

# **Comment on: Safety of Phakic Intraocular Collamer Lens (Visian ICL) Implantation in 95 Highly Myopic Special-Needs Children**

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We discussed the study by Reynolds *et al* during the ESCRS journal club on 7th July 2021.<sup>1</sup> In this retrospective case series, the investigators presented peri-operative and longer-term adverse event data from 95 special needs children or adults with myopia who could not comply with spectacles and/or contact lenses and underwent implantation of an intraocular collamer lens (ICL). Whilst this study addresses an important clinical question in a challenging patient group, we would like to highlight some points of discussion which are of relevance to the interpretation of the study.

The definition of adverse events as “minor” or “major” appears somewhat misleading. For example, removal of corneal suture designated as “major” since it necessitated a return to theatre whilst severe endothelial cell loss was classed as “minor” in this study. Whilst this nomenclature may be understandable in the context of a short-term clinical study following intervention, these definitions may not lend appropriate weight to possible serious longer-term safety concerns. The endothelial cell count was only measured in 31 of 160 eyes (i.e. less than 19% of the cohort). Consequently, firm conclusions about the long-term safety of ICL implantation in this patient group cannot be made. Furthermore, these eyes are likely to be unrepresentative of the cohort since they are presumably from the most co-operative individuals. A greater yield may be been possible through specular microscopy in the lateral decubitus position undertaken under general anaesthesia, although we appreciate that repeated anaesthesia may have a detrimental overall impact on special-needs children.

In this highly heterogenous patient group, a more detailed presentation of the data may have allowed the reader to appreciate the relationships between clinical parameters (i.e. age and refraction) and adverse events. For example, the mean preoperative

spherical equivalent refractive error was -11 (range: -4 to -22), and mean age was 9.3 years (range: 1.8- 25) with some non-paediatric patients. Illustration of distribution of refractive error and age as individual datapoints would have allowed the reader to determine, for example, whether there is a relationship between pre-operative refractive error or age and post-operative endothelial cell loss? Moreover, could these parameters predict the development of post-operative pupil block? Furthermore, the details of AEs by group (age, refraction, underlying disorder) would have been helpful.

Although the authors reported that there were 95 children and 160 implanted eyes, the paper states that 35 unilateral and 60 bilateral surgeries were performed: which adds up to 155 eyes.

Previous studies on the subject have shown that ICL implantation is safe in children with a low rate of adverse events.<sup>2</sup> Many of these studies were conducted by the same study group.<sup>3,4</sup> Nevertheless, randomized controlled studies are needed in a larger number of pediatric patients in order to argue that "the benefits outweigh the risks" as stated by the researchers in their conclusion. Specifically, measurement of post-operative endothelial cell counts in most individuals in such cohorts are required in order to make meaningful statements about long-term safety.

## References

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