ORIGINAL ARTICLE

Effect of Poly-D,L-Lactic Acid (PDLLA) Biostimulator on Facial Rejuvenation Markers in Late Middle-Aged Thai Women: A Quasi-Experimental Study

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Background: The quality of skin, especially its elasticity, hydration, and collagen, diminishes with age, contributing to visible signs of aging. Poly-D,L-lactic acid (PDLLA) has emerged as a biostimulator that can potentially improve facial skin quality through collagen stimulation.

Objective: To assess the efficacy of PDLLA in improving facial rejuvenation markers in late middle age Thai women.

Materials and Methods: A quasi-experimental design was conducted for a before-and-after design. Fifteen eligible participants, aged between 45 and 60 years old, were recruited from Mae Fah Luang University Hospital Asoke, Bangkok, Thailand. Two sessions of subdermal PDLLA injections were administered to each participant. Eight skin quality parameters were assessed at baseline, two, four, and six months using the Cutometer MPA580 for skin elasticity, Sebumeter SM815 for sebum level, Corneometer CM825 for skin hydration or skin capacitance, Tewameter TM300 for transepidermal water loss or TEWL, and Visia CR system for spots, pores, wrinkles, and texture.

Results: Significant improvements were noted in skin elasticity, hydration, TEWL, pores, and wrinkles compared to baseline. Skin elasticity increased by 0.11±0.02 at six months ($p<0.001$), and skin hydration improved, with skin capacitance rising by 6.19±0.86 at four months ($p<0.001$). TEWL dropped by 6.49±0.68 g/m^2/hour at four months ($p<0.001$), pores reduced by 3.04±0.51 at four months ($p<0.001$), and wrinkles decreased by 7.62±1.13 at six months ($p<0.001$). In contrast, the remaining three parameters, sebum level, spots, and texture, showed no statistically significant changes in the time series measurement. No severe adverse effects were reported.

Conclusion: PDLLA is an effective and safe biostimulator for enhancing facial skin quality in the late middle age Thai women.

Keywords: Poly-D,L-lactic acid; PDLLA; Facial rejuvenation

Received 26 December 2024 | Revised 24 April 2025 | Accepted 8 May 2025

J Med Assoc Thai 2025;108(6):457-63

Website: http://www.jmatonline.com

Aging is an inevitable biological process that affects all living organisms, notably manifesting in the skin, which serves as the body's largest organ and barrier against environmental factors. Over time, structural changes in the skin lead to visible signs of aging, such as wrinkles, sagging, and loss of elasticity[1]. This deterioration of skin quality can impact self-esteem, mental well-being, and overall quality of life. According to the data, Thailand officially became a complete aged society in 2023, with 14 million individuals aged 60 and above, representing 20 percent of the country's total population[2]. In response, various treatments, including biostimulators, have emerged to counteract these effects.

Poly-D,L-lactic acid (PDLLA) is a biodegradable biostimulator derived from renewable resources like corn and potato starch[3,4]. It stimulates collagen production, offering gradual, long-lasting improvement in skin quality by triggering a foreign body response, followed by a cellular inflammatory response that promotes neocollagenesis, as confirmed by experiments in animals and laboratory studies[5-7]. PDLLA's safety is well-documented, with studies involving PDLLA screws in knee surgery demonstrating complete biodegradability as shown by magnetic resonance imaging (MRI) scans after 22 months[8].

Despite the lack of evidence-based clinical trials[7,9,10], PDLLA has shown promising results in improving skin quality including studies using

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How to cite this article:

Srituravanich C, Rummaneethorn P. Effect of Poly-D,L-Lactic Acid (PDLLA) Biostimulator on Facial Rejuvenation Markers in Late Middle-Aged Thai Women: A Quasi-Experimental Study. J Med Assoc Thai 2025;108:457-63.

DOI: 10.35755/jmedassocthai.2025.6.457-463-02252

poly-L-lactic acid (PLLA)[11], a structurally similar substance, injected into the face. The results highlight PDLLA's potential role in enhancing facial skin quality, with improvements in elasticity, hydration, and reduced transepidermal water loss (TEWL). Therefore, the authors undertook this investigation to determine whether PDLLA could demonstrate clinical benefits within the Thai population. The primary objective of the present study was to evaluate the efficacy of PDLLA in enhancing facial rejuvenation markers. PDLLA was hypothesized to be an effective choice for skin rejuvenation, positioning it as a safe and viable option for non-invasive facial treatments.

Materials and Methods

Design and sample

The present study employed a prospective quasi-experimental design with a time series approach, in which dependent variables were measured at multiple points in time within one group, both before and after the researchers administered the manipulated treatment. This design is commonly used in aesthetic research to assess treatment efficacy over time within individuals[10]. The sample size estimation followed the two-dependent-mean-difference formula[12], using inputs from a previous study similar to the present study[11]. The sample size was calculated using the n4Studies, version 1.4.0, with a power of 0.80 and a 95% confidence level. An effect size of 0.20 was chosen, with alpha errors set at 0.05. To obtain reliable data and minimize the potential for dropouts, the authors increased sample size by 20% to 15 subjects.

Therefore, the authors recruited 15 volunteers who came to visit at Mae Fah Luang University Hospital Asoke, Bangkok, Thailand between May 2024 and June 2024. The flowchart of the study procedure is shown in Figure 1. The included participants were female aged from 45 to 60 years. The authors excluded those with poor medical conditions to ensure better cooperation and those with conditions that could interfere with the outcomes, such as active skin disease, acne scar, and those with pregnancy or on breast feeding. The withdrawal criteria included participants who chose to withdraw from the program for any reason, those who experienced significant treatment complications, illnesses, fatalities, or accidents, and participants who were no longer accessible for follow-up. The scope of the work was explained to all participants, and those who agreed to take part signed consent forms.

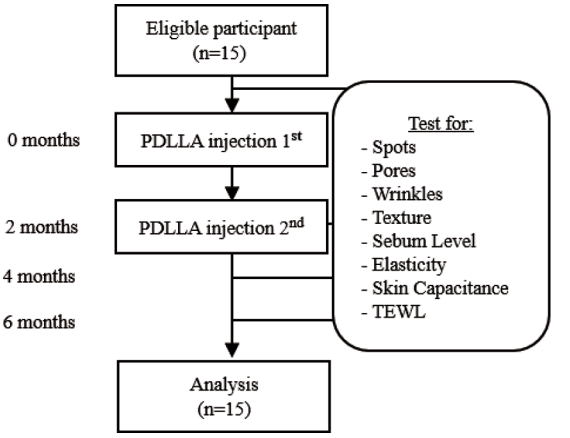

Figure 1. Flow chart of study procedure

PDLLA: Poly-D,L-lactic acid, TEWL: transepidermal water loss

Intervention

Participants in the present study were administered the biostimulator product. The authors used subdermal biostimulator PDLLA, known as AestheFill by REGEN Biotech, Seoul, Korea. This product received initial approval from the Korean Food and Drug Administration (FDA) in 2014[6] and was also approved by the Thai FDA, number 66-2-1-2-0004634. The product was provided in the form of freeze-dried powder within vials, each containing 200 mg that included 154 mg of PDLLA and 46 mg of carboxymethyl cellulose or CMC. PDLLA has been reported in literature as a safe and effective biostimulator for facial rejuvenation, especially due to its favorable degradation profile and safety advantages over PLLA[13]. Before injection, 8 mL of sterile water was introduced into the PDLLA vial. Just prior to the injections, an additional 2 mL of 2% lidocaine without adrenaline was added to achieve a final dilution of 10 mL of PDLLA using the back-and-forth technique[14]. Local anesthesia was administered at the pre-hole, with 0.2 mL per site, located at an imaginary line between the mid-pre auricular line and lateral canthus line. The injections were administered using a fanning technique into the subdermal plane, following a consistent pattern (Figure 2), and utilizing a 23-G needle, 5 cm in length, inserted at an angle of 30 to 40 degrees. Each injection line received 0.5 mL, totaling five lines. Each subject received up to 2.5 mL of PDLLA on each side, with 5 mL per participant per session. All participants received two sessions of PDLLA injections, at the month-0 and month-2 visits, as the maximal effect of collagenesis occurred around two months[6].

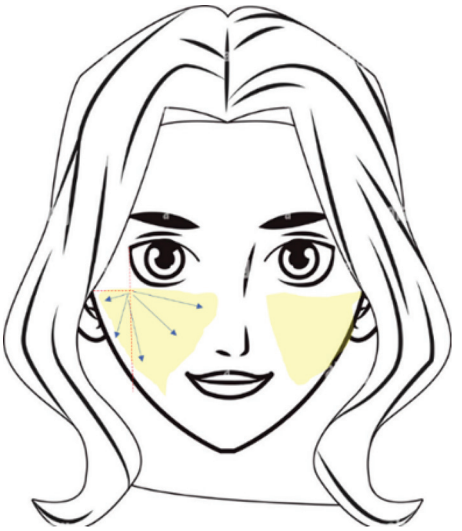

Figure 2. PDLLA injection technique.

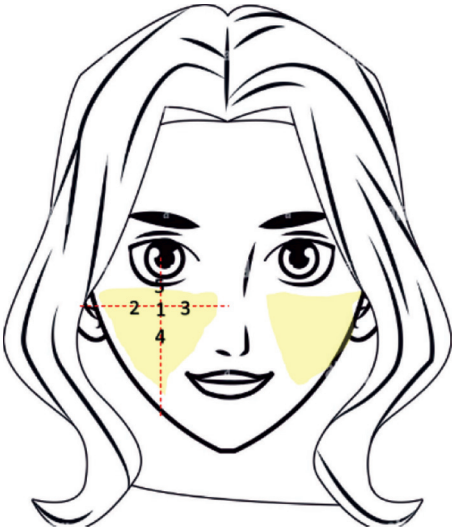

Figure 3. Measurement site for the data collection.

Outcomes measured

The assessments were conducted at specific time points, at zero, two, four, and six months. The primary outcome measures were facial rejuvenation markers, including elasticity, sebum level, skin capacitance, TEWL, spots, pores, wrinkles, and texture, assessed using validated instruments recommended by organizations such as the EEMCO group and cited in previous literature[15-19]. Specifically, elasticity was measured with the Cutometer MPA580, sebum level with the Sebumeter SM815, skin capacitance or hydration with the Corneometer CM825, TEWL with the Tewameter TM300, and spots, pores, wrinkles, and texture with the Visia CR system.

For each measurement, except the Visia CR, investigators used a probe to touch the skin at the designated measurement site (Figure 3). Measurements were taken five times on each side at each follow-up, totaling ten measurements per follow-up[20]. The first point was located on the imaginary line between the tragus line and the mid-pupil line. The second and third points were positioned 1 cm lateral to the first point, while the fourth and fifth points were placed 1 cm vertically from the first point.

For data on facial rejuvenation markers from the Visia CR system for Spots, Pores, Wrinkles, and Texture, the information was collected by positioning each participant on the machine, which automatically captured photos and analyzed the four parameters, Spots, Pores, Wrinkles, and Texture, in arbitrary units (a.u.).

The secondary outcome measured participants' satisfaction with the PDLLA injection at the end of the study using a self-reported five-point Likert scale questionnaire with 1 for Extremely dissatisfied, 2 for Dissatisfied, 3 for Neutral, 4 for Satisfied, and 5 for Extremely satisfied)[21]. The authors also assessed side effects using a side effect record form.

Ethical approval

Participants provided written informed consent prior to participating in the study. The present study was approved by the Ethics Committee on Human Research of Mae Fah Luang University (study code: EC24011-20).

Statistical analysis

Continuous variable values were presented as mean ± standard deviation (SD), while categorical data were expressed as frequency and percentage. Repeated measures ANOVA were used for normally distributed data, while the Friedman test was applied for non-parametric comparisons when normality assumptions were not met. Normality was assessed using the Shapiro-Wilk test. Pairwise comparisons were conducted with Bonferroni correction to control for multiple testing. A p-value of less than 0.05 was considered statistically significant. Data analysis was conducted using IBM SPSS Statistics, version 28.0 (IBM Corp., Armonk, NY, USA). Participant satisfaction and side effects were summarized in percentages.

Results

All fifteen female participants completed the

study with no withdrawals. The mean age of the participants was 52.33±3.44 years. Most participants were housekeepers at 26.7%, followed by therapists and nurses at 20% each. Fitzpatrick skin types were Type 3 in 60%, and Type 4 in 40%. Thirteen participants (86.7%) had no underlying diseases, while two had dyslipidemia (DLP). None reported food or drug allergies, smoking, or current medication such as antibiotics or NSAIDs. Alcohol consumption was reported by 13.3% of the participants (Table 1).

Over the study period, significant changes in mean differences were noted using Repeated measure ANOVA and post hoc test with Bonferroni for each time interval. Elasticity showed a gradual increase over time, with significant change from baseline to six months (–0.11±0.02, $p<0.001$). Sebum levels exhibited minimal changes with non-significant p-values across all intervals. Hydration levels significantly increased, especially from baseline to four months (–6.19±0.86, $p<0.001$) and baseline to six months (–8.19±1.45, $p<0.001$), showing an increase in skin hydration over time. TEWL decreased notably from baseline to later months, observed at four months (6.49±0.68, $p<0.001$) and six months (7.62±0.79, $p<0.001$), suggesting an improvement in skin barrier function with reduced moisture loss over time.

For the Pore marker, mean differences increased from baseline to four months (3.04±0.51, $p<0.001$) and baseline to six months (3.73±0.51, $p<0.001$), indicating a notable reduction in pore appearance. Similarly, the Wrinkle marker showed significant improvements, with mean differences increasing from baseline to six months (7.62±1.13, $p<0.001$), reflecting visible wrinkle reduction. In contrast, changes in Spot and Texture markers were minimal, with mean differences close to zero and non-significant p-values ($p=1.000$) across intervals (Table 2).

The analysis of facial rejuvenation markers was conducted through ANOVA with repeated measures. The results showed significant mean differences, with an increased value indicating a reduction in TEWL at four months and six months, Pore at four months and six months, and Wrinkle at six months. Conversely, a decreased value indicated an increase in Elasticity at six months and Hydration at four months and six months, as shown in Figure 4 and 5. Finally, participants were asked about their overall satisfaction. Results showed that 86.7% were extremely satisfied, and 13.3% were satisfied. No serious side effects were observed during the entire study. Participants reported no minor side effects such as pain, redness, swelling, or bruising throughout the follow-up period.

Table 1. Baseline characteristics of the 15 participants

Characteristic	Results
Age (year); mean±SD	52.33±3.44
Sex; n (%)	
Male	0 (0.00)
Female	15 (100)
Occupation; n (%)	
Housekeeper	4 (26.70)
Therapist	3 (20.00)
Nurse	3 (20.00)
Office employee	2 (13.30)
Business owner	1 (6.70)
Unemployed	2 (13.30)
Fitzpatrick skin type; n (%)	
Type 3	9 (60.00)
Type 4	6 (40.00)
Other	0 (0.00)
Underlying disease; n (%)	
None	13 (86.70)
DLP	2 (13.30)
History of food/drug allergy; n (%)	0 (0.00)
Current medication (antibiotic, NSAIDs); n (%)	0 (0.00)
Current smoker; n (%)	0 (0.00)
Alcohol drinking; n (%)	2 (13.30)

SD=standard deviation; DLP=dyslipidemia; NSAIDs=non-steroidal anti-inflammatory drugs

Discussion

The data indicated a statistically significant increase in skin elasticity and hydration among participants receiving PDLLA treatment. Specifically, Table 2 demonstrated a notable decline in elasticity scores from baseline to each subsequent time point, with the most pronounced reduction observed at six months ($p<0.001$). Similarly, the table also indicated a significant decrease in skin capacitance, which reflects skin hydration levels, throughout the study period. This improvement suggests that PDLLA not only stimulates collagen production but also enhances the skin's moisture-retaining capacity, leading to improved overall skin quality.

These findings align with prior research that has investigated the use of biostimulators for facial rejuvenation. For instance, a study by Lin & Lin (2022) reported significant enhancements in skin elasticity and hydration following the nonsurgical lower eyelid rejuvenation involved administering

Table 2. The comparison of the mean difference of facial rejuvenation markers at baseline, 2 months, 4 months, and 6 months (n=15)

Markers	Baseline to 2 months mean diff±SD	Baseline to 4 months mean diff±SD	Baseline to 6 months mean diff±SD	2 to 4 months mean diff±SD	2 to 6 months mean diff±SD	4 to 6 months mean diff±SD
Elasticity	0.01±0.01	−0.04±0.02	−0.11±0.02	−0.04±0.01	−0.11±0.01	−0.07±0.01
p-value	1.000	0.361	<0.001*	0.029	<0.001*	0.002
Sebum level	−0.01±0.06	0.26±0.35	0.17±0.56	0.26±0.40	0.17±0.61	−0.08±0.34
p-value	1.000	1.000	1.000	1.000	1.000	1.000
Hydration	−1.87±0.41	−6.19±0.86	−8.19±1.45	−4.31±0.65	−6.32±1.23	−2.00±0.81
p-value	0.003	<0.001*	<0.001*	<0.001*	0.001	0.160
TEWL	0.77±0.46	6.49±0.68	7.62±0.79	5.73±0.87	6.85±0.99	1.13±0.27
p-value	0.716	<0.001*	<0.001*	0.001	<0.001*	0.006
Spot	−0.01±0.12	−0.62±0.67	−0.32±0.66	−0.62±0.69	−0.32±0.68	0.30±0.11
p-value	1.000	1.000	1.000	1.000	1.000	0.082
Pore	−0.20±0.38	3.04±0.51	3.728±0.51	3.24±0.27	3.93±0.27	0.69±0.08
p-value	1.000	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*
Wrinkle	−1.46±1.51	2.57±1.13	7.62±1.13	4.04±0.64	9.08±0.83	5.04±0.35
p-value	1.000	0.238	<0.001*	<0.001*	<0.001*	<0.001*
Texture	0.47±0.77	0.78±0.62	0.56±0.71	0.31±0.23	0.09±0.35	−0.22±0.33
p-value	1.000	1.000	1.000	1.000	1.000	1.000

SD=standard deviation; Mean diff=mean difference; TEWL=transepidermal water loss
Data were analyzed using repeated measure ANOVA and post hoc test with Bonferroni
* p<0.001, statistical significance

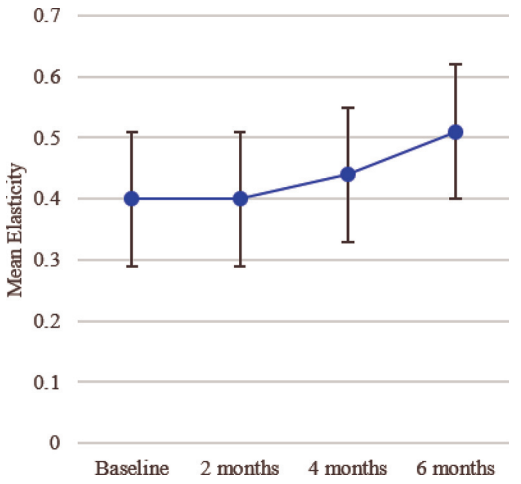

Figure 4. The comparison of the mean of elasticity at each timepoints.

* p<0.001

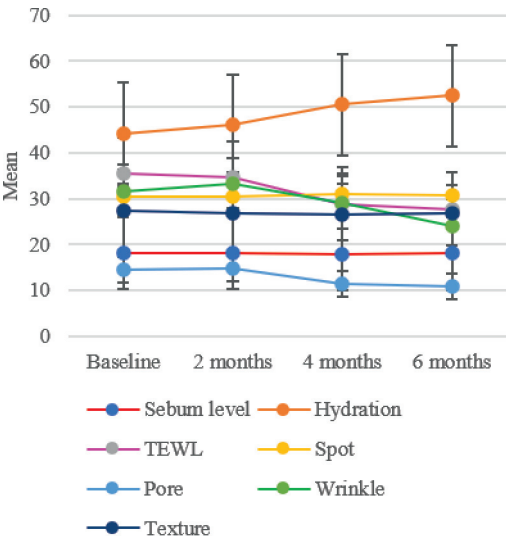

Figure 5. The comparison of the mean of facial rejuvenation markers at each timepoints.

* p<0.001

PDLLA injections every three months. This treatment led to improvements in skin texture, elasticity, wrinkle depth, and skin brightness, with no serious side effects reported in the total of 10 participants[9]. However, they also reported significant improvements in skin texture and brightness, unlike our study, which found no change. Similarly, a recent systematic review by Seo et al. (2024) noted that the use of PDLLA (Juvelook) for skin rejuvenation in a study involving 16 participants demonstrated promising results[10]. All participants underwent two or three treatment sessions spaced four weeks apart, leading to statistically significant improvements in various signs of aging, including skin elasticity, firmness, hydration, and reduced wrinkles and fine lines. Notably, 50% of the patients reported an overall improvement of more than 50%. Importantly, no severe adverse events

were reported, highlighting the treatment's safety. Furthermore, histological examination revealed increases in collagen and elastic fibers in the dermis, suggesting that PDLLA effectively stimulates dermal regeneration, corroborating with the present study's outcomes.

The reduction in TEWL further supports the efficacy of PDLLA in enhancing skin barrier function, as shown in Table 2. The results indicated significant reductions in TEWL at each follow-up interval, particularly from baseline to six months ($p<0.001$). This decrease suggests improved skin barrier integrity, which is critical for maintaining hydration and preventing moisture loss. The findings regarding TEWL reduction are consistent with the previous studies, such as the one conducted by Bohnert et al. Participants who received PLLA injections, which have a similar chemical isomer to PDLLA, showed significantly improved skin quality at the 12-month follow-up compared to those who received a saline solution or placebo. Additionally, the PLLA group demonstrated enhanced skin barrier function and experienced a greater reduction in TEWL, increased skin elasticity, and higher levels of satisfaction throughout all follow-up visits[11].

Additionally, the data in Table 2 regarding sebum levels, spots, and texture revealed negligible changes throughout the study, suggesting that while PDLLA treatment may improve skin hydration and elasticity, it does not significantly alter sebum production or melanin levels.

Patient satisfaction scores underscored the subjective efficacy of PDLLA treatment. The overwhelming majority of participants (86.7%) reported being "Extremely satisfied" with the results at the six-month follow-up, reflecting the treatment's acceptability and effectiveness. These findings are in line with the previous studies[9-11], which reported high satisfaction rates among patients receiving biostimulator treatments for facial rejuvenation. The combination of objective improvements in skin quality and subjective satisfaction points to the multifaceted benefits of PDLLA as a biostimulator. In this study, no minor side effects such as erythema, swelling, bruising, or discomfort were reported by any participants throughout the follow-up period. All participants tolerated the PDLLA treatment well, and the absence of both serious and minor adverse events further supports the favorable safety of the intervention. These mild reactions, when present, were expected and typically resolved within a few days.

While promising, the present study has limitations. This study was designed as a preliminary investigation focusing on a specific demographic. The quasi-experimental design lacks a control group, limiting causal conclusions regarding PDLLA's impact on facial rejuvenation. With only a six-month follow-up and a small sample size of 15 participants, results may lack durability and generalizability. Over-reliance on specific machines for measuring rejuvenation markers may lead to measurement errors if not properly calibrated or validated. Future research should include larger, randomized trials with longer follow-ups and objective assessments to verify these findings. Additionally, exploring PDLLA's long-term effects, interactions with other treatments, and molecular mechanisms would deepen understanding.

Conclusion

In conclusion, the present study demonstrated the efficacy of PDLLA as a biostimulator for facial rejuvenation, particularly highlighting the significant improvements in facial rejuvenation markers such as skin elasticity, hydration, and overall patient satisfaction. The product was safe, with no severe adverse effects reported.

What is already known about this topic?

PDLLA has emerged as a biostimulator that can potentially improve facial skin quality through collagen stimulation. Given the limited evidence of its effects and safety in clinical trials, the present study might support PDLLA as a potential option for facial rejuvenation.

What does this study add?

The results indicated that PDLLA is an effective and safe biostimulator for facial rejuvenation in late middle-aged Thai women, particularly in terms of elasticity, hydration, TEWL, pore size, and wrinkle reduction. However, PDLLA did not significantly impact sebum production or pigmentation.

Acknowledgement

The authors would like to express gratitude to the participants for their contribution to this research. Additionally, sincere thanks are extended to all the staff at Mae Fah Luang University Hospital Asoke, Bangkok, Thailand, for their invaluable assistance with data collection.

Conflicts of interest

The authors state that there are no conflicts of

interest.

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