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SYSTEMATIC REVIEW

Exploring digital technologies used in the design and manufacture of craniofacial implant surgical guides: A scoping review

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ABSTRACT

Statement of problem. Unlike intraoral implants, digitally planned surgical templates used for guiding the ideal position of the craniofacial implants are not well established, and clear methods and guidelines for their design and construction are lacking.

Purpose. The purpose of this scoping review was to identify the publications that used a full or partial computer-aided design and computer-aided manufacture (CAD-CAM) protocol to create a surgical guide that achieves the correct positioning of craniofacial implants to retain a silicone facial prosthesis.

Material and methods. A systematic search was conducted in MEDLINE/PubMed, Web of Science, Embase, and Scopus for articles published before November 2021 in the English language. Articles needed to satisfy the eligibility criterion of in vivo articles that created a surgical guide with digital technology for inserting titanium craniofacial implants to hold a silicone facial prosthesis. Articles that inserted implants in the oral cavity or upper alveolus only and articles that did not describe the structure and retention of the surgical guide were excluded.

Results. Ten articles were included in the review; all were clinical reports. Two of the articles used a CAD-only approach alongside a conventionally constructed surgical guide. Eight articles described applying a complete CAD-CAM protocol for the implant guides. The digital workflow varied considerably depending on the software program, design, and retention of guides. Only 1 report described a follow-up scanning protocol to verify the accuracy of the final implant positions compared with the planned positions.

Conclusions. Digitally designed surgical guides can be an excellent adjunct to accurately place titanium implants in the craniofacial skeleton for support of silicone prostheses. A sound protocol for the design and retention of the surgical guides will enhance the use and accuracy of craniofacial implants in prosthetic facial rehabilitation. (J Prosthet Dent 2023;■:■-■)

Defects in the craniofacial area can be caused by ablative cancer resections, traumatic injuries, or congenital deformities, leading to esthetic concerns and considerable psychological problems.[1-3] Plastic surgery reconstruction is challenging in such patients and often leads to a compromised esthetic outcome.[4]

Silicone prostheses provide an established approach to manage craniofacial defects. Retention of silicone prostheses has traditionally been achieved with the use of tissue undercuts, skin adhesives, or spectacle frames.[5] Undercut retention is usually weak, the use of adhesives requires daily application and is commonly coupled with skin reactions, and the spectacle option is neither available nor practical for every patient.[6] Retention with implants was introduced in 1977 to anchor hearing aids and auricular prostheses.[7] Over time, titanium craniofacial implants have been documented as a safe and reliable option for the adequate retention of craniofacial prostheses.[8] The sites in the craniofacial skeleton most frequently used for the insertion of craniofacial implants include the mastoid bone for auricular prostheses, the upper and lower orbital rims for orbital prosthesis, and the glabella and upper alveolus for nasal prostheses.[9] Digitally guided placement

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Clinical Implications

This scoping review demonstrated the need for further research into the design and retention of digitally planned surgical guides that direct the placement of titanium implants in the craniofacial skeleton for the retention of facial prosthetic rehabilitation.

of craniofacial implants can facilitate optimal rehabilitation with silicone prostheses.[5]

The evolution of craniofacial implant insertion followed a similar path to that of intraoral dental implant insertion. Freehand and custom laboratory-made surgical guides have been commonly used but with the inherent risk of implant placement in insufficient bone or in prosthetically inappropriate sites.[10] In more recent years, digital computer-aided design and computer-aided manufacture (CAD-CAM) technology has been used to assist with the correct insertion of craniofacial implants.[11] The use of computed tomography (CT) scans or cone beam computed tomography (CBCT) has been accepted because of the accuracy of the acquired images.[11-13]

For dental implants, software programs including NobelGuide (Nobel Biocare Services AG) and Simplant (Dentsply Sirona) are available to assist the practitioner with digitally planning and designing a surgical template to guide implant insertion in the predetermined location. Advances in digital technology have allowed the planning of implant insertion for the support and retention of maxillofacial prostheses.[10] The accurate position of a craniofacial implant is essential, as the surface contour of the prosthesis must be able to incorporate the attachment components in a safe and rigid manner. The prosthesis must then transition to the surrounding skin in a smooth and subtle way to allow for optimal esthetics and minimize bacterial contamination.[11]

Craniofacial implants are much less commonly used than intraoral implants. Nevertheless, publications have described the use of craniofacial titanium implants for prosthetic rehabilitation with variable use of digital technology.[14,15] This scoping review aimed at assessing the published literature that used a full or partial CAD-CAM protocol for creating a surgical guide to correctly position craniofacial implants to retain a silicone facial prosthesis.

MATERIAL AND METHODS

This scoping review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines.[16] The research question was: What is the current clinical practice for using digital (CAD-CAM) technology to create surgical guides to place craniofacial implants for the support of silicone facial prostheses?

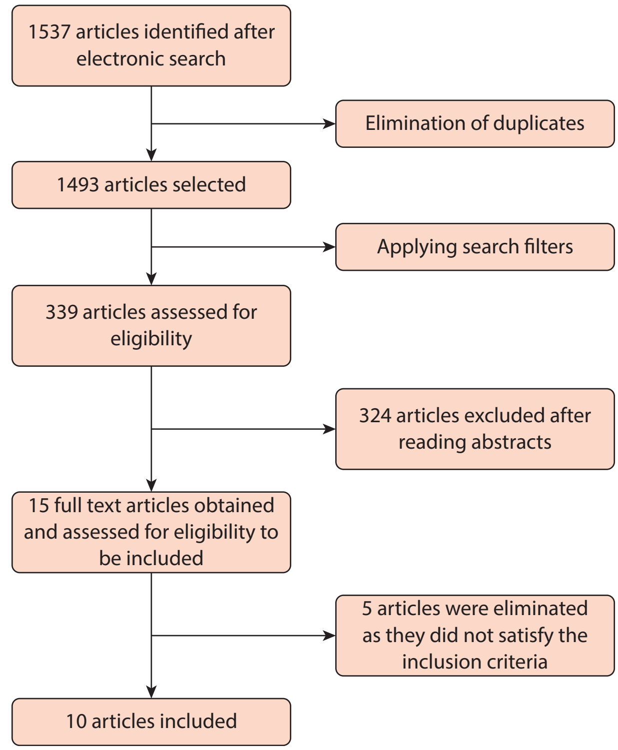

Figure 1. Flow chart of screening and selection process.

The search was done in November 2021 and was initially performed on MEDLINE/PubMed and then extended to include the Web of Science, Embase, and Scopus databases with the keywords "craniofacial implants." Combinations of the following terms were then used: "rehabilitation," "stent," "template," and "guide." The searches were then repeated using the term "maxillofacial implants" with the same combinations. A manual search was also conducted including the references in all the relevant articles.

The inclusion criteria were articles that inserted craniofacial implants using a digitally planned surgical guide for the purpose of supporting a facial prosthesis, articles published in the English language; in vivo articles only, and implants inserted in extraoral sites only were included. Implants inserted in the maxillary alveolus only to support nasal prostheses were excluded. Articles that used a surgical template but did not clearly describe the manufacturing process, structure, or the retention of the template were also excluded.

After identifying articles that met the inclusion criteria, the following data were extracted and tabulated: main author's name; publication year; country of origin; study design; site of prosthetic rehabilitation, digital workflow for planning and performing the treatment, reported outcomes, and whether follow-up protocols were implemented. This was all performed by 1 author (D.S.) and then reviewed by a second author (M.H.M.).

RESULTS

The initial search yielded 1537 articles. A reference manager (Endnote X9; Clarivate) was used to remove duplicates resulting in 1493 articles. Repeating the initial search with different phrases did not yield any further relevant articles. After assessing the titles, 339 articles were selected for further analysis. All abstracts were read, and the inclusion criteria applied, resulting in the elimination of 324 articles, leaving 15 articles for full review. The full-text versions of these 15 articles were scrutinized for their content, and articles that did not use a guide, or used one without any digital technology were eliminated. Articles that used the guides for placement in the maxillary alveolus only were also eliminated. One article[17] was eliminated because it lacked most details of the digital planning. Another article[18] that described the guided orbital treatment of 4 patients was excluded as it did not have any information on the design and retention of their surgical guides. The final number of articles was 10, all of which were analyzed in detail and are described (Fig. 1).

All included publications[19-28] were single clinical reports: 4 auricular, 3 nasal, and 3 orbital prostheses. Seven of 10 patients had defects created by cancer resection. Two patients had had traumatic injuries, and 1 had a congenital anomaly.

Uniformity pertaining to the protocol and implementation of the use of digital technology in creating and using the surgical guides for the insertion of craniofacial implants was clearly lacking. All articles[19-28] began with a conventional CT or cone beam CT scan of the whole head and face. Four articles[19-21,24] used a radiographic template of some description to determine the ideal bone for implant insertion, two[19,20] of which did not use a digital software program to plan the position of the implants and only relied on the CT scans (CAD only). They were included in this review as they explained in detail the process of design and retention of the surgical guide.

The acquisition of the defect was captured by conventional impression techniques in two articles[19,20] and with laser scanning in 3 articles,[21,23,25] two[21,23] of which used the NextEngine Desktop 3D scanner and one[25] the TRIOS 3Shape intraoral scanner to image the face. Four reports[22,24,27,28] used bony surgical guides and so did not acquire an image of the defect and used the CT scan only for planning. One article[26] did not specify how the digital image of the defect was acquired.

The planning of the surgical guide was different in all reports. Two articles[19,20] did not use a digital planning software program but used the radiographic stent as a surgical guide relying only on the CT imaging software program. Eight reports used advanced software programs for the design of the guide, including Rapidform CAD, v2006 (INUS Technology Inc),[21] Rhino,[23] EOIPlan,[24] a CAD software program (Implant Studio; 3Shape A/S),[25] and the Materialise software program (Simplant, Mimics and ProPlan CMF) was used in 4 reports.[22,26-28]

Similarly, diverse approaches were applied to retain the surgical guide. Two articles[19,20] on auricular prostheses used the maxillary teeth for retention with an arm connecting to the ear component of the guide. Three articles[24,27,28] that used a bony guide depended on a passive bony fit from surrounding bone(s). Four guides[21-23,26] used the soft tissues of the face for retention. Given the lack of rigidity of the soft tissues, complex patterns were adopted to facilitate an accurate fit. One report[23] used a helmet with a bar connected to a nasal guide. Another report[26] described the use of a frontal face guide with holes across the eyes and nose with guiding sleeves for nasal implants. One auricular prosthesis[22] used a full-frontal face guide with holes around the eyes, nose, and mouth, and with an arm extending to the mastoid for an auricular prosthesis. One report[21] used a passive fit to the lateral canthus of the eye with an arm connecting to the ear guide. The final report[25] used the external soft tissue shape of the orbit with 2 retention pins through soft tissue, 1 in the bone of nasion, and another in the bone of the fronto-zygomatic process. The digital printing of the surgical guides (CAM) was based on 2 predominant modes: fused-deposition modeling (FDM) and stereolithography (SLA). FDM involves the successive layering of a plastic filament material from an extrusion head. This technology uses polymers such as acrylonitrile butyro styrene (ABS). The SLA-based system prints layered monomer resin material that is successively polymerized by ultraviolet light until the structure is completed by this process of photopolymerization.[29] Six reports[21,22,24-26,28] used the resin printers and only 2 reports[23,27] used fusion deposition modeling with acrylonitrile butyro styrene. The 2 reports[19,20] that did not use a 3D (CAM) printer used a conventional resin-based radiographic template. A summary of the main characteristics of all articles is presented in Table 1.

DISCUSSION

This scoping review identified articles that described the full or partial use of the CAD-CAM process in fabricating surgical guides for the insertion of extraoral implants. The review highlights the scarcity of available literature describing this sophisticated level of design and manufacture.

The overall sequence of digitally producing a craniofacial surgical guide goes through several predictable steps. The first is to obtain a map of the defect. A surgical guide that is placed directly over bone will not need this

Table 1. Summary of selected clinical reports that used digital technology to plan surgical guides for craniofacial prostheses

Author and Publication Year	Article	Area of Rehabilitation	Timing	Defect Acquisition	Imaging Technique	Software Used	Guide and R etention	Verification of Implant Position
1. Alfano et al, 2005[19] USA	Clinical report	Auricular prosthesis	Prior to ear resection	Vinyl polysiloxane impression of ear defect and irreversible hydrocolloid of maxilla	CT scanning with a diagnostic guide	None	Acrylic guide retained on maxillary teeth with arm to ear	Not done
2.Arshad et al, 2017[20] IRAN	Clinical report	Auricular prosthesis	Pre-existing congenital deformity	Impression of ear defect, normal ear, and maxilla	CT scanning with a diagnostic guide	None	Acrylic guide retained on maxillary teeth with arm to ear	Not done
3.Ciocca et al, 2008[21] ITALY	Clinical report	Auricular prosthesis	After ear resection	Laser scan of defect (Desktop Next Engine).	CT scanning with a diagnostic guide	Rapidform CAD (Version 2006)[a]	3D printed resin guide (Z310 plus) with cylinders overlying ideal position retained with arm to lateral canthus of ipsilateral eye	Not done
4.Cotert and Yilmaz, 2016[22] TURKEY	Clinical report	Auricular prosthesis	After ear resection from traumatic injury	Not done as a bony guide was used for implant area.	Convention full head CT scan	ProPlan CMF, ProPlan STL+ Module[b]	A full-face resin guide printed (Projet 3d) following anatomy of facial soft tissue with guided sleeves over mastoid bone	Not done
5.Ciocca et al, 2010[23] ITALY	Clinical report	Nasal prosthesis	After nose injury	laser scan of defect (NextEngine Desktop 3D Scanner)	Conventional full head CT scan	NobelGuide software[c], Rapidform XOS[a], Rhino 3.0[d]	An acrylonitrile butyro styrene (ABS) helmet printed (Stratsys) with an extension glabellar arm down to the implant site. There were guided sleeves to the alveolus	Done and found to be accurate enough, but could have more stability using pins.
6.Zhang et al, 2010[24] CHINA	Clinical report	Ocular prosthesis	After eye enucleation	Not done as a bony guide was used for implant area.	Conventional CT with a radiographic template having 12 circumferential holes.	Ease Orbital Implant Planning Software (EOIPlan).[e]	A resin guide printed(Stratsys). Sat passively on orbital rim as bony guide	Not done
7.Machado et al, 2019[25] BRAZIL	Clinical report	Orbital prosthesis	After orbital exenteration	Laser scan of defect using an intraoral scanner (TRIOS® 3, 3Shape)	Conventional full head CBCT.	CAD software, Implant studio.[f]	A resin guide printed (Fromlab 2). St passively on soft tissue around orbit with 2 retention pins. There were guided sleeves	Not done
8.Wälivaara et al, 2011[26] SWEDEN	Clinical report	Nasal prosthesis	After nose resection	Not mentioned	Conventional full head CT scan	SimPlant Planner 9.2[g]	A resin guide, retention from soft tissue contours, frontal facial with holes across the eyes and nose	Not done
9.Huang et al, 2016[27] USA	Clinical report	Orbital prosthesis	After orbital exenteration	Not done as a bony guide was used for implant area.	Conventional full head CT scan	Mimics Innovation Suite.[b]	An ABS guide (Stratasys). Passive retention from bony contours of orbit	Not done
10.McHutchion et al, 2019[28] CANADA	Clinical report	Nasal and midface prosthesis	After nose, anterior maxilla and partial upper lip resection	Not done as a bony guide was used for implant area	Cone-beam CT of skull	Mimics Innovation Suite.[b], Geomagic Freeform Plus[h], Software ZBrush Software.[i]	Thermoplastic material printed (PC-ISO; Stratasys, Ltd.). Passive retention from bilateral maxillary rims and the glabella.	Not done

3D, 3-dimensional; CBCT, cone beam computed tomography; CT, computed tomography. [a]INUS Technology Inc. [b]Materialise NV. [c]NobelGuide, Nobel Biocare. [d]Robert McNeel & Associates. [e]Guangdong Provincial Hospital. [f]Implant Studio, 3Shape. [g]Materialise. [h]Geomagic. [i]ZBrush, Pixologic Inc.

step. The CT scans would be sufficient for planning in such treatments and have been reported to produce best accuracy in intraoral implants, but they do require a full open flap approach.[30]

CAD-CAM technology, introduced in the 1980s, has revolutionized oral rehabilitation and was introduced to maxillofacial prosthetics in the 1990s, with a reported improvement in treatment quality and efficiency.[31,32] The change in technology has led to the need for a digital image of the defect, especially with 3-dimensional laser scanning.[33] The advantages of laser scanning are ease of acquisition, patient comfort, better accuracy, and having the image immediately for processing, further enhancing efficiency and productivity.[34-36]

Conventional CT scanning has been the standard for obtaining a detailed bony structure of the face and skull.[37] CT offers 3-dimensional views, and each has high resolution leading to excellent accuracy. Conventional CT scans have the disadvantages of radiation exposure and high cost. The machines are spiral and use a fan beam making them bulky, restricting their use to larger institutional settings.[38]

Cone beam computed tomography (CBCT) scanners were developed for maxillofacial imaging, with lower radiation doses as the machine generates cone-shaped beams that use a single 360-degree rotation around the maxillofacial region. The images are captured by a flat panel detector or an image intensifier. Compared with conventional spiral CT scans, the lower radiation exposure and cost efficiency render CBCT ideal for maxillofacial imaging. A weakness of CBCT scans is the lower soft tissue image quality compared with a conventional spiral CT.[38]

In the craniofacial area, patients commonly receive conventional CT scans to assess tumor recurrence because of the improved soft tissue image. Hence, conventional CT scanning is much more commonly used for craniofacial applications.

A suggested spiral CT scanning protocol for orbital implants has been scanning at an axial plane (120KV, 25 mA, 1.25-mm slice thickness, 1.25-mm slice distance, voxel size 0.3×0.3×2-mm) from below the zygomatic bone to 4 cm above the supraorbital margin.[37]

A radiographic template has been used by some authors.[19-21,24,39] Similar to dental implants, this appears to facilitate implant placement.[40] Accurate implant placement in the temporal bone to support an auricular prosthesis has been reported to be facilitated by using spherical markers in the defective ear and normal ear and using the digitized image to create a radiographic template. This template is then CT scanned to determine the optimal position for the implants.[21]

Incorporation of the CT scan digital imaging and communications in medicine (DICOM) files integrated with the standard tessellation language (STL) scanned images in a specific software program allows for computer-guided surgery.[41] Van der Meer et al[10] stated in 2012 that there were no specifically designed software programs to aid with the planning of craniofacial implants. They used a combination of SimPlant (Materialise) or Nobel Guide (Nobel Biocare) and Mimics (Materialise) with the Autodesk software program (Autodesk Inc) to plan and guide the position of implants in the mastoid bone of cadavers. Most of the articles in this review used various types of software programs all of which are capable of manipulating scans of the facial skeleton.

CAM is used to transform the virtual plan into an appropriate surgical template. Advantages of fused-deposition modeling printed guides include the less expensive material and the lack of postprocessing chemical treatment. Advantages of stereolithography printed resin guides include the higher resolution and short working time.[42] Both technologies have been used for craniofacial surgical guides with stereolithography guides being more common.

For intraoral surgical guides, the teeth serve as a rigid and accurate base for achieving stability and good retention. For edentulous patients, an intraoral guide can be placed directly on the maxilla or the mandible after raising a flap or directly on the mucosa for flapless surgery. Retention pins have been commonly used to stabilize the mucosal guide.[30] An article comparing tooth-supported with bony and soft tissue-supported intraoral stereolithographic guides reported the increased placement accuracy of the tooth-supported guides,[43] attributing the lower accuracy to the flexibility of the soft tissues.

For extraoral craniofacial implants, the soft tissue envelope is more robust than in the oral cavity. Distortion of soft tissues would be expected to reduce retention of the guides and hence decrease the accuracy of implant placement.[44] The reports in this review have attempted to address this issue in different ways, including the use of a bony guide after raising skin flaps and the use of the dentition as a stable reference point in the face and connecting the guiding piece of the template with an additional arm to the mouth part. In addition, increasing the size and complexity of the guide to gain stability by following the apertures of various facial structures such as the eyes and nose has been reported[21-23,26] and 1 article[25] used retention pins placed directly through the soft tissues to the bone for further stability. A cadaver article compared passive soft tissue craniofacial surgical guides with soft tissue and pin-retained guides for the insertion of craniofacial implants, reporting that the pin retention reduced the accuracy of implant placement compared with the passive soft tissue fit.[44]

Most of the constructed guides did not use guiding metal sleeves, which is a standard feature of intraoral implant guides. Straightforward postoperative plain radiographs were used in most of the reports to verify appropriate placement of the implants. Only 1 report conducted a postoperative CT scan verification and digital comparison of the final position to the preplanned position of the nasal implants. The authors concluded the position was accurate.[23] The cadaver article that used soft tissue retention with and without fixation pins concluded that both techniques were not sufficiently accurate for precise implant placement, with the fixation pins yielding even less accurate results.[44]

CONCLUSIONS

Based on the findings of this scoping review, the following conclusions were drawn:

1. The difficulty in constructing craniofacial surgical guides and the relatively small number of reports, coupled with the lack of dedicated software programs has led to a less standardized approach compared with intraoral dental implants.
2. The standard full digital protocol of a CAD-CAM approach for digitally designed surgical guides has not been strictly adhered to in all the reports that qualified for this scoping review.
3. Drill guiding sleeves were not used in most of the reports; however, this could be acceptable on most occasions as the need for precise direction and angulation of implants is less critical compared with dental implants.
4. The soft tissues of the face create a new dimension of complexity for achieving the retention and stability required to enable the accuracy of a surgical guide.
5. The digital workflow to support surgical guides has not been explored to the same extent as for intraoral implants.
6. Significant research is warranted to achieve standard reproducible guidelines for the digital planning of craniofacial implants.

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