IMPLANTATION

KeraRing shows good biocompatibility in French study but longer follow-up is needed

by Dermot McGrath in Vienna

eraRing implantation using a femtosecond laser offers a minimally invasive treatment with good biocompatibility and a low rate of complications in patients with keratoconus, according to a study presented at the 2nd EuCornea Congress.

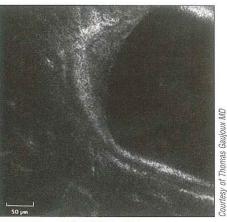
"In this small study we observed no complications in our patients and there was no modification of cell density in the central cornea and no modification of the epithelium, anterior stroma and endothelium around the rings, which indicates that the implant seems to be well tolerated by the ocular tissues," said Thomas Gaujoux MD, Department of Ophthalmology at the Quinze-Vingts National Ophthalmology Hospital in Paris, France.

Dr Gaujoux said, however, that the study team did observe an increase in keratocyte density in the mid and posterior stroma area surrounding the ring segments, suggesting possible keratocyte activation and compressed stromal layers.

Dr Gaujoux's study included nine eyes of keratoconus patients that were prospectively examined with the HRT 3 confocal microscope using the Rostock cornea module (Heidelberg Engineering) immediately before intracorneal ring implantation (KeraRing, Mediphacos) and again at six months and one year after implantation. Imaging software was used to analyse epithelial basal cell density, endothelial cell density and keratocyte density in the anterior, mid and posterior stroma and around the ring segments.

Eligibility criteria for the study included patients with at least grade two keratoconus, as denoted using the Krumeich classification system, clear central cornea, minimal pachymetry of more than 400 microns, and contact lens intolerance.

A 150-kHz femtosecond laser was used to create precise tunnels and the KeraRing PMMA segments were manually implanted to 70 per cent corneal depth. In terms of design, the KeraRing implants are characterised by a triangular cross-section that induces a prismatic effect by which the light coming through the implant is reflected, reducing the incidence of glare and haloes. Their apical diameter is 5.0mm and the flat basis width is 0.6mm with both



Confocal image of intracorneal ring segment

variable thickness and arc lengths. The optical zone provided by the ring segments is 5.0mm in diameter and depending on the case, one or two KeraRing segments of the same or different sizes may be implanted.

Looking at the overall results, Dr Gaujoux said that confocal images of the central basal cells one year after implantation showed no modification in the morphological structure of the central cornea. Nor was any modification found in endothelial cell density in either the central or peripheral cornea. In terms of keratocyte density, there was no modification of keratocyte density in the central cornea or the anterior stroma. However, the study authors did note an increase of keratocyte density in the mid and posterior stroma, as well as intrastromal deposits of unknown provenance, which increased over time.

"These intrastromal deposits are interesting but their clinical significance remains to be established. We are not sure about the composition of this material, which is perhaps some form of lipid substance or cholesterol crystals, but we do know that they increase over time and the long-term consequences are unknown," he said.

Dr Gaujoux said that a longer follow-up with a larger series of patients would help to confirm the findings of this initial study.

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