Int. J. Oral Maxillofac. Surg. 2019; 48: 1077–1083
https://doi.org/10.1016/j.ijom.2019.01.024, available online at https://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Research Paper
TMJ Disorders

Accuracy of custom-fitted temporomandibular joint alloplastic reconstruction and virtual surgical planning

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S. Sembronio, A. Tel, F. Costa, M. Isola, M. Robiony: Accuracy of custom-fitted temporomandibular joint alloplastic reconstruction and virtual surgical planning. Int. J. Oral Maxillofac. Surg. 2019; 48: 1077–1083.

Abstract. The purpose of this study was to evaluate the accuracy of temporomandibular joint (TMJ) custom-made replacements by means of virtual surgical planning.

The authors review 11 TMJ custom-made prostheses made of both mandibular and fossa components. Surgeries were virtually planned and patient-specific devices were designed together with surgical cutting and positional guides. Three-dimensional models for both preoperative planning and postoperative computed tomography scans were generated and overlapped in order to evaluate differences in measurements. Correlation between virtual preoperative and real postoperative prosthesis positioning was described by Lin's coefficient.

Results of statistical analysis showed an almost perfect concordance. Wilcoxon's matched-pairs test showed no statistically significant deviation between preoperative virtual surgical planning and postoperative results. Colour map analysis confirmed the correspondence between virtually planned positioning of the devices and postoperative results. All the prostheses were placed with great accuracy.

In conclusion, virtual surgical planning, surgical guides and patient-specific devices provide accuracy and precision in surgery for custom-made TMJ replacement.

Key words: accuracy; TMJ; custom made; virtual surgical planning; prosthesis; Facial Care Project.

Accepted for publication 28 January 2019
Available online 15 February 2019

Temporomandibular joint (TMJ) replacement is a reconstructive option for TMJ disease, including multi-operated temporomandibular joint disorders (TMD), end-stage osteoarthritis, severe inflammatory disease, fibrosis or bony ankylosis, failed tissue grafts, previously failed alloplastic implants, situations with loss of vertical mandibular height, bony resorption, non-repairable trauma, congenital or developmental skeletal abnormalities, pathological lesions[1,2]. Currently, stock and custom prostheses represent both options for TMJ alloplastic reconstruction. Stock prostheses are readily available in different sizes and geometries for reconstruction, but prostheses need to be adapted intraoperatively to the patient's anatomy[3].

Conversely, custom-made TMJ prostheses provide an optimal intraoperative fitting, but they require an accurate planning and manufacturing process[4,5].

Virtual surgical planning and three-dimensional (3D) printing technologies have become important aids to combine improved 3D visualization of patient's anatomy with the simulation of surgical steps. Virtual surgical planning enables the surgeon to optimize osteotomy planes and to deal with multiple surgical scenarios in a safe computerized environment[6,7].

The combination of virtual surgical planning and 3D printing has been used to produce surgical guides, defined as patient-specific intraoperative templates allowing surgeons to trace surgical osteotomies and insert screws according to the virtual project[8]. In fact, the use of computer-generated cutting guides and surgical templates allows for precise transfer of the virtual planning to the surgical field. The use of custom-made devices and virtual surgical planning is easier and has advantages in terms of precision and predictability, especially in difficult cases.

The purpose of this study was to evaluate the accuracy of TMJ alloplastic reconstruction by comparing preoperatively planned and postoperatively obtained positions of prostheses in a series of patients.

The authors hypothesize that the whole sequence starting with virtual planning, passing through 3D printing of cutting guides and ending with the surgical implantation of custom prostheses, provides accuracy in TMJ replacement.

Materials and methods

Patients and methods

Ten patients underwent TMJ alloplastic reconstruction at the Maxillofacial Department, Academic Hospital, University of Udine, Italy, from 2016 to 2017 and were retrospectively enrolled for this study. Eleven TMJ reconstructions were analysed, patient one undergoing bilateral TMJ replacement (Table 1). Patients underwent preoperative computed tomography (CT) scan and DICOM data were sent to a biomedical engineering company (SINTAC s.r.l. Biomedical Engineering, Trento, Italy) for preoperative virtual planning and manufacturing of prostheses. A titanium alloy was used for the mandibular component and ultra-high molecular weight polyethylene (UHMWPE) was used for the fossa component. Fossa was designed in order to completely enclose the condylar head, including a posterior lip to avoid posterior dislocation of the condyle. In addition to the customized prosthesis design, polyamide surgical guides allowed for intraoperative surgical bone resection and prosthesis placement, matching at the same time preoperative design and individual anatomy with surgical osteotomies, screws and prostheses positioning (Fig. 1).

Table 1. Patients enrolled for the study and pathology related to temporomandibular joint alloplastic reconstruction.

Patient	Age	Pathology	Prosthetic replacement
1	38	Multi-operated internal derangement	Bilateral
2	26	Ankylosis	Unilateral
3	45	Multi-operated internal derangement	Unilateral
4	60	Chondrochalcinosis	Unilateral
5	52	Multi-operated internal derangement	Unilateral
6	29	Condylar resorption	Unilateral
7	47	Multi-operated internal derangement	Unilateral
8	55	Condylar osteoma	Unilateral
9	33	Ankylosis	Unilateral
10	41	Ankylosis	Unilateral

Surgical procedure

All surgeries were performed under general anaesthesia with naso-endotracheal intubation. A single dose of 2.2 g amoxicillin-clavulanate was administered intravenously as antibiotic prophylaxis. Preauricular and retro-submandibular approaches were made to expose the TMJ, zygomatic arch, mandibular condylar head and the lateral side of the mandibular ramus. Surgical polyamide templates were inserted and optimal fit was achieved. Guides were then fixed by drilling screw holes which avoided the path of the inferior alveolar nerve as virtually planned. Precise osteotomies were traced by means of piezoelectric handpiece according to the guidance provided by surgical cutting templates. In patients with limited mouth opening (less than 25 mm) due to coronoid hyperplasia, temporalis muscle fibrosis or in cases of interference with the fossa component, a resection of the coronoid process was simulated and then performed.

The custom-made fossa prosthesis was then inserted and secured with screws of individual lengths according to the virtual plan.

Patients' occlusion was stabilized using intermaxillary rigid fixation and then mandibular ramus prosthesis was inserted and secured with the screws of individual length using the same holes previously drilled for the cutting guide fixation. During mandibular ramus prosthesis positioning surgeons made sure that the new condyle was seated in the fossa component prothesis in centric relation. Then the intermaxillary fixation was released and the patient's mandible was opened and closed in order to assess the range of motion and the correct function of the fossa and ramus components and their proper relationship.

No anterior or posterior dislocation of the condylar component and no mechanical interference nor occlusal change or instability were tolerated. Finally, a multilayer closure of the wounds was performed.

Models

One week after surgery, each patient underwent postoperative CT scan and the resulting data were imported into Mimics 20.0 (Materialise, Leuven, Belgium) for segmentation.

For each patient, models of postoperative CT were superimposed with originally planned STL files. Models were imported in 3-Matic 12.0 (Materialise, Leuven, Belgium) and a best-fit algorithm was used to align postoperative STL models with preoperative STL models. Therefore, it was possible to compare the virtually designed placement of prostheses with the actual position achieved after surgery.

Two alignment procedures were performed: in the first alignment, preoperative and postoperative mandibles were matched separately in order to evaluate the ramus component of the prostheses, in the second alignment, preoperative and postoperative skulls were matched to compare the glenoid fossa components.

Reference system

In order to make measurements comparable between different skull models, a local coordinate system was implemented. All models were reoriented defining a 3D space based on references provided by Chin et al.[9].

The origin of axes was represented by Po (Porion). The y-axis was the line Or-Po (Orbitale-Porion). The z-axis passed through Po and was parallel to the

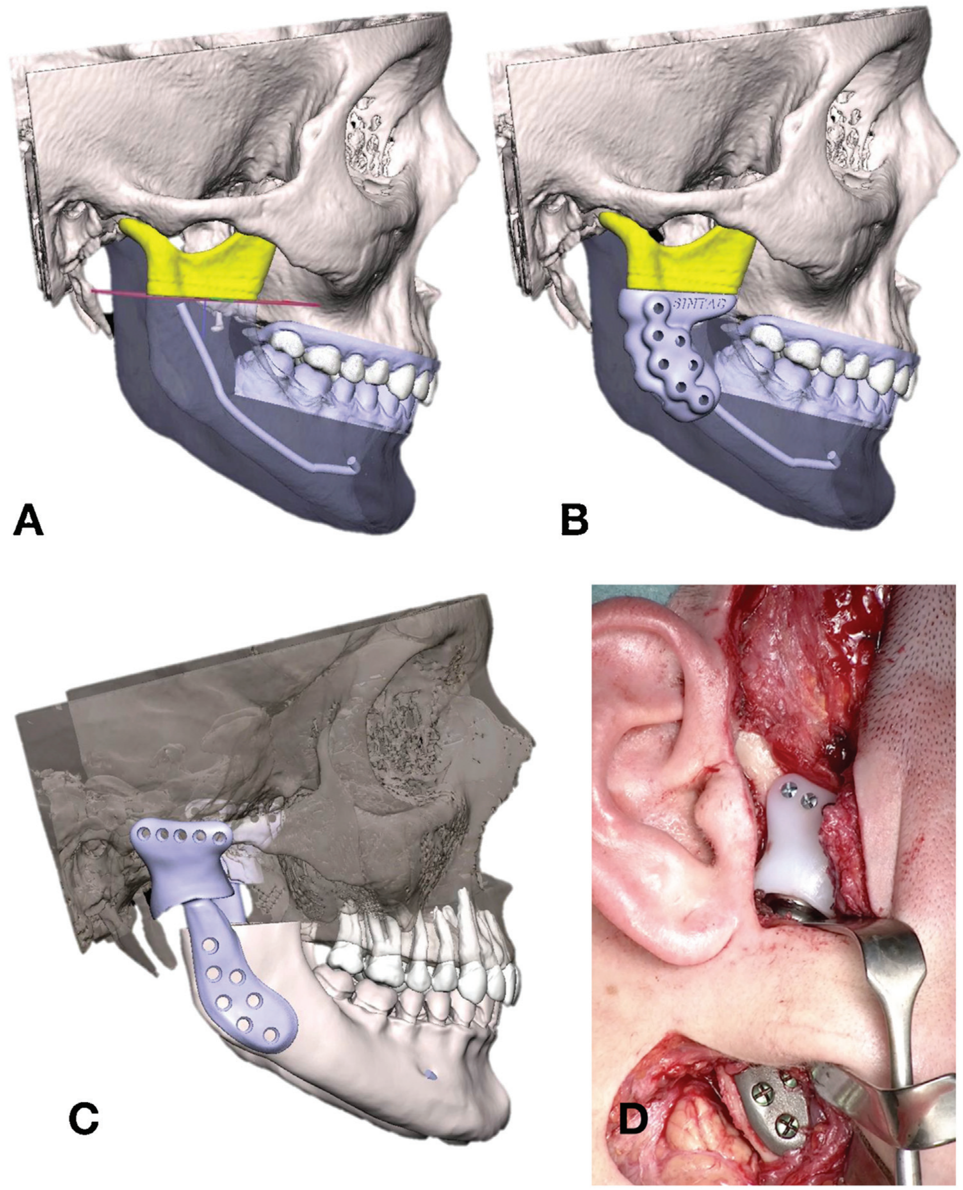

Fig. 1. Virtual surgical planning. (A) Cutting planes on mandibular ramus. (B) Surgical guides for osteotomies and screw positioning. (C) Prosthesis design. (D) Intraoperative view with mandibular ramus and fossa components.

midplane that intersected Na (Nasion), S (Sella) and Ba (Basion). The x-axis was consequently established according to y and z axes. Horizontal plane, midsagittal plane and coronal plane were defined as follows: (1) horizontal plane contained y-axis and included line Or-Po, thus representing Frankfurt plane; (2) midsagittal plane passed through N-S-Ba and was perpendicular to Frankfurt plane, therefore it represented the symmetry plane along the x-axis; (3) coronal plane was perpendicular to y-axis and passed through Po. Both preoperative and postoperative models shared the same coordinates, as they had been made previously coincident (Fig. 2). According to such reference planes, couples of distances were measured in Rhinoceros (Robert McNeel & Associates, Seattle, WA, USA) for the preoperative and postoperative models in order to assess possible discrepancies for TMJ prostheses positioning. Measurements were calculated from fixed and well-established cephalometric points (B point and Porion) to the centre of each screw for both mandibular ramus and glenoid fossa, preoperatively and postoperatively. Because skull and mandible were matched separately, the first couple of distances were calculated for the mandible and the accuracy for the ramus component was evaluated; the second couple of distances was calculated for the skull and estimated the accuracy of glenoid fossa positioning. Measurements were determined in the midsagittal plane for all patients. The accuracy of the ramus was determined by measuring the distance between B point and the centre of each screw, and the first couple of preoperative and postoperative distances was obtained. The accuracy of the glenoid fossa was estimated by measuring the distance between Po and the centre of each screw (Fig. 3). It is worth reporting that screw centre was chosen as target point for the measurements because it is an easily reproducible point and it is the only visible element of glenoid fossa in postoperative CT, as it is made of radiotrasparent UHMWPE.

Additionally, even if the accuracy for both ramus and mandibular components

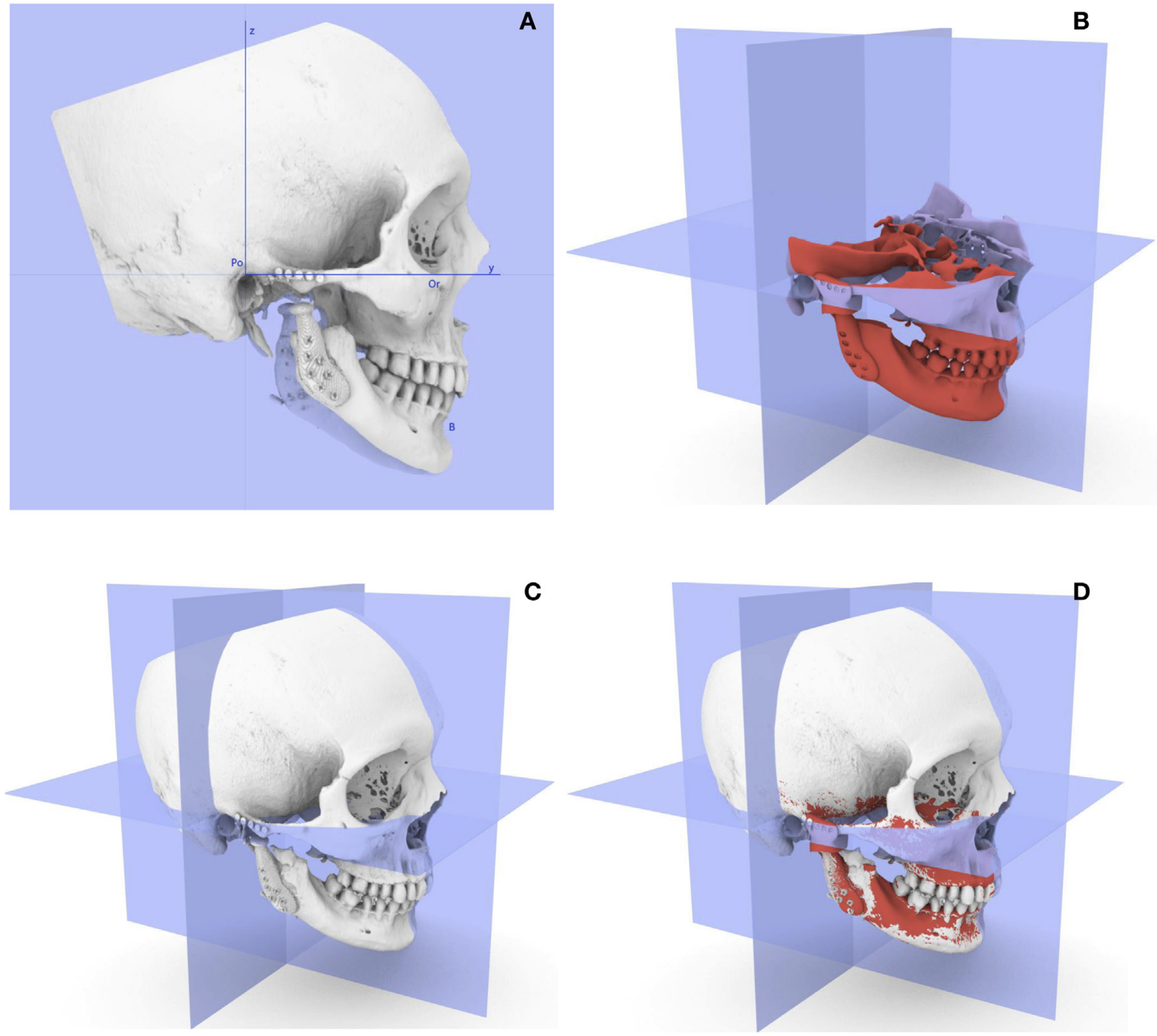

Fig. 2. (A) Orientation system used for skull models. Po is the origin of axes. Line Or-Po defines the y-axis. The z-axis is parallel to the midsagittal plane passing through Na, S, Ba. The y-axis also identifies the Frankfurt plane. Measurements of distances were achieved on the midsagittal plane. (B) Preoperative models and (C) postoperative models share the same reference system in order to make preoperative distances and postoperative distances comparable (D).

are separately evaluated, overlap analysis of the whole skeletal structure was performed (Fig. 2D).

Statistical analysis

Lin coefficient was estimated in order to describe the concordance between preoperative and postoperative distances. Lin concordance correlation coefficient describes agreement on a continuous measure obtained by two different methods, and combines measures of both precision and accuracy. Plotting preoperative vs. postoperative data, it determines how far the observed data deviate from the line of perfect concordance, namely the line whose slope is 1[10].

Limits of agreement at 95% and 99% for differences were estimated by Bland and Altman analysis, thus defining an interval of possible positional differences[11,12].

Wilcoxon matched-pairs test was performed to compare preoperative distances and postoperative distances and assess whether differences between couples of measurements were statistically significant. Statistical analyses were performed using Stata/SE 15.1 (Stata Corporation, College Station, TX, USA).

Moreover, for each pair of aligned meshes, a 3D surface deviation analysis was performed with 3-Matic software, assessing surface deviation of the postoperative model from the preoperative target entity. The differences were quantified based on calculating the Euclidean distances from all vertices of the surface mesh of one model to their nearest surface on the other model. Surface deviation colour maps were generated to visually describe the magnitude of displacement between preoperative planning and postoperative result. Red colour indicates positive differences, and blue colour negative differences, while green colour represents a neutrality zone. The range of distances was set to −1 mm and +1 mm.

Results

Differences between preoperatively planned distances and postoperative distances were measured. Distances were calculated for both mandible and skull in order to evaluate, respectively, the accuracy of ramus and glenoid fossa positioning.

Lin concordance correlation coefficient (Fig. 4) was 0.999 (95% confidence interval (CI), 0.999–0.999; 99% CI, 0.999–1.000), thereby showing almost perfect concordance.

Bland and Altman analysis estimated 95% limits of agreement ranging from −1.608 mm and 1.598 mm (Fig. 5); 99% limits of agreement ranged from

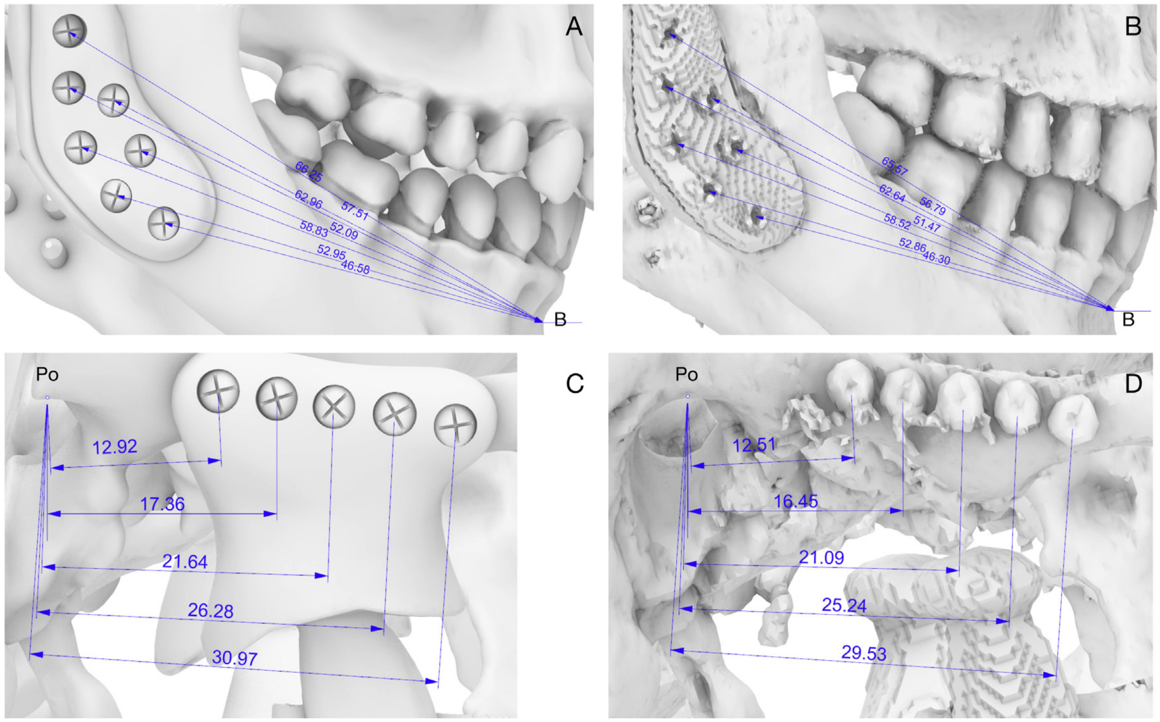

Fig. 3. (A, B) Preoperative and postoperative distances for the mandible. All distances were calculated on midsagittal plane. (B) B point is used as a fixed landmark to evaluate the accuracy of ramus positioning. (C, D) Preoperative and postoperative distances for the skull. Po (Porion) is used as a fixed landmark for distances assessing the positional accuracy of glenoid fossa component.

−2.112 mm and 2.101 mm. Additionally, 53.85% of differences were smaller than 0.5 mm, and 79.02% of differences were smaller than 1 mm. Wilcoxon matched-pairs test showed no statistically significant difference between preoperative distances and postoperative distances ($p = 0.83$).

As shown in Fig. 2D, although alignments were separately performed for the skull and the mandible, superimposition between planned and postoperative models and the resulting overlap analysis reported coincidence of the skeletal structures.

Referring to surface deviation analysis, all points of a colour map representing ramus component and screws of fossa were included within the range of −1 mm and + 1 mm and green colour was widely represented on the map showing no substantial variation between preoperative planning and postoperative results for both glenoid fossa and mandibular ramus component (Fig. 6).

Discussion

Custom-made reconstructions allow for unprecedented precision in restoring the anatomy and function of patients. TMJ pathology represents an important field for the application of reconstructions achieved by means of custom-made prostheses. Virtual surgical planning is the core process of any custom reconstruction, allowing analysis of multiple surgical possibilities in a virtual environment, creation of surgical guides and design patient-specific devices modelled on the original anatomy of the patient.

In the literature, alloplastic TMJ total reconstruction is an effective and safe long-term management of patients with severe and debilitating TMJ end-stage disease in terms of improved mandibular movement and jaw opening, improved diet consistency, improved quality of life and a significant reduction in pain after surgery[13,14]. Progress in computer-aided design and computer-aided manufacturing (CAD/CAM) planning allow for the production of patient-specific components, leading to substantial improvements in the construction of alloplastic TMJ prostheses. The goal

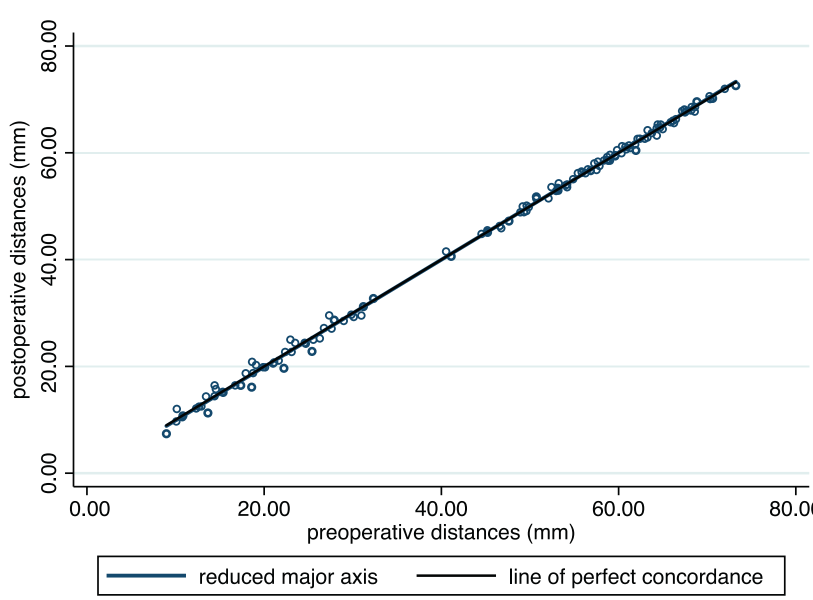

Fig. 4. Concordance between preoperative and postoperative distances is described by Lin's coefficient. The line of perfect concordance represents the perfect correspondence between measures and has slope of 1.

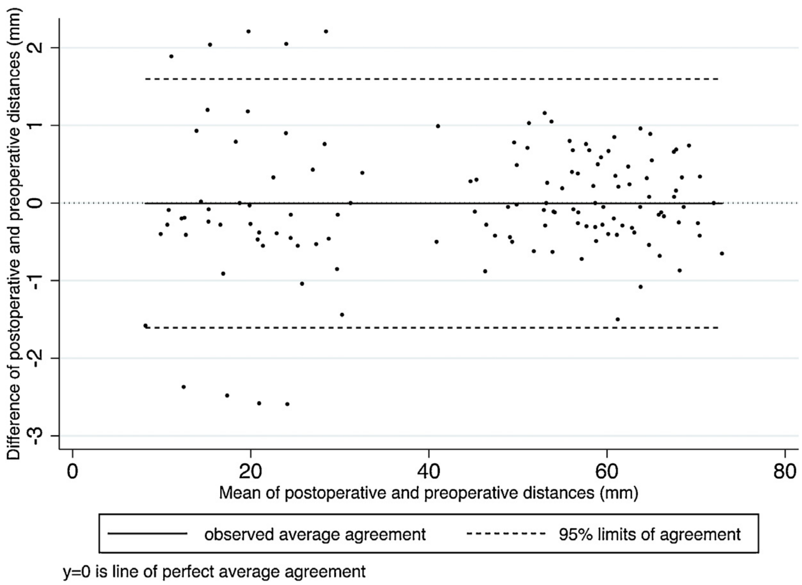

Fig. 5. Bland–Altman plot. 95% of differences between postoperatively measured distances and their preoperative virtual counterparts fall in an interval ranging from −1.608 to 1.598 mm.

of any TMJ custom reconstruction is to attempt to replicate the function of the joint while the anatomy in the area of condylar function is significantly displaced inferiorly by nature of the necessary design requirements and principles. At the same time, reconstruction needs to be accurate and precise.

Many authors have reported consistent results with CAD/CAM patient-specific devices following virtual surgical planning and a one-step procedure[15,16]. As reported by Gerbino et al.[17], the use of custom-made devices and virtual surgical planning is easier and has advantages in terms of precision and predictability compared with stock devices, especially in difficult cases and when jaw repositioning is deemed to be necessary. But such a concept needs to be demonstrated.

In literature several studies have tried to evaluate the accuracy of virtual surgical planning in orthognathic and oncologic procedures[9,18] showing accurate surgical results, but there are very few reports assessing the concordance between preoperative planning and postoperative results in TMJ alloplastic reconstruction.

Bai et al. evaluated the accuracy of stock prostheses positioning with the aid of surgical guides, overlapping preoperative models with postoperative CT scan, and concluding that surgical guides can be a useful tool for accurate prostheses positioning[19]. However, the authors did not analyse a custom-designed TMJ prosthesis, which can provide superior results in terms of precision and accuracy.

It appears that there is a lack of studies investigating the accuracy of implantation for TMJ alloplastic custom replacement.

Recently, Kraeima et al. reported the development of a new patient-specific TMJ prosthesis and also evaluated the accuracy of implantation in a cadaver study[20]. Measurements were determined using glass tracer spheres as references for the implanted prostheses. The authors analysed the degree of accuracy of TMJ prosthesis positioning using 3D surface deviation analysis based on colour maps, that represent a well-documented method in the literature to visually describe geometrical differences between two overlapped entities. The accuracy of implantation was evaluated by superimposing the virtual design file onto the postoperative CT scan, and a median error of 0.81 mm and a standard deviation of 0.29 mm were reported.

Using the same method based on colour map analysis, in our study surface deviation results are displayed within a given threshold, that was set between −1 mm and +1 mm, which approaches the mean error reported by Kraeima[20]. As visually documented by the broad presence of the green colour, which represents optimal alignment between mesh surfaces of prostheses (Fig. 6), our results indicate that mean positional error fell within the same range. This indicates that implants positioning was performed with accuracy.

Unfortunately, statistical validation based on results of colour maps analysis was not performed. Moreover, since mean error can be intended as a descriptive variable, it provides information only about its sample.

In order to assess whether discrepancies between preoperatively planned and postoperatively positioned prostheses are to be considered significant or not, and to state that TMJ reconstruction using custom-

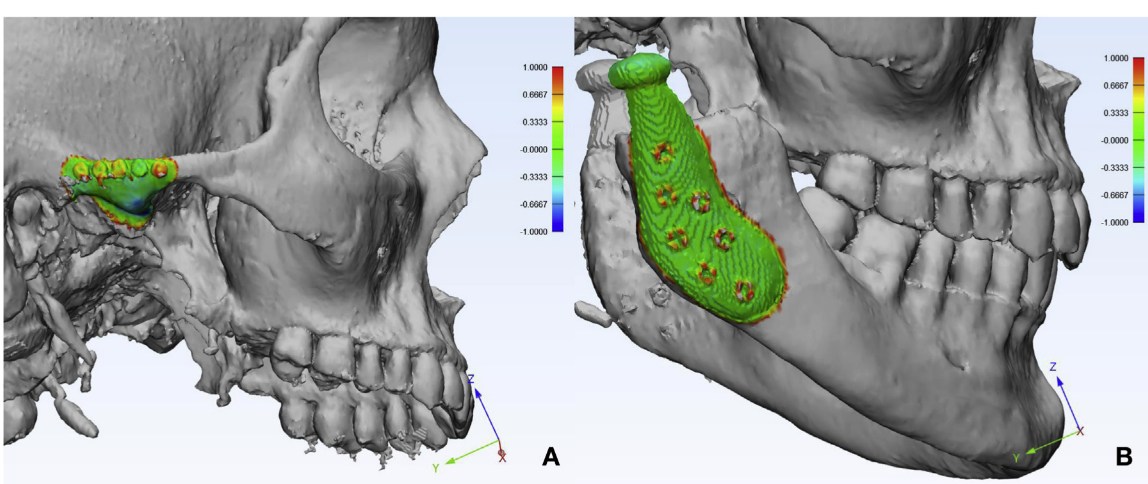

Fig. 6. Heatmap. Volumetric part comparison analysis visually describes the magnitude of discrepancy across the whole surface of the mesh. Image A analyses the fossa component, for which only screws are visible; image B analyses the ramus component. Results are displayed with a tolerance interval of −1 mm and +1 mm.

fitted devices is an accurate method, statistical validation is necessary. In our study we searched for a suitable statistical method to generalize results, because conclusions about accuracy of implantation need to be extended to the whole population of patients undergoing TMJ alloplastic replacement by means of custom-made prostheses. Therefore, the authors used the Bland–Altman limits of agreement method to define an agreement interval that includes 95% of the differences between distances that were measured, respectively, in preoperative virtual surgical planning and postoperative CT models. In other words, limits of agreement can provide an approximation of discrepancies occurring between virtually planned surgery and achieved outcome. Our results showed that 95% of positional differences between each postoperative result and its planned counterpart ranged from −1.608 mm to 1.598 mm, indicating that positioning of prostheses minimally differed from preoperative virtual planning.

Additionally, the use of Lin's coefficient for the strength of concordance had a value of 0.999 with a 95% confidence interval of 0.999–0.999, indicating almost perfect coincidence between virtual surgical planning and postoperative results.

Wilcoxon matched-pairs test confirmed that positional differences between preoperative and postoperative measurements were not statistically significant.

In our work the individual alignments for skull and mandible were performed separately to avoid any possible biases. However, accuracy was verified for both single components and this permitted to verify the same accuracy for the entire craniomandibular complex with both prostheses considered together. Fig. 2D shows correspondence between planned and postoperative models indicating accuracy and stability of the mating between fossa and ramus prostheses components.

Our results show that virtual surgical planning is a reliable method to preoperatively study and plan surgery, and surgical guides, including drilling holes and cutting templates, represent effective devices to transfer the preoperative plan in the operating room during surgery. In conclusion, custom-made TMJ alloplastic prostheses and virtual surgical planning have to be considered an accurate method to reconstruct TMJ as planned.

Funding

This study received no funding.

Competing Interests

The authors have no relevant financial disclosures.

Ethical Approval

This study was approved by the University of Udine ethics board. Approval number: 38/IRB_ROBIONY_18.

Acknowledgements. The authors acknowledge and appreciate the efforts of Manuel Leonardo Righetto and Andrea Sandi in providing essential help for preoperative planning, overlap and analysis of models.

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