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Enhancement of Mechanical and Biological Properties of Polyurethane Clear Aligners Using Sustainable SiO_2 Nanoparticles

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ABSTRACT

In this study, polyurethane (PU) was employed as the base material for the fabrication of clear dental aligners due to its favorable optical transparency, flexibility, and biocompatibility. The primary objective was to enhance the mechanical and biological performance of PU through the incorporation of sustainable SiO_2 nanoparticles. Four different nanoparticle loadings (0.1, 0.2, 0.3, and 0.4 wt%, with an average particle size of 57.7 nm) were dispersed within the polymer matrix. Fourier transform infrared spectroscopy (FTIR) was used to identify functional groups and assess possible interactions between the nanoparticles and PU chains. The dispersion state and surface morphology were examined using scanning electron microscopy (SEM). The results demonstrated that, at lower nanoparticle concentrations, SiO_2 nanoparticles were uniformly distributed within the PU matrix without noticeable agglomeration, which is essential for effective reinforcement. Mechanical testing revealed a significant improvement in hardness, increasing from 72 Shore D for neat PU to 96 Shore D for nanoparticle-reinforced samples. Tensile strength also exhibited a progressive increase from 45 MPa for pure PU to 51, 54, 58, and 64 MPa with increasing nanoparticle content. These improvements were attributed to restricted molecular mobility, enhanced stress transfer, and the formation of a more integrated and rigid microstructure due to the homogeneous dispersion of nanoparticles. Biological evaluations indicated that higher nanoparticle concentrations enhanced antibacterial activity, while all formulations remained non-toxic, confirming their suitability for biomedical applications. Overall, the findings demonstrate that sustainable SiO_2 nanoparticle reinforcement significantly improves the mechanical robustness and biological performance of polyurethane, highlighting its potential for advanced clear aligner applications.

1. INTRODUCTION

The use of clear aligners has increased significantly compared with conventional metallic orthodontic appliances due to their superior aesthetic appearance, removability, and enhanced patient comfort. Clear aligners are designed to provide effective and minimally invasive orthodontic treatment while maintaining acceptable mechanical stability, elasticity, and optical transparency. These devices are commonly fabricated from thermoplastic polymers such as polyurethane (PU) or polyethylene terephthalate glycol (PET-G), which enable controlled force delivery for gradual tooth movement [1-4].

Despite their clinical advantages, conventional clear aligner materials present several limitations, including reduced mechanical durability over time, susceptibility to surface wear and discoloration, and diminished force retention during prolonged intraoral use. Consequently, recent research has focused on improving the overall performance of aligner materials through material modification strategies, particularly the incorporation of nanotechnology-based reinforcements [5-8]. Nanoparticles have demonstrated significant potential to enhance the structural, mechanical, thermal, and optical properties of dental polymers due to their high surface-to-volume ratio, tunable physicochemical characteristics, and strong interfacial interaction with polymer matrices [9-13].

Orthodontic treatment has evolved considerably with the introduction of clear aligner systems, which represent a major advancement in both aesthetics and patient comfort. Commercial systems such as Invisalign® have gained widespread acceptance as removable alternatives to fixed metallic appliances. Unlike conventional braces that rely on metal brackets and archwires, clear aligners are fabricated from transparent thermoplastic materials and are custom-designed to apply controlled orthodontic forces, enabling gradual tooth movement with minimal visual impact [14-16].

The clinical effectiveness of clear aligners is highly dependent on the intrinsic properties of the materials used in their fabrication. Ideally, these materials should exhibit an optimal balance between mechanical strength, elastic recovery, optical clarity, biocompatibility, and resistance to thermal and chemical degradation. Thermoplastic polyurethane (TPU) has emerged as a widely used material owing to its favorable combination of flexibility, toughness, and durability [17, 18]. Previous studies have reported that reinforcing aligner materials with nanoparticles such as silver (Ag) or titanium dioxide (TiO_2) can improve transparency, mechanical strength, and biocompatibility. However, comprehensive evaluation of the influence of such nanoparticles on structural, mechanical, and optical properties remains essential to ensure safe and effective clinical application [19].

Clear aligners have revolutionized orthodontic therapy by providing a discreet, comfortable, and removable alternative to traditional braces. The increasing demand for aesthetic dental solutions has driven extensive research into improving aligner materials. Most commercial aligners are composed of thermoplastic polymers such as polyurethane (PU), polyethylene terephthalate glycol (PET-G), and polycarbonate (PC) because of their transparency, flexibility, and biocompatibility. Nevertheless, these materials are prone to mechanical degradation, wear, and discoloration, particularly under intraoral conditions involving moisture, temperature fluctuations, and mechanical loading [20, 21].

To address these challenges, several studies have investigated the reinforcement of polymer matrices with nanoparticles to enhance mechanical and optical performance without compromising biocompatibility. The effectiveness of nanoparticle reinforcement is primarily attributed to their large surface area, surface chemistry, and ability to modify polymer chain mobility and stress distribution [22]. In particular, sustainable nanoparticles—defined as nanoparticles synthesized through environmentally friendly, low-toxicity, and energy-efficient processes—offer additional advantages by minimizing environmental impact while maintaining biocompatibility.

Silica (SiO_2) nanoparticles have been widely used in dental composite systems due to their ability to improve tensile strength, hardness, and wear resistance. When incorporated into polymer matrices, they promote the formation of a more rigid and mechanically stable structure and can contribute to ultraviolet (UV) shielding [23]. Similarly, titanium dioxide (TiO_2) nanoparticles are known for their high refractive index and UV resistance; however, their tendency to agglomerate may result in increased light scattering and reduced optical transparency at higher loadings [24].

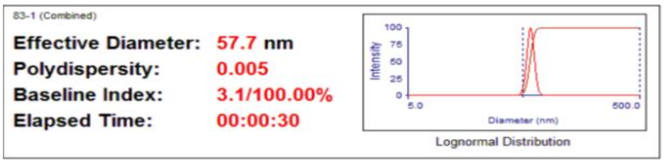
Advanced characterization techniques such as scanning electron microscopy (SEM), fourier transform infrared spectroscopy (FTIR), X-ray diffraction (XRD), and UV–Vis spectrophotometry are commonly employed to evaluate the structural, morphological, and optical properties of polymer nanocomposites. Previous investigations have demonstrated that uniform nanoparticle dispersion and appropriate surface functionalization are critical factors in maximizing reinforcement efficiency while preserving optical clarity [25]. Mechanical studies have further shown that low nanoparticle concentrations (typically ≤1 wt%) can significantly enhance the mechanical properties of clear aligner materials without adversely affecting transparency. In contrast, higher loadings may promote nanoparticle agglomeration, leading to reduced light transmittance and increased material brittleness [26].

Although promising in vitro results have been reported, there remains a lack of comprehensive studies addressing the long-term performance of nanoparticle-reinforced aligners under clinically relevant conditions. In particular, the combined evaluation of mechanical behavior, structural integrity, and biological performance requires further investigation. Therefore, the aim of this study is to examine the effect of incorporating sustainable SiO_2 nanoparticles on the mechanical, structural, and biological properties of polyurethane-based clear aligner materials. The study seeks to identify an optimal nanoparticle concentration that enhances material performance while maintaining biocompatibility, thereby supporting the development of advanced and durable clear aligner systems.

2. EXPERIMENTAL PROCEDURES

2.1 Materials

Polyurethane (PU) is a synthetic polymer formed through the reaction of polyols and isocyanates and exhibits tunable properties suitable for biomedical and industrial applications. In this study, PU was employed as the base material for the fabrication of clear dental aligners due to its biocompatibility, flexibility, and optical transparency. Sustainable SiO_2 nanoparticles with an average particle size of 57.7 nm were selected as reinforcing fillers, and four different weight fractions (0.1, 0.2, 0.3, and 0.4 wt%) were incorporated into the PU matrix to enhance its properties[/RED]. The particle size distribution of the nanoparticles is presented in Figure 1. Prior to incorporation, the nanoparticles were surface-treated and dispersed in ethanol using ultrasonication for 30 min at a frequency of 40 kHz to break down agglomerates and promote uniform dispersion. This procedure ensured homogeneous distribution of the nanoparticles within the polymer matrix and minimized particle agglomeration



83-1 (Combined)

Effective Diameter: 57.7 nm
Polydispersity: 0.005
Baseline Index: 3.1/100.00%
Elapsed Time: 00:00:30

Figure 1. Nanoparticles size

2.2 Material strength characteristics

2.2.1 Micro-scale hardness test

Shore hardness test is widely used for evaluating the hardness of polymers, especially elastomers and plastics. 5 samples tested of 1cm in size by applying a predetermined force while pressing a standardized indenter into the surface, it assesses the material's resistance to indentation. For thermoplastic materials, for example, Shore D is one of several Shore scales. The Shore device provides the hardness value directly. This test is perfect for quality control and material characterization in polymer testing since it is easy to use, rapid, and non-destructive.

2.2.2 Tensile strength

Five samples of tensile properties were determined in accordance with ASTM D638, as shown in Figure 2. Universal Testing Machine (UTM) with [insert machine capacity, including 50 kN or 100 kN and a constant crosshead speed of 2 mm/min was used for the tests. Stress-strain curves were created during the test. To obtain the tensile modulus, strain at failure, and ultimate tensile strength (UTS).

Figure 2. Tensile samples

2.3 Morphological and structural characterization

2.3.1 Fourier transform infrared spectroscopy

Identify functional groups and confirm chemical interactions between polymer and nanoparticles. Spectra for 5 samples of aligner materials recorded with the range of 600 to 4000 cm⁻¹ using an FT-IR spectrometer, and the resulting spectra were analyzed using specialized software.

2.3.2 Field emission scan electrons microscopy

The interaction of the electron beam with the pattern produces a multitude of signals. These indicators, which are obtained with the use of detectors inside the microscope, offer special insights into the composition and surface topography of the material by testing 5 samples. The scanning electron microscope's high magnification and advanced analytical abilities enable it to examine a large amount of a topic, making it a useful instrument for surface characterization.

2.4 Biological properties

2.4.1 Antibacterial test

The experiment demonstrates the degree to which polymeric composite surfaces can either retain or inhibit the development of a biofilm layer of 5 samples of 1 cm in size. The accumulation of bacterial cells on solid, immobile surfaces is referred to as biofilm as shown in Figure 3. The following steps are used to detect it:

First: After cleaning the surface and staining it with crystal violet dye, which dyes the bacteria on the surface, a visual (macroscopic) inspection is performed to see the development of bacterial aggregates.

Second: To count the quantity of bacterial cells on the surfaces, a smear made from the bacteria that have gathered on the polymer composites surface is put on a glass slide and inspected under a microscope.

Third: After removing the biofilm layer with ethanol, the optical absorbance is read using a Microtiter Plate Reader to determine the biofilm density. The percentage of removal or inhibition is calculated from these readings using Eq. (1). Materials that have been used: Polystyrene 6-well plates, Polystyrene 96 - well plate, 22 × 22-1 cover slip, 70% and 95% ethanol, Phosphate-buffered saline (PBS), Brain heart infusion (BHI) /broth growth media, Sterilize glucose solution 2%, Crystal violet solution, Normal saline, McFarland standard (0.5). Devices: Autoclave, Incubator, Microtiter plate reader, Microscope.

$$\text{Biofilm Inhibition}(\%) = \left(\frac{\text{Control OD}_{630\text{ nm}} - \text{Treated OD}_{630\text{ nm}}}{\text{Control OD}_{630\text{ nm}}}\right) \times 100 \quad (1)$$

Bacteria: Staphylococcus aureus (G+ve).

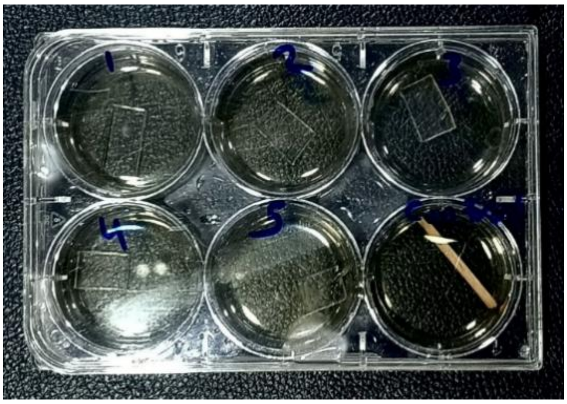


Figure 3. Biofilm inhibition assay of material

2.4.2 Cytotoxicity test by Hemolytic assay

The hemolysis method is based on assessing how toxic compounds affect the integrity of cell membranes and their capacity to preserve their internal components, it is regarded as one of the key methods for determining cytotoxicity. When the produced compounds come into touch with blood outside the body, this test particularly assesses how the compounds affect human erythrocytes and blood cells.

As a result, it aids in determining the chemicals' level of toxicity to blood cells as a preliminary test to identify whether they are hazardous or safe for human use in terms of their interaction with the blood tissue fluid. Furthermore, when examined at relatively high doses.

This technique relies on hazardous chemicals' capacity to disrupt cell membranes, which allows cell contents to seep into the surrounding medium. The level of cytotoxicity is then determined by measuring the concentration of the released hemoglobin.

The test was carried out in two main steps:

1. Determining the amount of hemoglobin produced by blood hemolysis.
2. Erythrocyte morphology is examined under a microscope and compared to the Phosphate Buffer Saline (PBS) solution as the negative control and the positive control, which shows total hemolysis of red blood cells.

Eq. (2) was used to calculate the Hemolysis ratio (HR%).

$$Hemolysis\ ratio(HR\%) = [OD(test) - OD(negative\ control)]/[OD(positive\ control) - OD(negative\ control)] \times 100\% \quad (2)$$

3. RESULTS AND DISCUSSION

3.1 Morphological and structural analysis

3.1.1 Spectroscopy (FTIR) analysis

The FTIR spectra of polyurethane (PU) reinforced with sustainable nano-silica were systematically analyzed to identify the characteristic functional groups and to evaluate possible interactions between the polymer matrix and the nanoparticles. The obtained spectra exhibited the typical absorption bands of polyurethane in addition to distinct peaks related to nano-silica, confirming the successful incorporation of the filler without altering the fundamental chemical structure of the polymer.

A broad absorption band observed in the range of 3300–3500 cm⁻¹ was attributed to O–H stretching vibrations originating from hydroxyl groups located on the surface of the nano-silica particles. The C–H stretching vibrations associated with aliphatic chains in the polyurethane backbone appeared at 2920–2950 cm⁻¹. The characteristic carbonyl (C=O) stretching band of urethane linkages was detected at 1700–1730 cm⁻¹, while N–H bending and C–N stretching vibrations corresponding to urethane or urea groups were identified in the 1530–1570 cm⁻¹ region.

Additional absorption bands in the ranges of 1100–1150 cm⁻¹ and 600–1000 cm⁻¹ were assigned to Si–O–Si and Si–O stretching and bending modes, respectively, confirming the presence of nano-silica within the composite. The absence of new absorption peaks or significant peak shifts indicates that the reinforcement mechanism is predominantly physical rather than chemical. Overall, the FTIR results confirm effective integration of nano-silica into the PU matrix while preserving the intrinsic chemical structure of polyurethane, as summarized in Table 1 and illustrated in Figure 4.

Table 1. Characteristic peaks of polyurethane matrix and the sustainable nanoparticles

Wavenumber (cm⁻¹)	Functional Group / Peak Assignment	Explanation
~3300–3500	–OH stretching	Due to hydroxyl groups on the surface of nano-silica (Si–OH groups)
2920–2950	C–H stretching (methyl and methylene groups)	Represents aliphatic chains in the polyurethane backbone (CH_2, CH_3)
1700–1730	C=O stretching (carbonyl groups in urethane)	Characteristic peak of polyurethane's carbonyl groups
1530–1570	N–H bending and C–N stretching (urethane/urea groups)	Typical of urethane or urea linkages in the polymer
1100–1150	Si–O–Si stretching	Indicative of the silica network from nano-silica reinforcement
600–1000	Si–O bending and stretching	Additional peaks related to the silica filler

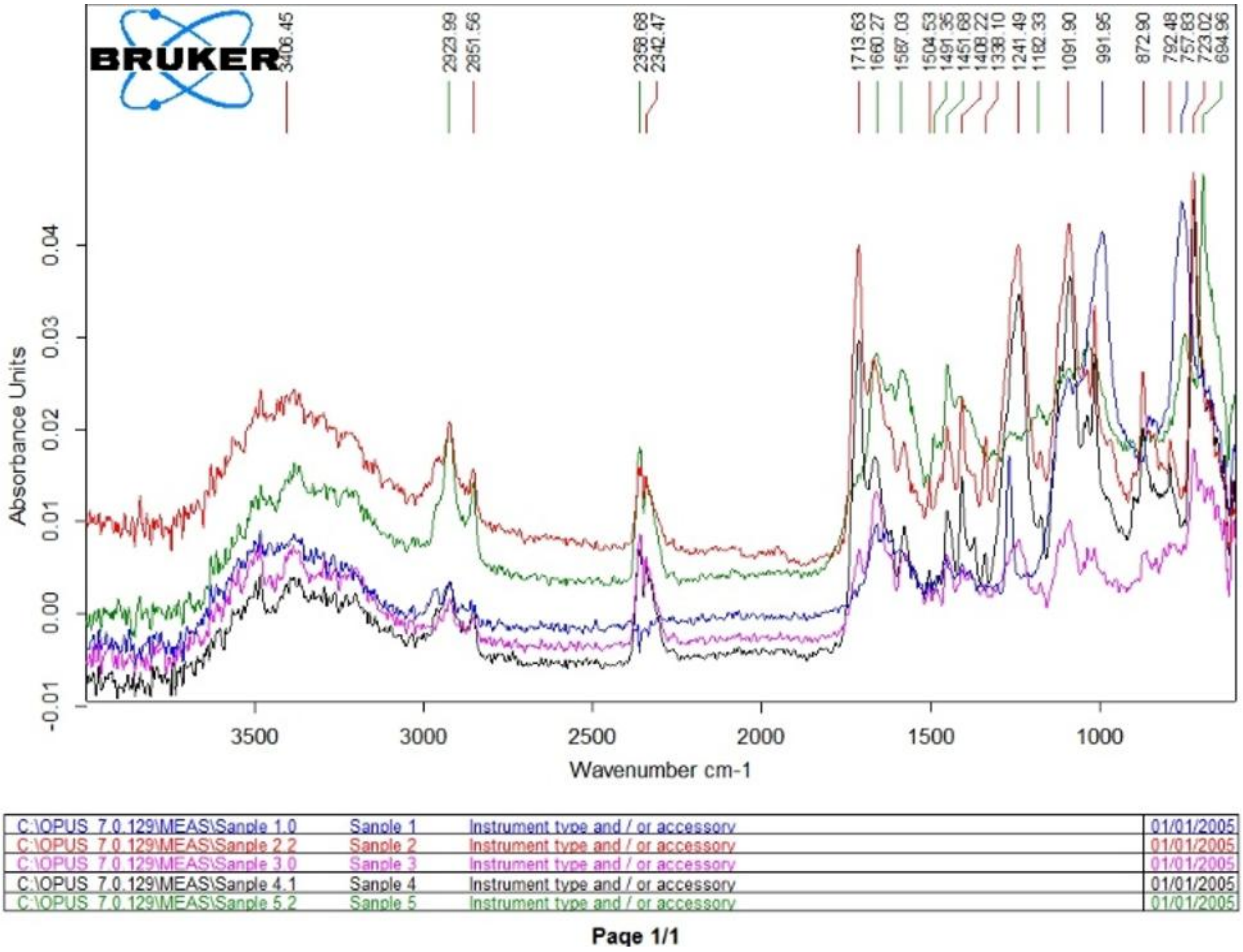


Figure 4. FTIR spectrum of polyurethane reinforced with nano-silica

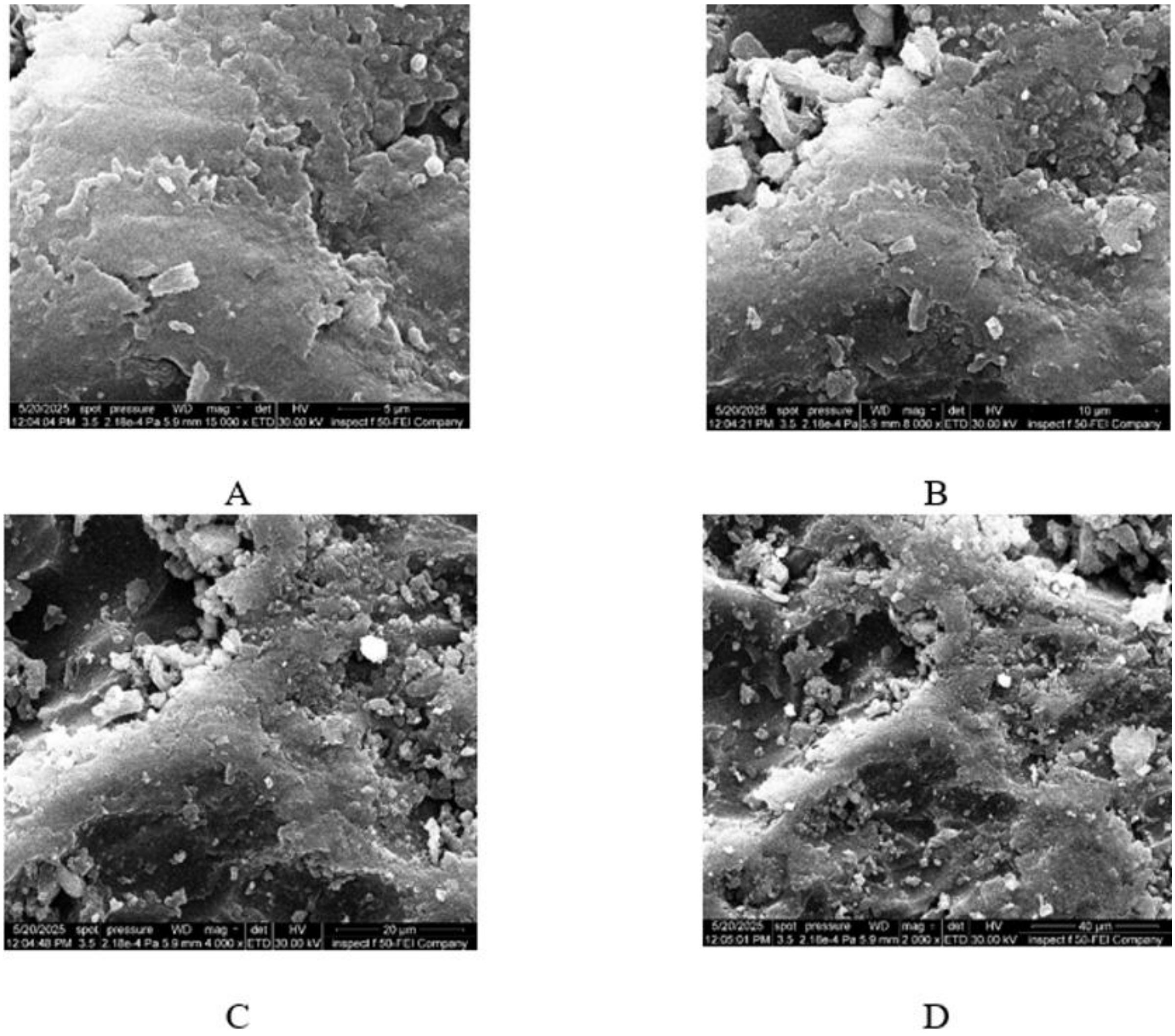


Figure 5. Morphology of polyurethane reinforced with 4 wt% (weight present) nano particles at various magnification

3.1.2 Scanning Electron Microscope analysis

Scanning electron microscopy was employed to examine the surface morphology and dispersion state of nano-silica within the polyurethane matrix. The SEM micrographs revealed a homogeneous distribution of nanoparticles at low filler concentrations, with no significant agglomeration observed.

Uniform nanoparticle dispersion is a critical factor for effective reinforcement, as it facilitates efficient stress transfer between the polymer matrix and the nanoparticles. The nano-silica particles were well embedded within the PU network, indicating good interfacial compatibility. This homogeneous microstructure is expected to enhance mechanical performance while maintaining the optical clarity required for clear aligner applications. Representative SEM images at different magnifications are presented in Figure 5.

3.2 Material strength characteristics

3.2.1 Micro-scale hardness test

The Shore D hardness of neat transparent polyurethane was measured at 72, which is consistent with values typically reported for flexible polyurethane materials used in orthodontic applications. Upon the incorporation of nano-silica, a progressive increase in hardness was observed with increasing filler content, reaching a maximum value of 96 Shore D.

The enhancement in hardness is attributed to the reinforcing effect of nano-silica particles, which restrict polymer chain mobility under applied load and increase resistance to surface deformation. The uniformly dispersed nanoparticles act as rigid fillers, resulting in a more compact and deformation-resistant microstructure. Importantly, this improvement was achieved at relatively low filler concentrations, preserving the flexibility and transparency required for clear aligner applications. The hardness results are presented in Figure 6.

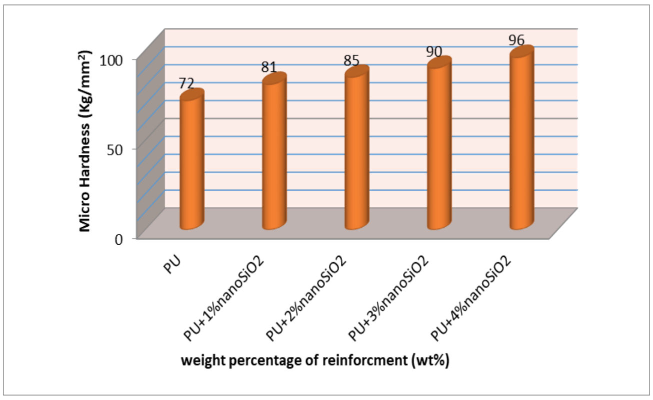


Figure 6. Hardness value of the pure polyurethane and various weight percentage of nano SiO_2 particles

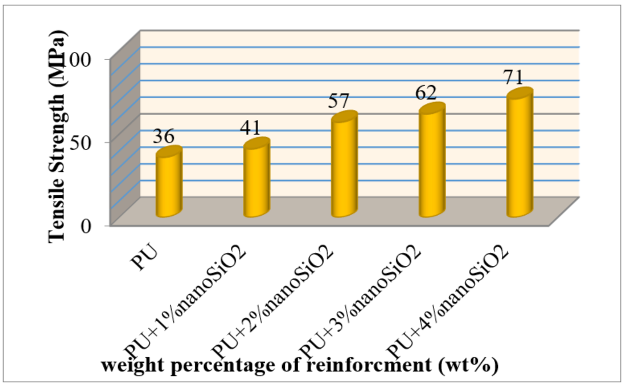
The hardness increase is explained by the fact that Nano-silica is a reinforcing filler, which enhances the load bearing capacity of the polymer matrix and prevents the movement of molecular within the force exerted on the polymer. Moreover the dispersed nanoparticles form more resistant nanoparticle microstructure that is more resistant to deformation. Nano-silica has received a significant reinforcement at low levels (1 percent or a little higher) without affecting the transparency of the material which is very important in dental aligners as in Figure 6.

The 72 to 96 Shore D increase might not sound very high, but it is huge as far as mechanical performance and durability are concerned especially in cases where repetition and mechanical resistance are important. This advancement posits increased ability to resist surface abrasion and deformation during clinical practice, and this may increase the life cycle of the aligners.

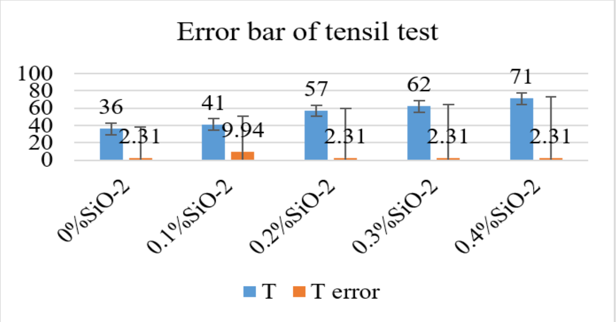
It should take care not to be too hard or too soft. The extreme hardness can decrease the conformational capacity of the material to the articulation of the teeth in comfort. This balance is attained because nano-silica reinforcement enhances hardness, but it probably does not remove the flexibility necessary.

3.2.2 Tensile results

The pure clear polyurethane utilized in dental aligners has an essential mechanical ability to resist the stresses that occur during ordinary orthodontic use, as demonstrated by its measured tensile strength of 45 MPa, which reflects its inherent mechanical capability to withstand stresses encountered during regular orthodontic use. As illustrated in Figure 7, the flexural strength values significantly increased upon reinforcing with sustainable nano-silica particles at different concentrations, showing values of 51, 54, 58, and 64 MPa.



(a)



(b)

Figure 7. Tensile strength value of the pure polyurethane and various weight percentage of nano SiO_2 particles

The reason for the increased tensile strength when adding sustainable nano-silica nanoparticles to polyurethane is that they disperse within it, preventing the polymer chains from sliding under tension, increasing resistance before breaking. This leads to a rise in tensile strength and stiffness. As the material is stretched, part of the load is shifted to the nanoparticles and the stress concentration in certain parts is reduced and the cracking is slowed down. The existence of nanoparticles restricts the freedom of movement of the polymer chains thus, rendering the core material more cohesive to mechanical load. The nanoparticles are useful in dispersing the stress throughout the material instead of it being concentrated in one location, preventing a spontaneous breakage.

Sustainable nanoparticles on the other hand may enhance the stiffness and modulus of elasticity by reducing the movement of the polymer chains within the matrix.

3.3 Biological results

3.3.1 Antibacterial results

The bactericidal results of 5 samples from polyurethane reinforced at different nano-silica loadings (0.1–0.4) (weight percent) clearly depended on the surface activity and dispersion quality of the included nanoparticles. Even a small amount of silica nanoparticles is sufficient to alter the surface shape and decrease bacterial adhesion, as seen by the dramatic increase in the inhibition percentage at high concentrations, where 0.4% nano-silica obtained a high antibacterial activity of 71%. This ideal dispersion increases the inhibition of bacterial growth and inhibits colonization on the surface of the material. The antimicrobial results were shown in Figure 8.

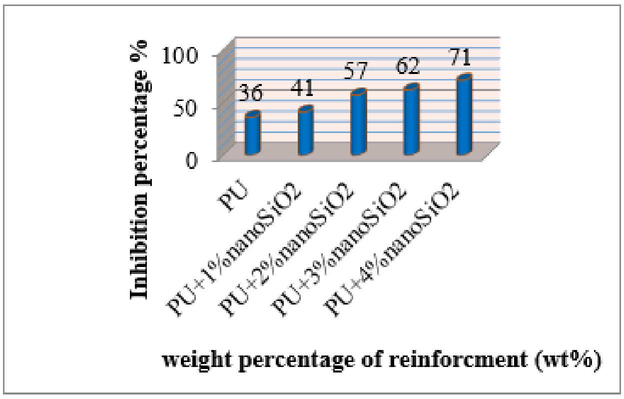


Figure 8. Antimicrobial results

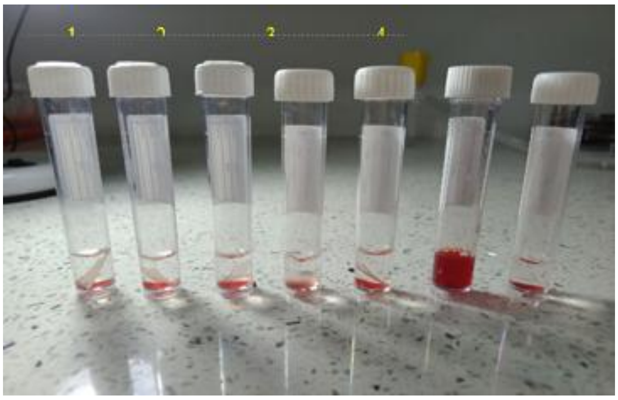


Figure 9. Results of the qualitative and morphological hemolysis test conducted within test tubes after incubation

3.3.2 Cytotoxicity test by Hemolytic assay results

Hemolytic rate (%) is used to express the results, and spectrophotometric measurements of the liberated hemoglobin's absorbance at 520 nm are made. Additionally, considering the materials' cytotoxic effect can be linked to their impact on cancer cells, as Figure 9 illustrates, this test may also reveal the materials' possible anticancer activity.

Compared to the positive control (+C), no hemolysis was seen, suggesting that the materials are safe and non-toxic to human cells.

4. CONCLUSION

From the conducted tests and obtained results, it can be concluded that:

1. Polyurethane (PU) was used as the clear aligners base material because of the flexibility, transparency, and biocompatibility and the addition of SiO_2 nanoparticles (57.7 nm) in four weight percentages (0.1%, 0.2%, 0.3%, 0.4%) to improve the properties of PU.

2. FTIR analysis confirmed the chemical interactions and presence of functional groups between the polymer and nanoparticles. The FTIR spectrum of transparent polyurethane with nano-silica shows peaks from both the polymer and the silica. These include signals for –OH groups (3300–3500 cm^{-1}), C–H bonds (2920–2950 cm^{-1}), carbonyl groups (C=O, at 1700–1730 cm^{-1}), and N–H and C–N bonds (1530–1570 cm^{-1}) from polyurethane. New peaks from the nano-silica appear at 1100–1150 cm^{-1} and 600–1000 cm^{-1}, showing Si–O–Si and Si–O bonds. These results confirm that nano-silica is well mixed into the material without changing the main chemical structure. It acts as a physical filler to improve the material's properties.

3. SEM analysis showed uniform dispersion of nanoparticles within the polymer matrix at low concentrations, preventing clumping or aggregation. Uniform nanoparticle dispersion improves mechanical strength and may enhance optical clarity and barrier properties.

4. Transparent PU is 72 Shore D, and is flexible enough and strong enough to use as dental aligners. The addition of nano-silica enhanced the hardness gradually to a maximum of 96 Shore A because of the reinforcing effect that prevented the movement of the molecules.

5. Pure PU showed a Tensile strength of 45 MPa, which increased significantly to 51-64 MPa with nano-silica reinforcement. The increased Tensile strength is due to improved stress transfer, crack resistance, and a more rigid microstructure from well-dispersed nanoparticles.

6. The effects of nanoparticles and the significance of obtaining the ideal dispersion of nanoparticles within the polymer matrix to optimize functional characteristics for non-toxicities and antibacterial behavior.

This research was able to examine the consequences of the integration of nanoparticles on the structure and mechanical character of clear aligner materials founded on polyurethane. With extensive characterization, it was established that nanoparticles silica addition can make the aligner films perform much better when dispersed within the polymer matrix in the right amount.

The findings indicated that low nanoparticles concentrations provided significant enhancement on Tensile strength and hardness.

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