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Case Report

Case Report of Idiopathic Masseteric Hypoplasia Treated With Polymethyl Methacrylate-Collagen Gel

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Abstract

Congenital hypoplasia of the masseter muscle is a rare condition most commonly associated with craniofacial or poly-malformation syndromes, with a small number of reported idiopathic cases. The condition is most commonly managed by orthodonture and later surgical intervention; however, surgery is not an option for all patients. Nonsurgical approaches to correcting asymmetry may be considered for patients for whom the functional impact of hypoplasia has been largely managed and the patient's concern is primarily aesthetic. In this case study, the patient presented for a consultation seeking a nonsurgical solution for marked facial asymmetry. The patient underwent physical examination and magnetic resonance imaging to confirm diagnosis of congenital masseter muscle hypoplasia. To treat the asymmetry, a total of 9.6 cc of polymethyl methacrylate (PMMA)-collagen gel (Bellafill; Suneva Medical, Inc., San Diego, CA) was injected along the border of the mandible from the gonial angle out to the area of the mental foramen and slightly above over the course of 6 months (2 visits spaced 3 months apart) to provide long-term, nonsurgical correction. The patient was very satisfied with the results, highlighting the potential for PMMA-collagen gel to be used in clinical situations in which durable, nonsurgical correction of lower-face asymmetry is needed.

Level of Evidence: 5

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Congenital unilateral hypoplasia of the masseter muscle is a rare condition that is most often associated with craniofacial or poly-malformation syndromes.[1-6] However, in very rare cases, significant hypoplasia of the masseter muscle can occur in the absence of other congenital abnormalities.[7] Treatment for the condition ranges from surgical options, which add tissue through grafting to restore facial symmetry, to treatment with orthodontic appliances to reduce asymmetry through promotion of growth for compensatory muscles.[7] While dermal fillers represent a nonsurgical option for correction of asymmetry, most have limited longevity. Even for non-hyaluronic acid (HA) fillers, such as calcium hydroxylapatite (Radiesse; Merz, Raleigh, NC) or poly-L-lactic acid (Scluptra; Galderma Laboratories, Fort Worth, TX), duration is limited to less than 2 years and patients return to baseline without retreatment. Thus, for all fillers with a shorter duration, the expense associated with the large volume needed to achieve optimal correction can be prohibitive. Fat transfer is a surgical option; however, the survival and therefore the results of the graft are variable. The long-term efficacy of polymethyl

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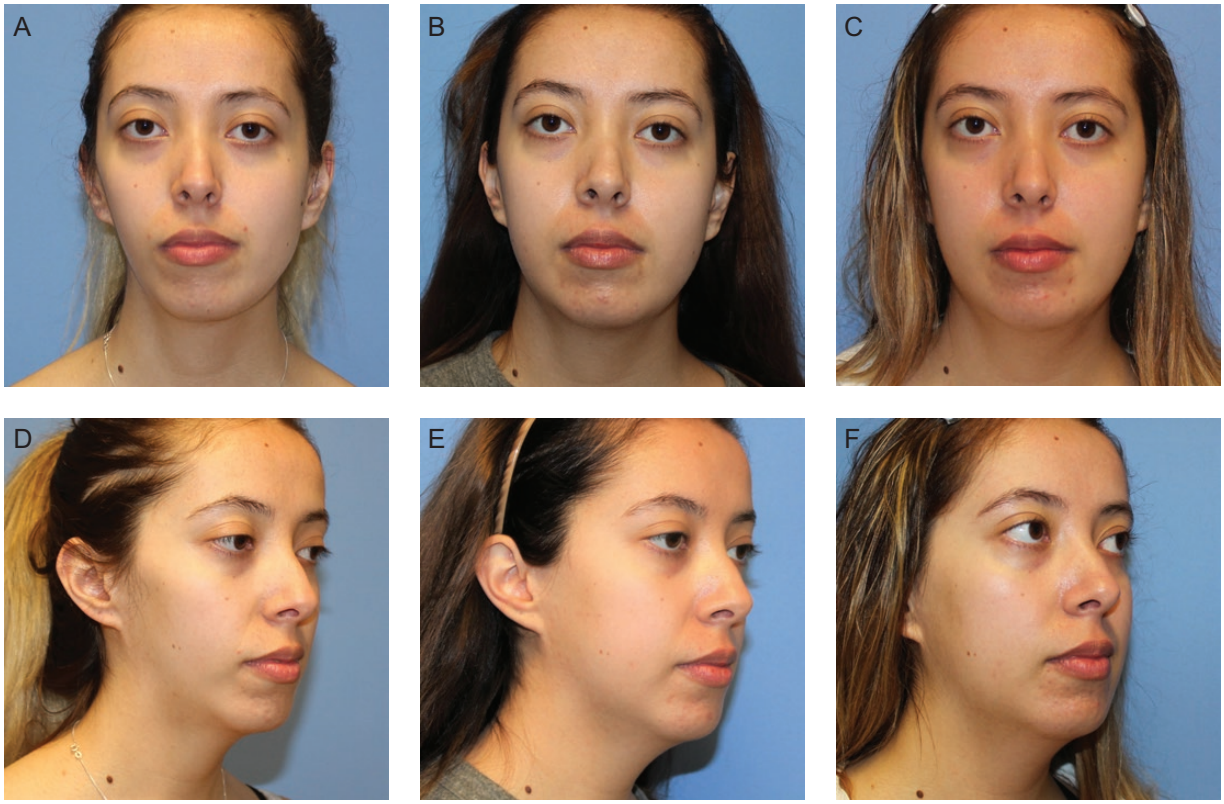

Figure 1. A 21-year-old female presented seeking nonsurgical correction of lower facial asymmetry. The patient is shown at baseline (A, D), 6 months (B, E), and 1 year (C, F) following her last treatment. Twelve syringes (0.8 cc per syringe) of PMMA-collagen gel were injected over the course of 2 sessions spaced 3 months apart.

methacrylate (PMMA)-collagen gel filler (Bellafill; Suneva Medical, Inc., San Diego, CA) offers a more predictable nonsurgical solution that is particularly well suited for applications in which avoidance of diminution is of paramount importance.[8,9]

CASE STUDY

A healthy 21-year-old female presented in August 2019, with right-side lower facial asymmetry. At the presentation, she had researched treatment options and was specifically seeking nonsurgical correction with fillers. Examination revealed facial asymmetry, with the right lateral jaw area being much less prominent than the left (Figure 1). The patient had a normal occlusion and opening and closing of her mouth and reported having been previously treated with 2 courses of orthodontics from the age of 14 to 21 for a class II malocclusion but had not received a formal diagnosis of masseter hypoplasia. The mandible was symmetrical on palpation, but significantly less soft tissue volume was present over the right lateral mandible compared with the left. Compared with the masseter on the left, the volume of the masseter on the right side was greatly diminished on palpation, especially with the patient biting down or contracting the masseter on the right side. The patient was diagnosed clinically with masseter hypoplasia and a static MRI of the masticatory muscles confirmed this diagnosis in January 2020 (Figure 2).

After a thorough discussion of both nonsurgical and surgical options, the patient voiced an unwillingness to undergo surgery but due to the nature of the deficit wanted to use a long-lasting filler to avoid both diminution and the cost of frequently repeated treatments. Ultimately, the patient was treated with PMMA-collagen gel. Following preparation of the treated area with a bactericidal skin prep, pilot holes were made in the skin along the mandibular border with a 20-G needle. A 25-G 2″ cannula was introduced through the pilot holes, and the product was injected using both linear retrograde and fanning techniques (Figure 3). The pilot holes were chosen to minimize the number of puncture sites while permitting even distribution of the product over the area where the volumetric deficit was present. A total of 12 syringes (0.8 cc per syringe) was injected into the subcutaneous tissue over the right mandible over the course of 2 sessions, spaced 3 months apart. In the first treatment, 8 cc (10 syringes) of PMMA-collagen gel was used and 1.6

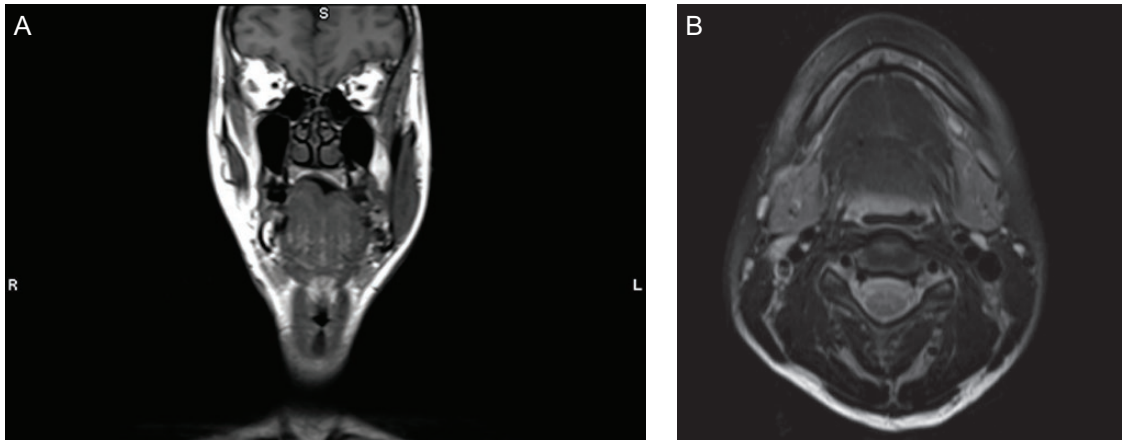

Figure 2. Static MRI revealed hypoplasia of the right masseter muscle without apparent hypoplasia of the mandible. Sagittal (A) and axial (B) views are shown.

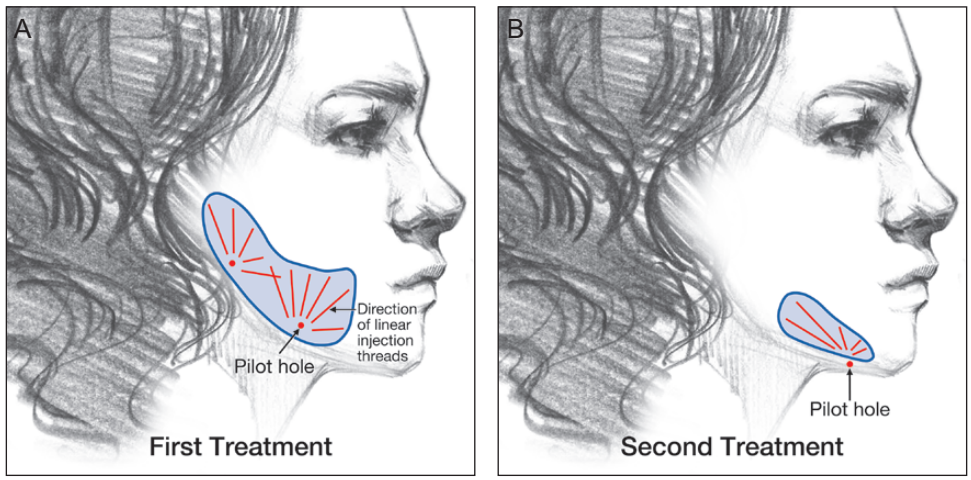

Figure 3. A total of 12 syringes (0.8 cc per syringe) were injected into the subcutaneous tissue over the right mandible over the course of 2 sessions, spaced 3 months apart. In the first treatment, 8 cc (10 syringes) of PMMA-collagen gel was used (A) and 1.6 cc (2 syringes) was used for the second treatment (B). Pilot holes and injection patterns for each treatment session are shown. PMMA, polymethyl methacrylate.

cc (2 syringes) was used for the second treatment. The patient is shown in Figure 1B and E at 6 months and in Figure 1C and F at 1 year following the final treatment session. The patient had no short-term complications from injection, and at the time of this writing (just over 1 year post injection), no late-onset events have been recorded. The patient remains highly satisfied with the treatment. Written consent was provided, by which the patient agreed to the use and analysis of her data.

DISCUSSION

PMMA-collagen gel was selected to treat this patient in part because of the need for long-term efficacy. This durability was required first not only to avoid diminution of the aesthetic effect within 12-18 months that is characteristic of other available fillers but also to circumvent the need for and the expense associated with repeated treatment using a large volume of temporary filler such as HA (a concern repeatedly emphasized by the patient). Because PMMA is not absorbed by the body, the microspheres continue to induce collagen formation for up to 10 years or longer.[10-12]

Equally as important, PMMA-collagen gel is an option with a long record of safety when injected properly and in anatomical areas away from concentric muscle groups. The only PMMA filler currently available in the United States is Bellafill, which was originally manufactured by Artes Medical, Inc. and marketed under the brand name Artefill from 2006 to 2008. In 2010, Suneva Medical, Inc.

purchased Artefill and rebranded the material as Bellafill. The formulations of these 2 products are identical and comprise 20% PMMA microspheres (30-50 µm in diameter) and 80%, 3.5% bovine collagen gel with 0.3% lidocaine. Bellafill is FDA approved for the correction of moderate to severe nasolabial folds and moderate to severe atrophic, distensible facial acne scars on the cheek in patients above the age of 21 years.[13] The 5-year efficacy and safety studies carried out for PMMA-collagen in the correction of nasolabial folds represent the largest and longest studies of dermal fillers published to date.[8,14] In these studies, confirmed late-onset granulomas occurred in 1.7% of patients, but at the end of the study, granulomas remained unresolved in only 0.9% of patients.[8] Further, post-market safety data support this low rate of late-onset adverse events, with only a 0.009% complaint rate for histology-unconfirmed granulomas (650,387 syringes sold over 12 years).[15]

When considering risk and benefit of treatment, it is critical to take into account that Bellafill is a distinct product from earlier PMMA-based products (Arteplast and Artecoll), which had a high (2.5%) rate of granuloma attributable to the rough surface and particle charge of the previous microspheres.[16,17] In addition, many of the most severe case reports in the literature for PMMA-based fillers are not for Bellafill but rather for other formulations available internationally that are not manufactured with uniform size beads, contain particles that are not negatively charged, and/or particles that are irregular and a wider range of sizes.[18-21] Furthermore, adverse events are most often reported for areas of the face where PMMA-collagen gel should not be used, such as the lips or infraorbital area.[13,15] With these factors in mind, it is important to educate the patient that while uncommon, there is a potential for late-onset effects, as PMMA is a permanent implant, and thus at higher lifetime risk for interaction with hyper-inflammatory events that may occur throughout the patient's life, such as infection or injury. Only those patients who understand and are comfortable with these risks and who do not have a history of severe allergies, allergy to collagen products, allergy to lidocaine, or known susceptibility to keloid formation or hypertrophic scarring should be treated. For PMMA collagen gel, the risk of granuloma formation is greatly reduced by evenly spreading the product, injecting over multiple sessions, and avoiding bolus injection. In clinical practice, granulomas may be treated with a combination of intralesional steroids and 5FU injections; however, multiple rounds of treatment may be needed. In difficult cases, especially when injected in areas around the eyes and lips, surgical removal may be needed.

While this study shows promising results for long-term correction of facial asymmetry, only a single patient is represented. A clinical study with a larger cohort would be useful for more formally establishing the efficacy of treatment with large volumes of PMMA-collagen gel as well as treatment duration and safety. Even so, this study provides an example of an important nonsurgical option for patients who require both substantial and durable correction and are unwilling to undergo surgery.

CONCLUSION

In the author's experience, PMMA-collagen gel has been used for 14 years with favorable clinical outcomes, high patient satisfaction, and minimal long-term side effects in carefully selected patients and specific applications. The clinical case study presented here supports the use of PMMA-collagen gel for more substantial, long-term correction of the lower face in patients who would likely benefit from surgery but who are opposed to or are unwilling to undergo a surgical procedure. The long-lasting nature of PMMA-collagen gel makes it uniquely suited for applications where return to baseline is not tenable, and this study is not entirely unique in its demonstration of efficacy in the correction of significant facial asymmetry.[22] The impact that the availability of a long-lasting nonsurgical procedure has on some patients should not be discounted. While it is tempting to view cost of surgery as peripheral in clinical decision making, it can be a determinant of patient access to care. In this case, the lack of "medical need" for surgery precluded reimbursement by medical insurance. Nevertheless, patients, especially those in formative years of career and social relationships, can (and often do) feel hindered by significant volumetric deficits and/or facial asymmetry while, at the same time, lacking the resources for surgical correction. In instances like the one described in this case report, the availability of a long-lasting nonsurgical option can be life-changing. The results apparent in the 1-year postprocedure photographs in Figure 1C and F illustrate the potential for use of PMMA-collagen gel as a long-term solution for management of asymmetry, an aesthetic issue for which many patients would appreciate a more durable treatment choice. The presented case study illustrates how the long-lasting filler PMMA-collagen gel may be used for durable correction of lower-face asymmetry in patients who do not wish to undergo surgery.

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Disclosures

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