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Analysis of 4725 Cases of Gluteal Augmentation with Intramuscular Fillers: A Clinical Cohort Study

Danuza D. Alves, MD*
Roberto Chacur, MD‡
Honório S. Menezes, PhD*
Rodrigo C. Mafaldo, MSc*
Nivea Maria B.S. Chacur, MD‡
Leandro D. Gomes, PhD*
Vicenzo S. Vargas, MD*
Manoela F. Barros, MD†
Gina Matzembacher, MD†
Gabriella Andressa M. Castro, Biomedical*

Background: In recent years, the aesthetic market has become more prominent for being not only a tool to correct unwanted features but also a social means for improving quality of life. The use of 30% polymethylmethacrylate (PMMA) as a gluteal filler has grown in popularity all over the world, being sought after by men and women for body remodeling because it provides a natural look as well as significant long-lasting results.

Methods: A retrospective, multicenter study analyzed the medical records of 2801 patients who underwent a total of 4725 gluteal filler procedures between January 2009 and December 2021 at the different locations of Clínica Leger. The study protocol was approved by the Brazilian National Research Ethics Commission.

Results: The medical records of 2801 patients (2666 women and 135 men) who underwent 4725 gluteal filler injections were retrospectively analyzed. A total of 922,776 mL of PMMA was used (average = 329 mL/patient). The occurrence of 101 adverse events (2.1%) was observed, and no statistically significant relationship between the mean injected volume and the incidence of complications could be found.

Conclusions: According to the data presented in this study, the use of PMMA injections with the appropriate volumes for aesthetic treatments and corrections is safe and effective. *(Plast Reconstr Surg Glob Open 2024; 12:e6002; doi: 10.1097/GOX.0000000000006002; Published online 24 July 2024.)*

INTRODUCTION

Nowadays, aesthetic procedures have grown in popularity. People have increasingly sought quality of life and a better appearance, above all else, while aging. In recent years, the aesthetic market has become more prominent for being able to aid patients in improving not only their appearance but also their quality of life.[1,2]

Aiming to minimize signs of aging, improve body contour, and correct physical deformities, patients have sought nonsurgical (minimally invasive) gluteal augmentation and remodeling alternatives—which have become increasingly promising. Polymethylmethacrylate (PMMA 30%; ie, 30% of the liquid in the syringe is PMMA and 70% is suspension vehicle) has stood out, being sought after by both men and women for gluteal augmentation and remodeling. In addition to providing a natural look, significant long-lasting results are achieved, as the polymer is not absorbed by the body.[1,3,4]

PMMA is a synthetic microsphere polymer suspended in a vehicle solution which, after being implanted, acts as a matrix (controlled inflammatory reaction) and stimulates collagen production and muscle tissue growth. It is widely adopted by the medical community, being used for bone reconstitution and corrections in neurosurgery, ophthalmology, and traumatology mainly due to its biocompatibility, stability at the application site, and low risk of complications and migration.[1,5–7]

It is well known that PMMA microsphere filling results in tissue growth by the body itself. The dramatic increase in product quality in recent years has directly influenced the decreasing complication rates. Currently, in Brazil, the fourth generation of PMMA is available for commercialization. With spheres that measure an average of 40 ± 3 µm of diameter suspended in an organic, absorbable, nonallergenic, water-based gel, it is characterized by its uniformity and absence of impurities and irregularities.

*From *Clínica Leger, Rio Grande do Sul, Brazil; †Clínica Leger, São Paulo, Brazil; and ‡Clínica Leger, Rio de Janeiro, Brazil.*

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The product must be chosen carefully and according to the application area. PMMA 30% is indicated for buttocks filling because this concentration is appropriate for intramuscular or deep subcutaneous implants, preferably, because it avoids the occurrence of palpable nodules and possible complications.[7] Necrosis is the most feared complication of the procedure; however, its incidence is 0.003%, namely the same rate as any other filling procedure, regardless of the product used. Generally, adverse reactions to gluteal fillers are mild and transient, such as hematomas and edema caused by local physiological stress.[1,4]

PATIENTS AND METHODS

All procedures performed in this study are in accordance with the ethical standards of the Brazilian National Research Ethics Commission (CONEP) and the 1964 Declaration of Helsinki (CAAE protocol no. 86722118.8.0000.5291).

In this retrospective study, the medical records of 2801 patients who underwent 4725 procedures were analyzed using a convenience sample at the different locations of Clínica Leger (São Paulo, Rio de Janeiro, and Porto Alegre, Brazil) between January 2009 and December 2021.

The eligibility criterion for the patients included in the study were: over 18 years old who underwent gluteal filling. Patients who had undergone previous gluteal procedures or who had chronic and inflammatory diseases were not included in this study, for these are considered contraindications.

The gluteal filler injection is performed using 2% lidocaine as a local anesthetic with vasoconstrictor (diluted 1:1 in saline solution). The 30% PMMA is injected in the intramuscular or deep subcutaneous plane using a retrograde injection technique with the aid of an atraumatic, blunt tip, malleable cannula (18G) at a 90-degree angle angle. [**See Video 1 (online),** which displays a practical demonstration of the procedure, including anesthesia, filling points, and patient position.] The entry point is made with a needle (18G 10 mm) and, therefore, does not cause vascular or nervous injuries. Intramuscular applications are used more commonly for volume augmentation of the buttocks, whereas subcutaneous injections are more associated with the treatment of skin irregularities. The choice between these different techniques and needs is made in consultation with the patient before the procedure is conducted.

The patient remains awake, often in the orthostatic position (standing upright position), and actively participates in the procedure to achieve the expected result. There is no standard application technique that could be used for all patients, as they all differ anatomically. Usually, two entry points are made for the cannula: one central and one lateral. However, their positioning may vary depending on anatomical features and the desired outcome.

Currently, in Brazil, there are two brands of medical PMMA allowed by the Health Regulatory Agency (Anvisa), Biosimetric and Linnea Safe, and both were used in the study. The use of PMMA is exclusively medical and its recommendation is only made after an evaluation consultation. The Student *t* test was used to analyze the data obtained from the medical records.

In this study, ultrasound was not used. The application layers were identified by the medical team according to their knowledge on anatomy and sensitive fascia recognition.

Patients have all their questions answered and are informed of the risks during a medical consultation. Moreover, they are given a folder with all written post-procedure instructions and a copy of the consent form. Patients are followed up for 1 year after the procedure.

Takeaways

Question: Is polymethylmethacrylate (PMMA) an option of choice for safe gluteal filler?

Findings: The medical records of 2801 patients who used 4725 gluteal filler injections were analyzed. In total, 922,776 mL of PMMA was used (average = 329 mL/patient). There were 101 adverse events (2.1%), and no statistically significant relationship was found between the average volume injected and the incidence of complications. According to this study's data, the use of PMMA injections with adequate volumes for treatments and aesthetic corrections is safe and effective.

Meaning: Injection of PMMA as a soft-tissue filler for corrective purposes following the doctor's recommended volume is safe and effective.

RESULTS

A total of 922,776 mL of PMMA was injected in 2801 patients (2666 women and 135 men; that is, 95.1% and 4.9%, respectively) who underwent 4725 gluteal filler injections.

The average total volume was 329 mL per patient, which could be injected in several sessions, depending on each patient's case. The unilateral volumes were predominantly similar; however, they could vary according to the patient's anatomical needs owing to existing anatomical asymmetries and hip structure.

Data from over 12 years were retrospectively analyzed in this study. The mean age of the participants was 39 ± 10 years (ranging from 18 to 79), with age groups being 18–29 years old (N = 1425; 15.2%), 30–39 (N = 1203; 43%), 40–49 (N = 762; 27.2%), and 50–79 (N = 408; 14.6%). The most prevalent age group was 30 to 39 years old (43%), and no statistically significant association between age group and the occurrence of complications could be identified.

The total number of sessions per patient ranged from 1 to 8, with 877 patients having had only one session (N = 877, 31.31%); 1300 patients, two sessions (N = 1300, 46.41%); 400 patients, three sessions (N = 400, 14.30%); 121 patients, four sessions (N = 121, 4.31%); 54 patients, five sessions (n = 54, 1.92%); 25 patients, six sessions (N = 25, 0.90%); 17 patients, seven sessions (N = 17, 0.60%); and seven patients, eight sessions (N = 7, 0.25%), according to Table 1.

Table 1. No. Patients per Session

No. Sessions	N	%
1 session	877	31.31%
2 sessions	1.300	46.41%
3 sessions	400	14.30%
4 sessions	121	4.31%
5 sessions	54	1.92%
6 sessions	25	0.90%
7 sessions	17	0.60%
8 sessions	7	0.25%

The patients who underwent more than one treatment session waited a minimum interval between one session and another of 30 days, due to the absorption of the vehicle and collagen formation. After this period, the implant is no longer malleable and, therefore, a new session can be performed.

Among the 4725 filler injections analyzed, there were 101 (2.1%) occurrences of adverse events; that is, 97.9% of the procedures did not have side effects. The most frequent events were seromas (N = 24; 0.50%), nodules (N = 24; 0.50%), and hematomas (N = 14; 0.29%), according to Tables 2 and 3.

The mean total volume injected in patients who experienced complications was greater than that of those who did not have any. to verify whether the difference in volume found in the study sample was statistically significant, the Student *t* test was used. No statistically significant difference was found between the mean volume injected in patients who did and did not experience adverse effects.

In this study, no cases of necrosis or other severe complications were observed.

Clinical Case 1

A 29-year-old female patient complained about gluteal shape but not the volume. She did weight training seven times a week. The patient had not undergone any previous buttocks procedures and did not have any significant medical history. At the first consultation, the injection of 180 mL was suggested, and the possibility of a second application to correct the upper gluteal pole was also discussed. The patient was injected with 180 mL in the first treatment (90 mL on each side). After 60 days, another 180 mL (90 mL on each side) was injected, totaling 360 mL (Figs. 1–4).

Clinical Case 2

A 38-year-old female patient complained about upper gluteal volume loss and trochanteric depression. She did four weight training sessions per week and aerobics every day. The patient had not undergone any previous buttocks procedures and did not have any significant medical history. At the first consultation, the injection of 240 mL was recommended for upper and lateral correction. In the first treatment, 240 mL (120 mL on each side) of PMMA was injected. After 186 days, 120 mL (60 mL on each side) was injected for a small volume correction in the lower and middle buttocks areas, totaling 360 mL (Figs. 5–8).

Table 2. Number of Side Effects in Total

Side Effects	N	%
No	4.624	97.9%
Yes	101	2.1%
Total	4.725	100%

Table 3. Types of Side Effects in Total

Side Effects	N	%
Hematoma	14	0.29%
Seroma	24	0.50%
Ecchymosis	7	0.14%
Lump	24	0.50%
Swelling (for up to 30 d)	6	0.12%
Pain (for up to 30 d)	8	0.16%
Granuloma	2	0.04%
Hyperemia	2	0.04%
Hyperchromia	3	0.06%
Paresthesia of the lower limbs (for up to 30 d)	2	0.04%
Decreased strength of the lower limbs (for up to 30 d)	2	0.04%
Scarring	2	0.04%
Infection	3	0.06%
Telangiectasia	1	0.02%
Stretch marks	1	0.02%

DISCUSSION

There has been an increasing demand for body remodeling procedures as more and more people have been searching for quality of life and self-esteem during their aging process. Currently, there are several options for gluteal remodeling, including silicone implants (surgical), fat grafting (surgical), and soft-tissue fillers (nonsurgical).[8]

PMMA is a synthetic polymer that is biocompatible with the human body and its physical, chemical, and biological characteristics. Improvements over the years have made PMMA the filler of choice for soft tissues in different concentrations (5%, 10%, 15%, and 30%). In the literature, the various uses of PMMA, such as biostimulation of the subcutaneous tissue, bone reconstruction, and intramuscular filling, among others, have already been discussed.

As shown in this study, the increasing demand for the use of PMMA for body remodeling is due to the material's benefits, because it provides long-lasting results (for not being phagocytosed) with few significant adverse events.[3,7,9–11] Its use as a soft-tissue filler is already well established in medicine, and its promising and satisfactory aesthetic results have been demonstrated for over 12 years.

In 2017, Oranges et al analyzed 52 articles, which had been published between 2015 and 2016, on different techniques of gluteal remodeling. The complication rate of silicone implants was 30.5%, whereas of autologous fat grafting, 10.5%. Nonetheless, even though the incidence rate of the latter was significantly lower, the severity of adverse events was greater, including a case of fat embolism leading to death. The authors did not evaluate the use of PMMA.[8]

Even when analyzing a larger population, the data found in this article demonstrated a very low incidence rate (2.1% among 2801 cases) of adverse events for PMMA

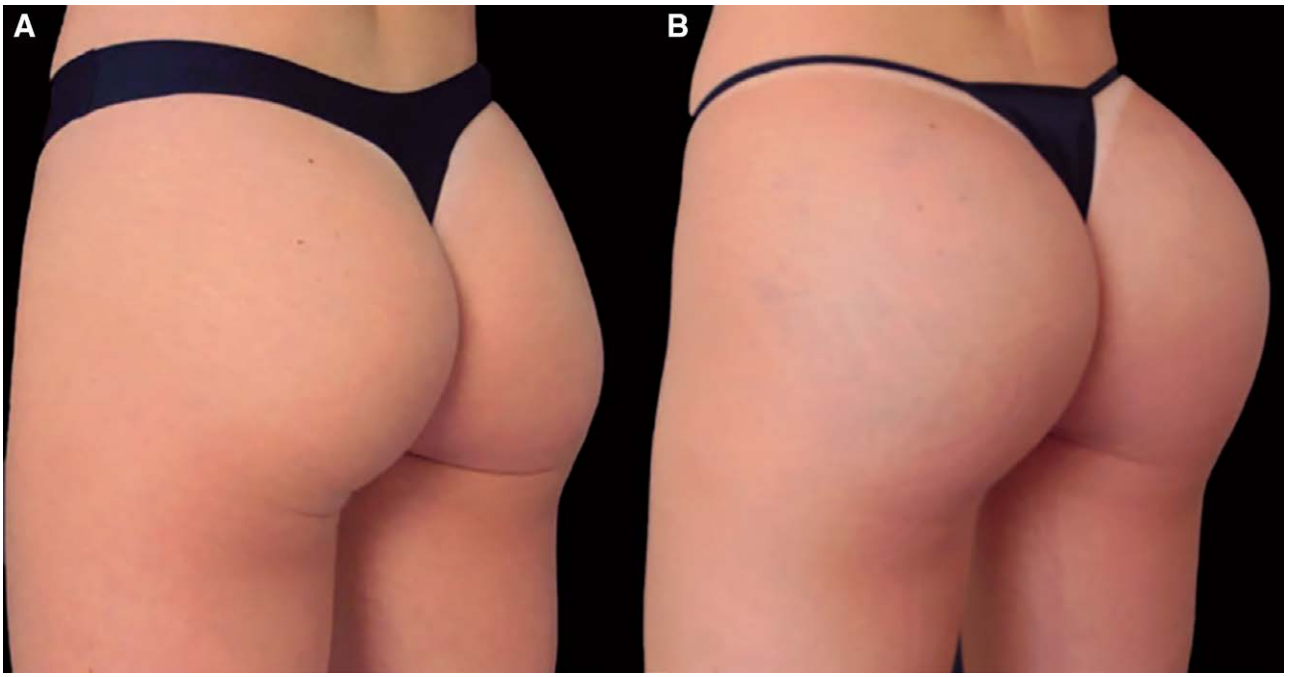

Fig. 1. Before (A) and 148 days after the last application (B), posterior diagonal position.

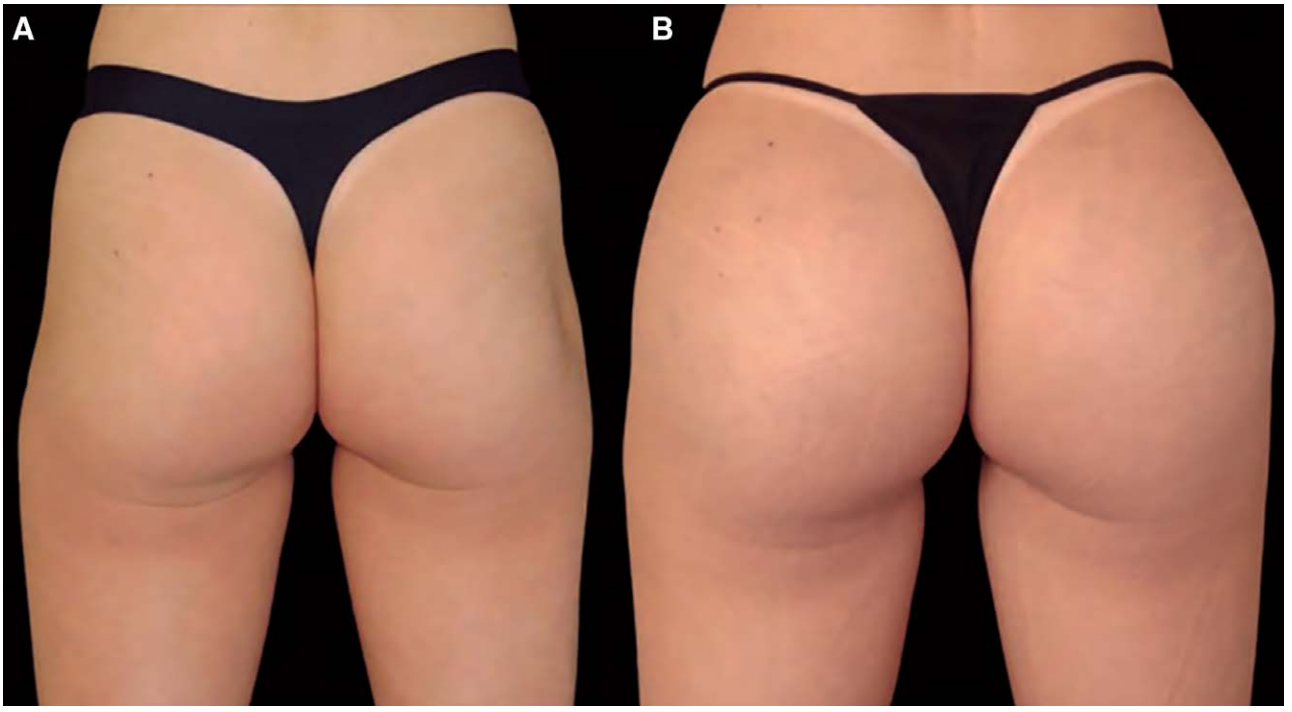

Fig. 2. Before (A) and 148 days after the last application (B), posterior position.

filling when compared to the study on fat grafting from 2017, which evidenced a rate of 10.5% among 2609 cases. Such difference is due to the fact that gluteal filling is a nonsurgical procedure; therefore, the risks related to general anesthesia and contamination are lower. Also, the use of PMMA, which is a solid substance, poses no risk of embolization if not applied directly into an artery. No embolism cases resulting from soft-tissue filling with PMMA have been reported hitherto.

This study is an update of the initial data published by Chacur et al. We carried out a statistical readjustment of events as the years passed and N increased.

In 2019, Chacur et al published a 10-year cohort retrospective study analyzing the use of PMMA, in which they

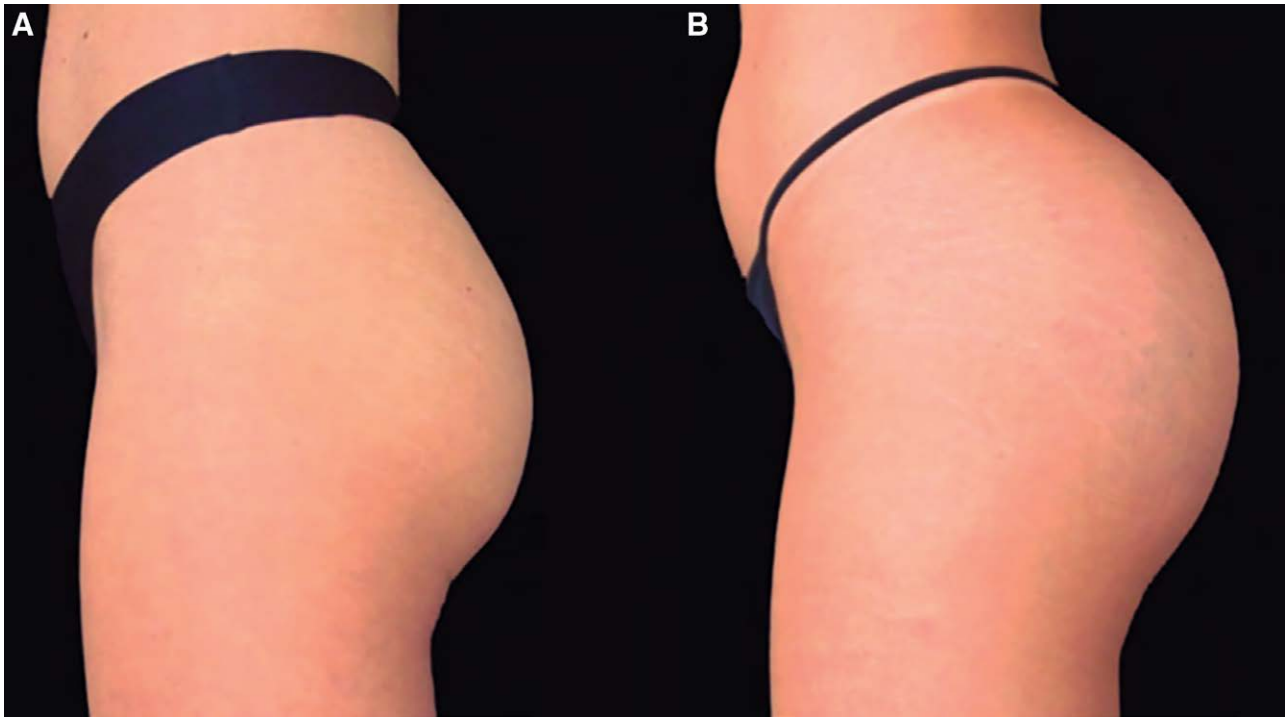

Fig. 3. Before (A) and 148 days after the last application (B), lateral position.

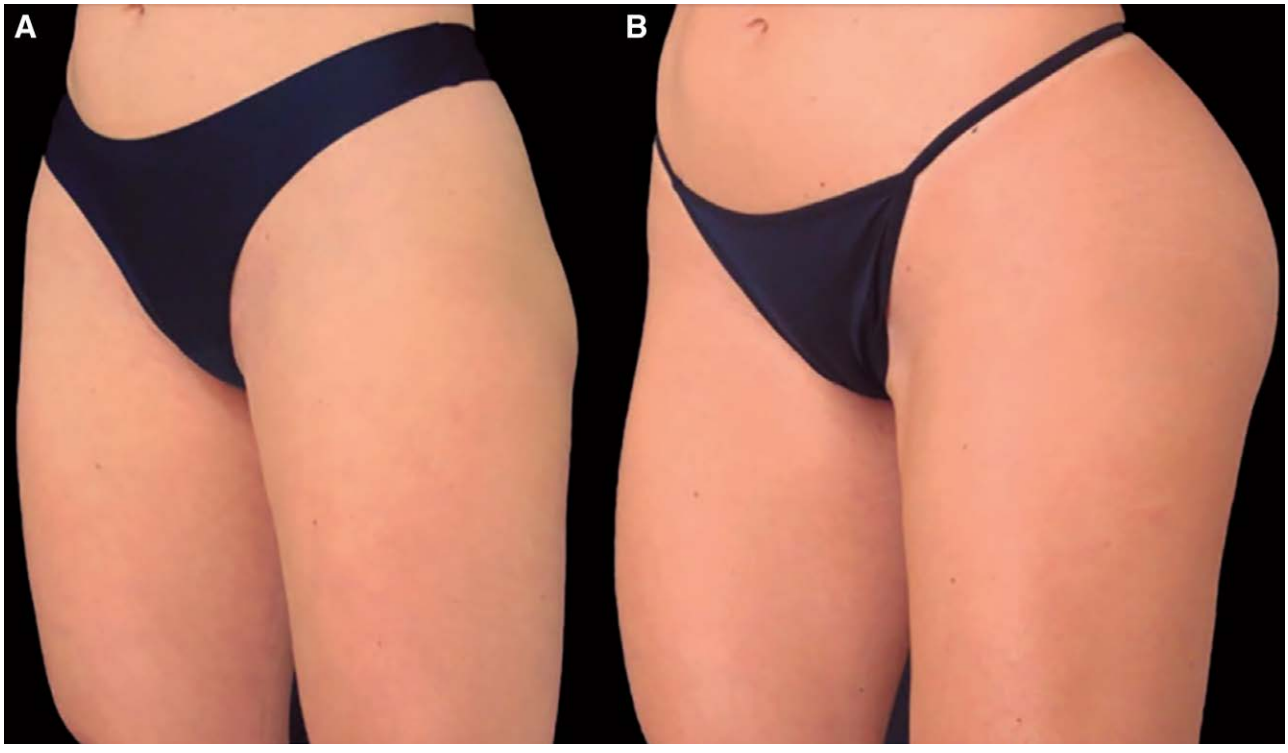

Fig. 4. Before (A) and 148 days after the last application (B), anterior diagonal position.

found a 1.88% rate of adverse events associated with 2770 procedures. In this study, however, the rate associated with the 4725 procedures analyzed was 2.1%. Therefore, it could be concluded that the adverse events related to the use of PMMA fillers are significantly less common compared to those of surgical procedures.[7]

The statistically insignificant increase in the percentage of adverse events in this study compared with the one

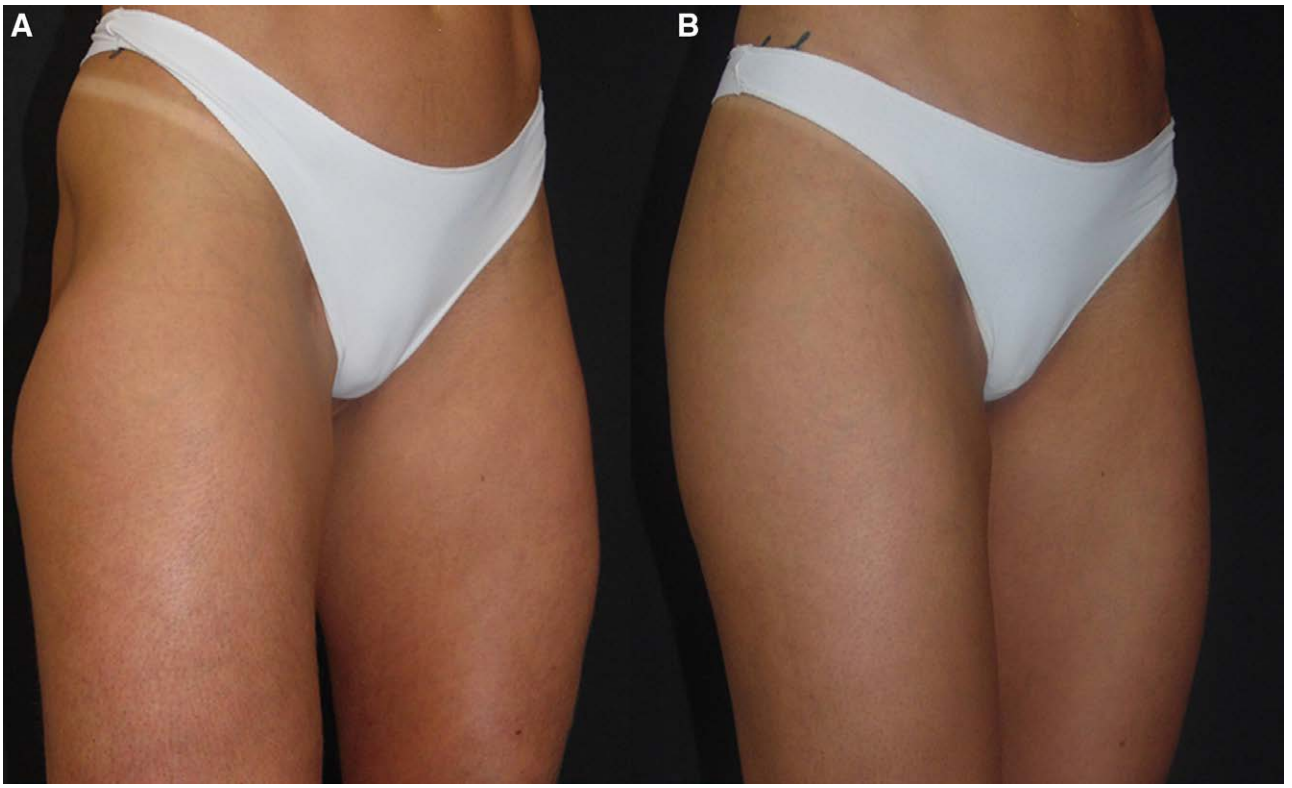

Fig. 5. Before (A) and 24 days after the last application (B), anterior diagonal position.

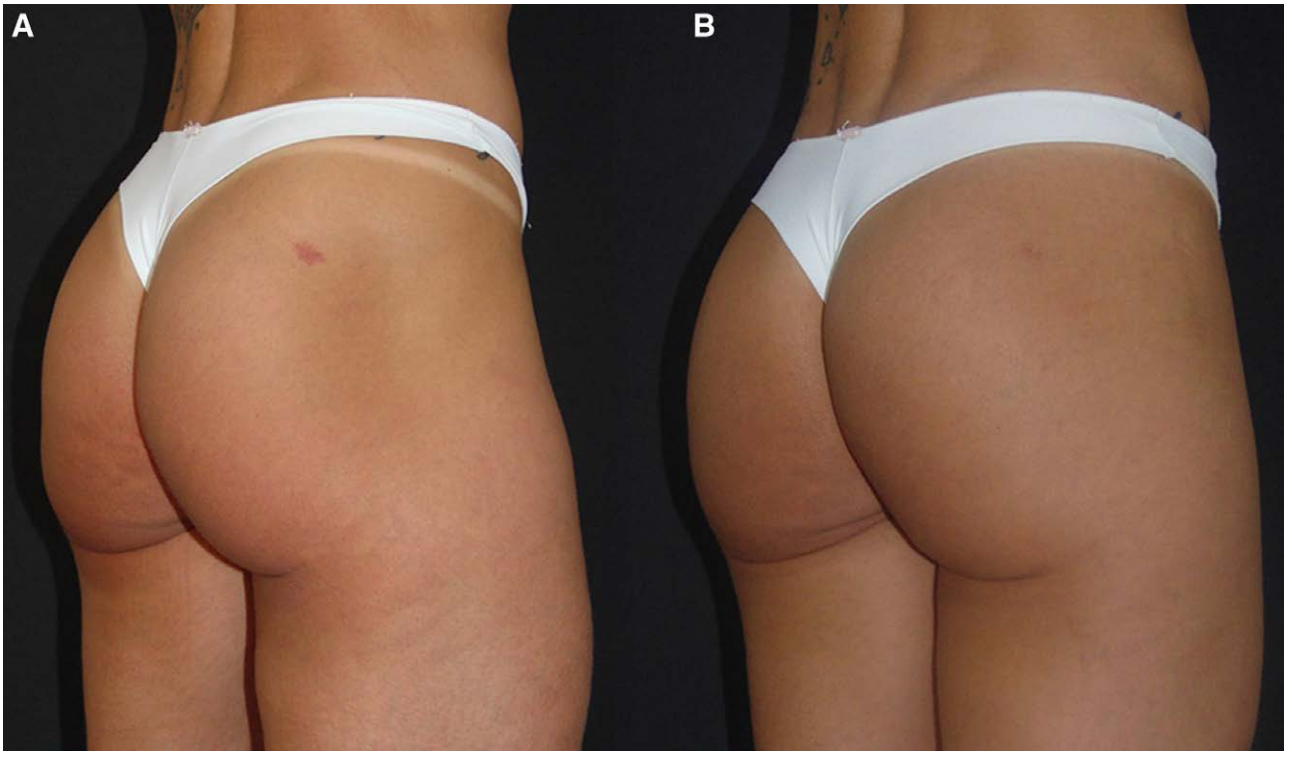

Fig. 6. Before (A) and 24 days after the last application (B), posterior diagonal position.

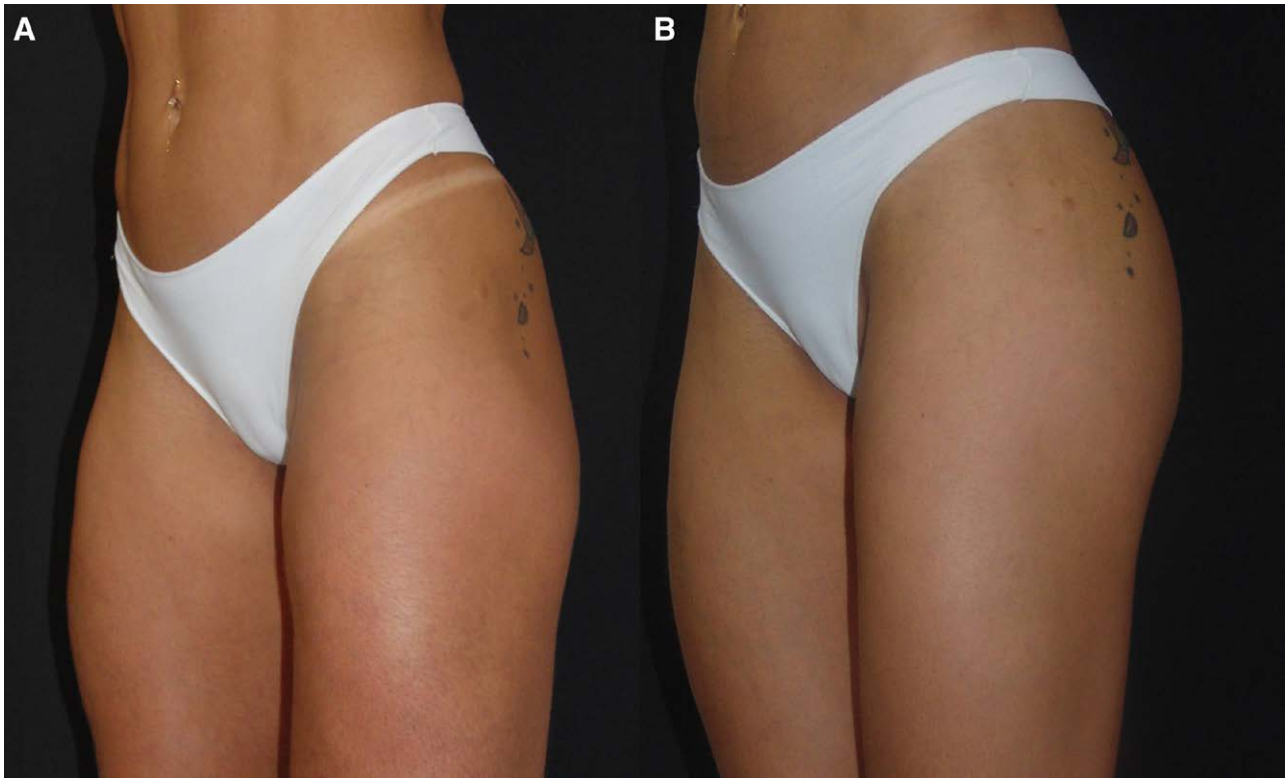

Fig. 7. Before (A) and 24 days after the last application (B), anterior diagonal position.

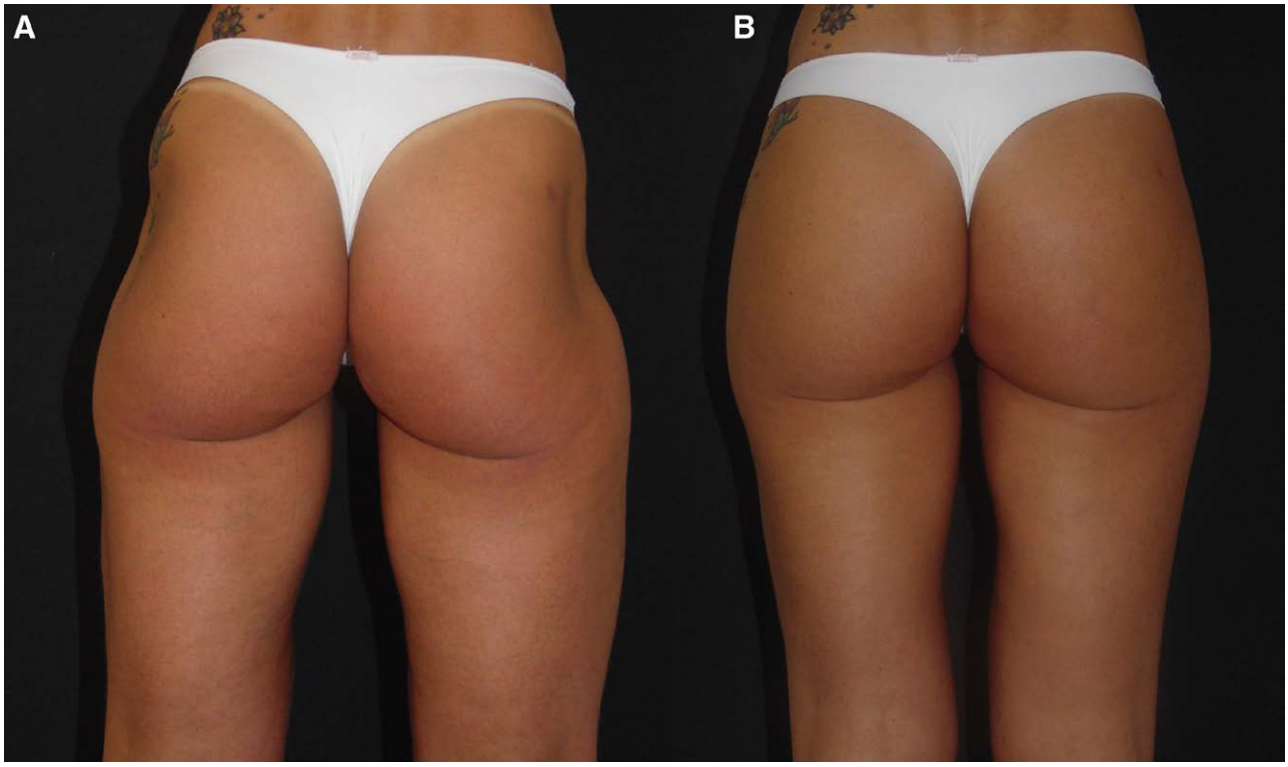

Fig. 8. Before (A) and 24 days after the last application (B), posterior position.

by Chacur et al may be explained by more advanced diagnostic methods, better ultrasound quality, a higher number of professionals with less experience performing the technique, and greater demand and awareness of patients regarding the understanding and identification of what is and is not normal in the postprocedure period.[7]

When analyzing specifically the rates of adverse events in this study, there were no records of some of them, such as ecchymosis, granuloma, hyperemia, paresthesia of the lower limbs, reduced mobility, and scarring, after the year 2018. This may be explained mainly due to the evolution of the application technique and how the cannula entry points are made (more than one point of entry in different regions).[7]

It is well-known, and in line with the Brazilian Health Regulatory Agency itself, that there is no preestablished volume or contraindications to the use of PMMA in the gluteal region. The need for and the feasibility of the procedure should be assessed by the patient's physician.[12]

Thus, based on the studies found in the literature and more than 12 years of clinical experience, the use of PMMA for aesthetic corrections, with the appropriate injection volumes, may be considered safe. In Brazil, the procedure must be performed exclusively by a physician, and its recommendation should only be made after careful evaluation of the patient.

CONCLUSIONS

According to the data presented in this study, the injection of PMMA as a soft-tissue filler for corrective purposes following the physician's recommended volume proved to be safe and effective. Therefore, that filler is an alternative for intramuscular injection in the gluteal region.

Danuza D. Alves, MD
R. Dr. Guimarães Rosa
155 Boa Vista, Porto Alegre
Rio Grande do Sul 90480-080
Brasil
E-mail: nucleodepesquisa@clinicaleger.com.br

DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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