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ORIGINAL ARTICLE • ELBOW - TRAUMA

Cadaveric assessment of a 3D-printed aiming device for implantation of a hinged elbow external fixator

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Abstract

Introduction Proper implantation of a hinged external elbow fixator (HEEF) is demanding since it requires precise alignment between the flexion–extension's and HEEF's axis. In order to optimize this alignment, we have developed a 3D-printed aiming device. The primary goal of the study was to compare the aiming device-based technique with the conventional pin technique. The secondary goal was to determine whether it is possible to share the aiming device with the surgical community.

Materials and methods A HEEF was implanted in cadavers with either the aiming device ($n = 6$) or the conventional pin technique ($n = 6$). For both techniques the duration of the procedure, the radiation exposure as well as the offset and angular divergence between the HEEF's and flexion–extension's axis were compared. To achieve the secondary goal, two surgeons used aiming devices 3D-printed from files sent by email in order to implant HEEF on cadaveric specimens ($n = 6$).

Results Duration of the procedure was not significantly different between both techniques. However, the aiming device allowed for reduction of the number of image intensifier shots ($p = 0.005$), angular divergence ($p = 0.02$) and offset between both axes ($p = 0.05$). The aiming devices have been delivered less than 15 days after ordering, and they have allowed proper implantation of six HEEF.

Conclusion The 3D-printed aiming device allowed less irradiant and more accurate implantation of HEEF. It is possible to share it with other surgeons.

Keywords Elbow instability · Terrible triad · Hinged elbow fixator · 3D printing

The present study was performed in the Ecole de Chirurgie de Paris (APHP), 7 rue du fer à moulin, 75221 Paris, France.

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Introduction

The complex elbow instabilities resulting from trauma represent a very challenging condition because they frequently lead to prolonged immobilization and disabling stiffness. Hinged elbow external fixators (HEEF) represent an attractive option to restore range of motion [1–9] since they allow early mobilization while preventing abnormal displacements of the elbow [10, 11]. By reestablishing correct biomechanical behavior of the elbow, a proper progressive healing of the ligaments is possible [12].

The humero-ulnar joint—which is mainly responsible for flexion and extension—rotates around an axis which orientation has very small variations throughout the range

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of flexion–extension. The rationale for the use of HEEF relies on the fact that it is therefore possible to regard this flexion–extension's axis as a single axis, similar to the hinge of the HEEF. Good clinical outcome implies precise alignment of the HEEF's and flexion–extension's axis which is technically challenging [13–17] (Fig. 1). It has been reported that a misalignment of 5° induced a 3.7-fold increase in energy expenditure, while a 10° misalignment led to a 7.1-fold increase [13].

In the conventional technique, the flexion–extension axis of the elbow is materialized by inserting a provisional pin in the distal humeral epiphysis through a lateral approach. When correctly placed, the pin appears like a dot on a true lateral view of the elbow and the hinge can be mounted on it. However, pin insertion is concerning for several reasons. First, it requires surgical approach which theoretically increases the septic risk. Second, it can be impossible to insert the pin if some devices (plates, screw, anchors) have been previously implanted in the distal humerus. Third, it is very challenging to real-time assess the orientation of the pin during insertion because the drilling motor is in line with the pin and impedes real-time fluoroscopic visualization of the latter. Fourth, it is difficult to correct an improper pin placement since each previous drilling attempt leaves a bone tunnel inside which the pin tends to return into.

In order to facilitate spatial positioning of the hinge, our team has previously developed an *extracorporeal technique* based on a custom-made aiming device [18]. Our previous results were very encouraging but the aiming device was hand-made, difficult to manufacture and therefore complex to share with the orthopedic community. To overcome these limitations, we have designed and 3D-printed a numerical model of the aiming device.

The primary goal of this study was to compare the *extracorporeal aiming device technique* with the *conventional pin technique* in terms of duration of the procedure, radiation exposure and spatial accuracy. The secondary goal was to determine whether the 3D-printed aiming device can be shared with other orthopedic surgeons.

Materials

The study was performed on upper limbs of freshly frozen cadavers with the mean death age of 85 (73–92 yo). They were thawed overnight prior to the experiment. Each specimen was thoroughly inspected looking for scars, deformities, abnormal range of motion of the elbow and signs of surgery. The presence of these characteristics led to sample exclusion.

Methods

Design of the study (Fig. 2)

In the first part of the study, we have compared the *extracorporeal aiming device technique* with the *conventional pin technique* in terms of duration for hinge positioning, radiation exposure and spatial alignment between the flexion–extension's and HEEF's axis. In order to induce a severe elbow instability, each elbow was medially approached and the medial collateral ligaments as well as the anterior and posterior capsule were severed (Fig. 3). Then the pins of an external fixator (Hoffman 3°, Stryker, Kalamazoo, MI, USA) were inserted in the humerus and ulna (Fig. 4). The elbow was relocated, and

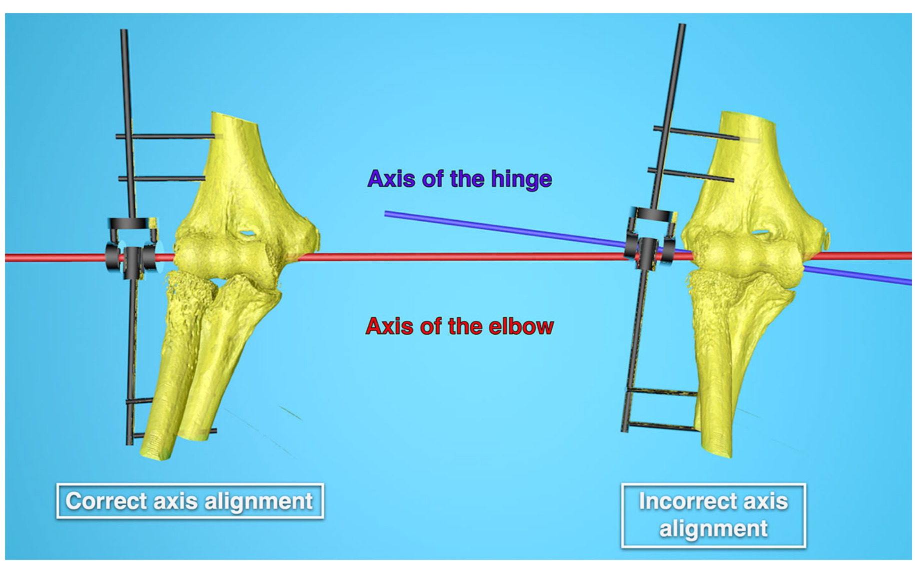
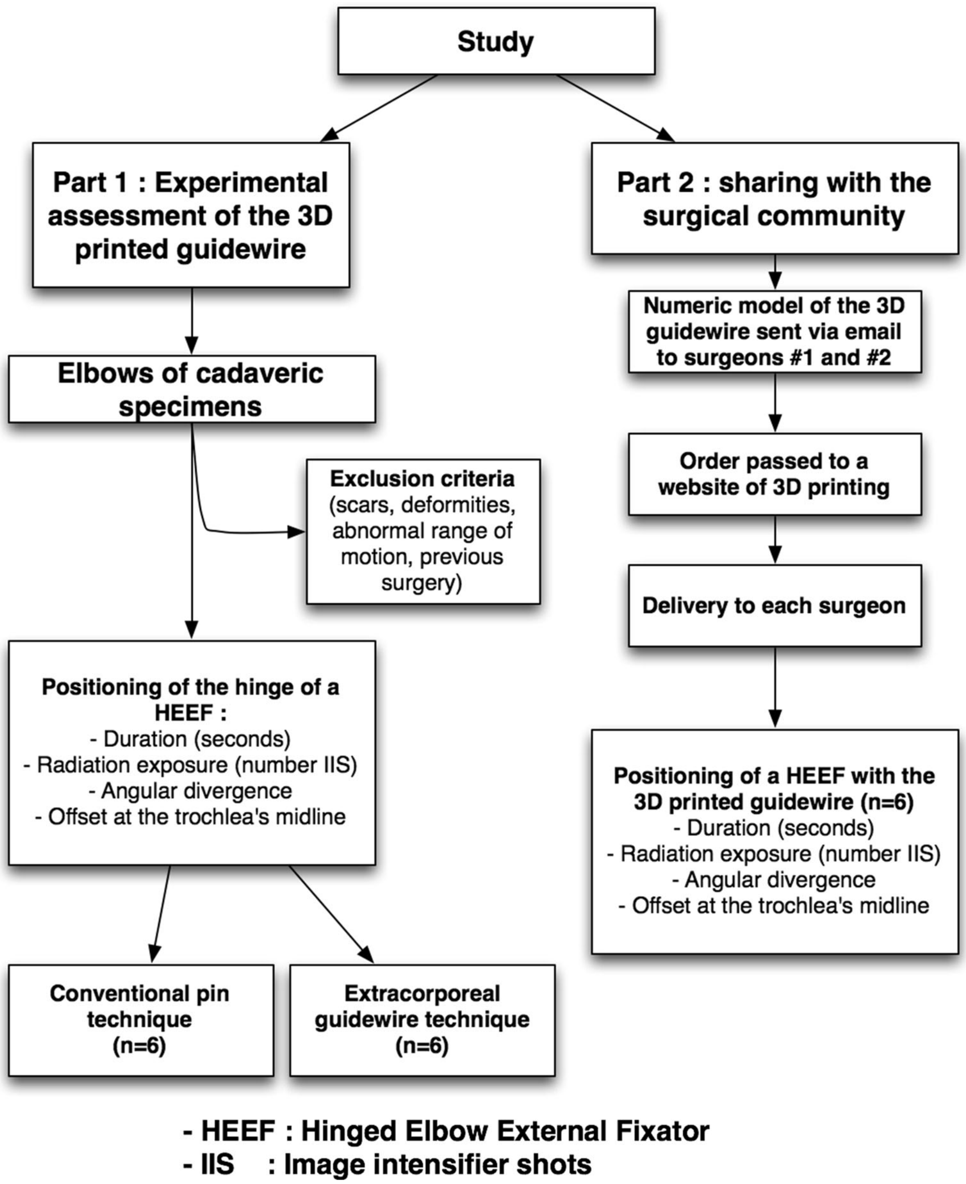


Fig. 1 Axis of the elbow and of the hinged fixator must coincide in order to restore the physiologic kinematic of the elbow during flexion–extension. This kinematic will guide the healing of ligaments

Fig. 2 Study design



the humeral and ulnar pins were connected together with the hinge of the external fixator (DJDII^{TM}, Stryker, Kalamazoo, MI, USA). Depending on the group to which each specimen was allocated, the hinge was positioned with either the *conventional pin technique* or the *extracorporeal aiming device technique*. The aim was to align the HEEF's and flexion–extension's axis. When the alignment was deemed satisfactory by the operator or when the latter estimated that he was not able anymore to improve the positioning, the hinge was finally connected to the humeral and ulnar pins. Both techniques were assessed with the three following measures: (1) number of image intensifier shots (taken as a measure of radiation exposure, as each shot had the same duration), (2) procedure duration, (3) angular divergence and (4) offset between the HHEF's and flexion–extension's axis. Moreover, for the *conventional pin technique* the number of drilling attempts to insert the provisional pin was measured.

In the second part of the study, we have assessed the ability to share the 3D-printed aiming device with the orthopedic community. Two more surgeons working in different institutions and with variable experiences in elbow surgery were involved. They were sent the 3D file of the aiming device by email. Then they had to order a 3D-printed version of the aiming device to a website of 3D printing (http://www.sculpteo.com). At last they each had to use their 3D-printed aiming device to position a HEEF on three cadaveric elbows. The conceptor of the aiming device (MS) was present in the operative room and was allowed to respond to potential questions of both surgeons.

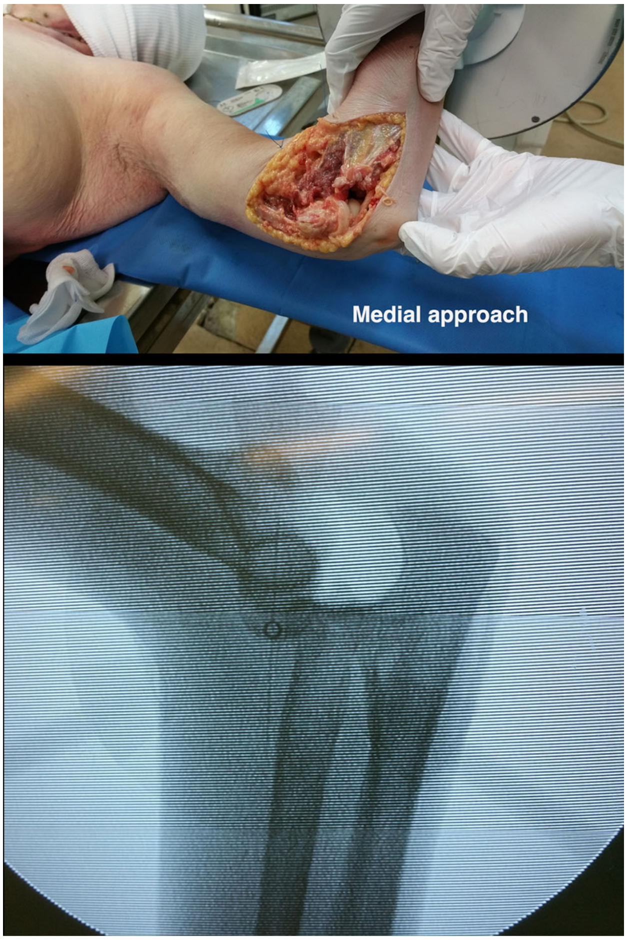


Fig. 3 Destabilization of the elbow through a medial approach

Given that the aim of this part was simply to assess the feasibility of sharing the aiming device, we did not compare the performances of each surgeon for both techniques. However, in order to obtain a preliminary estimation of the ability for a new user to position the HEEF with the 3D-printed aiming device, we measured the same four parameters as listed above.

Description of the extracorporeal aiming device technique

The aiming device is a sort of jaw, made of two plastic 3D-printed pieces connected together with three rods of an external fixator 11 mm in diameter (Hoffman 3, Stryker, Kalamazoo, MI, USA) (Fig. 5). The inferior piece is designed to be fastened on the image intensifier thanks to supplementary rods and adhesive tape. The superior part can be moved upward or downward in order to precisely fit the size of the elbow. On the superior part, there is a cylinder in which a 3-mm pin can be slid for materializing the axis of the aiming device.

Once the pieces were put together, the aiming device was fastened to the image intensifier so that the pin in the cylinder appeared as a single dot on the image. Therefore, the axis of the aiming device was aligned with the central beam of the image intensifier.

The body was supine on the table, and the image intensifier with the aiming device was positioned on the ipsilateral side (Fig. 6). In order to obtain a strict lateral fluoroscopic view, the c-arm of the image intensifier was tilted so that the medial side of the elbow could lie flat on the inferior part of the aiming device. Indeed, if the c-arm was strictly vertical it implied to force medial rotation of the shoulder which could be detrimental to obtention of a true lateral view. The humerus was progressively mobilized—with the humeral pins used as a joystick—between the pieces of the aiming device until the fluoroscopic projection of the pin was located precisely on the center of the circular projection of the trochlea. The hinge of the HEEF was mounted on the pin and connected to the humeral pins. Then correct relocation of the humero-ulnar joint was assessed under fluoroscopy, and the hinge was finally connected to the ulnar pins. Proper restoration of the elbow's kinematic was assessed on the lateral fluoroscopic view through the whole range of flexion–extension.

Description of the conventional pin technique

Installation of the body was the same as for the extracorporeal aiming device technique. The lateral epicondyle was exposed through a lateral approach (Fig. 7). A true lateral fluoroscopic view of the elbow was obtained by putting the elbow directly on the c-arm of the image intensifier. A provisional 3-mm pin was inserted in the center of the circular-shaped fluoroscopic projection of the trochlea, as close as possible to the estimated axis of flexion–extension of the elbow. Then the drilling motor was removed, and new fluoroscopic controls were made. Ideal placement of the pin was defined based on two criteria on two fluoroscopic views: (1) on a true lateral view the pin has to appear dot-like in the center of the circular projection of the trochlea and (2) on an antero-posterior view the pin has to pass through the tip of the lateral epicondyle, tangent to the inferior edge of the medial epicondyle. If the pin placement was not deemed correct, it was removed and a new drilling attempt was made. In case of successive imperfect placements, if the pin irremediably went back in one of the bone tunnels made by the previous drilling attempts, the procedure was stopped and a suboptimal placement was tolerated by way of default. Then the perforated hinge of the HEEF was positioned on the pin and connected to the humeral and ulnar pins.

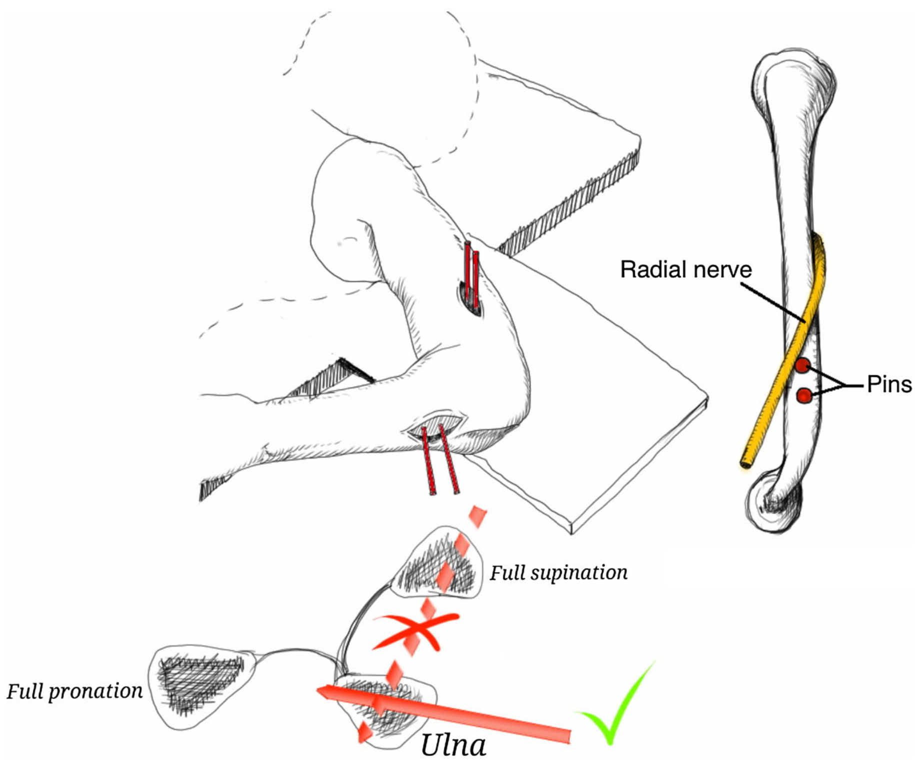


Fig. 4 Insertion of the humeral and ulnar pins through small approaches. Care must be taken to avoid lesion of the radial nerve. Correct orientation of the ulnar pins is essential in order to avoid any conflict between the radius and the pins and the resultant limitation in supination

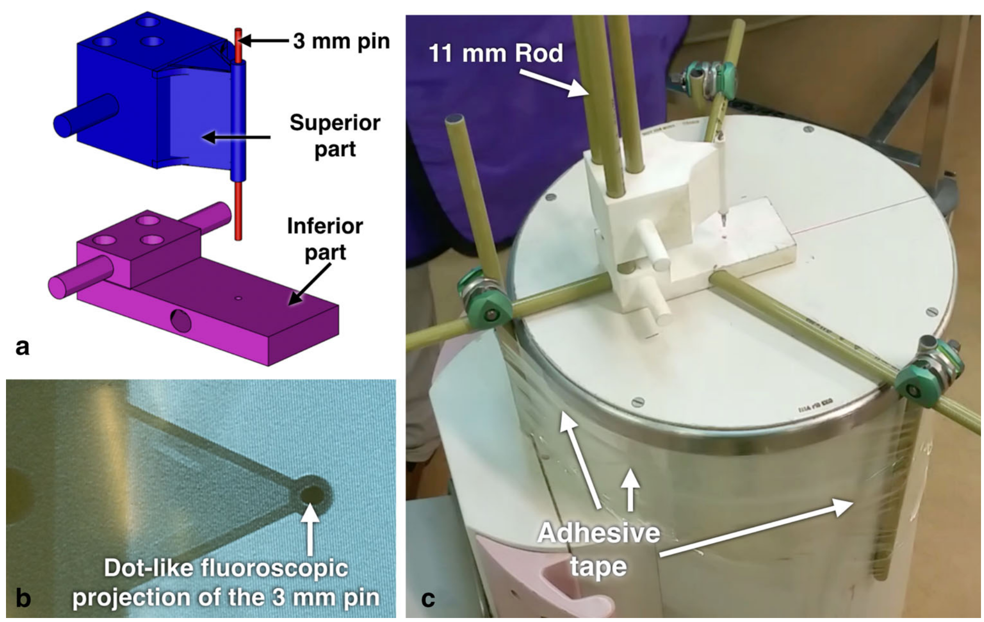


Fig. 5 Description of the 3D-printed aiming device. **a** The guide wire is made of a superior (*blue*) and an inferior (*purple*) piece. On the superior piece, a cylinder allows insertion of a 3-mm pin which materializes the axis of the aiming device. **b** Once fastened to the image intensifier, the aiming device is radiolucent and the 3-mm pin appears like a radio-opaque dot. **c** Both pieces are connected together and to the image intensifier thanks to rods 11 mm in diameter and adhesive tape (colour figure online)

Assessment of both techniques

Both techniques were assessed with the four following measures: (1) number of image intensifier shots (taken as a measure of radiation exposure, as each shot had the same duration), (2) procedure duration (in seconds), (3) angular divergence (in angular degrees) and (4) angular divergence between the HEEF's and flexion–extension's axis.

Procedure duration was measured with a chronometer as the time required to position and connect the hinge. The step of humeral and ulnar pins insertion was not included in these measurements since it was the same for both techniques.

The 3-mm pin used to position the hinge in the *conventional pin technique* was cut and left in the humeral epiphysis in order to materialize the HEEF's axis. After

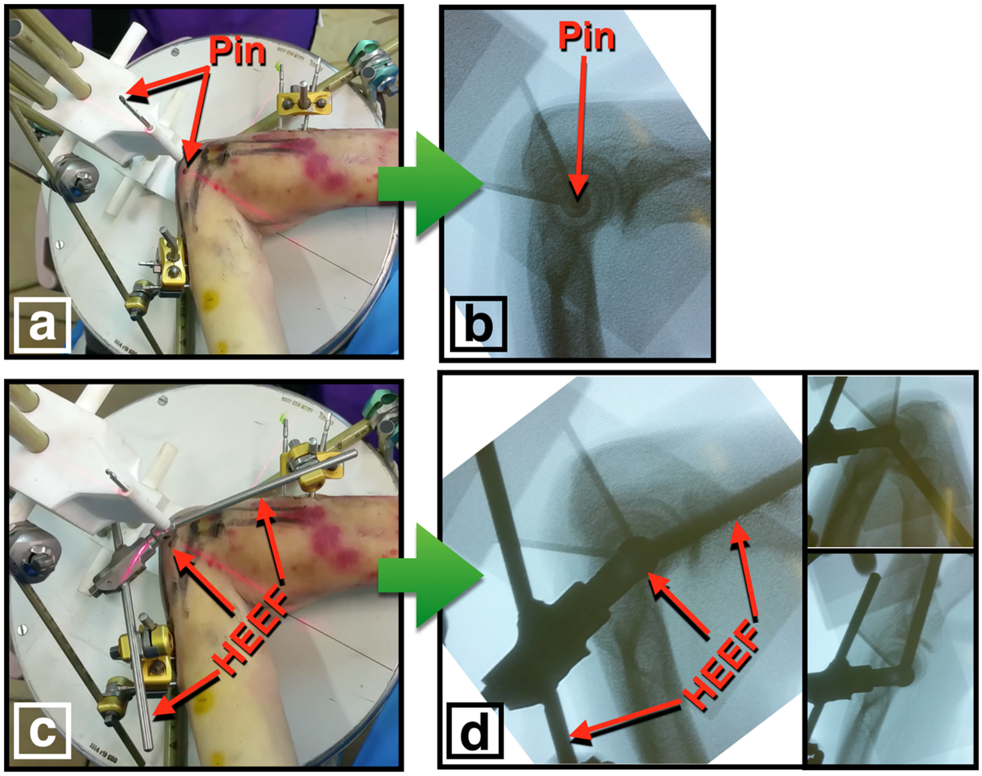


Fig. 6 Description of the extracorporeal aiming device technique. **a** Positioning of the elbow in the aiming device. **b** A true lateral view of the elbow is obtained. The elbow is moved so that the projection of the 3-mm pin corresponds to the center of the circular fluoroscopic projection of the trochlea. **c** The hinge is mounted on the pin and connected to the humeral and ulnar pins. **d** Once connected, kinematic of the stabilized elbow is assessed under fluoroscopy through the whole range of flexion–extension. *HEEF* Hinged elbow external fixator

performing the *extracorporeal aiming device technique*, since no pin was inserted in the epiphysis, a pin was finally inserted by using the hinge as a guide and eventually cut.

Each distal humeral epiphysis (including the pin materializing the HEEF's axis) was harvested and scanned with computerized tomography (CT). Off-line analysis first used the software Osirix° (Pixmeo°, Geneva, Switzerland) to generate a 3D model of each scanned epiphysis. Then the model was exported to the software Cinema 4D° (Maxon°, Friedrichsdorf, Germany), and the true flexion–extension's axis of the elbow was virtually materialized by using the following well-defined anatomical landmark [19]: the tip of the lateral epicondyle and the line tangent to the inferior edge of the medial epicondyle (Fig. 8). The angle between the axis and the pin was measured twice, and the mean value was recorded. A second measurement was made, namely the offset between both axes on the trochlea's midline in millimeter.

Statistical analysis

Data were analyzed using R® statistical software with COIN package (Version 3.1.3.) [20, 21]. Because the data were not normally distributed, they were described as medians with the interquartile range [IQR] and comparison of each parameter was made by exact permutation test between « extracorporeal aiming device technique » and « conventional pin technique » groups. Values of p lower than 0.05 were considered significant.

Results

Comparison between the conventional pin technique (CPT) and the extracorporeal aiming device technique (EGT) (Fig. 9)

The duration of hinge positioning was not significantly different when comparing the EGT (205 [28.8] s) and the CPT (390 [140] s).

The number of image intensifier shots with the EGT (16.5 [2.50]) was significantly inferior ($p = 0.005$) to the CPT (43.5 [8.25]).

Angular divergence with the EGT (3.50 [1.25]°) was significantly inferior ($p = 0.02$) to the CPT (6.74 [4.45]°).

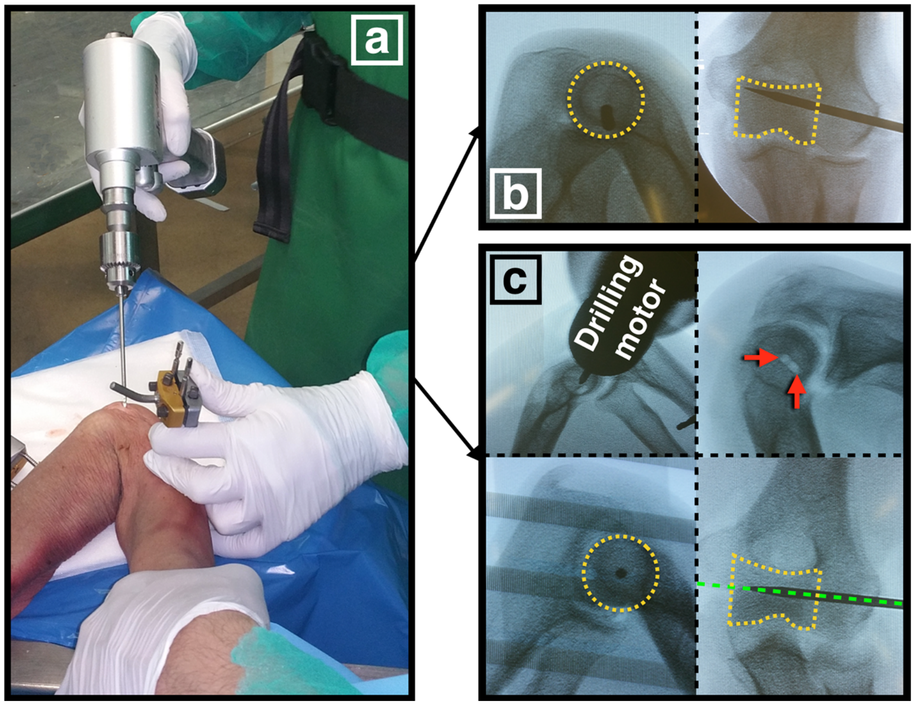


Fig. 7 Description of the conventional pin technique. **a** The lateral epicondyle is approached, and a 3-mm pin is inserted with a drilling motor. **b** Fluoroscopic assessment of the pin position and orientation. The pin is not at the center of the circular projection of the trochlea on the true lateral view. On the antero-posterior view, it is not tangent to the inferior border of the medial epicondyle. A new drilling attempt is therefore required. **c** The drilling motor impedes real-time fluoroscopic assessment of the pin's position and orientation since it is radio-opaque. The *red arrows* indicate the bone tunnels induced by two previous drilling attempts. During next attempts, the pin tends to go back into these tunnels. When properly positioned, the pin appears as a dot on the true lateral view and is tangent to the inferior border of the medial epicondyle on the antero-posterior view (colour figure online)

The offset between the HEEF's and flexion–extension's axis with the EGT (1.7 [0.7] mm) was significantly inferior ($p = 0.05$) to the CPT (4.1 [2.4] mm).

With the CPT the number of drilling attempts to position the pin was 3 [1.5].

Ability to share the 3D-printed aiming device

Both surgeons have received the 3D-printed aiming device less than 15 days after ordering. Thorough inspection of each aiming device revealed no flaw when compared to the numeric model. Both surgeons were able to position the hinge with a mean duration of 285 [117] s, 15 [6.5] image intensifier shots, an angular divergence of 3.50 [3.42]° and an offset between both axes of 1.2 [0.6] mm.

Discussion

In the present study, we found that our 3D-printed aiming device allowed for more accurate and less irradiating positioning of a HEEF's hinge than the *conventional pin technique*. However, it did not significantly reduce the duration of hinge positioning. We have also found that the 3D-printed aiming device was easy to share with other orthopedic surgeons. The latter were able to position the hinge of a HEEF with duration, a radiation exposure and an accuracy which were in ranges similar to those obtained in the first part of the study by the conceptor of the aiming device.

Despite small variations in the orientation of the elbow's flexion–extension axis (<10°) throughout the range of motion [22], it is possible to compare this axis to a single axis passing through the center of the trochlea. The conventional technique consists in materializing this axis with a provisional pin inserted in the distal humerus. However, this procedure is technically demanding for several reasons. First, it allows a very limited number of drilling attempts given the small size of the distal humeral epiphysis. Second, it becomes impossible if some device (plate, screw, anchor) is already implanted in the distal humerus. Third, it requires surgical exposure of the lateral epicondyle with supplementary risks of sepsis, especially if the elbow's capsule was opened (e.g., radial head arthroplasty or reduction-fixation). Fourth, there is a risk of ulnar nerve injury if the pin is pushed too medially given that the ulnar nerve crosses the anatomical axis of flexion–extension. Fifth, the pin tends to return into the bone tunnel

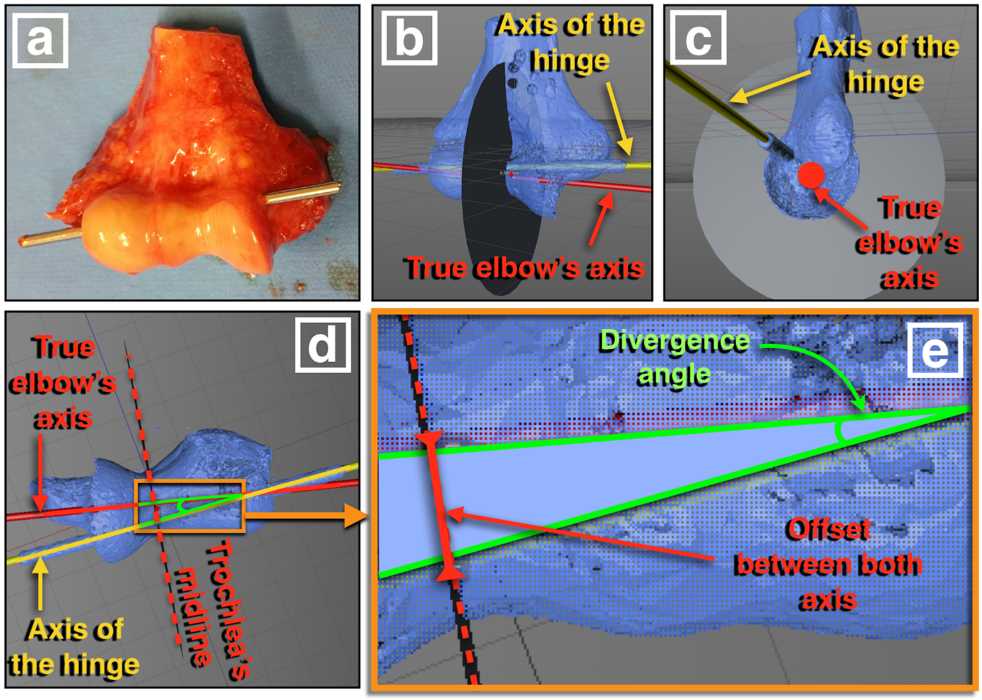
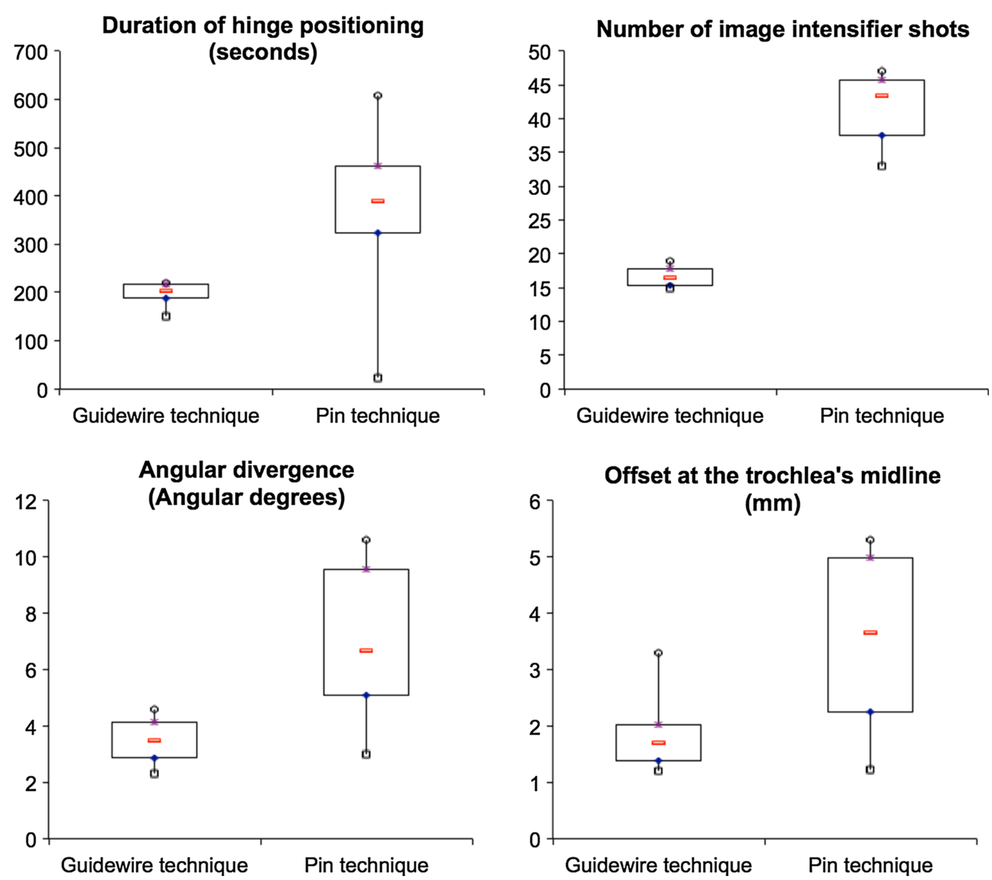


Fig. 8 Protocol for assessment of the accuracy of hinge's positioning. **a** Each distal humeral epiphysis was harvested and scanned with computerized tomography. **b**, **c**, **d** A 3D model was generated and used to perform the measurements. The axis of the hinge was materialized by the 3-mm pin inserted in the epiphysis (*yellow line*). The true elbow axis of flexion–extension was materialized by using anatomical landmarks (*red line*). **e** The divergence angle as well as the offset (on the trochlea's midline) between both axes was measured (colour figure online)

Fig. 9 Results of comparison between both techniques



created by the previous drilling attempts. In a previous study [18], we have shown that an extracorporeal aiming device could permit positioning of a HEEF with more accuracy and less radiation exposure. This kind of aiming device simplifies the procedure since it automatically allows the alignment between the central beam of the image intensifier and the HEEF's axis. As a consequence, the pin inserted in the aiming device (but not in the patient) appears like a single dot on the image intensifier. Once the aiming device is properly connected to the image intensifier, the operator has to focus on two objectives: (1) to obtain a true lateral view of the elbow and (2) to place the dot-like fluoroscopic projection of the pin at the center of the circular projection of the trochlea. The main difficulty that we have observed when using our device was to obtain a true lateral view. This observation is correlated by the findings of Brownhill et al. [23] and Wiggers et al. [24] who found in an in vitro study that fluoroscopic determination of the flexion–extension axis led to errors in the three planes of space up to 10°. In order to avoid the use of a provisional axial pin, Bigazzi et al. [25] have designed self-centering hinged external fixators. However, they did not compare their technique with the conventional pin technique, and to date, the fluoroscopic-based method remains the reference. Another limitation of our aiming device technique is the inability to assess the accuracy of the virtual axis on an antero-posterior view: The whole aiming procedure relies on true lateral views. However, we have found in the present study that spatial accuracy of the aiming device technique was significantly better than the conventional techniques. We therefore regard this limitation as negligible.

Recently, 3D printing has democratized for two reasons. On the one hand, the increase in power of the personal computer's processors allows for modeling of complex 3D structures like bones or devices. On the other hand, the technology of 3D printing has now reached such a maturity that several companies offer the possibility to print 3D objects in several materials. A 3D file designed on a personal computer can be uploaded to a website for 3D printing. Then the 3D-printed object can be delivered to the developer as any package. In the present case, we have chosen to use 3D printing in plastic for three reasons. First, the mechanical properties of this material provide enough stiffness to ensure that the accuracy of the aiming device is sufficient. Second, the plastic is radiolucent which is an indispensable property for a fluoroscopic-based device. Third, the price of 3D printing with plastic is affordable and it will progressively decrease within the incoming years. However, it is important to notice that this aiming device can not be used in the sterile operative field given that sterilization of surgical tools requires multiple authorisations that we do not have yet. However, given that the aiming device-based technique is purely extracorporeal, it can be performed after implantation of the humeral and ulnar pins and removal of the sterile drapes. Therefore, it is not necessary that the aiming device be sterile to be used and we now routinely use it for positioning of HEEF in patients: After inserting the humeral and ulnar pins under aseptic conditions, we remove the sterile drapes and then we start the positioning of the hinge with the 3D-printed aiming device. As a consequence, positioning of the hinge can not be performed prior to implantation of the humeral and ulnar pins. Therefore, the connection between the pins and the hinge requires a good modularity of the external fixator which is not the case for all commercially available devices.

There are several limitations to this study.

First, the conventional pin technique and the aiming device extracorporeal technique were performed by the designer of the aiming device. It may be argued that another operator—non-experimented with the aiming device—would face multiple difficulties when using the aiming device. However, we have found that new users of the aiming device could perform the aiming device technique with accuracy and radiation exposure in the same order of magnitude as obtained by the conceptor of the aiming device. However, the conceptor of the aiming device was present in the operating room and was authorized to reply to questions of the new users which represents a limit. Therefore, it will be necessary in the next study to more precisely assess the learning curve of new users.

The second limitation of the study is that the assembly of the aiming device requires rods of the Hoffman 3 external fixator. Surgeons who would not have access to this device would be unable to use the aiming device. However, Hoffman external fixator is one of the most used worldwide and we plan to provide the 3D numeric model for cylinders 11 mm in diameter.

Conclusion

The 3D-printed aiming device allows proper positioning of a hinged external fixator with better accuracy and lesser radiation exposure than the conventional pin technique. The aiming device can be easily shared with the orthopedic community even though the learning curve of the aiming device-based technique has to be quantified in further studies.

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Compliance with ethical standards

Conflict of interest The authors declared no potential conflict of interest with respect to the research, authorship and/or publication of this article.

Informed consent Research involving cadaver specimens.

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