

17 EGALITE (EUROPEAN GROUP FOR ACCREDITATION AND LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS)

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EGALiTE (European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments) is a European Project co-funded by the European Health and Digital Executive Agency. EGALiTE aims to optimize the use of resources available at the European level and enhance the capability of Substances of Human Origin (SoHO) Entities to respond rapidly and in a coordinated fashion to health threats. The project will define a set of guidelines for sharing knowledge resources and SoHO of mutually recognized quality, with the aim of improving patients' accessibility to treatment while enhancing the resilience of public organizations and health systems.

The goals of the project have been defined based on the needs long identified by the professionals in the field, which became more evident after the COVID-19 crisis when SoHO Entities were under unprecedented stress, putting at risk their capacity to provide adequate care.

The outcomes of EGALiTE aim to support the activities performed in Member States with distinct technical capacities by:

Establishing a European Accreditation Program for SoHO Entities as a means to achieve mutual recognition;

Developing an efficient database of resources (Blood, Tissues, and Cells (BTC), facilities, activities, and innovative techniques, etc.) which will be used to design sufficiency plans and promote collaboration among professionals and Competent Authorities to ensure an adequate supply of BTC in different Member States;

Providing contingency plans to assist the responsible persons in the decision-making process during a crisis;

Implementing a Technical Assistance Program to assist the implementation of good practices and optimization of activities in different Member States.

18 UNLOCKING CORNEAL MICROBIOLOGY

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Purpose Corneas are released with ongoing microbiological controls due to their short shelf life. For microbiological tests using automated culture systems, the European guideline (EDQM, 5th edition, 2022) is based on the method described in European Pharmacopoeia. Although the guide recommends 7 to 14 days of cultivation, it is not clear enough when these longer cultivation times are necessary. Our goal is to analyze different microbiological times to guarantee a reliable microbiological result.

Methods 1131 liquid samples from organ-culture medium during corneal storage were analysed for microbial contaminations between March to August 2023 with BACT/ALERT® 3D system. A blood culture BACT/ALERT iF Plus anaerobic and BACT/ALERT iF Plus aerobic was taken from each sample.

All microbiological samples were cultured until day 14. In addition, visual inspection of every sample for turbidity was performed on the last day.

Microbiologic tests were performed on the preservation medium on day 6 after the start of corneal culture (n=1131) and after transfer to the deswelling medium (n=1054). Microbiologic testing was also performed 1 day after final evaluation (n=789) and on the day after any manipulation (n=428) for DSAEK or DMEK.

Results The percentage of corneal contamination was 5.41%. Where 44% were yeasts and filamentous fungi, 27% were aerobic gram-positive cocci, 20% aerobic gram-negative bacilli, 7% strict anaerobes and 2% mycobacteria.

81.7% of the samples were positive before the fifth day. While 18.3% of them tested positive around the 14th. On average, the samples were positive after 2.99 days. The analytical method validation studies are also supportive with these data and equivalent growth times are observed.

We also observed a slight increase of contamination during summer season (June to August) in comparison with spring season (March to May), $1.83 \pm 0.76\%$ vs $1.37 \pm 0.45\%$ respectively.

Conclusions Based on the results and in accordance with the European guideline, moreover the measures already established by most eye banks (such as adequate decontamination and sampling of the conjunctiva or sclera at the recovery time or even storage of empty preservation media), it would also be advisable to analyse samples up to day 14 to ensure a reliable microbiological result. It would even be advisable to continue joining efforts to develop rapid microbiology methods that allow the release the corneal tissue with definitive microbiological results.

19 DONOR AND EYE BANK FACTORS INFLUENCING THE OUTCOME OF DMEK GRAFTS PREPARATION

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Purpose The aim of the study is to evaluate the donor characteristics on Descemet Membrane endothelial keratoplasty (DMEK) outcome to identify, if possible, the risk factors for unsuccessful preparation.

Methods A retrospective analysis was performed on a prospective database of FBOV tissues prepared for DMEK from January 2019 to October 2023. A total of 2205 grafts prepared from 1441 donors were analyzed and the principal characteristics were evaluated. Statistical analysis was performed to identify the risk factors for unsuccessful preparation of donor tissue for DMEK.

Results Analyzing the following groups, successful (S-DMEK, N=2114; 95.9%) and unsuccessful (U-DMEK, N=91, 4.1%) DMEK, there are apparently no significant differences respect the type of donation (NB vs NHB), corneas from septic and not septic donors, corneas from donors undergoing and not-undergoing brain radiotherapy and among the days in organ culture.

There was a significant difference between the above-mentioned groups (S-DMEK vs U-DMEK) in term of gender (Male: S-DMEK 61%, U-DMEK 78%, $p=0.001$), age (Age<60yr S-DMEK 10.1%, U-DMEK 16.5%, Age 60-69: S-