Flexible interventional imaging system based on miniaturized X-ray tubes (FlexScan)

https://doi.org/10.1515/cdbme-2018-0016

Abstract: In orthopedic hand surgeries C-arms are the standard imaging modalities for procedure and tool guidance. However, the currently used systems have a large footprint and high weight, which can lead to workspace restrictions and difficult positioning of the device at the desired imaging position. The aim of this paper is to present a prototype of a new, flexible, lightweight and small footprint X-ray system, which is capable to create 2D projection images from different orientations. The new design includes a miniaturized X-ray tube covered in a custom-made case mounted on a flexible holding arm attached to the standard OR table rail. With that, fast positioning and fixation for the subsequent image acquisition is achieved. A flat panel detector is placed in an adjustable metal sheet construction below the table. For safety aspects an overlay of the X-ray cone beam with an integrated light source visualizes the irradiation area. The acquired images are visualized on a 2-in-1 netbook. A foot pedal initiates the imaging process. A prototype of the free movable miniaturized X-ray system FlexScan was build. Workspace restriction, usability and general imaging needs were simulated and tested. FlexScan has the potential to improve X-ray guided interventions on extremities especially for small private surgery centers. It fulfills the general imaging needs and is capable of producing 2D projection images from different orientations within a small and lightweight setup.

Keywords: hand surgery, orthopedic surgery, miniaturized X-ray system, standard table rail, small footprint, free movable arm

1 Background

Extremity surgeries are procedures performed after injuries and other health conditions within the musculoskeletal system, which includes the bones, joints and the surrounding soft tissue containing muscles, ligaments and tendons. In orthopedic hand surgeries image guidance is of high importance, as some fractures are not visible from the outside. X-rays give a sufficiently good enough contrast for bones. It is the most suitable imaging modality for orthopedic surgeries.

In clinical procedures an easy and intuitive workflow is most favorable. Technologies like imaging systems should assist the operating team in the most effective and efficient way, rather than to disturb or delay the procedure. Nowadays conventional C-arm X-ray systems occupy a relatively large space in the surgery room and are rather heavy and bulky to move and position. That can limit the proper access to the surgery site. For the operation of the system additional staff is needed for correct alignment and manipulation of the imaging system. To optimize the usability and patient access of X-ray imaging in extremity surgeries a new design based on a miniaturized X-ray tube is proposed that is lightweight, easily movable and removable, and requires little installation space and effort.

2 Materials and methods

2.1 Clinical need identification

To define the clinical needs for an easy to use imaging system and to involve user experience into the development, a local orthopedic surgeon and the plastic, aesthetic and hand surgery department of the university hospital Magdeburg was consulted. X-ray guided closed hand reduction surgeries were observed in the clinic and the workflow was documented to detect limitations and define needed features and requirements [1]. A closed reduction of the hand is performed when bones of the hand got disarranged and need to be repositioned. This is done by using drilling wires to fix the position of the bones with respect to each other and hereby initiate and facilitate a correct healing process. For the hand surgeries different C-arm systems (Ziehm Vision, Ziehm Imaging...
GmbH, Nürnberg, Germany and Fluoroscan InSight-FD, Hologic Inc., Malborough, USA) were used for imaging.

Within the clinical procedures the following limitations of these imaging systems were observed:

- Long set-up time to arrange the system in the OR (approximately 10 minutes)
- Disturbance of workflow due to huge footprint and weight resulting in complicated location of the machine
- Orbital movement of X-ray system is not applicable due to limited free space
- High radiation exposure for the surgeon due to location problems and unclear radiation area
- Sterilization foil is complicated to locate due to C-arm design and disturbs the operating field
- Manual image saving requires attention of the user
- Cables cause danger and inflexibility in device location

The analysis of the observed procedures and the discussions with the surgeons showed the need for a new system geometry of the X-ray system especially for surgeries on extremities. This system should be free moveable and imply small dimensions to make the system easy to maneuver and to enable intuitive usage without workspace restriction. Besides a sufficient image quality, the system should provide an adjustable tube-detector-distance, short set-up time, smooth movement, low weight for easy handling and manoeuvrability and additional safety features for radiation protection of the surgeon.

2.2 Conceptual design

2.2.1 X-ray source & detector

To produce the X-rays, a miniaturized X-ray tube was chosen (60kV 12W MAGPRO® X-ray Source, MOXTEK Inc., Orem, USA). It provides a small and compact design (16.5 cm x 7 cm x 3.4 cm) and is lightweight (around 700g), which makes it portable and easy to integrate. The X-ray output is stable and high, allowing short sampling times. The focal spot size is around 400 µm and the tube has a range of 5 µA - 1000 µA of current and 4 kV - 60 kV of voltage [2]. No additional high-power generator is necessary. The X-ray tube needs to be connected to a 24V power supply.

For signal detection and image reconstruction a flat panel detector (XINEOS-2222HS GigE, Teledyne DALSA Inc., Waterloo, Canada) was chosen, which has dimensions of 292 mm x 235 mm x 55.6 mm. It features the 6th generation of CMOS technology with a pixel resolution of 1416 x 1420 and a pixel pitch of 151.8 µm in an active area of 214 mm x 215 mm [3].

2.2.2 Motion mechanism & case for tube

For the performance of the motion a flexible holding arm was chosen. After researching and analyzing different medical certified arms, a 3D holding arm (trimano fortis, MAQUET Deutschland GmbH, Rastatt, Germany) is the most suitable solution. It can easily be fixed in the standard OR table rails and allows six rotational degrees of freedom. With this it can cover a spherical workspace of 80 cm distance from the table rail fixation. To move it, only one hand is necessary to unlock and guide the arm into the desired position. On the frontal end an adapter pin allows connection of different tools. It is already clinically approved and can be used in a sterile environment [4].

To connect the X-ray tube to the arm, a case was designed, enclosing the tube completely. It includes cable guides and an opening for heat exchange. Additionally to the tube, a red LED is included in the case to later mark the radiation zone to address work safety aspects. The basic case was manufactured by 3D printing. An aluminum plate builds the back part including the connector for the trimano holding arm.

2.2.3 Detector housing

To minimize the space occupied by the system, the detector will be mounted directly under the surgery table. Therefore, an adjustable housing is made of two metal sheets, which slide inside each other. The housing is hanged inside the standard table rail. Two slides in combination with wing screws allow an adjustment to the table width. The detector is fixed inside the housing by four additional screws.

2.2.4 Display & human-machine-interface

A 2-in-1 netbook (Acer Aspire 1820PT, Acer Computer GmbH, Ahrensburg, Germany) is used to run the software for the image acquisition and to display the image.

A USB cable connects the tube to the computer. The software 12Watt (MOXTEK Inc., Orem, USA) is utilized to operate the tube. For control a food pedal (Stinkyboard, Stelulu Technology Inc., Montreal, Canada) is combined with the computer. The detector is connected to the power
supply and the netbook via GigE connector. It can be controlled by the program CamExpert (Sapera Vision Software, Teledyne DALSA Inc., Waterloo, Canada).

The completed setup of the prototype is shown in Fig. 1.

![Figure 1: FlexScan prototype set up on a surgery table](image)

### 2.3 Evaluation of the system

To determine the footprint, the dimensions occupied by the system were measured. The workspace is defined by the maximum/minimum distance of tube to the table surface and the maximum operating radius. Different system positions were evaluated. Therefore, the tube was placed vertically over a simulated surgery object and pictures were taken at different heights with fixed parameters (60kV, 200µA, 21 s). Afterwards, the arm with the tube was pivoted to acquire angulated projections. In each angle it was observed if all the parts of the object were clearly and completely visible in the image (see Fig. 2).

To test the usability, FlexScan was mounted on the OR table several times measuring the time needed. Therefore, the detector construction including the detector was hanged underneath the table and the arm with the tube was fixed in the standard table rail. Movements of the arm in all desired positions were performed. Different positions were obtained by moving the system with one hand out of a standing and also a sitting position.

Furthermore, the performance of the LED for marking the irradiated area was tested. As there is a lot of light in operating theaters, the LED light intensity needs to be sufficient from all distances. The tube was placed in the maximum vertical distance of 48 cm above the surgical table and was moved slowly towards the table in the vertical position until a clear circle of the red light was visible above the surgical table. The diameter of the light circle depending on the distance between tube and surgical table was documented. Additionally, the diameter of the irradiated area was calculated at the measured distances and compared to the measured light circle.

While performing the test scans, the user interface was tested being intuitive and easy to use.

### 3 Results and discussion

The FlexScan system was built up as a prototype and tested to meet the requirements. The holding arm is fixed in the table rail by its surgical clamp covering a footprint of 6.5 cm x 16 cm next to the surgical table. The detector is hanged in the table rails under the table by a flat housing (12 cm height). Table width can be adjusted from 35.5 cm till 64.4 cm for various surgery tables. The average time to mount the complete device is approximately 1 minute (27 s to mount the detector, 20 s to mount the arm).

The tube can be placed vertically over the table up to a maximum height of 48 cm. The surgical clamp of the arm can be located with a maximum distance of 80 cm to the center of the imaging object location. This position still allows reaching different image orientations with the arm.

In the test of movement of the arm it was possible to reach all desired positions with one hand out of a standing position. While sitting it is complicated to move the arm in any desired position with just one hand because of the weight of the arm and multiple joints.

The distance between tube and table can be easily adjusted. The minimum distance is 15 cm. The ideal height is between 20 cm and 25 cm for complete object representation completely on the resulting image. When performing the imaging with a distance above 29 cm, the image is darker and the details of the object vanish. Up to an angle of 31° measured from the vertical position and at a distance of 22 cm a good visualization of the object is given. Even a perpendicular view (-45°…45°) is possible, which is of high importance in imaging to impart a Bi-plane view of the surgical object.

Fig. 2 shows exemplarily images of an artificial spine phantom at different angles.

The focal spot size of the X-ray tube is larger than in conventional systems. An effect on image quality due to that was not observed. The other parameters are standard and make FlexScan an applicable system.
The test of the light for marking the irradiated area showed that a clear circle of the red light was visible below 26 cm above the surgical table. This corresponds with the optimum imaging distance. However, it was shown that the diameter of the light circle from the lamp is insignificantly smaller than the calculated irradiated area.

The interaction for system operation still takes several clicks to use the two programs for image acquisition. Therefore, a new graphical user interface is necessary.

4 Conclusion

The tests showed that the concept of FlexScan is feasible. It fulfills the imaging needs and is capable of producing 2D projection images from different orientations.

FlexScan provides an excellent footprint size and the tube detector distance is easily adjustable. Compared to the C-arm systems the new system does not block a complete table side and can be removed fast out of the working area when desired. The system offers a huge work space than conventional systems and is easier in use and installation. However, while the tests 3 main limitations were observed:

1. By acquisition of an angled projection the operator tries intuitively to keep the object in the focus of the tube. Due to the set-up, the detector is not visible from the top of the table. This leads to a shift of the imaged object to the side on the resulting picture (see Fig. 3). The user needs to keep in mind that either the focus of the tube or the object needs to be changed to obtain the right image.

2. The LED-tube geometry relation needs to be modified. This should ideally show the correct irradiated area and contain a safety margin of 1 cm.

3. The handling of the system with only one, hand especially in the sitting position is difficult. Therefore, an additional holding force to stabilize the arm would be beneficial.

FlexScan has the potential to improve X-ray-guided interventions on extremities especially for small private surgery centers. Improvements to address the identified limitations and more testing including clinical expertise are necessary.

Author Statement
Research funding: The authors state no funding involved. Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent is not applicable. Ethical approval: The conducted research is not related to either human or animals use.

References