

EFFECT OF IMMERSION TIME TO MECHANICAL STRENGTH OF POLYVINYL ALCOHOL-HYDROXY APATITE COMPOSITE AS BIODEGRADABLE BONE PLATE

(PENGARUH WAKTU PERENDAMAN TERHADAP KEKUATAN MEKANIS KOMPOSIT POLIVINIL ALKOHOL-HIDROKSI APATIT SEBAGAI FIKSASI FRAKTUR TULANG)

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Abstract

Polymer based material such as Poly-L-Lactic-Acid (PLLA) have been used for titanium substitution. However, the last research indicates that it was not an ideal material as bone fracture fixation device. It is a challenge to develop other materials as biodegradable bone plate for titanium substitution, such as polyvinyl alcohol (PVA). In this study, polyvinyl alcohol has composited with Hydroxy apatite (HA) and reinforced with catgut fiber. The aim of this study was to know the effect of immersion time to mechanical strength of PVA-HA composite with catgut reinforced as biodegradable bone plate after biodegradation test for 30 and 60 days. Specimens were prepared for tensile and bending strength tests, immersed in phosphate buffered saline (PBS) solution with pH 7.4 at 37°C. Specimens were weighed before and after biodegradation test, tensile and bending test were done after removed for 30 and 60 days. The result showed that PVA-HA composite reinforced with catgut fiber has stable mechanical strength after 30 and 60 days biodegradation process. The mechanical strength decreased in 30 and 60 days in all intervention groups, but it still has adequate mechanical strength as biodegradable bone plate. In conclusion, PVA-HA composite reinforced with catgut fiber can be developed as biodegradable bone plate replace titanium and other commercial bone plate.

Key words: biodegradable, fixation, fracture, polyvinyl alcohol, hydroxy apatite

Abstrak

Penggunaan bahan polimer sebagai alat fiksasi yang dapat diserap tubuh seperti Poly-L-Lactic-Acid (PLLA) telah digunakan sebagai pengganti titanium, tetapi penelitian terakhir menunjukkan bahwa bahan ini bukan sebagai bahan yang ideal sebagai alat fiksasi fraktur tulang. Merupakan suatu tantangan untuk mengembangkan bahan polimer lain sebagai alat fiksasi yang dapat diserap tubuh sebagai pengganti titanium, seperti polivinil alkohol (PVA). Pada penelitian ini, polivinil alkohol dikompositkan dengan hidroksiapatit (HA) dengan anyaman serat *catgut* sebagai penguat. Tujuan penelitian ini adalah mengetahui pengaruh waktu perendaman terhadap kekuatan mekanis komposit PVA-HA sebagai fiksasi fraktur tulang setelah mengalami biodegradasi selama 30 dan 60 hari. Spesimen disiapkan untuk uji kekuatan tarik dan tekuk, direndam dalam larutan *phosphate buffered saline* (PBS) pH 7,4 pada suhu 37 °C. Spesimen ditimbang sebelum dan sesudah perendaman, dikeluarkan setelah periode 30 dan 60 hari dan dilakukan uji kekuatan tarik dan tekuk. Hasil penelitian menunjukkan bahwa komposit PVA-HA dengan anyaman serat *catgut* memiliki kekuatan mekanis yang stabil pada proses biodegradasi selama 30 dan 60 hari. Sebagai kesimpulan, komposit PVA-HA dengan anyaman serat *catgut* dapat dikembangkan sebagai alat fiksasi fraktur tulang pengganti titanium dan alat fiksasi yang bisa diserap tubuh komersial lainnya.

Kata kunci: biodegradasi, fiksasi, polivinil alkohol, hidroksiapatit

INTRODUCTION

Fixation device to correct facial and jaw bone fracture (bone plate) used stiff and rigid material from metal such as titanium, titanium alloy or cobalt chrome. In addition to its advantage, titanium as fixation device has also advantage such as very high mechanical strength and stiffness, leads to mechanical stimulus continuously that cause bone atrophy under plate that causes bone growth disorder particularly in children.¹ Other disadvantages include it will be easy to detect visually or palpable, screw loosening, sensitive to temperature², infection and interference with radiation therapy and imaging.³ Further studies showed that material caused distribution of metal ion on regional lymph nodes and induced allergic reaction.³ Some of these factors might require secondary surgery to remove the titanium bone plate, so use of the polymer material as biodegradable bone plate begins to grow.

Polymer based material for biodegradable bone plate such as Poly-L-Lactic Acid (PLLA) had some disadvantages due to its high crystalline during degradation process.⁴ Lactic acid monomer released during degradation led to cellular response in implant site, which facilitated releasing chemical mediator such as prostaglandin (PGE_2) by fibroblast and macrophage as the cause of bone resorption.⁴ Thus, the development of other polymer materials that has good biocompatibility and has mechanical strength as biodegradable bone plate like polyvinyl alcohol (PVA) will be a challenge.

Polyvinyl alcohol (PVA) is used to replace damaged and infected body tissue because it has physico chemical characteristic particularly biotribological characteristic (smooth surface, friction and wear resistance).^{5,6} The material has good biocompatibility in some biomedical applications such as drug delivery, contact lenses, bone graft, wound dressing, and used widely in the management of articular cartilage problems.^{7,8} Unfortunately, PVA does not have sufficient mechanical strength as bone plate, so in this study PVA has composited with hydroxyapatite (HA) to increase its mechanical strength. Hydroxy apatite is bioactive, osteoconductive, and good biocompatible materials.⁹ To increase stiffness, PVA-HA composite is also added with catgut woven, an absorbable wound suture material. The material obtained from sheep intestine and has been used widely in medical field including orthopedic for the closure deep tissue, so it should not be removed.

The aim of this study was to investigate effect of immersion time to mechanical strength of polyvinyl alcohol-Hydroxy apatite composite as biodegra-

dable bone plate after biodegradation process for 30 and 60 days. The result is expected for developing bio-degradable bone plate substitute titanium, so secondary surgery can be avoided.

MATERIALS AND METHODS

This study used PVA Mowiol grade 56-98 (Aldrich-Germany), a fully hydrolyzed (98.0-98.8 mol %) with viscosity at 52.0-60.0 mPa-s. PVA composited with calcite hydroxy apatite obtained by synthesizing calcite (CaCO_3) powder with diammonium hydrogen phosphate solution (DHP , $(\text{NH}_4)_2\text{HPO}_4$; Merck-Germany). In each specimen layer added with chromic catgut 2/0 plait, with horizontal orientation, five layers in each specimen. PVA and calcite HA powder were weighed according to its ratio. PVA was dissolved in distilled water in comparison 7.5% (w/v) using stirrer machine (95°C , 600 rpm, 30 minutes). After PVA dissolved, calcite HA was added, stirred and heated (60°C , 300 rpm, 60 minute). In prepared mold with catgut plait (Figure 1a), lay up was done layer by layer (Figure 1b). Each layer was heated using oven (70°C , 15 minutes) until it reached the layer and thickness desired. Specimen was heated using oven (70°C , 120 minutes), then it was removed from the mold (Figure 1c).

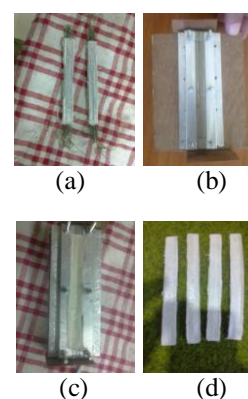


Figure 1. (a) Catgut fiber plait, (b) lay up process; (c) specimen with 5 catgut fiber layers; (d) specimens

There are four treatment groups (P) with the variation of concentration PVA-HA with catgut fiber, that were P1(80:20); P2(70:30); P3(60:40); P4 (50:50) and C(60:40) without catgut fiber as control group. To identify mechanical strength of specimen during degradation process, biodegradation test was done by immersing specimen in phosphate-buffered saline (PBS) solution at pH 7.4 and incubated at 37°C .⁹ In 30 and 60 days, specimen was weighed and performed for mechanical strength tests in-

cluding tensile (ASTM D 638-99)¹⁰ and bending test (ASTM 790-99).¹¹

RESULTS

Specimen was weighed before immersing in PBS solution and after 30 and 60 days period. Specimens was dried at 70°C for 2 hours, weighed and performed for mechanical strength tests.

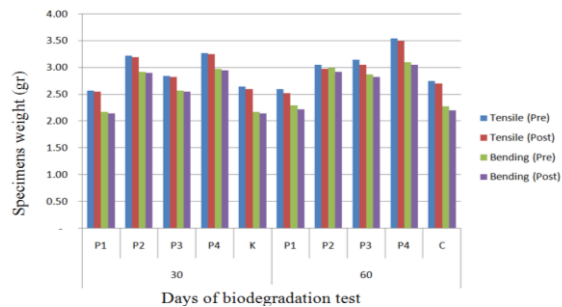


Figure 2. Weight loss of tensile and bending strength specimen after biodegradation test for 30 and 60 days

Table 1. Mean of tensile and bending tests after biodegradation test for 0, 30 and 60 days

Tests	P	n	Days			
			0	p	30	p
Tensile	P1	4	31.48 ± 2.26		28.57 ± 1.42	27.83 ± 2.91
	P2	4	34.85 ± 3.02		34.59 ± 1.28	32.46 ± 2.65
	P3	4	43.06 ± 0.18		40.21 ± 0.67	39.88 ± 1.13
	P4	4	37.96 ± 1.36		36.61 ± 1.28	35.99 ± 1.58
	K	4	14.04 ± 1.32	0.001	11.80 ± 0.80	10.78 ± 1.49
					0.001	0.001
Bending	P1	4	16.74 ± 0.72		11.95 ± 1.02	12.31 ± 1.01
	P2	4	21.09 ± 0.36		19.87 ± 0.90	18.79 ± 1.43
	P3	4	46.04 ± 2.57		34.56 ± 3.68	32.65 ± 2.62
	P4	4	26.92 ± 1.29		23.83 ± 1.49	22.82 ± 1.00
	K	4	10.51 ± 0.40	0.001	10.00 ± 0.27	05.97 ± 2.20
					0.001	0.001

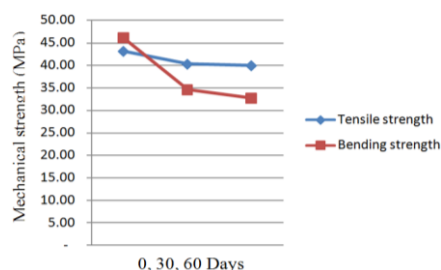


Figure 3. Decreasing in mechanical strength of PVA-HA (60:40) composite with catgut fiber after biodegradation tests at 0, 30 and 60 days

DISCUSSION

Biodegradable bone plate should be semi rigid, stable characteristic and degradable perfectly without various complications. During degradation process, the material should have sufficient strength until bone healing process. A clinical study showed some advantages of biodegradable bone plate such as decreasing mechanical strength and late aseptic swelling, osteolysis change in implant site, imperfect bone healing in mandibular canal.

Biodegradation is defined as cutting polymer chain to be oligomer and then to monomer. Polymer degradation process occurring begun with water inserted polymer mass marked with specimen swelling, triggering chemically degradation of polymer and caused oligomer and monomer formed. Progressive degradation changes micro structure of the mass through forming porous as the exit of degradation product, which has acid-base function. Releasing oligomer and monomer finally cause decreasing in specimen weight. Figure 2 indicates decreasing in specimen weight in all treatment group and controls during biodegradation test for 30 and 60 days. The decreasing specimen weight indicated biodegradation process has begun in this period.

There are two ways of biodegradation, passive process with hydrolysis and active process with enzymatic process. Most of the polymer degraded by hydrolysis process, while biopolymer such as polysaccharide, gelatin and collagen are degraded in enzymatic way. Some factors can influence the speed of biodegradation are chemical bound type, pH, copolymer composition and water content. Parameter used to monitor biodegradation besides the decreasing weight of specimen is a decreasing in mechanical strength.

Table 1 showed that control groups have mechanical strength below masseter muscle strength (tensile strength 14.04 Mpa; bending strength 10.51 Mpa) and there is a decreasing in mechanical strength far below standard at biodegradation test at 30 and 60 days. Table 1 also revealed that the addition of catgut fiber can be significantly increasing mechanical strength of PVA-HA composite ($p < 0.05$). Treatment group with PVA-HA (60:40) had the highest mechanical strength, and it was decreased in mechanical strength after biodegradation test for 30 and 60 days.

Based on result and discussion, it can be concluded that polyvinyl alcohol-hydroksiapatite composite with reinforced catgut fiber have sufficient mechanical strength after 30 and 60 days of biodegradation process. Polyvinyl alcohol hydroxyl apatite composite (60:40) with reinforced catgut

fiber can be developed as biodegradable bone plate substitute titanium and other commercial biodegradable bone plate. It is suggested for further study related to performed plate and screw prototype, include biocompatibility in vitro and in vivo tests.

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