

BD Atomic Edge™

Sharpness Redefined

Summary of 'Evaluation of a new disposable silicon limbal relaxing incision knife by experienced users'

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Introduction

Ophthalmic surgeons have had only two limbal relaxing incision (LRI) knife material choices, diamond and metal, available to them. BD (Becton, Dickinson and Company), Franklin Lakes, NJ has developed a safety engineered, single use, uni-directional cutting silicon knife for these incisions. Previous research has suggested that the silicon BD Atomic Edge™ slit knife has superior performance characteristics when compared to a metal knife and performance similar to a diamond knife when making various incisions.^{1,2} This study was designed to determine the performance characteristics of silicon accurate depth knives (used for limbal relaxing incisions) in comparison to diamond and steel knives in five performance characteristics.

Methods

Sixty-five ophthalmic surgeons with experience making limbal relaxing incisions evaluated six different types of knives used for limbal relaxing incisions in ex-vivo porcine eyes during the American Academy of Ophthalmology 2007 Annual Meeting. Each surgeon made eight incisions with silicon knives, eight incisions with diamond knives and two incisions with steel knives, in randomized order. Further, each ophthalmic surgeon evaluated one dulled knife of each type. The silicon and steel knives were disposed of after one use. The diamond knives were cleaned and reused during the study.

Each ophthalmic surgeon rated the following characteristics for each knife after each incision on a Visual Analog Scale (VAS): a) the smoothness of making the incision, b) how well the curvature of the eye was tracked, c) the control of the incision, d) the overall incision quality, and e) the sharpness of the blade.

Each evaluation was scored by placing a vertical line on a 150 mm Visual Analog Scale based on where they felt the characteristics of the knife being assessed fell. The Visual Analog Scales in this study were labeled using a negative descriptor on one end and a positive one on the other. For example, the sharpness scale's descriptors were 'Not Sharp' on the left end and 'Exceptionally Sharp' on the right end.

Results and Conclusions

Prior to the start of study it was decided to use a non-inferiority margin of 10% to establish equivalence of the silicon knife to the diamond knife with respect to the rated characteristics. To establish superiority over the steel knife it was decided that a greater than 10% performance increase must be observed.

The VAS measurements of the regular (not dulled) knife ratings were log-transformed and a general linear model with surgeon as a random effect was fitted for each characteristic. Pairwise comparisons using Tukey's adjustment for multiple comparisons were made among the three different knife types. Statistically, the observed differences between the silicon knives and diamond knives were insignificant (p -value $> .05$)

and the lower 95% confidence limit for the mean ratio was greater than 90% for all performance measurements. The silicon knife mean performance was statistically significantly higher than the mean performance of the steel knife for all characteristics (p -value $< .05$). The improvement in performance ranged from 11% to 24% depending on the specific characteristics. Similarly, the performance of the diamond knife was also found to be significantly higher than the performance of the steel knife (p -value $< .05$).

This study has demonstrated that the performance of the silicon accurate depth knife is equivalent to the diamond knife and superior to the steel knife in each characteristic assessed. The combination of these characteristics suggests that the silicon knife should perform as well as a diamond knife and better than a steel knife in making limbal relaxing incisions.



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¹ Angunawela R, Winkler Von Mohrenfels C, Marshall J. A New Age of Cataract Surgery. *Cataract & Refractive Surgery Today*. 2005 May; 36-38.

² Piovella M, Camesasca F, Kusa B. BD Atomic Edge Silicon Blade. *Cataract & Refractive Surgery Today*. 2007 June.