

Big Data Support for LASIK as an Option for Vision Correction in Patients with Contact Lens Intolerance

Version 1 · Intolerance Manuscript_v7.docx

JOURNAL

Journal of Cataract and Refractive Surgery

SUBMISSION TYPE

Full-Length

OVERALL SCORE

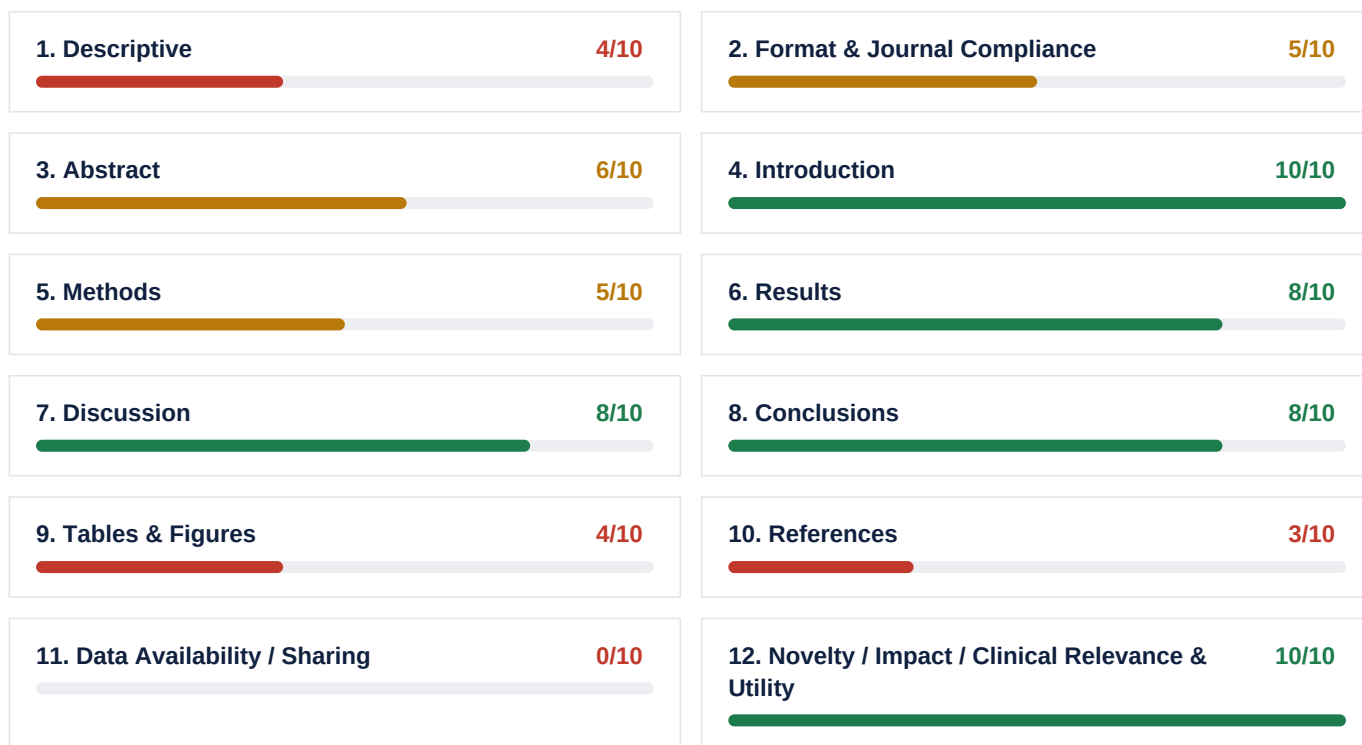
63/100

Recommendation: Major Concerns - Do Not Submit Yet

FATAL FLAWS — DESK-REJECT RISK

- No IRB approval or formal ethics waiver documented: The manuscript states IRB approval was not required based on an End User License Agreement. Most journals including JCRS require documented IRB approval or a formal exemption letter. This is likely to result in desk rejection.
- STROBE checklist not included: JCRS requires STROBE compliance for observational studies. The absence of a STROBE checklist is a common cause of desk rejection for observational studies at this journal.
- Abstract data discrepancies with manuscript body: The abstract reports different values for the SE treatment range (8D vs 7D), beta coefficient for SE prediction error (0.042 vs 0.037), and p-value for BCVA (0.68 vs 0.65) compared to the manuscript body. This undermines credibility.
- No sample size or power calculation: Despite the large dataset, the CLS intolerant group is small (316 patients). Without a power calculation, the ability to detect clinically meaningful differences is unverified, and the study may be underpowered for subgroup analyses.
- Bilateral eyes analyzed as independent observations: Both eyes from individual patients are included without accounting for intra-patient correlation. This violates the independence assumption of the regression models and inflates sample size, potentially producing misleading results.
- Reference numbering errors and misattributions: Multiple citation errors exist, including skipped numbers and references cited for claims they do not support. This suggests insufficient attention to detail and will concern editors and reviewers.

Section Scorecard



Bar = score achieved

Section-by-Section Review

1. Descriptive

4/10
FAIL

Several critical required items fail. The lack of formal IRB approval or documented waiver, the questionable COI disclosure, the absence of Helsinki Declaration compliance statement, and the sensationalistic title are significant issues. These deficiencies are likely to trigger immediate editorial concerns at JCRS.

- ⚠ Title accurately reflects content (no sensationalism) — Title uses the term 'Big Data Support for LASIK' which is somewhat sensationalistic and imprecise. The dataset, while large, may not meet the conventional definition of 'big data.' A more precise title reflecting the study design would be preferable.
- ⚠ COI disclosed for all authors (ICMJE format) — COI disclosures are provided but not in standard ICMJE format. The statement that Dr. Kezirian owns SurgiVision Consultants which provides the software used in the study, and then claims neither author has financial interest in the subject matter, appears contradictory and should be clarified. The COI should be in ICMJE disclosure form format.
- ⚠ Human subjects: Helsinki compliance and informed consent stated — The manuscript states IRB approval was not required because patients consented via an End User License Agreement. This is an insufficient substitute for proper Helsinki Declaration compliance and IRB review or waiver documentation. Most journals require documented IRB approval or a formal waiver, even for de-identified retrospective data.
- ⚠ IRB/ethics approval obtained and documented — IRB approval was not obtained. The manuscript claims it was not required, but a formal IRB waiver or exemption letter should be documented and referenced. Most journals, including JCRS, require evidence of ethics review.
- ⚠ Authorship diversity/global representation — Both authors are from the same institution (SurgiVision Consultants, Inc.), which is a private company rather than an academic or clinical institution. No geographic or institutional diversity.

SUGGESTED ACTIONS

- ☐ Obtain and document IRB approval or a formal IRB waiver/exemption letter for this retrospective registry study.
- ☐ Rewrite the COI disclosure in standard ICMJE format and clarify the apparent contradiction regarding Dr. Kezirian's ownership of SurgiVision and the claim of no financial interest in the subject matter.
- ☐ Add an explicit statement regarding compliance with the tenets of the Declaration of Helsinki.
- ☐ Revise the title to be more descriptive and less sensationalistic, e.g., 'LASIK Outcomes in Myopic Patients With and Without Contact Lens Intolerance: A Multi-Center Registry Analysis.'
- ☐ Clarify the role of Alcon in providing the DataLink platform and any potential indirect financial relationships.

2. Format & Journal Compliance

5/10
REVIEW

The word counts and figure/table numbers are compliant. However, the manuscript lacks a STROBE checklist, which JCRS requires for observational studies. This is a significant compliance gap.

-  Modifications needed (STROBE compliance required) — This is a retrospective observational study and the journal requires STROBE compliance. No STROBE checklist is referenced or appended.
-  Accessibility features (alt text, data availability statement) — No data availability statement is provided. While not explicitly required by the journal guidelines provided, best practice and ICMJE standards recommend one.

SUGGESTED ACTIONS

- ☐ Include a completed STROBE checklist as a supplementary document and reference it in the Methods section.
- ☐ Add a data availability statement describing how the registry data can or cannot be accessed.
- ☐ Verify formatting against JCRS author instructions for reference style, heading structure, and table/figure formatting requirements.

3. Abstract

6/10
REVIEW

The abstract has important numerical discrepancies with the manuscript body, which is a significant concern. The spheroequivalent limit, beta coefficients, and p-values do not match between the abstract and the results section. These must be reconciled before submission.

- ⚠️ Accurately describes manuscript content — The abstract contains data discrepancies with the manuscript body. The abstract states 'corrections up to 8 D spheroequivalent' while the methods and results state 'up to 7.00 D.' The abstract reports Beta 0.042 for SE prediction error but Table 2 and text report 0.037. The abstract reports p=0.68 for BCVA but Table 2 shows p=0.65.
- ⚠️ Data in abstract match manuscript body — Multiple numerical discrepancies exist between abstract and body text as noted above.
- ⚠️ Keywords relevant and optimized — No keywords are provided.

SUGGESTED ACTIONS

- ☐ Reconcile the spheroequivalent treatment range: abstract says 8 D, body says 7.00 D.
- ☐ Correct the Beta coefficient for SE prediction error in the abstract (0.042 vs 0.037 in body).
- ☐ Correct the p-value for BCVA in the abstract (0.68 vs 0.65 in body/Table 2).
- ☐ Add relevant keywords per JCRS requirements.
- ☐ Complete the phrase 'Differences in refractive and visual' in the Methods section of the abstract (word appears to be missing, e.g., 'outcomes').

4. Introduction

10/10
PASS

The introduction is well-constructed, providing adequate background, clearly framing the knowledge gap, stating two specific research questions, and articulating hypotheses. The literature review is relevant and appropriately scoped.

SUGGESTED ACTIONS

- ☐ Reference 10 is cited but appears to be a Russian-language article on eyelid hygiene
- ☐ consider whether a more directly relevant English-language reference would be more appropriate.
- ☐ The introduction skips from reference 9 to reference 11
- ☐ check numbering sequencing (reference 10 may be misplaced).

5. Methods

5/10
REVIEW

The methods section describes the study design and statistical approach reasonably well, but has critical gaps. The absence of a power or sample size calculation is a significant deficiency, especially given the markedly unbalanced cohorts. The handling of missing data and the large exclusion from total cohort to analyzed cohort need better documentation. The study also does not account for clustering of eyes within patients (both eyes analyzed), which is a methodological concern.

- ⚠️ Statistical power / sample size calculation — No sample size or power calculation is provided. While the dataset is large, the CLS intolerant group (n=316 patients, 598 eyes) is relatively small and the authors should demonstrate adequate power to detect clinically meaningful differences.
- ⚠️ Were sample sizes calculated for each outcome metric, and specify the desired accuracy — No sample size calculation is provided for each outcome metric, and no desired accuracy is specified.
- ⚠️ Data handling / missing values plan — Patients with missing data were excluded but no analysis of missing data patterns or potential selection bias from exclusions is provided. The flow from 89,585 total eyes to 38,400 analyzed eyes represents substantial exclusion that is not fully explained.

SUGGESTED ACTIONS

- ☐ Add a power or sample size calculation demonstrating adequate power to detect the pre-specified clinically meaningful differences (0.25 D for SE, 0.10 LogMAR for UCVA).
- ☐ Address the clustering of bilateral eyes within patients using generalized estimating equations (GEE) or mixed-effects models rather than treating eyes as independent observations.
- ☐ Provide a more detailed accounting of excluded patients and missing data, including analysis of whether missingness was random.
- ☐ Clarify the discrepancy between the total cohort (89,585 patients overall) and the study sample, and explain all exclusion steps in the flow chart.
- ☐ Specify whether the 21-day minimum postoperative follow-up was applied consistently and how variable follow-up timing was handled.

6. Results

8/10
PASS

Results are comprehensive with detailed stratification analyses. The primary outcomes are clearly presented and consistent with the statistical plan. However, safety reporting beyond BCVA change is absent, and there are some internal data inconsistencies (e.g., Table 2 shows CLS Intolerant N=598 eyes but abstract reports n=316 patients, and the CLS intolerant SE prediction error mean in Table 2 is listed as -0.031 but the text says 0.031).

⚠️ Adverse events / safety data reported — No adverse events or safety-specific data are reported beyond the change in BCVA. Complications such as flap complications, dry eye, infections, retreatment rates, etc., are not reported. While not a clinical trial, safety outcomes are important for this surgical comparison.

SUGGESTED ACTIONS

- ☐ Report complications and retreatment rates by cohort.
- ☐ Reconcile the CLS intolerant mean SE Prediction Error sign discrepancy: Table 2 shows -0.031 but text states 0.031.
- ☐ Clarify that 598 eyes correspond to 316 patients, as this can be confusing when switching between eye-level and patient-level counts.
- ☐ Consider reporting standard refractive surgery outcome metrics per the JCIRS standard graphs (achieved vs attempted, cumulative UCVA, etc.).

7. Discussion

8/10
PASS

The discussion addresses both study questions, acknowledges important limitations, and references relevant literature. However, it does not open with a concise summary of key findings as recommended, and the first sentence contains a grammatical error. The discussion could benefit from more critical analysis of why the intolerance rate was so low and what selection biases might account for this.

⚠ MUST begin with purpose, design, key conclusions — The discussion does not begin with a clear restatement of purpose, design, and key conclusions. It begins with goals but does not succinctly state the key findings upfront.

SUGGESTED ACTIONS

- ☐ Begin the discussion with a concise summary stating the study design, main findings, and key conclusions.
- ☐ Discuss the possibility that selection bias inherently limits the intolerance rate observed, since patients with severe CLS intolerance related to ocular surface disease may have been screened out as poor LASIK candidates.
- ☐ Discuss the lack of a standardized definition for contact lens intolerance and how this limits interpretation.
- ☐ Address the methodological limitation of analyzing bilateral eyes as independent observations.
- ☐ Fix the grammatical error in the opening sentence: 'to assess LASIK outcomes following differed between the two cohorts' should be revised.

8. Conclusions

8/10
PASS

Conclusions are mostly supported by the data, though the claim that intolerance should not be a contraindication to LASIK may overreach given that causes of intolerance were not differentiated and this was a retrospective uncontrolled study. The authors do appropriately note the need for prospective validation elsewhere.

SUGGESTED ACTIONS

- ☐ Soften the conclusion to state that CLS intolerance 'may not necessarily be' a contraindication rather than definitively stating it 'should not be considered' one.
- ☐ Note that certain causes of CLS intolerance (e.g., severe ocular surface disease) may still be contraindications to LASIK even though the composite intolerance group showed similar outcomes.

9. Tables & Figures

4/10
FAIL

Figure 1: Figure 1 shows the intermediate box after first exclusion as 53,719 eyes / 28,280 patients, while the document states Table 1 Total Cohort section shows Total N=28,290 patients with CLS history. A further 2 item(s) need a human check — values read from a rendered figure are a pointer, not quotable evidence.

▲ Figure 1 — Figure 1 shows the intermediate box after first exclusion as 53,719 eyes / 28,280 patients — document states: Table 1 Total Cohort section shows Total N=28,290 patients with CLS history (read as 28,280 patients; verify)

[review] Figure 2 — Sample sizes printed in Figure 2 subpanel headers may not match the cohort sizes reported in Tables 1 and 2 (read as 37802 and 598 (approximate reads); verify) Check: Read the n value printed in the top-left subpanel of panel A and confirm it reads 37,802 (matching CLS Tolerant in Table 2) and panel B reads 598 (matching CLS Intolerant).

[review] Figure 2 — Refraction stability data in panel B may not be readable or may show values inconsistent with reported means Check: Examine whether the SE refraction stability subpanel (F) in panel B shows data at the same time points as described. Verify whether the time-axis labels and mean SE values at each time point are legible and consistent wi...

▲ Legends / titles accurate and complete: Table 1 is confusing with two separate sections (total cohort and 1-month follow-up cohort) that have different sample sizes. (corroborated against the rendered figures)

▲ Accessible (alt text, clear labels): No alt text or detailed figure descriptions beyond brief captions. Figure 2 caption does not describe the axes or statistical overlays. (corroborated against the rendered figures)

▲ Restructure Table 1 to clearly separate the total cohort and the 1-month follow-up cohort, or present them as separate tables. (corroborated against the rendered figures)

▲ Explain the 'Overall N=89,585' column in Table 1 and how it relates to the study population. (corroborated against the rendered figures)

▲ Provide more detailed figure legends describing axes, statistical overlays, and what is depicted. (corroborated against the rendered figures)

▲ Fix the typo 'Figure2' (missing space) in the text. (corroborated against the rendered figures)

▲ Consider adding standard JCRS refractive surgery outcome reporting graphs. (from the text analysis)

SUGGESTED ACTIONS

■ Figure 1: Reconcile the patient count after the first exclusion step: Figure 1 shows 28,280 patients while Table 1 reports N=28,290. Verify the correct number and update both to match.

10. References

3/10
FAIL

References have significant issues including citation numbering errors, inconsistent formatting, and missing key recent literature. The citation of references 8-12 for LASIK satisfaction is inaccurate as some of those references address contact lens risk behaviors.

- ⚠ All cited references listed and vice versa — There are citation numbering issues. The introduction skips from reference 9 to 11, and references 8-12 are cited for LASIK satisfaction but some of these references (8,9) are about contact lens risk behaviors, not LASIK satisfaction. Reference 15 is cited but reference numbering in the list only goes to 23. References 15-16 cited in the introduction appear to correspond to references 15-16 in the list (Wallerstein and Lloyd-McKernan), but the numbering sequence is inconsistent.
- ⚠ Format conforms to journal style — Reference formatting is inconsistent. Some use DOIs, others do not. Journal name abbreviations are inconsistent. Some have PMID, others do not. The format does not consistently follow JCRS style.
- ⚠ Key/recent references missing — Several important recent references on LASIK outcomes, ocular surface disease and LASIK, and contact lens intolerance definitions are missing. The ASCRS/AAO LASIK safety and efficacy white papers and the PROWL-2 study could strengthen the manuscript.

SUGGESTED ACTIONS

- ☐ Thoroughly audit all in-text citations against the reference list to ensure correct numbering and matching.
- ☐ Fix the skip from reference 9 to 11 in the introduction.
- ☐ Ensure references 8-12 cited for LASIK satisfaction actually support that claim.
- ☐ Standardize reference formatting to JCRS style throughout.
- ☐ Add key recent references on LASIK outcomes and ocular surface disease relationship.

11. Data Availability / Sharing

0/10
FAIL

No data availability statement is provided. Given that the data comes from a proprietary commercial registry, this is an important omission that should be addressed.

- ⚠ Statement provided — No data availability statement is provided.
- ⚠ Compliant with journal/funder policy — Cannot assess compliance without a statement. The registry data is proprietary (SurgiVision/Alcon), which should be disclosed.
- ⚠ Data deposited in repository — No data repository is mentioned.

SUGGESTED ACTIONS

- ☐ Add a data availability statement explaining that the data are from a proprietary commercial registry and describing any conditions under which data could be made available.
- ☐ Clarify whether de-identified data could be shared upon reasonable request.

12. Novelty / Impact / Clinical Relevance & Utility

10/10
PASS

The study addresses a clinically relevant question with a large dataset. The finding that CLS intolerance does not appear to affect LASIK outcomes may be useful for clinical decision-making, though the retrospective nature and lack of intolerance cause differentiation limit the strength of this conclusion.

SUGGESTED ACTIONS

- ☐ Emphasize that these findings should be confirmed in a prospective study with standardized definitions of CLS intolerance and differentiation of causes.
- ☐ Acknowledge that the clinical impact may be limited by the inherent selection bias in the registry population.
- ☐ Consider discussing implications for clinical guidelines or referral patterns.
- ☐ Avoid overstating the findings given the study's limitations.
- ☐ Discuss how different definitions of contact lens intolerance might affect clinical recommendations.
- ☐ Note that the findings may encourage further investigation rather than immediate changes in practice.
- ☐ Clarify that the study provides preliminary evidence that may inform, but should not yet change, clinical practice.
- ☐ Consider discussing the potential for a multicenter prospective trial to validate these findings.
- ☐ Highlight the need for future studies to differentiate among causes of CLS intolerance.
- ☐ Discuss the potential impact on patient counseling and referral practices.
- ☐ Emphasize the importance of prospective validation before clinical recommendations are made.
- ☐ Note that the study's findings are hypothesis-generating rather than definitive.
- ☐ Discuss the potential for these findings to inform future clinical guidelines.
- ☐ Consider the implications for patient education and awareness campaigns.
- ☐ Highlight the need for standardized definitions of CLS intolerance in future research.
- ☐ Discuss the potential for these findings to influence LASIK candidacy criteria.
- ☐ Note that the study's large sample size provides a strong foundation for future prospective studies.
- ☐ Consider discussing the potential impact on healthcare utilization and costs.
- ☐ Emphasize the importance of individualized patient assessment regardless of CLS intolerance history.

Suggested Additional References

Check off each reference as you review it for inclusion — 0 / 7 reviewed

- Pucker, A.D., Jones-Jordan, L.A., Marx, S., Powell, D.R., Kwan, J.T., Srinivasan, S., et al. (2019). Clinical factors associated with contact lens dropout. *Contact Lens and Anterior Eye*. <https://doi.org/10.1016/j.clae.2018.12.002>

Relevance: The title suggests a focus on factors related to contact lens dropout, which is relevant to understanding reasons behind lens discontinuation.
- Pucker, A.D. & Tichenor, A.A. (2020). <p>A Review of Contact Lens Dropout</p>. *Clinical Optometry*. <https://doi.org/10.2147/opto.s198637>

Relevance: The title indicates a review on contact lens dropout, which would provide comprehensive insights into the topic.
- Asbell, P.A. (2017). Contact Lens Discomfort: Can We Prevent Dropout?. *Eye & Contact Lens: Science & Clinical Practice*. <https://doi.org/10.1097/icl.0000000000000358>

Relevance: The title implies a discussion on preventing discomfort leading to lens dropout, which is directly related to the issue of lens discontinuation.
- Price, M.O., Price, D.A., Bucci, F.A., Durrie, D.S., Bond, W.I., & Price, F.W. (2016). Three-Year Longitudinal Survey Comparing Visual Satisfaction with LASIK and Contact Lenses. *Ophthalmology*. <https://doi.org/10.1016/j.ophtha.2016.04.003>

Relevance: The title suggests a longitudinal study comparing LASIK and contact lenses, which could be relevant to discussions on visual satisfaction and treatment outcomes.
- Sandoval, H.P., Donnenfeld, E.D., Kohnen, T., Lindstrom, R.L., Potvin, R., Tremblay, D.M., et al. (2016). Modern laser in situ keratomileusis outcomes. *Journal of Cataract and Refractive Surgery*. <https://doi.org/10.1016/j.jcrs.2016.07.012>

Relevance: The paper discusses modern outcomes of laser in situ keratomileusis, which is relevant to advancements in LASIK techniques.
- Donnenfeld, E.D., Perry, H.D., Doshi, S.J., Biser, S.A., & Solomon, R. (2004). Hyperthermic treatment of post-LASIK corneal striae. *Journal of Cataract and Refractive Surgery*. <https://doi.org/10.1016/j.jcrs.2003.08.019>

Relevance: The paper addresses hyperthermic treatment for post-LASIK complications, which is pertinent to post-operative LASIK care.
- Dupps, W.J. (2016). LASIK outcomes: How are we doing and can we do better?. *Journal of Cataract and Refractive Surgery*. <https://doi.org/10.1016/j.jcrs.2016.07.017>

Relevance: The paper evaluates LASIK outcomes and potential improvements, which is directly relevant to the overall discussion of LASIK procedures.

Spelling, Language & Grammar

Check off each item as you correct it — 0 / 17 corrected

- ☐ vision (Abstract, Conclusions section, last sentence) -> vision
- ☐ postoperativeerative (Methods, Study Population section) -> postoperative
- ☐ plano to -3,00 D (Methods, Covariates and Outcomes section) -> plano to -3.00 D (use period, not comma, as decimal separator)
- ☐ refractive and visual were evaluated (Abstract, Methods section) -> refractive and visual outcomes were evaluated
- ☐ to assess LASIK outcomes following differed between the two cohorts (Discussion, first paragraph) -> to assess whether LASIK outcomes differed between the two cohorts
- ☐ not be considered clinically meaningful (Methods, Statistical Analysis section) -> not considered clinically meaningful (remove 'be')
- ☐ cause to up to (Introduction, third paragraph) -> cause up to
- ☐ Figure2 (Results, SE Prediction Errors section) -> Figure 2
- ☐ best-correct visual acuity (Discussion, third paragraph) -> best-corrected visual acuity
- ☐ contact lens wearer fail (Conclusions paragraph) -> contact lens wearers fail
- ☐ Spectable (Reference 23 title) -> Spectacle
- ☐ -0.029 90.054) (Table 4, Length of Prior Contacts Use <1 row) -> -0.029 (0.054)
- ☐ one's hand (Discussion, paragraph on non-compliance) -> one's hands
- ☐ Contacts Lens Dropout (Reference 5 title) -> Contact Lens Dropout
- ☐ Contacts Lens compliance (Reference 21 title) -> Contact Lens Compliance
- ☐ Contacts Lens Wear (Reference 20 title) -> Contact Lens Wear

- Fix the typo 'Figure2' (missing space) in the text. (Results, SE Prediction Errors section) -> Figure 2