Reducing intraoperative duration and ionising radiation exposure during the insertion of distal locking screws of intramedullary nails: A small-scale study comparing the current fluoroscopic method against radiation free, electromagnetic navigation.

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Conflict of Interests

Mr D Grimwood has nothing to disclose.
Ms JM Harvey-Lloyd has nothing to disclose.

Key Words

Orthopaedic Trauma, Intramedullary Nailing, Theatre Radiography, Radiation Exposure

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Abstract

Background

Intramedullary nailing is the standard surgical treatment for mid-diaphyseal fractures of long bones; however, it is also a high radiation dose procedure. Distal locking is regularly cited as a demanding element of the procedure and there remains a reliance on X-ray fluoroscopy to locate the distal holes. A recently developed electromagnetic navigation (EMN) system allows radiation free distal locking, with a virtual on-screen image.

Objective

To compare operative duration, fluoroscopy time and radiation dose when using EMN over fluoroscopy, for the distal locking of intramedullary nails.

Method

Consecutive patients with mid-diaphyseal fractures of the tibia and femur, treatable with intramedullary nails, were prospectively enrolled during a 9-month period. The sample consisted of 29 individuals, 19 under fluoroscopic guidance and 10 utilising EMN. Participants were allocated depending on the type of intramedullary nail used and surgeon's preference. These were further divided into tibial and femoral subcategories, relative to the fracture site.

Results

EMN reduced fluoroscopy time by 49 (p=0.038) and 28 seconds during tibial and femoral nailings respectively. Radiation dose was reduced by 18cGy/cm² (p=0.046) during tibial, and 181cGy/cm² during femoral nailings when utilising EMN. Operative duration was 11 minutes slower during tibial nailings using EMN, but 38 minutes faster in respect of femoral nailings.

Conclusions

This study has evidenced statistically significant reductions both in fluoroscopy time and radiation dose when using EMN for the distal locking of intramedullary nails. It is expected that overall operative duration would also decrease in line with similar studies, with increased usage and a larger sample.
Introduction

Mobile image intensifiers are commonly and increasingly used during surgery, upon the understanding that it allows greater accuracy of fracture alignment and offers the ability to check the positioning of surgical implants before leaving the operating theatre [1]. Whilst this dynamic imaging allows minimally invasive procedures to be performed with increased precision, it does result in increased radiation exposure to both the patient and notably all theatre personnel due to their circadian exposure [2]. This progression of theatre radiography has enabled minimally invasive surgical procedures to be developed; such is the case with the intramedullary (IM) nailing of long bones.

Roux et al. [3] and Muller et al. [4] remark on the increased awareness of health implications that ionising radiation poses during image intensification. Of all fluoroscopically guided procedures, femoral IM nailings are identified as being responsible for high levels of radiation exposure [5]. IM nailing constitutes the established surgical treatment for these mid-diaphyseal fractures as it permits early weight bearing and rapid rehabilitation [6-9]. Further benefits over external fixation or open reduction internal fixation (ORIF) include not exposing the fracture site, which can lead to infection, additionally, soft tissue dissection is spared, meaning an undamaged blood supply [7, 10]. These factors promote union rates of greater than 80% [7, 10].

Numerous techniques have been developed to aid insertion of distal locking screws, however, the fluoroscopically directed, freehand “perfect circle” approach remains the prevailing method of accurately locating and drilling the distal holes [11] (figure I). Despite the reliance on the process, Stathopolous et al., [12] recognise that distal locking often remains the most challenging part of the operation, with 36–49 seconds of fluoroscopy time typically demanded to accurately locate and secure the distal holes [13].
Studies by Tornetta et al., Chan et al., Langfit et al., Stathopolous et al. and Moreschini, Petrucci and Cannata [12, 14-17] are all focused on the recently developed Trigen Sureshot [18], an electromagnetic-navigation (EMN) system that negates the need for fluoroscopy during placement of distal locking screws. The device operates via a probe that is placed down the centre of the intramedullary nail, which projects real-time feedback of the location of the drill, relative to the locking hole, by way of a virtual image of the distal end of the nail on a screen [18] (figure II). This probe is single use only.

Patients with closed diaphyseal fractures of the femur or tibia were the subject of investigation, with exclusion criteria comprising of retrograde nailing, open wounds adjacent to the distal locking site and patients under the age of 18. Tornetta et al. [14] applied their research on cadavers.
Chan et al. [15] and Moreschini, Petrucci and Cannata [17] both utilised two groups of patients, one having the distal locking screws located using the fluoroscopic freehand approach, the other using the EMN device. A similar methodology was undertaken by Tornetta et al. [14], with the difference being cadaveric limbs were used apposed to live patients. Langfit et al. [16] concentrated on one collective group of participants, exercising alternating techniques for each of the two locking screws. Stathopolous et al. [12] collated data solely on the use of Trigen Sureshot.

Mean figures obtained from the above analysis have been converted to equivalent units per screw, and are summarised in the table below. Tornetta et al. [14] divided their results into tibial and femoral statistics, in Table I they have been combined in order to aid comparability.

<table>
<thead>
<tr>
<th>Study number</th>
<th>Sample size</th>
<th>Grade of orthopaedic surgeon(s)</th>
<th>Fluoroscopically Guided</th>
<th>EM navigation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Distal locking time (secs)</td>
<td>Distal locking fluoroscopy time (secs)</td>
</tr>
<tr>
<td>1</td>
<td>25 x 2</td>
<td>Senior</td>
<td>171</td>
<td>14</td>
</tr>
<tr>
<td>2</td>
<td>47</td>
<td>All ‘on call’</td>
<td>481</td>
<td>26</td>
</tr>
<tr>
<td>3</td>
<td>19</td>
<td>Senior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>25 x 2</td>
<td>Same senior surgeon</td>
<td>630</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>57</td>
<td>Residents with ‘some’ fluoroscopy experience</td>
<td>153</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Mean</strong></td>
<td><strong>17</strong></td>
</tr>
</tbody>
</table>

Table I: Mean distal locking times, per screw, for both techniques including fluoroscopy time [12, 14-17].

Each individual investigation established that both methods of distal locking were clinically effective. Although these figures do vary immensely, using EMN consistently reduced operative time, producing an average diminution of 161 seconds per screw based on the aforementioned amalgamated data and eliminated the need for radiation exposure. The cumulative reduction over an individual’s career is substantial.

The aim of this small-scale study is to establish if radiation exposure and intraoperative duration can be reduced during IM nailing procedures of the tibia and
femur, as a result of advances within specialist orthopaedic technology. In order to meet this aim, the following objectives will be achieved:

- To collate records regarding the techniques used when imaging for IM nailing procedures
- To compare radiation dose, fluoroscopy time and operative duration for alternative methods of IM distal locking
- To make recommendations based on the outcomes of this research

**Method**

Data for this study was collected in a prospective manner, recorded after each IM nailing operation on an easily assessable form, stored with the theatre image intensifiers and record logs. Two different mobile image intensifiers were used interchangeably during this study (Phillips BV Endura and Siemens Siremobil Compact) and all exposures were made using the automatic exposure control setting. Radiation doses were measured by the integrated dose area product (DAP) meters, which measure the radiation dose emitted from the X-ray tube, multiplied by the area of the X-ray field.

Data was compiled under the following headings:

- Date
- Patient hospital number
- Procedure – e.g. Tibial or femoral nailing
- Dose \((cGy/cm^2)\)
- Fluoroscopy Time \((seconds)\)
- Operation Start/End Time
- Method of distal locking – *Fluoroscopy or EMN*
- Comments

In case of data anomalies, the date of operation, patient’s hospital number and additional comments were recorded so that the case could be reviewed post sampling.
The research variable in this study is the method used by the surgeon to locate the distal locking holes during IM nailing procedures, one using X-ray fluoroscopy and the other, the EMN system as previously detailed. This variable is dependent on the type of IM nail that is used, as well as the surgeon’s experience and preference. The existing theatre image intensifier paper-based exposure logs were manually audited at the end of the sampling period to ensure that all IM nailing procedures were accounted for on the data collection tool. Any discrepancies were cross-referenced with the operating department’s own records to ascertain which method of distal locking was utilised and then added to the collection tool if the inclusion criteria were met.

The inclusion and exclusion criteria for this study are detailed below:

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients older than 18 years old</td>
<td>Paediatric patients</td>
</tr>
<tr>
<td>Femoral or tibial mid-shaft fractures</td>
<td>Proximal or distal fractures</td>
</tr>
<tr>
<td>Suitable for IMN</td>
<td>ORIF procedures</td>
</tr>
</tbody>
</table>

Table II: Sample inclusion and exclusion criteria

Although paediatric mid-diaphyseal fractures can be treated with IM nails, they were excluded from this study as flexible implants are normally used in order to allow unobstructed bone growth [19].

Data was compiled over a 9-month period, with every patient undergoing an IM nailing operation being recorded on the data collection tool. This form of nonprobability selection is documented as convenience sampling; it was impossible to predict how many patients would undergo IM nailing procedures over the course of the study, therefore it was unreasonable to create a sampling plan and randomly select participants [20]. Although Polit and Beck [21] infer that convenience sampling is less likely to be representative of the target population, it is regularly employed in many nursing and allied health professions studies when a sampling plan cannot be determined [22].

Inclusion and exclusion criteria were applied post compilation. In total, data was collected concerning 33 operations, with 4 subsequently being removed prior to running statistical tests on the data. These 4 were omitted for the following reasons:
1. Different technique used for distal locking other than fluoroscopy or EMN.
2. A shortened nail was inserted via a jig.
3. Change of procedure; fracture was deemed unacceptable for IM nailing.
4. Duplication of a previous entry.

Following these exclusions, the total sample consisted of 29 individuals \((n=29)\). Of these, 19 fell into the group with distal locking screws being inserted under fluoroscopic guidance \((n_1=19)\), and the other 10 into the EMN group \((n_2=10)\). These samples were further divided into tibial and femoral subcategories, depending on the location of fracture.

SPSS software was used to examine the collected data. Radiation dose, fluoroscopy time and overall operative time were documented using descriptive statistics and graphical analysis. The means between the fluoroscopy and EMN samples were compared with independent sample \(t\)-tests.

The manager of the imaging department granted authorisation for this small-scale study, with an ultimate intention of service improvement, to proceed in accordance with the previously submitted research proposal. Data was collected under this consensus.
Results

![Figure III: Column graph showing allocation of sample.](image)

Independent-samples $t$-tests with a 95% confidence interval were used to compare means and these results are reported in the order of $t$(degrees of freedom)=$t$-test statistic, $p$=probability (significance level). Confidence intervals were documented in the appendices. As samples $n_1$ and $n_2$ were unequal, $t$-tests were also executed on the subcategories to ascertain if they could be combined to add statistical power. Values of $p<0.05$ are to be considered statistically significant [23].

Mean overall operative duration was 11 minutes $t$(11)=0.96, $p=0.359$ slower during tibial IM nailings when using EMN, however, the opposite was seen during femoral IM nailings where EMN showed a reduction of 38 minutes $t$(14)=1.38, $p=0.189$ (figures IV and V). There was a statistically significant difference between subcategories in group $n_2$ ($p=0.026$). Outlier 26 is noted as an expeditious operation.
Mean fluoroscopy time was reduced by 49 seconds \( t(11)=2.36, p=0.038 \) and 28 seconds \( t(14)=0.65, p=0.525 \) during tibial and femoral IM nailings respectively, when using EMN for distal locking \( (figures \ VI \ and \ VII) \). Subcategories did not have a
statistically significant difference in either group ($n_1 p=0.438$ and $n_2 p=0.097$). Outlier 14 was noted as a difficult case at the time of initial data recording, hence the greater fluoroscopy time.

![Fluoroscopy Time](image)

**Figure VI:** Bar graph showing fluoroscopy time in seconds, for both methods of distal locking, during tibial and femoral IM nailings. Error bars represent one standard deviation.

![Fluoroscopy Time](image)

**Figure VII:** Box plot showing the distribution of fluoroscopy time in seconds (minimum, first quartile, median, third quartile and maximum).
EMN produced mean radiation dose reductions of $18.03 \text{cGy/cm}^2$, $t(11)=2.25$, $p=0.046$ during tibial IM nailings and $181.57 \text{cGy/cm}^2$, $t(14)=1.07$, $p=0.304$ during femoral IM nailings (figures VIII and IX). There was a statistically significant difference between subcategories in both samples ($n_1 p=0.005$ and $n_2 p<0.001$).

![Figure VIII](image1.png)

Figure VIII: Bar graph showing total radiation exposure in cGy/cm², for both methods of distal locking, during tibial and femoral IM nailings. Error bars represent one standard deviation.

![Figure IX](image2.png)

Figure IX: Box plot showing the distribution of radiation dose in cGy/cm² (minimum, first quartile, median, third quartile and maximum).
Discussion

The findings of the study will be discussed using the following sub-headings; operative duration, fluoroscopy time and radiation dose.

Operative Duration

Technological advances have allowed this to be addressed by development of an EMN system (Trigen Sureshot) that eradicates the reliance on X-ray fluoroscopy during placement of the distal locking screws. Whilst both methods are clinically effective, previous similar studies on this EMN device [12, 14-17] have produced combined data suggesting that an average of 322 seconds (5:22 minutes) can be eliminated from the overall intraoperative duration when using EMN for the distal locking aspect, which completely dissolves the associated radiation exposure. The individual results of Moreschini, Petrucci and Cannata [17] reported an extensive reduction of 656 seconds (10:56 minutes).

Conversely, this current study did not produce comparable reductions in overall operative time. EMN tibial IM nailings generated an average of 660 additional seconds (11 minutes) compared to fluoroscopic guidance, yet was 38 minutes faster for femoral IM nailings. Using the criteria documented in the results section, both of these values are however considered statistically insignificant ($p=0.359$ and $p=0.189$). The EMN group ($n_2$) demonstrated a statistically significant difference between the tibial and femoral subgroups ($p=0.026$) so have not been combined.

An outlier was encountered in the tibial fluoroscopy sample, which was 8 minutes outside of 1 standard deviation, suggesting that without this entry, figures could have been preponderant. EMN was only used during 3 operations of the femur, which may explain the greater difference.

EMN is still relatively novel; it was regularly observed that either a manufacturer representative was present providing advice, or a consultant was instructing a registrar, hence the additional intraoperative time recorded during tibial IM nailings. It is expected that with larger, equal sample sizes and circumspect surgeons, similar time reductions to the aforementioned studies could be achieved.
A reduced overall intraoperative duration benefits both the patient and hospital. A major factor from a medical perspective is a shortened general anaesthesia period for the patient. Although Li et al. [24] note that improved monitoring and anaesthetic techniques have reduced the anaesthesia-mortality risk from 1/1,000 in the 1940’s to 1/100,000 in the early 2000’s, these recent figures do vary in the literature. Gottschalk et al. [25] propose a current mortality rate of 0.4/100,000.

Despite this, adverse side effects remain a possibility, with postoperative nausea and vomiting (PONV) a common general anaesthesia complication [26]. Sinclair, Chung and Mezel [27] studied 17,638 consecutive postoperative patients and established that a 30-minute increase in general anaesthesia duration, increased the chance of PONV by 59%. Chung, Ritchie and Su [28] found that duration of anaesthesia also has a direct link to the level of postoperative pain experienced; 1/10 patients suffered severe pain after an anaesthetic duration of 90 minutes, yet when the length was extended by 30 minutes, this figure was increased to 1/5. Both of these factors can delay patient discharge [29,30].

It is conceivable that EMN can considerably reduce operative and respectively, anaesthesia duration, therefore preventing prolonged hospital stays. This in turn increases patient throughput and presents cost-saving opportunities. Additionally, it should allow resources, such as mobile image intensifiers, to be used in an efficient manner, preventing delays in operations.

Fluoroscopy Time

A major influence in overall radiation exposure is the duration of continuous fluoroscopy. Using the combined data recorded by this study, each second of fluoroscopy time during IM nailing of the tibia equates to 0.5cGy/cm² of radiation exposure. This increases to 2.9cGy/cm² per second with femoral IM nailings. It is essential that the radiographer acts in a confident and assertive manner if required, as excessive fluoroscopy time can greatly, and rapidly increase the radiation exposure.

Langfit et al. [16] highlighted that fluoroscopy duration is often directly related to the surgeon’s level of experience. Their study on IM nailing procedures revealed that
junior surgeons accrued 10% additional time than their senior colleagues. The experience of the radiographer could also produce a similar conclusion.

Mean fluoroscopy duration was substantially reduced when using EMN during this research. Tibial IM nailings bestowed a 49 second (46%) decline, which is to be considered statistically significant ($p=0.038$). This trend continued with IM nailings of the femur (28 seconds, 21%), though did not carry the same statistical significance ($p=0.525$).

As the tibial and femoral subcategories in this study had a statistically significant difference in both groups ($n_1 p=0.438$ and $n_2 p=0.097$), they can be combined as per the methodology of Chan et al. [15], Langfit et al. [16] and Moreschini, Petrucci and Cannata [17], who reported mean fluoroscopy time reductions of 28, 26 and 19.4 seconds respectively. Using a mean average based on our 49 (tibial) and 28 (femoral) second reductions in fluoroscopy time, these comparative studies presented reductions that are less than the averaged 39 seconds recorded in our research.

The small sample size and lack of statistical significance in the femoral subcategory could account for this difference. In respect of tibial IM nailings however, this research has similar figures as reported by Tornetta et al. [14], who documented a mean fluoroscopy reduction of 36 seconds.

**Radiation Dose**

This current study has shown that technology can appreciably reduce radiation exposure during IM nailing procedures. EMN for the distal locking aspect produced a statistically significant ($p=0.046$) mean radiation dose reduction of 18.03 cGy/cm$^2$ during tibial IM nailings. A 181.57 cGy/cm$^2$ dose reduction was seen during femoral IM nailings, though was not statistically significant ($p=0.304$). There was an obvious difference between the tibial and femoral subcategories in both samples ($n_1 p=0.005$ and $n_2 p<0.001$) due to the increased soft tissue density in the thigh, requiring greater exposure factors.

Unfortunately there are no equivalent studies with which to compare these results; Chan et al. [15], Langfit et al. [16], Strathopoulos et al. ([12] and Moreschini, Petrucci
and Cannata [17] concentrated exclusively on fluoroscopy and distal locking times and did not record radiation doses. Tornetta et al. [14] did record doses, however it was in the absorbed unit of mRad, which cannot be compared with the DAP recordings of this research. Furthermore, a percentage reduction cannot be calculated as only the distal locking aspect was documented as apposed to the entire procedure exposure seen by this study.

Despite this lack of comparability, this current research has evidenced 18% and 42% reductions in respect of radiation exposure during tibial and femoral IM nailings respectively, culminating in a combined reduction of 30%.

Conclusions

Interlocking IM nailing remains the benchmark for surgical treatment of mid-diaphyseal fractures of the tibia and femur, with the distal locking aspect cited as the most challenging part of the operation. Despite the development of alternative radiation-free techniques, the fluoroscopically guided approach has remained the prevailing method of locating the distal locking holes.

This study has exposed the ionising radiation exposure to staff and patients during these procedures, alongside the benefits of shorter operations. The recently developed, radiation-free Trigen Sureshot, which displays a virtual image providing real-time feedback to the surgeon, has been the basis of this research.

Although this was only a small sample study, it has produced statistically significant data demonstrating substantial reductions in fluoroscopy time, which directly impacts the overall radiation dose. It is expected that the overall operative duration would be shortened in line with similar studies, with a larger sample. Increased productivity should allow resources to be used in an efficient manner, preventing surgical delays.

It would appear that the only disadvantage of EMN is the initial financial outlay for the equipment, plus continuing probe replacement. Smith and Nephew’s [18] literature suggests that the technology is fast and easy to learn, which should enable prompt surgeon training.
This study is not without limitations, primarily the sampling methodology and size, resulting in a lack of generalisability, albeit representative of this specific hospital's patient population. Due to the restricted volume of suitable patients, it was not possible to predetermine a sample size, which could allow randomisation of participants, although as every applicable patient was enrolled, it could be said that this removed any selection bias. Furthermore, the surgeons were not aware that this data was being collected, implying they would have used fluoroscopy in accordance with their usual routine. They were also inadvertently randomising each patient into either the fluoroscopy or EMN groups; it would have been unethical for the researcher to manipulate this in view of the risks associated with radiation exposure.

Since two different mobile image intensifiers were used during this study, there could have been variances in radiation dose between the two units, despite both using the automatic exposure setting. A series of control examinations using each image intensifier and an X-ray phantom could provide baseline data, with the differences then being calculated into this study.

As this research focussed on the complete procedure rather than just the distal locking aspect, operative duration and radiation exposure could be influenced by uncontrolled variables such as patient habitus, bone density and difficulty of initial fracture reduction.

**Recommendations**

A further study should be undertaken using a larger sample with adequate power, which may need to be directed to a dedicated trauma centre. This sample would be again split into tibial and femoral subcategories, but would focus solely on the distal locking aspect, which should allow increased statistical significance in the results. It would also be advantageous to use either the same II throughout, or record which unit was used.

All surgeons should be aware of the benefits of EMN and utilise it whenever possible.

Intraoperative radiography obliges all staff to be educated in the risks of ionising radiation and have an awareness of the inverse square law and personal protective equipment.
Compliance with Ethical Standards

Disclosure of Potential Conflicts of Interest

Mr D Grimwood has nothing to disclose.
Ms JM Harvey-Lloyd has nothing to disclose.

Ethical Approval

This article does not contain any studies with human participants or animals performed by any of the authors.

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References


