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

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Administrative information

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Accuracy of Maxillary Obturator Bulb in Maxillectomy Defects

2. Funding

This trial is self-funded by the authors.

3. Roles and responsibilities

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Ethical approval for the protocol.

Introduction

Treatment of tumors in the paranasal region often necessitates either palatal maxillectomy or radical maxillectomy. Surgical and prosthetic interventions offer avenues to treat post-maxillectomy patients, ensuring both functional and aesthetic outcomes. However, despite the advantages associated with surgical procedures, reconstructive surgery may not always be feasible due to the patient's overall health condition and the extent of the defect. In such cases, prosthetic reconstruction becomes imperative. (1)

Temporary or permanent obturators serve as effective solutions in prosthetic reconstruction, aiming to separate the oral and sinonasal cavities, thus preventing issues like hypernasal speech and fluid leakage into the nasal cavity. These prosthetic devices also play a pivotal role in restoring functions such as chewing, swallowing, and speech, while providing support to the lips and cheeks, thereby aiding in the restoration of facial contour. Moreover, they contribute significantly to alleviating the social and psychological distress experienced by patients. (2)

The emergence of rapid prototype production technology, also known as rapid prototyping (RP) or laser-layered manufacturing, has revolutionized the creation of three-dimensional solid models. This technique, which has seen global advancement since 1995, enables the layer-by-layer production of physical models directly from computer-aided designs in a single step. Unlike traditional computer-assisted design (CAD)-computer-aided manufacturing (CAM) systems that involve material removal, rapid prototype techniques employ technologies like lasers and numerical control to build models layer by layer, facilitating the creation of intricate internal details and smooth surfaces, even in complex structures. (3)

Various rapid prototype techniques, including stereolithography (SLA), laminated object manufacturing, selective laser sintering, fused deposition modeling, and three-dimensional printing, offer diverse options for model production. These techniques, which utilize different materials and layering methods, can be combined to achieve desired outcomes. (4)

Rapid prototype production techniques present a viable alternative to conventional methods for constructing facial prostheses. By utilizing computer-aided imaging techniques such as computed tomography (CT), magnetic resonance imaging (MRI), and laser surface scanners, highly accurate extraoral facial prostheses can be crafted using CAD–CAM and RP technologies, ensuring excellent contours and tissue adaptation. (5)

While conventional gypsum models are typically used for prosthetic rehabilitation of intraoral deformities like maxillectomy defects, the integration of 3D CAD and RP technologies can significantly enhance outcomes. A crucial aspect of creating a functional and aesthetically pleasing prosthesis lies in obtaining an accurate impression. Factors such as the properties of the

impression material, the size and nature of the defect, the presence of undercuts, and the condition of remaining teeth influence the accuracy of the impression. Challenges such as pain, tears, and deformations during impression removal, as well as bleeding and mucosal adhesion, further complicate the process. Additionally, limitations in mouth opening may hinder optimal insertion of the impression materials. [6]

Aim of the Study

Research Question

In patients with maxillary defects, which type of denture base materials fulfill accuracy parameters regarding extent of the maxillary defect?

Research Hypotheses

There is no difference between different denture base materials of maxillary obturator regarding bulb accuracy over the extent of maxillary defect.

Outcomes

1. Accuracy, measuring device: metrology software (Geomagic Control X 20, 3D Systems, Rock Hill, SC, USA).
2. Patient satisfaction using Obturator Functional Scale (OFS).

Materials and Methods

Study Settings

Randomized controlled study. Patients will be selected and diagnosed by the investigators to be enrolled in the trial from the outpatient clinic of faculty of Oral and Dental Medicine, Badr University in Cairo.

Eligibility Criteria

Inclusion Criteria

- The study included participants of both male and female genders.
- The 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.
- The upper jaw (maxilla) had partial tooth loss or missing teeth in the defect.
- Cooperative patients who could follow instructions were selected for the study.

Exclusion Criteria

- Temporomandibular disorders
- Uncontrolled diabetes
- Bleeding disorders or anticoagulant therapy
- Flabby tissues or sharp mandibular residual ridge.
- Heavy smokers.
- Patient's with neuromuscular disorders
- Severe psychiatric disorders
- Children were not included in the study; only adult participants were considered.

Justifying Exclusion Criteria

Temporomandibular disorders (TMD) that could affect the direction of force applied on the dentures were exclusion criteria, as TMD symptoms may mask or influence the expected improvement and patient satisfaction with the overdentures.

Patients with severe systemic diseases like uncontrolled diabetes, bleeding disorders, neuromuscular disorders, psychiatric conditions, or those undergoing chemotherapy or radiotherapy were excluded. Management of their conditions requires special considerations like adjusted medication doses, shorter appointment times preferably in the morning, and they have a higher risk of dropping out during the trial follow-up period.

Patients presenting with flabby tissues or sharp/undercut mandibular residual ridges were excluded as they require modified impression techniques like sectional trays and plaster materials for flabby tissues. Frequent tissue conditioning is also necessary throughout follow-up, which could confound the trial results.

Heavy smokers were excluded as smoking can compromise the physical retention of complete dentures, which relies on surface tension and a thin salivary film between the denture and tissues for capillary attraction. Smoking decreases salivary flow causing dry mouth

(xerostomia), which jeopardizes denture retention. Additionally, smoking may affect the long-term success of implant osteointegration.

Interventions

A perforated stock tray underwent modifications including reduction, bending, or addition of modeling wax to accurately capture the entire defect. Undesirable undercuts in the defect were blocked using vaselinized gauze. Preliminary impressions were taken with irreversible hydrocolloid material, extending into the surgical cavity to replicate undercuts as closely as possible. Mandibular impressions were also made with alginate. After verifying details, impressions were poured to obtain diagnostic casts. These casts were surveyed to identify survey lines, guiding planes, and undercut depths, informing path of insertion selection. Mouth preparation followed, with guiding planes prepared on abutment distal surfaces and palatal tooth surfaces modified for proper reciprocal clasp positioning. Final impressions were taken using a special tray, with modeling wax border molding at the surgical site. After setting, impressions were boxed and poured to create master casts. Refractory casts and wax patterns were crafted for obturator framework planning, ensuring retention, stability, support, and reciprocation. Metal framework try-in was conducted to confirm accuracy before proceeding with acrylic resin application. Jaw relation registration was performed using the wax wafer technique.

Groups Design:

Group I: received maxillary obturators constructed with hard acrylic applied on the posterior part of the obturator.

Group II: received maxillary obturators constructed with injection-molded PMMA resin.

Sample Size Calculation and Statistical Analysis

Based on ***Abdelfattah Mohamed A, kothayer Marwa 2020***, we are planning a study of independent cases and controls with 1 control(s) per case. Prior data indicate that the probability of exposure among controls is 0.2. If the true probability of exposure among cases is 0.6, we will need to study 22 cases in each group to be able to reject the null hypothesis that the exposure rates for case and controls are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. We will use an uncorrected chi-squared statistic to evaluate this null hypothesis. Data will be analysed using IBM SPSS advanced statistics

(Statistical Package for Social Sciences), version 21 (SPSS Inc., Chicago, IL). Numerical data will be described as mean and standard deviation or median and range. Data will be explored for normality using Kolmogrov-Smirnov test and Shapiro-Wilk test. Comparisons between 3 groups for normally distributed numeric variables will be done using the ANOVA while for non-normally distributed numeric variables will be done by Kruskal Wallis test. A P-value less than or equal to 0.05 will be considered statistically significant. All tests will be two tailed.

Categorical data will be described as numbers and percentages and comparisons will be done by chi square test or fisher exact as appropriate.

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