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Assessment the thermoforming effect on the physical and mechanical properties of different thermoplastic orthodontic retainers: An *in vitro* study

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Abstract

OBJECTIVES: As patients are instructed to wear thermoplastic retainers for the rest of their lives, the durability of the materials is a critical factor in evaluating whether the expense is justified. This study examined the physical and mechanical properties of three different thermoplastic retainer materials before and after thermoforming (BT and AT).

MATERIALS AND METHODS: Clear Advantage Series I, Clear Advantage Series II, and Leone types were used, with each material having a thickness of 1 mm. The materials' tensile force, hardness, and water absorption tests have been measured for 90 thermoformed and 90 non-thermoformed specimens (30 specimens from each material).

RESULTS: The tensile force, hardness, and water absorption values of all the materials differed significantly ($P \leq 0.05$) BT. Additionally, the majority of the materials showed significant differences in water absorption, hardness, and tensile force ($P \leq 0.05$) AT, except the Leone materials, and Clear Advantage Series I did not significantly differ in the case of hardness value. All studied materials showed an increase in hardness and water absorption AT ($P \leq 0.05$). At the same time, all of the studied materials showed a significant decrease in tensile force after thermoforming.

CONCLUSION: Thermoforming increases the material's water absorption while decreasing its stiffness, affecting its mechanical and physical properties. Clear Advantage Series II (PP) stood out with superior flexibility, wear resistance, and minimal water absorption compared to other materials, highlighting its durability and superiority.

Keywords:

Mechanical properties, orthodontic thermoplastic retainers, physical properties, thermoforming

Introduction

Retention is required to maintain teeth in place and avoid recurrence after orthodontic treatment.[1,2] Additionally, it raises patients' satisfaction with these treatments over a prolonged period.[3,4] Most patients prefer thermoplastic retainers because of their transparent appearance and attractive design.[5,6] When the thermoformed thermoplastic materials are inserted into and removed from the oral cavity, they might mechanically deteriorate.[7] This deterioration manifests at the morphological level and might diminish the materials' properties.[8] Additionally, they may fracture, shorten their lifespans, crack, discolor, wear, and absorb water.[9]

According to many studies, long-term retention is the only way to guarantee stability.[10,11] Moreover, thermoplastic retainers wear out rapidly and must be replaced regularly.[12] Thermoplastic retainers need to be composed of more

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robust, more resilient materials to save costs and preserve the outcomes of orthodontic treatment.[13,14] In addition, durability is an important consideration when evaluating the cost-effectiveness of thermoplastic retainers because they are designed to last a lifetime.[15,16]

To the best of our knowledge, no study has examined how thermoforming affects the physical and mechanical characteristics of the following thermoplastic retainer materials and predicted their potential for possible clinical use[17]: Clear Advantage™ Series I, Clear Advantage™ Series II, and Leone materials. Particularly, the tensile force, hardness, and water absorption tests were measured before and after thermoforming (BT and AT) and compared their values.

Materials and Methods

Specimen preparation

This study is an *in vitro* investigation. After being approved by the ethics committee with project no. 762423, it was conducted with a total of 180 sheets of three different thermoplastic materials used for the fabrication of vacuum-formed retainers (VFRs) which were as follows:

- **Group 1:** Copolyester (CP) Clear Advantage™ Series I Retainer Material (Ortho_Technology, Tampa, Florida, USA), amorphous polymer thermoplastic sheets.
- **Group 2:** Polypropylene (PP) Clear Advantage™ Series II Durable Retainer Material (Ortho_Technology, Tampa, Florida, USA), crystalline polymer thermoplastic sheets.
- **Group 3:** Polyethylene Terephthalate modified with Glycol **(**PETG) Material of Leone® (Leone, Firenze, Italy), amorphous polymer thermoplastic sheets.

Each material was measured as not yet thermoformed, and after the thermoforming process, with a consistent thickness of 1 mm for each material. BT, there were 90 sheets in total. Each material included 30 samples for conducting tests on tensile force, Vickers hardness, and water absorption (10 samples for each test). The same sampling approach was followed AT.

A three-dimensional (3D) custom-made stone disk measuring 80 mm × 12 mm was used as a mold for the thermoforming machine. The sheets were thermoformed using a thermoforming machine (BIOSTAR®, Scheu Dental, Iserlohn, Germany) [Figure 1]. These sheets were cut using the dimensions given for each test. All the samples were measured under the room illumination at 37°C ± 1°C and a relative humidity of 20%.

Tensile test

Tensile tests were performed on 20 specimens of each material BT and AT. Dumbbell-shaped specimens, with dimensions of 63.5 mm in length and 9.53 mm in width [Figure 2], were prepared using a computer numerical control (CNC) machine (CNC Technology Co., Shandong, China), following the EN ISO 527-2 guidelines.[18] A universal testing machine (Laryee Technology Co., Beijing, China) was used for the tests, which were performed at 37°C ± 1°C, with an initial grip spacing of 20 mm and a crosshead speed of 12 mm/min.[19]

Vickers hardness test

The Vickers hardness of the three thermoplastic materials was determined using an HVS-1000 Vickers Hardness Tester (Laryee Technology Co, Beijing, China). Twenty specimens from each material BT and AT measuring 9 × 13 mm were prepared. Three indentations were made in each specimen using a pyramid-shaped diamond indenter under a 10 N force for 10 s, as the average reading of these three measurements was recorded as the micro-hardness value of a measured specimen. The diameter of the generated squares was measured using a light microscope at 40× magnification [Figure 3].

The Vickers number, or HV, was obtained using the following formula:

$$HV = 1.854\frac{f}{d^2}$$ [20]

where F is the loading force, and d is the mean of the indentation diameters.[20]

Water absorption test

For each material, 20 specimens from BT and AT were cut into 60 mm × 60 mm × 1 mm squares and stored in artificial saliva at 37°C ± 1°C. The samples were randomly stored in containers labeled with a letter and number. The uppercase letters "A," "B," and "C" represent the BT material types, while the lowercase letters "a," "b," and "c" represent the AT material types, whereas the number refers to the specimen number ranging from 1 to 10 [Figure 4]. The artificial saliva was modified Carter's solution as follows: 1.5 g NaHCO3, 1.2 g KCl, 0.7 g NaCl, 0.26 g Na2HPO4, 0.2 g K2HPO4, 0.13 g urea, and 0.33 g KSCN.[21] Weight measurements were taken at baseline, and 6, 12, 24, 48, 168, and 336 hours after immersion began using a sensitive electronic balance (Sartorius, TE214S, Gottingen, Germany). Weight increase ratios were calculated as follows:

$$\left[\frac{Wt - W0}{W0}\right] \times 100$$ [22]

where Wt. is the specimen weight at time t of immersion, and W0 is the weight before immersion.[22]

Statistical analysis

G Power software (version 3.1.9.7; Franz Faul, Kiel University, Kiel, Germany) was used to calculate the

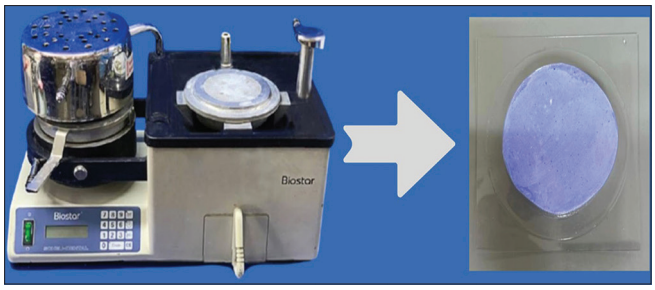

Figure 1: Thermoforming process of the specimens over a 3D stone disk

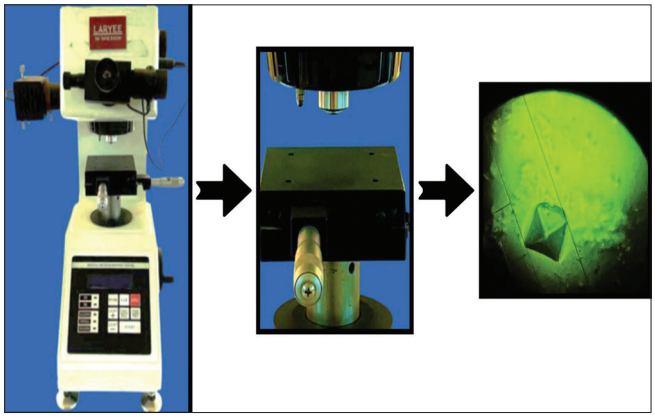

Figure 3: Diameters of the generated square are shown in the specimen under a light microscope (40×) of the Vickers indenter device

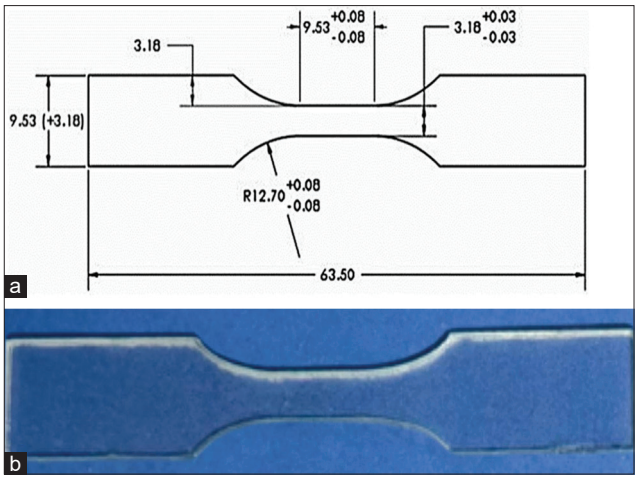

Figure 2: a) Sample's dimensions of the tensile test according to ASTM D 638-02a[19], b) sheets after cutting with CNC machine

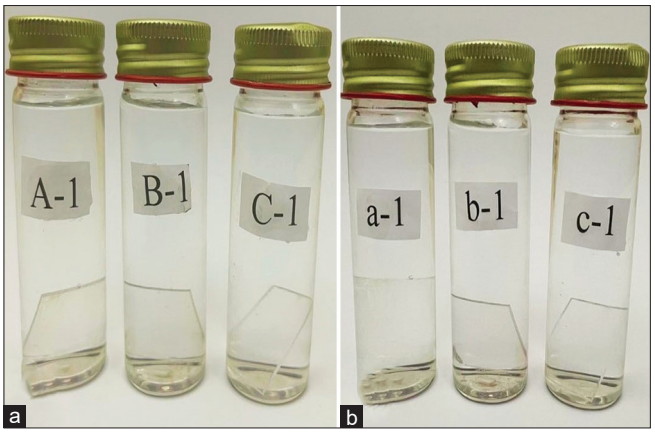

Figure 4: Samples stored in glass containers labeled and filled with artificial saliva, a) BT samples, b) AT samples

sample size. The calculation was based on a medium effect size of 0.25 with a power of 85% and α error of 0.05%, and the estimated sample size was 60 sheets for each group, both BT and AT (20 sheets for each test). The data were acquired from research published by Ryu *et al*. in 2018.[23] Moreover, the coding of samples aided the randomization during the study.

The Statistical Package for Social Sciences (SPSS) version 26 (SPSS Inc., Chicago, IL, USA) was utilized for statistical analysis. The mean and standard deviation (SD) were calculated for each data set. Shapiro-Wilk and Levene's tests revealed that the data were normally distributed and homogenous ($P > 0.05$) [Table 1]. *One-way analysis of variance (ANOVA)* and Tukey's *post hoc* test analyzed tensile force, hardness, and water absorption data. Two-sample *t*-tests compared pre- and post-thermoforming data. A *P* value less than 0.05 was regarded as statistically significant.

Results

Tensile test

The mean and SD values of the tensile test among groups and BT and AT are shown in Table 2. The tensile force of all tested materials decreased AT. Moreover, the comparison was made using the two-sample t-tests to estimate the effect of the thermoforming process (BT and AT) on the mean difference of the tensile test. There were significant differences ($P \leq 0.05$) between BT and AT [Table 2].

The comparison of the mean difference of tensile test among all groups using one-way ANOVA BT and AT indicated significant differences among all groups. In addition, Tukey's (HSD) *post hoc* test revealed that there were significant differences ($P \leq 0.05$) among all groups BT and AT, as shown in Table 3.

Surface hardness test

After the applied force removal by a square-based pyramidal-shaped indenter, a light microscope measures the generated squares. The mean and SD values of surface hardness among groups BT and AT are shown in Table 4.

All tested materials' hardness increased following thermoforming. The two-sample *t*-test revealed significant differences ($P \leq 0.05$) between BT and AT [Table 4].

Table 1: Normality and homogeneity of tensile, hardness, and water absorption tests

Thermoforming	Vars.	G1		G2		G3		Homogeneity of variances	
		Shapiro-Wilk test	*P*	Shapiro-Wilk test	*P*	Shapiro-Wilk test	*P*	Levene's test	*P*
BT	Tensile test	0.971	0.899	0.950	0.664	0.945	0.607	1.852	0.176
	Hardness	0.934	0.484	0.945	0.612	0.942	0.577	1.410	0.250
	Water abs.	0.962	0.802	0.946	0.525	0.856	0.076	0.095	0.923
AT	Tensile test	0.945	0.604	0.964	0.827	0.927	0.423	1.422	0.259
	Hardness	0.972	0.910	0.895	0.193	0.914	0.308	0.483	0.622
	Water abs.	0.853	0.069	0.985	0.983	0.943	0.575	0.097	0.932

BT: before thermoforming, AT: after thermoforming. G1: Copolyester (CP); G2: Polypropylene (PP); G3: Polyethylene Terephthalate modified with Glycol (PETG)

Table 2: Descriptive and inferential statistics of tensile test among groups before and after thermoforming

Groups	BT		AT		Comparison	
	Mean (*n*)	±SD	Mean (*n*)	±SD	*t*-test	*P*
G1	193.1	8.850	136.7	3.093	19.024	0.000*
G2	132.1	4.606	119.1	3.542	7.076	0.000*
G3	163.0	4.028	153.7	7.528	3.444	0.003*

*Indicates statistically significant differences at (*P*<0.05). BT: before thermoforming, AT: after thermoforming. G1: Copolyester (CP); G2: Polypropylene (PP); G3: Polyethylene Terephthalate modified with Glycol (PETG)

Table 3: ANOVA test and Tukey's HSD test of the tensile test in different groups BT and AT

Condition	Groups	Comparison			
		ANOVA test		Tukey's HSD test	
		F-test	*P*	Between subgroups	*P*
BT	G1	241.104	0.000*	G1_G2	0.000*
	G2			G1_G3	0.000*
	G3			G2_G3	0.000*
AT	G1	113.970	0.000*	G1_G2	0.000*
	G2			G1_G3	0.000*
	G3			G2_G3	0.000*

*Indicates statistically significant differences at (*P*<0.05). BT: before thermoforming, AT: after thermoforming. G1: Copolyester (CP); G2: Polypropylene (PP); G3: Polyethylene Terephthalate modified with Glycol (PETG)

Table 4: Descriptive and inferential statistics of the surface hardness among groups before and after thermoforming

Groups	BT		AT		Comparison	
	Mean	±SD	Mean	±SD	*t*-test	*P*
G1	9.816	0.464	11.184	0.388	7.147	0.000*
G2	7.914	0.252	12.034	0.262	35.817	0.000*
G3	10.949	0.872	11.497	0.382	2.531	0.014*

*Indicates statistically significant differences at (*P*<0.05). BT: before thermoforming, AT: after thermoforming. G1: Copolyester (CP); G2: Polypropylene (PP); G3: Polyethylene Terephthalate modified with Glycol (PETG)

Table 5 shows significant differences in the hardness values among all groups, BT and AT. In addition, Tukey's (HSD) *post hoc* test revealed that there were significant differences ($P \leq 0.05$) among all groups in BT, while in AT, there were significant differences ($P \leq 0.05$) between the groups, except between the G1 and G3, which showed no significant difference.

Water absorption test

The amount of water absorption variation percentage is shown in Table 6. The water absorption AT was significantly higher in all materials than BT. However, the water absorption in G2 AT was the lowest compared to the other materials. The two-sample *t*-test was significantly different ($P \leq 0.05$) except for G2 [Table 7]. In addition, ANOVA and Tukey's HSD test were significantly different ($P \leq 0.05$), except for G1-G3 BT, and Tukey's HSD test was not significantly different [Table 8].

Discussion

Many research studies focus on examining materials in their supplied state, even though they are often thermoformed for use in the mouth. However, these data can be valuable for improving and comparing materials. This study investigates how thermoforming impacts retainer materials' physical and mechanical properties, such as tensile force, hardness, and water absorption.

The tensile test conducted in this study aimed to evaluate the durability of the tested materials. The tensile force of the examined polymers is as follows: PETG > CP > PP. This finding may be explained in terms of the degree of crystallinity of the corresponding polymer. PETG and CP, being amorphous polymers, have a higher tensile force than PP, which is a crystalline polymer. This study's results support those of Ryokawa *et al*.[24] who noted a decrease in tensile force for thermoplastic materials in a simulated oral environment. Similarly, AT, all of the materials examined in this study showed a decrease in tensile force. This is consistent with the findings of Ryu *et al*.,[23] who studied the effects of thermoforming on the physical properties of materials used in aligners and found a decrease in tensile strength post-thermoforming. Additionally, Tamburrino *et al*.[19] studied the properties of Duran, Biolon, and Zendura aligner materials at varying stages. They observed slight changes in tensile force for Duran and Biolon materials AT but noted a significant decrease for Zendura material.

Another mechanical characteristic examined in this study was Vickers hardness. After the thermoforming process,

it was noted that the thermoplastic materials studied in this research showed a significant increase in hardness. The hardness of PP was greater than that of CP and PETG due to the increased pressure and temperature exerted on the material during thermoforming, resulting in straight polymer chains tightly organized across a relatively long distance. Furthermore, the buildup of the secondary bonding force in the crystalline polymer (PP), which maintains the polymer chains together, results in a stronger binding force than in amorphous polymers (CP, PETG) polymers.[25] This study's result is consistent with other research that examined the surface hardness of materials used in orthodontic retention and found that the thermoformed tested materials had significantly higher values.[26] In a study, Dalaie *et al*.[20] showed that both Duran and Erkodur materials became less hard AT. These differences might be attributed to two factors, one of which is the different molecular weights of the various polymers. The second of which is the thermoforming effect on the mechanical properties. Thermoforming may influence the molecular orientation, mean molecular weight, and residual stresses due to the rapid cooling of the thermoplastic materials on the stone models.[24] On the contrary, Ryu *et al*.[23] discovered that while thermoforming did not affect Duran's hardness, it increased the hardness of the examined materials. Additionally, Albilali *et al*.[27] noted significant differences in the hardness values of various thermoplastic retainer materials AT. Therefore, the observed increase in hardness across different materials might be explained by changes in molecular weight, chemical composition, density, additives, degree of polymerization, and crystallinity among the various types of thermoplastic polymers.

Table 5: ANOVA test and Tukey's HSD test of the surface hardness in different groups BT and AT

Condition	Groups	Comparison			
		ANOVA test		Tukey's HSD test	
		F-test	*P*	Between subgroups	*P*
BT	G1	100.400	0.000*	G1_G2	0.000*
	G2			G1_G3	0.000*
	G3			G2_G3	0.000*
AT	G1	7.889	0.000*	G1_G2	0.001*
	G2			G1_G3	0.462
	G3			G2_G3	0.049*

*Indicates statistically significant differences at (P<0.05). BT: before thermoforming, AT: after thermoforming. G1: Copolyester (CP); G2: Polypropylene (PP); G3: Polyethylene Terephthalate modified with Glycol (PETG)

The water absorption test was a part of this investigation. Post-thermoforming, an increase in the water absorption capacity of all materials was observed. Studies by Zhang *et al*.[22] indicated that incorporating polyurethane into PETG increased water absorption for the developed material. Furthermore, Albilali *et al*.'s[28] research highlighted Zendura as a material significantly impacted by thermoforming in terms of increased water absorption post-thermoforming. Another study by Ryu *et al*.[23] revealed that water absorption was higher AT than before for most aligner materials tested AT. As the water absorption depends on the free volume, crystalline polymers (PP) absorb water at a lower rate than amorphous plastics (CP and PETG), the latter absorb water at greater rates. In this research, Polypropylene Clear Advantage Series II (PP) exhibited the least water absorption post-thermoforming. A correlation between composition and properties was also established. Because of its high crystallinity, crystalline plastic has low water absorption, which explains why PP has low water absorption.[29]

When thermoplastic materials are exposed to temperatures beyond the glass transition temperature, they may undergo distortion and thinning. In contrast, their transition from an amorphous to a crystalline state upon temperature decrease is accompanied by changes in mechanical properties, as noted by Hallmann *et al*.[30] Also, aligning polymer chains more closely and increasing surface hardness due to enhanced secondary bonding forces is demonstrated by Gerard Bradley *et al*.[31] In addition, the water uptake and swelling phenomena may cause mechanical degradation processes to begin and progress, depending on the type of polymer material and additional operating factors (such as temperature or relative humidity). The absorbed water molecules act as plasticizers, reducing the intermolecular force that holds the polymer chains together. As a result, this could weaken the material's physio-chemical properties.[31]

Table 6: Weight variation of the material specimen due to saliva absorption before and after storage in artificial saliva, BT, and AT

Thermoforming	Groups	Before preserving in artificial saliva (Mg)	After preserving in artificial saliva (Mg)	Variation %
BT	G1	0.588	0.589	0.17%
	G2	0.431	0.432	0.23%
	G3	0.571	0.572	0.17%
AT	G1	0.541	0.546	0.92%
	G2	0.423	0.425	0.47%
	G3	0.481	0.489	1.66%

BT: before thermoforming, AT: after thermoforming. G1: Copolyester (CP). G2: Polypropylene (PP). G3: Polyethylene Terephthalate modified with Glycol (PETG)

Table 7: A two-sample *t*-test to compare the mean difference of water absorption values before and after thermoforming

Groups	Condition	Comparison	
		t-test	*P*
G1	BT	5.130	0.000*
	AT		
G2	BT	0.843	0.403
	AT		
G3	BT	9.935	0.000*
	AT		

*Indicates statistically significant differences at (P<0.05). BT: before thermoforming, AT: after thermoforming. G1: Copolyester (CP); G2: Polypropylene (PP); G3: Polyethylene Terephthalate modified with Glycol (PETG)

Table 8: ANOVA test and Tukey's HSD test of the water absorption values in different groups BT and AT

Condition	Groups	Comparison			
		ANOVA test		Tukey's HSD test	
		F-test	*P*	Between subgroups	*P*
BT	G1	195.412	0.000*	G1_G2	0.000*
	G2			G1_G3	0.149
	G3			G2_G3	0.000*
AT	G1	94.550	0.000*	G1_G2	0.000*
	G2			G1_G3	0.000*
	G3			G2_G3	0.000*

*Indicates statistically significant differences at (P<0.05). BT: before thermoforming, AT: after thermoforming. G1: Copolyester (CP); G2: Polypropylene (PP); G3: Polyethylene Terephthalate modified with Glycol (PETG)

However, the research's conclusions should be further examined because clinical settings differ significantly from the simulated oral circumstances employed in this study. Several limitations of this investigation need to be taken into account. For example, samples with a thickness of just 1 mm were employed in this investigation. Subsequent research ought to compare specimens with varying thicknesses. In addition, a limitation arises from the standardization of rectangular samples, as clinical settings utilize stone models that mimic the patient's teeth for retainer fabrication. Variations in the sample shapes may have led to variations not considered in this study as retainers resembling a patient's dentition were not evaluated.[32] The data gathered from this study should be helpful when analyzing the mechanical and physical characteristics of thermoplastic orthodontic retainer materials for stability and durability. As retainers are usually worn for considerably longer periods, future studies should investigate a longer duration of water immersion. Additionally, the materials' creep and tear strength need to be assessed. Furthermore, clinical research has to be conducted to assess how thermoforming affects the various materials that are utilized for producing thermoplastic retainers.

Conclusion

1. There were significant differences in the tensile force, hardness, and water absorption values between most of the investigated materials BT and AT.
2. The thermoforming process affects the physical and mechanical properties of the materials, making it less stiff, harder, and more prone to water absorption.
3. It was found that Clear Advantage Series II (PP) has more flexibility, excellent resistance to wear and abrasion, and the most negligible water absorption among other materials, which makes it more durable when wearing such appliances, while Leone materials (PETG) showed maximum resistance to deformation and high stiffness, but the highest water absorption among other tested materials. However, the Clear Advantage Series I (CP) showed intermediate values for nearly each of the properties that were tested. This balanced performance indicates that the material has a varied combination of strength, stiffness, moisture resistance, and hardness.

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Conflicts of interest

There are no conflicts of interest.

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