SPLIT THICKNESS SKIN GRAFT TAKE RATE AFTER TUMESCENT AND NON-TUMESCENT TECHNIQUE FOR HARVESTING – A RANDOMIZED TRIAL

A proposal for a dissertation to be submitted in part fulfillment for the requirements of Degree of Masters in Medicine in General Surgery, University of Nairobi.

Principal Researcher
Dr Marabi Gilbert Khoyo,
M.B.Ch.B (UoN)
H58/76692/09
DECLARATION
I declare that this research proposal is my own original work and has not been presented for a degree in any other University.

Sign______________________       Date ______________________

Dr Marabi Gilbert Khoyo

H58/76692/09

MBChB (UoN)

gmarabi@yahoo.co.uk

SUPERVISORS

Professor Peter Amollo Odhiambo.

MKNAS, FACC, FCS (ECSA), FRCS (Edin), MMed (Surg) Nbi, MBBS (Calcutta)

Thoracic and Cardiovascular Surgeon and Professor of Surgery

Department of Surgery,

University of Nairobi

Sign _________________________      Date ______________________________

Dr Wanjeri Joseph Kimani

M.B.Ch.B., MMed. (Surg.), IPTM (Tel Aviv)

Plastic and Reconstructive Surgeon

Department of Surgery ICT Champion

University of Nairobi

Sign________________________________       Date ______________________________
ACKNOWLEDGEMENT
First and foremost I would like to thank Almighty God for His favor upon my life and grace to go through my studies to fulfill my dream.

Special appreciation goes to my Supervisors Prof. Odhiambo and Dr Wanjeri for their invaluable contribution in the development of this proposal. Also thanks to Dr Nang’ole for birthing the idea in the first place.

Many thanks to Dr LoiseKahoro for agreeing to supervise all the surgeries. I salute theatre nurses Timwez and Mwamuu for ensuring the study guidelines were implemented in theatre.

Deep gratitude goes to my wife Kadi Josephine, my sons Jeremy and Matthew, my parents and siblings for their unwavering support and encouragement.

Last but not least I greatly appreciate the Department of Surgery fraternity for their dedicated criticism and contribution to my study.

God bless you all.
LIST OF ABBREVIATIONS

A & E – Accident and Emergency Department

BSA – Burn Surface Area

BTU – Blood Transfusion Unit

DM – Diabetes Mellitus

HB – Hemoglobin

HIV – Human Immunodeficiency Virus

HR – Heart Rate

HTN – Hypertension

KNH – Kenyatta National Hospital

LFT – Liver Function Tests

L-P Ratio – Lactate-Pyruvate ratio

MAP – Mean Arterial Pressure

PEM – Protein Energy Malnutrition

SPSS – Statistical Package for Social Sciences

STSG – Split Thickness Skin Graft

TBSA – Total Burns Surface Area

UEC – Urea, Electrolytes and Creatinine

UoN – University of Nairobi
DEFINITION OF TERMS

Tumescent technique: It is the subdermal or subeschar injection of fluid containing a vasoconstrictor prior to burn wound surgery to reduce blood loss. In this study the vasoconstrictor used is adrenaline.

Plastic Surgery Fellow: This is a graduate doctor pursuing a fellowship in plastic and Reconstructive Surgery. He/she has vast experience in plastic surgery and is involved in the day to day running of the burns unit including daily ward rounds. Currently the unit has two of these fellows (Dr Peter Biribwa and Dr Faith Wanjiru).

The Research Assistant: Only one is needed. This is the person who will assist the principal investigator to recruit participants and also to collect data on day five and day ten post operatively. The research assistant is a resident at the Burns unit. He has an undergraduate degree in medicine and is currently pursuing a masters degree program in Surgery.

Take rate: Take refers to the survival of the transferred graft occasioned by vascularization of the graft through the process of serum imbibation, inosculation and angiogenesis complete in four to five days. The take rate is expressed as a percentage of the surface area of the wound being grafted. Clinically the graft is immobile and has a healthy color ranging from red, brown, purple but not black or grey.

Healing rate of donor site: Refers to re-epithelialization of the site from which the graft was taken from. This occurs by cells migrating from the remnants of hair follicles, sebaceous and sweat glands in reticular dermis. This occurs in seven to ten days but may take as long as twenty one days depending on age and nutritional status of the patient. Clinically the donor site is dry, painless and covered by epithelium.
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ABSTRACT

**Background:** Adrenaline is used to harvest skin grafts due to its vasoconstriction effect which limits blood loss. Although adrenaline is widely used, its local and systemic effects vary from patient to patient. We lack studies elucidating its effects on the take of the graft. Aim of our study was to determine skin graft take after tumescent technique compared to non-tumescent technique for harvesting.

**Objective:** To compare graft take rate after harvesting with tumescent technique and non-tumescent technique.

**Design:** A prospective single blinded randomized trial

**Study Site:** This was at Kenyatta National Hospital surgical wards and Burns Unit

**Methodology:** Two treatment groups of patients who fulfilled the inclusion criteria were randomly assigned. After ethical approval from KNH/UoN Ethical Research Committee, forty patients underwent split thickness skin graft harvesting with tumescent technique and forty patients underwent non-tumescent split thickness skin graft harvesting. The recipient site was opened in both groups on the fifth day after surgery and take rate assessed. The donor site was assessed on day ten and if not healed, followed up for three weeks.

**Data Management and Analysis:** Principal investigator and research assistant collected data using a structured questionnaire. SPSS ver. 17.0 was used to analyze the data. Mean and median were calculated. Tables and graphs were used to present the results obtained in the study. Student t-test and Mann Whitney test were used for comparison of take rates in the two treatment groups.

**Results:** There was a statistically significant association between skin graft take rate and skin grafting technique ($p = 0.011$). The mean graft take rate was 2.5% higher in the tumescent group compared to the non-tumescent group (96.3% compared to 94%). On day 10, there was no difference in percentage healing of donor sites between the tumescent and non-tumescent groups, $p = 0.562$.

**Conclusion:** Tumescent technique before harvesting gives a better take rate than harvesting with non-tumescent technique.
INTRODUCTION

Burn surgery is associated with great blood loss\(^1\)\(^-\)\(^4\). This is typically controlled with electrocautery\(^5\), limb tourniquet\(^6\)\(^-\)\(^7\), thrombin solutions\(^8\)\(^-\)\(^11\), subcutaneous epinephrine\(^9\)\(^,\)\(^12\)\(^-\)\(^16\), phenylephrine\(^17\)\(^,\)\(^18\), vasopressin\(^19\); excision with laser\(^20\)\(^-\)\(^22\) and controlled intraoperative hypotension\(^23\). In this study we evaluate the use of epinephrine to control blood loss as used in tumescent technique. Tumescent technique\(^15\)\(^,\)\(^24\) is the subdermal or subeschar injection of fluid containing a vasoconstrictor prior to burn wound surgery to reduce blood loss. The tumescent technique has evolved over the past 20yrs mainly for the use in liposuction\(^25\). Studies have been done to confirm that tumescent technique reduces blood loss\(^4\). Adrenaline is commonly used but its local and systemic effects vary from person to person\(^28\)\(^,\)\(^29\). This study aims at determining whether the use of adrenaline before harvesting the graft has any effect on graft take rate.

The success of a skin graft or its take depends on nutrient uptake and vascular ingrowth from the recipient bed. This occurs in four phases namely inflammatory response/plasmatic imbibation, inosculation, angiogenesis and reinnervation. Proper skin graft dressing prevents graft mobility and seroma formation. Factors that affect take rate include seroma/hematoma formation, poorly vascularized wound bed, and contaminated bed, shearing of graft and technical aspects. Apart from these, comorbid conditions, some medicines like steroids, smoking and malnutrition affect take.

Split thickness skin graft failures can be attributed to flaws in the recipient bed which has to be well prepared. Tissues with limited blood supply such as bone, tendons, cartilage or sites with necrotic tissue or infection do not accept skin grafts. Wounds must be free of pus and should have a healthy pink to beefy red appearance with a ph of 7.4 or above. Streptococcus should be eliminated as it can ‘eat up’ the skin graft in twenty four hours. Systemic diseases, nutritional disorders and vascular disorders should be corrected before grafting.

Early tangential excision of burn wounds and split thickness skin grafts is standard practice. This has been shown to have take rate of 99+/- 3% in a study done in India. They compared it to honey dressing which had an inferior take rate of 74+/- 18\(^\%\)\(^40\).

Approximately 754 patients were admitted in KNH with burn injuries between the years 2005 to 2010\(^26\). Majority of these patients are from low socioeconomic areas and of reproductive ages\(^27\). Average burn surface area (BSA) is 40\% and thus requires STSG. In KNH, about 550
STSGs are done per year. The take rate of these surgeries especially with respect to use of tumescent technique has not been studied.
LITERATURE REVIEW

Tumescent technique significantly reduced intraoperative blood loss. It is safe, inexpensive and easy to use. The subdermal adrenaline/saline injection creates a smooth, tense surface which assists debridement and donor harvesting. In the preparation of the tumescent solution, the commonest catecholamine used is adrenaline. The effect of adrenaline on the skin is mainly mediated by its binding alpha adrenergic receptors leading to vasoconstriction and cutting off blood supply to the skin. As epinephrine is used to control bleeding from vasoconstriction, it is likely that it causes transient hypoxia of the skin. If this hypoxia is prolonged it could lead to reduced skin graft survival and also delay healing at the donor site when tumescent technique is used for harvesting STSG.

Antony A. Papp et al studied the effects of topical epinephrine on hemodynamic status and markers of tissue perfusion in burned and non-burned patients requiring grafting. He found that the use of topical epinephrine has systemic effects on hemodynamic status (increased heart rate, increased serum epinephrine) and increased lactate levels in burn patients more than in non-burn patients observed at one and two hours of the operation. Increased epinephrine levels in burn patients suggest increased absorption properties in these patients.

The increased lactate concentrations and L-P ratios suggest that there is likelihood of tissue ischemia in the skin. However the study is quick to point out that the hemodynamic changes were transient and similarly the lactate levels reduced at the end of the study time which was 360 minutes. Levy et al found in endotoxaemic rats that the epinephrine induced hyperlactatemia was not related to cellular tissue hypoxia. Samuelsson A. et al showed that patients with extensive burns have greater pyruvate concentrations in burn skin than in non-burned control patients within the first four days post burn.

Lactatemia is a common clinical finding in burn patients. The elevations in plasma concentrations have been estimated to be, at least partly, related to increased glucose flux as a mass effect from increased pyruvate availability and not entirely a reflection of any deficit in oxygen availability.

Levy B in his bench to bedside review stated that the use of epinephrine as a vasopressor maybe associated with acidosis and hyperlactatemia. On the contrary, Robert Cartotto et al showed that the use of subcutaneous or topical epinephrine appears to be safe and produces
minimal acute cardiovascular effects (increased heart rate (HR, MAP and arrhythmias) and was not related to the type and size of the wound, depth of anesthesia/sedation. Missavage A.E.\textsuperscript{29} also adds that the administration of either topical or tumescent adrenalin during acute burn excision does not cause any side effects for safe anesthetic management and there was no detectable increase in plasma levels of epinephrine or norepinephrine.

Tumescent technique has also been in other procedures like the digit surgery, mastectomy and flap surgery with varying results. Tzeng Y.S. and Chen S.G.\textsuperscript{37} did digital surgery with no complications while Theddeus\textsuperscript{38} lost one out of seven flaps. He advised one to avoid tumescent especially for perforator flaps. In a study by Abbott A.M. et al\textsuperscript{5}, sixty four patients had blood loss reduced by electrocautery and seventy tumescent technique was used during mastectomy. In both groups, flap necrosis was the most common complication and the risk increased if immediate reconstruction was done.

Different concentrations of adrenaline have been used in constituting the tumescent formula. In the study by Theddeus\textsuperscript{38}, he found that a concentration of 1/1000000 is a potential replacement for pneumatic tourniquet for upper extremities. Mitchell Ryan et al\textsuperscript{18} showed that the lowest concentration of subcutaneous phenylephrine (Neosynephrin) required for effective vasoconstriction at the skin graft donor site was 5µg/ml.

In a study by Robert Cartottoet al\textsuperscript{39} where they used tumescent technique to reduce blood loss the take rate was 96% +/- 4.2% (p=<0.001). One patient complicated with woundsepsis. However in this study the take rate of the control group was not done. There are very few studies that conclusively study graft take rates after tumescent technique.
STUDY JUSTIFICATION

Tumescent technique has been practiced for over twenty years especially in liposuction. A lot of studies have proved that it is useful in preventing blood loss. This is important in this era of inadequate blood and blood products. However, adoption of tumescent technique in STSG has been low due to inadequate information on the viability of the graft especially after using adrenaline. Many surgeons still use electrocautery, tourniquet and topical adrenaline gauze. All these still have significant blood loss compared to use of tumescent technique. Information on local and systemic effects of adrenaline vary in literature with some authors saying the effects are minimal and transient while others believe that it adversely affects the harvested graft and healing of donor site. Few local studies are available on take rate of split thickness skin grafts with use of tumescent technique. Cochrane library lacks adequate studies of high level of evidence to make conclusions on this debate. This study is structured to give a high level of evidence on the results of STSG after tumescent formula as compared to what is commonly done (non-tumescent technique).

NULL HYPOTHESIS

There is no difference in graft take rate after tumescent technique compared to that with non-tumescent technique.

STUDY QUESTION

Is there a difference in graft take when you use tumescent technique or non-tumescent technique for harvesting split thickness skin grafts?
BROAD OBJECTIVE
To compare graft take rate after harvesting with tumescent and non-tumescent technique.

SPECIFIC OBJECTIVES
1. To assess percentage graft take on day 5 for patients who had harvesting done by tumescent technique and those who had non-tumescent technique.
2. To assess age/gender differences in the two groups.
3. To assess percentage healing of donor sites on day 10 in both groups.
4. To assess final outcome of non-healed donor and recipient sites after short term follow up of three weeks.
METHODOLOGY/MATERIALS AND METHODS

Study area
This was at the Kenyatta National Hospital, a referral hospital in the city of Nairobi. All burns patients were initially managed at the Accident and Emergency (A & E)Department and then admitted to surgical wards and Burns Unit.

Study Populations
The study population included all burns patients at KNH. They presented at the A & E Department and later admitted to Burns Unit and general surgical wards depending on the severity of burns. KNH admits about 800 burns patients per year and this varies from time to time. Recruitment was done according to the inclusion/exclusion criteria with informed consent. The wound had to be well granulated and ready for grafting.

Study Design:
A prospective, single blinded, randomized trial with two treatment arms. One group underwent tumescent technique before harvesting STSG. The second group received non-tumescent technique for harvesting the graft.
Sample Size:
This was an equivalence study whose objective was to show the difference between tumescent grafting and non tumescent technique in terms of graft take. The formula used was as follows;

\[ N = \frac{q+1}{q} \left(\frac{Z_{1-\beta} + Z_{1-\alpha}}{d-\delta}/\sigma\right)^2 \]

Where:

- \( N \) = sample size for one treatment group with equal allocation \( q=1 \)
- \( d \) = size of treatment effect
- \( \delta \) = equivalence limits. And thus \( \delta=d/\sigma \) standardized equivalence limit is 0.70
- \( Z_{1-\beta} \) = true mean difference of 0 for the power of 80% (i.e. \( Z_{1-\beta} = 0.84 \))
- \( Z_{1-\alpha} \) = level of significance of 5% (i.e. \( Z_{1-\alpha} = 1.96 \))

Hence;

\[ N = \frac{1+1}{1} \left(\frac{1.96+0.84}{0.7}\right)^2 = 32 \]

Since the duration of study of the patients was only 5-10 days and the patients were still confined in the hospital, we expected a compliance of 95% in each arm. Compliance adjustment formula;

\[ N \text{ per arm} = \frac{N}{(c_1+c_2-1)^2} \]

Where;

- \( C_1 \) and \( C_2 \) are average compliance rates per arm.
- \( N \) is calculated sample size per arm

Hence;

\[ 32/(0.95+0.95-1)^2 = 32/0.81 = 39.506 = 40 \text{ patients.} \]

Randomization: This was done by the principal investigator and his assistant using the restricted shuffled approach which is a form of random allocation rule. The sample size was already identified as forty patients in each group. Eighty similar cards were prepared, forty
were written on them “tumescent” and forty “non-tumescent”. The cards were inserted into the envelopes and shuffling is done to produce a form of random assignment without replacement.

**Allocation Concealment Scheme**: Sequentially numbered, opaque sealed envelopes were used. The assignment cards mentioned above were put in the envelope together with carbon paper anteriorly (to transfer patient information to the card) and a cardboard or aluminum foil posteriorly (renders envelope impermeable to light). Now the patient details could be written on top of the envelope without knowing which treatment arm they belong to until the time of surgery. The operating surgeon was the one to open the envelope at the commencement of surgery.

**INCLUSION CRITERIA**
1. Patients aged 18-65 years with no comorbid conditions and who gave consent to participate in the study.
2. Patients with clean wounds prepared for grafting.
3. Patients with <30% TBSA from thermal burns.

**EXCLUSION CRITERIA**
1. Patients with comorbid conditions (HTN, Diabetes, Liver disease, Renal failure, malignancies, vasculitis, HIV/AIDS, PEM).
2. Patients with albumin levels <30g/dl, Hemoglobin level <10g/dl,
3. Patients who refused or were unable to give consent.
4. Patients with known allergy to adrenaline.
5. Pus swab growing β-hemolytic streptococcus, citrobacter and acinetobacter.
6. Patients who were currently smoking or had stopped smoking less than six months.
7. Patients with chemical and electrical burns.

There was room for inclusion of initially excluded participants once correction of physiology was optimized for example hemoglobin level.

**LIMITATIONS**
1. Patients who declined to have their HIV status known.
2. Difficulty in standardizing amount of tumescent solution formula injected.

**DELIMITATIONS**

Used a VCT counselor for pre- and post-test counseling to enhance compliance for the HIV test

**Procedure:** Patients who fulfilled the inclusion criteria were recruited from the burns unit and surgical wards. For the purposes of this study we recruited patients with TBSA below 30% with second degree burns because they had less systemic complications. Evaluation of the patient was done by the principle investigator (clinical history, physical examination). To determine the surface area to be grafted, tracing paper was used to mark area and then approximated on a paper with one centimeter boxes. Laboratory tests were done at the KNH laboratories i.e. hemoglobin level, HIV test, UEC, LFT and pus swab. A qualified laboratory technologist had been requested to handle all the laboratory tests for patients recruited into this study to minimize operator discrepancies. Patients gave consent for either procedure and were not allowed to choose.

Each patient was assigned an envelope that had a card with a number inside. This was opened in theatre at the start of the operation by the surgeon. The surgeries were done or directly supervised by a qualified plastic and reconstructive surgeon affiliated to the hospital (Dr Loise Kahoro).

The solution formula for tumescent procedure was made by 1 miligram adrenaline 1:1000 (manufactured by Laboratoire Renaudin LR, Itxassou, France) added to 999 millilitres of warm saline (37°C). This diluted the adrenaline to 1:1,000,000. The surgery site was infiltrated with the fluid formula by means of an 18G spinal needle attached to a 20 millilitre syringe until the tissue had a smooth, firm, even, slightly swollen appearance. The amount of solution used was recorded for each patient. Harvesting of STSG with electrical dermatome was done and meshing 2:1 for all areas except for hands, distal forearms and face. Grafts were placed immediately after complete hemostasis and secured with staples. In the non-tumescent group, the graft was harvested and the donor site was covered by serial application of abdominal packs soaked in adrenaline solution.
The recipient site was analyzed on day 5 for take rate and the donor site on day 10 for percentage healing. The percentage take was estimated by consensus of the burns nurse, registrar on duty and plastic surgery fellow. This was tabulated by the research assistant.

DATA COLLECTION AND ANALYSIS
Data was collected by the principal investigator and the research assistant using a structured questionnaire. The data collected was entered into the Statistical Package for Social Sciences (SPSS version 17.0) and cleaned for errors and inconsistencies to ensure high quality data. Descriptive univariate analysis of data on socio-demographic characteristics (age, gender) was analyzed and presented using percentages, frequencies, tables, pie charts and graphs. Also univariate analysis of take rate was analyzed and presented by use of measures of distribution, like frequency distribution tables, central tendency (mean, median and mode), dispersions (range and standard deviation). Then student t-test and Mann Whitney tests were used for comparison of continuous variable. All tests were performed at 5% significance level with 95% confidence.

ETHICAL CONSIDERATIONS
The study commenced upon approval by UoN/KNH Ethics and Research Committee. Informed consent was obtained from each participant after explaining purpose of study, risks and benefits to the patient. Confidentiality was maintained at every stage. Next-of-kin was required to sign the consent on behalf of the participant if he/she was unable to do so. Those who decline participation were not denied the surgery they deserved. No extra costs were incurred for participating in the study. After joining either study arm, patients were given all the care they needed e.g. blood transfusion when necessary. In this study, care was not compromised.

Raw Data: This will be stored under encrypted lock and key for a maximum of 3(three) years after publication or public release of the work of the research. During this time the records will be available to the research community. Destruction of the raw data/records will be done in accordance with all legal, ethical, UoN policy requirements and with particular concern for confidentiality and security.
RESULTS
Patients were recruited from March 2014 to October 2014. Table 1 summarizes the demographic characteristics of the burns patients included in the analysis. Mean age (SD) of patients in treatment group was 33 years (SD 10.6) compared to a mean age of 35.5 years (SD 14) in the control group. The modal age group in both the tumescent (45%) and non-tumescent (35%) group was 25-34 years (p = 0.574). The treatment groups comprised patients with similar gender distribution with males accounting for 55% and 50% of patients in tumescent and non-tumescent group, respectively (p = 0.654). The treatment groups did not differ in terms of reported occupation (p = 0.421).

Table 1: Demographic characteristics of patients in tumescent and non-tumescent groups

<table>
<thead>
<tr>
<th></th>
<th>Technique</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tumescent</td>
<td>Non-tumescent</td>
<td>P value</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22(55%)</td>
<td>20(50%)</td>
<td>0.654</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>18(45%)</td>
<td>20(50%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age group (in years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>9(22.5%)</td>
<td>11(27.5%)</td>
<td>0.574</td>
<td></td>
</tr>
<tr>
<td>25-34</td>
<td>18(45%)</td>
<td>14(35%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35-44</td>
<td>6(15%)</td>
<td>5(12.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>45-54</td>
<td>5(12.5%)</td>
<td>4(10%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>55-65</td>
<td>2(5%)</td>
<td>6(15%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-employment/ business</td>
<td>8(20%)</td>
<td>13(32.5%)</td>
<td>0.421</td>
<td></td>
</tr>
<tr>
<td>Formal employment</td>
<td>5(12.5%)</td>
<td>7(17.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Casual labor</td>
<td>10(25%)</td>
<td>6(15%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>17(42.5%)</td>
<td>14(35%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Most patients in the study treatment groups had TBSA between 11 and 20% (55% versus 42.5% in tumescent and non-tumescent groups, p = 0.24), table 2. The majority of burns in the recruited patients were caused by open flames: 75% in the tumescent group and 82.5% in the non-tumescent group (p = 0.412).

Table 2: Characteristics of burn injuries in patients recruited in RCT

<table>
<thead>
<tr>
<th>Technique</th>
<th>Tumescent</th>
<th>Non-tumescent</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cause of burns</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open flame</td>
<td>30(75%)</td>
<td>33(82.5%)</td>
<td>0.412</td>
</tr>
<tr>
<td>Scald</td>
<td>10(25%)</td>
<td>7(17.5%)</td>
<td></td>
</tr>
<tr>
<td>TBSA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 10%</td>
<td>9(22.5%)</td>
<td>16(40%)</td>
<td>0.24</td>
</tr>
<tr>
<td>11-20%</td>
<td>22(55%)</td>
<td>17(42.5%)</td>
<td></td>
</tr>
<tr>
<td>21-30%</td>
<td>9(22.5%)</td>
<td>7(17.5%)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1 shows that the mean burn surface area in tumescent group = 343.8 (SD 130.1) with median burn surface area of 300 and range 100 to 600. In comparison the mean burn surface area in non-tumescent group was 360.5 (SD 169.3), median = 350 range 150 to 800. There was no significant difference in BSA between groups (Mann-Whitney p = 0.98).
Figure 1: Burn surface area in the tumescent and non-tumescent groups

Duration to surgery

There were no cases of early excision with all surgical procedures being conducted at least two weeks after injury. The overall duration between burn injury and surgery ranged between 15 and 260 days. Median duration for treatment group 57 days, range 15 to 212 days compared to median duration for control group of 57 days, range 22 to 260 days (figure 2). There was no significant difference in the median duration from injury to surgery in the two groups (Mann Whitney p = 0.98).
Figure 2: Duration between burn injury and surgery in recruited patients

**Anatomical sites of skin grafts**

Figure 3 shows that the limbs were the most commonly grafted anatomical sites using both the tumescent (n = 31, 77.5%) and non-tumescent (n = 32, 80%) techniques. The other anatomical sites that were grafted but less frequently were: trunk, head and neck.
Outcomes in treatment and control groups

There was a statistically significant association between skin graft take rate and skin grafting technique \((p = 0.011)\). The mean graft take rate was 2.5% higher in the tumescent group compared to the non-tumescent group (96.3% compared to 94%), table 3. On day 10, there was no difference in percentage healing of donor sites between the tumescent and non-tumescent groups, \(p = 0.562\).

Table 3: Surgical outcomes on day 5 and 10 in burn patients

<table>
<thead>
<tr>
<th>Technique</th>
<th>Mean (SD) Tumescent</th>
<th>Mean (SD) Non-tumescent</th>
<th>Difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin graft take rate - day 5</td>
<td>96.3 (3.9)</td>
<td>94 (3.8)</td>
<td>2.3 (0.5 to 4.0)</td>
<td>0.011</td>
</tr>
<tr>
<td>Percentage healing of donor site - day 10</td>
<td>99.8 (1.6)</td>
<td>99.5 (2.2)</td>
<td>0.25 (-0.6 to 1.1)</td>
<td>0.562</td>
</tr>
</tbody>
</table>

During follow up for assessing final outcome at three weeks all the patients had 100% healing. Patients in the tumescent group were significantly more likely to heal earlier with 7.5% healing between day 10 and week 3 compared to 25% of patients in the non-tumescent group who also healed during the same period (day 10 and final follow up, \(p = 0.034\)).
<table>
<thead>
<tr>
<th>Final outcome at 3 week follow-up</th>
<th>Technique</th>
<th>Non-tumescent</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% healing by day 10</td>
<td>Tumescent</td>
<td>37(92.5%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non-tumescent</td>
<td>30(75%)</td>
<td></td>
</tr>
<tr>
<td>100% healing by week 3</td>
<td>Tumescent</td>
<td>3(7.5%)</td>
<td>0.034</td>
</tr>
<tr>
<td></td>
<td>Non-tumescent</td>
<td>10(25%)</td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION

Burn wounds are usually managed with early tangential excision and grafting. This is plagued by significant loss of blood with consequent transfusions albeit its complications. Tumescent technique is one of the ways of minimizing this iatrogenic blood loss.

The uptake of tumescent technique locally has been low in STSG surgery. This is probably because surgeons are not confident of the outcomes of the graft and the donor site. This study was designed to provide strong evidence towards this technique.

The patients in each treatment group had comparable demographic and physical characteristics (table 1). Open flame burns remain the commonest type of burn in our setting (table 2). House fires, gas and stove explosions were the major causes. This could be a point of public health intervention to prevent burns in our society. In both groups, limbs were the commonest part of the body burned and grafted due to their easy exposure. Other studies have confirmed this finding.

Majority of the patients had BSA 11% to 20% but small areas of grafting were done at each sitting. In the tumescent group the areas ranged from 100cm$^2$ to 600cm$^2$ compared to 150cm$^2$ to 800cm$^2$. Despite this wide range between the two groups, their median surface area is not statistically different. This means that the amount of tumescent solution used is not a factor of the outcome between the two groups.

Early excision (below two weeks) and grafting is not practiced at all despite overwhelming evidence that it is associated with increased survival\textsuperscript{41}, lowers rate of burn sepsis\textsuperscript{42}, shorter hospitalization, reduced costs and less time away from work or school\textsuperscript{43}. In our study the duration from burn injury to graft surgery was 15 to 260 days (figure 2). This could be attributed to large number of patients in the unit, inadequate facilities for surgery and lack of knowledge on its importance. However the median between the two groups was equal at 75 days. Therefore there is no statistical difference to influence outcome.

In our study we found that the skin graft take rate was 96.3%(3.9) in the tumescent group of patients and 94%(3.8) in the non tumescent group of patients, $p=0.011$, 95% CI 2.3. This showed in fact that tumescent technique gave better skin graft take rates. This is comparative to a study by Robert Cartotto et al\textsuperscript{39} who found a take rate of 96%(4.2). In his study he compared tumescent technique to a historical group of patients with non tumescent technique. This affirmed that the viability of the harvested graft is not affected by the infusion of tumescent
solution. We don’t know from this study why tumescent technique had better outcome but we postulate that there could be less hematoma/seroma formation on grafted site. This requires further study. However we wish to point out that the grafts were monitored relatively on day 5. More studies need to be done to follow up the progress of the graft passed day 5. In both groups the donor site had healed by day 10 (99.8% and 99.5% respectively) The few that remained had healed by day 21 and didn’t need repeat surgery.

CHALLENGES/RECOMMENDATIONS

The infusion of tumescent was done manually by hand. This was taking theatre time for critical care patients. We recommend use of an electrical infuser reduce theatre time. Inadequate analgesia at time of opening the wounds could have led to loss of a few of the skin grafts. We recommend adequate analgesia or sedation at that time of opening grafted wounds. We also recommend further follow up studies on grafted wounds after day 5.
## DISSEMINATION PLAN

**Dissemination Goal** – To communicate results of this study

**Key Message** - Difference in take rate after skin grafting with or without tumescent technique

<table>
<thead>
<tr>
<th>Target Audience</th>
<th>Surgeons in Kenya and beyond</th>
<th>Readers of Annals of Surgery</th>
<th>Facebook friends (632) and twitter followers(77) (mostly doctors)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dissemination Method</strong></td>
<td>Copies of the study kept in the main library and the department of surgery library</td>
<td>Presentation at the annual Surgical Society of Kenya (SSK) Conference 2015</td>
<td>Publishing results of the study in the Annals of Surgery Journal</td>
</tr>
<tr>
<td><strong>Budget/Funding</strong></td>
<td>No fees</td>
<td>Kshs 10,000 conference registration fees</td>
<td>No fees</td>
</tr>
<tr>
<td><strong>Timeline</strong></td>
<td>By December 2014</td>
<td>2015 (dates to be announced)</td>
<td>By June 2015</td>
</tr>
<tr>
<td><strong>Messengers</strong></td>
<td>Chief Librarian</td>
<td>Chairman SSK</td>
<td>Editor in Chef</td>
</tr>
<tr>
<td><strong>Evaluation Tools</strong></td>
<td>Number of people borrowing the study/library records</td>
<td>Number of people attending the conference/Attendance records</td>
<td>Number of copies of the journal sold</td>
</tr>
</tbody>
</table>
## IMPLEMENTATION TIMETABLE/GANTT CHART

<table>
<thead>
<tr>
<th>Study Item/Month</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Oct</td>
<td>Nov</td>
</tr>
<tr>
<td>Proposal Writing to Ethical approval</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Analysis and Dissertation Writing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presentation to Examiners</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## BUDGET

<table>
<thead>
<tr>
<th>Stationery</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Printing paper 5reams @ksh 800</td>
<td>Ksh 4,000</td>
</tr>
<tr>
<td>Printing costs 30pagesX12 @ksh 10</td>
<td>Ksh 3,600</td>
</tr>
<tr>
<td>Photocopy costs 30pages X 12 @ksh 2</td>
<td>Ksh 720</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Laboratory Tests</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pus swabs MCS 64 swabs @ksh 500</td>
<td>Ksh 32,000</td>
</tr>
<tr>
<td>Biochemistry 64 samples @ Ksh 600</td>
<td>Ksh 38,400</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statistician</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Counselor</td>
<td>Ksh 10,000</td>
</tr>
<tr>
<td>Research Assistant</td>
<td>Ksh 10,000</td>
</tr>
<tr>
<td>Ethics</td>
<td>Ksh 1,500</td>
</tr>
<tr>
<td>Miscellaneous 15%</td>
<td>Ksh 18,000</td>
</tr>
</tbody>
</table>

| TOTAL                           | Ksh 138,220|

Funding will be done by the principle investigator.
REFERENCES

27. Factsheet Number 365 www.who.int/mediacentre/factsheets May 2012.


APPENDIX 1: INFORMED-CONSENT-SKIN GRAFT SURGERY

Skin graft surgery is done by taking a split thickness skin graft from another area of the body to restore skin coverage to wounds that would otherwise not heal adequately.
Every surgery involves a certain amount of risk. Although majority of patients do not experience the following complications, they can occur in some patients; bleeding, infection, itchiness, scarring, reduced sensation, contour irregularities, color changes, delayed healing, anesthetic complications, pain, skin cancers and buried staples.
I have authorized the doctor(s) to perform the procedure/surgery of skin grafting and any other procedures that are in exercise of his/her professional judgment necessary and desirable.
I consent to administration of anesthesia and the use of adrenaline.
I consent that the procedure, its risks and benefits have been well explained to me.

__________________________                                  _______________________
Patient name/signature                                                    Date

____________________________________                 ________________________
Witness/Doctor’s Name/signature                                    Date

APPENDIX 2: KIBALI CHA UPASUAJI WA NGOZI

Upasuajiwangoziyahusishasehemuyangoziinayotolewasehemufulanimwilininakuwekwamaha lipengineambapohapawezikuponavizuribilakufunikwanangozi.
Upasuajiwaainayoyotehaukoshihatari.
Baadhiyawagonjwawanaofanyiwaupasuajiwangozihupatamadharayafuatayo;
kutokwanadamu, kupatawito/maradhi, kuwashwa, makovu, kupungukahisia,
APPENDIX 3: STUDY CONSENT FORM

Study Title

Comparison of Skin Graft take with or without subcutaneous adrenaline injection for graft harvesting – A Randomized Control Trial.

Study Number Hospital Number

Invitation
You are invited to participate in a research study evaluating outcomes after skin grafting at KNH, being conducted by Dr. Marabi Gilbert, a post-graduate student at the UoN.

**Purpose of Study**

The aim of the study is to compare skin graft outcomes in patients whose grafts were harvested with tumescent technique with those without the technique.

**Risks and Benefits**

The potential risks of the study are similar to those outlined in the informed consent for skin grafting. There will be no direct benefits to you upon participation in the study. No physical or mental harm will be imposed on you and you will not be denied any necessary care due to you during the study. You will incur no costs for participating in this study and any additional costs will be incurred by the principle researcher.

**Confidentiality**

The records of the study will be kept private. Your identity will be coded and will not be associated with any published results. All information related to you will be treated with utmost confidentiality. Your blood samples will be analyzed against your study results without any reference to your name.
**Voluntary Participation**

Participation is out of your own free will and will not affect your medical care. You are free to withdraw your consent at any time without prejudice to your effect on your medical care.

**Follow up**

This will occur for ten days only while you are in hospital and for rare instances for twenty one days if your wounds don’t heal well by the tenth day.

**Contacts**

You are free to ask any questions on your rights or your medical care now or at any time of the study. Use the following contacts:

- Dr Marabi Gilbert 0722620409, gmarabi@yahoo.co.uk
- Chairperson, The KNH Ethics and Research Committee 020-2726300, Ext 44355.

I have been explained to and fully understand the consent form and I sign it freely and voluntarily to participate in the study.

__________________________________  __________________
Signature of Participant/Next of Kin  Date

I certify that I have personally explained this document before requesting the participant to sign it.

_______________________________  __________________
Signature of Researcher  Date

**APPENDIX 4: KICHWA CHA UTAFITI**
Uchunguziwakubainitofautiyamatokeokatiyaupasujiwangoziukitumiamtindowakuwekadaway a adrenaline kwenyengozinabilakutumiamtindohuo.

NambariyaUsajiliNambariyaHospitali

Mualiko

UnaalikwakushirikikwautafitiwakuchunguzamatokeoyaupasuajiwangoziunaofanywanaDrMar abi Gilbert.

Lengo

Lengo la utafitihuunikubainimatekoeyaupasuajiwangozikatiyawagonjwawaliotumiamtindowa Tumescent na wale ambo hawakuutumiamtindohuokatikauvunajiwangozi.

HatarinaManufaa


Hiari


Usiri

HabarizozoteambazozitatelewaZWakwasirinapiajina la mhusikahalitachapishwapopote.
Kufuatiliwa

Uchunguzi utakuwawamudawasikukumituwakatiungalihospitalininahadisikuishirininamojaiki
wakidondahakitakuwakimeponasikuyakumi.

Maswali

Ukiwanaswalilolotekuhusahakizako au utafitihuu, unawezakuwasiliananawafuatao:

- Dr Marabi Gilbert 0722620409, baruapepe gmarabi@yahoo.co.uk
- Mwenyekiti KNH ERC 020 – 2726300 Ext 44355

Mimi nimelezwakuhusuutafitihuunamtafitinanimefahamuujumbewautafitihuu.
Nimekubalikwahariyangukuhusika

____________________________________   ________________________
Sahihiyamhusika/JamiiyamhusikaTarehe

Mimi
nadhabitishanimuemulezeakwamakinkimhusikakuhusuutafitikablayeyekuwekasahihikuji
husisha.

____________________________________   ________________________
Sahihiyamtafiti. Tarehe
APPENDIX 5: QUESTIONNAIRE

Study Number _____________________

Date ______________________________

Age ______ yrs

Gender: Male ____ Female _______

Occupation__________________________

When did you get burned?

What caused the burns?

When have been told you are going to theatre?

APPENDIX 6: DATA COLLECTION SHEET
Study Number

Hospital Number

Date of recruitment into the study.

Age

Gender

Occupation

Cause of burns: Scald ( ) Open flame ( ) Contact burns ( ) Others/Specify ( )

TBSA % Below 10% ( ) 11% - 20% ( ) 21% - 30% ( )

BSA to be grafted ( ) cm² Amount of Tumescent Solution used in cm³ ( )

Area to be grafted: Face ( ) Trunk ( ) Upper limbs ( ) Lower limbs ( ) Others/specify

Duration from burn to grafting; < 2weeks ( ) > 2 weeks ( )

Outcomes

❖ Day 5 Recipient Site, Take %
❖ Day 10 Donor Site, Healing %
❖ Final Outcome after 3-week follow up.

Complications +/-