

Revolutionary percutaneous fracture fixation applied in a fraction of the time of open reduction and internal fixation or arthroplasty.

Non-bridging fixation that allows for solid fixation and early active motion.



www.nutekortho.com

Introduction

· Proximal humeral fractures continue to increase in frequency with our aging population.

· Significantly displaced fractures have traditionally been treated with percutaneous pin fixation, open reduction and internal fixation, intramedullary rods and, with hemiarthroplasty.

· Outcomes of nonoperative and operative fracture care remain poorer than other non traumatic shoulder surgery. This may result from malunion, postoperative soft tissue scarring, tuberosity necrosis, and primary or secondary rotator cuff dysfunction.

· Non-bridging external fixation offers an easier fixation technique and greater rigidity than percutaneous pin fixation, markedly decreased operative time and little to no blood loss compared to open techniques.

• The goal of the NBX[®] non-bridging shoulder fixation system is to improve proximal humeral fracture care by:

- Decreased operative time
- Decreased operative blood loss
- Decreased postoperative pain
- Increased early active range of motion
- Rigid fixation and minimal additional soft tissue injury
- Increased final active range of motion
- Minimized post fracture scarring
- Preserved vascularity to tuberosities
- Preserved native rotator cuff function
- Prevention of malunion

Indications:

- Open fractures
- Reducible 2-, 3- and 4-part fractures with minimal traction, manipulation or percutaneous reduction
- Within 2 weeks of fracture to aid reduction
- · Medically cleared for operative procedure

Contraindications:

- Head splitting fracture
- Irreducible glenohumeral dislocation or fracture pattern

Table Of Contents

The NBX Shoulder Fixator System. Patient Positioning Fracture Reduction 2-Part Fracture Surgical Technique. 3-Part Fracture Surgical Technique. 4-Part Fracture Surgical Technique. Post Operative Care

Surgical Technique Described By:

Peter J. Evans, MD, PhD, FRCSC Director, Upper Extremity Center **Cleveland Clinic** Cleveland, Ohio

NBX[®] Shoulder Fixation System Designed and Developed By:

M. A. Hajianpour, MD, FICS Ft. Lauderdale, FL

Copyright Nutek® 2009





		•								 											-	-	•	•					• •			•	•	•	-	• •		•	•	 • •		2
						 	 																	 	 	 				-				-			 			 		4
	•	•	•									•	•																	•	•		-									5
	-	-																			-									-		-						-			.(6
	-	-	-	-	-			-	-		-	-	-			-	-	-	-	-						-	-	-			-	-									1	1
	-	-																		-	-	-				-	-	-		-		-						-			1	3
-	-	-	-	-				-	-				-	-	-		-	-													-		-		 						1	6

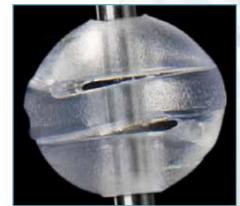




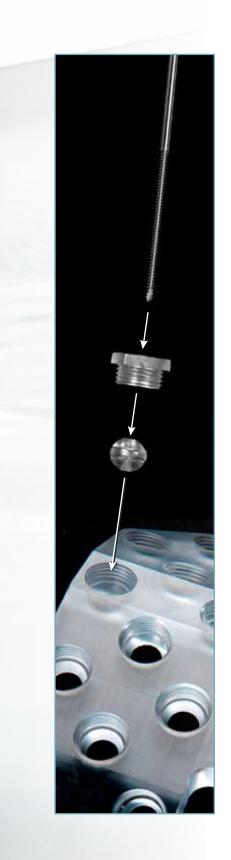
NBX[®] Shoulder Fixation System



The NBX® Shoulder Fixation System consists of 5 basic parts: the fixator, patented locking ball, locking nut, wrench, 4.0 mm and 3.0 mm partially threaded stainless steel fixation pins. The fixator comes fully assembled with all locking balls and nuts in their respective openings.

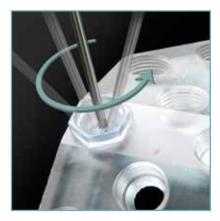


The patented locking ball is designed to deform and crimp when the locking nut is tightened, securing the fixation pin to the fixator and locking both the angle and depth of insertion of the pin.



NBX[®] Shoulder Fixation System





To place a fixation pin in the humerus, the pin is placed through the locking ball and drilled into the humerus at the desired angulation and level. The unique design allows for the fixation pins to be placed up to 30 degrees in any direction.



Tightening the locking nut will secure the pin to the frame at the desired level and angle. Slippage of the wrench on the nut will confirm that optimal locking has been achieved. Do not overtighten, and confirm integrity of fixation after tightening.



Patient Positioning

Intraoperative Flouroscopy:

Fluoroscopy should be set up and a dry run of the routine anterior-posterior and axillary views performed after patient positioning and prior to prepping and draping the patient to ensure the quality of images, accessibility for desired views, and to expedite the procedure.

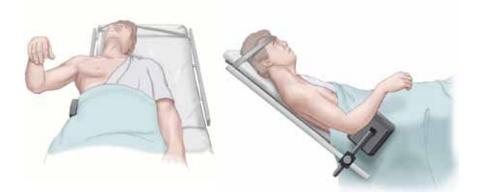
Beach Chair Positioning

Anterior-posterior (AP) View: Use of an operating table that is radiolucent or a dedicated beach chair with the operative shoulder accessible without obstruction by the table is preferred. However, the patient can be positioned upright on a regular bed or supine on a radiolucent fracture table. The fluoroscopy arm should be draped at both ends and a free 3/4 sheet should be clipped to the final drape to keep the lower arm separated from the operative field when it is rotated from the AP to the axillary view.

Axillary View: In order to obtain a clear view, the patient's head should be tilted away from the operative shoulder to allow room for the fluoroscopy receiver. The arm should be slightly abducted and the receiver should be above the head.



Standard Bed Positioning: The patient should be positioned with head at side of the bed and scapula supported. Head should be taped securely to bed.



A closed reduction is performed to assure that the fracture can be treated successfully by external fixation. If the head and shaft are not impacted this is often straight forward, but when they are mal-reduced and impacted this will require percutaneous reduction. For 3 or 4-part fractures the tuberosities will require percutaneous reduction and the assessment should be based on the ability to realign the head and shaft successfully. Greater and lesser tuberosities will be reduced secondarily.

Sagittal Plane Reduction (SPR)

The humeral head is typically rotated posterolaterally by the intact supraspinatus and infraspinatus and when the arm is at the side, parallel to the thorax. This results in a head-shaft fracture angle that is apex-anterior. This is best appreciated on the fluoroscopic axillary view.

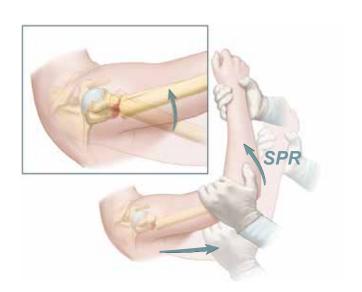
To reduce the fracture, provide longitudinal traction and forward elevation of the humerus. The change in position of the humerus relative to the thorax, from non-reduced to reduced, creates a sagittal plane reduction head-shaft angle (SPR). The SPR angle must be noted and reproduced prior to the second head-fixator pin placement.

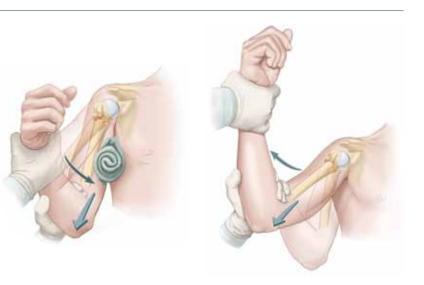
Coronal Plane Reduction

Valgus angulation is corrected with a rolled up towel in the axilla, humeral shaft adduction and caudal traction. Varus angulation is corrected with humeral abduction. The thoracohumeral angulation in the coronal plane to achieve reduction is noted for the first shaft-fixator pin placement which is typically placed in the anteriorposterior fluoroscopic view.

Closed Reduction











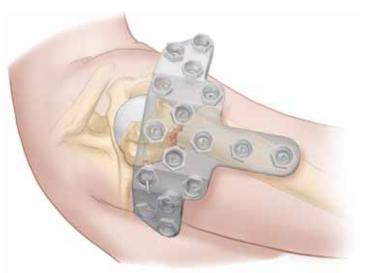
Initial Fixator Pin Placement

An 11-blade is used to make a small stab wound over the greater tuberosity. The pin is manually advanced to the superolateral part of the greater tuberosity and then advanced with a large collet wiredriver into the center of the humeral head up to the subchondral bone. This pin can be inserted in a direct lateral or posterolateral orientation. Confirm placement on the AP and axillary view.



Initial Fixator Placement

A hole in the top row of the fixator is chosen that allows the fixator to be centered over the lateral aspect of the arm. The locking ball and nut come loosely pre-assembled in each hole of the fixator. The fixator is placed over the first fixation pin, allowing the pin to go through the chosen ball. The locking nut is then thumb tightened.



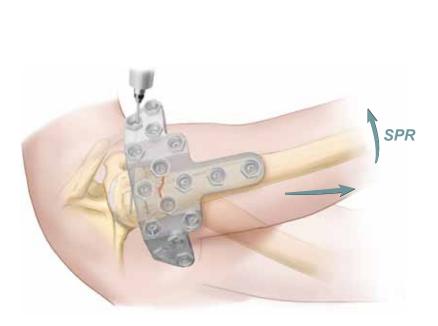
Fixator Alignment - KEY

The sagittal plane reduction must be performed prior to the second pin placement. The humerus is flexed to the SPR angle. Reduction is confirmed on the axillary view. The fixator is held 2 fingers breadth from the skin and the long axis of the fixator is lined up with the humeral shaft.

The second fixator pin is placed through the top row of the fixator. Select the desired hole, manually advance the pin through the locking ball, make a stab wound on the skin and manually advance the pin onto the bone. Use the driver to advance the pin into the bone through the center of the head into the subchondral area, typically in the anterior region of the head. Confirm the position of the pin on AP and axillary views then thumb tighten the locking nut.









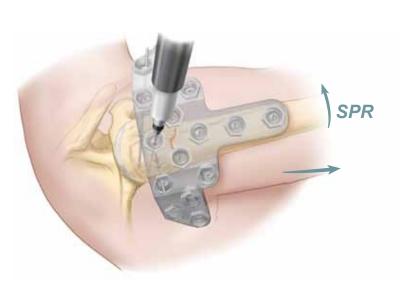




Securing Head Fixation

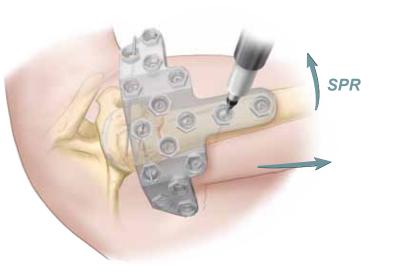
A third head fixation pin is placed through the locking ball in the desired hole in the top row of the fixator into the humeral head as described before.

With the humerus flexed to the SPR angle, all three locking nuts are firmly (but not maximally) tightened with the wrench. This three pin construct in the head allows for manipulation of the head for reduction to the shaft.



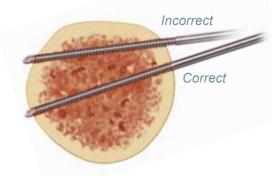
Humeral Shaft Reduction And Fixation

The fracture is reduced by forward elevating the arm to the SPR angle and correcting for varus/valgus malalignment. Using the second from most distal hole of the fixator, manually advance the fixation pin as before, taking care to assure that the fixation pin is on the most lateral portion of the humerus. Advance the pin with the wire driver to obtain bicortical purchase.



The humeral shaft fixation pins should be placed distal to one humeral head height or about 3 inches below the inferior glenoid rim to avoid the axillary nerve as it travels laterally from posterior to anterior in the deep layers of the deltoid.

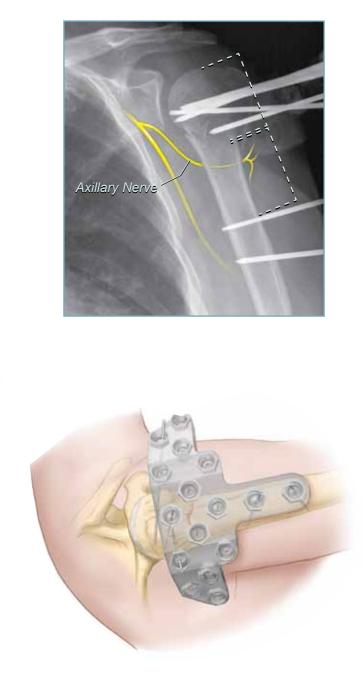
The shaft pin should be placed in the center of the humeral shaft to avoid cut out or weakening of the shaft and angled slightly superior (divergent to next pin) or inferior (convergent to next pin) to increase pull out strength.



Final reduction should be made and checked on the AP and axillary view and then all locking nuts tightened. The second shaft fixation pin is then placed in the most distal fixator hole as above at either a slightly divergent or convergent angle.

A third shaft fixation pin should be placed in the third from the bottom hole if the patient is obese to increase the construct strength. This pin should be directed distally to avoid the axillary nerve.









Final head fixation pins should be placed through the second row of the fixator for a minimum of 5 pins in the head (more can be added if necessary). If slight malalignment exists, the lock nuts can be loosened, re-manipulation performed, then re-tightened to finalize fixation.

A minimum of 5 fixation pins must be inserted into the humeral head. The pins should be inserted anterior, posterior and lateral in a balanced fashion.



Dressing & Pin Care

All pins should be cut flush to the fixator and pin protectors applied. The fixation pin-skin interface should not be under tension and relaxing incisions should be made accordingly. Pin sites should be dressed with antibacterial ointment, non-stick gauze, gauze, abdominal pads and tape.

Initial dressings are removed within the first week postoperatively. Daily showering with city water (not well water) is then permitted. Pin sites are cleansed daily with dilute hydrogen peroxide with a cotton swab and antibacterial ointment is re-applied. After initial dressing removal a 3" wide stockinet can be used to cover the fixator.



Three part fractures typically have a superior, lateral and posterior displaced greater tuberosity in addition to a displaced head and possibly a nondisplaced lesser tuberosity fracture.

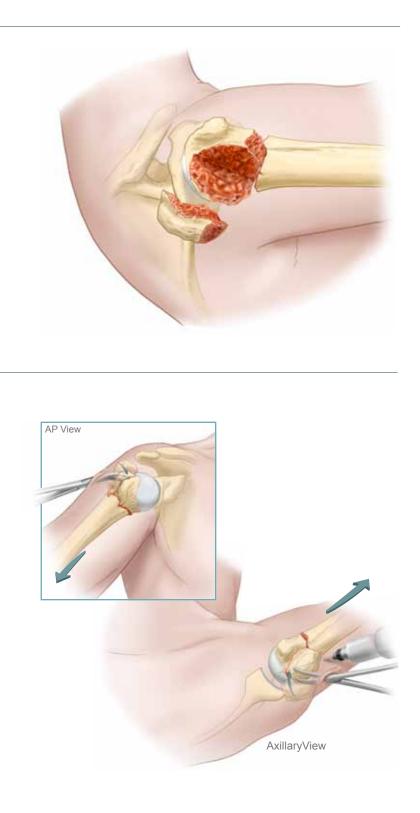
Initial head-shaft reduction is performed as per 2-part fractures described above. If determined amenable to external fixation, then greater tuberosity reduction and pinning is performed.

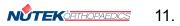
Greater Tuberosity Reduction

Initial reduction is attempted with a 0.62 in K-wire or one of the head-fixation pins. The greater tuberosity can be skewered with the pin and then if easily reduced, the head-fixation pin is advanced into the humeral head. If a headfixation pin was used it will then serve as the first external fixator pin.

If reduction cannot be achieved as above, a large tonsil hemostat is used via a posterolateral or direct lateral subacromial portal to manipulate the greater tuberosity into anatomic position. If it still cannot be reduced, expansion of the portal is made large enough to allow a finger in to obtain reduction, which is typically blocked by periosteum or bursa. Once reduced, a head-fixation pin is placed through the tuberosity and into the head. A second head-fixation pin is placed as per 2-part fractures described above.



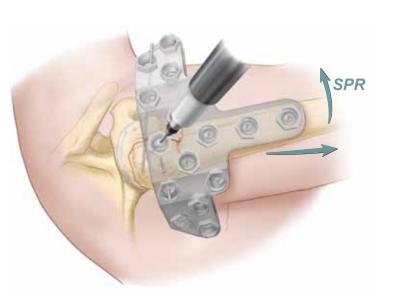






Surgical Technique: 3-Part Fracture Fixation

The third head-fixation pin should be placed through the greater tuberosity to secure its reduction and fixation.



Final pin placement is as per 2-part fractures described above. If slight malalignment exists, the lock nuts can be loosened, re-manipulation performed, then re-tightened to finalize fixation. A minimum of 5 fixation pins must be inserted into the humeral head.



Surgical Technique: 4-Part Fracture Fixation

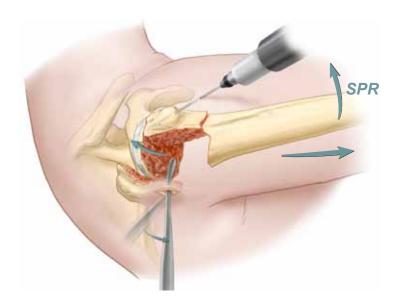
In 4-part fractures the head spins more posteriorly and the lesser tuberosity rotates off anteromedial being pulled by the intact subscapularis tendon.

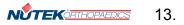
The key to reduction is humeral traction, percutaneous reduction and temporary K-wire fixation of the head to the lesser tuberosity.

With reduction and forward elevation, an elevator is placed through a lateral or posterolateral portal into the fracture site, under the humeral head, and then the head is disimpacted and levered up into anatomical position. (Finger manipulation can be used if necessary.) One or two k-wires are inserted through the lesser tuberosity and into the humeral head for temporary fixation.







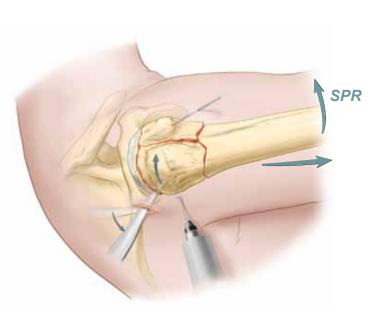




Surgical Technique: 4-Part Fracture Fixation

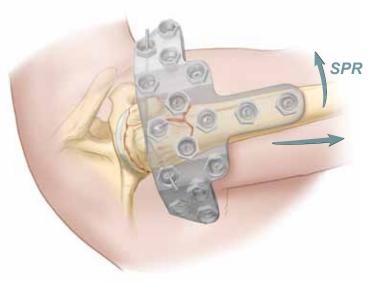
Surgical Technique: 4-Part Fracture Fixation

The greater tuberosity is then reduced into position with an elevator, tonsil forcep or finger. The first head fixation pin is placed in the greater tuberosity.



Holding the shaft of the humerus in traction and observing the reduction of the head onto the shaft, insert the shaft fixation pins as described before. A minimum of 5 fixation pins must be inserted into the humeral head.

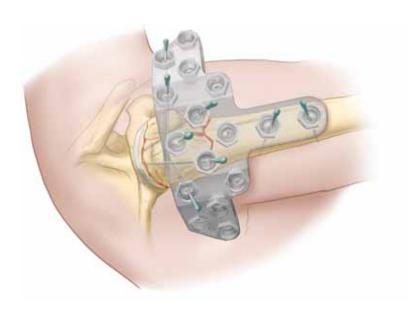
With the humerus held at the SAG angle, the fixator is placed over the first pin. The second and third pins are then placed to secure head fixation. The stem of the fixator should be positioned over the shaft of the humerus. If there is any question regarding the stability of the fixation of the fracture fragments, the fourth and fifth head fixation pins could be placed at this point.



Pre-op

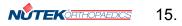








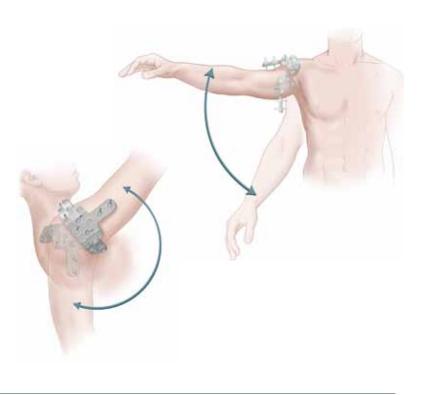






Active and passive lateral flexion up to 90 degrees can be initiated.

Active and passive forward abduction up to 120 degrees in the scapular plane can be initiated supine on a bed.



Supine assisted forward elevation stabilaizes the scapula and promotes glenohumeral mobilization and minimizes periscapular muscle spasm. Passive range of motion also reduces capsular adhesions.





Elevation can be facilitated by using a paint roller while facing the wall or off to the side. The roller reduces muscle recruitment and periscapular co-contraction compared with traditional wall-walk exercises.

Over-the door pulleys can be initiated after the first week. This exercise can be done either facing towards or away from the door or sideways.

Post Operative Course Of Care











NBX[®] Shoulder External Fixator Kit Complete, Sterile Packaged

NBX[®] Shoulder Fixator
NBX[®] Wrenches
3mm x 150mm Threaded Half-pins
4mm x 150mm Threaded Half-pins



Application of New Technologies in Orthopaedic Surgery

For product inquiries and information, contact info@nutekortho.com 301 SW 7th Street, Fort Lauderdale, Florida 33315 ph 954.779.1400 fx 954.779.1900

www.nutekortho.com