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Durability of Biodegradable Internal Fixation Plates

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Abstract. In this work prototypes of internal fixation plates of acetabular fractures were developed and manufactured. The injection moulding was used to produce polymeric and composite samples. The plates and paddle-like beam samples made of polylactide and the polymer composite modified with 7 wt. % of tricalcium phosphate were produced. The samples were incubated in physiological fluids for 8 months. During the *in vitro* tests their durability and mechanical properties were determined. In comparison to the pure polylactide the addition of TCP accelerated degradation process. The degradation of the composite started after about 100 days of incubation, whereas the initial polymer began to degrade about 50 days later. The obtained biodegradable plates revealed sufficient mechanical properties for internal fixation of acetabular fractures for bone joining.

Introduction

Bone fracture is considered as one of the most frequent injuries in treatment of which plates, screws or nails are used to join separated parts of the bone. Recently, most of the fractures are joined with metal implants, which is due to their better mechanical properties. However, the applied metals and their alloys reveal some disadvantages which may have crucial effect on patient's health. It is known, that metallic materials can cause allergies or can be toxic [1]. In comparison to the bone characteristics most of them reveal misfits of mechanical properties as well as weak corrosion resistance. In consequence, re-operation is needed [2].

In order to overcome such inconveniences metals and their alloys are substituted by resorbable polymers. Properly selected chemical composition of the polymers leads to adequate matching of their resorption time with time of tissue regeneration [3-5]. In contrary to metallic materials, they show better biocompatibility and rarely cause allergy [6,7]. Moreover, they can be resorbed by the human body and decomposed to natural components. For that reasons operation for removing implants can be avoided. However, inferior mechanical properties can diminish their use especially for elements which are accounted for receiving a load. Up to now resorbable materials were successfully applied in maxillofacial surgery, because of relatively low loads acting in maxilla as well as in mandible areas [8].

One of the well known polymers applied in the regenerative medicine including bone surgery is polylactide (PLA). Application of pure polilactide was limited to areas which are not expected to bear high loads. In order to improve its properties several composites were manufactured. For example the introduction of bioactive additives such as tricalcium phosphates (TCP) can improve its biological properties as well as osteointegration with bone tissue [9,10].

Presented paper reports results of on implants made from the pure polilactide and its composites with tricalcium phosphate. The implants in the form of plates can be applied in stabilization of fractured pelvis.

Materials and methods

Two series of internal fixation plates of different compositions were prepared (Fig.1). One series of the plates was made from the pure polylactide (PLA, NatureWorks, Ingeo 3051D) and the second contained 7 wt% of tricalcium phosphate (TCP, Sigma Aldrich) and was marked as PLA/TCP composite.

The plates were produced by injection moulding. The granulated PLA polymer and the TCP powder were dried at 50°C for 2 hours, and then the PLA was mechanically mixed with the TCP powder and injected into a casting mould. The injection was carried out at 160°C in the vertical injection moulding machine Multiplas.

Fig. 1 PLA/TCP (left) and PLA (right) plates –flat and finned side

In order to get information about durability and stability in water environment the studied materials were incubated in the Ringer's solution at 37 ± 1°C for 8 months.

During the incubation pH of the solution (CP-411, Elmetron) as well mass of the plates were measured. Surface of the plates was examined with optical microscope (Lynx LED Genration Beta) and scanning electron microscope (Nova NanoSEM 200, FEI). Wettability of the materials surface was characterized by the contact angle determined by the static sessile drop method (DST10, Kruss).

Mechanical properties of the plates i.e. tensile strength and Young's modulus were determined by tensile test carried out using Zwick 1435 universal testing machine. In this case paddle-shaped samples were used, which were produced using the same procedure as the plates. The paddles were incubated in distilled water at 37 ±1°C for 8 weeks, which is required time for receiving a stable joining of the fracture.

Results and discussion

Figure 2 shows changes of the pH in Ringer's solutions during incubation of the PLA and the PLA/TCP plates. For the TCP/PLA plates pH was 6.5 and remained constant up to 100 days, and after that time it dropped to 3. In the case of the PLA plates, pH of the solution was 6.5 and it was stable up to 120 days and then also dropped to 3. It indicates that, the addition of TCP accelerated the degradation process, probably because the presence of many polymer-ceramic phase boundaries facilitated penetration of the material by the solution. In the case of the composite plates acidification of the environment appeared after 3 months of the incubation, whereas the pure polylactide plates remained stable for one month more, and pH of their incubation solutions was similar to initial pH of Ringer's solution.

Changes of mass of the plates measured during the incubation also revealed faster degradation of the PLA/TCP composite (Fig. 3). The maximum increase of its mass, which could be related to the incorporation of water into the sample, was observed after 4 months, while for the pure PLA plates such increase was noticed after 5 months. After that time a significant decrease of the mass related to the degradation process was observed. The observed decrease of mass after 6,5 months was 2% and 6% for the pure PLA and the PLA/TCP composite, respectively.

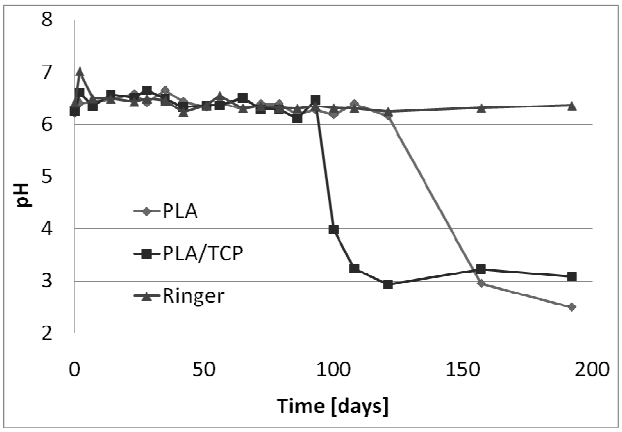

Fig.2 pH of Ringer's solution vs. incubation time of the PLA and PLA/TCP plates

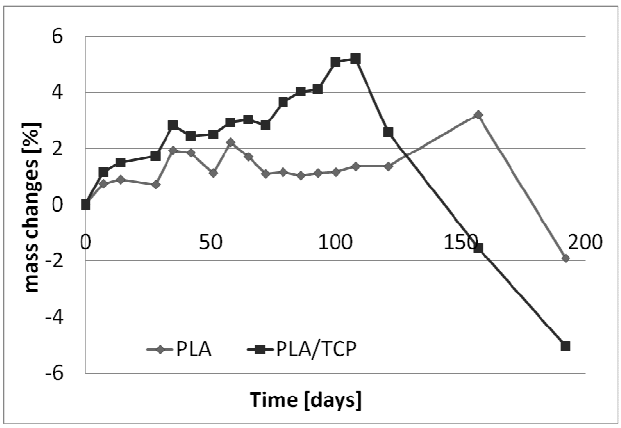

Fig.3 Changes of mass of the PLA and PLA/TCP plates vs. incubation time in Ringers solution

Generally the addition of 7 wt% of TCP did not influence mechanical properties of the polymer (Fig. 4 and 5). Tensile strength and Young's modulus of both materials were comparable before and during the incubation tests. After two weeks of the incubation tensile strength of the materials increased by 20%, and their Young's modulus increased by 50%, which could be related to water absorption and formation of hydrogen bonds between the polymer's chains.

After 8 weeks of the incubation values of tensile strength as well as Young's modulus decrease to its initial state. It is assumed that 6-8 weeks are necessary to achieve fracture joining. During that time it is expected from the fixation elements to maintain stable and sufficient mechanical properties. After 6 weeks the bone tissue starts to rebuild and create its structure following load distribution [11].

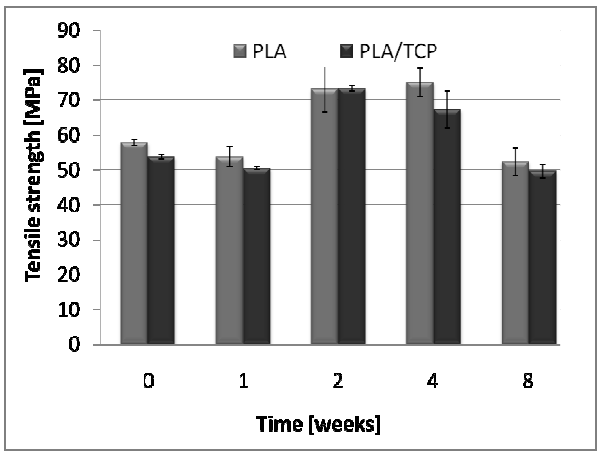

Fig.4 Tensile strength of the PLA and the PLA/TCP composite vs. incubation time

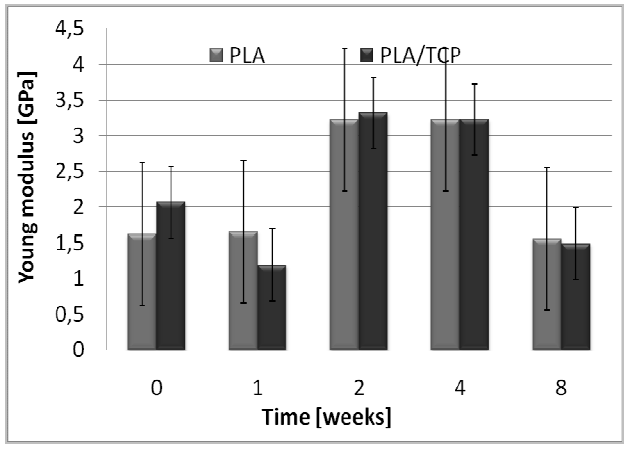

Fig.5 Young's modulus of the PLA and the PLA/TCP composite vs. incubation

Progress of the degradation process was confirmed by observations carried out with the optical microscope. Figure 6a shows surface of the plates after 8 months of the incubation. The PLA plate changed optically from transparent to white and opaque, but its surface remained smooth. In the case of the TCP/PLA composite cracks appeared on its surface. After 8 months of the incubation both materials revealed poor mechanical porperties and were very brittle.

Additional observations carried out with SEM (fig. 6b) revealed microstructure inhomogeneities in varius areas within both materials after the incubation. The degradation inside the samples proceeds faster than on their surface. After such long incubation time grains of TCP were not observed, and only empty holes remained that the TCP particles were used as the polymer matrix

reinforcement which means that, durign the incubation they were completely resorbed. The appearance of pores may be considered as an advatage in the human body environment, since it facilitates formation of stable biological bonding in which the implant can be overgrowth with the bone tissue.

a) b)

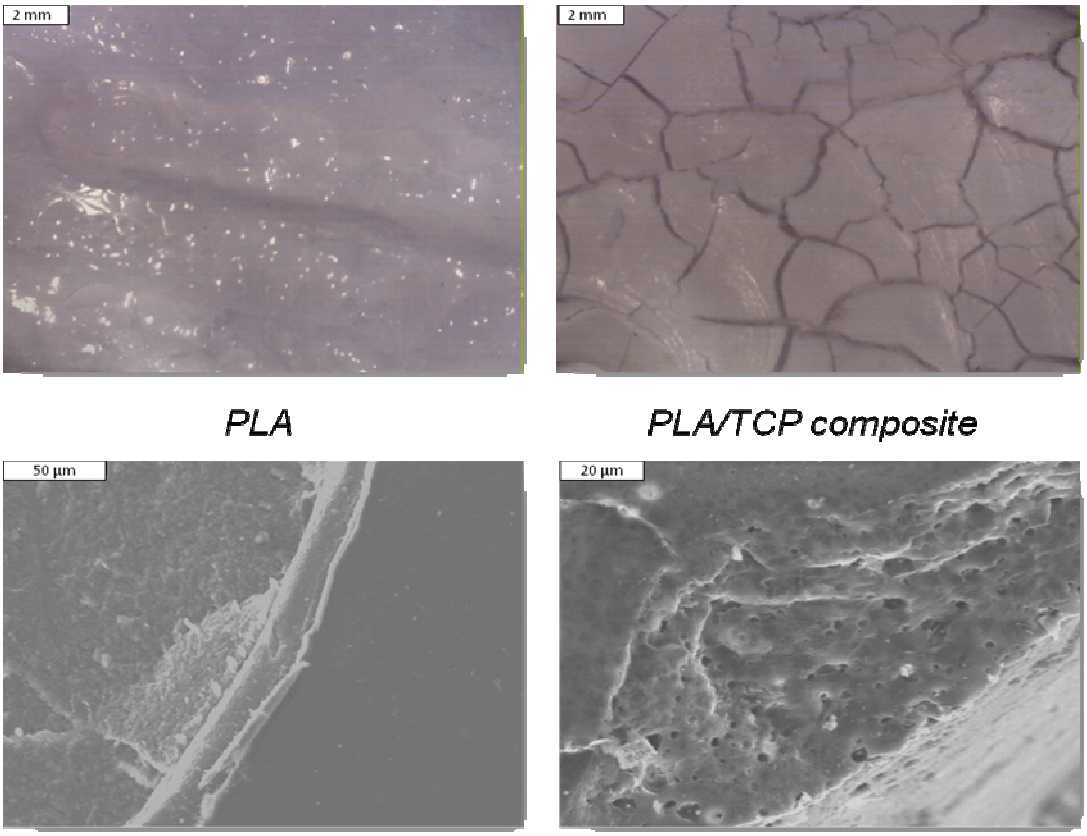

Fig. 6 Microscope (above – optical, below – SEM) images of; a) PLA, b) PLA/TCP plates surface after 8 months of incubation in Ringers solution

In the case of both materials changes of their wettability after 8 weeks of the incubation were small. The contact angle decreased of about 40% (Fig. 7), which is a desirable phenomenon from the point of view of the material resorption. Hydrophilic character of the material and the presence of cracks can facilitate its penetration by the liquid and additionally accelerate its resorption.

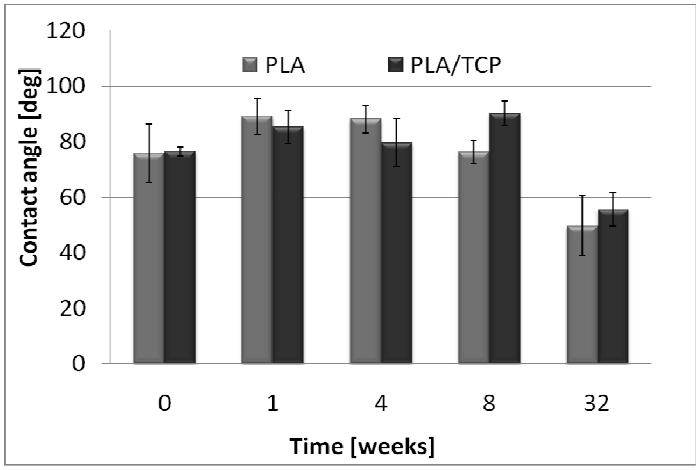

Fig. 7 Contact angle of the PLA and the PLA/TCP materials during incubation in Ringers solution

Conclusions

The obtained results can be summarized by the following conclusions:

1. The addition of TCP into the polylactide matrix accelerates its degradation process in water environment. The degradation of the composite started after about 100 days of the incubation, whereas the initial polymer began to degrade about 50 days later.
2. The modification of the polylactide matrix with 7 wt% of TCP allows to obtain composite with mechanical properties comparable to that measured in the pure polymer and sufficient for internal fixation of acetabular fractures.
3. Mechanical properties of the PLA and PLA/TCP plates remained stable for the assumed bone joining time i.e. 8 weeks.

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