PASS Information

Title	Post-Market Clinical Follow-up Study—Retrospective Evaluation of Endothelial Cell Density and IOL Explants Related to the Clinical Use of AcrySof® CACHET® Phakic Lens in Three European Countries
Version identifier of the final study report	1.0
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Device product	AcrySof® CACHET® Phakic Lens
Marketing authorisation holder(s)	Alcon Labs
Joint PASS	No
Research question and objectives	Low endothelial cell count may result in corneal oedema with subsequent clouding of the cornea and blurred vision. Anterior chamber phakic intraocular lenses are used for the correction of myopia. Endothelial cell loss after anterior chamber phakic lens implantation have been reported to the French Health Products Safety Agency (ANSM), leading in some cases to lens explantation and corneal grafts 2-3 years after implantation. In response to a request from the ANSM in France, this study was performed to describe changes in endothelial cell density in a real-life setting and to quantify endothelial cell loss and AcrySof® CACHET® Phakic Lens explants.
Country(-ies) of study	France, Germany, and Spain
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1 Abstract

Title: Post-Market Clinical Follow-up Study—Retrospective Evaluation of Endothelial Cell Density and IOL Explants Related to the Clinical Use of AcrySof® CACHET® Phakic Lens in Three European Countries

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Keywords: AcrySof® CACHET® Phakic Lens, non-interventional cohort study, phakic lens, endothelial cell loss, endothelial cell density, lens explant

Rationale and background: Corneal endothelial cell density (ECD) decreases with age and may decrease at a faster rate after the implant of phakic lenses, eventually leading to lens explantation or corneal transplant.

This post-authorisation safety study addresses the request of the French Health Products Safety Agency (ANSM) to evaluate endothelial cell loss (ECL) and lens explants among adult subjects who had an AcrySof® CACHET® Phakic Lens (CACHET lens) implanted in routine clinical practice settings in European countries.

Research question and objectives: To quantify the frequency of ECL perceived to put endothelial cell function at risk and the frequency of lens explants. To describe ECD changes and explore risk factors for the above mentioned endpoints in subjects with a CACHET lens implanted in routine clinical practice in selected countries in Europe.

Study design: Non-interventional cohort study with retrospective medical record review of subjects who had a CACHET lens implanted in routine clinical practice with central ECD measurements before and after surgery.

Setting: The study was implemented in ophthalmic surgery clinics in France, Germany, and Spain. At each centre, the study began after all ethics requirements were met and approvals obtained. Investigators extracted de-identified patient data into an electronic data capture system including preoperative information (demographics, ECD measurements, relevant medical history and clinical characteristics) and postoperative data (ECD measurements and information on explants or repositioning of the lens, or corneal transplant).

Subjects and study size: The study aimed at collecting data from 200 subjects (up to 400 eyes) that had at least one eye with a CACHET lens implanted across all countries.

Variables and data sources: The source of study data was the medical records of subjects who had a CACHET lens implanted in routine clinical practice prior to the start of data collection. The main endpoint variables were (1) the changes of ECD from the implant date, (2) decreases in ECD at threshold perceived to put at risk endothelial cell function (referred to as ECL-SE), (3) the explant or repositioning of the CACHET lens,

and (4) corneal transplant. Other variables included demographics, comorbidities, and relevant clinical data before and after surgery. Endpoints occurring within the 6 months after surgery were defined as acute, possibly related to surgical trauma, and events occurring 6 months or later after the surgery were defined as chronic.

Results: Five centres (one in France, two in Spain, and two in Germany) provided analyzable data on 179 subjects with 332 implanted eyes (14 from France, 190 from Germany, and 128 from Spain). The mean age was 35 years, and 61% of subjects were female. Mean follow-up per eye was 23 months. One year after surgery, the central ECD decreased 4% overall (19% in France, 1% in Germany, and 3% in Spain). Eight eyes had a measurement that met the criteria of ECL-SE, 6 cases recovered and 2 were stable with a low ECD. There were no lenses explanted or repositioned, and no corneal transplants. The main differences in care found between France and the other two countries are the universal preoperative use of topical medications in France (almost absent in Germany and Spain) and the use of general anaesthesia in France (peribulbar or topical in Germany and Spain). No clear risk factors for ECL were identified with regression analysis.

Discussion: In this study in the routine care setting, ECL at 1 year after surgery was consistent with other studies using this lens; ECL was larger in France and smaller in Germany. Of 8 cases with ECL-SE, 6 recovered and 2 were persistent at last visit, with no lens explants or repositioning. No clear risk factors for ECL were identified with regression analysis.

Marketing Authorisation Holder(s): Alcon Labs

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