

Three Month Clinical Evaluation of Two Contamac RGP Contact Lenses

FINAL REPORT

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A. INTRODUCTION

The Contamac RGP3 materials are rigid gas-permeable (RGP) materials for use in the manufacture of rigid lenses for the correction of myopia, hypermetropia and astigmatism. The two materials have similar constituents but differ in their oxygen permeability (Dk).

The lower Dk material has a Dk of 26 at eye temperature and the higher Dk material has a Dk of 123 at eye temperature. For the purposes of this study project code name of RGP3-Dk20 and RGP3-Dk80 were allocated; this was advised by Contamac Ltd. for confidentiality purposes.

The purpose of this study was to evaluate the clinical performance of RGP lenses made in these materials in comparison with two control RGP materials. These clinical study results support an FDA 510(k) application.

A.1 Purpose

- i. To evaluate the clinical performance of two rigid gas-permeable (RGP) lens materials.
- ii. To compare the clinical performance of a high Dk and a low Dk RGP material with existing high and low Dk materials.

A.2 Statement of Compliance

One hundred and thirty-six (136) subjects were enrolled in the study. Of the 136 subjects enrolled, 67 subjects (49%) wore high Dk lenses and 67 (49%) wore low Dk lenses bilaterally. Two subjects (1%) were enrolled but not dispensed lenses and one subject (1%) was disqualified.

In the high Dk group, 44 (66%, 44/67) wore the test lens material (RGP3-Dk80) and 23 (34%, 23/67), the control lens (Boston XO).

In the low Dk group, 44 subjects (66%, 44/67) wore the test lens material (RGP3-Dk20) and 23 subjects (34%, 23/67), the control lens (Boston ES).

A.3 Study Design

This was a three-month, partially masked, bilateral, randomised, daily wear study. One hundred and thirty six (136) subjects were enrolled in the study. Of these, 46 subjects were allocated to wear the Contamac RGP3-Dk80 lens, a further 44 subjects wore the Contamac RGP3-Dk20 material lens in both eyes while the remaining 46 subjects wore one of the two control lens in both eyes (23 each group).

The protocol received a favourable opinion from the British Contact Lens Association Research Ethics Committee prior to study commencement.

A.4 Summary of Safety and Effectiveness

In general, there were no differences between Contamac RGP3-Dk80 and the Boston XO lenses in respect of biomicroscopic findings, symptoms or vision safety measures. Likewise, Contamac RGP3-Dk20 and the Boston ES lenses were similar in terms of biomicroscopic findings, symptoms or vision safety measures. The two lens-related discontinuations in the high Dk group were probably due to the subjects being unadapted RGP lens wearers and not the lens materials. In the low Dk group, two of the five lens related discontinuations were probably also due to subjects being unadapted RGP lens wearers, and the remaining three, probably due a patient-dependent requirement for higher oxygen transmissibility.

B. CONCLUSIONS*

- i. Contact lenses manufactured in RGP3-Dk80 material ordered to practitioners' specifications performed well and are safe and effective over a 3-month period.
- ii. Contact lenses manufactured in RGP3-Dk80 and Boston XO materials perform equally well over a 3-month period contact lens wear.
- iii. Contact lenses manufactured in RGP3-Dk20 material ordered to practitioners' specifications performed well and are safe and effective over a 3-month period.
- iv. Contact lenses manufactured in RGP3-Dk20 and Boston ES materials perform equally well over a 3-month period contact lens wear.

*Additional data on file