Analysis for Oxygen Permeability of Cosmetic Silicone Hydrogel Contact Lens in Korea

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Abstract: Background/Objectives: To investigate the oxygen permeability of cosmetic silicone hydrogel contact lenses in the market in order to describe the current situation for consumers and provide recommendations for guidelines to prevent side effects.Methods/Statistical analysis: I consumers due to information such as the oxygen permeability, water content, and thickness of cosmetic silicone hydrogel contact lenses was collected from websites for the Ministry of Food and Drug Safety and retail stores that sell contact lenses. Descriptive and correlational analyses were performed to determine whether contact lens met high oxygen permeability standards set by the International Organization for Standards(ISO) as well as standards suggested by Holden & Mertz and Harvitt & Bonanno.

Findings: Cosmetic silicone hydrogel contact lenses were first approved in 2004. Out of the 270 brands of lenses (21 types) we identified, 119 brands (6 types) provided consumers with no information on oxygen permeability because they had been approved before September 2012. Only one brand of lenses (4.8%) had oxygen permeability levels that met ISO 18369-1:2017 standards. Testing revealed that correlations between the oxygen permeability and water content of cosmetic silicone hydrogel contact lenses on the market were strong at 0.555 (p = 0.009). This correlation does not meet ISO standards and shows that there is no relationship between the oxygen permeability and water content of lenses. Samples examined by the Consumers Union of Korea show that oxygen transmissibility values were significantly below standards at 14.38Dk, 8.86Dk, and 14.14Dk, and that lenses made of silicone hydrogel material performed poorly. The low quality of silicone hydrogel lens attributable to the lack of standards, and the lack of testing for oxygen permeability by the government during routine sample collections/examinations is a problem. Because side effects related to contact lens use are predicted to rise in Korea as long-term use of contacts continues to increase, and use of cosmetic contact lenses for young women in particular continues to grow, revised standards and improved sample collections/examination criteria are necessary.

Improvements/Applications: Because only one brand of lens we reviewed (4.8%) met current ISO standards and owing to the difficulty we had identifying the oxygen permeability of lenses, careful attention by consumers, mandatory reporting of oxygen permeability and water content levels by manufacturers, and improved standards for silicone hydrogel contact lenses are needed.

Keywords: Silicone hydrogel, Cosmetic lenses, Contact lenses, Oxygen permeability, Water content.

I. INTRODUCTION

Despite the increased use of hydrogel contact lens by their superior fit and lack of discomfort associated with glasses, side effects associated with the low oxygen permeability of contact lens have been criticized as problems. Recently, Holden and Mertz [1] found that daily use of contact lenses with oxygen permeability of 24×10^{-9}(cm×mlO^2)/(sec × ml× mmHg) or higher did not induce cornea edema. Similarly, Harvitt and Bonanno[2] found that contact lenses with an oxygen permeability of 125×10^{-9}(cm × ml O^2)/ (sec × ml × mm Hg) or higher did not induce stromal anoxia.

Because of the poor oxygen permeability of hydrogel contact lenses, side effects such as corneal edema, bloodshot eyes, itchiness, and the formation of new blood vessels can occur.[3] Silicone hydrogel contact lenses (which have very high oxygen permeability), were developed to prevent these side effects, and thus, help reduce these complications by allowing oxygen levels to the cornea comparable with not wearing contact lenses at all.[4,5]

Therefore, the widespread use of silicone hydrogel contact lenses can be advantageous in preventing some of the side effects associated with contact lenses.[6, 7] The increased prescription of silicone hydrogel contact lenses in Korea, which reached 45% in 2016, matches prescription rates for silicone lens worldwide.[7] Use of cosmetic lenses is also appears to be increasing among young female wearers.[8]

However, cosmetic contact lenses have higher rates of complications compared to hydrogel contact lenses. In the case of bacterial keratitis, cosmetic contact lenses are reported to have a 16.5 times higher risk of complications compared to hydrogel contact lenses.[9] In 2016, the prescription rate for cosmetic contact lenses in Korea was 41%, which is very high compared to prescription rates in English-speaking countries, which range between 0 and 4%.[7]

As of September 2017, 68 types of silicone hydrogel contact lenses had been approved by the Korean Ministry of Food and Drug Safety. However, when tested, 61 of the 68 lens types failed to meet standards for oxygen permeability set forth by ISO-18369-1:2017 (i.e., 30×10^{-11}(cm×mlO^2)/(sec × ml× mmHg)),[10] which is the international standard for contact lens materials claiming to have high oxygen permeability. In particular, all three of the three types of silicone lens that use polydimethylsiloxane (PDMS), five of the 47 types that used *Tris*(trimethylsiloxy)silane, and only one of 18 types of lens that use ETC 18 had oxygen permeability greater than 30×10^{-11}(cm×mlO^2)/(sec × ml × mmHg). Based on this, it is estimated that 89.7% of silicone hydrogel contact lens sold in Korea meet the definition for low oxygen permeability.[11] Moreover, 23 of the 42 types of silicone hydrogel contact lens approved for use in Korea (54.8%) are classified as cosmetic contact lenses.

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These lens have an average oxygen permeability of 15.27 ± 7.62×10^{-11}(cm×mlO^2)/(sec ×ml × mmHg), which shows that cosmetic contact lenses with oxygen permeability lower than the standards set forth by the ISO-18369-1:2017 (that is, 30×10^{-11} (cm × mlO^2)/(sec ×ml × mmHg)) have been approved for use as silicone hydrogel contact lens.[12]

Therefore, the goal of our study was to compare the current release status and oxygen permeability of cosmetic silicone hydrogel contact lenses being sold in Korea to promote safety standards for cosmetic contact lenses.

II. MATERIALS AND METHODS

2.1. Methods for Collecting Contact Lens Information

Information about the base curve, lens diameter, water content, graphic-size, and production approval number of 270 cosmetic silicone hydrogel contact lenses listed on the websites of four chain stores commonly used to sell contact lenses in Korea was collected. Information on the oxygen permeability and core width of contact lenses not listed on websites for these chain stores were collected using product approval numbers retrieved from the Ministry of Food and Drug Safety Medical Device's Electrical Civil Complaint Filing Website (https://emed.mfds.go.kr/#!CECAB01F010). Information on the production approval of contact lenses was only retrievable if lens had been approved after August of 2012.

2.2. Analyses of Contact Lens Information

For each type of contact lens we reviewed, the correlation between oxygen permeability and water content was analyzed, and lenses were checked to determine whether they met standards for high oxygen permeability defined by ISO-18369-1:2017, and for the standards for appropriate oxygen permeability suggested by Holden and Mertz.

2.3. Definition of the Counting Increments

Many types of contact lenses are sold under a single production approval number, and the same contact lens design can be sold under different brands names, depending on the chain store selling the lens. Therefore, the counting increment of each production approval number is referred to as 'type,' while the number of brands being sold is referred to as 'lenses.'

2.4. Statistical Analyses

For data analyses, Rex Ver. 1.0(Seoul National University Health Statistics Lab., Korea)as used for descriptive statistics to show the physical properties of cosmetic silicone hydrogel contact lens, as well as to describe the relationship between water content and oxygen permeability.

III. RESULTS AND DISCUSSION

3.1. Sales Status of Silicone Hydrogel Contact Lenses in Chain Stores

According to data posted on store websites, SA store sold 127, SB store sold 31, SC store sold 40, and SD store sold 72 brands of cosmetic silicone contact lenses, for a total of 270 lens brands. Of these, 121 had been approved before September 2012, and no information could be retrieved about them. For lenses that were approved after August 2012, information on 83 lenses (63.8%) was available from SA; information on 8 lenses (25.8%) was available from SB; information on 22 lenses (55.0%) was available from SC, and information on 38 lenses (52.8%) was available in SD [Table 1].

Table 1. Sales status of cosmetic silicone hydrogel contact lenses by company

Company	Total (%)	Non-Retrievable (%)	Retrievable (%)	Proportion of retrievable lenses per company (%)
SA	127 (47.0)	46 (38.0)	83 (54.4)	63.8
SB	31 (11.5)	23 (19.0)	8 (5.4)	25.8
SC	40 (14.8)	18(14.9)	22 (14.8)	55.0
SD	72 (26.7)	34 (28.1)	38 (25.5)	52.8
Sum	270 (100.0)	121 (100.0)	151(100.0)	55.2

The average size of the base curve for all lenses was 8.7 mm (range: 0.3). The average diameter of lenses was 14.2 mm (range: 0.5), and the average graphic size was 13.4 mm (range: 1.6). Compared to lens sold in SB and SC, the variability in base curve size was more variable for lenses sold in SA and SD. The stores that sold lenses with the most variability in lens diameter were SA, SB, and SC, and the store that sold lenses with the largest variation in graphic size was SA. Lenses from SA displayed the greatest variability in base curve, diameter, and graphic size out of the group of lenses approved after August 2012 as well [Table 2].

Table 2. Status of physical properties of cosmetic silicone hydrogel contact lens by company

Company	Total(range)			Retrievable (range)		
	Basecurve	Diameter	Graphicsize	Basecurve	Diameter	Graphicsize
SA	8.7 (0.3)	14.2 (0.5)	13.4 (1.5)	8.7 (0.2)	14.1 (0.5)	13.3 (1.5)
SB	8.7 (0.2)	14.3 (0.5)	13.5 (0.6)	8.6 (0.1)	14.0 (0.2)	13.5 (0.0)
SC	8.7 (0.2)	14.2 (0.3)	13.4 (1.2)	8.6 (0.0)	14.1 (0.2)	13.3 (1.1)
SD	8.7 (0.3)	14.2 (0.5)	13.4 (1.0)	8.7 (0.2)	14.2 (0.1)	13.4 (0.8)
	8.7 (0.3)	14.2 (0.5)	13.4 (1.6)	8.7 (0.2)	14.2 (0.5)	13.4 (1.6)

Compared to the other stores, SA sold the largest number of lens types and the greatest variety of in lens properties. SA also had a higher proportion of lenses with available information on oxygen permeability due to having been approved after August 2012. In contrast, SB sold a small variety of lenses and, therefore, was judged to not have a significant variation in physical properties. Although SB store had a small selection of lenses, the proportion of lenses sold by SB that had been approved before September 2012 was high, and therefore, the probability that consumers were purchasing lenses without retrievable information was high.

3.2. Status by Product Approval Number

Excluding two brands of lenses (whose product approval number could not be identified), 268 brands of contact lenses were divided into 27 product approval numbers, resulting in 9.9 lens designs per product approval number. Of these, 119 lens brands, spanning six product approval numbers, had been approved before September 2012. In all, we were able to check information such as oxygen permeability for 149 brands of lenses covering 21 product approval numbers.

Cosmetic silicone hydrogel contact lenses were first approved in 2004. Four brands of lenses we reviewed had been approved for use as cosmetic silicone hydrogel contact lenses in 2008, but information on these lens was not available. A total of 54 designs were being sold under product approval number 11-1168. As of June 3, 2012, 60 brands of lenses were approved with product approval numbers.

The average oxygen permeability of contact lens we reviewed was 18.9 ± 8.4×10-11(cm × mlO2)/(sec × ml× mmHg), and the average water content was 46.5 ± 5.9%. Only one brand of lens we reviewed (4.8% of the sample) met the standards for oxygen permeability set forth by ISO-18369-1:2017. Results of our analysis showed that water content of lens tended to be high [Table 3].

Among the daily use lenses we reviewed, 51 brands of lenses, covering 7 types, exceeded the standards for oxygen permeability needed to avoid corneal edema (which requires that oxygen in the air be transferred to the cornea), with an oxygen transmissibility of 24×10-9(cm × mlO2)/(sec × ml × mmHg). In addition, 15 brands of contact lenses we reviewed, covering two categories, exceeded the standard needed to prevent stromal anoxia, with an oxygen permeability value of 30×10-11(cm × mlO2)/(sec × ml × mmHg).

Table 3. Status by product approval number

Product Approval Number	Lenses	Approval Date	permeability (Dk)	Water content	Center thickness	Transmissibility (Dk/t)
04-173	1	Feb 2004	-	-	-	-
08-551	4	Aug 2008	-	-	-	-
11-1168	54	21 Oct 2011	-	-	-	-
12-732	1	11 June 2012	-	-	-	-
12-745	14	12 June 2012	-	-	-	-
12-756	27	12 June 2012	-	-	-	-
12-1517	1	29 Nov 2012	25	55	0.100	25.0
13-588	3	22 Mar 2013	12	43	0.087	13.8
13-1109	9	25 June 2013	25	55	0.070	35.7
13-1793	3	24 Oct 2013	25	55	0.100	25.0
14-521	4	3 Mar 2014	20	43	0.100	20.0
14-890	15	17 Apr 2014	21	48	0.80	26.3
14-1408	3	30 Jul 2014	11	45	0.087	12.6
14-1437	3	4 Aug 2014	12	43	0.087	13.8
14-2965	1	10 Dec 2014	20	55	0.085	23.5
15-459	5	2 Apr 2015	20	55	0.080	25.0
15-460	2	2 Apr 2015	12	46	0.087	13.8
15-889	19	5 June 2015	10	40	0.090	11.1
15-1133	12	10 Jul 2015	20	55	0.080	25.0
15-1549	2	4 Nov 2015	12.5	40	0.100	12.5
15-1580	21	13 Nov 2015	10	42	0.085	11.8
16-249	12	4 Apr 2016	15	42	0.110	13.6
16-751	2	13 Oct 2016	11	42	0.091	12.1
16-752	17	13 Oct 2016	11	42	0.091	12.1
16-1010	6	27 Dec 2016	32	40	0.080	40.0
17-395	5	13 June 2017	13	48	0.100	13.0
17-641	4	23 Aug 2017	11	42	0.090	12.1
평균	9.9		16.6±6.4	46.5±5.9	0.09±0.01	18.9±8.4

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3.3. Correlation between oxygen permeability and water content

Results of the correlation analysis: Spearman rank correlation coefficient (rs) analysis between oxygen permeability and water content for the 21 product approval numbers was 0.555 (p = 0.009), which shows a clear correlation.

Table 4. Spearman rank correlation coefficients for oxygen permeability and water content

	Oxygen permeability	Water content
Oxygen permeability	1.000	
Water content	0.555**	1.000

*p<0.05 **p<0.01 ***p<0.001

This linear relationship can also be illustrated as the scatter plot, with one outlier [Fig. 1].

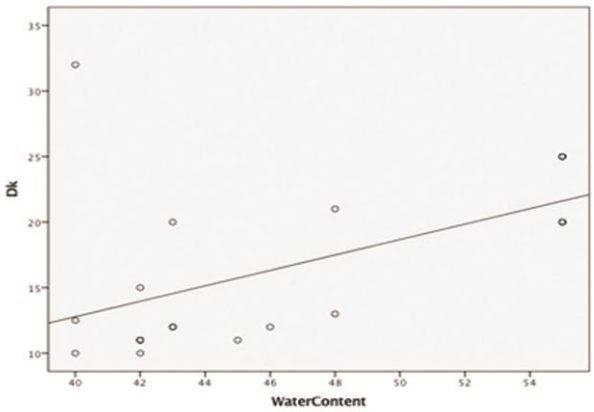

Figure 1. Scatter plot illustrating oxygen permeability and water content

Results of a second Spearman rank correlation coefficient between oxygen permeability and water content after excluding the outlier found an even stronger correlation of0.785 (p< 0.001) [Table 5]. This indicates that the oxygen permeability of cosmetic silicone hydrogel contact lens was due to the increase in the water content. However, ISO 18369-1:2017 specifies that oxygen permeability of high oxygen permeability materials, (which includes silicone hydrogel contact lens) should not be related to water content.

Table 5. Spearman rank correlation coefficients for oxygen permeability and water content, after excluding outliers

	Oxygen permeability	Water content
Oxygen permeability	1.000	
Water content	0.785***	1.000

*p<0.05 **p<0.01 ***p<0.001

According to the study by Efron and Morgan,13 the Spearman rank correlation coefficient between oxygen permeability and water content for hydrogel contact lenses was 0.940 (p<0.001). This shows that oxygen permeability increased as water content increased. However, though not applicable to all silicone hydrogel materials, silicone hydrogel contact lenses tend to decrease in oxygen permeability as water content increases.

The linear nature of the relationship between oxygen permeability and water content observed in the 21 approved brands of lens reviewed in this study was similar to that of hydrogel contact lenses. Silicone hydrogel is defined, in Section 4.4 of ISO 18369-1:2017, as a material having oxygen permeability greater than 30 Dk. However, of the 21 approved brands of lens we reviewed, only one brand (4.8%) exceeded 30 Dk, which is shown in Fig. 1 as an outlier.

Once we excluded this outlier, the mean oxygen permeability of lens was 15.8 ± 5.5 Dk, and the mean water content was 46.8 ± 5.9%. Compared to oxygen permeability before exclusion of the outlier, the mean oxygen permeability was lower and the mean water content higher, and the Spearman rank correlation coefficient changed to 0.784 (p<0.001), which was similar to that of hydrogel contact lenses.

Information on cosmetic silicone hydrogel contact lenses approved and sold before August 27, 2012 was not retrievable from Korea's Ministry of Food and Drug Safety homepage. Information on lens approved afterward these data, however, was available on the homepage. As there is no obligation to do so, many products are sold without displaying their oxygen permeability.

According to a report by the Consumers Union of Korea14 (which measured three of cosmetic silicone hydrogel contact lenses using methods outlined by ISO-18369-4:201715), two of the three lenses being sold to consumers had oxygen permeability values significantly below the values that were reported to the Ministry of Food and Drug Safety (MFDS) in order to receive a production approval number.

In addition, according to the report, one of the three lens types reviewed actually had better oxygen permeability than what was reported to the MFDS but were difficult to categorize as contact lenses of silicone hydrogel material [Table 6].

Table 6. Comparison between test results for consumers union of Korea and oxygen transmissibility reported to the Ministry of Food and Drug Safety

Product Approval Number	Oxygen transmissibility		Oxygen transmissibility error range (±20%)
	Test result	Reported	
14-890	14.38	26.3	9.60 ~ 14.40
15-113	8.86	25.0	6.40 ~ 9.60
15-1549	14.14	12.5	14.00 ~ 14.40

Because of this, improved standards, such as the mandatory reporting of oxygen permeability levels on contact lens labels, are needed so that consumers can obtain information on oxygen permeability and water content easily when purchasing contact lenses. Cosmetic silicone hydrogel contact lenses have low oxygen permeability and have physical properties similar to those of hydrogel contact lenses.

However, because silicone hydrogel contact lenses are known to have high oxygen permeability, people sometimes mistake cosmetic silicone hydrogel contact lenses (which actually have low oxygen permeability) for high oxygen permeability lens, and are likely to wear them for a long time.

Furthermore, because reporting the oxygen permeability level on labels for contact lens is not required by current Korean medical device standards, getting access to information on oxygen permeability can be difficult for consumers. 16 As described above, information on cosmetic silicone hydrogel contact lenses approved before September 2012 is not available. In addition, lenses that may have the physical properties needed for high oxygen permeability but which are difficult to categorize as silicone-material contact lenses may inadvertently be sold as silicone hydrogel contact lenses, adding to the difficulty for consumers. However, it is difficult to improve the low quality of silicone hydrogel contact lenses because there are no standards regulating them currently.

In addition, examinations conducted by the government to test whether contact lenses meet the current standards do not include oxygen permeability as standard component. As a result, the oxygen permeability of contact lenses in these tests is not checked for, even if the oxygen permeability levels being advertised to consumers are different than what was reported to the Consumers Union of Korea.

Therefore, increasing the quality of silicone hydrogel contact lenses to ensure they meet standards outlined in ISO 18369-1:2017 and terminating the sale of low-quality silicone hydrogel contact lenses can contribute to the eye health of contact users in Korea, where long-term use of contact lens, and use of cosmetic contact lens among young women in particular, are increasing.8, 17 In addition, the oxygen permeability of contact lens needs to be included in the sample collection and examination criteria, and guidance and strategies for addressing lenses that have lower oxygen permeability than what was reported need to be developed.

Data for this study were collected and analyzed using information from the Ministry of Food and Drug Safety based on data submitted by the manufacturers. As a result, a limitation of this study is that were not able to consider cases in which oxygen transmissibility values listed on contact lens packaging differed from data report to the Consumers Union of Korea, which is used in examinations performed by the government. Thus, further research is needed to collect the cosmetic silicone hydrogel contact lenses released on the market and analyze them using polarographic methods used to develop the ISO 18369-4:2017 standards.

IV. CONCLUSION

Of the 270 brands of cosmetic silicone hydrogel contact lenses being sold in the four chain stores evaluated in this study, only six (2.2%) samples (classified under one (3.7%) product approval number) satisfied the standards for oxygen permeability issued by the ISO silicone hydrogel lenses. Because current labels for silicone hydrogel contact lenses may not provide consumers with any information alerting them that the lens may have low oxygen permeability, people should exercise caution when purchasing them. Information about the oxygen permeability and water content of contact lenses should be mandatory for labels so that consumers can make an informed choice when buying contact lenses. Testing for oxygen permeability during sample collections and examinations is also needed to determine whether contact lenses being sold to consumers meet current standards. Additionally, results of this study identified the need for improvement in standards governing silicone hydrogel contact lenses to ensure they are on par with ISO 18369-1:2017.

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