An innovative non-penetrating artificial cornea with precision placement provides vision restoration without graft tissue.

Background
Corneal opacity and scarring secondary to a wide spectrum of infectious and inflammatory corneal diseases are a major cause of global blindness. Worldwide, the second leading cause of blindness is related to the cornea with about 4.9 million people having bilateral corneal blindness. Corneal blindness with a healthy posterior segment is often surgically reversible and keratoprosthesis may be one of the avenues to achieve this goal, especially in cases of high-risk graft failure. With advances in keratoprosthetic devices there is a move toward using these devices as a primary transplantation procedure in select patients. However, currently popular commercially available keratoprosthetic devices require a donor cornea and demand far exceeds supply, thus limiting the number of patients that can benefit from the procedure. In the current longitudinal pilot study we review the results of a novel artificial cornea (KeraKlear) with precise implantation achieved using the Ziemer FEMTO LDV Z6.

Methods
The KeraKlear keratoprosthesis (KeraMed, USA) is foldable and has a 4-mm central optic and total diameter of 7 mm. Unlike other commercially available artificial corneas, the KeraKlear can be implanted into the cornea in a non-penetrating fashion. Using the FEMTO LDV Z6 (Ziemer Ophthalmic Systems, Switzerland) a uniform and precise lamellar pocket is created within the recipient cornea, negating the requirement for donor tissue. After preparation of the cornea, the KeraKlear was inserted into the corneal pocket through the anterior opening in the cornea using non-toothed forceps. The rim of the device was tucked into the pocket recesses. In some cases, four sutures were placed in each quadrant. Postoperatively, patients wore a bandage contact lens and received prophylactic antibiotic eye drops. Nineteen patients with corneal blindness, defined as Snellen acuity less than 20/200, received the KeraKlear corneal implant. Patients had a wide range of diagnoses which included failed corneal transplants, limbal stem cell deficiency, corneal scars, corneal dystrophies and keratoconus. After implantation, patients were followed for four years and visual acuity data as well as tolerance to the implant was recorded.

Results
All patients had an initial improvement in their visual acuity, with an average improvement of 4.2 lines of vision at the last follow-up visit. Pre-surgical uncorrected visual acuity ranged from detection of hand movements only to 20/200. After implantation of KeraKlear, uncorrected visual acuity significantly improved for most patients: 5% of patients reached 20/40, 16% reached 20/60, 26% reached 20/100, 11% reached 20/200 and 32% reached 20/400. There were two complications in this series. One patient suffered from infectious keratitis as a result of noncompliance with the prescribed post-op medication regime. There was also one case of corneal melting in a patient with a history of chemical burn but visual acuity at last visit stabilized at 20/400. No cases of retroprosthetic membrane, glaucoma or endophthalmitis were observed which are common complications of penetrating keratoprostheses. Over the 4-year period, 89% of the KeraKlear artificial corneas were retained.

Discussion
This longitudinal pilot study demonstrates the viability of using the KeraKlear as a first-line treatment of corneal blindness. The device provides rapid visual recovery with improvement in vision evident immediately when the patient leaves the surgical table with vision typically stabilizing within several weeks. The device removes approximately 5% of the corneal tissue (by volume) and is non-penetrating. Therefore, it is possible to still perform corneal transplantation, including deep anterior lamellar keratoplasty or penetrating keratoplasty, if needed. With precise surgical placement and implantation through the FEMTO LDV Z6 KeraKlear pocket function, KeraKlear corneal implants offer a first or second line treatment option for corneal blindness.