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Influence of the intramedullary nail preparation method on nail's mechanical properties and degradation rate

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ABSTRACT

When it comes to the treatment of long bone fractures, scientists are still investigating new materials for intramedullary nails and different manufacturing methods. Some of the most promising materials used in the field are resorbable polymers and their composites, especially since there is a wide range of potential manufacturing and processing methods. The aim of this work was to select the best manufacturing method and technological parameters to obtain multiphase, and multifunctional, biodegradable intramedullary nails. All composites were based on a poly(L-lactide) matrix. Either magnesium alloy wires or carbon and alginate fibres were introduced in order to reinforce the nails. The polylactide matrix was also modified with tricalcium phosphate and gentamicin sulfate. The composite nails were manufactured using three different methods: forming from solution, injection moulding and hot pressing. The effect of each method of manufacturing on mechanical properties and degradation rate of the nails was evaluated. The study showed that injection moulding provides higher uniformity and homogeneity of the particle-modified polylactide matrix, whereas hot pressing favours applying higher volume fractions of fibres and their better impregnation with the polymer matrix. Thus, it was concluded that the fabrication method should be individually selected dependently on the nail's desired phase composition.

1. Introduction

The obvious advantages of intramedullary osteosynthesis, such as: a good stabilization of bone fragments guaranteeing elasticity of the fixation, minimal damage of the surrounding tissue and low surgical risk, make it a significant and valuable method of long bone fracture treatment [1–6]. Metals are frequently used for intramedullary nails, e.g. stainless steel and titanium alloys [7]. Metal implants, however, have to be removed from the organism after they have fulfilled their task. Therefore, a patient needs another surgical intervention, which involves negative medical and financial consequences. Moreover, although the mechanical strength of metallic nails is fully satisfactory for bone stabilization (the bending strength of stainless steel 316L is in the range of 240–770 MPa), their Young's modulus is too high in relation to the bone's ($E = 193$ GPa for 316L and $E = 110$–114 GPa for Ti6Al–4V, while $E = 10$–40 GPa for bone) [8,9]. This significant disproportion causes stress shielding and inadvisable changes in natural bone biomechanics, that can further lead to bone resorption and cause bone fracture [10]. Taking all these factors into account, it is clear that resorbable nails can be endowed with more desired mechanical properties creating better internal fixation devices. In the field of resorbable biomaterials, there is a large selection of medically approved degradable polymers [11–15]. However, due to the low strength of the pure polymers, a polymer-based reinforced composite would be more appropriate for use in intramedullary nails. The greatest advantage of composites is the fact that their properties can be easily tailored to required specifications therefore, it is possible to obtain composite nails of mechanical parameters fitted to the bone properties. A gradual transfer of load from the biodegradable nails to the bone, without stress shielding, should allow proper bone healing with the added benefit of no necessary additional surgery for implant removal.

One of the first attempts at applying resorbable materials for intramedullary osteosynthesis was undertaken by Saikku-Bäckström et al. in 2004 [16]. The tests involved using a copolymer of 96% L-lactide and 4% D-lactide (PLA96). The work was performed using

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intramedullary nails with SR-PLA96 applied together with Kirschner wires, which were implanted in the fractures of the femoral bone neck of large animals (sheep).

The manufacturing and processing methods used in creating polymer composites are key in the control of mechanical properties. Such parameters as homogeneity, interphase bond strength, and distribution of modifiers can be changed depending on the type, volume fraction, and properties of applied additives [17,18]. On the other hand, the form of modifiers can determine the processing method. The more diversified the phases in the composite, the more difficult the choice of an optimal processing method and its specific parameters [17].

This work constitutes an attempt at the development of intramedullary nails made of resorbable polylactide reinforced with resorbable magnesium alloy wires or long fibres (alginate and carbon fibres were used). All the applied phases demonstrate the ability of full or partial (in the case of carbon fibres) degradation. It has already been proven by the authors that carbon fibres, after their fragmentation, are able to assimilate with the bone tissue and, moreover, stimulate its growth (the apatite's nucleation begins at the surface of the fibres) [19–23]. Another group of material that were applied were magnesium alloys, which are becoming more and more popular among researchers in the fields of orthopaedics and bone surgery [24–28]. The most important merits of magnesium alloys are: superior mechanical properties to polymers (higher strength and Young's modulus with value similar to that of bone), as well as biocompatibility and biodegradation in the environment of a living organism. The polylactide matrix was also modified with tricalcium phosphate and gentamicin sulfate. These additives are responsible for biological properties described in the authors' previous work [29].

In this work, different multiphase, biodegradable intramedullary nails were manufactured using three various methods. The applied methods were: forming from solution, injection moulding and hot pressing. Authors focused on assessing the influence of the particular fabrication method and its technological parameters on the mechanical properties and degradation behaviour of the nails.

2. Materials

2.1. Initial materials

The following materials were used to manufacture composite nails:

— poly-L-lactide (PLA) — Ingeo™ 3051D, NatureWorks® LLC;
— long carbon fibres (CF) — Toho Tenax America, HTS 5631 (tensile strength of 4.3 GPa, Young's modulus of 238 GPa and elongation of 1.8%);
— long calcium alginate fibres (Alg) — Department of Material and Commodity Sciences and Textile Metrology of Lodz University of Technology. The fibres were formed by the wet solution method applying a 7.4% sodium alginate solution in water. The solidification and tension process was performed in a 3% $CaCl_2$ bath (fibre diameter of 17 μm, tensile strength of 220.8 MPa, Young's modulus of 12.7 GPa);
— magnesium alloy wires (Mg) — Leibniz University of Hannover, Institute of Materials Science. The wires differed in diameter and a composition of an alloy:

• MgII — $d_{MgII} = 0.97$ mm, magnesium alloy with the content of: aluminium 3%, lithium 9%, and calcium up to 1%;
• MgIII — $d_{MgIII} = 0.5$ mm, magnesium alloy containing the main elements: aluminium 5.5–6.5%, zinc 0.8–1.5% and the trace elements up to 1%: lithium, rare earth metals (an alloy addition obtained as rare earth metal ore), and calcium;

— tricalcium phosphate (TCP) — Sigma-Aldrich® ($Ca_3(PO_4)_2 \geq 96.0\%$);
— gentamicin sulfate (GS — *gemtamicini sulfas*) — Interforum Pharma wholesaler in Krakow.

2.2. Composites

Two main groups of composite nails can be specified:

I. PLA reinforced with Mg alloy wires

• PLA/Mg/GS
• PLA/Mg_{II}/GS

II. PLA reinforced with CF and Alg fibres — to map the anatomic structure of the bone, the fully degradable alginate fibres were placed inside the intramedullary nails, while the partially degradable carbon fibres were placed outside

• PLA/CF
• PLA/CF/Alg
• PLA/CF/Alg/GS
• PLA/CF/Alg/TCP/GS

➢ Pure PLA nails and PLA modified with TCP and GS were tested as reference

• PLA
• PLA/TCP/GS

3. Methods

3.1. Fabrication methods

Three different methods were used to manufacture designed composite nails: forming from solution (S), injection moulding (IM) and hot pressing (HP). The nails were fabricated in two sizes:

• small nails suitable for rabbit femoral bone — 2.5 mm in diameter, 100 mm long;
• large nails suitable for human forearm bone — 4.5 mm in diameter, 150 mm long.

3.1.1. Forming from solution

Polymer solution was prepared by dissolving PLA in dichloromethane CH_2Cl_2 (POCH) (40 g/100 ml), and then adding gentamicin sulfate distributed in 100 ml of the same solvent. In the next step alginate fibres were preliminary saturated with the PLA + GS solution and pulled through 1 mm cylindrical form to create the nail's core. After the solvent evaporated, a carbon outer layer was formed — alginate core was covered with uniaxially oriented carbon fibre rovings. The whole sample was then saturated with the polymer solution and pulled through a 2.5 mm cylindrical form (it was repeated three times).

Samples were left overnight to allow the solvent to evaporate and after that samples were cut into 100 mm nails (2.5 mm in diameter).

Nails of the following phase composition were obtained by forming from solution: PLA + CF + Alg + GS (S) — polylactide matrix modified with carbon fibres (20 wt.%), calcium alginate fibres (20 wt.%) and gentamicin (12 mg per implant) (Fig. 1A).

3.1.2. Injection moulding

Using the injection moulding method, pure polymer or polymer with tricalcium phosphate nanoparticles and/or gentamicin powder (dependent of the nails' phase composition) was plasticized at 160–170 °C and then injected in a vertical screw injection moulder (MULTIPLAS).