Concise and Focused Presentation

You are being asked to participate in this voluntary research study. This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family, and to ask questions before making your decision on whether or not to participate.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious, depending on the nature of the research.

You may qualify to participate in this study because you have a wound that was closed during surgery. These type of wounds are sometimes difficult to heal and we have designed a study in which you would be provided with additional care to possibly help the wound heal faster.

You have the choice to participate in this research project. The purpose of this project is to evaluate a new oxygen delivery system, which may potentially help heal surgically closed wounds faster than the current options used. It provides oxygen to the wound that may help to accelerate wound healing by providing better blood flow to the wound.

Participants will be placed in an internally randomized controlled trial. Internal randomization means that we will randomly decide which breast will receive regular care after your surgical closure and which will receive regular care plus a special device that provides oxygen to the area. So, only one of your breasts will receive the oxygen device, while the other will receive the standard, clinical glue and tape that is used to secure the surgical incisions.

Although there some risks involved in this study associated with the device and some of the procedures involved, the study may provide you with possible benefits. Therefore, the benefits outweigh the risks involved.

As expected with any new investigational device, there are some risks which are anticipated to be minimal in this study. Some of potential risks could be:

1) Skin related discomfort, erythema (redness), skin rash, dryness and itching due to proposed dressing.
2) Tenderness/minor ache around the dressing application area
3) Heat sensation and/or perspiration with wearing dressing
4) Some impairment of mobility due to dressing unit

It is important to notify us if you feel discomfort while wearing the dressing.

You should immediately notify us or contact your clinic, your doctor, or care provider if you feel that the condition of your wound is deteriorating. The signs of wound deterioration will be discussed with you by your doctor or care provider who treats your wound.

There may be no direct benefit to you by being in this study. However, 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 surgically closed wounds to reduce the likelihood of developing wound dehiscence.

You will receive the same standard of care whether or not you participate in the research. Your participation will not affect your current or future care in the clinic by your physician.

Alternative: You may choose to not participate in this study.

Background

Oxygen is one of the most powerful agents available to the modern medical practitioner. It is assumed that good delivery of oxygen to the wound may accelerate wound healing and reduce excessive scar formation. However, until now, there was not an easy way to deliver oxygen to the wound during the day and while sleeping. Recently a company named EO2 Concept has designed a new dressing named OxyGeni, which facilitates delivery of oxygen to a wound during every-day usage.

We are proposing a clinical study at Baylor College of Medicine to test the usefulness of the new system described above to boost the wound healing process of surgically closed wounds. Specifically, we will test whether this new system will improve tissue oxygenation and reduce likelihood of wound reopening, infection, or excessive scarring. This adjunctive therapy may also be helpful at reducing the level of pain during dressing changes, improve wound healing speed, improve vascular factors (increase blood flow to wound), and ultimately improve quality of life.

This research study is sponsored by EO2 Concepts

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

You have the choice to participate in this research project. The purpose of this project is to evaluate a new oxygen delivery system, which may potentially help healing surgically closed wounds. It provides oxygen to the wound that may help to accelerate wound healing by providing better blood flow to the wound.

All participants will be placed in a internal randomization. One surgical site will be treated with oxygen delivery and one site will receive regular care after your surgical procedure.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

There are a total of 5 study related visits required for completion of this study. Each visit is described

below. In addition, our study coordinator may call you or ask you to attend to the clinic for a follow-up visit up to 2 years after your last study visit to document the success of your wound healing and document any potential incident or hospitalization(s). The breast side that receives the treatment will be randomly (like by the flip of a coin) decided, and one will receive the intervention (Intervention group) while the other receives the standard of care (Control group). The side in the intervention group will receive standard of care plus Silagen (silicon sheet) and the study device (Oxygeni), while the side in the control group will receive standard of care.

If you are unable to come to the research site, or have any problems with the study device, it may be possible for the research personnel to visit you at your home.

At each visit, the research staff will complete the procedures in the following order
1) Questionnaires
2) Dressing Change
3) Wound assessments
4) All other procedures

Please see below all questionnaires that will be asked from you,

Medical History: We will collect your medical history like diagnosis of diabetes, cancer, cardiovascular problem, lung disease, arthritis, liver disease, cardio vascular problem, sleep apnea, or any other co-morbidity. We will measure height and weight to determine body mass index (BMI). We will document the type of surgery. We will evaluate and/or record some of your blood work (only if it is available per your standard of care). These results will be obtained from your medical record at screening/baseline visit.

Social Factors: We will evaluate the following 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.

Questionnaires (optional): To evaluate functional status, we will use the following well-accepted questionnaires: Promise Global (to assess Quality of Life), TSFI (to assess Frailty Status), MOCA (to assess Cognitive Abilities), PSQI (to assess Sleep Quality) CES-D (to assess depression), PASS (to assess your attitude towards your scarring), scarring satisfaction, and TAM (to assess Device Acceptability). These questionnaires could be done at any study visit upon time availability and your acceptability.

Wound Assessment: A digital photo/video of your wound location will be taken for wound size verification, estimation of wound size, success of wound healing, and determination wound reopening. Measurement will be performed at every visit.

Tissue Oxygen level: Tissue oxygenation level will be assessed using a digital camera (Kent Imaging system) at baseline and every study visit. The device uses light in the near-infrared (NIR) spectrum that,

harmlessly, passes through the skin and is reflected off the blood supplying the tissue to determine tissue oxygen saturation, a key indicator of tissue health.

Pain Intensity Assessment (VAS) and Breast Pain Questionnaire: You will be provided with a numerical pain scale and questions related to breast pain to report your pain intensity. Research staff will document your pain level. (Measurements will be done at every visit).

Adverse Event Reporting: Research Staff will document and report any study/non-study related incident as per institution regulations. (You will be asked on screening/baseline visit and visits 1- 5)

Device Education: Research staff will provide you with information on the device and instructions on how to use it.

Device Acceptability Questionnaire: You will be handed a questionnaire to evaluate the study device and provide feedback to the research team. (Visit 4)

At each visit, the research staff will change your dressing as described below:

Dressing Change: Your dressing will be changed weekly at each visit (screening/initial visit and visits 1-4), those in the intervention group will also be treated continuously with oxygen from the Oxygeni device.

Prior to application of the Oxygeni, the research staff will:
1. Select a dressing that will cover your wound.
2. Place and safely apply Oxyspur O2 dressing
3. Apply additional padding (silicon sheet) on top.
4. Wrap dressing as directed by physician

Now, please read very carefully the description of every visit. All procedures were described above.

Screening/Baseline Visit *duration of visit 90 minutes This visit research staff will perform as described above: Medical History, Questionnaires (Pain, Social Factors, and Quality of Life, Sleep Quality, Cognitive Assessment, Frailty), Upper Extremity Test, Peripheral Neuropathy, Heart Rate Monitoring, Vascular Assessment, Wound Assessment, Wound Monitoring, Dressing Change and Device Education.

Visit 1, One Week Later *duration 50 minutes This visit research staff will perform as described above: Pain Questionnaire, tissue oxygen, Adverse Event Reporting, Wound Assessment, Dressing Change and Device Education. The plastic surgeon will remove the CDO dressing in his normal post-operative clinic appointment, and the female research coordinator will obtain the tissue oxygenation 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, Two Weeks Later *duration of visit 50 minutes This visit research staff will perform as described above: Pain Questionnaire, tissue oxygen, Adverse Event Reporting, Wound Monitoring, Wound Assessment, Dressing Change and Device Education. The patient will be seen in the 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, Three Weeks Later *duration 50 minutes This visit research staff will perform as described. Pain Questionnaire, tissue oxygen, Adverse Event Reporting, Wound Assessment, and Dressing Change. If wound is healed, this will be the study termination visit and all baseline questionnaires will be performed.

Visit 4, Four Weeks Later. This will conclude the study and dressing will be removed and device will be collected. Pain Questionnaire, tissue oxygen, Adverse Event Reporting, Wound Assessment, Dressing Change, scarring satisfaction, and device acceptability.

Visit 5 (optional), at minimum 6-months after day of surgery (baseline) and at maximum up to 2 years after. During this visit research staff will take a digital photograph of the area and scar assessment. This visit can be done remotely if you are unable to attend, by providing a digital picture of the area and answering questionnaires via a secure website (RedCAP). The same questionnaires as the ones listed previously will be performed, including the PASS and POSAS questionnaire to assess your attitude towards your scarring. This visit will help us understand how the study dressing has affected your scarring long-term.

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

The researchers will take digital photographs of your wound (location of the present surgical wound example breast) during the study to monitor progress or deterioration (worsening) due to intervention. This is done using a normal digital camera for visual images and a KENT camera for oxygen saturation images. Both these methods are non-invasive. **We will blur your face out and the Areola area in the photographs/videos. While we do all our efforts to mask your face in some cases (for example. journal policy) this may not be practical. Wewill only use videos and photos of you for scientific presentations or scientific publications without recognition of the face.

Initial your decision below.

_____ I agree to have my photographs presented in scientific presentation or scientific publication

_____ I do NOT agree to have my photographs presented in scientific presentation or scientific publication

If you are eligible, the research personnel would like to contact you in the future for participation in other research studies. You are not required to participate in these studies and your medical care or involvement with the current research study will in no way be affected if you choose not to participate.

You may ask us to stop contacting you at any time.

_____ I agree to be contacted for future research studies

_____ I do not agree to be contacted for future research studies

Please provide below your Emergency contact information:

Contact name: _____

Relationship:_____

Phone number:_____

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Billing or financial records
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and EO2 CONCEPTS, INC (US) and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

The data coordinating center will have access to the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even

if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, EO2 CONCEPTS, INC (US) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, data coordinating center, Data and Safety Monitoring Board, and Baylor St. Luke's Medical Center (BSLMC) may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Baylor College of Medicine One Baylor Plaza Houston, Texas 77030 Department of Surgery ATTN: Bijan Najafi, PhD MS: BCM390

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

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 due to proposed dressing.
- Tenderness/minor ache around the dressing application area
- Heat sensation and/or perspiration with wearing dressing
- Some impairment of mobility due to dressing unit

It is important to notify us if you feel discomfort on wearing the dressing.

You should immediately notify us or contact your clinic, your doctor, or care provider if you feel the condition of your wound has been deteriorated. The signs of wound deterioration will be discussed with you by your doctor or care provider who treats your wound.

The study device and assessment tools that will be used in this study are non-invasive, safe, non-toxic and do not emit any radiation. However, like any battery powered systems, there is also a minimum risk of device malfunctioning and overheating. Please contact the research staff immediately if you experience overheating or device 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 or shock the provided devices like the oxygen delivery system (OxyGeni) should not be submerged or saturated with fluids during operations or cleaning. If you need to take shower or go swimming, you should remove these devices.

The study devices are costly and are developed for the purpose of this study. We appreciate if you pay extra attention to not damage or lose the device. However, in conditions that the device was damaged

for any reason, please notify the research staff at your earliest convenience. You will not be charged for any damage or loss of device. The device may be replaced upon availability.

You must be willing to charge device battery daily. Otherwise, you will not receive benefit from treatment.

The assessments described above are expected to be minimal risk and probability and significance of harm or discomfort anticipated in the research are not greater than those risks encountered in daily life or during the performance of routine physical exam.

To minimize risk, it is recommended that you do NOT remove your dressing. Your dressings will be changed during the study visits by your physician.

All information we will collect about you will be stored in a secure location and coded in a way to maintain confidentiality. Only study personnel will have access to your records. 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 you will not be made public or shared.

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 underneath your clothing. We will instruct you to place the tube correctly to minimize any risk of tripping.

There may be unknown risks or discomforts involved.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits
The benefits of participating in this study may be: This research utilizes a new dressing with active oxygen supply to wounds in hopes that it will potentially improve blood flow. It is part of a larger prevention initiative to reduce the high number of wound re-opening, which is known to be a cause of excessive scarring or infection. Therefore, information obtained from this study may help others undergoing surgical incision and reconstructive surgery as well as those with any type of surgical wounds.. However, you may receive no benefit from participating.

Alternatives
The following alternative procedures or treatments are available if you choose not to participate in this study: You may choose to not participate in this study..

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

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

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

You will be compensated $75 per in-person visit. If you attend the last, optional, visit (Visit 5) in-person you will be compensated $75. If you attend the last, optional visit (Visit 5) remotely, then you will be compensated $25. You will be paid up to a total of $450.

We will be also providing parking validations.

You will be given a debit card called "ClinCard" at the first day of your visit. Each time you complete an in-person visit, the coordinator will load $75 to your card. Please note that it may take up to 72 hours for the amount to be loaded in the card. The research coordinator will provide you with some instructions and useful information about your card.

Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you, your parent, guardian or legally authorized representative (LAR) reaches or exceeds $600 in a calendar year, Baylor College of Medicine will send an IRS Form 1099 to that person for tax purposes.

In order to issue the IRS Form 1099, Baylor will collect your first and last name, social security number, date of birth and home address. The name you provide should match the social security number. If you do not wish to provide a social security number, you can still participate in the study and decline all payment.

Please note study payments are considered income and may or may not affect government or public assistance benefit programs you or your parent, guardian or LAR may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 48-72 hours of visit completion. The research study team will provide you with a handout about the ClinCard. Your email address and/or cell phone number will be collected in the event you want email or text notification when payments are loaded to your ClinCard. Baylor College of Medicine and Greenphire (ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information.

The College will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, Baylor will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, BIJAN NAJAFI, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: BIJAN NAJAFI at 713-798-7536 and Maria Noun at 713-798-7538.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Legally Authorized Representative - Adult	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date