Health-Related Quality-of-Life outcomes in patients undergoing total hip and knee arthroplasty at Chris Hani Baragwanath Academic Hospital

Name: Dr KN Fang
Student number: 0603244T

Supervisors: Prof CT Frey
Dr B Milner

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Declaration

I, Kao-Wei Nico Fang declare that this research report in the format of a “submissible” paper is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

KWN Fang

24th day of June 2021 in Johannesburg

Dedication

"You don't really understand something unless you can explain it to your grandmother." – *Albert Einstein*

In memory of my Grandmother….

1901~2020

Acknowledgements

A special word of gratitude and appreciation to my supervisors Prof CT Frey and Dr B Milner for their invaluable time, mentorship, experience and knowledge, in making this dream attainable. I would also like to thank all the staff and patients at Chris Hani Baragwanath Academic Hospital who have made this project possible.

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Nomenclature

AKSS – American Knee Society Score

HRQoL - Health-related quality-of-life

MOS SF-36 - Medical Outcomes Study Short Form-36 Health Survey

SRM – Standardised Response Mean

THA - Total hip arthroplasty

TKA - Total knee arthroplasty

Title Page

Health-Related Quality-of-Life outcomes in patients undergoing total hip and knee arthroplasty at Chris Hani Baragwanath Academic Hospital

Fang K[1], Frey CT[2], Milner B[3]

[1]MBChB, FC Orth (SA), Orthopaedic Registrar, Division of Orthopaedic Surgery, Chris Hani Baragwanath Academic Hospital, University of the Witwatersrand, Johannesburg, South Africa

[2]MBBCH, FC Orth (SA), Professor and Head of Clinical Unit: Arthroplasty, Division of Orthopaedic Surgery, Chris Hani Baragwanath Academic Hospital, University of the Witwatersrand, Johannesburg, South Africa

[3] PhD, Associate Researcher, Division of Orthopaedic Surgery, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

Corresponding Author: Dr Kao-Wei Nico Fang, Division of Orthopaedic Surgery, Chris Hani Baragwanath Academic Hospital, University of the Witwatersrand, Johannesburg, South Africa; Tel: +27 11 933 3000, Email: nico_fang@msn.com

Abstract

Background: Total hip and knee arthroplasty are known for effective surgical interventions for relieving pain and restoring function for patients with end-stage osteoarthritis. Their success can be measured using health-related quality-of-life instruments to rationalise the costs and risks involved with surgery. This study aimed to evaluate the impact of total hip and knee arthroplasty on the quality-of-life of patients with end-stage osteoarthritis using disease-specific and generic health-related quality-of-life (HRQoL) outcome measures.

Methods: Patients scheduled for primary total hip arthroplasty or total knee arthroplasty for the indication of osteoarthritis were surveyed using the disease-specific outcome measures, Harris Hip Score (HHS) or American Knee Society Score (AKSS), as well as the generic instrument, Medical Outcomes Study Short Form-36 Health (MOS SF-36) survey. Follow-up surveys were administered to all patients at three months post-surgery.

Results: A total of fifty patients were included in the study. Twenty-four patients had total hip arthroplasty, and twenty-six patients had total knee arthroplasty. Pre-operative MOS SF-36 scores show the substantial burden of osteoarthritis on patients' quality-of-life when compared to the normative MOS SF-36 scores. Patients who had primary THA showed significant improvements in the HHS and all parameters of the MOS SF-36 scores. Similarly, patients who had TKA also expressed significant improvement in the AKSS and the MOS SF-36. Comparison between THA and TKA showed no significant differences in the MOS SF-36 outcome measures, except for the physical function parameter, in which THA was superior. A moderate correlation was expressed between the disease-specific instruments and the physical parameters of the generic MOS-SF-36. Post-operatively, patients with TKA scored higher than the norm in all domains of the MOS SF-36 instrument. The same was observed for patients with THA, except for the social functioning domain, which scored lower than the norm post-operatively.

Conclusion: THA and TKA are effective surgical interventions used for patients with end-stage osteoarthritis. The disease-specific HHS and AKSS, as well as the generic

MOS SF-36 instruments, are responsive in detecting the changes in the HRQoL outcomes in patients undergoing THA and TKA.

Level of Evidence: 4

Keywords: total knee arthroplasty, total hip arthroplasty, outcomes, quality-of-life, SF-36, HHS, AKSS

Introduction

Osteoarthritis is a degenerative disease that commonly affects the hip and knee joint cartilage and is the eighth leading cause of disability in the world.[1–3] Total hip arthroplasty (THA) and total knee arthroplasty (TKA) is widely accepted as the effective treatment of choice for osteoarthritis cases recalcitrant to conservative treatment. The success of THA and TKA has been well documented in the literature using appropriate Health-related quality-of-life (HRQoL) outcome measures.[4–6] HRQoL outcome measures can either be disease-specific (which focuses on the consequence of disease) or generic (which focuses on overall patient well-being).

Disease-specific HRQoL instruments are commonly used to assess the impact of a specific disease as well as the outcomes of an intervention. They have reliable responsiveness and are widely adopted in orthopaedic surgery. However, the disadvantages of these instruments are that they can be prone to clinician bias and comparisons between different medical conditions or interventions cannot be made using the same disease-specific instruments.[7] The Harris Hip Score (HHS) and American Knee Society Score (AKSS) are disease-specific instruments which are commonly used for the hip and knee, respectively and is the preferred instrument used at our institution.[8,9] The HHS is a clinician-completed instrument that consists of four domains: pain, function, absence of deformity, and range of motion. The subscales of these domains are calculated to a final score of 0 to 100; where 0 indicates worse disability and 100 indicates the least disability.[10] The AKSS is also a clinician-completed instrument that is divided into two components. The clinical component of the AKSS is a clinical evaluation of pain, stability, range of motion, alignment and the presence of contractures. The functional component assesses patients' walking distance, ability to use stairs and the use of walking aids. Both components score from 0 to 100 with lower scores specifying worse deformity and function and higher scores identifying less deformity and better function.[11,12]

Although the benefits of THA and TKA have well been validated using disease-specific instruments, the success and outcome of surgical intervention are also primarily determined by patients' subjective satisfaction and perception of quality-of-life.[13] This response may vary to those obtained using disease-specific instruments such as the HHS and AKSS. Furthermore, the subjective nature of patients' perception of quality-

of-life is challenging to quantify using disease-specific instruments as they do not take psychosocial factors into account. As a result, generic HRQoL instruments have been implemented to gauge the overall patient-related quality of life outcomes across varying disease types and medical interventions.[14]

The Medical Outcomes Study Short Form-36 (MOS SF-36) Health Survey is a generic HRQoL instrument that has been validated to quantify patients' health perception of quality-of-life.[15,16] The MOS SF-36 health survey was developed by the Rand Health Insurance experiment as a generic HRQoL instrument. It is a self-administered questionnaire consisting of 36 multiple choice questions weighted on eight different health domains. The eight domains interrogated are described in (*Table I)* and include physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. Each domain is calculated and converted to a score scale of 0 - 100, with a lower score indicating greater disability or compromised quality of life and a higher score defining.[17] The psychometric properties MOS SF-36 have been verified in past studies.[18]

Table I: The MOS SF-36 Health Survey Domains[17]

Domain	Description
Physical Functioning	Limitations in physical activity because of health problems.
Role Physical	Limitations in daily role activities or work because of physical health impairment.
Bodily Pain	Overall bodily pain severity.
General Health	Overall general health perception.
Vitality	The overall feeling of energy versus fatigue.
Social Functioning	Limitations in social activities because of physical or emotional problems.
Role Emotional	Limitations in daily role activities or work because of emotional problems.
Mental Health	Overall psychological distress and mental well-being.

Many studies evaluating the HRQoL outcomes of THA and TKA using the MOS SF-36 have been published, which showed significant improvement in outcomes.[19–21] These outcomes measured using the MOS SF-36 strongly correlated with the

outcomes obtained using HHS and AKSS disease-specific HRQoL instruments. Shields et al. (1999) found the most significant change in HRQoL outcomes at the three-month post-operative follow-up period and rarely any further change from three months onwards.[22]

Not many studies have analysed both THA and TKA concurrently and compared the two groups.

In our setting, there is a high prevalence of hip and knee osteoarthritis and an increasing demand for primary THA and TKA accounting for a significant portion of orthopaedic cases done at our institution. However, the outcomes of THA and TKA have not been well documented using generic and disease-specific HRQoL instruments. Thus, this study aimed to assess the impact of THA and TKA on the quality-of-life of patients treated for osteoarthritis at Chris Hani Baragwanath Academic Hospital.

Patients and Methods

This study was a non-randomised, prospective analysis on the change in the quality-of-life of patients who had received either THA or TKA for the single diagnosis of osteoarthritis. Patients that were scheduled for primary elective THA or TKA between November 2018 and June 2019 were identified from the Arthroplasty unit at Chris Hani Baragwanath Academic Hospital. A total of 70 patients were invited and were categorised either into the THA group (35 patients) or TKA group (35 patients). For the detection of a medium effect size (d= 0.5) with 80% power at the 5% significance level, a minimum sample size of n=34 was required. Sample size calculations were carried out in G*Power.[23] Patients were excluded if the indication for THA or TKA was not that of primary osteoarthritis, if post-operative complications developed, if patients had significant organic comorbidity or psychiatric disease, or if patients were unable to comprehend and autonomously respond to the survey. Incomplete responses were also excluded.

Ethics approval was obtained from the Human Research Committee (Medical), University of the Witwatersrand, and permission was obtained from the participating hospital before the commencement of the study. Participation was voluntary, and informed consent was obtained from each patient before enrolment. Furthermore, patients were assigned a unique study number to maintain confidentiality and anonymity. Patients were not blinded, nor did their participation affect the management planned for the patient. Patient management was standardised according to the institutional protocol, and surgical procedures were performed by three senior arthroplasty surgeons in the Arthroplasty unit at the institution.

The generic HRQoL MOS SF-36 health survey was administered pre-operatively for each enrolled patient undergoing elective primary THA or TKA. At the same time, the disease-specific HRQoL, HHS or AKSS was administered pre-operatively for patients undergoing THA or TKA, respectively. The surveys were conducted through a personal interview and clinical assessment by the principal investigator on the day of a patient's admission before the surgical date. The patient's age and gender were also recorded. All patients followed the same post-operative rehabilitation protocol. This standardised rehabilitation protocol was initiated the day after surgery and continued daily until the day of discharge once a robust rehabilitation programme was attained.

Outpatient follow-up was scheduled at two weeks for wound inspection and then four-weekly after that as part of the rehabilitation protocol. The HRQoL surveys were administered again for the same patient at the three month post-operative follow-up by the principal investigator

All data were digitalised and stored in a secure, protected database. Descriptive analyses of all study variables were conducted. P-values ≤ 0.05 were considered statistically significant. For each patient, scores were compared between pre-operative and post-operative MOS-SF-36, HHS (THA) or AKSS (TKA) measurement points using the paired-samples t-test. The standardised response mean (SRM) was calculated by taking the mean score change divided by the standard deviation of the score change. For each MOS SF-36 domain, comparison of SRM's between THA and TKA was made according to the method given by Borenstein et al.[24]

The Spearman's correlation coefficient was used to assess the correlation between the HHS or AKSS and the MOS SF-36 scores at pre-operative and post-operative time measures. The effect of surgery type and time (pre-operative or post-operative measurement points), as well as their interaction, on a given SF-36 domain score was determined by a repeated measures two-way Analysis of Variance (ANOVA) with the mean score as the dependent variable; surgery type, time and their interaction as independent variables, and the patient as the repeated measure. Post-hoc tests were conducted using the Tukey-Kramer adjustment for multiple comparisons. Deviation of the MOS SF-36 scores from the normative data was determined for the appropriate corresponding age and gender-based norms. The normative scores differ with gender and decrease with increasing age. Thus, the deviation of SF-36 scores from the normative age and gender-matched mean score was calculated as the difference between the patient's mean score and normative mean score. As no normative data for the MOS SF-36 is available for South Africa or other African countries, normative data from the Brazilian population were used as it is a country that resembles similar socioeconomic traits to South Africa.[25] Data analysis was carried out using Stata 15.1 for Windows ©.

Results

Of the 70 patients enrolled in the study, 50 patients met the inclusion criteria. Eighteen patients were lost to follow-up, one patient withdrew from the study, and one patient developed a post-operative complication. In the THA group, 26 patients were included. Eight patients were lost to follow-up, and one patient withdrew from the study. In the TKA group, 24 patients were included, 10 patients were lost to follow-up, and one patient developed a post-operative complication with neuropraxia of the common peroneal nerve.

Data for these patients were excluded from the analysis. The actual sample size of n=50 in this study allows for the detection of medium-large effect sizes only with 80% power at the 5% significance level. The final study cohort consisted of 40 females and 10 males with a median age of 64 years (range 51-84, interquartile range [IQR] 12). Median follow-up was 91 days (range 77-112, IQR 1277-112, IQR 12).

THA: Pre-operative versus three month Post-operative outcomes

Descriptive statistics, as well as the floor and ceiling effects for the THA group, are listed in (*Table II)*. All HRQoL instruments and subscales showed improvement in scores between the pre-operative and post-operative time periods with large (>0.8) SRM changes ($p<0.0001$). The HHS showed more significant changes (SRM 3.8) than any of the MOS SF-36 domains. For the MOS SF-36 domains: the greatest responses were recorded for the role physical domain (SRM 3.3), physical function domain (SRM 2.9), bodily pain domain (SRM 2.5) and social functioning domain (SRM 2.5). The vitality domain (SRM 2.3), role emotional domain (SRM 2.1) and general health domain (SRM 2.0) revealed positive changes. The domain that revealed the least change was the mental health domain (SRM 1.7). Considerable floor effects were recorded pre-operatively for the role physical and role emotional domains in the THA group. Significant ceiling effects were also observed for the same domains post-operatively.

Table II: HHS and SF-36 scores for patients with THA at pre-operative and post-operative timepoints

		PREOPERATIVE - 0 MONTHS					POSTOPERATIVE - 3 MONTHS				
	Subscale	Mean	Range	IQR	Floor (%)	Ceiling (%)	Mean	Range	IQR	Floor (%)	Ceiling (%)
HHS	HHS	31,3	18,5 - 62	8,2	0	0	78,9	62-95	7,9	0	0
MOS SF-36	Physical Function	15,8	0-80	25	35	0	76,3	55-100	20	0	4
	Role Physical	7,7	0-100	0	85	4	92,3	50-100	0	0	77
	Bodily Pain	22,6	0-78	10,5	19	0	76,4	52-100	3,5	0	4
	General Health	36,3	0-75	20	4	0	72,0	42-95	11	0	0
	Vitality	33,8	0-80	20	4	0	73,3	35-90	10	0	0
	Social Function	29,8	0-63	25	8	0	74,5	50-100	12	0	4
	Role Emotional	19,2	0-100	33,3	65	8	91,0	33-100	0	0	77
	Mental Health	48,5	0-80	16	4	0	74,5	52-88	12	0	0

THA: Correlation Between Disease-specific and Generic Outcome measures

The correlation between the HHS and MOS SF-36 score varied depending on the MOS SF-36 domain at both pre-operative and post-operative time frames as tabulated in *Table III*. The HHS revealed a moderate (rho 0.4-0.6), positive correlation with the MOS SF-36 physical function domain at the pre-operative timeframe. We also noted that the HHS was moderately, positively correlated with the MOS SF-36 physical function, bodily pain, vitality and social function domains post-operatively. Strong correlations existed between the post-operative MOS SF-36 vitality and social function domains; vitality and mental health domains; social function and mental health domains.

Table III: Relationships between the HHS and MOS SF-36 dimensions for patients with THA at pre-operative and post-operative timepoints

	HHS	Physical Function	Role Physical	Bodily Pain	General Health	Vitality	Social Function	Role Emotional	Mental Health
HHS[a]	1,000	0,497 [b]	0,128	0,485 [b]	0,337	0,481 [b]	0,474 [b]	0,062	0,307
Physical Function	0,470[b]	1,000	0,014	0,533 [b]	0,358	0,157	0,300	0,170	0,108
Role Physical	0,063	0,355	1,000	-0,061	0,165	-0,017	0,094	0,096	0,181
Bodily Pain	0,118	0,381	0,298	1,000	0,592 [b]	0,534 [b]	0,568 [b]	-0,233	0,596 [b]
General Health	-0,058	0,091	0,189	0,368	1,000	0,416 [b]	0,497 [b]	0,006	0,476 [b]
Vitality	0,013	0,537[b]	0,234	0,710 [b]	0,449 [b]	1,000	0,637 [b]	-0,098	0,628 [b]
Social Function	0,186	0,131	0,030	0,301	0,488 [b]	0,256	1,000	0,089	0,726 [b]
Role Emotional	-0,153	0,278	0,431 [b]	0,018	0,114	0,271	0,021	1,000	0,028
Mental Health	0,024	0,499 [b]	0,551 [b]	0,205	0,249	0,411 [b]	-0,005	0,120	1,000

The pre-operative correlation is shown in the lower-left half below the diagonal row number "1". The post-operative correlation is shown in the upper right half above the diagonal row number "1". [a]Harris Hip Score. [b]$p<0.05$

THA: Comparison with normative data

We considered the deviations of the pre-operative and post-operative MOS SF-36 scores from the age and gender-matched Brazilian normative data. *(Figure I)* shows the mean deviations from the norm for each domain as well as their 95% confidence intervals (denoted by the error bars). As expected, the mean pre-operative scores for all domains were significantly lower than the norms with the role physical domain (mean deviation: -61.5, CI 8.6); physical functioning domain (mean deviation: -48.4, CI 8.3), bodily pain domain (mean deviation: -47.1, CI 7.6), social functioning domain (mean deviation: -48.9, CI 6.6) and role emotional (mean deviation: -56.5, CI 12.9) showing the highest burden of disease. Interestingly, all post-operative mean scores except social functioning and mental health were significantly higher than the norm. The highest post-operative, positive mean deviations from the norm were the role

physical domain (mean deviation: +23.1, CI 7.1); role emotional domain (mean deviation: +15.3, CI 8.0) and the physical function domain (mean deviation: 12.1, CI 5.8). The general health domain (mean deviation: +8.2, CI 4.6); bodily pain domain (mean deviation: +6.7, CI 4.6); vitality domain (mean deviation: +5.0, CI 4.3) and mental health domain (mean deviation: +1.6, CI 4.0) scored higher than the norm post-operatively. However, the social functioning domain (mean deviation: -4.2, CI 5.7) scored lower than the norm post-operatively.

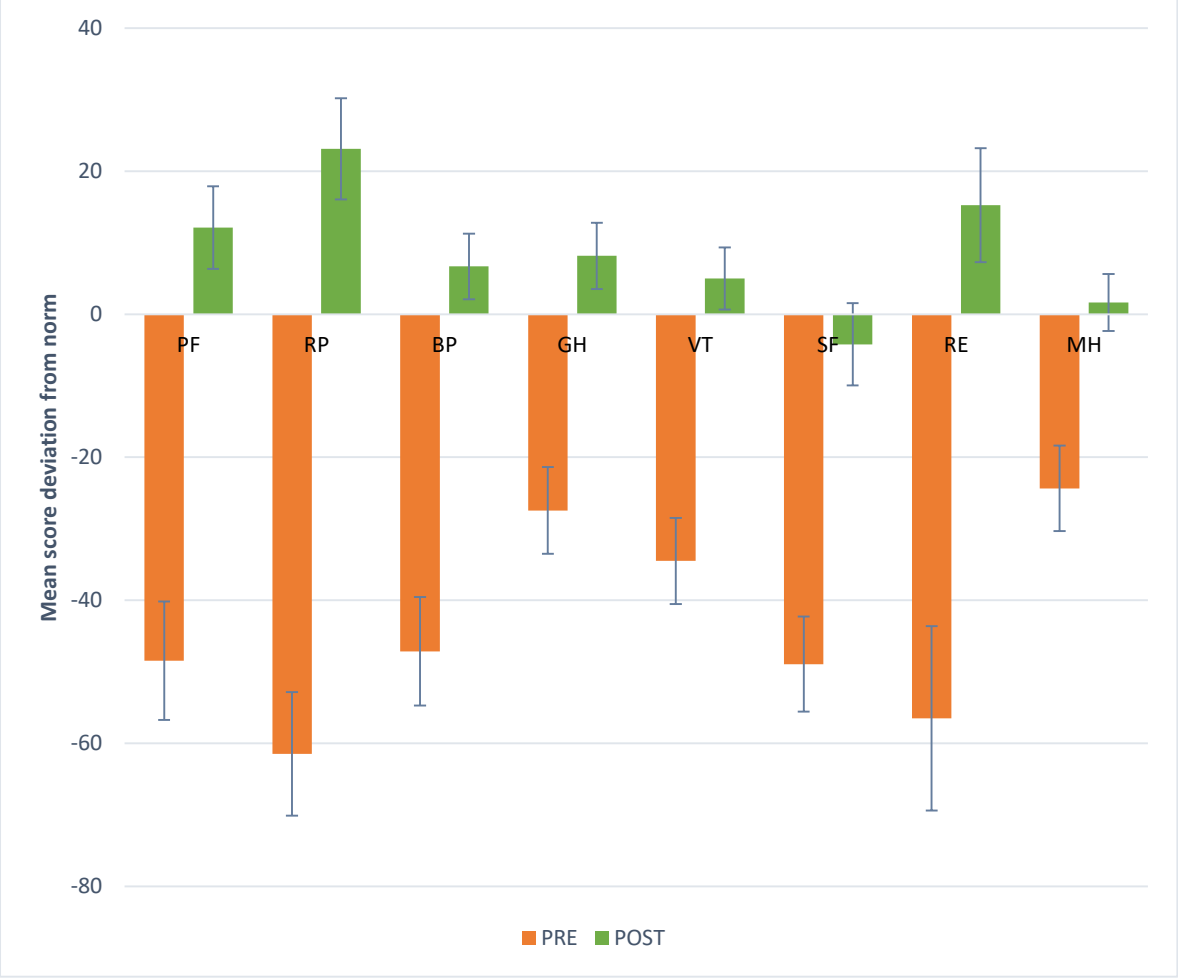

Figure 1: MOS SF-36 mean score deviations from normative data for patients with THA at pre-operative and post-operative timepoints. PF=physical functioning; RP=role physical; BP=bodily pain; GH=general health; VT=vitality; SF=social functioning; RE=role emotional; MH=metal health

TKA: Pre-operative versus three month post-operative outcomes

In the TKA group, we also observed significant increases in a mean score for the AKSS and all of the MOS SF-36 domains. *(Table IV)* lists the descriptive results at the pre-operative and post-operative time points. The SRM were large (>0.8) for the AKSS and each of the SF-36 domains had achieved significance ($p<0.001$) as illustrated in Figure 3. The results indicated that the AKSS (SRM 4.1) was more responsive than any of the MOS SF-36 domains. The AKSS Functional score yielded an SRM of 2.7. For the MOS SF-36 domains: the highest responses were observed in the role physical domain (SRM 3.1); bodily pain domain (SRM 2.6); general health domain (SRM 2.5); and social function domain (SRM 2.0). The physical function, bodily pain and role emotional domains all each yielded an SRM of 1.8. The SRM for the mental health domain was 1.6.

Table IV: AKSS and SF-36 scores for patients with TKA at pre-operative and post-operative timepoints

		PREOPERATIVE - 0 MONTHS					POSTOPERATIVE - 3 MONTHS				
	Subscale	Mean	Range	IQR	Floor (%)	Ceiling (%)	Mean	Range	IQR	Floor (%)	Ceiling (%)
AKSS	AKSS	26,9	5-50	17	0	0	73,2	62-87	5	0	0
	AKSS Functional	21,3	0-60	25	0	0	74,2	55-95	17,5	0	0
MOS SF-36	Physical functioning	16,7	0-90	15,0	17	0	71,5	10-100	27,5	0	8
	Role physical	5,2	0-75	0,0	92	0	89,6	25-100	12,5	0	75
	Bodily pain	24,9	0-78	12,8	4	0	75,3	23-100	22,5	0	21
	General health	35,8	20-60	22,5	0	0	75,9	40-100	6,5	0	4
	Vitality	39,0	20-70	15,0	0	0	73,1	45-90	17,5	0	0
	Social function	26,5	0-62	18,5	13	0	70,8	38-100	12,5	0	4
	Role emotional	22,2	0-100	33,3	67	17	91,6	33-100	0	0	83
	Mental health	47,5	0-76	16,0	4	0	75,7	36-96	14	0	0

Similar to the THA group, considerable floor effects were observed for the role physical and role emotional domains at both pre-operative and post-operative time points.

However, a higher floor effect in the TKA group compared to the THA group was found for the role physical domain. Similarly, a higher ceiling effect was observed in the TKA compared to the THA group for the role emotional domain.

THA: Correlation Between Disease-specific and Generic Outcome measures

The correlation coefficients between all scores at each of the pre-operative and post-operative time points are tabulated in *(Table V)*. No strong correlations (rho>0.6) between the AKSS, as well as the MOS SF-36 scores were evident at the pre-operative time point. Strong correlations were observed for the MOS SF-36 scores at the post-operative time point between the bodily pain and social function domains; the vitality and social function domains; and the vitality and mental health domains.

Table V: Relationships between the HHS and MOS SF-36 dimensions for patients with THA at pre-operative and post-operative timepoints

	AKSS[a]	AKSS[a] Functional	Physical Function	-Role Physical	Bodily Pain	General Health	Vitality	Social Functio n	Role Emotional	Mental Health
AKSS[a]	1,000	0,355	0,434 [b]	0,129	0,352	0,250	0,347	0,287	-0,063	0,218
AKSS[a] Functional	0,086	1,000	0,328	0,238	0,376	0,222	0,470 [b]	0,348	0,310	0,193
Physical Function	0,124	0,246	1,000	0,432 [b]	0,484 [b]	0,534 [b]	0,419 [b]	0,269	0,099	0,330
Role Physical	-0,154	0,291	0,084	1,000	0,599 [b]	0,248	0,500 [b]	0,496 [b]	0,282	0,462 [b]
Bodily Pain	-0,051	0,343	-0,106	0,355	1,000	0,462 [b]	0,467 [b]	0,676 [b]	0,067	0,436 [b]
General Health	-0,140	-0,137	-0,597 [b]	0,282	0,348	1,000	0,310	0,300	0,225	0,404
Vitality	-0,398	0,514 [b]	0,028	0,373	0,507 [b]	0,171	1,000	0,607 [b]	0,136	0,655 [b]
Social Function	0,014	0,379	-0,292	0,484 [b]	0,430 [b]	0,446 [b]	0,231	1,000	0,095	0,534 [b]
Role Emotional	-0,204	0,000	0,380	0,520 [b]	0,007	0,004	0,232	-0,168	1,000	0,193
Mental Health	-0,452[b]	0,077	0,114	0,344	-0,101	0,315	0,303	0,028	0,304	1,000

The pre-operative correlation is shown in the lower-left half below the diagonal row number "1". The post-operative correlation is shown in the upper right half above the diagonal row number "1". [a]American Knee Society Score. [b]$p<0.05$

We note that the AKSS was moderately, negatively, correlated with the MOS SF-36 mental health domain at the preoperative time point; and moderately, positively correlated with the MOS SF-36 physical function domain at the post-operative time

point. The AKSS Functional score was moderately, positively correlated with the MOS SF-36 vitality domain at both the preoperative and postoperative timeframe.

TKA: Comparison with normative data

(Figure 2) shows the pre-operative and post-operative mean deviations from the normative MOS SF-36 data, together with their 95% confidence intervals for the TKA group. As expected, the mean pre-operative scores were all significantly lower than the norms. The role physical (mean deviation: -60.8, CI 6.5), physical functioning (mean deviation: -43.7, CI 8.5), bodily pain (mean deviation: -41.9, CI 6.4), social functioning (mean deviation: -49.9, CI 6.5) and role emotional (mean deviation: -51.2, CI 15.6) domains showed the highest burden of disease. Interestingly, all mean scores were significantly higher than the norm after TKA.

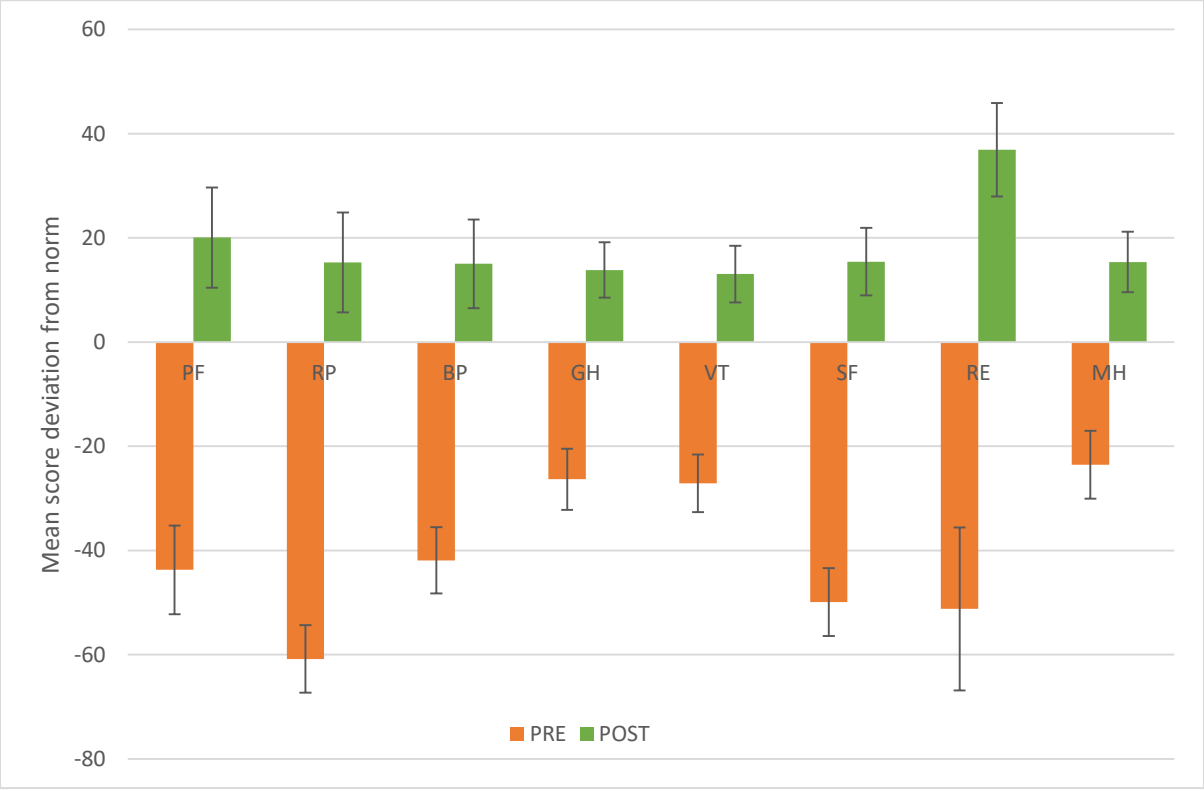

Figure 2*:* MOS SF-36 mean score deviations from normative data for patients with TKA at pre-operative and post-operative timepoints. PF=physical functioning; RP=role physical; BP=bodily pain; GH=general health; VT=vitality; SF=social functioning; RE=role emotional; MH=metal health

Comparison of THA versus TKA

For each of the MOS SF-36 domains, we compared the effect of surgery type (THA or TKA), the surgery-time interaction and the effect of time. The difference in mean scores for all MOS SF-36 domains were not significantly different between THA and

TKA at both pre-operative and post-operative time points (p>0.51). Only the effect of time was significant (p<0.0001).

We also compared the SRM's for each domain between the THA and TKA to compare the responsiveness of the respective surgeries on each MOS SF-36 domain as illustrated in *(Figure 3)*. We found that the SRM's do no differ significantly between the two surgery types (p>0,34) except for the MOS SF-36 physical function domain, where the SRM is significantly higher for THA compared to TKA (p=0,029).

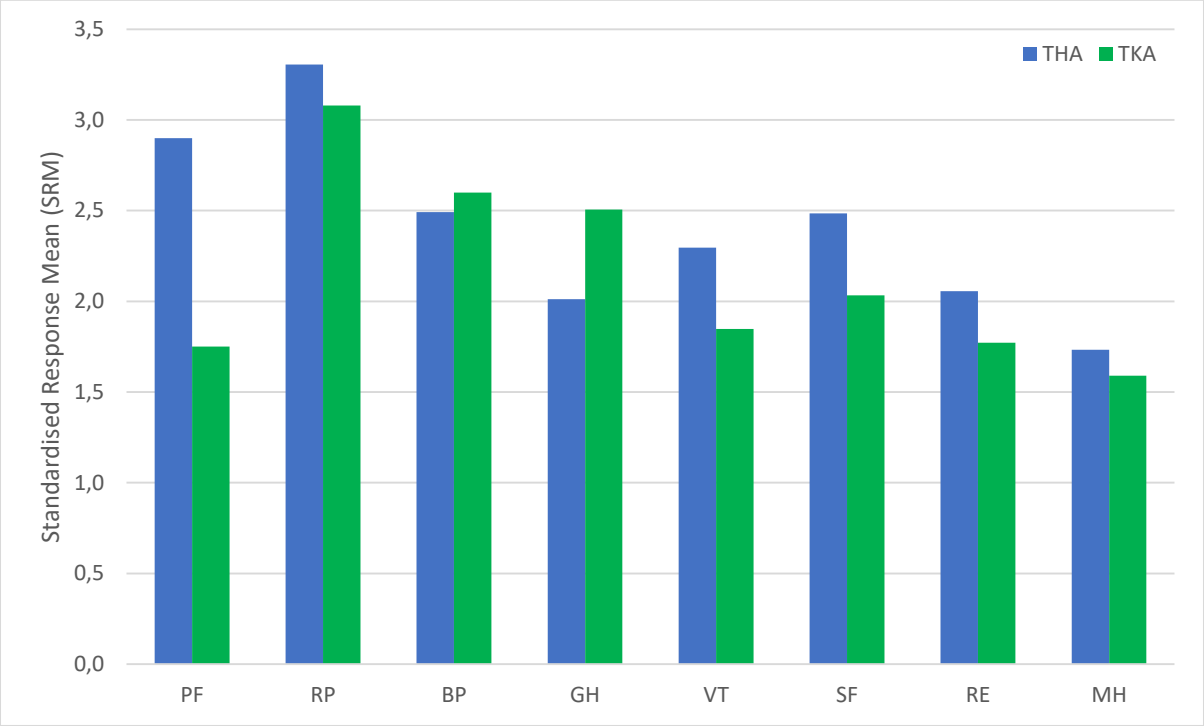

Figure 3: Comparison of standardised response means for each MOS SF-36 domain for THA versus TKA. PF= physical functioning; RP=role physical; BP= bodily pain; GH=general health; VT=vitality; SF=social functioning; RE=role emotional; MH=metal health

Discussion

Total hip and knee arthroplasty are found to be reliable and effective surgical treatment options for pain relief and the improvement of physical functioning in end-stage degenerative joint disease such as osteoarthritis.[2–4,26–28] In South Africa, the prevalence of osteoarthritis ranges from 55,1% in urban settings to 82,7% in rural settings.[20,22,26,28] This burden imposes a great demand for total hip and knee arthroplasty, which is reported as the most common elective orthopaedic procedure at our institution. The increase in demand for total joint arthroplasty parallels trends worldwide, where a fivefold increase in THA and TKA in the past 20 to 30 years has been reported.[29,30] As more patients readily opt for surgical management, we realise how degenerative joint disease not only inflicts physical disability but also has a direct, negative impact on the daily role functioning, psychosocial as well as financial well-being of the patient. Although the success of THA and TKA is well known, surgery is not without associated risk, complications and financial cost. Thus, the post-operative outcomes of any surgical intervention must outweigh the associated burden and cost associated with it. It is essential to utilise reliable outcome measure instruments to quantify the effect of surgery. Previously, the outcomes of THA and TKA have been based on the rates of surgical morbidity, complication, revision and mortality. While these measures provide an indirect means of measuring the success of surgery, there is rarely standardisation as to what qualifies as a good or poor outcome. For example, a patient who has had a THA or TKA may report poor satisfaction despite having no surgical morbidity or complication. For this reason, the use of appropriate outcome measures has been implemented for clinical and research use.

There is an array of outcome measures available with controversy as to which ones are optimal to measure outcomes for THA and TKA. These outcome measures can be broadly categorised into performance-based instruments, disease-specific instruments and generic instruments. Performance-based instruments focus on clinical or physical ability as a measure. In the hip and knee, the ‘Stair climbing test’ and ‘6-minute walk test’ are commonly used. Disease-specific instruments are specific to a condition or intervention. These can be patient-related outcome measures (PROMs), whereby outcomes are purely based on patient responses, or “hybrid” disease-specific measures where both patient and clinician responses are measured.

According to Lovelock et al. the HHS (63%; p=0.027) and AKSS (53%; p<0.001) are the most common disease-specific outcome measures used for the hip and knee, respectively. Generic outcome measures are non-specific to disease or intervention and apply to a greater diversity of conditions. These outcomes measures are commonly PROM's, of which the MOS SF-36 is the most commonly used instrument for hips and second most commonly used instrument for knees following the Visual Analog Scale.[31]

The use of PROMs in evaluating the outcomes of THA and TKA is increasing in literature.[32,33] It emphasises the importance of patients' perspectives on surgical outcomes and quality-of-life. While 'hybrid', disease-specific instruments are more objective, they may be more susceptible to clinical bias, especially if the clinician is more optimistic about the surgical outcome than patients are. Furthermore, increased costs and time may be involved in 'hybrid' outcome measures as clinical examination, and clinician-based input is required, whereas PROMs can be self-administered by the patient.

The validity of outcome measures needs to be appropriate for the disease and intervention implemented. These instruments should contain specific dimensions that are most relevant to the intended patient group. For total joint arthroplasty, the main reasons that patients opt for surgery are due to pain, compromised physical function and poor quality of life. The HHS and AKSS have domains that are specific to THA and TKA, respectively, with both evaluating pain and function. However, no evaluation is made on the patient's quality of life, mental and emotional well-being, thus lacking the psychometric properties of generic PROMs. On the contrary, the generic outcome measure MOS SF-36 possesses psychometric dimensions and is well suited to compare different patient populations across varying disease spectrums. Because the MOS SF-36 is not specific to THA and TKA, it results in diminished responsiveness when compared to HHS and AKSS. The holistic approach to adequately measuring outcomes for THA and TKA is to use a combination of disease-specific and generic outcome measures.[34]

In our prospective analysis, we used both disease-specific as well as generic outcome measures to evaluate the success of THA and TKA for patients with osteoarthritis. As expected, significant improvement in all outcome measures was found for both THA

and TKA. The disease-specific outcome measures, HHS and AKSS, were both more responsive than the generic MOS SF-36 outcome measure. Shi et al. also demonstrated that the disease-specific HHS was more responsive than the generic MOS-SF-36 for patients undergoing THA. Interestingly, their findings revealed that the HHS was only more responsive during the first year of follow-up after THA suggesting that disease-specific outcome measures may be more sensitive than generic outcome measures in detecting immediate or early changes. In contrast, generic measures are better suited for evaluating the long-term effects of surgery.[7] Bachmeier et al. also noted in their study that generic MOS SF-36 measures were slower to improve over time than disease-specific outcome measures.[35]

With regards to the disease-specific AKSS for TKA, we found that the clinical component of the score was more responsive than the functional component. These findings postulate that disease-specific instruments may be subject to bias as the clinical component of the score is based on clinician responses, whereas the functional component of the score is based on more patient responses. Ko et al. also published similar findings where the clinical component of the AKSS was more responsive than the patient-based functional component of the score.[36]. Both the HHS and AKSS pain measurements query pain specifically related to the hip and knee while the generic MOS SF-36 assesses general bodily pain that affects daily functioning. The MOS SF-36 does not differentiate between organic hip or knee pain, and thus pain as a result of concomitant medical conditions may skew the results when comparing disease-specific to generic outcome measures.

Using generic HRQoL outcome measures, we found that the THA and TKA significantly improved the patient's quality of life. Pre-operatively, patients scored poorly in the physical function and bodily pain domains, indicating the negative impact of osteoarthritis on pain and daily functioning. Patients scored the lowest in the role physical domain pre-operatively, as well showing that osteoarthritis impacts their work or daily activities more so than they experience bodily pain. These results are in keeping with findings published in past studies.[4,7] We also found that the low scores in the physical domains also negatively impacts on the role of emotional domain scores. A likely explanation for this finding is that patients with end-stage osteoarthritis have low self-esteem and confidence as a result of not being able to function at their baseline capacity. Our pre-operative THA and TKA MOS SF-36 mean scores were

higher in all domains when compared to findings from a similar study by Ritter et al. The results of their study also indicated that the physical function domain was most negatively impacted.[4] However, the emotional role, social functioning, mental health and bodily pain domains scored significantly less in their study compared to our results. Interestingly, in another similar study for a majority Asian population group, their pre-operative mean scores were mostly comparable to our results in all MOS SF-36 domains.[7] These comparisons may be attributed to how different patient population groups may perceive pain, as well as the presence or lack of social support systems within different communities.

Post-operatively, it was unsurprising that the domains that scored the least pre-operatively yielded the highest response. Our post-operative scores parallel with previously published results in all MOS SF-36 domains except for the social functioning and general health domains, where our results revealed higher post-operative scores than other studies.[37] Social and cultural factors that impact patient's perspectives on their quality of life and health may be a reason for the differences in these domains. Most results published in the literature are also from first-world countries as no data exists that has a similar patient population and research setting as our study. It may suggest that patients in our study perceive the benefits of THA and TKA as a significant improvement to their general health which contrasts to previous studies that show no improvement in the general health domain. However, pre-existing medical conditions could also impact responses to the general health domain.[38]

We need to consider the limitation of floor and ceiling effects of the MOS SF-36. A ceiling effect is when an individual scores the maximum of the subscale, in this case, "100". A floor effect is when an individual scores the minimum of "0". A floor and ceiling effect of 15% is considered as an acceptable limit in literature with significant floor and ceiling (>15%) rendering an instrument unable to demonstrate further worsening or improvement over time, respectively. We observed significant pre-operative floor effects for the physical functioning, role emotional and role functioning domains in both the THA and TKA group. Significant post-operative ceiling effects in the role physical and role emotional domains were evident in both THA and TKA group, with a significant ceiling effect for the bodily pain domain in patients with TKA. The relevant MOS SF-36 pre-operative floor and post-operative ceiling effects for our study mirror

what has been published in the literature.[32,36–40] Significant pre-operative floor effects have been repeatedly recorded for the physical functioning, role physical and role emotional domains for both THA and TKA in past studies. The role physical, role emotional, mental health, and social functioning domains also show.[40] It suggests that some of these MOS SF-36 domains may be redundant in detecting change before and after THA or TKA.

Our analysis also shows that there is no significant difference between the THA and TKA groups preoperatively, except for the physical function domain with regards to the post-operative MOS SF-36 scores. Other studies have shown no significant difference between THA and TKA preoperatively. However, other researchers have found more significant differences between THA and TKA postoperatively.[32,33,39] They found higher scores for THA in the physical functioning, bodily pain, general health, vitality, and mental health domains but also faster improvements when compared to TKA.[21] Although our study showed no significant surgery-time interaction on the MOS SF-36 outcome measures between THA and TKA, our follow up period was limited to 3 months compared to the more extended follow-up periods ranging between 2 to 5 years in other studies. These differences between THA and TKA were most pronounced from 9 months postoperatively, which may explain why we were unable to replicate this finding. The interpretation of the differences between THA versus TKA is not a simple task as multivariate factors such as age, gender, the severity of the disease, surgical approach, choice of implant and complications, for example, may have uncertain effects on PROMs which require further investigation and study. Nonetheless, as shown in this and previous studies, the use of generic HRQoL outcome measures such as the MOS SF-36 enables us to make this comparison between THA and TKA which is an advantage of this instrument.

To gauge the burden of osteoarthritis, we compared patient responses to previously published normative data of the Brazilian population. This indirect comparison accounts for the socioeconomic and demographic profiles that closely resembles our setting as no published data exists for South Africa. As expected, we observed significant differences for all domains of the MOS SF-36 between healthy individuals and individuals with osteoarthritis of the hip or knee. The domains most affected were those of physical functioning, bodily pain and role functioning, which reflect the physical disability of hip and knee osteoarthritis. The disease-specific HRQoL

instruments are also sensitive to this. However, unique to generic HRQoL instruments, the psychosocial impact that osteoarthritis has on affected individuals can be quantified. The physical impairment of osteoarthritis may undermine the patient's confidence, self-esteem, and perspective on personal health. This relationship between physical and mental burden of disease is further evidenced by the strong correlation found between the bodily pain and social functioning as well as the vitality and mental health domains in our study. Even though the pre-operative deviations from the norm for the mental health domain was generally smaller than the domains of physical functioning and bodily pain, it was interesting to see that osteoarthritis had a significant impact on social functioning and emotional well-being. Clinicians often oversee the psychosocial implications of disease on patients and focus purely on the physical impairment and pain. Both physical and psychosocial components are shown to contribute significantly to the burden of disease.

It is interesting to note that our post-operative scores were significantly higher than the normative data in all domains of the MOS SF-36 except for the social functioning domain for patients who had THA. This finding contrasts with other studies as their postoperative scores were lower than that of the normative data. These differences could be due to the limitations of comparing our data to a different population group whereby our norms may be higher than that of the Brazilian population or that our patients are subjectively more responsive to the outcome of THA and TKA. However, with this said, March et al. reported some cases where patients who had THA or TKA have exceeded population norms with appropriate data from the same population group. It warrants further research in our setting to accurately determine our population normative data before definitive conclusions can be made about the burden of osteoarthritis.

The MOS SF-36 is an advantageous PROM in evaluating outcomes in THA and TKA. It is easy to administer and found to demonstrate good validity and reliability, which is commonly used in orthopaedic outcome measures.[33,40] There are, however, limitations and shortcomings when using the MOS SF-36 as an outcome measure for THA and TKA as the MOS SF-36 is a generic outcome measure which investigates broader subscales non-specific to THA and TKA, certain subscales may not show appropriate responsiveness.[40] Some subscales of the MOS SF-36 show significant ceiling and floor, which impacts the responsiveness of those domains. Another

potential shortcoming of the MOS SF-36 to consider is the administrative burden for patients and clinician to complete the MOS SF-36 survey. The MOS SF-36 survey contains 36 items which have implications on the time it takes to complete. It can become cumbersome to implement in large patient groups or busy clinics and can take up to 15 to 30 minutes for patients to complete discouraging participation. Also, while manual calculations for the MOS SF-36 instrument is possible, scoring algorithms available from developers usually involve licensing costs to utilise the MOS SF-36 instrument efficiently. It renders the generic HRQoL outcome measures less accessible. Although the licensed software usually costs less than clinician consults required for clinician-based responses in disease-specific outcome measures such as the HHS and AKSS, the operational cost advantage of the MOS SF-36 becomes diminished. While the MOS SF-36 survey has been linguistically validated and translated into more than 50 different languages, English and Afrikaans remain the only official languages that are applicable in our setting. The MOS SF-36 may not meet the language requirements for patient populations who do not understand English or Afrikaans, limiting its use as an outcome measure to patient populations who understand English or Afrikaans only.

The strength of this study is its prospective design, negating potential biases of retrospective and cross-sectional studies. Multiple arthroplasty surgeons did the surgical cases as opposed to a single surgeon, which should allow some degree of external variability of the results. Based on the results of this study, comparative results have been reported in multiple European, American, Taiwanese and Australian studies. To our knowledge, this is the first study of this kind for our local setting. However, limitations of this study do exist. These include the non-randomised study design as well as the smaller sample size, which allows for detection of a medium effect size. Although the maximum response after THA and TKA is seen at three months follow-up, a more extended follow-up period is also needed to determine whether the improvement in HRQoL is maintained. Potential limitations in using different population normative data for our study population should be considered when interpreting these results. Furthermore, the MOS SF-36 questionnaire was conducted in English, which may not be the first language in the majority of the patient population and whether this affects the responses is yet to be determined.

In summary, THA and TKA are effective interventions for alleviating pain and restoring function for patients with end-stage osteoarthritis. Although this improvement in pain and physical functioning is well known, the use of instruments to measure HRQoL outcomes, especially from a patient's perspective is lacking. Based on the results of this study and of previous studies, the MOS SF-36 is an appropriate instrument to measure the impact of THA and TKA on HRQoL. It documents outcome measures that may be overseen by the more commonly used disease-specific instruments such as the HHS and AKSS. Documenting the HRQoL outcome measures not only enables us to measure the success or outcome of an intervention but also allows comparisons between varying diseases and interventions to be made. This may be practical in health care surveillance, practice quality control, or assessing and motivating for a new intervention, surgical technique, rehabilitation protocol or implant prosthesis, for example. In our state setting where THA and TKA are associated with increasing prevalence, risk, public health expenditure and resource allocation; the use of disease-specific and generic HRQoL outcome measures become a crucial tool in justifying the benefits versus the burdens of these surgeries.

Conclusion

The disease-specific HHS and AKSS, as well as the generic MOS SF-36 instruments, are responsive in detecting the changes in the HRQoL outcomes in patients undergoing THA and TKA. The use of patient perspective outcome measures is integral in understanding the health needs of patients requiring THA and TKA and how these factors influence the outcome of surgery.

Ethics Statement

Institutional ethics committee approval was obtained for this study (M180630). 'All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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Appendices

Appendix A: Ethics Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research & Post Graduate Affairs)

TO: Dr K-W N Fang
School of Clinical Medicine
Department of Surgery
Division of Orthopaedic Surgery
Chris Hani Baragwanath Academic Hospital

E-mail: nico_fang@msn.com

CC: Supervisor: Professor C Frey <cfrey@iafrica.com>
and <HREC-Medical.ResearchOffice@wits.ac.za>

FROM: Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 23/11/2018

REF: *R14/49*

PROTOCOL NO: **M180630** *(This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)*

PROJECT TITLE: *Health-related quality-of-life outcomes in patients undergoing total hip and knee arthroplasty at Chris Hani Baragwanath Academic Hospital*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr K-W N Fang

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M180630

NAME: (Principal Investigator)	Dr K-W N Fang
DEPARTMENT:	School of Clinical Medicine Department of Surgery Division of Orthopaedic Surgery Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Health-related quality-of-life outcomes in patients undergoing total hip and knee arthroplasty at Chris Hani Baragwanath Academic Hospital
DATE CONSIDERED:	29/06/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professor C Frey
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	23/11/2018

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

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

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

Principal Investigator Signature

02/07/2018
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix B: South African Orthopaedic Journal Guidelines

Scope and Policy

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

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

Original research articles.

Clinical research

Basic science and theoretical research

Review articles.

Invited expert opinions.

A review of significant local or international publications journal article or cluster of articles dealing with a similar topic for the purpose of conveying a useful message.

Editorials.

Letters to the editor.

Forum to raise issues or debate aspects of previously published papers.

Criteria for publication

The article falls within the scope of the journal.

Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.

Results reported have not been published elsewhere.

Conclusions are presented in an appropriate fashion and are supported by the data.

The article is presented in an intelligible fashion and is written in standard English (British usage).

The research meets all applicable ethical standards.

The article adheres to guidelines provided in the instructions for authors' section.

Guidelines for authorship

Each author should participate and is responsible for the content and design of the study, the preparation of the manuscript and its revisions, and final approval.

Other ‘contributors’ can be acknowledged at the end of the manuscript together with their contribution.

Authors of manuscripts representing a multi–centre study may list members of the group in the footnote on the title page of the published article and their affiliations are listed in an appendix.

The authors should clearly indicate the predominant surgeon or surgeons who have contributed patients to the study.

Registration of clinical trials

A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health–related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process–of–care changes.

Clinical trials should be registered in a public trials registry in accordance with International Committee of Medical Journal Editors recommendations.

Trials must be registered and approved by the relevant authorities before the onset of patient enrolment.

The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.

Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

Reporting guidelines

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

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

Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including

recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

Role of funding source

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

Formatting of Submissions

Text formatting

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

Headings

- Use no more than three levels of displayed headings.

Abbreviations

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

Units

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

Figures

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

Tables

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

References

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

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

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

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

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

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

  Chapter in a book:
  Young W. Neurophysiology of spinal cord injury. In: Errico TJ, Bauer RD,

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

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

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

Structure and content of submission

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

Title page

Title

- The title should be concise and informative.

Author names and affiliations

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

Corresponding author

- Clearly indicate who will handle correspondence at all stages of refereeing and publication, including post–publication.

- Ensure that the e–mail address and permanent address is given and that contact details are kept up to date by the corresponding author.
- Please note that the corresponding author's contact details will be provided in the final article.
- Provide the following information for the corresponding author:
    - Full names and title
    - Affiliation
    - Physical address
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Declarations

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

a. Authorship
   The authors confirm that all authors have made substantial contributions to all of the following:
    - The conception and design of the study, or acquisition of data, or analysis and interpretation of data
    - The drafting the article or its critical revision for important intellectual content
    - Final approval of the version to be submitted.

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

c. Plagiarism
   The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.
    - No data, text or theories by others are presented as if they were the authors' own.
    - Proper acknowledgements of others' work has been given (this includes material that is closely copied, summarised and/or

paraphrased); quotation marks are used for verbatim copying of material.
- Permissions have been secured for material that is copyrighted.

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

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

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

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

f. Compliance with ethical guidelines
- For all publications:

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

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

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

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

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

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

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

Blinded manuscript

Abstract

- A structured abstract (maximum of 350 words), summarising the most important points in the article is required.
- The abstract consists of four paragraphs with the subheadings:
  - Aims (it is unnecessary to include an introductory section)
  - Patients and methods
  - Results

    - Conclusion
- References should be avoided. Avoid uncommon abbreviations. If essential they must be defined at their first mention in the abstract itself

Key words

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

Level of evidence

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

Introduction

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

Patients (or Materials) and methods

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

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

Results

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

Discussion

- The question or hypothesis stated at the end of the introduction should be discussed and either supported or rejected.
- The results must be interpreted clearly and any deficiencies expressed. All possible confounding factors, sources of bias, or weaknesses in the study should be identified.
- Explore the significance of the results of the work, rather than repeating the results.

- The discussion must point out the relevance of the work described in the paper and its contribution to current knowledge.
- Explain what can be deduced from the results and how will it affect clinical practice.
- Include a review of the relevant literature, placing the results of the study in the context of previous work in this area.
- Discussion of relevant prior research and references must be concise. Avoid extensive citations and discussion of published literature but put emphasis on previous findings that agree (or disagree) with those of the present study.
- Do not repeat the introduction.
- Present the limitations of the study and suggest how the study could have been improved for a future study.
- Avoid making inferences from non–significant trends unless you believe your study is adequately powered to answer the question; in that case, provide a power analysis.

Conclusion

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

Conflict of interest

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

Ethical statement

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

- If identifying information about participants is available in the article, the following statement should be included: ‘Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.’

Funding sources

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

Acknowledgements

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

References

- Please refer to the section on Formatting of submissions.

<u>Tables and figures</u>

- 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.

Appendix C: Research Protocol

University of the Witwatersrand
Faculty of Health Sciences
Division of Orthopaedic Surgery

Health-Related Quality-of-Life outcomes in patients undergoing total hip and knee arthroplasty at Chris Hani Baragwanath Academic Hospital

[Document subtitle]

Name: Dr KN Fang
Student number: 0603244T

Supervisors: Prof CT Frey, Dr B Milner

Contents

List of abbreviations

HRQoL - Health-related Quality of Life

HHS - Harris Hip Score

AKSS American Knee Society Score

MOS SF-36 - Medical Outcomes Study SF-36 Health Survey

CHBAH - Chris Hani Baragwanath Academic Hospital

QoL - Quality of Life

HREC - Human Research Ethics Committee

1. Introduction

Osteoarthritis is the most common form of arthritis in humans. It is a degenerative disease of the joint cartilage and is the eighth leading cause of disability in the world (1). It affects 9.6% of men and 18% of women aged more than 60 years worldwide (2). In South Africa, the prevalence of osteoarthritis ranges from 55,1% in urban settings to 82,7% in rural settings, mostly due to a difference in nutritional and work habits (3).

Osteoarthritis commonly affects the hip and knee joints leading to loss of function as well as restriction on daily activities. Not only does it impose physical disability, osteoarthritis significantly affects the daily role functioning and psychosocial aspects of those affected compounding financial implications on a microscopic and macroscopic scale (2).

Joint replacement is widely accepted as the treatment of choice for advanced osteoarthritis whereby intolerable symptoms and restrictive function cannot be relieved by conservative means (4). The success of total hip arthroplasty and total knee arthroplasty for degenerative arthritis is well documented in the literature (5, 6). In past studies, the assessment of change before and after surgery has been quantified using appropriate and adequate health-related quality of life (HRQoL) measurement instruments. The ability of a HRQoL instrument to detect change is known as the responsiveness of the instrument (7). HRQoL instruments can either be disease-specific (focusing on the consequence of disease) or generic (focusing on overall patient well-being). Disease-specific HRQoL instruments are generally used to assess the impact of a specific disease as well as the outcomes after implementation of an intervention. In osteoarthritis of the hip and knee, disease-specific instruments such as the Harris Hip Score (HHS) and American knee society score (AKSS) are used respectively (8, 9). These disease-specific scores have shown

to have adequate responsiveness and are widely adopted; however, they are prone to clinician bias due them being clinician-based HRQoL instruments. Furthermore, comparisons between different medical conditions cannot be made using disease-specific HRQoL instruments (10). As a result, generic HRQoL instruments have been implemented in conjunction to disease-specific HRQoL instruments in order to gauge overall patient-related quality of life outcomes across varying disease types and medical interventions (7).

An accepted and recommended generic HRQoL instrument in osteoarthritis is the Medical Outcomes Study SF-36 Health Survey (MOS SF-36) (11). The MOS SF-36 health survey was developed by the Rand Health Insurance experiment as a generic HRQoL instrument. It is a self-administered questionnaire consisting of 36 multiple choice questions weighted on different HRQoL domains. Eight HRQoL domains are interrogated being: physical functioning, role functioning, bodily pain, general health, vitality, social functioning, role-emotional and mental health. Each domain is calculated and converted to a score scale of 0 - 100, with a lower score indicating greater disability (12). The MOS SF-36 displays the benefits of a self-administered, patient based holistic survey that eliminated clinician bias and is non-specific to patient population and disease. As a generic HRQoL instrument it is able to measure the outcomes stipulated in most clinical trials on osteoarthritis (13). The validity of the MOS SF-36 has been tested and found to be a reliable instrument to measure health perception in both developed and developing countries (11, 14).

The use of the MOS SF-36 to assess the change in quality of life of patients undergoing total hip arthroplasty and total knee arthroplasty is evident in current literature. In fourteen papers that utilised the MOS SF-36 instrument to assess quality of life before and after total hip or total knee arthroplasty, all showed significant

improvement with total joint arthroplasty (P-value < 0.05) (5, 7, 15). This improvement has also been correlated and benchmarked with disease-specific instruments such as the HHS and AKSS, which also showed significant improvement (10). This change in quality of life after total joint arthroplasty was documented between 3 to 24 months after surgery. Patients who underwent total hip arthroplasty showed more improvement over those who underwent total knee arthroplasty (16). The number of patients recruited in these studies ranged from 100 to 500 patients with a mean age of 70; however, the majority of these studies were retrospective studies and conducted in developed countries. No published data from Africa exists in literature. Some authors criticised the floor and ceiling effect as a limitation of the MOS SF-36 to score HRQoL on a fixed scale. Furthermore, factors other than the surgery such as co-morbidities, medication, psychological profile, rehabilitation and support systems may differ between individuals and impact their responses (5).

Currently in our local setting, the outcomes of total hip arthroplasty and total knee arthroplasty have not been well documented using generic HRQoL instruments. Given the burden of degenerative arthritis in our patient population there is an increasing demand for primary total joint arthroplasty.

At Chris Hani Baragwanath Academic Hospital (CHBAH), 500 arthroplasty cases are done per annum, with 656 total hip arthroplasties and 886 total knee arthroplasty cases awaiting elective surgery extending into the year 2024. It accounts for a major portion of orthopaedic cases done at our institution and is an area of focus on cost implications as well as surgical benefit. It is in our best interest to document the change in the quality of life after total hip arthroplasty and total knee arthroplasty using accredited HRQoL measurement instruments in order to quantify the burden of disease and responsiveness of our medical intervention.

2. Study aim

The aim of the study is to determine the impact of total hip arthroplasty or total knee arthroplasty on the quality of life (QoL) of patients with osteoarthritis at CHBAH.

3. Study objectives

- To document the change on the QoL of patients undergoing primary total hip arthroplasty or total knee arthroplasty for degenerative arthritis at CHBAH using accredited HRQoL instruments.
- To measure the disease burden of degenerative arthritis at our institution by comparing HRQoL scores to norm-based scores of similar patient population groups.
- To compare the disease burden and change on the QoL between degenerative hip and knee arthritis using results yielded in HRQoL instruments.

4. Study design

A prospective longitudinal cohort study will be conducted.

5. Study method

Patients undergoing elective primary total hip arthroplasty or primary total knee arthroplasty for degenerative arthritis will be approached for voluntary participation. This will be based on the clinical and radiological diagnosis according to the Kellgren and Lawrence criteria (4, 17, 18). Any cases pertaining to trauma or indications other than degenerative arthritis will be excluded from the study. Patients with severe organic or psychiatric diseases or who did not undergo surgery will also be excluded from the study.

Patients Inclusion Criteria

- Male or female adult patients > 18 years of age.

- Diagnosed with degenerative osteoarthritis of the hip or knee joint according to radiological and clinical criteria for osteoarthritis.
- Receiving elective primary total hip arthroplasty or total knee arthroplasty as part of the established treatment plan.
- Able to comprehend and autonomously respond to a survey.
- Able to autonomously consent to the study.

Patients Exclusion Criteria

- Diagnosed with conditions other than that of hip or knee osteoarthritis.
- Traumatic injuries requiring primary total joint arthroplasty.
- Unable to undergo elective surgery due to personal or medical reasons.
- Severe organic or psychiatric disease that significantly impacts QoL or the capacity to reliably complete a survey.
- Incomplete data or withdrawal from the study.

An information leaflet will be provided and explained to participants and informed consent obtained prior to participation in the study. All participants will be pooled from the Arthroplasty Outpatient's Department at CHBAH. Participants will either be categorised into the total hip arthroplasty group or total knee arthroplasty group depending on the surgery they undergo. Participants will not be blinded nor will the study affect the medical intervention already proposed for the patient.

Participants will be interviewed by the principal investigator (Dr KN Fang) prior to their surgery using the MOS SF-36 instrument. An interpreter will be available to clarify any misunderstandings encountered in the interview due to language preferences. In cases where the language barrier will compromise the result of the study, these patients will be excluded from the study. The data will be recorded digitally on a licensed application through an Apple iPad™ and stored on a secure cloud-based server using REDCap™ to ensure security and confidentiality of the data. No personal details of participants will be recorded. In order to validate the responsiveness of the MOS SF-36 score, a disease-specific HRQoL instrument will also be implemented at

the same time as the MOS SF-36 score. This will be the HHS and AKSS for total hip arthroplasty and total knee arthroplasty respectively.

After the primary joint replacement, participants will again be interviewed by the principal investigator using the MOS SF-36 and HHS/AKSS three to six months after their surgery date. This will allow adequate time for the rehabilitation program to be fulfilled.

Participation in this study will be completely voluntary with the right to withdrawal respected and not infringing on the access to medical care. Any changes regarding the study will be discussed with the participants and their rights reserved in continuation or withdrawal from the study. There are no financial implications for participants regarding the study. There are no financial benefits for participants.

We propose to interview 25 patients in each total hip arthroplasty and total knee arthroplasty group. Using the data collected, the responsiveness of the relevant HRQoL instruments will be calculated by determining the mean score difference between the preoperative and postoperative state for the given time period. The mean score difference between the total hip arthroplasty group and total knee arthroplasty group will also be compared. The responsiveness will also be compared between the generic HRQoL MOS SF-36 score and disease specific HRQoL HHS and AKSS by standardising the magnitude of change and determining the effect sizes for the respective HRQoL instruments. The data collected on the preoperative group and postoperative group will also be compared to normative population data for the respective HRQoL instrument to gauge the burden of disease. As no normative data for the MOS SF-36 is available for South Africa or any other African countries, therefore, normative data from Brazil will be used. The normative data from Brazil is

the only data available from a country that shares similar socioeconomic traits to our local setting (19).

With these results we wish to document the burden of degenerative arthritis in our patient population group and measure the significance of change on quality of life after total hip and knee arthroplasty. We will thus be able to internally audit the quality of the surgical intervention using a holistic approach from both the clinician and the patient. Furthermore, this study will enable us to justify the resources expended on one of the most common surgical procedures performed in the Orthopaedic faculty and perhaps allow us to motivate for additional resources to relieve the extensive volume awaiting total hip and knee arthroplasty.

6. Data analysis

The unit of the study will be the patient undergoing elective primary joint replacement. Descriptive statistics will include frequencies, percentages, means, standard deviations and confidence intervals. P-values ≤ 0.05 will be considered statistically significant. Significance testing of the mean difference between the preoperative and postoperative group will include Students t-test for samples which are normally distributed. Expert statistical analysis and access to validated statistical software will be required.

7. Ethics

Permission from the institute where the study will be conducted will be obtained. Ethical approval will be obtained from the Human Research Ethics Committee (HREC) (Medical), University of the Witwatersrand prior to commencement of the study. Ethical approval for the pilot study has been obtained (Ref: **M160951**). Patients will be provided with a patient information leaflet and informed consent will be obtained prior to enrolment to the study (see Appendix A).

8. Problems and limitations

Potential problems that may be encountered include participants who enrol and withdraw or do not undergo the arthroplasty surgery due to medical or personal reasons; this can compromise the endpoint of the study in terms of numbers.

Specific to the various HRQoL instruments utilised, differences exist in the assessment of pain. In the disease-specific HHS and AKSS pain is assessed specifically to that of the hip and knee respectively rather than generalised bodily pain as assessed in the generic HRQoL MOS SF-36 score. Furthermore, patients may be unable to differentiate from referred pain in these circumstances.

Another documented technical limitation of the MOS SF-36 instrument is the floor and ceiling effects of its scoring algorithm. As it is a fix ended score scale of 0 - 100, the MOS SF-36 instrument may be limited in evaluating serial changes for an individual over time. Despite this limitation it is still an effective and commonly used instrument in detecting change of an intervention in cohort groups (20).

9. Funding

Table 1: Proposed Budget

ITEM	COST
SF-36 LICENSED SOFTWARE	R1400.00
PRINTING	R470.00
TRANSPORT	R400.00
TOTAL	R2270.00

A proposal for research finance assistance will be sent to the Chris Hani Baragwanath Orthopaedic Syndicate.

10. Timing

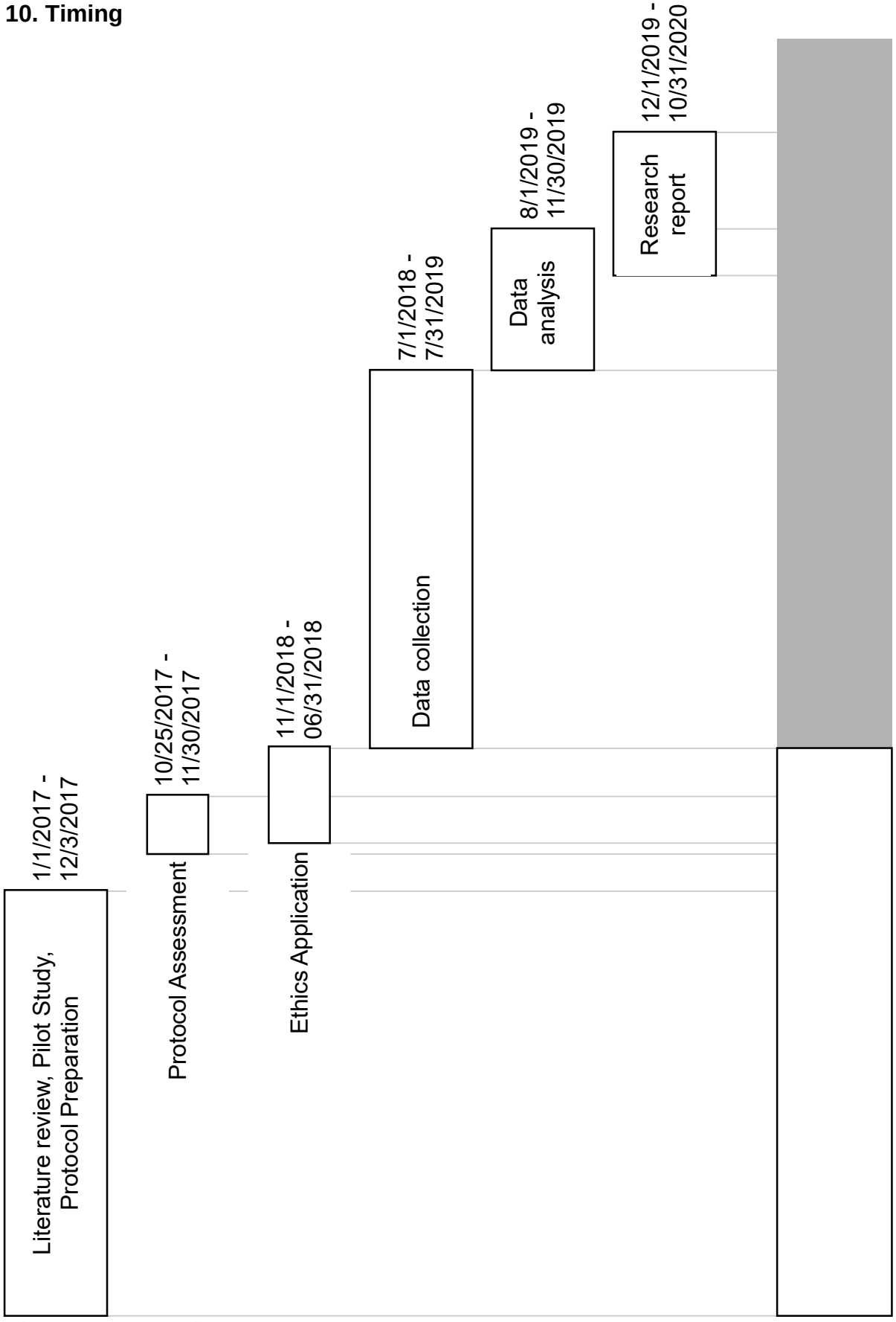

Figure 1: Gnatt Chart

11. References

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12. Appendix

PATIENT INFORMATION LEAFLET AND INFORMED CONSENT

Each patient must receive, read and understand this document before any study related procedure.

STUDY TITLE: Health-Related Quality-of-Life outcomes in patients undergoing total hip and knee arthroplasty at Chris Hani Baragwanath Academic Hospital

INVESTIGATOR: Dr KN Fang

SUPERVISOR: Prof CT Frey

INSTITUTION: Chris Hani Baragwanath Academic Hospital

INTRODUCTION

Good day, I am Dr KN Fang and a medical doctor at Chris Hani Baragwanath Academic Hospital.

You are most likely coming to our Arthroplasty Unit at Chris Hani Baragwanath Hospital because you have been diagnosed with hip or knee osteoarthritis. Total hip or knee arthroplasty may have been planned for you as discussed with your treating doctor. I would like to invite you to participate in our study if you are planned to undergo primary total hip or knee arthroplasty. Participating in this study will not have an influence of your proposed treatment.

The purpose of this study is to determine the participant's quality of life before and after total joint hip arthroplasty surgery. This will be done by a series of confidential questions asked by myself in two separate questionnaires. The first questionnaire will be asked prior to the primary total joint arthroplasty. The second questionnaire will be asked after the primary joint total arthroplasty at one of your routine follow-up visits.

In the questionnaires we will ask you questions related to pain, functioning, activities of daily living and quality of life. All questions will be clarified for you by the principal investigator if you do not understand a certain question.

You may or may not participate in the questionnaire. Participation is completely voluntary and will take about ten minutes of your time. You do not have to fill the questionnaire, if you do not want to.

The questionnaire does contain personal data, like your name and hospital number. This information will only be available to the investigators of this study. It will not be used in any other way other than the purposes of this study. The questionnaire contains mainly questions relating to your quality of life before and after the surgery and will be entered into a secure digital database.

Should you decide to participate, this would help us a great deal to understand the value of our work at Chris Hani Baragwanath Academic Hospital. As Orthopaedic Surgeons we are constantly looking for ways to improve the quality of life for our patients. We think that your opinion is a crucial stepping stone in guiding us and future patients in this regard.

TERMS

- Before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, risks, discomforts, and precautions as well as the alternative procedures that are available to you, and your right to withdraw from the study at any time.
- This information leaflet is to help you to decide if you would like to participate. You should fully understand what is involved before you agree to take part in this study.
- If you have any questions, do not hesitate to ask me.
- You should not agree to take part unless you are satisfied about all the procedures involved.
- You may not participate in another medical research study, nor take any other investigational medicine during your participation in this study.

LENGTH OF THE STUDY:

- The total amount of time required for your participation in this study will be a maximum of 30 minutes.
- You will be asked to visit me 2 times during the period of the study.

PROCEDURES:

- If you agree to take part in this study, you will first be asked questions and examined to see if you qualify for this study.

At each following visit you will undergo:

i. Visit 1 – (week 0): Questionnaire, clinical examination and scoring
ii. Visit 2 – (month 3 - 6): Questionnaire, clinical examination and scoring

Participants must be older than the age of 18 years

RISKS BEING INVOLVED IN THE STUDY?

There are no direct risks in participating in the study. The questionnaires will be conducted on your routine visits to the Arthroplasty Outpatients Department. The clinical examination will be routine follow-up clinical examinations to determine clinical scores for your hip or knee function.

BENEFITS:

- The potential benefit from your participation in this study may be that we can improve our service delivery in future.
- However, you may not benefit from this study directly.
- Your participation in this study will contribute to medical knowledge.

RIGHTS AS A PARTICIPANT IN THIS STUDY:

Voluntary:

- Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason. Your withdrawal will not lead to penalty, or loss of benefits to which the you are otherwise entitled. There is no requirement to provide a reason for withdrawing and any data collected on such a person will in default be destroyed, unless you specifically consent to its retention.

- of the study facility, you may be withdrawn from the study at any time.

FINANCIAL ARRANGEMENTS:

- Neither you nor your medical scheme will be expected to pay for any study medication, study related visit or study procedures.

REIMBURSEMENT FOR STUDY PARTICIPATION:

- You will not be paid to participate in this study.

ETHICAL APPROVAL:

This clinical study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee.

A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be

contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

CONFIDENTIALITY:

- All information obtained during the course of this study, including hospital records, personal data and research data will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.
- These records will be available to the principal investigator and the supervisor.
- The information might also be inspected by the University of the Witwatersrand, Human Research Ethics Committee (HREC), the South African Medicines Control Council (MCC).
- Any information uncovered regarding your test results or state of health as a result of your participation in this study will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this study but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exceptions - and all of them are rare - would normally be:

    1. Personal information may be disclosed if required by law.
    2. The Human Research Ethics Committees of the University may exceptionally require personal data to respond to a formal complaint, or for a compliance audit
    3. The South African Health Products Regulatory Authority (SAHPRA), which is the successor body to the South African Medicines Control Council (SAMCC), might conceivably require access to personal data, if conducting an investigation into a drug trial

SOURCE OF ADDITIONAL INFORMATION:

For the duration of the study, you will be under the care of the Arthroplasty Unit at Chris Hani Baragwanath Academic Hospital. If at any time between your visits, you feel that any of your symptoms are causing you any problems, or you have any questions during the study, please do not hesitate to contact me.

- If want any information regarding your **rights as a research participant, or complaints regarding this research study**, you may contact the University of the Witwatersrand, Human Research Ethics Committee (HREC).

- For **research information** you can contact the Principal investigator, Dr KN Fang, on telephone number 011 933 0000, or on email: nico_fang@msn.com. Alternatively, you may contact the supervisor Prof CT Frey on telephone number 011 933 000, or on email: ncfrey@iafrica.co.za.

Thank you for reading this Patient Information Sheet.

Appendix D: Plagiarism and Turn-it-in report cover page

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I Kao-Wei Nico Fang (Student number: 0603244T) am a student registered for the degree of Master of Medicine in the academic year 2020.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature:  Date: 28/11/2020

1

a0013221:MMED_KN_FANG_-_Final_(excluding_journal_guidelines,_patient_information_sheet.

ORIGINALITY REPORT

23%	17%	20%	6%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

MATCHED SOURCE

2	"Handbook of Disease Burdens and Quality of Life Measures", Springer Science and Business Media LLC, 2010 Publication	2%

2%

★ "Handbook of Disease Burdens and Quality of Life Measures", Springer Science and Business Media LLC, 2010

Publication

Exclude quotes	On	Exclude matches	< 3 words
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Division of Orthopaedic Surgery

Faculty of Health Sciences, 4M Room 12, Wits Medical School, 7 York Road, Parktown 2193
• Tel: +27 11 717-2538 • Fax: +27 11 717-2551

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Faculty of Health Sciences, University of the Witwatersrand 23/02/2021

RE: LETTER OF MOTIVATION – TURN-IT-IN REPORT

To whom it may concern,

Please accept Kao-Wei Nico Fang's Turn-it-in report for his MMed Research Report entitled Health-Related Quality-of-Life outcomes in patients undergoing total hip and knee arthroplasty at Chris Hani Baragwanath Academic Hospital. Despite the high similarity index (23% - flagged green), the research report has not been plagiarised as common medical terminology pertaining to the topic was used.

Yours sincerely,

Prof CT Frey

Supervisor

Dr B Milner

Supervisor

Appendix E: 36-Tem Short Form Survey Instrument

RAND HEALTH

RAND > RAND Health > Surveys > RAND Medical Outcomes Study > 36-Item Short Form Survey (SF-36) >

36-Item Short Form Survey Instrument (SF-36)

RAND 36-Item Health Survey 1.0 Questionnaire Items

Choose one option for each questionnaire item.

1. In general, would you say your health is:

- 1 - Excellent
- 2 - Very good
- 3 - Good
- 4 - Fair
- 5 - Poor

---

2. **Compared to one year ago**, how would you rate your health in general **now**?

- 1 - Much better now than one year ago
- 2 - Somewhat better now than one year ago
- 3 - About the same
- 4 - Somewhat worse now than one year ago
- 5 - Much worse now than one year ago

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	○ 1	○ 2	○ 3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○ 1	○ 2	○ 3
5. Lifting or carrying groceries	○ 1	○ 2	○ 3
6. Climbing **several** flights of stairs	○ 1	○ 2	○ 3
7. Climbing **one** flight of stairs	○ 1	○ 2	○ 3
8. Bending, kneeling, or stooping	○ 1	○ 2	○ 3
9. Walking **more than a mile**	○ 1	○ 2	○ 3
10. Walking **several blocks**	○ 1	○ 2	○ 3
11. Walking **one block**	○ 1	○ 2	○ 3
12. Bathing or dressing yourself	○ 1	○ 2	○ 3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	1	2
14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

---

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- 1 - Not at all
- 2 - Slightly
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

- ○ 1 - None
- ○ 2 - Very mild
- ○ 3 - Mild
- ○ 4 - Moderate
- ○ 5 - Severe
- ○ 6 - Very severe

---

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- ○ 1 - Not at all
- ○ 2 - A little bit
- ○ 3 - Moderately
- ○ 4 - Quite a bit
- ○ 5 - Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
24. Have you been a very nervous person?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
25. Have you felt so down in the dumps that nothing could cheer you up?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
26. Have you felt calm and peaceful?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
27. Did you have a lot of energy?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
28. Have you felt downhearted and blue?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
29. Did you feel worn out?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
30. Have you been a happy person?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
31. Did you feel tired?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- ○ 1 - All of the time
- ○ 2 - Most of the time
- ○ 3 - Some of the time
- ○ 4 - A little of the time
- ○ 5 - None of the time

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

ABOUT

The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

Hays R, Sherbourne C, Mazel R. The Rand 36-item Health Survey 1.0. Health economics.1993 Oct;2:217–27.

Appendix F: Harris Hip Score

Pain	None	44
	Slight, occasional, no compromise in activity	40
	Mild pain, no effect on average activities, rarely moderate pain with unusual activity, may take aspirin	30
	Moderate pain, tolerable but makes concessions to pain. Some limitations of ordinary activity or work. May require occasional pain medication stronger than aspirin	20
	Marked pain, serious limitation of activities	10
	Totally disabled, crippled, pain in bed, bedridden	0
Distance walked	Unlimited	11
	Six blocks (30 minutes)	8
	Two or three blocks (10 - 15 minutes)	5
	Indoors only	2
	Bed and chair only	0
Activities - shoes, socks	With ease	4
	With difficulty	2
	Unable to fit or tie	0
Public transportation	Able to use transportation (bus)	1
	Unable to use public transportation (bus)	0
Support	None	11
	Cane/Walking stick for long walks	7
	Cane/Walking stick most of the time	5
	One crutch	4
	Two Canes/Walking sticks	2
	Two crutches or not able to walk	0
Limp	None	11
	Slight	8
	Moderate	5
	Severe or unable to walk	0

Stairs	Normally without using a railing	4
	Normally using a railing	2
	In any manner	1
	Unable to do stairs	0
Sitting	Comfortably, ordinary chair for one hour	5
	On a high chair for 30 minutes	3
	Unable to sit comfortably on any chair	0
Deformity: • 30 degrees of fixed flexion • 10 degrees of fixed int rotation in extension • 10 degrees of fixed adduction • Limb length discrepancy of ≥ 3.2cm	Absence of all 4	4
	Presence of 1	0
Range of motion	Full	5
	Partial	4
	Limited	2
TOTAL SCORE		/100

Harris WH. Traumatic Arthritis of the Hip After Dislocation and Acetabular Fractures: Treatment by Mold Arthroplasty. An End-Result Study Using a New Method of Result Evaluation. The Journal of bone and joint surgery American volume. 1969 Nov;51:737–55.

Appendix G: American Knee Society Score (AKSS)

Pain	None	50
	Mild / Occasional	45
	Mild (Stairs only)	40
	Mild (Walking and Stairs)	30
	Moderate - Occasional	20
	Moderate - Continual	10
	Severe	0
Range of motion	5 degrees of flexion = 1 point	Maximum 25
Anteroposterior Stability	<5mm	10
	5-10mm	5
	10mm	0
Medial Lateral Stability	< 5 degrees	15
	6 – 9 degrees	10
	10 – 14 degrees	5
	> 15 degrees	0
Deductions		
Flexion Contracture	5 -10 degrees	2
	10 -15 degrees	5
	16 – 20 degrees	10
	>20 degrees	15
Extension Lag	<10 degrees	5
	10 – 20 degrees	10
	>20 degrees	15
Alignment (Varus & Valgus)	5 – 10 degrees	0
	0 – 4 degrees	3
	11 – 15 degrees	3
Total Score		/100

Function Rating		
Walking	Unlimited	50
	>10 blocks	40
	5-10 blocks	30
	<5 blocks	20
	Housebound	10
	Unable	0
Stairs	Normal Up and down	50
	Normal Up down with rail	40
	Up and down with rail	30
	Up with rail, down unable	15
	Unable	0
Deductions		
Walking aids used	None used	0
	Use of Cane/Walking stick deduct	5

	Two Canes/sticks	10
	Crutches or frame	20
Total Score		/100

Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. Clin Orthop Relat Res. 1989 Nov;(248):13-4.