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Investigation of the effects of different nanoparticle additionals on the mechanical properties of silicone elastomer used in maxillofacial prosthesis

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ABSTRACT

Objective: The aim of this study is to evaluate the change in the mechanical properties of silicone elastomer used in the production of maxillofacial prostheses with the addition of 3 different nanoparticles (TiO_2-SiO_2-ZnO).

Material and Method: TiO_2-SiO_2-ZnO nanoparticles were added to the A part of the M511 Platinum (Technovent Ltd., England) silicone elastomer at a rate of 2% by weight. Test specimens were produced in sizes by ASTM D412 standards for tensile strength and percent elongation, ASTM D624 for tear strength, and ASTM D2240-68 for hardness testing. For each mechanical test, 4 groups were formed together with the control group and 3 other groups to which nanoparticles were added, and a total of 132 samples were produced, 11 samples for each group (n=11), (N=132). The data of tensile strength, elongation percentage, and tear strength tests were analyzed by Shapiro Wilk's and/or Kolmogorov Smirnov/Mann Whitney U, Kruskal Wallis-H tests; for the hardness test, the values in each group showed a normal distribution within themselves, hardness test was analyzed with Oneway ANOVA/Tukey HSD tests.

Results: The addition of TiO_2 and SiO_2 to the silicone elastomer significantly increased the tensile strength compared to the other groups ($p<0.05$), the addition of TiO_2 increased the elongation percentage significantly compared to the other groups ($p<0.05$), all particle additions significantly increased the tear strength ($p<0.05$), SiO_2 addition significantly increased the hardness compared to the other groups.

Conclusion: The addition of TiO_2-SiO_2-ZnO nanoparticles to silicone elastomer may be an effective option to improve the mechanical properties of maxillofacial prostheses.

Keywords: Maxillofacial prostheses, nanoparticles, silicone elastomer

INTRODUCTION

Defects may occur in the maxillofacial region as a result of congenital, developmental or acquired causes (1). Congenital malformations in the maxillofacial region, and facial deformities that may occur due to head and neck surgery or trauma cause psychological problems and alienation of patients from society (2,3). Rehabilitation of patients with this type of defect is provided with maxillofacial prostheses, and these patients are reintegrated into society (4). For these reasons; The prosthesis made should be adequate in terms of aesthetics and function, should not have negative effects on the health of the remaining tissues, and should be able to maintain these properties for a long time (5). Even though plastic reconstructive and aesthetic surgery has made great progress today, maxillofacial prostheses are needed in the vast majority of cancer and trauma patients (6). One of the most important advantages of prosthetic rehabilitation in the maxillofacial region compared to surgical operations is that it better adapts to complex anatomical regions (7).

Silicones are the most frequently used materials in the manufacture of maxillofacial prostheses, due to their natural appearance, acceptable physical properties and good color stability (8,9). The duration of use of silicone elastomers used in maxillofacial prosthesis applications is limited to 1-2 years due to the decrease in their physical properties, tears in the margins and changes in their color (3,10). Despite their advantages such as easy manipulation, biocompatibility, and chemical inertness, silicone

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elastomers do not have the desired physical and mechanical properties (8,11). Research continues for a new polymer material with superior mechanical properties such as high tear and rupture strength and low hardness (3).

Tear strength, tensile strength, elongation percentage and hardness tests are used to determine the mechanical properties of silicone elastomers (8). Veres et al. (12) stated that the mechanical properties of an ideal maxillofacial prosthesis material as high tearing, tensile strength, elongation percentage, and low hardness values. Hardness gives information about the softness of materials. The hardness of materials is important for the prosthesis to have a more natural appearance and to adapt to the movements of the head and neck region (8,13). Veres et al. (12) reported that the ideal hardness value should be between 10-40 Shore A.

In terms of ease of use, the first feature desired in a maxillofacial prosthesis is its high tear strength. Tears are occurring quite commonly at the thin edges of the epitheses. The tensile strength of silicone elastomer gives information about the overall strength of the material and is considered an indicator of its elongation flexibility. Elongation percentage is an important parameter in terms of the flexibility of the prosthesis in head and neck movements. High tensile strength and high elongation percentage are the necessary features to prevent deformed prostheses while removed from the tissues (14).

Deteriorations in maxillofacial prostheses usually start from the marginal areas that need to be made thin. The thinly made denture edges are deformed by the effects of cleaners, medical adhesives and body fluids. The most important disadvantages of maxillofacial prostheses are edge tears and ruptures. To eliminate these problems, mechanical properties by adding various fillers such as glass and natural fibers, ceramic fibers, silica powder into silicone elastomers; especially tensile and tear strength is tried to be increased (15,16).

In the chemical industry, research has been undertaken for the past decade to initiate a different industrial process that combines nanoparticles into a polymeric matrix and provides a new class of polymeric materials by presenting the powerful properties of nano oxides. The nano oxide particles are tough and have a higher shear modulus than pure silicone elastomer. The enhanced properties discovered in adding nanoparticles to a polymeric matrix can be attributed to the particle's higher surface energy and chemical reactivity, thereby interacting with the silicone elastomer matrix and forming a 3-dimensional network in the silicon polyethylene structure. Thus, they can improve the physical and optical properties of the organic polymer, as well as provide resistance to environmental stress-induced cracking and aging. These new nano-oxides have been shown to be additive to coatings, rubbers, plastics, sealants, fibers, textiles, and cosmetics. Little has been reported on how the attachment of these particles to a maxillofacial elastomer might affect its properties (17). Nano TiO_2 (titanium dioxide) as an inorganic additive; It has been reported to be biocompatible, chemically stable, and antibacterial (18). The properties of SiO_2 (silica) nanoparticles can be counted as small dimensional structures, large interface areas, active functioning and superior interfacial connection with organic polymer. Thus, protect the structure against cracking and aging by improving the mechanical, optical and physical properties of the organic polymer (17). ZnO (zinc oxide) nanoparticles absorb of A-ultraviolet light and they have antibacterial activity (19).

The mechanical properties that these three nanoparticles with superior properties can impart to elastomers used in maxillofacial prostheses have not been compared in the literature before. This study aims to investigate the mechanical effects of 3 different nano oxide particles (TiO_2-SiO_2-ZnO) by adding them to a commercial silicone elastomer commonly used in an extraoral maxillofacial prosthesis. The null hypothesis of the study is; h0: TiO_2, SiO_2, ZnO nanoparticles addition will not make a difference in the mechanical properties of the silicon elastomer.

MATERIAL AND METHOD

The study was carried out with the permission of Fırat University Non-Interventional Research Ethics Committee (Date: 23.01.2020, Decision No: 02/14).All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

In this study, heat polymerized M511 Platinum (Technovent Ltd., England) brand HTV type silicone elastomer which consists of two components, Part A base, and Part B catalyst is used. The weight of the base part of the silicone elastomer in the amount to be sampled was detected using a precision scale (Denver Instrument GmbH, Göttingen, Germany). 2% of the measured weight was calculated and the amount of nanoparticles to be used in the sample was added to the base of the silicon. According to the manufacturer's recommendation, 1/10 of the weight of the base part without nanoparticles was added and the mixing process was started. The mixing process was done with the help of a vacuum mixer (Bego Easy Mix, BEGO, USA) and the silicone elastomer was made ready for polymerization. The mixture prepared for polymerization was placed in molds. In order to determine the number of samples in the study groups, power analysis (power analysis) was applied with the help of the G*Power 3 (Faul, Erdfelder, Lang, & Buchner, 2007) program and the sample number was determined as 11.

To standardize the samples for mechanical tests, metal molds were produced in accordance with the American Society for Testing and Materials (ASTM) standards. For the tensile strength and percent elongation test samples, metal molds were produced based on ASTM D412 (112) standards. The molds to be prepared for the tear strength test samples were made based on ASTM D624 (113) standards (**Figure 1**). Polymerization was carried out in accordance with the manufacturer's recommendation by keeping it at 100 ˚C for 1 hour.

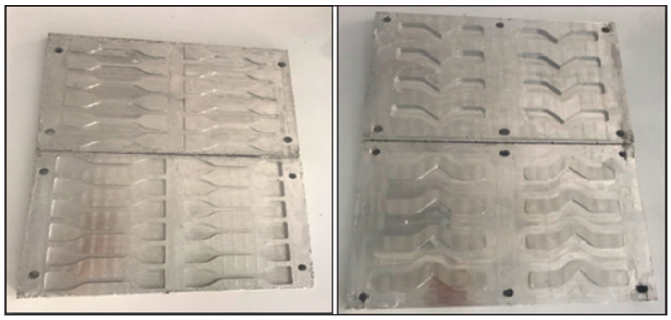

Figure 1. Metal molds prepared for tensile and tear strength tests

Test groups; it consists of 12 groups, with 11 samples (n=11) in each group for the control group and the groups to which nanoparticles were added (TiO_2, SiO_2, ZnO). A total of 132 specimens were produced, 44 for the tensile strength and elongation percentage test, 44 for the tear strength test and 44 for hardness test. For the tensile strength and elongation percentage test, barbell-shaped specimens produced by ASTM D 412 standards were placed in the tensile test device (Llyod Instruments LR 50K, Lyod instruments Ltd, Fareham, England). After the speed of the test device was set to 500 mm/min, the samples were tested. The tensile test was continued until the specimens ruptured. The results were calculated and recorded using the equation; Tensile stress: Load (N)\ Field (mm^2). The percentage of elongation that occurred in the specimen; relative to the first dimension after the rupture occurred in the specimens was calculated using the equation Elongation Percentage (%) = Elongation Amount / First dimension x 100 (**Figure 2**). For the tear strength test, the samples were placed in the same test device. Then the speed of the device was set to 500 mm/min and force was applied at a stable speed. The test was continued until the tearing process was completed. The obtained data were collected using the software of the system. The results were calculated with the formula tear strength = Load (N) / Thickness (mm) (**Figure 3**). For the hardness test, the samples were produced as circular specimens with a diameter of 30 mm and a thickness of 10 mm by ASTM D2240-68 test standards. The samples were prepared by the traditional flask method. Shore A surface hardness test was applied to measure the hardness values of the prepared samples. Five different measurements were made with a digital Shore A test device (Shore Scale Durometer Hardness Tester, England) by determining 5 different points equidistant from the center in each sample. The arithmetic average of the measurements was calculated and recorded as Shore A hardness degree for each sample (**Figure 4**).

Figure 2. Tensile strength and elongation percentage test

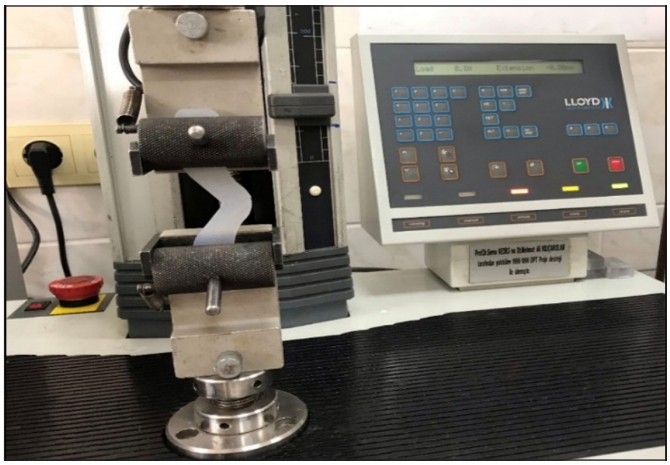

Figure 3. Tear strength test

Figure 4. Hardness measurement with shore a tester

The data obtained for tensile strength, elongation percentage and tear strength test analyzes were analyzed with the IBM SPSS 21 package program. Shapiro Wilk's and/or Kolmogorov Smirnov tests were used due to the number of units while investigating the normal distribution of the variables. When examining the differences between the groups, in case the variables did not come from a normal distribution, the Mann Whitney U test was used for comparisons with two groups, and the Kruskal Wallis-H test for more than two groups. In case of significant differences in the Kruskal Wallis-H test, the groups with differences were determined with the Post-Hoc multiple comparison test. In the evaluation of the groups in terms of hardness, the significant differences between the groups were examined with the Oneway ANOVA Test, and the Tukey HSD Post-Hoc multiple comparison tests were used to determine which groups the significance originated from. While interpreting the results, 0.05 was used as the level of significance; It was stated that there was a significant difference in the case of $p<0.05$, and there was no significant difference in the case of $p>0.05$.

RESULTS

In terms of tensile strength; there was no statistically significant difference between the control-ZnO ($p=0.533$) and TiO_2-SiO_2 ($p=0.309$) groups ($p>0.05$). There was a statistically significant difference between all groups other than these ($p<0.05$). The highest tensile strength mean was found in the SiO_2 added group (3.35 ± 0.18 MPa), and the lowest mean value was found in the control group (2.64 ± 0.27 MPa) (**Table 1**), (**Figure 5**).

In terms of elongation percentage; There was no statistically significant difference between control-ZnO ($p=0.577$), control-SiO_2 ($p=0.577$) and ZnO-SiO_2 ($p=0.67$) groups ($p>0.05$). There was a statistically significant difference between all groups other than these ($p<0.05$). The highest elongation percentage mean value was found in the TiO_2 group (1017.23 ± 89.37 %), while the lowest percent elongation mean value was found in the group with SiO_2 added (900.03 ± 88.92 %) (**Table 2**), (**Figure 6**).

There was no statistically significant difference between only ZnO-TiO_2 groups ($p=0.862$) in terms of tear strength ($p>0.05$). There was a statistically significant difference between all groups other than this ($p<0.05$). The highest tear strength mean was found in the SiO_2 added group (20,84 kN/m), and the lowest mean value was found in the control group (15,51 kN/m) (**Table 3**), (**Figure 7**).

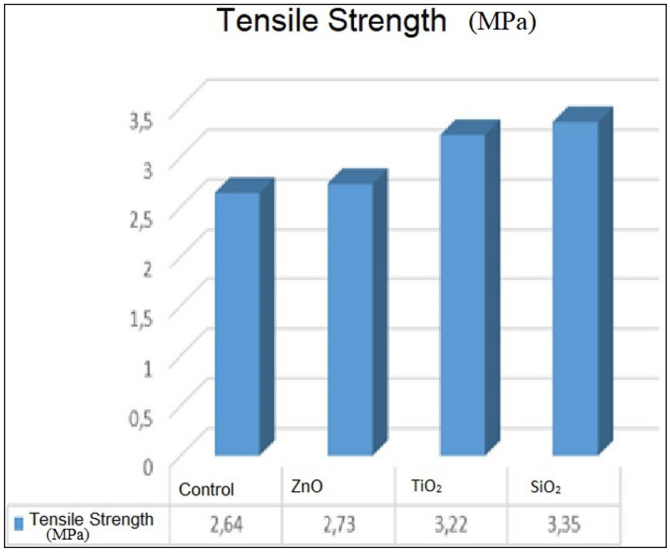

Figure 5. Differences between groups in terms of tensile strength

Table 1. Analysis results regarding the difference between groups in terms of tensile strength

Groups	n	Mean (MPa)	MD (MPa)	Min (MPa)	Max (MPa)	SD	Kruskal Wallis H Test		
							Mean rank	H	p
Tensile strength								24,97	0.001
Control (a)	11	2,64	2,57	2,33	3,25	0,27	11,73		
ZnO (b)	11	2,73	2,86	2,26	3,26	0,32	14,27		
TiO_2 (c)	11	3,22	3,25	2,78	3,71	0,32	29,73		
SiO_2 (d)	11	3,35	3,41	3	3,61	0,18	34,27		
Total	44	2,99	2,99	2,26	3,71	0,41			

* The groups are classified with the letters below, and groups with statistically significant differences are indicated.(p=0.001)a-c, (p=0.001)a-d, (p=0.004)b-c, (p=0.001)b-d.

Table 2. Analysis result regarding the difference between groups in percentage of elongation

Groups	n	Mean	MD	Min	Max	SD	Kruskal Wallis H Test		
							Mean rank	H	p
Elongation percentage								11,25	0,01
Kontrol (a)	11	909,26	898,43	814,25	1145,05	89,37	16,55		
ZnO (b)	11	918,41	948,53	811,96	1058,27	80,95	20,64		
TiO_2 (c)	11	1017,23	972,47	925,24	1151,7	77,61	33,45		
SiO_2 (d)	11	900,03	944,15	715,44	993,27	88,92	19,36		
Total	44	936,23	940,49	715,44	1151,7	94,35			

** The groups are classified with the letters below, and groups with statistically significant differences are indicated. (p=0.002)a-c, (p=0.02)b-c, (p=0.014)c-d.

Table 3. Analysis result regarding the difference between groups in terms of tear strength

Groups	n	Mean (N/mm)	MD (N/mm)	Min N/mm	Max N/mm	SD	Kruskal Wallis H Test		
							Mean rank	H	p
Tear Strength								25,161	0,001
Kontrol (a)	11	15,51	15,64	12,37	17,88	1,79	11,15		
ZnO (b)	11	17,93	18,08	14,2	20,82	1,9	25,5		
TiO_2 (c)	11	17,83	18,33	14,78	19,85	1,61	24,67		
SiO_2 (d)	11	20,84	19,75	18,51	24,72	2,17	39,83		
Total	44	17,98	18,29	12,37	24,72	2,65			

*** The groups are classified with the letters below, and groups with statistically significant differences are indicated. (p=0.006)a-b, (p=0.006)a-c, (p=0.001)a-d, (p=0.006)b-d, (p=0.003)c-d.

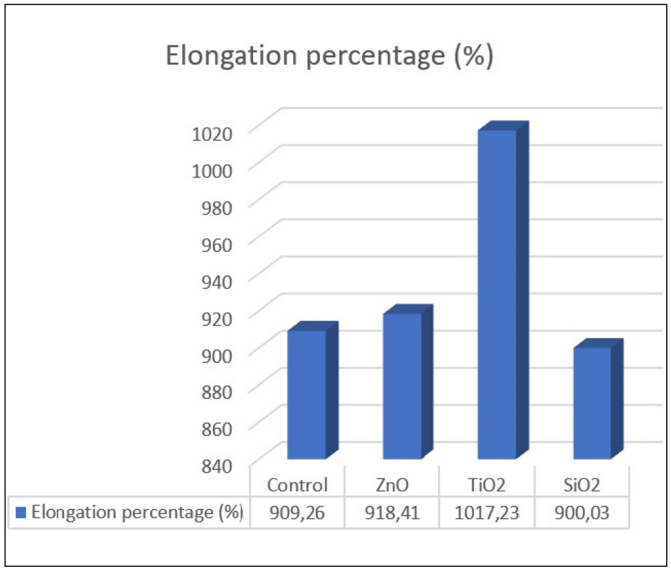

Figure 6. Differences between groups in percentage of elongation

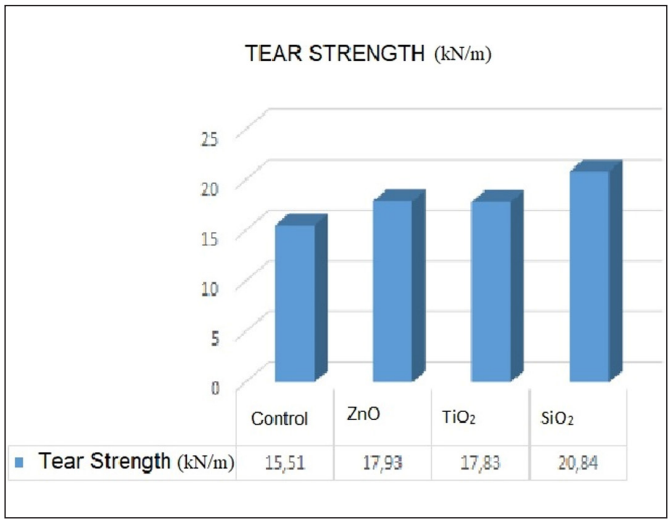

Figure 7. Differences between groups in terms of tear strength

There was no statistically significant difference between only ZnO-TiO_2 (p=0.490) groups in terms of hardness (p>0.05). A statistically significant difference was found between all other groups except this one (p<0.05). The highest hardness mean value was found in the SiO_2 added group (25,50±1,53 Shore), and the lowest mean value was found in the ZnO group (21,85±0,65 Shore) (**Table 4**), (**Figure 8**).

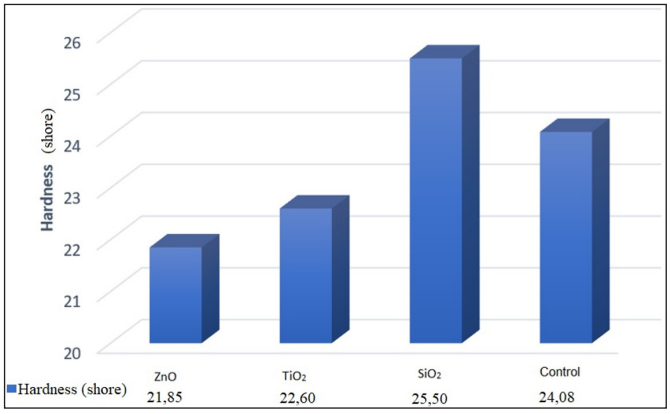

Figure 8. Differences between groups in terms of hardness test

Table 4. Evaluation of groups in terms of hardness

Oneway ANOVA test	Hardness	
	Min-Max	Mean±SD
ZNO (1)	20,5-22,8	21,85±0,65
TiO2 (2)	21,0-23,8	22,60±1,17
SiO2 (3)	23,3-28,3	25,50±1,53
Control (4)	22,8-26,8	24,08±1,17
P		**** 1-3, 2-4, 2-3, 3-4, 1-4,

**** The groups are numbered with the numbers below, and the groups with statistically significant differences are indicated (1-3; p<0.001), (2-4; p=0.001), (2-3; p<0.001), (1-4; p=0.038), (3-4; p=0.047).

DISCUSSION

The null hypothesis of the study was partially rejected. The addition of nanoparticles generally improved the mechanical properties of the silicon elastomer. Lewis and Castleberry (20) reported that not necessary to perform mechanical tests on elastomers under dynamic loads. For this reason, we decided not to apply dynamic loading tests in our study. Craig and Powers (21) stated that the mechanical properties of HTV type silicones are better than RTV type silicones. In our study, HTV type silicone elastomer belonging to the brand M511 was preferred.

Wang et al. (22) added 2%, 4%, and 6% TiO_2 by weight to RTV type MDX4-4210 silicone elastomer, after artificial aging they investigated the effect on its biomechanical properties. As a result of their research, was reported that the addition of 2% TiO_2 by weight improved the mechanical properties of the material, while the addition of 6% TiO_2 reduced the tear strength and elongation

percentage. In this study, the tensile strength (2.80 MPa) of the group to which 2% TiO_2 was added increased in parallel with our study (3.22 MPa) compared to the control group. In the elongation percentage test results, they explained that the test results of the group with 2% added were the highest with the value of 254.28, and that TiO_2 addition decreased the elongation percentage values after a certain. In our study, the addition of TiO_2 increased the elongation percentage values. Values of data are thought to be higher in our study due to the type of silicone elastomer used. Researchers stated that Shore A values increased in direct proportion with the addition of TiO_2. The reason why TiO_2 addition decreased the hardness values in our study; there may be differences in the silicone elastomer used or in the crosslinked structure and density that occurs.

Zayed et al. (23) compared the mechanical properties of RTV type A-2186 silicone elastomer by adding 0.5% - 1% - 1.5% - 2% - 2.5% - 3% by weight SiO_2. Results of the study stated that; there was an increase in tensile strength in all groups, the highest increase was in 3% SiO_2 concentration, the greatest value in the elongation percentage values was observed in the group with 1.5% SiO_2 added, elongation percentage there was a little decrease in the groups with the addition of 2% and 3% SiO_2. There was an increase in the tear strength results in all groups, the highest value was in the group with 3% SiO_2 added. There was an increase in the tear strength results in all groups the highest value was in the group with 3% SiO_2 added, it has been reported that the addition of SiO_2 increases the hardness values. In our study, in parallel with this research, a small decrease in the elongation percentage was detected with the addition of 2% SiO_2.

Nobrega et al. (24) added ZnO, BaSO4, and TiO_2 nanoparticles at 1% and 2% concentrations to silastic MDX4-4210 silicon elastomer and compared their mechanical properties after artificial aging. According to the results of their studies; they reported that hardness, tear strength and permanent deformation values changed in all groups to which nanoparticles were added, that the addition of nanoparticles decreased the hardness values, the highest tear strength occurred in the 1% BaSO4 group, and 1% ZnO group had the lowest permanent deformation value. In our study, while the hardness values increased with the addition of SiO_2, decreased hardness values with the addition of TiO_2 and ZnO show parallelism with this study.

The reasons for obtaining different values in our study from other studies may be factors such as the different physical and chemical properties of the nanoparticles used, cross-linked with silicone elastomer in different configurations and densities, diversity in polymerization methods, storage conditions of test samples, temperature of the room where the mechanical tests are applied, and the sensitivity of the test devices. Not being subjected to artificial aging can be considered a limitation of the study. New methods that can improve the mechanical, biological, optical and physical properties of the materials used in the manufacture of maxillofacial prostheses should be supported by advanced in-vitro and in-vivo research.

CONCLUSION

Within the limitations of this study, the following conclusions could be drawn:

1. The tensile strength of the silicon elastomer was increased with the added nanoparticles. The nanoparticle SiO_2, which provided the greatest increase in tensile strength, was determined as the second TiO_2. Although a slight increase in tensile strength was observed with the addition of ZnO nanoparticles, this result was not statistically significant.
2. The nanoparticle that the most increased the elongation percentage was determined as TiO_2. The increase in percent elongation values of ZnO and SiO_2 particles compared to the control group was not found to be statistically significant.
3. All nanoparticles used increased the tear strength. While the particle that the most increased was SiO_2, no statistically significant difference was found between the groups to which ZnO and TiO_2 were added.
4. It was determined that while SiO_2 nanoparticles increased the hardness value, ZnO and TiO_2 particles decreased it. There was no statistically significant difference between the ZnO and TiO_2 groups.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Fırat University Non-Interventional Research Ethics Committee (Date: 23.01.2020, Decision No: 02/14).

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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