Risk of corneal inflammatory events with silicone hydrogel and low Dk hydrogel extended contact lens wear: a meta-analysis
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CRD summary
This review evaluated the risks of corneal inflammatory events among patients using silicone-hydrogel versus low Dk hydrogel extended wear contact lenses. Silicone-hydrogel lenses worn for up to 30 days had a doubled risk for corneal inflammatory events than low-Dk worn for 7 days extended wear. The conclusions appear reasonable.

Authors’ objectives
To evaluate the risk of corneal inflammatory events in users of silicone hydrogel (SH) and low Dk (permeability) hydrogel extended wear contact lenses.

Searching
MEDLINE, EMBASE, the Cochrane Database of Systematic Reviews and Reference Sight were searched from 1990 to February 2006; the search terms were reported. Abstracts from the annual meetings of the American Academy of Optometry, the Association of Research and Vision in Ophthalmology, the Food and Drug Administration’s website for SH lens approvals and references of retrieved articles were searched, and experts in the fields were contacted for additional studies. No language restrictions were applied.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and prospective or retrospective design cohort studies were eligible. Case-control and observational studies were excluded.

Specific interventions included in the review
Studies evaluating high Dk SH and low Dk hydrogel extended wear lenses were eligible. Studies had to provide clear information about the lens type evaluated. Studies were excluded if extended wear lenses were used for therapeutic purposes, or if they reported on non-disposable low Dk hydrogels. Most of the included studies used low Dk lenses on a 7-day regimen and SH lenses on a 30-day regimen. In the SH arm, the lens types were lotrafilcon A, balafilcon A and senofilcon A. In the low Dk arm, etafilcon and polymacon were the most commonly evaluated types. Prototype and older design lenses were included.

Participants included in the review
Studies including healthy individuals who were followed up for at least 4 months were eligible. The median follow-up was 12 months (range: 4 to 36).

Outcomes assessed in the review
Any study which reported on the number of corneal inflammatory events over a defined period of time was eligible, regardless of the definition used for the inflammatory event. Outcomes results were provided on a per-eye or per-person basis. Definitions of adverse events differed amongst the studies. Studies reporting on ulcerative keratitis were excluded.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Subgroup analysis was performed according to study quality criteria. Nine items were rated as relevant: prospective study design; randomisation; 12 month minimum length of follow-up; direct evaluation of both arms; data provided on a per-eye basis; sample size above 200 units; and reporting of the definition of infiltrate, the percentage adapted to extended wear, or the use of only single events. The classification of subtypes of corneal inflammatory events, reporting
of the length of wear, specification of the disposal schedule, daily wear adaptation phase, the refractive error, and the
distribution of age and gender were also considered as quality items. The authors did not clearly state how many
reviewers performed the validity assessment.

**Data extraction**

Two reviewers independently extracted the data onto standardised forms, with any disagreements resolved by
discussion. When necessary, authors were contacted for additional data.

**Methods of synthesis**

How were the studies combined?

A random-effects model was used to calculate pooled risk ratios (RRs) and 95% confidence intervals (CIs). Only results
from studies assessing the outcomes on a per-eye basis were reported, since the estimates on a per-person basis were
either not reliable or not derived from a direct comparison between the two types of lenses.

How were differences between studies investigated?

Sensitivity analysis was conducted by calculating adjusted RRs for the following covariates: the presence of
randomisation, location of the study, use of older or prototype design SH lenses, length of follow-up, definition of
infiltrate, percentage of extended lens wearers, and length of wear by material. Stratified analysis was performed by the
method of definition of a corneal inflammatory event. A subgroup analysis was conducted which excluded studies
where the mean age was less than 2 standard deviations below the mean.

**Results of the review**

Twenty-three studies (9,336 participants and 18,537 eyes) were included in the review. The study designs were open
randomised (n=8), masked randomised (n=2), prospective randomised (n=1), prospective non-randomised (n=5) and
retrospective (n=5). Two prospective non-controlled series were also included.

Fifteen studies (8,173 patients and 16,211 eyes) reported data on a per-eye basis, while 8 studies (1,163 patients or
2,326 eyes) provided results on a per-person basis. SH lenses were associated with a higher risk of corneal inflammation
in comparison with Dk lenses (RR 2.22, 95% CI: 1.65, 2.98); there was no evidence of statistical heterogeneity
(p=0.21). The analysis restricted to the 5 high-quality RCTs that directly compared the two type of lenses confirmed a
greater rate of corneal inflammation with SH lenses (RR 2.18, 95% CI: 1.48, 3.19, p<0.005). Correcting for quality
items, age or length of wear by material did not substantially influence the overall results. The authors stated that it was
not possible to separately assess the effects of length of wear or disposal schedule since these two variables were
strongly associated with the lens material.

**Authors’ conclusions**

SH lenses worn continuously for 30 days are associated with a two-fold greater risk of corneal inflammatory events than
low Dk lenses worn for 7 days. A 30-day wear schedule may predispose to a corneal inflammatory event more than the
SH material itself.

**CRD commentary**

This review had clearly stated inclusion criteria with respect to the intervention, participants and outcomes, while a
broad definition of study design was used. Several relevant databases were searched and specific attempts were made to
locate unpublished studies, thus reducing the risk of missing relevant studies due to publication bias. No language
restrictions were applied, thereby limiting the risk of missing relevant studies due to language bias. The data extraction
was performed by two independent reviewers but it was not stated whether the study selection and quality assessment
processes were also performed in duplicate, therefore reviewer error and bias might have been introduced at these
stages.

Statistical heterogeneity was assessed, and it was non significant. However, given the apparent clinical heterogeneity
between the studies and lack of studies directly comparing the two lens types, pooling might not have been appropriate.
While the authors’ conclusions seem reasonable, the clinical heterogeneity between the studies and the methodological
weaknesses of the review might limit the generalisability and reliability of these results.
Implications of the review for practice and research

Practice: The authors suggested that, despite the findings of this review, SH lenses can be considered as the lenses of choice for extended wear and daily wear.

Research: The authors stated that future studies should compare a 7-day SH extended wear schedule with a control arm of non contact lens wearers.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.