
Bland-Altman Analysis of Maxillary Obturator Bulb Accuracy in Class III Brown Classification Maxillectomy Defects

[NCT ID not yet assigned]

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****Informed Consent****

Patient Name: Age: Gender:..... :

Address..... :

Telephone: Mobile :

Name of Guardian: Relationship..... :

.**Research Title:** Accuracy of Maxillary Obturator Prostheses for Maxillectomy Defects
(An In-Vitro Study)

** ·Scientific Background:** Published scientific research in specialized journals

** ·Research Objective**:

.1 Accuracy, measurement device: Metrology software (Geomagic Control X 20, 3D Systems, Rock Hill, South Carolina, United States).

.2 Patient satisfaction using the Visual Analog Scale (VAS).

.**Research Location:** Prosthodontics Clinic, Faculty of Oral and Dental Medicine, Badr University

.**Number of Participants:** 22

.Participant Selection Method**:**

o ****Inclusion Criteria**** The study included participants of both male and female genders. Patients had defects or abnormalities in both the hard and soft portions of their palate. The surgical wound or site had to be fully healed. There was partial tooth loss or missing teeth in the maxillary defect. Children were not included in the study; only adult participants were considered. Cooperative patients who could follow instructions were selected for the study.

o ****Exclusion Criteria**** Temporomandibular disorders. Uncontrolled diabetes. Bleeding disorders or anticoagulant therapy. Flabby tissues or sharp mandibular residual ridge. Heavy smokers. Patients with neuromuscular disorders. Severe psychiatric disorders. Children were not included in the study; only adult participants were considered.

.Research Steps Details:** Accuracy of Maxillary Obturator Prostheses for Maxillectomy Defects (An In-Vitro Study)**

.Number of Required Visits and Dates:** 7 to 9 visits**

.Total Time Required from the Volunteer:** Ninety days**

**** .Potential Risks/Side Effects:** Fracture of the maxillary obturator**

.Expected Benefits of the Research:** Measuring the accuracy of maxillary obturator prostheses for maxillectomy defects**

-Costs to be borne by the patient: None

-Costs to be borne by the researcher: All clinical and laboratory procedures

-Direct benefits to the volunteer participant: Maxillary obturator

-General indirect scientific benefits: Accuracy measurement

**** Available Alternatives:**** If you refuse to participate in this research, you will receive your regular treatment.....

**** Right to Withdraw:**** You have the right to withdraw from the research at any time without giving reasons and without any negative consequences.

Name of Principal Investigator: Dr. Shady El-Naggar Phone: 01122110085

Alternate Contact: Dr. Phone :

Ethics Committee Coordinator: _____ Phone: _____

****I acknowledge that I have read and understood the procedures that will be carried out through this research and have consented to them**.**

****Research Participant**:**

****Name**:**

****Signature (Fingerprint) **:**

****First Witness (if any/in case of verbal consent)**:**

****Second Witness (if any/in case of verbal consent)**:**

**** Date**:**

****Declaration of the Supervising Physician/Principal Investigator**:**

****I pledge to maintain the confidentiality of the personal information of the research subject**.**

****Signature of the Supervising Physician**:**

**** Date **:**

****Note**:**

1. ****The volunteer has the right to withdraw from the research at any time **.**

2. ****The volunteer must receive a copy of the consent form**.**

.3**The procedures of this research have been scientifically and ethically approved by the specialists at the Faculty of Dentistry, Badr University in Cairo on / / after ensuring that the research complies with the Faculty's ethical charter and that the expected benefits outweigh the potential risks**.

.4**Serial number of consent**