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Evaluation of Contact Lens Care Regimens in Removing Tear Lipids on Silicone Hydrogel Lens

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Purpose: An in vitro study was conducted to compare the lipid cleaning efficacy of care solutions on balafilcon A silicone hydrogel (SiHy) lens. **Methods:** Lipid spoilation was performed by incubating balafilcon A SiHy lenses in phosphate buffered saline (PBS) containing oleic acid, oleic acid methyl ester and cholesterol. Spoiled contact lenses rinsed with PBS were cleaned with surfactant cleaner, alcohol containing cleaner and multipurpose solution (MPS) respectively and repetitive spoilation and cleaning was conducted up to 14 times. To observe the cleaning effect of ultrasonic wave on the lipid deposit, each spoiled lens was ultrasonicated and then compared with non-sonicated lens. Lipids deposit on the contact lenses was extracted by methanol:chloroform (1:1, v/v) solution. High performance liquid chromatography was used to analyze and quantify lipid deposit extracts. **Results:** The effectiveness of alcohol containing surfactant cleaner on the lipid deposits was better than that of surfactant cleaner and MPS, and the cleaning efficacy was significantly higher in the ultrasonic wave treated group. Lipid deposits were not removed completely by contact lens care solutions so that lipid deposits increased continuously and cumulatively. **Conclusions:** The cleaning efficacy of contact lens care solutions was not satisfactory to remove lipid deposits on the SiHy lens that new cleaning products specially designed for SiHy lenses are needed to develop.

Key words: Silicone hydrogel lens, Lipid deposit, Contact lens cleaner, Ultrasonic wave, High performance liquid chromatography

Introduction

Contact lenses have several advantages over spectacles. Due to their direct contact with tear film, however, they progressively adsorb tear film materials, and form deposits on the lens surface[1,2]. Mainly, these deposits are proteins and lipids from the tear fluid[3-5]. In turn, these deposits are associated with infection, inflammatory complications, reduction in visual acuity, discomfort, and dryness[6-8].

The tear film is composed of mucous, aqueous and lipid layer. Among them the lipid layer protects the aqueous tear fluid from evaporation. The tear lipid layer is composed of two phases. One is a thin polar phase that is found adjacent to the mucin-aqueous phase and the other is thick nonpolar phase that is associated with the environment. The polar phase is 8% of the lipid layer and consists of 60% phospholipids such as phosphatidylcholine (PC), and phosphatidylethanolamine (PE). The nonpolar phase is 92% of the lipid layer and consists of cholesterol (CH) and cholesterol esters[9,10]. Taken as a whole, the contact lens adsorbs lipids from the two layers. What quantities of lipid deposits that are to be found on the worn contact lens depends upon the lens material and the lens care solution[8,9].

Silicone hydrogel (SiHy) lenses are composed of new materials unlike the conventional hydrogel lens[11,12]. Most importantly, they incorporate siloxane groups, giving SiHy lenses exceptional oxygen transmission capabilities. To the contact lens wearer this feature offers advantages over the traditional hydrogel lens. Hypoxia-related complications are

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reduced or eliminated, protein deposits on the lens surface are reduced and the user is afforded a greater ease of handling. For these benefits, however, the migration of siloxane moieties to the material surface produces surfaces that are extremely hydrophobic. To overcome hydrophobicity SiHy lenses are surface treated. Commercially available SiHy lenses are modified in a gas plasma reactive chamber to create an ultrathin surface, or they are treated in a gas plasma reactive chamber to transform the silicone components into hydrophilic silicate compounds to improve wettability[13]. And yet, hydrophobicity persists relative to traditional hydrogel lenses that lipid adsorption is greater in SiHy lenses than conventional soft lenses[13].

Products used in lens care cleaning are specifically designed to remove contact lens deposits. Even though many soft contact lens solutions have been used for the SiHy lenses, its cleaning effectiveness in removing lipid deposits on the SiHy lenses have not been proven.

We designed our study in vitro condition to investigate the lipid cleaning effect of contact lens care solutions on SiHy lens using high performance liquid chromatography (HPLC).

Subjects and Methods

1. Sample lens

Lens material used in this study was balafilcon A (PureVision, Bausch & Lomb). Table 1 details some of the characteristics of these lens. Five lenses of each group were used for the analysis.

2. Preparation of artificial lipid solution

To simplify the results of this study, we designed our study in vitro using artificial lipid solution. Oleic acid, oleic acid methyl ester and cholesterol were purchased from Sigma (Saint Louis, MI). Artificial lipid solution was prepared by modifying 0.9% saline solution containing oleic acid, oleic acid methyl ester and cholesterol at a concentration of 180 μg/mL respectively using phosphate buffered saline (PBS), pH 7.4[14,15]. Oleic acid and oleic acid methyl ester were identified as the major lipid deposits on the balafilcon A SiHy lens[16,17], that we chose them among five major lipids (cholesteryl oleate, cholesterol, oleic acid methyl ester, oleic acid and triolein) extracted from worn contact lenses[18].

Table 1. Characteristics of SiHy lens used in this study

Lens material	Balafilcon A
Surface modification	Plasma oxidation
Monomers	TPVC, NVP, NCVE, PBVC
FDA classification	Group III
Base curve	8.6mm
Total diameter	14.0mm
Water content	36%

TPVC; tris(trimethylsiloxysilyl) propylvinyl carbamate, NVP; N-vinylpyrrolidone, NCVE; N-carboxyvinyl ester, PBVC; poly(dimethylsiloxy) di(silybutanol) bis (vinyl) carbamate

3. Lipid spoliation and cleaning

Lipid spoilation was performed by incubating Balafilcon A lenses at 34.5°C in sealed vials with 1 mL of artificial lipid solution with gentle stirring (shaking at 50 rpm). Based on the report by Bontempo and Rapp[18], in vitro lipid-deposited lenses were incubated for 24 hours, a lipid accumulation time considered equal to that of contact lenses worn for one day in vivo condition. Each spoiled lens was rinsed with PBS and cleaned using digital rubbing with a designated contact lens care solutions for 10 seconds per each side. The three kinds of commercially available lens care solutions (surfactant cleaner, alcohol-containing clearer and multipurpose solution (MPS), Table 2) were used for contact lens cleaning.

For the repetitive lipid spoilation, each spoiled lens rinsed with PBS was cleaned using digital rubbing with lens care solutions (alcohol-containing cleaner and MPS) for 10 seconds per each side and they were also respoiled and cleaned up

Table 2. Ingredients of contact lens care solutions in this study

Solution	Manufacturer	Ingredients
Surfactant cleaner	Choongwae	poloxamer 407
Miraflow	Ciba Vision	poloxamer 407, isopropyl alcohol 15.7%, amphoteric 10
ReNu	Bauch & Lomb	poloxamine, hydranate(hydroxyalkyl phosphonate), EDTA

to 14 times.

4. Ultrasonic wave treatment for the cleaning

To observe the effect of ultrasonic wave on the lipid deposited contact lens, each lens was placed in saline containing 3 drops of care solutions in the lens case, and was then ultrasonicated for 1 minute, 5 times in a water bath (Branson 5210 ultrasonic cleaner, 40 KHz) and then digitally cleaned.

5. Lipid extraction from the spoiled lenses

Each lens was placed in an extraction solvent containing 50:50 methanol/chloroform (v/v) and double-extracted on an ultrasonicator (Branson 5210 ultrasonic cleaner, 40 KHz) for 1hour. After extraction, each lens was removed and rinsed with extraction solvent. The extraction solvent in the lipid extraction solution was completely removed by centrifugal vacuum evaporator (Eyera, Japan), and 150 μL of 66.7:33.3 acetonitrile/chloroform (v/v) solvent was used to resolubilize the extracted lipids. These samples were vortexed for 1 minute and transferred to HPLC vials.

6. Lipid analysis by HPLC method

We used an Agilent 1100 series HPLC instrument (Agilent, Santa Clara, CA) for the analysis. All mobile phase solvents were reagent grade and obtained from Aldrich (St Louis, MO). C-18 column (5 μm diameter particle size, 4.5 × 150 mm dimensions, Eclipse) and an 95:5 acetonitrile/water (v/v) solution as the mobile phase of isocratic flow were used for separation. The column was operated for 35 minutes at a flow rate of 1.2 mL/minute at 35°C and eluted lipids were detected at the UV absorbance at 205 nm with a UV spectrophotometer (Hitachi L 4000). Standard samples of oleic acid, oleic acid methyl ester, and cholesterol were purchased from Sigma and dissolved in a solvent system composed of 66.7/33.3 acetonitrile/chloroform (v/v). Ten μL of standard or each sample was injected and the amount of lipid was calculated by the integrated using software ChemStation (Agilent). For the calibration curve, 0.25 mg/mL, 1 mg/mL and 2.5 mg/mL of standard lipid solutions were used.

7. Measurement of contact lens parameters after ultrasonic wave treatment

Lens parameters were measured with Base Curve Screen (for base curve and total diameter, JCF, OPTIMEC), Electronic Thickness Gauge (for center thickness, ET-3, Rehder Development Company), and Magnon (for lens power, LM-770, NIDEC) before and after ultrasonic wave treatment respectively.

8. Light transmittance of lipid spoiled lens

Lipid spoilation was performed by incubating balafilcon A SiHy lenses in artificial lipid solution for 24 hours. Spoiled contact lenses were cleaned with alcohol containing cleaner and MPS respectively and light transmittances of the contact lenses were measured at the visible light (400~800 nm) by using spectrophotometer (Shimadzu, UV1601 PC).

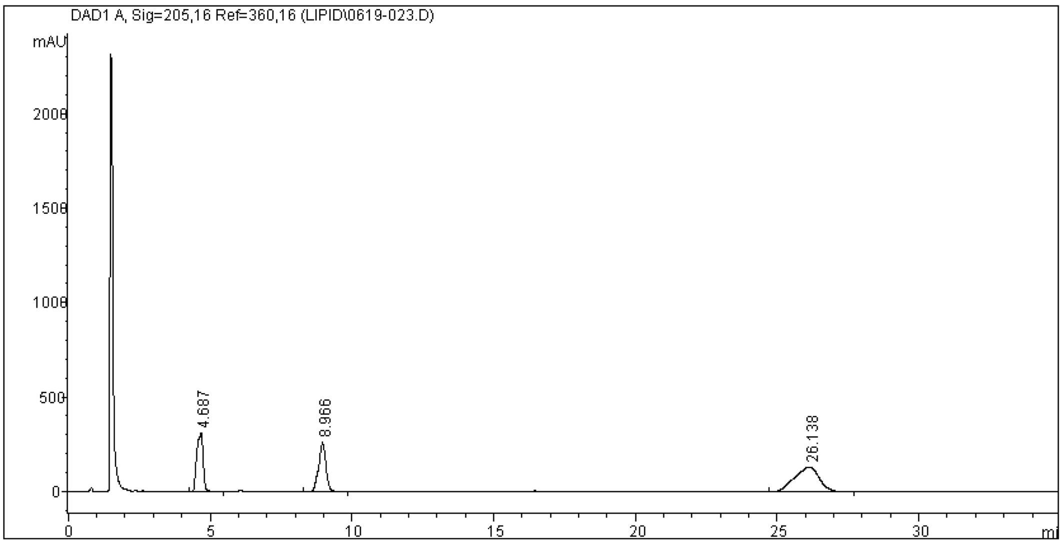

Fig. 1. Representative high-performance liquid chromatogram using the HPLC method from a 1 mg/mL standard sample mixture of oleic acid, oleic acid methyl ester, and cholesterol having retention times of 4.7, 9.0, and 26.1 minutes, respectively.

Results

1. HPLC profile

Fig. 1 shows typical HPLC chromatogram from a three-component mixture of standard oleic acid, oleic acid methyl ester and cholesterol eluted with 95% acetonitrile. The order of eluted compounds was oleic acid, oleic acid methyl ester followed by cholesterol and those three components separated well. The elution time of oleic acid, oleic acid methyl ester and cholesterol were 4.7 min, 9.0 min and 26.1 min respectively (Fig. 1). Each compound contains three-point calibration with linear correlation coefficients greater than 0.9995. Based on the calibration curves, we determined the amount of each lipid deposit on the contact lenses.

2. Amounts of lipid remaining on the balafilcon A lens cleaned by contact lens care solutions

Table 3 showed the percentage of lipid deposits on 24 hour-spoiled lenses removed by surfactant cleaner, alcohol based surfactant cleaner and MPS. The alcohol based surfactant cleaner showed the higher cleaning efficacy (37.9%) compared to surfactant cleaner (29.9%) and MPS (20.1%). And ultrasonic treatment enhanced the cleaning efficacy with 38.8% (surfactant cleaner), 49.4% (alcohol based surfactant cleaner)and 47.0% (MPS).

3. Changes of contact lens parameters after ultrasonic wave treatment

Table 4 showed lens parameter changes by ultrasonic wave treatment. There were no changes in total diameter, base curve, center thickness and lens power.

4. Lipids deposition on the balafilcon A lens over time

In vitro adsorption of the lipids to balafilcon A increased over the days of the spoilation and saturation was not complete by 14 times of spoilation (Fig. 2). The amounts of lipid adsorption to balafilcon A were 34.94±7.70 μg/lens, 114.50±5.00 μg/lens, 270.84±27.08 μg/lens and 605.57 ±38.92 μg/lens on 1, 3, 7 and 14 times of spoilation respectively.

Over time, lipid compounds showed different affinity to balafilcon A. Although oleic acid, oleic acid ester and cholesterol were adsorbed to balafilcon A similarly in the early spoilation, oleic acid was adsorbed more over repeated episodes of spoliation that oleic acid was the most prevalently adsorbed compound (about 64% of total lipid deposits) and cholesterol was the least sorbed compound. Cholesterol adsorption increased and plateaued after 7 times of spoilation, but saturation was not completed with oleic acid and showed a steady adsorption pattern (Fig. 3).

The lipid deposit was increased gradually with repetitive spoilation even with the cleaning process that total average amount of lipid deposit on SiHy lenses was 374.53± 27.83

Table 4. Change of parameters by repetitive ultrasonication on balafilcon A SiHy lenses (n=5/each group)

Group	contact lens parameter (Mean±SD)		
	control	sonicated	p-value
Total diameter (mm)	14.05±0.00	14.06±0.02	0.422
Base curve (mm)	8.45±0.00	8.42±0.00	0.184
Center thickness (mm)	0.095±0.000	0.092±0.000	0.118
Power (D)	−3.00±0.00	−3.00±0.00	.

All lenses were repetitive sonicated for 1 minute, 5 times in a water bath. The value of tolerance: total diameter; ±0.05 mm, base curve; ±0.025 mm, center thickness: ±0.02 mm, power: ±0.25D

Table 3. Amount of lipid deposits and cleaning efficacy on 24 hour-spoiled balafilcon A SiHy lenses cleaned with contact lens care solutions

Cleaner		Amount of lipids deposited	Cleaning efficacy (%)
Control (without cleaning)		124.55 ± 44.95	
non-sonicated	Surfactant cleaner	87.34 ± 22.93	29.9
	Alcohol based surfactant cleaner	77.51 ± 28.97	37.9
	Multipurpose solution (MPS)	99.47 ± 42.08	20.1
sonicated	Surfactant cleaner	76.24 ± 18.55	38.8
	Alcohol based surfactant cleaner	63.08 ± 13.81	49.4
	Multipurpose solution (MPS)	66.00 ± 15.35	47.0

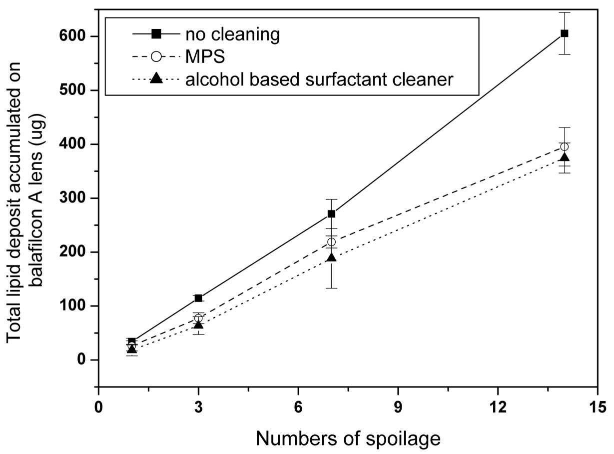

Fig. 2. The adsorption of lipid deposit on balafilcon A SiHy lenses with repeating spoilage and cleaning up to 14 times.

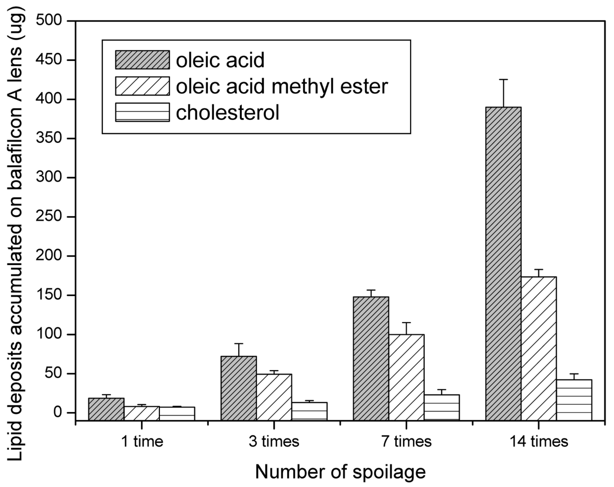

Fig. 3. The amount of oleic acid, oleic acid methyl ester and cholesterol deposition on balafilcon A SiHy lenses up to 14 times.

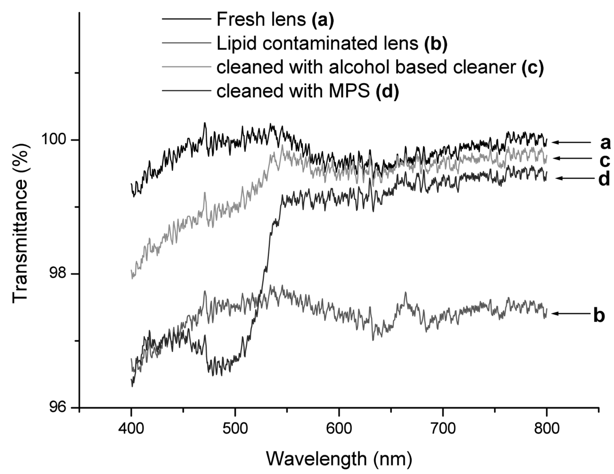

Fig. 4. The visible ray transmittance of fresh new, lipid contaminated lenses and lipid-deposited balafilcon A SiHy lens cleaned with alcohol-based cleaner and MPS after 24 hours of spoilation with shaking at 34.5°C.

μg/lens (alcohol based surfactant cleaner) and 395.37± 35.64 μg/lens (MPS) on the 14 times treated contact lenses (Fig. 2). At each time, alcohol based surfactant cleaner removed more lipids than MPS.

5. Light transmittance of lipid spoiled lens

Lipid spoiled lenses that were cleaned with alcohol-based surfactant cleaner or MPS showed lower transmittance, especially on the short wavelengths than that of fresh SiHy lens in the visible range (Fig. 4).

Discussion

Lipid adsorption may be more prevalent for SiHy lens compared with HEMA lens because of the relatively hydrophobic surfaces. A specific cleaner for SiHy lenses has not been manufactured and the efficacies of lens care solutions on the SiHy are not well known.

Despite surface treatment of the lens materials SiHy lenses had a strong attraction for lipids. The deposition of lipid is primarily driven by the hydrophobic lipids adhering to hydrophobic sites on the lens surface. It is known that nonionic lenses were more prone to lipid deposition, and low-water, ionic lenses (group III were the least prone to fouling of lipids in the traditional soft contact lenses. But this theory did not fit in the SiHy lenses currently used on the market[19]. Based on research by Carney et al[2] the highest amount of adsorption of lipid was with senofilcon A, galyfilcon A (group I lenses), whereas the lowest adsorption was with lotrafilcon A and B (group I lenses). And balafilcon A (group III lens) adsorbs lipid in higher amounts than lotrafilcon[16]. The deposition process is not completely understood but is known to be affected by a number of factors such as surface hydrophilicity, and surface charge that hydrophobic areas would be expected to attract lipids[16].

It was reported that SiHy lenses have a greater affinity for the nonpolar lipid than for the polar lipid in vivo condition[20,21]. However, it was also reported that SiHy lenses have a higher affinity for the polar lipid (oleic acid) than the nonpolar lipid (cholesterol) under the identical concentration of lipids in vitro condition[17]. In this study, we also found balafilcon A has a greater affinity for the oleic acid than for cholesterol under the identical concentration of lipids. The adsorption saturation of phosphatidylethanolamine (polar lipid) on balafilcon A occurred by day 14, whereas saturation was not completed for cholesterol by day 20 in vitro condition[2]. In this study oleic acid and methyl oleate showed a steady adsorption pattern however cholesterol adsorption increased and plateaued after the 7th spoliation, This result may also indicate a polar area of material on the balafilcon A contact lens remains and provides a hydrophilic area and plays a role in affinity to polar lipids.

The cleaning efficacy of the alcohol based surfactant cleaner was 37.9% which is higher than surfactant cleaner (29.9%) and MPS (20.1%). This disparity between cleaning efficacies of solutions may be due to surfactant, and alcohol may help in removing lipids. Efron et al.[22] reported that ultrasound devices are effective for removing mascara and bacteria on the surface of soft contact lenses. Ultrasound transfers energy from a mechanical generator of sound waves in the bathing medium to the interface between this medium and the contact lens. The energy released at the bathing medium-lens interface must be of a sufficient intensity to break the bond between the lens surface and the contaminant. We found ultrasonic treatment enhanced the cleaning that ultrasonic waves showed 1.3~2.3 times higher cleaning efficacy without any changes in contact lens parameters (in total diameter, base curve, center thickness and power). With this result we would suggest cleaning by exposure to ultrasonic waves in a water bath would be a very convenient method for removing lipids on SiHy lenses in the office or in the clinic.

To date, commercially available SiHy lenses are surface treated to enhance wettability by the tear film. However, hydrophobic areas on the lens surface and the loose silicone molecular structure make SiHy lenses permeable to lipid materials[23]. The lipid deposition was increased up to 395.37±35.64 μg/lens (cleaned by MPS) and 374.53± 27.83 μg/lens (cleaned by alcohol based surfactant cleaner) after 14 times of spoliation and cleaning tells us that there may be problems related to visual acuity.

The alcohol based surfactant cleaner showed higher cleaning efficacy for the SiHy lens compared to MPS, ultrasonic treatments enhanced the cleaning efficacy of both lipid deposits, but lipid deposit could be a weakness for the SiHy lens. Although these in vitro results may not be directly transferable to the in vivo state, in vitro study will provide valuable guidance for further in vivo studies and support predictable results in vivo state.

Conclusion

Lipid deposits were not removed completely by hydrogel lens care solutions suggesting cleaning SiHy lenses with hydrogel lens care solutions may not be an optimal situation. Although lens cleaning is significantly enhanced by ultrasonic waves treatment in a water bath that could be a convenient method to remove lipid, new cleaning products designed specifically for SiHy lenses are needed to develop.

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콘택트렌즈 관리방법에 의한 실리콘하이드로겔렌즈의 지방침전물 제거효과

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목적: 소프트콘택트렌즈 관리용액에 의한 balafilcon A 재질의 실리콘 하이드로겔렌즈에 부착된 지방 침전물 제거 효과를 비교하였다. **방법**: Balafilcon A 재질의 실리콘 하이드로겔렌즈를 실험실 조건에서 oleic acid, oleic acid methyl ester, cholesterol이 포함된 식염수에 담가 24시간 동안 오염시켰다. 오염된 콘택트렌즈는 식염수로 헹구어준 후 계면활성세척액, 알콜 성분이 포함된 세척액 및 다목적용액으로 각각 세척하였고, 반복적인 오염과 세척효과를 관찰하기 위해서는 오염과 세척과정을 14회 반복하였다. 초음파의 지방침전물 세척 효과를 관찰하기 위하여 오염된 렌즈에 초음파처리를 한 후 처리하지 않은 렌즈와 비교하였다. 지방침전물은 methanol:chloroform (1:1, v/v) 용액으로 추출하고 고성능액체크로마토그래피로 분석하여 정량하였다. **결과**: 실리콘 하이드로겔렌즈의 지방세척효과는 알콜성분을 함유한 세척액이 계면활성세척액 및 다목적용액보다 높았으며, 초음파를 함께 처리해준 경우에는 세척 효과가 상승하였다. 콘택트렌즈 관리용액으로 세척한 후에도 지방침전물은 완전히 제거되지 않아 오염과 세척을 반복한 경우 지방 침전물의 양은 지속적으로 증가하였다. **결론**: 실리콘 하이드로겔렌즈에 부착되는 지방 침전물에 대한 소프트 콘택트렌즈용 관리용액의 세척효과는 만족할 수준에 미치지 못하기 때문에 실리콘 하이드로겔렌즈의 지방 침전물 제거에 적합한 세척액의 개발이 필요할 것으로 사료된다.

주제어: 실리콘 하이드로겔렌즈, 지방침전물, 콘택트렌즈 관리용액, 초음파처리, 고성능액체크로마토그래피