“Out with the old and in with the new”

A retrospective review of Paediatric Craniocervical junction fixation: indications, techniques and outcomes

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SWNADR003

Master of Medicine in Orthopaedic Surgery,

University of Cape Town
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Declaration

The research reported is based on independent work performed by Dr Adrian Kenneth Swan and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree to any other university.

This work has not been reported or published prior to registration for the Master of Medicine in Orthopaedic Surgery (University of Cape Town).

Signed by candidate

Dr Adrian Kenneth Swan

30 September 2019
Abstract

Background:
The paediatric craniocervical junction has anatomical, physiological and biomechanical properties that make this region unique to that of the adult spine, vulnerable to injury, and contribute to the complexity of management. Traditionally, on-lay fusion with external Halo immobilisation has been used. Instrumented fusion offers intra-operative reduction and immediate stability.

Methods:
A retrospective review of a single surgeon’s prospectively maintained database was conducted for all cases of paediatric patients that had undergone a fusion involving the occipito-atlanto-axial region. Case notes were reviewed and a radiological analysis was done.

Results:
Sixteen patients were managed with on-lay fusion and external immobilisation and twenty-seven patients were managed with internal fixation using screw-rod constructs. The fusion rates were 80% and 90.5% respectively.
Allograft bone grafting was found to be a significant risk factor for non-union.

Conclusion:
The screws can be safely and predictably placed as confirmed on radiological follow-up with a high fusion rate and an acceptable complication rate.

Uninstrumented onlay fusion with Halo immobilization remains an acceptable alternative.
Allograft in the form of bone croutons or demineralised bone matrix is a significant risk factor for non-union and posterior iliac crest graft should be used preferentially.
Level of evidence: Level 4 – Case series

Key words: paediatric, craniocervical junction, occipito-atlanto-axial, Harms
Acknowledgements and Contributions

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

The conception and design of the study, or acquisition of data, or analysis and interpretation of data.

Drafting the article or revising it critically for important intellectual content.

Final approval of the version to be submitted.

Sound scientific research practice
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<th>Abbreviation</th>
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<td>CCJ</td>
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</tr>
<tr>
<td>CT</td>
<td>computer tomographic</td>
</tr>
<tr>
<td>DBM</td>
<td>demineralized bone matrix</td>
</tr>
<tr>
<td>MRI</td>
<td>magnetic resonance imaging</td>
</tr>
<tr>
<td>TASF</td>
<td>transarticular screw fixation</td>
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<td>VA</td>
<td>vertebral artery</td>
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</table>
**Introduction**

Craniocervical junction (CCJ) instability is caused by traumatic and atraumatic aetiologies with underlying pathology of congenital, syndromic, autoimmune, inflammatory, infectious or neoplastic aetiologies.¹, ²

CCJ instability may require surgical stabilization from the pathology itself or for iatrogenic instability from decompressive surgery.

A successful CCJ fusion requires re-creation of a stable biomechanical environment and bony preparation for biological bony on growth. Secondary goals include decompression and protection of neurological structures, restoration and maintenance of alignment, motion segment preservation, limitation of morbidity (including that of bone graft harvest), pain control, and the facilitation of nursing care.²-⁵

Consideration should be given to the benefits, risks and cost-effectiveness of the chosen method of stabilisation.³, ⁵

A variety of techniques are available for stabilisation and fusion of the CCJ in paediatric patients: onlay fusion with external halo immobilisation, wiring techniques, and screw/screw-rod instrumented techniques with or without adjuvant wiring and external immobilisation.

In children younger than 8 years, the relatively large head, small occipital condyles, horizontally orientated atlantooccipital and facet joints as well as capsular and ligamentous laxity make the CCJ the most significant transitional zone.³, ⁶-⁸

This unique anatomy of the CCJ in children complicates the interpretation of biomechanical studies that are largely done in adult cadaveric specimens.
Anatomic size constraints, craniovertebral anomalies associated with congenital and syndromic conditions, immature ossification, as well as future growth potential, further complicates the decision making process.\textsuperscript{3, 9-11} Consequently, surgeons have until recently avoided instrumentation in the paediatric population.

**Aim**

Having evolved from traditional onlay fusion with external halo immobilisation to internal fixation of the CCJ in paediatric patients with predominantly Harms technique, we present our institutional experience and radiological outcomes.

**Methods**

A retrospective review of a single surgeons’ prospectively maintained database was conducted for all cases of paediatric patients that had undergone a fusion involving the occipito-atlanto-axial region during the period 1\textsuperscript{st} of January 2002 until 31 August 2018.

Baseline demographic data, underlying pathology, indication for surgery, surgical technique, surgical parameters and intra-operative complications were assessed.

Pre- and post-operative radiology was used to assess implant placement and union. CT and MRI scanning were used at the discretion of the lead surgeon on a per case basis. Fusion was assessed on antero-posterior and lateral radiographs as either cross trabeculation of fusion mass (Figure 1); or the absence of peri-screw lucency, absence of instrumentation failure and stability on flexion/extension views when adequate visualisation of the fusion mass was not possible \textsuperscript{12}. Typically due to concealment of the fusion mass by the instrumentation (Figure 2).

Case notes were reviewed for any complications and progress during the follow-up period.
**Surgical technique**

**Halo external immobilisation**

The patient is positioned supine.

Between 4 and 8 pins are placed with between 40 and 60 pounds per square inch.

Reduction of the deformity is confirmed on lateral imaging and the Halo is secured to the jacket.

**Screw-Rod**

The patient is positioned prone on either a Relton Hall or Montreal mattress and the skull is held with a Mayfield clamp (*Figure 3*).

The patient’s neck is positioned in the “military chin-tuck position” and slight flexion to improve access and attempted reduction of the C0-C1-C2 joints is done when possible.

A midline skin incision used in all cases, with subperiosteal exposure of the intended fusion levels.

A Watson-Cheyne was placed into the C1-C2 joint to retract the C2 root inferiorly and gain access to the C1 lateral mass entry point.

A burr was used to create a cortical breach in the lateral mass as it joins the C1 arch.

A 2.7mm drill bit was used in oscillating mode and drilled with 10-15° convergence and parallel to the arch under lateral imaging.

During C2 pedicle screw insertion, the C2-C3 facet joint is identified but not exposed. The starting point is created using a burr in the infero-lateral quadrant of the C2 lateral mass to optimize screw length.

The medial border of the C2 pedicle is identified by palpation using a blunt hook or Watson-Cheyne and is drilled using oscillating mode with approximately 20° convergence and parallel to the C2 pedicle as visualized on lateral imaging.

All drill holes are probed to exclude cortical breech and to confirm screw length prior to screw placement.
A standard cervical set with 3.5mm screws was used for all cases.
The intended fusion levels are decorticated and in most cases, cortico-cancellous strips harvested from the posterior iliac crest are packed underneath the screw-rod construct and occasionally secured with an absorbable suture when deemed necessary.
When allograft has been used, it has been SA bone croutons or demineralized bone matrix (DBM).
A soft collar is used post-operatively for a period of 6 weeks.

**Statistical Analysis**
Analysis was performed using the R language and environment for statistical computing (version 3.5.2) (R Foundation for Statistical Computing, Vienna, Austria).

**Results**
Forty-three consecutive paediatric patients underwent a fusion involving the occipito-atlanto-axial region during the study period.

Sixteen consecutive patients with a mean age of 7.5 years (range 3.8-13.8 years) had uninstrumented onlay fusion with Halo immobilisation. Preoperative CT scan was done for two patients and preoperative MRI for one patient. Fifteen of these patients had adequate radiological follow-up for analysis.

Twenty-seven consecutive patients with a mean age of 9.8 years (range 2.2-16.7 years) had instrumented internal fixation. Preoperative CT scan was done for sixteen patients and preoperative MRI for fifteen patients. Twenty-one of these patients had adequate radiological follow-up for analysis.
The most common underlying diagnoses were trauma and os odontoideum. Indications for surgery included non-traumatic instability (17 patients), traumatic instability (13 patients) and instability with myelopathy. A breakdown of the underlying diagnosis and indication for surgery are given in Tables I and II.

The screw configuration for the twenty-seven instrumented fusion groups included 13 skull plates, 16 bilateral C1 lateral mass screws, 23 bilateral C2 pedicle screws, 3 bilateral C2 translaminar screws and 1 patient with unilateral C2 and C3 translaminar screws.

The median operative time for uninstrumented fusion was 45 minutes (interquartile range 44-61min), and 100 minutes (interquartile range 80-120min) for instrumented fusion. Operative time was found to be significantly different between the two groups ( W-statistic 45.5, p value <0.01).

The median blood loss for uninstrumented fusion was 100ml (interquartile range 50-100ml), and 150ml (interquartile range 100-250ml) for instrumented fusion. Blood loss was found to be significantly different between the two groups ( W-statistic 119.5, p value = 0.01).

Fifteen of the sixteen patients managed with uninstrumented onlay fusion were followed up for a median period of 19.5 months (interquartile range 11-27 months) and had adequate radiological follow-up for analysis. The union rate for this group was 80% at a median period of 2 months (interquartile range 2-8 months), with 2 patients achieving a stable pseudarthrosis and 1 patient who represented with a non-union and a myelopathy following a subtle injury 6 years later. A successful union was achieved in this patient with instrumented fusion and autograft.
Twenty-one of the twenty-seven patients managed with instrumented fusion were followed up for a median period of 22 months (interquartile range 11-37 months), and had adequate radiological follow-up for analysis. Unfortunately, as many of these patients were treated as out-patients and often followed up at institutions near their homes, X-rays were not available as frequently. A union rate of 90.5% was observed for this group in a mean period of 4 months (interquartile range 3-12 months). One patient achieved a stable pseudarthrosis and another managed initially with allograft had hardware failure, but was successfully revised and achieved union with autograft.

Autograft harvested from the posterior iliac crest was used for all but 2 patients in the halo group and 3 patients in the instrumented group, where allograft in the form of bone croutons or DBM was used. When comparing graft type across both groups, allograft use was found to be a significant risk factor for non-union ($p$ value = 0.01). In isolation, allograft was found to be a significant risk factor for non-union in the uninstrumented group ($p$ value = 0.03), but not for the instrumented group ($p$ value = 0.27).

Including patients who failed to achieve bony union, there was a 25% complication for the halo group. One patient developed pin site infection successfully treated with antibiotics and another with a non-union who presented myelopathic following a subtle injury at 6 years post attempted fusion.

The instrumented fusion group had a complication rate of 21%. One patient developed a wound infection requiring operative washout, 2 durotomies during dissection were repaired without incident and one presumed vertebral artery (VA) injury during dissection was controlled and resulted in no adverse outcome.

No malposition of screws was noted on any of the post-operative radiological imaging.
Discussion

Wiring techniques are biomechanically inferior to screw and screw-rod constructs and show a significant decrease in stability when physiological loading is applied.\textsuperscript{13-15}

This necessitates supplemental external immobilization and frequently the incorporation of subaxial levels to improve stability.\textsuperscript{1, 16, 17}

In patients younger than 2 years, the soft cartilaginous bone may not withstand the tensile load from wiring.\textsuperscript{6}

Congenital, dysplastic or absent posterior elements, or in cases when posterior decompression is required, limitation of fixation points may preclude the use of wiring techniques or require inclusion of additional subaxial levels.\textsuperscript{18}

Complications of wiring techniques include compression or injury to dura and neurological structures during sublaminar passage of wires especially with inadequate reduction, wire cut out or loosening and suboptimal non-union rates as high as 30%.\textsuperscript{1, 5, 13, 16, 17, 19}

A case control study of 27 adults comparing C1-C2 transarticular screw fixation (TASF) with collar and posterior wiring with halo, showed a significant 21 times improvement in union rate with TASF.\textsuperscript{20}

TASF is frequently augmented with posterior wiring techniques compounding the risks of the procedure.

Halo immobilisation is cumbersome, poorly suited for polytrauma patients who require stability to aid nursing care, and not without complications. Halo management can be labour intensive often requiring in-patient care for pin site hygiene and regular tightening.

Biomechanically in adults, halos have been shown to have less ability to reduce sagittal plane motion at the atlantoaxial complex (by 71%) than a Philadelphia collar.\textsuperscript{21}

Pin tract loosening and infection, dural puncture and neurological complications are all associated with halo use, and the overall complication rate is as high as 53-68%.\textsuperscript{16, 22-25}

We achieved an 80% union rate and had a 25% complication rate using this method.
Screw and screw-rod constructs have gained popularity for the improved stability, fusion rates and shorter duration to fusion.\(^1\), \(^5\), \(^14\), \(^18\), \(^26\)

A variety of fixation points are available: C1-C2 transarticular screw fixation; C1 lateral mass or pedicle screw; C2 pedicle, pars or translaminar screws; and subaxial translaminar or lateral mass screws.\(^27\)

Recently C1 pedicle screws have been advocated to reduce venous plexus bleeding, C2 nerve root injury and reduce reliance on fluoroscopy during insertion.\(^11\)

When interpreting biomechanical studies comparing the various fusion techniques, consideration should be given that the primary motion at the OC joint is in the sagittal plane, while primary motion at the atlantoaxial joint is axial rotation and anterior/posterior translation in pathological states.\(^28\)

Results of various adult cadaveric biomechanical studies vary slightly when comparing TASF and Harms technique, with some showing no difference \(^15\) and others showing a trend to improved stability with either Harms technique \(^1\), \(^29\), \(^30\) or TASF \(^31\). Both Harms technique and TASF have improved stability over translaminar screw techniques.\(^30\), \(^31\)

A tomographic analysis of children aged 2-6 years concluded that midline occipital plates could be used in 100% of cases, standard 3.5mm screws could be used in 100% of C1 lateral mass screws, 74% of C2 pedicle screws, 98% of bilateral C2 translaminar screws, yet only 4% were deemed suitable for TASF.\(^32\)

Another study done in 94 paediatric patients older than 6 years and older found 3.2% of bilateral sides were unsuitable for TASF, 18% unsuitable for unilateral TASF and 5.3% feasible but risky. It was suggest that careful scrutiny of CT scans be done for the course of the VA and preoperative planning.\(^33\)
Analysis of 69 patients younger than 16 years found only 30.4% of C2 suitable to accept bilateral translaminar screws.\textsuperscript{34}

It has been suggested that screws with a larger diameter than the cortex may be accommodated by the viscoelastic properties of bone in children.\textsuperscript{11}

C1-C2 TASF popularized by Margel for the longer screw length and purchase of at least 3 cortical surfaces may be precluded by anatomic variability in 20% of cases.\textsuperscript{1, 27}

This technique requires reduction of the C1-C2 facet joint prior to screw placement, and as the variable location of the transverse foramen and the medial trajectory of the screw increases the risk of vertebral artery (VA) injury, and preoperative CT planning is strongly advocated.\textsuperscript{1, 3, 4, 9, 16, 26, 35-38}

Other difficulties with TASF are the acute angle of screw placement in cases of kyphosis, obesity or barrel chest; and the additional risk during supplemental wire fixation which is frequently done.\textsuperscript{4, 10, 26, 29, 35, 36, 38, 39}

The major benefit of screw-rod constructs are the versatility of fixation options and constructs. The construct can be used as a means of intra-operative reduction through compression, distraction or cantilever techniques; is better able to conform to, and contour the individual anatomy; and can be used in congenital or decompressive cases with hypoplasia or absence of posterior elements.\textsuperscript{4, 18, 26, 37, 39, 40}

The morbidity of transoral decompression may be avoided by the indirect decompression gained by reducing the deformity using screw-rod techniques and the direct posterior decompression of lamina or foramen magnum that this technique allows.\textsuperscript{41-43}

The trajectory of the C1 lateral mass screw may make vertebral artery injury less likely than that of TASF, reducing the dependence on preoperative CT scanning.\textsuperscript{1, 4, 29}
A retrospective review of 191 adults managed with TASF showed that 92% of sides were suitable for TASF with a 1.4% chance of VA injury per screw placed. The overall complication rate was 16.7%.44

A retrospective review by the lead author (RD) of 19 adults patients who successfully underwent TASF had a 21% complication rate including 1 VA injury without consequence. Union was achieved in all patients.45

Several retrospective reviews of TASF in paediatric patients, most augmented with posterior wiring and autograft, had a union rate of 94-100% at a mean of period of 4-7 months. The complication rate for the procedure varied from 11.8-25% with the risk of VA injury between 1.6-2.9% per screw placed. All had preoperative CT planning and 89-95% of sides were deemed suitable for transarticular screw placement.35, 38, 46-48

A meta-analysis of mostly level 3 evidence of screw-rod fixation in patients over 18 years included 1073 patients across 24 studies. The overall union rate was 97.5% and complications directly attributable to surgery was 0.2%. The overall VA injury rate was 0.6% with 0.4% occurring during dissection, and 0.1% for C1 and C2 screw placement. Mention is made of exercising caution during dissection over the lateral aspect of posterior arch of C1. Screw malposition requiring revision for C1 LM was 0.3% and 0.1% for C2 pars/pedicle screws. The overall minor complication rate was 9.1% with 7.7% related to C2 root morbidity.49

Less data is available for union rate, period to union and complication rate for screw-rod constructs in paediatric patients than for TASF. Retrospective reviews of screw-rod fixation with mainly C1 lateral mass and C2 pedicle or pars screws indicate a 93-100% union rate with a mean time to fusion between 4.1-7.3
months. The minor complication rate varies between 7 and 33% if smaller case series are included. Only 1 VA injury was seen in a small retrospective review of 4 cases. Only 1 VA injury was seen in a small retrospective review of 4 cases.9

We achieved an acceptable union rate of 90.5% with a 21% complication rate (7.4% re-operation rate).

Mixed adult and paediatric retrospective reviews suggest a low risk of VA injury of up to 1.3% per side. Screw-rod fixation using C2 translaminar screws has also been used with a low complication and high union rate.

Retrospective reviews comparing adult and paediatric patients undergoing fusion with either Harms or TASF showed no difference in union rate, operative time, or risk of VA injury. Blood loss has been shown to be significantly higher for Harms technique.

In paediatric patients hardware failure is associated with skeletal dysplasia or congenital spine anomalies and not the fixation method. Deep wound infection is a risk factor for requiring surgical revision of instrumentation or graft.

Dunn et al in a retrospective series of 42 adults undergoing TASF or Harms found no difference in surgical time, however blood loss and cost of implants was higher for Harms technique. The VA injury rate was 14.8% for TASF and 6.7% for Harms. The higher overall VA injury rate may reflect the lack of CT scan availability at the time of the study.

In the paediatric population undergoing C1-C2 screw-rod fixation the mean operative time varies from 109 to 138 min and the mean blood loss varies from 68 to 155ml, with lower operative times and blood loss generally seen when allograft is used. This is comparative with our experience.
While it is widely accepted that autograft is the gold standard for achieving fusion, harvesting from the iliac crest is associated with increased blood loss, operative time and donor site morbidity.\textsuperscript{50, 58, 59} Open posterior cervical surgery creates a large potential “dead space”, allowing the graft to drift back when the patient is positioned supine post operatively. It is suspected that is a reason for the reduced fusion rate seen with the use of allograft croutons in this series. For this reason, structural graft that is secured to the fusion site is favoured. There has been success in paediatric patients with the use of structural allograft placed under compression at the C1-C2 fusion site with fusion rates of 97-100\%.\textsuperscript{50, 59} However, time to fusion may be significantly less than with autograft use.\textsuperscript{50}

**Study Limitations**

The retrospective nature of the study is an inherent limitation. Other limitations include concealment of the fusion mass on the x-ray by the screw-rod constructs, which can make interpretation of union difficult; as well as the patient fallout due local follow up, resulting in infrequent radiological follow-up and determining the period to union inaccurate, particularly in the instrumented fusion group.

**Conclusion**

Instrumentation of the paediatric cervical spine is both possible and safe, despite the anatomical size constraints. Instrumented fusion of the paediatric craniocervical junction using screw-rod constructs offers versatility, is useful as an intra-operative reduction aid, and allows immediate stabilisation following decompressive procedures. The immediate stability creates a biomechanical environment with a high fusion rate and an acceptable complication rate.
Uninstrumented onlay fusion with Halo immobilization remains an acceptable alternative despite the challenges of intensive outpatient care.

Allograft in the form of bone croutons or DBM is a significant risk factor for non-union and should not be used.
Appendices

Table I. Underlying diagnosis

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<td>Morquio syndrome</td>
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Table II. Indication for surgery

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<td>(13)</td>
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<td>Instability with myelopathy</td>
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<tr>
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<td>4</td>
</tr>
<tr>
<td>Instability with radiculopathy</td>
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Figure 1. Lateral cervical spine XR demonstrating C1-C2 fusion achieved with an uninstrumented fusion technique with Halo external immobilisation.
Figure 2. Lateral cervical spine XR demonstrating partial concealment of the fusion mass due to screw-rod instrumentation. This was accepted as fused as there is no implant loosening or failure and no motion demonstrated on flexion extension views.

Figure 3. The patient is positioned prone on a Montreal mattress and positioned in the “military chin tuck position”. The patient is draped for posterior iliac crest autograft harvest.
25 January 2019

HREC REF: 051/2019

Prof R Dunn
Division of Orthopaedic Surgery
H49
OMB

Dear Prof Dunn

PROJECT TITLE: A RETROSPECTIVE REVIEW OF PAEDIATRIC CRANIOCERVICAL JUNCTION FIXATION: INDICATIONS, TECHNIQUES AND OUTCOMES (MMED: DR A SWAN)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has formally approved the above-mentioned study.

Approval is granted for one year until the 30 January 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanehtics/forms)

We acknowledge that the students Dr Adrian Swan will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator must obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR H BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients based on the Medical...

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.
Thank you for submitting your manuscript entitled, “Out with the old and in with the new” A retrospective review of Paediatric Craniocervical junction fixation: indications, techniques and outcomes” to the South African Orthopaedic Journal (SAOJ). The review of your manuscript has been completed and the following decision has been reached:

It is a pleasure to inform you that the above-mentioned manuscript has been accepted, as is, for publication in the South African Orthopaedic Journal. The comments of the reviewers are attached.

You will be contacted by our Managing Editor if any further information is required. Any queries concerning your manuscript should be addressed to the Managing Editor at: pat@saoj.co.za

Thank you for your contribution to the South African Orthopaedic Journal and we look forward to receiving further contributions in the future.

Sincerely yours,

Prof L Marais
Editor: SA Orthopaedic Journal

robyn@jesser-point.co.za
South African Orthopaedic Journal- instructions to authors

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.
- 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

Registration of clinical trials

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

You 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 Arial font, size 11.
- Double space throughout the document.
- Pages of the blinded manuscript should be numbered consecutively.
- Use the automatic page numbering function to number the pages.
- 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**

Please use no more than three levels of displayed headings.


**Abbreviations**

Abbreviations and acronyms should be defined at first mention and used 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 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 6 figures.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have and can supply written permission from the copyright holder to use that content.
- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrollment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

**Tables**

- Tables should carry uppercase Roman numerals, I, II, III, etc.
- Tables should always be cited in 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 caption (title) 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 caption.
- 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.
- Table 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 1, Table 2, etc.
- We accept a maximum of 8 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 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.gov](http://www.nlm.nih.gov).
- The following format should be used for references:

**Journal Articles:**


Ideally, the names of all authors should be provided, but the usage of “et al” in long author lists (more than 6 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:**


**Web reference (with authors):**

Cierny G, DiPasquale D. Adult osteomyelitis protocol.
(date last accessed 05 March 2013).

**Web reference (no authors listed):**

Chapter in a book:

Dissertation:

Abstract:

Structure and content of submission

We accept a maximum of 3500 words including abstract, 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 (please check that all names are accurately spelled)
- Qualifications
- Affiliation and address (indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate affiliation details)
- ORCID ID (see Article Submission section)
Provide the full postal address of each affiliation, including the country name and, if available, the email address of each author.

Corresponding author

Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication.

Ensure that the email 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.

Please provide the following information for the corresponding author:

- Full names and title
- Affiliation
- Physical address
- Postal address
- Telephone Number
- Email address

Declarations

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

The following statements is required under the declarations section:

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.
- Drafting the article or revising it critically for important intellectual content.
- Final approval of the version to be submitted.
- Sound scientific research practice

The authors further confirm that:

- The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere
- No data have been fabricated or manipulated (including images) to support your conclusions
This submission does not represent a part of 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”).

Author contributions

Please state the contributions of each author

• For example: “A.B contributed to study conceptualization, design, data analysis and manuscript preparation. C.D. contributed to data collection and manuscript preparation. E.F. contributed to ....”

• The types of contributions are:
  o Conceptualization and design
  o Data collection or contribution
  o Data analysis
  o Manuscript preparation
  o Other contribution (please specify)

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 author’s own.
• Proper acknowledgements of other’s work has been given (this includes material that is closely copied, summarized and/or paraphrased), quotation marks are used for verbatim copying of material.
• Permissions have been secured for material that is copyrighted.

Conflict of interest statement

A conflicting interest exists when professional judgement concerning a primary interest (such as 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 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

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; the decision to submit the manuscript for publication. If the study sponsors had no such involvement, this should be stated.

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](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 consisting 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

Keywords

Immediately after the abstract, provide a maximum of 6 keywords, using standard searchable terms. These keywords will be used for indexing purposes.

Level of evidence

Level 1 to 5.

Please follow the level of evidence guidelines provided by the Oxford Centre for Evidence-Based Medicine (OCEBM); version 2.1.
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 if the study in 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 needs to be described:

- The study design and research methodology.
- Whether randomization (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.
- Description of procedure or intervention, including post-operative protocol.
- The outcome measures or scores were used.
- The minimum follow-up period.
- A statistical analysis section 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 in narrative format and use past tense.
- Where relevant, tables or figures may be included to provide information more clearly.
- Generally, no data should normally 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 supported or rejected.
• The results must be interpreted clearly and any deficiencies expressed. All possible confounding factors, sources of bias, 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 should be clearly stated
• Should 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.
• The limitations of the study must be presented and suggest how the study could have been improved for a future study.
• Authors should avoid making inferences from non-significant trends unless they believe their study is adequately powered to answer the question; in that case, provide a power analysis.

Conclusion

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 exists, please 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 organization that provided the funding.

If no funding was received please state as follows: “No funding was received for this study.”

Acknowledgements

Should be placed at the end of the discussion and prior to the references. In this section persons who were involved but did not earn authorship can be acknowledged. Should be brief and should not anonymous editors or referees. A person can be thanked for assistance or for comments.

Author contributions

Please state the contributions of each author

- For example: “A.B contributed to study conceptualization, design, data analysis and manuscript
preparation. C.D. contributed to data collection and manuscript preparation. E.F. contributed to ....”

- The types of contributions are:
  - Conceptualization and design
  - Data collection or contribution
  - Data analysis
  - Manuscript preparation
  - Other contribution (please specify)

References

Please refer to formatting of submissions section.

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.
References


