Research Protocol

HREC No:	**HREC/13/QPCH/69**
Protocol Name:	**Pilot Study: Adhesive silicone foam dressing versus meshed silicone interface dressing for the management of skin tears: a comparison of healing rates, patients' and nurses' satisfaction.**
Protocol version number:	**V4**
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Aim:

To compare the two skin tear products described above to determine which dressing achieves the best overall healing.

The hypothesis is that one of the dressings advantages verses disadvantages, in comparison to the alternative will result in improved healing outcomes.

Objectives:

To objectively quantify 3 key outcomes associated with each dressing:

1. Healing rates: flap quality, epithelial and granular regeneration
2. Dressing 'fit for purpose': ease of application, integrity, and exudate management
3. Patient experience: pain and comfort, affect on daily activities, overall satisfaction

Purpose

The main purpose of this study is to compare the two standard treatment options (dressings) in terms of their skin tear healing times. Secondary aims are to assess nurses' satisfaction with the dressings (fit for purpose) and patients' satisfaction (comfort etc.)

Design

The design is a randomised observational study of TPCH patients sustaining upper limb skin tears.

RESEARCH PLAN

Participants

All patients who have sustained a skin tear on their arm, during the specified data collection period, will be eligible to participate. Participants must be able to provide informed consent and be aged 18 years and over. They must also have the ability to re-attend a clinic a maximum of 3 times over the subsequent 3 weeks should they be discharged from hospital within the evaluation period. These clinics will be conducted at either the Australian Catholic University (ACU) Health Clinic (Approach Road Banyo QLD 4014) or The Prince Charles Hospital (TPCH) Day Investigations and Therapy (DUIT) Unit (Rode Road Chermside QLD 4032).

Inclusion criteria

- Skin tears occurring on the arms
- Skin Tear STAR category 1A, 1B, 2A, 2B, 3
- Skin tears equal to or less than 100 cm^2 area

Exclusion criteria

- Skin Tear that are older than 72 hours
- Skin tears occurring on other parts of the body
- Patients unable attend follow-up
- Patients with uncontrolled bleeding

- Patients with a clot beneath the skin flap which is unable to be evacuated

Sample size

A consecutive, convenience sample of 126 adults (aged 18 or over) will be recruited. Because there were no relevant data available, it was necessary to estimate a sample size based on the expected effect size. This was achieved by applying Cohen's convention values. An α level of 0.05 was selected for this study, with a power level of 0.80 with a medium estimated effect of 0.50. These values determined the sample size estimate of n = 63. As there are 2 arms to the study, the required sample size is 126.

Recruitment

While no definitive incidence data are available, based on TPCH experience, around 6 new skin tears are reported on the upper limbs weekly. Thus, it is estimated that data collection would need to occur over a minimum 21 week period. However, in order to allow for a 30% refusal to participate rate, the planned recruitment period will be 28 weeks.

Recruitment will occur following referral made to the TPCH Wound/Stomal Therapy Service for a skin tear. Each potential participant will be provided with an information letter by a researcher, explaining the study. Those who agree to participate will be required to provide written consent.

Randomisation

A random number generator will be used to allocate participants to the 2 treatment arms:

- Treatment Arm 1: Adhesive Silicone Foam Dressing (Mepilex Border).
- Treatment Arm 2: Meshed Silicone Interface Dressing (Mepitel or Mepitel One).

Data Collection

Baseline data will be collected when the skin tear is first assessed and dressed (T1). Follow-up data will be collected at 7 days (T2), 14 days (T3), and 21 days (T4) or until the Skin Tear has healed. Participants who are not in-patients at T2-T4 will be required to attend either the ACU Health Clinic or TPCH DUIT Unit, dependent on clinic availability.

Baseline data (T1)

The following data will be recorded:

- Participant demographics: age, gender, disease category (ICD code), co-morbidities
- Skin tear description: location (site, left/right/, arm dominance), time since occurrence, cause of tear, acquired at home/in hospital, skin flap quality, wound size and percentage flap cover (plenimetry), condition of surrounding skin.
- Skin tear classification: STAR category and Payne-Martin classification (See Appendix 1)
- Dressing 'fit for purpose': ease of application, conformity
- Patient experience: pain (visual analogue scale)

Follow-up data (T2-T4)

The following data will be recorded:

- Baseline data (excluding demographics)
- Wound healing: skin flap take: % revascularised, % new epithelial tissue, % granulation tissue
- Dressing: dressing change frequency over previous week (reason), dressing integrity, exudate management, ease of removal
- Patient experience: dressing comfort (Likert scale), impact on daily activities i.e. shower/bath, dressing, domestic activities, sleeping (Likert scale)

Data analysis

All data will be entered into SPSS Version 19 for analysis. Descriptive statistics will be used to describe the sample and inferential statistics will be used to analyse differences and relationships in the data. Significance is set at $p<0.05$.

Appendix 1

Skin Tear Classification

Payne-Martin classification system

This system categorises skin tears into three main groups with two subgroups within the first two categories. These subgroups deal with the skin flap type or the skin flap loss.

- Category I: Ability to approximate the wound borders, no tissue loss (type A = linear; type B = flap)
- Category II: Varying amounts of tissue loss (type A = scant tissue loss <25%; type B = moderate tissue loss >25%)
- Category III: Complete tissue loss.

STAR classification system

This is an Australian-validated consensus system developed by nurse experts in wound management. It was developed because skin tears vary widely in appearance at the time of injury and during the healing process. The system categorises skin tears into three main groups with two subgroups within the first two categories. However, the subcategories in the first two classifications only relate to the health quality of the skin flap and not the flap type (linear or flap) or the percentage of tissue loss:

- Category I: A skin tear where the edges can be realigned to the normal anatomical position without undue stretching (type A: the skin or flap colour is not pale dusky or darkened; type B: the skin or flap colour is pale dusky or darkened)
- Category II: a skin tear where the edges cannot be realigned to the normal anatomical position (type A: the skin or flap colour is not pale dusky or darkened; type B: the skin or flap colour is pale dusky or darkened
- Category III: a skin tear where the skin flap is completely absent