Title: Upper Limb Burns Sequelae, Functional Contractures and Pathological Scars: a Randomized Clinical Trial of Fat Grafting Versus Corticosteroid Injection.

Trial Registration:

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Abstract

Burns are a complex form of trauma with a high risk of complications. Involvement of the upper limbs frequently results in significant sequelae that negatively affect patients' quality of life, functional capacity, and psychological well-being. Traditionally, these cases are managed with surgical interventions and/or corticosteroid injections into lesions and scars. However, these treatments are only moderately effective, require prolonged therapeutic courses, and carry potential risks. They also present limitations in promoting true tissue regeneration and scar quality improvement. Furthermore, corticosteroid therapy often requires multiple injections, which can be painful, result in substantial time away from work, and generate high indirect costs.

Autologous fat grafting (lipofilling) has emerged as a promising therapeutic alternative within the field of regenerative medicine. As a biocompatible and autologous tissue, fat grafts are not associated with immunogenic risk and may exert regenerative effects through cellular and paracrine mechanisms. This may lead to both functional and aesthetic benefits.

This randomized clinical trial will include patients with upper limb burn sequelae—functional impairments and/or pathological scars—who will undergo either autologous fat grafting or standard corticosteroid-based treatment. All participants will be followed prospectively and assessed using validated scar and function assessment tools.

Given the current gaps in the literature and the lack of high-quality comparative studies on this topic, the primary objective of this study is to evaluate the efficacy of autologous fat grafting for the treatment of upper limb burn sequelae, in comparison to standard care.

Key words: Burn; Transplantation; Regenerative Medicine.

Introdução

Burn injuries are among the most complex forms of trauma and, when not resulting in death, are frequently associated with disabling physical and psychological consequences, leading to significant deterioration in quality of life for both patients and their families.

Burn trauma is widely recognized as a major public health problem (1,2,3). Understanding its epidemiology and etiological factors is essential for both the planning of preventive strategies and the development of effective treatment protocols (4). According to data from the World Health Organization (WHO), 111,196 deaths due to burns occurred worldwide in 2019, with approximately 90% of these deaths occurring in low- and middle-income countries (5).

In Brazil, data from the Ministry of Health (2015–2020) reported 19,772 burn-related deaths during that period. Of these, 53.3% were attributed to thermal burns, 46.1% to electrical burns, and 0.6% to other causes such as chemical, cold, or radiation burns. Thermal burns are most commonly sustained in the home, a trend that worsened during the COVID-19 pandemic. Notably, most fatalities caused by electrical trauma (70.1%) occurred outside healthcare facilities, due to the severity of the injuries at the site of the incident. Electrical burns are also frequently associated with major amputations, representing a leading cause of years of life lost and long-term work disability (6).

Burn injuries present a broad clinical spectrum and often result in long-term morbidity, impacting emotional and physical well-being as well as quality of life. Beyond the immediate acute management, these patients typically require prolonged rehabilitation due to frequent development of chronic and disabling complications. For this reason, burns are considered a high-cost public health burden with significant socioeconomic impact (5,6).

The most common burn sequelae include physical complications such as scars, contractures, chronic pain, and pruritus, as well as psychological effects such as insomnia, anxiety, depression, and post-traumatic stress disorder (7,8). In particular, upper limb involvement often leads to pathological scarring, retraction, and reduced

joint mobility, significantly impairing function and quality of life (9,10). The optimal approach to the rehabilitation of such patients remains under debate in the literature (10,11,12).

Autologous fat grafting (lipofilling), a technique involving the injection of processed adipose tissue, has emerged as a promising alternative for the treatment of hypertrophic scars and contractures resulting from burns. It offers not only aesthetic and contour improvements but also restoration of skin elasticity and joint function (13). Several mechanisms have been proposed to explain its beneficial effects, including the presence of mesenchymal stem cells and growth factors in the grafted adipose tissue, modulation of local inflammatory responses, reduction of oxidative stress, and promotion of tissue regeneration (14,15,16). Furthermore, fat grafting has proven to be a safe procedure with low complication rates, particularly because it uses autologous tissue and is therefore non-immunogenic (17,18).

In burn sequelae, fat grafting contributes to extracellular matrix remodeling and neovascularization of the scarred areas, leading to superior functional outcomes compared to conventional scar release techniques alone (15,16). Specifically in the upper limbs, its effect on scar contracture may significantly improve range of motion and functionality by attenuating dermal fibrosis, balancing collagen deposition, and reducing skin stiffness (14,15). After grafting, cellular differentiation and trophic factor secretion further contribute to skin and soft tissue regeneration, resulting in more pliable scars with reduced risk of retraction (19). Recent evidence also suggests that fat grafting can significantly reduce neuropathic pain associated with burn scars, thereby improving overall quality of life (20,21).

The use of autologous fat grafting in upper limb burn sequelae represents a meaningful advancement in reconstructive surgery. Increasingly, fat grafting is being adopted to treat contour and volume defects in various clinical contexts, including fibroproliferative scars following burns (22). Clinical benefits in this patient population include improved skin texture and elasticity, pain reduction in hypertrophic scars, and enhanced functional recovery of affected limbs. Although challenges such as variability in fat graft resorption remain, current literature supports its consideration as a therapeutic option, especially for patients with severe post-burn scarring (20,21,23).

Primary Objective:

To evaluate the efficacy of autologous fat grafting in the treatment of burn sequelae and pathological scars of the upper limbs, in comparison with the standard treatment using corticosteroid injections.

Secondary Objectives:

• To assess aesthetic and structural changes through standardized photographic analysis.

• To evaluate the quality of life of burn patients undergoing each treatment modality.

Methods

Trial Design

This is a single-center, randomized controlled trial (RCT) designed in accordance with the *Consolidated Standards of Reporting Trials* (CONSORT) guidelines and the *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT). The study will be conducted at the Federal University of São Paulo (Universidade Federal de São Paulo – UNIFESP), using a stratified randomization design (age 18–50 years) and a 1:1 allocation ratio. Participants will be randomly assigned to one of two parallel arms (autologous fat grafting vs corticosteroid injection). The study will be single-blinded, with outcome assessors blinded to treatment allocation. All participants will provide written informed consent prior to enrollment, in compliance with ethical regulations and after approval by the UNIFESP Research Ethics Committee.

Sample Size

A total of 40 participants will be enrolled from the outpatient clinics of the Burn Unit and the Pathological Scars Unit at the Plastic Surgery Division of UNIFESP.

Inclusion Criteria

- Adults ≥18 years of age of any sex.
- Burn injury involving the upper limb (hand, elbow, and/or axilla) occurring more than 12 months prior to screening.
- Presence of functional sequelae and/or pathological scarring.

- No ongoing treatment or history of any scar-related intervention within the past 6 months.

Exclusion Criteria

- Patients under 18 years of age.
- Presence of severe or debilitating systemic conditions contraindicating the proposed intervention or posing high surgical risk.
- Receipt of any surgical or medical treatment in the target area within 6 months prior to enrollment.

Withdrawal Criteria

Participants who fail to complete any stage of the study protocol will be withdrawn from the trial. Voluntary withdrawal from participation will be accepted at any time without compromising access to ongoing clinical care or follow-up.

Study Workflow

All participants will undergo an initial clinical evaluation including history-taking and physical examination to characterize burn sequelae and scar quality. Baseline assessment will include the application of validated scar questionnaires and standardized photographic documentation.

Participants will then be randomized into two groups:

- **Experimental Group (EG):** Autologous fat grafting (single session), with fat harvested from the lower abdomen.
- **Control Group (CG):** Single session of corticosteroid infiltration using triancinolone 20mg/mL.

Clinical Assessment

Clinical evaluation will include structured anamnesis, physical examination, and characterization of the scar area. Symptoms such as pain and pruritus will be scored using a Visual Analog Scale (VAS) ranging from 0 (no symptom) to 10 (maximum intensity). Erythema will be assessed through visual inspection and finger-press blanching for 3 seconds followed by capillary refill observation.

Validated Instruments and Follow-up

Three validated scar assessment tools will be used, administered at baseline, and at 3 and 6 months of follow-up:

1. **POSAS (Patient and Observer Scar Assessment Scale):** Developed by Draaijers (2003) and adapted by Lenzi (2019). It includes two 6-item scales (patient and observer), each scored from 1 (normal skin) to 10 (worst imaginable scar characteristic). Total scores range from 6 to 60; lower scores indicate better outcomes.
2. **Vancouver Scar Scale (VSS):** Developed by Sullivan et al. (1990), adapted to Brazilian Portuguese by Santos (2014). Evaluates four scar attributes: pigmentation, vascularity, pliability, and height. Total scores range from 0 to 13, with lower scores reflecting more favorable scar quality.
3. **PSAQ (Patient Scar Assessment Questionnaire):** Developed by Durani (2009), translated and culturally adapted by Ota (2017). Contains 39 items divided into two components: scar attributes (appearance, symptoms, texture) and patient satisfaction (appearance and symptoms). Responses range from "very satisfied" to "very dissatisfied."

Photographic Documentation

Standardized photographs will be taken at baseline, and at 1, 2, 3, and 6 months using the same camera and positioning protocol. Images will include frontal, lateral, and oblique bilateral views against a uniform blue background. A fixed floor marker will guide patient foot placement to ensure reproducibility. Patients will stand upright with gaze fixed on the horizon.

Randomization Process

Participants will be randomized into blocks of four using a randomization list generated through the Sealed Envelope platform (https://www.sealedenvelope.com). Allocation will occur after completion of baseline assessment. A schematic figure (Figure 1) will illustrate the pre-intervention flow of procedures.

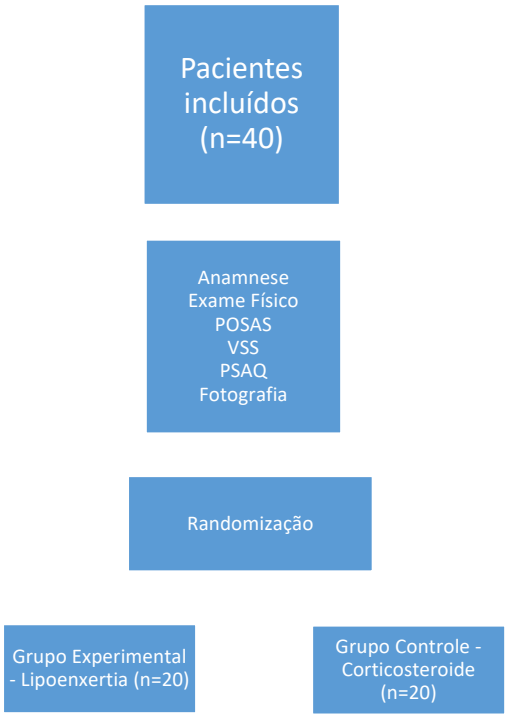

Figure 1: Study Flow Diagram

For all participants, a standardized treatment area of 10 cm² will be defined and demarcated within the scarred region. This delimited area will be used for both the intervention and subsequent clinical and photographic assessments, ensuring consistency and comparability across patients.

Adipose Tissue Harvesting Procedure (Fat Graft Collection)

Participants allocated to the fat grafting group will undergo the procedure in a dedicated surgical room at the Plastic Surgery Division of the Federal University of São Paulo (UNIFESP). Upon arrival, patients will have their vital signs, heart rate, and blood pressure checked by the nursing staff.

While in the supine position on a surgical stretcher, patients will receive local anesthesia at two sites:

1. The region surrounding the target scar on the thorax
2. The lower abdomen (donor area for fat harvest)

The anesthetic solution will consist of 2% lidocaine, 0.9% normal saline, and epinephrine at a final concentration of 1:100,000 to promote vasoconstriction.

Fat harvesting will be performed through a single transverse incision located at the midline of the lower abdomen, approximately 7 cm above the vaginal introitus or penile base. The subcutaneous area accessed will represent a semicircular segment. The incision will be approximately 2.5 mm in length to accommodate the introduction of a 3.0 mm diameter, 15 cm long blunt-tip cannula connected to a 10 mL syringe for low-pressure manual aspiration.

Fat Graft Injection Technique (Lipofilling)

The harvested fat will undergo gravity-based decantation for 10 minutes directly within the syringe, without environmental exposure. The liquid fraction will be discarded, and the remaining purified fat will be used for injection. The required volume will be estimated at 0.5 mL per square centimeter of scar tissue.

The fat will be injected using a 1.7 mm diameter, 5 cm long blunt cannula connected to a 1 mL Luer Lock syringe. The graft will be delivered into the subcutaneous plane beneath the scar, using a retrograde injection technique, parallel to the skin. Multiple intersecting and overlapping tunnels will be created through two perilesional micro-incisions (approximately 2 mm in length), oriented along the horizontal and vertical axes of the scar (Figure 2).

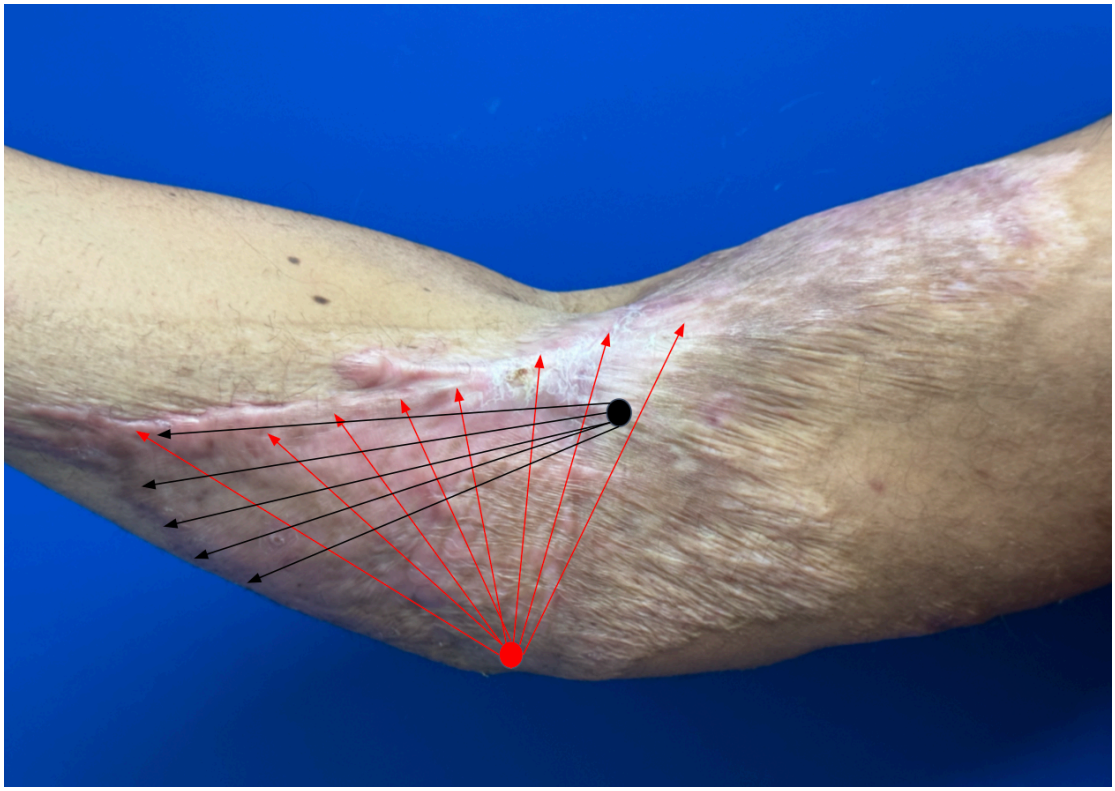

Figure 2: Schematic Representation of Lipofilling Technique

The black dot represents the incision site used for fat injection along the vertical axis of the scar, while the red dot marks the incision site along the horizontal axis. Black arrows indicate the direction of fat injection tunnels in the vertical subcutaneous plane, and red arrows represent the horizontal vectors. The schematic demonstrates the creation of a crisscross meshwork of injection tunnels covering the entire scar area.

Postoperative Care (Fat Grafting Group)

After the fat grafting procedure, an occlusive dressing will be applied over the treated scar and secured with microporous adhesive tape. The dressing will remain in place for 24 hours, after which it will be replaced with a similar dressing for an additional 24 hours. Further dressing changes will be performed as needed based on clinical assessment. The experimental group (EG) will undergo only one fat grafting session.

Donor Site Management

The 2.5 mm incision used for fat harvesting will be closed using primary suture with 5-0 nylon, followed by a simple dressing with sterile gauze and microporous tape.

Corticosteroid Infiltration Technique (Control Group)

Patients in the control group will undergo intralesional injection of triamcinolone acetonide at a concentration of 40 mg/mL. The corticosteroid will be distributed at a dose of 10 mg per linear centimeter of scar tissue, with a maximum total dose of 100 mg per session in the predetermined 10 cm2 area.

Injections will follow a radial pattern, beginning at the margins and progressing toward the center of the scar. A retrograde injection technique will be used. All infiltrations will be performed under local anesthesia, using a subcutaneous field block with 2% lidocaine containing epinephrine (Figure 3).

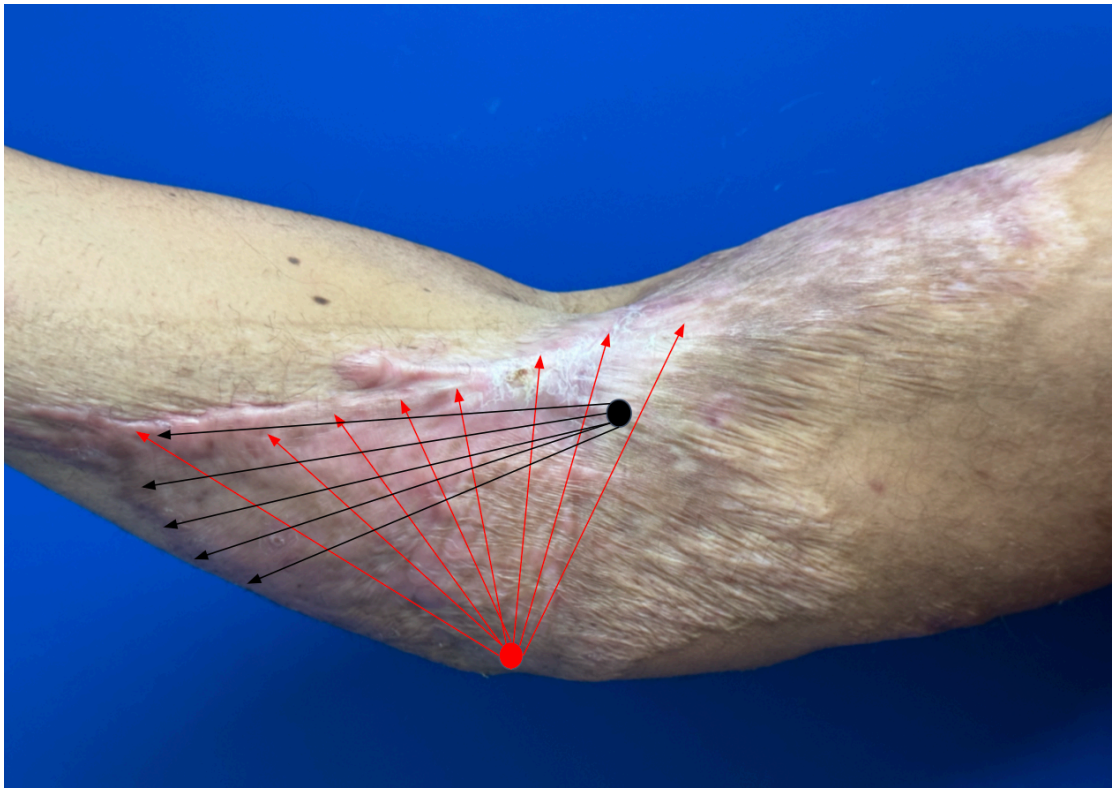

Figure 3: Radial Pattern of Corticosteroid Injection

The arrows indicate the radial injection pattern of corticosteroid infiltration, surrounding and covering the entire scar area.

Follow-Up and Periodic Evaluation

Participants in both groups will undergo scheduled follow-up assessments at 1, 3, and

6 months post-intervention. At each follow-up visit, standardized photographic documentation of the treated scar and the patient will be performed.
Two board-certified plastic surgeons with a minimum of 5 years of experience will independently evaluate the photographs in a blinded fashion, without knowledge of the participant's group allocation.
Each evaluation will include assessment of the following scar characteristics:

- Overall appearance
- Color and pigmentation
- Vascularity
- Height of the scar or keloid
- Global aesthetic improvement

All participants will be monitored for adverse events throughout the study period, including the perioperative phase and at each follow-up visit (1, 3, and 6 months). Any clinical complications such as infection, fat necrosis, contour irregularities, delayed wound healing, allergic reactions, or systemic effects will be documented and managed according to standard institutional protocols. All events will be classified by severity (mild, moderate, severe) and causality (related or unrelated to the intervention), following international clinical trial guidelines.

Serious adverse events (SAEs) will be immediately reported to the institutional Research Ethics Committee (REC/CEP) and recorded in the study database. Participants experiencing any complication will receive appropriate medical care and will not be withdrawn unless they or the research team deem it necessary. A Data and Safety Monitoring Plan (DSMP) has been outlined, and safety outcomes will be reviewed periodically by the principal investigator to ensure compliance with ethical and safety standards.

Outcomes

Primary Outcome Measure

Outcome Title:

Improvement in Scar Quality (Patient and Observer Scar Assessment Scale – POSAS)

Description:
The primary outcome is the change in scar quality in the upper limbs from baseline to 6 months post-treatment, assessed using a validated instrument: the Patient and Observer Scar Assessment Scale (POSAS). The POSAS includes both patient-reported and clinician-observed domains, each comprising six items scored from 1 (normal skin) to 10 (worst imaginable scar characteristic). Total scores range from 6 (best possible scar) to 60 (worst possible scar). Lower scores indicate better scar quality.

Time Frame:
6 months after intervention

Secondary Outcome Measures

1. Outcome Title: Patient Satisfaction with Treatment

Description: Subjective satisfaction with the aesthetic and functional outcomes of treatment, measured using a 5-point Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied).

Time Frame: 6 months after intervention

2. Outcome Title: Need for Additional Interventions

Description: Number and type of additional procedures required during the follow-up period, including surgical re-interventions, repeat corticosteroid injections, or secondary fat grafting.

Time Frame: 6 months after intervention

3. Outcome Title: Incidence of Adverse Events

Description: Occurrence of treatment-related adverse events, including fat necrosis,

infection, contour irregularities, delayed wound healing, or systemic complications. Events will be assessed clinically at follow-up visits.

Time Frame: 1 week, 1 month, and 6 months after intervention

4. Outcome Title: Scar Improvement Measured by Vancouver Scar Scale (VSS) and Patient Scar Assessment Questionnaire (PSAQ)

Description:
Changes in scar characteristics and symptoms (e.g., pain, pruritus, stiffness) as measured by two additional validated instruments:
– **Vancouver Scar Scale (VSS):** Evaluates pigmentation, vascularity, pliability, and height (range: 0–13; lower is better).
– **Patient Scar Assessment Questionnaire (PSAQ):** Assesses both physical attributes and patient satisfaction.
These scales will be administered at baseline and 6 months post-intervention.

Time Frame: 6 months after intervention

Statistical Analisys

Following data collection, descriptive statistics will be performed and relative frequency distributions will be compared using the two-proportion z-test. Pearson's correlation coefficient will be calculated to assess the relationship between quantitative variables.
For group comparisons:

- Categorical variables will be analyzed using the Chi-square test.
- Continuous variables will be compared using the paired Student's t-test when appropriate.
- For non-normally distributed data, a nonparametric test equivalent to the Wilcoxon signed-rank test will be applied.

A significance level of 0.05 will be adopted for all analyses, with 95% confidence

intervals reported.
All statistical analyses will be performed using SPSS® version 20, Minitab® version 16, and Microsoft Excel® (Office Suite).

All statistical analyses will follow the **intention-to-treat (ITT) principle**, meaning that all randomized participants will be analyzed within the group to which they were originally allocated, regardless of adherence to the intervention or protocol deviations. This approach ensures the preservation of randomization benefits and minimizes potential biases, particularly in the assessment of treatment effectiveness.

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