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Original Research Article

A scanning electron microscope evaluation of surface roughness of different clear aligners – A comparative in-Vitro study

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ABSTRACT

Introduction: Clear aligner are thermoplastic polyurethane materials which produces small increments of tooth movements by each aligner tray. Clinical effectiveness of the treatment largely depend on the mechanical properties of the material. The use of scanning electron microscopy (SEM) in invitro environment allows to evaluate the surface morphology of the aligners

Aim: The aim of the study is to compare the surface roughness of different types of clear aligners after thermoforming and after invitro aging.

Materials and Methods: A sample of 15 aligners from Group A (DURAN), Group B (ERKODUR), Group C (MONOFLEX) were taken for this study. After screening the subjects were scanned by intraoral scanner and STL file were imported to Maestero 3D software. Then resin models were printed and aligners were fabricated in the models by thermoforming machine. The first set of aligners were scanned by Scanning Electron Microscope and another set of aligners were placed in chewing simulator for simulating intraoral environment. Then the second set of aligners were sent for SEM evaluation.

Result: Mean comparison of surface roughness and root mean square surface roughness was compared by paired t test and comparison among the groups was done by one way ANOVA test.

Conclusion: The surface roughness of both aligners increased after thermoforming. This could be due to thermoforming process which could be due to temperature variation. After the ageing of the aligners in the invitro environment, there is homogenous and smooth layer of the aligner surfaces which could be due to adhesion of biofilm and polishing effect by chewing strokes.

1. Introduction

At the present time clear aligners have become a propitious alternative to conventional fixed mechanotherapy in orthodontics. There is a significant increase in patients seeking aesthetic treatment options due to evolving perception needs in the current era. Clear aligner are thermoplastic polyurethane materials which produce small increments of tooth movements by each aligner tray. The use of invisible materials for orthodontics started with Kesling, McNamara, Pontiz who used various materials for retainers.[1] In 1998 two Stanford graduates Zia Chishti and Kelsey Wirth developed aligners with CADCAM technology.[2] Clear aligners have evolved from the first generation used to treat simple malocclusions to the eighth generation with Smart force activation. Aligner sheets have developed from single-layered to multilayered sheets to ensure good durability and dimensional stability.

Aligner manufacturers typically utilize PET-G, polypropylene, polycarbonate, thermoplastic polyurethanes,

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and ethylene vinyl acetate. Thermoplastic materials must ensure biocompatibility, translucency and transparency, high elasticity, and good deformability. PET-G is the most commonly used material and encompasses most ideal aligner material properties. The clinical effectiveness of the treatment largely depends on the mechanical properties of the material. Most aligners after intraoral usage show changes in mechanical properties due to the influence of various factors.[2] Different types of aligner brands have been introduced by manufacturers. However, the effectiveness of these is still questionable.

Previous research has shown that changes in aligner surface morphology are influenced by resin content and hardness, which play a crucial role in wear resistance.[3] The surface roughness of the material changes after thermoforming which would affect the dimensional stability of the aligner.[4] The use of scanning electron microscopy (SEM) in invitro environment allows to evaluate the surface morphology of the aligners. The purpose of this study is to evaluate material changes and determine when aligners lose clinical efficacy while maintaining biological safety.

2. Aims

The aim of this current study is to investigate the surface roughness of clear aligners after thermoforming and after invitro aging.

3. Objectives

1. To compare the changes in surface roughness between clear aligners before and after in vitro aging.
2. To identify any differences in surface roughness between different brands of clear aligners.

4. Materials and Methods

A total of 15 samples were taken for this study. An in vitro study was conducted in Adhiparasakthi dental college and Hospital. As per grouping, each group consists of 5 samples. All the samples which satisfies the inclusion and exclusion criteria were included in this study.

4.1. Inclusion criteria

1. Patient age between 18-35 years
2. Angles Class I and Class II malocclusion with fully erupted teeth from 17-27 and 37-47
3. Mild crowding and spacing
4. Rotation < 30 degree
5. No history of parafunctional habits
6. Good oral hygiene and periodontal health

4.2. Exclusion criteria

1. Class III malocclusion
2. Severe skeletal deep bite and open bite
3. History of TMJ disorders
4. History of craniofacial abnormalities
5. Previous history of orthodontic treatment
6. History of any allergy.
7. Patients with poor oral hygiene
8. Patients with missing teeth, restoration or prosthesis

After intial screening the samples were grouped as Group A(Duran) and Group B(Erkodur) and Group C(Monoflex) by simple random sampling method. Each group consist of five samples. The subjects of Group A, Group B and Group C were scanned by intraoral scanner (Prime scan, Dentsply)(Figure 1). The scanned files were imported in STL file format to Maestro 3D software (Figure 2). Segmentation and labeling was done and then imported to model printer (Figure 3). Then the models are printed and washed with isopropyl alcohol (Figure 4) and post-cured (Figure 5) using UV light. Thermoforming machine (Ministar thermoforming machine) (Figure 9) was used for aligner fabrication. As the models of each group was ready aligner sheets were fabricated according to each brands manufacturer's instructions. Each aligners were trimmed manually and polished by single trained operator to prevent any bias in the study.

The first set of aligners after thermoforming were scanned by Scanning Electron Microscope (Figure 14) and high resolution images were obtained. To deeply investigate the surface morphology high resolution images were taken. Another set of aligners were immersed in oral chewing simulator (Chewing Simulator CS-4.4)(Figure 13) to chewing cycles using linear 2-axis motion. The chewing simulator (CS-4, SD Mechatronik, Germany) has four testing chambers within a thermocycling chamber. It has two moving parts, the vertical bar (Z-axis), and the horizontal table (X-axis). The samples were mounted onto the table, which can move back and forth. Customized antagonists measuring 4 mm in diameter (Steatite, SD Mechatronik, Germany) were connected to the vertical bar, which moves up and down with a load of 5 kg applied to the samples simulating a masticatory load intraorally. After 2 weeks all the retrieved aligners were then sent for SEM imaging.

All measurements were reassessed by the same operator. The method of error for all measurements were standardized by statistical analysis.

5. Results

Scanning electronic microscope (SEM) images of all pre treatment group shows that there were irregularities and jagged and grainy structures and after invitro ageing all the groups has similar smooth homogenous layer when compared with after thermoforming groups.

Table 1: Mean comparison of Root mean square surface roughness (Rq) between Pre treatment and Post treatment of different groups.

Group	Duration	N	Min	Max	Mean	SD	Mean difference	P value
Group A	Pre	5	13.10	14.80	13.90	0.75	1.20	0.001 S
	Post	5	12.00	13.70	12.70	0.72		
Group B	Pre	5	14.20	16.20	15.42	0.80	2.88	0.007 S
	Post	5	11.50	13.90	12.54	0.87		
Group C	Pre	5	14.80	17.30	16.08	0.91	2.60	0.004 S
	Post	5	12.40	14.30	13.48	0.77		

Statistical Analysis: Paired t test.
S: Statistically significant if P<0.05; NS: Not significant.

Table 2: Mean comparison of root mean square surface roughness (Rq) (Pretreatment-Post treatment) among the groups.

Groups	N	Minimum	Maximum	Mean	SD	P value
Group A	5	0.80	1.60	1.20	0.34	
Group B	5	1.40	3.80	2.88	1.26	0.034 S
Group C	5	1.30	3.40	2.60	0.98	

Statistical Analysis: ANOVA one way test.
S: Statistically significant if P<0.05; NS: Not significant.

Table 3: Mean comparison of (Ra) μm between Pretreatment and Post treatment of different groups.

Group	Duration	N	Min	Max	Mean	SD	Mean difference	P value
Group A	Pre	5	12.00	12.60	12.24	0.23	0.64	0.000 S
	Post	5	11.30	11.90	11.60	0.22		
Group B	Pre	5	11.70	13.20	12.12	0.63	0.80	0.014 S
	Post	5	10.50	12.80	11.32	0.94		
Group C	Pre	5	11.60	12.90	12.18	0.62	0.68	0.002 S
	Post	5	11.10	12.00	11.50	0.42		

Statistical Analysis: Paired t test.
S: Statistically significant if P<0.05; NS: Not significant.

Table 4: Mean comparison of(Ra) μm (Pretreatment-Post treatment) among the groups.

Groups	N	Minimum	Maximum	Mean	SD	P value
Group A	5	0.60	0.70	0.64	0.05	
Group B	5	0.40	1.40	0.80	0.43	0.652 NS
Group C	5	0.50	1.00	0.68	0.22	

Statistical Analysis: ANOVA one way test.
S: Statistically significant if P<0.05; NS: Not significant.

6. Discussion

This study investigates the surface characteristics and wear of different brands of commercially available aligner brands. The surface morphology of a material plays an important role in the treatment outcome of the Clear aligner treatment. There is a strong association between the mechanical properties of thermoplastic materials and force delivery.[5] This study contributes quantitative information on the surface characterization of aligners made in-house. In a study by Dongye fang et al,[4] the surface morphology changes of Invisalign material was done which showed voids, cracks and delamintation in surface of aligner material after 14 days of intraoral usage. Increased loss of transparency from reterieved Invisalign aligners was appreciated in a study conducted by Gracco et al.[6] In evolving scenario of In home aligners various commercially available aligner sheets should be investigated for their dimensional stability in the intraoral environment. So, this study mainly focuses on the surface characteristics of different brands of commercially available aligner brands and also it provides additional insights into the effect of the aligners in the invitro environment and compares the surface features of these appliances to commonly used aligner brands.[7]

The surface evaluation analysis is done Scanning electron microscope (ZEISS SIGMA,GERMANY). This allows to capture of the surface morphology photographs of the samples.[8] The surface roughness of the material is calculated by Image J ® (NIH ImageJ Software, https://

Figure 1: Intra oral scanner, dentsply sirona

Figure 2: Segmentation done in maestro software

imagej.nih.gov/ij/), software, an open-source software for image processing.[5]

The results of this study reveal all the retrieved aligners showed considerable changes in the surface roughness after thermoforming.[9] Roughness parameters increased after thermoforming aligners indicating material integrity and inbred traits.[10]

To obtain a deep investigation of their morphology, SEM images were obtained. The samples have been covered with a thin film of gold (Sputtering process) for 4 min. To investigate the aging effect both thermoformed and invitro-aged samples were taken. SEM investigation revealed surface morphology with micrometric particles, minor superficial changes, and an irregular impurity from the production process. Magnification at 500X reveals the multifaceted and unstructured form of agglomerates that emerge from the surface form different structures. The

Figure 3: Model printer – UNIZ, Nbee

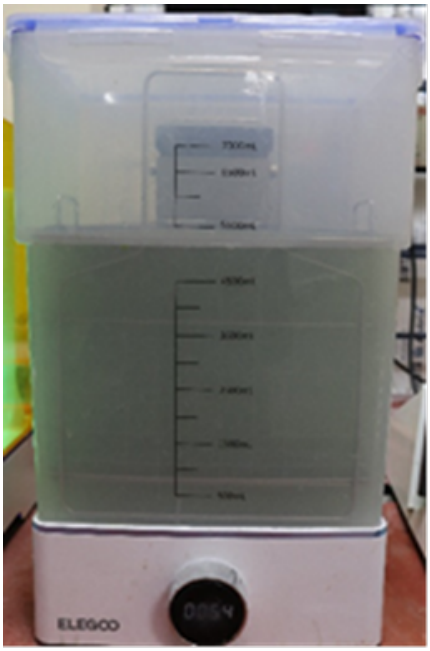

Figure 4: Elegoo -Isopropyl alcohol

Figure 5: Elegoo – Post curing

Figure 6: Group A - Duran aligner sheets

Figure 7: Group B - Erkodur aligner sheets

Figure 8: Group C - Monoflex aligner

Figure 9: : Ministar Thermoforming machine

Figure 10: Group A aligners

Figure 11: Group B aligners

Figure 12: Group C aligner

Figure 13: Chewing simulator

Figure 14: Scanning electron microscope zeiss sigma

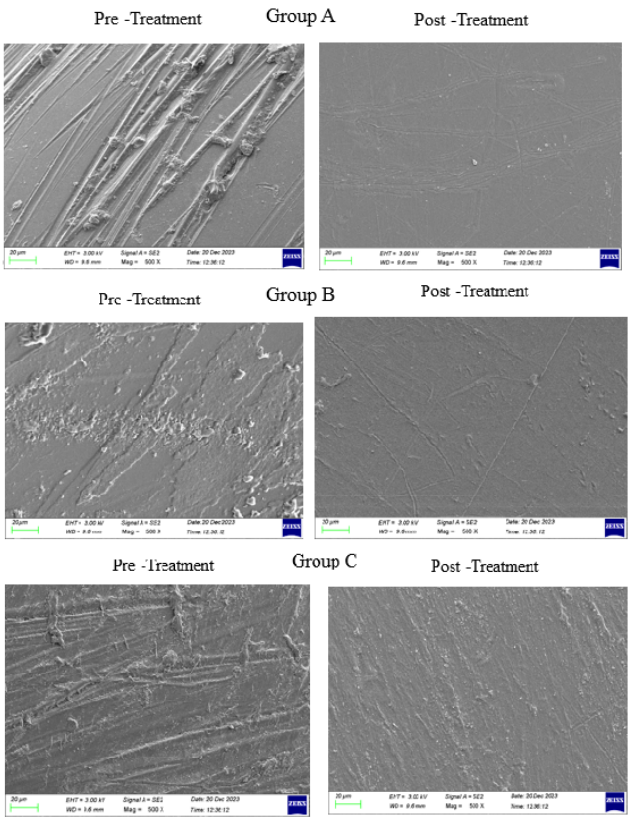

Figure 15: SEM images

surface layer appears partially covered with a laminar structure jagged, grainy, and marked by large grooves.[11]

After the invitro usage there are significant changes in surface altercations of the aligner surfaces. There is a smoother and more homogenous surface of the aligner materials. All the aligner brands showed similar changes which proved that all the aligner sheets are subjected to wear after exposure to the invitro environment and masticatory force.[12]

Choosing the right base material for orthodontic thermoplastic appliances requires understanding the chemical and physical features of each polymeric mixture. Orthodontic appliances are subjected to both short-term and long-term load forces when inserted into the oral cavity. Long-term loads in aligners include abrasion, while short-term loads include aligner insertion and removal from the dental arch. For tooth movement to occur, the thermoplastic appliance must be capable of transferring controlled orthodontic forces even under prolonged masticatory loads.[13] Bradly et al studied the mechanical and chemical properties of LD 30 material and found that the aligner material becomes more brittle and had less modulus of elasticity after intraoral exposure.[14]

To achieve better understanding of the surface morphology of the materials the average surface roughness (Ra) and increased amplitude peak (Rq) which is root mean square roughness were taken for investigation in this study.[12] Increased surface roughness of the material would lead to increased wear of the thermoplastic materials and in turn eventually would decrease the force magnitude. The increased roughness shows that the thermoformed aligners are more prone to the adhesion of biofilm and microbes. The surface roughness of a material influences the coefficient of friction and will affect the micromechanical retention of the appliance.

After the invitro usage, the roughness of the material decreases. This could be due to many attributing factors such as the adsorption of substances or contact with other materials like the polishing effect which would reduce the roughness the aligners. This could be due to the adhesion of biofilm on the aligner surface and the "polishing" effect of aligners when contacting the other surfaces.[12,15] Many aligners are prone to breakage due to increased wear of the material.

It is necessary to know that structural and morphological changes of the material which undergoes masticatory stress and thermal stress and chemical in the oral environment.

7. Conclusion

This study investigates the surface morphology of three different commercially available aligners. The ageing and surface roughness of the aligner material has detrimental effects on the property of the material.

The surface roughness of all aligners increased after thermoforming. This could be due to thermoforming process which could be due to temperature variation.

This increased roughness could lead to increased porosity which can alter the fit of the aligners and deteriorate the property of the aligners.

After the ageing of the aligners in the invitro environment there is homogenous and smooth layer of the aligner surfaces which could be due to adhesion of biofilm and polishing effect by masticatory forces.

To understand how orthodontic forces are affected by these qualities, investigation have been done under simulated clinical situations. Though further study is needed regarding the usage of appliance in intraoral environment. This study ensures that not much clinical significant differences could be seen to affect the stability of the aligners.

8. Source of Funding

None.

9. Conflict of Interest

None.

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