



A simplified CAD/CAM extraoral surgical guide for therapeutic injections

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Therapeutic injections into the craniofacial region can be a complex procedure because of the nature of its anatomical structure. This technical note demonstrates a process for creating an extra-oral template to inject therapeutic substances into the temporomandibular joint and the lateral pterygoid muscle. The described process involves merging cone-beam computed tomography data and extra-oral facial scans obtained using a mobile device to establish a correlated data set for virtual planning. Virtual injection points were simulated using existing dental implant planning software to assist clinicians in precisely targeting specific anatomical structures. A template was designed and then 3D printed. The printed template showed adequate surface fit. This innovative process demonstrates a potential new clinical technique. However, further validation and in vivo trials are necessary to assess its full potential.

Keywords: 3D Printing; CAD-CAM; Extra-Oral Scanning; Face Scanner; Lateral Pterygoid Muscle; Temporomandibular Joint.



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INTRODUCTION

Orofacial pain and temporomandibular joint disorders (TMDs) are one of the most common reasons for seeking dental treatment worldwide [1]. They have a very high percentage of muscle-related causes, particularly those related to the lateral pterygoid muscle (LPM). This muscle has a complex anatomy and physiology and is responsible for coordination between the disc and condyle complex motion and mandibular movements [2]. The use of therapeutic doses of botulinum toxin A injected into the LPM has been suggested to treat some TMD conditions [3-5]. Injections into the pterygoid muscles require special anatomic consideration. The use of

electromyographic guidance has been suggested to avoid diffusion of the toxin into the infratemporal fossa and its contents [6]. Extensive developments in virtual surgical planning of intraoral templates have also been suggested for LPM needle insertion [7]. This may also be utilized to locate the inferior compartment of the temporomandibular joint [8].

The integration of extraoral or facial scanning technology in computer-aided design/computer-aided manufacturing (CAD/CAM) has been utilized in several different health fields, including smile design diagnostics and implantology in dentistry [9-11]. Different methods have been proposed for the alignment of these facial scans and intraoral scans of both dentate and completely edentulous patients [12]. Alignment of surface scans and

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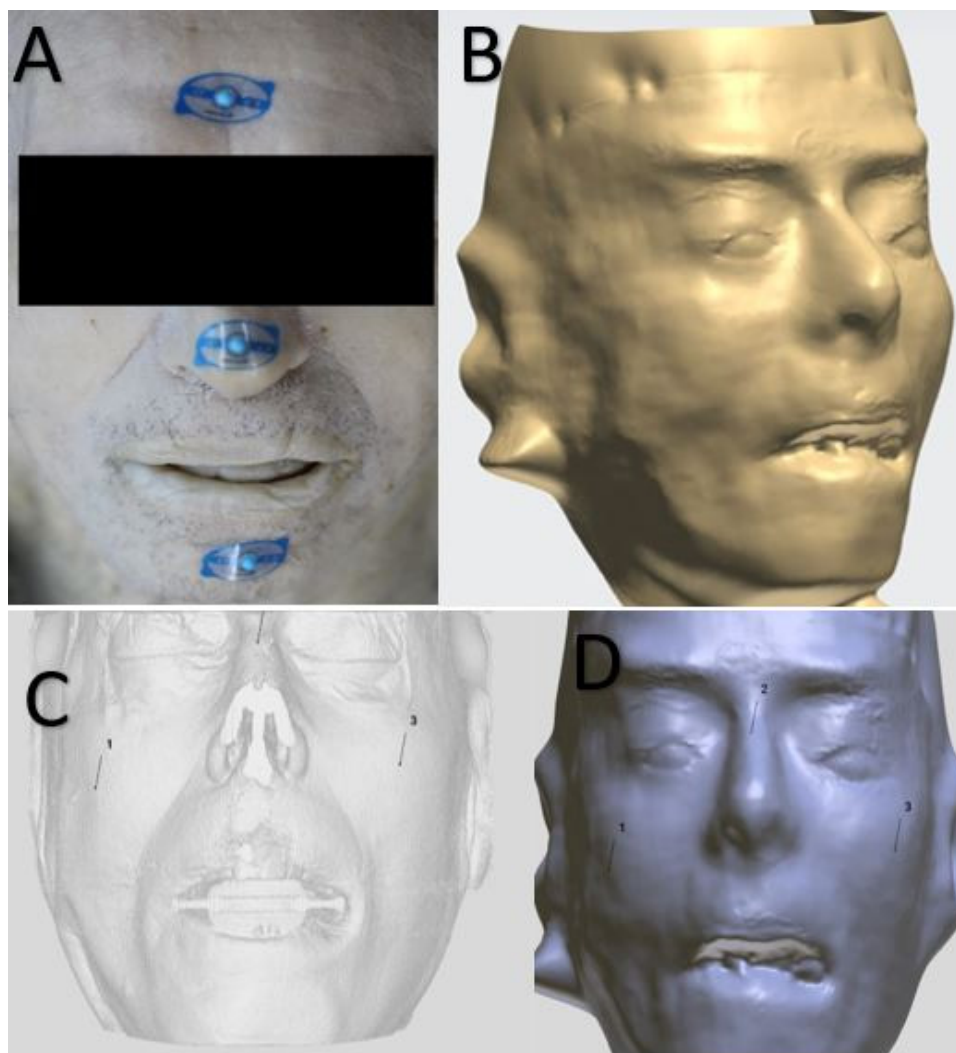


Fig. 1. (A) Radiopaque markers positioned on the surface of Cadaver test subjects' face, (B) standard tessellation language surface scan of subjects' face; (C and D) customizable visibility tool to establish defined surface on the skin of test subject.

cone-beam computed tomography (CBCT), where no hard tissue, either bone or dentition, is present for definitive alignment proves to be difficult and may require the use of a template or radiographic markers [13]. The alignment of facial scans and CBCT scans has not yet been reported.

This technical note describes a simplified digital workflow that enables the alignment of data, planning, construction, and application of extraoral templates. It also helps to guide the insertion of needles into the LPM and the inferior compartment of the temporomandibular joint, which are difficult-to-reach anatomical structures.

METHODS

Due to the experimental nature of this technique, an *in vitro* cadaveric study was developed. This was tested on 11 cadaver heads. Twenty-two templates were constructed, one for each side of the face. Four-millimeter radio-opaque markers (sure mark©, CT-40) were placed on the cadavers' nose, forehead, and chin in order to assist with the alignment (Fig. 1A). A CBCT scan was obtained for each head using a 17×13.5-cm field of view (Carestream CS 9300). Facial scans were performed with a smartphone (iPhone 11, Apple Inc.) on a facial scanning

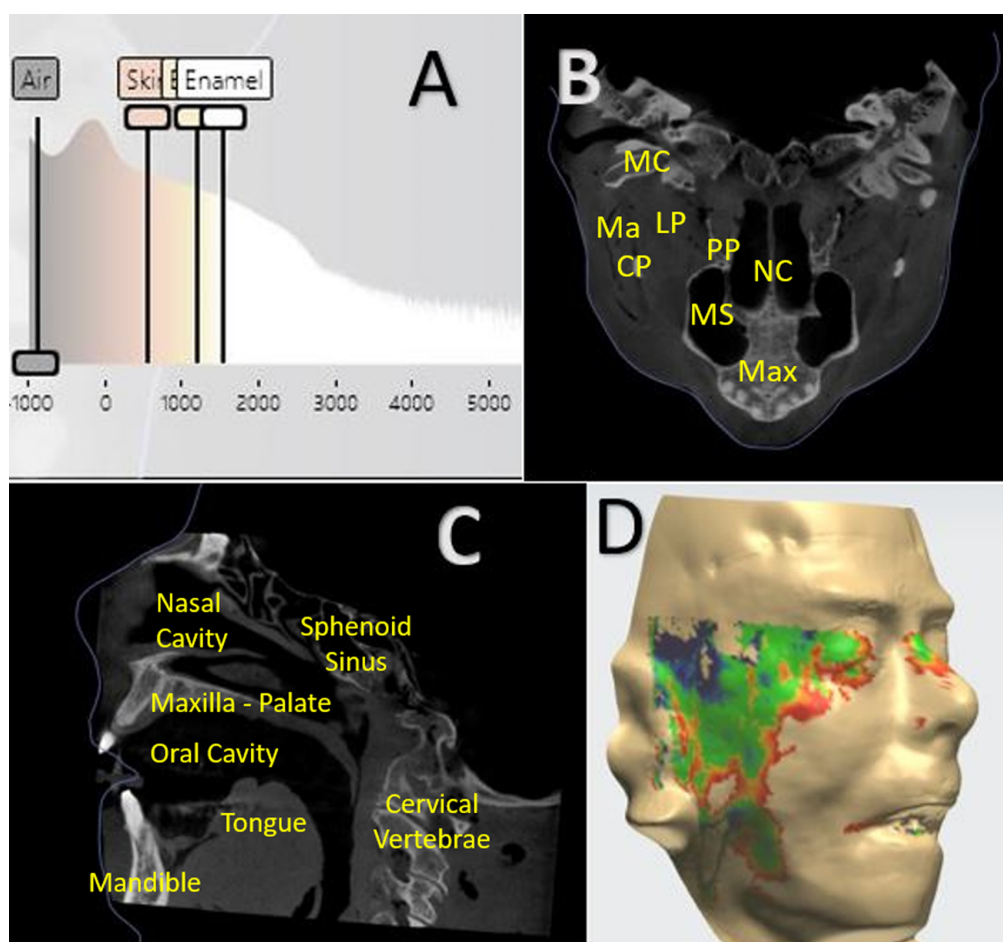


Fig. 2 (A) Visibility tool to modify the surface of CBCT in the context of Hounsfield Units; (B) axial and (C) sagittal views of face scan (blue outline) and CBCT indicating the alignment of facial and CBCT scans; (D) heat-map showing the alignment of CBCT to the face scan (green indicates < 0.2 mm, blue < 0.5 mm, and red < 1 mm). CBCT, Cone-beam computed tomography; CP, coronoid process; LPM, lateral pterygoid muscle; Ma, masseter muscle; Max, maxilla; MC, mandibular condyle; MS, maxillary sinus; NC, nasal cavity; PP, pterygoid.

application (Bellus 3D Dental Pro, Bellus 3D Inc.). The heads were stabilized using a plastic stand on a turntable, the face was scanned with the upper boundary as the hair implant line, and the lower limit consisted of the laryngeal prominence and lateral limits of the ears. This application helps to capture a subject's face and simply export a high-resolution standard tessellation language (STL) file, which is a 3D representation of a given object.

The digital planning phase was performed using implant planning software (Implant Studio, 3Shape A/S). A case was set up to replicate a subject receiving six implants. The STL files of the facial scan (Fig. 1B) were imported along with the corresponding CBCT data. The two datasets were initially aligned with a three-point comparison and then aligned with the custom alignment

tool built into the software (Fig. 1 C/D). The CBCT view was modified by changing the visibility of the Hounsfield units so that the skin surface of the subject was established (Fig. 2A). This value varied from -718 to -177, which has been established in several studies [14, 15]. This alignment section had a plain-cut tool that allowed movement through any 3D plain. This allowed the alignment to be examined on multiple plains (Fig. 2B/C) and for sections to determine the best fit adaption of the facial scan and CBCT (Fig. 2D). The alignment was examined in five key axial and sagittal planes for consistency among subjects (Fig. 2B/C).

A generic implant fixation pin was selected to simulate the injection path and site. Three sites were selected: one for the lower compartment of the temporomandibular

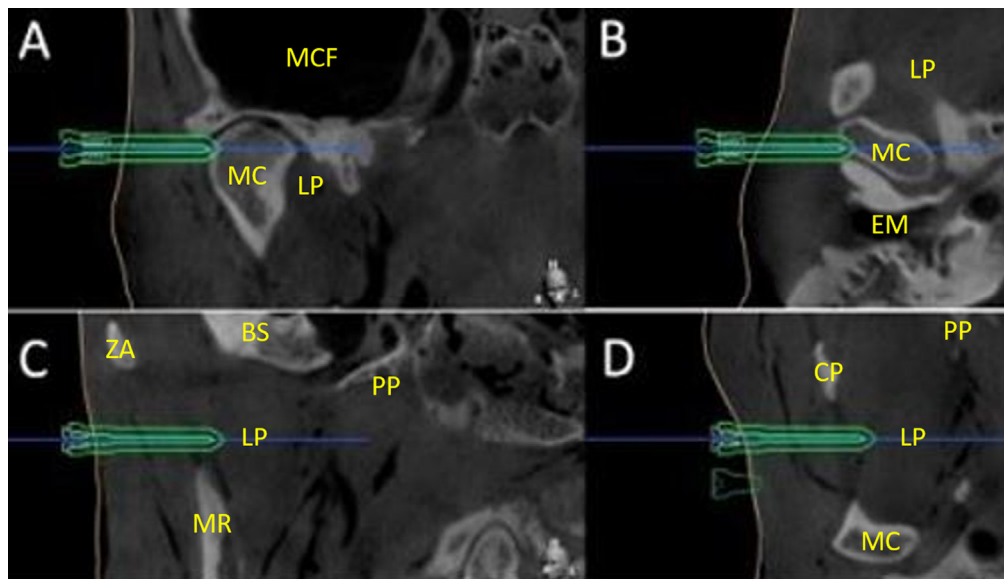


Fig. 3. Planning and construction of the surgical guide; lateral (A) and axial (B) view of the planned injection site for the lower compartment of the temporomandibular joint; coronal (C) and axial (D) view of the planned injection site for the LPM. Note that the blue line is indicative of the path of the needle only, not depth. BS, base of skull; CP, coronoid process; EM, external auditory meatus; LPM, lateral pterygoid muscle; MC, mandibular condyle; MCF, middle cranial fossa; MR, mandibular ramus; PP, pterygoid Process; ZA, zygomatic arch.

joint and two for the LPM. The temporomandibular joint injection site was directed toward the posterior and medial aspects of the condyle, aiming for the lower compartment area (Fig. 3A/B). The entry point of the “implant” was then positioned at a distal angulation so that the sleeve exit point was located close to the tragus.

Simulated implants were placed to reach the LPM (Fig. 3C, D). The path of the posterior injection began from the skin 0.5 cm in front of the condyle of the mandible, passed below the zygomatic arch, through the mandibular notch (between coronoid and condylar processes), intending to reach the LPM more posteriorly. The anterior LPM point was standardized to be 1 cm anterior to the posterior point, intending to reach the LPM more anteriorly, following a parallel path as the posterior injection. A digital template was then designed with small titanium sleeves (Stecco-system Technik GmbH & Co. KG) with an internal diameter of 1.16 mm and a length of 5 mm. The sleeves were positioned juxtaposed from the surface of the skin of the cadavers. A template was then designed on the STL file of the facial scan. The design covered key anatomical landmarks, including the supraorbital and infraorbital rims, zygomatic prominence,

and the mandible and temporomandibular joint area, providing stability of the template over the skin (Fig. 4A, B).

The template was printed on Form 2 (FormLabs, Massachusetts) stereolithography photopolymer printer and in FormLabs Surgical Guide material at a layer thickness of 50 μm (Form Labs, Massachusetts). Post-curing processes were performed according to the manufacturer’s instructions. The Stecco guide sleeves (GmbH & Co. KG) were inserted into the relevant positions as per planning sites (Fig. 4C).

It is important to note that sleeve selection must match needle choice. In the case reported here, the sleeves (1.16 mm) matched the 19G needles (1.10 mm). Figures 4C and 4D show the template with sleeves and the needles in position. For clinical use, the depth of penetration can be obtained from the planning software, measured from the outer border of the sleeve, and included in a PDF surgical report. Endodontic files with silicone stoppers can be used on the needles to precisely determine the depth of insertion as planned (Fig. 4D).

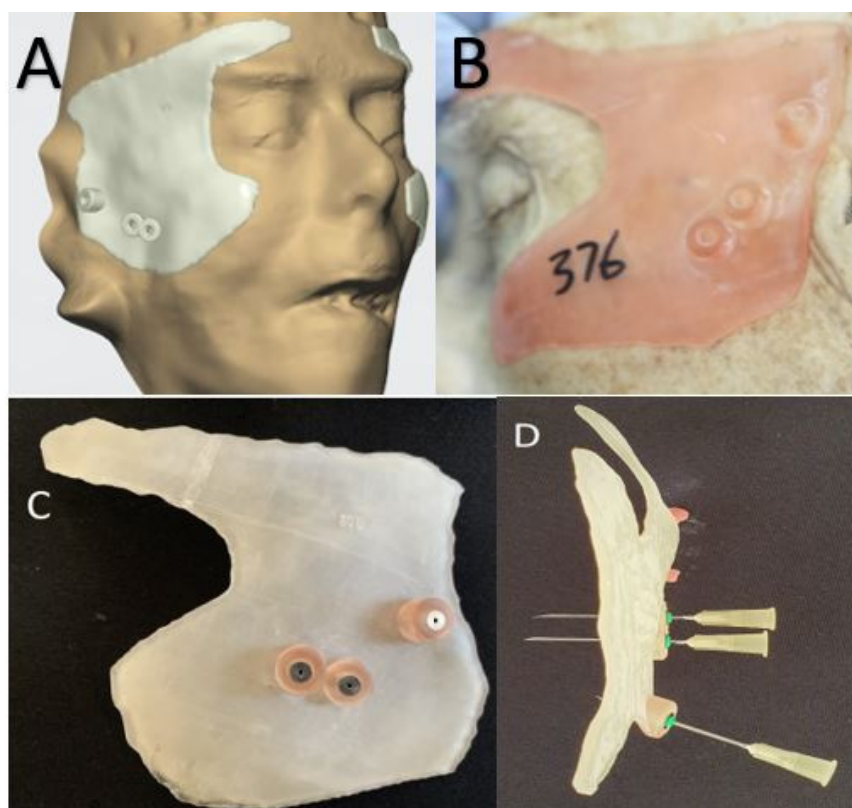


Fig. 4. (A) Design of the surgical guide; (B) printed guide for test fit before the insertion of the sleeves; (C) completed surgical guide with sleeves attached; (D) completed surgical guide with needles inserted including incorporating depth stops.

RESULTS

In total, 22 facial templates were created, without technical difficulties. They were clinically tested on each cadaver head on the right and left sides with clinically adequate adaptation and stability. The size of the template was sufficient to ensure good stability over the skin. This confirms that the designed resting areas had sufficient extension. The needles were inserted through the sleeves very tightly, with almost no deviation, ensuring an accurate insertion angle.

For the lower temporomandibular joint compartment injections, needle penetration was accurate, and contact with the condyle was obtained at the planned depths. For the LPM injections, the needle penetration did not touch the zygomatic arch or mandible as planned. This technical note aimed to describe the technique, particularly the alignment process. The proposed method was also tested

in a pilot study and the potential for this application was demonstrated. The results of precision and trueness, including needle deviations and depth measurements, for this study, has been covered in another publication [16].

DISCUSSION

When deciding on a face-scanning platform and implant planning system, the authors wanted to select two systems that were both readily available and had established user-friendly interfaces. Implant Studio software is a commercial software program in both clinical and laboratory settings [17]. This software was also selected because of its advanced CBCT viewing capabilities and its ability to import an STL file to design a template. The ability of the software to manually orient the STL mesh of the face scan and align it with CBCT was considered a key criterion for its selection. The

face-scanning software, Bellus 3D Dental Pro (Bellus 3D Inc.), was also selected because of its ease of use and accessibility. The accuracy of this application was recently validated [18]. This software can be downloaded onto any iOS device from iPhone X and iPad Pro onwards. It is also available on Windows 10 operating system with easy exportation of STL files.

The alignment phase of the scans is challenging. Several methods have been employed to align the STL file of the face scan with the CBCT data. Traditional digital techniques of data alignment rely on hard tissue markers, such as enamel or dentin, set at specific Hounsfield unit thresholds in the range of 1553 to 2850 for the enamel for example [14]. These alignments rely on the built-in software, creating an automatic alignment between the STL file and the preset-specific resolution. Attempts to achieve this automatic alignment by modifying the Hounsfield units have been unsuccessful (Fig. 2A). Radiopaque marks were also placed during CBCT and facial scans. A three-point alignment utilizing radio-opaque markers, which can be utilized in dual scan protocols for fully edentulous implant planning, was attempted. Due to movement in the soft tissue between the CBCT and the facial scan, the automatic alignment processes in the software could not accurately align the two scans. The final alignment, therefore, relied on a manual approach, as described in the Materials and Methods section.

The challenges the authors faced with existing techniques were the availability of equipment and infrastructure. Many large dental practices now use CBCT. The face-scanning technology utilized in this method is easy to use on current mobile devices, thus making this technology more readily available as opposed to expensive and cumbersome commercially available face scanners. The use of a face scanner via a mobile device might also help to disseminate the proposed technique. The planning and production of the template can be completed by third-party dental laboratories or clinical dental practices if the software is not available because 3D planning and printing of the template are now

becoming common in many places.

This innovative approach for the creation of extraoral 3D-printed surgical templates constitutes a new therapeutic option for injections into the LPM and the lower temporomandibular joint compartment. Botulinum toxin injection into the masseter and pterygoid muscles are currently used as an adjunct treatment tool for the management of TMDs, such as bruxism, clenching, masseteric hypertrophy, recurrent dislocation of the temporomandibular joint, oromandibular dystonia, and chronic myelogenous orofacial pain. This technique will be beneficial for procedures that rely on accurate injections into specific anatomical regions. Extraoral CAD/CAM templates for injections into the LPM have not been described. Kruse et al. [19] reported the use of a similar device to perform upper compartment arthrocentesis in clinical situations, indicating the use of these applications for other procedures in the head and neck. However, several other indications can benefit from this type of extra-oral template. These include guided external implant fixation for maxillofacial prosthesis, precise injections into other muscles, and guided radioactive isotope insertion or esthetic dermal fillers.

The technique described here helped create a clinically acceptable extra-oral template for injections into the LPM and the lower compartment of the temporomandibular joint. The alignment of datasets can be challenging. However, a systematic approach to this step simplifies and makes it clinically acceptable. It uses readily available contemporary devices to acquire 3D images, such as CBCT and face scanning with mobile phones. The planning phase used commonplace dental implant planning software, and the alignment challenges between the DICOM and STL data over soft tissues were overcome, as described. Printing of the template was also performed easily using commercially available 3D printers used in dentistry. The combination of the above factors makes this technique a timely and cost-effective option for safe and precise extra-oral injections with the potential for other future applications. There are some limitations to the proposed technique, including the

difficulty of checking if the needle has reached the inferior temporomandibular joint compartment, which could be verified radiologically by the use of a radiocontrast agent. Furthermore, as this proposed method was trialed on cadavers, further in vivo research studies are necessary to exclude any possible complications in human subjects.

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Peter Reher: Conceptualization, Resources, Supervision, Writing - review & editing

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