



Risk for microbial keratitis: Comparative metaanalysis of contact lens wearers and post-laser in situ keratomileusis patients

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Purpose: To compare the risk for microbial keratitis in contact lens wearers stratified by wear schedule with the risk after laser in situ keratomileusis (LASIK).

Setting: Hamilton Eye Institute and Department of Ophthalmology, University of Tennessee Health Science Center, Memphis, Tennessee, USA.

Design: Comparative metaanalysis and literature review.

Methods: An extensive literature search was performed in the PubMed database between December 2014 and July 2015. This was followed by a metaanalysis using a mixed-effects modeling approach.

Results: After 1 year of daily soft contact lens wear, there were fewer microbial keratitis cases than after LASIK, or approximately 2 cases fewer cases per 10000 ($P = .0609$). If LASIK were

assumed to have essentially a 1-time risk for microbial keratitis, 5 years of extrapolation would yield 11 more cases per 10000 with daily soft contact lens wear than with LASIK, or approximately 3 times as many cases ($P < .0001$). The extended use of soft contact lenses led to 12 more cases at 1 year than LASIK, or approximately 3 times as many cases ($P < .0001$), and 81 more cases at 5 years ($P < .0001$). When incorporating an estimated 10% retreatment rate for LASIK, these results changed very little.

Conclusions: Microbial keratitis is a relatively rare complication associated with contact lens use and LASIK postoperatively. The risk for microbial keratitis was similar between patients using contact lenses for 1 year compared with LASIK. Over time, the risk for microbial keratitis was higher for contact lens use than for LASIK, specifically with extended-wear lenses.

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Microbial keratitis, or infectious keratitis by causes other than viruses, can be a devastating ocular event. Contact lens wear has long been recognized as a significant risk factor in the development of microbial keratitis.¹ The risk for microbial keratitis is multifactorial and includes associations with lens type, wear schedule, and hygiene.^{2,3} Although contact lens wear has been long established as a major cause of microbial keratitis, microbial keratitis has more recently been described as a potential complication after refractive surgery.⁴

The burden of microbial keratitis, and specifically microbial keratitis associated with contact lens wear, has more recently come forth.² With approximately 38 million contact lens wearers in the United States, there were an estimated 1 million clinical visits secondary to microbial keratitis and contact lens-related ICD-9 codes in the year 2010. This correlated with an economic burden of

approximately \$174.9 million over this same period, including included more than \$70 million in costs for Medicare and Medicaid combined.²

The majority of contact lens wear can be considered elective for uncorrected refractive error rather than for aphakia or irregular astigmatism. Contact lenses have traditionally been considered safer than refractive surgery as a means of correcting refractive error; however, recent analyses and dialog have questioned this assumption.^{5,6} When assessed independently, comparisons between the rates of contact lens-related microbial keratitis and microbial keratitis after laser in situ keratomileusis (LASIK) can be inferred; however, the risk for microbial keratitis from contact lens use cannot be directly compared with the risk for post-LASIK microbial keratitis. Large-scale randomized studies comparing these 2 entities would be impossible given the relative rarity of each condition and the statistical power needed to obtain a significant

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conclusion. Furthermore, the risk for microbial keratitis with contact lens use accrues over years of wear while that of refractive surgery remains constant.

In the present study, we performed a systematic review of the current literature and a metaanalysis of the available data to compare the risks for microbial keratitis in contact lens wearers stratified by wear schedule with the risk in post-LASIK patients.

PATIENTS AND METHODS

Literature Search

An extensive literature search was performed in the Medline database via PubMed between December 2014 and July 2015 using English-language articles only. The contact lens literature search terms included *contact lens, keratitis, infection, incidence, prevalence, and complications*. The post-LASIK literature search terms included *laser in situ keratomileusis, refractive surgery, keratitis, infection, incidence, prevalence, and complications*. Appropriate studies were also searched from the reference lists of relevant reviews and clinical studies.

Inclusion and Exclusion Criteria

Studies regarding contact lens keratitis were included if an annualized incidence could be calculated from the available data, and cases of keratitis were subdivided based on lens wear type and schedule. In addition, each subcategory was required to have a number of at least 1000. Studies were excluded if lens type or a subset population of lens wear schedules could not be ascertained or the number was less than 1000 persons. Studies regarding LASIK keratitis were included if cases of nonviral infections could be determined from the study data with at least a number of 1000. Studies were excluded if the study population was less than 1000 cases.

Definitions

Microbial keratitis was defined by each study, respectively, and this definition was used to determine cases per each study. In studies in which a number of cases was given for presumed cases as well as culture-proven cases, the cases of presumed microbial keratitis were used in the analysis in this study. However, if there was a more stringent definition, those cases were included. In addition, cases that were not definitively linked to a lens wear schedule were excluded from analysis. Daily

wear of soft contact lenses was defined as no overnight wear of disposable daily, hydrogel, or silicone hydrogel lenses. Extended-wear soft contact lenses were defined as wearing the lenses at least overnight and included both hydrogel and silicone hydrogel lenses. Rigid gas-permeable (RGP) lenses in the studies selected were almost exclusively worn on a daily basis; therefore, the small sample of extended-use RGP lenses was omitted.

Statistical Analysis

Statistical analysis was performed using SAS/STAT software (version 9.4, SAS Institute, Inc.). For each study, the annualized rate per 10 000 patients was estimated and its Pearson-Clopper 95% confidence interval (CI) was provided. If an annualized number of cases was provided, that number was used. If it was not provided, the incidence per 10 000 was multiplied by the appropriate factor to obtain an annualized incidence. For soft daily-wear, soft extended-wear, and RGP contact lens data, further rates per 10 000 were extrapolated by multiplying the annualized rate by the number of years of lens wear. The annualized rate for LASIK patients was assumed to stay fixed regardless of the number of years of extrapolated lens wear in the initial analysis. In addition, a secondary analysis was performed assuming a 10% retreatment or enhancement rate. A mixed-effects modeling approach was used to obtain the meta-analysis results and to statistically compare the 4 treatment modalities.

RESULTS

Included Studies

Eight studies on the use of soft daily-use and RGP daily-use lenses and 9 studies of the use of soft-extended contact lenses were identified that met the inclusion and exclusion criteria (Table 1)⁷⁻¹⁵; these studies spanning from 1998 to 2008. Nine studies that met the inclusion and exclusion criteria for LASIK were identified (Table 2)¹⁶⁻²⁴; these studies spanned from 1999 to 2015.

Figures 1 to 4 show the metaanalysis results for each modality separately. Tables 3 and 4 show the results of a statistical comparison of each wear schedule modality by extrapolating years of wear at 1 year, 5 years, and 10 years. At 1 year, daily wear of soft lenses resulted in significantly fewer cases of microbial keratitis per 10 000 wearers than

Table 1. Contact lens studies that met inclusion criteria.

First Author	Study Type	Journal	Year
Morgan ⁷	12-month prospective epidemiological study in England	Br J Ophthalmol	2004
Cheng ⁸	3-month prospective survey-based, epidemiological study in Holland	Lancet	1999
Schein ^{9,*}	Prospective cohort post-market surveillance based on 12-month survey in U.S.	Ophthalmology	2005
Stapleton ¹⁰	12-month prospective population-based surveillance study in Australia	Ophthalmology	2008
Lam ¹¹	17-month prospective hospital- and population-based study in Hong Kong	Eye	2002
Seal ¹²	8-month prospective cohort study including a population in Western Scotland	Cont Lens Anterior Eye	1999
Poggio ¹³	3-month prospective survey-based epidemiological study in U.S.	N Engl J Med	1989
Nilsson ¹⁴	3-month prospective survey- and population-based study in Sweden	CLAO J	1994
MacRae ¹⁵	Retrospective review of clinical data from premarket studies 1980–1988 in U.S.	Am J Ophthalmol	1991

Am J Ophthalmol = *American Journal of Ophthalmology*; Br J Ophthalmol = *British Journal of Ophthalmology*; CLAO J = *CLAO Journal*; Cont Lens Anterior Eye = *Contact Lens & Anterior Eye*; N Engl J Med = *New England Journal of Medicine*

*Obtained data for soft extended-wear lenses only

Table 2. Laser in situ keratomileusis studies that met inclusion criteria.

First Author	Study Type	Journal	Year
Llovet ¹⁶	Retrospective case series review of consecutive cases	Ophthalmology	2010
Hammond ¹⁷	Retrospective case series of active service members in Army	Ophthalmology	2005
de Oliveira ¹⁸	Retrospective review of consecutive cases	J Refract Surg	2006
Solomon ¹⁹	Retrospective survey-based study	J Cataract Refract Surg	2003
Stulting ²⁰	Prospective observational clinical study	Ophthalmology	1999
Lin ²¹	Retrospective case series of consecutive first 1019 cases at 1 institution	Am J Ophthalmol	1999
Moshirfar ²²	Retrospective review of consecutive cases	J Cataract Refract Surg	2007
Sun ²³	Prospective study of consecutive patients treated for myopia	J Refract Surg	2005
Ortega-Usobiaga ²⁴	Retrospective case series review of consecutive cases	J Cataract Refract Surg	2015

Am J Ophthalmol = *American Journal of Ophthalmology*; J Cataract Refract Surg = *Journal of Cataract & Refractive Surgery*; J Refract Surg = *Journal of Refractive Surgery*

extended wear of soft lenses ($P < .0001$), while daily wear of soft lenses led to more cases per 10 000 than RGP daily wear ($P = .0085$) (Table 3).

A comparison of post-LASIK patients and contact lens wearers showed that soft-extended contact lens wear had on average significantly 12 more cases of microbial keratitis per 10 000 at 1 year (Table 4), or approximately 3 times as many cases ($P < .0001$). At 1 year, soft daily-wear lens use had more cases per 10 000 than LASIK; however, the difference did not reach statistical significance ($P = .0609$). Extrapolation to 5 years of wear showed that daily wear

of soft lenses and extended wear of soft lenses led to significantly more cases of microbial keratitis per 10 000 patients than LASIK (both $P < .0001$). At 10 years, both contact lens modalities also had significantly more cases of microbial keratitis per 10 000 than LASIK (both $P < .0001$). Daily use of RGP lenses had significantly more cases of microbial keratitis per 10 000 patients than LASIK at 1 year ($P < .0001$); however, the level was at approximately the same between the 2 modalities at 5 years ($P = .6437$). At 10 years, the difference was significant, again in favor of LASIK ($P = .0001$).

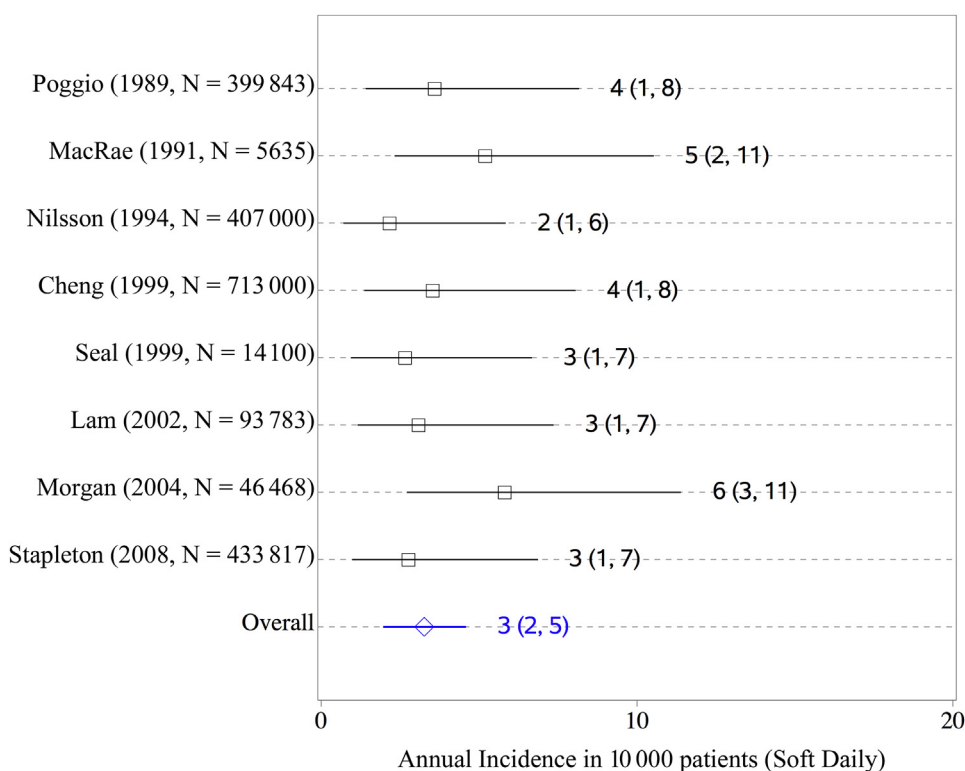


Figure 1. Annualized incidence (95% CIs) of studies (first author listed) included for daily-wear soft lenses.

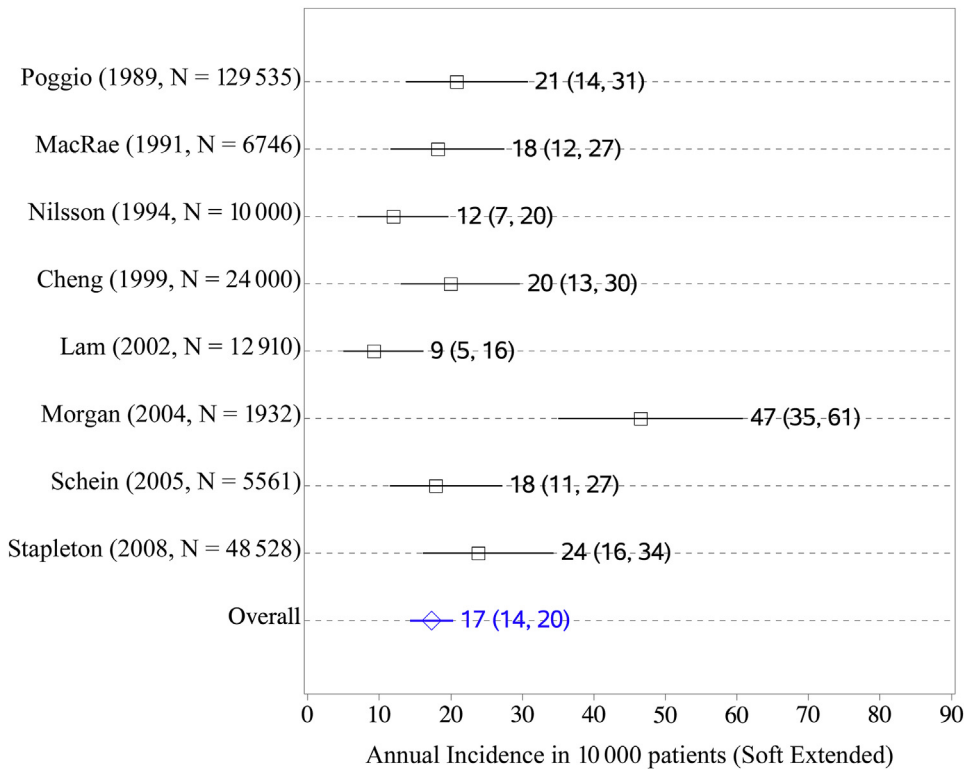


Figure 2. Annualized incidence (95% CIs) of studies (first author listed) included for extended-wear soft lenses.

Using a model for a 10% enhancement rate when comparing post-LASIK patients with contact lens wearers, the results were very similar (Table 5). At 1 year, soft daily-wear lenses had 2.6 less cases per 10 000 than LASIK ($P = .0229$). The remainder of the results accounting for enhancement showed an essentially stable number of events

in comparison with results generated from data not accounting for enhancements.

DISCUSSION

To our knowledge, this is the first comprehensive analysis comparing the incidence of microbial keratitis in contact

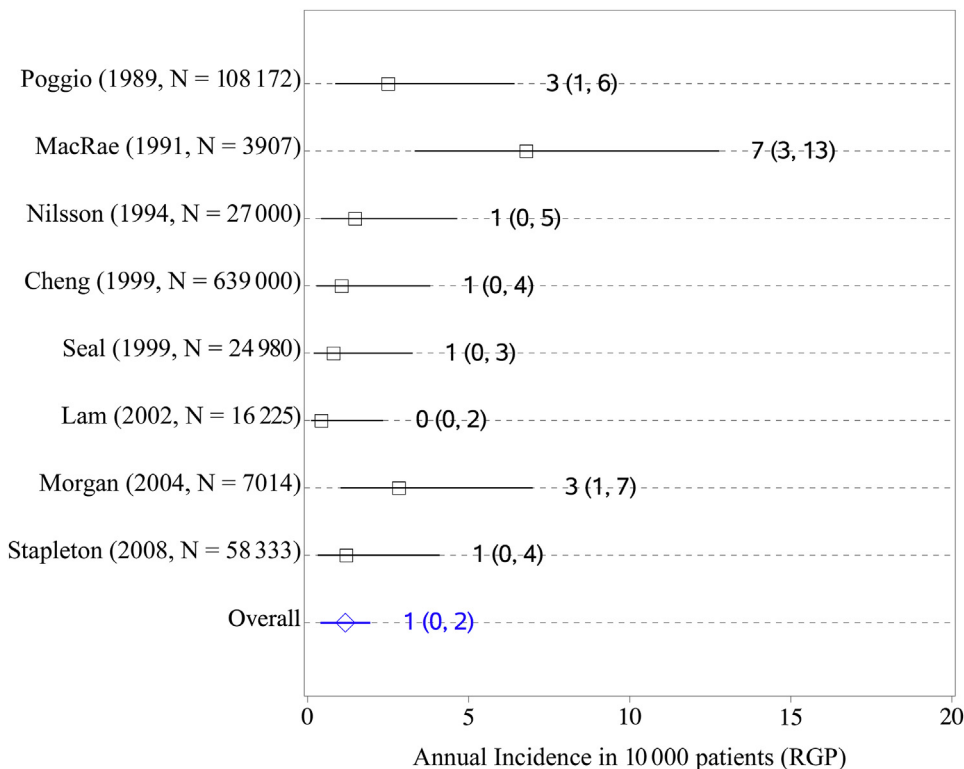


Figure 3. Annualized incidence (95% CIs) of studies (first author listed) included for RGP daily wear (RGP = rigid gas permeable).

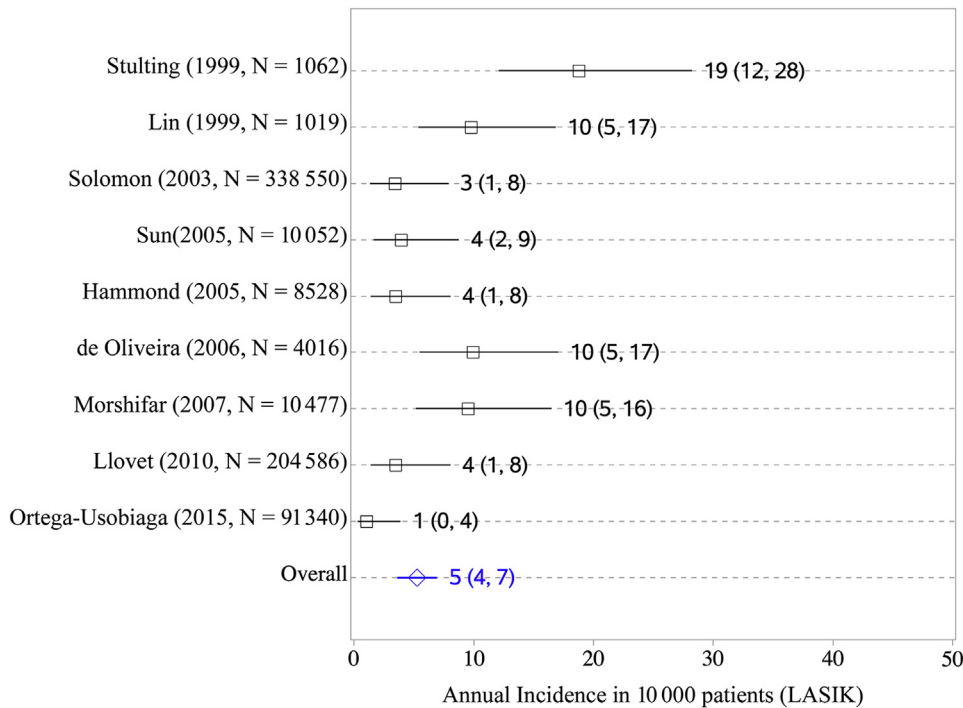


Figure 4. Annualized incidence (95% CIs) of studies (first author listed) included for LASIK (LASIK = laser in situ keratomileusis).

lens wearers with that of post-LASIK patients. The incidence of microbial keratitis in daily soft contact lens wear in the first year was statistically lower than that in post-LASIK patients, approximately 2 fewer cases per 10 000. However, if we assume LASIK poses essentially a 1-time risk for microbial keratitis (ie, after the healing period and without enhancements), at 5 years there would be significantly more cases of microbial keratitis with daily use of soft contact lenses, or approximately 3 times as many cases. Similarly, at 1 year there were fewer cases of microbial keratitis with daily RGP lens wear and no significant difference in the number of cases between with daily RGP wear and LASIK at 5 years. This is consistent with results in previous studies⁷⁻¹² that found RGP lens wearers have the lowest incidence of microbial keratitis among contact lens wearers. Our study showed that at 1 year extended wear of soft contact lenses led to 12 more cases of microbial keratitis per 10 000 than LASIK, or approximately 3 times as many cases. Many people wear contact lenses over extended periods, including overnight wear. Thus, this is

a large population that could conceivably benefit from LASIK in terms of the risk for microbial keratitis.

Assuming that a LASIK treatment carries a 1-time risk for microbial keratitis does not account for the possibility of infections occurring outside the observed period or the possibility of the risk for microbial keratitis from enhancements or retreatments, which might be as high as 5% to 28% as reported in the literature.^{25,26} Given that more recent studies have shown a decrease in the retreatment rate with better preoperative calculations and laser platforms,²⁶ we chose to repeat our analysis using an estimated 10% retreatment or enhancement rate. This addition to the analysis did not affect our overall comparison. We believe that using a model to incorporate a retreatment rate in this way strengthens our conclusions.

This analysis is limited. First, the weaknesses and limitations of each respective study inherently add bias to this study. For instance, epidemiological studies of contact lens wear can overestimate or underestimate the incidence depending on the methodology, response rate of those

Table 3. Statistical comparison of microbial keratitis incidence between modalities assuming 1 year, 5 years, and 10 years of contact lens wear.

Comparison	1 Year			5 Years			10 Years		
	Rate Diff per 10 000	95% CI	P Value	Rate Diff per 10 000	95% CI	P Value	Rate Diff per 10 000	95% CI	P Value
Soft daily vs soft extended	-14.0	-17.3, -10.8	<.0001	-70.3	-77.6, -63.0	<.0001	-140.9	-151.2, -130.0	<.0001
Soft daily vs RGP	2.1	0.6, 3.6	0.0085	10.5	7.1, 13.9	<.0001	21.0	16.2, 25.8	<.0001
Soft extended vs RGP	16.1	13.0, 19.2	<.0001	80.8	74.0, 87.8	<.0001	162.0	152.2, 171.7	<.0001

CI = confidence interval; RGP = rigid gas-permeable

Table 4. Statistical comparison of microbial keratitis incidence between contact lens modalities and LASIK assuming 1 year, 5 years, and 10 years of contact lens wear.

Comparison	1 Year			5 Years			10 Years		
	Rate Diff per 10 000	95% CI	P Value	Rate Diff per 10 000	95% CI	P Value	Rate Diff per 10 000	95% CI	P Value
Soft daily vs LASIK	-2.1	-4.3, 0.0	.0609	11.1	7.7, 14.4	<.0001	27.4	23.2, 31.9	<.0001
Soft extended vs LASIK	12.0	8.4, 15.3	<.0001	81.4	74.5, 88.3	<.0001	168.4	158.8, 177.9	<.0001
RGP vs LASIK	-4.1	-5.9, -2.3	<.0001	0.5	-1.9, 3.0	.644	6.4	3.4, 9.4	.0001

CI = confidence interval; LASIK = laser in situ keratomileusis; RGP = rigid gas-permeable

surveyed, or population estimates. Conversely, the LASIK studies included in the present study are limited because each study represents a series of cases reviewed retrospectively or prospectively and thus their results may not be generalizable to the population as a whole. In our analyses, there were several assumptions. We assumed that each case of keratitis is equal no matter the definition described in the individual studies. Most studies have similar clinical criteria for determining a case of presumed microbial keratitis; however, some studies might have been more stringent than others. We combined all soft lenses, whether silicone, hydrogel, or daily disposable, into categories based on their wear schedule and not their lens type. This was done in an effort to simplify analysis and can be justified because new innovations in lens material, such as silicone hydrogel, and type have not significantly changed the annualized risk.²⁷ Last, we did not account for the other complications of LASIK, such as flap complications or ectasia, and did not analyze the incidence of complications, such as vision loss or dry eye, of either modality.

The studies included in this analysis are spread over a number of years; that is, for contact lens wear 1989 to 2008 and for LASIK 1999 to 2015. Much has changed in the world of contact lens technology as well as with LASIK technology and postoperative care. We believe this to be a strength of this study in that we compared older technology with older technology and likewise with newer advances in each modality analyzed. As mentioned, newer advances in contact lenses, such as silicone hydrogel or daily disposable contact lenses, have not conclusively been shown to

decrease the risk for microbial keratitis.²⁷ Conversely, newer technology in LASIK, such as improved excimer ablation profiles and nomograms, might lead to more accurate procedures and less need for further treatment, which could theoretically decrease the overall risk for microbial keratitis associated with LASIK.

We believe that this is the first metaanalysis to compare the rates of microbial keratitis in contact lens wear with those post-LASIK. Attempts to compare the safety and efficacy of contact lenses and refractive surgery were slow in developing before the more recent large studies analyzing the rates of microbial keratitis in the postoperative LASIK patient. As more studies regarding LASIK outcomes with larger denominators are produced, more metaanalyses looking at several factors with more power can be performed. This study specifically looked at the incidence of microbial keratitis in contact lens wearers and compared it with the incidence of microbial keratitis in post-LASIK patients based on the available literature. Our results indicate that over time, the risk for microbial keratitis is higher for soft contact lens use than for LASIK, specifically for extended-wear lenses.

Further comparisons looking at vision loss, dry eye, flap complications, and other complications of each modality should be performed to fully describe the safety and efficacy of contact lenses in relation to LASIK and refractive surgery in general. The present analysis lends further evidence to support the shifting notion that over time the risks of contact lens use and LASIK are closer than previously thought.

Table 5. Statistical comparison of microbial keratitis incidence between contact lens modalities and LASIK assuming 1 year, 5 years, and 10 years of contact lens wear and assuming a 10% retreatment or enhancement rate.

Comparison	1 Year			5 Years			10 Years		
	Rate Diff per 10 000	95% CI	P Value	Rate Diff per 10 000	95% CI	P Value	Rate Diff per 10 000	95% CI	P Value
Soft daily vs LASIK	-2.6	-4.7, -0.4	.0229	10.5	7.1, 13.9	<.0001	26.9	22.4, 31.3	<.0001
Soft extended vs LASIK	11.5	8.0, 15.0	<.0001	80.8	73.9, 87.7	<.0001	167.8	158.2, 177.4	<.0001
RGP vs LASIK	-4.7	-6.6, -2.8	<.0001	0.0	-2.5, 2.5	.9968	5.8	2.8, 8.9	.0005

CI = confidence interval; LASIK = laser in situ keratomileusis; RGP = rigid gas-permeable

WHAT WAS KNOWN

- Contact lenses have long been described as a major cause of microbial keratitis. More recently, microbial keratitis has been seen after refractive surgery.

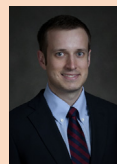
WHAT THIS PAPER ADDS

- The risk for microbial keratitis associated with soft contact lens wear over time seems to be higher than that after LASIK.
- Although more studies comparing complications after LASIK versus contact lens wear are needed, this study shows that in terms of microbial keratitis risk there might be a benefit for some patients, specifically extended-wear contact lens users, to have LASIK.

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DISCLOSURE: None of the authors has a financial or proprietary interest in any material or method mentioned.



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