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ORIGINAL ARTICLE

The Reproducibility and Applicability of an EFD® Dispenser in the Prosthetic Technology of Maxillofacial Prostheses

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Abstract A reproducible method of dosing pigments can be beneficial and more efficient in the current colour matching procedure in maxillofacial prosthetics. In this study the reproducibility and applicability for pigment dosing of a commercial available EFD® dispenser were tested. The reproducibility of a Performus™ II type EFD® dispenser was tested by repeating dosing experiments with a set of eight syringes filled with pigment pastes (Factor 2; Flagstaff, USA). To evaluate conventional colour matching, four conventionally colour matched samples were polymerized and compared to the original ones. To investigate the reproducibility of the dispenser in practice, a fifth recipe was dispensed 10 times and colour differences were evaluated visually and as well calculated from measurements with a colour and translucency meter (CTM, PBSensortechnology bv). All dispensed amounts of pigment pastes showed a coefficient of variation in weight of less than 10 %. Evaluating the reproductions of four skin batches compared to the original batches, a ΔE2000 colour difference of 3–7 was measured. Evaluating ten reproductions of one skin coloured batch made with the dispenser, color difference ΔE2000 values compared to the average L*a*b* values, were less than 2 and no visual colour differences could be estimated. Conform these results, low colour differences could be measured with the CTM, indicating no visually observable consequences. Despite the estimated coefficient of variation, the reproducibility of the EFD® dispenser in terms of colour difference ΔE2000 of successive dispensing is applicable for colour reproduction in facial prosthetics. Segregation of the current color pastes in due time needs to be taken into consideration.

Keywords Maxillofacial prosthetics · Colour matching · Pigments · Dispenser · Spectrophotometer

Abbreviations

CTM	Colour and translucency meter
CIE	Commission internationale de l'Eclairage
CIEDE2000	Colour difference described according to the CIE. CIE dE2000, ΔE2000 or dE00

Introduction

Facial prostheses have a relative short lifetime, caused by internal and external discolouring and disintegration. These aspects result in frequent indications for retreatment within a period of 1–2 years [1–3]. An inconspicuous prosthesis is of importance for both aesthetic and patient's psychosocial

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function and interpersonal interactions [4]. The aesthetic function of a facial prosthesis requires a good colour match with the surrounding skin areas. An isomeric spectral colour match of the prosthesis with the adjacent skin structures, under different light circumstances, is the ultimate goal [5].

The conventional procedure of colour matching in maxillofacial prosthetics based on a visually correct–correct procedure is time consuming and not reproducible [4]. A reproducible method of dosing pigments can be beneficial and more efficient within this current colour matching method in maxillofacial prosthetics [4]. Quantification and registration of the pigments by dosing with a dispenser might enable the prosthodontist to use the same composition of pigments for manufacturing a remake of a facial prosthesis. The pigment composition, once quantified for an individual patient, can easily be repeated to obtain a similar base colour.

The application of a reliable dispenser system in combination with a dedicated colour and translucency meter (CTM) might introduce a new method of colour formulation and colour matching in maxillofacial prosthetics [6, 7]. Reproducibility in pigment paste dosing is essential in improving colour formulation in the colour matching procedure.

The applicability of an EFD® dispenser system for use in maxillofacial prosthetics is subject to this study. The aim of this study was to test a commercially available EFD® dispenser for applicability and reproducibility in dosing pigment pastes for facial prostheses.

Materials and Methods

In this study an EFD® dispenser type Performus™ II with a piston type air compressor EFD® dispenser of Engineered Fluid Dispensing™ was selected (EFD Inc. a Nordson company, http://www.efd-inc.com/) (Fig. 1). The dispenser was connected to an air compression system to press a piston through a syringe. The dispenser had an adjustable function of pressure and dosing time. With a foot pedal, the dispenser presses the pigment pastes through the syringes (Fig. 2).

The dispenser was used in combination with eight general purpose syringes (30 cc) with white or red pistons and 12.70 mm and 23 gauge needles (orange, type 5123-B) or 6.35 mm and 27 gauge needles (white, type 5127-0.25B). The syringes were filled with eight different colour pigment pastes (Factor 2; Flagstaff, USA) (Fig. 2): white (Lot: R090805), black (Lot: R013003), red/brown (Lot: 200306), red (Lot: R052505), yellow (Lot: R061104), blue (Lot: RU041601), buff (Lot: R14461) and flesh (Lot: R1219055).

The syringes were filled with the pigment pastes with excluding air by manual centrifugation of the pastes into the syringes.

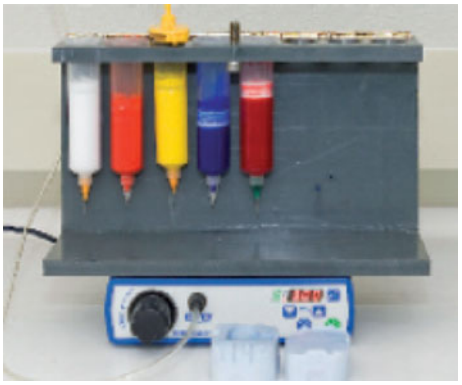

Fig. 1 EFD®, Engineered Fluid Dispenser, Performus™ II (source: http://www.efd-inc.com), adapted to several of the syringes with pigment pastes

Fig. 2 Syringes filled with pigment pastes (Factor 2; Flagstaff, USA) connected to air pressure with a yellow coloured adapter

The first tests were performed in order to make selections of variables (air pressure, piston type, needle size, whether or not dispensing in advance) to detect the most favourable circumstances for obtaining reliable and reproducible results. These initial tests lead to recommendations for use of the dispenser in maxillofacial prosthetic practice. The pressure of 4.0 bar for the following experiments was chosen because of the air pressure available in prosthetic practice and laboratory. Needle diameter selection was performed with regard to the different viscosities of the pigment pastes. The different pigment pastes had different viscosities, which had consequences for the choice of needle diameters. A higher viscosity of pigment paste required a larger needle diameter to obtain an effective paste flow through the needle. For each pigment paste the needles were tested upon reproducibility according to the quantities of pigment pastes expelled by the dispenser and the viscosity of the pigment pastes. The small needles (white, 6.35 mm and 27 gauge) were selected for pigments with a low viscosity: black, blue, buff, flesh and red. The wider needles (orange, 12.70 mm and 23 gauge) were

selected for pigment pastes with a higher viscosity: white, red/brown and yellow.

Previous to the measurements, the needle was levelled off 20 s in an angle of 45 degrees on a test cup in order to clear the needle from possibly dried pigment paste.

After this, the tip of the needle connected with the syringe was placed on a cup in an angle of 45 degrees and with careful manual handling pulled back in a straight line. All pigments were dispensed five times for 10 s using a pressure of 4.0 bar. The cups with the pigment pastes were weighed with a Sartorius microbalance (ME235P) before and after dosing with the dispenser. The data of all measurements were calculated and transferred in MS Excel. The averages, standard deviation and coefficient of variation (standard deviation/average, in %) were calculated.

Tests of colour matching and polymerisation of silicone with pigments were performed by reproduction of five original skin coloured batches of silastic elastomer of previous made prostheses. Five original batches were reproduced by the visual conventional colour matching (correct–correct) procedure, performed by an experienced maxillofacial prosthodontist. 20.0 g of platinum polymerised silastic elastomer (VST50 HD, Factor 2, Flagstaff, AR,USA), 10 % (2.0 g) catalyst (lot. R0505K115) were used for these samples. The amounts of different pigment pastes used in these copies were measured by weighing. The measured weights of the pigments, as well as seconds of dispensing were noted. The number of seconds to dispense each pigment for a certain batch was calculated in order to be able to reproduce the batch with the dispenser. This was calculated by dividing the milligrams pigment paste needed in the 'recipe' by the mg/s per pigment paste using the results of the first reproducibility test. In this way, five 'recipes' of pigment pastes for five reproduced skin coloured samples were obtained.

For spectrophotometric measurement and calculation of the colour difference a colour and translucency spectrophotometer (CTM) was used [6]. With the CTM spectrophotometer the samples were measured and the colour differences calculated. Colour differences are calculated with the colorimetric colour difference via **L*a*b*** values. ***L**** determines lightness, white (100) versus black (0). ***a**** Determines green (−) versus red (+) proportion and ***b**** blue (−) versus yellow (+) proportion in this three dimensional visual space [5, 8, 10]. The distance between 3 colour coordinates is used to calculate the difference between two colours. This calculated difference between two colours is delta E [5, 8–11]. A colour difference i.e., dE or ΔE of 2–5 is hardly visible for an untrained eye; a trained eye can not distinguish colour differences <dE 2. [7, 8].

Colour difference CIE dE2000, ΔE2000 or dE00, has been approved by the CIE and published as CIE Technical Report, "Improvement to Industrial Colour-Difference Evaluation" [10, 11].

After polymerization of four of the colour matched test batches, we calculated colour difference in ΔE2000 to the original batches in order to evaluate the visual conventional colour matching procedure.

Ten copies were made of the fifth recipe of the visually matched batches (no. V). With the CTM spectrophotometer the samples were measured and the colour differences calculated.

The colour difference (ΔE2000) was assumed to be satisfying when below 5, and very satisfying below 2, considering the minimal observable colour differences by an observer. [6, 10, 12].

The colour coordinates expressed in L*a*b* and their respective differences expressed in ΔE2000 (CIE) values, were compared to the average values. Chroma (C) was calculated ($\sqrt{(a^2 + b^2)}$) from these results and the range of batches ordered by ascending chroma. This order was compared to the colour order determined visually in the following experiment.

The observable differences between these ten samples were scored by three observers in standard light circumstances (clear sky, northern light). In this visual observation experiment, the ten copied batches were scored five times by three observers, to rank from light to dark chroma. The colour ordering according to CTM chroma measurements was considered the standard ordering and therefore was used as reference. The observer colour ordering was compared to the reference. Differences between the observed ranking and the reference were noted by absolute subtraction. A total difference of zero means complete agreement with the reference. A maximal deviation of 50 means complete disagreement. The data were analysed in SPSS using the Friedman test. The Friedman test is a non-parametric test to detect differences across multiple test attempts and is used as an analysis of variance by ranks.

Results

In the reproducibility tests of the EFD dispenser for the weight of all pigment pastes, with a selected pressure of 4.0 bar, selected syringe tips and a dispensing time of 10 s, there was a range of coefficient of variation in between 0.81 and 3.87 %, except for black (16.82 %) and red/brown (10.41 %) (Table 1).

In the second part of the reproducibility test, conventional colour matching of nine different skin colour batches resulted into measured quantities of pigment pastes. The colour difference in ΔE2000 comparing four test batches that were visually colour matched, polymerized and subsequently compared to the original samples, showed a ΔE2000 of 3.05–6.83 (Table 2).

Table 1 Coefficient of variation (SD/average in %) by repeated measurements of weight in mg): variation in needle tips related to viscosity: L = large; S = small and white pistons

Measurement	Pigment (Needle tip)								
	White (L)	Black (S)	Red/Brown (L)	Red (L)	Yellow (L)	Blue (S)	Buff (S)	Flesh (S)	Red (S)
1 (mg)	3.11	1.89	2.29	14.34	2.21	6.53	1.04	6.09	3.65
2 (mg)	2.79	1.58	2.40	13.57	2.31	6.47	1.09	6.00	3.62
3 (mg)	2.93	1.44	2.41	14.32	2.21	6.40	1.02	6.04	3.65
4 (mg)	2.97	1.36	2.84	14.64	2.32	6.31	1.02	6.10	3.67
5 (mg)	2.97	1.23	2.85	14.83	2.38	6.25	1.01	6.12	3.84
Average	2.95	1.50	2.56	14.34	2.29	6.39	1.04	6.07	3.69
SD	0.11	0.25	0.27	0.48	0.07	0.11	0.03	0.05	0.09
Coefficient of variation (%)	3.87	16.82	10.41	3.35	3.25	1.79	3.10	0.81	2.39

Table 2 Measured colour differences between four original and reproduced skin batch samples

	Original sample			Reproduced sample			
	L*	a*	b*	L*	a*	b*	ΔE2000
Recipe I	64.91	9.77	20.81	68.60	7.13	16.63	4.07
Recipe II	63.96	15.54	25.20	67.66	7.39	19.17	6.83
Recipe III	57.51	24.20	21.60	57.80	19.78	15.26	3.62
Recipe IV	54.93	23.44	14.26	53.31	18.78	13.16	3.05

The ten times reproduced batches of "Recipe V" were measured spectrophotometrically (Table 3). The measurements showed a colour difference of ΔE2000 of less than 1.52 compared to the average L*, a* and b* values of Recipe V.

These ten copied batches were ranked visually by three observers in order of increasing chroma. The average of the disagreement of the repeated ordering by three observers, compared to the CTM spectrophotometrical estimated ordering of measured C, was 24.5 (Table 4). No ordering, based on three observers in five sessions, can be estimated considering the results of the Friedman test (Chi square = 7.058, df, 9 $p = 0.63$). The results indicate a low intra-personal and interpersonal agreement of colour ordering.

Discussion

The need for frequent remakes of facial prostheses requires a reproducible colour matching procedure. Searching for an adequate pigment paste dosing system, we tested the EFD® dispenser system for this application.

During the initial testing procedure, the goal was to estimate and obtain information concerning factors contributing to reproducible results for the EFD® dispenser. The experiments led to adaptations in several variables like air pressure, piston type and needle size.

The dispersed pigment pastes disintegrated by segregation or demixing with the silicone oil base. Based on clinical observations this process of segregation occurred in approximately 12 weeks, for especially buff and red/brown pigment. The viscosity is influenced by the pigment concentration and differences in particle size. The segregation process has a negative influence on the reproducibility.

Calibration of the dispenser set is recommended, at least every month and especially following adjustments, to avoid inaccuracies in reproducibility. Moreover, in non-frequent use, dispenser needles should be refreshed weekly to avoid clotting of pigment pastes in the needle influencing reproducibility.

The presence of air (bubbles) in pigments was suspected to be a variable affecting the reproducibility of the dispenser. Meticulous centrifugation is advised to eliminate

Table 3 Measured L*a*b* values for ten reproductions of recipe V and calculated averages, measured C (chroma) values, colour differences in ΔE2000, compared to the average L*a*b*C values

Sample	1	2	3	4	5	6	7	8	9	10	Average Recipe V
L*	57.54	57.53	58.38	57.48	57.89	57.15	55.80	57.57	57.56	57.53	57.44
a*	16.50	17.14	17.22	17.14	17.74	17.83	17.77	18.01	18.31	18.45	17.61
b*	13.27	13.26	13.77	13.89	13.97	14.07	14.21	14.96	15.46	15.51	14.24
C	21.17	21.67	22.05	22.06	22.58	22.71	22.75	23.41	23.96	24.10	–
ΔE2000 Recipe V	0.79	0.62	0.91	0.32	0.47	0.35	1.52	0.46	0.76	0.80	–

Table 4 Visual ordering and ordinal difference from CTM chroma ordering, of 10 dispensed sample reproductions of recipe V, from low chroma to high chroma by 3 observers (I; II; III)

Reference (increasing chroma according to CTM)	Observer I (5 × visual ordering)					Observer II (5 × visual ordering)					Observer III (5 × visual ordering)				
1	8	1	3	3	4	2	4	3	3	5	6	2	4	8	6
2	6	3	5	6	2	8	5	2	6	3	9	4	2	10	3
3	4	2	2	9	5	6	3	5	1	2	2	3	3	9	5
4	2	5	1	4	3	5	2	4	2	1	1	5	5	1	2
5	1	4	10	5	6	1	6	8	4	6	4	9	1	3	1
6	9	8	4	1	7	3	1	10	8	4	3	6	6	2	8
7	10	10	7	8	1	10	9	6	10	10	8	8	10	5	10
8	7	9	6	10	10	9	8	9	9	8	7	1	9	6	9
9	5	6	9	7	9	4	10	1	5	9	10	7	8	7	4
10	3	7	8	2	8	7	7	7	7	7	5	10	7	4	7
Total difference between reference and visually observed	36	16	20	30	18	30	20	24	24	18	28	18	16	42	28

all air bubbles. In practice this has probably more effect in low viscosity pigment pastes.

The results of the tests in Tables 3 and 4 resulted in a minimal or non-observable colour difference ΔE2000. Therefore it was assumed that a coefficient of variation of equal or less than 10 % was clinical acceptable, to obtain reproducible results. Black and red-brown pigments need to be used with caution in respect of this. Considering these results, it was concluded that there are little or no visible colour differences when making reproductions with the dispenser. The results obtained by comparing the conventionally colour matched batches with the original ones (ΔE2000 3.05–6.83) indicated a minimal observable colour difference.

When mimicking skin colour, the use of nylon fibres is part of mimicking small superficial blood vessels [7, 9]. The presence of pigmented flocking (nylon fibres) in the original skin batch samples may have influenced the results. The effect of micro fibres in silicone samples on determination of L*a*b* coordinates was experienced in earlier research [12]. Initial experiments are yet performed concerning the addition of fibres with the dispenser, which is ongoing subject for research.

The use of spectrophotometer measurements on skin connected to the dispenser, will be subject to future studies concerning standardisation of the colour matching procedure. The final goal is to obtain a recipe-system by computed colour formulation. The results of skin measurements with a CTM should be converted to recipe software, connected to this calibrated pigment dispenser system. Reproducible results with this new technique will improve the colour formulation and mimicking skin in maxillofacial prosthetics. Reproducibility of this standardization method with a CTM (PBSensortechnology bv) in colour matching has to be evaluated.

In the meantime, the dispenser can be of value when conventional colour matching is used and the amounts of pigment are recorded. Considering that a prosthesis will require replacement by a new one between 12 and 18 months, the colour match for a replaced prosthesis can be reproducibly obtained [2]. The documented composition of pigment pastes in combination with the dispenser can easily be used for reproduction.

The hypothesis was that an EFD® dispenser system is a reproducible dosing system for pigment pastes, and suitable for use in maxillofacial prosthetics.

1. Reproducible results are obtained for the pigment set and the EFD® dispenser system. To avoid inaccuracies, periodical calibration has to be performed, i.e., every month.
2. The measured colour differences between the ten reproductions were not visually observable (<5) according to ΔE2000.

Conclusion

The EFD® dispenser is a reliable instrument in reproducible pigment paste dosing for application in maxillofacial prosthetics. The dispenser need to be used in the clinic on a day to day bases. Observation of sedimentation of pigments in the silicone oil, before use, need to be resolved by manual re-centrifugation.

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