Temporomandibular joint total replacement using the Zimmer Biomet Microfixation patient-matched prosthesis results in reduced pain and improved function

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Objective. The aim of this study was to evaluate pain and maximum interincisal opening (MIO) in patients treated with the Zimmer Biomet Microfixation patient-matched alloplastic temporomandibular joint (TMJ) prosthesis.

Study Design. We performed a retrospective cohort study of patients who had undergone bilateral or unilateral TMJ total joint replacement (TJR). The primary outcome variables were pain and MIO, which were measured at various time points between 12 and greater than 60 months. Secondary outcomes included perceived masticatory efficiency and patient satisfaction.

Results. A total of 33 patients (62 joints) met the inclusion criteria for the study. The relationship between time and the change in pain scores, although significant immediately after surgery in an unadjusted model, was not statistically significant in an adjusted model. A statistically significant improvement between time and MIO was noted in both adjusted and unadjusted models. The majority of patients (91%) reported subjective improvement in their diet. Similarly, 91% of patients felt that TJR was beneficial and, in retrospect, would repeat their decision to undergo TJR.

Conclusions. Patients treated with the Zimmer Biomet Microfixation patient-matched TMJ prosthesis experience improvements in pain, MIO, and ability to masticate. Future studies are needed to assess long-term outcomes prospectively. (Oral Surg Oral Med Oral Pathol Oral Radiol 2019;128:572−580)

Over the past 25 years, alloplastic replacement of the temporomandibular joint (TMJ) has become an accessible treatment option for patients with degenerative joint conditions. Various systems were developed but later discontinued, with a large variance in the reported success rates.[1,2] Indications for alloplastic TMJ total joint replacement (TJR) include degenerated joints, ankylosis, severe polyarticular inflammatory joint disease, failed autogenous grafts or alloplastic reconstruction, irreparable condylar fractures, neoplasia requiring extensive resection, and congenital conditions (e.g., hemifacial microsomia).[3,4] Relative contraindications for prosthetic joint replacement include hypersensitivity to prosthetic material, acute and/or chronic infection, skeletal immaturity, and/or uncontrolled systemic disease resulting in an increased susceptibility to infection.[3] The expected lifespan of alloplastic TMJ TJR is currently unknown, although recent publications have shown excellent durability of up to 20 years for 2 TJR systems.[3,5−7]

The U.S. Food and Drug Administration (FDA) has approved 2 TMJ alloplastic TJR systems: (1) Zimmer Biomet Microfixation (Biomet Microfixation Inc., Jacksonville, FL), and (2) TMJ Concepts (TMJ Concepts Inc., Ventura, CA). Components of the Zimmer Biomet Microfixation prosthesis and the surgical protocol (virtual planning, surgical set up and technique) have been described in detailed previous reports.[8,9] The stock Zimmer Biomet prosthesis was granted full approval by the FDA in September 2005 after completion of a 3-year follow-up in an investigational device exemption study that enrolled 442 joints.[10] The patient-matched system has yet to receive full FDA approval in the United States but is available in many other countries. In Canada, the Zimmer Biomet Microfixation stock TJR, the TMJ Concepts patient-matched TJR, and the Nexus CMF TJR system have been approved by Health Canada. In Canada, the Zimmer Biomet Microfixation patient-matched system receives approval on a case-by-case basis after special application to Health Canada.

Favorable subjective and objective patient outcomes have been reported with the use of the TMJ Concepts

Statement of Clinical Relevance

Patients in this retrospective study on the Zimmer Biomet Microfixation patient-matched temporomandibular joint prosthesis had good postoperative outcomes, with improvements in pain, maximum incisal opening, and diet.

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patient-matched prostheses.[2,5,7,11–13] To our knowledge, there is only 1 report in the literature evaluating the outcomes of Zimmer Biomet patient-matched TMJ TJR in a cohort of patients with a mean follow-up time of 14 months.[8]

The purpose of this study was to evaluate the use of the Zimmer Biomet Microfixation patient-matched TJR in a medium-sized sample of patients. The specific aims of the study were to evaluate changes in pain and maximum interincisal opening (MIO) after TJR and to evaluate masticatory efficiency and patient satisfaction after TJR. We hypothesized that when indicated, the Zimmer Biomet patient-matched TMJ prosthesis would provide favorable subjective and objective outcomes.

MATERIALS AND METHODS

Study design

A retrospective cohort study of patients who underwent TMJ TJR with the Zimmer Biomet patient-matched prostheses between May 2004 and March 2014 was designed and implemented. Patients with degenerative joint disease, fibrous/bony ankylosis, rheumatoid arthritis, benign tumors, or condylar resorption who underwent patient-matched alloplastic TMJ replacement and had a minimum follow-up of 12 months were included in the study. Exclusion criteria were less than 12 months of follow-up and unavailable or inadequate clinical records. Some patients who had undergone simultaneous LeFort 1 osteotomy and/or sagittal split osteotomy were not excluded from our study.

Surgical technique and postoperative management

TMJ TJR was carried out according to a standard protocol in 2 hospital centers, with a postoperative inpatient stay of 3 to 5 days. Diseased or pathologic joint tissue was excised aseptically by means of a preauricular and retromandibular approach. Intermaxillary fixation was applied to match either the patients' existing occlusal scheme or the planned occlusal change. The patient-matched prostheses were then fixated, and the surgical sites were closed according to standard protocol. Twenty-four hours postoperatively, patients were instructed to use a TheraBite appliance (Atos Medical, West Allis, WI), provided that there was no intraoperative joint dislocation. In the event of intraoperative joint dislocation, elastics were to be worn for 2 to 3 weeks, and patients were prescribed 4 to 6 weeks of passive jaw opening exercises before initiating use of the TheraBite appliance. If the patient had had a simultaneous LeFort I osteotomy, he or she was prescribed 4 to 6 weeks of passive jaw opening exercises before initiating TheraBite exercises. All patients were prescribed postoperative antibiotics and analgesics, and regular daily medications were to be taken as prescribed. Patients were advised to follow a soft diet. Panoramic and lateral/ posteroanterior cephalometric radiographs were taken at the first follow-up appointment. Postoperative follow-up occurred at regular intervals in the outpatient clinic of the senior author (DJP), who performed all of the evaluations.

Study variables

The primary predictor variable was the use of the Biomet Microfixation patient-matched TMJ prosthesis. The primary outcome variables were changes in pain and MIO scores from baseline. For data analysis purposes, follow-up intervals were grouped into the following categories: 12 to 35 months, 36 to 59 months, and 60+ months. Outcome measures were recorded preoperatively and postoperatively at various time points when patients presented for outpatient follow-up. Pain was measured subjectively by using a visual analogue scale (VAS) from 0 to 10, with 0 representing no pain and 10 representing the worst imaginable pain. MIO was measured objectively in millimeters by using a ruler between the incisal edges of maxillary and mandibular central incisors upon maximal mouth opening. Secondary outcome variables included perceived ability to masticate ("worse," "same," "improved") and attitude toward surgical TJR ("would repeat decision to undergo surgery in retrospect," "would not repeat decision to undergo surgery in retrospect," or "undecided"). Patient dependent variables included age, sex, number of previous surgical TMJ interventions, preoperative diagnosis, number of joints replaced, and attitude. The stability of the occlusal correction was clinically evaluated postoperatively for all patients by the senior author. Posterior interdigitation, midline symmetry, overjet, and overbite were examined, and the occlusion was said to be stable at follow-up if it remained as was set in planning/ surgery with no relapse or change.

Data analysis

Data were collected by means of retrospective analysis of charts from patient files.

Data were analyzed by using the software package R (v.3.5.0) (R Foundation for Statistical Computing, Vienna, Austria).[14] Descriptive statistics were used to summarize demographic data, such as sex, age, number of previous TMJ surgeries, number of joints replaced during the most recent surgery, perception of diet, and attitude toward surgery. Mean, standard deviation (SD), and range were computed for continuous variables, and frequency and percentage were computed for categorical variables. Linear mixed models (LMMs) were used to account for within subject correlation arising from repeated measures within the same individual. Each joint within a subject was treated as an independent observation. For each primary outcome,

an unadjusted model was used to assess the relationship between the time since surgery and the outcome of interest, with a random effect included to account for repeated measures within each subject. Next, separate unadjusted models were extended to include each demographic variable and to examine the relationship between the demographic variable of interest and the primary outcome after adjusting for time since surgery. Finally, an adjusted LMM containing all a priori specified variables of interest were used to account for confounding factors. A priori specification of variables allows for unbiased parameter estimates, standard errors, and R^2 values.[15] The adjusted model, examining the association between time and pain outcome, was adjusted for attitude, number of previous surgeries, and diet. The model examining the relationship between time and MIO was adjusted for sex, number of previous surgeries, and number of joints replaced. Although data were not available for all patients at all follow-up points, the LMM methodology still produces valid results.

Ethics

The study followed the tenets of the Helsinki Declaration. Approval for the study was granted by the Trillium Hospital (Credit Valley Hospital, Mississauga, Ontario, Canada) Research Ethics Board. Participants were not required to sign an informed consent agreement (ID#694). Because of the retrospective nature of this study, an exemption in writing was granted by the Mount Sinai Hospital Research Ethics Board (MSH REB 15-0070-C).

RESULTS

From May 2004 to March 2014, 71 patients (a total of 126 joints) underwent TMJ TJR with the Zimmer Biomet patient-matched prostheses. Of these, 33 patients (62 joints) met the inclusion criteria for the study; 11 (33.3%) of these patients had undergone simultaneous surgical occlusal change with LeFort 1 osteotomy or sagittal split osteotomy. Patient demographic characteristics are provided in Table I. The mean postoperative follow-up time was 34.9 (SD = 24.7) months (range 12 months to 10.2 years).

Pain

An unadjusted analysis indicated that there was a decrease of 6.1 VAS units immediately after surgery, but there was no significant association between time and change in VAS scores. Figure 1 illustrates the relationship between time and change in VAS scores. Table II shows the relationship between each patient-dependent variable (diet, attitude, diagnosis, number of previous surgeries, number of joints replaced, age, and gender) and the VAS pain outcome, with adjustment only for time since surgery. No variables showed a significant effect on the mean difference in pre- and postoperative VAS scores. Table III shows the results and 95% confidence intervals of the adjusted model for the VAS pain outcome. Similar to the unadjusted model, it indicates that there was no statistically significant relationship between time and change in VAS scores after adjusting for the other variables of interest.

Table I. Patient demographic characteristics

Sex	
Male	6
Female	27
Age at time of surgery	
Average age	40.4
Range	18–71
Number of prior surgeries	
No previous surgery	7
1–2 previous TMJ surgeries	16
3–5 previous TMJ surgeries	7
6+ previous TMJ surgeries	3
Preoperative diagnoses	
Degenerative joint disease	17
Fibrous/Bony ankylosis	7
Rheumatoid arthritis	3
Condylar resorption	2
Pathology	2
Condylar hyperplasia	1
Pierre Robin sequence	1

TMJ, temporomandibular joint.

Maximum interincisal opening

There was an overall increase in postoperative MIO. Figure 2 demonstrates the relationship between time and change in MIO scores. Table IV shows the relationship between each patient-dependent variable (diet, attitude, diagnosis, number of previous surgeries, number of joints replaced, age, and sex) and the MIO outcome, with adjustment only for time since surgery. Table V displays the results for an adjusted model examining the association between time and change in MIO scores after adjusting for sex, number of previous surgeries, and number of joints replaced. Similar to the unadjusted model that showed a significant relationship between time and change in MIO scores, the adjusted model found a statistically significant association of 0.14 (0.06, 0.21) mm per month with changes in MIO scores.

Diet and attitude

Table VI indicates that a large majority of patients experienced an improvement in masticatory efficiency after surgery and would repeat their decision to undergo TJR.

Clinically, all patients had stable occlusal relationships at their longest follow-up, and to date, no revisions have been carried out for biologic or mechanical reasons.

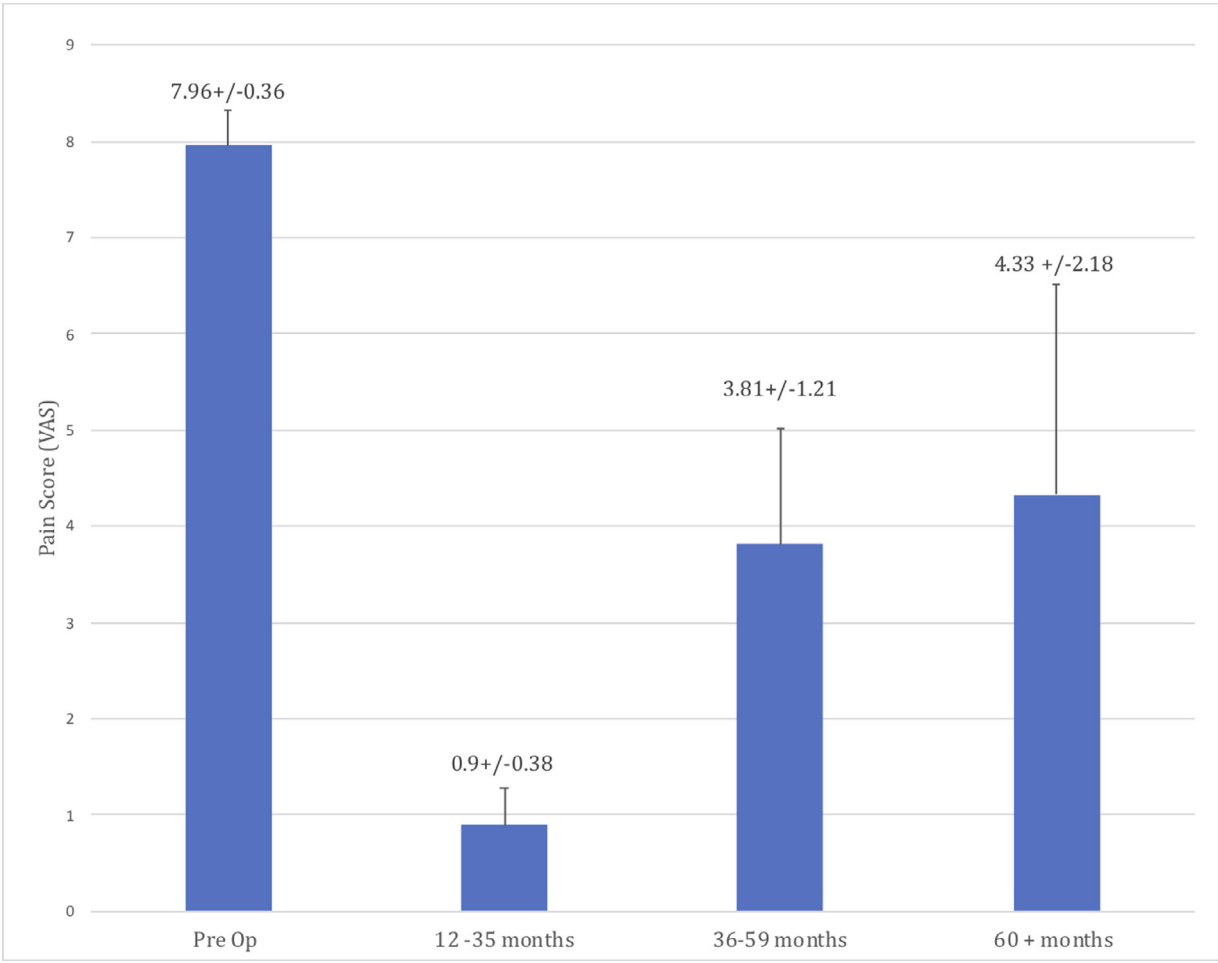

Fig. 1. Changes in preoperative versus postoperative VAS pain scores.

Table II. Unadjusted analysis of the relationship between patient-dependent variables and the VAS pain outcome*

	Parameter estimate	*Lower 95% CI*	*Upper 95% CI*
Diet	−1.39	−4.49	1.71
Attitude	−3.42	6.84	0.1
Diagnosis	−0.03	0.70	−0.652
Number of previous surgeries	0.04	−1.04	1.12
Number of previous joints replaced	−0.77	−3.72	2.17
Age	0.04	−0.05	0.13
Sex	0.46	−2.17	3.09

*No significant relationships.
CI, confidence interval; *VAS,* visual analogue scale.

DISCUSSION

The purpose of this study was to examine the subjective and objective outcomes of the Zimmer Biomet Microfixation patient-matched TMJ TJR by comparing pre- and postoperative variables, such as MIO, pain, and perceived ability to masticate. We hypothesized that patients would experience significant improvements in the above-mentioned variables over time.

Pain

Although the patients included in this study experienced immediate and clinically relevant reduction in postoperative pain, pain was not completely eliminated or found to significantly decrease over time. However, an unadjusted model showed a significant decrease in VAS scores by 6.1 points after surgery; there was no significant association between time and change in VAS scores after adjusting for patient-dependent variables. A 50% to 70% decrease in pain can reasonably be expected after TMJ TJR,[3] and this percentage was exceeded in this cohort of patients immediately after surgery. It has been previously documented that as the number of previous TMJ surgeries increases, subjective outcomes worsen.[5] Interestingly, we did not observe the number of previous surgical interventions influencing VAS scores over time. However, in the majority of our patient cohort, TJR was an early intervention.

Table III. Adjusted model for pain scores*

	Parameter estimate	*Lower 95% CI*	*Upper 95% CI*
Time	0.13	−0.32	0.55
Attitude	−3.64	−7.68	0.41
Number of previous surgeries	0.09	−1.04	1.21
Diet	0.20	−3.27	3.66

*Linear mixed model examining the association of patient- related variables and pain scores.*CI,* confidence interval.

Table IV. Unadjusted analysis of the relationship between patient-related variables and MIO

	Parameter estimate	*Lower 95% CI*	*Upper 95% CI*
Diet	−1.19	−12.63	10.25
Attitude	7.65	−6.99	22.29
Diagnosis	−1.15	−3.78	1.48
Number of previous surgeries	4.13	−0.24	8.50
Number of previous joints replaced	3.75	−7.34	14.84
Age	0.22	−0.10	0.54
Sex	−1.49	−11.27	8.31

CI, confidence interval; *MIO,* maximum interincisal opening.

Other reports have also documented pain reduction after Zimmer Biomet Microfixation TJR with a stock prosthesis. It has been reported elsewhere that mean postoperative pain scores were significantly reduced—from 7.2 preoperatively to 1.6 at the 3-month follow-up, 1.8 at 1 year, 1.2 at 2 years, and 1.6 at 3 years.[8] In other reports, mean postoperative pain scores decreased significantly from 7.9 to 3.8 at a mean follow-up of 30 months[16] and to 2.6 at the 3-year follow-up (67.5% decrease in pain, preoperative pain score of 8).[10] Pain scores on a 5-point VAS also decreased significantly over time, at a mean follow-up of 3.5 years.[17]

The pain process involved in temporomandibular disorders is complex, involving both biomedical and biopsychosocial factors.[18] Generally, postoperative pain measurement is complicated by the finding that patients may suffer from neuropathic pain, neuropsychiatric pain, myogenic pain, or other medical

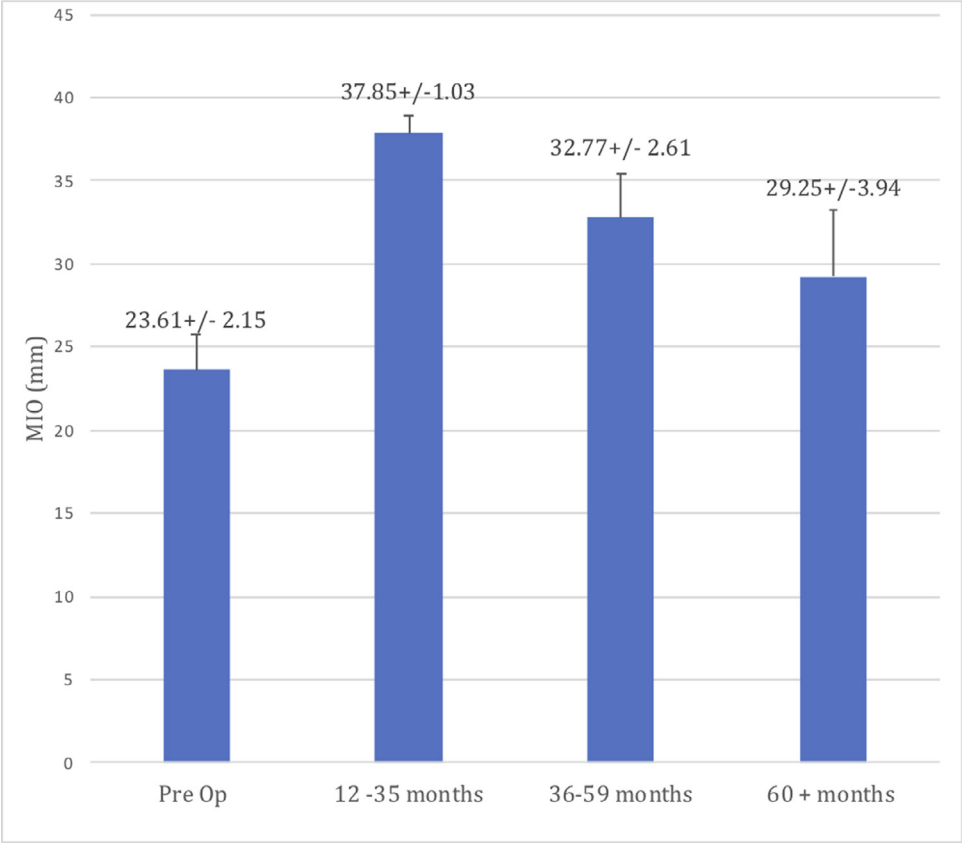

Fig. 2. Change in preoperative versus postoperative maximum interincisal opening.

Table V. Linear mixed model examining the association of patient-related variables and MIO outcome

	Parameter estimate	*Lower 95% CI*	*Upper 95% CI*
Time	0.14	0.06	0.21
Sex	−3.61	−13.79	6.57
Number of previous surgeries	3.35	−1.68	8.39
Number of previous joints replaced	1.01	−11.18	13.19

CI, confidence interval; *MIO,* maximum interincisal opening.

Table VI. Secondary outcomes of masticatory efficiency and patient satisfaction

Masticatory Efficiency	
Improved	30
Worsened	2
Unchanged	1
Patient Satisfaction	
Would repeat decision	30
Would not repeat decision	2
Unsure	1

diagnoses that influence the perception of pain. In our study, although some patients reported subjective perception of an equivalent amount of postoperative chronic pain, they indicated that it was more manageable with medication compared with the pain before surgery and that the character of the pain was different.

Maximum interincisal opening

The realistic expectation with regard to MIO after alloplastic joint surgery is 30 to 35 mm[3]. In our study, both unadjusted and adjusted models showed a statistically significant relationship between time and changes in MIO scores. The mean preoperative MIO was 23.6 mm (range 0−50; SD 11.9) and the mean postoperative MIO score calculated by using the last follow-up time point for each patient was 36.09 (range 22−55; SD 6.9). Our MIO findings were in line with those reported by other studies evaluating Zimmer Biomet Microfixation TJR[8,10,16,17,19] Postoperative MIO has been found to significantly increase to 36.4 mm at 3 months, 38.5 mm at 6 months, 38.7 mm at 1 year, 35.8 mm at 2 years, and 31.8 mm at 3 years (not significant) after patient-matched TJR.[8] Likewise, after stock TJR, mean postoperative MIO significantly increased to 34.4 mm (8 mm increase) at a mean follow-up of 30 months,[16] to 41.8 mm during a 3-year postoperative period,[17] to 29.5 mm (44.6% increase) at a mean follow-up of 3 years,[10] to greater than 35 mm at a mean follow-up of 5 years.[19]

Masticatory efficiency and patient satisfaction

The majority of our patient cohort (91%; n = 30) reported that their diet had improved after surgery, although most continued to follow some degree of protective diet modification. Quinn[10,16] found that in retrospect, 92% to 99% of patients would choose to undergo TMJ TJR. Similarly, in our study, 91% of patients agreed that they would repeat their decision to undergo the procedure. Patients with a negative attitude and those who were unsure cited a long recovery period or continued postoperative complications, such as facial muscle weakness as reasons.

Complications and revisions

Postoperative complications experienced by some of our patients included temporary changes in facial nerve function (temporal and marginal mandibular branches), which resulted in forehead weakness, eyelid weakness, and drooping of the lower lip of the affected side. These are not unexpected complications of the surgery, given the local anatomy of the TMJ and the placement of incisions. A number of the patients who underwent concomitant orthognathic surgery experienced temporary paresthesia of the lower lip. Last, in 1 patient, an auricular hematoma occurred postoperatively.

In this patient cohort, there have been no revisions for biologic or mechanical reasons. Other authors using stock Zimmer Biomet Microfixation prostheses have also reported no revisions for up to 3.5 years[17] and 5 years.[19] However, there have been some reports of revisions with use of Zimmer Biomet patient-matched prostheses as a result of infection, severe pain/dysfunction, and a possible but unconfirmed hypersensitivity (2 of 61 cases),[8] as well as removal of 6.4% of stock implants because of heterotrophic ossification, infection, and screw loosening.[16]

Advantages and disadvantages of patient-matched TMJ TJR

Anatomic aberrancy, deficient stock recipient bone, and severe malocclusion are surgical challenges that limited the application of stock prostheses in our patient cohort. Patient-matched prostheses are of particular benefit in managing end-stage joint disease (Figure 3). Virtual planning of patient-matched TJR facilitates fabrication of the prosthesis and results in a prosthesis design that conforms to the existing anatomy (Figures 4A and 4B). Virtual assessment of available bone facilitates optimal screw positioning/sizing and the avoidance of vital structures (Figure 5). Patient-matched TJR devices can also be used for simultaneous correction of facial contour (Figures 6A and 6B). Mirroring tools facilitate this correction during the design process. The intimate adaptation of patient-matched devices increases prostheses longevity and reduces the rate of failure.[20] Additionally, the reduction in

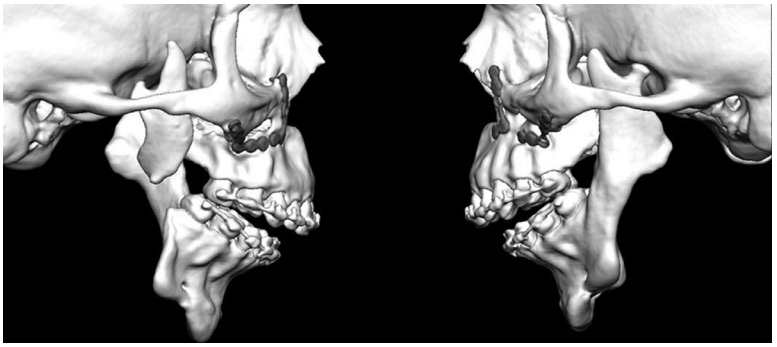

Fig. 3. Preoperative images of patient. The right side shows a continuity defect and the left side shows dislocation of the condyle into the infratemporal fossa. Note the presence of hardware in the maxilla from previous orthognathic surgery.

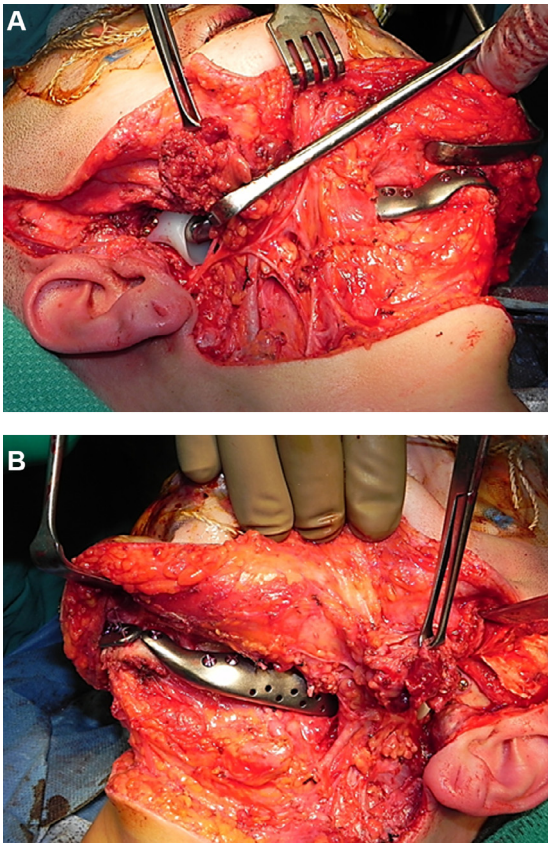

Fig. 4. **A,** Intraoperative images of the fossa and mandibular components *(right side)* of a Biomet Microfixation patient-matched temporomandibular jaw (TMJ) total joint replacement (TJR) prosthesis. **B,** Intraoperative images of the fossa and mandibular components *(left side)* of a Biomet Microfixation patient-matched TJR prosthesis.

intraoperative time required for the placement of patient-matched prostheses is an important determinant in minimizing surgical site infection after TJR.[21,22]

Increased cost is the main disadvantage of patient-matched TMJ TJR. However, it has been postulated that the high cost of patient-matched TMJ TJR is outweighed by the disadvantages of stock device placement, which include the risk of donor site morbidity, the unpredictable nature of autogenous grafting, and the added intraoperative time required.[20]

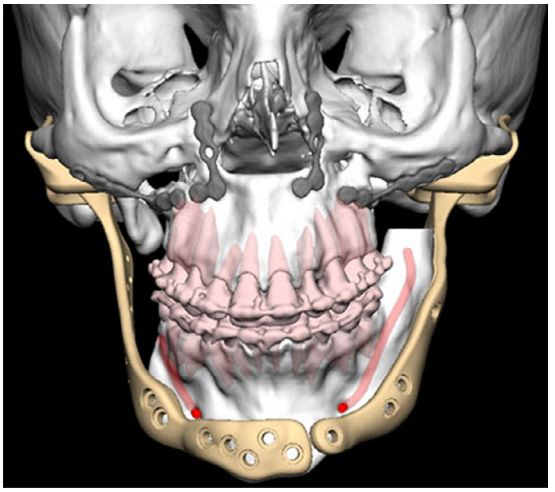

Fig. 5. Three-dimensional (3-D) virtual surgical planning for accurate positioning of screws and prosthesis to avoid vital structures, such as the inferior alveolar canal.

Study limitations

There are inherent limitations to a retrospective study. A number of factors were not controlled, including the nature of preoperative pain (neuropathic vs nociceptive), other contributing medical conditions, postoperative radiation, and the placement of fat grafts. In some chart entries, postoperative pain assessment findings were not documented by using a VAS, and not all patients presented for follow-up appointments at the specified time points; therefore data were not available for all time points. Another limitation of this study is that that a quality-of-life (QOL) variable was not used. Prospective studies have shown that despite incomplete pain relief, up to 87% of patients report significant improvements in QOL.[5,7,8] A postoperative survey assessing QOL, as well as diet with a scale measurement, the nature of postoperative pain, and quantification of pain medication may be of use. Last, because of the

Fig. 6. **A,** Preoperative and postoperative frontal photos of patient, showing improved facial appearance and contour. **B,** Preoperative and postoperative profile photos of patient showing improved facial appearance and contour.

retrospective nature of the study, patients were not assessed pre- or postoperatively by an independent examiner, and this may inherently introduce a degree of bias into the results.

CONCLUSIONS

Virtual planning and patient-matched TJR have numerous advantages over application of stock prostheses and autogenous grafting for complex clinical cases. Outcomes are most predictable when the surgical procedure is performed according to a defined and accepted standard protocol, with appropriate case selection. It is also critical for both the surgeon and the patient to have realistic expectations with regard to the outcomes of surgery. This study supports the use of Zimmer Biomet Microfixation patient-matched TMJ TJR in patients with complex TMJ anatomy. Postoperatively, the patients in our study population experienced a statistically significant improvement in MIO as well as in VAS pain scores, with the majority reporting subjective improvement in the quality of their diet at the longest follow-up. Studies with larger samples and longer-term data will strengthen the current findings.

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