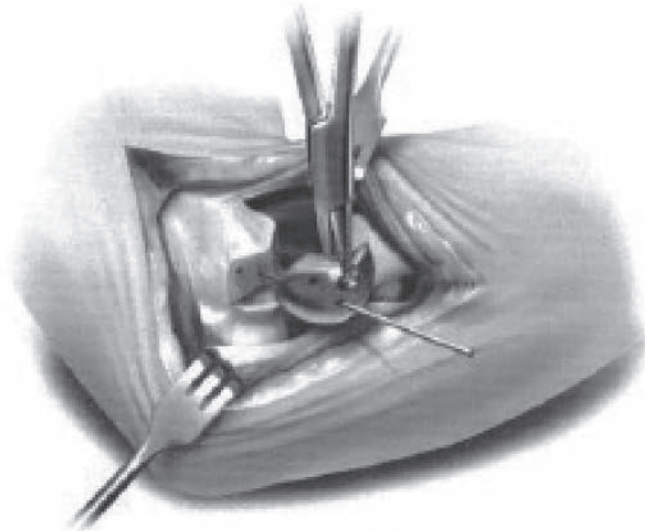


Fig. 9A

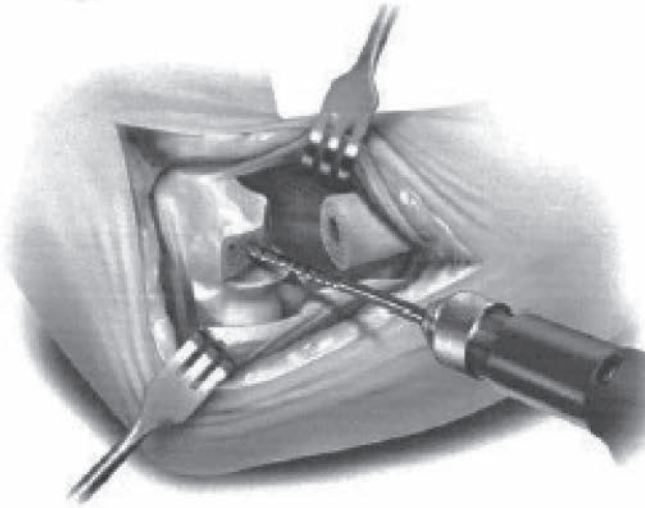


Fig. 9B

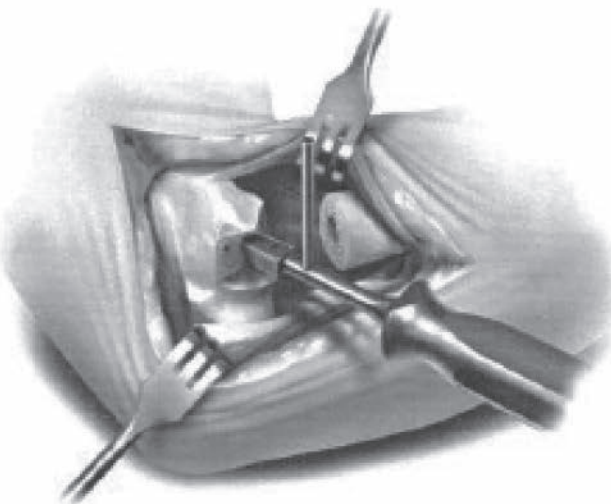


Fig. 9C

Operative technique

rHead Radial (Morse Taper) option: Implanting the final components

Note:

When using the UNI-Elbow, the polyethylene radial heads must be used at the time of final implantation.

Once broaching is complete, the definitive implant can be inserted. Distraction of the proximal radius as well as flexion of the elbow may be necessary to allow sufficient access for capitellum insertion (Fig. 10A).

Insert the capitellar stem into the canal and tap into place using the impactor. Bone cement (PMMA) is indicated for the capitellar component (Fig. 10B).

Insert the radial stem down the canal of the proximal radius and tap into place with the impactor. If a firm fixation is not present at the time of the insertion of the trial stem (i.e. stem can be easily extracted from or rotated in the medullary canal), then bone cement (PMMA) is recommended. The modular head is placed over the taper using longitudinal distraction and/or varus stress to distract the radio capitellum interface sufficiently to permit the radial head to be inserted. Once inserted, the radial head is secured using the impactor. The elbow is then reduced and tested again in flexion/extension and pronation/supination (Fig. 10C).

Note:

Care should be taken to protect the taper from any damage, including but not limited to scratches and contact with bone cement.

Note:

Implanting the final components the approach will vary slightly depending on the rHead radial implant that is used. The variations are outlined in the following steps.

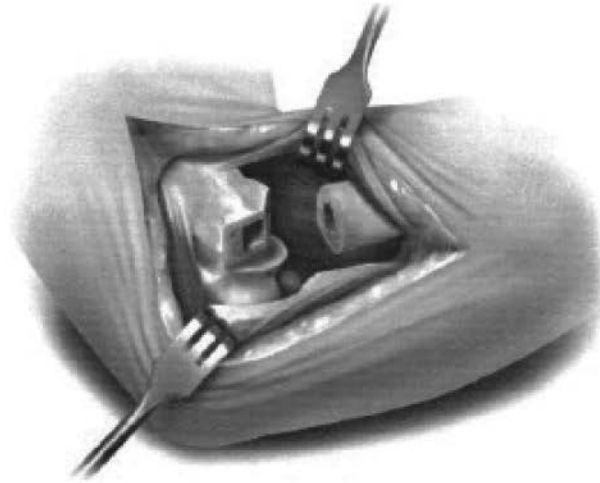


Fig. 10A

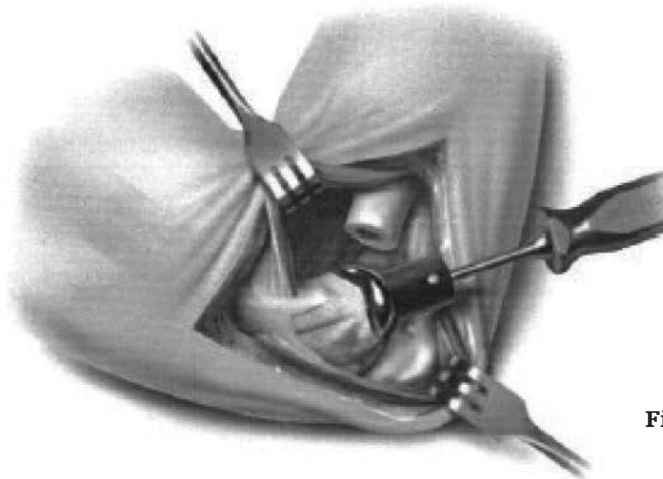


Fig. 10B



Fig. 10C

Operative technique

rHead Recon (Bi-Polar) option: Implanting the final components

Note:

When using the UNI-Elbow, the polyethylene radial heads must be used at the time of final implantation.

Once acceptable alignment has been determined, the trials are removed and the permanent prosthesis is inserted in two steps. First, using the same arc-like motion as shown in (Fig. 8A), the implant stem is placed in the medullary canal and tapped into place with the impactor (Fig. 10D). If a firm fixation is not present at the time of the insertion of the trial stem (i.e. stem can be easily extracted from or rotated in the medullary canal), then bone cement (PMMA) is recommended. Second, the implant head of the prosthesis is assembled to the implant stem. This is accomplished by carefully placing the implant head into the jaws of the assembly tool and tighten the locking nut (Fig. 10E).

While applying longitudinal distraction and/or varus stress to distract the radiocapitellar interface, insert the implant head between the capitellum and the spherical ball of the implant stem. Place the lever through the center of the assembly tool and engage the collar of the stem (Fig. 10F). Using the assembly tool like a plier, snap the implant head onto the stem. Carefully remove the assembly tool to avoid damage to the implant. The elbow is then reduced (Fig. 10G) and tested again in flexion / extension and pronation / supination.

Note:

Care should be taken to protect the articulating surfaces between the head and stem of any damage, including, but not limited to, scratches and contact with bone cement.



Fig. 10D

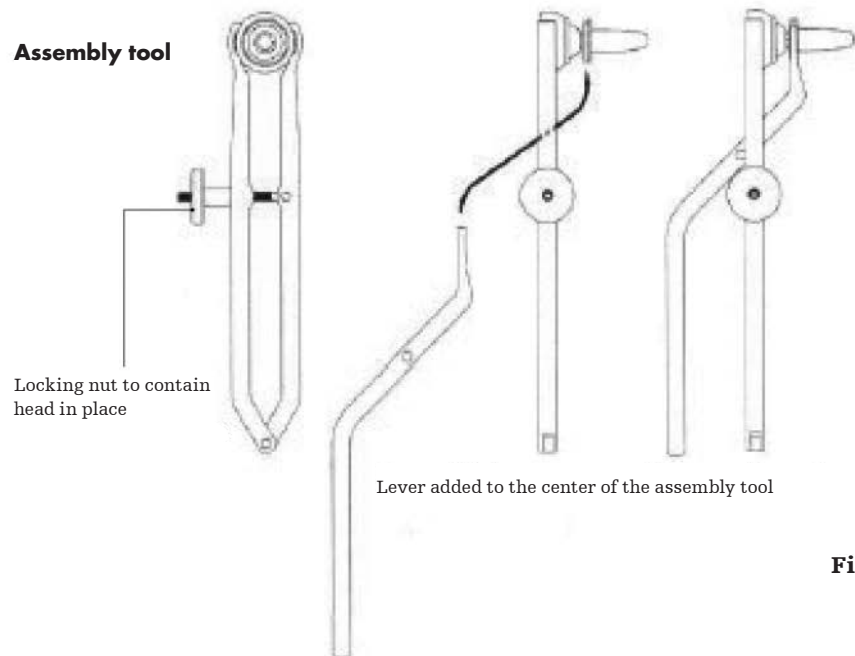
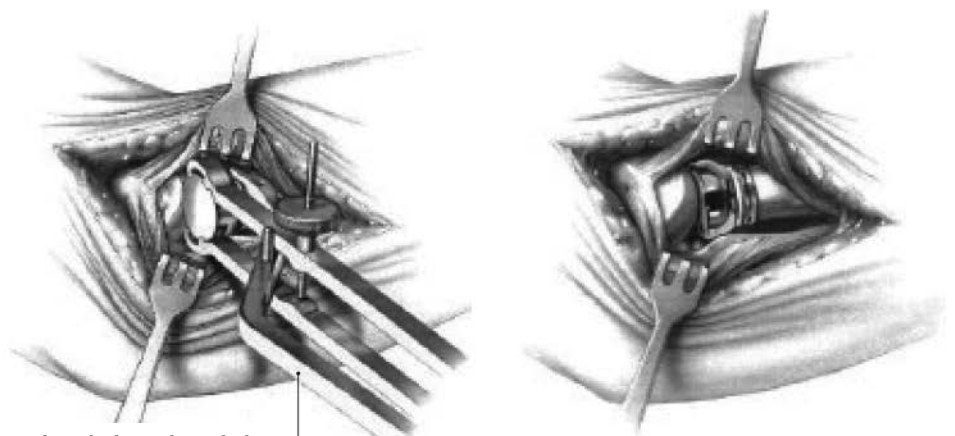


Fig. 10E



Place the lever through the center of the assembly tool and engage the collar of the stem

Fig. 10F

Fig. 10G

Operative technique

rHead Lateral option: Implanting the final components

Note:

When using the UNI-Elbow, the polyethylene radial heads must be used at the time of final implantation.

Connect the rHead lateral stem impactor to the collar of the appropriate size stem to be implanted (Fig. 10H).

Use the stem impactor to maneuver the stem and insert it into the prepared canal of the radius. When the stem is inserted correctly into the canal, the axis alignment bar on the shaft of the impactor should align with the patient's radial styloid (Fig. 10I). The stem should be inserted in an arc-like fashion, facilitated by the curve of the stem (Fig. 8A). Tap the end of the rHead lateral stem impactor until the stem is firmly seated in the medullary canal. If the stem can be easily extracted or rotated in the canal, bone cement, (PMMA), is recommended.

The head and stem components are coupled together using the rHead lateral assembly tool. Prior to beginning assembly, all soft tissue must be cleared away from the locking mechanism. Position the appropriately sized radial head implant so that the male portion of the head locking mechanism is engaged by the female portion of the stem locking mechanism (Fig. 10J).



Lateral stem impactor

Fig. 10H

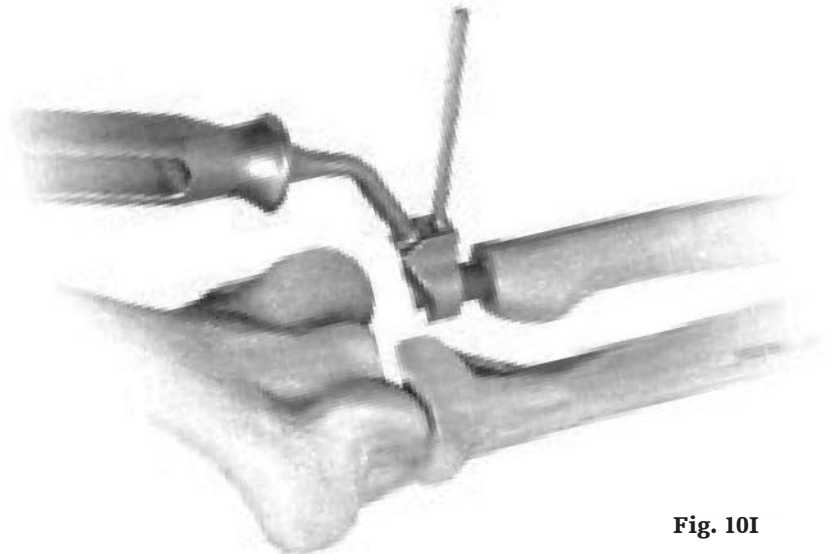
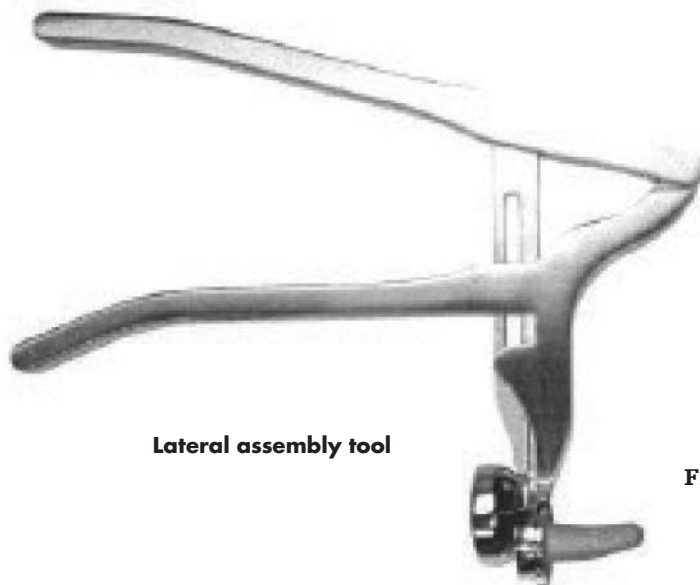


Fig. 10I



Lateral assembly tool

Fig. 10J

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Place the rHead lateral assembly tool around the grooved collar of the stem and ensure the dimple on the radial head implant is engaged by the pin on the advancer of the rHead lateral assembly tool (Fig. 10K). The trigger on the rHead lateral assembly tool is then compressed to advance the radial head implant until it is fully engaged by the stem. The head is fully locked to the stem when an audible “snap” is heard or felt. Visually, the head should be concentric with the stem when properly engaged (Fig. 10L). The assembly tool can now be removed.



Fig. 10K



Assembly side

Fig. 10L

If disassembly should be needed, rotate the forearm and reverse the rHead lateral assembly tool until the pin on the advancer is aligned with the dimple on the opposite side of the radial head implant (Fig. 10M). Compress the trigger on the rHead lateral assembly tool until the radial head implant disengages from the stem (Fig. 10N). Note that the radial head implant is intended for one time use. The radial head implant shall not be reused once it is disengaged from the stem. A new radial head implant must be used if the original head is disengaged for any reason.



Disassembly side

Fig. 10M

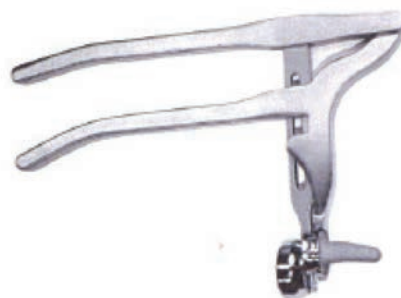


Fig. 10N

Note:

Care should be taken to protect the articulating surfaces between the head and stem from any damage including, but not limited to, scratches and contact with bone cement.

Operative technique

Closure

A simple closure is permitted if the collateral ligament is not disrupted. If the collateral ligament has been disrupted, a krakow stitch is used in the substance of the lateral ulnar collateral ligament. A No. 5 absorbable suture is placed distally, crosses the site of the lateral ulnar collateral ligament and then brought proximally. Both ends of the suture are brought through a drill hole at the anatomic origin of the lateral collateral ligament complex and exit posteriorly. The forearm is placed in full or partial rotation and the suture tied. The elbow is splinted at 90 degrees flexion and in neutral to full pronation (Fig. 11A, 11B).

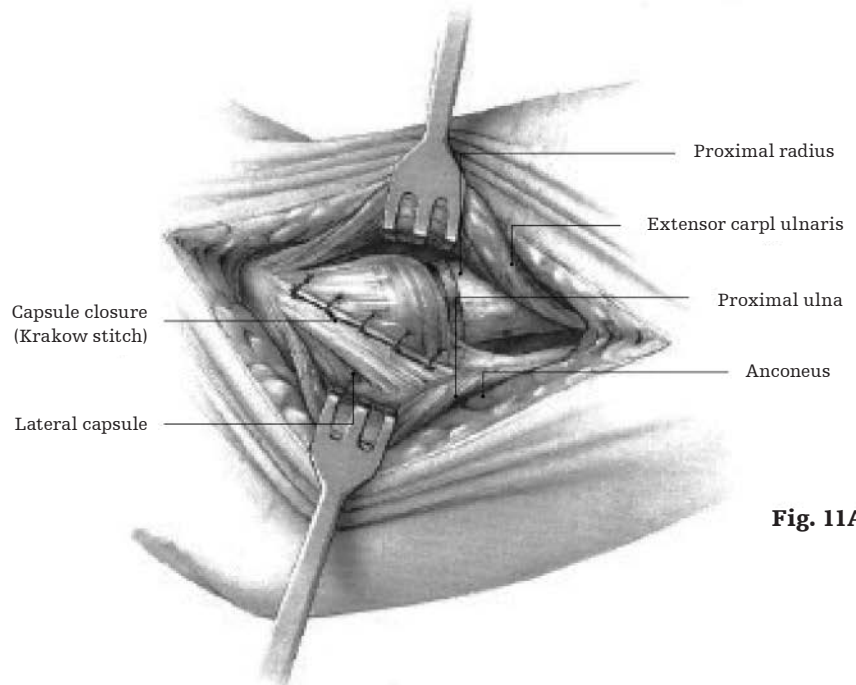


Fig. 11A

Aftercare

Passive flexion and extension may be allowed on the second day assuming the elbow is considered stable. The goal of radial head replacement and soft tissue repair is to achieve elbow stability. Both flexion/extension and pronation/supination arcs may be allowed without restriction. Active motion may begin by day five. Long term aftercare requires surveillance as with any prosthetic replacement. If the implant is asymptomatic and tracks well, routine removal may not be necessary.

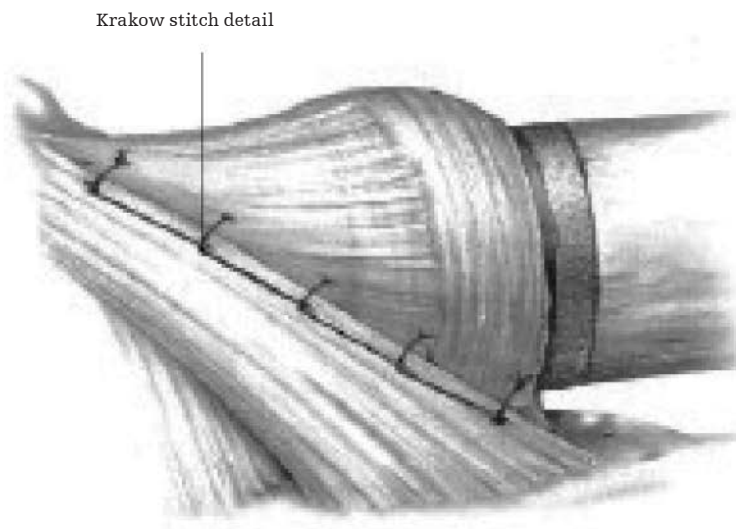


Fig. 11B

Notes:

Trauma & Extremities

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