

## EEBA STATEMENT ON PRE-PROCESSING MICROBIOLOGY TESTING IN EYE BANKS

Since 2007 when the European Directive 2006/17/EC had to be implemented into national law in the European member states many processes in eye banks had to be revised. When revisiting the different processes in some member states the discussion came up whether pre-processing microbiology testing in form of conjunctival/corneal swabs may be necessary to reduce the risk of microbial transmission via corneal grafts. However, from the literature there is no evidence that such pre-processing tests are helpful to reduce such risk of microbial transmission. Furthermore, when having a look at the risk of endophthalmitis following corneal transplantation, we know that the risk seems to be even lower than after cataract surgery. In a questionnaire from 2007 including all German eye banks a risk for endophthalmitis after corneal transplantation was calculated to be 0.035%. However, in the published literature a slightly higher endophthalmitis rate ranging from 0,1% (Birnbbaum und Reinhard 2006 (1)) to 0,38% (Taban et al. 2005(2)) is reported. Yet, this mainly depends on the storage method, where the microbial transmission rate may be higher in cold storage compared to organ culture as there is typically no sufficient method for sterility testing in cold storage techniques. Therefore, Pels et al. 2008 (3) report on an endophthalmitis rate of 0 – 0.1% using organ culture corneas compared to 0.2-1.3% for corneas from cold storage.

As there is a physiological microbial environment on the ocular surface most corneal/conjunctival swabs will show up with positive microbial culture results even after PVP iodine disinfection and intensive irrigation of the ocular surface of the potential donor. In fact, these procedures lead to a reduction of the microbes on the ocular surface but not to a complete sterilisation. Therefore, many corneal/conjunctival swabs will turn out to be positive ranging from 12.4 to 100% in the literature (Schimmelpfennig et al. 1977 (4), Pardos et al. 1982 (5), Polack et al. 1967 (6), Ritter et al. 1990 (7), Zirm et al. 1976 (8), Badenoch et al. 1988 (9), Wilhelm et al, 2001 (10)). Klarmann from Düsseldorf, Germany, as well as Fuest et al from Aachen Germany demonstrated on the annual meeting of the European Eye Bank Association in 2014 that positive conjunctival swabs were a weak indicator for the contamination of the organ culture medium (unpublished data). According to this high number of positive test results many corneal donations would be discarded and the lack of corneal grafts would be increased without a proof of decreasing the risk of microbial transmission. For these reasons pre-processing microbiology testing has not been performed by European eye banks during the last 20 years.

To reduce the risk of microbial transmission most European Eye Banks use culture media that contain antibiotics and antimycotics that lead to a significant reduction of microbial contamination of organ culture media (Hudde et al, 1997 (11), Pels and Vrensen 1999 (12)). Furthermore, in organ culture the culture media undergo a validated sterile testing procedure after a defined time of organ culture. Only in case of a negative sterile testing of the culture media the cornea will be released for transplantation, in case of a positive sterile test the cornea will be discarded. This is the reason why according to EU Directive 2006/17/EC, Annex 1, 1.1.5, corneal donations are also possible from persons that died from bacterial sepsis (Spelsberg et al. 2002 (13), Armitage und Easty 1997 (14)) when organ culture is used as the storage method. Furthermore, a year-long study to correlate pre-processing cultures to adverse reactions after corneal transplantation performed by the Eye Bank Association of America (EBAA) has been stopped as no correlation between positive cultures and outcome could be found (unpublished data, personal communication).

Taking together the knowledge on the low endophthalmitis rate following corneal transplantation, the high rate of positive corneal/conjunctival swabs, the efficient reduction of microbial contamination of the culture media during organ culture and the valid sterile testing of these media, it is the considered view of the European Eye Bank Association that pre-processing microbiology testing for corneal grafts does not seem to be helpful to decrease the risk of microbial transmission or to increase the safety of corneal transplantation.

*The European Eye Bank Association (EEBA) is a technical-scientific organization comprising individual members from 83 eye-banks from 24 European countries. Founded with the simple objective of sharing information regarding eye-banking, the Association is today the leading pan-national association in Europe dedicated to the advancement of eye-banking and an authoritative reference point for eye banks wishing to work according to quality standards.*



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