Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-46332
Status: Approved
Initial Submit Date: 10/21/2019
Approval Period: 3/18/2024 - 1/2/2025

Section Aa: Title & PI

A1. Main Title

CONTINUOUS DIFFUSION OF OXYGEN TREATMENT FOR INCISION WOUNDS

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: EO2 CONCEPTS, INC (US)

A5a. Associated ESP2 funding proposal linked to this protocol:

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
Baylor St. Luke's Medical Center (BSLMC)

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Yes

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?
The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,
- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:
NCT04307355

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Reduction mammoplasty is a procedure in which a volumetric reduction of the breast is done for cosmetic purposes. This technique includes an infra-mammary perpendicular incision joined by a T-inframammary fold in it; central area, that further continue vertically until surrounding the nipple perimeter.

The likelihood of poor healing outcomes and adverse events (e.g., wound dehiscence, thick scar, itchy or unsortable scars) at the T-inframammary fold (anchor incision) of the breast wound incision is relatively high (estimated to be 10%-15%). This pure outcome is attributed to the corner (as a result of the T-inframammary fold) low blood supply. Given the fact that there are two corners in this particular procedure, the chances of adverse events are higher due to the point of most tension for the entire breast. Continuous oxygen therapy may reduce the likelihood of poor outcomes and adverse events.

In our institution, the Plastic Surgery Department utilizes Dermabond glue (sano acrylic) and Prineotape (air and water sealed) to close the wound around the areola and over the T-inframammary fold. Depending on the incision size, a JP drain could be placed (10% of the cases). Furthermore, the Prineo tape is kept on for a period of 3 weeks. Once it is removed, the incisions are normally healed. However, if wound dehiscence presents, it normally happens between the second and third post-operative week. Then, the Prineo tape has to be removed before the expected time period. Therefore, an external dressing might be able to avoid wound dehiscence during this period.

Continuous Diffusion of Oxygen (CDO) is a treatment modality that delivers pure oxygen to wounds using the same basic mechanism as breathing, namely direct diffusion into the wound from a moist surface. Because impaired blood flow results in impaired oxygen supply to incisional wounds, investigators have researched the potential of oxygen saturation, or supersaturation, to reinitiate or even accelerate wound healing. Oxygen has been shown to result in not only faster wound closure, yet also better strength of repair and higher organization of collagen, which in turn can result in lower wound recidivism and better scar appearance.

In this feasibility and proof of concept study, we plan to investigate the effects of oxygen on incisional wound repair and scarring after mammoplasty. We will use a device (OxyGeni Oxygen Delivery System) which continuously supplies oxygen to the wound inside the wound dressing. The device we used, the OxyGeni System, (EO2 Concepts®, San Antonio, TX) is small, wearable and silent. The system is FDA-approved and CDO therapy has been the subject of a growing body of clinical experience and scientific investigations demonstrating good results. The therapy is similar in theory to the intermittent application of oxygen through Hyperbaric Oxygen (HBO) and Topical Oxygen (TO), with a few key differences summarizing in the following:

1) CDO provides continuous therapy, providing ~twenty-fold longer time of oxygen delivery versus intermittent therapies that are only applied 90 minutes a day. 2) CDO allows for full patient mobility during treatment, thereby reducing the risk of non-compliance and reducing overall costs

We have successfully used CDO therapy to reduce likelihood of tissue necrosis after surgical closure post lower extremity amputation as well as post anterior neck surgery, in which over 20 subjects were recruited and no adverse outcomes were reported. We plan to extend our study to determine whether CDO therapy would show decreased healing time and improved scar appearance early on for standardized incisional wounds such as breast reconstruction. We hypothesize that using CDO will reduce the likelihood of wound dehiscence as well as severe incisional scar post-surgical closure by improving transcutaneous oxygen levels during wound healing process. We will examine the validity of this hypothesis using a pilot randomized controlled trial using a convenient sample of 30 women undergoing bilateral mammoplasty.

Section D: Purpose and Objectives

This is an exploratory randomized controlled trial study to test feasibility, acceptability, and proof of concept efficacy of Continuous Diffusion of Oxygen (CDO) adjunct therapy for decreasing healing time and reducing tissue dehiscence post breast reconstruction. We will assess the benefit of this novel adjunct therapy on successful closure, tissue oxygenation, scar appearance, and patients centered outcomes including perception of benefit, pain, sleep quality, and quality of life. Since all procedures are bilateral, an internal randomization will be performed based on breast side (left or right). The patients will be given CDO in one breast defined as intervention breast. A 5x5 cm CDO dressing will be placed by the plastic surgeon over the T-inframammary fold after the Dermabond glue and Prineo tape are placed. Then, Silagen (a silicon sheet) will be placed on top of the CDO dressing to secure it in place. The remaining parts of the incision will be covered with Dermabond Glue and Prineo tape. On the contrary, the control breast will be given the standard dressing (Dermabond + Prineo tape). The study device OxyGeni is a Class II medical device which has US Food and Drug Administration (FDA) 510(k) clearance, CE-Mark approval and a Health Canada license for the treatment of wounds.

Outcomes will be assessed on weekly-basis up to 4 weeks. Here are the aims and hypotheses for this study:

Aim1: To assess effectiveness of CDO adjunct therapy in reducing the likelihood of wound complication post-surgical

closure.

H1: CDO adjunct therapy will reduce the likelihood of surgical wound complication including dehiscence and its volume, infection or surgical revision, compare to standard of care dressing.

Aim2: To assess changes in skin perfusion in patients treated with CDO adjunct therapy.

H2: CDO adjunct therapy will improve tissue oxygen saturation in >50% of the patients as compared to baseline (measurements at baseline, 2 weeks, and 4 weeks).

Aim3: To evaluate changes in quality of life, anxiety during dressing change, and psychosocial parameters in patients with a surgical wound treated by CDO adjunct therapy

H3: CDO adjunct therapy will improve subject quality of life, reduce anxiety, and reduce perceived pain and physiological stress response during dressing change compared to the control group.

Aim4: To assess feasibility, acceptability, user-friendliness, perception of benefit, and improved scar cosmetic appearance

H4: CDO adjunct therapy will be considered to be practical to use, easy to use, and is perceived to be beneficial from both practitioner and subject as assessed by user friendliness questionnaire adapted for the purpose of this study (assessment at the conclusion of the study). This questionnaire is attached to the protocol.

H5. CDO adjunct therapy will improve scar cosmetic appearance as assessed by practitioner using the Scar Cosmesis Assessment and Rating (SCAR) Scale.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 2: Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English, Spanish

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

This study will be a 4 weeks prospective, exploratory internal randomized controlled trial study to test feasibility, acceptability, and proof of concept efficacy of Continuous Diffusion of Oxygen (CDO) adjunct therapy for decreasing healing time and reducing wound dehiscence post reduction mammoplasty. The anticipated sample size is N=30, who are undergoing bilateral reductive mammoplasty surgical procedure.

The study visits are listed below (please note that no screening activities will take place prior to the patient signing a consent form):

1) Baseline (Surgery Day, Week 0) 2) Visit 1 (Week 1 Post-Op) 3) Visit 2 (Week 2 Post-Op) 4) Visit 3 (Week 3 Post-Op) 5) Visit 4 (Week 4 Post-Op) 6) Visit 5 (minimum of 6 months Post-Op) *optional

Baseline: Subjects will be randomized to internal control. Since all procedures are bilateral, an internal randomization will be performed based on breast side (left or right). The patients will be given CDO in one breast defined as intervention breast. A 5x5 cm CDO dressing will be placed by the plastic surgeon over the T-inframammary fold after the Dermabond glue and Prineo tape are placed. Then, Silagen (a silicon sheet) will be placed on top of the CDO dressing to secure it in place. The remaining parts of the incision will be covered with Dermabond Glue and Prineo tape. On the contrary, the control breast will be given the standard dressing (Dermabond + Prineo tape).

Visits 1-4: All patients will have baseline assessment including visual, dermal, and tissue oxygen saturation level. The status of wound closure and presence of wound complication will be monitored every week. Each subjects will need up to 5 visits including baseline assessment, and weekly assessment up to 4 weeks or full wound healing or surgical revision, whichever comes first. At each visit, patients will be provided standard of care treatment including regular wound dressing change. Table 1 in attachments' section summarizes the key measurement at each study visit. At Visit 4, the CDO therapy will be removed. Subjects will then have the option to return at minimum 6 months later for a final follow-up visit listed below.

Visits 5: Optional follow-up visits. This visit can also be done remotely should the person not be available to attend the clinic.

Inclusion Criteria:

18-85 years of age. Ability to provide informed consent. Presence of a wound due to surgical intervention and closure. Subject or responsible caregiver is willing and able to maintain the required Continuous Diffusion of Oxygen (CDO) system (if assigned to the intervention group) and applicable dressing changes

Exclusion Criteria:

Active Drug/alcohol abuse (or history of drug/alcohol abuse in last 1 month); excessive lymphedema; presence of active infection; subject has a history of or any intercurrent illnesses or conditions that would compromise the safety of the subject according to judgement of a qualified wound specialist.

F2. Procedure

Please note that subjects will be consented before performing any study related measurements. This study will not bring any direct costs to the subject. The subject's medical insurance will be billed for all standard of care procedures.

Eligible subjects will be internally randomized and will receive the intervention for 4 weeks. Each subjects will receive standard of care for wound treatment. Intervention side will receive adjunct Continuous Diffusion of Oxygen (CDO) therapy using a novel dressing, which facilitates continuous supply of oxygen to the wound inside the wound dressing using a portable device named OxyGeni . We will collect patient demographics (e.g., age, sex, height, weight, race, ethnicity, marital status, level of education, etc), relevant medical history (e.g., comorbidity, type of surgery, number of prescription and over counter medication, etc), and relevant social factors (e.g., marital status, years of education, type of work, tobacco history, etc) at baseline. Primary outcomes include tissue oxygenation (assessed using Kent Imaging system) and incidence of wound complications (e.g. dehiscence, infection, and surgical revision). Primary outcomes will be assessed at baseline and on a weekly basis for up to 4 weeks. Secondary and exploratory outcomes include inflammation (assessed using a KENT camera), pain (assessed visual analog scale). The secondary and exploratory outcomes will be assessed at baseline and week-4. Other optional assessments include quality of life (NIH Global Health PROMIS), depression (Center for Epidemiologic Studies Depression Scale, CES-D), cognitive function MoCA), and psychosocial metrics (e.g. fatigue, anxiety, frailty, sleep, etc). These assessments are optional and will be done upon time availability and patient acceptance. We anticipate that duration of all assessments will not exceed 60 minutes. We will be reviewing the billing records for our

patients to explore costs of both groups. We may visit the patient's home for an appointment that doesn't require the physician present or to fix any issues with the device.

There will be an optional follow up visit up to three and six months after the last visit to determine any potential wound complications (e.g., patient unhappiness with the appearance of scar, infection and quality of life etc). During this visit, study coordinator will photograph both incision sites using near-infrared spectroscopy (NIRS, KENT camera) and a digital photo. Practitioner will assess scarring using the SCAR and/or POSAS scale.

Dressing Change: All patients will have their dressing changed weekly (screening/initial visit and visits 1-4), the intervention site will be treated continuously with oxygen from the OxyGeni device. Prior to application of the OxyGeni, research staff will: Select a 5x5cm OxySpur O2 dressing that will cover the wound; Wrap dressing as directed by physician. This may facilitate delivery of oxygen to the incision site or wound bed.

Data collection: - Medical History: Relevant patient medical history (e.g. type of cancer, type of therapy, other comorbidity such as diabetes and stroke, history of surgery, number of prescription and over counter medication, etc) will be collected at baseline via questionnaire or patient electronic health record.

- Social Factors: marital status, years of education, type of work, tobacco history (pack years, current smoker, current use of chewing tobacco, previous smoker, no tobacco history), drug history (current, previous history, no drug history), and alcohol history. These factors will be collected at screening/baseline visit.

Tissue Oxygen Saturation (primary outcome): Tissue oxygenation level will be assessed using Kent Imaging system at baseline and every study visit. The device uses light in the near-infrared spectrum that harmlessly passes through the skin and reflects off the blood supplying the tissue to determine tissue oxygen saturation, a key indicator of tissue health. The NIRS light has two key features that make it useful for measuring the viability of living tissue. Firstly, NIRS light is not absorbed by tissue as much as visible or ultraviolet light. Secondly, NIRS light is mainly absorbed by hemoglobin and water. Most importantly, the wavelength dependent light absorption of hemoglobin differs if it is carrying oxygen from when it is not. This makes NIRS light very useful in detecting oxygenated and deoxygenated blood, which conveys a comprehensive picture of tissue health and the healing capacity of wounds or tissue transplants.

Wound Assessment (primary outcome): A digital photo/video of wound will be taken for wound size verification, estimation of wound size, success of wound healing, and determination of wound dehiscence. Measurement will be performed at every visit.

Pain Intensity Assessment (VAS) (secondary outcome): The subject will be provided with a numeric pain scale where he/she will report pain intensity. Research staff will document subject's pain level. (Collected at every visit)

Adverse Event Reporting: Research Staff will document and report any study/non study related incident as per institution regulations. (Collected at baseline and visits 1- 4)

Device Acceptability Questionnaire: To determine patient perception of benefit, perceived ease of use, and attitude toward the use of device, we will use a technology acceptance model (TAM) questionnaire tailored for the purpose of this study. This assessment will be done at the conclusion of the study (week-4)

Questionnaires (optional): Quality of Life (PROMIS), functional status, Frailty Status (TSFI), Cognitive Assessment, and Sleep Quality (PSQI). To evaluate functional status, we will use well accepted and validated general functional assessment instruments. PFIBS for Pain Frequency, Intensity and Burden Scale, MOCA for Mental Exam, and Visual analog scale for pain. (All questionnaires are optional and may be done at any study visit upon time availability and patient acceptability). We will add the already approved questionnaires for the parent study, which include pain. Additionally, we will include Likert Scales (Moon SH et al, 2011; Singer AJ et al 1997; Hollander JE et al 1995; and Ridway DM et al 2007) and Patient Attitude to Scarring Scale (PASS, Kantor J et al 2016) and Patient and Observer Scar Assessment Scale (POSAS) to assess the following patient-reported outcomes: patient satisfaction and cosmetic appearance to evaluate scar itchy, perception of scar thickness, scar discomfort, and pain for each wound side (i.e., left and right breast). SCAR may be used to assess plastic surgeon satisfaction with the scarring. These questionnaires will be answered to the best of the participant's abilities. Should the participant lack certain capacities that make it difficult for them to respond to these questionnaires, they will not be conducted with that participant.

The plastic surgeon (Dr. Sebastian Winocour) will perform the initial consultation with the patient in the clinical setting (initial and pre-operative consult). Once the patient is aware of the study protocol, the study coordinator will obtain consent on the day of surgery. Research coordinators are responsible to revise the medical records (e.g., Epic) on a weekly basis in order to screen possible candidates undergoing reduction mammoplasty that could fit for the study. If the patient fits the criteria, the research coordinator will communicate the candidate's information (e.g., name, date of surgery) to Dr. Winocour. Candidates will be consented on the day of surgery upon plastic surgeon approval.

Baseline visit: After consenting the patient, the research coordinator will attend to the surgery. When the plastic surgeon closes the incision, the research coordinator will obtain the tissue oxygenation image using (non-invasive) NIRS, and then the surgeon will place the dressing immediately (The CDO dressing will be applied on the T-inframammary fold of the breast incision), followed by Silagen directly on top. After surgery, the research coordinator will wait until the patient is coherent in the post-operative recovery area. Then, they will educate the patient on proper device use.

After the surgery, the study will include 4 weekly follow-up visits, with visits in between for additional dressing changes as-needed. The 4 weekly follow-up visits are described below.

Visit 1, 1 Week Post-Op *duration: 50 minutes. Research staff will perform tasks as described above: Pain Questionnaire, NIRS Imaging, Digital Photograph, Adverse Event Reporting, Wound Assessment, Dressing Change and Device Education. Plastic surgeon will remove the CDO dressing in his normal post-operative clinic appointment, and the female research coordinator will obtain the near-infrared spectroscopy image, digital image, and wound assessment. After that, the research coordinator will cover the incision with a new CDO dressing. All measurements and procedures will be performed by a female research coordinator under ethics protocols.

Visit 2, 2 Weeks Post-Op *duration: 50 minutes. Research staff will perform tasks as described above: Pain Questionnaire, NIRS Imaging, Digital Photograph, Adverse Event Reporting, Wound Monitoring, Wound Assessment, Dressing Change and Device Education. The patient will be seen in Vascular Clinic (Procedure Room) for CDO dressing replacement and wound assessment. Female research coordinator will perform all measurements and questionnaires under ethics protocol.

Visit 3, 3 Weeks Post-Op *duration: 50 minutes. Research staff will perform tasks as described above: Pain Questionnaire, Near-Infrared Spectroscopy Imaging, Digital Photograph, Adverse Event Reporting, Wound Monitoring, Wound Assessment, Dressing Change and Device Education. The patient will be seen in Vascular Clinic (Procedure Room) for CDO dressing replacement and wound assessment. Female research coordinator will perform all measurements and questionnaires under ethics protocol.

Visit 4, 4 Weeks Post-Op *duration: 50 minutes. Research staff will perform tasks as described above: Pain Questionnaire, NIRS Imaging, Digital Photograph, Adverse Event Reporting, Wound Monitoring, Wound Assessment, Dressing Change and Device Education. The patient will be seen in Vascular Clinic (Procedure Room) for wound assessment. Female research coordinator will perform all measurements and questionnaires under ethics protocol. This will conclude study and dressing will be removed and device will be collected. Optional questionnaire at this visit include the PASS (Patient Attitude Scarring Scale) and POSAS (Patient and Observer Scar Assessment Scale) which will assess patient attitude and satisfaction with scarring. POSAS and SCAR Scale will also be optional assessments for the plastic surgeon to assess their satisfaction with the scarring.

Visit 5, at minimum 6 months post-op *duration: 50 minutes. This is an optional visit where research staff will take a NIRS image, a Digital Photograph, report adverse events since last visit, and assess patient scar satisfaction using validated questionnaires (PASS and POSAS). Moreover, the plastic surgeon will provide their observation of the scarring using validated questionnaires (SCAR and POSAS). The patient will be seen in the Vascular Clinic (Procedure Room). Female research coordinator will perform all measurements and questionnaires under ethics protocol. Should the patient not be available to attend the clinic in-person, they will have the option to do the questionnaires remotely and upload digital photos of the area via RedCAP. This study visit is added to provide long-term information regarding scarring and effect of study device on long-term healing outcomes.

The research coordinator will make sure at all times that patient does not experience discomfort and all ethical protocols will be followed.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 30 Worldwide: 30

Please indicate why you chose the sample size proposed:

This is an exploratory proof of concept study. The anticipated sample size (n=30) is selected based on resource/budget availability and feasibility to be completed within one year. This sample size is estimated to be sufficient to determine feasibility and proof of concept efficacy of Continuous Diffusion of Oxygen (CDO) adjunct therapy to improve tissue oxygen supply and reduce likelihood of adverse events. Upon initial results and availability of budget, the sample size may be increased to clinically validate the initial observation. In this case, an addendum will be submitted to increase sample size if needed.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

The primary outcomes of this study are 1) tissue oxygen saturation level measured using Kent Imaging system and 2) incident of wound related adverse events (e.g., incident wound dehiscence , infection, scar size, and surgical revision). Secondarily outcomes include pain, wound outcomes (e.g. wound size, scar size, wound healing rate, etc assessed using digital photography), area of inflammation (assessed using KENT), and pain (assessed using VAS). Exploratory outcomes include patient quality of life, sleep quality, anxiety, and depression. Baseline between group comparison will be dine using two-sample t-tests, Mann-Whitney U-test, or Chi-square depend on scale/distribution of the variables (i.e., parametric, non-parametric, or binary). We will use general mixed linear model and post-hoc analysis to examine difference between

groups (time, group, and time X group effect) for skin perfusion. We will adjust the results based on baseline incision wound size and duration between baseline and last visit assessment. Subjects with at least one week continue treatment will be included in the analysis. Controlled variables include age, BMI, baseline vascular health. We will use chi-square to estimate whether the number of wound complication incidents is less in the intervention group compared to the control group. Chi-square or repeated ANOVA or Mann-U test depend on scale/distribution of the variable will be used for secondary and exploratory outcomes.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

As any new investigational device, there are some risks, which are anticipated to be minimal in this study. Some of potential risks could be: * Skin related discomfort, erythema (redness), skin rash, dryness and itching. * Skin allergic reaction to dressing adhesive. * Tenderness/minor ache around the dressing application area * Heat sensation and/or perspiration with wearing dressing * Some impairment of mobility due to dressing unit

Some of the study devices (OxyGeni, KENT) and technology are completely non-invasive, safe, non-toxic and non-ionizing. The potential risks are minimal. However, like any battery powered systems, there is a minimum risk of sensor malfunctioning. In addition, the study devices are not waterproof, and although they use a low powered battery (similar to a cell-phone battery), in order to avoid any risk of shock the monitor should not be submerged or saturated with fluids during operations or cleaning.

When wearing the study devices, there is a small risk of tripping. The dressing will be connected to the OxyGeni device through a thin tube that will be placed comfortably along the subject's legs underneath their clothing. We will instruct the subject to place the tube correctly to minimize any risk of tripping.

Subjects must be willing to charge device battery daily. Otherwise they will not receive benefit from treatment. OxyGeni is a wireless chargeable device to increase patient comfort.

The assessments described above are expected to be minimal risk and probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Please note that there is also the possibility for loss of confidentiality. The PI and the research team will minimize the possibility of for loss of confidentiality by keeping all the physical data locked in cabinets only accessible to the research team. The electronic data will be kept on network password protected institutional computers. Data collected during the study may be published and made publicly available. Data may also be shared with other research groups. However, data that could in any way identify the subject will not be made public or shared. And, subject PHI will be coded as much as possible to minimize the potential for loss of confidentiality.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

Yes

NOTE: The answer to the questions in H2 requires the completion of the form: 'Section H â€“ Data and Safety Monitoring Plan' as an attachment in Section S.

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There may be no direct benefit to the subject by being in this study. What the researchers find out from this study may help other people with surgical wound closures. This research utilizes a new dressing with active oxygen supply to the surgically closed wounds to reduce the likelihood of developing wound dehiscence.

Specialized wound dressings have the ability to improve specific physiological processes that facilitate healing. However, their specific benefits and target wounds is not well understood. Consequently, these are either underutilized in clinical

practice or over utilized without any well-defined criteria. OxyGeni oxygen delivery system is a novel wound healing therapy that promises to enhance vascular conditions at the wound bed and expediting wound healing.

Describe potential benefit(s) to society of the planned work.

There may be no direct benefit to the subject by being in this study. What the researchers find out from this study may help other people with surgical wound closures. This research utilizes a new dressing with active oxygen supply to the surgically closed wounds to reduce the likelihood of developing wound dehiscence, the main contributor to surgical revision.

Specialized wound dressings have the ability to improve specific physiological processes that facilitate healing. However, their specific benefits and target wounds is not well understood. Consequently, these are either underutilized in clinical practice or over utilized without any well-defined criteria. OxyGeni oxygen delivery system is a novel wound healing therapy that promises to enhance vascular conditions at the wound bed and expediting wound healing.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Although there some risks involved in this study associated with the device and some of the procedures involved, the study does provide the possibility of benefit to subjects. Therefore, the benefits outweigh the risks involved.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

We will be reviewing our subject's chart for screening and to verify subject eligibility.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

There is the possibility for loss of confidentiality. However, the PI and his team will employ ample measures to ensure that the data is coded as much as possible and that it is stored under lock and key at all times. Also, electronic data will only be kept on our network password protected computers

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

Subjects will receive the same standard regardless of their participation in the trial.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

Patients will receive the same standard of care whether or not they participate in the research. Subjects are patients of the PI in his clinic. So, their participation will not affect the current or future care in the clinic by their physician. By being able to review the patient charts, we can identify eligible patients. This also allows us to verify their eligibility which is crucial to being able to enroll a patient.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

NA

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

The PI and his designated research coordinator have both received training in the protection of confidential patient information. All study information obtained will be coded. The use or disclosure of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals. As there is a possibility of a loss of confidentiality in this study, the PI and his team will employ ample measures such as coding as much of the data as possible. In addition all physical information will be kept in locked file cabinets. All electronic data will be stored on our network password protected computers.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

We will destroy identifiers at the earliest opportunity consistent with conduct of the research absent a health or research justification for retaining them or a legal requirement to do so. The use or disclosure of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals. PHI is not disclosed to any other person or entity except for the authorized oversight of the research study by the PI and the clinical database administrator. The Division uniformly adheres to all patient and patient data security and confidentiality rules and regulations set forth by the College.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

Yes

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

Yes

Partial Social Security # (Last four digits):

No

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

Yes

Other:

No

Will additional pertinent information be provided to subjects after participation?

Yes

If Yes, explain how subjects will be provided additional pertinent information after participation.

We will be reviewing our subject's chart for screening and to verify subject eligibility.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and

consent procedures in detail.

In order to recruit or identify subjects, we will screen our patient charts for eligible subjects.

The subject will be fully informed about the study, and will verbalize understanding and voluntarily agree to participate with the guidelines as stipulated in the informed consent. The subject will be informed if he/she can withdraw from the study at any time without loss of benefits. Consent forms will be signed and dated by the subject and by the Principal Investigator or Investigators. The original (with patient's signature) will be maintained per IRB policy. Any critical information will be sent for inclusion in the medical records, if it affects patient¿s wellbeing and any future treatment. A signed copy of the consent form will be provided to the patient. Informed consent will be obtained prior to performance of any study procedures. Specifically: 1. No minors will be consented. 2. Subjects are given as much time as needed to ask questions and read over the consent. They are will be given a copy of the consent and can return at a later date if they need to discuss it with family members, etc.

Subjects will be recruited from the COI's own practice. He may get some referrals from his colleagues that work in the same clinic such as Dr. Sebastian Winocour, Dr. Alastair Thompson and other collaborators. We have included a Waiver of Partial Consent to cover our screening process. The COI will identify eligible subjects and alert the coordinator. The coordinator will review all the details of the study with the subject and/or their family. If the subject agrees to participate in the study, they will be screened and then enrolled into the study.

This study will include patients who are age 18-85. We understand that subjects who are older age may be at a greater risk for cognitive impairments. However, if the PI feels that a subject may have diminished cognitive capacity, he will determine that the patient can not be enrolled in the study. Therefore, the research team will have this information available when they consent the patient. As there is a risk of loss of confidentiality, the PI and staff will take ample measures to code as much of the information as possible.

Please note that all subjects will be consented before any screening procedures are done.

Spanish speakers will be consented using a full Spanish version of the consent. We have Spanish speaking coordinators on staff that can receive consent from Spanish speaking patients.

Reconsent plan: Patients who were previously enrolled will be called and asked if they are willing to participate in the optional follow-up visit. If they agree, the consent form will be mailed and they will be asked to sign and mail it back or they will come in-person to be consented.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

A full-length informed consent document

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

Yes

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
Yes

Specific information concerning drug abuse:
Yes

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
Yes

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Other:
No

At what institution will the physical research data be kept?
The physical research will be kept in our BCM offices housed in the Mcnair Building room B10.401.

How will such physical research data be secured?
Data will be kept in locked file cabinets that only the research team has access to.

At what institution will the electronic research data be kept?
Electronic data will be kept on network computers in our BCM offices, under the password protected server. Address : \\discovery1.ad.bcm.edu\bcm-dept-icamp

Additional electronic data may be stored on REDCap. REDCap is hosted by Baylor College of Medicine - Institute for Clinical & Translational Research.

The data from the eKare Insight camera is not stored on the camera itself, rather it is saved to the eKare cloud platform which research staff will be able to access via a web portal. This website is secure and follows all HIPAA , 21 CFR Part 11, Data Security and Protection Toolkit, and Cyber Essentials Certification requirements. Photos will not be able to be identified to patients and no PHI will be added.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
Yes, (describe below):
Electronic data will be stored using the REDCap (Research Electronic Data Capture) software. This software is used to electronically collect and manage research data. REDCap is a secure, web-based platform.

Electronic data will also be stored and secured under the password protected server provided by BCM IT Services.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

Transmissions, if any, will only happen via secure emails.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

NA

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

Participating in this study will take the subject's time and will not involve any direct cost to him/her. The subject's medical insurance will be billed for all standard of care related expenses including:

Wound care (CPT 97597), Post-op visit (99024) on visits 0, 2, and 4, Hba1c (CPT 83036) at visit 0 only if not previously available on EPIC

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

450

Distribution Plan:

Subjects will be compensated $75 per in-person visit. We will be also providing parking validations. If a patient attends a remote visit, compensation will be $25.

Subjects will be given a ClinCard where payments will be loaded after a study visit is completed. Additional information will be provided to the subject about how to manage the card.

We will be requesting subjects SSN for payment purposes. This is required in order to provide them with a ClinCard.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

Yes

Device 1: Transcu O2 device

Device 2: Sensilase

Device 3: Zephyr Bioharness

Device 4: Legsys

Device 5: Kent camera

Device 6: Silagen Silicone Sheet

Device 7: inSight

Section Q: Consent Form(s)

EVALUATION OF OXYGEN DELIVERY WITH TRANSCU O2 TO STUDY SUCCESS RATE OF SURGICALLY CLOSED WOUNDS - A RANDOMIZED CONTROLLED TRIAL.

Section R: Advertisements

None