Project Title:

LIDOCAINE IN THE TREATMENT OF POST-OPERATIVE PAIN MANAGEMENTFROM A DONOR SITE AFTER SPLIT THICKNES SKIN GRAFT HARVESTING FOLLOWING BURN INJURY OR WOUND TREATMENTS

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Protocol

1. **Project Title:**

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2. **Investigator(s):** **Brenda Fahy, MD**

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3. **Abstract:**

Burn pain is known to be one the most severe forms of acute pain often requiring large amounts of narcotics in addition to other adjuvants. Wounds can also cause a great deal of pain in this population. Topical lidocaine is effective for controlling pain in various settings including dressing changes of burns. The aim of this study is to demonstrate the effectiveness of topical lidocaine in decreasing pain scores and narcotic requirements when applied to donor graft sites while at the same time not interfering with the standard of care TheraBond dressing. During this study we will be monitoring for evidence of delayed wound healing, and surgical site infection.

4. **Background:**

Pain from burns is a severe form of acute pain that requires aggressive use of opiods.[1] Even with the implementation of multiple modalities for analgesia, pain from skin debridements and grafting procedures remains a challenge to control.[2,3] Local anesthetics have been used for pain relief in burn patients previously as a topical gel or IV infusion and have been found to significantly reduce medication consumption, without apparent adverse effects on wound healing. [2,4,5] Lidocaine actually has potent anti-inflammatory effects which could be advantageous on wounds.[1] In addition, topical application of lidocaine to wounds result in different degrees of systemic absorption. High concentrations of lidocaine have potential for central nervous system (seizures (>5mg/L)) and cardiovascular toxicity (arrhythmias (>9mg/L)).[4] Plasma concentration of lidocaine depend upon drug dose, rate of absorption, patient weight, physical status and thickness of skin harvested.[6]A prior study where up to 6.7mg/kg of 2% lidocaine with epinephrine was sprayed on donor

graft sites found that systemic lidocaine levels were far below toxic levels at their peak (average level of 1.4, with maximum level at 2.2). In this study the levels peaked between 30 and 60 minutes and systemic levels of lidocaine were detectable 6 hours following application of the solution.[2]Studies have demonstrated the beneficial effects of systemic lidocaine administered via IV infusions in reducing perioperative pain scores.[7, 8]Topical lidocaine is effective as a topical anesthetic in multiple clinical trials however only two studies to date has shown that topical lidocaine applied to skin-harvest sites produces an analgesic effect, reduces narcotic requirements while not affecting wound healing or causing toxic blood concentrations. In both these studies systemic intravenous lidocaine levels were monitored and were found to be significantly below toxic limits.[2,9] The use of topical lidocaine on donor sites is still not widely used, partly for fear the lidocaine will interfere with wound healing and/or dressing adherence. No study to date has demonstrated lidocaine solution to be effective on burn sites when used in conjunction with TheraBond silver foam dressing. TheraBond is an absorbent, atraumatic dressing coated with ionic silver that is routinely used on donor sites at our institution. This study will also offer additional supporting evidence that topical lidocaine is effective in post-operative pain management of donor skin sites and should be more widely utilized. In addition, this study will serve as a stepping stone for analyzing different local anesthetic solutions in the future and the potential for reapplication to surgical sites.

5. Specific Aims:

The purpose of this study is to offer the medical community data on a simple and relatively cheap adjuvant that can be utilized to help reduce the amount of post-operative pain and narcotic requirement in burn and wound patients requiring skin grafts.

6. Research Plan:

Study Design

a) Randomized Controlled Double-Blind Study
b) Burn and wound patients undergoing general anesthesia for split thickness skin graft with a 1-15% TBSA donor site who will be treated at UF Health Shands Hospital
c) Consent will be obtained from non-intubated patients willing to participate in the study that are admitted to the Burn Service for treatment of their burn or wound. All patients will undergo general anesthesia. Standard induction will be performed with Fentanyl and Propofol. Maintenance will primarily be with the volatile agent sevofluorane. Acetaminophen 1g IV and Ketorolac 30mg IV will be administered for baseline pain control intraoperative within the last 30 minutes prior to extubation. Fentanyl, Hydromorphone or Morphine will be

titrated in at end of the case as part of standard management. Hydromorphone, as needed (PRN), orders will be written for pain control in the recovery room as well as one time dose of Oxycodone 5-15mg PO. If patient requires more than 2mg of Hydromorphone then subsequent pain will be treated with Ketamine IV (10mg every 15 minutes up to 50mg total) and 1-2mg of IV midazolam. If pain is still not adequately controlled patient will be treated with an additional 2mg of Hydromorphone IV and Hydromorphone PCA will be initiated. Once discharged from the PACU to the surgical floor the patient will have PRN Oxycodone PO every 4 hours and/or Hydromorphone PO every 4 hours in addition to PRN Hydromorphone 0.2-0.5mg available. If pain control is still not adequate patient will be started on Hydromorphone PCA. The amount of hydromorphone required in PACU and in the first 24 hours following surgery will be compared between the two groups as well as self-reported donor site and overall pain according to the Verbal Numerical Rating Scale (VNRS) obtained from the patient by Research staff and by the hospital staff per standard of care.

d) Lidocaine 2% with Epinephrine 10µg/mL will be placed on the donor site immediately following harvesting until hemostasis has been obtained per the surgeon. The total of up to 7mg/kg, as recommended by leading anesthesia textbooks, of lidocaine solution will also be sprayed onto the patient's donor site based on patient's ideal weight (BMI 25 or actual patient's weight if BMI <25).[10]
e) 50patients split into two(study & control) groups.
    a. Group A patients will have sterile 2% lidocaine with Epinephrine 10 µg/mL (Solution A1) soaked in surgical grade cotton applied to the donor site immediately after donor harvest until hemostasis is obtained according to the surgeon. If additional hemostasis is deemed necessary by the surgeon following use of 20cc (1 vial) of this Solution A1 then additional Epinephrine 10µg/mL will be used as per standard burn protocol. Following hemostasis, patients will have a sterile, nonpyrogenic solution of lidocaine 2% in isotonic saline (Solution A2) sprayed on the donor site of the grafted skin prior to emergence from general anesthesia. A maximum of 7mg/kg of lidocaine solution will be available for spraying. The site will then be covered with TheraBond dressing as per standard burn care used at our institution.
    b. Group B (control group) patients will have sterile Epinephrine 10µg/mL solution (Solution B1) soaked in surgical grade cotton applied to the donor site immediately after donor harvest. A 20cc aliquot will prepared in such a way as to be indistinguishable from Solution A1 by the OR team. If additional hemostasis is deemed necessary by the surgeon following use of 20cc (1 vial) of this Solution B1 then additional Epinephrine 10µg/mL will be used as per standard burn protocol. Following hemostasis, patients will have a control (placebo) sterile, nonpyrogenic solution of isotonic saline (Solution B2) sprayed over the donor site. The site will then be covered with TheraBond dressing as per standard burn care used at our institution.

f) Assessment of the donor sites using the VNRS pain scores will be compared between groups in addition to the amount of narcotic pain medication required by these two groups. The amount of narcotic utilized will be analyzed per ideal body weight, per actual body weight in addition to donor site area.
g) Lidocaine levels will be drawn at sixty minutes and six hours from application of study solution. These levels will be analyzed on a per patient and per graft size area basis to trend for systemic levels.
h) Any adverse event occurring with the patient will be analyzed on a case-by-case basis. Wound infection rates of the donor sites at post op day 14-21 +/-5 days will be compared between the two groups. Any adverse event deemed serious by the Principal Investigator will be submitted to the Institutional Review Board per institution policy.
i) All care offered during this treatment, including intraoperative medication use, surgical application of dressing and post-operative wound assessments are currently part of standard burn care at our institution. The only new variable we are analyzing is the addition of the lidocaine/placebo solution to the donor site intraoperatively.

Intraoperatively a TheraBond dressing will be applied to the donor site that later "falls off" once the site has healed. Outer dressings of gauze, Bioguard and Acewraps will also be applied, covering the Therabond and will be changed daily per standard of care. Wound healing of the donor site will be evaluated visually by the burn research team and the time in days of TheraBond dressing removal will be analyzed. In addition, photographs of the donor sites will be obtained intraoperatively and at the time the TheraBond comes off.

Study Procedures

a. Subject selection procedures
    i. Inclusion criteria: Adult patients who have suffered second to third degree burns or have a wound requiring a single split thickness skin graft surgery. Donor sites will be estimated to be between 1-15% TBSA. Patients who have history of major renal and/or liver dysfunction, history of seizures or major neurologic deficiencies, allergy to local anesthetics, reported allergy to hydromorphone, pregnancy, or currently have other injuries that significantly contribute to pain (i.e. multi-trauma patients) will be excluded from the study.
    ii. Consent will be obtained from all patients. The risk and benefit topical lidocaine will be explained to each patient and a consent for this study will be obtained.Burn and wound patients require high doses during wound related procedures and for post-operative pain control. At other times their background pain is easily controlled by much lower doses of narcotics; they remain alert and are capable of making complex decisions.

iii. If a patient is found to be in pain out of proportion to injury at hand and demonstrate an inability to focus on the consent they will not be considered for enrollment in the study.

b. Randomization procedures: Numerical randomization will be created using a computer generated numbers. Randomization envelopes will be created by research staff and maintained by the Investigational Drug Pharmacy. The Burn Study Team will alert the Investigational Drug Pharmacy to randomize each patient. The Investigational Drug Pharmacy will dispense the appropriate blinded solution for treatment. The Investigational Drug Pharmacy will dispense Lidocaine with Epinephrine or Epinephrine alone in blinded fashion for the donor site soaks. A 20cc bottle of Lidocaine with Epinephrine or Epinephrine alone will be emptied into a sterile unlabeled container prior to application of sprayed study treatment. The surgeon and OR team will remain blinded for this portion of the study. If additional hemostasis is required beyond the first study soak treatment; then the standard of care epinephrine soak will be utilized. The Investigational Drug Pharmacy will also dispense the randomized spray study treatment in an assembled applicator (LMA MADgic™)purchased for this project only. No unblinding identifiers will be on either applicators. The investigator will be blinded to all groups. Study Intervention:
    i. Group A (Lidocaine Treatment Group): Graft site hemostasis will be obtained with 2% lidocaine and epinephrine 10µg/mL solution in normal saline soaked in surgical grade cotton gauze and placed over donor site for time determined by surgeon. Following hemostasis, 7mg/kg of 2% Lidocaine solution will then be sprayed on patient's donor site while under general anesthesia by burn surgeon in a sterile fashion Upon emergence and transfer to PACU patient will be asked to rate his/her pain according to the VNRS for both donor site and overall pain. The amount of narcotics required in PACU and first 24 hours on floor will be documented. Rate of increase of narcotic requirement within the first 24 hours will also be analyzed. VNRS scores will be obtained immediately post operatively on arrival to PACU and in 24 hours.
    ii. Group B(Placebo Group): Graft site hemostasis will be obtained with a epinephrine 10µg/mL solution in normal saline soaked in surgical grade cotton gauze and placed over donor site for time determined by surgeon. Following hemostasisa control solution will be sprayed on patient's donor site while under general anesthesia by burn surgeon in a sterile fashion. Upon emergence and transfer to PACU patient will be asked to rate his/her pain according to the VNRS for both donor site and overall pain. The amount of narcotics required in PACU and first 24 hours on floor will be documented. Rate of increase of narcotic requirement within the first 24 hours will also be

analyzed. VNRS scores will be obtained immediately post operatively on arrival to PACU, 6 hours post treatment during blood draw and in 24 hours for both donor site and overall pain.

Study Table of Events

Study Assessments	Baseline	Surgical Procedure	0-24 hours post op	24-48 hours post op	Follow up (14-21 days)*
Informed Consent	X				
Inclusion/Exclusion	X				
Demographic Data	X				
Medical History	X				
Physical Exam	X				
Randomization		X			
Treatment		X			
OR Data Collection		X			
VNRS Pain Assessment			X**	X**	
Self-Reported Pain Assessment			X	X	
Wound Healing Assessment					X
Photographs		X			X

Narcotic Medication Data Collection		X	X	X	
Adverse/SAE Assessment	X	X	X	X	X
Lidocaine Level			X***		

*** (+/- 5 days)**
****Performed at 30 minutes after extubation, 2 hours, 6 hours and 24 hours post-opfor both donor site and overall pain**
*****Performed at 60(+/-30 minutes) minutes and 6 hours (+/-60 minutes) post op**

Safety Monitoring Plan

a. The likelihood of adverse events in this study is very small. Lidocaine spray doses will be calculated (7mg/kg based on ideal body weight) to ensure patient is receiving safe doses. A safety analysis performed on our first 15 patients proved safety. All lidocaine levels obtained demonstrated levels significantly lower than potentially toxic dosing. We believe there could be improved pain control if more appropriate (higher) lidocaine doses are utilized. The method suggested for hemostasis with lidocaine and epinephrine is standard of care at some institutions including our own. It is regularly used by the ENT service. In addition, one of the surgeons in our study has used this method in the past.
b. Patients will be monitored with pulse oximetry overnight per standard of care.
c. All patients enrolled in the study will have risks and benefits thoroughly explained to them.
d. Any adverse events will be well documented and thoroughly investigated. Seriousness of event will be assessed by the Principal Investigator. All events deemed serious will be submitted to the University of Florida Institutional Review Board in accordance with institutional policy.
e. Dressing site will be evaluated daily per standard of care by the burn team until hospital discharge.
f. After 10 additional evaluable patients, have been enrolled a secondsafety analysis will be performed; all investigators will be involved in data interpretation.

Analysis Plan

An independent groups t-test (Student's t-test) will be performed to compare the mean rating between the difference of the two reported pain scale ratings. Each patient will be used as his/her own control by comparing the amount of narcotics utilized prior to surgery. An alpha level of 0.05 and power of 0.8 will be used to address the difference in the two groups. Given the desired alpha the sample size was estimated by pre-determined tables for certain values, by Mead's resource equation. With an effect size (Cohen's d) of 0.8 it is estimated that 25patients in each

group will be needed in order to show statistical significance. An interim analysis will be conducted at 10 patients in each group and significance will be analyzed.

The amount of hydromorphone utilized in the PACU immediately post op and within the first 24 hours will be compared between the two groups and trended within the same group. Once again, an independent groups t-test will be performed to compare the mean quantity of hydromorphone required between the two groups. An alpha level of 0.05 and power of 0.8 will be used to address the difference in the two groups.

7. Possible Discomforts and Risks:

The patient's regular medical care will not change because they are enrolled in this study.

Possible risks to you may include:

- The risks from skin grafting and donor site include those associated with any surgical procedure that involves general anesthesia. These include reactions to the anesthesia, medications, nausea, pain, problems breathing, excessive bleeding, and infection.
- If a wound becomes infected, it may result in the need for further surgical treatment. Surgical treatment could include debridement of the wounded area (surgical removal of dead or infected tissue of the wound), and/or regrafting. Because your doctor looks at the wounds very closely, he/she will try to take care of any complications as fast as they can. The treatment of side effects and complications will be the same that would be expected for the treatment of side effects and complications for any skin grafting and donor site procedure performed at the hospital.
- Side effects of Lidocaine include: Nausea, drowsiness, mental/mood changes, ringing in the ears, dizziness, vision changes, tremors, numbness, headache and backache. Serious adverse effects could include fever, unusually fast and slow pulse, trouble breathing, seizures and chest pain. An allergic reaction to Lidocaine could include: rash, itching, swelling, dizziness, and trouble breathing.
- Side effects of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure. Blood drawn each time will be approximately 5 teaspoons. The total amount drawn during the study will be approximately 10 teaspoons.

8. Possible Benefits:

Patients randomized to the treatment group may have increased satisfaction, increased pain control, decreased narcotic usage, and a decrease in chronic pain.

9. Conflict of Interest:

There is no conflict of interest involved with this study beyond professional benefit from academic publication or presentation of results.

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Appendix A.

DATA COLLECTION POINTS

Age

Race

Sex

Height

Weight

BMI

Date of Injury/Wound

Mechanism of Injury/Wound

TBSA % Burned /Size of wound

Medical History

Physical Exam

Randomization

OR Procedure

OR Date

OR Incision Time

OR ExtubationTime

OR Medication Data Collection

Donor Site Dimensions

Lidocaine levels at 60 minutes and 6 hours post op

Time of Study Treatment Soak Placement

Additional Epinephrine Soak Required

Time of Study Treatment Spray Placement

Time of Therabond Placement

Time of PACU/BICU Admission (Post-operatively)

PACU/BICU Post –op Narcotic Medication

Documentation of Verbal Numerical Rating Scale Pain Assessment (Time): 30 minutes after extubation, 2 hours, 6 hours and 24 hours post op obtained by research staff for both donor site and overall pain

Self- Reported Pain Assessment (Time): Collect from EPIC for first 24 hours

Wound Healing Assessment (14-21 days post op[+/-5days]) Performed per standard of care

Photographs (OR and 14-21 days post op[+/-5days])

Adverse/SA Event Assessment

Overall Narcotic Medication Data Collection from EPIC (0-72 hours post op)

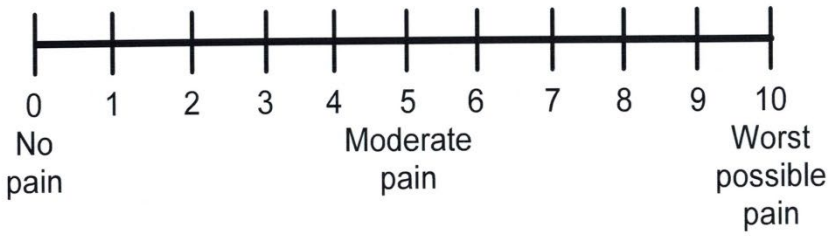
Date of new onset infection of donor site

Antibiotics for donor site infection

APPENDIX B.

Verbal Numeric Pain Rating Scale

0–10 Numeric Pain Rating Scale



Appendix C.

Case Report Forms

Patient Initials: __ __ __ **Page 1 of 1**

Patient ID: _____ **___-___-___**
Date

Inclusion/Exclusion Criteria

Inclusion Criteria (all must be checked Y)

Y	N	
[ ]	[ ]	Is the subject 18 years of age or older?
[ ]	[ ]	Has the subject suffered second to third degree burns or a wound requiring a single splitthickness skin graft surgery?
[ ]	[ ]	Are donor sites to be harvested estimated to be between 1-15%TBSA?
[ ]	[ ]	Is the subject willing and able to give informed consent? ICF Date: _____-____-____
[ ]	[ ]	The subject is not participating in another interventional clinical trial?

Exclusion Criteria (all must be checked N)

Y	N	N/A	
[ ]	[ ]	[ ]	Is the subject pregnant? Pregnancy Test Type: _____ Pregnancy Test Date: ____-____-____
[ ]	[ ]		Does the subject have a history of major renal or liver dysfunction?
[ ]	[ ]		Does the subject have a history of seizures or major neurologic deficiencies?
[ ]	[ ]		Does the subject have allergies to local anesthetics or hydromorphone?
[ ]	[ ]		Does the subject have any other injuries that could significantly contribute to pain? (ex: multi-trauma patient)

Eligibility Exceptions:

_____
_____
_____
_____
_____
_____
_____

Patient Initials: __ __ __

Patient ID: ___-____

___-___-___
Date

Baseline

Demographics:

Date of Burn Injury: ____ / ____ / ____ Date of Admission:____ / ____ / ____

Age: ____ Sex: [ ] M [ ] F Race: [ ] Caucasian
[ ] African American
[ ] Asian

Height: _____ in.Weight: _____kgs.BMI: _____ [ ] Hispanic
[ ] Other: _____

Mechanism of Injury:

[ ] Flame [ ] Scald [ ] Chemical

[ ] Electrical [ ] Contact [ ] Other (Non-Burn)

TBSA % Total: ____% or [ ] not applicable

TBSA % Partial Thickness: ____% or [ ] not applicable

TBSA % Full Thickness: ____% or [ ] not applicable

Illnesses/Past Medical History:

[ ] None	[ ] Cancer	[ ] COPD
[ ] CV Disease	[ ] Diabetes	[ ] ETOH
[ ] Hypertension	[ ] Renal Disease	[ ] Substance Abuse
[ ] Seizure Disorder	[ ] Stroke	[ ] Other: Specify _____

Comments:

_____
_____
_____
_____
_____

Patient Initials: __ __ __

Patient ID: ___-____

___-___-___
Date

<u>Baseline</u>

Physical Exam:

Vitals:

Temp: _____ C° HR: _____ bpm SAT: _____% BP: ____ /____ Resp: ____

Date of Exam: ___ / ___ /____ Time of Exam: ____ : ____

System	Abnormal	Normal	Explanation
General			
HEENT			
Cardiovascular			
Respiratory			
Gastrointestinal			
Genitourinary			
Musculoskeletal			

Skin			
Neurologic			
Psychiatric			
Endocrine			
Heme/Lymphatic			
Allergic/Immunologic			

Patient Initials: __ __ __ **Page 1 of 1**

Patient ID: ___-____ **___-___-___**
Date

Randomization

Date Randomized: **___-___-___** Time Randomized*: ___: ___

Order placed in EPIC to Randomize/Dispense Study Medication:

Date: ____ / ____ / ____ Time: _____

Randomization Materials to be stored in Investigational Drug Pharmacy until study completion.

*Time dispensed on study drug/placebo packaging

Comments:

_____
_____
_____
_____
_____
_____
_____

Patient Initials: __ __ __ **Page 1 of 1**

Patient ID: ___-____ **___-___-___**
Date

Surgical Procedure

Surgical Procedure Information:

OR Date: ____ / ____ / ____ Incision Time: ____ : ____ ExtubationTime: ____ : ____

Procedure Performed:

_____
_____
_____

Area of Donor Site Harvest*: [ ] Left Thigh
[ ] Right Thigh
[ ] Other: _____

Donor Site Harvest Time: _____

Donor Site Dimensions: _____ cm x _____ cm= _____ cm^2

Photos of Donor Sites Complete: [ ] Yes [ ] No

Time of Study Treatment Soaks:

Time ON ____ : ____ Time OFF ____ : ____

Time ON ____ : ____ Time OFF ____ : ____

Need for additional Epinephrine Soaks: [ ] Yes [ ] No

Time ON ____ : ____ Time OFF ____ : ____

Time of Study Spray Treatment: ____ : ____

Time of TheraBond Placement: ____ : ____

Post Op Admit to: [ ] BICU [ ] PACU

Post Op Admit Time: ____ : ____
* One page to be completed per donor site

Patient Initials: __ __ __ **Page 1 of 4**

Patient ID: ___-____ **___-___-___**
Date

Post-OP Study Assessments- 30 Minutes Post Extubation

30 Minute Post-extubation VNRS Pain Assessment:

Is the subject able to provide VNRS Pain Assessment related to donor site pain only:

[ ] Yes [ ] No

Time: ____: ____ Score : _____

Is the subject able to provide VNRS Pain Assessment related to overall pain:

[ ] Yes [ ] No

Time: ____: ____ Score : _____

VNRS Pain Assessment recorded by: _____

Comment: [ ] Yes [ ] No

Post-OP Study Assessments- 60 Minutes (+/- 30 minutes)

60 Minute Post-op Lidocaine Level:

Lidocaine Level Drawn By: [ ] Shands Lab Phlebotomy [ ] Research Staff

Time of Lab Draw: ___:___ Result: _____ mcg/mL **Normal Range 1.5-5.0 mcg/mL**

Lidocaine Level added to Participant Tracking Log: [ ] Yes [ ] No

Comment: [ ] Yes [ ] No

Patient Initials: __ __ __ **Page 2 of 4**

Patient ID: ___-____ **___-___-___**
Date

Post-OP Study Assessments- 2 Hours

2 Hour Post-op VNRS Pain Assessment:

Is the subject able to provide VNRS Pain Assessment related to donor site pain only:

[ ] Yes [ ] No

Time: ____: ____ Score : _____

Is the subject able to provide VNRS Pain Assessment related to overall pain:

[ ] Yes [ ] No

Time: ____: ____ Score : _____

VNRS Pain Assessment recorded by: _____

Comment: [ ] Yes [ ] No

Post-OP Study Assessments- 6-Hours (+/-60 minutes)

6 Hour Post-op Lidocaine Level:

Lidocaine Level Drawn By: [ ] Shands Lab Phlebotomy [ ] Research Staff

Time of Lab Draw: ___:___ Result: _____ mcg/mL **Normal Range 1.5-5.0 mcg/mL**

Lidocaine Level added to Participant Tracking Log: [ ] Yes [ ] No

Comment: [ ] Yes [ ] No

Patient Initials: __ __ __ **Page 3 of 4**

Patient ID: ___-____ **___-___-___**
Date

Post-OP Study Assessments- 6 Hours

6 Hour Post-op VNRS Pain Assessment:

Is the subject able to provide VNRS Pain Assessment related to donor site pain only:

[ ] Yes [ ] No

Time: ____: ____ Score : _____

Is the subject able to provide VNRS Pain Assessment related to overall pain:

[ ] Yes [ ] No

Time: ____: ____ Score : _____

VNRS Pain Assessment recorded by: _____

Comment: [ ] Yes [ ] No

Comments:

Post-OP Study Assessments- 24-Hours

24 Hour Post-op VNRS Pain Assessment:

Is the subject able to provide VNRS Pain Assessment related to donor site pain only:

[ ] Yes [ ] No

Time: ____: ____ Score : _____

Is the subject able to provide VNRS Pain Assessment related to overall pain:

[ ] Yes [ ] No

Time: ____: ____ Score : _____

VNRS Pain Assessment recorded by: _____

Comment: [ ] Yes [ ] No

Comments:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Date

Follow-Up Assessment- 14-21 Days Post-op (+/- 5 days)

Follow-Up Assessment:

Date of follow-up appointment: ___ / ___ / ___

Has there been any infections to the Study Donor Site area?

[ ] Yes [ ] No

Has the Therabond been completely removed from the Study Donor Site?

[ ] Yes [ ] No

Is the donor site 100% healed? [ ] Yes [ ] No : _____ % healed

Current Treatment for Study Donor Site: _____

Photographs taken of Study Donor Site? [ ] Yes [ ] No

Comments:

Patient Initials: **Page 1 of ___**

Patient ID: ___-____ **ADVERSE EVENTS**
Adverse Event # _____

AE Start Date: ___ /___ / ____ AE Stop Date: ___ / ___ / ____

AE Resolved: [ ] Yes [ ] No

AE Type: [ ] AE [ ] SAE

AE Description:_____

Is this event listed on the consent form? [ ] Yes [ ] No

Severity: [ ] Mild- Grade1
[ ] Moderate – Grade 2
[ ] Severe – Grade 3
[ ] Life Threatening – Grade 4
[ ] Fatal - Grade 5

Relationship: [ ] Not Related
[ ] Possibly Related
[ ] Probably Related
[ ] Related

Actions Taken: [ ] None
[ ] Medication Administered
[ ] Additional Treatment
[ ] Withdrawn from Study
[ ] Other

Clinical Outcomes: [ ] Death
[ ] Recovered Baseline
[ ] Recovered w sequelae
[ ] Symptoms Continue

Burn Sub-I Signature: _____

Investigator Signature: _____

Patient Initials: **Page 1 of _1__**

Patient ID: ___-____

All medication data information will be collected and entered into an excel spreadsheet.