Transferring optical designs across lens materials: a randomized, double-masked, two-way crossover clinical comparison of samfilcon A and kalifilcon A multifocal contact lenses

Poster 7

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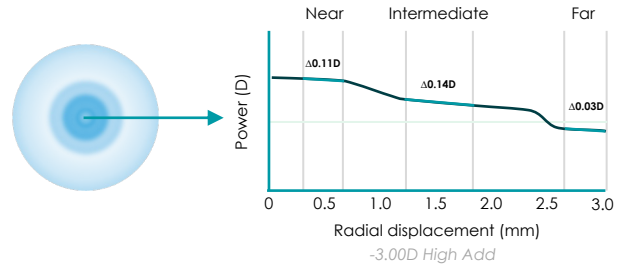
BACKGROUND

The kalifilcon A MFCL (ULTRA® ONE DAY Multifocal) incorporates **3-Zone Progressive™ Design** multifocal optics as also found in samfilcon A MFCLs, but **successful transfer of any optical design also needs to account for how different materials may influence CL fit on the eye** (which can then influence vision and comfort)



Key lens characteristics	Samfilcon A	Kalifilcon A
Modulus	0.7 MPa	0.5 MPa
Water content	46%	55%
Base curve	8.5 mm	8.6 mm
Diameter	14.2 mm	14.2 mm
Technologies	MoistureSeal®	Advanced MoistureSeal® +ComfortFeel Technology

Following computational and bench evaluations, **this study was conducted to assess the on-eye clinical performance** of the kalifilcon A MFCL versus the samfilcon A MFCL

METHODS

Study design: Randomized, bilateral, 2-way crossover, double-masked study (NCT05325931)

Participants: Experienced CL wearers ≥ 40 years of age

Study lenses: Randomised lens type worn in both eyes on a **daily-disposable basis for ≥8 hours per day for ~ 1 week** before crossover to the other lens type at Visit 3

Fitting: Bausch + Lomb MF fitting guide used

VISIT 1 — Screening/baseline Dispense first lens type
VISIT 2 — 1-week follow-up for first lens type
VISIT 3 — Dispense second lens type
VISIT 4 — 1-week follow-up for second lens type

Assessments

- **VISUAL ACUITY** — Binocular HCHI VA was measured at 6 m and 40 cm
- **VISUAL QUALITY** — Assessed on 0–100 VAS
- **COMFORT** — Assessed on 0–100 VAS

Other secondary assessments included centration, movement, redness, staining, CL deposits, wettability, and incidence of adverse events/device deficiencies.

PRIMARY ENDPOINT
Mean binocular logMAR VA, at both 6 m (distance) and 40 cm (near)

COMPARATIVE ASSESSMENT
A noninferiority margin of 0.06 logMAR (3 letters) was used to demonstrate noninferiority

NULL HYPOTHESIS
The true mean difference between the test and comparator lenses is ≥0.06 logMAR

SAMPLE SIZE
A sample size of 22 participants was calculated to have 90% power to reject the null hypothesis

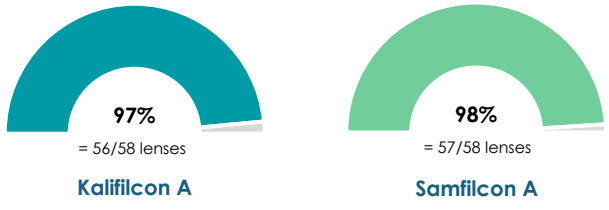
RESULTS

PARTICIPANTS

30 participants were enrolled and dispensed both lens types; 29 participants completed all four study visits with one discontinuation owing to participant travel.

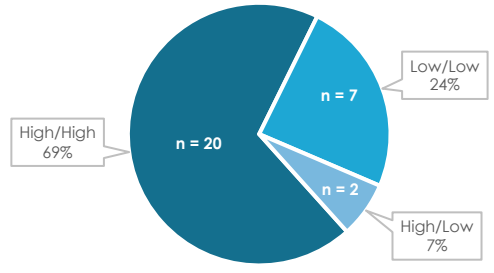
Demographics	N=29
Female, n (%)	13 (45%)
Mean (SD) age, years	53.9 (5.5)
Age range, years	42–63

FIRST LENS FIT CORRECT



Two of the lens changes were from high add to low add (same lens power to improve distance vision); one lens change was to a less minus power (same add power, to improve near vision).

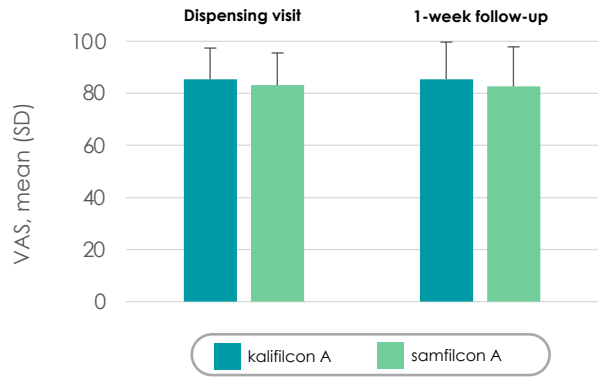
ADD POWERS FITTED



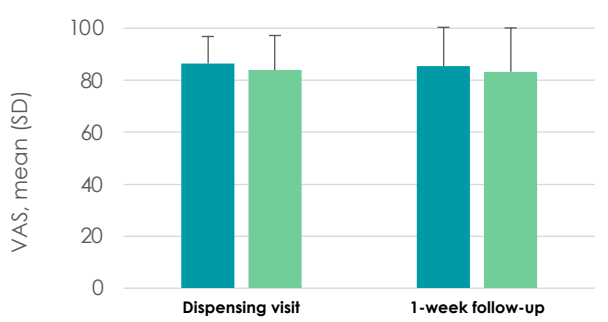
VISUAL QUALITY

There were no significant differences in visual quality between lens types, both at distance and near

Binocular visual quality at 6 m



Binocular visual quality at 40 cm

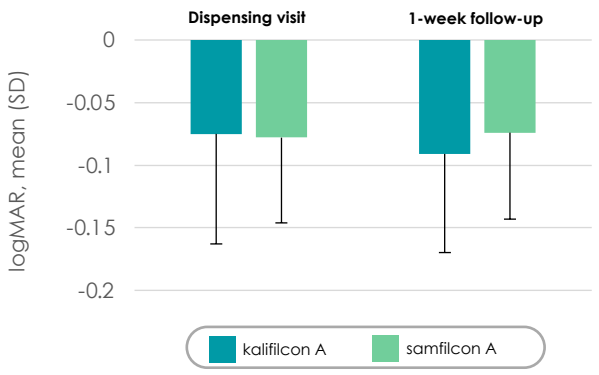


Descriptors of "good", "very good" and "excellent" were indicated for thresholds of 60, 80 and 100, respectively, on the VAS

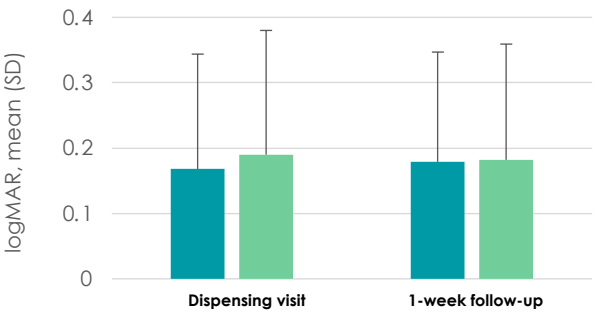
VISUAL ACUITY

There were no significant differences in visual acuity between lens types, both at distance and near

Binocular HCHI logMA VA at 6 m

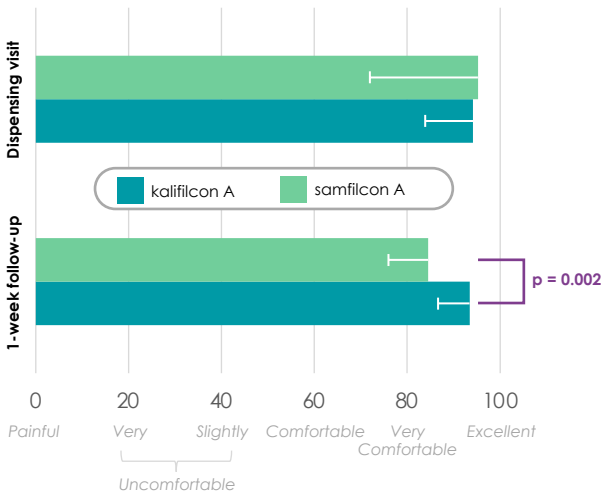


Binocular HCHI logMA VA at 40 cm



COMFORT

Comfort ratings were statistically significantly higher for kalifilcon A at follow-up (mean **93.4** vs. **84.5**, p = 0.002)



Error bars represent SD

Secondary assessments

- There were no clinically meaningful differences in **fit, movement, or ocular findings**
- All CLs exhibited **excellent wettability** and **minimal deposition**
- **No adverse events or device deficiencies** were reported

CONCLUSIONS

- Kalifilcon A MFCLs demonstrated straightforward fitting and strong visual performance equivalent to samfilcon A MFCLs, with greater overall comfort
- Results confirm the success of design transfer between these materials

DISCLOSURES

Omür Uçakhan-Gündüz is a Consultant and Advisor for Bausch + Lomb.
Ertuğrul Akbaş is an employee of Bausch + Lomb.

ABBREVIATIONS

CL, contact lens; HCHI, High Contrast High Illumination; MF, multifocal; MFCL, multifocal contact lens; VA, visual acuity; VAS, visual analogue scale

ACKNOWLEDGEMENTS

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