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Version Post-Print/Accepted Manuscript

Citation (published version) Ebrahimi H, Yee A, Whyne C. Surgical process analysis identifies lack of connectivity between sequential fluoroscopic 2D alignment as a critical impediment in femoral intramedullary nailing. *Int J Comput Assist Radiol Surg.* 2016 Feb;11(2):297-305. doi: 10.1007/s11548-015-1262-6. PMID: 26194487

Publisher's Statement The final published version of this article is available at Springer Verlag via <https://dx.doi.org/10.1007/s11548-015-1262-6>.

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Surgical process analysis identifies lack of connectivity between sequential fluoroscopic 2D alignment as a critical impediment in femoral intramedullary nailing

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Received: 15 March 2015 / Accepted: 2 July 2015
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Abstract

Purpose Identifying key steps and barriers within complex and simple surgical procedures can be accomplished in a structured and rigorous manner using surgical process modeling. For lower extremity long bone fracture stabilization, the current standard of care is closed intramedullary (IM) nailing, which despite its widespread use is associated with challenges that greatly impact operative time and lead to the frustration of medical staff. The aim of this study was to identify challenging surgical steps in IM nailing and understand their underlying causation.

Methods Eight semi-structured interviews with staff orthopedic surgeons and eight detailed surgical observations were conducted to understand the surgical steps, challenges and adapted techniques used in IM nailing. Hierarchical decomposition was then utilized to structure the IM nailing surgical procedure into phases, steps and activities.

Results In the developed IM nailing surgical process model, the most challenging steps were identified as fracture reduction (75 %) and entry point selection (25 %), both of which were associated with high levels of frustration in the observed surgeries. Both of these steps utilize 2D fluoroscopic imaging to guide 3D alignment. Challenges arise when the alignment

in one plane is lost while adjusting the alignment in the perpendicular plane. This leads to unpredictable repetition of activities which can be time-consuming and frustrating. **Conclusion** Identifying the causation of surgical challenges in IM nailing through surgical process modeling forms a knowledge base that can be used to guide future improvements to techniques and surgical instrumentation.

Keywords Intramedullary nailing · Entry point selection · Reduction · Surgical process modeling · Hierarchical decomposition · Sequential fluoroscopic 2D alignment

Introduction

IM nailing is a minimally invasive surgical (MIS) procedure typically performed under a general anesthetic and with fluoroscopic image guidance. The surgical phases associated with this type of surgery are well defined: patient preparation, access to the bone entry site, IM guide wire insertion (including fracture reduction for guide wire placement), IM nail placement, locking of the nail to control rotation and length, final clinical and radiographic assessment of fracture reduction/restoration of length/alignment/rotation, and surgical wound closure. Yet, despite widespread usage of IM nailing, significant surgical challenges may arise. Such challenges can significantly impede the surgical workflow, requiring additional operative time and radiation exposure to both patients and medical staff. Fracture reduction and proper localization for initial IM access are particularly challenging areas in the workflow pathway [1,2]. Lengthy delays in the procedure and unacceptable fracture reduction or stabilization can also significantly endanger patient safety, particularly in those who may suffer from polytrauma and/or acute respiratory issues.

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Clear description and analysis of the surgical process can expose challenging steps and activities that can also be used to develop a surgical process model [3]. The use of surgical process modeling may guide development of new surgical technologies/methodologies, improve surgical planning, assist surgical teams during the intervention and enhance surgical training and education [4].

Various methodologies have been proposed to generate individual surgical process models from collected intraoperative data [3, 5]. Generated individual surgical process models can then be utilized to develop generic surgical process models [6–8], evaluate a navigation system [9], compare procedure parameters such as operating time, adapted techniques, senior versus junior surgeon performance [10] and the sequentiality of activities during surgeries [11]. However, implementation of identified surgical models to understand surgical barriers and their root sources have received little attention [12]. Hence, the aim of this study was to scientifically map the IM nailing process, identify surgical challenges that impede the surgical process and elucidate their underlying causes.

Research design and methods

Semi-structured interviews

This study consisted of semi-structured interviews and surgical observations, conducted under institutional research ethics board approval. Orthopedic surgeons were identified by the research team and invited to participate in a semi-structured interview designed to allow participants to describe their work and experiences (Table 1).

Surgeons were selected with varying levels of experience and also including representation from community and academic teaching hospitals. Face-to-face interviews were conducted that lasted approximately 30–45 min in a private room. Participants were interviewed to identify the IM nailing surgical steps, surgical challenges and their use of adapted surgical techniques when encountering challenges. Eight interviews were conducted until saturation [13] was reached, and each interview was audio recorded and transcribed. Data collection and analysis were done in an iterative fashion. Data were transcribed concurrently with interviewing to allow for the interview guide to be refined. The study authors (HE, AY, CW) debriefed regularly to determine when saturation had been reached [14].

Surgical observations

Next, eight IM nailing surgeries of diaphyseal femoral fractures conducted by three interviewed staff surgeons were observed to gather additional information on the surgical

Table 1 Guiding questions used in the semi-structured interviews

How many femoral IM nailing surgeries do you perform per year?
Do you follow the proposed IM nailing procedure as listed below? If you are not following the same procedure, can you specify the steps you add/eliminate or modify?
What is/are the most challenging step(s)?
Can you rate the difficulty of the steps on a 1–10 scale? (1 = easiest and 10 = most difficult)
How many surgeons/assistants/residents generally assist you in this type of surgery?
What do you think about the reduction step? Have you experienced any difficulty/frustration during this step?
How many femoral reductions do you perform per year? How long does it usually take for an easy/difficult/average case?
What techniques do you use during this type of surgery to facilitate the process? What happens if you experience difficulties with these techniques?
Proposed IM nailing procedure
1—Patient positioning, 2—entry point selection, 3—use of straight or ball tip
4—Bending the tip (as necessary), 5—provisional reduction, 6—passing the guide wire
7—Reaming, 8—nail selection (choice of nail diameter and length)
9—Nail insertion, 10—proximal locking, 11—distal locking, 12—final assessment for length and rotation

procedure. In this, the term activities, steps and phases were used to represent different levels of granularity in the surgical process. An activity was defined by a physical task. A step was comprised of a sequence of activities which accomplish a specific surgical objective. A phase was used to describe a major event occurring during the surgical procedure [4].

In order to better understand challenges and barriers associated with this surgery, observations were recorded to identify individual activities, steps and phases focusing on surgeons as the operator. In addition, the total time for completing each phase of the procedure and the amount of radiation/fluoroscopy used were recorded for the entire surgery. In those steps identified as challenging, the individual activities were analyzed to elucidate their underlying causes. Finally, following a basic human problem-solving approach, the observed data were formalized using hierarchical decomposition [15].

Results

Semi-structured interviews

Semi-structured interviews were conducted with eight surgeons with varying levels of experience, three from community hospitals and five from academic teaching hospitals. On

Table 2 Reported number of IM nailing surgeries conducted per year by interviewed surgeons working at community and teaching hospitals

Centers	Community			Teaching hospital				
	A	B	C	D	E	F	G	H
Surgeons								
Number of surgeries/year	10	5	75	5	22	30	30	25

Fig. 1 Challenging steps identified by the interviewed surgeons along with the mean difficulty rating on a scale of 1–10

average, these surgeons perform 25 (range 5–75) IM nailing surgeries per year as shown in Table 2.

The sequence of surgical steps associated with IM nailing was discussed. The difficulty of surgical steps was then rated on a scale of 1–10 (with 1 being the easiest and 10 the most challenging). Seventy-five percent of surgeons identified fracture reduction as the most challenging step of IM nailing (Fig. 1). The greatest challenges were manipulation of fracture fragments for realignment. Adapted manipulation techniques used alteration of patient positioning and/or traction, reducer devices, mallets, surgical wraps, bone hooks and Shanz traction pins.

Entry point selection was identified as the most difficult step by 25% of surgeons (Fig. 1) due to challenges in surgical access and K-wire trajectory for bone canal starting point entry. Adapted techniques employed altering of patient positioning (torso abduction and/or knee adduction) or the elimination of the need for a straight access line to the IM canal through the use of a curved awl in place of the traditional K-wire. Lateral decubitus patient positioning instead

of traditional patient supine positioning was suggested to facilitate entry point access in obese or muscular patients.

Surgical observations

In the second part of this study, eight IM nailing surgeries for diaphyseal femoral fractures were observed. A short description of observed surgeries and identified phases/steps are presented below.

Once in the operating room and under anesthesia, each patient is transferred to a fracture or a radiolucent surgical table. This marks the beginning of the IM nailing procedure as described in this study. Patient positioning, skin preparation, draping and provisional reduction steps constitute the first phase of the operation. The second phase is focused on gaining access to the surgical site and included localization/marketing the incision site, performing the initial incision and dissection of the soft tissue. The third phase is focused on guide wire insertion. In this, following palpation of the greater trochanter, a straight short sharp tipped rod (i.e., K-wire) or a curved awl is inserted into the center of the greater trochanter or the piriformis fossa to introduce an opening into the IM canal. The identified entry point is confirmed on fluoroscopy. A longer 2.5- to 3-mm-diameter rod (i.e., guide wire) is then advanced into the IM canal through the opening to the fracture level. The fourth step is intraoperative fracture reduction, a process that realigns the fracture fragments in order to allow passage of a guide wire into the distal fragment. Successful advancement/docking of the long guide wire within the distal fragment is confirmed via fluoroscopy. The nail length is then measured using a probe surrounding the guide wire. Nail placement constitutes the fourth phase. In order to adapt the bone to the nail and maximize the contact area between the bone and nail, reaming is performed [15] while maintaining the obtained reduction. The reaming step begins with a small diameter reamer and progresses incrementally to a size 1–2 mm bigger than the selected nail diameter. Definitive IM nail insertion comprises the final step of this phase. The fifth phase secures the IM nail within the bone through proximal and distal locking steps, so as to control length and rotation of the surgically stabilized bone. The sixth phase is focused on the clinical and radiographic assessment of both leg length and rotation. The surgery is completed in the seventh phase, ending with skin closure. The sequence of phases and their associated steps for all eight surgeries are shown in Fig. 2.

Consistent with the interviews, the observations also identified the entry point selection and reduction steps in the guide wire insertion phase as the most challenging and frustrating steps of the procedure. This conclusion was qualitatively drawn by the observer from surgeons’ facial expressions, use of harsh language and brief discussion after the surg-

Fig. 2 Hierarchical decomposition of IM nailing. The seven phases of IM nailing are represented in *light gray boxes*, with the associated steps below in *white boxes*

Fig. 3 Activities associated with the **a** entry point selection and **b** reduction steps in the guide wire insertion phase

eries. The specific activities associated with these two steps are presented in Fig. 3.

Entry point selection

As shown in Fig. 3a, a series of activities must be performed iteratively for successful drilling of a K-wire inside the IM canal. In order to better understand these activities, a brief description of this step follows. When the K-wire is initially placed near the desired entry point (either trochanteric or piriformis insertion site), an anterior–posterior (AP) image is taken. This is used to confirm the K-wire entry point in the coronal plane. If the entry point is suboptimal, the K-wire is adjusted and another AP image is taken. Once the K-wire entry point is confirmed on AP fluoroscopy, the C-arm is rotated to capture a lateral (or oblique-lateral) image to confirm the K-wire entry point in the sagittal plane. Lat-

eral imaging and adjustments continue until the K-wire entry point in the sagittal plane is satisfactory. Once the optimal K-wire trajectory (entry point and orientation) is reached and confirmed with biplanar fluoroscopic images, the K-wire drilling is initiated to an initial provisional depth of ~1–2 mm. Upon reconfirmation of entry point on an AP image, the K-wire can be drilled to its full ~2–3 cm depth and reconfirmed on lateral images. Following insertion of the K-wire, a larger ~1 cm cannulated drill bit widens the entry into the IM canal. This then enables the insertion of the long guide wire used in subsequent surgical steps.

Reduction

As shown in Fig. 3b, the reduction step contains multiple activities. Once the long guide wire is advanced to the fracture level, AP images are taken to verify the alignment of

Fig. 4 Direct manipulation of fracture fragments can be performed by making an small incision close to the fracture site and inserting **a** Schanz traction pins or **b** bone hooks to realign fracture fragments

two/multiple fragments in the coronal plane. If the fracture is malaligned, several techniques can be utilized to facilitate control of the displaced fractured pieces in the sagittal plane in order to perform the reduction. For indirect bone manipulation, a sterile drape or towel wrap can be placed around the femur and used to pull the proximal fragment down to line up with the distal fragment. Alternative approaches to realign the fractured fragments employ manual elevation of the distal fragment by use of a crutch or lowering of the proximal femur through external pressure from a mallet. Preliminary reduction may also be followed by either the direct manipulation of the fractured femur via Schanz traction pins (Fig. 4a) inserted into the fractured fragments or by utilizing a bone hook device (Fig. 4b). These techniques impart more direct control of the fracture fragments and enable more secure stabilization of an anatomic alignment. The use of such hardware and manipulation of fracture fragments, however, must be performed carefully to mini-

mize soft tissue trauma and prevent damage to neurovascular structures.

The steps utilized in the eight surgeries were overall found to be quite similar with minor differences in the techniques utilized in activities during the guide wire insertion phase. The times for the individual phases are listed in Table 3 (surgeons often did not perform the closure, as such the time spent in this phase is not reported). The large range in times found for some phases can be better understood by highlighting challenges encountered in specific cases. The average time for the patient preparation phase was 24.88 min (SD = 14.26). In case 1, setting up the fracture table and the fluoroscopy C-arm, and in case 6, cleaning open wounds away from the closed fracture site took a relatively longer time. Accessing the surgical site phase took 4.75 min (SD = 4.30) on average. In both cases 3 and 4, readjustments of the patients' femur and torso were conducted that resulted in longer operative time. The average time for the long guide wire insertion phase was 26.88 min (SD = 8.69). For this phase, times for the entry point selection, reduction steps and overall fluoroscopy use are presented in Table 4. In case 2, the patient was muscular, which made the entry point selection challenging. The average time for the nail placement phase was 28.50 min (SD = 21.46). In cases 2 and 8, the guide wire was accidentally removed in the reaming step (which occasionally can occur unintentionally), which prolonged the nail placement phase. In case 7, due to unsatisfactory position of the nail, the fracture site was opened and additional reduction was required, which resulted in extended operative time for this step. The locking phase took longest average time; use of the fracture table (in cases 1 and 8) increased the difficulty of fine leg adjustments.

Discussion

Initial interviews highlighted two specific steps, entry point selection and reduction, as the most challenging and frustrating to the surgical team. During the interviews, each surgeon identified adapted techniques which they employ to tackle the challenges associated with these two steps. The described techniques were similar to slight differences based on surgeon preferences and the order in which they utilize the adapted procedures. During the observations, these identified challenges were encountered and adapted techniques utilized to overcome them. While the adapted techniques employed ultimately overcame the entry point and reduction challenges, they were associated with high levels of frustration. Opportunities to improve the surgical procedure lie in understanding the challenges associated with these steps as existing techniques do not offer an optimal solution. As such, activities associated with entry point selection and reduction steps were studied in depth.

Table 3 Time in minutes for individual phases associated with the IM nailing procedure

Case	Phases					
	Patient preparation	Accessing the surgical site	Guide wire insertion	Nail placement	Locking	Final assessment
1	40	3	26	16	51	1
2	32	2	42	60	38	3
3	14	13	25	15	14	4
4	21	10	22	16	37	1
5	16	4	33	16	32	1
6	50	2	18	17	29	1
7	10	2	16	66	28	1
8	16	2	33	22	54	1
Mean	24.88	4.75	26.88	28.50	35.38	1.63
SD	14.26	4.30	8.69	21.46	12.89	1.19

Table 4 Time spent during the entry point selection and reduction steps and overall fluoroscopy time for the entire surgical procedure in minutes

Case	Fluoroscopy time	Steps		Seniority level ^b	Challenges
		Entry point selection	Reduction		
1	–	5	3	Senior	Time to set up fracture table C-arm set up
2	1.7	18	5–13 ^a	Junior	Entry point selection reduction Accidental guide wire removal ^a Muscular patient
3	5.5	4	13	Junior	Reduction
4	1.8	10	10	Junior	Entry point selection Reduction
5	2.6	3	17	Senior	Reduction
6	3.5	9	2	Junior	Entry point selection Open wound
7	1.6	2	5–46 ^a	Senior	Reduction Fracture opened ^a
8	3.9	9	2–7 ^a	Senior	Time to set up fracture table Accidental guide wire removal ^a

^a The reduction step in this phase was conducted twice with the reason highlighted in the challenges

^b Seniority level was defined based on surgeons' number of years in practice. A surgeon with less than 10 years in practice was categorized as "Junior." A surgeon with more than 10 years in practice was categorized as "Senior"

Entry point selection analysis

While the series of entry point selection activities appear relatively straightforward, they sometimes proved frustrating and time-consuming (i.e., case 2 which required 18 min for this step). When modifications to the K-wire entry point are performed to achieve alignment in the coronal plane, correct positioning is often found to be lost in the sagittal plane. Therefore, multiple cycles of AP and lateral imaging may be required to confirm the optimal entry point positioning. In order to better understand the challenge associated with the entry point selection step, it is important to differenti-

ate between the entry point location and orientation, both of which are critical for the overall outcome of the procedure. Two independent studies by Roberts et al. and Kanawati et al. have shown that an entry point in the posterior one-third of the greater trochanter may result in cortical impingement which can lead to major complications [17, 18]. Similarly, if the orientation of the entry point is not in line with femoral shaft, subsequent reaming may lead to weakening of the medial cortex and the potential for a blow-out fracture complication [19].

Once adequate images with respect to entry point location and K-wire orientation are acquired in the AP direction

Fig. 5 K-wire positioning with *a* correct entry point location and orientation on the AP image. Perpendicular lateral images show: *b* correct location, incorrect orientation, requiring AP rotation; *c* incorrect location, correct orientation, requiring AP translation; and *d* incorrect

location and orientation of the entry point, requiring AP rotation and translation to obtain correct lateral entry point location and orientation (*e*)

(Fig. 5a), errors in sagittal placement must be addressed. Based on the analysis of the observed activities, if the sagittal entry point location is correct but the lateral orientation is incorrect (Fig. 5b), the surgeon must alter the anterior–posterior angle of entry of the K-wire about the identified entry location (ensuring no displacement of the K-wire tip from the entry site). If the sagittal entry point location is incorrect but the orientation is correct (Fig. 5c), the surgeon must adjust the anterior–posterior translation along the sagittal plane without any change in sagittal angulation of the K-wire. If the sagittal entry point location and orientation are both incorrect (Fig. 5d), then the surgeon must first readjust the entry location in the sagittal plane. Once the correct new entry location is verified with lateral fluoroscopy, the surgeon must then readjust the K-wire orientation in the sagittal plane to ensure parallelism in access to the IM canal (Fig. 5e); following this step, the surgeon needs to recheck the AP view to ensure that both the coronal plane entry point and wire orientation are acceptable.

Many experienced surgeons are able to maintain the movement of their hand in one plane while they are adjusting the

location and/or orientation of the K-wire in the corresponding perpendicular plane. However, this can be challenging, particularly for new or inexperienced surgeons when considering that even small hand or body movements can disrupt positioning/orientation and some motion may be required to maintain the sterile field during C-arm rotation. As well limited access to the surgical site due to the minimally invasive nature of this surgery and the presence of muscle/fat forces acting against the K-wire can present difficulties in maintaining in plane position.

Currently, commercially available devices do exist which are designed to facilitate entry point selection. These devices generally consist of a cannulated tissue protector (Fig. 6a) and a trocar with multiple parallel holes (Fig. 6b). This allows surgeons to insert multiple K-wires simultaneously when the initial K-wire placement is suboptimal. Such devices provide a finite number of alternative locations for the entry point, but do not allow for modification of the entry point orientation (orientation is fixed as per the initial K-wire inserted). As such, these devices do not address challenges with the entry point orientation vis-à-vis desired K-wire trajectory into the

Fig. 6 **a** A trocar with multiple parallel holes can be placed on the femur head through **b** a cannulated tissue protector to facilitate entry point selection step. **c** An awl can also be used alternatively to open the intramedullary canal and allow the passage of a guide wire

femoral IM canal. Another alternative utilized to open the IM canal is the manual advancement of a curved cannulated sharp tipped awl (Fig. 6c). Similar to the entry point selection needed for K-wire drilling, positioning and orientation of the awl must be confirmed on fluoroscopic AP and lateral images, with similar associated challenges.

Reduction analysis

Similar to entry point selection, challenges in the reduction step are encountered as the alignment in the coronal plane is difficult to maintain while aligning the fragments in the sagittal plane. However, unlike the entry point selection step, there is no direct access to the fracture fragments. Manipulation of the fragments using force applied on the leg through a mallet or crutch may not necessarily yield translation of the targeted fragment in the intended direction. Due to connectivity between the fragments (i.e., through soft tissue attachments), manipulation of one fragment may result in the unintended movement of other fragments.

One technique utilized to facilitate the reduction step is to slightly bend the guide wire tip to facilitate its entry into the distal fragment if perfect alignment has not been achieved. Rotation of the guide wire then makes picking up the displaced distal fragments easier. The same technique can be applied using a straight cannulated rod with a bent tip (reducer). The guide wire is inserted through the reducer, and the rotation of the reducer facilitates the reduction. The advantage of the reducer over the bending the tip technique is its flexural rigidity. The reducer gives a joy-stick-like control over the proximal section which decreases unintentional movement when manipulating the distal fragments. However, these techniques may still require multiple cycles of AP and lateral imaging (as described in Fig. 3b).

Navigation systems have also been used to facilitate IM nailing. The use of fluoroscopy-based navigation has been reported to reduce radiation exposure compared to conventional procedures and improve surgical hand-eye coordination by reducing the need for mental correlation of the acquired fluoroscopic images with the procedure [1, 20]. However, the complexity and time-consuming nature of utilizing navigation (including the attachment of optical trackers and registration), high financial costs, logistical issues and training demands have been major drawbacks limiting the clinical uptake of this technology. While surgical steps and activities associated with these navigation systems have been studied, the surgical processes have not been analyzed to elucidate the root sources of challenges or frustration [1, 21, 22]. Rather, entire steps or activities in IM nailing have been replaced with the use of a navigation system, which in turn involves its own adaptation challenges.

Common challenges and limitations

In both entry point selection and reduction steps, multiple 3D geometries (bone fragments, K-wire and guide wire) need to be aligned using 2D AP and lateral images. The reconstruction process requires the location and orientation of geometries to be aligned in both sagittal and coronal planes simultaneously. This can be challenging when considering the difficulty associated with the maintenance of location and/or orientation of geometries in the one plane while adjusting the position in the perpendicular plane. Reported and observed medical staff frustration during the entry point selection and reduction steps may also be due to the variability of the guide wire insertion phase, in terms of difficulties experienced and the time required to achieve alignment.

The observational findings in this study are specific to a teaching hospital where residents and fellows are generally present to assist in the operating room. Although in the interviews surgeons from community hospital identified same steps to be challenging, other factors may cause frustration in community operating room with fewer assistants. A further limitation may have been potential inaccuracies associated with hand-written recordings, rather than digitally acquired data, during the observations. Finally, this paper focused on surgeons as the operator; the role of imaging technicians, scrub nurses, residents/fellows and anesthesiologists and their challenges with specific steps or activities were not considered.

Conclusion

Significant challenges may arise during IM nailing that impedes the surgical workflow and elevate surgical frustration levels. Entry point selection and reduction were identified as the most challenging steps. Activities associated

with both steps attempt to achieve 3D alignment using 2D fluoroscopic images. Maintenance of the correct alignment (location and/or orientation) in one plane while adjusting the position in the perpendicular plane is critical in these steps. If the alignment is lost, the cycle must be repeated, causing an increase in time and frustration. Maintenance of location and/or in plane orientation in entry point selection may be facilitated with the utilization of surgical instrumentation/technique which restrict out of plane movements. The ability to consistently maintain the alignment obtained in one plane while adjusting positioning in the perpendicular plane may reduce the need for repetition in the entry point activity cycle. Similarly, the reduction step can be facilitated by utilizing a device/technique that maintains the alignment in one plane while adjusting positioning in the perpendicular plane or more complex solutions which incorporate real-time navigation. These findings provide new insights on the causation of surgical challenges in IM nailing and may be used as a platform for future development of improved techniques and surgical instrumentation.

Compliance with Ethical Standards

Conflicts of interest The authors declare that they have no conflict of interest.

Ethical standard All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent The informed consent to participate in this study is attached as a supplementary material.

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