

1 Reducing intraoperative duration and ionising radiation exposure during the
2 insertion of distal locking screws of intramedullary nails: A small-scale study
3 comparing the current fluoroscopic method against radiation free,
4 electromagnetic navigation.
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8 Mr. Darren Grimwood
9 West Suffolk Hospital NHS Foundation Trust
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12 Ms. Jane Harvey-Lloyd
13 University Campus Suffolk
14
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17 Contact: Darren Grimwood
18 +44 01284 3813329
19 darren.grimwood@wsh.nhs.uk
20
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22 23 Conflict of Interests

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26 Mr D Grimwood has nothing to disclose.
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28 Ms JM Harvey-Lloyd has nothing to disclose.
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31 32 Key Words

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35 Orthopaedic Trauma, Intramedullary Nailing, Theatre Radiography, Radiation
36 Exposure
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1 Abstract

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4 **Background**

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

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

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

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

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41 This study has evidenced statistically significant reductions both in
42 fluoroscopy time and radiation dose when using EMN for the distal locking of
43 intramedullary nails. It is expected that overall operative duration would also
44 decrease in line with similar studies, with increased usage and a larger
45 sample.
46

1 **Introduction**

2

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

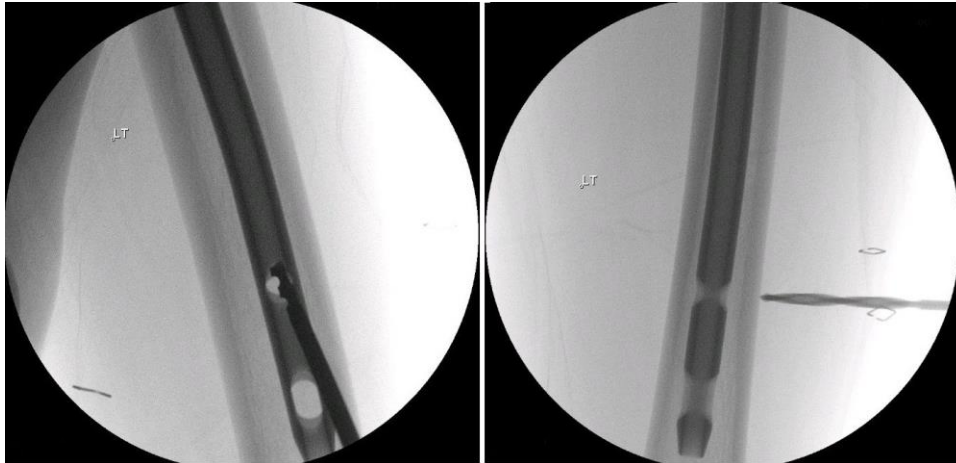
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13 Roux *et al.* [3] and Muller *et al.* [4] remark on the increased awareness of health
14 implications that ionising radiation poses during image intensification. Of all
15 fluoroscopically guided procedures, femoral IM nailings are identified as being
16 responsible for high levels of radiation exposure [5]. IM nailing constitutes the
17 established surgical treatment for these mid-diaphyseal fractures as it permits early
18 weight bearing and rapid rehabilitation [6-9]. Further benefits over external fixation or
19 open reduction internal fixation (ORIF) include not exposing the fracture site, which
20 can lead to infection, additionally, soft tissue dissection is spared, meaning an
21 undamaged blood supply [7, 10]. These factors promote union rates of greater than
22 80% [7, 10].

23

24 Numerous techniques have been developed to aid insertion of distal locking screws,
25 however, the fluoroscopically directed, freehand “perfect circle” approach remains
26 the prevailing method of accurately locating and drilling the distal holes [11] (figure I).
27 Despite the reliance on the process, Stathopolous *et al.*, [12] recognise that distal
28 locking often remains the most challenging part of the operation, with 36–49 seconds
29 of fluoroscopy time typically demanded to accurately locate and secure the distal
30 holes [13].

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Figure I: AP and lateral images showing a drill bit aligned with the distal hole of an intramedullary nail

Studies by Tornetta *et al.*, Chan *et al.*, Langfit *et al.*, Stathopolous *et al.* and Moreschini, Petrucci and Cannata [12, 14-17] are all focussed 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.



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Figure II: Image showing components of Trigen Sureshot (Smith and Nephew).

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.

1 Chan *et al.* [15] and Moreschini, Petrucci and Cannata [17] both utilised two groups
 2 of patients, one having the distal locking screws located using the fluoroscopic
 3 freehand approach, the other using the EMN device. A similar methodology was
 4 undertaken by Tornetta *et al.* [14], with the difference being cadaveric limbs were
 5 used apposed to live patients. Langfit *et al.* [16] concentrated on one collective group
 6 of participants, exercising alternating techniques for each of the two locking screws.
 7 Stathopolous *et al.* [12] collated data solely on the use of Trigen Sureshot.

8
 9 Mean figures obtained from the above analysis have been converted to equivalent
 10 units per screw, and are summarised in the table below. Tornetta *et al.* [14] divided
 11 their results into tibial and femoral statistics, in Table I they have been combined in
 12 order to aid comparableness.

13

Study number	Sample size	Grade of orthopaedic surgeon(s)	Fluoroscopically Guided		EM navigation
			Distal locking time (secs)	Distal locking fluoroscopy time (secs)	Distal locking time (secs)
1	25 x 2	Senior	171	14	114
2	47	All 'on call'	481	26	304
3	19	Senior			168
4	25 x 2	Same senior surgeon	630	10	302
5	57	Residents with 'some' fluoroscopy experience	153	18	97
Mean			358	17	197

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

15
 16 Each individual investigation established that both methods of distal locking were
 17 clinically effective. Although these figures do vary immensely, using EMN
 18 consistently reduced operative time, producing an average diminution of 161
 19 seconds per screw based on the aforementioned amalgamated data and eliminated
 20 the need for radiation exposure. The cumulative reduction over an individual's career
 21 is substantial.

22
 23 The aim of this small-scale study is to establish if radiation exposure and
 24 intraoperative duration can be reduced during IM nailing procedures of the tibia and

1 femur, as a result of advances within specialist orthopaedic technology. In order to
2 meet this aim, the following objectives will be achieved:

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- 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

10 **Method**

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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.

22 Data was compiled under the following headings:

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- Date
- Patient hospital number
- Procedure – *e.g. Tibial or femoral nailing*
- Dose (*cGy/cm²*)
- Fluoroscopy Time (*seconds*)
- Operation Start/End Time
- Method of distal locking – *Fluoroscopy or EMN*
- Comments

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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.

1 The research variable in this study is the method used by the surgeon to locate the
2 distal locking holes during IM nailing procedures, one using X-ray fluoroscopy and
3 the other, the EMN system as previously detailed. This variable is dependent on the
4 type of IM nail that is used, as well as the surgeon's experience and preference. The
5 existing theatre image intensifier paper-based exposure logs were manually audited
6 at the end of the sampling period to ensure that all IM nailing procedures were
7 accounted for on the data collection tool. Any discrepancies were cross-referenced
8 with the operating department's own records to ascertain which method of distal
9 locking was utilised and then added to the collection tool if the inclusion criteria were
10 met.

11

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

13

Inclusion Criteria	Exclusion Criteria
Patients older than 18 years old	Paediatric patients
Femoral or tibial mid-shaft fractures	Proximal or distal fractures
Suitable for IMN	ORIF procedures

14 **Table II:** Sample inclusion and exclusion criteria

15

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

19

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

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30 Inclusion and exclusion criteria were applied post compilation. In total, data was
31 collected concerning 33 operations, with 4 subsequently being removed prior to
32 running statistical tests on the data. These 4 were omitted for the following reasons:

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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.

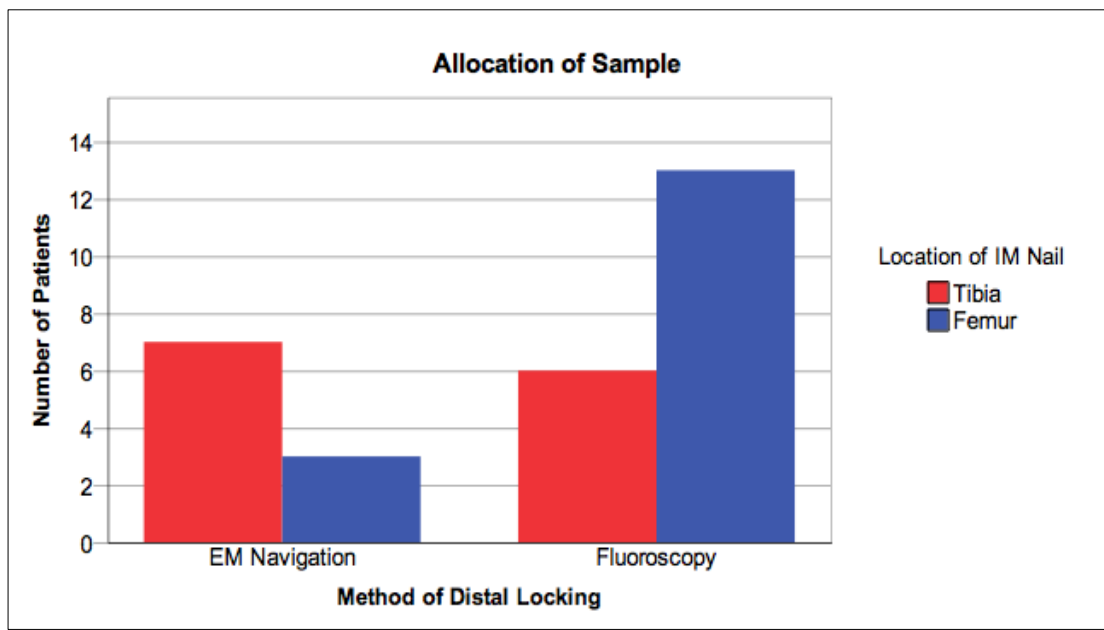
SPSS software was used to examine the collected data. Radiation dose, fluoroscopy time and overall operative time were documented using descriptive statistics and graphical analysis. The means between the fluoroscopy and EMN samples were compared with independent sample t -tests.

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.

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2 **Results**

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5 **Figure III:** Column graph showing allocation of sample.

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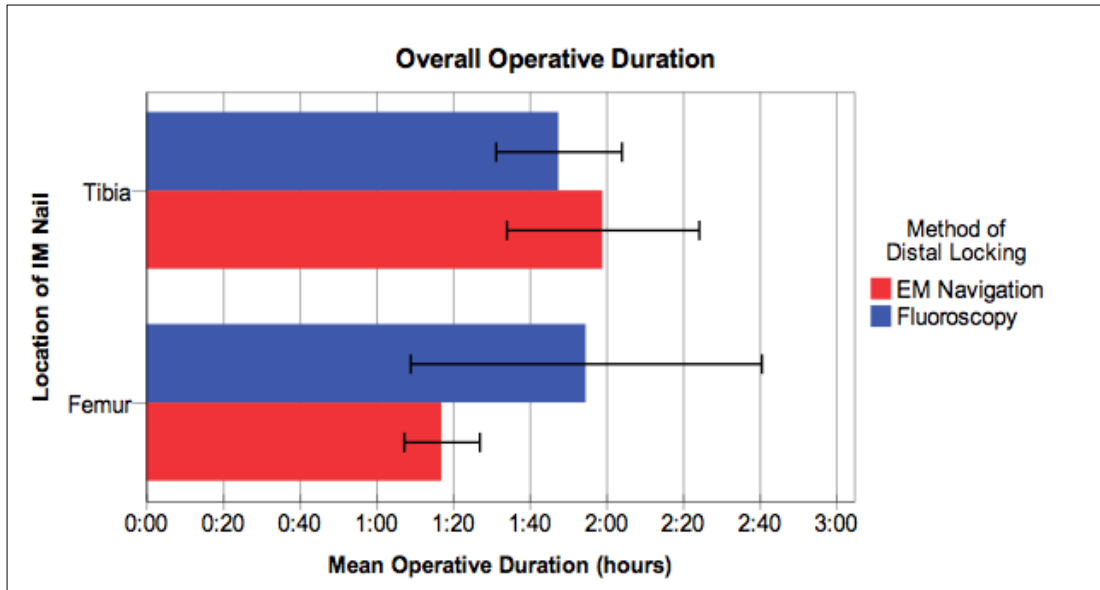
7 Independent-samples *t*-tests with a 95% confidence interval were used to compare
 8 means and these results are reported in the order of *t*(degrees of freedom)=*t*-test
 9 statistic, *p*=probability (significance level). Confidence intervals were documented in
 10 the appendices. As samples *n*₁ and *n*₂ were unequal, *t*-tests were also executed on
 11 the subcategories to ascertain if they could be combined to add statistical power.
 12 Values of *p*<0.05 are to be considered statistically significant [23].

13

14 Mean overall operative duration was 11 minutes *t*(11)=0.96, *p*=0.359 slower during
 15 tibial IM nailings when using EMN, however, the opposite was seen during femoral
 16 IM nailings where EMN showed a reduction of 38 minutes *t*(14)=1.38, *p*=0.189
 17 (figures IV and V). There was a statistically significant difference between
 18 subcategories in group *n*₂ (*p*=0.026). Outlier 26 is noted as an expeditious operation.

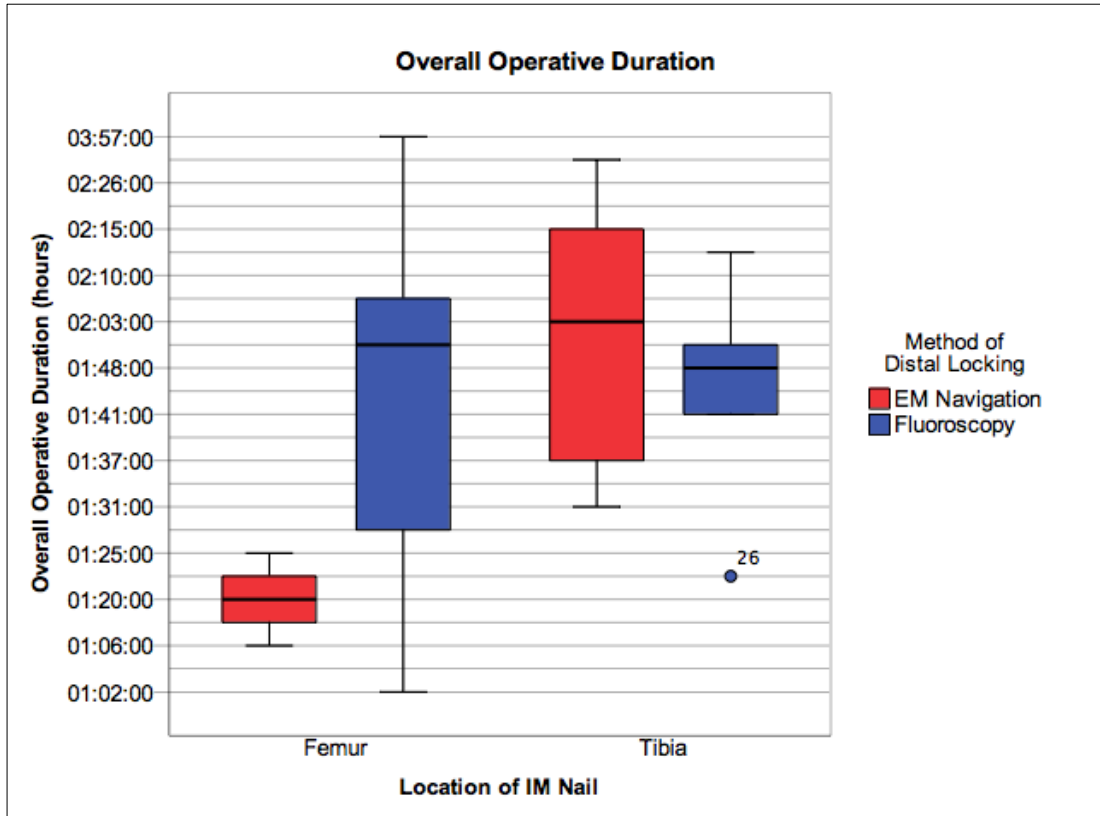
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Figure IV: Bar graph showing overall intraoperative duration in hours, for both methods of distal locking, during tibial and femoral IM nailings. Error bars represent one standard deviation.

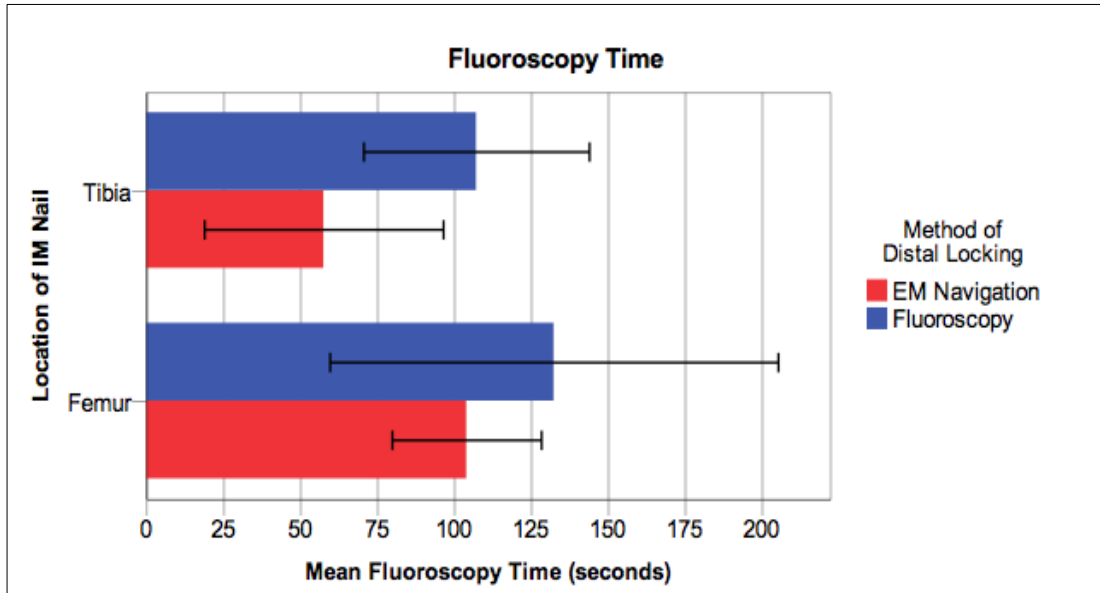


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Figure V: Box plot showing the distribution of operative duration time (*minimum, first quartile, median, third quartile and maximum*).

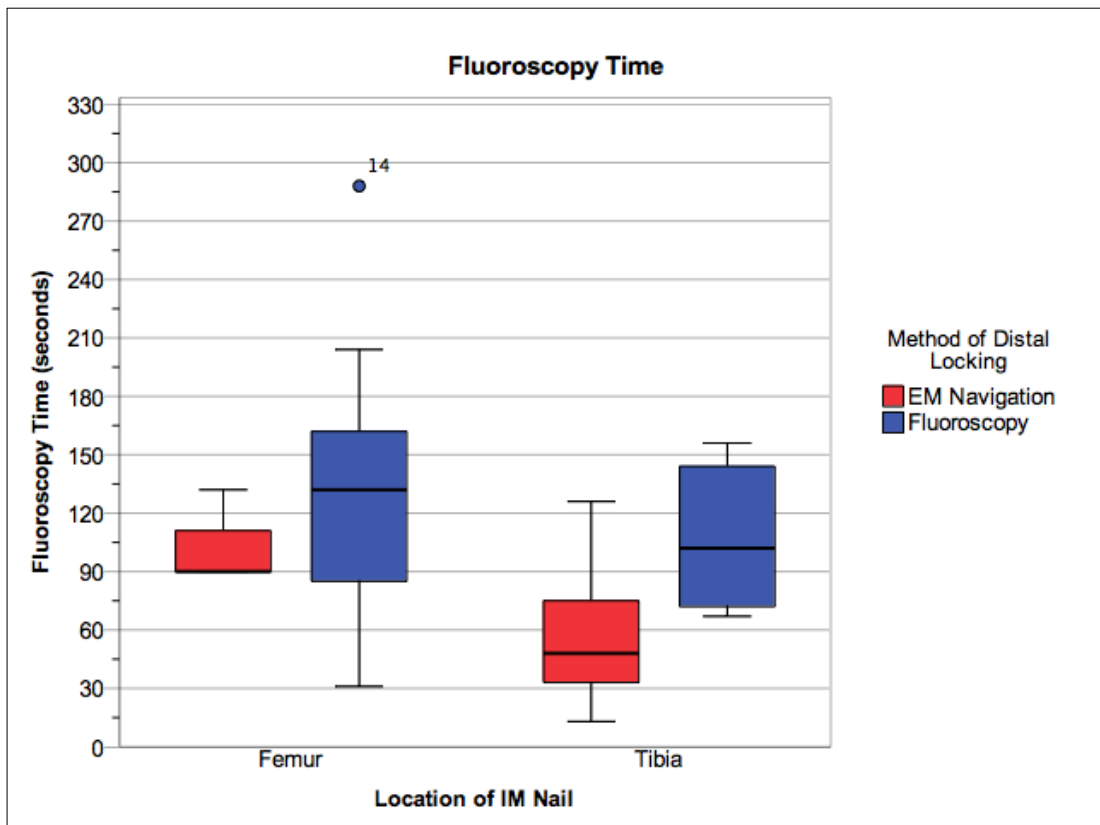
Mean fluoroscopy time was reduced by 49 seconds $t(11)=2.36, p=0.038$ and 28 seconds $t(14)=0.65, p=0.525$ during tibial and femoral IM nailings respectively, when using EMN for distal locking (*figures VI and VII*). Subcategories did not have a

1 statistically significant difference in either group ($n_1 p=0.438$ and $n_2 p=0.097$). Outlier
 2 14 was noted as a difficult case at the time of initial data recording, hence the greater
 3 fluoroscopy time.
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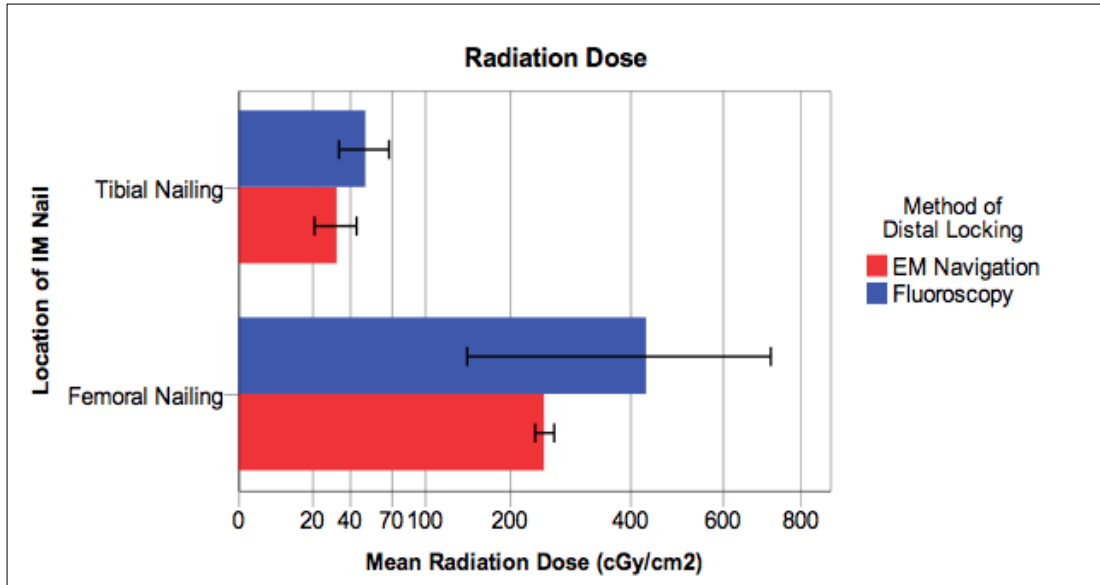
5 **Figure VI:** Bar graph showing fluoroscopy time in seconds, for both methods of distal locking, during
 6 tibial and femoral IM nailings. Error bars represent one standard deviation
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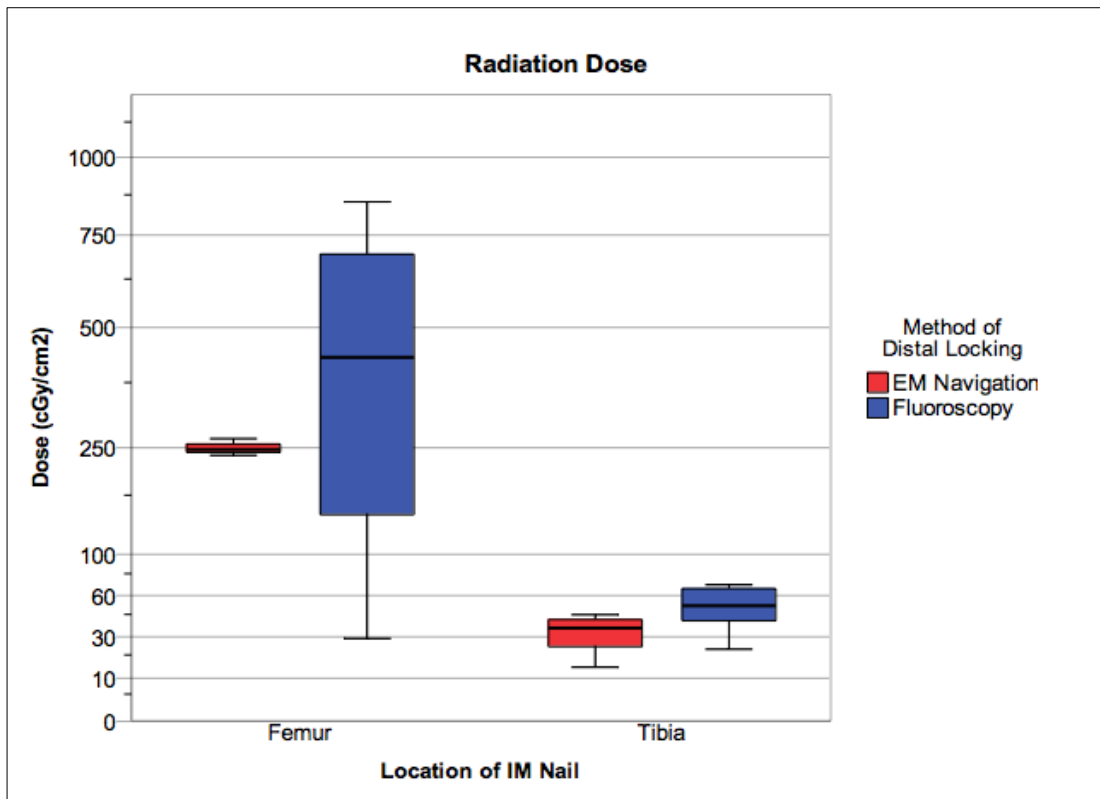


9 **Figure VII:** Box plot showing the distribution of fluoroscopy time in seconds (*minimum, first quartile,*
 10 *median, third quartile and maximum*).
 11

1 EMN produced mean radiation dose reductions of 18.03cGy/cm² $t(11)=2.25$, $p=0.046$
 2 during tibial IM nailings and 181.57cGy/cm² $t(14)=1.07$, $p=0.304$ during femoral IM
 3 nailings (*figures VIII and IX*). There was a statistically significant difference between
 4 subcategories in both samples ($n_1 p=0.005$ and $n_2 p<0.001$).
 5



6 **Figure VIII:** Bar graph showing total radiation exposure in cGy/cm², for both methods of distal locking,
 7
 8 during tibial and femoral IM nailings. Error bars represent one standard deviation.
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10 **Figure IX:** Box plot showing the distribution of radiation dose in cGy/cm² (*minimum, first quartile,*
 11 *median, third quartile and maximum*).
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1 **Discussion**

2
3 The findings of the study will be discussed using the following sub-headings;
4 operative duration, fluoroscopy time and radiation dose.
5

6 Operative Duration

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

18 Conversely, this current study did not produce comparable reductions in overall
19 operative time. EMN tibial IM nailings generated an average of 660 additional
20 seconds (11 minutes) compared to fluoroscopic guidance, yet was 38 minutes faster
21 for femoral IM nailings. Using the criteria documented in the results section, both of
22 these values are however considered statistically insignificant ($p=0.359$ and
23 $p=0.189$). The EMN group (n_2) demonstrated a statistically significant difference
24 between the tibial and femoral subgroups ($p=0.026$) so have not been combined.
25

26 An outlier was encountered in the tibial fluoroscopy sample, which was 8 minutes
27 outside of 1 standard deviation, suggesting that without this entry, figures could have
28 been preponderant. EMN was only used during 3 operations of the femur, which may
29 explain the greater difference.
30

31 EMN is still relatively novel; it was regularly observed that either a manufacturer
32 representative was present providing advice, or a consultant was instructing a
33 registrar, hence the additional intraoperative time recorded during tibial IM nailings. It
34 is expected that with larger, equal sample sizes and circumspect surgeons, similar
35 time reductions to the aforementioned studies could be achieved.
36

1 A reduced overall intraoperative duration benefits both the patient and hospital. A
2 major factor from a medical perspective is a shortened general anaesthesia period
3 for the patient. Although Li *et al.* [24] note that improved monitoring and anaesthetic
4 techniques have reduced the anaesthesia-mortality risk from 1/1,000 in the 1940's to
5 1/100,000 in the early 2000's, these recent figures do vary in the literature.
6 Gottschalk *et al.* [25] propose a current mortality rate of 0.4/100,000.

7
8 Despite this, adverse side effects remain a possibility, with postoperative nausea and
9 vomiting (PONV) a common general anaesthesia complication [26]. Sinclair, Chung
10 and Mezel [27] studied 17,638 consecutive postoperative patients and established
11 that a 30-minute increase in general anaesthesia duration, increased the chance of
12 PONV by 59%. Chung, Ritchie and Su [28] found that duration of anaesthesia also
13 has a direct link to the level of postoperative pain experienced; 1/10 patients suffered
14 severe pain after an anaesthetic duration of 90 minutes, yet when the length was
15 extended by 30 minutes, this figure was increased to 1/5. Both of these factors can
16 delay patient discharge [29,30].

17
18 It is conceivable that EMN can considerably reduce operative and respectively,
19 anaesthesia duration, therefore preventing prolonged hospital stays. This in turn
20 increases patient throughput and presents cost-saving opportunities. Additionally, it
21 should allow resources, such as mobile image intensifiers, to be used in an efficient
22 manner, preventing delays in operations.

23

24 Fluoroscopy Time

25
26 A major influence in overall radiation exposure is the duration of continuous
27 fluoroscopy. Using the combined data recorded by this study, each second of
28 fluoroscopy time during IM nailing of the tibia equates to 0.5cGy/cm² of radiation
29 exposure. This increases to 2.9cGy/cm² per second with femoral IM nailings. It is
30 essential that the radiographer acts in a confident and assertive manner if required,
31 as excessive fluoroscopy time can greatly, and rapidly increase the radiation
32 exposure.

33

34 Langfit *et al.* [16] highlighted that fluoroscopy duration is often directly related to the
35 surgeon's level of experience. Their study on IM nailing procedures revealed that

1 junior surgeons accrued 10% additional time than their senior colleagues. The
2 experience of the radiographer could also produce a similar conclusion.

3
4 Mean fluoroscopy duration was substantially reduced when using EMN during this
5 research. Tibial IM nailings bestowed a 49 second (46%) decline, which is to be
6 considered statistically significant ($p=0.038$). This trend continued with IM nailings of
7 the femur (28 seconds, 21%), though did not carry the same statistical significance
8 ($p=0.525$).

9
10 As the tibial and femoral subcategories in this study had a statistically significant
11 difference in both groups ($n_1 p=0.438$ and $n_2 p=0.097$), they can be combined as per
12 the methodology of Chan *et al.* [15], Langfit *et al.* [16] and Moreschini, Petrucci and
13 Cannata [17], who reported mean fluoroscopy time reductions of 28, 26 and 19.4
14 seconds respectively. Using a mean average based on our 49 (tibial) and 28
15 (femoral) second reductions in fluoroscopy time, these comparative studies
16 presented reductions that are less than the averaged 39 seconds recorded in our
17 research.

18
19 The small sample size and lack of statistical significance in the femoral subcategory
20 could account for this difference. In respect of tibial IM nailings however, this
21 research has similar figures as reported by Tornetta *et al.* [14], who documented a
22 mean fluoroscopy reduction of 36 seconds.

23 24 Radiation Dose

25
26 This current study has shown that technology can appreciably reduce radiation
27 exposure during IM nailing procedures. EMN for the distal locking aspect produced a
28 statistically significant ($p=0.046$) mean radiation dose reduction of 18.03 cGy/cm²
29 during tibial IM nailings. A 181.57 cGy/cm² dose reduction was seen during femoral
30 IM nailings, though was not statistically significant ($p=0.304$). There was an obvious
31 difference between the tibial and femoral subcategories in both samples ($n_1 p=0.005$
32 and $n_2 p<0.001$) due to the increased soft tissue density in the thigh, requiring
33 greater exposure factors.

34
35 Unfortunately there are no equivalent studies with which to compare these results;
36 Chan *et al.* [15], Langfit *et al.* [16], Strathopoulos *et al.* ([12] and Moreschini, Petrucci

1 and Cannata [17] concentrated exclusively on fluoroscopy and distal locking times
2 and did not record radiation doses. Tornetta *et al.* [14] did record doses, however it
3 was in the absorbed unit of mRad, which cannot be compared with the DAP
4 recordings of this research. Furthermore, a percentage reduction cannot be
5 calculated as only the distal locking aspect was documented as apposed to the entire
6 procedure exposure seen by this study.

7
8 Despite this lack of comparability, this current research has evidenced 18% and 42%
9 reductions in respect of radiation exposure during tibial and femoral IM nailings
10 respectively, culminating in a combined reduction of 30%.

11 12 **Conclusions**

13
14 Interlocking IM nailing remains the benchmark for surgical treatment of mid-
15 diaphyseal fractures of the tibia and femur, with the distal locking aspect cited as the
16 most challenging part of the operation. Despite the development of alternative
17 radiation-free techniques, the fluoroscopically guided approach has remained the
18 prevailing method of locating the distal locking holes.

19
20 This study has exposed the ionising radiation exposure to staff and patients during
21 these procedures, alongside the benefits of shorter operations. The recently
22 developed, radiation-free Trigen Sureshot, which displays a virtual image providing
23 real-time feedback to the surgeon, has been the basis of this research.

24
25 Although this was only a small sample study, it has produced statistically significant
26 data demonstrating substantial reductions in fluoroscopy time, which directly impacts
27 the overall radiation dose. It is expected that the overall operative duration would be
28 shortened in line with similar studies, with a larger sample. Increased productivity
29 should allow resources to be used in an efficient manner, preventing surgical delays.

30
31 It would appear that the only disadvantage of EMN is the initial financial outlay for the
32 equipment, plus continuing probe replacement. Smith and Nephew's [18] literature
33 suggests that the technology is fast and easy to learn, which should enable prompt
34 surgeon training.

1 This study is not without limitations, primarily the sampling methodology and size,
2 resulting in a lack of generalisability, albeit representative of this specific hospital's
3 patient population. Due to the restricted volume of suitable patients, it was not
4 possible to predetermine a sample size, which could allow randomisation of
5 participants, although as every applicable patient was enrolled, it could be said that
6 this removed any selection bias. Furthermore, the surgeons were not aware that this
7 data was being collected, implying they would have used fluoroscopy in accordance
8 with their usual routine. They were also inadvertently randomising each patient into
9 either the fluoroscopy or EMN groups; it would have been unethical for the
10 researcher to manipulate this in view of the risks associated with radiation exposure.

11

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

17

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

22

23 **Recommendations**

24

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

31

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

33

34 Intraoperative radiography obliges all staff to be educated in the risks of ionising
35 radiation and have an awareness of the inverse square law and personal protective
36 equipment.

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1 **Compliance with Ethical Standards**

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3 Disclosure of Potential Conflicts of Interest

4

5 Mr D Grimwood has nothing to disclose.

6 Ms JM Harvey-Lloyd has nothing to disclose.

7

8 Ethical Approval

9

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

12

13 Funding

14

15 Neither author received any payments in respect of this study.

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