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Engineering and Clinical Study of Surface Geometry of Clear Aligners at the Nanoscale

Monika Machoy [1], Renata Samulak [1] and Sławomir Kulesza [2,*]

[1] Periodontology Department, Pomeranian Medical University, 70-204 Szczecin, Poland; monika.machoy@pum.edu.pl (M.M.); renata.samulak@pum.edu.pl (R.S.)
[2] Faculty of Technical Sciences, Warmia and Mazury University in Olsztyn, 10-719 Olsztyn, Poland
* Correspondence: slawomir.kulesza@uwm.edu.pl

Featured Application: Control of the wearing process of clear aligners and resulting consequences of their improper functioning.

Abstract: This paper investigates the evolution of the outer surface geometry of Invisalign®—clear orthodontic aligners—caused by degradation triggered by wearing. The obtained results served to confirm whether or not the aligners could continue to be used once their wear time in the therapeutic procedure had ended, taking both their geometric and mechanical features into account. The measurements were performed using atomic force microscopy which allowed the mapping of nanomechanical properties. The obtained images were then processed to determine statistical and functional surface geometry parameters in accordance with relevant ISO standards. The results revealed that the unrepeatability of the manufacturing process causes the surface shape parameters of new aligners to be irregular; however, these features become gradually consistent for worn samples. On the other hand, properly used aligners may change in two ways: the outer layer flattens and its thickness decreases, and at the same time the Young's modulus of the material decreases. It follows that the degradation processes may be caused by tribological phenomena (abrasion of contact surfaces) and/or biochemical phenomena (biofilm growth, decomposition of the material under the influence of enzymes in the oral cavity).

Keywords: orthodontics; material engineering; clear aligners; AFM; surface texture

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1. Introduction

Orthodontics is a field of dentistry that has been developing particularly rapidly in recent years. Originally, it mainly involved the treatment of children with removable appliances [1], mainly due to material and technological limitations. The first tooth movements were made possible with the use of acrylic plates with wire retention clamps and an active screw; then came the era of fixed appliances. Currently, the most frequently chosen orthodontic therapy involves overlay appliances. The first aligner system was developed in 1998 when Invisalign® was created [2], but this method has only begun to gain global relevance in recent years, and is slowly gaining an advantage over the classic methods of malocclusion treatment—both due to the multifaceted aspects of patient comfort during treatment and the mechanical properties of the appliance [3]. Fixed orthodontic appliances have already been thoroughly researched in terms of materials. Various types of brackets have been studied: their structure, adhesion to enamel and impact on tissue health [4,5]. On the other hand, aligners—despite their wide clinical use—have not yet been tested as thoroughly as fixed appliances, and each manufacturer creates aligners from their own materials, often patented, with a hidden composition and structure. The structure of the aligner, its surface, sensitivity to conditions in the oral cavity, resistance to pressure (with a maximum chewing force of up to 600 N), deflection, abrasion—all these parameters have a direct impact on the effectiveness of a given system, the transfer of forces from the aligner onto the tooth, and thus on the possibility of proper treatment. Orthodontic treatment is time-consuming and requires a lot of patient commitment. The multitude of companies producing aligners is becoming a problem for doctors due to the inability to assess the effectiveness of specific aligners before choosing them. For this reason, the gap in the field of dental materials engineering should be reduced so that doctors can know what material parameters they should pay attention to when choosing aligners, and what information on the structure should be made available by the manufacturing company in order to increase treatment effectiveness. In the present study, the functional parameters of the SmartTrack® material, from which the pioneering Invisalign® aligners (AlignTechnology, Tempe, AZ, USA) are made, were examined. For this purpose, the surface structures of new and worn Invisalign® aligners were assessed, and the functional parameters of their surfaces were determined in order to evaluate resistance to degradation and abrasion during everyday use. Studies on tooth surface degradation processes date back to the early 1950s, when the relationship between mandibular movements, diet and specific microtraces left on tooth surfaces, observed using an optical microscope, was first demonstrated [6]. Over time, studies using better surface imaging techniques, including the scanning electron microscope (SEM) and advanced image analysis methods, were published [7]. Despite the undoubted progress, it was still impossible to eliminate the two basic problems of this type of research: (1) ambiguous identification and description of the examined surface features, and (2) strong dependence of the examined images on the measurement conditions [8]. It was not until about 20 years ago that standards of criteria for a consistent and repeatable evaluation of tooth surface features and materials used in dentistry were developed [9]. These methods were used in the present study to determine the abrasive wear and biological/chemical degradation of the outer surface of clear Invisalign® aligners using the ability of AFM to collect real, three-dimensional information about the surface shape, in conjunction with a functional analysis of the surface based on the statistical features of height distribution. This allowed us to verify the research hypothesis: “daily use might influence the functional roughness parameters of the clear aligners”. There is still a significant information gap in this area of research. Although papers presenting the results with regard to chemical changes and discoloration occurring in the aligner material under the influence of various factors [10] as well as changes in elastic [11], structural [12] and mechanical properties [13] have been already published, several inconsistencies appear when studying the degradation and wear of the surface from the point of view of changes in its texture, i.e., ordered shape. In other fields of engineering, similar problems were faced and successfully resolved with the identification of “unrepeatability”, i.e., the unstandardized practice of the manufacturing process [14].

2. Materials and Methods

In this study, 4 new aligners, taken out from the original packaging and referred to as “REF” in the following paragraphs, as well as 8 worn aligners were investigated. The term worn aligners refers to those in use for 10 days, 22 h a day (removed for meals and cleaning only). Water was the only liquid that could have been drunk with the aligners in place. Both surfaces of the appliance—internal and external—were cleaned twice a day mechanically with a hard brush and soap, and in the case of severe contamination they were subjected to additional wet chemical cleaning with Corega Tabs® (Haleon, Weybridge, UK) (one tablet per glass of water) for 30 min. The tablets contain: sodium bicarbonate, citric acid, potassium caroate (potassium monopersulfate), sodium carbonate, sodium carbonate peroxide, TAED, sodium benzoate, PEG-180, subtilisin and sodium lauryl sulfoacetate. After the cleaning, the aligners were rinsed and put back on the teeth.

In order to study the geometric surface features of the aligners, samples were prepared by cutting out square, flat fragments of the lower right incisor (approx. 2×2 mm^2) and gluing them to steel plates, exposing the outer surface. The imaged area was chosen considering two factors: (1) the front surface of the aligner was sufficiently flat, and (2) the front surfaces of the incisors are exposed to frequent contact with various solids and liquids, which may result in their faster degradation. The immobilized samples were washed with pure ethanol, blown with dry air and left to dry in the air. Optical images of the samples taken at small magnification (ca. 500×) are shown in Figure 1. The surfaces appear inhomogeneous in terms of numerous irregular grooves seen in the presented images. Three-dimensional images of the surface were recorded with an atomic force microscope (Multimode 8, Bruker, Billerica, MA, USA, with a Nanoscope V controller, Bruker) that scanned 500 nm square fields. In order to verify the homogeneity of the geometric surface features, each sample was scanned in at least 3 different locations separated at least 10 μm from each other. In total, 61 measurements were carried out for the worn aligners and 23 for the new aligners.

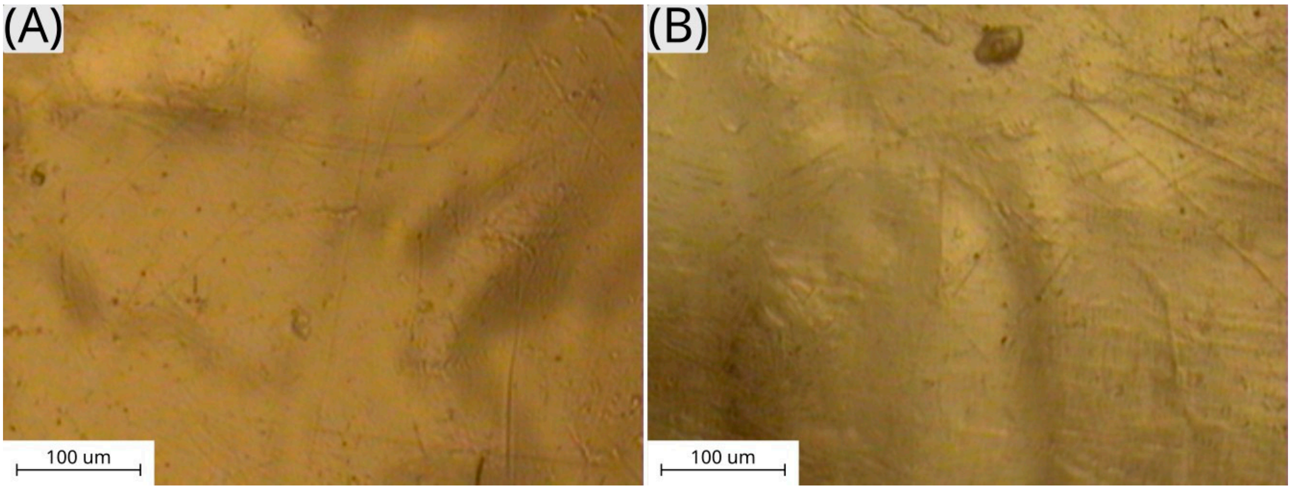

Figure 1. Visual images of the surface of Invisalign® aligners taken using a 500× magnification camera: (**A**) new aligners, (**B**) aligners worn for 14 days.

Imaging was conducted using the PeakForce Quantitative Nanomechanical Mapping (PF-QNM) mode. To this end, HQ:NSC16/Al-BS (MikroMasch, Wilsonville, OR, USA) probes were used with the following parameters: resonant frequency—190 kHz, spring constant—45 N/m, tip radius—8 nm. AFM images were collected with 256 × 256 resolution at a frequency of 1 Hz. The force curve was calibrated by taking an HD-PE (high-density polyethylene) disc with a Young's modulus of 850 MPa as a reference [15–19]. Measurements were carried out in the air at room temperature, using the maximum force of the probe (ranging from 10 to 60 nN) so as to achieve a constant 2 nm deflection of the surface under investigation.

The characteristic parameters of the geometric surface features were determined in accordance with international standards (ISO 25178-2) [20]. In general, these parameters belong to one of the following groups: statistical, functional or mechanical. Statistical parameters are classic measures of variability determined on the basis of the distribution of height samples registered in the AFM image, namely the root-mean-square roughness S_q, texture anisotropy coefficient Str and surface development ratio Sdr. Functional parameters are determined on the basis of the Abott–Firestone curve (AFC), i.e., the cumulative distribution of height samples, and reveal features important in tribology, e.g., contact of the aligner with another solid, abrasive wear, fluid transport, etc. Finally, mechanical parameters are determined using the force–distance curves recorded at any instant location on the sample when the tip approaches the surface. These parameters include the pseudo-Young's modulus and maximum adhesion force. Example images of the topographical view, the pseudo-modulus map as well as the map of the adhesion forces are shown in Figure 2. The obtained results were then tested to answer two important questions, concerning the normality of their distribution, and significant changes occurring due to the performed treatment. The first problem was addressed using the Shapiro–Wilk test of normality with a confidence level of α = 0.05, in which the null hypothesis states that the population is normally distributed. Having that tested negatively, the data from the new and worn samples needed to be compared. To this end, the non-parametric Mann–Whitney U test was used with the same confidence level (α = 0.05) and the null hypothesis stating that sampled groups come from the same population.

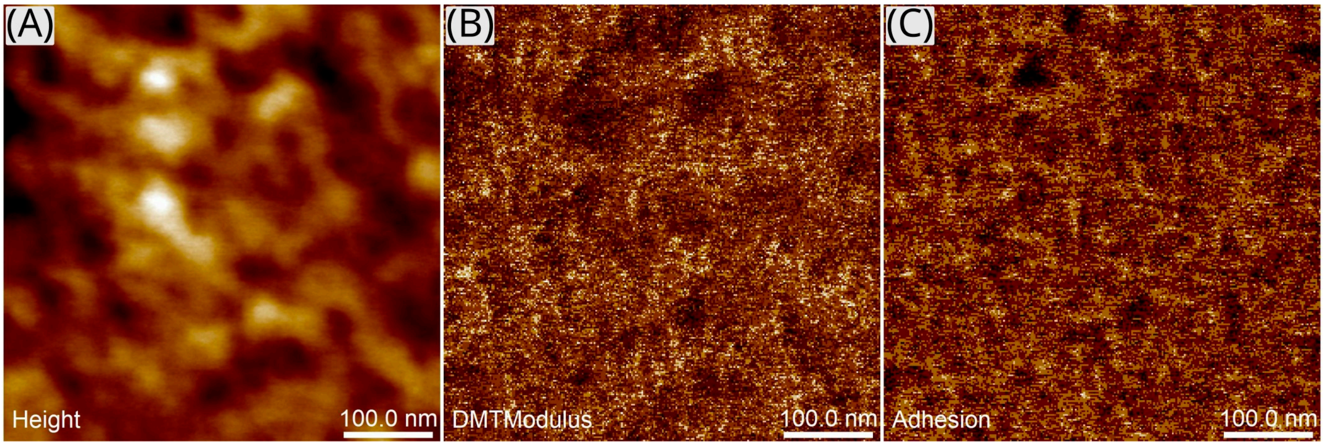

Figure 2. AFM images of the surface of the Invisalign® aligner: (**A**) topographical view, (**B**) map of pseudo-Young's modulus, (**C**) map of tip–surface adhesion forces.

Figure 3 shows an example topographic view of the surface of a clear aligner with a respective bell-like curved histogram of height samples and the depth map, in which three main functional layers are distinguished: peaks (red), core (green) and valleys (blue).

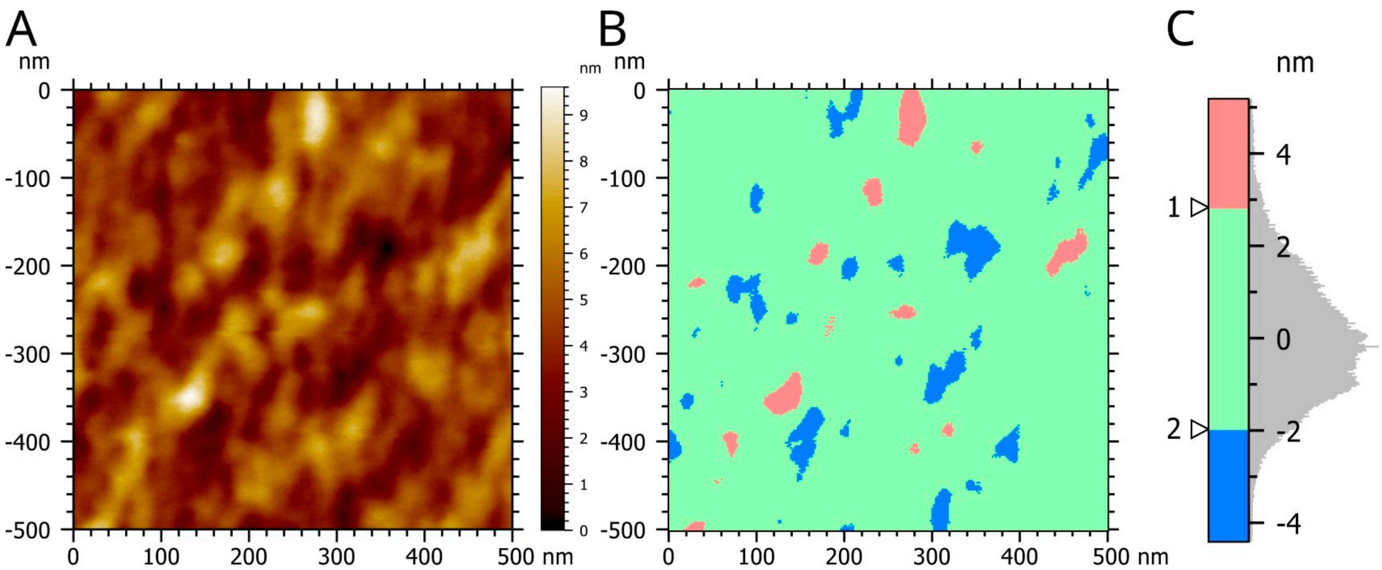

Figure 3. (**A**) AFM image of the Invisalign® aligner surface, (**B**) profile map of this surface with three main functional layers: peaks (red), core (green) and valleys (blue), (**C**) height sample histogram.

Figure 4A shows the same histogram as in Figure 3C (blue bars), together with the red solid line marking the AFC curve plotted from the highest peaks for 0% to the lowest valleys for 100%. In turn, Figure 4B,C also explain graphically how the functional parameters of the surface texture are derived from the AFC. The plot in Figure 4B establishes the thicknesses of the functional layers: peaks (Spk), core (Sk) and valleys (Svk) with the corresponding material ratios (Smrk1 and Smrk2), while that in Figure 4C defines the volumes of specific areas per surface unit at the levels determined by the material shares: peak volume (Vmp), core volume (Vmc) and valley void volume (Vvv). The boundaries between the mentioned functional layers were obtained by extrapolation of the tangent of the AFC at its flattest point towards 0 and 100%, followed by plotting two horizontal straight lines at the points where the tangent meets the vertical axes. The intersections of these lines with the AFC define the boundaries of the functional layers.

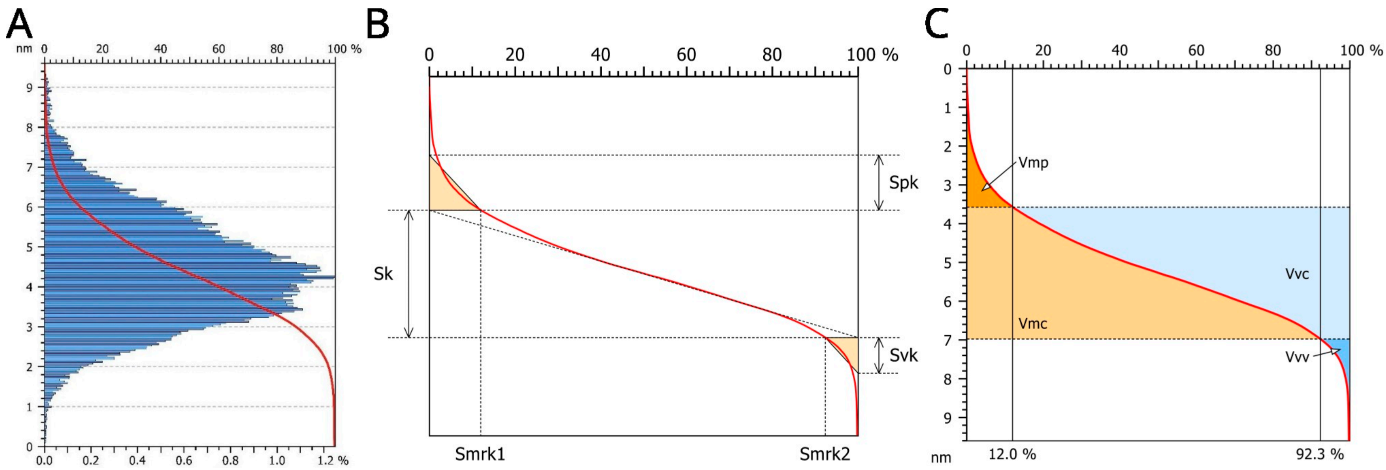

Figure 4. (**A**) Histogram of the height samples of the Invisalign® aligner (blue bars) and their corresponding AFC (solid red line) obtained from the AFM image, (**B**) functional areal parameters of the surface texture from the AFC: thicknesses of the three main layers: peaks (Spk), core (Sk) and valleys (Svk) with the corresponding material ratios (Smrk1 and Smrk2), (**C**) functional volumetric parameters from the AFC (the volumes of specific areas per surface unit at the respective material share levels): peak volume (Vmp), core volume (Vmc) and valley void volume (Vvv).

3. Results and Discussion

The following section presents the analyses of the obtained results. It is assumed that since the aligners under study might only slightly differ in their geometry, but not in chemical composition, the tested parameters should follow similar trends when similar conditions of daily use by the patient and AFM imaging are provided.

3.1. Statistical and Mechanical Parameters

Table 1 reports the basic statistical measures of surface variations of worn and new (reference) Invisalign aligners under investigation derived from AFM images. This includes the rms roughness Sq (deviation of the height samples from the mean plane), texture anisotropy ratio Str (directionality of surface patterns—unity indicates perfectly isotropic surfaces, whereas zero indicates highly anisotropic surfaces) and surface development ratio Sdr (the surplus of the surface triangulated using the height samples over the plane with the same edges). On the other hand, Table 1 also provides the results of the nanomechanical mapping of the pseudo-Young's modulus Y and tip–surface adhesion force Fadh taken in the PF-QNM mode together with the topography data. Apart from that, all the numbers presented therein are supplied with the results of the test of normality using the Shapiro–Wilk method, with a confidence level of $\alpha = 0.05$ [21].

The results of the S–W test shown in Table 1 allow us to reject the null hypothesis that the data tested are normally distributed in almost all cases, even though the data from a single measurement nearly passed the normality test (see Figure 2C). Only the surface development ratio Sdr in worn aligners and the texture anisotropy ratio Str in the new aligners (marked with gray colors) provide enough evidence that the null hypothesis cannot be rejected. Therefore, to find out whether or not there is a significant difference between worn and new aligners on any of the studied levels (topographical and mechanical), an additional non-parametric Mann–Whitney U test was carried out. The obtained results are summarized in Table 2, whereas the graphical comparison of these results is shown in Figure 4. Table 2 reveals that all surface roughness parameters (Sq, Str and Sdr) do not change significantly upon daily use of the aligners, while their ranges of variability decrease.

Table 1. Surface shape parameters of worn and new Invisalign® aligners: Sq—rms roughness, Str—texture anisotropy ratio, Sdr—surface development ratio, and results of nanomechanical mapping: Y—pseudo-Young's modulus, Fadh—adhesion force. The following statistical measures of variability are provided as well: Var—variance, StD—standard deviation, IQR—inter-quartile range, together with the results of the test of normality using the Shapiro–Wilk method, with α = 0.05.

Condition	*n*	Variable	Mean	Median	Var	StD	IQR	S–W Test $p < 0.05$
REF	23	Sq (nm)	1.80	1.59	0.48	0.690	1.45	0.015
		Str (-)	0.585	0.615	0.04	0.192	0.303	**0.141**
		Sdr (%)	1.51	0.931	3.33	1.83	0.798	<0.001
		Y (MPa)	1190	1010	94,900	308	528	0.001
		Fadh (nN)	4.23	4.42	0.88	0.936	0.870	0.014
WORN		Sq (nm)	1.61	1.56	0.17	0.411	0.640	0.013
		Str (-)	0.513	0.534	0.04	0.206	0.381	<0.001
		Sdr (%)	0.914	0.867	0.09	0.297	0.421	**0.221**
		Y (MPa)	917	917	28,700	169	179	<0.001
		Fadh (nN)	5.48	4.33	11.9	3.46	0.760	<0.001

Table 2. Results of non-parametric Mann–Whitney U test of significant changes among the parameters explaining the geometric and mechanical properties of the surfaces of worn and new Invisalign® clear aligners for assumed confidence level α = 0.05.

Variable	Sum of the Ranks REF	Sum of the Ranks WORN	U	Z	M–W Test $p > 0.05$
Sq	1085.500	2830.500	685.5000	−0.58405	0.559
Str	1162.000	2754.000	609.0000	−1.31055	0.190
Sdr	1082.500	2833.500	688.5000	−0.55556	0.579
Y	1322.000	2594.000	449.0000	**−2.83003**	**0.004**
Fadh	977.000	2939.000	701.0000	0.43685	0.662

In terms of mechanical parameters, Table 2 reveals that adhesion force Fadh remains the same regardless of the daily use of the aligners. However, the pseudo-Young's modulus (marked with gray colors) becomes statistically lower as its median value decreases from 1010 MPa to 917 MPa in new and worn aligners, respectively; that is, within ca. 10% compared to the reference value. The lower elasticity of the material might be due to the chemical transformation occurring in the structure of the aligner material, caused by contact with food and saliva. Alternatively, this could be also due to the growth of a new layer on the surface of the aligners—a biofilm that produces its own enzymes. On the other hand, the unaffected adhesion force might prove that both the tip–surface contact area and capillary layer remain the same, which is supported by the similar behavior of the roughness parameters. All of this strongly suggests that daily use provides no significant abrasive wear to the surface under study, and that the life span of the aligners is limited by the chemical stability of the material rather than specific geometry of residual surface.

Plots in Figure 5 not only show the trends in statistical measures of the parameters under investigation, but also reveal how the points corresponding to single measurements are spread around. It turns out from Figure 5A that even though the rms roughness Sq does not change significantly, single results are less deviated in worn aligners to those in the new aligners, which might prove that the roughness profile at the nanoscale becomes homogeneous. Similar changes might be seen in the surface development ratio Sdr, which is directly associated with the amplitudes of surface heights. Unlike that, however, the surface texture ratio Str shown in Figure 5B remains the same, considering the median value and how the points are distributed. Because these data points span over a range from 0.2 to 0.8, such a result might reflect the random character of the manufacturing process, in which the anisotropy decay length is definitely limited by the sampling separation (no less than several micrometers), and that the aforementioned degradation does not affect the directionality of the surface patterns.

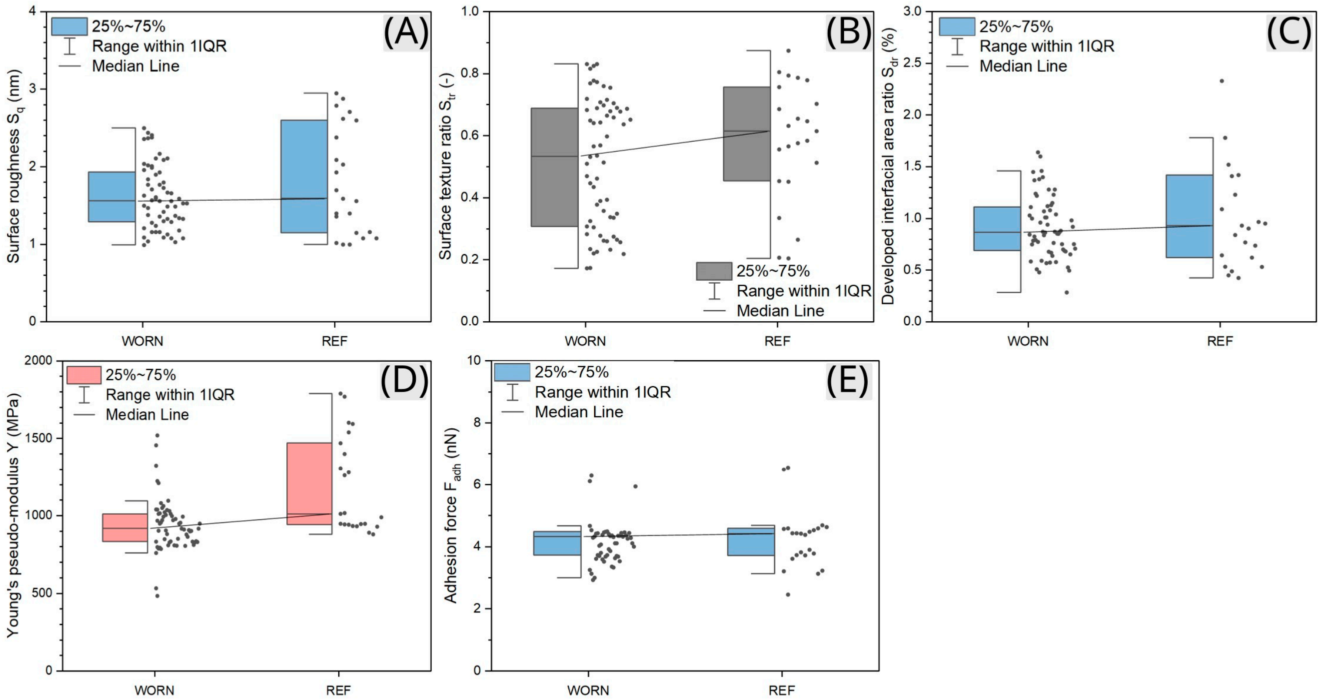

Figure 5. Graphical comparison of raw data and descriptive statistics of the variability of the surface shape parameters between new and worn Invisalign® clear aligners: (**A**) rms roughness Sq, (**B**) texture anisotropy ratio Str, (**C**) surface development ratio Sdr; mechanical parameters: (**D**) pseudo-Young's modulus Y and (**E**) adhesion force Fadh.

3.2. Functional Parameters

Table 3 summarizes the descriptive statistics of the functional parameters determined from the AFC. As a rule, all of the aligners under study exhibited a complex, degressive-progressive shape of the AFC, which may be considered to be an undesirable feature from the point of view of tribological properties. The reason for this is that the rapid abrasive wear of relatively few peaks sticking out of the surface during contact with other hard surfaces may change the outer geometry of the aligners at the level of hundreds of nanometers, which eventually may result in their improper corrective action. Apart from that, the results of the Shapiro–Wilk test of normality with a confidence level of $\alpha = 0.05$ are also provided in Table 3.

Similar to the roughness parameters, the majority of the functional parameters end up with *p*-values less than the assumed confidence level. Hence, the null hypothesis can be rejected and the data tested do not appear to be normally distributed. The exceptions (marked with gray colors) are the thickness of the peak layer Spk in worn aligners, and both material ratios (Smrk1 and Smrk2) in the new aligners. Therefore, in order to verify the hypothesis that daily use might influence the functional parameters, a non-parametric Mann–Whitney U test was performed with a confidence level of $\alpha = 0.05$. The obtained results are shown in Table 4, and Figure 6 shows a graphical comparison of raw data and the descriptive statistics of their distributions.

Table 3. Descriptive statistics of the functional parameters of the surface texture determined from the AFC: Spk—mean height of peaks above the core surface, Sk—mean height of the core surface and Svk—mean valley depth below the core roughness, Smrk1—material ratio separating the reduced peaks from the core surface, Smrk2—material ratio separating the reduced valleys from the core surface, Vmp—volume of the peak layer per unit surface, Vmc—volume of the core layer per unit surface and Vvv—volume of the valley void layer per unit surface. The following statistical measures of variability are provided as well: Var—variance, StD—standard deviation, IQR—inter-quartile range, together with the results of the test of normality using Shapiro–Wilk method with $\alpha = 0.05$.

Condition	*n*	Variable	Mean	Median	Var	StD	IQR	S–W Test $p < 0.05$
REF	23	Sk (nm)	4.29	3.66	2.67	1.63	2.69	0.043
		Spk (nm)	2.29	2.07	0.95	0.97	1.28	0.017
		Svk (nm)	1.45	1.22	0.54	0.74	1.02	0.012
		Smrk1 (%)	12.30	12.60	4.84	2.20	3.09	**0.660**
		Smrk2 (%)	91.30	90.70	5.00	2.25	2.58	**0.474**
		Vmp (nm^3/nm^2)	0.181	0.129	0.030	0.172	0.093	<0.001
		Vmc (nm^3/nm^2)	2.190	1.880	0.714	0.845	1.454	0.032
		Vvv (nm^3/nm^2)	0.067	0.052	0.002	0.046	0.070	0.002
WORN	61	Sk (nm)	3.99	3.84	1.07	1.03	1.55	0.003
		Spk (nm)	1.78	1.75	0.28	0.53	0.64	**0.091**
		Svk (nm)	1.40	1.21	0.20	0.45	0.79	<0.001
		Smrk1 (%)	11.4	11.1	4.38	2.09	3.56	**0.104**
		Smrk2 (%)	90.6	90.6	1.76	1.326	1.77	**0.616**
		Vmp (nm^3/nm^2)	0.104	0.107	0.002	0.044	0.063	0.003
		Vmc (nm^3/nm^2)	2.02	1.94	0.269	0.519	0.784	0.005
		Vvv (nm^3/nm^2)	0.067	0.057	0.001	0.026	0.047	0.001

Table 4. Results of non-parametric Mann–Whitney U test of significant changes among the parameters explaining functional properties of the surfaces of worn and new Invisalign® clear aligners for an assumed confidence level of $\alpha = 0.05$.

Variable	Sum of the Ranks REF	Sum of the Ranks WORN	U	Z	$p > 0.05$
Sk (nm)	1000.0	2570.0	679.0	−0.220	0.825
Spk (nm)	1195.5	2374.5	483.5	**−2.181**	**0.029**
Svk (nm)	934.0	2636.0	658.0	0.431	0.666
Smrk1 (%)	1133.5	2436.5	545.5	−1.560	0.119
Smrk2 (%)	1113.0	2457.0	566.0	−1.354	0.176
Vmp (nm^3/nm^2)	1234.5	2335.5	444.5	**−2.573**	**0.010**
Vmc (nm^3/nm^2)	1002.5	2567.5	676.5	−0.246	0.806
Vvv (nm^3/nm^2)	871.0	2699.0	595.0	1.063	0.288

The results of the Mann–Whitney U test prove that only the parameters related to the peaks (marked with gray colors) substantially decrease between new aligners and the worn aligners. These are namely the mean peak height Spk and, correspondingly, the volume of the peak layer per unit surface Vmp, which suggests that abrasive wear of the highest parts of the surface occurs. The median of the former parameter decreased from 2.07 to 1.75 nm for the new and worn aligners, respectively. In turn, the median of the latter parameter decreased from 0.129 to 0.107 nm^3/nm^2 for the new and worn aligners, respectively. Such a correlated trend strongly suggests the occurrence of abrasive wear within the outer part of the residual layer solely, namely the bare peaks being in contact with other surfaces—the opposing teeth and aligners, rather than chemical decomposition of the material by salivary enzymes. The observation that the remaining functional parameters explaining deeper-lying parts of the surface are found intact agrees well with that, and confirms that the wear is a process of superficial character. It should be noted that the previously studied rms roughness Sq and surface development ratio Sdr values appeared unchanged, which was not counterintuitive because these parameters were associated with the total thickness of the outer layer without dividing it into specific sub-layers (Table 2). Note, however, that single results for Sq and Sdr were found to be less deviated in worn aligners compared with the new aligners, from which the conclusion was drawn that the roughness profiles of worn aligners were becoming more similar to each other. This might have been equivalent to the smoothing of the overall surfaces under study.

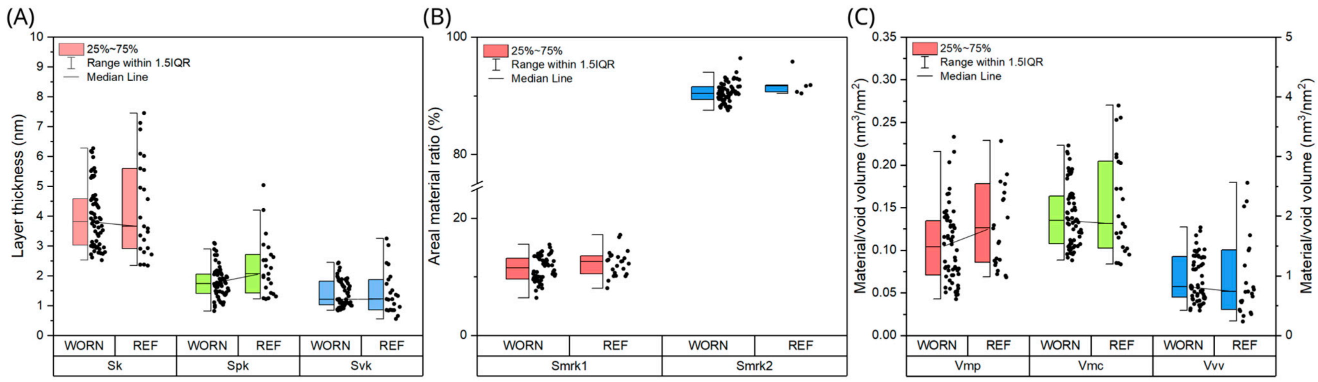

Figure 6. Graphical comparison of raw data and descriptive statistics of functional parameters: (**A**) thicknesses of the main tribological layers: peaks Spk, core Sk and valleys Svk, (**B**) material shares of individual surface layers, i.e., the boundaries between the layers of peaks and core Smrk1 and core and valleys Smrk2 and (**C**) volumetric specific shares of the layers: peaks Vmp, core Vmc and void valleys Vvv. The latter parameters comprehensively combine the thicknesses of the tribological layers with their material shares.

3.3. Comparison to Similar Studies

As mentioned in the preceding sections, there is still a significant information gap concerning elastic, geometric and mechanical changes occurring in the aligner material under the influence of various factors associated either with manufacturing procedures, pre-use handling or therapy treatment. Most of this is due to an inconsistency in the results obtained in studies on degradation and wear processes of the surface of the aligners from the point of view of changes in its texture, i.e., its well-defined shape. Fang et al. reported that the surface morphology of the aligners under study showed some defects after clinical use (2 weeks), however, there was no significant difference in mechanical properties [22]. However, Ryokawa et al. found that the mechanical properties of thermoplastic materials were influenced by both structural factors, such as molecular and crystal structures, and environmental factors, such as temperature, humidity, pressure and heat history. Therefore, the mechanical properties varied under the influence of both forming conditions and the conditions of use [23]. A similar conclusion was drawn by Bradley et al., who did not find any detectable chemical changes in their aligners; however, they revealed that intra-oral aging adversely affected the mechanical properties of the Invisalign® appliance [13]. Another study conducted by Gracco et al. brought the conclusion that Invisalign® aligners retrieved after 14 days of wear displayed optical, chemical and morphological changes compared to new specimens; however, further studies are required to evaluate how intra-oral conditions may influence the optical properties and chemical stability of aligners [24]. This problem is not solely limited to the thermoformed polymer of Invisalign®. In the work by Tamburrino et al., it was reported that on three different materials from which the clear aligners are manufactured (Duran®, Biolon® and Zendura®) the impact of the operating conditions on the mechanical properties could vary according to the specific polymer [11]. The common point in all of the mentioned works was studying the properties of the bulk material or the surface properties at the micro- or even macro-scale. Our approach is therefore different, and the obtained results cannot be directly compared due to allometricity (non-linear variations in some properties depending on the magnification).

The results presented here reveal the flattening occurring in the upper layer of the surface of the aligners, but the adhesion force Fadh remains the same regardless of the daily use of the aligners. Moreover, it is only the Young's modulus that statistically decreases from 1010 MPa to 917 MPa in new and worn aligners, respectively. Despite that, several other parameters describing surface geometry do not change significantly. Therefore, only the elastic properties and selected geometric properties measured at the nanoscale are found to vary under the influence of the conditions of use, but the majority of other measured parameters remain intact.

4. Conclusions

At the level of classic measures of surface variability (rms roughness Sq, texture anisotropy coefficient Str, surface development coefficient Sdr), very subtle differences in the characteristics of surface geometry of new and worn aligners was observed. Much more pronounced changes occur when the functional parameters that are considered are those that give insight into the thickness and material share of the tribological layers: peaks, core and valleys. This proves the uniformity of characteristics at the level of nano-roughness, regardless of the selected imaged area (on the same surface, as well as between surfaces of different aligners within the same group, i.e., new/worn aligners).

The obtained results show that the degradation of aligners is a complex process involving both mechanical and chemical/biological changes. On the one hand, the observed smoothing of the peak heights is undoubtedly due to abrasive wear, i.e., mechanical degradation, while on the other, the decrease in the Young's pseudo-modulus for the worn aligners compared to the new aligners may suggest the formation of a biofilm layer and/or chemical reactions within the material.

The presented results show that changes in the surface texture of the tested aligners and their mechanical properties on the nanoscale throughout the period of recommended use changed so little that that the aligners retained their resistance to damaging mechanical and chemical factors. Several previous reports [25,26] have demonstrated consistency in terms of measured forces and moments created by aligners of the Invisalign® system, which allow us to conclude that the material preserves its shape and form, and transfers planned forces to move the tooth throughout the treatment period. According to the manufacturer, the aligners can be worn for a maximum of 2 weeks (22 h a day). Then, the aligners might wear off quickly and lose their stiffness, especially on the chewing surface of the appliance, carrying the risk of inability to keep the teeth in the previously obtained shift and partial return to the previous position.

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