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The colour stability of 3D-printed, non-invasive restorations after 24 months in vivo – esthetically pleasing or not?☆

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ABSTRACT

Objectives: The aim of the present prospective study was to evaluate the colour stability of 3D-printed non-invasive restorations after 24 months in vivo.

Methods: The study included 29 patients, who received 3D-printed restorations made of a computer-aided design (CAD) / computer aided-manufacturing (CAM) hybrid material ($n = 354$). Restoration colour of 190 restorations was measured using a spectrophotometer. By applying the CIELAB system, *L (lightness), a* (red-green) and b* (blue-yellow) values were recorded. An evaluation of the colour differences (ΔE) after 6, 12 and 24 months was conducted.

Results: Analysis of colour differences of 3D-printed restorations showed continuous discolouration of the restorations. After one year 34 % and after two years 18 % of the restorations were rated alpha or bravo, indicating no or hardly visible colour change. After two years, 54 % of the evaluated restorations yielded a colour difference with $\Delta E > 6.8$ (delta). More than 82 % of the evaluated restorations showed values between ΔE 3.8 – 6.8 (charlie) and $\Delta E > 6.8$ (delta) after two years.

Conclusions: 3D-printed non-invasive restorations showed an overall reduced colour stability after 24 months in vivo.

Clinical Significance: The present study provides first clinical data regarding 3D-printed restorations. These restorations are recommended for a wearing time of about 6 months.

1. Introduction

In recent years, the clinical workflow has undergone major changes due to the establishment of computer-aided design and computer-aided manufacturing (CAD/CAM) [1,2]. In particular, additive manufacturing, also known as 3D printing, is becoming increasingly influential and popular [1,2]. This is mainly due to more economical material consumption and the simultaneous production of multiple tooth-coloured restorations [1,3,4].

With the development of 3D printing and the advantages mentioned above, new dental materials for additive manufacturing have appeared on the market [5-7]. These are currently mostly used for temporary and midterm restorations [8,9]. Since the aesthetic demands of patients increased [8], colour properties and colour stability of temporary restorations became important parameters for patients' acceptance [8]. However, clinical data on 3D-printed materials is limited [5].

The studies on 3D-printed restorations available so far have focused on the physical and mechanical properties, the dimensional accuracy and strength in vitro [1,4,10-13]. It has been shown that the printing orientation influences the mechanical stability and printing accuracy of 3D printed restorations [1,9-13].

In contrast, the colour values and colour stability of 3D-printed materials have hardly been investigated until now. Overall, there is little preclinical data on the colour behaviour of 3D printable hybrid materials [1,14] and those available showed heterogeneous results [1,5,8,15]. Clinical data are not available at all. However, a sound knowledge

☆ The present study is registered in the German Clinical Trials Register (application number: DRKS00024738).

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of the colour behaviour of a dental material is essential for clinical practice to choose a proper material and to achieve a natural appearance [1].

To the knowledge of the authors, the present study documents the first clinical data on the colour stability of 3D-printed, non-invasive restorations. An evaluation was conducted over a period of 24 months of clinical function. Quantitative colour differences of the restorations were evaluated using a spectrophotometer and the L*a*b* colour space according to International Commission on Illumination.

According to Khashayar et al. ΔE=3.7 was analysed as the threshold at which 50 % of observers accepted the colour difference [16]. Therefore, the working hypothesis was that after 24 months in vivo, ΔE values of the 3D-printed restorations did not exceed a value of 3.7.

2. Materials and methods

2.1. Background of the study

The present clinical study was approved by the local Ethics Committee in 2020 (application number: EA2/013/21). The study is further registered in the German Clinical Trials Register (application number: DRKS00024738). Since then, it is being conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research.

Patients of all ages, with a need for an alteration of the vertical dimension or an occlusal adjustment of single teeth were included in the study. No temporomandibular joint disorders should exist. Furthermore, all surgical, conservative and periodontal treatment procedures had to be completed before participation. Besides, patients with infectious diseases and pregnant women were excluded from the study. All patients included in the present study were part of American Society of Anesthesiologists Physical Status Classification System (ASA) class 1 [17].

All patients were informed about the study design and written informed consent was obtained. If a patient agreed to participate in the study, a thorough dental examination was performed.

2.2. Treatment procedure

Firstly, all teeth were scanned with an intraoral scanner (IOS, Primescan, Dentsply Sirona, Charlotte, North Carolina, USA) without any preparation after a professional dental cleaning. The scans of the upper and lower jaw had to cover all tooth surfaces whereas the sulcus area was of secondary importance. The current bite situation was also recorded with the same IOS. Secondly, the individual jaw movements were recorded using a digital facebow (Zebris for Ceramill, Amman Girrbach, Pforzheim, Germany). The aim was to take these parameters into account when designing the 3D-printed restorations. Therefore, a virtual articulator (Artex CR, Amann Girrbach) was used in the dental laboratory to reflect the mandible's individual movements and temporomandibular joint angles. If an alteration or calibration of the vertical dimension was necessary, it was digitally adjusted in the dental laboratory. The clinical treatment was conducted by several clinicans from the department. The restorations were designed and printed by one dental technician.

The design of the 3D-printed, non-invasive restorations was implemented using a CAD software (Exocad Dental CAD Galway 3.0, Darmstadt, Germany) and the printing process (material: VarseoSmile Crown plus, BEGO, Bremen, Germany; printer: Varseo XS, BEGO) (Table 1) were carried out continuously according to the instructions of the manufacturer. The post-processing was conducted with 1.500 flashes twice (Otoflash, BEGO). The margins of all 3D-printed restorations ended supragingivally and were manufactured in the same dental lab with the same printing parameters.

Table 1
Details of the tested 3D-printable material.

Material	Composition	Manufacturer
VarseoSmile Crown plus	Ceramic-filled (30–50 wt % inorganic fillers; particle size 0.7 μm) silanized dental glass, methyl benzoylfor-mate, diphenyl (2,4, 6-trimethylbenzoyl) phosphine oxide hybrid material	BEGO, Bremen, Germany

The restoration geometries were determined individually and defect-orientated (Fig. 1). Therefore, the restorations in the posterior region were limited to the tooth-structure defects and the occlusal surfaces for the purpose of an alteration of the vertical dimension. The restorations in the anterior region were extended to the labial tooth surfaces not only for aesthetic reasons but also according to the dental decay (Fig. 1). The minimal layer thickness of the 3D-printable material and the necessary vertical dimension alteration were also analysed in the dental laboratory. Speech tests were conducted clinically in advance.

For insertion, restorations were air-abraded with aluminium oxide 50 μm for 10 s and conditioned with a universal primer (Monobond Plus, Ivoclar, Schaan, Liechtenstein). The teeth, if enamel was present, were subjected to 37 % phosphoric acid etching for 30 s. Separate enamel etching was carried out in order to achieve a maximum bond strength for the non-invasive restorations. Enamel and dentin were furthermore pretreated with a self-etching universal adhesive (Scotchbond SE, 3 M Espe, Landsberg am Lech, Germany). A luting composite (RelyX Ultimate, 3 M Espe) was used for insertion. The proximal contacts were initially cleaned with dental floss since the restorations did not cover the proximal areas due to the non-invasive approach. After removal of cement residues in all other areas and light curing, static and dynamic occlusion were checked using shimstock foil. An anterior guidance was adapted if all teeth were rehabilitated and the vertical dimension was increased. If only single teeth were rehabilitated the existing dynamic occlusion was not changed. After fine adjustment of the occlusion, the restorations were polished using polishing wheels (Sof-Lex XT, 3 M Espe) (Fig. 2).

2.3. Evaluation of the colour stability

Colour measurements were performed using a spectrophotometer (VITA Easyshade V, Vita Zahnfabrik, Bad Säckingen, Germany) (Fig. 3). They were conducted right after insertion of the restorations and it was repeated at every follow-up examination after 6, 12 and 24 months by one clinician. No professional tooth cleaning was performed before measurements were conducted. A calibration of the spectrophotometer was conducted before each measurement according to the instructions of the manufacturer.

To ensure a reproducible positioning of the measurement head of the spectrophotometer, deep-drawing splints (Erkodur, Erkodent,

Fig. 1. 3D-printed, non-invasive restorations of the upper anterior teeth before insertion. The proximal areas were left out due to the non-invasive approach. An aesthetic design in the anterior region was aimed for.

Fig. 2. Initial situation after insertion of the 3D-printed, non-invasive restorations. The chosen restoration colour was Vita A 1.

Fig. 3. Clinical colour measurement with the help of a spectrophotometer (Vita Easyshade V, Vita Zahnfabrik) and deep drawing splints with openings at the buccal and labial surface for the measurement head, a reproductable colour measurement could be ensured.

Pfalzgrafenweiler, Germany) with a thickness of 0.8 mm were designed for each patient. The splints had openings at the buccal or labial surface and the size of the openings corresponded to the size of the measurement head (Fig. 3). The measurements were always conducted at the buccal and labial surface, no matter which geometry the restoration had. In case of a table top design to reestablish the VDO, the restoration was designed to such an extend on the buccal surface that it corresponded to the measurement head of the spectrophotometer.

The colour measurement was performed three times and the mean value was calculated. For an evaluation, the CIELAB colour space was used to obtain quantitative measurements in colour differences (ΔE). Here, the coordinate L* represents the lightness of the tested material. a* and b* correspond to differences in the red-green axis and the yellow-blue axis [18]. ΔE was calculated based on the recommendations of the Commission Internationale de lÉclairage [19] using the following formula:

$$\Delta E \equiv \sqrt{(L1 - L2)^2 + (a1 - a2)^2 + (b1 - b2)^2}$$

In accordance with the findings of Yuan et al. the following criteria for colour evaluation were selected (ΔE): "Alpha": ΔE 0 – 2.2; "Bravo": ΔE 2.3 – 3.7; "Charlie": ΔE 3.8 – 6.8; "Delta": ΔE > 6.8. [20].

If the entire upper and lower jaw of a patient were restored with 3D-printed non-invasive restorations, the colour measurements were carried out on a part of the restorations. These restorations were chosen randomly but there had to be one restoration from each tooth group. If only individual teeth were restored, all these restorations were measured.

2.4. Statistical analysis

Descriptive statistics, including mean values, and medians were performed using SPSS 29.0 (IBM, Armonk, New York, USA). Based on data situation and in consultation with the Institute of Biometry and Clinical Epidemiology solely a descriptive analysis was conducted.

3. Results

The colour values of a total of 190 restorations in 29 patients (17 male, 12 female) were evaluated in clinical function after 6, 12 and 24 months compared to baseline. Furthermore, a direct comparison of the colour values after 24 months in respect to the data after 12 months in vivo was drawn.

After 6 months, 43 (23 %) and 61 (32 %) of the restorations were scored as alpha and bravo, respectively (Table 2). In the course of the study the events occurring in alpha and bravo decreased steadily. After one year 34 % and after two years 18 % of the restorations were rated alpha or bravo (Table 2). Finally, 103 of the 190 (54 %) restorations were rated delta after two years (Table 2). There was no significant difference between colour change during the first year and the second year of the study but from baseline to the second year (Table 2). However, discolouration of the restorations happened evenly over the two-year time period (Fig. 4 and 5).

Furthermore, it could be shown that the colour stability of restorations after 12 and 24 months differed between the tooth region (Fig. 6). Restorations of 98 anterior teeth, 51 premolars, and 41 molars could be included in colour stability measurements. Premolar restorations showed the highest colour stability (43 %) of the restorations rated alpha or bravo after 12 months (Fig. 6). Compared to that, merely 31 % of front restorations and 26 % of molar restorations scored alpha or bravo after 12 months (Fig. 6). After 24 months in vivo, 92 % of front restorations and 78 % of molar restorations were rated charlie or delta. Still, 67 % of premolar restorations were rated charlie or delta (Fig. 6).

Besides, the restoration colour development during the study progress was evaluated (Fig. 7). After 6 months premolar restorations showed lowest values of colour difference and, therefore, the highest colour stability. Median colour difference of premolar restorations (ΔE=3.1) after 6 months was beneath the level of clearly visible colour change ($\Delta E = 3.7$). However, colour difference of about one third of premolar restorations exceeded the limit of 3.7. Colour stability of anterior teeth restorations was comparable to that of premolar restorations but with overall slightly higher values after 6 months (median $\Delta E = 3.5$). Molar restorations depicted the lowest colour stability with nearly 50 % of the restorations having colour difference values between 3.7 and 6.8. Colour differences of a quarter of restorations exceeded the limit of 6.8, meaning clinically unacceptable colour difference.

Over the course of the study, colour difference of all restorations increased (Fig. 7). Premolar restorations showed still highest colour stability after 12 and 24 months with median ΔE values of 4.2 and 4.9 after 12 and 24 months, respectively (Fig. 7). While colour stability of anterior teeth restorations was significantly better after 6 and 12 months in comparison to values of molar restorations, colour stability of front and molar restorations was similar after 24 months (Fig. 7). After 24 months most of the restorations of front (median $\Delta E = 7.5$) and molar teeth (median $\Delta E = 8.0$) exceeded the limit of 6.8 (Fig. 7).

In addition to the evaluation of colour differences depending on

Table 2
Colour difference (ΔE) of all measured 3D-printed, non-invasive restorations ($n = 190$) after 6, 12, and 24 months. The last column shows the colour change of the restorations solely in the second half of the study.

Colour stability		after 6 months		after 12 months		after 24 months		12 to 24 months	
ΔE	Rating	n	%	n	%	n	%	n	%
0–2.2	**alpha**	43	23	21	11	8	4	26	14
2.3–3.7	**bravo**	61	32	43	23	26	14	33	17
3.8–6.8	**charlie**	64	34	68	36	53	28	74	39
>6.8	**delta**	22	11	58	30	103	54	57	30

Fig. 4. Situation after 24 months in vivo. Obvious colour changes of the 3D-printed, non-invasive restorations were present. Besides, a chipping on the upper right front tooth was present and multiple plaque residues.

Fig. 5. To improve the aesthetic outcome, a professional tooth cleaning and polishing of all 3D-printed restorations was conducted if patients wanted to.

different tooth regions, the range of colour differences of restorations within a patient was analysed (Fig. 8). Therefore, lowest value of colour differences of restorations within a patient was subtracted from the highest value of colour differences of restorations of a patient after 6, 12, and 24 months separately. In the present study, two patients were treated with only one restoration and, therefore, no range of colour differences could be calculated. Consequently, box plots for 6, 12, and 24 months include the calculated range of colour differences of 27 patients.

The range of colour differences by calculating the discrepancy between highest and lowest value within a patient represent the variety of discolouration within a patient. Low values represent a consistent discolouration of all restorations of one patient without assessing the colour stability. Colour differences of most patients exhibited a calculated range between 2.5 and 6 after 6 months (Fig. 8). However, during the course of the study discrepancies between colour differences within individual patients increased and after 24 months most values were between 5 and 10. Range of colour differences of patients after 6, 12, and 24 months was in average 5, 6.6, and 7.7, respectively (Fig. 8).

Overall, colour difference values span over a wide range with several outliers. Especially after 24 months, values ranged from $\Delta E = 0.8$, indicating nearly no colour change, and $\Delta E = 31$, indicating a very strong change in colour (Fig. 7). Correspondingly, the calculated range of colour differences within individual patients was between 1.7 and 28.2 (Fig. 8).

4. Discussion

The aim of the present clinical study was to evaluate the long-term colour stability of 3D-printed, non-invasive restorations. The working hypothesis that after 24 months in vivo, ΔE values did not exceed a value of 3.7 had to be rejected.

The evaluation of colour differences resulted in 54 % of the restorations scored a ΔE value >6.8 (delta) after two years. According to Khashayar et al. ΔE = 3.7 was defined as the threshold at which 50 % of the observers accepted the colour difference [16]. The number of

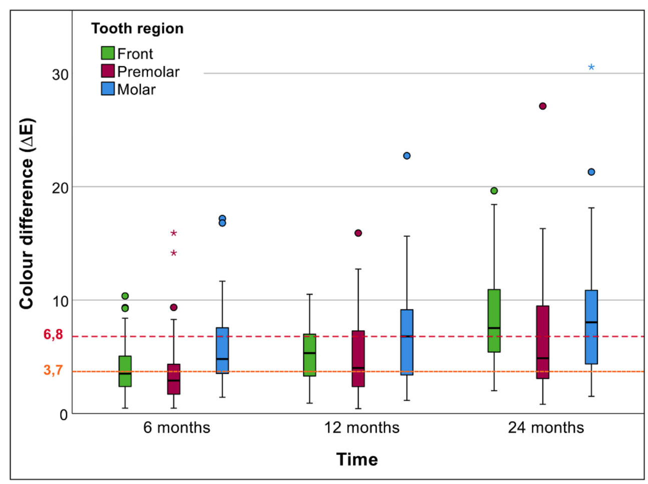

Fig. 7. Box plots of the colour difference (ΔE) of restorations categorized by tooth region after 6, 12, and 24 months. Horizontal lines represent $\Delta E = 3.7$ (dotted) and $\Delta E = 6{,}8$ (dashed) corresponding to the margin to visible colour difference (charlie) and clinically not acceptable colour difference (delta), respectively.

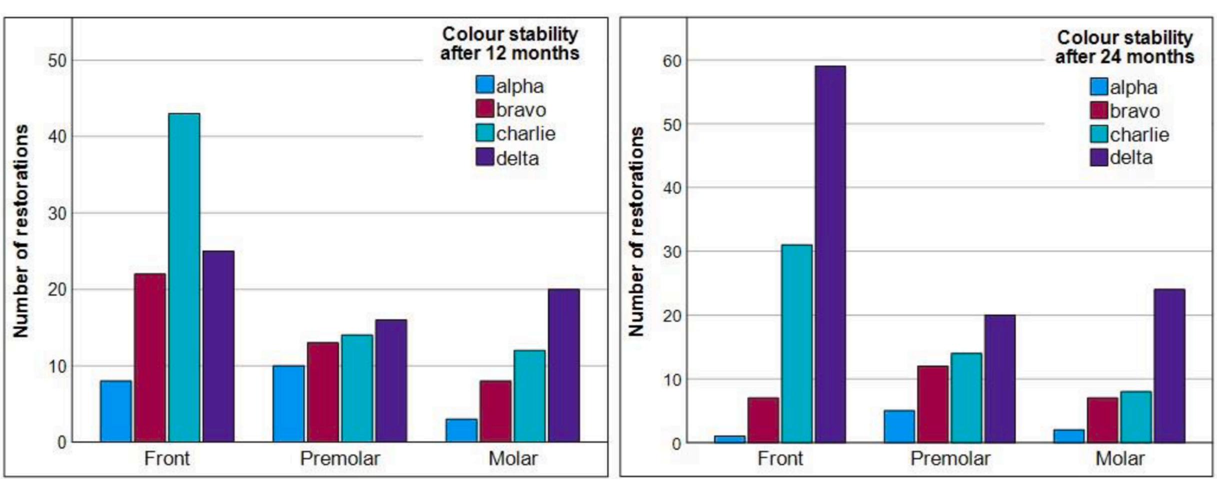

Fig. 6. Colour stability of restorations after 12 (left) and 24 (right) months categorized by tooth region. Colour difference was rated alpha ($\Delta E = 0$–2.2), bravo ($\Delta E = 2.3$–3.7), charlie ($\Delta E = 3.8$–6.8), or delta ($\Delta E > 6.8$).

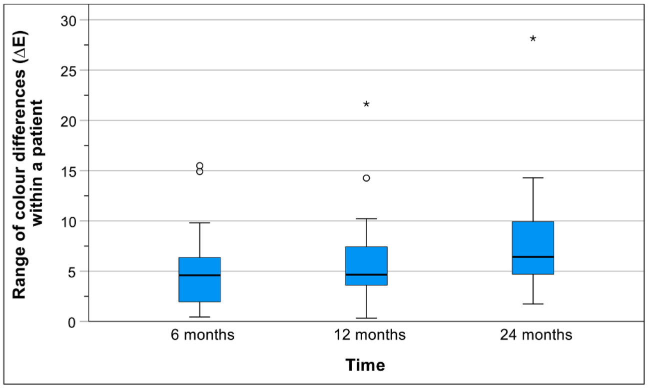

Fig. 8. Box plots of the range of colour differences (ΔE) of restorations within individual patients. Displayed values for the range of ΔE were calculated by subtracting the lowest colour difference of restorations within a patient at a certain time from the highest ΔE within restorations of the same patient. 27 patients with more than one restoration could be included in this analysis.

restorations that scored a ΔE value <3.7 (alpha or bravo), representing no or no immediately visible discolouration, was with 18 % rather small. Overall, colour differences increased steadily during the first and the second year of the study.

3D printing is still not common in dental offices. However, CAD/CAM manufactured provisional crowns and bridges have become increasingly popular because of their superior mechanical properties compared to conventionally, chairside manufactured provisional restorations [21-24]. Furthermore, patient expectations of the aesthetic appearance of dental restorations are high nowadays [25-28]. Therefore, the patients' acceptance depends on an accurate reproduction with a selected restorative material [25,29-34]. Proper colour stability over time is essential for patients' satisfaction. In the present study, colour measurements of the 3D-printed restorations were regularly conducted using a spectrophotometer after insertion. The measurements were performed to analyse the colour stability of 3D-printed restorations since to the knowledge of the authors, no clinical data of CAD/CAM hybrid materials for additive manufacturing exist so far. Colour measurements were performed right after insertion of the 3D-printed, non-invasive restorations and after 6, 12 and 24 months. No professional tooth cleaning was conducted before measurements were performed. To achieve reliable and objective values, studies have shown that spectrophotometers yield better results compared to conventional visual shade matching [25,31,35]. Consequently, these devices were recommended because they are independent on the lightning conditions [36,37] and the sex, age and experience of the examiner [36,38]. To the knowledge of the authors, clinical data on colour stability of a CAD/CAM hybrid material for 3D printing were not available so far. Thus, the present clinical study presents the first in vivo data of this class of newly dental restorative materials.

Evident reasons for discolouration of teeth and restorative materials are particular eating, drinking, and smoking habits. Common beverages (coffee, tea, red wine) and staining foods, such as turmeric, can cause significant discolouration [39,40]. Both, conventional cigarette smoke and heated tobacco products can affect the colour stability of aesthetic restorative materials [41]. The effect of the mentioned stainability of food and drinks on CAD/CAM hybrid materials for 3D printing only tested in vitro [39,42-46]. Mostly, the studies compared colour stability to CAD/CAM hybrid materials for milling. Here, the colour difference was significantly higher in all CAD/CAM 3D-printable materials compared to CAD/CAM millable blocks [39]. Song et al. showed that CAD/CAM millable blocks were resistant to discolouration for four weeks and then significantly increased [43,44]. CAD/CAM 3D-printable materials developed a significant increase of discolouration over time [43,44]. Both tested material groups revealed a faster change of discolouration after 8 weeks. This could be due to an unremoved layer on the surface for characteristics [43,44]. The surface of each 3D-printed restoration was treated with light-curing glazing material (Optiglaze, GC EUROPE N.V., Belgium). On the one hand, a surface sealant could protect the material from discolouration [39,47-52]. On the other hand, the surface sealant could be abraded clinically over time. A rough surface beneficial for staining foods and drinks could be the result. Furthermore, no significant reduction in surface roughness could be proven after sealant application preclinically and clinically [49,53-55]. Evaluation of colour differences of restorations over the course of the study revealed that at the first follow up examination after 6 months already 46 % of the restorations had a ΔE value >3.7 (charlie and delta) with 11 % scoring a ΔE value >6.8 (delta). However, discolouration of restorations began promptly after insertion of the restorations. The tested 3D-printable material was recommended for permanent restorations by the manufacturer. Due to the findings of the present study, only a temporary use could be recommended.

The applied glazing might detach during the first months of the study resulting in discolouration of the exposed restoration surface. The disappearance of the glazing material could be due to the surface hardness of the tested CAD/CAM hybrid material for 3D printing. Sufficient surface hardness is essential for high stress-bearing areas [49,56]. Some of the treated patients in the study suffered from pathological tooth wear. Rehabilitation and adaption of the occlusion could lead to higher forces on the restorations. Besides, a lot of the included patients suffered from strong bruxism before and after the treatment. Therefore, the 3D-printed, non-invasive restorations were exposed to higher forces compared to conventional provisional restorations. The surface hardness of the tested material might be not high enough and so susceptible to deformation [49,57].

Eating and smoking habits of patients included in this study were not recorded. For a better understanding of the discolouration of restorations, keeping a food and smoking log and including a control group could be beneficial in further research. Several studies proved that external factors such as food could lead to discolouration of 3D-printable materials [8,42]. Other studies showed heterogeneous results [1,5,8,15]. Discolouration of restorations occurred consistently over the course of the study for included patients. Analysis of the range of colour differences within individual patients yielded a wide span of values. This indicated that the restorations of several patients discoloured consistently and, therefore, discolouration was dependant on individual habits like eating and smoking. However, especially after 24 months a number of patients experienced a wider range of colour differences within their restorations, indicating an irregular discolouration. However, eating and smoking habits cannot explain the uneven discolouration within an individual patient. The direct comparison of different tooth types regarding colour stability yielded the least discolouration for premolar restorations. After 24 months molar restorations showed poorest colour stability. Molars suffered the most from bruxism or high masticatory forces. Consequently, the surface might be rough, irritated and/or fractured. Rough surfaces tend to be more susceptible to discoloration [58,59]. Therefore, the surface of molar restorations might be more susceptible to discolouration. However, cleaning of molars is in general more difficult which could yield presented results. To enable further insights in the performance of restorations of various tooth types more data deemed necessary. So far, studies on the discolouration tendency of different tooth regions with CAD/CAM printed restoration have not been conducted.

However, the microstructure of hybrid CAD/CAM restorative dental materials for milling and printing differ a lot. Millable, industrially preformed blocks might offer a more homogeneous microstructure compared to a viscous emulsion of the 3D-printable materials. It could be shown that the distribution of fillers of the tested CAD/CAM hybrid material (Varseo Smile Crown plus, Bego) was inhomogeneous after printing [60]. Consequently, a continuous mixing of the emulsion before printing might be necessary. Filler inhomogeneity, particle size, and printing direction might also affect the susceptibility to discolouration [60]. In the present study solely one printer and material as well as one kind of surface treatment was used. Furthermore, the layer thickness and or surface damages were not analysed in relation to discolouration. Besides, no dietary protocol was requested from the patients. Possible causes for discolouration could have been detected. Furthermore, a limitation of the present study was that the used spectrophotometer (Vita Easyshade V, Vita Zahnfabrik) is not suitable for evaluating the compositeścolour coordinates. It is only useful when evaluating dental hard tissues or ceramics. Since it is the most scientifically evaluated clinical and digital tool for shade measurements, the present study applied the above mentioned spectrophotometer. Since no clinical longterm colour values of the tested 3D-printed material are available so far, a first initial assessment of the colour stability was given. Therefore, the discussed results should be interpreted with caution and further clinical investigation on various materials and printers with different printing directions ought to be conducted.

5. Conclusions

3D-printed restorations made of a CAD/CAM hybrid material showed a steady and linear discolouration over time. After two years, 54 % of the evaluated restorations yielded a colour difference with $\Delta E > 6.8$. However, these ΔE values represented the threshold at which 50 % of observers accepted the colour difference. Overall, premolar restorations showed the highest colour stability. Contrary, molar restorations depicted the lowest colour stability with nearly 50 % of the restorations having colour difference values between ΔE 3.7 - 6.8. In summary, 3D-printed restorations exhibited a reduced colour stability after 24 months of clinical function.

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CRediT authorship contribution statement

Magda Doumit: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Investigation. **Florian Beuer:** Writing – review & editing, Project administration, Funding acquisition, Conceptualization. **Mats Wernfried Heinrich Böse:** Writing – review & editing, Visualization, Formal analysis, Data curation. **Robert Nicic:** Resources, Methodology, Conceptualization. **Jeremias Hey:** Writing – review & editing, Supervision, Project administration, Data curation, Conceptualization. **Elisabeth Prause:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Project administration, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Elisabeth Prause reports equipment, drugs, or supplies was provided by BEGO. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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