Research Study protocol

Study Title:

Evaluation of commercially available heel pads for the prevention of pressure ulcers: An observational study of incidence and usability in adult surgical patients.

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List of abbreviations

Pressure ulcer	**PU**
Standard deviation (*s*)	**SD**
Visual skin assessment	**VSA**
Subepidermal moisture	**SEM**
Royal College of Surgeons in Ireland	**RCSI**
Skin Wounds and Trauma	**SWaT**
Length of stay	**LOS**
Systematic Review	**SR**
European Pressure Ulcer Advisory Panel	**EPUAP**
National Pressure Injury Advisory Panel	**NPIAP**
Pan Pacific Pressure Injury Alliance	**PPPIA**
Nursing and Midwifery Board of Ireland	**NMBI**
Odds Ratio	**OR**
Confidence interval	**CI**
Data Protection Officer	**DPO**
General Data Protection Regulation	**GDPR**
Data protection impact assessment	**DPIA**
Primary Investigator	**PI**

1. Project Summary

Title:	Evaluation of commercially available heel pads for the prevention of pressure ulcers: An observational study of incidence and usability in adult surgical patients.
Short title:	Heel pads for pressure ulcer prevention.
Phase 1 Clinical investigation design and methods:	This is a multiphase research study with two phases. **Phase 1 with patient participants: Observational prospective study.** Phase 2 with staff participants: Qualitative useability study using semi-structured interviews with multidisciplinary theatre staff. Plans for phase 1 are outlined below:
Primary Objective:	To measure the incidence of heel Pressure Ulcers (PU) with Sub-Epidermal Moisture (SEM) assessment and Visual Skin Assessment (VSA) in a cohort of surgical patients whilst on the Oasis Elite Heel Pad (EL130).
Primary Endpoint	A determination of the incidence of heel PU development among the study participants measured with SEM assessment and VSA and to measure the change in hourly SEM delta values intraoperatively while using the heel pad.
Secondary Endpoint	(1) To measure the change in hourly SEM delta values intraoperatively while using the heel pad. (2) To measure the length of time it takes for a PU to develop during the study 3-day follow-up period.
Main inclusion/exclusion criteria:	**Inclusion criteria**: Consenting adults ≥18 years, admitted for elective surgery, with a planned length of stay 72 hours following the operation. Participants with a planned length of stay <3 days and with a planned surgical position that does

	not require heel pads intraoperatively (i.e., prone position) will be excluded.
Phase 2 Clinical investigation design and methods:	**Phase 2 with staff participants: Qualitative useability study using semi-structured interviews with multidisciplinary surgical theatre staff.** Plans for phase 2 are outlined below:
Primary Objective:	To explore the usability, acceptability, and perceived value of the heel pad among different multidisciplinary theatre staff for PU prevention.
Primary outcome **Secondary outcomes**	A comprehensive understanding of staff perceptions regarding the usability, acceptability, and perceived usefulness of the heel pads for intraoperative PU prevention. (1) Identification of key usability issues, contextual barriers, and facilitators influencing the adoption and sustained use of the heel pads. (2) To explore the usability, acceptability and perceived value of the heel pads among different multidisciplinary theatre staff for PU prevention.
Main inclusion/exclusion criteria:	Different members of the multidisciplinary surgical theatre team using the heel pads will be eligible to participate in the semi-structured interviews. Healthcare professionals working in theatre during phase 1 data collection will be involved if they volunteer.
Phase 1 Statistical methodology and analysis	During phase 1, PU incidence will be calculated as the number of new SEM and VSA PUs observed during the study period, divided by the number of at-risk participants (those without a PU at the anatomical site at baseline), multiplied by 100 (Beaglehole et al. 2006). The 95% confidence interval (CI) will be calculated using the binomial proportion method.

Clinical investigation duration per participant: Total number of participants planned:	Incidence rate = $\frac{Number\ of\ participants\ with\ new\ PUs}{Number\ of\ at-risk\ \ participants}$ *x100* Each consenting participant will undergo SEM assessment and VSA once pre-operatively, hourly intraoperatively, and then daily postoperatively for 72 hours. Analyses will be conducted according to the intention-to-treat (ITT) principle for observational studies (Olijnyk et al. 2022), whereby all participants who consent and are enrolled will be included in the final analysis regardless of study completion. Data collected up to the point of discharge or withdrawal (if these occur prior to 72 hours) will be retained and incorporated into the incidence calculations. Sample size will be calculated using the formula for estimating a proportion, as described by Lwanga & Lemeshow (1991): n= $\frac{Z^2 \times p \times (1-p)}{d^2}$, where Z=1.96 for a 95% CI, p is the expected incidence (2%), and d is the desired margin of error (5%). As this study focuses on patient safety and PU prevention with the heel pads, the expected PU incidence will be 2%, with a 95% CI and a 5% margin of error, the required sample size will be 31 participants. Thus, to account for drop out, a total of 35 participants will be recruited.
Phase 2 Statistical methodology and analysis	A thematic analysis will be undertaken during phase 2 following Braun and Clarke's (2006; 2022) thematic analysis framework.

Clinical investigation duration per participant:	Interviews will be conducted with approximately 15 different members of the multidisciplinary surgical theatre team that have used the heel pads intraoperatively for participants recruited during phase 1.
Total number of participants planned:	A sample size of approximately 15 different members of the multidisciplinary surgical theatre team will be selected based on recommendations in the qualitative research literature (Hennink & Kaiser, 2022), indicating that 9-17 interviews per group or 4-8 focus group discussions are typically sufficient to reach data saturation and ensure rich, nuanced insights for usability studies. Once data sufficiency / saturation has been reached, the recruitment for phase 2 will be complete.
Estimated total clinical investigation duration:	Study conduct, analysis and write up will be completed within a 12-month timeframe for both phase 1 and 2; **Months 1-3:** Ethical approval submission and hospital site preparation/training. **Months 4-8:** Data collection (4 months) **Months 9-12**: Data analysis, write-up
Planned sites:	**Single site**, Connolly Hospital Dublin.

2.Background and rationale

Pressure ulcers (PU) are localised areas of tissue damage arising due to excess pressure and shearing forces, ranging in severity from superficial tissue damage, to a cascade of cell and tissue damage involving multiple interacting pathways (EPUAP, NPIAP & PPPIA, 2025). PU's occur most often in individuals who have activity or mobility problems, and are exposed to prolonged periods of sustained pressure/shear forces (Coleman et al, 2013). Approximately 4% of Europe's annual healthcare budget is spent on PU's, with PU development increasing the length of hospital stay, readmission and mortality rates (EPUAP & EWMA, 2019; Posnett et al. 2009). PUs have substantial impact on affected individuals as wounds can become seriously infected, with pain being one of the most commonly cited complaints (Moore, 2017). Given PU seriousness, early detection and prevention is essential (Moore et al., 2017).

Early detection enables early intervention when the damage remains microscopic and reversible (Gefen, 2018). In clinical practice, visual skin assessment (VSA) is the gold standard method used to detect PUs, which relies on subjective parameters such as skin colour changes, which is challenging as deep tissue necrosis may occur before surface visibility (Gefen, 2018). PUs that develop early in the post-operative period links back to the pressure/shear the individual is exposed to in the interoperative period (Schoonhoven et al.2002). Further, the timing from the early PU development phase to the manifestation as a visible injury, ranges from 7 hours, up to 3 to 5 days before a PU is visible on the skins surface (EPUAP, NPIAP & PPPIA, 2019). Gefen et al. (2020) denotes that intraoperatively acquired PUs can be identified up to 72 hours following surgery. Gefen (2009) describes two pathways: superficial lesions (friction/shear/moisture) versus deep tissue injury from sustained pressure over bony prominences, necessitating advanced screening methods (Quintavalle et al., 2006; Ohura et al., 2007).

Subepidermal moisture (SEM), a biophysical marker of plasma leakage from inflammation, which can be detected before naked-eye visibility (Gefen & Gershon, 2018). A systematic review found SEM detects PUs 4.61 days earlier than VSA (95% CI: 3.94-5.28; p=0.0001) (Moore et al., 2022). In surgical populations, SEM

outperforms traditional methods (Martins de Oliveira et al., 2022; Wilson et al., 2024a, 2024b), measured via Provizio® SEM scanner (section 4.5.3). PU incidence remains high intraoperatively, emphasising the importance of preventative interventions during surgery (Martins de Oliveira et al. 2022; Wilson et al. 2024a).

Targeted PU prevention interventions significantly reduce risk, demonstrating lower SEM delta values (MD: 0.49; 95% CI: 0.59, 0.39; p<0.0001) versus standard care (Byrne et al., 2022). Heel offloading devices have shown to significantly reduce stage I heel PUs by >50% in orthopaedic wards (Koh et al., 2018). This study aims to measure heel PU incidence with both SEM assessment and VSA among surgical inpatients using Oasis Elite Heel Pads (EL130) (section 4.5.2), exploring multidisciplinary theatre staff perceptions of usability, acceptability, and value.

3. Objectives, endpoints and outcome measures

Phase 1 with patient participants: Observational prospective study.

3.1 Research aim and objective

The aim of this research is to determine the incidence of PU at the heels, detected with SEM assessment and VSA among adult surgical inpatients using the heel pad. The study will not require a change to standard of care as the heel pads are already in use at the site.

Objective: To measure the incidence of heel PU with SEM assessment and VSA in a cohort of surgical patients whilst on the Oasis Elite Heel Pad (EL130).

3.2 Primary outcome

To report the incidence of SEM and VSA detected PUs at the heels among adult surgical inpatients using the heel pad.

3.3 Secondary outcomes

1. To observe the hourly SEM delta values intraoperatively while using the heel pad.

2. To observe the length of time it takes for a PU to develop at the heels during the intraoperative and postoperative period (three days following surgery).

3.4 Study endpoints

Primary endpoint: A determination of the incidence of heel PU development among the study participants measured with SEM assessment and VSA and to measure the change in hourly SEM delta values intraoperatively while using the heel pad.

Secondary endpoints: (1) To measure the change in hourly SEM delta values intraoperatively while using the heel pad. (2) To measure the length of time it takes for a PU to develop during the study follow-up period (3 days following surgery).

Phase 2 with staff participants: Qualitative useability study using semi-structured interviews with staff.

3.5 Research aim and objectives

The aim of this research is to explore the usability, acceptability, and perceived value of the heel pad among different multidisciplinary surgical theatre staff for PU prevention. Specific objectives are below,

- Identification of key usability issues, contextual barriers, and facilitators influencing the adoption and sustained use of the heel pad.
- To explore the usability, acceptability, and perceived value of the heel pads among different multidisciplinary theatre staff for PU prevention

3.6 Primary outcome

A thematic synthesis of multidisciplinary surgical theatre staff's qualitative perceptions on the heel pad's usability, acceptability, and perceived value for intraoperative PU prevention, derived from semi-structured interviews

3.7 Secondary outcomes

1. Identification of key usability issues, contextual barriers, and facilitators influencing the adoption and sustained use of the heel pads.

2. Insights into necessary design or workflow improvements for optimal integration of the heel pad in clinical practice.

4.Study design

This is a multiphase research study with two phases. Phase 1 with patient participants: Observational prospective study. Phase 2 with staff participants: Qualitative useability study using semi-structured interviews with multidisciplinary surgical theatre staff.

Phase 1: Observational prospective study.

4.1 Research population

Early detection of PUs starts with identifying patients “at risk” of PU development. PUs directly linked to the operating room are as high as 45% (Bulfone et al. 2012 & Schoonhoven et al. 2002). Because of this evidence, a convenience sample of surgical patients will be included. Patients during surgery are immobile, positioned on a generally hard surface area, and are unable to feel the discomfort caused by both pressure and shear forces that accompany a surgical operation (EPUAP, NPIAP & PPPIA, 2019). All surgical populations demonstrate an “at risk” category of patients in relation to PU development.

4.2 Follow-up

Participants will be followed-up for 72 hours, with SEM assessment and VSA performed hourly during the intraoperative period, and daily during the postoperative period for 72 hours. All assessments will be performed at both heels only. The heels are among the predominant anatomical locations for PU development among this cohort of patients (Oliveira et al. 2017).

Participants will have a baseline assessment carried out once prior to their surgery, which will occur either on the day prior to their surgery, or the morning prior to their surgical procedure (depending on their pre-operative admission day). The participant will be followed-up for 3 days in total following their surgical operation.

4.3 Inclusion, exclusion and withdrawal criteria

4.3.1 Inclusion Criteria:

- Adult patients (≥18 years);
- Admitted pre-operatively for elective surgery;
- Planned surgery duration ≥1 hour
- Anticipated / planned length of stay of 3 days;
- Informed consent to participate.
- Intraoperative Oasis Elite Heel Pads (EL130) used/planned for routine PU prevention

4.3.2 Exclusion Criteria:

- Patients undergoing emergency surgery
- Patients with a planned surgical position that does not require heel pads intraoperatively (i.e., prone position)
- Anticipated / planned Length of stay <3 days at study enrolment
- Visual pressure ulcer at baseline present on both heels.
- Patients unable to provide informed consent.
- Not using the Oasis Elite Heel Pads (EL130) intraoperatively

4.3.3 Withdrawal Criteria:

- Patients who wish to withdraw from the study at any time during the course of this study.
- Patients will be withdrawn from the study whereby it is ethically or clinically indicated – reasons for this will be clearly documented.

4.4 Sample size

The sample size will be 35 patient participants in total. This sample size represents 70 SEM assessment and VSA measures for each observation (once pre-operatively, hourly intraoperatively, and once 24, 48 and 72 hours post-operatively). Each participant will have one SEM assessment and VSA measure for each heel, during each observation.

4.4.1 Calculated sample size explanation

Sample size was calculated using the formula for estimating a proportion, as described by Lwanga & Lemeshow (1991): n= $\frac{Z^2 \times p \times (1-p)}{d^2}$, where Z=1.96 for a 95% CI, p is the expected incidence (2%), and d is the desired margin of error (5%).

As this study focuses on patient safety and PU prevention with the heel pad, the expected VSA PU incidence will be 2%, with a 95% CI and a 5% margin of error, the required sample size will be 31 participants. Thus, to account for drop out, a total of 35 participants will be recruited.

4.5 Devices and assessment tools

4.5.1 Oasis Elite Heel Pads EL130

The heel pad is the Oasis Elite Heel Pads (EL130) (Trulife Limited, Airton Road, Tallaght, Dublin 24, Ireland) (Appendix 1) Trulife (2026). These Class I, reusable, non-sterile heel pads assist patient positioning during surgery by supporting the achilles tendon thereby distributing pressure away from the heel area and across a larger surface area to reduce the risk of PU development. Participants can lie directly on the heel pad or with a loosely fitted, unstarched sheet free of wrinkles or folds interposed between the patient and heel pad to eliminate direct contact.

The Oasis Elite Heel Pads (EL130) have been on the global market for over 28 years and are exempt from FDA 510(k) submissions. The Oasis Elite Heel Pad (EL130) is constructed of medical grade silicone and polyurethane flexible foam, covered in a polyurethane film that forms the patient-contacting surface.

4.5.2 Visual skin assessment

A visual assessment of the skin will be carried out and the results will be reported using the NPUAP, EPUAP & PIPPA (National Pressure Ulcer Advisory Panel, European Pressure injury advisory panel and Pan Pacific Pressure injury alliance) PU classification system (Appendix 2).

4.5.3 Provizio® SEM Scanner

The Provizio® SEM scanner (Bruin Biometrics, LLC, Los Angeles, California) is a hand-held, non-invasive device (Appendix 3), which is placed over an at-risk anatomical area and the moisture level of the subepidermal tissue is measured through the use of electrode structures placed on the surface of the skin (Bates-Jensen et al.2017). This device provides a reading after touching the skin for a few seconds, which enables the user to determine the presence or absence of inflammation, which is a precursor to tissue damage (Moore et al.2017).

Using a 4-7mm of depth (depending on anatomy examined), fluid contents of both the epidermis and subdermal tissues are assessed (Okonkwo et al. 2020). Four measurements in total are collected from each heel. These measurements enable an accurate assessment of the distribution of moisture from the underlying anatomy, finally a singular SEM reading for each heel examined is provided. This score is calculated as the mathematical difference between the highest and lowest reading (otherwise known as deviation) recorded at each individual site. This single reading is known as the “delta” value. Normal delta readings, which correspond to a low risk of PU development, are measurements of <0.6. Thus, a delta of 0.6 and above, corresponds to an increased risk of more severe PU.

Both SEM assessment and VSA will take approximately 30 seconds to complete.

4.5.4 Cleaning of equipment

The Provizio® SEM scanner will be disinfected according to the manufacturing instructions, and aligned with the Hospital sites infection prevention and control policy. Mandatory high standard of hygiene techniques will be employed prior to assessment and following each participant to ensure patient safety.

Phase 2 with staff participants: Qualitative useability study using semi-structured interviews with multidisciplinary surgical theatre staff.

4.6 Research population

Interviews will be conducted with approximately 15 different multidisciplinary surgical theatre staff involved in the surgery of participants recruited in phase 1 that have used the heel pad intraoperatively.

4.7 Semi-structured interviews

1:1 Interviews will be held in-person in a private room at the hospital site. Interviews will last no longer than 30 minutes, will be guided by a semi structured interview guide and will be recorded and transcribed. Measures will be systematically implemented to enhance rigor and trustworthiness during semi structured interviews, guided by Lincoln and Guba's (1985) four principles of credibility, transferability, dependability, and confirmability. The semi structured nature of 1:1 interview will ensure the discussion remains focused but at the same time allowing flexibility for issues of importance in relation to usability, acceptability, and perceived value of the heel pad to be elaborated on by participants.

4.8 Inclusion, exclusion and withdrawal criteria

4.8.1 Inclusion Criteria:

- Multidisciplinary surgical theatre staff using the heel pad intraoperatively
- Multidisciplinary surgical theatre staff working in theatre during the phase 1 data collection period
- Informed consent to participate.

4.8.2 Exclusion Criteria:

- Multidisciplinary surgical theatre staff that have not used the heel pad intraoperatively
- Multidisciplinary surgical theatre staff that were not involved in the surgery of participants recruited from phase 1.

4.8.3 Withdrawal Criteria:

- Multidisciplinary surgical theatre staff who wish to withdraw from the study at any time during the course of this study.

4.9 Sample size

A sample size of 15 different multidisciplinary surgical theatre staff that volunteer to participate will be selected based on recommendations in the qualitative research literature (Hennink & Kaiser, 2022), indicating that 9-17 interviews per group or 4-8 focus group discussions are typically sufficient to reach data saturation and ensure rich, nuanced insights for usability studies. Once data sufficiency / saturation has been reached, the recruitment for phase 2 will be complete.

4.10 Anticipated Study Duration for Phase 1 and 2

Study conduct, analysis and write up will be completed within a 12-month timeframe;
Months 1-3: Ethical approval submission and hospital site preparation/training.
Months 4-8: Data collection
Months 9-12: Data analysis, write-up

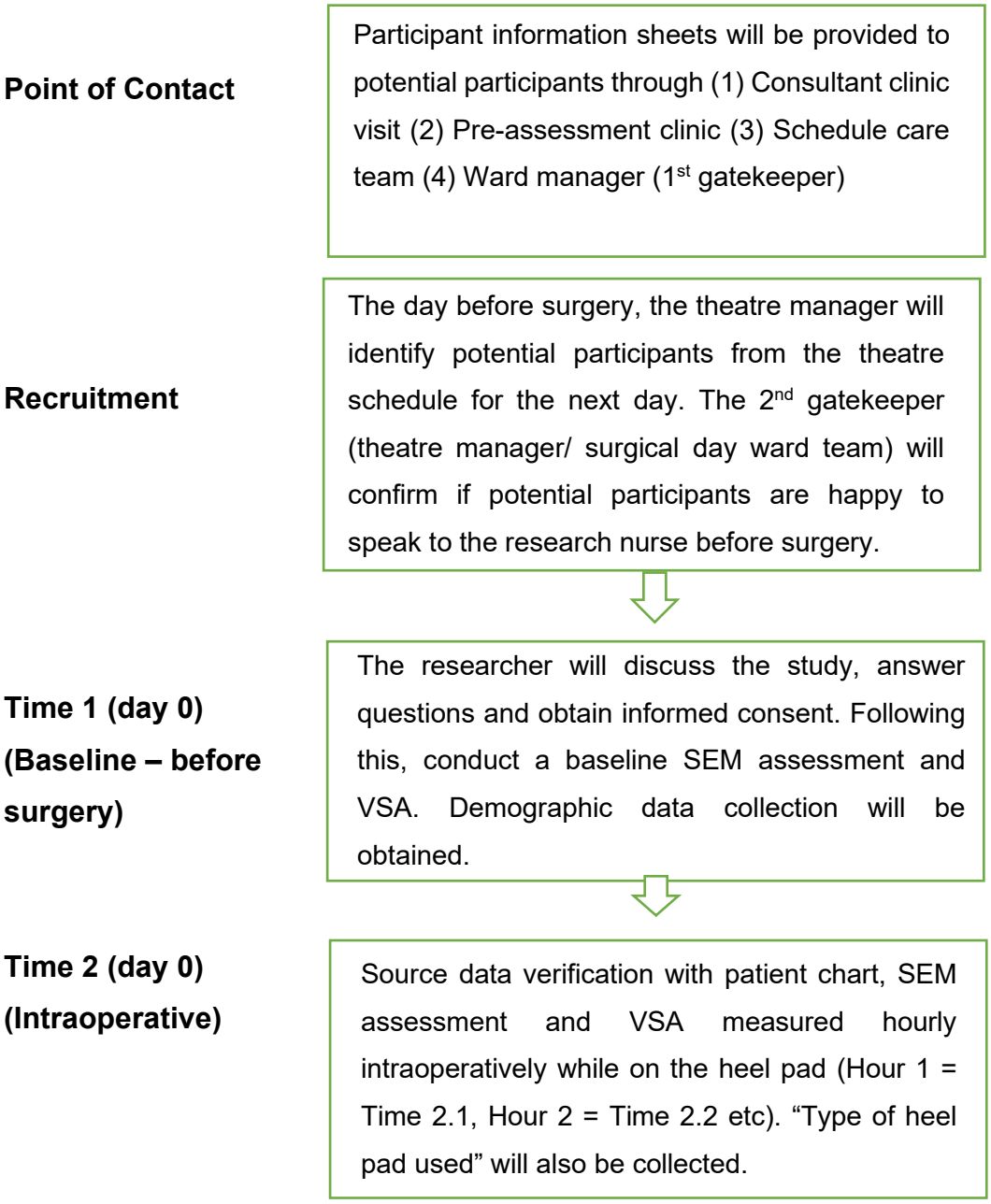
4.11 Pilot study

The pilot study will confirm the sample size calculation, test the feasibility of the population, recruitment and data collection methodology. The sample size will account for 10% of the total 35 patient participants in phase 1. Therefore, the first 4 patient participants recruited into the study, will be included in the pilot study (Burns & Grove 2005).

5.Treatment of study subjects (phase 1)

Figure 1 below illustrates the process to seek participant's consent and subsequent data collection.

Figure 1: Flowchart to support recruitment and data collection



Time 3 (day 0) (Immediately postoperative)

Source data verification with patient chart, SEM assessment and VSA postoperatively. Final demographic data collection "time spent in surgery" will be collected postoperatively on day 0.

Time 4 (day 1) (24 hours postoperative)

Source data verification with patient chart, SEM assessment and VSA.

Time 5 (day 2) (48 hours postoperative)

Source data verification with patient chart, SEM assessment and VSA.

Time 6 (day 3) (72 hours postoperative)

Source data verification with patient chart, SEM assessment and VSA.

5.1 Informed consent process

Key guidelines and legislation that underpin this consent process are:

- Article 29 – Guidelines on consent under Regulation 2016/679- revised and adopted 10/04/18
- National consent policy (2019)
- NMBI Code of Professional Conduct and Ethics (2025)
- Charter of fundamental rights of the European Union (2012) Official Journal of the European Union. (2012/C326/02).
- General Data Protection Legislation (GDPR) 2016

- European Treaty Series (1997) - Convention on Human Rights and Biomedicine. (European treaty series No. 164, 1997 chapter II consent)
- Council of Europe (2005) - Additional Protocol to Convention on Human Rights and Biomedicine Concerning Biomedical Research" (European treaty series No.195, 2005) with particular reference to the articles 6 ("Risks and Benefits") and 15 ("Protection of Persons not Able to Consent to Research").

5.1.1 Step 1. Point of contact

Potential patient participants will be identified in a number of ways;

(1) **Consultant clinic visit**: Participant information sheets will be provided to the relevant consultant secretaries for distribution to potential participants scheduled for surgery at the hospital site.

(2) **Pre-assessment clinic:** Participant information sheets will be provided to pre-assessment staff for distribution to potential participants during their pre-assessment clinic visit, which takes place before surgery.

(3) **Schedule care team:** Connolly hospital's schedule care team will provide patient information sheets to potential participants scheduled for surgery.

(4) **Ward manager:** Ward managers will provide information sheets to patients that have been scheduled for preoperative admission, 24 hours or more before the planned elective surgery.

When the patient visits the consultant in clinic or pre-assessment clinic prior to their surgery, patients that are suitable for inclusion will be given an information sheet, which describes the study outline. Similarly, patients suitable for inclusion that are scheduled for surgery will be provided with the information sheet by the schedule care team. The information sheet contains the name of the individual they can contact for further information on the study and who can answer any questions pertaining to the study that they may want to ask prior to coming into hospital. Additionally, patients admitted preoperatively before their planned elective surgery will be provided with a patient information sheet by the ward manager. There will be a time interval of no less than 24 hours, between giving information and seeking consent from the participant.

5.1.2 Recruitment. Patient attending hospital for preoperative admission for elective surgery

The day before the surgery during the theatre huddle, the theatre manager will identify potential participants from the theatre schedule for the following day. When the patient arrives to the hospital setting for admission for their elective surgery, the theatre manager or surgical day ward team, will ask the patient if they have chosen to participate in the research study. If they indicate a willingness to be involved, the researcher will then be invited to speak with the participant and begin the recruitment process (protocol section 5.1.3 obtaining consent). Once the recruitment process has been completed, a baseline assessment will be conducted. The baseline assessment will take place in a dedicated cubical in either the surgical day ward or pre-operative theatre holding bay area.

5.1.3 Step 3. Obtaining consent

When the participant agrees to take part in the study and agrees they feel sufficiently informed, the researcher will collect informed consent in the following way:

1. Maintain the participant's privacy and keep the area around the cubical closed. Invite the family or friends of the participant to be involved if the participant wishes.
2. Having explained the participant information sheet in a way the participant can easily understand, to include the particular aspects of aims, methods, sources of funding, possible conflicts of interest, institutional affiliations, benefits and risks of participation, potential discomfort the participant may encounter and any further topics of interest, the researcher will answer any questions the participant or their family have.
3. The researcher will then go through the consent form in full, asking each question, with the participant including the specifics of GDPR.
4. If the participant answers yes to every question, the researcher will invite the participant to sign and date confirming their consent to take part.
5. The researcher will then also sign and date the consent form. One copy will be given to the participant, one placed in the medical notes and the original kept in the site file.

This consent process will be revisited and assessed daily when visiting the patient.

5.2 Data collection schedule

SEM assessment and VSA at both heels will take place before surgery, hourly during surgery, and for three days following surgery. The data will be collected by following steps 1-6 outlined below, each time a visit is made to the participant.

1. The researcher will introduce themselves to the participant and draw the curtains around the bed to offer privacy.
2. A family member and/or friend will be invited to come along if the participant wishes to be accompanied.
3. The researcher will then confirm the participant is wanting to proceed with the study and they are comfortable for the assessments to be undertaken.
4. The researcher will start by assisting the participant into a comfortable position.
5. A VSA will be performed at each heel to assess if there is a normal or abnormal appearance.
6. The researcher will then perform the SEM assessment by gently pressing the probe against the skin surface on both heels to give a reading. Four readings in total are collected from each heel. This assessment takes a few seconds to perform on each heel and does not hurt in any way.

These assessments will take approximately 30-60 seconds. The participants (or nearest relative/NOK) will be invited to ask questions at any time.

The researcher will be accessing the participants' medical notes while they are in the study. The research visit will be documented in the medical notes each day. The participants' personal information will be collected for the purposes of the research (i.e., name and date of birth) so that the researcher can make sure participants are followed up for the duration of the study. The following demographic information will be collected from the medical notes at the beginning of the study in order to place this research into context with the demographic profile of the participants involved. Further to this, collecting surgery type, position during surgery, time spent in surgery and type of heel pad used at the heels intraoperatively, will enable an understanding into whether these factors influence the time to developing a PU. Time spent in surgery will be collected following the surgical operation.

- Age

- Sex
- Skin tone
- Surgery type
- Position during surgery
- Time spent in surgery (defined as; the intraoperative period commencing from anaesthesia administration to arrival time into recovery.)
- Type of heel pad used at the heels intraoperatively

Research data will not be shared with the clinical care team or used for clinical care decisions

5.3 Vulnerability of research participants

5.3.1 Unconscious patients

Following a routine surgical operation, patients may be intubated and ventilated, post-operatively, as part of their recovery process. These patients are often extubated on day 0-1, however, this will vary depending on the stability of their condition post-operatively. In light of this, these participants are regarded as vulnerable, as they will be unable to express their decision to withdraw from the study during these particular periods of intubation.

5.3.2 Patients highly dependent on medical care

The researcher will always liaise with the intensive care unit (ICU), in order to carry out the assessment when the participant's skin is assessed as part of their routine ICU care by the ICU staff, so no unnecessary repositioning will be needed. Further, due to the variability in post-operative recovery, the researcher will always respect the families and staff when planning to collect data, and if the participant becomes unstable, the researcher will not perform the assessments as planned.

5.3.3 Vulnerability and consent

When the participant regains consciousness or leaves an area of high dependency, consent will be reviewed with the participant in order to continue their participation in the study, as soon as reasonably possible. The participants consent will always be re-established at each visit.

5.4. Treatment of study subjects (phase 2: Staff participants)

Point of contact: Theatre staff will be informed verbally by the theatre manager during staff team huddles, which take place each morning in each theatre before every list, or during staff education sessions (Monday to Friday 15-minute sessions). A printed copy of the patient information sheet will be available for potential staff participants. Potential staff participants will be informed to self-express interest to the research nurse directly if they volunteer to participate.

Recruitment and obtaining consent: Once the potential staff participant has expressed interest to participate, the research nurse will take the potential staff participant to a private area and discuss the patient information leaflet, confirming they have understood the information and what is involved. Following this, written informed consent will be sought before the interview is conducted. If the staff participant answers yes to every question on the consent form, the researcher will invite the participant to sign and date confirming their consent to take part. The researcher will then also sign and date the consent form. One copy will be given to the participant, and the original kept in the site file. Once informed consent has been obtained, a study ID will be provided to the participant.

Data collection: Staff will be asked to undertake a 1:1 semi-structured interview following a semi-structured interview guide. The interview will last no more than 30 minutes to discuss the usability, acceptability, and perceived value of the heel pad among different multidisciplinary surgical theatre staff for PU prevention. Interviews with staff will be conducted on the day of surgery at a time that suits the staff participants. While interviews will be conducted in person, they will be recorded on Microsoft teams. Once the interview is completed, a transcript will be downloaded and the recorded interview will be deleted. While the interview guide does not contain any questions related to personal identifiable data, any identifiable information that the participant may have disclosed during the interview will be redacted on the transcript as no personal identifiable information will be collected. No other activities will be taking place other than one 1:1 semi-structured interview.

6.Safety Reporting

6.1 Information on how safety will be ensured

The safety of the research participants is at the forefront of ethical research practice (WHO, 2020).

6.2 Risks

This is a very low risk study with no change to standard of care, and no harm is anticipated to the participants in this study. Participant privacy and dignity will be maintained at all times. The participant should not experience any discomfort during the assessments, however following a surgical operation they may be experiencing pain on movement. Thus, the researcher will ensure the patient is comfortable prior to the skin assessment. The participant will always be aware of their rights to decide not to participate in the data collection on any particular day, if they so wish for their heels not to be examined or if they want to withdraw from the study in its entirety.

6.3 Procedures for reporting adverse events

A note of attendance will be documented in the medical notes on each visit. The skin assessments conducted as part of this study are additional to, and do not replace or inform, standard clinical assessments or decision-making. If a visible PU has been identified during the VSA, this will be documented in the medical notes, and the healthcare team will be notified in accordance with hospital policy. The nursing team will also be informed in person to ensure appropriate clinical follow-up. All clinical management decisions, including the prevention and treatment of PUs, remain the responsibility of the usual care team and will be delivered in line with standard hospital practice.

This study does not direct or influence clinical care decisions. Patient participants will receive standard clinical care at all times, including during the three-day follow-up period. Participants will be informed of this in the Participant Information Leaflet and Informed Consent Form.

6.4 Follow-up

Participant healthcare is the responsibility of the Hospital site, medical and nursing staff, before, during and after this research study, to monitor the health of participants. Participation in this study does not alter the provision of standard clinical care.

7.Statistics

7.1 Data analysis

The data will be analyzed using descriptive and inferential statistics. Data management, screening for anomalous data, and data analysis will be performed using the statistical software SATA by Stata Corp for Mac version 13.0. A Microsoft office excel spreadsheet will be utilized to document and store the collected data. A Microsoft office word spreadsheet will contain the data codes for the main dataset (displayed as variable and consequent label within the dataset). The device used for data collection will be password protected and the data collection spreadsheet and the key for the codes used will be kept separately on the device.

Stata will facilitate data cleaning and run simple descriptive statistics as the data collection is proceeding. This will allow investigation and testing for missing or spurious data. The researcher will regularly review data during the data collection period, in order to ensure good practice as per the RCSI University of Medicine and Health Sciences guidelines with a reliable, up to date and robust dataset.

Qualitative data collected in phase 2 (staff participants) will be obtained from transcripts generated from Microsoft Teams recordings. These transcripts will be checked for accuracy before thematic analysis is undertaken (see section 7.5).

7.2 Point estimates

In order to reflect variability within the data set means and standard deviations will be displayed for continuous data. Percentages and counts will be generated for categorical data. Standard of error will be calculated, in order to express the level of variability within the sample if parametrically distributed. If data are non-parametrically distributed, interquartile ranges will be applied (Kirkwood & Sterne, 2003).

7.3 A determination of the incidence of heel PU development

The primary outcome of this study is "To report the incidence of SEM and VSA detected PUs at the heels among adult surgical inpatients using the heel pad. This is a "multivariate population", as data are captured on more than two variables (Kothari, 2004). For the purposes of this study, SEM assessment is the dependant variable and VSA is the secondary dependant variable, as this is the standard practice for assessing PUs.

Table 1: Assessment measure scales and variable types;

Variable type	Assessment measure	Data measurement scale
Dependant variable	SEM (0.2 - 4.0)	Interval **continuous** numeric data
Secondary dependant variable	VSA (6 categories)	**Ordinal** categorical data

P values will be expressed with each measurement relationship, a *p* value <0.05 will be regarded as statistically significant.

7.4 Confidence intervals for proportions or prevalence

During phase 1, PU incidence will be calculated as the number of new PUs observed during the study period, divided by the number of at-risk participants (those without a PU at the anatomical site at baseline), multiplied by 100 (Beaglehole et al. 2006). The 95% confidence interval (CI) will be calculated using the binomial proportion method.

$$\text{Incidence rate} = \frac{Number\ of\ participants\ with\ new\ PUs}{Number\ of\ at{-}risk\ \ participants} x100$$

Analyses will be conducted according to the intention-to-treat (ITT) principle for observational studies (Olijnyk et al. 2022), whereby all participants who consent and are enrolled will be included in the final analysis regardless of study completion. Data collected up to the point of discharge or withdrawal (if these occur prior to 72 hours) will be retained and incorporated into the incidence calculations.

A SEM PU will be defined as two sustained elevated SEM measurements over two consecutive days, on the same anatomical location (i.e., SEM delta value ≥0.6, which corresponds to an increased risk of PU development), among those who had a normal SEM reading pre-operatively. A VSA PU will be defined as a grade 1 – 6, identified through the NPUAP/EPUAP/PIPPA PU classification system.

7.5 Thematic analysis

A thematic analysis will be undertaken following the completion of 1:1 semi-structured interview with multidisciplinary surgical theatre staff in phase 2.

Focus group and interview data will be analysed using Braun and Clarke's (2006; 2022) Thematic analysis framework. A combination of an open coding procedure, derived from grounded theory (Glaser & Strauss, 1967; Strauss & Corbin, 1998), in which codes are generated from the 1:1 interview transcript, a priori coding will also be used. A priori coding gives a structure within which to commence coding and open coding allows the researcher to be open to other ideas that emerge and ensure that no data is omitted just because it doesn't fit a code. Themes that are generated by the data will be discussed and agreed amongst the research team.

8 Data handling and record keeping

8.1 Relevant personnel with respect to this chapter;

The RCSI University of Medicine and Health Sciences is organising this study, the sponsor (Trulife), as initiator of the study is the data controller and the hospital site is the data processor. The hospital site is the data controller for the participants' healthcare records. Data Protection officer (DPO): Main data controller is within the health service executive.

Data Processors:

- The nurse researcher: To be confirmed
- Academic PI: Dr Hannah Wilson
- Hospital site clinical PI: Mr Achille Mastrosimone
- Academic research team: Professor Declan Patton, Professor Tom O'Connor and Dr Pinar Avsar
- Expert by experience: Mr Declan Naughton
- Project manager: Dr Lone Bertelsen
- Hospital site gatekeepers: (1st gatekeeper) Surgical consultants at Connolly hospital. (2nd gatekeeper): Hospital site theatre manager (Orlaith Leane), or surgical day ward team (Rosamma Gomez CNM2 Cyrina Canning CNM1, Ciara O'Donohue Deputy staff nurse in charge).

8.2 Key guidelines and legislation that underpin this process

- Data Protection Act. 2018 (Section 36(2)) (Health Research) Regulations. S.I. No. 314.
- General Data Protection Legislation (GDPR) 2016

Data in this instance encompasses the methodology to obtain, analyse and interpret results gathered through research practice (IUA, 2019). The researcher is responsible for the use, storage, retention and preservation of data, through following robust research law and principles and supported by the RCSI University of Medicine and Health Sciences. Research integrity will be upheld through compliance with data protection legislation. Data will be fairly obtained and processed only in ways in which it was voluntarily consented for the purpose. Data will be stored safely and secure, kept only for the specified and lawful purposes. Data will be kept accurate and up to date and measures will be taken to ensure adequacy and relevance of data collection.

8.3 Phase 1 with patient participants:

In light of the follow-up methodology set out within phase 1 of this study, the participant must have their identifiable personal data collected, in order for the participant to be correctly followed on each visit. The researcher will collect this data in a pseudonymised manor, whereby the data collection entries collected during each visit to the participant, will be kept separate from the participant's personal information.

8.3.1 Data handling

The data handling process for this study will be carried out as follows;

- A study number will be used to identify each participant who is recruited into the study. This study number will be used within the main data collection method. The researcher will use a research dedicated device to store this pseudonymised data, in which a password protected excel spreadsheet will gain access into the main dataset. Further to this, the device will be locked away when not in use and a password will protect the opening of the device itself. A backup of this dataset will be made on OneDrive, with a further password protected access.
- Personal data will be stored safely, securely and separately from the main dataset on a separate computer file, in which key code password protected access can only be used to access the personal data, linked to the individual study number. Access will be restricted to only relevant persons and all data will be locked in a secure room.
- The investigator site folder will contain a copy of the main participant list and consent forms, which will be locked in a secure room and further placed in a locked cabinet that is both fireproof and waterproof. The researcher will liaise with the gatekeeper, in order to gain access to this documentation when required.

8.3.2 Data controls in place

- The personal data will be backed up in electronic and paper format, which will be kept separate, safe and secure. Only relevant individuals will have access to this documentation and the data protection officer of the hospital site will be aware of this process.
- The electronic data format will be kept separate from the main dataset; this will be kept on an encrypted password protected computer, in which only relevant persons would have access to this. The dedicated research device which contains the pseudonymised information, will be locked in a separate cupboard in a locked office, and keys will be held by the hospital site theatre manager.

- Documents kept on paper format (i.e., consent forms) will be stored in a locked fireproof and waterproof cabinet, stored within a locked office in a ward at the hospital site, to which keys will be held by the theatre manager (2nd gatekeeper).
- Data stored within the college will be kept securely in the RCSI University of Medicine and Health Sciences Microsoft OneDrive for Business, a university-approved secure cloud storage platform compliant with relevant GDPR standards, featuring encryption, access controls, and multi-factor authentication.
- If personal data requires alteration, consultation or erasing, it will be performed by two personnel and actions documented to ensure a trace of records.
- If data has been disclosed, the Data Protection officer will be made aware immediately of the breach in disclosure and an investigation will be made in order to understand how this has occurred and by whom.

In light of the limited access, enhanced safety and security of this data, the risk of unauthorised consultation, alteration, disclosure, erasure or breach of personal data is minimised in this instance.

8.4 Phase 2 with staff participants:

Phase 2 with staff participants involves brief, one-on-one semi-structured interviews with multidisciplinary surgical theatre staff to explore usability, acceptability, and perceived value of the heel pad for PU prevention. No personal identifiable information is collected, ensuring minimal data protection risks.

8.4.1 Data Collection Process

Staff participants will complete a single 30-minute interview on surgery day, at their convenience, using a semi-structured interview guide without identifiable questions. Interviews occur in person but are recorded via Microsoft Teams for accuracy; recordings are deleted immediately after an interview transcript has been produced.

8.4.2 Data Handling and Security

Transcripts will be downloaded to Microsoft OneDrive. Any incidental identifiable information disclosed by participants will be redacted from transcripts; no other data

or follow-up activities occur. A unique study number will be assigned to each staff participant instead of pseudonymisation, as no follow-up is required.

8.4.3 Data Control and Retention

The same data controls apply as in phase 1. Transcripts are stored securely for analysis only, with access limited to study team members. No data sharing beyond the clearly defined research team will occur.

8.5 Transfer of study data from the hospital site to RCSI

No identifiable data will leave the hospital study site. The researcher will carry the research device to the RCSI, this device will be is password protected and the relevant IT protection software will be installed for encryption and enhanced security. The research database which is in a password protected file on the device, will contain the electronic pseudonymised study dataset. This dataset will be backed up on a password protected OneDrive account, with two-factor authentication and password protected files. The transfer of study data will therefore be through sharing documents within the OneDrive account which is stored on a dedicated password protected folder within the RCSI and protected by RCSI institutional IT and Data Protection Security.

8.6 Data Processing

In order to ensure personal data are processed in a transparent manner, the following measures will be applied;

- Individuals will be informed about the collection and use of their personal data. Details of this will be contained in the information leaflets. This is in plain English and an opportunity for questions or to raise concerns will be given at the time of recruitment and at any stage of the study.
- The researcher will explain the purposes of collecting the data, the length of time the data will be retained and who the data will be shared with.
- In accordance with Irish Health Research Regulations and Irish Data Protection Law, data can be withdrawn up to the time up until the time of publication. The data subjects/family will have the contact number of the Principal Investigator, data controller and data protection officer, as this is clearly outlined on the

participant information sheet. Should they wish to have access to their personal data, this will be provided in a clear and readable format. Information will generally be provided in written form.

8.6.1 Data Minimisation: Phase 1 patient participants

The data collected will be adequate, relevant and limited to what is necessary for the purposes of this research, in compliance with the data minimisation principle. Please see below table 2, which displays the data to be collected and subsequent justification for data collection within this study.

Table 2: An explanation of demographic data collected for the purposes of this study.

Data type collected	Justification
Name and Date of Birth	This information is collected to enable participant follow-up during the study.
Age (years)	This information will further explain the demographic profile of the participants.
Sex (Male/Female)	This information will further explain the demographic profile of the participants.
Skin tone (Assessed using the Fitzpatrick phototype classification scale)	This information will further explain the demographic profile of the participants and account for known variations in PU risk and VSA accuracy across skin tones.
Surgery type	To understand whether surgery type influences the incidence of PU development.
Time spent in surgery (time/minutes)	To understand whether time in surgery influences the incidence of PU development.
Position during surgery	To understand whether the position during surgery influences the incidence of PU development.

Type of heel pad used at the heels	To understand whether the type of heel pad used during surgery, influences the incidence of PU development.

Further to this, information will be regularly reviewed and updated to meet standards of the law and good clinical practice guideline requirements. Any new uses of an individual's personal data will be brought to their attention prior to processing if appropriate. Informing the participant of these specific processes, will ensure patient and public involvement, further to this, feedback will be taken into consideration from the participant to ensure this method is most effective for its purpose.

8.6.2 Data Minimisation: Phase 2 Staff Participants

The data collected will be adequate, relevant, and limited to what is necessary for the purposes of this research, in compliance with the data minimisation principle. The semi-structured interview question guide is focused on exploring the usability, acceptability, and perceived value of the heel pad among multidisciplinary surgical theatre staff for PU prevention and no personal identifiable information is requested or required.

9.Retention of essential documents

The study data will be securely stored locally at the hospital site for the duration of the study and then destroyed, as required by law. Under section 2(1)(c)(iv) of the General Data Protection Regulations, data shall not be kept for longer than necessary and will therefore be destroyed once it is no longer needed. Data will be retained for seven years following study completion. Personal data collected in paper records (consent forms and key codes) will be stored for three years, after which time they will be destroyed by witness shredding by the study Gatekeeper. Where the data forms part of the patient's healthcare records however, the timelines listed in the NHO code of practice on Records management apply (2007) (part 5 retention and disposal schedule) as followed by the hospital policy).

The research database will be stored for a period of seven years and then deleted by the RCSI University of Medicine and Health Sciences IT department. This will ensure these records are available for scrutiny in the event of investigations of malpractice.

Therefore, these timelines will ensure the data will not be held for longer than necessary to fulfil the purpose for which it was originally collected.

10.Quality Control and Quality assurance procedures

This study will be monitored by both the RCSI University of Medicine and Health Sciences and the hospital site. The researcher's wider research team members will support and oversee the research process. Approval will be sought from the relevant theatre management staff, hospital research ethics committee and medical device committee for the study to be conducted within the hospital. The primary investigator will oversee the research process. The hospital sites data protection officer (DPO) will have reviewed the data impact assessment form (DPIA) and advised any recommended changes to the protocol, patient information leaflet and consent prior to study conduct. The DPO will provide oversight regarding all data handling, control and processing throughout the duration of this study.

Further to this, each healthcare professional to which this research will be impacting will be included in all communication and research decisions to ensure a cohesive methodology, that works to enhance patient care. This involves the consultants, wider medical team, clinical nurse managers and wider healthcare staff.

10.1 Research Data Practices and management

- Data will be recorded in a clear and accurate format.
- Research data will be kept in a secure and accessible form, retained for an appropriate length of time in accordance with national and institutional requirements.
- Clear governance and protocol will enhance the protection regarding the access of sensitive data.
- Original data will be authenticated to ensure protection against allegations of falsification of data.
- FAIR research principles will be adopted to research data as per the "National framework on the transition to an open research environment" (Government of Ireland, 2019) i.e. findable, accessible, interoperable and reusable.

The fundamental principles of good research practice will be upheld to ensure research integrity (The European Code, 2017);

- *Reliability* reflecting quality of research design, methodology, analysis and resources.
- *Honesty* through development, reviewing, reporting and communication of research evidence whereby the process and outcomes are transparent, full, fair and carried out within an unbiased format.
- *Respect* for research participants, colleagues, society, ecosystems, cultural heritage and the environment.
- *Accountability* for the research process from beginning to end, through management and organisation, training, supervision and wider influence.

This research framework embedded with good clinical practice guidelines and legislation, will aim to prevent research misconduct through a fair, transparent and effective process.

10.2 Training and Qualification of the research team members

All research and academic team members will be certified in Good Clinical Practice and will have attended GDPR Training provided by the RCSI University of Medicine and Health Sciences. The research team will be responsible and accountable for their practice under the Nursing and Midwifery Board of Ireland (NMBI) and subsequent nursing registration. Through this professional code of conduct and ethics, the fundamental principles of confidentiality, quality and dignity for the participant is upheld at all times during the research process. Therefore, all members of the research team will underpin the integral practice of research integrity.

11.Audits and inspections

In order to ensure the study meets best international research standards and practices, study records and source documentation may be assessed for audit purposes by the National Research Ethics Committee, hospital site's Institutional Review Board regulatory authorities such as the Data Protection Agency. Clear,

accurate records will always be maintained, enabling verification and replication of the research evidence.

The data protection officer will be inspecting and overseeing each phase of the data handling and controlling process to ensure a robust methodology is applied. The Chief clinical investigator will oversee the delivery of any amendments to this protocol. Regular meetings will be scheduled with the wider academic research team, to oversee and monitor the research process. The hospital site's infection prevention and control team will be inspecting and auditing the antiseptic cleansing process for all devices utilised within this study.

12.Ethics

12.1 Key guidelines and legislation that underpin the ethical conduct of this research;

- NMBI Code of Professional Conduct and Ethics for registered nurses and midwives (2025)
- Charter of fundamental rights of the European Union (2012) Official Journal of the European Union. (2012/C326/02).
- General Data Protection Legislation (GDPR) 2016
- Data Protection Act. 2018 (Section 36(2)) (Health Research) Regulations. S.I. No. 314.
- Convention on Human Rights and Biomedicine" (European treaty series No. 164, 1997)
- Additional Protocol to Convention on Human Rights and Biomedicine Concerning Biomedical Research" (European treaty series No.195, 2005)
- Declaration of Helsinki (WMA, 2013)

12.2 Ethics committee approval

Ethical approval will be sought from the National Research Ethics Committee, hospital site's ethics committee and the medical device committee prior to study conduct. Secondary approval and overview will be sought from the RCSI University of Medicine and Health Sciences research ethics committee in advance of the study.

12.3 Ethical Principles

Principles of good research practice must always be conducted in accordance with ethical principles, reflecting the RCSI University of Medicine and Health Sciences code of conduct, these four core principles will be upheld at all times throughout the study duration;

1. Act according to the highest ethical principles at all times
2. Demonstrate professional responsibility and behaviour
3. Develop and maintain a high level of competence
4. Be accountable for own actions and self-care

The standard international recognised ethical principles of autonomy, beneficence, non-maleficence, justice, veracity, fidelity and confidentiality will be maintained throughout the entirety of the research process (NMBI, 2025);

- **Autonomy** will be promoted through the informed consent process, involving the patient through expression of individuality, and reinforcing the patients right to withdraw from the study at any time throughout the duration of the study.
- **Beneficence and maleficence** The information sheet, will outline the purpose and nature of the research as well as its consequences and risks. During the recruitment process, the researcher will confirm the participant is fully informed through open discussion regarding the research, and all outstanding questions will have been answered to the satisfaction of the participant, prior to proceeding with the informed consent.
- **Veracity** will be reflected throughout this process whereby, data collection with participants will follow best practice with respect to the provision of adequate information to make an informed decision, provide informed consent, and understand anonymity, storage of data and the freedom not to participate or withdraw without consequences.
- **Justice** The recruitment of participants will take place pre-operatively only using established methodology. Participant information sheets will be written in simple, non-technical terms, to be easily understood by a layperson. Short words, sentences and paragraphs with clear subheadings and an appropriate font size, and in a format has been used to make the text manageable and readable. The tone is invitational and not coercive or persuasive.

- **Fidelity** Each research participant will be safeguarded, whereby his or her health, safety and welfare will be maintained throughout the entirety of the research process. Respect for equality and diversity of all individuals will be upheld through taking into account differing age groups, gender, culture, religion, ethnic origin and social class, and adapting communication and procedures to suit all participants involved.
- **Confidentiality** The researcher will maintain the confidentiality of all study documentation, and take measures to prevent accidental or premature destruction of these documents. The data collection forms will not have identifiable information. The researcher will have received training in Good Clinical Practice (GCP) and data protection training by the RCSI University of Medicine and Health Sciences. Given the researcher will be aware of the implications of this privacy breach, best efforts will be made to ensure that this does not happen. Once the researcher collects identifiable information it will be immediately placed in a locked filing cabinet. The researcher will maintain the confidentiality of all study documentation, and take measures to protect the collected data at all times.

13.Financing and Insurance/Indemnity

Both the hospital site and the RCSI University of Medicine and Health Sciences provide insurance indemnity. Under the RCSI University of Medicine and Health Sciences insurance policy, the researcher will be insured and indemnified. Evidence and proof of appropriate insurance is attached with this application. The researcher will also be employed as a research nurse within the hospital site.

13.1 Table 3: Providing breakdown of funding

Period of funded research (months)	12
Salary (study personnel)	€67,540
Equipment	€1,000
Overheads	€19,998
Travel / dissemination	€562
Consumables	€10,000
Other	€900

Total funding amount (over the research period)	€100,000

14.Clinical Study Report and publication policy

Health research serves as a driver for the development of policy and good clinical practice. Therefore, it is vital throughout the research process that clinical study reporting and publication policy is rigorous and transparent, to maximise the quality and dissemination of research evidence.

Publication and dissemination (section 2.7 of the European Code) - IUA 2019

- The author of the publication will accept full responsibility for the content, ensuring reflection of good clinical practice.
- All authors will have agreed on acknowledgements and sequencing of authorship, taking into account those who have contributed to the research design, data collection process as relevant, analysis and interpretation of results.
- The researcher will ensure open communication with both colleagues, wider healthcare institutions and the public (as appropriate), through providing transparent results, accurate information and making information available within a reliable timeframe.
- Confidentiality will be upheld through all published and disseminated content.
- Contributions of those who have influenced the research will be acknowledged.
- Conflicts of interests will be disclosed including with any funding bodies involved to ensure transparency and prevent bias through publication. Further to this, conflicts of interests will aim to be avoided were possible.

The “National framework on the transition to an open research environment” (Government of Ireland, 2019) denote that research data should be “as open as possible and as closed as necessary.” Therefore, through upholding the confidentiality of individuals, the research evidence can be used in order to stimulate further research evidence, enhance public knowledge and shape both policy and practice. Further,

these principles reflect the RCSI University of Medicine and Health Sciences publication policy and guidelines on Good Research Practice.

Conflict of interest

The study Sponsor Trulife will provide financial support for the conduct of this study. The hospital site has implemented the Oasis Elite Heel Pad (EL130) products into routine surgical pathways.

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16.Appendices

Appendix 1: Oasis Elite Heel Pads (EL130)



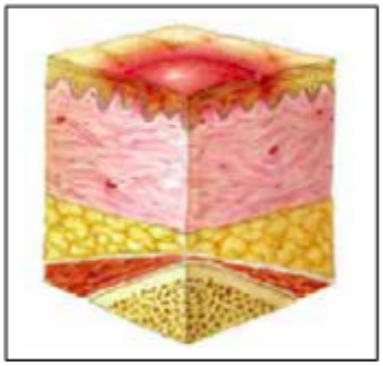
Note: Available from https://trulife.com/products/oasis-elite-heel-pads (accessed 02/12/25).

Appendix 2: NPUAP/EPUAP/PIPPA PU classification system

Category/Stage I: Nonblanchable Erythema

Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" individuals (a heralding sign of risk).

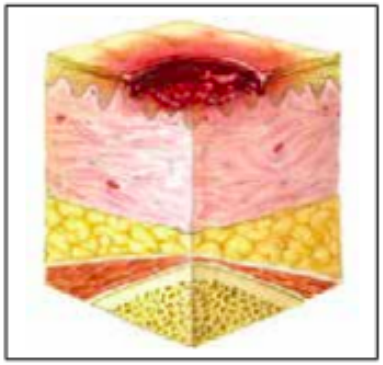


Category/Stage II: Partial Thickness Skin Loss

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

Presents as a shiny or dry shallow ulcer without slough or bruising.* This Category/Stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation.

**Bruising indicates suspected deep tissue injury.*



Category/Stage III: Full Thickness Skin Loss

Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.



Category/Stage IV: Full Thickness Tissue Loss

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

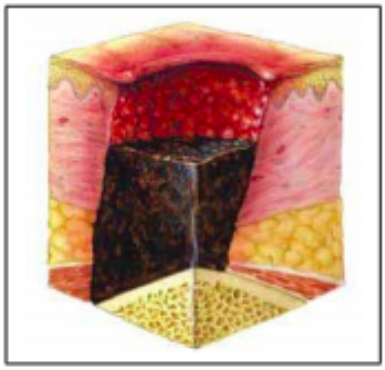
The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.



Unstageable: Depth Unknown

Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

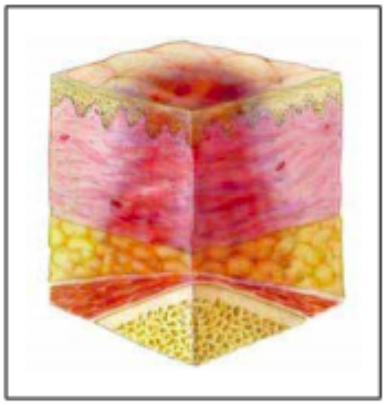
Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore Category/Stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as 'the body's natural (biological) cover' and should not be removed.



Suspected Deep Tissue Injury: Depth Unknown

Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.



Note citation: National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014

Appendix 3: The Provizio® SEM Scanner



Note: Available from https://sem-scanner.com/ (accessed 02/12/25)