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Artikel Asli/*Original Article*

Ocular Comfort Assessment in Hydrogel and Silicone Hydrogel Contact Lens Wearers

(Penilaian Tahap Keselesaan Okular Pemakaian Kanta Sentuh Hidrogel dan Silikon Hidrogel)

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ABSTRACT

The purpose of this study was to determine ocular comfort level in subjects wearing hydrogel and silicone hydrogel contact lens wear for 30 days on extended wear basis. A total of forty-two contact lens wearers were recruited in this study. The comfort level of contact lens wearers was graded using Visual Analogue Scale (VAS) with scale from 0 to 100. Comfort level was graded at the first, fifteenth and thirtieth day of wearing, followed by an overall grading for each type of contact lens. The median comfort level achieved by hydrogel and silicone hydrogel was 80.00 with interquartile range of 26.25 and 21.25 respectively. No significant difference ($p > 0.05$) were found. Over time both types of lens wearing showed deterioration in comfort, which was also not significant ($p > 0.05$). Comfort level can be achieved with either hydrogel or silicone hydrogel lenses. The level of comfort is independent of lens material or oxygen transmissibility.

Keywords: Comfort level; hydrogel; silicone hydrogel; lens material, oxygen transmissibility

ABSTRAK

Kajian ini bertujuan untuk menentukan tahap keselesaan okular pada subjek yang memakai kanta sentuh hidrogel dan silikon hidrogel selama 30 hari secara berpanjangan. Seramai 42 pemakai kanta sentuh telah menyertai kajian ini. Tahap keselesaan okular telah dinilaikan melalui Skala Visual Analogue (VAS) dari nilai 0 sehingga 100. Tahap keselesaan okular dalam hari pertama, ke-15 dan ke-30 telah dinilai, disertai dengan pengredan keselesaan okular secara keseluruhan bagi setiap kanta sentuh. Median tahap keselesaan okular keseluruhan yang dicapai oleh kanta hidrogel dan silikon hidrogel ialah 80.00, dengan julat interquartile 26.25 dan 21.25 masing-masing. Tiada perbezaan signifikan ($p > 0.05$) didapati antara dua jenis kanta sentuh. Terdapat penurunan dalam tahap keselesaan yang tidak signifikan ($p > 0.05$) dari segi tahap keselesaan okular, bagi kedua dua jenis kanta sentuh semasa tempoh pemakaian. Tahap keselesaan okular boleh dicapai semasa pemakaian kanta sentuh hidrogel ataupun silikon hidrogel. Tahap keselesaan okular tidak bergantung pada jenis material kanta atau transmisibiliti oksigen.

Kata kunci: Tahap keselesaan okular; hidrogel; silikon hidrogel; material kanta, transmisibiliti oksigen

INTRODUCTION

Extended wear basis is defined as an overnight modality of contact lens wear (AAO, 2013). In 2015, Food and Drug Administration (FDA) stated that in extended wear basis, contact lens wearers can sleep with the contact lens on for a maximum of 6 nights, followed by for one night laid-off. However, the chances of getting corneal infection are greater in extended basis, regardless of the contact lens material used (Poggio et al. 1989). Incidence of microbial keratitis during extended wear was investigated between silicone hydrogel and conventional hydrogel. It was found that the number of incidence was similar between both lenses (Schein et al. 2005). Nonetheless, both contact lenses used in this study had been approved by FDA to be worn as extended wear contact lenses.

A study was done to investigate ocular comfort level achieved with hydrogel and silicone hydrogel contact lens wear. At the end of the study, researchers reported that there was no significant difference between both contact lenses. Subjects also reported that there was a decline in comfort level when wearing both types of contact lenses at the end of the day. However, this declination was not significant between these two types of contact lenses (Santodomingo-Rubito et al. 2010).

In a double-masked study that involved randomised distribution of contact lenses to the subjects, it was found that there was no difference in the ocular comfort level between silicone hydrogel and hydrogel lenses, as well as in the lens performance after one month (Cheung et al. 2007). In the study, subjects were given silicone hydrogel (Acuvue Advance) in one eye and hydrogel (Acuvue 2) in another, randomly. For a one-month period, subjects were

instructed to wear the lenses for 8 to 12 hours in a day and at least 6 days in a week.

In 2003, Fonn and Dumbleton too did a study to determine the ocular comfort level achieved by silicone hydrogel and hydrogel lenses. Subjects were given one silicone hydrogel (Focus Night & Day) and 3 hydrogel lenses (Focus Dailies, Acuvue 2 and Proclear Compatibles) to try on. Subjects were asked to grade the comfort level given by each contact lens after 7 hours of wearing time. In that study, there was no difference in comfort level found between those lenses.

Nevertheless, the other important factor in determining comfort is the water content of the contact lens. As been mentioned in a study by Wild et al. (1995) the higher water content contact lens will pose more comfort compared to the lower one. However, no significant difference between the lenses in terms of ocular physiology, fitting performance, or spoilation.

The main aim of this study was to investigate whether Maxvue Hydrosoft being hydrogel lens which is suitable for extended wear, is comparable to silicone hydrogel in terms of the ocular comfort level it provides.

MATERIALS AND METHODS

Fourty two contact lens wearers (all females), who were students from Universiti Kebangsaan Malaysia (UKM) KL Campus participated in this study. The inclusion criteria of this study were; existing contact lens wearers with best corrected visual acuity (VA) of LogMAR 0.2 on both eyes, refractive error of PL to -8.00 DS and astigmatism with not more than -0.75 DC, tear break-up time (TBUT) of at least 4 seconds without symptoms of dry eye and free from any ocular or systemic diseases. The protocol of this study was approved by Ethical Committee of UKM (Reference Number: UKM PPI/111/8/JEP-2017-160), followed by informed consent obtained from all subjects.

This study was done in double-masked randomised manner. All subjects were given silicone hydrogel (Maxvue Airsoft™; Dk/t 190, water content 47%) to be worn on one eye and a hydrogel (Maxvue Hydrosoft™; Dk/t 26, water content 53%) on another. Both lenses were from the same company and were monthly disposable type. All subjects were given the same multipurpose solution (MPS) manufactured by Maxvue Company for lens care purposes. The wearing hour suggested was at least 8 to 10 hours daily for 30 days.

All assessments were done before and after lens wear and were conducted at Optometry Clinic, Faculty of Health Sciences, UKM. Assessments taken were ocular comfort level grading, VA, central corneal thickness (CCT), slit lamp biomicroscopy comprising of the evaluation of ocular status i.e. bulbar and palpebral redness, corneal staining and TBUT. Grades were given with reference to Efron Grading Scale. However, only thirty-five subjects managed to return for post assessment after 30 days wear.

GRADING OF OCULAR COMFORT LEVEL

Ocular comfort level was graded using Visual Analogue Scale (VAS), at a scale from 0 (least comfortable) to 100 (most comfortable). After 30 days of lens wear, subjects were allowed to grade the overall comfort level as well as the specific comfort level during three different times for both contact lenses.

ASSESSMENT OF VA, CCT AND SLIT LAMP BIOMICROSCOPY

VA was taken using LogMAR at 3 metres, with subjects' best correction on. Contact lens wearers whose corrective power and best corrected VA did not meet the inclusion criteria were excluded in this study.

CCT was measured using ultrasonic pachymeter (Pachymeter Tomey AL-2000). 10 measurements were taken in each eye and the average CCT was recorded. Prior to the measurement, topical anaesthetic (Alcaine, 0.5%) was instilled on both eyes. Subjects were asked to fixate at a target on the wall which was at their eye level while measurements were taken.

Slit lamp biomicroscopy was done to assess their ocular status. Grading of the ocular status was done with reference to Efron Grading Scale. Bulbar conjunctiva was being observed at all 4 quadrants, overall grading was recorded. Palpebral conjunctiva was examined by everting subjects' upper eyelid and an overall grading was recorded. Fluorescein was applied on both eyes to assess subjects TBUT and corneal staining.

ANALYSIS OF RESULTS

The data were all not normally distributed referring to Shapiro-Wilk normality test. Hence, Wilcoxon Signed-Rank Test was used to evaluate the differences of overall comfort level between silicone hydrogel and hydrogel. Friedman Test was used to evaluate the differences of ocular comfort presented at three different times with both contact lenses.

On the other hand, Wilcoxon Signed-Rank Test was used to evaluate the differences of VA, CCT and TBUT before and after the lens wear, followed by ocular status i.e. bulbar and palpebral conjunctiva and corneal staining, between silicone hydrogel and hydrogel. The statistic was assumed at significance level of 0.05. Median was taken in throughout this study as non-parametric analysis was being carried out.

RESULTS

A total of forty-two subjects were included in the grading of ocular comfort level whereas only 35 subjects managed to return for the assessments after lens wear. Seven subjects who failed to do so were contacted to give feedback on ocular comfort level via phone calls. Overall the median comfort level for both silicone hydrogel and hydrogel were

80.00 and there was no significant difference of comfort level found between these lenses ($T = 128.50$, $p > 0.05$). Both lenses showed deterioration in ocular comfort level from day 1 to day 30. However, the deterioration for both silicone hydrogel ($X^2 = 5.305$, $p > 0.05$) and hydrogel ($X^2 = 5.314$, $p > 0.05$) was not significant. The comfort level data are shown in Table 1.

TABLE 1. Ocular comfort level of silicone hydrogel and hydrogel lens wear

	Silicone Hydrogel ($N = 42$)	Hydrogel ($N = 42$)
Median Overall Comfort	80.00	80.00
Median Comfort Day 1	85.00	80.00
Median Comfort Day 15	80.00	80.00
Median Comfort Day 30	80.00	77.50

In terms of lens preference, equal lens preference was chosen with considerations of lens comfort and lens handling throughout the 30 days of lens wear.

Median VA showed no significant difference between silicone hydrogel ($T = 1.50$, $p > 0.05$) and hydrogel ($T = 2.00$, $p > 0.05$). Median TBUT on both silicone hydrogel ($T = 53.50$, $p < 0.05$) and hydrogel ($T = 53.00$, $p < 0.05$), showed a significant decline after the lens wear statistically, but it was not clinically significant. Median CCT after lens wear increased significantly for both silicone hydrogel ($T = 116.50$, $p < 0.05$) and hydrogel ($T = 154.00$, $p < 0.05$) as well. The overall percentage of median corneal swelling caused by silicone hydrogel is higher (Median = 1.01%) compared to the hydrogel (Median = 0.69%), however there was no significant difference between both lenses ($T = 301.00$, $p > 0.05$).

TABLE 2. Pre- and post-lens wear assessments

	Median VA (logMAR) ($N = 35$)		Median TBUT/ seconds ($N = 35$)		Median CCT/mm ($N = 35$)	
	Pre	Post	Pre	Post	Pre	Post
Silicone Hydrogel	0.00	0.00	3.00	3.00	556	561
Hydrogel	0.00	0.00	3.00	3.00	556	569

After wearing both contact lenses, the ocular status was being evaluated and compared between both lens types. Bulbar conjunctiva ($T = 0.00$, $p > 0.05$), palpebral conjunctiva ($T = 1.00$, $p > 0.05$) and corneal staining ($T = 0.00$, $p > 0.05$) showed no significant differences between both lens types after lens wear. Data is presented in Table 3.

TABLE 3. Ocular staining at the cornea, bulbar and palpebral conjunctiva

	Median Bulbar Conjunctiva ($N = 35$)	Median Palpebral Conjunctiva ($N = 35$)	Median Corneal Staining ($N = 35$)
Silicone Hydrogel	0.00	0.50	0.50
Hydrogel	0.00	0.50	0.50

DISCUSSION

This study proved that in terms of ocular comfort level, hydrogel lens does not have significant difference compared to silicone hydrogel. This finding is further supported by studies done by Cheung et al. (2007), Santodomingo-Rubito et al. (2010) and Fonn and Dumbleton (2003) using different types of contact lenses from hydrogel and silicone hydrogel material.

During contact lens wear, the ocular comfort level relies on the interaction between lenses and ocular tissues, wearers' ocular physiological condition and their compliance to contact lens wear (Guillon 2013). By referring to Tighe diagrammatic model which explains about contact lens tribology, it is shown that any factors that lead to the mechanical interaction between two surfaces will greatly affect one's ocular comfort level. For instance, when our tears are continuously secreted, eyelids can help to distribute the tear film evenly over our cornea on each blink. However, when there is tear break-up before blinking, the friction between our inner eyelid and the front surface of contact lens is present and therefore, causing ocular discomfort during lens wear (Naim 1995). On the other hand, mechanical interaction between contact lens and our ocular surface is highly dependent on contact lens elasticity. High modulus elasticity can cause friction on our ocular surface, leading to complications like corneal staining and superior epithelial arcuate lesion, which are highly correlated with ocular comfort during contact lens wear.

Undeniably, contact lenses which allow high oxygen permeability during lens wear are shown to have high correlation with elimination of limbal hyperaemia and neovascularisation (Dumbleton 2010). Therefore, Brennan et al. had done a study to investigate the relationship between oxygen transmissibility (Dk/t) and permeability of contact lenses and the ocular comfort achieved in 2006. The results of the study portrayed that Dk/t of contact lenses is not a significant factor that can affect ocular comfort during lens wear.

Moreover, the ocular comfort is dependent on wearer's compliance to lens care regimen i.e. replacement frequency, hygiene, lens cleaning regimen and the use of contact lens rewetting drops. Researcher Robertson (2011) had done a comparative study on contact lens wearers' awareness towards contact lens related complications

through questionnaires. Generally, in terms of contact lens wearers' incompliance, incidence of shower or swimming with lens on is most commonly seen, followed by sleeping with contact lens on, poor hygiene and failure of replacing lens case.

Commonly, ocular comfort deteriorates at the end of the day or when reaching the end of lens replacement period. According to Dumbleton et al. in 2010, this happens on biweekly and monthly disposable contact lens, too. Even though the deterioration in ocular comfort was not significant, it was partly due to the increase in accumulation of deposits on the lens surfaces. The decline in ocular comfort could also be due to superficial punctate keratitis (SPK) stimulated by MPS used during 30-day lens wear (Diec et al. 2012).

In this study, CCT increased significantly after the wearing of both types of contact lenses. This is due to corneal hypoxia during the lens wear (Hirji & Larke 1979). When cornea lacks oxygen, anaerobic metabolism will be stimulated and causes a rise in lactic acid in the stroma, increasing the hypertonicity. Hence, fluid will be drawn into the stroma that leads to stromal edema. In 1 month of wearing, contact lens wear does correlate with an increase in corneal thickness (Yeniad et al. 2003).

TBUT after lens wear showed a decline for both silicone hydrogel and hydrogel, and it is believed to be caused by accumulation of deposits on the lens surfaces, leading to lens hydrophobicity which can affect the tear film quality. Also, tear film can also be mechanically disturbed by the insertion of contact lens in our eyes (Roth 1992; Faber et al. 1991). In this study, significant difference in swelling ($p < 0.05$) was found in the ocular status between silicone hydrogel and hydrogel. For the eye wearing hydrogel lenses the percentage of thickness swelling is 1.01% compared to the eye wearing the silicone hydrogel whereby the swelling in only 0.69%. The difference observed indicates that the swelling process may be worst if chronic wear to be resumed. This insignificance might be due to the fact that the clinical trial was done in short period of time, and moreover most subjects recruited have relatively healthy ocular condition (Cheung et al. 2007).

One of the limitations found throughout this study was, only 35 subjects managed to return for post-lens-wear assessments. All data was not normally distributed might be due to small sample size. To overcome this, more subjects should be recruited in the upcoming research. In addition, it was difficult to ensure all subjects strictly follow the instructions given, in terms of lens care regimen and the wearing hours of contact lens. Researchers effortlessly tried to remind subjects constantly, however personal monitoring is difficult.

CONCLUSION

Maxvue Hydrosoft hydrogel contact lens offers similar ocular comfort to Maxvue Airsoft silicone hydrogel contact lens hence giving similar visual performance however the swelling response was different between both lenses. The silicone hydrogel lens gave less swelling after a period of 30 days wear.

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