Protocol v2: DIEP Flap Sensory Recovery Following Direct Neurotization in Breast Reconstruction – A Blinded Prospective Study

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Research Problem, Background, Hypothesis

The Deep Inferior Epigastric Perforator (DIEP) flap is the current standard of care in breast reconstruction. The DIEP flap does not normally have sensation restored. The presence of sensation in a reconstructed breast has been shown to improve patient-rated quality of life following mastectomy reconstruction and is an important safety factor for prevention of burns and other flap injuries. Unfortunately, women who have breast skin excised during mastectomy are reconstructed with a traditional DIEP flap that does not restore sensation to the skin. We hypothesize that the breast reconstructed with a DIEP flap and nerve coaptation will have improved sensory return compared to the breast reconstructed with a only a DIEP flap (and no nerve coaptation).

Study Objective

We aim to perform a prospective randomized single-blinded trial to evaluate sensory return to DIEP flaps following nerve coaptation.

Research Design and Methodology

- A blinded, prospective study will be performed involving Manitoban women over 18 years undergoing bilateral breast reconstruction with DIEP flaps. The women will have one breast reconstructed in the standard of care (DIEP flap with no nerve coaptation) and one breast reconstructed with both DIEP flap and sensory nerve coaptation; the side of coaptation will be randomized. Objective sensibility to the breast will be tested pre- and post-operatively (3, 6, 12 months) using the Pressure Specified Sensory Device (PSSD). Patients will also complete the Breast Q questionnaire postoperatively.
- The primary inclusion criteria are
    - (1) female subjects older than 18
    - (2) scheduled for immediate bilateral breast reconstruction following bilateral non-nipple sparing mastectomy
    - (3) using DIEP free flap reconstruction
    - (4) with a large skin paddle
- Patients will be excluded if:
    - (1) pre-operative radiation or chemotherapy was performed
    - (2) post-operative radiation or chemotherapy is planned
    - (3) reconstruction is performed in a delayed fashion
    - (4) a nerve conduit is necessary for nerve coaptation
- Sample size: 30
- Justification of statistical methods of analyzing results: To have adequate power (80%) to detect the MCID of 0.15 using a paired t-test at the alpha = 0.05 level, our required sample size ranges from 8 to 23 participants depending on our assumption of a weak or strong correlation of 0.2 or 0.8 between the sensation measurements in the left and right breast of an individual. We have also assumed a standard deviation of 0.1912 for a

single measurement. To allow for the possibility of dropouts, etc., we therefore propose a conservative sample size of 30 participants.

- Sensory nerve coaptation in the operating room (unilateral): The donor nerve is a cutaneous nerve that is identified with the most inferior lateral perforator vessels. The nerve is then dissected for neurotization and divided at the level of the fascia where it is a pure sensory nerve. The recipient intercostal nerve is usually easily identified in the third intercostal space during the dissection of the internal mammary artery and vein. The anterior branch of the third intercostal nerve can usually be found at the junction of the inferior portion of the third rib and the sternum, approximately 80% of the time. The nerve is dissected and transected medially. It is then mobilized to give it the longest length possible in preparation for neurotization. Neurotization is performed by coapting the donor nerve to the third anterior intercostal nerve directly with a 9-0 nylon suture in standard fashion.
- Blinding: Only the surgeon and principal investigator will know which breast had the nerve coaptation performed. Neither the patient nor health care team testing sensory recovery to the breast will know.

Definition of adverse and serious adverse events

Adverse events include neuroma formation at the sensory nerve donor or recipient site. However, there are no documented cases in the literature of this occurring during this procedure.

Budget Details

N/A.

Potential Benefits

The benefit is improved sensation to the reconstructed breast, which increases patient satisfaction with the surgery and improves safety and prevention of injury to the breast.

Potential Risks/Harms

There is a potential for neuroma development at the sensory nerve donor or recipient site. However, there are no documented cases in the literature of this occurring in this procedure.

Alternative Treatment

The alternative treatment is reconstruction of the breast in the standard of care – a DIEP flap without nerve coaptation.

Consent Process

Patients scheduled to receive bilateral breast reconstruction at Health Sciences Centre will be screened based on the above inclusion/exclusion criteria. If they qualify for this study, they will be contacted and offered enrollment. Prospective patients will be identified during their preoperative appointments. A nurse from clinic will seek permission from the potential patient to be contacted by research staff. The study protocol and details will be explained by the principal investigator or another member of the health care team; a physical copy of this

information will also be provided to the patients. The principal investigator will review the paraphrase and obtain informed consent of the client to participate, unless they are treating the participant in which case the co-investigator or another therapy staff member familiar with the project and protocol (including all risks and benefits) will review the paraphrase and obtain consent. The treating physician will not obtain consent. The potential participants will have 2-4 weeks to contemplate whether to participate in the study (from preoperative visit to prior to surgery).