Title of the Research Project:	

Evaluation of oral stereognosis in completely edentulous patients with maxillary tori.

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Introduction

Stereognosis has been defined as the appreciation of the form of objects by manual palpation without the use of eye-sight.[1] The term was introduced by H. Hoffmann in 1883. Whilst this definition holds good for the manual exploration of objects, it is also possible to extend the tactile perception of objects intraorally which is referred as Oral stereognosis (OS).[1] It was first introduced by Berry and Mahood in 1966. Oral Stereognostic tests are performed using test specimens intraorally to determine the extent to which patients are able to distinguish shapes and surface structures. The OS testing is an indicator of overall sensory ability of the patient as the intraoral tactile sensation is conveyed through various cranial nerves including of trigeminal nerve, hypoglossal nerve and glossopharyngeal nerve. [2]

Various studies have been designed to assess the oral stereognosis ability (OSA) by using a variety of test pieces with different shapes, materials, sizes, etc. with the objects kept away from patient's eyesight in order to evaluate the ability of patients to distinguish the shape and form of the test pieces.[1, 3, 4, 5, 6] Several studies has proved that OSA decreases with age and completely edentulous patient had lower OSA when compared to dentate patients.[3, 4, 6, 7] The level of oral stereognostic score demonstrated a definite relationship with denture performance, that is patients with poor stereognostic ability appeared more satisfied with their complete denture prosthesis than did those with better stereognostic ability.[1,] Thus, evaluating OSA in edentulous patients who require rehabilitation with complete denture prosthesis may provide useful information about the sensory abilities of edentulous patients and aid in interpreting the role of adaptation and adjustment to the complete denture prosthesis.

OSA was even evaluated in patients with palatal anomaly like cleft lip and palate where the palatal hard and soft tissues are compromised. OS levels of denture wearers with cleft lip and palate were lower than those observed in edentulous subjects without clefts. [8,9] However, there are no studies evaluating the effect of palatal tori on OSA. Torus palatinus (TP) are commonly found along the midline of the hard palate at the junction of the intermaxillary suture and the transverse palatine suture. Patients with TP may experience trauma or ulceration when masticating hard and sharp food since the soft tissue covering the bony

protuberances is reported to be thinner than the surrounding mucosa. In addition, speech difficulties due to limited tongue movement, food lodgement resulting in malodour, difficulty in recording oral impressions and seating of dentures are the common problems. The prevalence of TP in Malaysian population was found to range between 12% to 65%.[12, 13] Hence, it is clear that Malaysian population carry a significant prevalence of TP and its effect on OSA has not been studied and this has been taken into consideration while designing this study. Thus, this research is designed to achieve a better understanding of the oral stereognosis in completely edentulous patients with maxillary tori.

Aim and Objective

Aim : To evaluate the oral stereognostic ability in completely edentulous patient with maxillary tori.

Objective :

1. To compare the oral stereognostic ability of the completely edentulous patient with maxillary tori and patient without maxillary tori.

2. To compare the time duration taken for oral stereognosis of the completely edentulous patients with and without maxillary tori.

Background of the study

Mantecchini et al (1998)[10] evaluated oral stereognosis in edentulous subjects rehabilitated with complete removable dentures Stereognosis was evaluated with and without the denture in place. The results showed that the older subjects had poorer stereognostic ability than the younger ones, whereas the duration of edentulism appeared not to influence this ability. The presence of a correct prosthetic rehabilitation appeared to improve stereognostic ability. Subjects with poorer stereognostic ability appeared more satisfied with their rehabilitation than did those with better stereognostic ability.

Pedreira A et al (2004)[11] evaluated oral stereognosis in dentate and edentulous subjects with and without cleft lip and palate before and after chewing. The results demonstrated that oral stereognosis levels of dentate subjects were higher than those observed in edentulous subjects. Oral stereognosis levels of denture wearers with cleft lip and palate were lower than those observed in edentulous subjects without clefts. Chewing did not influence the oral stereognosis levels in edentulous patients.

Meenakshi S et al (2014)[1] evaluated the oral stereognostic ability after rehabilitating patients with complete dentures and concluded that covering the palatal mucosa with a denture does not reduce oral stereognostic ability. Oral stereognostic test is a reliable test to measure patients' oral stereognostic perception which would enable the patient to appreciate the functional limitations of the denture.

Bakhtiyari J et al (2014)[8] evaluated oral stereognostic ability and response time in children with cleft palate and normal children and showed that there was a significant difference between oral stereognosis and response time of children with cleft palate and that of normal

children (P < 0.05) The results can be used for developing intervention programs for children with cleft palate in the early years of their lives.

Jin-Hyuck Park (2016)[4] assessed the changes in oral stereognosis of healthy adults by age. This study investigated oral stereognosis in 184 healthy adults with normal eating and swallowing function. Results showed that oral stereognosis ability differ in age of the subjects and test pieces employed to test the OSA. The younger age group scored higher with short response time comparing to the older age group except for comparison between 20s and 30s age groups suggesting that aging negatively impacts in OSA in terms of speed in which sensory information is responded. Response time was negative correlated with test scores (r= -0.956, P < 0.001) and these proved that OSA decreases with age.

Materials and Methods

Study will be conducted at Faculty of Dentistry SEGi Oral Health Center to evaluate oral stereognosis in completely edentulous patients with maxillary tori.

Subject

Inclusion Criteria :

- Complete edentulous patient with maxillary tori and without maxillary tori
- Complete edentulous patient who give consent and is willing to participate

Exclusion Criteria:

- Patients with swallow and mastication dysfunction
- Patients with cognitive disturbances
- Uncooperative patients.
- Patients with oral lesions, pathologies and TMJ disorders.

- Patients with systemic diseases
- Patients allergic to acrylic resin

The study group will comprise of 20 completely edentulous patients with maxillary tori and 20 completely edentulous patients without maxillary tori who are willing to participate in this study. The patients who fulfill the above mentioned inclusion and exclusion criteria would be conveniently selected from among outpatients of the SEGi Oral Health Centre. Informed consent will be obtained from each patient following sufficient explanation of purpose and contents of the research.

Fabrication of test samples

The 6 test pieces were selected from the 20 shapes of test pieces from National Institute of Dental Research (figure 1). The test pieces comprises 6 shaped form which include circle, eclipse, square, rectangular, triangle and star shaped with 13mm length and 2mm thickness. 2mm stainless steel wire will be used to fabricate as the test pieces mould. After fabrication of the test piece moulds by the stainless steel wire, the mould will be stamp on 2mm thickness of light cured acrylic resin, followed by curing of the resin for 30 seconds in light cure chamber. The test samples would be trimmed and polished to meet the standardized measurements. A total of 240 test sample (6 samples for each patient) for 20 completely edentulous patients with maxillary tori and 20 completely edentulous patients without tori will be made for this study. The test pieces will attached with dental floss. The attaching dental floss would prevent any accidentally aspiration of the test pieces.
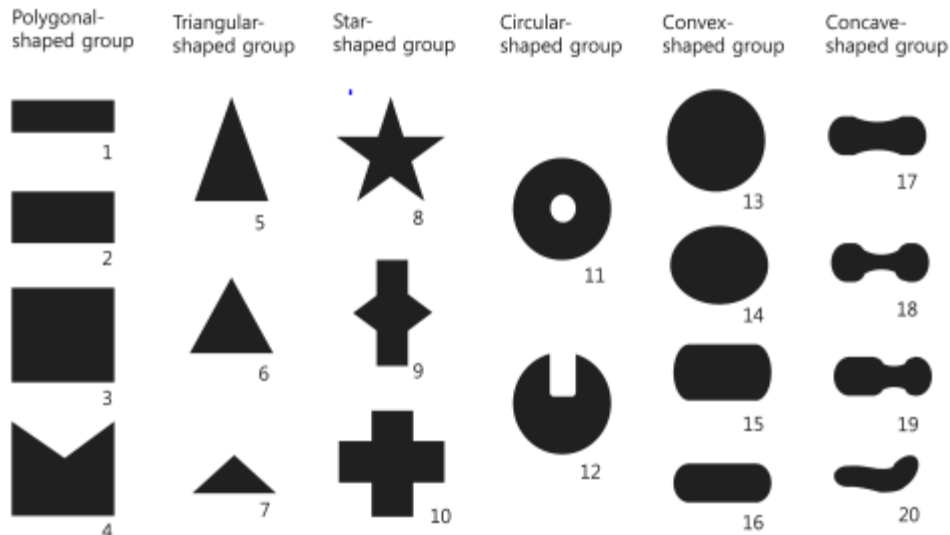
Polygonal-shaped group	Triangular-shaped group	Star-shaped group	Circular-shaped group	Convex-shaped group	Concave-shaped group

Fig. 1 The 20 shapes of the test pieces.

Fig. 2 6 test pieces shape that are chosen

Assessment of oral stereognostic test

The OSA test will be conducted in Segi Oral Health Centre under quiet condition. All patients will be seated comfortably in upright position on dental chair. All the test pieces will be kept out of sight of patient before and during the test. Test pieces will be placed intraorally and patients will be instructed to identify the shape of test pieces with their tongue and palate. A visual representation chart of all 6 shaped forms will be provided to patient for identification purpose. Patients will be asked to identify the correct shape form by pointing out on the

corresponding shape form on the chart. There will be no trial test held to avoid learning effect. The 6 test pieces will be presented randomly to the patients and correct answer will not be informed to the patients during the OSA.

The duration time for recognition of each shaped form for each patient will be noted and answers will be recorded on an OSA evaluation form. A correct answer will recorded as one point and incorrect answer is zero point. A full 6 points will be scored if all answers were correct. The response time and the OSA scores will be recorded. The response time will be the time between the placements of test piece in the oral cavity until the identification of the test.

Statistical analysis plan

The data collection will include the time duration and OSA scores for recognition of each shaped form and the answers recorded on an OSA evaluation form. All data analyses will be conducted using SPSS version 22. Descriptive statistic will be used to analyses the mean and standard deviation of the OSA test scores and the respond time for answering. Analysis of variants (ANOVA) will be applied to compare the test scores and respond time among the completely edentulous patient with maxillary tori and completely edentulous patient without maxillary tori. Spearman's rank correlation coefficient would to be used to investigate the relationship between response time and OSA test score.

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PARTICIPANT CONSENT FORM FOR ORAL STEREOGNOSTIC STUDY

Title: Evaluation of oral stereognosis in completely edentulous patients with maxillary tori.

Participant's name:

I.C / Passport No:

The details of the study have been explained to me in my own language. I confirmed that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided and can be used in future studies. However, such a use is only for scientific purpose(s). I fully consent to participate in the above study.

Signature of the participant: _____

Date: _____