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UNIVERSITI KEBANGSAAN MALAYSIA

The National University of Malaysia

PROJECT TITLE:

ASSESSMENT OF TEARS, CORNEAL STAINING AND COMFORT LEVEL AFTER ONE DAY WEAR OF CONTACT LENSES OF DIFFERENT FDA CATEGORIES AMONG UNDERGRADUATE STUDENTS OF UKM KUALA LUMPUR CAMPUS

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1.0 STUDY TITLE

Assessment of Tears, Corneal Staining and Comfort Level After One Day Wear Of Contact Lenses Of Different FDA Categories Among Undergraduate Students of UKM Kuala Lumpur Campus.

2.0 INTRODUCTION

2.1 The Food and Drug Administration (FDA) classifies soft contact lens materials into 5 groups, where hydrogels are in Group I, II, III, and IV, while silicone hydrogel (SH) is in Group V. Hydrogel silicone contact lenses are one of the results of contact lens innovations that were first introduced in the market in the late 90s (Sulley & Dumbleton, 2020). Silicone material allows for high oxygen permeability while hydrogel components maintain the softness and comfort of contact lenses (Gasson & Morris, 2003). The Group I FDA contact lens is a non-ionic hydrogel with the water content of <50%. Group II, on the other hand, is a non-ionic hydrogel with the water content of >50% (Peral et al. 2020). As for group III and IV contact lenses, they are ionic contact lenses. Group III contact lenses have a low water content of less than 50% compared to group IV with high water content of more than 50% (Peral et al. 2020). There are several examples of soft contact lens materials for each group, Polymacon and Crofilcon are examples of group I while Nelfilcon A and Omafilcon A are material examples of group II soft contact lenses. Examples of group III soft contact lens materials are Bufilcon A and Deltafilcon A while Ocufilcon B and Ocufilcon C are examples of group IV soft contact lens materials (Chatterjee et al. 2020). Material Lotrafilcon A and Balafilcon A are examples of group V soft contact lens material (Efron et al., 2010).

Protein deposits can result in multiple immune responses, including giant papillary conjunctivitis. Silicone hydrogel (SH) material contact lenses provide comfort and better performance compared to hydrogel material. The data show that very low protein deposits are present in silicone hydrogel material contact lenses after wear when compared with hydrogel material (Subbaraman et al., 2006). The application of contact lenses can cause changes in the level of production and tear quality. This can cause a feeling of discomfort in the eyes when wearing contact lenses (Fonn 2007; Maruyama et al., 2004). Based on the classification of dry eye diagnostics from the National Eye Institute and Industry Workshop, dry eye problems during contact lens wear are related to tear loss through evaporation (Lemp 1995; Pflugfelder et al., 2000). Studies from Asharlous et al. (2016) have also shown that there are significant

changes in the quality and quantity of tears after 6 hours of wearing hydrogel silicone contact lenses of the Air Optix Aqua brand, Lotrafilcon B from CIBA Vision. The level of tear production can be measured by the Schirmer test; together or without anesthetic, in which it represents the secretion of tears on the lower part of the eyelid and tear reflexes. The Schirmer test is still used for the measurement of tear production in primary eye care as it is simple, fast, cheap and practical (Razak et al., 2018). The Non-Invasive Breakup Time (NIBUT) test allows stability and tear quality to be studied without inserting foreign material into the eye. This method is more patient-friendlier and more accurate than the Tear Breakup Time (TBUT) Test method. The TBUT method is considered to have a deficiency because the presence of sodium fluorescein alters the physiology of tears (Mohidin et al., 2002). Finally, a questionnaire will be used to study the level of comfort throughout the wearing of contact lenses using the Contact Lens Discomfort Index (CLDI) questionnaire, Cristina Arroyo-del Arroyo et al. (2022). The choice of questions in this questionnaire is based on the existing questionnaire Contact Lens Dry Eyes Questionnaire (CLDEQ)-8. CLDI is a strong and reliable questionnaire and this questionnaire is designed to measure the comfort level of contact lens wearing (Arroyo-del Arroyo et al., 2022).

Contact lenses are not only used to replace the wearing of glasses but are also used for treatments and cosmetic purposes. It is estimated that there are 140 million contact lens wearers worldwide (Cope et al. 2017). Therefore, it is not surprising that the wearing of contact lenses is the latest follow-up. However, contact lens wearers need to know which type of contact lenses are suitable for everyday activities. This is because, as soon as the contact lenses are placed on the eye, the lens will be on the tear film.

The ability of a tear film to maintain its integrity in the presence of lenses is a prerequisite basis for the successful application of contact lenses. Lack of interaction between tears and lenses is the most common reason for contact lens wear failure (Downie & Craig., 2017). The most common symptoms reported by contact lens wearers are dryness and discomfort in the eyes (Nursyuhada. 2021).

2.1 LITERATURE REVIEW

Contact lens materials are classified by the Food and Drug Administration (FDA) and international organizations based on water content and balanced ionic properties, aligning with their clinical performance impact. Group I lenses, with low water content and non-ionic properties, tend to be the most stable and least influenced by tear film and environmental factors. Conversely, Group IV lenses, characterized by high water content and ionic properties, are more reactive and prone to interaction with positively charged proteins like lysozyme, with potential impacts from different pH solutions. Group II and III lenses fall between these extremes and exhibit varying performances (Jones & Dumbleton, 2019).

Over recent decades, the evolution of contact lens materials to meet consumer demands has posed a significant challenge for manufacturers. Consequently, numerous studies have been undertaken to evaluate ocular comfort levels associated with various types of contact lenses, such as hydrogel and hydrogel silicone lenses. Mutalib et al. (2018) demonstrated no significant difference in comfort levels between female students at Universiti Kebangsaan Malaysia KL Campus when wearing hydrogel versus silicone hydrogel lenses.

Assessment of contact lens application typically occurs before and after lens wear. Ocular comfort during lens wear depends on the interaction between the lens and ocular tissue, the wearer's ocular physiological state, and their adherence to lens wear. Mutalib et al. (2018) highlighted the significant impact of mechanical interaction between lens and ocular surfaces on comfort levels. Additionally, a study by Santodomingo, Rubito et al. (2010) found no significant difference in comfort levels between hydrogel and hydrogel silicone lenses, with both showing a decrease in comfort after a day of wear.

Conventional hydrogel lenses often feature high water content to enhance oxygen permeability, yet this can lead to increased dehydration and potential physiological eye disorders (Ruiz-Alcocer et al., 2018). Ruiz-Alcocer et al. (2018) demonstrated that disposable contact lenses can mitigate some issues associated with prolonged wear. Efforts to improve conventional lenses include the introduction of new hydrogels with a water content of 78%. Furthermore,

studies by Ruiz-Alcocer et al. (2018) found no difference in tear osmolality between contact lenses, suggesting that tear dryness symptoms may not be significantly impacted by lens type.

The corneal epithelium and conjunctiva play crucial roles in protecting the cornea and conjunctival layers. It's widely acknowledged that epithelial disorders can predispose individuals to fungal, viral, or bacterial eye infections. However, research also indicates that corneal infections can stem from conditions involving cellular epithelium, tear film biochemistry, and bacterial resistance to epithelial basal lamina (Brautaset et al., 2008).

In wearers of hydrogel soft contact lenses, staining on the conjunctival epithelium may result from various physical factors such as pressure from the lens edge, edge defects, and lens removal techniques (Brautaset et al., 2008).

Lakkis and Brennan (1996) conducted a study involving 50 hydrogel contact lens wearers and 50 non-contact lens wearers, revealing that 98% of lens wearers exhibited some degree of corneal staining compared to only 12% of non-wearers. Moreover, 62% of lens wearers experienced corneal staining exceeding grade 1 on the Efron scale.

Corneal staining in hydrogel contact lens wearers is attributed to tear film dysfunction, hypoxia, mechanical forces, exposure, metabolic disorders, toxic or allergic reactions, and infectious reactions. The prevalence of corneal staining in hydrogel contact lens wearers ranges from approximately 30% to 55.7% (Brautaset et al., 2008). Nicholas et al. (2000) also noted associations between staining presence and levels with non-compliance regarding contact lens care systems, use of rewetting drops, and absence of a lens replacement plan. However, no associations were found with age, gender, medications, continued wear versus daily wear, wearing time, lens type, water content, or contact lens care system (Brautaset et al., 2008).

Research by Nicholas and Sinnott (2006) revealed a higher likelihood of dry eyes associated with the use of high water content contact lenses. However, lens ionization was not found to be linked to dry eye symptoms. In a subsequent analysis, they demonstrated that compared to Group I FDA contact lenses, both Group II and IV FDA lenses were associated with a 2-3 times increase in the likelihood of dry eyes for contact lens wearers. Additionally, in a small study involving 10 subjects by Wilson et al. (1998), better comfort was reported for patients using randomly paired

lenses from Group II (high water content but non-ionic) and Group IV (high water content and ionic) FDA contact lenses (Jones et al., 2013).

Maïssa et al. (2012) conducted a study to investigate the impact of silicone hydrogel contact lenses on the ocular surface. They compared circumlimbal conjunctival staining and comfort levels among wearers of ACUVUE OASYS hydrogel silicone lenses (knife edge design), AIR OPTIX, Biofinity (chisel edge rounded edge combination), PureVision (rounded edge design), and ACUVUE 2 hydrogel lenses (knife edge design). Their findings indicated that rounded edge design lenses produced minimal circumlimbal staining but lower comfort levels, whereas knife edge design lenses resulted in higher circumlimbal staining but greater wearer comfort. However, the observed conjunctival staining and comfort levels were attributed to lens design rather than focusing solely on the material effects of different silicone hydrogel compositions.

Similarly, Efron et al. (1986), as cited in Jones et al. (2013), compared comfort levels among contact lenses based on water content. They found that lenses with lower water content (38%) were more comfortable than those with higher water content. Notably, the study excluded potential confounding factors such as lens edge design or surface finish, as all lenses were cut to the same shape and sourced from the same manufacturer.

Additionally, Young et al. (1997) conducted a study assessing comfort to predict successful contact lens wear. They evaluated lenses with low (38%), medium (54%-58%), and high (69%-74%) water content. Their findings recommended lenses with lower water content for greater wearing comfort.

Research on the evaluation of contact lens-related dehydration during initial application is extensive, as understanding the hydrating properties of hydrogel lenses is crucial due to various clinical implications. Dehydration can lead to changes in lens fit, discomfort, reduced oxygen transmission, and increased corneal drying (Nichols et al., 2002). Andrasko et al. (1983) reported that hydrogel lenses can dehydrate by 7%-11% during the first 30 minutes of wear, with thicker lenses exhibiting lower dehydration rates compared to thinner ones. Additionally, lenses with high water content experience more significant water loss than those with low water content, even at the same thickness.

The rate of oxygen absorption in the cornea is influenced by oxygen transmission (Dk) and lens thickness (t), with thinner lenses allowing more oxygen to reach the cornea (Jones & Dumbleton, 2019). Ideally, hydrogel lenses should have high oxygen transmission and thin central thickness.

However, this combination is impractical as it tends to lead to rapid dehydration and significant corneal staining (Jones & Dumbleton, 2019).

Maintaining a healthy ocular surface is essential for comfortable contact lens wear and to avoid serious complications. However, many contact lens wearers, even without underlying conditions such as blepharitis or meibomian gland dysfunction, report higher rates of dryness (Chalmers, 2014). The stability of the tear film and ocular surface greatly influences the success of contact lens

While there is no specific classification for hydrogel silicone contact lens groups, various materials such as somofilcon A, comfilcon A, fanfilcon A, samfilcon A, hilafilcon B, and others are utilized in their manufacture. Numerous studies have investigated the effects of wearing different material contact lenses on wearers. For instance, Iskeleli et al. (2013) compared tear evaluation before and after three months of wearing hydrogel silicone contact lenses from two different generations: Focus-Night & Day™ hydrogel silicone lenses for Group 1 and Air Optix ™ silicone lenses for Group II. Statistical analysis indicated no significant differences between the two groups in terms of tear break-up time (TBUT) and Schirmer test values.

Similarly, Uğurlu et al. (2019) examined tear quantity and quality before the initial use of contact lenses and after one month and three months of wear. They compared Bausch & Lomb Ultra (samfilcon A) hydrogel silicone lenses on the right eye with Johnson-Johnson Vision Acuvue Oasys hydrogel silicone lenses (senofilcon A) on the left eye. No significant differences were observed in TBUT and Schirmer test values between the application of hydrogel silicone lenses made from samfilcon A and senofilcon A materials.

2.2 Problem statement and study justification

Since 2019, there has been limited research conducted in Malaysia regarding tear quality, corneal effects, and comfort levels associated with FDA contact lens groups. Recent studies in the realm of soft contact lenses have predominantly focused on silicone hydrogel varieties.

Existing literature indicates that contact lens application can alter tear layer parameters, although quantitative data on tear production resulting from contact lens wear has received scant attention (Downie & Craig, 2017; Razak et al., 2018). Information regarding tear quantity following 8 hours of contact lens wear is particularly lacking, necessitating further investigation into the effects of different contact lens types over longer durations (Razak et al., 2018).

Various contact lens brands exhibit differences in water content and thickness, with hydrogel lenses typically thinner than soft lenses with higher water content (Jones & Dumbleton, 2019). Notably, individuals may respond differently to lens thickness and water content variations. While some wearers may prefer thin lenses with low water content, others may find thicker lenses with medium or high water content more comfortable (Jones et al., 2013).

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Differences in water content within soft contact lenses may contribute to corneal dehydration, leading to dryness in the eyes. Despite advancements in soft contact lens manufacturing, instances of corneal allergies or sensitivities to such lenses have been reported (Moreddu et al., 2019). Studies suggest that changes in the tear film may occur within the first hour of contact lens wear, but quantitative data on tear film thickness post-application is lacking (Nichols et al., 2004).

Furthermore, there is limited data available for tear assessment, corneal staining, and comfort levels among FDA contact lens groups I, II, III, and IV, with recent studies predominantly focusing on silicone hydrogel lenses. Therefore, this study aims to compare tear quality and quantity, as well as comfort levels, between these contact lens groups and silicone hydrogel lenses.

While tear assessment before and after wearing silicone hydrogel lenses may reveal significant changes, no substantial differences are observed between different silicone hydrogel materials. However, factors such as water content, material composition, wearing duration, and lens deposition are more closely associated with corneal staining than contact lens care solutions, ocular surface characteristics, tear composition, demographics, or medical factors (Nichols & Sinnott, 2011).

In response to consumer needs, advancements in contact lens technology continue, with efforts aimed at enhancing wearer comfort. Innovations such as the incorporation of wetting agents, hydrophilic monomers, surface treatments, and water gradient surface technology are introduced to mitigate the impact of wearing silicone hydrogel lenses on the tear layer (Sulley & Dumbleton, 2020). Therefore, ongoing research into technological and material developments in contact lens manufacturing is essential to understand their effects on consumers and to facilitate future improvements.

2.3 Research Questions

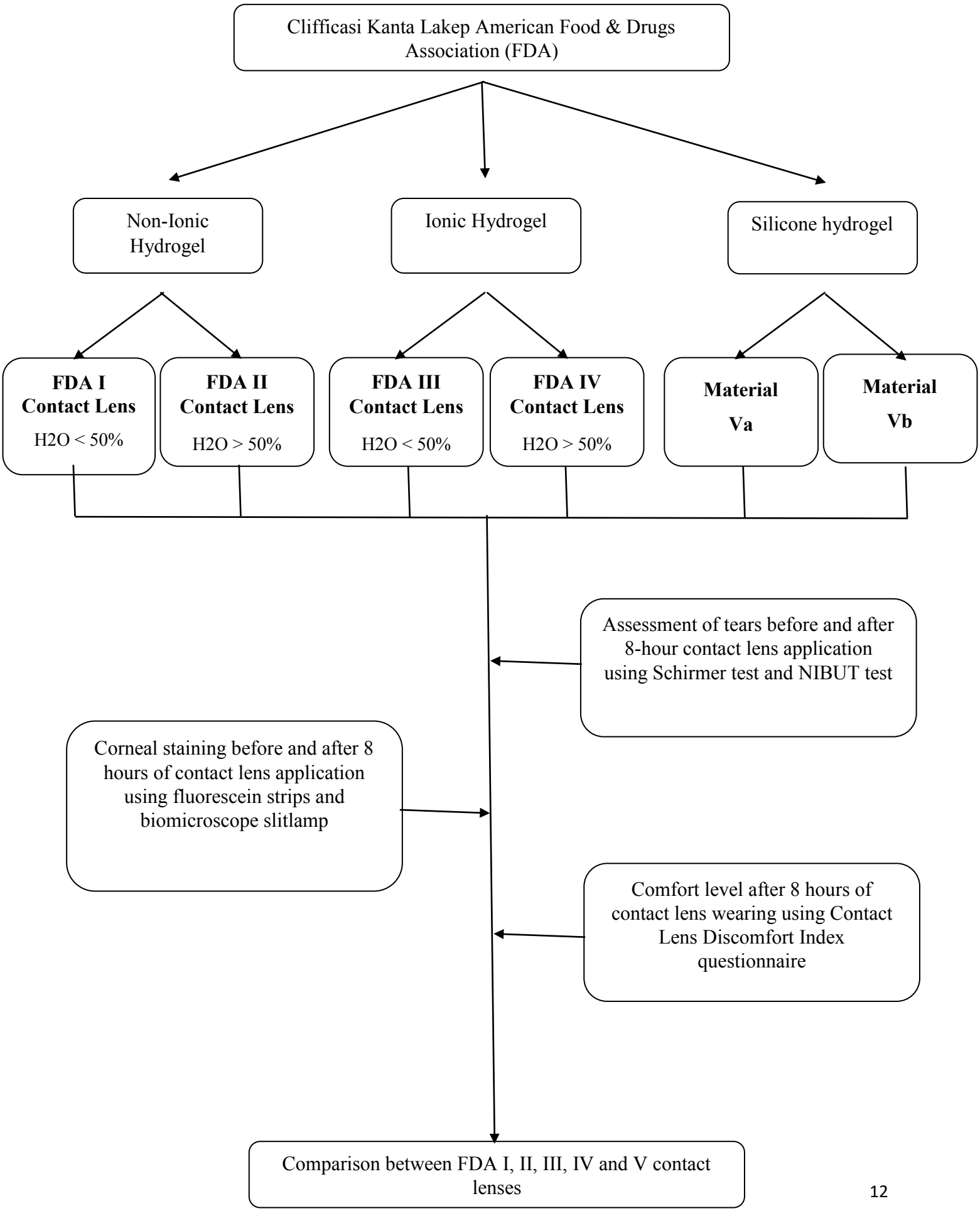
Is there a discrepancy in tear assessment, corneal staining, and comfort levels before and after one day (8 hours) of wearing FDA contact lenses Group I, II, III, IV, and V among undergraduate students at UKM Kuala Lumpur Campus?

2.4 Research Hypothesis

Among UKM undergraduate students at the Kuala Lumpur Campus, there was no significant disparity observed in tear assessment, corneal staining, and comfort levels before and after one day (8 hours) of wearing Group I, II, III, IV, and silicone hydrogel contact lenses.

2.5 Conceptual framework

Figure 1 illustrates the conceptual framework for assessing tear quantity, corneal staining, and comfort levels during the wear of FDA contact lenses Group I, II, III, IV, and V materials.


Clifficasi Kanta Lakep American Food & Drugs Association (FDA)
Non-Ionic Hydrogel
Ionic Hydrogel
Silicone hydrogel
FDA I Contact Lens
H2O < 50%
FDA II Contact Lens
H2O > 50%
FDA III Contact Lens
H2O < 50%
FDA IV Contact Lens
H2O > 50%
Material Va
Material Vb
Assessment of tears before and after 8-hour contact lens application using Schirmer test and NIBUT test
Corneal staining before and after 8 hours of contact lens application using fluorescein strips and biomicroscope slitlamp
Comfort level after 8 hours of contact lens wearing using Contact Lens Discomfort Index questionnaire
Comparison between FDA I, II, III, IV and V contact lenses

2.6 Objectives

2.6.1 General Objectives:

The objective is to examine the impact of FDA contact lenses Group I, II, III, IV, and silicone hydrogel on tear assessment, corneal staining, and comfort levels among undergraduate students at UKM Kuala Lumpur Campus.

2.6.2 Specific Objectives:

i. Assessing tear quantity, corneal staining, and comfort levels before and after 8 hours of wearing FDA contact lenses Group I, II, III, IV, and silicone hydrogel.
ii. Contrasting tear evaluation and corneal staining pre- and post-8-hour application of FDA contact lenses Group I, II, III, IV, and silicone hydrogel.
iii. Comparing comfort levels pre- and post-8-hour wear among FDA contact lenses Group I, II, III, IV, and silicone hydrogel (Va and Vb).

3.0 METHODOLOGISTS

3.1.1 Study Design

The studies is a mixed, clinical trials and cross-sectional studies.

3.1.2 Sampling Method

Random sampling is used in this study.

3.1.3 Study Location

The study will take place at the Optometry Clinic within the Optometry and Vision Sciences Programme, Faculty of Health Sciences, Universiti Kebangsaan Malaysia. This location was selected due to its status as the primary clinic for optometry practice within the Faculty of Health Sciences, equipped with all necessary equipment for the study. Situated centrally within the Faculty of Health Sciences, it offers convenient access for undergraduate subjects participating in the study.

3.1.4 Study Sample Calculation

The sample size for this study was determined using the Daniel formula (1999), with a total of 10% of the overall sample size allocated for the study. Considering a dropout rate of 10%, a total of 18 subjects were required for the study.

$$n = \frac{Z^2 P(1-P)}{d^2}$$

$$n = \frac{(1.96)\ \ (0.3)(1-0.3)}{(0.05)\ \ ^2}$$

$$n = \frac{0.4116}{0.0025}$$

n = 164.64

n study = 10% x 164.64

= 16.46

= 16

Dropout rate = 10% x 16

= 1.6

= 2

Total subjects = 16 + 2

= 18 subjects

n = required sample size

= 1.96, the value of Z when the confidence level is 95% Z^2

P = 0.3, prevalence of contact lens clinic patients at UKM Optometry Clinic in semester 2, session 2022/2023

d = 0.05, margin of error

3.1.5 Subject

UKM undergraduate students' Kuala Lumpur Campus was chosen as the subject of study because the location of the study was at the UKM Optometry Clinic located at the Kuala Lumpur Campus of UKM.

3.1.6 Participation Criteria

1. Healthy volunteered individuals between 19 and 29 years old.
2. Individuals with a refraction power of less than -6.00 spherical diopters and astigmatism power of less than -1.00 cylindrical diopters.
3. Experienced contact lens wearers. (Participants are asked to lay off contact lenses for at least 2 weeks before the clinical trial starts (McKernan et al., 2014))

3.1.7 Exclusion Criteria

1. Individuals who smoke (Ward et al. 2010)
2. Individuals with history of diseases on the ocular surface, ocular trauma, refractive surgery, intraocular and extraocular surgery.
3. Pregnant individuals (Yenerel &; Kucumen, 2015).
4. Individuals taking systemic drugs that can cause dry eyes (Fraunfelder et al. 2012).

3.1.8 Instruments

1. Hydrogel soft contact lenses Group I, II, III, IV, Va and Vb
2. Schirmer Strip
3. Fluoresine Strip
4. Saline solution
5. Multipurpose solution – Maxvue
6. Slitlamp Biomicroscope
7. Bausch & Lomb Keratometer
8. Contact Lens Discomfort Index Questionnaires (CLDI)

3.1.9 Study Protocol

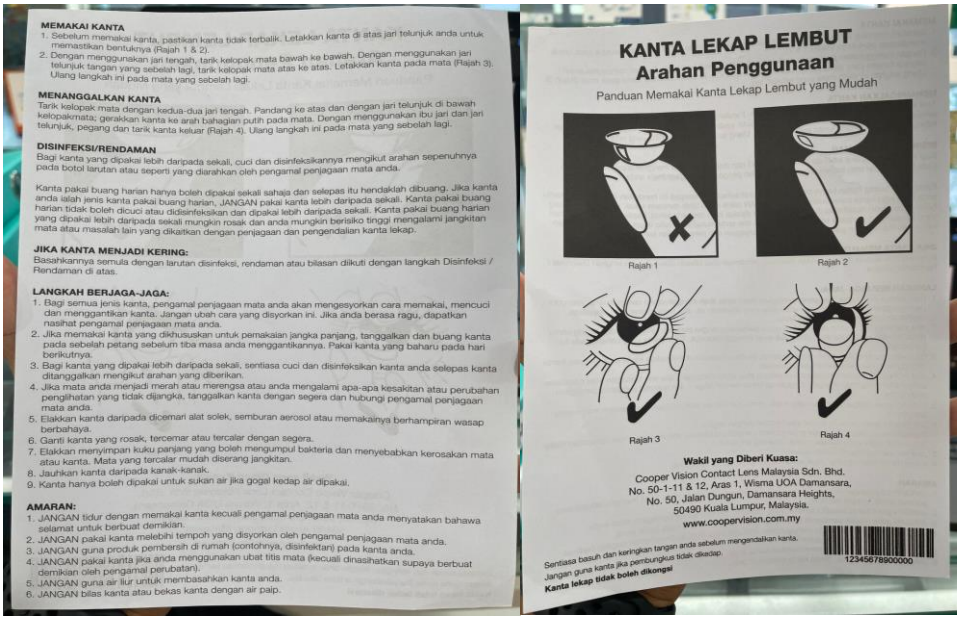
Participants for this study will be recruited from among UKM undergraduate students at the Kuala Lumpur Campus based on the inclusion and exclusion criteria. Recruitment of volunteers will be conducted through advertisement. Simple random sampling will be used for participant selection, with those meeting the inclusion criteria being eligible for the study, while those meeting the exclusion criteria will be dismissed.

Before the commencement of the clinical trial, all participants will be provided with a consent form to review. The study will take place at the UKM Optometry Clinic, Jalan Raja Muda Abdul Aziz, Kuala Lumpur, Malaysia.

Participants will be required to attend the UKM Optometry Clinic for three sessions, each lasting 8 hours, during which they will wear FDA hydrogel contact lenses (groups I, II, III, IV, Va and Vb). Each lens will be placed on one eye only. Hence, the study will involve three wearing sessions, with the first session focusing on groups I and II FDA contact lenses, the second session on groups III and IV FDA contact lenses, and the third session on hydrogel silicone contact lenses Va and Vb. A 2-week rest period will be provided between each session.
The complete study procedure is outlined as follows:

Care for Contact Lenses Leaflet.

Ensuring proper hygiene and technique is crucial to prevent eye health complications while wearing contact lenses. Subjects will receive thorough guidance on essential practices, including: maintaining hygiene care, correctly utilizing contact lens solution, applying and removing contact lenses, and adhering to permissible actions during wear. Additionally, subjects will be provided with a hotline for any inquiries or emergencies arising during contact lens use. Furthermore, they will receive a pamphlet titled "Soft Contact Lens Instructions" available at the UKM KL Optometry Clinic.



MEMAKAI KANTA
1. Sebelum memakai kanta, pastikan kanta tidak terbalik. Letakkan kanta di atas jari telunjuk anda untuk memastikan bentuknya (Rajah 1 & 2).
2. Dengan menggunakan jari telunjuk tangan yang sebelah lagi, tarik kelopak mata bawah ke bawah. Dengan menggunakan jari telunjuk tangan yang sebelah lagi, tarik kelopak mata atas ke atas. Letakkan kanta pada mata (Rajah 3). Ulang langkah ini pada mata yang sebelah lagi.

MENANGGALKAN KANTA
Tarik kelopak mata dengan kedua-dua jari tengah. Pandang ke atas dan dengan jari telunjuk di bawah kelopakmata; gerakkan kanta ke arah bahagian putih pada mata. Dengan menggunakan ibu jari dan jari telunjuk, pegang dan tarik kanta keluar (Rajah 4). Ulang langkah ini pada mata yang sebelah lagi.

DISINFEKSI/RENDAMAN
Bagi kanta yang dipakai lebih daripada sekali, cuci dan disinfeksikannya mengikut arahan sepenuhnya pada botol larutan atau seperti yang diarahkan oleh pengamal penjagaan mata anda.

Kanta pakai buang harian hanya boleh dipakai sekali sahaja dan selepas itu hendaklah dibuang. Jika kanta anda ialah jenis kanta pakai buang harian, JANGAN pakai kanta lebih daripada sekali. Kanta pakai buang harian tidak boleh dicuci atau didisinfeksikan dan dipakai lebih daripada sekali. Kanta pakai buang harian yang dipakai lebih daripada sekali mungkin rosak dan anda mungkin berisiko tinggi mengalami jangkitan mata atau masalah lain yang dikaitkan dengan penjagaan dan pengendalian kanta lekap.

JIKA KANTA MENJADI KERING:
Basahkannya semula dengan larutan disinfeksi, rendaman atau bilasan diikuti dengan langkah Disinfeksi / Rendaman di atas.

LANGKAH BERJAGA-JAGA:
1. Bagi semua jenis kanta, pengamal penjagaan mata anda akan mengesyorkan cara memakai, mencuci dan menggantikan kanta. Jangan ubah cara yang disyorkan ini. Jika anda berasa ragu, dapatkan nasihat pengamal penjagaan mata anda.
2. Jika memakai kanta yang dikhususkan untuk pemakaian jangka panjang, tanggalkan dan buang kanta pada sebelah petang sebelum tiba masa anda menggantikannya. Pakai kanta yang baharu pada hari berikutnya.
3. Bagi kanta yang dipakai lebih daripada sekali, sentiasa cuci dan disinfeksikan kanta anda selepas kanta ditanggalkan mengikut arahan yang diberikan.
4. Jika mata anda menjadi merah atau merengsa atau anda mengalami apa-apa kesakitan atau perubahan penglihatan yang tidak dijangka, tanggalkan kanta dengan segera dan hubungi pengamal penjagaan mata anda.
5. Elakkan kanta daripada dicemari alat solek, semburan aerosol atau memakainya berhampiran wasap berbahaya.
6. Ganti kanta yang rosak, tercemar atau tercalar dengan segera.
7. Elakkan menyimpan kuku panjang yang boleh mengumpul bakteria dan menyebabkan kerosakan mata atau kanta. Mata yang tercalar mudah diserang jangkitan.
8. Jauhkan kanta daripada kanak-kanak.
9. Kanta hanya boleh dipakai untuk sukan air jika gogal kedap air dipakai.

AMARAN:
1. JANGAN tidur dengan memakai kanta kecuali pengamal penjagaan mata anda menyatakan bahawa selamat untuk berbuat demikian.
2. JANGAN pakai kanta melebihi tempoh yang disyorkan oleh pengamal penjagaan mata anda.
3. JANGAN guna produk pembersih di rumah (contohnya, disinfektan) pada kanta anda.
4. JANGAN pakai kanta jika anda menggunakan ubat titis mata (kecuali dinasihatkan supaya berbuat demikian oleh pengamal perubatan).
5. JANGAN guna air liur untuk membasahkan kanta anda.
6. JANGAN bilas kanta atau bekas kanta dengan air paip.

KANTA LEKAP LEMBUT
Arahan Penggunaan
Panduan Memakai Kanta Lekap Lembut yang Mudah

Rajah 1 Rajah 2 Rajah 3 Rajah 4

Wakil yang Diberi Kuasa:
Cooper Vision Contact Lens Malaysia Sdn. Bhd.
No. 50-1-11 & 12, Aras 1, Wisma UOA Damansara,
No. 50, Jalan Dungun, Damansara Heights,
50490 Kuala Lumpur, Malaysia.
www.coopervision.com.my

Sentiasa basuh dan keringkan tangan anda sebelum mengendalikan kanta.
Jangan guna kanta jika pembungkus tidak dikedap.
Kanta lekap tidak boleh dikongsi

12345678900000

.

Figure 1 & 2. Soft contact lens use instructions

Pre-Assessment

A pre-assessment will precede the contact lens application during the initial session. The parameters measured will include these three tests: a) assessment of tear quantity using the Schirmer Test, b) evaluation of tear quality with the NIBUT Test, and c) examination of corneal staining using the Efron Grading Scale. These same tests will be conducted after the contact lenses have been worn for 8 hours and subsequently removed.

a) Tear Quantity Assessment (Schirmer Test)

To assess tear quantity, the Schirmer test will be employed using a 5mm x 30mm Schirmer strip. The strip will be positioned in the temporal area of the subject's lower eyelid. The subject will be instructed to look upwards and blink naturally for 5 minutes, after which the Schirmer strip will be removed. The length of the wet portion of the strip will be measured and documented. Three readings will be obtained in millimeters (mm), and the average reading will be calculated for data analysis (Kallarackal et al., 2002).

b) Tear Quality Assessment (NIBUT Test)

The assessment of tear quality was conducted using the Non-Invasive Break Up Time Test (NIBUT) technique with the Bausch & Lomb keratometer. The subject was instructed to rest their

chin on the designated chin rest and align their forehead with the headrest. Initially, the subject blinked several times and then refrained from blinking. Time was measured from the last blink until the appearance of any distortion or break in the "mires." This time interval was recorded as the NIBUT measurement. If the subject blinked during the measurement, the test was paused briefly, and resumed after a few blinks. A one to two-minute break was provided between each measurement. Three readings were taken, and the average of these readings was utilized for subsequent statistical analysis (Mohidin et al., 2002).

c) Corneal Coloring Assessment (Efron Grading Scale)

The evaluation of corneal staining will involve using the Efron Grading Scale to assess any marks or damage on the subject's cornea before applying contact lenses. Initially, fluorescein dye will be applied to the subject's eyes using fluorescein strips moistened with saline solution. The subject will be instructed to look up, and the moistened fluorescein strip will be gently touched to the lower eyelid, followed by blinking. Using a biomicroscopic slit lamp equipped with a blue cobalt light, any staining or markings on the cornea will be examined. Any observed findings will be documented according to the Efron Grading Scale. Subsequently, the subject's eyes will be rinsed with saline solution to remove the fluorescein dye. The cornea will be divided into five zones (central, superior, inferior, temporal, and nasal) for recording observations, as depicted in Figure 1. The Efron Grading Scale, recognized for its suitability in assessing corneal coloring, will guide the evaluation process (Dundas et al., 2001; Woods & Fonn, 2018). (Dundas et al., 2001; Woods & Fonn, 2018).

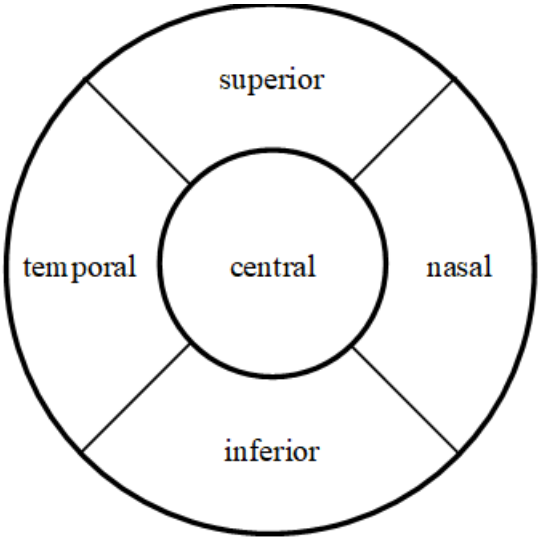


Figure 3. Grading Scale Based on 5 Corneal Zones

i. Contact lens application

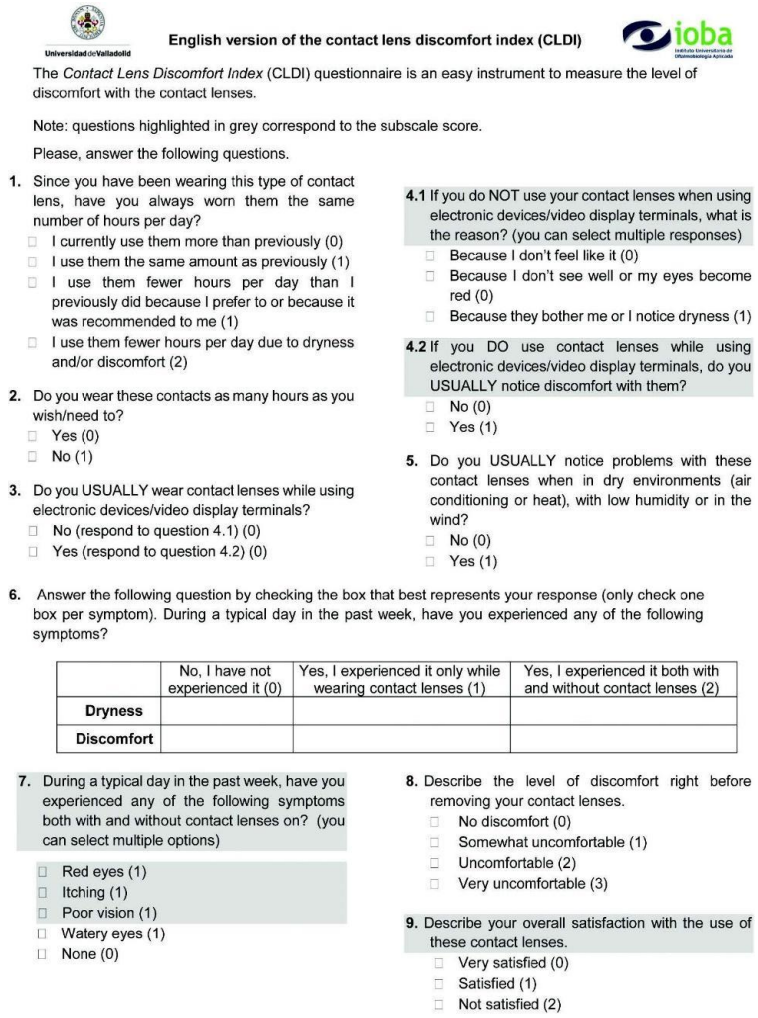
The placement of group I FDA contact lenses will occur on one side of the subject's eye, while group II FDA contact lenses will be positioned on the opposite side, with the positioning being randomized and unknown to the subjects. Researchers will delicately insert the contact lenses, providing clear instructions and precautions to the subjects regarding their wear. Subjects will be advised to remain near the UKM KL Campus throughout the contact lens application and return to the UKM Optometry Clinic after 8 hours for lens removal. Additionally, subjects will be instructed to promptly notify the researcher of any discomfort, pain, or unforeseen issues related to the wearing of contact lenses.

ii. Post-Wear Assessment

The researcher will remove the contact lenses from the subject's eyes. Subsequently, a post-wearing examination of the contact lenses will be conducted. This examination mirrors the pre-use assessment and includes a) evaluating tear quantity using the Schirmer Test, b) assessing tear quality with the NIBUT Test, and c) grading corneal staining based on the Efron Grading Scale. Following the removal of contact lenses, subjects will be required to complete the Contact Lens Discomfort Index (CLDI) questionnaire twice at each appointment: once for the right eye and once for the left eye. This allows for the measurement of comfort levels separately for each eye.

d) Contact Lens Discomfort Index Questionaires (CLDI)

The CLDI questionnaire will be employed to evaluate the comfort level during the usage of Group I and II FDA contact lenses. This questionnaire's selection of questions is rooted in the Contact Lens Dry Eyes Questionnaire (CLDEQ)-8. Known for its robustness and reliability, the CLDI questionnaire is specifically crafted to gauge comfort levels associated with contact lens wear (Arroyo-del Arroyo et al., 2022).



English version of the contact lens discomfort index (CLDI)

The *Contact Lens Discomfort Index* (CLDI) questionnaire is an easy instrument to measure the level of discomfort with the contact lenses.

Note: questions highlighted in grey correspond to the subscale score.

Please, answer the following questions.

1. Since you have been wearing this type of contact lens, have you always worn them the same number of hours per day?
- ☐ I currently use them more than previously (0)
- ☐ I use them the same amount as previously (1)
- ☐ I use them fewer hours per day than I previously did because I prefer to or because it was recommended to me (1)
- ☐ I use them fewer hours per day due to dryness and/or discomfort (2)

2. Do you wear these contacts as many hours as you wish/need to?
- ☐ Yes (0)
- ☐ No (1)

3. Do you USUALLY wear contact lenses while using electronic devices/video display terminals?
- ☐ No (respond to question 4.1) (0)
- ☐ Yes (respond to question 4.2) (0)

4.1 If you do NOT use your contact lenses when using electronic devices/video display terminals, what is the reason? (you can select multiple responses)
- ☐ Because I don't feel like it (0)
- ☐ Because I don't see well or my eyes become red (0)
- ☐ Because they bother me or I notice dryness (1)

4.2 If you DO use contact lenses while using electronic devices/video display terminals, do you USUALLY notice discomfort with them?
- ☐ No (0)
- ☐ Yes (1)

5. Do you USUALLY notice problems with these contact lenses when in dry environments (air conditioning or heat), with low humidity or in the wind?
- ☐ No (0)
- ☐ Yes (1)

6. Answer the following question by checking the box that best represents your response (only check one box per symptom). During a typical day in the past week, have you experienced any of the following symptoms?

	No, I have not experienced it (0)	Yes, I experienced it only while wearing contact lenses (1)	Yes, I experienced it both with and without contact lenses (2)
Dryness			
Discomfort			

7. During a typical day in the past week, have you experienced any of the following symptoms both with and without contact lenses on? (you can select multiple options)
- ☐ Red eyes (1)
- ☐ Itching (1)
- ☐ Poor vision (1)
- ☐ Watery eyes (1)
- ☐ None (0)

8. Describe the level of discomfort right before removing your contact lenses.
- ☐ No discomfort (0)
- ☐ Somewhat uncomfortable (1)
- ☐ Uncomfortable (2)
- ☐ Very uncomfortable (3)

9. Describe your overall satisfaction with the use of these contact lenses.
- ☐ Very satisfied (0)
- ☐ Satisfied (1)
- ☐ Not satisfied (2)

Figure 4. Contact Lens Discomfort Index (CLDI) Questionnaire

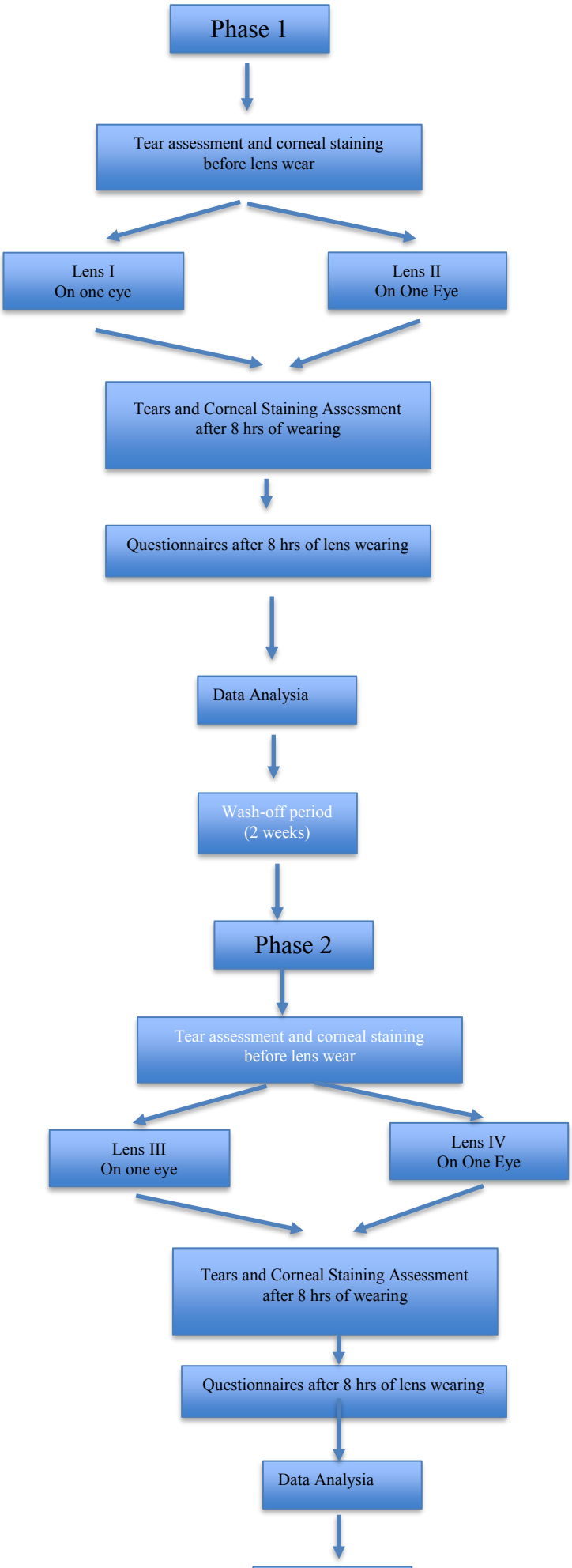
i. Rest Period

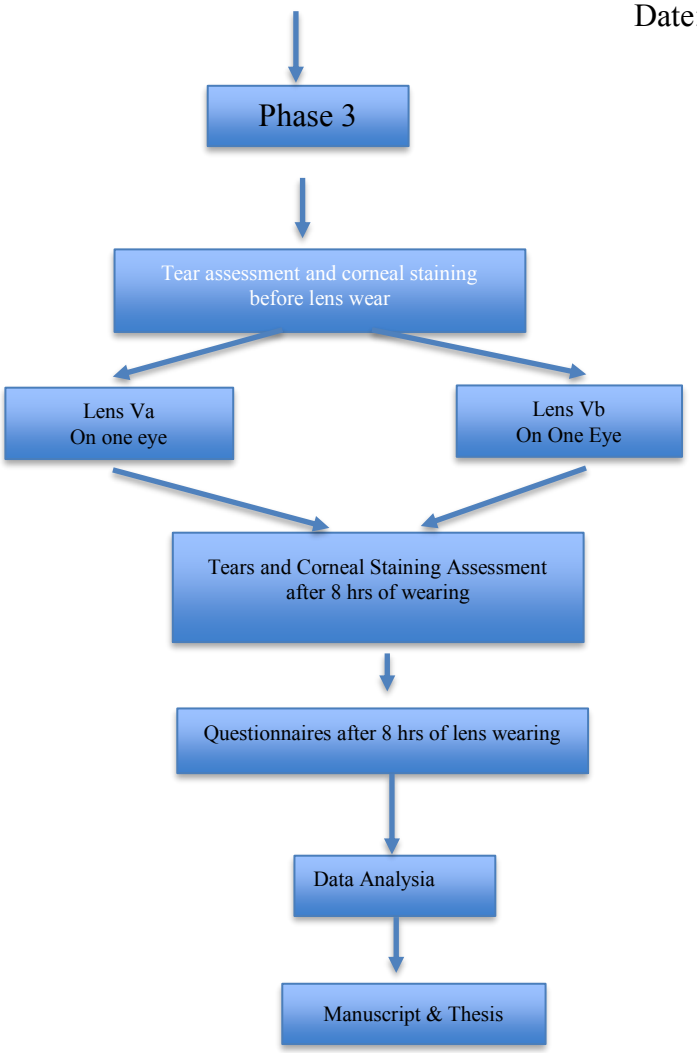
A "washout period," also known as a rest period, lasting for two weeks will be provided to the subjects to prevent any unauthorized observations.

ii. Second and Third Appointments

Subjects will be required to attend a second appointment following a rest period for the application of group III and IV FDA contact lenses. This appointment will involve the repetition of the procedure, including pre-application examination, contact lens wear, post-use examination, and subsequent rest period. The same procedure will be replicated for a third appointment involving the wearing of silicone hydrogel contact lenses Va and Vb.

3.1.10 Flow Chart





3.1.11 Data Analysis

The forthcoming study will employ IBM SPSS Statistics Version 27 for data analysis. The normality of the data will be assessed utilizing the Shapiro-Wilk test. Subsequently, the distribution of the data will be examined accordingly.

i. Utilize the Paired t-test for normally distributed data or the Wilcoxon signed-rank test for non-normally distributed data to assess the disparities in tear quality and quantity before and after

ii. Employ the Paired t-test for normally distributed data or the Wilcoxon signed-rank test for non-normally distributed data to compare the mean quality and quantity of tears between FDA contact lens application groups I and II, groups III and IV, as well as silicone hydrogel materials A and B.

iii. Employ the Paired t-test for normally distributed data or the Wilcoxon signed-rank test for non-normally distributed data to assess the comfort levels associated with the application of FDA contact lenses within groups I and II, groups III and IV, as well as silicone hydrogel materials A and B.

4.0 ETHICAL APPROVAL

Ethical approval has been approved by the UKM Research Ethics Committee, The National University of Malaysia JEP-2023_679 (18 Dec 2023 – 18 March 2025).

5.0 GANTT CHART

Year	2024											
Activity (Month)	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
Proposal Submission												
Ethics Approval												
Material Preparation												
Clinical Trial												
Data Analysis												
Manuscript Writing												
Presentation												
Manuscript Submission												

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