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Silicone hydrogel versus hydrogel soft contact lenses for differences in patient-reported eye comfort and safety (Protocol)

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[Intervention Protocol]

Silicone hydrogel versus hydrogel soft contact lenses for differences in patient-reported eye comfort and safety

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To evaluate the comparative effectiveness of silicone hydrogel compared with hydrogel contact lenses on self-reported comfort, dry eye tests, and safety in contact lens wearers.

BACKGROUND

Description of the condition

Description of the contact lens materials

The first contact lenses were manufactured in the late 1800s from ground glass, a material impermeable to oxygen, with severe hypoxia drastically limiting wear times (Jacob 2013). Innovations over the past 100 years or more have resulted in the development of gas permeable contact lenses as well as reusable and daily disposable soft contact lens materials that are primarily made of either hydrogel or silicone hydrogel polymers (Efron 2015; Jacob 2013). Hydrogel lenses generally have a higher water content and much lower oxygen permeability than silicone hydrogel lenses. Low oxygen transmissibility is a major contributor in contact lens-related complications, such as corneal inflammation or neovascularization (Dillehay 2007). Early studies suggested that contact lens materials required an oxygen transmissibility of 24.1 × 10-9 Dk/L to avoid corneal swelling during daily wear, and 87.0 × 10-9 Dk/L for overnight wear (Holden 1984). No hydrogel contact lenses meet the oxygen requirements for overnight wear and some do not meet the oxygen requirements for daily wear. Prescribing trends show the frequency of silicone hydrogel lens prescriptions have increased, while hydrogel lens prescriptions have declined (Efron 2015). Distributions between soft contact lens materials has remained steady since 2010, with silicone hydrogel and hydrogel lenses accounting for approximately 70% and 30% of the market share, respectively (Efron 2015).

Epidemiology and wearing patterns of contact lenses

Globally, approximately 140 million people are contact lens wearers, with 90% using soft contact lenses (Markoulli 2017). The USA is considered to be one of the largest markets with an estimated 38.5 million wearers (Efron 2015). Each year, the number of new contact lens users is nearly balanced out by a corresponding number of people who stop using contact lenses ('contact lens dropouts'), prompting numerous studies into potential reasons for discontinuation (Markoulli 2017; Pucker 2020). Despite innovations of lens materials over the last 50 years, the top reason for established contact lens wearers to discontinue use is ocular discomfort (Grant 2020; Pucker 2020). Other potential reasons for discontinued use of contact lenses include blurry vision, lack of motivation, and handling issues (Grant 2020; Pucker 2020). Ocular safety while wearing contact lenses is also a concern. Ocular safety is primarily evaluated with ocular surface signs, including corneal and conjunctival staining (Markoulli 2017). Meibomian gland health has also been recognized as an important factor associated with contact lens success (Pucker 2019). It is unclear whether ocular surface signs differ between hydrogel and silicone hydrogel contact lens wearers.

Diagnosis of contact lens discomfort and safety concerns

Information about contact lens comfort is typically collected informally from the wearer during routine contact lens fitting. Clinical evaluation of contact lens fit and tests for dry eye are sometimes used to further describe the etiology of discomfort complaints and identify safety concerns related to contact lens wear (Pucker 2019; Young 2002). However, patient questionnaires are rarely used to assess contact lens comfort in clinical settings. Well-designed research studies usually diagnose contact lens discomfort through formal questionnaires that are typically administered via paper or electronic format (Pucker 2018). The Tear Film and Ocular Surface Society (TFOS) International Workshop on Contact Lens Discomfort describes several potentially useful symptom-based questionnaires used for measuring patient-reported comfort (Nichols 2013).

McMonnies pioneered the first ocular surface specific symptom questionnaire, although it is not specific to contact lens use and lacks the ability to evaluate symptom severity (McMonnies 1986; McMonnies 1987). The 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8) has total scores ranging from 1 to 37; it was developed from the much longer CLDEQ that contains 36 questions with nine subscale scores (Chalmers 2012; Nichols 2002). The CLDEQ-8 is used primarily to compare baseline scores with change following contact lens refits (Chalmers 2012). A newer tool, the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire, was developed to improve assessment of lid wiper epitheliopathy-related eye discomfort symptoms (Blackie 2009; Korb 2005; Ngo 2013). The SPEED score is calculated using two subscales of frequency and severity of symptoms; scores range from 0 to 28, with a score of 1 to 9 points being diagnostic of mild to moderate dry eye, and 10 points or more considered severe dry eye (Blackie 2009; Korb 2005; Ngo 2013). Pucker 2018 psychometrically validated the CLDEQ-8 and SPEED questionnaire for tracking both the severity and frequency of symptoms in contact lens wearers. Another commonly used dry eye symptom questionnaire that is not validated for use in contact lens wearers is the Ocular Surface Disease Index (OSDI). This has three subscales to classify people as having mild, moderate, or severe forms of dry eye, on a scale from 0 to 100 (Schiffman 2000). Visual analog scales (VAS) are also frequently used to assess eye discomfort with a capped continuous linear scale.

Description of the intervention

It is possible to manage refractive ametropias (i.e. myopia, hyperopia, astigmatism, and presbyopia) using non-invasive or invasive options, or a combination of options. The most common ones include spectacles, contact lenses, and refractive surgeries. Contact lens options include corneal gas permeable, soft, hybrid (gas permeable optic zone with a soft skirt to support the optic zone), and scleral lens designs. Occasionally, a soft lens will be used under a corneal gas permeable lens to improve comfort or centration, or both. Of the contact lens options, soft contact lenses are by far the most commonly prescribed (Efron 2015).

Soft contact lenses may be broadly divided into either poly-2-hydroxyethyl methacrylate (poly-HEMA) or siloxane-based materials. The combination of two hydrogel copolymers led to the development of the first spin cast hydrogel soft contact lenses (Key 2007; Wichterle 1960; Wichterle 1961), and US Food and Drug Administration (FDA) approval in 1971. Hydrogel contact lenses improved comfort over rigid lens designs by significantly lowering the modulus of elasticity and providing whole corneal coverage, while reducing manufacturing costs (Jacob 2013). The demand for overnight wear began in England in the late 1970s (Carle 1972), and for continuous (30 night) wear in the USA in 1981 (Nicolson 2001). Continuous wear was rescinded by the FDA in 1989 in response to findings of increased risks of ulcerative keratitis (Poggio 1989). After the introduction of siloxane-based materials in 1999, continuous wear options became available again (Sankaridurg 2013). Further refinements were attempted to address comfort, vision, and safety issues, including adverse

physiological events, oxygen permeability (Dk), deposit formation and solution-related issues (Cho 2013; Covey 2001). Siloxane-based polymers released in the late 1990s were developed to address the comfort, lower modulus, and wettability issues encountered with dimethylsiloxane, while affording higher oxygen permeability than hydrogels (Morgan 2010). This led to a proliferation of research into bulk and surface properties across all wearing and replacement modalities, which did not eliminate physiological adverse events (Chalmers 2015), and introduced some novel mechanical interactions with the ocular surface (Sankaridurg 2013). The improvements in oxygen permeability did not alter rates of microbial keratitis (Alipour 2017; Diec 2018; Holden 2003; Lim 2018; Stapleton 2013; Sweeney 2013) or other adverse events, such as: increased inflammatory events (Richdale 2016; Szczotka-Flynn 2014), surface deposits (Millar 2003; Nichols 2013), and undesirable lens-solution interactions (de la Jara 2013; Diec 2013). Comfort issues remain due to their multifactorial nature (Guillon 2013; Lin 2013; Stapleton 2017; Varikooty 2013).

How the intervention might work

The tear film is a 2 µm to 5 µm thick layer of fluid that covers the ocular surface, hydrates the eye, and covers the irregularly shaped corneal surface; this smooth interface with the external world allows for comfortable, clear, and crisp vision (Bai 2018; Holden 2016; Maurice 1990; Szczesna 2006; Wang 2006). As described above, soft contact lenses are commonly used to correct refractive error. When a contact lens is applied to the eye, it splits the tears into two layers (Nichols 2003). This destabilizes the tears and may result in evaporation, resulting in the characteristic symptoms associated with contact lens discomfort (Begley 2000; Efron 1991). Contact lens discomfort may also stem from inherent individual factors such as age, contact lens care systems, and contact lens materials/designs (Nichols 2013). While the introduction of silicone hydrogel contact lens materials was intended to solve many of the contact lens-related issues, it is currently unclear whether silicone hydrogel contact lenses result in better ocular health and comfort than traditional hydrogel contact lenses (Guillon 2013; Stapleton 2017).

Why it is important to do this review

This systematic review is important as there remain unanswered research questions regarding self-reported contact lens comfort and safety (Doughty 1997). Discontinuation of contact lens wear is most frequently attributed to discomfort, though many people would still prefer contact lens wear over other vision correction modalities if comfort issues were resolved (Dumbleton 2013; Pritchard 1999; Richdale 2007). Globally, it is estimated that up to 30% of established contact lens wearers permanently discontinue lens wear because of ocular discomfort (Pucker 2020; Rumpakis 2010; Young 2002). While the comfort and safety of current contact lens designs have improved, the full etiology of contact lens discomfort remains largely unresolved, and conflicting results regarding safety and efficacy across soft contact lenses still exist (Nichols 2013). Therefore, ascertaining factors associated with contact lens comfort by comparing silicone hydrogel and hydrogel contact lens materials will help doctors and contact-lens wearers to make informed decisions about contact lens selection and wear.

OBJECTIVES

To evaluate the comparative effectiveness of silicone hydrogel compared with hydrogel contact lenses on self-reported comfort, dry eye tests, and safety in contact lens wearers.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomized controlled trials (RCTs) and quasi-randomized controlled trials. We will also include cross-over trials.

Types of participants

We will include trials that enrolled adults (age 18 years and over). We will impose no restrictions based on race, ethnicity, or gender.

Types of interventions

We will include trials that compared hydrogel and silicone hydrogel contact lenses, worn for vision correction as daily or continuous wear modalities.

Types of outcome measures

Primary outcomes

The primary outcome is the mean change from baseline in patient-reported comfort score (measured using CLDEQ-8) at one to four weeks.

Secondary outcomes

We will assess the following patient-reported comfort scores as secondary outcomes, measured as the mean change from baseline to follow-up at one to four weeks:

1. OSDI scores;
2. SPEED Questionnaire scores;
3. VAS scores.

If the selected studies do not report mean change from baseline, we will use the patient-reported comfort scores at one to four weeks. If a trial reports multiple measurements during the one to four-week time period, we will use data at the longest follow-up.

Adverse events

We will assess the proportion of participants with the following adverse events at one to four weeks:

1. discontinuation of contact lens wear;
2. corneal staining, assessed by any integer grading scale;
3. conjunctival staining, assessed by any integer grading scale;
4. conjunctival redness, assessed by any integer grading scale;
5. vision-threatening adverse events (e.g. microbial keratitis).

Search methods for identification of studies

Electronic searches

The Cochrane Eyes and Vision Information Specialist will search the following electronic databases for randomized controlled trials and

controlled clinical trials. There will be no restrictions to language or date of publication.

- Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) in the Cochrane Library (Appendix 1).
- MEDLINE Ovid (1946 to present) (Appendix 2).
- Embase.com (1947 to present) (Appendix 3).
- PubMed (1948 to present) (Appendix 4).
- LILACS (Latin American and Caribbean Health Science Information database (1982 to present) (Appendix 5).
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.ClinicalTrials.gov) (Appendix 6).
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp) (Appendix 7).

Searching other resources

We will search reference lists of identified studies, review articles, and guidelines for information about relevant studies that may not have been identified by our search strategy. We will impose no restriction on language or date of publication.

We will also contact experts in the field regarding information about any ongoing trials on silicone hydrogel and hydrogel contact lenses.

Data collection and analysis

Selection of studies

After removing duplicate records, two review authors will independently screen the titles and abstracts of potential studies using the internet-based review management software Covidence. The review authors will classify each record as 'definitely relevant', 'possibly relevant', or 'definitely not relevant' for full-text review. We will retrieve the full-text reports for records classified as 'definitely relevant' or 'possibly relevant'. Two review authors will then independently review the full-text articles for eligibility and classify articles as 'to be included' or 'to be excluded'. If there are questions regarding the eligibility of the studies, we will contact the authors of the studies to obtain further information necessary to determine study eligibility. If the trial authors do not respond within two weeks, we will use information available from publications and trial registers to determine eligibility. We will record reasons for exclusion for each report assessed as 'ineligible' after assessment of the full-text articles, in a 'Characteristics of excluded studies' table. We will classify studies that meet eligibility criteria but have not yet been completed as 'ongoing', and any relevant studies that have been completed but whose results are unavailable as 'awaiting classification'. We will resolve any disagreements between the review authors at each stage of the screening process by discussion and consensus.

Data extraction and management

Two review authors (two of ADP, KH, DF, SAA, DT) will independently extract data from included studies using the data collection form in Appendix 8 and Covidence software. One review author will export data from Covidence into Review Manager (RevMan) (Review Manager 2020), and a second review author will verify all data entries to ensure that data are consistent and free of errors. We will extract the following information: study setting, countries where participant recruitment took place, study design, sample size, study duration (planned and actual), participants, interventions, comparators, outcomes, sources of funding, and potential conflicts of interests. We will collect and use the most detailed numerical data available from the included studies to facilitate analyses. We will contact study investigators or organizations to obtain missing or unclear information. If the investigators do not respond within two weeks, we will proceed with existing information. Where data are only available in graphical displays, two review authors will independently extract the data using GetData Graph Digitizer 2.24 (GetData Graph Digitizer). In case of any discrepancies in data extraction between two authors, a consensus will be reached through discussion or by consulting a third review author (SAA).

Assessment of risk of bias in included studies

Two review authors (two of ADP, KH, DF, SAA, DT) will independently assess the risk of bias of included studies RoB2, as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019a). We will consider the following domains of bias:

- bias arising from the randomization process;
- bias due to deviations from intended interventions;
- bias due to missing outcome data;
- bias in measurement of the outcome, which will include a two day minimum wash-out period for cross-over studies;
- bias in selection of the reported result.

We will evaluate the risk of bias in every bias item as well as an overall risk of bias as either 'low risk of bias', 'high risk of bias' or 'some concerns'. The assessment of each domain is guided by signaling questions.

For an overall risk of bias judgement, we will consider a study to have:

- 'low risk of bias' if it is of low risk of bias for all domains for this result;
- 'some concerns' if the trial is judged to raise some concerns in at least one domain for this result, but not to be at high risk of bias for any domain;
- 'high risk of bias' if the trial is judged to be at high risk of bias in at least one domain, or to have some concerns for multiple domains in a way that substantially lowers confidence in the result.

In case of disagreement or discrepancy between two review authors, an adjudicator (SAA or ADP) will evaluate the risk of bias.

Measures of treatment effect

For continuous outcomes measured using the same scales, we will assess the normality of distributions and calculate mean differences (MDs) with 95% confidence intervals (CIs) where outcomes are normally distributed. Where trials measured continuous outcomes using difference scales, we will calculate standardized mean differences (SMDs). Continuous outcomes for this review include CLDEQ-8, OSDI, SPEED and VAS scores. We will calculated risk ratios (RR) with 95% CIs for dichotomous outcomes. We will consider the proportion of participants with an adverse event to be a dichotomous outcome. We will check data for skewness and will analyze skewed data use guidance outlined in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2019).

Unit of analysis issues

For the purpose of this review, the participant will be the primary unit of analysis. If a trial randomizes both eyes of participants (to the same or different interventions), we will extract the results that accounted for the correlation between eyes and will refer to Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* for guidance regarding including variants on randomized trials (Higgins 2019b). If the primary studies failed to consider the correlation between two eyes, we will exclude those studies in the sensitivity analysis. If we include studies with more than two groups, we will evaluate each relevant comparison separately, and select one pair-wise comparison that is relevant to the review to avoid double counting the studies in the analysis (Higgins 2019b).

Dealing with missing data

We will analyze outcomes on an intention-to-treat basis. We will contact the study authors whenever outcome data are missing, and will use the best information available to analyze data if we receive no response from investigators within two weeks. We will only analyze available data, and will not impute missing data for the purposes of this review.

Assessment of heterogeneity

We will assess clinical and methodological heterogeneity among studies by assessing the potential differences in participants, interventions compared (silicone hydrogel versus soft hydrogel), and study design features. We will also assess statistical heterogeneity among outcomes by examining the overlap in confidence intervals of forest plots, and by using the Chi^2 and I^2 statistics to determine the proportion of total variation due to statistical heterogeneity, as described in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2019). We will consider the following thresholds for the interpretation of the I^2 statistic:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

Assessment of reporting biases

We will assess selective outcome reporting for each study by comparing the outcomes specified in a protocol or clinical trial registry with those reported in study reports. Where trial protocols or trial registry records are unavailable or inaccessible, we will compare outcomes specified in the study methods section of the study reports with outcomes and reported in the study. Where we include more than 10 trials in a meta-analysis, we will use funnel plots to assess small-study effects, which could be due to publication bias.

Data synthesis

We will synthesize and analyze data by following the guidelines in Chapter 9 (McKenzie 2019) and Chapter 10 (Deeks 2019) of the *Cochrane Handbook for Systematic Reviews of Interventions*. When we have more than two studies that contribute data to a meta-analysis or where there is statistical or clinical heterogeneity, we will use a random-effects model to estimate intervention effects; otherwise we will use a fixed-effect model. If the direction of treatment effects is inconsistent across studies or we detect the presence of substantial or considerable statistical heterogeneity, we will not combine results in a meta-analysis and will present a narrative summary of results instead.

Subgroup analysis and investigation of heterogeneity

We will conduct a subgroup analysis based on contact lens replacement frequency:

- daily disposable replacement;
- two-week replacement contact lenses;
- monthly replacement contact lenses.

We will also conduct a subgroup analysis by subtypes of hydrogel and silicone hydrogel contact lens materials if enough data are available.

Sensitivity analysis

To assess the robustness of the effect estimates, we will re-run meta-analyses by excluding studies with high risk of bias, industry-funded studies, and studies that failed to handle the unit of analysis issue properly. We will compare the results to determine whether it makes a difference to the effect estimate.

Summary of findings and assessment of the certainty of the evidence

We will prepare a summary of findings table according to the methods described in Chapter 14 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2019), and will present the estimated effects of silicone hydrogel versus soft hydrogel at one to four weeks. We will include the following outcomes;

1. comfort scores measured using CLDEQ-8;
2. comfort scores measured using the SPEED Questionnaire scores;
3. comfort scores measured using the OSDI scores;
4. proportion of participants who discontinued contact lens wear;
5. proportion of participants with corneal staining;
6. proportion of participants with conjunctival staining;
7. proportion of participants with vision-threatening adverse events.

Two review authors will independently judge the certainty of the evidence for each outcome using the GRADE approach. We will judge the certainty of evidence as very low, low, moderate, or high (Langendam 2013). We will resolve any disagreements between the two review authors by discussion or consultation with a third review author.

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APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Contact Lenses] explode all trees
#2 ((contact or contacts) NEXT/2 (lens or lenses))
#3 ((hydrogel* or hydrophilic* or silicone*) NEXT/2 (contact or contacts))
#4 ((hydrogel* or hydrophilic* or silicone*) NEXT/2 (lens or lenses))
#5 ((soft or disposable or disposables or daily or dailies or monthly or monthlies or weekly or weeklies or "extended wear" or "continuous wear" or hybrid* or biweek* or replacement*) NEXT/2 (contact or contacts))
#6 ((soft or disposable or disposables or daily or dailies or monthly or monthlies or weekly or weeklies or "extended wear" or "continuous wear" or hybrid* or biweek* or replacement*) NEXT/2 (lens or lenses))
#7 {OR #1-#6}
#8 MeSH descriptor: [Surveys and Questionnaires] this term only
#9 MeSH descriptor: [Health Surveys] this term only
#10 MeSH descriptor: [Health Status Indicators] this term only
#11 MeSH descriptor: [Patient Reported Outcome Measures] explode all trees
#12 MeSH descriptor: [Self Report] explode all trees
#13 MeSH descriptor: [Patient Satisfaction] explode all trees
#14 MeSH descriptor: [Personal Satisfaction] explode all trees
#15 MeSH descriptor: [Patient Compliance] explode all trees
#16 MeSH descriptor: [Patient Dropouts] explode all trees
#17 MeSH descriptor: [Quality of Life] explode all trees
#18 MeSH descriptor: [Qualitative Research] explode all trees
#19 MeSH descriptor: [Focus Groups] explode all trees
#20 MeSH descriptor: [Self Disclosure] explode all trees
#21 (PROM or PROMS)
#22 ((quality NEAR/2 life) or (QOL or HRQL or HRQOL))
#23 (dropout* or "drop out" or "drop outs")
#24 (interview* or focus group* or qualitative* or survey or surveys or surveyed or questionnaire* or index or indices or scale or scales or rating or ratings)
#25 ((patient* or self or client* or participant* or subject* or personal or consumer* or wearer*) NEXT/5 (report* or guided or relate* or view* or expectation* or perception* or perspective* or experience* or described or outcome* or measure* or assess* or monitor* or symptom* or domain* or burden* or impact* or effect* or satisf* or response* or opinion* or comfort* or discomfort* or complaint* or safety))
#26 (("contact lens" or "contact lenses") NEXT/5 (comfort* or discomfort*))
#27 MeSH descriptor: [Patient Comfort] explode all trees
#28 MeSH descriptor: [Patient Safety] explode all trees
#29 MeSH descriptor: [Long Term Adverse Effects] explode all trees
#30 MeSH descriptor: [Dry Eye Syndromes] explode all trees
#31 MeSH descriptor: [Meibomian Glands] explode all trees
#32 MeSH descriptor: [Tears] explode all trees
#33 ("dry eye" or "dry eyes" or "eye dryness" or "lens dehydration" or "lens lubricant" or "lens lubricants" or "lacrimal fluid" or "lacrimal fluids")
#34 (tear* or meibomian* or schirmer* or ("phenol red" NEXT/1 thread*))
#35 (CLDEQ or "CLDEQ8" or SPEED or OSDI or VAS)
#36 ((corneal or conjunctival or epithelial) NEAR/2 (staining or redness))
#37 ("ocular surface" NEAR/3 (gland* or alteration* or response* or sign* or physiology or comfort* or discomfort*))
#38 ((ocular or vision* or eye or eyes) NEAR/3 (safe* or health* or comfort* or discomfort*))
#39 ((adverse or dangerous or harmful or indirect or injurious or secondary or side or undesirable) NEAR/2 (complication* or consequence* or effect* or event* or impact* or outcome* or reaction*))
#40 (symptom or symptoms or symptomatic or asymptomatic)
#41 {OR #8-#40}
#42 #7 AND #41

Appendix 2. MEDLINE (Ovid) search strategy

1. Randomized Controlled Trial.pt.

2. Controlled Clinical Trial.pt.
3. (randomized or randomised).ab,ti.
4. placebo.ab,ti.
5. drug therapy.fs.
6. randomly.ab,ti.
7. trial.ab,ti.
8. groups.ab,ti.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. exp animals/ not humans.sh.
11. 9 not 10
12. exp Contact Lenses/
13. ((contact or contacts) adj2 (lens or lenses)).tw.
14. ((hydrogel* or hydrophilic* or silicone*) adj2 (contact or contacts)).tw.
15. ((hydrogel* or hydrophilic* or silicone*) adj2 (lens or lenses)).tw.
16. ((soft or disposable or disposables or daily or dailies or monthly or monthlies or weekly or weeklies or "extended wear" or "continuous wear" or hybrid* or biweek* or replacement*) adj2 (contact or contacts)).tw.
17. ((soft or disposable or disposables or daily or dailies or monthly or monthlies or weekly or weeklies or "extended wear" or "continuous wear" or hybrid* or biweek* or replacement*) adj2 (lens or lenses)).tw.
18. or/12-17
19. "Surveys and Questionnaires"/
20. Health surveys/
21. Health Status Indicators/
22. exp Patient Reported Outcome Measures/
23. exp Self Report/
24. exp Patient Satisfaction/
25. exp Personal Satisfaction/
26. exp Patient Compliance/
27. exp Patient Dropouts/
28. exp "Quality of Life"/
29. exp Qualitative Research/
30. exp Focus Groups/
31. exp Self Disclosure/
32. (PROM or PROMS).tw.
33. ((quality adj2 life) or (QOL or HRQL or HRQOL)).tw.
34. (dropout* or drop out*).tw.
35. (interview* or focus group* or qualitative* or survey or surveys or surveyed or questionnaire* or index or indices or scale or scales or rating or ratings).tw.
36. ((patient* or self or client* or participant* or subject* or personal or consumer* or wearer*) adj5 (report* or guided or relate* or view* or expectation* or perception* or perspective* or experience* or described or outcome* or measure* or assess* or monitor* or symptom* or domain* or burden* or impact* or effect* or satisf* or response* or opinion* or comfort* or discomfort* or complaint* or safety)).tw.
37. (contact lens* adj5 (comfort* or discomfort*)).tw.
38. exp Patient Comfort/
39. exp Patient Safety/
40. exp Long Term Adverse Effects/ or adverse effects.fs.
41. exp Dry Eye Syndromes/
42. exp Meibomian Glands/
43. exp Tears/
44. (dry eye or dry eyes or eye dryness or lens dehydration or lens lubricant* or lacrimal fluid*).tw.
45. (tear* or meibomian* or schirmer* or phenol red thread*).tw.
46. (CLDEQ or "CLDEQ8" or SPEED or OSDI or VAS).tw.
47. ((Corneal or conjunctival or epithelial) adj2 (staining or redness)).tw.
48. (ocular surface adj3 (gland* or alteration* or response* or sign* or physiology or comfort* or discomfort*)).tw.
49. ((ocular or vision* or eye or eyes) adj3 (safe* or health* or comfort* or discomfort*)).tw.
50. ((adverse or dangerous or harmful or indirect or injurious or secondary or side or undesirable) adj2 (complication* or consequence* or effect* or event* or impact* or outcome* or reaction*)).tw.
51. (symptom or symptoms or symptomatic or asymptomatic).tw.
52. or/19-51
53. 11 and 18 and 52

The search filter for trials at the beginning of the MEDLINE strategy is from the published paper by Glanville et al (Glanville 2006).

Appendix 3. EMBASE.com search strategy

#1 'randomized controlled trial'/exp
#2 'randomization'/exp
#3 'double blind procedure'/exp
#4 'single blind procedure'/exp
#5 random*:ab,ti
#6 #1 OR #2 OR #3 OR #4 OR #5
#7 'animal'/exp OR 'animal experiment'/exp
#8 'human'/exp
#9 #7 AND #8
#10 #7 NOT #9
#11 #6 NOT #10
#12 'clinical trial'/exp
#13 (clin* NEAR/3 trial*):ab,ti
#14 ((singl* OR doubl* OR trebl* OR tripl*) NEAR/3 (blind* OR mask*)):ab,ti
#15 'placebo'/exp
#16 placebo*:ab,ti
#17 random*:ab,ti
#18 'experimental design'/exp
#19 'crossover procedure'/exp
#20 'control group'/exp
#21 'latin square design'/exp
#22 #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21
#23 #22 NOT #10
#24 #23 NOT #11
#25 'comparative study'/exp
#26 'evaluation'/exp
#27 'prospective study'/exp
#28 control*:ab,ti OR prospectiv*:ab,ti OR volunteer*:ab,ti
#29 #25 OR #26 OR #27 OR #28
#30 #29 NOT #10
#31 #30 NOT (#11 OR #23)
#32 #11 OR #24 OR #31
#33 'contact lens'/exp
#34 ((contact OR contacts) NEXT/2 (lens OR lenses)):ab,ti,kw
#35 ((hydrogel* OR hydrophilic* OR silicone*) NEXT/2 (contact OR contacts)):ab,ti,kw
#36 ((hydrogel* OR hydrophilic* OR silicone*) NEXT/2 (lens OR lenses)):ab,ti,kw
#37 ((soft OR disposable OR disposables OR daily OR dailies OR monthly OR monthlies OR weekly OR weeklies OR 'extended wear' OR 'continuous wear' OR hybrid* OR biweek* OR replacement*) NEXT/2 (contact OR contacts)):ab,ti,kw
#38 ((soft OR disposable OR disposables OR daily OR dailies OR monthly OR monthlies OR weekly OR weeklies OR 'extended wear' OR 'continuous wear' OR hybrid* OR biweek* OR replacement*) NEXT/2 (lens OR lenses)):ab,ti,kw
#39 #33 OR #34 OR #35 OR #36 OR #37 OR #38
#40 'questionnaire'/exp
#41 'health survey'/exp
#42 'patient-reported outcome'/exp
#43 'self report'/exp
#44 'patient satisfaction'/exp
#45 'satisfaction'/de
#46 'patient compliance'/de
#47 'patient dropout'/exp
#48 'quality of life'/exp
#49 'qualitative research'/exp
#50 'focus group'/exp
#51 'self disclosure'/exp
#52 prom:ab,ti,kw OR proms:ab,ti,kw
#53 ((quality NEAR/2 life):ab,ti,kw) OR qol:ab,ti,kw OR hrql:ab,ti,kw OR hrqol:ab,ti,kw
#54 dropout*:ab,ti,kw OR 'drop out*':ab,ti,kw
#55 interview*:ab,ti,kw OR 'focus group*':ab,ti,kw OR qualitative*:ab,ti,kw OR survey:ab,ti,kw OR surveys:ab,ti,kw OR surveyed:ab,ti,kw OR questionnaire*:ab,ti,kw OR index:ab,ti,kw OR indices:ab,ti,kw OR scale:ab,ti,kw OR scales:ab,ti,kw OR rating:ab,ti,kw OR ratings:ab,ti,kw
#56 ((patient* OR self OR client* OR participant* OR subject* OR personal OR consumer* OR wearer*) NEXT/5 (report* OR guided OR relate* OR view* OR expectation* OR perception* OR perspective* OR experience* OR described OR outcome* OR measure* OR assess* OR

monitor* OR symptom* OR domain* OR burden* OR impact* OR effect* OR satisf* OR response* OR opinion* OR comfort* OR discomfort* OR complaint* OR safety)):ab,ti,kw
#57 ('contact lens' NEXT/5 (comfort* OR discomfort*)):ab,ti,kw
#58 'patient comfort'/exp
#59 'patient safety'/exp
#60 'adverse event'/exp
#61 'dry eye'/exp
#62 'meibomian gland'/exp
#63 'lacrimal fluid'/exp
#64 'dry eye':ab,ti,kw OR 'dry eyes':ab,ti,kw OR 'eye dryness':ab,ti,kw OR 'lens dehydration':ab,ti,kw OR 'lens lubricant*':ab,ti,kw OR 'lacrimal fluid*':ab,ti,kw
#65 tear*:ab,ti,kw OR meibomian*:ab,ti,kw OR schirmer*:ab,ti,kw OR 'phenol red thread*':ab,ti,kw
#66 cldeq:ab,ti,kw OR 'cldeq8':ab,ti,kw OR speed:ab,ti,kw OR osdi:ab,ti,kw OR vas:ab,ti,kw
#67 ((corneal OR conjunctival OR epithelial) NEAR/2 (staining OR redness)):ab,ti,kw
#68 ('ocular surface' NEAR/3 (gland* OR alteration* OR response* OR sign* OR physiology OR comfort* OR discomfort*)):ab,ti,kw
#69 ((ocular OR vision* OR eye OR eyes) NEAR/3 (safe* OR health* OR comfort* OR discomfort*)):ab,ti,kw
#70 ((adverse OR dangerous OR harmful OR indirect OR injurious OR secondary OR side OR undesirable) NEAR/2 (complication* OR consequence* OR effect* OR event* OR impact* OR outcome* OR reaction*)):ab,ti,kw
#71 symptom:ab,ti,kw OR symptoms:ab,ti,kw OR symptomatic:ab,ti,kw OR asymptomatic:ab,ti,kw
#72 #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71
#73 #39 AND #72
#74 #32 AND #73

Appendix 4. PubMed search strategy

1. ((randomized controlled trial[pt]) OR (controlled clinical trial[pt]) OR (randomised[tiab] OR randomized[tiab]) OR (placebo[tiab]) OR (drug therapy[sh]) OR (randomly[tiab]) OR (trial[tiab]) OR (groups[tiab])) NOT (animals[mh] NOT humans[mh])
2. "contact lens*"[tiab]
3. ((hydrogel*[tiab] OR hydrophilic*[tiab] OR silicone*[tiab]) AND (contact[tiab] OR contacts[tiab]))
4. ((hydrogel*[tiab] OR hydrophilic*[tiab] OR silicone*[tiab]) AND (lens[tiab] OR lenses[tiab]))
5. ((soft[tiab] OR disposable[tiab] OR disposables[tiab] OR daily[tiab] OR dailies[tiab] OR monthly[tiab] OR monthlies[tiab] OR weekly[tiab] OR weeklies[tiab] OR "extended wear"[tiab] OR "continuous wear"[tiab] OR hybrid*[tiab] OR biweek*[tiab] OR replacement*[tiab]) AND (contact[tiab] OR contacts[tiab]))
6. ((soft[tiab] OR disposable[tiab] OR disposables[tiab] OR daily[tiab] OR dailies[tiab] OR monthly[tiab] OR monthlies[tiab] OR weekly[tiab] OR weeklies[tiab] OR "extended wear"[tiab] OR "continuous wear"[tiab] OR hybrid*[tiab] OR biweek*[tiab] OR replacement*[tiab]) AND (lens[tiab] OR lenses[tiab]))
7. #2 OR #3 OR #4 OR #5 OR #6
8. (PROM[tiab] OR PROMS[tiab])
9. ("quality of life"[tiab] OR "life quality"[tiab] OR QOL[tiab] OR HRQL[tiab] OR HRQOL[tiab])
10. (dropout*[tiab] OR "drop out*"[tiab])
11. (interview*[tiab] OR "focus group*"[tiab] OR qualitative*[tiab] OR survey[tiab] OR surveys[tiab] OR surveyed[tiab] OR questionnaire*[tiab] OR index[tiab] OR indices[tiab] OR scale[tiab] OR scales[tiab] OR rating[tiab] OR ratings[tiab])
12. ((patient*[tiab] OR self[tiab] OR client*[tiab] OR participant*[tiab] OR subject*[tiab] OR personal[tiab] OR consumer*[tiab] OR wearer*[tiab]) AND (report*[tiab] OR guided[tiab] OR relate*[tiab] OR view*[tiab] OR expectation*[tiab] OR perception*[tiab] OR perspective*[tiab] OR experience*[tiab] OR described[tiab] OR outcome*[tiab] OR measure*[tiab] OR assess*[tiab] OR monitor* OR symptom*[tiab] OR domain*[tiab] OR burden*[tiab] OR impact*[tiab] OR effect*[tiab] OR satisf*[tiab] OR response*[tiab] OR opinion*[tiab] OR comfort*[tiab] OR discomfort*[tiab] OR complaint*[tiab] OR safety[tiab]))
13. ("contact lens*"[tiab]) AND (comfort*[tiab] OR discomfort*[tiab])
14. ("dry eye*"[tiab] OR "eye dryness"[tiab] OR "lens dehydration"[tiab] OR "lens lubricant*" OR "lacrimal fluid*"[tiab])
15. (tear*[tiab] OR meibomian*[tiab] OR schirmer*[tiab] OR "phenol red thread*"[tiab])
16. (CLDEQ[tiab] OR "CLDEQ8"[tiab] OR SPEED[tiab] OR OSDI[tiab] OR VAS[tiab])
17. ((Corneal[tiab] OR conjunctival[tiab] OR epithelial[tiab]) AND (staining[tiab] OR redness[tiab]))
18. ("ocular surface" AND (gland*[tiab] OR alteration*[tiab] OR response*[tiab] OR sign*[tiab] OR physiology[tiab] OR comfort*[tiab] OR discomfort*[tiab]))
19. ((ocular[tiab] OR vision*[tiab] OR eye[tiab] OR eyes[tiab]) AND (safe*[tiab] OR health*[tiab] OR comfort*[tiab] OR discomfort*[tiab]))
20. ((adverse[tiab] OR dangerous[tiab] OR harmful[tiab] OR indirect[tiab] OR injurious[tiab] OR secondary[tiab] OR side[tiab] OR undesirable[tiab]) AND (complication*[tiab] OR consequence*[tiab] OR effect*[tiab] OR event*[tiab] OR impact*[tiab] OR outcome*[tiab] OR reaction*[tiab]))
21. (symptom[tiab] OR symptoms[tiab] OR symptomatic[tiab] OR asymptomatic[tiab])
22. #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21
23. #1 AND #7 AND #22

24. Medline[sb]
25. #23 NOT #24

Appendix 5. LILACS search strategy

("Contact Lens" OR " Contact Lenses" OR "Lentes de Contacto" OR "Lentes de Contato" OR MH:E07.632.500.276$ OR MH:VS2.006.001.009.001$ OR ((hydrogel$ contact$) OR (hydrophilic$ contact$) OR (silicone$ contact$) OR "soft contact" OR "soft contacts" OR "disposable contact" OR "disposable contacts" OR disposables OR "daily contacts" OR dailies OR "monthly contacts" OR monthlies OR "weekly contacts" OR weeklies OR "extended wear" OR "continuous wear" OR "hybrid contacts" OR "biweekly contacts" OR (replacement$ contact$)) OR ((hydrogel$ OR hydrophilic$ OR silicone$ OR soft OR disposable OR disposables OR daily OR dailies OR monthly OR monthlies OR weekly OR weeklies OR "extended wear" OR "continuous wear" OR hybrid$ OR biweek$ OR replacement$) AND (lens OR lenses))) AND (MH:E05.318.308.980 OR MH:N05.715.360.300.800 OR MH:N06.850.520.308.980 OR MH;E05.318.308.980.438 OR MH:N05.715.360.300.800.438 OR MH:N06.850.520.308.980.438 OR MH:SP5.006.062.213 OR MH:E05.318.308.980.438.475 OR MH:N05.715.360.300.800.438.375 OR MH:N06.850.520.308.980.438.475 OR MH:SH1.030.050.030 OR MH:SP2.001.030 OR MH:SP4.127.413.629.890 OR MH:SP5.006.067 OR MH:E05.318.308.980.344.500$ OR MH:N03.349.380.210.750$ OR MH:N04.761.559.590.399.875$ OR MH:N05.425.210.500$ OR MH:N05.715.360.300.800.344.500$ OR MH:N05.715.360.575.575.399.875$ OR MH:N06.850.520.308.980.344.500$ OR MH:E05.318.308.980.500$ OR MH:N05.715.360.300.800.500$ OR MH:N06.850.520.308.980.500$ OR MH:F01.100.150.750.625$ OR MH:F01.145.488.887.625$ OR MH:N04.452.822.700$ OR MH:N05.300.150.800.625$ OR MH:N05.715.360.600$ OR MH:F01.145.677$ OR MH:F01.100.150.750.500.600$ OR MH:F01.145.488.887.500.600$ OR MH:N05.300.150.800.500.600$ OR MH:F01.100.150.750.500.610$ OR MH:F01.145.488.887.500.610$ OR MH:N05.300.150.800.500.610$ OR MH:I01.800$ OR MH:K01.752.400.750$ OR MH:N06.850.505.400.425.837$ OR MH:SP4.077.593$ OR MH:H01.770.644.241.850$ OR MH:E05.318.308.112$ OR MH:N05.715.360.300.269$ OR MH:N06.850.520.308.112$ OR MH:F01.752.747.792.662$ OR PROM OR PROMS OR "quality of life" OR "life quality" OR QOL OR HRQL OR HRQOL OR dropout$ OR "drop out" OR "drop outs" OR interview$ OR "focus group" OR "focus groups" OR qualitative$ OR survey OR surveys OR surveyed OR questionnaire$ OR index OR indices OR scale OR scales OR rating OR ratings OR ((patient$ OR self OR client$ OR participant$ OR subject$ OR personal OR consumer$ OR wearer$) AND (report$ OR guided OR relate$ OR view$ OR expectation$ OR perception$ OR perspective$ OR experience$ OR described OR outcome$ OR measure$ OR assess$ OR monitor$ OR symptom$ OR domain$ OR burden$ OR impact$ OR effect$ OR satisf$ OR response$ OR opinion$ OR comfort$ OR discomfort$ OR complaint$ OR safety)) OR ((contact lens$) AND (comfort$ OR discomfort$)) OR MH:N02.421.585.683$ OR MH:N06.850.135.060.075.399 OR MH:C23.550.543$ OR MH:C11.496.260 OR MH:A09.371.337.614$ OR MH:A10.336.827.600$ OR MH:A12.200.882 OR "dry eye" OR "dry eyes" OR "eye dryness" OR "lens dehydration" OR "lens lubricant" OR "lens lubricants" OR "lacrimal fluid" OR "lacrimal fluids" OR tear$ OR meibomian$ OR Schirmer$ OR (phenol red thread$) OR CLDEQ OR "CLDEQ8" OR SPEED OR OSDI OR VAS OR ((corneal OR conjunctival OR epithelial) AND (staining OR redness)) OR ("ocular surface" AND (gland$ OR alteration$ OR response$ OR sign$ OR physiology OR comfort$ OR discomfort$)) OR ((ocular OR vision$ OR eye OR eyes) AND (safe$ OR health$ OR comfort$ OR discomfort$)) OR ((adverse OR dangerous OR harmful OR indirect OR injurious OR secondary OR side OR undesirable) AND (complication$ OR consequence$ OR effect$ OR event$ OR impact$ OR outcome$ OR reaction$)) OR symptom$)

Appendix 6. ClinicalTrials.gov search strategy

(Contact lens OR ((hydrogel OR hydrophilic OR silicone OR soft OR disposable OR "extended wear" OR "continuous wear" OR replacement OR hybrid OR biweekly) AND (contact OR lens)))

Appendix 7. WHO ICTRP search strategy

Contact lens OR Hydrogel contacts OR hydrophilic contacts OR silicone contacts OR soft contacts OR disposable contacts OR extended wear contacts OR continuous wear contacts OR replacement contacts OR hybrid contacts OR biweekly contacts OR hydrogel lens OR hydrophilic lens OR silicone lens OR soft lens OR disposable lens OR extended wear lens OR continuous wear lens OR replacement lens or hybrid lens or biweekly lens

Appendix 8. Data on study characteristics

Mandatory items		Optional items
Methods		
Study design	• Parallel group RCT *i.e. people randomized to treatment* • Within-person RCT *i.e. eyes randomized to treatment* • Cluster-RCT *i.e. communities randomized to treatment* • Cross-over RCT • Other, specify	Exclusions after randomization Losses to follow up Number randomized/analyzed

(Continued)

Eyes *or* Unit of randomization/ unit of analysis	• One eye included in study, *specify how eye selected* • Two eyes included in study, both eyes received same treatment, *briefly specify how analyzed (best/worst/average/both and adjusted for within person correlation/both and not adjusted for within person correlation) and specify if mixture one eye and two eye* • Two eyes included in study, eyes received different treatments, *specify if correct pair-matched analysis done*	How were missing data handled? *e.g. available case analysis, imputation methods* Reported power calculation (Y/N*), if yes, sample size and power* Unusual study design/issues

Participants		
Country		Setting Ethnic group Equivalence of baseline characteristics (Y/N)
Total number of participants	*This information should be collected for total study population recruited into the study. If these data are only reported for the people who were followed up only, please indicate.*	
Number (%) of men and women		
Average age and age range		
Inclusion criteria		
Exclusion criteria		

Interventions		
Intervention (n =) Comparator (n =) ***See MECIR 65 and 70***	• Number of people randomized to this group • Drug (or intervention) name • Dose • Frequency • Route of administration	

Outcomes		
Primary and secondary outcomes *as defined in study reports* ***See MECIR R70***	List outcomes Adverse events reported (Y/N) Length of follow up and intervals at which outcomes assessed	Planned/actual length of follow-up

HISTORY

Protocol first published: Issue 5, 2021

CONTRIBUTIONS OF AUTHORS

- Conception and design of study (ADP, KH, DF, SAA, DT).
- Drafting the review or commenting on it critically for intellectual content (ADP, KH, DF, SAA, DT).
- Final approval of the document to be published (ADP, KH, DF, SAA, DT).

DECLARATIONS OF INTEREST

- ADP: Alcon Research, LLC (Consulting, Research), Bausch + Lomb (Research), Contamac (Research), CooperVision (Consulting), Euclid Systems (Research, Consulting), EyeGate Pharmaceuticals, Inc. (Consulting), EpiTech (Consulting), Optikal Care Inc. (Consulting), Paragon Vision Sciences (Consulting), PentaVision (Honorarium), Southern College of Optometry (Honorarium), American Academy of Optometry (Honorarium), and American Optometric Association (Honorarium). None of these activities are directly related to the proposed review.
- KH: Integra LifeSciences (Research), Southern College of Optometry (Research, Honorarium), Association of Schools and Colleges of Optometry (Research). None of these activities are directly related to the proposed review.
- DF: Southern College of Optometry (Honorarium), American Academy of Optometry (Honorarium), Pentavision (Honorarium), Scleral Lens Education Society (Honorarium), Gas Permeable Lens Institute (Honorarium). None of these activities are directly related to the proposed review.
- SAA: None
- DT: None

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