An Innovative Total Temporomandibular Joint Prosthesis with Improved Safety and Efficacy

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ENGL 21007: Writing for Engineers

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October 27, 2020

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**Abstract**

A total temporomandibular joint (TMJ) replacement is a surgical treatment for TMJ disease patients who do not benefit from non-surgical treatments. The currently used TMJ prosthesis could cause complications such as severe pain or difficulty in opening the mouth. To test the safety and efficiency of our new TMJ prothesis, twenty New York City based patients who required TMJ replacement were recruited and assigned into two groups, A and B. Group A received our TMJ prosthesis and group B received the traditional TMJ prosthesis. The pain level and TMJ range of motion assessed by the patients from pre-surgery, 1-month, and 6-month post-surgery were obtained. The results show that our TMJ replacement provides a larger range of motion and lower pain levels than the traditional TMJ prosthesis, which supports that our TMJ prothesis is safer and more efficient for clinical use than the traditional TMJ prosthesis.

**Introduction**

The temporomandibular joint (TMJ) connects your jawbone to your skull, subject to constant cyclical loading and unloading. These repetitive performances along with trauma, or arthritic diseases may cause temporomandibular joint disorders (TMD). The TMD are clinical conditions affecting the temporomandibular joint, the masticatory or jaw muscles and the associated tissues. Prior to the surgical option, conservative therapy is given to TMD patients in order to reduce the pain or to prevent advanced TMDs. However, if these nonsurgical treatments do not benefit patients with TMJ disorders, a total temporomandibular joint replacement is considered, which aims primarily at restoring joint function and form, with pain relief as a possible secondary benefit (Onoriobe 2014).

A study shows an increasing demand for the use of TMJ replacement. The total number of TMJ devices distributed increased from 430 in the year 2000 to 1,004 in 2014. (133%) The number of devices distributed is expected to be 1658 by 2030, which represents a 65% increase in TMJ prosthesis (TMJConcepts.com).

We have designed a newly customized TMJ prosthesis based on the patient’s data provided by New York Presbyterian Hospital. We used the computer-aided design and manufacturing technologies and created the 3D skull model, which was used to check whether the TMJ prosthesis perfectly fitted into each patient’s operation site. The purpose of this study was to evaluate the safety and efficacy of the new TMJ prosthesis in clinical application.

**Methods**

A clinical study was conducted at the Department of Oral Surgery, New York Presbyterian Hospital, between Jan 2020 and June 2020. In this study, twenty patients were recruited for TMJ replacement. Patients who were allergic to prosthetic components materials, uncontrollable masticatory muscle hyperfunction or parafunctional habits such as clenching or grinding, and active infections around the implantation site of the prosthesis were excluded. All twenty patients had no history of previous TMJ surgeries. All patients were informed about the surgical purpose, management protocol, recovery period, and possible complications. An informed consent was obtained from all participants.

Prior to the surgery, the 3D craniomaxillofacial models were created for each patient based on their CT scans of the entire mandible, maxilla, and TMJ. These 3D skull models were used to check the stability and accuracy of the customized TMJ prosthesis. The dimension and slope of the articular surface of the fossa component were calculated based on the TMJ anatomy data from New York Presbyterian Hospital. The bony surface of the fossa part was customized to match the anatomic configuration of the glenoid fossa, zygomatic arch, and remaining articular eminence. All TMJ prothesis components were provided clean and non-sterile. No additional cleaning was required prior to sterilization.

The patients were assigned into two groups, A and B. Group A received our TMJ prosthesis whereas group B received the TMJ Concepts prosthesis, which is a traditional TMJ prosthesis. All patients were given the CT scans at 1 week and 6 months to check any displacement, loosening of the prosthesis components or breakage. The patients were also given the maxillofacial general check-ups at 1 week, 1, 3, and 6 months postoperatively. The routine blood and urine tests were performed for the patients at 1 week, 1, and 6 months postoperatively. The pain levels were assessed by the patients with the pain scale ranged from no pain at 0 to worst pain at 10. The mandibular functions scale and the range of motion of TMJ were assessed by their surgeons measuring maximal incisal opening in millimeters before and 1, 3, and 6 months after replacement. The mandibular functions scale ranged from no loss at 0 to complete loss of functions at 10. The range of motion included maximal interincisal opening (MIO), lateral movements, forward movement (MFM), movement towards the diseased side (MDS), and movement to non-operated side (MNS).

Data were analyzed using F-test and the paired t-test of one-way analysis of variance. Most F values were larger than their critical values where P was less than 0.05, which showed that data were considered statistically significant.

This study was approved by New York Presbyterian Hospital Human Research Ethics Committee and is in accordance with the ethical standards established in the 1964 Declaration of Helsinki.

**Results**

20 consecutive patients were included in this study with 10 females and 10 males. Their mean age was 45.3 years with a range of 33 to 68 years and the mean duration of the disease was 4.2 years with a range of 1 to 13 years. All patients were treated primarily with the conservative therapy for an average of 3.42 months with a range of 0.2 to 8 months without clinical improvements as shown in table 1.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Group | No. | Sex | Age (years) | Duration (years) | Conservative therapy (Months) |
| A | 1 | F | 47 | 3.5 | 1.8 |
| A | 2 | M | 51 | 4.2 | 1.2 |
| A | 3 | M | 60 | 3.7 | 2.5 |
| A | 4 | F | 49 | 2.6 | 1.3 |
| A | 5 | M | 55 | 7.1 | 3.0 |
| A | 6 | F | 62 | 12.5 | 8.0 |
| A | 7 | F | 38 | 6.8 | 4.2 |
| A | 8 | F | 63 | 13.0 | 7.5 |
| A | 9 | M | 33 | 1.2 | 0.2 |
| A | 10 | M | 55 | 11.4 | 5.8 |
| B | 11 | F | 41 | 6.9 | 2.0 |
| B | 12 | M | 37 | 2.3 | 1.8 |
| B | 13 | F | 68 | 8.7 | 7.5 |
| B | 14 | F | 45 | 4.0 | 2.8 |
| B | 15 | M | 43 | 2.3 | 1.5 |
| B | 16 | M | 49 | 5.4 | 1.9 |
| B | 17 | M | 34 | 1.3 | 0.5 |
| B | 18 | F | 57 | 9.6 | 3.8 |
| B | 19 | M | 52 | 8.5 | 6.4 |
| B | 20 | F | 63 | 10.7 | 8.0 |
| Mean |  |  | 45.3 | 4.2 | 3.42 |

Table 1. Basic Data of Selected Patients

All patients experienced no infection after surgery and had no serious postoperative scars. The postoperative CT scans revealed that there was no loosening of the prosthesis component, breakage, displacement, or and no low-density images between the prosthesis and host bone in all joints. No clinical significance in liver and kidney function, blood, urine, and stool analysis tests were found after surgery for all patients.

For group A, the mean preoperative pain level was 6.78, while the postoperative scores were 1.72, 0.89, 0.57 at 1, 3, and 6 months postoperative follow-up points. For group B, the mean preoperative pain level was 6.91, while the postoperative scores were 2.45, 1.47, 0.97 at 1, 3, and 6 months postoperative follow-up points as shown in Figure 1.

Figure 1. Pain Level Over Time

For group A, the mean preoperative MIO was 27.53 mm, and the mean postoperative values were 31.55, 37.00, and 39.53 mm at 1, 3, and 6 months after surgery. For group B, the mean preoperative MIO was 27.14 mm, and the mean postoperative values were 30.98, 34.72, and 36.04 mm at 1, 3, and 6 months after surgery. Between the two groups, there were statistically significant differences for MIO at 1, 3, and 6 months follow-up points (P < 0.01).

For group A, the mean preoperative MDS was 4.63 mm with postoperative means of 6.45, 7.11, and 7.40 mm. For group B, the mean preoperative MDS was 4.75 mm with postoperative means of 6.22, 6.89, and 7.14 mm. There were statistically significant differences between group A and group B (P < 0.01).

For group A, the mean preoperative MNS was 7.42 mm with the postoperative means of 3.19, 2.86, and 2.93 mm. For group B, the mean preoperative MNS was 7.38 mm with the postoperative means of 3.24, 2.51, and 2.85 mm. There were statistically significant differences between group A and group B (P < 0.01).

For group A, the mean preoperative MFM was 6.44 mm with postoperative means of 3.89, 4.10, and 4.56 mm at the corresponding follow-up points. For group B, the mean preoperative MFM was 6.36 mm with postoperative means of 3. 72, 4.02, and 4.40 mm at the corresponding follow-up points. It showed that there were statistically significant differences between the two groups (P < 0.05).

Figure 2. Maximal interincisal opening (MIO), lateral movement to diseased side (MDS), lateral movement to normal side (MNS), mandible forward movement (MFM).

For group A, the mean score of the preoperative mandibular function was 5.63 while the mean score of the postoperative mandibular function was 3.34, 2.68, and 2.21 at the respective follow-up points. For group B, the mean score of the preoperative mandibular function was 5.33 while the mean score of the postoperative mandibular function was 3.74, 2.93, and 2.42 at the respective follow-up points. It revealed that there were statistically significant differences between the two groups (P < 0.005).

Figure 3. Mandibular Function Score

There were statistically more significant improvements for pain, mandibular function at all postoperative follow-up interval for group A.

**Discussion**

Most papers presented for TMJ prosthesis are retrospective or observational research, representing limited literature addressing the clinical application of the traditional TMJ protheses. This study is a prospective self-control research evaluating the safety and efficacy of our new TMJ prosthesis. Both subjective and objective indices were used to confirm the efficacy of the prosthesis. Our study showed an average of 91.4% decrease in pain, 73.2% improvement in mandible function compared to an average of 84.6% decrease in pain, 68.04% improvement in mandible function of the traditional TMJ prosthesis. As a result, the safety and efficacy of the new prosthesis has been confirmed based on the subjective and objective outcomes.

**Conclusion**

With our new TMJ prosthesis, there was a larger decrease in pain levels and mandibular functions and a larger increase in TMJ range of motion than the other TMJ prosthesis. The subjective and objective measurements show that our TMJ prosthesis is safer and more efficient.

**Reference**

Clinical Publications. (n.d.). Retrieved from <https://tmjconcepts.com/clinical-publications/>

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Zheng, J., Chen, X., Jiang, W., Zhang, S., Chen, M., & Yang, C. (2019). An innovative total temporomandibular joint prosthesis with customized design and 3D printing additive fabrication: A prospective clinical study. Journal of Translational Medicine, 17(1). doi:10.1186/s12967-018-1759-1

### Audience Profile Sheet

|  |  |
| --- | --- |
| Reader's Name:  |  |
| N/A |
| Reader's Job Title: |  |
| Maxillofacial oral surgeon |
| Kind of Reader: | Primary\_\_X\_\_\_ Secondary\_\_\_\_\_\_ |
|  |
| Reader’s Level of Education: |  |
| DDS (Doctor of Dental Surgery) and DMD (Doctor of Medicine in Dentistry or Doctor of Dental Medicine) |
| Reader’s Professional Experience: |  |
| Some experience in TMJ replacement |
| Reader’s Job Responsibilities: |  |
| help patients manage diseases in their teeth and surrounding tissues, restructure bones to correct congenital defects or repair wounds |
| Reader’s Personal Characteristics: |  |
| N/A |
| Reader’s Cultural Background: |  |
| N/A |
| Reader’s Attitude Toward the Writer (you): |  |
| Willing to find out our new TMJ prosthesis |
| Reader’s Way of Reading the Document: | Skim it \_\_\_\_\_ Study it \_\_X\_ Read a portion of it \_\_\_ Which portion?Modify it and submit it to another reader\_\_\_\_ |
|  |
| Reader’s Reading Skill: |  |
| Good reading skills |
| Reader's Physical Environment: |  |
| In their office or home office |

Adapted from Markel (7th Ed.), p. 88

**Reflection**

I went independent for this lab report project as I was the only biomedical engineering student and otherwise would cause many challenges for me and my teammates. It was one of the most difficult decisions because I really enjoyed working with my teammates and their feedbacks were very helpful. Working on the group project alone reminded me of the sense of teamwork I had with my teammates and their feedback. I tried to give myself feedback with different perspectives, reading more lab report samples and comparing them to my lab report draft. It helped me meet one of the learning outcomes, enhancing strategies for reading, drafting, revising, editing, and self-assessment.

Through the audience analysis, I was able to formulate and articulate a stance in my writing. I initially chose my biomedical engineering colleagues as the audience, but I was not able to figure out what I persuaded them for. For my ultimate purpose of selling the product, maxillofacial oral surgeons are perfectly fitted into my audience. This process also helped me meet one of the course outcomes, negotiating my own writing goals and audience expectations regarding conventions of genre, medium, and rhetorical situation. I used library resource and TMJ Concepts website for my research, providing me with a lot of resources from various research website such as National Center of Biotechnology Information. It helped me meet the course outcome, practicing using library resources to locate sources appropriate to my writing project.

The purpose of this lab report is to persuade the readers to use our new TMJ prothesis. Although there is an increasing number of TMJ patients, there are only three TMJ manufactures in the United States. The lab report will give my audience more options when it comes to choosing TMJ prothesis products. I hope the readers will choose our product that is safer and more efficient as the lab report demonstrated. The audience for this project are maxillofacial oral surgeons who operate TMJ replacement and never used the new TMJ prothesis before. The exigence for this paper is that there is an increasing demand for the use of TMJ prothesis and there are only a few experimental research on the TMJ prothesis as most research on TMJ prothesis are retrospective observational studies. My stance is that our new TMJ prothesis is safer and more efficient, therefore it should be used for a lot of patients. The genre is a laboratory report, a document to describe and analyze a laboratory experiment. It will provide statistical evidence that support my hypothesis, which was confirmed to be true. The media is digital because I gathered the research of TMJ replacements from CCNY library and TMJ Concepts websites. I also created tables and graphs using Microsoft Word. Lastly, if possible, the lab report will be published on the AAOMS website (The American Association of Oral and Maxillofacial Surgeons) to avoid any kind of contact during the pandemic.

This is my first lab report and the longest paper I have ever written. Considering it was meant to be a group project, I had to spend much more time writing the lab report. Despite these challenges, I learned a lot doing everything by myself. I enjoyed the advantages of working alone, being flexible and being able to choose any topic I wanted. It will help me write future research or lab reports.