POLYURETHANE FILTRATION AS AN EFFECTIVE METHOD OF MATERIAL CLEANLINESS IMPROVEMENT FOR IMPLANT APPLICATIONS

BARBARA ZAWIDLAK-WĘGRZYŃSKA*, MAŁGORZATA GONSIOR, MACIEJ GAWLIKOWSKI, ROMAN KUSTOSZ, ADAM JAROSZ, MONIKA LEWCZUK, LECH CZERWIŃSKI

PROFESSOR ZBIGNIEW RELIGA FOUNDATION OF CARDIAC SURGERY DEVELOPMENT, POLAND
*E-MAIL: BZAWIDLAK@FRK.PL

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Introduction

Polyurethanes (PUs) are a gold standard biomaterial for medical devices applications due to its good biocompatibility [1]. Different PUs are used in pulsatile cardiac assist devices and total artificial heart prostheses (FIG. 1) for long-term utilization up to few years [2-4].

A B C

FIG.1. Pulsatile heart prostheses: A - BerlinHeart EXCOR [3], B – ReligaHeart EXT [2], C – CARMAT TAH [4].

Irrespective of detail heart prostheses design, the main parts of pulsatile prostheses made from PUs are elastic membranes responsible for blood flow in the prosthesis. The membranes have usually thickness below 1 mm and make analogical work to heart muscle, pumping from 40 to 80l of blood in every cycle, with frequency from 40 to 120 beats per minute. Therefore the elements should have extremely wear resistance for multiply work up to few millions cycles in biological active blood environment. PU membranes freedom of any contaminations and inclusions is one of the most relevant factor in order to confirm safety and reliability of the final device. The double filtration method was developed for PU solution cleanliness improvement for clinical utilization.

Materials and Methods

PU ChronoFlex AR/LT (AdvanSource Bomaterials, USA) is used for thin membranes manufacturing by dipping technology. Silica particles were observed in PU, derived from nano-silica aggregates added to the material during its manufacturing process. Size of inclusions observed in PU had been unacceptable for implant manufacturing, therefore the special double filtration process was developed in order to improve PU purity. The filtration process was performed in clean-room area in closed technological stand (tight cabinet) in argon atmosphere, with stain-less steel disposable removable filtration different sizes mesh utilization.

Thin foils (0.4 mm) of ChronoFlex AR/LT before and after double filtration process were examined. The following material properties were tested before and after filtration: viscosity (HAAKE Viscometer E), solid content, molar mass using GPC (DAWN HELEOS Wyatt Technologies and RI detection WGE Dr. Bures) and glass temperature using DSC (TA Instruments DSC2010) as well as mechanical properties - tensile strength, stress at break, elongation at max. tensile stress and elongation at break (according to PN-EN ISO 527-1:1998 and PN-EN ISO 527-3:1998). Biomaterial inclusions were investigated with KEYENCE Digital Microscope VHX-5000 utilization.

Results and Discussion

The molar mass and molar mass dispersion index of PUs before and after filtration process have not changed (FIGs. 2, 3). Glass temperature, mechanical properties, viscosity and solid content of ChronoFlex AR/LT do not differ before and after the filtration process (TABLE 1). Microscopic observation showed less inclusions in PU after filtration, in the thin foils randomly selected areas (FIG. 4).

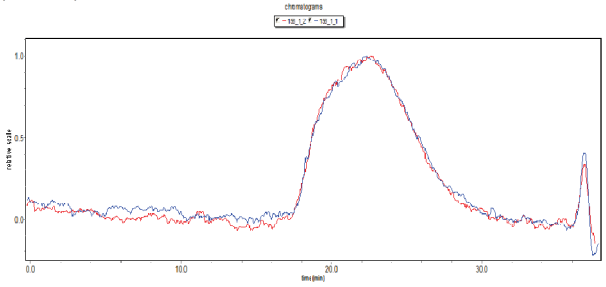


FIG. 2. GPC analysis of non-filtrated PU.

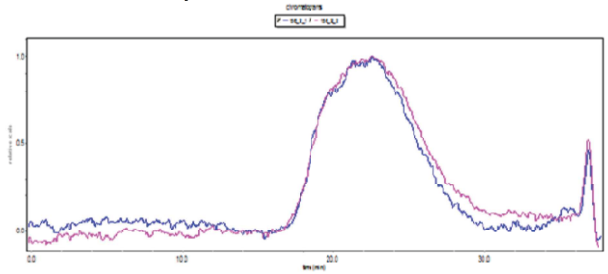
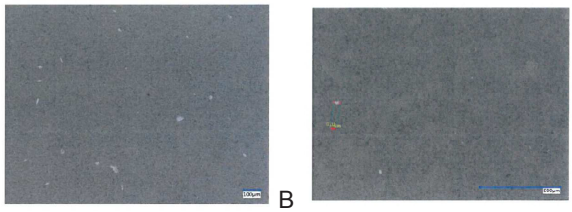


FIG. 3. GPC analysis of PU after filtration.

TABLE 1. Mechanical properties.

No.	TEST	Not filtrated material	Filtrated material
1	Tensile strength [MPa]	53.7	54.47
2	Stress at break [MPa]	53.7	54.46
3	Elongation at max. tensile stress [%]	951.18	929.06
4	Elongation at break [%]	951.22	929.16
5	Viscosity [cps] 30 400	30 410	30 390
6	Solid cont. [%] 23.06	23.04	23.05



A B

FIG. 4. PU inclusions: A before filtration, B after filtration

Conclusions

The results confirmed the new developed double filtration process of PU ChronoFlex decrease number of inclusions not changing PU mechanical and physical properties.

The filtration process final efficiency was validated after quality control of thin membranes produced from filtrated PU, showing lower number of inclusions in the final product.

References

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