Visual Inspection of Non-Prescription Monthly Colored Contact Lenses: Safety Issues for Contact Lens Wearers

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ABSTRACT

Objective: To survey the prevalence of non-prescription monthly colored contact lenses (CL) defects in an electronic marketplace (e-marketplace) in Thailand using visual inspection (VI).

Materials and Methods: This cross-sectional study included the 252 items listed from 23 online shops in an e-marketplace in Thailand during April 2021. Online customer reviews for each shop were examined and complaints regarding colored CL product defects, delivery, services and abnormal symptoms after use were collected. Product packing and visible internal and external product characteristics were visually inspected under sufficient light for the prevalence of defects by three examiners.

Results: Sixteen out of twenty-three online shops (69.57%) had customer complaints. Wrong delivery was the most common complaint (60.87%). Five characteristics of product defects were described by customers, of which abnormal scratches/marks on CL (8.70%) was the most common. Abnormal symptoms after use were found in 43.84% of the shops. Two hundred and thirty-seven pairs of colored CL (94.05%), 470 vials and four blisters from 19 shops were examined. Defective products were found to be 8.02%. The most common visible external and internal product defects were dirty products (3.80%) and foreign bodies in the original sealed manufacturer's containers (1.90%), respectively. Other defects, e.g. scratched or peeling label, incompletely closed aluminum cap, surface wear of CL, abnormal scratches or marks on CL and immobility of CL in solution were also found.

Conclusion: Non-prescription monthly colored CL in the e-marketplace have many visible defective characteristics that CL wearers should be concerned about. This study suggests that VI of CL products before use may be an important potential safety factor for CL wearers.

Keywords: colored contact lens, e-marketplace, defective product, dirty product, foreign body (Siriraj Med J 2021; 73: 587-593)

INTRODUCTION

Nowadays, the Centers for Disease Control and Prevention (CDC) warns about the risks to sight and eye health from using non-prescription colored contact lenses (CL).[1] In Thailand, these colored CL which are approved for permission by Thai Food and Drug Administration (FDA), are still found freely sold in the flea markets, on streets and at beauty shops.[1-4] It is noticeable that many colored CL are also sold in electronic marketplaces (e-marketplaces). The self-care process and awareness of Thai CL wearers are important in this situation due to there being no laws to regulate the sellers and no monitoring system for CL dispensation.[2,5]

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Visual inspection (VI) is a manual activity that involves careful and critical assessment of an object with reference to a predefined standard.[6] VI has been proposed for the detection and minimization of the introduction of unintended particles in various situations, e.g. industry, parenteral product vials and pharmaceutical products.[6-8] Compromised or defective products should be rejected due to the risk to sterility. Although there is a continuous process of improvement by manufacturers to meet the goal of zero defects, the defects still occur. In addition, the probabilistic nature of the human inspection process has limitations, especially concerning particles or foreign bodies less than 200 μm in diameter.[9]

Complications from CL use regarding CL-related microbial keratitis were found among CL wearers.[10-16] Recent studies have demonstrated many product defects and contaminations in the original sealed manufacturer's containers, e.g. expired products, dirty products, turbidity of fluid surrounding the CL, foreign bodies and bacterial contamination.[17-19] Purchasing colored CL from an e-marketplace is questionable with regard to the quality and sterility of these products. To investigate the presence of visible monthly colored CL defects in the e-marketplace, we conducted the current study to survey the prevalence and defective characteristics of non-prescription monthly colored CL in Thailand's e-marketplace. The results of this study can provide information to CL wearers that will help them avoid using CL with these visible defects that might result in the risk to eye health and sight.

MATERIALS AND METHODS

This study was a cross-sectional study and conducted in accordance with the Declaration of Helsinki, approved by the Committee for the Protection of Human Participants in Research, Ubon Ratchathani University, Thailand [UBU-REC-46/2564]. The primary objective of this study was surveying the prevalence of defects of non-prescription monthly colored CL in an e-marketplace by using the VI technique.

The subjects recruited in this study were the monthly colored CL items that are sold on an e-marketplace website in Thailand during April 2021. To find the total amount of monthly colored CL items, we used the keywords of "contact lenses" combined with the settings in the related categories bar, which were colored CL, zero power and monthly CL usage. The sample size in this study was calculated with Yamane's formula, and sampling was done by the systematic random sampling method. All online shops underwent shop characteristic assessment, including the period of time that they had been opened, types of monthly colored CL and customers' complaints about the colored CL, e.g. defective CL products, delivery, services and abnormal symptoms after use, via the online customer reviews.

All the samples were ordered from the website and sent by postal delivery. In the parcel boxes, the CL products from each shop were assessed for the packing methods. Each of the CL products were examined in a sufficient light room using VI by three examiners, an ophthalmologist, a pharmacist and a scientist. All of the examiners had normal color vision according to the Ishihara's test, as well as near and distant visual acuity with correction to 20/20 in both eyes. A result of 2 out of 3 opinions were considered a consensus regarding each variable. All CL products in their original sealed manufacturer containers were assessed for three parts. The first part was general product details, e.g. prices, brands, countries of manufacture and CL materials, which were assessed by observing the information on the CL boxes, labels and medical device documentation (MDD) and 2) the external product characteristics, e.g. packaging, FDA number, expired products, scratched or peeling of the labels, unclear/unreadable labels, unclear/unreadable MDD, application of other labels that obscure text, broken packages, dirty products and integrity of aluminum capping for the vial, were observed. In the third part, the internal product characteristics, e.g. clarity of the solution, sediment, amount of CL, scratches or marks on CL surface, surface wear of CL, CL movement in solution, visible foreign bodies and evidence of used CL in the CL case, were also observed. For the internal product characteristic examinations, we looked through the containers from the bottom up with diffused light across the inspection zone. The time used for inspection was at least 20 seconds per sample. Slow careful swirling of the CL solution and avoidance of making the air bubbles within the container were done for observation of the motion of any foreign body and its characteristics. If the position of a foreign body was uncertain, removal of the label was done to distinguish between the outside and inside foreign body. To confirm the findings for "immobility of CL in solution", we used the technique of turning the container upside down and slightly shaking it three times. If there was no free movement of the CL in the solution, it was classified as "immobility of CL". The images in this study were recorded with a smart phone (Samsung® Galaxy Note 20, Vietnam).

Statistical analysis: A descriptive analysis of categorical variables was presented as absolute frequency and percentages. Means ± standard deviations were used to summarize the continuous variables in this study.

RESULTS

There were 678 items listed that were found from searching with the keywords in the e-marketplace in Thailand. The results of the sample, 252 items listed from 23 online shops, were included in this study. Most of the shops (47.83%) had been open less than one year and about 3 out of 5 shops sold colored CL only for decorative purposes. Sixteen out of twenty-three online shops (69.57%) had complaint messages in their online customer reviews from customers who purchased monthly colored CL. The most common complaint was wrong delivery (60.87%). There were five characteristics of product defects, which were abnormal scratches/marks on CL (8.70%), surface wear of CL (4.35%), missing CL (4.35%), used CL found in CL case (4.35%) and unspecified external defect (4.35%) (Table 1). CL wearers from 10 online shops (43.84%) had posted reviews about their abnormal symptoms after use of colored CL, which were foreign body sensation, burning sensation, ocular pain, ocular discomfort, dryness, tearing, red eye, dizziness and loose CL fitting (Table 2).

Two hundred and thirty-seven pairs of monthly colored CL (94.05%) from 19 shops (82.61%) were sent via postal delivery. There were 15 items from four shops that were cancelled by the sellers. Air bubble wrapping was the most common method that the shops used for shock-proofing the CL product(s) (89.47%). Plastic bags and plastic trays were used for product packing via postal delivery at about 47.37% and 10.53%, respectively. Only three out of 19 shops (15.79%) sent CL boxes to the customers, and some of the CL (13.14%) were paired with a rubber band around the vial neck. CL packing in the parcel boxes is shown in Fig 1A - C.

Twelve brands, 470 vials and four blister packs of CL made from 2-hydroxy-ethyl methacrylate (HEMA) hydrogel were examined (Table 3). All of the CL products were imported from Korea and Taiwan with import approval by the Thai FDA. The average cost of a pair of CL was 99.36 ± 58.47 baht. Defective products were found in 38 out of 474 samples (8.02%). Dirty products were found to be the most common problem of the external product defects, 0.84% of the samples had scratched or peeling labels, and 0.21% of the vial containers had incompletely closed aluminum caps (Fig 1D - F).

The most common problem of the internal product defects was a foreign body in the original sealed containers (1.90%). Immobility of CL in solution when upside down and shaken, surface wear of the CL, and abnormal scratches/marks on CL were also found, as shown in Fig 2A - C. Regarding foreign bodies in the original sealed containers, dot-like foreign bodies were the most common type of foreign body, which were found in 7 out of 9 samples (77.78%). Thread-like foreign bodies were found having both white and black color (Fig 3).

DISCUSSION

This study demonstrated that non-prescription monthly colored CL in an e-marketplace in Thailand have seven characteristics of both visible external and internal product defects. Visible foreign bodies in their original sealed CL containers were the most common internal product defect with a prevalence of 1.90%. Dirty products were the most common external product defect (3.80%) similar to the previous research from beauty shops and flea market conducted in Thailand.[2] Introduction of a foreign body into the eyes may result in mechanical effects on the ocular surface, eye infection or specific reactions depending on the type of foreign bodies.[15,20] Surface wear of the CL can be found at 0.21%, which may lead to its edge scratching the cornea and causing corneal abrasion.[15] This study found that the sticking of CL to the bottom of the container causes the immobility of CL in solution. The CL may lose its shape and cause eye irritation when applied to the eyes.[2,15] Abnormal scratches or marks on CL and incomplete closure of aluminum caps for vials were also be found. All of these visibly defective products should be rejected by the CL wearers due to the lack of sterility and the risk of eye irritation, eye injury and even eye infection that could possibly occur.[2,9,15-16] Comprehensive VI of the external and internal of CL products to detect these visible defects before use may be the potential safety factor for the CL wearers.

Five defective characteristics of CL products were described in online customer reviews, which were abnormal scratches/marks on CL (8.70%), surface wear of CL (4.35%), missing CL (4.35%), finding used CL in CL case (4.35%) and unspecified external defects (4.35%). A foreign body in the original sealed container was found to be the most common internal product defect in this study, while there was no report of this defect by the customers. From this point, we speculate that most CL wearers were not aware of this existing small defect and thus, did not detect it. Human VI for detection of product defects involves tacit knowledge that is influenced by many factors.[6] Although VI is tedious, time-consuming and highly dependent on the inspectors' experiences, conditions or moods[8], it still crucial for CL wearers in this situation. To develop the VI tacit knowledge of CL wearers, the improvement of providing information, e.g. transferring the comprehensive knowledge about CL products, well written VI standards regarding pictures

TABLE 1. Complaints about CL product, delivery and services in online customer reviews [23 shops]

Variables	Frequency	Percent (%)
External CL products		
No medical device documentation	0	0.00
No FDA number	0	0.00
Expired product	0	0.00
Scratched or peeling label	0	0.00
Unclear/unreadable label	0	0.00
Unclear/unreadable medical device documentation	0	0.00
Application of other labels that obscure text	0	0.00
Broken package	0	0.00
Dirty product	0	0.00
Incomplete closed aluminum cap for vial	0	0.00
External defect, unspecified	1	4.35
Internal CL products		
Non-clear solution	0	0.00
Sediment	0	0.00
Missing CL in container	1	4.35
Abnormal scratch/ mark on CL	2	8.70
Surface wear of CL	1	4.35
Immobility of CL in solution	0	0.00
Foreign body in container	0	0.00
Used CL found in CL case	1	4.35
Delivery and services		
Delayed delivery	9	39.13
Wrong delivery	14	60.87
Poor product packing	1	4.35
Damaged parcel	1	4.35
Missing item	6	26.09
Missing CL case	1	4.35
Seller services	2	8.70
unsatisfied, unspecified	9	39.13

Abbreviations: FDA; Food and Drug Administration, CL; contact lens

TABLE 2. Abnormal symptoms after use colored CL in online customer reviews [23 shops]

Variables	Frequency	Percent (%)
Ocular discomfort	2	8.70
Dryness	2	8.70
Itching	0	0.00
Burning	5	21.74
Fluctuation of vision	0	0.00
Sensitive to light	0	0.00
Foreign body sensation	6	26.09
Tearing	1	4.35
Red eye	1	4.35
Ocular pain	4	17.39
Dizziness	1	4.35
Loose CL fitting	1	4.35

Abbreviation: CL; contact lens

TABLE 3. Product characteristics

Variables	Frequency	Percent (%)
Brands	12	100.00
Countries of manufacture		
Korea	11	91.67
Taiwan	1	8.33
CL materials		
HEMA hydrogel	470	100.00
External product characteristics		
Vial	470	99.16
Blister	4	0.84
No FDA number	0	0.00
Expired product	0	0.00
Scratched or peeling label	4	0.84
Unclear/unreadable label	0	0.00
Unclear/unreadable medical device documentation	0	0.00
Application of other labels that obscure text	0	0.00
Broken package	0	0.00
Dirty product	18	3.80
Incomplete closed aluminum cap for vial	1	0.21
Internal product characteristics		
Non-clear solution	0	0.00
Sediment	0	0.00
Missing CL or more than 1 CL in container	0	0.00
Abnormal scratch/ mark on CL	2	0.42
Surface wear of CL	1	0.21
Immobility of CL in solution	3	0.63
Foreign body in container	9	1.90
Used CL found in CL case	0	0.00

Abbreviations: CL; contact lens, HEMA; 2-Hydroxy-ethyl methacrylate, FDA; Food and Drug Administration

Fig 1. Contact lens packing in the parcel boxes and external product defects
A: air bubble wrap (top), plastic bag (middle), contact lens vials and cases (bottom); B: plastic trays; C: contact lens boxes; D: peeling labels; E: clean product (left) and dirty product (right); F: completely closed (left) and incompletely closed (right) aluminum caps for vials

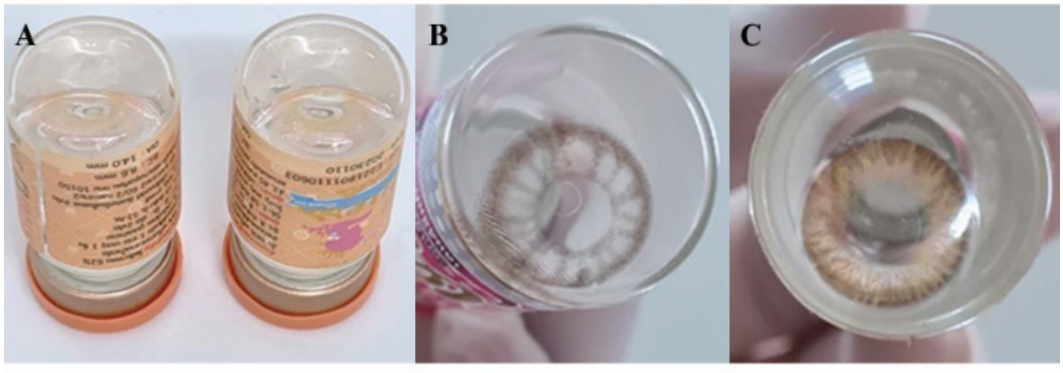

Fig 2. Internal product defects
A: contact lenses sticking to the bottom of vials, B: surface wear of the contact lens (circular shape), C: abnormal circular mark at the center of contact lens

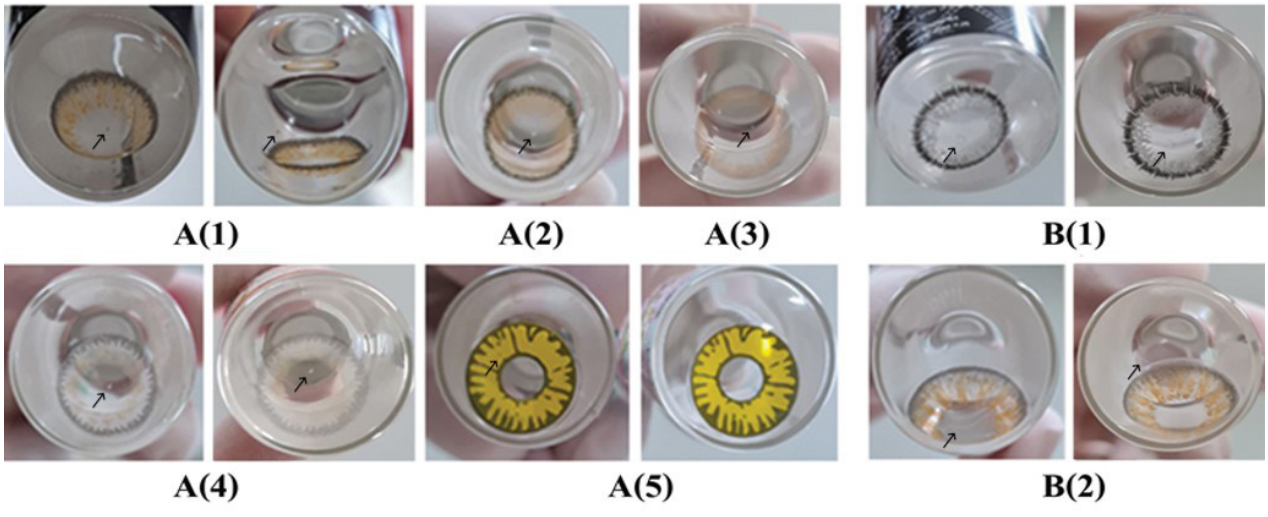

Fig 3. Foreign bodies in original sealed containers
A: Dot-like foreign bodies: A (1) movement of blackish dot-like foreign body when changing vial's position; A (2-4) whitish dot-like foreign bodies, A (5) brownish dot-like foreign body at 10 o'clock (left) compared to normal CL (right); B: Thread-like foreign bodies: B (1) black thread-like foreign body, B (2) white thread-like foreign body

or photographs, defect classification systems, e.g. defect type, defect location and characteristics, are needed.[6]

This study had the advantage of focusing on the visible product defects by VI, which is simulated as the CL wearers' situation with no special equipment required. However, there are some limitations of this study. First, the opinions expressed by customers in online customer reviews may not reflect the exact total of CL wearer problems in the e-marketplace. Some customers may have ignored these defects and did not provide feedback to the sellers via this channel, and some sellers may have edited the negative reviews of customers. Second, blister type CL was found at only 0.84%, which is too small a sample to perform a subgroup analysis between vials and bister containers. Third, microscopic examination and microbial culture were not done in this study, which therefore cannot lead to a conclusion of microbial contamination in these defects. More blister container sampling, microscopic examination and microbial culture should be planned and investigated in further study.

In conclusion, non-prescription monthly colored CL in the e-marketplace have many characteristics of both visible external and internal product defects. Raising CL wearers' awareness in order to make them concerned about these visible defects before use may be a potential safety factor. Most importantly, improvement of VI skills for CL wearers should be done in the correct way.

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