THE EFFECTIVENESS OF TRICLOSAN COATED POLYGLACTIN 910 IN REDUCING SURGICAL SITE INFECTION IN CLEAN WOUNDS:
A RANDOMISED CONTROL TRIAL

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A dissertation submitted in part fulfilment for the award of Master of Medicine in General surgery of the University of Nairobi
DECLARATION

I declare that this dissertation is my own original work and has not been presented for a degree in any other University.

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ABBREVIATION

CDC- Centre for disease control
CSF- Cerebrospinal fluid
KNH- Kenyatta National Hospital
NRC-National research council
PI-principal investigator
SSI- Surgical site infection
UON-University of Nairobi
ABSTRACT

Background: Surgical site infection (SSI) is a major cause of morbidity, mortality and financial burden in healthcare. Worldwide it accounts for as much as $10 billion annually in direct and indirect medical cost. Many strategies have been developed to try and reduce SSI.

Objective: To determine the effectiveness of triclosan coated polyglactin 910 sutures in reduction of superficial surgical site infection in clean wounds.

Study design: This was a non-blinded randomised controlled trial.

Setting: Kenyatta national hospital, the minor theatre in clinic 24.

Sample size: A total of 157 patients underwent excision of breast lump.

Methods: Patients scheduled for minor clean wound surgery were randomly divided into two groups. In one group the wounds were closed subcutaneously with triclosan coated polyglactin 910 suture, while in the second group plain polyglactin 910 suture was used. The wounds were examined on the 3rd, 7th and 30th day post operatively, for signs of superficial SSI. There was no use of antibiotics perioperatively. However for patients who developed SSI, treatment was offered.

Results: The prevalence rate of SSI in the study group was 5% (4 of 79 patients) while in the control group it was 4% (3 of 78). The difference between the two groups was not statistically significant (P-value 0.507).

Conclusion: This study did not demonstrate a reduction of superficial surgical site when triclosan coated polyglactin 910 suture was used in clean wounds. More studies are needed to look at its effects on other wounds. Currently, the clinical role and indication for use of vicryl plus is yet to be fully defined.
LITERATURE REVIEW

Introduction
About a century ago most wounds got infected, with high morbidity and mortality 70-90% \(^1\). The ideal surgical outcome is primary wound healing and cure of the primary pathology, however this is not always the case and complications do occur, one of which is infection. Infection has always been a feature of human life and sepsis in modern surgery continues to be a significant problem for healthcare providers across the globe. Surgical site infection is the third most commonly reported infection and accounts for 14-16% of all nosocomial infections among hospital inpatients\(^2\). It is a major cause of prolonged hospital stay, morbidity and mortality in healthcare\(^3\). Worldwide it accounts for as much as $10 billion annually in direct and indirect medical cost\(^3,4\).

Definition
Surgical site infection is an infection that develops within 30 days after an operation or within one year if an implant was placed and the infection appears to be related to the surgery\(^5\). The new CDC-definition for surveillance of surgical site infection (1992) devised by Horan and his colleagues takes into account 3 classes of surgical site infections (SSI): Superficial SSI, deep incisional SSI, organ/space SSI\(^6\). Superficial incisional infection involves the skin and subcutaneous tissues above the most proximal fascial plane. Deep incisional infections involve the fascia, muscle and other deep tissues, regardless of whether the skin and subcutaneous tissues are infected. Organ /space infections involve either the intra-cavitary space entered during the course of surgery or the specific organ operated on.

A detailed definition of these infections is provided below:-

Superficial surgical site infections is defined as infection occurring within 30 days after the operation, involving the skin or subcutaneous tissue, and at least one of the following

1. Purulent drainage from the superficial incision or a drain located above the fascial layer
2. Organisms isolated from an aseptically obtained culture of fluids or tissue from the superficial incision
3. Pain or tenderness, localised swelling, redness, or heat( at least one) , and surgical opening of the incision ( unless culture is negative)
4. Diagnosis of superficial incision SSI made by the attending physician

Deep incisional SSI
Infection within 30 days after the operation (up to 1 year if an implant is placed and infection appears to be related to the operation), involves deep soft tissues (e.g. fascial layer, muscle), and at least one of the following
  1. Purulent drainage from the deep incision
  2. Spontaneous dehiscence of deep incision or surgical opening when at least one the following is present: fever (temperature >38°C), localised pain, or tenderness (unless culture is negative)
  3. Abscess or other evidence of infection involving the deep incision found during direct examination, during reoperation, or by histopathologic or radiologic examination
  4. Diagnosis of deep incisional SSI made by a surgeon or attending physician

Organ/-space infections
Infection occurs within 30 days after the operation (up to 1 year if an implant is placed and infection appears to be related to the operation), involves any part of the anatomy (e.g. organs, space), other than the incision, that was opened or manipulated during operation, and at least one of the following is present:
  1. Purulent drainage placed through a stab wound into the organ/space
  2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
  3. Abscess or other evidence of infection involving the organ/space found on direct examination, during reoperation, or by histological or radiological examination
  4. Diagnosis of organ/space SSI made by the surgeon or attending physician

THE SCOPE OF THE PROBLEM
Before the use of prophylactic antibiotics, infection rates were 1-2% for clean wounds, 6-9% for clean contaminated wounds, 13-20% for contaminated wounds, and about 40% for dirty wounds\(^3\)\(^4\). With the introduction of antibiotics the infection rates have drastically dropped to clean 2.1%, clean contaminated 3.3%, contaminated 6.4% and dirty 7.1 %\(^7\). In a local study by
Bhatt in KNH in 2003, infection rates were found to be - clean wounds 3.1%, clean contaminated 7.4%, contaminated 22.2% and dirty wounds 38.8%. Overall wound infection rates was 17.4%. In the same study it was found that patients with SSI spent more money in hospital bills as well as time in hospital in treatment of SSI. From the above figures, it is clear that more efforts must be put in our facility to try and reduce SSI. One of the recommendations from his study was reduction of clean wound infection rates.

RISK FACTORS

The development of SSI is the result of a complex interaction between the local and systemic defence mechanisms of the patient and the contaminating organisms. The risk factors can be divided into 2 main groups:

- Patient related factors like obesity, diabetes, smoking, malnutrition, presence of infection at a remote body site etc
- Perioperative factors e.g. preoperative hair removal, skin antisepsis, length of surgery, use of drains etc

These factors increase the risk of a patient acquiring a SSI. The risk factors are generally related to the patient’s capacity to fight against an infectious threat, the infectious challenge itself as represented by the number and pathogenicity of the bacteria, the extent of the associated injury, and environmental factors such as the hospital bacterial flora. Surgical wounds can thus be classified based on the presumed magnitude of the bacterial load at the time of surgery. The National Research Council (NRC) of the National Academy of science was the first group to devise a classification system based on the estimated degree of bacterial contamination and demonstrated a direct relationship between the risk of infection and the degree of contamination. This classification is useful in estimating the risk of SSI, predicting the potential pathogens and determining the need of antimicrobial prophylaxis. It divides wounds into 4 classes namely:

1. Clean/ class I wounds
2. Clean-contaminated/ class II wounds
3. Contaminated/class III wounds
4. Dirty wounds
Clean/class 1

- No sign of acute inflammation or infection
- No entry into the respiratory, alimentary or genitourinary tract
- No violation of aseptic technique

The clean wound infection rates is purported to be the most valuable measure of surgical care in any hospital and is used in surveillance audit and quality assurance. And so it can be a useful tool in assessing the quality of infection control we offer to our patients.

Prevention

Multiple preventive strategies have been devised to try and reduce the rate of SSI. They can be broadly divided into

- Pre operative period
- Intra-operative period
- Post-operative period
- Intrinsic patient-related factors

Some of the risk factors are modifiable, while others are not. Lots of efforts have been put into reducing SSI by optimising the modifiable risk factors.

Some example of preventive strategies include

- Keep pre operative hospital stay as short as possible
- Control of glucose in diabetic patients
- Use of prophylactic antibiotics where indicated
- Stop tobacco use in patients
- Antiseptic skin preparation
- Gentle tissue handling

Although great strides have been made in trying to reduce SSI, none can guarantee total elimination of SSI and so it continues to pose a major challenge in healthcare provision.

Suture material is commonly used in modern surgery for wound closure, ligature etc, however they are foreign material. The presence of a foreign body like suture in a wound is known to lower the size of bacterial inoculi necessary to produce infection, and so it is an area that can be looked into with a view of reducing SSI. It is postulated that using antimicrobial coated sutures for wound closure might reduce SSI by preventing bacterial adherence to the suture and create overlapping zones of inhibition radiating outward from the suture. And so the novel idea of
antibiotic coated sutures was conceived. The actual development of antibacterial surgical suture has been under consideration since early 1980s\textsuperscript{13}.

**Pharmacology of Triclosan**

Triclosan 5-chloro-2 (2,4-dichlorophenoxyphenol) is a broad spectrum antimicrobial agent developed 40 years ago\textsuperscript{15}. It was first introduced in the healthcare industry in a surgical scrub of 1% concentration in 1972 and for oral care in toothpaste in Europe in 1985\textsuperscript{16}. Triclosan has been used in over the counter health products for more than 30 years, being non toxic, non-irritating, non carcinogenic, non teratogenic and non pyogenic\textsuperscript{16}. Triclosan acts at multiple cytoplasmic and membrane targets\textsuperscript{15,17}. At lower concentration, triclosan appears bacteriostatic and is seen to target bacteria mainly by inhibiting fatty acid synthesis\textsuperscript{17}, but at higher concentrations it is bacteriocidal. Triclosan binds to bacterial enoyl-acyl carrier protein reductase enzyme (ENR), which is encoded by the gene FabI. This binding increases the enzyme’s affinity for nicotinamideadenine dinucleotide (NAD\textsuperscript{+}). This results in the formation of a stable complex of ENR-NAD\textsuperscript{+}-triclosan, which is unable to take part in fatty acid synthesis\textsuperscript{17}. Fatty acids are necessary for building cell membranes. Humans do not have ENR enzyme, so are not affected. Triclosan has a broad range of activity that encompasses many, but not all, types of Gram-positive and Gram-negative non-sporulating bacteria, some fungi\textsuperscript{18}, *Plasmodium falciparum* and *Toxoplasma gondii*\textsuperscript{19}. The organisms most sensitive to triclosan are staphylococci, some streptococci, some mycobacteria, *Escherichia coli* and *Proteus* spp. Triclosan has been in cooperated into several products including sutures because of these effects\textsuperscript{16}. The tissue reaction, healing response, and absorption profile of triclosan-coated polyglactin 910 antimicrobial suture (Vicryl Plus) has not been found to be affected by the presence of triclosan\textsuperscript{20}. The effects of vicryl plus has been looked at in several studies, some of which are listed below.

A recent single centre prospective double blinded randomised control trial\textsuperscript{21} done in the United States of America looked at the use of triclosan coated sutures (polyglactin 910) in the closure of galea and fascia in cerebrospinal fluid shunts surgery and the resultant infection rates. The results were: the incidence of infection in the study group was 2 out of 46 (4.3%) while in the control 8 out of 38 (21%). The study was halted prematurely by the researchers after they realised significantly higher infection rates in the control group. The conclusion drawn from that study
was that antimicrobial sutures was associated with a reduced risk of postoperative shunt infection, however the study was terminated prematurely at 6 months and it recommended further studies be done to confirm this association.

A double blinded randomised control trial done in Thammasat university Thailand\textsuperscript{22}, evaluated the efficacy and safety of vicryl plus compared to vicryl in reducing surgical site infection in appendectomy operation. In the study either vicryl plus or vicryl was used to close the abdominal sheath and the patients were followed up for one year. The preliminary results showed that there was no statistical difference in the surgical site infection between vicryl and vicryl plus (8 and 10\%, p= 0.05)

Another study done in Japan\textsuperscript{23} looked at the use of triclosan coated sutures in colorectal surgery. All the patients received intravenous antibiotics pre and post operatively. In the study they also included patients with diabetes mellitus, smokers and those on steroids. The infection rates was 4.3\% for the vicryl plus group while 9.3\% for the control. There was a statistically significant difference in the two groups. The conclusion from the study was that triclosan coated sutures can reduce the incidence of wound infection in colorectal surgery.
STUDY JUSTIFICATION

SSI remains a major cause of prolonged hospital stay, morbidity and mortality in patients worldwide. Being such a major burden on the health system all efforts should be made to try and reduce this disease burden. Surgical practice often includes the use of topical or antimicrobial agents applied to the operative site to minimise post-operative surgical infections. Compared to systemic antibiotic therapy, topical or local delivery of antibiotic has several advantages including high and sustained concentrations at the site of infection where local physiological changes may hinder the efficacy of systemic antibiotics.\textsuperscript{24,25,26,27} Other benefits include the limited potential for systemic absorption and toxicity, reduced volumes of antibiotic use and finally novel agents like triclosan that are not available systemically can also be used.\textsuperscript{24} Antimicrobial coated sutures have shown a lot of promise in reducing SSI. However several studies that have been done have been inconclusive.

Although the CSF shunt surgery study\textsuperscript{21} showed benefits, generalisation cannot be made because of population differences that included; they targeted paediatric age group, there was use of antibiotics pre-operatively (vancomycin or cefazolin), use of iodine impregnated adhesive drapes, antibiotic wound irrigation before closure, presence of a foreign material- VP shunt and follow up for six months.

In the other two studies\textsuperscript{22,23} there was also use of antibiotics perioperatively thereby introducing a confounding factor. The other difference is that they were not Class 1 wounds and so it is not possible to extrapolate these results for clean wounds. The role of antimicrobial coated suture in reducing SSI has not been fully studied and lots of grey areas still exist as to their effectiveness. This study endeavoured to answer these questions as well being a foundation for more detailed and comprehensive studies.

NULL HYPOTHESIS

There is no difference in infection rate in clean wound when antimicrobial coated suture (triclosan coated polyglactin 910) is used compared to plainpolyglactin 910 suture.
STUDY OBJECTIVE

MAIN OBJECTIVE
To determine the effectiveness of antimicrobial coated sutures in reduction of superficial surgical site infection in clean wounds.

SPECIFIC OBJECTIVE
1. To determine superficial surgical site infection rate in clean wounds.
2. To find out whether triclosan coated polyglactin 910suture is better than plain polyglactin 910suture in reducing superficial SSI.

PATIENT AND METHODS

STUDY LOCATION
The study was conducted in Kenyatta National Hospital, the national referral and teaching hospital of the University of Nairobi.

STUDY DESIGN
This was a non blinded randomised control study.

STUDY POPULATION
Patients with breast lump for excision in minor theatre day care surgery

INCLUSION CRITERIA
- Adult patients, 18-50 years of age
- Class I wounds.
- Consent patients.
EXCLUSION CRITERIA

- Wounds requiring drains
- If shaving of operative site was done
- Known immune-compromised patients e.g. AIDS, diabetes mellitus
- If antibiotic was administered peri operatively

SAMPLE SIZE ESTIMATION

Formulae for sample size calculations for comparisons between proportions in a randomized control trial when the outcome is dichotomous

\[ N = c \left[ \frac{\mu_1(1 - \mu_1) + \mu_2(1 - \mu_2)}{(\mu_1 - \mu_2)^2} \right] \]

N = is the sample size for each group = 82 (i.e. 164 patients in total for the 2 arms)
C = 7.9 for a power of 80%
\( \mu_1 \) = Success rate in the control group (0.79) used polyglactin 910 suture
\( \mu_2 \) = Success rate in the study group (0.937) after a 30% improvement from the control group

The control figure is from the VP shunt study with infection rates of 21%.

There is no local study available.

Recruitment and enrolment

A total of 157 patients were enrolled for the study. Staff members at the minor theatre were sensitized about the study. The principal investigator stationed at the minor theatre screened all the patients who were scheduled for clean minor day care surgery, those who met the inclusion criteria for the study were then recruited on voluntary basis. Recruitment was verbal and consisted of an explanation of the nature, purpose and potential benefits of the study.

Those who agreed to take part in the study then signed an informed consent form and were expected to adhere to the protocol of not using antibiotics during the study period and to inform the PI in case they use them. They were also expected to come to KNH, on the 3rd, 7th, and 30th day for review visits and in between the review visits they were to inform the PI in case they
developed signs and symptoms of superficial SSI. Other than that they were advised to carry on with their normal daily activities but to avoid contaminating the wound.

**Randomization**

After enrolment, randomization of patients into 2 different groups was done by the use of random permuted blocks. This also ensured that the number of patients allocated in each group was equal.

We used a block size of 4, example ABAB (A=vicryl plus, B=vicryl). That is to say for each block of 4 patients, two patients received vicryl plus and two vicryl. A block size of 4, gave us 6 different permutations (example: ABAB, AABB, BBAA, BABA, BAAB, ABBA). Using a table of random numbers, number 1-6 was allocated to these permutations and numbers 0, 7-9 ignored. This generated permutations equivalent to the sample size, from which a randomization list was constructed. The randomization was be done by an independent statistician and he then passed the generated table of allocation to the PI.

**Intervention**

Patients were randomly divided into two groups, each with 82 patients. In one group, triclosan coated Polyglactin 910 suture was used while in the second group, plain Polyglactin 910 suture was used, in wound closure. The patients selected for the study were those undergoing excision of breast lump at the minor theatre. The surgeons for the study were senior house officers, who were not be blinded. The skin preparation was standardised, there was no shaving done and skin cleaned with three swabs with a povidine mixed with methylated spirit and lastly painted with aqueous povidine. Meticulous hemostatic control was encouraged and no suturing was done inside the wound. All wounds were closed by subcutaneous suturing. There was no use of antibiotics pre and post operatively. In cases where there was a break of aseptic technique, contaminated wounds or where the surgeon decided to administer antibiotics, the patients were excluded from the study so as to reduce confounding factors. Patients were then discharged home on adequate analgesia. Wound exposure was on the third post operative day and patients were also examined for SSI. Post operative wound care entailed Opsite spray (from smith & nephew) as a form of dressing for all the patients. Subsequently the patients were examined on day 7 and 30 post operatively for signs of SSI, however the patients were also instructed to come back to hospital
immediately and contact the principal investigator in case they developed wound infection. The criteria for making the diagnosis of superficial SSI was purulent discharge from the incision site, pain or tenderness, localised swelling, redness or heat. All the patients who developed SSI were referred to a consultant for treatment.

ETHICAL CONSIDERATION

1. Ethical approval was sought from the KNH/UON ethic and research committee to permit the study to be carried out in the institution.
2. The data collection was started after consent was given by the ethics committee.
3. Patients recruited to the study were explained to both verbally and through patient information booklet and they signed an informed consent to participate in the study.
4. All patients’ records were handled with confidentiality. Patients’ names did not appear in the final text.
5. The information obtained was not to be used for any other purpose but for the dissertation in part of fulfilment of masters of medicine in surgery

OUTCOME

The primary outcome was the development of superficial surgical site infection in class1 wounds. Wound infection was identified by the presence of erythema, localised swelling, raised local temperature, tenderness/pain, or purulent discharge.

DATA ANALYSIS

The data was analysed using SPSS version 12 data analysis package. Statistical significance was determined using Chi square, fisher’s exact test, and a P-value of <0.05 was considered to be significant. Results are presented in tabular and graphic form.
STUDY LIMITATION

- Follow up of some patients was a challenge, because it was on outpatient basis.
- Ascertaining that the patients were compliant the instruction given e.g. not taking antibiotics, was difficult.
- Screening for immune suppression e.g. Diabetes Mellitus, HIV-AIDS, was not done, so it’s not possible to tell whether they could have been a contributing factor in patients who developed SSI
RESULTS
A total of 157 individuals were enrolled into the study, of these 79 patients had their wound closed with vicryl plus while in 78 patients plain vicryl was used. The patients were then followed up for one month and examined periodically for features of SSI. Data from all patients were entered in a database on an EPI-INFOR platform. Fisher’s exact test and Chi-square test were used to test the differences between the categorical variables. Kruskal walls test was used to test the median size of the lump between the groups.

From the study population a total of 7 patients developed superficial SSI, giving an overall infection rate of Superficial SSI of 4.5%.

Table 1: summary of outcome

<table>
<thead>
<tr>
<th></th>
<th>Number of patients</th>
<th>Number of patients infected in each group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vicryl</td>
<td>78</td>
<td>3</td>
</tr>
<tr>
<td>Vicryl plus</td>
<td>79</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>157</td>
<td>7</td>
</tr>
</tbody>
</table>

CHARACTERISTIC OF PATIENTS

GENDER
Most of the patients who went underwent excision for benign breast lesions were females 156 (99%) and there was 1 male (1%)

Table 2: Gender distribution

<table>
<thead>
<tr>
<th>Gender</th>
<th>156</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
</tr>
</tbody>
</table>
AGE DISTRIBUTION
The median age of the patients was 25 years, with 111 patients (71%) being 18-29 years, 27 patients (17%) were 30-39 years, and while 19 patients (12%) were between 40-50 years old. There was no significant statistical difference between the age groups and developing SSI (P-value 0.761)

Table 3: Age distribution

<table>
<thead>
<tr>
<th>Age (in years)</th>
<th>Vicryl (N=78)</th>
<th>Vicryl plus (N=79)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29</td>
<td>56 (51%)</td>
<td>55 (49%)</td>
<td>0.761</td>
</tr>
<tr>
<td>30-39</td>
<td>14 (52%)</td>
<td>13 (48%)</td>
<td></td>
</tr>
<tr>
<td>40-50</td>
<td>8 (42%)</td>
<td>11 (58%)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1: Age distribution of the study patients

Graph shows the age distribution among the study patients. Most patients (71%) were between 18 – 29 years of age.
**DIAGNOSIS**

The most common diagnosis found in the study was fibroadenoma seen in 122 patients (77.7%), followed by undefined benign breast lump in 19 patients (12%), 9 patients (5.7%) had galactocele (5.7%), 6 patients (3.8%) had fibrocystic disease and 1 patient (0.6%) had a wart. There was no statistically significant difference between age groups and developing SSI (P-value 0.536)

**Table 4: Diagnosis**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Vicryl N (%)</th>
<th>Vicryl plus N(%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibroadenoma</td>
<td>61 (50)</td>
<td>61 (50)</td>
<td>0.536</td>
</tr>
<tr>
<td>Breast lump</td>
<td>8 (42)</td>
<td>11 (58)</td>
<td></td>
</tr>
<tr>
<td>Galactocele</td>
<td>6 (67)</td>
<td>3 (33)</td>
<td></td>
</tr>
<tr>
<td>Fibrocystic breast disease</td>
<td>2 (33)</td>
<td>4 (67)</td>
<td></td>
</tr>
<tr>
<td>Wart</td>
<td>0 (0)</td>
<td>1 (100)</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 2: Diagnosis**
The above figure shows the diagnosis among the study patients. Fibroadenoma was the most common diagnosis at 78%, followed by undefined benign breast lump. There was no statistical difference between the diagnoses (P-value 0.536) and developing SSI.

**LOCATION OF THE PATHOLOGY**

In 146 patients (93%) out of the study population of 157, the disease was unilateral (involving only one breast), while bilateral in 11 patients (7%). In the unilateral cases the left breast disease had 72 patients (46%) while the right side had 74 patients (47%). There was no statistical difference with regard to developing SSI and the location (P-value 0.290)

**Figure 3: Location of pathology**

![Location of pathology diagram]

The most frequently affected quadrant of the breast was the outer upper quadrant with 63 patients (40%), 24 patients (15%) upper inner quadrant, 25 patients (16%) lower outer quadrant, 24 patients (15%) lower inner quadrant and in 21 patients (14%) the periareola area. There was no significant statistical difference between the locations and developing SSI (P-value 0.214)
Table 5: Location of pathology on the various breast quadrants

<table>
<thead>
<tr>
<th>The breast quadrant involved</th>
<th>Number of patients</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper outer</td>
<td>63 (40%)</td>
<td></td>
</tr>
<tr>
<td>Upper inner</td>
<td>24 (15%)</td>
<td></td>
</tr>
<tr>
<td>Lower outer</td>
<td>25 (16%)</td>
<td>0.214</td>
</tr>
<tr>
<td>Lower inner</td>
<td>24 (15%)</td>
<td></td>
</tr>
<tr>
<td>Periareola</td>
<td>21 (14%)</td>
<td></td>
</tr>
</tbody>
</table>

There was no statistically significant difference among the quadrants and developing SSI (P value 0.214)

Figure 4: The involvement of the various breast quadrants
### SUMMARY OF THE STUDY POPULATION

**Table 6: summary of study population**

<table>
<thead>
<tr>
<th></th>
<th>All patients (N=157)</th>
<th>n (%)</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median age (years)</strong></td>
<td>25(21-32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-29 years</td>
<td></td>
<td>111(71)</td>
<td></td>
</tr>
<tr>
<td>30-39 years</td>
<td></td>
<td>27(17)</td>
<td></td>
</tr>
<tr>
<td>40-50 years</td>
<td></td>
<td>19(12)</td>
<td></td>
</tr>
<tr>
<td><strong>Suture</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vicryl</td>
<td></td>
<td>78(49.7)</td>
<td></td>
</tr>
<tr>
<td>Vicryl plus</td>
<td></td>
<td>79(50.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibroadenoma</td>
<td></td>
<td>122(77.7)</td>
<td></td>
</tr>
<tr>
<td>Breast lump</td>
<td></td>
<td>19(12)</td>
<td></td>
</tr>
<tr>
<td>Galactocele</td>
<td></td>
<td>9(5.7)</td>
<td></td>
</tr>
<tr>
<td>Fibrocystic breast disease</td>
<td></td>
<td>6(3.8)</td>
<td></td>
</tr>
<tr>
<td>wart</td>
<td></td>
<td>1(0.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Unilateral vs. bilateral disease</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both</td>
<td></td>
<td>11(7)</td>
<td></td>
</tr>
<tr>
<td>One</td>
<td></td>
<td>146(93)</td>
<td></td>
</tr>
<tr>
<td><strong>Side of breast involved</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td></td>
<td>74(51)</td>
<td></td>
</tr>
<tr>
<td>left</td>
<td></td>
<td>72(49)</td>
<td></td>
</tr>
<tr>
<td><strong>Location on the breast</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>upper outer</td>
<td></td>
<td>63(40)</td>
<td></td>
</tr>
<tr>
<td>upper inner</td>
<td></td>
<td>24(16)</td>
<td></td>
</tr>
<tr>
<td>lower outer</td>
<td></td>
<td>25(16)</td>
<td></td>
</tr>
<tr>
<td>lower inner</td>
<td></td>
<td>24(15)</td>
<td></td>
</tr>
<tr>
<td>periareola</td>
<td></td>
<td>21(14)</td>
<td></td>
</tr>
<tr>
<td><strong>Lump size</strong></td>
<td></td>
<td>3cm(2-4)</td>
<td></td>
</tr>
</tbody>
</table>
A total of 157 patients underwent surgery for minor breast lesions at the surgical outpatient minor theatre. 156 were female, 1 was male. The median age of the study population was 25 years. The most common diagnosis was fibro adenoma with 122 patients (78%), followed by the diagnosis of breast lump 19 (12%) who also had excisional biopsy done. The most common quadrant affected was the upper outer quadrant with 63 patients (40%). The mean diameter of the excised lesion was 3cm.

COMPARISON OF PATIENTS WHO DEVELOPED SSI AND THOSE WHO DID NOT.

A total of 7 patients out of the 157 patients developed SSI. The patients with SSI had variation in age, diagnosis and the breast quadrant involved, however when subjected to binary logistic regression they (age, sex, diagnosis, size and location) were not a risk factor in developing superficial SSI as far as the study was involved.

<table>
<thead>
<tr>
<th>Table 7: comparison of patients who developed SSI and those who did not</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall (all patients)</strong></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td><strong>Suture used</strong></td>
</tr>
<tr>
<td>Vicryl plus:</td>
</tr>
<tr>
<td>Plain vicryl:</td>
</tr>
<tr>
<td><strong>Location</strong></td>
</tr>
<tr>
<td>Upper outer:</td>
</tr>
<tr>
<td>Upper inner:</td>
</tr>
<tr>
<td>Lower outer:</td>
</tr>
<tr>
<td>Lower inner:</td>
</tr>
<tr>
<td>Periareola:</td>
</tr>
<tr>
<td><strong>diameter</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
</tr>
<tr>
<td>Fibroadenoma:</td>
</tr>
<tr>
<td>Breast lump /mass:</td>
</tr>
<tr>
<td>Galactocele:</td>
</tr>
<tr>
<td>Fibrocystic breast disease:</td>
</tr>
<tr>
<td>Wart:</td>
</tr>
</tbody>
</table>


SUMMARY OF PATIENTS WITH SSI

Out of the 7 patients who developed SSI, 4 patients were in the vicryl plus group while 3 patients in the plain vicryl group. Most of patients who developed SSI had a diagnosis of fibroadenoma 86%, with a mean age of 24 years, the youngest being 21 years, while the oldest was 35 years. The upper outer quadrant was the commonest involved site on the breast.

The prevalence rate of superficial SSI in the vicryl plus group was 5%, while in the plain vicryl group it was 4.5%, therefore there was no statistically significant difference between the two groups (P-value 0.507)

Table 8: summary of patients who developed SSI

<table>
<thead>
<tr>
<th>Suture used</th>
<th>Age</th>
<th>Diagnosis</th>
<th>location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plain vicryl</td>
<td>21</td>
<td>Fibroadenoma</td>
<td>Upper outer</td>
</tr>
<tr>
<td>Plain vicryl</td>
<td>23</td>
<td>Galactocele</td>
<td>Upper outer</td>
</tr>
<tr>
<td>Plain vicryl</td>
<td>27</td>
<td>Fibroadenoma</td>
<td>Upper outer</td>
</tr>
<tr>
<td>Vicryl plus</td>
<td>21</td>
<td>Fibroadenoma</td>
<td>Upper outer</td>
</tr>
<tr>
<td>Vicryl plus</td>
<td>20</td>
<td>Fibroadenoma</td>
<td>Upper inner</td>
</tr>
<tr>
<td>Vicryl plus</td>
<td>35</td>
<td>Fibroadenoma</td>
<td>Periareola</td>
</tr>
<tr>
<td>Vicryl plus</td>
<td>22</td>
<td>Fibroadenoma</td>
<td>Upper inner</td>
</tr>
</tbody>
</table>
DISCUSSION

Surgical site infection remains a major burden in healthcare\(^3, 4\) and so it is imperative that more research is done to find new innovative ways of reducing it. The purpose of this study was to evaluate the effectiveness of antimicrobial coated suture, vicryl plus from Ethicon (triclosan coated polyglactin 910 suture) in reducing superficial surgical site infection in clean wounds (this study was limited to minor breast surgery).

The clean wound infection rate is the most valuable measure of surgical care in any hospital\(^10\) and it is widely used in surveillance and quality assurance. It is for this reason that we also decided to study clean wound infection rates so as to assess the quality of surgical care we give to our patients. From the study we found the infection rate for clean wound to be 4.5%, which was considerably higher than the expected rate for clean wound which is 1-2%. Therefore, there is certainly need to do more in prevention and management of SSI at our facility.

The age of the patient was not found to be a contributing risk factor in the development of SSI. There was no age group associated with an increased risk of developing SSI (P value 0.761). However this study excluded the extremes of ages, which is a known risk factor\(^9\). Our study population had a median age of 25 years and a range of 18-50 years of age, this was done deliberately to exclude the extremes of ages, so as to reduce confounding factors.

The diagnosis and size of the lesion were not found to be contributing factors to developing SSI, however taking into accounts that the operations were done under local anaesthesia this limited the surgery to relatively small lesions i.e. mean diameter of 3 cm, so it’s not possible to infer whether size would be a risk factor in developing SSI.

From this study we failed to demonstrate a reduction of superficial SSI when triclosan coated polyglactin 910 (vicryl plus) was used as compared to plain vicryl. There was no significant statistically difference (P-value 0.507) demonstrated between the two sutures. This is in line with some previous studies\(^22, 28\) that also did not demonstrate any significant difference between the two sutures. It is important to note that the mechanisms leading to surgical site infections are not fully understood, however the presence of a foreign material like a suture is known to lower the size of bacterial inoculi necessary to develop infection\(^11, 12\), hence creating an antibacterial environment within the wound is supposed to reduce the risk of SSI\(^13\). This was the thinking behind the creation of antimicrobial coated sutures\(^13, 14\).

Although vicryl plus has been demonstrated to reduce SSI in some areas like abdominal surgery\(^22\), it has not been found to be effective in others\(^22, 28\). This therefore begs the question-
why? One possibility is that, like all good innovations it may be overused and misused. The widespread use of triclosan for many years in topical personal hygiene products like toothpaste, soap etc may lead to diminished antimicrobial activity. This can lead to the development of drug resistance, this has been demonstrated in some studies. The other issue of concern is safety when using triclosan coated sutures, although several studies have demonstrated triclosan to be relatively safe in classic toxicological terms, negative effects such as dermatitis, skin irritation and allergic reactions have been described. Currently in the United States, the Food and Drug Administration (FDA) is reviewing the safety and efficacy of triclosan. And so it would be prudent to exercise caution when using triclosan coated sutures.

In conclusion since there was no advantage inferred to the patients by using triclosan coated polyglactin 910 in clean wounds, it is the opinion of the researcher that triclosan coated sutures have a limited role to play in reducing SSI in clean wounds and its use should be confined to areas where its application has proven benefits. However more studies should be done to clearly define its role and indications in surgery.
CONCLUSION

• There was no significant difference in the rate of SSI in clean wound between plain polyglactin 910 and triclosan coated polyglactin 910

• There is no proven benefit of using triclosan coated sutures in closure of clean wounds

• The prevalence rate of SSI for clean wound at KNH is 4.5% which is significantly higher than the expected rate of 1-2%.

RECOMMENDATIONS

• More studies should be done to evaluate the effectiveness of antimicrobial coated sutures in other areas like dirty wounds, implants etc.

• Microbiological testing for local patterns of resistance to triclosan should also be done.

• Prudent use of antimicrobial so as to reduce the development of drug resistance.

• Healthcare providers should be educated on the various strategies available in prevention of SSI.
REFERENCES


8. Jaimin Bhatt. Early post-operative wound infection at the Kenyatta National Hospital, 2003


26


29. Suller MTE, Russell AD Triclosan and antibiotic resistance in Staphylococcal aureus


32. www.fda.gov/forconsumersupdates

33. Verunesi S, de Padova MP, Vanni D, Melino M Contact dermatitis to Triclosan. Contact Dermatitis 1986;15:257-258
APPENDIX 1: STATEMENT OF CONSENT

This Informed Consent form is for patients undergoing minor clean day care surgery at the minor theatre in clinic 24 during the study period. The title of the study “The effectiveness of triclosan coated polyglactin 910 sutures in reducing surgical site infection-a randomised control trial”

Principal investigador: Dr.Ogome Samuel
Institution: School of Medicine, Department of surgery- University of Nairobi
Supervisor: Dr Joseph Githaiga

This informed consent has three parts:
1. Information sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)
3. Statement by the researcher

You will be given a copy of the full Informed Consent Form.

Part I: Information sheet

Introduction
My names are Samuel Ogome, a Post-Graduate student at the University of Nairobi’s School of Medicine. I am carrying out a study to determine the effectiveness of triclosan coated polyglactin 910 suture in reducing surgical site infection in clean wounds. Surgical site infection is a common post operative complication worldwide. It is a major cause of morbidity, mortality and financial burden to our patients.

Study purpose
The aim of the study is to find out whether an antimicrobial coated suture can help reduce surgical site infections, in an effort to improve the quality of surgical care we provide to our patients.
Study procedure
I am inviting you to participate in my study and you are free to either agree to participate or decline. You will be given the opportunity to ask questions before you decide and you may talk to anyone you are comfortable with about the research before making a decision. After receiving this information concerning the study, please seek for clarification from either myself or my assistant if there are words or details which you do not understand.
If you agree to participate, you will be asked to provide personal information. All the information which you provide will be kept confidential and no one but the researchers will have access to it. The information about you will be identified by a number and only the researchers can relate the number to you as a person. Your information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UON-ERC).

Risk
Your involvement in this research will not expose yourself to any risks if you consent to participate. The materials used in this study are safe and standard universally accepted surgical techniques will be followed.

Benefits
Close personal follow up by the study team, making it easier and faster to pick post surgical complications and management. By agreeing to take part in the study you will be part of a scientific process that can potentially improve our understanding of wound management.

Compensation
Your participation in this study is voluntary and there will be no compensation in taking part. All the information that you give us will be used for this research only.

Alternative to participation
Those who decline to participate in this study will not be denied treatment they deserve because of their decision not to participate nor will it affect their future relationship with KNH.

All patients who meet the inclusion criteria and are undergoing minor day care surgery at the minor during the study period are being invited to participate.
This proposal has been reviewed and approved by the KNH/UON-ERC which is a committee whose work is to make sure research participants like you are protected from harm. It was submitted to them through the Chairman of the Department of Surgery at School of Medicine
of the University of Nairobi with the approval of the two university supervisors. The contact information of these people is given below if you wish to contact any of them for whatever reason:

- Secretary, KNH/UON-ERC
  P.O. Box 20723 KNH, Nairobi 00202
  Tel 726300-9
  Email: KNHplan@Ken.Healthnet.org

- Chairman,
  Department of Surgery, School of Medicine– University of Nairobi
  P.O. Box 19676 KNH, Nairobi 00202
  Tel # 0202726300

- University of Nairobi research supervisor
  Dr Joseph Githaiga
  Department of Surgery, School of Medicine, University of Nairobi
  P.O. Box 19676 KNH, Nairobi 00202
  Tel #0722526274

- Principle researcher:
  Dr. Samuel Ogombe
  Department of Surgery, School of Medicine, University of Nairobi
  P.O. Box 19676 KNH, Nairobi 00202
  Mobile phone # 0733662520

Part ii: Consent certificate
I………………………………………………………………freely give consent of myself to take part in the study conducted by Dr. Samuel Ogombe, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care being given to me. The results of the study may directly be of benefit to me and may assist in reducing surgical site infection.
Signature/left thumb print (Participant)

Date……………………………………………………………………………………..

Day/Month/Year

Statement by the witness if participant is illiterate

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness……………………………………………………………………

Signature of witness………………………………………………………………

Date…………………………………………………………………………………

Part iii: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate prevention of surgical site infections and quality of surgical care provision.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher taking consent………………………………………………

Signature of researcher taking the consent………………………………………

Date…………………………………………………………………………………………
APPENDIX 2: QUESTIONNAIRE

This is a questionnaire prepared by a post graduate student from the University of Nairobi, carrying out a study on effectiveness of antimicrobial sutures in preventing superficial SSI at Kenyatta National Hospital

The information given here will be treated with utmost confidentiality

To the administrator of the questionnaire:

- Please do not write a patient’s name on the questionnaire.
- Consent must have been obtained before proceeding

1. Patient’s outpatient number

2. Serial number

3. Suture used

4. Contact telephone number

5. Sex

6. Age

7. Diagnosis
8. Physical findings
   i. Location
   ii. Size
   iii. Tender

9. Procedure

10. Any adverse events
<table>
<thead>
<tr>
<th></th>
<th>3&lt;sup&gt;rd&lt;/sup&gt; post op day</th>
<th>7&lt;sup&gt;th&lt;/sup&gt; post op day</th>
<th>30&lt;sup&gt;th&lt;/sup&gt; post op day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purulent discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/tenderness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Localised swelling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raised local temperature</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 3: DECLARATION

I declare that there is no vested interest in Ethicon Inc and by extension the sutures used in this study. I also do not have any proprietary interest in the product used in the study. Neither I nor my affiliated institution will receive any compensation for using these products nor will it influence the outcome of the study.

Full name

Signature
APPENDIX 4: TIME FRAME AND BUDGET

TIME FRAME

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<td>Data analysis and presentation of findings</td>
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</table>

BUDGET

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</thead>
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<td>Research fee for KNH/ERC</td>
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</tr>
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<td>Stationery, printing, binding</td>
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</tr>
<tr>
<td>Sutures</td>
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<tr>
<td>Op site spray</td>
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<td>Research assistant</td>
<td>15,000</td>
</tr>
<tr>
<td>Statistician fee</td>
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<tr>
<td>Contingencies</td>
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</tr>
<tr>
<td>Total</td>
<td>90,000</td>
</tr>
</tbody>
</table>
APPENDIX5: DECLARATION FORM FOR STUDENTS

UNIVERSITYOFNAIROBI

Declaration Originality Form

This form must be completed and signed for all works submitted to the University for examination.

Name of Student ________________________________________________

<table>
<thead>
<tr>
<th>Registration Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>College</td>
<td></td>
</tr>
<tr>
<td>Faculty/School/Institute</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td></td>
</tr>
</tbody>
</table>

Title of the work

DECLARATION

1. I understand what Plagiarism is and I am aware of the University’s policy in this regard

2. I declare that this ______________________ (Thesis, project, essay, assignment, paper, report, etc) 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.

3. I have not sought or used the services of any professional agencies to produce this work

4. I have not allowed, and shall not allow anyone to copy my work with the intention of passing it off as his/her own work

5. I understand that any false claim in respect of this work shall result in disciplinary action, in accordance with University Plagiarism Policy.

Signature ____________________________________________________

Date _______________________________
APPENDIX 6 DECLARATION FORM FOR STAFF
UNIVERSITY OF NAIROBI

Declaration of Originality Form

This form must be completed and signed for all scholarly works produced.

Name of Staff ______________________________________________________
Payroll Number ______________________________________________________
College _____________________________________________________________
Faculty/School/Institute_______________________________________________
Department __________________________________________________________

Title and bibliographic details of the work
____________________________________________________________________

DECLARATION
1. I understand what plagiarism is and I am aware of the University’s policy in this regard.
2. I declare that this __________________ scholarly work (Paper, book chapter,
Monograph, review, etc) is my original work. 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.
3. I have not allowed, and shall not allow anyone to copy my work with the intention of
Passing it off as his/her own work.
4. I understand that any false claim in respect of this work shall result in disciplinary action,
In accordance with University Plagiarism Policy.

Signature ____________________________________________________________

Date ________________________________________________________________
APPENDIX 7: LETTER OF KNH/UON ERC APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P.O. BOX 30680 Code 00202
Telephone: (254-020) 2272380 Fax: 44355

Ref: KNH-ERC/A/304

Dr. Samuel Ogombe
Dept. of Surgery
School of Medicine
University of Nairobi

Dear Dr. Ogombe

RESEARCH PROPOSAL: THE EFFECTIVENESS OF TRICLOSAN COATED POYGLACTIN 910 IN REDUCING SURGICAL SITE INFECTION IN CLEAN WOUNDS: A RANDOMIZED CONTROL TRIAL (P98007/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 10th October 2013 to 9th October 2014.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period.
   (Attach a comprehensive progress report to support the renewal).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an executive summary report within 90 days upon completion of the study.
   This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN.

"Protect to Discover"
Yours sincerely,

[Signature]

PROF. M. L. CHINDIA
SECRETARY, KNH/UoN-ERC

c.c. Prof. A. N. Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
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