HIGH- STRENGTH BIORESORBABLE POLYLACTIDE FIBERS - PRODUCTION AND PROCESSING

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Introduction

Standard in surgical treatment of bone fractures is the use of metallic implants made out of bulk material with well defined mechanical characteristics, but without the ability to be resorbed nor to be radiolucent. A new generation of implants could, however, be seen as implants made of composite structures, either made of a single material or multiple materials, made of resorbable polymeric structures. This requires that these composite implants have mechanical properties close to, or equal to those of to date used metallic implants. Methods used in the production of metallic implants, as forging, casting or machining, however, are not well suited for the construction of bioresorbable composite implants. These problems could potentially be solved if highly oriented bioresorbable polymeric fibers are transformed into high-strength composite implants. The objective therefore is, to produce high - strength monofilaments made of resorbable polymers or co-polymers. Those monofilaments would then be used as basic building blocs for the construction of implant - structures.

Batch #	Polymer	Nozzle Ř [mm]	Nozzle temp [şC]	Fiber Ř [mm]
1	poly(L/DL)	0.5	203	0.40 ± 0.05
2	poly(L/DL)	0.3	205	0.22 ± 0.02
3	poly(L/DL)	0.5	214	0.62 ± 0.03
4	terpolymer	0.5	227	0.55 ± 0.08
5	terpolymer	0.5	227	0.50 ± 0.05

TABLE 1. Extruder parameters.

Materials and methods

Polymers

Polymers used in the study were poly(L/DL-lactide) 80/20% with a viscosity-average molecular weight of 160.000 dalton (PURAC CCA, Holland) and a terpolymer with a viscosity-average molecular weight of 370.000 dalton developed in our institution, based on L, DL-lactides-glycolide (PURAC CCA, Holland). Both polymers were dried to a constant weight under vacuum before melt extrusion into monofilaments with diameters between 0.2 and 0.65 mm (Brabender, Plasticorder PL 2100) (TABLE 1). The monofilaments were then subjected to hot-drawing.

Hot-drawing device

Hot drawing of the monofilaments was done with a custom made tool, equipped with feed roller, heater and drawing roller (FIG.1). The feed roller had a range of 0.25 m/s-1.0 m/s and the drawing roller a range of 1.85 m/s-8.95 m/s. The resultant draw ratio therefore was between 1.85 and 35.8 respectively. The temperature range of the heater was between 50°C and 175°C. The different rollers and the heater were microprocessor- controlled with an accuracy of ± 0.025 m/s of the rollers and ± 0.2 °C of the heater. The drawing zone had a total length of 210 cm with a heater zone of 6 cm in the middle. The relaxing zone was 13 cm and the takeup speed of the bobbin was equal to the speed of the drawing roller. The fibers were drawn with different draw-ratios and heater- temperatures (see TABLE 2).

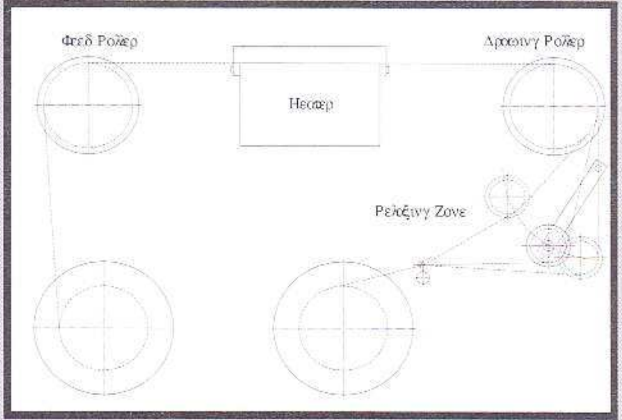

FIG. 1. Hot drawing device.

Testing

After treatment, the fibers were tested for their mechanical properties as tensile strength and Young's Modulus. The tests were done with a commercial test- rig (Instron model 4302 tester, High Wycombe, Bucks, England). The sam-

Batch #	Polymer	Draw ratio	Initial fiber Ř [mm]	Drawn fiber Ř [mm]	Heater temp. [oC]	Initial strength [MPa]	Strength drawn [MPa]	Modulus [MPa]
1	(L/DL)	8	0.4±0.05	0.18±0.02	135	62±2	549±25	6151±466
2	(L/DL)	8	0.22±0.02	0.1±0.02	125	61±4	692±65	7040±650
3	(L/DL)	9	0.62±0.03	0.26±0.04	155	50±18	595±60	6080±471
4	terpolymer	10	0.55±0.08	0.15±0.02	135	67±17	591±56	6630±1170
5	terpolymer	10	0.50±0.05	0.19±0.05	135	57±2	553±52	6560±560

TABLE 2. Hot-drawing conditions and mechanical parameters

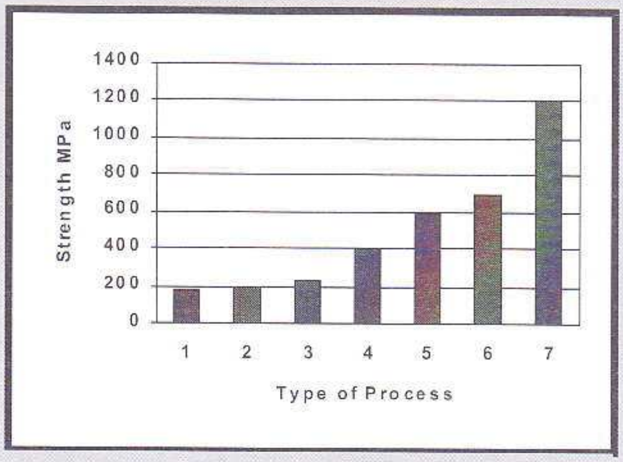

FIG. 2. Strength and elastic modulus of different monofilaments

Process	**oung's Modulus [GPa]**
1: Injection molding	**4**
2: Solid state extrusion KIST	**8.4**
3: Solid state extrusion SF & SG	**14**
4: Maxon monofilament	**0.9**
5: Author monofilament batch 3 & 4	**6**
6: Author monofilament batch 2	**7**

ples were clamped with fiber clamps with a grip distance of 100 mm. The load cell used had a range of 0.1 kN and an accuracy of 0.001 kN. The crosshead speed was 20 mm/min. The tests were carried out using three samples of each material and the average of the three values was used for further data- processing.

Results

Monofilaments with a tensile strength of >500 MPa and a Young's Modulus of >5500 MPa could be produced by hot- drawing of the melt- extruded material when drawn with a draw ratio of 8...10 and temperatures between 125 and 155°C. These conditions guarantee a continuous monofilament production. The strength of the monofilaments produced by the authors is more than twice of that reported in the literature (FIGURE 2).

Discussion

By hot-drawing, the fiber diameter was reduced by a factor of 2 to 2.5. To manufacture thin fibers, the initial fiber diameter needs therefore to be kept low. The limiting factors however are the processing parameters of the extruder, like nozzle diameter, pressure and temperatures. The strength of the monofilaments can further be increased if the thermo- oxidative degradation upon melt extrusion is diminished. The high- strength, high- modulus polylactide monofilaments can be transformed into high- strength internal fixation devices by solvent welding [8].

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EXPERIMENTAL MODEL FOR STUDYING EFFECTIVENESS OF TREATMENT AND PROPHYLAXIS PROCEDURESS ON THE BEGINNING AND DEVELOPPING OF PURULENT-INFLAMMATORY PROCESSES

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For many years the problem of purulent-septic *complications* stays one of actual as for clinics of cranio-maxillofacial surgery as well for other stomatological and surgical clinics. Nature of purulent complications evaluation has been changed within last years. Very often we meet hard forms of purulent infections when purulent process is located in some anatomic regions and have severe complications which cause danger for human life. That situation makes to elaborate new preventive, treatment and prophylaxis procedures, so there is necessity to do medico-biological examinations to appreciate effectiveness of some treatment procedures and to compare them.

Aim

of this research is to elaborate experimental models for studying effectiveness of treatment and prophylaxis procedures on the beginning and development of purulent-inflammatory process.

Materials and methods

Guinea pigs have been subjected into the experiment which has been performed on 21 animals of the same weight and age. Animals have been operated according to the same