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# Evaluating the Safety and Satisfaction of HYAcorp MLF2 for Noninvasive Buttock Augmentation: A Multicenter Study

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**Background:** The increasing demand for noninvasive gluteal augmentation using hyaluronic acid (HA) gel highlights the need for research into its safety and effectiveness. This study aimed to assess the safety and satisfaction levels of patients and physicians regarding HA body filler for buttock enhancement. It also explores variations in outcomes across different injection sites and among different practitioners.

**Methods:** This retrospective, observational, descriptive multicenter study analyzed the outcomes of using a body HA filler (HYAcorp MLF2) for buttock augmentation across 4 Italian centers, with a 6-month follow-up period. Patients' and physicians' satisfaction levels were measured immediately postprocedure, and adverse events were monitored throughout the study period.

**Results:** Thirty-five subjects received injections, with an average volume of 85.1 ± 42.2 mL per subject injected. Throughout follow-up, 94% of patients and 100% of physicians rated the improvement as "very good" or "good." Adverse events were generally mild-to-moderate, typically resolving within 2–7 days. The most frequently recorded adverse effects were swelling, pain, and redness. No significant differences were observed among injectors ($P > 0.05$).

**Conclusions:** HYAcorp MLF2 is safe and effective for buttock augmentation, demonstrated by high satisfaction rates and manageable, mild-to-moderate adverse events, with no significant variation based on practitioner experience or clinic site.
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## INTRODUCTION

In today's society, where perceptions of the human body are constantly evolving, there is a growing interest in body-shaping treatments. Buttock aesthetics are primarily influenced by their size and waist-to-hip ratio, with preferences for buttock size varying significantly across different ethnic groups.[1] The attractiveness of the buttocks is determined not only by a prominently projected gluteal area that forms a smooth, natural curve from the waist to the knee when viewed from the side but also by the softness and skin elasticity of the buttock area.[2,3] Several factors motivate individuals to pursue buttock augmentation or reshaping, including changes in buttock morphology due to aging or weight fluctuations, and the significance of the buttocks as a secondary sexual characteristic.[4,5] Fat accumulation in areas such as the supragluteal, lower paralumbar, infragluteal, and trochanteric regions often disrupts the natural contour of the buttocks, a situation exacerbated by insufficient lateral projection.[6]

Gluteal augmentation procedures must be both effective and safe, fitting seamlessly into daily routines.[7] Currently, several techniques are available for gluteal augmentation including autologous fat grafting, implants, local flaps, local tissue rearrangement, and hyaluronic acid (HA) gel injection.[8] The advancement of HA fillers

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for body contouring has allowed for less invasive techniques in posterior body reshaping. HA gluteal augmentation offers numerous benefits for both patients and clinics, as it is a nonsurgical procedure that provides predictable results with minimal risk when performed with the proper precautions.[9] Moreover, injectable HA is effective and well-tolerated.[10] Several studies have shown statistically significant improvements in patient satisfaction with low complication rates when using HA fillers for body augmentation.[11–14] However, there is a lack of published guidelines outlining best practices and safety protocols for gluteal augmentation with HA fillers. To our knowledge, no previous studies have examined comparisons or correlations between treatment effectiveness and the experience of the practitioner administering the injections.

This study presents the outcomes of using a HA-based body filler HYAcorp MLF2 (BioScience GmbH, Dümmer, Germany) for gluteal augmentation. This study aimed to evaluate the safety and satisfaction levels of patients and physicians immediately after treatment and at follow-up periods of up to 6 months. In addition, it compares results across different clinical sites and among practitioners with varying levels of experience.

### Takeaways

**Question:** What is the short-term safety and satisfaction of hyaluronic acid body fillers for gluteal augmentation?

**Findings:** This multicenter study evaluated the safety and satisfaction of HYAcorp MLF2 for gluteal augmentation during a 6-month follow-up. High satisfaction levels were reported by patients and physicians, with no serious adverse events or significant differences between centers and injectors.

**Meaning:** HYAcorp MLF2 demonstrates a good safety profile, minimal complications, and high satisfaction rates, irrespective of the injector or technique used.

## METHODS

### Study Design

This retrospective, observational, descriptive multicenter study gathered data from 4 clinics in Italy (2 in Rome and 2 in Milan). All subjects participated as part of routine clinical practice. Data were extracted from existing medical records.

Four specialists (3 plastic surgeons and 1 general surgeon) decided on HA body filler procedures based on each patient's clinical requirements, following standard practices such as thorough evaluations, medical history reviews, and aesthetic goal assessments. Established safety protocols were followed, including proper injection techniques, sterility measures, and postprocedure care. Follow-ups ensured optimal outcomes and addressed any concerns.

Participants signed consent forms allowing data use for research and completed their follow-up period. Exclusion criteria included mild ptosis, a body mass index less than 18 or greater than 30 $kg/m^2$, and other conditions listed in the product's instructions, such as keloid scarring, intolerance to Gram-positive bacteria, autoimmune diseases, pregnancy, or lactation.[15]

### Filler Properties and Technique of Injection

Subjects received HYAcorp MLF2 (BioScience GmbH), an HA-based body filler with cross-linking technology, Conformité Européenne-marked since 2013 for gluteal augmentation. It contains cross-linked HA (20 mg/mL), noncrosslinked HA (2 mg/mL), and sodium chloride (6.9 mg/mL).[15]

The injection techniques were similar across centers. Procedures were conducted under sterile conditions in a consulting room, with practitioners using sterile gloves, surgical gowns, and drapes. Patients stood while the treatment areas were outlined to identify where volume should be added or depressions filled. After finalizing the design, the patient was photographed and repositioned in a prone position, and the gluteal area was disinfected with povidone–iodine or chlorhexidine.

Entry points for the cannula were determined to allow access to all treatment areas. Depending on the case, a single or multiple entry points were created using an 18G needle. Local anesthesia was applied using a mixture of 2% lidocaine and saline solution (1 mL of lidocaine mixed with 9 mL of saline in a 10-mL syringe). After a 2- to 3-minute wait, the filler was injected using an 18G blunt cannula (10 cm in length) inserted through the entry points. The filler was deposited into the hypodermic or subdermal space, primarily using a retrograde technique in a fan pattern.

After the injections, the entry points were disinfected, and the puncture sites were sealed with sterile strips and dressings. If more than 50 mL of HA was injected in a single area, adhesive tape was applied for 24–48 hours. Ultrasound and aspiration techniques were not used during the study, and patients did not receive any touch-up treatments during the follow-up period.

### Study Endpoints

Demographic data, including sex and age, were recorded for each subject. Other information collected included the number and date of sessions, the volume of HA injected per side, the specific gluteal regions injected, and any previous treatments in the area (eg, fat grafting, implants, poly-l-lactic acid, or other fillers).

The effectiveness of the product was evaluated based on patient and physician satisfaction. Both participants and investigators assessed posttreatment satisfaction by comparing pre- and postprocedure photographs (Fig. 1). (**See figure, Supplemental Digital Content 1,** which displays representative photographs of a treated patient [39 years]. A, Before treatment. B, Three months after the first treatment. The patient was injected with 40 mL of HYAcorp MLF2 on the lateral and lower lateral sides of the gluteal area, **http://links.lww.com/PRSGO/D745**.) Satisfaction was evaluated at 2 intervals: 7–14 days and 3–6 months postprocedure. Improvement was rated as "very good" (optimal cosmetic result), "good" (marked improvement but not optimal), "slightly improved"

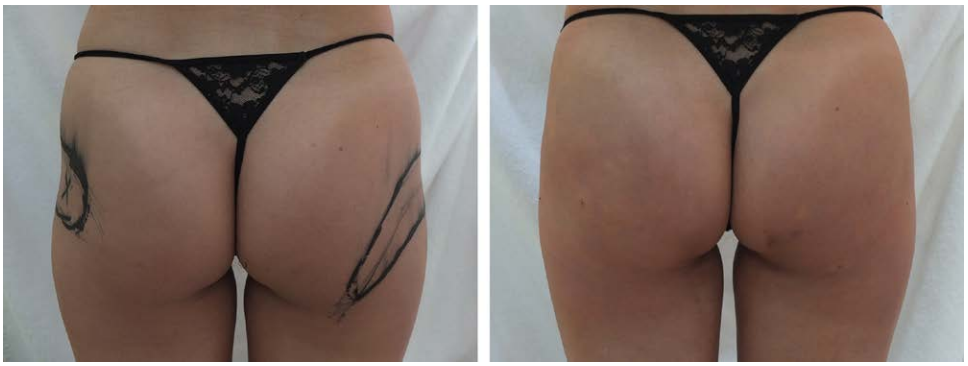

**Fig. 1.** Representative photographs of a treated patient (32 years). A, Before treatment. B, Six months after the treatment. The patient was injected with 40 cc of HYAcorp MLF2 on the left side and 50 cc on the right.

(improvement but retreatment was indicated), or "no visible improvement" (appearance remained essentially the same). No other scales were used.

To track short- and long-term adverse events (AEs), patients were asked about common symptoms, including itching, redness, rash, swelling, bleeding/hematoma, hardness, hypersensitivity, and other potential AEs. Long-term effects were assessed for bacterial infection, skin necrosis, filler migration, chronic inflammatory nodules, foreign body reactions, induration, rash, and granuloma formation. The severity of AEs (mild, moderate, or severe) and their duration were recorded on treatment days and during follow-up visits. In addition to AEs, patients were asked to rate their pain during or immediately after the procedure on a scale from 1 (least imaginable pain) to 10 (worst imaginable pain).

### Statistical Analysis

Subjects were identified from the databases of participating clinics, ensuring they met all inclusion criteria and no exclusion criteria. Each subject was assigned a dissociated code, and an electronic data collection form was completed for each case. All data were anonymized before export. Data types included numerical (eg, age, volume, and dates), Boolean (eg, intervention type and AEs), and categorical (eg, treatment locations). No additional interviews were conducted to collect study-specific data.

Statistical analysis was performed using GraphPad Prism version 10. Data were presented as absolute frequencies and percentages or as means and SDs. Comparisons between clinical sites were made using the analysis of variance (ANOVA) test. A 2-way ANOVA with Sidák multiple comparisons test was used to compare results across sites. Independent tests were conducted for each patient and physician evaluation at each time point. Results were evaluated for normality, and the Spearman correlation coefficient was used to assess correlations between variables, with a 95% confidence interval. For pain analysis, a 1-way ANOVA with Tukey multiple comparison test was used to compare scores between sites. A $P$ value of less than 0.05 indicated statistical significance.

### Ethical Aspects

The study was conducted in accordance with the Declaration of Helsinki principles and current legal regulations, adhering to the ethical and legal standards relevant to such research. Owing to its retrospective and observational nature, only data from clinical records were used. All data were handled with confidentiality and were deidentified, ensuring that no one other than the research team could link the data to individual patients.

## RESULTS

### Patients' Characteristics

The study included 35 female patients, with an average age of 38.7 ± 10.9 years (range, 20–59 years). Among these participants, 9 were smokers, and approximately half (16) engaged in regular physical activity. Ten of the subjects had undergone previous aesthetic procedures, but only 1 had received prior gluteal enhancement treatment (Table 1). All 35 patients attended the follow-up consultations.

### Treatment

HA body filler was injected using an 18G blunt cannula. Local anesthesia was administered to 24 subjects, and 1 subject received antibiotic prophylaxis.

The volume injected was determined by the treating physician based on the patient's anatomy and desired outcome. The average volume administered was 85.1 ± 42.2 mL per subject, ranging from 20 to 220 mL. Significant differences in injection volume were observed between centers ($P < 0.05$), specifically between sites 2 and 3 ($P = 0.003$), and between sites 2 and 4 ($P = 0.02$). No other significant differences were observed between sites ($P > 0.05$). At site 3, the average injection volume was the lowest at 63.6 ± 17.5 mL per subject (range, 20–80 mL), whereas site 2 had the highest average volume at 145.0 ± 52.6 mL per subject (range, 100–220 mL). (**See table, Supplemental Digital Content 2,** which displays volumes of HYAcorp MLF2 HA dermal filler injected in the 4 investigation sites. Values of volume are expressed in milliliters. n, number of patients, **http://links.lww.com/PRSGO/D746**.)

**Table 1. Demographic Information of Patients Included in the Study**

| Sites | n | Age ± SD (Minimum–Maximum) | Smokers | Physically Active | | Previous Aesthetic Interventions |
|---|---|---|---|---|---|---|
| All investigation sites | 35 | 38.7 ± 10.9 (20–59) | 9 | 16 | 10 | |
| Site 1 | 11 | 35.4 ± 10.8 (20–49) | 3 | 9 | 3 | Liposuction thighs, rhinoplasty, breast augmentation |
| Site 2 | 4 | 40.5 ± 8.6 (33–51) | 1 | 0 | 0 | — |
| Site 3 | 11 | 42.3 ± 12.7 (21–59) | 4 | 7 | 4 | Breast, liposuction (2), abdominoplasty, gynecomastia |
| Site 4 | 9 | 37.7 ± 9.7 (26–52) | 1 | 0 | 3 | Buttock augmentation, breast augmentation (2) |

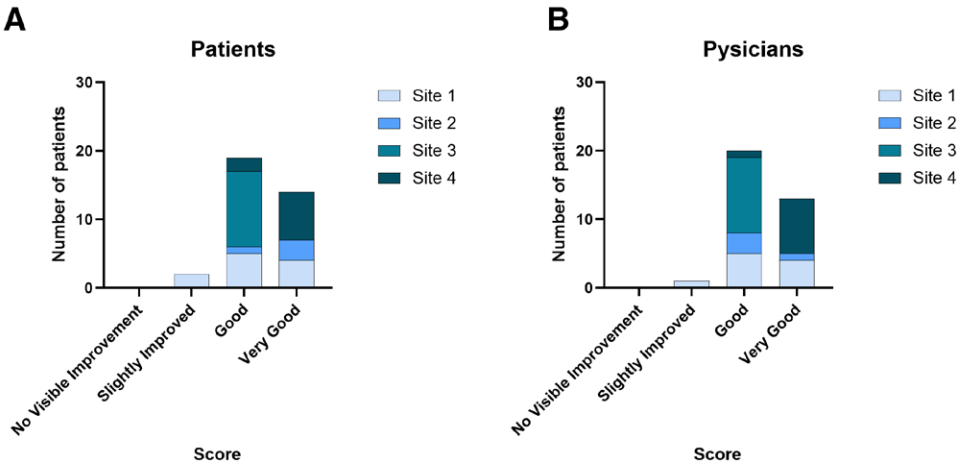


**Fig. 2.** Satisfaction rates among (A) patients and (B) physicians 7–14 days after the procedure.

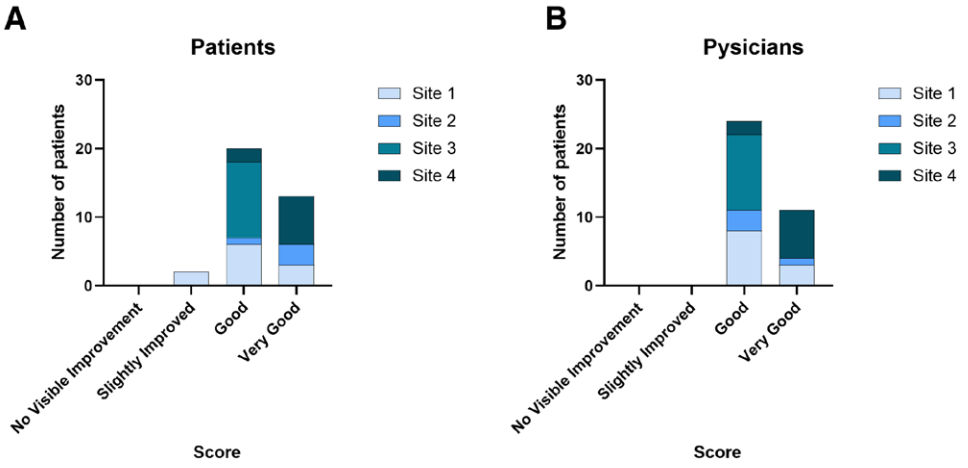


**Fig. 3.** Satisfaction rates among (A) patients and (B) physicians 3–6 months after the procedure.

**Patient and Physician Satisfaction**

At 7–14 days postinjection, 33 patients rated their improvement as either very good (n = 14) or good (n = 19) (Fig. 2A). (**See table, Supplemental Digital Content 3,** which displays patient satisfaction at the follow-up visits performed at 7–14 days and 3–6 months, **http://links.lww.com/PRSGO/D747**.) Similarly, physicians rated 33 patients as very good (n = 13) or good (n = 20) (Fig. 2B; **Supplemental Digital Content 3, http://links.lww.com/PRSGO/D747**). Therefore, 94% of both patients and physicians expressed satisfaction with the postinjection outcomes (**Supplemental Digital Content 3, http://links.lww.com/PRSGO/D747**).

During the 3- to 6-month follow-up period, the same 33 patients continued to rate their improvement as very good (n = 13) or good (n = 20) (Fig. 3A; **Supplemental Digital Content 3, http://links.lww.com/PRSGO/D747**). Physicians evaluated all 35 patients during this period, rating 11 as very good and 24 as good (Fig. 3B; **Supplemental Digital Content 3, http://links.lww.com/PRSGO/D747**). Satisfaction levels among both patients and physicians remained consistent throughout the 3- to 6-month

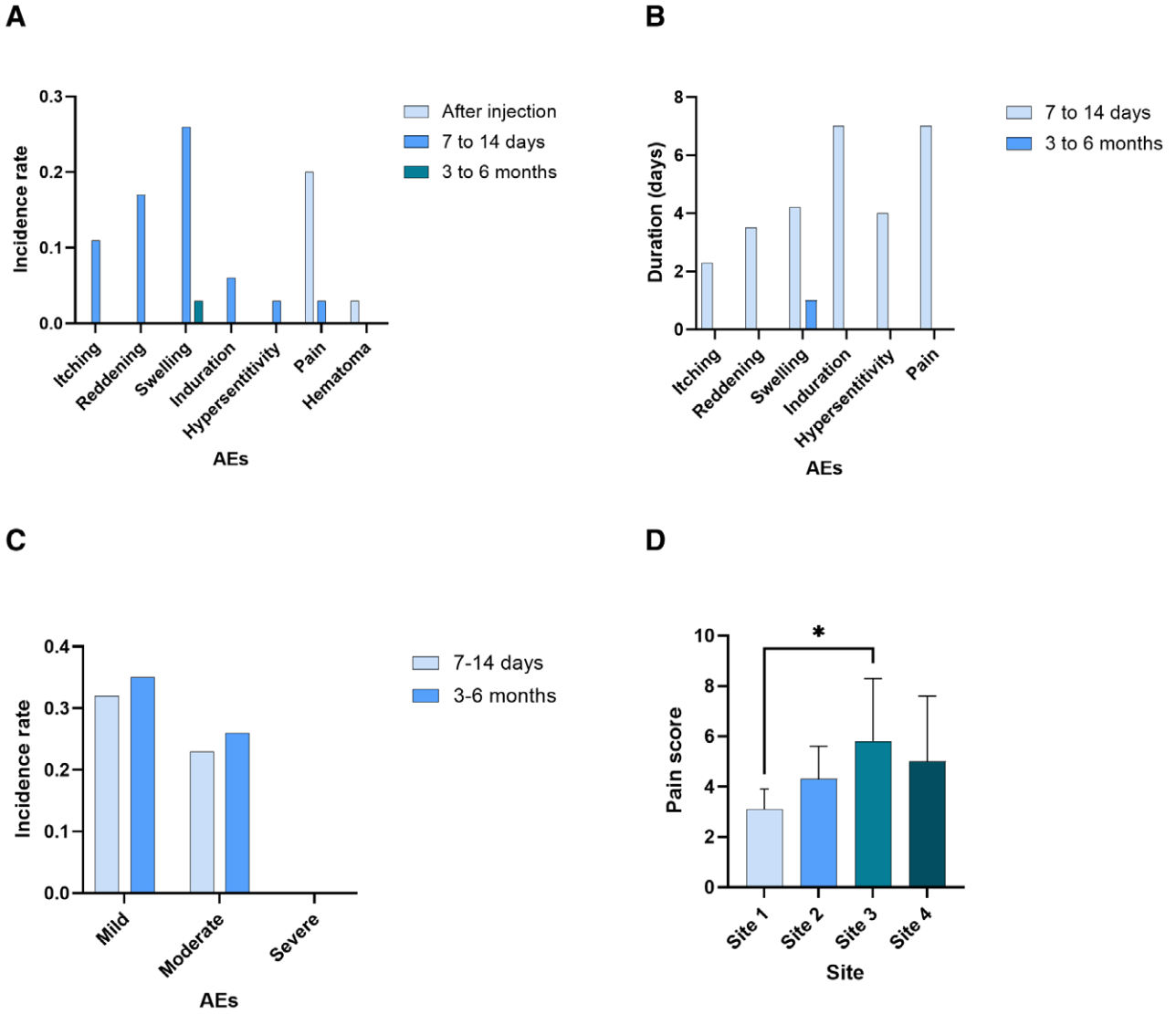


**Fig. 4.** Summary of the incidence, duration, severity, and pain levels associated with adverse events following the procedure, as assessed over multiple time points. A, Incidence rates of anticipated adverse events immediately after the injection, and at 7–14 days and 3–6 months postprocedure. B, Duration of adverse events at 7–14 days and 3–6 months after the procedure. C, Severity levels of adverse events recorded at 7–14 days and 3–6 months postprocedure. D, Pain levels assessed by each investigation site. *$P$ = 0.02.

follow-up period (**Supplemental Digital Content 3, http://links.lww.com/PRSGO/D747**).

**Safety and Tolerability**

A total of 8 of 35 patients reported AEs during or immediately after treatment. Seven subjects from site 3 experienced pain, and 1 subject from site 1 reported a hematoma, all classified as mild AEs. (**See table, Supplemental Digital Content 4,** which displays AEs observed at the 4 sites, **http://links.lww.com/PRSGO/D748**.) No patients reported rash, induration, or other AEs. The overall incidence rate of any side effects during or immediately after treatment was 0.23, with an incidence rate of 0.20 for severe pain and 0.03 for hematoma (Fig. 4A).

All 35 patients participated in both the 7- to 14-day and 3- to 6-month follow-up assessments. The average follow-up period for the 7- to 14-day assessment was 10.0 ± 4.5 days (range, 0–28 d), whereas the 3- to 6-month follow-up occurred at an average of 118 ± 29 days (range, 78–194 d) postinjection.

Eighteen patients reported 23 early AEs during the 7- to 14-day follow-up period (**Supplemental Digital Content 3, http://links.lww.com/PRSGO/D747**). No significant differences in AE frequency were observed between sites ($P$ > 0.05). The frequency of patients experiencing expected AEs was 0.51, with an incidence rate of 0.66. Approximately one-quarter of patients experienced swelling (n = 9), followed by redness (n = 6), itching (n = 4), induration (n = 2), hypersensitivity (n = 1), and pain (n = 1). The incidence rate for each symptom is detailed in Figure 4A. No cases of rash or hematoma were reported (**Supplemental Digital Content 4, http://links.lww.com/PRSGO/D748**).

Resolution times for symptoms varied: itching resolved within an average of 2.3 days, whereas redness, hypersensitivity, and swelling subsided within 3.5, 4.0, and 4.2 days, respectively (Fig. 4B). Both induration and pain typically lasted for 7 days (Fig. 4B). The AEs were classified as mild (affecting 11 individuals) or moderate (affecting 9 individuals), with no severe AEs reported (Fig. 4C). Oral analgesics, specifically nimesulide, were administered to 7 patients from site 3. No additional treatments, such as corticosteroids, antibiotics, or hyaluronidase were required.

During the 3- to 6-month follow-up, 1 case of mild swelling lasting a day was recorded as the only AE (Fig. 4A; **Supplemental Digital Content 4, http://links.lww.com/PRSGO/D748**). This patient had not experienced any AEs in the earlier follow-up stages. Other short-term effects, such as itching, redness, rash, hematoma, induration, or hypersensitivity were not observed. No delayed AEs, such as bacterial infection, skin necrosis, filler migration, chronic inflammatory nodules, foreign body reactions, induration, rash, or (sub)cutaneous granuloma were reported. None of the patients required further treatment. No correlation was found between the volume of HA injected and the incidence of AEs ($P = 0.75$).

Pain was assessed using a scale from 1 to 10. The average pain rating was 4.6 ± 2.3 (range, 1–8), with the highest pain levels reported at site 3 (5.8 ± 2.5; range, 2–8). Significant differences in pain scores were observed between sites 1 and 3 ($P = 0.02$) (Fig. 4D). However, no correlation was found between pain levels and the volume of HA filler injected ($P = 0.33$).

## DISCUSSION

This retrospective observational study aimed to evaluate the outcomes of patients receiving gluteal augmentation with HYAcorp MLF2 across 4 clinics in Italy. The analysis focused on the effectiveness of the treatment, as assessed by both patient and physician satisfaction, and the safety of the procedure, monitored through the occurrence of anticipated AEs at injection and during follow-up periods of 7–14 days and 3–6 months. Overall, the use of HYAcorp MLF2 for buttock augmentation was found to be both safe and effective, as evidenced by high satisfaction ratings and the manageable, mild-to-moderate AEs, with no correlation between outcomes and the experience level of the injector.

In this study, 94% of both patients and physicians expressed satisfaction with postinjection results. These findings are consistent with our previous research, where similar levels of satisfaction were observed in both groups.[16] Other published studies have also shown statistically significant improvements in patient satisfaction after similar treatments.

The study, conducted across 4 different sites, revealed no notable differences in outcomes based on the type of injection needle, local anesthetics used, or the administration of antibiotic prophylaxis. However, the volume of gel injected varied according to the patient's anatomy and desired results. Although site 3 recorded the lowest average volume of gel per subject, no correlation was found between the amount of gel used and the occurrence of AEs ($P = 0.75$). This suggests that other factors, such as patient characteristics or injection technique, may play a role in AE occurrence. Further research is necessary to explore these potential relationships.

As observed with dermal fillers in other applications, postinjection pain may occur despite the use of anesthesia,[17] potentially linked to the injection technique.[18] Hedén et al[19] reported that common postinjection reactions with HA gels include pain, swelling, redness, and hardness. In this study, the pain experienced was not associated with the injection volume of HA filler ($P = 0.33$). The only significant difference in pain scores was between sites 1 and 3 ($P = 0.02$), as shown in Figure 4D. The variability in pain assessments across clinics highlights the importance of involving multiple centers to gather more extensive and subjective data. As previously mentioned, AE incidence rates such as pain levels differed between investigation sites, which could be due to statistical differences or the unique assessment methods used by different physicians.

The AEs recorded in this study align with previously reported findings for dermal fillers, including those listed in the product's instructions for use.[9,16,19,20] The incidence rate for any AE was 0.23 immediately after treatment and 0.66 in the 7- to 14-day postinjection period. It is important to note that all AEs, including minor redness typically caused by injection, were registered and resolved within 7 days. No serious AEs were reported. A similar safety profile was observed by Crabai et al,[16] who also used HYAcorp MLF2, with early-onset AEs that resolved quickly. Both studies involved lower HA filler volumes per session, combined with a careful injection methodology under sterile conditions, which may explain the minimal AEs. Other authors have also reported a favorable safety profile for HA body fillers. For example, Oranges et al[8] documented a complication rate of 0.39 in 2 studies on gluteal augmentation. Mortada et al,[9] in a review of 168 patients, reported 2 major complications, 5 cases of bruising and erythema as minor complications, 5 cases of effusion and inflammation at the injection site, 3 instances of gel dislocation, and 1 case of irregular contours.

The use of dermal fillers for gluteal augmentation represents a significant advancement in aesthetic procedures. However, achieving high satisfaction rates and low AE incidences requires consideration of several factors. The filler must be injected into specific areas of the buttocks, targeting regions requiring volume enhancement or contour refinement, based on the anatomy of the gluteal region and the desired outcome for each patient. Knowledge of vascular anatomy is crucial to ensure safe injections, as the gluteal region contains a higher vascular density and larger vessels.[21] Furthermore, aseptic conditions and proper injection techniques (such as linear threading, fanning, and cross-hatching) are essential for achieving safe, even distribution and natural-looking results.

To date, no studies have evaluated the cost-effectiveness of stabilized HA body filler for gluteal treatments. However, the cost of this procedure should be considered relative to the patient's desire to avoid surgery and the simpler nature of HA injection procedures.[8] Physicians should also

consider the longevity of HA body fillers, which is influenced by both the product and the patient's metabolism and lifestyle. Crabai et al,[16] using the same HA body filler, performed touch-up injections between 12 and 20 months after the initial procedure. They found that patients required less volume at subsequent visits to maintain the same results and/or achieved satisfactory outcomes for a longer duration with the same volume of injection.

This study has certain limitations inherent in its design. Although it focused on variations in efficacy and safety across different clinics, a longer follow-up period (up to 24 months) and a larger patient cohort could have enriched the findings. Incorporating a quality-of-life survey or additional aesthetic evaluation scales could have further strengthened the research. In addition, having independent physicians assess the results and satisfaction rates based on photographs may have reduced potential biases. The use of different injection volumes across sites may have introduced some bias, although no significant differences in outcomes were observed. Data were retrospectively collected from clinical notes for each patient, and follow-up assessments were conducted clinically and through photographs. Despite the relatively small sample size, we believe that the number of cases (35) provides sufficient statistical power for observational purposes.

## CONCLUSIONS

Gluteal augmentation with the body filler HYAcorp MLF2 in 35 subjects resulted in a 94% satisfaction rate among both participants and physicians. The treatment was also shown to be safe in relation to early AEs. The most commonly reported AEs were swelling, pain, and redness, all of which were mild to moderate in severity and resolved within 2–7 days on average. No severe or delayed AEs were observed during the 6-month follow-up period.

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### DISCLOSURES

*Fontenete and Marques are employees at BioScience GmbH. The other authors have no financial interest to declare in relation to the content of this article. BioScience GmbH supported the analysis of this study.*

### ETHICAL APPROVAL

*All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.*

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