Poly-L-Lactic Acid for Gluteal Augmentation found to be Safe and Effective in Retrospective Clinical Review of 60 Patients

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BACKGROUND Poly-L-lactic acid (PLLA) is a well-established biostimulator that induces neocollagenesis, allowing for volume loss correction. Although PLLA is FDA approved to treat mid-to-lower facial wrinkling, it has grown increasingly popular as a nonsurgical, minimally invasive procedure for soft-tissue volume augmentation of other extremities. However, research detailing PLLA buttock injections is still lacking.

OBJECTIVE The purpose of this study is to determine the safety and efficacy of PLLA for buttock augmentation.

MATERIALS AND METHODS A clinical retrospective review of 60 patients (ages 23–54 years) were followed for 2 years by 2 investigators. Patients underwent 1 to 3 treatments, spaced 4 to 6 weeks apart, and received 2 to 12 vials per session (based on the patient budget). Pretreatment and post-treatment photographs were assessed by the primary and secondary investigator in blinded and double-blinded surveys, respectively. The Global Aesthetic Improvement Scale was used to quantify improvements in volume, skin texture, and cellulite dimpling.

RESULTS Poly-L-lactic acid allows for visible volume amplification, improved skin texture, and softened cellulite dimpling in the buttocks when at least 20 vials are used.

CONCLUSION Poly-L-lactic acid is safe and effective for overall aesthetic enhancement of the buttocks if used in adequate quantity (minimum 20 vials) for all women, independent of age or the number of sessions.

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Enhancement of the appearance of the gluteal region has become a popular patient concern with the advent of certain societally determined standards of attractiveness. Poly-L-lactic Acid (PLLA) is a nontoxic lactic acid polymer that is both biocompatible and biodegradable, metabolized along the same pathway as lactic acid.[1] Studies have shown that injected PLLA differs from traditional fillers in its ability to stimulate controlled neocollagenesis to increase dermal thickness, leading to long-term volumization. Because of its ability to effectively correct age-related facial volume loss, PLLA has recently been adapted to use in off-label areas, including the hands, neck, décolleté, abdomen, and gluteal region for long-term volume restoration.[2] Currently, 3 main methods of medical gluteal enhancement have been popularized: silicone implants, autologous fat transfer, and injectable fillers. Recent literature has shown that PLLA is the least invasive, yet still effective in restoring and improving volume in the body and its extremities through its ability to stimulate collagen production. Upon injection, PLLA stimulates an inflammatory reaction to the presence of the foreign-body material, as evidenced by infiltrating lymphocytes, giant cells, and activated fibroblasts.[3] In a study conducted by Lemperle and colleagues after injection of PLLA into a human forearm, PLLA microspheres were found to be

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surrounded by fine capsules (composed of collagen, fibroblasts, and foreign-body giant cells) and by macrophages and lymphocytes at the 3-month mark. After 6 months, giant cells were also found. After 9 months, PLLA had degraded, and by 12 months, PLLA had been replaced by giant cells, histiocytes, and collagen fibers. This collagen growth, observable after injection of PLLA, is the basis for PLLA's cosmetic utility in correcting the patient's facial volume loss.[4]

According to the 2018 American Society for Dermatologic Surgery (ASDS) Consumer Report, there was a 21% increase in soft-tissue filler procedures since 2017, with more than 122,000 PLLA procedures reported.[5] Poly-L-lactic acid has been used in aesthetics since 2004, when it was approved by the FDA to treat facial lipoatrophy in patients with HIV.[1] Since 2009, it has been approved for use in cosmetic patients for the correction of shallow to deep nasolabial folds, facial contour deficiencies, and other facial wrinkles. Poly-L-lactic acid has a well-determined safety profile and has been established as safe when injected into the subcutaneous tissue of the gluteal region, where largely no vessels or nerves are put at risk.[1,3,7] The "danger triangle," which lies deeper under the musculature, represents the superior and inferior gluteal arteries and veins as well as the sciatic nerve, should be properly identified before injecting in this area.[8] Improvements in soft-tissue augmentation within the gluteal region can be achieved with PLLA, especially in thinner patients who have a low body mass index.

Literature Review

Off-label use of injectable PLLA has been investigated in several studies concerning nonfacial areas, such as the neck, chest, abdomen, arms, and hands. In 2017, Sadick and Arruda studied PLLA use for abdominal contouring. They dispensed 0.1 mL of a 10-mL reconstituted solution (8 mL of sterile water and 2 mL of lidocaine) of PLLA per site. The author explicitly stated that each aliquot was delivered in a retrograde fashion "2 cm below the skin surface at a 60° angle." Furthermore, "the needle was inserted up to the superficial layer of the subcutaneous tissue at the level of the dermis, and 0.1 mL aliquots were placed at each injection point." Areas with a greater volume deficit were injected at sites spaced 1 cm apart, whereas areas with less deficit were injected at sites 2 cm apart. Each patient received a total of 2 vials during the course of treatment. Slight bruising at the injection site was noted by 2 patients that resolved after 3 weeks, but no other adverse reactions were reported. At the end of the 12-month evaluation period, the abdominal areas treated with PLLA showed observable improvement in skin tightening and quality.[7]

Coimbra and colleagues studied the effects of PLLA in the medial and inferior arms, thighs, abdomen, and buttocks. For the medial and anterior arms, 1.0 cc of reconstituted solution (0.4 cc of diluted PLLA with sterile water and 0.6 cc of water and 2% plain lidocaine) was prepared. Poly-L-lactic acid powder was mixed with 8 cc of sterile water to obtain the 0.4 cc diluted PLLA solution. Simultaneously, 8 cc of sterile water was mixed with 4 cc of 2% plain lidocaine without epinephrine to obtain the 0.6 cc solution. These 2 solutions were then combined together to form the total reconstitution of 1.0 cc. A linear retrograde injection technique (syringe at a 60° angle) was used to deliver boluses of 0.05 cc into the deep dermis level. Injections of PLLA into the buttocks, thighs, and abdomen had the same dilutions and achieved similar results as the arms. For the buttocks, injection sites were targeted toward areas with cellulite depressions and/or sagging skin; the needle was inserted at a 60° angle between the deep dermis and superficial fat tissue. Injection sites were spaced approximately 1 cm apart and each received 0.1 mL aliquots per site, using the cross-stick technique. Each patient received 2 to 4 treatments, spaced 4 to 6 weeks apart, with 1 vial per treatment. Immediately after treatment, the area was massaged for 10 minutes. No adverse reactions to the treatment were found. The investigators noted appreciable improvement in skin texture, volume loss, sagging, and the presence of cellulite, particularly after the second treatment and as more time passed.[9]

Another study investigating PLLA use in peripheral nonfacial locations was conducted in 2017 by Jabbar and colleagues to examine its efficacy in the neck, upper chest, medial arms, and buttocks. For the neck

and décolleté area, PLLA was initially diluted with 10 mL of sterile water and reconstituted in a 9:1 ratio with 2% lidocaine. Each injection site was spaced approximately 1 cm apart and received 0.5 mL of the PLLA solution. A fanning technique was used to inject linear strands. For PLLA use in the dorsal hands, the solution was reconstituted with 10 mL of saline and lidocaine HCl 1%, with 2 mL typically used per hand in total. A linear threading technique was used to deliver 0.05 to 0.1 mL aliquots into each injection site. The average person received 4 treatments, with treatments once a month for the first 3 months and then once every 3 months. For the gluteal region, each vial of PLLA was reconstituted with 8 mL of sterile water and 2 mL of 1% lidocaine. Each injection site was spaced about 1 cm apart and was on average 2 cm below the superficial cutaneous layer and into the subcutaneous layer. Aliquots of 0.2 mL were delivered through retrograde injections at a 60° angle. On average, the patients received 2.5 vials per treatment spaced 4 weeks apart. Only 1 adverse reaction was noted—an instance of transient ecchymosis. The results collectively showed at least an improvement of 1 grade or more in all cases reported by the study, and high marks of patient satisfaction were recorded.[2]

In 2016, Mazzuco and Sadick examined the use of PLLA in the buttocks and focused on 2 female patients who reported volume loss and loose skin in the buttocks. Poly-L-lactic acid was reconstituted to 12 cc (10 cc of sterile water and 2 cc of lidocaine). The investigators dispensed 0.1 cc of reconstituted PLLA into each injection site in a retrograde fashion, with the needle at a 60° angle relative to the skin in the superficial layer of the subcutaneous tissue. The injection sites were spaced and marked 1 cm apart. One woman received 4 vials per treatment and did 3 treatments, spaced 1 month apart. The other woman received 3 vials per treatment and did 2 treatments, spaced 1 month apart. Only 1 patient experienced mild bruising that resolved itself within 2 weeks. The authors determined that PLLA is a safe and effective method for the correction of gluteal volume deficiency and contouring.[6]

In 2019, Lin and colleagues discussed the use of PLLA for minimally invasive gluteal augmentation. Poly-L-lactic acid was reconstituted to 22 cc (2 mL of 2% lidocaine and 20 mL of normal saline). Injections were performed with an 18 G needle attached to 10 mL Luer lock syringes, at an infusion rate of 5 to 30 mL per minute. Injections were performed through a fanning technique at a 30° angle below the skin surface. Typically, a total volume of 40 to 240 mL is injected into each side according to anatomy, symmetry, and patient preference. The area was firmly massaged for 20 minutes immediately after the procedure to reduce the likelihood of nodule formation. Each patient underwent 3 treatments, spaced 6 weeks apart. No adverse events were reported in their particular study.[8]

Overall, PLLA is viewed as a favorable and efficient alternative to more invasive means of achieving facial rejuvenation. Poly-L-lactic acid's well-established safety profile for the face can be extended to usage of PLLA in the buttocks. A summary of all the presented literature can be found in Table 1.

Materials and Methods

In our retrospective clinical review, a total of 60 patients were observed from June 2017 to June 2019. Study subjects were collected through convenience sampling, relying on a voluntary response. Written informed consent for treatment and photograph release conforming to the policies of the primary investigator were obtained from all subjects before study enrollment. Study participants met all predetermined conditions for eligibility: women aged 23 to 54 years and in good health who were seeking gluteal enhancement through volume restoration and augmentation. After obtaining consent from the recruited individuals, participants were photographed to establish baseline gluteal condition immediately before treatment with PLLA. Each patient first required consultation, evaluation, and marking. Treatment areas of interest and hollowness were marked and palpated to ensure that any vasculature within these areas was avoided.

To reconstitute, 1 vial of PLLA was mixed with 5 mL of sterile water 24 hours before treatment. On the day

TABLE 1. Summary of the Present Literature on PLLA Use for Facial and Body Augmentation

Study	*Body Site*	*Final Dilution of PLLA*	*No. of Vials Per Treatment*	*No. of Treatment Sessions (tx)*	*Follow-up*
Neil S. Sadick and Suleima Arruda, 2017	Abdominal area	10 mL	1–2 vials	1–2 tx	Every 3 mo for 1 yr
Daniel Dal'Asta Coimbra, Betina Stefano de Oliveira, and Natalia Cabellero Uribe, 2016	Medial/ inferior arms	20 mL	1 vial/ treatment	2–4 tx	N/A
Daniel Dal'Asta Coimbra, Betina Stefano de Oliveira, and Natalia Cabellero Uribe, 2016	Gluteal region	20 mL	N/A	N/A	N/A
Ahmad Jabbar, Suleima Arruda, and Neil Sadick, 2017	Neck and Décolleté area	Varied, but 16 mL optimal	1 vial	1–3 tx	18 mo
Ahmad Jabbar, Suleima Arruda, and Neil Sadick, 2017	Dorsal hands	6–8 mL	1 vial	2–4 tx	N/A
Ahmad Jabbar, Suleima Arruda, and Neil Sadick, 2017	Gluteal region	10–12 mL	1–2 vials	1–2 tx	N/A
Rosemarie Mazzuco and Neil S. Sadick, 2016	Gluteal region	12 mL	3–4 vials	2–3 tx	N/A
Matthew J. Lin, Danielle P. Dubin, and Hooman Khorasani, 2019	Gluteal region	30 mL	40–240 mL/ side	3 tx	N/A

The summary demonstrates the discrepancies and inconsistencies between studies on PLLA fillers used for body augmentation.
PLLA, poly-L-lactic acid.

of use, the mixture was warmed to room temperature and mixed on a vortex for thorough agitation. Next, 1 mL of lidocaine was injected into the vial of the 5-mL mixture to the total 6 mL of the fluid. This was diluted with an additional 4 mL of sterile water, totaling 10 mL. A thin layer of topical lidocaine/tetracaine 23%/7% ointment was applied to the marked sites and left on for 15 minutes to effectively anesthetize into the skin.

One vial of PLLA was typically injected into each 6 × 4-cm area of hollowness. The 10-mL mixture was injected with a 21-gauge needle (0.8 × 40 mm), with aliquots of 1 mL per site, at a 45 to 60° angle through a cross-hatching technique. Injection sites were spaced 1 cm apart for areas with dense hollowness and 2 cm apart for less dense regions. Aliquots were delivered at 1.5 to 2 cm below the skin to the deep dermis or below the skin fat junction. After injection, patients were instructed to massage the buttocks for 5 minutes, 5 times daily, for 5 days to distribute the PLLA evenly and prevent the formation of any nodules. Most patients undergoing this treatment were already physically fit and thus encouraged to resume and maintain their workout regimens (roughly 40–50 squats each day) 24 hours after treatment. In addition to this, they were also recommended to consume a healthy balanced diet.

Each subject began with an initial treatment of 2 to 12 vials of PLLA. Patients were then asked to return for an additional 2 to 3 treatments of 2 to 12 vials of PLLA, spaced 4 to 6 weeks apart. Before each additional treatment, patients were photographed to track improvement in the appearance of the gluteal region.

Treatment efficacy was measured by blinded and double-blinded surveys provided to the primary and secondary investigators. Each investigator received a series of photographs documenting patient progress with PLLA injections. Each set of photographs included front, back, and side views of the buttocks at baseline and before each consecutive treatment. The survey criterion measured improvement in volume, skin texture, and dimpling using a rating scale of 1 to 5 on the Global Aesthetic Improvement Scale (GAIS). In

this scale, 1 indicates exceptional improvement, 2 indicates very improved, 3 indicates improved, 4 indicates unaltered, and 5 indicates worsened patient.

Results

Fifty-two of the 60 subjects who were enrolled completed the 20-week study. Six subjects were dismissed from the study because of the lack of follow-up with their appointments, and two subjects were disqualified because of inadequate photograph quality.

All 52 patients received 2 to 12 vials of PLLA per treatment and 1 to 3 treatments, spaced 4 to 6 weeks apart. Overall, patients received 4 to 42 vials in total and, on average, received a total of 17.2 vials over the course of treatment.

Of the 52 patients rated by the principal investigator for improvement in volume, 22 received a GAIS score of 1 (exceptional improvement), 20 received a score of 2 (very improved), 8 received a score of 3 (improved), 2 received a score of 4 (unaltered), and none received a score of 5 (worsened). Of the 52 patients rated by the secondary investigator for improvement in volume, 26 received a score of 1, 22 received a score of 2, 3 received a score of 3, 1 received a score of 4, and none received a score of 5. The trend, as shown in Figure 1 for both investigators, indicates that the higher the number of PLLA vials used per patients, the more significant the improvement.

For improvement in skin texture, the principal investigator gave 25 patients a GAIS score of 1, 20 patients a score of 2, 6 patients a score of 3, 1 patient a score of 4, and none received a score of 5. The secondary investigator then gave 42 patients a GAIS score of 1, 6 patients a score of 2, 3 patients a score of 3, 1 patient a score of 4, and none received a score of 5. The trend for both investigators (Figure 2) showed that increasing the number of PLLA vials used increased the improvement seen for skin texture.

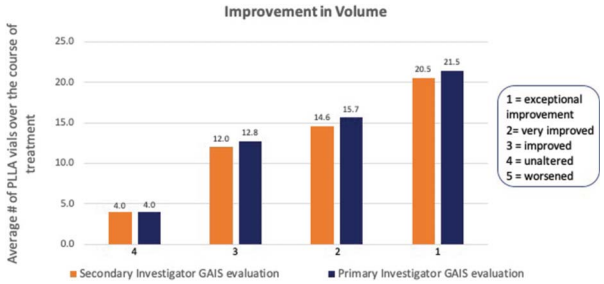

Figure 1. The principal and secondary investigators' improvement ratings: Improvement in volume was given a rating of 1 (= exceptional improvement) for the majority, which correlated with an average of 21.5 and 20.5 vials in total, respectively. GAIS, Global Aesthetic Improvement Scale; PLLA, poly-L-lactic acid.

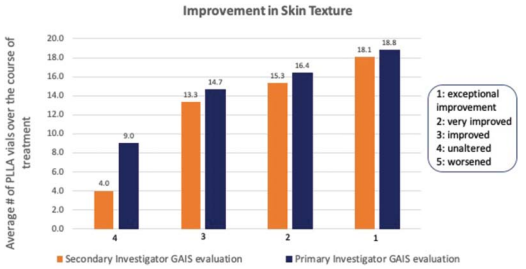

Figure 2. Improvement in skin texture was given a rating of 1 (= exceptional improvement) for the majority, which correlated with an average of 18.8 and 18.1 vials in total, respectively. GAIS, Global Aesthetic Improvement Scale; PLLA, poly-L-lactic acid.

For improvement in dimpling, the principal investigator gave 13 patients a GAIS score of 1, 21 patients a score of 2, 17 patients a score of 3, 2 patients a score of 4, and none received a score of 5. The secondary investigator gave 42 patients a GAIS score of 1, 6 patients a score of 2, 3 patients a score of 3, 1 patient a score of 4, and none received a score of 5. These data (Figure 3) show that to achieve more dimpling improvement, more vials of PLLA are required.

Statistical Analysis

To analyze our data, we produced a one-way analysis of variance to measure the effect of the total number of

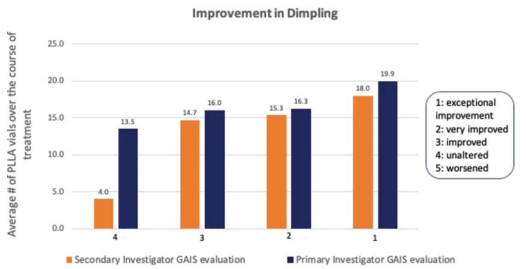

Figure 3. Improvement in dimpling was given a rating of 1 (= exceptional improvement) for the majority, which correlated with an average of 19.9 and 18.0 vials in total, respectively. GAIS, Global Aesthetic Improvement Scale; PLLA, poly-L-lactic acid.

TABLE 2. One-Way Analysis of Variance *p*-Values of the Principal Investigator's Improvement Ratings

	Volume	*Skin Texture*	*Dimpling*
p-Value	0.002	0.475	0.545

There was a significant association between the total number of vials of PLLA injected and the principal investigator's ratings of improvement in volume at the $p < .05$ level [$p = .002$], but not with the ratings of improvement in skin texture [$p = .475$] and dimpling [$p = .545$].

vials of PLLA injected on associated improvement rating. There was a significant association between the total number of vials of PLLA injected and the principal investigator's ratings of improvement in volume [$p = .002$] (Table 2). There was also a significant association between the total number of vials of PLLA injected and the secondary investigator's ratings of improvement in volume [$p = .016$] (Table 3).

There was no significant association between the total number of vials of PLLA injected and the principal investigator's ratings of improvement in skin texture or dimpling at the $p < .05$ level [$p = .475$, $p = .545$] (Table 2). The secondary investigator's ratings of improvement in skin texture and dimpling were also not shown to have significant associations with the total number of vials of PLLA injected at the $p < .05$ level [$p = .287$, $p = .346$] (Table 3).

Discussion

Our data demonstrates that the physicians' ratings of improvement in volume were clearly associated with the total number of PLLA vials injected. In particular, there was a positive correlation between physicians' ratings of volume improvement and vials of PLLA injected ($p = .002$, $p = .016$). Overall, the results with the highest ratings of improvement in volume were those of patients who had received an average of at least 20 total vials of PLLA over the course of treatment (Figures 4, 6, and 7). Treatment with a higher number of total PLLA vials yields more visible growth in buttocks volume (Figures 4, 6, and 7). These results were independent of age and the number of sessions.

The data also suggests that the total number of vials injected was not significantly associated with improvement in skin texture ($p = .475$, $p = .287$). Rather, visual improvement in skin texture of the buttocks seemed more dependent on the quality of skin texture at baseline (Figures 5 and 6). Patients who exhibited poorer skin texture at baseline showed more notable improvement than those who exhibited better skin texture at baseline (Figure 7). Similarly, the total number of vials injected was not significantly associated with improvement in dimpling ($p = .534$, $p = .346$). Visual improvement in dimpling of the buttocks also seemed to be more dependent on the severity of dimpling at baseline. Patients who exhibited severe dimpling at baseline saw more notable improvement than patients who did not have severe dimpling. These results were not significantly correlated with age or the number of sessions.

Our results provide substantial support for PLLA's efficacy in volumizing the gluteal region in a diverse sample of women, independent of age and the number of treatment sessions. This study establishes PLLA as an excellent alternative to invasive surgical

TABLE 3. One-Way Analysis of Variance *p*-Values of the Secondary Investigator's Improvement Ratings

	Volume	*Skin Texture*	*Dimpling*
p-Value	0.016	0.287	0.346

There was a significant association between the total number of vials of PLLA injected and the secondary investigator's ratings of improvement in volume at the $p < .05$ level [$p = .016$], but not with the ratings of improvement in skin texture [$p = .287$] and dimpling [$p = .346$].

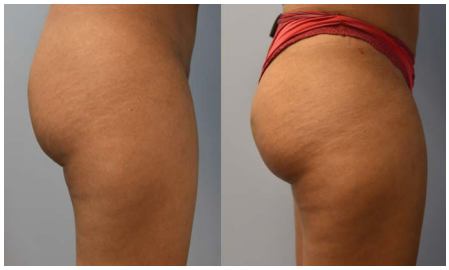

Figure 4. A 47-year-old woman before and after injection of 30 vials of PLLA over 3 sessions. PLLA, poly-L-lactic acid.

procedures, possessing the ability to procure visible amplification of the buttocks, particularly when patients are treated with at least 20 vials of PLLA over the course of treatment. However, an improvement in skin texture and dimpling could require more extensive treatment to provide more substantial support for its use in improving the overall cosmetic appearance of the buttocks and cellulite dimples.

All patients in the study were asked to come back for a 1-year follow-up. The general consensus for the duration of PLLA is that it can persist and induce collagen growth for up to 2 years after injection, although some researchers have indicated a duration of up to 3 to 4 years.

This clinical study had potential limitations that should be noted. Postprocedural patient assessment surveys were not obtained because there was inadequate patient response to these surveys after the procedures. In addition, the lack of a quantitative volumetric analysis can also introduce a bias because the results were obtained by the subjective evaluation of investigators. Another limitation to be noted is that this study only included the techniques of the primary investigator involved, and differences in the technique among other surgeons could change the data outcome positively or negatively. Furthermore, because participants were encouraged to resume and maintain their fitness regimens (40-50 squats daily), this could have potentially introduced a confounding factor. However, this presumption seems unlikely because before entering the study, the majority of these patients already stated that they were physically fit and active but still failed to see notable volume amplification improvement in the buttocks with their workouts alone. Finally, the consistency of the photographs between sessions and patients was difficult to fully standardize.

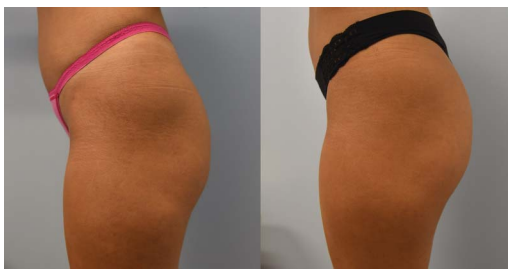

Figure 5. A 24-year-old woman before and after injection of 18 vials of PLLA over 3 sessions. PLLA, poly-L-lactic acid.

Before treating any patient for PLLA buttock injections, the financial cost of this product and the number of vials purposed per session should be discussed because 20 vials or more will give the best results but can be costly. This study accomplishes its main goal in demonstrating that PLLA (in quantities greater or equal to 20 vials) can safely and effectively be used to perform buttock augmentation when patients have realistic expectations. Interestingly patients in the 40 to 50 year old age range responded just as well to PLLA-inducedcollagen as those in their 20's and 30's. The frequency of visits had no bearing on the outcome if patients received at least 20 vials of the product, indicating that fewer visits with more vials can give similar results to more visits with an equal number of vials.

Side Effects and Complications

As previously noted in the Literature Review section, patients who received PLLA injections into various areas showed no major or long-term adverse reactions. Any observed adverse reactions noted (bruising and hematoma formation) were all attributed to the injection site or technique-related causes.

According to our own clinical studies, all adverse events reported with PLLA injections to the buttocks were minor and restricted to the injection site–related side effects, such as bruising, swelling, ecchymosis, and soreness. Less than 5% of the patients involved in the study noted some immediate side effects such as bruising and tenderness in the

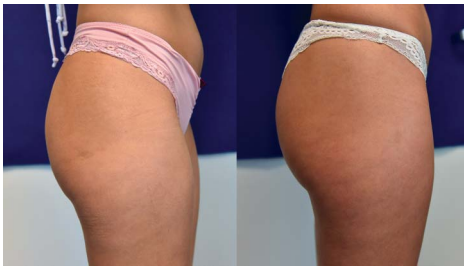

Figure 6. A 29-year-old woman before and after injection of 22 vials of PLLA over 3 sessions. PLLA, poly-L-lactic acid.

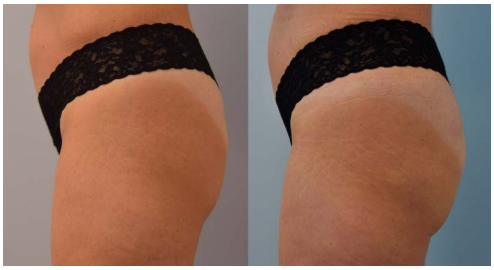

Figure 7. A 38-year-old woman before and after injection of 22 vials of PLLA over 3 sessions. PLLA, poly-L-lactic acid.

buttocks after injection. These complications were all rated as mild to moderate and resolved within 2 weeks without any intervention. No major adverse events, delayed-onset events, or long-term events such as infections, atrophy, vascular occlusions, or formation of nodules/granulomas were reported. The authors have concluded that PLLA injections to the buttocks are safer than other off-labeled treatment areas because of the thicker subcutaneous tissue surrounding this area.

Injections to this area should pose little to no risk of vascular compromise if the "danger triangle" is properly identified through palpating each buttock.[7] Within this triangle lies the superior gluteal artery and vein, the inferior gluteal artery and vein, and the sciatic nerve.[1] Generally, these anatomical landmarks are found deep to the musculature and can be avoided by maintaining injections superficially to the muscle within the deep dermis. This review of 60 patients demonstrates the safety and efficacy of PLLA for use in buttock augmentation and demonstrates that treatment with more than 20 vials results in appreciable improvements in buttock augmentation, based on the GAIS standard.

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