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Original article

Combined phacoemulsification and XEN45 surgery from a temporal approach and 2 incisions☆,☆☆

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ABSTRACT

Objective: To assess the safety and effectiveness of phacoemulsification combined with XEN45 implant surgery in patients with cataract and open-angle glaucoma, with 12-month follow-up.

Methods: A prospective study conducted on 30 eyes requiring phacoemulsification with, at least, 2 medications to control intraocular pressure (IOP). Phacoemulsification combined with XEN45 implant surgery was performed within 15 min of administering subconjunctival mitomycin C. Surgery was performed through 2 temporal incisions, separated by 90°, using the inferior to enter the XEN45 and to implant it in the superior nasal region. A record was made of the best corrected visual acuity, IOP before and 1 day, 1 month, 3 months, 6 months, 9 months, and 12 months after surgery, the number of antiglaucomatous medications, and complications.

Results: The best corrected visual acuity was 0.37 ± 0.2 and 0.72 ± 0.15 before and 12 months after surgery, respectively. The pre-operative IOP was 21.2 ± 3.4 mmHg, with 3.07 drugs, decreasing by 61.65% on the first day, 37.26% at 1 month, 35.05% at 3 months, 31% at 6 months, 30.6% at 9 months, and 29.34% at 12 months. The number of medications decreased by 94.57%. Complications occurred in 3 eyes, 2 of them were excluded because we could not complete the implantation (280° subconjunctival hemorrhage and XEN extrusion when trying to reposition). In a third case, the bleb was encapsulated at 5 months after surgery.

Conclusions: The phacoemulsification combined with XEN45 implant surgery can effectively reduce IOP and the number of drugs in mild-moderate open-angle glaucoma, as they rehabilitate the VA. The use of only 2 micro-invasive incisions makes it simple, quick and safe, with few complications at 12 months follow-up from surgery.

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Cirugía combinada mediante facoemulsificación e implante XEN45 con acceso temporal y 2 únicas incisiones

Palabras clave:
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Implante de drenaje glaucoma
Glaucoma de ángulo abierto/cirugía
Presión intraocular
Stents
Microcirugía

RESUMEN

Objetivo: Analizar la eficacia y seguridad de la técnica combinada de facoemulsificación e implante XEN45 empleando acceso temporal y 2 únicas incisiones, en casos de catarata y glaucoma crónico de ángulo abierto, con seguimiento de 12 meses.

Métodos: Estudio prospectivo de 30 ojos que requerían facoemulsificación y que precisaban, al menos, dos medicamentos para controlar presión intraocular (PIO). Se efectuó cirugía combinada de facoemulsificación e implante XEN45 a los 15 min de administrar mitomicina C subconjuntival. El procedimiento se realizó a través de 2 incisiones temporales, separadas por 90°, utilizando la inferior para introducir el XEN45 e implantarlo en región nasal superior. Se registró agudeza visual mejor corregida, PIO previa y en días 1-30-90-180-270 y 365 poscirugía, número de medicamentos hipotensores y complicaciones.

Resultados: La agudeza visual mejor corregida preoperatoria fue 0,37 ± 0,2 y 0,72 ± 0,15 a los 12 meses. La PIO previa fue 21,2 ± 3,4 mmHg con 3,07 fármacos, descendiendo un 61,65% el primer día, 37,26% al mes, 35,05% al tercer mes, 31% al sexto mes, 30,6% al noveno mes y 29,34% a los 12 meses. El número de fármacos disminuyó un 94,57%. Solo hubo complicaciones destacables en 3 ojos, de ellos, 2 se excluyeron al no poder completar implantación (uno por hemorragia subconjuntival en 280° y otro, por extrusión del XEN al intentar recolocarlo). En un tercero, la ampolla se encapsuló a los 5 meses poscirugía.

Conclusiones: La cirugía combinada de facoemulsificación e implante XEN45 reduce eficazmente la PIO y el número de medicamentos en el glaucoma crónico de ángulo abierto leve-moderado, al tiempo que rehabilita la AV. El empleo de solo 2 incisiones posibilita una cirugía microinvasiva sencilla, rápida y segura con escasas complicaciones tras 12 meses de seguimiento.

Introduction

Cataracts and glaucoma are among the main causes of visual loss worldwide.[1] The development of these 2 diseases, which frequently occurs simultaneously with aging, means that over 20% of patients who undergo cataract surgery also have glaucoma.[2] Traditionally, in combined surgery, trabeculectomy was associated to phacoemulsification. However, even though trabeculectomy is the gold standard for lowering intraocular pressure (IOP), it involves potentially severe complications.[3] For this reason, to minimize said complications micro-invasive surgery techniques have emerged, such as microinvasive glaucoma surgery – (MIGS).[3–5] One of the new devices is XEN (AqueSys Inc., California, USA). The third generation of this implant, XEN45, is a valve-free collagen tube measuring 6 mm long, 150 μm thick and 45 μm inner diameter (Fig. 1) that is implanted from the anterior chamber (AC) into the subconjunctival space (SC), creating a scleral channel which facilitates aqueous humor drainage.[6–9] Even though several multicenter studies are being developed in Europe and Canada, their results have not yet been published in impact journals even though the preliminary studies indicate that XEN45 is efficient and safe for diminishing IOP and the number of medicaments in glaucomatous patients.[10–15]

The purpose of this study is to assess the safety and efficacy of combined surgery comprising phacoemulsification and XEN45 implant (FACO-XEN) through temporal access and 2 single incisions. To this end, the procedure was completed in 30 cases referred for cataract surgery with slight or moderate chronic open angle glaucoma (COAG), with a follow-up period of 12 months.

Materials and methods

Study design

A prospective, non-controlled and non-randomized study to assess the efficacy and safety of combined FACO-XEN surgery with temporal access and 2 single incisions. Selected patients presented a diagnostic of cataracts and COAG. Informed consents in writing were obtained from said patients for performing said combined surgery and for the present study. The protocol was approved by the Ethics Committee of the authors' institution in compliance with the Helsinki Declaration guidelines as well as the stipulations of Spanish laws in force.

Subjects

Patients were recruited in the Glaucoma Section of the Ophthalmology Dept. of the University Clinic Hospital of Valencia (Spain). Each patient underwent a full ophthalmological examination comprising clinical history and anamnesis,