METAMERISM OF THREE DIFFERENT PIGMENTS FOR FACIAL PROSTHESES AND A METHOD TO IMPROVE SHADE EVALUATION

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521707

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of

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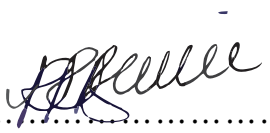
DECLARATION

I, Karen Ruet Bennie declare that this research report is my own work. It is being submitted for the degree of Master in Dentistry in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.



……Karen Ruet Bennie

…8th …day of May, 2017

ABSTRACT

Introduction: A maxillofacial prosthesis of acceptable dimension, surface and shade can improve the quality of life of the patient. Observer and illuminant metamerism may result in colour differences. The aim of this study was to visually assess the illuminant metamerism under three standard illuminations of a single silicone material using three different pigmentation techniques, and to use these data to determine if it is possible to construct a useful shade guide.

Methods and Materials: Nine silicone shade tabs were constructed for three volunteers representing light, medium and dark skin tones. The shade tabs were intrinsically pigmented using make-up, oil paint or silicone pigments. The shade matching and mixing was completed under colour corrected light. The recipe for the construction of each shade tab was recorded for the first three shade tabs. This was used for construction of the remaining six shade tabs at two separate sessions. Six examiners scored the match of each shade tab to the volunteer's malar region on a VAS under three standard illuminants: colour corrected light, incandescent light, and fluorescent light. The examiners were required to follow an observation protocol to score each shade tab under all three illuminants.

Results: The intra-rater and inter-rater reliability was assessed using the Intra-class Correlation Coefficient and revealed acceptable reliability (>0.6). A three-way ANOVA was used to assess the effect of

rater on the scores. Two outliers were excluded and the remaining raters' scores averaged. The two-way ANOVA revealed significant differences ($p<0.05$) for pigments and illuminant, and the interaction of pigments with illuminant on the raters' scores (table 4.7).

Conclusion: Illuminant metamerism affects the appearance of silicone prostheses. Oil paint and fluorescent or incandescent illumination had the worst effect. It is possible to construct a shade guide using the methods described.

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Table of Contents

DECLARATION ii

ABSTRACT iii

ACKNOWLEDGEMENTS v

List of Figures ix

List of Tables x

1. Chapter 1: Literature Review 1

1.1. Introduction 1

1.2. Silicone Elastomers 1

1.3. Colour Perception and Evaluation 3

1.3.1. Objective Shade Matching 4

1.3.2. Subjective Shade Matching 7

1.3.3. Pigment Loading 8

1.4. Conclusion 9

2. Chapter 2: Aims and Objectives 11

2.1. Aim 11

2.2. Objectives 11

2.3. Hypothesis 11

3. Chapter 3: Methods and Materials 13

3.1. Ethics Approval 13

3.2. Materials Used 13

3.2.1. Laboratory Materials and Equipment 13
3.2.2. Clinical Materials and Equipment 13
3.3. Inclusion and Exclusion Criteria 14
3.4. Preparation of Templates and models 15
3.5. Preparation of Shade Tabs 16
3.6. Evaluation Procedures 19
3.7. Data Analysis 22
4. Chapter 4: Results 24
4.1. Intra-rater Reliability 24
4.2. Inter-rater Reliability 25
4.3. The Interaction of Rater, Pigment, and Illuminant on the Scores of the Shade Tabs 25
4.4. The Effect of Pigment and Lighting on the Scores of the Shade Tabs Subsequent to Averaging Raters 28
4.4.1. Light Group 28
4.4.2. Medium Group 33
4.4.3. Dark Group 38
5. Chapter 5: Discussion 45
5.1.1. Rater Precision and Specificity 49
5.2. Homogeneity of Variances 53
5.2.1. The Effect of Pigment 54
5.2.2. The Effect of Illuminant 56
5.2.3. The Interaction between Pigment and Illuminant 56
5.3. Limitations 57
6. Chapter 6: Conclusions and Recommendations 59
7. References 61

APPENDIX A: Informed Consent and Participant Information Sheet.....65

APPENDIX B: Ethics and PG Approval Letters 74

APPENDIX C: Visual Analogue Scale.....76

APPENDIX D: Calibration PowerPoint Presentation.....77

APPENDIX E: Turnitin Report.....80

List of Figures

Figure 3-1: 3 x 20 x 10mm wax patterns invested in Type III dental stone..... 15

Figure 3-2: Trial and error method of mixing the base shade..... 17

Figure 3-3: Matching the base shade with the malar region..... 17

Figure 3-4: Loading the insulin syringes with base pigment..... 18

Figure 3-5: The ratio of silicone to base pigment..... 18

List of Tables

Table 4-1: ICC for each rater across sessions _____24

Table 4-2: ICC across raters per session _____25

Table 4-3: *Post-hoc* tests for the raters for the light group _____26

Table 4-4: *Post-hoc* tests for the raters for the medium group _____26

Table 4-5: *Post-hoc* tests for the raters for the dark group _____26

Table 4-6: Descriptive statistics for the light group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent. _____28

Table 4-7: Test of between-subjects effects _____29

Table 4-8: Multiple comparisons for the effect of pigment in the light group ___30

Table 4-9: *Post-hoc* test for the effect of pigment for the light group _____30

Table 4-10: Multiple comparisons for the effect of illuminant for the light group. C: colour-corrected; F: fluorescent; I: incandescent. M: make up; O: oil paint; S: silicone _____31

Table 4-11: *Post-hoc* tests for the effect of illuminant for the light group. C: colour-corrected; F: fluorescent; I: incandescent _____31

Table 4-12: Interaction effects for the light group. The pigment and illuminant combination are shown by their initial letters; e.g. MC is Make-up under colour-corrected light, SF is silicone pigment under fluorescent light, etc. Read the table from the first column, so that MF scored lower than MC and MI, etc. _____32

Table 4-13: Estimated marginal means for the interaction of illuminant and pigment in the light group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent _____33

Table 4-14: Descriptive statistics for the medium group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent _____34

Table 4-15: Test of between-subjects effects for the medium group _____34

Table 4-16: Multiple comparisons for the effect of pigment in the medium group. M: make up; O: oil paint; S: silicone. _____35

Table 4-17: *Post-hoc* tests for the effect of pigment for the medium group. M: make up; O: oil paint; S: silicone _____35

Table 4-18: Multiple comparisons for the effect of illuminant in the medium group. C: colour-corrected; F: fluorescent; I: incandescent. _____36
Table 4-19: *Post-hoc* test for the effect of illuminant for the medium group __37
Table 4-20: Interaction effects for the medium group. The pigment and illuminant combination are shown by their initial letters; e.g. MC is Make-up under colour-corrected light, SF is silicone pigment under fluorescent light, etc. Read the table from the first column, so that MF and SC scored lower than MI, etc. _____38
Table 4-21: Estimated marginal means for the effect of illuminant and pigment in the medium group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent _____38
Table 4-22: Descriptive statistics for the dark group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent_____39
Table 4-23: Tests of between-subjects effects for the dark group_____39
Table 4-24: Multiple comparisons for the effect of pigment for the dark group. M: make up; O: oil paint; S: silicone_____40
Table 4-25: *Post-hoc* test for the effect of pigment for the dark group. M: make up; O: oil paint; S: silicone_____41
Table 4-26: Multiple comparisons for the effect of illuminant in the dark group. C: colour-corrected; F: fluorescent; I: incandescent _____42
Table 4-27: *Post-hoc* tests for the effect of illuminant in the dark group. C: colour-corrected; F: fluorescent; I: incandescent _____42

1. Chapter 1: Literature Review

1.1. Introduction

Maxillofacial prosthodontics deals with the reconstruction of craniofacial defects by prosthetic means. Patients with craniofacial defects may experience significant psychological distress as a result of the presence of the defect (Beumer et al., 2011).

A maxillofacial prosthesis of acceptable dimension, surface and shade can improve the quality of life of the patient. A colour difference between the prosthesis and surrounding tissue may result in increased psychosocial distress and thus shade matching is an important step in the construction of a prosthesis (Beumer et al., 2011).

1.2. Silicone Elastomers

Silicone elastomers have been used in the restoration of craniofacial defects for more than five decades. Despite their favourable attributes compared with previous materials, silicone elastomers still have disadvantages. These include poor tear strength; degradation of mechanical properties; low adherence to adhesives due to low surface energy and solubility; low bond strength to underlying acrylic frameworks housing implant retentive elements; discoloration with time; and poor colour match under different illuminants (Montgomery and Kiat-Amnuay 2009; Beumer et al., 2011)

Whilst the mechanical properties of different silicones have been well evaluated, the optical properties such as pigmentation appear to be poorly understood (Wolfaardt et al., 1985; Al-Harbi et al., 2015).

There are numerous silicones available for the construction of facial prostheses. These can be broadly classified as high-temperature or room-temperature vulcanising silicones. The most commonly used silicone elastomer, according to a recent survey of several continents, is A2000 (Factor II, Inc., Lakeside, USA) (Montgomery and Kiat-Amnuay 2009).

Prostheses are coloured by adding pigments to the silicone before (intrinsic pigmentation) or after polymerisation (extrinsic pigmentation). A combination of both techniques may also be used (Beumer et al., 2011). Silicone manufacturers usually suggest specific pigments for their material. Traditionally clinicians have also used their own pigmentation techniques, which may involve the use of various organic and inorganic pigments. Several commonly used pigments include dry earth pigments, food colourants, rayon flocking, makeup, or oil based paints. This has made objective comparisons between different systems or clinical techniques difficult (Montgomery and Kiat-Amnuay, 2010; Beumer et al., 2011). There are very few studies that have evaluated the use of different pigments for constructing clinically acceptable maxillofacial prostheses.

1.3. Colour Perception and Evaluation

The perception of colour is affected by several factors. These include the incident illuminant e.g. sunlight or artificial light; the properties of the object being viewed e.g. surface texture; and the physiology of the observer (Figura and Teixeira, 2007).

Metamerism refers to the apparent colour match of two objects that have different spectral distributions i.e. reflect different wavelengths of light (Leow et al., 1999). *Illuminant* metamerism results when two objects appear to have a good colour match under one illuminant e.g. natural daylight, but have a poor colour match under a different illuminant e.g. fluorescent or incandescent light. Unlike discolouration of a prosthesis with time, illuminant metamerism may result in immediate dissatisfaction, and thus should be avoided if possible (Leow et al., 1999).

Observer metamerism results when two objects may have a colour match when viewed by one person but not by another. This may be as a result of anatomical differences in the retina or in the way colour is processed and perceived centrally. Observer metamerism can occur as a result of colour deficiency; the use of an inconsistent protocol for shade matching; inexperience; or age changes. Colour deficiency may be indicated by various validated colour assessment tests such as the Ishihara Colour Vision Test (Seelaus, Coward and Li, 2011) and confirmed by the use of an anomaloscope. Cole (2007) completed a

review of the literature regarding colour vision evaluations. The Ishihara colour vision test was suggested as easy to use and interpret (Ishihara, 1972). It is the most commonly used colour vision evaluation test for occupational purposes (Rodriguez-Carmona et al., 2012).

Shade matching has traditionally been accomplished by “trial and error” methods. Objective methods to complete shade matching may involve the use of spectrophotometers, colorimeters, or spectroradiometers (Coward et al., 2008).

1.3.1. Objective Shade Matching

The Commission Internationale de l’Eclairage (CIE) was established almost a century ago in an effort to quantify and standardise colour. Human colour vision can be described in terms of a colour space. A specific colour will occupy a specific position in the colour space. This position is designated by three coordinates that describe the position of the colour based on the amount of opposing colours. The coordinates are L^* (black-white), a^* (red-green), and b^* (blue-yellow) (Figura and Teixeira, 2007; Seelaus et al., 2011).

The CIE$L^*a^*b^*$ system allows for the quantification of colour difference, known as Delta E. The Delta E (ΔE) was initially described using a simple Euclidean distance formula. Several modifications of the formula have been developed resulting in a complicated mathematical calculation for colour difference. Initially the CIE defined a delta E of 1 unit as the minimum colour difference

perceptible to humans (Figura and Teixeira, 2007; Seelaus et al., 2011).

Spectrophotometers, colorimeters, and spectroradiometers have been developed in order to quantify and describe colour. Each device is capable of providing a CIE$L^*a^*b^*$ reading and calculating the ΔE. Each device differs in the way that it measures the wavelength of light emitted, reflected or refracted from an object (Coward et al., 2008; Hu, 2010).

The practical use of these instruments has shown much variation in colour quantification and discrimination when compared with visual observation. These instruments have been applied for use in maxillofacial prosthodontics in an effort to more reliably match silicone prostheses to adjacent skin. Unfortunately a correlation with clinical results has not been definitively established (Hu, 2010; Seelaus et al., 2011).

Some studies have shown ΔE readings greater than 3, which were considered clinically acceptable. The clinical tolerance for ΔE is yet to be defined. This shows that colour difference depends on numerous factors including on the incident illuminant, the properties of the skin, translucency etc. Due to the variable nature of ΔE readings, correlation with visual observation is still required. As such, objective measurements of colour as applied to maxillofacial prosthodontics

should be considered no more than an adjunct to visual evaluations (Leow et al., 1999; Coward et al., 2008; Seelaus et al., 2011).

Reflectance spectrophotometers and colorimeters have been used in several studies and have shown variable results. These instruments contact the skin in order to measure the light reflected from the object. Depending on the contact pressure, histological structure and surface texture of the skin, variable measurements may result. No studies have adequately described how pressure was standardised and how accuracy may be obtained. Also, edge loss, due to the scattering of some light by a translucent object such as skin or silicone may have occurred. This scattered light is usually beyond the instrument's aperture and is ultimately not measured, resulting in an inaccurate measurement (Leow et al., 1999; Coward et al., 2008, Hu, 2010; Seelaus et al., 2011).

Non-contacting spectroradiometers have been suggested as an alternative to more accurately measure objects with translucent features. Unfortunately in a series of evaluations the non-contacting spectroradiometer showed variable results in terms of accuracy compared with other contacting systems. It has been suggested that they are currently time-consuming, lack portability and are sensitive to surface features (Hu, 2010).

1.3.2. Subjective Shade Matching

Subjective shade matching of a silicone prosthesis with the skin may be affected by the illuminant, the optical properties of the skin and pigmented silicone, and the physiology of the observer (Piérard, 1998).

The visible portion of the electromagnetic spectrum ranges from 400-700nm. The light from the illuminant will interact with the skin resulting in scatter (reflection, refraction or diffraction) or absorption as the photons interact with the different skin components (Piérard, 1998; Fondriest, 2003).

Light absorbing components or chromophores, are located in the epidermis, dermis and dermal blood vessels. These include eumelanin, phaeomelanin, carotenoids, oxyhaemoglobin, deoxyhaemoglobin, and bilirubin. Each chromophore interacts, absorbs and scatters the different illuminant wavelengths in a heterogeneous way resulting in complicated optical and colour properties of the skin (Piérard, 1998).

Colour vision is not only a physiological interaction of the scattered light with the retinal cones but also appears to have a large subjective and psychological interpretation, which may be affected by gender, culture, memories etc. (Piérard, 1998).

Furthermore, the human visual system reduces the light stimulus through a process of trichromacy. This means that any particular

combination of different wavelengths of visual light may be reduced to a single signal by the retinal cones i.e. red, green or blue. This allows human beings to perceive objects with spectrally different properties as similar colours (Piérard, 1998; Fondriest, 2003). The human visual system also appears to fatigue during shade matching of two spectrally different objects. This fatigue is a normal physiologic property of the retinal cones, which suffer afterimages. During the observation the human eye tends to involuntarily shift from one point to another. As this occurs afterimages are formed. In colour observation these afterimages may tend to "blend" the different colours. As such shade matching must be completed as quickly as possible (Fondriest, 2003).

Visual shade matching for silicone prostheses has been completed using a "trial and error" method. There appear to be no articles detailing the exact "trial and error" procedure. This procedure, however, is still regarded as the standard method for shade matching (Seelaus at el., 2011). However, it has been shown that clinician experience improves the reliability and accuracy of subjective shade matching methods (Seelaus et al., 2011).

1.3.3. Pigment Loading

As skin consists of multiple layers of cells it is considered partially translucent. This is more so for individuals with lighter skin shades. Due to the translucency a number of different skin elements may be visible and affect the pigmentation, such as capillaries (Piérard, 1998).

This is why it may be very difficult to mimic the translucency of skin. Furthermore, the pigment loading affects the translucency of the silicone prosthesis. Troppman et al. (1996) stated that the pigment loading for light skinned individuals should range between 0.15% and 0.25%. This may be acceptably increased to 0.6% for darker skin shades (Coward et al., 2008).

Subjective methods to determine pigment loading are largely based on clinician experience (Coward et al., 2008). Hu et al. (2011) compared *in vitro* the translucency estimation of laser light diffusing methods with colour difference due to edge loss. They concluded that the laser light diffusing method was reliably able to estimate apparent translucency and thus pigmentation loading. However, this method has not been validated by any other studies and the method by which the translucency of the silicone was assessed was not clear and so it appears that this may not be clinically useful at this stage.

1.4. Conclusion

It seems that the use of instruments to objectively measure skin and silicone shade have the disadvantages of being time-consuming, expensive, and of a low accuracy. Visual evaluations by experienced clinicians on the other hand, have shown acceptable shade matching in terms of colour and translucency. There is currently no clinically applicable and reliable method to objectively determine shade matching of translucent materials (Hu, 2010; Seelaus et al., 2011).

It would seem appropriate to conclude that visual assessment by expert examiners is more likely to provide useful data regarding the colour match of silicone prostheses with skin. An observation protocol based on the illuminant, object and observer's physiological properties may enhance the visual assessment. These data may be used to improve cost-effective clinical procedures, and may also be useful in the production of shade guides for a given silicone material and pigmentation technique.

Therefore the principle aim of this study was to visually assess the illuminant metamerism under three standard illuminations of a single silicone material using three different pigmentation techniques, and to use these data to determine if it is possible to construct a useful shade guide.

2. Chapter 2: Aims and Objectives

2.1. Aim

To assess the metamerism of a facial silicone elastomer using three different pigmentation systems and to derive an appropriate method to construct a shade guide for clinical use.

2.2. Objectives

1. To standardise three different pigmentation techniques for a silicone elastomer
2. To visually assess the illuminant metamerism under three standard illuminations using observers experienced in shade matching of maxillo-facial prostheses.
3. To produce a reliable method to construct a shade guide for silicone elastomer maxillofacial prostheses.
4. To devise and assess a shade matching protocol for silicone elastomer maxillofacial prostheses.

2.3. Hypothesis

The null hypotheses were:

- Pigment type will not affect the scores of the shade tabs.
- Illuminant will not affect the scores of the shade tabs
- The interaction of pigment types and illuminants will not affect the scores of the shade tabs

- The method to devise and assess the shade matching protocol will not be reliable.
- The method to devise a shade guide will not be reliable.

3. Chapter 3: Methods and Materials

3.1. Ethics Approval

Informed consent was obtained from the volunteers and expert examiners (APPENDIX A) Ethics approval was obtained from the Human Research Ethics Committee of the University of the Witwatersrand. The clearance number was M160119 (APPENDIX B)

3.2. Materials Used

3.2.1. Laboratory Materials and Equipment

Toughened modelling wax (Kemdent, UK)

Type III dental stone (Dentstone KD, Saint-Gobain Formula, UK)

Flasks (FT Collins, USA)

Cold mold seal (John Winter and Co., Ltd, UK)

Vaseline petroleum jelly (Unilever, USA)

VPM2 vacuum mixer (Whipmix, USA)

SABAX sterile distilled water (Adcock-Ingram, RSA)

3.2.2. Clinical Materials and Equipment

Silicone Elastomer (Factor II, Inc., Lakeside, AZ)

Silicone pigments (Factor II, Inc., Lakeside, AZ)

Oil paints (Winsor and Newton, UK)

Base make-up (Kryolan, Germany)

Pros-aide Medical Adhesive (ADM Tronics Inc., USA)

Artificial daylight L36/954 fluorescent tubes 5400K, R_a >90 (Philips, Netherlands)

Fluorescent F36W/33 light tubes 4000K, R_a 58 (Philips, Netherlands)

Incandescent light bulb STD 60W B22 Clear 2500K, R_a >90 (Philips, Netherlands)

Paint brushes (Prime Art, RSA)

Insulin syringes (Braun, Germany)

Spatula

Glass slab

Neutral grey colour tile

Ishiara colour vision test (Ishiara, 1972)

3.3. Inclusion and Exclusion Criteria

The inclusion criteria were as follows:

Three volunteers, over the age of 18 years, were recruited from the Wits Oral Health Centre, who represented light, medium, and dark skin tones. The skin was to have a smooth quality and as little pigmentation variation as possible.

Six examiners who had experience in the management of maxillofacial prosthodontic patients and who had successfully completed an Ishihara Colour Vision test, were recruited from the Wits Oral Health Centre and allied workers.

The exclusion criteria included:

Volunteers under the age of 18

Examiners with no experience in managing maxillofacial prosthodontic patients

Examiners who failed the Ishihara colour vision test

Volunteers or examiners from whom informed consent had not been obtained

3.4. Preparation of Templates and models

Eighteen 3mm thick wax templates were be constructed. Each template had an area of 200mm^2 (20mmx 10mm) to allow enough silicone material for shade matching. The wax patterns were invested in a flask containing Type III dental stone (Dentstone KD, Saint-Gobain Formula, UK), proportioned and vacuum-mixed with sterile distilled water according to the manufacturer's instructions, and the wax eliminated to construct a mold for each silicone sample.

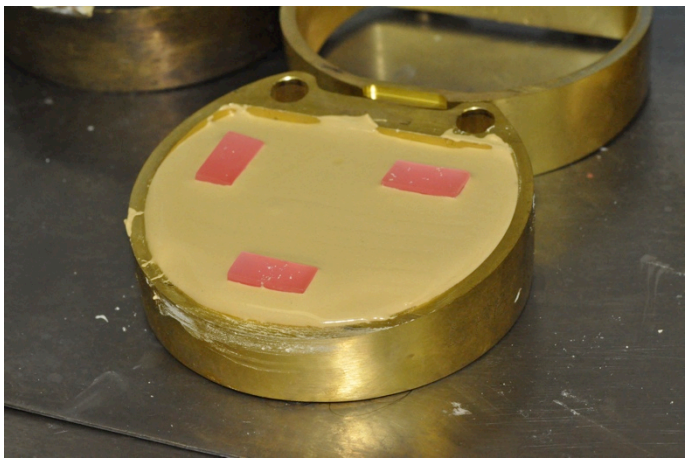


Figure 3-1: 3 x 20 x 10mm wax patterns invested in Type III dental stone

3.5. Preparation of Shade Tabs

The methods outlined below were created based on an initial pilot study.

The study consisted of three experimental groups using A2000 room temperature vulcanising silicone elastomer (Factor II, Inc., Lakeside, AZ). The silicone consisted of Parts A and B, which polymerised on mixing.

The pigment materials for each volunteer were as follows:

Group 1: Silicone pigments (Factor II, Inc., Lakeside, AZ)

Group 2: Oil paints (Winsor and Newton, UK)

Group 3: Base make-up (Kryolan, Germany)

The three volunteers were required to remove all facial make-up prior to shade matching. The shade matching was completed in one room with standard artificial daylight, Philips L36/954 light tubes, which had a colour temperature of 5,400K, and a Colour Rendering Index R_a >90.

The shade matching and pigmentation of the silicone was completed according to the “trial and error” method commonly used in the construction of maxillofacial prostheses at the University of the Witwatersrand. This consisted of mixing an initial burnt umber or burnt sienna base shade of pigment and thereafter adding pigments according to the opinion of the clinician.

One clinician (the Principal Investigator) completed all mixtures. The ratios of mixed pigments were recorded to create a shade formula. The pigments of each experimental group were mixed and matched to the participant's skin. This shade formula served as the base pigment, which was then added to both mixed silicone elastomers in the concentration (loading) that was considered acceptable by the principal investigator (PI) and two examiners. This loading ranged between 0.1% and 2% depending of the shade of the volunteer as outlined by previous studies (Troppman et al., 1996; Coward et al., 2008).

Figure 3-2: Trial and error method of mixing the base shade

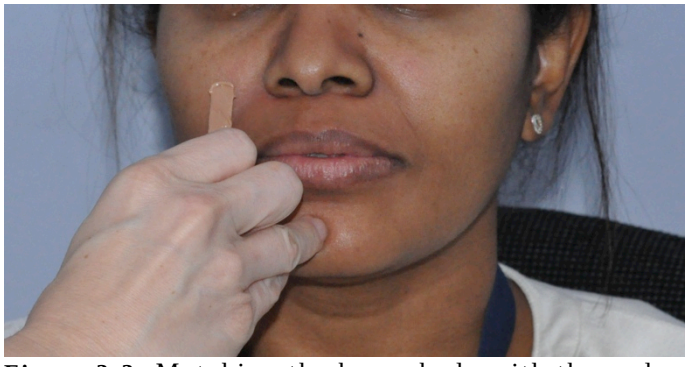


Figure 3-3: Matching the base shade with the malar region

A 1ml insulin syringe was loaded with the base pigment. The syringe is divided into 100 units, each equivalent to 0.01ml. The pigment loading could thus be calculated from the number of units of pigment used. For example if 2.5ml of silicone elastomer was used in total and 1 unit of pigment was added to this, the pigment loading was:

(0.01/2.5) x 100 = 0.4%.

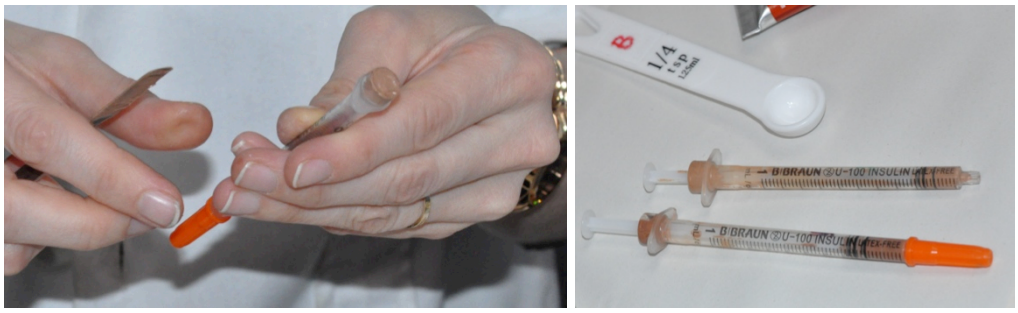


Figure 3-4: Loading the insulin syringes with base pigment

Further pigmentation was completed as required by using the tip of a 000 paint brush (Prime Art, RSA) and adding miniscule amounts to the silicone. This was also recorded in the formula.

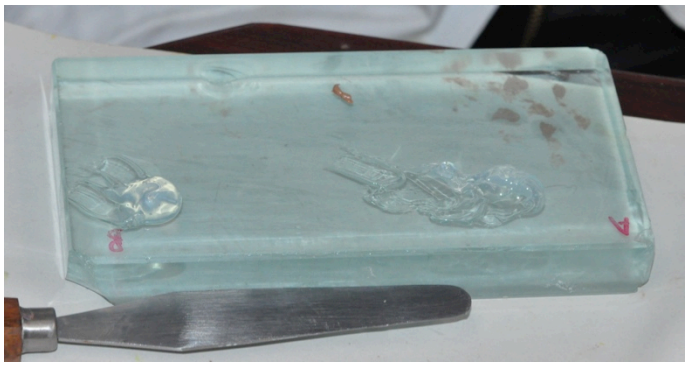


Figure 3-5: The ratio of silicone to base pigment

The pigmented silicone was matched to a circular area with a 2cm diameter on the right malar region. The anatomical landmarks, which corresponded to the centre of the area, were recorded to allow for future comparison.

Two examiners rated the shade match as acceptable or unacceptable. Consensus was reached prior to mixing the base pigment with the silicone elastomer. When there was a lack of consensus, the shade was discussed and methods to improve the shade match implemented until consensus was reached. If consensus could not be reached, the mixing clinician (the PI) made the final decision.

The silicone mixtures were de-aired by spatulation, packed into the moulds and flasked under constant pressure for 24 hours at room temperature.

The silicone pigmentation and mixing was completed in triplicate by replicating the previously approved formula at one-week intervals to evaluate consistency. The same clinician (the PI) did this.

3.6. Evaluation Procedures

Once the test group samples from all three mixing sessions had been processed, they were coded.

A silicone sample was randomly chosen and compared to the volunteer's skin by following the visual evaluation protocol outlined below. This visual examination was completed in separate rooms, each with a different illuminant: artificial daylight (colour temperature 5400K), white light (colour temperature 4000K), and incandescent

light, (colour temperature 2500K). All four walls of the rooms were painted light blue and there was no exogenous source of light.

The 3mm silicone tile was fixated adjacent to the malar region using a medical skin adhesive (Pros-aide Medical Adhesive, ADM Tronics Inc., USA). Six examiners rated the match of the tile on a Visual Analogue Scale from 0-10 (0=completely unacceptable, 10=excellent match) under each of the different illuminants (APPENDIX C).

The examiners were provided with the visual evaluation protocol several days prior to examination to allow them to familiarise themselves with the protocol. A pilot study was conducted to identify difficulties.

Calibration sessions were completed several days prior to the first evaluation session and prior to each subsequent evaluation session. This was done through the use of a PowerPoint (APPENDIX D) presentation (Microsoft, USA), and shade evaluation exercises.

The protocol was as follows:

OBSERVATION FEATURES

- The subject must be positioned such that the area of interest is situated at the same vertical and horizontal distance from the

illuminant at each observation session. (MacDougall, 2002; Fondriest, 2003)

SUBJECT

- Wear a neutral colour e.g. white or grey (Sproull, 1973)

OBSERVER

- Evaluate the colour match between the pigmented silicone and the adjacent skin region.
- Position yourself no less than 50cm from the patient (MacDougall, 2002).
- Assess the patient at a 0 degree observation angle (Sproull, 1973; Seelaus et al., 2011).
- Do not look at the area for longer than 5 seconds (Fondriest, 2003).
- Assess the patient at an approximately 45-degree angle, from left and right (Sproull, 1973; Seelaus et al., 2011).
- You may look at the area as many times as you require to make your decision but look at the neutral grey card in-between evaluations to re-sensitise your eyes (Sproull, 1973; Fondriest, 2003).
- Rate the shade match on a scale from 0 – 10 where 0=completely unacceptable and 10=excellent colour match.
- Complete this for each shade tab under all three illuminants.

The shade evaluation procedure was repeated three times, at daily intervals. Each evaluation session was completed at the same time of day.

Once the data were collected and analysed, the accuracy and precision of the shade determination method, as well as the applicability of the method for use to construct a shade guide were determined.

3.7. Data Analysis

Data were recorded on an Excel sheet (Microsoft, USA).

For each combination of the shade tabs and three skin tones (i.e. six data subsets), the following analyses were done on the appearance rating:

- Descriptive statistics (mean, standard deviation) were tabulated for the appearance rating, categorised by pigment type, preparation session, illuminant, rating session and rater.
- Intra-rater reliability between rating session 1, 2 and 3 using the intra-class correlation coefficient (ICC) for each of the six raters.
- Inter-rater reliability between raters 1-6 using the ICC for each rating occasion.
- A three-way Analysis of Variance (ANOVA) with factors Pigment type, illuminant, and rater to determine the effect of the rater among these factors. Rater was evaluated as both a fixed and random effect.

- The scores of raters with an acceptable degree of precision and specificity would be averaged for a given evaluation for subsequent analyses. Outliers would be omitted. The averaged scores were to be used in a two-way ANOVA with factors pigment type, illuminant, and interaction between pigment type and illuminant. The latter would be used to determine the effect of these factors on the combined rating. The *post-hoc* analyses would be completed using the Tukey HSD test. Estimated marginal means and confidence intervals would be used to illustrate the interaction effect.

Data analyses were carried using IBM SPSS Statistics (IBM, USA). A 5% significance level was used.

4. Chapter 4: Results

4.1. Intra-rater Reliability

The intra-rater reliability was completed per rater across the three rating sessions. All raters had an average ICC above the threshold of 0.6 (Chinn, 1991) and ranged from 0.681 to 0.820 (Table 4.1).

Table 4-1: ICC for each rater across sessions

Rater	Type of Measure	Interclass Correlation [b]	95% Confidence Interval		F Test with True Value 0			
			Lower Bound	Upper Bound	Value	df1	df2	Sig
1	Single Measures	.416[a]	0.28	0.55	3.115	80	160	0.000
	Average Measures	.681[c]	0.538	0.785	3.115	80	160	0.000
2	Single Measures	.486[a]	0.355	0.61	3.838	80	160	0.000
	Average Measures	.739[c]	0.623	0.824	3.838	80	160	0.000
3	Single Measures	.463[a]	0.317	0.597	3.991	80	160	0.000
	Average Measures	.721[c]	0.582	0.816	3.991	80	160	0.000
4	Single Measures	.515[a]	0.326	0.663	5.26	80	160	0.000
	Average Measures	.761[c]	0.592	0.855	5.26	80	160	0.000
5	Single Measures	.602[a]	0.486	0.707	5.508	80	160	0.000
	Average Measures	.820[c]	0.739	0.878	5.508	80	160	0.000
6	Single Measures	.486[a]	0.355	0.61	4.001	80	160	0.000
	Average Measures	.739[c]	0.622	0.824	4.001	80	160	0.000

Two-way mixed effects model where people effects are random and measured effects are fixed

a. The estimator is the same, whether the interaction effect is present or not
b. Type A intraclass correlation coefficients using an absolute agreement definition
c. The estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise

4.2. Inter-rater Reliability

The inter-rater reliability was completed using the ICC across raters per rating session and was above the threshold of 0.6 and ranged from an average of 0.778 to 0.853 (Table 4.2).

Table 4-2: ICC across raters per session

Session		Interclass Correlation [b]	95% Confidence Interval		F Test with True Value 0			
			Lower Bound	Upper Bound	Value	df1	df2	Sig
1	Single Measures	.452[a]	0.35	0.561	7.985	80	480	0.000
	Average Measures	.853[c]	0.79	0.899	7.985	80	480	0.000
2	Single Measures	.376[a]	0.275	0.487	6.22	80	480	0.000
	Average Measures	.808[c]	0.727	0.869	6.22	80	480	0.000
3	Single Measures	.334[a]	0.237	0.443	5.346	80	480	0.000
	Average Measures	.778[c]	0.686	0.848	5.346	80	480	0.000

Two-way mixed effects model where people effects are random and measured effects are fixed

a. The estimator is the same, whether the interaction effect is present or not
b. Type A intraclass correlation coefficients using an absolute agreement definition
c. The estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise

4.3. The Interaction of Rater, Pigment, and Illuminant on the Scores of the Shade Tabs

A three-way ANOVA revealed that there were significant differences ($p<0.001$) between the distributions of the scores by the different raters for each of the groups: light, medium and dark.

Post-hoc tests revealed that there were 5 subsets of raters for the light group (Table 4.3), four subsets for the medium group (Table 4.4) and two subsets for the dark groups (Table 4.5). Within each subset (column) there were no significant differences between raters. The significant difference revealed in the three-way ANOVA occurred between the subsets of raters.

Table 4-3: *Post-hoc* tests for the raters for the light group

Rater	N	Subset				
		1	2	3	4	5
6	81	5.8815				
2	81	6.3074	6.3074			
1	81		6.4728	6.4728		
3	81			6.9173	6.9173	
4	81				7.2160	
5	81					8.0654
Sig.		.093	.911	.070	.440	1.00

Table 4-4: *Post-hoc* tests for the raters for the medium group

Rater	N	Subset			
		1	2	3	4
6	81	4.4259			
1	81		5.3728		
3	81		5.4469		
4	81		5.6728	5.6728	
2	81			6.1457	6.1457
5	81				6.4852
Sig.		1.000	.600	.121	.461

Table 4-5: *Post-hoc* tests for the raters for the dark group

Rater	N	Subset	
		1	2
6	81	5.0432	
2	81	5.2679	
1	81	5.4605	5.4605
5	81	5.5519	5.5519
3	81	5.6605	5.6605
4	81		6.0494
Sig.		.080	.108

Examiner 6 consistently produced lower ratings and 5 produced higher ratings compared with the other raters. In the light group rater 6 was significantly lower ($p<0.001$) than raters 1, 3, 4, and 5. Rater 2 was not significantly different from rater 6 ($p = 0.93$ in subset 1) and rater 1 ($p =$

0.911 in subset 2). Rater 5 was significantly higher ($p<0.001$) than all other raters in the light group as revealed by the three-way ANOVA.

In the medium group rater 6 (subset 1) was significantly lower ($p<0.001$) than all other raters (subsets 2-4). Rater 5 was not significantly different to rater 2 ($p=0.461$ in subset 4) but was significantly higher than all other raters as revealed by the three-way ANOVA ($p<0.001$).

In the dark group rater 6 was similar to 1, 2, 3 and 5 ($p=0.080$ in subset 1). Rater 5 was similar to raters 1, 3, 4 ($p=0.108$ in subset 2).

After discussion with the final examiners the ratings of raters 5 and 6 were excluded from further analyses. This reduced the range of ratings. Their scores were statistically different in the light and medium groups and represented the extremes of average scores in the dark group. Although rater 5 did not have the highest average score in the dark group, the final examiners agreed that the data from the light and medium group were sufficient to exclude these scores from the study to decrease the range of scores overall.

The remaining ratings were averaged as the score ranges were within 9mm on the 100mm VAS (Zisapel and Nir, 2003). This was considered acceptable for the purpose of averaging raters' scores for further statistical evaluations through discussion and agreement amongst the final examiners and the PI.

4.4. The Effect of Pigment and Lighting on the Scores of the Shade Tabs Subsequent to Averaging Raters

4.4.1. Light Group

A two-way ANOVA revealed significant differences ($p<0.001$) for pigments and illuminant, and the interaction of pigments with illuminant ($p=0.011$) on the raters' scores (table 4.7). The Levene's test of equality of error variances was insignificant $p>0.05$. This test evaluates the homogeneity of data, which is required prior to completing ANOVAs. It is no longer considered a necessity to have homogenous data prior to completing a two-way ANOVA (Zimmerman, 2004). However, the SPSS software (IBM, USA) automatically completes this test and thus the results will be discussed.

Table 4-6: Descriptive statistics for the light group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent.

Dependent Variable: Score				
Pigment	**Illuminant**	**Mean**	**Std. Deviation**	**N**
M	C	7.7389	1.10254	36
	F	6.6222	1.17889	36
	I	7.0083	1.23135	36
	Total	7.1231	1.25084	108
O	C	7.4250	1.17774	36
	F	5.6750	1.13525	36
	I	6.0944	1.34014	36
	Total	6.3981	1.42284	108
S	C	6.9028	1.17534	36
	F	6.1667	1.08470	36
	I	6.9222	1.12963	36
	Total	6.6639	1.17429	108
Total	C	7.3556	1.19300	108
	F	6.1546	1.18829	108
	I	6.6750	1.29313	108
	Total	6.7284	1.31747	324

Table 4-7: Test of between-subjects effects

Dependent Variable: Score					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Corrected Model	125.678 (a)	8	15.710	11.377	.000
Intercept	14667.901	1	14667.901	10622.533	.000
Pigment	29.058	2	14.529	10.522	.000
Illuminant	78.342	2	39.171	28.368	.000
Pigment * Illuminant	18.278	4	4.569	3.309	.011
Error	434.961	315	1.381		
Total	15228.540	324			
Corrected Total	560.639	323			
a. R Squared = .224 (Adjusted R Squared = .204)					

4.4.1.1. Pigment

Multiple comparisons (table 4.8) revealed significant differences ($p<0.001$). Make-up was scored significantly higher than silicone ($p=0.012$) and oil paint ($p<0.001$) groups (table 4.8).

The Tukey HSD *post hoc* tests further illustrated this by revealing that there was no statistical difference ($p=0.222$ in subset 1) between oil paint and silicone pigments. Subset 2 contained only make-up and this was scored higher on average than oil paint and silicone pigments.

Table 4-8: Multiple comparisons for the effect of pigment in the light group

Dependent Variable: Score						
Tukey HSD						
(I) Pigment	(J) Pigment	Mean Difference (I - J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
M	O	.7250*	.15991	.000	.3483	1.1016
	S	.4593*	.15991	.012	.0827	.8358
O	M	-.7250*	.15991	.000	- 1.1016	- .3484
	S	-.2657	.15991	.222	- .6423	- .1108
S	M	-.4593*	.15991	.012	- .8358	- .0827
	O	.2657	.15991	.222	- .1108	- .6423
Based on observed means						
The error term is Mean Square(Error) = 1.381						
* The mean difference is significant						

Table 4-9: *Post-hoc* test for the effect of pigment for the light group

Score			
Tukey HSD (a,b)			
Pigment	N	Subset	
		1	2
O	108	6.3981	
S	108	6.6639	
M	108		7.1231
Sig.		.222	1.000

Means for groups in homogenous subsets are displayed

Based on observed means

The error term is Mean Square(Error) = 1.381

a. Uses Harmonic Mean Sample Size = 108.000

b. Alpha = .05

4.4.1.2. Illuminant

Multiple comparisons (table 4.10) revealed significant differences ($p<0.05$). Shade tabs were scored significantly higher under colour corrected light compared with incandescent ($p<0.001$) and fluorescent ($p<0.001$) light. Shade tabs were also scored significantly higher under incandescent light compared with fluorescent ($p=0.004$) light.

The *post-hoc* Tukey HSD (Table 4.11) revealed that shade tabs were scored higher under colour corrected light (subset 3) than incandescent (subset 2) or fluorescent light (subset 1). Scores were also higher under incandescent light (subset 2) than fluorescent light (subset 1).

Table 4-10: Multiple comparisons for the effect of illuminant for the light group. C: colour-corrected; F: fluorescent; I: incandescent. M: make up; O: oil paint; S: silicone

Dependent Variable: Score						
Tukey HSD						
(I) Illuminant	**(J) Illuminant**	**Mean Difference (I-J)**	**Std. Error**	**Sig.**	**95% Confidence Interval**	
					Lower Bound	**Upper Bound**
C	F	1.2009*	.15991	.000	.8244	1.5775
	I	.6806*	.15991	.000	.3040	1.0571
F	C	- 1.2009*	.15991	.000	- 1.5775	- .8244
	I	- .5204*	.15991	.004	- .8969	- .1438
I	C	- .6806*	.15991	.000	- 1.0571	- .3040
	F	.5204*	.15991	.004	.1438	.8969

Based on observed means.

The error term is Mean Square(Error) = 1.381

*. The mean difference is significant at the .05 level

Table 4-11: *Post-hoc* tests for the effect of illuminant for the light group. C: colour-corrected; F: fluorescent; I: incandescent

Score				
Tukey HSD (a,b)				
Illuminant	**N**	**Subset**		
		1	**2**	**3**
F	108	6.1546		
I	108		6.6750	
C	108			7.3556
Sig.		1.000	1.000	1.000

Means for groups in homogenous subsets are displayed

Based on observed means

The error is Mean Square(Error) = 1.381

a. Uses Harmonic Mean Sample Size = 108.000

b. Alpha = .05

4.4.1.3. The Interaction Effect

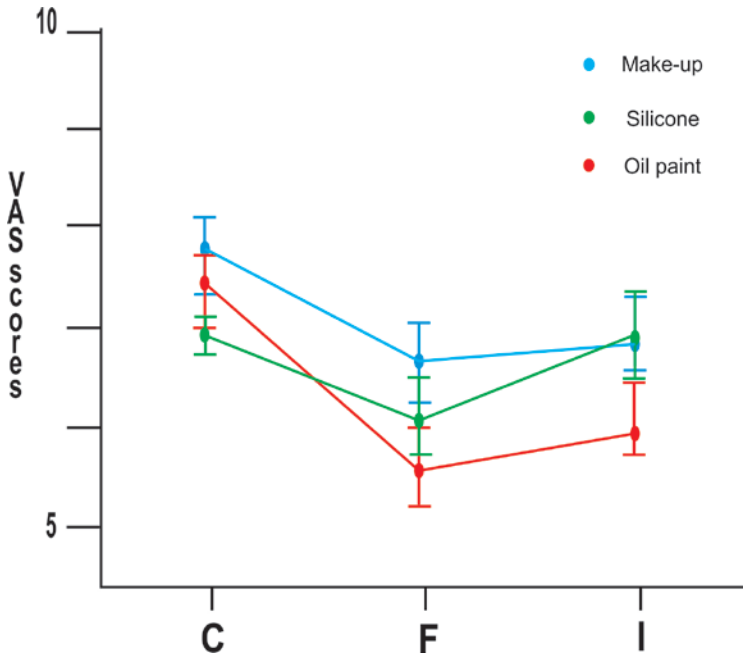


Figure 4.1: Profile plots of the effect of illuminant and pigment for the light group. C: colour-corrected; F: fluorescent; I: incandescent. Horizontal bars represent the Confidence Intervals.

The interaction effects are summarised in Table 4.12.

Table 4-12: Interaction effects for the light group. The pigment and illuminant combination are shown by their initial letters; e.g. MC is Make-up under colour-corrected light, SF is silicone pigment under fluorescent light, etc. Read the table from the first column, so that MF scored lower than MC and MI, etc.

	MC	MI	MF	SC	SI	SF	OC	OI	OF
MF	lower	lower							
SC	lower								
SF	lower	lower	lower						
OI	sig. lower	sig. lower		sig. lower	sig. lower		lower		
OF	lower	lower	lower	lower	lower				

Table 4-13: Estimated marginal means for the interaction of illuminant and pigment in the light group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent

Pigment * Illuminant					
Dependent Variable: Score					
Pigment	**Illuminant**	**Mean**	**Std. Error**	**95% Confidence Interval**	
				Lower Bound	**Upper Bound**
M	C	7.739	.196	7.354	8.124
	F	6.622	.196	6.237	7.006
	I	7.008	.196	6.623	7.394
O	C	7.425	.196	7.040	7.810
	F	5.675	.196	5.290	6.060
	I	6.094	.196	5.709	6.480
S	C	6.903	.196	6.517	7.286
	F	6.167	.196	5.781	6.552
	I	6.922	.196	6.537	7.306

4.4.2. Medium Group

A two-way ANOVA revealed significant differences ($p<0.05$) for pigments and illuminant, and the interaction of pigments and illuminant on the raters' scores (table 4.15). The Levene's test of equality of error variances was significant $p<0.05$.

Table 4-14: Descriptive statistics for the medium group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent

Dependent Variable: Score				
Pigment	**Illuminant**	**Mean**	**Std. Deviation**	**N**
M	C	6.1222	1.11691	36
	F	5.4083	1.31831	36
	I	6.3667	1.41744	36
	Total	5.9657	1.34186	108
O	C	5.8056	1.19665	36
	F	5.1361	1.38670	36
	I	5.1944	1.25606	36
	Total	5.3787	1.30614	108
S	C	5.5111	.89499	36
	F	5.2917	.72047	36
	I	6.1000	.91183	36
	Total	5.6343	.90628	108
Total	C	5.8130	1.09605	108
	F	5.2787	1.17466	108
	I	5.8870	1.30356	108
	Total	5.6596	1.22133	324

Table 4-15: Test of between-subjects effects for the medium group

Dependent Variable: Score					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Corrected Model	59.047 (a)	8	7.381	5.500	.000
Intercept	10377.950	1	10377.950	7732.765	.000
Pigment	18.713	2	9.356	6.972	.001
Illuminant	23.796	2	11.898	8.865	.000
Pigment * Illuminant	16.538	4	4.135	3.081	.016
Error	422.754	315	1.342		
Total	10859.750	324			
Corrected Total	481.800	323			
a. R Squared = .123 (Adjusted R Squared = .100)					

4.4.2.1. Pigment

Multiple comparisons (Table 4.16) revealed some significant differences ($p<0.05$). Make-up shade tabs ($p=0.001$) were scored significantly higher

than oil paint shade tabs. There was no statistically significant difference between silicone and make-up tabs or silicone and oil paint shade tabs.

The *post-hoc* Tukey HSD (Table 4.17) revealed two subsets of scores. Shade tabs pigmented with oil paint and silicone were scored similarly (p=0.238). Shade tabs pigmented with make-up was scored similarly to silicone (p=0.91) but higher on average than oil paint.

Table 4-16: Multiple comparisons for the effect of pigment in the medium group. M: make up; O: oil paint; S: silicone.

Dependent Variable: Score						
Tukey HSD						
(I) Pigment	**(J) Pigment**	**Mean Difference (I - J)**	**Std. Error**	**Sig.**	**95% Confidence Interval**	
					Lower Bound	**Upper Bound**
M	O	.5870*	.15765	.001	.2158	.9583
	S	.3315	.15765	.091	- .0398	.7027
O	M	- .5870*	.15765	.001	- .9583	- .2158
	S	- .2556	.15765	.238	. -.6268	.1157
S	M	- .3315	.15765	.091	- .7027	.0398
	O	.2556	.15765	.238	- .1157	.6268

Based on observed means

The error term is Mean Square(Error) = 1.381

* The mean difference is significant at the .05 level

Table 4-17: *Post-hoc* tests for the effect of pigment for the medium group. M: make up; O: oil paint; S: silicone

Score			
Tukey HSD (a,b)			
Pigment	**N**	**Subset**	
		1	**2**
O	108	5.3787	
S	108	5.6343	5.6343
M	108		5.9657
Sig.		.238	.091

Means for groups in homogenous subsets are displayed

Based on observed means

The error term is Mean Square(Error) = 1.342

a. Uses Harmonic Mean Sample Size = 108.000

b. Alpha = .05

4.4.2.2. Illuminant

Multiple comparisons (Table 4.18) revealed some significant differences ($P<0.05$). Shade tabs were scored significantly higher under colour corrected light ($p=0.002$) and incandescent light ($p<0.001$) compared with fluorescent light.

The *post-hoc* Tukey HSD (Table 4.19) revealed two subsets of scores. Shade tabs were scored similarly under colour corrected and incandescent light ($p=0.885$). Shade tabs were scored lower on average under fluorescent light.

Table 4-18: Multiple comparisons for the effect of illuminant in the medium group. C: colour-corrected; F: fluorescent; I: incandescent.

Dependent Variable: Score						
Tukey HSD						
(I) Illuminant	**(J) Illuminant**	**Mean Difference (I-J)**	**Std. Error**	**Sig.**	**95% Confidence Interval**	
					Lower Bound	**Upper Bound**
C	F	.5343*	.15765	.002	.1630	.9055
	I	- .0741	.15765	.885	- .4453	.2972
F	C	- .5343*	.15765	.002	- .9055	- .1630
	I	- .6083*	.15765	.000	- .9796	- .2371
I	C	.0741	.15765	.885	- .2972	.4453
	F	.6083*	.15765	.000	.2371	.9796

Based on observed means.

The error term is Mean Square(Error) = 1.342

*. The mean difference is significant at the .05 level

Table 4-19: *Post-hoc* test for the effect of illuminant for the medium group

Score			
Tukey HSD (a,b)			
Illuminant	**N**	**Subset**	
		1	**2**
F	108	5.2787	
I	108		5.8130
C	108		5.8870
Sig.		1.000	.885

Means for groups in homogenous subsets are displayed

Based on observed means

The error is Mean Square(Error) = 1.342

a. Uses Harmonic Mean Sample Size = 108.000

b. Alpha = .05

4.4.2.3. The interaction Effect

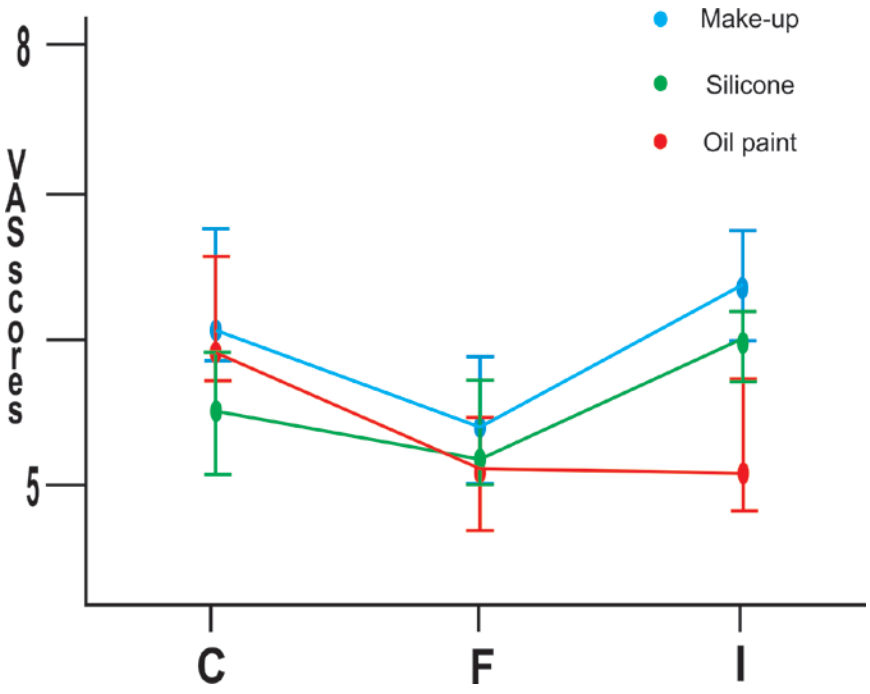


Figure 4.2: Profile plots of the effects of illuminant and pigments for the medium group. C: colour-corrected; F: fluorescent; I: incandescent/. Horizontal bars represent the Confidence Intervals.

The interaction effects are summarised in Table 4.20.

Table 4-20: Interaction effects for the medium group. The pigment and illuminant combination are shown by their initial letters; e.g. MC is Make-up under colour-corrected light, SF is silicone pigment under fluorescent light, etc. Read the table from the first column, so that MF and SC scored lower than MI, etc.

	MC	MI	MF	SC	SI	SF	OC	OI	OF
MF		lower							
SC		lower							
SF	lower	lower			lower				
OI	lower	lower			lower		lower		
OF	lower	lower			lower				

Table 4-21: Estimated marginal means for the effect of illuminant and pigment in the medium group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent

Pigment * Illuminant					
Dependent variable: Score					
Pigment	**Illuminant**	**Mean**	**Std. Error**	**95% Confidence Interval**	
				Lower Bound	**Upper Bound**
M	C	6.122	.193	5.742	6.502
	F	5.408	.193	5.028	5.788
	I	6.367	.193	5.987	6.747
O	C	5.806	.193	5.426	6.185
	F	5.136	.193	4.756	5.516
	I	5.194	.193	4.815	5.574
S	C	5.511	.193	5.131	5.891
	F	5.292	.193	4.912	5.672
	I	6.100	.193	5.720	6.480

4.4.3. Dark Group

A two-way ANOVA revealed significant differences ($p<0.05$) for pigments and illuminant and for the interaction of pigments and illuminant on the raters scores (Table 4.23). The Levene's test of equality of error variances was significant $p<0.05$

Table 4-22: Descriptive statistics for the dark group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent

Dependent Variable: Score				
Pigment	**Illuminant**	**Mean**	**Std. Deviation**	**N**
M	C	6.4306	1.28393	36
	F	5.2167	1.10647	36
	I	6.1917	1.30721	36
	Total	5.9463	1.33300	108
O	C	5.2556	1.34980	36
	F	5.0333	1.09753	36
	I	4.4694	1.49682	36
	Total	4.9194	1.35402	108
S	C	6.3222	2.00601	36
	F	5.3306	1.76325	36
	I	6.2361	1.85197	36
	Total	5.9630	1.91265	108
Total	C	6.0028	1.65385	108
	F	5.1935	1.35152	108
	I	5.6324	1.75972	108
	Total	5.6096	1.62688	324

Table 4-23: Tests of between-subjects effects for the dark group

Dependent Variable: Score					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Corrected Model	140.500 (a)	8	17.562	7.744	.000
Intercept	10195.390	1	10195.390	4495.442	.000
Pigment	77.171	2	38.585	17.013	.001
Illuminant	35.449	2	17.725	7.815	.000
Pigment * Illuminant	27.880	4	6.970	3.073	.017
Error	714.401	315	2.268		
Total	11050.290	324			
Corrected Total	854.900	323			
a. R Squared = .164 (Adjusted R Squared = .143)					

4.4.3.1. Pigment

Multiple comparisons (Table 4.24) revealed some significant differences ($p<0.05$). Make-up ($p<0.001$) and silicone shade ($p<0.001$) tabs were scored significantly higher than oil paint shade tabs.

The Tukey HSD *post-hoc* (table 4.25) evaluations confirmed the findings in the two-way ANOVA and revealed two subsets of data. Shade tabs pigmented with silicone or make-up were scored similarly ($p=0.996$), and were scored higher on average than oil paint shade tabs.

Table 4-24: Multiple comparisons for the effect of pigment for the dark group. M: make up; O: oil paint; S: silicone

Dependent Variable: Score						
Tukey HSD						
(I) Pigment	**(J) Pigment**	**Mean Difference (I - J)**	**Std. Error**	**Sig.**	**95% Confidence Interval**	
					Lower Bound	**Upper Bound**
M	O	1.0269*	.20494	.000	.5443	1.5094
	S	- .0167	.20494	.996	- .4993	.4659
O	M	- 1.0269*	.20494	.000	- 1.5094	- .5443
	S	- 1.0435*	.20494	.000	- 1.5261	- .5609
S	M	.0157	.20494	.996	- .4659	.4993
	O	1.0435*	.20494	.000	.5609	1.5261

Based on observed means

The error term is Mean Square(Error) = 2.268

* The mean difference is significant at the .05 level

Table 4-25: *Post-hoc* test for the effect of pigment for the dark group. M: make up; O: oil paint; S: silicone

Score			
Tukey HSD (a,b)			
Pigment	**N**	**Subset**	
		1	**2**
O	108	4.9194	
S	108		5.9463
M	108		5.9630
Sig.		1.000	.996

Means for groups in homogenous subsets are displayed

Based on observed means

The error term is Mean Square(Error) = 2.268

a. Uses Harmonic Mean Sample Size = 108.000

b. Alpha = .05

4.4.3.2. Illuminant

Multiple comparisons (Table 4.26) revealed some significant differences ($P<0.05$). Shade tabs were scored significantly higher under colour corrected light ($p<0.001$) compared with fluorescent light. There was no statistically significant difference between colour corrected light and incandescent light, and between incandescent light and fluorescent light.

The Tukey HSD *post-hoc* tests (Table 4.27) revealed two subsets of data. Shade tabs were scored similarly under fluorescent and incandescent light ($p=0.083$) and lower on average than colour corrected light, confirming the findings in the two-way ANOVA.

Table 4-26: Multiple comparisons for the effect of illuminant in the dark group. C: colour-corrected; F: fluorescent; I: incandescent

Dependent Variable: Score						
Tukey HSD						
(I) Illuminant	**(J) Illuminant**	**Mean Difference (I-J)**	**Std. Error**	**Sig.**	**95% Confidence Interval**	
					Lower Bound	**Upper Bound**
C	F	.8093*	.20494	.000	.3267	1.2010
	I	.3704	.20494	.169	-.1122	.8530
F	C	-.8093*	.20494	.000	-1.2929	-.3267
	I	-.4389	.20494	.083	-.9215	.0437
I	C	-.3704	.20494	.169	-.8530	.1122
	F	.4389	.20494	.083	-.0437	.9215

Based on observed means.

The error term is Mean Square(Error) = 2.268

*. The mean difference is significant at the .05 level

Table 4-27: *Post-hoc* tests for the effect of illuminant in the dark group. C: colour-corrected; F: fluorescent; I: incandescent

Score			
Tukey HSD (a,b)			
Illuminant	**N**	**Subset**	
		1	**2**
F	108	5.1935	
I	108	5.6324	5.6324
C	108		6.0028
Sig.		.083	.169

Means for groups in homogenous subsets are displayed

Based on observed means

The error is Mean Square(Error) = 2.268

a. Uses Harmonic Mean Sample Size = 108.000

b. Alpha = .05

4.4.3.3. The Interaction Effect

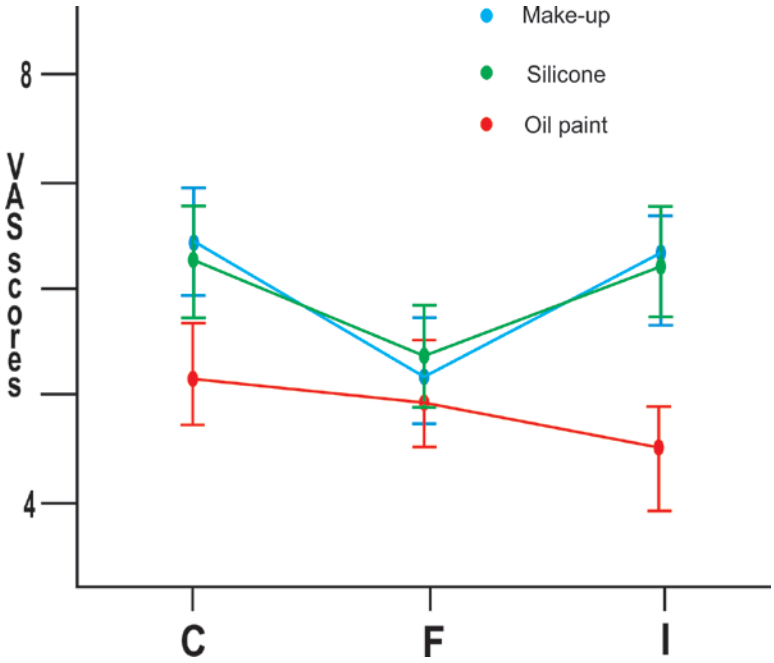


Figure 4.3: Profile plots of the effects of illuminant and pigment in the dark group. C: colour-corrected; F: fluorescent; I: incandescent. Horizontal bars represent the Confidence Intervals.

The interaction effects are summarised in Table 4.28.

Table 4-28: Interaction effects for the dark group. The pigment and illuminant combination are shown by their initial letters; e.g. MC is Make-up under colour-corrected light, SF is silicone pigment under fluorescent light, etc. Read the table from the first column, so that MF scored lower than SC and SI, etc.

	MC	MI	MF	SC	SI	SF	OC	OI	OF
MF				lower	lower				
SC									
SF	lower			lower					
OC	lower			lower	lower				
OI	lower	lower		lower	lower				
OF	lower	lower		lower	lower				

Table 4-29: Estimated marginal means for the interaction of illuminant and pigment for the dark group. M: make up; O: oil paint; S: silicone. C: colour-corrected; F: fluorescent; I: incandescent

Pigment * Illuminant					
Dependent variable: Score					
Pigment	Illuminant	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
M	C	6.431	.251	5.937	6.924
	F	5.217	.251	4.723	5.711
	I	6.192	.251	5.698	6.686
O	C	5.256	.251	4.762	5.749
	F	5.033	.251	4.539	5.527
	I	4.469	.251	3.976	4.963
S	C	6.322	.251	5.828	6.816
	F	5.331	.251	4.837	5.824
	I	6.236	.251	5.742	6.730

5. Chapter 5: Discussion

Shade determination is an important step in the construction of silicone maxillofacial prostheses. This has been achieved using different pigments and techniques (Beumer et al., 2011). Whilst the “trial and error” method is regarded as the most common method for shade determination, there are no studies that describe this/these methods completely (Coward et al., 2008).

Objective shade determination and assessment methods include the use of one of several devices such as spectrophotometers, colorimeters, or spectroradiometers. Whilst these devices have been useful in identifying colours in a predetermined colour sphere, there are many shortcomings and these methods should still be regarded as adjuncts to subjective shade determination and assessment (Coward et al., 2008; Hu, 2010). It appears that objective methods cannot be compared with subjective methods of shade determination, as the latter have yet to be fully described and evaluated in the literature.

This study used subjective methods to fulfil the aims and objectives, which sought to evaluate whether different pigments and/or illuminants affect the shade determination of silicone prostheses. Furthermore, this study sought to standardise an observation protocol and describe and assess a “trial and error” method of shade determination, which could be used to construct a future shade guide. The shade guide may ultimately improve shade matching efficiency and results.

The shade tabs were mixed under colour corrected light. The recipe for the construction of the shade tabs, using three different pigments, was established during the first mixing session. This recipe was meticulously recorded in order to assess the reproducibility at the future mixing sessions (two and three).

Each group (light, medium or dark) was considered separately and was not statistically compared with the two other groups as the evidence base suggested that different pigmentation techniques are required for different skin tones (Troppman et al., 1996; Seelaus et al., 2011).

Expert raters in the field of maxillofacial prosthodontics were identified, calibrated in the observation protocol and required to assess the shade match of tabs mixed with different pigments under three standardised sources of illumination for light, medium and dark skin tones.

Although this is a fairly unconventional use of the VAS scoring system, subjective assessment using this method has been validated in previous studies (Howells and Shaw, 1985). Unfortunately colour perception may be highly variable within and between raters. This may be due to physiological effects, such as observer metamerism, and/or psychological factors (Piérard, 1998). For this reason it is important to calibrate raters.

One of the objectives was to identify if there was a reliable method to construct a future shade guide. It is probable that the shade guide would have to be generic and only account for base shades. It would not be able to address factors such as skin texture or visibility of blood vessels etc. Thus the shade tabs would be smooth, only consist of one of the test pigments (silicone, oil paint or make-up), and would not include flocking for example. This meant that examiners, who were trained to assess maxillofacial prostheses, would not necessarily reliably and precisely assess base shade tabs.

A pilot study identified the difficulty in calibrating raters and thus a calibration protocol had to be developed and statistical analysis used to identify raters whose scores were similar enough to be averaged in subsequent analyses.

The calibration was completed through a process of “chunking” over six sessions (Miller, 1956). A PowerPoint (Microsoft, USA) presentation was initially used to explain the study, the aims and objectives, and to introduce the raters to the observation protocol detailing how this protocol was established (APPENDIX D). The initial presentation also introduced the different effects that surface texture and flocking had on prostheses and how the base shade tabs would not address these factors. We did, however, endeavour to select subjects with minimal textural and pigmentation variations in order to reduce the effect of this on the base shade tab assessment.

The second calibration session consisted of the raters assessing the shade tabs using their own method of assessment and not following the observation protocol. Later a discussion of the different assessments revealed large variability in their assessment scores.

The third calibration session consisted of discussion of the observation protocol and assessing whether this could be easily and reliably followed. The raters were required to evaluate the subjects' skin tones. For example: the medium skin toned subject had yellow, blue and white undertones. Thereafter the raters matched a few shade tabs using the observation protocol and a discussion ensued regarding the base shade match.

The fourth to sixth calibration sessions were completed prior to each assessment session. This included reinforcement of the observation protocol and assessment of the raters' ability to follow it. Subsequent to the matching of several shade tabs, the raters discussed the features of each shade tab under the different light sources that resulted in their scoring that match in a specific manner. These discussions culminated in an agreement of what they considered an acceptable match of the base shade.

The nature of the scoring process, however, may be considered complex in that there is no correct or true score of the shade match.

The scores were thus expected to result in rating variation, which could have confounded statistical analyses.

5.1.1. Rater Precision and Specificity

The intraclass correlation coefficient (ICC) indicated that all raters scored above the acceptable threshold 0.6 on average (Table 4.1 and 4.2). This suggested that both intra-rater reliability and inter-rater reliability were statistically acceptable and that the raters were calibrated in terms of their subjective assessments.

Since the raters' subjective scores appeared to correlate across assessment sessions it seems that the recipe is reproducible and that the "trial and error" approach described may be acceptable for constructing a future shade guide for silicone elastomer maxillofacial prostheses. However, the ICC represents the ratio of the variance between subjects to the sum of the error variance and the subject variance. If the variance between subjects is increased (numerator) the ICC will also be higher. This means that the reliability indicated by the ICC will appear higher as the range of data increases (Bruton et al., 2000).

The ICC analyses do not account for the range of scores provided by the raters. Whilst this statistical analysis indicated that the group of raters tended to score a certain tab similarly under different

illuminants across all three sessions, it did not reflect the precision of these scores.

For example, all the raters may have scored a particular shade tab well under colour corrected light and scored the same tab poorly under fluorescent light. One rater may have had scores of 7 and 4 respectively, and another rater may have had scores of 9 and 5 respectively. Both raters correlated in the direction of their score (high and low) but the positon on the VAS scale differed i.e. the precision and specificity was not addressed by the ICC. It was thus important to establish consistency, specificity and precision of the raters. Once calibrated raters were identified their scores could be averaged to determine the effect of pigments and illuminant on the colour perception.

A three-way ANOVA was completed to assess the effect of rater on the scores of the shade tabs. This revealed that there were some statistically significant differences ($p<0.001$) within all three groups (light, medium and dark).

The *post hoc* Tukey HSD test was used to distinguish statistically significant differences between raters. This revealed a number of subgroups of raters with similar average scores (Table 4.3-4.5).

In the light group the *post-hoc* tests revealed five subgroups (Table 4.3). This indicated that from a statistical perspective rater 6 and 2 were similar, but 6 scored significantly lower than 1. Rater 2 scored similarly to 1 but was significantly lower than 3 etc.
The average range over which these raters scored extended from 5.815 (rater 6) to 8.0654 (rater 5). This means that although there was acceptable interrater reliability, as indicated by the ICC, there was large variability in precision and specificity. This range was 2.1839 and this was considered both statistically and clinically significant by the final examiners. For example, a score of 5 to 6 may be considered acceptable but a score of 8 would be considered good.

In the medium group the *post hoc* evaluation revealed that there were four subsets of raters whose average scores were statistically different. Rater 6 had an average score of 4.4259, which was significantly lower than all other raters (Table 4.4). Raters 1 and 3 had scores significantly lower than raters 2 and 5 etc. The score range extended from 4.4259 (rater 6) to 6.4852 (rater 5). The range was 2.0593, which was considered both clinically and statistically significant by the final examiners.

In the dark group the *post hoc* evaluations revealed that there were two subsets of raters whose average scores were statistically different. Rater 6 again had the lowest score but this was similar to raters 2, 1, 3 and 5 (Table 4.5). The score range was 1.0062. This range is

considerably narrower compared with the light and medium groups. However, several trends are apparent in the ratings of the shade tabs.

The ranges for both light and medium tabs are wider than dark tabs. The maxillofacial prosthodontic clinic at the Wits Oral Health Centre manages substantially more dark skin toned patients than light and medium skin toned patients. This range may thus indicate that the examiners are more accustomed to assessing and matching darker skin tones and thus have a higher specificity and precision within this group.

The evaluation of the rater score ranges revealed another trend, which would allow us to exclude possible outliers and identify calibrated expert examiners. Rater 6 consistently scored lower on average compared with other raters. Rater 5 was consistently present in the subset of raters who scored higher on average, and was the highest scorer in both light and medium groups.

Rater 6 was the rater with the least experience of the examiners in the maxillofacial prosthodontic clinic. Rater 5 was not a maxillofacial prosthodontist but a make-up artist who assists in the maxillofacial prosthodontic clinic. These raters were thus excluded so that we could narrow the range of scores to below one score point and identify the four raters who demonstrated an acceptable degree of consistency, specificity and precision (Zisapel and Nir, 2003).

The four raters identified as having clinically acceptable precision and reliability was 1, 2, 3, and 4. The scores of these raters were thus averaged for the two-way ANOVA, which evaluated the effect of the pigment type and illuminant and their interaction. The averaging of the scores of these four raters was completed after discussion between the principal investigator and the final examiners. The score ranges were deemed acceptable for averaging for the purpose of further statistical evaluations (Zisapel and Nir, 2003).

5.2. Homogeneity of Variances

Prior to the two-way ANOVA a Levene's test of equality of error variances was completed for each of the groups. In the light group this did not reveal a significant difference but in the medium and dark groups it did reveal a significant difference ($p<0.05$). This indicated that the raters were not consistent in the rating variation.

The two-way ANOVA is considered robust enough to manage some heteroscedasticity provided the sample sizes are equal. Also, the preliminary Levene's test may not impart any substantial value to the two-way ANOVA (Zimmerman, 2004). It has been shown that type 1 errors occur within the preliminary tests themselves. It was suggested that sample size differences are more important than heterogeneity of the data and that the use of these tests is related to the statistical software rather than their usefulness in analyses (Zimmerman, 2004). Also, the spread of the data appeared to be similar.

This does further illustrate, however, the difficulty in calibrating raters for this form of subjective assessment. There may be any number of factors that could have affected the scores, which could not have been controlled in this study.

5.2.1. The Effect of Pigment

Multiple comparisons showed that there were significant differences ($p<0.05$) with regards to the different pigments used (Tables 4.8, 4.16, 4.24). Further *post-hoc* analysis revealed which pigment group/s were scored higher or lower compared with others.

In the light and medium groups the shade tabs mixed with make-up were scored higher than those mixed with oil paint or silicone pigments (Tables 4.9 and 4.17).

In the dark group both silicone pigments and make-up were scored higher than tabs mixed with oil paint (Table 4.25)

These findings suggest that oil paint may be an inferior pigment in the construction of silicone elastomer maxillofacial prostheses. Oil paint has, however, not been used in our clinic for more than five years and we currently lack the expertise for the use of this material. Thus these results are more likely due to operator error.

Make-up tabs were scored consistently higher despite a lack of expertise with this material. The pigment consisted of premixed make-up base skin hues. Oil paint and silicone in comparison had to be mixed from primary and secondary hues such as umber, blue, white etc. This means that significantly more evaluation of the underlying skin tones that form a subject's skin shade had to be completed. It is thus possible that make-up was scored higher as it presented with higher operator ease during the mixing of the shade tabs, which may have reduced errors.

Silicone pigments also had to be mixed from primary and secondary hues, yet scored higher in the dark skin shades than oil paint. This may be due to the ease of use and transparency of these pigments, which were developed specifically for use in silicone elastomers. Silicone pigments are routinely used in the clinic and thus the principal investigator was more familiar with this material.

Furthermore, the principal investigator found that oil paint was opaque and that small additions of pigments severely affected the hue of the shade being mixed. Silicone pigments may also have produced better results in the dark group as these are the skin tones most frequently encountered in our clinic and thus we may be both better at mixing for these skin shades as well as better at evaluating skin to shade tab match for darker skin tones compared with lighter ones.

5.2.2. The Effect of Illuminant

The two-way ANOVA revealed significant differences ($p<0.05$) with regards to the illuminant under which the shade tabs were evaluated Table 4.10, 4.18, 4.26). The *post-hoc* evaluations revealed where these differences lay.

In the light and dark groups shade tabs were scored higher under colour corrected light compared with incandescent and fluorescent light (Table 4.11, 4.27).

In the medium group shade tabs were scored higher under both colour corrected light and incandescent light compared with fluorescent light (Table 4.19).

Considering the randomising process of scoring shade tabs it seems logical to conclude that fluorescent lighting and thus illuminant metamerism does affect the shade perception of pigmented silicone.

5.2.3. The Interaction between Pigment and Illuminant

There appears to be an interaction with the variables illuminant and pigment types. The profile plots indicated that the interaction between oil paint and fluorescent and incandescent light reduced the scores of the shade tabs (Figures 4.1, 4.2, 4.3).

The interaction effects also seem to indicate that shade tabs pigmented with oil paint viewed under fluorescent and incandescent light, and tabs pigmented with silicone viewed under fluorescent light are scored lower on average. This could mean that make-up is easier to use and fluorescent light tends to result in worse illuminant metamerism. It may thus be recommended to complete shade matching and pigmenting of silicone under colour corrected illumination.

Since make-up may have a smaller learning curve this pigment may be more easily used by beginner maxillofacial prosthetists. An advantage of this is that the make-up can also be used by the patient to mask the prosthesis and improve its longevity. Patients could also be advised to use colour corrected or incandescent lights in their homes to reduce the effect of illuminant metamerism.

5.3. Limitations

Subjective shade matching may be affected by various factors, which could be both physiological and psychological. Although we attempted to control the shade matching and assessment methods as far as possible one cannot account for these factors. This may have resulted in the variations in the ratings, which may have confounded the findings.

The principal investigator was not familiar with oil paint as a pigment for maxillofacial prostheses and this could have resulted in the lower

scores for oil paint. There does appear to be a steep learning curve with the use of oil paint compared with make-up, with which the principal investigator was also not familiar.

6. Chapter 6: Conclusions and Recommendations

Within the limitations of the study the results indicate the following:

The null hypothesis that the pigment types do not affect the scores of the shade tabs was rejected.

Oil paint appeared to have the worst scores. This may indicate that make-up and silicone pigments have a smaller learning curve and greater ease of use than oil paint for constructing silicone elastomer maxillofacial prostheses. Make-up has the additional benefits of being cost-effective, readily available to both the clinician and patient, and allows patients to use it as a masking agent.

Future studies are required to explore the effect of pigments and illuminant metamerism on the perception of silicone elastomer prostheses. They may evaluate the effect of flocking and texture on the scores of the shade tabs. Investigators/clinicians who are familiar with pigments such as oil paint may yield different results.

The null hypothesis that the illuminant does not affect the scores of the shade tabs was rejected.

Shade tabs were scored significantly lower under fluorescent lighting indicating that illuminant metamerism affected the shade perception of maxillofacial prostheses. It is recommended that shade assessment and

mixing of maxillofacial prostheses be completed under colour corrected light. Furthermore, patients should be warned of the effect of illuminant metamerism, especially with regards to fluorescent lighting. It may be recommended to patients to use colour corrected or incandescent lights at home.

The null hypothesis that the interaction between the pigment type and illuminant does not affect the scores of the shade tabs was rejected.

The interaction between oil paint and fluorescent lighting consistently produced lower scores.

The null hypothesis that the method to devise and assess the shade matching protocol will not be reliable was rejected.

The null hypothesis that the method to construct a shade guide will not be reliable was rejected.

Whilst the raters were not consistent in their rating variation there appeared to be sufficient evidence that base shade tabs may be used for shade matching under colour corrected light. The corresponding recipe may be used to establish an initial silicone elastomer pigmentation, which can be further improved with flocking and surface texture. Furthermore, the shade matching protocol appears to improve shade assessment. Future studies may evaluate the ease of use of shade tabs for constructing maxillofacial prostheses.

7. References

Al-Harbi FA, Ayad NM, Saber MA, ArRejaie AS, Margano SM (2015). Mechanical behaviour and color change of facial prosthetic elastomers after outdoor weathering in a hot and humid climate. J Prosthet Dent 113:146-51.

Beumer J, Marunick MT, Esposito SJ. ed., (2011). Maxillofacial rehabilitation. 3rd ed. Quintessence: Chicago.

Bruton A, Conway JH, Holgate ST (2000). Reliability: what is it, and how is it measured? Physiotherapy 86:94-9.

Chinn S (1991). Statistics in medicine. 2. Repeatability and method comparison. Thorax 46:454-6.

Cole BL (2007). Assessment of inherited colour vision defects in clinical practice. Clin Exp Optom 90:157-75.

Coward TJ, Seelaus R, Li SY (2008). Computerised color formulation for African-Canadian people requiring facial prostheses: a pilot study. J Prosthodont17: 327-35.

Figura L, Teixeira AA (2007). Food physics: physical properties – measurement and application. Springer: Berlin.

Fondriest J (2003). Shade matching in restorative dentistry: The science and strategies. Int J Periodontics Restorative Dent 23:467–79

Howells DJ, Shaw WC (1985). The validity and reliability of ratings of dental and facial attractiveness for epidemiological use. Am J Orthod 88:402-8

Hu X (2010). Analysis of effects of pigments on maxillofacial prosthetic material [dissertation]. Ohio: Ohio State University.

Ishihara S (1972). Ishihara's tests for colour-blindness (concise edition). Kanehara Shuppan Co. Ltd: Tokyo.

Leow ME, Pereira BP, Kour AK, Pho RW (1999). Metamerism in aesthetic prostheses under three standard illuminants – TL84, D65 and F. Prosthet Orthot Int 23:174-80.

MacDougall DB ed (2002). Colour in food: improving quality. Cambridge: Woodhead Publishing Limited.

Miller GA (1956). The magical number seven plus, or minus two: Some limits on our capacity for processing information. Psychological Review 63:81-97.

Montgomery PC, Kiat-Amnuay S (2009). Survey of currently used materials for fabrication of extra-oral maxillofacial prostheses in North America. Europe, Asia, and Australia. J Prosthodont 19:482-90.

Piérard GE (1998). EEMCO guidance for the assessment of skin colour. J Eur Acad Dermatol Venereol 10:1-11.

Rodriguez-Carmona M, O'Niell-Biba M, Barbur JL (2012). Assessing the severity of color vision loss with implications for aviation and other occupational environments. Aviat Space Environ Med 83:19-29.

Seelaus R, Coward TJ, Li S (2011). Coloration of silicone prostheses: technology versus clinical perception. Is there a difference? Part 2, clinical evaluation of a pilot study. J Prosthod 20: 67-73.

Sproull RC (1973). Colour matching in dentistry II. Practical applications of the organization of color. J Prosthet Dent 29:556-66.

Troppmann RJ, Wolfaardt JF, Grace M, James AS (1996) Spectrophotometry and formulation for coloring facial prosthetic silicone elastomer: A pilot clinical trial. American Journal of Facial and Somato Prosthetics 2: 85-92.

Wolfaardt JF, Chandler DH, Smith BA (1985). Mechanical properties of a new facial prosthetic material. J Prosthet Dent 53:228-34.

Zimmerman DW (2004). A note on preliminary tests of equality of variances. Br J Math Stat Psychol 57:173-81.

Zisapel N, Nir T (2003). Determination of the minimal clinically significant difference on a patient visual analog sleep quality scale. J Sleep Res 12:291-8

APPENDIX A: Informed Consent and Participant Information Sheet

PARTICIPANT INFORMATION SHEET: ASSESSORS

Dear Assessor

I am Dr Karen Bennie and I am conducting research for the completion of my MDent degree in Prosthodontics at the Wits Oral Health Centre. As you know, patients with facial defects require prostheses which must conform to the correct shade, surface details and shade of the surrounding tissue. Unfortunately this process is widely completed as a “trial and error” procedure, which makes shade matching difficult. Poor shade match may affect a patient’s acceptance of the prosthesis and cause psychological stress. Shade can also be affected by the source of light that the patient is under. A colour difference of the same prosthesis due to the light source is known as illuminant metamerism.

Thus the aim of this research project is to assess the metamerism of a facial silicone elastomer using three different pigmentation systems and to derive an appropriate method to construct a shade guide for clinical use.

The benefit of constructing this research is the improvement of clinical results through a standardised approach to shade matching. Furthermore, it is hoped that pigments that may decrease metamerism will be identified and a method to construct a shade guide evaluated.

I am inviting you to be a part of this study as you are part of a pool of clinicians and allied health service providers in the Department of Oral

Rehabilitation at the Wits Oral Health Centre. You would be required to assess the shade of silicone tabs against three different skin tones, and to mark the degree of shade match on a 10cm Visual Analog Scale. The assessment will be done using the protocol set our below.

You will be required to undergo an Ishihara Colour Vision test prior to the visual evaluation. You will be required to evaluate a series of 38 colour plates and state the number on the plate or the number of lines present on the plate. You will be provided with the results of this test.

Three sessions of shade assessment will be required and it is envisaged that the entire session will take no longer than two hours. This study will most likely be performed on Tuesday, Wednesday and Thursday afternoons over a two-week period from 10 May 2016 to 20 May 2016. The research will be conducted at Polyclinic 1 at the Wits Oral Health Centre.

Your participation is voluntary and you may withdraw at any point should you wish. There will be no penalty to you should you withdraw from this study.

The results of the research will be made available through a research report, which will be published on the University of the Witwatersrand website for Theses and Dissertations. However, a summary can be made available to you should you request it. Your anonymity will also be maintained in the recording and publication of any results.

My and my supervisors' contact details are below:

Karen Bennie: karen.bennie@wits.ac.za, 011 4884883, 0828541477

Prof. CP Owen: peter.owen@wits.ac.za, 011 4884883

Dr. MM Thokoane: meriting.thokoane@wits.ac.za, 011 4884882

OBSERVATION PROTOCOL TO BE FOLLOWED

OBSERVATION FEATURES

- Illuminant source must be at a an equal vertical and horizontal distance from the observation area at each evaluation session.

SUBJECT (participant)

- Wear a neutral colour e.g. white or grey

OBSERVER

- Evaluate the colour match between the pigmented silicone and the adjacent skin region.
- Position yourself no less than 50cm from the patient.
- Assess the patient at a 0 degree observation angle.
- Do not look at the area for longer than 5 seconds.
- Assess the patient at approximately 45 degree angle, from left and right.
- You may look at the area as many times as you require to make your decision but look at the complimentary colour tile in-between evaluations.
- Rate the shade match on a scale from 0 – 10 where 0=completely unacceptable and 10=excellent colour match.
- Complete this for each shade tab under all three illuminants.

Thank you for you participation.

Kind regards,

Karen Bennie

Informed Consent for participation in the study “Metamerism of three different pigments for facial prostheses and a method to improve shade evaluation”

Dear Dr Bennie

I, _____, hereby confirm that the details of this study have been explained to me fully and that I understand the study, the risks and benefits.

I have been informed that:

There will be no remuneration for participation in this study.

I am allowed to withdraw from this study at any point should I wish. This will not result in any penalties.

I will be required to make several assessments of skin and silicone tab shade match, using a Visual Analogue Scale. This will be completed over a period of two weeks. There will be one session a day, on Tuesday, Wednesday and Thursday afternoons. This will take place from 10 May 2016 to 20 May 2016. Each session will be no longer than 2 hours.

I have been provided with a protocol for visual observation and have understood the procedure as explained to me.

I understand that my anonymity will be maintained.

The results of this study will be made available in the format of a research report, which will be published on the University of the Witwatersrand’s website for Theses and Dissertations. My anonymity will be maintained in any publications.

I have been provided with the contact details of the researcher and the supervisors of this study.

I hereby consent to participate in this study.

_____
_____
Name and surname of participant Date

_____
Signature of participant

_____
_____
Signature of witness Date

Dear Participant

I am Dr Karen Bennie and I am conducting research for the completion of my MDent degree in Prosthodontics at the Wits Oral Health Centre. Patients who have facial defects e.g. resected ears etc. require replacement of these tissues, which can be provided through construction of a silicone prosthesis. In order for this to appear natural, the prosthesis must conform to the correct shade, surface details and shade of the surrounding tissue. Prostheses are constructed from medical grade silicone and pigments are added to match the tissue shade. Unfortunately this process is widely completed as a "trial and error" procedure, which makes shade matching difficult. Poor shade match may affect a patient's acceptance of the prosthesis and cause psychological stress. Shade can also be affected by the source of light that the patient is under. A colour difference of the same prosthesis due to the light source is known as *illuminant metamerism*.

Thus the aim of this research project is to assess the metamerism of a facial silicone elastomer using three different pigmentation systems and to derive an appropriate method to construct a shade guide for clinical use. The benefit of constructing this research is the improvement of clinical results through a standardised approach to shade matching. Furthermore, it is hoped that pigments that may decrease metamerism will be identified and a method to construct a shade guide evaluated.

I am inviting you to be a part of this study. You were chosen because you have the required skin features necessary for evaluating shade matching in this study.

You will be required to attend a session where your skin shade will be assessed and several pigmented silicone tabs matched to your skin shade. On three separate occasions you will be required to remain seated in three separate rooms, where evaluators will assess the shade match several silicone tabs, which have been missed to match you skin shade. The silicone tabs will be adhered to your skin through a medical adhesive (Pros-aide Medical Adhesive, ADM Tronics Inc., USA). This adhesive has a very low reported rate of mild skin irritation. Prior to the study, a small test patch for skin sensitivity will be completed on the lower forearm. Should you wish, you will be referred to a General Practitioner or Dermatologist in the event that you develop a skin reaction. The adhesive may be removed with a lukewarm soapy water solution.

Three sessions of shade assessment will be required and it is envisaged that the entire session will take no longer than two hours. You will be required to wear clothes of a neutral grey or white on all four occasions.

This study will most likely be performed from 10 May 2016 to 20 May 2016, from 12:00 to 14:00 on Tuesday, Wednesday and Thursday afternoons over a two-week period. The research will be conducted at the Polyclinic 1 at the Wits Oral Health Centre.

By agreeing to be a part of this research you understand that there will be no payment for your participation. However, this participation is voluntary and you may withdraw at any point should you wish. There will be no penalty to you should you withdraw from this study.

The results of the research will be made available through a research report, which will be published on the University of the Witwatersrand website for Theses and Dissertations. However, a summary can be made available to you should you request it. Your anonymity will also be maintained in the publication of any results.

My and my supervisors contact details are below:

Karen Bennie: karen.bennie@wits.ac.za, 011 4884883, 0828541477

Prof. CP Owen: peter.owen@wits.ac.za, 011 4884883

Dr. MM Thokoane: meriting.thokoane@wits.ac.za, 011 4884882

Thank you for you participation.

Kind regards,

Karen Bennie

Informed Consent for participation in the study “Metamerism of three different pigments for facial prostheses and a method to improve shade evaluation”

Dear Dr Bennie

I, _____, hereby confirm that the details of this study have been explained to me fully and that I understand the study, the risks and benefits.

I have been informed that:

There will be no remuneration for participation in this study.

I am allowed to withdraw from this study at any point should I wish. This will not result in any penalties.

I will be required to attend several sessions where my skin tone will be matched to pigmented silicone. I will be required to remain seated in several rooms, each with different lighting.

This will be completed over a period of four weeks. There will be one session a day, on Tuesday, Wednesday and Thursday afternoons. This will take place from 10 May 2016 to 20 May 2016. Each session will be no longer than 2 hours.

I will be required to remove all make-up and wear neutral grey or white clothes.

I understand that my anonymity will be maintained.

The results of this study will be made available in the format of a research report, which will be published on the University of the Witwatersrand’s website for Theses and Dissertations. My anonymity will be maintained in any publications.

I have been provided with the contact details of the researcher and the supervisors of this study.

I am aware that the skin adhesive used may cause a mild skin reaction. I may undergo a small test patch on the lower forearm prior to participating in this study to assess skin sensitivity.

I may be referred to a General Practitioner or Dermatologist in the event of developing a skin reaction.

I hereby consent to participate in this study.

_____ _____

Name and surname of participant Date

_____

Signature of participant

_____ _____

Signature of witness Date

APPENDIX B: Ethics and PG Approval Letters

R14/49 Dr Karen Ruet Bennie

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160119

NAME: (Principal Investigator)	Dr Karen Ruet Bennie
DEPARTMENT:	Oral Rehabilitation University of the Witwatersrand
PROJECT TITLE:	Metamerism of Three Different Pigments for Facial Prostheses a Method to Improve Shade Evaluation
DATE CONSIDERED:	29/01/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof CP Owen and Dr MM Thokoane
APPROVED BY:	Professor P. Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	11/03/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

07 March 2016
Person No: 521707
PAG

Dr KR Bennie
261 Olivier Street
Brooklyn
0181
South Africa

Dear Dr Bennie

Master of Dentistry: Approval of Title

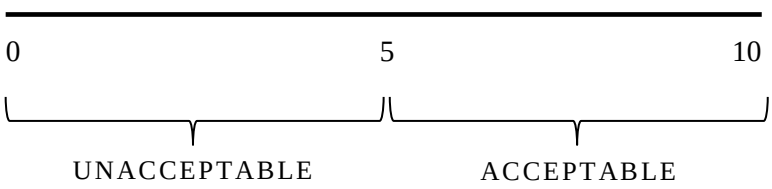
We have pleasure in advising that your proposal entitled *Matamerism of three different pigments for facial prostheses and a method to improve shade evaluation* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

APPENDIX C: Visual Analogue Scale

INVESTIGATOR CODE: _____ ROOM: _____ DATE: _____



APPENDIX D: Calibration PowerPoint Presentation

Metamerism of three different pigments for facial prostheses and a method to improve shade evaluation

KR Bennie: BDS, MScDent

Supervisors:
CP Owen
MG Thokoane

Department of Oral Rehabilitation

Aim

To assess the metamerism of a facial silicone elastomer using three different pigmentation systems and to derive an appropriate method to construct a shade guide for clinical use.

Objectives

1. Standardise three different pigmentation techniques
2. Visually assess the illuminant metamerism, three standard illuminations.
3. Produce reliable method to construct a shade guide.
4. Devise and assess a shade matching protocol.

Methods and Materials

- 3 volunteers: skin shades
- 6 expert examiners: Ishihara colour blindness test
- 3mm templates
- A2000 RTV silicone elastomer:
  - Group 1: silicone pigments
  - Group 2: Oil paints
  - Group 3: Kryolan make-up

- Principle investigator:
  - Match and mix silicone
  - Standard artificial daylight
  - "trial and error"
  - Measure quantity materials
  - 3mm tile: right malar
- 2 Expert examiners: rate shade match
- Completed in triplicate: consistency
  - One week intervals

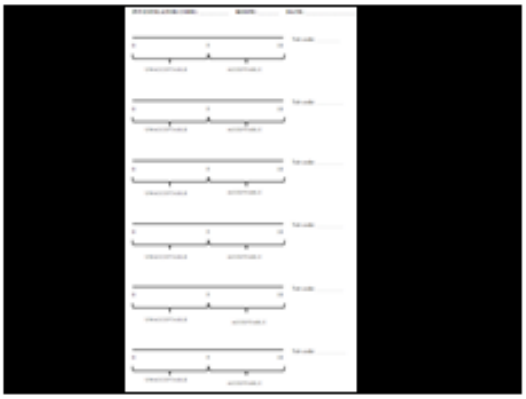
- Tiles will be coded
- 3mm tile adhered to skin
- 7 Expert examiners:
  - Observation protocol
  - VAS 0-10:
    - 0-5 = unacceptable
    - 6-10 = acceptable
  - 3 different illuminant sources

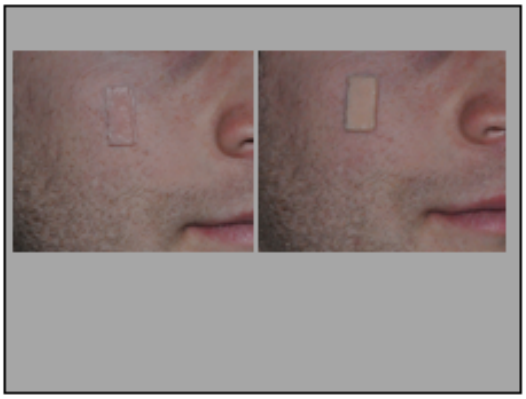
Observation Protocol

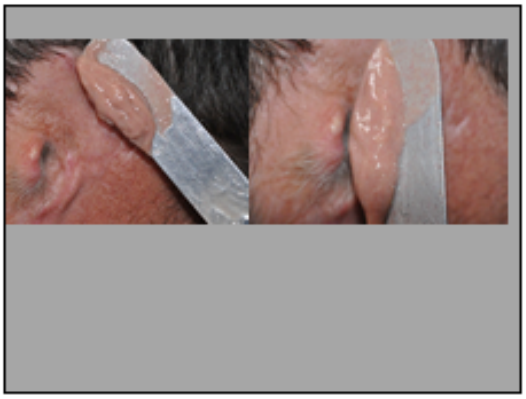
- Illuminant source 45 degree angle to subject
- Wear a neutral colour
- Evaluate the colour match
- 50cm from the subject
- 0 and 45 degree observation angle.
- 7 seconds
- Maximum 30 seconds
- Neutral grey colour tile in-between evaluations.
- Rate the shade match

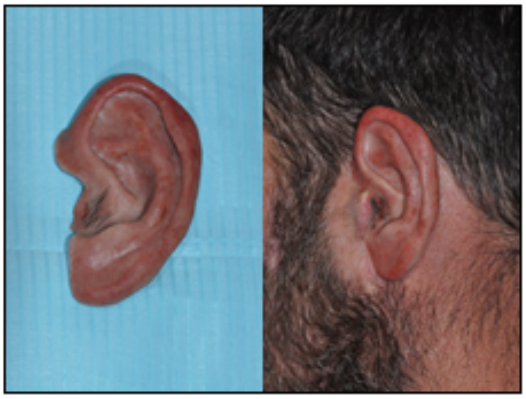
Base Shade

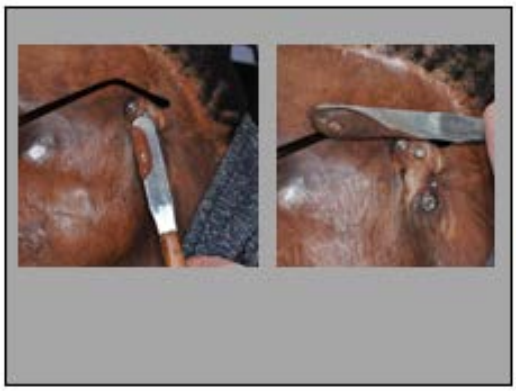
- Match tab to LEAST pigmented malar area
- NO FLOCKING
  - Flocking: fine vessels, decreases translucency, irregularities
- NO EXTRINSIC
- Base shade: last intrinsic colour without flocking
- Just need flocking or close without flocking: 8-10
- If shade is wrong: 0-5
  - orange vs pink:
- If acceptable: 6-7
  - requires flocking, make-up & extrinsic or
  - needs to be more concentrated (too translucent)
- Light skins: more translucent i.e. less concentration of pigment

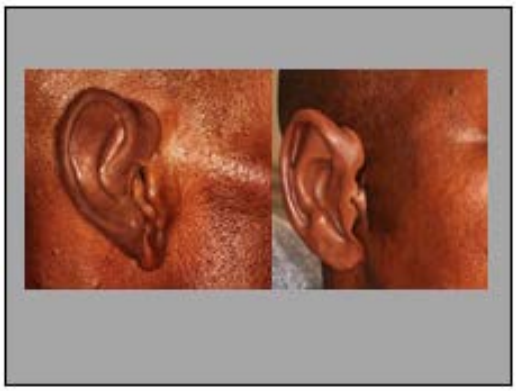












APPENDIX E: Turnitin Report

Turnitin screen shot of report showing zero matches.