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Outcomes and Complications Associated with Malar Onlays: Literature review and a case series of 119 implants.

Abstract

Alloplastic malar onlays have been used by surgeons to correct or enhance the midfacial skeleton for over 40 years. Case series have shown respectable results using different alloplastic materials in various maxillofacial subsites. However, these articles include small numbers of patients with limited follow-up. We present a literature review specifically concentrating on porous polyethylene (Medpor) and Polyethyl ether ketone (PEEK) malar onlays. We illustrate the technique used by a single Oral and Maxillofacial Surgeon for placement of 119 implants in 61 patients over a 14-year period and show the results of this work with long-term follow up. A complication rate of 2.5% in this cohort was reported, with follow-up of 3 years, demonstrating that this technique for midfacial correction is successful in both the short and long-term.

Introduction

Augmentation of the malar region of the facial skeleton was first described by Tessier in 1971.^{1,2} Autogenous bone from the rib, iliac crest or split calvarium is routinely used to correct craniofacial defects including the malar eminence. These techniques are also employed to enhance facial aesthetics in the setting of Oral and Maxillofacial trauma and orthognathic surgery. As an alternative, alloplastic materials have been developed that overcome the main drawbacks of graft resorption, contouring challenges and donor site morbidity that are associated with using autogenous bone.² In addition, reconstructive surgeons have overcome the challenges of correcting complex deformities through the use of three-dimensional computerised tomography (CT) imaging and models. Computer-assisted design (CAD) and computer-assisted manufacturing (CAM) have enhanced outcomes as a result of improving the accuracy of diagnosing craniomaxillofacial deformity and the ability to construct patient specific implants (PSI).³ PSIs are designed to fit the patient's anatomy precisely and can mirror normal contralateral anatomy where appropriate or anatomical normal values. This reduces both the degree of surgical exposure and manipulation required, and the operative time. ⁴ Medpor (Stryker,

Kalamazoo, USA) on the other hand offer a range of cost-effective off-the-shelf and customised malar implants manufactured from biocompatible porous polyethylene. Medpor implants were used for all the cases in this series except one where polyether ether ketone (PEEK, Synthes, Welwyn Garden City, UK) was placed in a patient with Treacher-Collins syndrome.⁵ PEEK is a biocompatible, semi-crystalline linear aromatic polymer, light, durable and amenable to contouring using high speed burs. PEEK retains integrity during sterilisation processes and does not create artefacts on radiographic imaging. Conventional osteosynthesis systems can be used to fixate both Medpor and PEEK implants to adjacent native bone.⁶

Recent studies have shown respectable results, with low failure rates using different alloplastic materials in various regions of the maxillofacial skeleton. However, these studies comprise small numbers of patients with limited or variable follow-up periods. To address the paucity in the literature we report a large case series with consistent long term follow up of patients receiving Medpor or PEEK malar onlays.

Materials and methods

Literature review methods

A literature review was carried out in June 2019 using the Pubmed (Medline), Scopus and Cochrane databases. Key words searched: ("malar onlay" OR "malar augmentation" OR "malar implants") AND ("reconstruction" or "augmentation") AND ("outcome" OR "failure" OR "success" OR "complications") AND ("MEDPOR" OR "PEEK"). A manual search using these terms was also carried out. 145 articles were identified, 19 were duplicated. 126 abstracts were screened; 110 were excluded for including work on the different site in the facial skeleton, unrelated to the topic (non-clinical, methodological only, using the different material or non-invasive techniques), not being full articles including a case series, or not having been written in the English language. 16 papers were included for full text review (Figure 1.).

Case series methods

We present a case series of 61 patients (119 malar onlays) treated by a single UK Oral and Maxillofacial Surgeon over a 14-year period, with a follow-up period of three years. Patients who had malar onlays placed in this time period were identified retrospectively using clinical notes, operating theatre logbooks and records held by Stryker. Follow-up for all patients was confirmed retrospectively, using joint clinic notes and/ or letters. Medpor implants were placed in orthognathic patients both with and without cleft and in patients undergoing reconstruction following facial trauma. One patient who had Treacher Collins syndrome with associated malar hypoplasia received custom made PEEK malar onlays and was excluded from this cohort and was therefore not included in the 61 patients.

Figure 1. Study Attrition Diagram- Articles screened and inclusion and exclusion criteria.

Technique

Malar implants can be placed transorally via a vestibular incision, transcutaneously via subciliary or rhytidectomy incisions, or transconjunctivally. The approach used depends on the surgeon's preference, and whether other procedures are being performed concurrently. An intraoral approach provides the best exposure of the malar and the submalar areas and avoids an external scar. This technique is utilised by the operating surgeon whose results are presented. Prior to insertion our implants are impregnated with Gentamycin solution in a syringe held under negative pressure.

An upper vestibular incision is made and subperiosteal dissection performed to expose the zygomatic body and arch and infraorbital nerve. Minimal periosteal elevation is performed to permit insertion of the implant, yet resist displacement from the desired location (Figure 2.). Screws may or may not be required to secure the implant and were only used in 9% of cases when there was no stability following insertion. Closure of the intraoral incision follows. Intravenous peri-operative antibiotics and a five-day course of oral antibiotics are given (i.e. Co-amoxiclav or suitable alternative when contra-indicated).

Figure 2: Subperiosteal positioning of malar implant via transoral approach.

Results

Table 1. Literature review results.

Key: * *Unclear if complications linked to malar onlays.*

There are a number of issues in the data from the studies shown in Table 1. Follow up data was inconsistent and most papers discussed malar onlays as part of a series of implants that included different regions of facial augmentation such as the nose, orbit and mandible. In some articles it was not possible to extract the malar data from the other sites. Many papers failed to present data on follow up duration, and those that did demonstrated high variation between patients. Cohort size was generally small, reducing confidence in the reported result, with possible selection bias and the indication for malar onlay placement was highly variable.

Table 2. Case series results.

In our large cohort of 119 implants, the surgical success rate of malar onlays was 97.5%. Follow-up ranged from 2.5 – 3 years with a mean average of 2.9 years (**Table 2**). Two Medpor onlays were removed from one patient as a result of trauma to one side and a dental abscess on the other. One onlay became infected but was retained following a course of intravenous antibiotic treatment. A further two implants were removed from another patient who did not like the postoperative appearance, however as discussed in the next section, this is contentious as a surgical complication and was therefore not included in the result.

Discussion

Sixteen studies were identified that included case series data for Medpor or PEEK malar onlays. Within these series the number of patients receiving malar onlays were small or in some studies not differentiated from implants placed at other sites. Cohort size ranged from three to 26 patients, with up to 40 malar implants placed. The length of follow-up varied from two weeks to 15 years and in some studies the average follow-up period was not provided. Note that malar onlays are used for a variety of purposes for example, orthognathic, cleft and trauma cases, rendering some results more

heterogenous than others and difficult to interpret. In our cohort, patients were receiving malar onlays for congenital (including cleft and class III skeletal malocclusion) or post-traumatic deformity.

In the past, midfacial onlay procedures whether autogenous or alloplastic were reported to have significant problems with relapse, resorption, non-union and infection.²⁰ In a study from 2005 Cenzi *et al* published data revealing that six out of 40 maxillary implants placed had been removed due to exposure and/or infection and another implant had to be reshaped. This cohort included patients with complex histories including syndromes affecting the development of the midface and patients who had previously undergone multiple procedures resulting in scarring of the midfacial tissues. This resulted in a complication rate of 17.5% of all patients treated with malar onlays in this study.¹⁵

However, more recently the incidence of reported complications has remained low. Such complications included isolated cases of infection,^{7&8} implant migration¹⁰ and transient paraesthesia.¹⁴ Two recent studies reported implant removal in a single case.^{7&8} Ridwan-Pramana *et al* presented a case series that included 19 malar onlays placed in 13 patients with aesthetic concerns. One implant was removed due to infection and another migrated towards the infraorbital nerve causing paraesthesia. Both implants were replaced and the patients experienced no further difficulties. In another case series, Khorasani *et al.* described the placement of 16 malar onlays in 10 patients. Only one malar implant was associated infection, in a unilateral reconstruction case associated with congenital deformity. This resolved following incision and drainage combined with intravenous antibiotic therapy.⁸ Schwaiger *et al* reported one case of an infected malar onlay that required surgical removal in a cohort of cleft patients undergoing secondary procedures.⁷

In combination with a Le Fort I osteotomy, when placing malar onlays, infraorbital nerve injury is a potential risk.²¹ Additionally, Sainsbury *et al.* described a rare complication using PEEK implants to treat Treacher-Collins syndrome, where the implant compressed the globe resulting in temporary anisocoria that was quickly recognised intraoperatively and removed with no visual disturbance. Subsequent procedures were performed with good aesthetic results.⁹ Abdullakutty *et al.* reported one failure from nine PEEK PSIs as a result of design failure. There were two further cases of post-operative infection in this study, but neither required removal of the implant.²⁵

In our study of 119 implants, only two (1.7%) failed and were removed from the same patient, one side following facial trauma and the other as a result of a dental abscess. Only one patient (0.8% of the cohort) underwent antibiotic therapy for an infection that resolved and the implant was retained. Our cohort included patients with scarring from previous midfacial surgery, but this surgeon did not experience the high complication rate formerly reported. In the other patient whereby two implants were removed because they did not like the post-operative appearance, it could be argued that this may be an example of either inappropriate case selection or inadequate pre-operative counselling and therefore should be accepted as a complication. However, all our patients are assessed pre-operatively in a multi-disciplinary team setting and are seen independently by a clinical psychologist as part of our protocol before the treatment plan is finalised, in an attempt to prevent such situations.

Limitations of our study

Retrospective studies are subject to selection and recall bias as well as confounding factors which will not have been recorded or collected. We tried to reduce convenience sampling by using operating theatre logbooks and records held by the implant manufacturer Stryker to capture as many cases as and as wide a sample as we could. Confounding factors, for example nerve deficits following surgery could be as a result of the orthognathic surgery and not malar onlay placement, with the retrospective study design making causal inference impossible. Similarly, most patients who have malar onlays placed in addition to orthognathic surgery develop more swelling in the immediate post-operative phase by comparison with orthognathic surgery alone, which would perhaps not be captured in the clinical notes or letters at later follow-up appointments when swelling has resolved.

Historically, reported patient follow-up for facial reconstructive techniques has been deficient, raising questions on the reliability of complication rates.²⁶ All of our patients were followed up at regular intervals for 3 years, adding confidence in the data, reinforcing low complication rates associated with malar onlays in these types of patients. There are few studies that focus solely on malar onlay placement and none with such a large cohort. The success and stability of the implants reported in this series reflect the biocompatibility and properties of the modern implant materials, as well as adherence to sound surgical principles for carrying out the procedure.

Conclusion

There is a high success rate amongst this large patient cohort with a 3 year follow up. This suggests that malar onlays are a predictable option for mid-face augmentation using the methods described.

Conflict of interest: None

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Table 1.

Study	Year	Implant material	Patient cohort	Follow up range	Follow up average	Number patients	Number implants	Surgical Complications (%)
Schwaiger ⁷	2019	Medpor	Cleft patients	1-106 months	34.2 months	20	38	One implant removed due to infection. (2.6)
Khoransani ⁸	2018	Medpor	Congenital deformity, trauma, aesthetic correction	5-6 years	5.3 years	10	17	One malar implant infected, surgical incision and drainage. (6.6)
Sainsbury ⁹	2017	PEEK	Treacher-Collins Syndrome	Not recorded	Not recorded	3	6	Anisocoria from globe compression, implant removed. (16.7)
Ridwan-Pramana ¹⁰	2015	Medpor	Aesthetic concerns	4-96 months	25.4 months	13	19	One infection, one migration of implant causing infraorbital paraesthesia. (10.5)
Atherton ¹¹	2014	Medpor	Teenage cleft	2 years	2 years	3	6	None. (0)
Neichajev ¹²	2012	Medpor	Unspecified malar hypoplasia	6 months-15 years	10 years	6	12	None. (0)
Deshpande ¹³	2010	Medpor	Cleft, trauma, facial asymmetry	15 days -100 months	46 months	6	6	Unclear if reported complications are related to malar implants. (*)
Eski ¹⁴	2007	Medpor	Secondary correction of zygomatic deformities	6-24 months	13 months	22	24	None. (0)
Cenzi ¹⁵	2005	Medpor	Craniofacial fracture, malocclusion, tumours, malformation	Data not presented	60 months	Data not presented	40	6 implants removed due to infection and/or exposure, 1 remodelled. (17.5)
Menderes ¹⁶	2004	Medpor	Congenital deformity, trauma, tumour resection and reconstruction, aesthetic.	Data not presented	12+ months	26 (malar and infraorbital rim cases recorded together)	30 (malar and infraorbital rim cases recorded together)	1 contour realignment (3). Uncertain if malar or infraorbital rim.
Yaremchuk ¹⁷	2005	Medpor	Cosmetic concerns	9-92 months	27 months	14	Data not presented	Short-term (12 week) paraesthesia of the infraorbital nerve. 2 patients required implant reshaping. (14)
Carboni ¹⁸	2002	Medpor	Crouzon's Syndrome, trauma, HFM, post tumour resection.	Minimum 12 months	Data not presented	19	24	One zygomatic patient had an infection, unclear if this was also malar. Implant not removed. (*)
Sevin ¹⁹	2000	Medpor	Atrophy and scarring	Data not presented	Data not presented	31 total, unsure how many malar	Data not presented	None. (0)
Frodel ²⁰	2000	Medpor	Hemifacial macrosomia, paramedian facial cleft, post maxillectomy	6-40 months	Data not presented	4	6	Not clear if malar implants had complications. (*)
Robiony ²¹	1998	Medpor	Orthognathic surgery	Data not presented	Data not presented	17	34	None. (0)
Wellisz ²²	1993	Medpor	Burns, scarring, thin soft tissue coverage	Up to 4 years	Data not presented	5	9	None. (0)

Table 2.

Implant material	Patient cohort	Follow up range	Follow up average	Number of patients	Number of implants	Surgical Complications
Medpor	Cleft, class III malocclusion, skeletal deformity and trauma	2.8 – 3.4 years	3 years	61	119	Two implants removed from the same patient due to infection (1.7%) One implant retained following infection resolved with antibiotics. (0.8%) Three complications total (2.5%)