ORIGINAL ARTICLE

Ocular Surface Integrity, Dry Eye Signs and Symptoms in Wearers of Coloured Soft Contact Lenses from Different Sources

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ABSTRACT

Background: This study explored the effects of wearing coloured soft contact lenses (CL), sourced from both optometry and non-optometry providers, on ocular surface integrity and dry eye signs and symptoms. **Methods:** Five participants were randomly assigned to wear a pair of contact lenses from one of the two sources for one month, followed by a one-month washout period, after which they switched to lenses from the other source. Ocular surface integrity was assessed through measurements of tear meniscus height (TMH), non-invasive keratograph tear film breakup time (NIKBUT), and tear breakup time (TBUT) at three intervals: during the initial visit, one week post-wear, and one month post-wear. Additionally, participants completed the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) at the one-week and one-month follow-up visits to evaluate dry eye status. Repeated measures ANOVA was used to analyse changes in ocular surface integrity over the one-month period, while paired sample t-tests were conducted to assess changes in CLDEQ-8 scores between the one-week and one-month follow-ups. **Results:** The repeated measures ANOVA showed no significant differences in TMH, NIKBUT, or TBUT between the two types of contact lenses over the one-month period ($p > 0.05$). Similarly, paired samples t-tests revealed no significant changes in CLDEQ-8 scores between the base line, one-week and one-month follow-up visits ($p > 0.05$). **Conclusion:** The study concluded that there were no significant differences in ocular surface integrity or dry eye symptoms between coloured soft contact lenses obtained from optometry and non-optometry sources after one month of wear.

INTRODUCTION

Contact lenses are vital medical devices used to correct vision, alter appearance, and manage specific ocular conditions. Despite their widespread use and proven benefits, they are not without risks (Wu et al., 2010). While generally considered safe when used properly, many wearers experience discomfort, including dryness, irritation, and fatigue, particularly with prolonged wear (Kojima, 2018). The Tear Film and Ocular Surface Society (TFOS) International Workshop on Contact Lens Discomfort (CLD) identified several factors contributing to this discomfort, especially the mismatch between contact lenses and the natural ocular environment (Nicholas et al., 2013). Research consistently demonstrates a strong correlation between contact lens discomfort and dry eye conditions, highlighting the importance of proper lens fit and care (Chalmers & Begley, 2006; Nichols & Sinnott, 2006; Kojima, 2018).

In the U.S., the Food and Drug Administration (FDA) enforces rigorous pre- and post-approval processes to ensure the safety and efficacy of contact lenses (Saviola, 2003). This regulatory oversight is crucial, particularly due to concerns about infections and complications linked to unregulated decorative lenses. In 2002, responding to growing health concerns, the FDA collaborated with organizations like the American Academy of Ophthalmology and the Contact Lens Association of Ophthalmologists. This partnership resulted in amendments to the Federal Food, Drug, and Cosmetic Act (Public Law 109–96), strengthening public safety by regulating all contact lenses—whether corrective or cosmetic—as medical devices (Rhee et al., 2022).

In Malaysia, the Medical Device Authority (MDA) rigorously regulates contact lenses under the Medical Devices Act 2012 (Act 737) for corrective lenses and the Medical Devices Order (Proclamation 2017) for non-corrective lenses. Section 5(1) of Act 737 mandates that all imported and marketed medical devices, including contact lenses, must meet strict registration and compliance requirements. These regulations ensure that only safe,

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high-quality devices, adhering to the Medical Devices Regulations 2012, are legally sold. Furthermore, the Optical Act 1991 stipulates that only registered optometrists and opticians with the Malaysian Optic Council (MOC) CL certification are authorized to prescribe, dispense, or sell contact lenses to the public, adding an essential layer of consumer protection. This regulatory framework safeguards the health of contact lens users and underscores the importance of purchasing lenses through licensed and compliant channels to minimize the risks associated with unregulated products.

Despite that, public awareness of the importance of purchasing MDA-certified contact lenses from registered optometry practices remains limited. This issue is exacerbated by the increasing trend of globalization, where consumers are turning to online platforms, as well as local flea markets, to purchase contact lenses. A study by Fogel and Zidile (2008) revealed that individuals who bought lenses through these unregulated channels often failed to adhere to regulatory guidelines, raising significant concerns about the quality and safety of these products. The use of unregulated contact lenses poses serious risks to eye health, including complications like those observed with improperly used traditional lenses (Lim et al., 2019).

The effects of using contact lenses from both registered optometry practices and unregulated sources on ocular surface integrity and dry eye symptoms remain insufficiently studied. This research aims to investigate these impacts, highlighting the differences in safety and quality, with the goal of raising consumer awareness and promoting safer, more informed practices.

MATERIALS AND METHODS

This was a double-masked, prospective pilot study designed to identify ocular surface integrity, and the signs and symptoms of dry eye associated with the use of coloured contact lenses. As this study involved human participants, ethical clearance (IREC 2023-KAHS/DOVS11) was obtained from the IIUM Research Ethics Committee (IREC), in compliance with the 2013 World Medical Association Declaration of Helsinki.

Five subjects were enrolled in the study. The inclusion criteria required participants to be neonates, healthy, non-smokers, with no history of allergies, medications, ocular disease, dry eye, or previous refractive surgery (Ward et al., 2010; Urgacz et al., 2015; Sambhi et al., 2020). Subjects had corneal parameters within a base curve range of 8.6 to 9.0 mm, refractive errors between 0.00 DS and -4.00 DS, astigmatism less than -1.25 DC, and were able to tolerate spherical equivalent correction.

All participants provided informed consent before data collection began. Subjects were initially screened using the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire, with a cutoff score of 19 (Ngo et al., 2013). Baseline data were gathered through a preliminary examination, including measurements of tear meniscus height (TMH), non-invasive keratograph tear film breakup time (NIKBUT), and tear breakup time (TBUT). TMH and NIKBUT were measured using the Oculus Keratograph 5M (OK5M), while TBUT was assessed using fluorescein dye instilled on the tarsal conjunctiva and examined with slit-lamp biomicroscope (SLB).

Each subject was then fitted with daily-wear coloured soft contact lenses (CL) with a replacement modality of one month. In this double-masked study, neither the participants nor the researchers knew the source of the CL being provided. It could be non-optometry contact lens (NOCL) or optometry contact lens, (OCL). All participants were supplied with the same lens care regimen, which included a multipurpose solution and a lens case. Subjects were asked to record the date, wearing duration, and any comments regarding their CL wear in a research diary, which was used to monitor their CL wearing behaviour.

After one week and one month, participants returned for aftercare visits. During these visits, they were asked about any symptoms experienced while wearing the CL. They were also required to complete the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8), which assessed symptoms such as dryness, discomfort, blurry vision, as well as coping mechanisms like resting eyes or removing lenses to alleviate discomfort (Chalmers et al., 2012). The primary aim was to evaluate the overall status of symptoms and satisfaction among soft contact lens (SCL) wearers. Following each visit, participants underwent a further assessment of TMH, TBUT, and NIKBUT. After the first month, subjects were given a one-month washout period before commencing wear with the second pair of CLs. The same procedures were then repeated during the subsequent follow-up period.

Data Analysis

The data were analysed using IBM SPSS Statistics (Version 29, SPSS Inc., Armonk, New York, USA). Normality was assessed using the Shapiro-Wilk test, along with evaluations of skewness and the coefficient of variation (Mishra et al., 2019; Demir, 2022). The data were considered normally distributed if skewness values fell within the acceptable range for standard error, and the

coefficient of variation was less than 30%. For normally distributed data, a one-way repeated measures ANOVA and paired t-tests will be used for statistical comparisons. If the data do not meet the normality assumptions, non-parametric alternatives such as the Kruskal-Wallis test and the Wilcoxon signed-rank test will be employed.

RESULTS

The study evaluated the changes in TMH, NIKBUT, TBUT and CLDEQ-8 scores over time for both non-optometry and optometry contact lens users. Given that the data were normally distributed, repeated measures ANOVA was applied to examine the changes in data collected over a one-month period. Additionally, paired sample t-tests were employed to analyse changes in the CLDEQ-8 scores between the one-week and one-month aftercare visits. The results showed no statistically significant differences across all measured parameters over the study period. Detailed statistical results are presented below.

Tear Meniscus Height

For the non-optometry contact lens users, TMH showed a slight decrease over time from a mean of 0.24 at baseline to 0.21 at the second follow-up, but this change was not significant ($F(2, 3) = 0.95$, $p = 0.48$). Similarly, for the optometry contact lens users, TMH fluctuated slightly, with a baseline mean of 0.24, an increase to 0.25 at the first follow-up, and a decrease to 0.23 at the second follow-up, which was also not statistically significant ($F(2, 3) = 0.41$, $p = 0.70$). Result of TMH is summarised in Table 1.

Non-Invasive Keratograph Break-Up Time

NIKBUT for non-optometry contact lens users decreased from a mean of 14.00 at baseline to 8.20 at the second follow-up ($F(2, 3) = 1.28$, $p = 0.46$). Optometry contact lens users also showed a decrease in NIKBUT from 14.00 at baseline to 9.20 at the second follow-up ($F(2, 3) = 3.42$, $p = 0.17$), but neither change was statistically significant. Result of NIKBUT is summarised in Table 2.

Tear Break-Up Time

TBUT for non-optometry contact lens users decreased from a mean of 6.40 at baseline to 5.20 at the second follow-up ($F(2, 3) = 1.69$, $p = 0.32$). Optometry contact lens users showed slight fluctuations in TBUT, from 6.40 at baseline to 5.60 at the first follow-up and then to 6.20 at the second follow-up ($F(2, 3) = 2.25$, $p = 0.25$), but these changes were not statistically significant. Result of TBUT is summarised in Table 3.

CLDEQ-8 Score

The CLDEQ-8 scores for participants NOCL showed a slight increase from a mean of 14.80 at one week to 16.40 at one month, although this change was not statistically significant ($t(4) = 0.94$, $p = 0.38$). Conversely, CLDEQ-8 scores for optometry CL remained stable, with a mean score of 10.20 at both time points ($t(4) = 0.00$, $p = 1.00$). Result of CLDEQ-8 score are summarised in Table 4.

Table 1: Analysis of TMH Changes Over Time in Non-Optometry and Optometry Contact Lens Users

Parameter	N	Mean (mm)	± SD	F(df)	p
TMH for NOCL				0.95 2(3)	0.48
Baseline	5	0.24	0.02		
1 Week	5	0.23	0.04		
1 Month	5	0.21	0.03		
TMH for OCL				0.41 2(3)	0.70
Baseline	5	0.24	0.02		
1 Week	5	0.25	0.04		
1 Month	5	0.23	0.05		

Table 2: Analysis of NIKBUT Changes Over Time in Non-Optometry and Optometry Contact Lens Users

Parameter	N	Mean (s)	± SD	F(df)	p
NIKBUT for NOCL				1.28 2(3)	0.46
Baseline	5	14.00	7.17		
1 Week	5	10.60	7.19		
1 Month	5	8.20	5.31		
NIKBUT for OCL				3.42 2(3)	0.17
Baseline	5	14.00	7.17		
1 Week	5	10.20	5.26		
1 Month	5	9.20	2.16		

Table 3: Analysis of TBUT Changes Over Time in Non-Optometry and Optometry Contact Lens Users

Parameter	N	Mean (s)	SD	F(df)	p
TBUT for NOCL				1.692(3)	0.32
Baseline	5	6.40	0.54		
1 Week	5	5.80	1.30		
1 Month	5	5.20	1.30		
TBUT for OCL				2.2502(3)	0.25
Baseline	5	6.40	0.54		
1 Week	5	5.60	1.14		
1 Month	5	6.20	0.83		

Table 4: Comparing mean CLDEQ-8 score between 1 week and 1 month for Non-Optometry CL and Optometry CL

Group	Time Point	Mean CLDEQ-8 Score	Standard Deviation (SD)	t value	p
NOCL	1 Week	14.8	3.114	0.94	0.38
	1 Month	16.4	2.191		
OCL	1 Week	10.2	1.643	0	1.00
	1 Month	10.2	2.168		

DISCUSSION

This study aimed to assess whether coloured soft contact lenses from optometry and non-optometry sources impact ocular surface integrity and dry eye symptoms in wearers. Our findings revealed no statistically significant differences in TMH, NIKBUT, TBUT, or CLDEQ-8 scores between the two groups over a one-month period as daily wear. Despite the material for non-optometry contact lenses being unknown, these results suggest that coloured soft contact lenses from both sources did not compromise ocular surface integrity or exacerbate dry eye symptoms. TMH values remained within established normal ranges (Lamberts et al., 1979; Savini et al., 2006), and NIKBUT and TBUT values aligned with expected limits for healthy individuals (Mohidin & Amran, 2004; Koh et al., 2016). Similarly, CLDEQ-8 scores, which reflect subjective experiences of dryness and discomfort, showed no significant differences between the two groups, suggesting comparable comfort for users (Chalmers et al., 2012).

The material composition of contact lenses plays a crucial role in wearer comfort, safety, and overall ocular health. Lenses obtained through optometry practices, such as the SEED Monthly Colour Lens UV used in this study, are made from hydrogel materials, Polymycon with 38% of water content, known for their oxygen permeability and material durability suitable for daily wear. In contrast, uncertified lenses from non-optometry sources pose significant risks due unknown properties to potential inadequacies in these properties, as well as the lack of regulatory oversight (Bhagat, 2022). The absence of proper certification raises concerns about oxygen permeability, moisture retention, and biocompatibility, which can compromise wearer safety. Additionally, expired contact lenses may deteriorate in quality, leading to complications such as irritation, infections, or reduced vision correction, especially when parameters shift after their expiry dates (Kim et al., 2017).

This pilot study emphasizes the crucial role of regulatory bodies in safeguarding public health through strict oversight of contact lenses (Nichols et al., 2013). Ensuring the quality and safety of lens materials is paramount in preventing ocular complications (Moreddu et al., 2019). Eye care professionals play a key role in educating patients about the risks associated with uncertified lenses, including unregulated coloured lenses that are widely available online and in markets. By advocating for certified lenses and proper usage practices, healthcare providers can reduce the incidence of complications such as corneal infections and allergic reactions.

Microbial keratitis, a severe eye infection often linked to contact lens wear, is a growing concern. In Hospital Serdang, 47.2% of microbial keratitis cases were associated with contact lens usage (Omar et al., 2017). Similarly, 45.5% of pseudomonas keratitis cases were connected to contact lenses (Balasegar et al., 2024). These statistics underscore the need for enhanced vigilance and regulatory enforcement in Malaysia to mitigate risks related to contact lens use.

Stronger enforcement is necessary, as our search through online Malaysian legal databases, including the Current Law Journal (CLJ), Lexis, and Westlaw, revealed no judicial cases related to the unauthorized sale of contact lenses under the Optical Act 1991 or Medical Devices Act 2012. Therefore, it is essential for regulatory bodies to enforce these laws rigorously to protect public health and ensure compliance within the optical industry.

Despite the insights provided, this study has limitations. Its short duration (one month) may not capture the long-term effects of contact lens wear from different sources. Future

research with a longer follow-up period is needed to better understand the potential long-term impact of uncertified lenses on ocular health.

CONCLUSION

In conclusion, while this study found no significant differences in ocular surface integrity or dry eye symptoms between coloured contact lenses obtained from optometry and non-optometry practices over a one-month period of use. It would be premature to assume that all non-optometric contact lenses are safe for long-term use. The lack of safety certification and regulatory oversight associated with non-optometry contact lenses still poses potential risks to ocular health. Therefore, caution should be exercised when selecting contact lenses, with a strong preference for those sourced from certified optometry practices to ensure wearer safety and long-term ocular health.

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