"TO EVALUATE AND COMPARE THE EFFECT OF NANOPARTICLES OF TITANIUM DIOXIDE, SILICON DIOXIDE AND NANOCOMPOSITE OF TITANIUM DIOXIDE – SILICON DIOXIDE ON TENSILE STRENGTH, TEAR STRENGTH, SHORE HARDNESS OF MAXILLOFACIAL SILICONE ELASTOMER: AN IN-VITRO STUDY"

BY

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Dissertation

Submitted to
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In partial fulfillment
of the requirements for the degree of

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In

PROSTHODONTICS AND CROWN & BRIDGE

(BRANCH – I)

Under the guidance of

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DEPARTMENT OF PROSTHODONTICS

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KAHER V.K. INSTITUTE OF DENTAL SCIENCES,

BELAGAVI, KARNATAKA.

2018 – 2021

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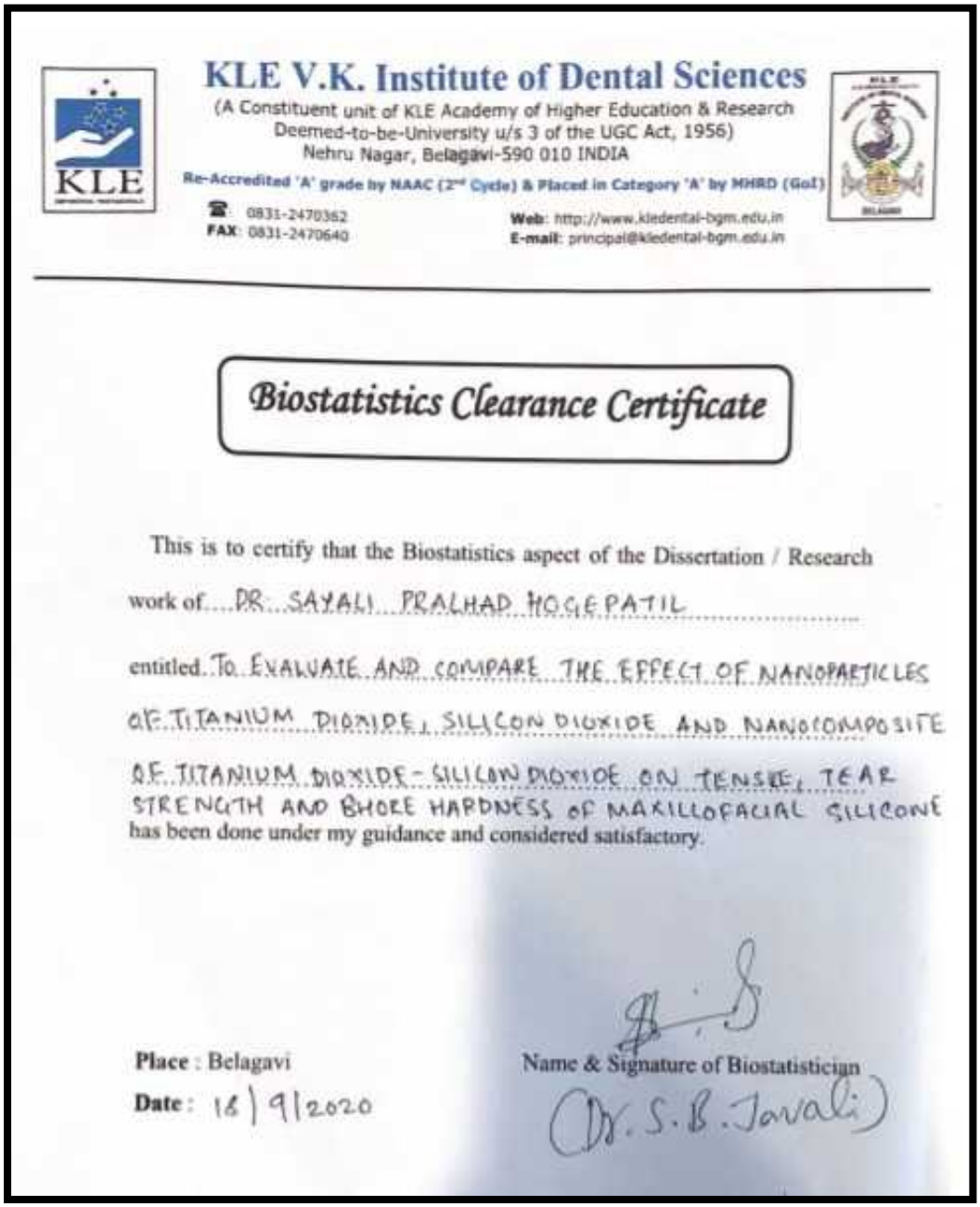

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ACKNOWLEDGEMENT

No endeavor can start, continue and complete without the blessings of ***LORD GANESHA.*** *I thank him for blessing me with the strength and patience to complete the task entrusted to me.*

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"The task of the excellent teacher is to stimulate "apparently ordinary" people to unusual effort. The tough problem is not in identifying winners: it is in making winners out of ordinary people."

I feel honored to be a student of my respected teacher and guide ***DR. ANANDKUMAR G. PATIL*** $_{MDS,}$ *Professor and HOD, Department of Prosthodontics and Crown and Bridge, KAHER Vishwanath Katti Institute of Dental Sciences, Belagavi, without whose everlasting inspiration, incessant encouragement, constructive criticism, and with valuable suggestions for improvement, the completion of this study would not have been possible. His unlimited patience, meticulous supervision at every step and everlasting zeal for perfection has not only enabled me to complete the dissertation, but has also helped me tremendously during the postgraduate programme.*

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I owe every success to them and I humbly acknowledge that everything I am today is because they believed in me.

Thank you, one and all.

DR. SAYALI PRALHAD HOGEPATIL

LIST OF ABBREVIATIONS USED IN THE STUDY

Group I	MDX4-4210 + 2wt% Titanium Dioxide nanoparticles
Group II	MDX4-4210 + 3wt% Silica Dioxide nanoparticles
Group III	MDX4-4210 + 1wt% Titanium Dioxide-Silicon Dioxide nanocomposite
Group IV	MDX4-4210 + 2wt% Titanium Dioxide-Silicon Dioxide nanocomposite
RTV	Room Temperature Vulcanized
HTV	High Temperature Vulcanized
ASTM	American Society for Testing and Materials
ISO	International Organization for Standardization
PDMS	Poly-dimethyl Siloxane
N	Newton
UV	Ultraviolet
Wt%	Percentage by weight
TiO2	Titanium Dioxide
SiO2	Silicon Dioxide
(TiO2/SiO2)	Nanocomposite Of Titanium Dioxide – Silicon Dioxide
µm	Micrometer
Psi	Pounds per square inch
MPa	Megapascal
ANOVA	Analysis of Variance
SD	Standard Deviation
SE	Standard Error

ABSTRACT

STATEMENT OF PROBLEM

Maxillofacial silicone prosthesis when fabricated present with problems within a few months of their use. These problems are related to the properties concerning the mechanics and physicality of the material. This has been the reason for the researches being circling around the development of this material.

PURPOSE

The purpose of this study was to evaluate and compare the effect of addition of Titanium Dioxide nanoparticles, Silica Dioxide nanoparticles and Nanocomposite (TiO2/SiO2) on the tensile strength, tear strength and shore hardness of maxillofacial silicone.

MATERIALS AND METHODS

A total of 4 groups were decided **GROUP I**: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 2wt% Titanium Dioxide nanoparticles. **GROUP II**: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 3wt% Silica Dioxide nanoparticles. **GROUP III**: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 1wt% TiO2 -SiO2 Nanocomposite. **GROUP IV:** Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 2wt% TiO2-SiO2 Nanocomposite.

The specimens after being fabricated were to be subjected to three tests. 1) Tensile Strength 2) Tear Strength 3) Shore Hardness.

All the samples were tested under universal testing machine with crosshead speed of 500mm/min for tensile and tear strengths both. Durometer was used to check

the shore hardness of the material. Data was obtained and subjected to statistical analysis using one-way ANOVA test and Tukey's multiple posthoc procedure.

RESULTS

A significant increase in the tear strength and tensile strength values was seen when the MDX4-4210 was incorporated with 2% (w/w) TiO2/SiO2 nanocomposite. (Group IV). Shore A hardness was seen greatly elevated in Group II that is MDX4-4210 incorporated with 3% SiO2 nanoparticles.

CONCLUSION

The study and its findings have indicated that there was a statistically significant positive effect of addition of TiO2/SiO2 nanocomposite when added in the concentration of 2% on the tensile, strength and hardness of the maxillofacial silicone elastomer and establishes as a better filler material when compared with TiO2 nanoparticles and SiO2 nanoparticles individually.

KEY WORDS

Maxillofacial silicone elastomer, SiO2 nanoparticles, TiO2 nanoparticles, TiO2/SiO2 nanocomposite, mechanical properties.

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INTRODUCTION

The patients who have endured maxillofacial mutilations display a bargained appearance making them unequipped for having a typical existence. These patients experience a dramatic change in social acknowledgment that influences their mind and also hampers their expectations of a normal life.

With progressions in plastic surgeries, rectifications of such deformities is conceivable, in any case, if medical procedure is contraindicated or the defect is broad to such an extent that full recovery is beyond the realm of possibility or if the patient is reluctant to undergo any surgical procedure, maxillofacial prosthetics present as a an alternative which was demonstrated to be reasonable.[1] Maxillofacial materials are used in the replacement of the parts of the face which have been lost after suffering from trauma or disease. The primary plan for the treatment is ablative surgery followed by rehabilitation with a prosthesis which may refine patient's quality of life.

Maxillofacial prosthetics may be referred to as the art, study of anatomic, functional, or restorative recreation, with non-living substitutes, of those areas of the face that are absent or faulty due to surgical intercession, damage, or congenital abnormality.

According to GPT 9, maxillofacial prosthesis is defined as – "Any prosthesis used to replace part or all of any stomatognathic and/orcraniofacial structures." [2]

The commonly used materials for the fabrication of maxillofacial prosthesis are: Acrylic resins, Plasticised methyl methacrylate, Vinyl polymers and copolymers, Chlorinated Polyethylene, Polyurethane and Silicones. Each of these materials have their own pros and cons but Silicone materials quite often allude to

polydimethylsiloxane considering that it is broadly utilized as the choicest material for the fabrication of maxillofacial prosthesis due to its enhanced mechanical, physical properties, ease of manipulation, durability, relatively long shelf life. They are quality insulators and resist oxidation.[3]

Maxillofacial silicone prosthesis can be classified as either: Vulcanized at normal or room temperature, or Vulcanized by the application of heat.

In an ideal situation, maxillofacial material must exhibit its tensile, tear strength, shore hardness and various mechanical properties in adequacy for it to perform well and sustain as a maxillofacial prosthesis. Even so, unfortunately the main limitation that has been observed with the silicone polymer material is its high chance of early degradation. This degradation could be concerning changes in shape, decreased tear strength, or any evident change in colour of the material. These changes are linked with factors like air pollution, ultraviolet rays etc. that the prosthesis is exposed to. [4]

Tensile strength along with the hardness of this material build an overall strength for the silicone elastomer and promise durability.[5]

The thin margin of a maxillofacial prosthesis holds importance as it is necessary for the prosthesis to mask its presence around the facial tissues giving it a more natural appearance. The same margin is very much prone to tearing when it is peeled away from the facial tissues while the removal and maintaining the cleanliness of the prosthesis. Needless to say, this renders the tear strength a clinically vital physical property. These mechanical characteristics are reported to deteriorate simultaneously with ageing of the prosthesis.[6]

Therefore, in the quest to enhance the mechanical and physical properties of this material, these silicones have been modified with various additives which include nano materials, fillers, fibres etc.

There have been quite a certain amount of studies which have confirmed the influence of these nanofillers or particles to have been successful in protecting this material against loss or degradation of its colour, the reason was hypothesized to be the size of these nano particles which are seemingly smaller than the wavelength of the UV light, they tend to dissipate a portion of the light as they absorb another. Therefore, better protection is provided against the radiation if the nano particles are smaller. [4]

This study concerns with these drawbacks or inefficient mechanical properties of silicone elastomer used in maxillofacial prosthodontics and attempts to contribute by incorporating a nanocomposite material and evaluate its tensile strength, tear strength, Shore A hardness while deriving support from previously performed studies.

This study is aimed to evaluate the effect of addition of Titanium Dioxide nanoparticles, Silica Dioxide nanoparticles and Nanocomposite (TiO2/SiO2) on the tensile strength, tear strength and shore hardness of maxillofacial silicone.

NEED FOR THE STUDY

Maxillofacial silicone when fabricated into a prosthesis is expected not only to restore form along with function of the part of face with the defect, but also to restore the patients social and psychological state which can in turn help them achieve a state of confidence and happiness.[7] These materials are envisioned to be desirable, and attain all the functional and biological properties in addition of them being easy to fabricate in a dental setting. [3]

Unfortunately, these polymers or silicone elastomers which are seen to be commonly used by prosthodontists across the globe, show some undesirable properties pertaining to its tensile strength, tear strength, insufficient hardness etc.[5] Hence, it was decided that it needed improvement in order for it to function to its full limits.

Consequently, in an offer to uplift their physical properties, elastomers have been modified with added substances like fillers and nano materials. One of these strategies is the addition of nanoparticles, which are opacifiers, for example, zinc oxide (ZnO), Barium sulfate (BaSO4) and Titanium dioxide (TiO2). [4]

Titanium dioxide nanoparticles were proposed for their use as supplementing fillers to resin composite. TiO2 as an additive has many encouraging properties as it is noted to be chemically stable, compatible with biological tissues and are non-toxic.[8] Among oxide nanoparticles, TiO2 are known to be popular because of their elevated properties. Due to the given reason, their use has been seen in a few in vitro studies and are established to be effective in addition to being harmless. [9]

Nanostructured TiO2 is popularized today as it sees a wide use in fuel cells, dye sensitized solar cells etc. [9]

SiO2 is the commonest materials to be recognized from crust of the earth. The material is present in complete purity or in combination with other metal oxides. Silica resists chemical materials and heat. It has density coming upto 2.65 to 2.70g/cm3 and hardness is 7 on scale. Heeding these properties this material is considered to show resistance to any abrasion and therefore is used as a filler.[10]

Biomedical and biotechnology fields have used the silicon dioxide nanoparticles in abundance. These nanoparticles have drug loaded in them, and the biocompatibility makes it a harmless material. SiO2 nanoparticles are observed to have a small size, and organic properties along with its large area of interface and strong interaction.

Therefore, they may improve the properties pertaining to the mechanical aspect of the polymers along with providing resistance to stresses which cause cracking and deterioration.[11] Till date TiO2 along with SiO2 nanoparticles sees a use as reinforcing material in maxillofacial silicone and have not had a deleterious effect on the materials properties.

Nano TiO2 / SiO2 composites replaces titania bulk as a catalyst support. Previous evidence based on the comparison of their properties physically point towards the promising nature of these TiO2/SiO2 solids. The incorporation of SiO2 may subdue the growth and elevate the stability of TiO2 gels. SiO2 seems to change the size and form of TiO2 thereby improving its thermal stability which suppresses anatase phase transformation to rutile. [12]

The synergism of the significant properties of TiO2, SiO2 in the nanocomposite of TiO2/SiO2 which will be fabricated by core-shell method can be considered as a promising filler or reinforcement to increase the properties of silicone elastomer.

A few too many studies have established that there is an effect of nanoparticles in resisting color deterioration of silicone, since nanoparticles obstruct the UV rays and therefore increase its durability. However, to increase material durability, other important properties should also be evaluated. The hardness of silicone determines its flexibility and enables the prosthesis to mimic the skin texture to the greatest extent possible, promoting greater comfort to the patient. Its tear strength should be adequate to allow the prosthesis to have good marginal adaptation and endurance during its removal, albeit very thin. [4]

Mechanical studies based on maxillofacial silicone have not been given much importance as most of the studies are seen to be revolving around color stability and discoloration.

Considering these pioneering and futuristic properties of TiO2/SiO2 nanocomposite as a base, this study being done the first time in the history of dentistry, attempts to reinforce the maxillofacial silicone elastomer with the Nano TiO2/SiO2 composite for the purpose of improving the mechanical properties.

HYPOTHESIS

NULL HYPOTHESIS: There is no significant effect of addition of 2% Titanium Dioxide nanoparticles, 3% Silica Dioxide nanoparticles and 1% and 2% Nanocomposite (TiO2/SiO2) on the tensile strength, tear strength and shore hardness of maxillofacial silicone elastomer.

ALTERNATIVE HYPOTHESIS: There is a significant effect of addition of 2% Titanium Dioxide nanoparticles, 3% Silica Dioxide nanoparticles and 1% and 2% Nanocomposite (TiO2/SiO2) on the tensile strength, tear strength and shore hardness of maxillofacial silicone elastomer.

AIM OF THE STUDY

Aim of the study is to evaluate and compare the effect of addition of 2% Titanium Dioxide nanoparticles, 3% Silica Dioxide nanoparticles and 1% and 2% Nanocomposite (TiO2/SiO2) on the tensile strength, tear strength and shore hardness of maxillofacial silicone (MDX4-4210)

OBJECTIVES OF THE STUDY

- To evaluate the effect of addition of 2% Titanium Dioxide nanoparticles on the tensile strength, tear strength and shore hardness of maxillofacial silicone. (MDX4-4210)
- To evaluate the effect of addition of 3% Silica Dioxide nanoparticles on the tensile strength, tear strength and shore hardness of maxillofacial silicone. (MDX4-4210)
- To evaluate the effect of addition of 1% and 2% Nanocomposite (TiO2/SiO2) on the tensile strength, tear strength and shore hardness of maxillofacial silicone. (MDX4-4210)
- To compare and evaluate the effect of addition of 2% Titanium Dioxide nanoparticles, 3% Silica Dioxide nanoparticles and 1% and 2% Nanocomposite (TiO2/SiO2) on the tensile strength, tear strength and shore hardness of maxillofacial silicone. (MDX4-4210)

REVIEW OF LITERATURE

Bulbulian (1965) has characterized maxillofacial prosthetics as the workmanship and study of anatomic, functional, or corrective reproduction, by methods for inanimate substitutes, of those areas of the face that are absent or inadequate succeeding surgical intercession, injury, or congenital distortion. He likewise expressed that," It is additionally huge that the achievement of numerous kinds of maxillofacial prosthetic gadgets relies upon full comprehension of the rules that underlie facial concordance, coordination of shades, maintenance, weight bearing and influence, solidness and quality of materials utilized, tissue compressibility, and tissue resilience." [13]

Chalian and Philips (1974) in their review "Materials in Maxillofacial Prosthetics" discussed the materials which were used for the prosthodontic rehabilitation of the maxillofacial defects, which involved intraoral prosthesis material, extraoral prosthetic materials and their history. They have also reviewed the criteria for materials which seemed ideal a in maxillofacial prosthetics. And have finally mentioned that hardy any reviewed materials fulfil the criteria and that researchers are constantly making improvements through close cooperation. [14]

Moore and Glaser in (1977) evaluated the polymeric materials used for maxillofacial prosthodontics. They mention that the techniques for starting assessment of another imminent material, MDX-4-4210, are depicted and tensile and compressive data was obtained. Assessment of the data shows this is an upcoming material with noteworthy potential for use in prosthodontics. [15]

D.H. Lewis et al. (1980) investigated the prerequisites of an ideal material and introduced a review of how a part of the newer systems, which were available in those days, coordinated those measures. A concise outline of a portion of the popular items which have discovered clinical use since the late 1960s had likewise be incorporated. As indicated by them, the silicones, vinyl plastics, and polyurethanes were the favoured materials; in any case, harder prostheses had been fabricated from different acrylates.[16]

Andreopoulos et al. (1989) inspected the impact of utilizing aramid fiber-reinforeced polyethylene in Thermoplastic polyurethane. Light weight, thermal obstruction and high modulus made aramid strands one of the promising reinforcement materials in the designing field. The fundamental issue was making a satisfactory adhesive bond between polyethylene matrix and aramid fiber; consequently fiber pretreatment was done to aramid strands so the strengthened polyethylene material could withstand raised temperatures .They demonstrated that there was heightened tensile strength with expanding the fiber volume and furthermore stated that there was a reasonable contrast between the resultant powers between surface-rewarded aramid filaments and the non surface-treated filaments. The surface-treated aramid filaments demonstrated a noteworthy increment in quality.[17]

Haug et al. (1992) assessed the properties of six maxillofacial prosthetic materials after their exposure to seven environmental factors like natural weathering, two sorts of adhesives, two cleaning agents and beauty products. The assessment comprised of tensile strength, elongation, along with tear strength, and Shore A hardness. They assessed Six maxillofacial elastomers: two as of late presented room

temperature-vulcanizing silicones and four mainstream elastomers; one polyurethane, one high temperature-vulcanizing silicone and two room temperature-vulcanizing silicones. Universal Testing machine was utilized to assess extreme elasticity, percent prolongation, and tear quality. Hardness was estimated with a Shore. One of the new materials, A-2186, indicated high quality qualities, in spite it being the softest material tried. Tragically, this new material lost these profitable attributes as it was debilitated and made stiffer by the majority of the tried natural variables of the environment.[18]

Andreopoulos et al (1992) assessed different additives as per their impact on mechanical properties of elastomer utilized for composition of maxillofacial prosthetic material. They gave accentuation on silicone fortifying fillers since fibrillar reinforcements (eg. short aramide,glass or high modulous polythelene) had appeared not to improve mechanical properties much. An ideal conduct at filler addition at 35% was resolved.[19]

Andreopoulos et al. (1994) considered compounds of silicone material appropriate for fabricating maxillofacial prosthesis, strengthened with different measures of silica powder for their mechanical reaction and wetting properties as related to the contact angle. The reasoned that tensile strength and elongation % indicated an expansion with increment in silica volume upto 35%. Swelling of samples is said to be influenced by silica concentration which is evidently then coordinated with mechanical properties. [20]

Lai et al. (1999) decided and thought about the physical properties regarding A-2186 and its curing in steel and stone molds. The impacts of added substances and fixed conditions on the properties were likewise contemplated. They inferred that the

hardness, rigidity of A-2186 restored in treated steel molds were significantly higher than those relieved in stone molds. Including a limited quantity of a shade, a kaolin and a fiber reduced hardness, tensile strength, elongation and tear quality. Aside from Hydrobond, the bond quality of the adhesives to A-2186 was not significantly influenced by the curing conditions and added substances.[21]

Aziz et al. (2003) surveyed the properties of industrially accessible silicone maxillofacial materials and made recommendations for enhancements. Examples of five regularly utilized maxillofacial materials (Factor II) were set up in dental flasks agreeing with the directions of use. Tear strength, elasticity, rate of elongation, hardness, were resolved for every material. Results demonstrated that none of the industrially accessible silicone elastic materials had perfect properties for use as a maxillofacial prosthetic material. Factor II silicone, be that as it may, indicated increasingly ideal properties because of its high tear strength, malleability and simplicity of control. [5]

Frogley et al. (2003) considered the impact of single-wall carbon nano tubes or fume developed carbon nano strands (SWNT) on RTV silicone elastomers subsequent to dissolving the silicone elastomer in toluene (1mg/ml) so the consistency can be diminished and furthermore in the wake of scattering the fillers in toluene to help scattering of the fillers. Nanofibrils have 200 nm distance across and not many several microns of length. RTV silicone elastomer was contrasted with the strengthened RTV silicone with 0.3 wt%, 0.6 wt% and 1.0 wt% single-divider carbon nano tubes, and contrasted likewise with 1.0 wt%, 2.0 wt%, and 4.0 wt% fibrils. They found that strength of reinforced RTV silicone elastomers were essentially higher than the non-strengthened RTV silicone elastomer; Forgley et al expressed that scattering

and interface of the filler in the network are the two significant adverse components in the helpfulness of the fillers utilized for reinforcements. SWNTs give a phenomenal degree of strength (by weight) to a RTV matrix. The evidence for SWNT and other carbon fillers proposes this given the high proportion and low density of the nanotube and that all around scattered single nanotubes ought to give superior reinforcement. [22]

Karayazgan et al (2003) has explained in a published report that tulle can be consolidated in silicone maxillofacial prosthesis to expand tear strength regarding the prosthesis at the edges. Substance conditioned nylon tulle was sewn with fake hair, and this tulle was clung to the skin by utilizing prosthetic glue. The utilization of the tulle into the silicone maxillofacial prosthesis margins bring about having margins increasingly impervious to tearing during fabrication by the dentist and application by the patient. They have concluded in their case report that the reinforcement of the tulle into the edges of a silicone prosthesis brings about edges that are more steady, more impervious to tearing, and less inclined to change shape during application or removal of cements, beauty care products, or then again cleaning agents.[23]

Han et al. (2008) contemplated the impact of expanding nanosized oxide concentration on tensile, tear strength and elongation % of maxillofacial material (A-2186). Nanosized oxides (Titanium, Zinc, or Ce) were included different concentrations (0.5% - 3.0% by weight) in a commercially used silicone elastomer (A-2186), normally utilized for fabricating extraoral maxillofacial prostheses. Silicone elastomer A-2186 without oxides served as a benchmark or a control group. Specimens(n=5) were polymerized as advocted by manufacturers proposal and thereon examined for tensile strength (ASTM D412) and tear strength (ASTM D624), and percent elongation in a UTM. Consistency of scattering inside the prepared

elastomer was surveyed utilizing scanning electron microscopic imaging. Results indicated that 2.0 percent and 2.5 gatherings of nanosized oxides exhibited fundamentally mechanical preoperties.[24]

Begum et al. (2010) assessed the tear, tensile strength, permanent deformation, water sorption of three accessible (Cosmesil, Cosmesil high compliance, prestige). They reasoned that none of the commercially accessible silicone elastic materials had perfect properties for use as a maxillofacial prosthetic material yet amidst the limitations of present investigation, Cosmesil high compliance shows progressively great properties among the three materials.[25]

Hatamleh et al. (2010) examined the mechanical characteristics of different maxillofacial elastomers and its bond strength to resin of acrylic. Samples of three maxillofacial elastomers were prepared as indicated by manufacturer instructions. Tensile, tear strength, along with elongation rate, hardness was assessed for every material. He assessed the bond strength of these elastomers to prepared acrylic resin surface. They inferred that all silicone elastomers tried indicated properties that were desirable. TechSil S25 had progressively great of high quality of mechanical. Cosmesil Z004 was impervious to shear debonding.[26]

Polyzois et al. (2011) researched the effect of time on some physical properties of 2 silicone facial elastomers (Silasto 30, Premium 2) subsequent to being sealed in glass and kept in obscurity for 1 year. Tensile, tear strength tests were led by ISO specification nos. 37 and 39, individually, in a testing machine. Hardness was estimated by the specification D 2240. They inferred that time is by all accounts a basic factor adding to the general deterioration of a maxillofacial elastomer. The majority of physical properties contemplated were altogether influenced as result of

time. Mechanical, physical properties of silicone maxillofacial elastomers can be changed with time section (common maturing in obscurity). The average time of supplanting a facial prosthesis is 6 to year and a half; therefore, it is significant that the findings of this investigation secured a time of a year.[27]

Zhang et al. (2011) conducted a study, "The influence of SiO2 and SiO2-TiO2 intermediate coatings on bond strength of titanium and Ti6Al4V alloy to dental porcelain" which evaluated the effects of TiO2– SiO2 sol–gel coating, under different firing temperatures, on the cpTi– porcelain bond strength. Prior to applying the low-fusing dental titanium porcelain, the phase, surface morphology, surface roughness and static water contact angle of the intermediate layer were evaluated.[28]

He explained that the strength of a cast cpTi and a low-fusing dental titanium porcelain after coating cpTi with a TiO2–SiO2 coating using the sol–gel technology and being fired at 750 °C for 1 h, was statistically higher than that of the same materials without any coating treatment.[28]

Elaska et. al (2011) evaluated the addition of Titanium Dioxide nanoparticles to a conventional GIC and checked the physical and the antibacterial properties of it thereon. They incorporated 3%,5%, and 7%). Unblended powder was control, Vickers microhardness tester was used to test the surface microhardness. They inferred from the study that Glass Ionomer containing 3 and 5% (w/w) TiO2 improved the fracture toughness, flexural strength, and compressive strength when compared to unmodified GI. The group with 7% GI was found to decrease the mechanical properties. The study further concluded that GI-containing 3% TiO2 nanoparticles (w/w) was reckoned to be a restorative material with better mechanical and antibacterial properties.[8]

Sodagar et al. (2012) concluded with a study which involved incorporation of nanoparticles of TiO2 along with SiO2 into acrylic resins to instigate antimicrobial properties as well as enhance mechanical properties. The study samples were distributed into 7 groups ie; Acrylic resins containing nano TiO2, SiO2 and a combination group TiO2 and SiO2 in concentrations of 1% and 0.5% including the control group. Samples were then fabricated in the size of 5 x 10 x 3.3 mm and subjected to universal testing machine. They state that within the limitations, conclusion was that incorporation of Nano TiO2 and SiO2 into resins was seen to adversely affect the flexural strength of the product, and is directly correlated with nanoparticles and the concentration.[29]

Rajkumar et al (2013) conducted a study in which Polymer-nano silica composite was readied utilizing SiO2 nanoparticles, the strengthening fillers in Acrylonitrile Butadiene Rubber (NBR). The scattering of the silica nanoparticles in Nitrile Rubber accomplished utilizing fluid NBR polymer network and was explored by FTIR, SEM-EDS. Mechanical tests exhibit that the NBR composites have significantly expanded the versatile modulus and elasticity, and much solid interfaces. [30]

Zayed and Alshimy (2014) conducted a study that developed a maxillofacial material being of ideal mechanical properties. To achieve this, formulations were created by the incorporation of varied concentrations of surface treated SiO2 nanofiller, trailed by assessment of the mechanical properties. SiO2 Nanoparticles were blended in with Silicone in 0.5%, 1%, 1.5%, 2%, 2.5% and 3%. The study rewarded the SiO2 nanoparticles as the reinforcing material of silicone A-2186

furnished it with increasingly ideal mechanical properties, particularly in relation to tear strength.[11]

Bangera et al. (2014) assessed the level of ultraviolet protection subsequent to incorporating changing concentration of nano-oxides in Cosmesil clinical silicone elastomer. In the study he compared ZnO and TiO2 (2% to 2.5%) incorporated into silicone elastomer, ZnO in lesser quantities gave more noteworthy and steady UV protections in Cosmesil elastomer.[31]

Wang and Liu (2014) evaluated how NanoTiO2 affected the mechanical, aging properties of MDX4-4210 and asses the compatibility with this novel combination. Nanoparticles were incorporated at 2%,4% and 6% into the silicone. The TiO2 elevated the materials Shore A hardness in addition to the tensile strength. However, a decline in elongation at break, tear strength was seen at 6% (w/w) composite. Cellular viability pointed that the composite showed biocompatibility. Thus, the study successfully obtained a restorative material which gives a favourable physical and antiaging properties and is seen biocompatible by invitro studies.[32]

Cevik et al. (2016) conducted a study which purposed mainly to identify the effect of types of silica and nano titanium dioxide when incorporated into two different RTV silicone elastomers. In this study he used A-2000, A-2006 silicone which were then divided into four groups (n=5) of which the first group being the control that is a group of specimens without any incorporated nano substance. Other groups were TiO2, fumed silica, along with silaned silica. Each specimen was prepared as advised by the manufacturer for tests according to ISO and ASTM standards. They inferred from the study that there was an effect of the different nanoparticles that were incorporated on the properties of the used material. They

found high value and significant interest in the high fumed hydrophilic silicas effect when incorporated into A-2006 silicone.[10]

Mustafa Tukmachi et al. (2017) conducted a study in which he tried to identify the effect of SiO2 nanoparticles on a few properties of HTV silicone elastomer. They evaluated the mechanical properties and colour of Cosmesil M511 HTV silicone elastomer. Standard procedures were followed for the testes as recommended by ISO standards after incorporating the nanoparticles in the silicone. The silicone was added in concentrations (4%, 5%, and 6%). They inferred that Shore A hardness showed a dramatic increase with all the nano filler concentrations. And finally concluded that the Cosmesil M511 silicone incorporated with 5% nano SiO2 improved all the mechanical properties but changed the colour of the silicone. [33]

Shakir et al. (2018) studied the effect when TiO2 nanofillers were incorporated on mechanical properties of RTV silicones VST50F and high temperature vulcanised HTV Cosmesil M511 maxillofacial silicone elastomers. They fabricated 120 specimens , 60 of each RTV and HTV elastomers. Further, 20 samples were used for each test and thereon went to divide into a control group without nanofillers and one with nanofillers. The specimens after being evaluated then resulted that the addition of 0.25 wt% and 0.2wt% into the silicone elastomer saw a statistically significant rise in their tear, tensile strength and hardness.[34]

Alsmael et al. (2018) conducted a study which evaluated the effect of the addition of varied concentrations of titanium silicate nanofillers in silicone elastomer on its tear, tensile strength and hardness. They decided to go ahead with concentrations of 0.5% and 1% weight% of the nanoparticles. 90 samples were prepared and subsequently tested for the properties. They inferred from the study

when 0.5% of nanoparticles were incorporated into the elastomer it enhanced the properties of the same with some increase in hardness.[35]

Ibrahim et al. (2018) conducted a study the aim of which was to see the effect of varied concentrations of chitosan particles into elastomer for its antifungal activity, and tear and tensile strength. Chitosan was added in 3 concentrations, (1.5%, 2.5% and 3.5 %) into RTV silicone elastomer. 220 specimens were prepared and tested. The results showed a decline in C. Albicans colony forming. Regarding the mechanical properties the tear strength seemed to have increased whereas the tensile strength decreased. [36]

Sonnahalli et al. (2020) conducted a study in which they saw how the incorporation of silver nanoparticles affected its hardness, colour stability and tear strength. 180 samples were fabricated in totality and with control and test samples with 20ppm concentration of the nanoparticles. The results show that the nanoparticles decreased its shore hardness of the elastomer and did not affect the tear strength and colour stability. [37]

Burman and Rashid (2020) conducted a systematic review in which they have reviewed the effect of various types of filler particles on the properties of silicone material. They considered tensile strength, tear, hardness and elongation at break. They decided to use 26 articles after elimination according to the PRISMA guidelines. Meta-analysis was conducted for 9 papers. They concluded that Nano fillers contributed to superior outcome of tensile strengths, tear strength, elongation at break and hardness when compared with studies using micro fillers.[38]

MATERIALS AND METHODS

SOURCE OF DATA

This in-vitro study was carried out in the Department of Prosthodontics and Crown and Bridge, KAHER'S KLE Vishwanath Katti Institute of Dental Sciences, Belagavi, and Dr. Prabhakar Kore's Basic Sciences Research Center, V.K Institute of Dental Sciences. Department of Nanoscience, KLS GIT, Belagavi. Praj Metallurgical laboratory, Kothrud, Pune.

SAMPLE SIZE:

In totality, 168 samples were fabricated, considering the 4 groups to be compared i.e, 2% Titanium Dioxide reinforced silicone, 3% Silica dioxide nanoparticle reinforced silicones. 1% TiO2- SiO2 nanocomposite reinforced silicone, 2% TiO2 - SiO2 nanocomposite reinforced silicone for testing three different mechanical properties i.e. tensile strength, tear strength and shore hardness. These four testing groups consisted of total 56 samples each, of which 14 samples each were fabricated for testing parameters of tensile strength, tear strength, shore hardness respectively.

Inclusion criteria:

Samples with identical size and shape according to the ASTM standards (D412 and D624) for tear and tensile tests and ASTM D2240 for shore hardness.

Exclusion criteria:

Samples with surface defects and deformities. Samples with gross porosities which were visible to naked eye.

TABLE 1: MATERIALS UTILIZED IN THE STUDY:

MATERIAL	DESCRIPTION	MANUFACTURER
Maxillofacial silicone elastomer	MDX4-4210 silicone material	(Dow Corning Corp, Midland, Mich)
Nanoparticles	Titanium Dioxide Nanoparticles (2wt%)	**(Ultrananotech, Bangalore)**
Nanoparticles	Silicon Dioxide Nanoparticles (3wt%)	**(Ultrananotech, Bangalore)**
Nanoparticles	TiO2- SiO2 Nanocomposite (1wt%) (2wt%)	**Fabricated at Gogte Institute of Technology, Belagavi.**

TABLE 2: ARMAMENTARIUM USED IN THE STUDY:

MATERIAL	DESCRIPTION	MANUFACTURER
Digital analytical balance	Model No. AR2130	Biobase
Mortar and pestle	-	-
Clamp and flask	Varisty Flask no 7	Classic products
Rubber bowl, plaster mixing spatula	-	-
Hydraulic press	P400	Sirio
Vaccum mixer	Model No: 26090	EasyMix BEGO
Digital vernier caliper	Mitutoyo 50019630	Absolute Digimatic
Universal testing machine (Computerized, software based)	Model No. UNITEST-10,	Company: ACME Engineers, India
Durometer	Kori	Kori, Japan

METHOD:

Preparation of the samples

To prepare identical samples for tear strength (ASTM D-624), tensile strength (ASTM D-412) two different three-piece metal mould dies were fabricated respectively and for Shore Hardness (ASTM D2240) a three-piece metal die which was separable and with cylindrical cavity was made.

METAL MOULD DIE PREPARATION:

Two customized, three-piece steel metal mold dies were fabricated, one consisting of five cavities as per ASTM D-624 DIE C [39] **(figure 14)** for tear quality test and the other with five cavities as per ASTM D-412 DIE C [39] **(figure 15)** for tensile test. These metal mould dies were utilized for fabrication of silicone test samples for tear and tensile strength tests.

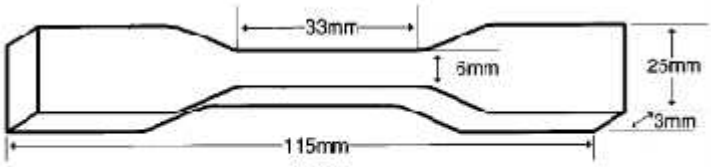


Fig. 1. ASTM No. D412 specifications for dumbbell-shaped specimens.

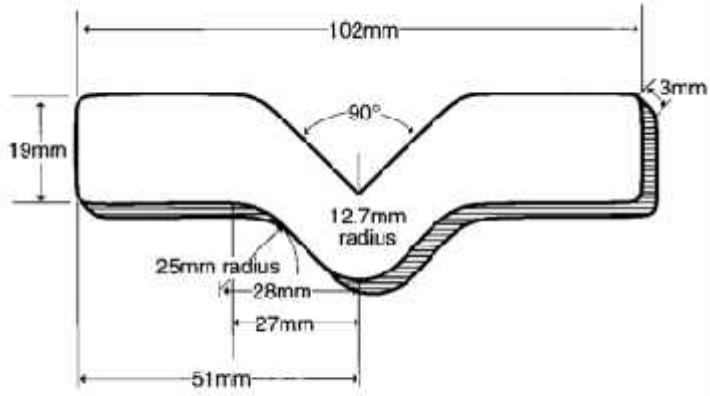
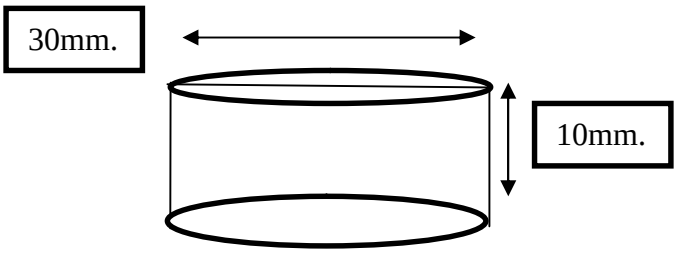


Fig. 2. ASTM No. D624 (die C) specifications for trouser shaped specimens.

METAL MOULD FOR HARDNESS (SHORE A) :

A metal mould die with 5 cylindrical cavities according to the ASTM D2240 was fabricated to test the shore hardness of the silicone testing samples which were 30 mm in diameter and 10 mm in height.[40] **(Figure 16)**



ASTM D2240

PREPARATION OF THE SAMPLES:

Addition of nanoparticles:

The maxillofacial silicone elastomer and nanoparticles were weighed with the help of a digital analytical balance and the nanoparticles were added according to the proposed groups.

The procured TiO2 nanoparticles, SiO2 nanoparticles and custom fabricated TiO2/SiO2 core-shell Nanocomposite were characterized to ensure quality and uniform distribution before their addition to the silicone polymer.

The maxillofacial silicone elastomer was manipulated considering manufacturer's specifications ie. (Base 10 : Catalyst 1). Each nanoparticle was mixed with silicone manually as per the specified testing samples using a mortar and pestle followed by vacuum mixing until a homogeneous mix was obtained. **(Figure 5,6,7).** Then the mixed material was loaded into a syringe after which it was injected into the cavities of the metal mould to ensure proper flow, avoid entrapment of air bubbles and provide homogeneity.

FABRICATION OF TEAR AND TENSILE TEST SAMPLES:

- A homogenous mix of maxillofacial silicone elastomer (MDX4-4210) obtained after mixing them with the nanoparticles of Titanium Dioxide (2%), Silicon Dioxide (3%), TiO2- SiO2 Nanocomposite (1%) and TiO2 – SiO2 Nanocomposite (2%) for the respective testing sample groups was poured into the metal mould dies that are mentioned above.

- All the three pieces of the moulds were approximated and fixed utilizing screws and nuts present at the fringe of the fabricated mould. Thereon, 200 psi pressure with a hydraulic press was applied slowly to allow the excess flash to stream out between the three parts of the moulds following which the excess was expelled.

- Complete cure of the material was achieved in about 3 days at room temperature.

- After the curing, they were retrieved from the moulds.

- Excess material was trimmed according to the specifications.

HARDNESS TEST SAMPLES:

- A homogenous mix of maxillofacial silicone elastomer (MDX4-4210) obtained after mixing them with the nanoparticles of Titanium Dioxide (2%), Silica Dioxide (3%), TiO2- SiO2 Nanocomposite (1%) and TiO2 – SiO2 Nanocomposite (2%) for the respective testing samples and were fabricated using the cylindrical metal mould die which was 10mm in height and 30 mm in diameter.[40]
- Thereon, 200 psi pressure with a hydraulic press was applied slowly to allow the excess flash to stream out between the three parts of the moulds following which the excess was expelled.
- Complete cure of the material was achieved in 3 days at room temperature.
- After complete curing, the specimen will be retrieved from the moulds.
- Excess material was then trimmed.

This is how 168 samples were fabricated and grouping of samples was done and labelled as follows: (n=14). **(Figure 17-28)**

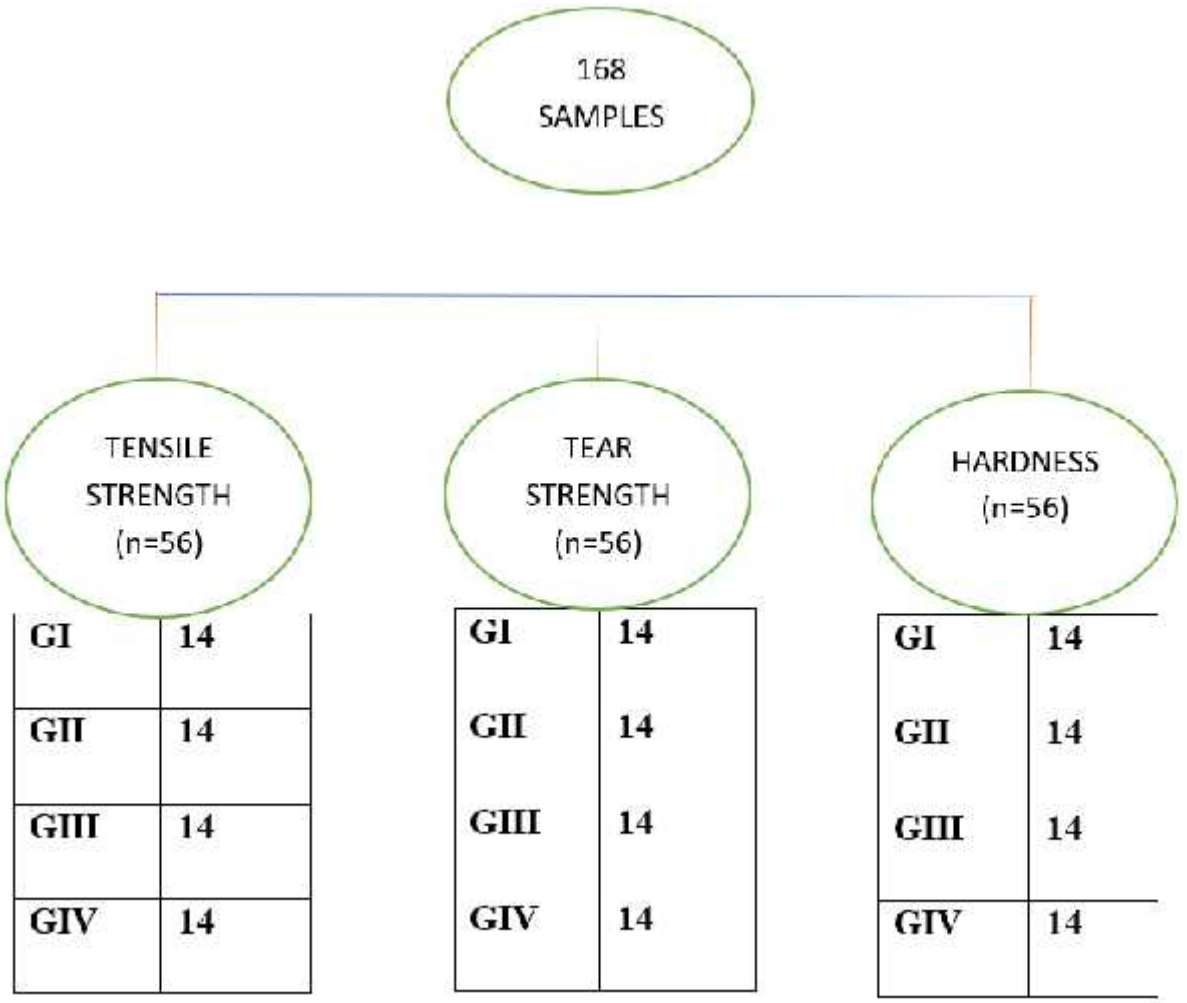
GROUP I: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 2wt% Titanium Dioxide nanoparticles.

GROUP II: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 3wt% Silica Dioxide nanoparticles.

GROUP III: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 1wt% TiO2 -SiO2 Nanocomposite.

GROUP IV: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 2wt% TiO2-SiO2 Nanocomposite.

Distribution of samples was done as shown in the table:



GI	**14**
GII	**14**
GIII	**14**
GIV	**14**

GI	**14**
GII	**14**
GIII	**14**
GIV	**14**

GI	**14**
GII	**14**
GIII	**14**
GIV	**14**

The prepared samples were subjected to universal testing machine to measure the tear strength and tensile strength and the samples prepared for testing of hardness were tested with the Shore A durometer.

TEAR STRENGTH TESTING:[39]

14 trouser-shaped samples for each group were fabricated. The tear strength test was completed according to the standards outlined by ASTM standard D 624 (Die C). Sample thickness was evaluated at the intersection of the sample with a Vernier calliper consisting of a digital readout. The sample was then secured in the holders of the Universal testing machine and stretched at a crosshead speed of 500 mm/min. **(Figure 31,32)** From these measurements the tear strength regarding the sample was calculated using the formula:

$$\text{Tear strength} = \frac{\text{Maximum force required to break the sample (N)}}{\text{Thickness of the sample (mm)}}$$

$$\text{Tear strength} = F/d$$

TENSILE STRENGTH TESTING:[39]

14 dumbbell - shaped samples for each group were fabricated, the tensile strength test was completed according to the standards outlined by ASTM standard D-412. The measurement of the thickness was made at the centre section of the sample using a vernier calliper consisting of a digital readout. The width of the centre section was 6mm, which was the width of the mould in accordance with the ASTM-D412 standard specifications. The sample was then secured in the holders of the universal testing machine and machine was operated at a crosshead speed of 500mm/min. **(Figure 29,30)** (The maximum load before breaking (in Newtons) was obtained and tensile strength of the sample was calculated using the formula:

$$\text{Tensile strength} = \frac{\text{Maximum force required to break the sample (N)}}{\text{Area of the unstretched sample (mm}^2\text{)}}$$

HARDNESS TESTING:[40]

14 cylindrical Silicone samples for each group were fabricated according to the standards outlined by ASTM D2240 and tested for Shore A hardness. The hardness measurements of the samples were made by using a Shore A durometer **(Figure 9)**. It is recorded as resistance to indentation at each point in shore units. Three hardness measurements were taken from each sample as Shore units and the average values were calculated as the final Shore A value of that particular sample. **(Figure 33,34)**

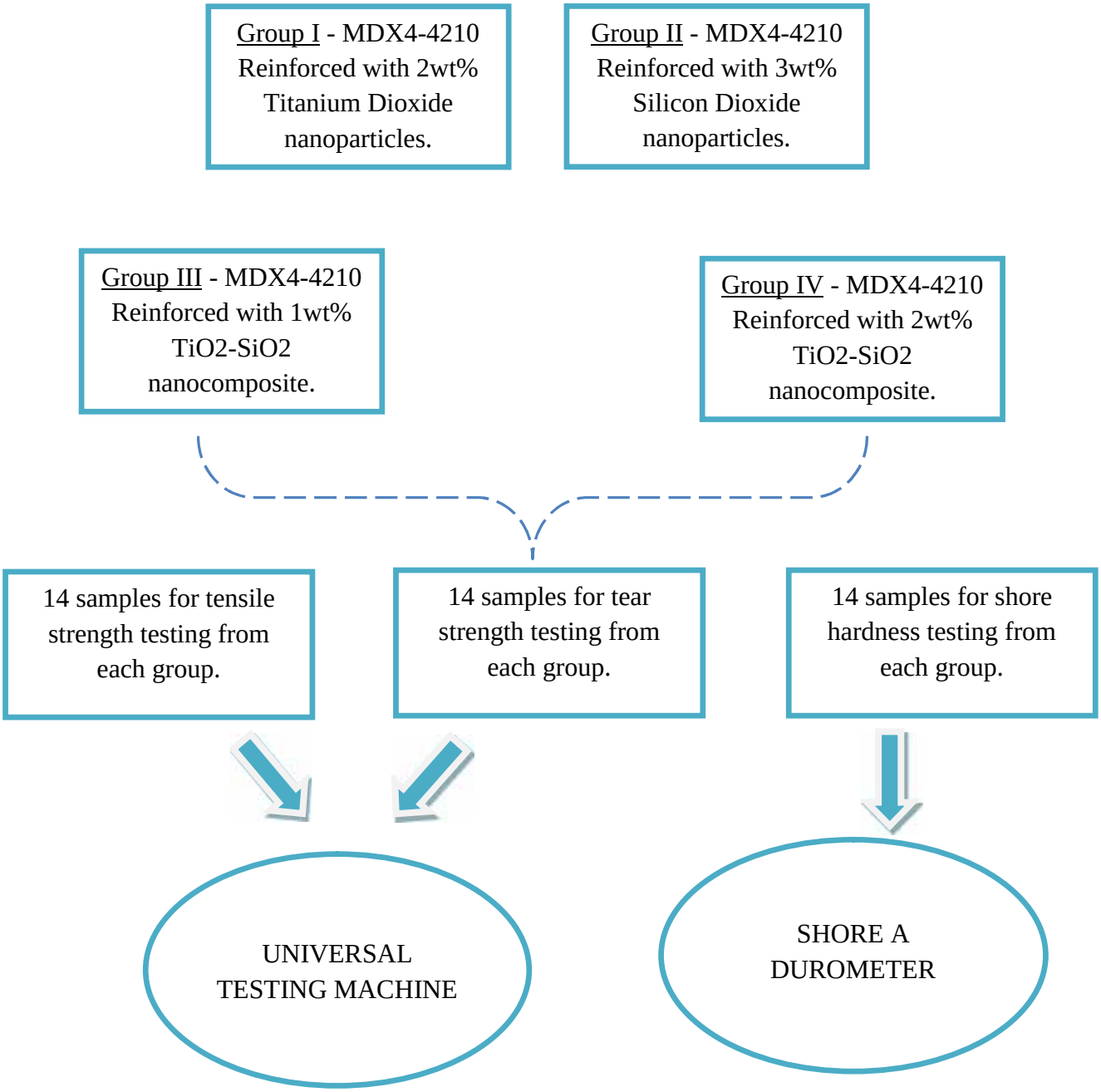

Group I - MDX4-4210 Reinforced with 2wt% Titanium Dioxide nanoparticles.
Group II - MDX4-4210 Reinforced with 3wt% Silicon Dioxide nanoparticles.
Group III - MDX4-4210 Reinforced with 1wt% TiO2-SiO2 nanocomposite.
Group IV - MDX4-4210 Reinforced with 2wt% TiO2-SiO2 nanocomposite.
14 samples for tensile strength testing from each group.
14 samples for tear strength testing from each group.
14 samples for shore hardness testing from each group.
UNIVERSAL TESTING MACHINE
SHORE A DUROMETER

Fig 1. MDX4-4210 MAXILLOFACIAL SILICONE ELASTOMER

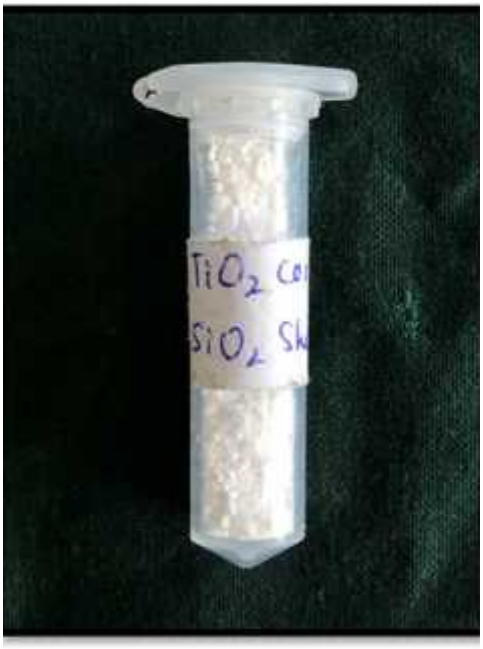


Fig 2. TiO2 – SiO2 Nanocomposite. Fabricated at GIT, Belagavi.

Fig 3. Silica Nanoparticles. Ultrananotech , Bangalore.

Fig 4. Titanium Dioxide Nanoparticles. Ultrananotech, Bangalore.

MIXING OF NANOPARTICLES WITH SILICONE.

Fig 5. Weighing of the materials.

Fig 6. Mortar and Pestle.

Fig 7. Vaccum mixing of the material.

EasyMix Bego.

Fig 8. Digital Vernier Calliper.

Fig 9. Durometer

Fig 10. Universal testing machine.

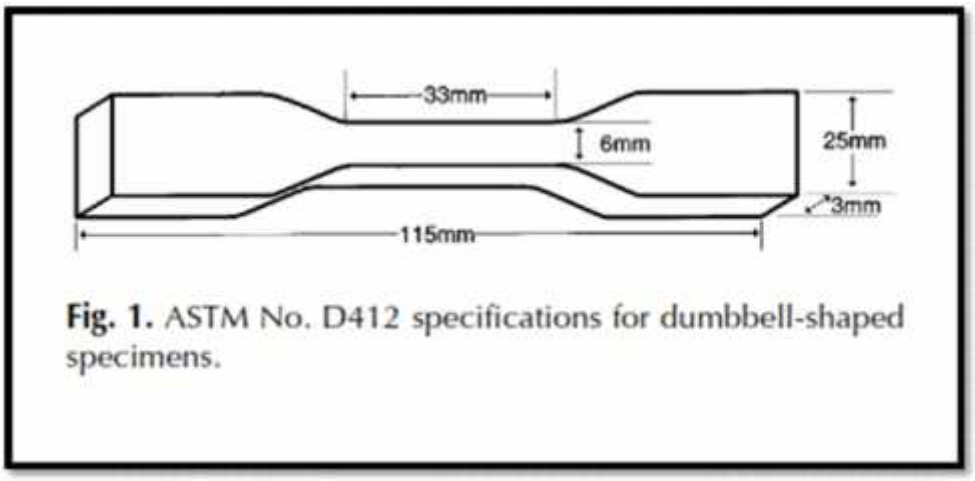


Fig. 1. ASTM No. D412 specifications for dumbbell-shaped specimens.

Figure 11.

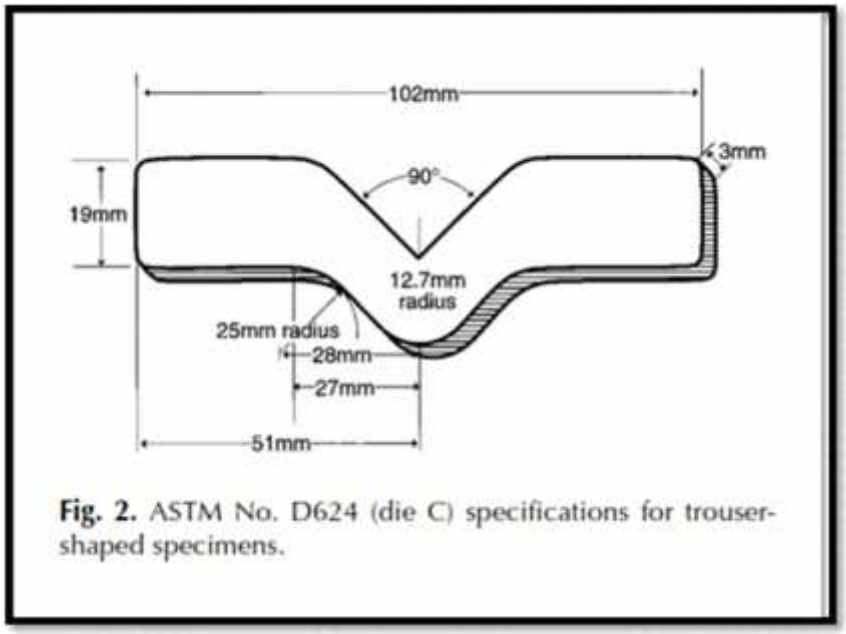


Fig. 2. ASTM No. D624 (die C) specifications for trouser-shaped specimens.

Figure 12.

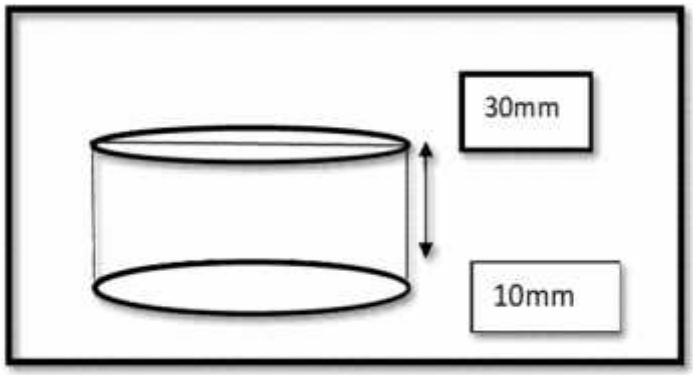


Figure 13.

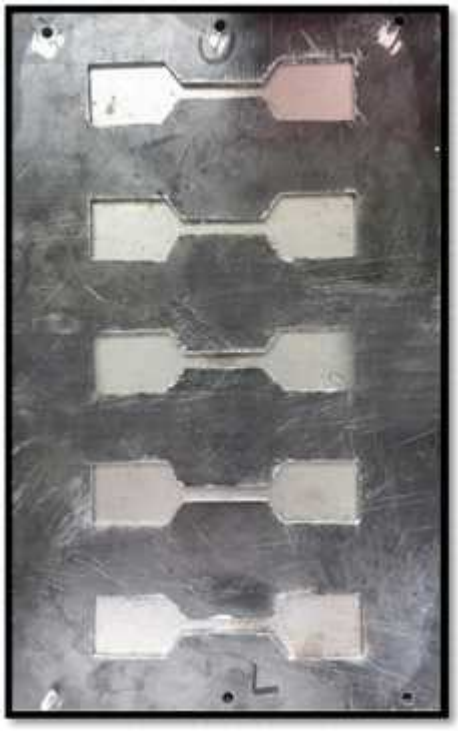


Fig 14. Mould for preparation of Tensile test samples. (ASTM D412)

Fig 15. Mould for preparation of Tear test samples. (ASTM D264)

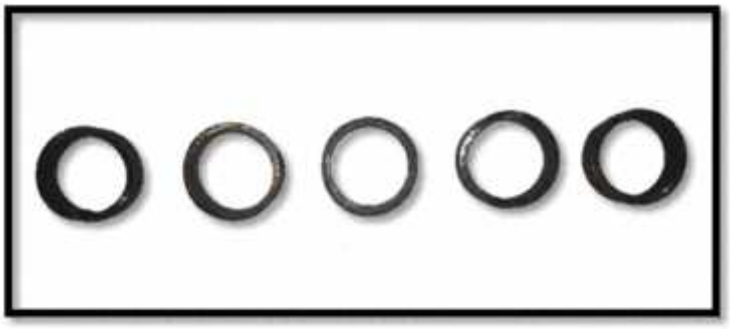


Fig 16. Moulds for preparation of Hardness Samples.

Group I Samples.

MDX4-4210 + 2wt% Titanium nanoparticles.

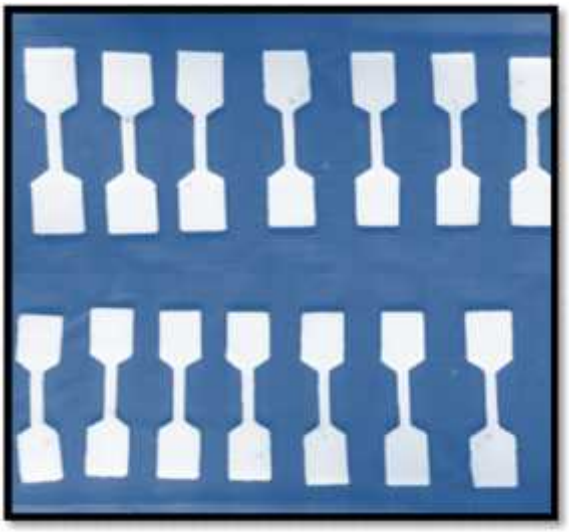


Fig 17. Tensile test samples. (ASTM D412)

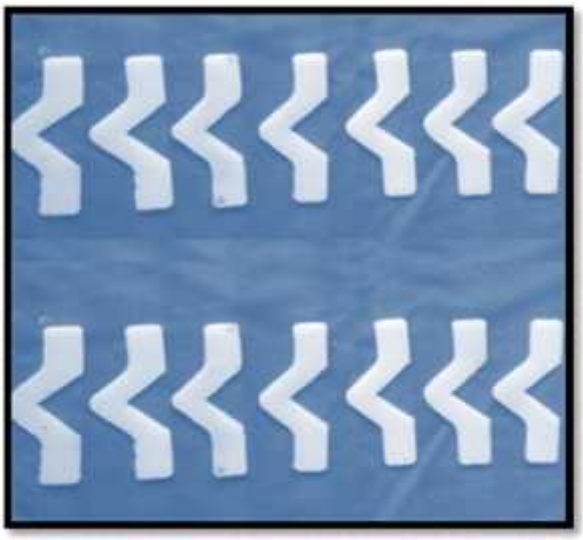


Fig 18. Tear test samples. (ASTM D264)

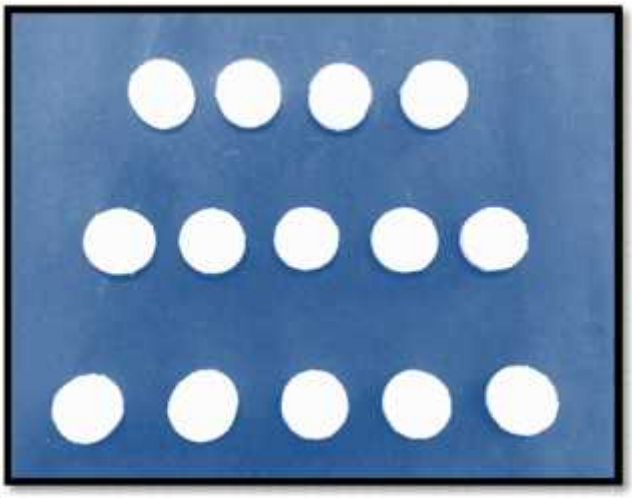


Fig 19. Hardness test samples.

Group II Samples.

MDX4-4210 + 3wt% Silica nanoparticles.

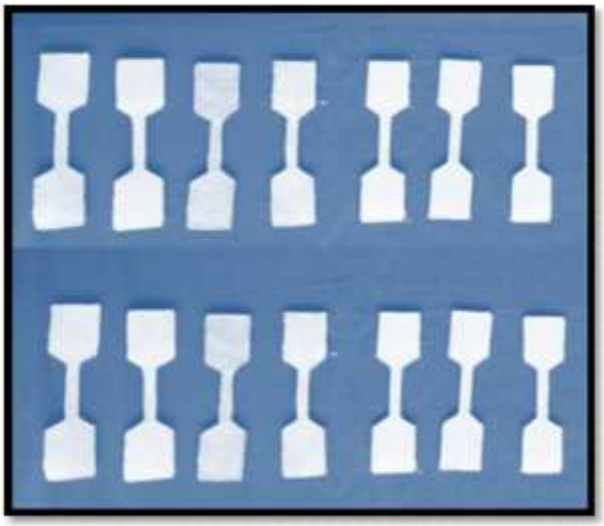


Fig 20. Tensile test samples. (ASTM D412)

Fig 21. Tear test samples. (ASTM D264)

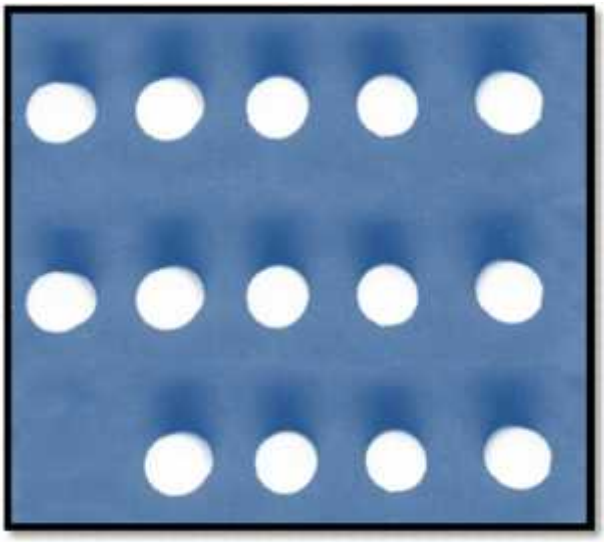


Fig 22. Hardness test samples.

Group III Samples.

MDX4-4210 + 1wt% TiO2-SiO2 Nanocomposite

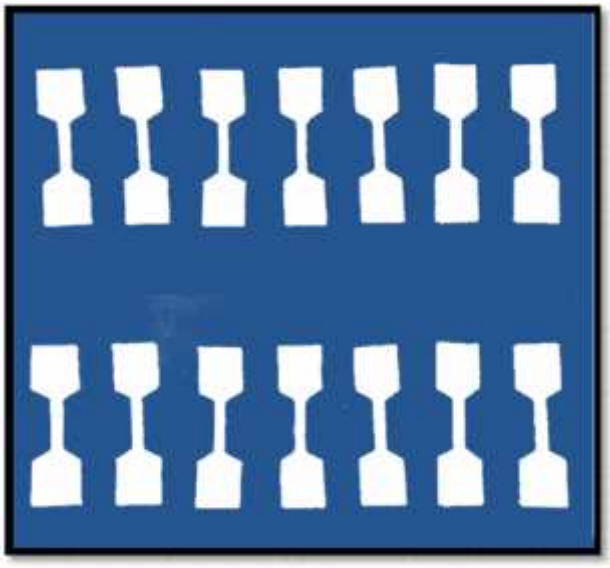


Fig 23. Tensile test samples. (ASTM D412)

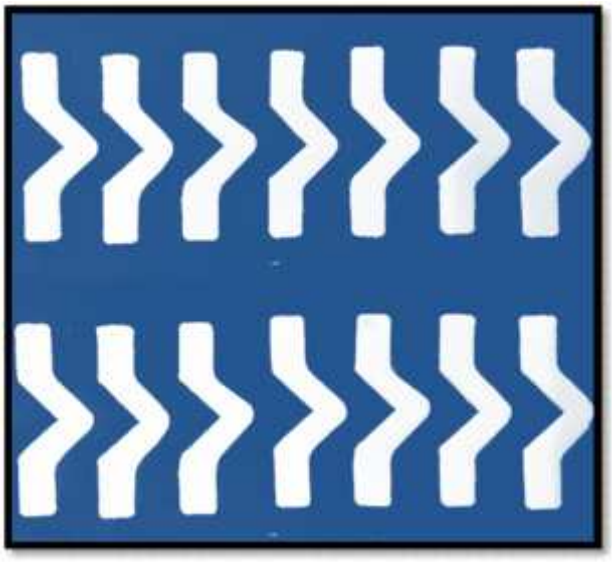


Fig 24. Tear test samples. (ASTM D264)

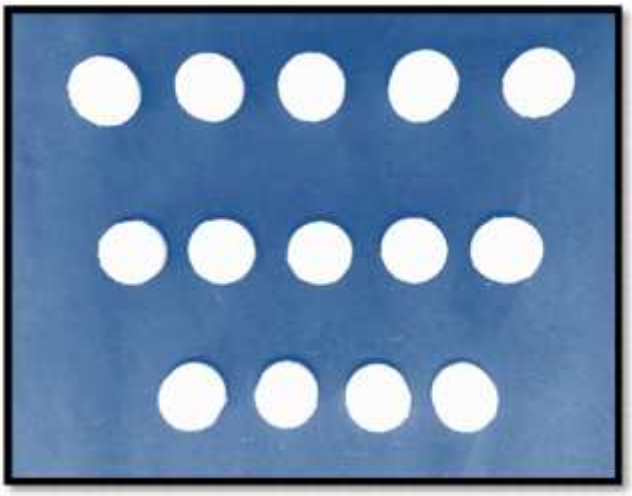


Fig 25. Hardness test samples.

Group IV Samples.

MDX4-4210 + 2wt% TiO2-SiO2 Nanocomposite

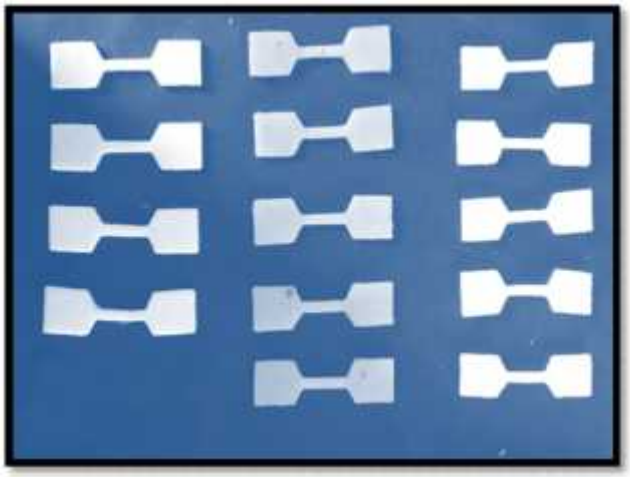


Fig 26. Tensile test samples. (ASTM D412)

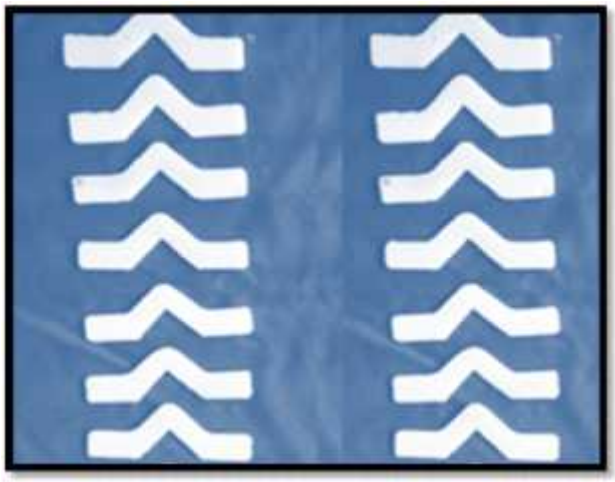


Fig 27. Tear test samples. (ASTM D264)

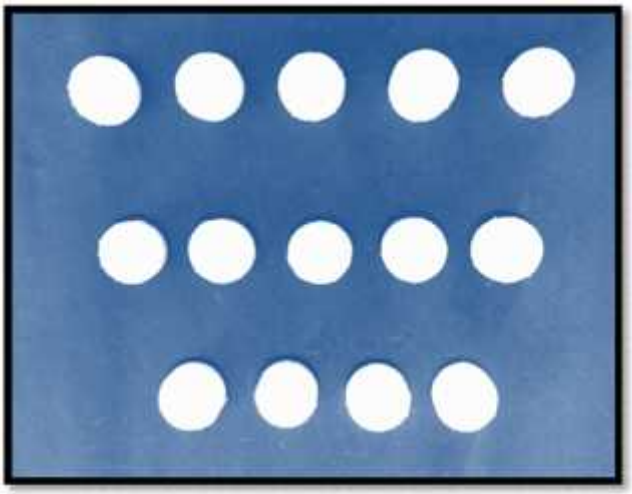


Fig 28. Hardness test samples.

Fig. 29, 30 Sample subjected to universal testing machine for tensile strength test

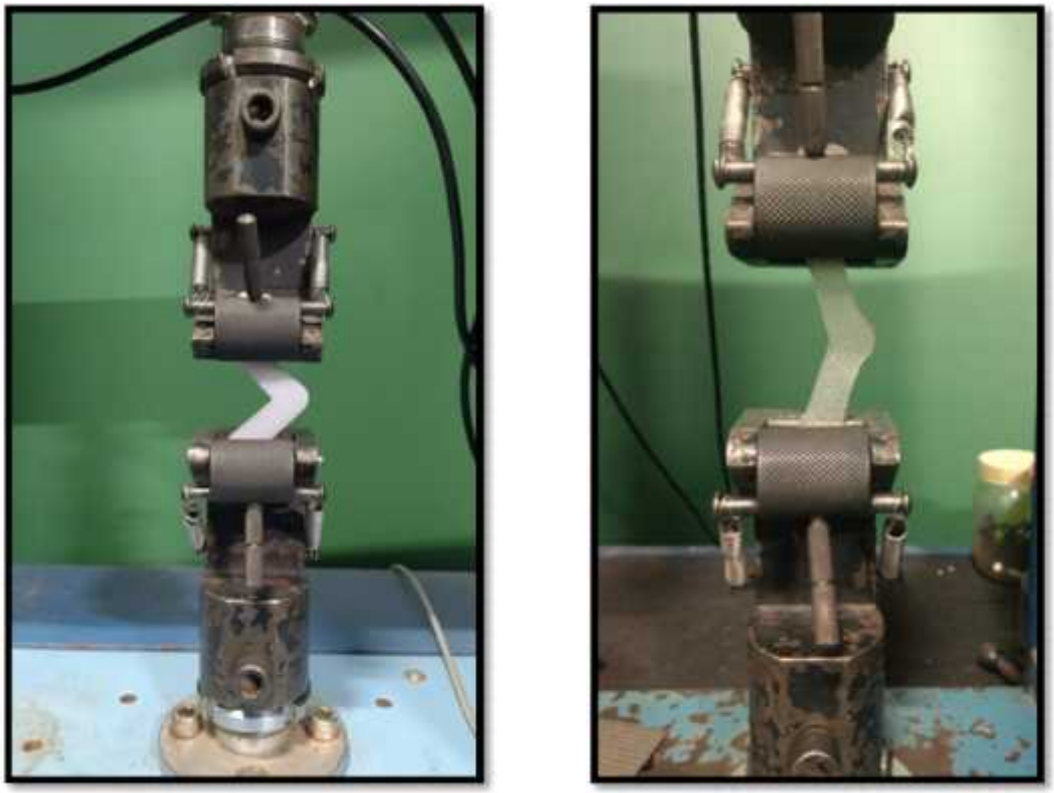


Fig. 31, 32 Sample subjected to universal testing machine for tear strength test

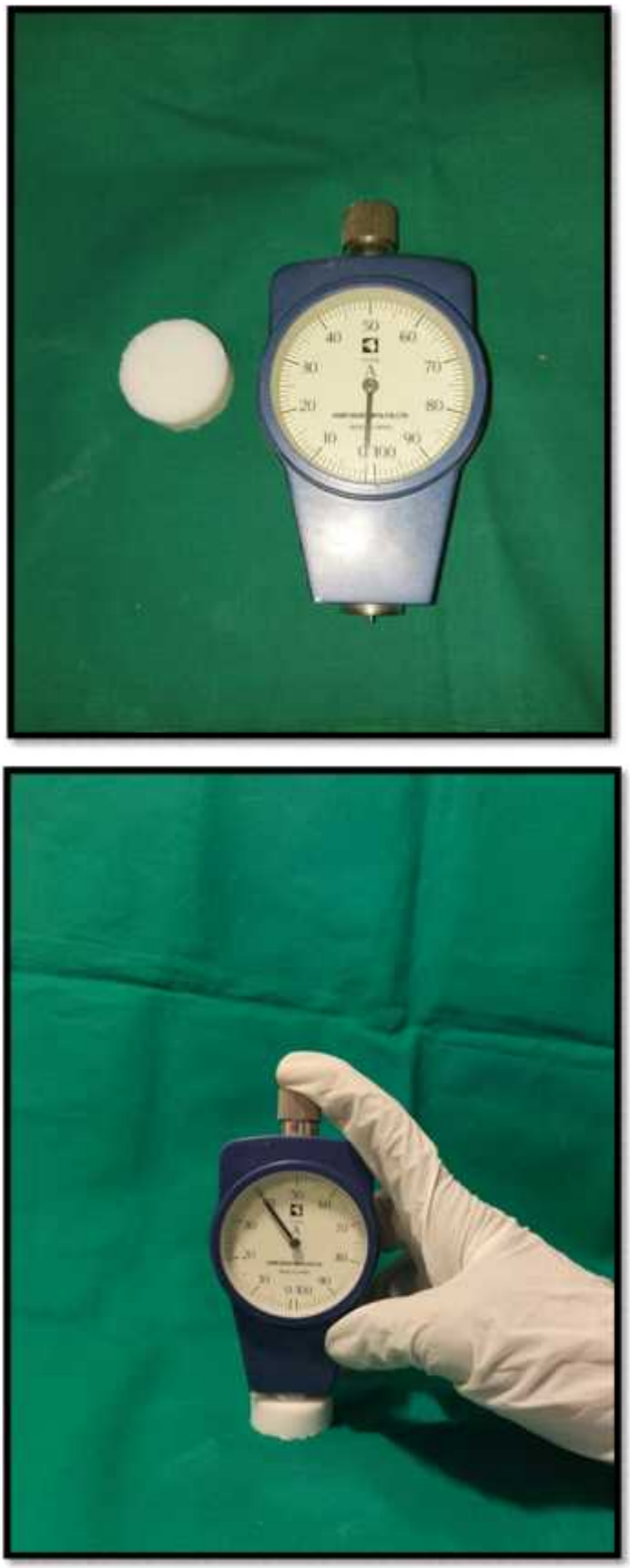


Fig. 33, 34 Sample subjected to a durometer testing machine for hardness test.

RESULTS

The results derived from this in-vitro study were analysed to evaluate and compare the effect of nanoparticles of 2% titanium dioxide, 3% silicon dioxide and 1% and 2% nanocomposite of titanium dioxide – silicon dioxide on tensile and tear strength, shore hardness of maxillofacial silicone elastomer.

The groups for the specimens of this study were as follows.

GROUP I: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 2wt% Titanium Dioxide nanoparticles.

GROUP II: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 3wt% Silica Dioxide nanoparticles.

GROUP III: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 1wt% TiO2 -SiO2 Nanocomposite.

GROUP IV: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 2wt% TiO2-SiO2 Nanocomposite.

The data that was obtained after testing of the 168 specimens under three parameters, ie. Tear and tensile strength and shore hardness was subjected to statistical analysis. Since the values obtained from tear strength, tensile strength and shore A hardness in the four study groups followed a normal distribution, the parametric tests were applied.

Descriptive statistical measures such as mean, standard deviation, coefficient of variation and standard error of means were computed and measured for all study groups. To compare the means of the study groups, they were subjected to one-way ANOVA test, pair wise comparison of the test group was done using Tukeys multiple posthoc test.

The results of the study pertaining to the tensile strength test concluded that the mean value of Tensile strength for Group IV testing sample (2% TiO2/SiO2 nanocomposite + Silicone) (2.49) is higher than the mean value tensile strength for Group I (2.21) Group II (2.14) Group III (2.36).

The table summarizes the mean values, standard deviation and the standard errors of the tensile strength test for the 4 groups of the study. **(Table 3)**

The table shows the comparison between the 4 groups with mean tensile strength (MPa) when subjected to One Way ANOVA suggests that there was a significant difference between their tensile strength. (p – 0.001*) **(Table 4)**

Table 3: Summary of tensile strength test (Mpa) in four groups (I, II, III, IV)

Groups	Min	Max	Mean	SD	SE	95% CI for mean	
						Lower Bound	Upper Bound
Group I	1.80	2.56	2.21	0.22	0.06	2.08	2.34
Group II	1.56	2.33	2.14	0.22	0.06	2.01	2.26
Group III	2.08	2.58	2.36	0.16	0.04	2.27	2.45
Group IV	2.20	2.69	2.49	0.15	0.04	2.41	2.58

Table 4 : Comparison of four groups (I, II, III, IV) with mean tensile strength test (Mpa) by one-way ANOVA

Sources of variation	Degrees of freedom	Sum of squares	Mean sum of squares	F-value	p-value
Between groups	3	1.0574	0.3525	9.6875	0.0001*
Within groups	52	1.8920	0.0364		
Total	55	2.9495			

*$p<0.05$

Table 5: Pair wise comparison of four groups (I, II, III, IV) with mean tensile strength test (Mpa) by Tukeys multiple posthoc procedures

Groups	Group I	Group II	Group III	Group IV
Mean	2.21	2.14	2.36	2.49
SD	0.22	0.22	0.16	0.15
Group I	-			
Group II	P=0.7498	-		
Group III	P=0.1603	P=0.0152*	-	
Group IV	P=0.0015*	P=0.0002*	P=0.2836	-

*p<0.05

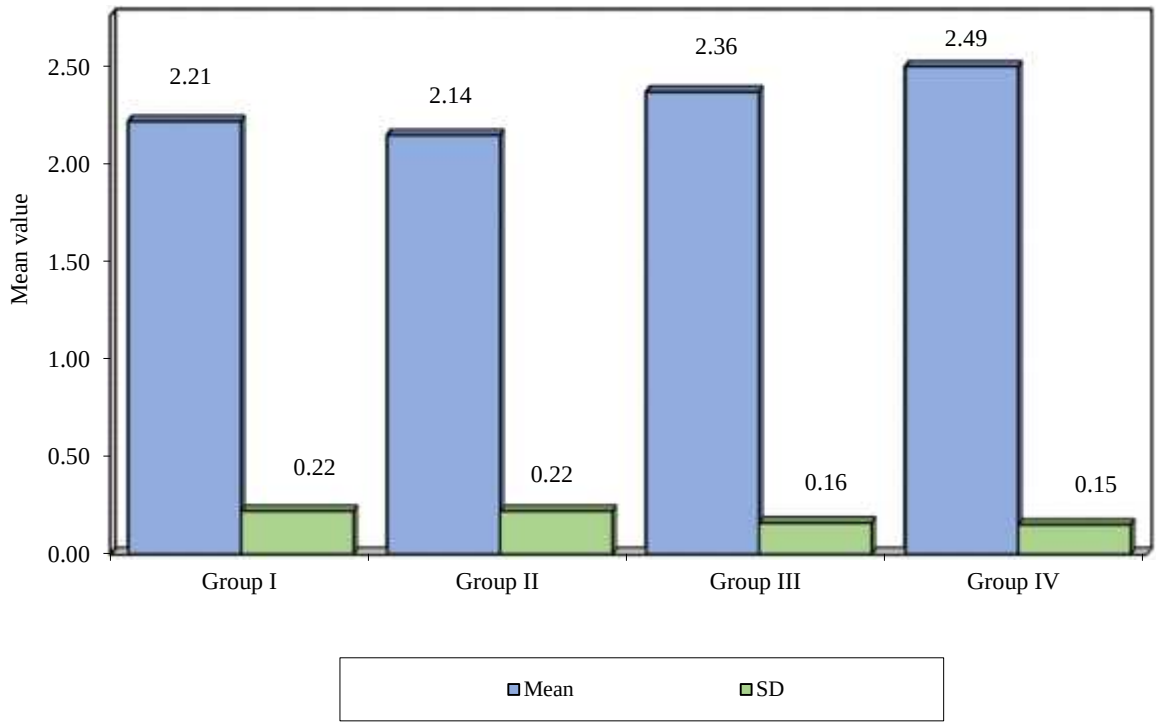
In the above (Table 5), pair wise comparison was done between the 4 groups under the parameter of tensile strength test (MPa).

For pairwise comparison between Group I and Group II (p = 0.7498) and Group I with Group III (p = 0.1603) there was no statistical significance observed. Whereas between Group I and Group IV there was a statistical significance observed. (p = 0.0015*)

For pairwise comparison of Group II when compared with Group III (p = 0.0152*), statistically significant values were obtained. Group II compared with Group IV (p = 0.002*), statistically significant values were obtained.

Whereas for Group III; When compared with Group IV (p = 0.2836), statistically significant values were not observed.

Figure: Comparison of four groups (I, II, III, IV) with mean tensile strength test (Mpa)



Graphical representation 1: of the parameter tensile strength (Mpa) of the four testing groups according to the obtained mean values shows that Group IV has the highest mean value (2.49) and lowest mean value was achieved by Group II (2.14) for tensile strength according to the derived data.

The results of the study pertaining to the tear strength test concluded that the mean value of Tear strength for Group IV testing sample (2% TiO2/SiO2 nanocomposite + Silicone) (13.20) is higher than the mean value tear strength for Group I (7.69) Group II (8.62) Group III (10.08).

The table summarizes the mean values, standard deviation and the standard errors of the tear strength test for the 4 groups of the study. **(Table 6)**

The table shows the comparison between the 4 groups with mean tear strength (MPa) when subjected to One Way ANOVA suggests that there was a significant difference between their tear strength. (p – 0.0001*) **(Table 7)**

Table 6: Summary of tear strength test (Mpa) in four groups (I, II III, IV)

Groups	Min	Max	Mean	SD	SE	95% CI for mean	
						Lower Bound	Upper Bound
Group I	6.50	9.20	7.69	0.70	0.19	7.29	8.10
Group II	7.47	9.52	8.62	0.71	0.19	8.21	9.03
Group III	7.90	11.82	10.08	1.00	0.27	9.50	10.66
Group IV	8.60	13.20	11.42	1.43	0.38	10.59	12.25

Table 7: Comparison of four groups (I, II, III, IV) with mean tear strength test (Mpa) by one-way ANOVA

Sources of variation	Degrees of freedom	Sum of squares	Mean sum of squares	F-value	p-value
Between groups	3	112.5989	37.5330	37.1191	0.0001*
Within groups	52	52.5798	1.0112		
Total	55	165.1788			

*$p<0.05$

Table 8: Pair wise comparison of four groups (I, II, III, IV) with mean tear strength test (Mpa) by Tukeys multiple posthoc procedures

Groups	Group I	Group II	Group III	Group IV
Mean	7.69	8.62	10.08	11.42
SD	0.70	0.71	1.00	1.43
Group I	-			
Group II	P=0.0806	-		
Group III	P=0.0002*	P=0.0020*	-	
Group IV	P=0.0002*	P=0.0002*	P=0.0048*	-

*p<0.05

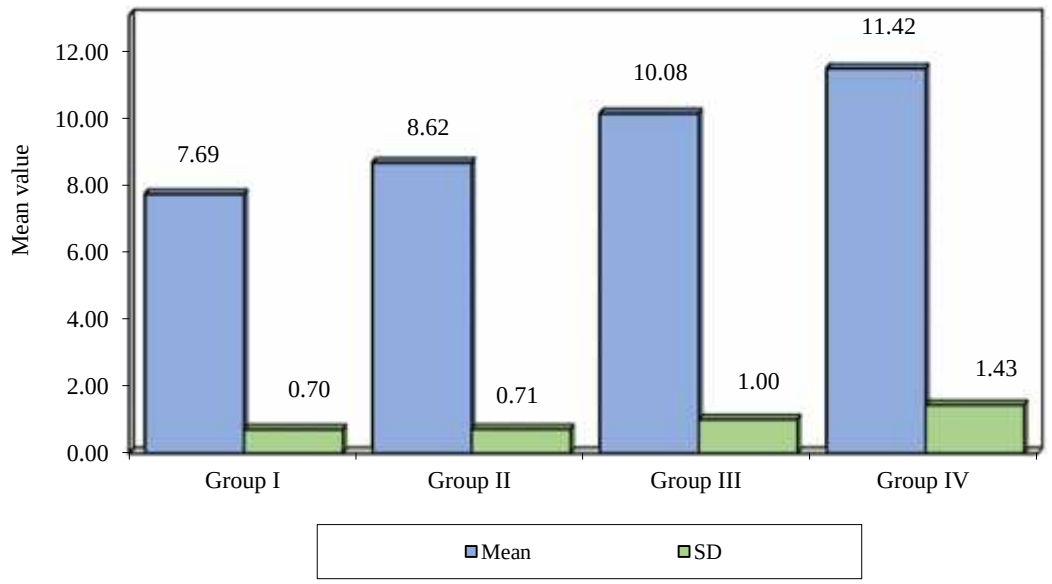
In the above table pair wise comparison was done between the 4 groups under the parameter of tear strength test (MPa).

For pairwise comparison between Group I and Group II (p = 0.0806) there was no statistical significance observed. Between Group I and Group III (p = 0.0002*) statistically significant results were observed. When compared Group I and Group IV statistically significant values were obtained. (p = 0.0002*)

For pairwise comparison of Group II, when compared with Group III (p = 0.002*), statistically significant values were obtained. Also, when compared Group II with Group IV (p = 0.0002*), statistically significant values were obtained.

Whereas for Group III; When compared with Group IV (p = 0.0048*), statistically significant values were observed.

Figure: Comparison of four groups (I, II, III, IV) with mean tear strength test (Mpa)



Graphical representation 2: of the parameter tear strength (Mpa) of the decided four groups according to the obtained mean values show that Group IV has the highest mean value (2.49) according to the derived data.

The results of the study pertaining to the shore hardness test concluded that the mean value of Shore Hardness for Group II testing sample (3% SiO2 nanoparticles + Silicone) (47.00) is higher than the mean value shore hardness for Group I (35) Group III (44) Group IV (43).

The table summarizes the mean values, standard deviation and the standard errors of the Shore Hardness test for the 4 groups of the study. **(Table 9)**

The table shows the comparison between the 4 groups with mean hardness (Shore A) when subjected to One Way ANOVA suggests that there was a significant difference between their hardness. (p – 0.001*) **(Table 10)**

Table 9: Summary of hardness test (Shore A) in four groups (I, II, III, IV)

Groups	Min	Max	Mean	SD	SE	95% CI for mean	
						Lower Bound	Upper Bound
Group I	27.00	35.00	30.07	2.34	0.62	28.72	31.42
Group II	44.00	47.00	45.21	0.80	0.21	44.75	45.68
Group III	42.00	44.00	42.64	0.74	0.20	42.21	43.07
Group IV	41.00	43.00	42.14	0.66	0.18	41.76	42.53

Table 10: Comparison of four groups Summary of hardness test (Shore A) in four groups (I, II, III, IV) with mean hardness test (Shore A) by one way ANOVA

Sources of variation	Degrees of freedom	Sum of squares	Mean sum of squares	F-value	p-value
Between groups	3	1922.7679	640.9226	361.4188	0.0001*
Within groups	52	92.2143	1.7734		
Total	55	2014.9821			

*p<0.05

Table 11: Pair wise comparison of four groups (I, II, III, IV) with mean hardness test (Shore A) by Tukeys multiple posthoc procedures.

Groups	Group I	Group II	Group III	Group IV
Mean	30.07	45.21	42.64	42.14
SD	2.34	0.80	0.74	0.66
Group I	-			
Group II	P=0.0002*	-		
Group III	P=0.0002*	P=0.0002*	-	
Group IV	P=0.0002*	P=0.0002*	P=0.7539	-

*p<0.05

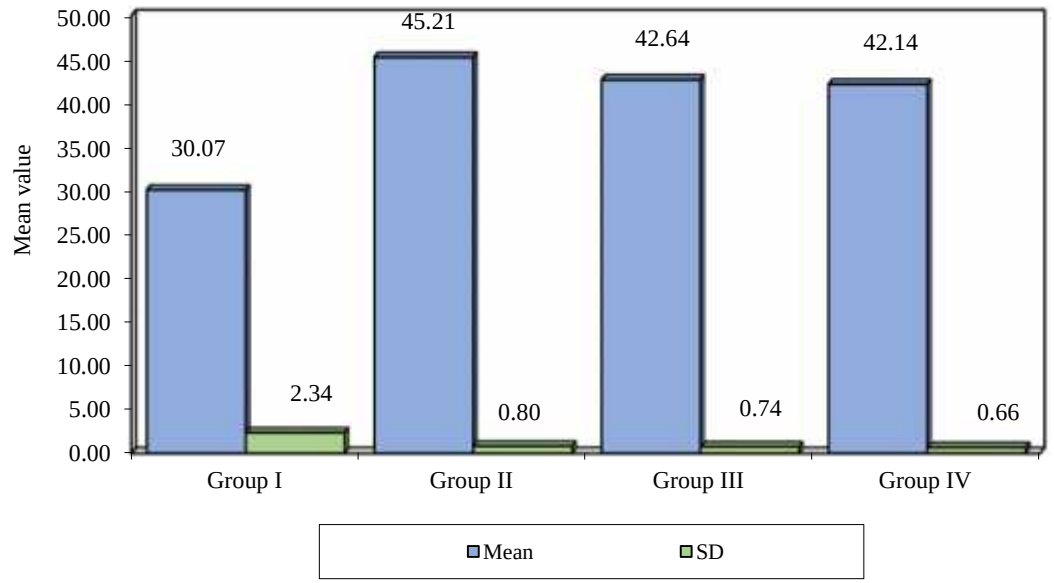
In the above table pair wise comparison was done between the 4 groups under the parameter of hardness test (Shore A).

For pairwise comparison between Group I and Group II (p = 0.0002*) statistical significance observed. When compared Group I with Group III (p = 0.0002*) statistically significant results were observed. Also, similarly when compared Group I and Group IV statistically significant values were obtained. (p = 0.0002*)

For pairwise comparison of Group II; When compared with Group III (p = 0.0002*), statistically significant values were obtained. And When compared Group II with Group IV (p = 0.0002*), statistically significant values were obtained.

Whereas for Group III; when compared with Group IV (p = 0.7539), statistically significant values were not observed.

Figure: Comparison of four groups (I, II, III, IV) with mean hardness test (Shore A)



Graphical representation 3: of the Hardness (Shore A) of the decided four groups according to the obtained mean values show that Group II has the highest mean value (45.21) according to the derived data.

DISCUSSION

The aim of maxillofacial prosthodontics or the prosthesis is to not only restore form and function of the part of face with the defect, but also to restore the patients social and psychological state which can in turn help them achieve a state of confidence and happiness.[7]

These materials are envisioned to be desirable, attain all the functional and biological properties in addition of them being easy to fabricate in a dental setting.[3]

Silicones are organo-silicone synthetic poly-dimethyl siloxane (PDMS) material. They are poly-molecular chains of silicone and oxygen atoms alternately, and a combination of inorganic and organic components. Silicone and its types vary due to their mechanical properties. This is owing to the compositional changes in the formulations which include length of the chain of the polymers, its size, type and size and amount of fillers and its molecular weight. Viscosity of this material is determined by the chain of the polymer, fillers, colorants, antioxidants etc. In order to procure optimum tear strength, tensile strength, hardness, resistance from heat, UV light exposure, the cross linking of this polymer is said to be essential. If any changes occur in the elastomer or the cross linker it causes a decline in the tensile strength.[11]

Cross-linking of elastomeric chains is fundamental so as to enhance the tear and tensile strength. If there is a higher crosslinking, a hard and more fragile elastomeric material is created, while a low cross-linking gives lower tensile and tear quality. [11]

Zayed et al. in his review discussed the alterations in the properties of the material which were caused due to UV radiation, temperature and the wettability that affects it and causes weathering of material.[41]

This deterioration of prosthesis was connected with fungal growth, and its inhibition proved to be better and stable for the prosthesis. [42]

These factors are seen to have detrimental effects on the silicone elastomer and its physical, mechanical properties along with its optical properties. Thin areas of the prosthesis were seen to be susceptible to degradation. This was then followed by a tear at the margins due to daily wear and tear of the prosthesis. The rigid borders may also cause minor trauma or ulceration to the underlying skin.[41]

A number of researchers have made several attempts in order to enhance these mechanical properties of the silicone elastomer. These materials perform well but deteriorate over the time which lead to fungal growth followed by irritation and trauma to the skin finally not rendered to be useful anymore in a mere span of 6 months.

Among the initial studies that were carried out, **Firtell et al**.[45] was the one who initiated the incorporation of fillers into the silicone material as a means for it to have better mechanical properties and overcome its limitations. He incorporated foam into the RTV silicone material to the normal elastomer in order to try and achieve a light weight prosthesis. They succeeded in the endeavor but compromised and deteriorated tear strength as the foam quantity was increased.

Kouyoumdjian in 1985 modified the RTV silicone with MF100cs which showed drastic decrease in the mechanical characteristics in the desire of a softer

material.[43] There have been studies which have evaluated in vitro effects on silicone of addition of such nano fillers or additives on the properties. Due to the increased incidence in the use of the silicone material, many researchers have recommended the use of such additives to be incorporated into the material. The nanoparticles have a surface reactivity which is innate, its surface areas are high and chemically absorb substances. These properties determine the uniqueness of the nanoparticles which further render enhanced performances of the material.

Zayed stated that the improvement in these materials after incorporation of the fillers or nanoparticles could be due to the surface reactivity and its possible interaction with the silicone elastomer, and in turn might increase the cross linking with the polymers therefore improving the properties. [41]

Wang in the year of 2014 conducted a study in which he used TiO2 nanoparticles as a nanofiller in silicone elastomer attempting to elevate the mechanical characteristics of the polymer. According to the inferences of his study, TiO2 elevated the tensile strength, hardness of the material. He mentioned the limitation in his study was the steady decrease regarding the tear strength which is one of the most vital and desirable property of maxillofacial silicone. The concentration that established to be better amongst the ones used was 2% (w/w).[32]

Keeping this concentration of 2wt% and the elevated properties of the silicone and titanium biocompatibility, TiO2 (2%) along with MDX4-4210 (Group I) was decided to be evaluated in comparison with the novel use of the TiO2-SiO2 nanocomposite.

In the year of **2014 Zayed**, used silica nanoparticles as a filler in order to try to improve the material strength or mechanical characteristics of the silicone polymer. He tried varied concentrations of the silica nanoparticles in his study (0.5 to 3% by weight). He mentions that out of all the concentrations 3% (w/w) enhanced the mechanical characteristics of the polymer in wholeness. This study also had its drawbacks regarding its percentage elongation which was small but significant. [11] This and previous studies were used as a reference for the selection of 3% (w/w) of Silica nanoparticles along with MDX4-4210 and was decided to be compared as Group II of the study.

The evidence of the TiO2/SiO2 nano composite being used in dentistry is extremely low, especially as a material for reinforcement which might increase the mechanical properties of the silicone elastomer.

This study deals with a customized nanocomposite material TiO2-SiO2 which is fabricated by core-shell method, the core of it being Titanium and shell being Silica was chosen given the exceptionally good performance of individual nanoparticles of Titanium Dioxide and Silica Dioxide on the properties of maxillofacial silicone polymer when used as reinforcement fillers. This TiO2/SiO2 nanocomposite was used in this study to reinforce the MDX4-4210 in an attempt to modify and enhance its physical and mechanical properties that are Tear and Tensile strength and Shore A Hardness as these three properties are important for better clinical performance of maxillofacial silicone prosthesis.

Tear strength is the ability of the material to resist transverse forces and relates to the marginal strength and resistance to shearing forces during service. It is a very important property which is needed to be achieved in a prosthesis for its longevity as

the margins of the prosthesis are kept to be very thin for it to give the illusion of merging with the surrounding skin.

If the tear strength of the material is very low, there is a chance of the prosthesis tearing during removal of the same for the purpose of cleaning. If the tear strength of the material is achieved closer to the ideal, the prosthesis could be rendered as strong and can have fine edge without having the chances of it tearing easily.[18]

In the present study, according to the derived data and results, Group IV (MDX4-4210 + 2% TiO2/SiO2 nanocomposite) (11.42) shows the highest increase in tear strength and is statistically significant when compared with Group I, Group II and Group III. There was no such significant difference observed between Group I (MDX4-4210 + 2% TiO2 Nanoparticles) and Group II (MDX4-4210 + 3% SiO2 nanoparticles), mean values being (7.69 and 8.62) respectively.

This increase in the tear strength maybe because of less agglomerations as the particles disperse evenly in the matrix or due to the adequate cross linking of the poly-siloxane polymer chain with the nanocomposite effectively. This may have increased the interfacial bonding between the nanocomposite and the silicone polymer.[32]

Tensile strength indicates the materials overall strength in general and the ability of the silicone elastomer to resist general wear and tear along with the environmental conditions as well as weathering.

In the present study, according to the obtained and derived data and results, Group IV (2.49 Mpa) shows the highest increase in tensile strength and was statistically significant when compared with Group I and Group II. Although there

was no such significant difference observed between Group III and Group IV, mean values being (2.36 MPa and 2.49 Mpa) respectively. It was also noted that lowest tensile strength values were seen with Group I.

Tensile strength of a material is increased when incorporated with a filler or a nanocomposite is thought to be due to the uniform dispersal of the nanocomposite or fillers in the continuous phase of the polymer of silicone elastomer, this in turn increased he cross sectional area and formed a cross linked structure of the material. [32]

In this study, there is straightforward evidence of improved strength by looking at strengthening tests for the silicone polymer pertaining to tensile strength as well as tear strength after incorporation of nanocomposite. It is mainly observed when the nanocomposite of TiO2/SiO2 was added in 2% (w/w) to the silicone polymer.

Hardness of a silicone material is said to be the resistance of it against vertical perforation. [44] The hardness of silicone polymer is determined by the cross links, density along with the characteristics of their polymer network and polymer molecular weight. [27]

The ideal surface hardness of a silicone elastomer material depends on the human skin and the surrounding area of the defect to be replaced relating to the patients age and type of skin to mimic the structures of the facial area it is surrounding.[26] Shore A hardness values 25 to 55 units are categorized as ideal.[40]

In the present study, hardness increased mainly in Group II mean being (45.21) followed by Group III (42.64) and Group IV (42.41) which did not show a statistically significant difference between the groups. Group I in this test seemed to

be the one with the lowest mean value that is (30.07). All the 4 testing groups showed mean Shore A hardness within the acceptable range.

The increase in hardness is due to the effect of addition of the nanoparticles on elastic modulus or due to the dispersion which elevates the cross-linking density and lengthened polymer chain further increasing the hardness.[11] However, the hardness value of Group IV is within the acceptable range and is in a balanced combination with high tensile strength, comparable tear strength. The area where the prosthesis has to be placed may be a deciding factor for using a certain nanofiller as the elasticity of the face varies according to region and person.[26] From this study, we can recommend the use of 2% TiO2/SiO2 nanocomposite as a filler material as we obtained a material with adequate hardness, softness which is pliable and adaptable to restore the required area of defect.

The study and its findings have indicated that there was a statistically significant positive effect of addition of TiO2/SiO2 nanocomposite when added in the concentration of 2% on the tensile strength, tear strength and shore hardness of the maxillofacial silicone elastomer and establishes itself as a better filler material when compared with TiO2 nanoparticles and SiO2 nanoparticles. Although, as the study has its own limitations of not simulating the extraoral and intraoral environmental conditions and not evaluating the nanocomposites effect on elastomer at a few more concentrations, a few clinical studies may be needed for the results to prove more significant.

SCOPE FOR FURTHER STUDY

1. Other mechanical preoperties such as compressive strength, permanent deformation, water sorption, percentage elongation, color stability, accelerated aging can be evaluated to arrive at a more definitive conclusion.
2. A prospective and retrospective clinical study with fabrication of maxillofacial prosthesis with incorporation of TiO2-SiO2 nanocomposite and Titanium Nanoparticles, Silica nanoparticles can be performed, and prosthesis can be evaluated on their clinical presentation and life span.
3. Before the clinical application of the silicone that was incorporated with the TiO2/SiO2 nanocomposite for silicone prosthesis on patients they should be attentively checked for its biocompatibility.
4. Further studies pertaining to the possible antibacterial effect of the nanocomposite of TiO2/SiO2 can be evaluated.
5. TiO2/SiO2 nanocomposite can be incorporated into different dental materials and be evaluated for their properties.

LIMITATIONS OF THE STUDY

1. As this is an in vitro study the material may behave differently in a clinical setup.
2. In this study the samples were not subjected to ageing. Ageing determines the effect of all the factors pertaining to the environment and various oral and extraoral conditions on the silicone elastomer. Therefore, the condition of the specimens and how they behave in various environmental factors was not evaluated.
3. The nanocomposite of TiO2-SiO2 was seen to change the shade and transparency of MDX4-4210 specimens. Although there is a scope that this acquired white shade could serve as a base shade before tinting of the prosthesis.
4. Study included groups that evaluated the effect of the mentioned nanocomposite of TiO2 and SiO2 in the concentrations of 1% and 2% (w/w). Different concentrations of the same could be incorporated into the material and tested in order for us to know the complete efficiency of the material at all concentrations and obtain even more accurate results.
5. Other mechanical characteristics and properties like color stability, permanent deformation, percentage elongation etc. can be evaluated to establish whether the incorporated nanocomposite can fulfil other ideal requirements of this MDX4-4210.

CLINICAL IMPLICATIONS

- TiO2/SiO2 nanocomposite when added in the concentration of 2% on the tensile strength, tear strength and hardness of the maxillofacial silicone elastomer and establishes as a better filler material when compared with TiO2 nanoparticles and SiO2 nanoparticles individually.
- From this study, we can recommend the use of 2% TiO2/SiO2 nanocomposite as a filler material as we obtained a material with adequate hardness, tensile strength and tear strength, softness which is pliable and adaptable to restore the required area of defect.
- This nanocomposite can be used as reinforcing agent to prevent the degradation of mechanical properties of maxillofacial prosthesis over the time which will in turn increase the service life of the prosthesis and patient's comfort.

CONCLUSION

The null hypothesis was rejected and the research hypothesis is accepted as there is a positive effect of addition of the TiO2/SiO2 nanocomposite on mechanical properties of maxillofacial silicone. The study and its findings have indicated that there was a statistically significant positive effect of addition of TiO2/SiO2 nanocomposite when added in the concentration of 2% on the tensile, tear strength and hardness of the maxillofacial silicone elastomer and establishes as a better filler material when compared with TiO2 nanoparticles and SiO2 nanoparticles individually.

In view of the results of this study, the following conclusions are drawn:

1. A significant increase in the tear strength and tensile strength values was seen when the MDX4-4210 was incorporated with 2% (w/w) TiO2/SiO2 nanocomposite. (Group IV)

2. There was no significant difference seen in Group III and Group IV of the study regarding all of the testing parameters. (Tensile strength, Tear strength and Shore A hardness)

3. Shore A hardness was seen greatly elevated in Group II that is MDX4-4210 incorporated with 3% SiO2 nanoparticles. However, the hardness values of all the testing samples were within the acceptable range. And there was no significant difference between the groups.

4. TiO2/SiO2 nanocomposite when incorporated in 2% (w/w) has established itself to be a worthy and a promising nanofiller to increase the strength of maxillofacial silicone elastomer.

SUMMARY

The present study was conducted with the aim of evaluating and comparing the effect of addition of Titanium Dioxide nanoparticles, Silica Dioxide nanoparticles and Nanocomposite (TiO2/SiO2) on the tensile strength, tear strength and shore hardness of maxillofacial silicone.

Four study groups were included in the study with total of 168 samples, 56 samples in each group.

GROUP I: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 2wt% Titanium Dioxide nanoparticles.

GROUP II: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 3wt% Silica Dioxide nanoparticles.

GROUP III: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 1wt% TiO2 -SiO2 Nanocomposite.

GROUP IV: Maxillofacial Silicone Elastomer MDX4-4210 Reinforced with 2wt% TiO2-SiO2 Nanocomposite.

A total of 168 samples were fabricated.

14 samples in each group were prepared for testing of tensile strength. (ASTM standard D-412)

14 samples for testing of tear strength. (ASTM standard D624)

14 samples for testing of shore hardness. (ASTM D2240) bringing them to a total of 56 samples in each group and 4 groups in totality.

The samples were subjected to universal testing machine to measure the tear strength and tensile strength and to a shore durometer to measure the hardness.

To compare the mean of the study groups after obtaining the values, they were subjected to one-way ANOVA test, pair wise comparison of the test group was done using Tukeys multiple posthoc test.

On analysing obtained data, the study and its findings have indicated that there was a statistically significant positive effect of addition of TiO2/SiO2 nanocomposite when added in the concentration of 2% on the tensile strength, tear strength and hardness of the maxillofacial silicone elastomer.

And within the limitations of this study TiO2/SiO2 nanocomposite establishes as a better filler material when compared with TiO2 nanoparticles and SiO2 nanoparticles.

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ANNEXURE - I

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CERTIFICATE

This is to Certify that the synopsis titled

To evaluate and compare the effect of nanoparticles of Titanium dioxide, silicon dioxide, 1% & 2% of titanium dioxide – silicon dioxide nanocomposite on tensile strength, tear strength, shore hardness of Maxillofacial Silicone Elastomer: An in-vitro study *Submitted by*

Dr. Sayali Hegepatil *P. G. Student / Staff, Guided by* Dr. Anand Kumar G Patil *from Department of* Prosthodontics & Crown & Bridge *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 24/06/2019

Member Secretary
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Chairman
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KLEVK Institute of Dental Sciences
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ANNEXURE – II

Tensile strength test (Mpa)				
Sample Number	Group I	Group II	Group III	Group IV
1	2.03	2.09	2.17	2.2
2	2.2	2.31	2.58	2.48
3	1.96	2.24	2.36	2.32
4	2.2	2.1	2.2	2.46
5	2.25	1.87	2.08	2.36
6	2.56	1.98	2.18	2.58
7	2.4	2.32	2.49	2.6
8	1.8	2.02	2.44	2.62
9	2.22	1.56	2.27	2.59
10	2.09	2.33	2.56	2.53
11	1.95	2.27	2.46	2.53
12	2.34	2.32	2.43	2.3
13	2.43	2.26	2.52	2.69
14	2.49	2.24	2.32	2.62

ANNEXURE - III

Tear strength test (Mpa)				
Sample Number	Group I	Group II	Group III	Group IV
1	7.03	9.48	9.9	8.6
2	8.3	7.62	8.62	13.03
3	7.09	8.18	7.9	12.98
4	7.23	9.52	11.82	9.9
5	9.2	7.93	10.56	9.89
6	8.33	7.47	9.89	10.89
7	8.2	8.54	11	10.5
8	7.9	9.48	10.13	10.7
9	7.23	9.28	9.9	11.87
10	6.5	8.56	9.45	13.2
11	7.3	7.9	10.02	10.99
12	8	8.8	11.23	12.56
13	7.5	9	10.45	12.99
14	7.9	8.98	10.23	11.78

ANNEXURE - IV

Hardness test (Shore A)				
Sample Number	Group I	Group II	Group III	Group IV
1	30	45	42	43
2	28	45	42	42
3	29	47	44	43
4	34	45	43	42
5	28	45	43	42
6	35	44	42	41
7	32	45	44	41
8	29	45	42	43
9	32	44	43	42
10	29	46	43	42
11	27	46	42	43
12	29	45	42	42
13	30	46	42	42
14	29	45	43	42