

STOCK VERSUS CUSTOM-MADE JOINT PROSTHESES FOR TOTAL TEMPOROMANDIBULAR JOINT RECONSTRUCTION

Mohamed Salah Elhawary*^{ID}, Mohamed Galal Behiery**^{ID}, Mohammed Mokhtar Khashaba***^{ID},
Samer Mohamed Noman****^{ID}, Mostafa Ibrahim Shindy***^{ID}

ABSTRACT

Aim: The current study aimed to evaluate the custom-made joints are superior to the ready-made joints regarding the post operative mouth opening following the joint replacement surgery.

Methodology: The study was performed on 14 patients(26 joints) indicated for total joint replacement surgery. Patients randomized into two groups; Group 1: (Study Group) Consisting of 7 patients (13 joints), custom made total joint prosthesis have been used. Group 2:(Control Group) Consisting of 7 patients (13 joints), ready-made total joint prosthesis have been used, post operative pain levels and maximum inter incisal mouth opening have been evaluated.

Result: All patients expressed satisfaction with the functional outcome and reduction of pain. There were statistically significance differences between the preoperative and post operative outcomes, while there were no statistically significant differences between the two groups, both types of the joints provide the same degree of improvement.

Conclusion: The results concluded that custom made total joint replacements are not superior to ready-made total joint prosthesis regarding the post operative inter incisal mouth opening but provide better surgical experience regarding the reduced intra operative time and simplicity of the fixation.

KEYWORDS: Temporomandibular joint replacement, custom made total joint, ready-made total joint, stock joint prosthesis

* Lecturer in Oral and Maxillofacial Surgery Department, Nahda University

** Professor in Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University

*** Assistant Professor in Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University

**** Lecturer in Oral and Maxillofacial Surgery Department, Faculty of Dentistry, sana University in Yemen

INTRODUCTION

The concept of the total joint replacement for the temporomandibular joint is not new, the first reported total joint replacement was recorded in 1965. (Van Bogaert W, De Meurechy N, and Mommaerts MY 2018)

There are two major categories of the total joint replacement of the temporomandibular joint, the first one is the ready made (stock) joints while the other is the custom (patient specific) joints. (Meurechy NKG, Zaror CE and Mommaerts MY 2020)

The ready made system is produced in three different sizes to accommodate all the different patients, small, medium, and large size, this is not the same for the custom made joints, which are prepared to fit the specific patient's anatomy (De Meurechy, A Braem, and M Y Mommaerts, 2017)

The joints are prepared by the usage of preoperative computerized tomography of the hard tissues of the head and neck. As such, the operator does not have to adapt the joint parts to the bony structures to obtain a proper position, and the time for surgery is minimal. Position of the metal screws are accurate with minimal risk on the inferior alveolar nerve. (De Meurechy, A Braem, and M Y Mommaerts 2017; Wolford LM et al 2003)

As stated by Mercuri, it is expected that patient specific joints, provide better results compared to ready made joints. (Mercuri LG 2012; Mercuri LG 2013) we designed this study to evaluate both systems to guide craniomaxillofacial (CMF) surgeons while choosing the proper prosthesis to perform the total joint replacement surgery.

MATERIALS & METHODS

The study was performed on 14 patients (26 joints) in the Oral & Maxillofacial Surgery Department – Cairo University indicated for total joint replacement surgery. Patients randomized in equal proportions into two equal groups:

- Group 1 (Study Group): Consisting of 7 patients (13 joints), custom made (patient specific) total joint prosthesis have been used.

- Group 2 (Control Group): Consisting of Consisting of 7 patients (13 joints), ready-made (stock) total joint prosthesis have been used.

All patients included in the study received 3D planning, which were used to create a preliminary plan along with a virtual surgical simulation, to create the final plan prior to being assigned into research groups.

Inter-Incisal Opening:

The primary outcome of the study was to evaluate the postoperative mandibular movement through the measurement of the inter incisal mouth opening.

Maximum inter-incisal opening (MIO) was evaluated clinically and recorded, a ruler or a sliding dental caliper was used to measure the MIO (the total range of movement of the central incisors in the upper jaw and the central incisors in the lower jaw) in millimeters.

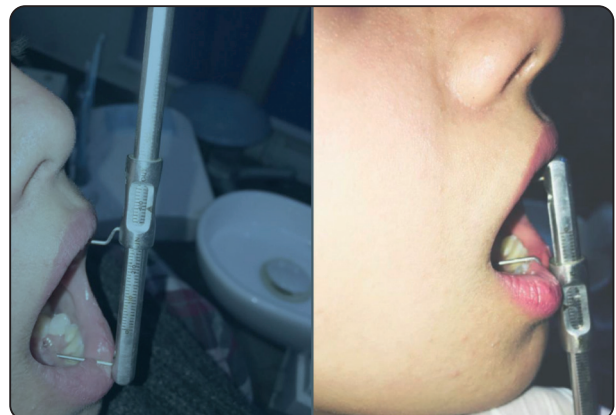


Fig. (1) Preoperative and postoperative inter incisal mouth opening of patient from the control group.

Virtual planning:

All selected patients had a CT scan, the Preoperative computed tomography (CT) should have interslice thickness of 1 mm and the CT should not be older than 3 months. We import the CT DICOM (Digital Imaging and Communications in Medicine) data of each patient into Mimics Materialize 19 (Belgium) and the dimensions of resected condyle can be measured, and 3D reconstruction of bone can be done.

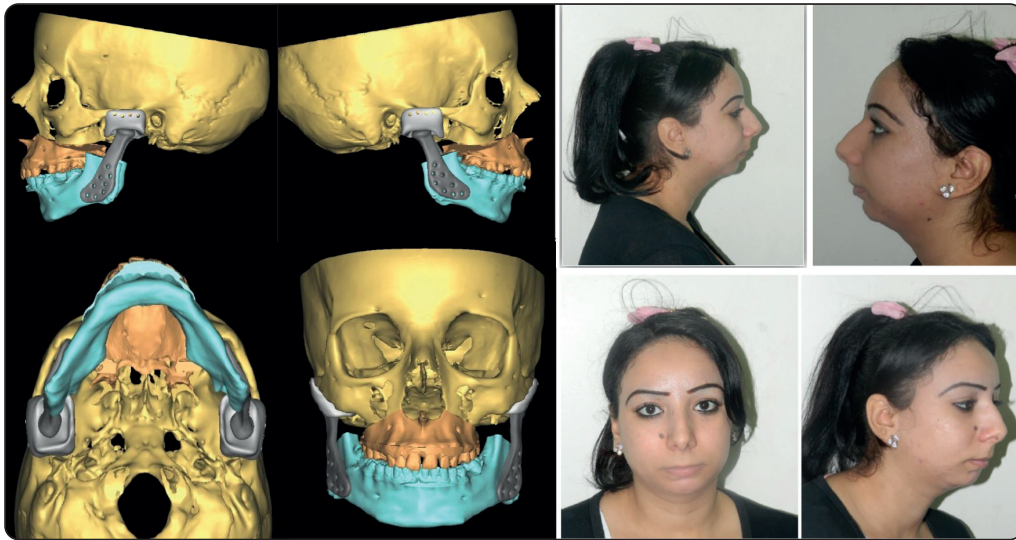


Fig. (2) Pre-operative extra oral images (right), virtual planning and design of the custom made joint (left).

Then, a virtual model of CT reconstructed osseous volume was built to aid in 3D analysis and diagnosis. A three-dimensional virtual hard tissue model of the patient was created.

For the control group(stock joints) we chose the suitable size of the joint according to the 3D reconstructed hard tissues images, while in the study group(custom made) we used the constructed image to manufacture the total joint and the cutting guides

Both systems were applied surgically through combination of pre auricular approach and retro mandibular approach

The pre auricular approach was used to resect the affected condyle or the ankylotic mass and fixation of the fossa component while the retromandibular approach was used to provide access for the fixation of the ramus component

The TMJ custom made total joint prosthesis has 2 basic components: a fossa component and a mandibular component.

The fossa component is made of Polyetheretherketone (PEEK) it is a polyaromatic semi-crystalline thermoplastic polymer with mechanical properties favorable for bio-medical applications and it is the same material used effectively in total hip and knee surgery for over 30 years.

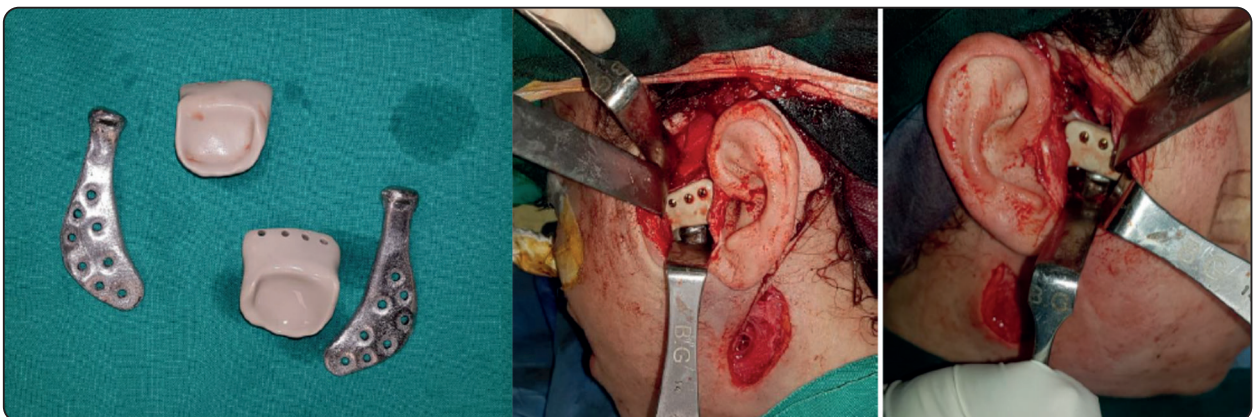


Fig. (3) Custom made joint fossa component and condyle component(left), pre auricular approach and fixation of the fossa(right)



Fig. (4) Retromandibular approach used for the fixation of the condyle component(left), post operative CT (right).

The mandibular component of the prosthesis is also constructed from titanium alloy containing 90% titanium, 6% aluminum, and 4% vanadium. This alloy is extremely hard, very biocompatible, and bend resistant.

The desired design of the condyle has been manufactured through two different ways:

First way is by the milling utilizing the CAD-CAM technology while the second way is for the large sizes of the condyles such as in case of tumor resection with a large, reconstructed segment, thus we have to use the 3D printing machine to fabricate the larger prosthesis.

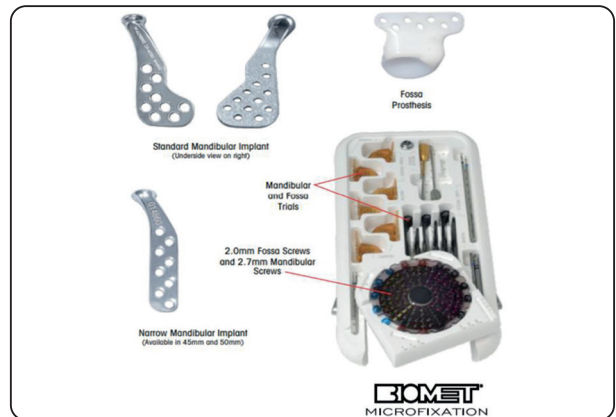


Fig. (5) Zimmer Biomet system

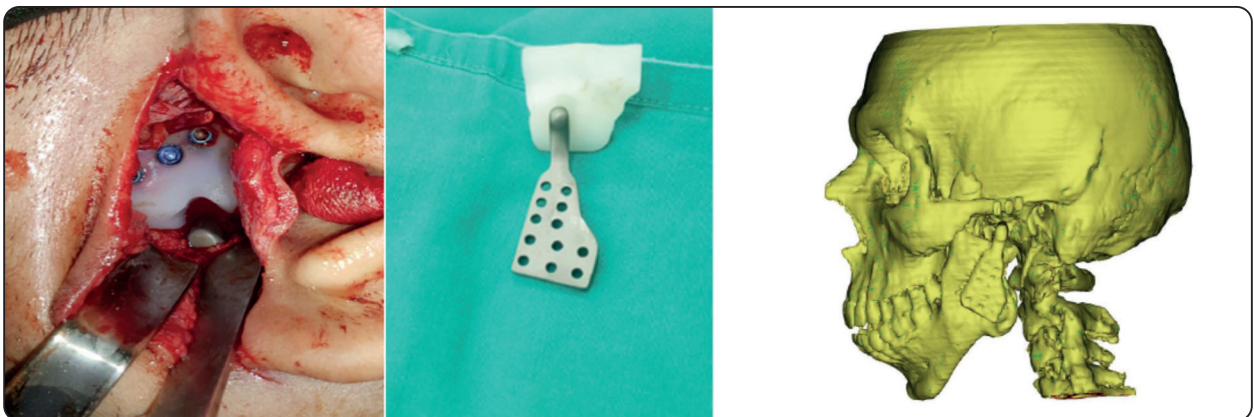


Fig. (6) Stock joint, intra operative fixation(left), the fossa and the condyle components(middle) , post operative CT(right).

The stock TMJ prosthesis is Zimmer Biomet®, mandibular prosthesis 45, 50, 55mm and fossa component including small, medium, large size

RESULTS

The study was conducted on 14 patients (26 joints) in the Oral and Maxillofacial Surgery Department – Cairo University indicated for total joint replacement. patients were randomly allocated into two groups; each included seven patients.

- Patients were divided into 2 equal groups according to the type of the prosthetic joint, the 2 groups received total joint replacement surgery either:
- Group 1 (study group): Consisting of 7 patients, (13 joint), patient specific custom made total joint replacement
- Group 2 (control group): Consisting of 7 patients, (13 joint), ready-made (stock) total joint replacement.
- In two cases intra operative bleeding occurred which controlled by the conventional methods.
- None of the patients suffered from post operative infection.
- Both groups began early mandibular functioning after the removal of elastics.

- Two patients suffered from slight malocclusion which has been managed by orthodontic treatment.
- All patients expressed satisfaction with the wound scar appearance.
- All patients expressed satisfaction with the improvement of the pain level
- All patients showed increased inter incisal mouth opening except with one patient, he was indicated for total joint replacement to remove a benign tumor (mandibular Ameloblastoma), thus his mouth opening before the surgery was not affected.

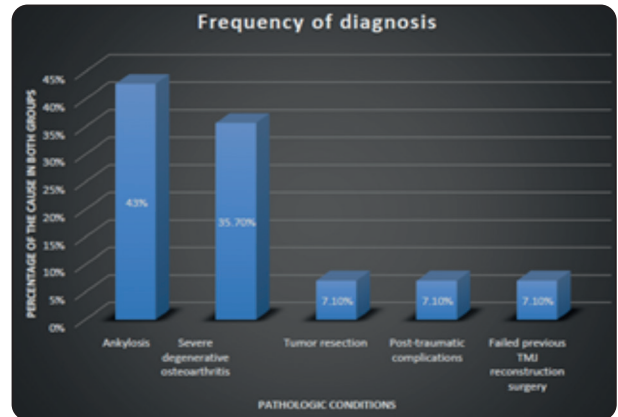


Fig. (7) Indications for the total joint replacement.

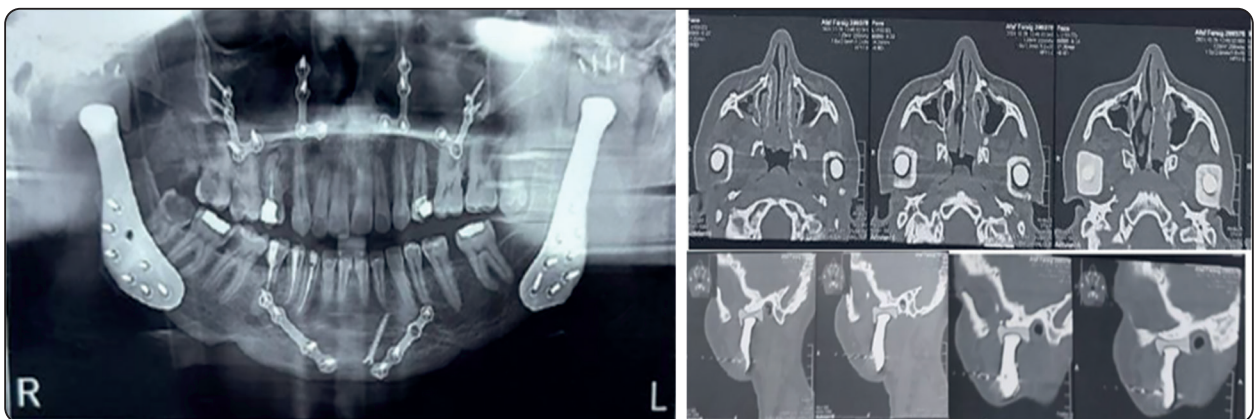


Fig. (8) Post operative radiographs of patient treated using custom made joint

Radiographic results: Within 4 weeks following the surgery. All patients performed a post operative radiograph, the primary goal of the post operative radiograph was to assess the proper position of the condyle component in relation to the fossa component.

All post operative radiographs showed properly positioned and fixed hardware with properly aligned condyles in relation to the corresponding fossa

After one week of the surgery, we measured the maximum painless mouth opening for each patient using a regular ruler or sliding dental caliber, all patients show improvement and increase in the mouth opening, except for one patient from the first group (patient 3, group1). He was treated surgically to remove benign tumor(ameloblast) the tumor did not affected the mouth opening thus the post operative mouth opening did not differ from the preoperative measure.

We measured the MIO at different intervals, starting from one week post operative till six months, but we took the last measurement as the primary outcome because the earlier measurements were affected by the surgery itself and related pain, also the application of elastics affected the accuracy of the measurement in the first few weeks of the follow up periods.

We analyzed the results statically to compare the two groups

In both groups all patients showed great improvement in the range of the mandibular movement post operatively, the increase in the mouth opening was statistically significant in both groups but no group showed more improvement than the other one, both groups provide the same range of improvement. In group 1 (custom – made) the pre- operative inter incisal mouth opening ranges from 18 mm to 33 mm, with mean of 21 mm. for the same group, the post operative results range from 30mm to 35 mm with mean of 33.3mm. While for group 2 (ready-made) the preoperative mouth

opening ranges from 14 mm to 27 mm, with mean of 19.7 mm, while the post operative inter incisal mouth opening ranges from 33 mm to 39 mm with mean of 36.7 mm.

The significant difference between the preoperative and post operative results is obvious for both groups but when We compared the improvement of each group to the other (table) and there was no statistically significant differences (P=0.0699).

TABLE (1) The statistical analysis of the comparison between the two groups

Difference	3.400
Standard Error	1.709
95% CI	-0.3235 to 7.1235
T – statistic	1.990
DF	12
Significance level	P = 0.0699



Fig. (8) Post operative view and measurement of the incisal mouth opening stem

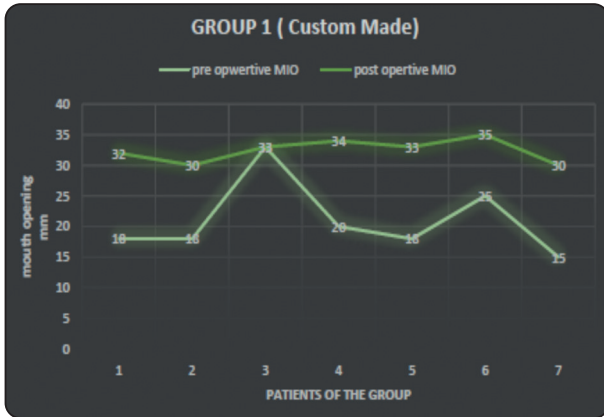


Fig. (9): Bar-chart graph represents the comparison of the preoperative and post operative maximum inter incisal mouth opening for each patient in Group 1.

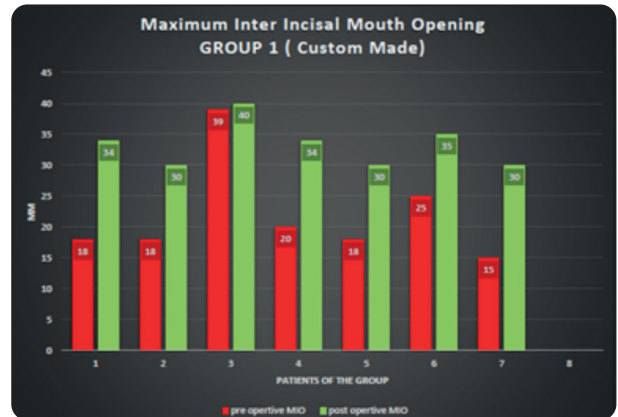


Fig. (10): Line-chart graph represents the comparison of the preoperative and post operative maximum inter incisal mouth opening for each patient in Group 1.

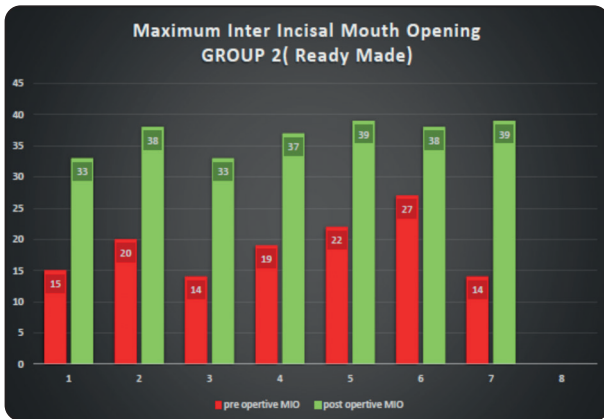


Fig. (11): Bar-chart graph represents the comparison of the preoperative and post operative maximum inter incisal mouth opening for each patient in Group 2.

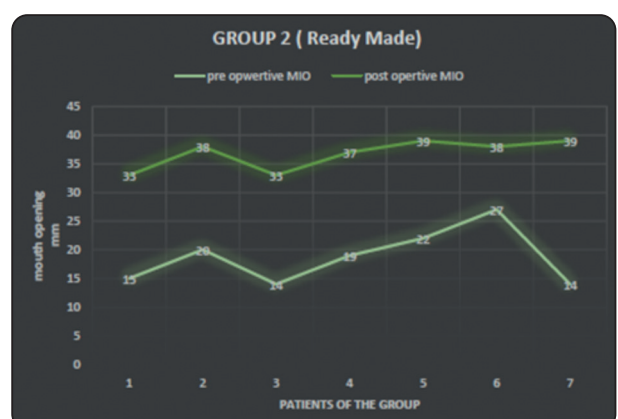


Fig. (12): Line-chart graph represents the comparison of the preoperative and post operative maximum inter incisal mouth opening for each patient in Group 2.

TABLE (2) The mean and standard deviatein of each group.

	Mean (mm)	Standard Deviation	Sample Size
Group 1	33.3	3.68	7
Group 2	36.7	2.627	7

DISCUSSION

The major advantage of alloplastic TJR is its resemblance to TMJ anatomy. It also allows immediate postoperative physiotherapy when

the chances of heterotopic bone formation are maximum, the high success rate of alloplastic joint replacement procedures is well documented in orthopedics (Learmonth ID, Young C and Rorabeck C 2007; NICE 2014; Evans JT et al 2019)

Alloplastic TMJ TJR can be considered as a definitive treatment protocol in an adult patient with end stage TMJ disease (Wolford LM et al 2015).

Although all the published studies of the custom joint replace surgery used the UHMWP as the material of the fossa component, In the current study

the authors used the PEEK as the fossa component material, PEEK (Polyetheretherketone) is a semi-crystalline linear aromatic polymer which has been widely used in different fields, including dental implants, maxillofacial trauma, and many other fields, but not in the TMJ replacement surgeries.

A comprehensive literature search was attempted to find any published studies that introduced the peek as the material used in the construction of the fossa component, however we didn't find any studies related to the PEEK in the total TMJ replacement.

This can be explained by the reliability of the Ultra High Molecular Weight Polyethylene (UHMWPE) which has been used more than 30 years ago as the fossa material (**Zou L et al.2018; Zou L, He D, and Ellis E 2017; Yoda T et al. 2020; Yaseen M et al., 2021**)

However, the authors in the current study aimed to introduce the peek as a reliable and compatible substitute for the UHMWPE, PEEK has been used clinically in the spine, knee and hip joints and also successfully used as a biomaterial in maxillofacial trauma and orthopedics.

due to its favorable mechanical properties (**Kurtz SM and Devine JN,2007;Howling G et al.,2003**)

In the current study we used medical PEEK (JUVORA™ PEEK), originally manufactured to withstand repeated cycles of forces, none of our cases showed any signs of infection, allergy, or and signs of adverse effects related to the usage of PEEK. By the time of writing this discuss, all cases have been followed up for more than three years

Mercuri LG and Dimitroulis G concluded that total joint prosthesis has been shown to provide superior results comparing to the autogenous rib graft (**Mercuri LG ,2018; and Dimitroulis G, 2012**) .

In the current study we recorded that most of the patients returned to their normal range of the maximum mouth opening, although these results are promising, the total joint replacement surgery

must only be considered when other less invasive approaches failed to provide accepted results

A disease or pathological lesion affecting the TMJ can lead to restricted mouth opening either by the formation of heterotopic bone in the joint area or affecting masticatory muscle thereby causing pain leading to inability to open mouth or chew normally.

Successful results with adequate mouth opening have been reported following the use of alloplastic joint replacement (**Wolford L et al., 2016; Sidebottom AJ and Gruber E 2013; Mercuri LG, Ali FA and Woolson R, 2008**)

The post operative complications were not severe in any case. The expected post operative pain and swelling, both have been controlled by the drugs and instructions and resolved eventually within the expected range.

There were two cases of post operative mal occlusion, both cases were ankylosis removal and joint replacement, one case from the custom-made group while the other was from the ready made group, both have been treated by orthodontic treatment.

The post operative mal occlusion seems to be the result of long standing ankylosis and growth deficiency for many years which can not be corrected by single stage surgery.

All other cases expressed good post operative occlusion.

There was no post operative neurosensory dysfunction in any case, except for one case have been treated by mandibular resection.

We didn't encounter any case of facial nerve paralysis following the surgery, this is another proof of the safety of the approaches used in the study (pre auricular and retromandibular).

The time consumed during surgery was reduced significantly by the application of custom made joint when compared to the ready-made joint, also the expenses of the hard were reduced when used the custom-made joints.

CONCLUSION

This study describes the management of 14 patients in whom 26 total alloplastic joints have been placed. The patients divided into two equal groups each group composed of 7 patients (13 joints).

We compared two different systems of the total joint replacement, the custom-made joint replacement system versus the ready-made joint replacement system.

Both systems reduced the patients' pain and increase the maximum inter incisal mouth opening

But The custom-made system reduced the operation time and the effort during the fixation step, also this system costed less than the ready-made joint. No systems provide better results than the other.

The custom-made system reduced the operation time and the effort during the fixation step, also this system costed less than the ready-made joint.

REFERENCES

- Van Bogaert W, De Meurechy N, Mommaerts MY. Autologous Fat Grafting in Total Temporomandibular Joint Replacement Surgery. *Ann Maxillofac Surg.* 2018 Jul-Dec;8(2):299-302. doi: 10.4103/ams.ams_165_18. PMID: 30693249; PMCID: PMC6327803.
- De Meurechy N, Braem A, Mommaerts MY. Biomaterials in temporomandibular joint replacement: current status and future perspectives-a narrative review. *Int J Oral Maxillofac Surg.* 2018 Apr;47(4):518-533. doi: 10.1016/j.ijom.2017.10.001. Epub 2017 Nov 7. PMID: 29126692.
- De Meurechy NKG, Zaror CE, Mommaerts MY. Total Temporomandibular Joint Replacement: Stick to Stock or Optimization by Customization? *Cranio-maxillofac Trauma Reconstr.* 2020 Mar;13(1):59-70. doi: 10.1177/1943387520904874. Epub 2020 Feb 27. PMID: 32642034; PMCID: PMC7311846.
- Wolford L, Movahed R, Teschke M, Fimmers R, Havard D, Schneiderman E (2016) Temporomandibular joint ankylosis can be successfully treated with TMJ concepts patient-fitted total joint prosthesis and autogenous fat grafts. *J Oral Maxillofac Surg* 74(6):1215–1227
- Mercuri LG. Temporomandibular joint reconstruction. In: Fonseca R, editor. *Oral and maxillofacial surgery*, vol. 51. Philadelphia: Elsevier; 2008. p. 945–60.
- Mercuri LG. The use of alloplastic prostheses for temporomandibular joint reconstruction. *J Oral Maxillofac Surg.* 2000;58:70–5.
- Mercuri LL, Swift JQ. Considerations for the use of alloplastic temporomandibular joint replacement in the growing patient. *J Oral Maxillofac Surg.* 2009;67:1979–90.
- Onoriobe U, Miloro M, Sukotjo C, Mercuri LG, Lotesto A, Eke R. How Many Temporomandibular Joint Total Joint Alloplastic Implants Will Be Placed in the United States in 2030? *J Oral Maxillofac Surg.* 2016 Aug;74(8):1531-8. doi: 10.1016/j.joms.2016.04.011. Epub 2016 Apr 23. PMID: 27186874.
- Zou L, He D, Ellis E. A Comparison of Clinical Follow-Up of Different Total Temporomandibular Joint Replacement Prostheses: A Systematic Review and Meta-Analysis. *J Oral Maxillofac Surg.* 2018 Feb;76(2):294-303. doi: 10.1016/j.joms.2017.08.022. Epub 2017 Aug 24. PMID: 28919368.
- Zou L, Zhang L, He D, Yang C, Zhao J, Ellis E 3rd. Clinical and Radiologic Follow-Up of Zimmer Biomet Stock Total Temporomandibular Joint Replacement After Surgical Modifications. *J Oral Maxillofac Surg.* 2018 Dec;76(12):2518-2524. doi: 10.1016/j.joms.2018.06.013. Epub 2018 Jun 15. PMID: 29990463.
- Yaseen M, Abdulqader D, Audi K, Ng M, Audi S, Vaderhobli RM. Temporomandibular Total Joint Replacement Implant Devices: A Systematic Review of Their Outcomes. *J Long Term Eff Med Implants.* 2021;31(3):91-98. doi: 10.1615/JLongTermEffMedImplants.2021037733. PMID: 34369728
- Howling G, Sakoda H, Antonarulrajah A, et al. Biological response to wear debris generated in carbon based composites as potential bearing surfaces for artificial hip joints. *J Biomed Mater Res B Appl Biomater* 2003; 67(2):758–764
- Kurtz SM and Devine JN. PEEK biomaterials in trauma, orthopedic, and spinal implants. *Biomaterials* 2007; 28(32): 4845–4869.2.
- van de Vijfeijken SECM, Schreurs R, Dubois L, Becking AG; CranioSafe Group. The use of cranial resection templates with 3D virtual planning and PEEK patient-specific implants: A 3 year follow-up. *J Craniomaxillofac Surg.* 2019 Apr;47(4):542-547. doi: 10.1016/j.jcms.2018.07.012. Epub 2018 Jul 25. PMID: 30745010.
- Mercuri LG, Anspach WE 3rd. Principles for the revision of total alloplastic TMJ prostheses. *Int J Oral Maxillofac Surg.* 2003 Aug;32(4):353-9. doi: 10.1054/ijom.2002.0447. PMID: 14505615.

- Mercuri LG, Giobbe-Hurder A. Long-term outcomes after total alloplastic temporomandibular joint reconstruction following exposure to failed materials. *J Oral Maxillofac Surg.* 2004;62:1088–96.
- Dimitroulis G. Comparison of the outcomes of three surgical treatments for end-stage temporomandibular joint disease. *Int J Oral Maxillofac Surg.* 2014;43:980–9.