STUDY PROTOCOL

Use of strain elastography in comparative evaluation of elasticity of masseter muscle in complete denture as against implant supported overdenture. [version 1; peer review: awaiting peer review]

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Abstract

Introduction
The masticatory muscles play an important role in natural function and functional disorders of craniomandibular system. Occlusal variables have an impact on the masticatory muscles' action and strength. The masticatory muscles cannot contract as forcefully as they do when natural teeth are present, which is caused by pathological ageing and tooth loss. Consequently, it can be demonstrated that edentulous patients have lower masticatory cycle amplitude, efficiency, and masticatory force than dentulous individuals.

Objectives
Using strain elastography, evaluate and compare the elasticity of the masseter muscle in complete edentulous individuals and have undergone rehabilitation with complete dentures against those who have undergone rehabilitation with implant-supported dentures.

Methodology
Two groups of totally edentulous patients would be chosen. The rehabilitation of one group would involve complete dentures, whereas the rehabilitation of the other group would use implant-supported dentures. At the moment of denture insertion and three months later, strain elastography will be used to scan both sides of the masseter muscle. Both groups' values would be compared.
**Expected results**
The study's anticipated result is that patients who receive rehabilitation with implant-supported overdentures have greater masseter muscle elasticity than patients who receive rehabilitation with complete dentures.

**Conclusion**
The study would give dental professionals a way to efficiently assess the masseter muscle's elasticity in patients who are completely edentulous. Also, it would compare the flexibility of the masseter muscle between a denture supported by implants and a complete denture.

**Keywords**
Strain elastography, masseter muscle, complete denture, implant supported denture

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Introduction
Background and rationale
Edentulism is defined as the complete absence of all dentition. According to the WHO criteria, due to their inability to properly chew and speak, edentulous patients are seen as physically impaired, disabled, and handicapped. Today, there are two possible options available for treatment of an edentulous patient: conventional complete denture and implant supported denture. Complete denture rehabilitation is still a popular and conventional prosthodontic therapy approach.

One of the many muscles involved in the intricate process of mastication is the masseter. Masseter is the elevator muscle which helps in closing of the mouth by elevating the mandible. Occlusal variables have an impact on the masticatory muscles' action and strength. The masticatory muscles cannot contract as forcefully as they do when natural teeth are present, which is caused by pathological ageing and tooth loss. Consequently, it can be demonstrated that edentulous patients have lower masticatory cycle amplitude, efficiency, and masticatory force than dentulous individuals.

Since the masseter is a superficial muscle, ultrasound technology that uses high frequency, linear, and real-time probes may easily access it. Linear sensors are easily adapted to the cheek surfaces while preventing image distortion, and high frequency provides a detailed portrayal of the structures being examined. Ultrasound elastography can provide information about tissue stiffness. Elasticity describes the quality and condition of a muscle. Moreover, elasticity provides knowledge about muscle contraction.

A review of the literature showed that there have been numerous prior investigations of the elasticity and thickness of the masseter muscle in both healthy dentate individuals and TMD patients. Yet, no study has looked into how totally edentulous patients' masseter muscle elasticity has changed. Hence, using strain elastography, the study compares the elasticity of the masseter muscles in patients with total edentulousness who have received rehabilitation with complete dentures to those who have had rehabilitation with implant-supported dentures.

Objectives
- To evaluate and compare the elasticity of masseter muscle in complete edentulous patients rehabilitated with complete dentures, immediately after denture insertion and after 3 months of follow-up, using strain elastography.
- To evaluate and compare the elasticity of masseter muscle in complete edentulous patients rehabilitated with implant supported dentures, immediately after denture insertion and after 3 months of follow-up, using strain elastography.
- To compare the elasticity of masseter muscle in the complete edentulous patient, rehabilitated with complete denture against the patient rehabilitated with implant supported dentures.

Study design
Observational study

Ethical considerations: Ethical approval received by Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha. (IEC ref no.- DMIHER (DU)/IEC/2023/852)

Study setting
The study would be conducted in Department of prosthodontics and crown & bridge, Sharad Pawar Dental College in collaboration with Department of Radiology, AVBRH, Sawangi, Wardha.

Study participants
Inclusion criteria
- Completely edentulous patients rehabilitated with complete denture for the first time.
- Patients with completely healed both upper and lower residual ridges.
• Complete edentulous Patients rehabilitated with implant supported denture for the first time.

• Patient willing to participate in the study.

Exclusion criteria

• Any systemic sickness or neuromuscular condition in the patient's past.

• Pulpable pain or discomfort in the masseter and temporomandibular joints on both sides.

• Remaining upper and lower ridges that have flabby tissues or bone spicules.

• Patient not willing to participate in the study.

Methods

24 completely edentulous patients would be selected for the study. Before beginning the procedure, all patients would have their questions about the study answered and would sign a consent form. Complete dentures would be constructed for 12 edentulous patients and implant supported denture would be fabricated for other 12 edentulous patients in the postgraduate clinic of Department of Prosthodontics and Crown & Bridge. These patients would be taken to Department of Radiology, AVBRH, for the sonographic scanning. The patient would be given the instruction to sit up straight, with their heads relaxed and unsupported. The transducer probe would be generously covered in water-based gel before being positioned with the best pressure 15 mm above the inferior border of the mandible and perpendicular to the anterior border of the muscle. After inserting the dentures, the initial scanning would take place while the wearer was at rest. The patient would be told to close his lips, with his jaw in a relaxed position and without making any contact with his teeth. A second scan would be conducted while your teeth are clenched the most. For which the patient would be told to clench their rear denture teeth in a centric relation for roughly five seconds on each side. A standard sonographic image is overlay with coloured images to display the strain ratio on the screen. With respect to subcutaneous fat, the masseter muscle ratio is calculated.

The patient would be sent home with the directive to wear the dentures every day for the next three months. After three months, the patient would be called back for follow-up, and another scan would be performed. The scanning would take place while the subject was at rest and maximum clenching tooth position. In the patient who has received rehabilitation with implant-supported dentures, the treatment would be repeated exactly as stated above.

Bias

Bias will be minimized by random selection of patients based on inclusion and exclusion criteria.

Sample size

Minimum Sample size required for piloting the study as no other studies found before for power analysis. We would be considering 12 samples per group for the comparative evaluation of the results between the groups.3

Statistical analysis

For the comparison of the masseter muscle elasticity for the completely edentulous patient, after rehabilitation with a complete denture and after rehabilitation with an implant-supported denture, immediately after denture insertion, and after three months follow up, paired t-test/Wilcoxon test would be employed.

When comparing the masseter muscle elasticity between patients who received complete dentures and those who received implant-supported dentures, an unpaired t-test or Mann Whitney U test will be employed.

Limitations

• Qualitative analysis

• Comparative evaluation would be performed between two groups of patients with different possible treatment and not in the same group of patient with different possible treatment.
**Dissemination**

The study would provide the dental practitioners with a method to effectively evaluate the elasticity of masseter muscle in complete edentulous patients. It would also provide comparison of elasticity of masseter muscle between the complete denture and implant supported denture.

**Discussion**

The study suggests that there would be increase in elasticity of masseter muscle in completely edentulous patient after rehabilitation. However, implant supported denture would show higher values than the conventional complete denture.

Many research has been conducted to examine the various traits of the masseter muscle as well as the alterations that take place with full tooth loss and temporomandibular disorders. For example, Parag Bhoyar *et al.* (2011) used ultrasonography to assess the impact of complete edentulism on the thickness of the masseter muscle and the alterations during rehabilitation with complete dentures. In complete denture wearers and dentulous people, masseter muscle scanning was done in both relaxed and constricted states. The study demonstrated an increase in muscle thickness following a 3-month follow-up from the time the denture was inserted, although it was still lower than that of patients who were dentulous and in the same age group.

Yoshiki Ariji *et al.* (2012) studied the link between the hardness measured by a hardness metre and the masseter muscle elasticity index (MEI) ratio acquired by sonographic elastography in healthy volunteers and found a substantial correlation between them. Also, he explained the characteristics of the masseter muscle hardness in TMD patients who also experience myofascial pain. As a result, it was determined that elastography might be utilised as an additional imaging tool to assess muscle hardness.

A study by Busato *et al.* (2015) examined the viability of using ultrasonic imaging to measure the pattern of muscle distortion in the masseter. Following the placement of a medical device that modifies the distance between the dental arches, ultrasound was performed while teeth clenched naturally and was repeated three times. The same strain patterns appeared again in many ultrasound scans of the same patient and changed as a result of the addition of a medical apparatus. This study proved that masseter strain measurement is a sensitive and reproducible instrument for the examination of the masticatory organ's functional analysis.

Meltem Mayil *et al.* (2018) evaluated the masseter muscle's ultrasonographic appearances in dentate and edentulous patients without TMDs. Bilaterally, the thickness was measured both at rest and at maximal contraction. The visibility and size of the interior echogenic bands were used to determine the masseter's appearance. The investigation made it clear that the masseter muscle's ultrasonographic characteristics varied between dentate and edentulous subjects.

A systematic review on the application of elastography to the evaluation of the masseter muscle in both healthy subjects and patients with masseter muscle diseases was published by Anna Olchowy *et al.* (2020). In his opinion, elastography is a useful tool for determining the elasticity of the masseter muscle.

Moustafa Abdou Elsyyad *et al.* (2021) studied at the masseter muscle's EMG activity in 18 patients who were completely edentulous and had atrophied mandibular ridges. He provided conventional complete dentures to these patients, who served as the control group. Next, using the “All-on-four” approach, four implants were promptly loaded and implanted between the mental foramina on the same patients after three months. Following osseointegration, the patients were randomly assigned either fixed prostheses (FPD) or milled bar overdentures (MBO). Three months after utilising CD, FPD, and MBO, the primary (amplitude) and secondary (chewing rate, time of the masticatory cycle, time of masticatory burst, and masticatory time) outcomes were assessed. MBO is not less effective than fixed prosthesis, he determined, and both considerably increased muscular activity, chewing rate, and time of chewing.

**Study status**

Study not yet started.

**Data availability**

**Underlying data**

It is not applicable as this is a study protocol.

**Extended data**

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References
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