

SURGICAL TECHNIQUE



uHead™ Ulnar Implant System



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SMALL BONE INNOVATIONS, INC.

uHead Ulnar Implant System

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Introduction

Ligament disruption, ulnar styloid fractures, and fractures into the distal radioulnar joint are common occurrences following fractures of the distal radius and other rotational instability injuries of the forearm. When there is loss of stability of the distal radioulnar joint, there is subsequent weakness in grip and pinch as well as potential loss of forearm rotation. Operative procedures with respect to treating the distal radioulnar joint have been to stabilize the ligaments about the joint or to resect the entire head of the distal ulna (Darrach procedure or equivalent). There have been variable results associated with the partial or complete resections of the distal ulna, particularly those performed by open resection. Similarly, ligament reconstruction of the distal ulna may be incomplete in restoring stability. With ulnar resection, both instability of the wrist and “snapping” of the forearm in rotational pronation/supination can occur. To date, the distal ulna remains an enigma with respect to procedures that provide adequate stabilization and support, and there has been no satisfactory effort towards replacing the distal ulna at this time.

Biomechanics research studies have demonstrated a need for prosthetic replacement of the distal ulna for load sharing across the carpus. The stabilizing elements of the triangular fibrocartilage (TFC), extensor carpi ulnaris (ECU) subsheath, and ulnar collateral complex are well recognized along with the importance of a distal ulna component (ulnar head) for transfer of compressive loads between the ulnar carpus and the distal ulna across the distal radioulnar joint.

It was with these areas of recognition that a design of an anatomic distal ulna prosthesis was initiated. Extended studies were performed to examine the soft tissue need for joint constraint (stability), as well as the anatomy of the distal radioulnar joint and the articular area between a prosthesis and the sigmoid fossa of the the distal radius. In addition, studies related to the center of rotation of the distal ulna as a reflection of a forearm rotation were analyzed. It was recognized that it was essential to have

an anatomic precise design to replace the distal ulna; to reattach the soft tissues to the distal ulna to provide a stabilizing influence; and to realign the forearm in order to duplicate the anatomy of forearm rotation. The consequence of the studies of the distal radioulnar joint has led to the development of a prosthesis that duplicates the normal anatomy of the distal ulna which aligns anatomically with the sigmoid fossa of the distal radius and is isosymmetric with the anatomic center of rotation of the forearm. It provides for reattachment of the triangular fibrocartilage, ECU subsheath, and ulnar collateral ligament complex to form a secure soft tissue pocket maintaining DRUJ stability.



Disorders of the Distal Radioulnar Joint

There are two disorders of the distal radioulnar joint which require surgical attention. The first is a fracture or dislocation involving the distal radioulnar joint in which there is a loss of forearm rotation related to either instability or incongruity between the sigmoid fossa of the distal radius and the ulnar head. A variety of different fractures involving the distal radius can cause this condition including the Colles' fracture and the Galeazzi fractures. Instability can be associated with either an injury to the triangular fibrocartilage or to the ulnar styloid. When instability is present, a number of ligament reconstructive procedures have been devised to assist in treating the unstable distal ulna. Where there is, however, incongruity of the joint surface involving either the articulation of the ulnar head with the sigmoid fossa of the distal radius or if there is a significant ulnar impaction syndrome between the distal articular surface of the head of the ulna and the ulna carpus, joint replacement of the distal ulna may be preferable to operative procedures designed to shorten the ulna or resect all or part of the distal ulna (i.e. Darrach, Bowers, or matched resection procedures).

The primary indications, therefore, for reconstruction of the distal radioulnar joint by prosthetic replacement (ulnar head replacement only) are generally related to a fracture of the distal ulna or a fracture extending into the distal radioulnar joint producing post-traumatic arthritis. Degenerative arthritis from other causes is also a primary indication. This is considered if there is associated arthritis and an ulnar shortening procedure is contraindicated. A third condition for primary ulna replacement is rheumatoid arthritis with a painful and unstable distal radioulnar joint. In these situations, prosthetic replacement of the distal ulna with soft tissue advancement can be beneficial.

A secondary prosthetic replacement (ulnar head prosthesis with an extended collar) is generally utilized when there has been a previous resection of the distal ulna such as A) partial resection of the joint articular surface, procedures which have been described by Feldon, Bowers, or Watson, or B) complete resection of the distal ulna as recommended by Darrach, Baldwin, and others. When faced with failed distal ulna resection, one has options towards reconstruction without restoring the distal radioulnar joint, for example by a pronator quadratus interposition, or, if there has been only a partial resection, a fusion of the distal radioulnar joint combined with a proximal pseudarthrosis (Suave-Kapandji procedure). These procedures, however, do not restore the normal DRUJ function of motion or load transfer and may be associated with instability of the distal ulna and proximal impingement of the ulna on the distal radius. In these cases, a distal ulna prosthesis may be a preferred option. Secondary reconstruction with distal ulna replacement has been beneficial under circumstances where there has been a failure of a partial or complete resection of the distal ulna or if there has been a previous prosthetic replacement such as a silicone ulnar head replacement which has failed.

Design Rationale

The distal radioulnar joint is a “shallow socket” ball joint. The radius articulates in pronation and supination on the distal ulna. The ulna, a relatively straight forearm bone linked to the wrist, translates dorsal-palmarly to accept the modestly bowed radius. Since the sigmoid fossa socket in most wrists is relatively flat, ligament support through the TFC, ECU subsheath, and ulnar collateral ligament complex is needed.

Prosthetic design to replace the distal ulna must, by the very nature of this joint, be anatomic. The normal forearm rotation of 150-170° should be accommodated within the design. The stability of the distal radioulnar joint requires that the support structures be intact, repaired, or advanced as indicated.

The uHead™ prosthesis is designed to replicate the anatomy of the ulnar head and its contact with the sigmoid fossa of the distal radius. It provides a very smooth, biocompatible cobalt chrome articulation with cartilage at the sigmoid notch and undersurface of the TFC. In addition, since a soft tissue pocket for maximum stability is required, the prosthesis provides for attachment of both the TFC and ulnocarpal ligament complex. Pre-set sites on the medial (ulnar) rim of the prosthesis allow for anchoring of soft tissues, whereby providing secure initial stability and potential for a long term anchor as soft tissue maturation occurs.

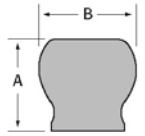
Biomechanics testing has been done on this prosthesis. Preliminary evaluation on a distal radioulnar joint simulator shows DRUJ normal kinematics; and isocentric center of rotation. In-depth stability testing including alternative methods for soft tissue reconstruction are in progress.

Three-dimensional CT studies have been used to determine the appropriate prosthesis size (ulnar head diameter and length) as well as size options for the intramedullary canal. The canal fit of the prosthetic stem determines alternatives of non-cemented press fit insertion or the use of bone cement. Bone cement would be preferred in the rheumatoid patient while a press fit would be acceptable in the post-traumatic patient. Experience to date demonstrates that a non-cement alternative should be satisfactory in most patients.

As part of the distal ulna prosthesis design, the ulnar head, standard stem, and extended collar stem have been made available in four interchangeable sizes.

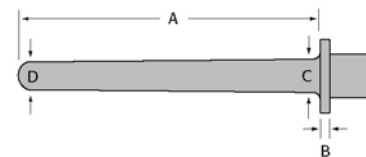
Ulnar Head Component

SIZE	CAT NO	DIMENSIONS (MM)	
		A	B
1	UHA-H1	12.0	13.0
2	UHA-H2	13.5	14.5
3	UHA-H3	15.0	16.0
4	UHA-H4	16.5	17.5



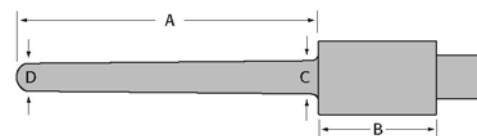
Standard Stem

SIZE	CAT NO	DIMENSIONS (MM)			
		A	B	C	D
1	UHA-S1	50	2	4.5	3.5
2	UHA-S2	50	2	5.5	4.5
3	UHA-S3	50	2	6.5	5.5
4	UHA-S4	50	2	7.5	6.5



Standard Stem

SIZE	CAT NO	DIMENSIONS (MM)			
		A	B	C	D
1	UHA-S120	50	20	4.5	3.5
2	UHA-S220	50	20	5.5	4.5
3	UHA-S320	50	20	6.5	5.5
4	UHA-S420	50	20	7.5	6.5



uHead Ulnar Implant System Surgical Technique

SURGICAL PROCEDURE

1 The Initial Incision, Ulnar Approach

The ulnar incision is made along the ulnar or medial shaft of the distal ulna in line with the ulnar styloid (**FIGURE 1**).

Dorsal Approach Alternative

The dorsal incision is used when there is a pre-existing incision or when the surgeon prefers the dorsal approach. The dorsal incision is centered over the distal radioulnar joint in line with the fourth metacarpal (**ALTERNATIVE FIGURE 1**).

After skin and subcutaneous tissue elevation, the extensor retinaculum is divided between the fourth and fifth extensor compartment and reflected ulnarly. The ECU subsheath and ECU tendon are left in place and elevated subperiosteally in a radial to ulnar direction as a capsular subperiosteal flap. With further distal subperiosteal release, the TFC and ulnar collateral ligament are in continuity with the ECU subsheath. After excision of the distal ulna, or in cases of previous partial or complete distal ulna excision, the subperiosteal dissection with the TFC and collateral ligaments will form a pocket to support the new head of the distal ulna.

NOTE: The extensor retinaculum should remain intact during reflection. Dissection of the capsule and subperiosteum should not violate the ECU subsheath. ECU subsheath and TFC should be repaired if there is soft tissue deficit or defect.

2 Incision of the Extensor Retinaculum

The extensor retinaculum is incised along the medial border of the distal ulna between the extensor carpi ulnaris (ECU) and flexor carpi ulnaris muscles (FCU). Care should be taken to protect the dorsal cutaneous branch of the ulnar nerve (**FIGURE 2**).

3 Ulnar Exposure of the Distal Ulna

With the extensor retinaculum reflected, the ECU tendon sheath is elevated subperiosteally off of the distal ulna along with the TFC and ulnar collateral ligament distally (**FIGURE 3**).

NOTE: The extensor retinaculum should remain intact during reflection in both radial to ulnar and ulnar to radial directions.

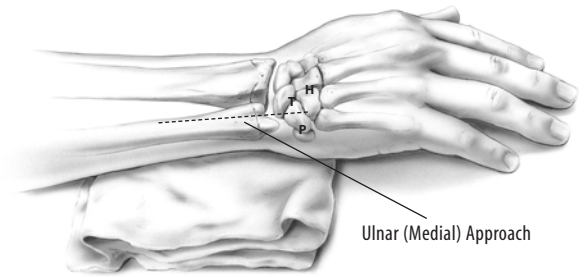
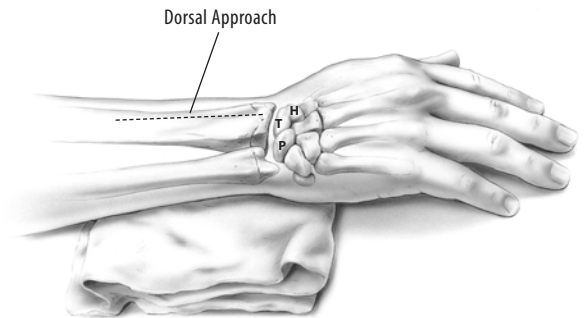


FIGURE 1



ALTERNATIVE FIGURE 1

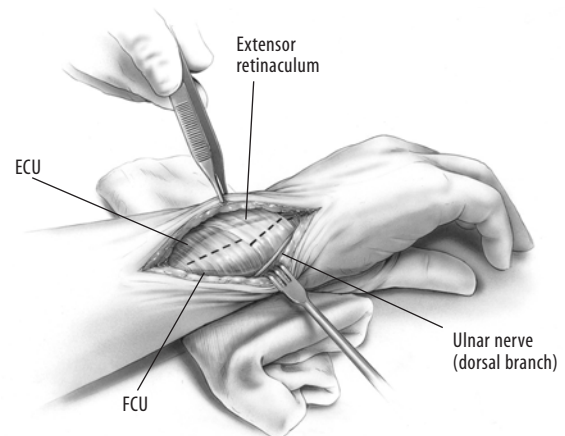


FIGURE 2

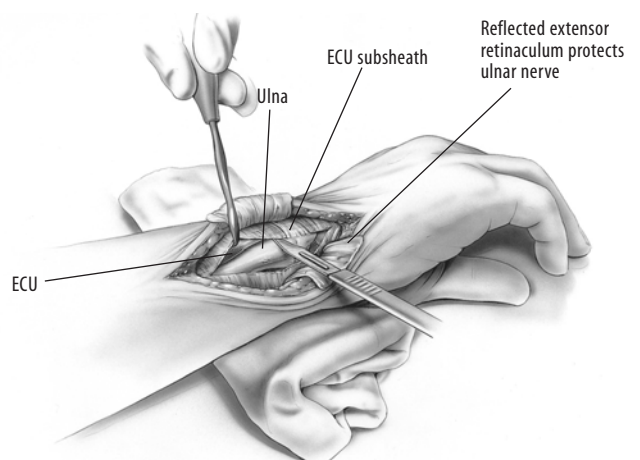


FIGURE 3

4 Determining Resection Length

The distal ulna resection template is used to determine the length of resection of the distal ulna. The template provides two groups of 4 notches (**FIGURE 4A**). Since all standard stems are the same length, differences in prosthetic length are achieved through different head sizes. The distal group of notches represents the four resection level options for a standard stem combined with one of four available head sizes. The proximal group of notches represents the resection level options for an extended collar stem combined with one of four head sizes. The extended collar stems are used when the distal ulna has been resected from a previous surgical procedure (Darrach procedure).

The template is located distally over the articular surface of the distal ulna. The appropriate resection length is marked with a pen or osteotome (**FIGURE 4B**). When the distal ulna is absent, the end of the sigmoid fossa of the distal radius can be used to estimate extended collar prosthesis length. The uHead™ x-ray template may also be used as an aid in selection of the appropriate size implants and their respective resection levels.

5 Resection of the Distal Ulna

The soft tissues about the distal ulna are protected with Hohmann retractors. The dorsal branch of the ulna nerve is protected distally. An oscillating saw is used to resect the distal ulna at the site marked by the resection template. Soft tissue attachments are released distally from the ulnar head if not performed earlier (**FIGURE 5A**).

After resection and removal of the ulnar head, the sigmoid notch of the distal radius is inspected for any incongruity or bone spurs. The under surface of the TFC is inspected for any tears. Any bone spurs should be removed and repair of soft tissues of the triangular fibrocartilage complex (TFCC) performed. The combination of periosteal sleeve elevation, ECU subsheath, ulnar collateral ligaments and TFC forms a pocket for support of the distal ulna prosthesis (**FIGURE 5B**).

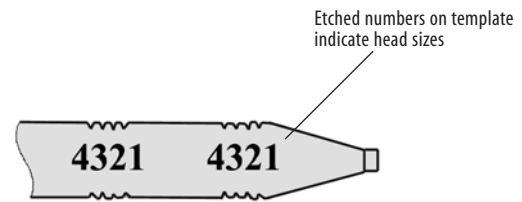


FIGURE 4A

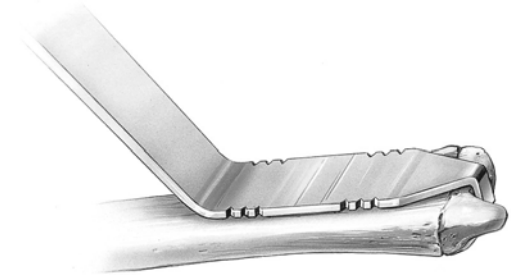


FIGURE 4B

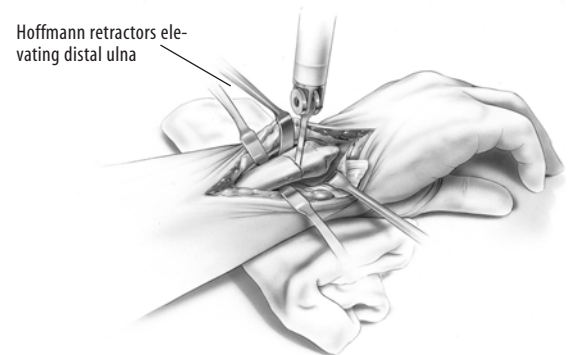


FIGURE 5A

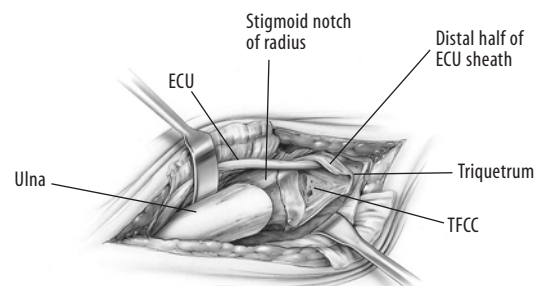


FIGURE 5B

6 Canal Preparation

The intramedullary canal of the distal ulna is identified with an awl or sharp broach and the canal is then reamed to the appropriate stem size (FIGURE 6).

7 Insertion of the Trial Stem

The appropriate size trial stem is inserted into the shaft of the distal ulna. The stem impactor is used to set the stem into the distal ulna. The collar should seat firmly against the resected surface of the distal ulna (FIGURE 7A).

If an extended collar stem is to be utilized, a trial spacer should be placed on the neck of the trial stem before the trial head is placed (FIGURE 7B).

8 Trial Head Insertion and Trial Reduction

The ulnar trial head is placed onto the neck of the implanted trial stem (or onto the spacer if an extended collar is to be used) and trial reduction into the sigmoid notch is performed. There should be smooth articulation of the ulnar head with the sigmoid notch without instability during forearm pronation and supination. Revision of the osteotomy of the distal ulna may be required if alignment is not anatomic. In some patients there may be a tendency for the prosthetic head to translate dorsally during passive forearm pronation. Gentle application of pressure dorsally by the surgeon should prevent this, indicating that stability should be achieved with the soft tissue repairs outlined in steps 10-13. Failure to achieve this stability may be the result of incorrect sizing of the components or level of osteotomy.

Any adjustments in length of the distal ulna are also made at this time. If the prosthesis is too distal, more distal ulna is resected. If the resection is too proximal, a build-up collar of bone cement may be required (FIGURE 8).

9 Implanting the Ulnar Stem Component

If the reduction of the distal ulnar head within the sigmoid notch is anatomically aligned, the trial ulnar head and stem are removed. Application of gentle, anteriorly directed pressure on the distal ulna may be necessary to dislodge the ulnar head from the sigmoid notch.

If a firm fit is obtained with impaction of the stem component, cement fixation is not necessary. Bone cement (polymethylmethacrylate) may be utilized, however, to fix the ulnar stem within the shaft of the distal ulna.

The final stem is inserted and impacted using the stem impactor. Care should be taken to protect the taper from any damage, including but not limited to scratches and contact with bone cement.

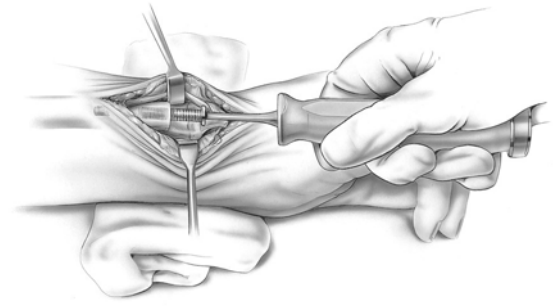


FIGURE 6

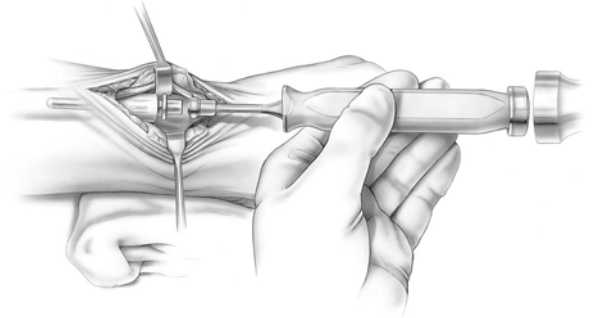


FIGURE 7A

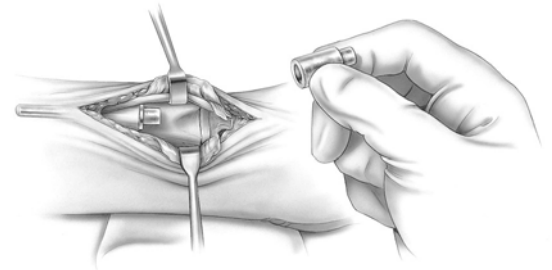


FIGURE 7B

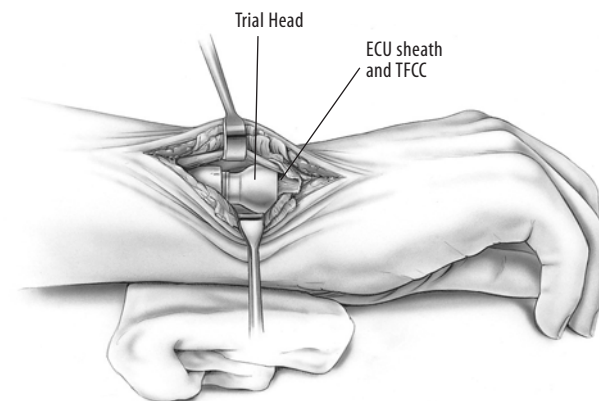


FIGURE 8

10 Securing the Ulnar Head

The ulnar head is secured to the soft tissues distally by placing non-absorbable sutures through the holes prepared in the head of the distal ulna and secured to the TFC and ulnar capsule. If the TFC proper is compromised by disease or previous surgery, the most ulnar remnant of the TFC is always present and can be used with the ECU subsheath as a suture anchor point. For a 2.0 suture a minimum of 5 knotted suture passes is suggested. Should a smaller diameter suture be used, more passes are required and for a larger diameter, suture fewer passes are needed. (FIGURE 10A and 10B).

The soft tissues of the distal ulna pocket are attached to the ulnar head. Non-absorbable sutures are recommended for secure fixation of the TFC, ECU subsheath and ulnar capsule to the prosthesis.

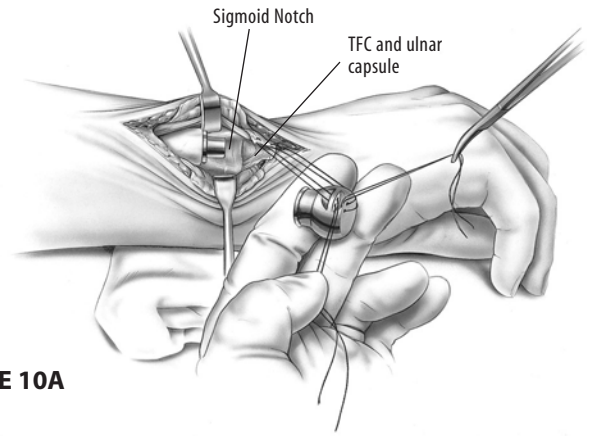


FIGURE 10A

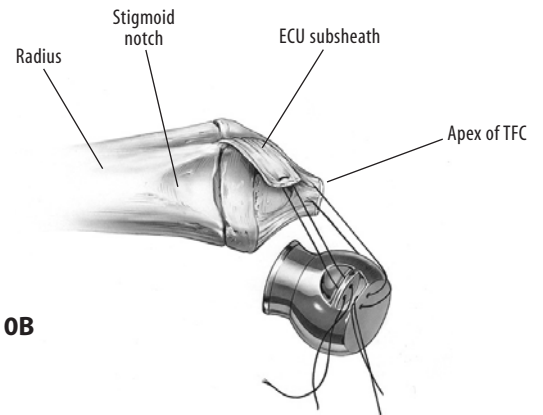


FIGURE 10B

11 Ulnar Head Impaction

The head of the distal ulna prosthesis is impacted on to the neck of the stem. Prior to assembly confirm that the tapers are dry and free from contaminant. The head should be placed on the stem gently while keeping the head and stem in alignment. Verify correct suture hole position prior to impacting. The head is then firmly attached by sharply hitting the head with the impactor or soft plastic hammer.

The head and stem should not be implanted if the tapers are possibly damaged. This includes repeated impaction and removal of the head.

The soft tissues are advanced ulnarly (medially) over the head of the distal ulna prosthesis. With the forearm in midrotation, the sutures are tied over the distal ulna.

NOTE: The placement of the soft tissue attachment holes should be medially in alignment with the the ulnar styloid axis distally and midline of the olecranon proximally (FIGURE 11B).

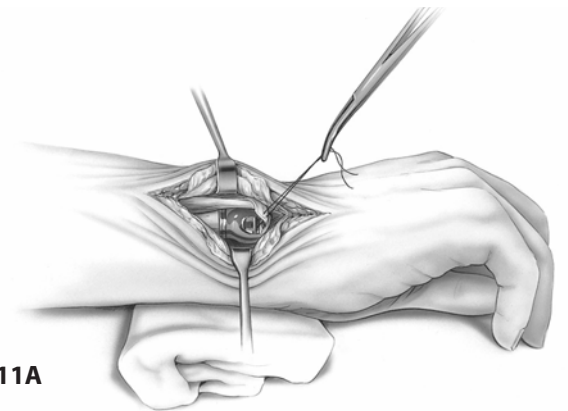


FIGURE 11A



FIGURE 11B

12 Capsular Closure

The remaining capsule over the distal ulna should be closed and imbricated, if possible, replacing the ECU tendon and tendon subsheath dorsally and closing the FCU-ECU interface. Stability of the prosthesis in pronation and supination can be tested at this time (**FIGURE 12**).

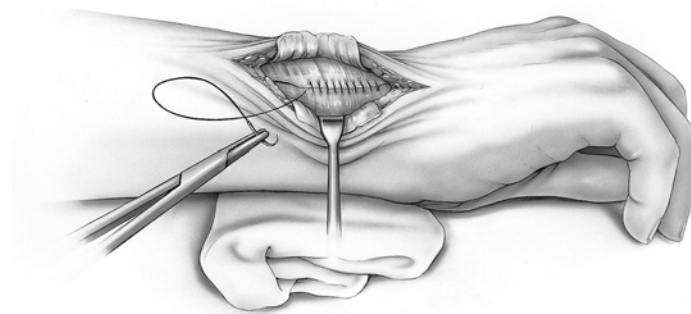


FIGURE 12

13 Extensor Retinaculum Closure

The extensor retinaculum is closed over the capsule, restoring the normal anatomic position of the extensor tendons (**FIGURE 13**).

After tourniquet deflation and sewing hemostases, the subcutaneous tissues and skin are closed over the appropriate sutures. A subcutaneous drain is recommended.

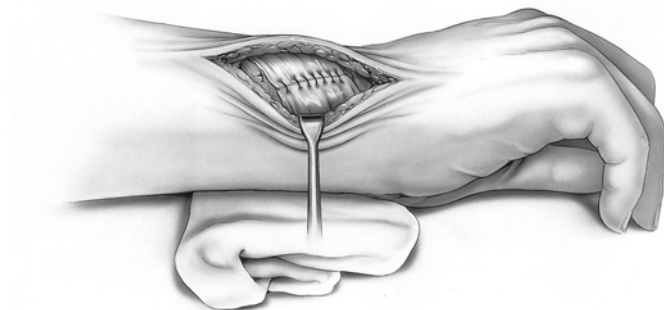


FIGURE 13

14 Rehabilitation

The forearm is immobilized in midrotation and held in a supportive long arm or muenster-type splint or cast for 3 weeks.

Active range of motion of the wrist and forearm are then initiated after 3 weeks, intermittently removing the splint up to 6 weeks. Therapy is then advanced as tolerated, beginning strengthening when the patient achieves a functional range of wrist and forearm motion.

Recheck of radiographs should demonstrate a stable distal radioulnar joint and are recommended at six week, six month, and yearly intervals.

In patients with soft tissue compromise, such as rheumatoid arthritis, the immobilization can be prolonged to 6 weeks prior to initiation of motion.

INDICATIONS

The uHead™ Ulnar Implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting the following:
 - Pain and weakness of the wrist joint not improved by conservative treatment
 - Instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes
 - Failed ulnar head resection

CONTRAINDICATIONS

- Malunited forearm fractures that preclude stabilization of the ulnar head during pronation/supination
- Tendon, ligament, or distal radioulnar joint which cannot provide adequate support or fixation for the prosthesis
- Inadequate soft tissue coverage
- Previous open fracture or infection in or around the joint
- Skeletal immaturity
- Known sensitivity to materials used in this device

WARNINGS, PRECAUTIONS AND PATIENT COUNSELING INFORMATION

WARNINGS (See also the Patient Counseling Information Section)

- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

PRECAUTIONS

- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and taper surfaces must not come in contact with hard or abrasive surfaces.
- The head and stem should not be implanted if the tapers are possibly damaged, this includes repeated attaching and detaching.
- The head of the prosthesis is impacted on to the neck of the stem. Prior to assembly confirm that the tapers are dry and free from contaminant.

PATIENT COUNSELING INFORMATION (See also Warnings)

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint 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, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.
- Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.

Please refer to implant package insert for additional product information including precautions and warnings.

Proper surgical procedures and techniques are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of this surgical technique based on his/her training, experience, and the patient's needs.

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