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FACIAL PLASTIC SURGERY CLINICS of North America

Facial Contouring and Alloplastic Implants

AUGUST
1994

Reconstruction of Posttraumatic and Congenital Facial Deformities with Three-Dimensional Computer-Assisted Custom-Designed Implants

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Reprinted from PLASTIC AND RECONSTRUCTIVE SURGERY *November 1994*

Reconstruction of Posttraumatic and Congenital Facial Deformities with Three-Dimensional Computer-Assisted Custom-Designed Implants

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The principles, method, and benefits of combining three-dimensional computed tomography (CT) and computer-aided design/computer-aided manufacture (CAD/CAM) technology for development of custom-designed prostheses are applied in the repair of posttraumatic and congenital facial contour deficiencies. Each prosthesis is generated to fit the bone defect exactly, with external contours adjusted to compensate for overlying soft-tissue disparities. Three representative case reports from a series of 17 demonstrate the applications and advantages of using this technique. Some patients had residual defects after primary repair of posttraumatic deformities. Others had defects after orthognathic relapses for congenital deformities. Without a relatively minor surgery and a high degree of predictability, many of these patients would not have pursued further treatment. All but one of the surgeries were performed on an outpatient basis, providing an accurate, simple, and cost-effective method of contour restoration with limited morbidity and reduced operative time. (*Plast. Reconstr. Surg.* 94: 775, 1994.)

Regardless of the surgical method chosen, accurate restoration of facial contour defects is a qualitative and quantitative challenge. Procuring precise implants or grafts for predictable reconstruction is equally demanding.

The kind of treatment rendered often depends on the treating surgeon: The oral maxillofacial or craniofacial surgeon tends to favor osteotomies and bone grafts, while others may propose the use of alloplasts, adjunctive soft-tissue procedures, or orthodontic surgery. Recently, basic tenets of orthognathic surgery have been challenged, whereby, in selected cases, the aesthetic outcome may take on greater importance than occlusal or functional considerations.[1–3] This trend points toward increased use of a broader range of alternative methods of treatment to solve traditional problems.

The complexity of head and neck anatomy, with overlapping shadows and magnification artifacts, defies accurate interpretation from information supplied by standard radiographs alone. Computed tomographic (CT) scanners have made standard x-ray analysis almost obsolete in the diagnosis and treatment planning of craniofacial abnormalities and maxillofacial trauma.

Recently, re-formatting of computerized data from CT scans into three-dimensional images has become more widely available.[4,5] These images offer an advanced tool for more accurate interpretation of skull and facial deformities and for a greater level of precision in the strategy and execution of complex craniofacial procedures.[6]

Linking this new imaging technology one step further to three-dimensional CAD/CAM software enables production of a life-sized model of the specific anatomic area, allowing the surgeon to analyze and examine spatial relationships in countless perspectives. The three-dimensional anatomic model is the foun-

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Presented at the 25th Annual Meeting of the American Society for Aesthetic Plastic Surgery, in Los Angeles, California, on May 7, 1992, and at the Annual Meeting of the American Academy of Facial Plastic and Reconstructive Surgeons, in Kansas City, Missouri, on September 27, 1991.

dation on which precise onlay implants are designed and fabricated. This results in enhanced implant stability, accuracy of placement and form, and a significantly greater refinement in facial contour restoration.

Technique

The surgeon must provide to the radiologist or CT technician specific instructions about the area to be encompassed in the CT scan. Commercial facilities that provide imaging or modeling services supply technical information, radiologic protocols, and a list of CT scanners compatible with this process (Cemax, Inc., Fremont, Calif.; Implantech Associates, Inc., Van Nuys, Calif.).

The area of maximal interest is scanned at minimum slice thicknesses; surrounding areas are scanned with low-dose techniques in contextual slices of greater thicknesses, thus ensuring complete CT assessment with minimal radiation exposure.[7] The imaging and modeling facility re-formats the CT data, generating an exact three-dimensional image of the anatomic structure. Any additional manipulation of data, such as mirror imaging or measurements, also may be performed at this time.

The re-formatted data are transferred via conversion CAD/CAM software to a milling machine to create the mold into which resin is poured to produce the anatomic model. Wax templates are then designed to fill defects or augment anatomic areas displayed by the model. In cases of concomitant soft-tissue deficiency, a moulage also may provide additional information in determining the configuration of the template's external surface.

Any aberrations surrounding the skeletal defect or variabilities in overlying soft tissue may be compensated for by manipulating the thickness, shape, and edges of this wax template. However, the posterior surface of the template remains constant. Once the wax template is completed, an exact replica is commercially produced as a stable, heat-vulcanized silicone elastomer implant.

Clinical Experience

Of 34 patients treated with implants fabricated by means of three-dimensional imaging and modeling, this study focuses on 10 patients with posttraumatic and 7 with congenital facial contour deficiencies. All patients were followed from 9 months to 4 years after surgery. In all patients, preoperative expectations were met or exceeded. The procedures achieved nearly 100 percent correction for specific defects limited to the bony skeleton. Where conditions of soft-tissue and/or bone loss also required augmentation, overall success of the procedure was ultimately determined by patient satisfaction and whether the results met the surgeon's original expectations.

Cases involving posttraumatic facial contour deficiencies are detailed in Table I. Seven cases of congenital facial contour deformities are presented in Table II. In some patients with prior, unsuccessful procedures, custom implants were indispensable for final resolution of the contour deficiencies. In one instance in which a secondary procedure was required, the availability of the anatomic model made it easy to produce a new implant (see Table II, case C1).

In patients with unilateral defects, the external contour of each implant was designed to match the contralateral normal bony prominence, thereby restoring symmetry. In many patients this proved to be an accurate and simple means to reconstruct difficult problems, while in others it was the only treatment that could provide a reasonable degree of success.

All but one of the surgeries were performed on an outpatient basis. Landmarks, measurements, and correct implant design and placement were determined preoperatively with the anatomic models. Whenever possible, incisions were placed in healthy tissue at some distance from the implant site or regions of excessive scarring. In each case, the fit between the implant's posterior surface and the underlying bone topography was so precise that it guided its exact placement. The enhanced stability obtained by the interlocking nature of the implant-bone interface made either internal or external fixation unnecessary.

Case Reports

Case 1

This patient is a 34-year-old woman who was involved in a motor vehicle accident and sustained a right Le Fort III fracture and multiple displaced, comminuted fractures of the anterior wall of the frontal sinus, nasal bones, right orbital rim, right zygoma, and both orbital floors with symptomatic diplopia. Open reduction and internal fixation of the acutely displaced facial fractures were performed initially (see Fig. 4, *left, above*), followed 3 months later by open reduction of the nasal fracture and septal reconstruction.

Eighteen months later, residual skeletal defects were

TABLE I
Posttraumatic Deformities Reconstructed with Custom Implants

Case	Age (years)	History	Implant Description	Results
T1	33	After primary repair of Le Fort II, III fractures. Bone loss and retrodisplaced orbitonasomaxillary complex. Facial dysfunction	Combined infraorbital and nasomaxillary: to fill in defect and augment frontal process and nasal bone	4 years postop; result maintained w/ return of normal function over facial defects
T2	33	Midforehead defect: crush injury over frontal sinus w/ bone loss	Midforehead	4 years postop; nonpalpable; return of normal function
T3	39	Zygomatic, infraorbital deformity; bone, ST loss	Onlay over zygoma	Bony defect restored; partial ST defect remained
T4	35	6 years s/p severe facial trauma: residual skeletal midface and R orbit deformity, ST loss, facial scarring. Rx: (1) scar revision plus rhinoplasty 1984–5, (2) tissue clay: 100% resorption 6 months (3) R periorbital reconstruction w/ custom implant 1991	For augmentation of R superior and lateral orbital ridge	3 years postop; results maintained; no complications
T5	44	Skeletal and soft tissue injury: infraorbital deformity	Combined zygomatic-periorbital	2 years postop; excellent contour obtained
T6	62	Depressed R zygomatic fracture	Right zygomatic complex; matched to L side	2 years postop; contour maintained
T7	62	R midfacial ST defect secondary to trauma	Designed to supplement ST defect	2 years postop; minor ST disparities remain
T8	45	Localized R lateral orbital rim defect	Site-specific; area less than 2 cm	1½ years postop; contour maintained
T9	70	S/p trauma R orbitomaxillary complex, loss of bone and posterior displaced premaxilla, alar retraction	Combined inferior orbital rim and premaxillary	14 months postop; stable; R alar position restored
T10	38	10 years s/p L zygomatic complex fracture w/ major bone loss, inferior displacement of inferior orbital rim	Combined L zygomatic-malar and inferior orbital rim	9 months postop; contour restored; sense of normal facial movement returned to area over bone defect

ST = soft tissue.

TABLE II
Congenital Deformities Reconstructed with Custom Implants

Case	Age (years)	History	Implant Description	Results
C1	33	Maxillonasal dysplasia; orthognathic correction rejected by patient Revision procedure via endonasal approach plus small lateral vestibular incisions via intraoral approach	Large premaxillary-midfacial plus supplemental lateral piriform added in secondary procedure	Extrusion of 1st implant in 3 mo., 3 yr, + 2 mo postop. follow-up for 2nd implant with excellent results (Fig. 6)
C2	38	S/p failure of ramus split and attempt at genioplasty for apparent mandibular asymmetry; 3-D model revealed condylar dysplasia as cause of asymmetry	Bilateral differentially sized mandibular body implants	2½ years postop; contour maintained w/ near symmetry
C3	51	Premaxillary deficiency	Premaxillary-midface	2¼ years postop; contour maintained
C4	34	Treacher-Collins syndrome—midface hypoplasia; resorption of bone grafts, relapse of orthognathic surgery	Posterior surface of implants made to fit over bone grafts	2 years postop; good contour maintained
C5	34	Micrognathia w/ relapse of anterior mandibular orthognathic procedure, residual mandibular deformity	Wrap-around mandibular implant to compensate for asymmetrical deformity	Minor 2nd procedure required to adjust inferior border of implant
C6	35	Treacher-Collins syndrome; infraorbital deformity s/p prior implant insertion	Periorbital	1½ years postop; good results; small ST discrepancy
C7	37	Congenital mandibular deformity; hemimandibular hypoplasia	Mandibular; compensate for asymmetrical mandibular deficiencies	9 months postop; excellent contour maintained

ST = soft tissue.

confined to the right orbitomaxillary and glabellar regions of the face, with posterior retraction of the right ala. The patient also had symptoms of facial dysfunction that were located over the areas of maximum bone loss.

In addition to the well-delineated bone defects, the anatomic model revealed a retrodisplacement of the right premaxillary-nasal complex that could not otherwise have been discerned preoperatively in so precise and quantitative a manner (Fig. 1). The maxillary wax template was devised to fill the defect and also match the normal contralateral left frontal process of the maxilla and nasal bone (Fig. 2). A second template was made to recontour the midforehead.

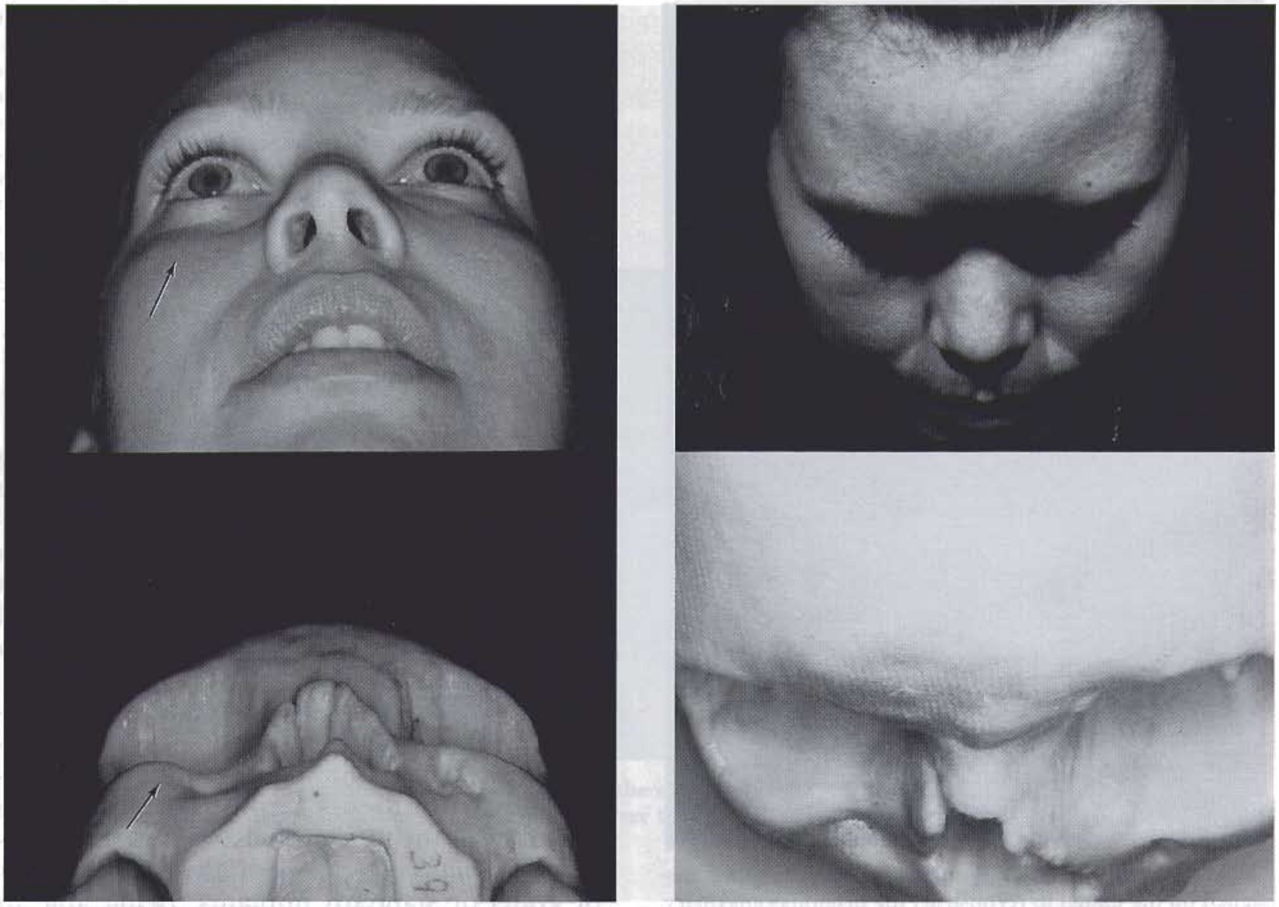

FIG. 1. *Case 1.* Two areas of residual surface contour defects 18 months after primary reconstruction: (*Above, left*) A bone defect presenting as a depression over the right infraorbital and nasomaxillary region (*arrow*). (*Below, left*) The defect in the anatomic model (*arrow*) directly corresponds to the clinical presentation above. (*Above, right*) The flattened area over the glabella and medial forehead corresponds to the bone defect within the glabellar area, illustrated by the anatomic model. (*Below, right*) In this view of the model, one can appreciate the degree of retrodisplacement of the right premaxillary-nasal complex.

During outpatient surgery, the right premaxillary defect was approached by means of an intraoral route and the midforehead defect by means of a coronal approach. Emphasis was placed on complete undermining and freeing of the periosteum, particularly if it was entrapped within old fracture sites. Once the implants were placed in position, the stability provided by the accurate fit between the implant and corresponding surface of bone made supplemental fixation with sutures or screws unnecessary (Fig. 3).

Fifteen-month postoperative photographs (Fig. 4) reveal the results. After 4 years of follow-up, there were no complications, the implants were nonpalpable and nondetectable, and the contour changes remained constant. The patient reported the return of normal facial function in the areas where the bone deficits were restored.

Case 2

This patient is a 34-year-old woman with congenital maxillonasal dysplasia ("dish face" deformity) (see Fig. 6). The patient, a dentist who was fully knowledgeable about the consequences of all potential surgical options, rejected orthognathic surgery and had already commenced orthodontic treatment. The three-dimensional computer modeling process was then used to design an implant for augmentation of the entire midface. In this patient, the anatomic model (Fig. 5, *left*) illustrates the severe retrusion and the abrupt changes in surface topography over the entire medial and premaxillary area.

Initially, a single premaxillary implant was designed on the model and inserted through a long intraoral vestibular incision, leaving only a small cuff of mucosa for closure. Augmentation rhinoplasty was performed 5 weeks later. Approximately 3 weeks after the nasal procedure, an area of dehiscence developed in the vestibular incision, necessitating removal of the implant.

Four months later, a similar premaxillary implant was inserted through an intranasal septocolumella incision (see Fig. 5, *right*). Two small buccal-gingival incisions were made to help position lateral segments of the implant and to add two small supplemental implants along the superolateral aspect of the piriform aperture. This approach left the majority of underlying vestibular mucosa completely intact. The implants conformed exactly to the defect and required no fixation.

Eleven-month postoperative pictures indicate the effect of premaxillary augmentation. The amount of anterior projection obtained over the premaxilla is demonstrated by the degree of vertical reorientation of the upper lip (Fig. 6, *above, right*). Three and one-half years following surgery confirmed

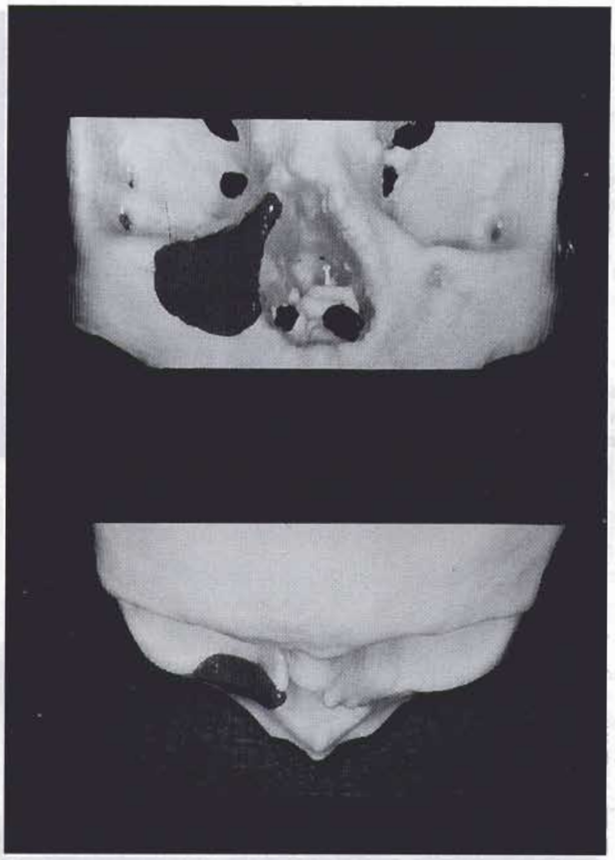

FIG. 2. *Case 1.* (*Above*) Frontal view with template designed on the model to reconstruct the orbitonasomaxillary defect. (The infraorbital nerve, avulsed in the primary injury, was not a factor in the design of the template). (*Below*) The template fills the bone defect and also compensates for the right posterior nasomaxillary displacement by matching its structure to the normal contralateral side.

no untoward postoperative sequelae and the implants and aesthetic improvement remain stable.

Case 3

This patient is a 38-year-old woman with a congenital mandibular deformity who had orthognathic surgery at age 27. Without rigid fixation or bone grafting, relapse of the osteotomy of the left mandibular ramus occurred within 6 months, with recurrence of the preoperative side-to-side motion of the mandible upon opening and closing the mouth.[8] Eight years later, a sliding genioplasty was attempted for treating the residual mandibular asymmetry and narrow chin, but was aborted immediately after the degloving procedure.

Two years later, the patient was referred to the senior author for correction of the mandibular deformity (Fig. 7, *left*). Physical examination revealed differing degrees of asymmetry dependent on the position of the mandible. With the mouth in a closed position, there appeared to be obvious asymmetry. With the mouth open, the mandible lined up in a more symmetrical midline position (Fig. 7, *center*).

An anatomic model of the mandible was obtained, showing the presence of a major degree of left condylar dysplasia and minor degrees of skeletal asymmetry of the symphyseal and parasymphyseal areas (Fig. 8). The patient rejected reosteotomy and repositioning of the mandibular condyle as a surgical option. Treatment consisted of the fabrication of differentially sized right and left implants to compensate for the variable skeletal and soft-tissue disparities on both sides of the mandible. The implants were inserted by means of an intraoral approach into subperiosteal pockets. The posterior surface of each implant, which matched the bone surface, guided the implants into the correct position along the body of the mandible. Conventional submalar augmentation also was performed. Nine-month postoperative results are presented in Figure 7 (*right*). The patient has been followed for 26 months, and the implants remain stable and provide the patient with satisfactory aesthetic results.

REVIEW OF THE CASE REPORTS

The preceding cases, although presenting different histories and problems, all have some element in common. Without the three-dimensional CAD/CAM model and implant design process, satisfactory diagnosis would have been more difficult and the degree of accuracy and quality and longevity of the reconstruction would have been unobtainable.

Case 1 illustrates the advantages of this process in the treatment of complex, finite posttraumatic facial contour deformities. The custom onlay prosthetics reconstructed the bone defects over the infraorbital and glabellar areas without incurring postoperative irregularities of grafts or standard implants. Being able to design the template prior to surgery to overlap margins around the bone defects or feather their edges renders the implant virtually nondetectable. Of particular significance was the patient's awareness of the return of normal facial function. Subsequent to this case, improvement in symptoms of facial dysfunction were reported by other patients who had posttraumatic facial contour defects restored by similar methods (see Table I, case T10).

The clinical picture in case 2 of congenital maxillonasal dysplasia consists of a retruded nasal base, midfacial concavity, and varying degrees of malar abnormality with or without cleft palate.[9,10] Surgical treatment of midline facial deformities includes bony segmental repositioning or onlay implants and grafts to mask the deformity.[11] Bimaxillary advancement must be considered with major occlusal abnormalities. However, limitations in the amount of aesthetic augmentation achievable or adverse secondary changes such as broadening of the nasal base also must be considered when determining the desired type of treatment.[12]

Autografts such as bone, cartilage, fat, and dermal grafts placed over the premaxillary area

FIG. 3. *Case 1.* (*Left*) An intraoral approach used to access the maxillary defect shows the implant being positioned. (*Right*) A coronal approach was used for placement of the implant over the midforehead.

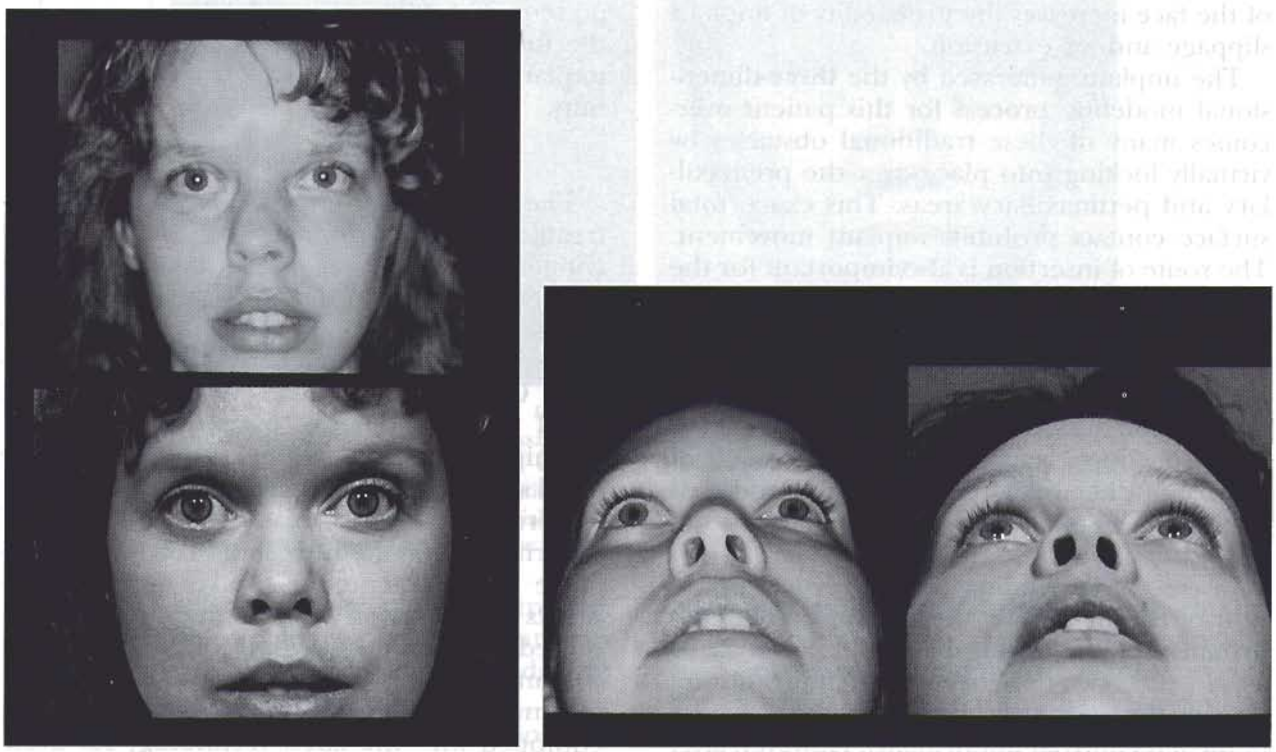

FIG. 4. *Case 1.* (*Above, left*) Preoperative view. (*Below, left*) Postoperative view. (*Right*) Preoperative (*left*) and postoperative (*right*) views. At 15 months after implant surgery, the postoperative photographs reveal complete reconstruction of the right orbitomaxillary and midforehead defects.

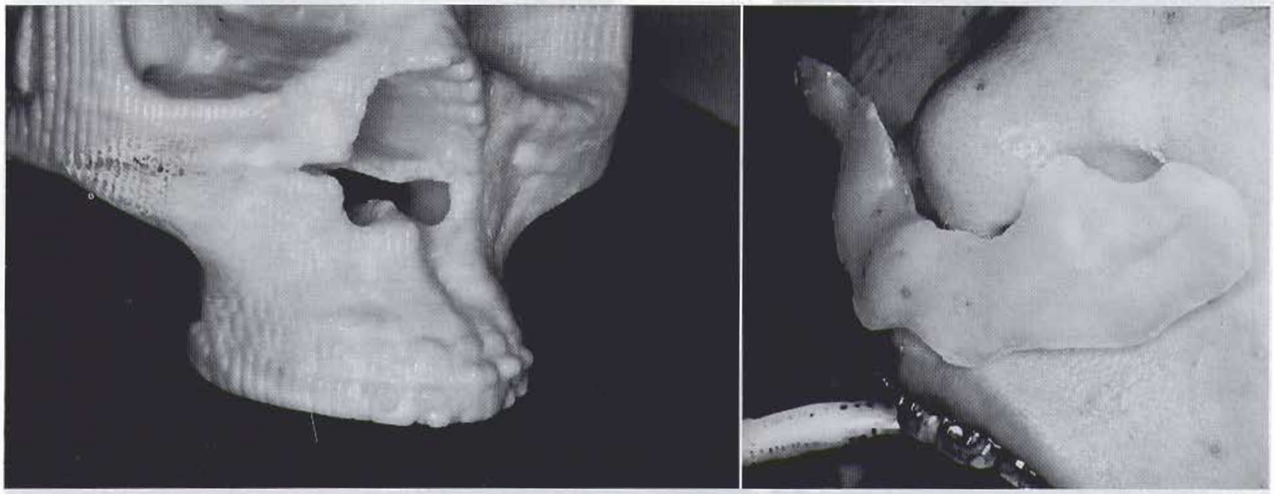

FIG. 5. *Case 2.* (*Left*) The anatomic model displays abrupt and jagged surface changes over the premaxilla and demonstrates the difficulty of stabilizing conventional implants or grafts in this area. (*Right*) Implant placed over the premaxilla during surgery. The molding process generates the implant to adapt to the irregular surface, providing nearly 100 percent contact between bone and implant.

all have high rates of resorption.[13] Perinasal and subnasal alloplastic implants are used most often during rhinoplasty to treat mild to moderate premaxillary deformities.[14,15] However, carving or fabricating implants to fit the irregular bone surface of the premaxillary and subnasal area is difficult. An inaccurate fit that places an unstable or hypermobile implant over any area of the face increases the probability of implant slippage and/or extrusion.

The implant generated by the three-dimensional modeling process for this patient overcomes many of these traditional obstacles by virtually locking into place over the premaxillary and perimaxillary areas. This exact, total surface contact prohibits implant movement. The route of insertion is also important for the successful outcome of implant procedures. After analysis of other patients with premaxillary implants and long-term follow-up after the second procedure, it also was concluded that the location and size of the incision during the first procedure, leaving an inadequate cuff of mucosa, rather than the site of placement or size of the implant, was the primary cause of wound dehiscence.

In case 3, depending on the vertical excursion of the mandible, the patient exhibited a dynamic and confusing picture of lower facial asymmetry. Two-dimensional CT films did not provide the means to appreciate fully the extent of the left condylar abnormality. However, after obtaining the anatomic model and analyzing the actual deformity, a correlation with the clinical picture was possible. Therefore, physical examination of the anatomic model proved essential for making the correct diagnosis and determining potential treatment plans.

It was concluded that the variability in symmetry resulted from lateral positional changes caused by the dysplastic condyle and in part from loss of soft tissue adjacent to an abnormally small and pointed soft-tissue chin component. The anatomic model was then used as the foundation for designing the mandibular implants ultimately used to correct the deformity.

DISCUSSION

The physical and emotional impact of untreated facial deformity caused by trauma or congenital causes makes it imperative that the surgical modalities selected be accurate and predictable. In large deformities, the need for repair is obvious, but few patients expect perfection. Correction of small- to moderate-sized facial contour defects, particularly those in prominent locations, under thin skin, or with small surface irregularities, leaves little latitude for error. Therefore, many of these types of deformities may go untreated because of reluctance to use osteotomies, onlay grafts, or implants that cannot provide the precision required to achieve successful long-term results.

Many patients with maxillofacial injury arrive in smaller medical centers that are not equipped with the latest technology for accurate diagnosis of complex facial fractures, nor do they have the availability of trauma teams to treat acute facial injuries properly in a timely

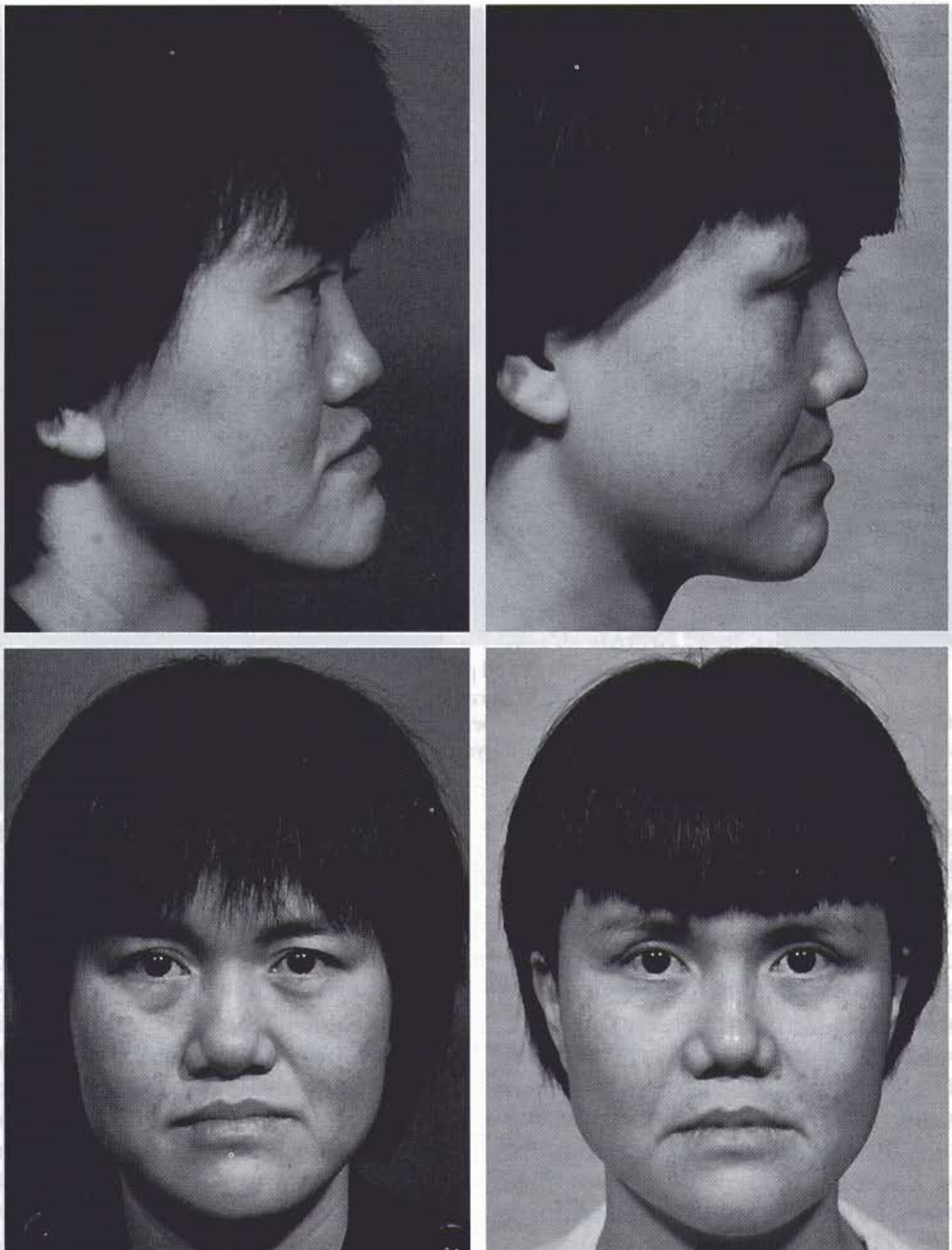

FIG. 6. *Case 2.* (*Above and below, left*) Preoperative views. (*Above and below, right*) Views 11 months postoperatively, after premaxillary augmentation, augmentation rhinoplasty, and upper blepharoplasty. Preoperative lateral view shows the marked degree of maxillonasal dysplasia illustrated by the horizontal inclination of the upper lip. Postoperatively, augmentation alone corrected the entire medial midfacial defect, the implants conforming precisely to a complex anatomic area without movement or displacement.

manner. Facial fractures also may go untreated because of life-threatening injuries that preclude additional surgical intervention during the immediate posttraumatic period.

In moderate to severe cases of maxillofacial trauma, a high rate of malunion, displacement, postoperative asymmetry, and problems in facial contour is often the result.[16] Even with adequate and timely management, comminuted bone fragments or incomplete reduction may cause late resorption or collapse, precipitating noticeable deformity that may not become apparent until months later.[17,18]

Late osteotomies and bony repositioning to correct zygomatic and periorbital deformities may incur external facial incisions, varying

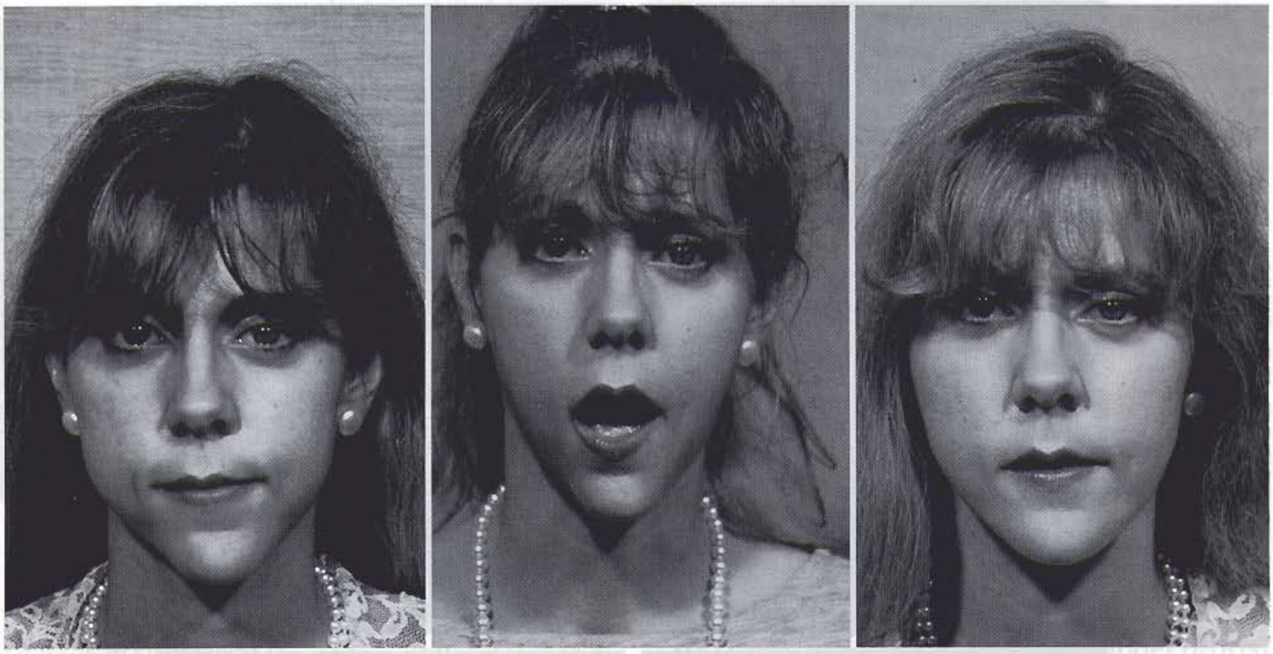

FIG. 7. *Case 3.* (*Left*) Preoperative view of mandible in closed position. Asymmetrical appearance due to left condylar dysplasia, a narrow anterior mandible, soft-tissue loss over the right parasymphysis, and a small soft-tissue chin button. (*Center*) Preoperatively, the mandible appears more symmetrical in an open position. (*Right*) Nine months postoperatively. The use of differentially sized and placed onlay implants balances out asymmetrical and abnormal mandibular contours.

degrees of morbidity, and a relatively high rate of skeletal relapse and bone resorption.[19] In orthognathic procedures, 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.[1,20] It is these inconsistencies of overlying soft-tissue change that can diminish the outcome of an otherwise correctly planned and well-executed skeletal procedure.

It is generally easier to predict soft-tissue displacement following direct augmentation using grafts or implants than with osteotomies and segmental bony repositioning. Therefore, in properly selected patients in whom major occlusal or functional abnormalities are absent, adequate treatment may be rendered with less extensive reconstructive procedures by simply masking the deformity with the use of onlay grafts or implants.[21,22]

Although preferable, bone or cartilage autografts undergo unpredictable amounts of resorption.[23,24] Harvesting autogenous bone or cartilage carries the additional disadvantage of donor-site morbidity. Carving either one to fit a particular defect is extremely difficult, prolongs operating room time, and incurs increased hospital costs.[25]

When used for the purpose of onlay restorations, biocompatible alloplastic implants are more predictable and durable than autogenous grafts. However, trying to carve blocks of alloplastic material to fit irregular skeletal defects is also difficult, time-consuming, and yields less than optimal results. Modifying "off-the-shelf" implants suffers from the same lack of adaptation and conformity to the underlying bone morphology, leaving rough edges that are often conspicuous or palpable.[17] Conventional moulage methods of fabricating custom implants use the skin surface as the base contour of the implant. Therefore, these implants also will remain unstable because of the uneven contact existing in the implant-bone interface.[26–28]

The most significant advantage of the custom implants produced by means of the three-dimensional imaging and modeling process is the accuracy of the posterior implant surface in conforming to the underlying bone. With the rapid advances being made in computer graphics and diagnostic imaging, we can certainly anticipate that within the near future the computer will assume a much greater role in determining implant design. Currently, the limitations of CT resolution and software analysis of complex spatial relationships restrict the reliability of the computer alone to produce a completely effective implant. The infinite variations in overlying integument also pose formidable challenges for the computer to accurately

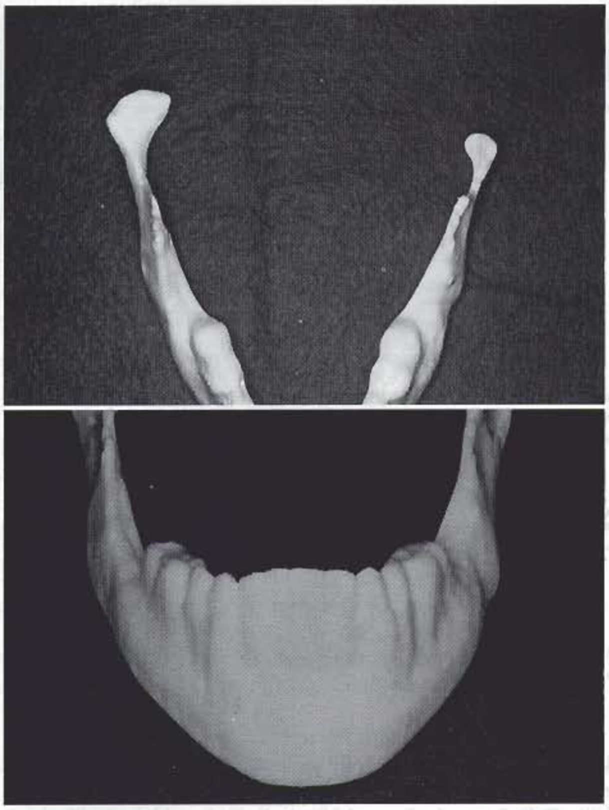

FIG. 8. *Case 3.* (*Above*) The model proved invaluable for establishing the correct diagnosis by demonstrating left condylar dysplasia as the major anatomic defect. (*Below*) The model also revealed the skeletal structure of the anterior portion of the mandible to be minimally asymmetric.

analyze and predict external contour changes produced by insertion of an implant or graft between bone and soft tissue. This assessment is still best done by visual estimate and direct measurement.

To resolve some of the limitations in implant design, we have combined computer imaging and modeling with manual surface molding techniques. The anatomic model displays the deformity; visual and physical analyses then ascertain the need for any additional design modifications in the template. Molding the wax template on the actual anatomic model factors in minor discrepancies that cannot be appreciated by the computer image alone. This additional step ensures a smooth transition from the borders of the implant to the surrounding aberrations of the defect and further reduces the propensity for implant movement. This process also allows for appropriate changes to be made in implant volume and projection to either compensate for soft-tissue loss or obtain a desired amount of augmentation.

Although different biomaterials can be used for augmentation, only a few work with the three-dimensional imaging–CAD/CAM process for the fabrication of custom prosthetic devices. The material must be relatively inert, noncarcinogenic, flexible, and easily carved or modified if further refinements are necessary at the time of surgery. It is preferred that the implant be nonporous for greater resistance to infection.[18]

Coralline-derived porous hydroxyapatite (Interpore-200) is brittle, prevents adequate milling, and has not been reliable when used as an onlay graft material in block form.[29,30] Rigid, inflexible implants such as methyl methacrylate or Medpor are unsuitable for facial contouring procedures that require large implants to retain properties of compressibility and flexibility to fit through small openings or adapt to gross surface changes. Polytetrafluoroethylene (PTFE, Proplast HA) was not considered suitable for use in the three-dimensional process and is no longer commercially available.[31]

At the present time, we have found silicone elastomer (rubber) to be the best FDA-approved biomaterial that can fulfill most of the ideal implant qualities and satisfy the demands of the custom molding process. Silicone rubber can be compressed without losing shape and detail and is flexible enough to adapt to gross surface changes.

Recent FDA regulations, recognizing certain aspects of silicone elastomer and its manufacturing process that enhance or detract from its purity and reactivity, have prohibited use of the compounds for on-site mixing of RTV (room-temperature-vulcanizing) silicone in producing self-fabricated implantable devices. Brantley et al.[32] also implicated the interaction of implant impurities with lymphoid cells as a possible cause for haptogenic effects. Therefore, the use of the traditional moulage methods of on-site custom implant fabrication is no longer possible.

Most facial implants, including the custom implants designed by means of the three-dimensional modeling process, are commercially produced by the heat-vulcanized method. This process implements strict sets of manufacturing guidelines for the production of a solid silicone elastomer that is purer, harder, and tougher than RTV silicone and meets FDA certification for general use and distribution. The custom implants are produced by means of the three-dimensional imaging–CAD/CAM process; they are FDA-approved and commercially available as 3D-Accuscan Implantech Associates, Inc., Van Nuys, Calif.).

The use of custom implants generated by three-dimensional CT imaging and modeling has proved to be a powerful tool that has greatly enhanced our ability to achieve better results in facial contour restoration. It has substantially reduced the need to carve and shape implants or grafts during surgery. This decreases surgical time, reduces the costs of operating room use, and in most cases eliminates hospitalization. In the current climate of declining health care coverage and rising costs of hospitalization, it is imperative that appropriate alternative procedures be available that are surgically effective and provide the patient with a meaningful aesthetic improvement.

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