The functional outcomes of intramedullary nails used in humeral shaft fractures in two urban public health facilities in South Africa

Mmangaliso Yoliswa Maseko

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

Johannesburg, 2025

DECLARATION

I, Mmangaliso Maseko, declare that this research project is my own work, which is being submitted for the degree of Master of Medicine in the branch of Orthopaedics Surgery at the University of Witwatersrand, Johannesburg.

It has not been submitted before for any examination or degree at this or any other University.

……

Signature of Candidate

……. Day of…….. 2025……in…….

DEDICATION

God works everthing for the good of those who love Him – and He has done nothing less for me on my journey.

My **entire** existence and capabilities are because of **Him**.

To my phenomenal **Mom and Dad**, thank you for the great genes☺ but more importantly thank you for an upbrining that has taught me to chase after my dreams wholheartedly with boldness and grace and to live my name out in its fullness. Your prayers have never been in vain.

To **Lyndsay, Sbusiso, Welcome, Andiswa and Andile**, you have made learning and breaking through seemigngly immovable ceilings effortless because of the countless number I've witnessed you tear apart in your own spaces. A sibling body doesn't get better than this one.

This is just the beginning.

PRESENTATIONS AND PUBLICATIONS ARISING FROM THE RESEARCH PROJECT

- None

ABSTRACT

Introduction

Humeral fractures account for nearly 3% of all recorded fractures. South Africa faces an array of societal challenges, including one of the highest rates of motor vehicle accidents (MVAs) globally, which are considered a significant contributing factor to humeral fractures. The management of these fractures has undergone significant evolution over the years, with various treatment methods becoming available, primarily involving plate osteosynthesis or intramedullary nailing (IMN). However, the associated complications of humeral shaft nails, such as rotator cuff injuries, have prompted surgeons to explore alternative treatment methods to mitigate these risks. Subsequent refinements in surgical techniques have reduced these risks over time, allowing plate humeral IMNs and osteosynthesis to be used interchangeably based on surgeon preference and expertise. This study aims to quantitatively assess the functional outcomes of surgically managed humeral shaft fractures using IMNs.

Methodology

The study focuses on the functional outcomes of humeral shaft fractures surgically managed with IMNs. A retrospective cohort study with prospective recall was conducted on patients who underwent surgical fixation for humeral shaft fractures that met the inclusion criteria over a four-year period (2019 – 2023). The study assessed patient demographics, time to return to work, post-surgical pain, patient satisfaction, and functional outcome using the Quick Disabilities of the Arm, Shoulder, and Hand (Quick DASH) scores.

Results

Out of 122 identified patients, 45 were included in the study. Surgeries were primarily performed by registrars and occasionally by medical officers in two facilities. There was a predominance of males, with the majority being right-handed and over 80% sustaining injuries in that group. Injuries were mostly sustained from Motor Vehicle Accidents (MVAs) and Pedestrian Vehicle Accidents (PVAs). On average, return to Activities of Daily Living (ADLs) was approximately 5 weeks, and of the over 70% of employed patients, over 80% were able to return to work in a mean time of seven weeks. Visual Analog Scale (VAS) scores averaged two on the 100-mm VAS scale. Quick DASH scores for 44 of the 45 recorded cases were all below 29, with patients averaging around seven out of 100. Patients reported an overall satisfaction level between good and very good, and only the mechanism of injury and analgesia use had a significant impact on these results.

Discussion

The average age recorded was 35 years, with the majority being employed men. Comparable return-to-work times, coupled with low VAS scores, indicated that working-class patients were able to resume everyday activities, including forms of employment. One patient reported having to change employment due to an inability to carry out heavy-duty activities, while the remainder returned to their previous jobs. Patient demographics, barring sex, showed insignificant differences for return-to-work times or VAS scores. Females were noted to take slightly longer to return to ADLs but not to return to work.

Conclusion

The use of IMN has frequently been linked to post-surgical shoulder impingement and our study showed that this is not as high as what was previously expected in literature. Humeral nail fixation shows benefit in allowing patients earlier function of their affected limb with little influences from their age, hand dominance and employment type.

ACKNOWLEDGMENTS

A special thank you to the people who helped immensely with making sure this work comes together

Supervisors

- Dr Ike Egbunike
- Dr Maxwell Jingo

Statistician

- Dr Michelle Henry

Orthopaedics Clerk

- Ms Sannah Skosana

TABLE OF CONTENTS

List of Figures

List of Tables

Nomenclature

ADLs	Activities of Daily Living
ASES	American Shoulder and Elbow Scores
CEO	Chief Executive Officer
CHBAH	Chris Hani Baragwanath Academic Hospital
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
COVID-19	Coronavirus disease 2019
DASH	Disabilities of the arm shoulder and hand score
HREC	Human Research Ethics Committee
IMN	Intramedullary nail
ORIF	Open reduction internal fixation
PACS	Picture Archiving and Communication System
RC	Rotator cuff
RTW	Return to work
PI	Principal Investigator
SA	South Africa

CHAPTER 1 - Introduction and Literature review

1. Introduction

Two decades ago, the idea of intramedullary (IM) splinterage with a nail or rush rod was seen to have no place in the treatment of acute humeral fractures (1). Damage to the rotator cuff, shoulder instability and interference with the shoulder joint were reason to not consider nailing for patients in that era (1). Twenty years later, these complications still hold weight in the decision making of plate *versus* nail for humeral fracture fixation (2). Perceptions around the management have however started changing with the advancing of medicine but still leave IM nailing as a second option for surgical management of humeral fractures often because of documented residual shoulder pain due to rotator cuff violation during surgery (1)(2).

Humeral shaft fractures make up 1 – 3 % of all fractures and are the third most common fracture in individuals over the age of 65 years in the world (2)(3). South Africa (SA) alone currently sits with an injury rate, of which homicide and car accidents are its highest contributors, nine times the average global rate (4). Statistics SA recorded that over 1 million motor vehicle accidents, which are a major cause of humeral fractures were recorded in 2018 (5). With this large contributor to humeral fractures occurring in a third world health system, the need for management that is both cost effective and beneficial for the early functioning of the patient is vital (5).

Multiple methods for the management of humeral shaft fractures exist, which include non-operative and operative options (6). Of the operative management options available, plate osteosynthesis is considered as the gold standard and is based on lower complication rates in comparison to intramedullary nailing (IMN) (7). Fractures that qualify for nailing are those that lie within the surgical neck of the humerus to roughly 5 cm above the olecranon fossa (8) (see Figures 1.1 – 1.3).

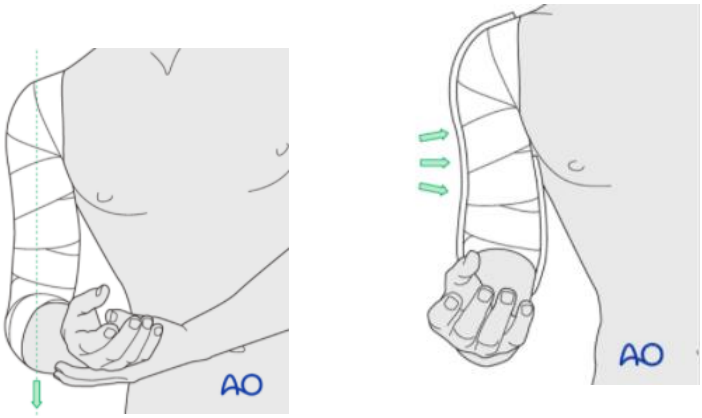


Figure 1.1: Conservative management of humeral (8).

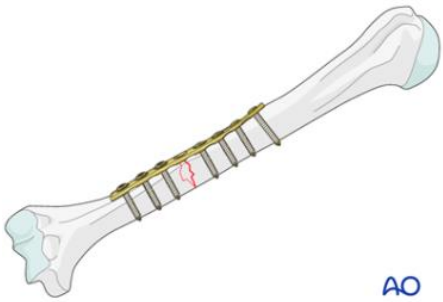


Figure 1.2: Open reduction internal fixation of humeral shaft factures (8).

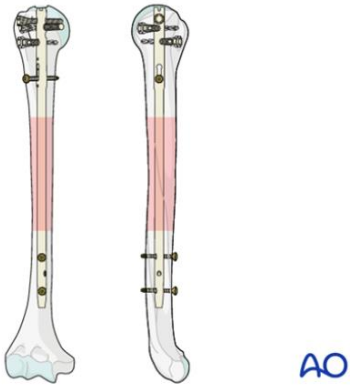


Figure 1.3: Intramedullary nailing of humeral shaft with nail (8).

1.1 Surgical fixation of humeral fractures

No one surgical option will work for every fracture pattern where surgical fixation is indicated in humeral shaft fractures (9). In general, surgical fixation for humeral shaft fractures is indicated in unacceptable alignments with closed reductions, the associated limb requiring early mobilisation, associated vascular or radial nerve injures, open fractures, floating elbow and polytrauma (see Table 1.1) (9). Specific to antegrade nailing, it is better suited in comminuted, segmental and pathological fractures whereas plating is often chosen where there is neurovascular injuries that require exploration (9).

Of the surgical options available, two common fixations exist. Open reduction internal fixation (ORIF) with a plate and screws and humeral nailing which can be subdivided into retrograde and antegrade nailing (8). ORIF involves making an incision along the humerus shaft, by

means of varying approaches, with careful identification and protection of the radial or ulnar nerve depending on the approach (Arbeitsgemeinschaft für Osteosynthesefragen plating).

Table 1.1: Parameters for non-operative management in a coaptation splint (4).

Parameter	Value
Anterior angulation	< 20 degrees
Varus/valgus angulation	< 30 degrees
Shortening	< 3 cm

1.2 Intramedullary nailing

Intramedullary nails (IMNs) are load-sharing implants i.e. the bone and the implant equally share the functional load in contrast to a load-bearing device, which carries the entire functional force applied on the affected limb (10). Advantages in the use of an antegrade nail, in comparison to plating, is that an IMN offers a less extensive dissection for the placement of an implant and this results in less soft tissue disruption and overall better healing. There is less risk or radial nerve injury and less bleeding and the preservation of fracture hematoma (11)(26).

Documented disadvantages with the use of antegrade nailing include shoulder pain, restriction of shoulder movement, and risk of delayed union (2). These are thought to be from the nail entry through the rotator cuff and its subsequent damage, damage to the articular cartilage covering the head of the humerus, as well as and subacromial impingement which leaves patients with residual shoulder pain and movement limitations post-surgery(11)(12). Two different nails are currently in use for humerus IMN fixation, straight nails and bent nails, which are differentiated by their shape as well as their entry points into the humeral canal (9).

1.3 Surgical technique/approach

Once indications for a humeral IMN insertion are met, a traditional approach for entry into the canal is undertaken (8). The patient is positioned supine or in a beach chair to allow for entry into the shoulder joint. This uses an anterolateral transdeltoid approach that ultimately results in exposure of the humeral head (8)(12) (see Figure 1.4). An initial incision to the subcutaneous tissue from the anterolateral acromion towards the deltoid insertion is made. The deltoid muscle is split and retracted, the deltoid bursa partially incised or resected and the supraspinatus tendon incised with a scalpel (8) (see Figure 1.5).

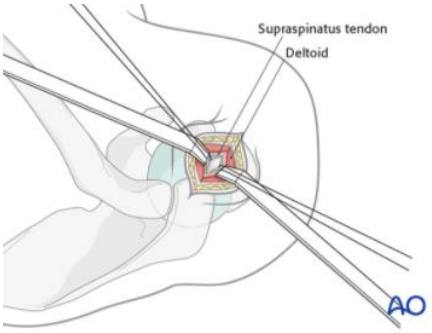


Figure 1.4: Anterolateral transdeltoid approach (8).

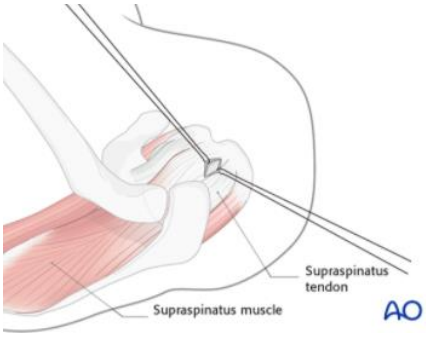


Figure 1.5: Supraspinatous incision through fibre (8).

The humeral head and its cartilage are then exposed and the entry is determined by the shape of the nail chosen (8). Bent nails, which are now less in use, would enter the canal medially so as to avoid the cartilage of the humeral head however, places the rotator cuff tendon and its footprint at risk for injury during nail placement (13).

Straight nails on the other hand are intended to lie under the rotator cuff, and are inserted through the fibres of the tendon, far from the rotator cuff footprint and more medially aligned to the humeral canal. In addition, they provide better bone stock around the nail and increase the strength and biomechanical stability of the nail (8)(13). A prospective study by Lopiz et al. showed that humeral shaft fractures fixed with a bent nail had 73% of patients with rotator cuff disease symptoms in comparison to 34.6% when a straight nail was used (internal fixation). The ideal entry is said to be just posterior to the longhead of the biceps tendon as this lies away from the supraspinatus foot print and additionally also preserves cartilage on the humeral head (8)(12).

It is important to note that the incision into the supraspinatous tendon should be made along its fibres for ease of repair and closure once the surgery is done. Protection of the supraspinatous tendon is achieved by making use of a sharp incision into the tendon fibres, ensuring that when reaming into the canal a tissue protector and careful passage through the tendon, further decreases risk of damage (8). Violation of the cuff has traditionally been mandatory and poses risk for future shoulder function. Its careful care as mentioned, lessens the risk for damage and improves better functional outcomes if well protected (8)(14). End to end closure (using non absorbable sutures) also encourages healing of the rotator cuff (8).

1.4 Measures of outcome

Shoulder Functional outcomes are measured using varying scoring systems (3)(15). Some of these scores include the American Shoulder and Elbow Scores (ASES), the Constant score and the Disabilities of the Arm Shoulder and Hand score (DASH) which are used interchangeably by the clinician (16). It was previously described that the use of IMNs showed a decreased functional outcome in comparison to plating, mostly attributed to complications related to antegrade nailing (11). A prospective study carried out on 47 participants showed that there was no significant difference in functional outcome at one year follow up in patients treated with IM nailing compared to plating (17). In addition, union rates and time to healing have all been reported as showing no difference for both anterograde nailing and plating (7)(26), in fact there has been an increase in non-union rates and complications in non-operative management, which is currently the gold standard for management.

Injury to rotator cuff and subsequent decrease in functional outcomes is a topic that has been debated for many years by many authors. Post-operative ultrasound investigations are often limited by mimics of teras, disruption of fibrillar matrix and heterogenous structures in scaring areas (2). Asymptomatic tears are far more common than clinically identified ones according to Muccioli et al. (18). Verdano et al. showed that 92% of patients with antegrade nails inserted had no significant clinical sonographic impact (2)(18). Full and deep supraspinatus tears were shown to have no functional impact on the shoulder and this was thought to be from one of three reasons: degenerative cuff lesions, pre-existing trauma that may well have been from the fracture itself and previous surgery (18). Insertion of the nail through the rotator cuff accounts for only fraction of the causes of shoulder pain (18).

Surgeons and their patients have begun having more in depth discussions surrounding management and the risks that exist amongst the options available (19). With the need to mobilise quicker, perform simple daily activities of living (ADLs), and a need for comfort, patients have found greater interests in IMN over conservative treatment and plating (20). With

this in mind, the surgeon's ability and experience coupled with the patient factors and requirements for less scarring and earlier return to mobility, intramedullary may soon become a more popular choice in future (22).

1.5 What is being changed?

Although not widely documented, the use of arthroscopy to assist with humeral nail insertion, allows for direct vision around the supraspinatus and humeral head (21). Results from Dedoeglu et al. showed that there were fewer functional complications when arthroscopy was used as opposed to conventional methods for antegrade nailing (21). In order to further decrease complication rates caused by antegrade nailing, third generation nails which are straight, shorter and smaller in diameter have been developed and have shown to have better outcomes than the first and second generation nails that were curved (1). When used in a in a multi-centre retrospective study they showed ultrasound, clinical and radiological features that conserved the rotator cuff in 88% of treated patients (11). Categorising nails into fixed- or bio-nails based on their interlocking mechanism of their opposite end to the entry portal, helps to make better nail choices tailored to the patient, selection of appropriate surgical techniques based on the nail choice as well as rehabilitation protocols post-operative (1).

1.6 Improved surgical technique

Clinical and functional outcomes post antegrade nailing are dependent on rotator cuff incision and nail insertion (15). Recent studies have shown that improving the surgical technique of antegrade nailing, lessens possible rotator cuff injuries (20)(22) Some of these techniques include anterior tendon splitting in line with fibres as described by Riemer et al., which showed excellent shoulder function results in comparison to lateral tendon splitting (11). Verdano et al. further described a method where a more medial incision in the vascularised cuff with appropriate suturing thereafter, preserved the cuff and lead to better healing (2)(20). A soft tissue sparing technique described by Giere et al. found that sparing the micro-circulature of the supraspinatus by soft tissue dissection did not lead to structural nature (23).

In addition to making the correct incision, the question to ream the canal is often left open as it has been beneficial in simple fracture patterns in long bones such as tibias and femurs where an enlarged canal that allows passage of a wider nail offers a stronger fixation and allows for earlier weight bearing (1). The humerus however is not a weight bearing bone and thus a wider nail does not hold as much importance (1). Reaming also further damages the rotator cuff if the surgeon begins reaming from outside the canal and reaming by-products may settle

underneath the rotator cuff, which may also be a contributor to the pathogenesis of post-operative shoulder pain (1)(18).

Intramedullary nailing is an under rated but soon becoming a popular method of surgical management for humeral shaft fractures (11)(13). Modifications in the surgical techniques and nail technology may well establish it as the preferred, gold standard of humerus fixation in the future; as its former reported disadvantages are being rectified with advances in medicine (25) .Our resource constraint environments will benefit from a method that decreases costs and proves to have the same functional outcomes as plating and now even non-operative treatment. Furthermore, injury to rotator cuff and shoulder instability, as has been evidenced, should no longer have bearing on making IMN inferior to other methods of management. Antegrade nailing performed with the correct tools and surgical technique is not solely responsible for shoulder pain (24)(25).

1.7 Problem statement

South African casualties are often overwhelmed with the burden of trauma. Fractures account for a large number of those cases and in particular, humeral fractures are prevalent. Humeral plating is the gold standard for operative management and although has better stability, place the patient at several intra and post of complications that may further burden the patient and the health system. The lack of beds in hospital, a need for the majority of our patients to return their jobs and a need to re-establish independence for survival, poses the question of whether the treatment of our humeral fractures (where indicated) is adequate in our third world setting with our ailing economy, unemployment and low health care resources. The correct use of humeral nailing may lessen the burden of prolonged hospital stays and decreased use of theatre time while equally promoting early return to function of patients.

1.8 Research Question

What is the functional outcome of humeral fractures fixed using antegrade humeral nails?

CHAPTER 2 - METHODOLOGY

2.1 Aim: To determine the post-operative functional outcomes of humeral shaft fractures fixed with intramedullary nails at Charlotte Maxheke Johannesburg Academic Hospital (CMJAH) and Chris Hani Baragwanath Academic Hospital (CHBAH)

2.2 Study Objectives:

- To assess the functional outcomes of antegrade humeral nails over a 48 month period (4 years)
- To establish average time to return to work or performance of ADLs
- To determine patient satisfaction post IMN

2.3 Research design: A retrospective review with a prospective recall of patients treated at CMJAH and CHBAH

2.4 Data Collection

2.4.1 Demographic

Data were collected from CMJAH and CHBAH between 30 June 2019 and 30 June 2023 on patients who met the inclusion criteria. Records were in the form of theatre record books at the various emergency and elective theatres at the respective theatre complexes. All patients that qualified for inclusion into our study had their x-rays reviewed *via* the Picture Archiving and Communication System (PACS). A total of 122 patients were selected. Only 94 patients had contact details attached to their profiles and 45 patients were reached with viable/working telephone numbers. Patient age, sex, handedness, and side of injury were recorded.

2.4.2 Return to ADLS

These patients were contacted telephonically and given appointment dates to be seen at the clinic, however due to financial and geographical constraints for a large majority of our patient cohort, in person, option was not feasible and we opted for telephonic consent and interview. The study was explained to the patient and voluntary participation was obtained. A consent form was signed (see Appendix C), and a unique study number was assigned to the participant. At the time of interviews, all patients were at a minimum three months post-surgery. Physical examinations were forgone and the use of descriptive terms was used to complete the questionnaires. On average telephonic consultations were roughly 7 – 10

minutes long depending on language barriers or clarity of the line. Questionnaire sheets were populated electronically on a code only accessible data bank (MS Word).

It is important to note that all eligible patients within the 4-year period were contacted telephonically for interviews. Although interval between surgery and interviews may vary for each patient, potentially affecting the scores obtained, we ensured that all patients were well beyond the 3-month mark (minimum) which is recognised for radiographic union and soft tissue healing. This was done to not undermine the validity of the answers given and that pain and function reflected patients with healed fractures.

2.4.3 Return to work

Patients were asked about the employment status pre- and post-fixation and documented as either employed or unemployed. Those who were employed were then sub-categorised into those doing manual labour (lifting of heavy objects, packing of goods etc.) and those who worked clerical jobs (little to no physical efforts required to carry out their job). Time to return to work was assessed as the amount of time it took patients to return to the previous employment post-surgery.

2.4.4 Patient Satisfaction

Patients were asked to comment on how they perceived their surgical outcome in general “are you happy with your surgery” those that had no issues were grouped into “very happy” and those that were not completely satisfied were then further probed on whether the lesser satisfaction was based on pain and its severity, the ability to return to independent ADLs and the ability to return to work. These were grouped into Happy, Satisfied or Unhappy (see Appendix A). All data collected were collated and securely kept on a Microsoft Excel Spreadsheet before data analysis.

2.5 Patient Selection Criteria

Inclusion criteria:

- Patients with humeral shaft (diaphyseal) fractures treated with IMN
- Patients aged over 18 years

Exclusion criteria:

- Patients with proximal and distal third humerus fractures

- Patients with neurological deficit at the time of injury (radial nerve palsy) that never improved
- Non unions related to injury

CHAPTER 3 - RESULTS

Data were de-identified and analysed using STATA version 15. A *p*-value of < 0.05 with a 95% confidence interval was considered statistically significant. Objectives and outcomes were measured as per Table 3.1 below:

Table 3.1: Statistical inference tests

Objectives	Data analysis
To establish average time to return to work or performance of ADLs	Summary of continuous variables was by the mean and the standard deviation. The Student's t-test compared time to return to work/ADLs between (a) sexes, (b) injury dominant side, (c) physiotherapy post-surgery, and (d) using analgesics since surgery. A one-way ANOVA compared time to return to work/ADLs by mechanism of injury. Pearson's correlation tested the association between time to return to work/ADLs and age.
To assess the functional outcomes of antegrade humeral nails over four-year period	A swimmers plot was used for response data. A one-way ANOVA compared age by functional outcomes. Chi-square tested the associations between functional outcome and sex, injury dominant side, physiotherapy post-surgery, using analgesics since surgery, and mechanism of injury.
To determine patient satisfaction post IMN	Frequencies and proportions gave summary. A one-way ANOVA compared age by patient satisfaction. Chi-square tested the associations between patient satisfaction and sex, injury dominant side, physiotherapy post-surgery, using analgesics since surgery, and mechanism of injury.

The estimated initial minimum data sample size was 139 participants to adequately power the study to 80%. This was however not feasible due to limitations in data collection process, our study managed to reach a sample size of 122 patients after the inclusion criteria.

3.1 Demographics

The average age of the 45 participants was 35 years with a majority being males (76%) who were employed (71%). Forty eight percent of the patients were employed as manual labourers and 16% worked clerical jobs. The majority were right-handed (73%) and had their injury on the right-hand side (78%), with just over two-thirds being injured on their dominant side. The most common method of injury was MVA (56%), followed by PVA (27%) (see Table 3.2).

Table 3.2: Demographics percentage distribution

	n	%
Sex		
Female	11	24.4
Male	34	75.6
Handedness		
Left	12	26.7
Right	33	73.3
Side of Injury		
Left	10	22.2
Right	35	77.8

Injury on Dominant Side		
No	14	31.1
Yes	31	68.9
Employment		
Unemployed	13	28.9
Employed	32	71.1
Mechanism of Injury		
MVA	25	55.6
PVA	12	26.7
GSW	6	13.3
FFH	2	4.4
Satisfaction		
Moderate	8	17.7
Good	29	64.4
Very Good	8	17.7

3.2 Average time to return to work or performance of ADLs

Participants took on average 7 weeks to return to work and 5 weeks to return to ADLs. The average Quick Dash score was 7.17, and the average VAS was 2.18 (see Table 3.3).

Table 3.3: Demographics

	n	Min	Max	Mean	SD
Age	45	19	76	34.53	14.20
Quick Dash Score	45	0	31.82	7.17	8.86
VAS	45	1	5	2.18	1.17
Time to return to work	29	4	20	6.55	3.07
Time to return to ADLs	45	3	8	4.62	1.25

3.3 Effect of demographics on RTW and performance of ADLs

Age was not significantly correlated with time to return to work (r = 0.205; p = 0.286) or time to return to ADLs (r = 0.217; p = 0.153). Return to work did not depend on sex, injury on dominant side, physiotherapy post-surgery and using analgesics since surgery. However, return to work differed significantly by mechanism of injury (p = 0.007). Those with a GSW took significantly longer to return to work compared to those with a MVA (p = 0.002) and PVA (p = 0.008). Return to ADLs did not depend on Injury on Dominant Side, Physiotherapy post-surgery, or Mechanism of Injury (see Table 3.4). However, females took significantly longer to return to ADLs compared to males (p = 0.023). There was also a trend towards those taking analgesics since surgery taking longer to return to ADLs (p = 0.067) (see Table 3.5).

Table 3.4: Effects of demographics on return to work

	Return to Work	*t*	*p*	*d*
Sex		0.58	0.284	0.25
Female	7.17 (2.54)			
Male	6.36 (3.24)			
Injury Dominant Side		-0.97	0.170	0.42
No	5.57 (0.79)			
Yes	6.86 (3.45)			
Physiotherapy post-surgery		-0.44	0.332	0.17
No	6.25 (2.09)			
Yes	6.76 (3.65)			
Analgesia since surgery		0.54	0.297	0.23
None	6.73 (3.19)			
Occasional	6.00 (2.77)			
Mechanism of Injury		6.25	**0.007***	0.34
MVA	5.57 (1.09)			

PVA	6.00 (1.52)
GSW	10.40 (5.94)

Note. For the variable Mechanism of Injury. A one-way ANOVA was run. The test statistics reported is F and the effect size is partial eta^2.

In terms of mechanism, falls from height only accounted for two participants and was not included as would not show any statistical significance.

Table 3.5: Effects of Demographics on ADL performance

	Return to ADLs	*t*	*p*	*d*
Sex		2.06	**0.023***	0.72
Female	5.27 (1.68)			
Male	4.41 (1.02)			
Injury Dominant Side		-0.44	0.332	0.14
No	4.50 (1.09)			
Yes	4.68 (1.33)			
Physiotherapy post-surgery		-0.33	0.370	0.11

No	4.53 (1.36)			
Yes	4.67 (1.21)			
Analgesia since surgery		-1.53	0.067	0.48
None		4.41 (1.02)		
Occasional		5.00 (1.55)		
Mechanism of Injury		1.60	0.214	0.07
MVA	4.52 (1.26)			
PVA	4.50 (1.00)			
GSW	5.50 (1.64)			

Note. For the variable Mechanism of Injury. a one-way ANOVA was run.

The test statistics reported is F and the effect size is partial eta^2.

3.4 Functional outcomes of antegrade humeral nails

Difficulty performing ADLs was not associated with age (see Table 3.6), sex (see Table 3.7), injury on dominant side (see Table 3.8), physiotherapy post-surgery (see Table 3.9), or mechanism of injury (see Table 3.11). However, difficulty performing all ADLs was associated with using analgesics since surgery – patients who used analgesics had greater difficulty compared to those who did not use analgesics (see Table 3.10).

Table 3.6: Quick Dash

	n	Age: Mean (SD)	*F*	*p*	Eta^2
Open Jar			0.90	.415	0.04
1 – No Difficulty	36	33.72 (15.05)			
2 – Mild Difficulty	8	39.63 (9.12)			
3 – Moderate Difficulty	1	23			
Heavy Chores			0.33	.720	0.02
1 – No Difficulty	21	32.76 (16.74)			
2 – Mild Difficulty	19	36.47 (12.42)			
3 – Moderate Difficulty	5	34.60 (9.37)			
Carry Bag			1.56	.222	0.07
1 – No Difficulty	26	33.12 (15.06)			
2 – Mild Difficulty	13	39.92 (13.98)			
3 – Moderate Difficulty	6	29.00 (6.93)			
Wash Back			0.20	.899	0.01
1 – No Difficulty	27	35.00 (6.73)			

2 – Mild Difficulty	15	34.53 (9.89)			
3 – Moderate Difficulty	2	27.00 (9.90)			
4 – Extreme Difficulty	1	37.00			
Recreational			0.69	.505	0.03
1 – No Difficulty	38	35.47 (14.82)			
2 – Mild Difficulty	5	31.40 (10.74)			
3 – Moderate Difficulty	2	24.50 (2.12)			
Limitations socially/family			0.37	.357	0.19
1 – No Difficulty	41	34.78 (14.48)			
2 – Mild Difficulty	4	32.00 (12.36)			
Limitations at work			1.87	.150	0.12
0 – not applicable (unemployed)	16	40.56 (20.09)			
1 – No Difficulty	19	29.58 (8.28)			
2 – Mild Difficulty	8	35.00 (7.29)			
3 – Moderate Difficulty	2	31.50 (12.02)			
Pain			0.61	.546	0.03

1 – No Difficulty	27	34.26 (14.47)			
2 – Mild Difficulty	15	36.60 (14.87)			
3 – Moderate Difficulty	3	26.67 (6.35)			
Night Pain			0.33	.718	0.02
1 – No Difficulty	35	34.11 (15.08)			
2 – Mild Difficulty	9	37.11 (11.19)			
3 – Moderate Difficulty	1	26.00			

Note: The variables *Use Knife* and *Tingling* were not included in the analyses as all 45 patients chose No Difficulty. For the variable Limitations socially/family, an independent sample t-test was run.

Table 3.7: ADLs by Sex

	Female	Male	*p*	*V*
Open Jar			.560	0.16
1 – No Difficulty	8	28		
2 – Mild Difficulty	3	5		
3 – Moderate Difficulty	0	1		
Heavy Chores				
1 – No Difficulty	4	17		

2 – Mild Difficulty	6	13		
3 – Moderate Difficulty	1	4		
Carry Bag			.284	0.24
1 – No Difficulty	5	21		
2 – Mild Difficulty	3	10		
3 – Moderate Difficulty	3	3		
Wash Back			.269	0.30
1 – No Difficulty	7	20		
2 – Mild Difficulty	3	12		
3 – Moderate Difficulty	0	2		
4 – Extreme Difficulty	1	0		
Recreational			.680	0.13
1 – No Difficulty	9	29		
2 – Mild Difficulty	1	4		
3 – Moderate Difficulty	1	1		
Limitations socially/family			.558	0.18

1 – No Difficulty	11	30		
2 – Mild Difficulty	0	4		
Limitations at work			.876	0.12
0 - not applicable (unemployed)	4	12		
1 – No Difficulty	5	14		
2 – Mild Difficulty	2	6		
3 – Moderate Difficulty	0	2		
Pain			.887	0.07
1 – No Difficulty	16	21		
2 – Mild Difficulty	4	11		
3 – Moderate Difficulty	1	2		
Night Pain			.206	0.27
1 – No Difficulty	8	27		
2 – Mild Difficulty	2	7		
3 – Moderate Difficulty	1	0		

Note. Fisher's Exact tests performed. The variables *Use Knife* and *Tingling* were not included in the analyses as all 45 patients chose No Difficulty.

Table 3.8: ADLs by Injury of Dominant Side

	Not Dominant Side	Dominant Side	*p*	*V*
Open Jar			.339	0.22
1 – No Difficulty	13	23		
2 – Mild Difficulty	1	7		
3 – Moderate Difficulty	0	1		
Heavy Chores			.273	0.24
1 – No Difficulty	7	14		
2 – Mild Difficulty	7	12		
3 – Moderate Difficulty	0	5		
Carry Bag			.203	0.27
1 – No Difficulty	9	17		
2 – Mild Difficulty	5	8		
3 – Moderate Difficulty	0	6		
Wash Back			.121	0.36
1 – No Difficulty	12	15		

2 – Mild Difficulty	2	13		
3 – Moderate Difficulty	0	2		
4 – Extreme Difficulty	0	1		
Recreational			.506	0.17
1 – No Difficulty	13	25		
2 – Mild Difficulty	1	4		
3 – Moderate Difficulty	0	2		
Limitations socially/family			.782	0.04
1 – No Difficulty	13	28		
2 – Mild Difficulty	1	3		
Limitations at work			.486	0.23
0 - not applicable (unemployed)	7	9		
1 – No Difficulty	5	14		
2 – Mild Difficulty	2	6		
3 – Moderate Difficulty	0	2		

Pain			.966	0.04
1 – No Difficulty	8	19		
2 – Mild Difficulty	5	10		
3 – Moderate Difficulty	1	2		
Night Pain			.256	0.25
1 – No Difficulty	13	22		
2 – Mild Difficulty	1	8		
3 – Moderate Difficulty	0	1		

Note. Fisher's Exact tests performed. The variables *Use Knife* and *Tingling* were not included in the analyses as all 45 patients chose No Difficulty.

Table 3.9: ADLs by Physiotherapy Post-surgery

	No Physiotherapy	Physiotherapy	*p*	*V*
Open Jar				
1 – No Difficulty	12	24	.755	0.11
2 – Mild Difficulty	3	5		
3 – Moderate Difficulty	0	1		
Heavy Chores			.777	0.11
1 – No Difficulty	7	14		
2 – Mild Difficulty	7	12		
3 – Moderate Difficulty	1	4		
Carry Bag			.630	0.14
1 – No Difficulty	10	16		
2 – Mild Difficulty	3	10		
3 – Moderate Difficulty	2	4		
Wash Back			.644	0.19
1 – No Difficulty	10	17		

2 – Mild Difficulty	5	10		
3 – Moderate Difficulty	0	2		
4 – Extreme Difficulty	0	1		
Recreational			.818	0.10
1 – No Difficulty	12	26		
2 – Mild Difficulty	2	3		
3 – Moderate Difficulty	1	1		
Limitations socially/family			.711	0.06
1 – No Difficulty	14	27		
2 – Mild Difficulty	1	3		
Limitations at work			.127	0.36
0 - not applicable (unemployed)	3	13		
1 – No Difficulty	7	12		
2 – Mild Difficulty	5	3		
3 – Moderate Difficulty	0	2		

Pain			.393	0.20
1 – No Difficulty	7	20		
2 – Mild Difficulty	7	8		
3 – Moderate Difficulty	1	2		
Night Pain			.284	0.24
1 – No Difficulty	12	23		
2 – Mild Difficulty	2	7		
3 – Moderate Difficulty	1	0		

Note. Fisher's Exact tests performed. The variables *Use Knife* and *Tingling* were not included in the analyses as all 45 patients chose No Difficulty.

Table 3.10: ADLs by Analgesic since Surgery

	No Analgesic	Analgesic	*p*	*V*
Open Jar			**<.001*** **	0.67
1 – No Difficulty	29	7		
2 – Mild Difficulty	0	8		
3 – Moderate Difficulty	0	1		
Heavy Chores			**.003** **	0.51
1 – No Difficulty	17	4		
2 – Mild Difficulty	12	7		
3 – Moderate Difficulty	0	5		
Carry Bag			**<.001*** **	0.56
1 – No Difficulty	21	5		
2 – Mild Difficulty	8	5		
3 – Moderate Difficulty	0	6		
Wash Back			**.012***	0.49
1 – No Difficulty	22	5		

2 – Mild Difficulty	7	8		
3 – Moderate Difficulty	0	2		
4 – Extreme Difficulty	0	1		
Recreational			**<.001*** **	0.58
1 – No Difficulty	29	9		
2 – Mild Difficulty	0	5		
3 – Moderate Difficulty	0	2		
Limitations socially/family			**.005** **	0.42
1 – No Difficulty	29	12		
2 – Mild Difficulty	0	4		
Limitations at work			**.008** **	0.51
0 - not applicable (unemployed)	7	9		
1 – No Difficulty	17	2		
2 – Mild Difficulty	5	3		
3 – Moderate Difficulty	0	2		
Pain			**<.001*** **	0.72

1 – No Difficulty	25	2		
2 – Mild Difficulty	3	12		
3 – Moderate Difficulty	1	2		
Night Pain			**<.001*** **	0.72
1 – No Difficulty	29	6		
2 – Mild Difficulty	0	9		
3 – Moderate Difficulty	0	1		

Note. Fisher's Exact tests performed. The variables *Use Knife* and *Tingling* were not included in the analyses as all 45 patients chose No Difficulty.

Table 3.11: ADLs by Mechanism of Injury

	MVA	PVA	GSW	*p*	*V*
Open Jar				.630	0.25
1 – No Difficulty	20	11	4		
2 – Mild Difficulty	4	1	2		
3 – Moderate Difficulty	1	0	0		
Heavy Chores				.409	0.30
1 – No Difficulty	14	5	2		
2 – Mild Difficulty	9	6	2		
3 – Moderate Difficulty	2	1	2		
Carry Bag				.310	0.33
1 – No Difficulty	16	7	3		
2 – Mild Difficulty	4	5	2		
3 – Moderate Difficulty	5	0	1		
Wash Back				.454	0.37
1 – No Difficulty	16	8	2		

2 – Mild Difficulty	6	4	4		
3 – Moderate Difficulty	2	0	0		
4 – Extreme Difficulty	1	0	0		
Recreational				.285	0.34
1 – No Difficulty	19	12	6		
2 – Mild Difficulty	4	0	0		
3 – Moderate Difficulty	2	0	0		
Limitations socially/family				.769	0.11
1 – No Difficulty	23	11	6		
2 – Mild Difficulty	2	1	0		
Limitations at work				.788	0.27
0 – No Limitations	11	4	1		
1 – Minimal Difficulty	10	5	3		
2 – Mild Difficulty	3	2	2		
3 – Moderate Difficulty	1	1	0		
Pain				.365	0.32

1 – No Difficulty	13	9	4		
2 – Mild Difficulty	11	2	1		
3 – Moderate Difficulty	1	1	1		
Night Pain				.642	0.24
1 – No Difficulty	19	11	4		
2 – Mild Difficulty	5	1	2		
3 – Moderate Difficulty	1	0	0		

Note. Fisher's Exact tests performed. The variables *Use Knife* and *Tingling* were not included in the analyses as all 45 patients chose No Difficulty.

The greatest difficulties in performing ADLs appeared to be heavy chores, washing back, carrying bag with injured arm, and pain (see Figure 3.1).

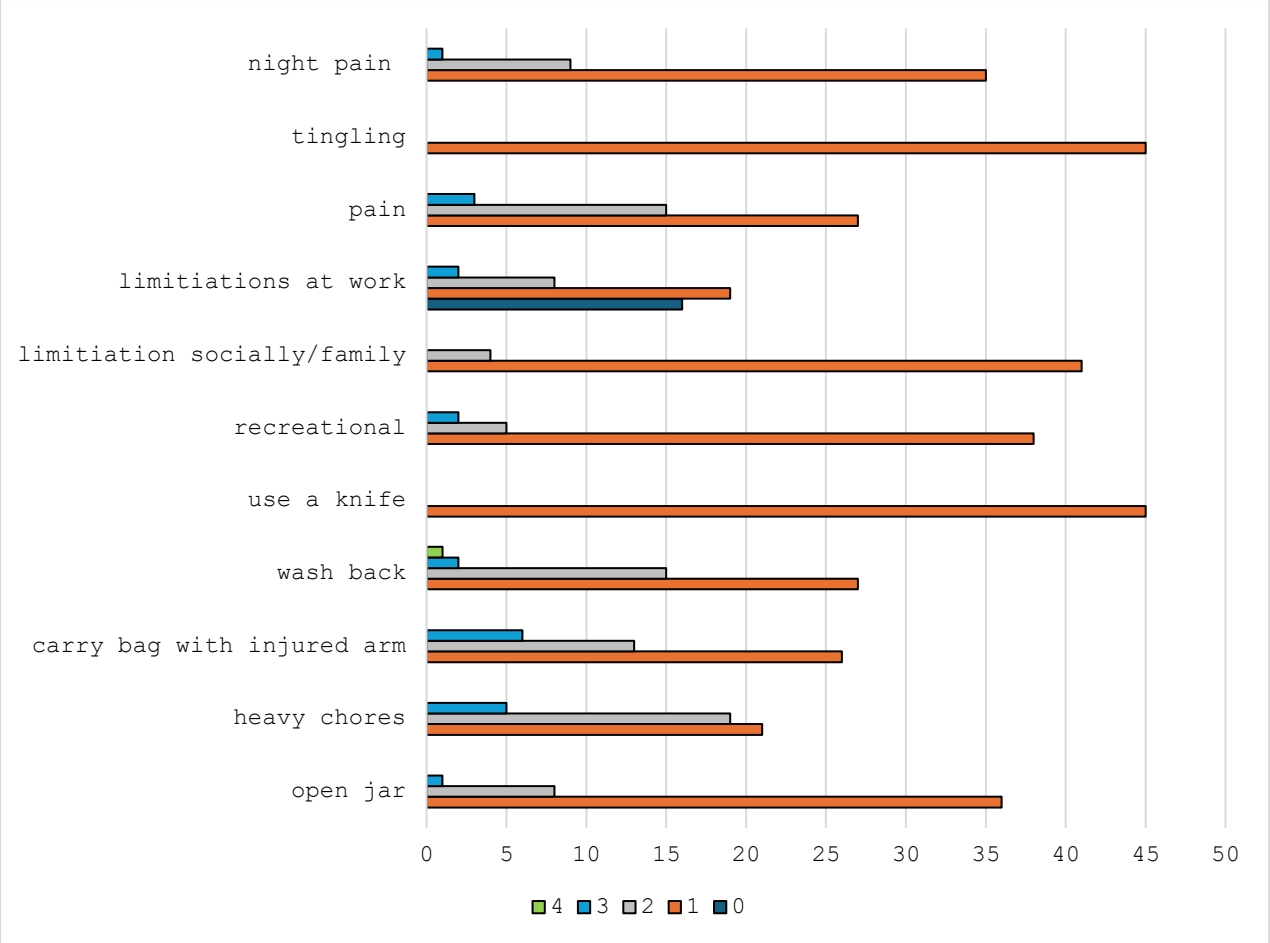


Figure 3.1: Horizontal bar graphical representation showing Quick Dash parameters with different scores: 0 = not applicable, 1 = no difficulty, 2 = mild difficulty, 3 = moderate difficulty, 4 = severe difficulty

3.5 Patient satisfaction post IMN

Patient satisfaction was not associated with age (see Table 3.12), sex, injury to dominant side, physiotherapy post-surgery or mechanism of injury (see Table 3.13). However, satisfaction was related to use of analgesics since surgery, hence, patients who did not use analgesics were more likely to be satisfied with the surgery they received in comparison to those who had not ($p < 0.001$).

Table 3.12: Patient satisfaction post IMN

	Age: Mean (SD)	*F*	*p*	Eta^2
Moderately happy	30.38 (9.27)	1.00	.376	0.05
Happy	36.76 (16.66)			
Very happy	30.63 (3.66)			

Table 3.13: Demographic effects on satisfaction post IMN

	Satisfaction			Test Statistics		
	Moderate	**Good**	**Very Good**	***X*^{2}**	***p***	***V***
Sex				0.004	.998	0.01
Female	2 (18.2%)	7 (63.6%)	2 (18.2%)			
Male	6 (17.6%)	22 (64.7%)	6 (17.6%)			
Injury Dominant Side				2.63	.269	0.24
No	1 (7.1%)	9 (64.3%)	4 (28.6%)			
Yes	7 (22.6%)	20 (64.5%)	4 (12.9%)			

Physiotherapy post-surgery				3.10	.212	0.26
No	4 (26.7%)	7 (46.7%)	4 (26.7%)			
Yes	4 (13.3%)	22 (73.3%)	4 (13.3%)			
Analgesia since surgery				18.01	**<.001*** **	0.63
None	0	22 (75.9%)	7 (24.1%)			
Occasional	8 (50%)	7 (43.8%)	1 (6.3%)			
Mechanism of Injury				2.80	.593	0.26
MVA	5 (20%)	17 (68%)	3 (12%)			
PVA	1 (8.3%)	7 (58.3%)	4 (33.3%)			
GSW	1 (16.7%)	4 (14.3%)	1 (16.7%)			

CHAPTER 4 - DISCUSSION

4.1 Demographics

This study showed a distribution in gender similar to literature (2, 4, 5) with males predominantly sustaining humeral shaft fractures secondary to MVA's. The average age affected in this study included participants in their 3rd decade which is no different to figures shown by Galusser et al. (28). Hand dominance is almost equally distributed in terms of site of injury (27) however, we found that almost 70% of patients injured their dominant hand. Employed participants in our cohort had a mean age in the 3rd decade which is much younger than what was described by Oliver et al. where the mean age was 47 years of age (27).

4.2 Demographic effects on RTW

Majority of patients who were employed were able to return to work post IMN albeit with mild difficulty with lifting heavy objects, our cohort showed that all 32 patients that were employed returned to work at an average time of seven weeks – almost half of what is recorded in literature by Oliver et al. that showed that 85% of their cohort were able to return to work between 12 –14 weeks post-injury and only 60% of those patients returned on a fulltime basis (27). Their study also showed that older age, female sex with right hand predominance with presence of comorbidities were factors associated with RTW in a single study (27). Factors, which played no significance in our study. We did find, however, that there was a correlation between RTW and Mechanism of injury that was associated with delays in RTW, notably GSW. No studies have recorded this particular demographic and its effect to RTW in literature, however GSW are known to cause severe soft tissue injury due to the large dissipated Kinetic energy on contact and can perhaps render an explanation for its effect (29).

4.3 Demographic effects on ADLs (see Tables 3.4 to 3.13)

With reference to effects on demographics on ADSL's (sex, injury dominant side, physical therapy post-surgery, use of analgesia post-surgery and the mechanism of injury) participants who were female or had ongoing use of analgesia were found to have longer times to return to ADLs compared to their counterparts. There are very studies reporting on the independent return of ADLs post-humeral shaft fracture and in particular, those with the demographics described in this study for comparison. All other demographics had no effect on return to ADLs.

4.4 Patient satisfaction post IMN

Patient satisfaction with surgery was based on persistent pain post-operatively (beyond expected union time of six weeks), ability to return to independent ADLS as well as RTW. Our study found that over 80% were happy with their surgical outcome and noted that they were either very happy or happy. Of those that rated their surgical outcome as moderately happy had based it on going pain or difficulties with completing ADLs when compared to those that were happy. All eight of the 45 patients that rated their surgical outcome as moderate required analgesia use due to pain. Of those that were employed, 100% returned to work within the same mean time of seven weeks as those who were happy with their surgeries. Demographics such as age, sex, injury to dominant side, use of physiotherapy or mechanism of injury had no effect on satisfaction.

4.5 DASH and VAS scores

4.5.1 DASH scores

No actual range exists for interpretation of the DASH score but its developers note that the closer to 0 the score is, the less the disability incurred, and the converse lies where score closer to 100 were interpreted as severe disability in the affected limb. Our cohort of patients showed that the average DASH score was roughly 7 which is way below the scores ranging from 10 to 29 thought to be found in patients who were at a point where they were ready for discharge or considered the limitation they had as non-problematic (28). No patient scored above 40 which is interpreted as patients who are considered to have difficulty with carrying out tasks

4.5.2 VAS scores

VAS score interpretation is based on cut-offs identified on the 100 mm VAS scale. With the average VAS score being 2, this showed that on average patients had no pain to mild pain post-surgery and may well explain the ability to return to previous employment. When probed about pain in those who had higher VAS scores, patients also expressed that pain was mostly along the diaphysis of the humerus (around the fracture site) and not at the shoulder as would be expected in patients with humeral IMNs as this has often been associated with iatrogenic rotator cuff injuries and long term dysfunction.

4.6 Recommendations

Based on the results in this study, the following recommendations can be made:

- Deductions can be made from study results that use of humeral IMNs have mild effects on the functional outcomes of patients being treated with them however due to the small cohort, we recommend that a larger sample size be used in further research and that higher evidence level be achieved by making it a prospective study.
- Pain scores post-surgery are on average in the range of none to mild pain and where surgical intervention needs to be undertaken, the use of an IMN is a suitable fixation option. With this, patient satisfaction should be better assessed with a validated scoring scale that focuses purely on patient satisfaction and not on function as in the case with many of the existing scores.
- With comparable RTW times as seen in literature, patients are able to continue with their day to day basic and complex ADLs with minimal impairment to how they are carried out. We recommend however that the reasons for RTW be documented better in future studies to see the drivers behind patients RTW times

4.7 Limitations

4.7.1 Sample size

A small sample size of only 45 patients makes for difficult extrapolation of statistical analysis on the general population. This then affects the confidence intervals we can implore based on this data. The sample also only included patients from two facilities in the Johannesburg region

4.7.2 Bias

Unintentional selection bias in data collection as patients seen were all those that were already admitted to the facilities and required surgical intervention.

4.7.3 Data collection

Poor data capturing played a role in ability to reach patients as both health institutions made use of paper based record keeping of patient details. Patients in our cohort are also predominately of lower socio economic status or from migrant provinces and could not finance additional trips to the hospital for in person interviews. Due to this, data were collected telephonically with consents obtained in the same manner.

Data collection via telephones means was previously thought to be inadequate as previous authors thought that face to face interactions were better. Glogowska et al. showed good evidence in support of telephonic interviews as a form of legitimate data collection (30). The data is comparable to face to face interviews is more cost effective allows for minimum disruption during the interview process and also takes away any emotional (anxiety) around doing face to face interviews.

CHAPTER 5 - CONCLUSION

Our study has demonstrated that using intramedullary nailing for humeral shaft fracture fixation yields comparable outcomes to existing data. Additionally, the return-to-work time was shown to be shorter than the expected duration observed in the literature, and the VAS scores are well within the range for functional use with minimal pain. The use of intramedullary nailing has frequently been linked to post-surgical shoulder impingement and our study showed that this is not as high as what was previously expected in literature. Humeral nail fixation shows benefit in allowing patients earlier function of their affected limb with little influences from their age, hand dominance and employment type.

REFERENCES

1. Garnavos C. Diaphyseal humeral fractures and intramedullary nailing: Can we improve outcomes? Indian J Orthop. 2011;45(3):208–15.

2. Verdano MA, Pellegrini A, Schiavi P, Somenzi L, Concari G, Ceccarelli F. Humeral shaft fractures treated with antegrade intramedullary nailing: What are the consequences for the rotator cuff? Int Orthop. 2013;37(10):2001–7.

3. Rajagopa HP, Madan Mohan M, Pilar A, Tamboowalla KB. Functional outcome of antegrade interlocking intramedullary nailing for humeral shaft fractures. Int J Res Orthop. 2017;3(6):1127–31.

4. Rosana N, Matzopoulos R, Groenewald P, Bradshaw D. The high burden of injuries in South Africa. Bull World Health Organ. 2007;85(8):695–702. .

5. Singaram S, Naidoo M. The physical impact of long bone fractures on adults in KwaZulu-Natal. S Afr J Physiother. 2020;76(1):1393.

6. Bisaccia M, Meccariello L, Rinonapoli G, Rollo G, Pellegrino M, Schiavone A, et al. Comparison of Plate, Nail and External Fixation in the Management of Diaphyseal Fractures of the Humerus. Med Arch. 2017;71(2):97–102.

7. Chaudhuri A, Dasgupta S, Datta S, Ghosh S, Halder T, Mitra U. Comparative study of operative treatment of mid shaft fracture of humerus by locking plate versus intramedullary interlocking nail. Med J DY Patil Univ. 2013;6(4):390–4.

8. AO Surgical refernce Humeral nailing [Internet]. Available from: surgeryreference.aofoundation.org [Date accessed: 16-10-2024].

9. Singisetti K, Ambedkar M. Nailing versus plating in humerus shaft fractures: A prospective comparative study. Int Orthop. 2010;34(4):571–6.

10. Mehmet E, Ahmet K, Fatih E, Orçun T, Didem V. Y, Salih Ç, Hasan H. Biomechanical effects of the distance from the fracture zone to the interlocking fixation screw of intramedullary nail. J Biomech. 2011;44(1):ee1–e21.

11. The anterior acromial approach for antegrade intramedullary nailing of the humeral diaphysis. Orthopedics. 1993;16911):1219–23.

12. Anterolateral transdeltoid approach for antegrade nailing [Internet].Available from: https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/humeral-shaft/approach/anterolateral-transdeltoid-approach-for-antegrade-nailing.[Date accessed: 16-10-2024].

13. Sears BW, Johnston PS, Garrigues GE, Boileau P, Hatzidakis AM, . Intramedullary nailing of the proximal humerus—not just for 2-part fractures. Ann Joint. 2020;5:32.

14. Cocco LF, Ejnisman B, Belangero PS, Cohen M, dos Reis FB. Quality of life after antegrade intramedullary nail fixation of humeral fractures: a survey in a selected cohort of Brazilian patients. Patient Saf Surg. 2018;12(1):4.

15. Pogliacomi F, Devecchi A, Costantino C, Vaienti E. Functional long-term outcome of the shoulder after antegrade intramedullary nailing in humeral diaphyseal fractures. Chir Organi Mov. 2008;92(1):11–6.

16. McClure P, Michener L. Measures of adult shoulder function: The American Shoulder and Elbow Surgeons Standardized Shoulder Form Patient Self-Report Section (ASES), Disabilities of the Arm, Shoulder, and Hand (DASH), Shoulder Disability Questionnaire, Shoulder Pain and Disability Index (SPADI), and Simple Shoulder Test. Arthritis Care Res. 2003;49(S5):S50–8.

17. Changulani M, Jain UK, Keswani T. Comparison of the use of the humerus intramedullary nail and dynamic compression plate for the management of diaphyseal fractures of the humerus. A randomised controlled study. Int Orthop. 2007;31(3):391–5.

18. Muccioli C, Chelli M, Caudal A, Andreani O, Elhor H, Gauci MO, et al. Rotator cuff integrity and shoulder function after intra-medullary humerus nailing. Orthop Traumatol Surg Res. 2020;106(1):17–23.

19. Spiguel AR, Steffner RJ. Humeral shaft fractures. Curr Rev Musculoskelet Med. 2012;5(3):177–83.

20. Metsemakers WJ, Wijnen V, Sermon A, Vanderschot P, Nijs S. Intramedullary nailing of humeral shaft fractures: failure analysis of a single centre series. Arch Orthop Trauma Surg. 2015;135(10):1391–9.

21. Dedeoğlu SS, İmren Y, Çabuk H, Tekin AÇ, Kır MÇ, Gürbüz H. Arthroscopy-assisted versus standard intramedullary nail fixation in diaphyseal fractures of the humerus. J Orthop Surg (Hong Kong). 2017;25(3):230949901772794.

22. Mocini F, Rovere G, De Mauro D, De Sanctis EG, Smakaj A, Maccauro G, et al. Newer generation straight humeral nails allow faster bone healing and better functional outcome at mid-term. J Orthop Surg Res. 2021;16(1):631.

23. Gierer P, Scholz M, Beck M, Schaser KD, Vollmar B, Mittlmeier T, et al. Microcirculatory sequelae of the rotator cuff after antegrade nailing in proximal humerus fracture. Arch Orthop Trauma Surg. 2010;130(5):687–91.

24. Flinkkilä T, Hyvönen P, Siira PT, Hämäläinen M. Recovery of shoulder joint function after humeral shaft fracture: A comparative study between antegrade intramedullary nailing and plate fixation Arch Orthop Trauma Surg. 2004;124(8):537–41.

25. Pidhorz L. Acute and chronic humeral shaft fractures in adults. Orthop Traumatol Surg Res. 2015;101(1 Suppl):S41–9.

26. Wang Y, Kayastha Y, Cao Y, Guo Z, Yuan Y, Bi Y. Outcome of Humeral Shaft Fracture Treated with Intramedullary Nail and Plate Fixation. J Coll Physicians Surg Pak. 2020;30(1):73–8.

27. Oliver WM, Molyneux SG, White TO, Clement ND, Duckworth AD. Return to work and sport after a humeral shaft fracture. Bone Jt Open. 2022;3(3): 236–44.

28. Gallusser N, Barimani B, Frédéric Vauclair F. Humeral shaft fractures. EFORT Open Rev. 2021; 6(1): 24–34.

29. Stefanopoulos PK, Pinialidis DE, Hadjigeorgiou GF, Filippakis KN. Wound ballistics 101: the mechanisms of soft tissue wounding by bullets. Eur J Trauma Emerg Surg. 2017;43(5):579–86.

30. Margaret Glogowska, Pat Young and Lesley Lockyer, **Propriety, process and purpose: considerations of the use of the telephone interview method in an educational research study**Higher Education Vol. 62, No. 1 (July 2011), pp. 17-26 (10 pages) Published By: Springer Nature

APPENDIX A: RESEARCH QUESTIONNAIRE

Participant study number	
Date of surgery	
Humerus nailed (Side)	
Hand dominance	

Employment status

Employed ☐ Unemployed ☐

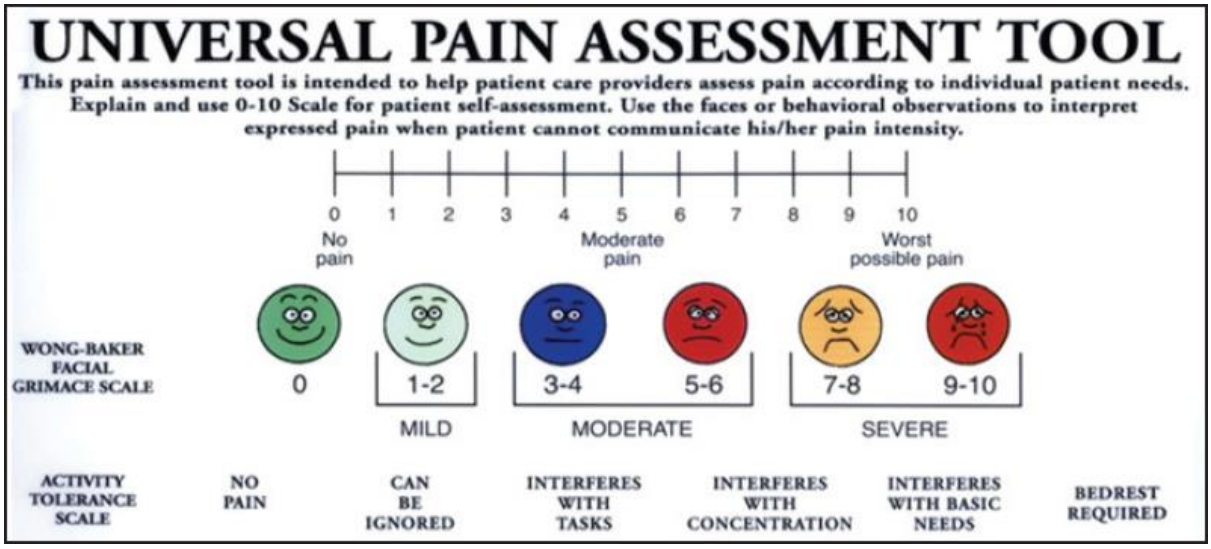
Nature of job (e.g. Manual labour, desk/clerical job)

Manual labour ☐

Clerical job ☐

N/A ☐

How much do you still have post the surgery in your shoulder (using universal pain assessment tool)



0 pain	
1 – 2 pain (mild)	
3 – 4 pain (moderate)	
5 – 6 pain (moderate)	
7 – 8 pain (severe)	
9 – 10 pain (severe)	

Time taken to return to independent ADLs post-surgery

0 – 4 weeks	
4 – 6 weeks	
6 – 8 weeks	
8 –- 10 weeks	
>12 weeks	

Time taken to return to work post-surgery

0 – 4 weeks	
4 – 6 weeks	
6 – 8 weeks	
8 – 10 weeks	
10 – 12 weeks	
Over 12 weeks	

Surgery satisfaction (patient perception of surgical outcome based on pain and function)

Very happy (near normal/baseline, no pain, no work limitations) ☐

Happy (able to carry out majority of normal functions with minimal pain, minimal limitations at work) ☐

Satisfied (carry out functions but moderate pain, moderated limitations at work) ☐

Unhappy (loss of function and normalcy with severe pain, unable to work) ☐

APPENDIX B: QUICK DASH QUESTIONNAIRE

THE QuickDASH OUTCOME MEASURE

INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* of which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

QuickDASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

QuickDASH DISABILITY/SYMPTOM SCORE = $\left(\left[\frac{\text{(sum of n responses)}}{n}\right] - 1\right) \times 25$, where n is equal to the number of completed responses.

A QuickDASH score may <u>not</u> be calculated if there is greater than 1 missing item.

APPENDIX C: STUDY INFORMATION DOCUMENT

Study title: **The functional outcomes of intramedullary nails in humeral shaft fractures in two urban public health facilities in South Africa**

Thank you very much for taking your time to consider involvement in this research study.

Introduction:

I, Mmangaliso Maseko, am a post-graduate student at the University of the Witwatersrand. I am doing research on "**The functional outcomes of intramedullary nails in humeral shaft fractures in two urban public health facilities in South Africa**". Research is a process used in seeking new knowledge in an attempt to improve care for future similar patients. In this study, we want to learn the use of humeral nailing still causes a significant decrease in shoulder function due to possible rotator cuff injury. We hope to show that its use is more cost effective, has fewer complications and placed correctly, has far less rotator cuff injuries making it a possible better option for surgical fixation

Invitation to Participate: We are asking for your permission to be included in the research study.

What is involved in the study?

1. The reason for requested participation in the study is based on the participant having sustained a humeral shaft fracture that was treated with a humeral nail.
2. The study will retrospectively assess the X-rays of the patient from admission as well as post operatively. The patient will then be called back for a routine follow-up visit, where the study will be discussed with the family and if they are willing to participate, an informed consent will be signed.
3. Each appointment will take roughly 20 minutes of the patient's time
4. A hardcopy questionnaire will be completed by the examiner for all patients. Questions will attempt to seek information around the clinical function as well as social impact of the injury on the patient
5. A physical examination of the shoulder (both operated and non-operated) will be performed
6. Information attained will be converted into an excel spreadsheet and viewed relevant results added to the collective and compared to available literature.

There are no risks associated with being included in the study.

Benefits of being in the study: There is no direct benefit for the patient of being involved in the study. The longer-term objective is the possibility of using nails more frequently in our health care facilities to lessen the length of stay in hospital, less soft tissue injury and maintain normal function post operatively

Any pertinent information on the study while involved in the project and after the results are available will be made available to the participant if requested.

Participation is voluntary, refusal to participate will involve no penalty and the participant may discontinue participation at any loss of benefits to which the Participant is 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 the Participant specifically consents to its retention.

Confidentiality: Personal information will be treated in the strictest confidence and will only be available to the Principal Investigator (PI) and his/her Supervisor. 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

If results are published, this may, exceptionally, lead to cohort, or more rarely, individual identification. All data collected in the course of the study will be securely retained for two (2) years, if a scientific publication arises from the study and six (6) years, if there is no publication. Thereafter it will be destroyed accordingly.

Contact details of researcher/s:
Dr Mmangaliso Maseko, Principal Investigator, telephone no. 074 217 6710, or by e-mail at ymmaseko@gmail.com

Dr I. Egbunike, Primary Supervisor, on telephone no. 076 896 7759, or by e-mail at iegbunike@yahoo.com

Dr M. Jingo, Co-Supervisor, on telephone no. 011 717 2202, or by e-mail at Maxwell.Jingo@wits.ac.za

Contact details of HREC administrator and chair – for reporting of complaints / problems.
This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("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

Thank you for reading this Study Information Sheet.

APPENDIX D: PATIENT CONSENT

WITS UNIVERSITY

PARTICIPANT CONSENT SHEET

The functional outcomes of intramedullary nails in humeral shaft fractures in two urban public health facilities in South Africa

1. I have been given a Participant Information Sheet which explains the nature and processes involved in this study, which is attached hereto;
2. I was given time to read it, or had it read to me, in the language I best understand;
3. I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
4. I believe I fully understand why the study is being conducted and what the intended outcomes will be;
5. I understand that there will be no immediate benefit to me, should I agree to participate, nor will I receive any payment; conversely, participation will not cost me anything but my time;
6. I understand that, even if I initially consent to take part in the study, I may subsequently withdraw at any time and would not be required to give any reasons; if that happened, any data collected about me for the purposes of the study would immediately be destroyed, unless I give consent for it to be retained
7. I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study, I am free to speak to any of these contacts.

Contact details:

Dr Mmangaliso Maseko, Principal Investigator, telephone no. 074 217 6710, or by e-mail at ymmaseko@gmail.com,

Dr I. Egbunike, Primary Supervisor, on telephone no. 076 896 7759, or by e-mail at iegbunike@yahoo.com

Dr M. Jingo, Co-Supervisor, on telephone no. 011 717 2202, or by e-mail at Maxwell.Jingo@wits.ac.za

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.
Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Name of Participant: _____

Date: _____

Place: _____

Signature or mark/Telephonic consent _____

Witnessed by:

Name of Witness: _____

Signature: _____

Date: _____

APPENDIX E: HREC ETHICS CERTIFICATE

M221023 MED22-05-099

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Mmangaliso Maseko

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M221023 MED22-05-099

NAME: (Principal Investigator)	Dr Mmangaliso Maseko
DEPARTMENT:	Orthopaedic Surgery Charlotte Maxeke Johannesburg Academic Hospital Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The functional outcomes of intramedullary nails used in humeral shaft fractures in two urban public health facilities in South Africa
DATE CONSIDERED:	28/10/2022
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Ike Egbunike
APPROVED BY:	Dr C Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	24/04/2023 **EXPIRY DATE:** 24/04/2028

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

DECLARATION OF INVESTIGATORS

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report** in October each year until study is closed. Failure to submit annual report will result in ethics clearance certificate suspension. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed October and will therefore be due in the month of October each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical). Login to upload signed copy of this ethics clearance certificate prior to commencing with the study https://www.witsethics.co.za/login.aspx

Principal Investigator Signature

3 May 2023
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX F: HOSPITAL CEO PERMISSION LETTERS (CMJAH & CHBAH)

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL (CMJAH)
OFFICE OF THE CLINICAL DIRECTOR

Enquiries: *Ms N. Mzila*
Email: Nolwazi.Mzila@gauteng.gov.za
Tel: *011 488 3365*
Ref: *1/7/2*
Date: 14 March 2023

GP_202208_045

Dear Mmangalios Maseko

RE: PROVISIONAL APPROVAL OF STUDY

TITLE: THE FUNCTIONAL OUTCOMES OF INTRAMEDULLARY NAILS USED IN HUMERAL SHAFT FRACTURES IN TWO URBAN PUBLIC HEALTH FACILITIES IN SOUTH AFRICA

Permission to conduct the above-mentioned study is provisionally granted subject to:

1. Submitting an Ethics Clearance Certificate from the University of Witwatersrand Human Research and Ethics Committee (HREC).

Please submit the above documents at your earliest convenient within 3 months from the date of this letter. This will prompt the Chief Executive Officer (CEO) of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) to grant you a final approval. It is important to note that your research can only commence once a final approval is granted. Failure to comply with the above-stated requirements may result in the withdrawal of your application.

Supported / ~~Not Supported~~
Signed by:Patricia Nokukhanya Africa
Signed at:2023-03-15 08:30:10 +02:00
Reason:Witnessing Patricia Nokukhanya

Dr P. Africa
Acting Clinical Director

Approved / ~~Not Approved~~
Signed by:Gladys Magugudi Bogoshi
Signed at:2023-03-15 11:20:47 +02:00
Reason:Witnessing Gladys Magugudi Bo

Ms G. Bogoshi
Chief Executive Officer: CMJAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 23nd August 2022

TITLE OF PROJECT:

The Functional outcomes of intramedullary nails used in humeral shaft fractures in two urban public health facilities in South Africa.

UNIVERSITY: Witwatersrand

Principal Investigator: Dr M Y Maseko

Department: Orthopaedic Surgery

Supervisor : Dr I Egbunike

NHRD Number: GP_202208_045

Permission Head Department (where research conducted): Yes

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Academic Hospital. The CEO / management of Chris Hani Baragwanath Academic Hospital is accordingly informed and the study is subject to:-

- **Permission having been granted by the Committee for Research on Human Subjects of the University of Witwatersrand.**
- The Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee Approval.

.....
Recommended
(On behalf of the MAC)
Date: 23/08/2022

.....
Approved/~~Not Approved~~
Hospital Management
Date: 24/08/22