IOL Angulation and Corneal Aberrometry in Patients With IOL Fixation Versus Akreos and Gore-Tex IOL Suture

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OBJECTIVE Which surgical technics outcomes are better comparing (intraocular lens) IOL angulation and corneal aberrometry between scleral IOL fixation vs Gore-Tex IOL suture in aphakic eyes

PURPOSE To evaluate wich technique is better in these complicated cases

METHODS In a large ophthalmological Hospital of Mexico City this prospective, observational, non-randomized and consecutive study was conducted. Eyes of 16 patients were included, 10 eyes were operated with Gore-Tex Akreos AO60 IOL suture technic (Gore-Tex group) and 11 with scleral MA60AC Alcon IOL fixation (Scleral Fixation group). Total aberrometry (high and low order aberrometry values) and 50 MHz Ultrabiomicroscopy (Aviso-S, Quantel Medical) with two projections: from 3 to 9 meridian, and 12 to 6 meridian. Decentration was measured calculating the difference in distance from the baseline to each side of the optic of the IOL.

RESULTS Main age was 63.6 and 66.1 years old for Gore-Tex group and Scleral Fixation group respectively (p 0.79). Average AL were 23.9 and 22.7 mm for each group respectively (p 0.19). BCVA pre op was 1.01 and 1.53 LogMar (p 0.24) respectively each group, and pos op was 0.66 and 1.14 LogMar (p 0.36) for each group respectively. Anterior chamber was 3.38 and 4.68 mm respectively each group (p 0.02). IOL angulation values were: for nasal 92.47 and

98.84 degrees (p 0.07), for temporal 89.22 and 85.49, for superior 88.77 and 85.79, and for inferior 95.42 and 89.85 for Akreos group and scleral fixation group respectively. Horizontal axis were 1.75±0.02 vs 0.01±0.01 nasaly for both groups respectively ($p > 0.05$). Vertical were -0.50±1.44 and -0.88±0.13 inferiorly for both groups respectively. High order corneal aberrometry value were 5.51±5.80 and 2.77±1.77 for each group respectively (p 0.13), and low order corneal aberrometry were -2.26±1.04 and -2.13±0.38for each group respectively (p 0.76).

CONCLUSION UBM and corneal aberrometry did not showed differences statistically significative. Horizontal and vertical axis and high and low order corneal aberrometry were not statistically different. Sample should be enlarge in order to identify differences between surgical technics. There iare no differences in surgical outcomes between both technics, and both technics are a good option for these cases.

HUMAN RESEARCH Yes: Approved by institutional review board

Optimization of the Port Delivery System With Ranibizumab (PDS) Implant Insertion Procedure in the LADDER Phase 2 Trial

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OBJECTIVE To examine the optimization of the implant insertion procedure for the Port Delivery System with ranibizumab (PDS) to improve surgical outcomes.

PURPOSE The PDS is an investigational treatment for neovascular age-related macular degeneration (nAMD). It consists of a refillable, indwelling, intraocular implant that provides diffusion-mediated continuous delivery of ranibizumab. To improve surgical outcomes, the implant insertion surgery was optimized in Ladder, and a robust surgical training plan has been implemented.

METHODS Ladder (NCT02510794) is an ongoing randomized phase 2 clinical trial in patients with nAMD comparing the PDS with 3 customized formulations of ranibizumab with monthly intravitreal ranibizumab 0.5 mg injections. At trial initiation, the original PDS implant insertion procedure involved a sclero-pars plana stab incision 4 mm posterior to the limbus in the superotemporal quadrant. The prefilled implant was then inserted in the scleral wound followed by conjunctival suturing. Here, we report how the occurrence of postoperative vitreous hemorrhage (VH) early on in the trial led to optimization of the insertion procedure to improve surgical outcomes.

RESULTS In Ladder, postoperative VH occurred in 11 (50%) of the first 22 PDS-treated patients who were implanted using the original insertion procedure. The trial was paused and a surgical study in minipigs was conducted; the pars plana (uvea) at the incision site was identified as the source of postoperative intraocular bleeding. Among alternative surgical methods tested, scleral dissection at the insertion site followed by thorough 532-nm laser ablation of the exposed pars plana using overlapping 1000-ms spots before PDS implant insertion was the most effective method to mitigate VH. Following adaptation for use in patients and implementation of this optimized implant insertion procedure in Ladder, postoperative VH occurred in 4.5% (7/157) of PDS-treated patients. Surgery video analysis showed that procedural consistency and

strict adherence to the PDS Instructions for Use document was key to mitigating occurrence of VH, as well as other postsurgical events.

CONCLUSION The optimized PDS implant insertion procedure with laser ablation of the pars plana at the incision site reduced the VH rate in the Ladder trial when standardized surgical steps were strictly followed. A robust training plan has been implemented for the ongoing phase 3 Archway trial (NCT03677934) to ensure procedural consistency and prioritize patient safety.

HUMAN RESEARCH Yes: Approved by institutional review board

A Biocompatible Basal Membrane to Restore Age-Related Macular Degeneration Photoreceptor Damage

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OBJECTIVE Age-related macular degeneration is the leading cause of legal blindness in adults of 65-years and older. Choroidal neovascularization can complicate AMD and lead to severe visual acuity reduction.

PURPOSE To describe the surgical outcomes of eight patients affected by age-related macular degeneration complicated with evolved choroidal neovascularization treated with a novel surgical technique to induce a photoreceptors regenerations and partially visual acuity restoration.

METHODS Eight patients with evolved AMD undergone pars plana vitrectomy (PPV) with the implantation of a biocompatible basal membrane containing several growth factors under the retina in the macular area after an induced retinal detachment and a peripheral retinectomy. Silicone oil was used as endotamponade and was removed after four months in all cases. Advanced diagnostic instruments as OCT angiography microperimetry and adaptive optics has been used during entire follow-up to monitoring the status of the new implant.

RESULTS Mean preoperative best corrected visual acuity (BCVA) was 20/2000 (2 logMAR), all the patient had a BCVA of counter finger or less. Mean final BCVA was 20/400 (1,31 logMAR), ranging from 20/2000 to 20/100 (2-0,7 logMAR). OCT Angiography scan was used to measure the retinal vascularization in the treated eye compared with the fellow eye. A high correlation between BCVA and Deep Vascular Density was showed. Adaptive optics was evaluated over the retinal area where the highest functionality was observed, using the microperimetry. The images showed a photoreceptors presence over the membrane.

CONCLUSION The film promotes a retinal photoreceptors restorations six months after surgery with a visual acuity improvement. The advanced diagnostic confirms the results obtained.

HUMAN RESEARCH Yes: Approved by institutional review board