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ORIGINAL ARTICLE BREAST SURGERY

Brazilian Consensus Recommendation on the Use of Polymethylmethacrylate Filler in Facial and Corporal Aesthetics

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Abstract
Background Considering that aesthetic benefits can be obtained with the use of permanent filling materials, this work focuses on the development of a consensus regarding the facial and corporal use of polymethylmethacrylate (PMMA) filler in Brazil.
Methods A questionnaire regarding PMMA treatment, which included items on the main indication, application site, volume of product applied, criteria for selection of the material, complications, contraindications, and individual professional experience, was distributed to the Expert Group members. In addition, the responses were summarized, constituting the starting point for the debate regarding the use of PMMA-based fillers on The First Brazilian PMMA Symposium to create a guideline to be followed in PMMA facial and corporal treatments.
Results This survey involved 87,371 cases. PMMA treatment is recommended for restorative and aesthetic purposes in facial and corporal cases, particularly for facial balance. PMMA 30% filler is recommended in specific facial sites (nose, mentum, mandible angle, zygomatic arc, and malar). PMMA filler is contraindicated in other sites (lips) regardless of concentration. With regard to facial treatment, the juxtaperiostal is the application plane most recommended. For PMMA corporal application, intramuscular is the application plane most indicated, while intradermal and justadermal planes are contraindicated. The submuscular plane application is relative to PMMA filler concentration. The experts also inquired regarding the amount of PMMA recommended in each corporal site (50 mL in the calf, 100–150 mL in the gluteal region).
Conclusion These recommendations provide a guideline for physicians, supporting them to perform safe and efficacious treatment with PMMA fillers.
Level of Evidence V This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Dermal filler · PMMA filler · Soft tissue augmentation · PMMA consensus

Introduction

Worldwide, health practices are directed toward a more preventive approach, perceiving postures that value healthier lifestyles and behavior based on disease prevention. Within this context, we also recognized that men and women seek strategies to reduce visible signs of aging. According to the American Society of Plastic Surgeons [1], the number of cosmetic procedures performed in the USA was 1,780,987 in 2016. Besides, more than 1.6 million dermal filler treatments were performed in the USA in 2011, making them the second most popular non-surgical cosmetic procedure performed after neuromodulators [2]. North America currently ranks first, considering the total number of surgical and non-surgical cosmetic procedures

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performed. Brazil is ranked second, being ranked first only when surgical procedures are considered [3].

Traditionally, facial rejuvenation was long focused on resection and skin resurfacing. However, in recent years, emphasis on minimally invasive cosmetic procedures has been increasing. This tendency has culminated with the use of a variety of non-incisional methods to counter the effects of aging, with soft tissue augmentation with infiltrative facial implants as being the most popular. A large number of filler materials are currently available for this purpose, each with its chemical composition, specific indications, and effectiveness. This wide range of available materials requires aesthetic specialists and cosmetic surgeons to choose the right filler for each aesthetic complaint of their patients [4].

The ideal filler applied for treating the signs of aging or for soft tissue augmentation should provide good aesthetic results and should have a long-term effect. It should also be safe, biocompatible, and stable in the implantation site, with low-risk complications and migration [5]. Among the various types of fillers currently used for cosmetic and medical indications in routine clinical practice, we can highlight the following: collagen (bovine, porcine, or human), hyaluronic acid of animal or synthetic origin, polylactic-L-acid, hydroxyapatite calcium, polymethylmethacrylate (PMMA), and polyacrylamide gel. These fillers differ in their modes of action and the time interval the material remains in the tissue before being absorbed [6, 7].

Currently, PMMA is highlighted as a filler material for soft tissue augmentation. PMMA is a permanent filling material that can provide immediate and long-term results. The PMMA molecule has no animal component in its structure, making this molecule a biocompatible and stable material even after decades from the initial implant [8]. Its commercial applications are PMMA microspheres suspended in bovine collagen. The microspheres exhibit highly uniform size, charge characteristic by lower rate of adverse effects compared with other acrylic materials fill [9]. The microspheres act as a matrix after injection by stimulating the patient's own fibroblasts to produce collagen to encapsulate each microsphere. In commercial applications, bovine collagen, in addition to acting as a vehicle for the PMMA microspheres, prevents the injection apparatus from clogging during application and stimulates the tissue growth where it is deposited [2, 7].

Non-permanent fillers, such as collagen and hyaluronic acid, produce short-term results and are eventually resorbed. Repeated injections are required to obtain long-term results. Semi-permanent fillers (e.g., calcium hydroxyapatite) tend to remain on the fabric long term in relation to the majority of non-permanent filling materials, but these fillers are also eventually resorbed. Only permanent fillers (such as PMMA) can produce long-term results with a single application. As indicated by its classification, these products will persist indefinitely in the tissue, a characteristic that may raise concerns about its safety and potential long-term side effects [4].

Practice and experience are required for professionals who perform the application of filler material. In addition, the choice of the agent and quantity of the material to be injected, which must be suitable for each patient and each anatomical site, are important [7].

The depth at which the fillers are implanted is another essential aspect to achieve a good result. A common misconception regarding filler products is adjectival them as "dermal filler." Although many products used for surface defects are injected directly into the dermis, some fillers, such as biosynthetic polymers, are suitable for deeper areas. This distinction is important because products preferably used for deep defects should not be injected into the dermis to prevent the occurrence of palpable lumps and/or contour abnormalities [4, 7]. Furthermore, the size of the apparatus used to implant the filling agent is determined by the viscosity of the material, and it may be replaced by an alternative device based on the experience of the surgeon. Generally, a smaller apparatus that can properly inject the filling material is the ideal choice to limit the pain after injection [4].

Despite all precautions observed in the choice of filler material and application technique used, certain complications may be associated with the use of infiltrative implants. Agents that degrade within months may induce severe complications, but these usually resolve spontaneously over a variable time period. All other filler materials can induce severe adverse reactions, showing little or no tendency for spontaneous improvement [5]. Therefore, special attention should be given to the development of granulomatous reactions. The dermis is known to be highly susceptible to immunogenic provocation, which means that the deeper the material is implanted, the lower the probability of developing granulomatous reactions [7].

Considering the aesthetic benefits that can be obtained with the use of infiltrative implants, particularly permanent filling materials, supporting the continued discussion of the use of these materials, as well as the exchange of information between physicians, is important. This work aimed to know the expert opinions with proven experience in PMMA-based filler treatments to create a consensus covering the fundamental principles for its use. We hoped that providing information would thereby enable the standardization of procedures to obtain optimum results from the standpoint of efficacy and patient safety.

Materials and Methods

Considering the paucity of prospective, randomized, comparative, and controlled studies on PMMA fillers, formal evaluation of published clinical evidence cannot be conducted. Thus, to determine which and how facial and corporal aesthetic treatments using PMMA in Brazilian patients are performed, Expert Group members (n = 36) were inquired in writing regarding the following: (1) the main indication for minimally invasive treatment using PMMA, (2) the application site on the face or body, (3) the volume of product applied, (4) the criteria for selection of the used material, (5) the complications resulting from the use of PMMA, (6) the apparatus for PMMA injection, and (7) the professional's experience in the number of procedures performed.

In addition, the responses provided in the questionnaire were summarized, constituting the starting point for the debate on use of PMMA-based fillers. Therefore, a larger number of experts (n = 150) were invited to attend the First Brazilian PMMA Symposium, wherein topics initially addressed in the questionnaire were discussed. The professionals shared their experiences and expressed their opinions on each issue addressed. The reports were recorded on video, and the recordings were used to broaden the debate, inserting additional reports of experiences in the use of PMMA fillers. The purpose of this meeting was to provide an overview of common standards of practice to create a guideline that can be followed in PMMA facial and corporal treatments. In addition, a 2-year meeting was proposed, with the objective of reviewing and updating the aforementioned guideline.

The survey was approved by the Ethics and Research Committee of the Federal University of Pampa, under number 1752627. Rare procedures and high-risk treatments requiring extensive experience were not discussed at the meeting or mentioned in this review.

Results and Discussion

The following content reflects the proceedings of the First Brazilian Symposium PMMA Aesthetics Expert Consensus Group meeting. The consensus statements presented here were extracted from the questionnaires and widely debated at the symposium by all the Expert Group members.

It should be emphasized that 50% of the professionals who answered the questionnaire have more than 12 years of experience, and 8% of them have 16 years of practice with PMMA. Considering the experience of the respondent physicians, this survey involved 87,371 cases, with 71,136 and 12,285 facial and corporal cases, respectively.

Indications and Treatment Areas

When asked about the general indication of PMMA fillers on the face, all physicians (100%) recommended the use of PMMA implants for aesthetic purposes, whereas 97% recommended the use of PMMA for restorative purposes. With regard to corporal use, all professionals interviewed (100%) indicated the use of PMMA for aesthetic and/or restorative purposes (Fig. 1).

In the context of restorative procedures, the treatment for lipodystrophy syndrome in patients with HIV can be possibly highlighted. This syndrome is characterized by alterations in the metabolism and distribution of body fat, causing peripheral fat loss (lipoatrophy) in the face, gluteal region, and upper and lower limbs, and the accumulation of central fat (lipohypertrophy) in the abdomen, cervical region, back, and breasts. Patients with HIV appear to have signs of early aging due to facial lipoatrophy, bringing back the old stigma of the "face of AIDS," negatively impacting their quality of life, which may result in the development of seropositivity, depression, isolation, social exclusion, low adherence, or even dropping out of treatment. In Brazil, the Ministry of Health included restorative surgeries for lipodystrophy in the Public Health System, established protocols for the indication of these surgeries, and normalized the completion of facial filling with PMMA at an outpatient level. In addition, a protocol focuses on the indication, assessment, and techniques for performing the repair treatment of facial lipoatrophy using PMMA filling [10, 11].

Most cases of PMMA application are facial (85%). In this context, 100% of the experts responded that the most common indication for facial treatment with PMMA is facial balance, resulting in better facial proportion (Fig. 2).

Observing the values shown in Fig. 2, some aspects are noteworthy, particularly regarding the restrictions of PMMA use. Considering its facial application, most professionals (65%) do not recommend the use of PMMA for treating dynamic wrinkles. The low percentage of absolute indication (represented by the term "always") of this material for treating static wrinkles (18%) and facial

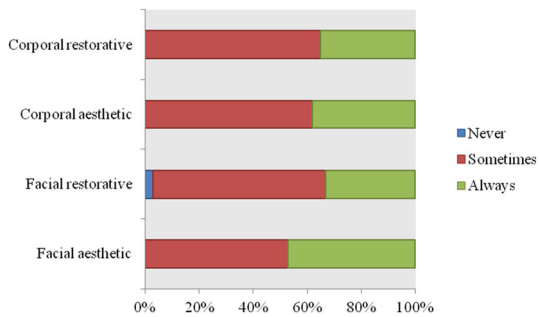

Fig. 1 General indication of PMMA fillers on the face and body

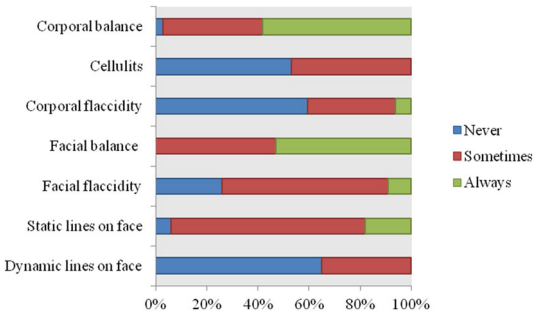

Fig. 2 Facial and corporal treatments used by the experts

flaccidity (9%) is also highlighted. In contrast, all the respondent physicians used PMMA to achieve volumetric adequacy of the face, and the majority (53%) reported an absolute indication.

With regard to corporal application, the restriction of the use of PMMA (represented by the term "never") stands out for treating flaccidity (59%) or cellulite (53%). These results confirm that the fundamental objective of implants using PMMA, which is not suitable for skin use, is its application to deep levels, with the intention of remodeling and volumetric adequacy [4, 6, 12]. In this way, secondary benefits, such as improved sagging and attenuation of static or dynamic wrinkles, may be obtained.

In Brazil, PMMA is commercially available in 2, 5, 10, 15, and 30% concentrations. Thus, experts were asked regarding the concentration of the product that is most used in each of the facial regions, considering 10% (PMMA-10) and 30% (PMMA-30) concentrations, which are the most common in Brazil. The results are presented in Fig. 3. The lip is the most contraindicated region for PMMA use, considering both PMMA-10 (61%) and PMMA-30 (97% of the experts never use). In this case, it should be taken into account that this is a region without bone structures in the depth, with softer tissues, which requires greater caution for application. Alternatively, it is possible opting for PMMA concentrations lower than those referenced in this research.

In other facial sites, the use of PMMA-30 is generally more recommended (Fig. 3). The contraindications (represented by the term "never") are more significant for PMMA-10 in the zygomatic arch (17% for PMMA-10 and 12% for PMMA-30), mandibular angle (43% for PMMA-10 and 9% for PMMA-30), mentum (31% for PMMA-10 and 9% for PMMA-30), and nose (29% for PMMA-10 and 9% for PMMA-30). In the malar region, the disallowance to PMMA-10 or PMMA-30 is the same (11%). In contrast, in this facial region, the absolute indication ("always") is preponderant for PMMA-30 (34%) in relation to PMMA-10 (8%). Considering the absolute indication in other facial sites, PMMA-30 is preferred (46, 40, 38, and 26% for the nose, mentum, mandibular angle, and zygomatic arch, respectively) to PMMA-10 (3, 6, 9, and 11% for nose, mentum, mandibular angle, and zygomatic arch, respectively) (Fig. 3).

The use of higher PMMA (30%) concentration should be taken into account for applying in the deeper planes (e.g., juxtaperiostal or submuscular). Thus, generally, areas, such as the zygomatic, mentum, malar, mandible, and nose, present excellent conditions for its use, provided that the application plans are respected. The PMMA concentration has a direct relationship with its density and, consequently, with the creation of connective tissue around the implanted product [12]. Thus, when the abovementioned deep planes are not feasible, and making a more superficial implant is necessary, the possibility of using PMMA-10 or a lower concentration of the product should be taken into account.

As noted above, the correct choice of PMMA should consider the concentration and location where the product will be applied. Thus, the experts were asked regarding the recommended application plans for PMMA-10 and PMMA-30. The compilation of their responses is given in Fig. 4, which shows that the lip is the most contraindicated region for PMMA use (67 and 89% for PMMA-10 and PMMA-30, respectively), supporting the values presented in Fig. 3.

For other facial sites, the juxtaperiostal application plane is most commonly referenced by the experts, accounting

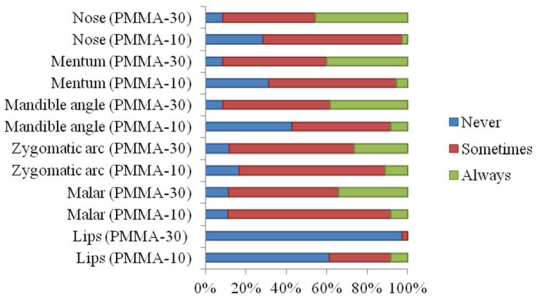

Fig. 3 PMMA use at 10% (PMMA-10) and 30% (PMMA-30) concentrations in each facial site

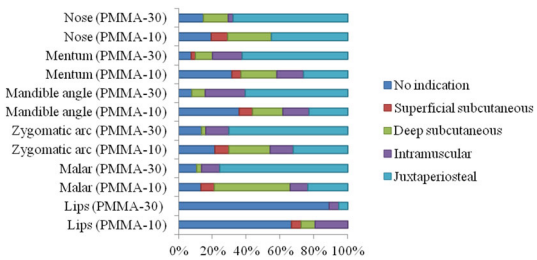

Fig. 4 PMMA application planes at 10% (PMMA-10) and 30% (PMMA-30) concentrations in each facial site

for 76, 70, 61, 63, and 68% of PMMA-30 use in the malar, zygomatic arch, mandible angle, mentum, and nose, respectively. The juxtaperiostal application is also the most used in PMMA-10 in the zygomatic arch, mandible angle, mentum, and nose (32, 23, 26, and 45% of indications, respectively). Only PMMA-10 in the malar region presented a different indication, reaching 45% of use in the deep subcutaneous tissue (Fig. 4). Once again, the results show that PMMA is basically a deep filler and, because this, it should be considered an infiltrative implant, particularly at higher product concentrations.

Similar to facial use, data regarding corporal application planes were also summarized in this research. Figure 5 shows the opinion of the experts regarding the corporal use of PMMA in different concentrations. Intra- and justadermal applications are obviously seen as the most contraindicated by professionals, both for PMMA-10 (97 and 69% of refusal, respectively) and PMMA-30 (97 and 100%, respectively).

Considering other planes, subcutaneous application of PMMA-30 (56%) stands out as a contraindication, but PMMA-10 (9% of contraindication) can be possibly used. Generally, PMMA-30 has lower rates of contraindication in the intramuscular (3%) and submuscular (26%) planes (Fig. 6). This result is analogous to that found for the use of PMMA on the face, considering the facial application planes (Fig. 4).

As previously mentioned for facial implants, deeper planes (intramuscular or submuscular) should be chosen whenever possible for corporal treatment with PMMA, allowing safe and effective results. In contrast, the most contraindicated planes must be the most superficial ones (intra- and justadermal). The subcutaneous, intramuscular, and submuscular planes may be used based on the needs of each patient. For example, PMMA-10 should be preferred when the subcutaneous plane is selected.

With regard to corporal application, the specialists were asked where most biopsies are performed, as well as the volumes used in each region. Most professionals (88%, data not shown) stated that the most corporal applications

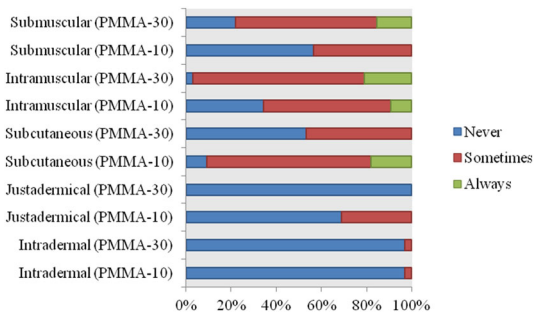

Fig. 5 PMMA application planes at 10% (PMMA-10) and 30% (PMMA-30) concentrations in each body site

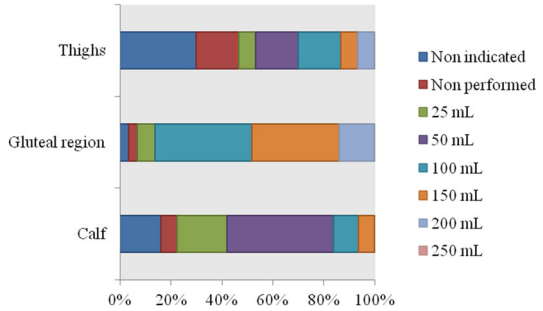

Fig. 6 Recommended amount of PMMA to three body sites (thighs, gluteal region, and calf)

are performed in the gluteal region. The high percentage of the application in the gluteal region meets the greater demand and greater effectiveness of results in this body area, as discussed at the Symposium.

Considering the application to the gluteus and to other body regions, the professionals responded on the amount of PMMA applied in each body site (Fig. 6). **According to the experts' recommendations, a maximum volume of 50 mL (indicated by 42% of experts) can be applied to the calves, whereas the volume can reach 100 (38%) or 150 mL (34%) in a single application in the gluteal region. The thigh is the least suitable region for PMMA application; however, the majority of experts who perform the procedure recommend the implantation of 50 (17%) to 100 mL (17%).

Considering the numbers above (Fig. 6), added to the discussions held at the Symposium, the volumes mentioned here are noted to be implanted in a single session. Because new application sessions may be necessary and/or possible, the final volume implanted depends on the need and capacity of each patient, which was carefully assessed by the expert's clinical experience. Noting that the minimum interval between applications should be 45 days is important.

Complications

Regardless of classification (permanent or non-permanent), dermal fillers have injection requirements, associated risks, and potential to cause complications. Adverse events are very common with any injectable dermal filler. Most of them are material-independent and related to incorrect injection techniques or poor patient and localization selection [13]. The majority of adverse reactions are mild and transient, such as bruising and trauma-related edema. Serious adverse events are rare, and most are prevented with proper planning and technique [2]. Thus, the occurrence of complications related to PMMA implant treatment can be expected, considering its minimally invasive feature. Therefore, knowing the frequency and types of

complications arising from the use of PMMA was one of the objectives of this research. The results are presented in Table 1.

Surprisingly, the number of complications reported with the use of PMMA was extremely low, accounting less than 1% of the total number of implanted cases (Table 1).

Complications, such as late edema, implant site infection, and seroma, presented low occurrence (0.157, 0.015, and 0.019%, respectively). Chronic inflammatory reactions reported due to PMMA injection occurred years after the injection and can be interpreted as foreign body reactions to the PMMA molecule. Enzymes in the tissue have been known not to break down PMMA microspheres, which can be integrated into collagen fibrils. Some patients could possibly produce antibodies against PMMA-binding proteins, and the reason for the sudden onset of an inflammatory reaction may be found in the memory of macrophages, which are suddenly stimulated by triggering events, such as a systemic infection or surgical trauma [13, 14].

Our study showed a very low rate of necrosis attributed to PMMA treatment (0.003%). Generally, technical mistakes are involved in the development of necrosis.

Necrosis can occur following injection with any dermal filler, although necrosis more likely develops with the use of particulate fillers. Areas most vulnerable are in those where blood supply depends strongly on a single arterial. Thus, avoiding hitting larger vessels during the procedure is important [2, 14].

Considering that the technique and apparatus used for the injection can be decisive for the occurrence or not of complications, we asked the physicians for the equipment that they used for PMMA injection. Figure 7 shows that the needle is clearly contraindicated (represented by the term "never") for PMMA injection. The needle is contraindicated by 58 and 86% of professionals for use on the face and body, respectively. In contrast, the disposable microcannula is the most recommended apparatus, being used "always" in facial applications by 39 and 56% of experts, respectively. In addition, the disposable microcannula is used "always" and "sometimes" for application on the body by 50 and 41% of the experts, respectively.

Table 1 Complications reported with PMMA use in the body and face

Complications	Cases (*n*)	Cases (%)
Nodules	290	0.332
Granulomas	259	0.296
Necrosis	3	0.003
Late edema	137	0.157
Implant site infection	13	0.015
Seroma	17	0.019
Non complications	86.652	99.177
Total complications	719	0.823
General total	87.371	100

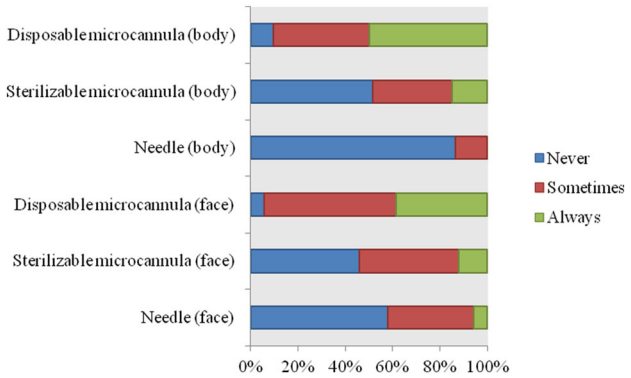

Fig. 7 Apparatus selected by physicians for PMMA injection on face and body

To increase the safety of the procedure, avoiding vascular, nervous, and other tissue injuries, it is agreed that microcannula must always be used for PMMA application [15]. Because they are not sharp, the microcannula prevents the intravascular application of the product, thus avoiding the main (or perhaps the only) cause of embolism and necrosis of the region supplied by such a vessel. In addition, because the microcannula makes divulsion of the tissues, it causes little trauma and causes ecchymosis very rarely. Therefore, PMMA application with a needle is contraindicated.

Granuloma formation attributed to PMMA is well known and reported in some cases [13, 14]. Erythema, transparency, unevenness, and dislocation were documented as late reactions to PMMA injection in the retrospective case series [16], wherein the overall complication rate was 3%. In a study published later [17], true granuloma formation was considered to be rare that occurs in less than 0.01% of patients. In our study, granuloma and nodule reactions occurred in 0.296 and 0.332% of the reported cases, respectively. These values were closer to the manufacturer's data, wherein the rate of granulomatous reaction was 1 in 1000 patients [18]. Each normal granulation tissue surrounding the PMMA microspheres could be considered as a foreign body granuloma. However, a growing granuloma histologically shows a wide distance between the microspheres filled with macrophages, giant cells, fibroblasts, and broad bands of collagen fibers. Besides, the significant improvement in the product quality of PMMA can be the reason for the reduction the incidence of granuloma formation [17].

In this context, many commercial PMMA filler options are presently available. However, understanding that all

these products are likely not equivalent and that regulatory approval standards in the different countries can be significantly different is important; therefore, product uniformity is not assured. A study [19] compared commercially available PMMA-based soft tissue fillers from the United States, Europe, Brazil, and Canada at various times in the past 7 years. Marked differences with respect to particle morphology and related particle characteristics were found, including variability in particle size and irregular morphology in some products.

In Brazil drastic evolutions in the quality of PMMA-based soft tissue fillers occurred in 2012. The first product commercially available was Metacrill® in 2006, but with very low quality [19]. Between 2006 and 2012, the quality of the PMMA gradually improved. Thus, the complication index also takes into account the periods wherein the materials had a great difference of quality in relation to the current period. Obviously, the recent evolution of the injection technique also promoted improvement in conditions [20].

Considering that the product quality is related to the occurrence (or no-occurrence) of complications, the physicians were asked about the criteria for choosing the PMMA used in the treatments they performed. Registration in the Brazilian Health Agency (*Agência Nacional de Vigilância Sanitária—ANVISA*), vehicle purity, microsphere size, and microsphere smoothness were the most import factors considered for selecting the PMMA-based product (Fig. 8).

Noting that adverse reactions can occur with all injectable tissue fillers is important. Granuloma formation, for example, occurs in selected patients at a rate of 0.1–1% with collagen, hyaluronic acid, and other particulate injectables, such as calcium hydroxylapatite [2, 21]. Besides, it should be highlighted that complications related to minimally invasive procedures, such as PMMA implantation, present a lower degree of severity than those related to invasive procedures, such as plastic surgeries. Published data reporting deaths and complications resulting from cosmetic surgeries demonstrate that the risks associated with procedures, such as liposuction and facelift, are considerable (surgical mortality risk of 0.02 and 0.1%, respectively). Moreover, general anesthesia, particularly in a prolonged operating time, may carry a risk approximately equivalent to or perhaps greater than cosmetic surgery [21].

With regard to cosmetic surgery, specific complications, such as hematoma, thrombosis, infection, seroma, necrosis, skin sloughing, and alopecia are adverse events related to rhytidectomy. Sensory nerve injury, particularly damage to the greater auricular nerve, is also common (7.1% of the cases) and may be permanent in some cases. Facial paralysis resulting from motor nerve damage during rhytidectomy can occur in up to 2.6% of surgeries [21].

To conclude, infiltrative implants constitute an effective alternative to surgery to bypass the signs of aging, to treat AIDS-related facial deformities, such as lipoatrophy, and to achieve facial and corporal symmetry in a wide range of cases. PMMA treatment has a low incidence of complications and low degree of severity. However, the practice and experience by the professional who performs this procedure, the understanding of the physical characteristics of commercially available agents, and the quantity of material to be injected, besides the depth at which the material should be implanted are essential points to reduce the risk of complications and improve patient outcomes. Thus, based on the extensive experience of the physicians, with the consensus of the panel members, an algorithm (Fig. 9) that can be used as a guideline for PMMA treatment on the face and body was provided.

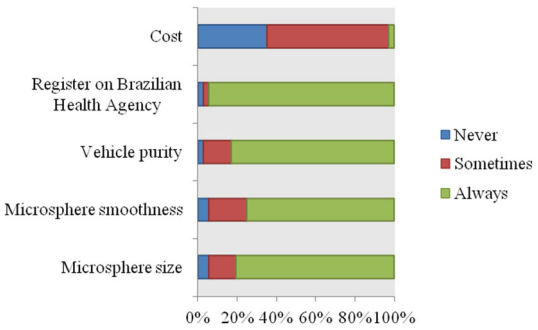

Fig. 8 Selection criteria for PMMA-based product used in\facial and corporal treatments

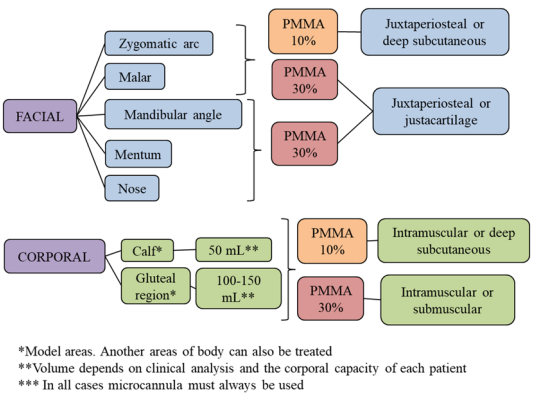

Fig. 9 PMMA treatment algorithm: consensus indications regarding the concentrations, amount, and application planes of PMMA infiltrative implants on the face and body

Conclusion

The recommendations presented in this article include general principles and information on the specific use of facial and corporal PMMA-based fillers. We hope to contribute with information that allows the standardization of procedures to achieve great results in terms of efficacy and patient safety.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflicts of interest.

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