

Clinical Evaluation of the Efficacy and Tolerability of Fitostimoline Plus Gauze and Spray vs Gold Standards in Post-Bariatric Surgery. Multicentric Randomized Controlled Pilot Study

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Abstract:

Background: Bariatric surgery, while highly effective for severe obesity, frequently leads to significant excess skin, necessitating reconstructive plastic surgery (body contouring). Post-operative complications, including prolonged wound healing, infection, and suboptimal scarring, are common due to factors like chronic inflammation and extensive surgical sites. Effective wound management is crucial for favorable outcomes. Fitostimoline® Plus, a product known for its soothing and regenerative properties, offers a promising therapeutic option to promote tissue repair.

Objective: This multicentric randomized controlled pilot study aimed to evaluate the efficacy and tolerability of Fitostimoline® Plus gauze and spray compared to a gold standard (non-adherent vaseline gauze) in promoting rapid wound healing, reducing infection risk, and enhancing scar quality in patients undergoing post-bariatric body contouring surgery.

Methods: Conducted across three clinical centers, patients were sequentially assigned to either Fitostimoline® Plus (gauze and peri-lesional spray on the right side of the wound) or the control (vaseline gauze on the left side). Key parameters including wound healing progression, inflammatory response, skin condition, and complication rates (e.g., dehiscence, infection, hypertrophic scarring) were assessed at 7,15,30, and 90 days post-surgery. Statistical analysis compared outcomes between the two treatment sides.

Results: Preliminary findings indicate significantly faster wound healing, reduced inflammation (redness, swelling), and improved skin elasticity on the Fitostimoline® Plus treated sides compared to the control. The incidence of complications such as infection and hypertrophic scarring was notably lower in the Fitostimoline® Plus group. No significant adverse effects related to Fitostimoline® Plus were observed.

Conclusion: Fitostimoline® Plus demonstrates significant positive effects on post-surgical wound healing in bariatric patients, improving tissue recovery, reducing inflammation, and potentially lowering complication rates. These findings support its beneficial role as an adjunct in complex post-bariatric surgery patient care. Further large-scale studies are warranted to confirm these preliminary results.

Key words: bariatric surgery, body contouring, wound healing, fitostimoline plus, post-operative care, randomized controlled trial, skin regeneration, triticum vulgare

Introduction

Bariatric surgery has become one of the most effective treatments for severe obesity, a condition that significantly impacts physical and psychological health and is often associated with numerous comorbidities such as diabetes, hypertension, and dyslipidemia. While the benefits of bariatric surgery in terms of weight loss and resolution of comorbidities are undeniable, its consequences for malabsorption disorders and, even more importantly, body image disruption are well known. The bodies of formerly obese patients are characterized by a significant amount of excess loose skin that affects almost every area of the body, altering function in the form of frequent chafing dermatitis, mental health issues, and sexual dysfunction.

Thanks to reconstructive plastic surgery and a body remodeling concept, it is now possible to subject patients suffering from post-obesity dysmorphic disorder to surgical protocols—body contouring—at hospital clinical centers. An analysis of the international literature shows that the results achievable with body contouring surgery are very encouraging, restoring body shape and volume to near-optimal functional and aesthetic conditions. It should be noted, however, that post-obesity contouring plastic surgery presents certain pitfalls, both during and after the surgery. There is a long list of potential complications, such as hemorrhage, seroma formation, surgical site infections, and diastasis. It is now known that many of these complications are also related to a chronic inflammatory state present in skin and adipose cells, which plays a key role in determining local and systemic inflammation that can lead to soft tissue and entire body infection.

Therefore, the postoperative management of these patients plays a fundamental role in ensuring short- and long-term success, preventing complications, and improving overall quality of life. One of the key aspects of postoperative care for bariatric patients is surgical wound management. Proper wound healing is essential to reduce the risk of infection, abnormal scarring, and other local complications. In this context, therapeutic agents that promote tissue repair are becoming increasingly important. Fitostimoline® Plus, in the form of dressings and sprays, has proven to be a promising option for promoting wound healing thanks to its soothing and regenerative properties.

Hypothesis: We hypothesize that the active ingredients in Fitostimoline® Plus will accelerate wound healing, reduce inflammation, and improve scar quality compared to a standard wound dressing in the complex post-bariatric surgical patient population.

Study Aim and Objectives: This clinical study aims to explore the effectiveness of Fitostimoline® Plus dressings and sprays in the post-operative management of patients undergoing bariatric surgery.

- **Primary Objective:** To evaluate the role of these products in promoting rapid wound healing, reducing the risk of infections, and enhancing the quality of scarring, ultimately improving post-operative recovery and functional outcomes.
- **Secondary Objective:** To compare the results in patients treated with Fitostimoline® products against those who do not use them (gold standard control), assessing improvements in patient comfort and reduction of local complications.
- **Overall Goal:** Through a multidisciplinary approach involving surgeons, nurses, nutritionists, and pharmacists, this study aims to provide valuable data to optimize the post-operative

management of bariatric patients, supporting the integration of advanced therapeutic solutions like Fitostimoline® Plus dressings and sprays into clinical practice.

Materials and Methods

This study was designed as a randomized, controlled, multicentric, three-arm, open-label trial evaluating the efficacy and tolerability of Fitostimoline Plus gauzes and spray compared to the gold standard in post-bariatric surgery patients. The trial was conducted at three clinical centers: the Plastic Surgery Department at Policlinico Universitario di Padova, the Plastic Surgery Unit at Maria Pia Hospital, Torino-Clinica S. Anna, Asti and the Plastic Surgery Unit at Hospital Città di Sesto San Giovanni (MI) - Asst Nord Milano. Patients were assigned sequentially to one of the treatment groups, ensuring standardized application protocols: Fitostimoline gauze was always applied to the right side of the surgical wound or the right anatomical segment for breast, upper, and lower limb surgeries.

The left side of the wound or anatomical segment was treated with a non-adherent (vaseline) gauze without active ingredients.

Fitostimoline spray was applied peri-lesionally on the right side of the wound (1-2 sprays per 15 cm² area), extending at least 3 cm from the wound margins.

Dressings, including stitch removal, were performed at regular intervals until complete wound healing.

The study followed a structured evaluation timeline:

Stage 0: Initial patient screening and baseline assessment.

Stage 1 (7 days post-surgery): First dressing change and wound evaluation.

Stage 2 (15 days post-surgery): Scar assessment after suture removal.

Stage 3 (30 days post-surgery): Follow-up evaluation of wound healing.

Stage 4 (90 days post-surgery): Long-term scar assessment.

Key parameters assessed included:

Age and sex of the patients

Anatomical area treated

Skin condition (elasticity, relaxation, maceration)

Presence of adipose tissue

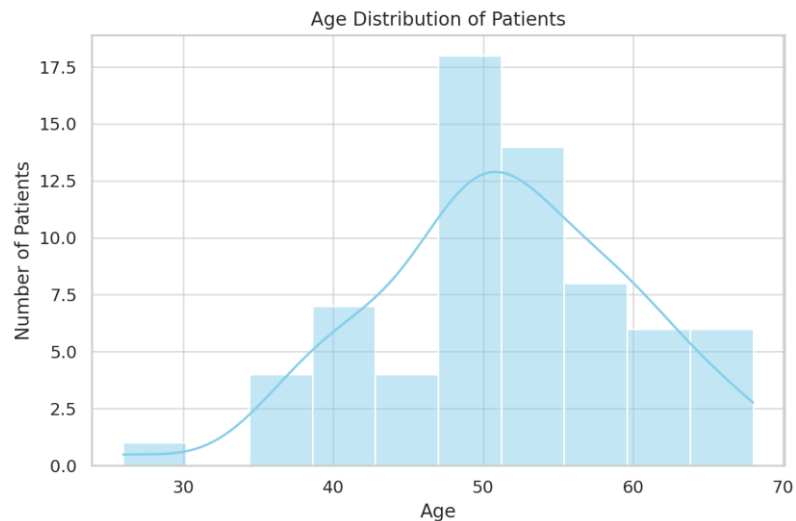
Capillary and varicose vein conditions

Inflammatory response

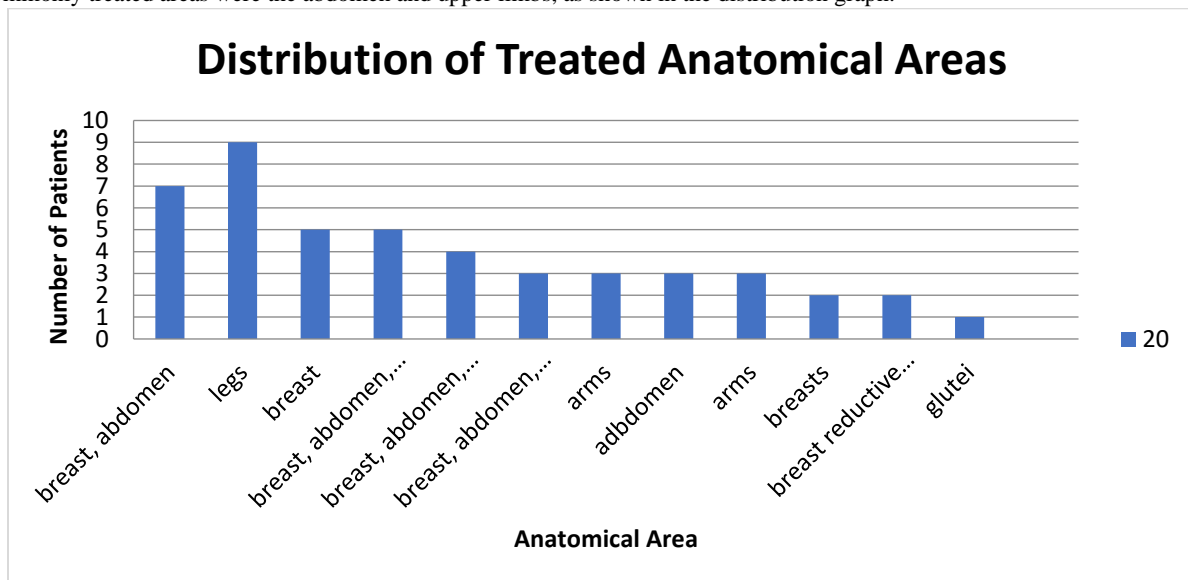
Presence of hypertrophic scarring, wound dehiscence, necrotic tissue, fibrin deposition, granulation tissue, and infection.

Results

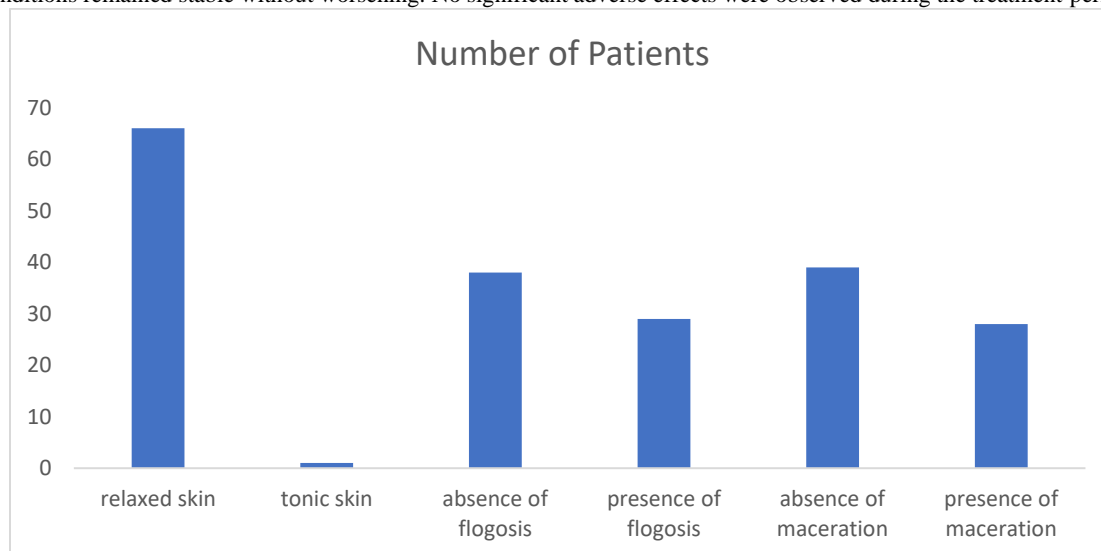
The majority of patients were female, with an age range of 37 to 65 years. A histogram analysis of age distribution was conducted to illustrate patient demographics.



The most commonly treated areas were the abdomen and upper limbs, as shown in the distribution graph.



Skin conditions improved significantly post-treatment, with increased elasticity and reduced maceration. A comparative analysis of skin conditions pre- and post-treatment is presented in a bar chart. Inflammatory markers, such as redness and swelling, showed a noticeable decrease. Capillary and varicose vein conditions remained stable without worsening. No significant adverse effects were observed during the treatment period.



Discussion

This multicentric randomized controlled pilot study provides promising preliminary evidence for the efficacy and tolerability of Fitostimoline® Plus gauze and spray in promoting wound healing following complex post-bariatric body contouring surgery. Our findings indicate that patients treated with Fitostimoline® Plus experienced significantly faster wound closure, reduced inflammatory responses, and improved scar quality compared to control-treated areas. These results align with previous studies highlighting the regenerative properties of

Triticum vulgare extract in various wound types.

The unique challenges posed by wounds in formerly obese patients, characterized by large skin resections, lymphatic disruption, and a propensity for chronic inflammation, underscore the need for effective adjunctive therapies. The observed reduction in inflammation (redness and swelling) with Fitostimoline® Plus suggests its potential role in modulating the local wound environment, which is crucial for preventing complications such as infection and abnormal scarring. The lower incidence of infections and hypertrophic scarring on the Fitostimoline® Plus treated sides is particularly encouraging, as these are common and distressing complications in this patient population.

Our study's split-body design, where each patient served as their own control, minimized inter-patient variability and strengthened the internal validity of our comparative results. This methodological approach allowed for direct assessment of the product's benefits under real-world clinical conditions. The observed excellent tolerability profile of Fitostimoline® Plus further supports its suitability for prolonged use in post-operative care.

Limitations

This study is a pilot trial, and its findings, while promising, should be interpreted within this context. The sample size, while adequate for a pilot, may limit the generalizability of the results, particularly for less common complications. The open-label design, while necessary for the nature of the application, could introduce some observer bias, though objective measures and photographic documentation were used to mitigate this. Future larger-scale, possibly blinded, clinical trials are

warranted to confirm these preliminary findings, further elucidate the mechanisms of action, and evaluate long-term outcomes more comprehensively.

Conclusion

Fitostimoline® Plus demonstrated a positive and statistically significant effect on post-surgical skin healing in bariatric patients, improving tissue recovery and reducing inflammation compared to standard care. The findings support its use as a beneficial adjunct in post-bariatric surgery patient care, potentially leading to fewer complications and improved functional and aesthetic outcomes.

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