### RESPONSE TO LETTER

# Safety and Effectiveness of Smooth Incision Lenticular Keratomileusis (SILK™) Using the ELITA™ Femtosecond Laser System for Correction of Myopic and Astigmatic Refractive Errors [Response to Letter]

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## **Dear editor**

The authors of the publication, Safety and Effectiveness of Smooth Incision Lenticular Keratomileusis (SILK<sup>TM</sup>) Using the ELITA<sup>TM</sup> Femtosecond Laser System for Correction of Myopic and Astigmatic Refractive Errors<sup>1</sup> (the paper), would like to respond to the Letter to the Editor from Dr. Alpins published on July 8, 2024<sup>2</sup> (the letter).

The paper<sup>1</sup> reported on the first clinical study demonstrating the safety and effectiveness of SILK<sup>TM</sup> and easy lenticule removal for the correction for myopic and astigmatic refractive errors. In the letter,<sup>2</sup> Dr. Alpins commented that the paper<sup>1</sup> used "inadequate" method, terminology, and references with respect to vector analysis for astigmatism, with which we disagree.

We strove and will continue to strive to apply the highest standards to everything we do. For statistical analysis for astigmatism, the clinical study protocol adopted the method and terminology recommended by the Astigmatism Project Group of the American National Standards Institute (ANSI) Z80.11 Working Group on Laser Systems for Corneal Reshaping<sup>3</sup> (ANSI paper), which was comprised of experts in astigmatism analyses from academia, government, and industry. The ANSI recommendation is based on an extensive literature review in the field of vector analysis for astigmatism. The Centre for Sight Institutional Ethics Committee and Narayana Nethralaya Ethics Committee reviewed and accepted the clinical study protocol prior to the start of the study.

With respect to Dr. Alpins' comment on the ANSI paper<sup>3</sup> in the letter,<sup>2</sup> it is worth pointing out that the ANSI paper appropriately recognizes all the significant contributions in this field, including Dr. Alpins' significant contributions, and it even recommends readers to read Dr. Alpins' review paper on vector analyses. In the letter,<sup>2</sup> Dr. Alpins also questioned why the two papers,<sup>4,5</sup> ie, references 31 and 32 in the paper,<sup>1</sup> cite his work but the paper<sup>1</sup> does not. Our response is that those two papers use the Alpins method and therefore should directly reference Dr. Alpins' work. We referenced the two papers for the purpose of comparing the astigmatism treatment results only but not for comparing the respective data analysis methods. Given that our paper focused on presenting all aspects of the safety and effectiveness of the SILK<sup>TM</sup> procedure for myopic refractive correction, the method, terminology, and references used in our paper are appropriate, comprehensive, and clear for readers in the ophthalmic field.

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# Disclosure

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