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Clinical Paper
TMJ Disorders

Reconstruction of the temporomandibular joint: a comparison between prefabricated and customized alloplastic prosthetic total joint systems

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Abstract. The implantation of an alloplastic total temporomandibular joint (TMJ) prosthesis is an innovative approach for the treatment of end-stage TMJ disorders. Two types of system exist: prefabricated (stock) and customized computer-aided design/computer-aided manufacturing (CAD/CAM) devices. A clinical study was performed to evaluate the effectiveness of these two designs. Twenty-eight patients treated between 2015 and 2017 were included and assigned to two groups: stock prostheses (group 1) and customized CAD/CAM prostheses (group 2). Clinical evaluations were performed at five time-points up to 6 months postoperative. Parameters included maximum interincisal opening, pain, diet, complications, and subjective well-being at the end of follow-up. Differences between pre-surgery and 6-month post-surgery values were highly significant ($P < 0.001$). No patient required a liquid diet at the end of treatment, and 66% of group 1 patients and 100% of group 2 patients reported improved well-being. Complications were observed in 32% of patients and included temporary paralysis of the facial nerve. In conclusion, clinical outcomes of stock and CAD/CAM prostheses suggested great improvements in mouth opening and reduction of pain as a result of the rehabilitation of TMJ function. Results showed comparable data for the two types of prosthesis design at 6 months postoperative.

Key words: alloplastic temporomandibular joint reconstruction; temporomandibular joint disorders; prosthetic total joint replacement.

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Temporomandibular joint disorder (TMD) is a collective term used to describe a number of clinical problems that involve the masticatory musculature and the temporomandibular joint (TMJ) itself[1]. The treatment of functional TMD is commonly based on conservative therapy including physical therapy, pain therapy, and splint therapy[2–4]. Depending on the severity of the TMD, treatment varies in the degree of surgical invasion. One effective method to achieve rapid improvements in mouth opening and pain reduction is TMJ reconstruction using an alloplastic total prosthetic joint replacement (TJR)[5–8]. This invasive approach is still regarded as the last resort for the treatment of TMD[9]. Complete resection of the diseased joint and the implantation of a fossa and a condyle component instead is an invasive and irreversible procedure. There are clear indications for the use of a TMJ TJR, for example diseases involving bone loss and failed conservative treatment, restricted mouth opening, occlusal failure, or a high level of pain[10].

In general, two different types of TMJ TJR system are available: stock systems and custom-made computer-aided design/computer-aided manufacturing (CAD/CAM) systems. While stock devices are prefabricated and available in different standard forms and standard sizes, each CAD/CAM component is manufactured using the patient's individual DICOM data (Digital Imaging and Communications in Medicine) (Fig. 1). A customized TMJ TJR system is developed for the patient-specific situation and should provide a perfect fit. However, the communicating joint surfaces of the fossa and the condyle of the implant are standardized, as in the stock system.

The treatment of TMD is diverse and depends on the type of disease, as well as the duration and subjective level of pain. Alloplastic reconstruction might be advantageous in achieving a rapid improvement of symptoms and fast rehabilitation of masticatory function. The study reported here was a clinical trial evaluating the results of unilateral alloplastic reconstruction of the TMJ using prosthetic TJR in patients treated between 2015 and 2017. The aim of this study was to evaluate the improvements after surgery with regard to mouth opening, pain, diet, and subjective well-being over a 6-month follow-up period. Special attention was paid to the difference between the stock and customized prosthetic systems.

Materials and methods

Subjects

The study included adult patients suffering from different end-stage TMD who were admitted to the Central Medical Center Bremen with the need for unilateral TMJ replacement by alloplastic prosthetic system between 2015 and 2017. Exclusion criteria were malignancies of the head and neck, previous radiotherapy or administration of anti-resorptive drugs, the need for adjustment of dental occlusion, skeletal dysgnathia with the need for orthognathic surgery, and previous TMJ replacement (either alloplastic device or autologous).

Patients were assigned to one of two groups: patients who received a prefabricated stock prosthesis (group 1) and patients who received a customized CAD/CAM prosthesis (group 2). Clinical examinations were performed and data were recorded at five different time-points: preoperative (T0), 72 hours post-surgery (T1), and 4 weeks (T2), 12 weeks (T3) and 6 months post-surgery (T4).

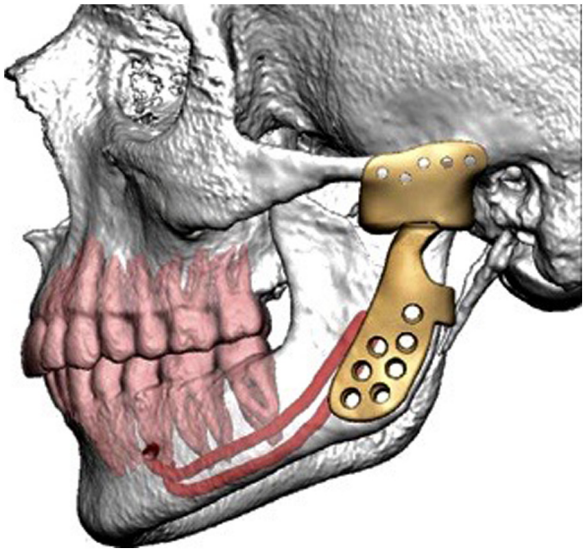

Fig. 1. CAD planning for a customized total joint prosthesis.

Alloplastic prosthetic TJR systems

Both prosthetic systems were provided by Zimmer Biomet (Jacksonville, FL, USA). The characteristics of these systems have already been reported elsewhere[11]. The condyle component is made of a metal cobalt–chromium–titanium–nickel alloy. The implant surface, which contacts the bone, is coated with a titanium plasma layer for improved osseointegration. The fossa component is made of ultra-high molecular weight polyethylene (UHMWPE) and the osteosynthesis screws are made of titanium alloy. The stock system provides three standard forms of condyle component (standard, narrow and offset) and three sizes of fossa and condyle component (small, medium and large). All components can be flexibly combined with each other. The CAD/CAM system was manufactured using the DICOM data of the respective patient following the standardized Zimmer Biomet protocol. The production process takes at least 8 weeks. The prosthesis material is the same for both the stock and CAD/CAM prostheses. In special cases, such as a nickel allergy, the mandibular component is made of titanium to avoid any reaction. For intraoperative use, the CAD/CAM system offers cutting guides (acrylate and epoxide resin) as templates for resection of the condyle and fossa and for exact positioning of the implants.

Surgery

In all cases, the surgical procedure was performed under general anaesthesia by one surgeon (J.R.). A preauricular and submandibular approach was used to expose the TMJ, the mandibular ramus, and the angle. Resection of the condyle was performed using a Piezosurgery device (Mectron GmbH, Cologne, Germany). Where a stock prosthesis was used, preparation of the fossa was performed using diamond-coated instruments. In all customized prosthesis cases, cutting guides and fossa templates were used to enable precise resection and prosthesis fitting; these guiding components are not part of the stock system. Occlusion was secured by intermaxillary fixation using

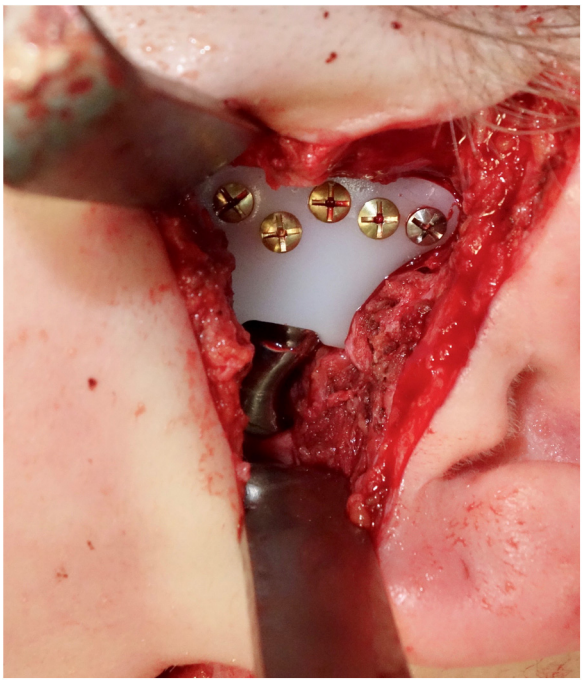

Fig. 2. Intraoperative view of an inserted left-sided total joint prosthesis.

transgingival screws and rigid wire fixation during surgery. After fixation of the fossa and condyle components with titanium screws (Fig. 2), the wound was closed in layers after insertion of a suction drain.

Postsurgical protocol

Food was taken in liquid form post-surgery. Patients were treated with intravenous antibiotics (ampicillin plus sulbactam) for 7 days. Mobilization of the TMJ was sustained by physiotherapy for approximately 12 weeks, including exercising and mouth opening under the guidance of a physical therapist. Postsurgical examinations at all time-points were done by the same surgeon (J.R.).

Wilkes stage

The Wilkes classification is a well-established clinical tool used to classify the stage of internal derangement of the TMJ[12]. This system divides the internal derangement of the TMJ into five stages. In cases of severe internal derangement (Wilkes stage IV and V), the TMJ shows irreparable effects. The affected patients report variable pain and reduced mouth opening, leading to reduced quality of life, nutritional deficiency, and social withdrawal. All of the study patients were classified using the Wilkes staging system at the beginning of treatment. The intention was to compare patients with similar clinical symptoms and radiological results even though they suffered from different TMD entities.

Outcomes

For the examination of jaw movement limitation and evaluation of postsurgical changes, the maximum interincisal opening (MIO) distance was measured with a metric ruler at all pre- and post-surgical time-points (T0–T4).

A visual analogue scale (VAS) was used for the assessment of pain. The level of pain was assessed on a scale from 0 (no pain) to 10 (maximum pain). Subsequently, patients had to specify their well-being at the end of 6 months (T4) (+1 = better; −1 = worse; 0 = no change).

A patient questionnaire was used to gather information including issues concerning food intake. Patients had to specify their diet — whether it was liquid, soft, or normal — at each time-point.

Complications, side-effects, and complications with respect to previous TMJ surgery were documented at all post-surgical time-points (T1–T4).

Statistical analysis

The statistical analysis was performed using IBM SPSS Statistics version 22 (IBM Corp., Armonk, NY, USA). Data were tested for a normal distribution using the Shapiro–Wilk test. Group comparisons of VAS were performed using the Kruskal–Wallis test or Mann–Whitney *U*-test. Regarding MIO, group comparisons were performed using the *t*-test. Changes over several time-points and progression were examined using the Friedman and Wilcoxon tests. Group comparisons regarding previous operations, group comparisons, and subjective well-being were evaluated using Fisher's exact test. Dietary changes were examined using McNemar's test. Significance was set at $P < 0.05$. The Bonferroni correction was used to adjust the *P*-value.

Results

Subjects

The study included 28 patients. The majority of patients were female (71%). The patients ranged in age from 25 to 78 years (mean 45 years). Twelve patients received a prefabricated stock TJR prosthesis (group 1) and 16 patients received a customized CAD/CAM TJR prosthesis (group 2). Patients in group 1 ranged in age from 26 to 78 years (mean 44 years), and 11 of the 12 patients were female. Patients in group 2 ranged in age from 25 to 67 years (mean 46 years), and nine of the 16 were female.

Wilkes stage

Of the 12 patients in group 1, 10 were graded as Wilkes stage IV and two as Wilkes stage V. In group 2, eight patients were graded as Wilkes stage IV and the other eight patients as Wilkes stage V.

Improvements in mouth opening

Before surgery (T0), all patients showed a limited MIO (group 1, mean 12.1 mm; group 2, mean 11.5 mm). Both groups showed a significant improvement after surgery, which was highly significant after 6 months ($P < 0.001$) (Fig. 3) (at T4: group 1, mean 32.8 mm; group 2, mean 33.7 mm). Comparison between the two groups revealed no significant difference at any time-point. In group 1, a significant improvement in MIO was observed at T3 ($P = 0.003$), which increased to a highly significant level at T4. Group 2 already showed a significant difference at T2 ($P = 0.012$), but the significance increased and was highly significant ($P < 0.001$) at time-points T3 and T4.

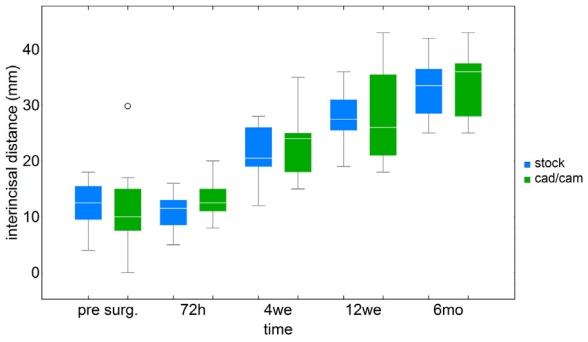

Fig. 3. Improvements in maximum inter-incisal opening (MIO) during the course of the study.

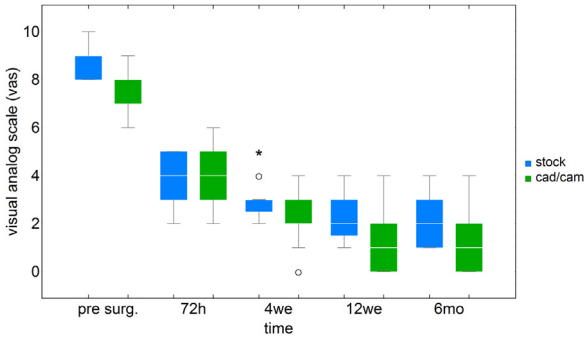

Fig. 4. Reduction in post-surgical pain (VAS score) during the course of the study.

Pain reduction

All patients showed a reduction of pain, with a highly significant difference between presurgery scores and those obtained at the end of the 6-month observation period (T4) (Fig. 4). There was no significant difference between the two groups at any of the postsurgical time-points. The mean VAS score at T0 was 8.9 in group 1 and 7.8 in group 2. Group 1 patients showed a significant difference in VAS at T2 ($P = 0.008$) and a highly significant difference at T3 and T4 ($P = 0.001$). In comparison, a highly significant difference was observed in group 2 already at 4 weeks (T2) ($P < 0.001$). After 6 months (T4), the mean VAS values were 2.1 in group 1 and 1.1 in group 2.

Diet

Dietary changes were observed in the comparison between the pre- and post-surgical time-points, from a liquid diet to a soft and then normal diet (Figs. 5 and 6). For statistical evaluation, liquid and soft diet was tested against a normal diet. An improvement was observed in both groups. With respect to the total number of patients, significance was high after 12 weeks (T3 and T4, $P < 0.001$). None of the patients required a liquid diet after 6 months.

Complications

Complications were experienced by 32% ($n = 9$) of all patients. These complications were temporary paresis of the facial nerve ($n = 7$), permanent paresis of the frontal branch of the facial nerve ($n = 1$), and the development of a salivary fistula of the parotid gland ($n = 1$). With respect to complications and previous TMJ surgery, all complications in group 1 occurred in patients who had not undergone any previous treatment. Complications in group 2 involved five patients who had undergone previous treatment. The postsurgical course showed no further major complications, such as infections, intraoperative or postoperative haemorrhage, loosening of screws, or loss of the implant, in any of the patients.

Patient well-being

No patient reported a worsening of subjective well-being. Among group 1 patients, 66% reported an improvement in well-being, while 34% reported no difference. In group 2, 100% of patients felt an improvement in well-being.

Discussion

The aim of this study was to evaluate the efficiency and stability of TMJ alloplastic TJR devices with respect to pain reduction and functional improvement. Clinical parameters evaluated were pain (VAS) and MIO, both of which are essential indicators of rehabilitation of the masticatory system and TMJ function. Hence, the use of alloplastic TJR systems seems to be a promising approach in cases of severe TMD. Comparison of the two types of system — stock prostheses and CAD/CAM prostheses — revealed no significant differences over a 6-month follow-up period, even though the patients who received a CAD/CAM prosthesis already showed highly significant differences to pre-surgical findings at a time-point 4 weeks earlier than the patients receiving stock prostheses. The advantage of the CAD/CAM custom-fit design of the implant components is that greater accuracy can be achieved and the fossa does not need to be trimmed during surgery, leading to time savings. On the other hand, the manufacturing process takes several weeks and the system is more expensive than the prefabricated systems.

In terms of postoperative complications, previous TMJ operations might play a role in facial nerve damage. Next to other patient-specific risk factors, one reason for this might be that the operation has to be performed in scarred tissue, which makes it difficult to identify anatomical structures. However, the implantation of an alloplastic joint prosthesis should be the final therapeutic option. Although the study presented here showed remarkable results, TJR should be considered carefully and a rapid decision regarding TJR is not recommended. The decision to use this method still depends on each patient's specific situation. The patient should be informed about every detail concerning invasiveness and the irreversibility of this procedure.

This study included some young patients at an age of about 25 years. These patients should be informed of the potential necessity for a change of prosthesis during their lifetime, in view of the estimated durability of about 10 years, and consideration should be given to the fact that a change of the endoprosthesis system implies a larger resection defect. Regarding the invasiveness and the irreversibility of this approach, the use of TJR systems

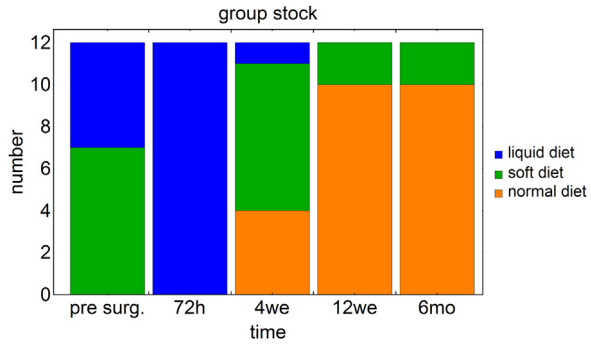

Fig. 5. Dietary changes over the course of the study in group 1 (stock total joint prosthesis).

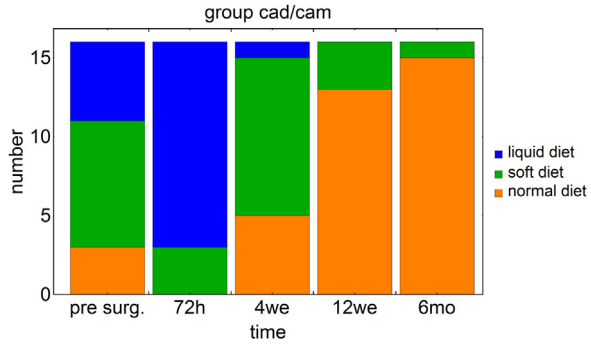

Fig. 6. Dietary changes over the course of the study in group 2 (CAD/CAM total joint prosthesis).

and invasive TMJ surgery is still under debate[13–15]. Nevertheless, over the last 20 years, prosthetic systems have undergone continuous development and alloplastic materials have changed and improved[15], leading to increased interest in alloplastic reconstruction using TJR systems[16]. Other authors have shown promising results using this method for the treatment of end-stage TMJ disease[17–21].

In agreement with this, the present study also showed promising results, although for a small sample of patients. Besides the fact that the patient sample in group 1 was smaller than that in group 2, there was also an uneven distribution of Wilkes stages in the two groups. While in group 2, half of the patients each had Wilkes stage IV and Wilkes stage V derangement, the majority of patients in group 1 showed Wilkes stage IV derangement. Differences in group size and the degree of internal derangement must be considered when interpreting the current results.

Capturing quality of life data has become an important tool in the analysis of joint replacement devices[22,23]. In this study, patients were asked about any improvement in subjective well-being experienced at the end of the follow-up period. Although data for pain reduction and increased MIO were comparable in the two groups, subjective well-being differed: 100% of patients in group 2 reported an improvement, while only 66% in group 1 felt an improvement. Furthermore, this is despite the fact that group 2 included more patients who had undergone previous TMJ surgery, data that showed a better outcome in subjective well-being. In the context of the literature, which describes a correlation between previous TMJ surgery and a lower chance of a significant subjective improvement[24], this is a noteworthy finding that has to be mentioned.

This study focused on follow-up of 6 months post-surgery, which represents short-term follow-up, and the patient sample was small. Nevertheless, the results are promising. Further studies involving a larger sample, focusing on long-term follow-up with a longer time period, and with a view to determining radiological differences might be the next step.

In conclusion, the clinical outcomes of both alloplastic replacement procedures — TMJ stock and CAD/CAM prostheses — suggest great improvements in mouth opening, diet, and pain relief as a result of the rehabilitation of TMJ function. Results showed comparable data after 6 months with no significant differences between the TJR systems.

Funding

None.

Competing interests

None of the authors have any conflict of interest to declare.

Ethical approval

This study was approved by the medical board of the ethics committee of the state of Bremen, Germany (study No. 588).

Patient consent

Not required.

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