

สถานการณ์ความปลอดภัยของเลนส์สัมผัสสีเพื่อความสวยงามชนิดรายเดือนที่จำหน่ายในท้องตลาด อำเภอแห่งหนึ่ง จังหวัดอุบลราชธานี

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บทคัดย่อ

ปัจจุบันเลนส์สัมผัสสีเพื่อความสวยงามเป็นที่นิยมในหมู่วัยรุ่น แม้ว่าเลนส์สัมผัสสีถูกกำหนดเป็นเครื่องมือแพทย์แต่ไม่ได้มีกฎหมายควบคุมร้านค้าจำหน่ายที่ชัดเจน และพบว่าส่วนใหญ่จำหน่ายโดยผู้ที่ไม่ได้เชี่ยวชาญด้านทัศนมาตรศาสตร์จึงอาจเกิดปัญหากับผู้บริโภค วัตถุประสงค์การศึกษานี้เพื่อศึกษาสภาพการณ์ที่ไม่ปลอดภัยของเลนส์สัมผัสสีที่จำหน่ายในท้องตลาด ได้แก่ ปัญหาผู้บริโภคได้ข้อมูลผลิตภัณฑ์ไม่ครบ เลนส์หรือบรรจุภัณฑ์เสื่อมคุณภาพ และการปนเปื้อน เป็นงานวิจัยแบบภาคตัดขวาง โดยสำรวจเลนส์สัมผัสสีชนิดรายเดือนจากร้านค้าที่ไม่ได้จำหน่ายโดยนักทัศนมาตรศาสตร์หรือร้านแว่นตาจำนวน 5 ร้านค้าในอำเภอแห่งหนึ่งของจังหวัดอุบลราชธานี ระหว่างเดือนมิถุนายน 2563 รวมทั้งสิ้น 58 ตัวอย่าง จากนั้นนำมาวิเคราะห์ข้อมูลผลิตภัณฑ์และตรวจวิเคราะห์ลักษณะกายภาพ โดยส่วนใหญ่พบว่ามีการจำหน่ายโดยร้านขายอุปกรณ์เสริมสวย และพบว่าจำหน่ายเฉพาะเพื่อความสวยงามร้อยละ 60 จากร้านค้าทั้งหมด การศึกษานี้พบเลนส์สัมผัสสีชนิดรายเดือนจำนวน 11 ยี่ห้อ 2 ขนาด มีราคาจำหน่ายเฉลี่ยคู่ละ 89.30 ± 12.70 บาท และยังพบว่าผู้ขายทั้งหมดไม่ได้ให้คำแนะนำและเอกสารกำกับเครื่องมือแพทย์แก่ผู้บริโภค ลักษณะบกพร่องของบรรจุภัณฑ์ภายนอกที่พบ ได้แก่ สีนํ้ามีฝุ่นหรือสิ่งแปลกปลอมติดรอบนอกขวด ฉลากอ่านได้ไม่ชัดเจน ติดฉลากอื่นทับ และสีนํ้าหมดอายุ โดยพบร้อยละ 46.55, 22, 5.17 และ 3.45 ตามลำดับ ปัญหาเลนส์สัมผัสสีติดกันขวดไม่สามารถเคลื่อนไหวได้อย่างอิสระพบมากที่สุดในความบกพร่องภายในบรรจุภัณฑ์ และพบสิ่งแปลกปลอม ร้อยละ 3.45 การที่ผู้บริโภคได้ข้อมูลเฉพาะที่อยู่บนฉลากทำให้ผู้บริโภคขาดข้อมูลเกี่ยวกับจุดประสงค์ของการใช้เลนส์ วิธีการใช้ วิธีเก็บรักษาภายหลังเปิด ค่าเดือน และข้อควรระวัง นอกจากนี้การควบคุมคุณภาพสีนํ้าในร้านจำหน่าย และการรับรู้ข้อมูลการใช้ที่ถูกต้องของผู้บริโภคอาจจะเป็นปัจจัยเสริมสำหรับการเพิ่มความปลอดภัยในการใช้เลนส์สัมผัสสีเพื่อความสวยงามชนิดรายเดือน การให้คำแนะนำจากผู้จำหน่าย และการส่งต่อข้อมูลสีนํ้าทั้งหมดแก่ผู้บริโภคอาจจะช่วยพัฒนาการดูแลเลนส์สัมผัสสีของผู้ใช้ให้ดีขึ้น ซึ่งจะลดปัจจัยเสี่ยงของการเกิดโรคกระจกตาอักเสบติดเชื้อและภาวะแทรกซ้อนอื่น ๆ จากการใช้เลนส์สัมผัสสีได้

คำสำคัญ : เลนส์สัมผัสสีเพื่อความสวยงาม, ร้านอุปกรณ์เสริมสวย, ฉลาก, เอกสารกำกับเครื่องมือแพทย์

Safety Situation of Monthly Colored Cosmetic Contact Lenses from Markets in One District of Ubon Ratchathani, Thailand

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Abstract

Nowadays, the cosmetic use of colored contact lenses (CL) is rising among the teenagers group. Although CL are regulated by notification of the Medical Devices Control Division, the Ministry of Public Health of Thailand as medical devices, there is ineffective control of the safety and performance of these medical devices by the sellers, because most of the CL are sold by untrained opticians. Lack of information about using CL and deteriorated and

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contaminated products are the unsafe conditions that are the objectives of this study. A cross-sectional study of monthly colored cosmetic CL that are sold in five non-optical shops in a single district of Ubon Ratchathani, Thailand was conducted during June 2020. The fifty-eight samples of every monthly colored CL brand underwent product information examination and physical property analysis. Most of the CL are sold in the beauty shops. Sixty percent of these shops sell them only for cosmetic purposes. A total of 11 brands and two vial sizes were examined in this study. The average cost of a pair of CL was calculated as 89.30 ± 12.70 baht. All of the sellers did not provide any advice or medical device documentation (MDD). External product defects, e.g. dirty products, unclear/unreadable labels, sticking on another label, and expired products were found at a rate of 46.55%, 22%, 5.17% and 3.45%, respectively. The CL being unable to freely move in the solution was the most common internal product defect. Foreign bodies were also be found in the vials at 3.45%. Also, the customers did not receive important information such as purpose of the product, how to use it, how to store CL after opening, and the warnings and cautions from the label of the product. Product quality control in the shops and the data recognition of the customers may be the potential factors for the safety of monthly cosmetic CL usage. Comprehensive advice about care from the seller and transfer of all of the product's information to the customers may improve the process of caring for CL, which could reduce the risk of CL-related microbial keratitis and other complications.

Keywords : colored cosmetic contact lens, beauty shop, label, medical device documentation

Introduction

Contact lenses (CL) are becoming popular among the young female population, including college students, undergraduates, and young working adults, in both Thailand and worldwide.¹ There are many purposes for which CL are used in various indications e.g. refractive error correction, corneal abrasion, keratoconus and cosmetic purposes.² The lens is directly placed on the anterior segment of the eye and classified into three major categories: hard, rigid and soft CL.³ In Asian countries, cosmetic soft CL represents a rapidly growing segment of the CL market. The use of colored cosmetic CL among all CL wearers ranges from 24% (Taiwan) to 39% (Singapore). In Thailand, it was found that colored cosmetic CL are used among 50% of CL-wearing teenage students.⁴ Cosmetic CL wearers tend to be younger female students who use them for social occasions.⁵ Lack of correct understanding of CL usage, care and complications were commonly found in Thailand. Forty-two percent of students wear CL more than 8 hours per day, 32.14% do not rub and rinse CL before storing, 22.86% wear CL while sleeping, 10.71% put CL in while swimming, 14.29% wear expired CL and 7.86% share CL with friends.⁴

CL have been regulated by notification of the Medical Devices Control Division, the Ministry of Public

Health of Thailand since 2010 as a medical device for vision correction, cosmetics or ocular therapy. This notification specifies the product details regarding packing, labeling, medical device documentation (MDD), life-time, warnings, contraindications and cautions for the purpose of the safe use and prevention of misuse.⁶ CL manufacturers and importers must have the appropriate license, but this does not include the sellers, so this product is freely sold in the markets, e.g. non-optical stores, markets or the online market. Regarding consumer safety, all CL products are approved for permission by the Food and Drug Administration (FDA) of Thailand and the Officials of Agencies attached to the Ministry of Public Health before being launched in the market.⁷ Labelling and MDD are required to provide necessary information to the CL users. However, there is currently no monitoring system for CL dispensation in Thailand as is stated in the laws¹, and therefore, the self-care process and awareness are important in this situation.

The purpose of this study is to evaluate the unsafe conditions of monthly colored cosmetic CL that are freely sold in the untrained optical shops in a district of Ubon Ratchathani, Thailand. The results from this study can provide benefits for both the ophthalmologists in

CL-related corneal ulcer prevention and the consumers in understanding the level of safety of the monthly colored cosmetic contact lenses sold in untrained optical shops.

Materials and Methods

This study was a cross-sectional study that was conducted in one district of Ubon Ratchathani, Thailand during June 2020 by three examiners (an ophthalmologist, a pharmacist and a scientist). All untrained optical shops in this district that sell monthly colored cosmetic CL were included in this study. Every brand and vial size of monthly colored cosmetic CL in each shop were sampled by an accidental sampling method for two samples. A result of 2 out of 3 opinions were considered a consensus for each variable. Data collection was conducted as follows.

Shop characteristics, prices and advice

In every untrained optical shop surveyed in the district, examiners observed the shop characteristics, product prices, the CL cases given and the responsibility of the sellers after CL purchases, for example, CL advice, case use, cleansing methods, warnings and cautions.

Product characteristics

Each sample was examined in a laboratory by visual inspection. All examiners had near and distant visual acuity with correction to 20/20 in both eyes. External product characteristics, including packaging, labels, MDD, expired products, unclear/unreadable labels, application of other labels that obscured text, broken packages, and dirty products were observed. Internal product characteristics, clarity of the solution, CL movement in solution, surface wear of the CL, sediment and foreign bodies were also observed.

Product information

Each product was examined for the information that should be provided as stated by law with a 4X handheld magnifier. CL information is classified into

three parts as 1) product details, 2) directions, and 3) warnings and cautions.

Statistical analysis

A descriptive analysis of all of the variables studied were performed using absolute frequencies and proportions for the qualitative variables. Mean \pm SD was used to summarize the quantitative variables with normal distribution.

Results

There were five untrained optical shops that sold monthly colored cosmetic CL in the district in Ubon Ratchathani, Thailand during June 2020. Fifty-eight samples, 11 brands and two vial sizes of monthly colored cosmetic CL were included in this study. Most of these were sold in beauty shops (Table 1), and all of them were imported from South Korea. CL containers in the beauty shops and on the street are shown in Figure 1. Most of the CL in the shop were paired with a rubber band. The average cost of a pair of CL was 89.30 ± 12.70 baht. All of the sellers did not provide any advice to the customers, and 4 out of 5 of the shops gave CL cases after the purchase.

Table 1 Store characteristics and advices

Variables	Frequency	Percent(%)
Type of store		
Beauty Shop	4	80.00
On the street	1	20.00
Type of monthly Colored CL in the shop		
Only decorative purpose	3	60.00
Decorative and refractive error purposes	2	40.00
CL case giving	4	80.00
Advices		
Direction of CL use	0	0.00
Direction of CL case use	0	0.00
Direction of CL cleaner use	0	0.00
Warning and caution	0	0.00

Abbreviation: CL; contact lens



Figure 1 : contact lens containers and cases [A: in the beauty shop; B: on the street; C: contact lens cases]

All colored cosmetic CL did not have a box and the customers did not receive MDD after making a purchase (Table 2). Dirty products were found to be the most common problem of the external product defects, 37.93% of the samples had unclear/unreadable labels, and 5.17% of the samples had a price sticker on the label, which obscured some information (Figure 2). The most common problem of the internal product defects was CL sticking to the bottom of the vial and being unable to freely move in the solution when upside down and shaken. Foreign bodies also were found in the vials, as shown in Figure 3.

Table 2 Product characteristics

Variables	Frequency	Percent(%)
Brands	11	100.00
Outside Characteristics		
Vial	58	100.00
Label	58	100.00
Packaging box	0	0.00
Medical device documentation	0	0.00
Expired product	2	3.45
Scratched label	12	20.69
Unclear/unreadable label	22	37.93
Application of other labels that obscure text	3	5.17
Broken package	0	0.00
Dirty or abnormal stain at vial	27	46.55
Inside characteristics		
Clear solution	58	100.00
CL movement in solution	53	91.38
Surface wear of the CL	0	0.00
Sediment	0	0.00
Foreign body	2	3.45

Abbreviation: CL; contact lens



Figure 2 : External product defects [A: dirty products; B: abnormal stain around bottleneck; C: unclear/unreadable label; D: scratched label; E: application of other labels that obscure text; F: expired product]

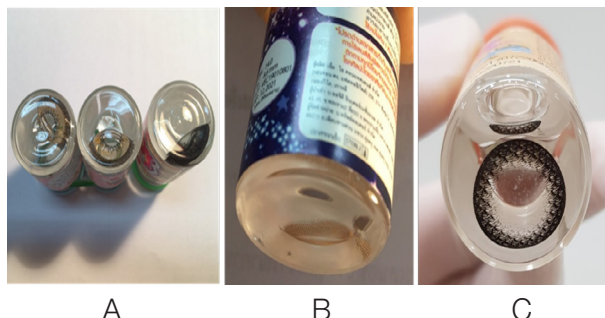


Figure 3 : Internal product defects [A: contact lens sticking to the bottom of vial; B: foreign body in the solution; C: whitish foreign body deposit on contact lens]

After observation of the product information of 12 samples (11 brands, from which one brand had two different vial sizes), the results revealed that customers received CL information only from the label, which showed product details and some amount of directions (Table 3). One brand of monthly colored cosmetic CL did not have the text “do not sell separately” on the label. For all of the brands, the customers did not receive the information about the purpose of the product, how to use it, how to store CL after opening, or the warnings and cautions.

Table 3 Product information

Variables	Frequency	Percent(%)	Positon of the text*
Product detail	12	100.00	Label or package, MDD
Brand	12	100.00	Label or package, MDD
Lens material	12	100.00	Label or package, MDD
Lens parameter	12	100.00	Label or package, MDD
Solution	0	0.00	Label or package, MDD
Preservative (if use)	12	100.00	Label or package
Expected useful life	12	100.00	Label or package
Lot number	12	100.00	Label or package
Amount in package	12	100.00	Label or package
Expired date	12	100.00	Label or package
FDA number	12	100.00	Label or package
Manufacturer or importer	12	100.00	Label or package
Message 'sterile'	12	100.00	Label or package
Message 'Do not sell separately'	11	91.67	Label or package
Direction			
Read MDD before use (red text)	12	100.00	Label or package
Should be followed up every year by ophthalmologist or optometrist (red text on label)	12	100.00	Label or package, MDD
Purposes, how to use, keeping	0	0.00	MDD
Wear and take off everyday	12	100.00	Label or package
Warning and caution			
Inappropriate use of CL is the risk of eye inflammation, infection and blindness	0	0.00	MDD
Do not enter more than the specified period	0	0.00	MDD
Do not share CL with other people	0	0.00	MDD
Do not wear when sleeping, should be take off and clean everyday	0	0.00	MDD
Who has eye abnormality e.g. pinguecula pterygium, red eye, abnormalities corneal sensation and blinking should not use CL	0	0.00	MDD
Changing of contact cleaner	0	0.00	MDD
Changing of CL case every 3 months	0	0.00	MDD
Do not use when swimming	0	0.00	MDD
Wash hand with soap before use	0	0.00	MDD
Stop using when abnormal eye symptom occur and see ophthalmologist	0	0.00	MDD
Do not use if defective product or open before use	0	0.00	MDD

*Notification of Ministry of Public Health "contact lens". Bangkok: Royal Thai Government Gazette; 2010

Abbreviations: FDA; Food and Drug Administration, CL; contact lens, MDD; medical device documentation

Discussion

According to the previous reports in Thailand, CL was found to be a predisposing risk factor (varying from 3.5 to 18.6%) for microbial keratitis^{8,9} and 10.7% in Asian studies.¹⁰ Fungal keratitis is less likely to be associated with CL wearers [OR = 0.02; CI 0.01 - 0.08].¹¹ *Pithium insidiosum* keratitis was also reported in cases of swimming in a pool without removing the contact lenses.¹² Regarding problems related to the care of CL, 34% of CL wearers did not practice proper CL care, and 67% wore contact lens overnight.⁹ Both poor lens hygiene and overnight wearing of lenses significantly increase the risk of microbial keratitis [OR = 2.3; CI 1.0 - 5.1, $p = 0.007$ and OR = 2.9; CI 1.3 - 6.2, $p = 0.012$, respectively].¹³ The recommendations about these problems include appropriate advice about the care and usage of CL¹³, the warnings from ophthalmologists about potential problems, and instructions for the storage of CL, which may reduce the risk.⁹ The safety of cosmetic CL is emphasized when properly prescribed by an eye care professional.⁵ In this study, through use of a marketing survey, the additional unsafe conditions were found, which are the lack of product information on the CL care process and usage, as well as the warnings and cautions. Although all of this necessary information should be provided as stated by law and shown in the MDD, the customers did not receive it.

Lack of CL information was also found in previous research. Some brands did not have information on the label as the law stated, for example expected useful life, amount in package, FDA number, directions, and the red text stating 'do not sell separately'.¹⁴ In this study, it was found that only one brand had the label that did not include the text stating 'do not sell separately', which is required by law. Information on

the MDD could not be examined in this study due to not receiving it.

Several reports revealed that the users who use colored CL that are not sold by medical personnel might not have any information about how to use take care of CL, which are prone to infection and inflammation.³ In this study, we found the similar results that non-medical sellers do not provide any advice to the customers. Moreover, twenty percent of the shops did not give a CL case to the customers, which may cause customers to have misunderstandings regarding monthly CL usage.

Monthly colored cosmetic CL are freely sold in the market due to there being no law for regulation. CL products from the flea market were previously found to have bacterial contamination¹⁴, while the CL products that are sold on the street in Bangkok were not found to have any bacterial contamination.³ In this study, most of the CL were sold in beauty shops. Dirty products were found to be the most common external product defect. Expired products were also be found, similar to the previous studies.³ Furthermore, foreign bodies in the solution and whitish foreign body deposits on CL can be found, which the customers should notice before buying. All of these may be the risk factors of bacterial contamination that require further study. Sticking of CL to the bottom of the vial is the most common problem of internal product defects. The CL may lose its shape, which can cause eye irritation during use. Heat and light may be associated with this defect, which requires product quality control.

In conclusion, the chain of customer safety in monthly colored cosmetic CL usage is linked with the product quality control and data recognition. Improving product hygiene and storage in the market may reduce the adverse effects of CL usage. Comprehensive ad-

vice regarding care from the sellers and transfer of all the product's information to the customers may be the potential factors for improving the process of caring for CL that can reduce the risk of CL-related microbial keratitis and other complications.

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