



Custom-Designed Facial Implants

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Accurate correction and restoration of facial contour defects have historically posed arduous challenges for reconstructive and aesthetic surgeons, but technological innovations in the design and manufacture of facial prostheses have significantly improved the precision, fit, and reliability of these restorative devices. In the mid-1980s, CT replaced standard radiographic analysis as the reference standard in the diagnosis and treatment planning of craniofacial abnormalities [1,2]. Leveraging the imaging capabilities of CT, computer-aided design (CAD) and computer-aided manufacture (CAM) methods subsequently were developed to replicate the anatomic topography and to enhance fitting of the implant in more complex cases requiring prosthetic restoration. In 1994, Binder and Kaye [3] reported their early clinical experiences using a three-dimensional (3D) CAD/CAM process for customizing implants in the reconstruction of post-traumatic and congenital facial deformities. Patients in this series experienced favorable aesthetic and functional outcomes with low morbidity, characterizing 3D CAD/CAM custom-designed implants as an accurate, simple, and cost-effective method for facial contour restoration [3]. In the ensuing years, this technique was extended to the customization of implants for augmenting and compensating skeletal and soft tissue discrepancies

in patients who had complex acquired and aesthetic contour deficiencies [4]. Today, 3D CAD/CAM technologies continue to be refined and used for a wide variety of reconstructive and aesthetic applications.

Overview and advantages of custom-designed implants using three-dimensional computer-aided design and computer-aided manufacturing technologies

The 3D CAD/CAM technique generates a life-size anatomic model based on images configured from digitalized and reformatted CT data [3]. The resulting model serves as the foundation on which a specific implant is fashioned. Using this method, the surgeon is able to examine and analyze anatomic subtleties not otherwise evident in a two-dimensional format. Produced by combined computer imaging and modeling, the posterior surface of the resulting implant forms an extremely precise fit to the underlying bone base. This interlocking implant–bone interface accurately guides exact placement of the implant and contributes to greater overall stability [4]. The degree of conformity between the custom implant and irregular bony surfaces is so precise that internal or external fixation typically is not required [5]. For well-defined bone

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defects, volumetric parameters can be estimated effectively by applying surface molding techniques to predict the degree of augmentation necessary for the optimal change in external contour. Custom implants also can be used for aesthetic augmentation of the facial skeleton or to correct soft tissue deficiencies. By configuring the implant with extended anterior dimensions that approximate the normal soft tissue contour, the implants also can replace deficient volume and simulate soft tissue replacement [5].

In addition to the primary benefit of heightened accuracy in conforming the implant surface to the underlying bone, the technical advantages of 3D CAD/CAM custom-designed implants include enhanced stability, accuracy of placement and form, and greater refinement in facial contour restoration [3]. It also is generally easier to predict soft tissue displacement following direct augmentation with grafts or implants than with orthognathic procedures, such as osteotomies and segmental bony repositioning. Thus, in properly selected patients who do not have major facial deformities and who lack major occlusal or functional problems, custom-designed onlay implants may be a more desirable option than more extensive reconstructive surgery [6,7].

When used for onlay restoration of soft tissue, biocompatible alloplastic implants are more predictable and durable than autogenous grafts. Bone or cartilage autografts undergo variable amounts of resorption, and harvesting these materials carries the risk of donor-site morbidity [8,9]. Carving blocks of alloplastic material to fit irregular bony defects is cumbersome, impractical, time-consuming, and frequently yields suboptimal results. Similarly, modified off-the-shelf implants lack the ability to adapt and conform to the underlying bone topography, often producing conspicuous or palpable rough edges [10]. Conventional moulage techniques also compromise implant stability, because these methods use the skin surface as the base contour of the implant, thereby promoting uneven contact within the implant–bone interface [11–13]. Injection of the longer-lasting fillers (eg, the hyaluronic acids or hydroxyapatite) also may mask a contour defect; however, these fillers are not permanent, require repetitive use, and have limitations in treating larger-volumetric defects or in creating structural changes in facial contouring. Fat transfer presents unpredictable results in resorption, may cause irregularity, and may require frequent injections.

Given the shortcomings of these methods, 3D CAD/CAM custom-designed implants may reduce substantially the use of autografts and the need to carve and shape implants or grafts during surgery. These advantages, in turn, decrease surgical time

and thereby minimize operating room facility fees, and, in most cases, eliminate the need for hospitalization [3]. Hence, as comprehensive health care continues to exclude coverage for facial disfigurement as a pre-existing condition, most cases requiring custom implants may be treated on a more cost-effective outpatient basis requiring less operative time [5].

Technique

To ensure accurate reformatting of the 3D image from a CT scan, it is important to follow specific protocols established by commercial facilities that provide imaging, modeling, and technical support services. After defining the exact anatomic region encompassing the defect, the surgeon should instruct the radiologist or CT technician regarding the targeted area to be scanned. The area of maximal focus is scanned at a minimum slice thickness; the surrounding areas are scanned using low-dose techniques in contextual slices of greater thickness [4]. This method ensures minimal radiation exposure with complete CT assessment of the target area [14]. The newer CT scanners can provide thin slices throughout the target area without a substantial increase in radiation exposure. Next, using either a high-resolution CT scanner with a 3D workstation or the services of a commercial facility, the CT data are reformatted into a 3D computer image of the scanned anatomic structure. In this process, an acrylic 3D model of the facial skeletal part is generated from the CT data with the use of laser crystallography technology. The surgeon then can examine and study a life-size plastic model in detail and determine areas that need augmentation. A template is fabricated by combining two silicone resins to form a soft malleable material that hardens as the desired form is created to fill defects or augment anatomic areas. In cases of concomitant soft tissue deficiency, a moulage also may be helpful in rendering additional information for configuration of the template's external surface [3]. To compensate for any additional irregularities surrounding the skeletal defect or variability in the overlying soft tissue, the surgeon may further refine or enhance the thickness, shape, and/or edges of the template manually once it has hardened on the model. This step represents an invaluable opportunity to approximate any anticipated changes in the actual external contour [4]. The posterior surface of the template remains constant, however. When the design of the template has been completed, both the model and implant template are sent to the implant manufacturer, and an exact replica is produced commercially as a stable, heat-vulcanized silicone elastomer implant [3].

Custom silicone implants manufactured using the 3D CAD/CAM technique comply fully with the requirements for approval by the United States Food and Drug Administration (FDA) [4]. Although various biomaterials may be used for augmentation, only a few are amenable to the 3D CAD/CAM process for fabricating custom prosthetic devices. Biomaterial for customized implants should be relative inert, noncarcinogenic, flexible, and easily carved if further refinements are required at the time of surgery. Preferably, the implant also should be nonporous for greater resistance to infection [15]. At present, the author and colleagues have found silicone elastomer (rubber) to be the optimal FDA-approved biomaterial that meets most of the ideal implant requirements and satisfies the demands of the custom molding process. Silicone rubber can be compressed for insertion through small incisions without losing its shape and detail and retains flexibility to adapt to gross surface changes [3].

Indications

Reconstruction of posttraumatic and congenital facial deformities

The physical and emotional consequences of untreated facial deformity resulting from trauma or congenital causes make the accuracy and predictability of selected surgical modalities critically important [3]. The spectrum of facial deformities may range from small- to moderate-sized facial contour defects to large, traumatic injuries. Notwithstanding the severity of the defect, several factors may preclude satisfactory repair of traumatic facial deformities. Patients who have particularly thin skin, small surface irregularities, or deformities in prominent locations leave little latitude for error. In these circumstances, the contour defects may go untreated because of the reluctance to use osteotomies, onlay grafts, or implants that cannot provide the precision required to achieve accurate and successful long-term results [3]. Timely treatment of acute facial injury may not always be feasible because of the lack of appropriate trauma personnel. Other patients may require primary surgical intervention for life-threatening injuries, which precludes surgical intervention of the facial injury during the immediate posttraumatic period.

Deferring appropriate management of traumatic facial injuries can lead to numerous and varied facial deformities. Consequently, a high percentage of patients who have moderate to severe maxillofacial trauma suffer from malunion, displacement, postoperative asymmetry, and problems in facial contour [16]. Even patients receiving adequate and timely treatment may be susceptible to late-onset deformities caused by incomplete reduction,

resorption of comminuted bone fragments, and resultant collapse of the remaining structure [10,15]. In correcting zygomatic and periorbital deformities, delayed osteotomies and bony repositioning may incur facial incisions, varying degrees of morbidity, and a relatively high rate of skeletal relapse and bone resorption [17]. In maxillofacial surgery, problems in predicting the final outcome may rest more with unequal movement and distribution of soft tissues that accompany the final positioning of facial bones. These inconsistencies of overlying soft tissue change can diminish the outcome of an otherwise correctly planned and well-executed skeletal procedure [18,19].

Custom CAD implants have been used successfully to treat selected patients who had posttraumatic and congenital facial deformities. For many patients, this method may prove to be an accurate and simple means to reconstruct difficult problems; in others, it may be the only treatment that can provide a reasonable degree of success [3]. In appropriate cases lacking major functional or occlusal abnormalities, adequate treatment of contour deficiencies may be achieved simply by using onlay alloplastic implants to mask the deformity [6,7]. This technique has demonstrated remarkable results in treating complex, finite posttraumatic facial contour deformities. Custom onlay prosthetics may be used to reconstruct bone defects over most areas of the face and skull, without incurring postoperative irregularities of grafts or standard implants [3]. A significant advantage of this method is the ability to design the template before surgery and to overlap margins around the bone defects or to feather edges, rendering the implant virtually undetectable. In some cases, defects also can be reconstructed with the advantages gained by using more than one biomaterial simultaneously.

The patient in (Fig. 1A) presented 2 years after a motor vehicle accident with a complex contour defect over the right anterior skull and temporal region resulting from bone loss incurred as a result of the primary injury and after two life-saving craniotomies. This case illustrates how the use of custom implants with 3D computer imaging and modeling can be used to optimal advantage in reconstructing a difficult contour defect completely and with good long-term results (Fig. 1A-E).

The patient in Fig. 2 (preoperative photographs 2A, C, and E) had bilateral acquired lateral parasymphysal defects as a result of a sliding genioplasty. Rather than revising the genioplasty, a custom implant was used. The postoperative results (Fig. 2B, D, and F) illustrate how a smaller defect can be restored permanently, precisely, and predictably. When the implant was configured to fit the defect, additional volume and dimension were added to

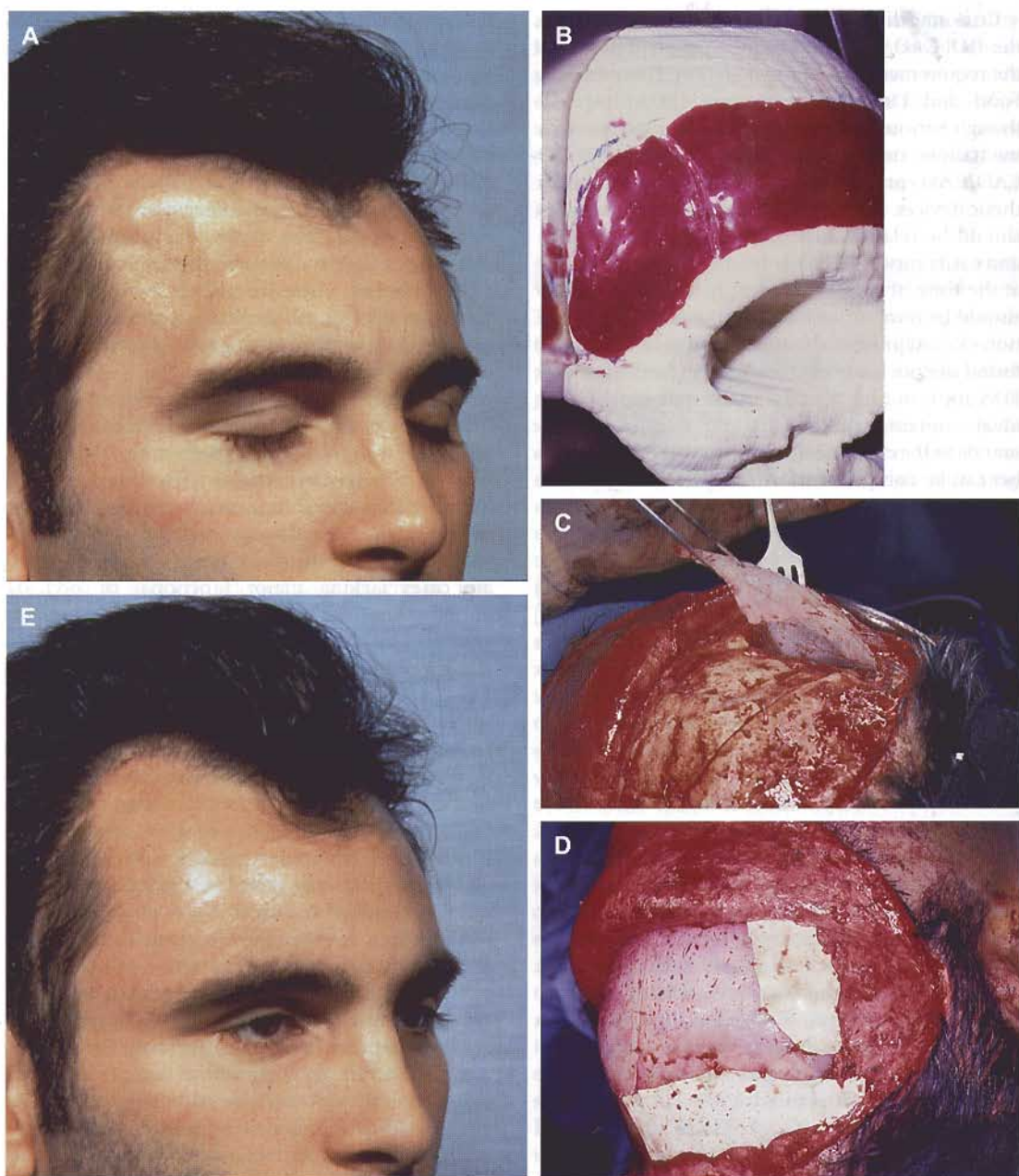


Fig. 1. A 28-year-old patient presented with a complex posttraumatic defect secondary to bone loss and muscle atrophy over the right frontal and anterior temporal region of the skull 2 years after two life-saving craniotomies had been performed. (A) Preoperative photograph. (B) Frontal view of the model with the initial template designed and molded on the anatomic model derived from 3D CT imaging. The template is formed to fill the frontal and temporal bone defect and also is designed to compensate for the atrophy of temporalis muscle within the temporal fossa. (C) Intraoperative view of the reconstruction of the entire frontal and temporal defects with the use of the custom implant. (D) Because of the absence of periosteum within and around the defect, two biomaterials (silicone rubber and expanded polytetrafluoroethylene) were used simultaneously to bridge the area of bone and to fixate the large implant to the surrounding soft tissues. (E) One year postoperatively the area is restored to a completely smooth and symmetric contour. To date, the results have been unchanged and without complication for over 14 years.



Fig. 2. A few years after sliding genioplasty, this patient developed areas of residual contour defects in the parasymphiseal region. (A, C, E) Preoperative photograph. (B, D, F) Postoperative photographs. One year after a custom mandibular implant and submalar augmentation, the deficiency noted over the parasymphiseal areas is reconstructed, and the entire contour of the chin and mandible is augmented. Overall aesthetics are improved with the use of one custom-designed implant.

the implant to improve the overall external contour of the mandible and chin aesthetically.

Patients who have congenital facial contour defects may present for primary treatment of their deformity or, in many cases, for final resolution of contour deficiencies following prior, unsuccessful procedures [3]. In patients who have unilateral defects, the external contour of each implant may be designed to match the contralateral normal bony prominence, thereby restoring symmetry [3]. The patient in Fig. 3, presented with microgenia and mandibular asymmetry that he desired to have

corrected (Fig. 3A). The anatomic model, however, revealed that the asymmetry was caused by congenital dysplasia of the left condyle and ramus. Although the patient was advised that the procedure of choice would be to lengthen the left mandibular ramus, he did not wish to have orthognathic surgery. Instead, a custom implant was devised on the anatomic model to compensate for the asymmetry (Fig. 3A–E). The model proved invaluable for demonstrating the correct diagnosis and degree of dysplasia and for establishing the correct size and shape of the implant (see Fig. 3B). Postoperatively,

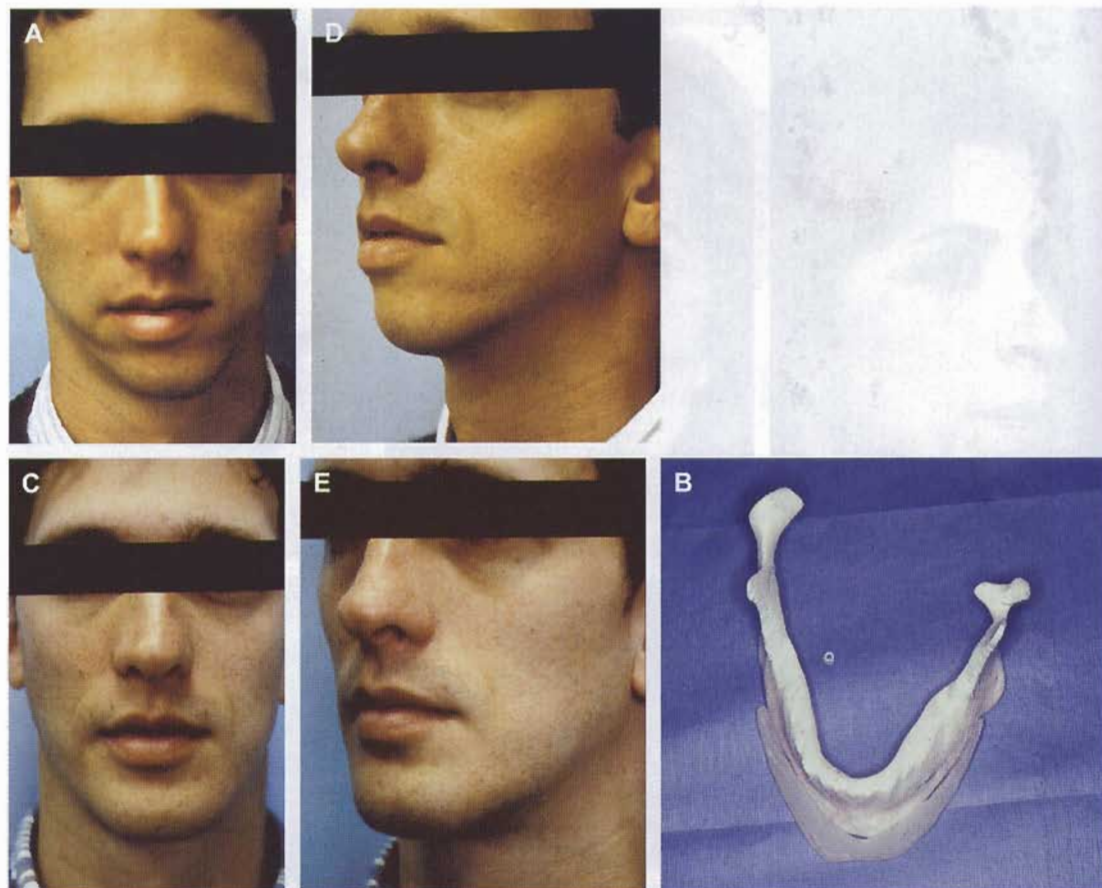


Fig. 3. In this patient, the asymmetrical appearance of mandible was caused by dysplasia of the left ramus and condyle causing a shift of the entire mandible to the left. (A, D) Preoperative photographs. (B) The model proved invaluable for establishing the correct diagnosis, by demonstrating the degree of mandibular asymmetry and for design of the template. (C and E) are postoperative photographs.

the implants remained stable and have continued to provide satisfactory long-term aesthetic results (see Fig. 3A, C, D–E).

The patient in Fig. 4, presented preoperatively with left-sided hypoplasia of the mandibular body and angle (Fig. 4A and C). Using a model, a unilateral extended mandibular body and angle implant was designed to provide a significant improvement in facial symmetry (Fig. 4B and D). Other cases of congenital facial deformities, including maxillonasal dysplasia, premaxillary deficiency, Treacher-Collins syndrome (midface hypoplasia), and micrognathia, also have been treated with CAD/CAM implants with adequate to excellent improvement in facial contour and stable outcomes reported over follow-up periods of up to 15 years (Fig. 5A–D).

Aesthetic enhancement or correction of complex facial contour defects

Although this technique offers significant benefits, most routine cases of aesthetic facial contouring

do not require the use of 3D CAD/CAM modeling. For these patients, current computer-designed off-the-shelf implants generally satisfy the needs of most procedures performed for aesthetic enhancement and facial rejuvenation [2,20–22]. Custom implants, however, may be an indispensable tool for achieving the desired contour changes in patients in whom previous attempts with grafts, implants, or other reconstructive modalities have been unsuccessful or in cases in which the contour defect is in an unusual location. In many cases, severe overlying soft tissue discrepancy is a common problem contributing to poor aesthetic outcomes [4]. This condition may arise as a consequence of injury to the overlying soft tissue, poor contour restoration or instability related to prior reconstructive efforts, or the normal aging process [4,23]. Use of the 3D image-modeling process may spare patients who require revision facial augmentation surgery from undergoing multiple surgical procedures. In Fig. 6, a patient presented with malpositioned malar



Fig. 4. Unilateral extended mandibular angle and body implant. (A) Frontal preoperative view demonstrating hypoplasia of the left mandibular body and angle. (B) Frontal view 18 months postoperative: a unilateral extended mandibular angle and body implant was used on the left side to improve overall facial symmetry. (C) Preoperative profile view. (D) 18 months postoperative profile view.



Fig. 5. Bilateral custom mandibular body and angle implants. Preoperative (A) frontal and (C) lateral views of hypoplasia of the mandibular body and angle. Postoperative (B) frontal and (D) lateral views showing results after bilateral custom mandibular body and angle implants.

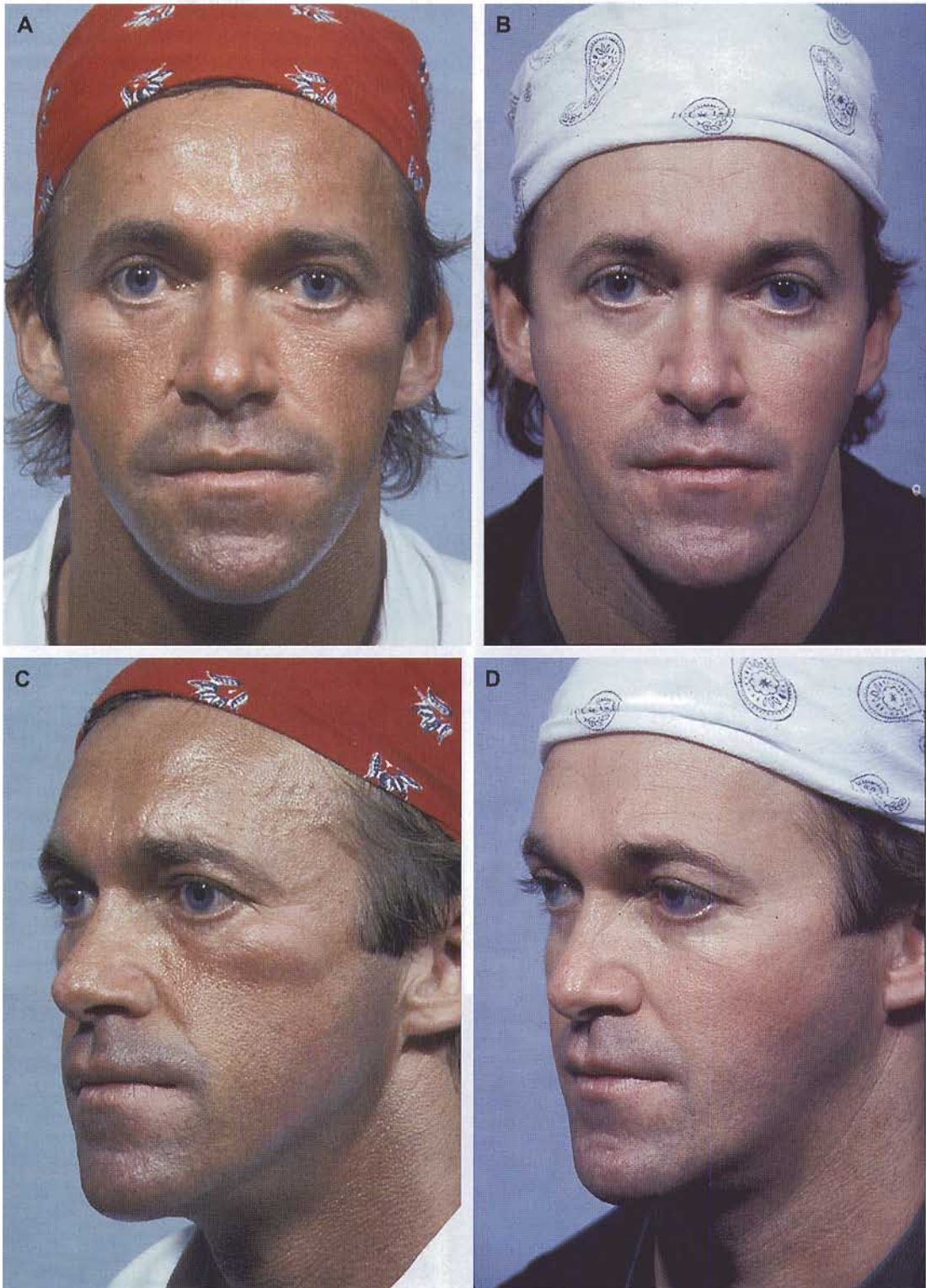


Fig. 6. Removal of the existing malar implants and insertion of the custom midfacial implants changed the abrupt, artificial topographic changes present preoperatively (A, C) to a smoother, more natural aesthetic outcome seen 8 months postoperatively (B, D). (From Binder WJ, Kaye A. Three-dimensional computer modeling. *Facial Plast Surg Clin North Am* 1994;2(3):368; with permission.)



Fig. 7. Preoperatively, the CT image with 3D radiographic reconstructions showed the implant was malpositioned above the orbital rim.

implants which camouflaged a major degree of the underlying skeletal asymmetry [4]. After the preliminary CT scan was obtained, a 3D rendering of the images showed that the existing implants were positioned over the orbital rim and encroached on the orbit (Fig. 7). After the model was generated, templates were designed according to the underlying skeletal deficiencies and a moulage. The thickness of the custom implants over the malar region was estimated using the computer-imaging measurements obtained from the existing implants which were subtracted out from the model image. This process facilitated removal of the old implants and insertion of the custom implants in a one-stage procedure with improved accuracy (Fig. 6A–D) [4].

Acute disease-induced changes in facial surface contour may require extreme precision in implant design. In restoring facial deformities, surgeons may customize alloplastic implants to fill large voids in the facial contour caused by substantial soft tissue loss [4]. In these cases anatomic models

are generated and, in conjunction with a moulage, are used to estimate implant thickness and volume. This estimation is important in patients who have thin skin and abrupt changes in underlying skeletal anatomy. Custom onlay implants also have been used to replace soft tissue in the periorbital area, with excellent results [4]. In this situation, the implants are designed to modify the configuration of the underlying periorbital skeletal structure so that the lower eyelid and infraorbital skin drape in a more horizontal and lateral orientation, thereby reducing the vertical extent of the deformity and supporting the lower eyelid.

Treatment of facial wasting syndrome

Facial wasting syndrome (FWS) is a corollary of lipodystrophy that occurs as a complication of highly active antiretroviral therapy (HAART). The loss of subcutaneous fat in the cheeks and temples manifests as a hollow-eyed, bony, emaciated appearance that is the characteristic hallmark of treatment for HIV. FWS does not improve upon discontinuing HAART, and termination of treatment most likely contributes to the rising number of drug-resistant HIV strains, viral-load rebound, and increased morbidity and mortality [24]. Because patients who have HIV currently live longer and healthier lives, many are beginning to seek surgical remedy for the cachectic appearance caused by FWS [25].

Although numerous different modalities have been used to treat patients who have FWS, none of these methods has produced satisfactory results. Traditional soft tissue augmentation modalities and standard rhytidectomy procedures have demonstrated limited success in cases of severe atrophy [24,25]. Other options, such as dermal fat grafts, local flaps, and free flaps have been tried also, but

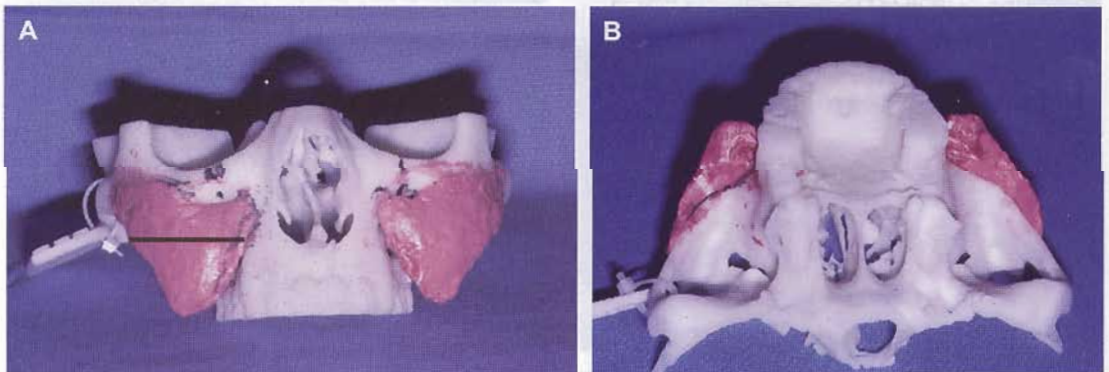


Fig. 8. High-resolution CT 3D CAD/CAM model demonstrating the fabrication of custom-designed silicone mid-facial implants that are used to correct the characteristic appearance of facial wasting syndrome. (A) The line on the right side of the model indicates the inferior border of the maxillary bone. (B) Note the thickness (9 mm) of the implant.

these techniques require multiple fields and lengthy procedures [24,26]. Similarly, other methods, such as fat transfer procedures, fat injections, and the use of injectable tissue fillers (eg, collagen and various

proprietary products), have been considered, but each is short-lived and does not address volumetric needs. The use of fillers in smaller amounts is an effective supplement to the primary implant

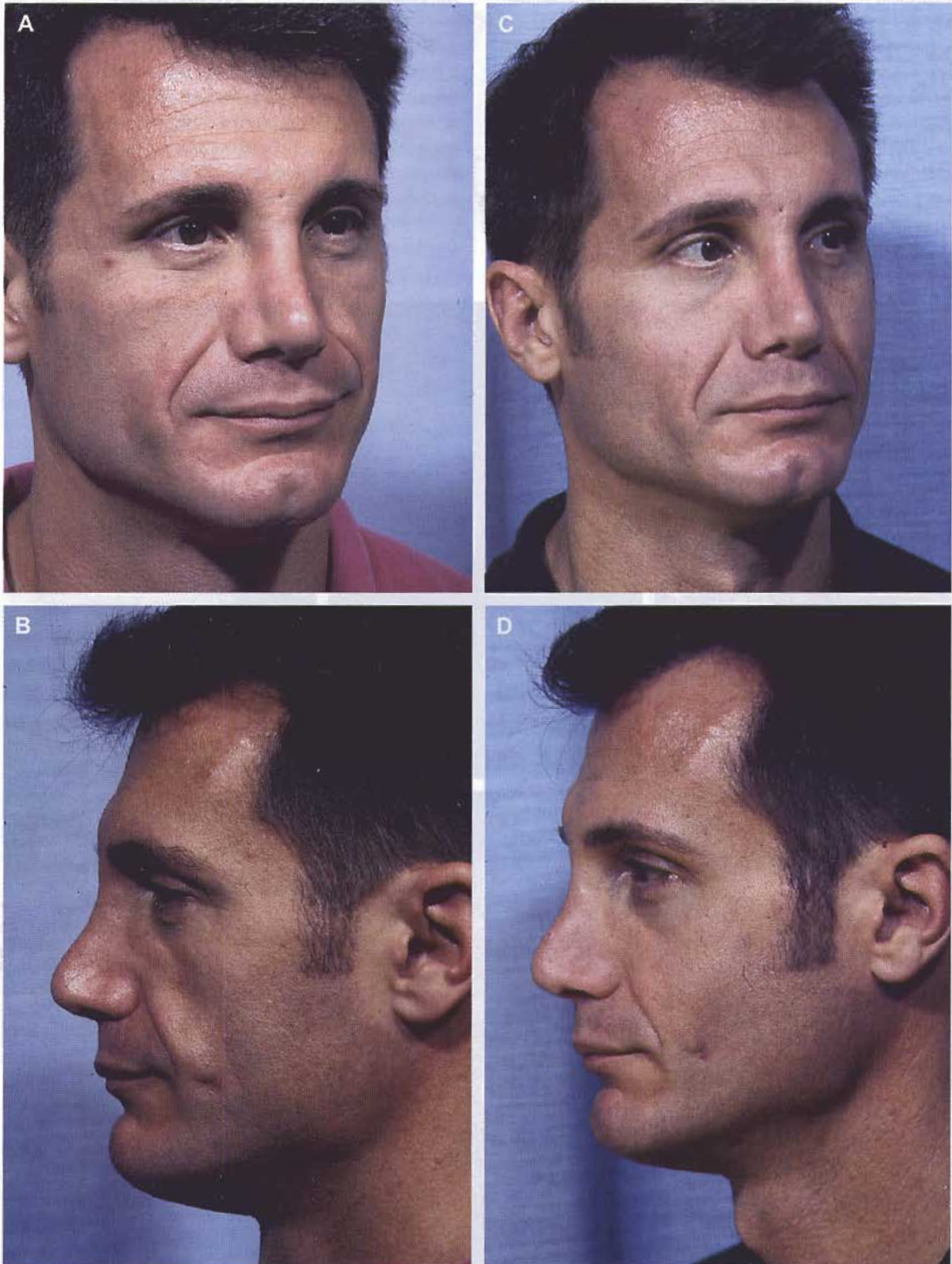


Fig. 9. A 38-year-old man (A, C) before and (B, D) 9 months after implantation of custom-designed midfacial implants.

procedure, however, particularly for small variations in the subcutaneous plane [25]. Local injection with synthetic soft tissue fillers, such as poly lactic acid or hydroxyapatite, has shown some promise; however, the quantity of material required to fill large defects and the frequency of injections in severe cases of FWS drive up costs to significant levels over time [24,25,27]. In contrast, the use of solid synthetic volumetric midface implants for surgical reconstruction of patients who have FWS, a relatively new development, has demonstrated excellent aesthetic outcomes. Talmor and colleagues [24] used submalar silicone implants for the correction of FWS in three patients. One patient required repositioning of the implant following

mild displacement. Two patients underwent additional soft tissue augmentation of the nasolabial fold to achieve satisfactory aesthetic result. In all cases, facial wasting was caused by atrophy of the subcutaneous fat with sparing of the deeper fat pads.

Binder and Bloom [25] reported on the largest series of 22 patients who had HIV-related FWS and who were treated with custom midfacial and submalar alloplastic implants. Contrary to the experience of Talmor and colleagues, this study found that atrophy in these cases occurred in both the superficial subcutaneous fat and the deeper buccal fat pads. Fourteen of the 22 patients received custom implants for more severe midfacial deformities,



Fig. 10. A 42-year-old man with facial wasting syndrome (A, C, E) before and (B, D, F) after implantation of custom-designed midfacial implants.

and 8 patients received off-the-shelf submalar implants for moderately severe conditions. Severe cases of FWS were fitted optimally using CAD/CAM implants because of the need to produce a more vertical, triangular-shaped, and thicker implant, which was positioned in a more medial position than in routine midfacial augmentation procedures. In cases of midfacial atrophy, the implant rests only partially on bone, with the major portion of the implant extending inferiorly over the masseter muscle (Fig. 8) [25]. Once the custom-designed implant is in position, the precise fit between the posterior surface of the implant and the underlying bone directs the implant into the correct anatomic position. Off-the-shelf submalar implants may be positioned and stabilized using various methods of fixation, such as the percutaneous suture and bolster technique [28].

As judged by the patients and surgeon, all 22 patients experienced excellent aesthetic improvement postoperatively. Because of the large size of the implants required in the severe FWS cases, some patients experienced a minor limitation in superior oral commissure excursion on extreme smiling; however, none found this limitation to be problematic or of any consequence compared with the overall degree of aesthetic improvement [25]. Serious complications, such as permanent infraorbital paresthesia, facial nerve paralysis, or implant migration, displacement, or extrusion did not occur. Two cases of wound infection required removal of the implant; in one case, the implant was replaced within 3 weeks without subsequent problems. In the second case, the patient decided not to replace the implants. All other patients expressed extreme satisfaction with their aesthetic outcome and would recommend the procedure highly to other patients (Figs. 9 and 10).

Summary

The availability of 3D CAD/CAM techniques for the customization of facial implants has expanded the application of augmentation surgery to a wider range of patients suffering from facial contour deformities. Before the advent of this technology, treating many of these patients might have been precluded by the high costs and morbidity associated with traditional orthognathic procedures. The sensitivity of the 3D imaging system allows the fabrication of versatile implants that wrap around corners and fit into niches to address effectively minor surface discrepancies surrounding defects. The 3D imaging and modeling system can produce the custom implant in a more stable, commercially processed silicone elastomer. The 3D state-of-the-art scanning, imaging, and modeling system increases

versatility and sets new standards in the design and use of onlay implants for treating many difficult and challenging problems in aesthetic and acquired facial contour deformities. As the future unfolds, the integration of 3D CAD/CAM technologies with concurrent advances in implant biomaterial technology will be exploited to provide other effective and cost-effective solutions for treating patients who have facial contour defects requiring restorative prostheses.

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