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Mechanical and radiological behavior of a bioresorbable polymer during *in vivo* degradation. An *in vivo* rat study to develop an Internal biliary stent to reduce biliary complications after liver transplantation.

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Abstract

Background:

Benefit of implantation of an internal biliary stent (IBS) during liver transplantation to reduce biliary complications was recently demonstrated [1]. Silicone IBS was used in practice, which require an endoscopic ablation procedure, a potentially morbid intervention for the patient [2]. In order to avoid this, and to reduce biliary complications after liver transplantation we develop a resorbable IBS, made from a radiopaque and degradable polymer visualizable by X-ray. The objective of this study was to evaluate mechanical and radiological behavior of this polymer during *in vivo* degradation after rats implantation.

Methods:

PLA₅₀-PEG-PLA₅₀ triblock copolymer was used as polymer matrix, in which was incorporated the X-ray visible triiodobenzoate-poly(ϵ -caprolactone) copolymer (*PCL-TIB/PLA₅₀-PEG-PLA₅₀*) component in order to make the compound visible by X-rays [3]. Polymer sample corresponding to a dogbone tensile specimen (36x6x0.6mm) were implanted in the abdomen of 17 rats. At each degradation time (1 week, 1 month, 2 months, 3 months and 6 months), a X-ray scanner was performed with contrast intensity and implant volume measurements. The specimens were then explanted to perform ex-vivo biomechanical tests. The mechanical tests consist in a load at two strain levels (5% and 10%) with a strain rate during loading of 1% per second followed by a tensile relaxation test. There were realised with a *Mechanical Tensile Service*[®] machine with a load cell of 25N, in physiological conditions (physiological serum immersed tests at controlled temperature of 37°C). A histological study at 3 and 6 months was also performed.

Results:

About radiological characteristics during degradation, the contrast intensity and the implant volume were stable over time up to 6 months (between 1000 and 2000 Hounsfield Units for the contrast intensity and 75 mm³ of median volume). The mechanical properties were tested between zero and 2 months, the evolution of the viscoelasticity of the materials was studied. After this period, mechanical tests were impossible due to the extreme brittleness of the specimens. Histological analysis indicated good tissue integration without major inflammation.

Conclusion:

In this study, radiological and mechanical behaviour of *PCL-TIB/PLA₅₀-PEG-PLA₅₀* biopolymer was describe during *in vivo* degradation, in order to allow development of an IBS to reduce biliary complications after liver transplantation.

References:

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