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Internet Access to Advanced 3-Dimensional Software for the Prototyping and Design of Complex and Precise Custom Mandibular Implants

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Abstract

A large percentage of patients with microgenia requesting chin augmentation also exhibit an associated component of micrognathia with either narrow or acutely angled mandibular bodies and/or hypoplasia of the gonial angles. Augmentation of the face and mandible should optimally address all regions of deficiency and can now be customized with a high degree of accuracy using software that can be accessed over the Internet. We discuss the advanced capabilities of merging a sophisticated software system (Geometric Freeform® software; Morrisville, North Carolina) and computed tomography (CT) imaging to design precise, total custom mandibular implants over the Internet without the need for physical modeling. In revision cases, this process also allowed for the implant to be removed and replaced within a single-stage procedure. We retrospectively reviewed 34 cases in an outpatient surgical center and described the preoperative evaluation, imaging protocol, customization process, and surgical procedure for custom mandibular and custom total mandibular augmentation. Between January 2004 and June 2015, 25 patients underwent total mandibular augmentation and 9 had custom extended mandibular angle and body augmentation. All patients received solid silicone rubber implants that were customized using virtual or acrylic prototypes digitally designed via real-time video conferencing. This custom process achieved an enhanced level of satisfaction with an improved ability to achieve symmetry based on quantitative measurements during the interactive design process, alloplastic facial implants can be customized with a high degree of accuracy, precision, and fit by combining the capabilities of 3-dimensional CT and advanced computer design software accessed via the Internet.

Keywords

custom mandibular implant, facial implants, chin augmentation, gonial angle implants, revision facial implants, facial plastic surgery, silastic facial implants

Introduction

The use of alloplastic materials in facial augmentation has been well established and is increasingly recognized as a key component in the correction and restoration of skeletal contour defects. In particular, implants play a prominent role in aesthetic facial contouring and the remediation of soft tissue volume loss in rejuvenating the aging face.[1-3] Early designs of prefabricated implants attempted to solve various challenges faced by reconstructive and aesthetic surgeons; however, the ability to improve the design of complex anatomical shapes was limited to the technology of the day (Figure 1A). Preliminary efforts to customize implants for complex cases were extrapolated from a facial moulage created over soft tissue topography (Figure 1B). This approach attempted to approximate topographical volume and variation but resulted in an implant that was poorly adapted to the underlying facial skeleton. Over the past decade, innovative advancements in computer technology have vastly improved the customization process to adapt the facial prostheses to the underlying bony topography with a greater degree of precision, fit, and reliability. In the mid-1980s, computed tomography (CT) imaging replaced standard radiographic techniques, resulting in the evolution of computer-aided design and

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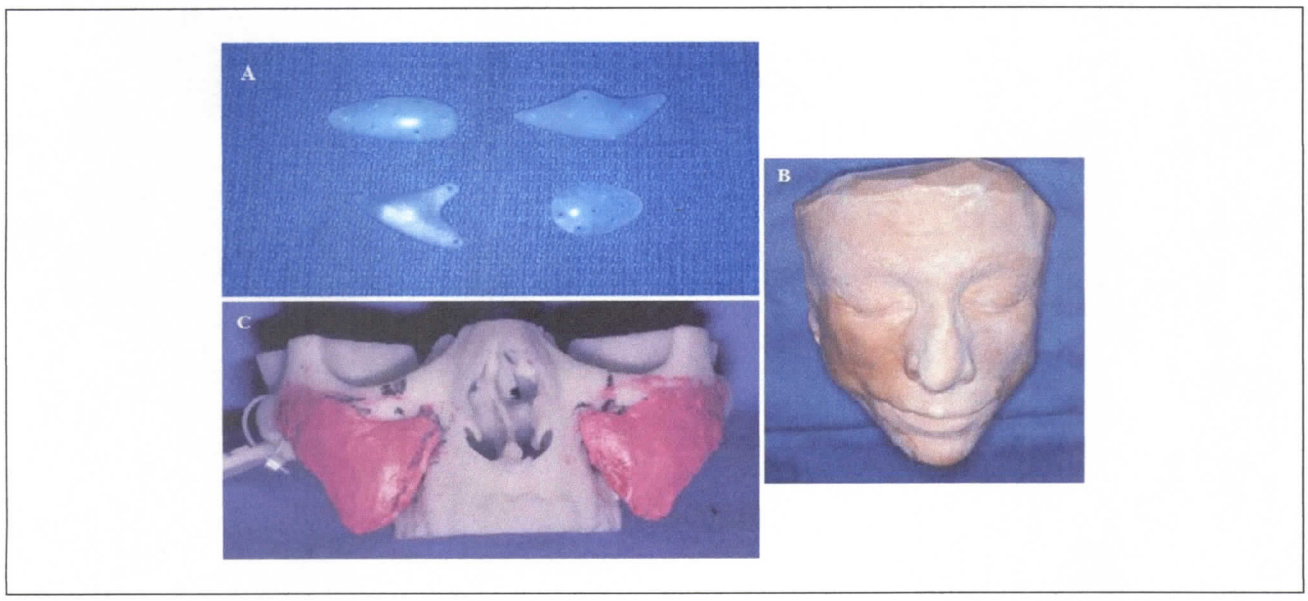

Figure 1. (A) Early prefabricated implants were limited by the technology of the day that hindered the production of complex, anatomically correct allografts. The resulting facial contour and projection were not aesthetically pleasing secondary to inaccuracies in volume and anatomic skeletal enhancement. (B) Early customized implants borne from facial moulage and designed over soft tissue topography did not adapt to the underlying skeletal surface, were unstable, and increased the risk of displacement. (C) Improvements in radiographic imaging and medical modeling allowed for molding of wax elastomer over an anatomically correct skeletal surface for improved customization and fit. Major asymmetry, inaccuracies in the degree of augmentation, and revision cases pose ongoing challenges in customizing implants.

manufacturing methods that use CT topographical data to produce anatomically correct 3-dimensional (3D) resin stereolithographic medical models (Figure 1C).[4] This not only enhanced the ability for surgical planning and execution in orthognathic surgery but also vastly improved the dependability of restorative onlay modalities.

In correcting contour skeletal deficiencies, the implant customization process has traditionally relied upon the use of wax and silicone clay to form and fit onlay implants over skeletal models. The wax and silicone clay molds were then converted to silastic implants that were better adapted to the underlying skeletal surface and produced favorable outcomes (Figure 1C).[1-3] This traditional approach to customizing implants, however, had several shortcomings. First, it did not achieve the optimal, aesthetically correct degree of augmentation due to the limited ability to precisely quantify volume, dimension, and asymmetry. Second, determining the method and approach to aesthetic augmentation was subject to the surgeon's sole discretion based on the patient's desires and input during the initial consultation. Although the design process primarily relies upon the experience of the surgeon and his ability to visualize and align the amount of augmentation and contour, the implant must ultimately coincide with both the patient's and surgeon's ideal of the end result. The ability to accurately predict and quantify the amount of augmentation remains an ongoing inherent limitation in all common chin or malar augmentation procedures. Therefore, adopting a method to assist in quantifying the degree of augmentation can be extremely useful to the aesthetic surgeon.

Facial asymmetry, particularly in revision cases with existing implants, poses a major impediment to fabricating new implants by obscuring the ability to accurately estimate size and dimension. This in turn hinders the ability to replace facial implants in a single-stage procedure. As such, past technology to customize implants was limited in the ability to subtract previously inserted implants and accurately address the complexities of revision cases without necessitating multiple surgical procedures. Prefabricated implants are difficult to customize intraoperatively around areas of significant topographical variability and abrupt surface changes. Moreover, attempts to optimize symmetry and the degree of augmentation may be further challenged by areas of osteoresorption and/or osteoneogenesis presenting from the region of the pre-existing implant.

The merging of capabilities offered by 3D CT imaging, 3D computer-aided modeling software, and the Internet represents a major contemporary advancement that enables the customization of facial implants while overcoming many limitations of prior methods. In this approach, the reconstructive and aesthetic surgeon can customize facial prostheses on a virtual platform by combining video conferencing protocols and collaboration with live technical support to design 3D onlay prostheses. This combined approach is performed digitally, thereby forgoing the absolute need for the physical model itself (Figure 2A). Digital measuring tools and techniques can now optimize the degree of 3D augmentation, quantify facial

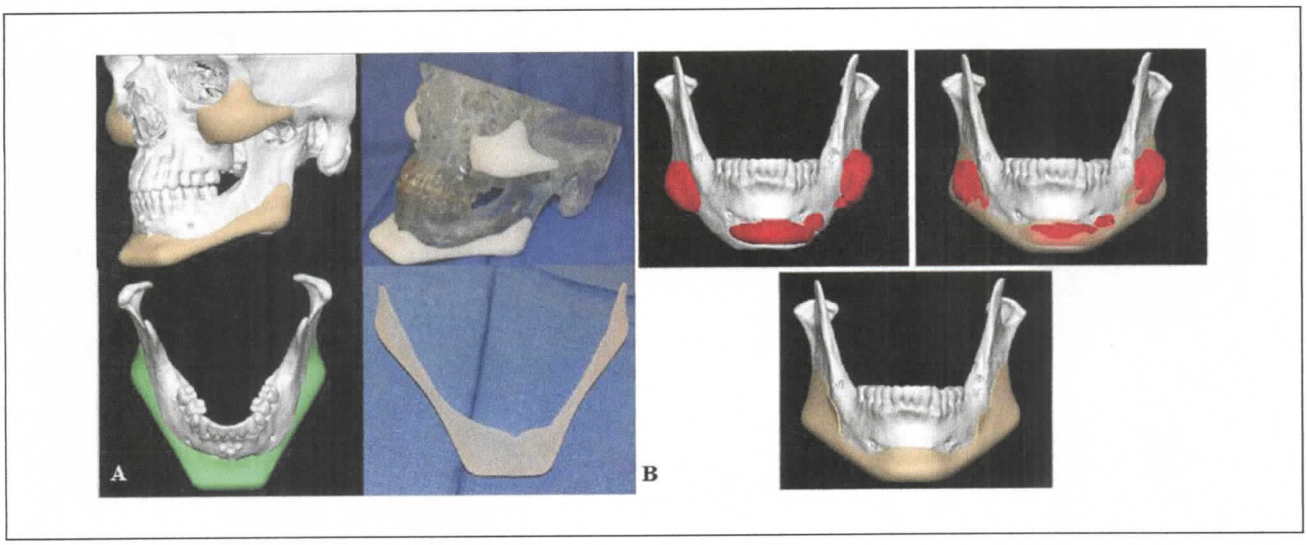

Figure 2. (A) With the advent of improvements in 3D digital software and CT resolution, the surgeon can now customize facial prostheses on a virtual stage by combining video conferencing protocols and collaboration with a live technical support staff. The enhanced design process can measure and account for inherent asymmetries and variations in skeletal topography, which results in a highly accurate onlay customized implant. (B) The improved ability to measure, subtract, or overlap previously inserted implanted materials allows customized implants to be designed to the specifications of the topography of the underlying mandible and alleviates the need for multistage (removal and replacement) procedures.
Note. 3D = 3-dimensional; CT = computed tomography.

asymmetry, and measure, subtract, or overlap previously implanted materials without the need for multistage removal and replacement procedures (Figure 2B). The software technology also enhances the assessment of spatial orientation and refines the implant design by accurately measuring asymmetrical differences. This improves precision in quantitatively predicting the amount of augmentation required (Figure 3A). Ultimately, the surgeon can become intimately familiar with the process of designing custom implants, particularly in refining the inherent differences and variations in skeletal anatomy and improving the ability to appreciate all 3D discrepancies.

The capacity for virtual mirroring, a primary benefit of the computer design, allows for precise matching of shape and contour while measuring the actual amount of augmentation required for the implant to match the contralateral side.[4] This design process has been utilized in customizing implants for mandibular reconstruction as well as enhancing skeletal deficiencies in the midface and forehead.[5]

In this article, we retrospectively reviewed 34 cases and described the design process, surgical procedure, management, outcomes, and complications of 3D customized implants for the augmentation of the entire mandibular complex.

Materials and Methods

Design and Fabrication of the Custom Implant

The preoperative evaluation includes a review of the patient's previous surgical and medical history and CT radiographic imaging reformatted into a 3D image. A radiographic evaluation of the region to be augmented is performed whereby the target area is scanned with a slice thickness of 0.625 to 1.2 mm, and the surrounding areas are scanned using low-dose techniques of greater thickness.[6] This method ensures minimal radiation exposure with complete CT assessment of the proposed area of augmentation. Once the scan is completed, DICOM (Digital Imaging and Communications in Medicine) images are transferred to the commercial manufacturer where the design process is initiated. Commercially available software is utilized to reformat the DICOM images into 3D skeletal and soft tissue images. Careful examination, analysis, and measurement of the virtual image are extremely useful in planning the implant design. The data are then uploaded to a commercial platform (3D Systems, Inc., Golden, Colorado). Using the Geometric Freeform© software, the technician manipulates a tactile joystick to emulate the physical process of sculpting clay to mold the implant to the underlying bony topography in 3 dimensions.

The surgeon is able to view the process over a peer-to-peer networking Internet protocol that allows him or her to communicate with the technician in real time. The technician can visually demonstrate 3D quantitative and qualitative digital data while utilizing virtual mirroring techniques to improve symmetry along a measurable midsagittal plane. As preexisting silicone or expanded polytetrafluoroethylene (ePTFE) implants can be visualized on CT and measured, new implants can be designed around these types of implants. In contrast, polyethylene (MEDPOR®; Stryker, Kalamazoo, Michigan) implants appear radiolucent or transparent on CT imaging and cannot be visualized. However, the density of the MEDPOR implant differs from that of bone and can be

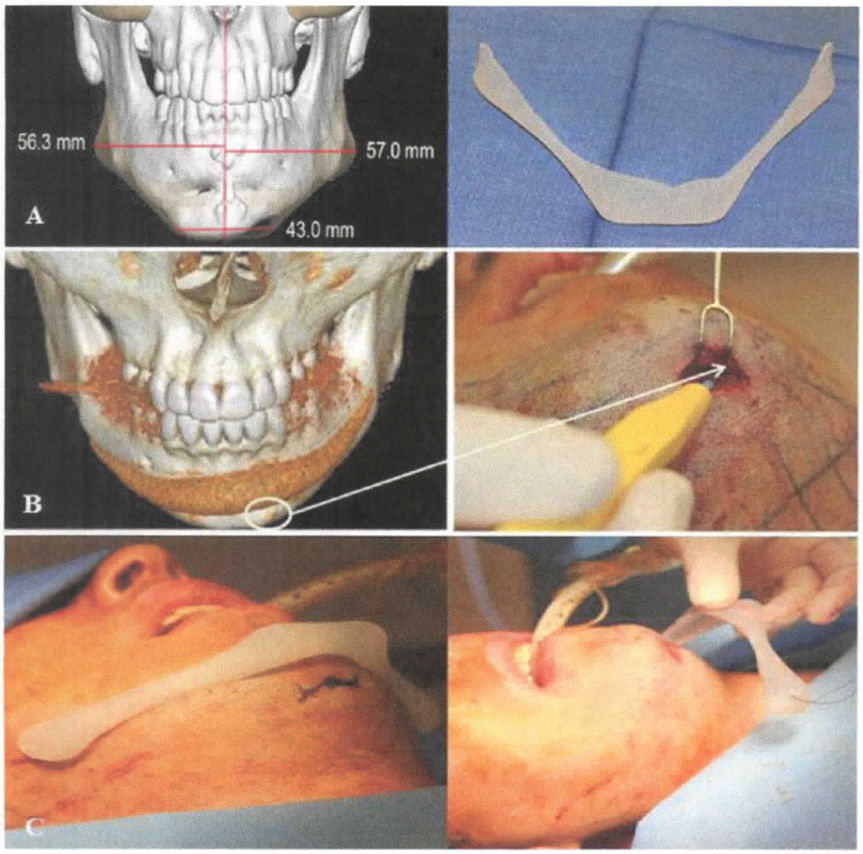

Figure 3. (A) Early attempts to customize implants were limited by variations due to asymmetry as well as difficulty in quantifying the degree of augmentation necessary for precise correction and contour. Currently, the merging of 3D CT imaging capabilities and 3D computer-aided modeling software represents a major advancement in the method for measuring asymmetrical differences and improving accuracy in quantitatively predicting the amount of augmentation required. (B) Detaching the anterior mental ligament at its insertion bilaterally allows for subperiosteal dissection to progress along the inferior border of the mandible and reduces the tendency for the dissection vector to be directed superiorly. This maneuver decreases risk of injury to the mental nerve intraoperatively and deters implant displacement superiorly during fibrosis postoperatively (left). Anterior mandibular ligament detachment at lateral incision border corresponding to radiographic imaging (right). (C) When inserting a single, whole implant, the gonial angle must be relatively small to limit injury to the mental nerve at the mental foramen. Alternatively, the implant may be cut in the midline and each hemi-implant is passed retrograde via the intraoral incisions and then reapproximated in the midline.
Note. 3D = 3-dimensional; CT = computed tomography.

discerned by the freeform software for digital subtraction.[7] The final customized implant design file is then transmitted, and a negative mold is produced through 3D printing. The final custom implant is then commercially produced from the computer mold into a solid silicone rubber implant (Figures 2A and 3A) Implantech Associates, Inc., Ventura, CA).

Surgical Technique for the Insertion of the Custom Total Mandibular Implant

The surgical placement of a total (angle-to-angle) mandibular implant is performed under general endotracheal or laryngotracheal mask anesthesia. The approach involves a 1- to 1.5-cm external submental incision and 2 intraoral angle or gonial incisions. A subperiosteal plane is dissected over the anterior surface of the mandible while limiting the superior extent of dissection to the vertical height of the chin component of the implant. Further surgical dissection is continued posteriorly with a 4-mm periosteal elevator along the parasymphyseal area and below the mental foramen bilaterally.[1-3] Surgical dissection along the inferior border of the mandible is aided by detaching the anterior mental ligaments lateral to the submental incision (Figure 3B). This allows the dissection to progress along the inferior border of the mandible and reduces the tendency for the dissection vector to be directed superiorly, thereby minimizing

potential injury to the mental nerve. This is the standard procedure for inserting an extended chin implant.

The posterior gonial incisions are made slightly lateral to the gingivobuccal sulcus to maintain a cuff of mucosa for ample primary closure. Wide (1-1.2 cm) periosteal elevators are utilized for subperiosteal dissection along with elevation of the overlying masseter muscle to reduce the risk of penetrating injury to the surrounding soft tissue and overlying muscle fibers. The posterior dissection is additionally controlled by placing the opposite hand held firmly against the border of the mandibular angle and ramus, preventing slippage of the elevator in a posterior direction. The masseter muscle is carefully dissected from the inferior ramus and the dissection pockets are joined to the anterior mandibular pocket previously dissected.

There are 2 approaches used for the placement of a total mandibular implant. Large implants can be inserted in 1 piece via the submental incision if the gonion component is relatively small (Figure 3C). Alternatively, if the gonion component is thick or has excess bulk, the silicone implant is then cut in the midline prior to implantation, inserted via a retrograde to antegrade direction, and passed through the gonial incisions. As the implant is advanced under the mental nerve, the risk of injury is avoided by expanding adequate dissection along the inferior border of the mandible while retracting the soft tissues inferiorly through the submental incision. With age or in the edentulous patient, the surgeon should be aware of a decrease in the vertical height of the mandibular body due to bone resorption; however, the distance between the inferior border of the mandible and mental foramen remains relatively constant.[8,9] Any large degree of resorption is found to occur in patients beyond the seventh decade of life and is observed mostly along the alveolar ridge, mandibular angle, ramus, and prejowl region.[9,10]

Intraoperatively, a 2.0 silk suture assists with passing of the implant along the mandibular pocket. The suture is placed through the anterior or mental portion of the hemi-implant. A long clamp is carefully inserted into the submental incision and passed below the mental foramen and extended laterally until the head of the clamp is directly visible within the intraoral gonial pocket. The suture loop is threaded between the tines of the clamp, and the implant is advanced toward the midline. Once both sides are seated correctly, the anterior ends of the implant appose each other in the midline. The bilateral implants are adjoined in the midline with permanent 4-0 clear nylon or polydioxanone suture (PDS) interrupted sutures.

The anterior inferior portion of the implant is further secured by suturing it to the periosteum along the inferior border of the mandible through the submental incision. If further fixation of the gonial portion of the implant is desired, a self-drilling screw may be secured either through the gonial incision or via a direct percutaneous approach. A small screw is used to engage the cortex for approximately 1 to 1.5 mm thereby avoiding the inferior alveolar canal. If excessive bleeding occurs, drains are inserted into the intraoral pockets and usually removed the next day. All incisions are closed primarily. A compressive contour dressing is applied by placing Elastoplast over the entire mandible for tamponade. The patient may be discharged either to home with supervision or to an aftercare facility (Figure 4A-D).

Results

During the period from January 2004 to June 2015, 25patients underwent custom total mandibular implantation and 9 underwent extended custom gonial angle and body augmentation utilizing the virtual custom design process. Patients were followed postoperative for at least 1 year to up to 6 years. All implant surgeries were performed in an outpatient ambulatory surgical care center. Of the 25 patients who received a total mandibular implant, 12 were revision cases from previously inserted chin implants and/or mandibular angle implants of various biomaterials. Each revision case was completed in a single-stage procedure. The preexisting implants in 5 of the 12 revision cases were silicone, 5 were MEDPOR, 1 was ePTFE, and 1 was Proplast; all revision cases were reimplanted with silicone elastomer implants designed from the digitally produced molds. Patients were discharged subsequently to either an aftercare facility or to home care. The custom process produced an enhanced level of satisfaction with an improved ability to achieve symmetry based on quantitative measurements. (Figures 4-6).

Complications included 2 (5%) cases of incision site granulomas, 3 (8%) cases of seroma/hematoma that were acutely drained, and 2 (5%) cases of local, unresolved infection that necessitated implant removal. Of the 2 patients requiring implant removal, one patient had a second implant reinserted without incident, and the second patient elected not to have the implant reinserted.

Discussion

The customization process can assist the aesthetic and reconstructive surgeon in accurately designing implants to solve a multitude of problems arising from the use of prefabricated or custom implants previously designed using physical modeling techniques. The senior author has over 20 years of experience utilizing clay modeling for customized implants and these patients have not been included herein.

In patients with facial asymmetry, the most notable asymmetry is found in the lower third of the face.[11] A large percentage of patients with microgenia have a relative component of associated micrognathia with either narrow or acutely angled mandibular bodies and/or hypoplasia of the gonial angles. Minor or major degrees of asymmetry in the ramus, angle, symphysis, or body can also accompany the relative deficiencies that are associated with the entire mandible.[11] Utilizing the custom process, implants can now be designed and fabricated to encompass all areas of the mandible while compensating for its asymmetrical contour, shape, and the inherent variability.

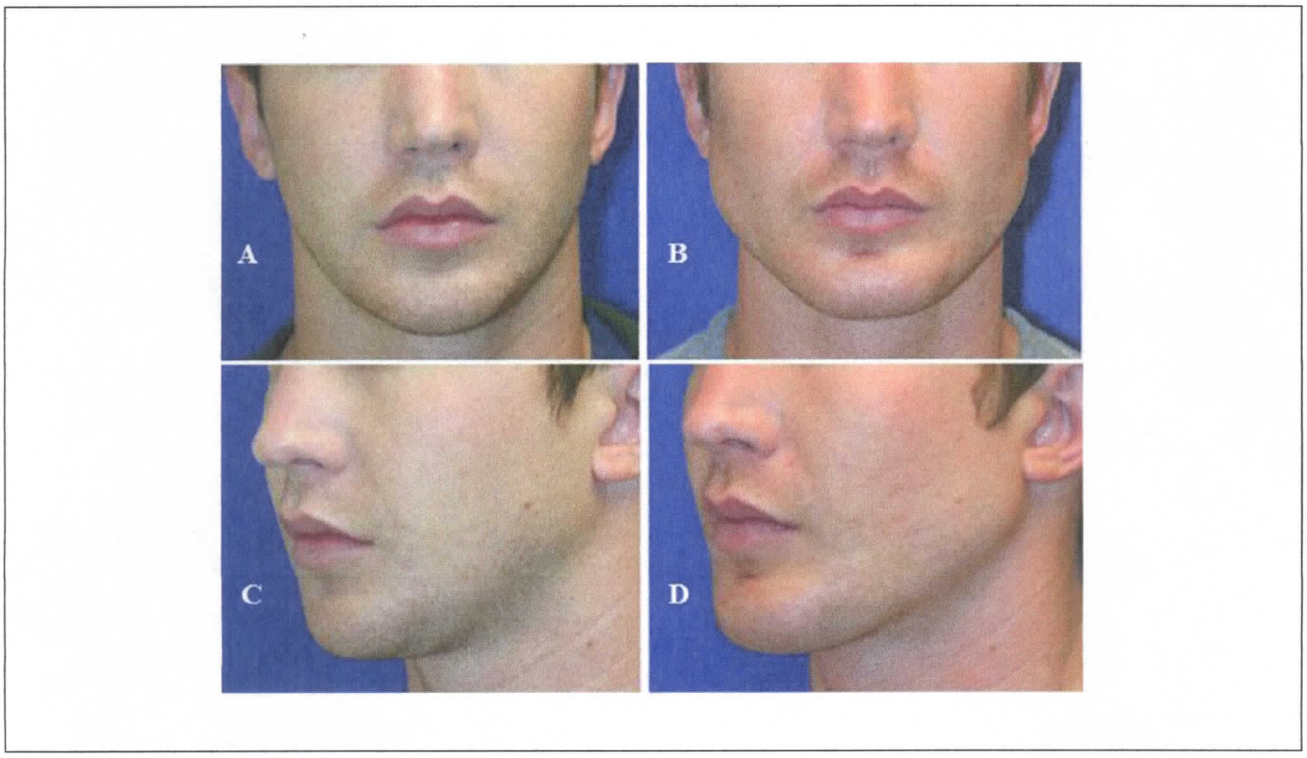

Figure 4. (A and C) Preoperative photographs of a patient demonstrating microgenia with a poorly defined jawline and gonial angle. (B and D) Postoperative photographs of the same patient (in A and C) after the custom total mandibular implant resulting in a bold mandibular contour.

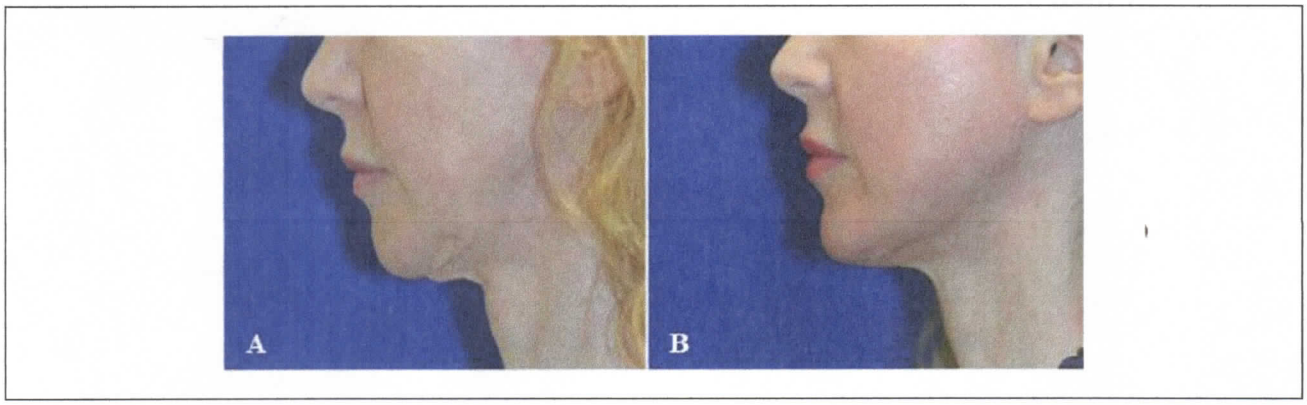

Figure 5. (A) Preoperative lateral view of a chin implant previously placed in an incorrect location about 1.0 cm above the inferior mandibular border. In addition, there is neck skin laxity in conjunction with an overall weak mandibular skeletal framework including a decrease in mandibular length, height, and chin projection. (B) One-year postoperative lateral view. Total custom mandibular implant augmentation of all 3 regions of the mandible including the gonial angle, parasymphysis, and symphysis was performed *without* any soft tissue or rhytidectomy (face or neck) procedures. A robust facial skeletal structure redistributes the soft tissue over a well-defined jawline, rendering an improved cervicomental angle and more youthful appearance.

Treating a single area with prefabricated gonion angle implants in conjunction with chin augmentation does not address mandibular parasymphyseal and body deficiencies. However, by utilizing the customization process, the surgeon can now create custom total mandibular implants that address all regions of mandibular deficiency, which in turn may confer a higher degree of surgeon confidence, predictability, and patient satisfaction. This is a novel approach for facial contouring of the lower third of the face by ameliorating the gap, or indentation, that occurs at the junction of

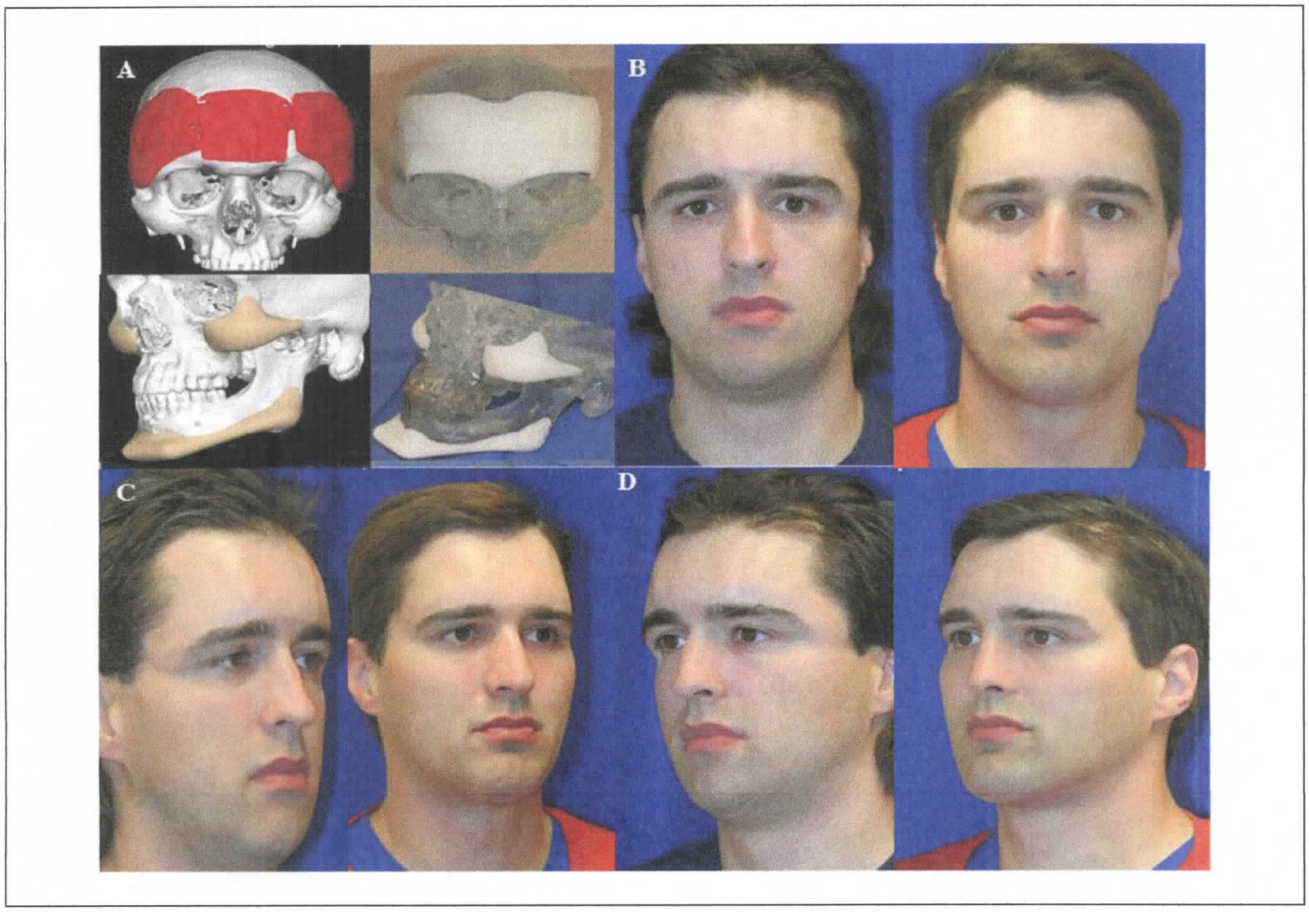

Figure 6. (A) The custom design process allows for novel approaches to facial contouring in areas including the cranium, midface, and entire mandible. The aesthetic objectives are achieved through improved quantification of volume, dimension, and asymmetry on a virtual stage. (B-D) Preoperative and postoperative photographs of a patient who underwent rhinoplasty facial implantation of the cranium, midface, and total mandible utilizing the 3D virtual custom design process. Postoperative photographs demonstrate improved symmetry, dimension, and aesthetic contour matching the patient's preoperative objectives.

anterior mandibular with gonial angle implants in the parasymphyseal region, thus providing a straight mandibular line that is sought in facial aesthetic surgery.

During the initial consultation, the patient's facial contour goals are discussed and the augmentation options continue to include standard prefabricated implants in addition to customized implants. For patients with extreme facial skeletal deformities and/or malocclusion, orthognathic surgical consultation is warranted. The safety and technical ease to insert custom total mandibular implants has evolved to be in line with a standard chin augmentation surgical approach utilizing a single external incision. Conversely, the custom process utilizes an outside technician and facility(3D Systems, Inc.; Golden, CO) that results in an increased cost for the design time. The additive cost to the customization process must be weighed and considered based on the goals of the patient, and the surgeon's need for technology to provide an improved fit for primary cases with gross asymmetry revision cases, and when dealing with the parasymphyseal deficiency that often occurs with prefabricated implants. For patients with microgenia and appropriate gonial angle projection, a standard prefabricated chin implant remains the standard and can be modified intraoperatively by shaving the implant for symmetry and proper sizing.

In aesthetic surgery, it is well established that a robust skeletal framework can provide a better foundation enabling improved and longer lasting effects of facial soft tissue procedures.[1-3,9,12] Similarly, it is well known that utilizing alloplastic augmentation to address skeletal volume deficiencies, particularly those resulting from the aging process, can dramatically enhance the results of rhytidectomy.[3] Extending or augmenting any of the key areas of deficiencies in the facial skeleton such as the chin, midface, and gonion angle improves the skeletal framework and facilitates more appropriate soft tissue draping (Figure 5). In many cases, the formation and recurrence or accentuation of the jowl particularly after rhytidectomy can result from an unrecognized skeletal deficiency of the gonial angle posterior to the soft tissue

component. We refer to these cases as the reformation of the "pseudo-jowl" where post-face-lift patients present with a relatively tight soft tissue envelope, but with a persistence of the jowl that appears to be aggregated at the mid-portion of the mandible posterior to the mandibulocutaneous ligament and anterior to a deficient skeletal gonial angle (Figure 6A and B). In addition, the virtual custom design process allows for the application of novel facial contouring tactics to all regions of the face, including the midface and cranium, to meet the expectations of both the patient and surgeon. We present a 35-year-old male with a prior history of forehead implantation who had requested consultation for facial contouring utilizing the custom design process. The patient arrived with specific aesthetic requests based on his ideals of facial contour. During the consultation, he desired a well-defined, lowered superior orbital rim with a well-projected forehead, malar implantation, and improved mandibular contour along all 3 segments of the mandible.

Utilizing the customization process described here, we subtracted the existing forehead implant virtually and despite an irregular skeletal topography, designed a smooth contoured prototype. A total mandibular implant was also designed to address areas of micrognathia and microgenia with the aesthetic goal of achieving a "square chin" and bold jawline (Figure 6A). The forehead implant was surgically implanted via a bicoronal approach in a single-stage removal and replacement procedure. The malar implants and mandibular implants were later implanted as described earlier (Figure 6B-D).

Conclusions

We described a process that utilizes contemporary technology to converge digital imaging and computer-aided design modalities into a practical, reproducible method for implant customization. This method yields highly predictable results in areas of the face that are particularly difficult to accurately and symmetrically augment when using off-the-shelf, prefabricated alloplastic implants. Customizing alloplastic implantation of the facial skeleton can be accomplished with a high degree of accuracy, precision, and fit by leveraging the combined capabilities of 3D CT imaging and Internet video conferencing protocols offered by the sophisticated design software. As such, at the preference of the surgeon, customizing implants can now also be performed without the absolute need for obtaining the physical model. Moreover, this process facilitates a collaborative approach to fulfilling the patient's aesthetic goals by availing input from a highly proficient software technician who can assist the surgeon in achieving the anatomical objectives of the procedure.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr. Binder is a shareholder and consultant of Implantech Associates, Inc.

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