Safety and Efficacy of XEN Implant Versus Trabeculectomy

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Background

In recent years, micro-invasive glaucoma surgery (MIGS) plays a big role in glaucoma surgery alongside trabeculectomy which has been the gold standard filtering surgery for glaucoma. This is due to its high safety profile, standardisation of the procedures, reduced surgical time, quick patient recovery (Lusthaus and Goldberg, 2019), and it can either be applied as a stand-alone surgery or combined with cataract surgery.

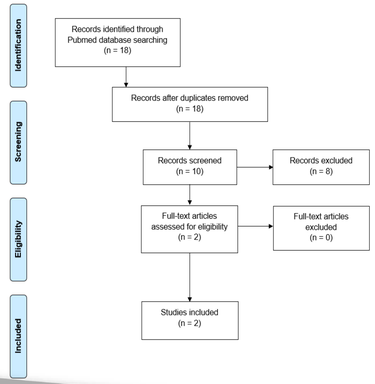
XEN implant is an ab interno gelatin stent currently used in MIGS. It applies a similar approach as standard trabeculectomy which targets the conventional outflow pathways creating a connection between anterior chamber and subconjunctival space without conjunctival dissection (Reitsamer *et al.*, 2019). XEN45 is a 6mm device with 45µm internal diameter, designed to optimise outflow as well as providing resistance to prevent hypotony (Hengerer *et al.*, 2018).

Objective

The aim of this review is to compare the safety and efficacy profile between XEN implant and trabeculectomy in glaucoma management.

Methods

Literature search was done via Pubmed database using the keywords: glaucoma AND trabeculectomy AND 'XEN OR gelatin', populating 18 articles. Articles available in English, full text and published within the last 5 years has been selected. Of these, 2 relevant articles obtained and included in this study. CASP tool has been utilised to assist the critical analysis of the studies selected.

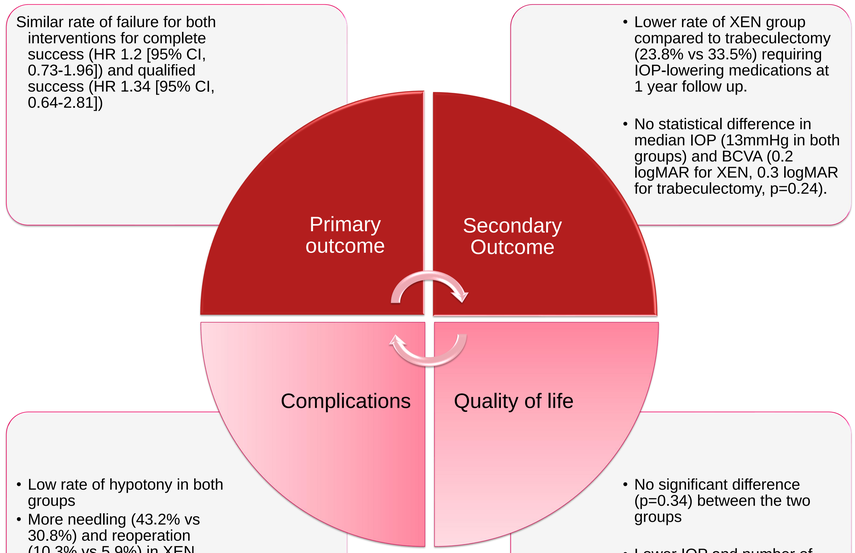


Discussions

The two studies included are:

Authors	Study design	Study length	Sample	Primary outcome
Schlenker et al. (2017)	Multicentre, retrospective, cohort study.	Jan 2011-Jul 2015. (FU 30 months)	354 eyes. (185 XEN, 169 trabeculectomy).	HR of failure
Basilio et al. (2018)	Cross-sectional study.	Oct 2015-Feb 2017.	34 eyes. (17 XEN, 17 trabeculectomy).	GSS score

Results



Limitations

- Confounding by indications
- Suboptimal findings for trabeculectomy as compared to recent trabeculectomy outcome data
- Varied surgical techniques and post op regimens (Bevacizumab and steroids given at the Belgium site)
- Total needling per sample unclear
- Time of the survey and sample size

Future Research

- Multi-centre (US), randomized, prospective, clinical trial study currently recruiting to compare the effectiveness and safety of XEN to trabeculectomy in subjects with open angle glaucoma refractory to topical medical therapy which will be due to finish in 2021.
- Multicentre (UK, Germany, Canada, Austria), prospective, observational, non-interventional study the treatment satisfaction and expectations in patients scheduled to receive surgical intervention either via XEN or trabeculectomy for open-angle glaucoma due to finish Nov 2019.

Conclusion

Currently, there is no strong evidence that XEN implant is superior to trabeculectomy. However, the selection of either type of surgery according to the patient's characteristics could possibly influence the success rate.

A large-scale RCTs looking at direct comparison between these two surgical methods is necessary to accurately compare their safety and efficacy to be able to safely put this into practice.

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