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 to the repair of posttraumatic and congenital facial cosmetic deficiencies. Each prosthesis is generated to fit the bone defect; exactly, with excusal contours adjusted to compensate for overlapping soft-tissue disarticulations. Representative case reports from a series of 17 demonstrate the advantages and applications of using this technique. Some patients had cranial 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 passed further treatment. All but one of the surgeries were performed on an outpatient basis, providing a secure, simple, and cost-effective method of cosmetic restoration with limited morbidity and reduced operative time. (Plast. Reconst. Surg. 94:775, 1994.)

Regardless of the surgical method chosen, accurate restoration of facial contour defects is a qualitative and quantitative challenge. Acquiring 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. 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, reformatting of computerized data from CT scans into three-dimensional images has become more widely available. 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.

Linking this new imaging technology one step further to three-dimensional CAD/CAM software enables reproduction of a life-sized model of the specific anatomic area, allowing the surgeon to analyze and visualize spatial relationships in countless perspectives. The three-dimensional anatomic model is the foun-
dation on which precise onlay implants are
designed and fabricated. This results in en-
hanced implant stability, accuracy of placement
and form, and a significantly greater refine-
ment 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. Com-
mercial facilities that provide imaging or mod-
eling services supply technical information,
radiologic protocols, and a list of CT scanners
compatible with this process (Cermax 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 con-
tinuous slices of greater thickness, thus ensur-
ing complete CT assessment with minimal ra-
diation exposure. 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
Computer Aided Design/Computer Aided Manu-
facture (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 fit defects or
augment anatomic areas displayed by the
model. In cases of concomitant soft-tissue de-

ciciency, a moulage also may provide additional
information is 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 thick-
ness, 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
clastomer implant.

**CLINICAL EXPERIENCE**

Of 34 patients treated with implants fabri-
cated 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 augmenta-
tion, 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 im-
plants 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 CI).

In patients with unilateral defects, the exter-
nal contour of each implant was designed to
match the contralateral normal bony promi-
nence, thereby retorting 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, measure-
ments, and correct implant design and place-
ment were determined preoperatively with the
anatomic model. 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 I

The patient is a 34-year-old woman who was involved in a
motor vehicle accident and sustained a right Le Fort I
fracture and multiple displaced comminuted fractures of
the anterior wall of the frontal sinus, maxillary 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 nasal reconstruction.

Eighteen months later, residual skeletal defects were
TABLE I

<table>
<thead>
<tr>
<th>Age</th>
<th>Lesion Description</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>35</td>
<td>Allous primary repair of Le Fort II, III fractures. Bone loss and retromolar trigone hyperplasty complex, Facial disfigurement</td>
</tr>
<tr>
<td>T2</td>
<td>35</td>
<td>Midline buccal defect: crush injury versus frontal sinus w/ bone less</td>
</tr>
<tr>
<td>T3</td>
<td>30</td>
<td>Zygomatic, infraorbital, bone, ST less</td>
</tr>
<tr>
<td>T4</td>
<td>20</td>
<td>5 yrs post operative facial trauma: craniocerebral soft tissues and R orbit defect ST less, for repair ST plus endoscopy (6/12)</td>
</tr>
<tr>
<td>T5</td>
<td>44</td>
<td>Orbital and soft tissue injury: infraorbital fracture</td>
</tr>
<tr>
<td>T6</td>
<td>62</td>
<td>Deepened R zygomatic fracture</td>
</tr>
<tr>
<td>T7</td>
<td>62</td>
<td>R malaligned ST defect secondary to trauma</td>
</tr>
<tr>
<td>T8</td>
<td>45</td>
<td>Localized R lateral orbital rim defect</td>
</tr>
<tr>
<td>T9</td>
<td>70</td>
<td>5 yrs status O (orbital cavity complex, loss of bone and prosthesis displaced pterygoid, +/− ran start)</td>
</tr>
<tr>
<td>T42</td>
<td>35</td>
<td>5 yrs post L (zygomatic complex fracture w/ range bone loss, inferior displacement of inferior orbit)</td>
</tr>
</tbody>
</table>

ST = soft tissue.

TABLE II

<table>
<thead>
<tr>
<th>Age</th>
<th>Lesion Description</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>33</td>
<td>Mandibular stylopore orthognathic correction repaired by patient</td>
</tr>
<tr>
<td>C2</td>
<td>35</td>
<td>5 yrs follow lysis stain and sent to gastroscopy for apparent mandibular asymmetry: SD model needed costal cartilage during cause of asymmetry</td>
</tr>
<tr>
<td>C3</td>
<td>51</td>
<td>Premaxillary correction</td>
</tr>
<tr>
<td>C4</td>
<td>54</td>
<td>Trencher-Gamma syndrome—midfacial hypoplasia: resorption of bone grafts, relapse of sub-symphysis cleft with ambiguity</td>
</tr>
<tr>
<td>C5</td>
<td>54</td>
<td>Micrognathia w/ agenesis of specific mandibular orthognathic procedure w/ mandibular deformity</td>
</tr>
<tr>
<td>C6</td>
<td>55</td>
<td>Trencher-Gamma syndrome: infraorbital defeat w/ prior implant wounds</td>
</tr>
<tr>
<td>C7</td>
<td>57</td>
<td>Congenital mandibular deformity, hemimandible hypoplasia</td>
</tr>
</tbody>
</table>

ST = soft tissue.

confined to the right orbitomalarial and glabellar regions of the face, with posterior extraction of the right ala. The patient 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 remodelling of the right

orthognathic and soft tissue complex that could not otherwise have been determined preoperatively in as precise and quantitative a manner (Fig 1). The midfacial care was devoted 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 reconstruct the midfacial.
During operative surgery, the right premaxillary defect was approached by means of an introral 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 secure fit between the implant and corresponding surface of bone made supplemental fixation with wires or screws unnecessary (Fig. 3).

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

Case 2

This patient is a 34-year-old woman with congenital maxilloonasal dysplasia ("dolphin 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 modelling 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 reversion and the abrupt changes in surface topography over the entire midfacial and premaxillary area.

Initially, a single premaxillary implant was designed on the model and inserted through a long introral 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 bicalar gingival incisions were made to help position lateral segments of the implant and to add two small supplemental implants along the superior lateral 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 recreation of the upper lip (Fig. 6, above, right). Three and one-half years following surgery confirmed...
no upward 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 protractive side-to-side motion of the mandible upon opening and closing the mouth. 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 kissing 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 symphysis and parasympyseal areas (Fig. 8). The patient elected reconstruction and repositioning of the mandibular condyle as a surgical option. Treatment consisted of the fabrication of different-sized right and left implants to compensate for the variable skeletal and subcutaneous disparities on both sides of the mandible. The implants were inserted in a manner similar to the submaxillary pocket. 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 subperiosteal augmentation was performed. Nineteen-month postoperative results are presented in Figure 7 (right). The patient has been followed for 26 months, and the implants remain stable and provide patient satisfaction 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 unattainable. Case 1 illustrates the advantages of this process in the treatment of complex, finite posttraumatic facial contour deformities. The custom onlay prosthetics reconstituted 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 non-detectable. 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 post-traumatic facial contour defects restored by similar methods (see Table I, case T10).

The clinical picture in case 2 of congenital maxillary atrophy dysplasia consists of a remodeled nasal base, midfacial concavity, and varying degrees of malar abnormality with or without cleft palate. Surgical treatment of midline facial deformities includes bony segmental repositioning or onlay implants and grafts to mask the deformity. 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. Antografts such as bone, cartilage, fat, and dermal grafts placed over the premaxillary area
FIG. 3. Case 1. (Left) An intracanal approach was 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.
all have high rates of resorption.19 Perinasal and subnasal alloplastic implants are used most often during rhinoplasty to treat mild to moderate premaxillary deformities.13,20 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 laying into place over the premaxillary and perinasal 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 was also 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 site 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 asymmetry. 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 less of soft tissue adjacent to an abnormally small and pocketed 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
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. 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.

Late osteotomies and bony repositioning to correct zygomatic and periorbital deformities may incur external facial incisions, varying
degrees of morbidity, and a relatively high rate of skeletal relapse and bone resorption.\textsuperscript{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.\textsuperscript{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.\textsuperscript{3,21}

Although pretoable bone or cartilage autografts undergo unpredictable amounts of resorption,\textsuperscript{22}\textsuperscript{23} 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.\textsuperscript{24}

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 severe lack of adaptation and conformity to the underlying bone morphology, leaving rough edges that are often conspicuous or palpable.\textsuperscript{17} Conventional modeling 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.\textsuperscript{26}–\textsuperscript{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 C.T. evaluation 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
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.25

Coralline-derived porous hydroxyapatite (In- terpore-200) is brittle, prevents adequate milling, and has not been reliable when used as an onlay graft material in block form.28,29 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.30

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. Beaulieu et al.31 also implicated the interaction of implant impurities with lymphoid cells as a possible cause for hyperergic effects. Therefore, the use of the traditional nasolabial 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.

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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