The role of prophylactic antibiotics in zone II and zone V acute flexor tendon injury

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Dr Rihangwele Christopher Tshisikule (MBBCh-WITS)

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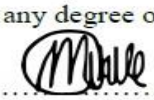
Declaration

I Dr Tshisikule Rihangwele Christopher 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.



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(Signature of candidate)

10 November 2023

Dedication

This study is dedicated to Prof. M. T. Ramokgopa, a mentor, a teacher and a father figure who afforded me an opportunity to study Orthopaedic surgery at University of the Witwatersrand and for his enormous support throughout this journey.

Secondly, this study is dedicated to my wife who is my best friend and my rock of stability for her tremendous support throughout these years and also to our children Wavhothe and Wavhutali.

Presentations and publications arising from the research project

Submitted for presentation in SAOA 2023 congress

Abstract

Background: In the literature, there is no universal consensus on the role of antibiotic prophylaxis in patients presenting with simple hand lacerations that has no macroscopic wound contamination. Our study sought to establish the necessity of prolonged pre-operative antibiotic prophylaxis in patients presenting with zone II and zone V acute flexor tendon injuries (FTI) at Chris Hani Baragwanath Academic Hospital (CHBAH).

Methods: This was a prospective study of 116 patients who presented with zone II and zone V acute FTI. The study period was between 01 November 2020 and 31 August 2021. Patients were randomised into a group receiving a single dose of prophylactic antibiotic in casualty and another group receiving a single antibiotic dose plus a continuous 8 hourly dose until the day of surgery. Each group was subdivided into occupational and non-occupational injuries. Their post-operative wound outcomes were documented 10 – 14 days after surgery. The wound outcome was reported as no infection, superficial infection (treated with wound dressings), and deep infection (requiring surgical debridement).

Results: There was 0.9% rate of deep post-operative wound infections, which was a single zone V acute FTI case in a single dose prophylactic antibiotic group. There was a 7.8% superficial post-operative wound infection rate, which was mainly zone II acute FTI in both antibiotic groups. There was a strong association between zone II acute FTI and post-operative wound infection ($p < 0.05$). There was no association between (antibiotic dosage or place of injury) with post-operative wound infection ($p > 0.05$).

Conclusion: There is no benefit in prescribing prolonged pre-operative antibiotic in patients with acute, simple lacerations to zone II and zone V FTI if there is no macroscopic wound contamination.

Acknowledgements

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Nomenclature

CEO	Chief Executive Officer
Covid-19	Corona virus disease 2019
CHBAH	Chris Hani Baragwanath Academic Hospital
CTR	Carpal tunnel release
ETI	Extensor tendon injury
FDP	Flexor digitorum profundus
FDS	Flexor digitorum superficialis
FTI	Flexor tendon injury
g	Gram
HREC	Human Research Ethics Committee
IVI	Intravenous infusion
SSI	Surgical Site Infection
TDS	Three times a day

CHAPTER 1

1. INTRODUCTION AND LITERATURE REVIEW

1.1. BACKGROUND

Antibiotic resistance is a growing concern and has required clinicians to re-assess their rationale for antibiotic usage (1, 2). In hand surgery, there is no clear consensus on indications for use of prophylactic antibiotics (3, 4). An increase in the prevalence of drug resistant bacteria has led surgeons to reconsider the need for peri-operative antibiotics (2, 5). Studies have attempted to answer questions around indications, dosage and duration of prophylactic antibiotics (1-3, 5, 6). In the literature, early prophylactic antibiotics are of great benefit in hand injuries such as open fractures, crush injuries, and human bite, however, these findings do not extend to other forms of hand trauma such as simple hand lacerations (without macroscopic contamination) (1-3, 5). The type and mechanism of hand injury has bearing on the quality of injured tendons and on the state of surrounding soft tissues, and therefore, influences post-surgical site infection (7).

Post-operative surgical site infection (SSI) in hand surgery and acute FTI is associated with poor clinical outcomes (1-3, 5). Functional outcomes for flexor tendon repair, especially zone II, have been of great concern to hand surgeons over the years due to the high incident of post-operative surgical site infections complicated by fibrosis and stiffness (8). These complications usually result in significant morbidity or impairment of hand function (1-3, 6). A thorough clinical assessment of a flexor tendon injury patient is important for the correct diagnosis of injured structures, planning of operation, and for patient counselling on possible complications, prognosis and expected outcomes (7).

The type of injury (pre-operative), surgical technique (intra-operative) and the host (patient) all play a role in post-operative surgical site infection (8). Pre-operative factors include the severity of trauma, degree of wound contamination, and the presence of associated injuries such as fractures, vascular injury and soft tissue cover (8). A laceration from a sharp smooth object results in fine wound edges with less wound complications as compared to a crush, torsional or avulsion type of injury which results in ragged wound edges and friable tissues (7). The use of antibiotics for all types of open hand injuries is largely based on fear of potential severe infections which may result in loss of a limb (1).

Given the emergence and burden of antibiotics resistance, it is therefore important to investigate if the prophylactic antibiotics are of any benefit with regard to post-operative hand infection in simple hand lacerations (8). This prospective study sought to investigate the differences in post-operative surgical site infection in acute zone II and zone V flexor tendon injuries on patients who received a continuous prophylactic Kefzol or Augmentin antibiotic doses *versus* those who received a single dose of Kefzol or Augmentin antibiotic prophylaxis. It will further give a report on the differences in surgical site infection on occupational *versus* non-occupational acute flexor tendon injuries in the continuous doses *versus* a single dose antibiotic prophylaxis group.

1.2. LITERATURE REVIEW

Timeous prophylactic antibiotics in open fractures have shown to reduce Orthopaedic infection (1-3, 5, 9). Lane et al. (2012) conducted a review of studies focusing on prophylactic antibiotics in trauma (10). They concluded that early administration of first-generation cephalosporin course was beneficial to patients with open fractures; however, there was no statistically significant benefit of using prophylactic antibiotics in management of simple hand lacerations. (10). Nicholas et al. (2014) conducted a prospective study in the United Kingdom and showed that 20% of accident and emergency department patients presented with hand trauma (11). Most of the patients in this study sustained injuries to their dominant hand (60%), 50% of the patients underwent surgery and their post-operation 30-day infection rate was 7% (11). The 30-day infection rate increased to 22% when prophylactic antibiotics were not administered (11). The study concluded that prophylactic antibiotics play a role in reducing infective complications in hand trauma (11).

In 2019, Chris Hani Baragwanath Academic Hospital (CHBAH) Orthopaedic casualty treated 14880 patients, of which 5026 were admitted. Hands unit admitted 1535 out of 5026 admissions, which is 30.5% of total Orthopaedic admissions. In this period, 406 acute tendon injuries were operated and 223 (54.9%) of these cases were isolated flexor tendon injuries. The CHBAH hand admission rate (30.5%) was higher than the 20% which is documented in the prospective study by Nicholas et al. (2014) (11).

The meta-analysis of literature review by Murphy et al. (2016) reviewed 2578 patients with simple hand injuries and concluded that prophylactic antibiotics did not significantly lower the infection rate when there was no pre-operative macroscopic wound contamination (1). Assessment of pre-operative wound contamination is subjective and can vary between clinicians (1). Whittaker et al. (2005) performed a prospective, randomised, placebo controlled, double blinded trial to determine the role of prophylactic Flucloxacillin on clean (no macroscopic contamination) hand laceration involving skin only, tendon injury, nerve injury and tendon plus nerve injuries (2). They also concluded that prophylactic antibiotics was not necessary if there is no macroscopic wound contamination, especially if definitive surgery is planned (2). Murphy et al. (2016) study looked at randomised control trials which lowered risk of bias, but five prospective studies lacked blinding, and three cohort studies were observational in design (1).

Whittaker et al. (2005) divided patients into three subgroups (i.e. **group A**-intravenous flucloxacillin at induction followed by oral placebo for five days, **group B**-intravenous flucloxacillin at induction followed by five days of oral flucloxacillin and **group C**-oral placebo for five days after operation) and found that post-operative infection rates were between 1% and 10% in wounds which were clean pre-operatively, as opposed to an infection rate of up to 40% in contaminated wounds (2). Infection rate in **group A** was 13%, group B had 4%, and 15% in **group C** (2). Both studies emphasized that antibiotic prophylaxis should not be used as a substitute for good intra-operative wound debridement (1, 2).

Harness et al. (2010) conducted a multicenter retrospective review of the carpal tunnel release (CTR) procedures which were performed over a period of 2 – 5 years between 2005 and 2007 by 98 different surgeons at 11 medical centers (12). The study showed variations in antibiotics prescription among the 11 medical centers with significant variations in infection rate among these centers, and among surgeons of same and/or different centers (12). Bykowski et al. (2011) conducted a retrospective study on over 8000 medical records of patients who had elective hand surgery (6). They also investigated the difference in sepsis rate in smokers, diabetic patients, different procedure length (less than 30 minutes, 30 – 60 minutes, and longer than 60 minutes), and the infection rate did not significantly differ amongst these patients (6). Li et al. (2018) conducted a retrospective study of over 500 000 patients who had elective hand surgery (5). Overall, 1.5% of the control group had surgical site infection after 30 days whereas the antibiotic group had 1.4% infection rate (5). These three studies concluded that there was no indication for prophylactic antibiotics in patients requiring elective hand surgery (5).

Harness et al. (2010) did not indicate the type of antibiotics given and timing of administration was not extracted from the patient files (12). In all these studies, 3003 CTR procedures were performed and five infections were noted in the prophylactic antibiotic group (with one case of organ/space infection), whilst the non-antibiotic group had six infections (with three organ/space infections) (12). In Bykowski et al. (2011) study; 31% of patients received prophylactic antibiotics *versus* 69% who did not, and the post-operative SSI was 0.26% in antibiotic group and 0.54% in the control group) (6). Li et al. (2018) study had 11% of cases who received prophylactic antibiotics and 89% was a control group (5).

A prospective study by Aydin et al. (2010) focused on the role of antibiotic therapy in hand surgery (3). This double blinded study that ran from 2003 to 2008 showed no significant statistical difference between the antibiotic and placebo subgroups amongst the four groups (3). Four specific groups were created and these included: "**group I**, surgery limited to the skin and subcutaneous tissue; **group II**, surgery of the tendons, nerves, arteries, and other soft-tissue components; **group III**, surgery of the bones, joints, or both; and **group IV**, defects of any of the soft-tissue elements with or without bony defects" (3). Post-operative wound infection was observed in the group that received prophylactic antibiotics (3.2%), as opposed to 3.43% in the group that received a placebo (3). Infection rate per group; **group I** = 3.5% on antibiotic *versus* 3% in placebo group, **group II** = 2.9% on antibiotic *versus* 4.3% in placebo group, **group III** = 2.6%on antibiotic *versus* 3.1% in placebo group, and **group IV** = 4% on antibiotic *versus* 2.6% in placebo group (3). The infection rate did not correlate with the severity of the injury (3) as opposed to findings in other studies (7). The findings by Aydin et al. (2010) had similar outcomes to the study done by Fitzgerald et al. (1977), whose conclusion was that prophylactic antibiotics were not necessary in mutilated hand injuries (3, 13). Fitzgerald et al. (1977) argued that it was best to wait for culture and susceptibility investigations instead of using prophylaxis of broad-spectrum antibiotics (13).

The East Practice management work group on open fractures in Orthopaedic practice recommends gram-positive targeting systemic antibiotics to be initiated as soon as possible after sustaining an open fracture type I and type II (9). They recommended broader antibiotic coverage for type III open fractures, and that antibiotics for type I and II open fractures can be stopped within 24 hours after closing the wound (9). Hand infections after flexor tendon repairs are uncommon according to Momeni et al. (2010) (8). The level of contamination during an initial hand trauma was found to be more predictive of post-operative infection (8). The risk of infection was also found to be dependent on the type of injury, replantation, associated fractures, and in immuno-compromised patients (8). Prophylactic antibiotics did not lower the rate of infection in simple flexor tendon injuries when thorough peri-operative care protocol is observed (8).

Angly et al. (2012) conducted a retrospective study with 100 patients to determine the outcomes of early *versus* delayed surgical intervention of simple flexor tendon injuries up to 24 hours post injury (14). Stone et al. (1997) conducted a retrospective study of flexor tendon injuries on 140 patients which showed an infection rate of 2.1% (15). Both studies concluded that timing of surgery (early *versus* late) was not a significant factor with regards to post-operative surgical site infection rate (14) both in simple and complex hand injuries (14).

In Angly et al. (2012) retrospective study, 52% of all cases were treated within six hours, 41 injuries were simple, whilst 59 were complex injuries and the overall infection rate was 14% (14). Complex hand injuries had an increased infection rate which correlated to severity, operation duration, a feature not observed with simple hand injuries (14). All cases in Stone et al. (1997) study were initially treated with wound irrigation and/or scrubbing of the hand with sterile saline solution, then wounds were loosely closed with a simple suture, dressed with sterile dressing and supported by a splint (15). Patients were divided into an early group (treated within 12 hours) and a late repair group (treated after 12 hours), and each group further subdivided into a placebo and antibiotic group (15). Two patients who received peri-operative antibiotics got a post-operative infection: one was treated with early repair, and the other one was treated with delayed repair (15). The last infection was on a patient who was treated without antibiotics in the delayed surgery group (15).

De Jong et al. (2014) conducted a 10-year population-based study on epidemiology and incidence of acute traumatic injuries to hand and wrist on 458 cases (16). Manninen et al. (2016) conducted a retrospective epidemiology study in 106 cases (88 males and 18 females) of FTI of the hand in the Northern Finnish population between 2004 and 2010 (17). Injuries of the hand and wrist had an incidence of 10% of all cases that presented to the emergency department and up to 20% of injuries, which were treated over this period (16, 17). De Jong et al. (2014) reported an incidence of 54.8% tendon injury in patients with superficial hand laceration, 92.5% in those with deep laceration, and 0.66% bilateral tendon injuries (16). Of those that sustained tendon injuries, 43% was FTI and 57% ETIs (16). Zone II acute FTIs was three times more prevalent than zone V acute FTI (16). Males had higher incidence compared to females at a ratio of 5:1 (16, 17), and this was attributed to more males operating the tools/objects that leads to hand lacerations compared to females (16, 17). The average age of males was 39 years and of females was 45 years with a mean age average of 42 years (17), whereas the study population in De Jong et al. (2014 had a combined mean average age of 35.9 years (16). Highest incidence was reported in the 20 – 29 years age-group (16-18) and this was attributed to younger age group being inexperienced or less cautious towards occupational safety (17, 18). The incidence of hand and wrist trauma was reported to decrease significantly with age (16-18). Amongst other complications, post-operative wound infection rate was 1.9% (17).

Lombardi et al. (2001) conducted a literature review on epidemiology of occupational acute traumatic hand injuries and found that fingers and hands were the most common industrial injuries (30%) than other anatomical sites (19). Hand lacerations accounted for 50% of all injuries and other types of injuries (contusion/abrasion/fractures/sprain etc.) accounting for the remaining 50% (19). One of the largest studies on hand and wrist injuries treated at the hospital emergency department showed that the incidence of finger injuries, hand injuries, and wrist injuries were 72%, 21%, and 6%, respectively (19). Occupational injury incidence was higher in males than females at a ratio of (2.4:1) and commonest in ages younger than 25 years (19). The incidence of occupational injuries was 24.9% in the study conducted by De Jong et al. (2014) (16). In the epidemiological study of FTI by De Jong et al. (2014), the highest incidence of acute FTI was due to an assault with a knife (28.2%), followed by glass/mirror injury (15.5%), followed by a saw injury (14.8%) (16) Mechanism of injury was not reported in (8.7%) of the cases; the remainder of the injuries were reported as either crush (5.9%), degloving (1.1%), or bite injuries (0.7%) .

In a retrospective study of occupational hand trauma from circular saw table conducted by Hassine et al. (2016), the left hand (64.6%) was two times more commonly injured than the right hand (34.6%), and there was one case (0.8%) with bilateral hand injuries (18). The right hand was more commonly injured (56%) than the left hand (44%) in the study conducted by Manninen et al. (2016) (17). Majority of patients (92%) in this study were right hand dominant, so, the left hand was usually the one closest to the circular saw when operating the machine, hence the increase in incidence of left-hand injuries compared to right hand (18). This ratio of hand dominance is the same as that reported in the study by De Jong et al. (16). Majority of patients in this study sustained complex, contused, contaminated injuries (18).

Pulos et al. (2012) conducted a review on the management of complications of acute FTI and concluded that infection was a less common complication when compared to adhesions and contractures (20). The hand is the most active part of the upper limb, and the least protected (21, 22). This explains the high incidence of hand injuries including flexor tendon injuries (21). Zone V flexor tendon injury is usually associated with neuro-vascular injuries (21). Flexor tendon injury is often caused by a sharp or penetrating injury to the hand or fingers such as those caused by knives, glass, or crush injuries (20-23). Understanding mechanism of injury is important as it gives an indication of level of contamination, for example, simple cuts by a knife compared to a cut by an oily scrapyard instrument (22). FTI are classified into to five zones (see Table 1.1 and Figure 1.1) (20-23).

Table 1.1: Flexor zones of the hand (23).

Zone I	Insertion of flexor digitorum profundus (FDP) to insertion of flexor digitorum superficialis (FDS)
Zone II	A1 pulley to FDS insertion
Zone III	From distal end of carpal tunnel to A1 pulley
Zone IV	Within the carpal tunnel
Zone V	Proximal to the carpal tunnel but distal to the musculo-tendinous junction

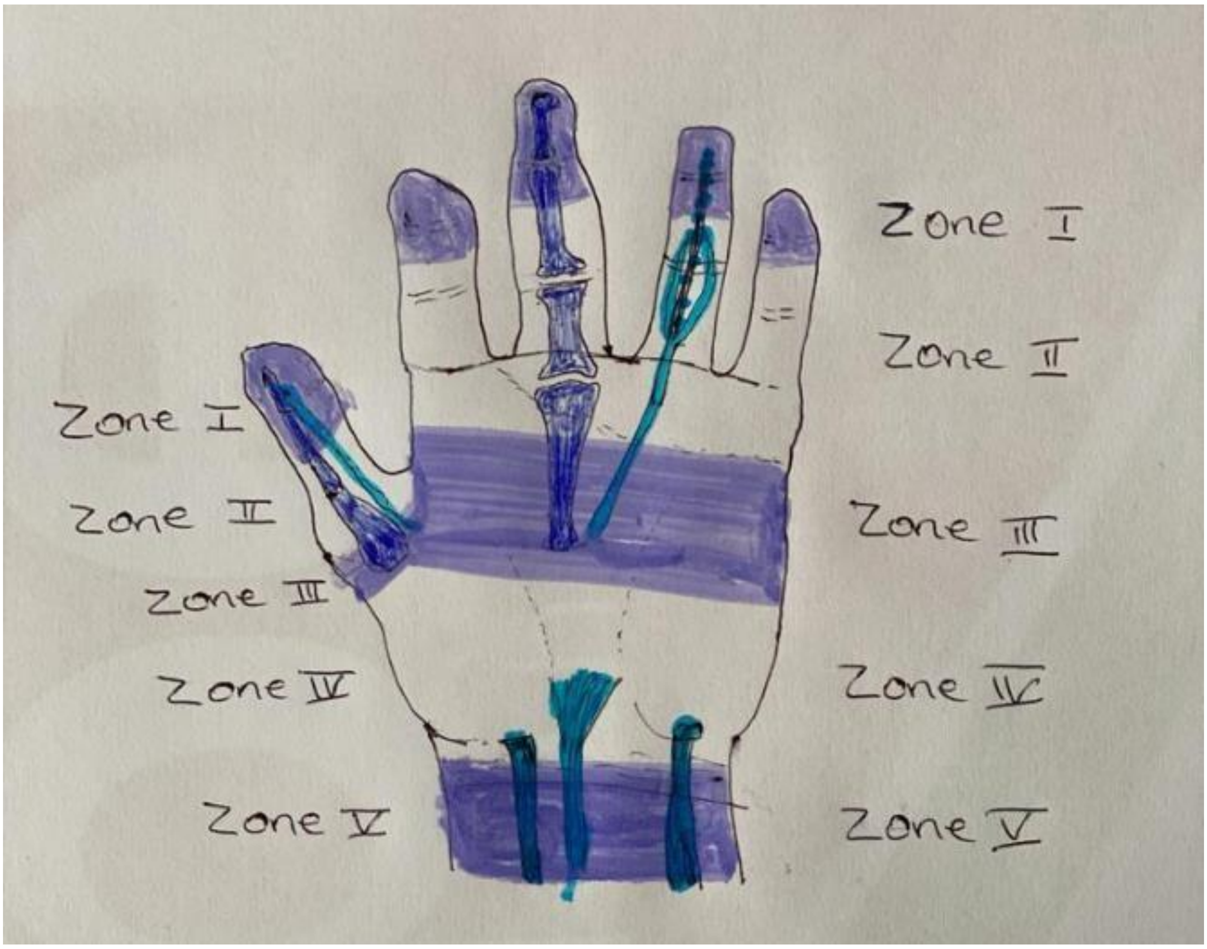

Figure 1.1: Illustration of the flexor zones of the hand.

In the 1920s, hand surgeons had difficulties in managing flexor tendon injuries because of associated complications such as infection, adhesions, and stiffness (22-24). A zone II flexor injury was termed “no man’s land” by Bunnell because it carried the highest complication rate (20, 22-24). Meticulous surgical technique was reported to lower infection rates and adhesion formation in zone II acute FTI (24)**.** Functional outcome was reported to be better when FTI was repaired early *versus* late repair (25). Zone III and V acute FTI have better prognosis than zone II because they are relatively easy to treat (22). Also, zone III and V FTI has better blood supply and more space than zone II (22).

1.3. STUDY AIM AND OBJECTIVES

1.3.1 Aim

- The role of prophylactic antibiotics in zone II and zone V acute FTI.

1.3.2 Objectives

- To compare post-operative wound sepsis rate in patients presenting with zone II and zone V acute FTIs after receiving either a single dose of prophylactic antibiotic in casualty and those receiving a single dose plus continuous prophylactic antibiotic doses whilst awaiting surgery.
- To determine the post-operative sepsis rate in patients presenting with occupational *versus* non-occupational zone II and zone V acute FTI.

1.4. STUDY RELEVANCE

As one of the largest hospitals in the world, CHBAH has one of the busiest Hand units in the country, and with that comes a shortage of theatre time to deal with the demand of trauma cases. This is unlike most international health institutions where flexor tendon injuries, especially zone V (highly likely to have an associated vascular injury) (21), are treated as emergencies and taken to theatre immediately or within 12 hours. At CHBAH, flexor tendon injuries that are perfusing well or have no vascular injury requiring immediate repair are treated in the procedure described below:

- A thorough washout of the wound is done in casualty or emergency department under local anaesthesia and a dose of intravenous prophylactic antibiotic (Kefzol or Augmentin) is given.
- Wound edges are opposed to cover exposed tendons or vital structures and then dressed with a wet dressing.
- A below the elbow back slab is applied for immobilization and pain management.
- The patient is then admitted to the Hand unit. In the ward, patients on continuous prophylactic antibiotic receives Kefzol (1g) or Augmentin (1.2g) ivi 8 hourly every day until they go to theatre.

Due to limited theatre availability, these cases along with other hand trauma cases tend to wait for theatre for 3 – 10 days on average. Our literature review shows that there is a role for prophylactic antibiotic use in complex or contaminated acute FTI, but there is no consensus when it comes to simple hand lacerations presenting without macroscopic contamination. Prophylactic antibiotics are administered routinely in all acute open FTI in our health institution at CHBAH and this might be contributing in the uprising of antibiotic resistance microorganisms. This study will provide guidance concerning prophylactic antibiotic administration in a developing country setting, regarding acute FTIs. It will also add to the existing studies looking at peri-operative antibiotic use in acute FTIs.

CHAPTER 2

2. METHODOLOGY

This chapter describes how the study was designed and conducted.

2.1. Research Question

Is there a difference in post-operative SSI rate in patients presenting with zone II and zone V acute FTI after receiving one dose of prophylactic antibiotic in casualty *versus* those receiving a single dose plus continuous prophylactic antibiotic dose whilst awaiting surgery?

2.2. Null Hypothesis

There is no difference in post-operative SSI rate in patients presenting with zone II and zone V acute FTIs after receiving one dose of prophylactic antibiotic in casualty *versus* those receiving a single dose plus continuous prophylactic antibiotic dose whilst awaiting surgery.

2.3. Research Design

This study was a prospective randomised control trial study of adult male and female patients from the ages of 18 years and older who presented with acute FTI at CHBAH, Orthopaedic Department Hand Unit. The study took place from 1st November 2020 to 31st August 2021. Ethics clearance was obtained from the Human Research Ethics Committee (HREC), Medical, University of the Witwatersrand (Clearance number: **M200720**).

2.4. Materials and Methods

Patients who are 18 years and older who presented to CHBAH with acute FTI zone II and zone V were seen by an Orthopaedic registrar in casualty; interviewed and examined, then counselled about inclusion into the study, and informed consent was obtained. All wounds were irrigated in casualty on admission by an Orthopaedic registrar, the wounds were approximated with a non-absorbable suture, dressed with paraffin gauze, then a below the elbow plaster of Paris (back slab) was applied. Patients were given a stat dose of intravenous Kefzol or Augmentin, the study group continued with 8 hourly antibiotic doses in the ward whilst the control group did not receive further antibiotics until the day of surgery. The pre-operative demographics, place of injury, hand dominance, mechanism of injury, and zone of injury were documented as shown in Appendix A. Informed consent for surgical debridement, wound exploration, and tendon repair in theatre was obtained. Date of surgery, rank of surgeon, length of surgery, and peri-operative antibiotics was documented during the date of surgery. Upon wound review in 10 – 14 days post-operative, the presence or absence of SSI was documented. When SSI was present, it was further documented if this was superficial infection (slough, not requiring debridement in theatre) or deep infection (oozing pus and requiring debridement in theatre).

2.5. Sample size and selection criteria

A total number of 116 patients were included in the study.

2.5.1. Inclusion criteria

- Patients who have sustained acute open zone II and V FTI, presenting within 24 hours from time of injury.
- Patients ≥ 18 years old (adults)
- Patients who gave informed consent to participate in the study

2.5.2. Exclusion criteria

- Patients with: associated extensors injuries, associated fractures, grinder/crush and/ bite injuries.
- Patients who: are diabetic, are on immunosuppressant medication, have a clinically septic (or macroscopically contaminated) wound on presentation, has no other confounding open injuries (this increases the rate of sepsis *via* haematogenous spread).

2.6. Data collection

Patients were randomised to either receive a stat IVI antibiotic dose only (**Group A**) or stat IVI antibiotic dose plus a continuous 8 hourly antibiotic doses (**Group B**) until definitive surgery using a block randomisation method. Patients entered the study as either Block A (non-occupational acute FTI) or Block B (occupational acute FTI) and each block was subdivided into treatment and control group to have a total of four blocks (**Block A1**-treatment group, **Block A2**-control group, **Block B1**-treatment group, **Block B2**-control group). Excel generated patient number (with a group allocation) was randomly allocated to participants by the Orthopaedic casualty officer.

2.7. Data analysis

Data was captured into Microsoft excel and analysed using IBM SPSS 28 software. The Pearson Chi-square test was used to interpret all categorical data. In cases wherein the assumption of use of this test was violated (not meeting the minimum expected frequency of 5 in 80% of the cells), we used the Fisher-Freeman-Halton test to interpret the data. In cases wherein there was an association between the variables ($p < 0.05$), a Cramer's V test was used to assess the strength of association. An independent samples t-test was also used to run a comparative analysis of continuous data. In order to run the independent samples t-test, we met the following assumptions; normal distribution our sample was > 30, independence of observation, homogeneity of variance, and random sampling. The homogeneity of variance for our data sample was confirmed using the Levene's test ($p > 0.05$) (see Table 2.1 below):

Table 2.1: Homogeneity of variance

Levene's test for Equality of Variance	
F	Sig
2.564	0.112

2.8. Limitations

The study was limited to patients with zone II and V acute FTI only. Some patients could not be included in the study due to late presentation due to lock down restrictions or lack of transport because of corona virus disease 2019 (Covid-19) pandemic rules/lockdown. A large number of non-occupational acute FTI cases as compared to occupational injuries were expected because non-essential service employees had to stop work or lost their jobs due to Covid-19 pandemic.

CHAPTER 3

3. RESULTS

We stratified and analysed our patients' demographic data and the injuries they sustained. We analysed surgical site for wound infection between the two study groups at 10 – 14 days after surgery, taking into consideration: place of injury, time to surgery, zone of injury (diagnosis), length of surgery and rank of surgeon.

3.1. Demographics and clinical assessment

A total of 117 patients who sustained zone II and zone V acute FTIs were randomised and included in the study from 1st November 2020 to 31st August 2021. Patients with bilateral injuries were recorded as one patient.

- One patient later refused operation and was removed from the study.
- Ninety five out of 116 patients received Kefzol whereas 21 received Augmentin.
- Six patients had bilateral zone II acute FTIs

The Tables and Figures below show the following demographic characteristics; age, gender, employment status, place of injury, hand dominance, side of hand injury in relation to hand dominance, mechanism of injury, and zone of injury.

3.1.1. Gender and age of patients

Table 3.1 below indicates that majority of patients who participated in this study were males (81%), with a combined overall age average of 31.5 years between males and females. The male to female ratio was 4.3:1. The mean average age of males was (31.3 years) and that of females was (32.4 years).

Table 3.1: Total number of males and females plus the characteristics of their ages.

Gender	Sample size (%)	Age (years) Mean	Min age (years)	Max age (years)	Standard Deviation	Overall mean age (years)	Overall Standard Deviation
Male	94 (81)	31.3	18	62	9.80	31.5	9.645
Female	22 (19)	32.4	21	49	9.11		

3.1.2. Employment status

The number of unemployed participants was almost as high as that of those who are employed; employed = 49%, unemployed = 47%, students = 3%, and pensioners = 1%.

3.1.3. Hand dominance

Figure 3.2 below compares the total number of right-hand dominant patients to those who are left hand dominant. Majority of patients who enrolled in this study were right hand dominant (94.8%) as opposed to 5.2% left hand dominant patients.

3.1.4. Side of hand injury

Majority of patients (71.55%) injured their dominant hand, whereas 23.28% injured their non-dominant hand, and 5.17% sustained bilateral injuries.

3.1.5. Place of Injury

A total of 108 patients (93.1%) sustained non-occupational injuries as compared to 8 patients (6.9%) who sustained occupational injuries.

3.1.6. Mechanism of Injury

Majority of patients (57.8%) presented after an assault with a sharp object, 36.2% because of accidental injuries, and 6% because of industrial injuries.

3.2. Sample size and randomisation

3.2.1. Sample size

Our study had a total of 116 patients, 108 patients sustained non-occupational injuries and eight patients sustained occupational injuries group (see Figure 3.4). Non-occupational injurygroup had 67 zone II acute FTI, 41 Zone V acute FTI, and six bilateral zone II acute FTI. Occupational injury group had five zone II acute FTI, three Zone V acute FTI, and no bilateral injuries.

3.2.2. Diagnosis

Majority of patients who enrolled in this study sustained injuries to their right hand; 52 patients with right zone II acute FTI (44.8%), 37 with right zone V acute FTI (31.9%), 15 with left zone II acute FTI (12.9%), six with left zone V FTI (5.2%), and six patients (5.2%) with bilateral hand injuries.

3.2.3. Randomisation

Table 3.5 below illustrates the total number of patients in each antibiotic group and their percentages. Fifty-seven patients (49.1%) were randomised into a continuous antibiotic group whereas 59 (50.9%) were randomised into a single dose antibiotic group as seen in Table 3.5.

3.3. Surgery

3.3.1. Time to Surgery

Table 3.6 below shows a combined mean average of 4.34 days to surgery and a standard deviation of 2.763. The earliest time to surgery for Zone II acute FTI was 1 day (12 – 24 hours) and for zone V acute FTI was two days (48 – 50 hours).

Table 3.2: Time to surgery.

Zone of Injury	Minimum (days)	Maximum (days)	Mean	Combined mean	Standard Deviation
Zone II	1	15	4.5	4.34	2.763
Zone V	2	19	3.9		

3.3.2. Rank of a primary surgeon

Table 3.7 below indicates that majority of operations were done by registrars (84 patients) with a standard deviation of 38.085 as compared to those done by consultants (32 patients) with a standard deviation of 27.708.

Table 3.3: Cases done by consultant *versus* registrar.

	Surgeon	N	Mean	Std Deviation	Std. Error Mean
Length of Surgery	Registrar	84	71.85	38.085	4.155
	Consultant	32	70	27.708	4.898

3.3.3. Length of surgery

Table 3.8 indicates that consultants had a mean average operating time of 56.4 minutes and 87.5 minutes for zone II and zone V acute FTI, respectively whilst registrars had a mean average operating time of 54.9 minutes and 103.9 minutes for zone II and zone V acute FTI, respectively. The longest operating time was a zone V FTI (full house) repair done by a registrar and the shortest operating time was a zone II acute FTI (FDP repair), also done by a registrar.

Table 3.4: Length of surgery in zone II and zone V acute FTI.

Surgeon	**Zone II**				**Zone V**			
	Total cases	Minimum length	Maximum length	Average time	Total cases	Minimum length	Maximum length	Average time
Consultant	18	25	95	56.4	14	30	130	87.5
Registrar	72	20	105	54.9	30	45	180	103.9

3.4. Wound review

3.4.1. Post-operative wound assessment and infection rate

Table 3.9 below indicates that 106 of patients (91.4%) did not get post-operative wound infection; nine patients (7.8%) had superficial wound infections, whilst only one patient (0.9%) had deep wound infection.

Table 3.5: Post-operative wound assessment.

	Frequency	**Percentage (%)**
No infection	106	91.38
Deep infection	1	0.86
Superficial infection	9	7.76
Total	**116**	**100%**

3.4.2. Wound review comparison

3.4.2.1. Continuous *versus* Single dose antibiotic groups

Table 3.10 below shows that there were 57 and 59 patients in the continuous dose antibiotic group and single dose antibiotic groups, respectively. Fifty-three patients were without any infection in each antibiotic group. The total number of patients with superficial infection was nine, four (44.4%) in the continuous dose antibiotic group and five (55.6%) in the single dose antibiotic group. The total number of patients with deep infection was one, and this was in the single dose antibiotic group.

Table 3.6: Continuous dose *versus* single dose infection rate.

		Not infected	**Deep infection**	**% of deep infection**	**Superficial infection**	**% of superficial infection**
Continuous dose antibiotic group	Number of patients	53	0	0	4	44.4
Single dose antibiotic group	Number of patients	53	1	100	5	55.6
Total	Number of patients	106	1	100	9	100

The association between antibiotic dosage and post-operative wound infection was assessed using the Pearson Chi-square test but four cells (66.7%) had expected count of less than 5, meaning we did not meet the expected frequency (5 in 80% of the cells) of assumption for Chi-square and therefore we used the Fisher-Freeman-Halton test to interpret the results. The Fisher-Freeman-Halton test showed that there was no association between giving a single dose of antibiotic prophylaxis or giving a prolonged antibiotic prophylaxis with post-operative wound sepsis in acute zone II and V FTIs ($p > 0.05$).

Table 3.7: Chi-Square Tests for antibiotic groups

	Value	df	Asymptotic Significance (2-sided)	Exact Sig (2-sided)
Pearson Chi-Square	1.077[a]	2	.584	1.000
Likelihood Ratio	1.463	2	.481	1.000
Fisher-Freeman-Halton	1.057			1.000
N of Valid cases	116			

a. 4 cells (66.7%) have expected count less than 5. The minimum count is.49

3.4.2.2. Occupational *versus* non-occupational injury groups

Table 3.12 below shows that there were 108 and 8 patients in the non-occupational injury group and occupational injury group, respectively. Ninety-nine patients were without any infection in the non-occupational injury group and seven were without any infection in the occupational injury group. The total number of patients with superficial infection was nine, eight (88.9%) in the non-occupational injury group and one (11.1%) in the occupational injury group. The total number of patients with deep infection was one, and this was in the non-occupational injury group.

Table 3.8: Place of injury.

		Not infected	Deep infection	% of deep infection	Superficial infection	% of superficial infection
Non-occupational injuries	Number of patients	99	1	100	8	88.9
Occupational injuries	Number of patients	7	0	0	1	11.1
Total	Number of patients	106	1	100	9	100

The association between place of injury and wound outcomes was assessed using the Pearson Chi-square test wherein three cells (50%) had expected count of less than 5, therefore this test did not meet the expected frequency of assumption. The Fisher-Freeman-Halton test was used to interpret the results. The Fisher-Freeman-Halton test showed that there was no association between occupational injuries or non-occupational injuries with post-operative wound sepsis in acute zone II and V FTIs ($p > 0.05$).

Table 3.9: Chi-Square Tests for place of injury

	Value	df	Asymptotic Significance (2-sided)	Exact Sig (2-sided)
Pearson Chi-Square	.337[a]	2	.845	1.000
Likelihood Ratio	.370	2	.831	1.000
Fisher-Freeman-Halton	1.835			.525
N of Valid cases	116			

a. 3 cells (50%) have expected count less than 5. The minimum is .07.

3.4.2.3. Diagnosis and wound outcomes

Table 3.14 below shows that there were 67, 43, and 6 patients with zone II FTI, Zone V FTI, and bilateral zone II FTI, respectively. Sixty patients were without any infection in the zone II FTI group, 42 patients were without infection in the zone V FTI group, and 4 patients were without infection in the bilateral zone II FTI group. The total number of patients with superficial infection was nine, seven (77.8%) unilateral zone II FTI, two (22.2%) had bilateral zone II FTI, and no superficial infection in all patients with zone V FTI. The total number of patients with deep infection was one, and this was a patient with zone V FTI.

Table 3.10: Diagnosis and infection rate.

		Not infected	**Deep infection**	**% of deep infection**	**Superficial infection**	**% of superficial infection**
Zone II FTI	Number of patients	60	0	0	7	77.8
Zone V FTI	Number of patients	42	1	100	0	0
Bilateral zone II FTI	Number of patients	4	0	0	2	22.2
Total	Number of patients	106	1	100	9	100

The association between tendon injury diagnosis and wound outcomes was assessed using the Pearson Chi-square test (see Table 3.15). The results shows that 10 cells (66.7%) have expected count of less than 5, the Fisher-Freeman-Halton test was used to interpret the results. The Fisher-Freeman-Halton test showed that there was an association between zone of injury and post-operative wound sepsis in acute zone II and V FTIs ($p < 0.05$), with zone II acute FTI group having significant post-operative wound infection rate.

Table 3.11: Chi-Square Tests for diagnosis and infection rate.

	Value	**Df**	**Asymptotic Significance (2-sided)**	**Exact Sig (2-sided)**
Pearson Chi-Square	25.924[a]	8	0.001	0.014
Likelihood Ratio	21.751	8	0.005	<0.001
Fisher-Freeman-Halton	22.335			<0.001
N of valid cases	116			

a. 10 cells (66.7%) have expected count less than 5. The minimum count is 0.05

The strength of association between zone of injury and post-operative wound infection was further assessed using the Cramer's V (see Table 3.16). The Cramer's V value of 0.334 indicates a medium association between zone of injury and post-operative wound infection. Cramer's V interpretation (small = 0.7 – 0.20, medium = 0.21 – 0.34, large > 0.34).

Table 3.12: Symmetric Measures.

		Value	Asymptotic Significance (2-sided)	Exact Sig (2-sided)
Nominal by Nominal	Phi	0.473	0.001	0.014
	Cramer's V	0.334	0.001	0.014
	N of Valid cases	116		

3.4.2.4. Rank of surgeon and length of Surgery

Table 3.17 indicates that majority of cases were done by registrars (84 cases) with a standard deviation of 38.085 and standard error mean of 4.155 whereas consultants did a total of 32 cases with a standard deviation of 27.708 and standard error mean of 4.898.

Table 3.13: Number of cases done per surgeon category.

	Surgeon	N	Mean	Std Deviation	Std. Error Mean
Length of Surgery	Reg	84	71.85	38.085	4.155
	Consultant	32	70	27.708	4.898

An independent sample t-test was done (see Table 3.18) to analyse the effect of surgeon's rank on length of surgery. The assumptions we met to run this test are; normally distribution with a sample size (> 30), independence of observation, random sampling and homogeneity of variance. The result from the independent sample t-test indicates that there was no significant statistical difference between rank of surgeon and length of surgery ($p > 0.05$).

Table 3.14: Independent Samples Test.

	t-test equality of Means						95% Confidence Interval of the difference	
	t	df	One-sided p	Two-sided p	Mean Difference	Std. Error Difference	Lower	Upper
Length of Surgery	0.250	114	.402	.803	1.845	7.388	-12.790	16.481

3.4.2.5 Rank of surgeon and wound outcomes

Table 3.19 below shows that there were 84 patients who were operated by registrars and 32 patients were operated by consultants. Sevent-six patients who were operated by registrars were 30 of those operated by consultants were without any infection. There were 7 (77.8%) of patients with superficial infection and 1 (100%) deep infection in the registrar group. There were 2 (22.2%) of patients with superficial infection and no deep infection in the consultant group.

Table 3.15: Surgeon and wound outcomes.

		Not infected	Deep infection	% of deep infection	Superficial infection	% of superficial infection
Registrar	Number of patients	76	1	100	7	77.8
Consultant	Number of patients	30	0	0	2	22.2
Total	Number of patients	106	1	100	9	100

The association between the rank of a surgeon and post-operative wound infection was assessed using the Pearson Chi-square test (see Table 3.20). The results show that 10 cells (66.7 %) have expected count of less than 5. The Fisher-Freeman-Halton test was used and it showed that there was no association between rank of a surgeon with post-operative wound sepsis in acute zone II and V FTIs ($p > 0.05$).

Table 3.16: Chi-Square test for surgeon and infection rate

	Value	df	Asymptotic Significance (2-sided)	Exact Sig (2-sided)
Pearson Chi-Square	.538[a]	2	.764	.807
Likelihood Ratio	.808	2	.668	.807
Fisher-Freeman-Halton	.540			1.000
N of Valid cases	116			

a. 3 cells (50%) have expected count less than 5. The minimum is .28

CHAPTER 4

4. DISCUSSION

The results and findings of this study are interpreted and compared to other related studies under this chapter. The implications and clinical application of these findings are also discussed. The study limitations and recommendations are highlighted at the end of this chapter.

4.1. Demographics and clinical assessment

4.1.1. Gender

Our study population was composed of more male than female patients with a ratio of 4.3:1 (see Table 3.1). This gender ratio was close to that in the epidemiological studies done by De Jong et al. (2014) and Manninen et al. (2017) who had a male to female ratio of 5:1 in their studies. Most of the injuries with a sharp object in our study were sustained at night during an attempted robbery followed by glass cut injuries when the victim was intoxicated with alcohol. CHBAH is based in Soweto, which is one of the townships with very high crime rate in South Africa. Most patients who presented with cuts with a knife/sharp object were males who reported that they were victims of robbery or violence. More males in our study population had a higher incidence of occupational injuries as compared to females at a ratio of 7:1. This ratio of occupational injuries is much higher than the 2.4:1 male to female ratio that was reported by Lombardi et al. (2001). Lombardi et al. (2001) explained that the high incidence of occupational hand injuries in males is as a result of males being the ones that usually operates these industrial machineries such as a chain saw, grinder etc.

4.1.2. Age

Our study population mean age (male = 33.3 years and female = 32.4 years) was generally younger than that from studies in our literature review (see Table 3.1). Males and females had a mean age average of 39 years and 44 years, respectively in the study done by Manninen et al. (2017). The mean age at the time of injury in our study was 31.5 years, which is slightly less than 35.9 years that reported by De Jong et al. (2014) and much less than 41.5 years that was reported by Manninen et al. (2017). Our data does not explain why our population study was younger than that in our literature review. The highest incidence of injury in our study was in the (20 – 29 years) age group (50.1% of injuries), which is in keeping with the (50%) that was reported by De Jong et al. (2014), Manninen et al. (2017), and Hassine et al. (2016). Manninen et al. (2017) proposed that the reason could be that, younger patients have higher exposure time and are less cautious towards sharp objects and industrial machineries. Young people, especially males, are more likely to sustain non-occupational hand injuries whilst under the influence of alcohol according to Manninen et al. (2017). Lombardi et al. (2001) described this age group (20 – 29 years) as being of high risk due to little experience with handling of industrial tools and are more likely to sustain occupational injuries as compared to the more experienced older age group. De Jong et al. (2014) described this age group as the workforce most likely to have more physical labour-intensive occupations, which may place them at an increased risk of injury. In addition, the incidence of injuries decreased significantly with age in our study (25% between 30 – 39 years, 18.1% between 40 – 50 years, 3.4% between 50 – 59 years and 0.9% over 60 years) similarly to that in studies by De Jong et al. (2014), Manninen et al. (2017), and Hassine et al. (2016). De Jong et al. (2014) described this decline in incidence was described as most likely due to improvement in occupational safety with age and experience, as well as due to a shift towards urban lifestyle.

4.1.3. Employment status

Our study findings showed that almost half of our study population was unemployed (47%) at the time of injury (see Figure 3.1). The unemployment rate in South Africa (35.3%) was at it is all time highest during the time of our data collection in year 2020 (from 28.5% in the previous year). The unemployment rate of our study population was much higher at 47% compared to 21.4% on the study done at our health institution "Diagnostic accuracy of pre-operative clinical examination in zone V FTI" in 2019. Job losses for majority of South Africans during the pandemic also explains the low rate of acute occupational FTI in our study.

4.1.4. Hand dominance and side of injury

The right-hand dominance of our study population (94.8%) (see Figure 3.2) was slightly higher than the (92%) in the study done by Hassine et al. (2016) and higher than (91.4%) in the study done by De Jong et al. (2014). The incidence of patients injuring their dominant hand in our study (71.55%) was higher than the (64.6%) that was reported by Hassine et al. (2016). However, the incidence of injuries to a non-dominant hand in our study population (23.28%) was lower than 34.6% that was reported by Hassine et al. (2016). In the study by Nicholas et al. (2014) and Manninen et al. (2017), there was a great proportion of occupational hand injuries, which explain their higher rate of non-dominant hand injuries (most likely to occur as an occupational injury) compared to our study sample that had very few occupationally injured patients. Occupational injuries resulted in more injuries to the non-dominant hand (87.5%) in our study; this was higher than the 64.6% reported by Hassine et al. (2016). The incidence of bilateral injuries (5.17%) in our study is higher than 0.66% reported by De Jong et al. (2014) and higher than (0.8%) reported by Hassine et al. (2016). Population diversity could explain the high incidence of bilateral FTI in our study as all of them got injured during robbery or when the patient was under the influence of alcohol.

4.1.5. Place of injury

Majority of injuries in our study (93.1%) (see Table 3.2) occurred outside working environment which is higher compared to (77%) in the study done by Manninen et al. (2017). Industrial hand injuries in our study accounted for (6%), which is less than the (13%) reported by Manninen et al. (2017), and less than the (24.9%) reported by De Jong et al. (2014). High unemployment rate meant that fewer injuries were presenting as injury on duty.

4.1.6. Mechanism of Injury

The incidence of patients who presented after an assault with a knife or a sharp object (57.8%) in our study (see Table 3.3) was slightly lower compared to (64%) that was reported by Manninen et al. (2017). However, the incidence of patients who presented with accidental injuries caused by a broken glass (36.2%) in our study was higher than the (14%) that was reported by Manninen et al. (2017). Our data does not describe the reason for the differences in mechanism of injury between our study and that in literature review, but perhaps the differences in cultural background could be the reason. The incidence of patients who presented with occupational acute FTI was (6%) in our study, which is lower compared to the (13%) that was reported by Manninen et al. (2017).

4.2. Surgery

4.2.1. Time to Surgery

The average time to surgery for patients in our setting is 4.34 days (4.5 days for zone II and 3.9 days for zone V FTIs) (see Table 3.6) , which is at least 2 – 3 times longer than that reported by Stone et al. (1998). Stone at al. (1998) regarded any tendon repair done in 12 – 24 hours as delayed whereas and Angly et al. (2012) regarded any debridement and tendon repair after 6 hours as delayed. All our tendon repairs would be considered as delayed as per our literature review as they were all done after 12 hours. The reason for delayed time to surgery in our institution is purely due to trauma load and lack of surgical time. Trauma load and surgical time might not be such a great obstacle in developed countries.

4.2.2. Rank of a primary surgeon and length of surgery

In our study, zone V cases generally took longer than zone II whether the primary surgeon was a registrar or a consultant; however, our statistical analysis showed that this difference was insignificant (see Table 3.7). Our findings are in keeping with the findings from literature review by Griffin et al. (2012), which indicates that zone V FTIs are often associated with arterial and nerve injuries and therefore likely to have a prolong surgical repair time. In our institution, consultants usually operate on more complex and old cases whilst registrars operate on relatively fresh and uncomplicated cases. If this factor is not mitigated, it may give an impression that consultants generally take longer surgical time for their cases.

4.3. Wound review

Only one patient (0.9%) in our study had deep post-operative wound infection requiring surgical debridement in theatre (see Table 3.9). This patient was in a single dose antibiotic group, he had sustained a zone V acute FTI that was operated on after 12 days from the date of injury. This infection rate is lower than the (1 – 10 %) infection rate that was reported by Whittaker et al. (2005), (2.9 – 4.3 %) infection rate reported by Aydin et al. (2010), and (1.9%) infection rate that was reported by Manninen et al. (2017). The superficial post-operative wound infections (7.8%) in our study were treated with wound dressings only and all these wounds were taken to complete healing in the subsequent follow up visits.

4.3.1. Continuous *versus* Single dose antibiotic groups

Our results showed that there was no association between prophylactic antibiotic dosage and post-operative wound infection rate between single dose and continuous dose antibiotic groups ($p > 0.05$) in patients with zone II and V acute FTI (see Table 3.10). Our results shows that it is not necessary to give continuous prophylactic antibiotic for patients with simple, acute zone II and V FTI. This is in keeping with the results found by Murphy et al. (2016) and Whittaker et al. (2005) who both found that there was no necessity to give prophylactic antibiotics in patients with macroscopically clean hand acute FTI.

4.3.2. Occupational *versus* non-occupational injury groups

Our results showed that there was no difference in post-operative wound infection rate between occupational and non-occupational zone II and V acute FTIs (see Table 3.12). Murphy et al. (2016) and Whittaker et al. (2005) concluded that infection rate was statistically insignificant if the wounds were macroscopically clean, which is in keeping with our findings. Griffin et al. (2012) found that there was high incidence of wound contamination and post-operative wound infection in patients with occupational injuries. Our low post-operative wound infection rate in occupational injury could have been influenced by multiple factors such as; low sample size of (6.9%) who presented with occupational acute zone II and V FTI, Covid-19 pandemic (increased unemployment rate, working from home, and lock down), and our exclusion criteria (crushed injuries, FTIs associated with ETIs, and FTIs associated with fractures).

4.3.3. Diagnosis and wound outcomes

Zone II acute FTI diagnosis frequency (62.9%) was higher compared to zone V acute FTI (37.1%) in our study (see Table 3.14) but not as high as the results reported by De Jong et al. (2014) wherein the ratio of diagnosis frequency was 3:1 (zone II *versus* Zone V acute FTIs). Majority of our patients presented post assault with a knife/sharp object. Usually, victims tend to want to grab the offending object, which leads to a zone II FTI. Zone V FTI is more frequent on injury on duty cases. Our post-operative wound results showed a strong association between zone II acute FTIs and post-operative wound infection. This finding was in keeping with results reported in multiple studies (Pulos et al. (2015), Goggins et al. (2017), Thien et al. (2010)) who all concluded that acute zone II FTI has high post-operative wound infection rate compared to other zones of FTIs or ETIs. The increase in post-operative wound infection in zone II FTI is due to the complexity of its anatomy, which calls for meticulous tendon exploration, and repair by an experienced hand surgeon.

4.3.4. Rank of surgeon and wound outcomes

Our results showed that there was no difference in post-operative wound infection rate between acute zone II and V FTI cases operated by consultants and those operated by registrars (see Table 3.19). Our findings are contradictory to that of Kotwal et al. (2012) who found that meticulous surgery, which comes with experience, was likely to lower post-operative complications including wound infections. In our setting, consultants operated on more complex or older cases which may have increased the chances of post-operative wound infection compared to if they were operating fresh and simpler cases.

4.4. Study limitations

Our data collection was done through the first and second Covid-19 waves wherein there was national lockdown, unemployment rate went up in South Africa and most people were working from home. This is most likely the reason for small sample size of occupational hand injuries. We recommended pre-operative wound swabs to rule out pre-existing infection/ contamination on our protocol, but this was not done by the surgeons.

4.5. Recommendation

In future, a study focusing on acute flexor tendon occupational injuries and their post- operative wound infection rate can be conducted. It will also be of great value to conduct an epidemiological study in acute FTI in our setting.

CHAPTER 5

CONCLUSION

Although acute hand laceration is amongst the most common reasons for admission to hands trauma unit, the role of prophylactic antibiotics in simple hand lacerations involving tendon injuries has not been universally adopted. Our results showed that in simple hand lacerations without macroscopic contamination, there is no association between pre-operative prophylactic antibiotic dosing (a single dose *versus* continuous doses until surgery) with post-operative SSI in acute zone II and V FTI. The results also showed no association between occupational or non-occupational injuries with post-operative SSI in acute zone II and V FTI from simple hand lacerations that are not macroscopically contaminated. This finding needs further exploration as our sample size for occupational injuries was very low to draw a statistical conclusion. There was a strong association between zone II acute FTI and superficial post-operative SSI in our study, as it was the case in previous studies.

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APPENDICES

Appendix A: Data Collection Form

<u>Date of Admission</u>……………………………….

Date of injury + time:

Study Number		
Age		
Gender	MALE	FEMALE
Occupation		
Hand of Dominance	RIGHT	LEFT
Place of injury	Domestic	Occupational
Mechanism of injury		
Diagnosis	Zone II FTI	Zone V FTI

<u>Study details</u>

Consent obtained	YES	NO
Randomised	Single Dose IVI Kefzol in casualty	Stat IVI Kefzol dose in casualty plus continuous tds dose in the ward

Wound irrigated and skin opposed in casualty by a registrar	YES	NO

Theatre

Date of Surgery		
Pre-op antibiotics given (tick)	**YES**	**NO**
Additional intra operative antibiotic given (tick)	**YES**	**NO**
Surgeon		
Wound swab barcode		
Length of surgery		

Wound review

Date of review			
Wound	No infection	Superficial infection	Deep infection
Wound comments			

Appendix B: Participant consent form

Study Title: The role of prophylactic antibiotics in zone II and zone V ac ute flexor tendon injuries

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

Contact details of researcher(s)

1. Principal researcher/investigator: Dr R. C Tshisikule: cell no: 072 692 6884, email: gr8tsai@gmail.com
2. Principal supervisor: Dr M. C. Sathekga: cell no: 072 239 7689, email: sathekgacynthia@hotmail.com
3. Co-supervisor: Dr A.R. Sekeitto: cell no: 082 932 5397, email: sekeitto@yahoo.com

For your complaints / concerns please contact

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

Name of researcher: ____

Signature: ____

Name of Participant/parent: ____

Date: ____

Place: ____

Signature or mark ____

Witnessed by:

Name of Witness: ____-

Signature: ____-

Date: ____

Appendix C: HUMAN RESEARCH CLEARENCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr RC Tshisikule

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200720

NAME: (Principal Investigator)	Dr RC Tshisikule
DEPARTMENT:	School of Clinical Medicine Department of Surgery Division of Orthopaedic Surgery Medical School University
PROJECT TITLE:	The role of prophylactic antibiotics in zone II and zone V acute flexor tendon injury
DATE CONSIDERED:	2020/07/31
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Drs C Sathekga and A Sekeitto
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	16 October 2020

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
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 submit details to the Committee. **I agree to submit a yearly progress report.** When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in July and will therefore reports and re-certification will be due early in the month of **July** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

01 November 2020
Date