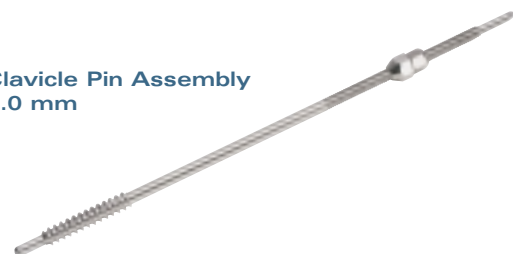


DePuy Clavicle Pin		
Cat. No.	U/M	Description
1129-10-020	ea	Clavicle Pin Assembly 2.5 mm
1129-12-020	ea	Clavicle Pin Assembly 3.0 mm
1129-14-020	ea	Clavicle Pin Assembly 3.8 mm
1129-16-020	ea	Clavicle Pin Assembly 4.5 mm

Clavicle Pin Assembly
3.0 mm



Instruments in Case		
Cat. No.	U/M	Description
2128-61-070	ea	Ratchet T-Handle
2129-51-000	ea	Clavicle Lateral Nut Wrench
2129-53-000	ea	Clavicle Medial Nut Wrench
2129-55-000	ea	Keyless Chuck
2129-55-500	ea	Chuck Key
2129-58-010	ea	Clavicle Pin 2.5 mm Tap
2129-58-012	ea	Clavicle Pin 3.0 mm Tap
2129-58-014	ea	Clavicle Pin 3.8 mm Tap
2129-58-016	ea	Clavicle Pin 4.5 mm Tap
2129-60-000	ea	Clavicle Pin Case Assembly
2428-14-000	ea	Elev FL CV, 9/16 BL

Additional Instruments		
Cat. No.	U/M	Description
2129-57-010	ea	Drill Bit 2.8 mm
2129-57-012	ea	Drill Bit 3.2 mm
2129-57-014	ea	Drill Bit 4.0 mm
2129-57-016	ea	Drill Bit 4.8 mm
2129-57-018	set	Drill Bit Set

Important This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications Orthopaedic screws and pins are intended to provide the orthopaedic surgeon a means of bone fixation and help in the general management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing and are not intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing.

Contraindications The Rockwood Clavicle Pin is contraindicated: in the presence of active infection; in cases with malignant primary or metastatic tumors which preclude adequate bone support or fixation unless supplemental means of fixation are used; in conditions that tend to retard healing such as blood supply limitations, previous infections etc.; if insufficient quantity or quality of bone does not permit stabilization of the fracture complex; in conditions that restrict the patient's ability or willingness to follow postoperative instructions; and in cases where material sensitivity is suspected.

Warnings and Precautions This device is intended for partial weight-bearing or non weight-bearing applications and cannot be expected to withstand the unsupported stresses of full weight bearing. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Adverse Events The following are the most frequent adverse events after fixation with orthopaedic screws and pins: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection and adverse reactions to the device material.

Contact your local DePuy sales representative for additional information about DePuy shoulder products, including the Global™ Advantage® Shoulder Arthroplasty System, the Global™ Fx Shoulder Fracture System and the Delta® CTA Reverse Shoulder System. DePuy also offers an entire range of implants for both upper and lower extremity joint replacement and a complete line of bone cement products.

REFERENCES

- Hill, J.M., et al. "Closed Treatment of Displaced Middle-Third Fractures of the Clavicle Gives Poor Results." *Journal of Bone and Joint Surgery* May 1998: 537-539.
- Boehme, D., et al. "Non-Union of Fractures of the mid shaft of the clavicle: Treatment with a modified Hagie Intramedullary Pin and Autogenous Bone Grafting." *Journal of Bone and Joint Surgery* Sept. 1991: 1219-1226.

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 For more information about the Clavicle Pin, visit our web site at www.jnjgateway.com.
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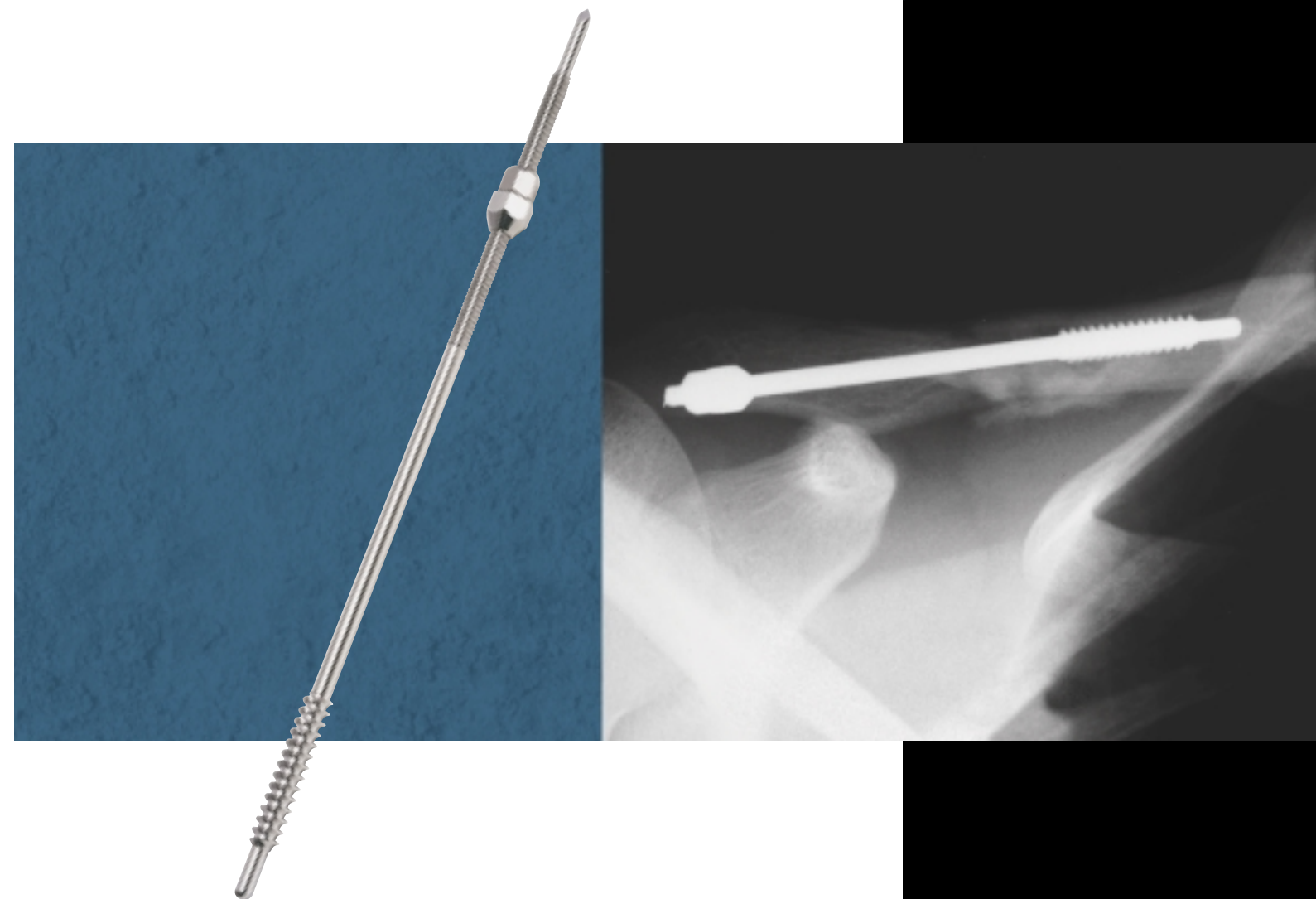
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Rockwood Clavicle Pin



DESIGN RATIONALE AND SURGICAL TECHNIQUE

THE NATURAL ALTERNATIVE FOR CLAVICLE FRACTURE



DePuy's intramedullary Rockwood Clavicle Pin is for use in the treatment of midshaft clavicle fractures, nonunions and malunions. Use of an intramedullary pin helps avoid issues such as:

- Impaired blood supply related to soft tissue stripping
- Presence of painful, prominent hardware
- Stress risers in the clavical related to removal of plates and screws

The Rockwood Clavicle Pin fits into the intramedullary canal of the clavicle through a small incision over the fracture site with minimal soft-tissue dissection. The device, specially designed to allow natural compression at the fracture site, minimises hardware migration. It can also be easily removed in an outpatient or clinic setting under local anaesthesia.



SURGICAL TECHNIQUE BY
 Carl Basamania, MD
 Kirk Jensen, MD
 Charles Rockwood Jr., MD

ILLUSTRATIONS BY
 Steve Lippitt, MD

BACKGROUND

Clavicle fractures account for 40 percent of all shoulder girdle fractures and about 10 percent of all fractures. Many of these fractures occur in young, athletic patients. Traditionally, nonoperative treatment has been accepted as the standard of care, likely the result of earlier studies showing unsatisfactory outcomes with operative treatment.

In the past, poor operative results related more to the technique used than the concept of treating these fractures operatively. Recent studies show significant **risks with nonoperative treatment**, including:

- chronic pain
- weakness
- a higher nonunion rate¹



Although various techniques have been tried, plate and screw fixation is most commonly used. However, placement of plate and screws on the clavicle requires significant soft tissue stripping, which may compromise blood supply to the bone and subsequent healing.

Furthermore, this treatment creates multiple stress risers in the clavicle, due to the use of several bicortical screws in the plate.

Another technique, smooth pin fixation, presents possible pin migration problems.



STEP 1 Positioning the Patient

Place the patient in a beach chair position on the operating table. Facilitate clavicle and shoulder access using a radiolucent shoulder-positioning device. An image intensification device or C-arm facilitates pin placement. Bring the C-arm base in from the head of the bed with the C-arm gantry rotated slightly away from the operative shoulder and

oriented with a cephalic tilt. Drape the C-arm with standard split sheets. Note: The procedure may also be done without C-arm equipment.² If a C-arm is not available, an X-ray cassette can be placed posterior to the shoulder prior to prepping and draping. X-rays can then be taken during the procedure to verify pin position.

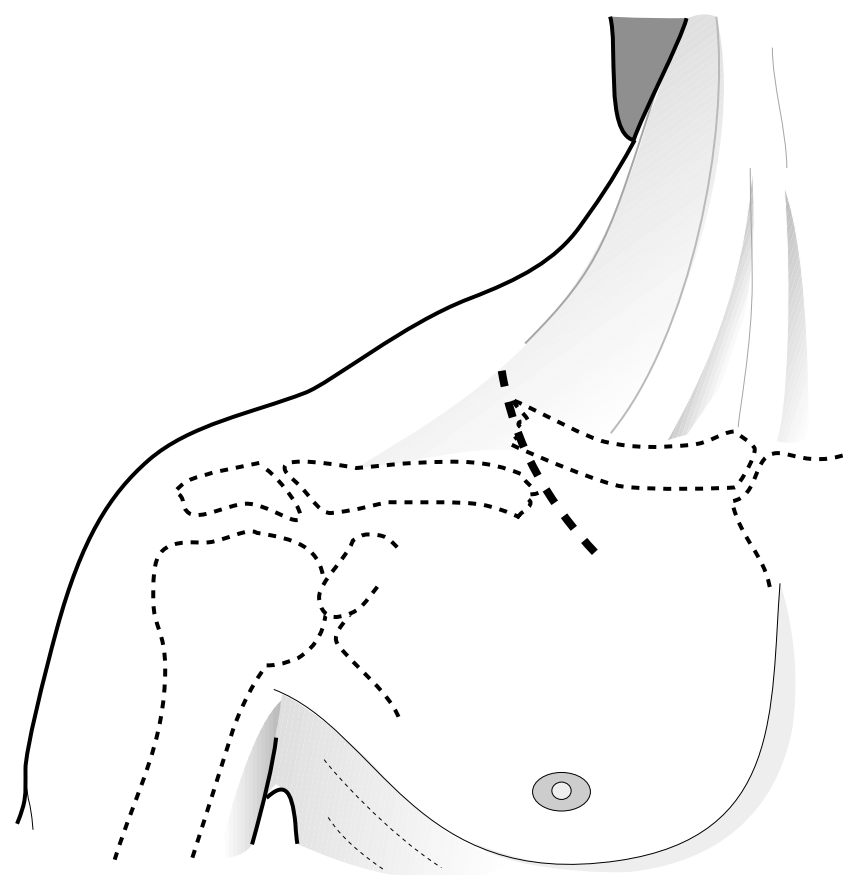


Figure 1

S. Lippitt, MD

STEP 2 Incision

Make a 3 cm incision in Langer's lines over the distal end of the medial fragment (*Figure 1*). This is done because the clavicle skin is moved medially more easily than laterally. Most patients have a deep skin crease in the same area where the incision is made. Placing the incision in this crease results in a more cosmetically pleasing scar.

Since little subcutaneous fat is in this region, take care to prevent injury to the underlying platysma muscle. Use scissors to free the platysma muscle from the overlying skin. Once the platysma muscle has been identified, divide its fibres longitudinally (*Figure 2*).

Take care to prevent injury to the middle branch of the supraclavicular nerve, usually found directly beneath the platysma muscle near the midclavicle.

Identify and retract the nerve to prevent injury. With acute fractures, the periosteum over the fracture site is disrupted and usually requires no further division. In most cases, there will be interposed muscle and soft tissue. Carefully remove them with an elevator or curette. Leave small butterfly fragments, usually found anteriorly, attached to their soft tissue envelope.

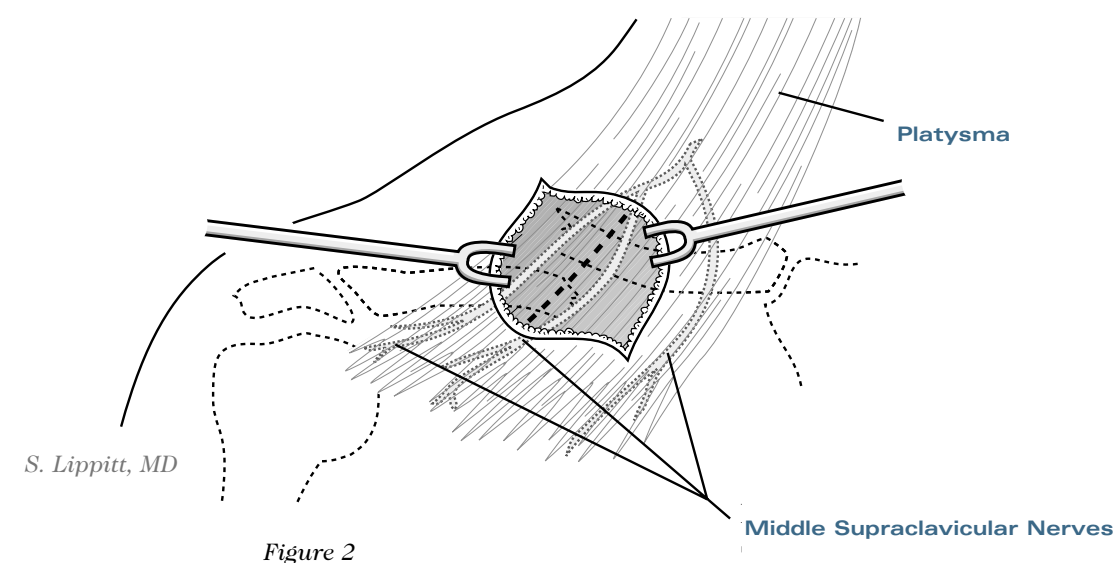


Figure 2

S. Lippitt, MD

Middle Supraclavicular Nerves

STEP 3 Drilling and Tapping the Intramedullary Canal

Elevate the proximal end of the medial clavicle through the incision using a towel clip, elevator or bone-holding forceps (*Figure 3*). Since the drills, taps and intramedullary pins are in sets, use either the smooth end of the taps or the drills to size the canal. Taking care not to penetrate the anterior cortex, attach the appropriate sized drill to the ratchet T-handle and drill the intramedullary canal (*Figure 4*).

The fit should not be too loose as this may compromise fixation or too tight as this may split the bone. A C-arm can be used to check orientation of the drill. Then, remove the drill from the medial fragment and attach the appropriate sized tap to the T-handle and tap the intramedullary canal to the anterior cortex (*Figure 5*).

NOTE: The drills are slightly larger than the corresponding clavicle pins and taps.

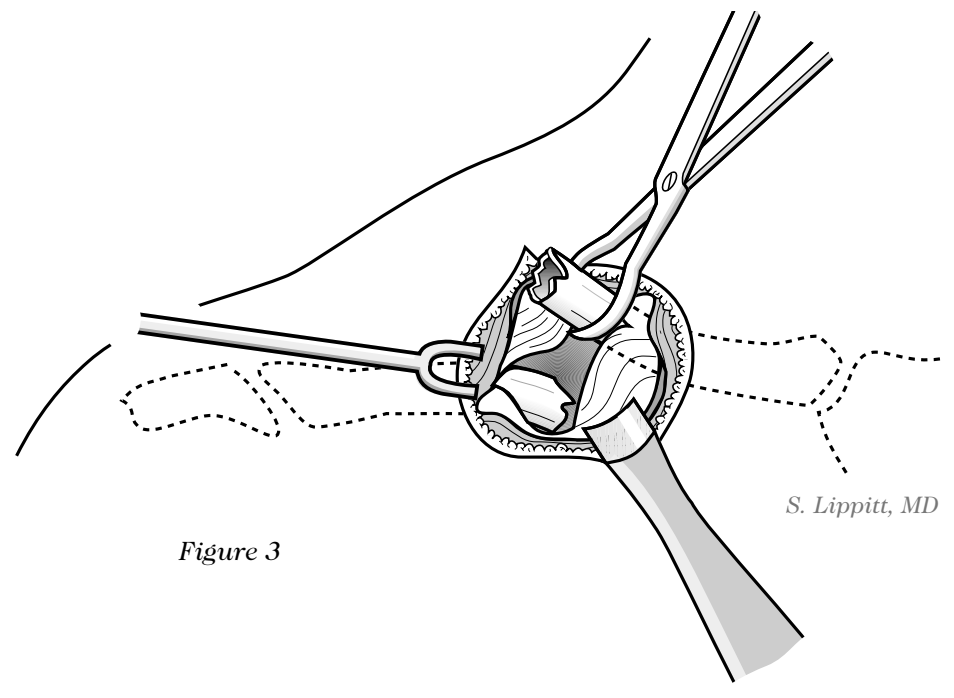


Figure 3

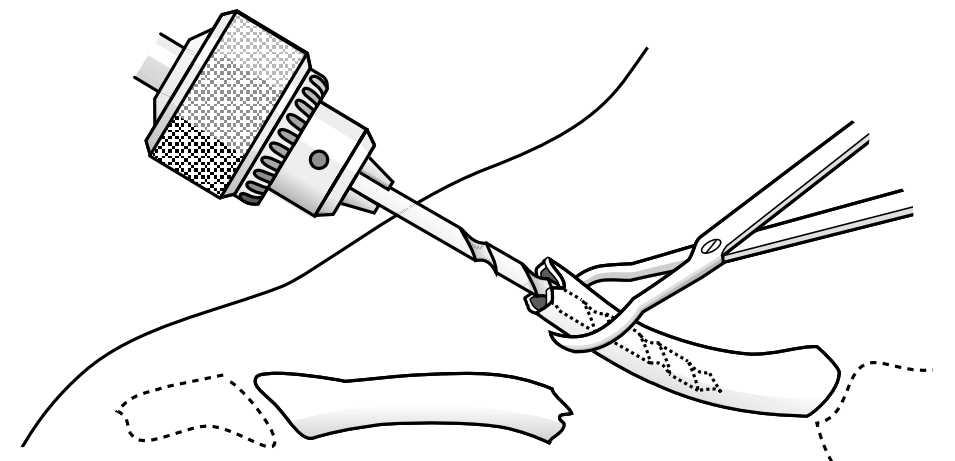


Figure 4

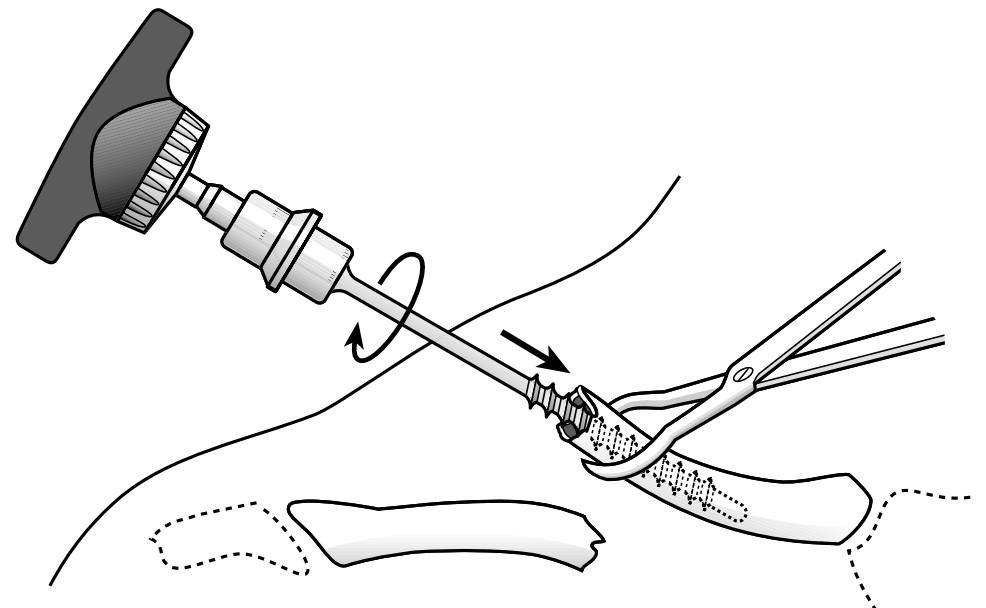


Figure 5

STEP 3 Drilling and Tapping the Intramedullary Canal continued

Next, elevate the lateral fragment through the incision. Connect the same sized drill used in the medial fragment to the ratchet T-handle and drill the intramedullary canal (*Figure 6*). Pass the drill under the C-arm guidance out through the posterolateral cortex of the clavicle, which will be posterior to the acromioclavicular joint (*Figure 7*).

Then, remove the drill from the lateral fragment, attach the appropriate sized tap to the T-handle and tap the intramedullary canal so that the large threads are advanced fully into the canal (*Figure 8*).

NOTE: Tapping reduces the torque required to insert the pin and reduces the possibility of pin failure.

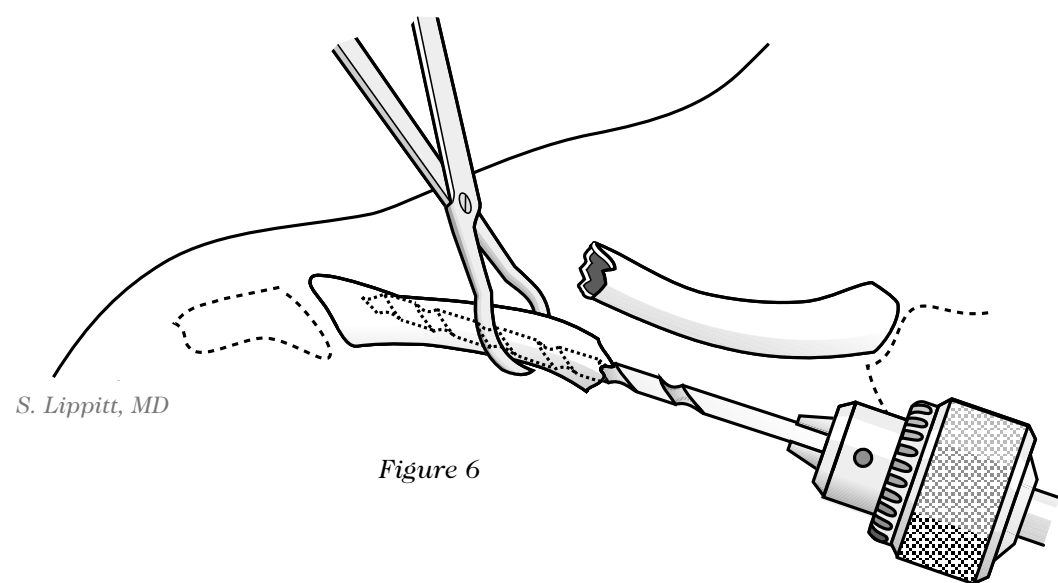


Figure 6

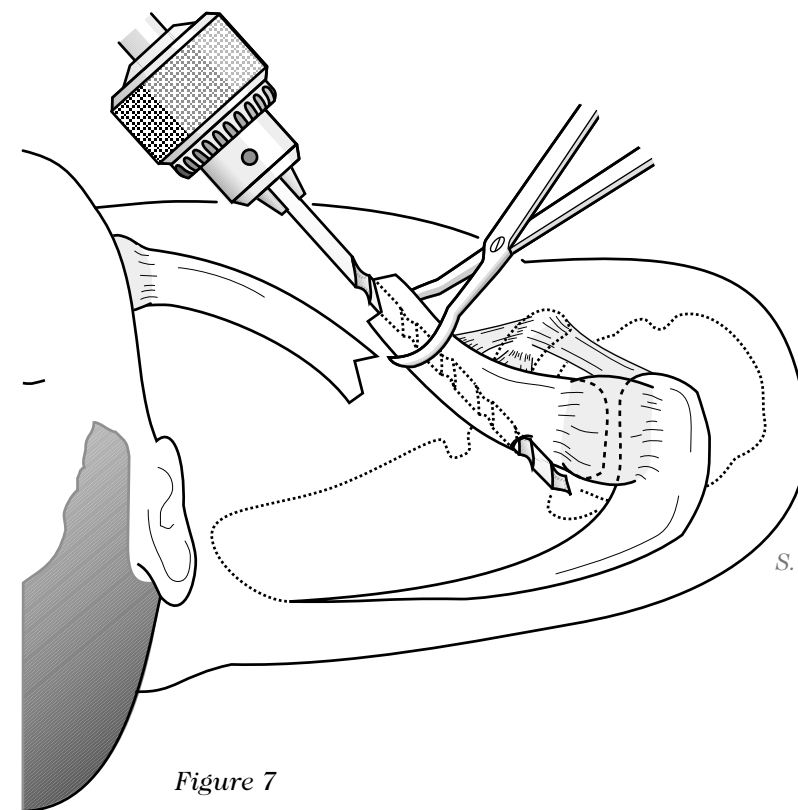


Figure 7

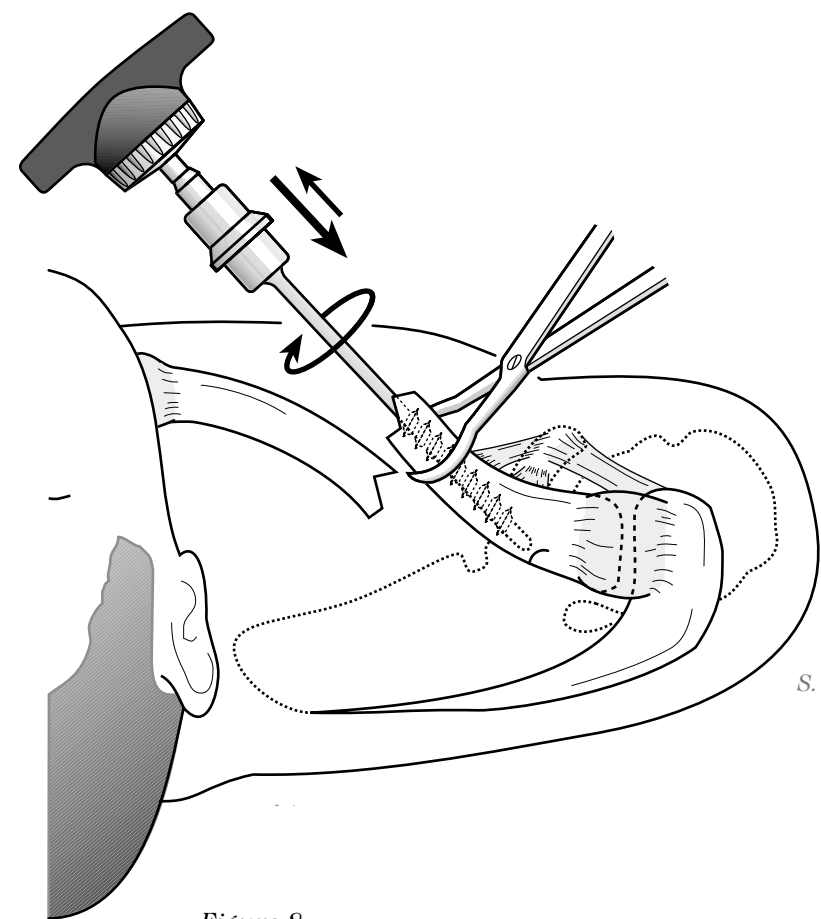


Figure 8

STEP 4 Inserting the Clavicle Pin

While holding the distal fragment with a bone clamp, remove the nuts from the pin assembly and pass the trocar end of the Rockwood Clavicle Pin into the medullary canal of the distal fragment. The pin should exit through the previously drilled hole in the posterolateral cortex. Once the pin exits the clavicle, its tip can be felt subcutaneously. Make a small incision over the palpable tip and spread the subcutaneous tissue with a hemostat

(*Figure 9*). Place the tip of the hemostat under the tip of the clavicle pin to facilitate its passage through the incision. Then, drill the pin out laterally until the large, medial threads start to engage the cortex. Attach the Jacobs chuck and T-handle to the end of the pin protruding laterally and carefully retract the clavicle pin into the lateral fragment (*Figure 10*).

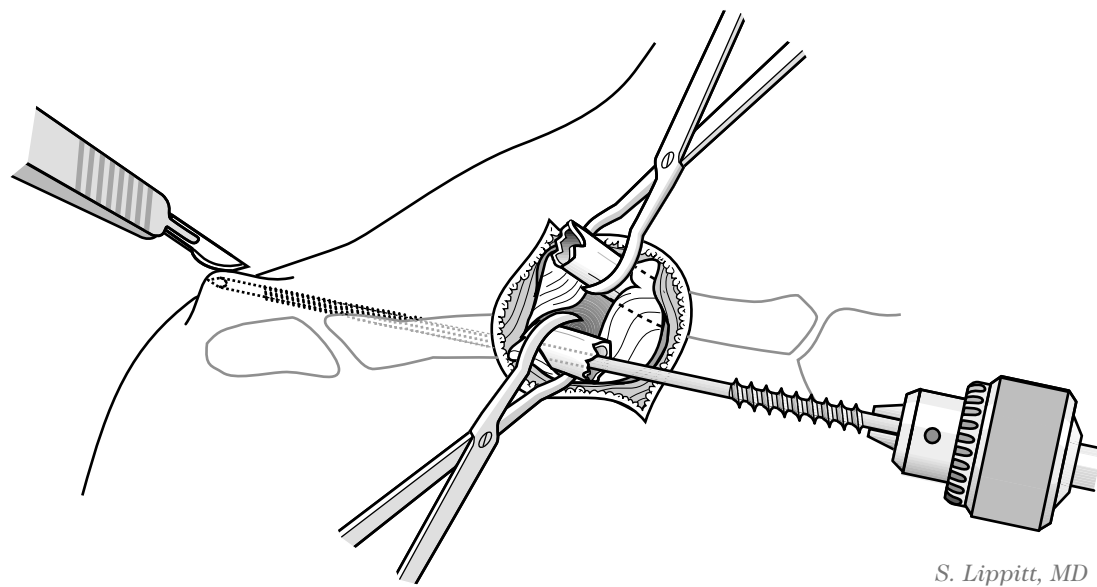


Figure 9

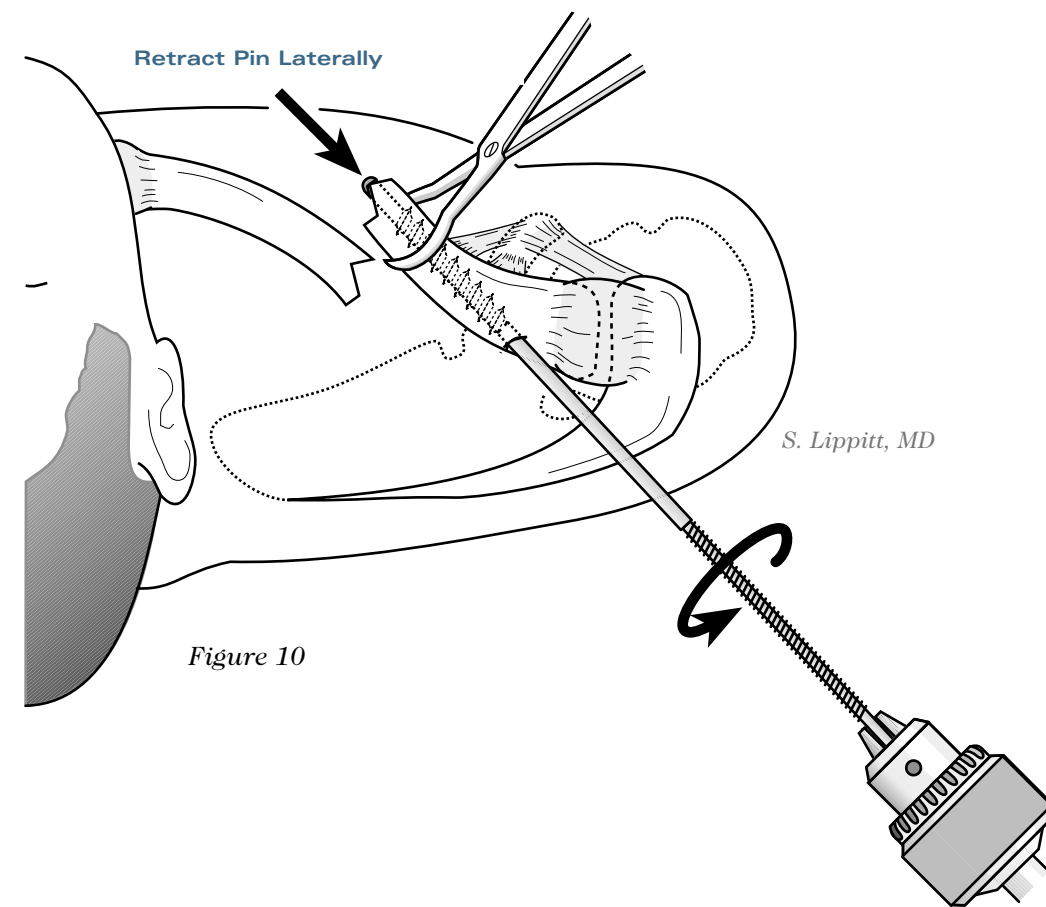


Figure 10

STEP 4 Inserting the Clavicle Pin continued

Reduce the fracture and pass the pin into the medial fragment. The weight of the arm usually pulls the arm downward; therefore, the shoulder needs to be lifted up to facilitate pin passage into the medial fragment. Place the medial nut on the pin, followed by the smaller lateral nut. Cold weld the two nuts together by grasping the medial nut with a

needle driver or needle nose pliers and tightening the lateral nut against the medial nut using the lateral nut wrench (*Figure 11*). Then, use the T-handle and wrench on the lateral nut to medially advance the pin down into the medial fragment until it comes in contact with the anterior cortex. This position can be verified by the C-arm or by taking an X-ray.

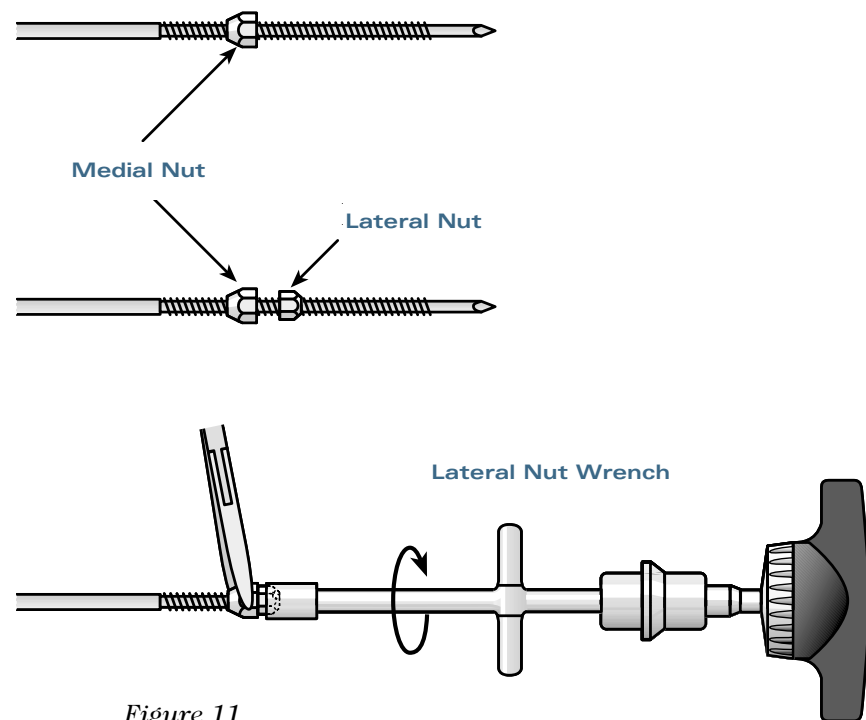


Figure 11

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STEP 5 Securing the Pin

Break the cold weld between the nuts by grasping the medial nut with a needle driver or pliers and quickly turning the lateral nut counterclockwise with the insertion wrench. Advance the medial nut until it is against the

lateral cortex of the clavicle. Then, tighten the lateral nut until it engages the medial nut (*Figure 12*). Use a pin cutter to cut the pin near the lateral nut.

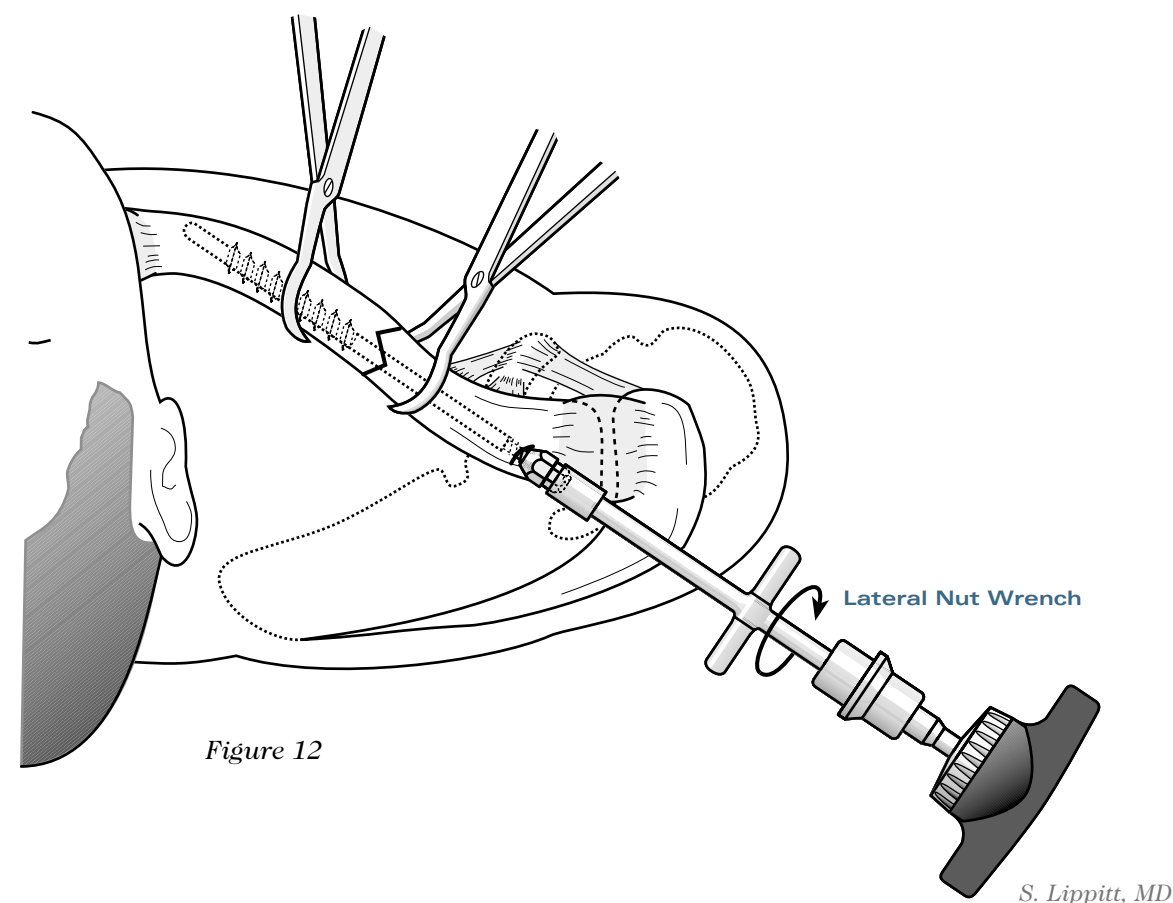


Figure 12

S. Lippitt, MD

STEP 6 Soft Tissue Closure

To reapproximate the anterior butterfly fragments, pass the Crego elevator beneath the clavicle in an anterior-to-posterior direction to protect the underlying structures. Use absorbable Ethicon #0 or #1 PDS® or Panacryl® Sutures loaded on a CTX or CT1 needle and pass it through the periosteum attached to the butterfly fragment. Then, pass it around and beneath the clavicle (*Figure 13*). Carefully direct the needle toward the Crego elevator so it will be deflected by the elevator.

Retrieve the needle posteriorly. Pass the suture in a figure eight manner or use multiple simple sutures to cerclage the butterfly fragment to the main fracture fragments.

Close the periosteum overlying the fracture with multiple figure eight sutures of #0 Vicryl™ absorbable suture. Reapproximate the platysma muscle with simple absorbable Ethicon #2-0 Vicryl sutures. Close both incisions with a running subcuticular suture.

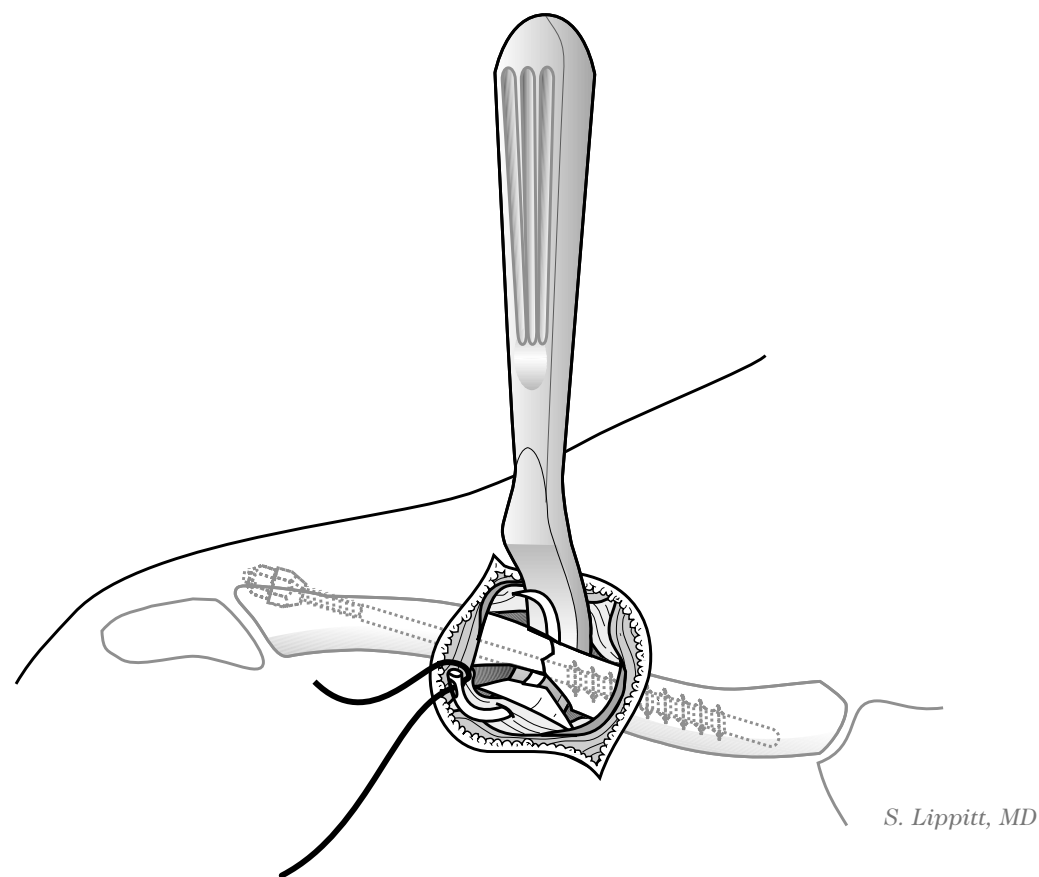
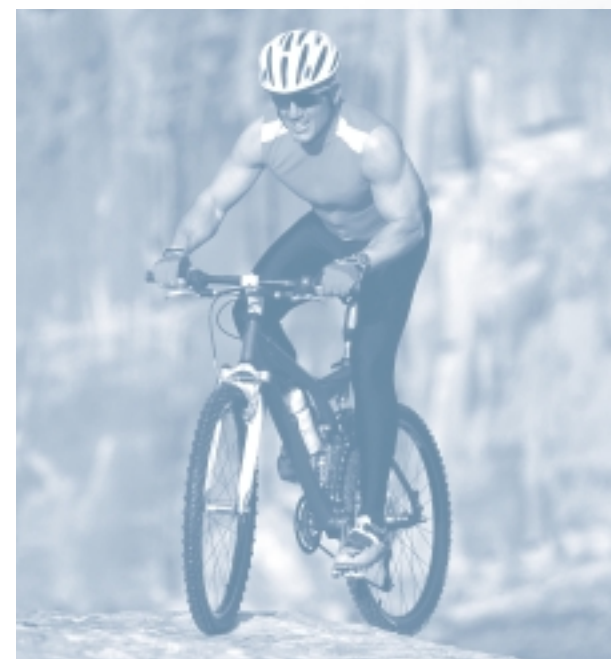


Figure 13

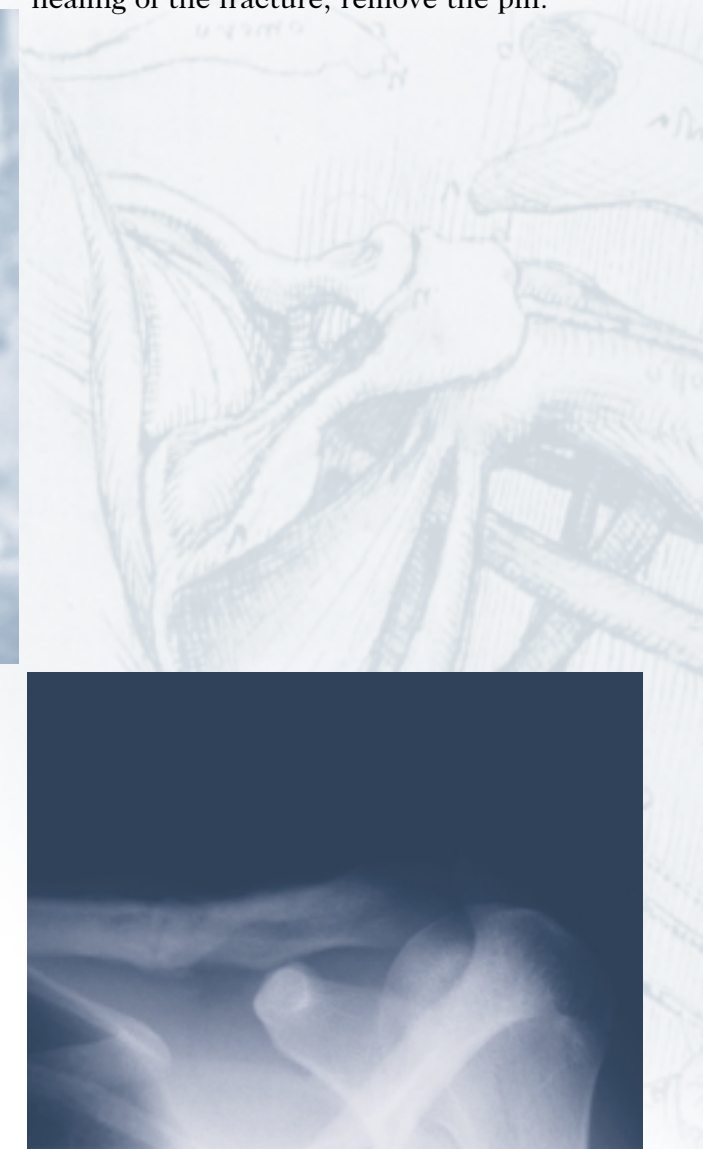
POSTOPERATIVE CARE OF ACUTE FRACTURES

Allow the patient to resume daily living activities as soon as tolerated but avoid strenuous activities such as pulling, lifting or pushing, and arm elevation higher than face level for four to six weeks. Excessive arm motion, particularly forward flexion, may result in rotation of the fracture fragments, causing irritation of the soft tissue by the lateral pin and nuts.



Remove sutures at seven to 10 days. Take postoperative X-rays at the four to six week postoperative clinic visit. If the fracture is clinically healed (not tender, palpable callus) allow the patient to advance daily activities as tolerated.

See the patient at eight to 12 weeks postoperatively. If repeat X-rays (AP and 45 degree cephalic tilt AP radiographs) show healing of the fracture, remove the pin.



OPTIONAL TECHNIQUE FOR CLAVICLE MALUNIONS AND NONUNIONS

Clavicle malunions and nonunions represent cases where the pin may also be used. For clavicle malunions, incise the periosteum overlying the deformity longitudinally as previously described. Once the periosteum is circumferentially elevated from the deformity, use a small osteotome to remove the callus from the fracture site. This is best performed under C-arm guidance to assure adequate removal of the fracture callus.

Use a rongeur to remove the callus from the ends of the medial and lateral fracture fragments. Then, find the canal with the smallest size drill bit, verify its position with a C-arm or an X-ray, and then drill the canal with the appropriate size drill. Pass the Rockwood Clavicle Pin as previously noted. Use a small osteotome to “fish scale” or “rose petal” the cortical bone about the fracture site. Morsellize the previously removed callus, and pack it about the fracture site. Use autogenous bone graft from the patient when indicated. Then, close the periosteum as previously noted.

Treat hypertrophic nonunions the same as clavicle malunions. In the case of atrophic nonunions, remove any tapered ends of the clavicle fragments. Carefully remove the scar tissue with a rongeur. Proceed with treatment as described for clavicle malunion, with the exception of using autologous or autograft bone.

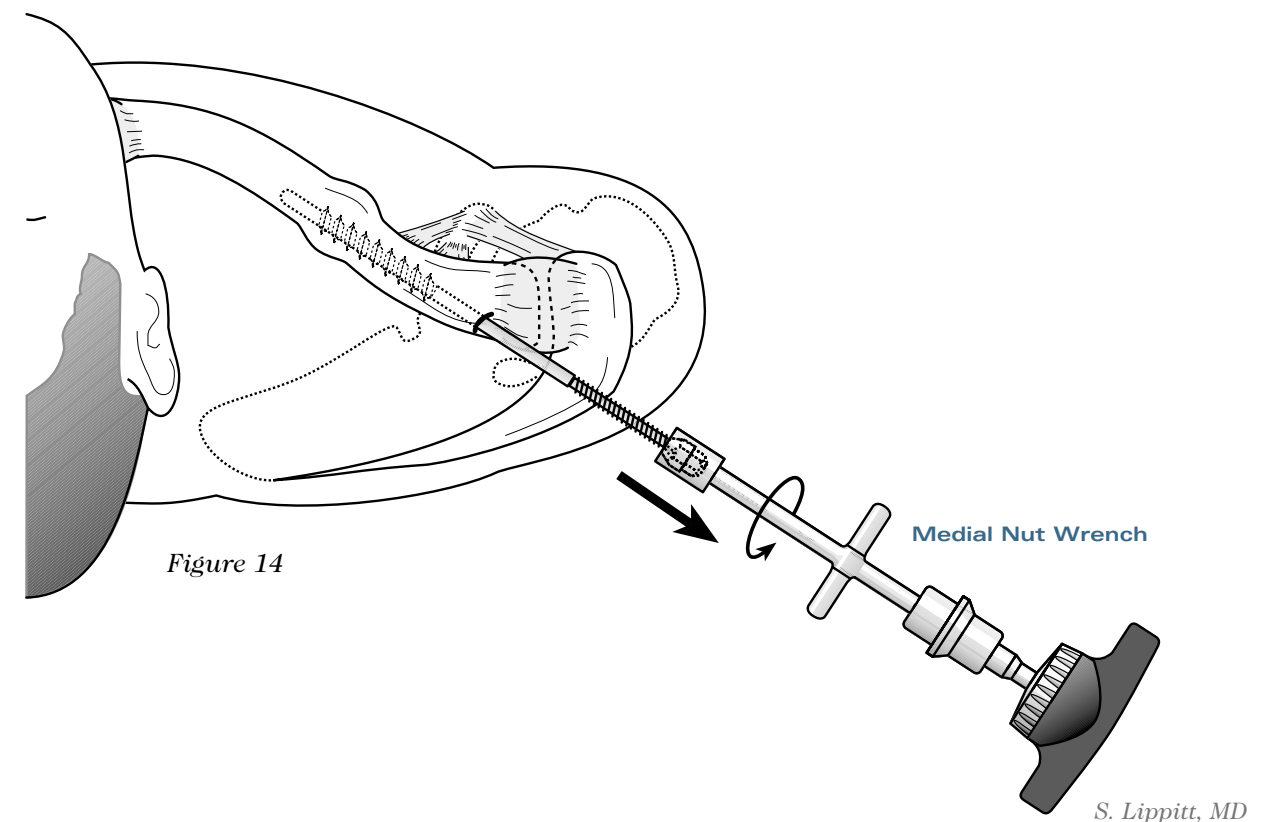
POSTOPERATIVE CARE

Modify postoperative care for malunions and nonunions as required.

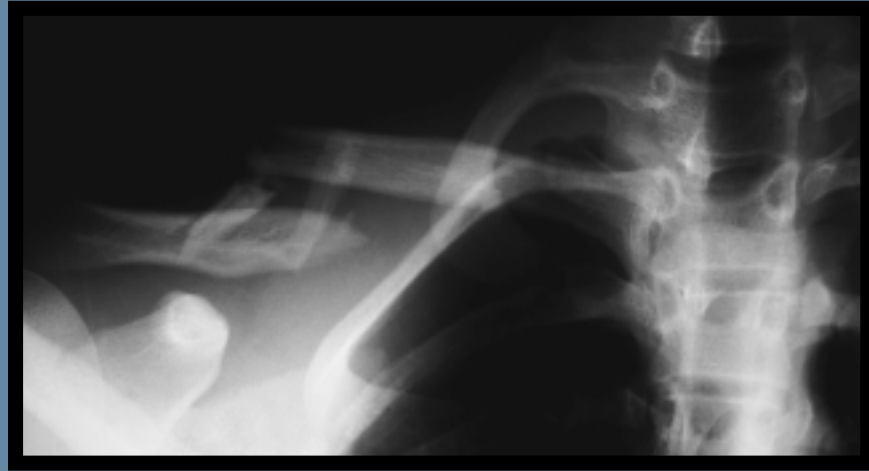
POSTOPERATIVE CARE | PIN REMOVAL

Place the patient in a beach chair or lateral decubitus position. Sterilize the lateral pin site and administer local anaesthesia. Open the incision and pass the extraction wrench over the pin until it engages the large medial nut and remove the pin (*Figure 14*). Take care to avoid removing the pin too quickly as this may cause the patient discomfort or pin breakage.

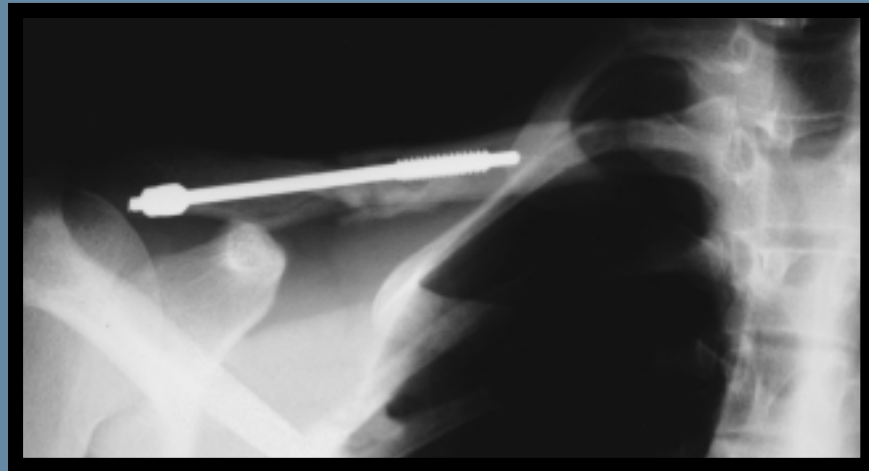
Patients can usually resume full, unrestricted activities after at least two to four weeks. With clavicle nonunions and malunions, leave the pin in place for a minimum of eight to 12 weeks or until there is evidence of good healing on radiographs. Then, remove the pin as previously described. Use both AP and 45 degree cephalic tilt AP radiographs to assess healing.



ROCKWOOD CLAVICLE PIN



ACUTE fracture preoperative at 45 degrees.

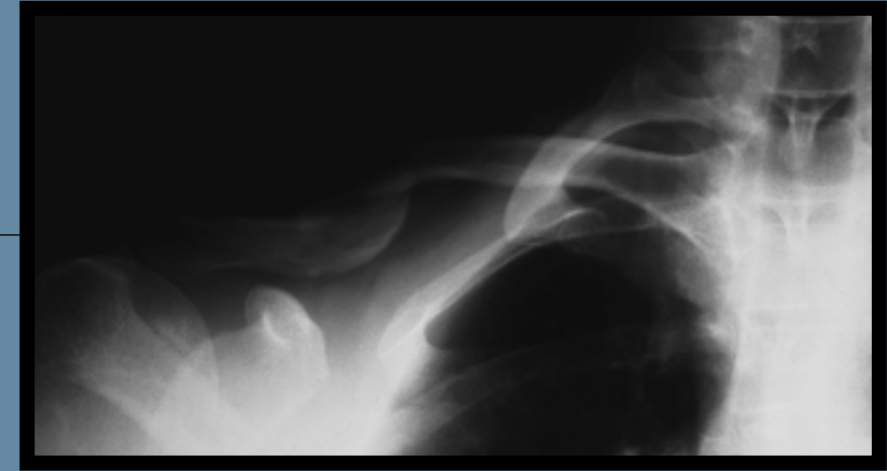


ACUTE 45 degree tilt at postoperative.



ACUTE 45 degree cephalic tilt at 10 weeks postoperative.

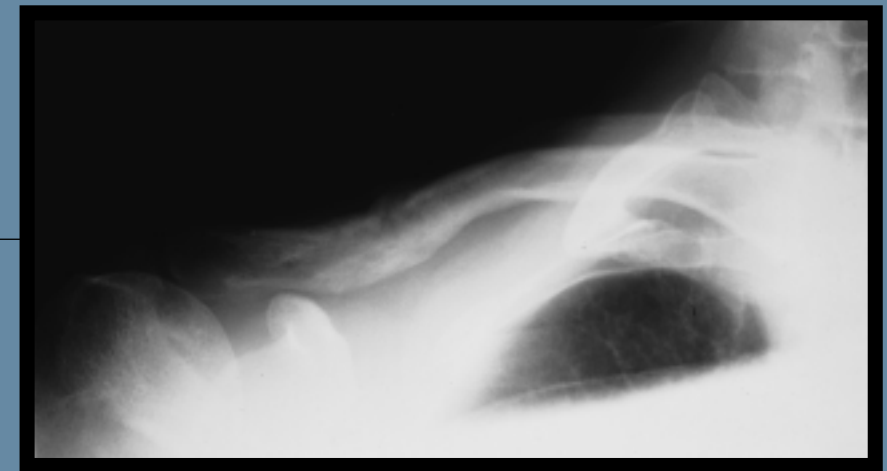
ACUTE FRACTURE



MALUNION 45 degree cephalic tilt A.



MALUNION at immediate postoperative.



MALUNION at 16 weeks postoperative.

MALUNION FRACTURE