UNIVERSITY OF NAIROBI

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COMPARISON OF THE EFFECTIVENESS OF PAINTING AND IMMERSING TECHNIQUES, IN PRE-OPERATIVE FOOT DISINFECTION WITH CHLORHEXIDINE.

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A dissertation submitted in part fulfillment of the requirements for the degree of Master of Medicine in Orthopedic Surgery of the University of Nairobi

DECLARATION

I declare that this dissertation does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university and that to the best of my knowledge it does not contain any material previously published or written by another person except where due reference have been made in the text.

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To my wife and family for their abundant and unconditional love and support

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ABSTRACT:

BACKGROUND: Pre-operative preparation of the foot is challenging due to the anatomy and the range of organisms found in this area.

Different antiseptic solutions are in current use for the preparation of skin. The technique used to apply the antiseptic solution has also been shown to be relevant to the effective clearance of microbes from the foot in particular.

OBJECTIVES: To compare the efficacy of painting chlorhexidine onto the foot and immersing the foot in a bag containing chlorhexidine, in pre-operative skin preparation.

METHODS:
Design:
This was a case control study.

Study Population and Sampling:
The study was carried out at the Kenyatta National Hospital, the main referral hospital in Kenya from 12th August to 30th September 2011. 25 individuals were recruited from our inpatient population and hospital staff, giving a total of 50 feet. Selection of subjects was by convenience sampling.

Data Collection Procedure:
Each subject had one foot prepared with the bag technique and the other foot prepared with the painting technique. Allocation of the feet to either technique was done using a table of random numbers.

Pre preparation swabs were collected from randomly selected feet to identify the amount of skin bacteria present. Microbial clearance for both techniques was then assessed by means of culture from swabs taken from both feet when dry.

RESULT: The results of the study show the technique of immersing the foot in a non-sterile bag to be more effective in microbial clearance than swabbing the foot with sterile gauze. In the painting technique, positive growth was obtained from nail folds in 56% of samples and 28% of samples from web spaces. With the bag technique growth was obtained from nail folds in 36% of samples and 12% of samples from web spaces, p-values 0.013 and 0.029 respectively. The sampled pre preparation swabs all grew bacteria.

CONCLUSION: Use of the bag technique with chlorhexidine was found to be an effective method of eliminating potential wound contaminants from the foot as a method of skin preparation prior to surgery

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INTRODUCTION:

Surgical site infection is one of the most common complications that a surgeon encounters. Since the patient's skin is a major source of pathogens, it is conceivable that improving skin antisepsis would decrease surgical site infections.

Well defined resident flora are present in the skin, but varies depending on the anatomic sites. This may be influenced by secretions, coverings such as clothes, or proximity to mucous membranes[1,2]. Studies done in tropical Africa by Nsanzumuhire and his colleagues suggest that there may be variations in the patterns of normal flora in different parts of the world[3]. This may be influenced by weather patterns and other factors such as humidity.

The use of effective preoperative preparation solution is an important step in limiting surgical wound contamination and preventing infection, particularly in orthopaedic surgery where bone infection is disastrous, causing severe long term morbidity. Several antiseptic preparations and methods of application have been used and been shown to be effective in preparing the skin[,4,5,6,7,8,9]. Chlorhexidine a cationic biguanide microbicide with a broad spectrum of activity against bacteria and fungi has been shown to be among the most efficacious and fast acting antiseptic solutions in microbicidal clearance[10]. Chlorhexidine gluconate acts to disrupt the cellular membranes of bacteria and is favoured for its long-

lasting activity against gram-positive and gram-negative organisms found on human skin[6].

Despite the need of adequately preparing the skin, the cost of doing this is always an important consideration in resource poor settings. Although the bag technique is relatively new, it appears at least at face value to be simple and cost effective[4]. It eliminates several processes involved in pre-operative skin preparation such as the need for sterile gauze, which is how it reduces the cost[4].

Justification of the study:

Pre-operative preparation of the foot has proved to be challenging due to the anatomy and the range of organisms found in this area [11, 12].

The aim of this study is to compare the bag technique efficacy using what is known to be an effective antiseptic solution (Chlorhexidine) and compare its efficacy in relation to validated and currently practiced techniques. There was no record found of a similar study having been done before in this part of the world.

LITERATURE REVIEW:

The foot provides a unique environment for the growth of numerous bacterial species and has many characteristics that differentiate it from other sites of the body. The lack of pilosebaceous units, the absence of apocrine sweat glands, and the wearing of occlusive footwear provide a unique habitat for microbes [11, 12].

Studies have demonstrated higher infection rates following orthopaedic procedures involving the foot and ankle as compared with those involving other areas of the body due to the difficulty of eliminating bacteria from the forefoot prior to surgery[13, 14]. Wukich and his colleagues reported a post-operative infection rate of 4.8%, whereas Miller and his colleagues reported a post-operative infection rate of 2.2% from series of 1841 foot and ankle procedures[15,16]. In the study by Wukich et al infection rates were higher in diabetic patients as compared to the general population [15].

The paronychium (lateral nail fold), web spaces and the hyponychium of the toes are considered to be the areas of the foot most difficult to prepare, and the most likely to have residual contamination, with the potential for cross-contamination to other surgical sites[10]. These areas are a potential barrier to antiseptic access [10]. Wolf and his colleagues suggest that the nail fold may be impossible to clear of all micro-organisms and that surgery in this area must be considered a dirty procedure [13]. Ostrander et al reported a 100% growth rate from swabs taken before skin preparation in the nail fold, web spaces and anterior aspect of the

ankle. After skin preparation with different antiseptic solutions growth rate from the nail fold was ranged from 30 to 95%. Growth rate obtained from the web space had a range of 23 to 98% with different antiseptic solutions. Tytiun and his colleagues found that after a two step cleaning procedure there was 80% growth from the nail folds and 25% from the web spaces respectively[17]. There was actually no difference in number of positive cultures pre-operatively and postoperatively from the nail fold and an overall increase in the growth obtained from the web space which was 5% pre-operatively. These findings were attributed to a high rate of recolonization after pre-operative cleaning of the feet. There have been no difficulties reported in elimination of micro-organisms from the anterior aspect of the ankle which is commonly used as a control site [17].

The normal flora of the skin comprises predominantly *Staphylococcus epidermidis*, *Staphylococcus* aureus (small numbers), *Micrococcus* species, non pathogenic *Neisseria* species, Alpha hemolytic and non hemolytic *Streptococci*, *Diphtheroids*, *Propionibacterium* species, *Peptostreptococcus* species among others[2, 3]. Differences in normal flora occur among different age groups and there may be geographical variations in normal flora of the skin with *Staphylococcus aureus* being more predominant in tropical Africa[2, 3]. These differences may be due to environmental, geographical or ethnic factors[3]. This pattern may present a greater risk for peri-operative infection as *S. aureus* is a far more potent disease causing organism and especially in the causation of osteomyelitis[3]. *S. aureus* is also more common in older age groups. Bacterial colonization in the

web space is more likely to be polymicrobial and include fungal species such as *Candida*[18].

Different antiseptic solutions are in current use for the preparation of skin; of these, alcohol application with the use of a bristled brush has been shown to give good clearance[5]. Some studies have used a combination of both chlorhexidine and alcohol with good results[6]. Similarly chlorhexidine on its own has been shown to be more effective than either alcohol or povidone iodine in microbial clearance [19, 20]. Its microbicidal effect is believed to be through the disruption of the permeability of the cell membrane, in a manner similar to polymixin, but it differs in the biochemical manner of the interaction with the membrane components[9]. Its broad spectrum of action extends to fungi[21]. It can however be inactivated by organic matter, soap, anionic detergents, hard water and some natural materials such as the cork liners used for closure of bottles.

The properties that make chlorhexidine effective include its strong affinity for binding to skin, its high level of antibacterial activity, and its prolonged residual effects[22]. In addition, its rapid activity has been found to surpass that of both povidone-iodine and chloroxylenol-containing solutions. Chlorhexidine has also been shown to be relatively less toxic to tissues than other antiseptics and overall to produce less adverse effects at currently used concentrations [23, 24]. It can however, produce adverse effects in some individuals including contact dermatitis, generalized urticaria, and profound anaphylactic shock [24].

Effective neutralization of active agents is essential to obtain valid efficacy results, especially when non-volatile active agents like chlorhexidine digluconate (CHG) are tested. Without effective neutralization in the sampling fluid, non-volatile active ingredients will continue to reduce the number of surviving microorganisms after antiseptic treatment even if the sampling fluid is kept cold straight after testing. The crucial step of neutralization seems to occur in the sampling fluid itself where any residual bacteriostatic or bactericidal activity should be stopped immediately after the preset application time. This is particularly important for short application times such as 30 seconds. [25, 26, 27]

The bag technique where the limb is placed in a non-sterile bag containing antiseptic solution has been used so far only with a povidone iodine solution and found to be more effective than the traditional method of painting the hand[4]. The mechanical effect of shaking the limb and the use of a larger volume of antiseptic solution may be the main contributory factors to the effectiveness of this technique[4].

It can therefore be considered that the bag technique used in combination with chlorhexidine which is an effective antiseptic solution will give better microbial clearance compared to standard skin preparation techniques and therefore can be recommended for pre-operative disinfection of the foot.

OBJECTIVES:

Hypothesis:

Null hypothesis: there is no difference in microbial clearance if chlorhexidine is painted onto the foot compared to when the foot is immersed in a bag containing chlorhexidine

Broad Objective: To compare the efficacy of painting chlorhexidine onto the foot and immersing the foot in a bag containing chlorhexidine, in pre-operative skin preparation of the foot

Specific objectives:

1. To assess the efficacy in microbial clearance of painting chlorhexidine onto the foot.

2. To assess the efficacy in microbial clearance of immersing the foot in a bag containing chlorhexidine.

3. To identify bacterial strains isolated from the feet after disinfection

4. To compare the difference in reduction of pathogens with painting and immersion techniques.

SUBJECTS AND METHODS:

i) Design:

The study design was a case control study.

ii) Study Population and Sampling:

The study was carried out at the Kenyatta National Hospital, the main referral hospital in Kenya from 12th August to 30th September 2011. In total, 25 individuals were recruited from the inpatient and hospital staff, giving a total of 50 feet. A power analysis indicated that a sample size of twenty-five feet in each group (a total of fifty feet in the study) would provide 80% power to detect a significant difference, between the two methods, with regard to the percentages of positive cultures of specimens from the nail folds, web spaces, and anterior aspects of the ankles. This sample size calculation was done using nQuery Advisor version 7.0 a power analysis software.

iii) Exclusion Criteria:

Each subject was required to give informed consent before inclusion in the study. Subjects who did not give consent were not included.

Subjects with active infection, open wounds or known allergy to chlorhexidine were also excluded from the study.

iv) Sample Collection Procedure:

Culture specimens were obtained from five randomly selected subjects (the Pre-Preparation Group) immediately before surgical preparation. This was done to find out the load of skin bacteria present prior to treatment with an antibacterial surgical scrub. Randomisation was done independently for each of the three sites where swabs were to be collected after skin preparation; the 2nd web space, the hallucal nail fold and the anterior aspect of the ankle.

Each subject then had one foot prepared with the bag technique and the other foot prepared with the painting technique. With the bag technique the foot was prepared by placing it, in a non-sterile plastic bag already containing 150 ml of 4% chlorhexidine solution, the limb was then shaken until a froth was created and the entire foot was covered with the chlorhexidine solution. The foot was then left in the bag for 1 minute. The bag was then peeled off, so as not to contaminate the prepared limb. Removal of the bag was done under aseptic conditions; that is with the data collector wearing a surgical gown, sterile gloves and a mask.

With the painting technique, the foot was painted with 4% chlorhexidine solution using a standard sterile kit and aseptic technique, the limb being painted three times. The kit consisted of three sterile gauze swabs and 150mls of 4% chlorhexidine. This was also left for 1 minute. The preparation of all the feet was done by the same individual under aseptic conditions that is while wearing a

surgical gown, sterile gloves and a mask. The chlorhexidine solution was a commercially available preparation of chlorhexidine gluconate, manufactured by Harleys pharmaceuticals. For the painting technique the sterile gauze swabs were pre-packed 4x4 inch swabs and the 4% chlorhexidine gluconate solution used was from Harleys pharmaceuticals.

After the foot had been fully draped and allowed to dry but not more than five minutes after preparation, swabs were then taken from three areas on both feet; the hallucal nail folds, the 2nd web space and the anterior aspect of the ankle. The hallucal nail fold and 2nd web space are considered to be the areas of the foot most difficult to prepare, and the most likely to have residual contamination, with the potential for cross-contamination to other surgical sites[8]. The anterior aspect of the ankle has been shown in other studies to have almost 100% microbial clearance and served as a control site[5,17]. The swabs were all taken by the same individual, different from the one preparing the surgical sites under aseptic conditions that is while wearing a surgical gown, sterile gloves and a mask.

These swabs were then placed immediately in a Stuart transport medium and cultured on standard agar plates used for culture of skin bacteria[28]. The transport media contained a neutralizing agent for the chlorhexidine, purified egg lecithin. The Lecithin was not placed directly on the prepared feet due to the risk of anaphylactic reaction in some individuals. All cultures were carried out at 37^0c [29].

Both transport medium and agar plates were coded as A (bag technique) and B (painting) to indicate the method used to prepare the skin from which the samples were collected. They were also numbered serially. The samples were inoculated into an amplifying solution, McConkey broth within 30 minutes of collection. Inoculation was again done by the one individual in one laboratory. The laboratory technician was blinded as to the origins of sample set A and B.

The swabs tip from the transport media were released into 5ml of sterile McConkey broth and left for 12 hrs to amplify microbial growth. From the diluents 100µL was inoculated onto each blood agar plate[28]. These were assessed after 48 hours for the presence or absence of growth and the number of colonies reported as scanty, moderate and profuse depending on the number of colonies observed. Both the McConkey broth and blood agar plates were prepared by Selecta Media (ISO 9001:2008). A standard data sheet was used to tabulate the number of colonies from agar plates from each foot. The bacteria grown were identified using standard biochemical methods (catalase test, coagulase test etc), but sensitivity testing was not performed.

v) Data Analysis:

Data was tabulated and analyzed using SPSS 17.0. The number of positive cultures and the mean number of colony forming units for each site was compared using the McNemar test[30], with results considered significant if

P<0.05. Data presentation was by means of tables and graphs as deemed appropriate.

vi) Study Limitation:

The study did not assess for a statistical difference in the numbers of colony forming units for the positive samples which may have given a clearer difference in the effectiveness of either technique in clearance of microbes.

The sample size used was only 50 feet; a larger sample size would have had more power to detect a statistical difference in the study findings

vii) Ethical Consideration:

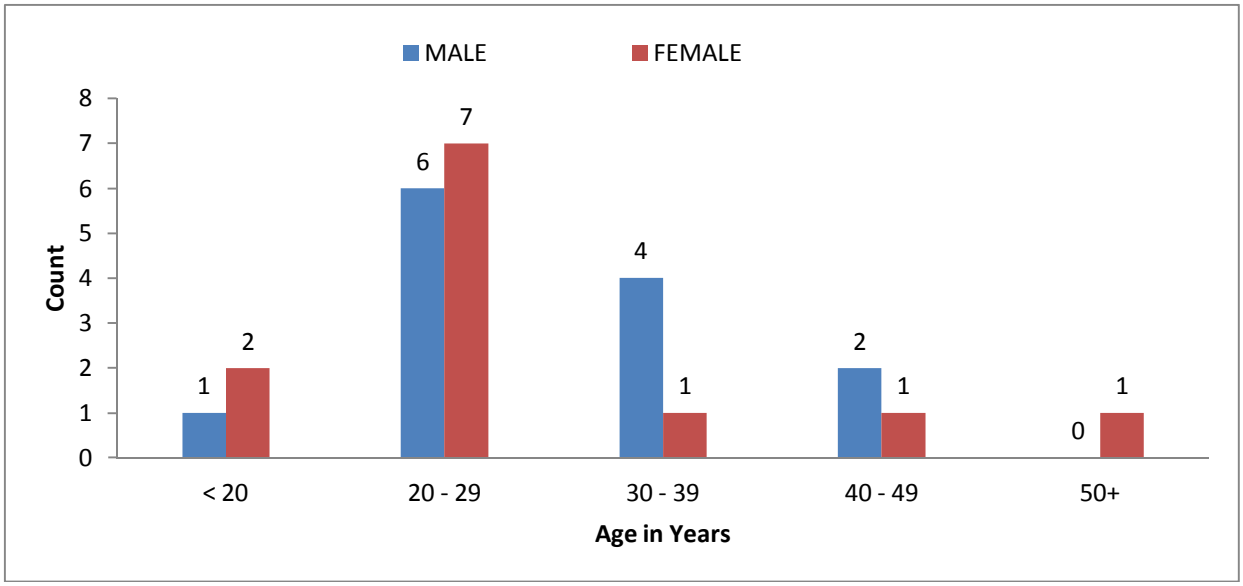
Ethical approval for this study was given by the Kenyatta National Hospital Ethical Review Committee. The participants in this study did not derive financial or any other benefit from this study. The principles of the Helsinki declaration as amended in 2008, on experimental research in human subjects was adhered to at all stages of this study[31].

RESULTS:

Table 1: Baseline Characteristics

Characteristic	Frequency	Percent
Sex		
Male	13	52.0
Female	12	48.0
Age		
< 20	3	12.0
20 – 29	13	52.0
30 – 39	5	20.0
40 – 49	3	12.0
50+	1	4.0

Figure 1: Age distribution v/s Sex



The mean age was 26.9 years. The mean age for male was 26.5 and that of female was 27.4 years. There was no significant difference in years of age between male and female, (p-value=0.860).

Table 2: Percentage positive culture rates from pre-preparation swabs and from feet prepared using immersion and painting techniques in different culture sites

Skin preparation technique	% (No.) of positive cultures		
	Nail folds	Web space	Ankles
Painting	56% (14)	28% (7)	0
Immersion	36% (9)	12% (3)	0
Pre-preparation	100% (5)	100% (5)	100% (5)

All the swabs taken prior to skin preparation had positive growth (100%).

A total of 14 (56%) out of the 25 swabs obtained from the nail folds of feet prepared using the painting technique had positive results.

A total of 9 (36%) out of the 25 swabs obtained from the nail folds of feet prepared using the immersion technique had positive results.

Table 3: Comparison of the effectiveness of the painting and immersion techniques in microbial clearance of the nail fold

		Immersion		
		+VE	-VE	Total
Painting	+ve	8	6	14
	-ve	1	10	11
Total		9	16	25

This is a two by two table comparing positive and negative growths from nail folds prepared using painting and immersion techniques respectively.

There was a significant difference between the number of positive cultures in the painting and immersion techniques with a p-value of 0.013 on the McNemer test.

Sensitivity and specificity was 88.9% and 62.5% respectively with a positive predictive value of 57.1% and negative predictive value of 90.9%

Table 4: Comparison of the effectiveness of the painting and immersion techniques in microbial clearance of the web space

		Immersion		
		+VE	-VE	Total
Painting	+ve	1	6	7
	-ve	2	16	18
Total		3	22	25

This is a two by two table comparing positive and negative growths from web spaces prepared using painting and immersion techniques respectively.

There was a significant difference between the number of positive cultures in the painting and immersion techniques with a p-value of 0.029 on the McNemer test. Sensitivity and specificity was 33.3% and 72.7% respectively with a positive predictive value of 14.3% and negative predictive value of 88.9%.

Table 5: Distribution of microbial growth patterns in Positive Cultures by Technique

Status	Painting	Immersion
Moderate Growth	16 (76.2%)	7 (58.3%)
Profuse Growth	2 (9.5%)	0 (0.0%)
Scanty Growth	3 (14.3%)	5 (41.7%)
Total	21 (100%)	12 (100%)

This table represents only positive cultures. There was proportionately more moderate and profuse growth in positive cultures prepared using the painting technique than in those prepared using the immersion technique.

Table 5: bacteria isolated from pre-preparation cultures

Bacteria Isolated	Number of Positive Cultures
Coagulase –ve *Staphylococci*	13
Gram –ve Bacteria	2

Most of the bacteria isolated were coagulase negative *Staphylococci*

Table 5: bacteria isolated from positive cultures

Bacteria Isolated	Number of Positive Cultures
Coagulase –ve *Staphylococci*	23
Gram –ve Bacteria	10

Most of the bacteria isolated were coagulase negative *Staphylococci*

DISCUSSION:

It has already been shown in previous studies that it is difficult to eliminate bacteria from the foot [11-15]. It is also evident from previous studies that chlorhexidine is one of the more effective antiseptic solutions used in surgical site preparation[11]. The purpose of this study was therefore to assess whether the technique used to apply the chlorhexidine can affect its effectiveness in clearing microbes from the foot.

The results of the study show the technique of immersing the foot in a non-sterile bag to be more effective than swabbing the foot with sterile gauze. It was found that growth from the nail folds was more with the painting technique than with immersion with positive growth reducing from 56% with the painting technique to 36% with the bag technique a statistically significant difference (p-value 0.013). Growth from the web spaces was also significantly less with the immersion technique than with the painting technique with only 12% positive cultures with immersion compared to 28% positive cultures with painting a statistically significant difference (p-value 0.029). These findings are in agreement with those of Incoll and his colleagues who found the immersion technique to be more effective than painting in clearing microbes from the hand[4].

No growth was obtained from the anterior aspect of the ankle in either arm of the study. Pre-preparation swabs taken from this area gave 100% positive culture rates and so bacterial clearance from this area was also 100%. Tytiun and his

colleagues also found no growth from swabs taken from this area which in their study served as a control[17]. The findings are also in keeping with findings of the study by Keblish and his colleagues[5]. They found minimal growth from swabs taken from the anterior aspect of the ankle prepared using four different techniques; only four positive cultures from feet prepared with alcohol and a bristled brush had positive growth from this area of the foot.

The number of positive samples obtained from the nail folds and web spaces was also less than in similar studies using other antiseptic agents [5, 6,7,17]. Wolf and his colleagues studied an iodine-based scrub and paint and reported that bacteria grew on culture of specimens obtained from 98% of nail folds and 83% of web spaces[13]. In the study by Ostrander et al they obtained 95% positive cultures in swabs from the nail fold and 98% positive cultures in swabs from the web space in feet prepared using iodine and alcohol based antiseptic preparation[6]. This might be a reflection of the greater effectiveness of chlorhexidine compared with these other antiseptics in clearance of microbes from the foot as supported by findings in the study by Ostrander et al where 30% positive cultures were obtained from nail folds and 23% of samples from web spaces prepared using a chlorhexidine and alcohol based preparation[6]. Aly and Maibach also found that chlorhexidine was significantly more effective for reducing bacterial counts from the hands when compared to povidone iodine and chloroxylenol solutions[20].

More moderate and profuse growth was obtained from positive samples prepared using the painting technique than was obtained from feet prepared using the immersion technique. This may further imply that the immersion technique is more effective in clearance of micro-organisms than the painting technique possibly due to the mechanical effect of shaking the limb, its greater access to hard to reach areas of the foot and possibly longer exposure time. The most common organism identified was *Staphylococcus epidermidis* which was again in keeping with findings of previous studies[6].

The use of the bag technique has obvious advantages in resource limited settings. Firstly it is easy to use and can be done even by lower cadre staff. The bag can even be applied in the ward before the patient is brought to theatre allowing adequate time for microbial clearance[4]. In addition it is a low cost method as it eliminates the need for sterilization of gauze and other instruments needed to swab the foot. The bag itself is non-sterile and being plastic very cheap, offering an obvious economic benefit. A possible disadvantage of using the bag is the possibility of contaminating the prepared site in the process of removing the bag[4].

No adverse events were reported in this study, which is testament to the safety of chlorhexidine.

Conclusion

It is known that infection following foot operations is higher than in other parts of the lower limb. One of the factors contributing to high infection rate is the anatomy of the foot which makes skin sterilisation difficult. Any improvement in skin preparation is expected to reduce this rate. As shown in this study immersion technique promises to give higher rate of elimination of bacteria than the traditional skin preparation technique of painting. There is need therefore, for further study of this method of foot skin preparation over a longer period, with a larger sample and with more operators.

Recommendations:

- A randomised control study with a larger sample size and involving more than one centre; would help to ascertain with more accuracy the efficacy of the immersion procedure.

- Further studies are required to assess how high up in the limb the bag technique can be effective in pre-operative skin preparation. For example, could the bag be as effective if applied up to a level above the knee.

- Finally it is recommended that after further observation; the immersion technique be adopted as the method of choice for pre-operative preparation of the foot and ankle

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APPENDIX A

COMPARISON OF THE EFFECTIVENESS OF PAINTING CHLORHEXIDINE ONTO THE FOOT AND IMMERSING THE FOOT IN A CHLORHEXIDINE CONTAINING BAG, IN PRE-OPERATIVE SKIN PREPARATION.

Subject Biodata:

Age: _____ Sex: _____

Wears Shoes: YES/NO

Use of antiseptic soap within last 48hrs: YES/NO

Use of systemic antibiotics within last 48hrs: YES/NO

Specimen Collection Form:

Sample No: ____

Method of Skin Preparation: **A/B**

Date of Specimen Collection: _____
Time collected: _____

Specimen Collected by:

Name: _____
Signature: _____

NB: before signing the collector must verify that he has clearly labeled the samples as either A or B, and that they are also serially numbered as per the described protocol

Date received at Laboratory: _____
Time received at Laboratory: _____

Received by:

Name: _____
Signature: _____

NB: before signing the recipient must confirm that the samples are clearly labeled as either A or B and also numbered serially.

APPENDIX B:

COMPARISON OF THE EFFECTIVENESS OF PAINTING CHLORHEXIDINE ONTO THE FOOT AND IMMERSING THE FOOT IN A CHLORHEXIDINE CONTAINING BAG, IN PRE-OPERATIVE SKIN PREPARATION.

Data Entry Sheet:

Sample No: _____

Date of Specimen Collection: _____
Time collected: _____

Date of Inoculation: _____
Time of inoculation: _____

Sample label: A/B

Growth Present: Yes/ No

If Yes,

No of CFU: ____

Bacteria Identified:

1.	
2.	
3.	
4.	
5.	

Laboratory Technician:
Name: _____
Signature: _____
Date: _____

APPENDIX C:

COMPARISON OF THE EFFECTIVENESS OF PAINTING CHLORHEXIDINE ONTO THE FOOT AND IMMERSING THE FOOT IN A CHLORHEXIDINE CONTAINING BAG, IN PRE-OPERATIVE SKIN PREPARATION.

CONSENT EXPLANATION FORM

Dear Sir/Madam,

My name is Dr. Nicholas Okumu, a post-graduate student at The University of Nairobi. In partial fulfillment of my degree course, I am required to conduct a research project. The main aim of my research is to compare the efficacy of painting chlorhexidine onto the foot and immersing the foot in a bag containing chlorhexidine, in pre-operative skin preparation of the foot

I request you to participate in this study, which will compare the microbial clearance obtained when the foot is either painted with the antiseptic solution, chlorhexidine using a swab held with a towel forceps or immersed in a bag containing the same antiseptic solution, chlorhexidine and shaken. In order to do the preparation of the feet you will be required to enter a sterile operating room.

In some individuals chlorhexidine has been known to cause a mild reaction lasting for a few hours and if you have ever had this experience you are required to inform us. In addition if you have any open wound on your feet you are also required to inform us. You will be able to observe the procedure performed on you at all times. There is no benefit financial or otherwise that you will gain by your participation in this study.

It is entirely dependent on your will to consent to participate in the study and should you refrain from the exercise, it will not under any circumstances adversely affect your care. A thorough physical examination will be done using adequate light, clean instruments, disposable gloves and face masks, with particular emphasis on the state of your feet, following which your feet will be

prepared with the already described techniques. To ensure confidentiality your personal identity will not be included in the records. Relevant findings from this exercise will be provided to your current health care provider to facilitate your health management. The results from this study may be used in the future to recommend which method is suitable for preparing feet pre-operatively.

Participation in this study is purely voluntary and all information collected is confidential. A written consent by you or your next of kin (in case you are unable to sign for whatever reason), will be required. You have a right to withdraw from the study at any stage without jeopardizing your treatment.

Thank you in advance for your co-operation.

Should you wish to contact me over any issues related to the study and your participation please use the following address:

Dr. Nicholas Okumu

P. O. Box 34657-00100,

Nairobi.

Mobile 0720 797450

APPENDIX D

CONSENT

Consent by patient/ next of kin to participate in this study

I…….hereby consent to participate in this study/research, the nature of which has been fully explained to me by Dr. Nicholas Okumu.

I participate with the full understanding of the purposes of the study and the procedures involved, which include a clinical examination and preparation of my feet using the antiseptic solution chlorhexidine, all of which have been explained to me by Dr. Okumu.

Date.....
Signed……..

I, Dr. Okumu, confirm that I have explained to the patient the nature of the study and procedures to be done.

Date.....
Signed……..

APPENDIX D

RIDHAA / IDHINI

Idhini ya mgonjwa / ndugu wa karibu ya kushiriki katika utafiti huu

Mimi……..nakubali kuidhinisha kushiriki kwangu katika utafiti huu. Nimeelezewa vizuri na kwa kina kabisa juu ya asili ya utafiti huu na daktari Nicholas Okumu.

Nakubali kushiriki kwa sababu nimeelewa na kufahamu vizuri sababu na umuhimu wa utafiti huu. Nimeridhika na kuulewa vizuri kabisa njia zitakazotumika katika kuangalia na kuandaa miguu yangu kwa dawa ya majimaji inayoitwa Chlorhexidine, ambayo pia nimeelezewa vizuri na kwa kina kabisa na daktari Okumu.

Tarehe…….

Sahihi……

Mimi, Daktari Okumu, nahakikisha kabisa kuwa nimemuelezea mgonjwa vizuri asili ya utafiti huu na njia ambazo zitatumika.

Tarehe…….

Sahihi……...