Acta Scientific Dental Sciences

Volume 10 Issue 5 May 2026

Research Article

A Prospective Observational Study of Clinical Outcomes After Total Alloplastic Temporomandibular Joint Replacement in End-Stage Disorders

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DOI: 10.31080/ASDS.2026.10.2110

Received: April 06, 2026

Published: April 15, 2026

Abstract

Aims and Objective: Prospective observational study was designed to assess clinical outcomes following total alloplastic temporomandibular joint replacement (TJR) in end stage temporomandibular joint (TMJ) disorders with study duration of 18 months. Primary objectives were to assess Maximum inter incisal opening (MIO) and Reduction in pain score. Secondary objective were to access Masticatory efficacy, Post-operative occlusion, Range of motion and Post-surgical Neurological deficit.

Material and Method: With inclusion and exclusion criterion total 11 patients kept in study. Data was collected and statistically analyzed using Statistical Package for Social Sciences (SPSS ver 21.0) [6].

Results: 12 month postoperatively mean MIO was 28.82 mm, with significant improvement in pain score, masticatory efficiency and stability of occlusion. For protrusive movement if bilateral TMJ replacement cases are excluded from data then there was no effect on the outcome. Data shows statistically significant improvement only after 12 months. With exclusion of bilateral cases test shows no significant improvement in contralateral laterotrusive movement.

Conclusion: Alloplastic TMJ TJR proved as an additional armamentarium for Maxillofacial Surgeons. However patients should be explained thoroughly regarding outcome achievable in protrusive and laterotrusive movements. MIO, pain score and masticatory efficiency improved a lot with TJR treatment.

Keywords: TMJ TJR; TM Joint Replacement; Alloplastic TMJ Replacement

Introduction

End-stage temporomandibular joint (TMJ) disorders resulting in anatomical architectural distortion and physiological dysfunction, require complete rehabilitation of joint which necessitate temporomandibular joint reconstruction (TJR). Ankylosis, congenital deformities, traumatic injuries, or tumors may require removal of deformed condyle and reconstruction to maintain the function.

Temporomandibular joint consists of a unique balance of muscles, articular disc, bony architecture as well as relation with occlusion. Thus, it is nearly impossible to mimic a natural joint and provide a structure which is similar to the premorbid condition. The function outcome expectation from alloplastic joint should be realistic [1].

Post removal of ankylotic mass, reconstruction has always been a challenge for the surgeons. Autogenous bone grafts like

costochondral graft, sternoclavicular graft, etc. are some of the treatment options in TMJ reconstruction. These procedures have their own disadvantages in the form of donor site morbidity, requirement of rigid fixation with plates or screws, asymmetric growth and re-ankylosis. Costochondral graft has been reported for the unpredictable growth resulting in facial asymmetry [2].

Apart from these modalities, there are some other methods by which the reconstruction of temporomandibular joint can be carried out such as Ramus-Condylar unit distraction osteogenesis (RCU DO)/Alloplastic Temporomandibular Replacement.

TMJ reconstruction methods has been revolutionized with alloplastic materials but the cost of joint are still very challenging fact for developing countries. Very less data available form south Asian countries regarding TMJ TJR. The present study is effort to provide a comprehensive assessment for clinical outcome of TMJ TJR.

Material and Methods

A Prospective observational study designed from mixed Indian population of patients with clinically and radiologically proven end stage TMJ disorders who has receive treatment with stock made total alloplastic TJR. The study was carried out in a tertiary care hospital in the Division of Oral & Maxillofacial Surgery. Period of study was 01 years.

The aim of this study was to assess clinical outcomes following total alloplastic TJR in end stage TMJ Disorders. The objectives have been divided into primary and secondary objectives. Primary objectives were to assess Maximum inter incisal opening (MIO) and reduction in pain score. Secondary objective was to describe clinical outcome on the basis of masticatory efficacy, post-operative occlusion, range of motion and post-surgery neurological deficit.

Inclusion criteria were clinically and radiologically diagnosed end stage TMJ disorder, Late-stage degenerative joint disease (osteoarthritis, rheumatoid arthritis, traumatic arthritis, etc., ankylosis/recurrent ankylosis, Irreparable high condylar fracture with avulsion of the fractured fragment and Congenital disorders.

Exclusion criteria were Subjects with the history of allergy with alloplastic materials, systemic diseases with increased susceptibility to infections, skeletal immaturity and history of recurrent ear infections.

All patients reporting with End-stage TMJ disorder during the period of study, who are satisfying inclusion criterion were selected for the study. All the patients selected has been reviewed board of specialist for treatment plan. Pre-surgical evaluation included clinical examination, radiological examination and formulation of a treatment plan which included both surgical treatment and orthodontic treatment. A thorough preanaesthetic assessment was carried out. All procedures were explained to the patients and a written informed consent in the language which they understand were obtained from all the participants before surgery. Preoperatively the appropriate condylar component and fossa component were selected. TJR carried out using standard operating approach as described by Mercuri LG 2000 [7] (Figure 1).

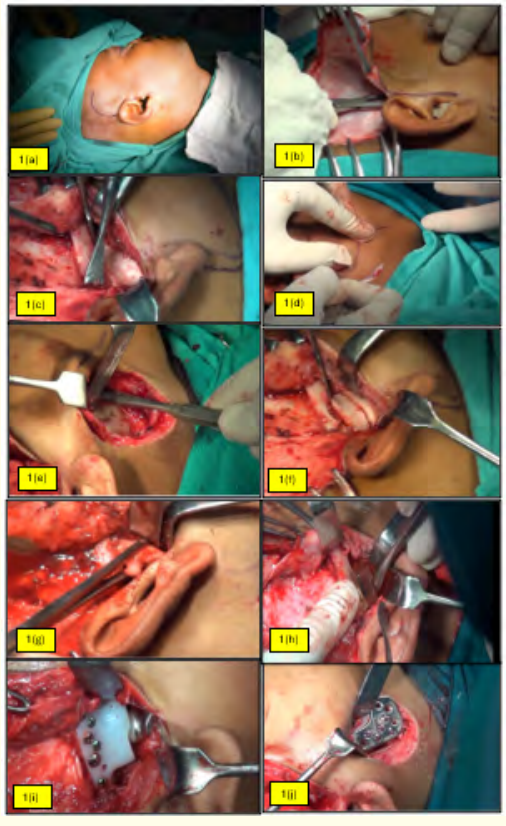


Figure 1: (a) Surgical site preparation with marking of Alkayat Bramley's incision with Popowich modification (b) Reveling of sub-gleal plane and Dissection over superficial layer of temporalis fascia (c) Exposure of ankylotic mass (d) (e) Submandibular incision on same side and Exposure of ramus(f) Removal of coronoid process (g) removal of coronoid process (h) Fixation of condylar templet (i) & (j) Insertion of ramus component from submandibular incision site. Fixation of ramus component with consideration of leaving holes to preserve inferior alveolar nerve. Final fixation of condylar component and checking of movements.

Maximum inter incisal opening (MIO) recorded in millimetre up to maximum limit but within the comfort of the patient. Reduction in pain score was obtained in visual analog score (VAS) as an instrument in this study. It was a subjective score, where 0 denotes no pain and 10 denote worse pain even much more before the surgery. Masticatory efficacy Masticatory efficiency was also measured in VAS (visual analog score) with 0 denote normal diet pattern i.e. patients is able to chew his/her regular food properly and 10 denotes that patient is on liquid diet for the survival. Post-operative occlusion score listed as habitual unchanged (01), improved (more stable functional contacts) (0), or worsened (less stable functional contacts) (02). Range of motion recorded in millimeters. It comprises two parts- Protrusive movements and laterotrusive movement. Post-surgery neurological deficit examined preoperatively for the any kind of facial neuromotor deficit. If it was present then it is recorded. Postoperative neuromotor deficit was recorded on objective basis using forehead furrow, tight closure of eye, ability to hold air, and drooping of corner of mouth on smiling.

The data was statistically analyzed using Statistical Package for Social Sciences (SPSS ver 21.0 [6], IBM Corporation, USA) for Microsoft® Windows.

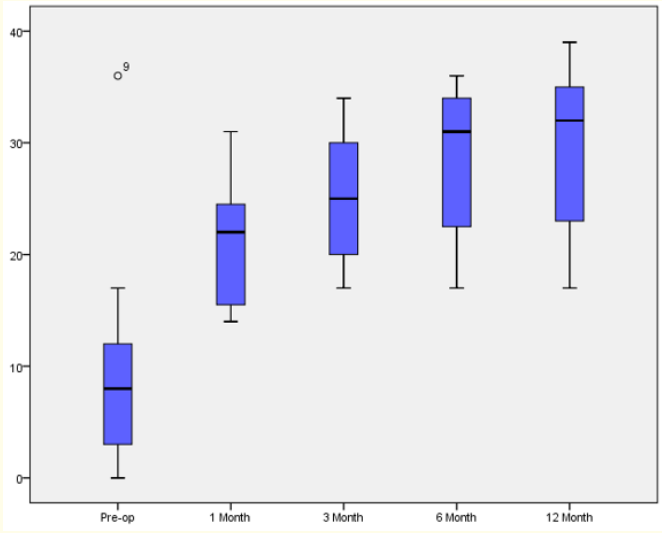
The data on categorical variables is presented as 'n' (% of cases) and the values on continuous variables are shown as median along with minimum - maximum. The pair-wise comparisons (pre-op with various follow-ups) of distribution of categorical variables and the distribution of medians of continuous variables is done using Wilcoxon's signed rank test. For the critical appraisal of the results the data tabulation as well as appropriate graphical representation was also done. In the entire study, the p-values less than 0.05 are considered to be statistically significant. All the hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference).

Results

Incorporating inclusion and exclusion criteria total 11 patients were selected in this prospective study. The evaluation of demographic data shows mean age of the patients was 38.73 year. The minimum age for use of total alloplastic TM joint replacement was 21 year and maximum was 76 year. Total 06 female and 05 male patients received this treatment modality. Total 09 unilateral and 02 bilateral TM joint replacement were carried out.

The most common reason for alloplastic TMJ replacement was TMJ ankylosis. However, its use has been done in varied types of disease in this small sample size, such as in cases of irreparable high condylar fracture, end stage TMJ disorders.

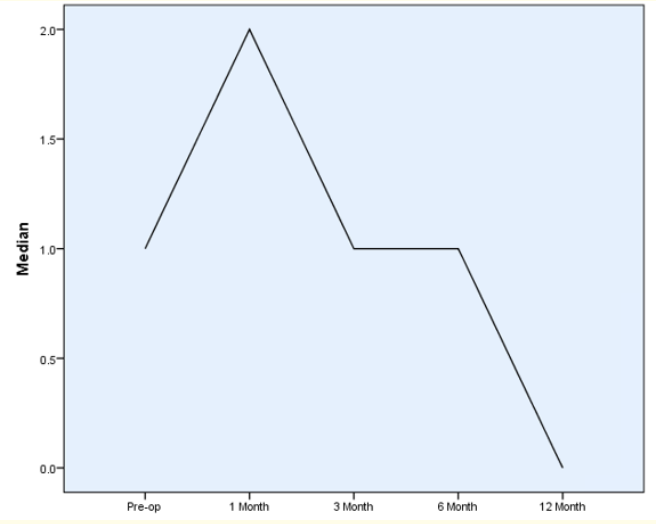
The distribution of median (min - max) maximum inter-incisal opening at pre-op, post-op 1-month, 3-month, 6-month and 12-month follow-ups was 8.00 mm (0 - 36), 22.0 mm (14 - 31), 25.0 mm (17 - 34), 31.0 mm (17 - 36) and 32.0 mm (17 - 39) respectively (Graph 1).



Graph 1: The distribution of median pre-op and post-op maximum inter incisal opening.

The mean interincisal mouth opening was 28.82 mm after 12 months postoperatively [3]. The data shows statistically significant improvement in interincisal mouth opening when comparing preoperative data with postoperative data. The distribution of median post-op 1-months, 3-months and 6-months and 12-months maximum inter-incisal opening was significantly higher compared to median pre-op maximum inter-incisal opening (P-value < 0.05). The case of end stage TMD (patient number 9) because of preoperative large interincisal mouth opening in comparison to ankylosis cases appear as outlier in box plot.

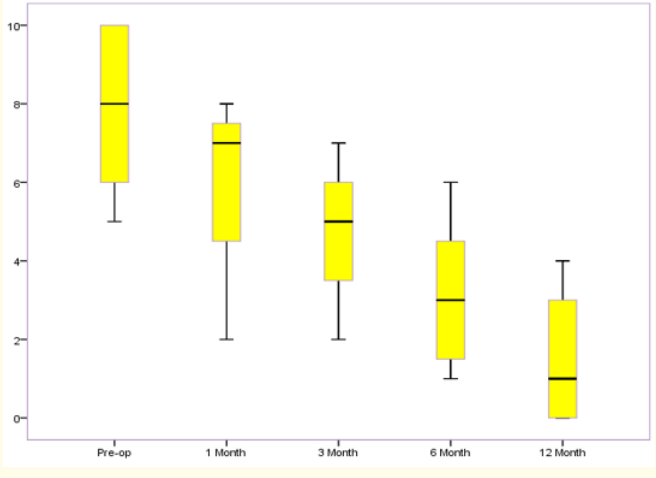
The distribution of median (min - max) maximum pain score (VAS) at pre-op, post-op 1-month, 3-month, 6-month and 12-month follow-ups was 1.00 (0 - 9), 2.0 (1 - 5), 1.0 (1 - 2), 1.0 (0 - 2) and 0.0 (0 - 2) respectively (Graph 2).



Graph 2: The distribution of median pre-op and post-op pain score (VAS).

The evaluation of data shows statistically non-significant improvement at 01 month till 06 months. However, it shows significant improvement in pain score at 12 months. The values for preoperative vs 01 month, 03 months, 06 month, and 12 months are 0.50, 0.60, 0.29, and 0.03 respectively. It ia considerable here that lesser the VAS score given by the patient is indicating lesser pain (Annexure 'B').

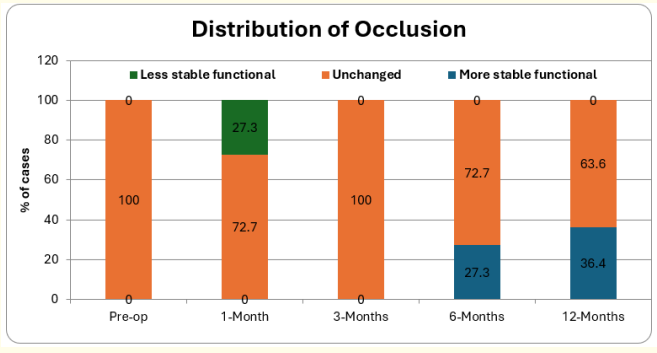
The distribution of median (min - max) masticatory efficiency at pre-op, post-op 1-month, 3-month, 6-month and 12-month follow-ups was 8.0 (5- 10), 7.0 (2 - 8), 5.0 (2 - 7), 3.0 (1 - 6) and 1.0 (0 - 4) respectively (Graph 3).



Graph 3: The distribution of median pre-op and post-op masticatory efficiency.

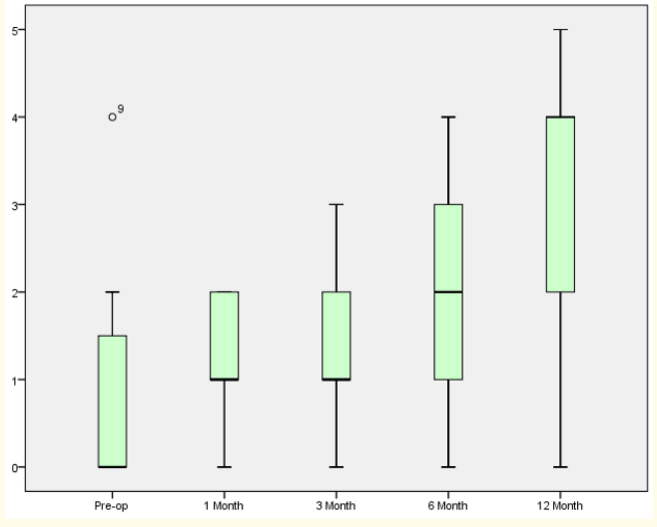
The distribution of median post-op 1-months, 3-months and 6-months and 12-months masticatory efficiency were significantly lower compared to median pre-op masticatory efficiency (P-value<0.05 for all).

The distribution of post-op stability of occlusion at 1-month and 3-months and 06 month did not differ significantly compared to pre-op occlusion (P-value>0.05 for all).The distribution of post-op stability of occlusion 12-months is significantly better compared to pre-op occlusion (P-value<0.05 for all) (Graph 4).

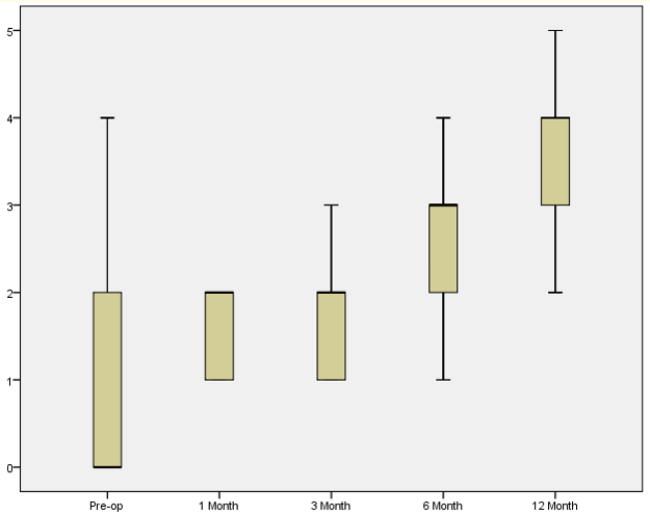


Graph 4: The distribution of pre-op and post-op occlusion.

The distribution of median (min - max) protrusive level at pre-op, post-op 1-month, 3-month, 6-month and 12-month follow-ups was 0 (0 - 4), 1.0 (0 - 2), 1.0 (0 - 3), 2.0 (0 - 4) and 4.0 (0 - 5) respectively. (Graph 5, 6).



Graph 5: The distribution of median pre-op and post-op protrusive movemets.



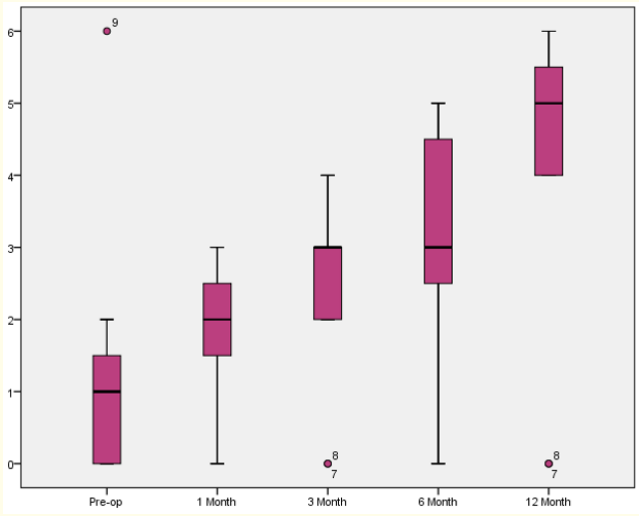
Graph 6: The distribution of median pre-op and post-op protrusive movemets (excluding bilateral cases).

The distribution of median post-op 1-month, 3-months and 6-months protrusive level were non-significant however the 12 month postoperatively statistically higher improvement (0.017 i.e. P-value<0.05). If the bilateral TM joint replacement cases are excluded from the data then still there is no effect on the outcome as data shows statistically significant improvement only at 12 months.

Laterotrusive movements were evaluated on ipsilateral side (the side of TM joint replacement) as well as contralateral side (normal side). However, in bilateral cases the laterotrusive movement in ipsilateral and contralateral has no stand thus data again analysed after excluding bilateral cases.

The distribution of median (min - max) laterotrusive Ipsilateral side (Graph 7) at pre-op, post-op 1-month, 3-month, 6-month and 12-month follow-ups was 1.0mm (0 - 6), 2.0 mm (0 - 3), 2.0 mm (0 - 4), 3.0 mm (0 - 5) and 5.0 mm (0 - 6) respectively. The comparison of preoperative values with intervals value shows significance at 06 month and 12 month with p value of 0.020 and 0.011 respectively.

When the bilateral cases were excluded from the above data the mean ipsilateral movement increases from 4.18 mm to 5.11 mm with p value of 0.011 (Preop vs 12 month) (Graph 8).

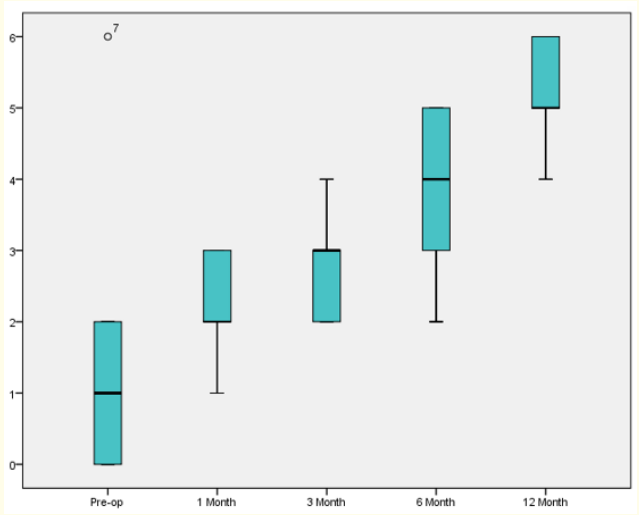


Graph 7: The distribution of median pre-op and post-op laterotrusive movemets (ipsilateral side).

o^9= in the spss data sheet it belongs to patient no 09 (case of end stage TMD)

o^7 = in the spss data it pertains to patient no 7 (bilateral joint replacement) in which no lateral excursive movement noted

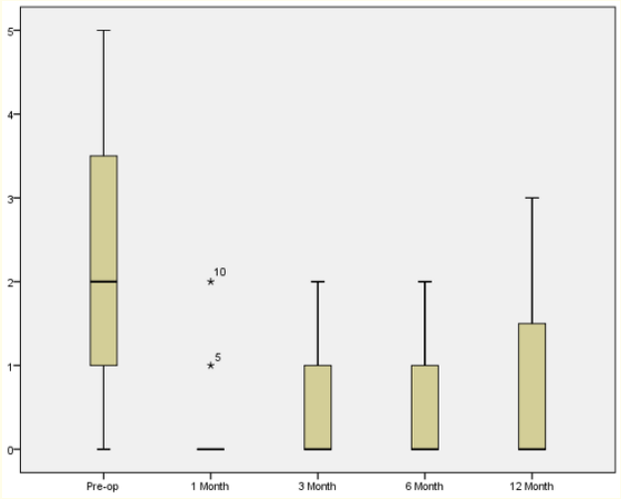
o^8 = in the spss data it pertains to patient no 8 (bilateral joint replacement) in which no lateral excursive movement noted.



Graph 8: The distribution of median pre-op and post-op laterotrusive movemets (ipsilateral side without bilateral cases).

o^7= in the spss data sheet it belongs to patient no 09 (case of end stage TMD).

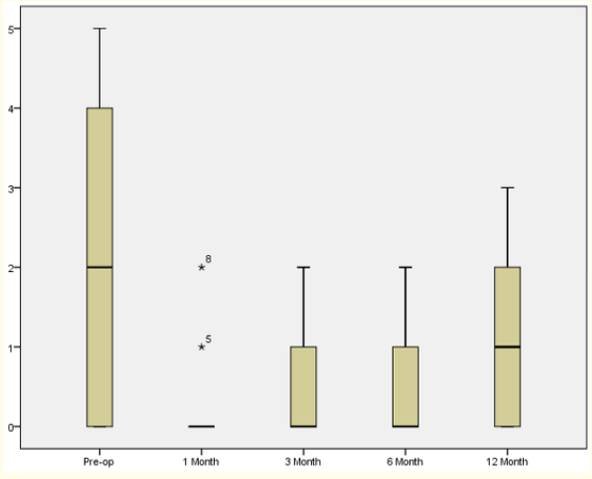
The distribution of median (min - max) laterotrusive ipsilateral side (Graph 9) at pre-op, post-op 1-month, 3-month, 6-month and 12-month follow-ups was 2.0mm (0 - 5) and 0.00 mm for rest all of the intervals With statistically significant outcome postoperatively with p-value of 0.019, 0.023, 0.027 and 0.056 for preop vs 1-month, 3-month, 6-month and 12-month respectively.



Graph 9: The distribution of median pre-op and post-op laterotrusive movemets (contralateral).

*5 & *10 are cases which shows significant improvement during 1st month of surgery.

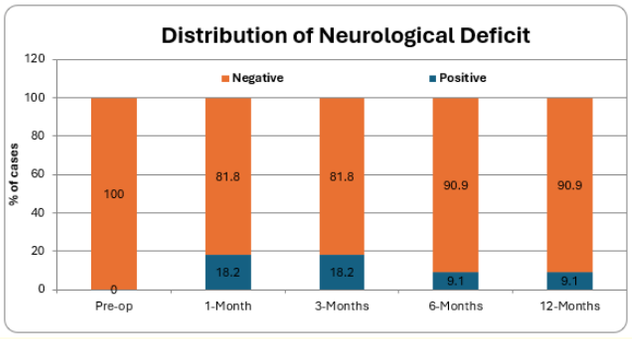
With exclusion of bilateral cases the test shows no significant improvement in contralateral laterotrusive movement in comparison to preop with all p-values above 0.05 (Graph 10).



Graph 10: The distribution of median pre-op and post-op laterotrusive movemets (contralateral side without bilateral cases).

*5 & *8 = Pertains to patient number 5 and 10 (the same patient which shows improvement during 1st month as in graph no).

The distribution of neurological deficit at post-op 1-month, 3-months and 6-months and 12-months did not differ significantly compared to pre-op neurological deficit (P-value>0.05 for all) (Graph 11).



Graph 11: The distribution of pre-op and post-op neurological deficit.

Discussion

The present study utilized Biomet® stock prostheses for total temporomandibular joint (TMJ) replacement, comprising two components: the glenoid fossa and the mandibular condylar unit [7]. In our cohort, 11 joints were reconstructed using 45 mm prostheses and 2 joints with 50 mm prostheses. All patients received the standard condylar design, with no offset components used. The ramal component was selected based on mandibular width, with all patients receiving the broader horseshoe-shaped plate, which offers enhanced screw placement options while minimizing risk to the inferior alveolar canal [8,9].

TMJ ankylosis was the most common indication for total joint replacement (TJR) in this study, consistent with global literature [10-12]. The irreversible anatomical distortion in ankylosis necessitates complete joint reconstruction. Our findings align with previous reports indicating that TMJ TJR is a reliable solution for restoring mandibular function in such cases [13,14].

Wojczynska., *et al*. demonstrated that alloplastic TMJ prostheses can mimic natural joint kinematics to a limited extent, reporting a median maximum interincisal opening (MIO) of 39 mm and ipsilateral laterotrusive movement of 2 mm in unilateral cases [15]. Our study found a median MIO of 32 mm and progressive improvement in laterotrusive and protrusive movements over 12 months, consistent with these findings [16,17].

Gonzalez-Perez., *et al*. reported significant improvements in MIO and pain scores in a 2-year prospective study of 52 patients undergoing stock TMJ TJR [18]. Our results corroborate these findings, with MIO increasing from a median of 8 mm preoperatively

to 32 mm at 12 months, and pain scores decreasing significantly on the visual analog scale (VAS) [19,20].

Voiner., *et al*. used magnetic jaw tracking to assess range of motion in 18 patients with Biomet® prostheses, reporting mean MIO of 28.7 mm and ipsilateral laterotrusion of 6.7 mm [21]. Our results are comparable, with a mean MIO of 28.82 mm and ipsilateral laterotrusion of 5 mm at 12 months. However, contralateral laterotrusion remained limited, particularly in bilateral cases, which is consistent with prior studies [22,23].

Facial nerve injury is a known risk in TMJ surgery. In our study, two patients experienced transient postoperative facial nerve deficits, which resolved within six months. This aligns with previous reports indicating that adherence to anatomical dissection planes and nerve preservation techniques minimizes long-term complications [24-26].

The heterogeneity of TMJ pathology must be considered when interpreting outcomes. Patients with internal derangement (ID) typically present with greater preoperative MIO than ankylosis cases, often appearing as outliers in statistical plots [27]. The architectural and muscular degeneration in ankylosis leads to more restricted outcomes postoperatively, as supported by comparative studies [28,29].

The literature supports the use of alloplastic TJR in complex cases, including failed autogenous grafts, congenital deformities, and syndromic conditions such as hemifacial microsomia and Goldenhar syndrome [30-32]. Additionally, simultaneous orthognathic surgery has been shown to be feasible and effective in selected patients requiring skeletal correction [33,34].

Despite the high cost of alloplastic joints, especially in developing countries, their long-term benefits in terms of function, pain relief, and reduced recurrence of ankylosis justify their use in appropriate cases [35,36].

This study has several limitations. The absence of a control group, small sample size, and limited follow-up (one year only) duration restrict the strength of conclusions and broader applicability. Future studies with larger cohorts, standardized outcome measures, and longer follow-up are warranted to validate these findings.

Conclusion

Alloplastic TMJ TJR is a robust and effective modality for managing end-stage TMJ disorders. Our study demonstrates significant improvements in MIO, pain reduction, and masticatory efficiency over a 12-month period. The outcomes are influenced by preoperative diagnosis, muscular condition, and adherence to postoperative physiotherapy protocols.

While range of motion in protrusive and contralateral laterotrusive directions remains limited, especially in bilateral cases, the overall functional gains are substantial. Surgeons must counsel patients regarding realistic expectations, particularly in terms of joint mobility.Given the evolving design of TMJ prostheses and accumulating evidence supporting their efficacy, alloplastic TJR should be considered a primary option in cases where autogenous reconstruction is contraindicated or has failed. Future studies with larger cohorts and longer follow-up are warranted to further validate these findings.

Declaration of Patient Consent

The author certifies that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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