2020

Clinical Evaluation Of The Temporomandibular Joint Function Using 4D Jaw Tracking Following Total Joint Replacement

Farhana Rahman
University of Alabama at Birmingham

CLINICAL EVALUATION OF THE TEMPOROMANDIBULAR JOINT FUNCTION USING 4D JAW TRACKING FOLLOWING TOTAL JOINT REPLACEMENT

by

FARHANA RAHMAN

CHUNG HOW KAU, COMMITTEE CHAIR
VLACHOS CHRISTOS
TERPSITHEA CHRISTOU
PATRICK LOUIS

A THESIS

Submitted to the graduate faculty of The University of Alabama at Birmingham, in partial fulfillment of the requirement for the degree of
Master of Science

BIRMINGHAM, ALABAMA

2020

CLINICAL EVALUATION OF THE TEMPOROMANDIBULAR JOINT FUNCTION USING 4D JAW TRACKING FOLLOWING TOTAL JOINT REPLACEMENT

FARHANA RAHMAN

DENTISTRY

ABSTRACT

The degenerative temporomandibular joint diseases such as osteoarthritis, rheumatic arthritis, TMJ ankylosis, condylar resorption is successfully treated by total joint replacement. The aim of this study was to examine the function of Temporomandibular joint after total joint replacement. 15 patients with unilateral or bilateral TMJ total joint replacements and 15 healthy controls were evaluated via SICAT JMT+ device. This non-invasive system measures 3D position and rotation in all degrees of freedom and allows undisturbed functional mandibular movements to provide a quantitative evaluation. In addition, a TMJ questionnaire consisting the subjective symptoms was also obtained. Mandibular movements after total joint replacements were recorded during opening closing, protrusion, and lateral excursive were all significantly decreased than those of controls. Maximum incisal opening in the treatment group was 33.5 +/-5.5mm, Left lateral movement was 1.9+/-2.7mm, right lateral movement was 1.7+/-1.7mm and protrusive movement was recorded 2.8+/-2.1mm. The p-value comparing study and control group indicated significant difference ($p < .0001$) between two groups. The study group stated a high level of satisfaction with the total joint replacement. In conclusion, proper treatment guideline is needed to be established for better understanding of the outcome of this comprehensive approach.

Keywords: Temporomandibular joint, idiopathic condylar resorption, total joint replacement, Jaw motion tracking, mandibular movements.

ACKNOWLEDGMENT

I would like to gratefully acknowledge various people who supported me during my entire residency on this thesis. First, my sincere gratitude and appreciation to Dr. Kau for his guidance and support during my thesis preparation and residency. Secondly, I am thankful to Dr. Louis, for his kind assistance with the sample collection from the electronic database and follow-up schedule. Thirdly, special thanks to Dr. Vlachos and all the faculties for providing me the strength and confidence with their affluent teaching. Fourthly, I would like to expresses my gratitude to everyone who agreed to participate in the study.

Lastly, most of all, I would like to thank my parents and my family who believed in me and encouraged me in every single step of my life.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

ICR	Idiopathic Condylar Resorption.
JMT	Jaw Motion Tracking.
MIO	Maximal Incisal Opening.
TMD	Temporomandibular joint Disorder
TMJ	Temporomandibular Joint

INTRODUCTION

The Temporomandibular joint (TMJ) is a unique synovial joint, consisting of the articular disc, mandibular fossa of the temporal bone, condyle of the mandible, fibrous capsule, synovial fluid, and ligaments. It is located below the posterior end of the zygomatic arch and in front of the external acoustic meatus[1,2]. Different mandibular movements such as opening, closing, protrusion, retrusion, and lateral excursions are carried out by TMJ. It withstands various forces for mastication, deglutition and phonation [1].

Temporomandibular joint disorders (TMD) are multifactorial and characterized by pain, clicking, difficulty with mouth opening and mastication. Studies suggested that 41% of the population reported at least one symptom and 56% showed one clinical sign[1]. However, TMD is currently the most prevalent source of orofacial pain among 12% of the adult population in the United States. Females are 10 times more prone [3-8] with the majority between the ages of 18-45yrs. Osteoarthritis, trauma, ankylosis of TMJ with severe anatomic alteration, failure of the previous reconstruction with autogenous graft, rheumatoid arthritis, and idiopathic condylar resorption are indicated for total joint replacement. The pathogenesis of TMJ degenerative diseases are due to hormone-mediated theory [4,9], avascular necrosis theory [10-12] and dysfunctional remodeling theory [13-15]. An increase in estrogen receptors has been reported to increase the TMJ load

leading to a breakdown of the ligamentous structures, synovial hyperplasia and results in condylar resorption [3-5]. According to avascular necrosis theory, pathological compression of the posterior part of the condyles can restrict the blood supply and causes aseptic necrosis. Arnett et al., suggested that increased mechanical loading to TMJ can cause dysfunctional remodeling of condyles which initiates the resorption phenomenon. Cytokines are secreted by the osteoblasts and synoviocytes. Tumor necrosis factor-alpha (TNF), interleukin (IL-6) and receptor activator nuclear factor kappa-beta ligand (RANKL) play a major role in the pathogenesis of condylar resorption [16]. Gunson and Arnett et al., revealed that cytokines activate the osteoclasts by osteoblasts. Osteoclasts then secrets proteinases which causes articular osseous resorption. In addition, matrix metalloproteinases (MMPs) are also found in the articular tissues of TMJ and play an important role in the degradation of bone and cartilages in TMJ. Besides, phospholipid metabolites like arachidonic acids modulate cellular activities in the articular tissues and responsible for chondrogenesis, osteogenesis and nociception in TMJ [17].

Several predisposing factors associated with the temporomandibular joint degenerative disease are gender (Female), nutrition, genetics, oral habits (bruxism) and iatrogenic compression to TMJ during orthognathic surgery, intermaxillary fixation or use of an improper occlusal splint. Females are more prone to condylar resorption. Studies suggested that estrogen plays an important role in bone and cartilage metabolism during the inflammation. Gunson et al., reported severe condylar resorption in the estrogen imbalance group. In addition, females with low serum levels of 17βestradiol presented severe idiopathic condylar resorption. Following the application of 17βestradiol, bone

resorption was prevented by up regulating Osteoprotegerin (OPG) in OPG-RANKL pathway.[16] Juvenile Idiopathic Condylar resorption has also been recently reported to cause significant destruction of the joint in the adolescent years[18-20]. In 2002, Thilander et al., reported that 25% patients with idiopathic condylar resorption have no TMJ symptoms.[21] The diagnosis of these patients are done by clinical and radiographic investigation.[21] Although panoramic and lateral cephalograms are routinely taken, it has been suggested that cone beam computed tomography (CBCT) is considered as the imaging modality of choice to provide more information on spatial and temporal changes in condylar head[13,22-24]. The radionuclide bone scan showed promising results to assess the active nature of ICR. According to Kaban et al., when the ratio of the radionuclide uptake of the condyle is more than two standard deviations in comparison to the fourth lumbar vertebra, the condition is considered as active ICR [25]. Wolford and Cardenas reported the average rate of ICR was 1.5mm/year which is 0.12mm/month [26]. Thus, early diagnosis and proper treatment planning is necessary to understand the etiology of the disease and to establish a treatment guideline.

Management of the degenerative diseases of TMJ is complex and controversial. It can be conservatively managed with occlusal splints to reduce the load of the condyle and relief TMJ pain and discomfort. Sansare et al., in a systematic review reported no relapse in 24-27months[13]. Orthognathic surgery alone had a mixed results with some studies showing improvements[27] but others high rate of relapse (83.3%-100%) over a follow up of 1-39 months[13]. Papadaki et al., suggested performing orthognathic surgery only when the ICR is inactive. Condylectomy and total prosthetic joint reconstruction of the TMJ

has been widely used to overcome the limitations of biological and mechanical adaptability of TMJ. Many case reports have been cited but few well controlled studies have been reported[28-30]. Wolford and Cardenas suggested stabilization with the Mitek mini anchor in the posterior part off condylar head with the removal of the hyperplastic tissue from the joint.[26] Definitive treatment plan should be delayed until the active resorption has completed. However, the successful treatment should provide aesthetic and functional outcomes together with long-term stability.[28,29]

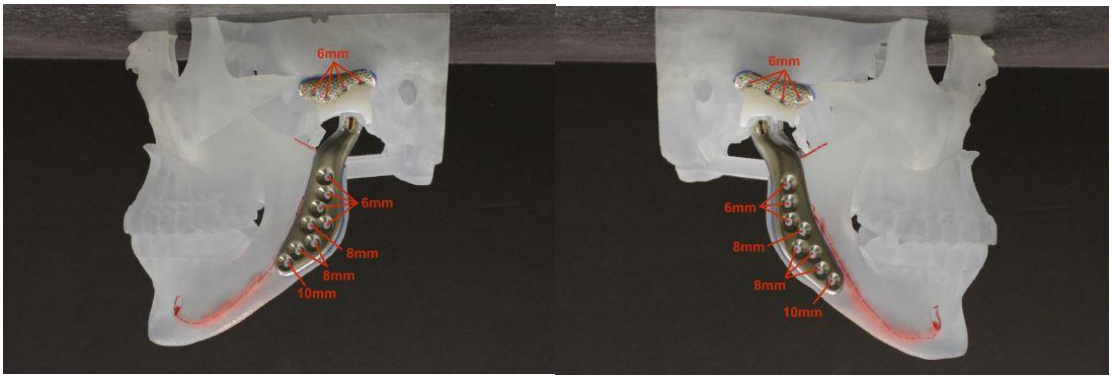
Carnochan, in 1840, first mobilized a patient's ankylosed jaw by placing a block of wood between the bony surfaces after resection at the condylar neck.[31] In 1960, Christensen restructured the glenoid fossa with thin cast vitallium fossa-eminence hemiarthroplasty prosthesis in TMJ ankylosis. However, in early 1990'e Christensen created total joint prosthesis with cast vitallium ramus-condyle component with polymethylmethacrylate condyle but due to wear under functional loading, it was replaced by metal on metal bearing surface device.[32]

The custom-made total joint prostheses was developed in 1990 by the Techmedica Inc. Camarillo, CA, USA, and are currently manufactured by TMJ Concepts, Inc. Ventura, CA, USA[33]. These CAD/CAM devices (computer assisted design/computer assisted manufacture), designed to fit the specific anatomical requirements for each patient. In 2000, a stock TMJ replacement device by Zimmer Biomet, Jacksonville, FL was introduced and found to be clinically useful.[34] Zimmer Biomet also manufactures a custom TMJ replacement device only available outside the US since it is not yet FDA approved. Long term studies support both the stock and custom TMJ replacement[35].

Advantages of using alloplastic joints benefits of providing counterclockwise rotation and minimize the risks. Some authors showed excellent long-term stability and reduction of TMJ symptoms with the total joint replacement over 5-12 years, but their studies lacked a large sample size. A systematic review by Sansare et al., revealed the need for long-term studies on the outcome of management of ICR with total joint replacement to establish a proper treatment guideline.[13]

Restoration of physiologic range of mouth opening and the normal lateral and protrusive movements of the mandible; is the main goal for TMJ replacement. The normal adult mouth opening ranges from 38-50 mm, the normal lateral excursions from 8-10 mm, and the normal protrusions from 8-12 mm. However, in patients after total joint replacement, there is an increase in maximum incisal opening compared with their preoperative condition but their jaw motion is significantly decreased in compare with normal. A number of case reports showed successful treatment of a case of bilateral idiopathic condylar resorption and anterior open bite with maxillary osteotomies and condylar replacement with TMJ concept custom condyle fossa (Fig 1).[28,29]

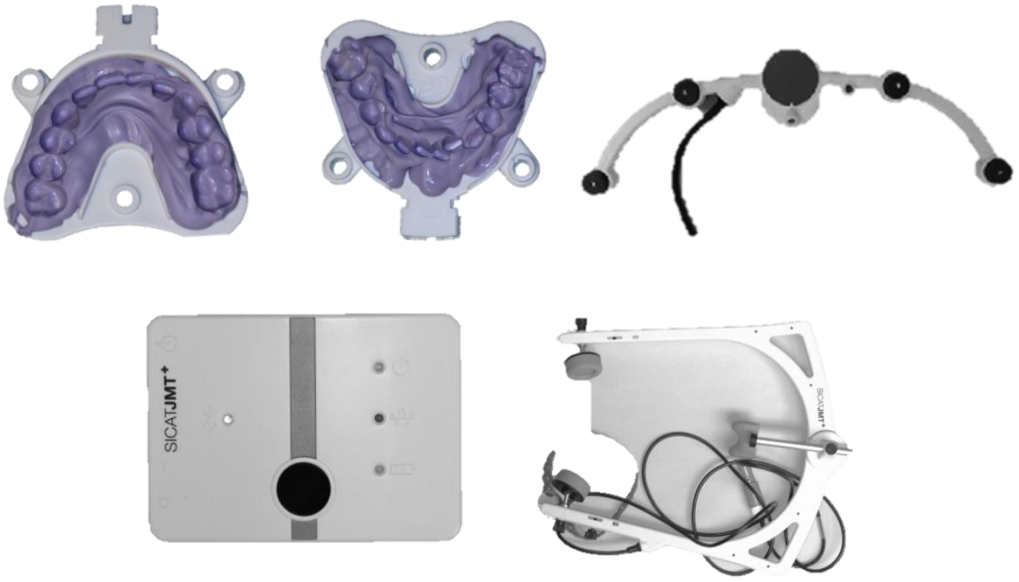
Figure 1: TMJ concept for total joint replacement of fossa and mandibular component.



Condylar movement is difficult to achieve because of the anatomy of TMJ. SICAT JMT+(Jaw motion tracking) is a sophisticated and reliable device (Fig 2) to assess the temporomandibular joint movements including opening-closing, lateral excursion and protrusion. This ultrasound-based system converts multiple acoustic signals into spatial information which records mandibular movements. Furthermore other authors have showed that this system is capable of measuring 3D position and rotation in all degrees of freedom and allows undisturbed functional mandibular movements[36]. The same system has also been used to evaluate TMJ function of patients after Orthognathic Surgery.[37]

No study has been reported on the measurement of TMJ function after total joint replacement using a 4D jaw tracking device. Therefore, the purpose of this study is to evaluate the treatment outcomes of patients who had undergone total TMJ replacement using 4D jaw tracking device and an assessment of jaw symptoms.

Figure 2: Parts of the SICAT JMT+.



Objective Of The Study

The objective of this study was to evaluate the long-term treatment outcomes of all the patients who had undergone TMJ replacement in the University of Alabama in Birmingham by comparing the mandibular movements and subjective symptoms with the norms.

Null Hypothesis

No differences in mandibular range of movements and subjective symptoms between a group of patients with Temporomandibular joint replacement and those with normal TMJ function.

MATERIALS AND METHODS

Study Design

The long-term treatment outcomes of the patients who had undergone TMJ replacement was evaluated and compared with the normal individuals to determine the differences in TMJ function and subjective symptoms.

Sample

Institutional Review Board approval (IRB-30000338) was granted for this research project. The database inquiry initiated by screening the oral and maxillofacial surgery and orthodontic department's electronic patient record databases from 1993- 2017. The inclusion criteria for the patients were

(1) anterior open bite (AOB),

(2) Class II malocclusion,

(3) Subject age range 18-66 years

These subjects (Table 1) had previously been diagnosed with condylar resorbtion and underwent joint replacement and orthognathic surgery in the Oral and maxillofacial surgery department at UAB. The exclusion criteria were patients under 18 years, patient with craniofacial deformities or associated with any orofacial trauma.

Control group. The control group consisted of subjects without any TMJ disorder. These subjects (Table 1) were composed of residents and clinical staff of the orthodontic clinic of UAB with no known TMJ disorders.

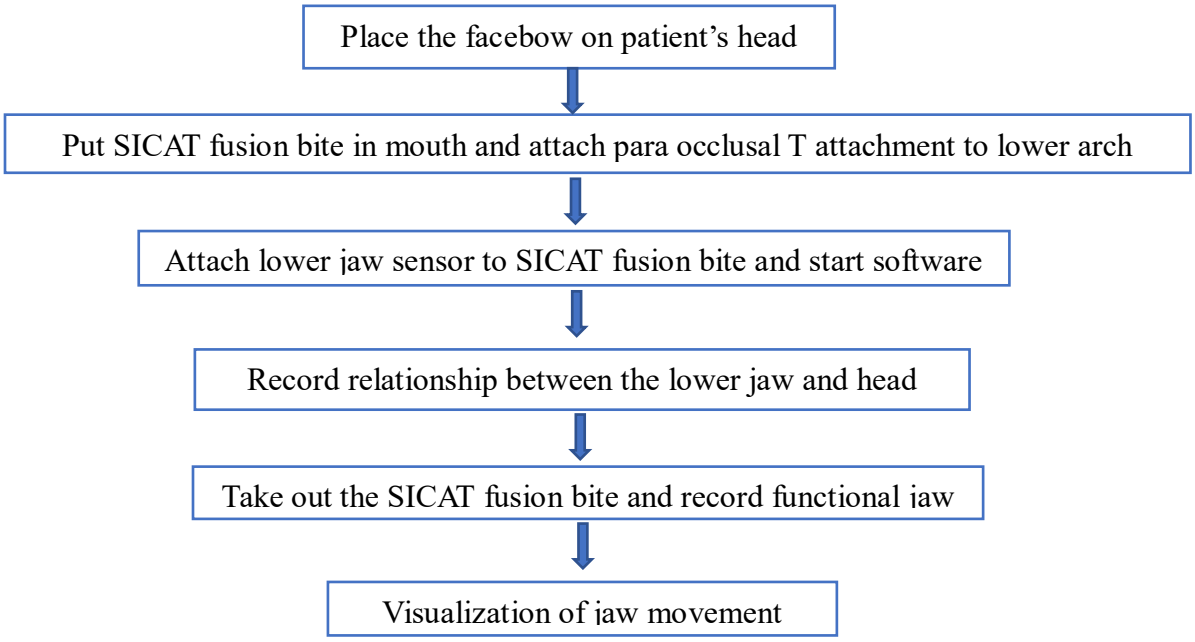
Informed consent. The informed consent was obtained in a closed treatment room in which the privacy of the patient and their treatment were maintained. Written and verbal informed consent was obtained. The consent form clearly stated the purpose of the study, description of the procedure, risk and benefit of the study, the ability to discontinue the study any time without penalty.

Both the study group and control group provided with a previously cited self-reporting questionnaire based on the TMJ pain (nature of pain, aggregating and reliving factors), clicking and popping, crepitus, locking, morning stiffness, chewing ability[37](Table 3). Pain perception was reported by the patients using the visual analog scale (VAS). VAS was graded from 0 "no pain" to 10 "worst pain". The muscles of mastication were examined; any muscular discomfort and joint crepitus or click were recorded.

TMJ movements (lateral excursion, protrusion and opening closing) were measured with SICAT JMT$^+$(Fig 3) This protocol was performed in both control and study subjects. The SICAT JMT$^+$ system has been previously reported and consists of a face bow, a lower jaw sensor, a SICAT Fusion Bite Tray, a SICAT Fusion Bite adapter, a para-occlusal T–attachment, SICAT JMT$^+$ basic unit and SICAT JMT+ application software[36-38](Fig 2). The face bow has a nose pad to locate the face bow and a rear headband to secure it with head. Six ultrasonic microphones receive four ultrasound transmitters in the

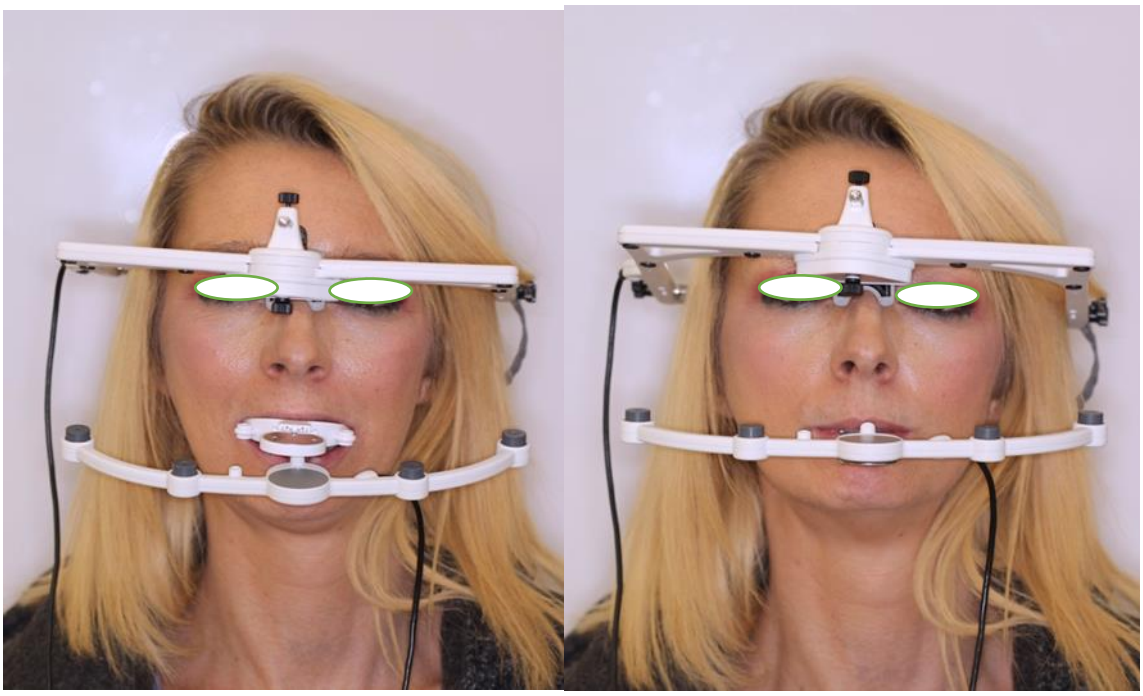
lower jaw sensor. SICAT JMT+ basic unit is connected with both the receiver and transmitter to evaluate the recording. The paraocclusal attachment of the ultrasonic transmitter attached to the patient and blocks occlusal bite relationships. It was adjusted to the lower jaw dental arch, supplemented with the auto polymerizing composite to the bending part of the T-attachment and adapted and hardened to the tooth surfaces. Excess and sharp material was removed. As a result of this procedure, the functional movement of the jaw in the occlusion was undisturbed since the maxillary teeth are not in occlusion. The measurement sensor technology consisted of a receiving sensor and a transmitting sensor.

Jaw tracking procedure



The upper jaw sensor was positioned stably on the patient's head; the head band did not stretch the skin in the forehead area. The Fusion Bite tray with the impression was positioned in the patient's mouth, and check that the patient is biting into the right position. The T-attachment was placed in the patient's mouth. The SICAT JMT+ software then started and prepared for measurement (Fig 3).

Figure 3: Extra-oral photos with SICAT JMT+



The lower jaw sensor technology was fitted with a special locking mechanism for fixing it to the attachment. After the lower jaw sensor was attached to the SICAT Fusion Bite then clicking “record,” the software guided the program throughout the whole calibration sequence. The SICAT JMT+ lower jaw sensor was attached to the paraocclusal T-attachment and then “record” within the software. Subsequently, the SICAT Fusion Bite

was removed and the sensor was mounted on the attachment so that the process of functional analysis could begin. Patient jaw movement including jaw opening and closing movements, lateral excursive movements and forward movements were recorded. Recordings were repeated twice to validate the consistency of the jaw movements. In case of large procedural discrepancies; the highest recording was accepted. The collected data was stored in an EXCEL spreadsheet with the only identifiable patient information being the medical records number. The EXCEL spreadsheet was password protected. Only the researchers participating directly in the study had access to this information.

Statistical analysis. Wilcoxon test was used to compare the continuous variables in two-sample data. The Wilcoxon test is a non-parametric statistical test used to compare two samples that are related to each other. Wilcoxon test is used in this study as an alternative to paired Student t-test because the distribution of the difference between the two samples cannot be assumed to be normally distributed. Moreover, this test is valid for small sample sizes. In addition, Fisher's Exact Test was also used to evaluate the distribution of the variables in total joint replacement patients and control group. Student's T-Test was used to compare the means and standard deviations between the two groups and determine whether there is a statistically significant difference.

RESULTS

Sample size

15 total joint replacement patients were included in the study. The mean age of the study group was 45.47yrs and 30.47yrs for the control group (Table 1). All patients in study group were females and the age range were 20yrs-66yrs. The study group had undergone either unilateral or bilateral TMJ replacement done 2yrs-20yrs before. The control group consisted of 15 healthy individuals (10 females and 5 males) aged between 21-58yrs.

Table 1

Demographic data for sample number, age and gender.

Variables	Number	Age (yrs)	Gender
Total Joint replacement group	15	45.4+_16.7	15 Females
Control group	15	30.5+_8.7	10 Females, 5 males

Clinical Evaluation

There were no significant symptoms of TMD such as pain in the joints, incidence of locking, stiffness, clicking-popping, crepitation, constant pain, pain in movement, muscular pain, headache, migraines, bruxism/clenching noted among two groups (Table 2). In addition, the VAS pain score was 1.9+/-1.8 in study group which was not

significant in compare to the control group (0.8+/-2.4). Study subjects mentioned that the quality of life became better after the total joint replacement surgery. Furthermore, they mentioned that chewing ability and mouth opening also improved in contrast to their pre-operative condition.

Table 2

Subjective symptoms and *p*-values of significance.

Outcome comparisons	Total Joint Replacement (n=15)	Control (n=15)	p-value
Clicking (Reported) Right	1 (6.7%)	3 (20.0%)	0.5977
Clicking (Reported) Left	1 (6.7%)	4 (26.7%)	0.3295
Clicking (On exam) Right	0 (0.0%)	3 (20.0%)	0.2241
Clicking (On exam) Left	0 (0.0%)	4 (26.7%)	0.0996
Popping Left	0 (0.0%)	1 (6.7%)	1.0000
Crepitation (Reported) Right	1 (6.7%)	2 (13.3%)	1.0000
Crepitation (Reported) Left	0 (0.0%)	2 (13.3%)	0.4828
Crepitation (On exam) Right	1 (6.7%)	2 (13.3%)	1.0000
Crepitation (On exam) Left	0 (0.0%)	2 (13.3%)	0.4828
Constant Pain Right	1 (6.7%)	1 (6.7%)	1.0000
Constant Pain Left	1 (7.1%)	2 (13.3%)	1.0000

Outcome comparisons	Total Joint Replacement (n=15)	Control (n=15)	p-value
Pain in movements Right	3 (20.0%)	1 (6.7%)	0.5977
Pain in movements Left	3 (20.0%)	2 (13.3%)	1.0000
Stiffness	3 (20.0%)	1 (6.7%)	0.5977
Muscular pain	1 (6.7%)	2 (13.3%)	1.0000
Headaches	2 (13.3%)	2 (13.3%)	1.0000
Migraines	1 (6.7%)	1 (6.7%)	1.0000
Bruxism/Clenching	3 (20.0%)	5 (33.3%)	0.6817
Chewing ability better	15 (100%)		
VAS Pain Score	1.9 ± 1.8	0.8 ± 2.4	0.1830

Jaw movement evaluation. Mean and median values and standard deviation of maximal incisal opening (MIO), right and left lateral excursive movements and protrusion were illustrated in Table 1 and 3.

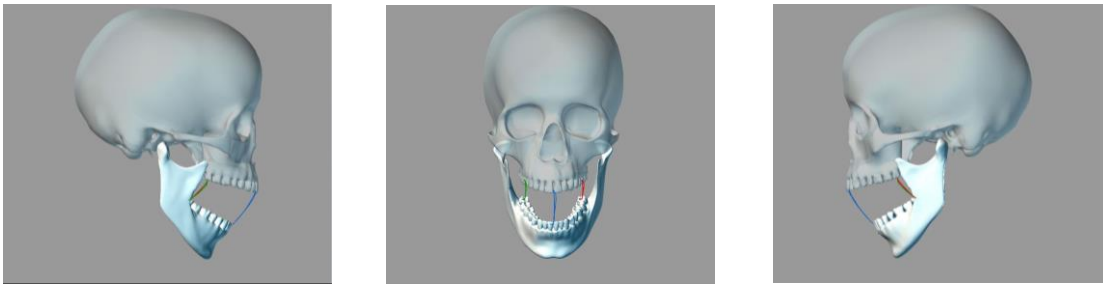
Table 3

Range of mandibular movements measured in millimeters

Mandibular movements	Total joint replacement group	Control group	*p* value

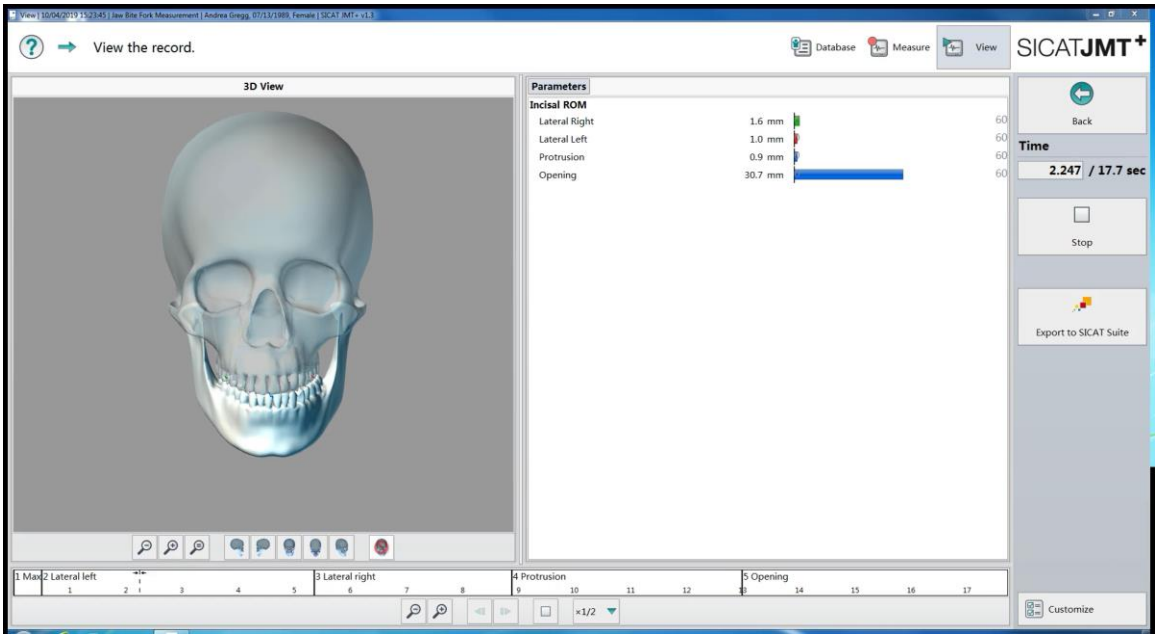
Left lateral	1.9 ± 2.7	9.9 ± 1.6	<.0001
Right lateral	1.7 ± 1.7	9.4 ± 1.9	<.0001
Protrusion	2.8 ± 2.1	9.8 ± 1.7	<.0001
Opening	33.5 ± 5.5	46.4 ± 8.1	<.0001

Figure 4: Maximal Incisal Opening (MIO) in total joint replacement patients with SICAT JMT+



The MIO for the treatment group was 33.5 +/-5.5mm and 46.4 +/-8.1mm for the control group. The p-value comparing two groups outcomes showed <.0001 (Table2). The left lateral movement was 1.9+/-2.7mm in the study group and 9.9 +/-1.6mm for the control group. The p-value comparing the left lateral movement between two groups was <.0001. The right lateral movement was recorded at 1.7+/-1.7mm in the study group and 9.4+/-1.9mm in the control group. The p-value was <.0001 among the two groups. The protrusive movement was found to be 2.83+/-2.05mm in the study group and 9.31+/-1.71mm in the control group. The p-value was <.0001indicating the significant difference between control and study group.

Figure 5: Visualization of mandibular movement with SICAT JMT+



DISCUSSION

This study represents the first study that compares subjects with after joint replacement using a 4D jaw tracker device. The success of the management of TMJ degenerative diseases depends on the functional and esthetics results and long-term stability[39,40]. Different approaches with variable relapse rates with short-term follow up data made the treatment outcome poorly understood[15,26,41-43]. Wolford proposed reposition and stabilization of the disc with the mini anchor at the posterior part of the condyle. Over a period of 1.5-2yrs, no relapse was shown[26]. The next successful treatment approach was condylectomy with a costochondral graft with no relapse until 12 months [44]. However, some studies showed excessive growth of the costochondral graft which resulted in the deviation of the chin, mandibular prognathism and ankylosis [39]. Orthognathic surgery had the highest relapse rate with a short-term follow-up due to an increased rate of condylar resorption [10,45-47]. In 2015, Sansare et al., reported that there is a lack of evidence for treatment management and further studies with long term follow-ups are needed to enable a proper treatment guideline[13]. A recent study reported that jaw tracker did not detect difference in TMJ function except some clinical symptoms after orthognathic surgery using jaw tracker[37].

All the subjects in our study group had undergone reconstruction of the TMJ with the follow-up of 2yrs to 20yrs. Alloplastic total joint replacement was done with TMJ

Concept is a custom-made prosthesis, consisting of the fossa and mandibular components [48-51]. The fossa is constructed from titanium custom-made sheet with a welded mesh that interfaced with the dense UHMWPE articulating surface, and the mandibular component is constructed of 2 basic materials: Ti6Al4 V alloy coated with Co–Cr–Mo alloy head. Many patients who had been treated in UAB oral and maxillofacial surgery were referred from far away due to the complexity of the management of condylar resorption. Initially, 40participants were contacted from the Oral and Maxillofacial Surgery database but only 5 patients showed up for the study. It is anticipated that due to the lack of pain and functional problems, they were unwilling to come for the follow-up visits. Thus, the rest 11 patients were chosen from their follow-up appointment and might have some issues with their joint and needed a follow-up intervention.12 subjects had both TMJ replacement whereas 2 has right joint replacement and 1 had left joint replacement. All the patients among the study group mentioned that they sought treatment due to functional problems and occlusal instability. 14 subjects had done orthodontic treatment.

Subjective Symptoms

Pain pathway in the temporomandibular disorders is complicated and involves both biomedical and bio psychosocial factors. According to Okeson et al., patients can often suffer from neuropathic, neuropsychiatric or myogenic pain or other underlying medical conditions that can influence the pain perception [1]. In our study, although some patients reported subjective perception of chronic pain, but they added that it was more manageable with medication compared with the pre-operative pain.13 among 15 subjects

mentioned that the pain was below 4 in VAS scale. 2 subjects scored pain as 5; dull chronic pain and manageable with pain medication. Interestingly, 1 subject in the control group scored pain as 9 with MIO of 30mm, reduced lateral excursive movements and clicking, crepitus, constant pain on left side. Studies showed that only 5% adults perceived need for treatment among 10-15% of adults who had the symptom of pain [52]. However, there was no statistically significant difference in VAS pain score between the study and control group.

Maximum Incisal Opening

In the literature, it is reported that the ideal maximum incisal opening in the female is 48+/-5mm which is highest at a young age and reduces with increasing age[53]. The mean age of our control group was 30+/-8yrs whereas the mean age of our study group was 45+/-16yrs indicates a large variation among study groups with comparatively aged subjects than the control group. According to Tzanidakis et al., 71% patients improved pain and 61% patients improved the range of the incisal opening following joint replacement [54]. The expected MIO after the TMJ replacement surgery is 30 to 35 mm [55]. In our study, the mean MIO was 33.4+/-5.47mm within the follow-up period of 2yrs-20yrs. MIO was reported to be increased significantly postoperatively. Pre-operatively the mean range of the MIO was 22-25mm. Thus, the improvement of the MIO has significantly improved. A recent study demonstrated no significant difference of MIO between control and orthognathic surgery group [37]. Wolford et al., showed average postoperative MIO following TMJ replacement was 26 mm at 6 months, 26 mm at12

months, 32 mm at 18 months, and 35 mm beyond 18 months follow-up [51]. 2 subjects in this study required additional TMJ surgical procedures, following reconstruction with the total joint prosthesis, for removal of the fibrotic tissue. Pain and limitation of the TMJ is a common problem noticed due to the fibrosis and reactive bone around the prosthesis. Mercuri et al., reported less success rate to reduce pain among the patients who had more than 9 previous surgeries [49]. However, Wolford et al., reported that the improvement was higher in multiple surgery patients. 30% of our sample had undergone multiple TMJ surgeries due to the lack of proper management guidelines before coming to the Oral maxillofacial surgery department of UAB. Therefore, there is a possible explanation of not recording a higher amount of MIO could be due to a small sample size and lack of unwillingness for patient participation in the study.

Lateral excursive movements. In our study, lateral excursion movements were decreased in all patients and significantly different to the control group. In a previous study, it was reported that the average lateral excursion was 2.1 mm and after total joint replacement, the average lateral excursion was decreased to 1.7 mm [51]. This finding is consistent with ours. An explanation of this outcome is possibly due to detachment of the lateral pterygoid muscle after the condylectomy procedure and subsequent fibrosis around the TMJ prostheses. In a previous study, Wolford et al., showed that even after the reattachment of the lateral pterygoid muscle to the neck of the prosthesis by permanent suture, there was no improvement of the lateral excursive movements [56].

Protrusive motions. Our study group showed significantly decreased in protrusive movement with 2.8+/-2.1mm in compare to the control group which was 9.8+/-1.7mm. A prospective cohort study reported the range of protrusive movement of 2-3mm in patients with total joint replacement [57]. The possible reasons for the could be the lack of lateral pterygoid, hypomobility of the masticatory muscles and presence of scar tissues from previous surgical procedures. Using a mandibular simulator it was observed that in cases where the MIO was not limited by the replacement; laterotrusion and protrusion were vastly impaired [58].

SICAT JMT is an electronic recording based on 3D ultrasound measurement that convert the propagation times of multiple acoustic signals into spatial information. Therefore, this system is capable of recording the mandibular movements in all degrees of freedom in case of control and study group.

Masticatory efficiency and quality of life. Majority of our subjects mentioned that their masticatory efficiency significantly improved. Despite of some chronic pain and discomfort in few patients, all agreed that their quality of life also improved remarkably. Our result suggested a significant difference among the TMJ movement such as opening-closing, protrusion and lateral excursive movements with the control group. Possible explanation probably due to majority of the sample (68.75%) was collected from the scheduled patient follow-up appointments where patient presented with some subjective pain or joint tenderness. Another possibility could also be the range of the post-operative follow-up which was 2yrs-20yrs.

Limitation of the study. One of the limitations of this study was the sample size. No sample size calculation was carried out due to the lack of previously reported data using 4D jaw tracking. Due to the novelty of management of the TMJ replacement with customized prosthesis, the study group was concise, and patients recalled had to come from a long distance. As a result, many patients denied participating for the study and many have even been shifted to another state. In addition, those that participated in the study may have either good or bad outcomes only possibly skewing the data set. before total joint replacement, Lastly, due to the retrospective nature of the study and also the length of time of treatment of such procedures, the patients were not assessed pre- or postoperatively by an independent examiner.

CONCLUSION

Within the limitations of the study, following conclusions can be drawn:

- Significant differences were found in TMJ movements among the study group and control group.
- No significant differences were observed in subjective reported symptoms of pain, clicking, crepitation, locking, popping, stiffness, muscular pain, headaches and migraines.
- Total Joint Replacement have showed promising treatment outcomes for subjective (pain, chewing ability and quality of life) and objective (TMJ movements) symptoms.

REFERENCES

1. Okeson J. Etiology and identification of functional disturbances in the masticatory system. *Management of Temporomandibular Disorders and Occlusion.* 2008:147-364.

2. Bordoni B, Varacallo M. Anatomy, Head and Neck, Temporomandibular Joint. In: *StatPearls.* Treasure Island (FL): StatPearls Publishing, StatPearls Publishing LLC.; 2020.

3. Abubaker AO, Raslan WF, Sotereanos GC. Estrogen and progesterone receptors in temporomandibular joint discs of symptomatic and asymptomatic persons: a preliminary study. *Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons.* 1993;51(10):1096-1100.

4. Milam SB, Aufdemorte TB, Sheridan PJ, Triplett RG, Van Sickels JE, Holt GR. Sexual dimorphism in the distribution of estrogen receptors in the temporomandibular joint complex of the baboon. *Oral surgery, oral medicine, and oral pathology.* 1987;64(5):527-532.

5. Tsai CL, Liu TK, Chen TJ. Estrogen and osteoarthritis: a study of synovial estradiol and estradiol receptor binding in human osteoarthritic knees. *Biochemical and biophysical research communications.* 1992;183(3):1287-1291.

6. Gunson MJ, Arnett GW, Formby B, Falzone C, Mathur R, Alexander C. Oral contraceptive pill use and abnormal menstrual cycles in women with severe condylar resorption: a case for low serum 17beta-estradiol as a major factor in progressive condylar resorption. *American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics.* 2009;136(6):772-779.

7. Li ZX, Chen CJ. [The effect of lowered serum levels of estrogen on the expression of ERalpha, ERbeta, OPG and RANKL in rat mandibular condylar cartilage]. *Shanghai kou qiang yi xue = Shanghai journal of stomatology.* 2015;24(4):437-441.

8. Nicolielo LFP, Jacobs R, Ali Albdour E, et al. Is oestrogen associated with mandibular condylar resorption? A systematic review. *International journal of oral and maxillofacial surgery.* 2017;46(11):1394-1402.

9. Aufdemorte TB, Van Sickels JE, Dolwick MF, et al. Estrogen receptors in the temporomandibular joint of the baboon (Papio cynocephalus): an autoradiographic study. *Oral surgery, oral medicine, and oral pathology.* 1986;61(4):307-314.

10. Schellhas KP, Wilkes CH, Fritts HM, Omlie MR, Lagrotteria LB. MR of osteochondritis dissecans and avascular necrosis of the mandibular condyle. *AJR American journal of roentgenology.* 1989;152(3):551-560.

11. Chuong R, Piper MA. Avascular necrosis of the mandibular condyle-pathogenesis and concepts of management. *Oral surgery, oral medicine, and oral pathology.* 1993;75(4):428-432.

12. Chuong R, Piper MA, Boland TJ. Osteonecrosis of the mandibular condyle. Pathophysiology and core decompression. *Oral surgery, oral medicine, oral pathology, oral radiology, and endodontics.* 1995;79(5):539-545.

13. Sansare K, Raghav M, Mallya SM, Karjodkar F. Management-related outcomes and radiographic findings of idiopathic condylar resorption: a systematic review. *International journal of oral and maxillofacial surgery.* 2015;44(2):209-216.

14. Arnett GW, Milam SB, Gottesman L. Progressive mandibular retrusion-idiopathic condylar resorption. Part II. *American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics.* 1996;110(2):117-127.

15. Arnett GW, Milam SB, Gottesman L. Progressive mandibular retrusion--idiopathic condylar resorption. Part I. *American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics.* 1996;110(1):8-15.

16. Yasuda H, Shima N, Nakagawa N, et al. Osteoclast differentiation factor is a ligand for osteoprotegerin/osteoclastogenesis-inhibitory factor and is identical to TRANCE/RANKL. *Proceedings of the National Academy of Sciences of the United States of America.* 1998;95(7):3597-3602.

17. Kubota T, Kubota E, Matsumoto A, et al. Identification of matrix metalloproteinases (MMPs) in synovial fluid from patients with temporomandibular disorder. *European journal of oral sciences.* 1998;106(6):992-998.

18. Stoll ML, Kau CH, Waite PD, Cron RQ. Temporomandibular joint arthritis in juvenile idiopathic arthritis, now what? *Pediatr Rheumatol Online J.* 2018;16(1):32.

19. Stoustrup P, Kristensen KD, Kuseler A, et al. Condylar lesions in relation to mandibular growth in untreated and intra-articular corticosteroid-treated experimental temporomandibular joint arthritis. *Clin Exp Rheumatol.* 2010;28(4):576-583.

20. Stoustrup P, Kristensen KD, Kuseler A, Verna C, Herlin T, Pedersen TK. Management of temporomandibular joint arthritis-related orofacial symptoms in juvenile idiopathic arthritis by the use of a stabilization splint. *Scand J Rheumatol.* 2014;43(2):137-145.

21. Thilander B, Rubio G, Pena L, de Mayorga C. Prevalence of temporomandibular dysfunction and its association with malocclusion in children and adolescents: an

epidemiologic study related to specified stages of dental development. *The Angle orthodontist.* 2002;72(2):146-154.

22. Bell RB. Computer planning and intraoperative navigation in orthognathic surgery. *Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons.* 2011;69(3):592-605.

23. Kau CH, Bozic M, English J, Lee R, Bussa H, Ellis RK. Cone-beam computed tomography of the maxillofacial region--an update. *Int J Med Robot.* 2009;5(4):366-380.

24. Palomo JM, Kau CH, Palomo LB, Hans MG. Three-dimensional cone beam computerized tomography in dentistry. *Dent Today.* 2006;25(11):130, 132-135.

25. Papadaki ME, Tayebaty F, Kaban LB, Troulis MJ. Condylar resorption. *Oral and maxillofacial surgery clinics of North America.* 2007;19(2):223-234, vii.

26. Wolford LM, Cardenas L. Idiopathic condylar resorption: diagnosis, treatment protocol, and outcomes. *American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics.* 1999;116(6):667-677.

27. Kau CH, Bejemir MP. Application of virtual three-dimensional surgery planning in management of open bite with idiopathic condylar resorption. *Ann Maxillofac Surg.* 2015;5(2):249-254.

28. Rahman F, Celebi AA, Louis PJ, Kau CH. A comprehensive treatment approach for idiopathic condylar resorption and anterior open bite with 3D virtual surgical planning and self-ligated customized lingual appliance. *American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics.* 2019;155(4):560-571.

29. Wang J, Veiszenbacher E, Waite PD, Kau CH. Comprehensive treatment approach for bilateral idiopathic condylar resorption and anterior open bite with customized lingual braces and total joint prostheses. *Am J Orthod Dentofacial Orthop.* 2019;156(1):125-136.

30. Kau CH, Almakky O, Louis PJ. Team approach in the management of revision surgery to correct bilateral temporomandibular joint replacements. *J Orthod.* 2020:1465312520908276.

31. Carnochan. Carnochan JM. Mobilizing a patient's ankylosed jaw by placing a block of wood between the raw bony surfaces after resection. . *Arch de Med 1860;284.* 1860.

32. Christensen. The correction of mandibular ankylosis by arthroplasty and the insertion of a cast vitallium glenoid fossa: a new technique. A preliminary report of three cases. Am J Orthop. . *American journal of orthodontics and dentofacial orthopedics :*

official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics. 1963;1963;5:16-24.

33. Mercuri LG WL, Sanders B, White RD, Hurder A, Henderson W. . Custom CAD/CAM total temporomandibular joint reconstruction system: preliminary multicenter report. . *J Oral Maxillofac Surg 1995;53(2):106–116* 1995.

34. Quinn. Total temporomandibular joint reconstruction. . *Oral and Maxillofac Surg Clin N Am 2000 pp 93-104.* 2000.

35. Leandro LF OH, Loureiro CC, Marinho K, Guevara HA. . A ten-year experience and follow-up of three hundred patients fitted with the Biomet/Lorenz Microfixation TMJ replacement system. . *Int J Oral Maxillofac Surg 2013;42(8):1007–1013.* 2013.

36. He S, Kau CH, Liao L, Kinderknecht K, Ow A, Saleh TA. The use of a dynamic real-time jaw tracking device and cone beam computed tomography simulation. *Annals of maxillofacial surgery.* 2016;6(1):113-119.

37. Aslanidou K, Xie R, Christou T, Lamani E, Kau CH. Evaluation of temporomandibular joint function after orthognathic surgery using a jaw tracker. *Journal of orthodontics.* 2020:1465312520908277.

38. Aslanidou K, Kau CH, Vlachos C, Saleh TA. The fabrication of a customized occlusal splint based on the merging of dynamic jaw tracking records, cone beam computed tomography, and CAD-CAM digital impression. *J Orthod Sci.* 2017;6(3):104-109.

39. Peltomaki T, Ronning O. Interrelationship between size and tissue-separating potential of costochondral transplants. *European journal of orthodontics.* 1991;13(6):459-465.

40. Guyuron B, Lasa CI, Jr. Unpredictable growth pattern of costochondral graft. *Plastic and reconstructive surgery.* 1992;90(5):880-886; discussion 887-889.

41. Wolford LM. Idiopathic condylar resorption of the temporomandibular joint in teenage girls (cheerleaders syndrome). *Proceedings (Baylor University Medical Center).* 2001;14(3):246-252.

42. Hoppenreijs TJ, Freihofer HP, Stoelinga PJ, Tuinzing DB, van't Hof MA. Condylar remodelling and resorption after Le Fort I and bimaxillary osteotomies in patients with anterior open bite. A clinical and radiological study. *International journal of oral and maxillofacial surgery.* 1998;27(2):81-91.

43. Mercuri LG. Total joint reconstruction--autologous or alloplastic. *Oral and maxillofacial surgery clinics of North America.* 2006;18(3):399-410, vii.

44. Troulis MJ, Tayebaty FT, Papadaki M, Williams WB, Kaban LB. Condylectomy and costochondral graft reconstruction for treatment of active idiopathic condylar resorption. *Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons.* 2008;66(1):65-72.

45. Scheerlinck JP, Stoelinga PJ, Blijdorp PA, Brouns JJ, Nijs ML. Sagittal split advancement osteotomies stabilized with miniplates. A 2-5-year follow-up. *International journal of oral and maxillofacial surgery.* 1994;23(3):127-131.

46. Kerstens HC, Tuinzing DB, Golding RP, van der Kwast WA. Condylar atrophy and osteoarthrosis after bimaxillary surgery. *Oral surgery, oral medicine, and oral pathology.* 1990;69(3):274-280.

47. Bouwman JP, Kerstens HC, Tuinzing DB. Condylar resorption in orthognathic surgery. The role of intermaxillary fixation. *Oral surgery, oral medicine, and oral pathology.* 1994;78(2):138-141.

48. Ferreira FM, Cunali RS, Bonotto D, Farias ACd, Cunali PA. Total temporomandibular joint alloplastic reconstruction. *Revista Dor.* 2014;15:211-214.

49. Mercuri LG. Alloplastic temporomandibular joint replacement: rationale for the use of custom devices. *International journal of oral and maxillofacial surgery.* 2012;41(9):1033-1040.

50. Guarda-Nardini L, Manfredini D, Ferronato G. Temporomandibular joint total replacement prosthesis: current knowledge and considerations for the future. *International journal of oral and maxillofacial surgery.* 2008;37(2):103-110.

51. Wolford LM, Dingwerth DJ, Talwar RM, Pitta MC. Comparison of 2 temporomandibular joint total joint prosthesis systems. *Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons.* 2003;61(6):685-690; discussion 690.

52. Macfarlane TV, Glenny AM, Worthington HV. Systematic review of population-based epidemiological studies of oro-facial pain. *Journal of dentistry.* 2001;29(7):451-467.

53. Mezitis M, Rallis G, Zachariades N. The normal range of mouth opening. *Journal of Oral and Maxillofacial Surgery.* 1989;47(10):1028-1029.

54. Tzanidakis K, Sidebottom AJ. Outcomes of open temporomandibular joint surgery following failure to improve after arthroscopy: is there an algorithm for success? *The British journal of oral & maxillofacial surgery.* 2013;51(8):818-821.

55. Gruber EA, McCullough J, Sidebottom AJ. Medium-term outcomes and complications after total replacement of the temporomandibular joint. Prospective outcome analysis after 3 and 5 years. *The British journal of oral & maxillofacial surgery.* 2015;53(5):412-415.

56. Wolford LM, Pitta MC, Reiche-Fischel O, Franco PF. TMJ Concepts/Techmedica custom-made TMJ total joint prosthesis: 5-year follow-up study. *International journal of oral and maxillofacial surgery.* 2003;32(3):268-274.

57. Wojczyńska A, Leiggener CS, Bredell M, et al. Alloplastic total temporomandibular joint replacements: do they perform like natural joints? Prospective

cohort study with a historical control. *International journal of oral and maxillofacial surgery*. 2016;45(10):1213-1221.

58. Celebi N, Rohner EC, Gateno J, et al. Development of a mandibular motion simulator for total joint replacement. *Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons.* 2011;69(1):66-79.

IRB APPROVAL

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 |
irb@uab.edu

APPROVAL LETTER

TO: Rahman, Farhana

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 29-May-2019

RE: IRB-300003383
Temporomandibular Joint Function after Total Joint Replacement in Idiopathic Condylar Resorption.

The IRB reviewed and approved the Initial Application submitted on 28-May-2019 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review:	Expedited
Expedited Categories:	4, 5, 7
Determination:	Approved
Approval Date:	29-May-2019
Approval Period:	Expedited Status Update (ESU)
Expiration Date:	28-May-2022

Although annual continuing review is not required for this project, the principal investigator is still responsible for (1) obtaining IRB approval for any modifications before implementing those changes except when necessary to eliminate apparent immediate hazards to the subject, and (2) submitting reportable problems to the IRB. Please see the IRB Guidebook for more information on these topics.

Documents Included in Review:

- surveyquest.190429
- hsp.clean.190524
- consent.clean.190522
- datacollection.190429
- pptletter.clean.190517

SURVEY QUESTIONNAIRE

AARHUS OROFACIAL EXAMINATION PROTOCOL
REGISTRATION OF PATIENTS WITH TMJ ARTHRITIS - ARTHROPATHY

NAME:_____ DATE:_____ JNB:_____

DIAGNOSIS:_____COURSE:_____

TISSUETYPE:_____ ANA:_____ RF:_____ DEBUT:_____Y____MD

ALLERGY_____

FAMILIAR DISPOSITION_____

GENEREL HEALTH _____

_____

_____

DATE						
ACTIVITY						

0: no disease activity *1: light to moderate, activity, single joint* *2: acute activity*

MEDICATION						
NSAID						
DMARD						
BIOLOGICS						
PREDNISOLON						
OTHER						

DATE PROFILE						
a: profile						
b: lower face height						
c: micrognathia						

a: 0: convex, 1: concave, 2: straight
b: 0: normal, 1: decreased, 2: increased
c: 0: present,1: tendency, 2: total

□ straight (a) □ slight convex (b) □ moderate (c) □ micrognathic (d)

	date	date	date	date	date	date
a						
b						
c						
d						

DATE FUNCTION						
a: lips						
b: respiration						
c: tongue						
d: mand.pos. dualbite						

a: 0: normal, 1: lip dysfunction, 2: insufficient lip closure
b: 0: normal, 1: mixed, 2: mouth breather
c: 0: normal, 1: dysfunction.
d: 0: normal, 1: dualbid >2mm, 2: forced bite

DATE CERVICAL SPINE						
a: tenderness palpation						
b: mobility						

a: 0: not present, 1: present
b: 0: normal, 1: decreased

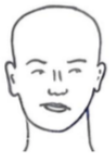
DATA COLLECTION

OBJECTIVE EXAMINATION

DATE SYMMETRY						
a: pupillary line						
b: mandibular basis						
c: occlusal plane						
d: menton						
e: dental midline UJ						
f: dental midline LJ						

0: symmetric, 1: z-axis asymmetry right, 2: z-axis asymmetry left, 3: y-axis asymmetry right, 4: y-axis asymmetry left

Symmetric



Asymmetric right

Asymmetric left

date								date								date							

DATE PROFILE						
a: profile						
b: lower face height						
c: micrognathia						

a: 0: convex, 1: concave, 2: straight
b: 0: normal, 1: decreased, 2: increased
c: 0: present,1: tendency, 2: total

□ straight (a) □ slight convex (b) □ moderate (c) □ micrognathic (d)

	date	date	date	date	date	date
a						
b						
c						
d						

DATE FUNCTION						
a: lips						
b: respiration						
c: tongue						
d: mand.pos. dualbite						

a: 0: normal, 1: lip dysfunction, 2: insufficient lip closure
b: 0: normal, 1: mixed, 2: mouth breather
c: 0: normal, 1: dysfunction.
d: 0: normal, 1: dualbid >2mm, 2: forced bite

DATE CERVICAL SPINE						
a: tenderness palpation						
b: mobility						

a: 0: not present, 1: present
b: 0: normal, 1: decreased

SUBJECTIVE

DATE TMJ												
	R	L	R	L	R	L	R	L	R	L	R	L
a: swelling												
b: click												
c: locking												
d: crepitation												
e: constant pain												
f: pain, movements												
g: morning stiffness												

a: 0: not present, 1: present
b: 0: not present, 1: moderate click, 2: click+pain, 3: intermittent
c: 0: not present, 1: present
d: 0: not present, 1: moderate crepitation, 2: severe crepitation
e: 0: not present, 1: moderate pain, 2: severe pain
f: 0: not present, 1: moderate pain, 2: severe pain
g: 0: not present, 1: present or minutes

DATE CHEWING MUSCLES												
	R	L	R	L	R	L	R	L	R	L	R	L
a: muscular pain												
b: head ache												

a: 0: not present, 1: moderate pain, 2: severe pain
b: 0: not present, 1: 2-4x/week, 2: 5-7x/week

VAS-scale

0 1 2 3 4 5 6 7 8 9 10

0 1 2 3 4 5 6 7 8 9 10

0 1 2 3 4 5 6 7 8 9 10

0 1 2 3 4 5 6 7 8 9 10

0 1 2 3 4 5 6 7 8 9 10

0 1 2 3 4 5 6 7 8 9 10

DATE FUNCTION						
a: bruxism						
b: chewing ability						
c: opening capacity						

a: 0: not present, 1: present
b: 0: normal, 1: decreased
c: 0: normal, 1: decreased

DATE CERVICAL SPINE						
a: pain						
b: stiffness						

0: not present, 1: present

DATE FUNCTION						
a: opening wo. pain						
b: opening w. pain						
c: symmetry opening						
d: laterotrusion r						
e: laterotrusion l						
f: protrusion						
g: symmetry pro.						

a: mm+vob
b: mm+vob
c: 0: symmetry, 1: asymmetry r, 2: asymmetry l
d: mm
e: mm
f: mm+hoj
g: 0: symmetry, 1: asymmetry r, 2: asymmetry l

DATE						
a: TMJ activity						

a: assessment based on total clinical examination
0: no present or earlier TMJ arthritis
1: active TMJ arthritis r
2: active TMJ arthritis l
3: earlier TMJ arthritis, present inactive/chronic r
4: earlier TMJ arthritis, present inactive/chronic l
5: obs arthritis r
6: obs arthritis l
7: other TMJ diagnosis

DATE												
a: time since last CBCT												
	R	L	R	L	R	L	R	L	R	L	R	L
b: condylar conditions												

a: months
b: 0: normal conditions, 1: signs of pathologic joint changes

CONSENT FORM

UAB IRB
Approved
29-May-2019

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Temporomandibular joint function after total joint replacement in Idiopathic Condylar resorption.

UAB IRB Protocol #: IRB-300003383

Principal Investigator: Farhana Rahman B.D.S, Ph.D

Sponsor: UAB School of Dentistry/ Department of orthodontics

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to evaluate the treatment outcome of Temporomandibular joint (TMJ) replacement surgery in Idiopathic condylar resorption.
Duration & Visits	You will be in this study for 30 minutes, one visit.
Overview of Procedures	This study will include a questionnaire, clinical measurements (muscle and joint palpation and visual inspection of jaw movements) and assessment of TMJ movements (opening-closing, forward-backward and side by side movement) with a Jaw Motion Tracker.
Risks	There is no risk associated with this study. There may be a minimal risk of loss of personal data.
Benefits	You may not benefit directly from taking part in this study. However, this study may help us better understand the outcome of TMJ replacement surgery has a beneficial, harmful or neutral effect on the function of the joints.
Alternatives	If you do not want to take part in the study, you will not lose any benefits you are otherwise owed.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this research study is to evaluate the treatment outcome of Temporomandibular joint (TMJ) replacement surgery. TMJ pain and TMJ movements (opening-closing, forward, backward and side by side jaw movement) will be assessed.
You are being asked to participate in the study because you have had Idiopathic Condylar resorption (ICR) and undergone TMJ replacement surgery and included in the study group or because have not had TMJ disorder and are a candidate for the control group. The total number of participants is expected to be 80; study group consisting 40 and control group of 40.

Study Participation & Procedures

If you agree to join the study, you will be scheduled for a study visit in Department of Orthodontics, UAB. After completing a questionnaire regarding jaw joint functions and symptoms; you will undergo the checking of your jaw muscles, joint palpation and visual inspection of jaw movements. The Jaw Motion Tracking device which is FDA approved will be used to measure the range of Jaw movements (maximum mouth opening-closing,

forward and lateral movements). All procedures are for research purposes. The estimated time to complete all study procedures is 30 minutes.

Risks and Discomforts

There are no risks or discomforts associated with the study. There may be a minimal risk of loss of personal data.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us better understand the outcome of TMJ replacement surgery has a beneficial, harmful or neutral effect on the function of the joints.

Alternatives

Your alternative is, not to participate in this study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

Your consent form will be placed in your dental record at UAB School of Dentistry/ Department of Orthodontics. The data obtained as part of this study will be stored on a UAB encrypted computer in the department of orthodontics, faculty of dentistry. Any paper information will be transferred to the electronic database and the paper material will be shredded. The database will be password-protected and access will be limited only to the researchers participating in the study

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your

information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- UAB School of Dentistry/ Department of Orthodontics
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All exams related to this study will be provided to you at no cost.

Payment for Participation

There is no compensation for participation.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Farhana Rahman at 347-371-2575 or after hours by paging her at 347-371-2575.
If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant	Date
Signature of Person Obtaining Consent	Date

PATIENT INVITATION LETTER

Department of Orthodontics, School of Dentistry, UAB

Invitation letter for patient recall

Date: ……..

Address: ……

Dear Invitee,

This is Dr. Farhana Rahman, a second year resident in department of Orthodontics, School of Dentistry, UAB. Together with oral surgeon Dr. Patrick Louis and Orthodontic Chair Dr. Chung How Kau; we are conducting a research project entitled: Temporomandibular Joint Function after Total Joint Replacement in Idiopathic condylar Resorption. We are kindly requesting your participation in this study. The purpose of this study is to evaluate the treatment outcomes of idiopathic condylar resorption (ICR) patients, treated at UAB by comparing the temporomandibular joint function (Opening, closing, forward movement, backward movement and lateral movement) with the normal individuals which will help clinicians to provide the proper comprehensive treatment planning for the patients with ICR.

This study will involve you to fill out a questionnaire regarding the temporomandibular joint pain and its character, intensity, any joint sounds. Checking of the muscles around the joint will be followed by the Temporomandibular joint function measurement.

Participation is completely voluntary and you may withdraw from the study at any time. The study is completely anonymous, therefore, it does not require you to provide your name or any other identifying information. You will receive a call from me in 3 days to confirming your participation and schedule a study visit if you agree to participate.

Please read the Informed Consent letter below if you would like to participate in the study.

Your participation in this research will be of great importance to evaluate the long term treatment outcome of idiopathic condylar resorption.

Thank you for your time and participation.

Sincerely

Dr. Farhana Rahman
2nd Year Resident, Department of Orthodontics
School of Dentistry, UAB.