



WHY CHOOSE THIN? ON-EYE INVESTIGATION

INVESTIGATING WHY THIN WORKS

Most soft lenses for keratoconus and irregular corneas tend to be manufactured relatively thick. The reasoning for this is that optimal VA is achieved by increasing center thickness in order to mask corneal distortion.

However, extensive research using computer modelling has shown that the most important factor for optimal VA is to ensure optimal fit. It is the excessive tear layer under the lens that contributes to the poor, fluctuating VA experienced with some lenses.

Soft lenses are designed to flex and drape as part of the fitting process. Using traditional soft lens designs with increased overall thickness can lead to uneven tear distribution under the lens.

Fitting 'Thin' allows more drapage which improves peripheral fit, evening out tear distribution and thus improving VA. The thinner design also increases oxygen transmission which is healthier for the eye.

INTERNAL STUDY

To investigate the efficacy of KeraSoft® Thin, an internal study was carried out comparing KeraSoft® Thin to IC on subjects already successfully adapted to the KeraSoft® IC lens.

The results demonstrated that in all cases, comfort was the same or increased significantly by the thinner design. Fit was very similar to IC and 95% of subjects experienced equal or improved VA.

This was achieved by maintaining the same parameters for the fit, demonstrating that KeraSoft® Thin could be fitted from KeraSoft® IC fitting lenses or powered lenses.

The small number who experienced worse VA represented 3 eyes out of a sample of 48. These subjects had central keratoconus and subsequent experience of the Thin design has shown that changing fit parameters in such cases will improve VA.

KERASOFT® THIN VS KERASOFT® IC COMPARING ON-EYE PERFORMANCE

INTRODUCTION

KeraSoft® Thin has approximately half the center thickness (0.20CT) of KeraSoft® IC, making it the thinnest custom soft specialty lens available for irregular corneas. As part of the validation process, an internal study was conducted to compare the two designs for on-eye performance.

METHODOLOGY

24 subjects (48 eyes), with a range of irregular corneal conditions took part in the study. The majority of subjects had keratoconus and a small number of patients with PMD/INTACS/post-graft were also included. All were successfully fitted with KeraSoft® IC lenses and had been wearing them for several months.

PATIENT DEMOGRAPHICS

Corneal Type*	
Central Cone	13
Offset Cone	14
Low Cone / PMD	14
Post-graft	4
INTACS	2
Post Hydrops	1

New lenses of both designs, using the same parameters, were issued to each subject.

They were instructed to wear each lens design for one week and then return for assessment, wearing the design they preferred.

Visual Acuity (VA) was measured using decimal notation. Baseline VA was established with KeraSoft® IC and the variance from this value was recorded with KeraSoft® Thin.

Subjects were asked to score comfort levels on a scale of 1 to 5 during home trials. Fit was assessed on the slit lamp using the MoRoCCo VA assessment technique.

RESULTS

70% of subjects returned wearing KeraSoft® Thin as their preferred lens type.

20% reported they found no difference between designs and returned wearing their original IC lenses.

10% reported that they preferred their original KeraSoft® IC design.

VISUAL ACUITY

In the graphs on the following page, positive values represent improved VA and negative values represent a decrease in VA. Thus all points on or above the 0.00D line represent unchanged or improved VA with the KeraSoft® Thin design.

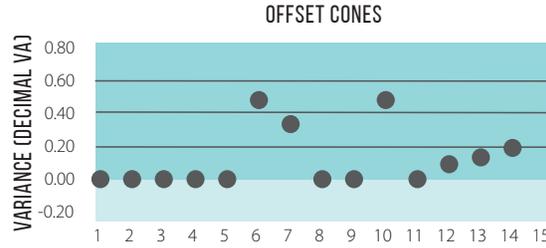
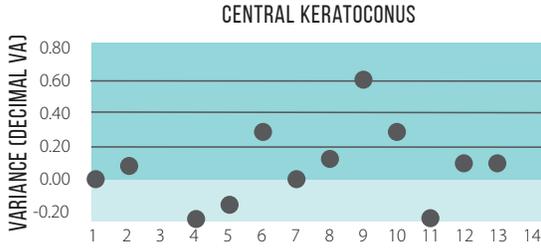
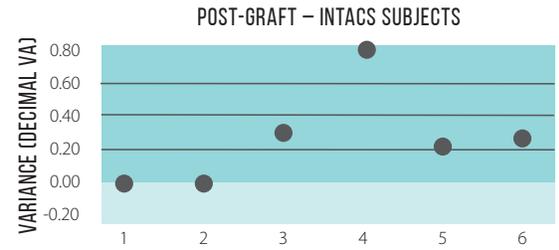
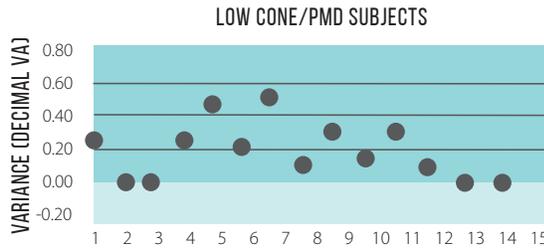
COMFORT

On comparing overall comfort between the two designs, all subjects felt that comfort was either equal to (17%) or superior to (83%) with KeraSoft® Thin compared to that of the KeraSoft® IC design. None felt that it was worse.

Of the subjects who found improved comfort, 85% felt that it was improved by up to 2 steps with KeraSoft® Thin, while the remainder said comfort was increased by 3 or 4 steps.

*13 patients had undergone corneal collagen crosslinking (CXL) treatment.

VARIANCE IN VA WITH DIFFERENT CORNEAL TYPES



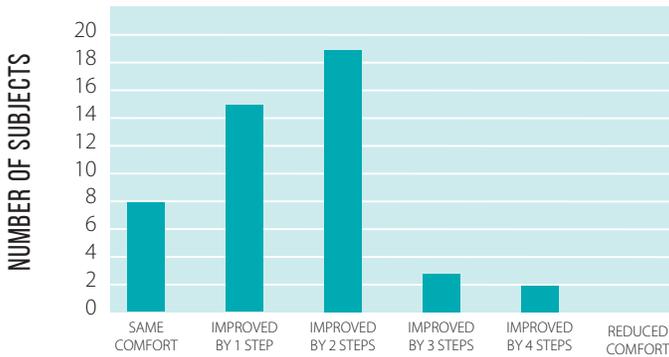
Subjects with Low Cones, PMD or post-graft corneas demonstrated better or equal VA with KeraSoft® Thin in comparison with KeraSoft® IC. Some individuals showed several lines of improvement using the thinner design.

Subjects with Offset Cones demonstrated either the same or slightly improved VA with KeraSoft® Thin compared to KeraSoft® IC. At no time was VA any worse with the Thin design.

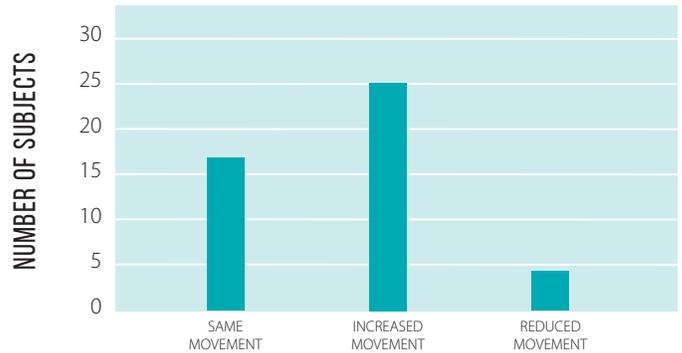
Subjects with Central Cones had more varied results. Most demonstrated equal or better VA but 3 eyes experienced lower VA with the KeraSoft® Thin design.

Overall, 45 (95%) eyes experienced equal or better VA with KeraSoft® Thin while 3 eyes demonstrated a 1 line drop in VA. This was achieved without changing any parameters. Subjects with Nipple Cones appeared to benefit most from the thinner design.

COMFORT SCORES COMPARING KERASOFT® THIN TO KERASOFT® IC



EFFECT ON MOVEMENT KERASOFT® THIN COMPARED TO KERASOFT® IC



Note: Subjects were asked to rate comfort in 5 steps: 1 being the lowest and 5 being the highest.

EFFECT ON FIT CHARACTERISTICS

There was little difference in rotation or centration between the two lens types. Movement was slightly increased for around 50% of the KeraSoft® Thin fittings, although 4 lenses fitted to Low Cone eyes demonstrated less movement. In these 4 cases, the reduction equated to a more stable fit.

DISCUSSION

Comparison of both lens designs in this study demonstrates that the reduced thickness of KeraSoft® Thin improves VA and comfort for most irregular conditions without negatively impacting fit or VA. The results also show that KeraSoft® Thin can be fitted from KeraSoft® IC Fitting Sets or powered lenses without any adjustment to parameters.

The conditions benefitting most from this design are Low Cones/PMD, post-graft and post-surgical cases. However, as all subjects benefitted from increased comfort and 96% experienced equal or better VA with the thinner design, it is suggested that KeraSoft® Thin should be the preferred First Choice design.

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