BIORESORBABLE PERIPHERAL VASCULAR STENT WITH SHAPE MEMORY EFFECT

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Introduction

Peripheral Arterial Disease (PAD) is primarily affected by the deposition of fat and calcification in the Legs arteries and is called atherosclerosis. PAD more common in the legs than the arms. Approximately 8.5 million people in the United States have PAD. General population awareness of PAD is estimated at 25%, based on prior studies [1]. The treatment of this illness mostly is a peripheral angioplasty which is a low invasive procedure. Under local anesthesia the fatty plaque or blockage is pressed against the peripheral artery walls using balloon or in some case balloon with stent. Nowadays, the peripheral stents are mostly NiTi alloys made which may affect the problems for patients because these stents are no degradable and stay with the patient for whole life. Any accident which may cause uncontrolled press in implanted stent area provides serious patient life risk.
Therefore the bioresorbable peripheral vascular stents have potential in the treatment of PAD.
The present result contains the part of work on manufacturing bioresorbable peripheral vascular stents with shape memory effect [2].

Materials and Methods

The vascular stents were prepared via microinjection of terpolymer lactide based using the MicroPower (battenfeld) mould injector

Results and Discussion

The stents manufacturing parameters allow to produce well repeatable shape. The primary set of MicroPower (battenfeld) equipment has possibility to inject polymers only in one stage of mould cooling. The hot material goes to heating mould(temperature of mould was near Tg glass transition of polymer). The elements were released easily from mould but high shrinkage of material generates deformation in key point of stent structure (FIG. 1A), which affect in shape crimped stent on balloon (FIG. 1B). This effect was observed because the stream of material in mould was cooled down too fast and reach temperature of shape memory transition in situation when mould was being filled. The problem could be solved in two way: preparation of post-processing procedure or change the system of mould cooling. Both methods were checked. During post-processing conditioning of stents in special grips were held the stent shape in correct position (FIG. 1B and FIG. 2A) but the material morphology was changed. The DSC thermal curve of conditioned stents revealed increase of crystallinity. These conditioned stents were also determined at in vivo test (the pig was used to this investigations). The results of it are presented in FIG. 2. B. shows the implanted stents behaviour after highly strength spasm of pig vascular and (down position of picture in FIG. 2B) shape stent recovery (temperature of shape transition similar to the body temperature).

Summarized of this experiment, the selected conditioning parameters (post-processing) allow to obtain stents with good working shape memory effect which was proofed at in vivo tests. The second way of solvatation of the problem of shrinkage is remodelling of set equipment (MicroPower Battenfeld) which was done and the experiment is still going with satisfying results of preliminary experiments.

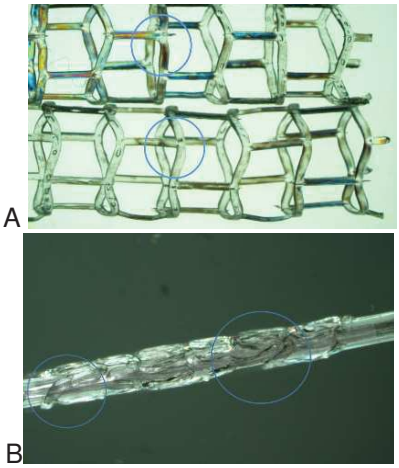

FIG. 1. A) stent with shrinkage effect and stent after post process conditioning, B) crimped shrinkage stent on catheter balloon with observed not regular deformation.

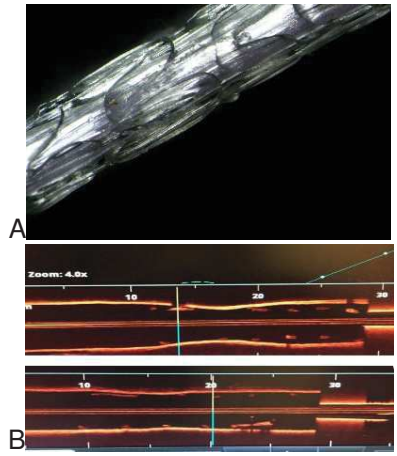

FIG. 2. A) crimped stent on catheter balloon with regular correct deformation, B) optical coherent tomography (OCT) image of a longitudinal section of pig leg vascular with stent during self-opening. (UP position) start opening, (down) full opened.

Conclusions

Presented results show next step forward to solve problem in PAD, nevertheless the production whole range of diameters/ lengths stents is unfortunately out of mould injector hardware limits.

Acknowledgments

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References

[1] Allison MA, Ho E, Denenberg JO, et al. Ethnic-specific prevalence of peripheral arterial disease in the United States. 2007 American Journal of Preventive Medicine 2007;32:328-333.
[2] Lendlein, A., Kelch, S., 2002. Shape-Memory Polymers. Angew. Chem. Int. Ed. 41,
2034-2057.