

First Animal Cadaver Study for Interlocking of Intramedullary Nails under Camera Augmented Mobile C-arm

A Surgical Workflow Based Preclinical Evaluation

Lejing Wang¹, Juergen Landes², Simon Weidert², Tobias Blum¹, Anna von der Heide², Ekkehard Euler², and Nassir Navab¹

¹ Chair for Computer Aided Medical Procedures (CAMP), TU Munich, Germany

² Trauma Surgery Department, Klinikum Innenstadt, LMU Munich, Germany

Abstract. The Camera Augmented Mobile C-arm (CamC) system that augments a regular mobile C-arm by a video camera provides an overlay image of X-ray and video. This technology is expected to reduce radiation exposure during surgery without introducing major changes to the standard surgical workflow. Whereas many experiments were conducted to evaluate the technical characteristics of the CamC system, its clinical performance has not been investigated in detail. In this work, a workflow based method is proposed and applied to evaluate the clinical impact of the CamC system by comparing its performance with a conventional system, i.e. standard mobile C-arm. Interlocking of intramedullary nails on animal cadaver is chosen as a simulated clinical model for the evaluation study. Analyzing single workflow steps not only reveals individual strengths and weaknesses related to each step, but also allows surgeons and developers to be involved intuitively to evaluate and have an insight into the clinical impact of the system. The results from a total of 20 pair cases, i.e. 40 procedures, performed by 5 surgeons show that it takes significantly less radiation exposure whereas operation time for the whole interlocking procedure and quality of the drilling result are similar, using the CamC system compared to using the standard mobile C-arm. Moreover, the workflow based evaluation reveals in which surgical steps the CamC system has its main impact.

1 Introduction

Many image guided surgery (IGS) systems have been introduced in the last decades, e.g. systems using external camera tracking for navigation or augmented reality visualization. All of them provide various promising solutions to either simplify surgery or improve patient treatment. However, very few IGS systems have succeeded to become clinically accepted and even a small number of them were integrated into daily clinical routine. Development of novel IGS systems involves a long and complicated process from the initial idea until their acceptance and use for clinical applications. This process includes the phases of

clinical problem investigation and analysis, problem modeling, system and algorithm design, system implementation and verification, and finally evaluating the system in terms of its clinical outcome. The practicability, efficiency and clinical suitability of a system are mostly confirmed within the clinical evaluation phase.

The assessment of IGS systems has been discussed in detail by Jannin and Korb [1]. They proposed an assessment framework with six levels ranging from technical system properties to social and legal impacts. These six levels are classified according to the progress of the clinical acceptance.

Mobile C-arms are a common tool to acquire X-ray images in the operating room during trauma and orthopedic surgery. The Camera Augmented Mobile C-arm (CamC) system that augments a regular mobile C-arm by a video camera was proposed by Navab et al. [2] for X-ray and video image overlay (see figure 1). Thanks to the mirror construction and one time calibration of the device, the acquired X-ray images are co-registered with the video images without any further calibration or registration during the intervention. This technology is expected to reduce radiation exposure during surgery without introducing major changes to the standard surgical workflow. Many works were conducted to quantify and qualify the CamC system regarding to the overlay accuracy [3] and absorbed and scattered radiation of the mirror [4], which can be categorized into the level of technical system properties and reliability [1]. The clinical performance of the CamC system has not yet been investigated in detail. Traub et al. [5] performed a reference based assessment, comparing the workflow when using the CamC system to the one of using CT for vertebroplasty on a simulated procedure using five spine phantoms. This interesting initial study involved only one surgeon and a very small number of samples, and could therefore not show significant results. It however showed that one way of estimating clinical impacts of the CamC system on trauma and orthopedic surgery is to evaluate it in a simulated clinical scenario. Interlocking of intramedullary nails has been recognized as a challenge surgical task, for which several ingenious methods and devices were developed, e.g. miniature robot based guide positioning [6] and optical tracking with using two non-constrained X-ray images [7]. Suhm et al. performed a clinical comparison study of interlocking using a surgical navigation system versus a standard C-arm system [8]. However, they did not compare the performance



Fig. 1. Thanks to a joint construction and calibration, the CamC system register the X-ray image (left) onto the video image (middle) to provide an X-ray and video image overlay (right).

of both systems for particular surgical steps. In this paper, a proposed workflow and reference based evaluation method is applied to evaluate the CamC system and to predict some of its possible clinical impacts. Carrying out an animal cadaver study, we compare the interlocking of intramedullary nails using the CamC system vs. a standard C-arm in order to evaluate and predict the clinical impact of this new IGS alternative. Five surgeons participated in this study. The results are presented and discussed in sections 3.5 and 4.

2 Surgical Workflow Based Evaluation for Image Guided Surgery Systems

In order to evaluate the clinical performance of a new IGS system and easily identify its advantages and disadvantages, we propose a workflow based comparison of the new system with a reference, i.e. conventional method. Assessment criteria, like patient outcome and radiation dose, are defined to compare the new method to the reference method. Instead of using only criteria for the whole procedure our workflow based method differentiates between single workflow steps. This has several advantages. Novel systems may introduce changes to the overall workflow or change the strategy within a single workflow step. While a system might have advantages in some steps of the procedure, it might also have disadvantages in other steps. Therefore, sometimes we may need to combine the functions of the novel solution and the traditional solution for the best result. A workflow based evaluation allows analyzing these aspects in more detail. Also the advantages and problems can be identified more clearly when estimating the impact on single steps instead of only investigating the impact on the whole procedure. For systems that can be used in different procedures it is usually not possible to deduce the possible impact on other procedures from the results of one procedure. Using a workflow based assessment it is easier to generalize results for single workflow steps that are common to several procedures. Moreover, workflow analysis plays a role of a connection between technical researchers and surgeons. This provides a way to involve surgeons intuitively to evaluate impacts of the system.

The workflow based assessment evaluation consists of the following steps:

- a. **Initial formulation of assessment objective.** It includes a description of the motivation, the system, surgical context, assessment level and a hypothesis of the anticipated result [1].
- b. **Modeling the workflows of the reference and the IGS based procedure.** First the workflow of the conventional method is modeled. Depending on the assessment objective and level a suitable workflow model has to be chosen. This can range from simple models, consisting only of few subsequent workflow steps, to more detailed methods [9]. Based on the reference workflow and the anticipated use of the IGS, the new workflow is designed. This is done jointly by surgeons and technical researchers which facilitates a common understanding of technical and medical advantages and challenges. In this step, the hypothesis might be refined for each workflow step.

- c. **Definition of evaluation criteria for each workflow step.** Based on the assessment objective, evaluation criteria for comparing the new system to the conventional one are first defined for each workflow step. In order to quantify the comparison, measurement parameters must be chosen, such that they represent the evaluation criteria. Then, measures of statistics are defined, e.g. mean value or standard deviation, and hypotheses for these measures are made.
- d. **Experiments and acquisition of measurement parameters.** A protocol for recording the measurement parameters must be established. This can be data done using e.g. video or live observations [10] or data that is captured from medical devices. When introducing a novel system, it often cannot be used on real patients. So the procedure can be performed in a simulated setup. To avoid a bias, also the conventional system has to be used in the simulated setup.
- e. **Comparison of values from reference and IGS based procedure.** A statistical comparison of the measured parameters is performed for each workflow step in order to obtain quantitative results.

3 Animal Cadaver Study of Interlocking of Intramedullary Nails: CamC vs. Mobile C-arm

Intramedullary nailing is a common surgical operation method that can be used mostly in fracture reduction of the tibial and femoral shaft. After implanting successfully a nail into the medullary canal, the nail must be fixed inside the bone by inserting locking screws through locking holes in the nail in order to avoid unwanted rotation and movement of the bone. This procedure is called interlocking of intramedullary nails and is performed in a minimally invasive way. Thus, intra-operative X-ray images are required for targeting and drilling the locking holes through the patient's skin. Currently, the clinical procedure for interlocking is generally performed with using mobile C-arms that can offer continuous intra-operative guidance based on a huge amount of X-ray images. Furthermore, interlocking of intramedullary nails involves various common surgical tasks, e.g. X-ray positioning, targeting, instrument alignment, and drilling. Therefore, interlocking is chosen in order to evaluate the clinical impact of the CamC system. The study design was approved by the veterinary public health office at the institution of our medical partners.

3.1 Assessment Objective

We evaluate the system at the level of surgical strategy and performance and we expect a reduction of x-ray images. Motivation, system and clinical context have been discussed above and in section 1.

3.2 Surgical Workflow for Interlocking of Intramedullary Nails

In this evaluation study, a single interlocking procedure starts after successfully implanting the long nail into the medullary canal, and ends in successfully inserting one locking screw. Based on the principle of the workflow-based evaluation presented in section 2, the workflow of interlocking is constructed manually in a close collaboration between scientists, engineers and surgeons. All the steps in the workflow are fundamental surgical tasks, and some of them, e.g. X-ray positioning, skin incision, and drilling, are also necessary steps in other surgical procedures. Thus, the results of the workflow-based evaluation for each single step of interlocking become very valuable and meaningful for understanding clinical impacts of the CamC system beyond this particular study. The general workflow for using CamC and normal C-arm is the same and includes seven steps:

- i. **X-ray positioning.** Position the C-arm from outside of the operation field into the operation workspace. It ends after the C-arm is moved to the desired position confirmed by an X-ray image showing the desired operation area.
- ii. **Adjustment of hole.** Turn the nail until the locking hole appears as a circle in the X-ray image in order to allow for orthogonal drilling.
- iii. **Skin incision.** Find the incision position and cut the skin. The correct incision position is confirmed by an X-ray image when using the standard mobile C-arm, or by the X-ray and video image overlay when using the CamC system.
- iv. **Center punch.** Align the sharp tip of a nail to the target hole. Then, form a small dimple on the bone surface in which the tip of the drill will fit with the help of a hammer.
- v. **Alignment of the tip of the drill.** Align the tip of the drill to the target hole. It ends after one X-ray image shows that the projection of the tip is located inside the circle of the target hole.
- vi. **Drilling.** Drill the bone and the drill bit must pass through the locking hole of the nail. It ends after a successful drilling is confirmed by an X-ray image.
- vii. **Locking screw insertion.** Insert a locking screw into the hole. One X-ray image is required to confirm the success of locking screw insertion, which indicates the end of the procedure for interlocking.

3.3 Evaluation Criteria

Modern trauma and orthopedic surgical procedures use X-ray images during surgery as intervention guidance, especially in minimally invasive surgery. This increases radiation exposure for both patient and surgical team. Radiation exposure should be reduced as much as possible, since the effects of exposure to radiation have been reported to increase the risk of fatal cancer [11,12] and genetic defects [13]. As demonstrated in the work of [3], employing the X-ray and video image overlays from the CamC system as image guidance has huge potential to reduce radiation exposure compared to just using a conventional

mobile C-arm. Thus, the first evaluation criterion is to compare the amount of applied radiation exposure using the CamC system to the standard mobile C-arm. Through the whole comparison study, we fix the tube voltage and radiation time to a setting we found was ideal for imaging the cow bone structures in order to produce constant radiation doses for each shot on the level of the x-ray tube. The number of X-ray shots can therefore be used to compare the radiation exposure. It is claimed that employing the CamC system for interventional procedures does not complicate the surgical procedure compared to using the standard mobile [3]. Thus, we record the parameters of operation time and quality of drilling.

The authors hypothesized that it takes less number of X-ray shots by using the CamC system than using the standard C-arm for the whole procedure, particularly in step 1, 3, and 6. We also expect both systems to have similar results with regard to operation time and drilling quality for the whole procedure.

3.4 Materials and Experiments

In this pre-clinical study, we use forelegs of cow cadavers (see figure 2), all of which have similar shape and size. We use the same medical instruments, e.g. long nail, locking screw and drill, as used in real surgeries. In the experiments, the cow leg is placed on a carbon table that is designed for medical experiments on animals. Different from the situation of real patients, our cow forelegs are too short to be held by operation assistants. Thus, we fix them roughly to a $30 \times 15\text{cm}^2$ wooden board to make the cow leg more stable (see figure 2), while not being totally fixed. So, some minor movements of the cow leg during our study are inevitable, which sometimes requires surgeons to hold it by themselves. This setup of leg is very close to the real clinical situation.

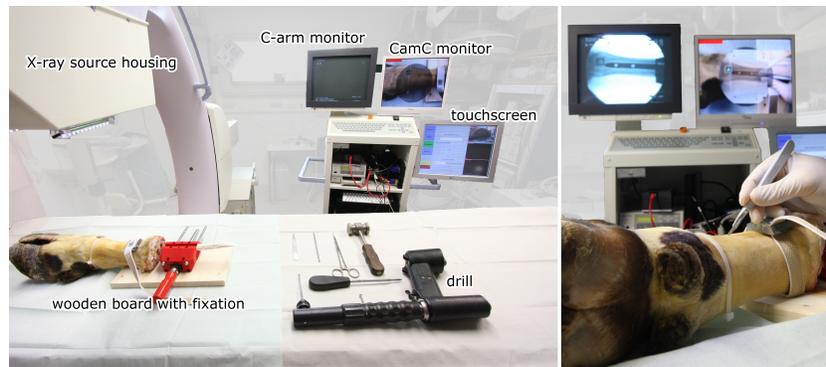


Fig. 2. The experimental setup for interlocking of intramedullary nails on a cow bone is shown in the left image. The right image demonstrates the system configuration for the procedure using the CamC system. In the system configuration for the procedure using the standard mobile C-arm, the CamC monitor is turned off.

The CamC system used in our study is built by attaching a video camera and mirror construction, covered by a X-ray source housing, to a mobile C-arm. The proposed one time calibration of [2] is used to calibrate the CamC system. An LCD monitor mounted on the top of the C-arm cart displays the live video overlaid by the X-ray image, and a touch screen monitor mounted on the side of the C-arm cart provides a user interface (see figure 2).

If the cow leg moves away from the initial position where the X-ray image was acquired, X-ray and video image overlay have a misalignment. For this reason, a visual square marker tracking method [14] is employed to track square markers that are rigidly attached to the cow leg surface. For visually informing surgeons about misalignments, the initial positions of markers are drawn as green quadrilaterals and their positions in the current video image are drawn as red quadrilaterals in the video images. Moreover, a gradient color bar is shown on the right side of the video images, whose length indicates the pixel-difference between the marker's initial and current positions (see figure 3).

For the interlocking procedure by using the standard C-arm, we employ the CamC system as a standard C-arm with the same setup except for turning off the CamC monitor of the X-ray and video image overlay (see figure 2), in order to reduce the bias from handling different C-arm systems.

Participated surgeons are selected such that they cover all following three groups, young surgeons with less than 20 surgical cases, experienced surgeons with 20-100 surgical cases, and expert surgeons with more than 100 surgical cases. Five surgeons participate in the study, i.e. two young surgeons, one experienced surgeon, and two expert surgeons. The study covers 20 pair cases (i.e. 40 procedures), 10 performed by expert, 6 by intermediate and 4 by young surgeons. Each pair carried out by the same surgeon consists of one interlocking using the CamC system and one using the standard C-arm system. The sequence of two procedures within one pair is randomized by coin flipping. The inserted nail has two distal locking holes inside the cow bone, and both of which are used for one pair experiment. One cow bone can be used for two pairs, since the nail is turned to another side of the bone for the interlocking of the second pair.

All parameters are recorded by a team of medical and technical participants by observing the experiments, which is verified by video recording. The quality of drilling through the holes in the nail is assessed by the surgeon as "successful without interference with the nail" given 1 point, "successful with slight interference with the nail" given 2 points, "successful with severe interference with the nail" (in this case the drill gets jammed and a correction of drilling angle has to be performed) given 3 points or "failure" given 5 points. In [8], the authors have employed a similar criterion to assess the quality of drilling in interlocking of intramedullary nails.

3.5 Results and Comparison

In order to obtain statistical results with regard to the number of X-ray shots, operation time and drilling quality, we calculate their mean and standard deviation

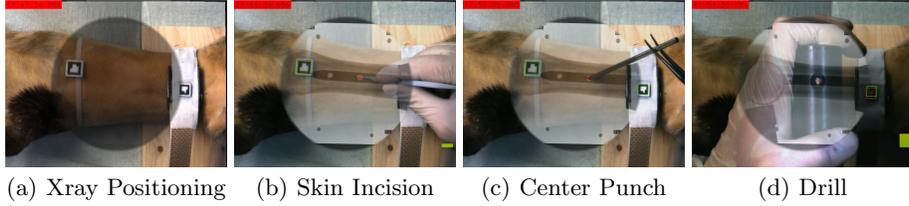


Fig. 3. The CamC system provides X-ray and video image overlays, which can give intuitive advanced optics-Xray image guidance for many surgical tasks, e.g. X-ray positioning (a) , skin incision (b), instrument alignment in center punch (c), and axis control of drilling (d).

(STD). Moreover, we apply paired t-test to find out the level of significant difference, i.e. p-value, for all three evaluation parameters between the two groups of CamC and C-arm, i.e. interlocking procedures performed by using the CamC system and using the standard mobile C-arm. Table 1 shows the mean, STD, and p-value of the number of X-ray shots and operation time for the whole interlocking procedure, as well as for each surgical step, in the two groups. The results of drilling quality are 1.80 ± 0.70 for the CamC group and 2.20 ± 0.77 for the C-arm group.

For the whole interlocking procedure, significantly less X-ray shots are needed in the CamC group compared to the C-arm group ($p < 0.0001$). The CamC group needs longer operation time, while demonstrating better drilling quality in our study. However, there are no significant differences in operation time ($p = 0.55$) and drilling quality ($p = 0.12$) between these two groups.

In the step of X-ray positioning, The CamC group performs better with significantly less X-ray shots ($p = 0.028$). The reason is that the live video with an overlaid X-ray image circle (like an aiming circle) provides an intuitive video-based guidance for moving C-arm to the desired position (see figure 3(a)). The CamC group takes significantly less X-ray shots ($p < 0.0001$) and significantly less operation time ($p = 0.026$) than the C-arm group in the step of skin incision, since surgeons can quickly find the target place for skin incision using the guidance of the video with an aligned X-ray image (see figure 3(b)). In the step of center punch, the number of required X-ray shots is significantly smaller in the CamC group than in the C-arm group ($p = 0.0066$), since surgeons can identify the location for center punch based on the guidance of overlay (see figure 3(c)). For aligning the tip of the drill, a smaller number of X-ray shots is needed, which, however, does not reach a level of significance ($p = 0.069$). In the step of drilling, the overlay of X-ray and video image can support the control of drilling axis (see figure 3(d)), and thus the CamC group needs significantly smaller number of X-ray shots ($p = 0.028$) than the C-arm group. Operation time seems to be the same ($p = 0.98$). The steps of adjustment of hole and screw insertion do not provide any signs of significant differences between the two groups.

In our study, the CamC group has smaller STD values for the number of X-ray shots in the whole procedure, as well as in each surgical step, than the C-arm group, whereas for operation time, the CamC group has smaller STD

values in step 1 and step 3, but larger STD values in other steps and the whole procedure.

	X-ray positioning	Adjustment of hole	Skin incision	Center punch	Alignment of the tip of the drill	Drilling	Locking screw insertion	Overall
The number of X-ray shots (mean±STD)								
CamC Group	1.05 ±0.22	2.65 ±1.09	0.05 ±0.22	2.15 ±1.50	1.65 ±1.27	1.30 ±0.73	1 ±0	9.85 ±3.10
C-arm Group	1.45 ±0.76	2.80 ±1.40	2.65 ±1.09	4.05 ±2.28	2.20 ±1.47	2.90 ±2.90	1 ±0	17.05 ±4.61
p-value	0.028	0.65	<0.0001	0.0066	0.069	0.028	1.00	<0.0001
Operation time (mean±STD)								
CamC Group (seconds)	21.95 ±5.93	23.70 ±18.88	19.30 ±5.58	55.15 ±22.02	26.55 ±19.01	161.00 ±115.40	59.65 ±54.25	367.30 ±173.70
C-arm Group (seconds)	25.05 ±9.90	19.35 ±10.73	28.75 ±10.78	52.30 ±26.19	22.85 ±9.77	160.40 ±91.28	39.75 ±17.34	348.45 ±114.07
p-value	0.17	0.40	0.0026	0.73	0.27	0.98	0.05	0.55

Table 1. The mean, standard deviation (STD), and p-value of the number of X-ray shots and operation time (seconds) for the whole interlocking procedure, as well as for each surgical step, in CamC group and C-arm.

4 Discussion and Conclusion

The technical characteristics of the CamC system, e.g. overlay accuracy, have already been well studied. In this work, the proposed workflow based method was applied to evaluate the clinical impact of the CamC system for Interlocking of intramedullary nails. We compared the performance of the CamC system with the standard mobile C-arm. Interlocking of intramedullary nails on cow forelegs was chosen as a simulated clinical model for our evaluation study. This study covered a total of 40 procedures and involved 5 surgeons with three different skill levels.

Surgeons performed surgical tasks more confidently when using an X-ray image augmented by a live video than a pure X-ray image. This reduced the number of unnecessary X-ray shots that depends on the experience and skill of the surgeon. This point was confirmed by all participating surgeons. The CamC group not only required less radiation exposure, but also showed relatively low variations, i.e. smaller STD, in number of taken X-ray shots. From our point of view, this could be a sign of enhanced reliability and stability on the surgeon’s side. The last step of screw insertion took much longer in the CamC group than in the C-arm group. The reason is that the surgeons tend to check the overlay image to find the hole to put the screw in, although they could definitely find it even faster without any image based guidance, since the hole is visible and easy to feel. This point was agreed by all participating surgeons. Due to the learning curve of the new system, the variation of operation time is higher in the CamC group than in the C-arm group for the whole procedure. The cow leg moved quite often in the steps of center punch and drilling. This resulted

in a misalignment of X-ray and video image. Informing surgeons about such a misalignment is compulsory, especially for real surgery. In our approach, we employed the visual marker tracking in order to visually inform surgeons about any misalignment in the overlay image. As the visual markers were attached on the skin surface and skin sometimes has a minor movement relative to the bone, there could be misinterpretations of the image alignment. However, this did not introduce any major problem during the study due to the fact that this movement was very small and skin generally moves back to its original position.

The results of our evaluation study show that the CamC group required significantly less radiation exposure but needed similar operation time, and also achieved a similar drilling quality for the whole interlocking procedure compared to the C-arm group. The workflow based evaluation reveals that the CamC system has its main positive impact in the steps of X-ray positioning, skin incision, center punch, and drilling. Due to the fact that X-ray positioning and skin incision are the necessary steps in many other surgical procedures, our results are also valuable and useful for predicting the clinical impact of the CamC system beyond this particular application. We are planning to use our proposed workflow based method to also evaluate the clinical performance of the CamC system on real patients in the near future.

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