Sponsor: Smith & Nephew

Negative Pressure Wound Therapy-PICO: Cosmesis in Repeat Cesarean Section

Device: PICO-7 Negative Pressure Wound Pump

NCT # 05266053

Document Date: 11/16/24

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Cosmetic Outcome of PICO-7 Dressing Compared to Standard Abdominal Dressing for Repeat Cesarean Section

ABSTRACT

Background and Objectives: This study was designed to compare cosmetic results in patients who have undergone repeat cesarean section through a Pfannenstiel skin incision when using a PICO-7 negative pressure wound dressing versus standard abdominal dressing postoperatively.

Methods: Twenty four English and Spanish speaking patients who underwent repeat Cesarean Section via Pfannenstiel skin incision from July 28, 2022 to January 4, 2023 at Eskenazi Hospital in Indianapolis, Indiana were enrolled. Patients were evaluated using the Patient and Observer Scar Assessment (POSAS) Scale at two, four and six weeks postoperatively. Healthcare providers were asked to fill out the Patient and Observer Scar Assessment Scale at the patients postpartum visit, which was between four to six weeks postoperatively.

Results: The median patient assessment scale and observer assessment scale (general) values were higher in the PICO group than in the standard abdominal dressing group at 2 weeks, equivalent at 4 weeks and lower at 6 weeks. There were no differences in the number of postoperative wound infections or readmissions, and there was 1 reported rash due to the adhesives in the PICO group that required it to be removed early.

Conclusion: Due to low recruitment and low response rate, this study as it currently stands cannot evaluate the PICO-7 dressing versus standard abdominal dressing. Because of the potential physical and psychological benefit of reducing complicated scar formation, further studies could be performed with a higher recruitment and follow up that would be able to provide information to determine if the PICO-7 versus other NPWT could be beneficial at improving patient's scar satisfaction after a repeat cesarean section.

Key Words: *Cesarean, POSAS, PICO, NPWT, cosmetic*

Disclosure: A portion of this study was supported financially by Smith and Nephew, the manufacturers of the PICO-7 NPWT device.

INTRO/Background:

There are millions of births each year with 32% of women undergoing cesarean sections (C-sections), which results in skin scarring. Repeat C-sections increased by 178% from 1979 to 2010. Given the frequency of C-sections, it is important to achieve a desirable cosmetic outcome. [1]

Pathological scars can result in functional impairment, disfigurement, a psychological burden, itch, and even chronic pain. All scars are at risk to develop into pathological scars, such as hypertrophic or keloid scars. [2] These types of scars can induce the need for long-term rehabilitation, revision surgery or other invasive therapies.

To reduce complicated scar formation, some have proposed the use of incisional negative pressure wound therapy (iNPWT). Although recent studies have shown certain limitations of the use of iNPWT, the general consensus remains that iNPWT helps to reduce surgical site complications such as infections and dehiscence in non-contaminated surgery. [3-5]

Furthermore, several studies have reported beneficial effects of iNPWT on scar development.[6, 7] The underlying mechanism is hypothesized to be the reduction of lateral wound tension. Excessive lateral tension is generally considered to be a factor in pathological scar formation, and reduction of incisional tension has previously been shown to result in more favorable scar outcomes.[13-16] Studies into the biomechanical properties of iNPWT demonstrated lateral tension reduction of the epidermis, fat, and muscle, supporting the hypothesis that negative pressure reduces sheer tension. In a recent systematic review by Zwanenburg et al., the conclusion was that there is a moderate level of evidence for clinically positive effects of iNPWT on scar outcomes in non-contaminated surgery. [7]

The PICO 7 dressing consists of a negative pressure wound therapy pump (NPWT) connected to an absorbent gentle adhesive dressing that is applied to a wound. When the pump is activated, it acts by pulling excess fluid from the wound. The dressing absorbs this fluid and helps to prevent bacteria from entering the wound.

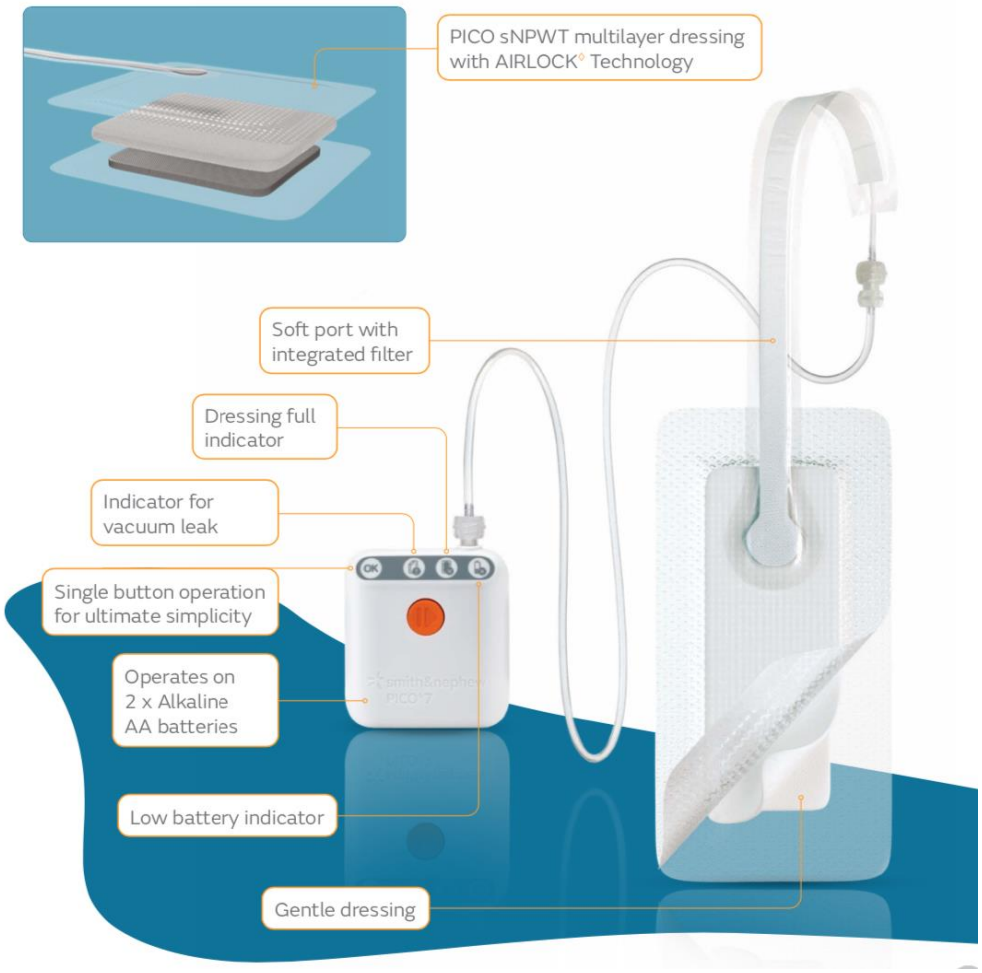


Figure 1: PICO-7 NPWT Device

Studies have been done using patient satisfaction scales to compare cosmetic outcomes of skin closure with tissue adhesive or staples in repeat cesarean section as well as cosmetic outcomes of cesarean section scar with subcuticular vs intradermal buried suture but none have been done to compare PICO

vs standard abdominal dressing.[8] The effect of negative pressure wound therapy on patients scar outcomes and quality has been studied for gender affirming chest masculinization surgery.[6]

Thus, this study aims to compare the aesthetic appearance by using The Patient and Observer Scar Assessment Scale (POSAS) scar assessment scale following closed incision negative pressure therapy with a PICO 7 dressing to the standard abdominal dressing in women undergoing repeat cesarean sections.

Methods:

Study design and participants:

This study was a single site, randomized controlled trial at a teaching hospital in Indiana for patients undergoing a repeat cesarean delivery. Participants were randomized using 1:1 block randomization to placement of a PICO-7 dressing or a standard abdominal dressing (generally telfa, ABD gauze dressing, tegaderm +/- steristrips) at the time of cesarean. The standard abdominal dressing was removed approximately on postoperative day (POD) 1-2 and the PICO-7 dressing was removed approximately on POD 3-4 (prior to discharge) or at POD7 in the office. If the patient with a PICO dressing remained inpatient for longer than 7 postoperative days, the PICO dressing was removed prior to POD7, in accordance with device instructions. The patients were given routine postoperative incision care instructions during their inpatient stay, which includes education per OB-GYN residents, attending staff, and nursing.

Participants in both groups were sent electronic POSAS surveys at the two, four and six week postop window with primary outcome being aesthetic appearance (cosmesis) at six weeks. Observers (healthcare providers) were asked to complete a POSAS survey at the postpartum visit (~4-6 weeks postoperative) to rate scar quality. Participants were offered compensation with a $25 Amazon gift card for participants who completed the requested follow up in the study. These were provided by Smith and Nephew.

The eligibility criteria is listed here as follows:

Eligibility Criteria

1.1 Inclusion Criteria-Patient

- Scheduled or non-labor repeat cesarean delivery
- One or more prior cesarean section(s) with prior pfannenstiel incision scar
- Gestational age > 23 weeks
- Age 18 and older

1.2 Exclusion Criteria-Patient

- Patients with malignancy in the wound bed or margins of the wound
- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar present
- Exposed arteries, veins, nerves or organs
- Exposed anastomotic sites
- Cellulitis or evidence of active infection
- Known allergy to adhesive tape
- Patient unwilling to follow-up
- Contraindication to NPWT
  - Bleeding disorder
  - Therapeutic anticoagulation
  - Allergy to any component of the dressing

- Prior irradiated skin

- Warnings to NPWT
  - The PICO 7 pump contains a Magnet that can cause other medical devices in close proximity to fail, leading to serious harm including death. The PICO 7 pump must be positioned at least 4 inches (10 cm) away from other medical devices that could be affected by magnetic interference. This applies to both patients and caregivers. These include but are not limited to:
    - Implantable cardioverter-defibrillator (ICD)
    - Pacemakers
    - Insulin pumps
    - Shunt valves
    - Neurostimulators
    - Cochlear implants

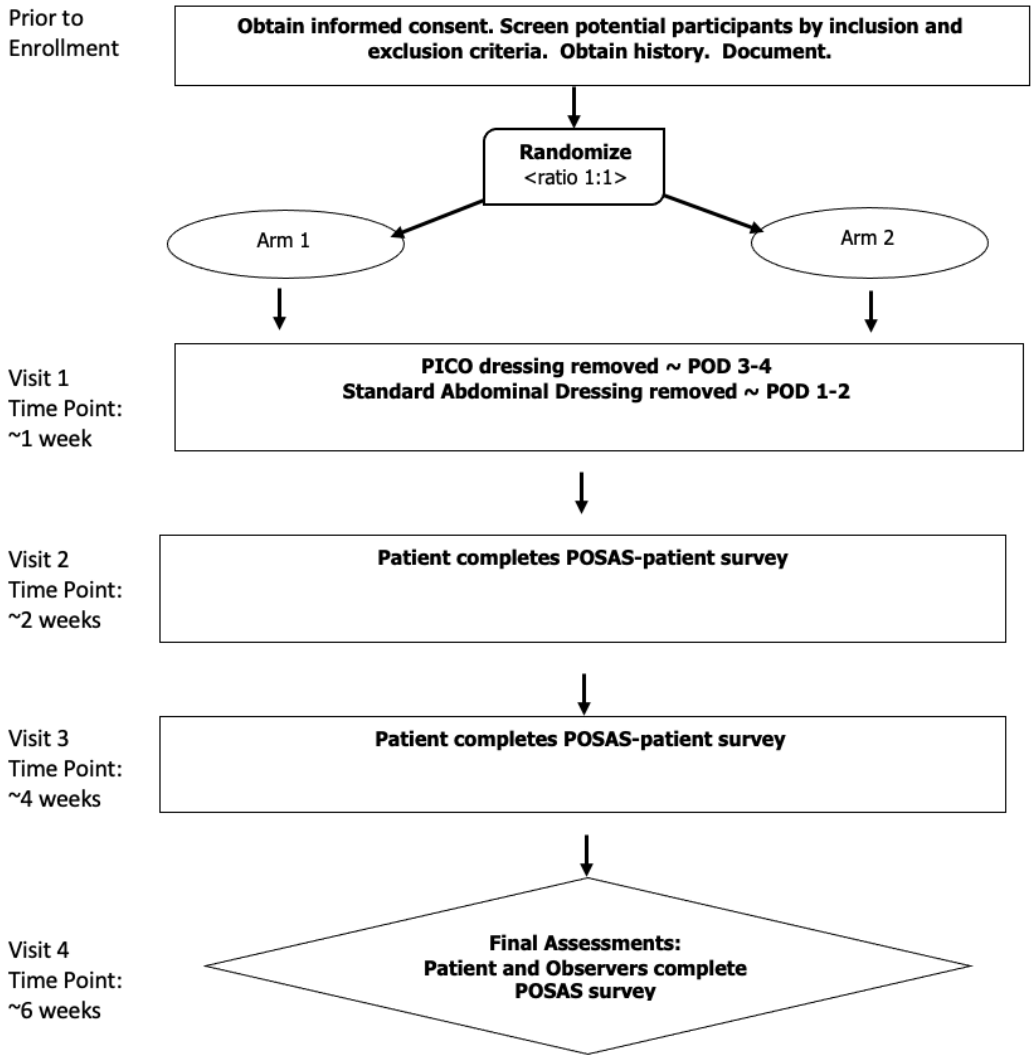


Figure 2: Study Design

Data Collection:

The Patient Scar Assessment Scale (POSAS) rates 6 variables: scar-related pain, itching, color, stiffness, thickness, and irregularity. Each parameter is scored on a 1- to 10-point ordinal scale, with 1 indicating that the scar is comparable with normal skin and 10 reflecting the worst imaginable scar. The sum of the 6 individual parameters ranges from 6 (normal skin) to 60 (worst scar).

The POSAS patient survey was e-mailed to participants at the two, four, and six-week time intervals and data collected and stored via REDCap. Participants were sent each survey up to 3 times until a response was logged. If they did not respond electronically, each patient was then called up to 3 times. The POSAS observer survey was completed and collected at the time of the patient interview (routinely a postpartum visit). The observer (MD/DO/NP seeing the patient) was also asked to upload a picture of the cesarean section scar into the EMR. Baseline patient characteristics including maternal age, BMI, and number of prior cesarean sections were abstracted from the EMR.

Randomization and blinding:
One half was randomly assigned to receive iNPWT versus the contralateral control side. An online block randomization tool was used for the within-patient allocation. Randomization of dressing was disclosed in the sealed envelope and revealed to the surgical team just prior to proceeding to the operating room. Blinding was not possible due to the nature of the intervention

Study outcomes:
The primary study outcome was to compare aesthetic appearance and patient satisfaction at 6 weeks postoperative of a repeat C-section in NPWT-PICO dressing vs. standard abdominal dressing. The primary time point of interest was at 6 weeks as we expected the most improvement to be seen at that later time point.

The secondary objective was to compare incision healing complications up to 42 days postoperatively between the standard dressing group vs. the PICO NPWT group.

Statistical Considerations
We planned to enroll approximately 100 women with a previous C-section. If approximately 20% drop-out by 6 weeks, then with N = 80 (40 per group), we will have 80% power to detect a .7 SD difference in mean scar assessment at 6 weeks between the two-groups using a two-sample t-test with equal variance and type I error set at 0.05 which provides conservative power compared to our linear mixed model. Based on a small RCT pilot study for C-section scars which used this instrument (Ekin et al., 2018), the effect sizes for the Patient, Observer, and Total POSAS were ES = 1.18, 1.03, and 1.15, respectively. Also, the pooled SD was 7.2 for the Patient version, thus assuming our population will have a similar SD in this measure; we will be able to detect approximately a 5-point change (0.7 x 7.2) in Patient POSAS. Thus, we should have adequate power to detect meaningful improvements in scar assessment.

Statistical Analysis:
Characteristics of the study population were summarized using descriptive statistics. 24 patients were recruited and enrolled in the study. Out of these 24, only 3 patients that responded to all three (2-, 4- and 6- week) POSAS surveys. 15 patients responded to the 6 week assessment survey, which was the primary outcome of this study. For this reason, statistical analysis that would provide a statistically significant value was unable to be performed.

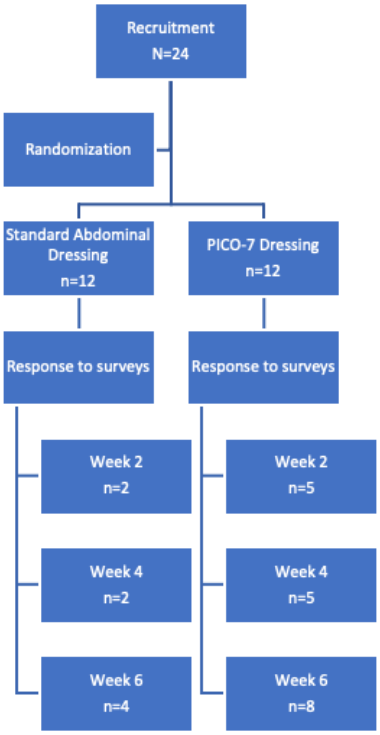


Figure 3: Enrollment and follow up

Results:

Patient demographics:

In total, 24 patients were recruited in this study. Follow-up moments were between August 2022 and March 2023. Inclusion and surgery took place between July 2023 and January of 2023. A total of 15 participants completed the primary study outcomes measures (on scar quality and patient-reported outcomes) and were included for analysis. The patient demographics are presented in Table 1. The median age of the participants was 29.8 years (range 25–34.5) in the standard dressing group and 34.6 in the PICO-7 group (range 27-42). The average prior cesarean sections were 1.4 (range 1-3) in the standard dressing group and 1.7 (range 1-3) in the PICO-7 group. Only one of the patients declared to have experienced any problematic scarring previous to surgery (e.g., hypertrophy and/or keloid). Most of the included patients were Caucasian (87.5%).

Table 1: Descriptive Statistics

Variable	**Standard dressing (N = 5)**	**PICO (N = 10)**
Age, Mean (SD)	29.8 (4.7)	34.6 (7.5)
BMI, Mean (SD)	37.2 (11.9)	34.0 (5.1)
Number of Prior C-sections, Mean (SD)	1.4 (0.9)	1.7 (1.1)

Language		
English	4 (100%)	5 (50%)
Spanish	0	5 (50%)
Missing	1	
Ethnicity		
Non-Hispanic or Latino	5 (100%)	6 (60%)
Hispanic or Latino	0	4 (40%)
Race		
Black/African American	4 (80%)	5 (50%)
White	1 (20%)	1 (10%)
Unknown/not reported	0	4 (40%)

The Patient Scar Assessment Scale (POSAS) rates 6 variables: scar-related pain, itching, color, stiffness, thickness, and irregularity. Each parameter is scored on a 1- to 10-point ordinal scale, with 1 indicating that the scar is comparable with normal skin and 10 reflecting the worst imaginable scar, as seen in Figure 4 and Figure 5. The sum of the 6 individual parameters ranges from 6 (normal skin) to 60 (worst scar).

At week 2, the average patient score was 33 in the standard dressing group versus 19 in the PICO-7 group. At week 4, the average patient score was 24.5 in the standard dressing group versus 25 in the PICO-7 group. At week 6, the average patient score was 26.5 in the standard dressing group versus 13.0 in the PICO-7 group. The observer score was measured between 4-6 weeks at the patients postpartum visit. The average observer score was 19 in the standard dressing group versus the 16 in the PICO-7 group.

Table 2: Comparison of patient POSOS scores between the groups

Variable	**Standard dressing**	**PICO**
POSAS score Week 2, Median (Q1-Q2)	33.0 (17-49) [N = 2]	19.0 (16-32) [N = 5]
POSAS score Week 4, Median (Q1-Q2)	24.5 (15-34) [N = 2]	25.0 (6-27) [N = 5]
POSAS score Week 6, Median (Q1-Q2)	26.5 (16-36.5) [N = 4]	13.0 (10-16.5) [N = 8]

Table 3: Comparison of observer POSOS scores between the groups

Variable	Standard dressing	PICO
Observer score, Median (Q1-Q2)	19.0 (11.5-39) [N = 4]	16 [N = 1]
Overall opinion of scar, Median (Q1-Q2)	7.0 (4-10) [N = 2]	2 [N = 1]

Secondary Outcomes

Table 3: Incisional Healing Complications

Variable	Standard dressing (N = 5)	PICO (N = 10)
Post-operative complications		
None	4 (80%) Where is the other person in the n	8 (80%)
Rash around incision due to adhesives	0	1 (10%)
Neuropathic pain	0	1 (10%)
Infection (superficial or deep)	0	0
Dehiscence	0	0

Discussion/Conclusions:

In this study, we assessed the influence of incisional negative pressure wound therapy on scar development and patient satisfaction with their cosmetic outcome. We performed a pilot randomized controlled trial to test two equivalent incisions. Generally, the results of this study showed a potential small difference in favor of iNPWT in patient-reported outcome measures with a lower score on the POSAS score at 6 weeks and a lower observer score and overall score of the scar at 4-6 weeks postpartum. These outcomes could not be analyzed for any sort of statistically significant values due to the low recruitment and even lower patient follow up and response rate despite attempting to reach patients by both several emails and phone calls.

Strengths of this study include an even 1:1 block randomization at a single site (Eskenazi Hospital) with a robust Labor and Delivery unit with a diverse patient population. Limitations of this study include a small sample size and low patient follow up response rate, which yielded data that was unable to be analyzed for statistical significance. In statistical considerations in study design, we expected a 20% drop-out by 6 weeks. However in our study, we had a 35% drop out rate (no response in any of the three surveys), and only 12.5% of patients filled out all 3 weeks of the surveys. 42% of patients did not attend their scheduled postpartum visit at the 4-6 week mark. Many of the other

studies that were performed using NPWT compared to standard abdominal dressing were done to evaluate the benefits on wound healing and preventing surgical site infections. The study that was performed to evaluate potential patient cosmesis benefits when using NPWT compared to standard dressing was a gender affirming mastectomy, which was ultimately an elective and cosmetic surgery which could have contributed to having higher patient follow up rates. It is possible that patient follow up and participation could have been lower than expected as a cesarean section is a medically necessary and not a cosmetic surgery, and the participants of this study were all recruited at a county hospital that serves a largely low income and resource population. Lastly, the participants of this study were all taking care of newborn children as well. All of these can cause difficulty with follow up and are also potential barriers to care, as seen by the overall low follow up for medical care at the post partum visit.

Due to the open-label nature of the study, neither the participant nor the observer were blinded to the intervention. The impact of attribution bias or placebo effect is difficult to assess in an open-label study. Additionally, the questionnaire used consisted of multiple sub-questions that equated to an overall score, which has the potential to result in false significant outcomes based on multiple testing and the non-linear conversion table from absolute value to the 0–100 scale. Lastly, only one patient questionnaire (POSAS) was used in this study.

Moving forward, to be able to attempt to achieve a recruitment value to be able to analyze for statistical analysis, it would be prudent to attempt to include a larger population of patients. At Eskenazi Hospital in particular, two languages were not inclusive enough for adequate recruitment in this study in the short amount of time that recruitment was open. It would be extremely beneficial for recruitment to be able to include languages such as Haitian Creole in addition to Spanish and English. In the literature, other clinical studies on iNPWT on scar outcomes present a variety of scar outcome measures such as the Vancouver Scar Scale (VSS), Stony Brook Scar Evaluation Scale (SBSES), Visual Assessment Scale (VAS), Manchester Scar Scale (MSS) and the BIS (Body Image Scale) were used. It could be useful to incorporate more scales to ensure that there was not a false interpretation of scar outcomes by using only one scale.

In conclusion, this pilot randomized controlled trial was unable to provide any statistically significant data, but did show a lower overall score in the PICO-7 group vs the standard abdominal dressing group at the 6 week mark for both patients themselves and for observers. Because of the potential physical and psychological benefit of reducing complicated scar formation, further studies should be performed with a higher recruitment and follow up percentage that would be able to provide information to determine if the PICO-7 or other NPWT could be beneficial at improving patient's scar satisfaction after a repeat cesarean section.

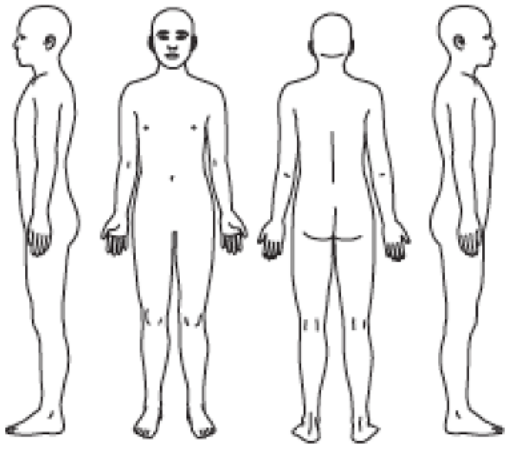
Qualitative scar assessment

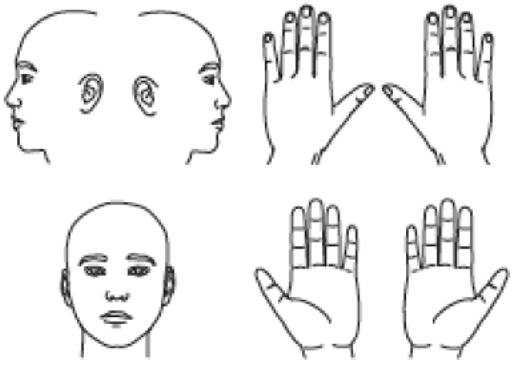
Figure 4: POSAS – Patient Scale

POSAS Patient scale

The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination:	**Name of patient:**
Observer:	
Location:	**Date of birth:**
Research / study:	**Identification number:**





	1 = no, not at all … yes, very much = 10
HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

	1 = no, as normal skin … yes, very different = 10
IS THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
IS THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
IS THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
IS THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

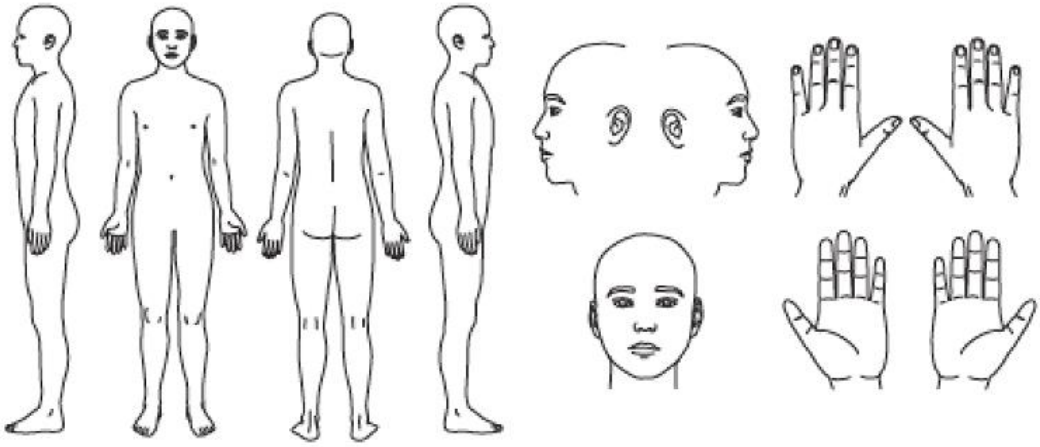
	1 = as normal skin … very different = 10
WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

Figure 5: ***Posas – Observer scale***

POSAS Observer scale

The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination:	**Name of patient:**
Observer:	
Location:	**Date of birth:**
Research / study:	**Identification number:**



	1 = normal skin								worst scar imaginable = 10		
PARAMETER	1	2	3	4	5	6	7	8	9	10	**CATEGORY**
VASCULARITY	○	○	○	○	○	○	○	○	○	○	PALE | PINK | RED | PURPLE | MIX
PIGMENTATION	○	○	○	○	○	○	○	○	○	○	HYPO | HYPER | MIX
THICKNESS	○	○	○	○	○	○	○	○	○	○	THICKER | THINNER
RELIEF	○	○	○	○	○	○	○	○	○	○	MORE | LESS | MIX
PLIABILITY	○	○	○	○	○	○	○	○	○	○	SUPPLE | STIFF | MIX
SURFACE AREA	○	○	○	○	○	○	○	○	○	○	EXPANSION | CONTRACTION | MIX
OVERALL OPINION	○	○	○	○	○	○	○	○	○	○	

Explanation

The observer scale of the POSAS consists of six items (vascularity, pigmentation, thickness, relief, pliability and surface area).
All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable').
The sum of the six items results in a total score of the POSAS observer scale. Categories boxes are added for each item. Furthermore, an overall opinion is scored on a scale ranging from 1 to 10.
All parameters should preferably be compared to normal skin on a comparable anatomic location.

Explanatory notes on the items:

- **VASCULARITY** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas
- **PIGMENTATION** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity
- **THICKNESS** Average distance between the subcutical-dermal border and the epidermal surface of the scar
- **RELIEF** The extent to which surface irregularities are present (preferably compared with adjacent normal skin)
- **PLIABILITY** Suppleness of the scar tested by wrinkling the scar between the thumb and index finger
- **SURFACE AREA** Surface area of the scar in relation to the original wound area

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