ISSN: 2754-494X

Journal of Dermatology Research Reviews & Reports

SCIENTIFIC Research and Community

Research Article

Open Access

The Use of Polymethylmetacrylate (PMMA) in Bioplasty

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ABSTRACT

Introduction: Polymethylmethacrylate (PMMA) is an alloplastic compound used for body and facial filling, commercialized in microsphere format diluted in purified vehicles, and used as polymer applied to bioplasty. In Brazil, infiltrative PMMA implants are being used in order to restore the volume lost during the aging process and the formation of wrinkles and other types of facial depressions or body asymmetries. PMMA is a polymer that stimulates neocollagenesis, causing a controlled inflammatory reaction, which stabilizes the material and defines the implant site. However, there is still a lack of documentation and research on possible adverse reactions to this material.

Methods: This is a restrospective study of bioplasty patients attended at a private clinic from 2005 to 2019. Demographic profile of the patients was registered, as well as the PMMA commercial brand used in them, concentration, site of implantation among other aspects related to the procedure. 506 charts were included; all patients were women, 49.4% were middle aged.

Results: The main complaint was aesthetic (94.3%). The most performed diagnostics were nasal alteration (33.6%). The most implanted site was the nose (84.4%) and the most used brand was Linnea Safe, at 30%. Only one patient (0.2%) presented complication which was infection.

Conclusion: PMMA implantation was mainly performed in the nose of middle-aged women and with low incidence of adverse reactions. More studies regarding incidence and epidemiology of PMMA implantation are needed.

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Received: October 12, 2024; **Accepted:** October 17, 2024; **Published:** November 30, 2024

Keywords: Polymethyl Methacrylate, Esthetics, Incidence, Female

Introduction

Polymethylmethacrylate (PMMA) is a thermoplastic polymer, rigid, colorless, malleable, non-absorbable and permanent filler used as dermal filler, bone cement and dental filler. PMMA as a dermal filler is considered biocompatible, stable on the implantation site, does not induce protrusion of skin, is not removed by phagocytosis, does not present migration potential to distant locations and does not induce the formation of foreign body granuloma, resulting in minimal immunogenic response [1-3].

The intramuscular implantation of PMMA in mice generated inflammation with collagen deposition and was considered biocompatible in spite of the use of a commercial brand that presented irregularities in the beads size which prevented the better stability of the used biomaterial. The knowledge regarding PMMA side effects, migration potential and the phagocytosis of the microspheres have grown in time and resulted in better manufacturing, quality control regarding microspheres size and biocompatibility [4-7].

PMMA Artefill™ (former Artecoll and current Bellafill) presents as vehicle bovine collagen which facilitates a better distribution of the 40 µm sized microspheres and is replaced by the body`s own collagen fibers. The microspheres are not digested by enzymes due to the methyl group which stabilizes the molecules. This product presents predictable results, but its implantation allows no mistakes as it results in permanent presence of the microspheres and collagen in the site requiring practice and experience for the professionals who will apply its implantation. Other commercial brands have been introduced in the market and its use as dermal filler and bone cement has been widely expanded [3,5,6,8,9].

PMMA is used as a filler for soft tissues augmentation with immediate and long-term results. The choice of material, depth of implantation, application technique and quantity to be injected must be suitable for each patient and anatomical site and will directly influence the result. It has been used in several different applications such as in HIV/AIDS related lipodystrophy; infraorbital rhytids, facial rejuvenation and atrophic acne scars. However, there are some complications related to the implantation procedures such as hypersensitivity, toxicity, embolism and thermal necrosis [2,8,10-15].

Since the PMMA indications are varied and related to medical and dermatological needs, this study aimed to determine the performance of PMMA implantations and the occurrence of

adverse reactions in a private clinic in Manaus, AM, North region of Brazil, in the period from 2000 to 2019.

Materials and Methods

This is a retrospective study performed with secondary data retrieved from patients' charts attended in a private clinic, Bioplastia Brasil, by Dr. Eduardo Luiz da Costa in Manaus, Amazonas, Brazil. The analyses were performed in the Tropical Pathology and Public Health Institute, Federal University of Goias, Goias, Brazil. The inclusion criteria were: complete charts from patients that had a PMMA implantation, the procedure was performed from 2005 to 2019. The exclusion criteria were: incomplete chart and/or not attend the inclusion criteria. All patients` personal identification data were kept in confidentiality.

The analyzed variables were: gender, housing, age, main complaint that originated the PMMA implantation, previous diseases, current disease, previous surgeries, obstetric history, use of medications, allergies to medications, body mass index, diagnosis or methodological indication, site of implantation, concentration of PMMA used, quantity of PMMA implanted, PMMA brand used in the procedure, presence of complications, type of complication, affected region, outcome or treatment of the complication and medical conduct.

This study was approved by the Ethics in Research Committee from the Federal University of Goias (CEP/UFG), protocol number 3.611.775. The data were organized and described using the IBM SPSS Statistics 22 software. Correlations and associations between the main complaint of the patient with the outcome after PMMA implantation; the concentration of the product, volume and anatomical site of implantation, PMMA brand used and the presence of adverse reactions and complications; between the type of adverse reactions. Also, the correlations analyzed enabled to enlarge the knowledge regarding the bioplasty using biomaterials, its usefulness and applicability.

The correlations and associations were performed using the STATA software, version 15.0. The descriptive analyzes were performed regarding all variables related to the epidemiological profile of the patients submitted to PMMA implantation. Quantitative variables were presented as median and interquartile range (IQR) and qualitative variables were presented as absolute (n) and relative (%) frequencies. In order to verify the variables related adverse effects (dependent variables) due to PMMA implantation, bivariate and multiple Poisson analyses were performed with robust variance. In the Poisson multiple regression only the variables that presented with p-value ≤ 0.20 in the bivariate analysis were included. The magnitude of the association in the regression model was presented as the Adjusted Prevalence Ratio (PR) and respective 95% confidence interval (95% CI). The standard error (SE) of the estimates was also presented. Variables with p-value < 0.05 were considered statistically significant.

Results

A total of 506 patients were submitted to PMMA implantation in a private clinic in Manaus, Amazonas, Brazil, in the period of 2005 to 2019. All patients submitted to this procedure were women (100%). The demographic and clinical characteristics added to the obstetric data of the patients submitted to PMMA implantation are described in Table 1. The majority of them (49.4%) were in the age brackets of 31 to 50 and resident in Manaus (96.8%), Amazonas, Brazil. The BMI showed that 63.4% of them were eutrophic. The most frequent morbidities reported were arterial hypertension (5.5%) and hormonal disbalance (4.5%). The most used medication reported was oral contraceptive (23.5%). Regarding previous surgeries the patients reported Caesarean section (38.3%), breast implant (25.15), liposuction (19.2%) and abdominoplasty (10.5%) (Table 1).

Table 1: Demographic, clinic and obstetric characteristics from women submitted to PMMA implantantion in the period from 2000 to 2016 in a private clinic from Manaus, AM, Brazil.

Variables	(N=506)	%
Age brackets (years)		
18-30	170	33.9
31-50	248	49.4
> 50	84	16.7
Not informed	4	0.7
Residency		
Manaus	490	96.8
Others	16	3.2
Body Mass Index		
Low body weight	23	4.7
Eutrophic	323	63.4
Over weight	137	27.7
Obesity	21	4.3
Not informed	12	2.37
Previous Morbidities*		
Arterial hypertension	28	5.5
Autoimmune disease	3	0.6
Cardiovascular disease	3	0.6
Chronic neurologic disease	5	1.0
Dermatologic disease	2	0.4
Diabetes	9	1.8
Gastrointestinal disease	3	0.6
Genital tract disease	4	0.8
Hepatic disease	2	0.4
Hormonal disbalance	23	4.5
Hypercholesterolemia	2	0.4
Muscle skeletal disease	5	1.0
Ophtalmologic disease	2	0.4
Psiquiatric disease	4	0.8
Respiratory tract disease	7	1.4
Other	4	0.8
Alergies		
Acetylsalicylic acid (ASA)	17	3.4
Penicilin	11	2.2
Sulpha	14	2.8
Other	84	16.6

Medications currently in use		
ASA	2	0.4
Isotretinoin	6	1.2
Oral contraceptive	119	23.5
Other	218	43.1
Previous surgeries		
Appendectomy	16	3.2
Bariatric	6	1.2
Breast fibroadenoma removal	8	1.6
Cardiac	3	0.6
Cesarian section	194	38.3
Cholecystectomy	31	6.1
Dilation and curettage	4	0.8
Hernia surgery	10	2.0
Hysterectomy	23	4.5
Myomectomy	7	1.4
Odontologic	8	1.6
Oophorectomy	8	1.6
Ophtalmologic	7	1.4
Orthognathic	2	0.4
Ortopedic	15	3.0
Thyroidectomy	8	1.6
Tonsillectomy	5	1.0
Tubal sterilization	25	4.9
Obstetric history	314	62.8
Previous plastic procedure **	227	44.9

* Multiple responses; ** Includes: rhynoplasty; mamoplasty; blepharoplasty, abdominoplasty, liposuction, perineoplasty, facial plastic surgery, falcelift (rhytidectomy) and lipograft.

The motives and main complaints regarding the PMMA implantation procedures are described in Table 2. The main complaint was aesthetic (94.3%). The most performed diagnostics were nasal alteration (33.6%) and expression wrinkles (28.5%). The most frequent sites of PMMA implantation were nose (84.4%) and eyelid (40.9%). The most used PMMA brand was Linnea Safe (75.3%) and the percentage of PMMA most implanted was 30% (96.4%)

Table 2: Characteristics of the PMMA Implantation in Patients from a Private Clinic in Manaus, Amazonas, Brazil

Variables	**N**	**%**
Main complaint		
Aesthetic	477	94.3
Acquired deficiency	1	0.2
Genetic deficiency	1	0.2
Post-procedure deformity	11	2.2
Diagnostics		
Bone loss	1	0.2
Calf disproportion	2	0.4
Cartilage sinking	1	0.2
Dark under-eye circles	29	5.7
Expression wrinkles	144	28.5
Facial assimetry	5	1.0
Facial fat	5	1.0
Facial ptosis	72	14.2
Fat pads	30	5.9
Gluteal depression	4	0.8
Tear trough	9	1.8
Lip disproportion	13	2.6
Lipodistrophy	1	0.2
Malar depression	1	0.2
Micrognathia	38	7.5
Mini liposuction	1	0.2
Nasal alteration	170	33.6
Nasolabial fold	9	1.8
Rhinolasty sequelae	13	2.6
Cicatricial deformities	3	0.6
Trochanteric depression	8	1.6
Site of implantation		
Bichatt balls	10	2.0
Calf	10	2.0
Chest	2	0.4
Chin	195	38.5
Cranial fossa	166	32.8
Ear	2	0.4
Eyelid	207	40.9
Forehead	1	0.2
Genitalia	1	0.2
Glabella	1	0.2
Gluteus	36	7.1
Goteira lacrimal	3	0.2
Hands	3	0.6
Interline	18	3.6
Lip	139	27.5
Malar	174	34.4
Mandible	142	28.1
Nasojugal sulcus	57	11.3
Nasolabial sulcus	153	30.2
Nose	427	84.4
Thigh	2	0.4
Zigomatic	54	10.7
PMMA brand used		
Art Safe	56	11.1
Biossimetric	28	5.5
Linnea Safe	281	75.3

New Plastic	71	14.0
Quantity applied, median (IQR)	0.48 (0.32-0.68)	
Quantity of anatomical sites implanted, median (IQR)	6.0 (4.0-9.0)	
Percentage of PMMA implanted		
2	232	45.8
10	286	56.5
30	488	96.4

IQR: Interquartile Range

The most common adverse effects were considered acute ones such as erythema (3.4%) and edema (2.8%). Granuloma which is considered a chronic adverse effect was observed in one patient (0.2%). While complications were less frequent such as infection (0.6%) and nodules (0.6%). Ischemia and necrosis were not observed in the analyzed patients. The most frequent site of adverse reaction was the nose which was also the most common site of application (Table 3).

Table 3: Adverse Effects Observed after the PMMA Implantation

Variable	N	%
Acute adverse effect		
Edema	14	2.8
Erythema	17	3.4
Hematoma	3	0.6
Chronic adverse effect		
Granuloma	1	0.2
Complication		
Infection	1	0.2
Ischemia	0	0
Necrosis	0	0
Nodules	3	0.6
Site		
Calf	1	0.2
Chin	7	1.4
Eyelid	1	0.2
Gluteus	1	0.2
Jaw line	3	0.6
Lip	8	1.6
Malar	4	0.8
Nose	28	5.5
Zigomatic	1	0.2
Total	42	8.3

The multiple regression model of Poisson performed regarding the association between adverse effects and independent variables showed that the implantation site in Bichat balls (PR=4.21; CI95%=1.12-15.89; p-value = 0.034), in the nose (PR=7.40; CI95%=1.0452.80; p-value = 0.046) and the quantity of anatomical sites implanted (PR=1.14; CI95%=1.05-1.23; p-value = 0.001) were associated to an increase in PMMA implantation adverse effects. This analysis indicates that the prevalence of complications was 4.21 times higher in patients with PMMA implantation in the Bichat balls, 7.4 times when the PMMA implantation site was the nose and 1.4 times higher at each increase in number of anatomical sites implanted.

Discussion

Soft tissue augmentation fillers have been used in aesthetics for several years and there is a worldwide trend for less invasive procedures that present rapid results. The use of injectable fillers can lead to the replacement of more traditional surgical approaches which are invasive techniques. Also, the use of injectable fillers tends to significantly decrease the cost of procedure making it more accessible to the population. PMMA has shown to be a good filler substance used both in aesthetics and other non-aesthetic indications such as correction of deep static folds, acne scars, bone cement and others.

All the patients submitted to PMMA implantation, in our study, were women. This fact reflects the major interest of women in cosmetic procedures in comparison to men's interest. This is in accordance to the report of Milothridis et al. who detected in a systematic review that most women (48%) were interested in one or more of these procedures. A survey performed by Rini et al. regarding cosmetic surgeries performed in a private clinic from a developing country detected that 93.4% of the patients were female, which is in accordance to our finding. These data show the greater dissatisfaction of women regarding their body image. Slevec and Tiggemann described that body dissatisfaction, age anxiety and media exposure were directly correlated to the performance of such procedures. Also, the age of women who most sought cosmetic procedures are middle aged (40-55) which is in accordance to our findings. Most patients in our study were eutrophic which reflects that body mass index is not a predictive indicator of interest in cosmetic procedures [16-24].

Regarding the history of previous surgery, 38.3% of the patients had undergone cesarean section. This datum shows the preference of Brazilian women in submitting to cesarean section in detriment of natural labor. Also, the prevalence of cesarean section in private clinics is related to the access to health care systems which are greater in a population of higher income25. Additionally, Brazil presents a high rate of elective cesarean delivery performed in maternities due to several socioeconomic, obstetric and hospital characteristics [25-27].

Another interesting finding is that 44.9% of the patients had been submitted to previous plastic procedure. This reflects the great presence of body dissatisfaction amongst women and the role of cosmetic procedures such as PMMA implantation which contributes to alter the self-perception of image. This is also reinforced by the fact that 94.3% of the patients in our study presented aesthetic as the main complaint [28,29].

According to Lin et al. the most common sites of soft tissue fillers implantation are face and hands, which is in accordance to our findings, in which the face was the most implanted site, especially the nose. This also influences the percentage of PMMA used in the implantations as the recommendation from the Brazilian consensus on the use of PMMA for nose implantation is 30% concentration and is in accordance to our findings. The use of higher PMMA concentrations such as 30% in indicated in deeper planes, i.e. nose, mentum, malar and zygomatic, as long as there is the respect for the application planes in order to avoid complications. This fact is explained due to higher concentrations reflects higher density of PMMA which are able to induce more connective tissue on

Site [2,18,16,30].

Regarding the complications, vascular occlusion leading to skin necrosis is the most reported complication linked to soft tissue fillers. However, in our study we reported no ischemia neither necrosis in the patients implanted with PMMA. Other adverse reactions reported in soft tissue fillers implantation in the first few days after the procedure are erythema, edema, hematoma and infection. Late complications related to these procedures are granuloma formation, compound migration, skin discoloration, nodules and ulcers. In an experimental essay comparing the incidence of vascular complications after the use of different dermal fillers, it was shown that PMMA presented less risk of embolism and necrosis in comparison to hyaluronic acid showing the safety of PMMA use [15,18,21,31].

Immediate complications such as hematomas and ecchymosis may happen when the patient ingests antiplatelet-aggregating or anti-inflammatory drugs. In our study only 0.4% of the patients reported the use of drugs that interfere in blood coagulation, such as acetylsalicylic acid, and only 2.8% presented edema, 3.4% erythema and 0.6% hematoma. Later adverse effects were observed in only 4 patients, from which, 1 reported granuloma (0.2%) and 3 presented nodules (0.6%). It is considered that these rates of complications are lower than the reported by the literature and indicate the quality of the implantation technique performed in this study. The occurrence of high rates of adverse effects after PMMA implantation are directly related to poor surgical technique, therefore, the adequate training of the professionals who are performing PMMA implantations is crucial for the prevention of such complications. The occurrence of adverse effects is not related to the composition of the filler as it is rather related to the implantation technique and ability of the professional [7,8,10,32].

Regarding the most used brand of PMMA, Linnea Safe™, it has been shown previously that it induces a localized chronic inflammation without the formation of granulomas due to the size of the microspheres which prevent phagocytosis. There was no migration of the microspheres into lymphatic nodules or other locations. In comparison to other brands, Linnea Safe™, is considered safe and with lower adverse reactions registered.
In conclusion, it was possible to observe that in a private clinic from Manaus, Amazonas, Brazil, there was the predominance of PMMA implantation in middle aged women who had already been through a previous plastic procedure and presented aesthetic as main complaint. The occurrence of adverse reactions was very low and in the nose which was the most implanted site. More studies regarding the prevalence and epidemiology of PMMA implantation are needed to show the populations preferences and the incidence of adverse effects [33,34].

Ethical considerations
All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

IRB Approval Statement
This study was approved by Ethics in Research Committee (CEP) from Federal University of Goias (UFG), protocol n. 3.611.775

Declaration of Conflicting Interests
The authors have nothing to disclose.
Funding Acknowledgements
No funding was received for this article.

Description of Individual Author Contributions
ELC, ACM, ACS and IMSJ - Made a substantial contribution to the concept or design of the work; or acquisition, analysis or interpretation of data.
ACM, MCV and RSLJ - Drafted the article or revised it critically for important intellectual content.
ELC, MCV and RSLJ - Approved the version to be published.

Level of Evidence
Level III: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

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