TITLE:	A monadic 8 week pilot case series evaluation of **RejuvaSil® Silicone Scar Gel** for scar management to safely improve scar appearance of scars.
SPONSOR	Scar Heal, Inc. 13191 Starkey Rd, Bldg. 11 Largo, FL 33773-1438 USA
BACKGROUND	The formation of scar tissue is the body's natural healing mechanism following an injury to the skin such as a surgical procedure or traumatic insult. Following an injury, collagen synthesis increases in an attempt to heal the damaged tissue.(1) The result of this collagen and fibrin proliferation is scar tissue. Although the development of such tissue is an important and necessary response, rarely does the resulting scar tissue have the same strength (2) or appearance as the original tissue. From a cosmetic perspective, many patients are self-conscious of their scars and desire that scar tissue be minimized. Functionally scar tissue that is thick and firm can be uncomfortable and limit range of motion. A non-invasive methodology of treating scar tissue in an attempt to improve the color, texture, height, and overall appearance of the tissue is therefore of significant value to physicians, surgeons, and patients. In a study of 34 scar patients quality the impact on quality of life of the patient's was assessed. Over half of respondents (53%) felt their personal relationships suffered due to their scars. Over two-thirds (68%) took measures to hide their scars including make-up, body positioning, and clothing capable of covering the scars. Additionally, the majority of patients (56%) were unsatisfied with the appearance of their scars.(3) Many people seek treatment to approve the cosmetic appearance of their scars. In a survey of 97 patients 91% of patients would value even small improvements in their scarring. Additionally, 71% of patients felt they were more concerned with their scar than their physician indicating that scar cosmesis may be a commonly overlooked component of patient care.(4) Numerous modalities are available for the treatment of scarring including laser therapy, surgical scar revision, and topical formulations(5). Scar Heal Inc. has developed a novel Silicone Gel formulation, RejuvaSil® with Emu Oil, Vitamin C and Squalane as a topical approach to treating post-surgical and traumatic scarring.
OBJECTIVES:	Evaluation of RejuvaSil® Silicone Scar Gel to improve scar cosmesis.
TREATMENT AND RATIONALE:	Active Study Product(s): Scar Heal: RejuvaSil® (Scar Heal Inc., Largo, FL) RejuvaSil® Scar Gel contains Liquid Silicone, Emu Oil, Vitamin C and Squalane to improve the appearance of scars. RejuvaSil® Scar Gel has been used for improving scar cosmesis for surgical scars, traumatic scars, and burn scars. Patients will be treated for the duration of the study (8 weeks)
STUDY DESIGN:	10 subjects to complete the protocol at an independent research laboratory.
VISITS:	Visit 1: Prescreening and (Week 0) Baseline. Visit 2: Interim Visit (Week 4) Visit 3: Study Termination (Week 8)
CONCOMITANT MEDICATIONS	Concomitant medications will be recorded at each visit. Sun avoidance must be practiced during the study treatment period.
PRIMARY ASSESSMENTS	1. Methodology. a. Expert Clinical Grading b. Clarity Lite Photography
INCLUSION/ EXCLUSION	Inclusion Criteria: 1. Subjects with a visible scar caused by trauma or surgery

CRITERIA	2. Males and females aged 18-65 3. Subjects will abstain from using all creams or lotions other than study material. 4. Exclusion Criteria: 1. Allergy to any ingredient in either the study product 2. Inability to comply with the study protocol 3. Presence of major medical illness requiring that in the opinion of the PI will impact treatment. 4. Clinical diagnosis of bacterial infections of the skin, including impetigo or abscesses 5. Individuals unable to communicate or cooperate with Principal Investigator
ANALYSIS POPULATIONS:	Analyses will be performed to assess safety and efficacy of the study treatment based on the per-protocol (PP) population, defined as all subjects who completed the evaluation with no protocol violations and missed no more than one study visit.
SAFETY:	Safety and tolerability will be assessed at each study visit and conclusions will be based on a review of frequency and severity of treatment emergent adverse reactions observed
OUTCOME:	After 8 weeks of RejuvaSil® application tid, 100% of study participants exhibited improved texture/smoothness of the scar and 100% of the study participants exhibited overall improvement in the appearance including the color of the scar and texture as compared to baseline. 70% of subjects exhibited a decrease in scar length measurement. Image analysis using Clarity Lite showed a directional improvement in the lightening of the scar after 4 weeks. The use of RejuvaSil® for 8 weeks resulted in statistically significant improvements in Texture/Smoothness and Overall Appearance of the scars. Maximum improvement in texture/smoothness and appearance was noted at 8 weeks. The p value was noted to be <0.001

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