MMSL
Military Medical Science Letters
Since 1925

Mil. Med. Sci. Lett. (Voj. Zdrav. Listy) 2022, 91 (supplementum 1)
ISSN 0372-7025 (Print)
ISSN 2571-113X (Online)

MEETING ABSTRACTS

INTERNATIONAL TRAIN-SAFEMD PROJECT: COLLABORATION TOWARDS IMPROVED SAFETY ASSESSMENT OF MEDICAL DEVICES

Helena Kanďárová [1], Dagmar Jírová [2], Winfried Neuhaus [3], Kristína Kejlová [2], Peter Pôbiš [1], Markéta Dvořáková [2], Ana Spilak [3], Markéta Dvořáková [2], Lada Svobodová [2], Alena Moulisová [2]
Presenting author: Helena Kanďárová (helena.kandarova@savba.sk)

[1] Center of Experimental Medicine, v.v.i., Slovak Academy of Sciences, Dúbravska cesta 9, 841 04 Bratislava, Slovakia
[2] National Institute of Public Health, Šrobárova 48, 100 00 Vinohrady, Czechia
[3] OAIT Austrian Institute of Technology, Giefinggasse 4, 1210 Vienna

Medical devices (MDs) have an irreplaceable role in modern healthcare. The term 'medical device' covers a broad spectrum of products that are crucial in diagnosis and treatment, disease prevention and improving the quality of life of people suffering from disabilities or injuries. MDs used in the oral cavity are usually those helping in the treatment of aphthae or canker sores irritations and lesions of the oral mucosa by forming a barrier that adheres to the oral mucosa and promotes healing. Dental materials and dental prosthetic devices are also an important group of MDs with apparent contact with oral mucosa.

Most of the MDs bio-compatibility assessments is still conducted in animals. However, thanks to the advances in cell and 3D tissue engineering and due to the accelerated progress of validation of alternative methods, the MD regulations are also *in vitro* tests, as demonstrated recently by the adoption of the *in vitro* reconstructed epidermis test for intra-cutaneous testing into the ISO standard 10993-23. Biocompatibility testing of MDs is based on the toxicity assessment of extracts from MDs, that are in fact highly diluted solutions of potential irritants. Therefore any already validated *in vitro* tests and prediction models must be fine-tuned to achieve different levels of sensitivity for this specific type of materials.

The TraiN-SafeMD (i.e. Training Network for improving knowledge on safety of medical devices) project builds on the practical experiences gained in the validation study for intra-cutaneous testing of MDs in which the research teams from Slovakia and Czech republic participated between 2012-2018. The current project, with partners from Austria, Czech republic and Slovakia uses 3D reconstructed tissues of oral/buccal epithelia and cell cultures with the origin in the oral cavity with the aim to develop a highly sensitive testing strategy for local tolerance testing *in vitro*. The project also aims into the training of PhD students and early career scientist in the use of *in vitro* methods for the safety assessment of MDs. The TraiN-SafeMD project has 5 tasks and is divided into 7 stages over 72 months. The team's efforts aim in: 1. establishing an international collaboration focused on safety testing of medical devices (MD). 2. development of a training network for PhDs and young scientists engaged in methods *in vitro* for the safety assessment of medical devices. 3. identification of the most promising *in vitro* methods and strategies for *in vitro* safety assessment of MDs used in the oral cavity. 4. standardisation of selected *in vitro* methods and generation of first data for selected MD materials as a part of the preparation for a larger international collaborative project.

The presentation will summarise the activities in the final year of the project and will discuss the next steps toward validation and implementation of innovative testing strategies into the ISO standards.

Acknowledgement: This project has received funding from three member states of the European Union's programme Danube Strategy under grant agreements numbers: DS-FR-19-0048 in Slovak republic (APVV grant)/ 8X20026 in Czech republic (MTMŠ grant), MULT 06/2020 in Austria (OEAD grant).

Keywords: Medical devices; Biocompatibility; Prevalidation; Training networks