• Brief Report •

# Xen45 Gel Stent implant: patient reported outcomes

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## Abstract

**• Our aim was to report quality of life (QOL) outcomes following Xen45 Gel Stent implantation surgery in patients suffering with primary open angle glaucoma (POAG). A retrospective analysis was performed on all patients who had Xen45 implantation surgery during a 2-year period (Jun, 2016-Apr, 2018). Of 52 consecutive patients were included with a total of 58 eyes being operated on. QOL was compared both pre-operatively and 6 weeks post-operatively using the GQL-15 questionnaire. There was an overall improvement in GQL-15 summary scores for our patient group. All item scores showed either no change or some degree of improvement. The Xen45 Gel Stent Implant is a promising new intervention which has shown improved QOL scores in our patient group. Further, higher power studies are now needed to compare the Xen45 to trabeculectomy (TE), which is currently the gold standard.**

**• KEYWORDS:** glaucoma; minimally invasive glaucoma surgery; Xen45 Gel Stent implant

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## INTRODUCTION

Ophthalmological diseases have been known to exert a strong impact on quality of life (QOL) due to psychological pressure and visual disability[1]. Of these conditions, glaucoma is the second leading cause of blindness worldwide with the number of glaucoma patients suffering from bilateral blindness projected to exceed 11 million by 2020[2]. Such patients require prolonged courses of treatment which rarely meet their expectations. Development of the disease also causes progressive loss of visual acuity (VA); further contributing towards patients' anxiety and fear of blindness[3]. Although clinical indicators such as VA are useful in monitoring disease progression, clinicians' do not regularly consider the importance of QOL in glaucoma patients. Several studies demonstrate a correlation between clinical indices and QOL; with particular emphasis on VA and visual fields[4-10].

The most important risk factor for visual field loss in glaucoma is increased intraocular pressure (IOP) as this causes damage to the optic nerve[11]. Traditional surgical interventions for glaucoma include trabeculectomy (TE) and episcleral aqueous drainage implants with the aim of reducing IOP. Though effective, these interventions report high complication rates[12]. Recently, several new surgical methods have been introduced with the aim of avoiding said complications; collectively called "minimally invasive glaucoma surgery"[13]. The Xen45 Gel Stent implant (Allergan) is one such surgical procedure which reduces IOP by draining aqueous fluid from the anterior chamber into the subconjunctival space. It is used in patients with primary open angle glaucoma (POAG) and for refractory glaucoma where previous surgical interventions have proved ineffective[11]. As visual fields are strongly associated with QOL in glaucoma patients, we used the Glaucoma GQL-15 Questionnaire to assess whether the insertion of the Xen45 Gel Stent implant had an effect on patient's QOL.

## SUBJECTS AND METHODS

**Ethical Approval** All patients were properly informed about their inclusion and gave verbal consent. This study complied with the principles of the Declaration of Helsinki.

Totally, 58 eyes were identified from 52 consecutive patients who underwent Xen implantation surgery for POAG between June 2016 and April 2018. Inclusion criteria were that patients were operated on by the same surgeon and had an established diagnosis of POAG. Patients with a diagnosis of neovascular glaucoma were excluded from the study. These patients were then further divided into 2 subgroups; those who had Xen45 Gel Stent implantation only, with clear, healthy lenses and those who had Xen45 Gel Stent implantation as well as intraocular lens (IOL) insertion during the same operation due to cataract. Data collection was performed by 2 of the authors. Patients were contacted *via* telephone and QOL was assessed retrospectively, both before the operation and 6 weeks post-operatively.

QOL was measured using the GQL-15 questionnaire. This questionnaire includes 15 items which are thought to have the strongest relationship with visual field loss in glaucoma. These are further divided into 4 domains: peripheral vision,

central/near vision, outdoor mobility and dark adaptation/glare. The items are represented by a number which ranges from 0 to 5 depending on how difficult the patient finds the activity as follows: 0) patient does not perform activity for reasons unrelated to vision; 1) no difficulty; 2) little bit of difficulty; 3) some difficulty; 4) quite a lot of difficulty; 5) severe difficulty.

Item scores were calculated both pre- and post-operatively. A summary score was also calculated for each patient with the maximum summary score being 75; higher scores indicate a poorer QOL.

Analysis was performed on the item scores both pre and post-operatively using the paired *t*-test. The Mann-Whitney *U* test was also performed on subgroups to determine statistical significance. For both tests, $P<0.05$ was considered statistically significant.

## RESULTS

Thirty-six out of 52 patients were contactable which correlated to 40 out of 58 eyes. The male:female ratio was 7:5 with an average age of 74.2 years.

All patients successfully completed the GQL-15 questionnaire. Of 32 eyes had Xen45 Gel Stent implantation only and the remaining 8 eyes had both Xen implantation as well as IOL insertion.

Results of the summary scores are presented in Table 1. There was an improvement in GQL-15 scores for 11 eyes, 20 eyes showed no change and 9 eyes showed a decline in QOL for the patient. Considering overall scores, there was an improvement in the average GQL-15 score for all 40 eyes.

Table 2 shows analysis of individual item scores presented as a mean. All items showed either no change or some degree of improvement. Strong statistical significance was shown using the paired *t*-test with a *P* value of 0.0005435 ($P<0.05$).

The Mann-Whitney *U* test also showed statistical significance between subgroup outcomes with a *P* value of 0.02034 ($P<0.05$).

## DISCUSSION

To our knowledge, this is the first study that has analysed patient reported outcomes after insertion of the Xen45 Gel Stent implant. Our study shows an overall improvement in average summary scores when comparing the pre-operative setting to post-operative. However, several patients reported either no change in summary scores ($n=20$) or a worsening of scores ($n=9$). For these individuals, the majority had very low pre-operative GQL-15 scores to begin with and it was expected that a drastic change would not be observed. In patients who did show an improvement in summary scores, the majority were significant. For example, eye 29 improved their GQL-15 score by 26 and eye 1 by 15.

In terms of item scores, the most significant change was seen in the dark adaptation domain with an improvement in all item scores; particularly seeing at night (-0.3). Improvement was also seen in 4 out of 6 items in the peripheral vision domain. These are 2 of the most beneficial domains in terms of QOL as several studies have shown an association between dark adaptation/peripheral vision and binocular visual field

**Table 1 GQL summary scores**

| Eye | Operation performed | Pre-op | 6 weeks post-op | Degree of improvement |
|---|---|---|---|---|
| Eye 1 | X+I | 41 | 26 | -15 |
| Eye 2 | X+I | 31 | 19 | -12 |
| Eye 3 | X+I | 29 | 15 | -14 |
| Eye 4 | X+I | 16 | 16 | 0 |
| Eye 5 | X+I | 19 | 15 | -4 |
| Eye 6 | X+I | 17 | 23 | 6 |
| Eye 7 | X+I | 20 | 15 | -5 |
| Eye 8 | X+I | 23 | 15 | -8 |
| Eye 9 | X | 19 | 19 | 0 |
| Eye 10 | X | 16 | 16 | 0 |
| Eye 11 | X | 19 | 19 | 0 |
| Eye 12 | X | 15 | 15 | 0 |
| Eye 13 | X | 15 | 17 | 2 |
| Eye 14 | X | 17 | 18 | 1 |
| Eye 15 | X | 15 | 15 | 0 |
| Eye 16 | X | 23 | 21 | -2 |
| Eye 17 | X | 14 | 20 | 6 |
| Eye 18 | X | 16 | 16 | 0 |
| Eye 19 | X | 17 | 17 | 0 |
| Eye 20 | X | 34 | 36 | 2 |
| Eye 21 | X | 20 | 20 | 0 |
| Eye 22 | X | 21 | 19 | -2 |
| Eye 23 | X | 30 | 30 | 0 |
| Eye 24 | X | 49 | 51 | 2 |
| Eye 25 | X | 19 | 19 | 0 |
| Eye 26 | X | 19 | 19 | 0 |
| Eye 27 | X | 17 | 17 | 0 |
| Eye 28 | X | 17 | 17 | 0 |
| Eye 29 | X | 45 | 19 | -26 |
| Eye 30 | X | 17 | 23 | 6 |
| Eye 31 | X | 17 | 20 | 3 |
| Eye 32 | X | 19 | 19 | 0 |
| Eye 33 | X | 56 | 55 | -1 |
| Eye 34 | X | 20 | 17 | -3 |
| Eye 35 | X | 17 | 17 | 0 |
| Eye 36 | X | 17 | 17 | 0 |
| Eye 37 | X | 20 | 20 | 0 |
| Eye 38 | X | 18 | 22 | 4 |
| Eye 39 | X | 15 | 15 | 0 |
| Eye 40 | X | 17 | 17 | 0 |
| Average | | 22.15 | 20.65 | -1.5 |

X+I: Xen45 Gel Stent Implantation and IOL insertion; X: Xen45 Gel Stent implantation only.

**Table 2 GQL item scores**

| Items | Scores preop. | Scores postop. | Degree of improvement |
|---|---|---|---|
| Dark adaptation/glare | | | |
| Walking after dark | 1.25 | 1.15 | -0.1 |
| Seeing at night | 1.775 | 1.475 | -0.3 |
| Adjusting to bright lights | 2.025 | 1.9 | -0.125 |
| Adjusting to dim lights | 1.7 | 1.625 | -0.075 |
| Going from a light to dark room or vice versa | 1.825 | 1.725 | -0.1 |
| Tripping over objects | 1.375 | 1.2 | -0.175 |
| Central/Near vision | | | |
| Reading Newspapers | 1.725 | 1.5 | -0.225 |
| Recognising faces | 1.125 | 1.125 | 0 |
| Outdoor mobility | | | |
| Walking on uneven ground | 1.2 | 1.2 | 0 |
| Peripheral vision | | | |
| Seeing objects coming from the side | 1.6 | 1.525 | -0.075 |
| Crossing the road | 1.375 | 1.375 | 0 |
| Walking on steps/stairs | 1.15 | 1.15 | 0 |
| Bumping into objects | 1.25 | 1.175 | -0.075 |
| Judging the distance of foot to step/curb | 1.55 | 1.375 | -0.175 |
| Finding dropped objects | 1.225 | 1.125 | -0.1 |

loss[14-17]. Improving visual field loss benefits patient's QOL by increasing their ability to mobilise, reducing the risk of falls and increasing the ability to perform activities of daily living[18].

Unfortunately, there are no GQL-15 QOL studies to demonstrate a direct comparison to the gold standard for POAG which is TE. The closest comparison we could find was a recent study by Pahlitzsch *et al*[19] which compared QOL between several minimally invasive glaucoma surgeries (iStent, Trabectome) and TE. This study found no significant difference in QOL between the techniques using the NEI-VFQ-25 questionnaire. However, they state that due to the fact TE patients need lower numbers of anti-glaucoma medications post-operatively, this has an impact on QOL despite the parameter not being included in the NEI-VFQ-25 questionnaire. Although Xen45 is also an example of minimally invasive glaucoma surgery, we cannot compare our findings directly to Pahlitzch's study as we have used a different questionnaire (GQL-15) which primarily evaluates visual field related QOL. In order to evaluate the impact of Xen on QOL when compared to the gold standard, we recommend a randomised, controlled trial comparing a group where patients have had Xen45 Gel Stent implantation to a patient group who has had TE performed. GQL-15 data should then be compared in these groups ideally for a follow-up period of at-least 24 months post-operatively.

There are several reasons why we chose to use the GQL-15 questionnaire in our study. Recent literature has shown the GQL-15 questionnaire to demonstrate reliability, validity and reproducibility[3]. It has been evaluated using Rasch analysis and the results showed well-spaced category thresholds as well as excellent measurement precision[20]. Moreover, the questions are known to correlate closely with visual field loss[3]. The questionnaire is also easy to understand and can be completed within a short period of time.

Though our study shows promising results for the Xen45 implant, it was subject to several limitations. Patients were asked to report retrospectively which, of course, can lead to recall bias. Several of the patients also had concomitant IOL insertion during the operation which was shown to be statistically significant and may have contributed to worse or better outcomes. Other limitations included a lack of control group, short follow-up period and observational bias due to 2 authors collecting GQL-15 information. The GQL-15 questionnaire is also prone to several limitations despite strong validity. Primarily, the GQL-15 focuses on the physical effects of the disease process and does not consider broader QOL considerations such as psychological factors.

In conclusion, the Xen45 Gel Stent implant is a promising new intervention which has shown improved QOL scores in our patient group. Further, higher power studies are now needed to compare the Xen45 to TE, which is currently the gold standard.

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**REFERENCES**

1 Quaranta L, Riva I, Gerardi C, Oddone F, Floriani I, Konstas AG. Quality of life in glaucoma: a review of the literature. *Adv Ther* 2016;33(6):959-981.

2 Quigley HA, Broman AT. The number of people with glaucoma worldwide in 2010 and 2020. *Br J Ophthalmol* 2006;90(3):262-267.

3 Wang Y, Alnwisi S, Ke M. The impact of mild, moderate, and severe visual field loss in glaucoma on patients' quality of life measured *via* the Glaucoma Quality of Life-15 Questionnaire: a Meta-analysis. *Medicine (Baltimore)* 2017;96(48):e8019.

4 Sawada H, Fukuchi T, Abe H. Evaluation of the relationship between quality of vision and the visual function index in Japanese glaucoma patients. *Graefes Arch Clin Exp Ophthalmol* 2011;249(11):1721-1727.

5 Orta AÖ, Öztürker ZK, Erkul SÖ, Bayraktar Ş, Yilmaz OF. The correlation between glaucomatous visual field loss and vision-related quality of life. *J Glaucoma* 2015;24(5):e121-e127.

6 Sun Y, Lin C, Waisbourd M, Ekici F, Erdem E, Wizov SS, Hark LA, Spaeth GL. The impact of visual field clusters on performance-based measures and vision-related quality of life in patients with glaucoma. *Am J Ophthalmol* 2016;163:45-52.

7 Ringsdorf L, McGwin G Jr, Owsley C. Visual field defects and vision-specific health-related quality of life in African Americans and whites with glaucoma. *J Glaucoma* 2006;15(5):414-418.

8 Peters D, Heijl A, Brenner L, Bengtsson B. Visual impairment and vision-related quality of life in the Early Manifest Glaucoma Trial after 20 years of follow-up. *Acta Ophthalmol* 2015;93(8):745-752.

9 Sherwood MB, Garcia-Siekavizza A, Meltzer MI, Hebert A, Burns AF, McGorray S. Glaucoma's impact on quality of life and its relation to clinical indicators. A pilot study. *Ophthalmology* 1998;105(3):561-566.

10 Chan EW, Chiang PP, Liao J, Rees G, Wong TY, Lam JS, Aung T, Lamoureux E. Glaucoma and associated visual acuity and field loss significantly affect glaucoma-specific psychosocial functioning. *Ophthalmology* 2015;122(3):494-501.

11 Ozal SA, Kaplaner O, Basar BB, Guclu H, Ozal E. An innovation in glaucoma surgery: XEN45 gel stent implantation. *Arq Bras Oftalmol* 2017;80(6):382-385.

12 Landers J, Martin K, Sarkies N, Bourne R, Watson P. A twenty-year follow-up study of trabeculectomy: risk factors and outcomes. *Ophthalmology* 2012;119(4):694-702.

13 Lavia C, Dallorto L, Maule M, Ceccarelli M, Fea AM. Minimally-invasive glaucoma surgeries (MIGS) for open angle glaucoma: a systematic review and meta-analysis. *PLoS One* 2017;12(8):e0183142.

14 Nelson P, Aspinall P, Papasouliotis O, Worton B, O'Brien C. Quality of life in glaucoma and its relationship with visual function. *J Glaucoma* 2003;12(2):139-150.

15 Mbadugha CA, Onakoya AO, Aribaba OT, Akinsola FB. A comparison of the NEIVFQ25 and GQL-15 questionnaires in Nigerian glaucoma patients. *Clin Ophthalmol* 2012;6:1411-1419.

16 Onakoya AO, Mbadugha CA, Aribaba OT, Ibidapo OO. Quality of life of primary open angle glaucoma patients in lagos, Nigeria: clinical and sociodemographic correlates. *J Glaucoma* 2012;21(5):287-295.

17 Goldberg I, Clement CI, Chiang TH, Walt JG, Lee LJ, Graham S, Healey PR. Assessing quality of life in patients with glaucoma using the glaucoma quality of life-15 (GQL-15) questionnaire. *J Glaucoma* 2009;18(1):6-12.

18 Gutierrez P, Wilson MR, Johnson C, Gordon M, Cioffi GA, Ritch R, Sherwood M, Meng K, Mangione CM. Influence of glaucomatous visual field loss on health-related quality of life. *Arch Ophthalmol* 1997;115(6):777-784.

19 Pahlitzsch M, Klamann MK, Pahlitzsch ML, Gonnermann J, Torun N, Bertelmann E. Is there a change in the quality of life comparing the micro-invasive glaucoma surgery (MIGS) and the filtration technique trabeculectomy in glaucoma patients? *Graefes Arch Clin Exp Ophthalmol* 2017;255(2):351-357.

20 Khadka J, Pesudovs K, McAlinden C, Vogel M, Kernt M, Hirneiss C. Reengineering the glaucoma quality of life-15 questionnaire with rasch analysis. *Invest Ophthalmol Vis Sci* 2011;52(9):6971-6977.