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# Developing Biodegradable Polymeric Composite for Nails Manufacturing of Bone Fracture Fixation

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*In Loving Memory of Late Professor Doctor ""Mohamed Refaat Hussein Mahran""*

**Abstract**
Biodegradable implants, a popular research focus, aim to address issues associated with traditional titanium and stainless-steel implants, including bone abnormalities and the need for additional surgeries. Our novel protein-based thermoplastic material, derived from blood albumin, serves as a promising biodegradable implant. Despite inherent weak mechanical properties in biodegradable materials, we enhance our biopolymer by incorporating reinforcing components like Nanoclay, PVA, and PLA. Three composite groups were tested, and various fabrication techniques were explored, revealing that dry casting with pure protein or 20% nanoclay concentration yields the best mechanical properties for bone fixation plates. The tensile strength of the dry casting plate is 8.3 MPa for pure protein. Our results indicate that this novel protein-based material, particularly with dry casting, presents a promising alternative to traditional fixation plate materials for pediatric or maxilla bone fractures with lower load requirements.
Keywords: Natural biomaterials, protein-based biomaterials, biodegradable implants.

## 1. Introduction

Healing of fractured bones requires stabilization allowing bone cell regeneration. Other bone fractures are complex and cannot be healed through ordinary external fixation or support but need internal fracture fixation using plates and screws. Nowadays, titanium (Ti) and stainless steel are the most often utilized materials for manufacturing plates and screws for implant internal fixation. Ti and stainless steel have excellent mechanical properties, allowing good bone fixation in place during the healing [1]. However, titanium implants have drawbacks such as temperature sensitivity, growth limitations, radiographic imaging interference, and stress shielding of the underlying bone [2-5].

The general idea that the strongest fixation properties give the best results for bone fracture healing does not always the right thing. The high mechanical properties which we denoted before as their main advantage can become a difficulty or disadvantage throughout the bone healing process. These high mechanical properties disturb the normal healing processes of the bone. The high strength and stiffness of these implants harm bones and can cause damage under the fixation plates [6, 7]. This phenomenon is called stress shielding results from the huge difference between the elastic modulus of these fixation implants and that of human bones creating a stress shielding effect around the bone fracture [8]. Metal implants have less bioactivity and less osteo inductivity that help fracture repair [9, 10]. Stress shielding may necessitate repeated operations to remove the bone implant fixation plates, causing additional health-care expenses and patient health hazards [11]. Because these materials do not degrade in the body, another surgical procedure is required to remove them in 5–38 % of cases [12].

Alternative materials for use in the fabrication of fracture plates and screws have been the focus of modern research. Biodegradable materials used for implant fixation have many advantages, including low elasticity modulus that is close to that of bone decreasing the stress shielding effect. These implants disappear from the body after a long time during bone healing avoiding the need for other surgeries to remove them.

Biodegradable fracture fixing implants have various advantages over stainless steel and Ti-alloy fixation. They have no corrosion behavior, no sensitivity, and a reduced stress-shielding effect since

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the implants transfer the load as they degrade gradually to bones during the healing process causing less pain [13–16]. During the degradation of the implants, the strength and stiffness of the polymeric implants decrease, permitting load transfer and bone regeneration.

Polymers are one of the most appealing materials that degrade in aqueous media [17]. The degradation behavior of polymers is a strong advantage that permits the polymeric implants disappearance during the healing process, eliminating the need for other operations to remove the implants. The most common disadvantage of using polymers is their poor mechanical properties compared to Ti or stainless steel. Polymers react with human living tissues producing foreign substances in the body [18] and need more implanting operation time more than titanium implanting. Clinical applications for polymeric fixation systems for bone fractures are not widely used [17]. The polymer plates have lower stiffness than that of Ti-alloy plates so they need to be thicker to compensate for this low stiffness to fix the healing bone.

Biodegradable materials can be improved or reinforced to limit the disadvantage of their less mechanical properties to increase bone stability. Self-reinforced polymeric composites enhance the strength of biodegradable polymer implants. Many tests are carried out to determine the best fixation materials, including mechanical test stands. The purpose of this article is to compare established fixing plate materials, such as Ti-alloy and stainless steel, to newer biodegradable materials. There are already more than 36 different biodegradable bone fracture fixation systems in compositions or mechanical properties on the market [18, 19].

More research focuses on Biodegradable polymers in many medical applications such as tissue engineering, drug delivery, and surgical implants [20-24]. Although biodegradable polymeric implants eliminate the need for a secondary surgical operation to remove as for permanent implants made from metal [25], A few types of biodegradable polymers have been approved commercially for humans in vivo applications as poly (lactic acid) (PLA) and poly (lactic-glycolic acid) (PLGA). One of the drawbacks of biodegradable polymeric medical applications is the formation of acidic byproducts causing cellular necrosis and bone resorption [26- 28]. Many researchers focus on limiting this side effect to permit use for clinical applications [29]. Scientists found that polymer composites such as poly (propylene carbonate) (PPC) and starch have degradation products that limit the effect on cellular necrosis and bone resorption [30]. Some polymers as PGS have good bending strength (122.01 ± 8.82 MPa) making them very suitable as bone fixation devices.

Natural biomaterials are substances that are natural in origin or substances that need modifications to be used for medical applications. Natural materials such as polysaccharides or proteins have many advantages as they are biocompatible, biodegradable, and also have excellent cell attachment, growth, and good ductility [31]. However, their main disadvantages are their poor mechanical properties and the formation of degradation products and impurities as endotoxins [32].

Protein-based biomaterials are one of the most interesting natural biomaterials. Proteins consist of recombinant proteins with amino acids that provide structural support [33]. Proteins are enormously present in natural sources such as vegetables and animals solving the problem of resources and costs. Proteins can be easily processed to generate new biodegradable plastics. Serum albumin is one of the most numerous protein sources, Serum albumin represents approximately 55% of blood plasma protein. Rhodes and Zolle prepared human serum albumin microspheres to determine abnormal pulmonary circulation for the first time using serum albumin in medical applications in the mid-twentieth century [34, 35].

As mentioned before Proteins can be easily modified to meet the requirements of many desired applications. One of the introduced processing methods of protein is subsequent polymerization for Serum albumin forming biodegradable plastic residuals (PBSA) as shown in (figure 4) [36]. This process could be applied to serum albumin taken from animal blood to synthesize novel biodegradable thermoplastic material [36]. It is a natural enormous source of polymers [37]. This thermoplastic material is excellent as it joins normal metabolism in the human body, making it very suitable for tissue engineering applications.

Our purpose is to use this novel material for the first time to manufacture bone fixation biodegradable plates. Natural protein-based polymers are hard to handle during manufacturing processes. We are aiming to investigate the most suitable technique for manufacturing bone fixation plates with the best mechanical properties using our protein-based material. Solvent casting, dry casting, and melting casting are the most common and popular techniques for manufacturing of bone plates and screws.

As mentioned before the most common disadvantage of using polymers is their poor mechanical properties compared to Ti-alloys. The addition of certain materials as nano-filler montmorillonite (Nanoclay) and graphene oxide can dramatically improve the polymer's mechanical properties. We are trying to investigate the effect of many additives on our novel material to increase its mechanical properties.

## 2. Materials and methods

### *2.1. Materials*

Polyvinyl alcohol (PVA) 87-89% hydrolyzed, solid particles, was purchased from the Alfa Aesar A Johnson Matthey Co., United Kingdom. PBSA particles are prepared by subsequent polymerization for Serum albumin. Nanoclay, surface modified contains 25-30 wt. % trimethyl stearyl ammonium powder was purchased from Sigma-Aldrich (Average Particle Size <_ 20 microns). PLA threads used in 3D printers were purchased from Ezzat New Tec, Co. Distilled water (DW) was used to prepare all aqueous solutions.

### *2.2. Methods*

#### *2.2.1. Preparation*

##### *2.2.1.1. Solvent casting method:*

Solvent casting or solution casting is a very simple technique that doesn't need complex equipment making it so popular. In general solvent casting technique includes the mixing of polymer with any compound or filler in suitable solvent using continuous mechanical stirring magnetic stirring or ultrasonic, then the casting step is followed by solvent evaporation or removal steps leaving the structure remains resulting in polymer composite [38].

As mentioned before the advantages of solution casting include the simplicity of manipulation without the need for complex equipment or complex systems such as extrusion or injection molding processes, avoiding fiber damage due to high temperature in melt-mixing process. The solvent casting for polymer composites doesn't require a very high temperature that affects the degradation rate of polymers. These advantages make fabrication beneficial for natural fiber reinforced to form polymer composites.

First, we perform further processing to convert the raw PBSA particles into soft powder. PVA/ PBSA / Nanoclay composite was prepared with different concentrations as shown in Table 3 for this purpose, the PVA amount was mixed with DDW mixed in a magnetic stirrer at (500 rbm) for 1.5 hours until complete dissolution. Then add nanoclay to the mixture during stirring for half an hour then add PBSA powder to the PVA/ Nanoclay mixture. The mixture was kept under stirring to form a homogenous mixture for another half hour at 80C to evaporate excess water. Then the mixture was poured into a plastic mould and placed in a hot oven at 80C for 3 h.

##### *2.2.1.2. Dry casting method:*

All components were strongly dry mixed manually to get the homogeneous mixtures. After mixing we put the BPSA powder composite prepared with different concentrations as shown in Table 1 in the steel mold. Apply a pressure of 150 Bar to the mold for 2 hours. The powder under the pressure bonded giving one piece that can be removed from the mold. We put the piece in the oven for 2 hours at 200 C ° to produce the desired specimens (figure 1).

Table 1: The percentage of the PVA/ PBSA / Nanoclay composite

| Exp | PBSA | Nanoclay |
|---|---|---|
| 1 | 100% | 0% |
| 2 | 80% | 20% |

Fig. 1. Pure PBSA circle and dimple shape specimens resulted from dry mixing

##### *2.2.1.3. Melting method:*

Since solvents have drawbacks, melt mixing solves most of the solvents issues as it is the most practical method used in industry. Melt mixing can be applied to the polymer processing industry to produce nanocomposites in mass production using devices such as extruders or mixers [39- 41]. The melting method is considered the simplest, and most economical technique for the fabrication of polymer silicates [42, 43], and clay/polymer nanocomposites of a thermoplastics polymeric matrix [44]. The manufacturing technique is simply relaying in combining or dry mixing the polymer with any desired amount of substance and applying heat to melt the mixture using Banbury or an extruder to form the desired polymer nanocomposites. Melt mixing has many advantages as the very excellent spread of the fillers in the polymer matrix, no need for organic solvents, and compatibility with popular industrial techniques such as extrusion and injection molding. However, melt mixing uses a temperature that should be performed carefully to avoid polymer degradation at a high temperature [45].

First, we melt the PLA threads on the metal sheet at low fire flame until it melts then we mix the melted PLA with PBSA, Nanoclay, and powder with concentrations according to table 2. Then we put the mixture in the mold and left it to dry at room temperature Figure 2.

#### *2.2.2. Mechanical properties testing*

Mechanical testing measures the properties of a material when force is applied to it to examine the properties of the materials as tensile strength, bending, fracture, and compressive strength as shown in Figure 3. A mechanical test shows whether the material can or cannot be suitable for use in the specific application.

Table.2: The percentage of the PBSA /PLA / Nanoclay composite

| Exp | PBSA | PLA | Nanoclay |
|---|---|---|---|
| 1 | 60% | 40% | 0% |
| 2 | 55% | 35% | 10% |

Fig. 2. PBSA / PLA / Nanoclay composites specimens resulted from melt casting


Fig. 3. The universal testing machine

The mechanical testing was performed using a Tinius Olsen Company, HK50KT (Philadelphia, USA) universal testing machine (UTM) having a maximum force of 10 KN at a crosshead speed of 300 mm/min.

***2.2.2.1. The tensile strength***

Tensile strength testing was performed based on the ASTM D638 standard [46] to measure the sample's tensile strength until failure. The properties such as ultimate tensile strength are measured and associated with the maximum elongation of the sample just before break. The samples for tensile tests of width were 1.5 mm, length was 30mm thickness of 2mm and speed was 10 mm/min. The test process is performed by placing the sample between the Jews of the grip tool of the tester and extending the Jews until the sample gets fracture.

***2.2.2.2. The bending strength***

Meanwhile, we performed the bending strength test based on ASTM D790 standard [47] using the same universal testing machine using a bending grip tool with a crosshead speed of 2.0 mm/min. Samples (1 × 2.5× 0.03125 inch) were bent with a crosshead speed of 10 mm/ min at ordinary room temperature.

We found that mechanical test methods were rarely described in sufficient detail as the type of test and the dimensions of the test specimen.

***2.2.3. Fourier Transform Infrared red spectroscopy (FTIR)***

PBSA specimen The FTIR spectra were measured on a Fourier Transform Infra-Red using Bruker VERTEX 80 (Germany) combined Platinum Diamond ATR, including a diamond disk as that of an internal reflector in the spectral range 4000–400 cm− 1 with resolution 4 cm− 1, refractive index 2.4. The result of transmittance values was determined.

***2.2.4. X-ray diffraction (XRD) analysis***

We determine specimen microcrystalline structure using XRD (Bruker D8 Advanced, Germany) at 40 kV and 40 mA at wavelengths of 20.095 Å and 27.175 Å. The result analyzed using DIFFRACT.SUITE software and standpoint with 2θ between 5_ and 80_ with 0.01_/step scanning rate.

***2.2.5. Scanning Electron Microscopy (SEM)***

We scanned PBSA specimen to observe its micromorphology using SEM (TESCAN VEGA 3, Brno Czech Republic) with an acceleration voltage of 20 kV. Specimen first was treated using liquid nitrogen and coated with gold before SEM analysis to inspect the fracture surface. The magnification was coordinated at 4,000 times scale to inspect the cracks of PBSA specimen after stress load.

***2.2.6. Biodegradability tests***

The Biodegradability test was applied according to ISO 10993-5 (section of Biological evaluation of medical devices and in vitro cytotoxicity tests) [48, 49]. Dry casting specimen samples were put into a tube filled with 20 mL of phosphate-buffered saline (PBS) at pH 7.3 _ 0.2 and then the samples were examined at 7, 14, 21, and 28 days and removed and dried at 90 C ° for 30 min until the weight becomes fixed. We checked the PH of the solution at each point (at 7, 14, 21, and 28 days) and measure the weights of samples at each time stage.

## 3. Results

### 3.1. Mechanical Properties

#### 3.1.1. Solvent casting

Applying tensile and bending tests gives the results summarized in Table 3. The addition of PVA to the PBSA/Nanoclay composite at concentrations 40% to 45% by weight increase tensile strength, and bending strength values as shown in Figure 4.

Table 3: The percentage of the PVA/ PBSA /MMT composite

| Exp | PBSA | PVA | Nanoclay | Tensile strength MPa | Bending strength MPa |
|---|---|---|---|---|---|
| 1 | 40% | 40% | 20% | 9.5 | 10.5 |
| 2 | 65% | 25% | 10% | 4.7 | 37.5 |
| 3 | 45% | 35% | 20% | 3 | 9.72 |
| 4 | 25% | 45% | 30% | 5 | 6.7 |

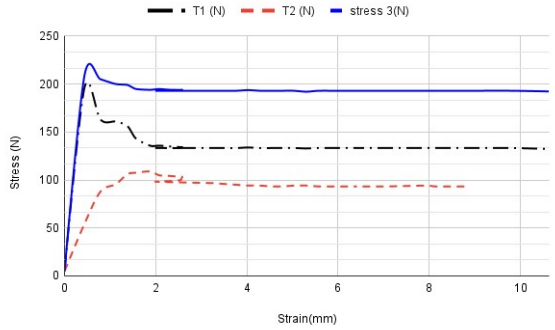


Fig. 4. The tensile strength resulted from different composite concentrations of PBSA / PVA /Nanoclay (T1(25%/ 45%/ 30%)) (T2(45%/ 35%/20%)) (T3(40%/ 40%/ 20%))

#### 3.1.2. Dry casting

Applying pressure of 150 Bar for 1 hour to dry powder of pure PBSA or PBSA / Nanoclay composite produce good specimens. Applying tensile and bending tests gives results summarized in Table 4.

Table 4: The percentage of the PBSA / Nanoclay composite

| Exp | PBSA | Nanoclay | Tensile strength MPa | Bending strength MPa |
|---|---|---|---|---|
| 1 | 100% | 0% | 8.3 | 5.6 |
| 2 | 80% | 20% | 6.25 | 2.78 |

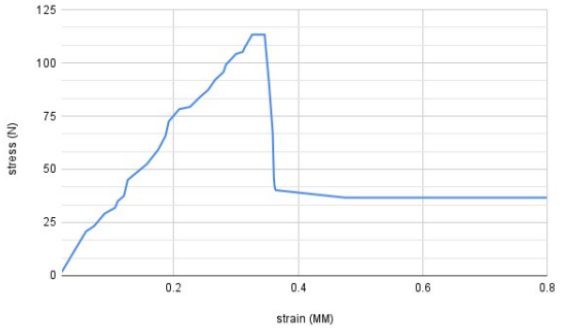


Fig 5. The tensile strength resulted from pure PBSA by dry casting.

#### 3.1.3. Melt mixing

Adding PLA to the PBSA to form composites at concentrations from 30% to 40% by weight as shown in table 6 reduce the tensile strength, and bending strength values (3.8MPa) as shown in Fig 6.

Table 5: The percentage of the PBSA / Nanoclay composite

| Exp | PBSA | Nanoclay | PLA | Tensile strength MPa | Bending strength MPa |
|---|---|---|---|---|---|
| 1 | 60% | 0% | 40% | 3.2 | 15.5 |
| 2 | 55% | 10% | 35% | 3.8 | 37.5 |

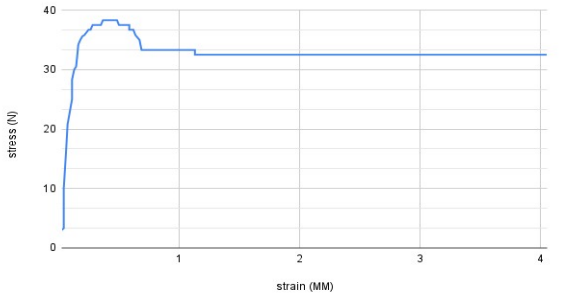


Fig 6. The tensile strength resulted from melt mixing (PBSA/PLA)

Table 6: Summery of mechanical tests results

| Materials | | Method | Tensile MPa | Bending MPa |
|---|---|---|---|---|
| Pure PBSA | | Dry casting | 8.3 | 5.6 |
| PBSA / PVA/ Nanoclay composite Concentrations | 65%/25% /10% | Solvent casting | 4.7 | 37.5 |
| | 40%/40%/20% | | 9.5 | 10.5 |
| | 45%/35%/20% | | 3 | 9.72 |
| | 25%/45%/30% | | 5 | 6.7 |
| PBSA / PLA composite | | Melt casitng | 3.2 | 15.5 |
| PBSA / PLA/ Nanoclay composite | | | 3.8 | 32 |

### 3.2. Fourier Transform Infrared red spectroscopy (FTIR)

Our specimen was observed using FTIR, as shown in Figure 7. We identified several absorption bands in the infrared range for pure PBSA specimen. The specimen was subjected to infra-red (IR) spectra between 422.80 and 3697.18 cm_1. As shown in Figure 7 there is strong absorption band at 3266.94 cm_1 and strong band of stretching peaks at 2919.55 and 2850.10 cm_1.

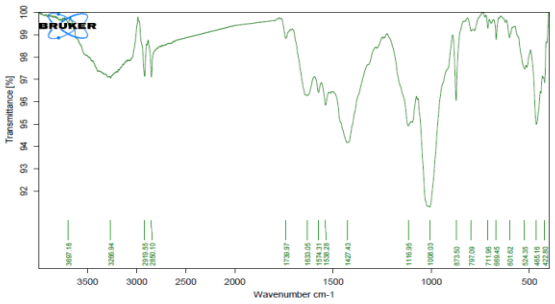


Fig 7. Fourier transform-infrared (FT-IR) spectra range for pure PBSA

Pure PBSA also recorded slightly absorption band at 1739.97 cm_1 followed by heavily strong absorption bands at 1633.05, 1574.31, 1538.28, and then larger absorption at 1427.43 cm_1. Pure PBSA is identified by very strong absorption band at 1008.03 cm_1 followed by several absorption bands at 873.50, 797.09, 711.96, 669.45, 601.62, 524.35, 465.16, and 422.80 cm_1.

### 3.3. X-ray diffraction (XRD) analysis

The diffraction pattern obtained from pure PBSA specimen is shown in Figure 8. The diffraction angle, 2θ, was presented from 5_ to 80_. From observing the figure, there is no characteristic peak in the diffraction pattern for pure PBSA indicating that the structure of PBSA is amorphous.

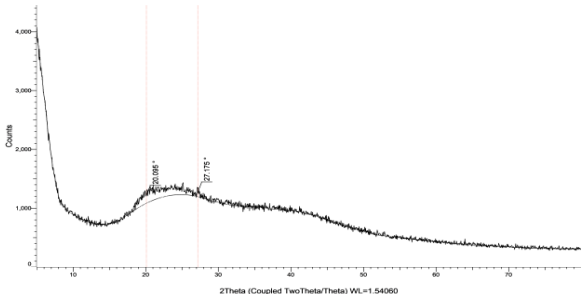


Fig 8. XRD analysis of the crystalline phase and molecular interaction of the specimen of pure PBSA

### 3.4. Scanning Electron Microscopy (SEM)

We Observed the micromorphology of the specimen after coating it with gold was observed with SEM (TESCAN VEGA3, Brno Czech Republic) with an acceleration voltage of 20 kV, Scale bar = 50 μm to inspect the fracture surface.

The magnification was coordinated at 4,000 times to observe the level of adhesion and cracks of specimen to figure the quality of manufacturing technique. The SEM images (Figure 7) visualize the cracks of specimen of pure PBSA after suffering loads test examining its mechanical properties.

By analyzing the SEM images for specimen, it is found that the pure PBSA were uniformly distributed, had a smooth surface and good straightness, the fracture surface of pure PBSA specimen showed uniform pores between grains. The SEM images show that the PBSA make evident cracks explaining the loss of strength under the load tests.

### 3.5. Degradation results

The mass degradation of the pure PBSA samples in the PBS environment is recorded. The degradation rate of samples at 7, 14, 21, and 28 days reveals that the samples degrade at around 3% rate. The samples degrade losing strength and shape after 9 weeks of observations.

## 4. Discussion

The biodegradable implant materials available commercially for medical uses according to US Food and Drug Administration are currently five biodegradable materials. The commercially biodegradable implants are made of PGA, PLA, PGA, and PLA [13]. Biodegradable fixation systems are ideal for bone fixation for pediatric fractures, but have not been approved to be used for the fixation of fractures in large bones in adults as titanium fixation systems.

Mechanical properties

Mechanical properties including Tensile and bending tests were performed to our PBSA specimens in order to examine their tensile strength, elongation break, and flexural strength. Pure PBSA using dry casting method gives 8.3MPa (as shown in Table 6) which is approximately good tensile strength compared to commercial biodegradable plates as PCL (12MPa to 35MPa with other materials addition) [48, 49].

Believing that we can further enhance the mechanical properties of our protein-based polymer, we subject it to other additives to explore the effect.

Our attempts to enhance the mechanical properties involve the addition of PVA to PBSA matrix at concentrations 25% to 40% by weight and Nanoclay at 20% to 30% by weight which consistently increases the tensile strength slightly (9.5MPa), and bending strength. The addition of Nanoclay to the PBSA matrix increases the brittleness of specimens reducing their tensile strength, and bending strength. We found that by adding PLA to the PBSA matrix at concentrations 30% to 40% by weight the tensile strength, and bending strength reduced (3.8MPa).

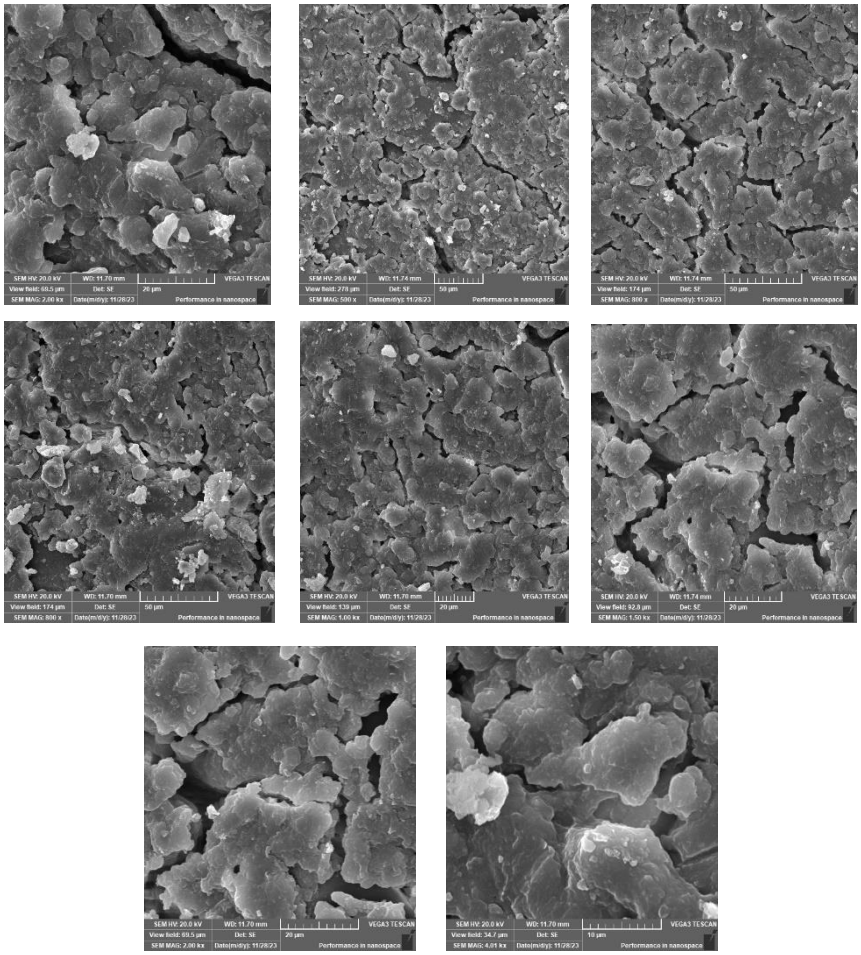

Fig 9. Scanning electron microscopy (SEM) images of the fractured surface of pure PBSA with different magnification powers after mechanical tests

Mechanical properties were reviewed for PLA, PGA, PCL, PDO, POE, PGA, PCL, and PLGA. All these biodegradable polymers are thermoplastic as our PBSA. Table 7 summarizes mechanical properties studies of varies commercials bone fixations systems. It provides comparisons of tensile strength and Flexure strength of common biodegradable implant material polymers with our PBSA.

Table 7: Summery of mechanical properties of materials used for bone fixation systems.

| Material | Tensile strength MPa | Bending strength GPa |
|---|---|---|
| Ti6Al4V | 860 | 110 |
| Stainless steel | 550 | 200 |
| Co-Cr alloy | 650 | 240 |
| Magnesium | 100 | 45 |
| Poly (glycolic acid) PGA | 340-920 | 7 |
| Poly (L-lactic acid) PLA | 80-500 | 2.7 |
| Poly (lactic-co-glycolic acid) PLGA | 40-55 | 2.0 |
| PCL composite | 12-40 | 7.59-35.33 |
| PVA/ PBSA /MMT composite | 9.5 | 37.5 |
| PBSA /Nanoclay composite | 8.5 | 5.6 |

From the table, most of the materials didn't reach more than 15% of the tensile strength of stainless steel except for PGA and PLA with reinforcement. The highest reported tensile strength (340 MPa) was for PLA. We here try to focus on PCL from all this commercial material because of many reasons, PCL is biocompatible, biodegradable, and has good flexibility. PCL has been used in medical applications since the 1930s [50]. PCL is now enormously used in tissue engineering including sutures, wound dressings, and drug delivery. PCL allows bone ingrowths, and regeneration in the treatment of bone defects [51-54], making it suitable for orthopedic application [55, 56].

What makes PCL very suitable for the bone fracture fixation is its degradation rate. Bone fracture healing usually takes between 9–12 months to heal in humans. PGA and PLA bone implants only maintain their

strength for less than 12 weeks before they begin to degrade [57]. PCL on the other hand maintain its strength more than 33 weeks [58], it has extremely slow degradation rate (24 months) until it begins to degrade after surgery [59, 60].

The long degradation time for PCL makes it is very suitable as a bone fixation system permitting bones fracture healing in humans. Acid-base changes regulate bone metabolism which play important rule in choosing biodegradable polymers. An acidic environment affects osteoclasts regulation up or down [61, 62]. The degradation of PGA and PLA produce lactic acid which reduces the normal bone healing process [63, 64]. The extremely slow degradation of PCL allows the fracture healing even before its degradation that affect the acid-base media which affect the bone treatment, so it extremely reduce the degradation effect providing a great advantages in as a bone fixation system.

Also, PCL shows drawbacks such as lower mechanical properties [65,66]. The known advantage that the high mechanical strength for fixation is the best choice for bone fracture fixation does not always true because metallic plates cause the stress-shielding effect. Biodegradable implants allow loads to transfer gradually during degradation to the healing bone permitting the bone to withstand the load as the fracture heals, preventing stress shielding [67]. Melt blending technique has been used to reinforce PCL with several materials as fillers [68]. The fillers addition improves the mechanical properties but increasing the filler content more than a certain level makes the PCL/fillers composites too brittle for clinical use [69].

PCL's prolonged degradation time, surpassing 33 weeks, makes it a compelling choice for bone fracture fixation compared to the 12-week strength retention of PGA and PLA implants [58]. It's extremely slow degradation rate (24 months) facilitates bone healing before degradation sets in, reducing the negative impact on acid-base conditions crucial for bone metabolism [59, 60]. While acidic environments from PGA and PLA degradation hinder normal bone healing, PCL's gradual degradation minimizes this effect, offering significant advantages in bone fixation systems [63, 64].

Despite PCL's lower mechanical properties [65, 66], the conventional notion that high mechanical strength is always optimal for bone fracture fixation is challenged, as metallic plates induce stress-shielding effects. Biodegradable implants, like PCL, enable gradual load transfer during degradation, supporting the healing bone and preventing stress shielding [67]. To enhance mechanical properties, the melt blending technique incorporates various fillers into PCL [68]. However, exceeding certain filler content makes PCL/fillers composites too brittle for clinical use [69]. Processing and fabrication techniques of polymers play important rule in their mechanical properties and their rate of degradation.

## 5. Conclusions

This study aimed to develop a PBSA composite system that can serve as biodegradable implant for medical applications. The implant can address bone fracture fixation in skull or arms, and fingers for adults which don't require much load. PBSA composite system is also ideal choice for bone fixation for pediatric fractures or adult fractures in maxilla bones.

In order to enhance our protein-based material, we introduce the combination of other compounds to it to form Composite biomaterials to combine the benefits or good properties of each component to address mainly the mechanical properties and bioactivity of implant. We combines Nano clay, PVA, and PLA with PBSA to form PBSA /PVA/Nano clay, PBSA / Nano clay and PBSA /PLA, and PBSA /PLA/Nano clay composites.

Based on an analysis of the mechanical properties of PBSA composites, PVA and Nanoclay increase PBSA mechanical properties, on other hands PLA decrease PBSA mechanical properties. Results were compared against commercially available biodegradable implant bone fixation materials, which are commonly used in the clinical applications. PBSA / PVA / Nanoclay were proven to be as effective as the commercially available biodegradable implants.

Future work should be focused on adaptability, enhancing the mechanical properties, and control the degradation rate of PBSA composite to be suitable for any desired application. The structure and properties of protein based material allow us to flexibly study fabrication techniques of PBSA composites to enhance mechanical properties. This study can serve as a solid base for further analysis and processing on PBSA to explore more medical applications. Further in vivo experiments in animals must be allowing the biodegradable PBSA fixation system to be placed with invasive for clinical application and record the outcomes. Comparisons should be implemented between PBSA implants and existing titanium implants for time taken in implantation surgeries and the degradation behavior of PBSA compared to PCL materials.

## 6. Conflicts of Interest

The authors declare no conflict of interest.

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