Passive Pneumatic Stabilization Device for Assisting in Reduction of Femoral Shaft Fractures

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Abstract

During treatment of femoral shaft fractures, not only the actual fracture reduction but also the retention of the achieved reduction is essential. Substantial forces may apply to the bone fragments, due to multidirectional muscular contraction. Furthermore, forces from manipulation of one bone fragment may be transferred over the soft tissues onto the other fragments, thus hindering accurate fracture reduction. Once a sufficient reduction has been achieved, this position must be retained whilst definitive internal fixation is performed. Conventional methods comprise mounting patients on a traction table and applying manual distraction or employing special distraction devices, such as the AO distractor device. These approaches, however, only insufficiently stabilize both main fragments. For example, on the traction table the proximal femoral fragment can pivot around the hip joint thus complicating precise reduction. A novel pneumatic stabilization device to assist surgeons during operative procedures is described. This passive holding device "Passhold" connects to one main fragment through a minimally invasive bone interface and statically locks the fragment's position. Thereafter, only the other main fragment is manipulated to achieve reduction. Mutual interference of the reciprocal fragment positions, due to soft-tissue force transfer during manipulation, is avoided. The authors examined the stability of the novel retention device on a test rig and proved its functionality under sterile settings using cadaver tests. It is concluded that this device largely facilitates the operative procedure in femoral shaft fractures, is sufficiently stable and ergonomically suitable for intraoperative deployment.

Key Words

Fracture · Distraction · Reduction · Retention

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Introduction

Femoral shaft fractures are often treated with minimally invasive techniques such as intramedullary nailing or LISS (less invasive stabilization system) plating. Closed reduction is a key element of these surgical procedures. Due to multidirectional muscular contraction, substantial forces may apply to the main fracture fragments. Unpublished preliminary investigations (Messmer P, Schmucki D, Wunderle D, et al. Reduction forces and their influence on treatment. Personal communication, "Biomechanik Symposium", Berlin, Germany, December 13, 2003) reveal axial forces of up to 400 N during reduction. These forces must be overcome to distract the fracture and align the fragments before osteosynthesis can be performed. The entire procedure is only successful, if appropriate retention of the reduced fracture is possible until insertion of the definitive internal fixation.

Already in the early 1920s, pioneers of fracture treatment recommended mounting the patient on a special fracture table to facilitate indirect reduction

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[1]. The main muscular traction, to overcome during reduction, follows a longitudinal direction. Such forces are well handled with a traction table that applies axial distension to the patient's foot. However, in reality multidirectional forces apply to the femur. Axial traction alone inadequately stabilizes the proximal and distal main fragments, which are almost free to pivot and rotate in various directions around the adjacent large joints. In particular, the gastrocnemius muscle heads, which originate at the femoral condyles, cause the distal femoral fragment to pivot dorsally, corresponding to a knee flexion movement. Likewise, the adductors and hip flexor muscles cause the proximal femoral fragment to pivot around the hip, corresponding to a hip flexion-adduction movement. Both contraction forces do not apply in the axial direction and can only partially be compensated by an indirect reduction approach with mere longitudinal distraction.

To achieve a direct force transmission onto the bone fragments, the AO distractor [2] was developed. It facilitates manual efforts to overcome interfragmental forces in long bone fractures. The AO distractor percutaneously connects to the bone via long pins resembling Schanz screws that are drilled bicortically. Axial distraction is possible over a connection bar. Although indirect reduction can be performed using the distractor pins as levers to manipulate the fragments in various directions, the AO distractor is mainly designed to overcome axial forces. A specific problem arises as the bicortical pins obstruct the intramedullary bone canal, thus hindering nail insertion and practically making the distractor unsuitable for nailing procedures. The main deployment of the AO distractor is thus open reduction and plating. Methods for minimally invasive LISS plating using the AO distractor have been described [3] but are not yet routinely employed.

To account for the need to manipulate the distal femoral fragment in multiple directions during indirect reduction, the small reduction table (also known as "Repo-Table") was designed [4]. It consists of a sterilizable frame mounted onto the operating table and connected via a transcondylar pin. The distal femoral fragment can thereafter be manipulated over a lever on the "Repo-Table" frame. Thus, multidirectional forces can be overcome and reduction retained in a position suitable for osteosynthesis. The "Repo-Table" did, however, never reach routine deployment, as its frame is quite bulky and can hinder the surgeon.

Recently, a robotic arm has been reported to assist surgeons in fracture reduction and retention. The robot was validated in an in vitro model [5]. However, whilst the robot arm grips and freely manipulates the main distal bone fragment, the proximal fragment lacks adequate immobilization and is prone to shift, due to force transmitted over the soft tissues.

Current minimally invasive techniques focus on indirect reduction with correction of length, rotation and axis whilst omitting exact positioning of all fracture fragments. Nevertheless sufficient retention remains essential, particularly as during indirect reduction there is no direct sight onto the fracture zone to help verify the alignment is being correctly maintained. Just too easily can an axial deviation or rotational error be introduced during manipulations for insertion of the definitive load carrier. Such misalignment may then be arrested permanently and only discovered when the procedure is completed. None of the above retention apparatuses satisfactorily solves this general issue of reduction and retention. Our aim was, therefore, to develop a new tool to assist surgeons during indirect reduction of long bone fractures, in particular of the femur. We suggest employing a passive stabilization arm to maintain the position of one main fragment, whilst reduction is performed by manual or robotic manipulation of the other.

Such a passive holding device was developed in collaboration with the AO Development Institute in Davos, Switzerland [6]. This passive stabilization arm is designed for clamping onto the side railing of any standard operation table. It has a purely static function and is not motorized in any way. To emphasize its passive holding purpose, we refer to it as the "Passhold arm". The Passhold arm has one vertical, three horizontal and two rotational degrees of freedom (Figure 1). The passive arm percutaneously connects to the femoral bone via newly developed minimally invasive bone-tool interfaces that do not obstruct the intramedullary bone canal [7].

Typical Deployment Scenario

A typical deployment scenario for osteosynthesis of a femoral shaft fracture using the Passhold arm is as follows: preoperatively, the Passhold device is mounted onto the side railing of the operation table. First, the surgeon percutaneously attaches the bone-tool interface onto the fragment that is to be immobilized. Then the stabilization arm is manually positioned to connect to the bone-tool interface. Once the fracture fragment is

Figure 1. Passive pneumatic holding device. Minimally invasive bone-tool interface with Schanz screws.

positioned in the suitable orientation, the surgeon arrests the Passhold stabilization arm with a pneumatic foot switch, whereupon the arm retains the given position. Now the surgeon performs the fracture reduction, solely manipulating the not arrested main fragment. After reduction, the minimally invasive internal fixation can be performed with intramedullary nailing or LISS plating. The Passhold arm can easily be manually repositioned and arrested in a different position, if necessary, by toggling the pneumatic foot switch. After internal fixation is completed, the Passhold arm is disconnected from the bone-tool interface and the latter removed.

Before deploying the device on the patient we sought to validate its functionality in a laboratory setup. Sufficient stability of the passive arm should be established to ensure it would resist the forces applied during an operation. In particular the newly designed pneumatic locking mechanism of the Passhold's articulations should be tested in various configurations. Due to leverage the forces on each articulation can vary considerably depending on an extended or flexed position of the neighboring segments. The introduction of a new device in the sterile setting of an operating room (OR) also requires prior feasibility testing to detect possible deficiencies in installation and deployment. Particular focus of such testing must be to avoid later time-consuming iterations during the effective operative procedure. Possible problems could occur when localizing the positioning for clamping the device to the table in relation to the fracture zone and operation site. Depending on the selected setup the surgeon could be severely hindered by the Passhold device and the entire operation would thus be compromised. Furthermore, correct sterile draping of the device must be practiced. The objectives of this study were thus: (1) to test load bearing of the newly designed Passhold arm in the lab; (2) to verify deployment of the Passhold arm in a sterile setting similar to intraoperative conditions; (3) to demonstrate the feasibility of the procedure for a selection of established surgical techniques and implants.

Material and Methods

Load-Bearing Measurements

The stability of the Passhold device was analyzed on a test rig in the Biomechanical Laboratory of the Orthopedic University Hospital Balgrist, Zurich, Switzerland. The Passhold device was clamped to the test rig with its vertical axis in intermediate extension. Over an inelastic cord attached to the distal end of the arm, forces were consecutively applied in each of the three spatial directions. In ascending order 10-N, 20-N, 50-N, 100-N, 150-N, and 200-N weights were attached (1–20 kg). The distortion at the distal end of the Passhold arm was measured in millimeters for each force vector direction. For this purpose, an electrographic distortion sensor was employed. Prior calibration of the sensor showed a linear distortion in the range of 0–300 N. The Passhold arm was examined in various flexed and extended configurations to reflect possible intraoperative deployment states. The ascending load-bearing sequences were repeated five times for each configuration. The fully extended arm was loaded up to 150 N and the flexed arm up to 200 N. These maximal loads were chosen according to recommendation of the developers to avoid permanent material damage. Disruption tests were not performed, as the Passhold arm is still a unique prototype. Figure 2 shows a sample test rig setup.

Feasibility Demonstration

The deployment under sterile conditions in an intraoperative setting was simulated with cadaver tests as approved by our institutional review board.

Typical setups for osteosynthesis of femoral shaft fractures were examined: LISS plating for distal and antegrade intramedullary nailing for mid-shaft fractures (AFN). For LISS plating, the Passhold arm was mounted on the ipsilateral table side-rail. For antegrade nailing, the Passhold arm was mounted on the contralateral table side, such as not to hinder the surgeon's access to the hip region. Initially, the Passhold arm was complete-

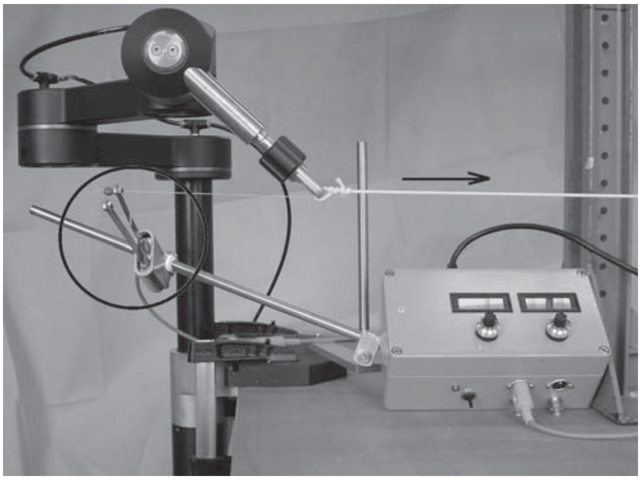

Figure 2. Sample test rig setup. Force applied in horizontal left to right direction. Distortion sensor placed opposite (highlighted).

ly extended to point away from the patient so that the patient's lower extremities could be draped in the usual sterile manner (Figure 3a). Then the Passhold arm was itself draped with the sterile plastic foil usually employed to cover the fluoroscopy C-arms (Figure 3b). Only now was the sterile end-connecter, onto which the bone-tool interface later clips, attached to the distal Passhold segment. Then the Passhold arm was manually brought into place by the surgeon, connected to the bone-tool interface and pneumatically arrested.

For distal femoral fractures, the ipsilaterally mounted Passhold was brought into flexed position (Figure 3c) and the bone-tool interface percutaneously connected to the proximal main fragment. Thus, the distal thigh and knee region remain freely accessible to the surgeon. For antegrade nailing of a mid-shaft fracture, the contralaterally mounted Passhold was extended, thus ventrally crossing over the patient's legs. The bone-tool interface was percutaneously attached to the distal main fragment (Figure 3d). In this configuration, the patient's hip and proximal thigh remain free for nail insertion.

Reduction and internal fixation was performed using standard operation techniques for LISS plating and intramedullary nailing. Whilst one fragment was arrested with the Passhold arm, the nonarrested main fragment was directly manipulated over the definitive load bearer, i.e., over the nail insertion grip.

Results

Load Bearing

Loading the Passhold arm resulted in a practically linear distortion curve measured at the arm's distal segment (connector to the bone-tool interface). The distortion ranged from 1 to 7 mm, depending on configuration and force vector direction. Compared to the first load-bearing sequence, the second sequence in the same configuration showed a lesser distortion (approximately 1 mm less). The subsequent three load-bearing sequences were, however, all comparable to the second. Figure 4 shows the load-bearing sequences for two distinct Passhold configurations. The average distortion and standard error for each force vector direction (transverse, longitudinal, vertical) are represented.

Practicability

The easy deployment under sterile intraoperative conditions was proven on a cadaver setup. The pneumatic foot toggle was attached via a standard connector to the compressed air valve for power drills available in the OR. Alternatively, the pneumatic toggle could be connected to a compressed air cylinder for stand-alone operation. Both ipsilateral and contralateral installation proved viable. After covering the Passhold with sterile dressing, the surgeon could freely and effortlessly position the arm. Once positioned, the pneumatic arresting and releasing mechanism could be activated with the foot toggle. Use of the foot switch was intuitive and, being a well-known device similar to the fluoroscopy activator, caused no operative problems. Two minimally invasive bone-tool interfaces [7] were percutaneously placed laterally in the proximal third of the femur, through a 2-cm incision each. They were then connected to the Passhold arm's distal segment using a snap-on mechanism. By attaching the bone-tool interface to the bone with monocortical screws, the intramedullary nail insertion was not hindered. For distal LISS plating, the bone-tool interfaces were mounted ventrolaterally (45–60° vertical angle) to the femur, to avoid interference with the laterally applied LISS plate. Both osteosynthesis procedures could be completed without any problems, i.e., the Passhold arm did not obstruct or hinder the surgeon. Also, there was no interference of the Passhold arm with the fluoroscopy device.

Discussion

Indirect reduction and retention of the reduction can be challenging, particularly in femoral fractures. Femoral shaft fractures are a typical example of long-bone shaft fractures that are treated with indirect reduction and minimally invasive osteosynthesis (LISS, nailing). However, for patients with multiple injuries, the primary focus is damage-control surgery, and long-bone fractures are at first temporarily stabilized with an external bridging [8]. During post-primary operation, muscular contraction forces must be overcome and the correct reduction held whilst the definitive weight carrier is inserted. We are unaware of any conclusive data about the actual forces required to overcome contraction of the thigh musculature. Data from our preliminary studies (Messmer P, Schmucki D, Wunderle D, et al. Reduction forces and their influence on treatment. Personal communication, "Biomechanik Symposium", Berlin, Germany, December 13, 2003) indicate forces in the range of 100–400 N under full anesthetic drug relaxation. These forces were measured, in the axis of the long bone, using an AO distractor modified to incorporate a distraction sensor. However, besides axial distraction, also multidirectional forces of a lesser magnitude must be intercepted.

Figures 3a to 3d. Passhold arm positions under sterile draping.
a) Preparations: passhold arm extended.
b) Sterile dressing for Passhold arm.
c) Ipsilateral for distal LISS plating (left).
d) Contralateral for antegrade femoral nailing (right).

Mere manual efforts are often futile for indirect reduction, as the grip applies to the soft tissues surrounding the bone and not to the fragments themselves. Even though minimally invasive procedures do not require precise positioning of all fracture fragments, it is nevertheless essential to achieve and retain correct length, rotation and axis of the main fragments until definitive fixation. A review of current reduction procedures reveals that none of the current reduction and retention apparatuses such as the reduction table, the AO distractor or the Repo-Table are satisfactory on their own. They are either cumbersome like the Repo-Table or not suited for nailing like the AO distractor whose bicortical pins obstruct the medullary bone canal.

New bone-tool interfaces are being designed and were published recently [7]. They can be inserted through a minimal soft-tissue incision and directly connected to the bone with monocortical locking screws or with crossed Kirscher wires mounted on a tension ring. Both variants do not or only partially enter the medullary canal and thus permit unrestricted nailing. Besides connecting a tool to such bone-tool interfaces, also a handgrip can be attached and used as lever for manual reduction. However, manual retention is not as stable as mechanical arresting, as the assistant inevitably reacts in a viscous iterative cycle trying to balance out forces induced by the surgeon's manipulations.

The passive retention arm facilitates reduction by statically arresting one main fragment, thus avoiding re-

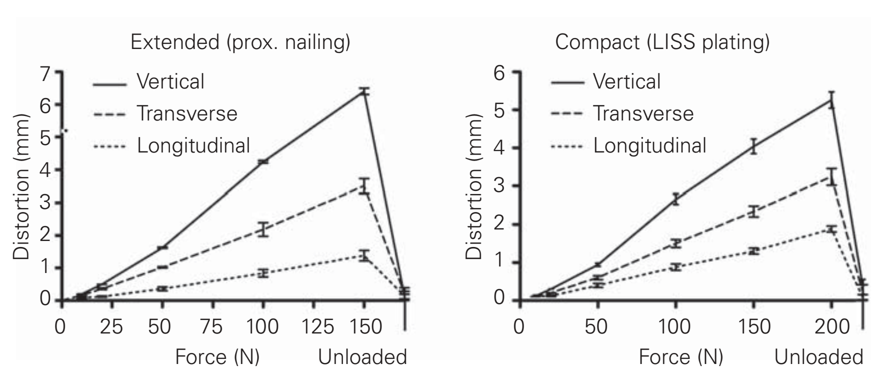

Figure 4. Test rig distortion measurement sequences for three force vector directions.

ciprocal interference between the main fragments. The actual reduction is still performed manually. Either the assistant can seize the nonarrested segment of the limb to achieve the reduction, or the surgeon can himself perform the reduction using the instruments for insertion of the definitive load carrier, i.e., the carbon grip of the intramedullary nail or of the LISS plate. Once again, note that only one fragment must be manipulated, whilst the other is retained in position by the Passhold arm.

Besides facilitating reduction and retention, and thus shortening operation duration, we anticipate that a passive retention arm can lower costs by rationalizing the third assistant. Similar schemes are already implemented in laparoscopic surgery, where a steady robot arm replaces the trembling assistant's hand to hold the endoscope camera (AESOP [9], EndoAssist [10]).

Computer-aided reduction requires well-defined positioning of both main bone fragments. Whilst the distal fragment is being manipulated by the active device, the proximal main fragment shall not change its position or orientation. Implementing a second active device, to also retain the proximal fragment, would be costly and cumbersome in the OR. Instead, a compact passive retention device, such as the Passhold arm, would be useful to statically arrest one fragment. The stability of the proposed construction is proven sufficient for clinical use, where distortion in the millimeter range is acceptable. However, for robot-assisted surgery, where automated reduction is targeted, even minor distortion could be significant and hinder correct alignment of the medullar canal by the reduction robot. If this approach is chosen, further improvement of the arm's stability may be necessary.

For clinical, nonautomated use, the combination of the Passhold arm with a traction table is particularly suitable. The traction table thereby helps overcome the main longitudinal forces, which are mainly induced by the quadriceps muscle. The Passhold arm helps stabilize the remaining multidirectional forces. These are in particular a dorsiflexion of the distal femoral fragment by the gastrocnemius and a ventral adduction of the proximal fragment by the adductor muscles. Even though these are less intensive than the main longitudinal forces, these multidirectional forces are inadequately compensated by mere longitudinal distraction and can impair precise fracture reduction.

For LISS plating, the Passhold arm is mounted on the ipsilateral operation table railing. It is positioned in a flexed configuration to immobilize the proximal femoral fragment. In this setting, the distal femur is freely accessible to the surgeon for manipulation. For proximal nailing, the Passhold is mounted on the contralateral table railing, crosses over above the pelvis in an extended configuration and immobilizes the distal femoral fragment. In this setting, the proximal fragment is manipulated directly over the insertion grip of the nail to align the fragments.

The Passhold arm is easy to install preoperatively as it is simply clamped to the operation table's side-rail and can be draped with standard sterile foil used also for C-arm covering. Only the connector to the bone-tool interface requires sterilizing. When introducing the Passhold in the OR, some training will be necessary for OR personnel doing the installation. In particular, determining the optimal craniocaudal clamping position depending on fracture location and selected surgical procedure might be challenging and require direct instructions from the surgeon.

The Passhold has many advantages and is intuitive to use. Thanks to its compact design, it is not cumbersome in the OR and requires little storage space. Depending on the chosen setup with the Passhold arm, the use of a fracture table is no longer necessary. This simplifies preoperative installation and curtails time required for installing the patient on the fracture table. The inguinal and scrotal soft-tissue damages, occasionally caused by the reduction table, can be avoided. A great advantage, compared to an active robot arm, the Passhold apparatus has no hazardous electrical connectors. The Passhold is operated solely by the surgeon and no technician is required in the OR. Also, except sterilization of the bone-tool interfaces, no preparatory procedure is required.

Further Investigations

More precise data on the prevailing reduction forces must be collected and those results matched with the stability tests performed in this study. Ideally, disruption tests should be performed to determine the maximal load bearing of the Passhold arm. Further clinical trials must also evaluate which bone-tool interface is most suitable for use with the Passhold arm. The interfaces must be examined for stability and insertion-time requirements in relation to total operation duration. Larger clinical trials must thereafter prove the advantages of the Passhold arm, particularly the anticipated time savings for reduction and retention. Finally, the deployment of the Passhold arm also in other operation sites, e.g., pelvic reconstruction, could be examined.

Conclusion

We successfully demonstrated using a passive stabilization arm by simulation of two distinct operations on the femur: antegrade nailing of a mid-shaft fracture and minimally invasive osteosynthesis of a distal shaft fracture in LISS technique. Test rig investigations proved sufficient static stability of the device (up to 200 N), and first practicability tests demonstrated the easy deployment in an intraoperative setting. The well-known iterative process of reduction, manipulation of one fragment with subsequent redislocation of the other and realignment of the former were completely avoided. The procedure is more straightforward and time-effective. This passive pneumatic device could in future be employed in conjunction with an active reduction device that manipulates the second main fragment [11].

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