Design and Analysis of Composite Biomaterial Bone Graft Plate

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Abstract

The mixing technique was applied in this study to enhance the strength performance of the cement. The addition of 3% by weight of hydroxyapatite (HA) nanoparticles were mixed with 97% polymethyl methacrylate (PMMA) acrylic polymer, which has a nano size to serve as the matrix material. The surface roughness and continuous porosity of the bone cement were found to be slightly increased by the incorporation of nanoparticles, which enhanced bone-implant osseointegration and ingrowth. Atomic force microscopy (AFM) analysis revealed that the addition of hydroxyapatite (HAp) nanoparticles resulted in a surface roughness value (Sa) of 16.25 nm, which is similar to that of natural bone. The energy-dispersive X-ray spectroscopy (EDS) mapping results discover precentor material and uniform distribution. The Sample exhibited promising results in the antibacterial test, showing efficacy against bacteria both with and without sterilization, confirming its antibacterial properties. The mechanical tests conducted on the sample, including tensile, compression, bending and Vickers hardness tests, yielded favorable results and indicated that the sample is suitable for its intended application. In the theoretical works the design of the bone, screw, and bone plate was conducted using SolidWorks, followed by an analysis using ANSYS under both axial and bending load conditions. The theoretical analysis revealed that the safety factor was less than 1 when an axial load of 13 N was applied and a bending load of 2 N was applied, indicating that the structure may not be able to withstand these loads safely. Under both ambient and physiologically relevant conditions in the human body, HA and PMMA have demonstrated to be excellent choices for enhancing the clinical performance of bone cement. This, in turn, can lead to increased longevity of implants, decreased patient risk, and lower healthcare costs.

Keywords; Hydroxyapatite, Polymer, Solid Work, ANSYS

تصميم وتحليل مسند لترقيع العظام من المواد الحيوية المركبة معصم كروي

دنيا عبد الصاحب حمدي ، فاطمة موفق خضير

الخلاصة:

تم تطبيق تقنية الخلط في هذه الدراسة لتعزيز أداء قوة الأسمنت. تم خلط إضافة ٣٪ وزنًا من جسيمات الهيدروكسيباتيت النانوية (HA) مع بوليمر أكريليك بولي ميثيل ميثاكريلات (PMMA) بنسبة ٩٧٪، والذي له حجم نانو ليكون بمثابة مادة المصفوفة. لاحظ أن خشونة السطح والمسامية المستمرة لأسمنت العظام قد زادت بشكل طفيف من خلال دمج الجسيمات النانوية، مما عزز التكامل العظمي والنمو الداخلي للعظام. كشف التحليل المجهري للقوة الذرية (AFM) أن إضافة جسيمات الهيدروكسيباتيت النانوية (HAp) جعلة خشونة السطح (Sa) تبلغ ١٦,٢٥ نانومتر، وهي مماثلة لتلك الموجودة في العظام الطبيعية. تكتشف نتائج رسم خرائط التحليل الطيفي للأشعة السينية (EDS) المشتتة من الطاقة المواد الأولية والتوزيع الموحد. أظهرت العينة نتائج جيدة في اختبار مضاد البكتيريا، حيث أظهرت فعاليتها ضد البكتيريا سواء مع أو بدون تعقيم، مما يؤكد خصائصها المضادة للبكتيريا. وقد أسفرت الاختبارات الميكانيكية التي أجريت على العينة، بما في ذلك اختبارات الشد والضغط والانحناء وصلابة فيكرز، عن نتائج إيجابية وأشارت إلى أن العينة مناسبة للتطبيق المقصود منها. في الأعمال النظرية، تم إجراء تصميم العظم والمسمار ولوحة العظم باستخدام برنامج SolidWorks، متبوعًا بالتحليل باستخدام ANSYS في ظل ظروف الحمل المحوري والانحناء. أظهر التحليل النظري أن عامل الأمان كان أقل من ١ عند تطبيق حمل محوري قدره ١٣ نيوتن وحمل انحناء قدره

٢ نيوتن، مما يشير إلى أن الهيكل قد لا يكون قادرًا على تحمل هذه الأحمال بأمان. في ظل الظروف المحيطة والفسيولوجية ذات الصلة في جسم الإنسان، أثبت HA و PMMA أنهما اختياران ممتازان لتعزيز الأداء السريري للأسمنت العظمي. وهذا بدوره يمكن أن يؤدي إلى زيادة طول عمر الغرسات، وتقليل المخاطر على المريض، وانخفاض تكاليف الرعاية الصحية.

1. Introduction

Bone is a mineralized connective tissue ande exerts important functions in the body, such as locomotion, support and protection of soft tissues, calcium and phosphate storage and harboring of bone marrow. Despite its inert appearance, bone is a highly dynamic organ that is continuously resorbed by osteo-clasts and new formed by osteoblasts **[1]**. Bone is the main component of the skeleton system and differs from connective tissues in rigidity and hardness. The hardness and rigidity of the bone enables the skeleton to maintain body shape to soft tissue protection in the cranial, thoracic and pelvic cavities, in addition, bone is a self-repairing skeletal material, able to adapt its mass, shape and properties to changes in mechanical requirements and withstand a voluntary physical activity for a lifetime without breaking or causing pain [2-4]. Bone grafts and bone graft substitutes are indicated for a variety of orthopedic abnormalities such as comminuted fractures delayed unions, non-unions, arthrodesis, osteomyelitis and congenital diseases and are used to provide structural support and enhance bone healing [5]. Fracture-fixation by bone-plate is intended to provide immobilization at the fracture site and reduce the fracture gap, thus allowing primary bone-healing or healing by endosteal callus formation. The role of bone-plate and screws is to hold the fractured bone segments in position. [6] , Biomaterials as synthetic or natural materials to be used to replace parts of a living system or to function in intimate contact with living tissue. Ceramic-based bone graft substitutes include calcium phosphate, calcium sulphate, and bio glass used alone or in combination; for example Osteo Graf. BioPolymer-based bone graft uses as degradable and nondegradable polymers alone or in combination with other materials, for example, open porosity polylactic acid polymer [7]. Hydroxyapatite (HAp), [Ca10 (PO4)6(OH), is a calcium phosphate preferably used in application of body that is found naturally in bone. PMMA is more types of polymer used as an orthopedic bone cement to bind the prosthetic component to the bone. Composite materials HAp and PMMA are Polymerization occurs during the mixing of powder and liquid components, they do together to give the composite unique materials in the composite work properties [8]. The aim fabricate plate from bio composite material that have mechanical, microstructure properties similar to biological of materials and biocompatible to achieve the osseointegration such as PMMA and HAp that are used to treat bone fractures by grafting them. And treat the patient with least cost, losses and better healing than past treatments and without side effects on the body.

2. Material

1. polymethyl methacrylate (PMMA) acrylic poly with its solution, has chemical formula ($C_5H_8O_2$) used as matrix.
2. Hydroxyapatite (HAp) with purity 99.0% and particle size 40 nm, as reinforced material.

3. Material preparation

The addition of 3% by weight of hydroxyapatite (HA) nanoparticles were mixed with 97% polymethyl methacrylate (PMMA) acrylic polymer, its beast percentage depends on previous studies [4]. Powder composition is (PMMA+HAp), and the liquid is (methylmethacrylate, dimethyl- paratoluidine, ethylene glycoldimethacrylate) with ratio 1:3 used as matrix and reinforced by (HAp). under 10 kN pressure the pressing was done by using hydraulic press (enerpac) for 30 min. Pressing is mechanical process use to produce a sample (tensile and compression) with same dimension of mold.

4. Experimental wok

4. 1 Mechanical tests

4.1. 1.Tensile test

Tensile test was performed ASTM D638 by using Testometric machine at room temperature to improve the reproducibility decrease, and the softness increases. The cross-head speeds are 1 mm/min with pressure 25 N/m.

4.1.2. Compression test

Uniaxial compression tests provide much of the same information about material properties as tension tests. test was performed ASTM D695 by using Testometric machine and the cross-head speeds are 1 mm/min until the failure of the sample.

4.1.3. Bending test

Test was performed ASTM D7900 by using tenuis Olsen machine with load 500N and the cross-head speeds are 2 mm/min until the failure of the sample.

4.1.4. Vickers Hardness test

Mechanical analysis Vickers hardness is a test method that has the widest application range, this test has an extremely large number of application fields especially for hardness tests conducted with a test force less than 9.807N (1kg).

4.2. Microstructure tests

(SEM) in a scanning electron microscope, an electron beam is generated by heating a tungsten filament. The wavelength of the electron beam, λ, is determined by the operating excitation voltage. The image magnifications that can be obtained in an SEM are typically about 10,000–50,000.

5. Theoretical Works

Theoretical work includes the design of the radius bone, a plate for fixation of the bone, and screws for fixation by the Solidwork program. The dimensions of the bone were adopted from a previous study, while the dimensions of the screws and plate were adopted from the dimensions of the plate from Tikrit General Hospital.

5.1. Design

5.1.1 Bone design

The model of radius bone is a hollow cylinder representing a cortical bone have dimension 10 mm as inner diameter, 14 mm as outer and 200mm length of the bone. A five-hole plate is applied to stabilize the fracture site. And crack with depth 1cm as shown in (Fig. 1) and Table .1 [9] .

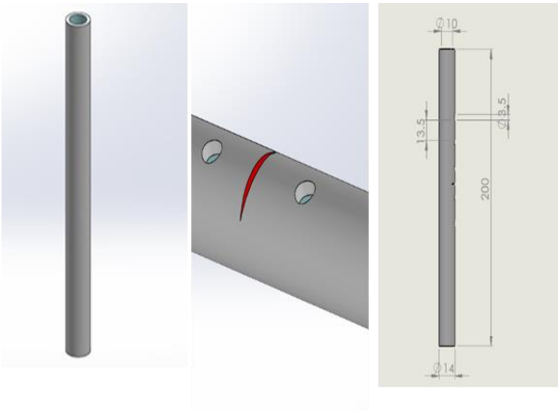


Figure (1): Design model of radius forearm bone [9].

Table (1): Dimension of radius forearm bone [9]

Object	Internal diameter (mm)	Outer diameter (mm)	Length (mm)
Bone	10	14	200

5.1.2. Bone plate design

According to the obtained dimensions of bone plate reference as shown in fig .2 and (table 2), the bone plate model is designed in Fig. 3.

Figure (2): Dimensions of bone plate

Table (2): Dimension of bone's plate

Object	Length (cm)	Thickness (cm)	Width (cm)	Radius of plate(cm)	Radius of Ellipse hole(cm)
Bone Plate	9	0.5	1.13	3.75	R1=0.6 R2=0.4

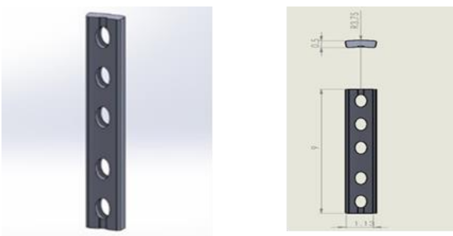
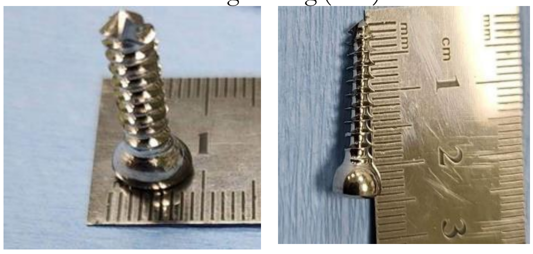


Figure (3) : model of bone plate

5.1.3. Screw design

According to the obtained dimensions (Table 3) the screw model is designed Fig.(a&5).



(a) (b)

Figure (4): Dimension of screw

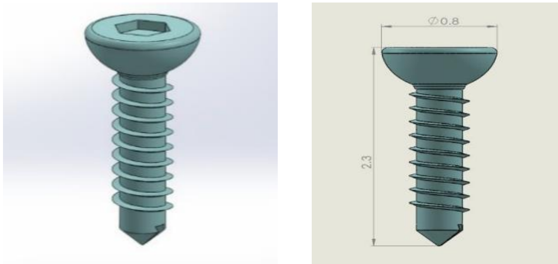


Figure (5): Model of screw

Table (3): Dimension of screw

Object	Length (cm)	Diameter (cm)	Number of Thread
Screw	2.3	0.8	9

5.1.4. Assemble of parts

Assembling the parts (bone, plate, and screws) together using the SolidWorks program to get the final model.

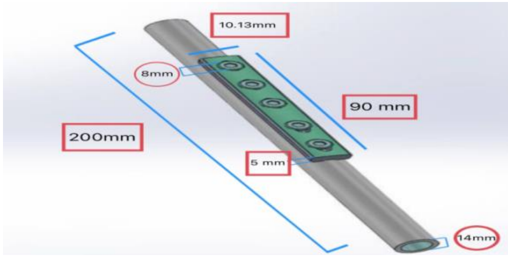


Figure (6): Assemble of parts

5.2. The finite element method

To obtain approximate solution to physical problems, a numerical technique the finite element method usually (FEM) is used. Because of its capability to flexibility as an analysis tool and its handle complex problems because the FEM can only give an approximate solution so, it is not the most desired way to solve a physical problem. The differential equation is best way to solve a physical problem to obtain a closed form analytical solution [10]. In this work, maximum stress, total deformation, and safety factor behaviour were determined using FEM and ANSYS Workbench 2017. Building the geometry as a model, applying the boundary conditions load, finding the solution, and analysing the results are the three steps of the general analysis process utilized by ANSYS.

5.2.1. Mesh generation

The meshing process has been done by choosing the size as medium shown in Figure (7) including 44519 nodes and 22915 elements

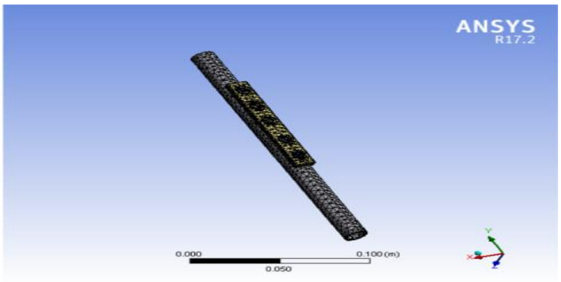


Figure (7): The model with meshing

5.2.2. The boundary conditions in applying axial load

The boundary conditions for model analysis in axial load was defined as a fixed support in lower surface and applied axial load on upper surface, Fig.8.

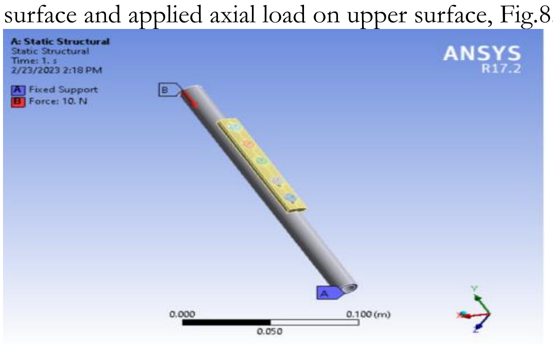


Figure (8): Boundary conditions in axial load (10N)

5.2.3. The boundary conditions in applying bending load

The boundary conditions for model analysis in bending load was defined as a fixed support in upper surface then applied force as shown in Fig. (9).

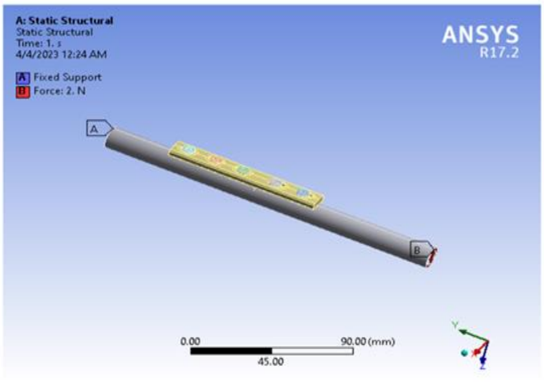


Figure (9): boundary conditions in bending load(2N)

6. Results and Discussion

6.1. Experimental work

6.1.1. Mechanical tests results

A. Tensile test

The results of the mechanical properties (tensile test) from testometeric for the (PMMA + HAp) shown in tables (4) and the stress-strain curve for them shown in Figure 10.

Table (4): The mechanical properties from tensile test

No.	Deflection peak (mm)	Stress break (MPa)	Stress peak (MPa)	Strain break (%)	Strain peak (%)	Stress yield (MPa)
1	10.153	95.613	95.613	39.972	39.917	20.611
2	5.875	60.57	60.34	23.8	24.05	14.76
Average	8.014	78.0915	77.9765	31.886	31.983	17.6855

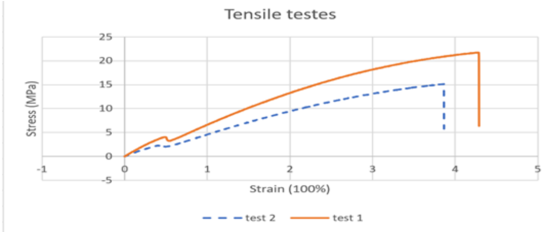


Figure (10): Stress-strain curve of the composite (97%PMMA +3% HAp)

From this curve we realized the material is brittle so it has low tensile strength so the Brittle fracture of material occur without plastic deformation or with very small plastic deformation before fracture. Depends on literature review, the result is better than compared with PMMA without adding ceramic deformation before fracture. Depends on literature review, the result is better than compared with PMMA without adding ceramic

B. Compression test

Test metric machine and the cross-head speeds are 1 mm/min until the failure of the sample. Like all other brittle materials, application PMMA cement is brittle in nature it is weak under tension but it has strong specifications under compression. The measurements of compression strength values of the prepared cements are very important because compression is a main direction of load on bone cement in a plate implant. The results of the mechanical properties (compression test) from testometeric for the (PMMA + 3%wHAp) shown in table (5-2). PMMA cements containing 3 percent HA had the maximum value of ultimate compressive strength and compression yield strength. It was depending on two out of three samples were adopted because failed in the examination and the stress-strain curve for them shown in Figure (11) and table 5.

Table (5): the mechanical properties from compassion

Number	Elong peak (mm)	Stress break (MPa)	Strain peak (MPa)	Strain break (%)	Strain peak (%)	Stress yield (MPa)	Young modulus(MPa)
1	2.433	6.118	20.91	4.268	4.268	4.682	726.860
2	2.202	5.551	14.572	3.865	3.863	2.931	510.809
Average	2.317	5.8345	17.741	4.077	4.0655	3.8065	618.834

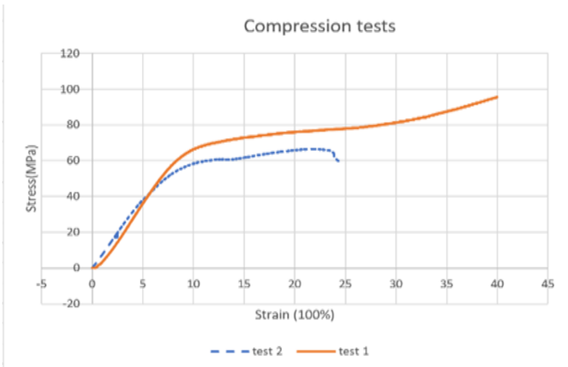


Figure (11): Stress-strain curve (97%PMMA +3% HAp) of compression test

C. Bending test

The bending test is often more suitable to check the strength of brittle materials, because the materials are subjected to bending stress only. It was depending on one out of three samples were adopted because failed in the examination and the stiffness curve for them shown in figure (12) the sample showed flex strength 34.75 MPa and E-Modulus 1855 MPa.

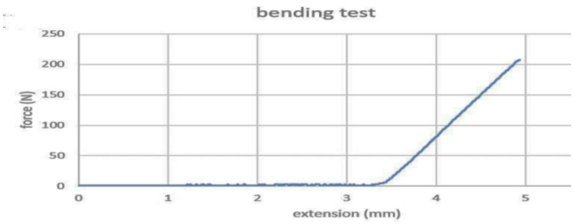


Figure (12): The stiffness curve (97%PMMA +3% HAp) for bending test

D. Hardness test

Vickers micro hardness with condition Load applied on the surface =4.2 (0.5 kg) upon at addition PMMA composites. V Hardness has done for mid-point for each sample. Hardness is to determine the material resistance to plastic deformation. Brittle materials commonly have a high resistance to plastic deformation, because this is one of the main things which makes them brittle. According to the results obtained, a comparison has been acquired for Vickers micro hardness. Nano particles have a direct effect to the crystal structure of the polymer because of voids occurrence of agglomerated and aggregated particles, in the case of 3 wt% of HAps there is a good distribution of nano particle that gives a good match between tissue and bone cement, table 6 and Fig.13.

Table (6): the mechanical properties of samples from Hardness test

Sample No.	Diagonal length (mm)	Load (kg)	HVP (kg/mm^2)	Mean HVP (kg/mm^2)
1	0.0362	0.5	71.9524	64.7980
2	0.0405	0.5	57.64365	

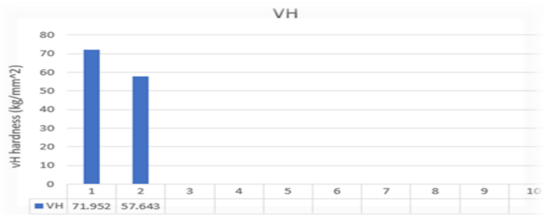


Figure (13): Results97%PMMA +3% HAp) of Hardness test

6.1.2. Microstructure tests results

A. Optical microscopy

The optical microstructure of PMMA composite and interfacial bonding between matrix and reinforced particles which are bright white dots due to low density (HAp) was shown in fig 14. Optical microscopy provides good indication in evaluation of surface morphology, agglomeration of nanoparticles and their distribution

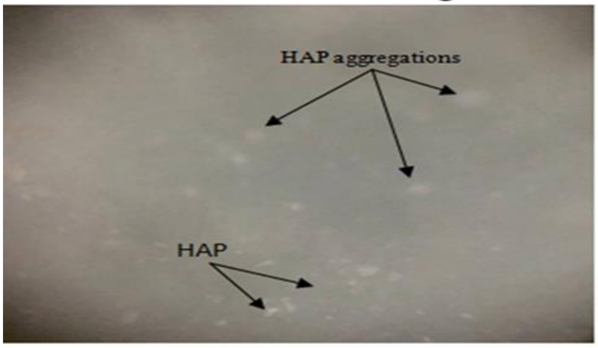


Figure (14): Optical microscopy image (97%PMMA +3% HAp)

B. Scanning electron microscopy (SEM) and (EDS)

Fig (15) SEM with magnification 20µm, indicates a homogenous distribution of small amounts of Nano particles with relatively small agglomerates being seen which positively reflected on the mechanical properties and worked as reinforcement to the matrix PMMA. The EDS, MAPS results in Fig. (16 a.b) supports the results of SEM and OPT

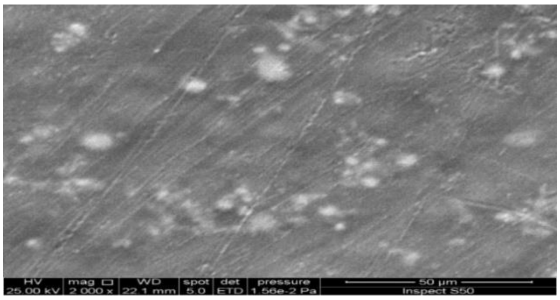
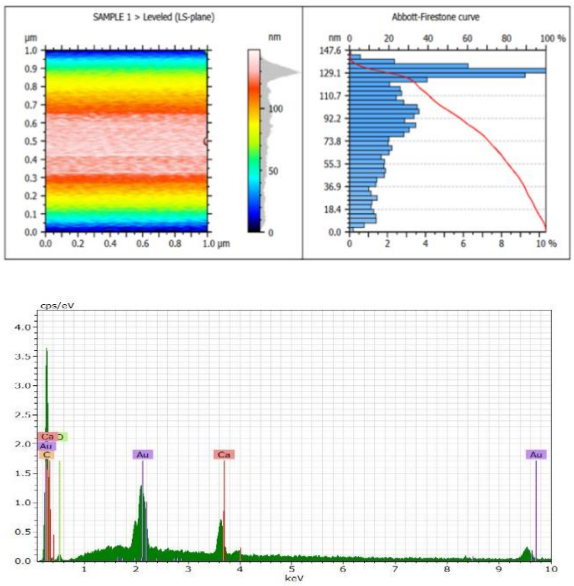
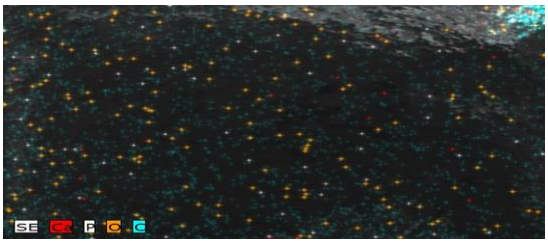


Figure (15): SEM image (97%PMMA +3% HAp) (The image is magnification 2000 X by using a voltage of 2500 kV and Everhart–Thornley detector (E–T detector or ET detector))



(a)



(b)

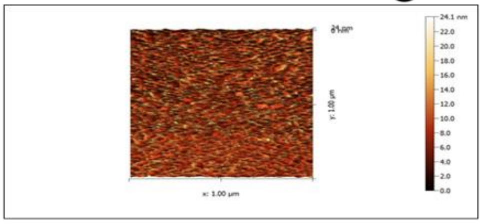
Figure (16): a. result of EDS, b. MAPS results of (97%PMMA +3% HAp)

To detect the components of the substance (PMMA+HAp) using EDS and MABS results. Particles (Ca) belong within components Hap, and particles (C) &(O) belong to polymer. We note that the appearance of gold particles (Au) is due to the coating of the sample for the purpose of making the composite material conductive to complete the working mechanism of the SEM device. The MABS result agreement with EDS results.

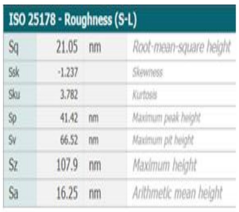
C. Atomic Force Microscopic

To study surface morphology on a micro nano-scales, atomic force microscopy AFM) is considered as an excellent tool. The composite samples of nano HA particles with acrylic approach exhibited morphology as shown in figure (17.a, b) with acrylic as matrix reinforced with HAp .Homogenous distribution that is clear for concentration particle with more nano size in the canter of sample in edge.

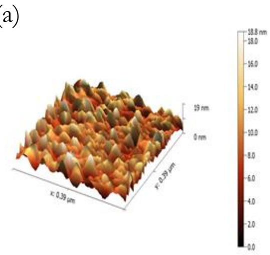
The micrographs show that with nano particles of Hydroxyapatite particle sizes in these composites are quite uniform that may significantly surface effective compatibility acrylic as show in fig (17,a). Figure (17.c) were used to determine surface topography and properties of surface sample of nano composites in 3D. The figures exhibit distribution of nanoparticles HAp in the acrylic matrix. It can be seen; the HAp particles are surrounded and embedded into the polymer chain of acrylic. Indicating the HAp particles has a core effect on the polymerization of composites. It seems penetration of HAp particles into the acrylic matrix leads to similar formations of aggregates and agglomerates on the surface of composites. Can be resulted from the interface binding between HA particles and the matrix, that it seems due to high specific surface energy of n-HA particles resulting in their aggregations too. Results of granularly cumulating distribution chart figure (17.b) shows molecular weight of composite in the range between 15.00 and 147.00 nm and the maximum percentage range between 129.00 and 145.00 nm. The existence of nanoparticle HAp increases surface roughness with value sa=16.25nm along with the AFM images. The aggregations and high roughness increasing from adhesion of plate with tissue.



(a)



ISO 25178 - Roughness (S-L)			
Sq	21.05	nm	Root-mean-square height
Ssk	-1.237		Skewness
Sku	3.782		Kurtosis
Sp	41.42	nm	Maximum peak height
Sv	66.52	nm	Maximum pit height
Sz	107.9	nm	Maximum height
Sa	16.25	nm	Arithmetic mean height



(b) (c)

Figure (17): (a) AFM image of the surface of acrylic with (97%PMMA +3% HAp), **(b)** Granularly distribution chart (97%PMMA +3% Hap), **(c)**3D topographic of nano composite of (97%PMMA +3% HAp)

6.2. Results of Theoretical work

A. Analyses results

The model was analysed by using Workbench software 17 to calculate the total deformation, equivalent stress (Von-Mises) and safety factor. The safety factor will be safe in design if the safety factor about or more than (1.25) so because the radius bone is tiny bone, we started applied load from small value until we reached to load caused minimum safety factor least than 1 (failure of system) for sample (97%PMMA +3% HAp) with axial load

B. bending load

In the case of bending, the flexural strength was adopted as the ultimate tensile strength, and the Young's modulus for bending was used instead of axial modulus. A force was applied starting from 2 N and it that caused a safety factor of less than 1. Figures (18, 19 and 20) and table 7 shows total deformation, equivalent stress (Von-Mises) and safety factor in load 2N.

Table (7): applied forces (bending) and results

Applied force (N)	Min safety factor	Max equivalent stress (MPa)	Max deformation (mm)
2	0.042	0.139	68.45

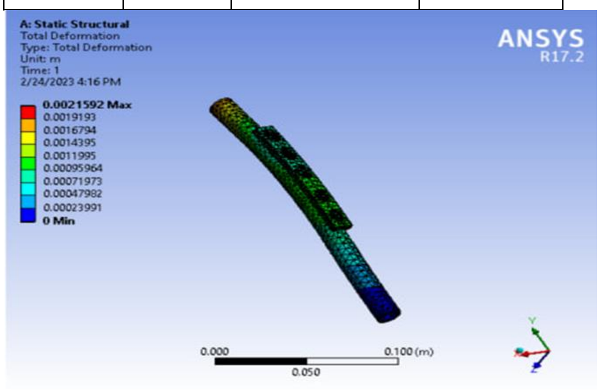


Figure (18): total deformation

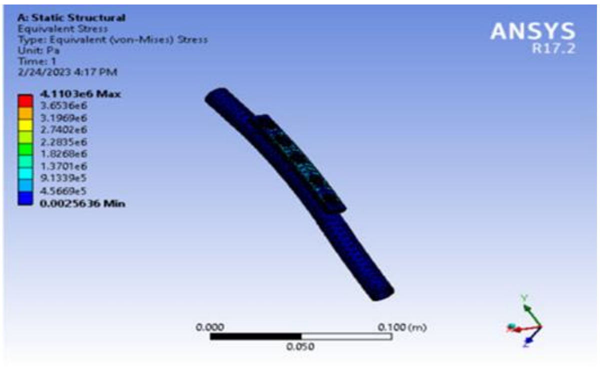


Figure (19): equivalent stress (Von-ises)

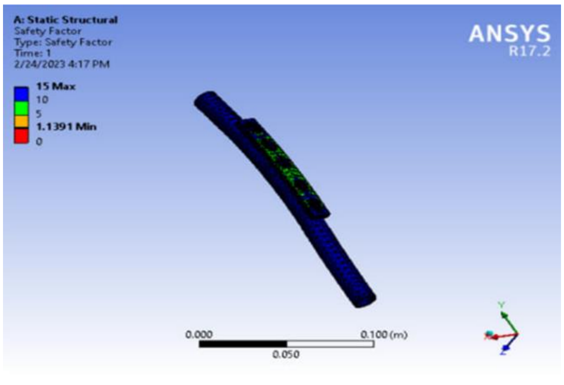


Figure (20): safety factor

The failure of a model of a hollow cylinder that assumes it as bone with a plate and screw in Ansys can be described in the following way when subjected to axial load and bending load:

When the model is subjected to an axial load, the plate and screw system is designed to provide stability to the bone and prevent any collapse or deformation under the applied load. However, the accuracy of the model depends on how well it represents the bone's mechanical behaviour. In reality, the bone is not a homogenous and isotropic material, but instead has varying properties throughout its structure, such as cortical and cancellous bone. The presence of these different bone types may affect the stress distribution within the bone and lead to areas of high stress that are not accounted for in the model. Similarly, when the model is subjected to a bending load, the plate and screw system is designed to provide stability against the bending moment and prevent any deformation or failure of the bone. However, the model's accuracy depends on the assumptions made about the bone's mechanical behaviour. In reality, the bone's mechanical behaviour is complex and nonlinear, depend on several factors such as the bone's geometry, material properties, and the orientation. In addition, the case of bending represented by Cantilever Beam, A cantilever beam may experience more deformation than other types of beams because it is fixed at one end and free at the other which means that it is subjected to a concentrated load at the fixed end.

7. Conclusions

The microstructure and mechanical test were done for sample composite from (polymer PMMA+3%hydroxyapatite).

1. Biodegradable materials are designed to break down naturally in the body over time, reducing the need for additional surgery to remove the implant.so biodegradable materials offer a safer and more sustainable alternative to traditional metal implants, reducing the risk of complications and promoting better long-term outcomes for patients.
2. Mechanical strength decrease because of agglomeration phenomena appears in Nano composites which causes cutting in the polymer chain depending on the synthesis method making a continuous porosity which has benefits in bone implantations to catalyse bone grown inside the implant, which is clear in the application failed in terms of bending. Using mixing method without vacuum technique reduce the mechanical properties of bone cement that leads to increasing in agglomeration.
3. Atomic force microscope (AFM) pictures show a roughness of the surface composites. This is important to the bone implant materials. The continuous porosity makes micro the composite to allow bone ingrowth, while roughness is important for adhesion of implant with the surrounding tissue of bone and improves Osseo integration with the existence of Nano particles.
4. Theoretical analysis shows that the safety factor is less than 1 when applying axial load at 13 N, and when applying bending load at 2 N, indicating that the structure may not be able to withstand these loads safely.

8. Recommendations

1. Studying the polymer composites and hybrids in vivo by implanting these materials in a bone of rabbit or mouse since these animals have bone tissue nearest to the human bone tissue is worthwhile.
2. Researching for biocompatible materials with better mechanical properties, to be utilized as reinforcements for the used material
3. Using the vacuum method in both mixing and mould the material to avoid the formation of agglomerates, porosity and to obtain better mechanical properties.

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