Scar appearance after hydrocolloid dressing versus petrolatum ointment: a randomized control trial

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1.0 Background and Introduction:

Cosmetic satisfaction has become increasingly important in modern era especially for elective surgical procedures(1). While postoperative scarring is inevitable, improved scar treatment and prevention has the potential to improve a patient's health-related quality of life (2). Although there are multiple scar assessment scales, but five most frequently used scales are: Vancouver Scar Scale (VSS), Visual Analogue Scale (VAS) and Patient and Observer Scar Assessment Scale (POSAS), Manchester Scar Scale (MSS) and Stony Brook Scar Evaluation Scale (SBSES)(3).

We will be using a Visual Analog Scale (VAS) for our study. For this study scar assessment will be performed by review of photographs to allow for inclusion of a larger group of assessors and eligible patients than would be possible with in-person assessment. The patient will also be asked to provide assessment based on these parameters. Evaluators will be physicians including medical students, residents, fellows, and attending surgeons.

Our main aim of this study is to evaluate the difference in cosmetic outcomes for patients whose post-operative wound was treated with hydrocolloid dressing vs petrolatum ointment (Vaseline) after excision or Mohs surgery for cutaneous malignancy or other cutaneous conditions that require surgical intervention. Scar cosmesis will be assessed using the VAS.

2.0 Objective:

2.1 Primary Objective

1) To determine the difference in scar cosmesis using a hydrocolloid dressing vs petrolatum jelly after Mohs surgery or conventional excision.

2.2 Secondary Objective:

2) To compare the complication rate in patients using a hydrocolloid dressing vs petrolatum jelly after Mohs surgery or conventional excision.

3.0 Outcome measures:

3.1 Primary outcome measure:

- Both the patient and external evaluators (residents, Mohs fellow, other surgeons) will score the outcome of the scar based on the VAS. External evaluators will assess and score the scar by reviewing a high-quality photograph taken 7 days, 30 days and 90 days after surgery.

3.2 Secondary outcome measure:

- Complication rate including hematoma, seroma, wound infection requiring antibiotics, opening and drainage of wound, dehiscence. Complications will be assessed by physicians other than operating surgeon.

4.0 Eligibility Criteria:

4.1 Inclusion Criteria:

1) Adult > 18 years of age
2) Linear scars
3) Patients underwent conventional excision or Mohs micrographic surgery for primary cutaneous cancer or other cutaneous condition that required surgical intervention

4.2 Exclusion Criteria:

1) Age < 18 years of age
2) Scar localization on acral or hair bearing sites
3) Patients unable to converse in English
4) Patients requiring flap or graft for closure of wound
5) History of allergy to adhesives
6) Patient using topical chemotherapy agents on the surgical site or planning to start it within 3 months after surgery
7) Use of hydrocolloid dressings for post-operative wound care in the past

5.0 Study Design:

- Subjects >18 years of age admitted to the Indiana University Department of Dermatology for an excisional surgery by Dr. Syril Keena Que

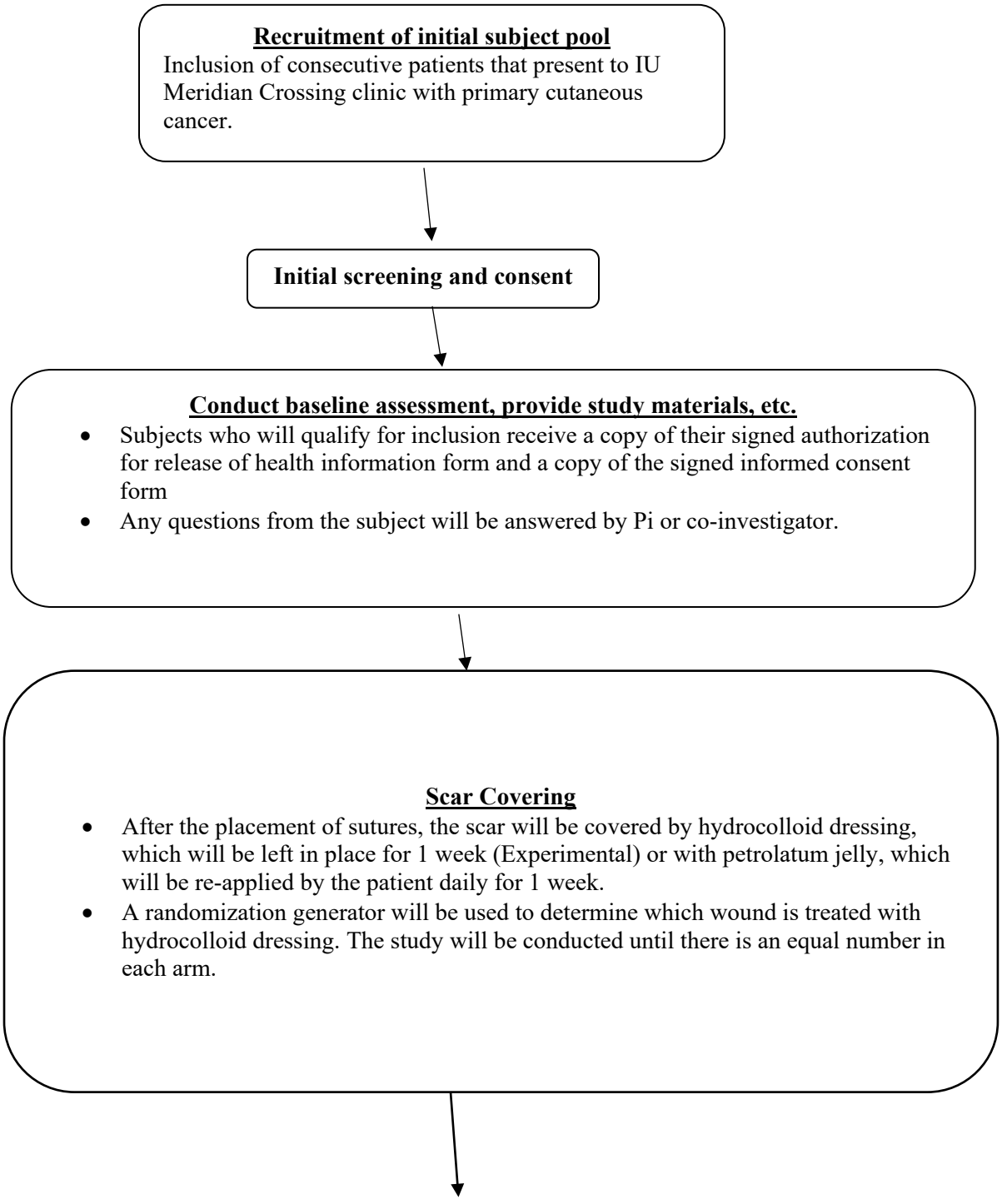
- After informed consent is signed, patients will be randomized either to receive standard daily dressing or hydrocolloid dressing using a randomization generator. After closing the wound with the sutures, the scar will be covered by a hydrocolloid dressing, which will be left in place for 7 days (Experimental) or the standard dressing (Control) that will be covered with petrolatum jelly and bandaging during this time period, which has to be re-applied daily.

- Patients will be followed up at 7, 30 and 90 days after surgery for photographic scar evaluation by multiple physicians.

- Variables recorded: name, DOB, sex, contact information, primary cutaneous condition diagnoses, anatomic site, pathologic report, postoperative scar length, postoperative complications, patient VAS scores, and external evaluator (physician or medical student) VAS scores. External evaluators will be blinded as to the side treated with hydrocolloid dressings. One week after undergoing the procedure, patients will be contacted over the phone by study staff (other than the primary surgeon) and will be asked for their responses to the Modified Bluebelle Questionnaire. Version 1 of this questionnaire is for patients who received conventional dressing and version 2 for patients who received hydrocolloid dressing. Patients will be given the option to mail back a paper version of the completed survey, if they prefer.

- Data will be captured in Redcap and exported in excel file for statistical analysis.

- Statistical tests: Will be performed with the assistance of an experienced biostatistician.



Scar Assessment

A follow-up assessment will be conducted **7 days, 30 days AND 90 days after** the surgery. Patients will be given VAS assessment questionnaire and the modified bluebelle questionnaire on the day of surgery, will be contacted via phone at specific time periods. Clinicians will evaluate the scar outcome through the use of high-quality photographic images.

6.0 Enrollment/Randomization

Participants will be identified by their general dermatologists as candidates for excision or Mohs surgery. After a discussion of risks, benefits, and alternatives, if the patients choose to undergo surgical excision via conventional excision or Mohs, they will be given the option to participate in this study. After explaining the study, patient consent will be taken on the day of surgery.
One week after surgery, patients will be followed up either in clinic or contacted over the phone to fill the VAS questionnaire. Patients will also be given an option to complete the questionnaire via email, if they prefer.

All surgical procedures and physical interventions will be conducted as part of standard clinical care. The only element performed as part of research is collection of survey data relating to scar assessment and satisfaction.

7.0 Reportable Events

All adverse events or deviations of the protocol will be documented as per date, reason and all deviation will be presented to the clinical trials team and communicated to the IRB committee as required per institutional policies and federal regulations.

8.0 Data Safety Monitoring

This is a minimal risk study and data will be stored in a secure database to ensure patient privacy and confidentiality.

9.0 Study Withdrawal/Discontinuation

Patients may withdraw from the study at any time on the day of their procedure by letting their nurse or surgeon know they no longer wish to participate. Incomplete surveys will be collected and destroyed. Patients may be withdrawn from the study if they meet any exclusion criteria that were not immediately apparent at time of enrollment.

10.0 Statistical Considerations

Statistical power will be set at 0.80 with an assumed effect size of 0.2. With an alpha value of 0.05, the study will require 100 patients to achieve this statistical power. A 95% confidence interval will be used to determine significance.

Any feasible potential outliers have been identified and will be included in the survey and statistical analysis. Statisticians will provide ongoing assistance with data analysis throughout the study.

11.0 Statistical Data Management

Primary data will be collected on REDCap and Excel with the survey administered in office via tablet or a paper version. Phone interviews will be conducted as mentioned timelines after the surgery, with patients given the option to complete the survey via email if they prefer. Medical records will be assessed, and data will be stored electronically in REDCap and Excel on the Dermatology Department Server. The storage location will be backed up manually every week. Other data sources include data from the Cerner medical record system, which will be incorporated into the Excel sheet or REDCap workbook, as needed. Quality assurance steps will include: testing of database by study team prior to moving to production mode. The following quality control methods will be used: extraction and cleaning of data that will be used for analysis every 3 months.

12.0 Privacy/Confidentiality Issues

All patient identifying information (name, MRN, phone number, skin cancer type, date of surgery, etc.) collected in this study will be deidentified prior to data analysis. All written records will be converted to a computerized database and subsequently destroyed.

13.0 Follow-up and Record Retention

Data will be collected for 5 years after patient enrollment, beginning on or after July up until 1 years after the last patient is enrolled or until study termination. Data will be entered into a computerized database on a rolling basis as it is collected. Written records will be destroyed.

14.0 References

1. Corrado G, Calagna G, Cutillo G, Insinga S, Mancini E, Baiocco E, et al. The Patient and Observer Scar Assessment Scale to Evaluate the Cosmetic Outcomes of the Robotic Single-Site Hysterectomy in Endometrial Cancer. Int J Gynecol Cancer. 2018;28(1):194-9.
2. Huang LC, Chen DZ, Chen LW, Xu QC, Zheng ZH, Dai XF. The use of the Scar Cosmesis Assessment and rating scale to evaluate the cosmetic outcomes of totally thoracoscopic cardiac surgery. J Cardiothorac Surg. 2020;15(1):250.
3. Fearmonti R, Bond J, Erdmann D, Levinson H. A review of scar scales and scar measuring devices. Eplasty. 2010;10:e43.