LOW DISLOCATION RATES ACHIEVED WHEN USING DUAL MOBILITY CUP HIP IMPLANTS FOR FEMUR NECK FRACTURES

By

Lourens Jacobus Erasmus

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Supervisor: Dr JF van der Merwe

I, Lourens Jacobus Erasmus, declare that the coursework Master's Degree mini-dissertation that I herewith submit in a published manuscript format for the Master's Degree qualification in Orthopaedic Surgery at the University of the Free State is my independent work, and that I have not previously submitted it for qualification at another institution of higher education.

L.J. Erasmus

Acknowledgments and dedication

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Abstract

Background

Total hip replacements (THA) done for intracapsular neck of femur fractures (NOF) have a dislocation rate of up to 14%. This is seven times higher than in THA done for osteoarthritis. Using a dual mobility cup (DMC) has been shown to be effective in addressing dislocation in elective THA. Our hypothesis is that the use of DMC in NOF will do the same. This study aims to determine the incidence proportion of dislocation of DMCs one year after surgery in patients who received THA for NOF and to compare it to dislocation rates as documented in existing studies.

Methods

A retrospective study was done on 86 patients treated with DMC-THA for an intracapsular NOF fracture from 2012 until 2016. A minimum one-year follow-up period was required for inclusion into the study. The number of dislocations at one year after surgery were noted.

Results

Forty-one patients with a mean age of 60,7 years were included (26 females and 15 males). All patients were operated via the posterior approach. None of the patients had dislocated after one year.

Conclusion

Low dislocation rates can be achieved using DMC THA in the management of intracapsular NOF fractures. Our one-year dislocation rate of 0% compares favourably to conventional THA and is comparable to similar DMC studies done outside of South Africa.

Key words: Dual mobility cup, Neck of femur fracture, Dislocation, Total hip arthroplasty, Intracapsular

Oxford Level of Evidence: Level 3 (Retrospective cohort study)

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Chapter 1

Introduction

Neck of femur fractures are a major contributor to orthopaedic disease burden. It is the most common fracture seen in patients older than 60 years and it is estimated that these fractures will occur at a rate of 6,26 million per year worldwide by the year 2050.[1]

These fractures are most commonly caused by falls in the elderly and by high energy injuries, such as motor vehicle accidents, in younger patients. Several risk factors increase the chances of sustaining this type of injury and may include factors that increase the risk of falls, for instance dementia or alcohol abuse, and decreased bone density, mostly due to osteoporosis, that lead to bones breaking more easily.[2]

Neck of femur fractures can be divided into intracapsular and extracapsular fractures. This is an important distinction to make, as it has major consequences for the prognosis and treatment of the injury. The blood supply to the head of the femur runs intracapsularly in the retinaculum on the neck of the femur. Intracapsular neck of femur fractures very often damage these blood vessels, thereby impairing blood supply to the femoral head and leading to femoral head avascular necrosis and non-union of the fracture. The risk of these complications are much higher in displaced neck of femur fractures, as these carry a higher risk of disrupting the above mentioned blood vessels. Extracapsular neck of femur fractures are not prone to the same complications and are approached and managed in the same way as intertrochanteric fractures.[2,3,4]

There are several different treatment options for intracapsular neck of femur fractures. These treatment strategies try to minimise the risk of complications such as avascular necrosis of the femoral head and fracture non-union. Which one is used is dependent on the fracture pattern, and the age and general medical condition of the patient. In young patients with undisplaced intracapsular fractures the indicated treatment is open reduction and internal fixation of the fracture. This is done because there is a lower risk of complications in undisplaced fractures and because young patients are not good candidates for joint replacement surgery. Joint replacement is avoided in younger patients because of limited prosthesis lifetime and the need for revision surgery when the prosthesis is worn out or loosens. There is a limit on the amount of successful revision hip replacement surgeries that can be done and this needs to be factored in when deciding on the best course of treatment.[2,3,4]

In older patients with displaced intracapsular neck of femur fractures, replacement of the hip joint is the mainstay of treatment. This is because of the high risk of non-union and avascular necrosis that these fractures pose and because age and subsequent prostheses wear and revision surgery is not a limiting factor in old patients. Of these older patients, the younger, more active ones are usually treated with a total hip replacement as this allows greater mobility, better function and lasts longer than the alternative. In the very old patient with comorbid diseases, low demand, low activity levels and a life expectation of less than five years a hemiarthroplasty of the hip is done. This gives less mobility and does not last as long as a total hip replacement but has the benefits of being much cheaper and requiring less operative time to do, which makes it a preferable choice in the very elderly.[2,3,4]

Besides wear and the need for revision surgery, total hip replacements have other complications as well. These include periprosthetic fractures, loosening of the prosthesis, periprosthetic infections and dislocation of the prosthesis. Of these, dislocation of the prosthesis is the most common complication.

In primary hip replacements for osteoarthritis dislocation rates of between 1,9% and 7% have been found, depending on the time elapsed since implantation of the prosthesis, the lower figure being at one year post-operatively and the higher number 25 years post-operatively.[5] Dislocation of hip prostheses are the main indication for revision surgery, making up 22,5% of cases.[6] Dislocation is a complication that is to be avoided at all costs as even after revision surgery 30% of patients still have persistent instability.[7]

There are multiple patient and surgical risk factors that increase the risk of hip dislocation after total hip replacement. Patient risk factors include advanced age (older than 80 years), dementia or psychiatric illnesses, non-compliance with post-operative instructions, neuromuscular disorders, alcohol abuse and an ASA score of three or more pre-operatively.[8,9] These factors all contribute to poorer post-operative compliance with movement patterns that avoid dislocation or increase the risk of falls in the patient, both of which can lead to dislocation of the hip prosthesis. Surgical risk factors include the surgical approach used, the positioning of the femoral and acetabular components, soft tissue tension and the surgeon's level of experience.[8,9] In the past there used to be a great emphasis on placing especially the acetabular cup in the "safe zone" of 40˚± 10˚ inclination and 15˚± 10˚ anteversion.[10] However, Abdel recently showed that correct positioning of the acetabular component is not a guarantee of hip stability and that 58% of all hip prosthesis dislocations were correctly positioned in the "safe

zone". It thus appears that hip dislocation after arthroplasty is multifactorial and not as simple as just placing the acetabular cup in the "safe zone" (although this should still be adhered to).[11]

Dislocation rates in total hip replacements done for neck of femur fractures are much higher still. Rates of 12% - 14% have been reported when using the posterior approach.[12] These high rates of dislocation are improved to 2% - 8% when using the anterolateral approach.[13] When done for a failed open reduction and internal fixation the dislocation rate can go up to 22%. Rates as high as 32% have been found if patients are also demented.[14] A local study done in Cape Town reported an early dislocation rate (within one year of surgery) of 4,3%.[15] It is clearly evident from these studies that dislocation is a major contributor to morbidity after total hip replacement for fractures. A solution to this problem needs to be found.

Dual mobility cup hip arthroplasty

A suggested modern solution to the problem is the dual mobility cup hip prosthesis. This prosthesis was developed in France in the 1974 by Prof. Gilles Bousquet and an engineer, André Rambert.[16,17,18] It consists of a non-retentive metal acetabular cup within which a retentive polyethylene insert (liner) with a metal head articulates. There are thus two surfaces at which movement takes place: between the acetabular cup and polyethylene liner and between the polyethylene liner and metal head. This has several theoretical benefits. The first is reduced wear because of decreased friction and movement between the surfaces as compared to a standard hip prosthesis with only one articulating surface. Lab studies done by Stulberg and Netter corroborate this.[19,20] Grazioli *et al.* raised some concerns about increased wear rates and aseptic loosening, but 15-year survival rates of sockets have been reported at 96,3% ± 3,7% by Phillipot.[17,21] The second theoretical benefit arises for the same reason that hip prostheses with larger femoral heads have a lower risk for dislocation. The risk reduction stems from an increased head-neck ratio and an increased jump distance.[22,23] The increased head-neck ratio allows for a greater range of motion before impingement of the prosthesis neck on the rim of the acetabular cup takes place. The increased jump distance allows a greater amount of lateral movement of the head inside the acetabular cup before dislocation takes place. Theoretically, and so far supported by lab data and 15-year follow-up of implanted prostheses, these benefits and the associated decreased risk of dislocation seem to hold true.

Comparable studies

Dual mobility cups have been used in both primary and revision total hip arthroplasty and have been proven to decrease instability and risk of dislocation.[24,25,26,27,28,29,30,31,32,33] A newer application for this type of hip prosthesis was to use it for the patients most at risk for dislocation after total hip arthroplasty, namely those who receive arthroplasty for trauma and specifically for neck of femur fractures. The first author to mention this use of dual mobility cup implants was Tarasevicius in 2010.[34] After his initial study several more papers looking at this novel application of the prosthesis were published, three of them in 2018.[35,36,37] This is a current topic and new studies from around the world are appearing in journals at the time of this writing.

So far seven studies looking at whether dual-mobility cup hip implants can reduce the dislocation rate when used for neck of femur fractures have been published. These publications were all in the past eight years. All the studies done used the posterior approach, except for the study done by Adam *et al*., where 20% of the patients were operated via the anterolateral approach.[38]

The first study was done by Tarasevicius *et al*. in 2010. They did a retrospective study on 42 patients and found zero dislocations at one-year follow-up.[34]

The second was done by Adam *et al*. in 2012. They did a retrospective study on 214 patients and found three dislocations at nine-months follow-up.[38]

Bensen *et al*. looked at 175 patients in 2014 and found eight dislocations at 21-months follow-up.[39]

Nich *et al*. did a retrospective study in France in 2016 where they followed up 45 patients for two years. They found three dislocations during this time.[40]

Boukebos *et al*. also from France, reported in 2018 that out of 98 patients included in their study, three had dislocated at 24-months follow-up.[38]

Zagorov *et al.* did a study in Bulgaria in 2018 and looked at 49 patients who had dual-mobility cups inserted for neck of femur fractures. At 29-months follow-up none of the patients had dislocated.[37]

Lastly, Rashed *et al*. did a study in Egypt that was published in 2018. They included 31 patients in their study and reported zero dislocations at one-year follow-up.[35]

Hypothesis, research question, aim and objectives

With the background given in the above paragraphs, we hypothesized that using dual mobility cup implants for total hip replacements in neck of femur fractures would decrease the very high dislocation rates reported for standard hip prostheses in other studies.

The central research question asked was whether low dislocation rates can be achieved when dual mobility cup total hip arthroplasty is used for neck of femur fractures instead of the standard prostheses.

We aimed to retrospectively gather data on patients who had neck of femur fractures and were treated with dual mobility cup total hip arthroplasty. This data was then to be compared to existing data on standard total hip replacements to determine whether the dislocation rates are higher, lower or similar.

The main objective of our study was to determine the dislocation rates at a minimum of one-year follow-up. As a secondary objective we also wanted to determine whether there were any other complications associated with this type of prosthesis and the incidence of these complications.

We thus set out to answer the question: DUAL MOBILITY CUP HIP ARTHROPLASTY USED IN FEMUR NECK FRACTURES: CAN LOW DISLOCATION RATES BE ACHIEVED?

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Chapter 2

Introduction

The total hip replacement may have been rated as the best operation of the 20th century, but it is not without its complications.[1] Dislocation of the hip prosthesis post-operatively remains one of the most common complications encountered after total hip arthroplasty (THA). Rates of 1.9% at one year and increasing up to 7% over 25 years have been reported in primary THA.[2] Post-operative dislocations are the indication for surgery in 22.5% of revision cases and even after revision surgery 30% of patients will have persistent instability of their hip.[3,4]

The dislocation rate of THA done for fractures are much higher still, and thus of even more concern than in primary THA.

When using the posterior approach for THA done for femur neck fractures, Enocsen found a dislocation rate of 12–14%.[5] This is seven times higher than in primary hip arthroplasty. Hummel reported a dislocation rate of 2–8% when using the anterolateral approach for similar indications.[6] If done for a failed open reduction and internal fixation of a femur neck fracture, 22% of hips dislocated post-operatively.[7] When the patient was also demented, dislocation rates shot up to 32%.[7] As a local comparison, a study done at the University of Cape Town and published in 2018 found a 4.3% risk for early dislocation after total hip arthroplasty for neck of femur (NOF) fractures.[8]

There are several patient risk factors that increase the risk for dislocation after THA. These include dementia, psychiatric disorders, alcohol abuse, age higher than 80 years old, neuromuscular disorders and non-compliance with post-operative movement and rehabilitation instructions.[9,10]

Besides patient risk factors, there are also surgical risk factors that contribute to dislocation. Some of these are the surgical approach used, the positioning of the acetabular and femoral components, soft-tissue tension and the surgeon's experience.[9] Great emphasis was previously placed on putting the implant in the so-called 'safe zone' with the acetabular cup at 40°±10° inclination and 15°±10° anteversion.[11] This has recently been found not to be as much of a protective factor as previously thought, with 58% of all hip prosthesis dislocations being in the safe zone. Abdel, who headed the study, concluded that hip dislocations post THA are multifactorial in cause, and a holistic approach needs to be taken to minimise the risk of dislocation.[12]

A modern solution to the problem of dislocation after THA has been suggested, namely the dual mobility cup (DMC). Designed by Prof Gilles Bousquet and André Rambert in France in 1974, it features two articulations: the acetabular cup with the polyethylene insert and the polyethylene insert with the head of the femoral component.[13-15] It is available in both cemented and uncemented options. This implant has been suggested as an option to reduce dislocation rates in very high-risk patients.

DMCs theoretically decrease dislocation risk for the same reasons a large effective femoral head does. It increases the head-to-neck ratio, allowing for a greater range of motion before impingement starts taking place.[16,17] It also increases jump distance, allowing for a greater amount of lateral head movement before dislocation takes place.[17]

Some authors recommend caution when using it for standard primary THA and in young patients as there is some concern about increased wear rates and aseptic loosening. This concern is mainly because of the lack of long-term follow-up data and not because high rates of wear or aseptic loosening have actually been found.[13] There may in fact be decreased wear with DMCs as there are two articulating interfaces and thus less friction and sliding at each.[18,19] Regarding real-world outcomes measured thus far, medium-term follow-up of these prostheses has been done by Philippot, who found a very favourable 15-year socket survival rate of 96.3% (±3.7%).[20]

Several companies currently offer DMC options for THA. Some examples are shown in *Table I*.

This study aims to determine whether DMCs used in NOF fractures are a possible solution to the high dislocation rates mentioned above. It intends to do so by retrospectively determining the cumulative incidence of dislocation in our study group at one year post-surgery and then comparing the numbers found to existing studies of dislocations in conventional total hip replacements as well as DMC studies done in other countries.

Methods

We did a retrospective cohort study at a single tertiary level hospital in Bloemfontein (Universitas Academic Hospital). We identified all the patients who had received DMC hip arthroplasty for intracapsular NOF fractures from July 2012 until December 2016. A total of 86 patients were identified. Electronic records (Meditech) and admission data, clinic files,

radiological records and telephonic follow-up were then used to determine whether these patients had dislocated their hips post-operatively. Surgeon experience and the method of implant fixation were also documented.

A minimum follow-up time of one year (at our clinic or telephonic) was required to be included in the study. Patients who did not complete a full year of follow-up at our clinic were phoned to find out whether they had dislocated or not. Patients with incomplete records were excluded from the study. Those who had less than one year of follow-up time and were untraceable telephonically or otherwise were excluded. The Department of Home Affairs assisted in identifying patients who passed away within the first year of surgery. These patients were also excluded. Those who had arthroplasty done for failed open reduction and internal fixation of intracapsular NOF fractures were also excluded. Age was not an exclusion criterion. Some younger patients received DMC hip arthroplasty because of a high risk for dislocation. This decision was at the discretion of the attending consultant.

After determining the cumulative incidence of dislocations in our study group, we planned to compare our numbers to those of existing studies on hip dislocation in standard and DMC hip arthroplasty done for intracapsular NOF fractures.

All patients had a primary hip arthroplasty with a Polarcup® prosthesis. This product is manufactured by Smith & Nephew Orthopaedics AG of Rotkreuz, Switzerland. Several other companies also manufacture similar prostheses and the choice of this specific implant was based on departmental protocol. Both cemented and uncemented techniques were used for acetabular cups and femoral components, depending on patient indications. All the patients were operated via the posterior approach (Kocher-Langenbeck approach). This is departmental protocol and makes comparison with other DMC studies done much easier and more accurate, as the vast majority (>95%) of similar studies previously done also utilised the posterior approach.

Results

Forty-one of the 86 patients identified were included in the study. A total of 45 patients were excluded. Eight had incomplete files, four passed away during the first year after surgery and the rest did not complete a full year of follow-up and could not be contacted telephonically.

Thirty-four of these patients followed up at our clinic for one year or more. Seven patients did not complete a full year of follow-up at the clinic but were reached telephonically more than one year after surgery was performed and were confirmed not to have dislocated.

The mean age of the patients included was 60.7 years (SD 8.6). Twenty-six (63.4%) of the patients were females, with the youngest being 42 years, the oldest 81 years and with a mean age of 62 years (SD 9.5) old. There were 15 (36.6%) males among the patients included, with the youngest being 49, the oldest 67 and with a mean age of 58.4 years (SD 6.3). Patient demographics are shown in *Table II*.

The risk factors for dislocation common to all the patients in the cohort were that they received THA for a NOF fracture via the posterior approach. Surgeon experience could not be controlled for and prostheses fixation was variable (according to patient indications).

Regarding the experience of the surgeon, 24 cases (58.5%) were performed by a registrar, 12 cases (29.3%) by a registrar with consultant supervision and five (12.2%) by a consultant.

Both cemented and uncemented prostheses were used in different combinations depending on specific patient indications. A cemented cup and stem was used in 29 of the cases (70.7%). An uncemented cup and cemented stem (hybrid implant) was used in six patients (14.6%). A cemented cup and uncemented stem (reverse hybrid implant) was used in four of the cases (9.8%) and an uncemented cup and stem was used in two patients (4,9%). Details of the surgeries performed are summarised in *Table III*.

Some complications other than dislocation were encountered. Two of the patients developed deep wound infections. One of these patients ended up having a Girdlestone excisional arthroplasty and the other had to undergo two-stage revision surgery.

The main aim of this study was to determine the cumulative incidence of dislocation of DMC hip prostheses used for intracapsular NOF fractures one year after surgery was performed. We found that none (n=0) of the patients included in our study had dislocated one year after surgery.

Discussion

By using DMC THA in the management of intracapsular NOF fractures we achieved a 0% dislocation rate at one-year follow-up. This is significantly better than the rates reported with

conventional THA for this indication.[5,7,8] (This is compared to total hip replacements for NOF fractures in general, and not for specific prostheses like big femoral head components that might compare more favourably with DMC implants.[23] The dislocation rates for DMCs found in this study are similar to the results found by other authors in recent years. *Table IV* shows a comparison of the results of similar studies done. All the studies shown in *Table IV* used the posterior approach, except for the study done by Adam *et al.* in which 20% of cases were performed via the anterolateral approach.[24]

A limiting factor to this study is the large number of patients lost to follow-up. Universitas Academic Hospital has a catchment area that includes the Free State, Northern Cape, Lesotho and parts of the Eastern Cape. Many of these areas are very remote and rural which makes it difficult for patients to follow up in the long term. This is coupled with inadequate record-keeping, with many patients being admitted to hospital without having their telephone numbers or identity numbers captured. Despite excluding these patients from the study, we believe it is unlikely that many, or even any, of them dislocated. The structure of the health system in the Free State is such that patients who dislocated would have to be referred to Universitas Academic Hospital for reduction and would likely have been picked up in this manner.

Future researchers may consider doing a prospective study in which they can better control data capture and possibly attain a higher level of long-term follow-up. A prospective study could also look at whether patients have other risk factors for dislocation besides the ones that the patients in our cohort shared, namely THA done via the posterior approach for NOF fractures.

Conclusion

The results obtained in this study were comparable to similar studies done abroad and show promise for the use of DMCs to achieve low dislocation rates in this high-risk group of patients.

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Table I: Dual mobility cups available

Company	Trade name	HXPE*	Cemented	Head sizes (mm)
Smith & Nephew	Polarcup	Yes	Yes	22, 28
Tornier	Dual Mobility Cup	Yes	Yes	22, 28
Stryker	Mobile Hip System	Yes	Yes	22, 28
Zimmer-Biomet	Avantage	Yes	Yes	22, 28
	Active Articulation	Yes	No	28
DePuy	Gyros	Yes	No	22.5, 28

*HXPE: highly cross-linked polyethylene

Table II: Demographics of patients

Characteristics (n=41)	
Age in years (mean, SD)	60.7 (8.6)
Females (mean, SD)	62 (9.5)
Males (mean, SD)	58.4 (6.3)
Sex	
Females (n, %)	26 (63.4%)
Males (n, %)	15 (36.6%)

Table III: Details of surgeries performed

Surgeries performed (n=41)	
Prostheses	**n (%)**
Smith & Nephew Polarcup	41 (100%)
Approach	
Posterior (Kocher-Langenbeck)	41 (100%)
Surgeon experience	
Registrar	27 (58.5%)
Registrar with consultant supervision	12 (29.3%)
Consultant	5 (12.2%)
Fixation method	
Cemented cup and stem	29 (70.7%)
Uncemented cup and cemented stem	6 (14.6%)
Cemented cup and uncemented stem	4 (9.8%)
Uncemented cup and stem	2 (4.9%)

Table IV: Dislocation rates of dual mobility cups used for neck of femur fractures

Authors	Year	Country	Follow-up	Number of patients (n)	Dislocations (n)	Dislocation rate (%)
Current study	2019	South Africa	12 months	41	0	0%
Tarasevicius *et al*.[23]	2010	Lithuania	12 months	42	0	0%
Adam *et al*.[22]	2012	France	9 months	214	3	1.4%
Bensen *et al*.[24]	2014	Denmark	21 months	175	8	4.6%
Nich *et al*.[25]	2016	France	36 months	45	3	6.7%
Boukebos *et al*.[26]	2018	France	24 months	98	3	3.1%
Zagorov *et al*.[27]	2018	Bulgaria	29 months	49	0	0%
Rashed *et al*.[28]	2018	Egypt	12 months	31	0	0%

Appendices

Appendix A

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

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

07 February 2017

DR LJ ERASMUS
DEPT OF ORTHOPAEDICS
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr LJ Erasmus

HSREC 165/2016 (UFS-HSD2016/1327)
PROJECT TITLE: DUAL MOBILITY CUP HIP ARTHROPLASTY USE IN FEMUR NECK FRACTURES: CAN LOW DISLOCATION RATES BE ACHIEVED?

1. You are hereby kindly informed that the Health Sciences Research Ethics Committee (HSREC) approved this protocol after all conditions were met. This decision will be ratified at the next meeting to be held on 28 February 2017.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the HSREC NR as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services-(HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

.....
DR SM LE GRANGE
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Cc Van Der Merwe, Johan JF

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | F: +27 (0)51 444 4359 | E: ethicsfhs@ufs.ac.za
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa
www.ufs.ac.za

Appendix B

health
Department of Health
FREE STATE PROVINCE

23 January 2017

Mr. LJ Erasmus
Dept. of Orthopaedics
Faculty of Health Science
UFS

Dear Mr. LJ Erasmus

Subject: Dual Mobility Cup Hip Arthroplasty Used In Femur Neck Fractures: Can Low Dislocation Rates Be Achieved?

- Permission is hereby granted for the above – mentioned research on the following conditions:
- Serious adverse events to be reported and/or termination of the study.
- Ascertain that your data collection exercise neither interferes with the day to day running of Universitas Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and no names will be used.
- Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of the Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of the Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** khusemj@fshealth.gov.za or sebeelats@fshealth.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution managers/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day
- Future research will only be granted permission if correct procedures are followed see http://nhrd.hst.org.za

Trust you find the above in order.

Kind Regards

Dr D Motau
HEAD: HEALTH
Date: 23/01/2017

Head : Health
PO Box 227, Bloemfotein, 9300
4th Floor, Executive Suite, Bophelo House, cnr Maitland and, Harvey Road, Bloemfotein
Tel: (051) 408 1527 Fax: (051) 408 1556 e-mail:sebeelats@fshealth.gov.za@fshealth.gov.za/chikobvup@fshealth.gov.za

www.fs.gov.za

Appendix C

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

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Bloemfontein
14 October 2016

ATT:

Dr. S. Matshidza
HOD Orthopaedic Surgery
Universitas Hospital

We would like to inform you of our intention to perform the following study:

DUAL MOBILITY CUP HIP ARTHROPLASTY USED IN FEMUR NECK FRACTURES: CAN LOW DISLOCATION RATES BE ACHIEVED?

HSREC reference number: UFS-HSD2016/1327

We are currently awaiting ethical clearance from the Health Sciences Research Ethics Committee of the University of the Free State to perform this study.

I have attached a copy of our research protocol for your inspection and approval.

Yours truly,

Dr. LJ Erasmus
Department of Orthopedic Surgery
University of the Free State

I, Dr. Steven Matshidza, Head of Department of Orthopaedic Surgery at Universitas Hospital, hereby give my permission and approval to go ahead with the above stated study.

Signature

DR S Matshidza
Printed Name

21/10/2016
Date

Appendix D

Study Protocol

Title:

DUAL MOBILITY CUP HIP ARTHROPLASTY USED IN FEMUR NECK FRACTURES: CAN LOW DISLOCATION RATES BE ACHIEVED?

Researchers:

Dr. LJ Erasmus, Dr. FF Fourie, Dr. JF van der Merwe
Department of Orthopaedic Surgery
Universitas Academic Hospital
University of the Free State
Tel. 051 401 7960
Cell: 0741498383 / 0832811157 / 0825772108

Declaration of confidentiality: We understand that all information obtained from the participants in the course of this study is confidential. We agree not to divulge or otherwise make known to unauthorized persons any of this information, unless specifically authorized to do so by approved protocol or by the local principal investigator acting in response to applicable law.

_____ _____

Dr. FF Fourie Dr. JF van der Merwe

_____

Dr. LJ Erasmus

Date : 27 September 2016

Summary in lay terms

Neck of femur fractures (broken hips) are very common injuries in the elderly, and we expect to see increasing numbers with an aging population. The ideal management of a patient with a broken hip remains controversial. However, the latest literature suggests that a total hip replacement has the best outcomes with regards to chronic pain and function.

Unfortunately, a hip replacement in this specific group of patients, has a very high risk of dislocation (the ball of the replacement jumps out of the socket). One of the ways to decrease the risk and prevent dislocation, is by using a specific hip prosthesis: the dual mobility cup. This prosthesis has been shown to be an effective way to decrease the dislocation rate for hip replacement where the risk of dislocation is high.

Since 2009, our arthroplasty unit has inserted the dual mobility cup for patients who required a hip replacement for a neck of femur fracture (broken hip) as a way to prevent dislocation. However, many of these prostheses were inserted by less experienced orthopaedic surgeons.

We aim to do a retrospective study on all the patients who received a dual mobility cup for a neck of femur fracture (see selection criteria below). We will review all these patient's clinical files and X-rays (where available) and collect the necessary data.

Our primary aim is to show that our patients, who received a dual mobility cup, have low dislocation rates compared to standard hip replacements. Our secondary aim is to look at the amount of replacements that were done by less experienced surgeons, and see what their dislocation rates were. We suspect it will also be low, showing that this replacement can be done safely in a high risk group of patients, even if done by the less experienced surgeons. In the hips that dislocated, we want to review the case to see why the dislocation occurred.

Approval will be obtained from various authorities.

Introduction

DUAL MOBILITY CUP HIP ARTHROPLASTY USED IN FEMUR NECK FRACTURES: CAN LOW DISLOCATION RATES BE ACHIEVED?

Neck of femur fractures are frequent injuries and with the growing aging population the number of hip fractures are expected to triple over the next 50 years. Especially in the elderly, management and care of these patients have a major economic impact on the global health care system.[1,2]

Hemiarthroplasty (HA) and total hip arthroplasty (THA) remain the most widely acceptable management options for displaced neck of femur fractures in patients older than 60 years old, although the optimal treatment choice, especially in the elderly, is the subject of ongoing scientific debate.

Several studies, including a recent meta-analysis, concluded that THA can be done safely in these patients and leads to better functional outcomes, even in elderly patients.[3,4] THA should be considered the treatment of choice in the patient over 60 years of age and hemiarthroplasty should be reserved for the patient with limited life expectancy and/or very low functional demands.[3]

Unfortunately, despite better functional outcomes, it has also been shown that THA has a three times higher dislocation rate compared to hemiarthroplasty. A meta-analysis comparing THA versus HA, showed the risk of dislocation in the THA group to be 9%, compared to 3% in the HA group.[3]

The risk of dislocating a THA is influenced by patient factors and surgical factors. Patient risk factors include advanced age, female sex, previous surgery, and cognitive or neurologic disorders and neck of femur fractures. Surgical factors include the surgical approach, implant position, choice of implant, soft tissue balance, impingement and surgeon experience.[5,6]

Neck of femur fractures have been shown to be one of the most significant patient specific risk factors for hip dislocation after THA.[6,7] A meta-analysis revealed that patients managed with THA for femur neck fractures have a five times higher risk for dislocation as compared to a patient with osteoarthritis.[8] A possible explanation for this is increased laxity of the hip due to lack of capsular hypertrophy and fibrosis as we see in degenerative arthritis.[6,9] Cognitive

dysfunction and muscle impairment, specifically in the older patient, increases the dislocation risk even further in this patient group.[5,6]

Patient specific risk factors, although beyond the influence of the treating surgeon, should be identified and consideration should be given to modify the surgical technique to prevent dislocation. Correct implant selection may decrease the risk of dislocation in the very high risk patient. The use of bipolar arthroplasty and constrained liners, as used in salvage procedures for recurrent instability, provide stability, but reduce functional outcome and implant longevity.[10,11] Dual mobility acetabular components, despite being used in France for many years, have recently gained wider attention as an alternative option in addressing instability in both primary and revision THA.

A Dual Mobility Cup (DMC) combines a large articulation, between the metallic shell and a mobile polyethylene (PE) insert, with a small articulation between the insert and the prosthetic head. This concept allows increased hip range of motion (ROM) until impingement occurs through its two articulations design. In the first articulation the head is "engaged" but mobile within the polyethylene (PE) liner and follows the typical mechanical behaviour of a hard-on soft bearing. However, if the femoral neck and the rim of the PE liner come into contact, a second articulation begins to function and effective ROM is increased until impingement of the femoral neck against the rim of the shell ultimately occurs. In this way, the head- liner complex theoretically functions as a large femoral head, increasing the head-neck ratio and subsequently the jump distance before dislocation.[12]

The DMC concept has been proven efficient in the treatment and prevention of instability both in primary and revision THA, with low rate of osteolysis and good midterm survival rate.[12,13,14,15] Tarasevicius *et al*. [9] compared dislocation rates of DM cups with that of conventional cups in patients with neck of femur fractures treated with THA through a posterior approach. At one-year follow-up, there were eight dislocations (14.3%) in the conventional THA group and no dislocations in DM group. Several other studies have concluded that the use of a dual mobility cup total hip arthroplasty for neck of femur of fractures reduces the risk of dislocation, although some feel it is a technically demanding procedure.[16,17]

At our unit we insert the POLARCUP® dual mobility cup system (Smith and Nephew Orthopaedics AG, Rotkreuz, Switzerland) for selected patients with displaced femur neck fractures. Due to staff shortages, many of these procedures are performed by relatively inexperienced surgeons and even registrars. We asked ourselves how effective the DMC-THA

system is at preventing dislocation in patients with a neck of femur fracture. We hypothesized that use of this component would have a low dislocation rate, despite a very high risk of dislocation after THA.

Study goal

Primary aim: To determine the dislocation rate of dual mobility cup hip arthroplasties done for neck of femur (NOF) fractures.

Secondary aim: In cases where dislocation occurred, we will analyse the data in an attempt to describe the circumstances under which the dislocation occurred and the reason why the dual mobility cup failed to prevent the dislocation. We also want to determine what the dislocation rate was when inexperienced surgeons performed the surgery.

Study design

We propose to do a single-centre retrospective descriptive study.

Methods

Study subjects:

Approximately 180 patients that received a primary hip arthroplasty with a dual mobility cup for a neck of femur fracture between September 2009 and November 2015.

Inclusion criteria:

All patients in the stated time frame who underwent a primary hip arthoplasty with a POLARCUP® (Smith and Nephew Orthopaedics AG, Rotkreuz, Switzerland)

Use of either cemented or uncemented cup and stems

Indication for surgery: displaced neck of femur fracture

Age: older than 55 years

At least one year of follow-up visits.

Data collection

All the study subjects' (patients who met the selection criteria) clinical files and X-rays, where available, will be reviewed. Files from patients operated at National and Universitas Hospitals will be used. These files will kept secure on the premises of Universitas Hospital in the

orthopaedic outpatient clinic and will not leave the hospital. All data capture will be done in the orthopaedic outpatient clinic.

The data collected will be recorded on an Excel spreadsheet (see attached form 1). In cases where a dislocation occurred, a more in depth review of the case notes will be done, in an attempt to identify the possible cause for the dislocation. (See attached form 2 – patient associated risk factors; Form 3 – surgical risk/causes).

In cases where we are unable to obtain the clinical files of the study subjects, we will attempt to obtain the necessary information by contacting these patients telephonically. Theatre and admission records will also be reviewed if additional information is required.

Data interpretation

Data will be collected on a data form (see attached). Dr. Erasmus and Dr. Fourie will collect the data.

A pilot study will be performed with 3 patient files and reviewed by the Department of Biostatistics.

Statistical analysis: Descriptive statistics, namely means and standard deviations or median and percentiles will be calculated for categorical data. The analysis will be done by the Department of Biostatistics.

The collected data, results and interpretation of data will be illustrated using tables, charts and graphs.

Implementation of findings

We want to use the data collected to determine if, by using the dual mobility cup arthroplasty prosthesis, decreased dislocation rates in patients with femur neck fractures can be achieved.

In cases where dislocation occurred, we hope to identify the cause for the dislocation from the data collected.

We intend to present the data at an orthopaedic congress and publish an article on this study in a peer reviewed orthopaedic journal.

Timeframe

The protocol will be submitted to the ethics committee office by 4 October 2016.

The study will commence as soon as ethics committee approval has been granted. Data collection and interpretation will be completed within a 3 month period.

Budget

We do not foresee any major costs involved in this study.

The researches will personally fund the costs that include:

Stationary

Printing of forms and data sheets

Telephone calls to patients where telephonic follow-up is required

See form: Budget layout.

Ethics

The study is subject to approval of the ethics committee. We do not foresee any ethical problems.

We have submitted a copy of this protocol to the Head of Department Orthopaedic Surgery to obtain approval for this research.

As research is to be conducted at Universitas Academic Hospital, a public healthcare facility, approval from the Provincial Department of Health will be obtained after ethical approval has been granted.

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Appendix E

Information for Authors (South African Orthopaedic Journal)

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.

Formatting of submissions

Text formatting

- Use Helvetica or Arial font, size 11.
- Use 1,5 spacing throughout the document.
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- Do not use field functions.
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- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

- Use no more than three levels of displayed headings.

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

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Figures

- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3, etc.
- The figure should be listed in the text as follows: … wound irrigation and splinting (*Figure 1*).
- Figures should be clear and easily understandable with a full descriptive legend stating any areas of interest and explaining any markings, letterings or notations. All figures should be understandable without the main text.
- For radiographs please ensure you state the view used and the time point at which it was taken, as well as the demographic details of the patient if applicable.
- Figures should not be imbedded in the text file but should be submitted as separate individual files. Each figure should be a separate file, entitled Figure 1, Figure 2, etc.
- Remove all markings, such as patient identification, from radiographs before photographing.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of six figures.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

Tables

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

References

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- References should not be a listing of a computerised literature search but should have been read by the authors and have pertinence to the manuscript.
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Journal article:

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

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

On-line journal article:

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

Web reference (with authors):

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

Web reference (no authors listed):

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

Chapter in a book:

Young W. Neurophysiology of spinal cord injury. In: Errico TJ, Bauer RD, Waugh T (eds). *Spinal Trauma*. 3rd ed. Philadelphia: JB Lippincott; 1991: 377-94.

Dissertation:

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

Abstract:

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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)
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Title page

Title

- The title should be concise and informative.

Author names and affiliations

- Please provide the following information for each author:
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- Clearly indicate who will handle correspondence at all stages of refereeing and publication, including post-publication.
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Authors are to insert a section at the end of the title page entitled declarations (please provide name of author, signature and date). The following statements are required under the declarations section.

Authorship

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

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- The drafting the article or its critical revision for important intellectual content.
- Final approval of the version to be submitted.

Sound scientific research practice

The authors further confirm that:

- The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere.
- No data have been fabricated or manipulated (including images) to support conclusions.
- This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami-publishing').

Plagiarism

The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.

- No data, text or theories by others are presented as if they were the authors' own.

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Conflict of interest statement

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

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If no conflicts of interest exist, state this as follows:

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Funding sources

All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; and the decision to submit the manuscript for publication.

List all funding sources as follows: 'This work was supported by the xxxx (grant numbers xxxx, yyyy).'

When funding is from a block grant or other resources available to a university, college or other research institution, submit the name of the institute or organisation that provided the funding.

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

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

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

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

'Informed written consent was or was not obtained from all patients for being included in the study.'

For studies with animals include the following sentence: 'All institutional and national guidelines for the care and use of laboratory animals were followed.'

For articles that do not contain studies with human or animal subjects: 'This article does not contain any studies with human or animal subjects.'

If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. If any identifying information about patients is included in the article, the following sentence should also be included: Additional informed consent was obtained from all patients for which identifying information is included in this article. The Helsinki Declaration 2008 can be found at http://www.wma.net/en/30publications/10policies/b3/

Title Page Example

Title of Submission

John Smith*
MBChB, FC Orth SA, MMed (Ortho)
University of South Africa, 123 High Street, Pretoria
ORCID No https://orcid.org/1234-1234-1234-1234

Paula Taylor
MBChB, FC Orth SA
University of South Africa, 123 High Street, Pretoria
ORCID No https://orcid.org/1234-1234-1234-1234

* Corresponding author:

Prof John Smith
University of South Africa
123 High Street, Waterkloof, Pretoria, South Africa, 0001
PO Box 1001, Waterkloof, Pretoria South Africa, 0001<br/ Tel: 012 123 4567
e-mail: johnsmith@unisa.ac.za

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.
- The drafting the article or its critical revision for important intellectual content.
- Final approval of the version to be submitted.

Sound scientific research practice

The authors further confirm that:

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Conflict of interest statement

John Smith declares that he has no conflict of interest. Paula Taylor has received research grants from Drug Company A.

Funding sources

No funding was received for the purposes of performing this study

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Informed written consent was or was not obtained from all patients for being included in the study.

Author Name	**Signature**	**Date**
J Smith		15/8/2017
P Taylor		16/8/2017

Blinded manuscript

Abstract

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

Key words

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

Level of evidence

- Level 1 to 5.
- Please follow the level of evidence guidelines provided by the Oxford Centre for Evidence-Based Medicine (OCEBM); version 2.1.

- Available from: OCEBM Levels of Evidence Working Group. 'The Oxford Levels of Evidence 2'.Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653

Introduction

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

Patients (or Materials) and methods

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

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

Results

- Describe the relevant results and analysis thereof.
- Provide details of the number of patients included and excluded, as well as the reason for exclusion.
- It is important to state the follow-up period (mean and range).
- The results can be broken down into separate sections, e.g. Treatment, Functional outcome, Complications, etc.
- Tables may be used but avoid repeating data reported in the text in the tables.
- All appropriate data should be presented as means with ranges, not with standard deviations (SDs). Medians should only be used when the data is skewed, accompanied by an interquartile range (IQR).
- Avoid using percentages in studies involving well under 100 subjects.
- All results must be backed up with p-values or survivorship analysis. All Kaplan-Meier data should be presented with the confidence intervals. Always present exact absolute p-values, whether significant or not, unless $p < 0.001$.
- However, p-values do not always convey the entire picture and where relevant the confidence interval will also be required (in addition to the power of the study reported in the methods section).

Discussion

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

Conclusion

- Provide a summary statement which conveys the conclusions of the findings.
- Do not draw conclusions not supported by the data obtained from the specific study presented.

Ethics statement

- For studies involving human subjects please include an ethics statement as follows: ‘All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.’
- For animal studies please include the following ethical statement: ‘All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.’
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- Please also include an informed consent statement: ‘Informed consent was obtained from all individual participants included in the study.’
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- If identifying information about participants is available in the article, the following statement should be included: ‘Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.’

Acknowledgements

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

Author contributions

- Please state the contributions of each author
- For example: ‘A.B contributed to the study conceptualisation, design, data analysis and manuscript preparation. C.D. contributed to data collection and manuscript preparation. E.F. contributed to ....’
- The types of contributions are:
    - Conceptualisation and design
    - Data collection or contribution
    - Data analysis
    - Manuscript preparation
    - Other contribution (please specify)

References

- Please refer to the section on Formatting of submissions.

Tables and figures

- Table and figures should not be imbedded in the text file but should be submitted as separate individual files. Each table should be a separate file, entitled Table I, Figure 2, etc.

- Each table and figure should be provided with a heading or legend.
- Please refer to the ‘Formatting of submission’ section for further guidelines.

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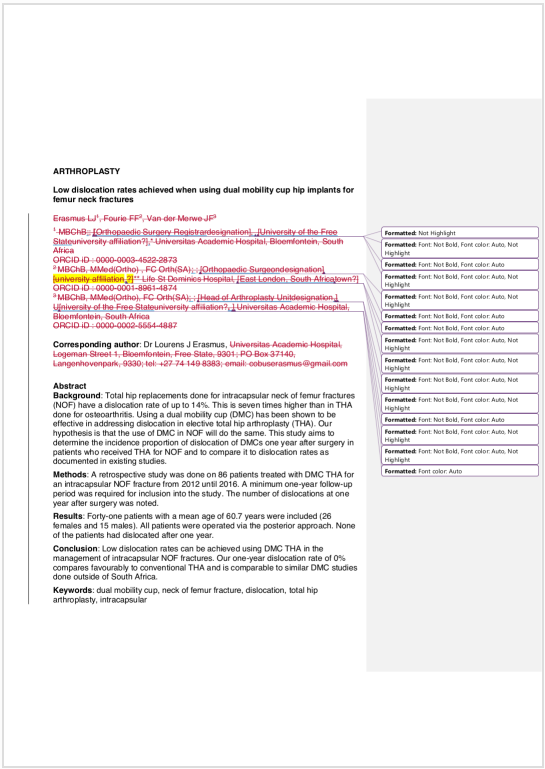

ARTHROPLASTY

Low dislocation rates achieved when using dual mobility cup hip implants for femur neck fractures

Erasmus LJ[1], Fourie FF[2], Van der Merwe JP[3]

[1] MBChB; [Orthopaedic Surgery Registrardesignation]; [University of the Free Stateuniversity affiliation?],[2] Universitas Academic Hospital, Bloemfontein, South Africa
ORCID ID : 0000-0003-4522-2873
[2] MBChB, MMed(Ortho) , FC Orth(SA) ; [Orthopaedic Surgeondesignation]; [university affiliation ?],[3] Life St Dominics Hospital, [East London, South Africatown?]
ORCID ID : 0000-0001-8961-1874
[3] MBChB, MMed(Ortho), FC Orth(SA) ; [Head of Arthroplasty Unitdesignation]; [University of the Free Stateuniversity affiliation?],[1] Universitas Academic Hospital, Bloemfontein, South Africa
ORCID ID : 0000-0002-5554-4887

Corresponding author: Dr Lourens J Erasmus, Universitas Academic Hospital, Logeman Street 1, Bloemfontein, Free State, 9301, PO Box 37140, Langenhovenpark, 9330; tel: +27 74 149 8383; email: cobuserasmus@gmail.com

Abstract

Background: Total hip replacements done for intracapsular neck of femur fractures (NOF) have a dislocation rate of up to 14%. This is seven times higher than in THA done for osteoarthritis. Using a dual mobility cup (DMC) has been shown to be effective in addressing dislocation in elective total hip arthroplasty (THA). Our hypothesis is that the use of DMC in NOF will do the same. This study aims to determine the incidence proportion of dislocation of DMCs one year after surgery in patients who received THA for NOF and to compare it to dislocation rates as documented in existing studies.

Methods: A retrospective study was done on 86 patients treated with DMC THA for an intracapsular NOF fracture from 2012 until 2016. A minimum one-year follow-up period was required for inclusion into the study. The number of dislocations at one year after surgery was noted.

Results: Forty-one patients with a mean age of 60.7 years were included (26 females and 15 males). All patients were operated via the posterior approach. None of the patients had dislocated after one year.

Conclusion: Low dislocation rates can be achieved using DMC THA in the management of intracapsular NOF fractures. Our one-year dislocation rate of 0% compares favourably to conventional THA and is comparable to similar DMC studies done outside of South Africa.

Keywords: dual mobility cup, neck of femur fracture, dislocation, total hip arthroplasty, intracapsular

Low dislocation rates achieved when using dual mobility cup hip implants for femur neck fractures

by Lj Earsmus

Submission date: 13-May-2020 06:08PM (UTC+0200)
Submission ID: 1323397251
File name: LJ_Erasmus_1.docx (68.01K)
Word count: 2084
Character count: 11059

ARTHROPLASTY

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[1] MBChB;; [Orthopaedic Surgery Registrardesignation], ,[University of the Free Stateuniversity affiliation?],* Universitas Academic Hospital, Bloemfontein, South Africa
ORCID iD : 0000-0003-4522-2873
[2] MBChB, MMed(Ortho) , FC Orth(SA); ; [Orthopaedic Surgeondesignation], [university affiliation 2]** Life St Dominics Hospital, [East London, South Africatown?]
ORCID iD : 0000-0001-8961-4874
[3] MBChB, MMed(Ortho), FC Orth(SA); ; [Head of Arthroplasty Unitdesignation,] U[niversity of the Free Stateuniversity affiliation?,] Universitas Academic Hospital, Bloemfontein, South Africa
ORCID iD : 0000-0002-5554-4887

Corresponding author: Dr Lourens J Erasmus, Universitas Academic Hospital, Logeman Street 1, Bloemfontein, Free State, 9301; PO Box 37140, Langenhovenpark, 9330; tel: +27 74 149 8383; email: cobuserasmus@gmail.com

Abstract

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Level of evidence: Level 3

Citation: Erasmus LJ, Fourie FF, Van der Merwe JF. Low dislocation rates achieved when using dual mobility cup hip implants for femur neck fractures. *SA Orthop J* 2020;**19**(2):XX-XX. http://dx.doi.org/10.17159/2309-8309/2020/v19n2a2
Funding: No funding was received for this study.

Introduction

The total hip replacement may have been rated as the best operation of the 20th century, but it is not without its complications.[1] Dislocation of the hip prosthesis post-operatively remains one of the most common complications encountered after total hip arthroplasty (THA). Rates of 1.9% at one year and increasing up to 7% over 25 years have been reported in primary THA.[2] Post-operative dislocations are the indication for surgery in 22.5% of revision cases and even after revision surgery 30% of patients will have persistent instability of their hip.[3,4]

The dislocation rate of THA done for fractures are much higher still, and thus of even more concern than in primary THA.

When using the posterior approach for THA done for femur neck fractures, Enocsen found a dislocation rate of 12–14%.[5] This is seven times higher than in primary hip arthroplasty. Hummel reported a dislocation rate of 2–8% when using the anterolateral approach for similar indications.[6] If done for a failed open reduction and internal fixation of a femur neck fracture, 22% of hips dislocated post-operatively.[7] When the patient was also demented, dislocation rates shot up to 32%.[7] As a local comparison, a study done at the University of Cape Town and published in 2018 found a 4.3% risk for early dislocation after total hip arthroplasty for neck of femur (NOF) fractures.[8]

There are several patient risk factors that increase the risk for dislocation after THA. These include dementia, psychiatric disorders, alcohol abuse, age higher than 80 years old, neuromuscular disorders and non-compliance with post-operative movement and rehabilitation instructions.[9,10]

Besides patient risk factors, there are also surgical risk factors that contribute to dislocation. Some of these are the surgical approach used, the positioning of the acetabular and femoral components, soft-tissue tension and the surgeon's experience.[9] Great emphasis was previously placed on putting the implant in the so-called 'safe zone' with the acetabular cup at 40°±10° inclination and 15°±10° anteversion.[11] This has recently been found not to be as much of a protective factor as previously thought, with 58% of all hip prosthesis dislocations being in the safe zone. Abdel, who headed the study, concluded that hip dislocations post THA are multifactorial in cause, and a holistic approach needs to be taken to minimise the risk of dislocation.[12]

A modern solution to the problem of dislocation after THA has been suggested, namely the dual mobility cup (DMC). Designed by Prof Gilles Bousquet and André Rambert in France in 1974, it features two articulations: the acetabular cup with the polyethylene insert and the polyethylene insert with the head of the femoral component.[13-15] It is available in both cemented and uncemented options. This implant has been suggested as an option to reduce dislocation rates in very high-risk patients.

DMCs theoretically decrease dislocation risk for the same reasons a large effective femoral head does. It increases the head-to-neck ratio, allowing for a greater range of motion before impingement starts taking place.[16,17] It also increases jump

distance, allowing for a greater amount of lateral head movement before dislocation takes place.[176]

Some authors recommend caution when using it for standard primary THA and in young patients as there is some concern about increased wear rates and aseptic loosening. This concern is mainly because of the lack of long-term follow-up data and not because high rates of wear or aseptic loosening have actually been found.[13] There may in fact be decreased wear with DMCs as there are two articulating interfaces and thus less friction and sliding at each.[18,19] **[ref 17 not mentioned yet]** Regarding real-world outcomes measured thus far, medium-term follow-up of these prostheses has been done by Philippot, who found a very favourable 15-year socket survival rate of 96.3% (±3.7%).[20]

Several companies currently offer DMC options for THA. Some examples are shown in *Table I*.

This study aims to determine whether DMCs used in NOF fractures are a possible solution to the high dislocation rates mentioned above. It intends to do so by retrospectively determining the cumulative incidence of dislocation in our study group at one year post-surgery and then comparing the numbers found to existing studies of dislocations in conventional total hip replacements as well as DMC studies done in other countries.

Methods

We did a retrospective cohort study at a single tertiary level hospital in Bloemfontein (Universitas Academic Hospital). We identified all the patients who had received DMC hip arthroplasty for intracapsular NOF fractures from July 2012 until December 2016. A total of 86 patients were identified. Electronic records (Meditech) and admission data, clinic files, radiological records and telephonic follow-up were then used to determine whether these patients had dislocated their hips post-operatively. Surgeon experience and the method of implant fixation were also documented. A minimum follow-up time of one year (at our clinic or telephonic) was required to be included in the study. Patients who did not complete a full year of follow-up at our clinic were phoned to find out whether they had dislocated or not. Patients with incomplete records were excluded from the study. Those who had less than one year of follow-up time and were untraceable telephonically or otherwise were excluded. The Department of Home Affairs assisted in identifying patients who passed away within the first year of surgery. These patients were also excluded. Those who had arthroplasty done for failed open reduction and internal fixation of intracapsular NOF fractures were also excluded. Age was not an exclusion criterion. Some younger patients received DMC hip arthroplasty because of a high risk for dislocation. This decision was at the discretion of the attending consultant.

After determining the cumulative incidence of dislocations in our study group, we planned to compare our numbers to those of existing studies on hip dislocation in standard and DMC hip arthroplasty done for intracapsular NOF fractures.

All patients had a primary hip arthroplasty with a Polarcup® prosthesis. This product is manufactured by Smith & Nephew Orthopaedics AG of Rotkreuz, Switzerland. Several other companies also manufacture similar prostheses and the choice of this specific implant was based on departmental protocol. Both cemented and uncemented techniques were used for acetabular cups and femoral components, depending on patient indications. All the patients were operated via the posterior approach (Kocher-Langenbeck approach). This is departmental protocol and makes comparison with other DMC studies done much easier and more accurate, as the

vast majority (>95%) of similar studies previously done also utilised the posterior approach.

Results

Forty-one of the 86 patients identified were included in the study. A total of 45 patients were excluded. Eight had incomplete files, four passed away during the first year after surgery and the rest did not complete a full year of follow-up and could not be contacted telephonically.

Thirty-four of these patients followed up at our clinic for one year or more. Seven patients did not complete a full year of follow-up at the clinic but were reached telephonically more than one year after surgery was performed and were confirmed not to have dislocated.

The mean age of the patients included was 60.7 years (SD 8.6). Twenty-six (63.4%) of the patients were females, with the youngest being 42 years, the oldest 81 years and with a mean age of 62 years (SD 9.5) old. There were 15 (36.6%) males among the patients included, with the youngest being 49, the oldest 67 and with a mean age of 58.4 years (SD 6.3). Patient demographics are shown in *Table I*. [not the Table II have, which looks like Table IV]

The risk factors for dislocation common to all the patients in the cohort were that they received THA for a NOF fracture via the posterior approach. Surgeon experience could not be controlled for and prostheses fixation was variable (according to patient indications).

Regarding the experience of the surgeon, 24 cases (58.5%) were performed by a registrar, 12 cases (29.3%) by a registrar with consultant supervision and five (12.2%) by a consultant.

Both cemented and uncemented prostheses were used in different combinations depending on specific patient indications. A cemented cup and stem was used in 29 of the cases (70.7%). An uncemented cup and cemented stem (hybrid implant) was used in six patients (14.6%). A cemented cup and uncemented stem (reverse hybrid implant) was used in four of the cases (9.8%) and an uncemented cup and stem was used in two patients (4,9%). Details of the surgeries performed are summarised in *Table III*. [missing]

Some complications other than dislocation were encountered. Two of the patients developed deep wound infections. One of these patients ended up having a girdlestone excisional arthroplasty and the other had to undergo two-stage revision surgery.

The main aim of this study was to determine the cumulative incidence of dislocation of DMC hip prostheses used for intracapsular NOF fractures one year after surgery was performed. We found that none (n=0) of the patients included in our study had dislocated one year after surgery.

Discussion

By using DMC THA in the management of intracapsular NOF fractures we achieved a 0% dislocation rate at one-year follow-up. This is significantly better than the rates reported with conventional THA for this indication.[5,7,8] (This is compared to total hip replacements for NOF fractures in general, and not for specific prostheses like big femoral head components that might compare more favourably with DMC implants.[23]) The dislocation rates for DMCs found in this study are similar to the results found by other authors in recent years. *Table IV* [looks like my Table II] shows a comparison of the results of similar studies done. All the studies shown in *Table IV* used the posterior approach,

except for the study done by Adam *et al.* in which 20% of cases were performed via the anterolateral approach.[24]

A limiting factor to this study is the large number of patien[8]ost to follow-up. Universitas Academic Hospital has a catchment area that includes the Free State, Northern Cape, Lesotho and parts of the Eastern Cape. Many of these areas are very remote and rural which makes it difficult for patients to follow up in the long term. This is coupled with inadequate record-keeping, with many patients being admitted to hospital without having their telephone numbers or identity numbers captured. Despite excluding these patients from the study, we believe it is unlikely that many, or even any, of them dislocated. The structure of the health system in the Free State is such that patients who dislocated would have to be referred to Universitas Academic Hospital for reduction and would likely have been picked up in this manner.

Future researchers may consider doing a prospective study in which they can better control data capture and possibly attain a higher level of long-term follow-up. A prospective study could also look at whether patients have other risk factors for dislocation besides the ones that the patients in our cohort shared, namely THA done via the posterior approach for NOF fractures.

~~[references 25-30 have not been mentioned in the text]~~

Conclusion

The results obtained in this study were comparable to similar studies done abroad and show promise for the use of DMCs to achieve low dislocation rates in this high-risk group of patients.

~~***Ethics statement***~~

Low dislocation rates achieved when using dual mobility cup hip implants for femur neck fractures

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Appendix G

Published article.

ARTHROPLASTY

Low dislocation rates achieved when using dual mobility cup hip implants for femur neck fractures

Erasmus LJ[1], Fourie FF[2], Van der Merwe JF[3]

[1] MBChB; Orthopaedic Surgery Registrar, University of the Free State, Universitas Academic Hospital, Bloemfontein, South Africa
[2] MBChB, MMed(Ortho), FC Orth(SA); Orthopaedic Surgeon, Life St Dominic's Hospital, East London, South Africa
[3] MBChB, MMed(Ortho), FC Orth(SA); Head of Arthroplasty Unit, University of the Free State, Universitas Academic Hospital, Bloemfontein, South Africa

Corresponding author: Dr Lourens J Erasmus, Universitas Academic Hospital, 1 Logeman Street, Bloemfontein, Free State, 9301; PO Box 37140, Langenhovenpark, 9330; tel: +27 74 149 8383; email: cobuserasmus@gmail.com

Abstract

Background: Total hip replacements done for intracapsular neck of femur fractures (NOF) have a dislocation rate of up to 14%. This is seven times higher than in total hip arthroplasty (THA) done for osteoarthritis. Using a dual mobility cup (DMC) has been shown to be effective in addressing dislocation in elective THA. Our hypothesis is that the use of DMC in NOF will do the same. This study aims to determine the incidence proportion of dislocation of DMCs one year after surgery in patients who received THA for NOF and to compare it to dislocation rates as documented in existing studies.

Methods: A retrospective study was done on 86 patients treated with DMC THA for an intracapsular NOF fracture from 2012 until 2016. A minimum one-year follow-up period was required for inclusion into the study. The number of dislocations at one year after surgery was noted.

Results: Forty-one patients with a mean age of 60.7 years were included (26 females and 15 males). All patients were operated via the posterior approach. None of the patients had dislocated after one year.

Conclusion: Low dislocation rates can be achieved using DMC THA in the management of intracapsular NOF fractures. Our one-year dislocation rate of 0% compares favourably to conventional THA and is comparable to similar DMC studies done outside of South Africa.

Level of evidence: Level 4

Keywords: dual mobility cup, neck of femur fracture, dislocation, total hip arthroplasty, intracapsular

Citation: Erasmus LJ, Fourie FF, Van der Merwe JF. Low dislocation rates achieved when using dual mobility cup hip implants for femur neck fractures. *SA Orthop J* 2020;**19**(2):70-73. http://dx.doi.org/10.17159/2309-8309/2020/v19n2a2

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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.

Introduction

The total hip replacement may have been rated as the best operation of the 20th century, but it is not without its complications.[1] Dislocation of the hip prosthesis post-operatively remains one of the most common complications encountered after total hip arthroplasty (THA). Rates of 1.9% at one year and increasing up to 7% over 25 years have been reported in primary THA.[2] Post-operative dislocations are the indication for surgery in 22.5% of revision cases and, even after revision surgery, 30% of patients will have persistent instability of their hip.[3,4]

The dislocation rate of THA done for fractures is much higher still, and thus of even more concern than in primary THA.

When using the posterior approach for THA done for femur neck fractures, Enocsen found a dislocation rate of 12–14%.[5] This is seven times higher than in primary hip arthroplasty. Hummel reported a dislocation rate of 2–8% when using the anterolateral approach for similar indications.[6] If done for a failed open reduction and internal fixation of a femur neck fracture, 22% of hips dislocated post-operatively.[7] When the patient was also demented, dislocation rates shot up to 32%.[7] As a local comparison, a study done at the University of Cape Town and published in 2018 found a 4.3% risk for early dislocation after total hip arthroplasty for neck of femur (NOF) fractures.[8]

There are several patient risk factors that increase the risk for dislocation after THA. These include dementia, psychiatric disorders, alcohol abuse, age higher than 80 years old, neuromuscular disorders and non-compliance with post-operative movement and rehabilitation instructions.[9,10]

Besides patient risk factors, there are also surgical risk factors that contribute to dislocation. Some of these are the surgical approach used, the positioning of the acetabular and femoral components, soft-tissue tension and the surgeon's experience.[9] Great emphasis was previously placed on putting the implant in the so-called 'safe zone' with the acetabular cup at 40°±10° inclination and 15°±10° anteversion.[11] This has recently been found not to be as much of a protective factor as previously thought, with 58% of all hip prosthesis dislocations being in the safe zone. Abdel, who headed the study, concluded that hip dislocations post THA are multifactorial in cause, and a holistic approach needs to be taken to minimise the risk of dislocation.[12]

A modern solution to the problem of dislocation after THA has been suggested, namely the dual mobility cup (DMC). Designed by Prof. Gilles Bousquet and André Rambert in France in 1974, it features two articulations: the acetabular cup with the polyethylene insert and the polyethylene insert with the head of the femoral component.[13-15] It is available in both cemented and uncemented options. This implant has been suggested as an option to reduce dislocation rates in very high-risk patients.

DMCs theoretically decrease dislocation risk for the same reasons a large effective femoral head does. It increases the head-to-neck ratio, allowing for a greater range of motion before impingement starts taking place.[16,17] It also increases jump distance, allowing for a greater amount of lateral head movement before dislocation takes place.[17]

Some authors recommend caution when using it for standard primary THA and in young patients as there is some concern about increased wear rates and aseptic loosening. This concern is mainly because of the lack of long-term follow-up data and not because high rates of wear or aseptic loosening have actually been found.[13] There may in fact be decreased wear with DMCs as there are two articulating interfaces and thus less friction and sliding at each.[18,19] Regarding real-world outcomes measured thus far, medium-term follow-up of these prostheses has been done by Philippot, who found a very favourable 15-year socket survival rate of 96.3% (±3.7%).[20] Several companies currently offer DMC options for THA. Some examples are shown in *Table I*.

This study aims to determine whether DMCs used in NOF fractures are a possible solution to the high dislocation rates mentioned above. It intends to do so by retrospectively determining the cumulative incidence of dislocation in our study group at one year post-surgery and then comparing the numbers found to existing studies of dislocations in conventional total hip replacements as well as DMC studies done in other countries.

Methods

We did a retrospective cohort study at a single tertiary level hospital in Bloemfontein (Universitas Academic Hospital). We identified all the patients who had received DMC hip arthroplasty for intracapsular NOF fractures from July 2012 until December 2016. A total of 86 patients were identified. Electronic records (Meditech) and admission data, clinic files, radiological records and telephonic follow-up were then used to determine whether these patients had dislocated their hips post-operatively. Surgeon experience and the method of implant fixation were also documented.

A minimum follow-up time of one year (at our clinic or telephonic) was required to be included in the study. Patients who did not complete a full year of follow-up at our clinic were phoned to find out whether they had dislocated or not. Patients with incomplete records were excluded from the study. Those who had less than one year of follow-up time and were untraceable telephonically or otherwise were excluded. The Department of Home Affairs assisted in identifying patients who passed away within the first year of surgery. These patients were also excluded. Those who had arthroplasty done for failed open reduction and internal fixation of intracapsular NOF fractures were also excluded. Age was not an exclusion criterion. Some younger patients received DMC hip arthroplasty because of a high risk for dislocation. This decision was at the discretion of the attending consultant.

After determining the cumulative incidence of dislocations in our study group, we planned to compare our numbers to those of existing studies on hip dislocation in standard and DMC hip arthroplasty done for intracapsular NOF fractures.

All patients had a primary hip arthroplasty with a Polarcup® prosthesis. This product is manufactured by Smith & Nephew

Table I: Dual mobility cups available

Company	Trade name	HXPE*	Cemented	Head sizes (mm)
Smith & Nephew	Polarcup	Yes	Yes	22, 28
Tornier	Dual Mobility Cup	Yes	Yes	22, 28
Stryker	Mobile Hip System	Yes	Yes	22, 28
Zimmer-Biomet	Avantage Active Articulation	Yes Yes	Yes No	22, 28 28
DePuy	Gyros	Yes	No	22.5, 28

*HXPE: highly cross-linked polyethylene

Orthopaedics AG of Rotkreuz, Switzerland. Several other companies also manufacture similar prostheses and the choice of this specific implant was based on departmental protocol. Both cemented and uncemented techniques were used for acetabular cups and femoral components, depending on patient indications. All the patients were operated via the posterior approach (Kocher-Langenbeck approach). This is departmental protocol and makes comparison with other DMC studies much easier and more accurate, as the vast majority (>95%) of similar studies done previously also utilised the posterior approach.

Results

Forty-one of the 86 patients identified were included in the study. A total of 45 patients were excluded. Eight had incomplete files, four passed away during the first year after surgery and the rest did not complete a full year of follow-up and could not be contacted telephonically. Thirty-four of these patients followed up at our clinic for one year or more. Seven patients did not complete a full year of follow-up at the clinic but were reached telephonically more than one year after surgery was performed and were confirmed not to have dislocated.

The mean age of the patients included was 60.7 years (SD 8.6). Twenty-six (63.4%) of the patients were females, with the youngest being 42 years, the oldest 81 years and with a mean age of 62 years (SD 9.5). There were 15 (36.6%) males among the patients included, with the youngest being 49, the oldest 67 and with a mean age of 58.4 years (SD 6.3). Patient demographics are shown in *Table II*.

The risk factors for dislocation common to all the patients in the cohort were that they received THA for a NOF fracture via the posterior approach. Surgeon experience could not be controlled for and prostheses fixation was variable (according to patient indications). Regarding the experience of the surgeon, 24 cases (58.5%) were performed by a registrar, 12 cases (29.3%) by a registrar with consultant supervision and five (12.2%) by a consultant. Both cemented and uncemented prostheses were used in different combinations depending on specific patient indications. A cemented cup and stem was used in 29 of the cases (70.7%). An uncemented cup and cemented stem (hybrid implant) was used in six patients (14.6%). A cemented cup and uncemented stem (reverse hybrid implant) was used in four of the cases (9.8%) and an uncemented cup and stem was used in two patients (4.9%). Details of the surgeries performed are summarised in *Table III*. Some complications other than dislocation were encountered. Two of the patients developed deep wound infections. One of these patients ended up having a Girdlestone excisional arthroplasty and the other had to undergo two-stage revision surgery.

The main aim of this study was to determine the cumulative incidence of dislocation of DMC hip prostheses used for intra-capsular NOF fractures one year after surgery was performed. We found that none (n=0) of the patients included in our study had dislocated one year after surgery.

Table II: Patient demographics

Characteristics (n=41)	
Age in years (mean; SD)	**60.7; 8.6**
Females	62; 9.5
Males	58.4; 6.3
Sex (n; %)	
Females	26; 63.4%
Males	15; 36.6%

Discussion

By using DMC THA in the management of intracapsular NOF fractures we achieved a 0% dislocation rate at one-year follow-up. This is significantly better than the rates reported with conventional THA for this indication.[5,7,8] (This is compared to total hip replacements for NOF fractures in general, and not for specific prostheses like big femoral head components that might compare more favourably with DMC implants.)[21] The dislocation rates for DMCs found in this study are similar to the results found by other authors in recent years. *Table IV* shows a comparison of the results of similar studies done. All the studies shown in *Table IV* used the posterior approach, except for the study done by Adam *et al.* in which 20% of cases were performed via the anterolateral approach.[22]

A limiting factor to this study is the large number of patients lost to follow-up. Universitas Academic Hospital has a catchment area that includes the Free State, Northern Cape, Lesotho and parts of the Eastern Cape. Many of these areas are very remote and

Table III: Details of surgeries performed

Surgeries performed (n=41)	
Prosthesis	**n (%)**
Smith & Nephew Polarcup	41 (100%)
Approach	
Posterior (Kocher-Langenbeck)	41 (100%)
Surgeon experience	
Registrar	27 (58.5%)
Registrar with consultant supervision	12 (29.3%)
Consultant	5 (12.2%)
Fixation method	
Cemented cup and stem	29 (70.7%)
Uncemented cup and cemented stem	6 (14.6%)
Cemented cup and uncemented stem	4 (9.8%)
Uncemented cup and stem	2 (4.9%)

Table IV: Dislocation rates of dual mobility cups used for neck of femur fractures

Authors	Year	Country	Follow-up	Number of patients (n)	Dislocations (n)	Dislocation rate (%)
Current study	2019	South Africa	12 months	41	0	0%
Tarasevicius *et al*.[23]	2010	Lithuania	12 months	42	0	0%
Adam *et al*.[22]	2012	France	9 months	214	3	1.4%
Bensen *et al*.[24]	2014	Denmark	21 months	175	8	4.6%
Nich *et al*.[25]	2016	France	36 months	45	3	6.7%
Boukebous *et al*.[26]	2018	France	24 months	98	3	3.1%
Zagorov *et al*.[27]	2018	Bulgaria	29 months	49	0	0%
Rashed *et al*.[28]	2018	Egypt	12 months	31	0	0%

rural which makes it difficult for patients to follow up in the long term. This is coupled with inadequate record-keeping, with many patients being admitted to hospital without having their telephone numbers or identity numbers captured. Despite excluding these patients from the study, we believe it is unlikely that many, or even any, of them dislocated. The structure of the health system in the Free State is such that patients who dislocated would have to be referred to Universitas Academic Hospital for reduction and would likely have been picked up in this manner.

Future researchers may consider doing a prospective study in which they can better control data capture and possibly attain a higher level of long-term follow-up. A prospective study could also look at whether patients have other risk factors for dislocation besides the ones that the patients in our cohort shared, namely THA done via the posterior approach for NOF fractures.

Conclusion

The results obtained in this study were comparable to similar studies done abroad and show promise for the use of DMCs to achieve low dislocation rates in this high-risk group of patients.

Ethics statement

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

Ethical clearance for the study was received from the University of the Free State Ethics Committee (HSREC 165/2016). Permission to use medical records was obtained from the Free State Department of Health. Formal consent was not required for this study.

Declaration

The authors declare authorship of this article and that they have followed sound scientific research practice. This research is original and does not transgress plagiarism policies.

Author contributions

LJE collected and analysed the data, and wrote and edited the manuscript. FF contributed to the protocol and management of patients. FJvdM proposed the study concept, supervised the study and managed patients.

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ORCID

Erasmus LJ https://orcid.org/0000-0003-4522-2873
Fourie FF https://orcid.org/0000-0001-8961-4874
Van der Merwe JF https://orcid.org/0000-0002-5554-4887

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