Impact of intraoral scanning conditions on the accuracy virtual aligners (VA)

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Objective: In recent years, clear aligners (CA) have become a popular treatment option whose efficacy depends upon the close adaptive fit of the appliance. The aim of this study was to evaluate micron-level surface imperfections found in virtual aligners (VA) caused by the conditions at the time of acquisition of the digital models required for appliance fabrication.
Methods: Fifty patients were recruited for the study. Four digital models were acquired from each patient under four different conditions using a 3Shape TRIOS intra-oral scanner (Copenhagen, Denmark). The conditions for digital model acquisition were, Group 1: No saliva isolation and scanning in daylight (S + DL), Group 2: Saliva isolation and scanning in daylight (NS + DL), Group 3: No saliva isolation but scanning under reflected light (S + RL), Group 4: No saliva isolation but scanning in relatively dark conditions (S + RDC). For each of the 200 digital models, 1 mm thick VAs were created using the Appliance Designer (Copenhagen, Denmark) software. Using the Geomagic Control X (Geomagic; Morrisville, USA) program, the four VAs of each patient were overlaid and common boundaries were obtained by three planes of section. In all comparisons, the VAs in Group 2 were used as a reference and the three other groups were evaluated. Surface deviations between VAs were assessed using the quantitative data of maximum, minimum, negative mean, positive mean, root mean square (RMS), out of the total area (OTA).
Results: Total surface deviation (OTA) was found to be the highest in Group 4 (9.57%). OTA values in Group 1 (7.19%) and Group 3 (7.02%) were similar. Of the other parameters, the greatest data was obtained from Group 4. The distribution of RMS values between groups was: 56 microns in group 1 (S + DL), 53 microns in group 3 (S + RL), 61 microns in group 4 (S + RDC). However, the data comparison indicated that there was no statistically significant difference between the groups.
Conclusion: The conditions for obtaining digital models caused imperfections on the surface of the VAs. The total deviation (OTA) of 7-9% was considered excessive and so it was concluded that the conditions for obtaining digital models could affect the adaptation and success of CAs.
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Introduction

Technological developments in recent years and the increasing demand for aesthetics and the comfort of patients have made clear aligners (CA) a popular orthodontic treatment option.[1] Cases presenting with mild malocclusions were treated using CAs in the early years following the system's introduction, but after a decade of use, more complex cases were successfully managed.[2] In contemporary times, most types of malocclusion may be treated using aligners.

As well as being less visible and arguably causing less root resorption,[3,4] CAs may be removed while eating, brushing and flossing. These system advantages have made aligner treatments more attractive for both patients and clinicians.[5] However, the simulated configuration may sometimes not be entirely consistent with the clinical outcomes of the intended plan. This situation requires revision or refinement by additional CAs in a final phase of treatment.[6] The discrepancy between virtual simulation and clinical outcomes may be related to the manufacturing process of CAs of which an important step is the acquisition of digital models.

Manufacturing process of aligners

Digital scanning systems, CAD / FEM software and rapid prototyping technologies are used in the manufacturing process of aligners.[7] The four basic steps of the general CA production process are:[8]

Step 1: The digital models are acquired at the outset by a direct or indirect approach.
Step 2: The digital model setups are conducted using propriety software (ClinCheck, Align Technology, USA) and the teeth are virtually aligned.
Step 3: At this stage of the process, the digital models are converted into physical models by rapid prototyping technology for each step of virtual planning. The physical models are called a stereolithography apparatus (SLA) mould.[8]
Step 4: Clear orthodontic aligners are produced using polyurethane resin sheets from SLA moulds in a final vacuum thermoforming stage.[9]

Each of the four steps is crucial and the methodology involved and the performance of the materials used in the manufacturing process might have an impact on the efficacy of the CA. In the present study, it was planned to analyse the effects of Step 1 related variables on CA production.

Intraoral scanners (IOS) and their image acquisition techniques

Digital 3D models have also become popular, and today, IOS devices are routinely clinically used. No storage space requirements, easy and selective repeatability, a shorter chair time, easy electronic transmission, and more accurate model analysis are significant reasons for the transition from traditional methods to digital models.[10]

IOS devices are available in a wide range of brands and models. Data capture principles of the devices produced by various companies vary but involve:[10]

3 Shape (Trios 3): Confocal laser technology.
Lava COS (3M Espe): Wavefront sampling.
Align Technology (iTero Element): Confocal microscopy.
Planmeca (PlanScan): Triangulation.
MFI (Condor): Stereophotogrammetric video.

The style of the complex data capture technique affects the speed and accuracy of the devices.[11] Only the image acquisition mechanism of the 3Shape TRIOS scanner (Copenhagen, Denmark) was used in the present study and is described.

The TRIOS system is based on the principle of confocal laser scanning microscopy (CLSM) introduced in 1957.[12] The combination of a laser as a light source and the confocal microscopy technique enables the rapid capture of large numbers of images for transfer to a computer.[13] The system uses a laser reflection that passes from a handheld camera to the scanned objects during image acquisition. The different depths of the target area are identified with the aid of an optical sectioning process incorporated in the CLSM managing software. Each sectioned small area (called a POI, point of interest) is a triangular dataset with x, y and z coordinates. The first two POI coordinates (x and y) are defined on the objects, and the third coordinate (z) is calculated by a method of triangulation (a measurement generated by dividing the area into triangles to determine an unknown coordinate of length, height or mapping). Thousands of triangular datasets (POIs) identified by unique coordinates are subsequently combined and transformed into an STL file[14] (Fig. 1).

The laser light reflection reveals behavioural differences in objects of varying surface properties. The angle and direction of light reflection might be influenced by whether the scanned object is glossy or matt. Dryness or wetness could also be a factor by causing the dispersal of light. If the digital models are influenced by confounding variables, the subsequently manufactured CAs may also be affected. Therefore, the present study aimed, as the first stage of CA production, to investigate how the digital model acquisition phase affects this process.

Material and methods

The study groups

The experimental protocols of the present study were approved by Afyonkarahisar Health Science University Clinical Research Ethics Committee. Fifty patients who applied to the faculty and signed an informed consent form were included in the study. Since the maxilla was

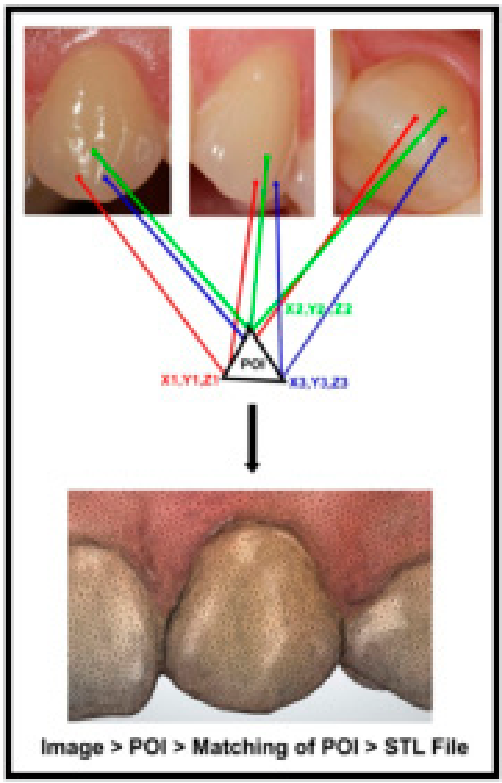

Figure 1. Image acquisition mechanics of the IOS devices.

easier to isolate and largely away from moving soft tissues, only upper jaw digital models were acquired. Patients with missing maxillary teeth, partially erupted teeth, or decayed teeth were excluded. For each of the fifty patients, the upper arch was scanned four times under different environmental conditions, which generated 200 digital models in total. The conditions for obtaining the digital models were:

- Group 1: No saliva isolation and scanning in daylight (S + DL).
- Group 2: Saliva isolation and scanning in daylight (NS + DL).
- Group 3: No saliva isolation but scanning under reflected light (S + RL).
- Group 4: No saliva isolation but scanning in relatively dark conditions (S + RDC).

Saliva isolation was only performed in group 2. During the isolation, a cheek retractor and cotton rolls were applied, and all the scanned surfaces were air dried before acquisition. To ensure consistent lighting conditions, all digital models were generated at noon (11.30 am-12.30 pm time interval). For the group 4 scan, the clinical curtains were closed and, during the scan, the researcher covered the patient's mouth with a hand to limit the effect of daylight. All scans were performed by a single researcher using 3Shape TRIOS (Copenhagen, Denmark) with TRIOS 2015-1, version 1.4.7.5 software. For the effective use of the device for all scans, the scanning path recommended by the 3Shape company was followed and the colour calibration setting was reset for each patient.[15]

Creation of virtual aligners

The 'Create Shell' option in the Appliance Designer (Copenhagen, Denmark) software was applied. A total of two hundred VAs were created from the scanned digital models. Both the teeth and the palatal roof of the models were covered by the VA, and the appliance margins were positioned 1–2 mm above the gingival level on the labial and buccal aspects (Fig. 2). In addition, the thickness of all VAs was standardised and set to 1 mm (Fig. 3).

VA superimposition and calculation of surface deviations

All VAs were imported into Geomagic Control X (Geomagic; Morrisville, USA) software in STL format. Initially, the four different VAs created from each patient's digital models were superimposed. The margins of the VAs were then re-contoured by the use of the three sectioning planes (one horizontal plane positioned 1–2 mm above the gingival level and two vertical planes located distal of the right and left upper first molars), and common boundaries were identified (Fig. 4). Since the environmental conditions (NS + DL) in Group 2 are recommended by the manufacturers, the virtual VAs produced from the models in this group were used as a reference. Group 1, Group 3 and Group 4 VAs overlapped with Group 2 VAs by using a best-fit algorithm. The superimpositions were performed using the best-fit surface registration (global and fine) feature with an 80-iteration count (Fig. 5).[16,17] After each superimposition, a colour map illustrating the surface imperfections between the reference VA and the tested VA was automatically displayed by the software and converted into numerical data (Fig. 6). The numerical data included: Means of Negative Deviation (MND), Means of Positive Deviation (MPD), Root mean square (RMS), In Total Area (ITA), Out Total Area (OTA). OTA was divided into two and described as Positively positioned areas (PPA) and Negatively positioned areas (NPA).

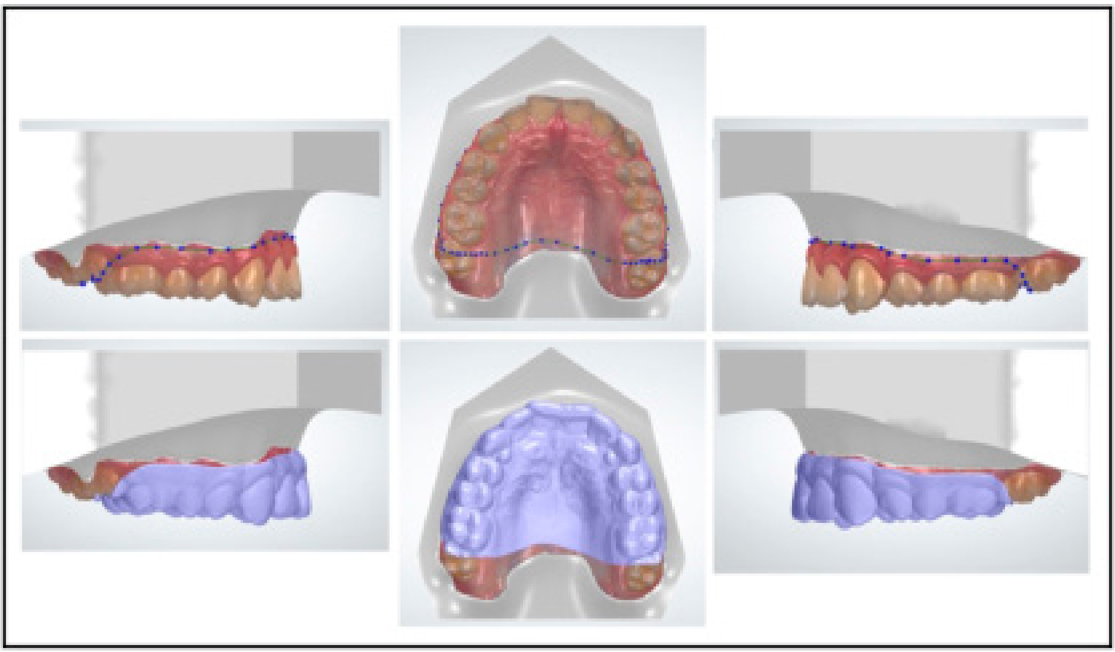

Figure 2. Creation of the virtual aligners.

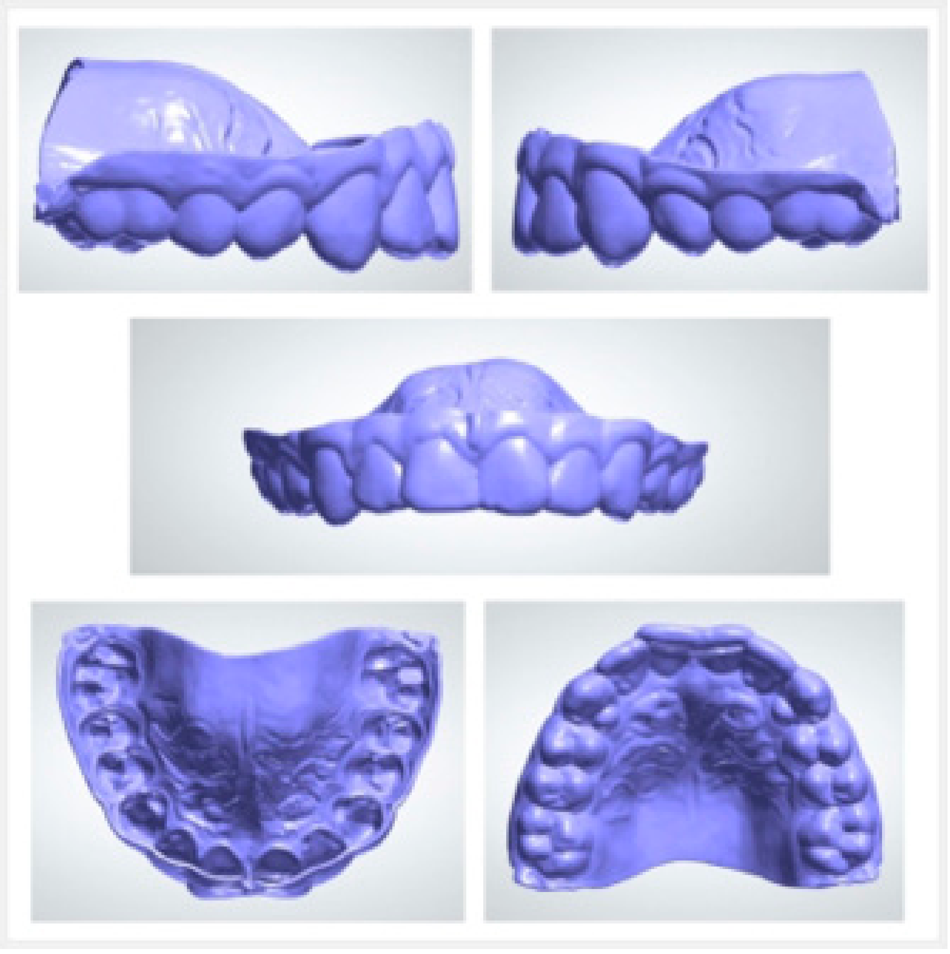

Figure 3. Picture of a 1 mm thick VA from various angles.

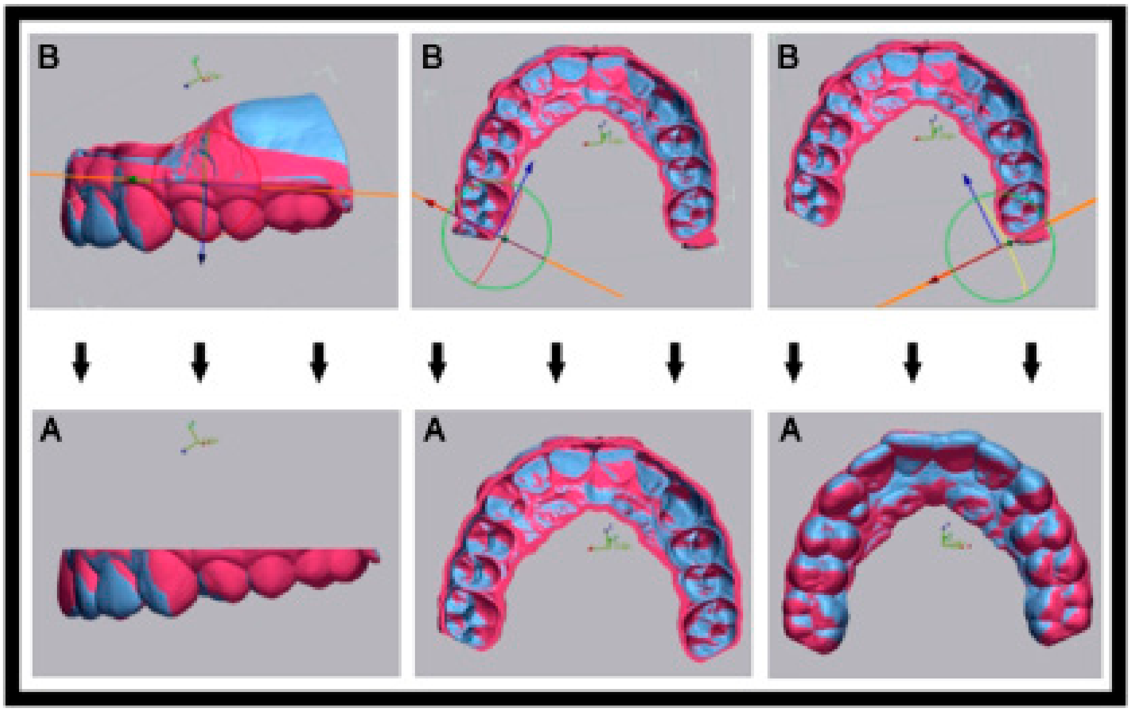

Figure 4. Three planes of section (orange lines) used to achieve common boundaries. (B) Before sectioning, (A) after sectioning.

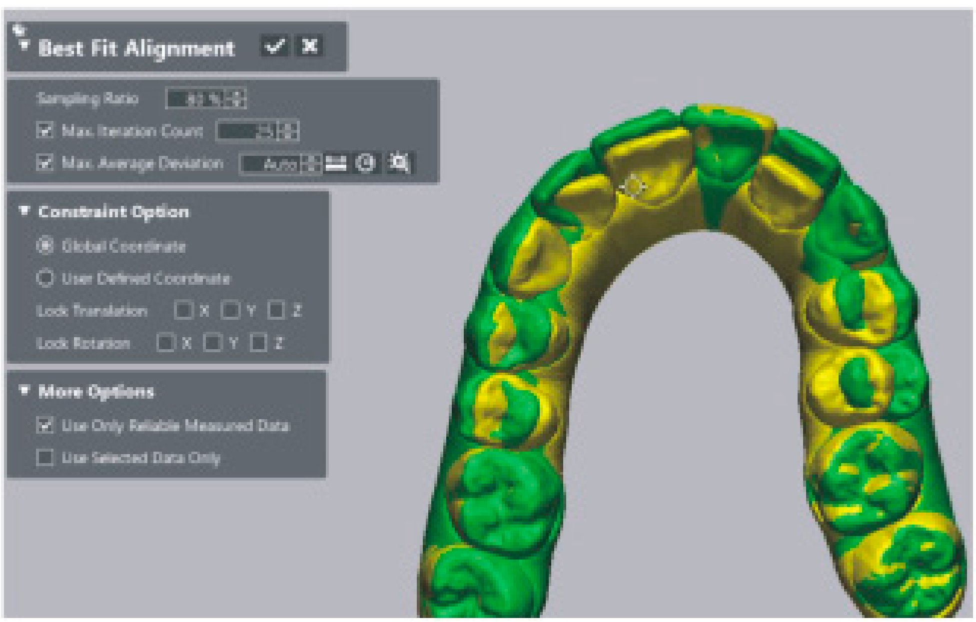

Figure 5. Illustration of the settings that were applied prior to the best-fit alignment.

Statistical analysis

All statistical analyses were performed using the SPSS 22.0 package program (SPSS Inc., Chicago, Ill). The one-way ANOVA test and post-hoc Tukey test were applied to compare the numeric data between the test groups.

Results

The findings of the digital model superimpositions are presented in Table I. The presence of saliva in Group 1 resulted in an average discrepancy of 7.19% (OTA). A mean of -43 micron negative deviation (MND) and an average of 34 micron positive deviation (MPD) were

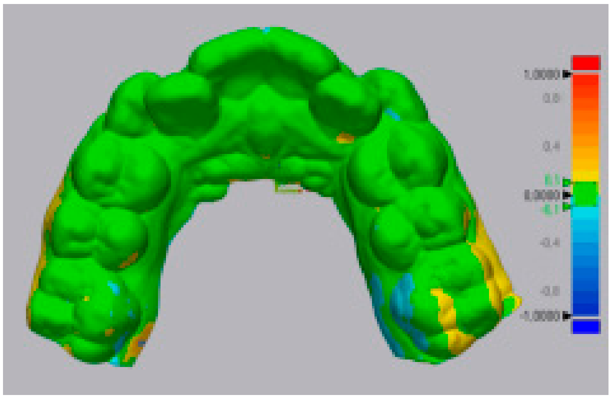

Figure 6. Overlapping of the VAs. The meanings of the color codes: green; perfectly aligned areas, red; positively positioned areas (PPA) relative to the reference model, blue; negatively positioned areas (NPA).

observed in this group. The RMS value of Group 1 was 56 microns.

In Group 3, only the reflected light was found to cause a deviation of 7.02% (OTA). The distribution of other findings assessed in Group 3 was: MND:-42 microns, MPD: 40 microns and RMS: 53 microns.

The data obtained in Group 4 revealed that the dark environment increased the surface discrepancy by an average of 2% (from 7.19 to 9.57%) compared with the presence of saliva. The other examined parameters in this group also showed greater deviations (MND: -48 microns, MPD: 35 microns, RMS: 61 microns) relative to Groups 1 and 3.

The irrational distribution of results between the groups was linked to the unpredictability of the behaviour of light. An average of 7–9% of the total surface (OTA) was considered problematic in the experimental groups. The results showed that environmental conditions had a negative impact on the acquisition of digital models. The adaptation and performance of the CAs would therefore be impaired.

In an examination of a single model, it was noted that the negative discrepancy could decrease accuracy by -74 microns in Group 1 and that a positive discrepancy could increase accuracy by +74 microns. These values were -70 microns and +70 microns for Group 3 and -60 microns and +60 microns for Group 4 (Table I). In a comparison of all parameters, there was no statistically significant difference between the groups. It is considered that these discrepancies, ranging from 60 to 70 microns, may prevent CAs from fitting firmly and therefore achieving effective tooth movement.

Discussion

Contemporary patients desire improved aesthetics following orthodontic treatment, but do not want to compromise aesthetics during treatment. Therefore, the popularity and use of CAs has become widespread among young people and adults.[18]

There are many factors affecting orthodontic tooth movement (OTM) produced by CAs and are related to age, gender, patient compliance, root length, systemic diseases, drugs, bone level and density.[19,20] Apart from patient-related factors, variations in any of the four basic stages of CA production can alter the effectiveness and precise fit of the appliances. Martorelli et al. stated that the manufacture of CAs using two different techniques (rapid prototyping (RP) systems and computer numerical control milling machines) had an impact on the fit of appliances and the speed of tooth movement.[21] In addition, the material types (polyvinyl chloride or polyethylene terephthalate glycol) and the thickness of the CAs are

Table I. Mean values of the parameters and comparison of findings among groups.

	RMS (μ) Mean ± SDs	MPD (μ) Mean ± SDs	MND (μ) Mean ± SDs	ITA(%) Mean ± SDs	OTA(%) Mean ± SDs	PPA(%) Mean ± SDs	NPA(%) Mean ± SDs
Group 1	56.3 ± 22.7^a	34.9 ± 13.5^a	-43.5 ± 14.7^a	92.8 ± 5.4^a	7.1 ± 5.4^a	2.1 ± 2.3^a	5.0 ± 3.3^a
Group 3	53.9 ± 22.0^a	35.2 ± 13.4^a	-42.1 ± 14.8^a	92.9 ± 6.1^a	7.0 ± 6.1^a	2.3 ± 2.5^a	4.6 ± 3.6^a
Group 4	61.9 ± 19.1^a	40.3 ± 13.1^a	-48.4 ± 13.3^a	90.4 ± 6.7^a	9.5 ± 6.7^a	3.2 ± 3.0^a	6.2 ± 3.8^a
Total	57.4 ± 21.4	36.8 ± 13.5	-44.7 ± 14.5	92.0 ± 6.2	7.9 ± 6.2	2.6 ± 2.7	5.3 ± 3.6
	P = 0.164	*P* = 0.79	*P* = 0.78	*P* = 0.72	*P* = 0.72	*P* = 0.89	*P* = 0.61

Note: In each column, different superscripts indicate statistically significant difference between groups ($p < 0.05$). (unit: μ (micrometer) and % (percentage)).

other factors that affect the biomechanical behaviour and success of the appliances.[22]

Dasy et al. stated that the retention of an aligner was influenced by the shape of applied attachments and the level of CA stiffness (soft, medium or hard)[23]. Force generation and the efficiency of CAs could be improved by altering the manufacturing method (vacuum-formed or pressure-formed). The pressure-forming method maximises the adaptation of CAs to the teeth[24]. In addition, the present findings have shown that the conditions during the acquisition of the digital models could negatively affect the effectiveness and adaptation of the CAs. This significantly affects the predictability of CA therapy.

The orthodontic effectiveness of CAs is still controversial.[25–27] Nevertheless, it is believed that the predictability of CA treatment could be improved by determining and ensuring that ideal conditions were present during the production stage. The observance of optimal conditions could reduce or eliminate the need for refinement at the end of CA treatment.[6]

Recently, digital impression systems have become a routine part of orthodontic and general practice dentistry.[28,29] Ender et al. reported that digital measurement systems had equal or higher accuracy than conventional impression techniques.[30] Manufacturers of IOS devices recommend that digital models are created in daylight and after saliva isolation. The companies now warn that the reflection of the hand-held camera beams on the surface of a scanned object could be affected by environmental conditions (light and saliva). The same often applies with traditional impression materials. Drying the teeth before taking an impression with a silicone-based material increases the accuracy of the impression and the quality of the dental prosthesis.[31] The total surface imperfections (OTA) obtained in Group 1 (7.19%), Group 3 (7.02%) and Group 4 (9.57%) emphasise the importance of environmental conditions during digital model acquisition. However, the level of surface irregularity and its location is unpredictable and difficult to estimate. Furthermore the behaviour of light reflected from complex, wet or dark surfaces is also unpredictable. In addition to the environmental conditions, the textural properties and the anatomical complexity of the scanned object could change the reflection of surface light[32] (Fig. 7). Su et al. stated that the acquisition of the digital model intraorally or extraorally induced a discrepancy of 88 microns on the model surface.[33] Even after repeated scans of the same model using the same device, a 10 micron discrepancy could be observed even when the environmental conditions remained constant.[34] In general, a 42–48 micron negative discrepancy (MND) and 34–40 micron positive discrepancy (MPD) were noted in the present study. Mantovani et al. found voids of 100–400 microns on the surfaces of the teeth while researching the thermoforming procedures of two different aligner materials.[9] Therefore, the present findings may be related to the presence of scanning voids. Furthermore, the variable surface discrepancies might be related to the different image acquisition techniques and the unpredictability of the behavioural movement of light. There is a further possibility that the variations may be associated with the different software versions associated with the devices.

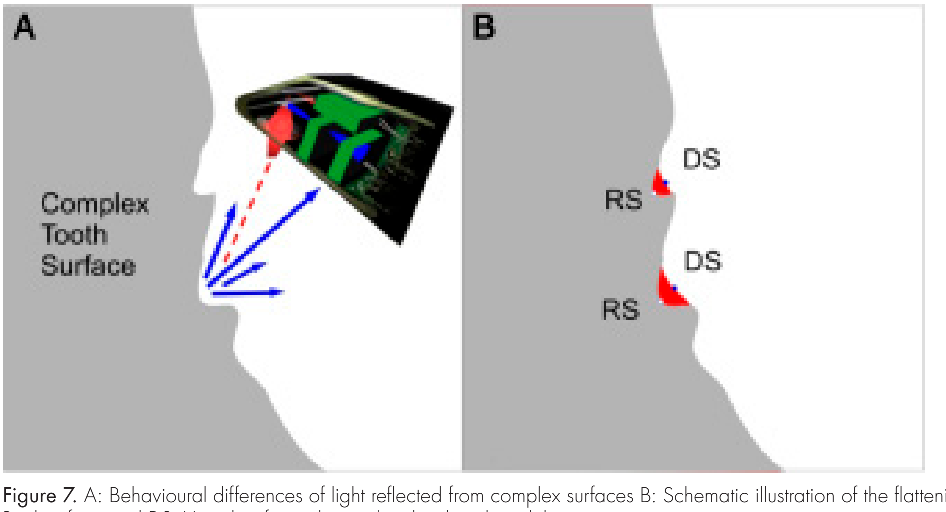

Figure 7. A: Behavioural differences of light reflected from complex surfaces B: Schematic illustration of the flattening occurring on complex surfaces, RS: Real surface and DS: Virtual surface obtained in the digital model.

After sectioning in the horizontal plane, areas of the palatal mucosa (which is not required for aligner manufacture) remained as no detailed palatal sectioning was performed. This situation should be considered as a limitation of the present study. Another limitation may relate to a lack of standardisation of the levels of patient crowding which should be managed by future research.

Conclusion

1. The conditions for the acquisition of digital models have an impact on the adaptation of CAs. However, the location, degree or type (positive or negative) of the iregularities cannot be predicted.
2. Standardisation of the environmental conditions and the observance of the manufacturer's instructions may increase the consistency of clinical outcomes with the virtual set-up. It may also reduce the need for refinement at the end of treatment.
3. Further research is needed to test the level of crowding and clinical outcomes of the present fully digital study.

Ethics approval

This study was approved by Afyonkarahisar Health Science Clinical Research Ethics Committee.

Consent for publication

Written consent for publication was obtained from each participant.

Availability of data and materials

Data and materials are available at the Orthodontic Department in the Faculty of Dentistry, University of Afyonkarahisar Health Science.

Conflict of Interest

The authors declare that there is no conflict of interest.

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