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# Preparation and characterization of silicone rubber socket liners modified by nanoparticles additives

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## ABSTRACT

**Purpose:** The upper part of the prosthesis is called a socket, which contacts the amputated part. While wearing the prosthesis, there are several problems that the patient may suffer from, such as shear force between the socket and amputated part, pressure on the bony prominences, sweating, and bacteria generation, all leading to skin problems and a bad smell. It makes the patient refuse to wear the prosthesis because it is uncomfortable. Therefore, the aim of this study was comfortable lining from silicone rubber which cross-links at room temperature, with properties corresponding to the needs of this application, such as stress distribution, moisture absorption, and antibacterial.

**Design/methodology/approach:** In the current work, silicone rubber was selected with the addition of nano-fillers (ZnO, Mg(OH)<sub>2</sub>, and Chitosan). Mechanical and physical properties were studied (tensile strength, tear strength, hardness, water absorption, porosity, and antibacterial).

**Findings:** Chitosan showed the highest effect on the mechanical properties of silicon, as it achieved the highest value of tensile strength of 2.2 MPa elongation of 572%, tear strength 13.9 kN/m, and shore A hardness of 33.3. While the highest value of the modulus, 0.636 MPa was achieved by adding ZnO. The results also showed an increase in the water absorption and the porosity, which were the highest values at 1.6 % and 0.24%, respectively with the addition of Mg(OH)<sub>2</sub>. The samples showed a clear resistance to preventing the microorganism's growth.

**Research limitations/implications:** Manufactured linings require additional improvement in mechanical properties by mixing more than one type of additives mentioned in the research. Thus, physical and biological properties can be obtained simultaneously with mechanical properties.

**Practical implications:** The above results qualify the silicone rubber composites for use as a socket liner due to their flexibility and ability to absorb water in addition to their resistance and prevent the growth of fungi and bacteria.

**Originality/value:** The method of preparation and properties of the lining material and additives qualify it for such applications as physical and biological properties.

**Keywords:** Silicone rubber, Mechanical properties, Nano additives, Porosity, Water absorption, Antibacterial

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BIOMEDICAL AND DENTAL MATERIALS AND ENGINEERING

## 1. Introduction

The remaining part of the amputated limb is characterized by soft tissues that cannot bear the loads [1,2], so when wearing the prosthesis, several problems will be generated that lead to tissue ulceration, which limits the patient's ability to perform his daily functions. Socket and liner materials and design not only do they allow him to walk well, but they must provide him with comfort while wearing the prosthesis [3]. Therefore, providing a comfortable prosthesis is one of the challenges that researchers are working on [4,5].

The amputation of lower limbs is caused by several reasons which directly affect their living activities, such as wars, diabetes, vascular diseases, and cancer [6,7]. So, lower limb prostheses are considered important devices for patients to perform their daily functions [8]. The contact area between the socket and the amputated part, which is considered an important point for lower limb prostheses, should provide a convenient and appropriate point of contact for the patient [9].

Several disadvantages appear with the prosthesis use, such as pressure points, shear forces between the socket and the amputated part, and bacteria generated due to the accumulation of sweat [10,11]. So the socket must have several properties such as good pressure distribution, moisture absorption, and antibacterial properties. The socket liner (Fig. 1) is often considered a key factor for the success of the prosthesis [12]. This can be achieved using flexible liners and having those required properties [6,13,14].

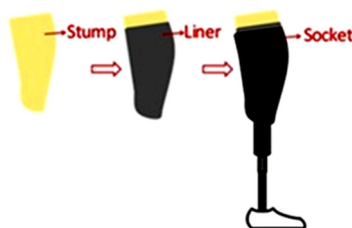


Fig. 1. Represent the socket liner that provides stability between the stump and the socket [6]

The flexible lining is not limited to transferring stress or moisture absorbing; it also contributes directly to the suspension of the prosthesis and makes it fixed in the amputated part and not be extracted during movement [15].

Socket liners can cause many problems if they do not have the required properties [16]. A shear force created between the socket and the amputated part while walking can affect the skin due to the generation of friction force [17], which leads to the patient getting ulcers simultaneously

with the accumulation of sweat and bacteria, which causes not to wear the prosthesis [18].

A compression set is the permanent deformation percentage when rubber is compressed under a specified time and temperature. In silicone rubber, the compression set is consistent over a wide temperature range from  $-60$  to  $+250^{\circ}\text{C}$  and relatively low around room temperature, as shown in Figure 2. Therefore, silicone rubber is very suitable for socket lining applications because the highest load applied to it is the patient's weight and normal human body temperature [19].

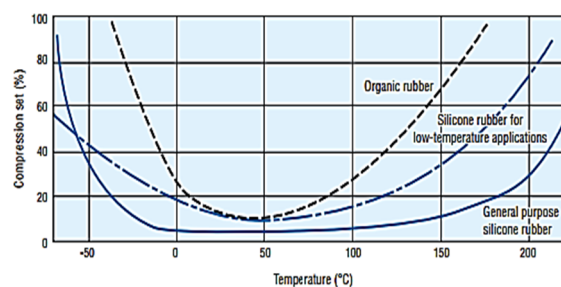


Fig. 2. Represent the effect of temperature on the silicone rubber compression set [19]

The current research aims to develop and improve the properties of the socket lining for lower limb amputees. Several problems arise when the patient wears the prosthesis, such as the pressure points on some parts of the amputated limb. To overcome this problem, silicone rubber was chosen, as it can provide a comfortable cushion for the patient. The other problem is the accumulation of sweating fluids, which leads to the growth of bacteria and fungi, causing inflammation and unwanted odours, These problems can be dissolved by adding nanoparticles such as ( $\text{ZnO}$ ,  $\text{Mg}(\text{OH})_2$ , and Chitosan) to achieve porous and antibacterial socket lining.

Silicone rubber's special features have inorganic and organic properties at the same time. The siloxane bond ( $\text{Si-O}$ ) in silicone rubber has high energy bond (106.0 kcal/mol) than the  $\text{C-C}$  bond (84.9 kcal/mol), so the silicone rubber shows good heat resistance, electric conductivity, and chemical stability [20-22]. Silicone rubber can be exposed to weather, such as water and UV rays, for a long time without changing its physical properties. Silicone rubber has many characteristics, such as high biocompatibility, durable material, resistance to a wide range of temperatures, non-adhesive properties, non-toxic, chemical resistance, and good resistance to oxygen, ozone, and sunlight [23-25].

Zinc oxide nanoparticles are widely used due to their special properties [26]. Initially, it mixed with the rubber to improve durability, toughness, ageing resistance, and other

properties [27]. Zinc oxide nanoparticles have strong UV absorption and superior antibacterial, non-toxic, and antimicrobial. In general, zinc exists in body tissues, including the muscle, brain, skin, bone, etc. Nano-ZnO is used as an additive in the food industry. Moreover, according to the Food and Drug Administration (FDA), ZnO is graded as a “GRAS” (generally recognized as safe) [28]. Currently, zinc oxide nanoparticles are used in many medical applications due to these special properties such as drug delivery, anticancer, wound healing, antibacterial, and anti-inflammation [29,30].

Magnesium hydroxide has the chemical formula  $Mg(OH)_2$ , and it is a non-toxic material. The solid magnesium hydroxide is known as “brucite”. It has low solubility in water and is a common component of antacids and laxatives. Magnesium hydroxide is also used against canker sores, alleviating constipation, indigestion and heartburn, seborrheic dermatitis, and antiperspirant armpit deodorant [31,32]. The form of nano-magnesium hydroxide is a white powder with low toxicity, so it is suitable for some applications, such as mechanical engineering, polymer science, biology, chemistry, physics, pharmaceutical drug manufacture, cosmetics, and optical components [33].

Chitosan is a polysaccharide prepared from chitin; chitin is a widely available polysaccharide from a variety of natural sources. Chitosan has many good properties such as biodegradability, biocompatible, non-toxic, natural origin, abundance, reactivity, and soluble in acidic aqueous media. It is used in many applications, including biomedical and pharmaceutical applications, agriculture, food processing, cosmetics, and water treatment [34]. Chitosan is safe for healthcare applications [35,36], so it is also used as an antimicrobial, sutures, wound dressings, and artificial skins. Chitosan is an anti-fungal, analgesic, antibacterial material, and haemostatic properties. Chitosan decomposition residues are simple, non-toxic materials and biocompatible with physiological mediums. Because of the ability to prepare chitosan in different forms, its medical applications have expanded to include periodontal and orthopaedic surgery, drug delivery, and tissue engineering [37,38].

In the current research, silicon samples were prepared. Their mechanical and physical properties were studied by adding different percentages of nan powders to be used as socket liners in prosthetics for amputated lower limbs.

## 2. Material and experiments

The silicone rubber type: RTV-2, ITEM: C-810 Chinese origin, Chitosan (75% of degree deacetylation, molecular weight 161 g/mol from Xianm Shaanxi, China), Zinc oxide nanopowder (China, 50-80 nm), and magnesium dioxide (China, 80-120 nm).

The samples were prepared by hand casting as sheets were made by dimension (130x80x6) mm. Three types of powders were added ZnO,  $Mg(OH)_2$ , and Chitosan, with proportions by weight 0.1, 0.3, and 0.5 %. First, the powder was added to the silicon and mixed well mechanically for ten minutes; then 1% hardener was added and remixed until homogeneity was achieved, then poured into a glass mould and left for 24 hours to solidify. To avoid the differences between the samples because they were prepared in different periods, they were cured at 60°C for half an hour to complete the cross-linking. Tensile test samples were cut according to the ASTM D638 Type IV specimen dimensions as shown in Figure 3 [39], While tear strength was cut according to the ASTM D624-07 type B, specimen dimensions as shown in Figure 4, test rate 50 mm/sec. Calculating the tear strength (T) by maximum force (P) in kilonewtons per thickness (d) in meters [40]. The tensile test machine used a micro-computer-controlled electronic universal testing machine model (WDW-5E), and the tear strength was carried on by the Monsanto T10. Shore A durometer was used for hardness measurements according to ASTM D-2240 [41].

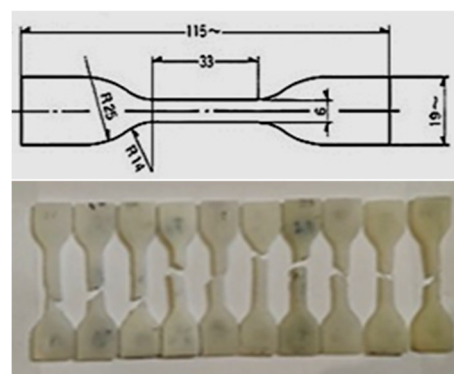


Fig. 3. Tensile test samples

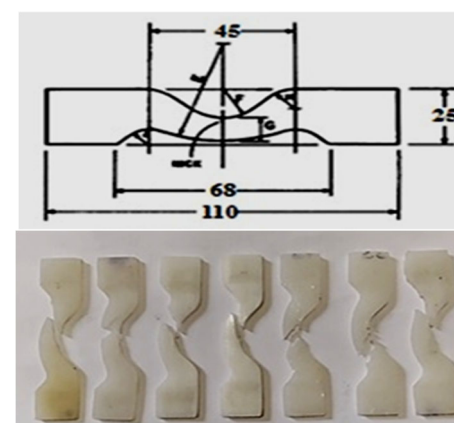


Fig. 4. Tear test samples

Specimens of water absorption test achieved according to ASTM D570 with dimensions (45 mm in diameter and 3 mm thick) [42]. Samples were dried at 50°C for 1 hour, measured the dry weight  $W_0$ , and then immersed in water (0.9% NaCl) for 60 minutes. The excess solution was removed, the wet weight  $W_1$  was measured, and the water absorption per cent  $W$  was calculated according to equation 1.

$$W\% = (W_1 - W_0) / W_0 * 100\% \quad (1)$$

The porosity samples were calculated depending on the wet and dry weights. A small piece with dimensions (20 x20) mm was placed in the deionized water for 24 h and removed the water was from the surface then measured; the wet weight  $W_w$  was to calculate the dried weight  $W_d$  samples were put in the oven at 50°C for 1 h, the porosity per cent  $P$  is calculated according to equation 2.

$$P(\%) = [(W_w - W_d) / (\rho_w A T)] * 100\% \quad (2)$$

where  $W(\%)$  is the porosity of the silicone rubber,  $W_w$  (g) is the wet and  $W_d$  (g) is the dry weight,  $\rho_w$  ( $g/cm^3$ ) is the water density,  $A$  ( $cm^2$ ) is the area, and  $T$  (cm) the thickness of samples in the wet state [43,44].

The antibacterial activity test (achieved in BPC ANALYSIS CENTER, Baghdad) of the silicone rubber with and without additives was carried out using the agar plate diffusion method. Two types of Bacteria, Escherichia coli (E. coli) as negative grams and Staphylococcus Aureus (S. Aureus) as positive grams and one type of fungi (Candida), were used in this search. Selected bacteria, achieved by adding 100 mg of cultured bacteria, do an incubation period of 5 minutes to 24 hours at 37°C. 100 mg of activated bacteria are included or transported to alarm nutrients to all areas. Samples were prepared with dimensions (10x10x4) mm; the samples were loaded onto the sterilized discs then 24 hours of incubation at 37°C was applied. After the incubation, the inhibition was measured based on the clear zone surrounding the samples.

### 3. Results and discussions

The cross-link, secondary bonds, and additives can greatly effect on properties of silicone rubber, which have a direct effect on the mechanical and physical properties.

Additives are important factors that affect silicone rubber properties; according to the type and quantity of the additives can improve or reduce these properties. Because silicone rubber consists of two parts, polymer and hardener, interconnections between chains occur after mixing. Hence, the additives raise the cross-link density or reduce it according to the amount and chemical structure of additives, as discussed by Linglong Feng [44].

Figure 5 shows the effect of additives on tensile strength; additives have a slight effect on the tensile properties because the amount of addition is low, so its effect on the polymer's primary and secondary bonds is unclear. In general, the tensile strength decreases with an increase in ZnO and  $Mg(OH)_2$  per cent, this is due to the presence of those particles, which may hinder the formation of some interconnections, leading to a decrease in the cross-link density, as discussed by M.J. Jweeg [45]. This negatively affects tensile strength. This was consistent with the hardness values shown in Figure 6. The hardness values decreased with the increase in the percentage of the additive for the same reason mentioned above.

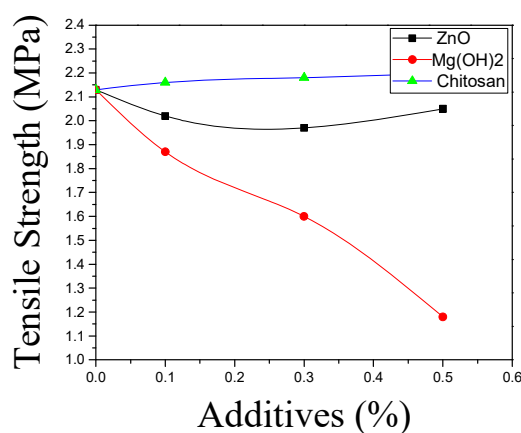


Fig. 5. Tensile Strength curves

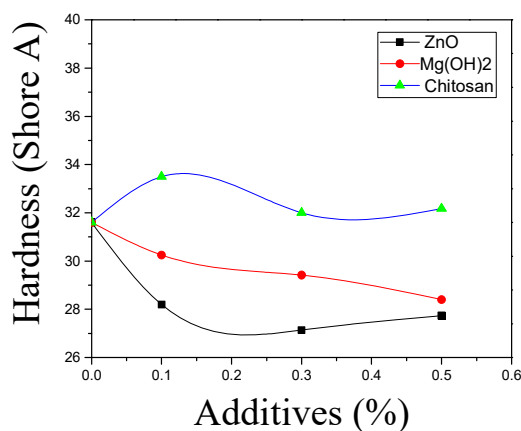


Fig. 6. Hardness curves

On the other hand, a slight increase in tensile strength and hardness is observed with the addition of chitosan. This could be due to the generation of secondary bonds due to the presence of active side groups in the chitosan structures, such as OH,  $NH_2$ , and  $CH_2OH$ , as shown in Figure 7, which

can be linked with silicone rubber chains. This increases the bonding strength between the polymer chains, which is positively reflected in both the tensile strength and hardness, as discussed by Xinxin Yang [46]. The silicone rubber presented the best tensile strength reaching 2.20 MPa for silicone rubber with an addition of 0.5% chitosan.

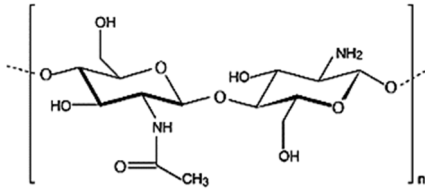


Fig. 7. Chemical structures of chitosan [37]

Also, we can notice that the elongation properties decrease due to the additives, and their diffusion between the chains can impede the elastic movement of the polymer chains, which requires greater strength to yield those chains, and this obviously can be positively reflected on the elastic modulus of silicone rubber, and these are important properties that increase the socket life during use as shown in Figures 8 and 9.

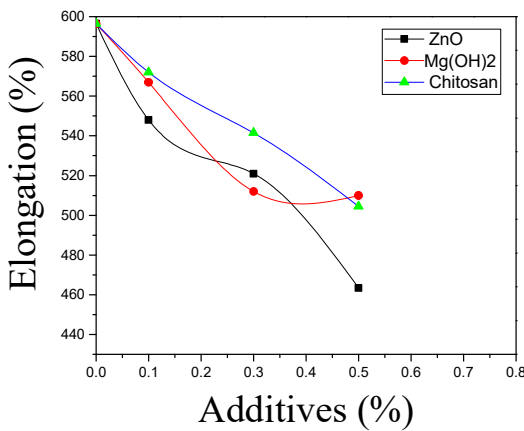


Fig. 8. Elongation curves

The structure and amount of additives are well-known to play an important role in the properties of addition-cured silicone resins, as discussed by D.R. Paul [47]. Figure 10 shows three different additives (ZnO, Mg(OH)<sub>2</sub>, and Chitosan) for silicone rubber with a constant per cent of crosslinkers. The three additives chosen are commercially available. The results showed a change in the tear strength values with the change in the type and percentage of addition. The improvement in tear strength is due to the increase in the bonding strength between the chains and

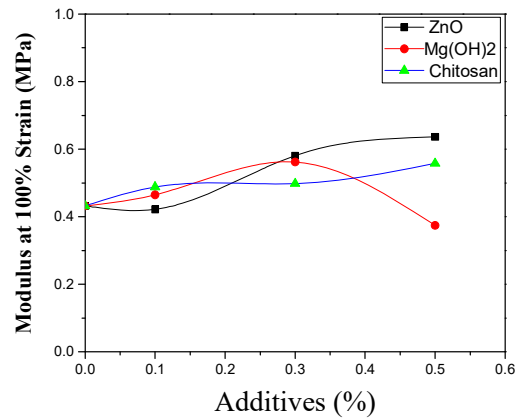


Fig. 9. Modulus at 100% Strain curves

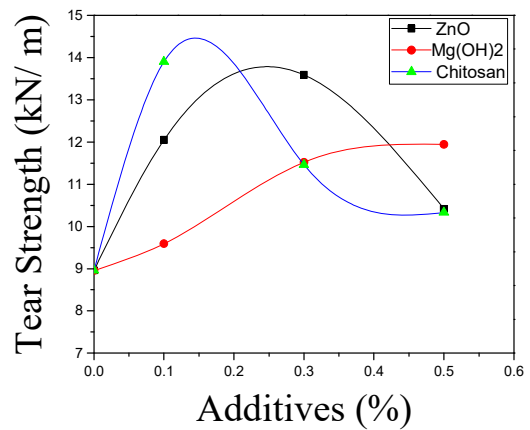


Fig. 10. Tear Strength curves

additives impeding the sliding of the chains on each other, as was clarified when discussing the elongation and modulus results. As discussed by Xinxin Yang [46]. This improvement is evident in the case of the chitosan due to the presence of the functional groups, as discussed by Chad M. Brick [48], with the best tear strength reaching 13.9 kN/m for silicone rubber with an addition of 0.1% chitosan. With an increase in the percentage of the additive, there is a clear change in the values of tear strength due to reduces the cross-link density by an increase in the additive, which leads to an increase in the flexibility of the polymer as noted from the elongation results.

Pure silicone rubber showed a low ability to absorb water, but it is noticed that, with the addition of nanoparticles, the moisture absorption percentage increases with the increase in the percentage of additives because of the hydrophobic properties of the polymer, as shown in Figure 11. In general, Magnesium Hydroxide showed a significant increase in the water absorption rate with an



increase in the percentage of addition due to the presence of the hydroxyl group in the structure of the material. The water absorption ratio was increased from 0.725 % to 1.628% by adding 0.5% Mg(OH)<sub>2</sub>.

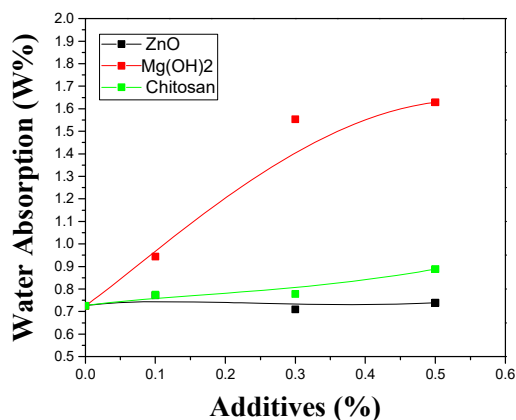


Fig. 11. Water absorption curves

Adding chitosan and ZnO had little effect on water absorption compared to adding magnesium. The silicone rubber can absorb 0.888% water with the addition of 0.5% chitosan compared to silicone rubber without additives because of chitosan's moisture sensitivity due to its structure containing several groups, such as acetal, hydroxyl, and amine groups. Similar results were also reported by other studies by T. Rihayat [49,50].

Incorporating ZnO nanoparticles into the silicone rubber showed an ineffective increase in water absorption. This implies that the incorporation of a ZnO nanoparticle can enhance the silicone rubber composite properties as it is considered a reinforcing material.

The high ability of the polymer to absorb moisture when used as a socket for prosthetics is an important thing that helps prevent the accumulation of sweat, which can cause the growth of fungi and types of bacteria that cause foul odours and patient skin infections in the contact area with the socket. As a result, the socket becomes more comfortable and acceptable to the patient.

Porosity is one of the important things to be taken into account when manufacturing the socket, for the possibility of getting rid of the formed vapours and absorbing moisture, thus preventing its accumulation in the contact area between the skin and the socket, which can lead to several problems that make the patient refuse the prosthesis. Figure 12 shows the effect of additives on the silicone rubber porosity. It is noted from the figure that the percentage of porosity increased with the increase in the addition ratio while noting the effect of adding magnesium more than chitosan and ZnO

may be due to the presence of hydroxyl groups, the porosity increased from 0.092 for pure silicon to 0.247% with the addition of 0.5% Mg(OH)<sub>2</sub>. In general, the increase in porosity may be due to the generation of gases from additives by the heat generated from silicon and hardener reactions due to the presence of the functional groups in its structures.

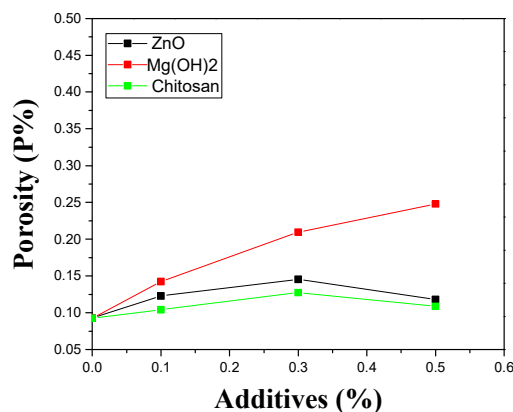


Fig. 12. Porosity curves

The effects of the number of crosslinkers used on the mechanical properties of silicone rubber were investigated. The optimum proportion of crosslinkers was found to be when the number of crosslinkers was 2%, as shown in Table 1. In this case, the silicone rubber presented the best mechanical properties, with tensile and tear strength reaching 2.56 MPa and 9.379 kN/m. In addition, the modulus at 100% strain reached the maximum value of 0.650 MPa. When the ratio of crosslinkers used decreases, the amount of hardener is insufficient to bond with all the radicals of the polymer chains; thus, the mechanical properties are decreased. When the ratio of hardener increases by more than 2%, excess amounts of hardener extend between the polymer chains instead of binding to them, which leads to a decrease in the mechanical properties. This was evident when adding a 4% hardener, as this led to the failure of the samples, as discussed by Linglong Feng [44].

Table 1.  
Effect of hardener percent on mechanical properties

Hardener, %	1%	2%	3%	4%
Tensile strength, MPa	2.13	2.56	2.18	fail
Modulus at 100% strain, MPa	0.432	0.650	0.548	fail
Elongation, %	596.5	598.5	512.5	fail
Tear strength, kN/m	8.958	9.379	8.814	fail
Hardness, shore A	31.6	34.3	31.8	fail

There is a great interest in generating self-sterilization polymers because they avoid harmful chemicals which cause side effects to human beings. Therefore, the generation of antibacterial polymers used as socket lining can provide greater comfort for the patient and avoid many problems, such as allergies or skin inflammation.

Silicone rubber has many characteristics, such as high biocompatibility, durable material, resistance to a wide range of temperatures, nonadhesive properties, non-toxic, and chemical resistance, which make it resistant to the growth of microorganisms. Figure 13 shows the inhibition zone in the case of exposing the samples to three types of microorganisms *Escherichia coli*, *Staphylococcus Aureus*, and *Candida*; this supports the possibility of using silicone rubber in medical applications.

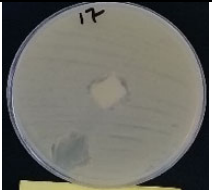
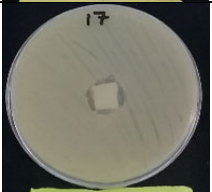

Microorganisms	Inhabitation zone	
E. Coli.	15	
Staph	15	
Candida	13	

Fig. 13. Inhibition zone of silicone rubber

Table 2 shows the increase in the inhibition area for the growth of microorganisms by adding nanoparticles. From the Table, we can notice the highest inhibition by adding ZnO particles, when it attaches to the walls of the cell and

Table 2.  
Effect of additives on Inhibition zone

Material	Inhibition zone (mm) for <i>S. aureus</i>	Inhibition zone (mm) for <i>E. coil</i>	Inhibition zone (mm) for <i>Candida</i>
Silicon Rubber	15	15	13
Silicon Rubber + ZnO	27	23	37
Silicon Rubber + Mg(OH) <sub>2</sub>	19	17	22
Silicon Rubber + Chitosan	25	21	29

damages the permeability of the cells' wall and cellular respiration, murders the microbes by hindering the enzyme's effectiveness and halts the uptake of oxygen where the microbes depend on it to live, which makes ZnO have larger antibacterial properties, as discussed by Jinhuan Jiang [24]. ZnO nanoparticles can also interfere with the function of the fungal cell, causing internal abnormalities that prevent the development of fungal strains, as is seen through the effectiveness of these nanoparticles on the inhibition of fungal growth, as shown in Figure 14.

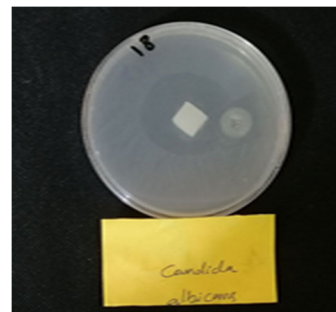


Fig. 14. Inhibition zone of silicone rubber + ZnO

The effect of adding Mg(OH)<sub>2</sub> as an antibacterial is shown in Table 2; the results showed the effectiveness of Mg(OH)<sub>2</sub> nanoparticles in killing microorganisms, but with less efficiency than ZnO. The antibacterial activity is inversely related to the size of the particles. The antibacterial mechanism can be through the adsorption of Mg(OH)<sub>2</sub> on the surface of bacteria due to the external adsorption ability resulting from the electrostatic reaction and then destroying the cell walls, which leads to the death of bacteria in the end, as discussed by Xiaohong Pan [51].

Chitosan has antibacterial and antifungal properties due to the presence of functional groups in its structure, such as the amine group, which it a positive charge; when in contact with microorganisms, it reacts with its negative charge, which leads to cell damage and loss of its membrane. The ability of chitosan to permeate the cell of fungi inhibits the synthesis of protein and enzymes by a bond to DNA, and it can bond to metals which help the growth of microorganisms, as discussed by Zahra Atai [52].

## 4. Conclusions

Silicon rubber is the most suitable material for socket lining in prosthetics applications, which makes the prosthesis more comfortable for the patient. Mechanical and physical properties are very important in such applications to increase the durability of the lining and provide the greatest amount of protection for the amputated part. In the current research, good mechanical properties were achieved by adding nanopowders. Which were selected for their mechanical and chemical properties; it is also considered a biomaterial, which can give protection against bacteria and prevent infections. All materials showed an effect on the mechanical properties, but the effect of chitosan was greater due to its different chemical structure, the improvement per cent 50.8%, 60.8%, and 51.4% for tensile strength, tear strength, and hardness, respectively. While the highest improvement per cent in the modulus, 59.5%, was achieved by adding ZnO. The results also showed increased water absorption, porosity, and resistance to microorganisms. By achieving these mechanical and physical properties, silicone rubber becomes more suitable and comfortable for the patient by using it as a lining for amputated limbs.

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