Flexafix: The development of a new dynamic external fixation device for the treatment of distal radial fractures
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Chapter 5

The development of a new dynamic wrist fixator


5.1 Introduction

Rigid internal fixation of the fracture fragments, with early motion of the adjacent joints, has been widely advocated for the treatment of intra-articular fractures.\textsuperscript{10} Prolonged immobilisation of synovial joints results in arthrosis, persistent stiffness and pain.\textsuperscript{13} Often intensive and prolonged physical therapy is required.\textsuperscript{17,18,165} On the other hand, early active motion showed beneficial effects on the healing and regeneration of articular cartilage, as compared to immobilisation.\textsuperscript{6,10,13} It can be hypothesised that the injured wrist joint in intra-articular fractures also would benefit from early mobilisation.\textsuperscript{20}

The first surgeon who suggested a benefit of early motion after a fracture of the distal radius was Championière. In 1867 he introduced early, passive motion in minimally displaced fractures. He stated that in intra-articular fractures, early motion was necessary to recover full function of the wrist.\textsuperscript{20,166}
At the wrist, however, when there is severe comminution of the distal radius, internal fixation of the fracture fragments is difficult, if not impossible, to achieve. The intra-articular fracture of the distal end of the radius is one of the few fractures commonly seen for which no early motion can be achieved easily. Rigid immobilisation of the fracture fragments for as long as ten weeks has been advocated. To prevent some of the complications mentioned earlier, the need for a method of mobilising the wrist at an early stage seems evident. The need for a way to mobilise the wrist during treatment of a distal radial fracture has lead to the idea of modifying the small AO external fixation device to provide a means of dynamic external fixation.

5.2 The development of a first prototype

In order to achieve this goal, a research project was initiated in a coöperative effort between the department of Surgery of the Academic Medical Centre in Amsterdam and the department of biomechanics of the AO Research Institute (former Laboratory for Experimental Surgery) in Davos. The idea was discussed in a team formed by a mechanical engineer, a senior trauma-surgeon and a medical student. The project was named Flexafix.

It was felt that a mechanism which allows motion about all three axes, while keeping the centre of rotation at one point, would be a good solution. A ball joint, as some other dynamic external fixation devices have (see Chapter 4), does not meet with these criteria because the centre of rotation of a ball joint can only be in accordance with another centre of rotation (i.e. that of the wrist) about one axis. This means that in a device with a ball joint only one type of movement (either flexion-extension or radial-ulnar deviation) can be in accordance with the centre of rotation of the wrist. To overcome this disadvantage, a design in which the centre of rotation could be located outside the device (i.e. in the wrist) was developed. Detailed technical drawings of this idea were made (Fig. 22), after which a first prototype, named the Flexafix device, was...
The development of a new dynamic wrist fixator manufactured (Fig. 23). It was made of stainless steel and machined by hand by the workshop of the Product and Development Department of the AO/ASIF-group.

The prototype has the following features. The device consists of a kinematic pair. The first part is a section of a spherical shell with a diameter of 100 millimetres. The section of the shell is ring shaped with an outer diameter of 60 millimetres and an inner diameter of 21 millimetres. A second part, consisting of two metal discs, linked together by a screw through the hole in the section of the shell, is attached to the shell. This results in a sliding mechanism with its centre of rotation in the centre of the sphere, that is, 50 millimetres from the surface of the shell (Fig. 24). To enhance sliding, the metal shell is polished; Teflon rings were inserted in the discs. This sliding mechanism allows rotation about all three axis without a change of the centre of rotation. Universal four millimetre diameter rods of the small AO external fixation device are attached to both parts of the sliding mechanism.

Figure 23. The first prototype of new dynamic external fixator.

Figure 24. Drawing of first prototype of the new dynamic external fixator showing the centre of rotation of the wrist coincident with the centre of rotation of the device.
This device can be connected to the fixator pins penetrating the radius (2.5 mm threaded Kirschner wires) and the second metacarpal by using the universal AO clamps. If the device is mounted at the wrist with the surface of the shell at a distance of 50 millimetres from the centre of rotation of the wrist (i.e. the head of the capitate), it provides a means of maintaining fracture alignment, while allowing rotation of the wrist in all planes. When placed in a lateral position relative to the wrist, the device allows free flexion and extension and 20 degrees of combined radio-ulnar deviation. If the sliding mechanism is tilted towards the dorsum of the wrist, the range of flexion-extension will decrease, whereas the range of radio-ulnar deviation will increase.

After the prototype was made, at first several simple, orientating tests were done. To prove that the centre of rotation does not alter during movement, the prototype was mounted on two wooden rods (Fig. 25). One end of each rod was sharpened; these sharp ends pointed towards each other. When the prototype was mounted in the right position, it was clearly visible that the sharp ends of the rods remained in contact with each other during movement about all axes.

Subsequently, the device was mounted on a plastic model of the forearm and hand (Fig. 26). The fixator pins were placed as advised by Jakob for the small AO external fixator. The hand proved to be able to move without much resistance in a full range of motion. It should be noted that the wrist of this model consists of plastic bones linked together by a latex coating and thus is not fully representative of a human wrist.
Encouraged by the positive results of these two tests the prototype was mounted on a cadaver wrist (Fig 27). The device allowed free dorsal extension and palmar flexion and 20 degrees of combined radio-ulnar deviation. It was also found that distraction (ligamentotaxis), if applied, was not lost during movement of the hand. This was confirmed by cineradiographic recordings. In Chapter 6 and 7 further biomechanical and kinematic experiments with the new prototype of the modified small AO external fixator will be presented.
5.3 First clinical experience

Following these in-vitro experiments, the new device was used in the clinic in one patient. After a fall on the outstretched left hand a 35 year-old male sustained an impression fracture (or pilon fracture) of the distal radius (Fig. 28). In this case, the scaphoid bone was responsible for the impression of the distal radius (Fig. 29). Fracture fragments like these are unlikely to be reduced by ligamentotaxis because they do not have soft tissue attachments. Since an articular incongruence of more than two millimetres strongly predisposes to the development of post-traumatic arthrosis, the treatment of choice is anatomical reconstruction and cancellous bone grafting followed by a form of fixation which allows a functional treatment. This could be one of the indications for the new fixator.

Under general anaesthesia and tourniquet control, a dorsal incision was made over the wrist. The depressed fragment was elevated and the resulting gap under the fragment was filled with a cancellous bone graft from the iliac crest (Figs. 30 and 31).

The device was mounted with the usual 2.5 millimetre threaded Kirschner wires and the universal AO clamps. The centre of rotation of the spherical shell was pointed towards the capitate bone as the centre of rotation of the wrist. The distance between the shell and the capitate was 50 millimetres. With the patient still under anaesthesia, flexion-
The development of a new dynamic wrist fixator extension and radio-ulnar deviation were tested through the full range of motion without problems. The operative result was checked by image intensifier and showed normal movement of the carpus without collapse of the fracture fragment. At the end of the procedure, a second bar was mounted to create a temporary rigid fixation for the first three post-operative weeks. With this extra bar the fixator was locked and the wrist immobilised (Fig. 32).

The cross-bar was removed after three weeks and the patient was encouraged to move his wrist again (Fig. 33). After one week of exercising with the fixator in place, dorsal extension

Figure 30. Operative view. Articular surface impressed (arrow) by the scaphoid bone.

Figure 31. Situation after elevation of the fragment and cancellous bone graft.

Figure 32. Device mounted at the wrist and locked by cross-bar.
was found to be unrestricted but palmar flexion was not yet optimal. There was 20 degrees of radio-ulnar deviation in total. Pronation and supination were slightly reduced (Fig. 34). The patient was able to play his guitar again. After three weeks with a locked fixator another three weeks with a dynamised fixator, the device was removed. The end result was a fully functional recovery.

Figure 33. Patient playing his guitar with Flexafix in situ.

Figure 34. Situation after one week of exercising (four weeks post-operatively). Left: Flexion and extension. Right: Pronation and supination.
5.4 Continued development

After evaluation of the first clinical case it was decided to continue the Flexafix project and improve the design of the modified small AO external fixator. The first prototype of the Flexafix had several inconveniences. Having been made by hand, its construction was labour-intensive. The parts were made from stainless steel which is a relatively heavy material. The sliding properties were not optimal, in spite of the inserted Teflon rings. This could result in a form of resistance felt by the patient during exercising. Further, the screw linking together the two discs could not be locked optimally. Therefore, the discs were able to unlock and thus cause a mechanical failure of the device. The standard AO four millimetre diameter rods were fixed by welding to the sliding mechanism and could not be varied in length. Another important problem to be solved was the elaborate positioning of the fixator due to the absence of an aiming device. Furthermore, the sliding mechanism could only be locked by mounting a second crossbar over the device.

Based on these experiences the design was adjusted. The parts were designed in such a way that they could be produced by machine (Fig. 35). Instead of steel a choice was made for aluminium because of its mechanical properties (i.e. stiffness and sliding properties), weight, cost and ability to be machined. The parts were to be made on a numerically controlled turning machine. This is a computer guided turning machine which, after programming, automatically converts a chosen piece of aluminium into the desired shape. To further enhance the sliding of the discs on the ring, the aluminium parts were to undergo a special process called ‘ematalieren’. During this process the aluminium surface is hardened and coated by anodising. After assembling the parts, the screw linking together the disc would be locked with glue (Araldit epoxy AY 103, hardener HY 951). The sliding mechanism was supplied with a hole in which standard rods from the small AO external fixator set in any desired length could be fixed by tightening a hexagonal allen screw.

To be able to lock the sliding mechanism, a small extra aluminium disc was added to the device. It was placed between the upper disc and the middle part of the sliding mechanism (that is, the ring-shaped section of a spherical shell). By adding two threaded holes to the upper disc with a small allen screw in them, the sliding mechanism could be locked by tightening the allen screws, which would press the extra aluminium disc to the middle part. This gave the possibility of locking and unlocking the sliding mechanism and improving the stability and strength of the fixator in the period in which it was not dynamised.

On the edge of the upper disc a rim was made to be able to attach an aiming device to the sliding mechanism. Finally, a hole with a diameter of one millimetre was made
This hole has a role to play during the positioning of the device at the operation (see below).

5.5 Patent

The design of the sliding mechanism, accompanied by explanation with drawings and text, has been patented by the European Patent Office in Munich, Germany (pat. nr. 92917550.3-2305) and the United States Patent and Trade Mark Office in Washington, D.C. (pat. nr. 5437666).

5.6 The development of an aiming device

For an optimal functioning of the dynamic fixator it is necessary that during the operation the device is positioned in such a way that the centre of rotation of the sliding mechanism is coincident with the head of the capitate bone as the centre of rotation of the wrist. This means that this point has to be found in three planes. To accomplish this, an aiming device was designed (Fig. 36). This device consists of a ring with a rectangular bar attached to the side of it (Fig.37). In the outrigged bar, there is a one millimetre diameter hole through which a Kirschner wire can be slid. This hole was made at exactly 50 millimetres from the surface of the shell in the sliding mechanism. Several versions in various materials, including plastic and aluminium, were made by hand and by machine. The aiming device is attached to the upper disc by clamping it over the rim on this disc. Next, one Kirschner wire with a diameter of one millimetre is slid through the hole in the side-bar of the aiming device and another Kirschner wire is slid through the hole in the centre of the sliding mechanism. In this way, both Kirschner wires are pointing to
the centre of rotation of the dynamic fixator, irrespective of the position of the discs relative to the shell. If both wires were pushed forward they would touch each other exactly in the centre of rotation of the spherical shell.

During the actual operation the wires of the aiming device would not be pushed in so far but only until they touch the skin. The imaginary point of intersection of the two wires, however, is still located exactly in the centre of rotation of the device. Prior to the exact positioning of the device, the anatomical snuffbox (tabatière anatomique) and the long axis of the third metacarpal can be marked as a reference point for the location of the capitate bone and thus for the direction of the wires. With the use of an image intensifier, the two wires will be seen and the device can be manipulated until the imaginary intersection of the wires is located in the head of the capitate bone. If the fixator is mounted at the lateral side of the wrist and the image intensifier view is made in the antero-posterior direction, the fixator will be in the right position in the frontal and sagittal planes. The correct position in the transversal plane is then found by aiming the wire through the centre of the sliding mechanism at the central part of the wrist as seen from a lateral view. The procedure of aiming will be explained further in the operative instructions for the Flexafix device (see Chapter 8).

![Figure 36. Technical drawing of design of aiming device.](image)

![Figure 37. The aiming device.](image)
5.7 Maintenance of the device

The sliding mechanism can be sterilised according to standard hospital procedures. The aiming device may be sterilised up to a temperature of 120 degrees Celsius. Higher temperatures could result in damage or breaking of the aiming device. When the fixator is dynamised, it is advisable to apply a thin layer of silicone spray between the shell and the discs of the sliding mechanism to improve the sliding properties.

5.8 Conclusion

The Flexafix project resulted in the development of an external fixation device with special properties. The sliding mechanism provides three degrees of freedom of movement while at the same time the centre of rotation of all these movements is located in one point. The construction with the shells is the explanation for its main feature, this being a sliding mechanism with its centre of rotation located outside the device itself. In this way there is a possibility of combining the centre of rotation of the wrist and the centre of rotation of the dynamic external fixator. If mounted correctly, this should result in a technique which provides a method of maintaining fracture alignment, while permitting movement of the wrist in all planes.

After a successful application of the Flexafix prototype in an initial clinical test case, the design was further improved and adjusted. In addition, an aiming device was developed to facilitate the application of the fixator.