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Scanning Electron Microscopy Findings With Energy-Dispersive X-ray Investigations of Cosmetically Tinted Contact Lenses

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Objective: To investigate the surfaces and principal elements of the colorants of cosmetically tinted contact lenses (Cos-CLs).
Methods: We analyzed the surfaces and principal elements of the colorants of five commercially available Cos-CLs using scanning electron microscopy with energy-dispersive x-ray analysis.
Results: In two Cos-CLs, the anterior and posterior surfaces were smooth, and colorants were found inside the lens. One lens showed colorants located to a depth of 8 to 14 μm from the anterior side of the lens. In the other lens, colorants were found in the most superficial layer on the posterior surface, although a coated layer was observed. The colorants in the other three lenses were deposited on either lens surface. Although a print pattern was uniform in embedded type lenses, uneven patterns were apparent in dot-matrix design lenses. Colorants used in all lenses contained chlorine, iron, and titanium. In the magnified scanning electron microscopy images of a certain lens, chlorine is exuded and spread.
Conclusions: Cosmetically tinted contact lenses have a wide variety of lens surfaces and colorants. Colorants may be deposited on the lens surface and consist of an element that has tissue toxicity.

Key Words: Cosmetically tinted contact lens—Scanning electron microscopy energy-dispersive x-ray analysis—Colorant—Elemental analysis.

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Cosmetically tinted contact lenses (Cos-CLs), including colored corrective lenses, are widely available to the public and are especially popular among teenage girls and younger women in Pacific Asians. Although the sale of Cos-CLs is regulated by prescription in most Western countries, they can be easily purchased without a prescription in other countries. In such regions, young wearers use Cos-CLs with little or no supervision from professional eye care providers. Many of those wearers are uninformed about appropriate lens use and care, including proper hygiene practices for handling and storage. Therefore, we may see an increasing trend in corneal disorders related to the unregulated use of Cos-CLs.[1–5]

Lens materials and surfaces play an important role in the adherence of bacteria to the lens surface[6–9] and are also believed to influence the manifestation of microbial keratitis related to contact lens (CL) wear.[7–9] Given the potential role of Cos-CLs in microbial infections, a better understanding of the nature of the tinted surfaces in such lenses is desirable. Additionally, if colorants, which are printed, dot-matrix patterned tint on the anterior/posterior lens surfaces, potentially induce changes in corneal epithelial cells,[10,11] the elements of those colorants should be fully published; however, this information is mostly unknown, or the characteristics including the manufacturing methods used for colorants are unclear in the information provided on the Internet.

In the article reported by Begley and Waggoner,[12] nodular deposits on soft CLs were investigated using scanning electron microscopy with energy-dispersive x-ray analysis (SEM-EDX). The results provide a breakthrough for analysis of CL surface and indicated that most CL deposits contained calcium. The aim of this study was to use SEM-EDX to observe the surfaces of several commercially available Cos-CLs and to analyze the chemical elements in the colorants used in those lenses.

METHODS

Five commercially available Cos-CLs were investigated in this study. These lens types selected are widely used across Pacific Asia. The five Cos-CLs we assessed were obtained arbitrarily without a prescription from the Internet, a general pharmacy, or a mass merchandise outlet. The product names of the lenses and lens characteristics specified in the instructions or packaging are shown in Table 1.

For evaluation by SEM-EDX, the Cos-CLs were first washed by soaking for 10 min in their blister package with ultrapure water (Milli-Q academic; Merck Co., Ltd, Tokyo, Japan) after withdrawal of original saline in the package, cut to the suitable size, and then desiccated on a cellulose-mixed ester membrane filter (Advantec Toyo Co., Ltd, Tokyo, Japan) to flatten the lens. Specifically, the lenses were cut into approximate quarters before desiccation, and individual pieces were made and then desiccated. Afterward, the pieces were manually broken using clean, sterile forceps, and the piece that was apparently flat was observed using SEM. Both lens surfaces (both anterior and posterior) of all lenses were examined using the Tabletop Microscope TM3030 (Hitachi High-Technologies

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TABLE 1. *Information of Lenses Released in Their Instructions or Packages*

Lens	Group	Material	Country	Power (D)	Colorants	BC	DIA	Dk	Dk/t[a]	Water Content (%)
1-DAY ACUVE DEFINE	IV	2-HEMA MAA	Ireland	–0.50	Anthraquinone dye, metallic oxide	8.50	14.2	28×10^{-11}	33.3×10^{-9}	58
EYE COFFRET 1-DAY UV	I	2-HEMA EGDMA	Taiwan	0.00	Azo dye, isoindoline dye, oxazine dye, carbon-based material, metallic oxide	8.70	14.0	12×10^{-11}	24.0×10^{-9}	38
EVER COLOR 1-DAY NATURAL	I	2-HEMA EGDMA	Taiwan	0.00	Azo dye, phthalocyanine dye, triphenylmethane dye, quinolone dye	8.70	14.5	N.S.	N.S.	38
TUTTI VANITY RICH	I	2-HEMA EGDMA	Taiwan	0.00	Azo dye, phthalocyanine dye, aromatic compound, carbon-based material	8.70	14.0	N.S.	N.S.	38.5
JOY POP RICH	I	2-HEMA EGDMA	South Korea	0.00	Azo dye, phthalocyanine dye, anthraquinone dye, quinolone dye	8.60	14.8	9.0×10^{-11}	N.S.	38

[a]Dk/L value means oxygen transmissibility of the center area of the −3.0 D lenses.

2-HEMA, Poly (2-hydroxyethyl methacrylate); BC, base curve (mm); Colorants, colorants released in instructions; Country, country of manufacture; D, diopters; DIA, lens diameter (mm); Dk, oxygen permeability (cm^2/sec) (mLO_2/[mL×mm Hg]); Dk/t, oxygen transmissibility (cm/sec) (mLO_2×mm Hg); EGDMA, ethylene glycol dimethacrylate; Group, Standard by the US Food and Drug Administration; MAA, methacrylic acid; N.S., not shown.

Corporation, Instruments Co., Ltd, Tokyo, Japan). After localizing the colorant, elemental analysis and their distribution maps were measured by an energy-dispersive x-ray spectroscopy using Quantax 70 (Bruker AXS Microanalysis GmbH, Berlin, Germany). When colorants were located inside the lenses, the cross sections of the lenses were examined to measure the depth, and the elements were also analyzed using the same instruments as described above.

RESULTS

Surface Observation and EDX-Mapping Analysis

Surface observations for each lens are shown in Table 2. Regarding EDX-mapping, carbon and oxygen are found to be diffusely distributed throughout lenses. Chlorine, titanium, and iron are found to be distributed where the colorants are embedded or printed.

1-Day Acuvue Define

The lens had a smooth surface on both sides (Fig. 1A,B). In the cross-sectional image, the colorants were found embedded inside the lens to a depth of 8 to 14 μm from the anterior surface (Fig. 1C,D).

Eye Coffret 1-Day UV

The anterior side was smooth (Fig. 2A). The print design was uniform (Fig. 2B). The posterior surface appeared wrinkled under high magnification (Fig. 2C). A thin-coated layer covering the colorants was detected, and the coated layer was wrinkled because of desiccation. The colorants were found embedded in the most superficial layer of the posterior surface of the lens at a depth of 1 μm. Only chlorine was found in the print (Fig. 2D).

Ever Color 1-Day Natural

Colorants were deposited on the posterior surface of the lens, although the anterior surface was smooth (Fig. 3A,B). The colorants were not printed uniformly, and small amounts of colorant were scattered between a dot-patterned print (Fig. 3B). Two kinds of print patterns were observed, and chlorine covered most of the print area, whereas titanium oxide seemed to be overglazed in the midperiphery of the print (Fig. 3C,D). In the magnified image, chlorine is exuded and spread (Fig. 3E,F).

Tutti Vanity Rich

Colorants were deposited on the anterior surface, although the posterior surface was smooth (Fig. 4A,B). Colorants on the anterior side were deposited heavily in the periphery, and a dot-patterned print was overglazed in the midperipheral area (Fig. 4A). Oxygen and iron were painted heavily on the peripheral side of the print and painted as a dot-pattern in the midperiphery (Fig. 4C,D).

Joy Pop Rich

Colorants were deposited on the posterior surface, and the anterior surface was smooth (Fig. 5A,B). In some areas of the lens, uneven coatings were apparent (Fig. 5B). Chlorine was printed heavily on the periphery, and prints were uneven. In some areas, iron seemed to be overglazed (Fig. 5C,D).

TABLE 2. *Lens Surface and Principle Component of Colorants*

Lens	Eyelid Side	Corneal Side	Elements	Depth
1-DAY ACUVE DEFINE	Smooth	Smooth	Iron, oxygen	Approximately 8–14 μm
EYE COFFRET 1-DAY UV	Smooth	Scabrous[a] moderately	Iron, chlorine	Less than 1 μm (most superficial layer)
EVER COLOR 1-DAY NATURAL	Smooth	Scabrous	Iron, titanium, chlorine	—
TUTTI VANITY RICH	Scabrous	Smooth	Iron, oxygen	—
JOY POP RICH	Smooth	Scabrous	Iron, oxygen, chlorine	—

[a]"Scabrous" denotes that colorants caused lens surface irregularities.

Bars mean colorants are not inside the lens but deposited on the surfaces; Depth, depth of colorants from the nearest surface.

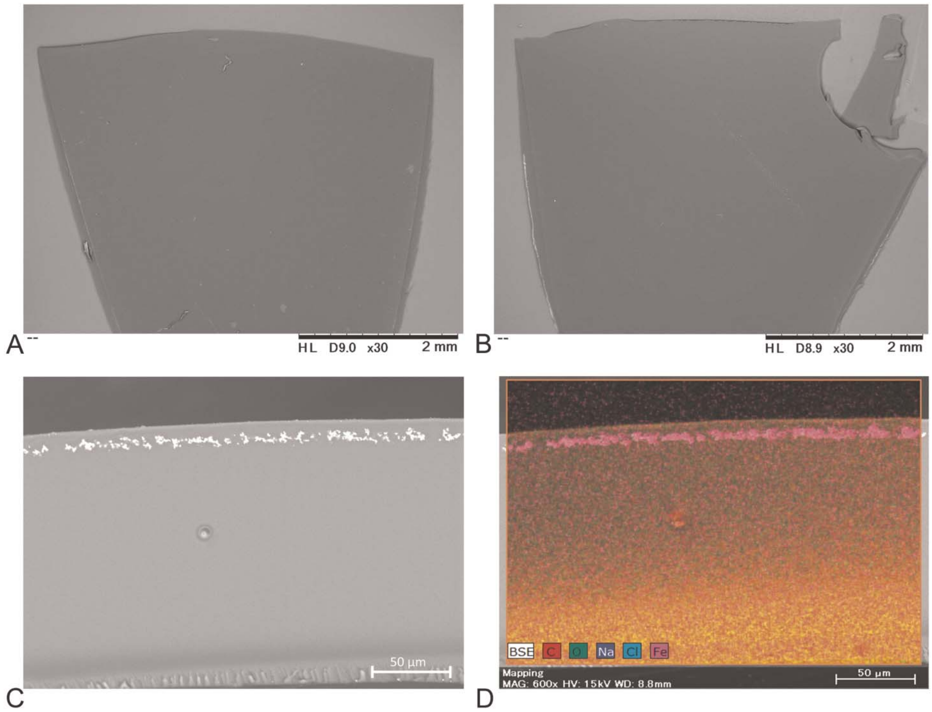

FIG. 1. Scanning electron microscopy views and energy-dispersive x-ray mapping analysis of 1-DAY ACUVUE DEFINE. (A) The surface of the eyelid side is smooth. (B) The surface of the corneal side is also smooth. (C) The cross section reveals that the colorants are located to a depth of 8 to 14 μm from the eyelid side of the lens. (D) The main component of the colorants is iron.

Elemental Analysis of Colorants

Results from the elemental analysis of colorants are shown in Table 2. Colorants detected in the cross section of 1-DAY ACUVUE DEFINE consisted of iron and oxygen (Fig. 1D). Colorants in EYE COFFRET 1-DAY UV consisted of chlorine (Fig. 2D). Colorants in EVER COLOR 1-DAY NATURAL consisted of chlorine and titanium (Fig. 3C,D). Colorants in TUTTI VANITY RICH consisted of iron and oxygen (Fig. 4C,D). Colorants in JOY POP RICH consisted of chlorine, iron, and oxygen (Fig. 5C,D).

DISCUSSION

This study showed a wide variation in the location, surface quality/roughness, and chemical composition of the tinted portion

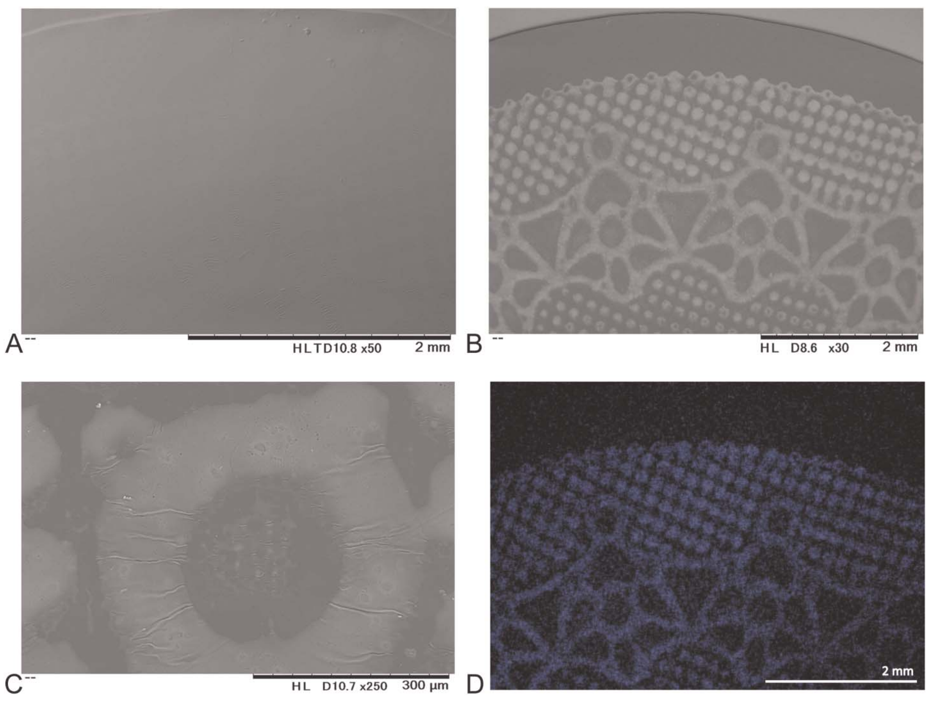

FIG. 2. Scanning electron microscopy views and mapping analysis of EYE COFFRET 1-DAY UV. (A) The surface of the eyelid side is smooth. (B) The print design is apparent on the posterior side, and the pattern is uniform. (C) A coated thin layer is wrinkled. (D) Blue shows the distribution of chlorine.

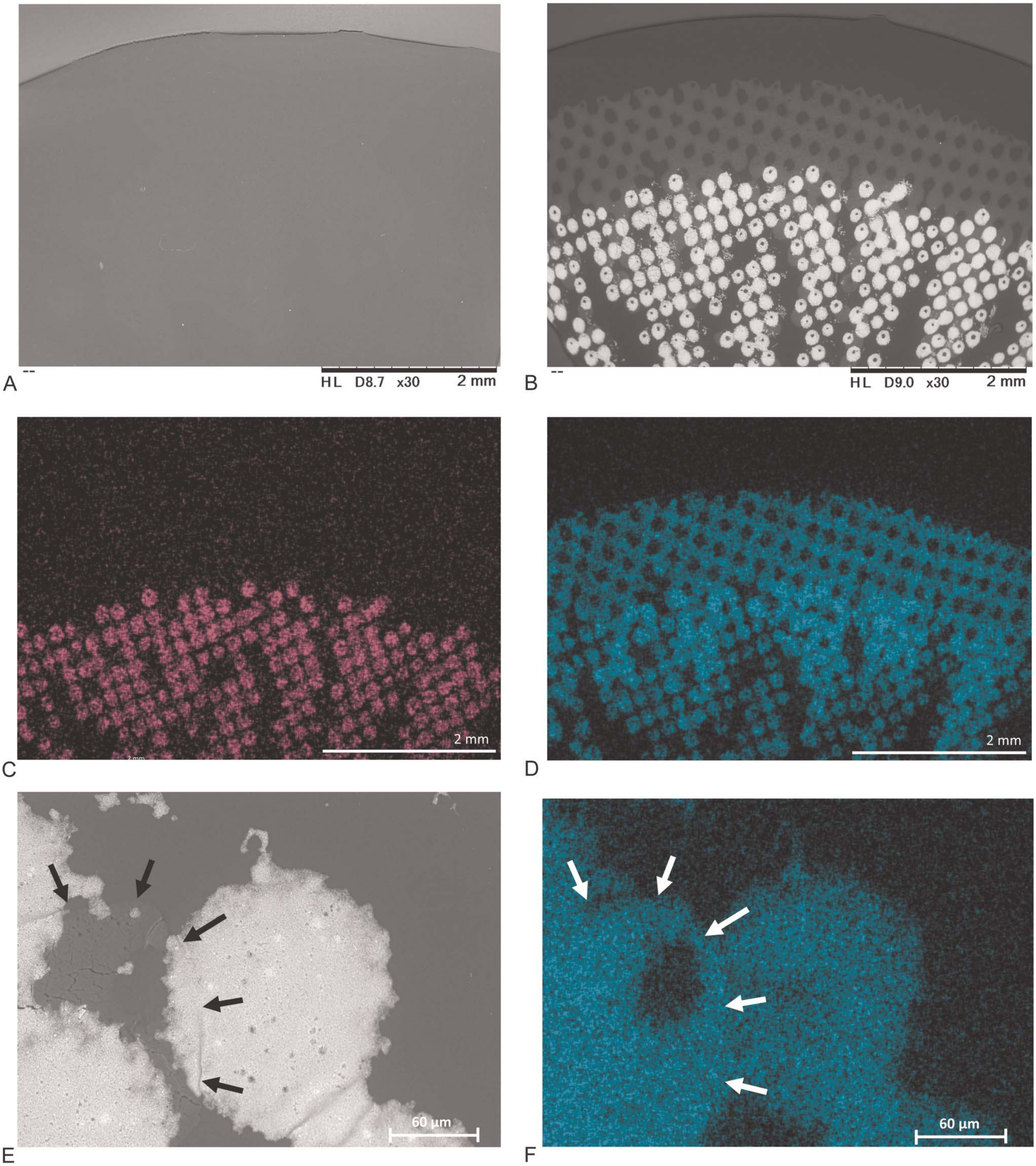

FIG. 3. Scanning electron microscopy views and mapping analysis of EVER COLOR 1-DAY NATURAL. (A) The surface of the anterior side is smooth. (B) Colorants are deposited on the posterior side. (C) Purple shows the distribution of titanium. (D) Light blue shows the distribution of chlorine. (E) Black arrows show exuded chlorine in high magnification. (F) White arrows show exuded chlorine.

of the lenses examined. Lorenz et al.[13] analyzed seven Cos-CLs using SEM and atomic force microscopy, and they also revealed that pigment on the surface of six lenses. For multiple reasons, the fact that some Cos-CLs have scabrous surfaces on the posterior sides is a matter of critical concern. Because most Cos-CLs are made of Poly (2-hydroxyethyl methacrylate), which has a lower oxygen

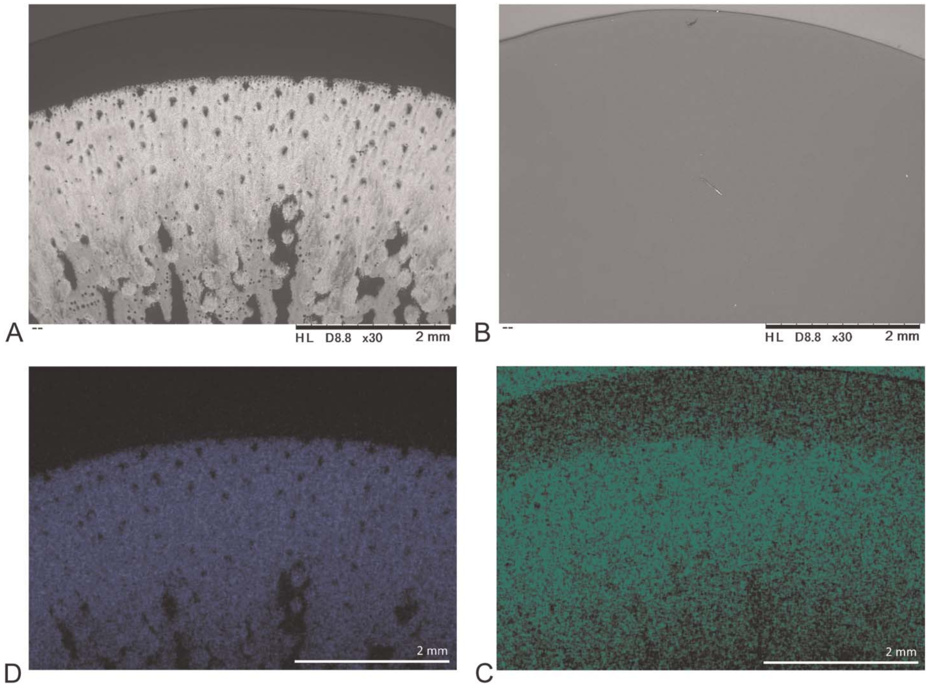

FIG. 4. Scanning electron microscopy images and mapping analysis of TUTTI VANITY RICH. (A) Colorants are deposited on the anterior side. (B) The surface of the posterior side is smooth. (C) Blue shows the distribution of iron. (D) Green shows the distribution of oxygen.

permeability than recent silicone hydrogel, which is the material commonly used for corrective lenses. Although the oxygen permeability values (Dk value) of most Cos-CLs are provided, the oxygen transmissibility values (Dk/t value) are not disclosed. Moreover, the deposited colorants are a cause of friction on the corneal epithelium. Heavily applied colorants may alter the rigidity of the lens, and this alteration may also cause friction on the cornea. Corneal epithelial disorders with low oxygen concentration are an important risk factor for corneal infections related to CL wear.[13–16] Chan et al.[17] reported that surface pigments on Cos-CL resulted in significantly higher bacterial adherence after the examination of 15 commercially available Cos-CLs. They also concluded that bacterial adherence to surface pigments in some two lenses exhibited significantly higher adherence compared with their clear counterpart.

Colorants should be made of noncytotoxic or low-cytotoxic materials if they are deposited on the surfaces of lenses and touch

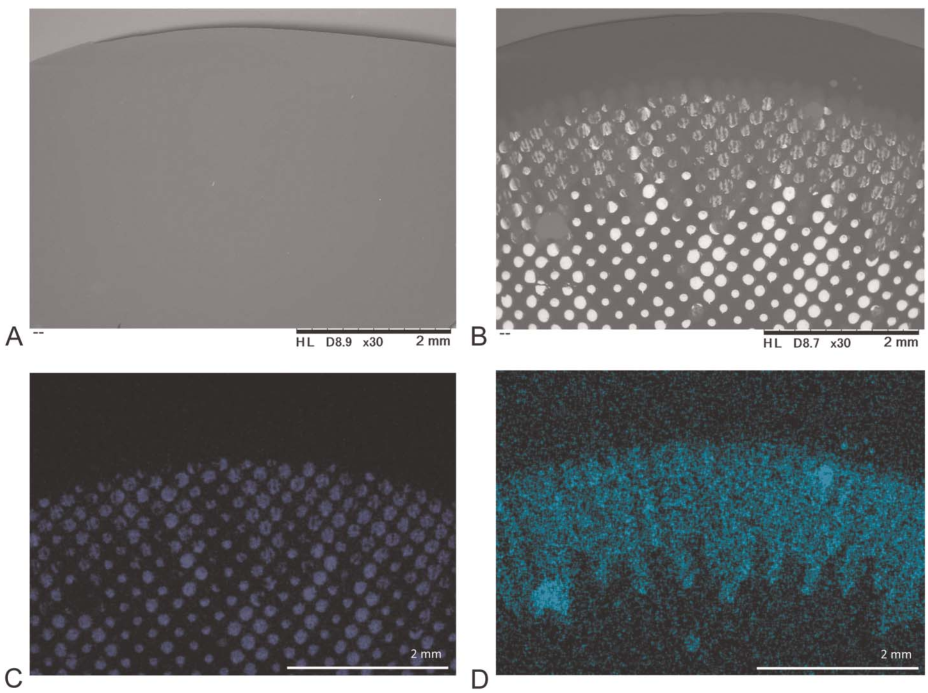

FIG. 5. Scanning electron microscopy views and mapping analysis of JOY POP RICH. (A) The surface of the anterior side is smooth. (B) Colorants are deposited on the posterior side. (C) Blue shows the distribution of iron. (D) Light blue shows the distribution of chlorine.

the corneal epithelium directly. It is a great matter of concern that publicly available information about the principal elements of colorants is limited. This study found chlorine in the prints of three lenses and obtained an image suggesting that prints on EVER COLOR 1-DAY NATURAL exuded chlorine. We also found iron in the prints of four lenses. Initially, we presumed that chlorine originated from the saline in the blister package. However, we determined that chlorine was a component of the colorants because sodium was not detected from the area where we detected chlorine in EDX-mapping analysis. A more detailed investigation capable of identifying the chlorine element of organic compounds and the chlorine ion of inorganic salts is necessary, because we found no evidence indicating the presence of the counter ion of chlorine.

Moreover, the print technique is likely not secured in some lenses because colorants were deposited unevenly in the print areas of the same pattern. Colorants printed in a variety of textures may cause exposure of colorant elements to the corneal epithelium, and also may cause stronger friction than regularly patterned prints. In this study, it is possible that the uneven prints originated from irrigation in our experimental manipulation with ultrapure water. In that case, discoloration suggests that elements in colorants can easily be exposed in the process of routine daily lens care. In either case, the uneven print pattern that we found may be one of the risk factors for corneal infections and/or corneal insults related to Cos-CL wear. The amount and/or percentage of iron should be released to the public because it has been reported that overloaded iron lead to many diseases[18] and to toxicity and cell death through free radical formation.[19]

Although we believe that this study provides a new insight into Cos-CLs, two limitations remain. First, we desiccated all lenses for SEM investigation, and the desiccation altered the shapes of those lenses. Therefore, the images we obtained with SEM are not representative of the actual lens shape on the human cornea. For example, EYE COFFRET 1-DAY UV seemed to have a slightly scabrous surface on the posterior side, but the scabrous surface most likely resulted from the desiccation process; therefore, because it may have a smoother surface on the cornea than indicated by our image, we should be aware of the possibility of overestimation. Second, only five commercially available Cos-CLs were investigated in this study. Because there are many Cos-CLs widely distributed in the marketplace, it was impractical to assess all lenses available to determine if most Cos-CLs have results similar to the five lenses we investigated. Although some manufacturers, including 1-DAY ACUVUE DEFINE and EYE COFFRET 1-DAY UV (Table 1), readily provide more detailed lens information, others do not provide the same level of detail. Consequently, further investigations are required.

In conclusion, ophthalmologists must be aware that Cos-CLs have a wide variety of lens surfaces and colorants. Some lenses have scabrous surfaces with colorants deposited on the surfaces, and the colorants consist of elements with tissue toxicity. It is not unwarranted for ophthalmologists to have a skeptical attitude about the quality of most Cos-CLs. Additionally, it is preferable for eye care professionals to recommend creditable lenses to wearers after detailed examinations of the lens surface and colorants. Further scientific investigations of Cos-CLs that are distributed internationally are necessary.

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