BIOMEDICAL RESEARCH PROTOCOL
UNIVERSITY OF MISSOURI

Project Title: **Effect of drain care on infection rate and quality of life in implant-based breast reconstruction.**
IRB Number: **2092673**
Version Number: V1
Version Date: **11/14/22**

Principal Investigator: Dr. Stephen Colbert
Funding Source: N/A

Research Objectives/Background

1. Include primary, secondary, and exploratory objectives.
   Primary goal: to evaluate whether allowing showering after a certain number of days post breast reconstruction has an effect on the infection rate
   Secondary goal: to evaluate whether allowing showering after a certain number of days post breast reconstruction has an effect on the quality of life of patients

2. Include background and rationale for initiating the study. Includes pre-clinical and clinical data, current experiences with procedures, drug, or device, and any other relevant information to justify the research.
   Currently, there is a lack of consensus on best practices regarding showering with drains in place following first stage breast reconstruction. There is anecdotal concern for an increased risk of Surgical Site Infection (SSI), but the current literature to support this is lacking. There is also some evidence that showering with drain tubes in place has no increase risk of infection. It is not known whether showering with drain tubes decreases the risk of SSI. Surgical drains can remain in place upwards of two to three weeks in the postoperative period. The recommendation not to shower until drain removal can present a significant challenge for patients resulting in distress and decreased quality of life. Our study will assess the infection rates in patients allowed to shower at 48 hours postoperatively compared to those not showering until drains are removed. Our hypothesis is that this study will reveal no difference in the rates of SSI and improved quality of life in patients who are allowed to shower with drain tubes in place.

Drugs/Biologics/Devices

1. Include the product, dose, route, and regimen.: N/A
2. Include the rationale for choosing the drug/biologic and dose, or for choosing the device to be used: N/A

3. Include the standard reference therapy against which the study product is being compared, or if the reference is a placebo. Include justification for inclusion of a placebo or non-treatment group: N/A
4. Include justification and safety information: N/A
5. If an IDE (for investigational devices) or IND (for investigational drugs) is not necessary, provide justification.: N/A

Recruitment Process

1. Describe the recruitment process; including how and where recruitment will take place.
   Recruitment will take place in the UMHC PRS clinic. Patients scheduled to receive first stage breast reconstruction will be asked for their participation in the study and randomized to either the control or experimental arm.

2. Describe any screening/baseline procedures.
   Patients will be assessed via physical exam and obtainment of past medical history to determine need for first stage breast reconstruction.

Consent Process

1. Describe the consent process; including who will be approached for consent and what type of consent will be obtained from each subject population, if there is more than one.
   A written consent using the IRB consent template will be used for each new patient undergoing implant-based breast reconstruction. Consent will be obtained by any of the staff included in the IRB application at the initial pre-operative appointment ranging from one week to one month pre-op. Written consent will then be obtained and stored in the medical record.

Inclusion/Exclusion Criteria

1. List the inclusion and exclusion criteria.
   Inclusion criteria:
   Patients undergoing first stage breast reconstruction at the University of Missouri.
   Age range: 18 years of age and older.
   Exclusion criteria:
   Patients may not have any existing wounds, nor any existing infections related to an implant device.

2. Describe restrictions on participation and appropriate screening procedures to ensure that the restrictions are maintained, including pregnancy testing.
   Restrictions will be any patient's that have any existing wounds or infection or have been on antibiotics within in the past ten days.

Number of Subjects

1. Include anticipated enrollment number in this study. Include a break-down in numbers if there is more than one subject population.
   Our goal is to achieve an *n* of 100 with 50 patients allocated to the experimental arm (showering at 48hrs) and 50 allocated to the control (current standard of care).

2. Include statistical analysis or other justification for the number of subjects enrolled.
   An *n* of 100 provides us with adequate power for a statistically significant difference between subject arms to be detected if one is present.

Study Procedures/ Design/Treatment Plan

1. Include study procedures/design/plan; include the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care). Include study duration and number of study visits required.
   Study will last 90 days. Patient's will be admitted to the hospital following surgery if the reconstruction takes place immediately following mastectomy. If the reconstruction does not occur at the same time as mastectomy, patients are not admitted. This is part of our routine care. Regardless, they will be evaluated on post operative day one. Following the initial post operative day one visit, patient's will be evaluated on a weekly basis for 90 days. Vitals will be taken at the visits, and routine physical examination (including evaluation for surgical site infection) will be performed. Patient reported outcomes will be obtained at these visits as well. We will also ask patients if they have been showering or not and if so how often. This will be documented. For example: patient evaluations will be as follows:
   - **One-month preoperative visit**
   - **Day of surgery**
   - **Post Operative Day one evaluation (In the hospital or clinic)**
   - **Clinic Visit 1: One week after surgery**
   - **Clinic Visit 2: Two weeks after surgery**

These visits will not differ from our routine care. At the conclusion of 90 days patients will receive a survey asking if drain care and the ability or inability to shower with drain tubes in place adversely affected their quality of life.

2. Blinding, including justification for blinding or not blinding the trial. Describe un-blinding procedures.
   The study will not be blinded. Participants will be randomly assigned to treatment arm. Researchers and patients will know which arm they are assigned to.
3. Justification of why participants will not receive routine care or will have current therapy stopped.
   The goal of the study is to determine if there an effect on infection rate with allowing patients to begin showering 48 hours after surgery rather than waiting to shower until drains are removed. There is no definitive literature on this, and the care of surgical drains is ultimately decided by the surgeon. There is currently no defined standard of care regarding showering with surgical drains in place.

4. Definition of treatment failure or participant removal criteria.
   Removal criteria: failure to shower within 48 hours (experimental arm) or showering before surgical drain removal (Control group). Other removal criteria will be participants that have violated the post operative instructions in any way.
5. Description of what happens to participants receiving therapy when study ends or if participation in the study ends prematurely.
   At the end of the study or if patients choose to withdraw prematurely from the study, patients will continue to follow up at designated intervals for general postoperative monitoring.
6. Include sub-studies or banking information (correlative/special studies)
   Data must be kept for seven years after the study has been completed.

Potential Risks/Adverse Events

1. Describe reasonably foreseeable risks or discomforts to the subjects and steps to minimize risks.
   The study involves minimal risks and steps will be taken to mitigate these risks. Risks include: soft tissue infection, breast implant infection, decreased quality of life, breach of confidentiality. Infection risk may be higher, lower, or the same in those who allowed to shower with drains in place compared to those not allowed to shower. There is a lack of literature to support increased risk of infection with showering with JP drains in place. Timing of showering is ultimately surgeon dependent. Regardless, this risk will be mitigated by continuing with sterile surgical technique with proper prepping and draping of the patient as well as sterile placement of drain tubes intra-operatively. Patient's will also be instructed to not soak in water, such as in a bath tub. Rather, they will be instructed to shower and let water run over the drain tube sites. Patients will be immediately treated if there any signs of infection. In terms of decreased quality of life, patients who will not be allowed to shower until drain tubes are removed will be allowed to sponge bath to help mitigate any discomfort. The final is risk is possible breach of confidentiality. These risks will be minimized by de-indentification of data collected on a separate file, a link between randomly assigned number and identifiable data will be listed. All data collected will be secured on a password protected excel spreadsheet. No persons outside those listed. Accidental removal of a surgical drain is not increased by this study. It is part of our routine care to suture the drain tubes to the skin. Accidental dislodgement of drains is an extremely rare event and is part of the normal post operative surgical risks.

2. Describe any stopping rules.
   We would immediately withdraw patients per their request. We would also stop the study all together if there was a clear statistical benefit in one of the study arms.
3. Include the plan for reporting unanticipated problems or deviations. This plan must include a five-day reporting requirement to the IRB once becoming aware of an event.
   Patients will be educated on the signs concerning for SSI and appropriate protocol for reporting any concerns. This will consist of calling the UMHC PRS clinic to schedule immediate follow-up to be assessed for SSI. If a patient is found to have a

SSI they will be treated with appropriate antibiotics. The IRB office will immediately be notified within the five day reporting requirement.

Anticipated Benefits

1. Include both direct and indirect benefits for either the individual or society.
   Direct benefits include better understanding factors that contribute to SSI in the postoperative period following first stage breast reconstruction. Indirect benefits include the ability to change current standard practice regarding showering with drains to improve patient quality of life.

Compensation

1. Describe the amount, method, and timing of disbursement. Compensation can include checks, cash, gifts, extra/course credit, etc.
   No compensation will be provided. Patients will be recruited for this study on a volunteer basis.

Costs

1. Detail costs of study procedures, drugs, biologics, or devices and identify who will cover the cost.
   There is no attributed cost for study procedures. We will be implementing two treatment arms: showering after 48 hours post operative with JP drains in place vs showing after JP drain removal. Survey will be voluntary

Multiple Sites

1. Specify who is the lead site and describe the roles of each site in the study.
   UMHC PRS Clinic is the primary and only site being included in this study.

2. Indicate that all required approvals are already in place or will be in place at each site prior to project implementation. If the study will utilize a reliance agreement or a single IRB, please describe which institution(s) will be relying on another IRB for review, and which institution will be responsible for the IRB oversight of the relying IRB(s).
   A single IRB will be utilized for this study.

3. Describe the plan that is in place to manage information obtained from multiple sites that may be relevant to the protection of human subjects such as reporting unanticipated problems, protocol modifications, and interim results.
   We will only be operating from on clinical site.

References/Appendices

1. Include findings from a literature search or pilot study must be outlined including appropriate detailed references to earlier studies and data.

This study highlighted the considerable heterogeneity in surgical practices aimed at preventing SSI in implant-based breast reconstruction and that surgeons may benefit from high-level studies designed to create standardized evidence-based practice guidelines.

Gowda, Arvind U., et al. "Preventing Breast Implant Contamination in Breast Reconstruction." *Annals of Plastic Surgery*, vol. 78, no. 2, 2017, pp. 153–156., https://doi.org/10.1097/sap.0000000000000822.

This study found that postoperative showering for patients with closed suction drainage is safe and does not increase the incidence of postoperative complications, including surgical site infection in patients that had undergone DIEP flap breast reconstruction.

Ogawa, Haruo, and Shinya Tahara. "Postoperative Showering for Patients with Closed Suction Drainage: A Retrospective Cohort Study of Deep Inferior Epigastric Perforator Flap Breast Reconstructions." *Cureus*, 2022, https://doi.org/10.7759/cureus.23665.

Looked at patient quality of life and overall satisfaction compared to the general population following mastectomy with first stage breast reconstruction. Study showed quality of life scores were equivalent at 1yr post-op.

Elder, Elisabeth Edström, et al. "Quality of Life and Patient Satisfaction in Breast Cancer Patients after Immediate Breast Reconstruction: A Prospective Study." *The Breast*, vol. 14, no. 3, 2005, pp. 201–208., https://doi.org/10.1016/j.breast.2004.10.008.

Hanna, Kasandra R. MD; Tilt, Alexandra MD; Holland, Michael MD; Colen, David MD; Bowen, Byers MD; Stovall, Madeline BA; Lee, Andy BS; Wang, Jessica BS; Drake, David MD; Lin, Kant MD; Uroskie, Theodore MD; Campbell, Chris A. MD Reducing Infectious Complications in Implant Based Breast Reconstruction, Annals of Plastic Surgery: June 2016 - Volume 76 - Issue - p S312-S315. doi: 10.1097/SAP.0000000000000760

2. Additional references to supporting data or additional information may be included in an appendix.