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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 for the study: The natural appearance of the prosthesis affects the patient's emotional and psychological well-being. Therefore, aesthetics is a prime concern now. So, the problem with colour matching of the maxillofacial prosthesis is profound. So, there is a need to develop customised shade guides and more advanced digitised shade-matching applications with Artificial Intelligence (AI) help. Therefore, a concoction of a customised silicon shade guide was 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 on a survey of 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 prosthesis.

Methodology: A cross-sectional study. The shade guide will be fabricated with 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 from lighter to darker skin shades, and its accuracy evaluation is done by spectrophotometer. APDS AI-based digital application will be developed using reference from broad-spectrum customised maxillofacial shade guide, and efficacy will be evaluated with visual assessment of colour matching by fabricating facial veneers for participants through investigators to investigate the consent of perfect colour match. 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 prosthesis is made with acrylic resin and silicone and is personalised to the patient's facial structure. Such flaws are found in an area of the body that is visible and linked to one's face. Slight changes in facial appearance harm a patient's mental health. The aesthetic maxillofacial prosthesis can help patients with various issues and improve their quality of life. More thorough and high quality prosthetic care is required for maxillofacial anomalies brought on by cancer, trauma, or congenital disease [1,2]. Prosthodontists often face a considerable barrier in colour matching to human skin throughout the prosthesis creation. As the demand and awareness about maxillofacial prostheses increase, more precision in giving a natural appearance is essential. Therefore, exact shade identification is an utmost priority. Due to documented proof of silicone elastomers' superior qualities as a maxillofacial prosthetic material, silicones are now the most generally suggested material above acrylic resins.

Traditionally, the trial-and-error method has been used to replicate natural skin colour in the maxillofacial prosthesis [1]. This is a chairside procedure in which colours are gradually added to silicone elastomers. The final colour match's precision is influenced by translucency, metamerism, and the subjective nature of human colour perception [2]. Many methods and procedures have been applied to match skin colour. Colourimeters or handheld spectrophotometers are not commonly used in India for colour determination. Colourimeters can provide consistent and repeatable colour readings. Skin colour measurements in maxillofacial prosthesis patients are presently obtained using colourimetric technologies, such as e-skin (spectro match, bath, techno vent, UK). Colour measurements are examined and compared to those in the digital library, which are then used to assemble maxillofacial prostheses using known formulas [3]. These systems rely on specialist colourimeter instruments, which are both expensive and scarce. In today's world, smartphones with built-in digital cameras are ubiquitous. The technical capabilities of these devices have rapidly advanced, allowing virtually everyone to own a portable, network-connected vision sensor. Different colourimeter software programs are now available for mobile phones. The software translates the natural colour data of each pixel into colour coordinates such as CIE L*a*b* values. There needs to be more evidence in the realm of maxillofacial prostheses. 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].

Now a days, colourimeters and spectrophotometers are used. They are reliable but less accessible, expensive, and lack details [6]. The software converts each pixel's raw colour information into colour coordinates like CIE L*a*b* values. There needs to be more research in the field of maxillofacial prostheses, which also have drawbacks, including being more difficult to obtain, more expensive, and needing more specifics. In contrast to current methods for evaluating skin colour, the study's primary need is to create a more sophisticated application that might offer an economical, precise, and generally accessible tool for creating silicone colours for face prostheses [7]. Hence, the study's primary goal is to figure out the skin shade for the maxillofacial prosthesis 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 also, it will address two research questions whether a customised, comprehensive spectrum silicone shade guide is more effective in the shade selection of maxillofacial silicone prosthesis than the conventional method of shade selection. Also, an indigenously developed 'APDS AI-based digital application will be more effective in the shade selection of a maxillofacial silicone prosthesis than the conventional method of 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 on a survey of the Indian population. Objectives of phase 1 will be, to evaluate the most typical skin shade in the Indian general population for the fabrication of a shade guide and to fabricate the broad-spectrum manual shade guide for shade identification for the maxillofacial prosthesis. Another objective will develop the 'APDS' AI-based digital application using reference from a broad-spectrum maxillofacial shade guide for the Indians using a reflectance spectrophotometer.

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 for silicone maxillofacial prosthesis. Furthermore, the objective of phase 2 will be, to standardise and validate the customised, comprehensive spectrum silicon shade guide for shade selection in maxillofacial prosthesis with the help of a spectrophotometer and also to evaluate and compare the efficacy of the 'APDS' AI-based digital application for colour matching by fabricating silicon facial veneers for a participant.

Methodology

The present study will be a cross-sectional study. The subjects to be studied will be selected from the general population from various regions in India, and 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 expert statistician calculated the sample size calculation. Based on percentage agreement values for groups given 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 ordinary skin shade with available skin shade analysis system (observational survey): An observational study will be done for the commonest skin shade identification in India's general population (n-200) to fabricate a shade guide from the lightest to the darkest skin tone. Simple random sampling will be done. For colour, the identification face will be divided into three regions-forehead to glabella, glabella to nasion, and nasion to chin. Skin tone will be recorded in hue (amount of colour type), croma (amount of black, red, yellow, white, and blue), and value (amount of darkness and lightness) coordinated with the help of a colourimeter currently available on the market. It will be apparent to the subjects that participation will be voluntary, and written informed consent will be gained from those who accept to contribute. Readings will be taken and sent for data analysis. Subjects with informed consent, 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. Both, male and female equal ratios will be maintained during the study. Subjects with skin disorders, example- hypopigmentation or hyperpigmentation, skin tanning, post-radiation therapy, and subjects with any makeup or cosmetics product application modifying the skin colour will be excluded. Convenient sample size is suggested to develop the broad-spectrum manual shade guide for the Indian population.

Objective 2: Fabrication of custom-made silicon shade guide (4 mm thickness) with silicon material and pigments with the help of survey findings: The most prevalent skin tones in the population will be mined from the survey study results. Using room temperature vulcanising, a bespoke shade guide will be created. Grade medical vent made of silicone (UK) A-2000 addition to factor Ii (platinum) excellent elongation properties, Shore A 20 cure hardness, silicone elastomer 1:1 cure system, and intrinsic pigments will be used factor ii silicone paste colours and self-cure acrylic material-acralyn R materials. Square specimens of silicone with a clear acrylic base will be fabricated with a thickness of 4 mm. The metal mold will be fabricated with the above given dimensions. A maxillofacial silicone specimen will be prepared with the base of clear acrylic and room temperature vulcanising medical grade silicone with intrinsic pigments. The formulation formula will be recorded for each shade guide with the quantity of silicon material and the quantity of each pigment incorporated.

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 with the help of the application developer, the android studio will develop a mainframe application to analyse the image, object detection, and tracking using a Machine Learning (ML), subset of AI) kit. The details of broad-spectrum shade guide distribution given in [Table/Fig-2]. Along with that will find out the histogram image store and process mechanism for further analysis. Using ML will find out the targeted object and separate three different segments, and each segment will analyse colour shade with the help of ML object detection API. This analysis will collect a row 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

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.

heavy mathematical computation. In addition, image processing uses more memory and is time consuming. Therefore, the authors will look after this parameter by optimising the shade identification algorithm. Android/linux platforms, java, XML language, and ML SDK library will be used for image processing.

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.

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 employed to evaluate whether the data is standard. 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. The p-value=0.05 significance level will be chosen.

OUTCOME

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 needing a conventional shade guide or digital spectrophotometer because of their difficult accessibility and cost. In addition, it will reduce the need for extrinsic pigmentation.

DISCUSSION

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 vulcanizing 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 prosthesis 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 prosthesis [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].

REFERENCES

[1] Sanmartin P, Chorro E, Vazquez-Nion D, Martnez-Verd F, Prieto B. Conversion of a digital camera into a non-contact colorimeter for use in stone cultural heritage: the application case to Spanish granites. Measurement. 2014;56:194-202. Doi: 10.1016/j.measurement.2014.06.023.

[2] Coward TJ, Seelaus R, Li SY. Computerized color formulation for African-Canadian people requiring facial prostheses: a pilot study. J Prosthodont. 2008;17(4):327-35. Doi:10.1111/j.1532-849X.2007. 00288.x.

[3] Spectro match E-skin; website: http://www.spectromatch.com/products/technologies/e-skin/ease-of-use. Last Accessed: Jun 25,2021.

[4] Mulcare DC, Coward TJ. Suitability of a mobile phone colorimeter application for use as an objective aid when matching skin color during the fabrication of a maxillofacial prosthesis. J Prosthodont. 2019;28(8):934-43. Doi:10.1111/jopr.12955.

[5] Over LM, Andres CJ, Moore BK, Goodacre CJ, Muñoz CA. Using a colorimeter to develop an intrinsic silicone shade guide for the facial prosthesis. Journal of Prosthodontics. 1998;7(4):237-49. Doi: 10.1111/j.1532-849x.1998.tb00212. x. PMID: 10196844.

[6] Ranabhatt R, Singh K, Siddharth R, Tripathi S, Arya D. Color matching in facial prosthetics: A systematic review. J Indian Prosthodont Soc. 2017;17(1):03-07. Doi:10.4103/0972-4052.197935.

[7] Guttal SS, Patil NP, Nadiger RK, Kulkarni R. A study on reproducing silicone shade guide for maxillofacial prosthesis matching Indian skin color. Indian Journal of Dental Research. 2008;19:191-95. Doi: 10.4103/0970-9290.42949.

[8] Anitha KV, Behanam M, Ahila SC, Jei JB. A custom-made intrinsic silicone shade guide for Indian population. J Clin Diagn Res. 2016;10(4):ZC27-ZC30. Doi:10.7860/JCDR/2016/17116.7539.

[9] Rosner B. Fundamentals of Biostatistics. 7th ed. Boston, MA: Brooks/Cole; 2011.

[10] Wee AG, Beatty MW, Gozalo-Diaz DJ, Kim-Pusateri S, Marx DB. Proposed shade guide for human facial skin and lip: a pilot study. Journal of Prosthetic Dentistry. 2013;110(2):82-89. Doi: 10.1016/S0022-3913(13)60344-3.

[11] Kurt M, Nemli SK, Güngör MB, Bal BT. Visual and instrumental color evaluation of a computerized color matching system for color reproduction of maxillofacial prostheses. The Journal of Prosthetic Dentistry. 2021;ISSN 0022-3913, Doi: 10.1016/j.prosdent.2021.01.009.

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