Evaluating the Effect of Complete Dentures on Signs and Symptoms of Temporomandibular Disorders Analyzed by Craniomandibular Index in Completely Edentulous Patients- A Study Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Study Protocol

ABSTRACT

Background: A Temporo-mandibular disorder (TMD) itself is a cumulative terminology used to indicate the situations which entails the pain alone or in association with dysfunction of the Temporomandibular joint (TMJ) with or without involving the associated structures. One of the main cause of developing TMD is the loss of tooth. The completely edentulous patients also have reported high prevalence of TMD as in dentulous patients.
Methods: It is a prospective interventional study that will be carried out in three years. The sample size will be those completely edentulous subjects, who has not used dentures for a duration of six months to five years of tooth extraction. Such subjects will then be subjected to anamnestic component of Helkimos Index for screening purpose.110 subjects exhibiting mild to severe signs

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and symptoms of Temporomandibular disorders will be considered as the study participants for the study. Study participants will be categorized as Group A (study participants having mild symptoms of TMD, n=55) and the second will be Group B (study participaants having severe symptoms of TMD, n=55). The Craniomandibular Index will be used to score the severity of the TMD before denture insertion. The initial recorded score will be then correlated with the score obtained after 3 months of delivery of denture. Descriptive as well as analytical statistics will be performed. The statistical relevance among the Group A and Group B before intervention and after 3months of intervention will be assessed at p<0.05.

Discussion: Through the study results we anticipate a fall in CMI score i.e improvement by lowering the intensity of TMD due to intervention by complete dentures in completely edentulous subjects. In case the above Hypothesis is not proved, then prevalence of TMD among patients who are completely edentulous needs to be anticipated with the factors such as anatomical or pathological diversities in TMJ and not to be associated with changes in vertical dimensions because of teeth loss.

Keywords: Complete denture; craniomandibular index; Helkimo's index; temporomandibular joint disorders.

1. INTRODUCTION

TMD is a very broad terminology used to indicate the disorders or dysfunctions associated with TMJ, muscles of mastication, or/and occlusion. Its cardinal symptoms are joint sounds, TMJ pain, tenderness of masticatory muscles, and restricted movement of the lower jaw.

The exact etiology of TMD is still debatable. However psychosocial, psychological, and physical factors were reported to contribute towards TMD. Many studies reported TMD due to Occlusal discrepancies and loss of posterior teeth in fully or partially dentulous patients. At the same time, the high prevalence of TMD among completely edentulous patients was also documented [1]. This further raised the controversies and need for research in the area of TMD. The study conducted by by Canales G et al reported very severe dishevel and melancholy among patients suffering from TMD [2].TMD has poor effect over the life of an individual suffering from it in terms of the quality and also has reported psychological distress [3-6]. Tay KJ et al and Bitiniene D et al reported an direct correlation of TMD with lower quality of life [7,8].

The TMD can be diagnosed on the basis of knowledge and skill of the dentist. Indices are used in diagnosing and grading the severity of TMD. Helkimos was the first to introduce the indices in the field of TMD [9]. Fricton and Schiffman developed and validated the craniomandibular index (CMI). CMI is a reliable index that can be used to score the treatment outcome in TMD [10].

Early detection of TMD in asymptomatic population can prevent the worsening of the condition. This study protocol will help to undertake the study to evaluate the efficacy of restoring lost vertical dimension and centric relation on the TMD through complete dentures.

2. METHODS

2.1 Study Design (Fig. 1)

The study design of the present study is a prospective interventional type and the duration for which it will be carried out is three years. Sample size is 110, completely edentulous subjects reporting to the Department of Prosthodontics, for complete dentures prosthesis.

Sample size Calculation

$$n = \frac{2\alpha/2^2 \cdot P \cdot (1-P)}{d^2}$$

Where,

$2\alpha_{/2}$ = level of significance at 5% i.e 95% confidence interval=1.96

P = prevalence of signs and symptoms =15% =0.15

D = error of margin =7% =0.07

$$n = \frac{1.96^2 \times 0.15 \times (1-0.15)}{0.07^2}$$

= 99.96

= 100

Assuming 10% non response rate, Sample size will be

  100 + 10

    = 110

110 patients needed in the study

Anamnestic component of the Helkimos Index will be used to screen the samples. Total of 110 samples will be grouped into Group A and B. Group A will comprise of 55 sample size having mild to moderate symptoms of TMD, and Group B will have 55 sample size having severe symptoms of TMD.
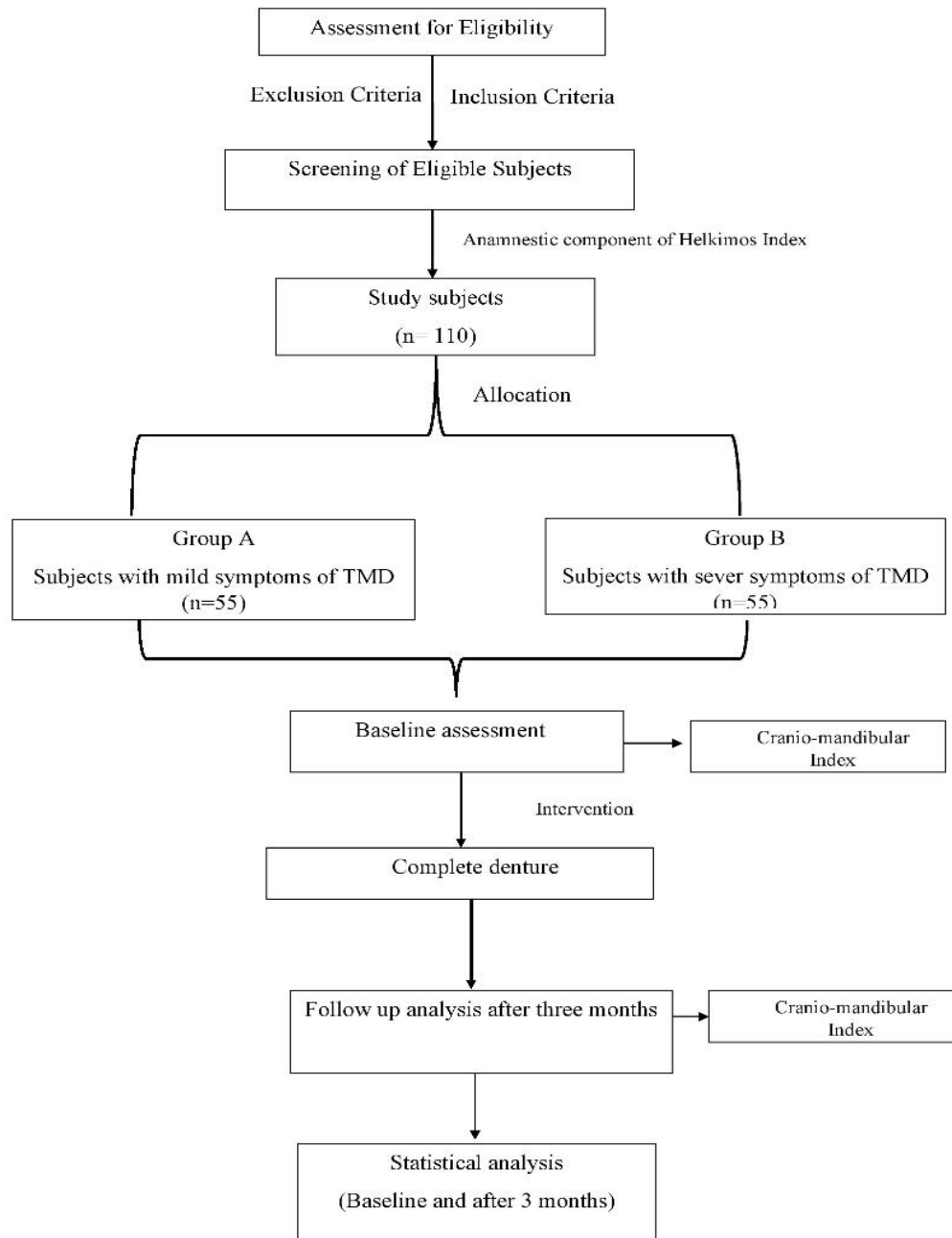

Fig. 1. Flowchart of the study

2.2 Inclusion Criteria

1. Non gender specific Healthy subjects.

2. Subjects between 40-70 years of age.

3. Subjects who are completely edentulous for a period of a minimum of 6 months to a maximum of 5 years.

4. Subjects having mild to severe symptoms related toTMD as per the Helkimos Index (Anamnestic component).

2.3 Exclusion Criteria

1. Uncooperative Subjects.

2. Denture wearer subjects.

3. Subjects with an history of TMD (Diagnosed and Treated Cases for TMD).

4. Subjects having no symptoms related to TMD as per scale the Helkimos Index (Anamnestic component).

2.4 Intervention

2.4.1 Complete denture

Complete dentures will be fabricated for selected subjects for both the groups. All the clinical and laboratory steps will be meticulously followed with standard instruments and materials by a single operator for all the subjects under the observation of two subject experts. All the dentures will be fabricated in Heat cure acrylic resin (DPI).

2.5 Investigations

2.5.1 Helkimos index -anamnestic component (Table -1)

The preliminary screening will be done to select the study participants by identify the TMD with the help of its signs and symptoms in patients who are completely edentulous using anamnestic component of the Helkimos Index. This Anamnestic component is a questionnaire-based survey who's the answer is in the form of "Yes or No".

This anamnestic component comprises of the questionnaire that included sounds in the area of TMJ, Jaw rigidity, fatigue in the jaw area,

difficulty in opening mouth, jaw locking while opening of the mouth, TMJ pain, pain while movement of mandible, luxation of mandible, referred pain in neck and earache.

The patient's responses will be analyzed and graded as follows-.

Grade O –No symptoms of TMD.

Grade I - Mild symptoms of TMD –Fatigueness of the jaw, Stiffness of the jaw, TMJ noise.

Grade II – Sever symptoms of TMD - has one or more among these conditions – (a) difficulty during mouth opening, (b) locking of the jaw, (c) dislocation of mandible and pain during its movement and (d) pain in the TMJ region and/or masticatory muscles (e) pain in the ear (f) stiffness of the neck.

The 55 subjects with mild to moderate symptoms of TMD will be categorized into Group A and 55 samples having sever symptoms into Group B.

2.6 Cranio-Mandibular Index (CMI)

After screening, the patients with mild and severe symptoms will be subjected to CMI before Denture insertion to record the baseline measurements.

CMI will be recorded under its two components, namely the DI (Dysfunction Index) and the PI (Palpation Index).**(Tables-2 and 3)**.

Dysfunction index or (DI) will be scored as 1 for positive and 0 for negative findings for the range of motion, mandibular deviation, pain in motion, and TMJ noise.

DI = The sum of responses that are positive/ Total items in number

Palpation index (PI) will be scored as 1 for positive and 0 for negative findings for the pain or tenderness in the extra-oral and intraoral muscles of face and neck and the capsule of TMJ

PI = The sum of positive responses / Total items in number

CMI = DI+PI / 2

CMI will be again recorded after three months of denture insertion.

Table 1. Questionnaire for anamnestic component of Helkimos Index

Sr.No	Questions	Yes/No
1	Do you have a sound (clicking or crepitation) in the area of TMJ?	
2	Do you have jaw rigidity during awakening or slow movement of mandible?	
3	Do you feel fatigue in the jaw area?	
4	Do you have difficulty while opening mouth?	
5	you have locked mandible during opening the mouth?	
6	Do you have pain in the TMJ in the area of masticatory muscles?	
7	Do you have pain during movement of mandible?	
8	Do you have luxation of mandible?	

Table 2. Clinical examination form of Dysfunction index (DI)

Sr.No	Feature	Positive (1)		Negative (0)	
1	Maximum opening -- mm (40-60 mm)				
2	Passive stretch opening -- mm (42-62mm)				
3	Restriction on opening				
4	Pain on opening				
5	Jerky opening or closing				
6	"S" deviation on opening or closing (52 mm)				
7	Lateral deviation at full opening (52 mm)				
8	Protrusion – Pain				
9	Protrusion - Limitation - mm (27 mm)				
10	Right laterotrusion – Pain				
11	Right laterotrusion - Limitation - mm (27 mm)				
12	Left laterotrusion – Pain				
13	Left laterotrusion - Limitation - mm (27 mm)				
14	Clinically can lock open (subluxate)				
15	Clinically can lock or is locked closed with condylar translation (right or left)				
16	Rigidity of jaw on manipulation				
17	TMJ noise				
18	Reciprocal click	R	L	R	L
19	Reproducible opening ,click	R	L	R	L
20	Reproducible laterotrusive click only	R	L	R	L
21	Reproducible closing click	R	L	R	L
22	Nonreproducible opening click	R	L	R	L
23	Crepitus - Fine	R	L	R	L
24	Crepitus - Coars	R	L	R	L
25	Popping	R	L	R	L

Where R- Right and L-Left

2.7 Outcome Measure

The primary outcome will be the change in the score of CMI from baseline to the end of 3rd month of intervention complete dentures.

2.8 Safety Evaluation

Adverse events (AEs), including AEs related to PMMA allergy, TMJ pain or muscle pain due to any change in vertical dimension of occlusion, gag reflex and other will be recorded. For safety assessment, details of all such adverse events will be recorded by a research assistant in the case report form.

3. RESULTS

The baseline measures before intervention with complete dentures will be compared with the readings recorded after 3 months of post insertion of the denture prosthesis. The statistics that will be done are descriptive and analytical. The data will be presented in mean and standard deviations. The normality of data will be analysed (Shapiro-Wilk test). If the facts follows usual

distribution parametric tests will be employed and if it does data varies from the normal distribution, non-parametric tests (Mann-Whitney U test and Wilcoxon Signed Rank test) will be used. The statistical significance will be adjusted at p<0.05. SPSS (Statistical Package for Social Sciences, IBM Corporation, Chicago) will be adopted as statistical software.

4. DISCUSSION

Loss of the tooth has direct relation with the TMD [11]. The prevalence as well as the severity of TMD is very high among population who are completely edentulous. It has been reported that alterations in various angles due to loss of teeth affect the TMJ mechanics that in turn result in TMD [12]. The lack of complete denture prosthesis for a long period results in a shift of mandible from its centric relation to a habitual centric position due to loss of vertical dimensions [13]. Similarly, the psychological problems due to tooth loss, advancing age, emotional stress, also contribute significantly to developing TMD among the edentulous population [14].

Shetty R had undertaken a research so as to know the widespread presences of TMD among completely edentulous population [15]. He reported 59% of the study subjects showing more than two signs of TMD. Meyerowitz et al reported 32% of total study participants had muscle pain on palpation [16]. AlZarea BK in 2019 also documented a high prevalence of TMD in asymptomatic completely edentulous subjects (60.5%) [17]. Similar results were documented by Shi and Wang et al who found clinically positive signs of TMD among 43.2% of their study subjects (completely edentulous subjects) [18].

TMD is diagnosed clinically by evaluating its signs and symptoms that are facial pain, headache, pain over the joint, pain which aggravates while opening the mouth, muscle tenderness, pain which is to the angle of the lower jaw and cervical muscles, restricted mouth opening, deviation of the jaw while opening the mouth, crepitus, and clicking sounds in the joint region [19]. These signs may appear in various combinations and degrees. Shi and Wang et al observed TMJ noise to be a highly prevalent symptom on the contrary AlZarea BK found joint sounds to be the least common finding in his study [17,18]. Similar results were documented by Shetty R also who found the joint sound to be the most common symptom which was 47% [15].

Table 3. Clinical examination form of Palpation index (PI)

Sr.no	Muscles/TMJ	Structure to be Examined	Right		Left	
			Positive (1)	Negative (0)	Positive (1)	Negative (0)
1	Extraoral jaw	Anterior temporal Deep temporal Middle temporal Deep masseter Anterior masseter Inferior masseter Posterior digastric Medial pterygoid Vertex				
2	Intraoral jaw	Lateral pterygoid Medial pterygoid Temporalis insertion				
3	Neck	Superior sternocleidomastoid Middle sternocleidomastoid Inferior sternocleidomastoid Insertion trapezius Upper trapezius Splenius capitis				
4	TMJ	Lateral capsule Posterior capsule Superior capsule				

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Some studies have found a strong correlation between advancing age, wearing of the complete denture, and the symptoms of TMD [20]. The study documented by Szenpetery et al and Mercado et al is in agreement with the above statement whereas the study performed by Zissis et al and Gibson et al denys the correlation between the above parameters [21-24]. The possible reason for this might be the acceptance of the symptoms as a physiologic process with increasing age without any complaints by the elderly patients.

Some authors have found a correlation between the number of sets of complete dentures used by the individuals and the severity of TMD. Faulkner et al observed that individuals with a history of using fewer sets of complete dentures have shown severe symptoms of TMD [25].

However, Dervis E denys this and did not found any such correlation [26]. The other probable reason for this might be the more the sets of complete denture indicates the awareness of the patients towards the oral health and hence the dentures are frequently replaced before they lose the stability, retention and vertical occlusal dimensions resulting into lower chances of developing TMD due to lost vertical or incorrect centric relation. A study by Sakurai et al is in favor of the above hypothesis who reported that subjects who used the single set of the denture for 6 long years had severe symptoms of TMD [27].

Hansen et al found TMD symptoms in patients who did not use complete dentures while sleeping.   edentulous patients had TMD symptoms when they slept without their complete dentures [28]. However, it is not ascertained whether the complete denture wearer who does not use dentures during sleep does any parafunctional mandibular movements. The chances are that the use of dentures during sleep would reduce and if not may preclude the unfavorable stress to the TMJ and the masticatory muscles.

Indices are the safe and reliable tool used in diagnosing and grading the severity of the TMD. Many authors have used various documented and validated indices in their epidemiological studies related to TMD [29,21].

Treatment options for TMD vary according to individual findings and mostly include, self-care, physical treatment, splints, behavioral remedy,

relaxation approach, and drug therapy [30].Together with the well fabricated complete dentures restoring the lost vertical dimension and correct centric relation, providing support to the muscles   to improve its coordination and preventing muscle spasm is also necessary [31-34].

Presently there are insufficient randomized clinical trials to prove the reliability of treatments that are currently being executed for treating TMD in completely edentulous subjects. This study is an attempt to assess the efficacy of accurately fabricated complete dentures in reducing the severity of TMD among the population who are completely edentulous. CMI will serve to score the severity of symptoms before the complete denture insertion and after three months to determine the therapeutic effect of complete dentures in the field of TMD. Thus this study will not only help to set a protocol of early intervention of completely edentulous patients with complete dentures to put a stop to the exacerbation of issues associated with joint problems but will also keep up consonance related to orofacial musculature.

5. CONCLUSION

Presently there are insufficient randomized clinical trials to prove the reliability of treatments that are currently being executed for treating TMD in completely edentulous subjects. This study is an attempt to assess the efficacy of accurately fabricated complete dentures in reducing the severity of TMD among the population who are completely edentulous. CMI will serve to score the severity of symptoms before the complete denture insertion and after three months to determine the therapeutic effect of complete dentures in the field of TMD. Thus this study will not only help to set a protocol of early intervention of completely edentulous patients with complete dentures to put a stop to the exacerbation of issues associated with joint problems but will also keep up consonance related to orofacial musculature.

CONSENT AND ETHICAL APPROVAL

The synopsis of the study has received the approval from the IEC (Institutional Ethical committee) (DMIMSDU)/IEC/18-19/7344). Any serious adverse events will be reported within 24 h to the Institutional Ethics Committee. The subjects involved will be informed regarding the study and signed consent will be obtained from the subjects before starting the study.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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