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Synthesis of Auricular Prosthesis Based on Nanoparticle Silicone/TiO_2 for Microtia Case

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Abstract. Microtia occurs in about 1 to 10 cases per 10,000 birth rates, affects person's physical appearance which lead to increased depression and individual anxiety. Solution of microtia is ear prostheses. Silicone rubber (SR) or polydimethylsiloxane (PDMS) is as chosen material for ear prosthesis due to its durability, is inert, easy to manipulate, and biocompatibility. SR has disadvantages, such as low tear and tensile strength, inadequate elasticity and degradation of physical, and colour properties over time. The aim of this study is to synthesize and characterize SR / nanoparticles composite TiO_2 auricular prosthesis. Composites were obtained by mixing SR with TiO_2 nanoparticles with a percentage of 1%, 2%, and 3% (w / w), the casting method was used to obtain ear prostheses and test specimens. The compressive modulus values for the percentage of 0%, 1%, 2%, and 3% respectively were 0.47 MPa; 0.29 MPa; 0.42 MPa; 0.35 MPa and the tensile modulus, respectively were 0.33 MPa; 0.35 MPa; 0.34 MPa; 0.31 MPa. SEM test results showed that the addition of TiO_2 nanoparticles at a all percentage experienced agglomeration on a micrometric scale. FTIR test revealed that the occurrence of crosslinks in wave number 1384.71 cm^{-1} and 1384.54 cm^{-1}.The occurrence of peak shifts in wave numbers containing OH groups indicated some interaction between the polymer matrix and the filler. It can be concluded that there was no percentage addition of TiO_2 nanoparticles in mechanical test results that showed the closest value to the control value due to agglomeration.

INTRODUCTION

The ear as an organ of the human body which is located on the side of the head serves to detect or recognize sounds and plays a role in the balance and position of the body. There are three parts of the ear, namely the outer ear, middle ear, and inner ear. The outer ear consists of auricula, external auditory canal, and tympanic membrane [1]. Auricula is formed from elastic cartilage that is firmly attached to the oblique skin. According to previous study, the function of the auricula or also called pinna is still debated [2]. In physiology studies, auricula seems to be useful for amplifying intermediate frequencies (2-4 KHz) and facilitating the placement of a sound source in three-dimensional space. The auricle consists of the helix, spiral, antiheliks, scaphoid fossa, triangular fossa, antiheliks crura, antitragus, lobule, and tragus [1].

Microtia is a congenital auricular reduction, with or without structural abnormalities [2]. An acceptable classification of microtia was proposed by Marx [2]. Marx's classification showed that all features of a normal auricular still exist in grade I, but the pinna size is smaller than normal size. Grade II, some anatomical structures can still be identified. In its most common form, grade III (the peanut-shell type), only soft tissue abnormalities occur. The most extreme cases where there is no external ear and auditory canal called anotia or grade IV microtia [3]. Microtia occurs in about 1 to 10 cases per 10,000 birth rates [4]. It has also been reported that the right ear is affected twice more often than the left ear and nearly 90% of all cases are unilateral. External auditory canal atresia and middle

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ear anomalies are usually (80-90%) associated with microtia [5]. In patients with microtia, hearing tresholds usually range from 55 to 65 dB HL, while in normal humans it ranges from 0-20 dB HL [2].

Suurtarla stated that there are four ways to overcome the problem of microtia, such as using autologous costal cartilage reconstruction, alloplastic reconstruction, tissue engineering approach, and ear epithesis or also called ear prosthesis. Silicone is one of the non-biodegradable materials that can be used to make facial prosthesis [2] [6]. A study on the addition of nano-TiO_2 to medical silicone elastomer by Linlin Wang about the addition of TiO_2 nanoparticles with variations of 2%, 4%, and 6% (w/w) [7]. Tensile strength values for control by adding 2%, 4%, and 6% are 2.65 MPa, 2.8 MPa, 3.01 MPa, and 3.29 MPa respectively. Meanwhile, there was a decrease in which the control value of 203.23% decreased to 142.15% in the addition of 6% TiO_2 nanoparticles in the elongation break, but an increase to 254.28% in the addition of 2%. Cell viability tests indicate that composites are biocompatible. Based on the results of a study by Linlin Wang [7], the use of TiO_2 nanoparticles as a filler in composites improves the mechanical properties of the silicone elastomer matrix, TiO_2 nanoparticles are also heat-resistant additives which can increase the cross-link reaction of polysiloxane groups to temperatures which can delay aging prosthesis due to heat. Furthermore, TiO_2 nanoparticles were chosen because they have a strong ability to resist ultraviolet (UV) light, nanoparticles not only absorb but also reflect and scatter UV rays due to their refractive index and optical activity which increases resistance to UV radiation in the environment. According to previous study, the addition of TiO_2 nanoparticles to glass-ionomer (GI) improves mechanical and anti-bacterial properties. Regarding the advantages mentioned earlier, it can be assumed that the use of TiO_2 nanoparticles can increase the lifetime or duration of use of prosthesis [7].

Based on the results given from variations in the percentage addition of TiO_2 nanoparticles and auricular prosthesis material that have not been compared with the mechanical value of the original ear, composite materials and additional mechanical tests are needed to mimic the mechanical value of the original ear. Auricular prosthesis is made of composite silicone / TiO_2 nanoparticle for microtia solutions and it is hoped that in addition to completing the microtia solution it can also mimic the mechanical value of the original ear.

MATERIALS AND METHODS

Materials

Acrylonitrile Butadiene Styrene (ABS) Filament, RTV-2 Silicone Rubber Platinum Cure (Model: RT-820A) with 1 kg skin warrants (Dongguan Guochuang Organic Silicone Material Co., Ltd., China), Titanium Dioxide Powder (TiO_2) Nanoparticles with a particle size of 15-25 nm (Jiangsu XFNANO Materials Tech Co., Ltd, China).

Making Ear Molds with 3D Printing

Making the ear mold was performed in several stages. First, the ear's three-dimensional data for the form of auricular prosthesis was obtained by using a 3D Scanner: EinScan-Pro. The data set obtained was used to create a digital model of three negative print dimensions auricular prosthesis. Mold modeling used three-dimensional modeling software such as Autodesk Fusion 360 and MeshMixer. Then, the three-dimensional model file that has been designed was converted to .STL format thus it can be read by a 3D printer. Next, the printing stage where using a 3D printer with the method of Fused Deposition Modeling (FDM). For the 'ink' used in this 3D printer, the polymer filament was acrylonitrile butadiene styrene copolymers (ABS).

Manufactur of Auricular Prosthesis with Silicone Elastomer/TiO_2

Making auricular prosthesis with silicone / TiO_2 was conducted in several steps. First, weigh the weight of the mold used a scientific scale. After getting the weight of the mold, pour silicone elastomer part A in liquid form into the mold and weigh again to get the weight of silicone elastomer part A on the mold. After getting the weight of silicone elastomer part A weigh TiO_2 nanoparticles according to the percentage of 1%, 2%, and 3%, then weigh silicone elastomer part B. Mix silicone elastomer part A with TiO_2 nanoparticles for 5 minutes in a 50 mL beaker glass, then added the mixture silicone elastomer part A and TiO_2 nanoparticles with silicone elastomer part B with a ratio of 1: 1. Mix for 15 minutes and vacuum pump for 3 minutes thus the trapped trapped in the mixture disappears. Pour the mixture into a mold and curing for 3 hours at room temperature [7,8,9].

CHARACTERIZATION

Tensile Test

Tensile testing was performed by the aim of getting tensile modulus, where the pull modulus itself was obtained from stress and strain curves. For specimens using dumbbell-shaped type two, there were 8 samples which were repeated 2 times for each treatment adding TiO_2 nanoparticles 0%, 1%, 2%, and 3%. Tensile testing was performed by using a universal testing machine (UTM): Gotech AI-7000 s. The specimen size was based on the ASTM D412 standard, but the thickness used was around 5 mm. The crosshead speed was set at 500 mm / minute. The following were specimen shapes and their sizes [7].

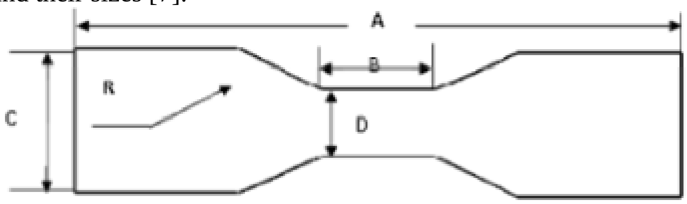

FIGURE 1. Tensile Test Sample Size (mm) A = 115 mm, B = 38 mm, C = 20 mm, D = 7 mm

Compressive Test

Compressive testing was conducted by using a Universal Testing Machine (UTM) in order to obtain compressive modulus from each specimen. In the test 8 cube-shaped specimens of 3x3x3 cm were pressed with a speed of 0.05 kN / s and a maximum force of 0.2 kN for 10 minutes used a universal testing machine [10]. Each addition of TiO_2 nanoparticles 0%, 1%, 2%, and 3% each repeated 2 times thus they get 8 samples.

Morphological Characterization with SEM

SEM test was performed to determine the surface morphology of the composite being tested, the aim revealed whether agglomeration occurs in the addition of TiO_2 nanoparticles or not. Specimens to be tested were coated with a thin layer of gold using a sputter coater (Quorum Q150R S) and the specimens tested were the result of mechanical test fracture. A set of SEM microscopes (Hitachi TM 3000) was used. The number of SEM test samples amounted to 4 where each percentage of TiO_2 addition was 0%, 1%, 2%, and 3% each for one sample.

Characterization of Functional Groups with FTIR

FTIR test was carried out to determine the composite functional groups tested, the aim determined whether there was a cross link on the silicone rubber and the effect of adding TiO_2 nanoparticles to silicone rubber. There were four samples that will be tested by FTIR spectrophotometer (Perkin Elmer-Spectrum One) namely Silicone rubber- TiO_2 composite with a percentage of 0%, 1%, 2%, and 3% each for one sample.

RESULTS AND DISCUSSION

Result of Synthesis of Silicone Rubber/TiO_2 Nanoparticles

The synthesis process in this study consisted of several stages, namely the synthesis of molds for both ear prosthesis molds and test specimen molds and ear prosthesis synthesis and test specimens using silicone elastomer / TiO_2 nanoparticles. Referring to the synthesis method described previously, it was found that silicone rubber without the addition of TiO_2 has a light brown color like skin color with the addition of TiO_2 to silicone rubber, the color of the silicone rubber changes to become whiter in line with the large percentage of TiO_2.

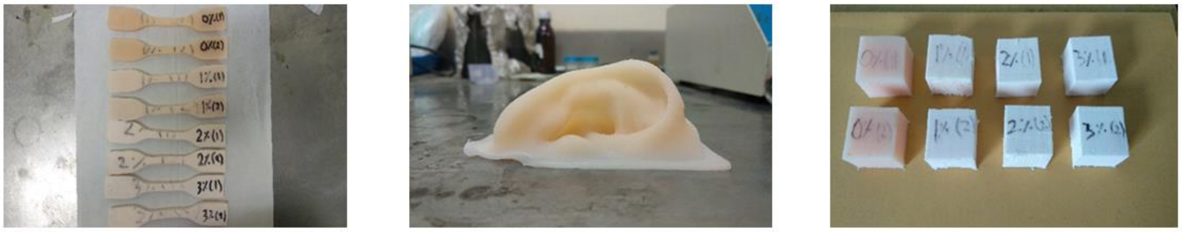

FIGURE 2. Mechanical Test Specimens and Auricula Models

Tensile Test Results

The stress-strain curve results in this study indicated that although in the elastic deformation region, silicone rubber exhibits non-linear behavior. Previous study conducted by Schneider [11] entitled 'Mechanical Properties of Silicone for MEMS', in his study to calculate the modulus of elasticity of silicone rubber using linear slope of the stress-strain curve from the results of the tensile test of silicone rubber. It obtained slope stress behavior - linear silicone rubber strain in the strain range from 0 to 100%. Referring to the study, using a strain range of 0 to 100% obtained linear slope from the tensile test results curve for silicone rubber / TiO_2 nanoparticles. By calculating stress compared to the strain on the stress-strain slope linear curve, the tensile modulus values obtained in Table 1 along with the positive control values, namely the elastic modulus of the auricular cartilage [11].

TABLE 1. Tensile Test Result

Sample	Tensile Modulus
Auricular Cartilage (Positive Control)	5,02 ± 0,04 MPa [23]
SE-0% (Negative Control)	0,33 ± 0,08 MPa
SE-1% (w/w) TiO_2	0,35 ± 0,02 MPa
SE-2% (w/w) TiO_2	0,34 ± 0,03 MPa
SE-3% (w/w) TiO_2	0,31 ± 0,02 MPa

Compressive Test Results

The stress-strain curve generated from the results of the TiO_2 silicone rubber / nanoparticle compressive test results in this study was similar to the curve results of the RTV silicone rubber compressive test conducted by previous study [12]. Silicone rubber was a material that did not follow Hooke's Law or it can be said silicone rubber was a material that has non-linear mechanical properties because the deformation was not directly proportional to the load given and when the load was applied to the silicone rubber there was a very large strain increase in the elastic deformation region which was characteristic of hyperelastic material [10,12]. To characterize the mechanical properties of a non-linear material, non-linear material modeling such as Mooney-Rivlin modeling or Neo-Hookean modeling using finite deformation theory where stress-strain relationship was defined through strain energy potential. To calculate the mechanical value of TiO_2 silicone rubber / nanoparticles in this study, namely young modulus, the linear material approach was based on Hooke's Law. Referring to recently research [13] the stress-strain curve of silicone rubber compressive test results were divided into several regions and obtained at strains 0 to 0.3 showed almost linear elastic deformation. Table 2 showed the comparison between compressive modulus of TiO_2 silicone rubber / nanoparticle compressive test results and positive control of auricular cartilage compressive modulus.

TABLE 2. Compressive Test Results

Sample	Compressive Modulus
Auricular Cartilage (Positive Control)	2,08 ± 0,7 MPa [14]
SE-0% (Negative Control)	0,47 ± 0,158 MPa
SE-1% (w/w) TiO_2	0,29 ± 0,01 MPa
SE-2% (w/w) TiO_2	0,42 ± 0,04 MPa
SE-3% (w/w) TiO_2	0,305 ± 0,03 MPa

Mechanical Tests

This study seeks to examine the mechanical value of silicone rubber, namely modulus of elasticity, there were several factors that affect the mechanical properties of silicone rubber namely the molecular weight of the polymer chain, cross-link density, cross-link system, filler characterization (particle size or specific surface area, structure, and surface activity), number of fillers, and conditions when processing. TiO_2 nanoparticles were added with an average particle size of 15-25 nm at 0%, 1%, 2%, and 3%. The addition of TiO_2 nanoparticles as a filler aimed to increase the modulus of elasticity of silicone rubber. However, the results of the modulus of elasticity both the tensile modulus and the compressive modulus in this study showed smaller results compared to positive control (native cartilage). There was no increase in the modulus of elasticity of the addition of TiO_2 nanoparticles to silicone rubber. FIGURE 3 displays a plot of the silicone rubber modulus elasticity chart for the percentage addition of TiO_2 nanoparticles.

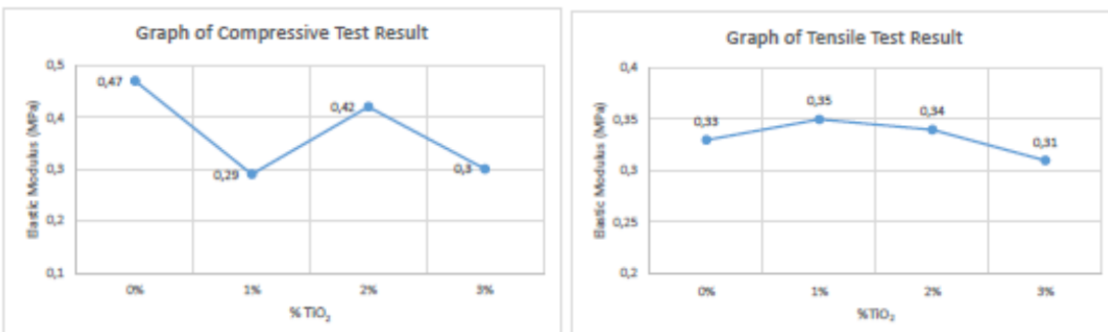

FIGURE 3. Graph of Mechanical Test Results

These results were not in accordance with the expected objectives of increasing the modulus of elasticity. The decrease in modulus of elasticity was thought to be due to the agglomeration of TiO_2 nanoparticles in the silicone rubber matrix. Nano-oxide particles were very small in size and have high surface energy and chemical reactivity, allowing them to be subside in the silicone matrix. The agglomeration occurs due to the electrostatic force called the Van der Waals force between filler and the tendency of TiO_2 nanoparticles was difficult to spread in organic solutions. The agglomeration will refer to the reduction in the aspect ratio of TiO_2 nanoparticles, the surface contact between the silicone matrix and the nanoparticles will be reduced, if the agglomeration can reach a micrometric scale larger than the polymer particles hence an empty area can form around the agglomeration, and the agglomeration of the TiO_2 nanoparticles can act as a place concentrated stress. When the agglomerated composite was applied to force or stress in the form of a pull or pressure, the agglomeration will be destroyed and will weaken the silicone matrix causing detachment, and de-bond nanoparticles of the polymer matrix and will refer to the formation of tears. The formation of TiO_2 nanoparticle agglomeration in this study was associated with the results of the Scanning Electron Microscope in the next subchapter [15,16,17,18].

SEM Test Results

The Scanning Electron Microscope test was conducted with the aim of seeing how the TiO_2 nanoparticles were spread inside the silicone rubber matrix. Four samples were tested for SEM as each representative for the addition of TiO_2 nanoparticles by 0%, 1%, 2%, and 3%. Each sample was coated with an AuPd coating using a Sputter Coater

(Quorum Q150R S) before being tested with SEM. FIGURE 4. shows the SEM test results with each target for each sample was 100x and 1000x.

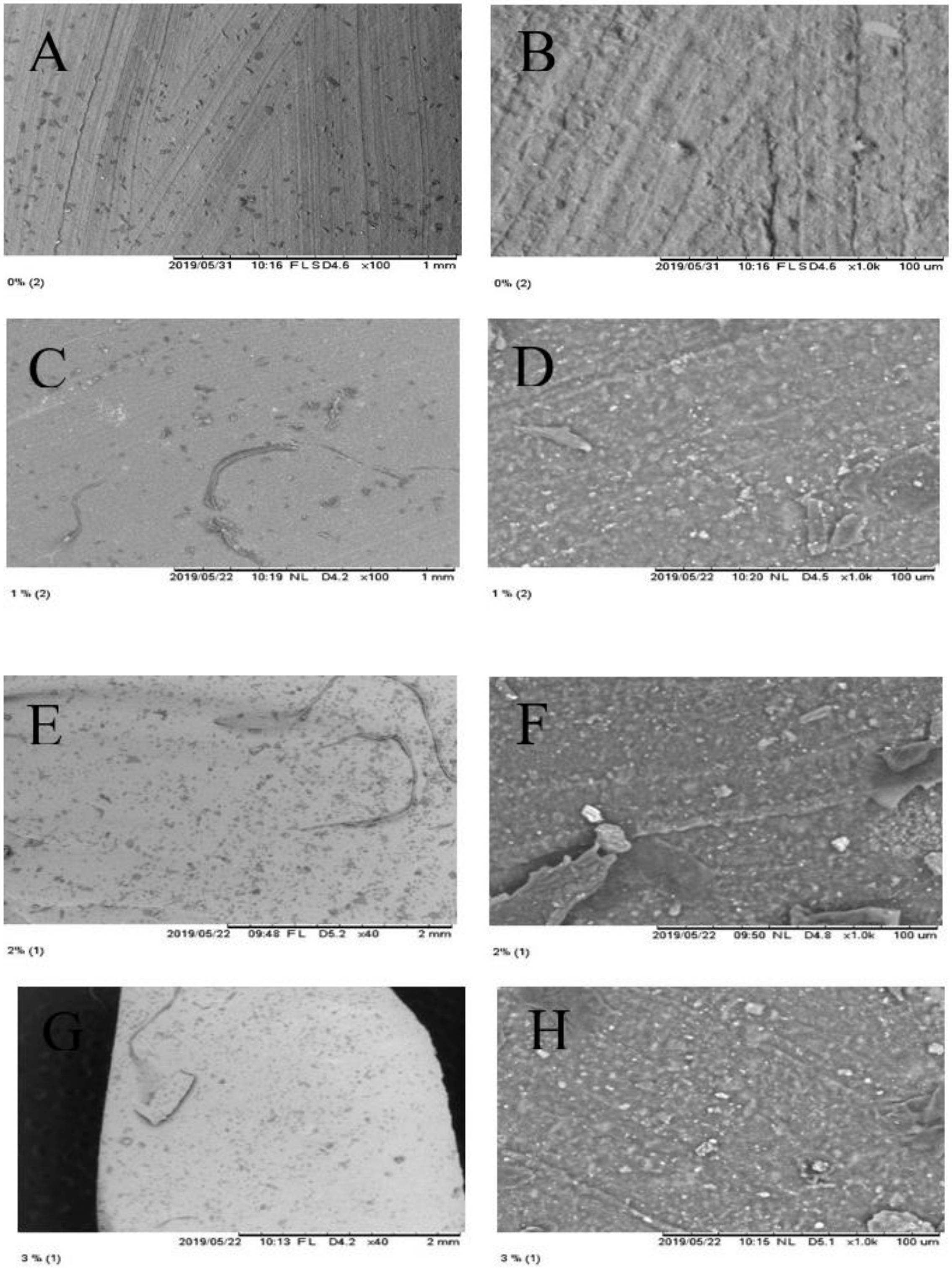

FIGURE 4. SEM Test Results Silicone Rubber / Nanoparticle of TiO_2 (A–B) 0% (C-D) 1% (E-F) 2% (G-H) 3%. (A-C-E-G) Magnification 40x (B-D-F-H) Magnification1000x

Based on the SEM test results, TiO_2 nanoparticles were presented as white particles with irregular lumps where the particle diameter was calculated by using ImageJ software. It was depicted in Figure D with the percentage addition of TiO2 nanoparticles by 1% having fewer white colored particles compared to F and H images with particle sizes ranging from 3 µm. While, Figure F potrayed the addition of 2% TiO_2 nanoparticles that showed the occurrence of large white lumps which were indicated as clumps of TiO_2 nanoparticles with sizes of 3 to 8 µm. Large white lumps also appeared in the addition of nanoparticles by 3%, that was in the H image, but tended to be seen more than the F image. Seen at 1000x magnification, TiO_2 nanoparticles experienced good agglomeration for the percentage of 1%, 2%, and 3% and seen also that agglomeration reaches the micrometric scale. The agglomeration occurs due to electrostatic forces called Van der Waals forces and the tendency of TiO_2 nanoparticles to diffuse in organic solutions. Besides that, the agglomeration may be due to human error factors such as lack of time in mixing, unfavorable preparation of samples for testing, and so on. Proven agglomeration of TiO_2 nanoparticles in the silicone rubber matrix both at 1%, 2%, and 3% is one reason why the modulus of elasticity of silicone rubber / TiO_2 nanoparticles decreases [16,18].

FTIR Test Results

Fourier Transform Infrared (FTIR) test was conducted with the aim to find out whether there was a cross linking between silicone rubber part A and part B. Silicone rubber used in this study was platinum cure silicone rubber with 2 parts where when the two parts were combined it would cross-linking occurs between parts A and B where part A contains platinum which will act as a catalyst. In addition to seeing whether crosslinking occurs, the FTIR test also aimed to find out how the effect of adding TiO_2 nanoparticles to silicone rubber.

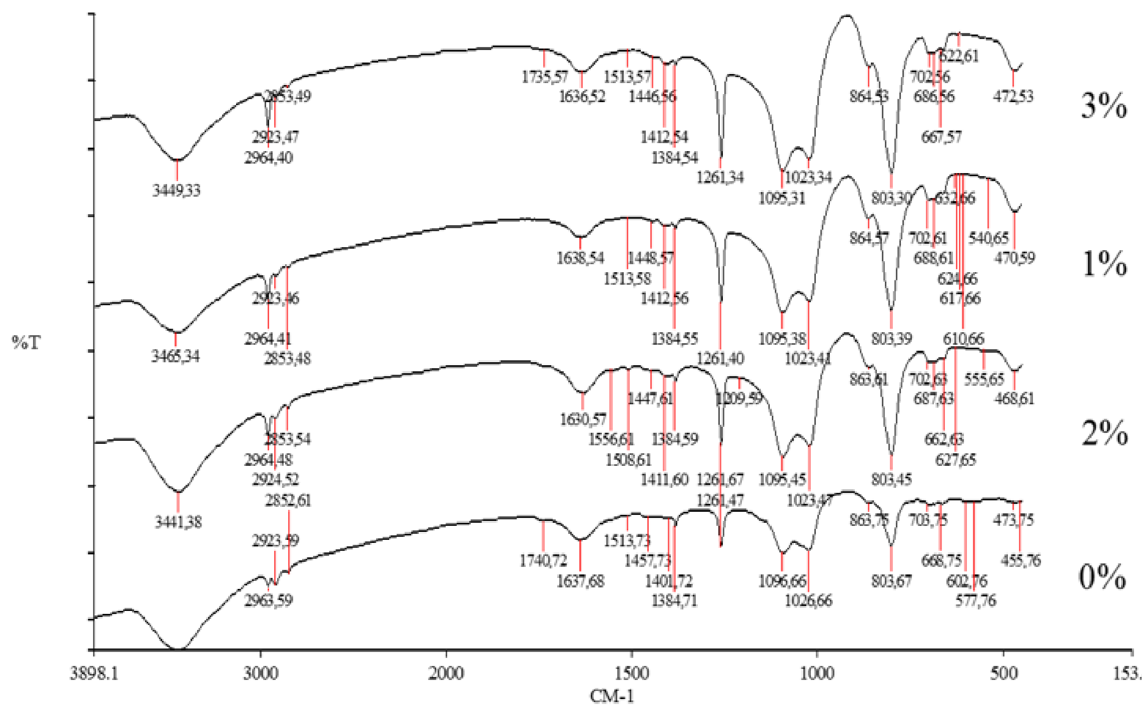

FIGURE 5. FTIR Test Results

FIGURE 5 showed the spectra of TiO_2 silicone rubber / nanoparticles with each additional percentage. There were several peaks that indicated certain functional groups in the silicone rubber / nanoparticle TiO_2 composite. At wave number 3465.34 cm^{-1} - 3441.38 cm^{-1}, there was a stretching function group Si-OH, wave number 2964.48 cm^{-1} - 2963.59 cm^{-1} showed asymmetric stretching CH_3, wave number 1384.71 cm^{-1} - 1384,54 cm^{-1} showed the Si-CH_2-CH_2-Si functional groups with asymmetric bending vibrations, wave number 1261.67 cm^{-1} - 1261.34 cm^{-1} indicated the Si-CH_3 functional groups. There were two peaks that were showed asymmetric stretching functional groups Si-O-Si namely 1096.66 cm^{-1} - 1095.31 cm^{-1}, and 1026.66 cm^{-1} - 1023.34 cm^{-1}, functional groups (Si-CH_3)$_2$ at the wave number

803.67 cm^{-1} - 803.30 cm^{-1}, as well as the asymmetric stretching function group Si-CH_2-CH = CH_2 at wave number 1638.54 cm^{-1} - 1630.57 cm^{-1} [19, 20, 21, 22].

Si-O-Si functional groups that appear with asymmetric stretching vibrations at wave numbers 1096.66 cm^{-1} - 1095.31 cm^{-1}, and 1026.66 cm^{-1} - 1023.34 cm^{-1} indicated that the functional groups were backbone on the silicone rubber polymer chain and indicated the formation of 2 or 3 dimensional Si-O bonds. The formation of crosslinks was also marked by the presence of Si-CH_2-CH_2-Si functional groups, this was evidenced by the existence of a peak in the spectrum of FTIR test results at wave numbers 1261.67 cm^{-1} - 1261.34 cm^{-1}. As published in the literature study regarding the addition of TiO_2 nanoparticles that the nanofiller strengthening mechanism acted as a multifunctional crosslink by forming strong hydrogen bonds between the surface hydroxyl group and the polydimethylsiloxane chain (PDMS) [17,21].

CONCLUSIONS

The characterization result of compressive and tensile tests for modulus values, both tensile modulus and compressive modulus show a tendency to decrease with the increase in the percentage of TiO_2 nanoparticles compared to the positive and negative control values. The decrease in tensile and compressive modulus values due to the agglomeration of TiO_2 nanoparticles and proven based on the results of SEM test characterization show that all the addition of TiO_2 nanoparticles on silicone rubber experienced agglomeration that reach the micrometric scale. FTIR test results prove that the occurrence of cross bonds on the silicone rubber matrix is showed by the appearance of the peak of the spectrum at wave number 13841.71 cm^{-1} - 1384.54 cm^{-1} with asymmetric bending vibrations and it is proved that a bond between the silicone rubber matrix and TiO_2 nanoparticles is showed by the occurrence of a peak shift at the wave number containing the OH group. Due to agglomeration, there is no percentage addition of TiO_2 nanoparticles to the mechanical test results that show the closest value to the control value.

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