





T-FixUp - Proximal Humerus External Fixator

The right compromise in proximal humerus fractures

INTRODUCTION

The T-FixUp fixator is made up of various components which, assembled together on PinFix pin, inserted into the bone, according to the surgical technique reported below, forms an external osteosynthesis system capable of stabilizing the fracture until healing. The technique illustrates the individual procedures to obtain correct percutaneous stabilization of proximal humerus fractures.

Key elements

- PinFix 2.5x300mm thread 60mm (code 16-0050/NS)
- Pin clamp (code 02-81090 PATENT PENDING)
- Bar to bar 6mm clamp (code 02-81080)
- Carbon bar 6x100mm (code 02-82100)
- Carbon bar 6x125mm (code 02-82125)
- Carbon bar 6x150mm (code 02-82150)
- Carbon bar 6x175mm (code 02-82175)
- 10mm wrench (cod. 05-202020)

Note: Complete in-depth reading is recommended before using the product



PREOPERATIVE PLANNING

Radiographic examinations (anteroposterior projection, axial projection, Y projection, Grashey and transthoracic projections) are essential for studying shoulderfractures. A computed tomography (CT) scan with multiplanar (MPR) and three-dimensional (3D) reconstruction is strongly recommended, especially in 3-4 fragment fractures.

POSITIONING OF THE PATIENT

Initially the patient is positioned supine on the operating table to perform the indirect external reduction maneuvers; subsequently the patient is placed in the beach chair position with the C-arm positioned on the contralateral side of the injured shoulder. Before preparing the operating field, it would be better to try an X-ray where the glenoid is perfectly tangent (true anteroposterior projection or Grashey projection) and an axial projection (or the so-called Taranto projection). The use of a modular operating table with the possibility of removing the proximal components is recommended.

OPERATING FIELD

Before starting the normal skin preparation according to the own hospital protocol, shoulder washing (especially the armpit) with chlorhexidine solution is strongly recommended. The sterile drapes applied must leave the entire glenohumeral, coracoid-clavicular and clavicle-acromial joints visible: half of the distal clavicle, the coracoid process and the acromial process must be visible. Furthermore, the arm must be free to move in space. The application of a sterile sleeve up to the elbow is recommended.

INTRODUCTION

ANATOMICAL LANDMARKS

Drawing the precise points of the shoulder bony processes helps the surgeon during the percutaneous fixation technique, moreover, it reduces the exposure to the x-rays. It is important identify the coracoid process and the entire acromial edge process.

Draw a longitudinal line starting from the anterolateral corner of the acromial process along the anterolateral edge of the humeral shaft (MacKenzie approach). The axillary nerve runs approximately 5-7cm transversely, it originates posteriorly and passes anteriorly into the deltoid muscle. Finally, on the same line mark the entry point of the oblique pins at about 10 cm away.

In case of an open reduction is required, it could be necessary to perform a deltopectoral approach or an antero-lateral approach (MacKenzie approach) according to the fracture's pattern and the surgeon preference.

CLOSED REDUCTION WITH EXTERNAL MANOEUVRES

Most frequent pattern fracture of the proximal humerus is a varus head displace in addition to a tuberosities dislocation and a shaft antero-medialization pulled by pectoral muscle.

The reduction manoeuvres have the objective of realigning the bone segments in the correct anatomical position counteracting the muscular forces vectors.

Initially, the surgeon must stabilize the upper part of the scapula with one hand while, using the second one, he carries out an abduction of the arm. Usually, traction is not necessary, and the degrees of abduction depend on the severity of the varus head displacement. Secondly, at about 45 degrees of abduction, the surgeon must push posteriorly the shaft using the second hand, always keeping the scapula stabilized. It is important to consider the rotation of the head and consequently the shaft. The most frequent tuberosity displacement concerns the great tuberosity which is posteriorly pulled by the superior-posterior cuff (supra and infraspinatus muscle). In these cases, the humeral head results in intra-rotation because it is pulled by the subscapularis muscle. The surgeon must consider this event and adapt the forearm rotation in order to obtain the correct alignment of the fractured segments.

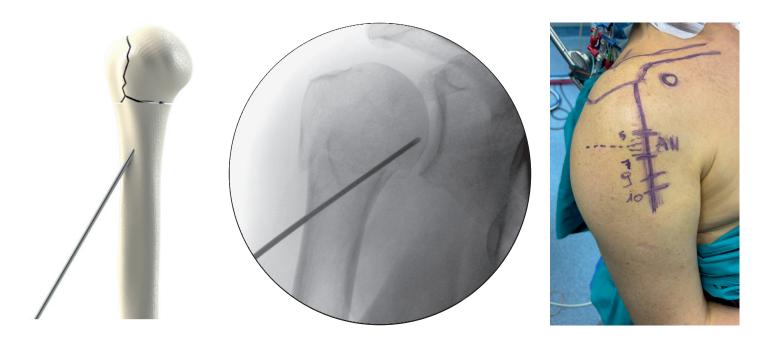
CLOSED REDUCTION WITH EXTERNAL MANOEUVRES USING A JOYSTICK

In difficult cases where the reduction of proximal humeral fractures is not satisfactory, a K-wire can be used as a Joystick. A valgus impacted fracture of the head can be reduced with an external instrument such as K-wire or a small Cobb or a hook. Subsequently a small incision to introduce the devices or using a percutaneous K-wire, it is possible to deimpact the head until the correct anatomy is achieved.

Also, the greater tuberosity can be percutaneously reduced and fixated with a K-wire. Our suggestion is to practice this manoeuvres after the head-shaft stabilization (see below): at this point the humerus can be externally rotated while the greater tuberosity undergo to an internal rotation achieving the correct anatomy of the proximal humerus.

PERCUTANEOUS FIXATION

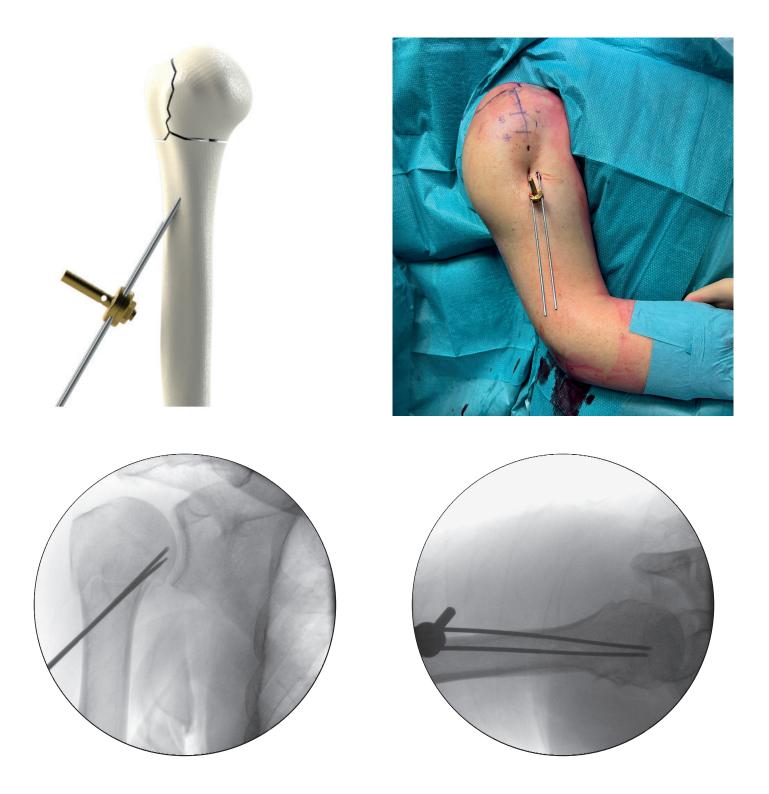
1) Make a small incision on the drawn line at 10 cm from the antero-lateral corner of the acromial process and on the antero-lateral edge of the humeral diaphysis. Thus, insert the first 2.5mm pin pre-loaded on the powered drill motor while with the other hand (or with a help of a second surgeon) keep the arm push behind and with a slight shoulder abduction to maintain the reduction. Check the entry point under fluoroscope and insert the first 2.5mm pin oblique inside the bone. Parameters to consider are:



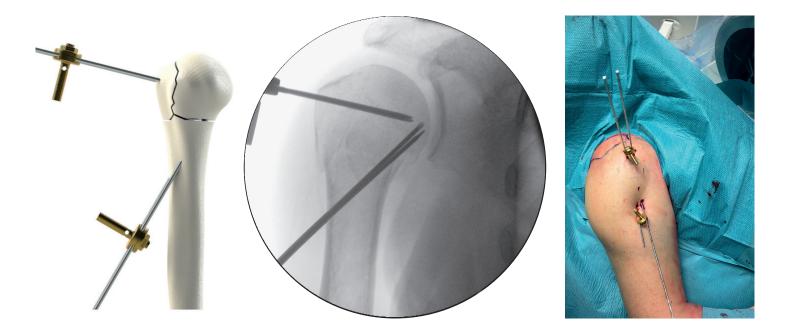
- a. Insert slowly the pin inside the soft tissue and pay attention to the transversal course of axillary nerve at 5-7 cm from the acromial process;
- b. Use the drill with low speed during the pin insertion;
- c. The target should be the coranoid process, ideally the wire should go towards the head with an inclination of both 20 degrees on the coronal and sagittal plane (considering the normal retroversion of the humeral head);
- d. The pin must be run at 0,5-1 cm from the humeral medial calcar;

- e. The pin must keep the lateral diaphysis cortical and the subchondral bone of the head;
- f. Always check the procedure under fluoroscopy;
- g. It is important to keep the correct reduction before inserting the first oblique pin into the bone. In case when the fractures need an external instrument, perform this surgery with a second surgeon;
- h. Do not bend the pin, in case of an unsatisfactory position of the wire, remove it and re-positioning the pin as desired.

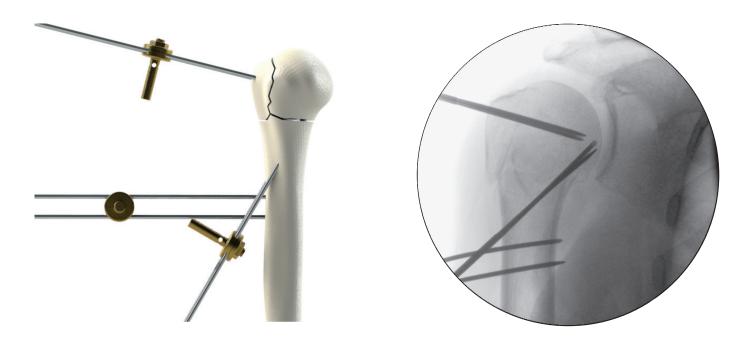
2) Using the pin clamp as a guide, insert it onto the wire using the first hole, slide it over the pin up to 1/2 cm to the skin. Insert the second pin into the second hole of the clamp. Make a small incision again and use all recommendations above for proper insertion into the bone. Using the clamp as a guide, you will obtain a parallel insertion of the two pins on the sagittal plane but posterior on the coronal plane compared to the first pin. Monitor the procedure with fluoroscopy. After the second pin placement, primary stability is achieved. The threads as well as the reduction of the head shaft must be checked in axial projection and in internal and external rotation. If the pins are not in the correct position, remove them and reposition them as desired. Remember to remove the pins by a power drill at low speed in counterclockwise position.



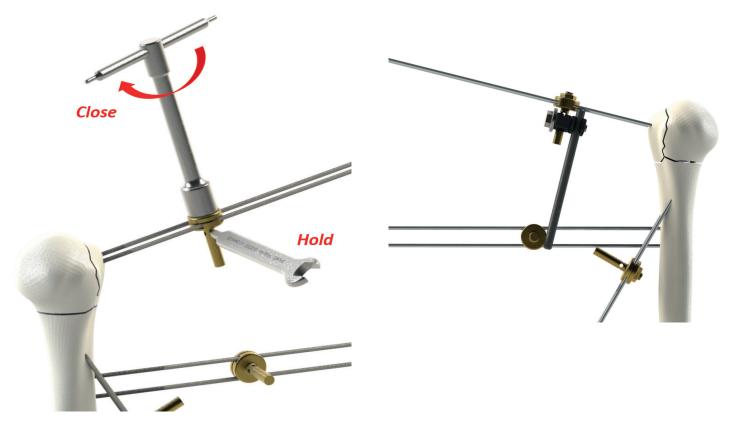
3) Insert the third pin starting from the greater tuberosity apex to the third lower humeral head. Use the same technique reported about the second wire: place the clamps on the third pin at 1 cm from the skin and use its slide to insert the fourth one. This pin must be more parallel on the sagittal plane but posterior on the coronal one compared to the third.



4) Insert the fifth and sixth pins in the shaft on the drawing line at about 8-9 cm high from the anterolateral corner of the acromial process. Use the same technique reported about the second pin: place the sixth pin through the clamps inserted on the fifth one. The sixth pin must be superior on the sagittal plane but parallel on the coronal one compared to the fifth pin. Each pin should have a bi-cortical grip.



5) Position all pin clamps 3-4 cm from the skin. Use the pin in the wrench to hold the clamp and close it with the T-Wrench. Use a suitable 6 mm carbon bar to connect the pin clamp of the humeral shaft and the pin clamp placed on the humeral head; then connect a 6mm carbon bar between the pin clamp, placed obliquely, to the carbon bar positioned previously; thus, obtaining a Lambda construct suitable to oppose the rotational forces.



6) Check intra-operatively the construct and fixation stability. At this point, cut the wires close to the clamps and cover them with the appropriate caps.



FRAME APPLICATION IN OPEN SURGERY

An open reduction of the proximal humeral fracture can be performed in case of important bone comminution or difficulty reduction with external manoeuvres. Two approaches are described in literature: deltoid-pectoral the classical access and the antero-lateral trans-deltoid way (MacKenzie approach). Both approaches allow to manage the humeral fragments, advantages but each one has and disadvantages. The deltoid-pectoral way is easier to extend distally the incision and probably most of the surgeons have more confidence, because of the well-known and famous shoulder approach. However, it could be difficult to manage the greater tuberosity and the posterior part of the shoulder. MacKenzie approach allows a larger view of the proximal humerus, but its distal extension is complicated by the axillary nerve course.

Once the fracture is exposed, proceed with the reduction of the head and tuberosities using instruments and/or sutures (we recommend tying the tendons and closing them together to stabilize the humeral head). Finally, reduction of the head with the diaphysis is attempted. Temporary K-wires can be used to stabilize the fractures.

Concerning the fixation, start with the oblique pins to synthesize the diaphysis with the head, as described above in the percutaneous technique. Always remember the course of the axillary nerve. Thus, fixated the humeral head and shaft with the remaining 4 wires.

Take a look at the antero-posterior positioning of the proximal wires in the head: the surgical approach performed and the flaps mobilization must be considered when the 3rd and 4th pin are inserted. Finally, complete the external construct as in steps 5 and 6 of the percutaneous technique.

The external fixator should be kept for 45 days (at least 6 weeks). Considering the intra-operative construct and fixation stability, we recommend stimulating the passive shoulder motion after the first week, while active shoulder motion after the 4th week according to the pain. The pin site should be medicated once a week. The shoulder and arm must be dry.

Remember to check the frame stability before the patient leaves the operating room.

DEVICE REMOVAL

At the time of removal, normally after 40/45 days after placement, the external construct must be disassembled using the related wrench. Remove the pins by a power drill at low speed in counterclockwise position.

ADDITIONAL APPLICATIONS

The T-FixUp external fixator also finds valid applications in other bone segments, such as:

• In the pediatric field for the stabilization of small fractures (also using pins with shorter threads) or as a complementary accessory in more complex fixation systems.

• In adults for the fixation of the radius or ulna or both to avoid pronosupination when necessary. Furthermore, T-FixUp is an ideal complementary system to support the fixation of the forefoot and calcaneus, in a complex system of circular external fixation, allowing the stabilization of bone components that are difficult to reach.

COMPONENTS

PinFix

2.5 x 300mm, thread 60mm, with tip and thread detail



Bar to bar clamp





Pin clamp





COMPONENTS

T-FixUp wrench

T-FixUp T-Wrench





T-Fix bars 6mm

 Dialmed T-Fix Bar 50mm 02-82050 Lot.Demo123

 Dialmed T-Fix Bar 100mm 02-82100 Lot.Demo123

 Dialmed T-Fix Bar 125mm 02-82125 Lot.Demo123

 Dialmed T-Fix Bar 150mm 02-82150 Lot.Demo123

Dialmed T-Fix Bar 175mm 02-82175 Lot.Demo123

T-FixUp Tray



COMPONENTS

Tray components list

NAME	CODE	QUANTITY
PinFix x 2.5mm	16-0050/NS	8
T-FixUp Pin clamp	02-81090 PATENT PENDING	4
T-FixUp bar to bar clamp	02-81080	5
T-FixUp Key 10mm	05-202020	1
T-FixUp T-Wrench	05-202021	1
T-FixUp Tray	05-4997	1
Protection caps	N.A.	8
T-Fix Bar 6mm	02-82075	2
T-Fix Bar 6mm	02-82125	2
T-Fix Bar 6mm	02-82175	2

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