THREE-DIMENSIONAL COMPUTER MODELING

Use in Creating Custom-Designed Implants for Treating Aesthetic and Acquired Facial Contour Deformities

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Accurate correction of facial contour defects poses both quantitative and qualitative challenges to reconstructive and aesthetic surgeons. The psychologic implications of untreated facial deformity underscore the need to procure more accurate and reliable implants or grafts to ensure greater predictability in the treatment of complex forms of contour deficiencies.

Recently the use of CT scanners has been replacing standard radiographic analysis, becoming the state of the art in the diagnosis and treatment planning of craniofacial abnormalities and maxillofacial trauma.[15,17] The digital information from a CT scan can be reformatted into a three-dimensional (3D) image that is then used by computer-aided design/computer-aided manufacture (CAD/CAM) to produce a life-size 3D anatomic model. This model allows the surgeon to examine physically and analyze anatomic subtleties not available in the two-dimensional format, and provides the foundation on which the specific onlay implant is produced.

The posterior surface of the implant produced by combined computer imaging and modeling forms an extremely accurate fit to the underlying bone base. This interlocking implant-bone interface correctly guides exact placement of the implant, contributing to a greater degree of stability. This technique, originally employed to improve the treatment of posttraumatic and congenital deformities, has been extended to augment and compensate for skeletal and soft tissue disparity in cases of complex acquired and aesthetic contour deficiencies.[5]

Using surface molding techniques is an effective way of estimating volumetric parameters used to predict the amount of augmentation required for the most desirable change in

The authors have a financial interest in the patent used in the molding process to produce the custom implants.

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external contour. Reliance on these techniques is necessary because current CT scan resolution and software do not yet provide the means for total computerized assessment of the spatial relationships essential in calculating the anticipated external contour or in generating a completely effective implant.

The use of 3D modeling, although offering significant advantages, is not required in most routine cases of aesthetic facial contouring. Current computer-designed "off-the-shelf" implants satisfy the needs of the majority of operations performed for esthetic enhancement and facial rejuvenation.[3,4,9,16] In this article we present three clinical cases that benefitted from the use of this new method and are representative of the many complex aesthetic and acquired problems encountered in contour restoration.

METHOD

To ensure an accurate reformatting of the 3D image from a CT scan it is necessary to follow the specific radiologic protocols available at commercial facilities that provide imaging, modeling, and technical support services. (Cemax, Fremont, California; Implantech, Van Nuys, California). The exact area of interest is scanned at minimum slice thicknesses and the surrounding areas are scanned with low-dose techniques in contextual slices of greater thicknesses. This gives the advantage of minimal radiation exposure while assuring complete CT assessment of the target area.[21] Using either a new high-resolution CT scanner with 3D workstation capability or via the commercial facility, the CT data are reformatted to generate a 3D image of the scanned anatomic structure. Any manipulation of data, such as mirror imaging or measurements of other parameters, may also be performed at this time (Fig. 1).

Conversion CAD/CAM software then transfers the reformatted data to a milling machine that produces a life-size 3D model of the anatomic area scanned. The resulting anatomic model is used as the foundation to design a wax template to augment deficiencies of skeletal structure, overlying soft tissue, or both. Molding the wax template directly on the model highlights the need to compensate for unusual aberrations surrounding skeletal

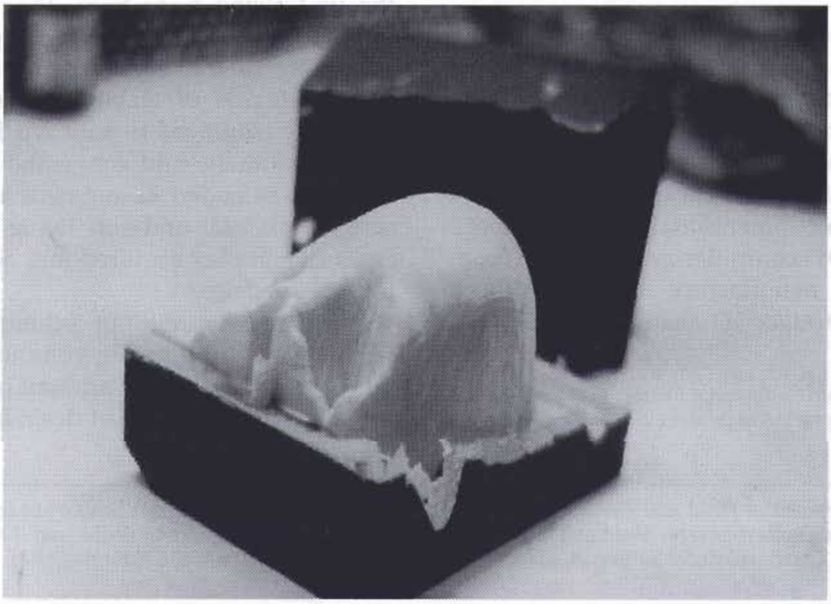


Figure 1. The three-dimensional digital image originating from CT data is transferred via conversion CAD/CAM software to a milling machine to create the mold into which resin is poured, producing the anatomic model.

defects and adjust for the variabilities in overlying soft tissue.

Manipulation of the thickness and shape of the wax template on the model before fabrication of the implant provides an invaluable opportunity to estimate the changes anticipated in actual external contour. The implant is then produced commercially from a stable heat-vulcanized medical-grade silicone elastomer that replicates exactly the final wax template.

The key to the long-term success and stability of larger implants is the exact fit between the implant's posterior surface and the underlying skeletal framework. In cases where the amount of external contour correction was in doubt, the implant was fabricated slightly larger than the estimated ideal and modified slightly during surgery.

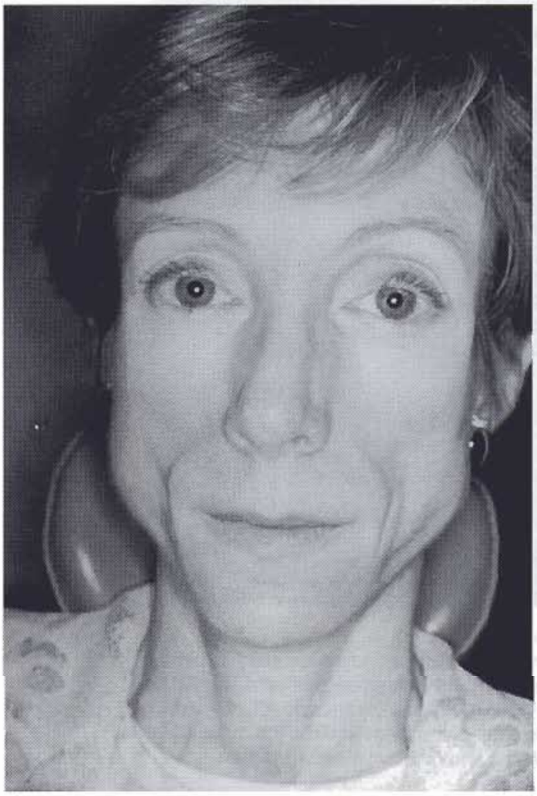


Figure 2. After anorexia nervosa, the resultant soft-tissue wasting (complicated by angular bone structure, masseteric hypertrophy, and the presence of a central chin implant) further accentuates the severity of the midfacial and lateral mandibular concavities.

CLINICAL EXPERIENCE

The current study was limited to 21 patients with complex and problematic aesthetic and acquired contour deformities. The use of custom implants was indispensable to provide the desired contour change in patients who had previously been unable to obtain successful results with grafts, implants, or other reconstructive modalities.

In conditions of severe overlying soft tissue discrepancy, successful implant design was also dependent on the individual surgeon's ability to estimate the amount of augmentation required and on precise measurement of the amount of soft tissue loss contributing to the topographic defect. In some cases a moulage was also helpful in obtaining the optimal configuration of the implant's external surface.

All patients were followed for 6 months to 3.5 years. The procedures were performed on an outpatient basis using standard surgical approaches. Landmarks, measurements, and correct implant design and placement were determined preoperatively using the anatomic models. Wherever possible incisions were placed in healthy tissue at some distance from the implant site. The implant's stability was achieved by the interlocking nature of the implant-bone interface that guided its exact placement and made internal or external fixation unnecessary.

CASE STUDIES

Case 1

A 41-year-old woman presented with permanent soft tissue and muscle wasting after recovery from anorexia nervosa that was complicated by vitamin A toxicity. Even after a 20-lb weight gain, the patient was unable to regain soft tissue mass in the face and had an emaciated facial appearance (Fig. 2).

Anatomic models of the mandible and maxilla were created and a moulage was used to estimate implant thickness and volume (Fig. 3*A*,*B*). The acute disease-induced changes in surface contour required extreme precision in

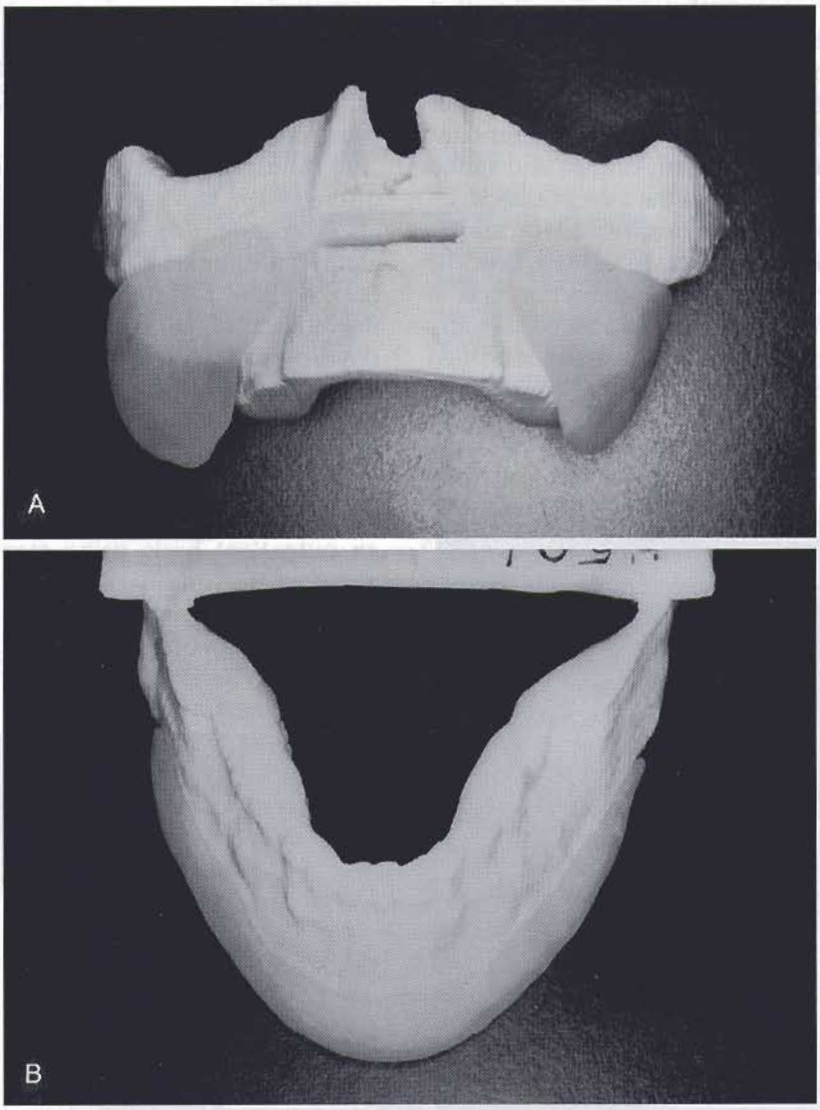


Figure 3. The maxillary and mandibular implants used in case 1 are shown in position on the anatomic models. *A,* A substantial portion of the maxillary implant is designed to extend inferiorly into the submalar space and over the masseter muscle. *B,* Numerous adjacent depressions and elevations in the lower half of the face required the mandibular implant to extend from angle to angle to establish a smooth, continuous contour.

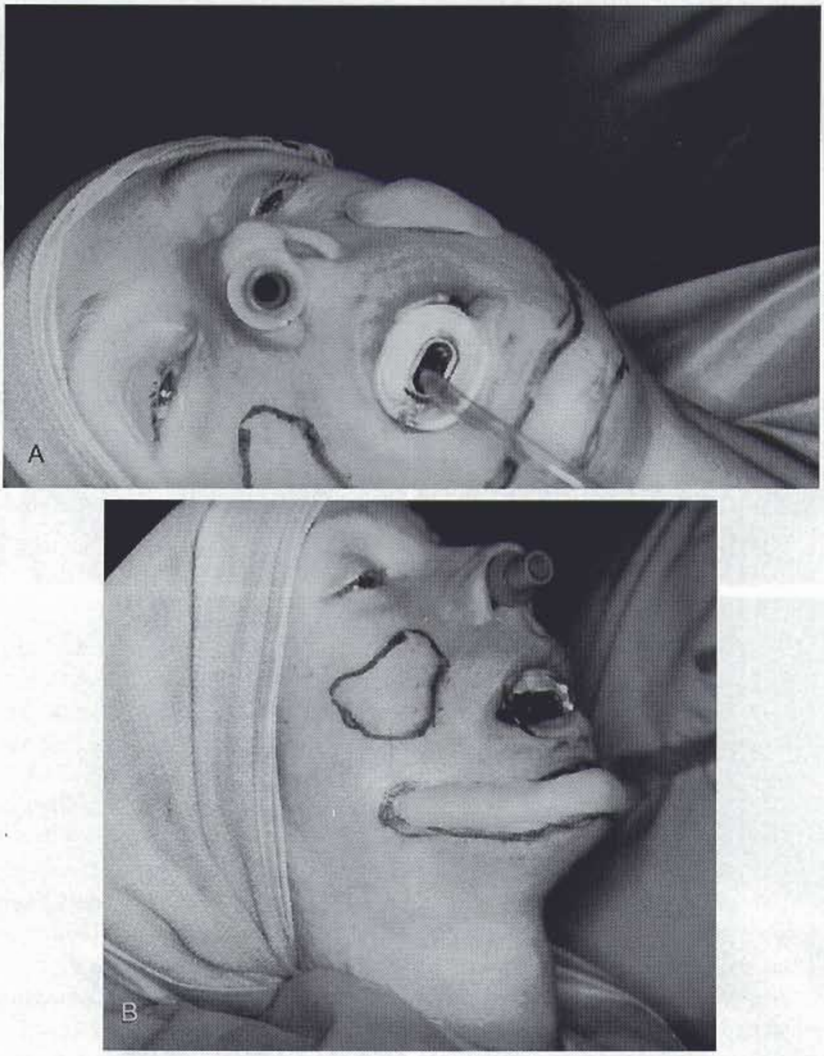


Figure 4. The implants, placed over the actual external defects during surgery. *A*, The thick medial component of the maxillary implants required abrupt transition to a finely tapered edge superiorly abutting the zygoma. *B*, Maximum width (vertical height) and thickness of the mandibular implant are matched to the deeper concavities along the lateral mandibular body.

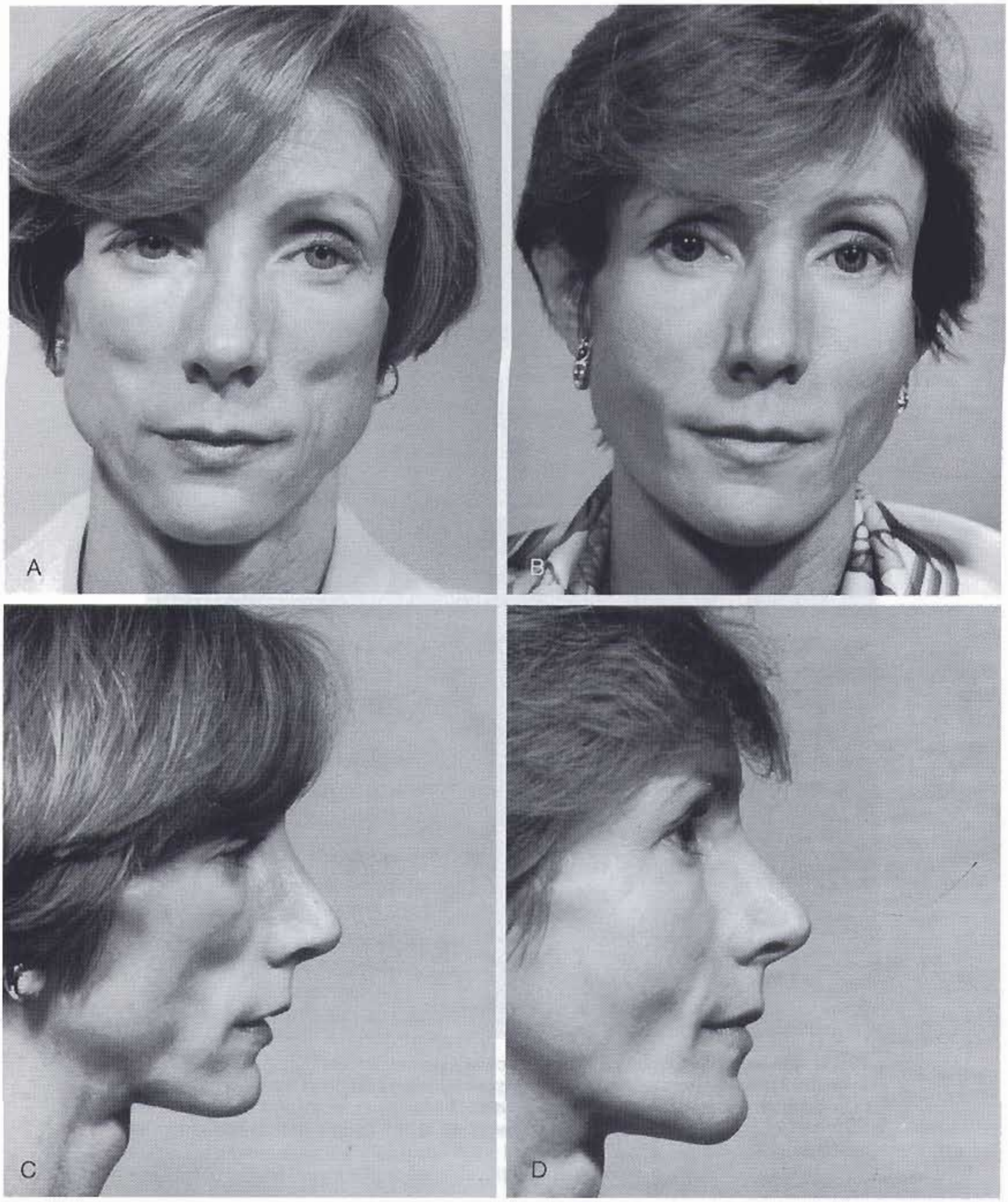


Figure 5. *See legend on opposite page*

Figure 5 *(Continued).* Case 1. Preoperative photographs *(A,C,E)* and the postoperative results 9 months after surgery *(B,D,F).*

implant design. The maxillary implants that were produced extend medially and inferiorly from the canine fossa and upper half of the masseter muscle to the zygoma superiorly and laterally (Fig. 4*A*). A third implant wraps around the mandible and extends from the posterior body of the mandible on the right side to the same position on the left side (Fig. 4*B*). An intraoral approach was used for the insertion of the maxillary and mandibular implants. Dissection was carried out in the subperiosteal plane and a previously inserted central chin implant was removed. The exact configuration of the posterior surfaces stabilized the implants without requiring additional fixation. The patient has been followed for 3.5 years and to date the implants remain stable, with no postoperative sequelae (Fig. 5*A–F*).

Case 2

A 45-year-old woman presented with an unusually severe periorbital soft tissue problem: the postoperative sequelae of two blepharoplasties and numerous chemical peels had caused severe atrophy, discoloration, and permanent wrinkling of the lower eyelid skin, dermis, and subcutaneous tissue. Other attempts to reconstruct this area, including fascial and dermal fat grafts and numerous fat injections, provided no improvement (Fig. 6).

Because these previous soft tissue procedures had not been effective, custom onlay implants were designed to change the configuration of the underlying periorbital skeletal structure and cause the lower eyelid and infraorbital skin to drape in a horizontal and lateral orientation, thus reducing the vertical extent of the deformity (Fig. 7). Due to the laxity of the lower eyelids, an intraoral approach was used to develop a pocket along the infraorbital rim, circumferentially dissecting out the infraorbital nerve. The precise fit to the bony contour correctly positioned the implants and required no fixation. There were no paresthesias of the infraorbital nerve or other postoperative complications. The patient has been followed for over 2.5 years; the implants

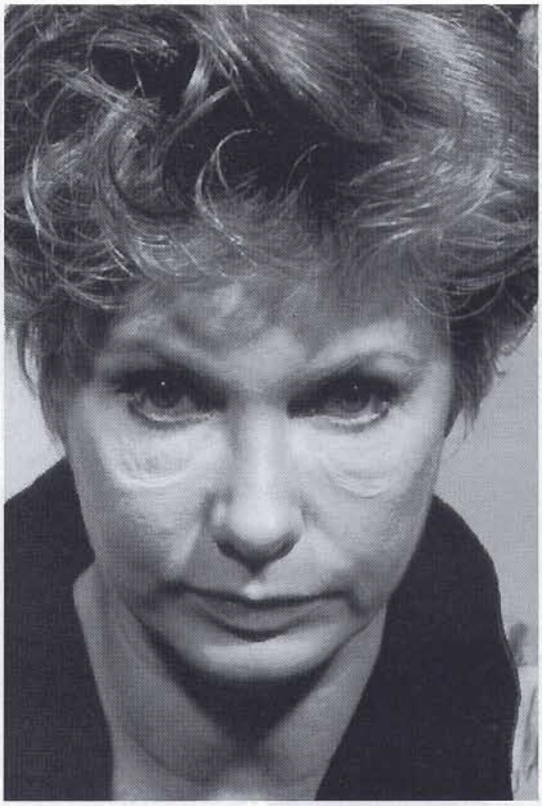


Figure 6. Case 2. Preoperative photograph. Due to severe atrophic skin changes, a distinct line of demarcation and obvious disfigurement developed between the damaged eyelid skin and the normal, thicker cheek skin.

remain stable and the results of surgery are maintained successfully (Fig. 8*A–D*).

Case 3

This 42-year-old man had undergone malar augmentation a few years prior to evaluation. The patient had two previous unsuccessful chin implant procedures after which the implants were removed each time. The laterally positioned malar implants were malpositioned, producing an unsatisfactory cosmetic result (Fig. 9*A,C,E*). Because the patient's personal circumstances necessitated performing a one-stage procedure, and with the existing implants camouflaging a major degree of underlying skeletal asymmetry, it was decided that the most accurate way to obtain a successful result was to design custom implants via the 3D imaging-modeling process.

After the CT scan was taken, a second set of 3D images was made that included the existing implants. The 3D radiograph showed that a portion of each malar implant was positioned above the orbital rim and encroaching on the orbit (Fig. 10).

After the model was obtained, wax templates were designed according to the underlying skeletal deficiencies. Augmentation was required in both the submalar and malar areas. The measurements taken of the existing implants from the computer image were used as a guide for approximating the thickness of

Figure 7. Intraoperatively, the implant positioned over the defect. The shape and thickness of the implant was designed to displace the skin in an anterior and lateral direction.

the custom implants over the malar region. This enabled the revisional midfacial augmentation to remove the old and insert the new custom implants in a one-stage procedure. A wraparound chin implant was also designed to balance the face by increasing the overall dimensions of the symphyseal and parasymphyseal portions of the mandible (Fig. 9*A–F*).

Review of Case Reports

In cases 1 and 2, onlay implants were used to treat specific facial deformities. In case 3 the onlay implants were used for the purpose of esthetic augmentation.

In case 1 the use of alloplastic implants was necessary to fill large voids permanently with mass sufficient to restore normal facial contour. Due to the extraordinarily thin integumentary covering, this patient presented major challenges for even partial attempts at contour restoration regardless of the modality used. Other forms of localized soft tissue atrophy are also seen after trauma, premature lipodystrophy, cachectic disease states, or facial liposuction. Such atrophy is acquired most commonly through the normal process of aging.[2,7,19]

In this patient, maxillary implant design required a thick medial component over the upper portion of the masseter muscle and lateral canine fossa that changes abruptly to a finely tapered and feathered edge abutting the sharp, prominent malar bones superiorly and laterally. A portion of the maxillary implant was designed to lock into place adjacent to bone, correctly positioning the implant, while the inferior portion of the implant, adjacent to the underlying masseter muscle, displaced the appropriate area of skin outward to achieve the desired contour change. The mandibular implant was designed to treat simultaneously a mild degree of anterior microgenia as well as the narrow lateral portions of the mandible. The lack of mobility caused by the precise fit of the implant-bone interface, particularly with the use of such large implants, helped to ensure a successful long-term result.

In case 2, the patient presented with an unusual but very distinct soft tissue deformity. Implants were used to change the draping and orientation of the skin from a vertical to a hor-

Figure 8. *A* and *C*, preoperative, and *B* and *D*, 11 months postoperative, demonstrating the severe periorbital integumentary disfigurement and the degree of permanent correction achieved by the implant procedure.

izontal position by augmenting the periorbital bone structure. The augmented contour also expanded the contracted, atrophic skin outward to a more superior and anterior location, additionally smoothing out some of the wrinkling and providing the appearance of an increase in soft tissue bulk to this area.

The patient described in case 3 presented with a problem often encountered in aesthetic facial contouring whereby implants already in place from previous surgery present unknown variables and camouflage existing asymmetries. Current software enables manipulation of the digital information provided by the CT scan so that the existing implants can be subtracted from the image to obtain a true 3D rendering of only the skeletal structure for more accurate analysis and optimal correction of skeletal asymmetry.[10]

DISCUSSION

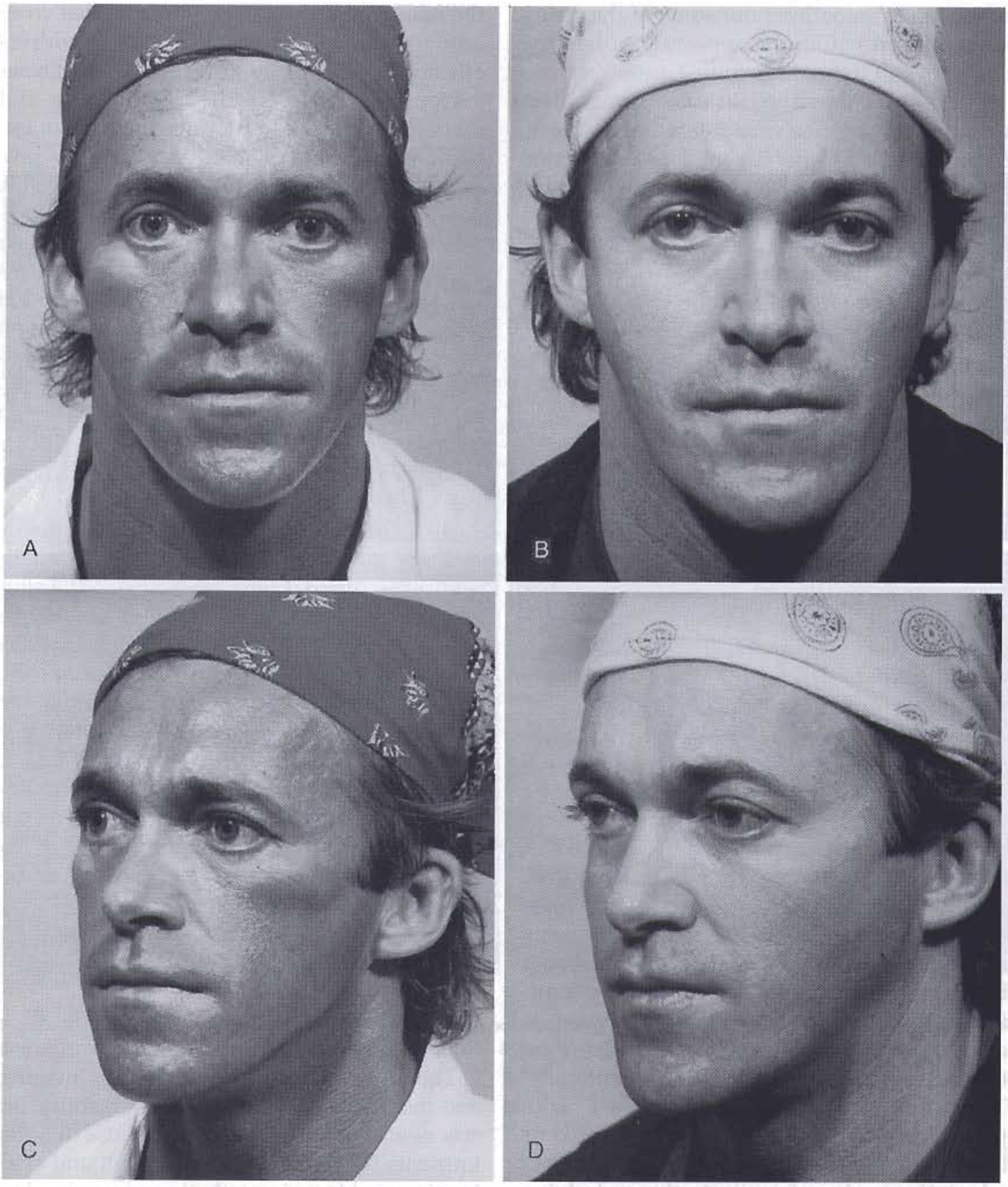
In properly selected cases where major functional or occlusal abnormalities are absent, adequate treatment of contour deficiencies may be rendered by simply using onlay grafts or implants to mask the deformity.[1,20] Although theoretically it is preferable to use the patient's own tissues when augmentation is desired, the disadvantages of doing so are many. There is no soft tissue material that can be guaranteed to last or retain its volume and stability as replacement for original tissue or abnormal structure. Harvesting autogenous bone or cartilage carries the risk of donor site morbidity. Accurately shaping and adapting bone or cartilage to fit a defect precisely is difficult and increases surgical time.[12] Used as onlay grafts, both bone and cartilage have extremely unpredictable rates of resorption.[8,13] The use of conventional "off-the-shelf" alloplastic implants or prefabricated implants based on a moulage have similar problems of adaptation and conformity to the underlying skeletal morphology, thereby remaining unstable and leaving residual rough edges that may often be conspicuous or palpable.[6,11,14]

The long-term success of using large implants or those placed over irregular topographic surfaces depends on implant conformity to the underlying bone base. 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 the more stable, commercially processed, heat-vulcanized silicone elastomer, in full compliance with all Food and Drug Administration (FDA) and Good Manufacturing Process standards and requirements. (Custom implants produced via the 3D imaging and modeling process are FDA-approved and commercially available as 3D-Accuscan [Implantech, Van Nuys, California]). This is significant because new FDA regulations prohibit on-site mixing of room-temperature-vulcanized silicone to produce self-fabricated implantable devices.

As a first step in the evolutionary integration of computerized imaging, laser scanning, and other modalities in facial contouring, physical models and supplemental moulages are used to predict appropriate implant size and shape for optimal correction of skeletal and soft tissue discrepancies.[18] Although variabilities in soft tissue distortion often preclude total reliance on any single technique, to date the method of 3D imaging and modeling has been reliable and accurate for successful correction of difficult problems in contour restoration that were, in some instances, considered untreatable.

CONCLUSION

The 3D state-of-the-art scanning, imaging, and modeling system increases versatility and sets new standards in design and use of onlay implants for treating many difficult and challenging problems in aesthetic and acquired facial contour deformities. It provides a complete reconstructive modality with reduced operative time that can be performed in an outpatient setting.



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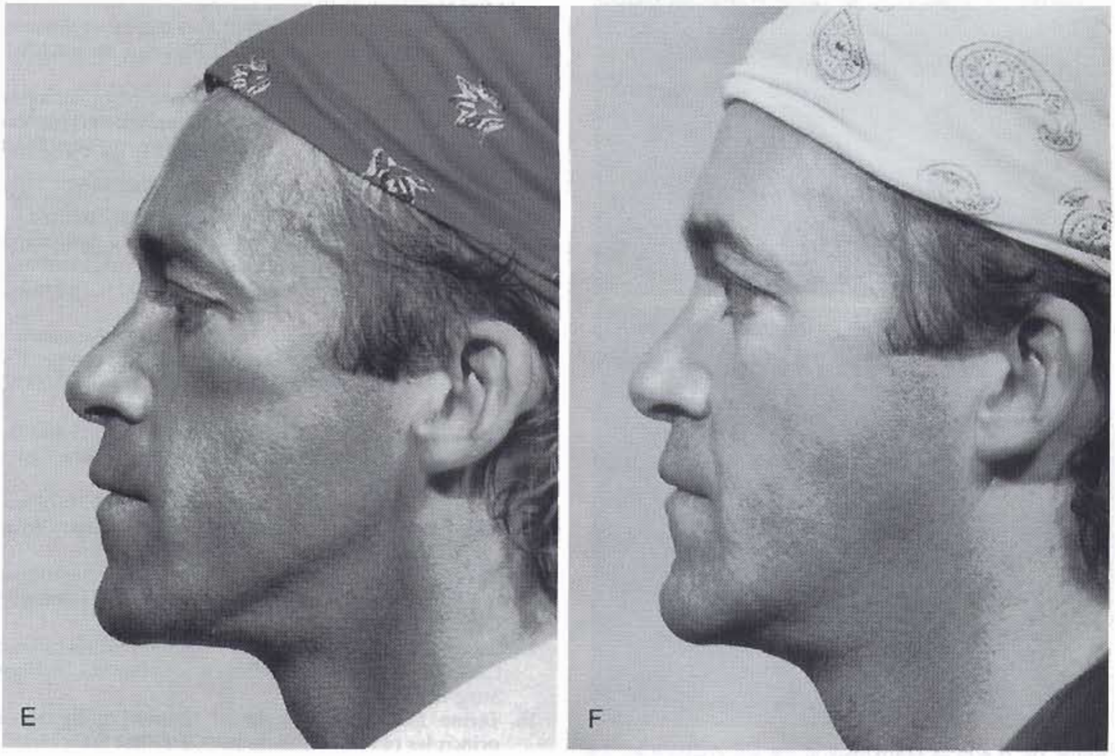

Figure 9 *(Continued).* Case 3. Preoperative *(A,C,E)* and 8 months postoperative *(B,D,F)* photographs. Removal of the existing malar implants and insertion of the custom midfacial (submalar-malar) implants and mandibular implant were performed in a one-stage procedure.

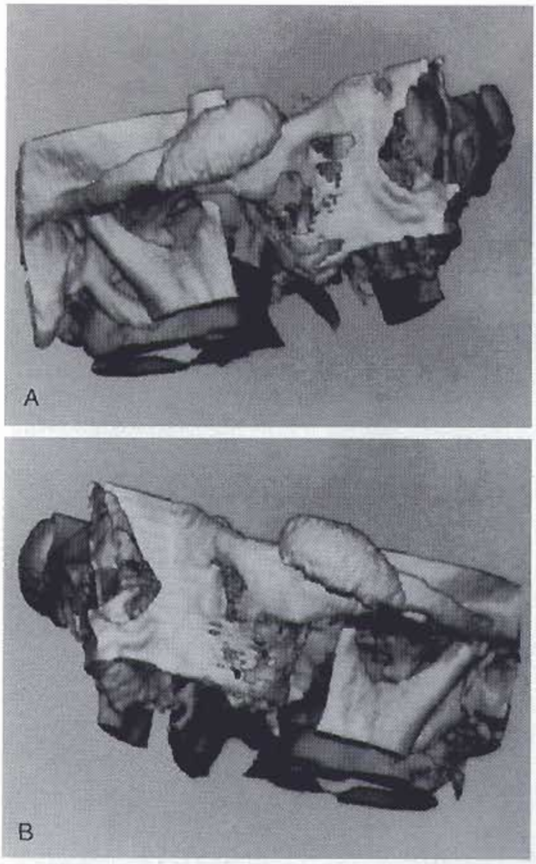

Figure 10. *A* and *B*, Manipulating the CT image from the computer workstation produced 3-dimensional radiographic reconstructions of the midface that included the existing implants. The implants are clearly shown to be malpositioned above both right and left infraorbital rims.

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Guest Editors' Comments

The editors would like to point out that it is only a matter of time until computer technology becomes totally integrated into the practice of facial plastic surgery. This article emphasizes the concept of using three-dimensional imaging and CAD/CAM technology to produce custom-designed implants for the treatment of facial contour deformities. The authors clearly illustrate the unique ability of the implant's posterior surface conforming exactly to the underlying bone mass of the actual deformity. The ability to produce customized implants, particularly in genetic and injury related asymmetries of the face, validates the importance of this article. By integrating and using emerging technologies in plastic surgery, the editors agree that we have just begun to touch the tip of the iceberg as it relates to alloplastic aesthetic and reconstructive procedures.