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Short-term Outcomes in obese patients undergoing anterior minimally invasive total hip arthroplasty

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Short-term Outcomes in obese patients undergoing anterior minimally invasive total hip arthroplasty



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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine

Johannesburg, 2023

Declaration

I, Dr Nabila Goga, declare that this research report in the format of a "submissible" paper is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



……

(Signature of candidate)

19th day of July 2023 in Johannesburg

Dedication

This research paper is dedicated to my family, both by blood and choice.

Presentations and publications arising from the research project

SAOA	September 2022	Cape Town
Wits Orthopaedic Research Day	November 2022	Johannesburg

Acknowledgements

This paper would not have been possible without my supervisors who sacrificed time and energy for this project; Dr JRT Pietrzak for his encouragement and guidance through each step of the process, Dr JN Cakic who trusted me to utilize his data and provided support and feedback despite his busy schedule and Prof SK Magobotha who availed himself as both a mentor and supervisor. I would also like to mention Dr M Jingo for his assistance, enthusiasm and efficiency and Dr I Cassimjee who assisted with the data visualisation.

Table of contents

Declaration ..... **i**

Dedication ..... **ii**

Presentations and publications arising from the research project ..... **iii**

Acknowledgements ..... **iv**

Table of contents ..... **v**

List of Figures ..... **vi**

List of Tables ..... **vii**

Nomenclature ..... **viii**

"Submissible" format of a paper **1**

Appendices **21**

List of Figures

Figure 1: A. Obese patient positioned on conventional surgical table. B. Obese patient positioned on AMIS® Mobile Leg Positioner……4

Figure 2: Perioperative Findings: A. Surgical duration. B. Estimated blood loss. C. Radiation dose. D. Radiation exposure. E. Length of stay……8

Figure 3: Radiographic Outcomes: A. Preoperative limb length discrepancy. B. Postoperative limb length discrepancy. C. Acetabular cup inclination. D. Acetabular cup version. E. Femoral stem version. F. Femoral offset differential……9

List of Tables

Table 1: Patient demographics…….7

Table 2: Clinical and Functional Outcomes……...10

Table 3: Complications……..11

Nomenclature

AMIS	Anterior minimally invasive surgery
ASA	American Society of Anesthesiologists
AVN	Avascular Necrosis
BMI	Body Mass Index
CI	Confidence Interval
COPD	Chronic obstructive pulmonary disease
DAA	Direct anterior approach
DVT	Deep vein thrombosis
FAI	Femoroacetabular impingement
FJS	Forgotten joint score
mHHS	Modified Harris Hip Score
LLD	Limb length discrepancy
LOS	Length of stay
OR	Odds ratio
PE	Pulmonary embolus
PJP	Patient joint perception
PROM	Patients reported outcome measures
SD	Standard deviation
THA	Total Hip Arthroplasty
TJA	Total Joint Arthroplasty
UPAT	Universal Pain Assessment Tool
WHO	World Health Organization

“Submissible” format of a paper

Short-term outcomes in obese patients undergoing anterior minimally invasive total hip arthroplasty

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ABSTRACT

Introduction

Obesity affects over 774 million individuals worldwide. It is associated with an accelerated onset and progression of osteoarthritis, resulting in an increased need for total hip arthroplasty (THA). Obese patients have a higher risk of perioperative complications. The direct anterior approach (DAA) for THA is gaining popularity globally, however, there are concerns over its suitability for obese individuals. This study compares short-term clinical, functional, and radiological outcomes of obese and non-obese patients undergoing THA *via* the DAA.

Methods

We conducted a retrospective study of 356 consecutive patients who underwent elective primary THA *via* the DAA using a specialised leg positioner (Medacta International, Switzerland) and intraoperative fluoroscopy. Obese patients (BMI ≥ 30 kg/m^2) were compared to the control group using baseline patient information, perioperative data and postoperative outcomes at minimum one-year follow-up.

Results

The study included 107 (30%) obese patients. Cohorts were well-matched for age, sex, preoperative diagnosis and baseline PROMs. In the obese cohort, surgical time and blood loss increased by a mean of 8.32 ± 6.9 minutes (p = 0.03) and 58.19 ± 25.37 ml (p = 0.0003) respectively. There were no significant differences in intraoperative radiation (mGys), time to discharge and discharge destination between the groups. Obese patients had a higher incidence of wound-related complications (5.6% *versus* 2.4%), however overall complication rates were similar (9.3% *versus* 6.8%, p = 0.67). Functional outcomes were equivalent with a mean postoperative mHHS of 97.57 ± 4.86 and 98.05 ± 5.59 in the obese and non-obese cohorts respectively (p = 0.54). PROMs including the Forgotten Joint Score (p = 0.34), Patient Joint Perception score (p = 0.2) and patient satisfaction rates (p = 0.085) were comparable.

Conclusion

The AMIS® DAA is a safe and effective approach for obese patients with excellent short-term outcomes, however an increased risk of wound-related complications remains.

Keywords: Total hip arthroplasty, Direct anterior approach, Obesity, Anterior minimally invasive total hip arthroplasty, AMIS

1. INTRODUCTION

The worldwide prevalence of obesity has risen exponentially over the last few decades with obesity affecting over 774 million individuals.[1] Within South Africa, 41% of women and 11% of men are classified as obese.[2] Obesity is associated with an earlier onset of osteoarthritis due to physiological and biomechanical mechanisms.[3,4] Obesity results in a state of chronic inflammation, which contributes to the severity, and progression of osteoarthritis by reducing pain tolerance, accelerating cartilage degradation, and stimulating osteophyte formation.[3–5] Affected individuals typically have altered gait patterns and abnormal joint loading.[4,5] The relative risk of undergoing total joint arthroplasty (TJA) correlates with increasing body mass index (BMI). [3,4] Morbidly obese patients are 8.5 times more likely to require THA than non-obese individuals.[3,4] Obese and morbidly obese individuals respectively are likely to require THA two and nine years earlier than their non-obese counterparts.[3,4]

Obesity is associated with a cluster of comorbidities, which contribute to increased perioperative risk.[4] Obese individuals typically have increased surgical duration, length of stay (LOS) and analgesic requirements.[3,6–9] Obesity is an independent risk factor for complications during TJA including combined complications; systemic complications; hip dislocation; re-intubation; re-operation; surgical site and deep infections.[3,4,6–8,10–13] A 2019, meta-analysis by Onggo *et al*. of over two million patients found an increased risk of all complications in obese patients undergoing THA (OR = 1.53, 95% CI:1.30 – 1.80, $p < 0.001$).[8]

THA is a highly regarded and cost-effective surgical intervention with reported survivorship of up to 95% at 10 years, > 80% at 25 years and patient satisfaction of > 96% at 10 years.[10,14–16] Utilisation of THA continues to grow and current projections suggest a perpetuation of this trend as demand, eligibility, technology, and skills evolve, however there is still no consensus on the optimal surgical approach.[14,17]

The DAA has seen a recent surge in popularity with DAA utilisation for primary THA amongst American Association of Hip and Knee Surgeons' members increasing from 12% in 2009 to 45% in 2020.[18,19] The DAA is an anterior-based minimally invasive surgical approach that accesses the hip via intermuscular and internervous planes, potentially limiting muscle damage.[20–22] Reported advantages include reduced postoperative pain, LOS and dislocation risk; improved mobility; and superior HHS during the early postoperative period.[20,21,23–26] Despite these benefits, the DAA is not the panacea as it has been associated with a steep learning curve, longer surgical duration, and a higher rate of certain complications, most notably surgical site infections (SSI) and intraoperative fractures.[7,10,12,13,19–21,24–27] Fifty-three percent of DAA surgeons consider obesity to be a relative contraindication for DAA use.[19]

While common, the use of specialised leg positioners for the DAA remains controversial.[28,29] The AMIS® mobile leg positioner (Medacta International, Switzerland) was developed for use with the AMIS®DAA technique to allow controlled intraoperative manipulation of the hip.[30] A potential benefit of this device in obese patients, is that the suspended thigh allows some of the excess adipose tissue to fall away from the surgical site compared to a conventional table on which the excess adiposity is supported by the table and pushes up towards the surgical site thus making exposure more challenging (Fig. 1).[28]

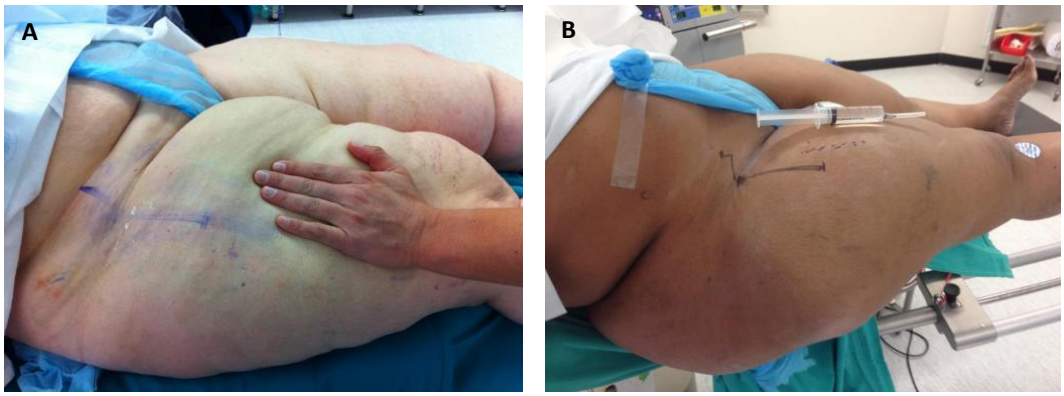


Figure 1.
A. Obese patient positioned on conventional surgical table. B. Obese patient positioned on AMIS® Mobile Leg Positioner

Considering the trifactor of THA demand, DAA utilisation and the global obesity epidemic outlined above, we sought to compare short-term outcomes of obese and non-obese patients undergoing THA *via* the AMIS® DAA.

2. MATERIALS AND METHODS

2.1 Study Design

This was a retrospective analysis using prospectively collected data from a single-surgeon, evaluating 356 consecutive, adult patients who underwent elective, unilateral primary THA *via* the AMIS® DAA, between 01 January 2018 and 31 December 2020. Exclusion criteria included patients who declined or were incapable of giving informed consent, and/or did not complete a minimum one-year follow-up. Ethics clearance was obtained from the Human Research Ethics Committee, University of the Witwatersrand.

2.2 Surgical Protocol

A standardised protocol was utilised with all patients undergoing preoperative medical evaluation and optimisation by a single physician. All patients were operated on in a single laminar-flow theatre under general anaesthesia and a lumbar plexus block, administered by a fellowship-trained anaesthetist. Patients were positioned supine with padded perineal support. The affected leg was placed in the AMIS®Mobile Leg Positioner, controlled by an experienced table-operator. A weight-adjusted dose of intravenous antibiotic prophylaxis (Cefazolin or Clindamycin in cases of a known allergy) was administered preoperatively and for 24 hours postoperatively.

A longitudinal skin incision of 6 – 10cm was made 2 – 3 cm lateral and parallel to a line between the anterior superior iliac spine and Gerdy's tubercle. The underlying perimysium was divided to allow access to the interval between tensor fascia lata and sartorius. The lateral aspect of the rectus femoris was retracted medially to expose the joint capsule. An anterior capsulotomy was used to enter the joint. The femoral neck was osteotomised under traction while protecting the posterior capsule. The acetabular labrum was preserved where possible, and the acetabulum prepared as per conventional THA. Preparation of the femur was done in a position of extension and external rotation, optimising access to the proximal femur. Soft tissues were released as necessary to allow adequate access to the femoral canal while protecting the ligaments. Femoral broaching was performed using AMIS® broaches *via* conventional broaching techniques. Uncemented implants with 36 mm ceramic femoral heads and highly cross-linked polyethylene cups were used preferentially as allowed by patient anatomy.

Intraoperative fluoroscopy (Philips, BV Pulsera) was performed by a single radiographer at three different time points: 1) to assess optimal positioning of the acetabular cup; 2) to assess optimal sizing and position of the femoral component during broaching; and 3) after reduction of the implants, prior to soft tissue closure. An intra-articular negative-pressure drain was placed intraoperatively and removed within 24 hours. Intermittent pneumatic compression devices were employed postoperatively until discharge and inpatient physiotherapy provided twice daily. Patients were required to be ambulatory on crutches before discharge. Patients were discharged on oral thromboprophylaxis (Rivaroxaban 10 mg daily) for two weeks.

The surgical site was assessed by a clinical associate 10 days postoperatively and all suspicious wounds reviewed by the primary surgeon. A routine duplex Doppler was performed three weeks postoperatively to assess for occult deep vein thrombosis (DVT). The surgeon conducted follow-up assessments at six weeks, six months and one year postoperatively.

2.3 Variables and outcome measures

Preoperatively, the following baseline patient information was captured for all patients: age (years), sex, primary diagnosis, comorbidities, and BMI. Limb length discrepancy (LLD) was measured radiographically using Woolson's technique.[31] Patients' preoperative functional status were evaluated using the mHHS – a validated tool that factors in pain, gait and activities.[32] Pain was quantified using the Universal Pain Assessment Tool (UPAT); a combination tool comprising the verbal numeric rating scale, the verbal descriptor scale and the Wong-Baker FACES® pain rating scale.[33,34]

Intraoperatively, the following data was collected: surgical duration in minutes from incision to completion of the last suture; estimated blood loss in millilitres and fluoroscopy use (radiation exposure in milligrays and duration of exposure in seconds). Perioperative data included: the use of blood products; LOS in days measured from date of admission to date of discharge and discharge destination; home or step-down facility.

Postoperatively, at minimum one year, clinical, functional and radiographic outcomes were assessed using the following tools: mHHS, UPAT, Forgotten Joint Score (FJS), joint functionality, Patient Joint Perception (PJP) and a Likert-type patient satisfaction scale. The FJS is a validated PROM, designed to determine patient awareness of the artificial joint.[35] The PJP is a single-question PROM that correlates moderately with FJS.[36] Standard radiographic imaging was used to assess LLD, component position and component loosening.

Complications were classified as intraoperative or postoperative; medical (related to the patients' baseline and physiological effect of the surgery) or surgical (directly related to the surgery); and temporal (early $\leq$ 4 weeks, late > 4 weeks).

2.4 Data Analysis

The study compared the outcomes of obese (BMI $\geq$ 30) and non-obese (BMI < 30) patients, based on a series of parameters.[1] The means of these parameters were compared using t-tests with statistical significance at $p < 0.05$. Confidence intervals were calculated at 95%, and used in conjunction with the *p*-values to determine clinical significance. Groups were tested for linear model assumptions: normality and homogeneity of variances. In the event of a violation of the linear model assumptions, the Wilcoxon rank-sum alternative was used to hypothesis test between the two cohorts. The statistical package used was the R version 4.0.4 (2021-02-15); University of Auckland, New Zealand.

3. RESULTS

3.1 Demographics

In total, there were 356 patients of which 107 (30%) were obese and 205 (57.6%) were female (p = 0.05). The mean age of the obese group was 60.19 years *versus* 60.82 years in non-obese patients. The most common diagnosis was primary osteoarthritis, affecting 67.1% of non-obese and 74.8% of obese patients (p = 0.7). For further demographic details see *Table 1*.

Table 1: Patient Demographics

	Total ***n* = 356 (%)**	**Obese** ***n* = 107 (%)**	**Non-obese** ***n* = 249 (%)**	***p*-value**
Sex (*n*; %)				0.05
Male	151 (42.4%)	56 (52.3%)	95 (38.2%)	
Female	205 (57.6%)	51 (47.7%)	154 (61.8%)	
BMI (kg/m^2) (± SD)	27.95 ± 5.37	35.34 ± 3.7	25.21 ± 3.2	< 0.000
Age, years (± SD)	60.33 ± 12.75	60.19 ± 11.65	60.82 ± 13.23	0.73
Diagnosis (*n*; %)				
Primary Osteoarthritis	247 (69.4%)	80 (74.8%)	167 (67.1%)	0.7
Congenital hip dysplasia	37 (10.4%)	12 (11.2%)	25 (10.0%)	
AVN	22 (6.2%)	5 (4.7%)	17 (6.8%)	0.66
Inflammatory arthritis	16 (4.5%)	5 (4.7%)	11 (4.4%)	
FAI	16 (4.5%)	3 (2.8%)	13 (5.2%)	0.84
Previous trauma	4 (1.1%)	1 (0.9%)	3 (1.2%)	
Other	12 (3.4%)	1 (0.9%)	11 (4.4%)	
Comorbidities (*n*; %)				
Hypertension	69 (19.4%)	23 (21.5%)	46 (18.5%)	0.48
Asthma/COPD	34 (9.6%)	9 (8.4%)	15 (6.0%)	
Diabetes	33 (9.3%)	12 (11.2%)	21(8.4%)	0.21
Cardiac	26 (7.3%)	11(10.2%)	15 (6.0%)	1
Epilepsy	19 (5.3%)	6 (5.6%)	13 (5.2%)	
Thyroid	19 (5.3%)	4 (3.7%)	15 (6.0%)	0.51
Previous DVT/PE	12 (3.4%)	3 (2.8%)	9 (3.6%)	
Cancer	7 (2%)	2 (1.9%)	5 (2.0%)	0.21
Other	25 (7.0%)	7 (6.5%)	18 (7.6%)	
ASA grade (*n*; %)				
1	132 (37.1%)	34 (31.8%)	98 (39.4%)	
2	204 (57.3%)	66 (61.7%)	138 (55.4%)	
3	20 (5.6%)	7 (6.5%)	13 (5.2%)	

BMI, Body mass index; AVN, avascular necrosis; FAI, Femoroacetabular impingement; COPD, chronic obstructive pulmonary disease; DVT, Deep vein thrombosis; PE, Pulmonary embolus; ASA, American Society of Anaesthesiologists

3.2 Perioperative findings

Mean surgical duration was 92.71 ± 24.24 minutes for obese and 84.39 ± 23.92 minutes for non-obese patients (p = 0.03). Blood loss averaged 233.05 ± 100.93 ml and 174.86 ± 99.11 ml for obese and non-obese individuals respectively (p = 0.0003). One obese patient required a transfusion. Intraoperatively, the mean radiation dose was 3.51 ± 1.16 mGy in the obese cohort (range 1.87 – 7.91 mGy) with an average exposure time of 28.31 seconds (range 17.61 – 51.17 seconds). The mean radiation dose in the non-obese cohort was 3.13 ± 1.81mGy (range 1.58 – 7.21 mGy) and average exposure time was 24.56 seconds (range 14.9 – 46.75 seconds). The average LOS of obese patients was 2.4 ± 0.49 days and non-obese patients 2.5 ± 0.72 days (p = 0.16). Two obese and four non-obese patients required discharge to a step-down facility (p = 1). For further details, *see Fig. 2*.

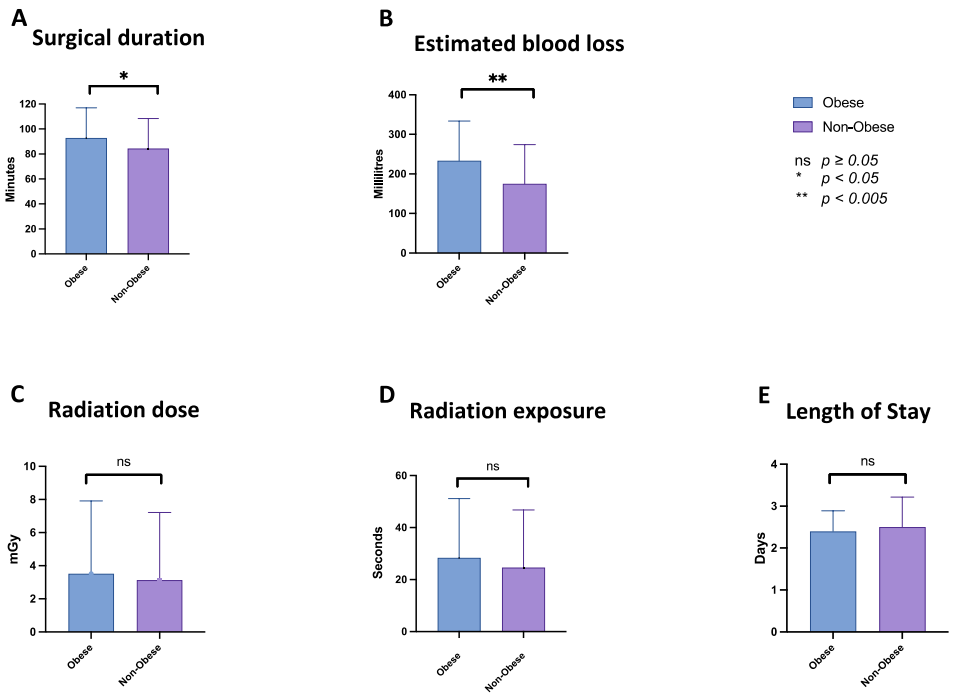


Figure 2. Perioperative Findings
A. Surgical duration (p = 0.03). B. Estimated blood loss (p = 0.0003). C. Radiation dose (p = 0.2). D. Radiation exposure (p = 0.17). E. Length of stay (p = 0.16)

3.3 Radiographic outcomes

Eight (7.5%) obese patients and two (0.8%) non-obese patients had acetabular cup inclination of 31°– 40° (p = 0.01) with an inclination of 41° – 55° achieved in 99.2% of the non-obese cohort *versus* 90.7% of the obese cohort (p = 0.02). LLD and other aspects of the implant placement demonstrated no statistical difference (*see Fig. 3*).

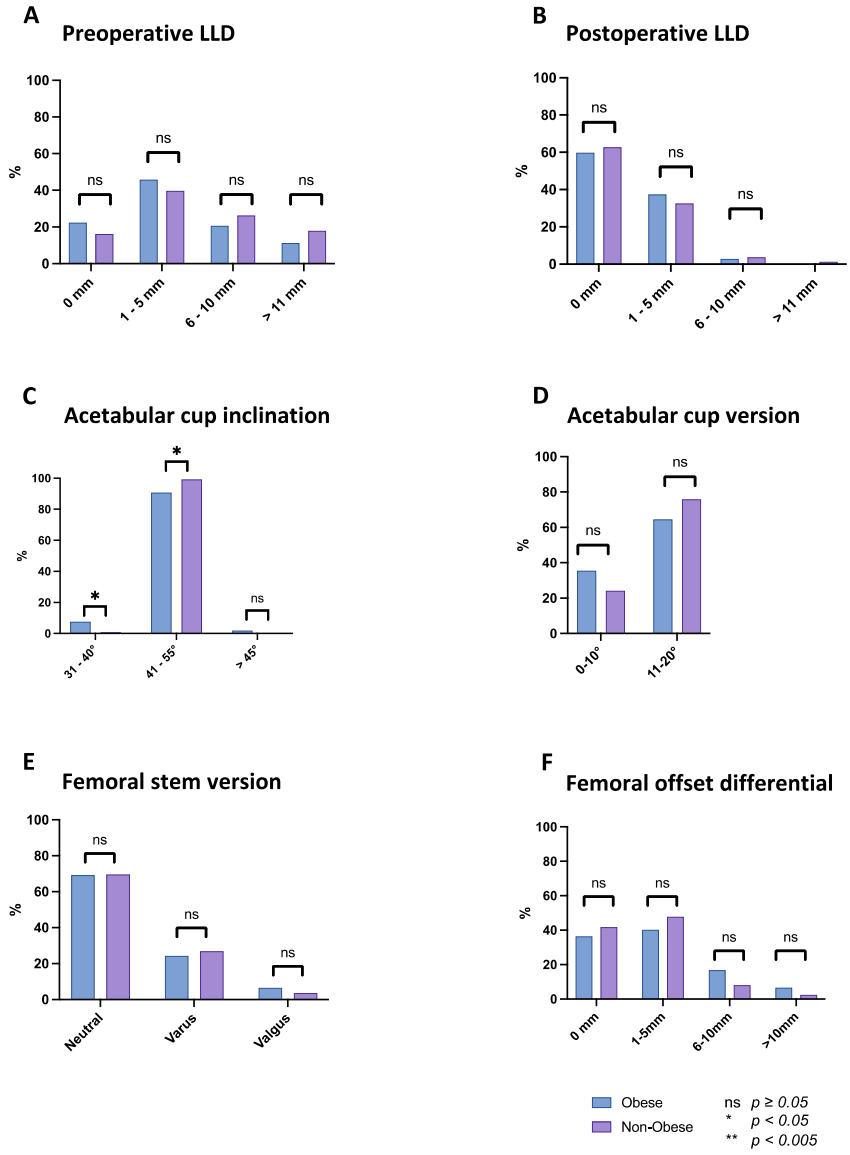


Figure 3. Radiographic Outcomes
A. Preoperative limb length discrepancy. B. Postoperative limb length discrepancy. C. Acetabular cup inclination. D. Acetabular cup version. E. Femoral stem version. F. Femoral offset differential

3.4 Clinical and Functional Outcomes

Postoperative mHHS scores were 97.57 ± 4.86 and 98.05 ± 5.49 in the obese and non-obese cohorts, respectively ($p = 0.54$). The mean FJS in obese patients was 77.81 ± 22.19 *versus* 71.43 ± 28.56 in the non-obese ($p = 0.34$). Satisfaction was > 92% in both cohorts ($p = 0.085$). For details on other PROMS, see *Table 2.*

Table 2: Clinical and Functional outcomes

	Total ***n* = 356 (%)**	**Obese** ***n* = 107 (%)**	**Non-obese** ***n* = 249 (%)**	***p* -value**
mHHS				
Preoperative ± SD	51.74 ± 12.02	49.92 ± 13.44	52.51 ± 11.22	0.19
Postoperative ± SD	97.91 ± 5.3	97.57 ± 4.86	98.05 ± 5.49	0.54
Change in mHHS	46.17	47.65	45.54	
FJS ± SD	73.34 ± 25.67	77.81 ± 22.19	71.43 ± 28.56	0.34
Satisfaction rate (*n*; %)				
Overall satisfaction	333 (93.5%)	99 (92.6%)	234 (94%)	0.085
Very dissatisfied	7 (2.0%)	2 (1.9%)	5 (2.0%)	
Dissatisfied	6 (1.7%)	2 (1.9%)	4 (1.6%)	
Neutral	10 (2.8%)	4 (3.7%)	6 (2.4%)	
Satisfied	66 (18.5%)	22 (20.6%)	44 (17.7%)	
Very satisfied	267 (75%)	77 (72.0%)	190 (76.3%)	
PJP (*n*; %)				0.2
Natural joint	216 (60.7%)	62 (57.9%)	154 (61.8%)	
Artificial joint, no restriction	71 (19.9%)	22 (20.6%)	49 (19.7%)	
Artificial joint, minimal restriction	61 (17.1%)	19 (17.8%)	42 (16.9%)	
Artificial joint, major restriction	5 (1.4%)	2 (1.9%)	3 (1.2%)	
Non-functional joint	3 (0.8%)	2 (1.9%)	1 (0.4%)	
Joint Functionality (*n*; %)				0.53
Severely limited	8 (2.2%)	2 (1.9%)	6 (2.4%)	
Limited	17 (4.8%)	4 (3.7%)	13 (5.2%)	
Can do most things	136 (38.2%)	40 (37.4%)	96 (38.6%)	

Can do anything	195 (54.8%	61 (57.0%)	134 (53.8%)	
UPAT ± SD				
Preoperative day	5.81 ± 1.98	5.99 ± 1.79	5.44 ± 2.3	0.13
Postoperative day	0.4 ± 1.28	0.45 ± 1.43	0.28 ± 0.82	0.29
Change day	5.39 ± 2.31	5.49 ± 2.24	5.2 ± 2.47	
Preoperative night	5.15 ± 2.62	4.92 ± 2.54	5.28 ± 2.65	0.42
Postoperative night	0.35 ± 1.33	0.23 ± 0.96	0.41 ± 1.46	0.32
Change night	4.82 ± 2.64	4.91 ± 2.32	4.78 ± 2.79	
Preoperative sport/activity	7.16 ± 2.21	7.13 ± 2.75	7.17 ± 2.06	0.97
Postoperative sport/activity	1.31 ± 3.19	0.43 ± 1.33	1.59 ± 3.58	0.2
Change sport/activity	5.64 ± 4.01	5.33 ± 4.73	5.72 ± 4.05	

mHSS, modified Harris Hip Score; FJS, forgotten joint score; LLD, Limb length discrepancy; PJP, Patient joint perception; UPAT, Universal pain assessment tool

3.5 Complications

Overall, the complication rate was 7.6% (n = 27), 9.3% and 6.8% of the obese and non-obese groups respectively (p = 0.67). Twenty-six of the complications were surgical and resulted in eight re-admissions (two obese (1.8%) and six (2.4%) non-obese). Three cases were revised at a mean follow-up of 29.45 months (one obese and two non-obese). Twelve patients presented with wound complications, six (5.6%) obese and six (2.4%) non-obese patients. In the obese cohort, one prosthetic joint infection (PJI) and one intraoperative fracture were diagnosed. Three postoperative periprosthetic fractures (1.2%), two dislocations (0.8%) and one confirmed DVT were documented in the non-obese cohort. Aseptic loosening occurred in two obese (1.9%) and five (2.0%) non-obese patients (2%). (*See Table 3*).

Table 3: Complications

	Total ***n* = 356**	**Obese** ***n* = 107**	**Non-obese** ***n* = 249**	***p*-value**
Total	**27 (7.6%)**	**10 (9.3%)**	**17 (6.8%)**	**0.67**
Early (<4 weeks)	15 (4.2%)	4 (3.7%)	11 (4.4%)	0.4
Late (>4 weeks)	12 (3.4%)	6 (5.6%)	6 (2.4%)	

Medical	**1 (0.3%)**	**0**	**1 (0.4%)**	
DVT	1 (0.3%)	0	1 (0.4%)	
Surgical	**26 (7.3%)**	**10 (9.3%)**	**16 (6.4%)**	0.8
Wound Problems	**12 (3.4%)**	**6 (5.6%)**	**6 (2.4%)**	
Wound dehiscence	11 (3.1%)	5 (4.7%)	6 (2.4%)	
Surgical site infections	1 (0.3%)	1 (0.9%)	0	
Deep PJI	**1 (0.3%)**	**1 (0.9%)**	**0**	
Aseptic loosening	**7 (2.0%)**	**2 (1.9%)**	**5 (2.0%)**	
Acetabular loosening	1 (0.3%)	0	1 (0.4%)	
Femoral component loosening	6 (1.7%)	2 (1.9%)	4 (1.6%)	
Dislocation	**2 (0.6%)**	**0**	**2 (0.8%)**	
Periprosthetic Fractures	**4 (1.1%)**	**1 (0.9%)**	**3 (1.2%)**	
Intraoperative Fractures	1 (0.3%)	1 (0.9%)	0	
Postoperative Fractures	3 (0.8%)	0	3 (1.2%)	
Vancouver B2	2 (0.6%)	0	2 (0.8%)	
Vancouver C	1 (0.3%)	0	1 (0.4%)	
Readmissions	**8**	**2 (1.9%)**	**6 (2.4%)**	
<30 days	3 (0.8%)	1 (0.9%)	2 (0.8%)	
31 – 60 days	2 (0.6%)	0	2 (0.8%)	
61 – 90 days	3 (0.8%)	1 (0.9%)	2 (0.8%)	
Re-operations	**3 (0.8%)**	**1 (0.9%)**	**2 (0.8%)**	
< 4 weeks	2 (0.6%)	0	2 (0.8%)	
> 4 weeks	1 (0.3%)	1 (0.9%)	0	

DVT, Deep vein thrombosis; PJI, prosthetic joint infection

4. DISCUSSION

To our knowledge, this is the first study in South Africa to compare outcomes between obese and non-obese patients undergoing THA *via* the AMIS®DAA. Cohorts were well-matched in terms of age, gender, primary diagnosis, and comorbidities. No differences were found in LOS, discharge destination, intraoperative fluoroscopy use, functional outcomes, PROMS and overall

complication rates however, increases in surgical duration, blood loss and risk of wound complications were noted in the obese group.

In this study, mean surgical duration was longer in the obese cohort by 8.32 minutes. Obesity adversely affects surgical time regardless of approach.[6–8,10,28,37,38] Onggo *et al*. calculated a difference in the mean surgical duration of 8.71 minutes between obese and non-obese patients, which widened further with increasing BMI, without assessing specific approaches.[8] In the DAA, Russo *et al*. reported an increased surgical duration of 12.7 minutes in obese patients.[7] Prolonged surgical duration is associated with increased perioperative risks including: prolonged admission; re-admission and re-operation; surgical site complications; systemic complications; and the need for blood transfusion.[9,39]

Despite the increased intraoperative blood loss noted in the obese cohort, only one patient required a transfusion implying limited clinical impact. Blood transfusions in THA are associated with a higher risk of PJI, increased LOS and cost.[40] Neither Argyrou *et al*. nor Hartford *et al*. found a relationship between BMI and blood loss in the DAA, however, Antoniadis *et al*. noted increased blood loss in severely obese patients (BMI $\geq$ 35kg/m^2) undergoing the DAA.[10,28,37] Onggo *et al*., did not find a significant difference in blood loss between obese and non-obese patients regardless of approach.[8]

There were no statistically significant differences in average fluoroscopy duration or dosage between the obese and non-obese cohorts. Previous research by Curtin *et al*. identified a relationship between radiation dose and BMI based on the energy required to create the image.[41] While the average fluoroscopy duration and dosage was greater than elsewhere in the literature, with Baksh *et al*. noting a mean fluoroscopy time of 21.4 seconds and a mean patient radiation dose of 1.8 mGy; the radiation dose across both cohorts remained within safe limits.[41,42] Intraoperative fluoroscopy improves the accuracy of component positioning at the expense of radiation exposure to patient and staff.[42]

The authors found no difference in LOS or need for step-down facilities. Antoniadis *et al*. reported a longer LOS in both cohorts than found in this study and further noted a higher LOS in the severely obese cohort (7.3 *versus* 5.3 days).[10] In obese patients, Russo *et al*. noted an increased LOS (2.4 *versus* 2.6 days) and need for step-down care (7.6% *versus* 15.4%).[7] Hartford *et al*. noted

equivalent outcomes regardless of BMI in terms of LOS (p = 0.70) and discharge destination (p = 1.7).[37]

There was a significant improvement in UPAT score in both cohorts ($p < 0.000$). Postoperatively, obese patients reported higher levels of day pain (0.45 ± 1.43 *versus* 0.28 ± 0.82, p = 0.29) and lower night (0.23 ± 0.96 *versus* 0.41 ± 1.46, p = 0.32) and activity-related pain (0.43 ± 1.59, p = 0.2) however this trend existed preoperatively and differences were statistically insignificant. Macheras *et al*. found equivalent postoperative pain scores for the obese and non-obese cohorts who underwent the DAA with both groups scoring significantly better than matched candidates who underwent the Hardinge approach.[43] Though statistically insignificant, we found a greater improvement in mHHS scores in the obese cohort, despite the mean postoperative mHHS remaining lower than those of the non-obese. This was similar to the findings of Argyrou *et al*., Antoniadis *et al*. and Macheras *et al*.[10,28,43] Macheras *et al*., in an RCT, noted better mHHS in DAA patients than Hardinge patients regardless of BMI.[43] FJS in both of our cohorts reflected successful surgery but contrary to Singh *et al*., who noted a trend of higher scores in non-obese patients, (68.11 *versus* 62.45; p = 0.349), our study demonstrated higher scores in the obese cohort (77.81 ± 22.19 *versus* 71.43 ± 28.57) however these findings were statistically insignificant (p = 0.34).[44] Other PROMS were similar indicating equivalent functional outcomes between obese and non-obese patients.

There were no statistically significant differences in overall complication rates, re-admissions or re-operations. These have all been associated with increased risk in obese patients, regardless of approach.[7,8,10,13,28,37,38] In our study, obese patients were more likely to have late complications and more likely to have wound complications (5.6% *versus* 2.4%, OR 2.4). An increased risk of wound complications and PJI in the obese cohort is in keeping with previous literature.[7,10,13,28,37] Russo *et al*. noted a 3.6 times risk for wound complications in obese patients with an 8.8 times risk of major complications.[7] Purcell *et al*. noted an incidence of 2.5% for PJI and 2% for SSI in patients with a BMI of ≥ 35kg/m^2; Argyrou *et al*. noted an SSI rate of 8.1% in the obese *versus* 1.2% in the non-obese and Antoniadis *et al*. documented a 2.3% incidence of deep infection and 4.7% incidence of SSI in the obese compared to 0.8% of each respective complication in the non-obese cohort.[10,13,28] In our study, non-obese patients were more likely to have early complications, including fractures and dislocations. There were no dislocations in the obese cohort. Onggo *et al*. and Lui *et al*. both noted an increased dislocation risk for obese patients undergoing THA however, Verhaegen *et al*. who only assessed patients undergoing the DAA did not find a difference.[8,45,46] In our population, potentially protective factors include the tendency towards a more closed acetabular cup in the obese cohort and the intermuscular nature of the approach.

There were several limitations to this study including its retrospective nature. As the dataset was limited to a single, high-volume hip surgeon at a single institution, results may not be replicable in settings without equivalent expertise or resources. The BMI was used to classify obesity due to widespread use and convenience however it is often considered to be a crude measure of obesity. While we used broad categories of obese and non-obese patients, the further grading of BMI would have allowed for a more refined analysis of the data and comparison to other literature.

5. CONCLUSION

This study shows that AMIS® DAA is a safe option for obese patients with equivalent outcomes to non-obese patients. As in other THA approaches, obese patients have a higher risk of wound-related complications, longer duration of surgery and increased volume of blood loss. This should be discussed during preoperative counselling and surgical planning.

Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethics approval and consent to participate

Ethics clearance was obtained from the Human Research Ethics Committee: University of the Witwatersrand (Ethics clearance No.: **M210819**).

Author contributions

NG: Analysis, Writing – original draft, Visualisation. JRTP: Conceptualization, Analysis, Writing - Review and editing, Supervision. JNC: Writing - Review and editing, Supervision. SKM: Writing - Review and editing, Supervision.

Declaration of competing interest

None. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Appendices

Appendix A: Data Collection Form

Appendix B: Ethics Certificate

Appendix C: Hospital Manager Consent

Appendix D: Universal Pain Assessment Tool

Appendix E: Journal guidelines

Appendix F: Student's contribution to research & writing of the "submissible" paper

Appendix G: Research protocol

Appendix A: Data Collection Form

Title: A Comparison of the Short-Term Outcomes of Obese and Non-obese Patients undergoing Total Hip Arthroplasty using the Direct Anterior Approach

Demographic Data

Study Number:

Age: ___ years

Sex: M/F

Height:____m

Weight: ____kg

BMI: ____kg/m2

Medical comorbidities:

☐Diabetes ☐Hypertension ☐Epilepsy ☐Asthma ☐Previous MI

☐Cardiac Arrythmias ☐Thyroid disease ☐HIV

ASA grade: ____

Allergies:

Intraoperative Data

Surgical time: _____minutes

Cemented femoral component: Y/N

Intra-operative complication:

☐Femoral fracture ☐Acetabular fracture ☐Nerve injury

☐Vascular injury ☐Need for cables

Blood loss: _____ml

Blood transfusion: Y/N

Acetabular component size: ___

Polyethylene component size: ___

Femoral component size: ___

Screws acetabular component: Y/N

Clinical Data

Preoperative

Modified Harris Hip Score: _____

UPAT score (at rest): _____

UPAT score (with activity): _____

LLD:_____mm

Postoperative

Length of hospital stay: _____days

Blood transfusion in ward: Y/N

6 weeks/6 months/1 year post operatively

Modified Harris Hip Score: _____

UPAT score at rest: _____

UPAT score on activity: _____

Complications

Early (<4weeks): Y/N

Late (>4weeks): Y/N

Type of complication: ☐Medical ☐Surgical

Medical complications

☐Cardiac ☐Pulmonary ☐Renal ☐Deep vein thrombosis ☐Other

Surgical complications

☐ Intraoperative ☐Postoperative

☐SSI ☐Deep PJI ☐Wound dehiscence

☐Periprosthetic fracture

☐Hip dislocation

☐Loosening. If Yes ☐Acetabular component ☐Femoral component

☐Nerve injury ☐Vascular injury

☐Greater trochanter pain syndrome

☐Iliopsoas impingement

☐Leg length discrepancy ____mm

Radiological Evaluation

Fixation Type

☐ Cemented ☐ Uncemented ☐Hybrid

Acetabular Cup Inclination

☐<30° ☐30-40 ☐41-55° ☐>55°

Acetabular Cup Version

☐0° ☐1-10° ☐11-20° ☐>20°

Femoral Stem Version

☐Neutral ☐Valgus ☐Varus

Appendix B: Ethics Approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Dr N Goga

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M210819

NAME: (Principal Investigator)	Dr N Goga
DEPARTMENT:	School of Clinical Medicine Department of Surgery Division of Orthopaedic Surgery Medical School University
PROJECT TITLE:	*Short-term outcomes in obese patients undergoing anterior minimally-invasive Total Hip Arthoplasty* *New study title noted on 2023/03/29*
DATE CONSIDERED:	2021/08/27
DECISION:	Approved unconditionally
CONDITIONS:	
NOTE:	If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>
SUPERVISOR:	Drs J Pietrzak & JN Cakic; Professor SK Magobotha
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2021/12/02

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **August** and therefore reports and re-certification will be due in the month of **August** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

2023 · 03 · 31
Date

Appendix C: Hospital Manager Consent

Life Fourways Hospital Proprietary Limited
Cnr Cedar Road and Cedar Avenue West, Fourways 2055
Postnet Suite 141, Private Bag X033, Rivonia 2128
Telephone: +27 11 875 1000
Telefax: +27 11 875 1001
www.fourwayshospital.co.za

15 July 2021

Dr Nabila Goga
Per email: nabila.goga@gmail.com

Dear Dr Goga

RE: APPLICATION TO CONDUCT RESEARCH USING DR CAKIC'S PATIENT DATABASE | DR NABILA GOGA

This letter serves to confirm that Dr Goga has been granted permission to perform the following research using Dr J.N. Cakic's database of patients operated on at Life Fourways Hospital:

- ***Short-term Outcomes following Total Hip Arthroscopy in Obese versus Non-obese patients using the Direct Anterior Approach***

The Health Research Ethics Committee of Life Healthcare Group has granted permission to Dr Goga to collect information using the patient database of Dr Josip Cakic for their research. However, the researcher and surgeon must ensure the following:

- The information collected must be anonymised
- Comply with the POPIA in terms of data security and confidentiality
- The information collected must be for the sole use of the research project

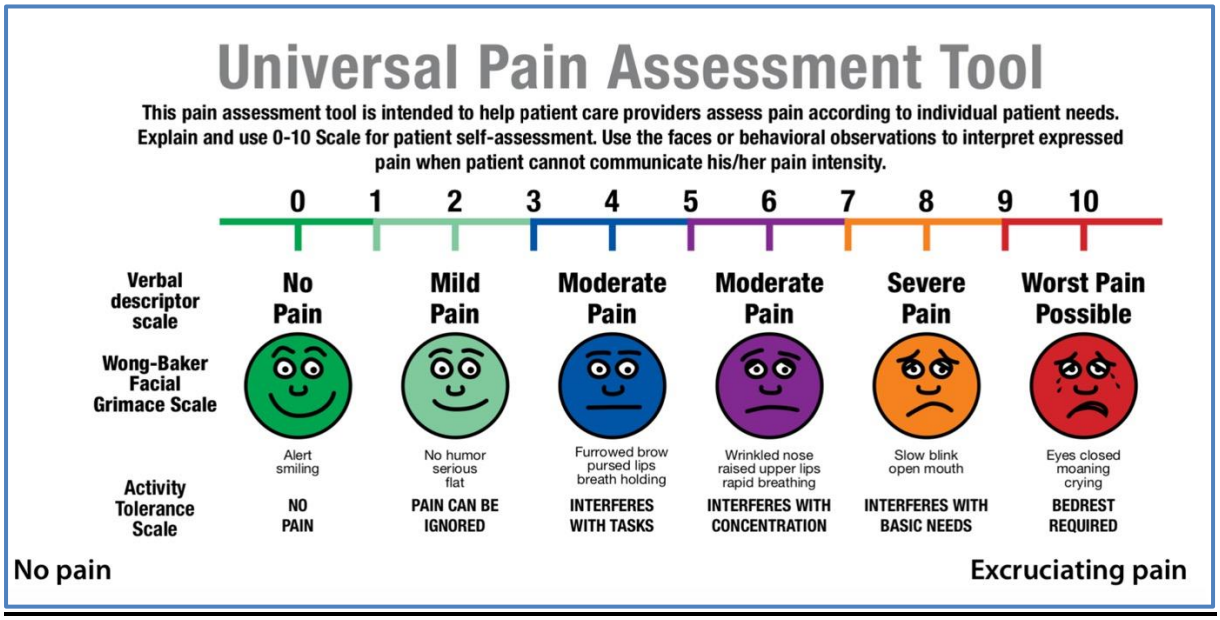
This letter has been issued in good faith and should you require any further information, please do not hesitate to contact the undersigned.

Yours sincerely

Carey MacColl
Hospital Manager
Life Fourways Hospital

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Appendix D: Universal Pain Assessment Tool: Available from: South African Acute Pain Guidelines



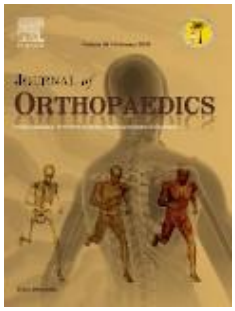
Appendix E: Journal guidelines

JOURNAL OF ORTHOPAEDICS

An official publication of the Prof. PK Surendran Memorial Educational Foundation and Indo Korean Orthopaedic Foundation

AUTHOR INFORMATION PACK

TABLE OF CONTENTS



- **Description p.1**
- **Abstracting and Indexing p.1**
- **Editorial Board p.2**
- **Guide for Authors p.6**

ISSN: 0972-978X

DESCRIPTION

Journal of Orthopaedics aims to be a leading journal in orthopaedics and contribute towards the improvement of quality of orthopedic health care.

The journal publishes original research work and review articles related to different aspects of orthopaedics including Arthroplasty, Arthroscopy, Sports Medicine, Trauma, Spine and Spinal deformities, Pediatric orthopaedics, limb reconstruction procedures, hand surgery, and orthopaedic oncology. It also publishes articles on continuing education, health-related information, case reports and letters to the editor.

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Appendix F: Student's contribution to the research and writing of the "submissible" paper



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26/02/2023

Faculty of Health Sciences, University of the Witwatersrand

RE: NABILA GOGA'S CONTRIBUTION TO THE RESEARCH AND WRITING OF THE "SUBMISSIBLE" PAPER

To whom it may concern,

This letter serves to confirm that the co-authors of the "submissible" research paper have agreed to its use by Nabila Goga, student number 0503841V, as part of her MMed research report. Nabila Goga made a substantial contribution to conducting the research study and writing the manuscript.

Yours sincerely,

.....

Dr [redacted] Pietrzak
Primary Supervisor

.....

Nabila Goga
MMed Candidate

Appendix G: Research protocol

Short-term outcomes in obese patients undergoing anterior minimally invasive Total Hip Arthroplasty



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Table of contents

List of Tables ..... **iii**

Nomenclature ..... **iv**

1. INTRODUCTION / BACKGROUND **1**

2. STUDY AIM AND OBJECTIVES **10**

3. METHODS **11**

4. DATA ANALYSIS **14**

5. ETHICS **15**

6. TIMING **15**

7. FUNDING **16**

8. ANTICIPATED PROBLEMS **16**

References **18**

List of Tables

Table 6.1 Gantt Chart……..……13

Table 7.1 Funding……...……13

Nomenclature

ADL	Activities of Daily Living
AL	Anterolateral approach
AKI	Acute kidney Injury
AAHKS	American Association of Hip and Knee Surgeons
BMI	Body Mass Index
CA	Cardiac Arrythmia
CK	Creatine Kinase
DAA	Direct Anterior Approach
DL	Direct Lateral Approach
DM	Diabetes Mellitus
HIV	Human Immunodeficiency Virus
HHS	Harris Hip Score
HOOS	Hip Disability and Osteoarthritis Outcome Scores
HS	Hip Society
LLD	Limb Length Discrepancy

MIS	Minimally Invasive Surgery
OECD	Organisation for Economic Co-operation and Development
PA	Posterior Approach
PROM	Patient Reported Outcome Measures
QALY	Quality of Life Years
QOL	Quality of Life
TFL	Tensor Fascia Lata
THA	Total Hip Arthroplasty
TJA	Total Joint Arthroplasty
USA	United States of America
UPAT	Universal Pain Assessment Tool
VAS	Visual Analogue Scale
WHO	World Health Organization

1. INTRODUCTION / BACKGROUND

1.1 Total Hip Arthroplasty

Total Hip Arthroplasty (THA) is one of the most successful interventions in the field of orthopaedic surgery (1,2). A 2007 article published in *The Lancet* labelled it 'The operation of the century' (1,2). Since Sir Charnley popularised the procedure in the latter part of the 20th century, the number of patients undergoing THA have continued to grow year on year with approximately one million THAs being performed annually worldwide and an average of 184 THA surgeries per 100 000 people in Organisation for Economic Cooperation and Development (OECD) countries (2–4).

The demand for THA surgery shows no signs of abating and current projections support a continuation of this trend for the foreseeable future with the annual number of procedures performed in the United States of America (USA) alone expected to increase by over one million from 400 000 to 1 429 000 by the year 2040 (5). The market for THA has expanded with widened of criteria for eligibility and increased demand from younger patients as technology and skills evolve (6,7).

The reason this procedure is held is such high esteem is due to the significant improvement in quality of life (QOL) for the majority of patients who undergo it (1,2,8). About ninety-four percent (93.9%) of patients who have undergone primary THA report being satisfied with the procedure (9–11). Primary THA has excellent outcomes with reported survivorship of up to 95% at 10 years and > 80% survivorship at 25 years (3). It has been shown to result in a significant increase in quality of life years (QALY) and from an economic perspective is a cost

effective surgical intervention (12,13). The majority of patients (78-96%) who undergo primary THA surgery are able to return to work within one year, however this number is lower in patients with more physically demanding roles (14,15).

1.2 The Direct Anterior Approach (DAA)

Despite the success and high usage of THA, there are still many areas of controversy. One of the hotly debated issues is that of the optimal surgical approach. Historically, the commonly used approaches were the anterolateral (AL), direct lateral (DL) and posterior approach (PA) however; this is rapidly changing with the growing interest in minimally invasive surgery (MIS) especially the direct anterior approach (DAA) (16).

The DAA has been described since the early days of arthroplasty however it has only become popularised over the last two decades (16,17). It is an MIS approach that uses intermuscular and internervous planes to access hip joint (17). Additional advantages are that it can be performed with the patient supine and it is amenable to the use of intraoperative fluoroscopy (17). As the DAA is a relatively novel and rapidly expanding focus within THA, there is a relative dearth of clinical information concerning long-term outcomes (18). The surgical approach plays a role in the incidence and type of complications (19,20). The DAA and PA have been noted to have superior outcomes than the AL and DL approaches with better Hip Disability and Osteoarthritis Outcome Scores (HOOS) for pain, activities of daily living (ADL), sports and QOL as well as lower rates of self-reported limping (21,22).

Currently there is no consensus on optimal surgical approach in terms of blood loss or need for perioperative blood transfusion (18,23–25). Radiographic outcomes have demonstrated no significant difference in implant position following surgery *via* DAA and PA groups however

cup anteversion tended to be greater in the following PA (24,26). Wang et al. conducted a metanalysis of randomised control trials (RCT) comparing outcomes of the DAA and PA and found no significant differences in hospital stay, operative time, complications or Harris Hip Score (HHS) at 12 weeks or one year (23). A 2017 systemic review by Meermans et al. concluded that there is limited evidence for improved kinematics or better long-term outcomes when using the DAA for THA however, there was a need for high quality RCT comparing the approaches before any final conclusions could be made on the optimal approach (27). Awad et al. noted that the DAA resulted in a short-term functional benefit which equalized by six to eight weeks postoperatively along with a higher cumulative cost when compared to the PA (25).

Frequently cited benefits of the DAA include improved early outcomes; lower postoperative visual analogue scale scores (VAS) for pain and reduced use of postoperative analgesia, shorter time to discharge and better Harris Hip Scores (HHS) at two, four and six weeks postoperatively (17,18,23–26,28). The incision length is usually smaller (23,29). Many surgeons believe the DAA results in less muscle damage owing its intermuscular nature; a theory which is supported by a 2011 study by Bergin et al. that noted a significantly lower increase in Creatine Kinase (CK) levels in patients following DAA than PA (28,29). There is a lower dislocation risk following THA using the DAA and patients are frequently given less restrictive postoperative guidelines when compared to other approaches (24,28,30–32). Surgeons generally allow DAA patients to return to sports and a wider variety of activities earlier during the postoperative period than they would following other approaches (32). Patients are reported to have earlier restoration of gait kinematics in the early postoperative (three month) period with more patients able to walk, climb stairs and higher total HHS scores during early follow-ups (24,30). Sun et al. conducted a metanalysis comparing outcomes of

the DAA and PA. They noted that the DAA group achieved better HHS scores initially but these equalised by the six month follow-up (24). In a matched retrospective review with a minimum two-year follow-up, Maldonado et al. showed similar patient reported outcome measures (PROM) when comparing the DAA and matched PA groups including comparable patient satisfaction and VAS scores however the QOL outcome scores were higher for the DAA cohort (34). Five year follow-up studies show comparable outcomes to the PA in terms of function, QOL and survivorship as well as patient satisfaction (11,30).

1.3 Attitudes and Trends around the DAA

There is still trepidation amongst many surgeons about using this approach (19,35). Surgeons who do not perform the DAA cite concerns that the DAA results in poorer outcomes, has no clinical benefit and expressed concern about the steep learning curve (35). In a survey of Hip Society (HS) members, 49.3% of respondents had used the DAA for THA however, 42.9% of the surgeons who had used it were no longer using it at the time of the survey (19). Only 22.5% of participants believed that the DAA had significant benefits over other approaches when considering the risks (19).

In a poll done at the 2018 meeting of the American Association of Hip and Knee Surgeons (AAKHS), the most common approach for routine THA was the PA (47%), followed closely by the DAA (40%). This showed a 28% increase in usage of the DAA in under a decade (36). In an email survey of members of the AAKHS the following year, it was noted that over 56% of respondents were comfortable performing the DAA (35). These surgeons overall had less years in practise than those who did not perform the DAA suggesting that the newer generation of surgeons are more likely to adopt this approach (35).

Surgeons report increased patient interest in the DAA: a survey of surgeons AAHKS revealed that the majority of participants felt that offering the DAA resulted in improved patient market share with 76.1% of surgeons who performed it reporting increases and 65.8% of surgeons who did not perform it reporting losses in their patient market share (35).

1.4 Concerns regarding the DAA

The general consensus amongst surgeons is that the DAA is a difficult technique with a steep learning curve and may not be suitable for inexperienced surgeons (24,27,30). Even for otherwise experienced surgeons, it is recommended that they have someone proficient in the approach assist and guide them during their initial surgeries to reduce the risk of surgeon-related complications.

There is a higher rate of certain complications noted in DAA patients namely surgical site infection, intraoperative fractures and postoperative lateral femoral cutaneous nerve (LFCN) neuropraxia (18,20,24,26). The higher rate of surgical site infection is thought to be due to the pannus overlying the surgical site (27). Operative time is typically longer in the DAA than the PA which is an independent risk factor for postoperative infection (11,17,24–26,37). Intraoperative fracture risk declines as the surgeon's experience grows and is thus a modifiable risk factor (27). LFCN neuropraxia has been reported in as much as 15 – 80% of patients undergoing THA, however the majority of these resolve without any long-term complications (27). The high incidence of LFCN neuropraxia is due to the nerve's significant anatomical variations and branching patterns with injuries to branches of the LCFN considered to be unavoidable in up to 42% of patients during the DAA due to the variations in its course (27,39,40). Increased pain may be caused by the rare complication of a postoperative neuroma (27).

There are certain patient factors that lead surgeons who preferentially use the DAA to use the PA instead. Specifically, revision cases (79.3%), complex anatomy (65%), and body habitus (53%) (35). Some institutions consider a high body mass index (BMI) to be a relative contraindication to the DAA (27).

1.5 Obesity and the DAA

Overweight or obesity are defined by the World Health Organisation (WHO) as abnormal or excessive fat accumulation that presents a risk to health (41). Obesity, which was first recognised as an epidemic in the USA, has become a global pandemic (42). Worldwide obesity has increased significantly over the last century and almost tripled since 1975 (41). In 2016, 39% of adults (more than 1.9 billion people) worldwide were overweight with over 650 million classified as obese (41).

BMI is calculated using an individual's weight in kilograms divided by the square of their height in metres, i.e. BMI = weight / $(\text{height})^2$ (41). A BMI of over 30 is classified as obese (41).

Obesity is a significant public health concern with a high prevalence across all population groups in South Africa. In a 2016 survey, it was noted that 41% of South African women were obese, 20% were classified as severely obese and a further 27% were classified as overweight. Only 30% of women had a BMI in the normal range with a further 3% classified as underweight (43). South African men fared better than their female counterparts with 59% classified as having a BMI within the normal range, 10% underweight, 20% overweight and 11% classified as obese. A further 3% were severely obese (43). In terms of demographics, South African white men were more likely to be overweight or obese (75%) with the prevalence much lower amongst black African males (27%). Women had a fair distribution across racial divides.

Women tended to have the highest prevalence in the age group 45 – 64 years (81 – 82%) while men aged 65 years or older were the age group most affected (54%). Severe obesity correlated with increased wealth among both men and women (43).

Obesity is linked to an earlier onset of osteoarthritis (44,45). This is due to a combination of biomechanical and physiological mechanisms, which are compromised, in the obese patient (45). Obese patients are likely to have altered gait patterns and increased vertical ground reaction forces (45). Articular cartilage is subjected to increased loading which can lead to tissue damage and earlier degenerative disease (45). Adipose tissue releases Adipokine, a protein that causes an increase in inflammation of the cartilage with resulting cartilage degradation (45). Obese patients have higher levels of inflammatory markers. This state of chronic inflammation is thought to contribute to the severity of the patients' symptoms including pain, functional limitation and disease progression (46).

The relative risk of undergoing THA increases with increasing BMI (45). Patients classified as morbidly obese are 8.5 times more likely to require a THA than non-obese patients (45). Obese individuals are more likely to require TJA at a younger age than their non-obese counterparts. Patients with class I obesity were on average two years younger, and class II and III obese patients between seven and nine years younger than non-obese patients at the time of THA (44,45).

Obesity is rarely found alone. It is associated with a cluster of comorbidities including Diabetes mellitus, dyslipidaemia, hypertension, coronary artery disease and obstructive sleep apnoea; all of which may contribute to the increased perioperative risk (45). Obesity is an independent risk factor for complications in TJA. Obese patients have an increased risk of combined complications, acute kidney injury (AKI), cardiac complications, hip dislocation, reintubation,

reoperation, superficial infection, wound complications and deep infection (11,44,47–53). The risk of these complications increase progressively with higher BMIs, specifically with BMI ≥ 35, BMI ≥ 45 or patient weight of ≥ 100 kg (47,48,53). Obesity is also related to an increased risk of deep vein thrombosis (DVT) and pulmonary embolism (PE) (54). Obese patients have increased operative times, duration of admission and require more analgesia (51,52). They are more likely to require assistive devices two weeks postoperatively and step down facilities for rehabilitation on discharge (51). The overall incidence of wound infection or deep infection following THA is comparable between the DAA and PA however obesity, in particular morbid obesity, puts patients at a greater risk for superficial wound complications following DAA, often requiring further operative management (49,50). Obese patients undergoing a DAA have an 8.8 and 3.6 fold increase in major and wound complications respectively, compared to patients with a BMI < 30.

Antoniadis et al. compared outcomes of THA *via* the DAA in non-obese and Class II Obese patients. Functional outcomes improved significantly with the HHS of both cohorts improving by a mean delta value of 45 from preoperative to postoperative. Radiologically, there were no significant differences between acetabular version, inclination, vertical centre of rotation or leg length however the non-obese cohort had a slightly medialized horizontal centre of rotation compared to the obese group (11). They noted a four-fold increase in the reoperation rate in the obese cohort. This was primarily due to wound complications such as wound infection and dehiscence. The higher complication and reoperation rates were comparable to the rates of the standard approach noted in the literature and were deemed by the authors to be acceptable suggesting that the DAA is an acceptable option for obese patients (11).

1.6 Anti-Fat bias

Implicit bias amongst health care providers has come under the spotlight in recent years with increased reportage of its detrimental effects on health care (55). In a study done on medical doctors to assess for weight bias it was noted that there were very strong implicit and explicit (self-reported) anti-fat attitudes (55). The strong explicit bias implies that participants may find it more socially acceptable to express negative attitude towards overweight people, which may result in overweight patients receiving suboptimal care (55). Considering the increased demand for THA, increasing usage of the DAA along with the growing prevalence of obesity, the aim of this study is to assess if there are differences in outcomes of obese and non-obese patients undergoing THA *via* the DAA and to assess whether the DAA is a viable option for obese patients.

2. STUDY AIM AND OBJECTIVES

Aim

- To compare short-term outcomes of obese and non-obese patients undergoing THA using the DAA.

Objectives

- The primary objective is to evaluate short-term outcomes in terms of clinical and functional outcomes; radiological parameters, intraoperative, early and late complications in obese and non-obese patients undergoing THA using the DAA.

  - ***Clinical and functional outcomes:***

    This includes preoperative and postoperative limb length discrepancy (LLD), HHS and pain scores.

  - ***Radiological parameters:***

    We will compare the range of preoperative radiological diagnosis as well as postoperative component positioning on standard radiographic images at a minimum of one-year.

  - ***Intraoperative:***

    Our study will evaluate any differences in surgical time, intraoperative blood loss, need for blood transfusion as well as intraoperative complications.

- ***Complications:***

  Our study will assess early and late, surgical and medical complications. We will look at the postoperative time to discharge, review data recorded during follow-up appointments for other complications and will review the results of duplex doppler scans done three weeks postoperatively to record the incidence of early asymptomatic DVTs.

- The secondary objective of our study is to determine a change in patient-reported outcome measures, pain scores and satisfaction rates in obese and non-obese patients who have undergone DAA primary THA at a minimum of one-year follow-up.

3. METHODS

Study design

The study will be a retrospective chart analysis of patients who have undergone an elective primary THA using DAA. A single high-volume hip surgeon practising in a single theatre in a single private institution performed all cases. He performed a total of 416 elective THAs from the period of January 2017 to January 2020. We will retrospectively assess all patients who were followed-up for at least one year postoperatively.

Site of study

The study will be conducted at Life Fourways Hospital. This is a private institution, which provides a wide range of medical and surgical services as well as a spectrum of ancillary

services including physiotherapy, radiology and wound services. The primary surgeon is an experienced hip surgeon and is based at this institution.

Data Collection: Main variables and outcome measures

The following baseline demographic data were collected for all participants preoperatively on a uniform data collection form designed by the primary surgeon (see appendix section). Baseline preoperative data collected included age (years), gender, primary diagnosis, BMI and comorbidities. Preoperative pain scores were assessed using the Universal Pain Assessment Tool (UPAT). Patients were assessed for LLD in cm and PROMs using the HHS.

- The Body Mass Index (BMI) is calculated as mentioned in **Section 1.4**.
- The LLD is measured in cm as the difference between the leg length (measured from the ASIS to the medial malleolus of each leg) of the contralateral and ipsilateral legs.
- The HHS is a validated assessment tool developed to evaluate the results of hip surgery. It assesses various outcomes including pain, function, deformity and range of motion. It covers pain, function, deformity and range of motion. It has good to excellent retest and inter-rater reliability.
- The UPAT is combination tool comprising of the verbal numeric rating scale, the verbal descriptor scale and the Wong-Baker FACES® pain rating scale.

Intraoperative data collected included surgical time (minutes), estimated blood loss (ml), techniques and implants used, and intra-operative complications as well as fluoroscopy.

Postoperatively the need for blood transfusion was documented along with time to discharge (days) and the residual LLD.

At subsequent follow-ups of six-weeks, six-months and one-year, the following functional, clinical and radiographic data were collected:

- Functional outcomes were assessed using the HHS and pain was assessed using the UPAT.
- Clinical information assessed included complications, which were classified as early (< 4 weeks) *versus* late (> 4 weeks) as well as medical *versus* surgical. Medical complications were classified as being related to the patients' baseline ± the physiological effect of the surgery. Surgical complications were considered as being directly related to the effects of the surgery. These included wound complications, infection, periprosthetic fractures, dislocation, psoas tendon impingement, subsidence of prosthesis, nerve injury and mechanical complications.
- Standard radiological imaging was done postoperatively and at the follow-ups. These images were assessed for acetabular inclination and version, femoral version, femoral subsidence and for the presence of any radiolucent lines surrounding the acetabular or femoral components. Radiolucent lines surrounding the acetabular cup were be classified according to the Charnley and DeLee classification system while similarly radiolucent lines surrounding the femoral were described using Greun's zones.

Moreover, patients were asked about their postoperative satisfaction according to a five level Likert-type scale that included the following options; significantly dissatisfied, dissatisfied, neutral, satisfied, significantly satisfied. The Likert-type scale was used to assess patient satisfaction, which is a commonly used tool for the assessment of participant attitude. Patients were subsequently classified as satisfied if they chose satisfied or significantly satisfied and

dissatisfied if they chose neutral, dissatisfied or significantly dissatisfied at one-year follow-up.

Patient Selection Criteria

Inclusion criteria:

- Patients over the age of 18 years who underwent an elective total hip arthroplasty *via* the DAA done by Dr JN Cakic.
- Patients who had consented for the collection of their data by the primary surgeon.

Exclusion criteria:

- Patients who did not complete the minimum of one-year follow-up schedule as described.
- Patients incapable of informed consent.
- Patients who underwent THA due to trauma.
- Patients who underwent bilateral simultaneous THA.
- Patients who underwent revision THA by the primary surgeon.

4. DATA ANALYSIS

The control and obese patient cohorts will be statistically compared based on a series of parameters. The means of these parameters will be compared using T-tests with statistical significance at $p < 0.05$. Confidence intervals will be calculated at 95%, thereby subsequently, used in conjunction with the *p*-values to determine clinical significance. Groups will be tested for linear model assumptions: normality and homogeneity of variances. In the event of violation of the linear model assumptions, the Wilcoxon rank-sum alternative will be used to

hypothesis test between the two cohorts (These tests can be used to demonstrate any changes in PROMS pre- and post-operatively within the same cohort). Implant survival will be plotted on a Kaplan-Meier curve to produce the empirical probably of implant survival over the study period. The statistical package to be used is the R version 4.0.4 (2021-02-15); University of Auckland, New Zealand.

5. ETHICS

All patients' data will be retrospectively collected from database that is kept securely by Dr JN Cakic. Dr Cakic has previously received ethical approval for the prospective collection of data for his hip patients. All the data are currently housed securely in a single server. All patients have consented for their data to be used for academic research purposes. All patients have been assigned a file number and names and other identifying data are kept separately from clinical information. The primary investigator has signed a non-disclosure agreement. The Human Research Ethics Committee has granted provisional approval for the study (Protocol no: **M210819**). We will await the clearance certificate before accessing the database.

6. TIMING

	July 2021	**August 2021**	**September 2021**	**October 2021**	**November 2021**	**December 2021**	**January 2022**
Protocol Development							
Protocol Submission							
Ethics Application							

Data collection							
Data Analysis							
Write up of Research Report							

7. FUNDING

Study will be self-funded (see Table below):

Item	**Estimated Cost (ZAR)**
Stationary	R400
Printing	R600
Laptop	Own
Transport/fuel	R200
Statistician	R500
Total	**R1700**

8. ANTICIPATED PROBLEMS

This is a retrospective chart analysis and therefore there may be some concerns with collecting all the data for all patients across all the subsets and time variables with absolute consistency and uniformity. Evaluation also demands that patients have been consistent in complying with

their follow-up appointments, thus some patients may be lost if they did not complete their scheduled follow-up appointments.

We have classified obese and non-obese patients as those with a BMI of < 30 and ≥ 30 respectively; however, we are aware that BMI is not considered the most accurate measure of obesity. Concerns noted are that it does not differentiate between muscle and fat, does not take into account the distribution of adiposity and or variations across populations or gender. We chose to use it due to the ease of use and because it is widely accepted and utilised (45).

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