NOVEL MEASUREMENT METHODS IN THE EVALUATION OF BIOMATERIALS' PROPERTIES

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[ENGINEERING OF BIOMATERIALS 138 (2016) 101]

Introduction

Hernias are serious health problems and if left untreated, can lead to severe complications and even death. One of the most common methods of treatment of hernia is the use of a polymer implant, which allows the "tension free" surgical operation in the course of which the gap is filled with synthetic material (in the form of mesh) instead of manual stitching of tissue's walls. In terms of the application of such implant in the environment, apart from the polymer used and its physical, chemical and mechanical properties, extremely important are structural parameters of the implant. It is expected that the changes in the structural characteristics have impact on a number of product's characteristics, especially surface properties, such as the free surface energy or specific surface area. This in turn influences the final application of the product or material e.g. in catalysts, sorbents, ionic fillers, thermal insulators etc. Unfortunately, harmonized standards of Directive 93/42/EEC [1] do not include this aspect in evaluation and also, at the stage of implants' design standardized methods in this respect are not in use. Mainly biological, chemical and physical properties are included, as the ones having significant impact on the implants' further performance in biological conditions. The ability to assess the basic structural features, such as surface mass, thickness, diameter of the fibres, type of weave and etc. and its correlation to the surface properties like specific surface area or free surface energy are important elements in the design of a medical devices and should be standardized, as the literature confirms the important influence of the structure parameters on the properties of implants. The ability of assessing surface properties will allow predicting the mechanism of action of the implant within the human body. It will also enable to create a more complete picture of the properties of the biomaterial and it will bring also the possibility to predict its mode of action in biological conditions.

Materials and Methods

In the present study an attempt to determine the possibility of using novel measurement techniques for the evaluation of medical implants was made. As a part of examination, three methods of examination were compared - adsorptive porosimetry, inverse gas chromatography and mathematical method of determination of specific surface area. In the frame of the presented work, two kinds of hernia meshes, commonly available on the market, were examined. The monofilament hernia meshes are made of polypropylene and are intended for medical use (implantable materials with over 30 days of use within the body). Basic structural characteristics, such as surface mass were tested in accordance with applicable standards – examination was performed in accordance with PN-EN 29073-1: 199. The surface mass determination was carried out in air-conditioned laboratory, at normal climatic conditions, that is T = 20°C, RH = 65%. Thickness of the knitted fabrics was measured in accordance with PN-EN 5084:1999. The measurements were carried out using the apparatus - Porosimeter ASAP 2020 V3.01 H (adsorptive porosimetry) and Energy Analyzer (SEA) by Surface Measurement Systems (SMS) Instruments (Inverse gas chromatography). Examination of the surface morphology was carried out using high resolution scanning electron microscope NOVA Nanos 230 manufacturing company FEI equipped with an X-ray microanalyzer EDAX Apollo SDD.

Results and Discussion

The obtained results of the specific surface area confirm the hypothesis given at the beginning of work.

TABLE 1. A summary of results obtained by the use mathematical method

	BET Adsorptive porosimetry	BET Inverse gas chromatography	Mathematical method
	m^2/g	m^2/g	m^2/g
Sample I	100,16	17,13	2,114
Sample II	87,60	9,28	1,604

The differences between the results derive from the specificity of the measurement. In the case of analytical methods (adsorptive porosimetry and inverse gas chromatography), the main difference lies in the selected gas for analysis - namely the type and size of the gas molecules used for measurements, which determines the amount of particles deposited on the test surface, which then has an impact on the calculation of specific surface area.

Conclusions

Both of the selected analytical methods are suitable for evaluation not only specific surface area, but also associated characteristics like free surface energy of the sample, acid/base properties, pore size, pore volumes and etc. The third applied method - mathematical one, turned out to be irrelevant to be used in the case of hernia meshes.

Apart from the physical, chemical and mechanical properties of the implant, extremely important are structural and surface parameters. The ability to determine these parameters would allow predicting the mechanism of action of the implant within the human body. Application of these measurement methods in the design of the implant will contribute to shaping the structural properties of implants/medical devices for their final application, as well as shaping their biological characteristics (which are heavily influenced by surface properties). These methods should be incorporated in the design stage of medical devices, as their results are a perfect complement to other methods of evaluation, thereby allowing to a fuller extent determine the expected properties and actions of the implant in a natural environment.

Acknowledgments

The project was finances by the Department of Material and Commodity Sciences and Textile Metrology, Lodz University of Technology, Poland.

References

[1] European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices