CONDOM STERILITY IN PERIPROSTHETIC JOINT INFECTION MANAGEMENT AT UNIVERSITAS ACADEMIC HOSPITAL IN BLOEMFONTEIN 2018

by

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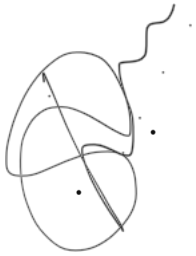
DECLARATION

I, Dr. Ntsikelelo Tyumre, declare that this research report represents my own independent work. It is being submitted for the degree Master of Medicine (MMed) in Orthopaedic Surgery at the University of the Free State. It has not been submitted before for any degree or examination at any other university, neither has any part of it been published before.



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LIST OF ABBREVIATIONS

CRP	C-reactive protein
CSSD	Central Sterilisation Services Department
DAIR	debridement, antibiotics and implant retention
ESR	erythrocyte sedimentation rate
H_2O_2	hydrogen peroxide
LE	leukocyte esterase
MC&S	microscopy, culture and sensitivity
NHLS	National Health Laboratory Services
PJI	periprosthetic joint infection
PMN	polymorphonuclear
SABS	South African Bureau of Standards
THA	total hip arthroplasty
TKA	total knee arthroplasty
WBC	white blood cells

SUMMARY

Joint replacement surgery, especially of the hip and knee, is one of the most rewarding operations for both the patient and the orthopaedic surgeon worldwide. Hip replacement has been dubbed the operation of the century. This is because these replacements improve the quality of life for the elderly population crippled with arthritis, and in recent years, due to better implants, also improves quality of life in the younger generation presenting with joint problems. It is, however, not without complications, the most important being periprosthetic joint infections. Other complications include aseptic loosening, periprosthetic fractures and dislocation.

Periprosthetic joint infection is the most dreaded of the complications because of its difficulty to manage and association with significant morbidity and bone loss. We therefore began by describing and defining periprosthetic joint infection and investigated the current epidemiological data available. We have reviewed literature and looked at the diagnostic criteria from the different societies and meetings from around the world. Parvizi et al. developed an algorithm and proposed criteria that are based on the latest data and tests. This is explained in detail in the first chapter of this dissertation. The management of periprosthetic joint infection is dependent on the amount of time from the index joint surgery. An outline of the deferent management options are presented, while bearing in mind that two-stage revision surgery is the gold standard of management.

Management of periprosthetic joint infection is associated with bone loss, either with the removal of infected implants or removal of the cement spacer in the second surgery of the two-stage procedure. A recent unpublished study done locally in our department showed that putting a cement spacer in a condom and then placing the condom-cement spacer in the joint to allow it to set, and then taking out the condom-cement spacer after the cement had set, was associated with no bone loss. The study also showed that female condoms were stronger and more durable compared to the male condoms.

The question that needed to be addressed, was whether it is safe to introduce condoms into the joint? Based on the literature, there is a 10% chance that condoms maybe contaminated. We investigated the sterility of condoms from the packaging and how to improve the sterility of the

condoms. Sixty government-issued female condoms were used for the study, of which 30 were tested straight from the packaging and the other 30 were first put through hydrogen peroxide gas plasma sterilisation and then tested by means of MC&S.

Similar to previously published studies, contamination of the condoms was confirmed, although in our study, the rate of contamination was 60%. We also isolated nonvirulent environmental and implant contaminants. The most important aspect of the results was that we were able to achieve 100% sterility of the condoms with hydrogen peroxide gas plasma. This was significant because we can place condoms for its intended use in the joints without introducing further infection in the joint. Once sterilised, condoms can also be used for other sterile/aseptic medical procedures, such as ultrasound probe covering and temperature probe covers.

CHAPTER 1

LITERATURE REVIEW

1.1 Introduction

In the field of orthopaedics, total knee and hip replacements are performed as treatment modalities for patients with extensive hip and knee disease. It improves pain, joint function and overall quality of life, and are cost-effective.[1] These procedures, although done frequently, are not without complications. The most important complication is periprosthetic joint infection (PJI).[2] It almost always leads to implant failure, implants loosening, pain, subsequent multiple surgeries and prolonged hospitalisation, and serious morbidity.[3] The treatment of this infection poses a significant challenge.

The incidence of PJI following total hip arthroplasty ranges from 0.5% to 2% and may increase to 4% in immunocompromised patients.[4] The incidence of PJI following total knee arthroplasty is 1% to 2%.[2]

1.2 Aetiopathogenesis of prosthetic joint infection

Periprosthetic joint infection occurs as a result of bacteria that attach to the implants in the joint. This is the first step in the formation of biofilm. The second step involves the cell-to-cell attachment between the micro-organisms. Biofilm is a complex three-dimensional structure consisting of glycocalyx that contains colonies of microorganisms of either single or multiple species.[5]

Biofilm is initially self-sustainable and produces its own extracellular matrix. It is important that in addition to providing protection to the micro-organisms, it also protects against antibiotics. It also plays a central role in the pathogenesis of PJI.[5,6] The most common micro-organisms in the pathogenesis of PJI are Gram-positive cocci, such as *Staphylococcus aureus* and coagulase-negative staphylococci.[5] Other causative organisms include Gam-negative cocci and fungal species.

1.3 Diagnosis of PJI

A number of defining criteria for the diagnosis of PJI has been proposed by different organisations and societies. The International Consensus Meeting (ICM) convened in 2014 and 2018 to decide on the criteria, although the proposed criteria were criticised for not accounting for chronic, low-grade PJIs.[7] In 2018, The European Bone and Joint Infection Society proposed new criteria that also accounted for chronic, low-grade PJIs[1]. The new criteria are listed in Table 1.

Table 1. Criteria for the diagnosis of periprosthetic joint infection.[1]

Test	Criteria	Sensitivity	Specificity
Clinical feature	Sinus tract, purulence	20–30%	100%
Leukocyte count in synovial fluid	>2 000 leukocytes per µl, or >70% PMN leukocytes	90%	95%
Periprosthetic tissue histology		73%	95%
Microbiology	Microbial growth in:		
	Synovial fluid	45–75%	95%
	>2 positive tissue samples	60–80%	92%
	Sonication	80–90%	95%

PMN: polymorphonuclear

At our institution, however, we use the Musculoskeletal Infection Society (MSIS) criteria.[8] The MSIS initially proposed the criteria with the Centres for Disease Control and Prevention (CDC) in 2011. These criteria were reviewed and amended in 2018. The criteria are as follows:

1. A sinus tract communicating with the prosthesis has been identified; or
2. A pathogen is isolated by culture from two separate tissue or fluid samples obtained from the affected prosthetic joint; or
3. Four of the following six criteria exist:
    a. Elevated serum erythrocyte sedimentation rate (ESR) or serum C-reactive protein (CRP) concentration;
    b. Elevated synovial white blood cell (WBC) count;
    c. Elevated synovial polymorphonuclear neutrophil percentage (PMN %);

d. Presence of purulence in the affected joint;
e. Isolation of a microorganism in one culture of periprosthetic tissue or fluid;
f. Greater than five neutrophils per high-power field in five high-power fields observed from histologic analysis of periprosthetic tissue at 400 times magnification.

Parvizi et al.[9] proposed new criteria of PJI in 2018. They evaluated at all the current evidence including current tests and methods of diagnosing PJI. Based on these new criteria, a sinus tract or two positive cultures from the same joint are the major criteria and are regarded as diagnostic of PJI. They also assessed the serum and synovial inflammatory markers and gave each marker a score based on the random forest analysis. A combined score of more than 6 is diagnostic of PJI, while a score between 2 and 5 is inconclusive and requires intra-operative testing for purulence, histology and a single positive culture. The new criteria have a higher sensitivity compared to the previous MSIS criteria for the diagnosis of PJI.[9] Table 2 simplifies these new criteria on the diagnosis of PJI.

Table 2. Simplified criteria for the diagnosis of periprosthetic joint infection[9].

Major criteria (at least one present)			**Decision**
Two positive cultures of the same organism Sinus tract communicating with joint or visualisation of joint			Infected
Pre-operative diagnosis		***Score***	***Interpretation***
Serum	Increased CRP/D-dimer	2	≥ 6: infected 2–5: possible infected 0–1: not infected
	Increased ESR	1	
Synovial fluid	Increased synovial WBC/LE	3	
	+ Alpha defensing	3	
	Increased synovial PMN	2	
	Increased synovial CRP	1	
Intra-operative		***Score***	***Interpretation***
Pre-operative score		–	>/= 6 infected 4 – 5 inconclusive =/< 3 not infected
Positive histology		3	
Positive purulence		3	
Single positive culture		2	

CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; WBC: white blood cells; LE: leukocyte esterase; PMN: polymorphonuclear neutrophils

1.4 Classification of PJI

The classification of periprosthetic joint infection is based on the time elapsed from the index joint replacement procedure[7]. The time period from the index surgery is important because it has both clinical and management implications. The treatment options will be dictated by the time from the initial surgery. The route of infection is also used often to classify PJI. Based on time since the primary procedure, PJIs are classified as either acute of chronic, with the following features:

1.4.1 Acute PJI

- Onset less than 4 weeks after the primary procedure.
- Clinical features: the patient presents with fever, joint pain, and reddening, swollen and post-surgical discharge/purulence.
- The microbial causes are usually highly virulent organisms such as *Staphylococcus aureus*, *E. coli*, and *Klebsiella* species
- The surgical management commonly involves debridement, antibiotics and implant retention (DAIR).

1.4.2 Chronic PJI

- Symptoms occur after 4 weeks from the index joint surgery.
- Divided into delayed (> 4 weeks) and late (> 1 year) PJI.
- Clinical features: the patient presents with chronic purulence, implant loosening, chronic joint pain and sinus tract formation.
- The micro-organisms are almost always low virulence organisms and include coagulase-negative staphylococci such as *Staphylococcus epidermis* and other cutibacterial species.
- Management always involves removal of the implant, either through single-stage or two-stage procedures.

The route of infection can be used in the classification of PJI,[3] namely (i) haematogenous spread, where the infection develops through either blood or the lymph system from a distant focus; (ii) contiguous spread, where the infection develops from an adjacent focus, such as

trauma in the bone, soft tissue infection or skin infection; and perioperative spread where inoculation occurs during surgery or immediately thereafter.

1.5 Diagnosis of PJI

A prompt and accurate diagnosis of PJI is imperative. Therefore, a combination of clinical findings, imaging, laboratory tests, microbiological and histological tests are performed in order to identify the causative micro-organism, determine its virulence and the duration of the infection.[3,7,9,10]

1.5.1 Clinical findings

In the acute setting, patients present with persistent local joint pain, swelling, fever, discharge (secretion), tensioned soft tissues, and pyrexia and reddening of the skin surrounding the joint. In rare cases, patients may present with sinus tract draining pus. In patients with chronic PJI, persistent discharge, sinus tract and joint pain are present.

1.5.2 Laboratory tests

Full blood count: Shows leucocytosis. The specific type of infection has no effect on the differential count.
CRP (persistent): C-reactive protein is an acute phase reactant and increases immediately after infection. It is raised after surgery but comes down within weeks. Persistent elevation with infection is an important indicator of infection. It is important to check the trend of CRP rather than a single raised reading, because the trend shows a better response to treatment as opposed to just one reading.
Procalctonin is another acute phase reactant for diagnosing and checking for treatment response in infection.
ESR is done but non-specific, and it takes longer to come down and therefore cannot be used to monitor response to treatment.
Synovial fluid: Aspiration done under aseptic conditions pre-operatively, mainly to differentiate PJI from aseptic loosening. The synovial fluid is analysed for leukocyte count, percentage of granulocyte in the fluid and MC&S. A count of 200 leukocytes in the fluid is diagnostic of PJI. More than 70% granulocytes is also diagnostic. Both these tests carry sensitivity of

approximately 45% to 75% and specificity of 95%. Incubation of cultures is done and kept for at least 14 days to culture the low virulence organisms as well.

Alpha defensin is another test performed on the synovial fluid either in theatre or immediately after the procedure. It indicates the antimicrobial peptide released by activated neutrophils.

Microbiology tests: Require tissue samples from at least 3 to 5 different sites in the same joint that are closely related to the implants.

Sonication: The implant that has been removed is placed in a container with saline fluid with low-frequency ultrasound waves being passed through the container. The waves cause detachment of the bacteria from the implant. In instances where ultrasound waves are not available, the container is sealed and the shaken lightly to detach the bacteria from the implant. The fluid is taken to the laboratory for MC&S, which is 79% sensitive and 99% specific.

PCR (polymerase chain reaction) is also used to identify the offending pathogen. It has the advantage of producing results more rapidly than culturing.

Histology: Samples from the tissues surrounding implant may show acute inflammation. Histological tests are done to determine inflammatory cells count and the degree of infiltration.

1.5.3 Imaging

Imaging: Plain x-rays are not sensitive or specific. They show lucency around the implants, which may be due to infection, or loosening or instability of the implant. With the addition of a contrast, x-rays may show the presence of an abscess formation.

Ultrasound: Shows fluid collection around the implant and also assists with the guiding of aspiration procedures.

Bone scan: Technetium^{99} scan has sensitivity but low specificity. It shows decreased blood flow around the implant, which implies dead bone.

CT scans are better to delineate the extent of bone involvement and necrosis.

PET scan (positron emission tomography): Has higher sensitivity and specificity but is expensive. The specificity is increased by the use of a fluorodeoxyglucose (FDG-PET scan) tracer, which shows increased uptake in the presence of bacteria.

1.6 Management of PJI

The management of PJI requires a multidisciplinary approach. All the members of the multidisciplinary team should be well informed and have vast knowledge on treating patients with PJIs in order to assist with early diagnosis, psychosocial stress and rehabilitation. The team should include a senior/specialist orthopaedic surgeon, microbiologist, physiotherapist, occupational therapist, psychologist and a social worker.[8,10]

Treatment with antibiotics is initiated until after the cultures (MC&S) have been done. If a patient was on any antibiotics before the diagnosis of PJI, he/she is taken off antibiotics for 14 days, after which debridement and sampling is performed. Based on the microbiological findings, they are re-stared on antibiotics. The standard practice is that surgical debridement is performed, followed by empirical, broad-spectrum antibiotic treatment administered intravenously.[3,7,10] Once the culture results are available, the specific organism with its antibiotic sensitivity is known. Based on this information, target antibiotics are given intravenously initially for 2 to 6 weeks, or until a downward trend occurs in the CRP levels, and the patient's wound is drying up and shows clinical improvement. The antibiotics are then changed from intravenous to oral antibiotics for a period of up to three months in total.

As noted in the classification PJIs, the treatment options depend on the period of time between the onset of infection and the index joint surgery. The treatment options include DAIR, one-stage revision, two stage-revision and girdle stone or amputation.

1.6.1 Debridement, antibiotics and implant retention (DAIR)

When the infection is diagnosed less the four weeks from the initial joint surgery, DAIR is the best management option.[11,12] At this stage, the biofilm has not yet fully formed or matured. The advantage is that because there is no biofilm formed, debriding the joint and the implant will get rid of the bacterial burden. The success rate of DAIR is up to 88%. The requirements for successful DAIR are a diagnosis of acute PJI of less than 4 weeks' duration, the patient should be medically stable and have persistent drainage, but no sinus tract and abscess formation.

The standard procedure for DAIR is as follows:[11,12] The patient is taken to theatre and surgery is performed under general anaesthesia. The patient is positioned, cleaned and draped under

sterile conditions. The initial skin incision from the index surgery is used and should include the area of persistent drainage. Wound debridement is carried out with removal of necrotic and devitalised tissue, septic capsule and synovial tissue. Tissue samples are taken at different sites in the same joint. The polyethylene liner is exchanged or sterilised. Six to nine litres of saline irrigation with pulse lavage is applied. After debridement, empirical intravenous antibiotics are given and once culture results have been received from the laboratory, target antibiotics are given for a period of three months, initially 2 to 4 weeks of intravenous antibiotics and then administered orally.

1.6.2 One-stage revision surgery

One stage revision surgery was first introduced in the early 1980s by Buchholz from the ENDO-Klinik in Hamburg, Germany.[8,13] Because the patient only undergoes one surgical procedure, it is associated with less morbidity, reduced cost and possibly shorter hospital stay. The patient must be a good host with no medical comorbid conditions and the surgeon has to be familiar with one-stage revision surgery. The most important factor or requirement for one-stage revision surgery is to identify and culture the bacteria and have sensitivity results before surgery. This means that the patient must have a joint aspiration prior to surgery and the synovial fluid or joint pus should be analysed by means of MC&S, percentage of granulocytes, the amount of leukocytes, leukocyte esterase and alpha defensin in the fluid.[13]

Contra-indications to one-stage revision surgery include failure to identify bacteria and its sensitivity prior to the revision surgery, two previously failed one-stage revisions and involvement of neurovascular structures.[8,13]

The procedure follows the previous skin incision, but care should be taken to also include the sinus tract, abscess area and devitalised skin. A thorough debridement of the wound is carried out, necrotic tissue is removed, and the joint is thoroughly debrided. The infected implants are removed as they now have a biofilm. A thorough debridement of the joint including the bone cavities that had implants is then carried out. Nine litres of saline are used and chlorhexidine is also used to eradicate the infection burden. Tissue sampling is done. A change of gloves and sterile dressings is done. In the same setting/surgery, implants are inserted into the joint with antibiotic-laden bone cement.[8,13] After surgery, the patient is placed on intravenous antibiotics and changed to oral antibiotics accordingly.

1.6.3 Two-stage revision surgery

Two-stage revision surgery is considered the gold standard of treatment of PJI.[8] It has a success rate of up to 95% with the use of antibiotic-impregnated cement spacers. The procedure was first introduced in 1983.[18] Comparative studies showed that it has a higher success rate when compared the one-stage revision surgery.

First stage – removal of the infected implant: The first stage involves a thorough debridement of all the necrotic tissue and devitalised bone within the joint. Multiple specimens from different sites in the joint are sent to the laboratory for MC&S as well as histological examination. Irrigation is performed with 6 to 9 litres of saline. The implant from the index surgery is removed completely. After the debridement, an antibiotic-impregnated cement spacer is inserted into the joint, which delivers the antibiotic locally and also upholds soft tissue tension in the joint by maintaining joint space. The patient is put on intravenous antibiotics for six weeks.[4,5,14] The antibiotics given are culture- and sensitivity-directed.

Second stage: After six weeks of antibiotic treatment and with the inflammatory markers within the normal range, the cement spacer is removed, further debridement is performed and a new implant is inserted into the joint.[4,5,14] Although it eradicates the infection, this treatment strategy is often associated with significant bone loss.[14,15] This occurs either with the initial removal of the implant or removal of the cement spacers. Bone loss could be attributed to the cement forming a strong bond with the bone, leading to cement-bone complex, which consequently causes bone loss upon removal.

Different kinds of joint spacers for both the knee and hip joints are available, broadly classified as either static or mobile spacers.[14] The static spacer is indicated if severe bone loss has occurred, or in the event of severely compromised soft tissue and severe infection. There is also the associated disadvantage of limb immobilisation, which leads to poor outcomes after re-implantation. Making a static spacer involves placing a large ball of cement into the joint. Occasionally, cement beads impregnated with antibiotics are placed in the joint.[14] The only rehabilitation is partial weight bearing and minimal joint movement.

Mobile spacers are the mainstay of spacer treatment. They are indicated when there is minimal bone loss has occurred. It has the advantage of limb mobility, which has a better clinical outcome upon re-implantation. Mobile spacers are further classified based on whether they are handmade, moulded or pre-fabricated.[14] Handmade spacers are advantageous in that they are made in theatre during surgery to fit into a specific patient's joint cavity, can be made into any shape, and are inexpensive. The antibiotic mixing is done by the surgeon in theatre plus a k-wire or pin can be used to increase their strength for weigh bearing. The moulded spacer are also made in theatre. Cement is placed in a pre-fabricated mould and allowed to set. Once set, it then taken out of the mould and placed in the joint. Pre-fabricated spacers are made by the manufacturing companies and are available in different sizes, which is also a disadvantage in that limited sizes are available. Furthermore, there is no control of the amount of antibiotics added to the cement when the spacers are manufactured by the industry away from theatre.

The antibiotics incorporated into the cement needs to meet certain requirements, which include heat stability, being in powdered form, are not destabilising the mechanical properties of the cement and able to be released in quantities above the minimal inhibitory concentration (MIC) of the given organism causing the PJI.[14] Common antibiotics used in cement spacers include vancomycin, gentamycin and tobramycin.

All the joint spacers have complications, with the most important being dislocations and significant bone loss on the removal of the cement during stage 2 of the two-stage revision surgery.[14,15] In a local study, it has been shown that putting cement in a condom and then placing it in the joint prevented the formation of cement-bone complex and hence bone loss (unpublished data).

The question that needs to be addressed, is whether these condoms are safe to be placed in the joints? Sooraj et al.[16] studied microscopy performed on ten condoms fresh from packaging, and found that 10% of the condoms were turbid and not clear in colour,[16] providing sufficient evidence of contamination. However, they did not indicate exactly which organisms were present. This study could not tell whether the clear condoms were all sterile or not.[16]

The South African Bureau of Standards (SABS) has no information on condom sterility, but have recommendations on condoms packaging and manufacturing.[17] The South African Department of Health has the same recommendations as the SABS.

2. Identification of gaps for further research

From the literature review it is clear that the joint spacers cause bone loss, which further complicates the management of PJI. It is also evident from the unpublished local study that placing the cement spacer in a condom and then inserting the whole package into the joint space so that it sets in the desired shape of the joint . Afterwards, the entire package is removed. After setting and condom removal, the spacer is placed back in the joint, without the risk of forming tight cement-bone complexes, hence ensuring no bone loss. We therefore identified the need to evaluate the sterility of condoms and whether they can be used in the management of periprosthetic joint infection.

2.1 Research question

"Are the condoms used to package the cement spacer sterile or uncontaminated enough to be introduced into a deep joint space?"

3. Aims and objectives

3.1 Aim of the study

The aim of the study was to determine whether condoms were sterile for the use in joint surgery, and if they were not sterile, to check if sterility could be achievable.

3.2 Objectives of the study

1. To investigate the sterility of the condoms by ascertaining that there is no microbial contamination of the condom used in the management of periprosthetic joint management;
2. To test and compare the sterility of these condoms with condoms that have first been through a hydrogen peroxide gas plasma sterilisation process.

4. Hypothesis

Based on the current knowledge at our disposal and the evidence of the yet unpublished study in our department, our working hypothesis was that the condoms straight from the packaging have a 10% chance of being contaminated. We endeavoured not to only prove this level of contamination, but also to attempt the improvement of this high contamination rate.

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CHAPTER 2

PUBLISHABLE ARTICLE

Title

Condom sterility in periprosthetic joint infection management at Universitas Academic Hospital in Bloemfontein 2018

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Abstract

Introduction: Periprosthetic joint infections following joint arthroplasty are difficult to manage, which involves two-stage revision arthroplasty. A cement spacer impregnated with antibiotics is implanted in the joint and forms tight cement-bone complexes leading to massive bone loss on removal of the spacer. At our setting, we started using condoms to prevent the formation of these cement-bone complexes and therefore prevent massive bone loss. The aim of this study was to determine whether it was safe to insert condoms straight from the packaging into the hip or knee joint or whether sterilisation was required before introducing condoms into the joint.

Methods: Microscopy, culturing and sensitivity (MC&S) were performed on 60 government-issued condoms. Thirty condoms were sterilised by means of hydrogen peroxide (H_2O_2) gas plasma prior to testing. The remaining 30 were not sterilised.

Results: Hydrogen peroxide gas plasma-sterilised condoms were found to be completely bacteria-free. However, bacterial contamination was noted on 60% of the non-sterilised condoms. The organisms isolated were non-virulent common environmental or implant colonisers.

Conclusion: From these results we concluded that it is important to first sterilise condoms using heat-sensitive sterilisation method prior to introducing them into the joint. The sterilisation process can be done at any hospital central sterilisation service, making it readily available and cost-effective. With regard to arthroplasty, using sterile condoms during the procedure will save the need and cost of acquiring revision implant, expensive joint spacers and mega-prostheses. It is recommended that further prospective studies be conducted to determine the durability of these condoms.

Keywords: periprosthetic joint infection; condoms; sterility; arthroplasty; prevention

Introduction

Periprosthetic joint infection is the most common and dreaded complication of joint arthroplasty in orthopaedics.[1] It can lead to implant failure, implant loosening, pain and high morbidity. The risk of periprosthetic infection is 2% in knee arthroplasty and 1–4% in hip arthroplasty, immunocompromised patients being at higher risk.[2]

It is common practice to perform a two-stage revision arthroplasty procedure to control or eradicate the joint infection.[3,4] The first stage entails removal of the infected implant and thorough debridement of the joint and residual bone. Specimens are taken to the laboratory for microscopy, culturing and sensitivity (MC&S). A cement spacer impregnated with antibiotics is positioned in the joint space and the patient is placed on intravenous antibiotics for six weeks. The second stage of the procedure is performed after six weeks of antibiotics and when the infection has been controlled. The cement is removed and re-implantation with new sterile prosthesis is done.

The two-stage revision is not without complications. There is notable bone loss upon cement removal, as it tightly attaches to bone, similar to grout.[4,5] This renders the revision surgery not only difficult due to the excessive amount of bone loss, but also costly as the use of large revision stems and mega-prostheses would be required.

Condoms have been used to minimise bone loss.[6] The cement spacer is placed in a condom and then into the joint before the cement sets. Once the cement sets, the spacer-condom complex is then taken out if the joint and then condom is removed.[6] The spacer is then implanted in the joint without formation of the tight bone-cement complexes. However, it is not known whether government-issued condoms used in these procedures are sterile off the packet or whether the condoms should t first be sterilised to decrease chances of infection.

The South African Bureau of Standards (SABS)[7] does not include condom sterility as part of the measures of product quality, but only focuses on condom fit, type and production design. The South African Department of Health follows the same guidelines as the SABS. Sooraj et al.[8] noted a turbid colour change in 10% of condoms fresh from packaging. They did not, however, conduct any further testing to determine if these were indeed contaminated and with what microorganisms. No known study has been done to determine the sterility of condoms.

The aim of the study was to determine the sterility of condoms taken from the sealed packaging and condoms that were sterilised before use by means of standard microbiological laboratory testing. The NHLS Medical Microbiology laboratory at Universitas Academic Hospital (UAH) was approached and MC&S was done on government-issued nonsterile and sterile female condoms. The data were sent to a biostatistician for analysis and comparison between the two groups.

We used government-issued female condoms, the reason being that in a local unpublished study conducted in our department, it was found that female condoms were stronger and had less chance of becoming damaged compared to male condoms, when placed in the joint space with bone cement. Another reason was that condoms provided by the government are free and readily available in all hospitals, clinics and public spaces, as determined by national guidelines and regulations.

Method

Study design and setting

A prospective, descriptive study was conducted in 2019 with collaboration between the Microbiology and Orthopaedic Units at Universitas Academic Hospital in Bloemfontein, Free State Province, South Africa.

Sample

The sample consisted of 60 government-issued female condoms, obtained from the outpatients department at National District Hospital.

Inclusion criteria

- Government-issued female condoms, Max condoms.
- All from the same batch.
- Same production date and expiry date.
- All the condoms were in a sealed box and sealed individual packaging.

Exclusion criteria

- Male condoms.
- Non-government issued condoms
- Condoms with broken or open packaging.

Ethical considerations

The study was done at the NHLS Medical Microbiology laboratory at Universitas Academic Hospital. Permission to conduct the research was obtained from the Head of Department of Orthopaedic surgery, Head of Department of Medical Microbiology, the NHLS (Appendix C); the theatre (Central Sterilisation Services Department; CSSD) matron, University of the Free State Health Sciences Research Ethics Committee (HSREC; reference number UFS-HSD2018'0604/2509) (Appendix B), and the Free State Province Department of Health (Appendix A). Individual consent was not required as this study did not include patients or their hospital files.

Procedure

Thirty condoms were first unpacked under aseptic conditions and sterilised in CSSD by means of H_2O_2 gas plasma sterilisation.[9,10] The remaining 30 condoms did not go through H_2O_2 gas plasma sterilisation and were tested directly from the packaging. The collection of data was done under aseptic conditions, which included wearing a masks, sterile theatre gown and sterile gloves. Sterile linen was provided on the working table and the principal researcher (NT) oversaw the process to ensure sterility and decrease environmental contamination.

The research was carried out as follows:

Group 1

- Under aseptic conditions, i.e. wearing a face mask, hand scrubbing, sterile gown and sterile gloves, 30 condoms were opened in a biosafety level 2 cabinet to ensure minimal environmental contamination. Working in the cabinet, 10 ml of brain-heart infusion (BHI) broth were transferred into sterilised conical tubes and labelled according to the condoms' laboratory numbers.

- Each condoms was then taken with sterile forceps and placed into a conical tube containing BHI.
- Forceps were sterilised and placed in 70% alcohol after every use.
- Tubes with condoms were incubated for 48 hours at 35°C in a CO_2 incubator.
- After 48 hours, all broths were sub-cultured onto half blood and MacConkey agar, streaked out and incubated for another 48 hours.
- Gram staining, microscopy, culturing and identification of isolates were done using standard laboratory phenotypic identification methods.

Group 2

Thirty more condoms were opened in CSSD, placed in sterile covers and put through H_2O_2 gas plasma sterilisation for 45 minutes at a temperature of less 50°C and low pressure of 67 Pa (5.7 Torr).[8] Once sterilisation was complete, the condoms were taken to the microbiology laboratory where they were processed as described for Group 1, and results were analysed.

Measurement and data collection

The findings were recorded in a Microsoft Excel spreadsheet (Appendix D) that was custom-designed for the purpose of the study. Data were analysed by the Department of Biostatistics, University of the Free State.

Statistical analysis

Results were summarised by frequencies and percentages (categorical variables) and means, standard deviations or percentiles (numerical variables). The two groups were compared using 95% confidence intervals (95% CI) for differences in means, medians or percentiles, with appropriate hypothesis testing.

Results

Sixty government-issued female condoms were used. They were all from the same batch and all were sealed. Thirty of these condoms were not sterilised by means of H_2O_2 gas plasma sterilisation.

Table 1 summarises the results of the MC&S done on both groups of condoms. In the non-sterilised group, 11 condoms had a turbid appearance while all of the sterilised condoms were clear in appearance. All of the turbid specimens showed the presence of bacteria on microscopy and Gram-positive organisms were cultured. Seven of the clear specimens from the non-sterilised group also showed the presence of bacteria under the microscope and also cultured Gram-positive organisms. The sterile group had no bacterial contamination. The chi-squared test showed a p-value of <0.0001 for the MC&S findings when comparing the two groups, which was a statistically significant difference.

Table 1. Microscopy, culture and sensitivity (MC&S) findings of the two groups of condoms.

	Unsterile (n=30)	**Sterile (n=30)**
	n (%)	**n (%)**
Broth macroscopic Appearance		
Turbid	11 (36.7)	0 (0)
Clear	19 (63.3)	30 (100)
Microscopy – Gram stain		
Gram-positive	18 (60.0)	0 (0)
Gram-negative	0 (0)	0 (0)
No bacteria observed	12 (40.0)	30 (100)
Culture		
Growth	18 (60.0)	0 (0)
No growth	12 (40.0)	30 (100)

As shown in Table 1, Gram-positive bacteria were only cultured from condoms in the non-sterile group. These organisms included *Bacillus* species (n=14), *Staphylococcus epidermis* (n=1) and *Micrococcus luteus* (n=3).

Discussion

In this study, we aimed to determine whether condoms straight from the packaging were sterile and safe to use in joints without introducing infection. We also wanted to determine whether we should first sterilise the condoms before we could use them in infected joints. It is important to avoid further infecting the joints with microorganisms from the condoms. We

could demonstrate that sterilising condoms by means of H_2O_2 gas plasma sterilisation before placing them in the joint, yielded 100% micro-organism free condoms and could safely be placed in the joints without introducing further infection.

The results clearly showed that condoms that were not sterilised had a 60% chance of colonisation by bacteria. The bacteria isolated from the non-sterilised condoms included *Bacillus* spp., *Micrococcus luteu*s and *Staphylococcus epidermis* that are known to be common colonisers of implants and skin. Although they are not as virulent as many other pathogens, they may cause clinically significant invasive infection under favourable conditions such as decreased immunity or breach in the protective mucosal layer or if introduced into the body with invasive procedures.

Bacillus spp. are Gram-positive, rod-shaped and endospore-forming bacteria[11.] *Bacillus spp*. are rarely implicated in actual clinical infections but are common culture contaminants. *Staphylococcus epidermis* is a member of the coagulase-negative staphylococci.[12] These are common nosocomial pathogens in immunocompromised, immunosuppressed and critical ill patients. *S. epidermis* is considered non-pathogenic colonisers of the human epithelium and mucous membranes and only cause infection once there is a breach in the protective epithelial barrier. *Micrococcus luteus* are strict aerobic Gram-positive cocci that grow in clusters, are catalase- and oxidase-positive.[13] *Micrococcus luteus* colonise human skin, mucosa and oropharynx and only cause clinical disease in immunocompromised patients.

It is important to prevent introducing infection when performing joint arthroplasty or any other invasive procedures. In their study, Sooraj et al.[8] only reported that the turbid appearance of condoms was associated with the presence of microbial contamination, in which was confirmed by the results of our study. We have also shown that even with specimens that appeared to be clear, bacterial contamination could not be excluded as a significant portion of the clear non-sterilised condoms were contaminated and yielded growth on culture plates.

These results evidently supported the importance of sterilising condoms prior to use, especially for our intended use in periprosthetic joints. Our findings also stressed the importance of taking the further step of performing MC&S, as the lack of a turbid appearance was not sufficient to be interpreted as a marker of contamination.

Hydrogen peroxide gas plasma sterilisation was used. Condoms are made of latex rubber which would deform and lose their structural properties with heat sterilisation.[9,10] The 100% lack of contamination on the sterilised condoms is sufficient evidence to justify the sterilisation condoms. The hydrogen peroxide gas plasma autoclave is available in the theatre and at the CSSD of the hospital. The H_2O_2 gas plasma sterilisation was used because of its properties that include low temperature and low pressure and therefore does not damage durability and integrity of the heat sensitive condoms.[8]

This study is important in that due to the increased clinical use of condoms in invasive medical procedures, contamination can be decreased by sterilising the condoms. Most of the CSSDs in our hospitals have facilities to provide H_2O_2 gas plasma sterilisation, which means that condoms can readily be sterilised.

To our knowledge, no literature on the testing of condoms by means of MC&S and sterilisation of condoms followed by MC&S prior to use, is currently available. The clinical significance lies in the fact that condoms that have been sterilised, can be considered to be microbiologically safe for use and placement in infected joint without concern of introducing a new infection into the joint. These result also have importance in that condoms that have been sterilised can be used for other invasive procedures without fear of introducing an infection.

Conclusions

The results showed that condoms directly from its packaging have a 60% chance of contamination with normal commensal flora and environmental micro-organisms. The study also shows that contamination occurs on specimens with both a clear and turbid appearance. Sterilisation eliminated this contamination, which has implications for the use of condoms for invasive procedures.

Limitations to the study

Batch-to-batch and lot-to-lot variations were not studied. The small sample size could be regarded as a limitation. The spectrum of microbes investigated was limited to phenotypic and not molecular investigation and identification of viruses or mycobacteria was not performed.

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APPENDIX A

FREE STATE PROVINCE DEPARTMENT OF HEALTH APPROVAL

health
Department of Health
FREE STATE PROVINCE

27 August 2018

Dr. N Tyumre
Dept. Of Orthopedics
UFS

Dear Dr. N Tyumre

Subject: Condom sterility in pre-prosthetic joint infection management at Universitas Academic Hospital in Bloemfontein. 2018

- Please ensure that you read the whole document, Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary.
- A written consent by each participant must be obtained.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of Universitas Academic Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- **Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).**
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** sebeelats@fshealth.gov.za or lithekom@fshealth.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day

Trust you find the above in order.
Kind Regards

Dr D Mutau
HEAD: HEALTH
Date:

Head : Health
PO Box 227, Bloemfontein, 9300
4th Floor, Executive Suite, Bophelo House, cnr Maitland and, Harvey Road, Bloemfontein
Tel: (051) 408 1546 Fax: (051) 405 1656 e-mail: [illegible]

www.fs.gov.za

APPENDIX B

HSREC APPROVAL

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

05-Sep-2018

Dear **Dr Ntsikelelo Tyumre**

Ethics Clearance: **CONDOM STERILITY IN PERI-PROSTHETIC JOINT INFECTION MANAGEMENT AT UNIVERSITAS ACADEMIC HOSPITAL BLOEMFONTEIN 2018**

Principal Investigator: **Dr Ntsikelelo Tyumre**

Department: **Orthopaedics Department (Bloemfontein Campus)**

APPLICATION APPROVED

Please ensure that you read the whole document

With reference to your application for ethical clearance with the Faculty of Health Sciences, I am pleased to inform you on behalf of the Health Sciences Research Ethics Committee that you have been granted ethical clearance for your project.

Your ethical clearance number, to be used in all correspondence is:**UFS-HSD2018/0604/2509**

The ethical clearance number is valid for research conducted for one year from issuance. Should you require more time to complete this research, please apply for an extension.

We request that any changes that may take place during the course of your research project be submitted to the HSREC for approval to ensure we are kept up to date with your progress and any ethical implications that may arise. This includes any serious adverse events and/or termination of the study.

A progress report should be submitted within one year of approval, and annually for long term studies. A final report should be submitted at the completion of the study.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this proposal for ethical clearance and we wish you every success with your research.

Yours Sincerely

Dr. SM Le Grange
Chair : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | E: ethicsfhs@ufs.ac.za
IRB 00006240; REC 230408-011; IORG0005187; FWA00012784
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa

APPENDIX C

NHLS APPROVAL

NATIONAL HEALTH LABORATORY SERVICE

Office of the Business Manager
UNIVERSITAS ACADEMIC LABORATORIES

Practice No. 5200296

REQUEST FOR APPROVAL OF LABORATORY RESOURCES FOR ACADEMIC PURPOSES

Dear Dr. Tyumie,

Your request for use of laboratory facilities / data is hereby granted under the following conditions:

1) That University Ethics Committee approval is obtained
2) All existing laboratory data remain confidential to the patient and doctor (accessible as mandated)
3) This office must be notified before any publication of any results / findings is made.
4) NHLS is acknowledged in all publications
5) Only existing data may be used. Any new approval of relevant manager and supply of consumables
6) Patient data relevant to the project may be obtained via NHLS Corporate Data Warehouse following submission and approval of a formal research protocol
7) An account with NHLS necessary application forms are attached

May your project be successful.

Regards,

Prof Henry Sickles
Business Manager

Chairperson: Professor Barth Reinhardt (CEO) Executive: Dr Kamisha Chetty
Physical Address: 1 Modderfontein Road Sandringham, Johannesburg, South Africa Postal Address: Private Bag X5 Sandringham, 2131, South Africa
Tel +27 (0) 11 386 6000/ 0860 00 NHLS(6457) www.nhls.ac.za Practice number 5200296

APPENDIX D

STUDY PROTOCOL

UNIVERSITY OF FREE STATE

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF ORTHOPAEDIC SURGERY

CONDOM STERILITY IN PERIPROSTHETIC JOINT INFECTION MANAGEMENT AT UNIVERSITAS ACADEMIC HOSPITAL IN BLOEMFONTEIN 2018.

AUTHOR:

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TABLE OF CONTENTS

1. Literature review and background

In the field of orthopaedics, total knee and hip arthroplasty are regarded as treatment modalities for patients with both knee and hip disease. These surgical procedures improve the quality of life for the patient, improve pain and are cost effective and safe.

The above mentioned procedures, though done frequently, are not without complications. The most important complication is peri-prosthetic joint infection. This may lead to implant failure, implant loosening, pain and high morbidity. The risk of peri-prosthetic knee infection is about 1 to 2% after TKA and this may go up to 4% if the patient is immunocompromised. Infection risk is 0.5 to 2% after THA.

In these cases, it is common practice that a two-stage procedure to avert/control and eradicate infection is used. This involves:

a) First stage: Removal of the infected implant and thorough debridement of the joint and residual bone. Specimens are taken to the lab for microscopy, culture and sensitivity. A cement spacer is often impregnated with an antibiotic and is then inserted into the joint space.
b) Second stage: This occurs after 6 weeks of antibiotics and once the infection has been controlled, as evidenced by normal infective/inflammatory markers as well as negative cultures. This stage involves removal of the cement spacer and placement of a new implant into the joint space.

In our facility, Universitas Academic Hospital, we have recently started using government-issued condoms during the first stage of this procedure. **The reason for using condoms is that they are cost-free and readily available in all government hospitals, clinics and public areas, as per national department of health guidelines and recommendations.** The condom is used in the first stage of the procedure. **The cement is placed inside the condom. The condom acts as a barrier between the cement and the bone so as to prevent a permanent bond once the cement has set. The prosthetic cement complex is extracted after six weeks, and the condom is removed. This is based on a study done at Universitas Academic hospital. The study number/reference is: UFS-HSD2017/1533. The cement was solely used as a spacer to keep the joint space open, this is because condoms act as a barrier and as such prevent antibiotic availability in the joint. The above study also showed that female condoms yielded better results compared to male condoms.**

The reason for doing this study is to determine how clean/sterile the condoms that we use are. The less bacteria they contain, the more beneficial it is for the patient. If they are however found to be unsterile, then that would mean that more microorganisms are being introduced in the joint space, and would further complicate the disease process.

There is no similar study to ours. According to Sooraj et.al, there is about a 10% contamination of condoms fresh from the packaging. This study, however, showed only the presence of infection but did not show the actual microorganisms present [4]. The South African bureau of standards (SABS) website does not have any documented data/information with regards to the sterility of the condoms. The SABS addresses issues such as condom fit, packaging and production design which according to them ensures quality and safety of the final product. The South African department of health has adopted the same guidelines as the SABS and has no specifications or data on the sterility of the condoms.

2. **Research question**

To determine condom sterility for use in infected peri-prosthetic joint management at Universitas Academic hospital complex in Bloemfontein.

3. **Study aim**

To assess the sterility of government issued condoms from the same batch and compared with condoms from the same batch that have gone through gas sterilization.

4. **Study Objective**

To find out if the condoms are sterile and there is no contamination in the condom used in the management of peri-prosthetic joint management. Furthermore, to test and collect data from condoms that have first been through gas sterilization in theatre.

5. **Methodology**

A prospective descriptive study will be conducted at Universitas Academic hospital to evaluate sterility of government issued condoms from the same batch and assess sterility of condoms that have been sterilized with gas sterilization. About 50 to 60 condoms will be needed for this study. The study will be done in the microbiology lab. **Permission to conduct the research** will be requested from the head of department of orthopaedics, head of department of microbiology department, theatre (CSSD) matron, and Free State department of health and University of the Free State health sciences research ethics committee (HSREC). Individual consent will not be required in this study because this study does not include patients or their files. The results of this study will be requested to be published in the SAOJ and will be presented at the 2018 South African orthopaedic congress.

a) **Study design**

This is a prospective descriptive study design to be conducted at Universitas Academic hospital microbiology and orthopaedic units in Bloemfontein, Free State province, South Africa in 2018.

b) **Study population**

50 to 60 government issued condoms, from the same batch, will be used for this study.

c) **Study setting**

The testing and collection will be done in the microbiology lab at Universitas Academic hospital, Bloemfontein. Furthermore half of the condoms in the study population will first be sterilised in CSSD through gas sterilization. Stationery will be paid for by the researcher. Data collection will be done by the researcher. Research of information regarding this study will be collected using the medical library from the University of the Free State, SABS website and online article search. Supervisor of the study is a senior orthopaedic specialist and the co- supervisor will be the head of department of microbiology.

d) **Data collection tools**

Data collection will be done by testing the condoms for MC&S and collecting the results of the tests. Inclusion criteria will be condoms from the same batch and government issued condoms because they are freely available. Exclusion criteria condoms with broken packaging and condoms with expiry dates that have passed. The stationery will be paid for by the researcher and the Post Graduate committee will be requested for financial support for consumables used by NHLS.

e) **Study process**

The research will carried as follows:

Group 1

Under sterile and aseptic environment, i.e. face mask, hand scrubbing, sterile gown and sterile gloves, 30 condoms will be collected and placed on a nutrient broth. Gram staining and MC&S will done. The test results will be will be analysed at 24, 48 and 72 hours from the start of the tests.

Group 2

Under sterile conditions described above, 30 more condoms will be opened in CSSD. They will then be placed in sterile covers and put through a gas autoclave sterilization for 45 minutes. Once sterilization is complete, the condoms will be taken to the microbiology laboratory for MC&S. The results will also be analysed after 24, 48 and 72 hours.

f) **Data management**

Data will be captured into excel by the researcher analysis will be requested from the statistician at the University of the Free State, Bloemfontein. Research and interpretation of the data will done by the researcher.

g) **Ethical considerations**

This will be a prospective descriptive study done under the rules and regulations of the department of health. The University of the Free State health sciences research ethics committee (HSREC) approval will be requested. **Permission to conduct the research** will

be requested from the head of department of orthopaedics. Permission will also be requested from the head of department the microbiology department. Informed consent from the CSSD department in theatre will requested from the theatre matron. Permission from the Free State department of health will only be requested after HSREC approval from the University of the Free State. **The National Department of Health through the National Strategic Plan showed that over 25 million female condoms were used in 2016 nationally and about 2 million of these were distributed in the Free State Province on. This data showed a steady rise in the use and distribution of the female condoms. Although it is not ethical to use this resource as it is meant for another purpose and maybe considered unethical, we only ask to use 60 female condoms and only use them for research related purposes. This low number will not affect distribution to the intended users.**

h) **Pilot study**

Ten condoms female condoms will be used for the pilot study. Five of these will be on group 1 and will be tested from packaging under sterile conditions. The other five will form group 2 and will first be sterilised in gas sterilization before being tested for MCS. This data will be send to the biostatistician for analysis. This will improve the quality of the study, help detect flaws and give an indication of possible results.

i) **Limitations of the study**

Data limitation will include condoms that have broken packaging and condoms that have passed their expiry date. Condoms from different batches will excluded from the study. Non-government issued will be excluded from the study.

j) **Analysis**

The findings will be compiled in the form of a data sheet and an excel spread sheet given to the Biostatistics department for analysis. Results will be summarised by frequencies and percentages (categorical variables) and means, standard deviations or percentiles (numerical variables). The two groups will be compared using 95% confidence intervals for differences in means, medians or percentiles, with appropriate hypothesis testing.

6. **Dissemination of findings**

Once the MMed study has been approved by the Ethics Committee, the research will be introduced to the members of the Faculty of Health Sciences at the Real Short Registrar presentations for 2018. When the MMed has been completed, it will again be presented to the members of the Faculty of Health Sciences at the short presentations organised by the research committee. The results of the study will also be presented at South African orthopaedic congress (SAOC) 2019. The South African orthopaedic Journal as well Journal of infectious disease will be requested for publication.

7. **Time schedule and action plan**

Task	Duration
Protocol	February to April 2018
Ethics approval	May to July 2018
Data collection	August to October 2018
Data analysis	November to January 2019
Writing thesis	February to April 2019

8. **Budget**

Motivation	Cost
Paper for data collection	R 150
Pens for data entry	R 50
Paper for printouts	R 250
Paper for thesis printing	R 100
Data for literature search and review	R 200
Microscopy, culturing and sensitivity testing	R 12 000
Total	R 12 750

. The stationery will be paid for by the researcher. The post graduate committee will be requested for funds to cover the consumables used by the NHLS to do the MCS.

9. **References**

1. Chun KC, Kim KM, Chun CH, et al: Infection following total knee replacement. Knee surgery and related research 25(3): 93-99, 2013
2. Hudetz D, Rod E, Radic A, et al: Diagnosis and treatment of peri-prosthetic infection in total hip replacement. Med Glas (Zenica), 9 (1): 152-9, 2012
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methods used from 1979 to 1998. Actar Chir Orthop Traumatol Cech 70(1):17-24, 2003

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8. Condom specifications. www.sabs.co.za
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10. South African National Department of Health. HIV and AIDS and STI National Strategic Plan for South Africa, 2012 – 2016.
11. Beksinska M, Nkosi P, Mabude Z, et al: twenty years of the female condom in South Africa: past, present and future. South African Health Review. vol 2017(1): 147 – 156, 2017
12. Using autoclaves safely. www.calstatela.edu/sites/defaultfiles/groups/enviromental

APPENDIX E

DATA SHEET

CONDOM STERILITY IN PERI-PROSTHETIC JOINT INFECTION MANAGEMENT

Universitas Academic Hospital Bloemfontein

ORTHOPAEDIC DATAFORM

SPECIMEN No			1-3
DATE OF PRODUCTION:			4-11
EXPIRY DATE:			12-19
BATCH NUMBER:			20-35
CONDOM TYPE	MALE (1)		
	FEMALE (2)		37
GAS STERILISATION	YES (1)		38
	NO (2)		39
SEALED PACKAGING	YES (1)		40
	NO (2)		41
SAME BATCH	YES (1)		42
	NO (2)		#
GRAM STAIN	POSITIVE (1)		#
	NEGATIVE (2)		45
	NOT DONE (3)		46
MICROSCOPY	POSITIVE 1)		47
	NEGATIVE (2)		48
APPEARANCE	TURBID (1)		49
	CLEAR (2)		50

CULTURE	POSITIVE (1)		#
	NEGATIVE (2)		#

APPENDIX F

AUTHOR GUIDELINES SOUTH AFRICAN ORTHOPAEDIC JOURNAL

South African Orthopaedic Journal author guidelines

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.
- 1,5 spacing 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.govshould
- The following format should be used for references:

Journal Articles:

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 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:

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 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

Please provide the names and email addresses of two potential reviewers.
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

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.
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 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:

o Conceptualization and design

o Data collection or contribution

o Data analysis

o Manuscript preparation

o 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.

Current Concepts Review

Background

In November 2018 the SAOJ Editorial Board commissioned the inclusion of one "Current Concepts Review" paper per issue. All University departments will be scheduled to contribute one paper ever 2nd year. The University via the Head of Department will the nominate expert author to be responsible for preparation the review article. We recommend that multiple authors are involved and in particular advocate collaborating with experts from other institutions to get a broader view on the topic.

General Guidelines

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

Outline of Article

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

Review Process

- Each submission will be peer-reviewed by 2 members of the editorial board

APPENDIX G

DECLARATION OF TECHNICAL AND EDITORIAL ASSISTANCE

DECLARATION OF TECHNICAL AND EDITORIAL ASSISTANCE

TO WHOM IT MAY CONCERN

I hereby declare that with regard to the following document:

Author: Dr. Ntsikelelo Tyumre
Title: Condom sterility in periprosthetic joint infection management at Universitas Academic Hospital in Bloemfontein 2018

- I have performed the language editing (grammar, vocabulary and syntax).
- I assisted the author with the technical preparation of the manuscript, including layout and formatting.
- I verified the accuracy of the citations in the list of references.
- I obtained and verified the most recent active Uniform Resource Locator (URL) for internet-based and digital object identifier (DOI) for journal references.

I hereby state that I am not responsible for any changes or errors that might have occurred after my completion of this work. Should any changes or errors occur in the work that is submitted by the candidate, the final documents that I have provided to the candidate are available on request.

_____

DR. DALEEN STRUWIG
BSc, BSc (Hons), MMedSc, PhD

Address: 16 Harrismith Street, Dan Pienaar, Bloemfontein
Telephone: +27 82 562 8461
Email address: daleenstruwig@gmail.com

Date: 18 April 2020

APPENDIX H

TURNITIN PLAGIARISM REPORT

condom sterility in periprosthetic joint infection management at universitas academic hospital

by Ntsikelelo Tyumre

Submission date: 19-Apr-2020 09:20AM (UTC+0200)
Submission ID: 1301002069
File name: N_Tyumre_MMed_dissertation_FINAL.docx (1.35M)
Word count: 10193
Character count: 58779

condom sterility in periprosthetic joint infection management at universitas academic hospital

ORIGINALITY REPORT

15%	12%	12%	12%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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4	www.sajch.org.za Internet Source	<1%
5	www.thieme-connect.de Internet Source	<1%
6	Josephine Olsen Kipp, Martin Lamm, Kjeld Søballe, Stig Storgaard Jakobsen. "Periprosthetic hip infection treated with two-stage stage-one Select Spacer– complication rate and restoration of anatomy", Journal of Orthopaedics, 2020 Publication	<1%
7	Submitted to Sefako Makgatho Health Science	