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Research Protocol

Dentistry Section

Development, Evaluation, and Comparison of an Indigenous 'APDS' AI-based Digital Application for Effective Shade Selection of Silicone Maxillofacial Prosthesis: Protocol for a Cross-sectional Study

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ABSTRACT

Introduction: Reconstruction of maxillofacial defects is challenging in achieving aesthetic results. Replicating natural skin colour in maxillofacial prosthesis has been traditionally done using trial-and-error methods. However, with their respective limitations, multiple methods have been developed recently, like colourimeter and spectrophotometer.

Need of the study: The natural appearance of the prosthesis significantly impacts the emotional and psychological well-being of patients. Thus, aesthetics have become a primary concern. Consequently, the challenge of accurately matching the colour of maxillofacial prostheses is evident. To address this, there is a need to develop customised shade guides and advanced digitised shade-matching applications with the assistance of Artificial Intelligence (AI). Therefore, a concoction of a customised silicon shade guide is contemplated with Advanced Programme in Data Sciences (APDS) AI-based digital application, and its reproducibility in clinical practice will be analysed.

Aim: Phase 1- To develop and validate a customised broad spectrum silicon shade guide and APDS AI-based digital application for the Indian population.

Phase 2- Comparative evaluation of the efficacy of indigenous APDS AI-based digital application with available shade guide systems for shade selection for silicone maxillofacial prostheses.

Materials and Methods: This cross-sectional study involves fabricating the shade guide using medical-grade room temperature vulcanising silicone, based on an observational survey. The shade guide will consist of three main groups (ABC), divided into different subgroups representing lighter to darker skin shades. The accuracy of the shade guide will be evaluated using aspectrophotometer. The APDS AI-based digital application will be developed using the reference from the customised broad-spectrum maxillofacial shade guide. The efficacy of the application will be evaluated through visual assessment of colour matching by fabricating facial veneers for participants. Investigators will assess the consent of perfect colour match. The data will be statistically analysed.

Keywords: Advanced programme in data sciences, Artificial intelligence, Shade matching, Silicone shade guide

INTRODUCTION

During maxillofacial reconstruction, artificial replacements for intraoral and extraoral structures such as the nose, maxilla, mandible, esophagus, cranial bones, and palate are fixed. Maxillofacial prostheses, made with acrylic resin and silicone, are personalised to the patient's facial structure. These prostheses address visible flaws that are linked to the face, as even slight changes in facial appearance can harm a patient's mental health. Aesthetic maxillofacial prosthesis can improve patients' quality of life, especially for those with issues resulting from cancer, trauma, or congenital disease [1,2]. Prosthodontists face a significant challenge in colour matching human skin during prosthesis fabrication. As demand and awareness of maxillofacial prostheses increase, achieving a natural appearance with precise shade identification becomes crucial. Silicone elastomers have shown superior qualities as maxillofacial prosthetic materials, surpassing acrylic resins in recommendations.

Traditionally, a trial-and-error method has been used to replicate natural skin colour in maxillofacial prosthesis [1]. This chairside procedure involves gradually adding colours to silicone elastomers. However, the precision of the final colour match is influenced by factors such as translucency, metamerism, and the subjective nature of human colour perception [2]. Various methods and procedures have been applied to match skin colour, although colourimeters or handheld spectrophotometers are not commonly used in India for this purpose. Colourimeters offer consistent and repeatable colour readings. Currently, skin colour measurements for maxillofacial prosthesis patients are obtained using colourimetric technologies, such as e-skin (Spectro Match, Bath, Techno Vent, UK). These measurements are then compared to a digital library, and known formulas are used to assemble maxillofacial prostheses [3]. However, these systems rely on specialised and scarce colourimeter instruments that are expensive. In today's world, smartphones with built-in digital cameras are ubiquitous, and their technical capabilities have rapidly advanced. This allows almost everyone to own a portable, network-connected vision sensor. Various colourimeter software programs are now available for mobile phones. These programs translate the natural colour data of each pixel into colour coordinates, such as CIE L*a*b* values. However, more evidence is needed in the realm of maxillofacial prostheses [3]. Compared to present skin colour evaluation methods, such an application could provide an affordable, widely available tool for developing silicone hues for face prostheses [4,5].

Nowadays, colourimeters and spectrophotometers are commonly used but they are reliable yet less accessible, expensive, and lack certain details [6]. The software converts raw colour information of each pixel into colour coordinates, such as CIE L*a*b* values. However, more research is needed in the field of maxillofacial prostheses. In contrast to current methods, the primary goal of this study is to create a more sophisticated application that can offer an economical, precise, and generally accessible tool for creating silicone colours for facial prostheses [7]. Hence, the study's primary goal is to figure out the skin shade for the maxillofacial prostheses by developing a broad spectrum of silicone shade guides and 'APDS' AI-based digital applications for shade identification that will be more conventional and easily accessible for the Indian population. The present study will be divided into two phases and aims to address two research questions: whether a customised, comprehensive spectrum silicone shade guide is more effective in shade selection compared to conventional methods, and whether an indigenously developed 'APDS' AI-based digital application is more effective in shade selection. The aim of phase 1 will be, to develop and validate a customised, comprehensive spectrum silicon shade guide and APDS AI-based digital application for the Indian population.

The aim of phase 2 will be, to compare the efficacy of the indigenous 'APDS' AI-based digital application with available shade guide systems for shade selection in silicone maxillofacial prostheses.

MATERIALS AND METHODS

The present study will be a cross-sectional study. The subjects will be selected from the general population across various regions in India, and the fabrication will be done in the Department of Prosthodontics and Crown and Bridge, Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India. The Institutional Ethics Committee (DMIMS (DU)/IEC/2022/1048) has granted ethical committee permission as a part of the PhD in prosthodontics and crown and bridge and implantology scholar proposal.

Sample size calculation: An expert biostatistician calculated the estimated sample size to evaluate and compare the efficacy of the APDS application for colour matching by facial veneers (n=86) (aim 2, phase 2) and an observational study for the commonest skin shade identification in India's general population-random sample size (n-200) (aim 1, phase 1). The sample size was calculated based on percentage agreement values for groups provided in [Table/Fig-1] of the reference article [8]. Study parameters: Incidence (group 1)-87%, incidence (group 2)- 49.3%, alpha-0.05, beta-0.2, power-0.8. Final estimated sample size-86 (group 1=43, group 2=43) [9].

$$N_1 = \left\{ z_{1-\alpha/2} * \sqrt{\bar{p} * \bar{q} * (1 + \frac{1}{k})} + z_{1-\beta} * \sqrt{p_1 * q_1 + (\frac{p_2 * q_2}{k})} \right\}^2 / \Delta^2$$

$$q_1 = 1 - p_1$$

$$q_2 = 1 - p_2$$

$$\bar{p} = \frac{p_1 + kp_2}{1 + K}$$

$$\bar{q} = 1 - \bar{p}$$

$$N_1 = \left\{ 1.96 * \sqrt{0.637 * 0.363 * (1 + \frac{1}{1})} + 0.84 * \sqrt{0.78 * 0.22 + (\frac{0.493 * 0.507}{1})} \right\}^2 / 0.287^2$$

$$N_1 = 43$$

$$N_2 = K * N_1 = 43$$

p_1, p_2 = proportion (incidence) of groups #1 and #2
$\Delta = |p_2 - p_1|$ = absolute difference between two proportions
n_1 = sample size for group #1
n_2 = sample size for group #2
α = probability of type I error (usually 0.05)
β = probability of type II error (usually 0.2)
z = critical Z value for a given α or β
K = ratio of sample size for group #2 to group #1

[Table/Fig-1]: Sample size calculation.

Phase 1

Objective 1: Evaluation of most common skin shades using available skin shade analysis systems (observational survey): An observational study will be conducted to identify the most common skin shades in the general population of India (n=200). A shade guide will be fabricated, ranging from the lightest to the darkest skin tones. Simple random sampling will be employed. The face will be divided into three regions for color identification-forehead to glabella, glabella to nasion, and nasion to chin. Skin tone will be recorded in hue (colour type), chroma (amount of black, red, yellow, white, and blue), and value (amount of darkness and lightness) using a commercially available colorimeter. Participation will be voluntary, and written informed consent will be obtained from those who agree to participate. Readings will be taken and sent for data analysis. Subjects aged between 20 to 40 years, without any skin diseases, postsurgical scars, facial abnormalities, skin bleaching, or burn injuries, will be included in the present study after obtaining informed consent. Both male and female subjects will be included in equal ratios. Subjects with skin disorders such as- hypopigmentation or hyperpigmentation, skin tanning, post-radiation therapy, and those with makeup or cosmetics product application modifying the skin colour will be excluded.

Objective 2: Fabrication of custom-made silicon shade guide (4 mm thickness) using silicone material and pigments based on the survey findings: The most prevalent skin tones identified in the population through the survey study will be used. A bespoke shade guide will be created using room temperature vulcanising. Medical-grade silicone (UK) A-2000 addition to factor II (platinum) with excellent elongation properties, Shore A 20 cure hardness, and a silicone elastomer 1:1 cure system will be used, along with intrinsic pigments. Square specimens of silicone with a clear acrylic base, with a thickness of 4 mm, will be fabricated using a metal mold. Maxillofacial silicone specimens will be prepared using clear acrylic as the base and room temperature vulcanising medical-grade silicone with intrinsic pigments. The formulation formula for each shade guide, including the quantity of silicone material and each pigment incorporated, will be recorded.

Objective 3: Develop APDS AI-based digital application using a reference from a broad-spectrum customised maxillofacial shade guide: The customised shade guide with its formulation formula and recorded coordinates will be included in the APDS AI-based digital application. The application will be developed using the Android Studio by the application developer. The mainframe application will analyse images, perform object detection and tracking using Machine Learning (ML) techniques, which is a subset of AI. The distribution details of the broad-spectrum shade guide are provided in [Table/Fig-2]. Additionally, a histogram image store and process mechanism will be implemented for further analysis. The ML model will identify the targeted object and segment it into three different segments. Each segment will be analysed for colour shade using the ML object detection API. This analysis will involve capturing a raw image from a mobile camera with minimum pre-set parameters. Image processing applications typically demand more power than other applications since, they process the pixel-by-pixel image with heavy mathematical computation. In addition, image processing uses more memory and is time consuming. Therefore, the authors will optimise the shade identification algorithm to address these concerns. The image processing will be implemented using Android/Linux platforms, Java, XML language, and ML SDK library.

A (Light)	B (Medium)	C (Dark)
A1	B1	C1
A2	B2	C2
A3	B3	C3
A4	B4	C4
A5	B5	C5

[Table/Fig-2]: Details of broad-spectrum shade guide distribution.

Phase 2

Objective 1: Evaluate and validate the accuracy of the customised silicon shade guide through a spectrophotometer: All shade tabs from a lighter shade to a dark shade will be analysed under a spectrophotometer in hue (amount of colour type), croma (amount of black, red, yellow, white, and blue), and value (amount of darkness and lightness) coordinated will be recorded, and the obtained result will be verified for accurate shade duplication with the coordinates available from the survey.

Objective 2: Evaluation and comparison of the efficacy of the "APDS" AI Based digital app for colour matching by fabricating veneers for participants: Facial silicone facings will be created for participants with light, medium, and dark complexions to test the accuracy of app shade guides based on shade given by the digital application. Three observers (a maxillofacial prosthodontist, a prosthodontist, and a postgraduate student) will visually evaluate the APDS app and assess the colour match. The evaluators will be examined for any colour vision deficiency. Scoring for each will be done on the score sheet. At first sight, each evaluator shown colour match will be identified immediately. Extended time will not permit avoiding misleading due to fatigue. The scoring sheet systems will be clarified as follows: Inconsistent and unsatisfactory, almost similar and agreeable, colour match and satisfaction and colour match perfection.

Anticipated translatory component of research: "APDS" AI-based digital applications may produce better shade identification than the available shade guide system. It will be the first AI-based digital shade guide application to facilitate prosthodontists or technicians to achieve prosthesis smoothly. Users can determine a patient's skin shade with a touch of a button by taking a photo of the chosen area and matching it with an inbuild shade system. The user will then know the essential shade directly, avoiding the need of a conventional shade guide or digital spectrophotometer because of their difficult accessibility and cost. In addition, it will reduce the need for extrinsic pigmentation.

STATISTICAL ANALYSIS

The data analysis will be done using Statistical Package for Social Sciences (SPSS) version 20.1. (IBM Corporation, Chicago, USA). Descriptive and analytical statistics will be provided. The Shapiro-Wilk test will be used to assess the normality of the data. The Chi-square test for independence will be used to determine whether two variables in a contingency table are connected. It examines if categorical variable distributions differ from one another in a more general way. Cohen's kappa coefficient will be used to test inter-rater reliability for qualitative (categorical) items (and intrarater reliability). The kappa value will be calculated according to Landis and Koch's interpretation, with values ranging from 0 to 0.20 indicating no agreement, 0.21-0.40 indicating fair, 0.41-0.60 indicating moderate, 0.61-0.80 indicating considerable, and 0.81-1 indicating nearly perfect agreement. A p-value $\leq$0.05 was considered as statistically significant.

DISCUSSION (REVIEW OF LITERATURE)

It has been established that prosthetic rehabilitation has helped patients with congenital or acquired maxillofacial abnormalities. Since, 1600 AD, the patients' physical and emotional health has been traumatised by the functional and aesthetic deficits that result from major surgery. A multidisciplinary strategy can be useful for positive reconstruction. The patient is unsatisfied with a simple physical restoration with a carefully positioned prosthesis. It has become necessary to provide an aesthetically pleasing natural, lifelike prosthesis. Guttal SS et al., developed the shade guide for the Indian population [7]. However, due to the limitations of his study in terms of sample size and a smaller number of colours, AI needs to be used to increase the arena of mapping of colour based on colour image pixel, hue, and saturation. Therefore, there is a need to generate a new method that includes high-resolution quality and a more accessible, handy, standardised modality [7]. In 2013, Wee A et al., examined 119 people and the effect of race, age, gender, and anatomic areas on skin colour values in a convenience sample stratified by age, sex, and race [10]. Analyses revealed five distinct skin colour clusters. They concluded that, the study revealed variances in the blue and yellow axis across gender and age groups and a substantial variance in luminance among gender groups. CE of the five skin shade tabs in the facial shade guide is slightly over human vision's colour tolerance. On the other hand, this proposed face shade guide may improve the efficiency of attaining an excellent match to human skin for silicone facial prostheses [10].

In 2016, Anitha KV et al., aimed to create 15 circular custom made shade tabs with medical grade, room temperature vulcanising silicone. Based on the yellow, red, and blue hues, the shade guide was divided into three primary groups: I, II, and III. Five well-defined intrinsic pigments were blended precisely to divide each group of distinct values from lighter to darker colours. Four investigators visually examined colour matching to investigate the consent of perfect colour correlation to authenticate the use of the guide. Accordingly, the red and yellow based tone shade tabs harmonised well and had statistically good colour matching. As a result, an inherent silicone shade guide can fabricate maxillofacial prostheses in the Indian population. A transparent colour solution with a specific proportioning of intrinsic pigments is offered to achieve an aesthetic match to skin tone [8]. The study by Ranabhatt R et al., colour matching in maxillofacial prosthesis has been studied in the literature [6]. 7 of the 15 articles dealt with colouring techniques such as tinting, spraying, milling, and commercial cosmetics. Only one study looked into the role of colour in maxillofacial prostheses. Only one investigation resulted in a silicone shade guide that matched the colour of Indian skin. There needs to be more information describing the optimum way to match the colour for maxillofacial prosthesis construction flawlessly. Colour matching abilities have increased in recent technologies such as spectrophotometers and colourimeters. They concluded that, colour matching is an important phase in manufacturing maxillofacial prosthetics. There are numerous approaches for matching colour to facial skin in maxillofacial prostheses. The practice of colouring has been more exact and time effective since, the introduction of better approaches. According to this comprehensive investigation, the trial-and-error method is the most typical methodology tested in clinical practice for the colour matching facial prosthesis. Although, data on the colour matching facial prosthesis is available, there is no proof that one procedure is superior to the other [6].

After 2019 the digitalisation of shade matching in maxillofacial prostheses started, and new devices like a colourimeter and spectrophotometer got introduced. Mulcare DC et al., studied the applicability of a mobile phone colourimeter in matching natural skin tones with maxillofacial prostheses [4]. 10 pigmented maxillofacial silicone elastomer samples were made to simulate a variety of human skin complexions. A test instrument (e.g., Red, Blue and Green (RGB) colourimeter) and a reference device (e-skin spectropolarimeter, a commercially available skin colour measurement device) were used to report colour measurements of these swatches (spectro match, bath, UK). The recorded findings for each parameter were checked against a white and black background at 25 mm, 30 mm, and 35 mm distance of test equipment from the mark. The colourimeter application's accuracy concerning the colourimeter hardware is diverse based on distance from the mark and backdrop colour. A mobile phone colourimeter software was demonstrated to be a beneficial tool for actualising the data-driven colour matching of a silicone maxillofacial prosthesis. To improve the accuracy and control of variables such as background noise, illumination coherence, and predicting distance, more picture calibration research is needed [4].

In the study by Kurt M et al., a computerised colour matching method was used to test the acceptability of light and dark skin silicone reproductions on 15 light skinned individuals and 15 dark skinned participants [11]. The skin colour of these 30 volunteers (all in their 20's and 30s) was measured using a spectrophotometer and a spectropolarimeter incorporated into a computerised colour matching system. Following the creators' instructions, silicone skin imitations were created for every participant using the colour compositions offered by the system's online calculator. CIE L*a*b*

(E ab) and CIEDE2000 (E00) colour difference formulas were used to calculate the colour difference between original skin colour measurements and skin replica colour measurements for all patients. To evaluate the instrumental and visual judgments of colour match, three observers (two maxilla-facial prosthodontists and one postgraduate student) visually assessed and graded each silicone replica on a 5-point scale. Statistical calculations from the first skin colour measurements and their silicone replica colour readings show no differences between the dark and light skin complexion groups. The dark and light skin groups, on the other hand, were distinguished [11].

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