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A New Corneal Presbyopia Inlay: Pilot Study and Case Report

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Abstract

A tiny spherical gold inlay of 280 microns in diameter was implanted into a corneal pocket at 300 microns depth. The inlay is designed to shift corneal tissue into its surrounding in order to create a multifocal zone in the central cornea. The topographic images show a multi-focal zone in the central cornea which extends the dimensions of the inlay. The surgical procedure is quick and easy to perform. The presented data indicate that the new concept permits the creation of a multifocal optical zone in the corneal center which extends the dimension of the inlay.

Introduction

Presbyopia is a condition which affects humans beyond the age of 40 when the ability to focus on near objects decreases over time. Optical aids such as reading glasses or progressive glasses are required to compensate for that deficit. Efforts to find a surgical solution for that problem have been made. The currently most successful and most commonly used surgical approach which is already used in a clinical routine environment is refractive lens exchange by replacing the crystalline lens by a Multifocal Intra-Ocular Lens (mIOL) [1,2]. The implantation of corneal inlays is a further option. The currently available intra-corneal inlays suffer however from a fundamental disadvantage: The optical pathway passes either through the tissue-inlay interface or is

closely surrounded by such an interface. Tissue reactions at or close to the tissue-inlay interface can therefore result in haze formation in the optical pathway resulting in serious vision loss over time **[3]**. I present here a pilot study of a new cornea inlay concept which is designed to avoid such disadvantages because it does not require a direct optical interface between tissues. It avoids also a situation where such an interface closely encircles the optical pathway where even little haze extension can obstruct the optical pathway **[4]**.

Patients and Method

The pilot study was made according to the tenets of the declaration of Helsinki. A highly amblyopic eye of a female patient was treated after informed consent. The surgical procedure was performed in 2 steps. First, creation of a corneal pocket of 8 mm in diameter at 300 microns depth by means of the PocketMaker Ultrakeratome (DIOPTEX GmbH, Austria) as described elsewhere **[5,6]**. Second, implantation of a tiny spherical Multi-Focal-Cornea (MFC) inlay (DIOPTEX GmbH, Austria) of 280 microns in diameter made of pure gold into the corneal pocket via the small entry tunnel using a McPherson forceps **(Figure 1 and 2)**. The inlay is not transparent and should create a multi-focal zone at the cornea in its surrounding at distance from the inlay without the need of an optically active tissue-inlay interface. Since the inlay is so tiny it should not act as an optical obstacle despite of its non-transparent nature. The cornea can therefore be divided into 3 different zones **(Figure 3 and 4)**: A central blind zone of some 0.3 mm which should not significantly affect the vision, a surrounding near-vision zone which corresponds to the tissue shifting by the inlay into its surrounding and a distance-vision zone which remains unchanged by the inlay. No suture was required in that procedure because the lamellar entry is self sealing. Postoperative treatment was a combination of steroid and antibiotic eye drops 5 times a day for 10 days. Follow-up was performed the first time on day 1 and then before day 30 after treatment and included slit-lamp examination and topography performed by means of Pentacam (Oculus GmbH, Germany).

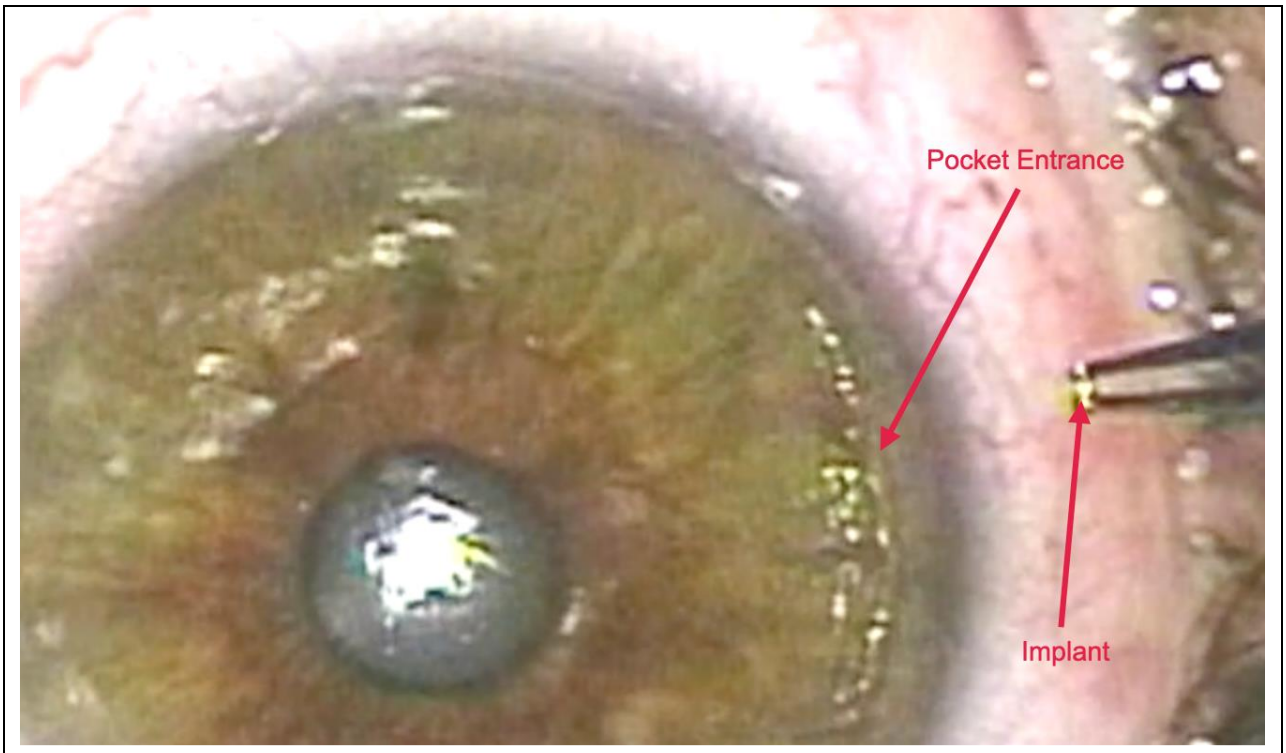

Figure 1: Surgical microscope view: MFC inlay mounted in the Mc Person forceps prior to implantation into the corneal pocket.

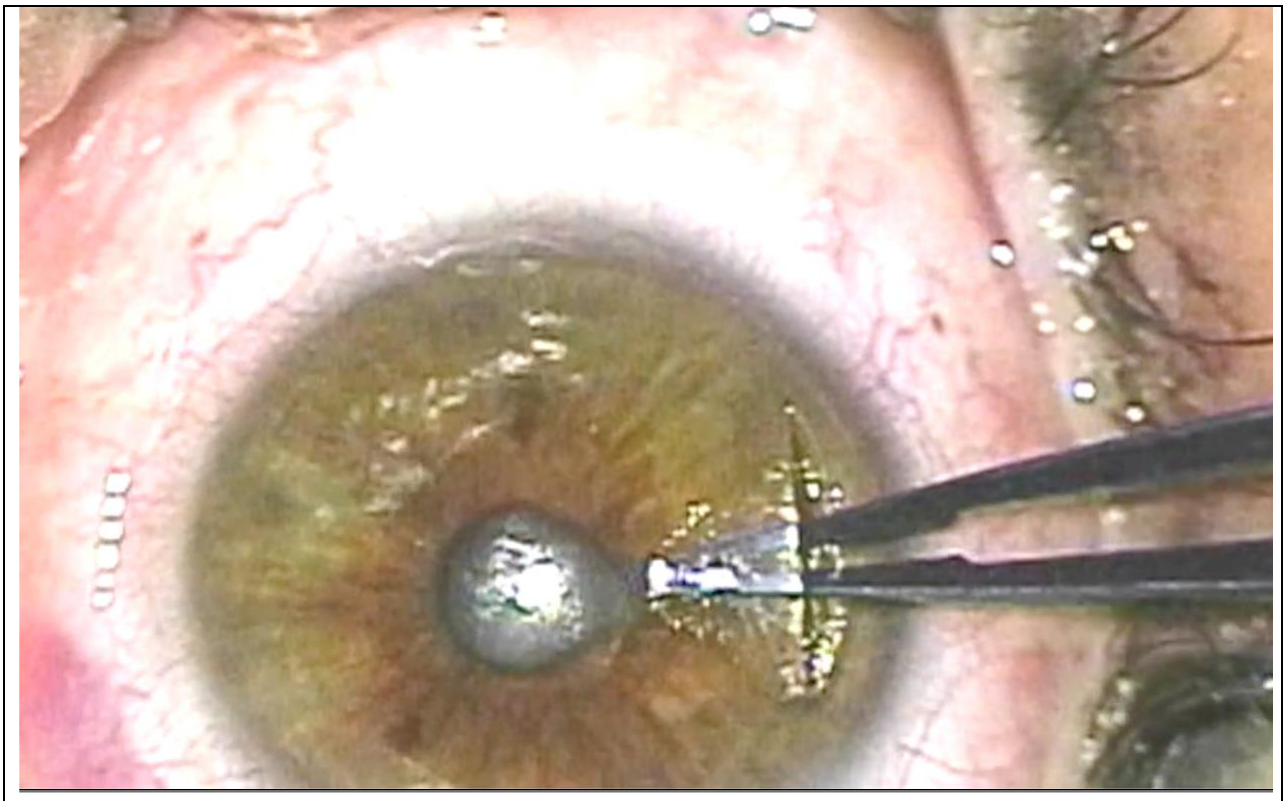

Figure 2: Surgical microscope view: Implantation process into the corneal pocket via the pocket entrance.

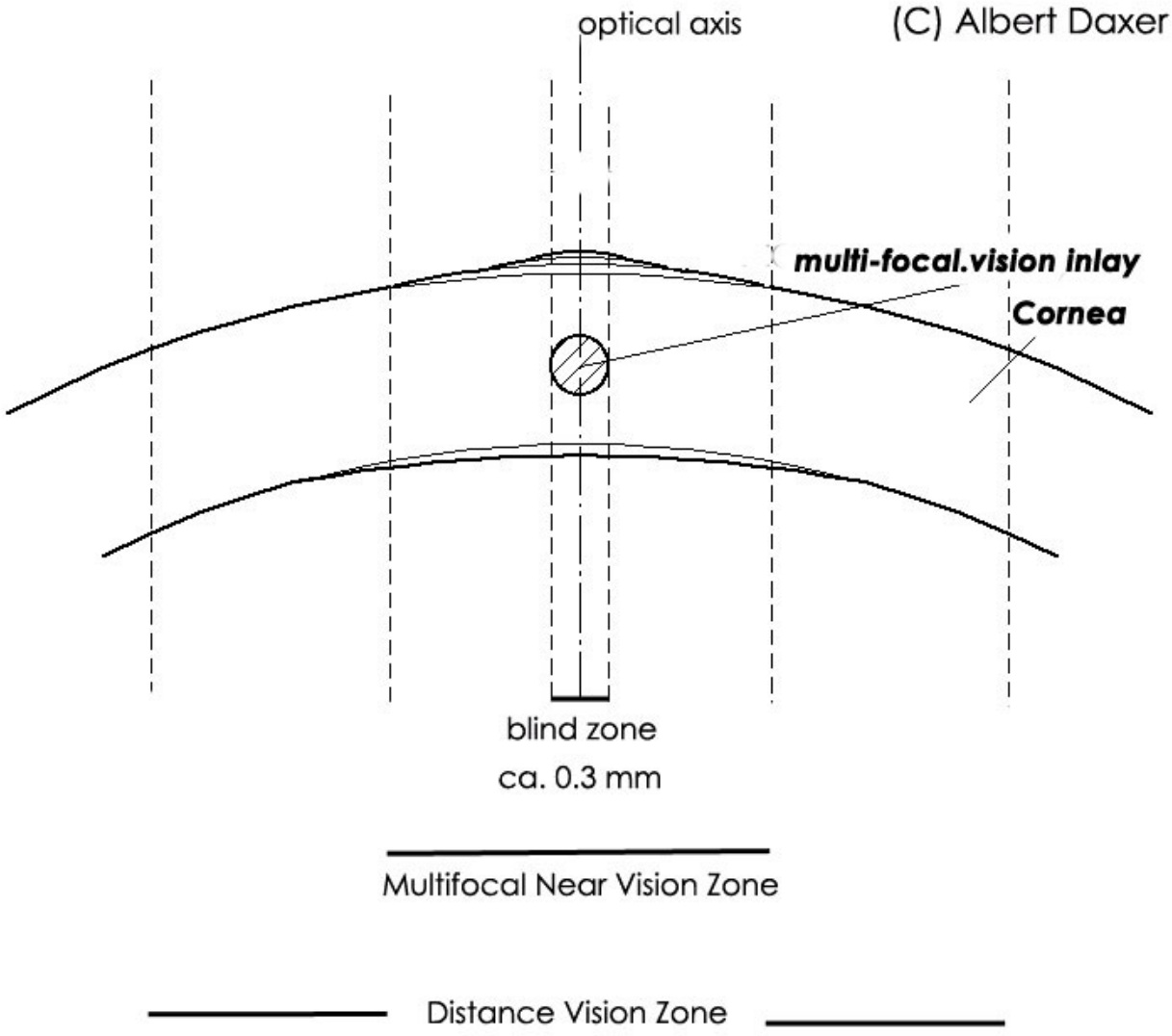

Figure 3: Mechanism of action for the creation of a near- and distance optical zone.

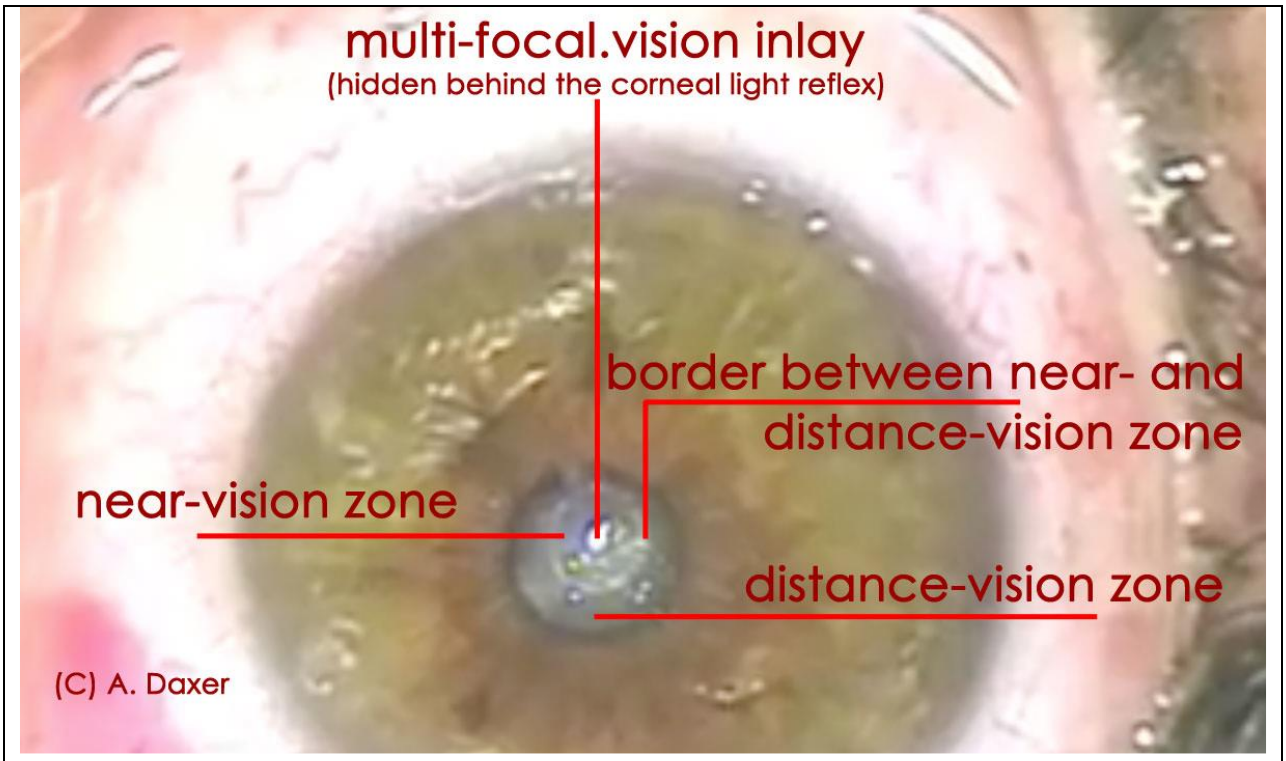

Figure 4: Surgical microscope view: Cornea after implantation of the MFC inlay.

Results

Figure 5 shows the topography (True net power) before and 3 weeks after surgery as well as the difference map. It can be seen that in all cases a near vision addition can be found topographically which extends the dimension of the inlay.

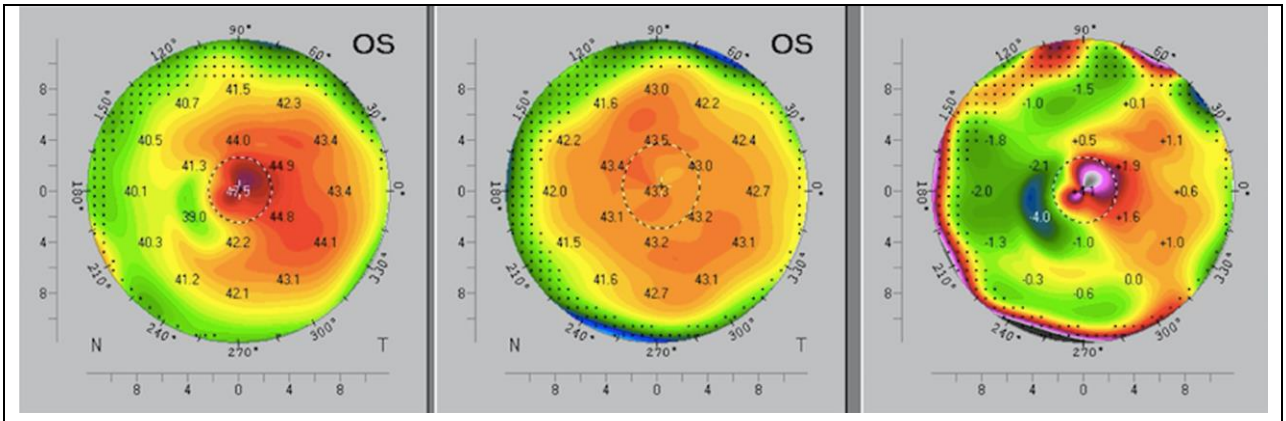

Figure 5: True Net Power before (middle image) and 3 weeks after (left image) implantation of the MFC inlay. The image on the right side shows the difference map and the power addition induced by the inlay. The small blue circular spot at the right upper corner demonstrates the size of the inlay in the right relation to the dimensions of the images.

Discussion

Although the majority of the patients are happy after mIOL implantation there is still a significant number who do not tolerate multi-focal imaging [1,2]. Patient selection is therefore important for the success when using mIOL´s. In the case a patient does hardly tolerate the imaging of the mIOL it is usually not so easy to exchange the multi-focal IOL, especially after a certain period of time. Corneal inlays on the other hand have a long history but not yet shown satisfying long-term results. A main concern is haze formation resulting from tissue reactions at the interface between corneal tissue and inlay. Since the interface of that inlays is usually part of the optical pathway for image formation these kinds of reactions can result in significant loss of vision over time [3]. The same can happen if the inlay closely surrounds a small central aperture. In that case even a small extension of the haze from the inlay can obstruct the optical pathway [4]. Even after removing the inlays it might not be possible to restore an adequate vision in a reasonable period of time. The idea of the new inlay technology is to place a very tiny inlay of only 0.3 mm in diameter or even less into the corneal center which does not have a direct optical function but shifts tissue into the surrounding in order to create a multifocal zone there **(Figure 5)**. The operating distance (near-zone diameter) should then depend on the inlay volume or inlay dimension. The unchanged area beyond the near-vision zone is terminated by the pupil size and corresponds to distance-vision zone. In a first view it might seem paradox to place a non-transparent body as a kind of optical obstacle into the optical center of the cornea. However, ophthalmologists know from their everyday experience on traumatic and rusty foreign bodies in the corneal center that most of these patients still have 20/20 vision if the foreign body is smaller than 0.5 mm. The intended advantage of the fact that the tiny inlay is non-transparent should be that even haze formation at its interface does not result in visual impairment since the area is already non-transparent in the small central blind zone. If the inlay would however be made of a transparent material, tissue-interface reaction could result in scattering centers there which may cause glare. This should therefore not happen if the inlay is a priori non transparent. The case shows a small decentration of the optical power addition relative to the pupil center. The inlays was carefully centered in the optical center (pupil center) using a surgical microscope with the possibility that the patient can focus on a concentric light source. Since the eye was highly amblyopic the centration process was most probably not fully sufficient due to a paralaxis error from partial malfixation of the patient. The surgical procedure is very quick and easy to perform and centration as well as removal of the inlay is quite simple. On the other hand it may be that the multifocal imaging of such a slight decentration of the effective zone may perhaps give also good results. Such questions have to be addressed in further studies. The theory behind that concept requires a relation of structural features such as inlay diameter and implantation depth into functional features such as near-addition and near-zone diameter which have to be addressed also by further studies. The current case shows that a tiny inlay implanted into the corneal center can cause a multi-focal zone which extends significantly the dimension of the inlay.

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