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Evaluation criteria for mobile X-ray devices – a novel benchmark based on literature review and lead user interviews in trauma surgery and orthopaedics

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Abstract

Objectives: The study aims on evaluation criteria applicable for the development process of new mobile 3D X-ray imaging devices, based on existent knowledge from literature and user expertise.
Methods: For this purpose, a structured literature review was performed to outline limitations and opportunities of established systems on the market. Additionally, medical professionals from various medical fields were interviewed, following a structured interview protocol, to identify critical evaluation aspects from a user perspective.
Results: The study identified a total of 52 evaluation criteria, which were categorized into the following domains: clinical application and manageability, image quality, radiation dose and risk of infection. The analysis of user needs, subsequent summarization, and rating of these needs will serve as a new benchmark for the evaluation of both existing and new devices. This will provide guidance to procurement, medical experts, and manufacturers.
Conclusions: While the structured evaluation of mobile X-ray devices is possible, consultation of the users regarding their weighting of varying needs will remain an important aspect of the process. The evaluation items can serve as a starting point for this analysis.

Keywords: c-arm; evaluation guide; mobile radiography; mobile x-ray; radiographer perspectives; quality control

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Introduction

C-arm computed tomography has been developed for over three decades. It has since then been used to improve image quality in the field of interventional radiology [1]. Surgeons previously relied exclusively on their anatomical knowledge and experience to localize intracorporeal findings [1, 2]. The introduction of intraoperative imaging provided them with a more comprehensive, patient-specific diagnostic and treatment capability, being essential for minimally invasive surgeries. In addition to intraoperative ultrasound (IUS), devices based on X-ray radiation are increasingly utilized [3]. While 2D X-ray methods are common, 3D devices, such as intraoperative CTs, are gaining popularity, albeit being stationary and costly. Mobile O-arms are also employed, but they share the drawbacks of being expensive, large, and less suitable for 2D imaging [4]. Furthermore, 3D C-arms are either fixed with robot-assisted arms or fully mobile. Mobile devices are cost-effective, lighter, smaller, and more manoeuvrable than CTs [4]. Based on Cone-Beam CT technology, they allow the acquisition of image datasets from defined rotational positions and enable 3D reconstruction

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similar to CT [5, 6]. This technology facilitates intraoperative detection of implant misplacements [6–8] or bone residues [9], as well as the assessment of fracture misalignments [6] and by that supports repositioning [7]. During a research study, a prototype of a new type of x-ray-based mobile 3D-C-arms was developed, which is even able to detect soft tissue, such as muscles and nerves. This is particularly advantageous with regard to minimally invasive surgeries such as minimally invasive plate osteosynthesis, where pinched soft tissue and nerves may cause medical difficulties.

Despite some aforementioned advantages, mobile 3D C-arms have limitations that can influence the outcome of a surgery. Successful imaging with 3D C-arms depends on factors such as the physical pixel size of the X-ray detector and associated volume data with sufficient resolution, the choice of the reconstruction algorithm, a sufficiently large imaging area, easy alignment of the device on the patient, short acquisition and reconstruction time, and swift transfer of image data into standardized formats [10]. Additionally, considerations such as radiation dose and infection risk, which can pose dangers to both the patient and the personnel, must be taken into account.

Evaluations of C-arms in the literature are mainly related to safety and performance criteria, linked to a regulatory perspective. Aspects for the evaluation of soft tissue recognition or comprehensive user aspects are mostly neglected [1, 11–14]. From a normative point of view, usability requirements, unlike safety and performance requirements (e. g. IEC 60601), are only defined in very general terms for medical devices (IEC 62366), which means that there is no direct reference to mobile X-ray devices. During procurement of X-ray devices, also mobile X-ray devices, purchasing costs are a dominating factor. So, there is no assessment of these devices based on strengths and weaknesses known in literature or needs of lead users.

Aim of this study is to derive evaluation criteria for (new) mobile 3D X-ray devices, which is even applicable to devices that are able to resolve bone and soft tissue. Based on existent knowledge from literature and users, evaluation categories were mapped and refined evaluation items were established. This shall enable more structure and detailed evaluation process of mobile X-ray devices, give guidance during a development process and can be another factor apart from simple procurement costs. The focus of this study lies on the area of orthopaedics and trauma surgery, even though the results may be transferable to other application areas.

Materials and methods

Two methods were used to identify the critical aspects of mobile 3D X-ray devices. The first approach was structured literature research. The second approach was a lead user survey. The results of both approaches were then used to map relevant aspects for the evaluation of mobile 3D X-ray devices.

Literature review

The structured literature review was performed to outline limitations and opportunities of established systems on the market. Different search terms were used for different search categories (s. Table 1). Two search categories were defined for the search in all publication types (“3D imaging of minimally invasive plate osteosynthesis” and “specific devices”). Another search category was used to search for critical aspects in reviews (“intraoperative 3D imaging in orthopaedics”).

The literature search, was conducted in PubMed and Europe PMC in a time frame between 2000 and 2019. An additional free search was performed. All titles were screened to exclude mismatching literature and duplicates. Afterwards, all abstracts were screened to find potentially relevant publications according to the relevance criteria in Table 2. Full texts were then screened and evaluated according to the grading system. The inclusion criteria were defined as the

Table 1: Categorization of used search terms for the literature search.

All types	Search terms aspect 1: Devices	Search terms aspect 2: Type of surgery
3D imaging for minimally invasive plate osteosynthesis	“3D-C-arm” “3D imaging” “C-arm”	“Minimal invasive” “Minimal invasive plate osteosynthesis” “MIPO”
Specific devices	“Ziehm VISION FD VARIO 3D” “Siemens arcadis orbic 3D” „Siemens siremobil Iso 3D“ „Siemens CIOS spin“	
Reviews		
Intraoperative 3D imaging in orthopedics	“3D-C-arm”	“Orthopaedic”

Table 2: Grading system for the relevance of the search results.

Relevance criteria	Description	Grading system
Appropriate device	Were the data generated from an intended device?	D1 actual device D2 equivalent device D3 other device
Appropriate device application	Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 same use A2 minor deviation A3 major deviation
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc.) and clinical condition (i.e. disease, including state and severity)?	P1 applicable P2 limited P3 different population
Acceptable report/ data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 high quality R2 minor deficiencies/ outdated R3 Insufficient information

first two categories of each relevance criterion. Exclusion criteria were other devices, inappropriate device application, different population or insufficient information.

An example for exclusion based on categorisation into "other devices" (D3) is that the study was not performed with an X-ray device. Other c-arms would be an example for an "equivalent device" (D2). Dried human skull as used in Schulze et al. [15] is an example for an exclusion based on the appropriateness of the patient group. Examples for exclusions based on A3 and R3 can be found in the section results of the literature review. Further examples regarding the exclusion can be found in the annex of the structured literature search.

Lead user survey

A survey was conducted in order to identify critical evaluation aspects through user complaints and requests. As no validated questionnaire was available, an expert panel discussed relevant aspects and drafted an interview guideline including a non-validated questionnaire. The included items were based on the discussion of the panel and supplemented by items that emerged from the results of the literature research.

After piloting, the questionnaire was implemented into the survey. The final guideline contained four questions on demographic data related to their profession. Additionally, five open questions and six questions based on a Likert-Scale from 1-5 were included, addressing experiences and expectations of intraoperative imaging with regard to:

- Devices used (3D) and reasons to avoid 3D imaging
- utilisation of 3D imaging
- typical work steps of the personnel when c-arms are used (pre-, intra- and postoperative)
- Problems with the use of c-arms regarding handling, image quality, operation, visualisation, surgery results and hygiene
- improvement requests about handling, image quality, operation, visualisation, diagnostics, surgery results and hygiene
- tolerance with regard to interruptions of the surgery due to image acquisition, Likert-Scale: 1 (absolutely unacceptable) – 5 (absolutely acceptable)
- relevance of workflow improvement, Likert-Scale: 1 (not relevant) - 5 (highly relevant)
- relevance of handling, Likert-Scale: 1 (not relevant) - 5 (highly relevant)
- relevance of operation (hardware, software), Likert-Scale: 1 (not relevant) - 5 (highly relevant)
- relevance of visualization (monitors, software visualization), Likert-Scale: 1 (not relevant) - 5 (highly relevant)
- relevance of image quality (noise, artifacts, soft tissue representation) (Likert-Scale), Likert-Scale: 1 (not relevant) - 5 (highly relevant)

For each open question, a guideline for the interviewer was defined. For example, an interviewer guideline for typical workflow steps included preoperative aspects (i.e. sterile covering, alignment or test runs), intraoperative aspects (i.e. scanning, image optimization or operation with specific tools such as touchscreen, mouse and keyboard), and postoperative tasks, to ensure that the participants give comprehensive answers.

Aspects such as cost and radiation dose were not asked in depth, as the focus of the interview was on the user experience and medical staff are not experts in the purchasing process or exposures to nuclear radiation. To cover diverse user groups, medical professionals from various fields and roles were interviewed by one specific interviewer. The results of the interviews were mapped into five categories: image quality, clinical applicability and operability, handling, risk of infection and radiation dose.

Evaluation of mobile X-ray devices

Based on the content-related results of the literature research and user perspective, main evaluation categories

Table 3: Derived evaluation criteria for X-ray applications.

No.	Clinical application and operability	Image quality	Radiation dose	Risk of infection
1	Manoeuvrability (e. g. to avoid collisions)	Soft tissue visualization	Acquisition time	Recording and reconstruction time
2	Possibility to set the patient and radioscopy levels (intuitiveness)	Statistical image quality	Number of scans during surgery	Data transfer speed
3	Intuitive and harmonized software design (e. g. for user interface and program selection, colour coding)	Number, size, position and orientation of the monitors and the images on the monitor	Field of view delimitation-features	Initialization and shutdown time
4	Solutions for automatic data transfer	Reduction of metal artifacts	Unforeseen interference within the operation	Operation time (focus on possible time for preparing, selecting or analyzing image data)
5	Extent and quality of additional and standard modalities	Reduction of further artifacts and of loss of image quality, e. g. due to obesity	Use of different exposure modes (in case if high- and low-dose modes are available)	Interruption time for the scans
6	Presentation of images	Detection of penetration		Frequency of application during the operation
7	Easy shunting and positioning	Detection of trapped muscle/nerve tissue		Operation of the X-ray device by sterile assistant
8	Centralized (e. g. by joystick, touchpad, smart eye) and reproducible positioning	Detection of foreign objects		Sterility gaps (e.g. with covers, cable entries, collision with non-sterile objects)
9	Simple alignment of the isocenter and planes	Detection of fracture repositioning errors		Effort required to attach the cover
10	Unplanned movement of the device during surgery	Detection of bone defects		Other disruptions to the workflow
11	Obstructions by cables or protruding parts during the operation	Detection of bleeding		Data transfer to the HIS system (manual, automatic)
12	Possibility to switch between 2D and 3D display	Detection of tumours		Time required for operation
13	Possibility to switch between basic and advanced menus	Detection of vessels		Number of cover parts
14	Application and application-error related extension of the operating time	Detection of bone density		
15	Use of standard and additional modalities during surgery	Detection of intraarticular fracture displacements and malposition or rotation of bone fragments		
16	Computer capacity (e.g. for volume display)	Enhanced visualization of the surgical results (positioning of osteosynthesis material, implant malposition, possibility of assessing the articular surfaces and joint reconstruction		
17	Failure frequency of functions	Enhanced visualization during surgery (localization of the surgical site, bone residues, positioning of screws, screw perforations, possible sites for punctures)		

were established. To achieve this, both results were categorized and order based on the most frequently and severe aspects mentioned in the literature and interviews. To summarise and order the derived aspects, five main categories were established. Subsequently, all categories were further divided into subcategories, reflecting final items to be evaluated during the validation and verification process to cater the needs regarding the user perspective. In total, 52 subcategories were defined and linked to the category with the strongest alignment (s. Table 3).

Results

Literature review

In total, 149 publications were screened for inclusion based on the defined criteria and search terms (s. Table 1 & 2). 69 publications were categorised as potentially relevant based on their title. Three papers were excluded based on the full text analysis.

(1) Pieroh, P., et al. "Intra-and interrater reliabilities and a method comparison of 2D and 3D techniques in cadavers to determine sacroiliac screw loosening." Scientific reports 9.1 (2019): 1–10. as insufficient information were presented for evaluation (exclusion criteria: R3);

(2) Kageyama, H., et al. "Advantages and disadvantages of multi-axis intraoperative angiography unit for percutaneous pedicle screw placement in the lumbar spine." Neurologia medico-chirurgica 57.9 (2017): 481. as the research was not focused on the device application but on the pedicle screw placement (exclusion criteria: A3);

(3) Kapila, S., et al. "The current status of cone beam computed tomography imaging in orthodontics." Dentomaxillofacial Radiology 40.1 (2011): 24–34. as the research was highly focused on orthodontics specific needs instead of in trauma surgery and orthopaedics (exclusion criteria: A3)

66 underwent a full-text analysis and were all included in the study (s. Figure 1). During the literature research, the papers were screened for negative and positive aspects of the devices and imaging techniques to identify potential evaluation items. These are presented in the following sections. For further information of the literature, we added an appendix with an overview of the structured literature search.

The scoping review revealed different limitations and advantages of the devices, which were mapped into the six categories image quality, clinical applicability, radiation dose, surgical outcomes, infection risk and costs. All content-related results are summarized subsequently, to give an

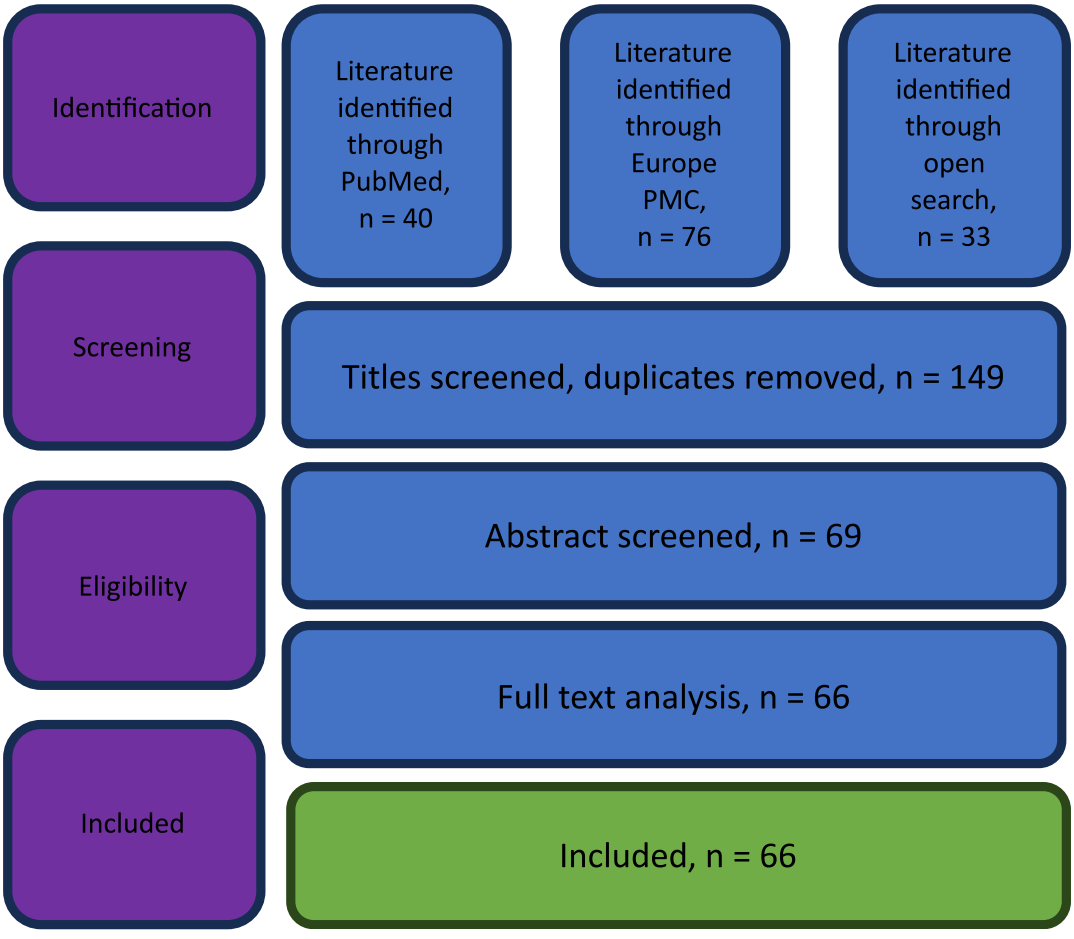


Figure 1: Inclusion of publications of the systematic literature research.

overview about relevant aspects in current X-ray design and evaluation.

Image quality

Various influencing factors, including tissue thickness, scanning arc, and the presence of pre-existing implants, have been investigated in literature [16]. The subjective evaluation of image quality emerges as a central aspect. 3D C-arms are generally rated lower compared to CT image data [3, 4, 17–21]. The intricate relationship between signal-to-noise ratio (SNR), radiation dose, and subjective image quality is investigated in different publications [18, 19]. They reveal nuanced findings challenging the assumption of straightforward correlations. Insights from numerous studies illustrate the complexity inherent in assessing subjective image quality, particularly in the context of comparing different devices and settings [16, 17, 19, 22, 23]. The persistent challenge of metal artifacts in medical imaging, particularly in scenarios involving medical implants, is another important critical aspect of X-ray devices [5, 6, 16, 17, 21, 24, 25]. Literature and manufactures highlight various strategies for artifact reduction [23, 26, 27]. Additionally, the impact of patient-specific factors such as obesity and osteoporosis on image quality is addressed in literature [6, 24]. The role of motion-induced artifacts during image acquisition is another limitation that is particularly important for procedures such as spinal surgeries [5, 8, 24]. Some studies focus the significance of variables such as the number of captured images, the rotation angle of the C-arm, and technological advancements like elliptical rotations influencing image quality [16, 28].

Clinical applicability and operability

In medical imaging, surgical teams often prioritize workflow efficiency over image quality [4]. Important, influencing factors are positioning and manoeuvring, operation of the mobile X-ray, presentation of images and seamless function [16, 29]. Factors like manual positioning can pose a challenge, especially due to weight, dimensions [16] and the aim of repositioning on the exact same initial position of the previous imaging, e.g. for postoperative control [30]. A solution to overcome this are hybrid operating rooms which benefit from digitally connected C-arms with operating tables. This is reducing collisions and can potentially lowering radiation doses as the positioning is improved [31]. Other c-arm have switches to allow singular rotation or translational movements [10] which is otherwise intricate due to various rotational joints [30]. Laser markings aid in centring surgically relevant areas [10, 32], though laser availability varies between devices [16]. Height adjustment alignment of the c-arm with the surgical table is critical for clinical applicability [10]. Software-based operation is of importance for seamless application [16]. Some devices advantageously feature intuitive program selections [16, 33, 34]. Furthermore, system failures cause delays [29] which are linked to the restart time that differs between devices [16]. Also, technical limitations like generator heat need to be considered as these can limit functions [34]. In some devices cooling systems optimize the temperature of the generator [33].

Radiation dose

Literature underscores the utmost importance of minimizing radiation exposure for both medical personnel and patients [16]. The influence of the scanning procedure on radiation dose is emphasized, highlighting a direct correlation between the number of scans conducted, the image quality-requirements of the surgeon, the size of the patient, the expertise of the scanning person and the level of radiation dose [4]. Specifically, mobile 2D C-arm have a time-consuming nature of image acquisition which is not only time-intensive but may also elevate the infection risk for the patient [35]. Furthermore, the acquisition of 3D image datasets is initially associated with higher radiation intensity, yet the repeated use of 2D imaging during an operation might lead to higher doses in comparison to reusing of 3D images, highlighting the compromise between 3D and 2D imaging [5, 22, 32].

A measure to reduce radiation for medical personnel is the effective use of lead aprons [4, 16] which reduces the radiation exposure at least about a factor of 16 [16]. In 2D image acquisition, the surgeon is exposed to scattered radiation [36] which can be avoided with mobile c-arms by leaving the exposure area [10, 36, 37]. Leaving the operating room is a time-consuming interruption, especially if the medical staff has to clothe again. Another option is to locate sidewise to the detector as a low Compton scattering is assumed there [16].

Even if radiation exposure is minimized in more modern devices, patients are exposed to this [22]. In general, for mobile c-arms this radiation is lower compared to CTs [5, 32, 37]. Differences regarding radiation exposure and image quality exist between devices [16], but a direct comparability of studies on radiation dose is not feasible due to the lack of standardization in methods, units and the various presentation of results [4]. A higher radiation exposure cannot be linked to linear improvement regarding a higher image quality, especially to the subjective image quality, and differentiability between structures even though contrast and radiation exposure are correlated [22]. Regarding radiation exposure for the patient, various devices offer different settings to adjust radiation exposure. For example,

influencing aspects such as fluoroscopy time, radiation filtering and collimation, acquisition volume, rotation time, radiation pulsation and dose levels to minimize potential organ damage from radiation are emphasized in literature [7, 10, 16, 22, 29, 31, 36, 38]. Therefore, in order to improve the image quality with low radiation exposure, a skilful selection of the constructive implementation, the device parameters and the filtering must be considered [10, 16].

Surgical outcome

Positive and negative aspects of different methods regarding the surgical outcome are analysed and summarised to identify potential evaluation items. The use of 2D methods in surgeries has some weaknesses, including the potential risk of damaging arteries, nerve roots, or the spinal cord in the case of vertebral interventions [24]. In complex anatomical regions or with complicated fractures involving multiple fragments, 2D images may lead to virtual bone superimpositions, hindering the assessment of articular surfaces [6, 7]. 2D fluoroscopy allows only a limited evaluation of intra-articular fracture displacements and bone fragments, joint reconstructions, bone misalignment, instabilities and implant displacement [7, 18, 32, 39]. Studies indicate that the use of intraoperative 3D procedures leads to improved surgical outcomes, shorter operation times, and a reduction in the rate of incorrect implant placements [6, 7, 18, 24, 25, 29, 32, 39–41]. Intraoperative 3D imaging also enables the detection of complications such as screw perforations independent of the positioning [37] and vertebral rotations that could lead to screw misplacement [42]. Compared to postoperative CT scans with 2D methods, intraoperative 3D procedures can minimize registration errors and streamline the operative workflow [43].

Risk of infection

Mobile C-arms pose an infection risk, which can be mitigated through the use of a sterile cover [41]. Operation time is also crucial, considering not only the acquisition time of image data. A study by Frink et al. in 2007 assessed the image data acquisition time using the Siemens Siremobil Iso-C 3D, from preparation through image capture to reconstruction, selection of data for evaluation, and actual interruption of the operation [40]. The preparation time averaged 200 s, image capture took 120 s, and reconstruction time added an additional 250 s. Data selection and evaluation averaged 210 s. The actual interruption of the operation lasted an average of 430 s [40]. More recent studies reported operation extensions ranging from four to 6.7 min [7, 39]. The lower frequency of scan processes with 3D C-arms is associated with reduced operational handling, making certain techniques superior to other methods in terms of sterility, e. g. 3D in comparison to 2D techniques [44]. Equally important is the need for a device that allows for simple and precise operation as the risk of infection may also be increased by the operating the device. Therefore, the operation is often performed by sterile surgical assistants. In modern operating rooms, the imaging system can be sterilely controlled from a covered operating unit at the operating table. This allows the surgeon to work independently without assistance [31]. Apart from covering the imaging system, the surgical area must be covered before positioning the C-arm [9, 32]. Other tools, such as navigation references, must also be sterile covered. C-arms can rotate beneath the operating table based on their large rotation angles, requiring precautions to prevent contamination. Measures may include encasing the patient in a sack or using disposable operating towels [23].

Costs

The acquisition and operating costs of different mobile X-ray devices differs significantly. Procurement costs are neglected for this evaluation as other evaluation items shall be distinguished. So, this section focusses on the “hidden” costs during application phase. Nonetheless, procurement cost is an important factor to rate a mobile X-ray devices and have to be weigh against the derived evaluation items. However, the acquisition costs of 3D mobile X-ray devices are notably lower than those of conventional CT scanners [19]. The following highlights factors that influence these application costs. Intraoperative detection of misplaced implants or inadequate repositions can prevent postoperative revisions, reducing the need for subsequent CT scans and lowering overall costs. A cost analysis conducted at the Trauma Surgery Clinic of the Hannover Medical School in 2003 demonstrated savings of nearly €13,000 due to a 19 % reduction in intraoperative revisions among 126 patients based on usage of 3D C-arms. Thus, the acquisition of a mobile 3D C-arm is particularly beneficial for centres dealing with a high volume of complex joint fractures [45]. Studies, such as the one by Watkins et al. (2010), reported cost savings and reduced revision rates for surgical procedures using mobile 3D C-arms [29]. Based on this, it is clear that other categories as “Clinical Applicability and Operability”, “Surgical Outcome” and “Risk of Infection” influence the overall costs as operating time and revision rate have a high impact on the operating costs. Approaches to save operating costs and minimize radiation exposure can be software based. For example, software can enable 3D image reconstruction using a conventional 2D C-arm. The process involves rotating the previously centred 2D C-arm by approximately 120° during

image acquisition. Reconstruction relies on a target surrounding the patient, defining spatial localization. While the scan time is significantly shorter than that of 3D C-arms, an additional processing time is required for the image data to become available and the image quality has been rated as being inferior [46]. Typically, acquisition costs are based on the device itself. These cost of conventional 2D C-arms are lower than for 3D mobile X-ray devices [45]. These costs include not only the image intensifier itself but also radiolucent operating tables, leading to additional expenses [25, 45]. Therefore, costs cannot be seen as single category but have to be investigated together with other categories. Based on the high costs of revision rates and the dependency of risk of infection of other categories, risk of infection is a good fit to merge with the cost categories.

Interview

The interviews were conducted by 11 participants, three advanced surgical trainees and eight surgeons. The surgeons and advanced surgical trainees were included if they had experience in trauma surgery and orthopaedics. Surveys were handed out to the medical staff at the Universitätsklinikum Schleswig-Holstein in the department of trauma and orthopaedics. Of the participating physicians one surgeon was a neurosurgeon, seven were orthopaedic and trauma surgeons. Three surgeons indicated advanced trainings, one in specialised trauma surgery, one in knee surgery and one in spinal surgery. The surgeons' professional experience ranged from 1 to 25 years with an average of 14.5 years. The experience of surgical assistants ranged from 4.5 to 9 years with an average of 6.5 years.

From the respondents, seven surgeons and three surgical technologists exclusively used 2D C-arms intraoperatively in the past. Only one surgeon incorporated 3D imaging in less than 5 % of surgeries. There are various reasons that deter surgeons from using 3D-imaging. Four surgeons consider the implementation of a 3D C-arm to be cumbersome due to intricate setups, while two surgeons consider the time required to use a 3D C-arm to be too high. Additionally, three surgeons consider the radiation exposure to patients during 3D imaging to be excessive. Two surgeons find 2D representation sufficient in their specialties, rendering 3D imaging unnecessary, and for two surgeons, a 3D device is unavailable. For the surgical assistances no preferences were identified, as the decision regarding the choice of imaging modality is made by the responsible surgeons.

The interview included a general rating (1–5, irrelevant-relevant) of which user-related aspects an improvement is most urgent: improvement of workflow, handling and operation regarding the category clinical applicability and operability as well as improvement of image quality and improvement of visualization regarding the category image quality. The respondents rated the aspects as follows: improvement of workflows - 4.8, easier handling - 4.3, easier operation - 5.0, better visualization - 4.0 and better image quality - 4.2.

Image Quality

According to the majority of respondents, the image quality is considered good and sufficient. However, there are occasional disturbing artifacts that occur due to metal components on the table so that next to the image quality the occurrence chance and intensity of artifacts are good evaluation items. As a result of artifacts, the patient's position may need to be adjusted, or the image frames may not be optimal. One surgeon suggests that improved soft tissue visualization could be beneficial for documenting surgical outcomes and suturing tendons so that this can be another item for evaluation. A desire for improving image quality includes the differentiation of various anatomical structures to make hematomas, foreign objects, and nerves more visible for surgeons. Some of these, e. g. foreign objects, can already be detected by AI-powered software support [47]. Another wish is to enhance the automatic regulation of partial image brightness, especially in thoracic images, to improve overall image quality which indicates a need for automatic detection. Another aspect of optimizing image quality is that these improvements should be achieved without increasing the patient's radiation exposure.

Following evaluation aspects can be derived: reduction of (metal) artifacts, improved soft tissue visualization and visualization of the surgery result, improved statistical image quality and detection of different tissues to detect, e. g., hematomas, nerves, muscles and bones and their defects.

Clinical applicability and operability

In this category, challenges encountered in the operation of hardware and software were investigated. Concerning hardware, three surgeons mentioned that the alignment of planes is complicated in some cases due to the use of non-transparent operating tables. Additionally, criticism was directed at some devices for having positioning, patient input, and image capture functions on different user interfaces, lacking centralization. Regarding software operation, a central issue of all professional groups is the absence of automatic data transfer from the C-arm to the hospital system, as manual input is time-consuming. Another issue is

the lack of intuitiveness, making it challenging to operate the device.

Regarding user interface improvement, there are distinctions between hardware and software. Concerning hardware, surgeons desire to control both patient positioning and device adjustments themselves, using tools such as a touchpad, tablet, joystick, 3D glasses, or voice control. It is crucial that these tools can be used in a sterile environment. Another participant suggests tracking systems for positioning and automatization. Regarding software, most respondents emphasized the importance of an easy and intuitive user interface. Proposed implementations include explanatory texts, i.e. for adjusting the radiation dose, or integrating two different user interfaces for beginners and advanced users. Additionally, a contingency plan for direct access to images via a USB stick in the event of an IT failure is considered important. Suggestions also include any data that is not transmitted during an IT outage to be automatically sent once the issue is resolved. Further software operation desires include real-time image reconstruction, automated settings (e.g., radiation dose) based on the surgical procedure and anatomical location, a digital angle display, and automated software updates to keep all devices on the same version. It's essential to maintain the old operating system until the new one is fully installed and operational, especially for emergency situations.

Further, the respondents mentioned the following problems: inadequate computing power for volume rendering in 3D imaging, challenges in operation due to a variety of devices from different manufacturers with diverse hardware and software, issues with the use of foot switches, as they sometimes fail during surgery.

Based on these challenges and wishes several evaluation items can be derived: software user interface regarding intuitiveness, automatic data transfer, alignment of the isocentre and planes, positioning related items, e. g. simultaneously control of patient and device control and obstructions, extent and quality of additional and standard modalities, intuitive/harmonised interfaces, presentation of images, failure safety (few operational failures of the system), switch between simple and more advanced interfaces and sufficient computing power.

Handling

In this category, issues related to the handling of the devices were analysed. It is noteworthy that seven respondents from both professional groups assess the currently used devices as too heavy and poorly manoeuvrable. This poses a significant problem, especially in small operating rooms where space is limited. The following aspects were additionally identified as problematic in this category: difficulty in accurately relocating the previous scanner position; challenging adjustment of the illumination plane in certain surgeries, such as shoulder, pelvic, and spine surgeries; errors in assembly and startup are only noticed during image acquisition, requiring a device restart and causing delays in the operation; slow startup of the devices; trained operating room personnel are required for intraoperative imaging with a C-arm, and currently, there is insufficient trained staff; cable issues, such as cable breakage and detachment from connection points; particularly for neurosurgeons, the limited distance between the X-ray source and detector is problematic, making surgery challenging without removing the device due to the short distance; swivelling the device is difficult due to the bulky X-ray generator, as it often gets stuck; the automatic angle adjustment performs poorly due to rapid stopping during collision checks.

The most common desire for C-arm devices was that it should be lighter and more manoeuvrable than the existing ones to simplify handling and positioning. Suggestions include using the screens already present in the operating room, so that additional screen apparatus is no longer needed except for emergencies. Additionally, monitors could be directly attached to the C-arm without making it too large and unwieldy. Another crucial aspect is the use of fewer cables, needed for the foot pedal or hand trigger, as these can become tripping hazards in the operating rooms. Further suggestions to simplify handling include color-coding the positioning buttons on the device and providing haptic support, possibly through a motor, to fundamentally simplify the device's positioning.

This leads to various aspects than can be rated on a mobile X-ray system as manoeuvrability, obstacles of surrounding features, i. e. cables of food pedals, alignment of planes and iso-centre, failure frequency of the system, presentation of images (closer attachment), easy shunting and positioning and reduction of obstruction by cables or protruding parts during the operation.

Risk of infection

Ensuring sterility is a crucial aspect of intraoperative C-arm use. The most common issue with sterile handling of the devices pertains to the use of sterile covers. These covers usually consist of several parts that need to be mounted on the device. These covering systems are labour-intensive, and sterile gaps may occur between the individual parts, leading to sterility problems. Another problem is the rotation process of the C-arm, as the swivelling motion brings part of the C-arm from below the operating table up into the surgical area (sterile zone), causing sterility issues. In cases where the C-arm

remains with the patient during the operation, surgeons may inadvertently touch unsterile areas of the device with longer surgical instruments (e.g., guide wires), rendering the instruments unsterile and unusable. For the use of the 3D C-arm, one surgeon mentioned that additional gloves must be worn for adjustments and collision checks to maintain sterility. This results in increased material consumption.

To facilitate improved sterile handling with the device, there is a request for optimizing the currently used sterile covers. These covers need to be more robust and user-friendly. A suggestion was to develop a solid, sterile cover behind which the C-arm rotates in order to eliminate gaps, prevent the lower non-sterile section from entering the sterile area, and ensure that the surgeon does not touch non-sterile parts of the device with sterile surgical instruments.

Next to time delaying task that increase infection risks, following evaluation items can be derived: the number of needed cover parts, complexity to attach the sterile cover (effort), gaps in the cover and possibility to operate the system by sterile assistant.

Radiation dose

In addition to the requests and suggestions in the predefined four categories, the following improvement requests were also expressed: minimization of radiation exposure for both patients and surgical personnel, radiography of two planes simultaneously, detector and X-ray source on both sides of the C-arm, application and application-error related extension of the operating time and by that redundant X-ray images. Due to these suggestions and interview, some evaluation items can be extracted: short acquisition times, minimization of necessary number of scans and reduction of unforeseen interference within the operation, delimitation of the field of view and various exposure modes (e. g. low and high-dose modes).

Evaluation of mobile X-ray devices

Based on the literature and the interview, following four main subjects were mapped as main evaluation categories:

1.) clinical application and manageability
2.) image quality
3.) radiation dose
4.) risk of infection

As costs for this study were focussed on operational cost during application phase there is a high degree of overlap with several different subcategories, as many of these have a negative effect on time delays. Thus, operational costs weren`t given an own main evaluation category but are spread over the other four main categories. These have to be weighted with the procurement cost to achieve a more profound assessment of mobile X-ray devices. Overlaps of subcategories were categorized based on their mayor influence on one of the categories. A total of 52 subcategories were established. The result is shown in Table 3.

Based on the results, evaluation items for mobile X-ray systems were acquired. Furthermore, suggestions for improving current systems can be derived from the interview and structured literature search. Highlighted improvements for these systems regarding the hardware are a reduction in size and weight compared to previous devices. This shall reduce restrains with a focus on small surgery rooms but also improve the handling during operation. This links with the urge of an optimization of the manoeuvrability of the device. Additionally, a combination of the C-arm with a monitor and use of the screens available in the surgery rooms, having only one monitor for emergencies can contracept doubling of medical devices and by that improve the overview and clarity during operation while leaving more space for other crucial devices. A further necessary improvement mentioned is the optimization of the number and allocation cables, aiming for a minimization of the number of cables. These can hinder medical staff and pose a risk of trapping, creating new hazards and harms. Another important optimization mentioned are the sterile covers that can lead to infects due to loss of sterileness during operation. These shall be adapted to secure the whole operating area of the mobile X-ray device as well as close gaps in between the sterile covers. Finally, the reduction of radiation exposure for the patient and medical professionals is an ongoing improvement area.

As further enhancement regarding the hardware, nine other improvements are named, which are not as essential as these first listed. These are the optimization of automatic angle adjustment, an improvement of the foot control (fault correction), a haptic support for positioning, a colour coding of the positioning buttons, positioning and alignment of the patient with an intuitive controller (touchpad, tablet, joystick or voice control) navigated by the surgeon, centralization of positioning, patient input and image resolution or automated positioning using tracking systems, the capability to use X-ray of two planes simultaneously, additional detector and X-ray source so that on both sides of the C-arm these can be used and an increased distance between the detector and X-ray source.

Regarding software, following improvements are derivable: the automatic data transfer from the device to the hospital system and a more intuitive GUI. Furthermore, as potentially improvements the following points were

perceived and derived from the results: differentiation of anatomical structures to better visualize hematomas, foreign bodies and nerves, automatic regulation of the partial image brightness, real image reconstruction and an automated setting of irradiation parameters, e.g. radiation dose.

Discussion

It is shown that the evaluation process of medical products is complex in the field of radiology. This is especially due to the fact that no standardized evaluation criteria exist. This is a common problem, not only for mobile X-rays but also, e. g., for radiological software solutions as discussed in [48, 49]. Thus, this work attempts to give guidance for mobile X-ray devices. The results highlight the persistent endeavours within the field to enhance image quality and mitigate artefacts in medical imaging, while maintaining a discerning awareness of limitations, notably in specific mobile 3D systems. Despite challenges, understanding the clinical applicability of imaging systems is vital for effective integration into surgical workflows. The ratings of key users suggest that choosing an adequate mobile X-ray device is crucial but from user perspective the importance of certain areas is differentiating. The respondents place the highest importance on an easier operation, considering it very relevant (rated 5.0), followed by the improvement of workflows (rated 4.8). Easier handling, better image quality, and better visualization also received high ratings, indicating their significance in the respondents' perspectives. This indicates that the weighting of the evaluation items might not be equally distributed. This highlights that feedback from medical personal using the mobile X-ray devices is still necessary for reasonable buy decisions or rating of systems regarding their usefulness but the developed scheme gives different aspects to support this process, can act as a starting point for evaluation and enables to rate the devices, even if the weighing may differ based on the field of application, the environment and the users.

Due to the considerable overlap in the influence of the evaluation items across the four categories, multiple factors exert a substantial influence on each other. To facilitate a comprehensive understanding, these items were grouped into the field with the most significant impact. However, it should be noted that these impacts may vary depending on individual circumstances and the specific evaluation item, rendering them not always readily quantifiable. Consequently, the presented structure should not be interpreted as implying the absence of effects on the other categories by individual evaluation items. Furthermore, some evaluation items can be analysed in more depth, e. g. usability of image visualisation as described in [49]. This might be useful if a specific item is of utter most importance in a special use scenario. Thus, the resulting table with evaluation items should be used as a general overview which can be more detailed if needed.

Limitations

This research study implies some limitations. The literature review was not following the PRISMA guideline for scoping reviews. The inclusion process was conducted by a single individual only, which may have introduced bias and limit the scope of the reviewed literature due to the inherent subjectivity and potential oversight of relevant studies. A more collaborative approach could enhance the review's comprehensiveness and objectivity. This shortcoming was partly compensated by an inspection of the results by another researcher. As the results of the structured literature search influenced the survey, this shortcoming has been further compensated. The lead user survey aimed at gathering insights from users. There was no validated questionnaire available for this unique topic. Although validation is crucial for ensuring reliability, it was deemed unnecessary for this project's exploratory scope, intended to identify broad trends rather than establish precise metrics. Another limitation is based on the low number of surveyed lead users, especially users working on a daily basis with 3D techniques or tissue detection methods. Nevertheless, the utilization of 3D techniques or tissue detection methods was a recurring theme in the discourse. This is, to a certain extent, negligible, as several elements of 2D and 3D imaging are analogous, for instance, in terms of handling. Additionally based on the hospital environment in which the questionary was conducted, the focus of the lead users lies in the field of orthopaedics. This limits the significance of results regarding affected statements and generalizability to other medical application areas. Therefore, special needs of other medical fields, e. g. cardiac surgery, may not be considered during the expert interviews. Thus, to assure transferability of the proposed system of evaluation further investigation and more expert interviews are needed to enhance the significance and application scope. On the other hand, the focus on orthopaedics and trauma surgery leads to a specialized result than has a better match than a more generalized approach for departments and heath care providers with a focus on trauma surgery and orthopaedics.

Conclusions

A system for the structured evaluation of mobile X-ray systems was created, highlighting four different evaluation categories divided into 52 sub categorical evaluation items. These items and categories were derived by a structured literature review and user interviews, allowing for a deduction of important hazards and suggestions for device improvements from clinical practice. The combination of literature research and user expertise led to an overview of important features of novel mobile X-ray-based C-arms. The criteria, even if not mandatory by law or standards, can act as a new benchmark to evaluate established and new devices, giving guidance to procurement, medical experts and manufacturers. Nonetheless, feedback from the users will stay an important tool to order the importance of the developed items. The results of the evaluation of the proposed criteria then can be used to enable better buying decisions without primarily relying on the procurement costs.

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