Towards Better Safety Standards for Vitreoretinal Medical Devices

In this issue of *Ophthalmologica* you will find a review by Januschowski et al. [1] on the toxicity of medical devices we frequently use during vitreoretinal (VR) surgery.

Having witnessed a toxic effect of a product in a patient undergoing VR surgery is a nightmare come true for every surgeon because of the heavy impact on the patients' visual acuity. The latest dramatic outcomes after the use of a faulty perfluorocarbon liquid across Europe [2] have caused much insecurity among many of us. While it initially was assumed that this toxicity could not be identified by current test methods, data review lately showed that regular chemical testing methods could have worked, if they would have been applied, leading to even more insecurity about this subject [3].

Looking back on the past of vitrectomy, several toxic effects were described, starting in the early days of perfluorocarbon liquid usage but also associated with vital

dyes such as indocyanine green/AV-17 and silicone oil [4, 5]. All these materials have in common that they are in intimate contact with the structures within the eye, for periods varying from minutes to years. Tests on their safety and biocompatibility, however, fall short of the requirements that drugs must meet and are closer to the requirement for surgical instruments.

The review of Januschowski et al. [1] brings together important information in this very sensitive and important matter and represents a starting point for improvements. A productive focus group has formed around the authors, including industry, clinicians, and regulatory boards. Hopefully, in the future we will be able to increase the level of safety for our patients, while continuing the remarkable success story of VR surgery.

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References

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