Alloplastic Facial Implants

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Abstract

As the face ages, there is thinning of the epidermis, volume loss and rearrangement of the soft tissues, and malabsorption of the skeletal framework. It is essential to have a thorough understanding of the aging process for successful facial augmentation and rejuvenation. Alloplastic implants can be used to provide a long-lasting solution for augmentation of skeletal deficiencies, restoration of facial irregularities, and rejuvenation of the face. In this study, we describe the ideal implant characteristics along with the advantages and disadvantages of various implant materials. We also present techniques in nasal and premaxillary augmentation, midface augmentation, mandibular augmentation, and lip augmentation. Additionally, computer-aided design and manufacturing as well as bioprinting are emerging technologies with growing applications in facial plastic and reconstructive surgery. We discuss their role in the creation of patient-specific custom implants. The overall goal of facial rejuvenation is to address multiple aspects of the facial aging process including deficiencies in the skin, soft tissues, and skeletal framework. The use of alloplastic implants alone or synergistically with additional surgical procedures can restore a wide range of anatomical deficits that occur with age.

Keywords

- alloplastic implant
- ► facial implant
- mandibular augmentation
- chin augmentation
- cheekbones
- CAD-CAM

Facial aging is a dynamic process that involves epidermal thinning, soft tissue volume loss and repositioning, and skeletal malabsorption.^{1,2} Integumentary changes with aging include epidermal thinning, collagen loss, and decrease in elasticity. Soft tissue volume decreases with age, but also descends with gravity, creating a predictably rectangular-shaped face from the youthful full and angular face.¹ Lastly, age-related morphological changes to the facial skeletal is well described, including resorption of bone along the orbit, midface, and mandible.² The reduction in skeletal framework thus exaggerates the skin and soft tissue effects of aging. To reverse the stigmata of aging, many aesthetic procedures

have begun to focus on volume correction. These include fat transfer, deep plane facelift, midface lift, and lip augmentation. Injectable facial fillers and fat transfers have gained popularity due to the perception of being "less invasive"-type procedures. As a result, augmentation using alloplastic implants can often be overlooked. While soft tissue procedures provide transient correction, skeletal augmentation using implants can provide more lasting enhancements and provide proper scaffolding and support to the soft tissue unit. Implantation is also potentially more cost-effective as it avoids the need for frequent and repetitive injection procedures.

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Address for correspondence Tsung-yen Hsieh, MD, Division of Facial Plastic and Reconstructive Surgery, Department of Otolaryngology, Head and Neck Surgery, University of Cincinnati, Cincinnati, OH 45219 (e-mail: yhsieh323@gmail.com). Alloplastic implants offer several advantages. They allow for customizable shape and volume as well as provide improved symmetry. There is no donor site needed. There is low risk of complications and operative times are generally shorter. Implants are also potentially reversible. Disadvantages of implants include risk of infection, mobility of osseous implants, and implant migration. Bone resorption, soft tissue changes, and capsular contraction may also occur in rare cases.

Facial rejuvenation thus involves addressing all aspects of the facial aging process, including skin, soft tissue, and skeletal framework. Facial enhancement using alloplastic implants thus presents a long-term option for augmentation of skeletal deficiencies, restoration of volume while smoothing out deep and superficial facial irregularities, which will permanently rejuvenate the face.^{1,2}

Ideal Implant Characteristics

The ideal implant should be safe for the patient. It should be immunologically inert, nontoxic, and noncarcinogenic. The material should be resistant to infection and cause minimal injury to surrounding tissue.

An ideal implant should also be patient specific. It should easily conform while remaining resilient to stress and maintaining its shape permanently. An anatomical, tapered margin with smooth contours is desirable to blend naturally to adjacent anatomical areas. The structure of the implant material, if able to be folded and compressed, would allow its placement through a relatively small incision. It should also be cost-effective. With regard to technique, an ideal implant can be placed and fixated which reduces mobility. It should also be easily exchangeable if necessary. Materials that result in significant ingrowth should be avoided due to difficulty with removal and exchange.

Implant Materials

Polymeric Materials/Solid Polymers

Silicone polymers or polymerized dimethylsiloxane can be solid, gel, or liquid depending on polymerization and crosslinkage. Solid silicone elastomer has a high degree of chemical inertness, is hydrophobic, and very stable. It is also easy to sculpt. With over a 70-year history of use, there is no evidence of long-term adverse events, toxicity, or allergenicity.³ Most adverse reactions related to injectable silicone are due to excessive injections and use of impure silicone. They can present as inflammatory nodules or "siliconomas" several years after injection.⁴ When applied in a limited number of injections, the silicone appears to be stabilized by a fibrous capsule. This capsule forms as tissue reacts to the presence of the implant without tissue ingrowth. Rarely, capsular contracture and implant deformity can occur when implants are placed too superficially or migrate into overlying skin.⁵ This is more apt to occur if the implant is placed in a supra-versus sub-periosteal plane. When unstable or placed without adequate soft tissue coverage, implants can cause inflammation and seroma formation. Silicone elastomer has unique qualities of modifiability, compressibility, and re-expansion

to full restoration of the original shape. This provides the advantage of the ability to insert larger implants through smaller incisions. Silicone elastomer (Silastic, Dow Corning) is easily removed and replaced without surrounding soft tissue deformation.

Polymethylmethacrylate (Acrylic) Polymers

Polymerization of methyl methacrylate creates polymers of high strength and rigidity, known as polymethylmethacrylate (acrylic) polymers (PMMA). A powdered mixture is catalyzed to create a very rigid material. As polymerization occurs, the viscosity of the preparation increases until the material solidifies. The polymerization process is an exothermic reaction that can heat up to 80°C causing thermal injury to soft tissues. Thus, the material should be removed from the tissue during the molding process. PMMA has high biocompatibility, low toxicity, and can be molded in situ as the polymerization occurs. In its preformed state, the implant cannot be adapted to underlying bony contours due to its rigidity.⁵ PMMA implants can also be customized to specific patient needs in advance of surgery based on computed tomography (CT) images.

Polyethylene

High-density polyethylene solid implants are often used in augmentation and reconstruction. The porous form is most commonly used. Porous polyethylene (Medpor, Porex Surgical, Inc.) is strong, nonbiodegradable, and biologically inert. Pore sizes are usually 100 to 150 µm which facilitates tissue ingrowth with minimal inflammatory cell reaction (Fig. 1). Recently, an ultrahigh molecular weight polyethylene (UHMWPE) implant has been developed (SynPOR, Synthes, Inc.) with pore sizes of 150 to 250 µm that also allow for more tissue ingrowth instead of encapsulation. UHMWPE has been used alone or in combination with titanium for anatomical reconstruction of the craniofacial skeleton. The material's porosity promotes extensive fibrous tissue ingrowth which enhances implant stability within the soft tissue. However, this makes it difficult to remove the implant without significant bleeding, disruption of the surrounding soft tissues, or damage to adjacent sensory nerve trunks such as the infraorbital and/or mental nerve.⁶



Fig. 1 Connective tissue ingrowth into the center of porous polyethylene implant. (Off-white areas are polyethylene structure).

Polytetrafluorethylene and Expanded Polytetrafluorethylene

Polytetrafluorethylene is a material that under mechanical stress is subject to breakdown, intense inflammation, thick capsule formation, infection, and eventual exhaustion or explantation. However, expanded polytetrafluorethylene (ePTFE; Gore-Tex, W.L. Gore and Associates), originally used in cardiovascular applications as vascular grafts,^{7,8} is an excellent implant material. ePTFE has limited tissue ingrowth without capsule formation and minimal inflammatory cell reaction, which allow for easy removal if needed. It can be used in subcutaneous tissue augmentation or as prefabricated implants.

Mesh Polymers

Mesh polymers include Marlex (Marlex Pharmaceuticals, Inc.), Dacron (INVISTA), and Mersilene (Ethicon, Inc.). They are able to be folded, sutured, and shaped with relative ease. However, removal can be difficult as these polymers promote fibrous tissue ingrowth. Supramid is a polyamide mesh derivative of nylon which is unstable and can elicit a foreign body reaction from multinucleated giant cells. Over time, this can cause implant degradation and resorption.⁹

Polyether Ether Ketone

Polyether ether ketone is one of the highest rated thermoplastic materials in terms of heat resistance, chemical and hydrolysis resistance, resistance to the effects of ionizing radiation, high strength, and extensive biocompatibility.⁶ It was developed as an alternative to conventional metallic implants. It is commonly used in head and neck reconstruction as healing caps for dental implants or prefabricated implants for craniomaxillofacial defects. Some of its advantages over conventional metals include lack of allergenicity, radiolucency, and low artifact on magnetic resonance imaging (MRI) scans.

Metals and Alloys

Metals and alloys for biomedical application are limited by biocompatibility, mechanical properties, corrosion resistance, cost, and capability of volumetric augmentation. Thus, there are only a few metals that can be used as implant materials in the body.

Titanium has a high strength to weight ratio, exceptional corrosion resistance, and excellent biocompatibility. It has capacity for osseointegration which makes it an outstanding choice for bone replacement implants. In addition, it is non-magnetic and nonparamagnetic making it safe for MRI use. There is widespread use of titanium for craniomaxillofacial reconstruction in the correction of congenital deformities, trauma repair, and reconstruction following oncologic resections (**-Fig. 2**).

Gold and platinum are chemically inert and evoke minimal tissue reaction with excellent biocompatibility. It is often used in upper eyelid reanimation procedures, which utilize 24-carat, highly polished eyelid weights to assist with eye closure in facial paralysis patients.^{9,10}

Platinum has excellent biocompatibility and is the preferred implant material for gold-sensitive patients undergoing eyelid-loading surgery.¹¹ It is denser than gold and has



Fig. 2 Placement of an orbital floor implant with a porous polyethylene and titanium combination implant.

the advantage for lower profile implants compared with gold of the same weight.

Calcium Phosphate

Calcium phosphate (hydroxylapatite)-based ceramics and cements are used often as bone substitutes in craniofacial reconstruction.^{12,13} These materials are generally not osteoconductive but provide a foundation on which surrounding bone can be deposited. A recently developed injectable, Hydroset, is a self-setting calcium phosphate cement bone substitute. Once set, it is an effective osteoconductive and osteointegrative material due to its crystalline structure and porosity. Its granules can be used for augmenting the alveolar ridge. In block form, it can be used as interposition grafts in osteotomies.¹⁴ However, due to its brittle character and poor ability to contour to surface irregularities, it is less effective as augmentation or onlay material. It also does not have sufficient tensile and compressive strength for load bearing applications. It is useful for cranioplasties as it can be sculpted with precision.

Composite Implants

Composite implants are created from combinations of various biomaterials. For example, ePTFE Composite (Implantech, Ventura CA) facial implants utilize both ePTFE and silicone. This takes advantage of the favorable characteristics of multiple materials. Continued research and development of composite implant materials should aim to balance ideal characteristics with cost effectiveness.⁵

Nasal and Premaxillary Augmentation

Nasal Alloplastic Implants

Nasal augmentation is often achieved using nasal alloplastic implants made of silicone, ePTFE, or porous polyethylene materials. Silicone implants can cause skin atrophy over time, and they need to be anchored to prevent movement. In our experience, silicone seems to be less prone to infection compared with ePTFE, with ePTFE infection rates at approximately 5%. However, they can be easily removed and replaced if needed. Porous polyethylene implants can cause significant tissue ingrowth which can make removal difficult. In regions with soft tissue mobility, extrusion rates of implants are higher. An example is the columella or ala due to nasalis muscle contracture. This has been largely substituted with autologous cartilage grafts or diced cartilage fascia grafts.¹⁵

Premaxillary Augmentation

Premaxillary augmentation is often used in rhinoplasty, particularly in the Asian or Latino and African American populations, to improve an acute nasolabial angle, elevate nasal projection, or to produce an overall more appealing midface contour. To place an alloplastic implant, the periosteum of the premaxilla is elevated to create a pocket for implant placement. The implant is then placed through an intranasal inferiorly based hemi-transfixion incision. Usually it is necessary for the entire premaxilla extending laterally to the pyriform aperture to be augmented. Premaxilla alloplastic augmentation can be achieved with prefabricated silicone implants or rolled sheets of ePTFE or solid prefabricated ePTFE implants specific for this area which are inserted via a hemi-transfixion incision and secured to the periosteum over the nasal spine (**~Fig. 3**).

Midface Augmentation

A major contributor to aging of the face is volume maldistribution and atrophy of the soft tissues in multiple facial planes. Midface suspension along with augmentation of the soft tissue and skeletal foundation is used for midface rejuvenation.



Fig. 3 ePTFE implants more easily conform to the abrupt topographical variability of the peri-pyriform, or premaxillary area. ePTFE, expanded polytetrafluorethylene.

Alloplastic implants can be used with consistency and predictability in the replacement of lost facial tissue volumes to increase anterolateral projection. They improve midface laxity and decrease the depth of nasolabial folds. Furthermore, they are readily reversible and can be used in combination with standard rhytidectomy.

For some patients, moderate rejuvenation can be obtained with a submalar or midface implant without needing concomitant rhytidectomy. In other patients, midface augmentation and rhytidectomy are combined for a synergistic approach. Following implant placement, skin and soft tissue can be re-draped over a broader, more convex midface region. This allows for minimal traction on the lower eyelid, perioral tissues, and lateral commissure during rhytidectomy and avoids an "over-pulled" appearance. In addition, release of underlying osteocutaneous ligaments at the zygoma during implant placement can improve the ability of vertical lift of soft tissues during rhytidectomy.

There are specific criteria for determining regions of aesthetic deficit.^{16,17} In the periorbital and midface region, aging causes weakening of the orbital septum and herniation of the periorbital fat. Subcutaneous tissue atrophy can further result in hollowness of the eye in advanced age. Skeletal insufficiency can occur due to primary congenital hypoplastic development and the aging process. There can be descent of the midface from ptosis of the subcutaneous tissues, malar fat pad, suborbicularis oculi fat, and orbicularis muscle. As aging progresses in the midface, there is increased prominence of the nasojugal/tear trough area and infraorbital rim, hollowing of the lower eyes, and deepening of the nasolabial folds.

Soft tissue deficiencies are found in the "submalar triangle," which is an inverted triangular area bordered by the zygoma prominence, the nasolabial fold, and the body of the masseter muscle.¹⁸ The aged appearance is exaggerated when involutional changes occur in patients with deficient underlying bony structure. Patients with strong cheekbones and thin skin can have a gaunt appearance with facial depressions in areas lacking subcutaneous or deep supporting fat. In a situation with volume loss associated with aging, rhytidectomy alone may be insufficient for complete facial rejuvenation. Use of computer-assisted, patient-specific, facial implants can also, in combination with rhytidectomy, help achieve successful facial rejuvenation.

Midface deformity classification is used in the analysis of areas to address. To determine the most appropriate surgical procedure, the bony malar region and the soft tissue submalar area are assessed separately (Fig. 4). A Type I deformity is a primary malar hypoplasia with adequate submalar soft tissue. This is best addressed with larger surface area malar shell implants that cover the bony midface and project the cheek in a more lateral direction (Fig. 5). A Type II deformity is a submalar soft tissue deficiency with a normal malar skeleton and is the most common deficiency in the aging population. The midface develops a flat and hollowed appearance from descent and atrophy of the soft tissue. This deformity is best addressed with a submalar midface implant to create a greater anterior projection and convexity to the midface. Submalar implants or conform-type implants can be used alone or in combination with rhytidectomy. A Type III deformity occurs when there is

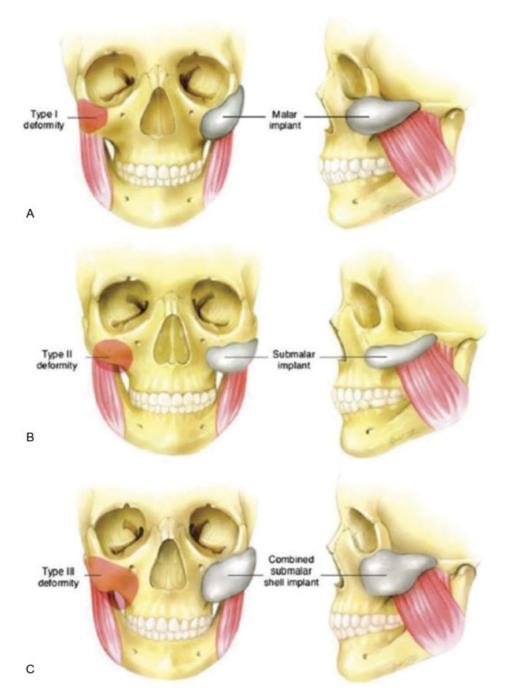


Fig. 4 Implant placement by facial deformity type (Reproduced with permission of Binder WJ, Kim BP, Azizzadeh B. Aesthetic midface implants. In: Azizzadeh B, Murphy MR, Johnson CM, eds. Master Techniques in Facial Rejuvenation. Philadelphia: Saunders; 2007:197–215).

bony malar hypoplasia and submalar soft tissue deficiency. These cases exaggerate the effects of aging due to ptotic soft tissues with poor bony support. Rhytidectomy alone is not sufficient to address these deformities as there is limited skeletal support to resuspend the soft tissue. Combined malar-submalar midface implants are best to address these deformities¹ (\succ Fig. 6). Volume augmentation in areas of age-related soft tissue loss that develop in areas without an underlying osseous foundation is difficult to achieve with solid implants as the implant is suspended in the soft tissues which are normally mobile. A solid implant in these areas can create an

unnatural look with capsular contraction and soft tissue distortion especially with animation. Soft tissue hollowing in the lower cheek lateral to the oral commissure is an example of this challenge.

Currently, injectables, such hyaluronic acid, have become popular in malar and midface augmentation due to ease of administration, longer lasting properties, and cross-linking that provides lifting of the soft tissue envelope. For patients with midface skeletal deficiencies, alloplastic implants may be necessary in providing the proper facial contour that soft tissue fillers cannot provide.



Fig. 5 Patient with Type 1 midface deficiency with insufficient malar development. Malar shell implants placed intraorally to augment zygoma to produce a natural high cheekbone effect (Left: preoperative; Right: postoperative). (Reproduced with permission of Dhir and Binder.¹).



Fig. 6 Patient with soft tissue and skeletal volume loss (type III) treated with alloplastic implant of the midface (A: preoperative; B: postoperative). (Reproduced with permission of Dhir and Binder.¹).

Mandibular Augmentation

Appropriate chin projection and shape can be used to complement facial rejuvenation and rhinoplasty aesthetics. A poorly projected chin can exaggerate the appearance of the nose. A prejowl sulcus can develop with soft tissue atrophy and bony erosion in the symphysis.

A method developed by Gonzalez-Ulloa can be used to assess chin projection. First, establish the Frankfurt plane by drawing a horizontal line between the supratragal notch and the infraorbital rim in profile view. A perpendicular line, called the 0-degree meridian, can then be drawn from the Frankfurt plane at the level of the nasion to determine chin projection. For men, the pogonion is generally at the 0-degree meridian. For women, the pogonion is generally 1 to 2 mm posterior to the 0-degree meridian.¹⁹

Zonal principles of anatomy can be used to establish the specific chin and jawline contour to be addressed.¹⁶ Traditionally, the central zone, which is demarcated by the area between the mental foramina, was used for chin implant placement. However, a lack of lateral extension with these implants can result in abnormal round protuberances that are unappealing.

The midlateral zone is the area that extends from the mental foramen to the oblique line of the horizontal body of the mandible. To widen the anterior jawline contour, both the central and midlateral zones need to be augmented. An extended anatomical chin implant can be used (**Fig. 7**).

The third zone of the premandibular space is the posterior lateral zone. This area comprises the posterior half of the horizontal body including the angle of the mandible and the first 2 to 4 cm of the ascending ramus. A mandibular angle implant can be placed in this zone to widen and/or elongate the posterior mandible angle. This can help generate a strong posterior jawline contour.

As the face ages, the prejowl region begins to involute. This becomes more apparent over time due to thinning of the soft tissues as well as a lack of underlying masseter and mentalis muscle of the surrounding regions. Placement of anterior and angle implants can amplify this involution. To avoid this, a total mandibular implant can be used to provide simultaneous augmentation of all areas of the mandible. These implants can be formulated to be patient-specific using computer-aided design²⁰ (\sim Fig. 8).

Anterior Mandibular Implants/Chin Augmentation

In anterior mandibular implants, the average central projection necessary is 6 to 9 mm in men and 4 to 7 mm in women. In patients with severe micrognathia, 10 to 12 mm of augmentation may be needed. Access to the premandibular space can be achieved from either an intraoral or external (submental) approach.

Mandibular Angle Implants

For mandibular angle implants, a 2 to 3 cm mucosal incision is made along the retromolar trigone to access the mandibular angle. Subperiosteal dissection is performed along the ramus, body, and angle. A 90-degree dissector is usually needed to elevate the posterior border of the angle. The implant is then placed to fit the posterior bony border of the ascending ramus. A titanium screw is used to secure the implant.

Total Mandibular Implants

Total mandibular implants are performed in patients that require augmentation in all elements of micrognathia. The surgical dissection combines submental and retromolar trigone approaches. The dissection pockets are connected to allow for insertion of the implant. If the gonion component is relatively small, the implant can be placed through the submental incision and the lateral components placed from a posterior approach.



Fig. 7 Lateral view of patient that underwent chin augmentation with silicone implant. (A) Preoperative; (B) Postoperative.

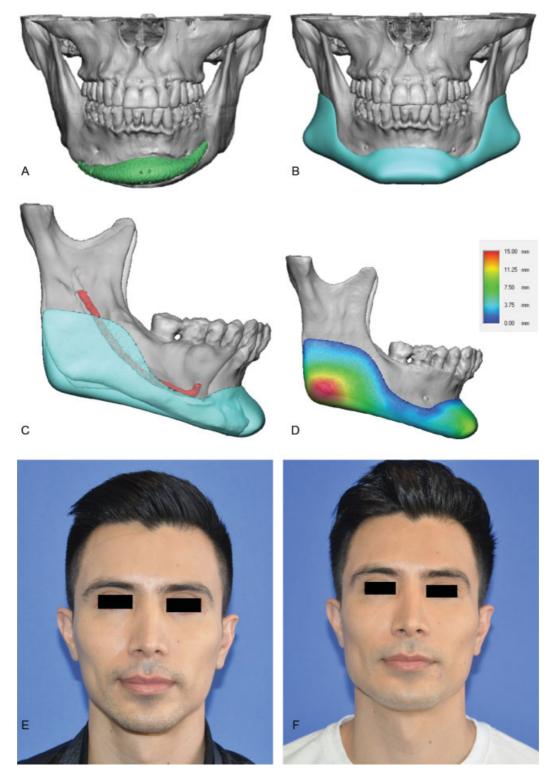


Fig. 8 Virtual surgical planning for a custom total mandibular implant (A) 3D reconstructed imaging of previously placed mandibular implant. (B) 3D image of virtually planned patient-specific total mandibular implant with previously placed implant subtracted. (C) Position of the inferior alveolar nerve demarcated on the virtual plan. (D) Topographic representation of variation in thickness of the implant. (E) Preoperative photo. (F) Postoperative photo.

The implant should be placed below the mental nerve along the inferior border of the mandible. If the implant is large, it can be split down the midline and placed through the dissection pocket. A 2–0 silk suture can be used to assist the implant placement through the intraoral gonial dissection pocket and

inserted via a posterior-to-anterior approach by gently guiding the anterior chin component of the implant forward through the submental incision. Once the implant is positioned appropriately, the two halves of the implant are reunited in the midline using a 4–0 clear nylon suture or a 4–0 PDS suture. The

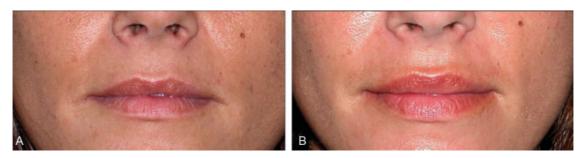


Fig. 9 Frontal view of patient with lip augmentation with Advanta implant. (A) Preoperative; (B) Postoperative.

anteroinferior portion of the implant can be secured to the periosteum with either a suture or a titanium screw into the bone. 20

Lip Augmentation

Lip augmentation is one of the most requested aesthetic treatments. While this is generally accomplished with injectable fillers nowadays, lip augmentation can also be accomplished with implants for more long-lasting results.

Advanta (Atrium Medical Corporation) is a tube-shaped form of ePTFE that was developed for lip augmentation. It contains a dural porosity architect that consists of a soft, high porosity center core of 100 μ m and a smooth, medium porosity outer layer of 40 μ m. The dual porosity structure provides a softer, less palpable facial implant.²¹ Small incisions are placed a few millimeters medial to the oral commissure. The implant is then placed using a tunnel created with a trochar that is attached to one end of the implant. Alternatively, a tendon passer can be used to thread the implant through the tunnel. The tunnel should be just slightly smaller than the implant to prevent migration of the implant. It is important to place the implant under the dermal layer to prevent visibility through the skin. The incisions are then closed once the implant is in proper position (**– Fig. 9**). Extrusions of alloplastic implants are most notable in mobile regions of the face. The orbicularis oris muscle is important in facial expression, deglutition, and control of respiration. This may lead to increased risks of infection and extrusion over time. Fillers and surgical lip lift procedures have become more commonplace in the clinical setting. Other silicone lip implants include solid soft silicone lip implants as well.

Computer-Aided Design and Manufacturing

Three-dimensional (3D) printing, also known as additive manufacturing or rapid prototyping, has been expanding in applications in the medical setting. As the technology of additive manufacturing and 3D printing continues to improve and becomes increasingly more affordable, its use in facial plastic and reconstructive surgery has also expanded.²²

The combination of computer-aided design and manufacturing provides the ability to create customized patient-specific implants. This allows for increased accuracy of reconstruction, decreased intraoperative time, decreased fatigue of the implant, and ease of use.^{23–25} Utilization of 3D CT imaging capabilities and 3D printing software and technology allows for fabrication of customized facial implants that can be designed virtually prior to surgery.²⁶ This process is particularly useful for complex cases and revision cases with the

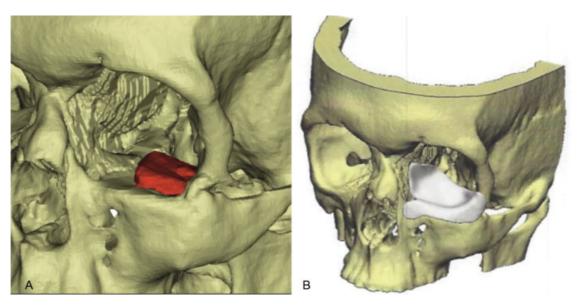


Fig. 10 Software manipulation demonstrating previously placed orbital implant (A) and virtual subtraction with virtually placed patient-specific orbital implant (B) in a revision case.

ability of the software to account for patient facial asymmetries, irregularities, and areas of osteoresorption, and even digitally subtract previously placed implants (**~Fig. 10**).

Conclusion

Aging of the face involves the skin, the underlying soft tissues, and the skeletal framework. A rigorous understanding of the aging process is crucial to optimize facial rejuvenation. Alloplastic implants should be considered alone or in combination with other surgical procedures such as rhytidectomy or minimally invasive soft tissue augmentation techniques. Careful examination of the facial skeleton is necessary for aesthetic contour enhancement, facial rejuvenation in skeletal deficiency, and cases with significant soft tissue volume resorption. Furthermore, alloplastic implants can be used synergistically with other procedures to address multiple anatomical deficiencies and improve patient satisfaction in facial augmentation and rejuvenation.

Conflict of Interest None declared.

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