IDENTIFICATION AND CHARACTERIZATION OF MICROBIOLOGICAL CONTAMINATION SOURCES IN THE ENVIRONMENT OF PRODUCTION OF PERSONALIZED FEMORAL IMPLANT

NATALIA GNIADA[1]*, MARTYNA LESZCZEWICZ[1], KRZYSZTOF MAKOWSKI[1,2], PIOTR KOMOROWSKI[3,4], BOGDAN WALKOWIAK[3,4]

[1] INDUSTRIAL BIOTECHNOLOGY LABORATORY, BIONANOPARK LTD., POLAND
[2] BIOTECHNIKA, POLAND
[3] MOLECULAR AND NANOSTRUCTURAL BIOPHYSICS LABORATORY, BIONANOPARK LTD., POLAND
[4] DIVISION OF BIOPHYSICS, INSTITUTE OF MATERIALS SCIENCE, LODZ UNIVERSITY OF TECHNOLOGY, POLAND
*E-MAIL: N.GNIADA@BIONANOPARK.PL

[ENGINEERING OF BIOMATERIALS 158 (2020) 47]

Introduction

Microbiological contamination is a serious problem in medical implants manufacturing [1]. The high number of microorganisms on the surface of implant can lead to ineffective sterilization process and, as a consequence, to patient infection [2]. The first and fundamental step to reduce the risk of contamination is identification of its sources. The study shows changes in the number of microorganisms, at critical control points, in subsequent seasons, in the femoral implant manufacturing environment.

Materials and Methods

The researches were carried out in a Polish tools factory. The main microbiological contamination sites were: emulsifying oils used during material processing, surfaces around the production stations and the air in the production hall. We determined the total number of mesophilic bacteria, as well as yeasts and moulds. Additionally, in the case of emulsifying oils and surfaces, the number of spore-forming and anaerobic bacteria was count. Airborne microbiological contamination was evaluated using the Koch sedimentation method. Other environments were examined using the swab and pour plating method. TSA medium was used for determination of the number of mesophilic and spore-forming bacteria. The anaerobic bacteria were isolated on Schaedler's agar, whereas yeasts and moulds on Sabouraud's agar with chloramphenicol.

Results and Discussion

Regardless of the season, the total number of bacteria in the air was around 10^5 cfu/m^3 (FIG. 1A). The number of yeasts and moulds were varied significantly. Maximum values were detected in spring and summer (FIG. 1B). Nevertheless, microbiological air pollution was high.

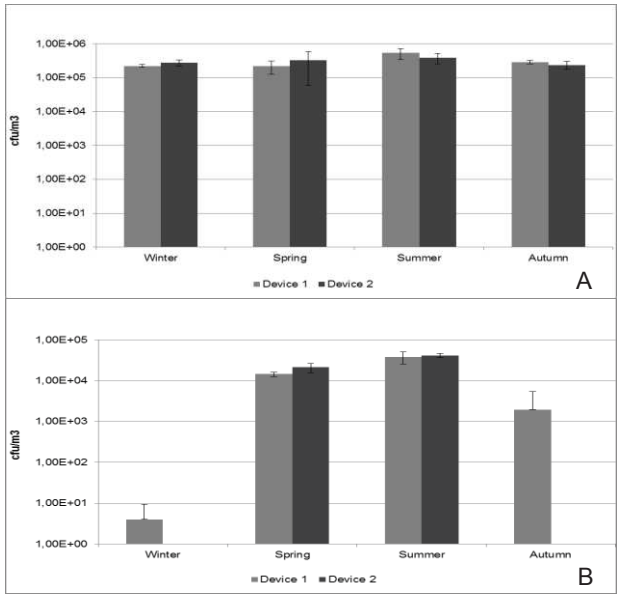

FIG. 2. Number of bacteria (A) and yeasts and moulds (B) in the air.

The main source of microbiological contamination was the emulsifying oil used in the device 2. The total number of aerobic bacteria reached 10^7 cfu/ml, the other groups of microorganisms were also presented in high number. Whereas, in the emulsifying oil used in device 1, microorganisms were usually not detected. This had an impact on microbiological contamination inside the devices used for implants manufacturing (TABLE 1). The total number of microorganisms in device 2 reached even 10^4 cfu/cm^2.

TABLE 2 Microbiological contamination inside and outside of the devices

	Total number [cfu/cm^2]	
	Inside	Outside
Device 1		
Mesophilic bacteria	8,76±8,73	(9,50±9,20)·10^1
Anaerobic bacteria	<1	<1
Spore forming bacteria	<1	<1
Yeasts and moulds	1,51±1,50	6,00±4,90
Device 2		
Mesophilic bacteria	(5,76±3,15)·10^4	(1,45±0,77)·10^1
Anaerobic bacteria	(3,43±3,10)·10^4	<1
Spore forming bacteria	(8,55±5,77)·10^1	<1
Yeasts and moulds	(8,79±6,09)·10^2	4,50±4,43

Conclusions

Evaluation of microbiological contamination is necessary to develop the control program which aims to reduce the risk of lack of sterility of medical implants. Determining the source and level of impurities is necessary to choose the appropriate sterilization method.

Acknowledgements

This work was supported by The National Centre for Research and Development (POIR.04.01.04-00-0058/17-00).

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