Clinical experience with a fluoroscopy-based guidance system in orthopaedic surgery

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Introduction

Computer assisted systems are being used in orthopaedic surgery for many years. Different advantages were described in the literature, among these the most important are an improvement in accuracy of implant positioning and a reduction of ionising radiation [1]. However, most published works describe the use of such systems in spine and pelvis surgery. Its use in general orthopaedic surgery and especially in trauma surgery is limited to a few published works [2, 3]. Regular navigation systems depend on fixed reference devices that must be firmly attached to the subject of interest. This dependence limits its use in trauma surgery, since a fractured bone consists of different fragments and not all can be reached with fixed reference devices.

Aim of this work was to examine a 2D based image guidance system which superimposes surgical relevant information (e.g., trajectories, length estimation) on the standard 2D fluoroscopic image. The aim of this study was to examine the usability of this system and to identify potential advantages.

Material and Methods

This was a prospective, not randomised therapeutic study. A total of 46 procedures performed on 45 patients, 22 female (48%), 23 male (52%), were included in this study. The procedures included a wide variety of indications at different anatomical regions (foot n=12, shoulder n=10, long bones n=7, ankle n=7, hand and wrist n=6, spine and pelvis n=4). For each procedure, the surgery was performed following the departmental standards based on principles of the AO/ASIF. The guidance system (Surgix® Ver. 1.0, Surgix, Tel Aviv, Israel) was connected to the image outlet of a fluoroscope. Two fluoroscopes (Arcadis Orbic 3D®, Siemens, Erlangen, Germany; Iso-C-3D®, Siemens, Erlangen, Germany) were configured to be used with the system. Consecutively each image was transferred automatically to the workstation. The main function is the display of a trajectory as an aiming device in the current fluoroscopic image. Since the system does not use fixed reference arrays or a camera, live tracking of objects and instruments is not possible. If the position of the object or instrument is changed, i.e. if the patient moves or the surgeon moves, a new image has to be obtained. Outcome measures were the number of trials for optimal positioning of the K-wire (if applicable), total surgery time, adverse event rate, failure rate (defined as the inability to use the system or technical defects) and radiation exposure (defined as the total duration of radiation). Following each procedure, the usability was scored via a user questionnaire.

Results

The system was successfully integrated in different surgical procedures at different anatomical regions, including surgeries where traditional navigation systems are not used for various reasons. A total of 56 implants were successfully inserted using the system's trajectory function. The average number of trials was 1.4 ± 0.8 (1; 5). In 29 cases the length measurement tool was employed and was accurate to the millimetre in comparison to the standard measurement method (figure 1). The trajectory was the most popular feature used by surgeons (n=43, 93.5%), followed by the length measurement tool (n=29, 63%) and the

bending function (n=17, 37%). The functions could be freely activated by the performing surgeon. Following each procedure, surgeons had to rate the general importance of a certain topic (1=not important, 5=very important) and the usability of the system contributing to achieve the respective aim (1=useless, 5=perfect assistance). The usability of the system was rated good for procedures on smaller bones (hand and foot surgery, 26.4 of 32.7 points, 80.7% achieved points of general importance of each topic) and very good for other indications (all other indications, 27.2 of 29.7 points, 91.6% of general importance). The overall usability was good, with a total of 26.9 of 31.9 points, resulting in 84.3% of the ratings of general importance.

The system was not successfully engaged in three cases: one with a fracture of the first lumbar vertebra, one with an acetabular fracture and one with a fracture of the dens axis, resulting in a total failure rate of 6.5% (n=3) of all included cases.

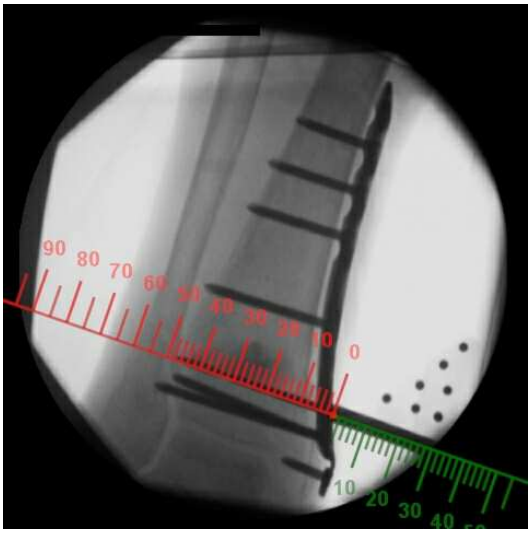

Figure 1: Beside trajectories length measurement is a helpful tool

Discussion

This pilot study validated the clinical application of a fluoroscopy-based image guidance system for various musculoskeletal injuries. Its major advantage is the high integrability in the accustomed surgical workflow and its connectivity with existing technical equipment. It can hardly be compared to known navigation solutions, since instruments are not tracked and fixed reference arrays are not required. First published results showed a reduced number of trials to place K-wires in trauma surgery and an improved learning curve [4, 5]. It was very usable for all guide- or K-wire-based indications but was limited in other surgical fields such as spinal or pelvic surgery. The ability is very promising to stitch single images and create long leg X-rays on the OR table, to achieve a straight axis following fracture treatment on the femur and tibia. The ultimate requirement for assistance in fracture reduction has still not been reached and no technical solution overcomes the technical limitations in solving the problem of guiding multiple fragments under permanent control, but we present a usable technical extension of existing intraoperative imaging modalities to potentially improve surgical outcome parameters. In particular, the long leg X-ray function should be further developed and examined in prospective clinical series.

Reference List

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