

Xen45 Gel Implant in Open Angle Glaucoma: Efficacy, Safety and Predictors of Outcome

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Abstract : The most widely performed surgical procedure in Open-Angle Glaucoma (OAG) is trabeculectomy. Although this filtering procedure is extremely effective, surgical failure and postoperative complications are reported. Due to its invasive nature and possible complications, trabeculectomy is usually reserved, in practice, for patients who are refractory to medical and laser therapy. Recently, a number of micro-invasive surgical techniques (MIGS: Micro-Invasive Glaucoma Surgery), have been introduced in clinical practice. They meet the criteria of micro-incisional approach, minimal tissue damage, short surgical time, reliable IOP reduction, extremely high safety profile and rapid post-operative recovery. Xen45 Gel Implant (Allergan, Dublin, Ireland) is one of the MIGS alternatives, and consists in a porcine gelatin tube designed to create an aqueous flow from the anterior chamber to the subconjunctival space, bypassing the resistance of the trabecular meshwork. In this study we report the results of this technique as a favorable option in the treatment of OAG for its benefits in terms of efficacy and safety, either alone or in combination with cataract surgery. This is a retrospective, single-center study conducted in consecutive OAG patients, who underwent Xen45 Gel Stent implantation alone or in combination with phacoemulsification, from October 2018 to June 2019. The primary endpoint of the study was to evaluate the reduction of both IOP and number of antiglaucoma medications at 12 months. The secondary endpoint was to correlate filtering bleb morphology evaluated by means of anterior segment OCT with efficacy in IOP lowering and eventual further procedures requirement. Data were recorded on Microsoft Excel and study analysis was performed using Microsoft Excel and SPSS (IBM). Mean values with standard deviations were calculated for IOPs and number of antiglaucoma medications at all points. Kolmogorov-Smirnov test showed that IOP followed a normal distribution at all time, therefore the paired Student's T test was used to compare baseline and postoperative mean IOP. Correlation between postoperative Day 1 IOP and Month 12 IOP was evaluated using Pearson coefficient. Thirty-six eyes of 36 patients were evaluated. As compared to baseline, mean IOP and the mean number of antiglaucoma medications significantly decreased from $27,33 \pm 7,67$ mmHg to $16,3 \pm 2,89$ mmHg (38,8% reduction) and from $2,64 \pm 1,39$ to $0,42 \pm 0,8$ (84% reduction), respectively, at 12 months after surgery (both $p < 0,001$). According to bleb morphology, eyes were divided in uniform group (n=8, 22,2%), subconjunctival separation group (n=5, 13,9%), microcystic multiform group (n=9, 25%) and multiple internal layer group (n=14, 38,9%). Comparing to baseline, there was no significant difference in IOP between the 4 groups at month 12 follow-up visit. Adverse events included bleb function decrease (n=14, 38,9%), hypotony (n=8, 22,2%) and choroidal detachment (n=2, 5,6%). All eyes presenting bleb flattening underwent needling and MMC injection. The higher percentage of patients that required secondary needling was in the uniform group (75%), with a significant difference between the groups ($p=0,03$). Xen45 gel stent, either alone or in combination with phacoemulsification, provided a significant lowering in both IOP and medical antiglaucoma treatment and an elevated safety profile.

Keywords : anterior segment OCT, bleb morphology, micro-invasive glaucoma surgery, open angle glaucoma, Xen45 gel implant

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