

The quality of life in patients living with chronic osteomyelitis in Johannesburg, South Africa



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Master of Medicine

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Declaration

I, Sanushka Pillay, declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

..........

(Signature of candidate)

.....15...day of July.....2025.....in.....Bryanston.....

To Mum and Dad, my brother Viven and my extended family

Presentations and publications arising from the research project

None

Abstract

Chronic osteomyelitis (COM) is a debilitating inflammatory condition of the bone and bone marrow. While its clinical and surgical management is well documented, little is known about the impact it has on the quality of life (QOL) in the South African context. The aim of the study was to compare the quality of life of patients living with chronic osteomyelitis to those who are not affected by the disease using the Medical Outcomes Study 36 – Item Short Form Health Survey (SF-36). Our results show that patients with COM experience significantly poorer physical functioning and psychological well-being equating to a reduced quality of life. This suggests a considerable amount of physical and psychosocial burden associated with the disease. Non-smokers with COM reported better QOL in the vitality and mental health domains.

Further studies are required incorporating larger multi-centred designs with appropriate data collection instruments tailored specific to the local population. This will enable a more comprehensive analysis to strengthen healthcare and support services to manage this complex condition.

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Nomenclature

ADL	Activities of Daily Living
AIDS	Acquired Immunodeficiency Syndrome
CEO	Chief Executive Officer
CHBAH	Chris Hani Baragwanath Academic Hospital
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
COM	Chronic Osteomyelitis
FRI	Fracture Related Infection
HIV	Human Immunodeficiency Virus
HRQOL	Health related Quality of Life
LMIC	Low and Middle-Income Countries
OM	Osteomyelitis
OPD	Out-Patients Department
PACS	Picture Archiving and Communication System
QOL	Quality of Life
ICS	Infection, Callus, Stability
SCVs	Small Colony Variants
SF-36	Medical Outcomes Study 36 – Item Short Form Health Survey

CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Infection of the bone is called osteomyelitis. It is an acute or chronic inflammatory response to infection of the bone and its structures with suppurative organisms, including bacteria, fungi, parasites or a combination thereof.

This research study is about the quality of life of individuals that suffer from chronic bone infection compared to healthy individuals. To assess the difference the SF-36 short form questionnaire was used. It is a universal, self-reported health survey to assess quality of life. The 36 questions of the score assesses various domains of physical and mental health. The score is internationally used, reliable, valid and responsive.

1.2 Background

The definition of chronic osteomyelitis (COM) is quite simple to understand. It is a microbial infection with an inflammatory process involving the bone and bone marrow (1).

In a healthy patient, bone is normally resilient to infection and for osteomyelitis (OM) to occur a large bacterial load is usually present with comorbid necrosis or ischaemic tissue, trauma and/or the presence of foreign material (2). Once susceptible bone is infected the local defences are overwhelmed and a local acute inflammatory mediated response involving a complex osteoblastic and osteoclastic interplay ensues. Traditionally, COM was known to be a characterised by the presence of sequestrum and involucrum and is the final stage of the disease process. Acutely, infective OM predominantly uses two means of spread either *via* a haematogenous route or direct inoculation with a 10 – 30% continuing as chronic infection (2). The alarming number of high velocity skeletal trauma and increased use of orthopaedic implants has also been implicated in the recent rise of OM

Non-infectious complications of COM are not a direct cause of the infection but are consequences of existing with COM. These patients don't "live"...they try to survive their ordeal. More importantly, these patients suffer significant social and functional decline causing

poor quality of life and psychosocial deterioration Prolonged hospitalisation, unpredictable results, continuous pain, cosmesis and functional concerns are issues that COM patients face daily (3) Depression, narcotic dependency, separation from spouses and significant others contribute to the psychosocial ordeal that these patients live with (3) The ability to maintain employment and to function within an intact social structure are daily challenges that these patients face and are considered the biggest complications of COM (3-5). While these patients seldom have serious clinical complications, the greatest challenge to them is the social and personal “death” that accompanies this condition

Physical limitations and psychosocial adjustment are important variables that ascertain quality of life (QOL) in COM patients (5). These patients continue to seek medical care in the hope of a cure (5). They require strong social support, effective coping skills and resilient mental health (5). The available data on the QOL of people living with COM is limited particularly in Sub-Saharan Africa. Recognising negative effects on the QOL of these patients will impact how we manage this condition going forward

1.3. Literature review

The word “Osteomyelitis” (OM) has Greek origins with “Osteo” referring to bone, “Myelo” the marrow and “itis” indicating inflammation making its definition straightforward to interpret. Yet the ramifications of this condition, particularly in its chronicity, is a challenging task for both patient and orthopaedic surgeons worldwide to manage. OM is an ancient disease with evidence dating back to over 200 million years ago found in the spine of pre-historic Reptilia and paleopathological analysis of the hominid *Australopithecus africanus* conducted at Sterkfontein, South Africa revealed an early infective process of the vertebrae attributed to Brucellosis (6, 7). Early medical texts such as the Edwin-Smith Papyrus speak of “pus pouring from the bone” probably alluding to OM (8) and later on in 1773, William Bromfield described it as an “*abscessus in the medulla*” (9). The start of the 20th century and before the advent of antibiotics, a methodical surgical approach to the management of OM was detailed (10) however, the work of antimicrobial pioneers such as Alexander Fleming and Albert Schatz, and their discovery of antibiotics single handily reshaped the management of OM (11, 12). The advancement of surgical techniques and optimal use of antimicrobial therapy shifted the fearful OM disease path from a lethal condition to one of survival and reduced morbidity (1) .

1.3.1. Epidemiology of OM

In spite of the evolution of diagnostic and treatment modalities, the incidence of OM has seen a steady increase in the last century with a plausible explanation for this being a change in the causes and associated risk factors (1, 2). The significant rise in diabetes mellitus is thought to be partly responsible for the rapid rise of OM in America amongst the elderly (13). There is very little data originating out of Sub-Saharan Africa regarding OM with a few studies providing epidemiological evidence (14-17). In more resource constraint countries, a misdiagnosis during the acute and subacute phase contributed to the rise of COM while ignorance and financial difficulties were the top socioeconomic factors (15). Other important factors were the high prevalence of OM during juvenescence, immunosuppression and malnutrition (2). COM was shown to have its highest occurrence during the second decade of life between the ages of 10 and 21 years with a higher incidence in males (14-17). Long bones were primarily affected and due to its function, vulnerability and limited soft tissue coverage, the tibia was the most affected bone (31-35%) closely followed by the femur (16, 17). *Enterobacteriaceae* and *Staphylococcus aureus* were the most isolated pathogens with a higher frequency of gram negative bacteria and antibiotic resistance present than previously reported (1, 18). The alarming number of high velocity skeletal trauma and increased use of orthopaedic implants has also been implicated in the recent rise of OM (2).

1.3.2. Pathophysiology of COM

As we delve deeper into the pathology of COM, our understanding of the disease has evolved, and we appreciate why chronicity and the presence of implants warrant intense management. Healthy bone is normally resilient to infection and for OM to occur a large bacterial load is usually present with comorbid necrosis or ischaemic tissue, trauma and/or the presence of foreign material (2). Traditionally, COM was known to be a chronic inflammatory destructive process involving the bone and marrow secondary to an infective process characterised by the presence of sequestrum and involucrum (2). This definition stemmed from the observation that if left untreated, acute haematogenous osteomyelitis resulted in necrotic bone segments that provided a nidus for on-going infection (2). The increased use of surgical implants in orthopaedic surgery came with an increased prevalence of post-operative OM (2). Cierny put forward the concept of COM being a biofilm-initiated infection where most of the offending pathogens were encased in a glycocalyx slime, the biofilm, and adherent to devitalised bone,

implants in situ or foreign material (19). Bacteria inside the biofilm have the ability to change their pattern of gene expression thereby altering their phenotypic, mechanical and metabolic process making them extremely resistant to host defences and antimicrobials (2). Once bacteria adhere to the substrate, they are able to come into contact with other circulating bacteria and form microcolonies (2). Once the optimum bacterial density is reached, cell to cell signalling occurs propagating the formation of a polysaccharide slime that encases the micro-colonies of bacteria (2). The interacting communities of bacterial sub-populations within the biofilm can mutate into resistant phenotypes and develop drug resistant genes making antibiotic penetration challenging (2). As the biofilm environment deteriorates, bacteria undergo further alteration in gene expression and change to an invasive phenotype allowing them to disperse and find other surfaces that provide a better location (2). This biofilm dynamic of resilient pathogens protected by an impenetrable matrix makes COM resistant to non-surgical treatment.

1.3.3. Classification of COM

Historically, Waldvogel *et al.* used a descriptive classification system that encompasses the mode or origins of the infection, the existence of peripheral vascular disease and duration (20). The origin of infection was either haematogenous or contiguous. As surgical management increased so too did the incidence of contiguous OM and therefore the need to categorise it (21). Kelly's classification in 1984 differentiated OM from haematogenous and contiguous either from post-surgical or post-traumatic causes (22). The classification systems developed by Ger and Weiland *et al.* highlighted the role of soft tissues and the nature of skeletal involvement to guide treatment protocol (23, 24). Romano *et al.* provided a classification system for OM post osteosynthesis called the Infection, Callus, Stability (ICS) classification (25). This system stages the infection by the presence of a stable or unstable fixation and development of bony union (25). Other than the ICS classification, the rest do not provide adequate information to develop a management strategy and a more comprehensive classification that included important criteria and guidance towards appropriate treatment strategies was needed (21). Today, OM is commonly staged using the Cierny and Madar Classification which was developed over 30 years ago and is displayed in Table 1.1. Cierny and Madar proposed a holistic approach to the OM patients by acknowledging the role of the immune competency and the host's physiological capacity to heal (21). These are systemic and local factors that can influence monitoring, metabolism and blood delivery (see Table 1.2.) (21, 26).

Table 1.1: Cierny and Madar Classification of OM (26)

Anatomic Type	
1	Medullary OM - limited to medulla and endosteum
2	Superficial OM – confined to exterior superficial tissues, does not extend through cortex
3	Localised OM – penetrates cortex and medulla
4	Diffuse OM – circumferential, bi-cortical and medullary
Physiological	
A	Good immune system and vascular delivery
B	Compromised locally (Bl) or systemically (Bs) or both (Bls)
C	Treatment morbidity higher than current disease status

Table 1.2: Systemic and Local factors affecting physiological host status (26)

Type of compromise	Factors
Systemic (s)	• Malnutrition • Renal • Hepatic failure • Diabetes Mellitus • Chronic Hypoxia • Immune disease, malignancy • Extremes of age • Immunosuppression/Immune deficiency

Local (I)	• Chronic Lymphodema • Vascular stasis • Major vessel compromise • Arteritis • Extensive scarring • Radiation fibrosis • Small vessel disease • Tobacco use (>2 year packs/day) • Neuropathy
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This perspective reshaped the way in which OM is viewed and treated. The principles behind this staging is not limited to the extent of the osseous necrosis but incorporates the hosts immune competency and the impact of disease function which collectively play a role in treatment algorithms (19). Patients' physiological status and the impact of OM on their function are classified into three host categories with A-hosts being healthy individuals while B-hosts are those persons with pre-existing conditions that can affect responses to stress, infection and trauma (19). C-hosts are those patient's in which the risk of treatment outweigh the benefits and are treated expectantly or palliated (19). B-hosts are at a higher risk for treatment failure due to the local and systemic co-morbidities that can affect tissue healing therefore optimisation of their physiological status throughout treatment is advocated to improve outcomes (19). The anatomic variants of OM progress from Type 1 to type 4 and represent the natural evolution of the disease complexity (19). The combination of three host classes and four anatomical variants assign patients into one of twelve clinical stages (19). These clinical stages formulated by Cierny and Madar aid in treatment planning, recognise the progressive stages of the disease and assist with prognostication (19). The anatomic type of the infection (see Figure 1.1.) dictates the surgical technique and the host status directs the choice of therapeutic options (19).

The interaction between the anatomic extent of OM, host status, the impact of function as well as the experience of the caregiver will guide treatment to be palliative *versus* curative, staged or simple or limb sparing or ablative (19).

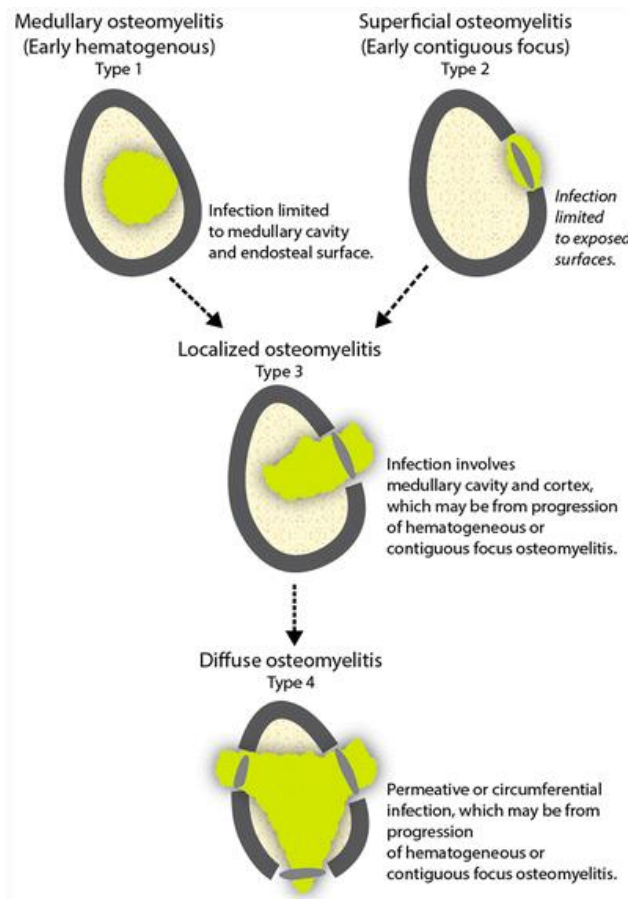


Figure 1.1: Anatomical staging of OM (27)

1.3.4. Shifting the Paradigm – COM in South Africa

Open fractures contain some degree of contamination with debris and microbes which can develop into osteomyelitis in up to 50% of cases based on the extent of soft tissue damage and initial management (28). In closed fractures carried out as elective trauma surgery, the infection rate was much less at 1 – 5% (28). Elective primary lower limb knee and hip arthroplasty carry an infection risk between 0.5 – 2% (29) and a much higher risk associated with revision surgery for peri-prosthetic joint infection (30). Orthopaedics has progressed to primarily a surgical field with greater use of implants for fracture treatment and joint replacement hence changing the patho-mechanism of COM from haematogenous to contiguous spread either from an open injury or postoperatively. Interpersonal violence and road traffic injuries are the main contributors to high occurrence of morbidity and mortality in low- and middle-income countries (LMIC) (31). Our country has a trauma related mortality rate that is six times more

than the global rate with twice the global average for a road traffic injury (32). The implications of these figures suggest, in an analogous way, a high level of morbidity associated with road traffic accidents and a subsequent increased incidence of post traumatic OM (2). The human immunodeficiency virus (HIV) epidemic is a growing concern for public health in Southern Africa. The increased immunosuppression associated with the virus predisposes patients to more systemic infections with common and opportunistic pathogens (33). The high number of South Africa's population that live with HIV together with the crippling effects of COM these patients endure, begs the question as to whether COM in these patients is due to HIV immunosuppression. Surprisingly, data from limited studies indicate COM is not commonly seen in patients with HIV (34, 35). These studies were conducted on a small number of patients prior to the exponential rise of HIV infection and in non-endemic countries which could be a possible reason for the above finding. Adult haematogenous OM of the long bones along with late haematogenous infection of implants has been reported among the HIV population (36). Research has shown that HIV infected individuals have increased rates of post-surgical wound infection following open fracture fixation particularly if wounds are contaminated (37, 38). Risk factors identified for surgical wound infection in the HIV orthopaedic trauma patient include: Centers for Disease Control (CDC) clinical classification B, CD4 count <500 and contaminated wounds (39). This along with resource constraints and the increased burden of trauma, the sequelae of surgical wound infection in the form of COM can result in substantial personal loss. To worsen an already difficult situation is that South Africa has a severe shortage of qualified orthopaedic surgeons (2). In 2011, the central Kwa-Zulu Natal population of approximately 3.5 million had only 0.37 qualified full time orthopaedic surgeons per 100 000 (2). Developed countries such as Canada and the United States of America have up to 15 times more full-time qualified orthopaedic surgeons (40, 41). Furthermore, regular out-patient follow-up is a challenge even when patients are extensively counselled to return for review, with some returning only when there are serious complications. These shortages and non-compliance woes lead to inappropriate treatment and worsening of the incidence of COM (2).

1.3.5. Complications of COM

Infectious

Persistent and recurring infections are the hallmark of COM. Sinus tracts, development of abscesses and extension into surrounding tissues are some of these manifestations (42). This is partially due to biofilm formation (43). This sticky matrix protects against antimicrobial pharmaco-kinetics and host immune responses while slowing down the metabolism of the resident micro-colonies and providing a nutrient rich environment (43). Along with biofilm formation, the persistent small colony variants (SCVs) found within the proteinaceous medium are able to lie dormant intra-cellularly for many years before re-appearing as the new parent strain and subsequently causing re-infection (43).

Non-infectious

Non-infectious complications of COM are not a direct result of the infection but are consequences of existing with COM. Osteoblasts and osteoclasts work alongside each other to maintain bone remodelling haemostasis (43). Infection and inflammation upsets this balance resulting in weakened bone and pathological fractures (43). Patients with chronic draining sinuses can develop a malignant transformation called a Marjolin's ulcer (44). This aggressive squamous cell carcinoma along with secondary amyloidosis are long term complications pertaining to treatment failure (3).

More importantly, these patients suffer significant social and functional decline causing poor quality of life and psychosocial deterioration (3). Progressive loss of working ability and subsequent financial instability leads to dependency on disability grants (3). A knock-on effect of this is loss of medical aid as patients are unable to afford it. Most patients agree to amputation as a quick solution to eradicate the disease mainly owing to the uncertainty of cure (3). Prolonged hospitalisation, unpredictable results, continuous pain, cosmesis and functional concerns are issues that COM patients face daily (3). Depression, narcotic dependency, separation from spouses and significant others contribute to the psychosocial ordeal that these patients live with (3).

1.3.6. Defining the research problem – Relevance of the study

Physical limitations, as well as psychosocial adjustment are important factors that determine QOL in patients living with long term illness (5). While these patients continue to seek medical care in the hope of a cure, they require strong social support, effective coping skills and resilient mental health (5). To date, there are no studies done on the QOL of people living with COM in South Africa or Africa. Not much is known about the limitations these patients experience that compromise their QOL. Recognising the negative effects on the QOL of these patients will allow for the prioritisation of specialised bone infection surgical units with multidisciplinary input such that this complex condition can be managed holistically. It will also sensitise surgeons to enhance pre-operative sterility, as well as allow for proper patient optimisation at initial surgery.

1.4. Study Aim and Objectives

Aim:

To determine the quality of life of patients affected by Chronic Osteomyelitis at two specialist centres in Johannesburg, South Africa.

Objectives:

- i. To assess self-reported quality of life using the Medical Outcomes Study 36 – Item Short Form Health Survey (SF-36) questionnaire tool (45) in patients with COM.
- ii. To determine if quality of life correlates with disease complexity.
- iii. To provide recommendations on treatment strategies for improved service provision for patients with chronic osteomyelitis.

CHAPTER 2

METHODOLOGY

2.1. Study design and setting

This was a cross-sectional study with a sample size of 108 patients divided into a COM group of 54 patients and a matched size control group of 54 patients without COM. Originally, we calculated the power of the study of 142 participants. This was an estimated sample size calculated with an anticipated incidence of a given outcome for study groups with 80% to 60%, Alpha (type 1 error false-positive rate) 0.05, Beta (type 2 error false-negative rate) 0.2, Power 0.8. However, the differences between the two examined groups were marked. On recalculation a target size of 76 participants would have sufficed. Data was collected prospectively over a 12 month period. The Chris Hani Baragwanath Academic Hospital (CHBAH) and the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) provide tertiary level orthopaedic services to Johannesburg and surrounding areas. The Orthopaedic outpatient departments (OPDs) at these hospitals operate weekly and a number of patients attend follow-up appointments for their musculoskeletal conditions. Participants were recruited from these OPDs.

2.2. Materials and Methods

Ethics approval for the study was acquired from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (see Appendix A). Before commencement of the study, permission to conduct the study at CHBAH and CMJAH was obtained from the respective Chief Executive Officers (CEOs) as well as from the Orthopaedic Units Clinical Heads of Trauma, and Tumour and Sepsis (see Appendix B). Participation was purely voluntary and non-participation incurred no loss of benefits or penalties. Participants were able to discontinue participation at any time. Patients who met the inclusion criteria for COM either by clinical presentation, radiological findings or by identification of micro-organisms on bone samples were invited to take part in the study. Patients who were not diagnosed with COM but attended the orthopaedic OPD's for other ailments formed the control group. Upon agreement and signing of the informed consent, the patient was provided with an SF-36 QOL questionnaire to complete (see Appendix C). The duration of COM was defined as either

symptom's lasting longer than six months or infection refractory to multiple attempts at eradication.

2.3. Data Collection

Data were captured from data collection sheets and transcribed into an Excel sheet. An anonymised excel spreadsheet was uploaded, using SPSS version 29 for further analysis. Descriptive statistics were conducted. Categorical variables were presented as frequency and percentages. Continuous variables were reported as mean $\pm$ standard deviation for normal data or median and interquartile range (if not normally distributed). An association of categorical variables was processed using the Pearson's Chi-Square test or the Fisher exact test. A statistically significant association was set at a p -value < 0.05 . No comparative normative data exists for the SF-36 in South Africa or other African countries hence data from Brazil was utilised because of its similar socioeconomic status characteristics to South Africa (46).

2.3.1. Quality of life

Data on the of the QOL of the sample population was collected using the SF-36 questionnaire (45). This instrument is a widely used generic tool designed to analyse the health related quality of life (HRQOL) of a participant and has 36 questions that are measure health across 8 domains: physical functioning, role limitations due to physical functioning, pain, general health perceptions, energy & vitality, social interaction, emotional aspects and mental health (45). Each item is coded, transformed and aggregated in order to score each domain from 0-100, with 0 corresponding to the most poor health status and a higher score representing improved health (45). The SF-36 instrument was applied in the form of an interview by the principal investigator, questions were read by the interviewer with a translator available if needed.

2.3.2. General and clinical

Along with the information from the SF-36 instrument, patient's demographics, co-morbidities, anatomical site, original pathology, fracture type, culture and serological markers (if done), impairment in activities of daily living (ADL) and specific major and minor risk factors associated with COM according to Marais *et al.* (47) was accessed from clinical records.

Radiographic images were assessed using hard-copy X-ray films provided by the patients or analysing digital copies stored on the hospital's Picture Archiving and Communication System (PACS).

2.3.3. Selection Criteria for COM group

Inclusion Criteria:

- Age: Patients who are 18 years and older
- All COM patients attending the Trauma, and Tumour and Sepsis OPDs at both hospitals were included.

Exclusion Criteria:

- Patients presenting with aseptic OM
- Patients presenting with peri-prosthetic joint infections

CHAPTER 3

RESULTS

3.1. General characteristics of participants with COM

In total, 54 individuals were enrolled. The mean age of the sample was 43.3 years of age. Males made up majority of the study (79.6%; $n = 43$). Sample characteristics are presented in Table 3.1. Fracture related infection (FRI) was the commonest cause of COM accounting for 81.5% ($n = 44$) of the population with closed fractures accounting for most of the FRI cases (53.7%; $n = 29$). Non-smokers were more than smokers (59.3%; $n = 32$ and 40.7%; $n = 22$, respectively). Most patients presented with a draining sinus (79.6%; $n = 43$) and were HIV negative (83.3%; $n = 45$). In terms of physiological host status, Type A hosts made up the majority (61.1%; $n = 33$) of patients and a type 3 combined stable medullary and cortical involvement was the most frequently (77.8%; $n = 42$) occurring patho-anatomy. A biofilm-based infection in the presence of an orthopaedic implant accounted for large amount (70.4%; $n = 38$) of the initial nidus found in patients with COM. Minimal impairment in ADL was reported by most of the cohort (88.9%; $n = 48$).

Table 3.1: Data of participants with COM ($n = 54$)

		Average (range)
Age	Male	40.2 (18 - 64)
	Female	46.4 (18 - 65)
		Number (%)
Gender	Male	43 (76.6)
	Female	11 (20.4)
Original Pathology	FRI	44 (81.5)
	Haematogenous	6 (11.1)
	Contiguous	4 (7.4)
If FRI – Open vs Closed fractures	Open	15 (34.1)
	Closed	29 (53.7)
Smokers	Yes	22 (40.7)
	No	32 (53.3)
Draining sinus	Yes	43 (79.6)
	No	11(20.4)
HIV status	Positive	9 (16.7)
	Negative	45 (83.3)
Diabetes	Yes	6 (11.1)
	No	48 (88.9)
Physiological host (47)	A – No Risk factors	33 (61.1)
	B - < 3 minor risk factors	20 (37.0)
	C – 1 major or/& 3 or > minor risk factors	1 (1.9)
Patho - anatomy (47)	1- Medullary	0
	2 - Cortical	1 (1.9)
	3 - Combined stable	42 (77.8)
	4 – Combined unstable	11 (20.4)
Nidus (47)	Sequestrum	12 (22.2)
	Implant	38 (70.4)
	No identifiable nidus	4 (7.4)
Impairment of functional capacity	Minimal	48 (88.9)
	Severe	6 (11.1)

The anatomical sites of infection are displayed in Figure 3.1. The tibia was the most commonly affected bone, followed by the femur.

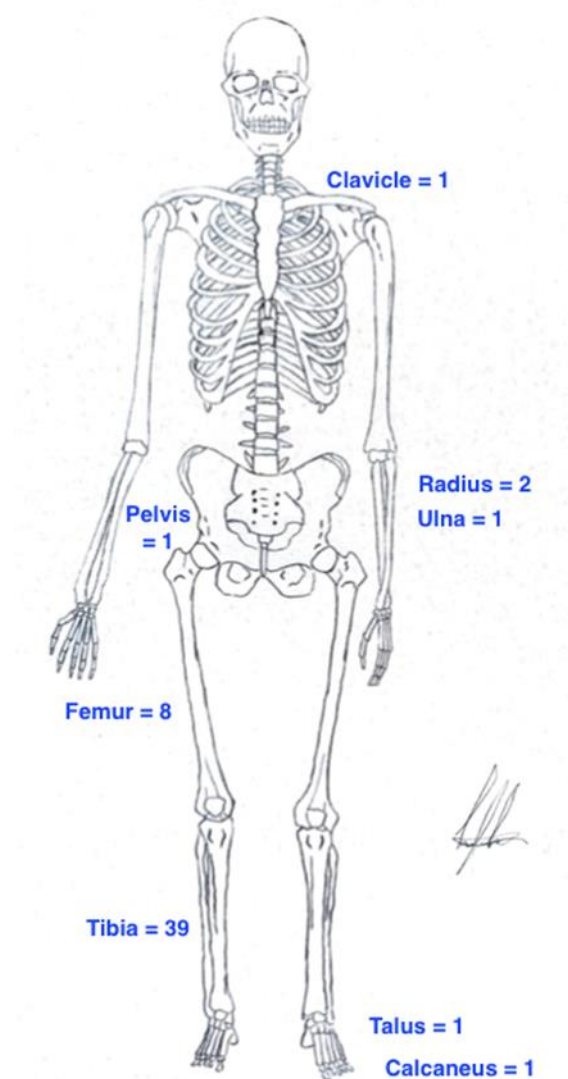


Figure 3.1: Anatomical sites affected by Chronic Osteomyelitis

3.2. Quality of life in patients living with COM

The means and standard deviations for each of the SF-36 domain scores are represented in Table 3.2. All 8 domains scored below the means of the normative data for a country of comparative socioeconomic status to South Africa (46).

Table 3.2: Mean, standard deviations (SD) and independent t-test of the SF-36 domains in the samples

SF 36 Domains	Mean (SD) OM	Mean (SD) healthy	<i>p</i> -value
Physical functioning	46.48 (27.02)	72.22 (32.34)	0.01
Role limitation due to physical health	31.48 (35.75)	94.44 (5.89)	0.01
Role limitation due to emotional problems	43.82 (44.82)	100 (0)	0.01
Vitality	61.11 (24.18)	68.88 (14.25)	0.06
Mental Health	64.89 (22.46)	80 (14.14)	0.01
Social functioning	62.27 (27.42)	100(0)	0.01
Pain	55.00 (28.23)	95 (7.70)	0.01
General health	62.31(20.87)	71.1(18.10)	0.03

Except for “Vitality” domain, a statistically significant difference ($p < 0.05$) was documented in the other SF-36 domains between COM and control groups. Independent t-tests were conducted to assess if a relationship was present between the COM individuals characteristics and the 8 domains of the HRQOL SF-36. Characteristics not included in the analysis due to disparate subgroup sizes were Original pathology, HIV status, Diabetes, Nidus and Impairment in ALDs. Application of Levene’s test was done to assess whether the assumption of equal variances was met between the subgroups of each characteristic. Practical effect for the sample

size was done using the Cohen's d test (point estimate). Effect size were as follows: small: $d = 0.2$, medium: $d = 0.5$ and large: $d = 0.8$. Results will be reported in a Table format for Age, Gender, Open or closed fracture, Draining sinus and smoking. Patho-anatomy was regarded as complexity of disease and will be addressed under Subsection 3.4. below.

3.3 Age, Gender, Open or closed fracture, Draining sinus and smoking

After using the Pearson correlation to analyse age with the other SF-36 domains, it was found that there was no correlation between age and the 8 domains of QOL (see Table 3.3).

Table 3.3: Relationship between Age and SF-36 domains

SF 36 Domains	Pearson correlation with Age
Physical functioning	0.209
Role limitation due to physical health	0.932
Role limitation due to emotional problems	0.589
Vitality	0.544
Mental health	0.078
Social functioning	0.234
Pain	0.690
General health	0.898

*PF = Physical functioning, RP = Role limitations due to physical health, RE = Role limitation due to emotional problems, Vitality = VT, Mental health = MH, Social functioning = SF, Pain = P, General health = GH.

The difference between male and female participants regarding QOL was investigated by means of an independent samples t-test (see Table 3.4). Levene's test showed that the variance between males and females only differed significantly ($F \text{ sig} = 0.006$) for Role limitations due to emotional problems therefore t-test for equal variance not assumed was used for that domain. No statistical significant difference ($p < 0.05$) existed between the SF-36 scores of male and female participants.

Table 3.4: Independent samples t-test across gender and the SF-36 domains

Gender	Statistic	PF	RP	RE	VT	MH	SF	P	GH
Male	Mean	48.14	33.72	48.06	59.42	63.16	61.05	52.09	60.81
	SD	28.39	37.35	46.18	24.55	22.13	28.64	28.52	21.85
Female	Mean	40.00	22.73	27.27	67.73	71.64	67.05	66.36	68.18
	SD	20.62	28.41	35.96	22.51	23.56	22.55	25.08	16.01
Levene's test for equality of variances	F-test	3.369	1.205	8.196	0.441	0.123	1.117	0.559	2.828
	sig	0.072	0.277	0.006	0.510	1.718	0.295	0.458	0.099
Equal variances	Assumed	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
	t-Test	- 0.890	0.909	-1.608	1.017	1.119	0.644	1.514	1.046
	Two-sided p	0.295	0.298	0.124	0.299	0.298	0.467	0.120	0.223

*PF = Physical functioning, RP = Role limitations due to physical health, RE = Role limitation due to emotional problems, Vitality = VT, Mental health = MH, Social functioning = SF, Pain = P, General health = GH.

The independent sample t-test for assessing the relationship between open and closed fractures with the SF-36 showed no correlation between fracture type and SF-36 scores (see Table 3.5). The variance did not differ significantly between the two groups across all 8 domains.

Table 3.5: Independent samples t-test across FRI and the SF-36 domains

FRI	Statistic	PF	RP	RE	VT	MH	SF	P	GH
Open fractures	Mean	43.67	40.00	44.44	65.33	69.33	65.00	63.00	64.00
	SD	20.22	40.97	44,84	23.93	23.93	29.96	25.96	19.92
Closed fractures	Mean	46.90	25.00	37.93	60.86	63.31	61.64	50.78	60.69
	SD	27.37	32.04	42.47	24.09	21.68	35.42	30.02	19.72
Levene's test for equality of variances	F-test	3.557	3.671	0.142	0.002	0.121	1.395	0.749	0.010
	sig	0.066	0.062	0.708	0.969	0.730	0.244	0.392	0.920
Equal variances	Assumed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	t-test	0.403	-1.337	-0.473	-0.585	-0.843	-0.391	-1.337	-0.526
	Two-sided p	0.660	0.229	0.646	0.562	0.422	0.714	0.171	0.604

*PF = Physical functioning, RP = Role limitations due to physical health, RE = Role limitation due to emotional problems, Vitality = VT, Mental health = MH, Social functioning = SF, Pain = P, General health = GH.

There was no correlation between the presence and absence of a draining sinus and the SF-36 HRQOL domains (see Table 3.6). Equal variances were assumed across all domains.

Table 3.6: Independent samples t-test across draining sinus and the SF-36 domains

Draining sinus	Statistic	PF	RP	RE	VT	MH	SF	P	GH
Yes	Mean	48.37	33.72	48.06	60.58	63.63	63.95	56.28	61.63
	SD	27.55	38.53	45.02	25.05	22.81	27.31	28.51	19.02
No	Mean	39.09	22.73	27.27	63.18	69.82	55.68	50.00	65.00
	SD	24.58	20.78	41.68	21.36	21.34	28.15	27.84	27.93
Levene's test for equality of variances	F-test	0.592	8.386	1.929	0.646	0.315	0.145	0.003	1.226
	sig	0.445	0.006	0.171	0.425	0.577	0.705	0.959	0.273
Equal variances	Assumed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	t-test	-1.017	-0.909	-1.386	0.316	0.813	-0.891	-0.664	0.475
	two-sided p	0.291	0.210	0.165	0.732	0.410	0.395	0.516	0.711

PF = Physical functioning, RP = Role limitations due to physical health, RE = Role limitation due to emotional problems, Vitality = VT, Mental health = MH, Social functioning = SF, Pain = P, General health = GH.

The relationship between smoking and the SF-36 domains was investigated using the independent sample t-test (see Table 3.7). Levene's test indicated equal variances. There was a correlation between smoking and the domains of Mental health and Vitality (both domains $p < 0.05$). Non-smokers scored higher in vitality (Mean = 68.13, SD = 24.59) and mental health (Mean = 70.88, SD 21.96). Cohen's d test reflected a sample of 0.75 for Vitality and 0.69 for mental health which confirm a medium effect.

Table 3.7: Independent samples t-test across smoking and the SF-36 domains

Smoking	Statistic	PF	RP	RE	VT	MH	SF	P	GH
Yes	Mean	48.41	27.27	46.97	50.91	56.18	61.36	50.80	58.41
	SD	28.84	31.73	43.23	19.98	20.67	22.46	26.86	15.46
No	Mean	45.16	34.38	41.66	68.13	70.88	62.89	57.89	65.00
	SD	26.07	38.50	46.38	24.59	21.96	30.70	29.20	23.76
Levene's test for equality of variances	F-test	0.714	1.703	0.920	2.011	0.361	4.687	0.539	2.046
	sig	0.402	0.198	0.342	0.162	0.550	0.035	0.466	0.159
Equal variances	Assumed	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
	t-test	-0.431	0.714	-0.424	2.722	2.473	0.211	0.906	1.144
	two-sided p	0.674	0.463	0.669	0.007	0.016	0.834	0.362	0.223

PF = Physical functioning, RP = Role limitations due to physical health, RE = Role limitation due to emotional problems, Vitality = VT, Mental health = MH, Social functioning = SF, Pain = P, General health = GH.

3.4. Correlation of QOL and disease complexity

Independent t-tests were used to analyse if a relationship was present between disease complexity and the 8 domains of the HRQOL SF-36 (see Table 3.8). Disease complexity was illustrated by the anatomic Cierny and Madar classification modified by Marais *et al.* (47) which was collected under the data characteristic of “patho-anatomy” in our cohort.

Table 3.8: Independent samples t-test across disease complexity and the SF-36 domains

Disease complexity	Statistic	PF	RP	RE	VT	MH	SF	P	GH
Type 3 – Combined stable i.e. both cortex & medulla involved	Mean	49.88	33.93	45.24	60.95	62.95	62.50	55.54	55.54
	SD	26.86	36.97	45.87	24.20	23.43	27.47	28.40	28,40
Type 4 – Combined unstable i.e. Same as 3 + unstable prior to debridement	Mean	36.36	15.91	33.33	61.36	72.00	57.96	51.82	61.36
	SD	25.50	20.23	39.44	26.37	18.76	26.97	29.81	27.85
Levene's test for equality of variances	F - test	0.174	6.302	5.541	0.244	1.973	0.033	0.033	2.201
	sig	0.678	0.015	0.022	0.623	0.166	0.857	0.857	0.144
Equal variances	Assumed	Yes	Yes	Yes	Yes	Yes	No	No	Yes
	t-test	1.500	1.550	0.787	-0.049	-1.183	0.496	0.372	0.128
	Two-sided p	0.141	0.039	0.401	0.963	0.194	0.627	0.715	0.901

PF = Physical functioning, RP = Role limitations due to physical health, RE = Role limitation due to emotional problems, Vitality = VT, Mental health = MH, Social functioning = SF, P = Pain, GH = General health.

The relationship between disease complexity and the SF-36 domains was investigated using the independent sample t-test. Equal variances was confirmed by the Levene's test. There was a correlation between disease complexity and the domain of role limitation due to physical function (RP) ($p = 0.039$). Type 3 – Combined stable (Mean = 33.93, SD = 36, 96) scored

higher than type 4 combined unstable (mean = 15.91, SD = 20.23). Cohen's d test reflected a sample size effect of 0.51, which implies a medium effect.

CHAPTER 4

DISCUSSION

Bone infection is a catastrophic consequence of traumatic orthopaedic injuries and imposes a substantial burden on the patient, their families and the health system. As far as we know, no published studies have documented the QOL of patients living with COM in South Africa or the broader Africa context. This study aimed to assess patients perceived QOL using the SF-36 instrument and to explore whether a relationship exists between QOL outcomes and the complexity of the disease.

The discussion above is structured in the following way:

4.1. The General characteristics of participants with COM

4.2. The QOL of patients living with COM

4.3. The correlation of QOL with disease complexity

4.1 The General characteristics of participants with COM

Male participants outnumbered their female counterparts (43 *versus* 11) which equated to 76.6% of the total sample. In other words, for every 1 female patient affected by COM there was approximately four male patients suffering with the same disease. This is in keeping with other studies conducted in other regions in South Africa (18, 48) and in Sub-Saharan Africa (1). A staggering number of patients had a FRI as the cause of their COM (81.5%). Our country has an alarming high trauma related mortality rate and road traffic injury when compared to the global average (32). The associated high velocity skeletal injury and the increase in the use of orthopaedic procedures to manage these injuries can attribute to the high rise in FRI and the subsequent increase in COM seen in South Africa (2). The detrimental effects of smoking in musculoskeletal health are well documented. In both development and management of COM smoking causes weakened immune response, micro and macro-vascular dysregulation reducing oxygenation, impaired healing and higher risks of treatment failure (49). Current smokers are 3.7 times higher risk for developing OM (50, 51). So, it was rather unexpected that slightly more than half (53.3%) of our participants were non-smokers. A relatively smaller sample may act as a confounding factor, possibly reducing the generalisability of this finding.

Additionally, the reliability of the data may be affected as patients may not have accurately disclosed their smoking status introducing potential bias into the analysis. Another surprising statistic was that 80.3% of our cohort were HIV negative. HIV can have profound ramifications on the immune system and can impact the outcome of COM. Besides an increase in susceptibility of wound infections, HIV infection poses an increased presence of atypical pathogens and higher risk for mal-unions (52, 53). A smaller sample size can also be implicated in this controversial finding. A local study that identified pathogens that cause COM found that 82% of their cohort was HIV negative which is in keeping with our findings (18). They also had a small sample size which underscores the needs for a larger sample size with further studies. The orthopaedic management of COM involves a structured process of surgical debridement, management of the resulting dead-space, skeletal stability, soft tissue reconstruction if required and tailored antibiotic therapy (54). The physiological host status of the patient directly impacts their ability to overcome infection and resist recurrence, heal bone and tolerate the above surgical treatment and post-operative risks. Type A hosts have the best prognosis made up approximated 61.1% of our study population with Type B hosts making up the rest. This implies that should these patients undergo surgical management for their COM the outcome would be promising. Type B hosts generally require optimisation to improve their physiological status prior to any surgical management. The patho-anatomy of the anatomical extent of the COM is essential as it directly impacts surgical planning, approach and outcomes (48). Type 3 and 4 patho-anatomy involves infection of the cortex and medulla with either the bone affected locally and stable or diffuse and skeletally unstable respectively. These are generally more complex and sometimes requiring multistage surgeries. Our participants were predominantly Type 3 (77.8%) and type 4 (20.4%). Another study with a larger sample size ($n = 80$) had similar results with Type 3 and type 4 accounting for 30% and 26% of their sample (48). A plausible reason for the high prevalence of severe disease observed in our setting is the delay in seeking or receiving definitive treatment. Many of these patients wait for extended periods (months to years) after initial diagnosis for their treatment. Several factors contribute to the prolonged waiting times encountered by these patients. Resource limitations within the healthcare system cannot be understated. Johannesburg had two specialised tumour and sepsis units in the public sector to manage these conditions with children and non-benign conditions taking priority. The high burden of skeletal trauma overwhelms available services and poor compliance with follow-up review contribute to the delay in timely intervention and ultimately progression of disease occurs by the time patients receive definitive treatment. The increased

use of surgical implants in orthopaedic procedures has been associated with a corresponding rise in the prevalence of post-operative OM (2). Cierny introduced the concept of COM as an infection associated with biofilm, wherein a large number of causative microbes are embedded within a glycocalyx matrix—commonly referred to as biofilm—and adhere to necrotic bone, implants, or other foreign materials (19). The biofilm dynamic, characterised by resilient pathogens protected within an impenetrable extracellular matrix, renders COM particularly resistant to non-surgical treatment modalities, thereby necessitating surgical debridement for effective infection control. In our study, 70% of patients had a biofilm-based nidus—specifically related to implants—contributing to the persistence of chronic osteomyelitis. Functional activities of daily living include the capability to bathe, to dress and undress oneself, toileting, and feeding, all of which may be preserved in patients who have adapted well to their condition. Despite the severity of lower limb chronic osteomyelitis, patients may remain capable of performing ADL due to gradual adaptation to their disability (55). Many develop compensatory movements, modify tasks, or use the non-infected limb more. Intermittent symptomatology, using assistive devices, and strong motivation to maintain independence are factors that can mask the functional burden of the disease. In our study, 88.9% of patients indicated minimal restrictions in performing functional activities, further supporting the idea that ADLs may not fully reflect the underlying disease burden in chronic osteomyelitis.

4.2. The QOL of patients living with COM

The findings of this study validate the deduction that patients affected by chronic osteomyelitis (COM) experience significantly poorer physical functioning and psychological well-being. In the absence of normative SF-36 data for Southern Africa or for the African continent, reference values from Brazil (46) were utilised, given its comparable socioeconomic characteristics. When benchmarked against these norms, our results demonstrate that South African patients living with COM score below average across all domains of the SF-36, highlighting the substantial impact of the disease on overall quality of life.

Among patients affected by COM, non-smokers had scored better in the vitality and mental health domain. The Vitality domain analyses perceived of energy and fatigue levels which is indicative of physical and emotional well-being. The higher scores reflected by the non-smoker

group suggest greater energy and decreased fatigue. This was also noticed in the mental health domain as non-smokers score better implying better psychological function and emotional resilience. Albeit Vitality and mental health scores were not markedly high across the COM cohort, the benefits of not smoking are widely established and provides a plausible explanation for the minor but relatively improved QOL observed in these domains experienced by the non-smokers.

We set out to determine, through the SF-36 questionnaire tool, the perception of QOL of patients living with COM. Our results confirm that patients affected by COM have a remarkably diminished perception of their QOL across all health domains when compared to the control group. Functional and social repercussions of chronic illness and the acceptance that medical treatment seeks to prolong and improve the quality of life are important factors in health care during this era (56). The main aim of treating a chronic disease in patients is to lift their quality of life by reducing the impact of disease (56). People living with COM often present to an out patients department (OPD) with a limb deformity or persistent pus drainage (1). Understandably, these patients experience a great deal of economic and personal burdens further exacerbating an already poor socio-economic situation. The psychosocial decline of patients with COM is well known. The ability to maintain employment and to function within an intact social structure are daily challenges that these patients face and are considered the biggest complications of COM (3-5). In one study, 70% of patients lost employment, 62% lost health insurance and half had separated or filed for divorce from their partners (3). These three social areas also affected patients the most with the inability to maintain employment as the initiating factor for their personal decline (3). The hope for a definitive cure diminished as the deprivation of health insurance increased (3) with some patients opting for amputation as a solution for the eradication of infection and decreased contact with the medical system (3, 5). These patients also suffer from depression, low self-esteem and anxiety in addition to chronic pain being an important contributor to the poor quality of life (QOL) (57, 58). The severity of COM experienced was also associated with QOL as one study in the United Kingdom documented that, patients with stable disease had higher QOL scores compared to those with complex OM requiring surgical management (59, 60). While these patients seldom have serious clinical complications, the greatest challenge to them is the functional and personal “death” that accompanies this condition (3).

4.3. The correlation of QOL and disease complexity

In this study the anatomical extent of COM within the affected bone was used as a measure of disease complexity. Almost all our patients presented with severe disease classified as either Type 3 – ‘Combined stable i.e. both cortex and medulla’ and Type 4 – ‘Combined unstable i.e. same as type 3 but unstable prior to debridement’ according to Marais *et al.* (47). Notably the only significant finding that emerged when comparing disease complexity was that individuals with Type 3 COM reported better scores in the ‘role limitation to physical health’ domain of the SF-36 HRQOL tool when compared to the type 4 group. The sample size was a moderate effect on this statistic indicating a meaningful clinical variation. One postulation for the above observation is that type 3 individuals have a relatively stability of their bony architecture compared to their type 4 counterparts. In type 3 disease there is full thickness cortical sequestration but the medulla often remains intact despite being involved providing mechanical support and mobility (61). Type 4 COM is more diffuse than type 3 with greater structural compromise and soft tissue involvement leading to instability (62). The more severe type of COM may result more physical limitations and reduced capacity for day-to-day activities and negatively impacting QOL. While type 3 and type 4 are considered severe forms of the disease their anatomical disparities appear to affect QOL. This suggests that not all severe disease impacts QOL equally and the anatomical extent should be a key consideration and the prioritisation and expedition of multidisciplinary care for these patients.

4.4. Study Limitations

A drawback of this study was a smaller than anticipated sample size. However, this is not uncommon in similar studies assessing quality of life in patients with chronic osteomyelitis. For example, a study by Vos *et al.* analysing functional outcomes in post-traumatic osteomyelitis had only 47 patients and acknowledged limited generalizability due to its small sample size (63). Rodham *et al.* in their study of extended outcomes of patients suffering with post-traumatic osteomyelitis of their lower limbs noted that their findings were limited by a relative small sample of 72 patients (64).

A second potential limitation was the involvement of a single interviewer, who even though was not a regular figure to the participants, may still have affected a few biases. Interviewer bias may have been introduced, where the interviewer’s manner or tone might subtly affect

participant responses (65). Participants might have felt compelled to provide answers they believed the interviewer expected or preferred, leading to social desirability bias (65). Confirmation bias may've resulted in interpreting responses in a way that aligns with preconceived notion or expectations of the study (65). Additionally, using only one interviewer may have led to inconsistencies in data collection techniques, as their approach could vary from participant to participant.

Another restriction was the potential for inaccurate self-reporting regarding undesirable social qualities such as smoking and HIV status which may have led to underreporting of these findings. The presence of multiple sources of pain could have influenced their perception of symptoms related to COM, leading to an over- or underestimation of the severity of their condition. These factors may have limited the studies ability to draw conclusions of COM-related symptoms and impacted findings on QOL and functional outcomes.

4.5. Recommendations

After assessing the results the subsequent recommendations are suggested:

4.5.1. Further studies

While our study represents the first known investigation into the QOL of patients living with COM in South Africa, future research is required. Larger sample sizes incorporating multi-centred studies are needed to provide a more comprehensive picture on the national burden of COM and its impact on QOL. This data base is required for informing health care planning and provision such that orthopaedic services are prioritised for patients with COM.

4.5.2. Adaption of HRQOL instruments to South African context

Although the SF-36 instrument is a globally used tool to measure HRQOL it was not always linguistically or culturally appropriate. The HRQOL tools used in studies going forward need to be adjusted to reflect South African socio-economic realities, local languages and literacy levels. This will improve accuracy and relevance when using patient reported outcomes in research settings.

4.5.3. Strengthen healthcare and support services

Given the complex nature of COM and the impact it has on QOL there is a clear need for the provision of dedicated bone infection units equipped with multidisciplinary team expertise. The units should include orthopaedic surgeons, plastic surgeons, infectious disease specialists, nutritionists, physiotherapists and social workers to manage this condition in a more patient centred and holistic manner.

CHAPTER 5

CONCLUSION

It has been established that COM is a devastating sequelae in orthopaedic surgery and has a negative impact on QOL amongst individual who live with it. This was not previously reported locally, and our study provided evidence from a South African perspective that echoes these sentiments. We conclude that patients who suffer from COM have a low perception of their quality of life in all domains emphasising the substantial impact this disease has on physical functioning and emotional well-being. For non-smokers living with the condition better energy levels and less fatigue serve as minor positive elements for the long and bumpy journey to recovery. Majority of patients are affected by severe disease and those with anatomic stability have less limitations to physical functioning. Health related QOL is a multifaceted idea that encompasses physical, mental and social factors that represents the overall wellbeing and functional capacity. As an indicator of “health” in a population, it is not surprising that patients living with COM require a great deal of attention.

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Appendices

Appendix A: Ethics clearance certificate

M230444 MED23-02-072

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG



R14/49 Dr Sanushka Pillay

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M230444 MED23-02-072

NAME: Dr Sanushka Pillay
(Principal Investigator)
DEPARTMENT: Orthopaedics
Charlotte Maxeke Johannesburg Academic Hospital
Chris Hani Baragwanath Academic Hospital

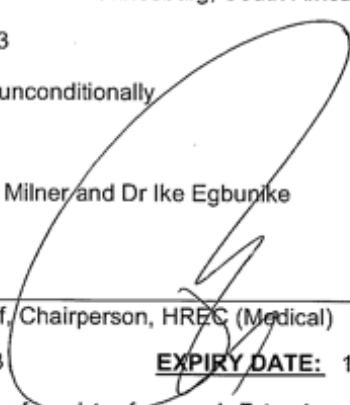
PROJECT TITLE: The quality of life in patients living with chronic osteomyelitis in Johannesburg, South Africa

DATE CONSIDERED: 05/05/2023

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Dr Brenda Milner and Dr Ike Egbunike

APPROVED BY: 
Prof P Ruff, Chairperson, HREC (Medical)

DATE OF APPROVAL: 16/10/2023 **EXPIRY DATE:** 15/10/2028

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 January 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 in April and will therefore be due in the month of April each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical). Email signed copy of this ethics clearance certificate prior to commencing with the study hrec-medical.researchoffice@wits.ac.za


Principal Investigator Signature

25/10/2023
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix B: CEO permission letters

 **GAUTENG PROVINCE**
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 2nd March 2023

TITLE OF PROJECT:
The quality of life in patients living with chronic osteomyelitis in Johannesburg, South Africa.

Principal Investigator: Dr S Pillay

Department: Orthopaedic Surgery

Supervisor: DR Ike Egbunike

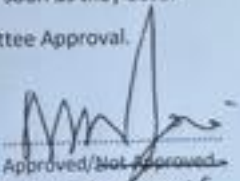
NHRD Number: GP_202301_013

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 the 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: 02/03/2023


Approved/~~Not Approved~~
Hospital Management
Date: 06/03/2023



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG
ACADEMIC HOSPITAL

Enquiries : Mr E Mosiamo
Email: edward.mosiamo@gauteng.gov.za
Tel: 011 488 4206
Ref: 1/7/2

To: DR SANUSHKA PILLAY

NHRD Ref: GP_202301_013

FINAL APPROVAL OF STUDY

STUDY TITLE: THE QUALITY OF LIFE IN PATIENTS LIVING WITH CHRONIC
OSTEOMYELITIS IN JOHANNESBURG, SOUTH AFRICA

Permission to conduct the above-mentioned study at Charlotte Maxeke Johannesburg
Academic Hospital (CMJAH) is granted subject to the following:

- Charlotte Maxeke Johannesburg Academic Hospital will not in any way incur or inherit costs as a result of the said study.
- Your study shall not disrupt services at the study sites.
- Strict confidentiality shall always be observed.
- Informed consent shall be solicited from participants in your study.

Before commencing data collection, please liaise with the relevant Head/s of Department and / or Unit to confirm arrangements, and agree on dates and times that suit all parties.

Once the research is completed, kindly forward the results to the CMJAH research committee Secretariat on cmjahresearch@gauteng.gov.za

Approved

Prof. Mary Kawonga

Chairperson: CMJAH Research Committee

Signed on behalf of the CEO, CMJAH

Date: Mar 18, 2025

Version3

Appendix C: SF 36 Instrument



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

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

RAND 36-Item Health Survey 1.0 Questionnaire Items

Choose one option for each questionnaire item.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ABOUT

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