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Feasibility Study on a Device for Ultrasound-assisted Placement of External Fixator Pins in Low-Resource Settings

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Abstract

External fixation is a therapy option for operative treatment of open fractures, especially in low-resource settings. Pins for the fixator need to penetrate cortical bone on both sides of the target bone to ensure mechanical stability, but without extensive protrusion. Evaluation of pin placement is challenging, since medical imaging like radiography may not be available in low-resource settings. To address this, we propose a device for ultrasound-assisted pin placement using a portable, robust and low-cost ultrasound probe. The device comprises a guiding sleeve and an arm that centers the probe on the opposite side in the pin axis. Penetration of the opposite cortical bone can thus be easily detected in the ultrasound image in real-time, without the need for manual probe placement. We evaluated our concept in small scale experimental feasibility study on porcine lower legs, where we used a prototype to place 4 pins. Afterwards, we assessed pin protrusion in the ultrasound images as well as manually on the dissected bone. Mean pin protrusion measured in the US images was 1.6 mm, compared to 1.4 mm for manual measurement, with a mean deviation between measurements of 0.5 mm. Pin penetration of the opposite cortical bone was easily detectable in the ultrasound images, and the device facilitated central pin placement. Moreover, our device allowed for use by a single operator. We have thus demonstrated the feasibility of our concept. Future studies will focus on further optimization of the device and evaluation in a cadaver study with medical experts.

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1 Introduction

The external fixator is a standard procedure for operative treatment of open fractures. It shows advantages over internal fixation in terms of lower infection risk and lower requirement for experience and surgical skills, which is especially relevant for low-resource settings [Höntzsch 2017]. The percutaneous approach requires the evaluation of pin positioning [Sen 2023], since the pins need to penetrate cortical bone on both sides for optimal mechanical stability. For intraoperative evaluation, C-arm fluoroscopy is desirable, as are radiography or computed tomography (CT) for postoperative follow-up. However, they are expensive, not always available in low resource settings and can be sensitive to extreme temperatures or humidity under these conditions. Servicing and repairs can be problematic as well as they are expensive and qualified engineers are not always available nearby [Creeden 2016]. Ultrasound (US) imaging may present a robust, cost-efficient and portable alternative that performs well in diverse environments and can be a worthwhile tool for real-time evaluation, although training for image acquisition and interpretation is required [Creeden 2016; Russell & Crawford 2013]. Dahl et al. already showed the feasibility of US imaging for the evaluation of pin positioning for external fixators via detecting pin penetration of the opposite cortical bone. Nevertheless, their approach requires the US operator to find the pin axis and is thus only applicable retrospectively and time-consuming [Dahl et al. 2013]. In this paper, we propose a new concept for US-assisted pin positioning for external fixators which allows for easy integration into the surgical workflow.

2 Materials and Methods

The concept comprises a mechanical device that centers an US probe in the pin axis on the posterior side, facing the pin's anterior entry point. The device is positioned around the leg with the guiding sleeve located at the desired insertion point. The distance between the probe and sleeve is adjustable to provide contact for the probe as well as for the guiding sleeve. Central pin placement can easily be controlled by centering the bone contour in the US image. After fine positioning, the sliding elements can be fixed to ensure that the device stays in place during the procedure and the pin can be inserted in the bone, until penetration of the opposite cortical bone can be detected in the US image. The guiding sleeve must be detachable or shiftable to be able to remove the device after pin placement. The US probe is also detachable as it can be used for other diagnostic purposes. Based on this concept, a first prototype was built comprising sliding elements for distance adjustment, a wireless US probe (L15HD, Clarius, Vancouver), and a guiding sleeve made from aluminum (Figure 1).

The basic idea of the concept is evaluated in a preliminary porcine study. For the study, two porcine lower legs were fixated with clamps on a table. Non-medical experts used the prototype device to insert four pins into the porcine legs. In the first step, the posterior fat and skin layer of the porcine legs were removed due to strong image interferences, which caused the invisibility of the bone. This effect does not occur when scanning human lower legs.

Initially, the device was aligned and adjusted to ensure contact of probe and sleeve with the leg (Figure 1). The alignment was achieved by palpating the bone from the anterior side and centering the posterior bone contour in the US image. Secondly, a drill was used to tap the bone for easier pin insertion in our setting. The pin was fastened until local changes in the bone contour became visible in the US image. For evaluation purposes, the soft tissue around the bone was dissected, and the pin penetration or bone splintering caused by the pin was measured using a caliper. For comparison, the US images were recorded, and the pin penetration distance was determined in the images by a technical expert.

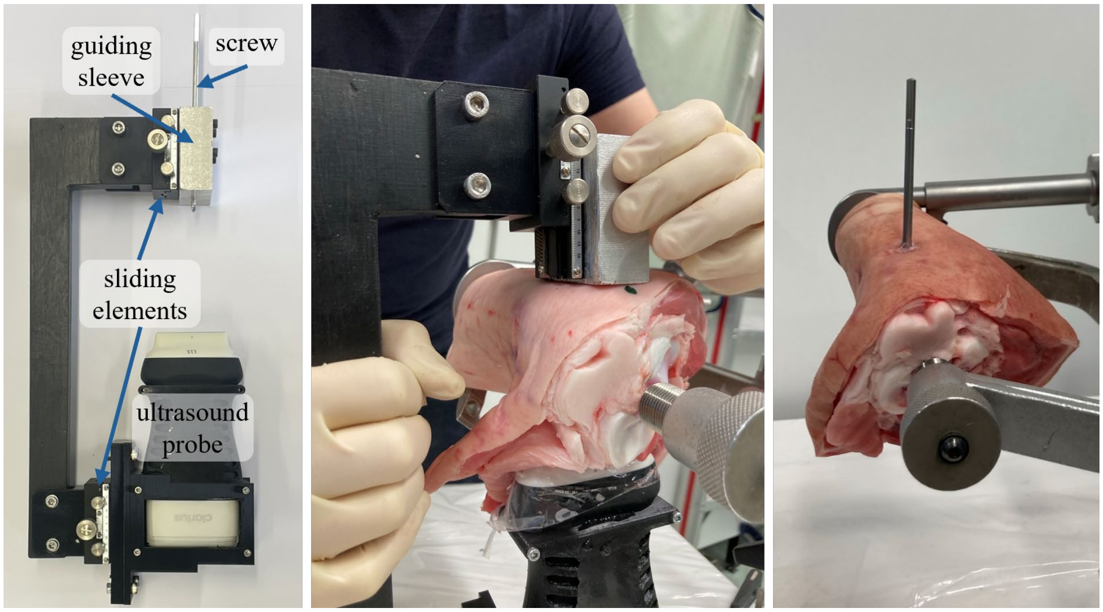

Figure 1: Device (left), positioning (middle), placed pin (right)

3 Results

Mean pin protrusion measured with caliper was 1.4 mm [0.5 mm, 2.0 mm, 2.5 mm, 0.5 mm], compared to a mean protrusion of 1.6 mm [1.1 mm, 2.1 mm, 2.0 mm, 1.2 mm] for US-based measurement. The mean deviation between caliper- and US-based measurement was 0.5 mm. Two of four pins did not fully penetrate the bone, as is exemplarily shown in Figure 2.

4 Discussion

In our experimental study we showed feasibility of our concept for US-assisted pin placement for external fixators. The device could be operated by a single examiner to both place the device and drill the pin. It allowed for easy detection of posterior pin penetration and furthermore assisted central posterior pin placement.

For US-based length assessment of pin penetration, we found a mean deviation from dissected measurement of 0.6 mm. In comparison, Dahl et al. found an average deviation of 1.2 mm for 16 pins placed in cadaver femoral and tibial bone. Dahl et al. concluded that the orientation of the US probe is

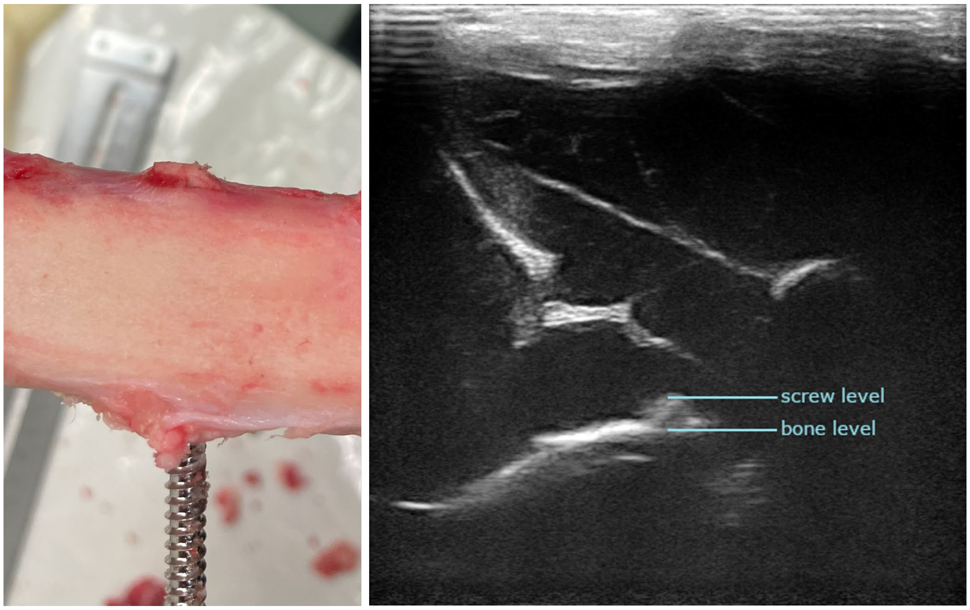

Figure 2: Intra-experimental US-image used for measurement (right), corresponding specimen with dissected tissue (left).

essential for accurate pin length measurements (Dahl et al. 2013). Our device is designed so that the US image is always centered on the pin axis. This is a major advantage of our method, as it allows real-time evaluation and ensures accurate length measurement. Our approach also simplifies the challenging interpretation of US images, as only an alteration of the image in a specific area needs to be recognized.

The significance of our study is limited by the use of porcine specimens. Moreover, it was conducted by non-medical experts with a small sample size.

5 Outlook

The device used in this study was only a prototype, and small adaptations are desirable to further improve its usability. Furthermore, if the device should be placed between the target anatomy and a table, the side with the probe should be as flat as possible. This could be achieved by rotating the probe by 90 degrees and using an acoustic mirror to keep the US image in the pin plane. The usability could be further improved by integrating a handle and allowing distance adjustment on one side only. Moreover, distance to the bone contour in the ultrasound image in combination with the adjustment slide could be used to estimate the screw-in depth in advance.

After revising the prototype, the next step comprises a cadaver study conducted by medical experts. Additionally, automated segmentation of bone contour and pin tip using deep learning-based methods [Broessner et al. 2023] could simplify use of the device even further. Finally, research should focus on the use of ultrasound imaging for the intraoperative evaluation of fracture reduction as part of the external fixation procedure.

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