ORIGINAL ARTICLE

Coloured Contact Lens Impact on Visual Function and Ocular Surface Integrity: Legit vs Non-Legit Sources Contact Lenses

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ABSTRACT

Background: The popularity of purchasing coloured contact lenses (CLs) from non-optometry sources, such as night markets and online platforms, has risen due to cosmetic appeal. The rapid growth of e-commerce platforms that lack regulatory oversight is a concern to the safety, effectiveness, and quality control of these lenses to the wearers. Therefore, this article aims to investigate the changes in visual function, including visual acuity (VA) and contrast sensitivity (CS), as well as ocular surface integrity, encompassing corneal topography, corneal endothe0m, and central corneal thickness (CCT), in wearers of coloured CLs purchased from either optometry or non-optometry sources. **Methods:** A pilot study with five participants meeting the inclusion criteria were enrolled in this study. Preliminary assessments were conducted per the usual contact lenses clinic routine in the IIUM Optometry Clinic. The CL fit on the eyes was observed and noted. A double-masked crossover approach was used to reduce bias and enhance validity. Participants were randomly assigned to wear each type of coloured CL for one month, with a two-week washout in between. Measurements of VA, CS, mean K-reading, corneal endothelial cell density (ECD), and CCT were taken before lens usage, after one week, and after one month. A comparison of these parameters between the two types of CLs was made. **Results:** There were no significant differences in any measurements between lenses from optometry and non-optometry sources across all three time periods ($p>0.05$).**Conclusion:** The pilot study's findings suggest comparable effects on visual function and ocular surface integrity between coloured CLs obtained from optometry and non-optometry sources worn daily for a month.

INTRODUCTION

Coloured or cosmetic CLs alter eye appearance and enhance eye colour to achieve specific looks and enhance beauty. Their popularity is rising, especially among younger individuals (Thiraviam et al., 2022).

In Malaysia, the regulation and distribution of contact lenses (CLs), including coloured CLs, are governed by the Optical Act 1991. According to this act, CLs are classified as medical devices, and their prescription and fitting must be performed by registered optometrists or opticians with contact lens permits only (Optical Act, 1991). Following this act, a "Guideline for Online Sale of Optical Appliances and Contact Lenses" was published by the Malaysian Optical Council, Ministry of Health, a professional body that regulates optometry practices in Malaysia (Malaysian Optical Council, n.d.). According to the guidelines, only CLs registered with Malaysia's Medical Device Authority (MDA), Ministry of Health Malaysia can be displayed and sold in-store and on a website with strict criteria. The CLs must meet the safety and quality standards before being approved for the market (Medical Device Act, 2012).

However, a significant regulatory gap exists due to the lack of effective enforcement of these regulations. This enforcement challenge has led to the alarming proliferation of unauthorised sales of CLs, especially coloured lenses, by non-practitioners through various channels such as online platforms, beauty shops, and even night markets. This enforcement challenge has inadvertently facilitated a growing trend among consumers to purchase CLs without proper professional guidance, often influenced by social media and online

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influencers. The increasing popularity of these easily accessible sources raises significant concerns about potential impacts on visual function, ocular surface safety, and overall eye health among CLs wearers in Malaysia.

Improper prescription or fitting of coloured CLs can lead to severe complications, including infectious keratitis, a serious vision-threatening condition (Singh et al., 2012). Studies highlight the risks associated with coloured CLs, particularly those obtained from unauthorised sources, which can result in severe infections and inflammation (Steinemann et al., 2003, 2005). Research further emphasises that individuals acquiring CLs from unlicensed vendors face increased risks of ocular complications and are less likely to receive proper usage and care instructions, elevating the risk of complications (Gaiser et al., 2017).

With the surging popularity of coloured CLs from non-authorised sources, the safety of these lenses is questionable. Therefore, this study aimed to investigate whether coloured CLs purchased from optometry practices and those obtained from non-optometry sources available in the Malaysian market, such as unauthorised e-commerce platforms and the night market, affect the visual function and ocular surface integrity of the wearers.

MATERIALS AND METHODS

Study Design

This cross-sectional study enrolled five undergraduate students from the International Islamic University Malaysia (IIUM) Kuantan campus who met the inclusion criteria of a healthy ocular surface and normal visual function.

This study adhered to the Tenets of the Declaration of Helsinki for research involving human subjects and received ethical approval from the IIUM Research Ethics Committee (IREC 2023-KAHS/DOVS12). The participants gave their written informed consent, agreeing to participate in this study. Participants were warned to discontinue CL wear and notify the researcher if they experienced any discomfort or changes to the eye and vision, as explained during the CL delivery session.

For this pilot study, five participants were recruited to fit the standard soft contact lens parameters of 14.2 lens diameter and 8.6 base curve. Two types of coloured CLs were used. One type was sourced from an optometry practice with FDA approval, while the other was purchased from night markets and e-commerce platforms. These were monthly disposable CLs for daily wear. A double-masked approach was used in the study. A randomisation sheet determined the order in which participants wore the CLs, either those obtained from optometry practices or non-optometry sources. The allocation was known only by a third researcher who was not involved in the data collection stage, ensuring both the participants and the researchers were unaware of the lens type during the study period.

Participants underwent preliminary examinations before the study. For the initial month, each participant wore one type of CL (either from optometry practices or non-optometry sources) binocularly. Following the first month, a two-week washout was given, during which participants did not wear any CL. After the washout period, participants switched to the other type of CL and wore it for another month. This method allowed a direct comparison of how each participant responded to both types of lenses.

Subsequently, after the CLs were delivered and worn for 8 to a maximum of 10 hours daily for 6 days/ week, aftercare examinations were conducted at two specific time points: one week and one month. These examinations involved a comprehensive assessment of various ocular parameters, including VA measured with the LogMAR chart, CS evaluated using the Pelli-Robson chart, CCT measured with the Oculus PARK 1 (Oculus GmbH, Wetzlar, Germany), mean K-reading obtained with the Oculus Keratograph 5M (Oculus GmbH, Wetzlar, Germany), and ECD assessed using specular microscope (NIDEK CEM 530, NIDEK Co., Ltd., Gamagori, Japan).

Statistical Analysis

All data collected was analyzed using the Statistical Package for Social Science Software (SPSS) (version 29 for Windows, SPSS, Inc., Chicago, IL, USA). The normality of the data was analyzed using Shapiro-Wilk, skewness and coefficient of variation. All the data were normally distributed, and the Analysis of Variance (ANOVA) was used to compare VA, CS, CCT, mean K-reading and ECD for the respective lenses from optometry and non-optometry sources across all three time periods (before lens usage, one week after, and one month after wearing the lenses) to observe for any differences. Only data for either eye was included in the analysis (Armstrong, 2013).

RESULTS

The study compared optometry and non-optometry CLs across three time periods, evaluating changes in VA, CS, CCT, mean K-reading, and ECD. Table 1 shows the mean values at each time point and the significance levels for all parameters in this study. Repeated measures Analysis

Table 1: Comparison of visual function and ocular surface parameters in optometry and non-optometry sources CLs across three time periods (n=5)

Parameters	Baseline (Mean ± SD)	1 Week (Mean ± SD)	1 Month (Mean ± SD)	p-value
Optometry CL				
VA (LogMAR)	-0.17 ± 0.07	-0.07 ± 0.14	0.05 ± 0.22	0.263
CS (log contrast sensitivity)	1.95 ± 0.00	1.95 ± 0.00	1.89 ± 0.08	0.178
CCT (µm)	542.20 ± 14.26	545.20 ± 14.20	544.80 ± 21.53	0.746
Mean K-reading (Dioptre)	43.81 ± 0.77	43.96 ± 0.76	43.79 ± 0.74	0.703
ECD (cells/ mm^2)	2803.60 ± 261.50	2938.00 ± 331.96	2884.00 ± 261.21	0.091
Non-Optometry CL				
VA (LogMAR)	-0.17 ± 0.07	-0.05 ± 0.12	-0.04 ± 0.15	0.397
CS (log contrast sensitivity)	1.95 ± 0.00	1.92 ± 0.07	1.92 ± 0.07	0.465
CCT (µm)	542.20 ± 14.26	554.00 ± 21.30	549.00 ± 20.58	0.220
Mean K-reading (Dioptre)	43.81 ± 0.77	43.72 ± 0.75	43.77 ± 0.65	0.592
ECD (cells/ mm^2)	2803.60 ± 261.50	2835.40 ± 315.05	2805.80 ± 255.78	0.602

showed no significant differences across the three time periods for the measured parameters (>0.05).

Both CL types showed a trend towards a slight VA decline over time. For optometry CLs, mean VA changed from -0.17 ± 0.07 at baseline to 0.05 ± 0.22 after one month, a decline of 0.22 logMAR units. For non-optometry CLs, the mean VA changed from -0.17 ± 0.07 to -0.04 ± 0.15, a decline of 0.13 logMAR units. These changes were not statistically significant (p=0.263 for optometry, p=0.397 for non-optometry CLs). While the optometry CL group change exceeds 0.1 logMAR units (equivalent to one line on a standard acuity chart), the high variability (as indicated by the standard deviation) and lack of statistical significance suggest caution in interpreting this as a clinically meaningful change. Contrast Sensitivity (CS) remained largely stable for both CL types. Non-optometry lenses showed a slight decrease from 1.95 to 1.92 (p=0.465), while optometry lenses decreased from 1.95 to 1.89 in one month (p=0.178).

Neither CL type significantly affects the CCT. Non-optometry lenses showed a slight increase and decrease (542.20 to 549.00 µm, p=0.220), while optometry lenses had a slight, stable increase (542.20 to 544.80 µm, p=0.746). The corneal power remained relatively stable for both CL types. Non-optometry lenses showed minor fluctuations (43.81 to 43.77 D, p=0.592), as did optometry lenses (43.81 to 43.79 D, p=0.703). Both changes were not statistically significant. For non-optometry CLs, ECD showed minimal changes (2803.60 to 2805.80 cells/ mm^2, p=0.602). Optometry lenses demonstrated a trend towards increased ECD (2803.60 to 2884.00 cells/ mm^2), but this was not statistically significant (p=0.091).

DISCUSSION

This study found that neither type of contact lens notably affects the visual function and ocular surface integrity of the participants. Visual acuity (VA) did not show significant changes with either non-optometry or optometry lenses. These findings differ from previous research suggesting that CLs from unauthorised sources may cause ocular issues, impacting VA and refractive errors (Gaiser et al.,

2017). This discrepancy might be due to several factors, such as the controlled wear schedule implemented in our study, or potentially higher quality standards of non-optometry lenses in the Malaysian market compared to those examined in previous studies. Another explanation is that the participants of this study were carefully selected based on the suitability of the CL base curve.

Central corneal thickness (CCT) was not significantly affected by either type of lens, supporting the notion that short-term use of CLs does not alter corneal thickness, aligning with findings by Ramakrishnan et al. (2016). This stability in CCT suggests that both optometry and non-optometry-sourced coloured CLs, when used for a short duration, may not cause significant corneal swelling. However, other studies have reported higher CCT values with CL wear (Noya-Padin et al., 2022). This discrepancy might be due to differences in study duration, as this study was limited to one month.

Similarly, the corneal power remained stable, indicating no adverse effects on corneal curvature from either CL source, consistent with Yeniad et al. (2003). However, other studies reported increased corneal curvature with contact lens usage (Ramakrishnan et al., 2016; Badawi, 2015; Liu & Pflugfelder, 2000). The difference might be attributed to the short duration of the study, as changes in corneal power occur over longer periods of lens wear. Additionally, the specific design and material of the lenses used in the study may have contributed to the lack of observed changes in corneal power.

Corneal endothelial cell density (ECD) was not significantly affected by either type of lens, supporting the safety of short-term use of coloured CLs from both sources, as also observed by Badawi (2015). This is particularly important as the corneal endothelium is indispensable in sustaining corneal transparency (DelMonte & Kim, 2011) and cannot regenerate (Van den Bogerd et al., 2018). However, it is important to note that the study's short duration may not reveal potential long-term effects on ECD since all participants followed the recommended wearing hours and did not exceed its monthly modality. An otherwise outcome may be seen if the lens is worn for three months. Some studies have suggested that long-term CL wear may affect endothelial cell morphology (Mohd-Ali & Chen, 2021).

In this study, contrast sensitivity (CS) results showed no notable difference between the two sources of CLs, suggesting stability in CS regardless of the source. This finding aligns with previous studies indicating stable CS with CL use (Sapkota et al., 2020). On the contrary, research by Briggs (1998), Mahjoob & Heydarian (2021), and Ozkagnici et al. (2003), observed lower CS among CL wearers than their controlled subjects of non-CL wearers. This difference might be attributed to improvements in lens materials and manufacturing processes over time or the specific brands of lenses used in the study. Additionally, the participants' knowledge of lens care as optometry students may have contributed to better lens maintenance, potentially mitigating negative effects on CS.

Approximately 18% of individuals obtain CLs from friends and family, while around 24% make purchases online (Gaiser et al., 2017). Most unauthorised sellers revealed that they did not follow proper protocols for selling CLs or provide adequate instructions on lens wear and care, potentially increasing the risk of contact lens-related complications (Gaiser et al., 2017). Wearing CLs from unauthorised sources can lead to corneal complications, visual impairment, and severe eye damage (Steinemann et al., 2003).

This study had limitations, including not accounting for potential long-term effects, and the lack of information about manufacturing standards for CLs from non-optometry sources, both of which could have influenced the results. Additionally, the small sample size and short study duration may limit the generalisability of these findings. A notable limitation was that all participants were final-year Optometry students, who may have exercised more caution in CL care and wear than the public. This specialised knowledge and training could have influenced the results, potentially minimising differences between the two lens types that might be more apparent in a broader, less informed population.

For upcoming research, studies should aim to cover longer periods and include more participants to understand the lasting effects and improve the reliability of the findings. Additionally, future investigations should examine the manufacturing standards and safety protocols of non-optometry sources and compare several types of coloured CLs from various sources. This comprehensive approach would provide a clearer understanding of how different sources and production processes impact ocular health and visual function over extended periods of use.

CONCLUSION

The findings of this study suggest that coloured CLs obtained from both optometry and non-optometry sources have comparable effects on visual function and ocular surface integrity. This indicates potential safety and efficacy across both types of lenses. However, it is crucial to note that this study does not endorse using coloured CLs from non-optometry sources.

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