



**Does the Intra-operatively measured Leg Length
Correction compare to the Post-operative
radiograph in Total Hip Replacement surgery?**

by

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

Master of Medicine in Orthopaedic Surgery

University of Cape Town

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December 2020

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Declaration

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Abstract

Aims

This study aims to compare the leg length correction (LLC) measured intra-operatively using the Vertical Measurement System™ (VMS) in total hip arthroplasty (THA), with the LLC measured on a 6-week post-operative Xray. We also wanted to quantify any residual leg length discrepancy (LLD) using this method.

Patients and Methods

A prospective cohort study was conducted, in which patients undergoing primary THA were enrolled at two centres in Cape Town, over a period of 19 weeks. THA's were performed by four surgeons. Pre-operative leg length discrepancy measurements were obtained in 92 patients. The VMS was used to predict intra-operative leg length correction (LLC), and this measurement was compared to the post-operative leg length correction measured on the 6-week follow-up X-ray. These measurements were statistically compared using Mann-Whitney U Test.

Results

The difference between the intra-operative VMS calculation and the 6-week radiological measurement was not significant ($p > 0.05$), with the difference in their mean values being $0.07 \pm 3.26\text{mm}$. In the cohort, 81.52% of the patients ($n=75$) were within 5mm of the target LLC, and 95.65% of patients ($n=88$) were within 10mm of the target LLC. The mean absolute residual LLD at 6 weeks was $3.22 \pm 3.13\text{mm}$.

Conclusion

The intra operative LLC measurement obtained using the VMS accurately predicts the 6-week post op radiographic LLC measurement.

Acknowledgements

Supervisor: Dr Marc Nortje

Collaborated in the concept and design of the study.

Assisted with patient recruitment and counselling, as well as consent-taking from patients.

One of the surgeons involved in operating on study patients.

Assisted with data collection and measurements.

Advised during write-up phase of study.

Proof-read and suggested amendments of final draft.

Approved final submission for publication.

Co-Author: Dr Roopam Dey

Assisted with data clean up and mining.

Performed statistical analysis and drawing up of graphs and figures.

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Abbreviations:

CAS	Computer-assisted surgery
CT	Computerised tomography
IC	Height of implanted components
LLC	Leg length correction
LL	Leg length
LLD	Leg length discrepancy
LT	Lesser trochanter
MRI	Magnetic resonance imaging
THA	Total hip arthroplasty
VH	Vertical height of resected bone
VMS	Vertical Measurement System

Part A:

Does the Intra-operatively measured Leg Length Correction compare to the Post-operative radiograph in Total Hip Replacement surgery?

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Declarations:

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.
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Conflict of Interest:

- The Authors declare they have no conflicts of interest that are directly or indirectly related to the research

Funding:

- No Funding was received for this study

Ethics Statement:

Prior to commencement of the study, Ethical approval was obtained from the following ethical review boards:

University of Cape Town, Faculty of Health Sciences, Human Research Ethics Committee, HREC REF: 117/2019; Institutional Review Board (IRB) Number: IRB00001938.

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

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.

The Instrument used by the Vertical Measurement system is made of plastic (polyethylene) that is sterilised by autoclave prior to surgery. This instrument does not get used inside the human body, but measures the femoral head once it has been excised. The femoral osteotomy aiming guide is made of surgical grade stainless steel, that is similarly autoclaved prior to use.

Informed written consent was obtained from all patients prior to being included in the study.

Abstract

Aims

This study aims to compare the leg length correction (LLC) measured intra-operatively using the Vertical Measurement System™ (VMS) in total hip arthroplasty (THA), with the LLC measured on a 6-week post-operative Xray. We also wanted to quantify any residual leg length discrepancy (LLD) using this method.

Patients and Methods

A prospective cohort study was conducted, in which patients undergoing primary THA were enrolled at two centres in Cape Town, over a period of 19 weeks. THA's were performed by four surgeons. Pre-operative leg length discrepancy measurements were obtained in 92 patients. The VMS was used to predict intra-operative leg length correction (LLC), and this measurement was compared to the post-operative leg length correction measured on the 6-week follow-up X-ray. These measurements were statistically compared using Mann-Whitney U Test.

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The difference between the intra-operative VMS calculation and the 6-week radiological measurement was not significant ($p > 0.05$), with the difference in their mean values being $0.07 \pm 3.26\text{mm}$. In the cohort, 81.52% of the patients ($n=75$) were within 5mm of the target LLC, and 95.65% of patients ($n=88$) were within 10mm of the target LLC. The mean absolute residual LLD at 6 weeks was $3.22 \pm 3.13\text{mm}$.

Conclusion

The intra-operative LLC measurement obtained using the VMS reliably predicts the 6 week post-op radiographic LLC measurement.

Introduction

Leg length discrepancy (LLD) can arise due to numerous pathologies affecting the lower limb. Some of these causes arise at the hip. In adults the commonest causes include degenerative diseases of the hip joint. Other causes would include osteonecrosis, acetabular abnormalities or trauma. Total Hip arthroplasty (THA) is commonly undertaken to address these pathologies and can often address leg length discrepancies arising due to hip pathology. Total hip arthroplasty is one of the most successful orthopaedic operations with high patient satisfaction and low revision rates.¹ Accurate leg length correction (LLC) in total hip arthroplasty is imperative for a good clinical outcome. Therefore, equalisation of leg length (LL) remains one of the primary objectives of THA. Nevertheless, leg length inequality remains a recognised complication of the procedure.^{2,3} Leg length discrepancy accounts for 4.7% of all medical errors, as per the Joint Commission on Accreditation of Healthcare Organisations (JCAHO),⁴ and remains one of the leading causes of litigation against orthopaedic surgeons in the USA.⁵ The complications of LLD after THA include sciatic, femoral and peroneal nerve palsy, hip or low back pain, abnormal gait and posture and aseptic loosening.⁶⁻¹³

The incidence of LLD after THA has been reported to range from 1% to 27%,¹⁴ with some studies reporting values of LLD from 3mm to 70mm, with a mean from 3mm to 17mm.² Small discrepancies may be a source of dissatisfaction for some patients; however several studies have shown that up to 10mm of LLD may be well tolerated by most patients.¹⁵ Leaving the operated leg short seems to be more acceptable to patients than lengthening the operated leg, since patients can detect relatively small increases in length, and are particularly unhappy if they have to wear a shoe raise on the contralateral, unoperated side.¹⁶

The importance of attempting to equalise leg length is recognised amongst all orthopaedic surgeons in all sub-specialties, not just arthroplasty surgeons. This is attested to by the large amount of literature on LLD in THA. In order to mitigate the occurrence of LLD after THA, various methods have been used. These include pre-operative templating,^{17,18,19} a wide range of intra-operative techniques, such as measurements from a fixed point on the pelvis using a suture or ruler, to drilling Steinman pins or K-wires into a point in the pelvis.¹⁵ More recently, computer navigation has been used.^{20,21} In order to achieve consistent LLC, the surgeon needs to be familiar with the various surgical techniques and the accuracy of these in the clinical or operative setting.

The objective of this study was to assess our method of using a pre-determined LLC amount to guide the intra-operative LLC, as measured by the Vertical Measurement System™ (VMS), and compare the VMS measurement to that of the 6-week post-operative X-rays. The basic principle of this system is that the difference in vertical height between the excised femoral head and neck, and the combined vertical height of the implants determines the change in leg length. Our hypothesis was that the LLC measured using the intra-operative VMS method would equal the post-operative radiological measurement.

A secondary objective of the study was to quantify the residual LLD post-operatively, and to confirm they fall within clinically acceptable limits.

Patients and Methods

A prospective cohort study was conducted at two hospitals in the Western Cape, South Africa. Ethics (UCT HREC no. 177/2019) and Institutional Review Board approval was obtained. Patients who were booked for total hip arthroplasty (THA) were invited to participate, after careful explanation of the study design and methods. Informed consent for the study was obtained from all patients. Inclusion criteria were all patients undergoing primary THA, as per standard protocols utilised in the arthroplasty units at the two hospitals. Exclusion criteria were THA's performed for trauma (fractures of the femoral neck or pelvis), severe acetabular abnormality (e.g. dysplasia, erosion or previous pelvis fractures) and revision THA. Patients were recruited between May and October 2019, over a period of nineteen weeks.

Pre-operative Assessment

Prior to surgery (at the routine pre-operative clinic visit) clinical assessment of the true and apparent leg length was performed, to exclude other causes of LLD such as hip adduction, abduction or flexion contractures, or knee flexion contractures. Digital X-rays were obtained using the Philips IntelliSpace PACS Enterprise system. A standard AP Pelvis standing X-ray, centred at the symphysis with the legs 15° internally rotated and neutral adduction/abduction was used for planning. The images were scaled using a radiological sphere marker at the level of the greater trochanter (GT). An assessment was made on X-ray to determine if the LLD arose from femoral causes or changes in acetabular position due to wear or erosion. OrthoView Digital Planning software was used for pre-operative templating, sizing and positioning of implants and calculation of

the pre-operative radiological LLD at the hip. The method described by Woolson¹⁷, using the distance measured between a line drawn at the inferior aspect of each acetabular teardrop (the reference line) and the medial vertex of each lesser trochanter, was used to measure LLD (*Figure 1*).¹⁷ The 3 possible pelvic reference points include the inferior aspect of the obturator foramen, the ischial tuberosities, and the acetabular teardrop. The teardrop is the most reproducible and accurate when calculating limb length discrepancy.¹⁸ This measurement in combination with the clinical assessment of LLD, was used to inform the intra-operative LLC to be achieved.

Intra-operative measurement and calculation

The THA's were performed by four surgeons at two hospitals. Each THA proceeded in the routine manner, utilising the modified Hardinge or direct anterior approach. Implanted components were mostly Triloc, Summit and C-stem stems with Pinnacle cups (De Puy Synthes, Warsaw, IN, USA), while a small proportion were Accolade stems and Tritanium cups (Styker, Kalamazoo, MI, USA). The Vertical Measurement System (Peninsula Orthopaedics, Cape Town, South Africa) comprises of a stainless-steel femoral neck osteotomy guide, which aligns with the anatomical axis of the femur, a measuring device (the jig) that measures the height of the resected femoral head and neck and a web-based application (the App). The app is a database containing engineering specifications from most major manufacturers of the heights of their implanted components, including the femoral stem height, acetabular component radii and head radii and vertical height. The osteotomy guide is angled at 45° which matches the base plate of the jig. Too vertical an osteotomy will over-read and too horizontal will under-read the vertical height of the excised bone. This amounts to approximately 1 mm per 5°.²² After the femoral neck osteotomy, the vertical height (VH) of the excised bone (resection measurement) was measured using the Vertical Measurement System jig. This height is measured between the inferior and superior reference points. (*Figure 2*). Acetabular and femoral preparation, trial implantation and reduction were performed, and the hip tested for ROM, stability and tension. The resection measurement and implanted component data are then utilised by the app to calculate the leg length correction. The difference between what is resected, i.e. the height of the excised femoral head and neck (VH), and the height of the implanted components (IC) (*Figure 3*) will determine the leg length correction (i.e. $IC - VH = LLC$).²³

Patients with acetabular abnormalities were excluded from the study, however if it was felt that there had been a change in the centre of rotation (COR) of the hip, due to placing the cup more proximal or distal, this could be accounted for in the calculation by inputting the amount of COR change into the app.

At this point, if it was found that the LLC achieved (per the VMS system) does not match what was planned (per the X-ray measurement), intra-operative adjustments were made to further correct the LL, until the objective has been achieved. The surgery is concluded in the normal manner.

Post-operative

Standard rehab protocols were followed, and the patients were followed up at 6 weeks. Standardised, calibrated X-rays and templating software were again utilised to measure the radiological LLC achieved. This radiological LLC was compared to the intra-operative LLC measurement provided by the VMS.

Statistics

All data analyses were performed using IBM SPSS ver. 25 (Armonk, New York, USA) and G*Power ver. 3.1.9 (open source).^{24,25} The distribution of VMS and X-ray measurement data were analyzed using Shapiro-Wilk test for normality. The two sets of measurements were compared using Mann-Whitney U test for statistical significance and Spearman's correlation coefficient (r_s) was calculated. The cut-off for Type I error (α) was set at 0.05.

Results

For this study, 98 patients were enrolled over the period of nineteen weeks. Prior to the 6-week follow-up, 1 patient died, from an unrelated cause. A further 4 patients were later excluded from the final analysis, due to incomplete data and 1 patient failed to return for their 6-week follow up. This left 92 patients who completed the 6-week follow-up and whose data was complete for analysis. Baseline characteristics of the study group are listed in Table I.

The datasets were found to be not normally distributed and hence non-parametric statistical tests were performed to compare and correlate them. The difference between the means of the VMS measurements and the X-ray measurements was -

0.06 ± 3.26 mm (*Figure 4*). The mean absolute measurement difference between the two sets of values was 2.41 ± 2.18mm. These differences were not found to have any statistical significance (p=0.74). The difference of each patient's values (VMS and X-ray) was plotted against their mean (*Figure 5*). The mean difference of all these values was very close to zero, which was ideal and most measured differences were found to lie within the 95% confidence interval. Strong correlation was observed between the X-ray and VMS measurements with the r_s value of 0.773 (p<0.001)

When compared to the target LLC decided on pre-op, the mean absolute residual LLD post-op was 3.22 ± 3.13mm. Of the 92 patients, 81.52% (n=75) had a residual post-op LLD of ≤5mm, while 95.65% patients (n=88) had a LLD of ≤10mm.

Discussion

The primary goals of THA include pain relief and the restoration of normal hip biomechanics, gait and function. However, restoring or maintaining equal leg lengths is critical for patient satisfaction and return to function. The orthopaedic literature is replete with articles on LLD, the effects thereof, and methods to achieve adequate LLC during THA. Nevertheless, the amount of LLD at which it becomes clinically significant, or that leads to symptoms, is still debated. Generally, a leg length discrepancy of less than 10mm is widely accepted.¹⁵ Beard et al found patients had worse Oxford Hip scores at 3 years if LLD was greater than 10mm.²⁶ Our clinical aim was to achieve equal leg lengths since even small discrepancies are associated with functional impairment and pain.^{27,28}

In our study, the desired LLC was decided on pre-operatively, using a combination of measuring the LLD on a templating pelvic X-ray and clinical measurement. We then aimed to achieve this LLC intra-operatively, by using the Vertical Measurement System (VMS). Intra-operative adjustments were therefore possible (in component sizing and positioning), allowing restoration of LL to near equal.

When comparing the intra-operative VMS measurements to the 6-week post-operative radiographic measurements, there was no statistically significant difference (p>0.05) between the two sets of values. Strong correlation was found between the two sets of values. The mean absolute difference of 2.41 ± 2.18mm is very similar to the values quoted in other studies, where an intra-operative method was compared to the post-operative radiograph. Barbier *et al*²⁹ utilised a mechanical measurement device (LOOD) fixed to the pelvis to correct LLD, and the mean deviation from target length was 2.31mm (range 0.04 – 10.6mm).

More recently Tagomori *et al* proposed a simpler intra-op technique of LLC. They utilised a reference mark cut into the posterior acetabular wall with a saw and referenced this off a marking on the greater trochanter. Their measurement error, as calculated by intra-op measurement versus post-op CT LLD measurement, was $1.86 \pm 1.4\text{mm}$.³⁰

Other studies reporting on residual post-operative radiographic LLD found results of between 1.8mm and 3.5mm.^{31,32} Using intra-operative fluoroscopy is an available option, particularly in the anterior approach where supine positioning is conducive to imaging, as discussed by Austin *et al*, who compared two different techniques of LLC.³³ Using a radiographic overlay technique, the LLD was 4.8mm, and their transverse rod method yielded a LLD of 4.4mm. However, this involved increased surgical time, radiation exposure and increased surgical cost.

More invasive measures have been utilised, which involve fixing a reference device into the pelvis and obtaining measurements to the greater trochanter or other reference point on the femur. The reference can be iliac fixation pins, intraoperative callipers, infracotyloid pins, and fixed suture lengths. In order for these devices to work properly, the operating table must be level with the floor and the position of the hip must be reproduced precisely in all planes before and after reconstruction is performed.³⁴

Ranawat *et al* used a Steinman pin fixed to the ischium in the posterior acetabulum and achieved LLD < 6mm in 87% of their cases.³⁵ Shiramizu *et al* compared a series of patients operated on with or without the use of a caliper fixed to the anterior superior iliac crest, and found a mean post-op LLD of 2.1mm using the caliper versus 8.2mm without.³⁶ A plethora of other examples of similar techniques have been reported on. However, due to these techniques having their own problems – inconsistent leg positions during measurement, extra skin incisions, additional invasiveness of inserting devices into the pelvis, reference pins or devices loosening during surgery, greater surgical time and greater cost – most of them are not widely used.

Modern advancements in arthroplasty include the use of computer-assisted navigation to enhance the accuracy of implant placement. This method of Computer-assisted Surgery (CAS) uses two different techniques, i.e. imageless and image-based (using CT, MRI or intra-operative fluoroscopy). Imageless systems use a generic simulated model, whereas CT-based systems allow visualisation of a patient-specific model.³⁷ CAS systems require the registration of landmarks on the pelvis and femur. This requires placement of a reference frame on the pelvis, commonly involving placement of Steinman pins or similar into the iliac crest, and other landmarks on the pubis

sometimes requiring mini-incisions to accurately locate them. Femur landmarks are registered using a dynamic sensor array, which the surgeon controls. This intra-operative method can lead to complications during surgery, including failure to calibrate the CAS station and fracture of the iliac crest, greater trochanter and distal femur when inserting the pins for the sensor arrays.

In a study by Brown *et al*, where CAS was compared to conventional freehand technique, no difference was found in component positioning, LL and Harris Hip Scores (HHS) in their series. They reported an increased operative time of 18 minutes in the CAS group, increased blood loss (69ml), and a higher cost of surgery, with no additional benefit over freehand THA.³⁸ In contrast, Ellaparajda *et al* used navigation in a series of 152 THA's, and produced very good results, with 96.04% of THA's restoring the LL to within 6mm of the contralateral side. They also reported minimal extra surgical time or surgical cost required in the navigated THA's.³⁹ Similarly, Renkawitz *et al* compared the intra-operative values provided by the CAS system they used to the post-operative LLC measured on radiographs, and found a high degree of correlation between the two measurement methods, and recommended CAS as a good intra-operative tool.⁴⁰

According to Rajpaul and Rasool, CAS enables the surgeon to more accurately and reproducibly correct LL, with fewer outliers and no major complications. However, the improved accuracy does not translate into better outcome scores, and the technique is associated with complications including fractures, pin site infections and pain.³⁷ Longer term studies are required to assess the effect of CAS on implant longevity and revision rates.

All the methods discussed here have their drawbacks. Some intra-operative tools are invasive, cumbersome or expensive, many are not user-friendly or accurate enough, more modern tools have steep learning curves, are very costly to acquire and have potential complications with their use. A simple, accurate and reliable method that is easy to use, and that gives live feedback or results, allowing intra-operative adjustments to be made in order to accurately achieve the desired LLC, would be the panacea of LLC in THA.

We found that the VMS method enabled us to achieve a reliable intra-operative LLC, and this correlated well to the post-op 6 week X-ray. The accuracy of the method is in keeping with that of other methods, with a mean absolute measurement difference of 2.42mm compared to the 6-week X-ray. This is a reliable and trustworthy method, indicating that the LLC calculated by VMS is very close to what one will actually

achieve. The residual LLD measured on X-ray was $3.21 \pm 3.13\text{mm}$, which is well below what most patients would notice, and is similar to the results achieved by other authors 20, 29-32, 34-40

Nevertheless, we analysed why the results could not be even better. We utilised standardised AP pelvis X-rays, utilising a spherical marker at the GT. Nevertheless, this may introduce a margin of error with respect to magnification and sizing, and hence the final absolute measurement. The average error is 3,7% when the marker is placed adjacent to skin at the level of the [greater trochanter](#), however this position was shown to have the most accuracy.⁴¹

In determining the desired LLC, we used a combination of X-ray determination of LLD, per Woolson method,¹⁷ and clinical measurement of LLD. This introduces an element of human error, which could skew the effectiveness of whatever method is used to correct LLD. Clinical measurement of LLD at the medial malleolus is open to a margin of error and inter-observer variation. Furthermore, the Woolson method relies on measuring the difference of two lines drawn between a reference pelvic line and the vertex of each lesser trochanter (LT), to calculate the LLD. Determining the lowest point of the acetabular teardrop on X-ray to draw the pelvic reference line is often a bit difficult, with only moderate inter-observer correlation.⁴² In addition, there is inter-observer difference in determining exactly where the vertex, or most medial point, of the LT is. This is due to the differing shape of the LT amongst individuals, and some LT's having a long vertex (in the vertical plane), making the determination of the point to measure to quite inconsistent. A further variable which would influence the final outcome is the determination of the exact measurement of the height of bone excised (VH). The measurement jig is designed to measure the height from a reference point on the inner cortex of the calcar, which the surgeon needs to pay attention to when placing the head and neck on the jig, to avoid any errors.²²

A potential limitation of the study was that we compared the intra-operative measurement to the LLC measured on the 6-week post-operative X-ray. In some patients, at 6-weeks there may have been some implant subsidence, which would affect the correction measurement. Perhaps an immediate post-op X-ray would have been more appropriate.

Our technique was not compared to a control group, in which no measurement protocol was used, and where the surgeon used more traditional methods of estimating LLC, such as comparison to the other leg by feeling the heels and knees. Further studies would be required in this regard.

We did not look at surgical time involved in utilising the system compared to more traditional methods, nor did we include any data on complications using the VMS. Further research would be required in this regard.

Conclusion

In this study, we found that the VMS method of LLC in THA correlates well with the 6-week post-operative X-ray. It offers the surgeon a reliable, accurate, simple method of quantifying LLC intra-op, where adjustments can be made to fine-tune the outcome. Provided that the surgeon pays careful attention while templating and with intra-operative measurements, the VMS can reliably predict the post op radiographic LLC.

Conflict of interest

The authors declare they have no conflicts of interest that are directly or indirectly related to the research.

Ethical Statement

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.

Informed consent was obtained from all individual participants included in the study.

Funding Sources

No funding was received for this study.

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Part B: Addenda

a. Figures and tables

Figure 1:

The method used by Woolson to measure LLD. A reference inter-teardrop line is drawn between the most inferior aspect of each teardrop. The distance to the medial vertex of each lesser trochanter is measured (Wo^A and Wo^N)

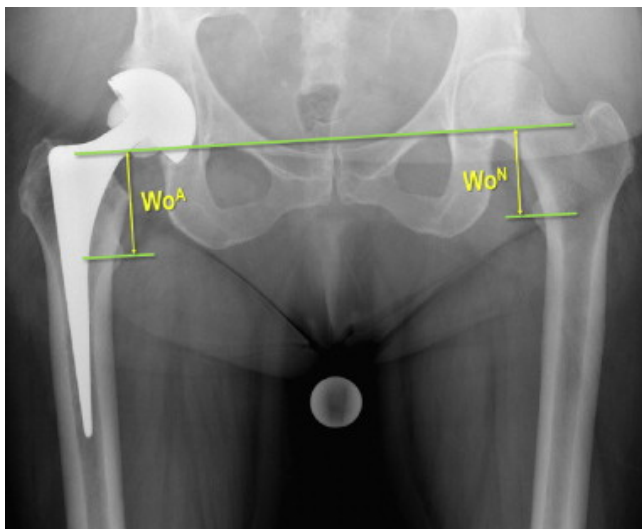


Figure 2:

The measurement jig utilised by the Vertical Measurement System (VMS) to measure the vertical height of the excised femoral head and neck.

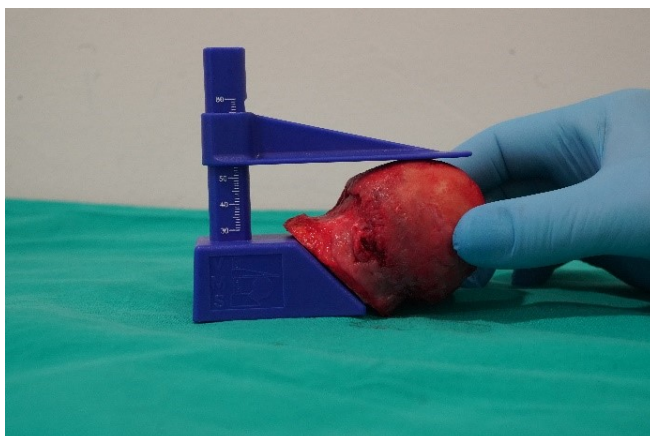
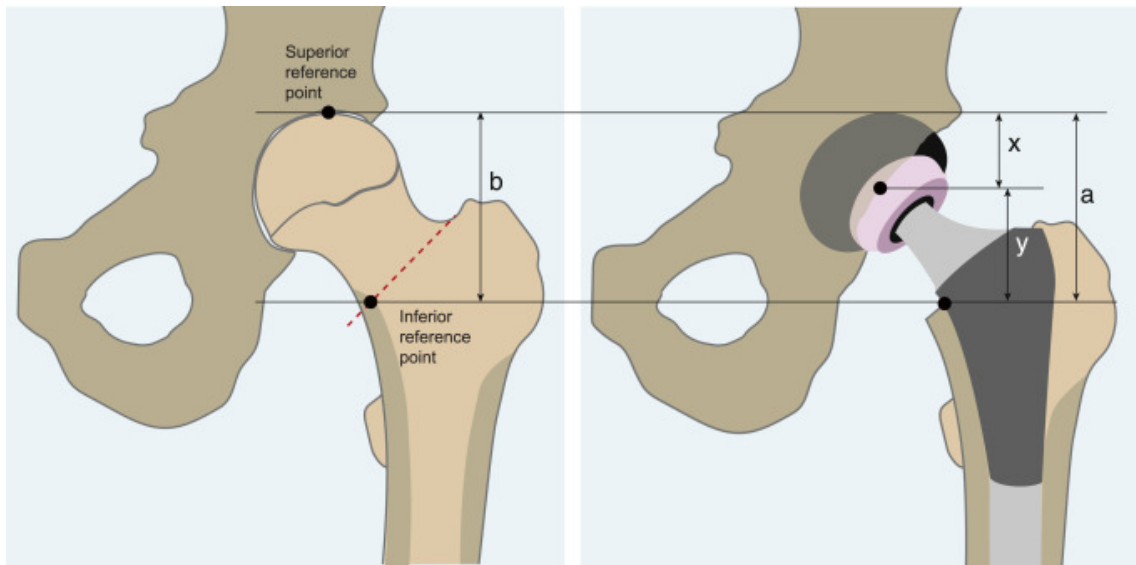


Figure 3:

Vertical Measurement System: The combined height (a) of the femoral stem (y) and the radius of the acetabular component (x) (“Implanted components” – IC) minus the height of the resected bone (b) (“Vertical Height” – VH)



$$LLC = \text{Implanted component Height (a)} - \text{Vertical Height (b)}$$

Figure 4:

The two data sets are shown, VMS and X-ray measurements. Depicted are their means, standard deviations and ranges. The difference between the two means was $-0.07 \pm 3.26\text{mm}$.

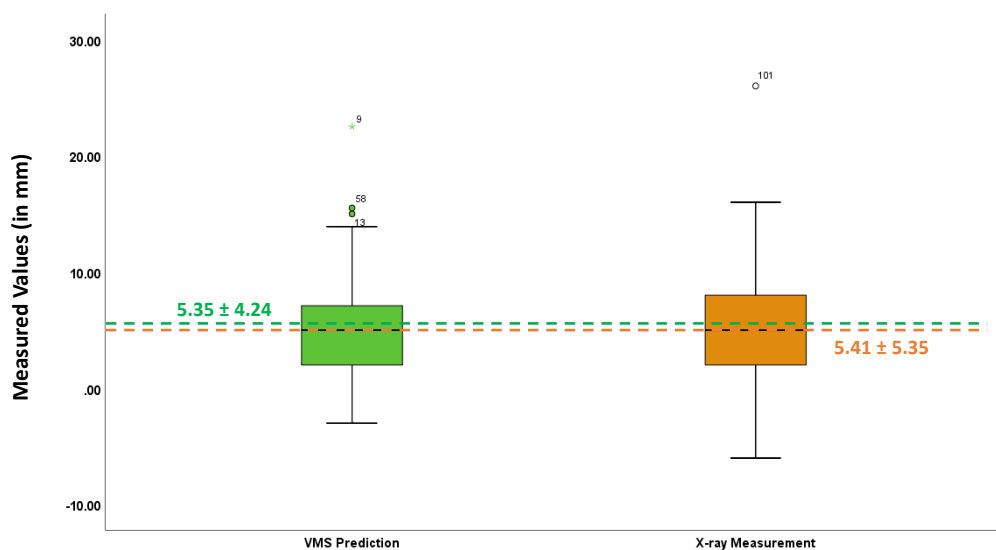


Figure 5:

Bland-Altman plot showing each patients' values. The difference between the VMS and X-ray measurements are plotted against their mean. The green line is the mean difference between the values - X-ray vs VMS (very close to zero here, which is ideal). The red lines are the upper and lower limits of the 95% confidence interval of the measured differences

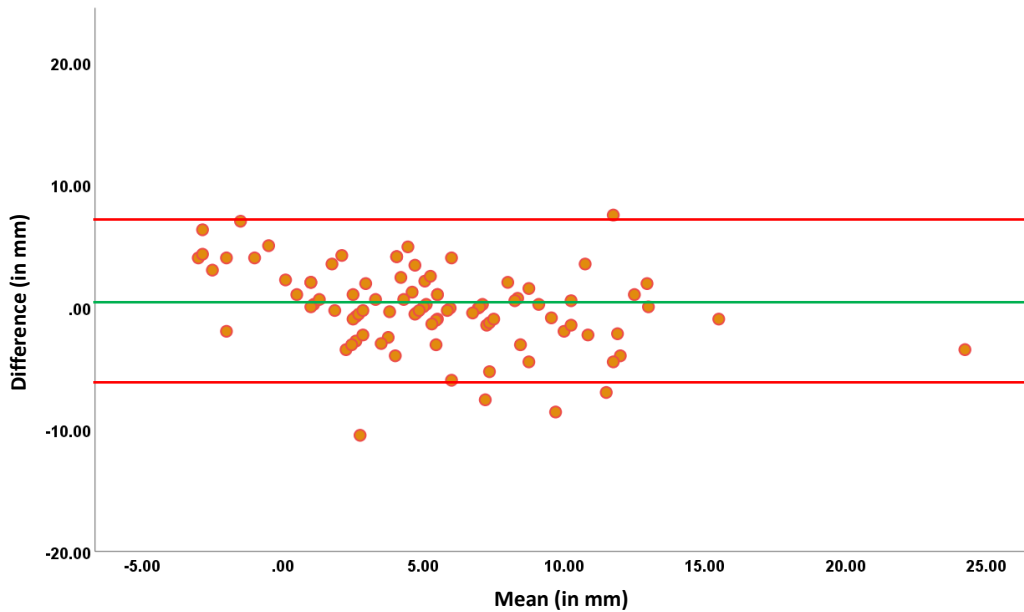


Table I: Baseline Characteristics of the study group.

Variable	Result
Number of patients	93
Male: Female	43 (46,2%) : 50 (53,8%)
Mean Age (years)	60,77 yrs
Laterality (Right/Left)	47 / 46

b. Journal Information:

South African Orthopaedic Journal

ISSN: 1681 – 150X

<http://journal.saoa.org.za>

Medpharm Publications

Instructions for Authors:

Criteria for publication

- The article falls within the scope of the journal.
- Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
- Results reported have not been published elsewhere.
- Conclusions are presented in an appropriate fashion and are supported by the data.
- The article is presented in an intelligible fashion and is written in standard English (British usage).
- The research meets all applicable ethical standards.
- The article adheres to guidelines provided in the instructions for authors section.

Guidelines for authorship

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

- The authors should clearly indicate the predominant surgeon or surgeons who have contributed patients to the study.
- On submission of your article the ORCID (Open Researcher and Contributor ID) identifier of at least the corresponding author 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 recognised. 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 be registered and approved by the relevant authorities before the onset of patient enrolment.
- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

Reporting guidelines

- All articles should be prepared in accordance with the guidelines relevant to the study design, as described in the Equator Network Guidelines (<https://www.equator-network.org/reporting-guidelines/>)
- 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.

Structure and content of submission

- We accept a maximum of 3 500 words including the abstract and body of the text (excluding references).
- Exceptions to this rule may be made for systematic reviews and meta-analysis, at the discretion of the Editor-in-Chief.
- Please follow the following structure when preparing your submission. Each of the following should be submitted as a separate file.
- 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, ethics statement, acknowledgements and references)
- Tables (with headings), each table as a separate file.
- Figures (with legends), each figure as a separate file.

c. Journal Reviewer's comments and responses thereto

Reviewer B:

Overall the paper is of good quality. The study looks at a novel intra-operative measurement system (VMS) and its ability to accurately predict postoperative leg length correction (LLC) after total hip arthroplasty (THA). The VMS measurement of LLC was statistically compared to the postoperative Xray measurement.

The paper was placed in context and is relevant to any orthopaedic surgeon performing THA. Residual leg length discrepancy is one of the issues in THA that have not been resolved.

Title: good

Abstract: line 5, remove capitals total hip arthroplasty. Line 6, hyphenate intra-operative; otherwise good

Level of evidence: Correct

Patients and methods: remove capitals line 64 total hip arthroplasty, line 67 arthroplasty units and line 90 vertical height.

Line 88: Consider giving information on the THA implant systems used

Line 89: use "routine" rather than "normal"

Line 91: change to "... measured using the Vertical Measurement System jig..." and it is protocol to add the name and address of the manufacturer of the system used.

Figure 2: change the caption to "... to measure the vertical height of the excised..." for clarity

Figure 3: if the LLC is a positive number then the equation should be IC minus VH and not as stated VH minus IC

Results: line 122: the VMS measurement mean is 5.35 and the X-ray measurement is 5.41 (as stated on figure 4) the difference in the means should be -0.06 and not -0.07

Discussion: good. First sentence might be clearer as: The primary goal of THA include pain relief and the restoration of normal hip biomechanics, gait and function.

Conclusion: good Further requirements:

Was the research question clearly elucidated in the introductory section? yes

Was sufficient detail provided in the methods section so that another researcher can replicate the study? yes

Was the statistical methodology employed sound? yes

Was the conclusion supported by the data presented in the study? yes

Were all necessary references provided? yes

Was the necessary ethical standard maintained? yes

Does the article satisfy the requirements set out in the Instructions for Authors section? yes

Was subject recruitment procedure, inclusion and exclusion criteria accurately described? yes

Was the follow-up period adequate? Yes

Were the limitations of the study adequately explored? yes

The following response was sent to the Journal Editor:

The Editor, South African Orthopaedic Journal 05 March 2020

Dear Dr L Marais

Thank you for the response regarding our article " Does the Intra-operatively measured Leg Length Correction compare to the Post-operative radiograph in Total Hip Replacement surgery?"

All amendments as suggested by the reviewer have been made. All changes are highlighted and tracked in the revised manuscript, as detailed below.

We will upload the manuscript onto the website, as well as email same to Robyn Marais. Many thanks for accepting the article for publication in the SAOJ.

Kind regards

Dr Zaheer Moonda

Reviewer B:

Overall the paper is of good quality. The study looks at a novel intra-operative measurement system (VMS) and its ability to accurately predict postoperative leg length correction (LLC) after total hip arthroplasty (THA). The VMS measurement of LLC was statistically compared to the postoperative Xray measurement.

The paper was placed in context and is relevant to any orthopaedic surgeon performing THA. Residual leg length discrepancy is one of the issues in THA that have not been resolved.

Title: good

Abstract: line 5, remove capitals total hip arthroplasty. Line 6, hyphenate intra-operative;

otherwise good

Response: Capitals removed and words hyphenated

Level of evidence: Correct

Patients and methods: remove capitals line 64 total hip arthroplasty, line 67 arthroplasty units and line 90 vertical height.

Response: Capital letters removed

Line 88: Consider giving information on the THA implant systems used *Response:* THA implants systems information now included

Line 89: use "routine" rather than "normal"

Response: Changes to "routine"

Line 91: change to "... measured using the Vertical Measurement System jig..." and it is protocol to add the name and address of the manufacturer of the system used.

Response: change of wording effected, and the manufacturer name and address included.

Figure 2: change the caption to "... to measure the vertical height of the excised..." for clarity

Response: changes to wording in Figure 2 effected

Figure 3: if the LLC is a positive number then the equation should be IC minus VH and not as stated VH minus IC

Response: Equation has been changed in Figure 3.

Results: line 122: the VMS measurement mean is 5.35 and the X-ray measurement is 5.41

(as stated on figure 4) the difference in the means should be -0.06 and not -0.07

Response: Difference in the means calculation has been changed to -0.06.

Discussion: good. First sentence might be clearer as: The primary goal of THA include pain relief and the restoration of normal hip biomechanics, gait and function.

Response: First sentence has been amended to be clearer, as suggested.

Conclusion: good

Further requirements:

Was the research question clearly elucidated in the introductory section? yes

Was sufficient detail provided in the methods section so that another researcher can replicate the study? yes

Was the statistical methodology employed sound? yes

Was subject recruitment procedure, inclusion and exclusion criteria accurately described? yes

Was the follow-up period adequate? Yes

Were the limitations of the study adequately explored? yes

Was the conclusion supported by the data presented in the study? yes

Were all necessary references provided? yes

Was the necessary ethical standard maintained? yes

Does the article satisfy the requirements set out in the Instructions for Authors section? Yes

d. Letter of acceptance from the Journal

(email communication dated 11/03/2020):

Zaheer Munda, Marc Nortje, Roopam Dey:

Thank you for submitting your revised manuscript entitled, " Does the Intra-operatively measured Leg Length Correction compare to the Post-operative radiograph in Total Hip Replacement surgery?" to the SA Orthopaedic Journal.

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

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

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

Sincerely yours,

Prof L Marais
Editor: SA Orthopaedic Journal

robyn@jesser-point.co.za

Participant information and informed consent.

Study.

A clinical investigation aimed to improve leg length correction following total hip replacement surgery.

Introduction.

A lot of patients presenting for a Total Hip Replacement have a Leg length difference (known as a Leg Length Discrepancy or LLD for short). One of the aims of having a Hip Replacement is to correct the LLD, and to equalise the leg lengths as much as possible. A LLD following total hip replacement of up to 1 cm is accepted internationally.

We are using a measuring device during surgery which aims to improve the LLD as much as possible, to try to achieve equal leg lengths to within 5 mm of each other. The device will be used as well as other usual measuring techniques.

The device is a plastic measuring tool to measure the height of the bone that is cut out. This device will be shown to you by the investigators.

This device is not used inside the body during surgery, but only to measure the bone after it has been removed. We then try to match the height of the bone cut out with implants (the Hip Replacement) of a height that make the leg length as close to the other side as possible. The tool and its associated online App will tell us how much we are lengthening by.

This study will look at how accurate the measuring tool is. We will measure how much correction we achieve in the surgery (how much the tool and the App measure), and we will compare this to how much we have actually lengthened by. This will be measured on the X-ray taken at the 6 week visit to our clinic for your check-up. The difference between what the measuring tool and App told us, and the X-ray measurement will tell us how accurate the tool actually is.

Do I have to take part?

We are inviting patients having Hip Replacement surgery to take part. Your participation is voluntary. You do not have to take part in the study if you choose not to. Participation may help to improve Hip Replacements for other patients in the future.

What are the risks?

There are no risks associated with being in the study. We are only taking extra measurements during surgery using the tool.

How much of your time will be needed?

No extra time will be needed from you. We will take the measurements in theatre, and then at your routine check-up at 6 weeks.

What are the benefits of taking part in this research?

There are no direct benefits to taking part in the study. By using the tool, we will attempt to make sure that we equalise your leg lengths as much as possible.

There is no financial benefit to you by participating.

What will happen to the results of the study?

The results will be analysed and submitted for publication in Orthopaedic journals. No patient details will be included in the publication of the results.

Who do I contact?

Dr. Marc Nortje (MBChB FC Orth)

0845777761.

I hereby declare that I have been informed of the study I will be enrolled in, and have discussed it with one of the Investigators of the study. I have had an opportunity to ask questions, and I understand my role in participating in the study.

I hereby agree to take part in this study.

Participant Name: _____

Date: _____

Signature: _____

Witness 1:

Witness 2:

Name:

Name:

Signature:

Signature :

Research Protocol

Does the intra operatively measured leg length correction compare to the postoperative radiograph in Total Hip Replacement surgery?

Author(s): Dr M Nortje, Dr Z Moonda

Study coordination centre: Groote Schuur Hospital

Sponsor: UCT

Date: 18 March 2019

Protocol Version: 3

Study Management Group

Principal Investigator: Dr MB Nortje

Study Coordination Centre

For general queries, supply of study documentation, and collection of data, please contact:

Study Coordinator: Dr MB Nortje

Address: Department Orthopaedic Surgery, H49 OMB, Groote Schuur Hospital, Observatory

Tel: 0845777761
marc.nortje@uct.ac.za

E-mail:

Clinical Queries

Clinical queries should be directed to the study coordinator who will direct the query to the appropriate person.

Sponsor

UCT will act as the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Deputy Director at:

University of Cape Town, Clinical Research Centre

Old Main Building, L51

Groote Schuur Hospital

Observatory

0214066281

Funder

Currently there is no funding. All the interventions and materials are currently used as routine care. All printing will be funded by the PI. Data collection will also be done by the PI. The option for funding will be considered.

Every care was taken in drafting this protocol, but corrections or amendments may be necessary. These will be circulated to investigators and approved before implementation. Problems relating to this study should be referred, in the first instance, to the Principal Investigator.

This study will be conducted in compliance with the protocol, data protection and other relevant regulatory requirements.

STUDY SUMMARY

TITLE	Does the intra operatively measured leg length correction compare to the post-operative radiograph in total hip replacement surgery?
DESIGN	Clinical study
AIMS	To determine if our method, using the Vertical Measurement System (VMS), of assessing the leg length correction during hip replacement surgery is accurate when compared to the radiographic measurement obtained post operatively.
POPULATION	We aim to recruit at least 50 patients for this study. The sample size has been confirmed previously with a statistician.
Inclusion Criteria.	All Patients undergoing primary Total Hip Replacement (THR) are eligible for the study. Standard protocols will be followed in selecting patients for THR, as per usual practice in our Arthroplasty Unit.
Exclusion Criteria:	Patients requiring THR for trauma, i.e. fractures of the proximal femur or pelvis, as well as patients requiring revision THR's will not be included in the study.

BACKGROUND

Accurate leg length correction (LLC) in total hip arthroplasty is imperative for a good clinical outcome. Equalisation of leg length remains one of the primary objectives of THR's. This is not always achieved, as can be attested to by the fact that leg length discrepancy remains a common reason for litigation in the USA (1). We believe that with accurate intra-operative measurements, unexpected post-operative leg length discrepancy can be prevented.

In the Arthroplasty Units at Groote Schuur and Vincent Pallotti Hospitals, we have been utilising the Vertical Measurement System for all THR's. The basic principle of this system is that the difference in vertical height between what is removed during the surgery (i.e. the excised femoral head and neck), and what is inserted (the combined vertical height of the implants) determines the change in leg length. There are currently numerous methods used during surgery to assess the leg length, however, of the currently available methods, none provide a specific measurement that can be compared directly to the radiographically measured difference post-operatively.

METHODS

1. Pre-operative assessment:

Prior to surgery (at the routine pre-operative clinic visit) clinical assessment of the true and apparent leg length is performed, to exclude other causes of leg length discrepancy (LLD) such as hip adduction contractures.

Pre-operative templating of the X-ray is performed using a digital PACS X-ray system. A standardised pelvis X-ray is taken with a marker placed at the level of the greater trochanter to scale the image.

Leg length difference is calculated by measuring the distance from the inferior aspect of the tear drop of the pelvis to the most prominent aspect of the corresponding lesser trochanter, and comparing it to the other side, as described by Woolson(2). Woolson reports acceptable inter-observer reliability when using this technique. A decision is then made as to how many millimetres of lengthening is required to achieve equal leg lengths.

2. Intra-operative calculation:

The surgery proceeds using normal surgical techniques for THR, including resection of the femoral head and neck. The vertical height (VH) of the resected femoral head and neck is then measured using the tool shown in Fig 1. The acetabulum is prepared using acetabular reamers and the acetabular component implanted. The femur is

prepared, and the appropriate femoral component and modular head implanted. The excised femoral head and neck are then disposed of in the normal manner as in all hip replacements, i.e. they are either discarded or handed back to the patient after the surgery, if so requested by the patient.

The resection measurement and implanted component data are then utilised by the available application (Vertical Measurement System – an online calculator with a database of implant sizes and measurements that obviates the need to use multiple charts) to calculate the leg length correction. The difference between what is removed (height of the excised femoral head and neck) and the height of the implanted components (IC) will determine the leg length.

Formula:

Change in leg length (LL) = VH – IC. (Fig 2).

The measured change in leg length, as calculated by the above measurement and formula, is then recorded in the patients' notes, and on the Redcap Database utilised by the UCT Orthopaedic Department. This database is accessible only by approved Orthopaedic staff members, and is individually password protected.

At this point, if it is found that the LLC achieved (per the VMS system) does not match what was planned, then intra-operative adjustments are made to further correct, until the objective has been achieved. The surgery is concluded in the normal manner.

3. Post-Operative

Once the post-operative control X-ray is obtained (usually at the 6 week post-operative clinic visit), the leg length correction is measured radiologically, as per Woolson (2). This measurement is compared to the intra-operative measurement provided by the VMS.

Our clinical aim is to achieve equal leg lengths. However, the gold standard is to achieve leg lengths to within 5mm of the planned pre-operative lengths. This is due to 5mm being the threshold above which the leg length difference becomes clinically significant, and noticeable to the patient. A leg length difference of greater than 5mm may be noticed by the patient, however in a lot of instances up to 10mm will be

tolerated without any discomfort experienced. In the event of a significant leg length difference, this will be discussed with the patient, and if required, the patient will be referred to an orthotist for fitting of shoe inserts or raises, in order to correct the discrepancy.

Figure 1

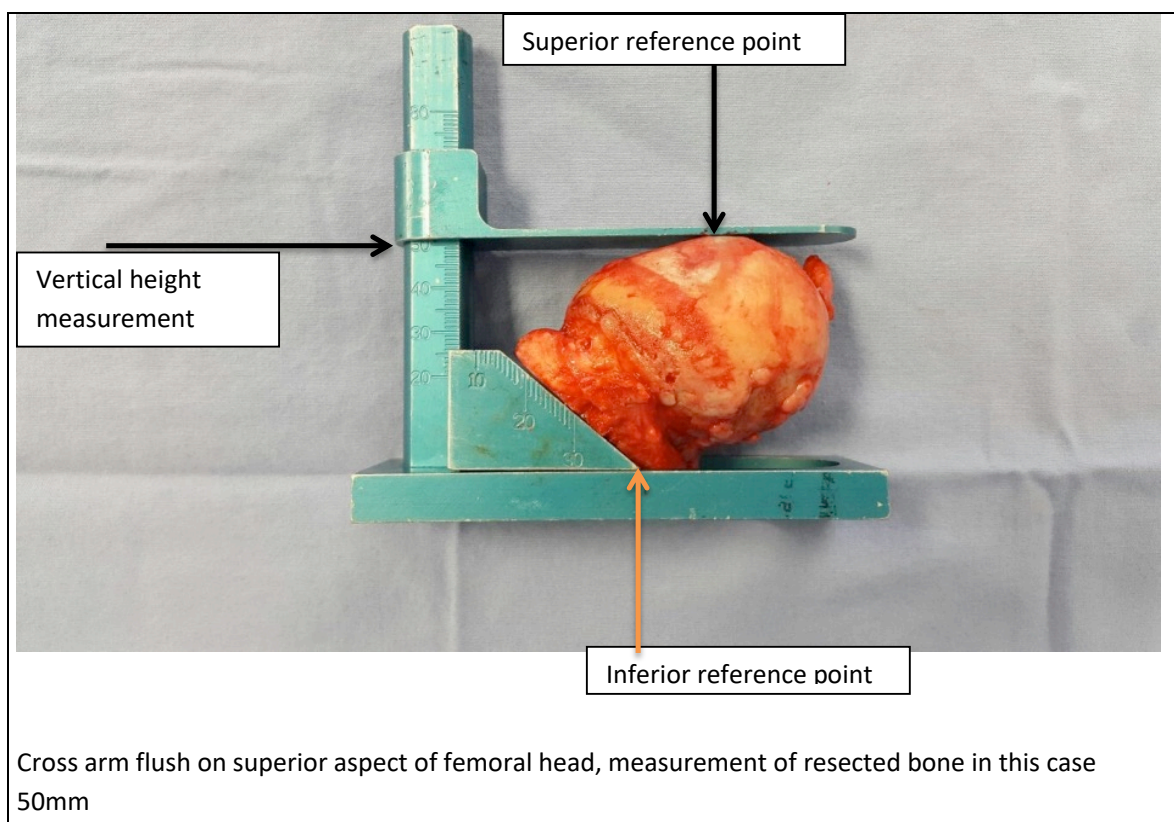
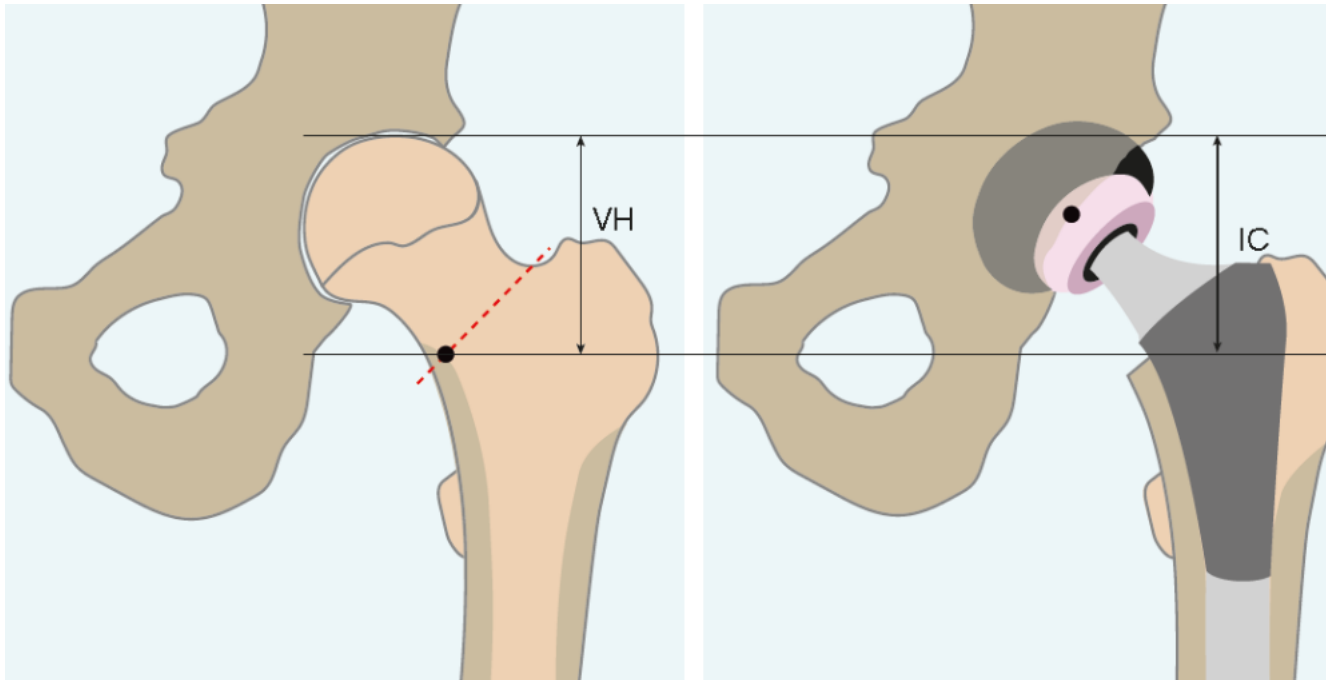


Figure 2



Data analysis

The intraoperative change in leg length will be recorded and compared to the post-operative measured leg length correction obtained by digital measurement on the calibrated post op radiograph (PACS).

Ethics approval

Approval will be obtained from the UCT Human Research Ethics Committee. All sites where patients will be recruited from will be applied to for Institutional Ethical Approval.

Consent

Study consent will be obtained, separate from the normal Surgical consent for the operation. The Investigators will obtain the consent, after explanation of the study and Protocol to the patient enrolled. No identifying patient information will be recorded in the study, and no alteration of surgical procedure will take place.

Confidentiality

The Principal Investigator will preserve the confidentiality of participants taking part in the study in compliance with data protection legislation.

Indemnity

UCT holds a non-negligent harm insurance policy, which applies to this study.

Funding

Funding for administrative and statistical support will be applied for.

Audits

The study may be subject to inspection and audit by UCT CRC under their remit as Sponsor and other regulatory bodies to ensure adherence to South African Good Clinical Practice if required.

Study Management

The PI, who will be present on the grounds during working hours and available telephonically after that, will run the study.

Publication Policy

The aim will be to publish the results in a peer review Journal.

REFERENCES:

1. Clark CR, Huddleston HD, Schoch EP, 3rd, Thomas BJ. Leg-length discrepancy after total hip arthroplasty. *J Am Acad Orthop Surg.* 2006;14(1):38-45.
2. Woolson ST. Leg length equalization during total hip replacement. *Orthopedics.* 1990;13(1):17-21.

HREC Approval

Please see accompanying letter from UCT HREC.

HREC Ref: 117/2019

Approval granted 05 April 2019



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925

Telephone [021] 406 6624

Email: shuretta.thomas@uct.ac.za

Website: www.health.uct.ac.za/fhs/research/humanethics/forms

05 April 2019

HREC REF: 117/2019

Dr Marc Nortje
Orthopaedics
H49, OMB

Dear Dr Nortje

PROJECT TITLE: DOES THE INTRA OPERATIVELY MEASURED LEG LENGTH CORRECTION COMPARE TO THE POST OPERATIVE RADIOGRAPH IN TOTAL HIP REPLACEMENT SURGERY?

Thank you for submitting your response to the Faculty of Health Sciences Human Research Ethics Committee received on 28 April 2019.

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

Approval is granted for one year until 30 April 2020.

Please update the Informed consent form to include the HREC contact details, with a statement that participants may contact the HREC if they have any ethical concerns, or questions about their rights and welfare with taking part in this study.

Please submit the updated Informed consent form to the HREC before the commencement of any research-related activities.

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

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

Please quote the HREC REF in all your correspondence.

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

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

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

