

TRUE/FLEX® Upper Extremity IM Rod System

Surgical Technique



encore™

***TRUE/FLEX*[®]**
**INTRAMEDULLARY ROD SYSTEM FOR
THE HUMERUS, RADIUS, AND ULNA**

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INTRODUCTION

**The TRUE/FLEX[®]
Intramedullary Rod System
for the Humerus, Radius, and Ulna**

US Patent Nos. 5,053,035; 5,100,405

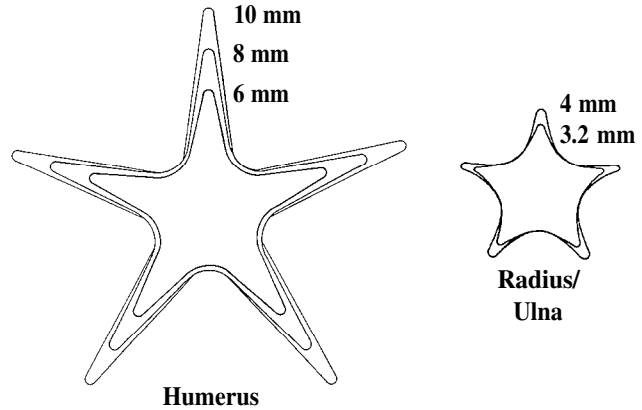
**Normal Fracture Healing Biology
-- Exceptional Fracture Control --**

The non-reamed **TRUE/FLEX[®]** humerus, radius, and ulna intramedullary rods maximally preserve normal fracture healing biology. Mechanically, the rods have optimal flexibility and are physiologically proportional between bending and torsion.

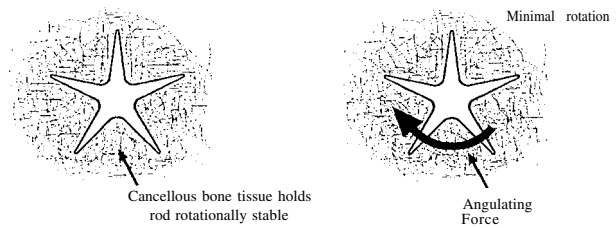
Five flutes on the rod make up a star cross section which interact with cancellous bone tissue to resist torsional forces (Figures 1&2). Traditional designs required interlocking screws to resist these forces. Implanting screws requires additional tissue dissection and presents a risk for nerve damage. In addition, traditional rod designs are much stiffer than bone, not allowing load sharing at the fracture site.

TRUE/FLEX[®] intramedullary rods employ a unique screw cap which secures the rod from migrating and is key to axial locking (Fig. 3). When the distal end of the rod is advanced into the far fracture fragment, axial length is maintained. The screw cap provides for adjustment of rod length and assists in rod removal.

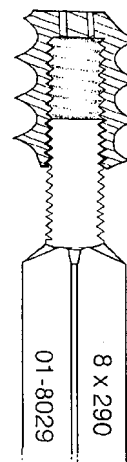
With non-reamed rods insertion time is significantly reduced, reducing the patient's anesthesia-related risks. Surgeon and patient benefit from less radiation exposure during the procedure. In addition, the design of the **TRUE/FLEX[®]** intramedullary rod allows insertion and fixation with less tissue dissection and blood loss than traditional rodding or plating techniques.



**Figure 1:
Cross Section of TRUE/FLEX[®] Rod**



**Figure 2:
Rotational Stability of Fluted Rod**



**Figure 3:
TRUE/FLEX[®] Axial Locking End Cap**

The **TRUE/FLEX[®]** intramedullary design optimizes rod flexibility to promote more normal healing. The unique design is of sufficient structural rigidity to maintain stability while remaining flexible enough to permit stress transmission to the fracture site to promote more natural healing.

TRUE/FLEX[®] humerus rods are provided sterile in 6mm, 8mm, and 10mm diameters of various lengths (see Table 1 and Figure 4). Each of the rod lengths has an effective continuum of an additional 1 cm by advancing the screw cap.

Diameter	6mm	8mm	10mm	
ROD LENGTH	23cm	23cm	23cm	
	25cm	25cm	25cm	standard rod sizes
	27cm	27cm	27cm	
	29cm	29cm	29cm	
	31cm	31cm	31cm	custom size

Table 1:
TRUE/FLEX[®] Humerus Rod Sizes

TRUE/FLEX[®] screw caps are provided sterile in small, medium, and large sizes (see Table 2). Each cap size will fit with any of the rod diameters. Appropriate cap size selection is based on patient anatomy and the condition of the bone (choosing the largest size possible will provide the best axial fixation -- especially in osteoporotic bone tissue).

Cap Size	Small	Medium	Large
Indicated Use	typically used on smaller patients or those with dense cancellous bone tissue	typically used on average sized patients or those with normal cancellous bone tissue	typically used on large patients or those with osteoporotic cancellous bone tissue

Table 2:
TRUE/FLEX[®] Humerus Screw Cap Sizes

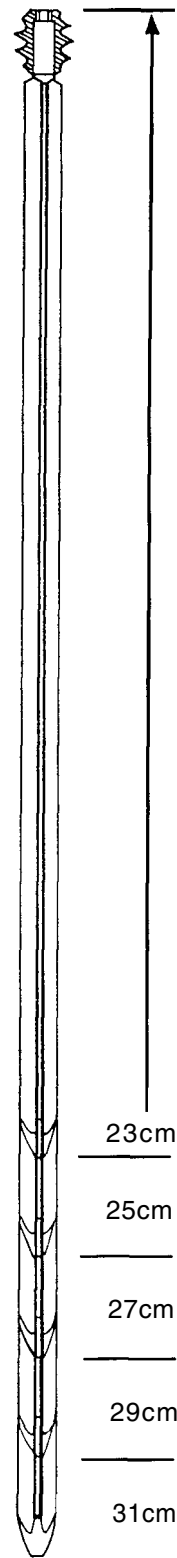


Figure 4:
TRUE/FLEX[®] Humerus Rod Lengths

TRUE/FLEX[®] radius rods are provided sterile in 3.2mm and 4mm diameters of various lengths (see Table 3 and Figure 5). Each of the rod lengths has an effective continuum of an additional 1cm by advancing the screw cap.

Since **TRUE/FLEX[®]** intramedullary rods are designed for anatomical conformity, radius rods come in right and left configurations.

Diameter	3.2mm	4mm
ROD LENGTH	19cm	19cm
	21cm	21cm
	23cm	23cm
	25cm	25cm

Table 3:
TRUE/FLEX[®] Radius Rod Sizes

TRUE/FLEX[®] ulna rods are provided sterile in 3.2mm and 4mm diameters of various lengths (see Table 4 and Figure 5). Each of the rod lengths has an effective continuum of an additional 1cm by advancing the screw cap.

Diameter	3.2mm	4mm
ROD LENGTH	21cm	21cm
	23cm	23cm
	25cm	25cm
	27cm	27cm
		29cm

Table 4:
TRUE/FLEX[®] Ulna Rod Sizes

TRUE/FLEX[®] radius/ulna end caps are provided sterile threaded or unthreaded. The threaded end caps allow the surgeon to adjust the rod length up to 1cm deeper into the intramedullary canal as well as assisting in rod removal by retracting the rod from the canal. The unthreaded end cap guards soft tissue from the machine threads of the rod and protects the machine threads of the rod to allow for easy attachment of the radius/ulna rod driver/extractor in the case that rod removal is desired.

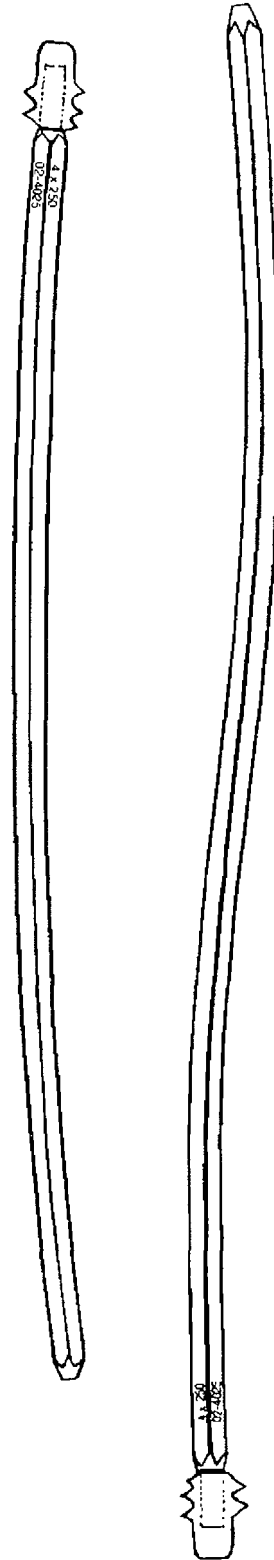


Figure 5:
TRUE/FLEX[®] Radius and Ulna Rod Lengths

INDICATIONS

Midshaft fractures of the humerus, radius, and ulna of all patterns (transverse, short oblique, long oblique, butterfly, segmental, and all grades of comminution) may be treated with the **TRUE/FLEX[®]** intramedullary rod system.

HUMERUS: The suggested limitations are that the humeral head, and the humeral condyles, with 5cm proximal to the olecranon fossa, must be intact (please see Figure 6). For very proximal shaft fractures the surgeon may wish to use a tension band wire(s) to supplement fixation.

RADIUS: The suggested limitations are that the radius must have 5cm intact proximal to the insertion site at the distal epiphysis and that the bone segment proximal to the biceps tuberosity must be intact (please see Figure 7).

ULNA: The suggested limitations are that the ulna must have 3cm intact from the articular surface distally and that the bone segment proximal to the level of the biceps tuberosity must be intact (please see Figure 7).

Associated soft tissue injuries can dictate limitations for use of the **TRUE/FLEX[®]** intramedullary rod system, as with all internal fixation devices. As non-reamed devices, **TRUE/FLEX[®]** intramedullary rods may be appropriate for grade 1 and grade 2 open injuries.

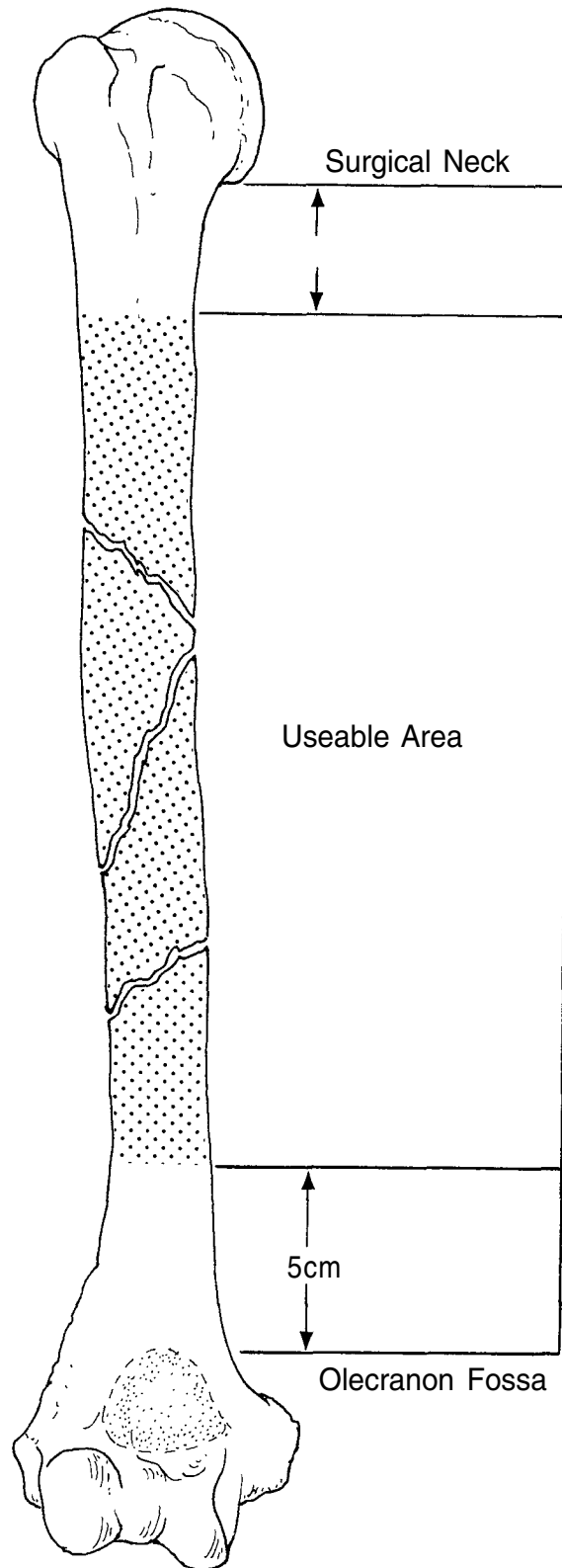


Figure 6:
Indicated Treatment Sites for the
TRUE/FLEX[®] Humerus Rod

CONTRA-INDICATIONS

The use of the *TRUE/FLEX[®]* humerus, radius, or ulna intramedullary rod is not recommended for:

- cases where there is active infection
- cases where the rod would cross open epiphyseal plates

When there is marked osteopenia, the surgeon should choose the largest end cap size available to obtain as much purchase in the cancellous bone as possible. There are some cases in which the bone is deteriorated to the point where the end cap will not gain sufficient purchase to provide adequate axial locking. In these cases the rod should only be used in the dynamic mode.

As with all intramedullary rods, it is possible to incarcerate the *TRUE/FLEX[®]* humerus, radius, or ulna rod in an intramedullary canal that is too small in diameter.

CAREFULLY MEASURE THE CANAL DIAMETER BEFORE INSERTING THE ROD.

DO NOT ATTEMPT TO INSERT A ROD WHICH IS LARGER THAN THE CANAL DIAMETER. Stop advancing the rod if there is resistance in the diaphyseal region.

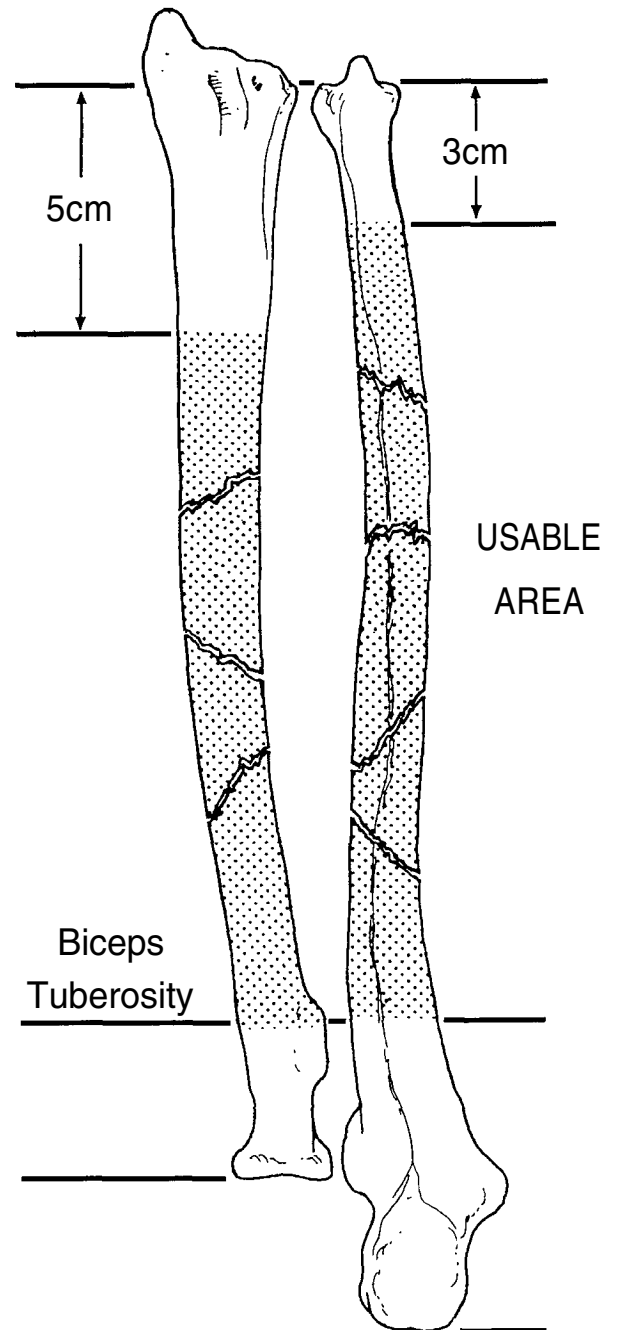


Figure 7:
Indicated Treatment Sites for the
TRUE/FLEX[®] Radius and Ulna Rods

PREOPERATIVE PLANNING

NOTE: Selecting the appropriate rod size is critical to the success of the procedure. The rod chosen must be 1cm shorter than the length of the intramedullary canal and narrower than the canal at its narrowest section.

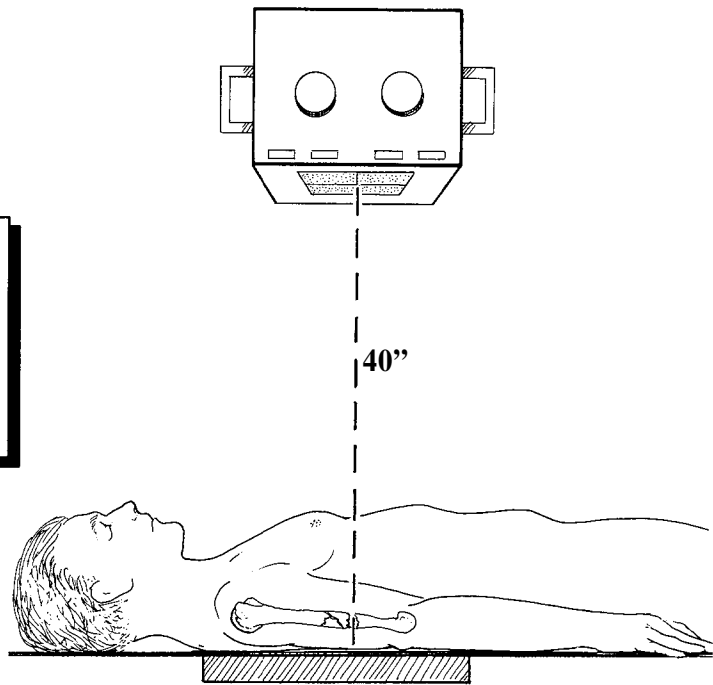
The security of the fixation is dependent on the stability of the interfaces -- both between the rod and the proximal fragment, and between the rod and the most distal fragment. The intervening fracture lines and comminution are unimportant for fixation.

Satisfactory X-rays are required to determine if the key fragments, proximally and distally, are suitable to provide sufficient purchase for the rod. These X-rays are best obtained using a focal-film distance of 40 inches with the humerus or forearm lying directly on the film cassette (Figures 8 and 9).

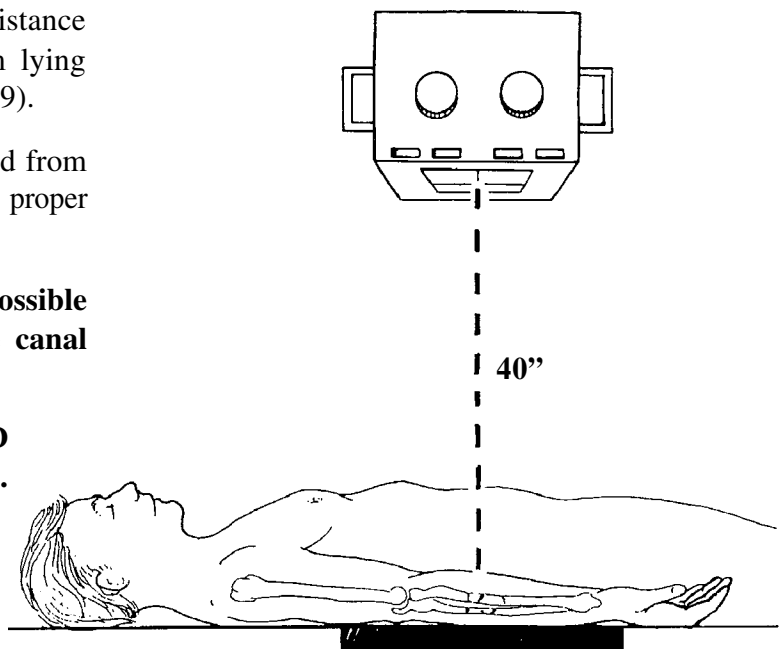
The length of the fragments can be measured from the X-ray and added together to determine the proper rod length

The rod chosen should be the largest possible diameter, but must be smaller than the canal width measured at the smallest point.

DO NOT ATTEMPT TO INSERT A ROD THAT IS LARGER THAN THE CANAL. IT MAY BECOME INCARCERATED.



**Figure 8:
Measuring Length and Canal Diameter
of Fractured Humerus**



**Figure 9:
Measuring Length and Canal Diameter
of Fractured Radius and/or Ulna**

Frequently, fracture comminution or angulation make measurement of the fractured bone inaccurate. In such cases the appropriate bone in the opposite arm may be X-rayed to determine the rod length. A true lateral view, taken from the medial to the lateral with the arm fully abducted and a focal distance of 72 inches will give the most accurate measurement (Figures 10 and 11).

Intraoperatively the length can be measured using the 2.5mm intramedullary measuring rod. The rod, calibrated in 2cm increments (starting at 17cm) is inserted to the terminal end of the canal, removed, and the length measured with a metric ruler (Figure 12).

Whenever possible, the intraoperative measurement technique is recommended over the X-ray measurement method.

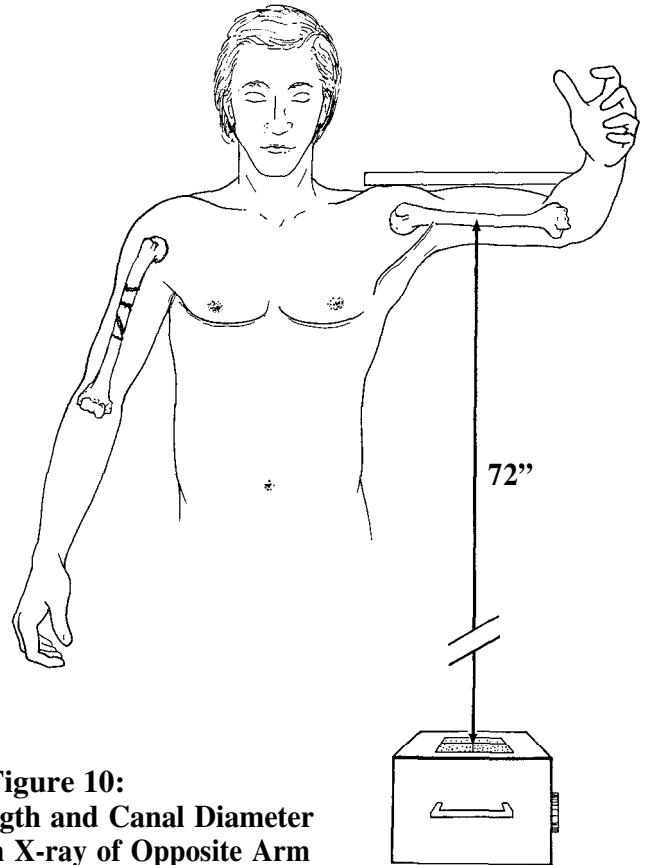


Figure 10:
Measuring Length and Canal Diameter
of Humerus with X-ray of Opposite Arm

NOTE: If X-ray magnification makes it difficult to accurately determine the canal diameter, it is often advantageous to place an object of known size (e.g. an 8mm or 4mm Rush Rod) at the same level as the injured bone during the X-ray. The object will be magnified to the same extent as the IM canal. This will provide a relative indication of the appropriate diameter rod to use.

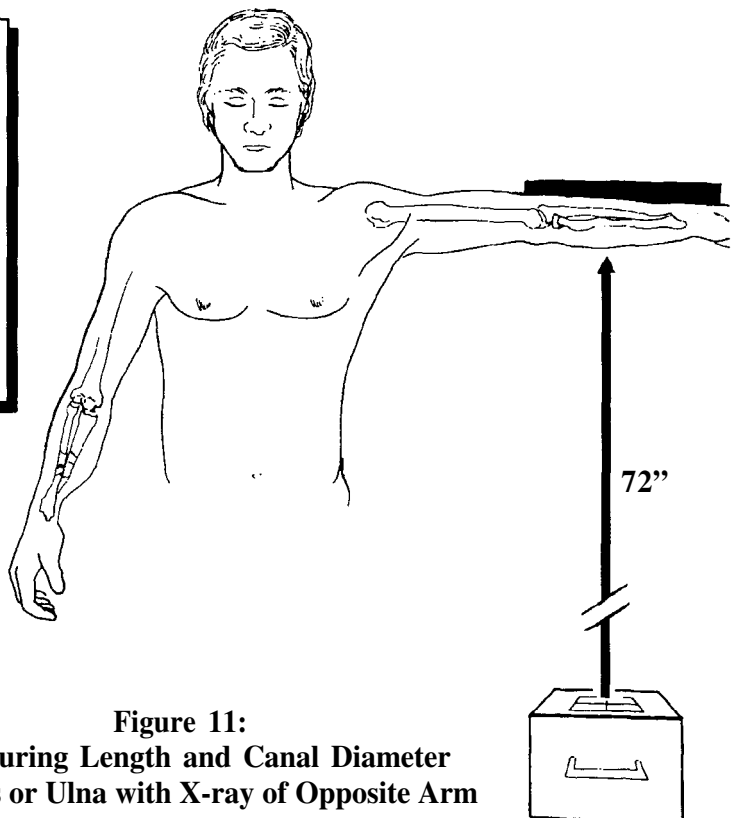


Figure 11:
Measuring Length and Canal Diameter
of Radius or Ulna with X-ray of Opposite Arm

PREOPERATIVE PLANNING (cont)

HUMERUS: The humerus rod chosen should be 1cm shorter than the canal from the subchondral region of the humeral head to the terminal taper above the olecranon fossa. (Figure 13) The diameter of the humerus rod should be 1mm narrower than the narrowest section of the intramedullary canal.

RADIUS: The radius rod chosen should be 1cm shorter than the canal from the entry point (5mm proximal to the distal articular surface) to the subchondral bone of the radial head. (Figure 14) The diameter of the radius rod should be 0.5mm narrower than the narrowest section of the intramedullary canal.

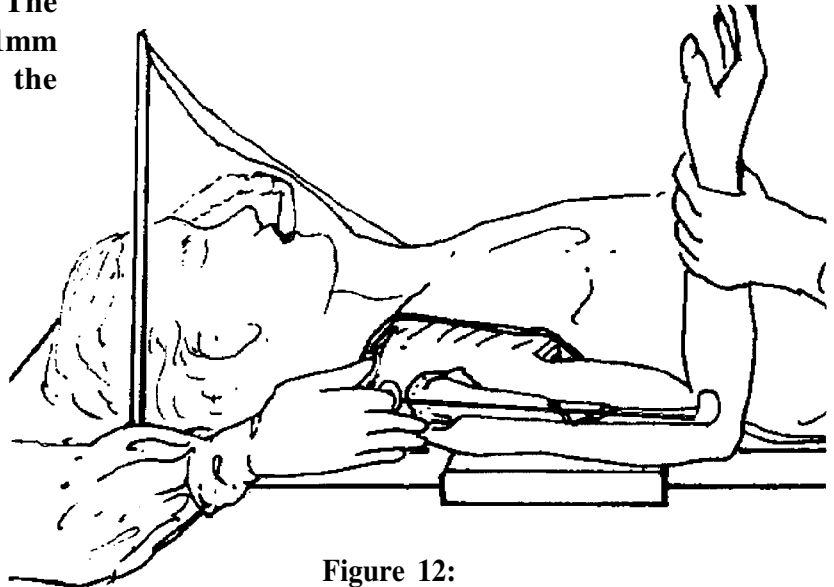


Figure 12:
Using Measuring Rod to Determine Canal Length

ULNA: The ulna rod chosen should be 1cm shorter than the canal from the entry point (the olecranon process) to the subchondral bone at the distal end of the ulna. (Figure 14) The diameter of the radius rod should be 0.5mm narrower than the narrowest section of the intramedullary canal.

NOTE: Remember that the cap adds an extra 0.2cm-0.8cm to the overall implant length. In addition the differential pitches between the cap/rod interface and the cap/bone interface allow the overall implant to be advanced up to 1cm below the cortical surface.

If these factors are not considered it is common to choose a rod length that is too long for the chosen procedure.

It is important to choose a rod which is at least 1cm shorter than the distance from the bone surface at the entry point to the end of the IM canal of the injured bone.

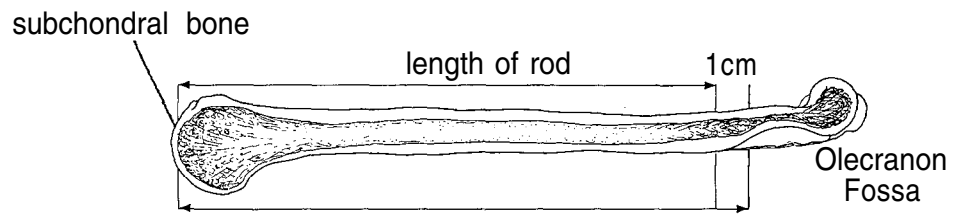


Figure 13

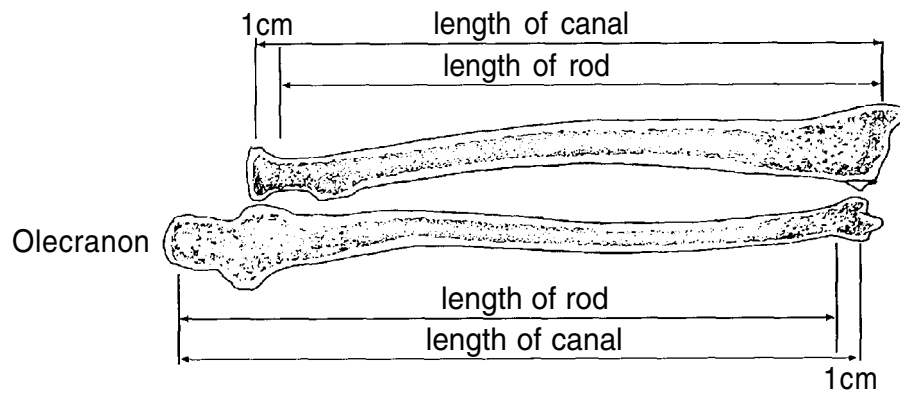


Figure 14

OPERATIVE PROCEDURE: HUMERUS

POSITIONING

Patient and arm positioning can dramatically affect the ease of reduction and rod insertion.

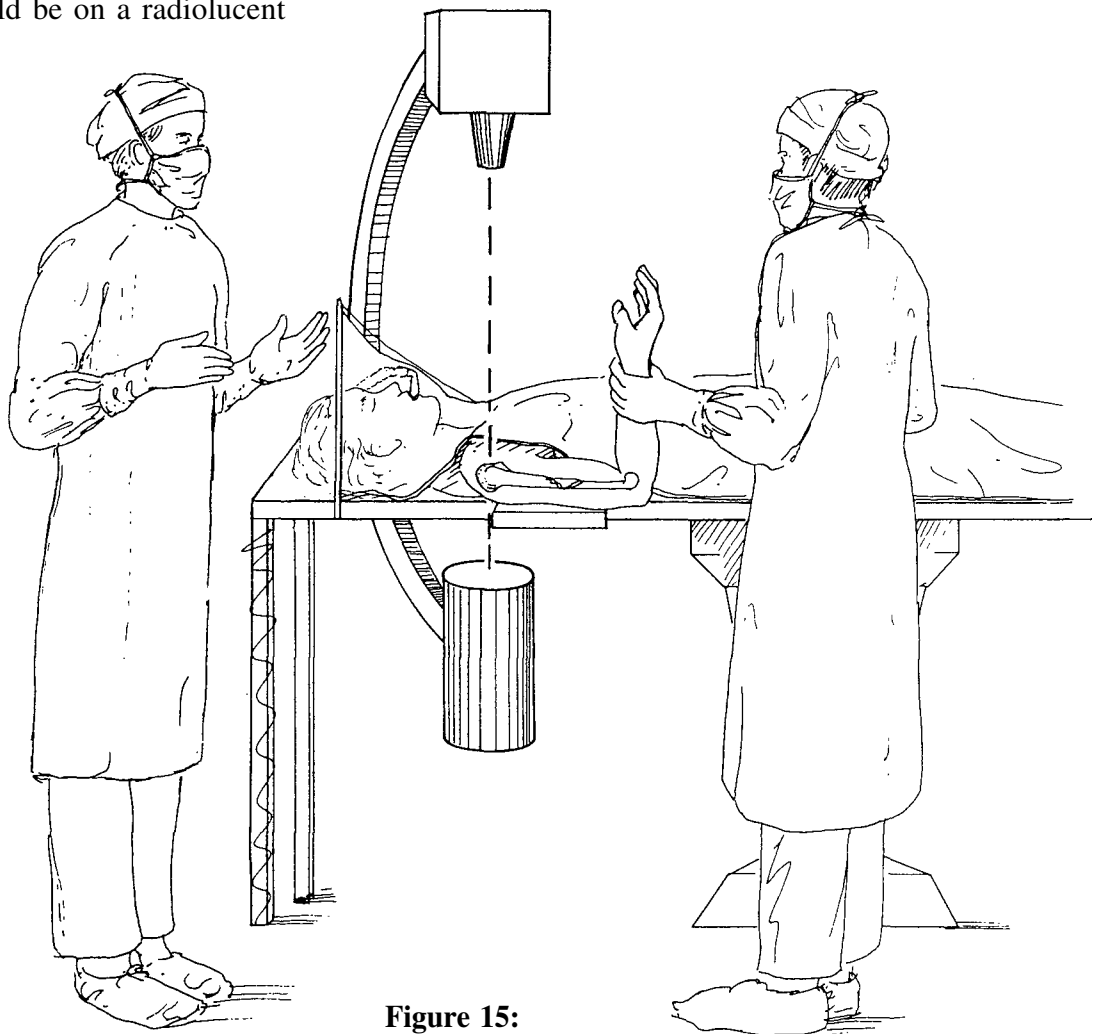
The patient is supine with the shoulder elevated above the level of the heart.

To gain adequate visualization with the C-arm, the head, neck, and chest should be on a radiolucent table extension, such as an extension used for cardiac pacemaker insertion (Figure 15).

The C-arm is positioned perpendicular to the patient on the side opposite to the fracture. The C-arm goes over the top to obtain the lateral scapular view.

The arm may be supported on a radiolucent board. A small support under the scapula is used to elevate the shoulder.

The operating surgeon stands at the shoulder, and the assistant stands at the elbow.



**Figure 15:
Patient Positioning**

FLUOROSCOPIC VIEWS

The AP view is obtained in the routine manner: The C-arm is vertical with the intensifier under the shoulder and the cone is above (Figure 16). This is the desirable position for the entire humerus.

If an orthogonal view to the lateral scapular view at the shoulder is desired, a C-arm that goes past the AP position is required. The lateral scapular view is generally better than the full lateral view, because of the overlying shadows from the thorax on the lateral view and because the proximal fragment is difficult to rotate to a lateral position.

To obtain a lateral scapular view of the proximal humerus, the C-arm is brought to a position 35° less than the full lateral position. The view is used to check that the entry point is not too far posterior. The radioluscent table extension allows free movement of the C-arm under the patient and an unobstructed view of the proximal humerus.

The majority of the procedure is done in the AP plane, using the lateral scapular plane intermittently to check the entry point, the reduction, and the intramedullary position of the rod.

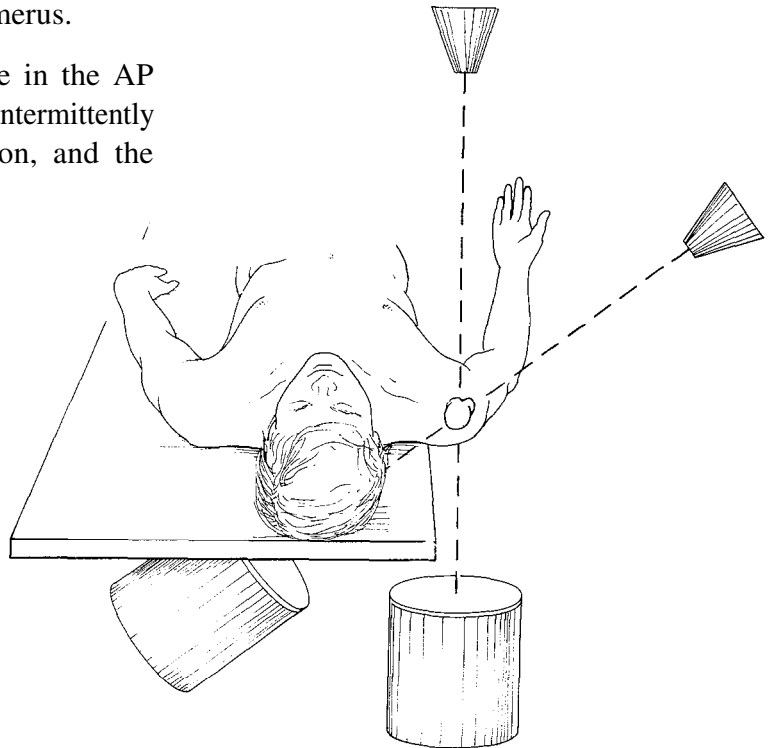


Figure 16:
Fluoroscopic Views

HUMERUS PROCEDURE (cont)**SURGICAL APPROACH**

With the patient positioned as described previously, trial reduction can be performed under fluoroscopy on a radiolucent table extension.

The upper extremity is scrubbed and prepared and draped free. Prepping and draping is facilitated by abducting the shoulder. The shoulder is then adducted to a position near the patient's side.

The incision is made starting over the lateral corner of the acromion, directed obliquely in the direction of the fibers of the deltoid muscle, at the junction of its anterior and middle thirds.

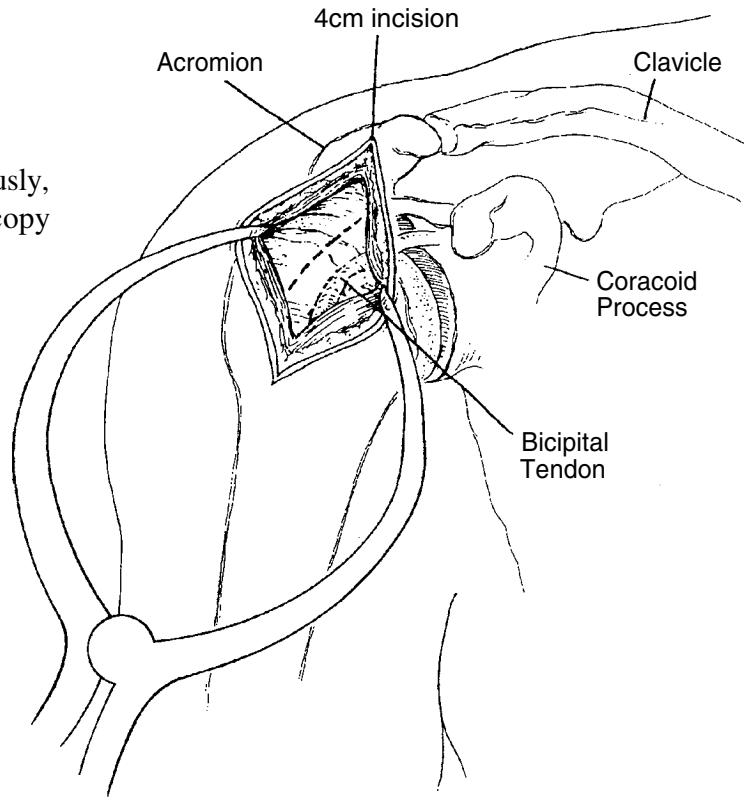
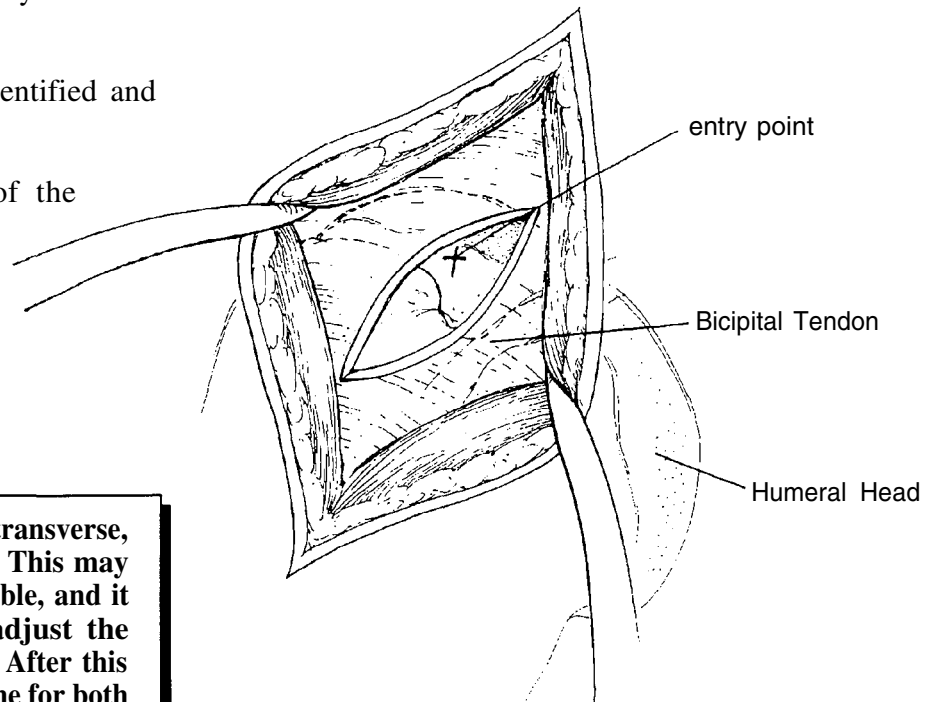
The deltoid is split in the direction of its fibers (Figure 17).

The subdeltoid bursa is entered.

The bicipital groove and greater tuberosity are identified.

The tendon of the supraspinatus is identified and split in the direction of its fibers.

The edge of the articular surface of the humerus is then identified (Figure 18).

**Figure 17****Figure 18**

NOTE: An alternate skin incision is transverse, just distal to the acromion. This may be cosmetically more desirable, and it allows more latitude to adjust the location of the deltoid split. After this step the procedure is the same for both incisions.

ENTRY POINT

The entry point is between the greater tuberosity and the articular surface of the humeral head, 1cm-1.5cm posterior to the biceps tendon (Figure 19). In some cases this will be slightly lateral to the center of the intramedullary canal. This is acceptable, however, because the flexibility of the *TRUE/FLEX*[®] intramedullary rod will accommodate minor variations in the entry point.

The bone is penetrated with the hand awl (Figure 20). The position of the awl is then confirmed on AP and lateral scapular views with fluoroscopy. If the awl is centered correctly over the canal it is then advanced until the cone is fully flush with, **but not deep** to, the cortical surface. Penetrating the cortex beyond the top of the cone of the awl could compromise the ability of the threads of the cap to engage the cancellous bone.

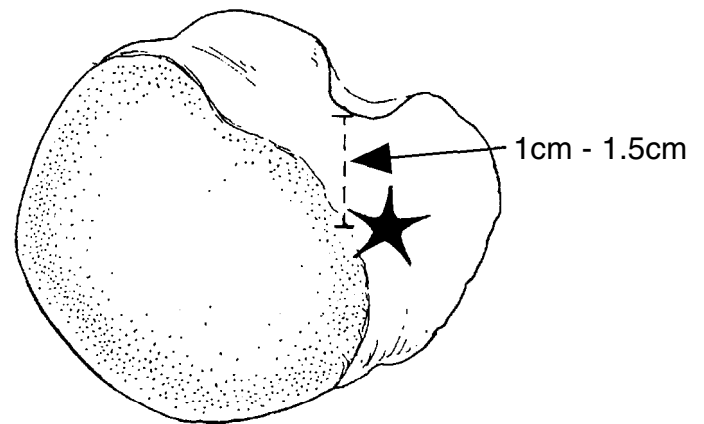


Figure 19:
Entry Point for *TRUE/FLEX*[®] Humeral Rod

ROD INSERTION

If there is uncertainty with respect to choosing the correct rod size after measuring the preoperative X-rays, then measure the canal using the intramedullary measuring rod before opening the IM rod implant box. The intramedullary measuring rod is inserted through the entry hole, down the canal, and across the fracture into the distal fragment (in a manner similar to passing a guide wire for reamed rods).

A rod of the pre-measured length and diameter is screwed onto the driver. **Make certain that the driver is completely screwed on to the rod.** This protects the threads on the rod from excessive stress.

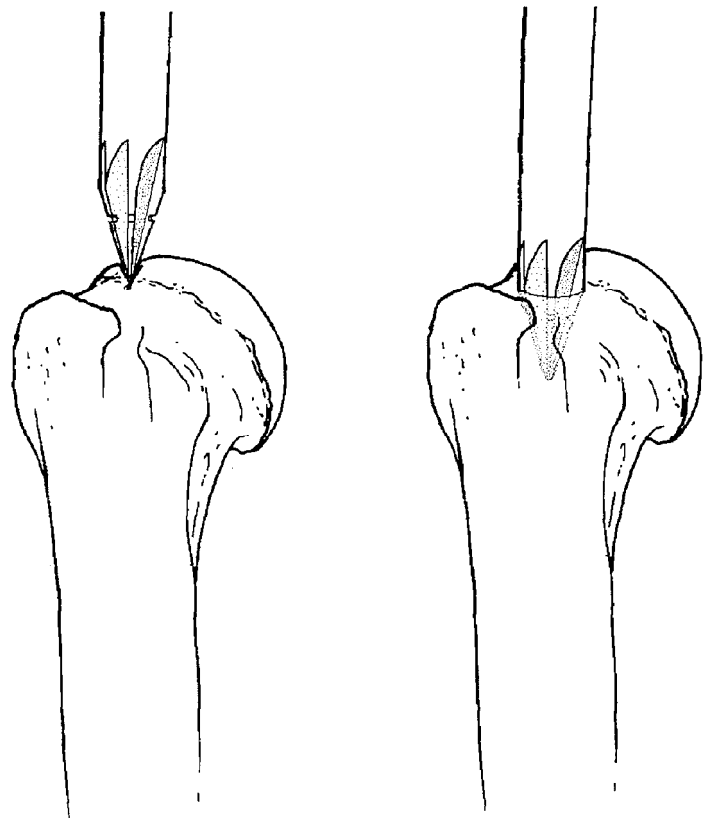


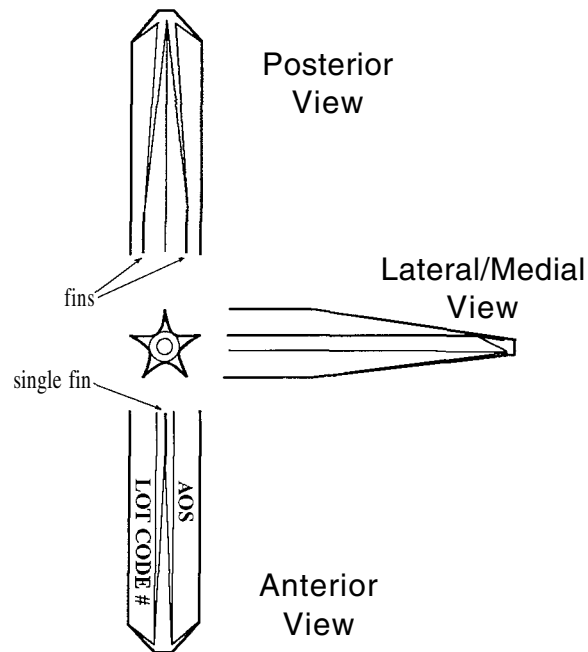
Figure 20:
Penetrating Humerus with Awl

HUMERUS PROCEDURE (cont)

Obtaining correct rod orientation is critical before starting to drive it into the cancellous bone of the humeral head.

As depicted in Figure 21, the **TRUE/FLEX®** humerus rod has a distinct anterior/posterior geometry. The rod is flattened in the medial lateral plane with a single sharply beveled fin directed toward the anterior and two sharply beveled fins directed posterior.

The rotation **must** be oriented with the flattened distal end in the medial lateral plane. This will put a single, sharply beveled fin directly anterior.



**Figure 21:
Rod Flute Orientation**

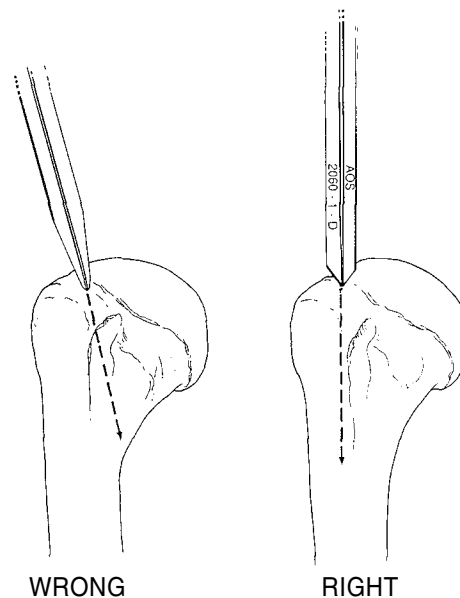
NOTE: The correct single fin, which must be oriented anteriorly, can be identified by etched writing on the adjacent two fins (Figure 22).

NOTE: Once the rod has been driven even 1cm into the cancellous bone, angular realignment is difficult, and rotational realignment is impossible.

The rotational alignment is confirmed by the orientation of the anterior fin. The angular alignment is confirmed on AP and lateral scapular views using fluoroscopy before advancing the rod down the canal.

With the rod engaged 1 cm into the cancellous bone, the orientation, both rotationally and angularly, is reconfirmed. If the orientation is incorrect, the rod should be removed and reinserted in the correct position. If a larger hole is required to reinsert the rod the surgeon should use a larger end cap during the axial locking procedure.

Using a hammer, the rod is advanced into the fracture site until approximately 1mm-3mm of rod extends beyond the fracture gap (Figure 23).



**Figure 22:
Rod Insertion**

NOTE: *If resistance is met during the advancement of the rod into the diaphysis, insertion must be stopped to prevent incarceration. When resistance is met, remove the rod and insert a new one of the next smaller diameter.*

After the rod is advanced to the fracture site, the fracture is reduced. The rod is then advanced a few more millimeters into the distal bone fragments.

NOTE: *During reduction, it is usually better if the surgeon and the assistant change places. The surgeon can perform the reduction while the assistant advances the rod (with gentle hammer strikes to the driver).*

The reduction is checked in both planes with fluoroscopy before advancing the rod further across the fracture site.

Rotational malalignment may be impossible to correct after the rod has engaged the distal fragment by 1cm or more. If there is a rotational malalignment at the fracture site after the rod has been passed into the distal fragment, the rod *must* be backed out to the fracture site *before* the rotation can be corrected.

The correct rotational alignment is best achieved with the proximal fragment left in the neutral position. The distal fragment is aligned with the elbow bent 90° and the forearm pointing toward the ceiling.

With rotational alignment correct, and the rod about 1cm into the distal fragment, the angular alignment is confirmed on both fluoroscopic views. The rod is then advanced into the distal fragment until the proximal end of the rod is still 2-3cm outside of the soft tissue of the shoulder.

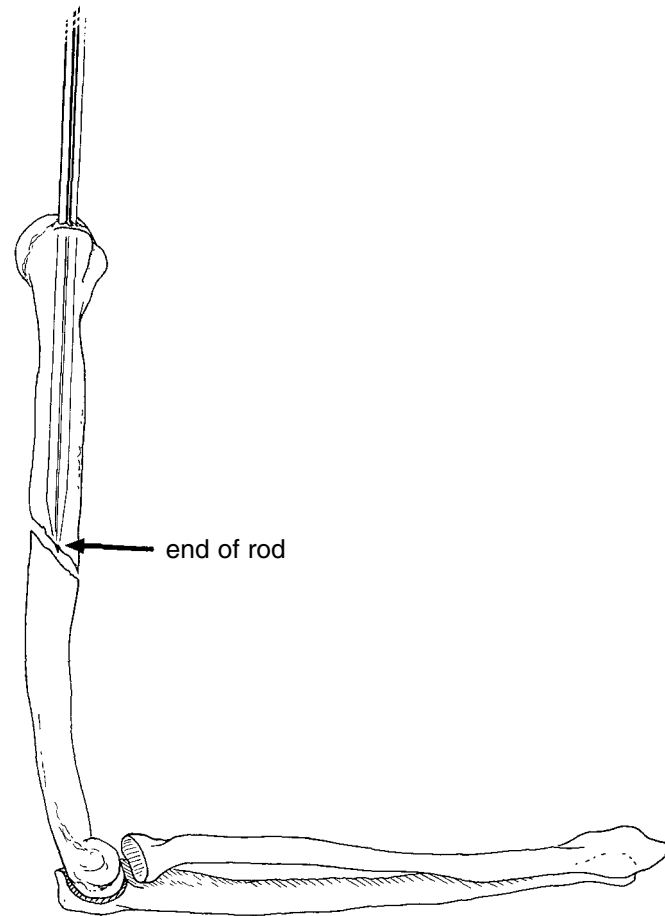


Figure 23

HUMERUS PROCEDURE (cont)

LOCKING THE ROD
WITH THE SCREW CAP

The locking screw cap has an outer self-tapping cancellous thread and an inner machine thread to match the threaded end of the rod.

The cap may be driven by a standard 3.5mm hexagonal screwdriver.

When the cap is screwed onto the rod, each complete revolution of the cap around the rod has the net effect of advancing the rod 2mm into the canal. This movement is the result of the difference between the smaller machine threads on the rod/cap interface and the larger external cancellous threads on the cap.

Place the hex end of the screw cap on the hex screwdriver. The screw cap is secured to the rod with 2 turns onto the threaded end of the rod (Figure 24). **Do not attach the cap onto the rod with more than two 360° turns at this time.**

NOTE: If the cancellous bone tissue is severely osteoporotic, then it is recommended that the screw cap be attached with an additional 2-3 360° turns so that the cap is resting on the shoulder of the rod after the rod has been fully advanced.

To ensure proper seating of the screw cap into the entry hole of the bone, gently tap the end of the screwdriver until the cancellous threads of the screwcap are flush with the entry hole.

With the cap threads seated in the entry hole, gently tap the hex screwdriver while simultaneously turning the driver (Figure 25). This will help the threads engage in the cancellous bone of the humeral head. Once the threads are securely engaged in the cancellous bone tissue, the screw cap may be turned into the head until it is flush or just below the cortical bone.

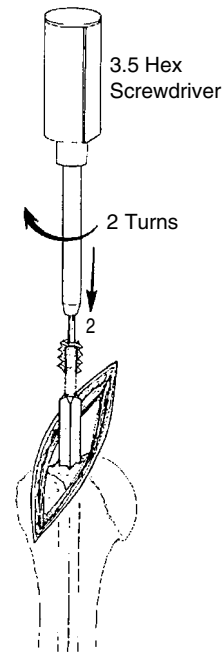


Figure 24:
Attaching Screw Cap to Rod

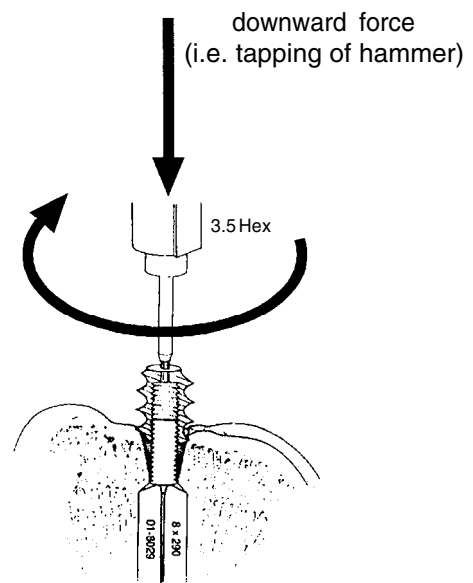


Figure 25:
Advancing Screwcap

The cap does not have to be fully seated on the threads of the rod. It is important to make certain visually, and fluoroscopically, that the screw cap is deep into the bone surface to prevent impingement in the rotator cuff under the acromion (Figure 26).

NOTE: At this point the rod is about 5mm deeper than the top of the cap. It is important that the rod be at least 1cm shorter than the measured canal length.

NOTE: Watch the distal end of the rod and the fracture site intermittently in the AP view on fluoroscopy during the final seating of the rod.

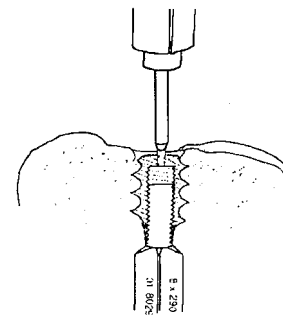


Figure 26:
Advance Screw Cap Until Flush With Cortical Surface

Intrinsic to the design of the rod is rotational and angular stability from the fin engagement in the cancellous bone proximally and distally. Additional fixation to lock motion in these planes is not necessary.

Axial locking, however, is not provided by the fins. A non-locked rod can migrate axially. It is, therefore, important to use the screw cap locking mechanism in every case.

If the rod is to be used in the dynamic mode, choose a shorter rod which will not engage in the tapered distal end of the canal.

If static locking is desired to prevent limb shortening, the distal end of the rod must engage the taper of the distal canal above the olecranon fossa.

The screw cap can be advanced up to 1cm below the cortex of the humeral head to precisely adjust the length of the rod accordingly (Figure 27).

If the fracture site begins to distract, stop advancing the screw cap. The final position and alignment of the fracture fragments and the rod (including the distal tip and the screw cap) *must* be confirmed in both fluoroscopic views.

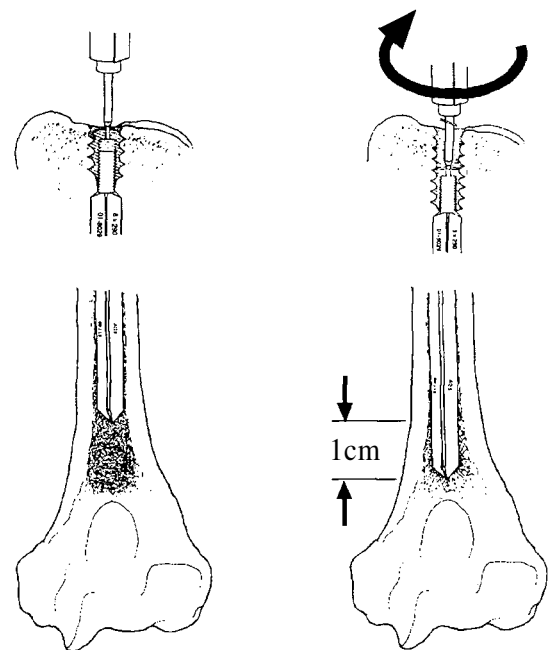


Figure 27:
Adjusting Rod Length with Screw Cap

HUMERUS PROCEDURE (cont)

If the fracture site begins to distract before the screw cap is fully seated, check the distal end of the rod with the fluoroscope. If the rod has fully seated with the distal taper of the canal, a shorter rod must be chosen.

NOTE: If the distal end of the rod is not advancing into the distal canal properly, the problem may be the rotation of the rod.

There is about 30° of rotational tolerance between the rod geometry and the geometry of the intramedullary canal at the distal end of the humerus (Figure 28). If the rod is malrotated more than 30°, it will not advance into the distal canal.

To check this possibility look at the lateral view on the fluoroscope carefully. The narrow, tapered section of the rod should match the narrow tapered section of the canal. If the wide fins (with the 45° taper) are seen at the tip of the rod in the lateral view (Figure 29), the rod must be removed completely and reinserted after rotating the rod one fin slot (72°) in either direction at the entry hole.

The distal end of the rod will then align sufficiently in rotation with the distal canal to allow advancement to the final position, engaging the distal taper of the canal (Figure 30).

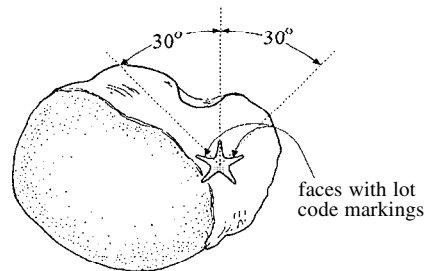


Figure 28:
Rotational Tolerance of Rod Alignment



Figure 29:
Incorrect Rotational Alignment

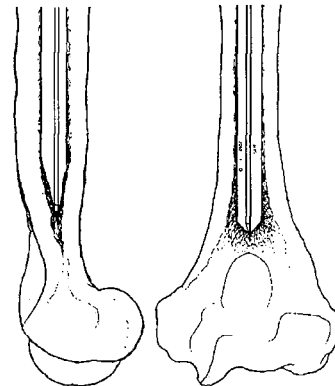


Figure 30:
Correct Rotational Alignment

NOTE: If the patient has severely osteoporotic bone it is important that the cap be securely engaged on the rod and cannot be engaged further.

Since each turn of the cap will advance the cap 2.4mm into the bone, (the cap is 13mm long, and there are approximately 11 revolutions of thread on the cap), it would be appropriate to attach the cap with up to 5 360° rotations before advancing the cap into the bone.

WOUND CLOSURE

The wound is closed in layers.

The supraspinatus tendon is closed (Figure 31).

The deltoid fascia, the fat, and the skin are all closed separately.

The wound is covered with sterile dressing and a compressive bandage is applied to the entire upper extremity, from hand to axilla, with the elbow flexed.

A collar and cuff sling is then applied.

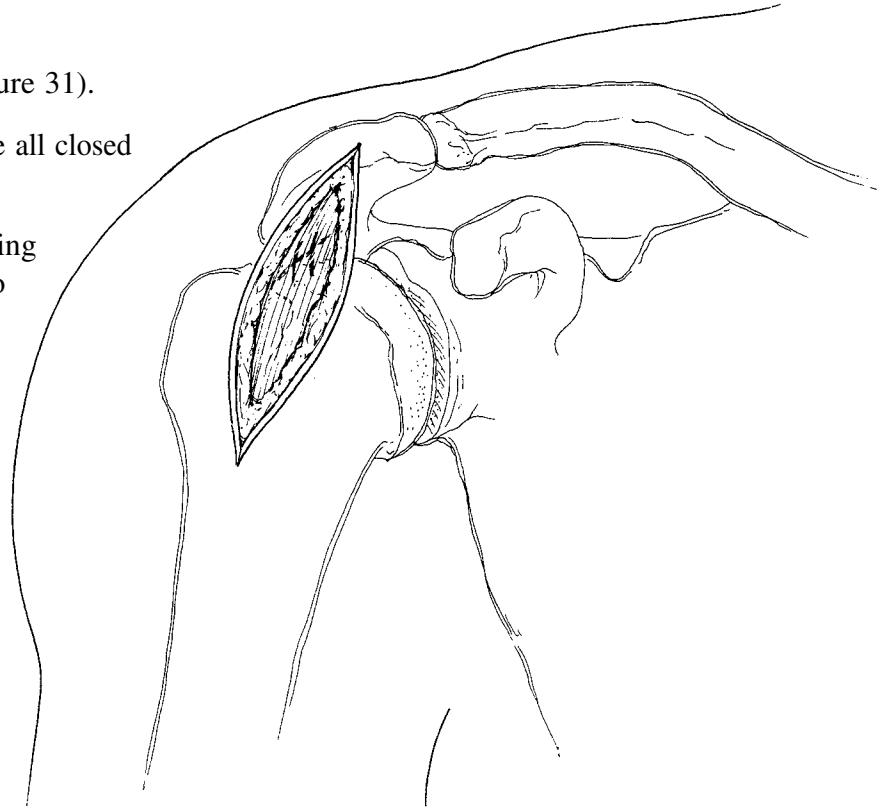


Figure 31

POST-OPERATIVE MANAGEMENT

The patient is started on immediate assisted motion of the shoulder, elbow, forearm, wrist, and hand.

The sling is removed for short periods when symptoms allow, progressing to independence over a few weeks.

Weight bearing through crutches is not recommended until the fracture has united.

Resisted strengthening is started when there is fracture callus present on X-ray. Return to strenuous, unrestricted physical activities is delayed until denser callus is seen bridging the fracture, and the patient has completed a work hardening and endurance training program of physiotherapy.

OPERATIVE PROCEDURE: RADIUS /ULNA

POSITIONING

Patient and arm positioning can dramatically affect the ease of reduction and rod insertion.

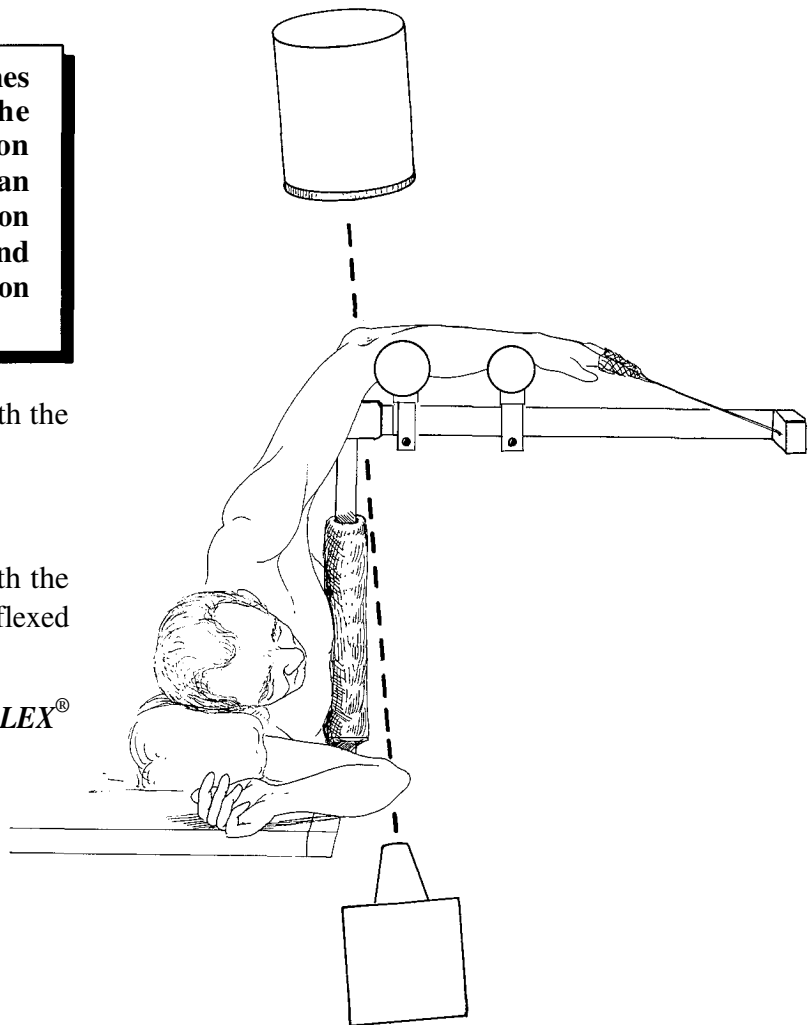
NOTE: The following procedure assumes that the physician is using the *TRUE/FLEX*[®] forearm traction frame. If another device, such as an arm board or other form of traction device, is used for distraction and reduction, then an alternate position may be more appropriate.

The patient is placed in the lateral position with the injured extremity up.

A normal operating table is used.

The patient is stable in the lateral position with the forearm in traction and with the hips and knees flexed (Figure 32)

The forearm is placed in traction in the *TRUE/FLEX*[®] forearm traction frame.



**Figure 32:
Patient Positioning**

THE TRUE/FLEX[®] FOREARM TRACTION FRAME

Shaft fractures of the forearm can be reduced with minimal manipulation using the *TRUE/FLEX*[®] forearm traction frame. This device attaches to the standard rails of most operating tables.

The clamp used to attach the frame (A) is first placed on the rail that the patient will be facing (positioned laterally with the injured extremity up).

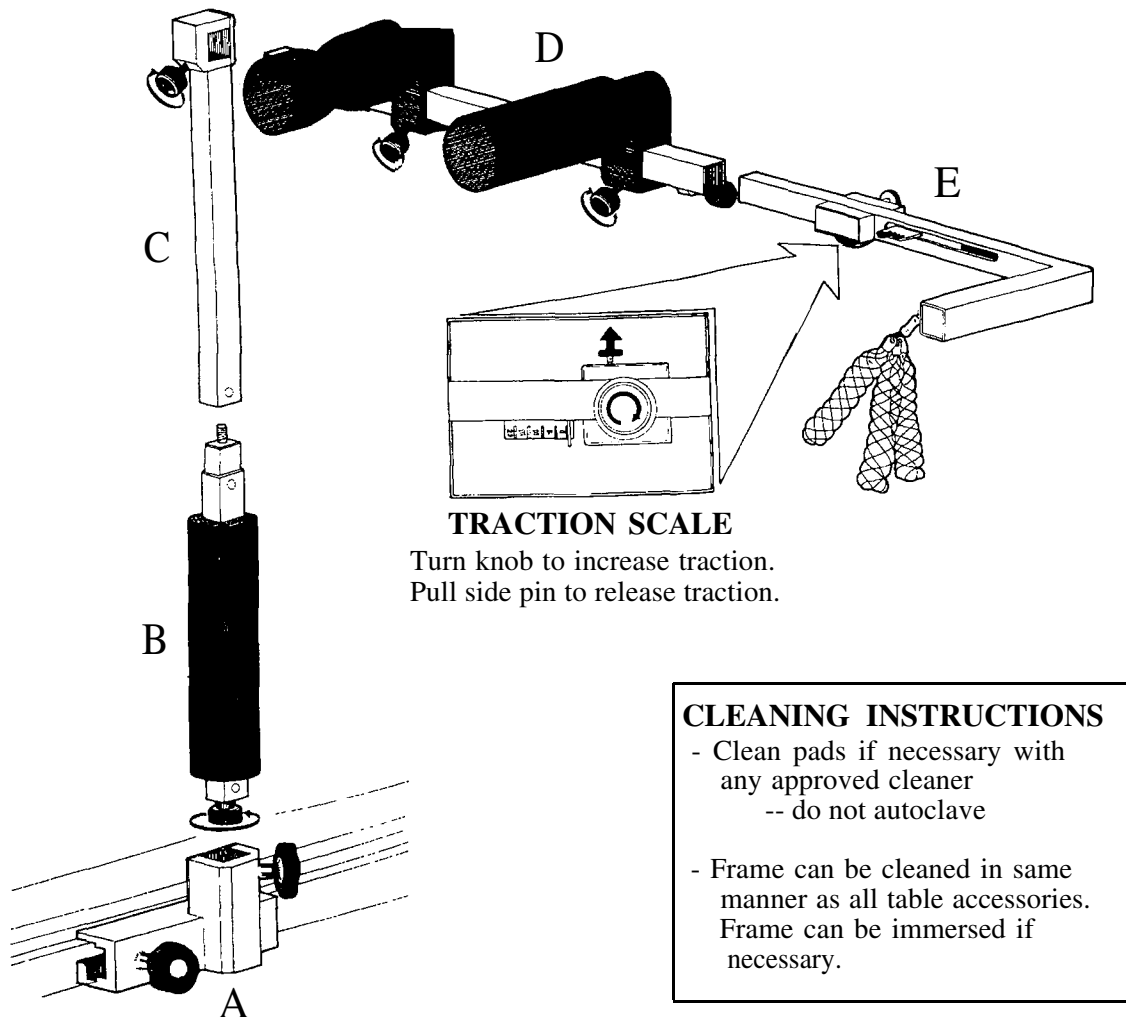


Figure 33:
TRUE/FLEX[®] Forearm Traction Frame

RADIUS/ULNA PROCEDURE (cont)

The traction frame is preassembled before it is inserted into the clamp.

- The foam-covered pad is placed on the vertical post (B).
- The lower vertical post (B) is attached to the upper vertical post (C). The knob at the base of the lower vertical post is rotated clockwise to lock the components.
- The grooved and non-grooved arm pads are placed on the proximal horizontal bar (D) in a manner such that the grooved pad is nearer the vertical post when the proximal horizontal bar is placed in the clamp on the vertical bar. The pads should be directed toward the patient's upper body in a plane slightly above the level of the horizontal bar.
- The distal horizontal bar (E) is attached to the proximal horizontal bar in a manner such that the 90° bend is facing in the same direction as the grooved and non-grooved arm pads. The distal horizontal bar is locked to the proximal bar by tightening the screw clamp on the proximal bar.
- The locked horizontal bar (D/E) is placed in the locked vertical bar (B/C). The screw clamp on the upper vertical bar is used to lock them together.
- The assembled frame is placed in the clamp on the table in a manner such that the horizontal bars are directed away from the table and the grooved and non-grooved arm pads are in a plane above the horizontal bars.

After the frame is locked on the table the patient is rotated in the lateral position while the traction frame is attached to the table.

- The patient is stable in the lateral position with the forearm in traction and with the hips and knees flexed (Figure 32).
- An assistant holds the humerus vertically and the forearm horizontally, away from the operating table.

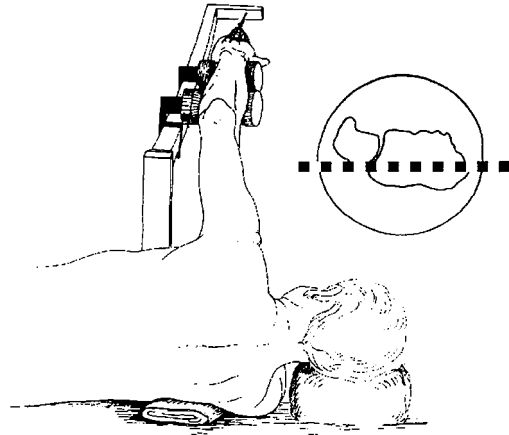
- The forearm is placed on top of the grooved and non-grooved pads.
- If necessary the frame may be loosened from the table clamp, lowered to make arm placement easier, then raised and locked after the forearm is resting on the arm pads.
- The frame height is adjusted so that the forearm rests on the pads.
- The grooved and non-grooved pads are adjusted in a manner such that the elbow is resting on the grooved pad and the wrist on the non-grooved pad.
- The index, long, and ring fingers are put into the finger traps.

NOTE: If there is not sufficient slack in the finger trap cable, pull the pin on the adjustment crank while pulling on the cable.

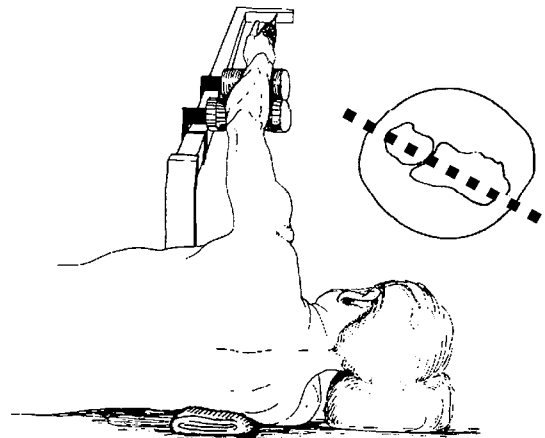
- The forearm is placed in supination to have the distal radius and ulna oriented parallel to the floor (Figure 34).
- If the patient lacks supination (Figure 35), the frame is then moved down the table toward the foot. The vertical bar of the frame is then lowered and the shoulder adducted. This allows the distal radius and ulna to be in the horizontal plane with less supination (Figure 36).
- The wrist pads are checked to assure that a pad is under the distal radius.

The fracture is reduced.

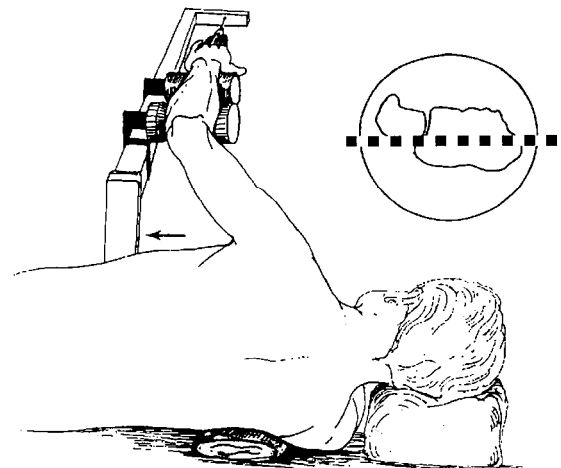
- Traction applied to the fingers causes about 10° of flexion at the wrist. The amount of traction is monitored with the tensiometer on the horizontal bar.
- Reduction is achieved using traction and direct manipulation of the unrepred forearm.



**Figure 34:
Proper Forearm Alignment**



**Figure 35:
Improper Forearm Alignment**



**Figure 36:
Adjusting Patient Position
to Achieve Proper Forearm Alignment**

RADIUS/ULNA PROCEDURE (cont)**FLUOROSCOPIC VIEWS**

For the AP view, the C-arm is placed in the routine AP position.

NOTE: Occasionally, the elbow is difficult to see in the AP plane. In this situation the C-arm is pivoted a few degrees out of the vertical plane (Figure 37) bringing the proximal forearm into view.

The forearm is scanned from the elbow to the wrist by swivelling the C-arm (Figure 38).

The lateral view is achieved by rotating the cone under the forearm to the lateral position, and by adjusting the height to bring the forearm into view. The forearm is scanned in the lateral plane by swivelling the C-arm (Figure 39). The height may be left at the lateral level for the AP view to minimize adjustments between the two views.

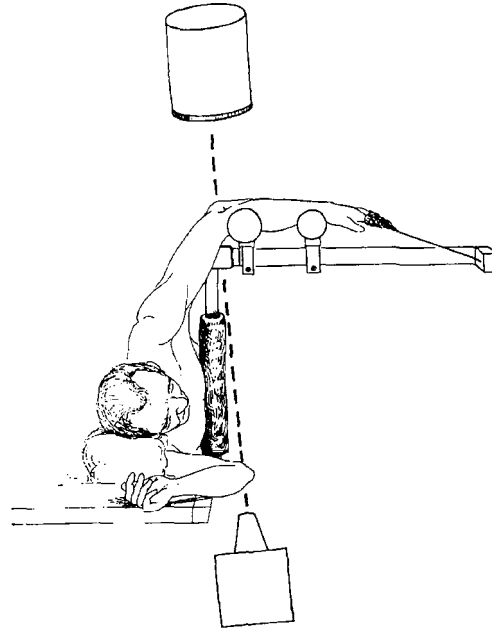


Figure 37:
Alternate AP Angle of C-arm

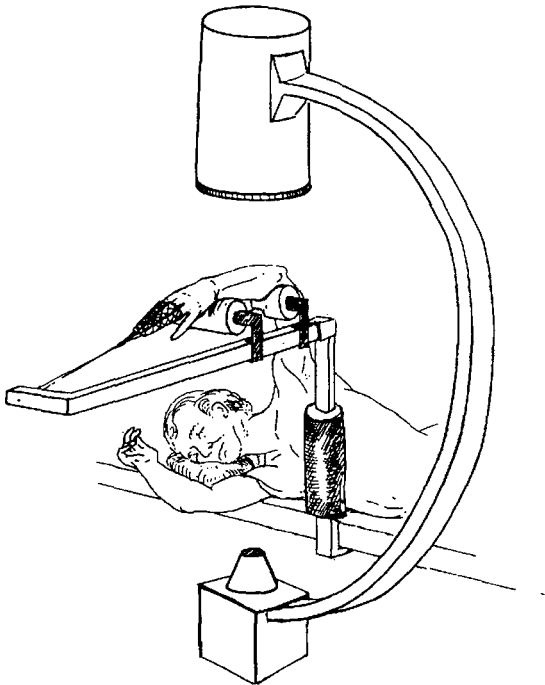


Figure 38:
AP Angle

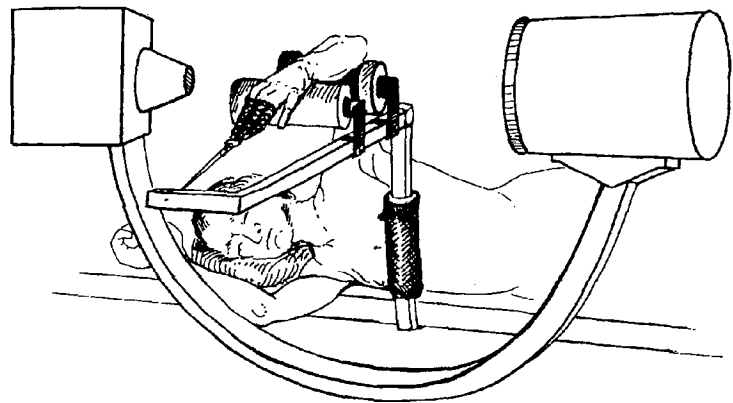


Figure 39:
Lateral Angle

PATIENT PREPARATION

The patient is positioned as described with the forearm in the traction frame.

Fracture reduction can be confirmed with fluoroscopy.

The extremity is scrubbed and prepped. Using a vertical isolation drape (normally used for hip fractures), the arm is draped from the fingers to above the olecranon on the dorsal surface.

SURGICAL APPROACH:
ULNA

THE ULNA IS FIXED FIRST.

An incision (approximately 2.5cm) is made longitudinally over the olecranon (Figure 40)

Dissection is taken sharply down through subcutaneous tissue and the triceps tendon, taking care not to dissect medial to the olecranon in the region of the ulnar nerve.

THE ENTRY POINT: ULNA

The entry point for the ulna is the center of the olecranon process, directly in line with the center of the proximal IM canal of the ulna (Figure 41).

The position of the awl at the entry point is checked on both AP and lateral fluoroscopic views before penetrating the bone with the awl.

The awl is advanced until the groove in the middle of the cone is flush with the cortical surface (Figure 42). This hole allows for introduction of the **TRUE/FLEX[®]** ulna rod and screw cap.

NOTE: Take care not to advance awl too deep into the cortical bone as this will create a hole too large for the **TRUE/FLEX[®] screw cap to obtain proper purchase.**

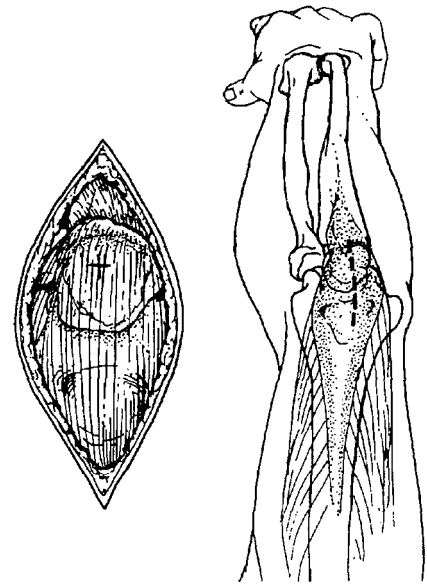


Figure 40:
Surgical Approach for Ulna Fixation

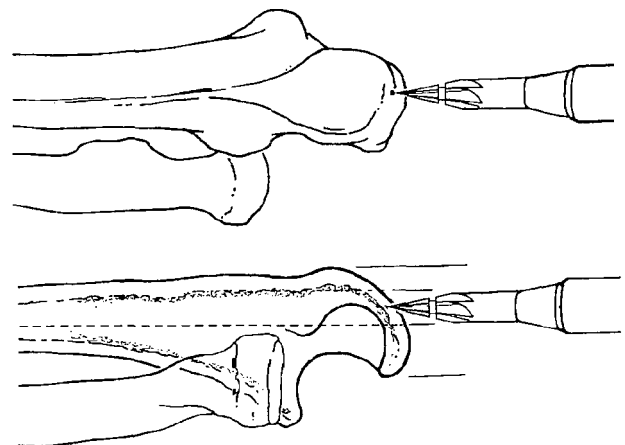


Figure 41:
Aligning Awl to Penetrate Ulna

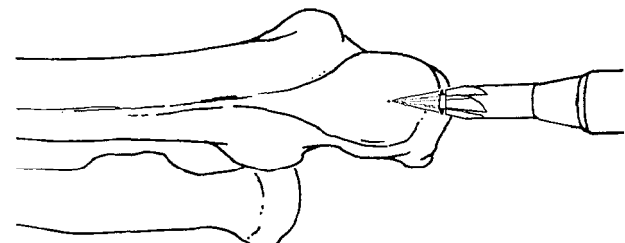


Figure 42:
Penetrating Ulna to Cone on Awl

RADIUS/ULNA PROCEDURE (cont)**SURGICAL APPROACH:****RADIUS**

The incision is longitudinal over the 4th extensor compartment of the wrist, about 2.5cm-3cm in length.

Dissection is taken bluntly through the subcutaneous tissue and the extensor retinaculum is identified.

The extensor retinaculum is partially divided in the longitudinal direction (Figure 43).

The extensor digitorum tendons are retracted to one side.

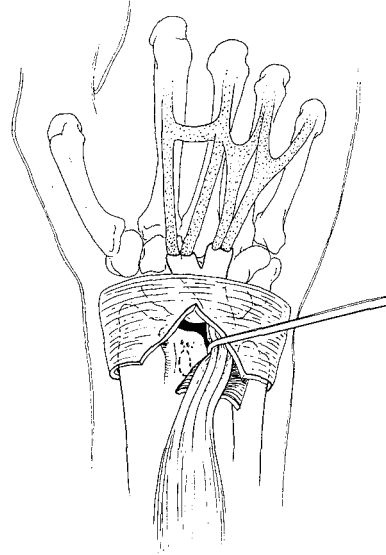


Figure 43:
Dividing the Extensor Retinaculum
to Expose the Entry Point

THE ENTRY POINT:**RADIUS**

The entry point for the radius is on the dorsal aspect of the distal radius, halfway between the dorsal and radial tubercle of Lister and the distal radioulnar joint, at least 5mm proximal to the articular surface (Figure 44).

The position of the awl at the entry point is checked on both the AP and lateral fluoroscopic views before penetrating the bone with the awl.

For the radius, the awl is used in a slightly modified technique. After the tip of the awl has penetrated the cortex, the awl is angled to near 30° from the line of the radius, and advanced to the depth of the groove in the cone of the awl. The resulting oval hole allows for introduction of the *TRUE/FLEX*[®] radius rod into the canal of the radius.

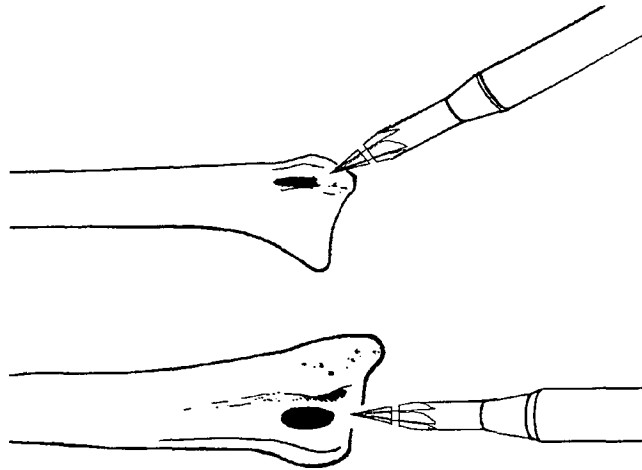


Figure 44:
Penetrating the Radius with the Awl

NOTE: Take care not to advance awl too deep into the cortical bone as this will create a hole too large for the *TRUE/FLEX*[®] screw cap to obtain proper purchase.

NOTE: In some cases the surgeon may wish to create a 2cm pilot hole in the distal radius to help guide the rod and stabilize placement. A 2mm awl, such as a rush awl, may be used for this purpose.

ROD INSERTION

If there is uncertainty with respect to choosing the correct rod size after measuring the preoperative X-rays, then measure the canal using the intramedullary measuring rod before opening the I rod implant box. The intramedullary measuring rod is inserted through the entry hole, down the canal, and across the fracture into the distal fragment (similar to passing a guide wire for reamed rods).

A rod of the pre-measured length and diameter is screwed onto the driver. **Make certain that the driver is completely screwed onto the rod.** This protects the threads on the rod from excessive stress.

Correct rod orientation is critical before starting to drive it into the cancellous bone of the humeral head. The *TRUE/FLEX*® radius rods are anatomically shaped. The orientation of the rod must match the anatomical orientation of the bone before the rod is advanced into the cancellous bone. **Once the rod has been advanced even 1cm into the cancellous bone, angular realignment is difficult and rotational alignment is impossible.**

ULNA: The correct rotational orientation of the ulna is perpendicular to the distal humerus -- not horizontal related to the room.

With the *TRUE/FLEX*® ulna rod rotated onto the correct plane, place the rod along the subcutaneous border of the ulna to determine the orientation (Figure 45). **DO NOT skip this seemingly small and insignificant step.** The straight proximal portion of the ulna rod, attached to the driver, should angle from the olecranon towards the radius. The long distal curve will then be concave towards the radius.

When the rod is held in the correct rotation, the *TRUE/FLEX*® ulna rod is introduced into the starter hole and aligned with the IM canal (Figure 46). The IM canal proximally is angled toward the radius in the plane perpendicular to the humerus.

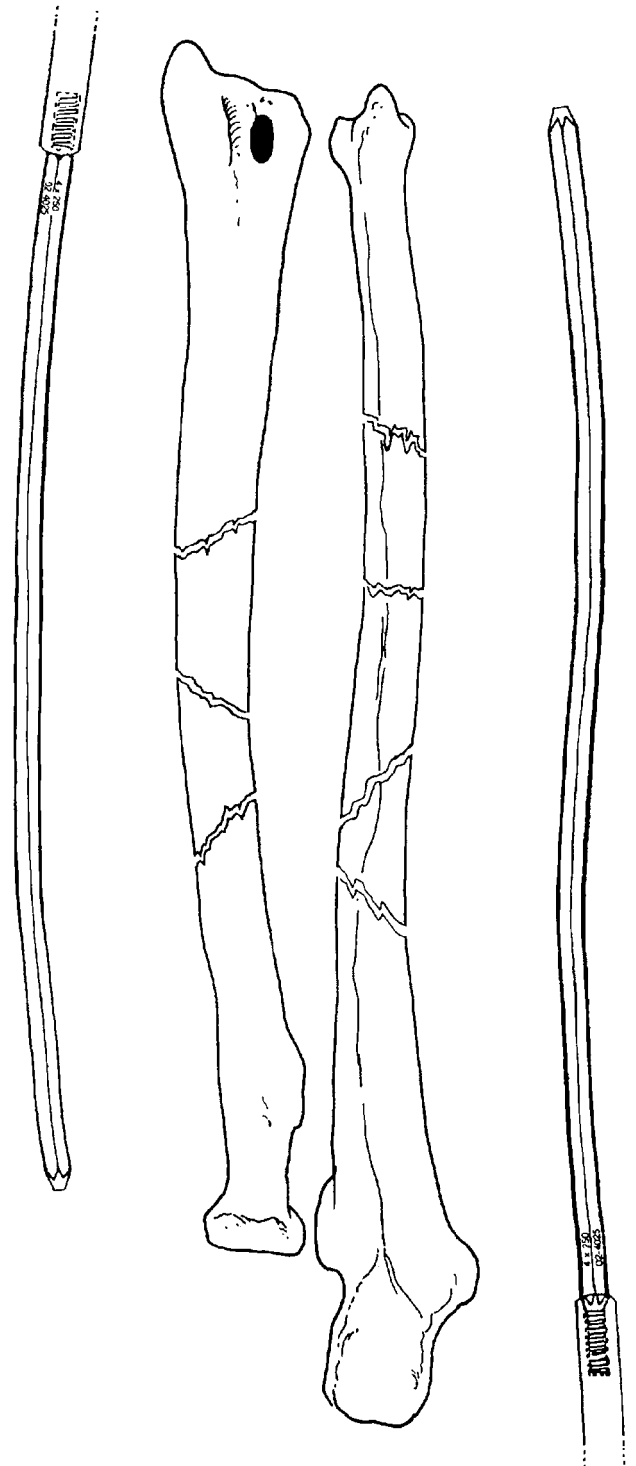


Figure 45:
Checking for Correct Anatomical Alignment

RADIUS/ULNA PROCEDURE (cont)

RADIUS: The correct rotational orientation of the radius is with the curve of the *TRUE/FLEX*[®] radius rod in the plane of the distal radius and ulna, with the concave side toward the ulna. Before insertion, align the radius rod over the forearm to reproduce the orientation of the distal radius (Figure 45).

When the rod is held in the correct rotational alignment, the *TRUE/FLEX*[®] radius rod is introduced into the starter hole and aligned with the IM canal (Figure 46). The IM canal is oriented in the plane of the distal radius along the curve that is concave toward the ulna.

When both rotational and angular alignment are correct, the rod is advanced by gently tapping the end of the driver with a hammer.

When the rod has engaged the cancellous bone about 1cm, both rotation and angulation are reconfirmed. If the orientation is incorrect, the rod is removed and reinserted in the correct orientation.

NOTE: The IM canal of the radius is entered via the dorsal cortex of the wrist. This forces the *TRUE/FLEX*[®] radius rod to angle toward the volar cortex on insertion.

The angle must be minimized by making an oval hole (as previously described) and pushing the rod maximally into the horizontal plane.

NOTE: The rod is too flexible to control the introduction angle with the driver. To keep the introduction angle as small as possible, the free hand is used to place pressure on the upper surface of the rod near the insertion end.

NOTE: The assistant can tap the driver gently with the hammer for initial insertion.

If there is difficulty aligning and stabilizing the radius nail at the entry point, use a 2mm awl (similar to a RUSH awl) to create a pilot guide hole 2cm along the distal end of the canal.

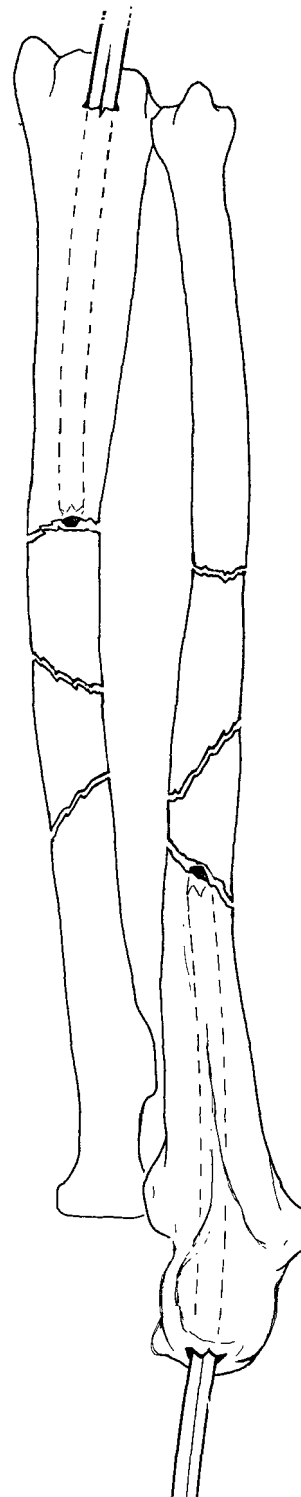


Figure 46

After the orientation is confirmed by fluoroscopy in the horizontal plane, progress is watched in the lateral plane until the *TRUE/FLEX*[®] rod advances into the intramedullary canal.

If there is difficulty getting the rod into the canal, the hole should be further elongated.

The *TRUE/FLEX*[®] rod (either ulna or radius) is advanced to the fracture site until 1-2mm of the rod extends beyond the fracture site. Any additional required reduction maneuvers are then performed.

NOTE: After the rod is advanced more than 1cm into the distal bone fragment it is not possible to rotate the distal bone fragment. Any reduction procedures requiring rotational alignment should be performed before the rod is advanced more than 1cm beyond the distal bone fragment.

NOTE: During reduction, it is usually better for the surgeon to perform the reduction while the assistant advances the rod (with gentle hammer strikes to the driver).

The rod is advanced a few millimeters at a time with additional reduction (if needed) until proper reduction is confirmed with fluoroscopy in both planes.

When proper reduction is confirmed, the rod is advanced across the fracture site.

Rotation of the reduction at the fracture site cannot be adjusted when the rod has advanced more than a few millimeters across the site. Relative cortical thickness of the fragments, the alignment and shape of the fracture ends, restoration of the radial bow, and the interosseous distance, are all indicators of rotational alignment. Rotation, also, has a significant effect on the angular alignment.

If there is a rotational malalignment at the fracture site after the rod has passed into the distal fragment, the rod must be backed out to the fracture site before this rotation can be corrected.

With rotational and angular alignment correct, the rod is advanced until the end of the driver is approximately 1-2cm from the soft tissue.

RADIUS/ULNA PROCEDURE (cont)

LOCKING THE ROD
WITH THE SCREW CAP

The locking screw cap has an outer self-tapping cancellous thread and an inner machine thread to match the threaded end of the rod.

The cap may be driven by a standard 3.5mm hexagonal screwdriver.

When the cap is screwed onto the rod, each complete revolution of the cap around the rod has the net effect of advancing the rod 2mm into the canal. The movement is the result of the difference between the smaller machine threads on the rod/cap interface and the larger external cancellous threads on the cap.

Place the hex end of the screw cap on the hex screwdriver. The screw cap is secured to the rod with 2 turns onto the threaded end of the rod (Figure 47). **Do not attach the cap onto the rod with more than two 360° turns at this time.**

To ensure proper seating of the screw cap into the entry hole of the bone, gently tap the end of the screwdriver until the cancellous threads of the screw cap are flush with the entry hole.

With the cap threads seated in the entry hole, gently tap the hex screwdriver while simultaneously turning the driver (Figure 48). This will help the threads engage in the cancellous bone. Once the threads are securely engaged in the cancellous bone tissue, the screw cap may be turned into the head until it is flush or just below the cortical bone.

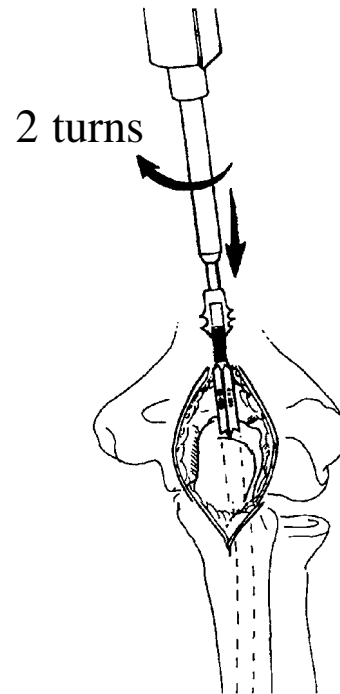


Figure 47:
Attaching Screw Cap to Rod

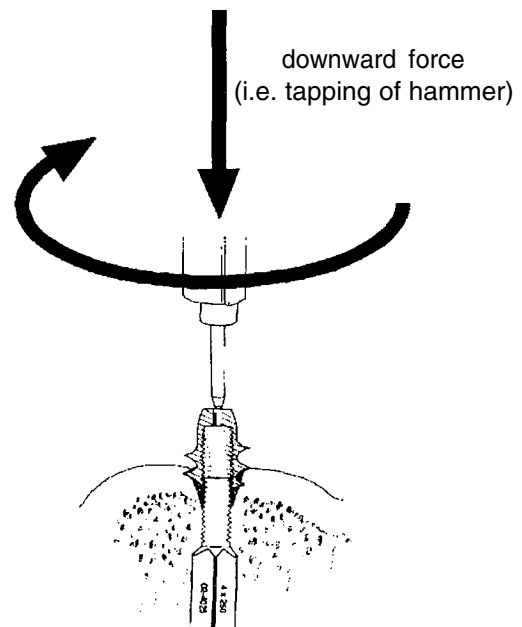


Figure 48:
Advancing Screw Cap

The cap does not have to be fully seated on the threads of the rod. It is important to make certain visually, and fluoroscopically, that the screw cap is flush with the cortical surface (Figure 49).

NOTE: At this point the rod is about 5mm deeper than the top of the cap. It is important that the rod be at least 1cm shorter than the measured canal length.

NOTE: Watch the distal end of the rod and the fracture site intermittently in the AP view on fluoroscopy during the final seating of the rod.

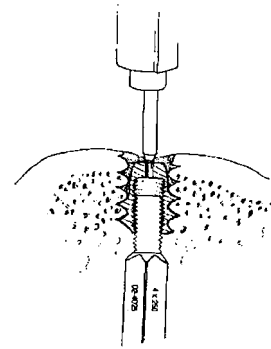


Figure 49:
Advance Screw Cap Until Flush With Cortical Surface

Intrinsic to the design of the rod is rotational and angular stability from the fin engagement in the cancellous bone proximally and distally. Additional fixation to lock motion in these planes is not necessary.

Axial locking, however, is not provided by the fins. A non-locked rod can migrate axially. It is, therefore, important to use the screw cap locking mechanism in every case.

If dynamic locking is desired, choose a shorter rod which will not engage in the tapered distal end of the canal.

NOTE: It is important that a cap, whether smooth or threaded, be used to cover the threads on the end of the TRUE/FLEX[®] rod in every case.

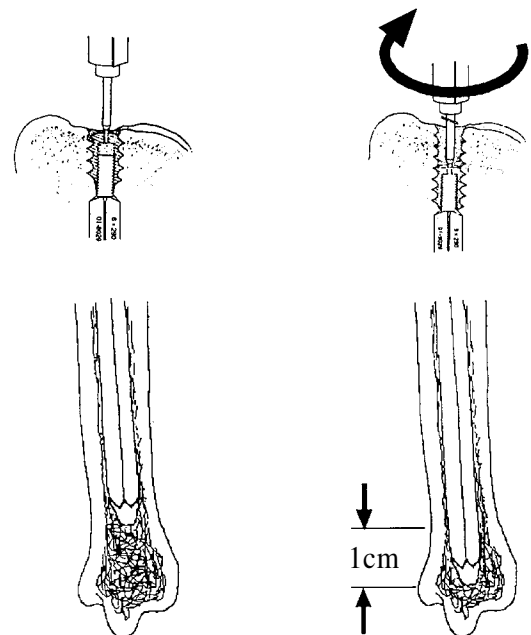


Figure 50:
Adjusting Rod Length with Screw Cap

If static locking is desired to prevent limb shortening, the distal end of the rod must engage the subchondral bone of the far fragment.

RADIUS/ULNA PROCEDURE (cont)

The screw cap can be advanced up to 1cm below the cortical bone tissue to precisely adjust the length of the rod accordingly (Figure 50).

If the fracture site begins to distract, stop advancing the screw cap. The final position and alignment of the fracture fragments and the rod (including the distal tip and the screw cap) *must* be confirmed in both fluoroscopic views (Figure 51).

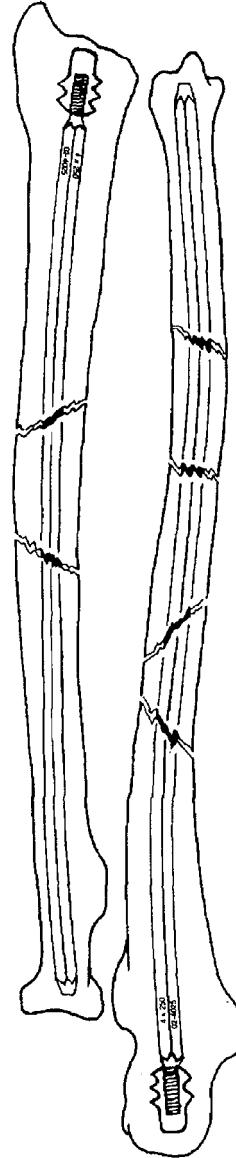


Figure 51:
Assure Proper Fracture Alignment
With Fluoroscopy

NOTE: The distal end of the *TRUE/FLEX[®]* radius rod is curved dorsally to keep the end from dropping into the IM canal (Figure 52). This makes the radius rod asymmetrical, requiring **RIGHT** and **LEFT** configured implants. The ulna rod is symmetrical. The same rod may be used for either forearm.

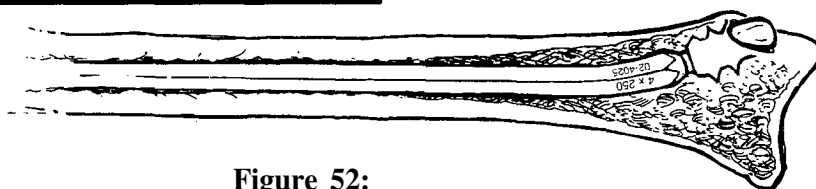


Figure 52:
Adjusting Rod Length with Screw Cap

WOUND CLOSURE

The wound is closed in layers.

The extensor retinaculum is usually not completely divided in the approach to the distal radius; therefore it may not require repair.

The wound is covered with sterile dressing and a compressive bandage is applied to the forearm, including the hand and the elbow.

A sling is applied.

POST-OPERATIVE MANAGEMENT

The patient is started on immediate assisted motion of the shoulder, elbow, forearm, wrist, and hand.

The sling is removed for short periods when symptoms allow, progressing to independence over a few weeks.

Weight bearing (either through crutches or other axial loading) is not recommended until the fracture has united. Platform crutches with weight bearing through the elbow is possible.

Resisted strengthening is started when there is fracture callous present on X-ray. Return to strenuous, unrestricted physical activities is delayed until denser callous is seen bridging the fracture, and the patient has completed a work hardening and endurance training program of physiotherapy.

ROD REMOVAL

Removing the rod is only recommended if there are specific symptoms or problems attributable to the rod.

If rod removal is required, the approach to the end of the rod is the same as previously described in the humerus and radius/ulna surgical procedures.

If the locking cap was advanced below the bone surface, a curette may be needed to remove fibrous tissue and bone which may form over the cap.

A standard 3.5mm hexagon screwdriver is placed in the end of the cap and the cap is unscrewed counter-clockwise (Figures 53 and 54). Because of the differential thread pitches on the rod/cap interface and the cap/bone interface, the cap will pull the rod out as it (the cap) is removed.

When the cap disengages from the rod, the end of the rod will be proud by two threads and will be centered in the space left by the cap (Figure 55).

The slap-hammer is attached to the rod, either using the *TRUE/FLEX*[®] implant driver or an appropriate slap-hammer attachment.

The rod is extracted and the wound closed as previously described.

NOTE: If a smooth cap was used with the *TRUE/FLEX*[®] radius or ulna rod, removing the cap will not cause the rod to back out. Since, during insertion, the smooth cap could not force the end of the rod past the point where the implant tool could attach to the rod, the rod should be easily accessible when the smooth cap is removed.

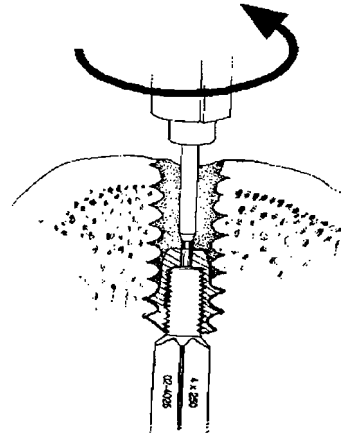


Figure 53:
Backing Rod out with Screw Cap

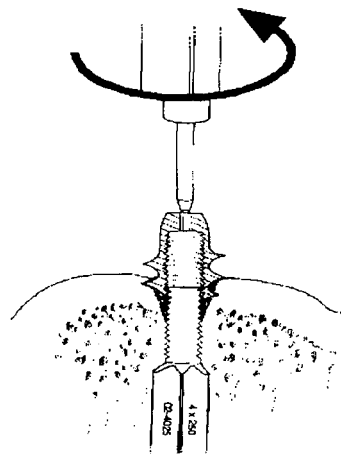


Figure 54:
Backing Rod out with Screw Cap

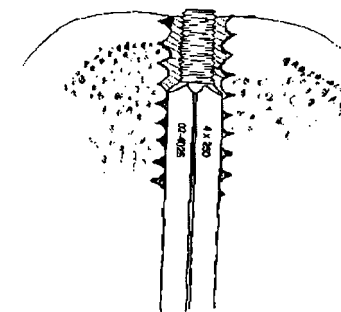


Figure 55:
Threaded Rod End Exposed In Bone



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