TITLE: Force Modulating Tissue Bridges for Dermal Closure after Breast Reduction

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IRB: IRB Committee, UTSouthwestern

TRIAL DESIGN: Prospective, randomized, single blinded,
patient self-controlled, single center*

INTRODUCTION AND PURPOSE

1.1. *Purpose*

Current methods of wound closure including sutures, staples, skin adhesives, and alternative technologies are invasive, actively induce new scar through force concentration leading to focal tissue necrosis and can induce foreign body reactions. All of these factors can lead to scar induction above and beyond the scar directly attributable to the wound itself. Furthermore, current technologies fail to adequately control wound closure forces leading to tension on tissue in the wound zone. Unmitigated tension induces a cascade of tissue reactions including activation of mechanical tension receptors in the fibroblast/fibrocyte cell membrane which ultimately lead to increase fibroblast activation, chemotaxis, and increased collagen deposition, among other outcomes. The cumulative effect of these factors is increased scar burden, increased scar visibility, and an increased risk of pathological scars (hypertrophic scars and keloids).

2. BACKGROUND

Breast reduction surgery is an extremely common surgical procedure with over 97,000 cases performed in the United States in 2020, with approximately two-thirds done for reconstructive purposes, including alleviation of chronic shoulder, back and neck pain, and approximately one-third done for aesthetic purposes.[1] Although satisfaction rates are high after reduction mammaplasty, complications can include wound infection, dehiscence, suture spitting, and hypertrophic scars, and revision of scars is common.[2,3]

Force modulating tissues bridges (FMTB) represent a new class of wound closure and mechanomodulation devices which are non-invasive and designed to approximate wounds as well as off-load skin tension during both the immediate and ongoing wound healing phases in order to improve scar outcomes. Prior pre-clinical studies show that the devices are more effective than suture at off-loading skin tension and that they can provide superior skin eversion during closure.[4] Initial clinical use began in September of 2020 and approximately 1000 clinical cases have been performed primarily in the plastic surgery and dermatological surgical areas. Initial clinical feedback based on survey results including 240 of the initial surgical procedures, including 108 bilateral mastopexy and breast reduction procedures incorporating vertical breast incision closure (216 breasts) suggests that the devices indeed improve initial scar outcomes, are well tolerated by patients with minimal skin reaction or irritation, and are anecdotally associated with a reduction in T-junction wound complications This study is designed to confirm and quantitate these wound healing and patient benefits.

2.1. *Rationale for Study Design*

Given the large number of variables in wound healing leading to scar formation, including anatomical location, orientation, genetics, nutrition, disease states, ethnicity, etc., it is very difficult to effectively demonstrate improvement in scar appearance using parallel groups. Standard, symmetrical wound, self-controlled study designs have the advantage of accounting for all of these variables while decreasing the number of enrollees required for adequate sample size.[2]

2.2. Sample Size/Power Analysis Factors:

The sample size calculation will be determined by the primary outcome: POSAS-O score. The study will enroll 42 patients which will allow us to detect a moderate effect (Cohen's d=0.5) in scar quality measured by POSAS-O with at least 80% power, accounting for an estimated 20% loss of patients.

In a study evaluating the effect of platelet-rich plasma glue on surgical scars following breast reduction mammoplasty, the control group had a mean POSAS-O score of 20.4 (SD 12.5) at 1-year.[6] Although a minimal

clinically important difference (MCID) for POSAS has not been established in the literature, Cohen's d effect size (0.2 represents "small" effect, 0.5 represents "moderate" effect, 0.8 represents "large" effect) can be used to estimate a difference that may be clinically important.

	Effect Size (Cohen's d)			
	0.2	0.3	0.4	0.5
Change in POSAS-O score	2.5	3.75	5	6.25
Proportional change to maximum POSAS-O score	4.2%	6.3%	8.3%	10.4%

	Effect Size (Cohen's d)			
Power	0.2	0.3	0.4	0.5
80%	199	90	52	34
85%	227	102	59	38
90%	265	119	68	44

3. CONCISE SUMMARY OF PROJECT

3.1. Clinical Study

This is a prospective, within-subject randomized, single blinded study designed to follow up to forty-two (42) qualified and consenting adult females, 18-70 years of age scheduled for elective breast reduction surgery using a standard inverted Wise (inverted "T") incision pattern. The sample size determination of this study is based on a structured power analysis using the observer portion of the Patient and Observer Scar Assessment Scale result as the primary outcome metric. Subjects will be randomized to the method of closure and wound support of the WISE-pattern incisions.

On the intervention side, subjects will have FMTBs applied for final layer closure of the vertical breast incision and, if eligible (incision >5cm in length), final layer closure of the lateral incision. Patients will continue with repeat application every two weeks for ongoing wound support for a total of 8 weeks of therapy. On the control side standard suture closure and wound dressings will be utilized. Patients will be evaluated at two-week intervals up until 8 weeks post-operative, then will have 3 additional follow up visits at 3-months, 6-months and 12-months post-operatively. The effects of the therapy will be analyzed during the follow up visits through photography, skin assessments and POSAS (Patient and Observer Scar Assessment Scale) results.

This is a single-site study at UT Southwestern Medical Center at Dallas in the Department of Plastic Surgery. The Principal Investigator has been selected based on his expertise, qualifications (credentials, training, and medical specialty), subject access, previous clinical research, facilities, and interest in this particular field of research. Subjects will be identified from the clinical practices of Drs. Jeffrey Kenkel, Abby Culver, Bardia Amirlak at the University of Texas Southwestern Medical Center. All surgeries for this trial will occur at the Outpatient Building located on the UT Southwestern campus

3.2. Primary Outcomes

- Patient and Observer Scar Assessment Scale (POSAS)
- Photographic Assessment

3.3. Secondary Outcomes

- Scar volume/Surface area
- Gene regulation
- Genetic analysis
- Collagen volume/appearance on pathology
- Colorimetry
- Time of length of adherence
- Skin lab assessments (see below)

4. TEST MATERIAL INFORMATION

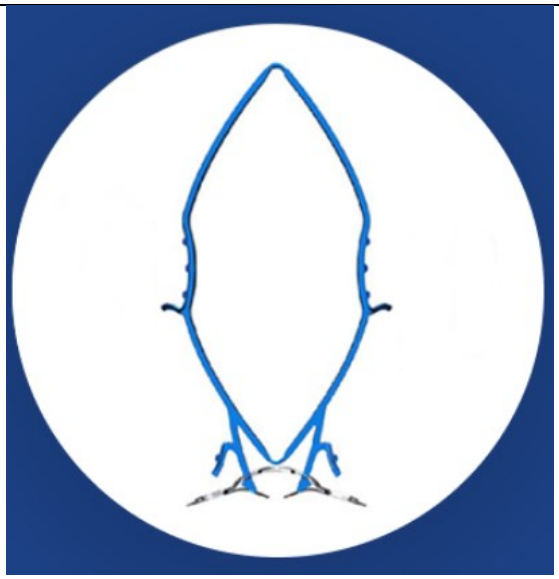
4.1 Study Material Description(s)

The following device will be evaluated during the study:

Proprietary Name	Device Description	Regulatory information
BRIJJIT BP100-6	Force Modulating Tissue Bridges for Cutaneous Wound Closure and Wound Support	Device Class 1 FDA Product Code KGX Regulation Number 21 CFR 880.5240

4.2 Study Device

BRIJJIT BP100-6 is a non-invasive wound closure device that reduces tension on scars and aids improving scar appearance.

Image 1- Fingertip Applicator	Image 2- Shield and adhesive
Easy place and release applicator used to position the BRIJJIT device to the skin.	Flexible bridge shields the wound during movement to promote healing and support.
	

5. SUBJECT ENROLLMENT AND INSTRUCTIONS

5.1. *Informed Consent Form*

An IRB-approved informed consent form (ICF), consistent with the requirements in 21 Code of Federal Regulations (CFR) 50.25, will be given to each candidate subject before participation in any study procedures. The candidate subject will be given as much time as needed to read the ICF and will have the opportunity to have any study related questions answered to their satisfaction prior to signing the ICF. If further questions exist, the candidate subject will be given sufficient time during the first visit to clarify open questions and concerns regarding the study and/or the ICF with the Investigator, Sub-Investigator or the study coordinator prior to signing. An original signed copy for each subject participating in the study will be retained in the study file and each subject will receive a signed copy. The candidate subject will be ineligible to participate in this study without a signed ICF.

5.2. Subject Identification

Subjects will be assigned a 2-digit number which, when used in conjunction with the clinical study ID, will uniquely identify every subject on the study. This ID will remain with the subject throughout the study and should be used in all references to the individual in this study.

5.3. *Eligibility Criteria*

Inclusion Criteria

1. Healthy adult females 18-70 years of age
2. Planned procedure is bilateral breast reduction with modified Wise (anchor, inverted “T”) scar pattern

3. Lateral incision measuring > 5 cm (for additional Brijjit application on lateral incision)
4. Ability to adhere wound therapy after surgery for 8 weeks or have a willing family member/partner to assist with wound therapy care.
5. Willing to follow wound care therapy as instructed by study staff.
6. Willing to return for follow up visits and undergo study evaluations.

Exclusion Criteria

1. Age less than 18 or greater than 70
2. Individuals diagnosed with known allergy to general adhesives/adhesive tape
3. Individuals with a history of using the following prescription medications:
    - Accutane within the past year;
    - Systemic steroid use within the past year
4. Individuals who have significant scarring on the test site/area(s)
5. Individuals with malnutrition
6. Individuals who have a body mass index >40
7. Individual who have a history of radiation therapy
8. Individual who have a history of breast cancer
9. Active smokers
10. Individuals with a disorder known to negatively affect wound healing (e.g. autoimmune disease, connective tissue disease
11. Individual who have an observable pre-operative or intra-operative breast asymmetry that, in the investigators opinion, would interfere with the evaluation of the efficacy of the wound therapy

5.4. *Randomization*

Randomization via www.randomizer.org computer-based method: sealed pre-numbered randomization envelopes will be provided and opened by research staff and used to obtain randomization assignment. Unmasking of randomization assignment will occur after all portions of the surgical procedure are complete excepting only final skin layer closure and with intraoperative procedural symmetry confirmed.

5.4.1 Randomization Groups

Group 1	
Side 1 Final layer dermal closure with poliglecaprone 25 suture (Monocryl ®, Ethicon, Inc. Bridgewater, NJ)	**Side 2** Final layer closure with force modulating tissue bridges (FMTB) (Brijjit BP100-6, Brijjit Medical Inc., Marietta, GA)
Group 2	
Side 1 Final layer closure with force modulating tissue bridges (FMTB) (Brijjit BP100-6, Brijjit Medical Inc., Marietta, GA)	**Side 2** Final layer dermal closure with poliglecaprone 25 suture (Monocryl ®, Ethicon, Inc. Bridgewater, NJ)

6. STUDY DESIGN

6.1. Outline of Procedures

Schedule of Events									
	Screening	Surgery	Wound Therapy Visits				Follow-Up Visits		
Procedures	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4***	**Visit 5***	**Visit 6**	**Visit 7**	**Visit 8**	**Visit 9**
	Pre-Op	Surgery	2 Weeks	4 Weeks	6 Weeks	8 Weeks	3 Months	6 Months	12 Months
ICF/Qualification/ Enrollment	X								
Randomization	X								
Standard/3D Photographs	X		X	X	X	X	X	X	X
Apply FMTB		X	X	X	X				
Skin Lab Measurements	X			X		X	X	X	X
Skin Biopsies		X		X		X	X		X
Colorimetry	X		X	X	X	X	X	X	X
POSAS						X	X	X	X
Blinded Evaluations									X

** Visit can be offered as in-person or telehealth visit*

6.2. Pre-Study Procedures

1. Prior to the start of the study, potential subjects will be screened for eligibility requirements by telephone, e-mail, or in person during their pre-op appointments.

6.3. Screening Visit: Visit 1

The purpose of the study, eligibility criteria and potential risks will be discussed with the potential study subject. The following enrollment and screening activities will be performed:

1. Candidate subjects will be given an IRB-approved Informed Consent Form (ICF), as detailed in section 5.1, with adequate time for review. The Investigator and/or his designee will address questions and concerns raised by the subject. If the subject agrees, they will sign one copy of the ICF. They will receive a copy, and the original will be kept in the study file.

2. Candidate subjects will be screened to ensure they meet all of the study criteria. A brief medical history will be taken and the subject will be questioned about inclusion and exclusion criteria.

3. Candidate subjects that sign the initial paperwork will be assigned a screening number.

4. After consent has been obtained, the subject will be randomized into one of the treatment groups and all members of the research team will be notified.

5. Obtain standard photography.

6. Examination of the treatment area by research staff.

7. Obtain pre-treatment high-resolution ultrasound images, transepidermal water loss (TEWL) measurements (Bio Aquaflux) and BTC-2000 images.

8. Colorimetry assessment of skin in the treatment area using the Pantone SkinTone Guide (STG201).

This visit will take 30-45 minutes

6.4. Surgery: Visit 2 (Day 0)

Subjects will arrive for their previously scheduled surgical procedure. A member of the research team may visit with the subject prior to the surgical procedure beginning.

1. A clinician will record any changes to the subjects' concomitant medications and will ask subjects if they have experienced any changes in their health since the previous visit. If an adverse event (AE) is reported, then the Investigator will be informed and an AE form will be completed.

2. The Principle Investigator will be utilizing the proper wound closure method based on the group the subject was randomized into.

3. A total of four skin biopsies will be obtained during the procedure as described in section 7.3. Two 0.33mm biopsies using a Well-Tech Rapid-Core 0.33mm Biopsy Punch will be obtained from the excised tissue from each breast.

The surgical procedure is expected to take 2-3 hours. Preoperative and intraoperative patient variables recorded by the surgeon will be collected by the research team via chart review to factor into analyses of wound healing and scar quality. These include, but are not limited to: BMI, base width, ptosis grade, nipple to inframammary fold distance, and sternal notch to nipple distance. Intraoperative variables may include, but are not limited to, total anesthesia time and resection weight of each breast.

6.4.1 Post-Surgical Procedures

- Subjects will be provided standardized instructions to encourage wound care for a total of 8 weeks.
- Supporting products (dressings etc.) will be provided to ensure compliance and an adequate supply to change dressing before next visits.

6.5. Wound Therapy Visits: Visits 3-6 (Weeks 2,4,6 and 8)

1. A clinician will record any changes to the subjects' concomitant medications and will ask subjects if they have experienced any changes in their health since the previous visit. If an adverse event (AE) is reported, then the Investigator will be informed and an AE form will be completed.

2. A clinician will clean and assess wounds. FMTB will be reapplied every two-weeks. If the visit

is being performed virtually, via telehealth, than the patient will be observed while cleaning his/her wound as well as during the reapplication of the FMTBs.

3. If in person, photographs will be taken of the wounds as described in section 7.1

4. If in person, skin lab measurements will be taken at visits 4 and 6 (weeks 4 and 8) as described in section 7.2.

5. If in person, biopsy samples will be obtained at visits 4 and 6 (weeks 4 and 8) as described in section 7.3

6. Supporting products will be provided to subject to ensure compliance. If patients opt to have telehealth visits for visits 4 and 6, FMTBs will be provided, as well as alcohol swabs for cleaning the skin. Patients will also be properly trained on how to apply the FMTBs themselves at prior visits if they plan to opt for telehealth visits.

These visits will take about 45 minutes

6.6. Follow-Up Visits: Visit 7-9 (Months 3, 6 and 12)

1. A clinician will record concomitant medications and will ask subjects if they have experienced any changes in their health since the previous visit. If an adverse event (AE) is reported, then the Investigator will be informed and an AE form will be completed.

2. Photographs will be taken of the wounds as described in section 7.1

3. Skin lab measurements will be taken during each visit as described in section 7.2

4. Biopsy samples will be obtained as described in section 7.3

5. Patient and Observer Scar Assessment Scale will be completed by both the subject and clinician as described in section 7.4.

These visits will take about 45 minutes

7. ASSESSMENTS

7.1. Photography Procedures

Prior to photography procedures, clinic personnel will ensure that subjects will remove any jewelry and clothing from the area(s) to be photographed and equilibrate for at least 15 minutes to ambient conditions within the clinic before any photographs are taken.

1. Nikon D7200
   Standard and close-up photography will be utilized for evaluation of the appearance surgical scars. These photographs will be taken utilizing the Nikon D7200 at screening/baseline, week 2, week 4 (if in-person), week 6 (if in-person), week 8, 3-month post-surgery, 6-months post-surgery and 12-months post-surgery.
2. e-Kare

e-Kare 3D wound management software will be used to obtain high quality 3D wound images in real time that will provide wound dimensions, max depth, surface area and volume.

7.2. Noninvasive Skin Assessments

Noninvasive measurements are being collected for research purposes only.

1. High-Frequency Ultrasonography
   Ultrasonography will be used to evaluate the skin thickness and density.
2. Transepidermal Water Loss (TEWL)
   TEWL will be used to evaluate the barrier functions of the skin's epidermal layer to determine the progress of epidermal healing.
3. BTC-2000
   BTC will be used to measure the skin's laxity, viscoelastic deformation, stiffness, energy absorption, elasticity, and deformation values.

7.3. Biopsies

Four 0.33mm biopsies, two from each breast scar, will be obtained during multiple visits to assess histological evaluation and gene expression assessment. A subgroup of 10 patients will be selected to participate in the biopsy group. A local numbing agent, 0.5% Lidocaine with epinephrine, will be used to anesthetize the area being biopsied. The biopsy site will be cleaned and marked in the patients file, to keep consistency at all visits.

- Histological assessments will include epidermal and dermal ultrastructure, and immunofluorescence staining of collagen 1, collagen 3, elastin and fibroblast markers associated with fibrosis (smooth muscle actin and Dlk1).
- Gene expression assessment will include collagen and other major extracellular matrix (ECM) molecules and related to scar development.

7.4. Colorimetry

The Pantone SkinTone Guide is a handheld tool consisting of 110 color swatches that realistically mimic human skin tones, with stepwise variations in lightness and undertone. The guide was specifically formulated to be the closest physical representation of skin colors and is the only internationally available color standard to accurately match skin tones. Each SkinTone number is comprised of a four-digit alphanumeric number; the first two numbers reflect the hue or undertone of the skin while the second two represent the tone or lightness and darkness of the skin. This tool will be utilized to establish a clinically acceptable objective assessment for assessing the coloring of patients' scars.

7.5. Patient and Observer Scar Assessment Scale (POSAS)

This validated scale will be used to assess the scar quality after surgery from the patient and observer (clinician) prospective.

This scale should be completed in two steps:

- Patient Self-Assessment: Subjects will be asked to visually assess their scar appearance and complete the 10-point scale. The patient scale will include questions regarding pain, itch, thickness, color, stiffness, irregularity, and overall opinion.
- Observer Assessment: Clinician will visually assess the scar appearance during the visit and complete the 10-point scale. The observer scale will include items with subcategories related to

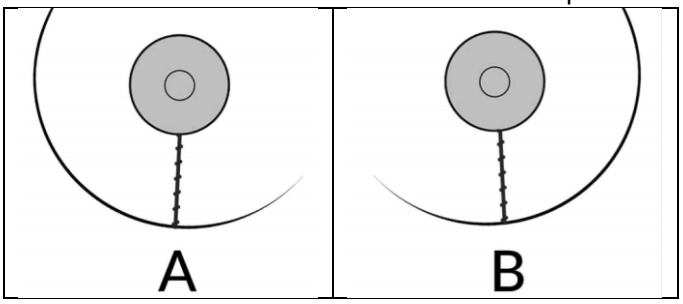
vascularity, pigmentation, relief/texture, thickness, pliability, surface area and overall opinion.

7.6. Blinded Photography Evaluation

Blinded photography evaluation will be performed by three physicians (plastic surgeons) to determine if the force modulating tissue bridges (FMTBs) are effective in improving the appearance of postoperative scars.

Three qualified, non-treating clinicians will be trained to independently review standard photographs for each subject taken at 12 months postoperatively. The reviewers will be blinded to subject information and to information regarding the closure technique utilized. No information will be provided to the reviewers that may allow them to determine which closure technique, FMTBs or suture, was used.

A pair of photographs (labeled A and B) for each subject will include the FMTB closure and the suture closure at 12 months postoperatively. The blinded reviewers will be asked to review a presentation of each subject's photographs and rate which scar has healed better of the options on the screen (A & B).



Additionally, each scar image will be organized individually, and the blinded reviewers will score each photograph using the Manchester Scar Scale (MSS).

MANCHESTER SCAR SCALE (MSS)

SCAR CATEGORY		POINTS (circle score) Untreated Area	Treated Area
Colour	Perfect	1	1
	Slight mismatch	2	2
	Obvious mismatch	3	3
	Gross mismatch	4	4
Shine	Matte	1	1
	Shiny	2	2
Contour	Flush with surrounding skin	1	1
	Slightly proud/indented	2	2
	Hypertrophic	3	3
	Keloid	4	4
Distortion	None	1	1
	Mild	2	2
	Moderate	3	3
	Severe	4	4
Score: (4-14)	**Total Score:**		

The identified reviewers will be instructed that their participation is completely voluntary and has no impact on performance review at their institution. It will be clearly stated that consent is implied with the institution's survey completion. No identifying information about these blinded reviewers will be published but will be maintained in a secure manner by the research team. A wavier of documentation is requested

as no subject Personal Health Information (PHI) will be collected, recorded or shared. Prior to completing the review, the study PI/coordinator will ask for a verbal consent from the reviewers indicating approval to use their responses in the study.

7.7 *ImageJ Scar Area Analysis*

Photographs will be analyzed using ImageJ software to quantitatively measure pigment, redness, surface area, and volume of the scar area. Chroma and pigmentation from the images will be obtained using the Pantone Connect extraction. The scar area where noninvasive measurements were obtained with the skin around it will be analyzed.

8. POTENTIAL RISKS

Allergic Reaction: (Rare <5%)

There is a possibility of an allergic reaction to the adhesive on the device. Subjects will be questioned with regard to any history of allergies and carefully monitored for signs of allergic reaction during pre-screening.

Wound Infection: (Rare)

While subjects may experience many side effects after their surgery including but not limited to: oozing, strong pain, swelling persisting for more than 24 hours, or signs of infection (e.g., pus, drainage, fever) are cause for immediate concern and they should contact the investigator and/or his designee, to be evaluated. In the first 216 breasts treated with FMTBs, there have been no reports of wound infection.

Irritation & Blistering: (Rare <5%)

A crust, blister or superficial wound can occur at the treatment area. The risk of infection will be minimized by proper wound care. Subjects will be requested to contact a member of the research team should irritation or blistering occur at any time point after surgery.

Hypertrophic or Keloidal Scar: (Rare)

There is a small risk for abnormal scarring with any wound closure technology. However, this is minimized by proper technique and wound care. This risk may be higher if the patient has a prior personal or family history of pathologic scarring. In the first 216 breasts treated with FMTBs, there have been no reports of hypertrophic or keloidal scar.

Symptoms including the examples discussed above, will not be treated as adverse reactions if they are mild in nature. These conditions may or may not resolve over time. Symptoms that are persistent and moderate to severe in nature, or that involve elevation (e.g. edema, papules, vesicles, spreading) will be considered AEs. The Investigator will have the final determination as to whether a reaction will be considered an AE.

8.1. Adverse Events

At each visit, the Investigator will question the subject about adverse events using an open-ended question. If a potential adverse event is reported by the subject or identified during examination, directed questioning and examination will be performed when appropriate. At this time, the following will be performed:

1. Obtain a complete history of the event in question as well as conduct an examination of the subject and determine if the reported event qualifies as an Adverse Event. If the event is

determined to be an Adverse Event, an Adverse Event (AE) case report form and Event Follow-up (EF) Visit case report form must be completed. One AE case report form should be used to track the history of an individual AE throughout the period of the study.

2. Collect an updated medical and surgical history along with recording of concomitant medications or treatments.
3. Take photographs of the subject with attention to the area in question.
4. Render treatment for the event, if any, as determined by the medical judgment of the investigator.

Photographs will be taken to document any AEs if possible.

For the duration of the study, medical assistance will be provided to the subject for study-related problems at no expense, if in the opinion of the Investigator, the reaction was caused by the study device. Should a subject choose to seek their own medical treatment, no reimbursement will be offered.

When an AE persists at the end of the study, the Investigator will ensure a follow-up of the subject until the Investigator believes that the event is satisfactorily resolved.

9. SUBJECT SAFETY AND DATA MONITORING

9.1. Research Standards/Good Clinical Practice

The conduct of this study will follow all applicable guidelines for the protection of human subjects for research as outlined in 21 CFR 50, in accordance with the accepted standards for Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and the standard practices of UT Southwestern.

9.2. Data Monitoring

For this protocol, which involves the use of a non-significant risk device, the Investigator will monitor accrual, subject experience, attrition, patterns of adverse events and/or unexpected adverse events, any protocol deviations or violations any changes in the risk/benefit analysis.

Subjects will be asked about any adverse events throughout the study. Subjects will be asked to contact the Investigator if adverse events develop between visits. If necessary, an unscheduled visit will be arranged so that the Investigator can clinically evaluate and photograph these findings.

9.3. Procedures to Maintain Confidentiality

All study records and information will be identified by the subject number. All subject identifiers will be removed from all documents. The link between subject name and study ID number will be kept in separate password-protected files. Documents containing identifying information will be kept in locked files in the research staffs' locked office. All electronic study data will be password protected with access limited to members of the research team. No direct identifying information will be shared with any outside entities. Electronic data (electronic data entry - Case Report Forms) will be password protected.

Photographs of subject's surgical scars will be taken at enrollment and follow-up visits. These photographs will be identified by subject numbers and will not include any identifying marks [such as tattoos]. Subject confidentiality will be protected to the greatest extent possible.

This study will be performed in accordance with Health Insurance Portability and Accountability Act. These guidelines will be followed specifically with regard to the privacy and confidentiality of patient care and study records. Personnel associated with Investigator's office, the U.S. Food and Drug Administration (FDA) and the governing Institutional Review Board, have the right to review the data, including photographs, collected during this study.

10. REFERENCES

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Appendix I: POSAS Observer Scale

POSAS Observer scale

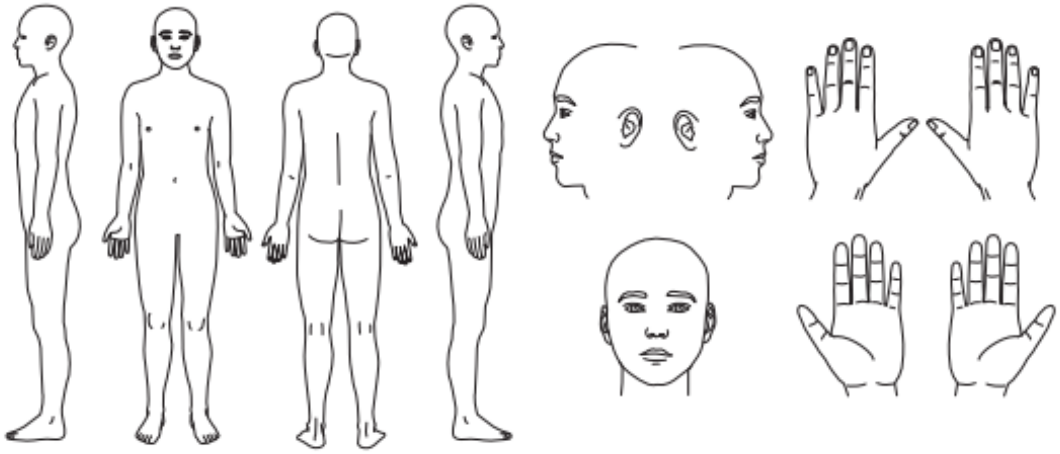
The Patient and Observer Scar Assessment Scale v 2.0 / EN

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:

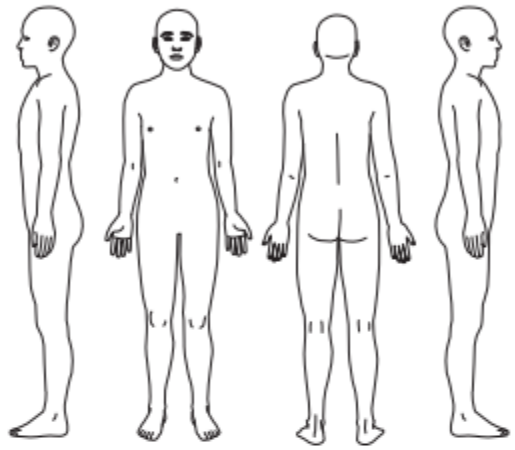
- **VASCULARITY** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas
- **PIGMENTATION** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate 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

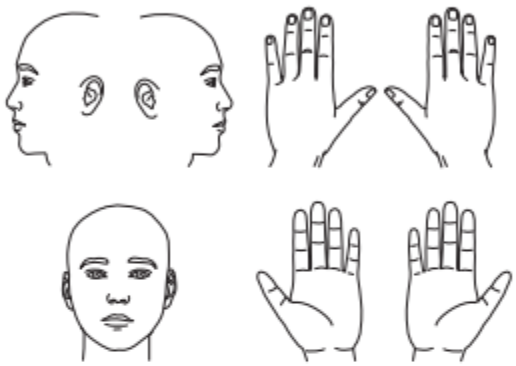
Appendix 2: POSAS: Patient Scale

POSAS Patient scale

The Patient and Observer Scar Assessment Scale v 2.0 / 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
	1 2 3 4 5 6 7 8 9 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
	1 2 3 4 5 6 7 8 9 10
S THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
S THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
S THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
S THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

	1 = as normal skin … very different = 10
	1 2 3 4 5 6 7 8 9 10
WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

Appendix 3: Handheld Pantone SkinTone Guide