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Original article

LASIK and surface ablation in patients treated with amiodarone☆

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ABSTRACT

Objective: To determine the anatomical and functional outcomes of corneal refractive surgery in patients on amiodarone, a drug listed as being contraindicated in patients undergoing this procedure.
Material and methods: A retrospective observational study was conducted on all consecutive patients who took amiodarone and who underwent LASIK or surface ablation from January 2003 to December 2014. Functional (visual and refractive) outcomes are described.
Results: A total of 20 patients (33 eyes) were included. No significant intraoperative or postoperative complications were found.
Conclusions: In our experience, LASIK and surface ablation did not produce significant clinical complications in selected patients taking amiodarone. The absolute exclusion of certain systemic medications should be reconsidered.

LASIK y ablación de superficie en pacientes tratados con amiodarona

Palabras clave:
Amiodarona
Queratomileusis in situ asistida por láser

RESUMEN

Objetivo: Determinar los resultados anatómicos y funcionales de los pacientes intervenidos con cirugía refractiva corneal que estaban en tratamiento con amiodarona, la cual ha sido considerada como una posible contraindicación en estas intervenciones.

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Queratectomía fotorrefractiva
Queratectomía subepitelial asistida por láser
Ablación de superficie

Material y métodos: Se ha realizado un estudio observacional retrospectivo. Los pacientes se incluyeron consecutivamente.

Se incluyó a todos los pacientes que tomaban amiodarona y fueron operados mediante LASIK o ablación de superficie entre enero de 2003 y diciembre de 2014. Se pretenden describir los resultados funcionales (visuales y refractivos).

Resultados: Se incluyó a un total de 20 pacientes (33 ojos). No se encontraron complicaciones intraoperatorias o postoperatorias significativas.

Conclusiones: En nuestra experiencia los pacientes tratados con amiodarona e intervenidos mediante LASIK o ablación de superficie no presentaron complicaciones clínicas significativas. La contraindicación absoluta por tomar determinadas medicaciones sistémicas debería ser reconsiderada.

Introduction

Following the recommendation of the first Excimer laser companies, the health authorities of the United States (Food and Drug Administration, FDA) established a set of absolute and relative contraindications for cornea and refractive surgery during the first years of this technique. Said contraindications comprised some systemic medicaments, including amiodarone. The FDA publication titled «Facts you need to know about LASIK laser treatment» indicated that amiodarone could affect LASIK precision or healthy corneal response after LASIK, as it could potentially produce poor vision (http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4353b1-06.htm; visited April 13, 2015).

At present, the American Academy of Ophthalmology considers the use of amiodarone as a relative contraindication for corneal refractive surgery.[1] Moreover, a recent review on laser excimer refractive surgery contraindications stated that it should be avoided in patients taking amiodarone.[2]

The objective of the present study is to assess the anatomical and functional results of a group of patients treated with amiodarone and intervened with LASIK or surface ablation (refractive keratectomy or PRK and laser assisted subepithelial keratectomy or LASEK).

Subjects, material and methods

This retrospective case study included patients operated in the Baviera Clinic (Spain) with LASIK or surface ablation between January 2003 and December 2014. Said private institution, comprising 19 clinics and 84 ophthalmological surgeons in Spain, carries out over 40,000 refractive procedures each year.

Data were obtained in accordance with national laws, and the approval of the responsible institution was also obtained. Due to the retrospective nature of the study, no special informed consent was required.

Patients in treatment with amioradone at the time of surgery were identified in the clinic database with an electronic search process utilizing LASIK/surface ablation and amioradone as keywords. Patient clinic records are computerized in the institution and include an “indications” field that details the type of surgery applied to the patient. The two corneal laser refractive treatment options are LASIK and surface ablation, which includes PRK and LASEK. Epithelial LASIK or epi-LASIK is not carried out in said institution.

Clinic records were reviewed to obtain the following data: age, sex, operated eye, procedure type (LASIK, LASEK, PRK), post-surgery corrected distance visual acuity (CDVA), post-surgery uncorrected distance visual acuity (UDVA) and complications.

Surgical technique and post-surgery protocol

Prior to the procedure, patient refraction should remain stable during the previous year. Complete ophthalmological examination is performed before surgery in accordance with a standard protocol to assess whether patients are adequate candidates for corneal refractive surgery. Informed consent in writing was obtained in each case. All the procedures followed the standard protocols. LASIK was performed utilizing the Moria LSK-1 manual microkeratome (Microtech, Inc./Moria, Antony, France). Epithelial raising of surface ablation was performed mechanically with or without exposure to 20% alcohol solution during 20 s, depending on surgeon preference. Mitomycin C was applied during 12–15 s immediately after surface ablation. Said ablation was performed with Technolas 217C and 217-Z-100 (Bausch & Lomb, Munich, Germany), Mel 80 (Carl Zeiss Meditec AG, Jena, Germany), or Wavelight Allegretto (Alcon Surgical, Inc., Fort Worth, United States) excimer laser devices.

The patients underwent post-surgery checkups at 12 h, 7 days, one and 3 months after surgery unless the appearance of effects required additional checkups.

Refractive and functional results

The following parameters were analyzed:

a. Efficacy: percentage of eyes with postop UDVA equal or better than preop CDVA. The efficacy index was calculated as the postop UDVA/preop CDVA ratio. Eyes scheduled for monovision were excluded.
b. Safety: percentage of eyes that lost over 2 CDVA lines (Snellen) after the procedure compared to presurgery CDVA. The safety index was calculated as the postop CDVA/preop CDVA ratio.