TRAUMA AND GENERAL ORTHOPAEDICS

Intramedullary nailing of tibial non-unions using the suprapatellar approach: a case series

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Abstract

Background: A number of treatment options are available for diaphyseal non-unions of the tibia, including intramedullary (IM) nailing. An infrapatellar entry point with the knee in deep flexion can make this procedure challenging, especially with associated deformity or an obliterated canal. The suprapatellar approach allows nail insertion with the knee extended, which facilitates correction of malalignment in the sagittal and coronal planes. The aim of our study was to review the outcome of diaphyseal tibia non-unions, treated with an intramedullary nail, using the suprapatellar approach.

Method: We retrospectively reviewed consecutive cases with non-union of the tibial shaft, treated with a suprapatellar entry nail between May 2016 and January 2018. Patients who were previously managed with a nail or who had active sepsis were excluded. The rate and time to union, as well as complications were assessed.

Results: Thirteen cases were included and followed up until union at a mean of 5.8 months. All were performed percutaneously, without opening of the non-union site. Two patients developed complications, although bony union was still achieved.

Conclusion: A suprapatellar entry tibial nail is an acceptable treatment option for tibial non-unions not previously treated with a nail.

Keywords: tibia, non-union, suprapatellar, intramedullary, nail

Level of evidence: Level IV

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DECLARATION

I, Nicolaas Hendrik Snibbe Botma, hereby declare that the work on which this dissertation/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.

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Ethics statement

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.

Prior to commencement of the study ethical approval was obtained from the ethical review board: HREC reference number 315/2018.

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.

Declaration
The authors declare authorship of this article and that they have followed sound scientific research practice. This research is original and does not transgress plagiarism policies.

Author acknowledgments and contributions
Botma contributed to the conception and design of the work, the acquisition, analysis, and interpretation of the data for the work; drafting the work and submitting the final version to be published
Graham contributed to the acquisition of data for the work, revising it critically for important intellectual content and final approval of the version to be submitted to the journal.
Held contributed to revising it critically for important intellectual content and final approval of the version to be published
Laubscher contributed to the conception and design of the work, the acquisition, analysis, and interpretation of the data for the work; drafting the work and revising it critically for important intellectual content.

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Introduction

The reported incidence of tibial shaft non-union ranges from 4 to 48%.[1-3] Non-unions are costly to treat and add a large financial burden to healthcare services worldwide.[4] Various options are available to treat tibial shaft non-unions. For aseptic tibial non-unions with an intramedullary nail (IMN) in situ, an exchange nail is an excellent treatment option.[5] With other failed initial treatment modalities, the use of a circular external fixator with or without bone grafting and a fibular osteotomy is a popular and successful treatment modality.[6] Yet, although high rates of union can be achieved, this option is not always well tolerated by patients[6-8] and is associated with high costs. Frequent outpatient visits are often necessary, which makes regular follow-up challenging, especially for patients with low incomes or long travel distances to the hospital. Lastly, some patients are reluctant to undergo external fixator treatment, especially those who previously had treatment with an external fixator.

Literature is limited on the use of IMN as treatment for non-union of the tibia in cases which have not previously been treated with a nail,[2,8,9] as percutaneous IMN insertion across a non-union is challenging and time-consuming.

The suprapatellar approach is a recent variation of the traditional infrapatellar approach for the insertion of a tibial nail. The suprapatellar approach allows insertion of the nail in an extended knee, which aids correction of malalignment in the sagittal and coronal planes.[10-13] It also creates a straight working channel, allowing the passage of rigid, straight reamers to cross the non-union site, facilitating IMN for shaft non-unions not previously treated with IMN. Currently there is no literature available on the use of this technique to treat non-unions of the tibia.

The aim of this study was to evaluate the outcome in the form of rate and time of union and complications of a series of non-unions treated with suprapatellar entry IMN.

Patients and methods

Patients with an aseptic tibial non-union, who were treated with a suprapatellar entry IMN from May 2016 to April 2018, were reviewed retrospectively.

We included non-unions of diaphyseal tibial fractures initially treated with a cast, external fixator or plate. Patients initially treated with an IM tibial nail, non-union of peri-articular tibial fractures and non-unions with signs of active sepsis were excluded. Active infection was defined as the presence of a draining sinus or local clinical signs of infection. Inflammatory markers were not routinely used to exclude infection. Suspected active infection, using these parameters, was diagnosis by an experienced limb reconstruction surgeon. Patients younger than 18 years of age were also excluded.

Patients in this series were referred to a tertiary care limb reconstruction unit in Cape Town, South Africa. Ten (out of 13) patients had their index treatment for the tibia fracture at referral units in district or secondary care facilities.

Demographic data such as age and sex, as well as risk factors for non-union such as smoking, vitamin D deficiency and open fractures, were recorded. Open fractures were graded according to the Gustilo-Anderson classification.[14] Modifiable risk factors, such as smoking and vitamin D deficiency, were addressed as per our unit protocol.

Definition and classification

A non-union was defined as a fracture which has not healed within six months of treatment and is unlikely to heal without further intervention.[15] The diagnosis of a non-union was based on the clinical and radiological assessment by two orthopaedic surgeons.

Radiological union was graded using the radiographic union score for tibial fractures (RUST) score on post-operative radiographic films.[16,17] According to Whelan *et al*.,[16] a score is assigned to each cortex on an anteroposterior and lateral X-ray, based on the assessment of healing at each cortex (*Table I*). The individual scores are added. A minimum of 4 indicates a definite non-union and a maximum of 12 indicates a definite union.

Functional union was defined by the ability of the patient to weight bear on the treated leg without the use of an assistive device and without experiencing pain. 'Stiff' and 'mobile' non-unions were identified on a clinical basis according to the Ilizarov classification.

Procedure

Treatment with a tibial nail was offered to patients with a mobile non-union without a significant bone defect or in stiff non-unions without a significant deformity. If an external fixation device was used to treat the initial fracture, it was removed prior to the index procedure. No exchange from external fixation to intramedullary fixation was performed in a single sitting. The mean time from removal of external fixator to insertion of an intramedullary nail was 3 months (range1–7).

A reamed suprapatellar entry IMN was used (Metanail, Smith & Nephew, Memphis, Tennessee).[18] For this, the patient was positioned supine on a radiolucent table with the knee flexed at 10–20°. A 3–5cm midline incision was used extending from the superior pole of the patella proximally. The quadriceps muscle was divided or mobilised to gain access to the patellofemoral joint, thus establishing the suprapatellar portal.

Tibia alignment was achieved with the use of blocking or Poller screws if necessary. Three patients required a fibula osteotomy at the same sitting for which a 10 mm section of fibula was excised using an oscillating saw. A fibular osteotomy was only performed if the fibula was united.

The non-union site was not opened and bone graft was not added in any cases. A set of solid, elastic reamers was used to cross the non-union site.

In all cases the fracture site was compressed. This controlled compression was achieved by performing distal locking first, followed by utilising the dynamic compression tool of the nail[19] (*Figure 1*).

Medullary tissue samples were routinely collected from the intramedullary reaming and sent for microscopy, culture and sensitivity (MCS) in all cases.

Post-operative management

Patients were mobilised with partial weight bearing as tolerated from day 1 post-surgery. Physiotherapy was initiated to maintain knee and ankle range of motion. Cases with subclinical infection confirmed with intra-operative tissue cultures were treated with at least six weeks of culture-specific antibiotics. This included an agent active against biofilm-based infections (rifampicin in Gram-positive infections if sensitive; ciprofloxacin in Gram-negative infection if sensitive). Of note is that these cases did not meet the exclusion criteria of this study, as the infection was not active at time of surgery, but subclinical.

Patients were routinely followed up with radiographs every six weeks until union (*Figure 2*).

Results

Thirteen cases were included for review. Twenty-six tibial non-unions were excluded because of treatment using other treatment modalities. Characteristics and treatment of the study group are listed in *Table II*. All patients achieved functional and radiological union without further intervention. The mean time to radiological union was 5.8 months. All patients were followed up until union was achieved. The median length of follow-up was 7 months (inter-quartile range 6.5 months) (*Table III*).

Complications/sepsis

Three patients grew a positive bacterial culture on tissue taken at time of surgery. In two this was a methicillin-sensitive *Staphylococcus aureus* species (MSSA), and one culture result was positive for a *Morganella* species as well as a MSSA species. All three patients were treated with culture-specific antibiotics for at least six weeks. Of these three patients, two developed implant sepsis, evidenced by a draining sinus. The third patient did not develop wound complications, nor signs of implant sepsis and was therefore not considered a complication. The implant sepsis resolved in one of the two patients after completion of an antibiotic course, and his implant was removed following union. This patient had no signs of chronic osteitis at his last follow-up. The other patient developed chronic osteitis. This was treated with intermittent suppressive antibiotics until union, after which the implant was removed, followed by reaming and an antibiotic cement nail implantation. Of note is this patient previously had chronic osteitis and the non-union was the result of a pathological fracture through the site of chronic osteitis. Consideration was given to treat this non-union with a circular external fixator, but the patient refused the application of an external fixator. At this patient's last follow-up (18 months) the chronic osteitis was quiescent and there were no signs of recurrence of infection (*Figure 3*).
No patients developed implant failure, hardware irritation or any other complication in the follow-up period.

Discussion

In this series we achieved union in all cases, using a suprapatellar entry IMN. Limited recent literature is available regarding the use of interlocking nails for the treatment of tibial non-unions not previously treated with a nail.[2,9] A reamed exchange nail is an excellent treatment option for aseptic tibia non-unions with a nail in situ.[5] Reamed nailing with use of larger nails creates greater stability and is believed to provide local bone graft at the fracture or non-union site that may stimulate healing.[3,20] According to Tsang *et al.*, the union rate with exchange nailing ranges from 63% (after the first non-union procedure) to 100% following subsequent non-union procedures.[21]
Megas *et al.* demonstrated that reamed infrapatellar entry IMN resulted in union in all included patients within a period of six months, with a low infection rate (2%).[2] Yet, in 16 of 50 cases, opening the non-union site was necessary to enable insertion of the nail.
The suprapatellar approach is a variation on the standard infrapatellar nail. The advantages of the suprapatellar nail above the standard nail include easier and improved tibial alignment, improved post-operative knee range of motion and a

decrease in the incidence of anterior knee pain. No additional complications with the use of the suprapatellar approach had been proven in the literature.[10-13]
Crossing the non-union site is difficult in some cases. It is necessary to have specialised equipment available in the form of solid flexible reamers. We managed closed insertion of the nail in all cases which was facilitated by the suprapatellar nail entry, enabling a straight working channel for reamers in knee extension and facilitating access for intra-operative fluoroscopy.
A potential advantage of avoiding extensive debridement of the non-union site by opening it, might be that the 'biology' remains undisturbed and, especially with local bone grafting caused by reaming the medullary canal, this might assist healing.
By adding controlled compression at the non-union site, the stability is further increased and as such, union was achieved in both hypertrophic and atrophic/oligotrophic non-unions alike by addressing the stability at the non-union site.[19,22,23]

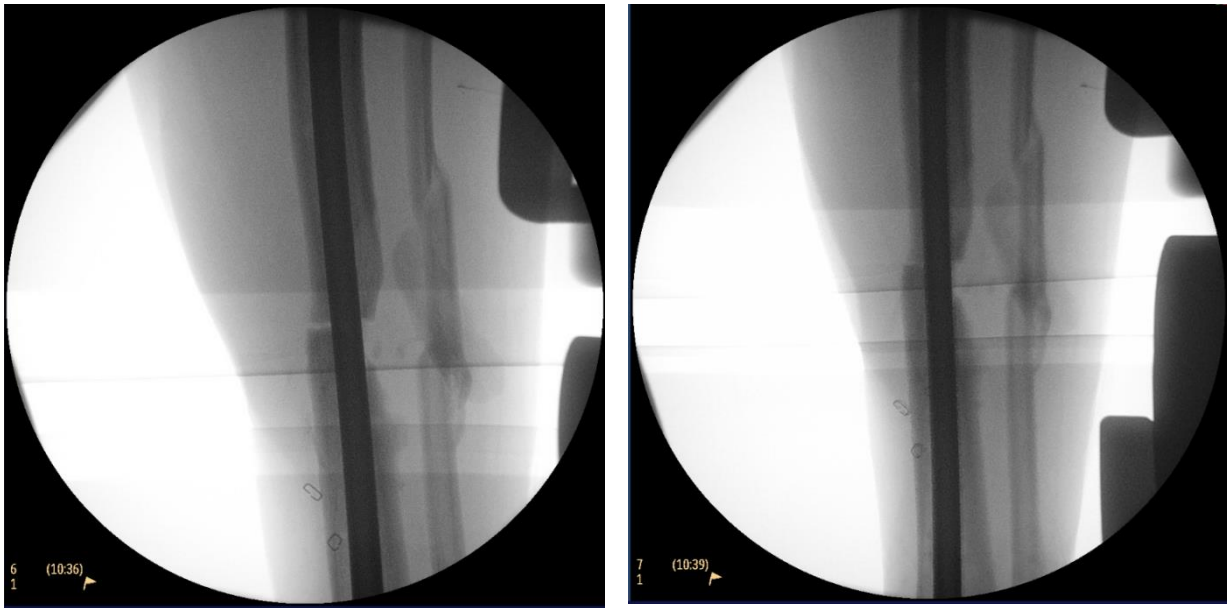
Complications

Of the three patients with positive intra-operative cultures, two (15%) developed signs of implant sepsis which persisted in one patient. This was subsequently successfully treated with further intervention. At the final follow-up all infections were quiescent and all patients with treated non-unions had united. Non-union and chronic sepsis often co-exist in a similar environment and these complications were not specific to the suprapatellar approach.
We acknowledge the limitations in this study. This was a retrospective single centre study with a small sample size. Due to the novel nature of this treatment option and heterogeneity of cases, a large prospective study was not feasible in our setting but could be considered as a multicentre trial in future.

Conclusion

In cases of tibial shaft non-union, without signs of active sepsis, not previous managed with a nail, suprapatellar entry IMN is a safe and reliable treatment option. The use of the suprapatellar approach makes the surgery technically easier, achieving a high union rate with an acceptable low complication rate.

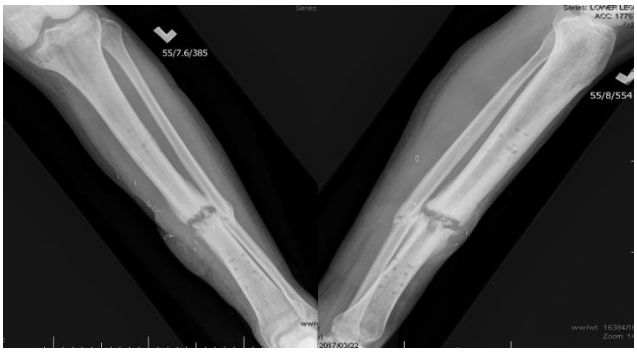
Tables and figures



b **b**

Figure 1: Controlled compression

Fluoroscopic picture a) before and, b) after compression. Note the obliteration of the fracture gap.



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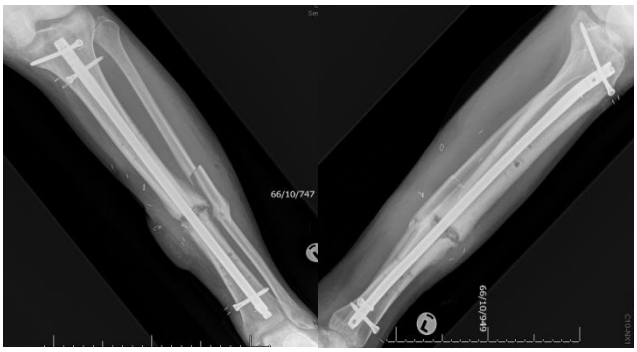

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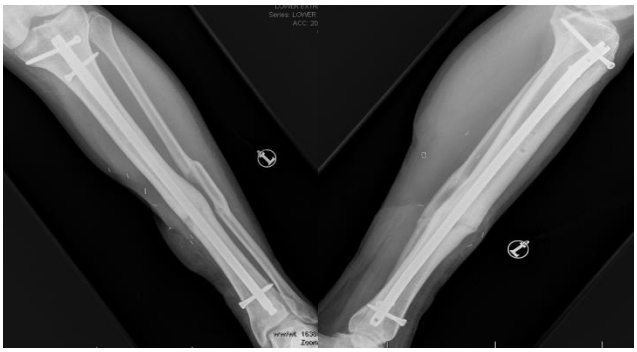


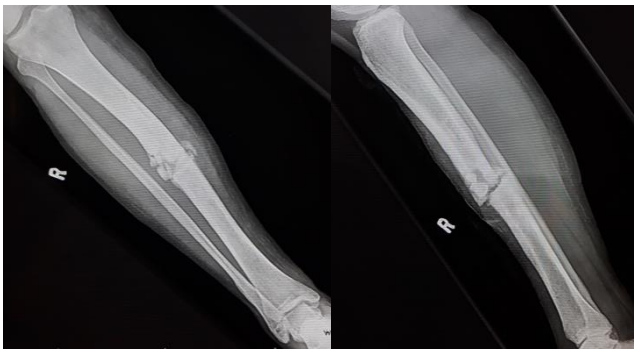
c

Figure 2: 30 year old male. He sustained an open tibia fracture and was initially managed with a biplanar external fixation. Other risk factors for his tibia non-union included substance abuse, smoking and a low vitamin D level. He had positive intraoperative cultures, but responded well to culture specific antibiotics.

a) Films before suprapatellar tibial nail

b) Day 1 post-operative films

c) Final films indicating bony union



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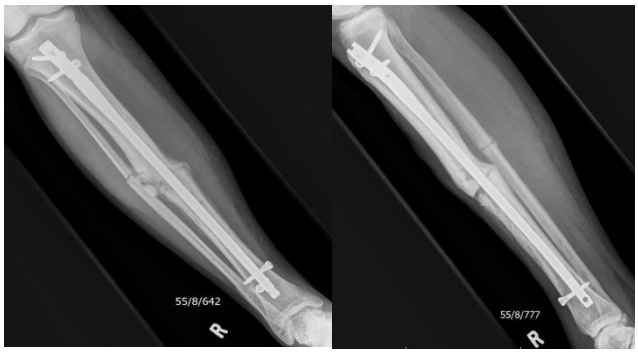

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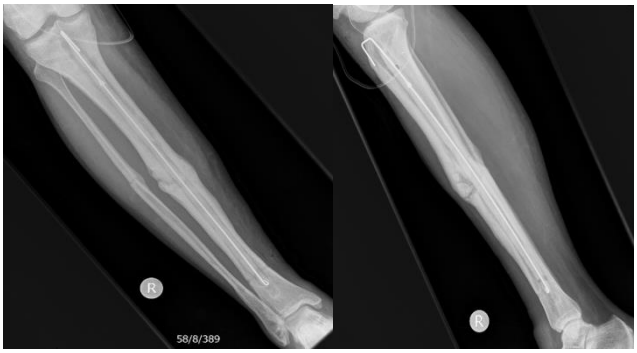

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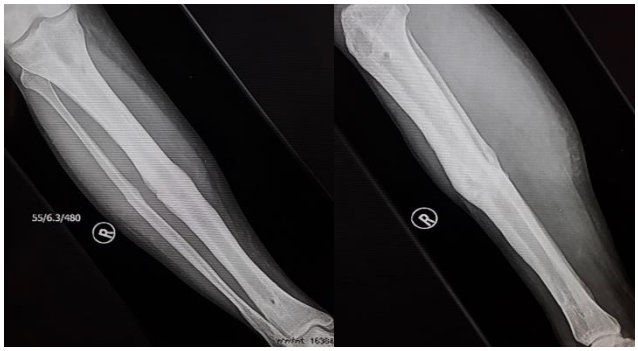

d

Figure 3: 43 year old female. Her tibia fracture was managed in a plaster cast. She has positive intra-operative cultures and proceeded to develop active osteitis. She required removal of her implant and the subsequent insertion of an antibiotic impregnated cement nail and culture specific antibiotics. The osteitis resolved without further sequelae

Radiographic images taken a) before surgery, b) at the first follow up consultation, c) after insertion of antibiotic impregnated cement nail and, d) at the final consultation.

Score per cortex	Callus	Fracture Line
1	Absent	Visible
2	Present	Visible
3	Present (bridging)	Invisible

Table I: RUST scoring system. (16,17)

Table II: Characteristics and treatment of the study group

No	Age	Gender	Initial treatment	Classification	Risk factors for non-union	Operation
1	40	Male	Circular frame	Mobile	Gr 3 open fracture Vit D deficient	SP IM nail
2	32	Male	Circular frame	Stiff	Gr 3 open	SP IM nail
3	29	Male	Cast	Stiff	Gr 3 open fracture Smoker	SP IM nail
4	43	Female	Circular frame	Mobile	Vit D deficient	SP IM nail
5	29	Male	Circular frame	Stiff	Vit D deficient	SP IM nail
6	43	Female	Cast	Stiff	Smoker Previous chronic osteomyelitis Non compliance	Fibular osteotomy & SP IM nail
7	36	Male	Circular frame	Mobile	Gr 3 open fracture Failed Masquelet technique	SP IM nail
8	30	Male	Biplanar ex-fix	Stiff	Gr 3 open fracture Vit D deficient Smoker Cannabis	Fibular osteotomy & SP IM nail
9	50	Male	Circular frame	Mobile	Gr 3 open fracture Smoker	Fibular osteotomy & SP IM nail
10	34	Male	Biplanar ex-fix	Mobile	Gr 3 open Smoker Cannabis	SP IM nail
11	30	Male	Cast	Mobile	GSW injury with large zone of comminution	SP IM nail
12	29	Male	Circular frame	Mobile	Gr 3 open fracture	SP IM nail
13	40	Male	Circular frame	Mobile	None	SP IM nail

Gr: Grade

SP: Supra-patellar

IM: Intramedullary

GSW: Gunshot wound

Non-union classification according to the Ilizarov clinical assessment.

Open fracture grading done according to the Gustilo Anderson classification (14)

Table III: Results and outcomes of study group

No	Time to union (months)	Length of follow up (months)	Complication (Y/N)	Details	Further surgery
1	3	4	N		None
2	5	5	N		None
3	5	5	N		None
4	8	8	N		None
5	7	7	N		None
6	4	17	Y	Chronic osteomyelitis quiescent after treatment	Removal of infected nail at union, reaming and antibiotic cement nail
7	8	11	N		None
8	6	13	N	Positive intra-operative cultures. No signs of implant sepsis.	Implant removal
9	5	5	N		None
10	4	12	Y	Positive intra-operative cultures Implant sepsis.	Implant removal
11	5	6	N		None
12	7	7	N		None
13	3	3	N		None

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Appendix

SA ORTHOPAEDIC JOURNAL

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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.
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    - 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
- All correspondence will be sent by e–mail.
- Articles can be submitted be e–mail to: pat@saoj.co.za.