Determining pull-out strength for screws engaging posterior cortex, compared to screws placed into the tibia metaphysis for medial malleolus ankle fractures. A comparative cadaver model.

By

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DECLARATION

I, Gerhard Petrus Conradie, hereby declare that the work submitted here is the result of my own independent investigation. Where help was sought it was acknowledged. Further I declare that this work is submitted for the first time at the University and Medical faculty towards a magister degree in Medicine in Orthopaedic Surgery and that it has never been submitted to any other institution for the purpose of obtaining a degree.

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Gerhard Petrus Conradie **Date**

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- My study leader, Dr Johan van der Merwe, for his continued guidance and support through all the steps in this project.

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- Department of Radiology for assistance with all radiography during the study.

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OVERVIEW OF RESEARCH REPORT

This research report for evaluation is structured in the format of a publishable paper. The publishable paper submitted is titled: Medial malleolus factures - are we fixing them correctly. This paper will be submitted to the South African Orthopaedic Journal (SAOJ) for consideration for publication after the work has been evaluated as part of the MMed research report. SAOJ author guidelines were followed and the article is presented here in the format required. The only deviation is that the paper is presented as a single document with tables and figures included. SAOJ author guidelines are attached as an appendix.

The researcher has included an introductory chapter in order to give a more comprehensive overview of the research conducted and methodology used. The protocol is not included for examination purposes since it had already been evaluated and approved within the Faculty of Health Sciences, University of the Free State, before the study commenced.

When compiling the article the author adhered to the "author Guidelines" as stipulated by the South African Orthopedic Journal" and hence tables explaining data collected and means are provided as appendices after the written article and are not placed within the text.

Ethics approval, data collections sheet and journal guidelines are included in the appendices.

CHAPTER 1: ORIENTATION TO THE STUDY

1.1 Introduction:

Ankle factures are one of the most common fractures in an Orthopaedic trauma unit. Typically some of the most junior surgeons are tasked with the management of these patients. Complications rates vary in the literature and have been reported to be between 1% and 20%.[1][2][3]

According to a study by Pincus, D et al the re-operation rates for Open Reduction Internal Fixation of ankle fractures (ORIF) is 19.6%. The majority of these can be attributed to poor local vascularity and circulation from tobacco use, Diabetes Mellitus, and old age. The Odds Ratio of repeat surgery for ORIF or Implant breakage is 2.17 (P=0.008).[4]

Taking this into account, it is clear that the majority of complications can be attributed to patients with poor bone quality, and the elderly. According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) Foundation, the recommended post-operative rehabilitation protocol for an ankle ORIF is non weight bearing mobilization for the first week after surgery, and this has to be extended for longer periods in osteoporotic bone.[5]

A study by Kammerlander et al.[6] has found that the elderly population find it difficult to keep these restrictions in weight bearing. Therefore a large proportion of this population will start early weight bearing, and increase the amount of strain placed on the fixation of an ankle fracture.

Changes in osteoporotic bone will appear firstly in cancellous bone and later in the cortices. With the decrease in bone mass, the recipient bed for a screw fixation is decreased in quality.[7] The pullout strength of a screw is dependent on the number of threads available for purchase into bone ,the depth of the thread and the caliber of the core of the screw. A cancellous screw has the following characteristics: a thin core, large threads, deep troughs and a decreased number of threads per inch. Cortical screws in general have a thicker core, with shallower threads but a higher thread count per inch. Due to these characteristics cancellous screws have better purchase in trabecular and osteoporotic bone.[8]

Due to the above named factors, the stability of the fixation is determined by the pullout strength of the screw. When we accept the quality of trabecular bone decreases in old age

and osteoporotic changes, and the prescribed screw for insertion is a partial threaded screw, then the options available to increase pullout strength is to increase the number of screws inserted, change the type of screw inserted, or attempt to increase the bone quality into which the screw is inserted.

Current practice is to inserted 2 cancellous screws into the metaphysis of the distal tibia for medial malleolus fixation.[5] This can be difficult in small bone fragments. Tension band wiring has also been advocated, but due to prominent implants and irritation, this fixation method are better for small avulsed fragments and severely comminuted fragments.

Previous authors proposed using a 3.5mm cortical full threaded screw, inserted to engage the lateral cortex of the distal tibia. By engaging the denser cortical bone of the tibia the pullout strength can be improved. This was a cadaver model and in vivo studies are not available to confirm a reduction in failure. In the study by Pollard et al. the screws were inserted from the medial malleolus engaging the opposite lateral cortex of the distal Tibia. This lead to a longer screw inserted. As the cortical screws are full threaded screws, the distal fragment need to be overdrilled. This leads additional intra-operative steps.[9]

According to the AO Manual using a screw of excessive length in the distal tibia gain poor purchase in the often sparse cancellous bone of the metaphysis.[5]

In our study we propose the use of a 4.0mm partial thread cancellous screw inserted from antero-inferior to supero-posterior across the fracture site of a medial malleolus. We postulate that the pullout strength can be improved when compared to the current practice of insertion into the tibia metaphysis.

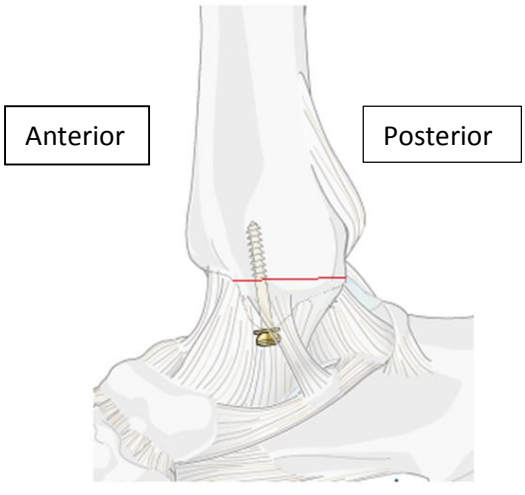

Figure 1: Current advocated insertion direction

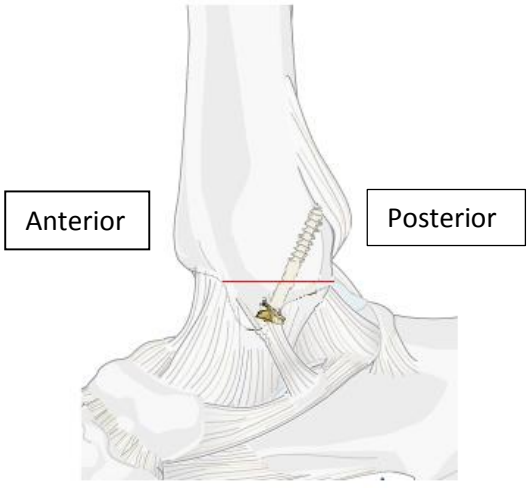

Figure 2: Proposed insertion technique

1.2 Aim:

The aim of the study was to establish if medial malleolus fixation could be improved by changing the angle of screw fixation and engage the posterior tibial cortex. This would increase the pullout strength of the construct and be advantageous to ankle open reduction internal fixation construct strength.

1.3 Objectives of the study:

To identify a difference in the pullout strength of a screw engaging the posterior cortex of the medial malleolus, compared to a screw inserted into the distal tibia metaphysis in a simulated medial malleolus fracture. The proximity of the screw tip to the posterior Tibialis tendon for screws engaging the posterior cortex was also measured and evaluated.

1.4 Study design:

This was a comparative study comparing the pullout strength of screws inserted in two different ways into cadaver ankles after a medial malleolus fracture was simulated. The proximity of the screw tip to the posterior tibial tendons were also evaluated.

1.5 Methodology:

To accurately compare the two fixation methods, they had to be compared in two ankles of similar bone quality. The simulated fracture had to be on the same level and of similar morphology. The applied stress across the fixation also had to be standardized to ensure uniformity.

All available cadavers were obtained from the department of anatomy after obtaining the necessary permission. The medial malleolus was approached with a direct medial approach. A transverse osteotomy was performed on the level of the tibia plafond simulating a Herscovici C isolated medial malleolus fracture using a 20mm osteotome.

Reduction of the osteotomy was performed with a pointed reduction forceps under direct vision. A hole was drilled in the desired direction and the depth measured with a depth gauge to obtain appropriate screw length.

On all cadavers the left medial malleolus was fixated using a 4.0mm partially threaded screw

that engages the posterior cortex of the tibia metaphysis. The right medial malleolus was fixated using a similar 4.0mm partially threaded cancellous screw, but care was taken to insert the screw into the metaphysis and not engaging the posterior cortex.

On all ankles the position of the screw was evaluated using image intensifiers obtained from the department of radiology and performed by a trained radiographer. For ankles where the screw engages the posterior cortex of the metaphysis, the posterior aspect of the tibia was dissected to identify the tip of the screw and measure the proximity of the screw to the neurovascular structures posterior to the ankle.

After placement of the screw, confirming its position and evaluating the proximity to any possible vital structures in the posterior compartment of the leg, the screw was connected to a traction scale. Axial traction was performed until failure of fixation. Fixation failure was defined, as distracting the screw from the bone, distracting the fracture reduction by more than 2mm, breakage of the screw, facture of the medial malleolus, or rotating the medial malleolus leading to loss of reduction. At the point of failure, the maximum force was measured and noted. This enabled the researcher to compare the difference in the strength of the fixation methods.

Measurements were taken for the left and right ankle of each cadaver in order to compare the fixation strength of the screws.

1.6 Sample:

To obtain as large a sample size as possible, all cadavers available in the dissection laboratory of the University were included in the initial process. A total of 13 cadavers, 26 ankles, were available. Cadavers excluded were those with previous lower limb amputations, lower limb fractures (Tibia fractures), and cadavers with previous ankle fractures and internal fixation. Cadavers with previous tibial fractures were excluded as the loss of stability would lead to uneven counter traction during the stress process of the fixation which would lead to inaccurate readings on the traction-scale used.

One cadaver was excluded due to a previous mal-united medial malleolus fracture with an implant in situ. The presence of the implant and remodelled bone would also lead to inaccurate results as our aim was to identify a difference in fixation strength in acute medial malleolus fractures and not revision surgery or non-unions. Two cadavers were excluded due to

fractures caused in the tibia during testing.

1.7 Measurement:

After the medial malleolus was osteotomized, the fixation was performed as stipulated. Screening was performed to ensure a perfect anatomic reduction of each malleolus, and to evaluate the location of the screw. The length of screw was noted. The length of protrusion of the screw tip from the posterior tibia was measured and the proximity of the screw tip to tendons posterior to the malleolus was measured with a depth gauge.

Once reduction was evaluated and the position and length measured, a traction scale was applied and axial traction performed on the screw over the fixation. For each ankle the direction of pull was in line with the anatomical axis of the tibia.

Axial traction was decided on over rotational force, as this study was to determine the difference in pullout strength between the 2 techniques of screw placement. It was clearly identified in the pilot study that a rotational force across the ankle would put more strain on the midfoot, joints and not give an accurate reading of the isolated strength of the screw fixation itself. This would lead to inaccurate results.

An inversion and eversion force over the ankle would put more stress on the ankle syndesmosis and failure would be seen in the ligamentous complex around the cadaver ankle and not necessarily in the medial malleolus fixation. Hence an accurate indication of fixation could not be derived from stressing the ankle in this manner.

Traction was performed by attaching a traction scale to the screw head. Traction was slowly increased to the point where failure of fixation was obtained as previously discussed. At the point of failure the maximum reading on the scale was noted and this was taken as the maximum pullout strength of the screw inserted. These readings taken were evaluated and compared in the data analysis.

1.8 Methodological and measurement errors:

The quality of bone used was dependent on the cadavers available. The cadavers available for this study were embalmed, and not fresh thawed. Hence the bone quality could be less than in live bone. A study by Topp[10] however, showed that there are no difference in thawed

versus embalmed bone for mechanical testing. For each cadaver the fixation strength was compared between the two ankles in the same cadaver in order to ensure the quality of bone would not impact on the different fixation methods.

The angle of traction chosen was done to isolate the fixation strength of the medial malleolus and to isolate the pullout strength of the screw. We chose not to use rotational or angular forces as this would also test other stabilising structures of the ankle joint. The aim was to identify the difference in strength of the pullout force for the medial malleolus screw as a contribution to an ankle open reduction internal fixation.

The measurements that was taken, gives a representation for a single static force applied over the medial malleolus fixation. We concede that the fixation in a real life situation could fail due to repetitive stress. This however would be very difficult to test in vivo in order to give an accurate representation of subsequent failure. In vivo we will also find healing of the fracture over the initial 3 to 6 week period that would reconstitute the integrity of the medial malleolus and lessen the stress placed on the screw up to the point of union, where no stress would be applied on the fixation.

It would be a reasonable deduction that there should be a relation to the initial pullout strength of a screw and its ability to resist repetitive motion as mode of failure. We must also consider the fact that if the pullout strength is improved over a single event between the 2 fixation methods, the strength would also be increased for repetitive stress cycling for example during non-weight bearing gait in a patient. As previously stated however, this would be difficult to accurately demonstrate in a cadaver model and, in vivo testing would need to be performed.

1.9 Pilot study:

A pilot study was conducted on 2 cadavers to identify any technical difficulties related to the measurements of the pullout strength. During this process it was identified that a pure axial force would give the most accurate reading for the screw pullout. The medial malleoli were osteotomized and fixated as stipulated in the methodology section and imaging obtained with an image intensifier to confirm optimal imaging quality to ensure optimal screw placement.

Tension was applied over the fracture site and measured with the traction scale to ensure an accurate reading could be obtained. During the pilot study it was identified that no major problems existed in the technical aspects of the measurements of the pullout strength if a

pure axial force was applied on the screw fixation.

1.10 Data analysis:

All data was collected on a data form. Statistical analysis of all data was performed by the Department of Biostatistics UFS.

Statistical analysis:

Statistical calculation was performed using SAS Version 9.3. Results were summarized by frequencies and percentages (categorical variables) and means. Placement methods were compared using 95% confidence intervals for paired differences in means, with appropriate paired t-test.

1.11 Budget:

The necessary equipment needed to perform the dissection and osteotomies were provided by Universitas hospital. The traction scale was provided by the lead author. Radiographic equipment, including the radiographic image intensifier and all protective clothing, including lead aprons and thyroid shields, were provided by the department of Radiology of Universitas hospital. Imaging was performed by trained radiographers from this department.

The consumables (i.e 4.0 mm partially threaded cancellous screws) were sponsored by Johnson and Johnson.

All cadavers were provided by the department of Anatomy of the UFS.

1.12 Ethical considerations:

Approval for the study was obtained from the ethics committee of the University of the Free State. Consent was obtained from the department of anatomy to work on the cadavers available in the university. All human tissue was handled with the utmost respect while performing the data collection. Tissue was disposed of by the department of anatomy according to their ethical guidelines after completion of the study.

The anonymity of all cadavers included in the study was maintained throughout the study. Identifiable numbers on the cadavers were not included and all cadavers were given a different number to identify the test subject during the course of data collection and further analysis of

the data. The cadavers included in the study were numbered from 1 to 12.

Protective clothing was made available for all persons present while performing screening of the cadavers in the department to maintain safety as stipulated by the radiation board.

1.13 Implementation:

The value of this study was to identify if the fixation of medial malleolus fractures could be improved by altering the direction of the screw used to engage the posterior cortex of the tibia, for fixation as stipulated by the AO manual. By improving the pullout strength of the medial malleolus screw, we could increase the strength of fixation of an ankle ORIF.

Even though the medial malleolus fixation would only be a part of the overall fixation in an unstable ankle fracture, increasing the pullout strength of the medial structures in an ankle open reduction internal fixation, could increase the overall strength of fixation in an unstable fracture, leading to less implant failure with mal-union.

CHAPTER 2: PUBLISHABLE ARTICLE

Title:

MEDIAL MALLEOLUS FRACTURES - ARE WE FIXING THEM CORRECTLY?

Format:
As for submission to the South African Orthopaedic Journal

Medial malleolus fractures - Are we fixing them correctly?

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Declaration

I, Gerhard Petrus Conradie, hereby declare that all named authors made a significant contribution to the concept and design of the study, acquisition of data and the analysis thereof. The authors further confirm that the manuscript, including related data, figures and tables have not been previously published and is not under consideration elsewhere. No data has been fabricated or manipulated to support conclusions made. The submission does not represent part of a single study that has been split into smaller articles to increase the number of submissions by the author. The author further confirms that the work submitted is the original work and does not transgress the plagiarism policy of the journal.

The author declares that he has no conflict of interest.

The authors 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.

Ethical approval has been obtained from the Ethics committee of the Faculty of Health Sciences, University of the Free State. Reference no: **ECUFS NR69/2014**

Abstract

Aim: Failure of fixation of an ankle fracture is common in bone of poor quality. Improving the strength of fixation could lead to better results.

The aim of this study is to evaluate if the pullout strength of a medial malleolus screw can be increased if it is inserted in such a way that the screw engages the posterior metaphyseal cortex of the tibia.

Method: Comparative study on 13 cadavers, fixing a medial malleolus osteotomy with a 4.0mm partial threaded cancellous screw. The right ankle of each cadaver was fixed with a screw engaging the posterior metaphysical cortex, the left ankle was fixed with a screw only engaging the trabecular metaphyseal bone. Axial traction was applied to the screw until failure of fixation occurred. Failure being defined as 2mm distraction over the fracture site. Axial traction was applied with a traction scale calibrated in kilograms.

Results: In all ankle osteotomies an anatomic reduction was achieved. The mean strength was 87.66N for metaphysical purchase screws, compared to 208.88N for cortical Purchase screws. (p-value 0.002). For screws inserted not engaging the posterior cortex of the tibia, the lowest recorded pullout strength was 15.69N. The maximum recorded pullout strength, for a screw not engaging the cortex, was 181.42N. For screws engaging the posterior tibia cortex the minimum recorded pullout strength was 72.57N and the maximum recorded 414.82N.

Conclusion: The results show a significant improvement in the pullout strength of medial malleolus screws inserted to engage the posterior tibia cortex.

Key words:

Cadaver, Medial Malleolus, Pull-out strength, Non-union, Mal-union, ankle, Fracture

List of Abbreviations:

AO	Arbeitsgemeinschaft für Osteosynthesefragen
BMD	Bone mineral density
NIDDM	Non-insulin dependent Diabetes Mellitus
N	Newton
ORIF	Open reduction internal fixation

List of appendices:

Appendix A: Illustration of Herscovici classification for medial malleolus fractures

Appendix B: Screw inserted not engaging posterior tibia cortex

Appendix C: Screw inserted engaging posterior tibia cortex

Appendix D: Graphic representation of the difference in pullout strength between two fixation methods

Appendix E: Complete description of data obtained

Appendix F: Summary of data

Introduction

Ankle fractures are among the most common fractures in orthopaedics, with an incidence of 107 per 100 000 population in Finland reported in 1998,[1] and 187 per 100 000 people per year reported in Rochester Minnesota.[2] A bimodal distribution is seen with the highest incidence reported as sports injuries in men below the age of 50 and low energy injuries reported in females over the age of 60.

Obesity, Non-insulin Dependent Diabetes Mellitus (NIDDM), and poor bone quality were identified as clear risk factors for fractures of the ankle.[3]

More than 50 % of the above named cases were deemed unstable and admitted for surgery.

Of all ankle fractures treated with open reduction internal fixation (ORIF) we find that roughly 1% of ankle surgery will need re-operation for failure of reduction due to implant failure or fixation failure. Open fractures, peripheral vascular disease and DM has been identified as risk factors for fixation failure.[3]

The medial structures that includes the deltoid ligament and medial malleolus, play a vital role in the stability of the ankle in bi- and tri-malleolar fractures.[4][5] Therefore surgical fixation of the medial malleolus is imperative in these circumstances.

It has been shown that failure typically occurs due to a poor pullout strength. This can be attributed to poor bone mineral density found in smokers, patients with peripheral vascular disease, diabetes mellitus and old age.[6]

Current practice, as suggested by the Arbeitsgemeinschaft für Osteosynthesefragen (AO) foundation, stipulates that a medial malleolus fracture be fixed with two 4mm cancellous screws perpendicular to the fracture line into the cancellous bone of the distal tibia metaphysis.[7] This is also advocated by numerous other publications like Rockwood and Green, Fractures in Adults, and Campbell's operative Orthopaedics.[8][9]

There are multiple other ways of fixing a medial malleolus, like bio-absorbable screws and tension band wiring, but these are only advocated for use in highly comminuted fractures, or fragments too small to fixate with screw placement. For this article the authors only focused on the use of screws for fixation of a medial malleolus fracture.

In this study the authors compare two fixation methods of the medial malleolus to determine if the pull out strength of the medial malleolus fixation can be increased.

Methods

Specimens

Sixteen embalmed cadavers were obtained from the department of Anatomy of the University of the Free State. The age of the cadavers were not known. All cadavers were dissected to expose the medial malleolus of both ankles. The ankle joint was not violated, the deltoid ligament was preserved and all lateral structures kept intact for all specimens.

Exclusion criteria included specimens with previous ankle surgery and previous lower limb fractures.

On each of the specimens an osteotomy was performed of the medial malleolus simulating a fracture at the junction of the medial malleolus and the tibia metaphysis described by the Herscovici classification as a Type C fracture.

Fixation:

On each cadaver the right medial malleolus was fixated with one 4.0mm partial threaded screw according to the AO principles. The left medial malleolus of each ankle was fixated with one 4.0mm partial threaded screw, however the screw was inserted in a direction that the screw tip engaged the posterior cortex of the tibia metaphysis at an angle of approximately 40^{o} to 50^{o}.

In addition to visual confirmation, an image intensifier was used to evaluate the following:

1. An anatomic reduction was obtained
2. No intra-articular screw placement occurred
3. Screws placed in the right ankles did not engage the posterior cortex
4. Screws placed in the left ankles did engage the posterior cortex

When confirmation of screw placement was done, the posterior aspect of the tibia metaphysis was dissected to evaluate the location of the screw tip, to measure the distance of protrusion, and to evaluate the proximity to the posterior tibia structures.

Testing:

Testing was performed with a traction scale calibrated in Newton. The scale was attached to the screw with a two hole semi-tubular plate. Gradual increase in traction was applied until failure of fixation was achieved. Failure was defined for this study as distraction of the fracture more than 2mm, extraction of the screw and screw breakage. Rotational force was not applied to the ankle, as this would not give an isolated reading of pullout strength of the screw alone, but would instead evaluate the stability of all ankle structures.

At the point of failure the maximum recorded force was noted from the scale.

Statistical analysis:

Statistical calculation was performed using SAS Version 9.3. Results were summarized by frequencies and percentages (categorical variables) and means. Placement methods were compared using 95% confidence intervals for paired differences in means, with appropriate paired t-test.

Results:

In the sixteen cadavers available, 1 was excluded due to a previous ankle fracture with three K-wires in situ. Two more cadavers were excluded due to underlying tibia fractures that would deem the results obtained unreliable. Thirteen cadavers were included in the study. Of the cadavers studied, 4 were female and 9 male.

All osteotomies were reduced and fixed anatomically, irrespective of fixation method. None of the screws engaging the posterior cortex protruded more than 2mm from the posterior cortex. None of the screws came into contact with any of the anatomic structures posterior to the tibia.

All pullout strength values are provided in *Table I* and *Table II.*
The mean strength for screws engaging the posterior cortex was 219.67N compared to 76.49N for screws not engaging the posterior cortex. This is statistically significant with a p-value of 0.002 and a 95% confidence interval of 3.9% to 22%.

The highest pullout strength for a screw engaging the posterior cortex was 414.82N on the right ankle of specimen 3. The pullout strength, not engaging the cortex, for specimen 3's left ankle was 48.05N. The pullout strength was increased with 863% by engaging the posterior cortex. For screws placed not engaging the posterior cortex, the maximum pullout strength was 181.42N on the left ankle of specimen 1. Compared to the right ankle, screw engaging the posterior cortex, with a pullout strength of 209.86N. The pullout strength was increased with 116%.

The lowest pullout strength for cortex engaging screws were 72.57N, compared to the lowest reading of 15.69N for the screws not engaging the cortex.

Of the thirteen specimens, only one cadaver had a screw engaging the cortex having a lower pull-out strength than the contralateral side not engaging the cortex, with a difference of 72.57N versus 76.49N. A reason for the results in this one specimen could not be found.

There were no statistical significant difference in screw length between left and right ankles. Screws used measured between 38mm and 50mm in length.

Discussion

Ankle fractures are one of the most common lower extremity injuries, with a bimodal distribution in younger males and older females. Due to the large number of surgeries performed, a large number of complications will arise. These complications are typically found in older patients due to underlying comorbidities eg. osteoporosis, tobacco use, chronic pulmonary disease and poorly controlled diabetes mellitus.[3]

In a study by Hu et al. the incidence of delayed union, non-union and mal-union for medial malleolus fractures in 296 patients were 20.3%. These patients also had lower AOFAS scores at 6 months compared to patients with no complications. He found non-anatomic reduction, smoking and soft tissue interposition to be risk factors for poor outcome.[8] In all these risk factors poor perfusion to the extremity and poor bone quality are two of the biggest determinate factors for post-operative complications and implant failure.[9]

Numerous techniques have been described for the fixation of medial malleolus fractures of which a partial threaded medial malleolus screw, and medial tension band wiring is advocated by the AO foundation. Multiple biomechanical testing and comparative studies have been performed on these different techniques to identify if better patient outcomes could be found with less complications.[6][9][10][11]

A study by Aigner et al. demonstrated that the biggest modifiable factor in the prevention of post-operative complications is prolonged surgical time. When the intra-operative steps are minimized, intra-operative time can be shortened.[12] By inserting a cancellous screw there is no need to overdrill the distal fragment. It has been proven by numerous articles that the use of a tap for the insertion of a screw into the metaphysis and cortex does not alter the pullout

strength of the fixation.[13][14] In this study the author experienced no difficulties inserting a cancellous screw into the posterior cortex of the distal tibia metaphysis without using a tap.

The bone mineral density (BMD) for our specimens were not known or tested in this study. However, the fixation methods were allocated to left and right ankles respectively for each cadaver. Accepting that the bone quality was similar between the left and right ankle of each cadaver, we compared the two fixation methods on ankles of similar bone quality and found a clear improvement in pullout strength for screws engaging the posterior cortex.

In this study only one screw is used to stabilize the medial malleolus. This is done to isolate the pullout strength measurement for that screw. We postulate that inserting two screws to engage the posterior cortex would still be superior than inserting two screws not engaging the distal tibial cortex. This would however have to be confirmed with further testing.

As far as we know this technique of engaging the posterior cortex of the tibia has not been described before. Previous articles examining the fixation techniques for medial malleolus screws, angle the screw to engage the lateral tibial cortex.[16][6][17] The geometry of the medial malleolus is such that it is difficult to place this screw perpendicular to the fracture line and engage the lateral cortex of the tibia. It is also difficult to prevent penetrating the ankle joint if the screw is placed too horizontal in an attempt to engage the lateral cortex. Inserting a partial threaded cancellous screw, directed at the posterior tibial cortex, can be inserted with the patient in a supine position. Therefore a figure of four positioning or lateral positioning of the patient is unnecessary.

Limitations

The study examined the effect of a single event of maximal axial traction on the pullout strength of the screw inserted. This is not representative of repetitive load on the fixation method. To

examine the effect of repetitive sub-clinical load, an Instron FastTrack machine and software can be used, but this was not available to the author. Axial traction was measured by manually increasing the axial traction to the point of failure. Mechanical traction could render a more accurate reading, however for this mechanical testing equipment is needed.

In cadaver bone variability may exist in the quality and density of bone between cadavers. In each specimen the left and right ankle of each cadaver where compared with each other, which would eliminate variability between specimens eliminating bias in this regard.

Axial traction was performed for testing the pullout strength of the screw and not rotation across the tibio-talar joint. This was done to isolate the strength of the medial malleolus screw, and exclude contributions from the lateral ankle structures and syndesmosis. During a rotational force, the syndesmosis and lateral structures have to be compromised before failure of the medial malleolus would occur, and hence the reading obtained would not give an accurate result for isolated medial malleolus pullout strength.

The study focussed primarily on increasing the pullout strength of the medial malleolus. In bi- and trimalleolar ankle fractures it is also integral to correctly stabilize the lateral structures of the ankle, as shown by Svend-Hansen.[15]

This study shows a clear increase in pullout strength between these two fixation methods in cadaver models, however the findings needs to be correlated with in vivo findings and further research in this regard is needed.

Conclusion:

The pullout strength of the screw in medial malleolus fixation is increased by inserting a 4.0mm partially threaded screw to engage the posterior metaphyseal cortex. This method does not

impede the surgeon's ability to obtain an anatomical reduction of a transverse medial malleolus fracture.

Acknowledgements:

I would like to express my gratitude to the following people who assisted me with the completion of this research project. My study leader, Dr Johan van der Merwe, for his continued guidance and support through all the steps in this project. Dr G van Staden for assistance in data collection of this study. My gratitude to the department of Anatomy UFS for making their facility available to for the collection of data. Department of radiology for assistance with all radiography during the study.

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Appendix A:

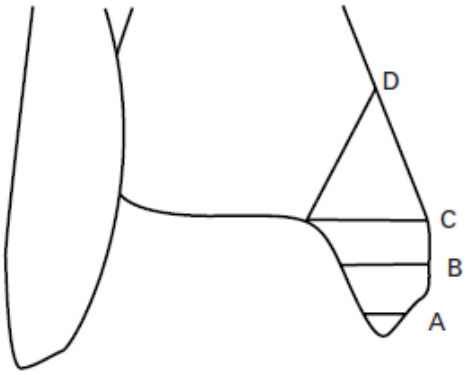

Figure 1: Herscovici classification of medial malleolus fractures.(5)

Appendix B:

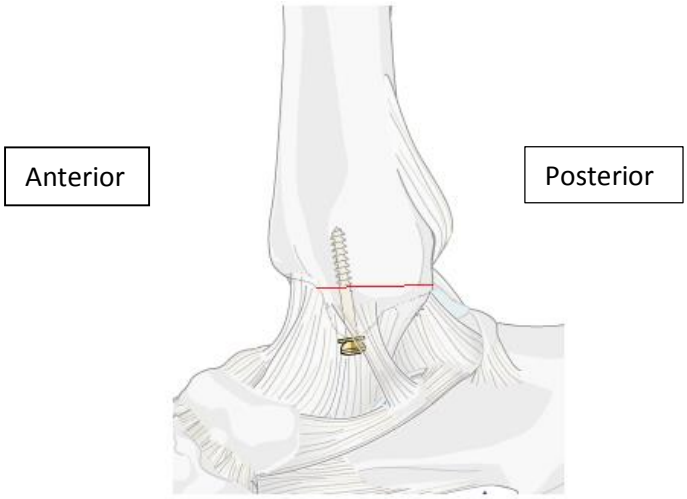

Figure 2: Screws inserted not engaging the posterior tibia cortex

Appendix C:

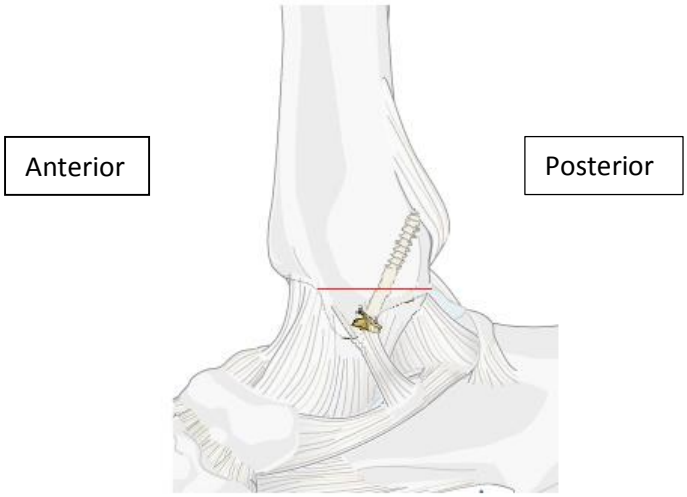

Figure 3: Screw inserted to engage posterior tibia cortex

Appendix D:

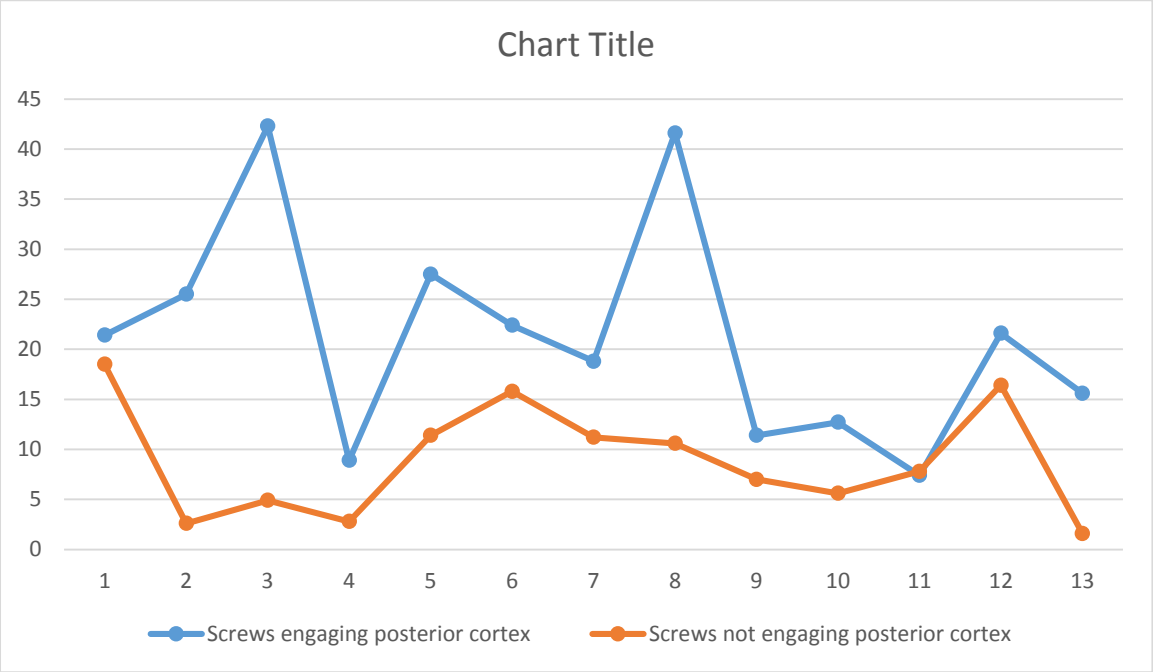

Figure 4: Difference in Pull-out strength between subjects

Appendix E:

Specimen no	Specimen ID	Anatomic reduction	Screw not engaging cortex (N)	Screw engaging cortex (N)	Strength difference (N)	Comparison ratio
1	1	Yes	181.42	209.86	28.44	1:1.16
2	2	Yes	25.5	249.09	223.59	1:9.8
3	3	Yes	48.05	414.82	366.77	1:8.6
4	5	Yes	27.46	86.3	58.84	1:3.14
5	7	Yes	111.8	269.68	157.88	1:2.41
6	8	Yes	154.94	219.67	64.73	1:1.42
7	9	Yes	109.83	184.37	74.84	1:1.67
8	10	Yes	103.95	407.96	314.01	1:3.92
9	11	Yes	68.65	111.8	43.13	1:1.63
10	12	Yes	54.92	124.55	69.63	1:2.27
11	13	Yes	76.49	72.57	-3.92	1.05:1
12	14	Yes	160.83	211.83	51.0	1:1.32
13	15	Yes	15.69	152.98	137.29	1:9.75

Table I: Study results

Appendix F:

Study population	Metaphyseal Purchase Means (N) (range in N)	Cortical Purchase Means (N) (range in N)	p - Value
All subjects (n=13)	87.66 (15.69 - 181.42)	208.88 (414.82 - 72.57)	0.002
Females (n=4)	88.26 (25.5 - 154.94)	247.13 (407.96 - 111.8)	0.086
Males (n=9)	87.38 (15.69 - 181.42)	191.88 (414.82 - 72.57)	0.022

Table II: Summary of data

Reference list

1. Aigner R, Salomia C, Lechler P, Pahl R, Frink M. Relationship of Prolonged Operative Time and Comorbidities With Complications After Geriatric Ankle Fractures. Foot Ankle Int [Internet]. SAGE Publications Inc; 2016 Sep 23;38(1):41–8. Available from: https://doi.org/10.1177/1071100716667315
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Appendix A: Ethics approval

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
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Ms H Strauss/hv

2014-05-27

REC Reference nr 230408-011
IRB nr 00006240

DR GP CONRADIE
DEPT OF ORTHOPEDIC SURGERY
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr Conradie

ECUFS NR 69/2014
DR GP CONRADIE **DEPARTMENT OF ORTHOPEDIC SURGERY**
PROJECT TITLE: DETERMINING PULL-OUT STRENGTH FOR SCREWS ENGAGING POSTERIOR CORTEX VERSUS SCREWS PLACED INTO TIBIA SHAFT FOR MEDIAL MALLEOLUS ANKLE FRACTURES.

1. You are hereby kindly informed that at the meeting on 20 May 2014 the Ethics Committee approved the above study on condition that the applicant consults a biostatistician or explain how statistical analysis will be done.

   [For notification: *Very limited literature review to provide background and support to this study]*

2. Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.

3. Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

4. The Committee must be informed of any serious adverse event and/or termination of the study.

5. All relevant documents e.g. signed permission letters from the authorities, institutions, changes to the protocol, questionnaires etc. have to be submitted to the Ethics Committee before the study may be conducted (if applicable).

6. A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

7. Kindly refer to the ETOVS/ECUFS reference number in correspondence to the Ethics Committee secretariat.

8. Thus, this letter only serves as conditional approval.

Yours faithfully

.....

PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

Cc Dr JF van der Merwe

Appendix B: SAOJ Author Guidelines

SA ORTHOPAEDIC JOURNAL

ISSN 1681-150X *printed version*
ISSN 2309-8309 *online version*

INSTRUCTIONS FOR AUTHORS

Scope and Policy

The scope of publication encompasses all orthopaedic surgery sub–disciplines including paediatric orthopaedics, hip, knee, tumour and sepsis, spine, shoulder and elbow, foot and ankle and hand surgery. In addition the journal addresses the subjects of orthopaedic service delivery, teaching, training and research. Publications should influence orthopaedic care on our continent.

The *South African Orthopaedic Journal* aims to advance the knowledge of all aspects of musculoskeletal medicine through publication of:

- Original research articles.
  - Clinical research
  - Basic science and theoretical research
- Review articles.
- Invited expert opinions.
  - A review of significant local or international publications journal article or cluster of articles dealing with a similar topic for the purpose of conveying a useful message.
- Editorials.
- Letters to the editor.
  - Forum to raise issues or debate aspects of previously published papers.

Criteria for publication

- 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 in an appropriate 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.
- Other 'contributors' can be acknowledged at the end of the manuscript together with their contribution.
- Authors of manuscripts representing a multi–centre study may list members of the group in the footnote on the title page of the published article and their affiliations are listed in an appendix.
- The authors should clearly indicate the predominant surgeon or surgeons who have contributed patients to the study.

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 recommendations.
- 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 that was used (listed below):

Randomised trials	CONSORT
Observational studies	STROBE
Systematic reviews	PRISMA
Case reports	CARE
Qualitative research	SRQR

Diagnostic / prognostic studies	STARD
Quality improvement studies	SQUIRE
Economic evaluations	CHEERS
Animal pre–clinical studies	ARRIVE
Study protocols	SPIRIT

-
- 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.

Role of funding source

- Authors are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. If the funding source(s) had no such involvement, then this should be stated.

Formatting of Submissions

Text formatting

- Use Helvetica or Arial font, size 11.
- Use double line spacing throughout the document.
- Number the pages of the blinded manuscript consecutively.
- Use italics for emphasis.
- When referring to an article with multiple authors please use the following format: Rabinowitz *et al*. published their retrospective review.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

- Use no more than three levels of displayed headings.

Abbreviations

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

Units

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

Figures

- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3, etc.
- The figure should be listed in the text as follows: … wound irrigation and splinting (*Figure 1*).
- 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 should be understandable without the main text.
- For radiographs please ensure you state the view used and the time point at which it was taken, as well as the demographic details of the patient if applicable.
- Figures should not be imbedded in the text file, but should be submitted as separate individual files. Each figure should be a separate file, entitled Figure 1, Figure 2, etc.
- Remove all markings, such as patient identification, from radiographs before photographing.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of six figures.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

Tables

- Tables should carry uppercase Roman numerals, I, II, III, etc.
- Tables should always be cited in the text in consecutive numerical order.
- The table should be identified in the text as follows: Details of results are listed in *Table I*. Or, alternatively, … high–energy trauma that is often associated with these fractures (*Table II*).
- Tables should be used to present information in a clear and concise manner. All tables should be understandable without the main text.
- For each table, please supply a table heading explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table heading.
- Footnotes to tables should be indicated by superscript lower–case letters and included beneath the table body.
- Please submit tables as editable text and not as images. They should be created using the Table tool in Word.

- Do not embed tables in the text file, but submit them as separate individual files. Each table should be a separate file, entitled Table I, Table II, etc.
- We accept a maximum of eight tables.
- Do not duplicate information given already in the text.
- Do not submit any figures, photos, tables or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

References

- References should be numbered consecutively in the order that they are first mentioned in the text and listed at the end in numerical order of appearance.
- Identify references in the text by Arabic numerals in superscript after punctuation.
- References should not be a listing of a computerised literature search but should have been read by the authors and have pertinence to the manuscript.
- Authors should add DOIs to all references in articles.
- Accuracy of references is the author's responsibility and the author is to verify the references against the original documents.
- Manuscripts in preparation, unpublished data (including articles submitted but not in the press) and personal communications may not be included in the reference listing. They may be listed in the text in parentheses only if absolutely necessary to the contents and meaning of the article.
- The titles of journals should be abbreviated according to the style used in Index Medicus, obtainable through the website http://www.nlm.nih.govshould
- The following format should be used for references:

Journal article:
Sidhu GS, Ghag A, Prokuski V, Vaccaro AR, Radcliff KE. Civilian gunshot injuries of the spinal cord: a systematic review of the current literature. Clin Orthop Relat Res 2013;471:3945-55.

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.

On–line journal article:
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.

Dissertation:
Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant (MI): Central Michigan University; 2002.

Abstract:
Peterson L. Osteochondritis of the knee treated with autologous chondrocyte transplantation [abstract]. ISAKOS Congress, 2001.

Structure and content of submission

- We accept a maximum of 3500 words including the abstract and body of the text (excluding references).
- Exceptions to this rule may be made for systematic reviews and meta–analysis, at the discretion of the Editor–in–Chief.
- Please follow the following structure when preparing your submission.
    - Title page (Title, authors and affiliations, corresponding author and declarations)
    - Blinded manuscript (Abstract, key words, introduction, methods, results, discussion, funding sources, conflict of interest statement, ethical statement, acknowledgements and references)
    - Tables (with headings), each as a separate file.
    - Figures (with legends), each as a separate file.

Title page

Title

- The title should be concise and informative.

Author names and affiliations

- Please provide the following information for each author:
    - Full names and surname, as well as title
    - Qualifications
    - Affiliation and address
    - ORCID ID (see Article Submission section)
- Please check that all names are accurately spelled.

- Indicate all affiliations with a lower–case superscript letter immediately after the author's name and in front of the appropriate affiliation details.
- Provide the full postal address of each affiliation, including the country name and, if available, the e–mail address of each author.

Corresponding author

- Clearly indicate who will handle correspondence at all stages of refereeing and publication, including post–publication.
- Ensure that the e–mail address and permanent address is given and that contact details are kept up to date by the corresponding author.
- Please note that the corresponding author's contact details will be provided in the final article.
- Provide the following information for the corresponding author:
    - Full names and title
    - Affiliation
    - Physical address
    - Postal address
    - Telephone Number
    - E–mail address

Declarations
Authors are to insert a section at the end of the title page entitled declarations. Following the declarations all authors need the to sign the document (please provide name of author, signature and date). The following statements are required under the declarations section:

a. 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 the article or its critical revision for important intellectual content
    - Final approval of the version to be submitted.

b. 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').

c. 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 has 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 material that is copyrighted.

d. Conflict of interest statement
A conflicting interest exists when professional judgement concerning a primary interest (such as the patient's welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It represents a situation in which financial or other personal considerations from authors, reviewers or editors have the potential to compromise or bias professional judgment and objectivity. It may arise for the authors when they have a financial interest that may influence their interpretation of their results or those of others. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. All potential conflicts of interest need to be declared. The conflict of interest statement should list each author separately by name, i.e.,

> 'John Smith declares that he has no conflict of interest. Paula Taylor has received research grants from Drug Company A. Mike Schultz has received a speaker honorarium from Drug Company B and owns stock in Drug Company C.'

If multiple authors declare no conflict, this can be done in one sentence.

e. 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. If the study sponsors had no such involvement, this should be stated.

f. 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 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.'
- 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/

Blinded manuscript

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:
  - Aims (it is unnecessary to include an introductory section)

    - 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

Key words

- Immediately after the abstract, provide a maximum of six key words, using standard searchable terms. These key words 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 procedure for common operations. Only include new procedures or adaptations to standard procedure.
- If you name any specific product, then it requires the name, city and state/country of the manufacturer.
- 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 the 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 but put emphasis on 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 which conveys the conclusions of the findings.
- Do not draw conclusions not supported by the data obtained from the specific study presented.

Conflict of interest

- 'Author A.B. (*use initials of relevant author, not full name in order for the document to remain blinded*) has received research grants from Company A. Author B.C. has received a speaker honorarium from Company X and owns stock in Company Y. Author C.D. is a member of committee Z.'
- If no conflicts of interest exist, state this as follows: 'The authors declare they have no conflicts of interest that are directly or indirectly related to the research.'

Ethical statement

- For studies involving human subjects please include an ethical 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.'

- Or 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.'

Funding sources

- 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.'

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 for comments.
- Should not include contributions by editors or referees.

References

- Please refer to the section on Formatting of submissions.

Tables and figures

- Table 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.

Instructions for Reviewers

Introduction

- Comprehensive, high–quality, blinded peer review is essential to maintain an adequate publication standard.
- Peer reviewers are orthopaedic surgeons or physicians from other disciplines who possess special expertise and who have demonstrated their willingness to perform timely and thorough manuscript reviews for the journal. Guest

reviewers are invited if unique experience or knowledge is required on a specific topic.
- Reviewers are asked to follow the structure and guidelines described below.
- A methodological review is conducted for papers that have received a favourable content review and are being considered for publication.
- Please also see our peer review policy

General guidelines

- When you receive the invitation to review please consider the following question:
    - Do you have time to complete the review before the deadline?
    - Are you familiar enough with the content area and/or methods to provide a high–quality review?
    - Do you have any potential conflicts of interest?

  If you are unable to review for any of these reasons please reply promptly to the invitation e–mail in order to for another reviewer to be appointed.

- Please attempt to complete your review within the provided deadline. If you will not be able to complete your review in time, please contact the Editorial Office.

- A well–organised, detailed, thoughtful review will often be passed on to the authors.

- Make your review as objective and evidence–based as possible. Perform a literature search on the topic in order to familiarise yourself with the current literature on the topic (OVID, Google Scholar and Pubmed, at least).

- Your review can be as critical as you judge necessary. Always provide constructive criticism. Your comments should be helpful to the author(s) and should never be demeaning or pejorative. The authors are likely to have put a huge amount of time and energy into their work. Disparaging comments are not helpful.

- Do not spend a lot of time correcting language, grammar or spelling. If errors in these areas interfere with the

overall message, make a general comment to this effect. If a specific error confuses a point, make a specific comment.

- Please keep the content of the manuscript confidential.

- Please avoid including a signature or any other ways of identifying you as a reviewer.

- If you have any concerns please contact the section editor directly.

- Follow a systematic procedure to review the manuscript and to write your review (see below).

Structure of review

- Recommendations following review
    - Reject (resubmission not recommended)
    - Reject and resubmit
    - Major revision required
    - Accepted with minor revision
    - Accepted as is

- Summary
    - Summarise the article in a short paragraph. The aim is to demonstrate your understanding of what the work is about.
    - Briefly state your understanding of the research question and methodology.

- General comments
    - Please provide a paragraph for this to put the study in the context of previously reported information.
    - Is it relevant to clinical practice in South Africa?
    - Is the relevance to the South African orthopaedic surgeon discussed?

- Specific comments
    - Title
    - Abstract

- Level of evidence
- Introduction
- Methods
- Results
- Discussion
- Conclusion
- References
- Illustrations
- Tables
- Organisation
- Language, punctuation, grammar and spelling

- Further requirements:
    1. Was the research question clearly elucidated in the introductory section?
    2. Was sufficient detail provided in the methods section so that another researcher can replicate the study?
    3. Was the statistical methodology employed sound?
    4. Were subject recruitment procedures, and inclusion and exclusion criteria accurately described?
    5. Was the follow–up period adequate?
    6. Were the limitations of the study adequately explored?
    7. Was the conclusion supported by the data presented in the study?
    8. Were all necessary references provided?
    9. Was the necessary ethical standard maintained?
    10. Does the article satisfy the requirements set out in the Instructions for authors section?

        Note: If the answer to any of these questions is no, the paper should either be rejected, rejected and resubmitted, or returned to the authors for major revision.

Specific comments

This part of the review should consist of a detailed listing of your specific concerns with the manuscript. Each item in the list should refer to a specific location in the text (including the page, paragraph and line numbers). Your specific, precise comments will be valuable to the authors when they revise their work. Constructive criticism will be appreciated. In addition to the text, the following elements of the manuscript should be assessed.

- Title
    - Does it clearly describe the subject of the paper?

- Abstract

- Is it an accurate, succinct reflection of the aims, methods, results and conclusion?

- Level of evidence
  - Is the proposed level of evidence appropriate?
  - 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
  - Is it an unbiased introduction to the topic?
  - Is an adequate background given?
  - Does it mention the relevance of the research question?
  - Do the authors give a research question or hypothesis?
  - Are the aims and objectives communicated clearly?

- Methods
  - Was the methodology employed appropriate for the research question that was posed?
  - Could the study be replicated with the details given?
  - Was the sampling described?
  - Are the inclusion and exclusion criteria adequate?
  - Is the statistical analysis sufficiently and correctly described and is it appropriate?

- Results
  - Do the results address the research questions?
  - Are there unnecessary duplications (i.e. results in text also shown in tables?)
  - Are the results described logically and in a clear fashion?

- Discussion
  - Is a logical and meaningful interpretation of the results made?
  - Is the interpretation of the results within the boundaries of the study limitations?

    - Are the results brought into context with current knowledge and evidence?
    - Has it been done in a balanced manner?
    - Did the authors describe the implications of the findings?
    - Is there a statement made regarding the generalisability of the findings?
    - Are limitations given adequately?

- Conclusion
    - Is there a clear and logical summary of the findings?
    - Is the conclusion scientifically valid in terms of the results that were presented?
    - Do the authors give suggestions for future research?
    - Is a take–home message given?

- References
    - Is the bibliography adequate and was all relevant literature discussed (without being excessive)?
    - Have all the important statements been referenced?

- Illustrations
    - Do illustrations support the main point of the article?
    - Are all the illustrations appropriate and necessary? If not, which ones would you delete?
    - Are the legends adequate?

- Tables
    - Are all the tables necessary, or could several tables be combined?
    - Are clarifications or additional columns needed?
    - Please suggest changes if you believe that they would help the author to present the information more clearly.

- Organisation
    - Is the organisation of the manuscript satisfactory?
    - Does the text provide the reader with all the information that is needed in each section?

- Language, punctuation, grammar and spelling
    - Is this of an acceptable standard?

Decision categories

- Reject and resubmission not recommended

  This means that the paper is considered inadequate for publication in the journal, either because the quality is too poor, or because the paper is out of scope for the journal, or because of ethical problems (duplicate submission, self–plagiarism or plagiarism). List two or three major reasons why you believe the manuscript should be rejected. If you are recommending a rejection of the manuscript it is neither necessary nor desirable to complete a comprehensive specific comments section as these are intended to help the authors who are invited to revise their submission.

- Reject and resubmit

  This is relevant in the following situations:
    - The submission is incomplete.
    - The submission fails to comply with the Instructions for authors guidelines.
    - The content of the paper could potentially be of interest but the paper has too many deficits to expect that it will be of sufficient quality to allow publication following major revision. Compared to a simple 'reject' decision, this is a signal to the authors that they may have an interesting idea but that they need to write a new paper and not to try to enhance the existing one.

- Major revision

  This implies that in its present state the paper is below standard for publication and requires substantial revision. However, the reviewer believes that the authors can correct these deficiencies. Reasons may include lack of putting the work into perspective, lack of sufficient experimental validation, or serious flaws in the way the work is presented or justified, etc. A major revision decision is in no way a commitment to ultimately accept a revised version of the paper for publication. If the revised version of a paper has not addressed the initial concerns and still raises major concerns after major revision, it is probably better to reject it than to extend the reviewing process.

- Accepted with minor revision

  This means that the major aspects of the paper are considered to be of sufficient quality for publication. This is actually a commitment to ultimately publish the paper, provided that the authors adequately answer the remaining concerns (which should be relatively minor) and correct the relevant language/grammar/spelling problems.

- Accepted as is

  Article is suitable for publication as is, without further revision or corrections. This decision is not typically used following the first review but frequently applied to papers after minor/major revision.

Article Submission

Submission declaration and verification

With the submission of an article the authors confirm that:

- The work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis or as an electronic preprint). Please see our ethics policy for more information.
- That it is not under consideration for publication elsewhere.
- The content of the article is the sole work of the author(s) and that the article has been prepared with cognisance of our plagiarism policy.
- That its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in any other language.

Prior to submission

- Please familiarize yourself with the policies of the SAOJ.
- Please read Instructions to Authors prior to submission. It will also be beneficial to familiarize yourself with the Instructions for Reviewers section.
- It is the responsibility of the authors, and not the reviewers, to ensure that the language, grammar, or spelling is acceptable for publication.
- Crosscheck all references to ensure that the bibliography is accurate.

Submission procedure

- On submission of your article the ORCID (Open Researcher and Contributor ID) identifier of all authors will be required. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and supports automated linkages between you and your professional activities ensuring that your work is recognized. To register and find more information please visit: http://orcid.org
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