EVALUATION OF N,N-DIMETHYLACETAMIDE LEVEL IN POLYURETHANE IMPLANT ELEMENTS MANUFACTURED IN DIP-MOLDING PROCESS

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Introduction

Polyurethanes are the excellent biomaterials used in many medical applications, particularly in cardiovascular implants, such as artificial heart diaphragms, vascular grafts etc. ChronoFlex AR/LT (prod. AdvanSource Biomaterials, USA) are polycarbonate urethanes designed for dip-moulding applications [1] and have confirmed biocompatibility properties. These unique materials are fully synthesized in solvent such as N,N dimetyloacetamid (DMAc). The thin membranes are manufactured within the dip-moulding process, as the part of long-term implant device. The level of DMAc concentration in the final implant element is one of the technological and biological problem, which has to be solved for clinical application. The final product must be biocompatible and the maximum level of residual DMAC acceptance is: 1090 ppm [2].

Materials and Methods

The aim of the study was the DMAc level concentration measurements in polyurethane Chronoflex AR/LT thin elements manufactured in the dip-moulding process in Artificial Heart Laboratory.

The DMAc residual concentration examination in polyurethane samples collected form final implant elements, was performed by gas chromatography analysis. The samples were selected from the different areas of implant element (membrane elements with different surface topography and thickness, n=6 for each area). The measurements were performed for classical and modified polyurethane elements washing technology made after dip-moulding process. The DMAc content was analysed after polyurethane samples extraction in water. Calibration experiments were performed using a number of samples basing on the sample enrichment method. Measurements were performed for samples with a known amount of the substance added (DMAc) as well as for research samples.

The polyurethane sample (approximately 0.2g) was placed into 20µl of water (measuring sample) for DMAc extraction. The extracted DMAC was analysed utilizing: PerkinElmer Clarus 500 gas chromatograph with chromatographic column HP-INNOWAX (30cmx0.53mm x1µm).

Results and Discussion

The DMAc level obtained in the elements manufactured with the modified washing technology is presented in TABLE 1.

The DMAc residual content in the thin elements manufactured in the dip-moulding process depends on samples thickness and surface topography. DMAc level for samples taken from the “mirror” (thickness 0,32mm) ranges from 200ppm to 330ppm; for samples taken from the “sphere” (thickness: 0,35mm) ranges from 120ppm to 280ppm and for samples taken from the “ring” (thickness 0,38 mm) ranges from 410 ppm to 990 ppm. The study shows that the highest concentration of DMAc is in samples taken from the ring (the thickest area of implant element manufactured within the injection process). However, the measured values qualifies the whole product (implant element) as conform and safe in the aspect of biocompatibility connected with the maximum accepted level of DMAc.

TABLE 1. DMAc content level.

No.	DMAc cont. [ppm] in mirror	DMAc cont. [ppm] in sphere	DMAc cont. [ppm] in ring
1	220	120	460
2	220	130	410
3	220	140	600
4	280	280	990
5	200	130	410
6	330	170	490

Conclusions

DMAc residual content analysis in the elements manufactured with Chronoflex AR/LT in the dip-moulding process, has shown that the solvent content does not exceed the required level of 1090 ppm, staying on the level about from 10% to 60% of maximum accepted value. The tests have confirmed the Chronoflex AR/LT elements utilisation in the long-term implants.

Acknowledgments

Tests performed within the commercial project.

References

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