UNIVERSITY OF NAIROBI

RISK OF BLOOD CONTAMINATION DURING ORTHOPAEDIC SURGERY AT KENYATTA NATIONAL HOSPITAL

BY

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DECLARATION

I declare that this dissertation is my original work and has not been submitted elsewhere for examination, award of a degree or publication. Where other people's work or my own work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi's requirements

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This is to certify that this dissertation is the original work of the author.

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LIST OF ABBREVIATIONS

KNH	Kenyatta National Hospital
UoN	University of Nairobi
WHO	World Health Organization
CDC	Centre for Disease Control
BBF	Blood and Body Fluid
SPSS	Statistical Package for the Social Sciences
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HCWs	Health Care Workers
PEP	Post Exposure Prophylaxis

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OPERATIONAL DEFINITIONS

BLOOD CONTAMINATION - Is defined as the presence of visible blood or body fluid on the barrier garment (eye protection and masks) removed at the conclusion of the procedure. In cases of gloves, it is reflected by puncture or tears which carry a potential exposure to blood and tissue fluid.

SURGEON – The lead, primary or main person during a procedure who performs majority of the operation and gives instructions to those scrubbed with him/her in the procedure. This role is easily identifiable from their position on the operating table.

FIRST ASSISTANT- the second lead during the procedure, actively participates by aiding the main surgeon in providing exposure to the surgical field, ensuring hemostasis and can assist with closure of wounds.

G-VIR - the name of a surgical glove that contains a disinfecting liquid to decrease the amount of viral load transmitted in case of a percutaneous accident. It comprises of three layers, 2 mechanical outer layers and a middle layer incorporating the disinfecting solution

WATER LEAK TEST – a standard test for detection of holes in medical gloves. It is an FDA validated and approved testing technique as designed by the American Society for Testing and Materials (ASTM) International.

ABSTRACT

Background
The likelihood of transmitting viral diseases that are deadly cannot be refuted when contaminated blood is introduced through injury or when blood gets into contact with non-intact skin. Pathogens can be transmitted through a myriad of routes. Percutaneous injury has the highest risk of transmitting infective pathogens but, there's a chance of transmission via contact with skin or mucous membranes. Operating room personnel are at a greater risk particularly surgeons to whom contact with blood and body fluid are a daily occurrence.
Orthopedic surgeons have an even elevated risk since they have an extended contact with open wounds, aerosolized virus particles coupled with manipulation of sharp bone fragments and instruments such as power saws, drills and reamers which project fluids at high velocities.

Objectives To quantitatively illustrate the frequency of blood contamination during orthopedic surgery

Hypothesis Risk for blood contamination during orthopaedic surgery in Kenyatta National Hospital is higher than other international studies.

Study Design Prospective cross-sectional study

Study Setting Kenyatta National Hospital Theatres

Methodology At the end of an operation, visors/goggles and masks were collected and inspected for blood splatters with the number of blood splatters counted. Gloves were also collected to assess for tears/perforations. This data was documented and analyzed using SPSS version 23 with statistical level of significance designated as $P < 0.05$.

Results The rate of blood splashes to goggles and masks was 44.6% and 48.3% respectively for surgeons, 53.6% and 44.9% respectively for first assistants. The rate of glove perforations was 25.7% and 28.7% for surgeons and first assistants respectively.

Conclusions The risk of blood contamination through glove perforations and blood splashes is comparable to the other international studies. The duration of surgery and type of procedure influence the risk of contamination. The use of power tools influences the risk of glove perforations but not blood splashes. There is no difference in risk between the primary surgeons and first assistants.

CHAPTER 1: INTRODUCTION

The patient's safety and its value in a surgical context is well recognized with resultant development of tools such as the World Health Organization surgical safety checklist that remarkably curbed in hospital mortality (1).
Much less priority is however placed on the surgeon's and his/her teams welfare in published data.

Evidence exists on the risk of transmission of disease from patients, notably Human Immunodeficiency Virus, hepatitis B and C viruses (2).
Contamination has also been documented by healthcare workers from bodily and blood fluid splashes to the eye (3-5).
A surgeon has a chance of contracting multiple HBV infection in his/her lifespan. Furthermore, it is estimated that 1 in 1500 surgeons will possibly have been infected with HIV in the upcoming 35 years (6).

Many surgeons are cognizant of this risk of occupational blood borne infections, yet few abide by the universal precaution guidelines, which reflects a glaring trivialization of probability of contracting blood borne diseases.
In Kenyatta National Hospital, a handful of surgeons, approximately 5.2% regularly use eye protection (7) during operations, yet protecting the eyes is routine in centers worldwide to alleviate the risk of blood contamination with resultant likelihood of infection.

The consistent use of eye protection coupled with a mask or helmet is encouraged regardless of their supposed discomfort since splattering of blood or aerosols of blood can result to 3% to 5% of contaminations (8) and gloves should be put on anytime contact with blood is expected.

This study sought to illustrate the level of risk of contamination during orthopedic surgery by quantifying how frequently orthopedic surgeons are exposed to blood and body fluids via punctured gloves and splashes to masks and goggles.
This will aid in changing the perception of surgeons and encourage complete donning of barrier attire and for hospital administration to ensure adequate supply of the same.

CHAPTER 2: LITERATURE REVIEW

Orthopedic surgeons have an increased risk of contamination to face, neck and other body parts due to the projection of blood from power tools and use of irrigation fluids (9).

Since viruses (particularly HIV, hepatitis B and C) can cause deadly disease when inoculated parenterally or comes into contact with non-intact skin, there is considerable reason to reduce blood contact to the least level possible (2-5).

Non-intact skin is an inevitable occurrence in operating room staff attributed to dermatitis from frequent scrubbing and from cuts and abrasions obtained during recreational activities outside of duty.

The frequency of blood contamination in the operating room is high, and the location of the contamination covers all areas of the body. Therefore sufficient protective clothing should be put on to include impenetrable gloves, protective eye wear and masks (9).

OCCUPATIONAL BLOOD –BORNE VIRUSES

HIV is a human RNA retrovirus that binds to CD4 receptors on lymphocytes, is internalized and replicates within them (10). This leads to a depletion of CD4 cells. The infection progresses in three stages

-Acute stage lasting 2-6 weeks after inoculation during which patients remain seronegative, but have high contaminating probability.

-Chronic phase lasting several years whereby patients are still asymptomatic but have developed anti-HIV antibodies. There's a concrete potential for contamination during this stage.

-AIDS, a full blown manifestation of the disease coupled with a 100- to 1000-fold increase in viraemia per milliliter of blood thus a greater potential for contamination.

The risk of transmitting HIV after an occupational exposure of percutaneous nature is 0.3%, and 0.1% for muco-cutaneous membrane exposure (11).

In a certain case-control study (12), PEP was linked to a 79% reduction in the seroconversion risk following a percutaneous injury ideally, began within two to 72 hours after the exposure and at least for 4 weeks (13-14).

An estimated 90% to 95% of acute HBV infections are self-limiting with attendant lifelong immunity. Only 5% to 10% result in chronic infection remaining serologically positive for hepatitis B surface antigen (HBsAg); approximately 25% of these develop to chronic active hepatitis with an associated 20% lifetime risk of death from cirrhosis and 6% risk of death from hepatocellular carcinoma (15). Hepatitis B vaccine was introduced for human use since 1981.
The uptake of HBV vaccination among Health Care Workers (HCWs) in Kenya is however average as only 59.6% had been vaccinated and only 32% had completed the recommended 3 dose as per a study in selected Kenyan hospitals. The risk of HBV transmission to a health care worker who has received the full immunization and who has manifested a positive immune response after vaccination is basically zero (16-17).
HBV transmission risk varies depending on e-antigen status of source, it ranges from 6% in e- antigen negative patient to 30% in e-antigen positive source (18). HBV exposure in a non-vaccinated individual is managed with an accelerated vaccine series and HBV immunoglobulins (18).

HCV infection results in symptomatic acute hepatitis in less than 25% people. Most will however eventually develop chronic HCV infection with persistent viraemia. Individuals may be asymptomatic but more than 60% have concurrent liver damage detected by a surge in liver enzymes.
About 26% to 50% progress to chronic active hepatitis and between 3% and 26% develop cirrhosis after a couple of years (15).
Immunization against HCV is not yet available and HCV infection does not lead to generation of protective antibodies.
Risk of transmission of HCV after percutaneous exposure is 10% (18).
Acute HCV infection is now managed with pegylated interferons and ribavirin though the access to medication is low.

RISK OF INFECTION

Risk of transmission is influenced by factors such as the depth of injury, quantity of injected blood, hollow bore needle and viremia as measured in titers which could be higher in advanced disease stages and reduced in antiretroviral compliant patients.

The cumulative risk of occupational infection in HCWs is influenced by (19),
a) Prevalence of the viral disease amongst the population being managed;
b) Frequency and nature of occupational exposures to BBF; and
c) The seroconversion rate, a measure of risk of transmission from a single exposure.

Kenya has the joint fourth largest epidemic in the world (20) alongside Mozambique and Uganda with a prevalence of 4.8% in men and 5.2% in women Current estimates also put the prevalence of HBV infection in Kenya at 5-8% (21), this varying depending on the region of the country.
Serological observation of multiple HCWs has reported that the risk of HIV seroconversion after a single percutaneous exposure is estimated at 0.3%, and 0.1% for mucous membrane exposure (11) much less than that reported for hepatitis which is of the order of 10% for HCV and 30% for HBV (18, 22).

Despite the risk of occupational exposure rate being at a minimum, the HIV prevalence is considerably great that the relative cumulated seroconversion risk for surgeons in Africa is approximately 15 times more likely than in the West. Thus, revealing that one in every 300 healthcare workers in tropical Africa are likely to incur an occupational infection with HIV (23). This conclusion was arrived at from a prospective study conducted in Zambia comparing the risk of occupational transmission to the West. The prevalence was determined by testing the surgical patients' blood being admitted for operation. The number of parenteral exposures was obtained upon interviewing the surgeons about accidental injuries on conclusion of an injury and the cumulative risk calculated as 1-(1-fp) ny with f being prevalence in the population, p the probability of transmission per event, n is number of yearly exposures and y the years of practice (23).

Pietrabissa et al (1997) in an Italian multi-centric prospective survey proposed that compliance to the codes for 'universal precautions' can lead to a decrease in the life-time risk of seroconversion for HIV, Hepatitis B and C infection by about half (24).

DOCUMENTED CASES

Not much is known about the worldwide burden of occupational injury among HCWs. However, a 2005 report approximated that greater than 3 million occupationally acquired percutaneous injuries occur globally each year (25). Furthermore, roughly 40% HBV and HCV infections and 2.5% of HIV infections in HCWs were as a result of percutaneous accidents (26). Therefore, each year, occupationally-related percutaneous injury led to about 66 000 HBV, 16 000 HCV and 1000 HIV infections, which as a whole resulted in around 1100 mortalities as well as noteworthy disability (25). Most of these, 90% of infections were in third world countries, primarily in Africa, where infection prevails and there is poor adherence to set precautions (26).
Locally, a study conducted at Rift Valley Provincial General Hospital looking at prevalence of percutaneous injuries and splash exposures in HCWs recorded prevalence of 19.3% percutaneous and 7.2% mucous membrane exposure (27).

The first case of documented seroconversion following a definite occupational exposure to HIV was recorded in 1984 (28).By 1999, 102 accounts of confirmed occupational HIV infection of HCWs had been documented globally, with an additional possible 217 cases of infection (29-30). These were as follows: France - 11, Spain -5, Italy -5, UK -4, Germany- 3, Belgium- 2 and Switzerland -2.Another 43 possible occupational seroconversions, are also not fully documented (29-30). Additional definite documented reports were three in South Africa, one in Zambia, four in Australia, one each in Canada and Argentina.
There also were nine possible seroconversions in Mexico, one in South Africa, two in Canada and one in Israel. Majority of the infections (87.2%) were after an isolated percutaneous injury, commonly a needle stick. The injury followed a scalpel accident in 2 events and was caused by an orthopaedic pin in a different case. 8 infections were a consequence of mucous membrane exposure while 2 cases had both percutaneous and muco-cutaneous exposure to blood (29-30).
Out of the incidences whereby the HIV stage of infection in the source patient was documented, the patient had AIDS in 77% of incidences, showed no symptoms in 15%, and was symptomatic though hadn’t progressed to AIDS in 7.6%; a single exposure was reported to have occurred during the ‘window period’(29-30).

From the period 1999 and end of 2002, an additional six definite and 18 possible cases of occupationally acquired transmission were reported internationally (31).The true incidence is likely underestimated as it relies on prevailing surveillance system with measures in place to report cases, thus information for Africa, South East Asia and South Asia is evidently lacking (31).

UNIVERSAL PRECAUTIONS

In 1987, the CDC proposed a list of guidelines, to be enforced universally, in prevention of contact with BBF and tissues (32).
The recommendations were published by the American Academy of Orthopedic Surgeons in 1989 (33) and new guidelines were introduced in 1996 (34).

Gerberding et al (1995) observed that the attitude towards them however is largely hinged on the perception of danger (35).
In a San Francisco General Hospital whereby the prevalence of HIV was generally approximated as 20%, Gerberding, Lewis and Schecter (35) reported that about 80% surgeons did customary double gloving. In comparison, with a different hospital whereby 80% of the procedures were non-trauma and the HIV prevalence in the latter population was much lower, 10% to 15% of surgeons double gloved yet the magnitude of trauma patients was largely similar in both institutions.

Multiple surveys have been carried out in various countries, for example by McCarthy et al (35) from the United States or by Asante and Tait (36) from Scotland. These in agreement observed that many surgeons were not totally compliant with the proposed universal precautions albeit having moderate to very high concerns regarding the possibility of contracting HIV while working.
Another survey from Netherlands (37) submitted identical results and it too noted inadequate protection by orthopaedic and general surgeons against blood-borne viral transmission. This was demonstrated by either absence of indicated protecting devices or, mainly at emergency departments, by failure to comply by the surgeons.

A rural north Indian study in 2005 assessing the understanding and knowledge of universal rules observed that not only was the understanding of universal guidelines limited, but also the adherence to them was less than optimal. Only 32% of participants put on eye protection when required, and 40% recapped needles at least sometimes (38).

A local study by Professor Ogendo confirmed that the compliance is wanting with only 5.2% of surgeons and 3.5% of assistants using eye protection. Various reasons were tabled such as causing discomfort, unavailability, and misting to prescription glasses being sufficient. Only 1% reported being unaware of their necessity (7).

GLOVE INTEGRITY

Gloves are considered a necessity for protection (39) because the risk of infection from blood borne pathogens is dependant on probability of a percutaneous injury. However, this protective barrier can be violated, with a substantial risk of surgical site infection, in the event a perforation of surgical gloves takes place (38) with resultant collapse of the barrier that usually prevents reciprocal contamination. Whatsoever defects in gloves or perioperative perforations will lead to prolonged contact with the patient's blood (39) and yet detection of glove perforation is more common postoperatively than intraoperatively (40).

Numerous studies have ascertained that glove perforation is more frequent in orthopaedic surgery in comparison to other surgical specialties (6, 40-41), accounting for 61% of all surgical glove perforations (42).
The prevalence of perforation rates have been as high as 43-64% (43).
Even more disturbing, up to 73% are not recognized intra-operatively (40).

Palmer et al. (1992) (8) reported more severe injuries in operations involving manipulation of instruments deeper inside a wound with much greater rate of glove perforations compared to superficial wounds. Moreover, the risk of glove perforation was associated with an increase in the length of the procedure, substantially so on operations exceeding two hours (43-45).
Consistent with other reports, Partecke et al (46) in 2009 advised that surgeons, first assistants and nurses in the operating field should change gloves after 90 minutes because of increased incidence of micro-perforation with time.

Double gloving reducing the risk of contact with blood from 29% to 18% was investigated by Gerberding and Quebbeman, (47). They however submitted that the outer pair should be changed at least every 1-2 hours for trauma surgery.
Punyatanasakchai et al. (2004) (48) also confirmed that utilizing double gloves markedly decreased the contact of a surgeon's hands with the patient's blood, when he compared this to using single gloves during repair of episiotomies.
Laine et al. (2004) (49) also documented that the risk of being contaminated with blood is thirteen times much more when utilizing single-gloving method in comparison to double-gloving technique.
However, utilizing double gloves only does not reliably deter both inner and outer glove perforations (43) and the nature and/or type of procedure may also remarkably impact the risk for glove perforation (45).

The risk of injury from needle sticks can also be appreciably decreased with the assistance of cut-resistant inner gloves. Gloves can be reinforced with Kevlar or polyester/stainless-steel wire weave liners which are crafted to decrease perforations of the inner glove. These are reported as offering variable protection and comfort but should nonetheless be of consideration when bone fragments are to be manipulated or sharp instruments or saws are in use (50).
Sutton et al. (51) tested this inner protective glove and also found it to outstandingly lessen the rate of perforations to the inner glove.
This was again analyzed by Salkin et al. (52). They demonstrated that 100% more exertion was needed to perforate the inner liners with a scalpel and an additional 50% more force was necessary to penetrate these with a needle in comparison to using double gloves with no protective inner liner.

Double indicator gloves can decrease unnoticed sharp occupational accidents. These include a green inside-glove, put on beneath the surgical gloves. Penetration of the outer glove, more so in the presence of fluid, is accentuated by a visible green spot at the location of perforation. Double indicator have been reported to be even more effective than double gloving, when differentiating the number of perforations in the under glove in cases where the outer glove was damaged (49).

An advanced surgical glove known as G-VIR, containing a disinfecting agent for enveloped viruses, has also been developed (53). It demonstrates a significant and invariable decrease in infection by passing through its virucidal layer.
Caillot and Voiglio (54) in 2008 conducted a clinical trial to investigate the tolerance, ergonomics and glove barrier value of the G-VIR and concluded that it provides an excellent mechanical protection, is satisfactory for daily surgical practice and can be recommended in high risk surgical operations.

Orthopedic gloves are rubber latex gloves with a higher average thickness greater than standard surgical gloves. Han et al (55) in his 2013 study of effectiveness of thick surgical gloves during arthroplasty concluded that they offered no superior protective effect over conventional gloves and had lower tactile sensitivity.
Turnquest et al (56) in 1996 compared glove perforation rate with orthopedic gloving versus double gloving technique. No statistically significant rates were found in perforation rates but they were preferred by surgeons for dexterity and comfort.

WATER LEAK TEST

Glove punctures / tears was assessed postoperatively using an acceptable standard test for detection of holes in medical gloves.
It is an FDA validated and approved testing technique as designed by the American Society for Testing and Materials (ASTM) International (57) and European standard (EN 445) (58).
Precisely, gloves were suspended in air for 2 minutes with a minimum of 1000ml water inside and observed for water droplets or streams.
Positive perforation was defined as presence of water droplets or streams outside the glove.
This test has been used in Li Tao and Deepak Kumar's (40) 2014 study on glove perforation during hip arthroplasty. The gloves were filled with a litre of water and the cuff twisted through 360 degrees for maximum pressure while testing for leakage. It was used again by Egeler et al (59) in 2016 to determine the glove perforation rate in tibial plateau leveling osteotomy in veterinary medicine.

EYE PROTECTION AND MASKS

On the contrary, while endeavors are undertaken by many surgeons in prevention of needle-stick injuries, much less emphasis is placed on alternative routes of transmission such as the muco-cutaneous membranes which provide a barrier to BBF splashes into the eye and buccal mucosa.
Bone cutting machines and power saws, utilized in various orthopedic procedures result in BBF being spattered across the operating field and room as an airborne mist.

Marasco et al (1998) (60) observed that the risk of splash injuries to the eye during operations is higher than that realized by most surgeons and residents. He had 44% eye shields testing positive for blood with the surgeon only cognizant of it in 8% cases. Furthermore, in only 16 % cases were the splashes macroscopic, the rest were detected microscopically

Bell et al. (1991) (61) documented contamination of 65% of goggles used by orthopaedic surgeons with BBF, the highest risk being in procedures involving the hip joints, an increasingly common orthopaedic procedure. Use of irrigation and power-tools was related to higher levels of contamination.

Davies et al. (2007) (62) reported 45% of BBF splashes found on the lens of the protective eye wear which was only detected intra-operatively in 50% cases. BBF was present on the mask following 24% of operations. In every event whereby blood/body fluid was noticed on the mask, BBF was also present on the lens of the protective eye-glasses.

Eandi et al. (2008) (63) observed 55% of surgeons' masks bearing proof of contamination with blood splashes following percutaneous nephrolithotomy.
Berridge et al (1993) (64) found 51% of contamination on principals surgeons visors and 42% for the mask. The rate for the second surgeon was also high at 36% for the visor and 42% for the mask in vascular surgery.
Brearley et al (1989) (65) noticed at least one splash of blood after 25% operations with the incidence of contamination slightly greater for one surgeon than the other (28% v 22%), attributed to a higher proportion of lengthy or complex procedures.
Pitto RP et al (1990) (66) found contamination on the surgeons and assistant's glasses in 67% of cases in orthopedic surgery

Alfred A. Mansour et al (2009) (67) simulated experiment suggested that current prescription glasses should not be substituted for eye protection devices and shouldn't be worn solely as protective eye-wear when expulsion of debris is anticipated. Especially high-risk surgeries such as osteotomies, high-flow pulsatile irrigation, high-speed burring or drilling, and reaming.
Brearley et al (1989) (65) also noted that conventional spectacles unfortunately provided only partial protection as numerous blood splatters were on the inside surfaces of their lenses.

Silva R.D et al (2009) (68) in this study, 45% of the visors worn by surgeons/assistants had blood splashes. Over two-thirds, of the contaminated visors had macroscopic blood splashes, (73%) of which had microscopic blood splashes. (32%) visors had only microscopic splashes, and (27%) visors had only macroscopic splashes

Prof Ogendo et al (7) examined a conjunctival contamination rate of 53.1%, average number of blood splashes found per operation was about 2.48 splashes for the surgeons and 1.49 for their assistants.

In conclusion, the risk of occupational blood borne infection is perceived to be minimal yet the likelihood is a reasonable concern. The achievability of barrier protection in preventing this risk is dependant on integrity of gloves and absence of BBF splashes into eyes and non-intact skin.

CHAPTER 3: STUDY RATIONALE

JUSTIFICATION

Although HBV is far more infectious than HIV, it's not deadly and both natural and vaccine mediated immunity are in existence. AIDS is thus a major concern with greater fear of contracting with a cumulative lifetime risk of seroconversion from percutaneous injury at 0.3% and mucous membrane exposure at 0.1%.,a figure that can be 15 times higher in tropical African countries (17).

Occupational infection by viral diseases does not merely raise a medical concern; it's a personal dilemma with physical, psychosocial, professional and financial implications.

These circumstances are normally dealt with utmost confidentiality; since neither the victim nor the institution would publicize such an accident. Occupational infections with HBV, HCV and HIV are handled as an occupational accident in some European countries therefore it is imperative that the hospital attempts to decrease these incidences. This may not apply to surgeons working independently who must consider optional insurance for covering occupational accidents.

It is not known how often orthopaedic surgeons in KNH are contaminated with BBF. This study aims to:

-Enlighten and change the attitude of the surgical team on frequency of risks of contamination injury thus define more appropriate selection of protection

-Aid relevant authority consider enforcing policies on use and constant provision of effective barrier attire including goggles or visors and cut resistant gloves.

OBJECTIVES

Broad Objective

To quantitatively illustrate the frequency of blood contamination during orthopedic surgical procedures

Specific Objectives

1. To determine the frequency of glove perforations intra and post-operatively
2. To quantify the number of macroscopic splashes on goggles and masks during orthopedic surgery.
3. To investigate the factors affecting the risk of exposure such as role of surgeon, type and duration of procedure and use of power tools.

CHAPTER 4: METHODOLOGY

Study design Prospective cross sectional study design

Study population Surgeons and their first assistants working in theatre.

Study duration Data collection was done between July and August 2019

Study Setting

Kenyatta National Hospital (KNH) orthopaedic theatres (Theatres 4, 5 &Trauma)

KNH is the largest referral hospital in the country and receives patients from all over the country by virtue of its size and central location. It has three theatres set apart for orthopedic operations.

Theatres 4 and 5 are part of the 11 main theatres in the facility that are operational during the day therefore mainly conduct elective cases. An average of 4 procedures is undertaken daily in each of these theatres, except for weekends.

Trauma theatre is located in the Accident and Emergency section of the hospital therefore sees a lot of emergency cases. It therefore runs 24hours a day, 7 days a week with an average of 6 cases performed daily.

Inclusion criteria

All primary surgeons and his/her first assistants utilizing the relevant orthopedic theatres.

Exclusion criteria

1. Surgeons not willing to take part in the study.
2. Any other scrubbed persons besides primary surgeon and first assistant.
3. Minor non-purely orthopedic procedures such as skin grafting.
4. Surgeons using prescription glasses as a form of eye protection.

Sample size estimation

Sample size was calculated using Fisher's formula (Daniel WW, 1999) (69) formula;

$$n=\frac{Z^2 \times P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 53.1% from a study by Prof .Ogendo et al (7) in 2007 on risk of conjunctival contamination from blood splashes during surgery at the KNH)

d = desired precision (0.05)

$$n_0=\frac{1.96^2 \times 0.531(1-0.531)}{0.05^2}=382$$

A Sample size of 382 participants was required for the study which translated to 191 procedures.

Data collection

A research assistant was employed solely to undertake this study with none other responsibilities in caring for patients or administrative. The assistant sought consent from the participants prior to the procedure to observe them and record adverse events including blood splashes, and glove perforations. At the end of the operation, the visors were collected and inspected against a white background in good lighting using a magnifying glass for macroscopic BBF splashes counting the number of blood splatters.

Gloves were carefully removed and inspected for tears using the water leak test (WLT), an FDA validated and approved testing technique as designed by the American Society for Testing and Materials (ASTM) (57) International. Precisely, gloves were suspended in air for 2 minutes with a minimum of 1000ml water inside and observed for water droplets or streams.
Positive perforation was defined as presence of water droplets or streams outside the glove. An ink dye was used to help clearly visualize the water droplets outside the glove.

The number of splashes on masks and eye protective wear during each procedure and punctured gloves were documented on a data collection sheet provided.
The role of the participants and duration of surgery (from skin incision to closure) and use of powered tools was also recorded.
"Surgeon" was designated to the person performing most of the procedure. The other was ascribed “assistant”
Contamination was defined as the presence of visible BBF on the barrier garment removed at the conclusion of the procedure.

Data Analysis and Management

Upon collection of the recorded forms, data was verified, entered and transferred to a Microsoft Excel worksheet
The statistical level of significance was designated as $P \leqslant 0.05$.
SPSS version 23, a software for processing statistical analyses was used in data analysis.
Categorical data such as role of surgeon and type of procedure is presented as frequencies and proportions for the objectives of determining frequency of glove perforations and quantifying number of splashes.
Continuous data such as duration of procedure is presented as means with standard deviations or medians with interquartile range where applicable for the objectives of determining frequency of glove perforations and quantifying number of splashes.

Ethical considerations

Ethical approval was obtained from Department of Orthopedic Surgery UoN Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH/UoN ERC) before engaging in any activity related to this study.
This process was conducted by the primary investigator or one of the research assistants by describing our objectives and methods of the study

Study limitations

1. Glove perforation may be a reflection of specific brand used
2. Microscopic splashes were not determined.

CHAPTER 5: RESULTS

PART 1: UNIVARIATE ANALYSIS

PROCEDURE TYPE

Procedure Type	N = 236	%
Upper Limb	48	20.3
Lower Limb	107	45.3
Spine	8	3.4
Arthroscopy	3	1.3
Arthroplasty	3	1.3
Debridement	20	8.5
Others eg biopsy, implant removal,etc	47	19.9

Table 1: Type of procedure

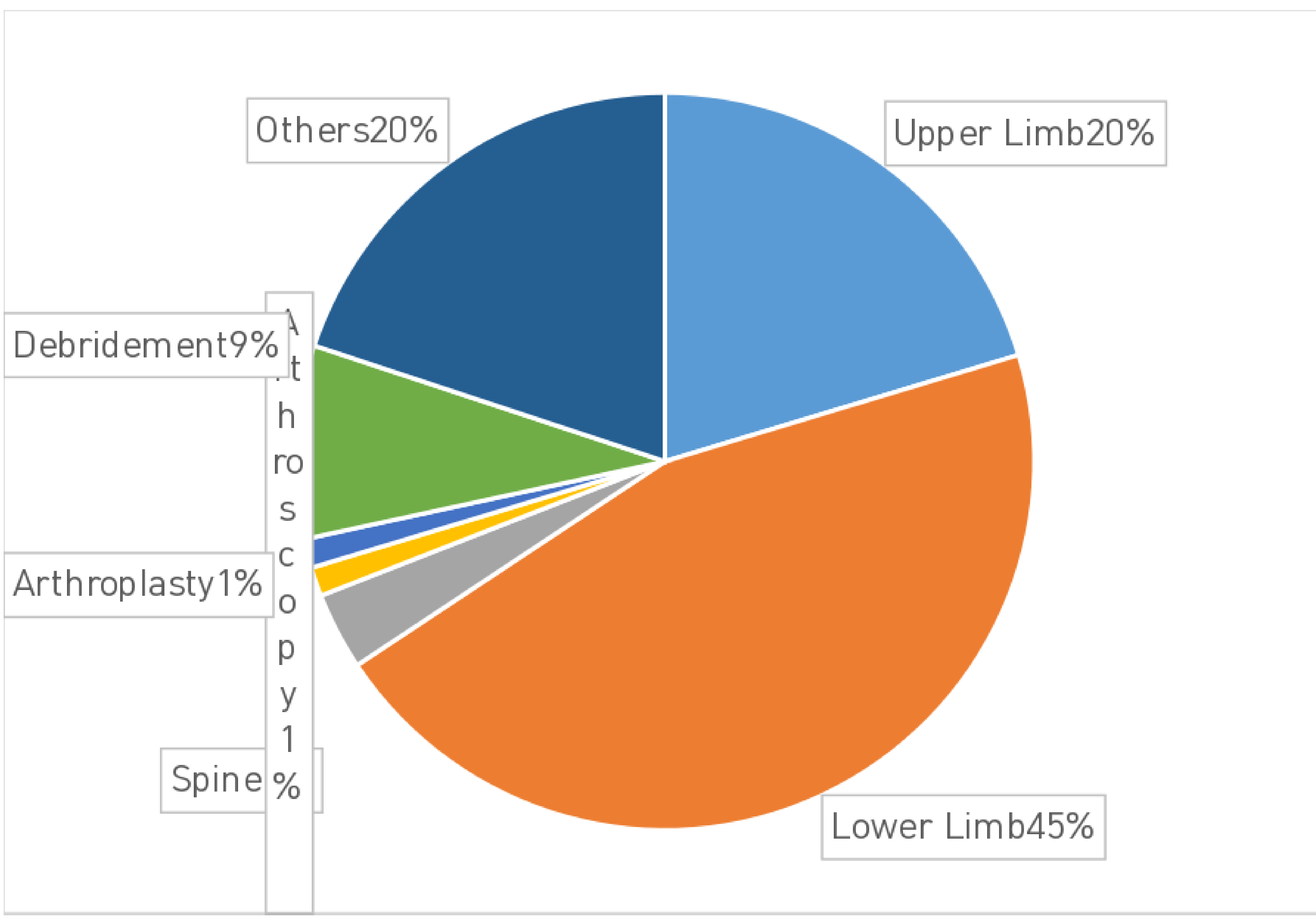

Figure 1: Type of procedure

DURATION OF SURGERY

	Mean	Standard Deviation	Median	Minimum	Maximum
Duration of surgery in hours	1.76	.97	1.50	.33	7.00

Table 2: Duration of surgery.

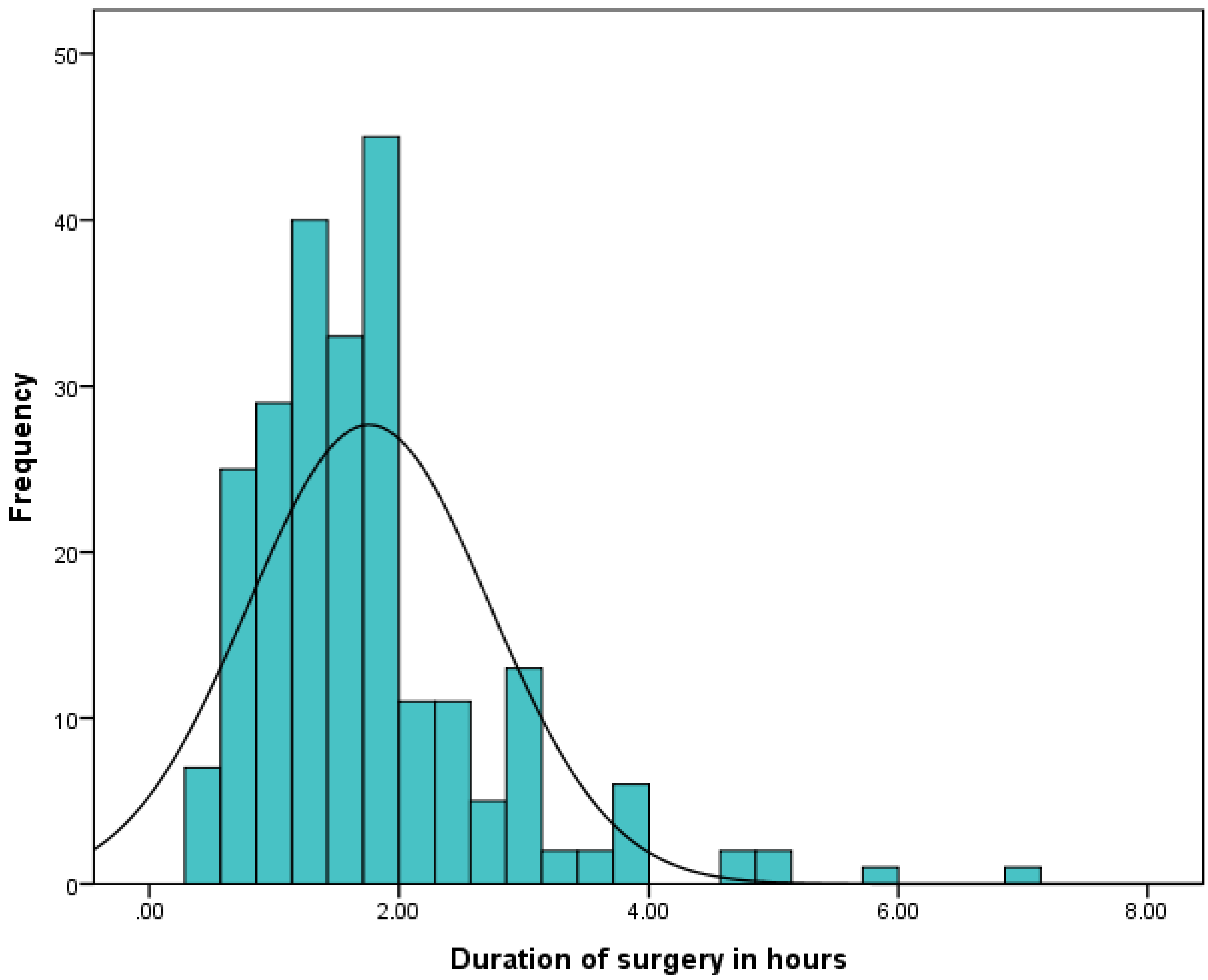

Figure 2: Duration of surgery

USE OF POWER TOOL

		N = 223	%
Power tool used	Yes	144	64.6
	No	79	35.4

Table 3: Power tools usage

USE OF EYE PROTECTION AND GLOVES

	N = 237	Yes		No	
		n	%	n	%
Glove Change Operatively	Surgeon	57	24.1	180	75.9
	First assistant	26	11.0	211	89.0
Glove Change Postoperatively	Surgeon	61	25.7	176	74.3
	First assistant	68	28.7	169	71.3
Goggles/visors	Surgeon	55	23.2	182	76.8
	First assistant	67	28.3	170	71.7

Table 4: Glove changes due to perforations and goggle use

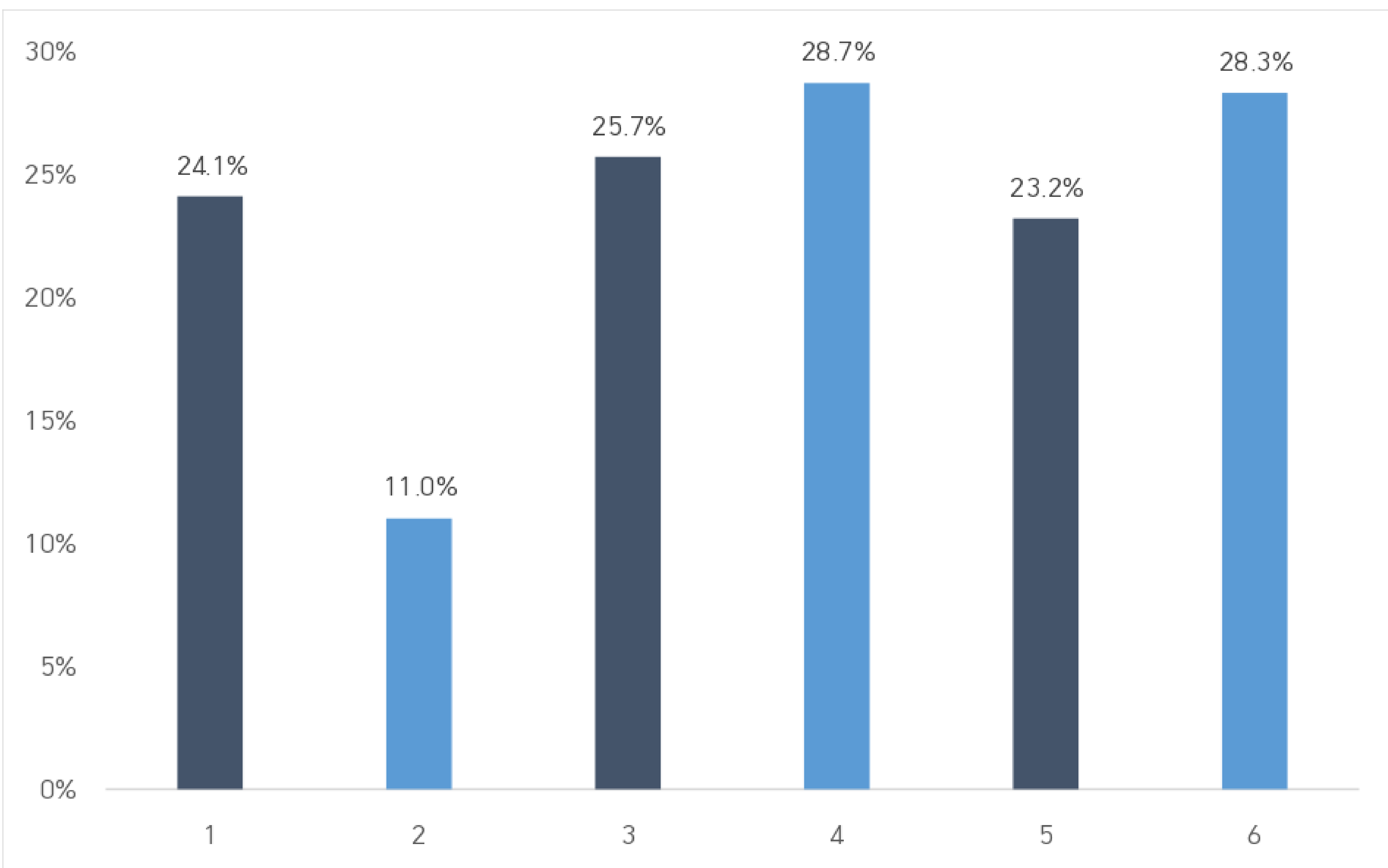

Figure 3: Glove perforations and Goggle usage

NUMBER OF DROPS

	Mean	Standard Deviation	Median	Minimum	Maximum
Surgeon (Goggles) drops	6	7	4	1	45
First assistant (Goggles) drops	5	6	3	1	32
Surgeon (Mask) drops	5	4	4	1	20
First assistant (Mask) drops	6	13	3	1	108

Table 5: Number of blood drops on goggles and masks.

N= 56 for surgeon goggles N= 69 for 1st assistant goggles N= 236 for masks	No contamination		Contamination	
	n	%	n	%
Goggle contamination (Surgeon)	31	55.4	25	44.6
Goggle contamination (Assistant)	32	46.4	37	53.6
Mask contamination (Surgeon)	122	51.7	114	48.3
Mask contamination (Assistant)	130	55.1	106	44.9

Table 6: Overall rates of blood splashes on masks and goggles

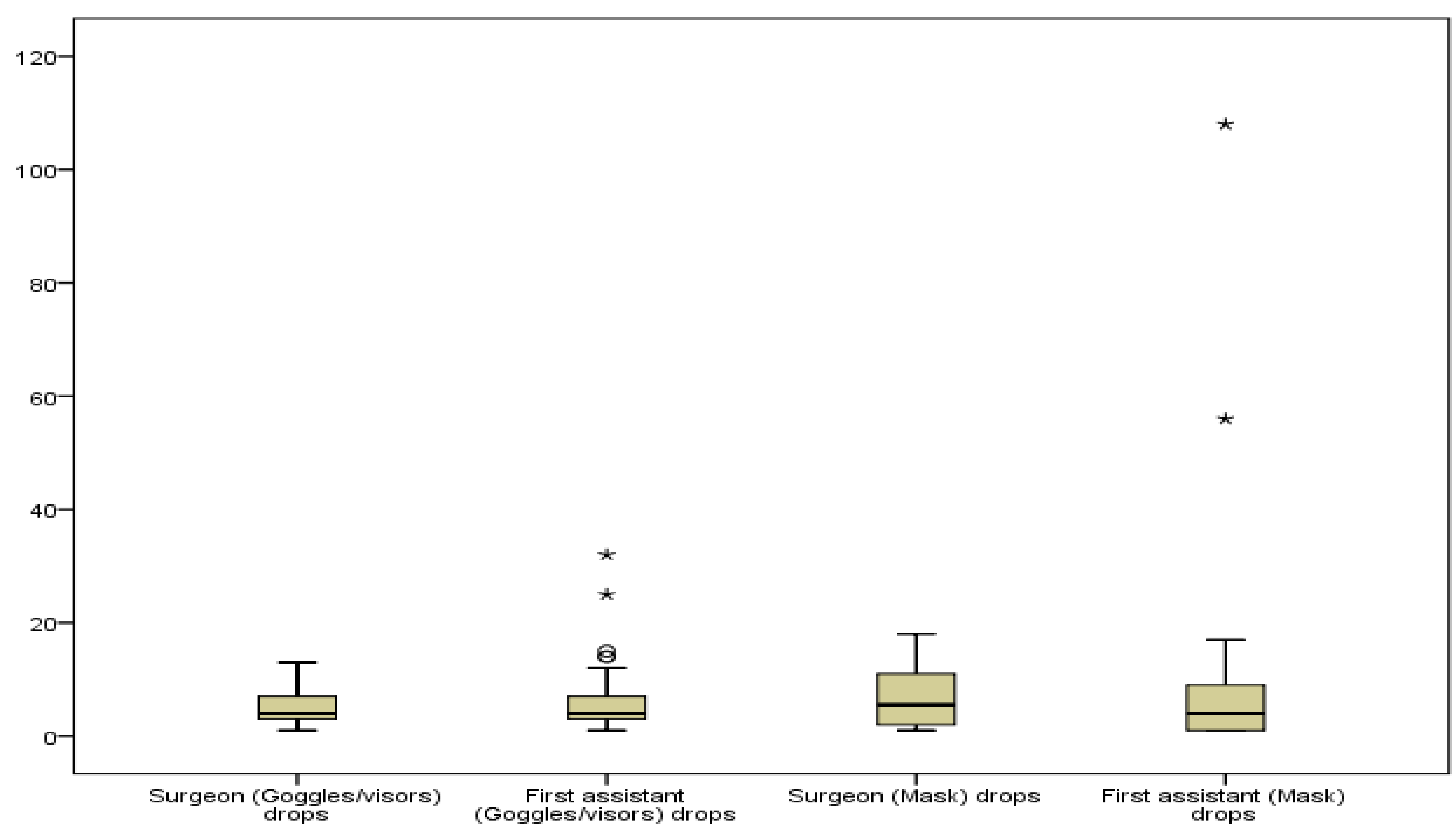

Figure 4: Box graph on number of blood splashes

PART 2: BIVARIATE ANALYSIS

SURGEONS VS FIRST ASSISTANTS (EYE PROTECTION)

		Correlation			Differences		
		N	Coefficient	P value	Mean	Std. Deviation	P Value
Pair 1	Surgeon (Goggles/visors) drops & First assistant (Goggles/visors) drops	36	.210	.220	-.833	8.882	.577
Pair 2	Surgeon (Mask) drops & First assistant (Mask) drops	74	.530	.000	-1.203	12.206	.399
Pair 3	Surgeon (Goggles/visors) drops & Surgeon (Mask) drops	49	.242	.093	-.939	7.448	.382
Pair 4	First assistant (Goggles/visors) drops & First assistant (Mask) drops	57	.795	.000	-2.351	11.590	.131

Table 7: Comparison of surgeon's and first assistant's blood splashes

SURGEONS VS ASSISTANTS (GLOVE PERFORATIONS)

		Yes		No		
		n	%	n	%	p-value
Glove Change Operatively	Surgeon	57	24.1	180	75.9	0.062
	First assistant	26	11.0	211	89.0	
Glove Change Postoperatively	Surgeon	61	25.7	176	74.3	0.235
	First assistant	68	28.7	169	71.3	

Table 8: Comparison of surgeon's and first assistant's glove perforations

TYPE OF PROCEDURE VS NUMBER OF DROPS

		N	Mean	Std. Deviation	p-value
Surgeon (Goggles/visors) drops	Upper Limb	7	3.29	1.604	0.757
	Lower Limb	40	6.35	7.536	
	Spine	1	2.00	.	
	Arthroplasty	3	7.00	.000	
	Debridement	1	6.00	.	
	Others	4	2.50	1.915	
	Total	56	5.64	6.549	
First assistant (Goggles/visors) drops	Upper Limb	11	3.36	2.580	<0.0001
	Lower Limb	45	5.04	4.666	
	Spine	2	3.50	.707	
	Arthroplasty	3	23.00	10.149	
	Debridement	1	7.00	.	
	Others	7	2.14	1.215	
	Total	69	5.25	5.819	
Surgeon (Mask) drops	Upper Limb	15	5.13	3.182	<0.0001
	Lower Limb	71	5.03	4.133	
	Spine	6	3.67	3.011	
	Arthroplasty	3	16.67	1.528	
	Debridement	7	3.86	3.579	
	Others	12	3.42	2.109	
	Total	114	5.04	4.177	
First assistant (Mask) drops	Upper Limb	13	3.46	2.025	<0.0001
	Lower Limb	73	4.64	4.354	
	Spine	4	3.50	2.517	
	Arthroplasty	3	58.33	48.542	
	Debridement	2	9.00	1.414	
	Others	11	3.91	2.548	
	Total	106	5.98	11.847	

Table 9: Association between type of procedure and number of splashes

TYPE OF PROCEDURE VS GLOVE PERFORATIONS

		Surgeon (Glove use - intraoperative)					First assistant (Glove use - intraoperative)				
		Yes		No			Yes		No		
		n	%	n	%	p-value	n	%	n	%	p-value
Procedure Type	Upper Limb	7	14.6	41	85.4	0.001	4	8.3	44	91.7	0.042
	Lower Limb	44	41.1	63	58.9		20	18.7	87	81.3	
	Spine	0	.0	8	100.0		0	.0	8	100.0	
	Arthroscopy	1	33.3	2	66.7		0	.0	3	100.0	
	Arthroplasty	0	.0	3	100.0		0	.0	3	100.0	
	Debridement	3	15.0	17	85.0		1	5.0	19	95.0	
	Others	8	17.0	39	83.0		1	2.1	46	97.9	

Table 10: Association between type of procedure and glove perforations

DURATION OF SURGERY VS NUMBER OF DROPS

Duration of surgery		N	Mean	Std. Deviation	p-value
Surgeon (Goggles/visors) drops	Up to 1.5 hours	11	4.45	4.009	0.507
	>1.5 hours	45	5.93	7.037	
	Total	56	5.64	6.549	
First assistant (Goggles/visors) drops	Up to 1.5 hours	20	2.85	1.424	0.027
	>1.5 hours	48	6.27	6.680	
	Total	68	5.26	5.861	
Surgeon (Mask) drops	Up to 1.5 hours	35	3.57	2.953	0.012
	>1.5 hours	78	5.69	4.511	
	Total	113	5.04	4.196	
First assistant (Mask) drops	Up to 1.5 hours	35	3.77	2.613	0.082
	>1.5 hours	70	7.07	14.371	
	Total	105	5.97	11.904	

Table 11: Association between surgery duration and blood splashes

DURATION OF SURGERY VS GLOVE PEFORATIONS

		Surgeon (Glove use - intraoperative)					First assistant (Glove use - intraoperative)				
		Yes		No			Yes		No		
		n	%	n	%	p-value	n	%	n	%	p-value
Grouped duration of surgery	Up to 1.5 hours	13	11.0	105	89.0	<0.0001	2	1.7	116	98.3	<0.0001
	>1.5 hours	50	42.7	67	57.3		24	20.5	93	79.5	

Table 12: Association between duration of surgery and glove perforations

POWER TOOLS VS NUMBER OF DROPS

Power tools used		N	Mean	Std. Deviation	p-value
Surgeon (Goggles/visors) drops	Yes	48	5.54	6.913	0.626
	No	7	6.86	3.848	
	Total	55	5.71	6.590	
First assistant (Goggles/visors) drops	Yes	57	5.81	6.223	0.170
	No	9	2.89	1.833	
	Total	66	5.41	5.899	
Surgeon (Mask) drops	Yes	86	5.31	4.541	0.242
	No	24	4.17	2.777	
	Total	110	5.06	4.235	
First assistant (Mask) drops	Yes	79	6.54	13.614	0.487
	No	22	4.50	2.874	
	Total	101	6.10	12.126	

Table 13: Association between power tools and blood splashes

POWER TOOLS VS GLOVE PERFORATIONS

		Power tool used				
		Yes		No		
		n	%	n	%	p-value
Surgeon (Glove use - intraoperative)	Yes	44	30.8	19	24.1	0.288
	No	99	69.2	60	75.9	
First assistant (Glove use - intraoperative)	Yes	23	16.1	3	3.8	0.006
	No	120	83.9	76	96.2	
Surgeon (Glove use - postoperative)	Yes	56	39.2	15	19.0	0.002
	No	87	60.8	64	81.0	
First assistant (Glove use - postoperative)	Yes	52	36.4	13	16.5	0.002
	No	91	63.6	66	83.5	

Table 14: Association between power tools and glove perforations

DISCUSSION

A total of 236 procedures were observed with majority being lower limb, n=107 and the least arthroscopy and arthroplasty, n=3. The other procedures recorded were upper limb n=48, spine n=8, debridement n=20 and non-specified n=47 which included operations like implant removal and biopsies among others (Table 1).

The average duration of surgery is 1.76 hours with a median of 1.5hours.The least duration of surgery recorded was 33minutes and longest was 7hours(Table 2). Most procedures, 64.6% (n= 144) involved use of a power tool such as a drill or oscillating saw (Table 3).

It was observed that less than 1/3 of orthopaedic personnel in KNH theaters use eye protection with rates being 23.2% (n=55) for primary surgeons and 28.3% (n=67) for first assistants (Table 4) for varied reasons such as unavailability and causing discomfort. Several studies have oberved this poor adherence to proper protective equipment including an Indian study by Kermonde et al (38) and a local study by Professor Ogendo et al (7).

There was at least one splash of blood in 44.6 % (25 of 56) of the operations for surgeons and 53.6% (37 of 69) of the operations for first assistants (Table 6), a prevalence similar to that quoted by most studies (57-63) with reports of contamination ranging from 44% to 67% of the operations.

The number of blood splashes ranged between 1 to 45 with a median of 4 for surgeons and 3 for their assistants (Table 5). This compares to Brearley et al (65) study who quoted a median of 4.

Mask contamination was recorded in 48.3% (n= 114, N= 236) of procedures for the surgeons and 44.9% (n=106) of the procedures for the first assistants (Table 6). This is in keeping with Berridge et al (64) records of contamination of masks in 42% of the operations.

There was no difference (Table 7) in the number of drops found on goggles/visors between the surgeon and first assistant (n=36, P = 0.577). This contrasts an earlier study by Prof. Ogendo et al (7) that demonstrated persistently greater counts of blood splashes on the surgeons compared to assistants. The number of drops found on the assistant's masks was higher in comparison to the goggles ($p<0.0001$), which is a reflection of the greater surface area the mask covers than the goggles. This association however was not replicated with the surgeon's goggles and masks.

This divergence is likely due to the overall low rates of eye protection wear among the surgeons resulting to a lack of power to detect that association.

The type of procedure had an influence on the number of blood splashes to the goggles and masks (Table 9) with the highest detected in arthroplasty and the lowest in other minor procedures such as obtaining a biopsy ($p<0.0001$). This could be attributed to the length or complexity of the procedure.

A longer duration of surgery was also associated with higher number of blood splashes. Surgeries exceeding 1.5 hours experienced higher contamination rates than those less than 1.5hours (Table 11).

Contrary to a study by Bell et al (61), the use of power tools (Table 13) had no effect on the contamination rate on the goggles/visors ($p=.626$ for surgeons and $p=.17$ for assistants). There also was no association identified between use of power tools and contamination on masks ($p=.242$ surgeons and $p=.487$ assistants).

Most glove perforations are unnoticed intraoperatively and are confirmed post-operatively, 24.1% (n=57 of 237) versus 25.7% (n=61) respectively for surgeons and 11% (n=26) versus 28.7% (n=68) respectively for first assistants (Table 8). This is in keeping with Tao et al (40) who recorded that most glove perforations are not recognized intraoperatively.

There was no detectable difference noted in the rate of glove perforations between the surgeon and first assistant both intra ($p=0.062$) and postoperatively ($p=0.235$).

The type of procedure translated to the rate of glove perforations with the highest being in lower limb procedures ($p<0.001$) and least frequency of glove tears observed in arthroscopy (Table 10). This is explained by the length and complexity of the procedure. Carter et al (45) also confirmed higher glove perforations in revision versus primary joint arthroplasty.

The duration of surgery also influenced the frequency of glove perforations (Table 12). Procedures taking longer than 90minutes experienced more glove perforations (50 of 63 for surgeons, 24 of 26 first assistants) than those lasting up to 1.5hours.This is comparable to a study by Yinusa et al and other studies(43-46) that established the effect of duration on rate of glove perforations. This is due to the prolonged manipulation of instruments deep inside a wound.

The use of power tools also had an association with the frequency of glove perforations recorded in this study ($p=.002$) (Table 14)

CONCLUSION

The risk of blood contamination during orthopaedic surgery at KNH is comparable to other international studies.

There is no difference in contamination risk between the chief surgeon and first assistant.

The duration of surgery and type of procedure have an influence on the risk of contamination via gloves perforations and blood splashes.

The use of power tools has an effect on contamination through glove perforations but not via blood splashes.

RECOMMENDATIONS

1. Both the chief surgeon and first assistants during orthopaedic procedures should wear eye protection.

2. The surgeon and first assistants should consider routine glove changes after 1.5hours of surgery.

3. The administration should consider acquiring and providing eye protection, orthopaedic gloves or indicator gloves for orthopaedic operations.

DISCLAIMER

I, Dr. Bernadette Zembi Akinyi, have not received any financial benefits or incentives from any party or individuals that may directly benefit from this study.

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CHAPTER 9: APPENDICES

APPENDIX 1: DATA COLLECTION FORM

DATE		
PROCEDURE TYPE		
DURATION (Skin incision to closure)		
POWER TOOLS USED		
	SURGEON	FIRST ASSISTANT
GLOVE CHANGE INTRAOPERATIVELY FROM PERFORATION		
POSTOPERATIVELY		
GOGGLES/VISORS NO. OF SPLASHES		
MASKS NO. OF SPLASHES		

APPENDIX 2: CONSENT FORM

CONSENT INFORMATION DOCUMENT

Title: Risk of blood contamination during orthopedic surgery at Kenyatta National Hospital.

Investigator: Dr. Bernadette Zembi Akinyi

Supervisors: Prof. John E.O. Atinga and Dr. Vincent M. Mutiso

Introduction: There exists a minimal but irrefutable risk of transmitting deadly viral diseases from contamination with infected blood. This risk is more so in orthopedics because of the nature of surgery and instrumentation. The principal method of preventing occupational contamination is by effective barriers such as masks, googles and double gloving.

Study Objectives: To quantitatively illustrate the frequency of blood contamination during orthopedic surgical procedures. This will enlighten and change the attitude of the surgical team on frequency of risks of contamination injury to define more appropriate and adequate selection of protection

Procedure: I will observe you during the surgery noting any adverse events such as blood splashes and punctured gloves. I will collect your gloves, masks and goggles at the end of the operation, inspect them and document the number of splashes on facial protection and tears/punctures on gloves.

Benefits: This information will aid relevant authority consider enforcing policies on use and constant provision of effective barrier attire including goggles or visors and cut resistant gloves

Risks: There will be no risks posed to you by participating in the study

Voluntarism: Please take note that your participation is voluntary and are allowed to decline or withdraw from the study without explanation. Your decision to participate or withdraw will not affect your work in any way.

Confidentiality: The information obtained from you will be handled discreetly by me.

CONSENT CERTIFICATE

I certify that the study has been adequately explained to me and I am willing to participate.

Participant's Signature…………………… Date………………….

I confirm that I have clearly explained the nature of the study and the contents of this consent form in detail to the participant and he/she has willingly agreed to take part without any coercion or undue pressure.

Investigator's Signature……………………. Date……………………

Witness' Signature………………………….. Date……………………

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APPENDIX 3: BUDGET

Budget

ITEM	COST(KSH)
Research Fees (KNH/ ERC)	2,000
Stationery ,Printing and Binding	8,000
Statistician	25,000
Research Assistants	60,000
Contingencies	10,000
Total	105,000

APPENDIX 4: IMPLEMENTATION TIMETABLE

<u>Implementation timetable</u>