EFFECT OF DIFFERENT STORAGE ENVIRONMENTS ON DIMENSIONAL STABILITY OF OCCLUSAL DEVICES MADE BY 3D PRINTING TECHNOLOGY

A Thesis

By

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ABSTRACT

Statement of problem. There are no published data about the storage guidelines for the 3D printed occlusal devices.

Purpose. The objective of this in vitro study is to investigate the dimensional stability of the 3D printed occlusal device, stored under different conditions.

Material and methods. Maxillary and mandibular dental models were scanned and exported in STL form to 3D print 40 occlusal devices. The specimens were stored under three different storage conditions (n=10); group DL air-dried and stored under natural light, group W stored in a dark box, and group D air-dried and placed in a dark box. The intaglio surfaces of the occlusal devices were scanned by a laboratory scanner in four-time intervals as follows: right after post-curing process of the 3D printed appliance at 0 hours (t_0, control), after 1 day (t_1), after 7 days (t_2) and after 27 days (t_3). The dimensional changes of whole internal surfaces between t_0 and t_1 (Δt_1), t_0 and t_2 (Δt_2), t_0 and t_3 (Δt_3) were measured by best fit algorithm in computer-aided designing software. In addition, comparison among different areas such as the posterior and anterior sections was performed. Statistical analysis was completed with Kolmogorov- Smirnov, one-way ANOVA, Friedman, Kruskal- Wallis and Mann-Whitney, unpaired t-test.

Results. The root mean square (RMS) of group DL between Δt_1 and Δt_2, and between Δt_1 and Δt_3 showed statistically significant difference ($P<.05$). The RMS of group W between Δt_1 and Δt_3 showed statistically significant difference ($P<.05$). When the groups were compared with each other at the different time intervals group, DL group showed statistically significant ($P<.05$) difference compared to groups W and D at Δt_1. The examination of different areas of the occlusal device (right molars site, incisors site, left molars site) indicated that there was no statistically significant difference in RMS among different areas for all groups ($P>.05$).

Conclusions: The occlusal devices stored under natural light showed the least dimensional change at Δt_1 which was statistically significant ($P<.05$) compared to W and D. However, at Δt_2 and Δt_3 the dimensional change of the different groups was not statistically significant, indicating that the storage method does not clinically affect the fit of the occlusal device. When the dimensional change among the different locations was compared, there was no significant differences among the three different locations, for all groups after 27 days.

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The work of this thesis was overseen and supported by the thesis committee: Dr. Seok-Hwan Cho, Dr. Matthew Kesterke, Dr. Elias Kontogiorgos.

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NOMENCLATURE

TMJ	Temporomandibular Joint
EMJ	Electromyography
AM	Additive Manufacturing
SM	Subtractive Manufacturing
STL	Standard Tessellation Language
SLA	Stereolithography
DLP	Digital Light Processing
IPA	Isopropyl Alcohol
CAD/CAM	Computer Aided Design/Computer Aided Manufacturing
EVA	Polyvinyl-acetate-polyethylene
RMS	Root Mean Square
PMMA	Polymethyl Methacrylate

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1. INTRODUCTION

Occlusal devices are routinely used in the treatment of disorders of the temporomandibular joint (TMJ) and masticatory system.[1,2] They were introduced by Karolyi in 1901, while Posselt in the 1950s initiated their modern use for the treatment of occlusal dysfunction.[3,4] There are four basic types of occlusal devices: the stabilization device, the repositioning device, the pivot device, and the soft device.[1] The first type is commonly used for treatment of masticatory dysfunction signs and symptoms. The repositioning devices keep the mandible forward, changing the condyle-disc-fossa relation; however, there is no long-term data indicating their effectiveness.[1] The pivot device is a hard splint with single posterior contact on each side, which is not used often because it could change teeth position.[1,5] Soft appliances are used for protection from trauma in sports and other physical activity.[6] While the occlusal device is fabricated primarily on the maxillary arch, it is essential to fabricate the occlusal device on the arch with the highest number of edentulous spans to increase the stabilizing effect by the creation of additional occlusal contact points. In cases of Class II malocclusion, it is difficult to achieve proper anterior contacts and guidance with a mandibular occlusal device.[7]

A successful treatment with an occlusal device provides symmetrical activities of masseter and temporalis muscles, the relief of force applied on TMJ, and the redistribution of the occlusal force.[2] Williamson demonstrated the clinical benefits of anterior guidance, which inhibits masseter and the anterior temporalis muscle action that normally occurs with posterior tooth contact.[8,9] In addition, freedom in centric relation on a flat plane and centric occlusal contacts should be established. It is apparent that recording the centric relation often changes as the muscles relax and joint and myofascial pain decreases.[9,10,11] Thus, it is extremely important that the appliance is adjusted in centric relation during follow-up adjustments. Creating optimal centric relation may take months of adjustments every 2 or 3 weeks.[12] This therapy has been found to be effective in pain reduction or elimination for 70-90% of patients, some of them stating that they are free of pain after a few days or weeks after using the occlusal device.[13,14]

The occlusal devices can be fabricated by a variety of materials including vinyl resins, natural rubber, acrylic resins, and polyurethane. The orthodontic acrylic resin, also known as polymethyl methacrylate (PMMA), is one of the materials most used to fabricate hard occlusal devices because of simplicity to adjust, pliability preventing hyperactivity in periodontal ligaments, and high success rate in TMD symptom reduction.[14,15] A physical property of PMMA is water sorption, resulting expansion of the appliance during use due to saliva absorption. When the patient removes the device, due to the absence of liquid element, it can potentially dry and shrink. This constant dimensional change affects the mechanical and physical properties of the material, leading to reduced strength, distortion, and ill-fit. Therefore, it is proposed to immerse the appliance in water after use.[16] Rubber material is used for soft occlusal devices and utilized primarily as mouth guards in sports.[17] The elastic properties of the occlusal device material are essential to provide adequate absorption of impact energy as it is transmitted to underlying oral tissues. The impact absorption properties of the occlusal device material may be improved by increasing thickness, but must be balanced against a reduction in wearer comfort due to speech and swallowing restrictions and lip seal.[4.9] Consequently, the devices are fabricated as thin as possible, approximately 1 – 2 mm in the molar regions, with a smooth and flat surface without any cusp indentations.[4]

Computer-aided design (CAD) and computer-aided manufacturing (CAM) were first adopted to the dental profession in 1989 by Mormann and Brandestinni, and today are widely used in dentistry for the construction of dental restorations and prostheses.[18] The stages in fabrication of the prostheses with CAD/CAM technology are: computer surface digitization, computer-aided designing, and computer assisted manufacturing. Optical cameras, LASER surface scanning devices, and digital scanning devices are some of the technologies used for computer surface digitization. Design of the restoration is performed with CAD software once a 3D image is created, which in turn sends commands to the CAM unit to fabricate the restoration. The final stage (CAM) can be achieved either with a "subtractive" process called milling, or with an "additive method" like rapid prototyping or selective laser sintering. Some CAD/CAM systems use a combination of these two methods.[18]

The CAD/CAM was applied to fabricate occlusal appliances for patients in some previous studies.[19,20] Edelhoff et al fabricated occlusal devices made of polycarbonate, while Ye et al also digitally designed devices of different offsets to confirm their precision.[19,20] However, there is a dearth of knowledge on the guidelines for the short- and long-term storage of CAD/CAM fabricated occlusal appliances. The aim of this study is to measure the dimensional stability of CAD/CAM designed and fabricated occlusal devices stored in different storage environments. This study investigates whether the presence or absence of light and/or humidity affects the dimensions of the occlusal device. The null hypothesis is that there are no differences in the dimensional change of the occlusal devices among the different storage conditions at the three time intervals observed.

2. MATERIAL AND METHODS

A dental model (1560 Articulated Dentoform; Dentalez Inc) of maxillary and mandibular arches was scanned with the lab scanner (D900; 3 Shape Inc) and the scanned models were saved as Standard Tessellation Language (STL) format (Fig. 1A). The STL files were imported to CAM software (Splint Designer program; 3 Shape Inc) to design the occlusal devices according to manufacturer's guidelines. The undercuts of the maxillary arch were virtually blocked and a device of 1 mm thickness and 0.1 mm offset was designed up to the 2nd molar.[6] The model was exported in STL format and uploaded to 3D Printer (Form 2; Formlabs) to print 40 occlusal devices with printing resin (light-cured Dental LT Clear Resin; Formlabs) (Fig. 1B). The 40 specimens were washed in isopropyl alcohol (IPA 96%; SWAN) for 2 minutes in an ultrasonic bath to dissolve any uncured or excess resin, and were then transferred to a new bath of clean alcohol solution and were rinsed for additional 3 minutes in an ultrasonic bath. The samples were allowed to air-dry and post-cured for 20 minutes at 80° C in a curing machine (Form Cure; Formlabs).

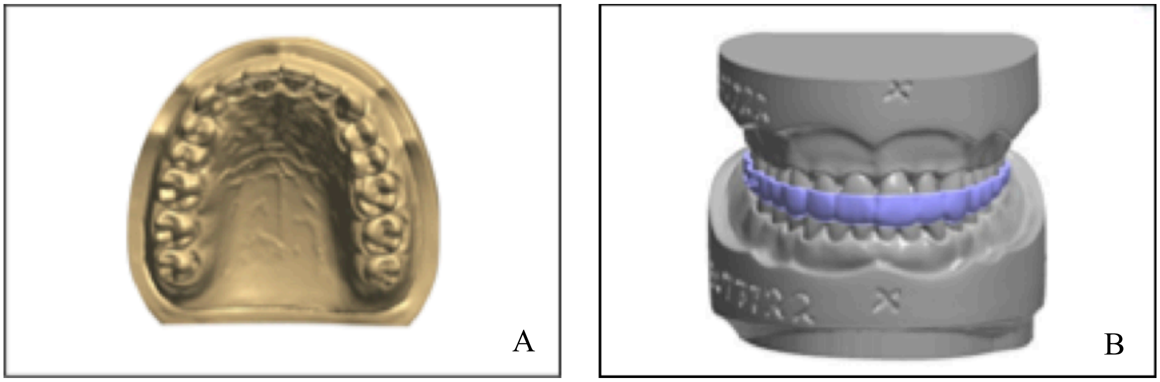

Fig. 1. A, Scanned dental model of maxillary arch. B, Occlusal devices designed in 3Shape Dental system.

The samples were distributed into 3 groups (n=10), with group DL air-dried and stored under natural light, group W stored in water in a dark box, and group D air-dried and placed in a dark box. The dimensional change of internal fit of the specimens was investigated at three time intervals and compared to the models directly after curing (t_0, control): after 1 day (t_1), after 7 days (t_2) and after 27 days (t_3). The difference between t_0 and t_1, t_2, t_3 were represented by Δt_1, Δt_2, Δt_3 (Fig. 2).

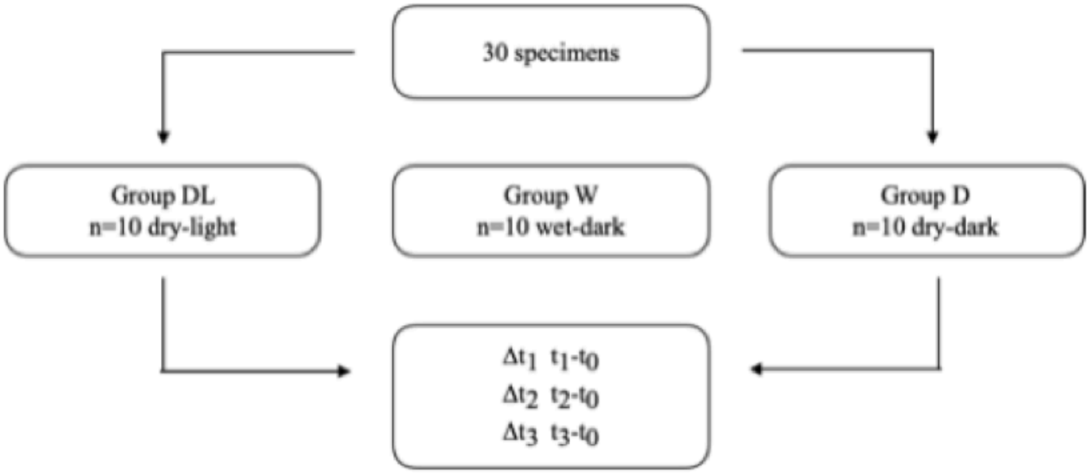

Fig. 2. Design of study.

Specimens were compared by best fit alignment of surface analysis software (Geomagic Control 2020; 3D systems) to analyze dimensional changes. The best fit algorithm is a virtual alignment based on the STL point cloud surface matching to maximize the amount of matching surface data points while minimizing the amount of deviations. The default settings were changed to 100 µm maximum deviation for a sample size of 5,000 points. The software (Geomagic Control 2020; 3D Systems) calculates the root mean square (RMS) by measuring the average deviation of a random 5,000 points evenly distributed on the surface according to the following equation:

$$\sqrt{}\sum(R_i - C_i)^2 \ RMS = n$$

where R_i is a point of the original STL image, C_i is the same point of the scanned guide, and n is the full number of points. A lower RMS indicates less error and greater accuracy.

The dimensional changes of whole internal surfaces between t_0 and t_1 (Δt_1), t_0 and t_2 ($\Delta t2$), t_0 andt_3 (Δt_3) were measured by best fit algorithm in surface analysis software (Geomagic Control 2020; 3D systems) (Fig. 3A). In addition, comparison among different areas such as the right and left molars and incisors was investigated (Fig. 3B).

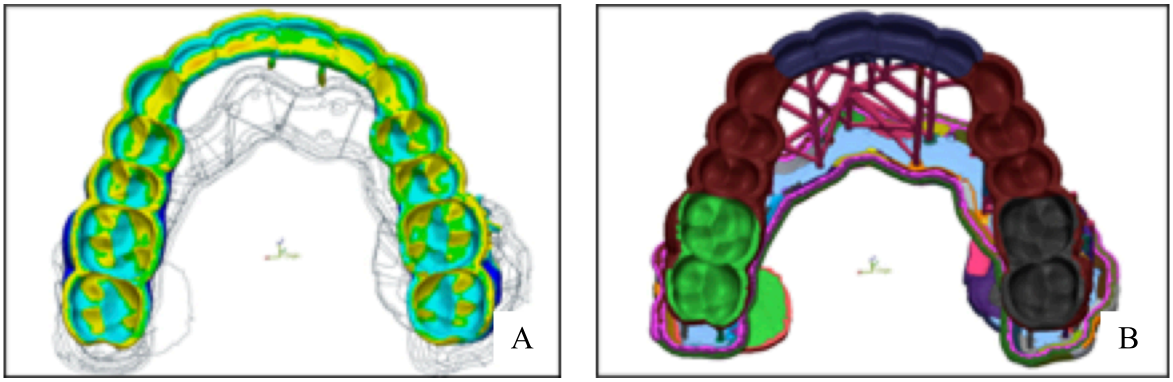

Fig. 3. A, Best fit alignment on whole internal surface. B, Right molars site, incisors site and left molars site selected for comparison. Different colors on selected areas are present.

Geomagic output was recorded in Microsoft Excel and subsequent statistical analysis was completed with GraphPad Prism (8th edition 2020; GraphPad Software). Statistical analysis was performed: 1) Kolmogorov-Smirnov test to examine the normality of the data, 2) One-way ANOVA to compare the root mean square (RMS) for normal data between the different groups, between the different times, and the different areas of the occlusal devices, 3) Friedman test to compare the RMS for non- parametric data between the different groups, 4) Kruskal Wallis test to compare RMS between different times and between different areas of the occlusal devices, 5) Unpaired t-test to compare RMS between group stored under natural light (group DL) and groups stored in a dark box (group W, D), and 6) Mann-Whitney test to compare RMS between groups stored air-dried (group DL, D) and group stored in water (group W). Differences were considered significant at $P<.05$.

Qualitative analyses were completed for each group at the Δt_3 time intervals. The specific tolerance was set at ±.01 mm. Red color mapping are positive discrepancies indicating areas of the model which are above the test comparison. Blue color mapping represents negative discrepancies showing areas of the model which are below the test comparison. Green, yellow-green, and aqua colors are relatively normal, as scored as acceptable error.

3. RESULTS

Table 1 demonstrates the dimensional change values (mean and standard deviation) of all groups during at the different time intervals; .17 ± .08 mm in group DL, .21 ± .05 mm in group W, and 21 ± .07 mm in group D. Statistically significant differences between Δt_1 and Δt_2 and Δt_1 and Δt_3 in group DL (*P*< .05) were found. In addition, there was statistically significant difference between Δt_1 and Δt_3 in group W (*P*<.05). No statistically significant differences were found in group D at the different time intervals (*P*>.05).

Table 1. Mean and Standard Deviation of group DL, group W, and group D at Δt_1, Δt_2, Δt_3.

Time	**Groups**		
	DL	**W**	**D**
Δt_1	0.04 ± 0.01 mm$^{*\#}$	0.12 ± 0.06 mm$^{\Delta}$	0.15 ± 0.08 mm
Δt_2	0.15 ± 0.08 mm*	0.17 ± 0.07 mm	0.18 ± 0.09 mm
Δt_3	0.17 ± 0.08 mm$^{\#}$	0.21 ± 0.05 mm$^{\Delta}$	0.21 ± 0.07 mm

Note. Different symbols (*, #, Δ) show significant difference between time intervals within the group.

Among the different groups at each time interval, there were statistically significant differences (*P*<.05) between group DL and W, and group DL and D at Δt_1, while there were no significant differences among all groups at Δt_2 and Δt_3 (Fig. 4).

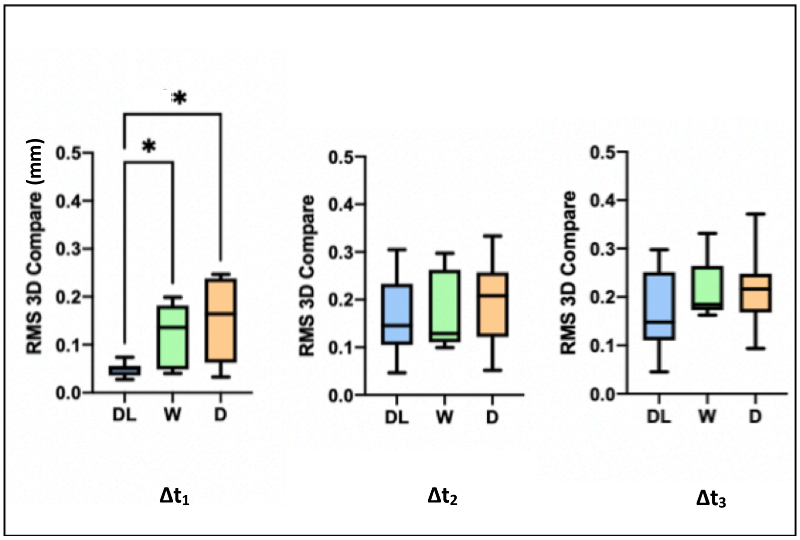

Fig. 4. RMS of each time interval between different groups.
Note * demonstrates statistically significant difference (*P*<.05).

Figure 5 demonstrates the dimensional change of each group by different time intervals. After 1 week (t_2), all three groups showed consistent stability, with relatively flat slope as time increased. Even though group DL showed the highest difference at the beginning, the final dimensional change at Δt_3 was the lowest value (.17 ± .08 mm), compared with group W (.21 ± .05 mm) and group D (.21 ± .07 mm).

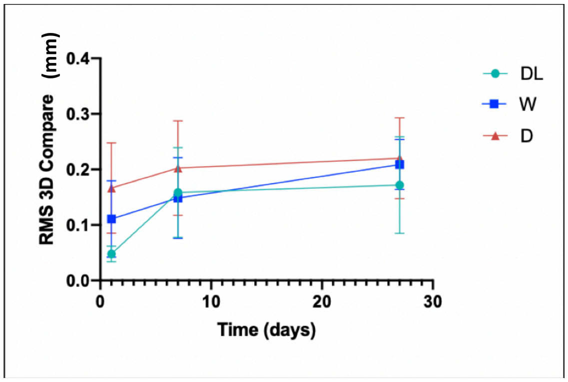

Fig. 5. RMS of each group at different time intervals.

Figure 6 demonstrates the location analysis by calculating the RMS on specific areas, specifically the right molars, left molars, and incisors at the Δt_3 time interval. There was no statistically significant difference in RMS among all different areas for all groups.

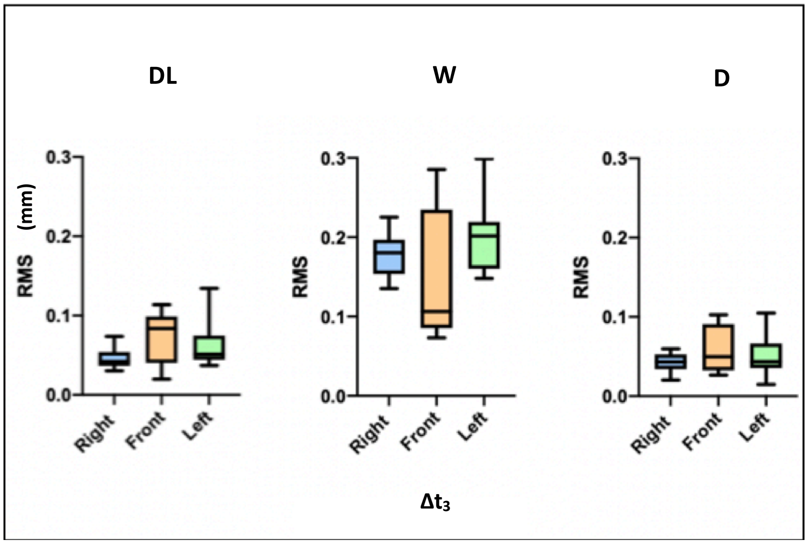

Fig. 6. RMS at Δt_3 comparing three different locations, right molars area, incisors area and left molars area. No statistically significant difference was found at Δt_3 among groups and different locations (*P*>.05).

In terms of qualitative analysis, the color maps of each group are presented (Fig. 7, 8 and 9). Figure 8 shows the least color map error in group DL, as the dominant color on the map is green at Δt_1, Δt_2, Δt_3. In Figure 9 and 10, the color maps of groups W and D had yellow, orange, and light blue colors indicating that there was no extreme discrepancy form the reference model at any time interval (Fig. 9 and 10). However, overall analysis of all three groups shows that the anterior area had more positive dimensional distortion (yellow) while the right and left molar areas had more negative dimensional change (blue) at Δt_3. In addition, in all groups, the cusps showed positive dimensional distortion (yellow), compared with the grooves (blue).

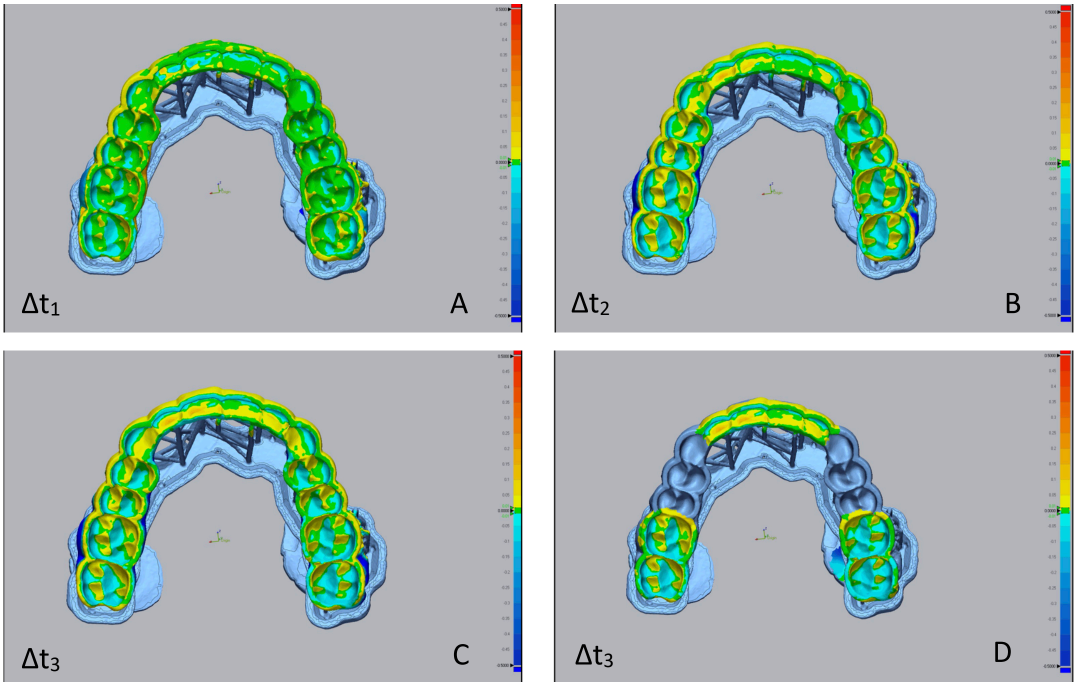

Fig. 7. Qualitative 3D analysis of group DL. A at Δt_1, B at Δt_2, C at Δt_3, D location analysis at Δt_3.

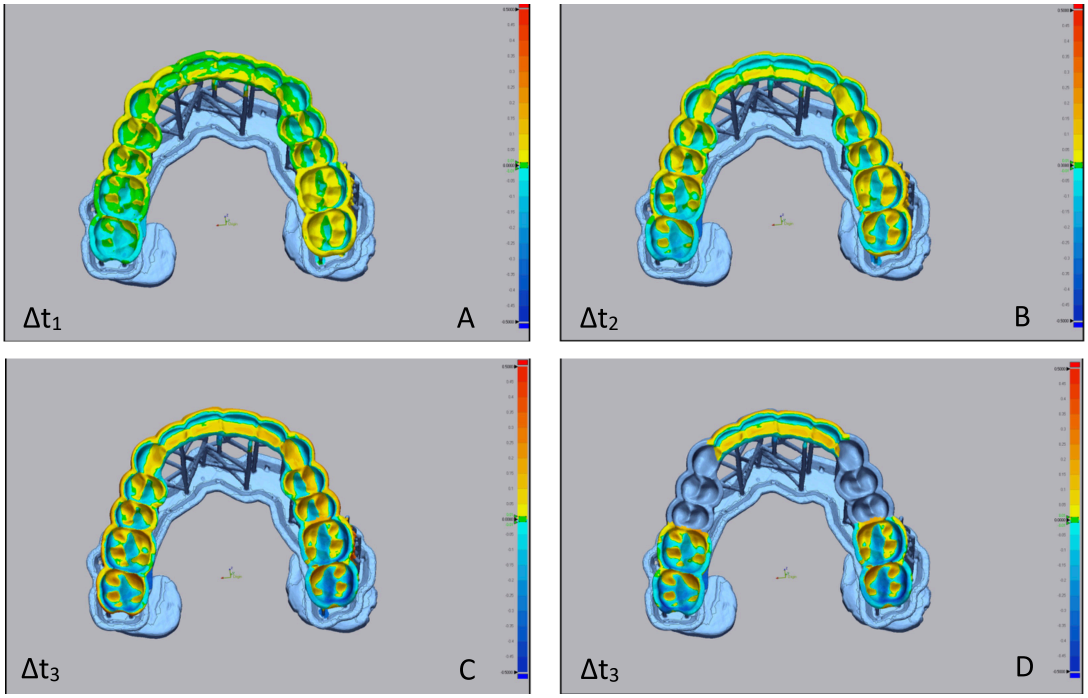

Fig. 8. Qualitative 3D analysis of group W. A at Δt_1, B at Δt_2, C at Δt_3, D location analysis at Δt_3.

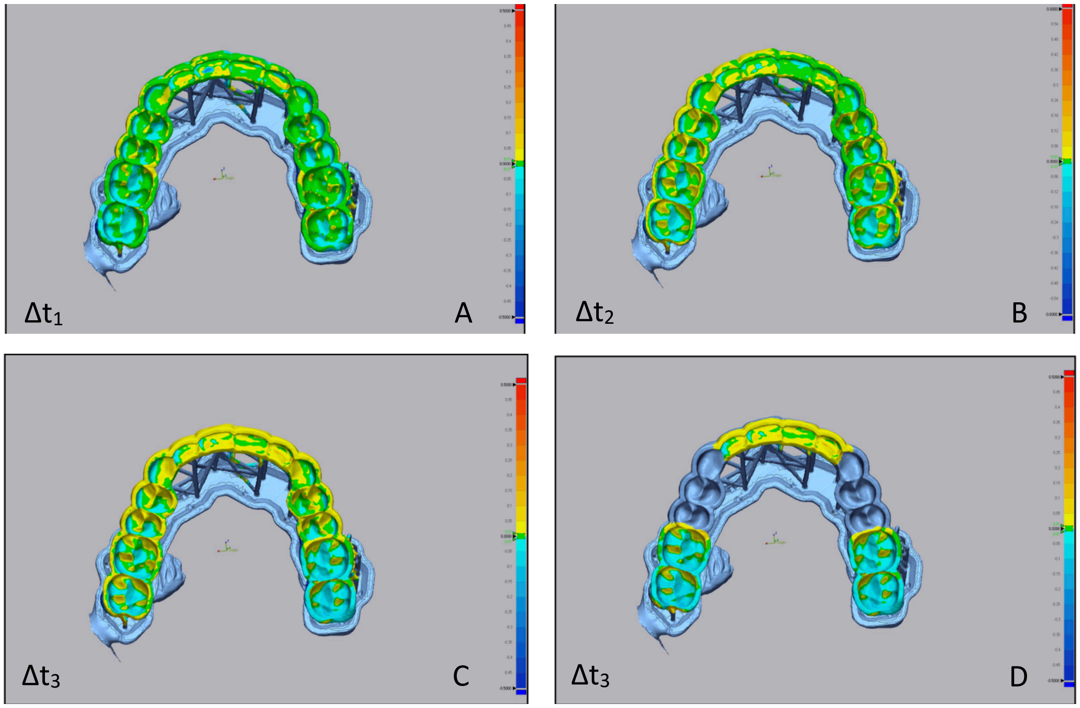

Fig. 9. Qualitative 3D analysis of group D. A at Δt_1, B at Δt_2, C at Δt_3, D location analysis at Δt_3.

4. DISCUSSION

This in-vitro study investigated the effect of different storage environments on dimensional stability of occlusal devices fabricated by 3D printing technology at different time intervals, such as Δt_1 (t_1- t_0), Δt_2 (t_2-t_0), and Δt_3 (t_3- t_0). The evaluation of dimensional stability revealed that there were statistically significant differences among the groups only at $\Delta t_{1.}$ At Δt_2 and Δt_3, and there were no statistically significant differences between the groups. Therefore, the null hypothesis was rejected.

The samples were re-grouped as two subgroups; the devices (group DL) stored in light and the devices (group W and D) stored in a dark area, in order to analyze the light effect on the dimensional stability (Fig. 10). In terms of light effect there was no statistically significant difference between the two subgroups (group DL and group W, D). This comparison shows that a patient can store the occlusal device either under light or at dark area. In addition, the samples were re-grouped to a dry group (group DL and D) and a wet group (group W) to investigate the effect of a wet environment (Fig. 10). There was no significant difference between the subgroups (dry and wet). This indicates that, in a clinical setting, a patient can store the occlusal device either in a wet or dry container. According to the results of this present study, the dimensional stability of the 3D printed occlusal devices that have been post-cured and cleaned is not affected by the humidity or the light exposure of the storage environment chosen.

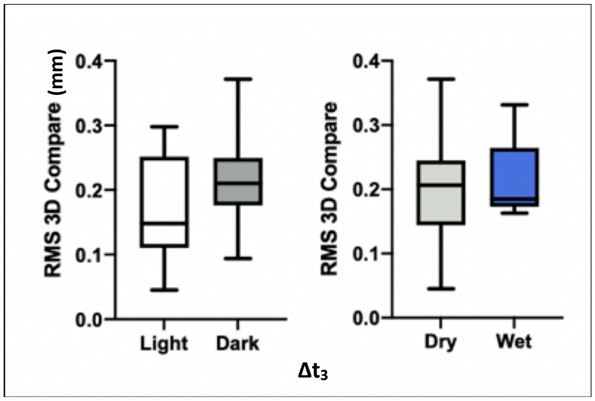

Fig. 10. RMS 3D compared between occlusal devices stored under natural light and dark box (left), between devices stored in a dry and wet environment (right).

According to Zafar et al,[16] polymethyl methacrylate (PMMA) has been used as denture base material and occlusal device. The immersion of PMMA in water is suggested to reduce the residual amount of monomer during the polymerization process, thus eliminating the cytotoxicity of the material. A physical property of PMMA is water sorption. Therefore, when the patient is wearing the prosthesis saliva sorption occurs and the appliance expands. If the device is not stored in water after use, the residual monomers won't be released in the water and could cause toxicity to the patient, and the device will get dry and shrink, resulting in distortion and ill-fit.[16]

Berli et al[21] compared the mechanical properties including water sorption and water solubility of pressed, milled, and 3D-printed resins for occlusal devices. After immersing the specimens in 37° C water for 50 hours followed by 20,000 thermocycles at 5 ° C and 55 ° C, they found that the water sorption and solubility were significantly affected (*P*<.001) by the material used. Comparing the pressed and milled resins to the 3D-printed resin materials showed greater water sorption and solubility, indicating an increase in weight. After drying out, two of 3D printed occlusal device materials showed decrease in weight, while other resin materials had a slight increase in their weight. In the present study, the qualitative analysis demonstrated a similar phenomenon; color map of group W showed more yellow color area (volume increase) than blue color area (volume decrease) after 27 days, compared with other groups (dry condition).

Reyes et al,[20] demonstrated that surgical guides fabricated from CAD/CAM technology had less fit accuracy than the ones conventionally fabricated with acrylic resin. The CAM/CAM guides were designed on a scanned cast and printed with a 3D printer, while the conventional guides were fabricated by using a stone model. The scanned casts were also 3D printed and the guides were cemented to their casts and cross-sectioned. The space between the guide and the model was calculated; .32 ± .36 mm for the CAD/CAM surgical guides and .15 ± .17 mm for the conventional guides. In the present study, the distortion amount was between .04 ± .01 mm at Δt_1 and .21 ± .07 mm at Δt_3. This amount is minimal, compared to the space between the guide and cast, therefore indicating that the amount of distortion of the present study is not clinically significant.

Kessler et al[5] assessed the post-curing monomer release of resins applicable for 3D printing of surgical guides. In their study, they used five different resins and three different printers. They immersed their samples to water and monomers' concentration was calculated. The highest concentration of monomer was found after three days. Among the thirteen different monomers eluted from the resin after post-curing process, methyl methacrylate had the highest concentration. Their results indicate that the printing technique and the resin material plays an important role in monomer elution. This monomer elution could lead to dimensional changes of the samples no matter what storage media is used, therefore potentially affecting the internal fit of the 3D printed appliance.

When the different locations of each group were compared, there was no statistically significant difference found. However, the qualitative evaluation showed that that the front area of device had positive dimensional change (yellow) while the right and left molar areas had negative dimensional change (blue) at Δt_3. In a clinical setting, this indicates that the patient would experience a tighter fit on the anterior site and a looser fit on the posterior site of the occlusal device. However, the difference was not statistically significant.

One of the limitations of this study is that the present study did not simulate the actual use of an occlusal device intra-orally, like in vivo study would do. More specifically, the temperature change that occurs in an intra-oral situation was not taken into consideration in this study. When the device is not in use, it is exposed to room temperature. However, when in use, the temperature changes to body temperature. In the future, an in vivo study about dimensional stability should be made to investigate the effect of actual occlusal force and the clinical distortion that could happen in a clinical setting.

CONCLUSIONS

Within the limitations of this in vitro study, the following conclusions were drawn:

1. Within the same group, group DL showed the highest dimensional change after 24 hours.
2. However, at Δt_2 and Δt_3, the dimensional change among the different groups was not statistically significant, indicating that the storage method does not clinically affect the fit of the occlusal device.
3. In terms of location comparison, there was no statistically significant differences among the three different locations, for all groups after 27 days.

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