

How safe are coloured contact lenses illegally sold on street in Thailand?

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Objectives: To assess the incidence of contamination from bacteria, fungus, and protozoa in colored contact lenses illegally sold on the street in Thailand and to specify contaminated microbial species by microbial culture in order to generate empiric antimicrobial guidelines.

Design: cross-sectional study

Methods: This is a cross-sectional study of colored contact lenses illegally sold in street markets in 50 districts of Bangkok. We had 350 samples of colored contact lenses. All of the colored contact lens samples underwent microbial culture using broth agar in the laboratory. We evaluated the safety of the samples by observing the number of colored contact lenses that show positive microbial culture, reported as a percentage of all tested colored contact lenses. We set an acceptable microbial growth value at 0.5%. If more than 0.5% of all contact lens samples had positive microbial culture, we considered these contact lenses contaminated and unsafe. Each positive bacterial growth sample would be confirmed by subculture and the growing colony was evaluated and identified by biochemical tests.

Results: The 350 samples of colored contact lenses were from 6 brands: 26 samples of Barbie contact lens, 81 of Dream Color contact lens, 6 of Eye Berry contact lens, 34 of Kawaii contact lens, 6 of Lollipop contact lens, 8 of Mimi contact lens, 68 of Pretty Doll contact lens, and 121 of Sweet Plus contact lens. All of the colored contact lenses were made of Polyhema and immersed in normal saline. We performed microbial culture. Brain heart infusion broth, which is specific to growths of gram-positive bacteria, gram-negative bacteria, anaerobic bacteria, fungi, and protozoa

Conclusion: Our study shows no microbial growth in every sample so we can conclude that colored contact lenses illegally sold on streets in Bangkok are uncontaminated.

Conflicts of interest: None

Keywords: contact lenses, microbial culture

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Introduction

Contact lenses are widely used for refractive error correction (including myopia, hyperopia, and astigmatism), for treatment of eye diseases such as corneal abrasion and

keratoconus, and sometimes for cosmetic purposes. The lens is directly placed on anterior segment of eye and can be classified into major categories: hard, rigid, and soft contact lenses. Accordingly, these lenses are determined as medical devices in Article 4¹ of Medical Device Act 2008 by the Thai FDA, which also made an announcement regarding consumer safety in medical-purposed and cosmetic-purposed contact lenses sold in medical device stores or sold by contact lens importers/sales representatives. Contact lenses must be produced by certified manufacturers and imported by licensed importers; moreover, quality must exceed Thai FDA standards. Currently, incidences of corneal abrasion from contact lens use are rising worldwide, and we have noted an increase at Thammasat University Hospital as well. These destructive consequences are usually caused by overnight contact lens use, erroneous methods of cleaning, and the wearing of non-standardized colored contact lens illegally sold by sidewalk vendors and in markets. As a result, we conducted a small survey of non-standardized colored contact lens to detect possible microbial contamination. This will benefit both ophthalmologists in terms of antimicrobial treatment criteria and also consumers in understanding how safe the illegally sold colored contact lenses are. However, our study did not cover consumer behaviors such as contact lens wearing time, cleaning methods and storage methods after first-time use.

Methods

This is a cross-sectional study of colored contact lenses illegally sold in street markets in 50 districts of Bangkok. We assumed that samples from 50 districts of Bangkok. The sample size was estimation for our study was based on a one-sample comparison of proportions to hypothesized values that is two sided with alpha of 0.05

and power of 90%. With our postulated maximally accepted prevalence of microbial growth in widely sold contact lenses being 0.5% and our hypothesized assumption that safe and standardized medical devices should have a microbial culture incidence of 0%. Hence, our sample size was estimated to be 327, with 33 extra samples to account for various factors of unacceptable data collection. We assumed that samples from 50 districts would be sufficient to represent most of the lenses illegally sold in Bangkok. We randomly selected 7 vendors in each district of Bangkok. Without discerning between types and brands, we then randomly selected 1 sample of colored contact lens, from each vendor. After this, we had 350 samples of colored contact lenses; the sample size was calculated by the equation below.

$$n = \left[\frac{z_{1-\alpha/2} \{p_0(1-p_0)\}^{1/2} + z_{1-\beta} \{p_A(1-p_A)\}^{1/2}}{p_A - p_0} \right]^2$$

Null hypothesis is $p=p_0$ and alternative hypothesis $p=p_A$ (Pagano and Gauvreau 2000, 332)

All of the colored contact lens samples underwent microbial culture using broth agar in the laboratory. We evaluated the safety of the samples by observing the number of colored contact lenses that show positive microbial culture, reported as a percentage of all tested colored contact lenses. Theoretically, safe and standardized medical devices should not have any bacterial growth and should be reported as “0% of tested medical devices has positive microbial culture”. However, we did not find any previous research about possible bacterial contamination in contact lenses at point of sale, so we set an acceptable microbial c manufacturing process, their quality, or their storage methods. However, for our particular study, we determined the lenses as safe or unsafe

for consumers without identifying the actual causes. After we had gathered all of the colored contact lens samples, we recorded the brands, types, manufacturing dates, expiration dates, lot numbers of materials, and contact lens solution. In the microbiological laboratory, we removed the lenses from their containers using sterile techniques and cultured them in brain heart infusion broth at 35 degree Celsius for 18-24 hours. Afterwards, microbial growth was observed by evaluating turbidity of the media. Each positive bacterial growth sample would be confirmed by subculture using sheep's blood agar and macconkey agar at 35 degree Celsius for 18-24 hours. The growing colony was then evaluated and identified by biochemical tests. If there is no grown colony at 18-24 hours, subculture will be continued to 72 hours. After 72 hours of subculture, the specimens that showed no growing colony were reported as no growth after 3 days. Similarly, the contact lens samples that initially underwent microbial culture in heart brain infusion broth and showed no turbidity were continued for cultivation under the same environment until 72 hours. These samples that showed no turbidity of the media were reported as no growth after 3 days.

Data Analysis

Exact probability was used to analyze the data.

Results

The 350 samples of colored contact lenses were from 6 brands: 26 samples of Barbie contact lens, 81 of Dream Color contact lens, 6 of Eye Berry contact lens, 34 of Kawaii contact lens, 6 of Lollipop contact lens, 8 of Mimi contact lens, 68 of Pretty Doll contact lens, and 121 of Sweetie Plus contact lens. All of the colored contact lenses were made of Polyhema and immersed in normal saline. Some have lens power and some do not. Each colored contact lens was contained in a small glass

bottle sealed with aluminum plate. No bottles were broken. There were various manufacture dates of the contact lenses. There were 3 samples of colored contact lens that had already been expired for 5 months before we performed microbial culture. Brain heart infusion broth, which is specific to growths of gram-positive bacteria, gram-negative bacteria, anaerobic bacteria, fungi, and protozoa, was used as the first media. Every sample in the media was cultivated at 35 degree Celsius for 18-24 hours. After that, we evaluated the turbidity of the media in each test tube. All of the contact lenses showed no bacterial growth in brain heart infusion broth. Therefore, microbial specifying methods, which are subculture with sheep blood agar and Macconkey agar and biochemical test, were not performed. Accordingly, we were unable to generate antimicrobial guidelines.

Product data	Quantity (%)
Brands	
•Barbies contact lens	26 (7.42)
•Dream color	81 (23.14)
•Eye berry	6 (1.71)
•Kawaii contact lens	34 (9.71)
•Lollipop	6 (1.71)
•Mimi contact lens	8 (2.28)
•Sweetie plus	68 (19.42)
•Sweetie plus	121 (34.57)
Material	
•Poly hema	350 (100)
Contact lens solution	
•Saline solution	350 (100)
Expiratory date	
•Non expired	347 (99.15)
•Expired	3 (0.85)

Discussion

Corneal infection is a serious complication of contact lens use. Previous studies showed various factors of infection which

are age of user, gender, types of contact lens, user hygiene, and contact lens wearing time. Young, male, overnight users are prone to infection.^{10,11,12,13} Some studies found that expired contact lens use exacerbates microbial accumulation which causes inflammation, allergic reactions, corneal hypoxia, corneal epithelium micro trauma which leads to infection. This information shows that user behavior is one of the main factors of infection. Some reports reveal that users, who used colored contact lens not sold by medical personnel, might not have got any information about how to use contact lens and contact lens care. Therefore, they were prone to infection and inflammation.^{1,2,3,4} Tsukiyama J, et al. describe that contact lens and colored contact lens have different sagittal depth because of the color pigment on colored contact lens⁵. Fitting pattern is also changed so colored contact lens users should see ophthalmologists regularly for eye examination.

Conclusion

Apart from contact lens user behaviors, illegally sold colored contact lenses are unsafe because consumers might be uninformed about how to safely use contact lenses and contact lenses themselves are non-standardized. Our study shows that 350 samples of illegally sold colored contact lenses have no growth of bacteria, fungus, and protozoa. This study is a novel study; we set acceptable microbial growth value at 0.5% in order to be able to calculate the sample size. Actually, acceptable microbial growth value in medical devices must be zero. Our study shows no microbial growth in every sample so we can conclude that colored contact lenses illegally sold on streets in Bangkok are uncontaminated.

Comments

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University and is not relevant to contact lens manufacturers and sale representatives. Therefore, the results can be used, without conflict of interest, as a reference for consumers and everyone who is interested in colored contact lens safety. For further study, our suggestion is to focus on product storage and product distribution. Moreover, further research should be performed in larger sample size.

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