UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES

"Removing the nail from the coffin"

Outcomes of intramedullary nailing of femur fractures: a comparison of anterograde- and retrograde nails

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DECLARATION PAGE

I, Johann, Abraham, Christoffel Groenewald hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce this work for the purpose of research, either the whole or any portion of the contents, in any manner whatsoever. I further declare the following:

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This study was conducted under the supervision of Professor Maritz Laubscher, Department of Orthopaedic Surgery, University of Cape Town. As the candidate's Supervisor, I have approved this dissertation for submission.

The planned publication meets all requirements to be included in the dissertation, the planned journal is accredited by the department of higher education and training and the candidate is the first author on the paper; the candidate contributed the most to the paper, the candidate developed the protocol and wrote the paper under supervision; the candidate was involved in the analysis, presentation and interpretation of results; the other authors and their contributions to the paper are stated.

Signature: Signed by candidate **Date: 09/05/2024**

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A special word of appreciation to Shaun Linde who assisted with the data analysis and provided valuable statistical support.

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Finally I would also like to thank Robyn Waters for your kind guidance

throughout my manuscript evolution process.

Format Publication - ready format

Authors' Contributions

J Groenewald : data collection, data analysis, writing of manuscript
M. Laubscher: study design, data collection support, review and editing of manuscript
M. Held: review of manuscript
S. Maqungo: review of manuscript
N. Ferreira: review and editing of manuscript
S. Graham: review of manuscript
R. Waters: review of manuscript

LIST OF TABLES AND FIGURES

LIST OF ABBREVIATIONS

AFN : Anterograde Approach / Anterograde Femoral Nail

AIS : Abbreviated Injury Scale

BMI : Body Mass Index

CDC : Centre for Disease Control and Prevention

DRI : Disability Rating Index

EQ-5D : EuroQol Five-Dimensional Questionnaire

HIV : Human Immunodeficiency Virus

HOST : HIV in Orthopaedic Skeletal Trauma

IM : Intramedullary

RFN : Retrograde Approach / Retrograde Femoral Nail

RUST : Radiological Union Score for Tibial fractures

SSI : Surgical Site Infection

ABSTRACT

Background

Intramedullary (IM) nailing for femoral shaft fractures is the current most effective, gold-standard treatment modality for femoral shaft fractures in the adult population. In the past, intramedullary femur nails were primarily performed utilising the anterograde approach (AFN). Recently, the retrograde approach (RFN) has become an attractive alternative option. The retrograde approach requires no traction table during surgery, a viable solution where, in polytraumatized patients, multiple procedures might have to be combined. The retrograde insertion technique, conversely, utilizes a through-knee approach with potential injury to surrounding anatomical supporting structures of the knee. This approach also raises concerns about post-operative knee pain, stiffness and sepsis thus with a potential negative impact on functional knee scores.

Methods

This is a retrospective review of a prospectively collected database of the HIV in Orthopaedic Skeletal Trauma (HOST) Study database. Patients who had an anterograde or retrograde femoral nail done in the HOST study were included in our data collection. Our primary aim was to compare the outcomes of AFN vs RFN comparing health-related quality of life measures. The secondary aim of our study was to compare the RFN and AFN groups with regards to surgical time and the incidence of complications, these including the presence of post-operative infections documented during subsequent follow-up visits.

Results

196 patients underwent intramedullary nailing for diaphyseal femur fractures that was included in the study. 125 of them had an AFN performed and 71 a RFN. There was no significant difference in the compared health-related quality of life measures and its surrogate categories that represented post operative knee function. Both the AFN and RFN nailing techniques effectively accomplished high union rates and adequate alignment. Infection fortunately occurred at a very low rate within both the two groups.

Conclusion

In the cohort of patients with femoral fractures treated with intramedullary nailing during the HOST study, anterograde - and retrograde femoral nails achieved similar outcomes with similar complication rates.

PART A: PUBLICATION-READY MANUSCRIPT

"Removing the nail from the coffin''

Outcomes of intramedullary nailing of femur fractures: a comparison of anterograde- and retrograde nails

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Abstract

Background

Intramedullary (IM) nailing for femoral shaft fractures is the current most effective, gold-standard treatment modality for femoral shaft fractures in the adult population. In the past, intramedullary femur nails were primarily performed utilising the anterograde approach (AFN). Recently, the retrograde approach (RFN) has become an attractive alternative option. The retrograde approach requires no traction table during surgery, a viable solution where, in polytraumatized patients, multiple procedures might have to be combined. The retrograde insertion technique, conversely, utilizes a through-knee approach with potential injury to surrounding anatomical supporting structures of the knee. This approach also raises concerns about post-operative knee pain, stiffness and sepsis thus with a potential negative impact on functional knee scores.

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196 patients underwent intramedullary nailing for diaphyseal femur fractures that was included in the study. 125 of them had an AFN performed and 71 a RFN. There was no significant difference in the compared health-related quality of life measures and its surrogate categories that represented post operative knee function. Both the AFN and RFN nailing techniques effectively accomplished high union rates and adequate alignment. Infection fortunately occurred at a very low rate within both the two groups.

Conclusion

In the cohort of patients with femoral fractures treated with intramedullary nailing during the HOST study, anterograde - and retrograde femoral nails achieved similar outcomes with similar complication rates.

Keywords

Anterograde intramedullary femur nail, Retrograde intramedullary femur nail, Knee function, Health-related quality-of-life measures, Infection, Non-union

Level of evidence: Level 3

Introduction

Intramedullary nailing is the current, gold-standard treatment of femoral shaft fractures in the adult population.(1–7) Historically, most femur nails were performed using AFN. RFN was developed specifically to address more distal, metaphyseal fractures. With time, the indications for RFN expanded, specifically because a traction table were unnecessary. Thus adding to the attractiveness of the approach, especially in polytraumatized patients where multiple procedures might have to be combined. Both these nailing techniques nevertheless, are known to demonstrate similar healing rates and time to union.(1,2,4,7,8)

With AFN, the use of a traction table can be time-consuming. The surgical insertion of the nail through the piriformis fossa or greater trochanter can also be difficult in obese or multiple-fractured patients.(1,2,9) Varus malalignment, lateral hip pain, Trendelenburg gait and heterotopic ossification are all complications following AFN.(3,10)

RFN utilises a through-knee approach with potential injury and damage to the anatomical structures within the knee joint. Some concerns about post-operative knee pain, stiffness, sepsis and the negative impact on functional knee scores exist.(6,8–10) Therefore, some surgeons suggest that a through-knee approach should only be used if really necessary.

Irrespective of the approach and nailing technique, the surgical goals should be aimed at achieving stability at the fracture site, preserving length, and restoring anatomical alignment and rotation to ensure the desired functional outcome.

It is our course of action to utilise a retrograde approach in any case where the surgeon determines that it may be beneficial, including:

- The multiple-injured patient where it is inconvenient to use a traction table
- Bilateral femur shaft fractures
- Obese patients
- Any case where the surgeon’s preference is the retrograde approach.

The primary aim of our study was to compare the outcome of RFN versus AFN, specifically comparing health-related quality of life measures; the well-established EuroQol five-dimensional questionnaire (EQ-5D), and the disability rating index (DRI). The DRI is a patient-reported outcome measure developed by Salén et al. in 1994. The EQ-5D is a popular generic, preference-based instrument which considers five dimensions of health. This including: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.
We were particularly interested in the post-operative knee function of our two study groups (AFN and RFN) – that is, identifying and analysing specific categories from the patient-reported outcome scores (EQ-5D and DRI) that acted as surrogates for the post-operative knee function.

We also established some secondary aims that we regarded as being essential for comparison, namely the surgical time and the incidence of complications such as post-operative malalignment, delayed- or non-union, as well as infection documented at the post-operative follow-up visits.

Patients and methods

This study was a retrospective cohort study of a prospectively collected database (HOST 1 Study database, HREC number 590/2016.) The HOST study was a multi-centre, prospective case-cohort study of participants undergoing intramedullary nailing of their tibia and femurs for fracture fixation. The main objective of the study was to determine if HIV infection is a risk factor in the development of non-union or delayed bone union following a fracture.

All the participants who had AFN or RFN intra-medullary nailing done for their femur fractures between September 2017 and December 2018 were included in our data collection. In the AFN group, there were 125 participants and 71 in the RFN group. Participants who were lost to follow-up were excluded from our data collection.

Recruited participants were followed up for a minimum of 12 months after their surgery to evaluate the effects of HIV on bone healing. Radiographs were performed post-operatively to determine the fracture classification, alignment and again at six weeks, at three, six, and nine months to assess union.

In the study, delayed union was defined as a fracture that had not healed at six months and a non-union as a fracture that had not healed at nine months. Clinically, a fracture was considered united if there was no associated pain with weight-bearing and range of motion of the affected limb with an accompanying return of function.

The Radiological Union Score for Tibial fractures (RUST), a validated X-ray scoring system that has proven to be an accurate tool with consistently good interobserver and intraobserver reliability was used to asses for radiographic union on standard AP and lateral radiographs that was requested at the follow up visits. A RUST score of ≥ 9 was classified as united.

'Superficial surgical site infection (SSI)' was defined using the Centre for Disease Control and Prevention (CDC) definition of a wound infection involving 'only the skin and subcutaneous tissue of incision' that occurs within 30 days of surgery (where day 1 = the procedure date). Deep surgical site infection was defined – using the CDC definition as one involving the tissues deep to the skin and subcutaneous tissue planes that occurs within 30 days of injury (closed reduction of fracture) or 90 days (open reduction of fracture) (where day 1 = the procedure date). Late implant infection was defined as any late wound breakdown (>30 days for closed reduction of fractures or >90 days for open reduction fractures), sinus formation or unexplained late pain with associated radiological changes consistent with peri-implant sepsis.

We also included and analysed patient demographics; body mass index (BMI); human immunodeficiency virus (HIV) status; polytrauma patients with significant traumatic injuries on presentation with a total injury severity score (ISS) of greater than equal to 16 or two injuries that are greater or equal to 3 on the abbreviated injury scale (AIS) with the inclusion of physiological parameters based on the international consensus; the presence of two fractures on presentation; fracture characteristics and grading; mechanism of injury; additional surgery added, and whether the fracture had been surgically opened to aid in fracture reduction.

Descriptive statistics were used to describe the dataset. The cases (retrograde nails) were compared to the control group (anterograde nails). The distributions of data were reported using means, proportions and the appropriate distributional measures (standard deviations and interquartile ranges). The data was tabulated employing an Excel spreadsheet and a comparison was made between the two treatment groups and their characteristics (RFN & AFN). Statistical analysis was performed using the Fisher's exact - and the Chi-square test to examine whether categorical variables were independent in influencing the tested statistic within the two groups; T-tests were used where the two groups' data parameters showed normal distribution, and the Mann-Whitney tests for non-parametric statistics.

Results

Insert table I here.

A retrospective review of the HOST 1 Study database identified 227 patients who underwent intramedullary nailing of their femur fractures; 86 had an RFN, and 141 had an AFN performed. In the AFN group, 16 patients, and 15 patients in the RFN group, were lost to follow-up and were excluded for the current study. A total of 196 patients were included in the study, comprising 125 in the AFN group and 71 in the RFN group.

The median age of the participants was 30.0 years (Interquartile range [IQR] 25-40 years) and the majority of the participants were male, 156 (78.8%). Participants had a median body mass index (BMI) of 23.0 kg/m2 (IQR: 20.1–26.4). With regard to the aforementioned demographics, no statistically significant difference was found between the two groups.

None in either group demonstrated any statistically significant difference with regards to the cause of injury, the femur fracture characteristics, left or right, open vs close and the Gustilo Andersen classification vs the Winquist & Hansen classification. This also including whether or not the fracture was opened during surgery to aid in fracture reduction.

In the RFN group, the average patient was frequently polytraumatized with an Injury Severity Index score (ISS) ≥16, RFN 41.1% and AFN 19.2% ($p=0.00151$); the patients in the RFN group had, more regularly, two fractures on presentation – RFN 38.4% and AFN 7.2% ($p<0.001$).

The patients in the RFN group more frequently undergone additional surgeries – (RFN 54.8% and AFN 18.4% ($p<0.001$) – in combination with the orthopaedic procedure (intramedullary femoral nail) since such patients were often more severely injured. The above findings were statistically significant with regards to retrograde femur nails being the favoured treatment modality in the polytraumatized patient with two fractures.

Health-related quality of life scores

Insert Figure 2 and 3 here.

There were no statistically significant differences between the two groups in any of the health-related quality-of-life scores (Table II and III). Even the specific dimensions (EQ-5D) and physical activities (DRI) that we identified as surrogates for the assessment and comparison of post-operative knee function showed no statistically significant difference between the two groups. These surrogates being: running ($p=0.589$), outdoor walks ($p=0.633$), climbing stairs ($p=0.195$), participating in exercise/sports ($p=0.668$) and from the EQ5D, mobility ($p=0.94$) and pain/discomfort ($p=0.367$).

Surgical time

The mean surgical time (hours) in the RFN group was 2.23 (SD 0.698), and 2.08 (SD 0.667) in the AFN group ($p=0.133$).

Infection

Infection occurred in 2.5% of cases (5 of 198). In the RFN group, one case of early, deep surgical site infection (1.4%) and in the AFN group, four cases of early infection – two being superficial- and two being deep-surgical site infections (3.2%). There was no late-onset implant infection recorded between the two groups. With regards to infection – early and late, superficial and deep – postoperatively, there was no statistically significant difference between the RFN and AFN groups ($p=0.65$).

Union, delayed union and non-union

In 187 out of 198 (94.4%) fractures united utilising the retrograde or anterograde intramedullary femoral-nailing technique, 71 out of 73 (97.3%) united in the RFN group and 116 out of 125 (92.8%) united in the AFN group. In the RFN group, eight (11%), and in the AFN group 15 (12%), had delayed union at the 6/12-month follow-up visit. Two (2.7%) patients in the RFN and nine (7.2%) in the AFN groups were clinically and radiographically (RUST score) evaluated as having a non-union at the 9/12-month follow-up visit. There was no statistically significant difference between the RFN and the AFN groups with regards to union (p=0.28), delayed union (p=1) and non-union (p=0.317) of the treated femur fractures post-operatively at the scheduled follow-up visits.

Malalignment

Malalignment was assessed on postoperatively taken radiographs (anteroposterior- and lateral x-rays) and was evaluated in the coronal and sagittal planes. Rotational malalignment and the presence of a fracture gap in millimetres (mm) were also assessed. Coronal malalignment was defined as being more than 5 degrees angulated and sagittal alignment as more than 10 degrees angulated. There were four cases (3.2 %) that had malalignment in the coronal plane (p=0.65) in the AFN group and two cases (2.7 %) – one in the coronal plane and one being rotationally malaligned (p=0.37) – in the RFN group. With regards to post-operative alignment and the comparison of the two intramedullary nailing techniques, there was no statistically significant difference between the RFN and AFN groups.

Discussion

Our primary aim was to compare health-related quality-of-life measures (EQ-5D and DRI) within the two study groups (AFN and RFN), and we specifically identified surrogate categories within these two patient-reported measures that would reflect on post-operative knee function and pain. We did not find any difference between the two groups with regard to the EQ-5D health-related quality-of-life scores in any of the tested dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Comparing the 12 items in the disability rating index questionnaire by Salén et al.(11) – intended to detect clinical changes in the patients' disability and to screen for impairment from pain in the hip or knee joint – there was no statistically significant difference between the two study groups.

This is a controversial topic with conflicting reports regarding the incidence of knee pain and function postoperatively. Holmenshager et al.(12) reported that the incidence of knee pain after retrograde intramedullary nailing was 32%; this finding was echoed by Ricci et al. (3) who found that the frequency of knee pain was significantly higher in their retrograde group (36%) compared to the anterograde group (9%). Tornetta et al.(2) found that knee pain was commonly reported by the retrograde group in the period soon after surgery. This, however, resolved in most cases, usually after the return of quadriceps strength: at the time of union of the fracture, there was no difference in knee pain between the two groups. An interesting finding was also mentioned in both the studies by Njoroge et al.(6) and Darglar et al.(9) who found a negative correlation between age and knee functional outcome regardless of the method of nailing used. This is probably related to the onset of arthritis with advanced age and the lack of enthusiasm towards post-operative rehabilitation. In contrast, Ostrum et al.(13) – in a prospective study of 100 consecutive femoral interlocking nails (54 retrograde and 46 anterograde) – reported that knee pain and knee motion were equal in both groups of patients –98.1% of the RFN group had knee flexion more than 120 degrees compared to 97.8% in the AFN group. In the findings of Yu et al.(1) the retrograde nailing technique did not result in significantly higher knee complications compared to the anterograde group. The results showed that the outcomes with regard to knee pain, swelling, knee flexion and extension deficits were similar in both groups. In our study, the surrogate categories that we identified that represented post-operative knee function showed no statistically significant difference between the RFN and AFN groups – that is, in the

DRI, running, outdoor walks, climbing stairs, participating in exercise/sports, and the EQ-5D, mobility and pain/discomfort.

With regard to the patient demographics, femur fracture characteristics and classification, the two groups (AFN and RFN) were evenly matched. The median age of the participants was 30.0 years, and the majority of the participants were male.

One of the significant results in this study demonstrated that, in the RFN group, 41.4% were polytraumatized and that 38.4% of these patients had two fractures on presentation. The patients in the RFN group also more frequently required additional surgery 54.8% , owing to them being more severely injured. The above findings suggest that surgeons at our institution more often select the RFN approach in polytraumatized patients and patients undergoing multiple procedures. This concurred with the findings of the prospective randomised trial by Tornetta et al.(2), and of the retrospective study by Durigan et al.(10). These studies also recommended the use of retrograde intramedullary nailing in multiply injured patients with possible bilateral or ipsilateral injuries that needed simultaneous fixation, or fixation through a single through-knee surgical approach.

In the review article by Ricci et al. (5), it is mentioned that surgical time was increased when a traction table was used during the anterograde intramedullary nailing of femur fractures. In our study, there was no significant difference between the groups in the mean surgical time – 2.23 hours (SD 0.698) in the RFN group, and 2.08 hours (SD 0.667) in the AFN group (p=0.133). The above finding in the AFN group, with a traction table assisted closed reduction, was not included in the surgical time in the AFN group.

Infection rates, noted in a large series by Malik et al.(14) of femoral shaft fractures treated with intramedullary nails, were low, ranging from 1%–3.8%. Theoretically, there is an increased risk of infection (septic arthritis) following the retrograde insertion technique of intramedullary nails utilising an intra-articular entry point, which is not used during AFN of femur shaft fractures.

In the cohort of Durigan et al. (10), four cases of infection (3.1%) were documented, three were septic arthritis of the knee, related to their retrograde intramedullary nail group and one chronic osteomyelitis related to their anterograde intramedullary nail group.

We observed in our study an infection rate of 2.5% (5 of 198): in the RFN group, one case of early, deep surgical site infection (1.4%) and, in the AFN group, four cases of early infection, two of which were superficial, and two deep surgical site infections (3.2%). Infection occurred at a low rate and was not affected by the insertion technique, or entry point, of the femoral nail within the RFN and AFN groups (p=0.65). Even in the RFN cases that developed sepsis, the sepsis did not progress to septic arthritis of the knee. According to the review article by Ricci et al. (5) the rate of non-union after nailing of femoral shaft fractures, regardless of the starting point, is low – usually <10 %. Tornetta et al. (2) documents in their prospective, randomized trial that equal rates of time to union may be related to the reaming, and the improved mechanics obtained by over-reaming the canal in all cases, whether retrograde or anterograde. In the meta-analysis conducted by Zhang et al.(8) and in the retrospective study by Chan et al. (1), all fractures treated with reamed intramedullary nailing – and both nailing techniques – resulted in high union rates. Our study produced similar results with a union rate of 94.4% (187 out of 198 fractures). In the RFN group 97.3 % united and in the AFN group 92.8 %. In the RFN group, eight (11%) and, in the AFN group,15 (12%) had delayed union at the 6/12-month follow-up visit. Two (2.7%) patients in the RFN and nine (7.2%) in the AFN groups were clinically and radiographically (RUST score) evaluated as having a non-union at the 9/12-month follow-up visit. There was no statistically significant difference between the RFN and AFN groups with regards to union (p=0.28), delayed union (p=1) and non-union (p=0.317) of the treated femur fractures at the scheduled follow-up visits.

Both nailing techniques provided satisfactory results with regard to alignment in the coronal, sagittal and axial planes that were assessed on standard anteroposterior and lateral x-rays taken postoperatively. Only four cases (3.2%) had malalignment in the coronal plane in the AFN group and two cases (2.7%) – one in the coronal plane and one with rotational malalignment in the RFN group – made both these intramedullary nailing techniques suitable for addressing various femoral shaft fractures. It is self-explanatory that specific fracture characteristics would also dictate and influence the surgical decision.

Limitations of our study include its retrospective design and the sub analysis of data that was not powered. The latter contributing to the fact that data needs to be cautiously analysed and interpreted.

Both the study groups were also remarkably similar with regards to patient demographics (age and gender).

Given these results, we propose that the surgical decision regarding insertion technique for IM nailing of different femoral shaft fractures should include the following relevant factors:

- Body habitus / Body mass index of the patient
- Associated injuries
- Fracture characteristics
- Patient positioning (considering the possibility of other surgical teams being involved simultaneously)
- Surgeon familiarity with implants and surgical technique.

Conclusion

In the retrograde and anterograde femoral nail groups, similar outcomes were achieved with regards to disability and health-related quality-of-life scores. Surrogate categories that was identified in the health-related quality-of-life measures to detect any difference in post operative knee function within the two groups, failed to do so. A well designed prospective multicenter study is however necessary that needs to include functional long term outcomes of the knee post operative following retrograde and anterograde intramedullary nailing. The study also utilising specific and directed knee scores to accurately assess patient knee function, range of motion, pain and satisfaction post operative.

In certain circumstances the retrograde approach was the preferred surgical technique in our study. This was dependant on the patients physiological state, the extent of the injuries according to the Injury severity score and whether the patient was to be involved in multiple surgical procedures.

Infection was not more prevalent with the retrograde surgical approach as previously suggested. Infection fortunately occurred at a very low rate within both the two groups. Both nailing techniques achieved high union rates and adequate alignment that concurs with and supports current literature findings.

With modern, meticulous surgical techniques and well-designed implants, good results can be obtained using either retrograde or anterograde approach (RFN or AFN) for various femoral shaft fractures with different demographics and fracture characteristics to evidently assist the surgeon in *“removing the nail from the coffin”.*

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I would like to thank my supervisor, Professor Maritz Laubscher,

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throughout my manuscript evolution process.

Format Publication - ready format

Authors' Contributions

J Groenewald : data collection, data analysis, writing of manuscript
M. Laubscher: study design, data collection support, review and editing of manuscript
M. Held: review of manuscript
S. Maqungo: review of manuscript
N. Ferreira: review and editing of manuscript
S. Graham: review of manuscript
R. Waters: review of manuscript

TABLES AND FIGURES

Table I: Demographics (N=198) study participants, comparing the outcomes of RFN vs AFN

Categories	AFN	RFN	Total	P.value
	(N=125)	(N=73)	(N=198)	
Age (Years)				
N	125	71	196	0,422
Mean (SD)	33.8 (12.2)	32.5 (10.2)	33.3 (11.5)	T-test
Median (IQR)	30.0 (25.0-40.0)	31.0 (25.0-39.0)	30.0 (25.0-40.0)	
Range	18.0-71.0	18.0-67.0	18.0-71.0	
Missing	0 (0%)	2 (2.7%)	2 (1.0%)	
Gender				
Female	23 (18.4%)	19 (26.0%)	42 (21.2%)	0,277
Male	102 (81.6%)	54 (74.0%)	156 (78.8%)	Chi-Square
Body Mass Index				
N	110	60	170	0,0266
Mean (SD)	23.2 (4.71)	25.1 (5.54)	23.9 (5.08)	T-test
Median (IQR)	22.5 (19.8-26.3)	24.1 (21.5-27.0)	23.0 (20.1-26.4)	
Range	15.7-43.7	17.3-47.5	15.7-47.5	
Missing	15 (12.0%)	13 (17.8%)	28 (14.1%)	
Body Mass Index Category				
Underweight (<18.5)	16 (12.8%)	3 (4.1%)	19 (9.6%)	0,10703
Normal (18.5-25)	58 (46.4%)	32 (43.8%)	90 (45.5%)	Chi-Square
Overweight (25-30)	28 (22.4%)	14 (19.2%)	42 (21.2%)	
Obese (30-35)	7 (5.6%)	9 (12.3%)	16 (8.1%)	
Extremely Obese (>35)	1 (0.8%)	2 (2.7%)	3 (1.5%)	
Missing	15 (12.0%)	13 (17.8%)	28 (14.1%)	
HIV Status				
Negative	105 (84.0%)	52 (71.2%)	157 (79.3%)	0,0503
Positive	20 (16.0%)	21 (28.8%)	41 (20.7%)	Chi-Square
2 Fractures on Presentation				
No	116 (92.8%)	45 (61.6%)	161 (81.3%)	<0.001
Yes	9 (7.2%)	28 (38.4%)	37 (18.7%)	Chi-Square
Fracture Side: Right/Left				
Right	68 (54.4%)	43 (58.9%)	111 (56.1%)	0,64
Left	57 (45.6%)	30 (41.1%)	87 (43.9%)	Chi-Square
Cause of Injury				
Low energy	12 (9.6%)	2 (2.7%)	14 (7.1%)	0,0884
High energy	9 (7.2%)	2 (2.7%)	11 (5.6%)	Chi-Square
MVA (car,motorbike)	37 (29.6%)	33 (45.2%)	70 (35.4%)	
MVA pedestrian	32 (25.6%)	15 (20.5%)	47 (23.7%)	
GSW	31 (24.8%)	21 (28.8%)	52 (26.3%)	
Sharp trauma	2 (1.6%)	0 (0%)	2 (1.0%)	

Blunt trauma	2 (1.6%)	0 (0%)	2 (1.0%)	
Fracture: Open/Close				
Open	39 (31.2%)	26 (35.6%)	65 (32.8%)	0,63
Closed	86 (68.8%)	47 (64.4%)	133 (67.2%)	Chi-Square
Gustilo Andersen Classification				
Type 1	33 (26.4%)	21 (28.8%)	54 (27.3%)	0,936778
Type 2	1 (0.8%)	1 (1.4%)	2 (1.0%)	Chi-Square
Type 3A	3 (2.4%)	3 (4.1%)	6 (3.0%)	
Type 3B	2 (1.6%)	1 (1.4%)	3 (1.5%)	
Type 3C	0 (0%)	0 (0%)	0 (0%)	
Missing	86 (68.8%)	47 (64.4%)	133 (67.2%)	
Winquist Hansen femur fracture classification				
Type 1	39 (31.2%)	17 (23.3%)	56 (28.3%)	0,766
Type 2	24 (19.2%)	15 (20.5%)	39 (19.7%)	Chi-Square
Type 3	30 (24.0%)	19 (26.0%)	49 (24.7%)	
Type 4	9 (7.2%)	6 (8.2%)	15 (7.6%)	
Missing	23 (18.4%)	16 (21.9%)	39 (19.7%)	
Polytrauma : Injury Severity score = 16				
No	101 (80.8%)	43 (58.9%)	144 (72.7%)	0,00151
Yes	24 (19.2%)	30 (41.1%)	54 (27.3%)	Chi-Square
Surgery Added				
No	102 (81.6%)	33 (45.2%)	135 (68.2%)	<0.001
Yes	23 (18.4%)	40 (54.8%)	63 (31.8%)	Chi-Square

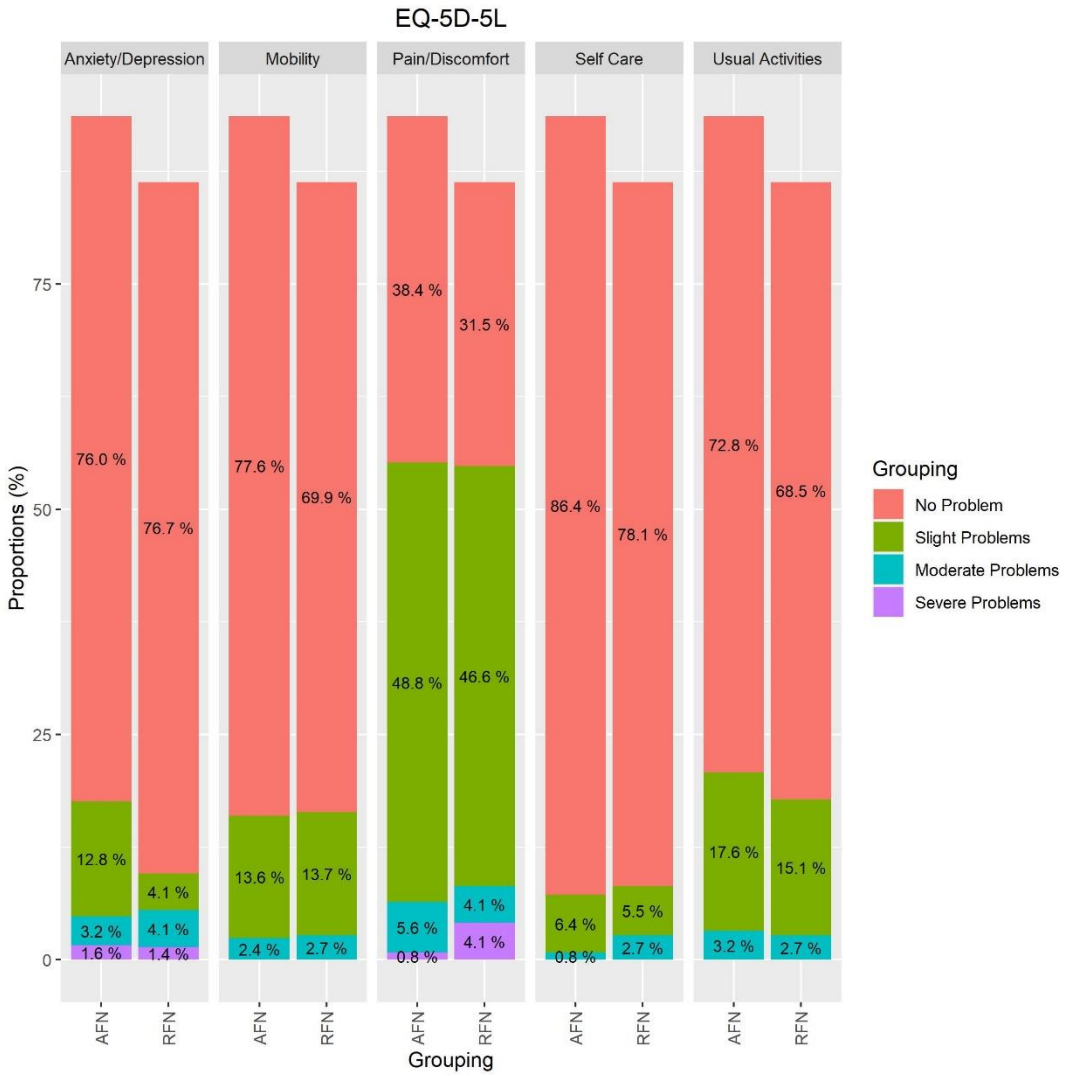

Figure 1: EQ-5D Stacked Bar for the study participants in the AFN and RFN groups respectively

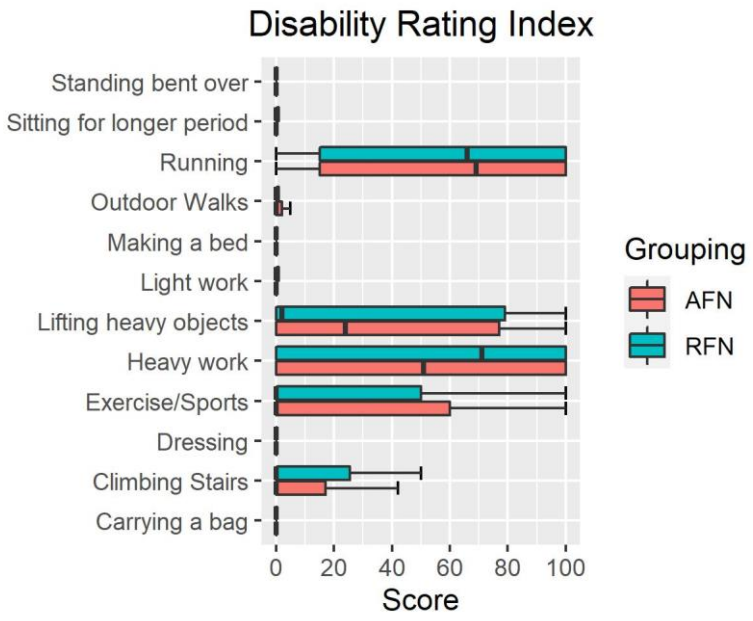

Figure 2: DRI box plot for the study participants in the AFN and RFN groups respectively

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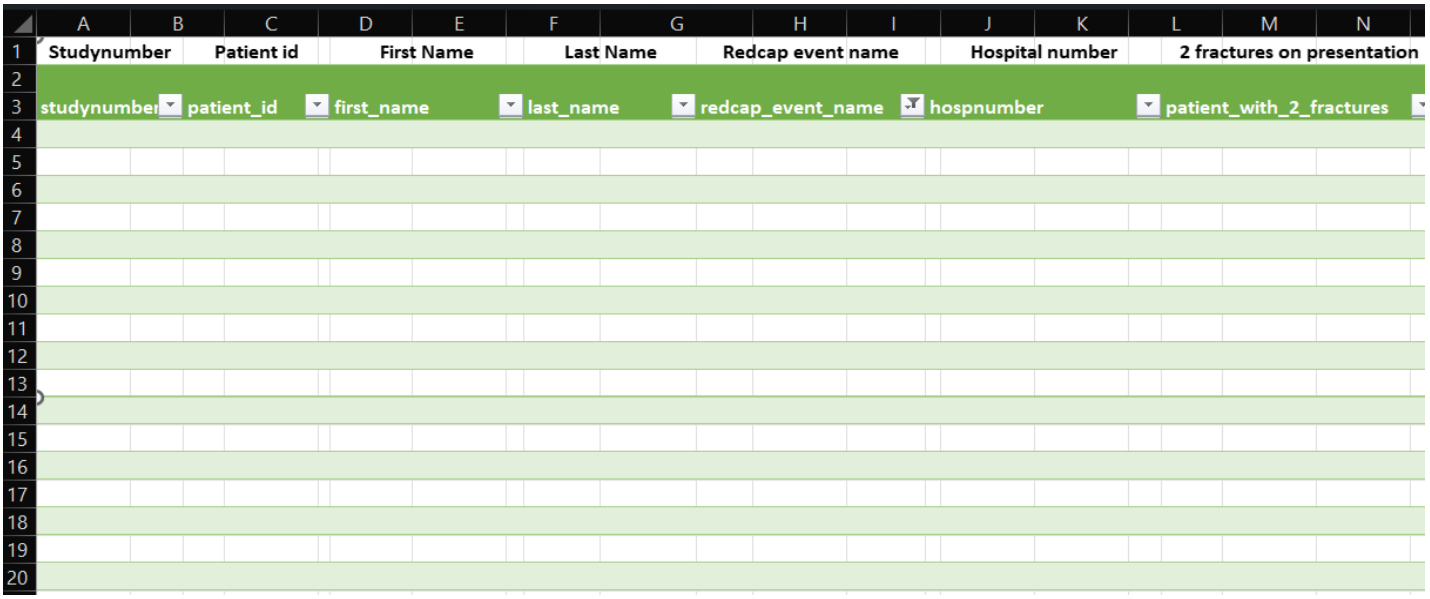
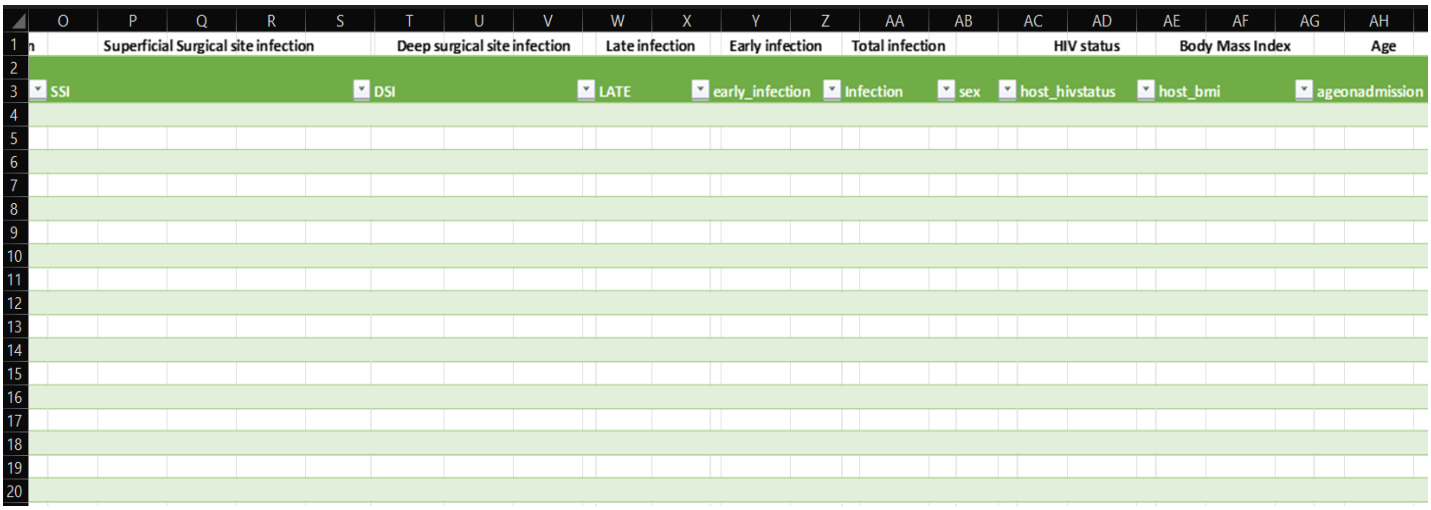
PART B: APPENDICES

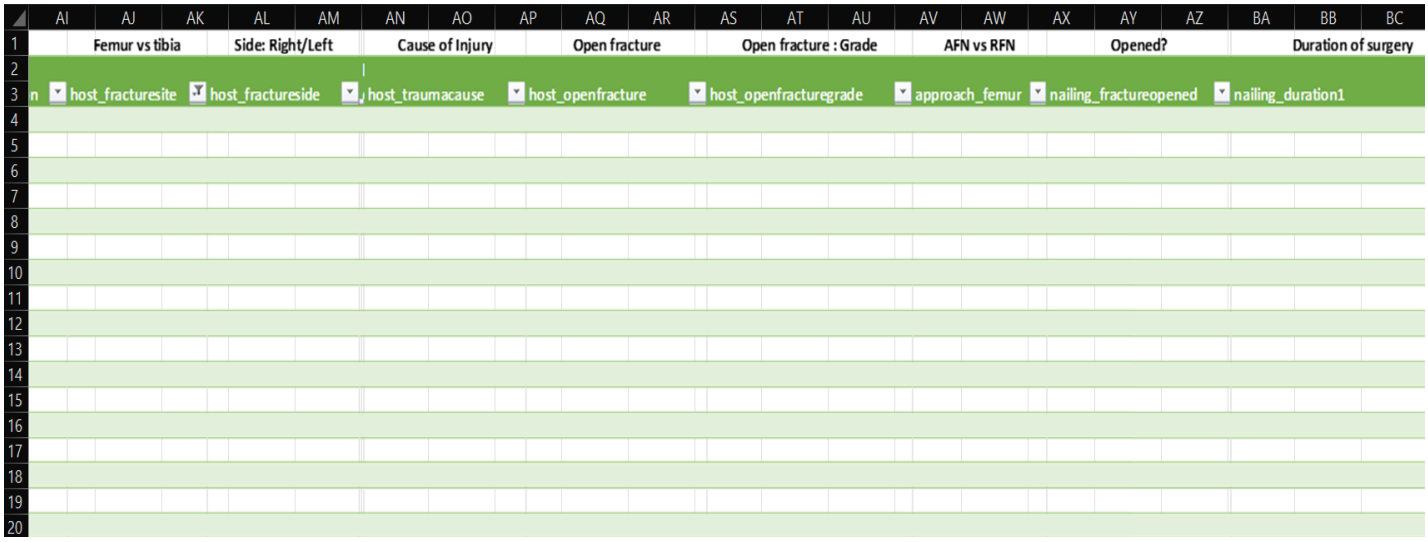
Data collection tables



Studynumber	Patient id	First Name	Last Name	Redcap event name	Hospital number	2 fractures on presentation
studynumber	patient_id	first_name	last_name	redcap_event_name	hospnumber	patient_with_2_fractures



Superficial Surgical site infection	Deep surgical site infection	Late infection	Early infection	Total infection	HIV status	Body Mass Index	Age
SSI	DSI	LATE	early_infection	Infection	sex	host_hivstatus	host_bmi	ageonadmission



Femur vs tibia	Side: Right/Left	Cause of Injury	Open fracture	Open fracture : Grade	AFN vs RFN	Opened?	Duration of surgery
host_fracturesite	host_fractureside	host_traumacause	host_openfracture	host_openfracturegrade	approach_femur	nailing_fractureopened	nailing_duration1

BD	BE	BF	BG	BH	BI	BJ	BK	BL	BM	BN	BO	BP	BQ	BR	BS	BT	BU	BV	BW	BX	BY
1	Intra operative complications				Intra operative complications specified					Add surgery?				Winquist Hansen femur fracture classification				Polytrauma : Injury Severity score ≥ 16			
2																					
3	nailing_intraop___99				nailing_intraopspec					nailing_anyaddsurgery		class_sev		win_han_class				class_sevscoreabove16			
4																					
5																					
6																					
7																					
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BZ	CA	CB	CC	CD	CE	CF	CG	CH	CI	CJ
1	6	Malalignment coronal plane >5			Malalignment sagital plane >10			Malalignment Rotational		
2										
3	malig_corplane5			maligsagittal10			malig_rotational			fracturegap
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										

ED	EE	EF	EG	EH	EI	EJ	EK	EL	EM	EN	EO	EP
1	Disability Rating Index Total score						EuroQol-5Dimension questionnaire					
2												
3	_total				dri_complete	eq5d_date					eq5d_typeofassess	
4												
5												
6												
7												
8												
9												
10												
11												
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16												
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18												
19												
20												

	FE	FF	FG	FH	FI	FJ	FK	FL	FM	FN	FO	FP	FQ	FR	FS	FT
1		EQ5D score		EQ5D visual analog scale			Union		Delayed Union at 6/12 follow up			Nonunion at 9/1+PR1:RR12 follow up				
2																
3		score		eq_5d_scale			outcome_union		outcome_union_delayed			outcome_nonunion				
4																
5																
6																
7																
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- The article falls within the scope of the journal.
- Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
- Results reported have not been published elsewhere.
- Conclusions are presented appropriately fashion and are supported by the data.
- The article is presented in an intelligible fashion and is written in standard English (British usage).
- The research meets all applicable ethical standards.
- The article adheres to guidelines provided in the instructions for authors section.

Guidelines for authorship

- Each author should participate and is responsible for the content and design of the study, the preparation of the manuscript and its revisions, and final approval.
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    2. Drafting the work or revising it critically for important intellectual content; AND
    3. Final approval of the version to be published; AND
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- Other 'contributors' or 'collaborators' can be acknowledged at the end of the manuscript together with their contribution. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g., "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript".
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Registration of clinical trials

- A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes.
- Clinical trials should be registered in a public trials registry in accordance with International Committee of Medical Journal Editors
- Trials must be registered and approved by the relevant authorities before the onset of patient enrolment.

- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

Reporting guidelines

- All articles should be prepared in accordance with the guidelines relevant to the study design, as described in the Equator Network Guidelines (https://www.equator-network.org/reporting-guidelines/)
- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

Reporting of statistics

In terms of the statistical reporting, the Equator Network advises on the use of the SAMPL guideline: https://www.equator-network.org/2013/02/11/sampl-guidelines-for-statistical-reporting/

The SAMPL guidelines provide two guiding principles

1. *"Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results."* When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as *P* values, which fail to convey important information about effect size.
2. *Provide enough detail that the results can be incorporated into other analyses.* This requires reporting the descriptive statistics from which other statistics are derived, such as the numerators and denominators of percentages, especially in risk, odds, and hazards ratios. Likewise, P-values are not sufficient for re-analysis. Needed instead are descriptive statistics for the variables being compared, including sample size of the groups involved, the estimate (or effect size) associated with the P-value, and a measure of precision for the estimate, usually a 95% confidence interval.

Some specific guidelines applicable to the SAOJ:

- Consistency is one of the most important factors in presenting a well-formatted, professional manuscript.
- The nature of the measurements and variables reported on will often dictate the amount of precision required. Report numbers - especially measurements? with an appropriate degree of precision. For ease of comprehension and simplicity, round to a reasonable extent.
- The recommendation is to report the number of decimals that have both clinical and statistical meaning and consistently reporting all other variables in the same manner.
- Note: Generally, for descriptive purposes, percentages are reported as whole numbers except when dealing with really large sample sizes
- At least for the primary outcomes, report a measure of precision (a confidence interval).
- Although not preferred to confidence intervals, if desired, *p* values should be reported as equalities to three decimal places (e.g., $p = 0.031$ and not as inequalities: e.g., $p < 0.05$). Do NOT report NS; give the actual *P-value*. The smallest *P*-value that needs to be reported is $P < 0.001$.
- Report numerators and denominators for all percentages
- Summarize data that are approximately normally distributed with means and standard deviations (SD). Use the format: mean (SD) not mean ?

- Summarize data that are not normally distributed with medians and interpercentile ranges, ranges, or both.
- Do NOT use the standard error of the mean (SE) to indicate the variability of a data set. Use standard deviations, inter-percentile ranges, or ranges instead.

Formatting examples:

- $p = 0.028$ or $p < 0.001$
- (43% vs 21%; p = 0.002)
- (odds ratio (OR) 0.38; 95% confidence interval (CI) 0.71 to 1.82; $p = 0.822$) or after first use (OR 1.62; 95% CI 1.41 to 1.86; $p < 0.001$)
- *Descriptive stats normal distribution:* mean age 36 years (SD 4 years) or 36 years (SD 4; range 40 to 97 years)
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- *Descriptive stats percentage:* (149 of 202; 74%)

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- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

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- Use no more than three levels of displayed headings.

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- Define abbreviations and acronyms at first mention and use consistently thereafter.

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- Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

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- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3, etc.
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- Figures should be clear and easily understandable with a full descriptive legend stating any areas of interest and explaining any markings, letterings or notations. All figures and figure legends should be understandable as a stand-alone item, without having to read the main body of the text.
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Ideally, the names of all authors should be provided, but the usage of *et al*. in long author lists (more than six authors) will also be accepted: Fong K, Truong V, Foote CJ, *et al*. Predictors of nonunion and reoperation in patients with fractures of the tibia: an observational study. *BMC Musculoskelet Disord* 2013;**14**:103.

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Caetano-Lopes J, Lopes A, Rodrigues A, *et al*. Upregulation of inflammatory genes and downregulation of sclerostin gene expression are key elements in the early phase of fragility fracture healing. *PLoS One* 2011;**6**:e16947.

Web reference (with authors):

Cierny G, DiPasquale D. Adult osteomyelitis protocol. http://www.osteomyelitis.com/pdf/treatment_protocol.pdf.

(date last accessed 05 March 2013).

Web reference (no authors listed):

No authors listed. International commission on radiological protection. http://www.icrp.org (date last accessed 20 September 2009).

Chapter in a book:

Young W. Neurophysiology of spinal cord injury. In: Errico TJ, Bauer RD, Waugh T (eds). *Spinal Trauma*. 3rd ed. Philadelphia: JB Lippincott; 1991: 377-94.

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- Figures (with legends), each figure as a separate file.

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- The title should be concise and informative.

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The authors confirm that all authors have made substantial contributions to all of the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- The drafting of the article or its critical revision for important intellectual content.
- Final approval of the version to be submitted.

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'The authors declare they have no conflicts of interest that are directly or indirectly related to the research.'

Funding sources

All sources of funding should be declared. Also, define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; and the decision to submit the manuscript for publication.

List all funding sources as follows:

'This work was supported by the xxxx (grant numbers xxxx, yyyy).'

When funding is from a block grant or other resources available to a university, college or other research institution, submit the name of the institute or organisation that provided the funding.

If no funding was received, state as follows:

'No funding was received for this study.'

Compliance with ethical guidelines

- For all publications:

'The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.'

Available from: http://publicationethics.org/resources/international-standards-for-editors-and-authors

Institutional Review Board (IRB) ethical approval must have been given if the study involves human subjects or animals. Please provide the approval number. IRB documentation should be available upon request.

'Prior to the commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number*'

- For studies with human subjects include the following:

'All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.'

'Informed written consent was or was not obtained from all patients for being included in the study.'

'Consent was obtained from patients for the use of clinical photographs and these images were adequately anonymized'

- For studies with animals, include the following sentence:

'All institutional and national guidelines for the care and use of laboratory animals were followed.'

- For articles that do not contain studies with human or animal subjects:

'This article does not contain any studies with human or animal subjects.'

- If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. If any identifying information about patients is included in the article, the following sentence should also be included: Additional informed consent was obtained from all patients for which identifying information is included in this article. The Helsinki Declaration 2008 can be found at http://www.wma.net/en/30publications/10policies/b3/

Please provide the names and email addresses of two reviewers.

Title Page Example

Title of Submission

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Declarations:

Authorship

The authors confirm that all authors have made substantial contributions to all of the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- The drafting of the article or its critical revision for important intellectual content.
- Final approval of the version to be submitted.

Sound scientific research practice

The authors further confirm that:

- The manuscript, including related data, figures and tables, has not been previously published and is not under consideration elsewhere.
- No data have been fabricated or manipulated (including images) to support conclusions.
- This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami-publishing').

Plagiarism

The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.

- No data, text or theories by others are presented as if they were the authors' own.
- Proper acknowledgements of others' work have been given (this includes material that is closely copied, summarised and/or paraphrased); quotation marks are used for verbatim copying of material.
- Permissions have been secured for copyrighteed material.

Conflict of interest statement

John Smith declares that he has no conflict of interest. Paula Taylor has received research grants from Drug Company A.

Funding sources

No funding was received for the purposes of performing this study.

Compliance with ethical guidelines

The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.

Prior to the commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number.*

All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Informed written consent was or was not obtained from all patients for being included in the study.

Consent were obtained from patients for the use of clinical photographs/ and these images were adequately anonymised.

Author Name	**Signature**	**Date**
J Smith		15/8/2017
P Taylor		16/8/2017

Blinded manuscript

To ensure a blinded review, the main body of the manuscript should not contain any identifying information, including author's names, institutions or affiliations. Please do not include the name of the ethics committee, this information should be provided in the title page.

Abstract

- A structured abstract (maximum of 350 words) summarising the most important points in the article is required.
- The abstract consists of four paragraphs with the subheadings:
    - Background (must include the aim of the study)
    - Patients and methods
    - Results
    - Conclusion
- References should be avoided. Avoid uncommon abbreviations. If essential, they must be defined at their first mention in the abstract itself.

Keywords

- Immediately after the abstract, provide a maximum of six keywords using standard searchable terms. These keywords will be used for indexing purposes.

Level of evidence

- Level 1 to 5.
- Please follow the level of evidence guidelines provided by the Oxford Centre for Evidence-Based Medicine (OCEBM); version 2.1.
- Available from: OCEBM Levels of Evidence Working Group. 'The Oxford Levels of Evidence 2'.Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653

Introduction

- The introduction should contextualise the study by providing the background to the research; explain the problem that is to be addressed, and provide the rationale for the study.
- Briefly outline the relevance of the study with respect to the current literature. Avoid a detailed literature survey or a summary of the results.
- The last sentence should outline the research question or hypothesis.

Patients (or Materials) and methods

- State the methods, outcome measures, and selection criteria. The following aspects need to be described:
    - The study design and research methodology
    - Whether randomisation (with methods) was applied
    - If case-controlled, how the controls were selected
    - The time period under review
    - Number of patients/subjects under investigation and why this number was chosen
    - Inclusion and exclusion criteria
    - Case and outcome definitions
    - A description of the procedure or intervention, including post-operative protocol
    - The outcome measures or scores used
    - The minimum follow-up period
    - Statistical analysis paragraph. This should be included at the end of this section to detail statistical tests and package used, the reasons why these tests were used, and what p-value was considered statistically significant. A power analysis is recommended for studies comparing two or more groups.
- Provide sufficient detail so that another researcher can replicate the study.
- The reader should understand from this description all potential sources of bias such as referral, diagnosis, exclusion, recall or treatment bias. This includes the manner in which investigators selected the patients. Consecutive inclusion implies all patients with a given diagnosis are included, while selective implies patients with a given diagnosis but selected according to certain explicit criteria (e.g., state of disease, choice of treatment).
- Do not describe standard procedures for common operations. Only include new procedures or adaptations to standard procedures.
- If you name any specific product, it requires the manufacturer's name, city and state/country.
- Present information in the narrative format and use the past tense.
- Where relevant, tables or figures may be included to provide information more clearly.
- Generally, no data should be presented in this section.

Results

- Describe the relevant results and analysis thereof.
- Provide details of the number of patients included and excluded, as well as the reason for exclusion.
- It is important to state the follow-up period (mean and range).
- The results can be broken down into separate sections, e.g. Treatment, Functional outcome, Complications, etc.
- Tables may be used but avoid repeating data reported in the text in the tables.
- All appropriate data should be presented as means with ranges, not with standard deviations (SDs). Medians should only be used when the data is skewed, accompanied by an interquartile range (IQR).
- Avoid using percentages in studies involving well under 100 subjects.
- All results must be backed up with p-values or survivorship analysis. All Kaplan-Meier data should be presented with confidence intervals. Always present exact absolute p-values, whether significant or not, unless $p<0.001$.
- However, *P-values* do not always convey the entire picture and where relevant, the confidence interval will also be required (in addition to the power of the study reported in the methods section).

Discussion

- The question or hypothesis stated at the end of the introduction should be discussed and either supported or rejected.
- The results must be interpreted clearly, and any deficiencies expressed. All possible confounding factors, sources of bias or weaknesses in the study should be identified.
- Explore the significance of the results of the work rather than repeating the results.
- The discussion must point out the relevance of the work described in the paper and its contribution to current knowledge.
- Explain what can be deduced from the results and how will it affect clinical practice.
- Include a review of the relevant literature, placing the results of the study in the context of previous work in this area.
- Discussion of relevant prior research and references must be concise. Avoid extensive citations and discussion of published literature emphasize previous findings that agree (or disagree) with those of the present study.
- Do not repeat the introduction.
- Present the limitations of the study and suggest how the study could have been improved for a future study.
- Avoid making inferences from non-significant trends unless you believe your study is adequately powered to answer the question; in that case, provide a power analysis.

Conclusion

- Provide a summary statement that conveys the conclusions of the findings.
- Do not draw conclusions not supported by the data obtained from the specific study presented.

Ethics statement

- For studies involving human subjects, please include an ethics statement as follows: ‘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.’

- For animal studies, please include the following ethical statement: 'All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.'
- If the study did not involve human or animal subjects, state that: 'This article does not contain any studies with human participants or animals performed by any of the authors.'
- Please also include an informed consent statement: 'Informed consent was obtained from all individual participants included in the study.'
- Alternatively, for retrospective studies, please add the following sentence: 'For this study formal consent was not required.'
- If identifying information about participants is available in the article, the following statement should be included: 'Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.'

Acknowledgements

- Acknowledgements should be placed at the end of the discussion and before the references.
- In this section, persons who were involved but did not earn authorship can be acknowledged.
- Statements should be brief. A person can be thanked for assistance or comments.
- Do not include contributions by editors or referees.

Author contributions

- Please state the contributions of each author
- For example: 'A.B contributed to the study conceptualisation, design, data analysis and manuscript preparation. C.D. contributed to data collection and manuscript preparation. E.F. contributed to ….'
- The types of contributions are:
    - Conceptualisation and design
    - Data collection or contribution
    - Data analysis
    - Manuscript preparation
    - Other contributions (please specify)

References

- Please refer to the section on Formatting of submissions.

Tables and figures

- Tables and figures should not be imbedded in the text file but should be submitted as separate individual files. Each table should be a separate file, entitled Table I, Figure 2, etc.
- Each table and figure should be provided with a heading or legend.
- Please refer to the 'Formatting of submission' section for further guidelines.

Case reports

In addition to the preceding guidelines the following applies:

- The following headings need to be adhered to in the body of the manuscript:
    - Abstract
    - Keywords
    - Background
    - Case report
    - Discussion

    - Conclusion
    - Ethics statement
    - References

- Abstract: Minimum 250 words (350 maximum), using the following headings:

    - Background
    - Case report
    - Discussion
    - Conclusion
- Statement of informed consent must be included in the ethics statement.

Current Concepts Review Article (by invitation only)

General Guidelines:

- A narrative review will suffice (and systematic or scoping review not necessary)
- A thorough literature review needs to be done prior to writing the manuscript to ensure that the author is well acquainted with the current concepts related to the topic (with emphasis on the most recent developments)
- A balanced and unbiased view of the current clinical aspects of the topic.
- Focus on clinical aspects like diagnosis and treatment.
- Discuss controversies and state both sides of the argument.
- Avoid extensive discussion of basic science (anatomy/physiology/pathology) aspects, except for some really novel and clinically relevant new developments in the field.
- The topic may be adapted, but only with the permission of the Editor-in-Chief.

Outline of Article:

- Abstract = One paragraph, no headings, ≤350 words.
- Introduction = Brief introduction to the topic
- Contents = Please use headings (in bold) and sub-headings (in italics) to structure the manuscript in a reader-friendly manner
- South African context = Discuss matters which may be particularly relevant or unique to the South African clinical setting.
- Learning points = Make use of tables to summarize important learning points
- Conclusion = Brief evidence-based conclusion and summary
- Conflict of interest statement
- References = As usual

DRC AND HREC APPROVAL LETTER

UNIVERSITY OF CAPE TOWN

Department of Surgery
Departmental Research Committee
A/Prof Maritz Laubscher
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Observatory 7925
South Africa
Tel (021) 404 5108
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17 Jul 2022

Dr J Groenewald

Department of Surgery
University of Cape Town

Dear Dr Groenewald

RE: Project 2022/074

PROJECT TITLE:
Outcomes Of Intramedullary Nailing Of Femur Fractures: A Comparison Of Retrograde Versus Anterograde Nails

The above protocol has been reviewed by the Department of Surgery Research Committee. I am pleased to inform you that the committee approved the scientific merit of the study, and endorse the protocol for submission to the relevant ethics committee.

Although this letter serves as confirmation that the above protocol has successfully passed through the surgical DRC, respective ethics committees still require DRC chair signature before submission.

Please use the above project number in all future correspondence,

A/PROF MARITZ LAUBSCHER
CHAIR SURGICAL DRC

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.01.2025
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	1/2/2024

Note: Please email this form and supporting documents (if applicable) in a combined pdf file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown.
Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

HUMAN RESEARCH ETHICS COMMITTEE
31 JAN 2024
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	29/01/2024		
HREC REF Number	590/2016	Current Ethics Approval was granted until	30/01/2024
Protocol title	Fracture healing in HIV positive patients – HIV in Orthopaedic Skeletal Trauma Study (HOST study)		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes	x No	
If yes, could you please provide the HREC Reference number for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Prof Sithombo Maqungo		
Department / Office Internal Mail Address	Division of Orthopaedic Surgery, H49 OMB, Groote Schuur Hospital Marilyn van der Berg, (021) 404 5108, marilyn.vanderberg@uct.ac.za		

1.1 Does this protocol receive US Federal funding?	☐ Yes	x No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)