

**IN-HOSPITAL POSTOPERATIVE MORTALITY OF ELDERLY PATIENTS WITH PROXIMAL FEMUR FRACTURES IN A SOUTH AFRICAN SETTING**

By

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As the candidate's supervisor I have/have not approved this thesis for submission.

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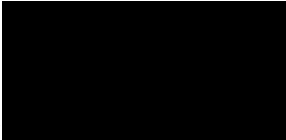
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## Overview of the thesis

Epidemiological studies project that the incidence of proximal femur fractures in the elderly will triple within the next 30 years. This is due to a projected increase in population size as well as improvement of life expectancy. The World Health Organization in their 2015 report called for plans to prevent and manage fragility fractures in Sub-Saharan Africa. Historically fragility fractures of the hip were lower in black Africans compared to Europeans, but recent literature shows an increasing incidence. These fractures are associated with significant morbidity and mortality despite ongoing efforts to improve outcomes. To improve outcomes, the American Academy of Orthopaedic Surgeons clinical practice guidelines recommend, a multidisciplinary approach, a 48-hour window for surgical fixation, thromboprophylaxis as well as osteoporosis management.

In-hospital mortality in elderly patients with proximal femur fractures ranges between 1-10% and is usually higher in men. It increases to 26-33% at 1 year and approaches 50% at 48 months. A recent study in Free State, South Africa showed a higher mortality rate compared to international studies. In our resource constrained healthcare system, there are often long delays before surgery due to a high trauma burden. This study's primary aim was to determine the in-hospital mortality rate of surgically treated elderly ( $\geq 65$  years) patients with proximal femur fractures. Secondary aims were to critically analyse the subpopulation that died and review the management of these fractures in a busy orthopaedic unit in rural KwaZulu Natal, South Africa

We performed a retrospective analysis of the data collected from the clinical records of all deceased elderly patients with proximal femur fractures who underwent surgery at our hospital from 01 January 2017 to 31 December 2021. The in-hospital mortality rate, time from injury to

admission, admission to surgery and from surgery to death were assessed. Additionally, the workup for osteoporosis, and multidisciplinary approach to this subset of patients were evaluated.

Out of 358 patients who underwent surgery during the study period, 24 died in the same admission resulting in an in-hospital mortality rate of 6,7%. All the deceased patients sustained fractures due to low-energy falls. 62,5% were females. No multidisciplinary approach and apart from one patient, a cause of the fragility fracture was never actively sought.

The median age was 70 years (IQR 66-81). 66,67% had right proximal femur fractures. 50% had neck of femur fractures and the rest were pertrochanteric. 50% had surgical fixation and the rest had arthroplasty. The median time from injury to admission was four days (IQR 2-19), from admission to surgery was seven days (5-26) and from surgery to death was four days (IQR1-22). The median duration of surgery was 90 minutes (IQR 65-155) and there was a moderate negative correlation between the duration of surgery and age ( $r=-0,37$ ).

We found an in-hospital mortality rate of 6,7% which is in keeping with the global trend. Delays in both injury-to-admission and admission-to-surgery intervals may contribute to this mortality. The absence of a fragility fracture workup and subsequent medical treatment highlights potential gaps in current practices. In keeping with other South African studies, there are still long delays to surgery for these fractures and urgent attention to reducing waiting times and implementing multidisciplinary approaches may be crucial in enhancing the overall management and outcomes of elderly patients with proximal femur fractures.

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## Part 1: The Review of Literature

It is estimated that the incidence of proximal femur fractures globally will triple by 2050, <sup>1,2</sup> with Hawley et al. making similar projections for South Africa. The World Health Organization in their 2015 report called for plans to prevent and manage fragility fractures in Sub-Saharan Africa.<sup>3</sup> Even in developed countries, 30-day mortality has remained largely unchanged in the past decade and despite ongoing work to improve outcomes most patients never recover their quality of life or independence with the mortality rate remaining high for up to 5 years post-operatively. This signifies that continued work needs to be done to improve outcomes.<sup>4,5</sup>

Fractures of the proximal femur in the elderly are generally fractures of fragility secondary to minimal trauma largely caused by osteoporosis.<sup>6</sup> Up to 95% of these fractures include neck and pertrochanteric fractures with the remaining 5% being subtrochanteric.<sup>2</sup> The lifetime risk for a hip fracture ranges from 11-23 % and is higher in women but this gender difference tends to become negligible with increasing age.<sup>7</sup> Historically the incidence of fragility fractures of the hip were lower in black Africans compared to Europeans, but recent literature shows an increasing incidence.<sup>8</sup>

In-hospital mortality in elderly patients with proximal femur fractures ranges between 1-10% and is usually higher in men. It increases to 26-33% at 1 year and approaches 50% at 48 months. <sup>3,4,5</sup> A study by Du Toit et al. in 2018 showed higher mortality rates in Free State, South Africa

compared to international studies, but this study only analyzed patients managed with hemiarthroplasty.<sup>9</sup> The causes of early mortality in proximal femur fractures are well documented in the first world but not in Sub-Saharan Africa. There is a need for more studies on this subset of patients to provide a framework for health policy and allocation of resources.<sup>10</sup>

Multiple studies abroad and locally have shown a poor effort at diagnosing and managing osteoporosis in proximal femur fractures in the elderly with only 2% to 8% of these patients being referred for osteoporosis treatment.<sup>11,12</sup> As osteoporosis is the main cause of proximal femur fractures in the elderly, it is imperative that this diagnosis is actively sought, and appropriate treatment instituted along with prompt fracture management at the initial admission. The American Academy of Orthopaedic Surgeons clinical practice guidelines recommend a multidisciplinary approach, a 48-hour window for surgical fixation, thromboprophylaxis as well as osteoporosis management. The suggested workup for secondary osteoporosis in all patients should include a full blood count, urea and electrolytes, liver function tests, calcium, phosphate and magnesium, parathyroid hormone as well as 25-hydroxy vitamin D (25 OHD) levels. This comprehensive approach has been shown to decrease mortality and morbidity and prevent subsequent fragility fractures.

Although mortality is affected by time to surgery, it is also affected by too many other confounders.<sup>4</sup> In 2010, A meta-analysis by Simunovic et al. showed a significant association between surgical delay and increased in-hospital mortality despite accounting for confounders. Other studies have also shown a direct increase in mortality in patients operated after 48 hours with a higher mortality both in-hospital and up to 1 year. Pioli in a prospective observational study reported that the 1-year mortality risk increased by 12% per day of surgical delay.<sup>12,13</sup> Paruk et al.

in a cohort study of 200 patients in 5 Durban hospitals showed a median time to surgery of 19,0 days (IQR 12,3-25,0) and a mortality rate of 13% at 30 days and 33,5% at 365 days.<sup>14</sup>

Delaying surgery is sometimes necessary to medically optimize patients, this delaying of surgery in high-risk patients has been shown to improve mortality rates.<sup>15,16</sup> Patients delayed more than seven days usually have serious medical problems and the observed rise in mortality in this subgroup might be related to the comorbidities and not the prolonged time to surgery.<sup>17,18</sup> The presurgery waiting time should only be allowed for medical management of unstable or uncontrolled co-morbid conditions.

In-hospital mortality is determined largely by the prehospital status of the patient and an objective measure of this for all patients may help improve mortality rates.<sup>19</sup> Prehospital status may be assessed using the Physical Self-Maintenance Scale (PSMS) and the Lawton Instrumental Activities of Daily Living scale (IADL), which have good inter-rater reliability (0.87 and 0.91, respectively).<sup>15,19</sup> Comorbidities commonly associated with increased mortality include renal failure, heart failure, anaemia, lung tumour, asthma, delirium at admission and/or post-operatively, male gender, and increasing age.<sup>20</sup> Parkers mobility score and a comorbidity index are reliable predictors of in-hospital mortality and long-term mortality.<sup>21,22</sup>

The purpose of this retrospective cohort study was to determine the in-hospital mortality rate of surgically treated elderly ( $\geq 65$  years) patients with proximal femur fractures who underwent surgery at Ngwelezana Hospital Orthopaedic Department in rural KwaZulu Natal, South Africa. Data was collected between 01 January and 31 December 2021. Furthermore, the mechanism of

injury, time from injury to admission, admission to surgery and from surgery to death, workup for osteoporosis, and overall management approach was analyzed for the patients who demised.

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**Part 2: A submission ready manuscript.**

## **In-hospital postoperative mortality of elderly patients with proximal femur fractures in a South African setting**

### **Abstract**

**Background:** Epidemiological studies project that the incidence of proximal femur fractures in the elderly will triple within the next 30 years. These fractures are associated with significant morbidity and mortality despite ongoing efforts to improve outcomes. To improve outcomes, the American Academy of Orthopaedic Surgeons clinical practice guidelines recommend a multidisciplinary approach, a 48-hour window for surgical fixation, thromboprophylaxis as well as osteoporosis management. We aimed to determine the in-hospital mortality rate of surgically treated elderly patients with proximal femur fractures, as well as describe the series that died within the same admission and review the management of these fractures in a busy orthopaedic unit in rural KwaZulu Natal, South Africa.

**Methods:** We performed a retrospective analysis of the data collected from the clinical records of all deceased elderly patients with proximal femur fractures who underwent surgery at our hospital from 01 January 2017 to 31 December 2021. The in-hospital mortality rate, time from injury to admission, admission to surgery and from surgery to death were assessed. Additionally, the workup for osteoporosis and clinical management to this subset of patients was evaluated.

**Results:** Of 358 patients who underwent surgery during the study period, 24 died in the same admission resulting in an in-hospital mortality rate of 6,7%. 15 (62,5%) were females. All patients sustained fractures due to low-energy falls at home. Apart from one patient, with a pathological fracture secondary to known metastatic breast cancer, a cause of the fragility fracture was never actively sought. The median time from injury to admission was four days

(IQR 2-19) and from admission to surgery was seven days (IQR 5-26). The median time from surgery to death was four days (IQR1-22).

**Conclusions:** The in-hospital mortality rate of 6,7% is in keeping with global figures. Delays in both injury-to-admission and admission-to-surgery intervals may contribute to this mortality. The absence of a fragility fracture workup and subsequent medical treatment highlights important potential gaps in current practices. Urgent attention to reducing waiting times and implementing multidisciplinary approaches may be crucial in enhancing the overall management and outcomes of elderly patients with proximal femur fractures.

**Keywords:** in-hospital mortality, proximal femur fractures, elderly, post-operative

**Level of evidence:** Level 4

## **Introduction**

It is estimated that the global incidence of proximal femur fractures will triple by 2050,<sup>1,2</sup> with Hawley et al. making similar projections for South Africa. The World Health Organisation in their 2015 report called for plans to prevent and manage fragility fractures in Sub-Saharan Africa.<sup>3</sup> Even in developed countries, 30-day mortality has remained largely unchanged in the past decade and, despite ongoing work to improve outcomes most patients never recover their quality of life or independence with the mortality rate remaining high for up to five years post-operatively. This signifies that continued work needs to be done to improve outcomes.<sup>4,5</sup>

Fractures of the proximal femur in the elderly are generally osteoporotic fragility fractures secondary to minimal trauma.<sup>6</sup> Up to 95% of these fractures include neck and pertrochanteric fractures with the remaining 5% being subtrochanteric.<sup>2</sup> The lifetime risk for a hip fracture

ranges from 11-23 % and is higher in women but this gender difference tends to become negligible with increasing age.<sup>7</sup> Historically the incidence of fragility fractures of the hip was lower in black African compared to European populations, but recent literature shows an increasing incidence in black Africans.<sup>8</sup>

In-hospital mortality in elderly patients with proximal femur fractures ranges between 1-10% and is usually higher in men. It increases to 26-33% at 1 year and approaches 50% at 48 months.<sup>3,4,5</sup> A study by Du Toit et al. in 2018 showed higher mortality rates in Free State, South Africa compared to international studies, but this study only analyzed patients managed with hemiarthroplasty.<sup>9</sup> The causes of early mortality in proximal femur fractures are well documented in the developed world but not in Sub-Saharan Africa. There is a need for more studies on this subset of patients to provide a framework for health policy and allocation of resources.<sup>10</sup>

This study's primary aim was to determine the in-hospital mortality rate of surgically treated elderly ( $\geq 65$  years) patients with proximal femur fractures. The secondary aims were to critically analyse the subpopulation that died and review the management of these fractures in a busy orthopaedic unit in rural KwaZulu Natal, South Africa.

## **Materials and methods**

This was a retrospective cohort study. Ethics approval was obtained via BREC (BREC/00003775/2022). A search of the theatre slate database was done to identify all elderly patients who underwent surgery for proximal femur fractures from 01 January 2017 to 31 December 2021. Mortuary records and patient files were used to determine which patients died

during their index admission. Data was collected from these hospital files, theatre records and mortuary records for analysis. The in-hospital mortality rate was calculated as the number of deaths divided by the total number of elderly patients undergoing surgery for proximal femur fractures. For the patients that died, patient demographics, mechanism of injury, time from injury to admission, admission to surgery and from surgery to death, workup for osteoporosis, and overall management approach were collected and assessed. The inclusion criteria were all deceased elderly patients who had surgery for proximal femur fractures from 01 January 2017 to 31 December 2021 at Ngwelezana Hospital. The exclusion criteria were, patients who were discharged and died on subsequent readmission(s), non-operatively managed patients, or those who died while awaiting surgery.

Collected data was captured on a Microsoft® Excel spreadsheet, version 16.59 (© 2022 Microsoft. All rights reserved). Stata/IC version 15.0 (© Stata Corp LLC) was used to analyse the data. We used descriptive statistics presented as percentages for categorical data and median (IQR, inter-quartile range) for skewed continuous data.

## **Results**

From theatre records, 358 elderly patients underwent surgery for proximal femur fractures during the study period, and 24 died in the same admission, this resulted in an in-hospital mortality rate of 6,7%. All the deceased patients sustained fractures due to low-energy falls. 23 (95,83%) fell at home from a standing height and one (4,17%) sustained a fracture whilst turning during sleep. 15 (62,5%) were females. Apart from one patient with a pathological fracture secondary to known metastatic breast cancer, workup for a cause of secondary osteoporosis was not done and no multidisciplinary approach or treatment thereof was instituted. There was no objective measure of pre-morbid function recorded in the notes of all deceased patients and

comorbidities weren't used to stratify patients according to mortality risk. All the patients got skin traction and were started on analgesia and low molecular weight heparin at admission. Chronic treatment for their comorbidities was continued in the ward. In this series, 13 patients (54,1%) had hypertension on treatment, 9 (37,5%) were HIV positive on antiretroviral therapy and 5 (20,8%) presented with confusion at admission.

The median time from injury to admission was four days (IQR 2-19). The median time from admission to surgery was seven days (5-26). The median time from surgery to death was four days (1-22).

The median age of the deceased patients was 70 (IQR 66-81). The age distribution of the series is shown in Figure 3. 12 patients (50,00%) had neck of femur fractures which were managed with arthroplasty (10 bipolar hemiarthroplasty (41,67%), one unipolar hemiarthroplasty (4,17%) and one total hip arthroplasty (4,17%)). Seven (29,16%) had intertrochanteric fractures and four patients (16,66%) had subtrochanteric fractures managed with surgical fixation (Sliding hip screw (20,17%) or cephalomedullary nail (29,83%)). The fracture types are shown in Figure 1 and the types of surgery are shown in Figure 2

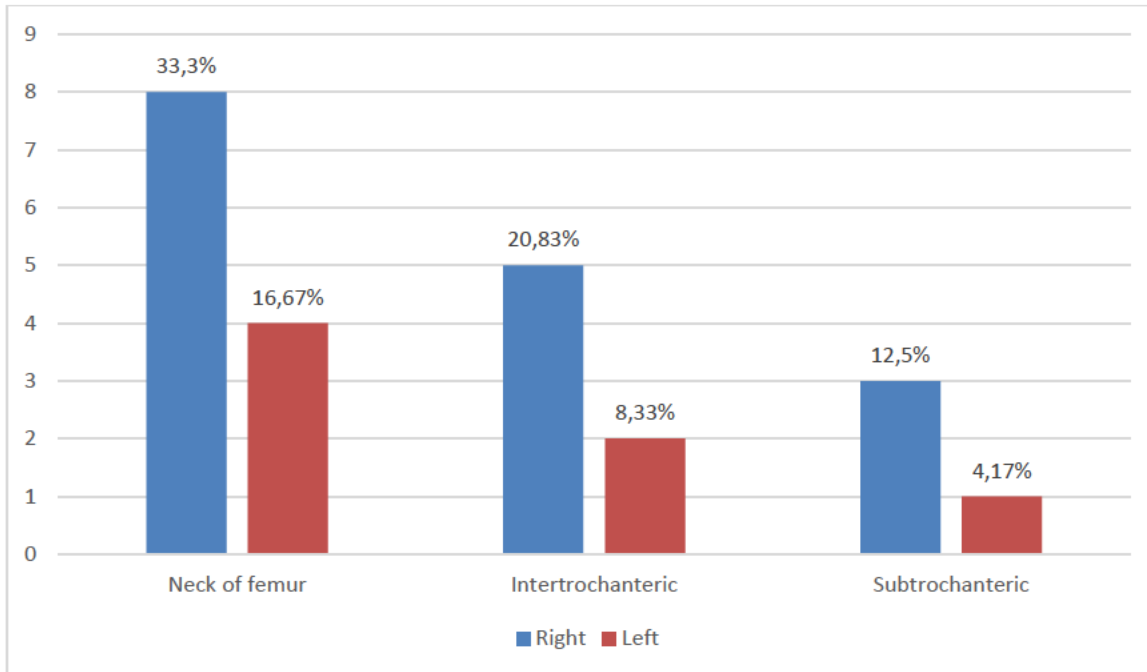


Figure 1. Fracture type

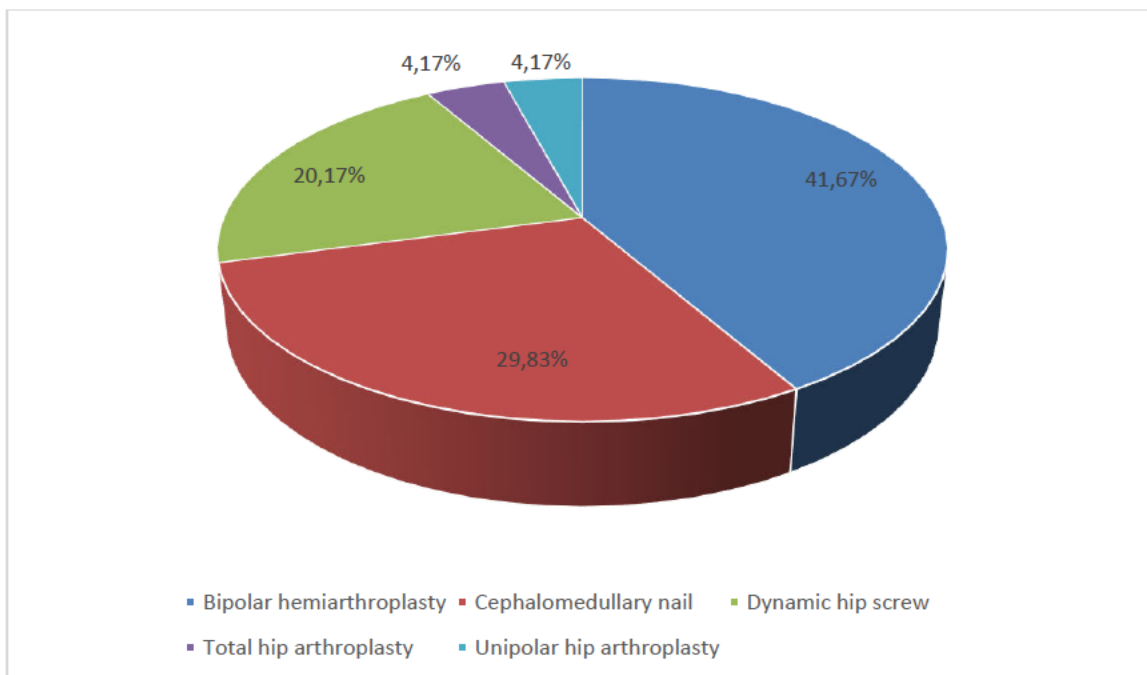


Fig 2. Type of surgery

## Discussion

In our study we found an in-hospital mortality of 6,7% which is in keeping with current literature. All the patients in our study sustained proximal femur fractures due to low-energy mechanisms. Multiple studies have shown a poor effort at diagnosing and managing osteoporosis in proximal femur fractures in the elderly with only two to eight percent of these patients being referred for osteoporosis treatment.<sup>11,12,13,14</sup>As osteoporosis is the main cause of proximal femur fractures in the elderly, it is imperative that this diagnosis is actively sought, and appropriate treatment instituted along with prompt fracture management at the initial admission. The American Academy of Orthopaedic Surgeons clinical practice guidelines recommend a multidisciplinary approach, a 48-hour window for surgical fixation, thromboprophylaxis as well as osteoporosis management. The suggested workup for secondary osteoporosis in all patients should include a full blood count, urea and electrolytes, liver function tests, calcium, phosphate and magnesium, parathyroid hormone as well as 25-hydroxy vitamin D levels. This comprehensive approach has been shown to decrease mortality and morbidity and prevent subsequent fragility fractures. In our study, osteoporosis workup and treatment were not started in any of the patients.

Although mortality is affected by time to surgery, it is also affected by many other confounders.<sup>4</sup> In 2010, a meta-analysis by Simunovic et al. showed a significant association between surgical delay and increased in-hospital mortality despite accounting for confounders. Other studies have also shown a direct increase in mortality in patients operated after 48 hours with a higher mortality both in-hospital and up to one year. Pioli in a prospective observational study reported that the 1-year mortality risk increased by 12% per day of surgical delay.<sup>11,12,13</sup> Paruk et al. in a cohort study

of 200 patients in five Durban hospitals showed a median time to surgery of 19,0 days (IQR 12,3-25,0) and a mortality rate of 13% at 30 days and 33,5% at 365 days.<sup>14,15</sup> It is interesting that despite the long average waiting times for surgery, in this study, the in-hospital mortality rate is still in keeping with global in-hospital mortality rates. However, the 30-day and 1-year mortality rates may be higher.

Delaying surgery is sometimes necessary to medically optimize patients, this delaying of surgery in high-risk patients has been shown to improve mortality rates.<sup>16</sup> Patients delayed more than seven days usually have serious medical problems and the observed rise in mortality in this subgroup might be related to the comorbidities and not the prolonged time to surgery.<sup>17,18</sup> The presurgery waiting time should only be allowed for medical management of unstable or uncontrolled co-morbid conditions. In our study, the median time from admission to surgery was seven days (5-26). Reasons for the delay to surgery were not individually stated but likely due to the high trauma load that the unit experiences.

In-hospital mortality is determined largely by the prehospital status of the patient and an objective measure of this for all patients may help improve mortality rates.<sup>19</sup> Prehospital status may be assessed using the Physical Self-Maintenance Scale and the Lawton Instrumental Activities of Daily Living scale, which have good inter-rater reliability (0.87 and 0.91, respectively).<sup>15,19</sup> Comorbidities commonly associated with increased mortality include renal failure, heart failure, anaemia, lung cancer, asthma, delirium at admission and/or post-operatively, male gender, and increasing age.<sup>20</sup> Parkers mobility score and a comorbidity index are reliable predictors of in-hospital mortality and long-term mortality.<sup>21, 22</sup> In our series, there was no objective measure of premorbid function used when assessing these patients. In our study, 13 patients (54,1%) had hypertension on treatment, nine (37,5%) were HIV positive on antiretroviral therapy and five

(20,8%) presented with confusion at admission. In a resource limited unit with long delays to surgery, objective measures of premorbid function and comorbidity indices to stratify risk may be a useful strategy to identify high risk patients and make appropriate clinical decisions.

The average time from injury to admission was 4 days (IQR 2-19). The delays to admission to an orthopaedic unit may be due to late presentation to base hospital as well as an overburdened referral system. Future research will have to include data from base hospitals as this may increase the inhospital mortality rate due to patients who die prior to transfer to an orthopaedic unit.

Our study had multiple limitations; it is a retrospective single-center study with a small sample size. Poor record keeping precluded a more extensive data analysis due to the loss of entire or portions of files in the wards or mortuary as well as inadequate clinical notes on the premorbid status at admission and during the hospital stay.

## **Conclusion**

We found an In-hospital mortality rate of 6,7% in keeping with the global trend which is encouraging but there are still significant unexplained delays to surgery which need to be improved upon. An important finding of the study was that the diagnostic work-up and management of osteoporosis could be improved, which could result in a significant reduction of further fragility fractures and improvement of mortality in morbidity. The data presented here provides a basic reference and may be useful for further studies and to help drive awareness of

the need for a thorough workup of all fragility fractures of the proximal femur and starting osteoporosis treatment promptly.

#### **Conflict of interest statement**

Ndumiso Mavuso and Rainer Rosin declare that they have no conflict of interest.

#### **Funding sources**

No funding was received for the purposes of performing this study.

#### **Ethics statement**

For this study formal consent was not required.

#### **Acknowledgments**

We want to thank Catherine Connolly for her assistance with statistical analysis.

#### **Author contributions**

NM contributed to conceptualization, design, data collection, and manuscript preparation. RR contributed to the design and manuscript review.

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## **Appendices**

### **Appendix 1: The final Study Protocol (Include the final protocol which was given full approval by Brec and/or the postgrad office)**

#### **Title of study**

In-hospital post-operative mortality of elderly patients with proximal femur fractures in a South African setting

#### **Aim of study**

To determine the in-hospital mortality rate of elderly patients with proximal femur fractures and compare the rates associated with different treatment modalities and risk factors.

#### **Specific objectives**

1. To determine the in-hospital mortality rate in elderly patients with proximal femur fractures managed surgically
2. To compare mortality rates associated with different types of surgery in the proximal femur
3. To determine the average time to theatre and its effect on mortality
4. To identify risk factors associated with in-hospital mortality in patients with proximal femur fractures mainly renal impairment, anaemia, HIV, delirium and the overall number of comorbidities

#### **Background**

Ngwelezana Hospital is a tertiary hospital in rural Empangeni, Northern KwaZulu-Natal, South Africa. It has a large catchment area which is predominantly rural comprised of 3 district municipalities with an estimated population of 2,5 million people and a rising number of the elderly population based on the South African census of 2011. The orthopaedic department in Ngwelezana Hospital sees a large number of elderly patients with proximal femur fractures often due to low energy falls. These patients often present late to Ngwelezana with unresolved medical problems. Because of the high levels of trauma in this region, there are often further delays in getting these patients to theatre. There is a preconceived notion that there is an increased in-hospital mortality rate associated with proximal femur fractures in the elderly in Sub-Saharan Africa but there is very limited literature on this in the region. The results of this

study will further our knowledge of in-hospital mortality and associated risk factors and thus lead to standardized treatment protocols for proximal femur fractures in the elderly as seen in more developed regions in the world.

## **Literature review**

In this study, all patients over 65 years of age are considered elderly, and proximal femur fractures include all fractures of the neck, pertrochanteric and subtrochanteric fractures. It is estimated that the incidence of femoral neck fractures will triple by 2050 (1,2,10). In the UK, 30-day mortality has remained largely unchanged in the past decade signifying the need for more work to be done to improve outcomes (3). Despite ongoing work to improve outcomes most of the survivors never recover their quality of life or independence and the mortality rate remains high for up to 5 years post-operatively (1,2,5,10)

Fractures of the proximal femur in the elderly are largely fractures of fragility with a high morbidity and mortality rate. They occur as a result of low energy trauma, usually a fall from a standing position at home (1). Up to 95% of proximal femur fractures include the neck and pertrochanteric fractures, the remaining 5% are subtrochanteric (2). The lifetime risk for a hip fracture ranges from 11-23 % and is higher in women but this gender difference tends to be negligible with increasing age (2, 7).

Historically fragility fractures of the hip were lower in black Africans compared to Europeans but recent literature shows an increasing incidence (9, 15).

In-hospital mortality in elderly patients with proximal femur fractures ranges between 1-10% and is usually higher in men. It increases to 26-33% at 1 year and approaches 50% at 48 months (3,4,5,15). A study by Du Toit et al in 2018 showed higher mortality rates in Free state, South Africa compared to international studies but this study only analysed patients managed with hemiarthroplasty (11).

The causes of early mortality in proximal femur fractures are fairly documented in the first world but not in Sub-Saharan Africa. It is believed that in-hospital mortality is determined largely by the prehospital status of the patient but these risk factors are not uniform in the literature (1,2,3,4). Research identifying these risk factors could help reduce the mortality rate. Despite a clear association between comorbidities and in-hospital mortality, literature varies greatly as to

which comorbidities are the most significant (5). Evidence shows that the greater the number of comorbidities, the greater the rate of in-hospital mortality (4,5).

A large meta-analysis by Hu et al in 2012 showed evidence of 12 strong predictors of mortality. These include advanced age, male gender, living in a facility, poor mobility pre-fracture, poor activities of daily living, poor mental state, high Asa score, multiple comorbidities, cognitive impairment, diabetes, cancer, and cardiac disease(14,15, 16). Xu et al in 2019 showed the same predictors and 2 new ones namely handgrip strength and frailty in a large systematic review (17).

Comorbidities commonly associated with increased mortality include renal failure, heart failure, anemia, lung tumor, asthma, delirium at admission and/or post-operatively, male gender, and increasing age(3, 5). Parkers mobility score and a comorbidity index are reliable predictors of in-hospital mortality and long-term mortality (4, 5, 14,19, 20, 21)

There is contradicting evidence with regards to a clear association between fracture type and mortality (2,3,4,5)

A systematic review by Parker and Gurusamy showed no difference in mortality rate between the different surgical options however internal fixation has lower morbidity compared to arthroplasty (2). Elective arthroplasty also has lower in-hospital mortality compared to trauma-related arthroplasty (2,6).

Time to surgery affects mortality but it is affected by too many other confounders (4). Most research shows that a delay in performing surgery is associated with higher mortality both in-hospital and within 1 year (1). This was demonstrated by a significant association between surgical delay and increased in-hospital mortality despite accounting for confounding preoperative factors in a meta-analysis by Simunovic et AL in 2010 (7). Some studies show a direct increase in mortality in patients operated after 48 hours (5). Consequently, in most of the developed world, guidelines require surgery to be done as soon as possible but not later than 48 hours (6). Pioli in a prospective observational study reported that the 1-year mortality risk increased by 12% per day of surgical delay (12). Paruk et al in a cohort study of 200 patients in 5 Durban hospitals showed a median time to surgery of 19,0 days (IQR 12,3-25,0) and a mortality rate of 13% at 30 days and 33,5% at 365 days (18)

Early surgery allows early mobilization, therefore, reduces complications due to prolonged immobility such as pressure sores, deep vein thrombosis, and chest and urinary tract infections (3,4,5,6, 7). Therefore, patients with a greater delay in surgery have greater non-surgical

postoperative complications(5, 6,7,8). However, these complications do not significantly change the in-hospital mortality rate (6).

Delaying surgery is sometimes necessary to medically optimize patients, this delaying of surgery in high risk has been shown to improve mortality rates. This evidence is demonstrated in a recent systematic review and meta-analysis by Chen which shows a gross reduction in mortality with early surgery for a carefully selected subset of patients(8). Patients delayed more than 7 days usually have serious medical problems and the observed rise in mortality in this subgroup might be related to the comorbidities and not the prolonged time to surgery(6, 7).

When comparing early surgery with non-operative management, there is improved 30-day mortality but interestingly the 1-year mortality is similar (3). Type of fracture, age, and the number of comorbidities did not affect time to surgery (1). There are currently no national guidelines for the time to surgery in South Africa and the majority of public hospitals, surgery is often delayed(9)

Postoperative pneumonia is the most common cause of death following a hip fracture followed by cardiovascular disease (3).

Asymptomatic deep venous thrombosis (DVT) is very common in hip fractures, up to 50% but the rate of symptomatic DVT is much lower at about 2,5% (10). Fatal pulmonary embolism (PE) is estimated at 0,6%. Low molecular weight heparin reduces the incidence of DVT but does not affect mortality due to fatal PE (10). Interestingly, earlier surgery has not been shown to reduce the risk of deep venous thrombosis or pulmonary embolism (15)

A quarter of patients will develop post-operative delirium which is often transient but can persist in 20% of patients. Delirium is associated with significant morbidity and mortality and its prevention is paramount (4,13, 15). Risk factors for delirium include visual impairment, pre-existing cognitive impairment, severe illness, dehydration, anticholinergic drugs, uncontrolled pain, hypotension and sepsis (15)

### **Search Strategy**

Electronic search engines used to search relevant literature from the past 10 years including

- Pubmed
- Medline
- Cochrane
- Google Scholar
- EBSCO

- UpToDate
- Clinical key

## **Keywords**

- Proximal femur fractures
- In-hospital mortality
- Elderly

## **Key References**

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## **Study design**

### Study population

All elderly patients who had surgery for proximal femur fractures from June 2015 to June 2020 at Ngwelezana

### Sampling strategy

This is a retrospective descriptive study. Convenience sampling used where the files of all elderly patients with proximal femur fractures that managed operatively will be analysed

### Inclusion criteria

All patients aged 65 years who underwent surgery for a proximal femur fracture

### Exclusion criteria

1. Elective surgery
2. Patients that get discharged and die on subsequent readmission are not included

3. Non-operatively managed patients
4. High energy trauma

### Data collection

1. File numbers of all elderly patients with proximal femur fracture surgeries will be traced from the daily theatre lists between June 2015 and June 2020 and files retrieved from the file bank
2. All mortality data will be collected from patient files kept at the mortuary
3. Pre-operative radiographs will be analysed to classify the fracture type according to the AO classification system
4. Data will be collected and tabulated from the patients outpatient file into a datasheet

### **Study location**

Ngwelezana Tertiary Hospital, Empangeni, South Africa

### **Study period**

1 June 2015 to 1 June 2020

### **Limitations**

1. Single centre study
2. Retrospective review
3. Inadequate clinical notes on the premorbid status of the patient as well as a probable cause of death
4. Incomplete mortality records in the ward
5. Most files of patients that survived lost at records

### **Ethical considerations**

No ethical considerations as this is a descriptive, retrospective study that does not require informed consent.

- All patient names, information, and relevant data will be kept confidential
- Patients will be assigned a number to keep their identities confidential on the datasheets and database
- Data will be kept on a password-protected personal computer

## **Appendix 2: The Guidelines for Authorship for the Journal selected for submission of the manuscript**

### **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 appropriately 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.
- In order to qualify for authorship, authors should satisfy all four the criteria for authorship as specified by the ICMJE:
  1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
  2. Drafting the work or revising it critically for important intellectual content; AND
  3. Final approval of the version to be published; AND
  4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- Other 'contributors' or 'collaborators' can be acknowledged at the end of the manuscript together with their contribution. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g., "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").
- The South African Orthopaedic Journal accepts a maximum of 8 authors per article. If there are more than eight authors, the first eight authors must be listed along with the group name at the end. The remaining authors and their affiliations must then be listed in an appendix.
- On submission of your article, the ORCID (Open Researcher and Contributor ID) identifier of at least the corresponding author will be required. ORCID provides a

persistent digital identifier that distinguishes you from every other researcher and supports automated linkages between you and your professional activities, ensuring that your work is recognised. To register and find more information, please visit: <http://orcid.org>

### Registration of clinical trials

- A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes.
- Clinical trials should be registered in a public trials registry in accordance with [International Committee of Medical Journal Editors](#)
- Trials must be registered and approved by the relevant authorities before the onset of patient enrolment.
- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

### Reporting guidelines

- All articles should be prepared in accordance with the guidelines relevant to the study design, as described in the Equator Network Guidelines (<https://www.equator-network.org/reporting-guidelines/>)
- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

### Reporting of statistics

In terms of the statistical reporting, the Equator Network advises on the use of the SAMPL guideline: <https://www.equator-network.org/2013/02/11/sampl-guidelines-for-statistical-reporting/>

The SAMPL guidelines provide two guiding principles

1. *“Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results.”* When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as *P* values, which fail to convey important information about effect size.

2. *Provide enough detail that the results can be incorporated into other analyses.* This requires reporting the descriptive statistics from which other statistics are derived, such as the numerators and denominators of percentages, especially in risk, odds, and hazards ratios. Likewise, P-values are not sufficient for re-analysis. Needed instead are descriptive statistics for the variables being compared, including sample size of the groups involved, the estimate (or effect size) associated with the P-value, and a measure of precision for the estimate, usually a 95% confidence interval.

Some specific guidelines applicable to the SAOJ:

- Consistency is one of the most important factors in presenting a well-formatted, professional manuscript.
- The nature of the measurements and variables reported on will often dictate the amount of precision required. Report numbers - especially measurements? with an appropriate degree of precision. For ease of comprehension and simplicity, round to a reasonable extent.
- The recommendation is to report the number of decimals that have both clinical and statistical meaning and consistently reporting all other variables in the same manner.
- Note: Generally, for descriptive purposes, percentages are reported as whole numbers except when dealing with really large sample sizes
- At least for the primary outcomes, report a measure of precision (a confidence interval).
- Although not preferred to confidence intervals, if desired, *p* values should be reported as equalities to three decimal places (e.g.,  $p = 0.031$  and not as inequalities: e.g.,  $p < 0.05$ ). Do NOT report NS; give the actual *P-value*. The smallest *P-value* that needs to be reported is  $P < 0.001$ .
- Report numerators and denominators for all percentages
- Summarize data that are approximately normally distributed with means and standard deviations (SD). Use the format: mean (SD) not mean ?
- Summarize data that are not normally distributed with medians and interpercentile ranges, ranges, or both.
- Do NOT use the standard error of the mean (SE) to indicate the variability of a data set. Use standard deviations, inter-percentile ranges, or ranges instead.

Formatting examples:

- $p = 0.028$  or  $p < 0.001$
- (43% vs 21%;  $p = 0.002$ )
- (odds ratio (OR) 0.38; 95% confidence interval (CI) 0.71 to 1.82;  $p = 0.822$ ) or after first use (OR 1.62; 95% CI 1.41 to 1.86;  $p < 0.001$ )
- *Descriptive stats normal distribution:* mean age 36 years (SD 4 years) or 36 years (SD 4; range 40 to 97 years)
- *Descriptive stats non-normal distribution:* median age 36 years (IQR 44 to 88 years) or 36 years (IQR 44 to 88 years; range 40 to 97 years)
- *Descriptive stats percentage:* (149 of 202; 74%)

## 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 and figure legends should be understandable as a stand-alone item, without having to read the main body of the 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.
- Please submit the original JPEG (300 dpi) or TIFF of all photographs, as well as the figure saved as a Word document. The Word version of the figure should be complete with the legend and any necessary markings such as letters or arrows.

- Figures such as graphs and algorithms should be in Word or PowerPoint in order to be editable.
- 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. Clinical photos must be adequately anonymised.
- A statement of patient consent for clinical photographs must be provided on the title page.
- In images depicting X-rays of children there should exhibit adequate shielding of radiation.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of six figures. You may apply to the Editor-in-Chief for permission to include more figures if considered critical to the clarity and completeness of the submission.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or 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 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.
- Accuracy of references is the authors' 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.gov>
- 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.

*Online 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](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 3 500 words, including the abstract and body of the text (excluding references).
- Exceptions to this rule may be made for systematic reviews and meta-analysis at the discretion of the Editor-in-Chief.
- Please follow the following structure when preparing your submission. Each of the following should be submitted as a separate file.
- Title page (title, authors and affiliations, corresponding author and declarations)
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- Tables (with headings), each table as a separate file.
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- The title should be concise and informative.

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- Clearly indicate who will handle correspondence at all stages of refereeing and publication, including post-publication.
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- Please note that the corresponding author's contact details will be provided in the final article.
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#### *Declarations*

Authors are to insert a section at the end of the title page entitled declarations (please provide the author's name, signature and date). The following statements are required under the declarations section:

#### *Authorship*

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

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

#### *Sound scientific research practice*

The authors further confirm that:

- The manuscript, including related data, figures and tables, has not been previously published and is not under consideration elsewhere.
- No data have been fabricated or manipulated (including images) to support conclusions.

- This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami-publishing').

### *Plagiarism*

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

- No data, text or theories by others are presented as if they were the authors' own.
- Proper acknowledgements of others' work have 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 copyrighted material.

### *Conflict of interest statement*

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

*'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.'*

### *Funding sources*

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

List all funding sources as follows:

'This work was supported by the xxxx (grant numbers xxxx, yyyy).'

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

If no funding was received, state as follows:

'No funding was received for this study.'

#### *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 the 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.'

'Consent was obtained from patients for the use of clinical photographs and these images were adequately anonymized'

- 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/>

Please provide the names and email addresses of two reviewers.

*Title Page Example*

Title of Submission

John Smith\*

MBChB, FC Orth SA, MMed (Ortho)

University of South Africa, 123 High Street, Pretoria

ORCID ID 1234-1234-1234-1234

Paula Taylor

MBChB, FC Orth SA

University of South Africa, 123 High Street, Pretoria

ORCID ID 1234-1234-1234-1234

\* Corresponding author:

Prof John Smith

University of South Africa

123 High Street, Waterkloof, Pretoria, South Africa, 0001

POBOX 1001, Waterkloof, Pretoria South Africa, 0001

Tel: 012 123 4567

e-mail: [johnsmith@unisa.ac.za](mailto:johnsmith@unisa.ac.za)

## **Declarations:**

### *Authorship*

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

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

### *Sound scientific research practice*

The authors further confirm that:

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

### *Plagiarism*

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

- No data, text or theories by others are presented as if they were the authors' own.
- Proper acknowledgements of others' work have 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 copyrighted material.

### *Conflict of interest statement*

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

### *Funding sources*

No funding was received for the purposes of performing this study.

*Compliance with ethical guidelines*

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.

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

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.

Consent were obtained from patients for the use of clinical photographs/ and these images were adequately anonymised.

<b>Author Name</b>	<b>Signature</b>	<b>Date</b>
J Smith		15/8/2017
P Taylor		16/8/2017

Blinded manuscript

To ensure a blinded review, the main body of the manuscript should not contain any identifying information, including author's names, institutions or affiliations. Please do not include the name of the ethics committee, this information should be provided in the title page.

*Abstract*

- A structured abstract (maximum of 350 words) summarising the most important points in the article is required.
- The abstract consists of four paragraphs with the subheadings:
  - Background (must include the aim of the study)
  - Patients and methods
  - Results
  - Conclusion

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

### *Keywords*

- Immediately after the abstract, provide a maximum of six keywords using standard searchable terms. These keywords 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 procedures for common operations. Only include new procedures or adaptations to standard procedures.
- If you name any specific product, it requires the manufacturer's name, city and state/country.
- 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 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 emphasize 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 that conveys the conclusions of the findings.
- Do not draw conclusions not supported by the data obtained from the specific study presented.

### *Ethics statement*

- For studies involving human subjects, please include an ethics statement as follows: 'All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.'
- For animal studies, please include the following ethical statement: 'All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.'
- 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.'
- 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.'

### *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 comments.
- Do not include contributions by editors or referees.

#### *Author contributions*

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

#### *References*

- Please refer to the section on Formatting of submissions.

#### Tables and figures

- Tables 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.

#### **Case reports**

In addition to the preceding guidelines the following applies:

- The following headings need to be adhered to in the body of the manuscript:
  - Abstract
  - Keywords
  - Background
  - Case report
  - Discussion
  - Conclusion
  - Ethics statement
  - References
- Abstract: Minimum 250 words (350 maximum), using the following headings:

- Background
- Case report
- Discussion
- Conclusion
- Statement of informed consent must be included in the ethics statement.

### **Current Concepts Review Article (by invitation only)**

#### General Guidelines:

- A narrative review will suffice (and systematic or scoping review not necessary)
- A thorough literature review needs to be done prior to writing the manuscript to ensure that the author is well acquainted with the current concepts related to the topic (with emphasis on the most recent developments)
- A balanced and unbiased view of the current clinical aspects of the topic.
- Focus on clinical aspects like diagnosis and treatment.
- Discuss controversies and state both sides of the argument.
- Avoid extensive discussion of basic science (anatomy/physiology/pathology) aspects, except for some really novel and clinically relevant new developments in the field.
- The topic may be adapted, but only with the permission of the Editor-in-Chief.

#### Outline of Article:

- Abstract = One paragraph, no headings, ≤350 words.
- Introduction = Brief introduction to the topic
- Contents = Please use headings (in bold) and sub-headings (in italics) to structure the manuscript in a reader-friendly manner
- South African context = Discuss matters which may be particularly relevant or unique to the South African clinical setting.
- Learning points = Make use of tables to summarize important learning points
- Conclusion = Brief evidence-based conclusion and summary
- Conflict of interest statement
- References = As usual

## Appendix 3: Ethical approvals

# Site approval letter



KWAZULU-NATAL PROVINCE

**HEALTH**

REPUBLIC OF SOUTH AFRICA

Postal Address: Private Bag x 20021 Empangeni 3880

Physical Address: Thanduyise Road- Empangeni 3880

Tel: 035-9017273 Fax: 0865196873 Email address : tobias.gumede@kznhealth.gov.za  
www.kznhealth.gov.za

**DIRECTORATE:**

**MEDICAL SERVICES**

SENIOR MANAGER : MEDICAL SERVICES

Enquiries: Mr TB

Gumede Date:

02.03.2022

To: Dr NB Mavuso

School of Clinical Medicine

Medical School

Dear Sir / Madam

### **RE: PERMISSION TO CONDUCT RESEARCH AT NGWELEZANA TERTIARY HOSPITAL**

I have pleasure in informing you that permission has been granted to you by Ngwelezana Tertiary Hospital Ethics and Research Committee to conduct research titled "In hospital post-operative mortality of elderly patients with proximal femur fractures in a South African setting"

Please note the following:-

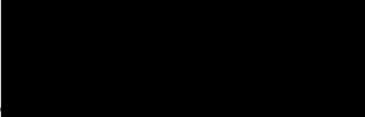
- 1 . Please ensure that you adhere to all policies, procedure, protocols and guidelines of the Department of Health with regards to research.

- 2 Confidentiality of hospital information, including staff and patients or contact information must be kept confidential at all times, patient records are not to be removed from the hospital premises nor you are not allowed to photocopy/ photograph them,
- 3 This Facility will not provide any resources for this research.
- 4 You will be expected to provide feedback on your findings to the facility.
- 5 The Department of Health and hospital's staff will not be held responsible for any negative incidents and or consequences including injuries and illness that may be contracted on site.
- 6 You are requested to make contact with Dr RS Moeketsi, Senior Manager: Medical Services at Ngwelezana Tertiary Hospital once you are ready to commence your study.

We would like to take this opportunity to wish you all the best in your future endeavours.

Thank you,

Recommended/Not recommended by:

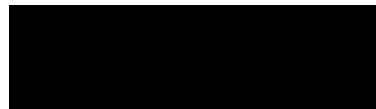


DR RS MOEKETSI  
SENIOR MANAGER: MEDICAL SERVICES

ACTING CHIEF EXECUTIVE OFFICER  
CHAIRPERSON, ETHICS AND RESEARCH COMMITTEE  
NGWELEZANA TERTIARY HOSPITAL

DATE 02/03/2022

Approved/Disapproved-by:



SENIOR MANAGER: MEDICAL SERVICES

NGWELEZANA TERTIARY HOSPITAL

DATE 02/03/2022

# Department of health approval letter



**health**

Department:  
Health  
PROVINCE OF KWAZULU-NATAL

**DIRECTORATE:**

Physical Address: 330 Langalibalele Street, Pietermaritzburg  
Postal Address: Private Bag X9051  
Tel: 033 395 2805/ 3189/ 3123 Fax: 033 394 3782  
Email:  
[www.kznhealth.gov.za](http://www.kznhealth.gov.za)

Health Research & Knowledge  
Management

NHRD Ref: KZ 202206 016

Dear Dr N. Mavuso  
(UKZN)

## Approval of research

1. The research proposal titled 'In-hospital post-operative mortality of elderly patients with proximal femur fractures in a South African setting' was reviewed by the KwaZulu-Natal

Department of Health (KZN-DoH).

The proposal is hereby approved for research to be undertaken at Ngwelezana Tertiary Hospital.

2. You are requested to take note of the following:

- a. A/t research conducted in KwaZulu-Natal must comply with government regulations relating to Covid-19. These include but are not limited to: regulations concerning social distancing, the wearing of persona/ protective equipment, and limitations on meetings and social gatherings
- b. Kindly liaise with the facility manager BEFORE your research begins in order to ensure that conditions in the facility are conducive to the conduct of your research. These include,

but are not limited to, an assurance that the numbers of patients attending the facility are sufficient to support your sample size requirements, and that the space and physical infrastructure of the facility can accommodate the research team and any additional equipment required for the research.

- c. Please ensure that you provide your letter of ethics re-certification to this unit, when the current approval, expires.
- d. Provide an interim progress report and final report (electronic and hard copies) when your research is complete to HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10. 102, PRIVA TE BAG X9051, PIETERMARITZBURG, 3200 and e-mail an electronic copy to [hrkm@kznhealth.aov.za](mailto:hrkm@kznhealth.aov.za)
- e. Please note that the Department of Health shall not be held liable for any injury that occurs as a result of this study.

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely



**Dr E Lutge**

Chairperson, Health Research Committee

Date:

# BREC APPROVAL LETTER



26 July 2022

Dr Ndumiso Briance Mavuso (220110501)  
School of Clinical Medicine  
Medical School

Dear Dr Mavuso,

Protocol reference number: BREC/00003775/2022  
Project title: Inhospital postoperative mortality of elderly patients with proximal femur fractures in a South African setting  
Degree: MMed

## EXPEDITED APPLICATION: APPROVAL LETTER

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application.

The conditions have been met and the study is given full ethics approval and may begin as from 26 July 2022. Please ensure that any outstanding site permissions are obtained and forwarded to BREC for approval before commencing research at a site.

This approval is valid for one year from 26 July 2022. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2020) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be noted by a full Committee at its next meeting taking place on 16 August 2022.

Yours sincerely,



Prof D Wassenaar  
Chair: Biomedical Research Ethics Committee

---

Biomedical Research Ethics Committee  
Chair: Professor D R Wassenaar  
UKZN Research Ethics Office Westville Campus, Govan Mbeki Building  
Postal Address: Private Bag X54001, Durban 4000  
Email: [BREC@ukzn.ac.za](mailto:BREC@ukzn.ac.za)  
Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>

Founding Campuses: Edgewood Howard College Medical School Pietermaritzburg Westville

INSPIRING GREATNESS

## Appendix 4: Data collection tools (for example)

### DATA SHEET



Injured leg:

### Demographics

Gender:

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Age:

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IP Number:

### Perioperative data

Date of injury:

Mechanism:

Date of admission:

Date of operation and type:

Duration of op and Surgeon involved:

Premorbid function and comorbidities:

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Date of death and suspected cause:

**History & Examination**

Pain: \_\_\_\_\_

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Problems: \_\_\_\_\_

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Function: \_\_\_\_\_

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**Radiology**

Xray number: \_\_\_\_\_

Pre-op

Fracture type: \_\_\_\_\_

Fracture level: \_\_\_\_\_

: \_\_\_\_\_

X

## Appendix 5: Raw data (for example)

68F170201

### DATA SHEET

Injured leg: Right

### Demographics

Gender: F

Age: 68

IP Number: 490321

### Perioperative data

Date of injury (Death or Surgery): 08/02/17 7-surgery-15-Death

Mechanism: Low energy fall at home

Date of admission: 10/02/17

Date of operation and type: 15/02/17 cephalomedullary nail

Duration of op and Surgeon involved: 1h30 minutes, Consultant + medical officer.

Premorbid function and comorbidities: Known RVD on HAART

Hypertensive on medication

DM on oral meds

Anemia and renal dysfunction at admission

Date of death and suspected cause: 23/02/17. HAP

## **History & Examination**

Referred from Benedictine hospital. Slipped and fell at home whilst walking in the yard on 08/02/17. Presented to Benedictine hospital same day. Admitted and discussed with Ngwelezane orthopaedic unit for transfer the following day. Patient arrived at Ngwelezane Hospital on 10/02/17. Previously walked unaided.

Known RVD on HAART > 10 years. Unknown CD4/VL. Hypertensive on Hydrochlorothiazide + amlodipine

Function: "good"- nil objective assessment

## **Radiology**

Xray number: pre PACS. Hard copies

## **Pre-op**

Fracture type: Subtrochanteric fracture reverse oblique type.

Fracture level: Subtrochanteric