Fabrication of biodegrdable bone plates using polymer and nanocomposite matrix

Gopu Govindasamy, Srividhyasakthi Vijayakumar, Kavya P, Ranganayaki M and Sangavi M
Dept. of BME, Sri Ramakrishna Engineering College, Coimbatore, India.
***Corresponding author: E-Mail: gopu.govindasamy@srec.ac.in**

ABSTRACT

Owing to the frequent occurrence of bone fractures, it is important to develop fixation plates for fractured bones. Over 40 years composite material, plastics, and ceramic have been the dominant emerging material. The material used should be light weighted, compatible with human tissues and ought to allow stiffness. But these fixation plates used require further operation to remove it. This operation after fixation makes patient feel discomfort. In order to overcome this problem biodegradable fixation plates are used. For making this biodegradable bone plates, polymers and additives are used. The material is fabricated by compression moulding technique. The characteristics of fixation plates are observed through tensile test, compatibility and biodegradability test. The secondary operation can be avoided using these biodegradable plates which make patients to feel comfort and less pain. The materials used here are a biodegradable Polymer called PCL (Polycaprolactone), and an additive called Montmorillonite (a Nanoclay). The surface analysis study has been done by the FTIR (Fourier Transform Infra-red spectroscopy). The bonding of chemical groups is studied with the help of AFM (Atomic Force Spectroscopy).The use of the Montmorillonite along with the Polymer increases the strength of the material.

KEYWORDS: Fixation plate, Compatible, Biodegradable, Polycaprolactone, Nanoclay, FTIR, AFM.

1. INTRODUCTION

Bone tissue has the fortunate ability to regenerate itself unlike other tissues. If the fractured bone is held together, tissue can be regenerated and regain its original strength. For holding the fractured bone together bone plates are used Iron and steel were the most widely used employed material for making bone plates in the 1920s due to their tensile strength. However they rapidly they provoked erosion of adjacent bones and stainless steel are suitable only for temporary implant devices. By the 1930s, titanium was being used. It is light and has good mechanochemical properties and its strength per density is greater than other alloys. But titanium has poor shear strength and less desirable for making bone plates. The main disadvantage of all metallic implants is that a secondary surgery is required to remove the implant. The surgery itself could cause damage to the bone. Hence to overcome this problem we have employed biodegradable polymers along with a nano-filler which increases mechanical strength of a polymer for making bone plates. The polymer we used is PCL which has a longest degradation rate than any other polymer and the nano filler used is montmorillonite.

Bone injuries in fore arm: Forearm comprises of two bones radius and ulna. The ulna is located in the inner part of the forearm and ulna forms joints at the humerus (at the elbow) and along with the radius (near the elbow and wrist). Frequently in most cases, both bones get broken in adult forearm. Fractures often occur, near the wrist which is at the farthest (distal) of the bone, in the middle of the forearm and near the elbow which is at the top (proximal) end of the bone. The ulna is large at the elbow and it forms the point of the elbow and the radius is large at the wrist. The primary action of the forearm is the rotation motion which has the ability for flexion and extension of the forearm. Bone involved in forearm fracture will affect the ability of rotation of the arm, as well as bending and straightening position of the wrist and elbow. When forearm is fractured or even if the bone has punctured the surface of the skin, surgery is required. The fractured forearm is shown in Fig 1. The most common type surgical procedure for forearm fractures is open reduction and internal fixation with plates. During the repairing procedure, the fractured bone fragments are first repositioned into their original alignment. They are held together with bone plates which are attached to the outer surface of the bones.

Fracture of ulna bone: Ulna fracture is common in all age groups such as in elderly people, younger patients and even for athletes. Ulna fracture as shown in Fig. 2 can vary in location, severity and type. Patients with ulna fracture often experience a sudden onset of sharp elbow, intense wrist, and forearm pain at the time of injury. Ulna fracture results in swelling of; the wrist, bruising and intense pain on the affected regions of the bone. Pain even increases during certain movements of the wrist and positioning of the elbow, gripping or dropping during weight-bearing activity. This ulna bone fracture can be treated using bone plates (biodegradable bone plates, metal plates)[1]. If fracture is untreated it causes osteoporosis or bone tumor.

Need for polymer bone plates: In the case of severe fracture, bone plates are surgically implanted to hold the bone in place. It is common for broken bones (fractures) to be fixed with metal plates, especially if the fracture is unstable or the joint surface has been damaged (primary surgery). The role of the plates is to stabilize the fracture in the correct position while it heals. Once the fracture has healed, the plates which has been placed should be removed (secondary surgery). There are some disadvantages of using metal plates such that it produces corrosion and needs surgery for the retrieval of the internally fixed implant. But the use of polymer bone plates which is bioabsorable in nature are widely used. A bioabsorable polymer such as PCL is used in alternative to the metal plates. PCL is the excellent thermoplastic material and it undergoes hydrolysis to form metabolites in the human body. So it is widely used in the fabrication of bone plate applications.

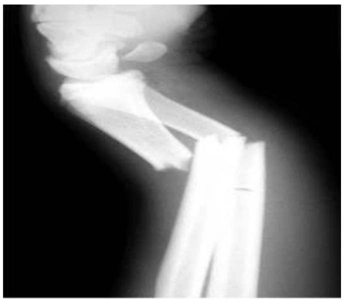

Fig.1.Fractured Forearm

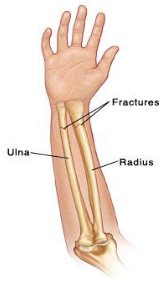

Fig.2.Ulna Bone Fracture

2. MATERIALS AND METHODS

While designing bone plates, design, material selection, biocompatibility, and biodegradability are the four important factors to be considered. The bone plates must be strong enough to support the load normally applied on the bone, while it heals. For the fabrication of the bone plates, polymer along nano-filler is used. Polymer such as PCL is a bio-resorbable polymer is used. It is semi-crystalline and has a low melting point of approximately 60 degree Celsius. PCL has high molecular weight and also it results in higher degradation rate. Due to the availability and cost of the PCL it is favorable to use it as a structural implant.

PCL Properties: PCL is biodegradable polyester with a low melting point of around 60 degree Celsius. The degradation speed of this polymer is less when compared to other polymer such as PLA (Polylacticacid), PLLA (poly L-lactic acid) and PGA (polyglycolicacid). Polymer PCL is biocompatible in nature because of these properties, PCL is chosen for our application. The polymer PCL is shown in the Fig. 3.

Fig.3. Polycaprolactone

Forearm surgical techniques: The normal surgical techniques involved in forearm repair are as follows:

Step 1: The surgeon exposes the surgical
Site by his preferred approach. If both the bones (radius and ulna) are fractured, the bone with simple fracture should be reduced first.

Step 2: Appropriate plate length is determined by pre-operative x-Ray templating and Fracture assessment. The selected plate is placed onto the bone such that the middle of the plate positioned over the fracture site, to optimize compression.

Step 3: Compression in the axial plane is ensured by the No locking bicortical screws. Screws of size 3.5mm are recommended for optimal fixation. Screws should be inserted by alternatively from one side of the fracture to other. The rotation of the forearm should be checked regularly during the procedure.

Step 4: Compression at the fracture site is given using the gold end of the offset drill in compression mode.3.5mm no locking screws are used for engaging at least 6 cortices on each side.

Step 5: The locking drill guide is Threaded into a locking hole in the plate to insert the 3.5mm locking screws. 2.8mm drill is drilled, measured for depth and 3.5mm locking cortical screw is inserted.

The polymer PCL which is a biodegradable polymer as said earlier hence we chose this polymer for our application. The PCL was bought from Sigma Aldrich. This high cost polymer is kept safe inside desiccators for preventing it from contamination. Mould is prepared with the given specification using MS(Mild Steel). 10g of Polymer PCL and 0.4g of montmorillonite is taken, and then the mixture is kept in a mould. The mould is kept in the compression molding machine gently as shown in the Table I. Further process is done by using compression molding machine under the pressure of 20,000 psi and temperature of 60 degree Celsius [7-12]. The sample material is taken out after the completion of the process. Then the sample material is underwent for further tests such as mechanical, biocompatibility and biodegradability test.

Table.1.Design and parameters

Materials	Temperature (ºC)	Pressure (psi)
PCL	65	500
PCL with nano clay	70-75	600-700

FTIR Studies: Infrared spectra of samples were obtained using an FTIR-Atr Spectrometer, Burker, Germany. The values obtained from FTIR indicates that the OH bond present in the Pcl lies with the wave number around 3500-3800 cm¯. FTIR spectra shows peaks of the ester bonds between 1500-1600 cm.

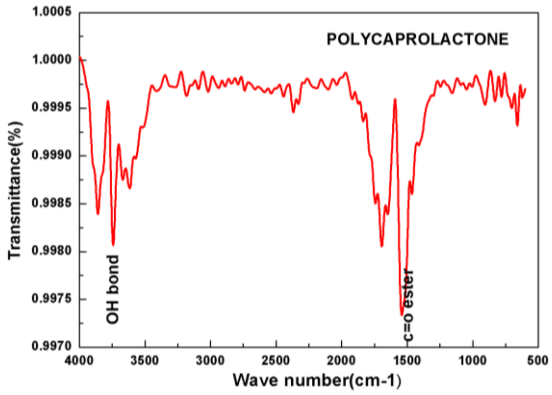

Fig.6.FTIR of PCL

Mechanical testing: Mechanical testing reveals the properties of a material when force is applied dynamically or statically. A mechanical test shows whether a material or part is suitable for its intended application by measuring properties such as elasticity, tensile strength, elongation, hardness fracture toughness, impact resistance, stress rupture and the fatigue limit.

Universal Testing Machine: The tensile and compressive strength of the material is measured using universal testing machine as shown in the Fig.4. A bicentric pressure distribution was found in the joint at 30 degrees to 120 degrees of flexion, with contact pressures of up to between 2.5 and 3MPa in the ventral and dorsal aspects of the ulna joint surface, but less than 0.5MPa in the centre.

Tensile Tester: Tensile testing is done to evaluate the samples tension strength until failure. With the help of tensile tester several properties of the material can be identified. The properties such as ultimate tensile strength are evaluated along with the maximum elongation and reduction in area of the sample. The test process involves placing the sample in the testing machine and slowly extending the jaws of the tester until sample gets fracture. The sample material with the length of about 40mm and thickness of 5mm is taken and the force is applied to it as shown in the Fig.5. Following results has been obtained using the tensile tester.

Fig.4.Universal Testing Machine

Fig.5. Material Placed in-between Jaws

3. RESULTS AND DISCUSSION

Result obtained for a sample plate contains polymer PCL and nano-filler montmorillonite. Result obtained for a sample plate contain polymer PCL only. The results obtained from the tensile tester shows that, tensile strength for the sample bone plate which is made up of only PCL is obtained as 44.6933 kg/cm3 but the tensile strength for the sample bone plate which is made up of PCL and montmorillonite is obtained as 153.5107 kg/cm3 .Thus the tensile strength of bone plates increases drastically by adding a nano-filler (montmorillonite) which is shown in the Fig. (7-10).

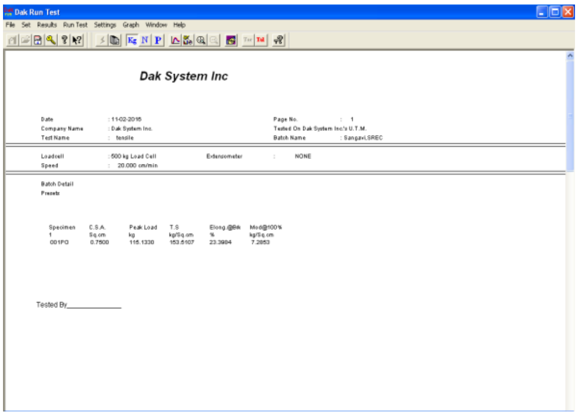

Fig.7. Tensile strength of PCL and MMT

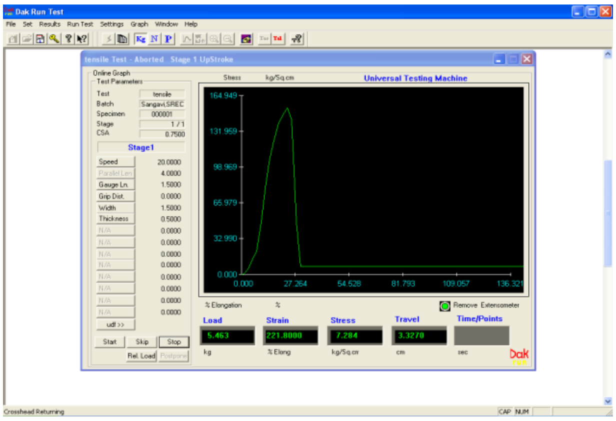

Fig.8. Stress curve obtained for PCL and MMT

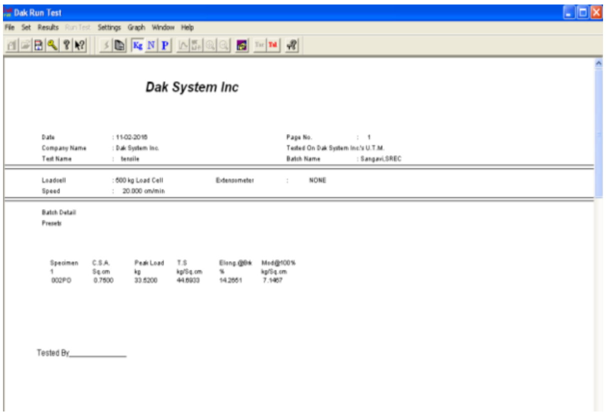

Fig.9. Tensile strength of PCL

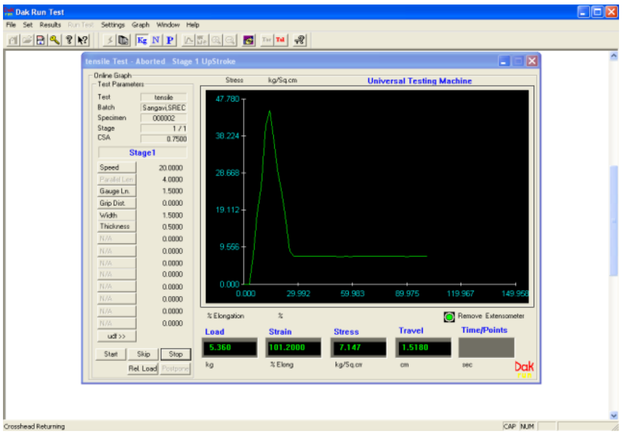

Fig.10.Stress curve obtained for PCL

Biodegradability testing: Biodegradability test is done by immersing bone plate in phosphate-buffered (PBS) saline solution maintained at (pH 7.4). The bone plate is of width 15mm, thickness 5mm, length 40mm. The buffer solution was changed every week under sterile condition [8-11]. The material was taken away, rinsed with distilled water under air dried atmosphere at room temperature of 37ºc. For every 24 hr the measurement of weight loss for 1 week is evaluated.

4. CONCLUSION

Biodegradable sample was initially prepared by using thin film casting techniques but the results inferred were not matches with our requirements. Secondly the cast was prepared under suitable pressure, temperature and atmospheric condition in the crucible. But the setting process of the material is not in uniform manner. Finally the material is compression molded and the results obtained were matches, which give the suitable mechanical and degradation properties as expected.

REFERENCES

Ashwinkumar, Properties of Biodegradable Polymers and Degradation for Sustainable Development, International Journal of Chemical Engineering and Applications, 2(3), 2011.

Georg Enislidis, KaanYerit, GerdWittwer, Robert Kohnke, Stefan Schragl, Rolf Ewers, Self-Reinforced Biodegradable plates and Screws for fixation of Zygomatic Fractures, Journal of Cranio -Maxillofacial Surgery, 33, 2005, 95–102.

Jin-Hae Chang, YeongUk An, Donghwan Cho, Emmanuel P. Giannelis, Poly (Lactic Acid) Nano-composites: Comparison of Their Properties with Monmorillonite and Synthetic Mica (II), Polymer, 44, 2003, 3715-3720

Bilewicz M, Polymer Composite Strengthen By Developed Injection Molding Technique, International Scientific Journal of Materials and Manufacturing Engineering, 30(2), 2008.

Mária Mihaliko, Miroslav Német, Elena Cižmáro-Materials Engineering, Analysis Degradation of Polystyrene with Nano-fillers, Acta Metallurgica Slovaca, 19(4), 2013, 254-260

Masahiro Funabashi, Fumi Ninomiya and Masao Kunioka, Bio Degradability Evaluation of Polymers, International Journal of Molecular Sciences, 10(8), 2009, 3635-3654

Medha Murali, Finosh GT, Jayabalan M, Studies on Biodegradable Polymeric Nano-Composited Based on Sheet Moulding for Compound Orthopedic Applications, Advances in Materials Science and Application, 2(2), 2013, 73-87.

Razak, SaifulIzwan Abd; Sharif, Noor Fadzliana Ahmed; Rahman, WanAizan Wan Abdul, Biodegradable Polymers and Their Bone Applications: A Review, International Journal of Basic and Applied Sciences, 12(1), 2012, 31.

Suzan Aline Casarin, Study of Invitro Degradation of Bioresorbable Polymers Poly Hydroxybutyrte CoValerate (Phbv) and Polycaprolactone (pcl), Journal of Biomaterials and Nanotechnology, 2, 2011, 207-215

Tatiana Patrico, Mechanical and Biological Behaviour of PCL and PCL/PLA Scaffolds for Tissue Engineering Application, The Italian Association of Chemical Engineering, 32, 2013

Vaidehee A. Deshpande, Preparation of Nano-Composites Based on Thermosetting Resins, The International Journal of Science and Technology, 3(4), 2015, 110-113