Clinical Protocol

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Department	Dermatology
Protocol Number	1710792979
Study Title :	Effect of replacing buried sutures with tissue adhesive on aesthetic outcome of surgical wounds.

1. Subjects will be recruited from patients scheduled for surgery at the WVU University Town Centre (UTC) dermatology clinic.
2. Criteria for enrolment consists of the following: age 18 years or older with postoperative defects of at least 3 cm, resulting from either Mohs micrographic surgery or surgical excision at the West Virginia University dermatology clinic. Those eligible will be willing to give informed consent and return for follow-up visits 3 months and 6 months following surgery. Patients will be excluded if they are pregnant, unable to understand English, mentally impaired, incarcerated, or have nonlinear closures.
3. Potential subjects who meet criteria and express interest will be given a written consent form at the WVU UTC dermatology clinic by study personnel prior to enrolling in the study.
4. Potential subjects will be verbally informed of all pertinent information regarding the study. They will be given ample time to ask questions and make an informed decision as to whether or not they wish to enroll in the study.
5. Patients undergoing multiple surgical repairs on the same visit can include up to three closures in the study.
6. Each closure will be assigned a study number.
7. Surgeons of varying experience levels (i.e. attending, fellows, and residents) will be included in the study in order to increase external validity.
8. Wounds halves will be labeled as A (left/superior) or B (right/inferior), the halves will be randomized to receive either tissue glue or deep sutures. The nurse will refer to the randomization list and inform the surgeon which side of the wound will receive tissue glue and which side will receive deep sutures. Following common practice of wound labeling, side A will always be left or superior from the surgeon's perspective, whereas side B will always be right or inferior from the surgeon's perspective.
9. Per randomization, half of the wound will be closed with deep absorbable sutures followed by superficial non-absorbable sutures. The other half of the wound will be closed with superficial non-absorbable sutures followed by tissue glue (Dermabond). Tissue glue will be spread to cover an area extending one cm from the wound margin on both sides.
10. Patients will be instructed to use a cotton-tipped applicator to apply petroleum jelly only to the side of their wound without tissue glue two times a day for one week following surgery.
11. After suture removal, tissue glue will be re-applied to both halves of the wound.
12. We plan to enroll 70 wounds in the study in order to detect a difference of 4 on the Patient Observer Scar-Assessment Scale, since the scale is based on a 60-point system. We calculated that we would need to enroll at least 40 subjects using an assumed standard deviation of 7.6,

alpha of 0.05, and a power of 90. However, due to the length of the study we expect a dropout rate of approximately 40%.

13. Wounds will be evaluated at 3 month and 6 month follow-ups. These time points were chosen due to the ability to see differences in surgical interventions at these time points, while differences in surgical interventions are more difficult to distinguish over time. In addition, study quality will decrease over time since patients will be more likely to drop out of the study.
14. The efficacy of intervention methods will be assessed at the 3 month and 6 month follow-ups by having the patient and two blinded observers rate the healing progression of the wound using the POSAS. The observers will be either dermatology faculty or dermatology. The POSAS is a standard metric in measuring wound healing in cutaneous surgery studies since it does not require training but takes into account the scar assessment of the patient and observers. Subsequently, the height and width of the scar will be measured and compared to the surrounding unaffected skin. The assessments of the two blind observers will be averaged. Data will be managed using REDCap, a World Wide Web-based data collection page. All adverse events and any complications will be consistently monitored and recorded for each side of the scar.
15. After the patients have their scar observed at the 3 month and 6 month follow-ups, they will be financially compensated for their travel and participation in the study. Patients will be paid $50 for each visit, potentially earning a total of $100 for their participation in the study. This money will be provided by funds from the WVU Department of Dermatology. Patients will be asked to provide their Social Security Number and verification of U.S Citizenship or Permanent Resident Status to receive payment.
16. We will use a paired Wilcoxon test to compare the mean POSAS scores for the two wound closure techniques at 3 and 6 months after surgery. To compare differences in scar height, width, and depth between the two closure techniques at the 3 and 6 month follow-ups paired Wilcoxon tests will be used. McNemar tests will be used to calculate differences in the proportion of scars with measurable heights and depths between the two wound closure techniques. This will help account for instances where patients have a scar height and depth of zero. R statistical computing software will be used to run statistical analyses (R Foundation for Statistical Computing, Vienna, Austria). The intent-to-treat principle will be used to compute the study outcomes.