Research Article

BIOMEDICAL Journal of Scientific & Technical Research

ISSN: 2574 -1241

DOI: 10.26717/BJSTR.2025.61.009534

Safety and Efficacy of Ha Volume Filler for Buttock Enhancement

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ARTICLE INFO

Received: February 17, 2025

Published: March 18, 2025

Citation: Prof. Antonio Scarano, MD PhD, Prof. Domenico Amuso MD, Prof. Roberto Amore MD, Dr. ssa Luana Leggieri, Dr. Luca Nencini, Dr. ssa Gloria Bettini Prof. Andrea Sbarbati and Dr. Ali Alamri. Safety and Efficacy of Ha Volume Filler for Buttock Enhancement. Biomed J Sci & Tech Res 61(1)-2025. BJSTR. MS.ID.009534.

Background

The popularity of dermal fillers has grown rapidly in recent years; this because employing fillers we can obtain aesthetic improvements previously only achievable with surgery at lower cost and with lower risks than surgery; furthermore, by using fillers the results are modulable and reversible and the recovery time is limited/absent. Main indications for face fillers are defects like rhytides and folds, and soft tissue loss (due to disease or aging) [1]; moreover, fillers are used for procedures of volume replace¬ment and enhancement [2], including cheek and chin augmentation, midfacial volumization, tear trough correction, nose reshaping, lip enhancement, and the correction of facial asymmetry [3]. As the use of fillers has increased and expanded to new facial targets, there has been a trend towards using them in areas beyond the face, such as the buttock, calves, and external genitals, with often inconsistent results in terms of efficacy and safety. In order to improve the outcomes and to reduce complications, it is essential that injectors know different characteristics, capabilities and limitations of available fillers and choose and develop the best injection technique for each of them. For the injector to have an high expertise in a wide range of products is essential, including products not available in injector's country of practice, as patients may present with adverse reactions to fillers injected abroad [3].

Particularly important is understanding how the incidence of local adverse events following treatment is related to the injection technique versus the chemical composition of the dermal filler [4]. Aim of the present study is to evaluate the safety and efficacy of buttock enhancement with dermal filler using a specific hyaluronic acid (HA) medical device using an "adhoc" technique.

Materials and Methods

The study was a multicentric, observational, non-controlled clinical trial, in accordance with the Standards of Good Clinical Practice of the European Union and the ethical principles expressed in the Declaration of Helsinki. The study began on 01-02-2021 and lasted until 01-05-2022. Patients were recruited from 01-11-2020 to 31-01-2021. Candidates were recruited through an initial interview in which

the doctor assessed the characteristics of their buttock to determine if they have got the inclusion criteria for the study. Additionally, during the interview, the doctor provided the candidates with information about the study. Interested candidates underwent an information session with the doctor to discuss adverse events and the candidate's active role in the study, including completing evaluation surveys and reporting any adverse events. The doctor then provided the candidate with three forms: an information sheet, an informed consent form, and a personal data management sheet. The candidate was asked to carefully review the forms at home and ask any additional questions if necessary. After a minimum interval of 14 days, the candidate returned the completed and signed forms with all requested data. At this point, the candidate was assigned an alphanumeric identification code and could be considered effectively recruited into the study.

Study Inclusion Criteria

Healthy subjects with buttock to be increased laterally and/or posteriorly.

Study Exclusion Criteria

Psychological problems (indecisive or immature personality, anxious, dysmorphophobic, with factitious disorders or with family disapproval), minors, pregnancy or breastfeeding, known allergies to HA filler, severe or skin-related autoimmune diseases, current acute infections, immunosuppression, haemorrhagic diathesis, oral anticoagulant therapy, platelet disorders, hormonal, metabolic and organ diseases in acute phase or with functional deficiency, patients with tendency to develop hypertrophic scars, keloids or skin inflammation. The contraindications relating to the area to be treated were represented by acute pathologies in progress (inflammations, burns, continuous solutions, acute dermatological lesions), infections (including herpetic reactivations), skin tumours, prosthesis, foreign bodies or permanent fillers in the involved area.

Medical device used in the study was Neofound BODY (LOVE COSMEDICAL srls - Via Toniolo 9, 57022 Castagneto Carducci, ITALY) containing Sodium Hyaluronate/Hyaluronic Acid HIGH molecular weight (1.500<HA<2.000 KDA) 20%, Sodium Hyaluronate/Hyaluronic Acid LOW molecular weight (155<HA<230 KDA) 9%, Niacinamide, Glycine, Proline, BDDE. Patients were treated with 100-200 ml of filler in a single session by the authors through the modality and in accordance with the following protocol and technique.

Draw

Before carrying out the treatment, buttock was evaluated and drawn carefully with patient in standing position [5-8]. The margins of the area to be filled, as well as the "point of maximal projection", where the maximum filling effect was desired, were marked. The drawing should be conservative, considering that 30-40ml of gel are required for every 10cm x 10cm area. Entry points were signed medially upper at a minimum distance to the drawn area of minimum 1cm.

Preparation

The patient lay on the back. Buttock has been thoroughly disinfected with iodopovidone 10% solution.

Anesthesia

Anesthetic solution was composed by 25% of lidocaine 2% solution and 75% saline solution. A total amount of 40ml (10ml lidocaine and 30ml saline) was enough for both sides. First anesthesia was performed with 30 Gauge 13mm needle and a dermal infiltration (papula) of 0,5 ml anesthetic solution on the entry points. Second anesthesia was performed with a fun technique and retrograde release in the drawn area, just on the subcutaneous layer, with a 23 Gauge 100 mm needle.

Technique

10ml syringes of filler with a cannula of 16G x 100mm were used. Eighty percent of the quantity decided during the physical examination was distributed with the centrifugal fan technique, that is, filling the point where the maximum projection (already marked during the draw) was required and subsequently moving away progressively towards the edges of the drawn area. This allows to obtain the maximum effect from the predetermined quantity of filler, without having to resort to further quantities. The correct release plan was the hypodermis, being careful not to infiltrate the dermis superficially and the muscle deeply (see the discussion paragraph). Infiltration was done with retrograde release and at boluses not exceeding one milliliter. After the infiltration of both sides, the subject was placed in standing position, re-evaluated and any asymmetries and irregularities were drawn. The subject was then placed prone again and the remaining 20% infiltrated to correct these defects or simply to improve the result. This allows to obtain a symmetrical, homogeneous and satisfactory result while remaining with the quantity of filler previously decided.

Immediately after the Treatment

A patch was applied to the access point which was removed after 24 hours.

Post-Treatment

Subjects were asked to avoid strenuous physical activity, prolonged exposure to sunlight and heat sources, tanning lamps, or extreme weather conditions for 24 hours after treatment in order to reduce redness, edema, and irritation. Elastic compression was not applied. Subjects were asked for the first week not to wear clothing with an elastic part passing through the treated area (e.g. low-waisted trousers, Brazilian-style underpants). Throughout the study period, the recruited subjects did not undergo any concomitant therapy and aesthetic treatment in the gluteal region. Recruited subjects were evaluated 1, 6, 12 months after treatment. The clinical evaluation aimed to detect the efficacy and safety of the filler and its protocol.

The effectiveness was assessed by the degree of satisfaction of the treated subjects and by the photographic comparison carried out by the doctors who performed the treatment. The improvement value was expressed according to the Global Aesthetic Improvement Scale (GAIS) (1 optimal improvement, 2 good improvement, 3 moderate improvement, 4 no improvement, 5 worsening). Safety was evaluated using an adverse event onset form.

Results

The study recruited 210 subjects, across three different centres; among these, 203 completed the one-year follow-up. The average amount injected in the single session was 143 ml (100 ml -200 ml). The subjects that completed the study were 178 women and 25 men (average age 41 years) and were evaluated both for efficacy and safety of the procedure.

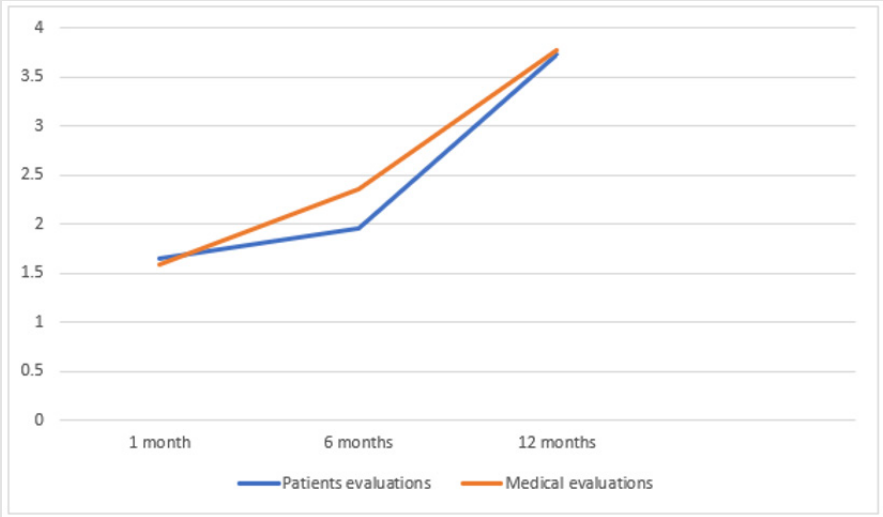
Safety

The following adverse events occurred during the study: Bruising 126, pain 89, itching 7, bumps/lumps - asymmetries 2, erythema 2, contour irregularities 1, edema (more than 48h) 0, infection 0, hypersensitivity 0, skin discoloration 0, vascular compromise 0, nodule/abscess 0, non-fluctuant nodules 0, compromised muscle function 0, dysesthesias/paresthesias/anesthesia 0, foreign-body granuloma 0, migration of filler material 0, persistent scarring 0, tissue necrosis 0, embolism 0. Out of 203 sessions, bruising was the most frequent adverse event and lasted for maximum 10 days (average 6.03). Pain was mild in 74 cases, was moderate and required pain killer (FANS) for maximum 48 h in 15 cases. Itching and erythema were mild and self-resolved in maximum 3 days. Bumps/lumps, asymmetries, contour irregularities were due to technical mistakes occurring during the procedure. Rare adverse events described in literature after injecting filler, such as embolism, nodules, or fibrosis did not occur in this study.

Effectiveness

After one month, the 203 patients who completed the study attributed an average score of 1.65±0.58 (median value 2). The percentage of therapeutic failure, judged with a score equal to or greater than 4, was 0%. After six months, the average score was 1.96±0.69 (median value 2), and 23.64% judged the result as optimal. In this case, the therapeutic failure rate was 2.46%, even though nobody reported worsening. The last check-up, performed at 12 months, reported an average score of 3.72±0.53 (median value 4), with 77.34% reporting that they had lost the result. Again, no one reported worsening (see Tables 1 & 2). Similarly, the medical evaluation reported an average score of 1.59±0.58 (median value 2) after one month, and 3.77±0.56 (median value 4) after one year. However, after six months, the evaluation was 2.36±0.99 (median value 2), a value higher than the one obtained by patients. Even in these evaluations, no value of 5 (indicating worsening) was observed, while the percentage of lost results was 19.21% and 84.23% after six months and one year, respectively. The result decreased progressively over time (Graph 1). The loss of the result, judged with a score equal to 4, occurred in 50% of the subjects in 9.22 months (val. treated subjects) and 8.45 months (val. medical). The results described above were statistically analysed using a t-test, demonstrating that:

- There is no statistically significant difference between patient-reported (subjective) and medical (objective) evaluations, with a p-value > 0.05 at 1 and 12 months (Graph 1).
- There is a statistically significant difference between patient-reported (subjective) and medical (objective) evaluations, with a p-value < 0.05 at 6 months.



Graph 1: Graphical representation of medical and patient evaluations at 1, 6, 12 months.

Discussion

Clinical data emerging from this study showed that the filler used is effective and safe to treat buttock area (Figures 1 & 2). The protocol used in this study proved to be valid, effective, safe and of good compliance by patients. After a month the study demonstrated therapeutic success, judged as sufficient, good or excellent, in all subjects who completed the entire protocol, demonstrating the effectiveness of buttock enhancement filler procedure. This study shows the safety of proposed procedure for buttock enhancement with HA volumizing filler: this is due to the filler characteristics (inherent safety) and to the employed technique (extrinsic safety/procedural safety). Filler's characteristics are diriment for safety and effectiveness [9]. The chemical composition of body fillers used in past (high percentage of cross linking and high concentration of HA in addition to the type of hyaluronic acid used with very high molecular weight) has caused a high onset of adverse events, such as inflammatory and non-inflammatory nodules, edema, abscesses, systemic responses to infection. The reduction in the molecular weight of the HA used (<2,000,000 Daltons) and the concentration of the HA (20mg/ml) have drastically reduced the incidence of these adverse events, making body fillers safe at least as face fillers. The procedure is extremely important, and it is aimed at minimizing extrinsic risk.

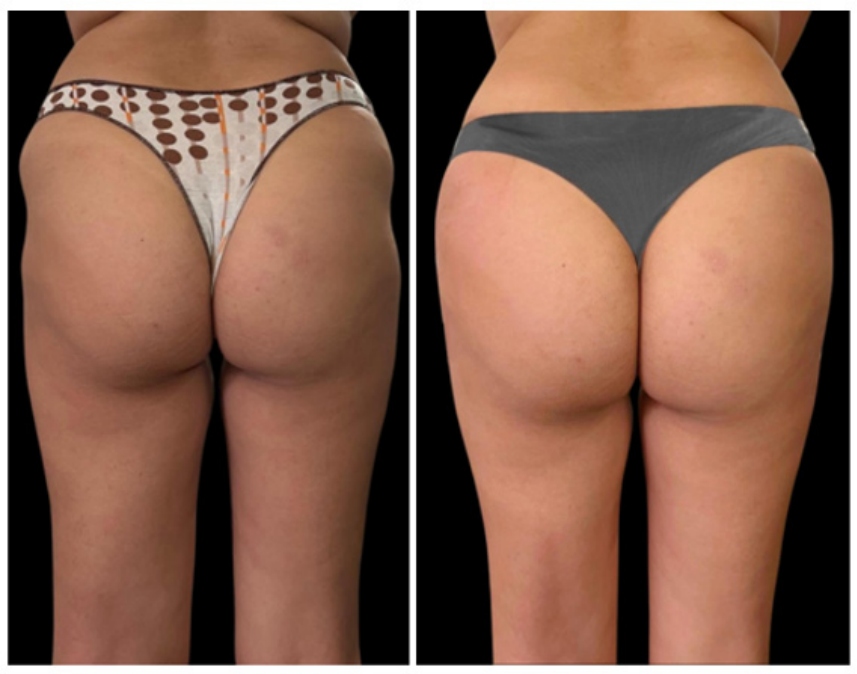


Figure 1: Pretreatment (1a - left) and 1 month's posttreatment photographs (1b, right) of female subject 38 y.o. Pazient was treated with 130 ml of filler (60ml on left side and 70 ml on right side) for remould the shape of the gluteus in the lateral portion.

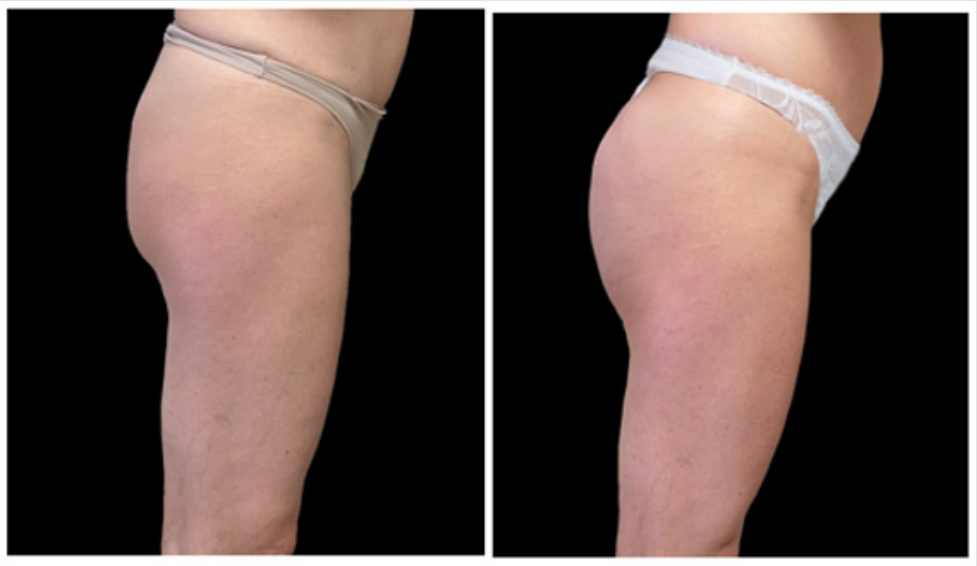


Figure 2: Pretreatment (1a - left) and 6 months posttreatment photographs (1b, right) of female subject 46 y.o. Pazient was treated with a total amount of 200 ml filler to increase the posterior projection of the gluteus.

Draw

During the procedure the patient is prone, and the conformation of the buttock is very different from the standing one, as gravity acts differently. To have a guide map during the procedure is important to draw the margins of the area to infiltrate, and to sign the "point of maximum projection", or anyway the point where you want to obtain the maximum effect from the filling when the patient is in orthostatism. The drawing will also give a realistic indication of the quantity of gel to be used (30-40ml in each 10cm x 10cm). The choice of entry points is also important; using cannulas or needles larger than 19 G, the entry hole remains patent for a few hours, leaving a link between the implanted area and the outside, thus exposing the implant itself to possible contamination and resulting infections. By performing high access points, in an anti-gravity direction, the so-called backfire is avoided and the risk of leakage of the infiltrated gel from the entry point is reduced. Furthermore, the entry is performed medially, because it is easier to mobilize laterally the buttock during the procedure. The medial portion is very attached to the bony structures by means of strong ligaments that do not allow movement. Furthermore, distraction of the anal orifice during the procedure is uncomfortable for the patient.

Preparation

Disinfection of the buttock reduces the risk of infections. Even the proper use of sterile material, respecting the rules of asepsis (e.g. using waterproof gloves, not contaminating the infiltration cannula by touching it), is a fundamental safeguard against this adverse event.

Anesthesia

Local anesthesia is essential for this type of procedure, considering that the gel is distributed with cannulae or needles larger than 19G and is therefore very painful. A mixture of 20ml of 0.5% anesthetic solution per side is more than sufficient to guarantee minimal discomfort for the patient. Furthermore, local anesthesia reduces the margin of error of gel infiltration on the wrong plane, i.e. dermal or muscular. If during the gel infiltration procedure, the cannula is brought too superficially (dermal plane) or too deeply (muscular plane) and therefore in both cases in a non-anesthetized plane, the patient will feel sudden pain. This provides important feedback to the operator who retracts the cannula without releasing the filler, avoiding risks of surface irregularities due to dermal infiltration and embolic risks from muscle infiltration (the gluteal muscles, unlike the gluteal subcutaneous tissue, have large-caliber vessels and therefore at risk of accidental intravascular infiltration).

Technique

Our technique aims to obtain the maximum result with the quantity of gel initially budgeted, avoiding irregularities, asymmetries, lack of results and, consequently, the necessity to use a further amount of gel to correct such defects. Performing the filling in a centrifugal way, starting from the point of maximum projection and progressively moving towards the edges of the drawing, allows you to obtain an adequate projection, avoiding a lack of results. Implanting 80% of the quantity, re-evaluating the subject while standing and using 20% as retouch reduces the risk of asymmetries and/or irregularities. Injection exclusively on the subcutaneous plane is extremely safe from a

vascular point of view, considering that the caliber of the cannula is greater than that of its vessels (unlike in the muscular plane) [10-13].

Immediately after the Treatment

Patch applied to the access point reduce the risk of infection. The indication to avoid wearing clothes with an elastic part passing through the treated area reduces the risk of skin irregularities.

Conclusions

The combination of a specific body filler injected with specific technique, with the dosage and protocol used in this study, proved to be valid and safe [14-16]. In future investigations it will be interesting to use the same filler in different body areas. This study will provide clear guidance for buttock filler treatment using Hyaluronic Acid (HA) fillers, as well as instil greater confidence in the low risk of adverse events related to injection technique and the chemical composition of the dermal filler, and how to avoid them.

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ISSN: 2574-1241

DOI: 10.26717/BJSTR.2025.61.009534

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