**PROTOCOL TITLE:** Adhesive Strips in Dermatologic Surgery: Is Cosmetic Appearance Improved?

## 1) Protocol Title

Adhesive Strips in Dermatologic Surgery: Is Cosmetic Appearance Improved?

## 2) Author of Protocol

☒ **UC Davis Researcher**
☐ **Researcher from other institution**
☐ **Private Sponsor**
☐ **Cooperative Group**
☐ **Other: _____**

## 3) IRB Review History*

n/a – this is an initial submission

## 4) Objectives*

To determine whether the addition of adhesive stripping to a wound closed with dermal sutures improves outcome of wound closure. We hypothesize that the combination of adhesive strips to a wound closed with dermal sutures does not add significant cosmetic improvement of the resultant scar.

## 5) Background*

Much has been published regarding adhesive stripping in comparison to suturing, acrylate adhesives, and staples as single closure methods for small incisions. However, little is known regarding the effect of adding adhesive strips to larger wounds that are already closed by dermal suturing. Regardless, the combination of suture closure and adhesive strips has evolved into a well accepted method of wound closure based primarily on anecdotal evidence. There is a single study that does examine the outcome of combination closure with absorbable subcuticular sutures and adhesive strips compared to absorbable subcuticular closure alone in foot procedures. This study showed no clinical benefit of adding adhesive strips but despite this, a combination approach with adhesive strips remains common clinical practice. We also feel that we can improve upon the structure of this previous study which used alternate day allocation instead of true randomization and did not assess the quality of the scar. We propose a randomized prospective study examining the cosmetic outcome of combination closure of scars with dermal sutures and adhesive strips compared to dermal sutures alone when repairing dermatologic surgery defects.

References:

-Gkegkes ID, Mavros MN, Alexiou VG, Peppas G, Athanasiou S, Falagas ME. Adhesive strips for the closure of surgical incisional sites: a systematic review and meta-analysis. Surg Innov. 2012 Jun;19(2):145-55. doi: 10.1177/1553350611418989. Epub 2011 Sep 16.

-Kolt JD. Use of adhesive surgical tape with the absorbable continuous subcuticular suture. ANZ J Surg 2003; 73 :626-629.
-Vaughan P, Haworth J, Humphrey J, Dega R. Optimal closure of surgical wounds in forefoot surgery: are adhesive strips beneficial? Acta Orthop Belg. 2006 Dec;72(6):731-3.

## 6) Inclusion and Exclusion Criteria*

All potential participants will be approached by a study staff member at the time of their appointment in the clinic to avoid direct recruitment by their care provider in the clinic. In order to avoid coercion, participants will not be approached by the PI about participating in the study. Instead, the research coordinator will determine if patients are considering participating as a first step. Subsequently, one of the physicians will discuss the consent form Inclusion/Exclusion criteria.

Inclusion Criteria:

- 18 years of age or older
- Able to give informed consent themselves
- Willing to return for follow up visit.

Exclusion Criteria:

- Mentally handicapped
- Unable to understand written and oral English
- Unwilling to return for follow up
- Wounds less than 3 cm in length
- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers 17 and under)
- Pregnant women
- Prisoners

All data will be analyzed in an intention to treat manner, so that results have greater external validity and less potential for bias. We will also perform a per protocol analysis, from which patients will be excluded if their steri strips remain in place less than 4 days. Metrics regarding all wound complications will be recorded including: dehiscence, infection, hematoma, seroma, suture abscesses, etc.

## 7) Study Timelines*

The study will be conducted in the UC Davis outpatient dermatology clinic. We anticipate collecting data over 3 month's time. A research participant will present for their initial surgery, the time for which will be determined by their surgical indication (generally a maximum of one day for Mohs) and then at the 3 months (+/- 10 days) for standard of care follow up, wound measurements, and photographs. We anticipate that the follow up visits (including wait times) will not exceed one hour.

## 8) Procedures Involved*

The authors wish to conduct a split-scar comparison study with the half of the wound closed with buried subcuticular sutures and overlying adhesive strips and half the wound closed with buried subcuticular sutures alone. All body areas may be included in the analysis, with treated wounds on facial, genital and acral areas. We would use buried dissolving subcuticular sutures for both sides of the wound to approximate wound edges and then steri-strips for the adhesive stripped half of the scar and no closure material for the second half. Patient's wounds would be randomized using a randomization list as to which side of their wound receives which treatment; a randomizing program will be used based on atmospheric noise (random.org) to assign a side (A, left/superior) or (B, right/inferior) randomly to with adhesive stripping or without adhesive stripping. The treatment allocation will be determined prior to study onset and the assignments kept in opaque folders. A nurse will be asked to be the arbiter of these to assure allocation is not biased. Digital images of all wounds would be taken immediately after the closure, and again at approximately 3 months (10 day window around this time would be allowed). The images would be used for evaluation and possibly for publication or presentation purposes in both future scientific publications and meetings. The Patient and Observer Scar Assessment Scale (POSAS) will be used to qualitatively and quantitatively evaluate the cosmesis of both adhesive stripped and non-adhesive stripped aspects of the wounds. This instrument has been validated in several trials and is the only one that includes patient input as part of its assessment. The scar area for each side will be calculated using tracing paper to sketch out the area of the scar. This will be done by two observers. These sketches will be later scanned and measured with software. The area will also be computed from digital photographs by two blinded investigators. All complications and adverse events would be monitored and recorded for both sides of the scar. Assessment of the scar will be blinded in nature. The scars will be measured at follow up points, and two blinded investigators will then assess the scar at these time points. The blinded investigators at each follow-up interval need not be the same, though this will be our goal. The

patient will also be asked to fill out the POSAS validated questionnaire evaluating the scar characteristics at follow-up.

Prior to study recruitment staff will all be trained on how to apply steristrips using mastisol adhesive.

## 9) Data Management*

Digital images of all wounds will be taken immediately after the closure, and again at approximately 3 months (10 day windows around these follow up times would be allowed). Unique identifiers will be used for all images. Images will be stored on an encrypted computer and also uploaded to the redcap webbased database system. All other data will be stored in the redcap database system with access limited to approved research personnel. All data downloaded for analysis will be done without personal identifiers. Consent forms will be stored in a locked cabinet in the clinical trials unit. Tracing paper sketches of scar area will be stored in a binder in the research until they can be scanned. The scanned file will be uploaded to the redcap database and the paper copy then shredded. Only research staff listed on the protocol will have access to the data.

All research data collected will be retained for at least three years and destroyed thereafter.

## 10) Provisions to Monitor the Data to Ensure the Safety of Subjects*

Other than questionnaires and/or surveys, all procedures are standard of care. Provisions to monitor subject safety will be consistent with UCDHS Patient Care Standards. Incidence of infection, dehiscence and bleeding will be recorded and monitored

## 11) Withdrawal of Subjects*

There is no risk to study withdrawal to the patient.

We do not anticipate withdrawal of any subject in this study without their consent.

In the case of subjects withdrawing themselves from the study, no continued data collection will be undertaken.

## 12) Risks to Subjects*

The primary risk is that one side of the scar may not look the same as the other. We will offer revision if this occurs. In two prior studies using this split scar model, no patients requested revision, indicating a relative low likelihood of adverse outcomes.

## 13) Potential Benefits to Subjects*

There is no direct benefit to individual subjects or to the group of participants in the study.

## 14) Vulnerable Populations*

Targeted population will include patients as research subjects. Patients will not be encouraged or coerced to participate. We will make them aware of the study taking care to note participation is optional.

## 15) Setting

The subject population will include patients who present to the principle investigator and co-investigators for surgical excision of the skin at the Department of Dermatology and who consent to participate in the study.

Subjects unable to give consent themselves will not be included in the study. All potential participants will be approached by a study staff member at the time of their appointment in the clinic to avoid direct recruitment by their care provider in the clinic. Consent will be obtained as outlined in questions 14 and 15. Subjects unable to give consent themselves will not be included in the study. In order to avoid coercion, participants will not be approached by the PI about participating in the study. Instead, the research coordinator will determine if patients are considering participating as a first step. Subsequently, one of the physicians will discuss the consent form and take consent.

## 16) Resources Available

The study will be coordinated by the investigators. The investigators will include: Drs. Daniel Eisen, Thomas King, Kenny Omlin, and Trenton Custis as well as the dermatology residents at UC Davis, Sarah Fitzmaurice, Anabella Pascucci, Jayne Joo, Larissa Laren, Renu Behal, Cynthia Chambers, Shurong Chang, MaryAnn Johnson, April Armstrong, and Oma Agbai. This research will take place at the UC Davis Dermatology Clinic, 3301 C Street Sacramento, CA. The procedures to be examined in this study are regularly performed, therefore the clinic's resources will be sufficient.

## 17) Recruitment Methods

On any given day, patients who present to the UC Davis Department of Dermatology for surgery will be gauged for their interest in participating in the study by the research coordinator. If the patient is amenable to participating, they

will be consented prior to their scheduled surgical procedure with sufficient time given to review the consent form.

We do not plan to advertise this study, as the patient population in are department will produce sufficient opportunities to identify patients.

Subjects are not compensated for participation in this study.

## 18) Local Number of Subjects

48 subjects will be recruited as suggested by an a priori power analysis using a paired t test with enough power (>90%) to detect a difference of 5 on a 60 point scale, assuming a standard deviation of 11 and a confidence level of 5%. This calculation includes an assumption of a 10% drop out rate.

## 19) Confidentiality

3 digit numerical identifiers will be used for all images. Images will be stored on an encrypted computer. All other data will be stored in the redcap database system with access limited to approved research personnel. All data downloaded for analysis will be done without personal identifiers. Consent forms will be stored in a locked cabinet in the clinical trials unit. Only research staff listed on the protocol will have access to the data.

All research data collected will be retained for at least three years and destroyed thereafter.

## 20) Provisions to Protect the Privacy Interests of Subjects

In order to protect the privacy interest of subjects researchers will consider the characteristics of the vulnerable populations involved if any and reassess procedures that my introduce coercion or bias. Interaction or intervention with subjects will occur in a location offering adequate privacy. Subjects will be adequately informed of the risks of breach of confidentiality. Subjects will be reassured that all information will be properly stored with access only to appropriate research personnel. Research staff shall have the appropriate training as to the appropriateness of accessing any sources of information about the subjects. Subjects will be given opportunities before, during, and after the study to ask questions.

## 21) Compensation for Research-Related Injury

The surgical procedures performed in this research study are routine standard of care and covered under UCDHS patient consents for minor procedures. Injuries related to standard of care will be addressed in a manner consistent with UCDHS policies.

## 22) Economic Burden to Subjects

There are no additional costs to subjects for their participation.

## 23) Consent Process

As described previously, potential subjects are identified in clinic on the day of their schedule routine care. Potential subjects are given the opportunity to review the consent form and ask questions before the start of any research procedure. Subjects will review consents and ask questions in a private setting (a clinic room or the research coordinator's private office). Subjects will be given a copy of their signed consent.

Non-English Speaking Subjects

Non-English speaking subjects will be excluded,

Vulnerable population patients will be excluded.

## 24) Process to Document Consent in Writing

We will be following SOP: Written Documentation of Consent (HRP-091).