

# A meta-analysis of studies on cosmetically tinted soft contact lenses

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**Background:** Concerns regarding the safety of cosmetically tinted contact lenses have been reported in the literature. The purpose of this paper is to evaluate the safety of cosmetically tinted contact lenses in a large number of patients across six clinical trials that varied from 1 week to 3 months in duration.

**Methods:** Lenses tested included: Naturelle limbal ring daily disposable, Lacelle limbal ring daily disposable, Lacelle colored cosmetic daily disposable, Lacelle limbal ring planned replacement at 2 weeks, and Alamode traditional/annual colored cosmetic lens. The primary safety outcome was slit-lamp examination, including epithelial edema, epithelial microcysts, corneal staining, bulbar injection, limbal injection, upper lid tarsal conjunctival abnormalities, corneal neovascularization, and corneal infiltrates. High contrast logMAR visual acuity with lenses, and lens wearing time, movement, and centration, are also presented.

**Results:** A total of 871 subjects (1,742 eyes) and 23 clinical investigators participated in the six studies, with an average completion rate of 96.4% across all studies. The mean age of the patients was  $26.8 \pm 6.6$  years, and 86.7% of participants were female. The total number of slit-lamp examinations across the six studies was 2,456 visits by eye (1,228 visits by patient). There were no slit-lamp signs  $>$  grade 2 for any finding, with the exception of corneal staining in one study. In this study, grade 3 corneal staining was noted in one eye (0.1%) at follow-up visit 1 and four (0.6%) of all eligible dispensed eyes at follow-up visit 2, with no eyes requiring medical treatment. No adverse events were reported during any of the trials.

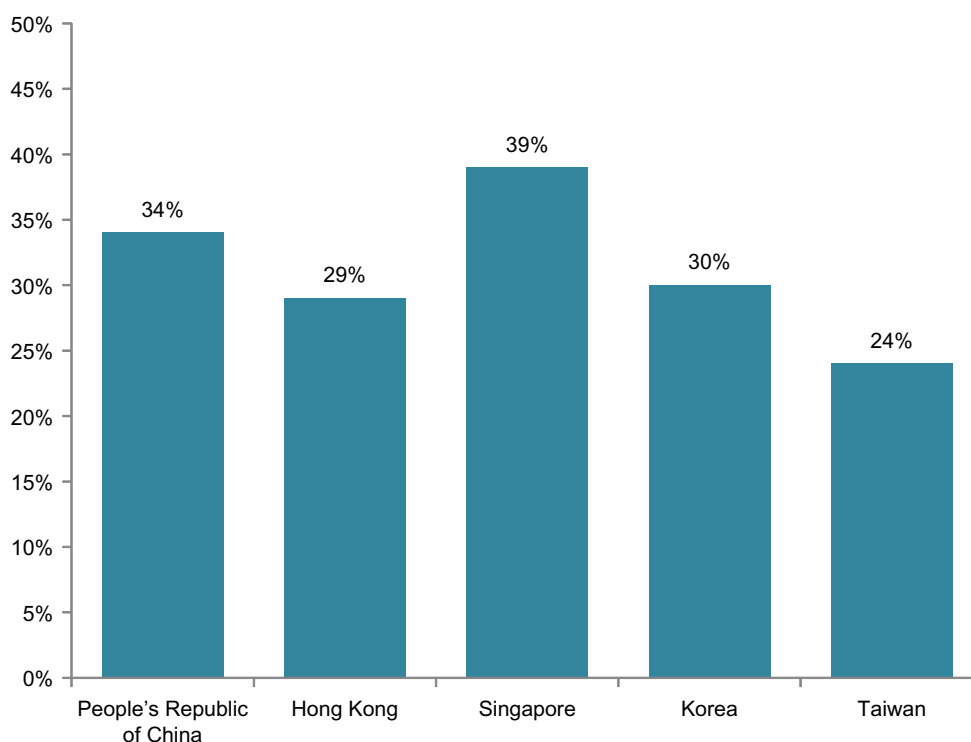
**Conclusion:** The cosmetically tinted lenses evaluated in this meta-analysis appear to be safe when properly prescribed by an eye care professional and used in a compliant manner.

**Keywords:** contact lens, hydrogel, cosmetically tinted contact lens, compliance

## Introduction

Cosmetic soft contact lenses represent a rapidly growing segment of the contact lens market, especially in Asian countries. According to the 2010 Study of the International Market for Contact Lenses conducted by Multi-sponsor Surveys International LLC, the use of cosmetically tinted lenses among all contact lens wearers ranges from 24% in Taiwan to 39% in Singapore (Figure 1).<sup>1</sup> In a study of cosmetically tinted lenses in the UK, the proportion of all soft lens fits between 1997 and 2008 that were cosmetically tinted lenses has been reported to be lower than in Asian countries with significantly more females than males fitted (females 4.6% and males 1.6%).<sup>2</sup> In contrast with Asian countries, the authors reported that the proportion of cosmetically tinted lenses fitted in the UK declined between 1997 and 2008.<sup>2</sup> In their analysis of international contact lens prescribing, Morgan et al reported the proportion of soft lens fits that

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**Figure 1** Cosmetically tinted lens use among all contact lens wearers.

were cosmetically tinted to be 1% for both the UK and the US in 2012.<sup>3</sup>

In the People's Republic of China, cosmetic contact lens wearers tend to be younger female students.<sup>4</sup> Compared with clear lenses, cosmetically tinted lenses are worn more for social occasions.<sup>4</sup> In the UK, cosmetically tinted lenses were fitted to younger patients (average age  $27 \pm 11$  years) compared with noncosmetically tinted lenses ( $33 \pm 13$  years), and significantly more tinted lenses were fitted for part-time wear compared with full-time wear, ie, the opposite of non-cosmetically tinted lenses.<sup>2</sup>

Although there are case reports of safety concerns in the literature, there is a paucity of prospective clinical studies reporting on the safety of cosmetically tinted contact lenses. The purpose of this work was to evaluate the safety of cosmetically tinted contact lenses in a large number of patients across six clinical trials. This represents the first such large-scale report of the safety of cosmetically tinted soft contact lenses.

## Methods and materials

A meta-analysis was performed on all studies in which slit-lamp examination, high contrast logMAR visual acuity with lenses, lens wearing time, lens centration, and movement results from six consecutive, prospective clinical studies conducted between February 2010 and December 2011

were combined. Results from all eligible subjects at all visits while using the cosmetically tinted lenses are included. The description of each study, including study duration and study designs, for the six studies are shown in Table 1.

All studies were approved by an institutional review board and informed consent was obtained from each subject prior to participation. Subject recruitment for each study was only open to currently adapted wearers of soft contact lenses. Eligible subjects had to wear a lens in each eye and each lens must have been of the same manufacture and brand. Eligible subjects had to wear plano or require myopic correction and had to have visual acuity correctable through spherocylindrical refraction to 0.3 logMAR or better in each eye. In addition, subjects had to have clear central corneas and be free of any anterior segment disorders. Subjects with slit-lamp findings greater than grade 1 or corneal infiltrates of any grade were not eligible. Subjects who had worn gas permeable lenses within 30 days or polymethylmethacrylate lenses within 3 months prior to enrollment, and those who were aphakic, amblyopic, or who required monovision, multifocal, or toric contact lenses were not eligible to participate.

Distance high contrast visual acuity was calculated as the logMAR by converting the number of letters correctly identified in the eye examination to the logMAR equivalent. Lens centration was assessed as excellent (fully centered), good (slight decentration, no corneal exposure), fair (decentration,

**Table 1** Profile of study design for the six studies included in the meta-analysis

Study	Design	Study duration	Visits	Sites (n)	Study dates	Lens designs tested
A	Parallel, bilateral, randomized, open-label	One month	Baseline, 2 weeks, one month	10 sites (one Hong Kong, 2 Taiwan, 7 United States)	April to August 2010	Naturelle Limbal ring daily disposable (Bausch + Lomb) and I-Day Acuvue Define Accent* (Johnson & Johnson Vision Care, Inc.)
B	Bilateral, single arm, open-label	One month	Baseline, 2 weeks, one month	6 sites (4 Singapore and 2 Hong Kong)	February to June 2010	Lacelle Limbal ring planned replacement at two weeks (Bausch + Lomb)
C	Bilateral, single arm, open-label	One week	Baseline, one week	7 sites (5 Hong Kong, 2 Singapore)	August to November 2010	Naturelle Limbal ring daily disposable (Bausch + Lomb)
D	Bilateral, single arm, open-label	Three months	Baseline, one month, 3 months	6 sites (3 Hong Kong, 3 Singapore)	August to December 2011	Alamode Traditional/annual cosmetic tinted lens (Bausch + Lomb)
E	Bilateral, single arm, open-label	One month	Baseline, one month	6 sites (3 Hong Kong, 2 Malaysia, 1 Singapore)	November to December 2011	Lacelle Colored – cosmetic Daily disposable. (Bausch + Lomb)
F	Bilateral, single arm, open-label	One week	Baseline, one week	7 sites (6 Hong Kong and 1 Singapore)	September to October 2011	Lacelle Limbal ring daily disposable (Bausch + Lomb)

**Notes:** \*For study A, only data for Naturelle lenses are represented in the meta-analysis. Bausch + Lomb is used for Bausch & Lomb Incorporated.

intermittent corneal exposure), or poor (incomplete corneal coverage and/or edge lift). Lens movement was assessed as adequate, excessive, insufficient, or adherence.

Slit-lamp findings for each eye, including epithelial edema, epithelial microcysts, corneal staining, bulbar injection, limbal injection, upper lid tarsal conjunctival abnormalities, corneal neovascularization, and corneal infiltrates, were graded for severity on a scale from 0 (no finding) to 4 (severe finding). Slit-lamp data from baseline visits were not included in the analysis, because it did not reflect exposure to the lenses being tested. An adverse event was defined as a sight-threatening condition, which may include but was not limited to the following: corneal ulcers, anterior uveitis (iritis), other ocular infections or inflammations,

corneal scarring (central 4 mm), corneal neovascularization (central 4 mm), and/or permanent loss of vision.

## Results

We reviewed data from six unique previously unpublished studies sponsored by Bausch & Lomb Incorporated (Rochester, NY, USA) that included a total of 1,742 eyes (871 subjects) and 23 unique clinical investigators. Table 2 shows the accountability of subjects for each study. A very high proportion of subjects completed the various studies, with an average completion rate of 96.4% across all studies. The mean study duration across all studies was  $29.7 \pm 28.4$  days.

The mean age of patients was  $26.8 \pm 6.6$  years, and 86.7% of participants were female. Demographic data are

**Table 2** Accountability of subjects for each study

	Study A	Study B	Study C	Study D	Study E	Study F	Total n (%)
Total enrolled	100	140	218	145	140	140	883
Eligible	95	139	212	145	140	140	871 (98.6%)
Completed	85	135	209	143	139	140	851 (96.4%)
Discontinued	10	4	3	2	1	0	20 (2.3%)
Ineligible at baseline	5	1	6	0	0	0	12 (1.4%)
Completed	2	1	2	0	0	0	5 (0.6%)
Discontinued	3	0	4	0	0	0	7 (0.8%)

provided in Table 3. Average daily lens wearing time for the study lenses was  $10.1 \pm 2.8$  hours. Mean high contrast distance logMAR visual acuity with the study lenses was  $0.0002 \pm 0.0715$ .

Lens centration was graded as excellent or good in 97.9%, 98.1%, and 98.9% of patients at the dispensing, follow-up 1, and follow-up 2 visits, respectively. Lens movement was graded as adequate in 82.7%, 76.5%, and 83.1% of patients at the dispensing, follow-up 1, and follow-up 2 visits, respectively.

The total number of follow-up slit-lamp examinations across the six studies was 2,456 visits by eye (1,228 visits by patient). There were no slit-lamp signs > grade 2 for any finding, with the exception of corneal staining in study D (Table 4). In study D, grade 3 corneal staining was noted in one eye (0.1%) at follow-up visit 1 and four eyes (0.6%) of all eligible dispensed eyes at follow-up visit 2. No eyes with slit-lamp findings required medical treatment, and there were no reports of adverse events during any of the trials.

## Discussion

The six prospective clinical trials reported in the present analysis provide eye care practitioners with an extensive assessment of the safety of cosmetically tinted contact lenses when properly prescribed by an eye care professional. Despite the popularity of cosmetically tinted lenses, there have been negative reports regarding safety in the literature.<sup>5–10</sup> Compliance-related reports in the literature all have in common patient histories of receiving the contact lenses without a prescription, with no or limited care, limited handling and wearing instructions, and no follow-up examinations.<sup>6,8–10</sup> Complications related to compliance are not limited to cosmetically tinted contact lenses. Any contact lenses, when used in a noncompliant manner, could lead to complications.

**Table 3** Patient demographics summarized across all studies

Age (years) (mean $\pm$ SD)	26.8 $\pm$ 6.6
Sex	
% female	86.7
% male	13.3
Race	
% Asian	100
Baseline sphere, D (mean $\pm$ SD)	−3.30 $\pm$ 1.7
Baseline cylinder, D (mean $\pm$ SD)	−0.40 $\pm$ 0.4
Iris color	
% brown	96.4
% hazel	1.6
% other	2.0
Prestudy average daily lens wear time, hours (mean $\pm$ SD)	10.4 $\pm$ 2.6

**Abbreviations:** SD, standard deviation; D, diopters.

**Table 4** Number and percentage of all eligible dispensed eyes with each slit-lamp grade for follow-up visit 1 (all studies) and follow-up visit 2 (applicable only for studies A, B, and D)

	Epithelial edema n (%)	Epithelial microcysts n (%)	Corneal staining n (%)	Bulbar injection n (%)	Limbal injection n (%)	Upper lid tarsal abnormality n (%)	Corneal neovascularization n (%)	Corneal infiltrates n (%)
Follow-up visit 1								
Grade 0	1,729 (99.9%)	1,730 (100%)	1,089 (62.9%)	1,340 (77.5%)	1,330 (76.9%)	1,122 (64.9%)	1,601 (92.5%)	1,727 (99.8%)
Grade 1	1 (0.1%)	0 (0.0%)	586 (33.9%)	387 (22.4%)	388 (22.4%)	606 (35.0%)	129 (7.5%)	3 (0.2%)
Grade 2	0 (0.0%)	0 (0.0%)	54 (3.1%)	3 (0.2%)	12 (0.7%)	2 (0.1%)	0 (0.0%)	0 (0.0%)
Grade 3	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Grade 4	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Follow-up visit 2								
Grade 0	726 (100%)	726 (100%)	341 (47.0%)	558 (76.9%)	496 (68.3%)	477 (65.7%)	664 (91.5%)	725 (99.9%)
Grade 1	0 (0.0%)	0 (0.0%)	310 (42.7%)	166 (22.9%)	224 (30.9%)	245 (33.7%)	62 (8.5%)	1 (0.1%)
Grade 2	0 (0.0%)	0 (0.0%)	71 (9.8%)	2 (0.3%)	6 (0.8%)	4 (0.6%)	0 (0.0%)	0 (0.0%)
Grade 3	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Grade 4	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

The key differences between the six studies described here and previous reports in the literature are compliance-related and education-related. When patients are properly fitted, instruction is provided, and follow-up examinations are performed, as in the six studies presented here, cosmetically tinted lenses are safe and effective. Wearers in the present investigation were experienced wearers who had, on average, myopic refractive error, which is not the case with previous compliance-related reports. This, along with the controlled nature of a clinical trial, could account for the increased safety margin in the present work.

In 2003, Steinemann et al reported six cases of ocular complications related to use of cosmetically tinted contact lenses obtained from unlicensed retail vendors.<sup>10</sup> None of the patients had previously worn contact lenses for vision correction, and all patients had purchased the lenses without a prescription from vendors such as gas stations, flea markets, video stores, grocery stores, or mini marts. None of the patients had an accompanying eye examination, proper lens fitting, wear and care instructions, or follow-up. The authors stated that “with proper fit and appropriate instruction and follow-up by an eye care professional, the risks of decorative cosmetic contact lenses can be minimized, and lenses can be worn safely”.

A subsequent publication by Steinemann et al in 2005 surveyed 159 patients who reported for routine care regarding their use and experience with cosmetically tinted contact lenses.<sup>9</sup> Twenty-three percent of those surveyed reported they had used decorative contact lenses, and 74% reported that their friends used decorative cosmetic lenses. Patients using the lenses reported obtaining them from unlicensed vendors approximately 41% of the time. The authors also reported 12 cases of patients who experienced complications while wearing cosmetically tinted contact lenses. All of the patients in these case reports were naïve contact lens wearers who obtained the lenses without prescription, fitting, instructions, or follow-up examination. Risk-taking and noncompliant behavior were also noted by the authors. More recently, Singh et al reported 13 cases of complications in patients wearing cosmetically tinted contact lenses.<sup>8</sup> Much like the cases reported by Steinemann et al, none of the patients were aware of or instructed about proper lens handling techniques prior to use, and poor compliance was a common factor in all cases.

A case report by Lee et al illustrates the worst extreme of the consequences of noncompliance with soft contact lenses.<sup>6</sup> They reported on a 17-year-old female

cosmetically tinted contact lens wearer who presented with *Acanthamoeba* keratitis. The patient had purchased the lenses over the Internet with no instructions on care and handling. In addition, although she reported use of a multipurpose solution to care for her lenses, she also admitted to occasionally rinsing and storing the lenses in tap water.

## Conclusion

The studies presented in this report provide direct clinical evidence of the safety of the cosmetically tinted lenses tested. Ninety-nine percent of slit-lamp grades for corneal staining were  $\leq 2$  and there were minimal slit-lamp findings  $> 2$  across the six studies in a total of 1,742 eyes (871 patients) for a total of 2,456 slit-lamp examinations by eye (1,228 by patient). The cosmetically tinted lenses evaluated in this report appear to be safe when properly prescribed by an eye care professional and worn by experienced users. With the increasing consumer demand for cosmetically tinted contact lenses, there is a need for eye care professionals to encourage compliance and proactively engage consumers on the wear and care of contact lenses.

## Disclosure

The authors were employees of Bausch & Lomb Incorporated, Rochester, NY, USA, at the time of writing this report.

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