Official Title: Evaluation of a Novel Sutureless Drain Securement Device (K-Lock Device) and Comparison to Standard Suture-based Drain Securement Techniques

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Principal Investigator: Lisa David, MD, MBA
Co-investigator(s): Adam Katz, MD, Cassandra Driscoll, MD

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BACKGROUND, RATIONALE AND CONTEXT:

Surgical drains are used in a variety of surgical specialties and procedures. Drains are placed prior to closing the operative wound, and serve to allow draining of bodily fluids that would otherwise fill the new potential space created during an operation. Though there are various drain designs, the core structure of a drain involves tubing placed in the wound, exiting through the skin, and attached to a collection device that uses negative pressure to allow drainage of serosangunious or other fluids produced at the drain site.

To prevent the premature removal of surgical drains, the tubing is traditionally attached to the skin at the drain exit point using a suture. The suture is passed through the skin and then tied and wrapped around the tubing multiple times in a variety of patterns to hold the drain in place but not so tight as to occlude the tubing. When the suture is wrapped around the tubing multiple times over a distance, the technique is often referred to as the "Roman garter (RG) technique."

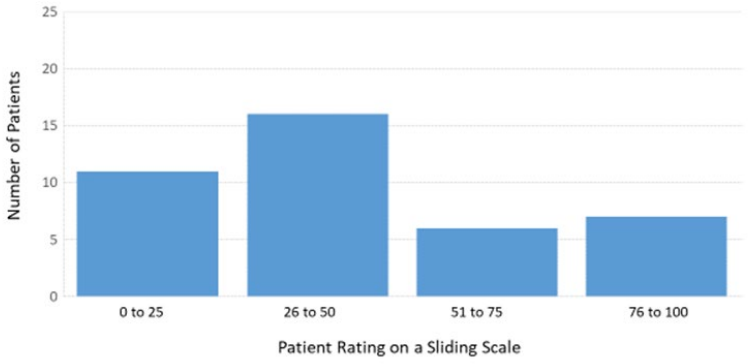

Figure 1. Patient Experience with Surgical Drains Compared to Pre-Operative Expectations. Patients were asked to use a sliding scale to characterize their experience with 0 = Experience Much Worse than Expected, 50 = Experience as Expected, 100 = Experience Much Better than Expected

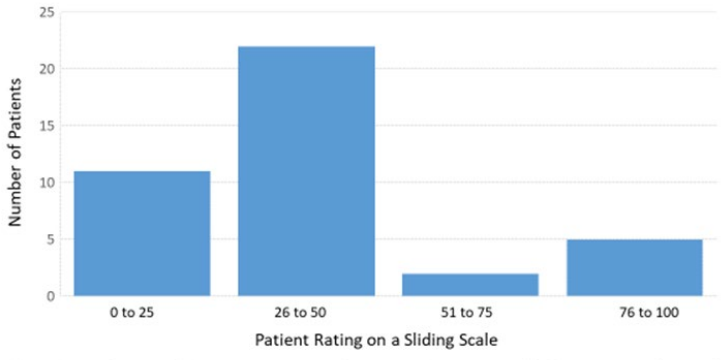

Figure 2. Patient Drain Securement Experience. Patients were asked to rate comfort and pain at the drain insertion site with 0 = Experience Much Worse than Expected, 50 = Experience as Expected, 100 = Experience Much Better than Expected

Traditional suture-based drain fixation is known to cause significant patient discomfort, predominantly at the site of skin suture fixation, where any pull on the drain tubing is transmitted to a focal point on the skin. Over time, this can result in significant skin irritation, inflammation and pain, skin erosion, loosening of the drain, suture failure, and possibly even early, unintended loss of the drain. Early loss of a drain, in turn, can lead to complications of seroma and/or infected abscess. In a survey of 40 Wake Forest Plastic Surgery Patients with drains, patients were asked to rate their experience with surgical drains compared to their expectations on a sliding scale. The majority of patients reported experiences that were worse than or as expected (Figure 1). When specifically asked about irritation at the drain site, 33 of 40 patients rated comfort and pain as worse than

or as expected (Figure 2). With the known negative patient experiences associated with suture-based drain securement, there is a need for novel drain securement techniques and devices that can improve patient comfort and drain security.

The K-Lock® Device is a novel sutureless drain securement device that may improve patient experiences with surgical drains. The K-Lock Device is an FDA Class I device exempt from 510k requirements.

OBJECTIVES:

To evaluate the feasibility, safety and efficacy of a novel suture-less drain securement device (K-Lock) via direct comparison to suture-based techniques.

To evaluate patient satisfaction with their surgical drain sites post operatively.

DESIGN:

Randomized controlled trial

SETTING:

Academic Medical Center

SUBJECTS SELECTION CRITERIA:

Inclusion Criteria:

Age 18 or older
Patient of the Department of Plastic and Reconstructive Surgery
Able to sign English language Consent form
Undergoing any of the following procedures requiring placement of 2 or more drains (preferably bilateral) including:

- Breast reconstruction
- Bilateral Breast Reduction
- Abdominoplasty
- Body Contour surgery (e.g. panniculectomy, brachiplasty, thighplasty)

Exclusion Criteria:

Patients with unilateral drain placement
Unable to sign English language consent form
Allergy to Tegaderm Dressing
Allergy to skin adhesives

SAMPLE SIZE:

We plan to enroll 40 patients allowing analysis of 80 (20 paired) drain sites: 40 prototype drain securement sites and 40 suture-based drain securement sites.

INTERVENTIONS AND INTERACTIONS:

Patients will be randomized to either A) left side K-Lock with right side suture-based technique or B) right side K-Lock with left side suture-based technique. Randomization will occur before study initiation with group A or group B being assigned to a study enrollment number.

Preoperatively:

The novel suture-less prototype device will be described and/or demonstrated to the patients, and the rationale for its development will be explained. They will have opportunity to ask questions and then they will be invited to participate in the study.

Written informed consent will be obtained.

Intraoperatively:

Surgical drains will be placed per the usual routine of the surgeon. However, prior to definitive fixation, the drains will be temporarily secured to the skin with a towel clamp and covered and/or positioned out of the way to allow for closure of surgical incisions. Definitive drain fixation will occur when all of the pertinent incisions are closed and dressed. At that time, each drain will be secured according to the randomization scheme.

The amount of **time it takes to secure and dress each drain will be recorded** using a time-stamped video (e.g. iphone). No identifying data/information will be recorded, only the zoomed field pertinent to drain securement. For the prototype drain securement device, the 'video clock' will be started when the device is passed to the surgeon and stopped when the device/dressing is attached in place. For the standard suture-based technique, the 'video clock' will be started when the suture is passed to the surgeon and will be stopped when the dressing has been placed and secured. Use of a Biopatch with the drain will be up to the surgeon's preference. The standard dressing for the suture-based techniques will include a split 4 x 4 dressing covered with a tegaderm. All dressing materials must be ready and available prior to handing the surgeon the suture/device.

Postoperatively:

The time until drain removal will be recorded for both groups.

On postoperative visit(s) on which a drain is removed, patients will complete a **survey** about their experience with the pertinent securement method/drain site.

Feasibility and **ease of use** of the novel drain device will be evaluated by evaluation of video recordings, qualitative feedback obtained from surgeons and/or O.R staff and nurses that handle and observe use of the device. Any failed application of the device will specifically be noted. In the event that a test device will need to be replaced for continued drain securement because the device has become loose or otherwise fouled, the replacement process will be performed by clinic staff using the IFU for such, and will be video recorded

Safety of the novel drain device will be evaluated by inspecting device sites for instances of skin irritation at each office visit and at the time of drain removal, including photographs of drain sites immediately before and after removal. It will also be assessed by feedback obtained in the patient surveys.

Postoperative review of patient charts will collect the following information up to 1 month from the removal of a subject's final drain:

- Date of drain removal (i.e. duration of drain)
- Accidental vs Planned drain removal
- Loosening of the drain
- Any need for new device/new suture material to secure drain
- Reinsertion of drain
- Patient calls to triage regarding drain issues/concerns and the estimated or actual time/effort devoted to each issue/concern by clinic staff
- Photos of the drain site at time of removal

As a follow-up to previous study activities, subjects will be contacted either by phone or at future clinic visits to gauge their interest in further participation. Subjects will be asked to have pictures taken of their drain sites and to fill out a survey to measure their satisfaction with their surgical drain sites further out from their procedures. Pictures will be attained at a scheduled research visit or a regular clinic visit if possible. A blinded evaluator will view the photos to assess in addition to the subject's self-reported outcomes. The tool the subjects will complete is the Patient and Observer Scar Assessment Scale (POSAS).

OUTCOME MEASURES:

Primary:
Feasibility

Secondary:
Safety
Satisfaction

ANALYTICAL PLAN:

Results will be analyzed initially using descriptive statistics. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Regression analysis will be performed to identify independent outcome predictors. Other inferential statistical analysis will be conducted as appropriate.

HUMAN SUBJECTS PROTECTION:

Patient-identifying information will be limited to what is necessary to conduct retrospective analysis and longitudinal analysis of drain securement that is accurately linked to a given subject. MRN and DOB will be captured to ensure data about a subject's drain is accurately recorded during chart review. Other than the master 'linkage' file, patient names, DOB, and medical record numbers will be removed and subjects will be associated with an abstracted unique Study ID. Data will be stored electronically on the Wake Forest School of Medicine's secure REDCap server, a HIPAA-compliant web platform.

Information for each subject will be entered directly from EPIC to the secure REDCap database, so data will not be stored on portable storage devices (including thumb drives).

SUBJECT RECRUITMENT METHODS:

Patients will be identified by review of the departmental surgery schedule with study team members and identifying patients undergoing eligible surgical procedures.

For the follow-up portion, subjects will be contacted either by phone or at future clinic visits to gauge their interest in further participation.

INFORMED CONSENT:

Signed informed consent will be obtained from each subject. Study coordinators and/or study investigators will obtain consent at either clinic appointments or during preoperative intake. Subjects

being consented during preoperative intake will be contacted prior to their visit by phone and will undergo a phone screening.

CONFIDENTIALITY AND PRIVACY:

Confidentiality will be protected by collecting only information needed to conduct outcomes research and related research to improve breast reduction outcomes. All database data will be entered into the Wake Forest School of Medicine's secure REDCap server. To help ensure subject privacy and confidentiality, a linkage file will be maintained containing each patient's medical record number and unique REDCap ID. Patient names will not be maintained in this file. The linkage file will be stored separately from the data available to researchers and will be kept secure, with access limited to designated study personnel. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study. Following data collection subject identifying information will be destroyed, within three years of closure of the study.

DATA AND SAFETY MONITORING:

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

REPORTING OF UNANTICIPATED PROBLEMS, ADVERSE EVENTS OR DEVIATIONS:

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

APPENDIX:

1. Patient Survey
2. Consent Form
3. K-Lock Informational Sheet
4. K-Lock Instructions for Use