Influence of Skin Tone and Background Color on the Accuracy of Auricular Scanning: A Clinical Trial

Authers:

Dr/ Yasmine Said Elsherbeeny, (DDS, MSc, PhD), Department of oral and maxillofacial Prosthodontics, Faculty Of Dentistry, Ain Shams University, Cairo, Egypt.

Dr/Amany Mostafa Saad Farahat, (DDS, MSc, PhD), Department of oral and maxillofacial Prosthodontics, Faculty Of Dentistry, Ain Shams University, Cairo, Egypt.

Dr/Mohamed Talaat Elmohammady Mohammed, (DDS, MSc)

Dr/ Omnia Mohamed Sameh Omar El Sayed Refai, (DDS, MSc, PhD), Department of oral and maxillofacial Prosthodontics, Faculty Of Dentistry, Ain Shams University, Cairo, Egypt.

Corresponding author:

Yasmine Said Elsherbeeny, yasmineelsherbeeny@dent.asu.edu.eg, Department of oral and maxillofacial Prosthodontics, Faculty Of Dentistry, Ain Shams University, Cairo, Egypt.

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I- Abstract

Statement of the problem

Manufacturing the Extraoral prosthesis is troublesome for the patient, the dental practitioner and the dental technician. When a person misses his ear congenitally or due to trauma, he wishes to have an accurate replacement for his ear with minimum steps and effort. Digital technology has been providing the dental field with the most helpful equipment in such cases. Owing to the innovation of intraoral scanners with its continuous refinement, this patient now can rest assured that he will have his auricular prosthesis with less number of visits and less effort. There are different environmental factors that can affect scanning accuracy such as patients skin tone and scanning background.

Aim of the study

This study aims to evaluate the different backgrounds and skin tones effect on the trueness of auricular scanning.

Materials and methods

Participants with intact ears and different skin tones (black, white and intermediate) will be selected from the outpatient clinic, then conventional impression will be taken and stone cast will be obtained and scanned via an extraoral scanner, then intraoral scanner will be used to scan the auricle three times, first with a black background, second with white background, third without background. Trueness of the scans will be evaluated by metrological software. Data will be collected, tabulated, and statistically analyzed.

II- Introduction

Auricular deformity can be a congenital condition or happens due to trauma or surgical removal. [1,2] Restoring such a defect is a challenging process as the prosthodontist and the dental technician should work together to reproduce and replace the missing ear with a much more lifelike prosthesis with its minute details, which needs a great level of skill that usually comes with time and experience. Conventional fabrication techniques of auricular prothesis involves many time consuming and difficult steps like; taking an impression of both the intact and the defect side to facilitate sculpting the wax pattern of the ear guided by the cast of the contralateral side, creation of a mold to cast the prosthesis and manufacturing the prosthesis from biocompatible materials like silicones which can be pigmented to match the patient`s skin tone. [3,4] This technique is somehow troublesome as it involves making a stable backing from acrylic or more recently a plastic ring around the ear which allows pouring the impression which is usually more flowy than the usual impression. [5] The patient has to sit with his auricle parallel to the floor without any movement to enable the practitioner to take the impression with the least possible distortion which can be 1-3 mm approximately. [6]

This has led to the development of different innovative methods for creating the extraoral prosthesis and managing to make this prosthesis unnoticeable to the sight. Implementing the digital technology into the dental field has provided the dental team with more feasible methods to fabricate an accurate replica of the deformed ear through data digitization, computer-aided design (CAD), and computer-aided manufacturing (CAM). Data acquisition is the first step in the digital workflow and of great importance. [7] It can be done via different methods such as computed tomography (CT) scan, three-dimensional (3D) photogrammetry, magnetic resonance imaging (MRI), laser scanners and intraoral scanners. [8,9]

One of the drawback of computed tomography (CT) scan is the hazardous x-ray exposures, furthermore, magnetic resonance imaging (MRI) provides less resolution , laser scanners expose the patient to laser which can be harmful to the eyes and it takes several minutes which is quite disturbing for the patient who is required to stay still meanwhile, they cannot record all the surface details asapores , undercuts or wrinkles, which is also true for extraoral scanners. [10,11]

Intraoral scanners offer a better outcome for the entire experience as they eliminate the use of impression materials and reduce the time taken to take one. They also allow easy data transfer

between the dental office and the dental lab which can be saved for future reference. [12-14] There are different types of intraoral scanners that can be handheld, which give the practitioner the opportunity to scan from different angles allowing him to capture the minute undercuts. [15,16] The differences between each type of intraoral scanner depends on its technology, which can be based on active wavefront sampling, confocal technology, triangulation theory or a combination of two or more of them to improve accuracy. [12,17] In Active wavefront sampling technology, optical rays are projected which create three-dimensional simulations. [18] While in IOSs using the triangulation theory, a light is projected onto the surface in a pattern which is then captured by a camera or sensor positioned at an angle. In confocal technology a laser beam is reflected via a pinhole aperture which is captured with sensors without requiring specific angles between light sources and sensors like triangulation technology. [18,19]

The field of intraoral scanning is in continuous shift for developing better outcomes such as decreasing scanning time, eliminating the usage of scanning powder and enhancing the image color which eventually results in better user experience, patient comfort and better data acquisition. [20] This also leads to different outcomes regarding the accuracy of the acquired data. Accuracy is recognized by two elements: trueness and precision. Trueness means how close a scanned subject is to its original design and precision is the ability of a scan to be consistently repeated. [21]

Accuracy of scanning is also affected by multiple environmental factors such as the lighting condition, [22,23] the background and the skin tone of the patient. [24] Considering the nature of how light works, it transfers its energy to the material it reaches, [25] then light is absorbed and reflected based on the type of the material. Dark backgrounds absorb more light than lighter backgrounds which are expected to reflect more light instead. [26] Light absorption leads to fewer shadows and less edge and corners recognition, which affects the result accuracy accordingly. [27-30]

Evaluation of accuracy of the auricular scanning done under different environmental factors compared to the conventional techniques is not well documented in the literature. So, this study aims to evaluate trueness of auricular scanning scanned with different types of backgrounds and skin tones The null hypothesis is that there will be no difference in trueness between different backgrounds with different skin tones.

III- Research Question:

Do different backgrounds and skin tones affect the trueness of auricular scanning scans?

Problem	Lack of precise data on the trueness of auricular scans done under different backgrounds and skin tones.
Intervention	Auricular scanning by intraoral scanner with different backgrounds and skin tones.
Comparator	Scan of a cast obtained via conventional auricular impression by extraoral scanner.
Outcome	Evaluation of the effect of different backgrounds and skin tones on trueness of auricular scans via intraoral scanner.
Time	No follow-up period
Setting	(Faculty of Dentistry, Ain Shams University)

IV- Aim of the Study, Research Objectives, and Clinical Relevance

Aim:

This study aims to evaluate the trueness of auricular scanning scanned with different types of backgrounds and skin tones

Outcome:

Evaluation of the effect of different backgrounds and skin tones on trueness of auricular scans via intraoral scanner.

Clinical Relevance:

This study helps the dental practitioner to choose and adjust backgrounds according to different skin tones in the process of making auricular scans in order to achieve best accurate scans.

V- Hypothesis

The null hypothesis is that there will be no difference in trueness between different backgrounds with different skin tones.

VI- Ethical consideration

This study will be performed on healthy individuals without auricular deformity who come to the outpatient clinic to receive any dental treatment. The participant will have his dental treatment done for free. A conventional auricular impression will be made. Then a cast will be poured and scanned via extraoral scanner. Then each participant will have his auricle scanned via an intraoral scanner with a white background, a black background around his ear and with his own skin as a background.

• **Risks and Discomfort to Patients:** There are no serious risks regards this study, however, mucosal irritation, slight pain, and discomfort are commonly related to conventional procedures during impression making.

• **Minimization of Risk:** mouth rinses and oral gel medications will be prescribed in case of mucosal irritation.

• **Criteria for Discontinuation of Study or Enrollment or Modification of Intervention:** In case of patient sickness, incompliance, or refusal to continue in treatment.

• **Privacy:** Privacy for participants is protected by several procedures, such as informed consent and transparency in how patient data is accumulated and analyzed. Data will be kept in a specific folder on a computer with passwords known only by the main operator.

• **Confidentiality:** Confidential data of the patients will be privately kept with the main operator.

• **Data Management:** Data will be saved in a specific folder with passwords known only by the main operator on his personal computer.

• **Consent Procedures if Applicable**: Before the provision of the procedures, each participant will read and sign a consent form supplied by the ethical committee of the Faculty of Dentistry, Ain Shams University, written in the Arabic language. The consent describes the steps of each procedure, their rights, and their role in the study. The consent will be kept with the main operator.

• **Adverse Event Reporting**: Any adverse reaction will be reported and written in the patients' data folder.

VII- Study design

This is a comparative experimental study.

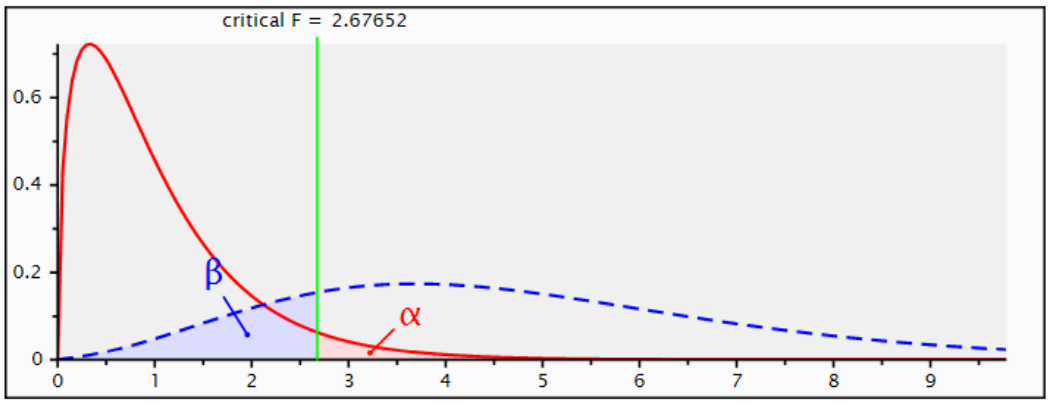
VIII- Materials and methods

Study settings:

The study will be conducted in the Department of Oral and Maxillofacial Prosthodontics at the Faculty of Dentistry, Ain Shams University.

Sample size:

Sample size calculation was performed using G*Power version 3.1.9.7 based on the results of a previous study. [30] A power analysis was designed to have adequate power to apply a two-sided statistical test to reject the null hypothesis that there is no difference between groups. By adopting an alpha level of (0.05) and a beta of (0.2), i.e. power = 80% and an effect size (d) of (0.289) calculated based on the results of a previous study. The predicted sample size (n) was (135), i.e., 45 samples for each of the three groups; and each group are divided into three subgroups.



Study procedures:

1- <u>Sample grouping:</u>

This study will comprise three main groups based on participants skin tone type determined by the Fitzpatrick Scale.

1. Group 1: Participant Type I
2. Group 2: Participant Type III
3. Participant Type VI

Then each participant group will be stratified into four subgroups:

- Subgroup 1.1: Auricular scan done via an extraoral scanner by making an auricular cast obtained by conventional auricular impression.

- Subgroup 1.2: Auricular scan done via an intraoral scanner with a black background will be put around the ear.
- Subgroup 1.3: Auricular scan done via an intraoral scanner with a white background will be put around the ear.
- Subgroup 1.4: Auricular scan done via an intraoral scanner with no background will be put during the scan; participant skin is the background.

2- Participant selection:

Participants will be selected from the outpatient clinic of the Oral and Maxillofacial Prosthodontics Department, Faculty of Dentistry, Ain Shams University to acquire the models needed to accomplish this study.

• Inclusion criteria

1- Healthy individuals without auricular deformity who come to the outpatient clinic to receive any dental treatment. The participant will have his dental prosthesis done for free.

2-Three types of skin tones will be selected; type I, type III and type VI according to The Fitzpatrick Scale.

3-Participants not exposed to sun burns or tans.

The Fitzpatrick Scale classifies skin into six types, ranging from very fair (Type I) to deeply pigmented (Type VI). It considers two primary factors:

- Baseline skin color (without sun exposure).
- Response to sun exposure, including the tendency to burn or tan.

Skin Type	Description	Sunburn/Tan Response
Type I	Very fair, pale	Always burns, never tans
Type II	Fair	Usually burns, tans minimally
Type III	Medium	Sometimes burns, tans uniformly

Skin Type	Description	Sunburn/Tan Response
Type IV	Olive	Rarely burns, tans easily
Type V	Brown	Very rarely burns, tans darkly
Type VI	Dark brown/Black	Never burns, deeply pigmented

• Exclusion criteria

− Uncooperative participants.

_ Participants without intact ears.

• Participant evaluation

*** History**

Medical and dental history will be taken from all patients.

*** Examination**

Comprehensive extraoral examinations will be carried out to verify participants fulfilling the selection criteria.

3- Study procedures:

After participants selection according to the aforementioned scale, they will be assigned to three groups, every participant will receive four types of intervention, the first type comprises of conventional auricular impression with a flowy impression material while being in a supine position with right ear facing upward. In order to preserve the external auditory canal intact, a piece of cotton roll will be placed in it. A ready-made open-sided cylinder from the top and the bottom will be used as an impression tray with an appropriate distance between the tray and the ear, allowing for sufficient thickness of the impression material. A flowy consistency impression mix will be applied to the ear's internal surface and border. A second mix of impression with normal consistency will be loaded and placed passively over the first mix, filling nearly three-quarters of the tray. Dental plaster will be loaded after a complete set of the

impression mate- rial to fill the upper portion of the tray. After the complete set of the plaster, the tray will be retrieved in a twisting movement in an outward, downward direction. Then the impression will be poured into stone, and the resultant cast will be scanned via an extraoral scanner.

The participant will be given time for rest, then an intraoral scanner will be used to scan his ear with two different backgrounds made around his auricle from two different colours; black and white. Then the background will be removed, and scanning will be done this time with participant own skin as the background.

The resultant standard tessellation files (STL) of every scan done via the intraoral scanner will be compared to the STL of the scan done via the extraoral scanner of the same participant by a metrological software to evaluate trueness.

IX- Data Management

The data will first be recorded manually and then transferred into digital form. The obtained data will be stored in the Oral and Maxillofacial Prosthodontics Department, Ain Shams University library.

X- Statistical Analysis

The collected data will be tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 23.0. Normality will be explored using the Kolmogorov-Smirnov and Shapiro-Wilk Test. Descriptive statistics will be done for numerical parametric data as mean±SD (standard deviation) and minimum & maximum of the range and for numerical non parametric data as median and 1st& 3rd inter-quartile range, while it will be done for categorical data as number and percentage. Inferential analyses will be done for quantitative variables using A one-way analysis of variance (ANOVA) when comparing between more than two means. Post Hoc test: Least Significant Difference (LSD) was used for multiple comparisons between different variables with parametric data and Kruskall Wallis test: for multiple-group comparisons in non-parametric data & Mann Whitney U in cases of two independent groups with non-parametric data. and Two-way ANOVA was used to study the effect of different tested variables and their interaction. Comparison of main and simple effects were done utilizing pairwise t-tests with Bonferroni correction. Inferential analyses will be done for qualitative data using Chi

square test for independent groups. The level of significance will be taken at P value <0.050 is significant, otherwise is non-significant. The p-value is a statistical measure for the probability that the results that will be observed in a study could have occurred by chance.

XI- Funding

This study will be self-funded

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