Performance of Non-Solvent Processed Biodegradable Polymeric Scaffolds : An Animal Study for Orbital Reconstructive Surgery

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1. Introduction

In recent years, there has been a growing interest in using porous implant for orbital reconstructive surgery. Application of various forms of biodegradable polymeric scaffolds are also being investigated and the long-term clinical studies have demonstrated the potential for the successful use[1]. Most biodegradable scaffolds were produced by using solvent in one way or other during processing. Hence, not only the process lengthy but a strict quality control becomes necessary to ensure the level of solvent elimination. In order to solve this problem, we developed a novel method to fabricate biodegradable porous scaffold implant without using solvent[2]. In this abstract, *in vitro* mechanical properties and the results from *in vivo* animal study are presented with regard to the tissue growth into the newly processed scaffold.

2. Materials and Methods

Poly(L-lactic acid) and Poly(glycolic acid) were obtained as milled particles(10-500 μm) and the viscosity of PGA was estimated to be 40,000 poise (240℃, shear rate of 10/sec) while PLLA had the weight average molecular weight of 180,000. The pharmaceutical grade salt (NaCl) crystals of 300 μm average size was obtained from Duksan company as the elimination source. In the first step, polymers were meshed and uniformly filled in the mold, applied predetermined time-pressure schedule after being heated to range of temperature between T_g and T_m of each polymers. In the second step, formed polymeric sample was placed in the mold between salt crystals and again being applied predetermined time-pressure schedule above T_m of each polymers. Samples were cooled to

room temperature, washed in dynamic distilled water below T_g of each polymers to remove salt particles, and vacuumed to eliminate residual water. An animal study was performed using the rabbit model in durations up to 6 months were studies. The scaffold was taken out from the rabbit at every one week period and observed under the scanning electron microscopy(SEM).

3. Results and Discussion

Tissue ingrowth into scaffold began after 1 week time, and the porous were completly filled within 2 weeks. period. Figure 1 shows the original morphology of the porous implant and an interconnected open cell structure is clearly illustrated. The cell shape and the size are similar to original salt crystals, hence indicating a way by which the cell shape and size can be controlled. Scaffold taken out after 4 weeks clearly indicated high content of material ingrowth (Figure 2). At higher magnification the filled material is clearly seen to be fibrous, thus indicating the presence of successful tissue ingrowth. Bone tissue ingrowth was observed to occur at about 4 months, hence demonstrating the feasibility of the present scaffold to be used in the orbital restructive surgery.
Pathological examination did not indicate the presence of any side effect.

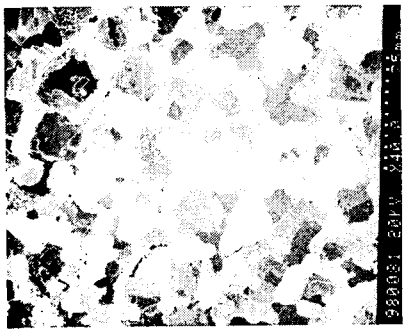

Figure 1. Open cell structure of non-solvent processed porous scaffold.

Figure 2. SEM photographs of tissue growth into PLLA scaffold (4 week).

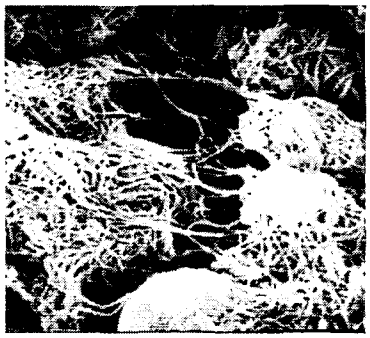

Figure 3. SEM photomicrographs of
tissue growth into PLLA scaffold(×10,900).

4. Conclusions

PGA and PLLA based polymeric scaffolds are produced by a non-solvent processing method. The technique is simple and involved the use of salt as the removable component and steps of temperature-time-pressure schedules predetermined from thermal characteristics of polymers. The animal study showed a successful tissue and bone ingrowth into the pores of the scaffold at different times and no side effect was observed. Hence, indicating the feasibility of the present scaffold to be applied in the orbital restructive surgery. The advantage is clear in that not only the lengthy process of solvent method necessary but polymers such as PGA can also be easily converted to scaffold without the use of solvent.

References

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2. S. W Choi and H. Y. Kim, Biomaterial Research P-28(1998).