The Fc Orth (SA) final examination
The short-term outcome of hip revision arthroplasty with Trabecular Metal™ components and augments.

By

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NCNLUB001

This study is in partial fulfilment of the requirements for the degree

Masters of Medicine in Orthopaedic Surgery

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November 2020

DECLARATION

I, Lubabalo Noconjo, 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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Format

The format is in accidence with South African Orthopaedic Journal guidelines

Contributions

The authors confirms that all authors have made a substantial contribution to this manuscript.

Lubabalo Noconjo : Primary author, Study Deign, Data collection, Data analysis

Marc Nortje : Conceptualisation, study design, manuscript revision and supervision

Archibald Mutsambiwa : Information technology and Data analysis

GLOSSARY OF ABBREVIATIONS

THA	Total Hip Arthroplasty
PJI	Periprosthetic Joint Infection
TM.	Trabecular Metal
MSIS	Musculoskeletal Infection Society
EBJIS	European Bone and Joint Infection Society
IDSA	Infection Disease Society of America
PACS	Pictoral Archive Communication System
HREC	Human Science Research Council
UCT	University of Cape Town
SAOJ	South African Orthopaedic Journal

Keywords: Trabecular Metal, Augments, Total Hip Arthroplasty, Revision hip Arthroplasty.

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ARTHROPLASTY

The short-term outcome of hip revision arthroplasty with Trabecular Metal™ components and augments

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Abstract

Background: Highly porous Trabecular Metal™ acetabular components are increasingly being used in revision hip arthroplasty as they facilitate ingrowth, provide a useful mechanism to deal with bone loss and may decrease the risk of infection. The purpose of this audit was to describe: 1) the short-term radiological outcomes of revision hip arthroplasty with Trabecular Metal™ components and augments. 2) the total number of hip arthroplasty surgeries over five years, and indications for revision.

Methods: A retrospective folder and radiograph review of all patients who had revision total hip arthroplasty (THA) at a tertiary level hospital from February 2012 to February 2017 was done.

Results: There were 979 THAs performed over the period – 863 (87%) primary THAs, and 116 (12%) hip revision cases performed in 107 patients. Of the 116 (107 patients) hip revisions, there were seven (6%) re-revisions in five patients. Trabecular Metal™ was used for revision in 16 hips (14 patients), which is 13.7% of the total 116 revisions. There were ten females and four males with an average age of 61 years. The average duration of follow-up in this group was 18.5 months (1.5–39.2). In these 16 Trabecular Metal™ hips, there were three (18.7%) early failures of fixation due to technical errors.

The indications for revision were aseptic loosening 67 (58.6%), septic loosening 11 (9.5%), liner wear 18 (15.5%), periprosthetic fracture five (4.3%), other 15 (13%).

Conclusion: In our institution, Trabecular Metal™ revisions had a 18.7% early failure rate due to technical error. 12% of the arthroplasty is revision surgery. The indications for revision are similar to published literature.

Level of evidence: Level 4

Keywords: Trabecular Metal, augments, total hip arthroplasty, revision hip arthroplasty

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directly or indirectly related to the research.

Introduction

Total hip arthroplasty (THA) is reported as one of the most successful procedures to relieve pain and restore function. It has evolved from a salvage procedure with poor long-term outcomes reserved for the most infirm patients, to one of the most successful and frequently undertaken elective surgical procedures. [1]

The porous metal tantalum (Trabecular Metal™ Zimmer/Implex, Warsaw, IN) has been in use since 1997. A rough surface micro texture provides a high co-efficient of friction for increased initial stability. It has a lower modulus of elasticity than that of titanium which creates a potential for improved transfer of forces to the pelvis and reduced stress shielding. Elbanzoury *et al.* in a prospective study of 18 consecutive patients showed that Trabecular Metal™ acetabular components and augments for acetabular defects appear to be a promising solution to a complex situation. [2] Unger *et al*. evaluated 60 consecutive patients undergoing revision THA with 42 months mean follow up, he reported excellent bone apposition and graft incorporation and concluded that Trabecular Metal™ acetabular cups appear suitable for use in revision THA. [3] A report on short term outcome of revision THA using tantalum augments in patients with severe acetabular bone defects showed satisfactory clinical and radiological outcomes in 2 year follow up. [4] Another retrospective study of 41 patients revised with acetabular porous tantalum showed good to excellent short term and mid-term functional results and acceptable complication rates. [5] While outcomes on use of Trabecular Metal™ are reported in the international literature, in South African literature this has not been previously reported. In our study all Trabecular Metal™ cups were TM Revision cups and if augments were used with the TM cup, they were Zimmer Biomet Trabecular Metal™ augments.

Aseptic loosening is a leading cause of failure in the intermediate and long term post-operative period. It is hypothesised to be the result of a harmful combination of mechanical and biological events destroying the bond between the implant and the bone bed. To date, a variety of host, implant and surgery-related factors have been

delineated to explain the development of aseptic loosening and osteolysis.[6] Osteolysis can lead to problematic bone loss. Several classifications exist for acetabular bone loss in THA. The most commonly cited classification is that by Paprosky. [7]

Periprosthetic joint infection (PJI) is a devastating and costly complication of total joint arthroplasty. Diagnosis is challenging and a mixture of multiple tests can reasonably increase the diagnostic accuracy. Some criteria from the Musculoskeletal Infection Society (MSIS), European Bone and Joint Infection Society (EBJIS), and Infection Disease Society of America (IDSA) have been published. [8] In our institution we prefer to use the MSIS criteria.

Dislocation is a complication occurring in approximately 0.3% to 10% of all primary procedures and up to 28% in revision surgery. It is a multifactorial problem caused by patient, implant and surgeon factors and can be reduced by thoughtful pre-operative planning and a careful surgical technique. [9]

Periprosthetic femur fractures in hip arthroplasty can occur intra- or post-operatively. Intra-operative fractures are estimated to occur in 1% of cemented and in 5.4% of uncemented primary THA. In revision surgery, incidence is higher, reaching 3.6% in cemented and 20.9% during uncemented procedures. Post-operatively, the incidence has been estimated to be less than 1% after THA and up to 4% following revision THA. [10]

Technical errors are of greater concern. Poor exposure, under sizing, malposition, intra-operative fractures and failure to achieve correct soft tissue tension can cause any implant to fail despite optimal design characteristics. Lastly, implant fracture after THA is a relevant complication leading to technically demanding revision surgery, with an incidence of 304 fractures per 100 000 implants from a pooled worldwide arthroplasty registry dataset. [11]

The purpose of this audit was to describe:
1. The short-term radiological outcome of revision hip arthroplasty with Trabecular Metal™ components and augments.
2. The total amount of hip arthroplasty surgeries over five years, and the indications for revision.

Materials and methods

After receiving approval from the institutional ethics board (HREC REF:149/2017), we performed a retrospective audit on the use of Trabecular Metal™ acetabular components and augments in revision hip arthroplasty at Groote Schuur Hospital from February 2012 to February 2017. Eligible patients were identified from an orthopaedic surgery registry. Clinical data including patient demographics, date of surgery, surgeon, type of implant and indication for revision were recorded. Clinical follow up and complications were recorded from patient folders. Pictorial archive communicating system (PACS) was used to access digital radiographic images. Pre-

operative pelvic anteroposterior and lateral X-rays were reviewed, and defects classified as per Paprosky.[7]

All hip X-rays were evaluated for osseous integration using the method of Moore *et al.*[12]
All patients that had revision hip surgery with Trabecular Metal™ were included in the study. For this audit any total hip replacement performed for either trauma or elective degenerative arthropathy was counted as a primary hip arthroplasty, hemi arthroplasty was not included. Revision hip arthroplasty was defined as exchange of any of the components of a hip arthroplasty. For the purposes of the study excision arthroplasty and implantation of an antibiotic-impregnated cement spacer followed by re-implantation of components in the same joint were considered as a single two-stage revision procedure. Trabecular Metal™ was used in 2012 and since then used for most revision surgeries requiring a change of acetabular component. It was not specifically reserved for large bone defects and was not used in every case.

Aseptic loosening of the acetabular component was defined as symptomatic lysis in all three zones or change in component position after at least a 6-month period of no symptoms. Components that showed a change in position within the 6 months were defined as 'early failure of fixation'. Septic loosening was defined as per the MSIS criteria.[13] Liner wear was defined as eccentric migration of the femoral head in the polyethylene and without aseptic loosening. All radiographs were reviewed by the investigator (registrar) and supervisor (senior consultant); a CT scan was not routinely performed. Patients with incomplete clinical and radiographic information, internal fixation, revision to THA and revision for tumours were excluded from the study. The data is presented using descriptive statistics including ranges, means and percentages.

A posterior or antero-lateral approach was used depending on previous surgery. After acetabular exposure, loose components were removed. A Hohmann retractor was placed over the anterior and posterior wall to better expose the acetabulum, overlying soft tissue was excised and careful reaming performed. A trial with a hemispheric cup was done and any defects were prepared to accept a suitable augment which was fixed with screws as necessary. Cement was placed between the cup and augment to unitise the components and prevent micro motion and additional cup screws were used if required.

Results

There were 979 THAs performed over the period: 863 (87%) primary THAs, and 116 (12%) hip revision cases performed in 107 patients. *Figure 1* shows a breakdown of primary and revision THA procedures done per year.
In the revision group there were 43 (40%) males and 64 (60%) females with an average age of 60.8 years (range 50–71). The average follow-up of the revisions was 15.9 months (4.7–25.8).

Of the 116 (107 patients) hip revisions, there were seven (6%) re-revisions. One of these seven re-revisions have not been performed yet due to medical reasons; the patient remains dislocated but is included in the numbers as a revision is indicated.

The indications for re-revision and procedure summary for the remaining six re-revisions in five patients are shown in *Table I*. There were three females and two males, with an average age of 60.2 years (47–71).

Trabecular Metal™ was used for revision in 16 hips (14 patients), which is 13.7% of the total 116 revisions. There were ten females and four males, with an average age of 61 years (38–86). The average duration of follow-up in this Trabecular Metal™ group was 18.5 months (1.8–39.2). One patient (patient number 5 in Table *I)* had three revision hip arthroplasties with TM accounting for the 16 hips in 14 patients.

Three hips (18.7%) of the 16 that were revised with Trabecular Metal™ showed component position change on serial radiographs and were defined as 'early failure of fixation'. Patient number 5 in *Table I* was revised with a Trabecular Metal™ cup and screws which failed and was re-revised with a cup and augment, which failed and then re-revised with a cup cage construct. This accounts for two hips defined as early failure of fixation. Patient number two in *Table I* was revised to a TM cup and augment and less than a year later had excision arthroplasty due to early failure of fixation, accounting for the third hip.

The indications for revision were aseptic loosening 67 (58.6%), septic loosening 11 (9.5%), liner wear 18 (15.5%), periprosthetic femur fracture five (4.3%), cortical perforation of the femur four (3.4%), recurrent dislocation four (3.4%), early failure of fixation four (3.4%), broken stem two (1.7%) and ankylosis one (0.9%).

The Paprosky classification of the revision cases is shown in *Table II.*

Discussion

Achieving initial implant stability and providing biological fixation is the key concept in in revision hip surgery. With this concept in mind and the use of Trabecular Metal™ gaining popularity in the management of acetabular bone defects and promising published results [14], we started using Trabecular Metal™ at our institution in 2012. In this audit, we found that Trabecular Metal™ usage in revisions still requires attention to detail to prevent early failure.

In Table *I,* Patient 2 was revised to a Trabecular Metal™ cup and augment and the augment grew in, but the cup failed due to cement extravasation during liner insertion that prevented osseous integration, evident at excision arthroplasty a year later. The patient had comorbidities precluding further major surgery. This phenomenon has not been described to our knowledge and possibly results from placement of the cement too early or use of cement with low viscosity.

Patient 5 had posterior superior acetabular bone loss which occurred with acetabular preparation at the first revision (*Figure 2A*). No augments had been ordered and the cup screw fixation failed in 3 months (*Figure 2B*) The second revision included an augment (*Figure 2C*) and the cup failed a year later (*Figure 2D*). This was converted to a cup cage construct (*Figure 2E*) and at revision the cup and augment were found to have no osseous integration. Unlike in patient 2 there was no sign of cement extravasation to the implant bone interface. There was no sign of infection at any stage and the reason for early failure of fixation was thought to be instability of the

construct. This patient continues to be monitored and there is no sign of loosening of the cup cage construct at final follow-up. The series of X-rays is shown in *Figure 2*.

Tokarski *et al.* believe that tantalum is more protective against infection due to higher potential of tantalum for osteointegration, thereby obliterating any dead space. [15] The ability of osteoblasts to proliferate and integrate onto the surface of the uncemented component may then deprive infecting organisms' access to the surface. A second reason may relate to the topographical three-dimensional structure of the surface of tantalum that may be difficult for organisms to access and colonise. Finally, tantalum as an element may carry specific charge or have surface characteristics that are hostile to infecting organisms. Furthermore, they showed encouraging findings in the use of tantalum components which may be protective against failure due to infection at least in patients who had undergone revision surgery for infection. A case series by Malkani *et al.* showed that all 21 patients developed ingrowth along the tantalum surface despite compromised bone loss, and he concluded that porous tantalum appears to be a promising material to use in revision hip arthroplasty to facilitate biological ingrowth in patients with acetabular bone loss. [16]

In most cases of acetabular component revision, there will be some degree of bone loss. [17] Our usual management of Paprosky type 3A and 3B includes the use of augments. Our approach is similar to that described by Abolghasemian *et al.* which suggests that type 1 and type 2 defects do not usually require the use of acetabular augments. In type 1, conventional cemented or cementless components can be used. Type 2 defects are usually managed with morselised bone graft and normal uncemented acetabular cups. If there is less than 50% contact of the cup with viable host bone, the use of an ultra-porous acetabular component is recommended to ensure sufficient initial stability and potential for subsequent bone ingrowth. Type 3 defects are mostly associated with the use of augments. [18] Porous acetabular components are manufactured by numerous implant companies; we have used different manufacturers in our series but are focusing on the tantalum RevisionTM components from Zimmer Biomet.

In *Table I*, patient 1 had failure of an uncemented 62 mm spiked cup in a 3B defect and was revised successfully to a 64 mm multi-hole uncemented cup with screws. In the first case, augments were incorrectly not ordered, probably causing the early failure of fixation and in the second, the cup screw construct was deemed stable and therefore augments not used. This should be considered a technical or surgeon error as augments should probably be available when performing acetabular revision surgery, regardless of the defect.

The annual reports of the national arthroplasty registry of Sweden, Norway, Finland, Denmark, Australia and New Zealand show a mean of 1.29 revisions per 100 observed component years. This corresponds to a revision rate of 6.45% after five years and 12.9% after ten years. [19] In our study 12% of the procedures were revisions, not necessarily from our unit as we are a tertiary referral centre.

We found similar indications for revision to the published literature. [20] Aseptic loosening was the most common cause of revision surgery in our study. Ulrich *et al.* evaluated the indications for revision hip arthroplasty and showed that 51% were revised for aseptic loosening. [21] It is probably a combination of several events and there is a growing evidence indicating that cyclic mechanical loading, production of prosthetic wear particles and ensuing adverse tissue response are important contributor to local osteolysis and bone resorption at the bone-prosthesis interface. [22]

In our study, liner wear was the second most common indication for revision. There are three fundamental mechanisms of wear: abrasive, adhesive and fatigue. Abrasive wear constitutes the main wear type in hip arthroplasty. The criteria for revision surgery due to a worn polyethylene hip cup or liner, have long been controversial. Often there is a dilemma in choosing polyethylene exchange alone or revising the acetabular components. Grobbelaar *et al.* reported a correlation between cup wear on the one hand, and pain, interface widening and osteolytic failure on the other. [23] In our institution, if a cup is radiologically aligned and well-fixed, we prefer to do polyethylene exchange alone.

Periprosthetic joint infection is a devastating complication for both patient and surgeon. Sepsis was the cause of 9.5% of our revisions. This figure is higher than that reported by Ulrich *et al.* [21] probably because our institution is a tertiary referral centre. We did not analyse reasons for infection.

A periprosthetic fracture of the femur in association with THA is increasingly common and often difficult to treat. Similar to our study, Marsland *et al.* reported an overall incidence of 4.1% of periprosthetic femur fractures with higher rates for uncemented and revision THA. [24]

This study is limited due to its retrospective nature. Follow up was short due to only recently starting to use Trabecular Metal™ and the fact that patients are lost to follow-up due to social factors and geographical movement. This is particularly true if patients are doing well, if they are having problems they would tend to get back to our institution as we are a tertiary referral centre. Our small numbers make statistical analysis difficult This audit needs to be repeated with larger numbers and longer follow-up.

Conclusion

Trabecular Metal™ was used in 13% of revisions. Three hips (18.7%) failed to remain stable and were classified as early failure of fixation, probably due to technical error. In our institution 12% of the arthroplasty performed is revision surgery. The indications for revision are described and are similar to the published literature.

Acknowledgement

I would like to acknowledge the assistance of Mr Archibald Mutsambiwa for information technology contributions.

Ethics statement

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. The article does not contain any studies with human participation or animals performed by any of the authors. For this study, formal consent was not required and approval was give by our institutional Human research ethics Committee (HREC REF:149/2017).

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 contributions

L N: Primary author, study design, data collection, data analysis and manuscript preparation
M.N: Conceptualisation, study design, manuscript preparation, supervised the study

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Figure 1. Summary of primary and revision THR procedures done during the five-year period

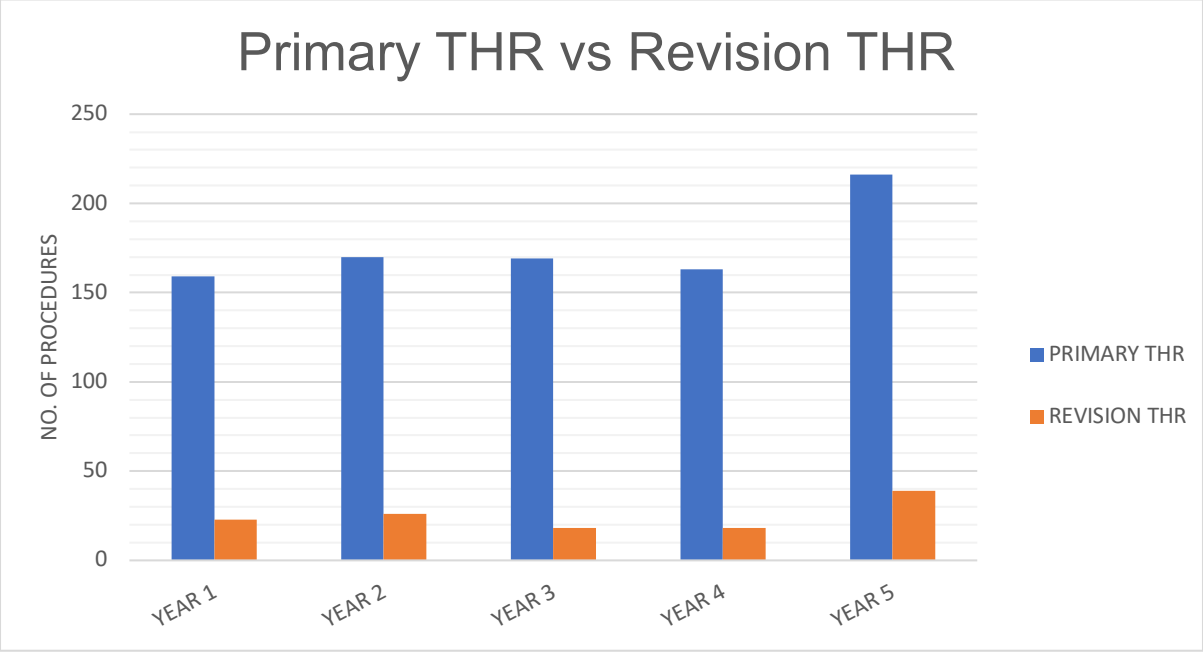
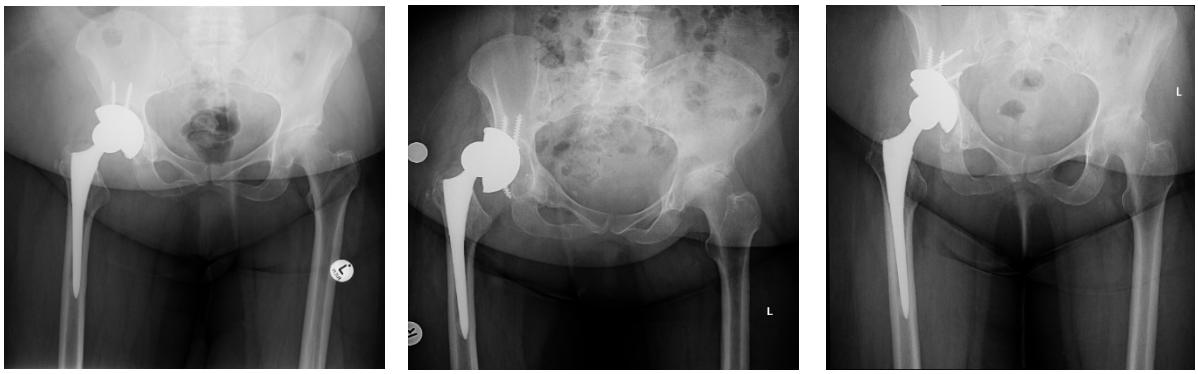
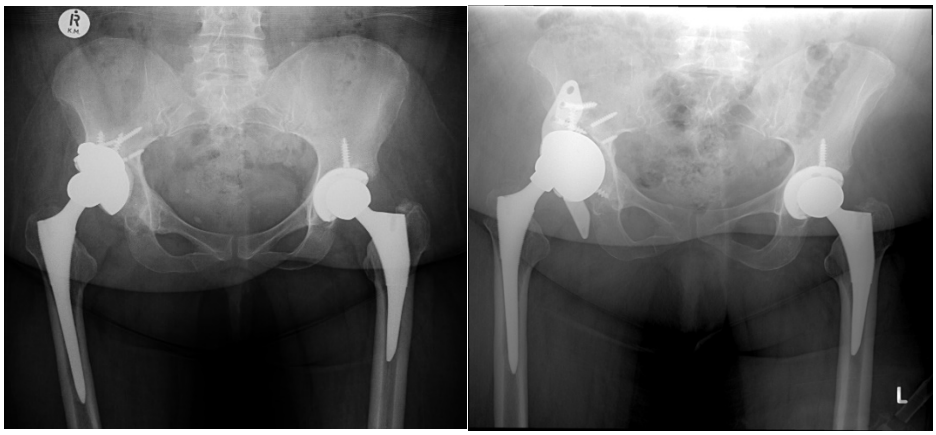


Figure 2. X-ray series of patient 5.



A B C



D E

(A) A 63-year-old female underwent revision with TM cup with screws for aseptic loosening of acetabular component; (B) Subsequent loosening showing a vertically positioned acetabular cup; (C) Re-revision with TM augment secured with screws; (D) Loose acetabular augment; (E) Re-revision with a cup cage.

Table I: The indications for re-revision and procedure

Patient	Primary procedure	Revision 1	Revision 2	Revision 3
1	1980s Uncemented stem and cemented cup	2012 Aseptic loosening of cup Paprosky 3B Cemented cup to uncemented spiked cup	2013 Failure of fixation of cup Spiked cup to multi-hole cup with screws	
2	2014 Cemented stem and uncemented cup	2016 Aseptic loosening of cup Paprosky 3A Uncemented cup to TM revision cup and augment	2017 Failure of fixation of the cup Excision arthroplasty	
3	1990 Cemented stem and cup 2004 Long stem for periprosthetic fracture Uncemented cup stable	2014 Aseptic loosening and liner wear Loose long stem exchanged and new liner, cup stable	2017 Aseptic loosening cup Paprosky 3B Uncemented cup to custom acetabular component	
4	1990s Cemented stem and cup	2015 Long stem for aseptic loosening of the femur Cemented cup stable	2015 Recurrent dislocations Cemented cup to uncemented cup with screws	
5	2001 Uncemented stem and cup	2016 Aseptic loosening of uncemented cup to TM cup and two screws	2017 Failure of fixation Paprosksy 3A TM cup to TM cup and augment	2018 Failure of fixation TM cup and augment to TM cup cage construct

Table II: Paprosky[8] classification of the revision cases

Type	Non-TM revisions (n=100)	Trabecular Metal™ revisions (n=16)
1	42	1
2A	13	3
2B	29	1
2C	8	3
3A	2	6
3B	6	2

PART B: APPENDICES
ETHICS APPROVAL

UNIVERSITY OF CAPE TOWN

HUMAN RESEARCH ETHICS COMMITTEE 01 JUL 2020 HEALTH SCIENCES FACULTY

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001837; IRB00001838)		
☑ Approved	☑ Type of review: Expedited	☐ Full committee
This serves as notification that all changes and documentation described below are approved.		
Signature Chairperson of the HREC	Signature Removed Date	8/7/2020

Note: All major amendments must include ... justifying the changes for the amendment.
Please note that incomplete amendment submissions will not be reviewed.

Comments from the HREC to the Principal Investigator:
Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	06/07/2020
HREC REF Number	149/2017
Protocol title	**The short-term outcome of hip revision arthroplasty with Trabecular Metal™ components and augments**
Protocol number (if applicable)	
Principal Investigator	Dr M. Nortje
Department / Office Internal Mail Address	mbnortje1@gmail.com

1.1 Is this a major or a minor amendment? (see FHS006hlp) Major (tick box) Minor (tick box)	☐ Major	(X) Minor
1.2 Does this protocol receive US Federal funding?	☐ Yes	(X) No

1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval? Note: Any protocol amendments for Full Committee review MUST be submitted on the monthly HREC submission dates. (Please email an electronic copy to hrec-enquiries@uct.ac.za)	☐ Yes	☐ No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.
This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.

1. Re-wording of the title
2. Re- wording of the purpose of the study

3. Protocol status (tick ✓)

☐	Open to enrolment
(x)	No participants have been enrolled
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

	Protocol
☐	Study objectives, design (including investigator's brochure, clinical activities, study length)
☐	Study instruments, questionnaires, interview schedules
☐	Sample size
☐	Recruitment methods
☐	Eligibility criteria (inclusion and exclusion criteria)
☐	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
☐	Data collection/ analysis
☐	Principal investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013)
☐	Consent form and information sheet
☐	Recruitment materials (e.g. advertisements)
☐	Administrative (e.g. change in sponsor's name, change in contact information)
(x)	Other. Please specify: None of the above. We re-worded the title and the purpose of the study

4.1 In your opinion, will there be any increase in risk, discomfort or inconvenience to participants?	☐ Yes	(x) No
If yes, please provide a detailed justification/explanation:		

4.2 What follow-up action do you propose for participants who are already enrolled in the study?	
☐	Inform current participants as soon as possible
☐	Re-consent current participants with revised consent/assent forms (append)
☐	No action required
☐	Other. Please describe:

5. Detailed description of the change(s)

Please attach, for each **amendment, a summary** of all **changes** which **clearly indicates:**

i. **Old wording (e.g. strikethrough text, CHANGED FROM and CHANGED TO)**

ii. **New wording (e.g. *italicized*, bold, tracked)**

iii. **Detailed rationale/** justification/ explanation for each change

6. Ethics Review Levy – cost including vat

Cost for Major Amendments - R3 661.26

(Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from charges)

For invoicing purposes, please provide

Sponsor's name	
Contact person	
Address	
Telephone number	
Email Address	

7. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval **I will seek** further approval **from** the HREC.

Signature of PI	Signature Removed	Date	6/7/2020

SAOJ PUBLICATION GUIDELINES

INSTRUCTIONS FOR AUTHORS

Scope and Policy

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

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

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

Criteria for publication

- The article falls within the scope of the journal.
- Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
- Results reported have not been published elsewhere.
- Conclusions are presented in an appropriate fashion and are supported by the data.

- The article is presented in an intelligible fashion and is written in standard English (British usage).
- The research meets all applicable ethical standards.
- The article adheres to guidelines provided in the instructions for authors section.

Guidelines for authorship

- Each author should participate and is responsible for the content and design of the study, the preparation of the manuscript and its revisions, and final approval.
- Other 'contributors' can be acknowledged at the end of the manuscript together with their contribution.
- Authors of manuscripts representing a multi–centre study may list members of the group in the footnote on the title page of the published article and their affiliations are listed in an appendix.
- The authors should clearly indicate the predominant surgeon or surgeons who have contributed patients to the study.

Registration of clinical trials

- A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health–related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process–of–care changes.
- Clinical trials should be registered in a public trials registry in accordance with International Committee of Medical Journal Editors recommendations.
- Trials must be registered and approved by the relevant authorities before the onset of patient enrolment.
- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

Reporting guidelines

- All articles should be prepared in accordance with the guidelines relevant to the study design that was used (listed below):

Randomised trials	CONSORT
Observational studies	STROBE
Systematic reviews	PRISMA
Case reports	CARE
Qualitative research	SRQR
Diagnostic / prognostic studies	STARD
Quality improvement studies	SQUIRE
Economic evaluations	CHEERS
Animal pre–clinical studies	ARRIVE
Study protocols	SPIRIT

-
- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

Role of funding source

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

Formatting of Submissions

Text formatting

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

Headings

- Use no more than three levels of displayed headings.

Abbreviations

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

Units

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

Figures

- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3, etc.
- The figure should be listed in the text as follows: … wound irrigation and splinting (*Figure 1*).
- Figures should be clear and easily understandable with a full descriptive legend stating any areas of interest and explaining any markings, letterings or notations. All figures should be understandable without the main text.
- For radiographs please ensure you state the view used and the time point at which it was taken, as well as the demographic details of the patient if applicable.

- Figures should not be imbedded in the text file, but should be submitted as separate individual files. Each figure should be a separate file, entitled Figure 1, Figure 2, etc.
- Remove all markings, such as patient identification, from radiographs before photographing.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of six figures.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

Tables

- Tables should carry uppercase Roman numerals, I, II, III, etc.
- Tables should always be cited in the text in consecutive numerical order.
- The table should be identified in the text as follows: Details of results are listed in *Table I*. Or, alternatively, … high–energy trauma that is often associated with these fractures (*Table II*).
- Tables should be used to present information in a clear and concise manner. All tables should be understandable without the main text.
- For each table, please supply a table heading explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table heading.
- Footnotes to tables should be indicated by superscript lower–case letters and included beneath the table body.
- Please submit tables as editable text and not as images. They should be created using the Table tool in Word.
- Do not embed tables in the text file, but submit them as separate individual files. Each table should be a separate file, entitled Table I, Table II, etc.
- We accept a maximum of eight tables.
- Do not duplicate information given already in the text.
- Do not submit any figures, photos, tables or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

References

- References should be numbered consecutively in the order that they are first mentioned in the text and listed at the end in numerical order of appearance.
- Identify references in the text by Arabic numerals in superscript after punctuation.

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

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

Ideally, the names of all authors should be provided, but the usage of 'et al.' in long author lists (more than six authors) will also be accepted: Fong K, Truong V, Foote CJ, et al. Predictors of nonunion and reoperation in patients with fractures of the tibia: an observational study. BMC Musculoskelet Disord 2013;14:103.

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

Web reference (with authors):
Cierny G, DiPasquale D. Adult osteomyelitis protocol. http://www.osteomyelitis.com/pdf/treatment_protocol.pdf. (date last accessed 05 March 2013).

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

Chapter in a book:
Young W. Neurophysiology of spinal cord injury. In:

Errico TJ, Bauer RD, Waugh T (eds). Spinal Trauma. 3rd ed. Philadelphia: JB Lippincott; 1991: 377-94.

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

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

Structure and content of submission

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

Title page

Title

- The title should be concise and informative.

Author names and affiliations

- Please provide the following information for each author:
    - Full names and surname, as well as title
    - Qualifications
    - Affiliation and address
    - ORCID ID (see Article Submission section)
- Please check that all names are accurately spelled.
- Indicate all affiliations with a lower–case superscript letter immediately after the author's name and in front of the appropriate affiliation details.

- Provide the full postal address of each affiliation, including the country name and, if available, the e–mail address of each author.

Corresponding author

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

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

a. Authorship
   The authors confirm that all authors have made substantial contributions to all of the following:
    - The conception and design of the study, or acquisition of data, or analysis and interpretation of data
    - The drafting the article or its critical revision for important intellectual content
    - Final approval of the version to be submitted.
b. Sound scientific research practice
   The authors further confirm that:
    - The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere
    - No data have been fabricated or manipulated (including images) to support conclusions.
    - This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami–publishing').

c. Plagiarism
   The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.
   - No data, text or theories by others are presented as if they were the authors' own.
   - Proper acknowledgements of others' work has been given (this includes material that is closely copied, summarised and/or paraphrased); quotation marks are used for verbatim copying of material.
   - Permissions have been secured for material that is copyrighted.

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

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

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

e. Funding sources
   All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; and the decision to submit the manuscript for publication. If the study sponsors had no such involvement, this should be stated.

f. Compliance with ethical guidelines
   - For all publications:

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

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

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

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

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

     'Informed written consent was or was not obtained from all patients for being included in the study.'
   - For studies with animals include the following sentence: 'All institutional and national guidelines for the care and use of laboratory animals were followed.'
   - For articles that do not contain studies with human or animal subjects:
     'This article does not contain any studies with human or animal subjects.'
   - If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. If any identifying information about patients is included in the article, the following sentence should also be included: Additional informed consent was obtained from all patients for which identifying information is included in this article.

The Helsinki Declaration 2008 can be found at http://www.wma.net/en/30publications/10policies/b3/

Blinded manuscript

Abstract

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

Key words

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

Level of evidence

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

Introduction

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

Patients (or Materials) and methods

- State the methods, outcome measures, and selection criteria. The following aspects need to be described:

    - The study design and research methodology
    - Whether randomisation (with methods) was applied
    - If case controlled, how the controls were selected
    - The time period under review
    - Number of patients/subjects under investigation and why this number was chosen
    - Inclusion and exclusion criteria
    - Case and outcome definitions
    - A description of the procedure or intervention, including post–operative protocol
    - The outcome measures or scores used
    - The minimum follow–up period
    - Statistical analysis paragraph. This should be included at the end of this section to detail statistical tests and package used, the reasons why these tests were used, and what p–value was considered statistically significant. A power analysis is recommended for studies comparing two or more groups.

- Provide sufficient detail so that another researcher can replicate the study.
- The reader should understand from this description all potential sources of bias such as referral, diagnosis, exclusion, recall or treatment bias. This includes the manner in which investigators selected the patients. Consecutive inclusion implies all patients with a given diagnosis are included, while selective implies patients with a given diagnosis but selected according to certain explicit criteria (e.g., state of disease, choice of treatment).
- Do not describe standard procedure for common operations. Only include new procedures or adaptations to standard procedure.
- If you name any specific product, then it requires the name, city and state/country of the manufacturer.
- Present information in the narrative format and use the past tense.
- Where relevant, tables or figures may be included to provide information more clearly.
- Generally, no data should be presented in this section.

Results

- Describe the relevant results and analysis thereof.
- Provide details of the number of patients included and excluded, as well as the reason for exclusion.
- It is important to state the follow–up period (mean and range).
- The results can be broken down into separate sections, e.g. Treatment, Functional outcome, Complications, etc.

- Tables may be used but avoid repeating data reported in the text in the tables.
- All appropriate data should be presented as means with ranges, not with standard deviations (SDs). Medians should only be used when the data is skewed, accompanied by an interquartile range (IQR).
- Avoid using percentages in studies involving well under 100 subjects.
- All results must be backed up with p–values or survivorship analysis. All Kaplan–Meier data should be presented with the confidence intervals. Always present exact absolute p–values, whether significant or not, unless $p < 0.001$.
- However, p–values do not always convey the entire picture and where relevant the confidence interval will also be required (in addition to the power of the study reported in the methods section).

Discussion

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

Conclusion

- Provide a summary statement which conveys the conclusions of the findings.

- Do not draw conclusions not supported by the data obtained from the specific study presented.

Conflict of interest

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

Ethical statement

- For studies involving human subjects please include an ethical statement as follows: 'All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.'
- For animal studies please include the following ethical statement: 'All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.'
- If the study did not involve human or animal subjects state that: 'This article does not contain any studies with human participants or animals performed by any of the authors.'
- Please also include an informed consent statement: 'Informed consent was obtained from all individual participants included in the study.'
- Or alternatively, for retrospective studies, please add the following sentence: 'For this study formal consent was not required.'
- If identifying information about participants is available in the article, the following statement should be included: 'Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.'

Funding sources

- List all funding sources as follows: 'This work was supported by the xxxx (grant numbers xxxx, yyyy).'
- When funding is from a block grant or other resources available to a university, college or other research institution, submit the name of the institute or organisation that provided the funding.
- If no funding was received, state as follows: 'No funding was received for this study.'

Acknowledgements

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

References

- Please refer to the section on Formatting of submissions.

Tables and figures

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

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.

REVIEWER'S COMMENTS

Peer- Review of Article:

The short-term outcome of hip revision arthroplasty with Trabecular Metal™ components and augments.

Reviewer A:

Recommendation: Major revision required.

I believe the information in this article is relevant but the focus is currently too broad and some of the conclusions are not related to the original aims. I think the audit can be improved upon by changing the focus of the audit slightly, focusing the aims and making conclusions in line with the aims.

Relevant information to this study:

Institution: Tertiary level training hospital

Experience: Arthroplasty unit with significant hip revision experience

Focus: Large acetabular defects, revision hip arthroplasty and the use of Trabecular metal components and augments

Specific outcome: Short term results. Even though the numbers are low the results as part of an audit are still relevant.

Title: I suggest changing it in line with the above comments.

The short-term outcomes of hip revision arthroplasty with Trabecular Metal™ components and augments.

The time period and level of institution could also be added but the title becomes very long and then it may be better to add that information to the methods. I suggest not putting the institution's name in the title.

Abstract: I believe the focus of this audit should be narrowed down

Background and aims

1. The total amount of hip arthroplasty surgeries over 5 years, the ratio of revision to primary hip arthroplasty and the indications for revision. (The main aim here is to show that the institution has a significant amount of experience in primary and revision hip arthroplasty).

2. The short-term outcomes of revision hip arthroplasty when managing significant acetabular bone loss with Trabecular Metal™ components and augments.

Reviewer B:

The major problem with the audit is that the aim of the study (line 62 to 64) does not correlate with the conclusion, which states that the use of Trabecular acetabular components in the audit was not associated with infection. The purpose of the audit read as follows.

1. The use of acetabular components and augments at Groote Schuur Hospital.
2. The rate of revision surgery to primary surgery and our reason for revision.
3. To assess the amount of acetabular bone loss in our revision.

The purpose of the study as stated is not described in the conclusion. The conclusion ends by stating that their use of acetabular components and augments was not associated with infection and this is not in the purpose of the study.

Their aseptic revision rate in the audit is stated as 58% in line 87 and 67% in line 112, these figures do not correlate. The spelling of discussion is wrong in line 104 (Discussion)

I am therefore of the opinion that the submission needs a major revision and resubmitted for publication. The purpose of the study must correlate with the conclusion.

ACCEPTANCE LETTER FOR PUBLICATION

Lubabalo Noconjo
Department of Orthopaedic Surgery
Groote Schuur Hospital
University of Cape Town
South-Africa

24 April 2020

Dear Dr Noconjo

Title: The short-term outcome of hip revision arthroplasty with Trabecular Metal components and augments (Lubabalo Noconjo, Marc Nortje)

The above manuscript has been accepted for publication and will be published in the Vol 19 No 3 (2020) issue of the South African Orthopaedic Journal.

Thank you for supporting the South African Orthopaedic Journal.

Yours sincerely

Signature Removed

pp
Prof L Marais
Editor: South African Orthopaedic Journal