THE EFFECT OF MAKEUP ON CONTACT LENS WEAR

UNA WHITCOMBE

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CHAPTER 1

INTRODUCTION

1.1Summary

Aim: the purpose of this thesis was to investigate the incidence of contact lens wear and makeup, to determine if any advice regarding lens insertion/makeup application could aid comfort.

Method: A questionnaire of a student population at Aston University Optometry department and to patients attending branches of The Optic Shop, South Wales, was conducted to determine wearing patterns for contact lenses and makeup. Those who regularly wore make-up and contact lenses were invited to take part in a subjective study to investigate differences in the level of comfort between inserting lenses before and after applying makeup over a 5 day period. Finally a more detailed objective study was conducted into the objective effects on myopes, hyperopes and presbyopes of inserting lenses before and after makeup, with and without the use of an eye makeup primer and with no makeup.

Results: There were different wearing patterns and experience between a student population and a patient cohort. No subjective differences inthe levels of comfort with inserting contact lenses before and after the application of makeup was identified $p<0.05$). There was also no objective differences found between the insertion of contact lenses before and after the application of makeup, regardless of refractive error (p,0.05). However, ocular comfort and anterior eye health was adversely affected by the use of make-up in combination with contact lenses ($p=0.025$, $p=0.001$) and this could be reduced by the application of eyelid primer.

Conclusions: The use of make-up in combination with contact lenses is common in females. The sequence of contact lens and make-up application does not affect ocular comfort and anterior eye health, however, it is adversely affected by the application of make-up and this effect can be reduced by the use of eyelid primer.

Keywords Contact Lenses, Makeup, Comfort, Wearing times

1.2 Contact lenses and the tear film

When contact lenses are inserted onto the eye they are bathed in the tear film. This disrupts the natural flow of the tear film and depending on the material of the lens[1,2], may result in a build-up of deposits[1, 2]. This leads to a reduction in comfort and vision and increases the risk of infection. One potentially controllable deposit is makeup, which can contaminate the tear film and/or contact lenses when applied[1,2].

The central corneal tear film is about 3μm thick (Figure 1.1)[3]. The outermost lipid layer is only about 50 to 100 nm thick[3] and is produced by the meibomian glands and secreted through the orifices at the mucocutaneous lid margin. There is also a contribution from the glands of Zeiss and Moll[3]. There is a thin inner polar layer on top of the tear film which is a thick nonpolar layer. It slows down evaporation from the eye surface and prevents the tears overflowing onto the skin[4 5,6] Proteins (lipocalin, lysozyme and mucins) are intercalated in and/or adsorbed into the lipid layer[3, 4]At the polar nonpolar interface the polar lipids are thought to be orientated perpendicularly with their polar ends exposed in the aqueous layer and their nonpolar ends immersed in the lipid sublayer[6]

King-Smith proposed a multi-lamellar sandwich model of the tear film lipid layer with layers of polar and nonpolar lipids that slide over each other during blink. The outer non polar layers consist of wax esters, sterol esters, triglycerides, diglycerides, monoglycerides, free sterols and free fatty acids. The inner non polar layers consist of phospholipids and W-hydroxy fatty acids[7].

The main part of the tear film thickness is made up of the aqueous phase[3], it is an estimated 3 μm thick[8]. It comes from the main lacrimal gland, the accessory lacrimal glands of Krause and Wolfring; it also contains soluble gel forming mucins which are produced by the goblet cells[9,

[10].Additional electrolytes and fluid are secreted by ocular surface epithelial cells. The rate of tear flow varies according to the demands of the external environment.[9, 10].

The inner most layer is a mucoidal basal layer. The dissolved mucins increase in concentration through the aqueous to the basal layer[11]

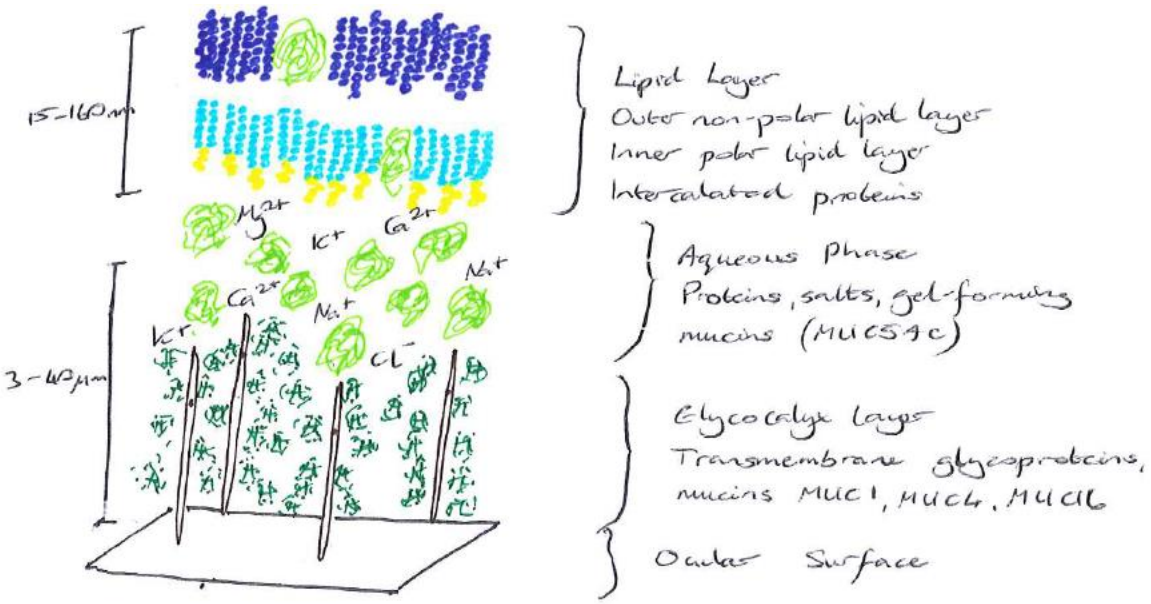

FIGURE 1.1 A proposed model of theprecorneal tear film showing the relationshipand interaction of lipidbinding proteins and the outer lipidlayer

The average tear film osmolarity is 302 mmol/kg[12, 13]; insertion of contact lenses initially causes a reduction in osmolarity due to reflex tearing[12, 13]. The normal pH of the tear film is between 6.5 and 7.8 and varies throughout the day [12].

The tear film itself contains antibacterial lysozyme and lactoferrrin, as well as secretory antibodies, mainly IgA. Lysozyme is a bacteriolytic protein that depolarizes mucopolysaccharides[14]. Ocular

irritants cause the onset of reflex lacrimation, which quickly dilutes the irritants, with an increase in tear flow of 3 to 4 fold [15]. Tear integrity is important in corneal wound healing and any tear deficiency may compromise wound healing[11].

The tear film is a relatively unstable structure and is reformed and maintained by blinking[16]. During the blink the lipid layer is squashed between the lid margins. The mucin, contaminated by lipid during tear break up, is moved to the upper and lower fornices and excreted through the tear duct. It is replaced by a new layer created by the lids pushing against the ocular surface. During eye opening a new aqueous layer spreads over the epithelial surface and the lipid spreads out creating a new layer. The new layer is relatively unstable and tear evaporation occurs; this results in reduced tear film thickness and lipids start to migrate towards the mucous. The mucous starts to lose its hydrophicity and the tear film starts to rupture, resulting in small islands of tear break up; this stimulate the blink and the cycle continues[16].

Contact lens wear has been associated with an decrease in pre-lens tear film thickness and stability, increased tear osmolarity, loss or shortening of the meibomian glands, alterations in corneal sensitivity, cellular changes in the conjunctival and corneal epithelium [17] The presence of a soft contact lens provides challenges for the tear film. There is the need to provide a wettable surface and to maintain lens hydration. The fit, movement of a lens and its geometry may also affect the pre-lens stability – less movement favouring more stability[1,4, 5, 18, 19].

Changes also occur in the tear film with age. The tear film is less stable associated with tear lipid layer changes resulting in less protection from evaporation in the older population[20]; these changes are more marked in women than men)[20,21,22,23,24].

Dry eye and contact lens wear have been shown to be associated with a reduction in the tear lipid layer thickness and rapid prelens tear film thinning[19,21]. Tear film osmolarity has been shown not

to be affected by age, gender, ethnicity or contact lens wear[20,21,22,23,24]. It is not associated with discomfort or dryness symptoms in normal subjects[22]. Tear film break up time increases with age[23].

Patel et al proposed that the lower tear film stability found with age was possible due to tighter lipid-lipid interactions in infants and children compared with adolescents and adults [24]. The tear break up time has been shown to be significantly shorter with age, the lipid layer also being significantly thinner [25]. The lipid part of the tear film is most affected by their immobility on a contact lens surface as this increases their susceptibility to autoxidative degradation[26].

1.3 Contact Lens Materials and the Tear Film

Tear-lens interaction is affected by the differing aspects of the properties and composition of the lens material such as its iconicity, water content, moduli and surface properties[26,27,28,299,30].

Hydrophilic and hydrohobic polymer chains are found in both silicon hydrogel lenses and conventional HEMA soft lenses[27]. These polymer chains orientate themselves with their environment; dryness around the lens will draw the hydrophobic chains towards the surface[27]. This can result in disruption of tear spreading and result in lipid deposition[27].

The introduction of siloxy groups in lens materials has resulted in an increase in oxygen permeability and hydrophobicity to the lens surface[27].

Silicone hydrogel lenses contain alot more hydrophic chains than HEMA type lenses and therefore have to rely on surface modification to control this. Silicon hydrogel lenses undergo plasma treatment, changing of the length and composition of the polymer chains and addition of wetting agents. These techniques all result in different degrees of resistance to lipid deposition[27]

Silicone hydrogel type lens had a significant difference in tear film surface quality compared with group II non-ionic and group IV ionic type lens[28]. In a couple of studies cholesterol and phosphatidylcholine were cumulative over time and silicone hydrogel lenses deposited more lipid than conventional group IV lenses: however these studies were done in vitro not in vivo[29, 30]

Carney et al [31] showed that cholesterol was adsorbed more than phosphatidylcholine in silicone hydrogel lenses than group IV lenses. Coated silicone hydrogel lenses have been found to attract less lipid than uncoated ones[26]. Lipids deposited on the anterior lens surface become immobilised, reducing lipid turnover which results in prolonged exposure to light and oxygen resulting in degradation. This results in reduced lens wettability and is linked to problems with contact lens intolerance and discomfort[32,125].Group IV hydrogel lenses bind more phosphatidylcholine than other lenses. This might reflect the interaction between their negatively charged surface and the positively charged choline group [32, 33]

1.4 Contact Lenses and Makeup

The use of contact lenses alone exposes the eye to an increased risk of eye infections and ocular complications such as dry eye. Contact lens infections that affect the cornea occur in about 4 out of 10,000 contact lens wearers per year and vision loss is less common affecting about 6 in 100,000. However, the addition of makeup to the level of risk and its implications has been studied very little[34, 35].

It is estimated that 55 to 60% of contact lens wearers in most practices are female and 70 to 80% of these wear makeup on a regular basis [36, 37]. In France 75% of women wear makeup[38] and 64% of contact lens wearers are female. In the UK 93% of women use colour cosmetics[39], with total value of about £15 billion. Eyebrow products make up £28 million of this, 7% of the eye colour

cosmetics[39]. The cosmetic market is large and UK sales rank 4th in Europe, exceeding 8.5 billion euros. An increase in eye cosmetic sales of 38% has been reported by Mintel[41].

In Europe, the makeup market grew by 2.9% to $14,608.6 million in 2013[39]. Face makeup is the largest part of this accounting for 33.6% of the total value and eye makeup 32.9%. The UK accounts for 15% of the total in Europe[40].Studies have shown that the average age when beauty products are first used has decreased from 17 years of age in 200 to 13.7 years in 2011 (NPD Group Inc.). It is also estimated that 70% of women used makeup around the eye area and there are no published papers on the effects of tear contamination on normal tear film physiology by eye makeup. This data all shows that a large proportion of contact lens wearers also wear makeup.

There have been some studies into the effect of different types of makeup on contact lenses. Tripathi et al[42] in their study into the spoliation level in soft contact lenses showed that all lenses were subject to deterioration; common causes that they listed included ocular secretions, finger dirt and cosmetics[42].Srinavasan et al[43,44] looked at the effect of 3 types of mascara as well as hand cream and makeup remover on different types of silicone hydrogel lenses. They found that some types of mascara caused an increase in the contact angle (wettability) and pixel brightness of lenses when applied generously in vitro. They also found that some waterproof mascaras changed the shape and optical performance of some silicone hydrogel lenses. It was shown that non waterproof mascara was mostly removed by a one-step hydrogen peroxide cleaning system. Though this type of lens contamination is not usual in vivo as the mascara wand is not rubbed against the lens surface, particles may enter the tear film and hence ocular system and contact lenses[43, 44].Cosmetic products can produce adverse effects on the ocular surface ranging from mild discomfort to vision threatening conditions. Complications can be related to allergy or toxicity[45].

The effect of wearing makeup and contact lenses has been studied little [46, 47]. Cosmetics contain a wide range of ingredients such as oils, waxes, pigments and preservatives and their application may

bring them into close proximity to the eye and its surrounding tissues[38,40,41]. Despite this there has been little understood or studied about the impact of makeup on contact lenses and the best way to combining the wear of both.

The movement of cosmetics from the external eye area to the ocular surface is thought to occur due to mechanical push, suction due to tear surface tension and blinking of the eyelids[48]. Their movement across the lipid tear film layer is determined by an individual's tear film chemistry. Lipophilic parts of cosmetics initially diffuse through the lipid bilayer and are then insoluble in the aqueous, so they tend to aggregate under the lipid layer[48].

The most commonly used preservatives are benzalkoniumchloride, thiomersal (used in mascara), chlorhexidine and colophony (used in eyeshadow and mascara[47]. Benzalkonium chloride is a quarternary ammonium salt with surfactant properties, its molecules are cationically charged and polar; at air/water interfaces and low concentrations (<0.01%) it exists as monomers and at higher concentrations as micelles[47]. It is suggested that benzalkonium chloride acts as a cationic and polar detergent, solubalising the lipid layer and promoting free evaporation and therefore corneal drying[48].

The most commonly used cosmetics used around the eye area are mascara, eyeliner and eyeshadow[48]. Mascara in cake form is composed of pressed together waxes and soap (paraffin, carnauba or beeswax). In liquid preparation it contains preservatives, waxes, resins, pigments, thickening additives (such as nylon rayon fibres) polyvinylpyrrolidone[47]. If water resistant it contains dodecane[48]. Eyeshadow consists of pressed powder on cake (hydrated magnesium silicate) as a base. With kaolin (hydrated aluminium silicate, titanium dioxide and calcium carbonate) along with potato starch to attain coverage and absorption of oil from the skin. Zinc stearate is used to attain smoothness and adhesion. Micronized titanium dioxide, zinc oxide and silicone derivatives are used as pigments. Binders such as lanolin, mineral oils, isopropyl stearate

are added to avoid flaking and to aid pigment dispersion[48]. Eyeliner consists of pigments, water, cellulose gum, thickeners (magnesium and aluminium silicate) and water soluble styrenebutadiene latex or a polymer ammonium acrylate[48].

The anterior lipid layer consists of two parts – a polar phase made up of mostly phospholipid and glycolipids which act as a surfactant between the hydrophilic aqueous-mucin layer and the thick non-polar layer. The non-polar layer consists of mainly wax, cholesterol esters and triglycerides[48]. Once cosmetic products are in the tear film. changes in tear osmolarity and pH may occur resulting in decreased tear stability and discomfort [47]. Make up may have a role in tear film contamination and has been linked to meibomian gland dysfunction[49, 50]. However, Marren in her study in 1994[51] found no relationship between meibomian gland dysfunction, contact lens wear, use of cosmetics and eye rubbing.

The impact of the adherence of makeup to contact lenses and its implications on the comfort, dry eye symptoms and lens tolerance is not well understood[46]. It may be that makeup has a role in dry eye, tear film stability, lacrimal gland dysfunction, hypersensitivity, allergy, infection contact lens intolerance and well as possible toxic effects. All these aspects may contribute to lens intolerance and complications. Schaeffer et al[52] found that contact lens wear was the leading risk factor in bacterial keratitis infections.

There is little literature on the long term side effects of Western eye cosmetic use, though there are documented complications due to lead toxicity and periocular pigmentation from the use of kohl[47,53]. There have been some reported cases of an increase in conjunctival pigmentation following the use of Western formulated mascara and eyeliner, though these are dated with regard to modern cosmetic designs[53]. There have been reports, though these are rare, where the accumulation of cosmetic products in the lacrimal system and ocular surface have looked like melanomas[48,53]. The incidence of allergic contact dermatitis around the eye area is approximately

4%; the primary causes of this are preservatives and fragrances[47]. Preservatives commonly used in cosmetic products that can cause eyelid allergic contact dermatitis include parabens, imidazolydinil urea, diazolydinil urea, formaldehyde, benzalkonium chloride and 2-bromo-2-nitropropane-1,3-diol[54]. Some manufacturers have formulated hypoallergenic products which have less sensitising ingredients[54].

Particles and pigments that may be suspended in coloured eye makeup products may cause foreign body sensations when they come into contact with the ocular surface. It is recommended that particles of no more than 10μm are used in ophthalmic preparations[54].

Goto et al[55] showed that eye drop instillation exacerbated cosmetic product material migration in those to applied it to the inner eyelash line compared with those who applied it to the outer eyelash line and eyelash line within 5 minutes. At 30 minutes the cosmetic product migration in the inner eyelash line and eyelash line groups was not significantly different. They also showed that cosmetic product migration was exacerbated by eye drop instillation, even when applied 2mm from the eyelid. They propose several possible causes: warping of eyelids or excessive force; surface tension of the tears drawing the product; the considerable outflow that occurs might induce excessive blinking; and squinting which might facilitate product migration. This could be extrapolated to contact lens wear, as solution as well as a lens is inserted into the eye. Soft contact lens wear is implicated in half of all bacterial corneal infections and often occurs with combined cosmetic wear and contact lens wear[52].

Compliance with the European Cosmetics directive (76/768/EEC) is a legal requirement for all cosmetic products manufactured for sale in Europe[54]. According to the American Optometric Academy and the American Academy of Ophthalmology, cosmetics are among one of the common sources of problems for contact lens wearers. Misuse can lead to severe adverse reactions including deposits, irritation, allergy, injury, infection and dryness[56].

1.5The Structure of the Cornea

The surface cells of the cornea are stratified squamous epithelial cells, connected by tight junctions that seal the intracellular space (Figure 1.2)[57,58]. These cells have microplicae which increase the surface area and facilitate interactions with the tear film. The apical membranes of these cells express a glycocalyx, mainly composed of transmembrane mucins, which results in wettability of the corneal surface[57, 58]. There is a similar arrangement in the conjunctiva. The tight junctions along with the glycocalyx, results in a relatively impervious barrier to the passage of small water-soluble molecules (such as Fluorescein)[59, 60].The deeper cells are highly interdigitated and are connected by desmosomes[60,61]. Columnar basal cells about 10μm diameter make up the deepest layer.[61]

The stroma is highly organized and made up of flat lamellae of collagen fibrils, which lie in a matrix of proteoglycans. There is more of an interweave anteriorly, where some collagen fibrils insert into Bowman's layer[8]. The normal keratocyte density in the anterior stroma is about 993 cells/mm^2 and decreases to the posterior to about 621 cells/mm^2[8]. The more posterior keratocytes seem to have flatter and larger nuclei and are less densely packed. Contact lens wear has shown an apparent decrease in keratocyte density of 18 to 30% in the anterior stroma and 7 to 18% in the posterior stroma[62,63, 64, 65, 66, 67]. The basal endothelial lamina is Descemet's membrane.

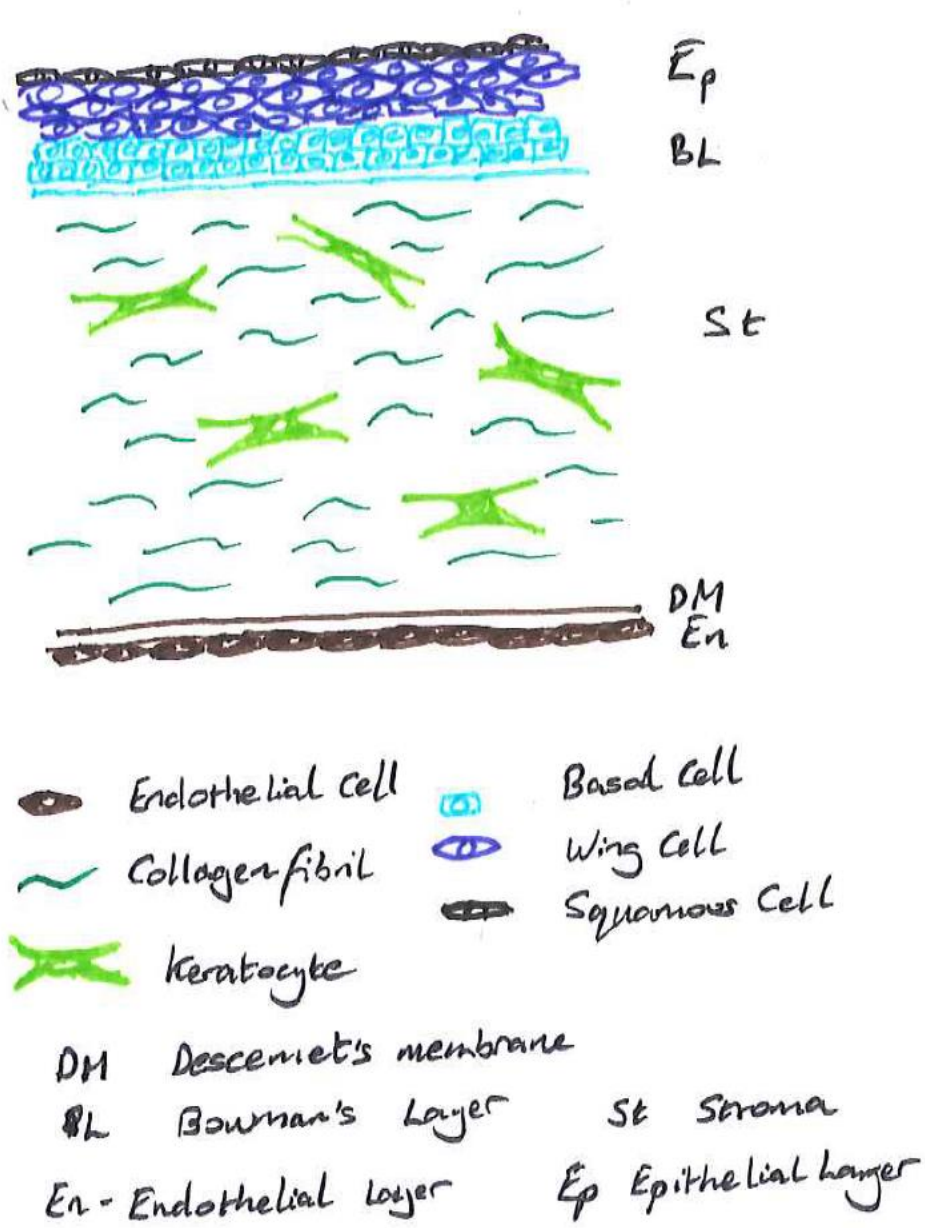

FIGURE 1.2 A three-dimensional representation of the corneal anatomy

The limbus is the transition between the cornea and the sclera, it is a ring of about 1.5mm wide. The epithelium becomes thicker and the cell layers increases to about 10[(68)] and become arranged into a parallel series of radially disposed bars which are separated by vascular connective tissue which are the palisades of Vogt.

Contact lens wear has been shown to have an effect of epithelial thinning and increased cell size [69, 70, 71, 72]. Contact lens wear has also been shown to decrease the normal cell exfoliation[71,73, 74]. The cornea is the main area over which a contact lens sits and therefore could play a significant role in contact lens discomfort (CLD). Epithelial thinning and increased cell size are some of the effects of contact lens wear on corneal morphology and ultrastructure[8]. Apoptotic and morphological changes to the corneal epithelium and corneal epithelial barrier function changes have not been associated with contact lens discomfort during contact lens wear[75].

1.6 The Conjunctiva

The conjunctiva is a thin transparent mucous membrane that links the cornea to the eyelids (Figure 1.3). The palpebral part lines the inner surface of the lids from the lid margin up into the fornix where it turns sharply as is reflected back as the bulbar conjunctiva and covers the sclera to the limbus. The palpebral part is firmly attached to the tarsal plate and the bulbar conjunctiva is loosely attached to the underlying sclera[11,76].

The membrane itself consists of 2 layers – a superficial epithelial layer that contains mucin-secreting goblet cells (MUSAC) and a deeper connective tissue stroma[11,76]. The stroma can be divided into 2 layers – a superficial adenoid layer containing lymphocytes and lymphatic vessels and a deeper fibrous layer that contains most of the nerves and blood vessels. The accessory lacrimal glands of Wolfring and Krause along with mast cells are found throughout the stroma[11,76].

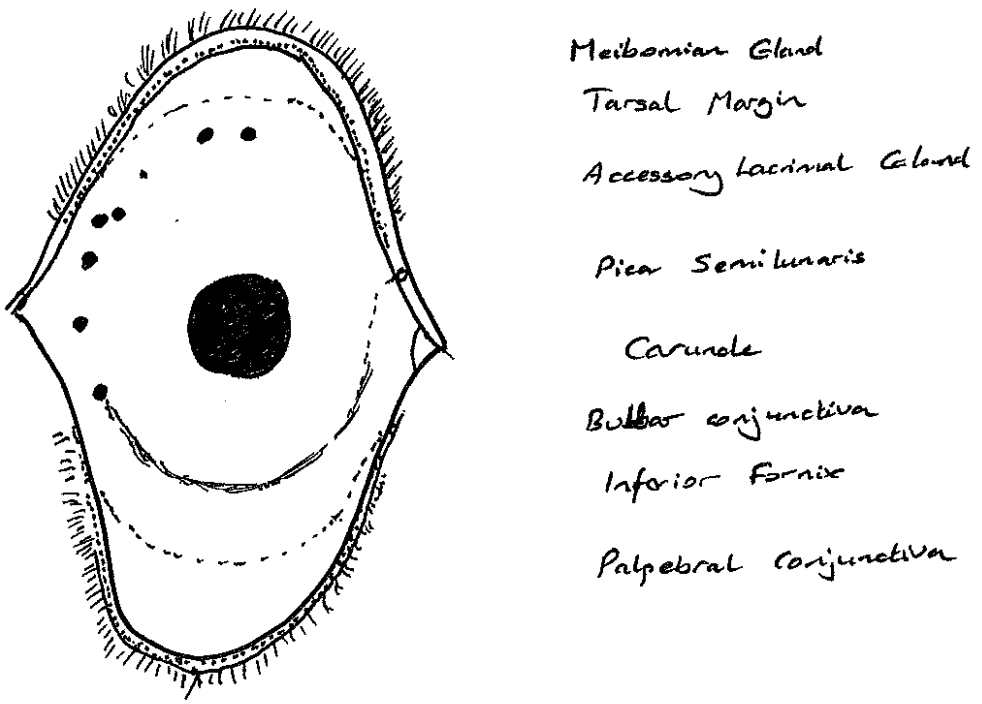

Figure 1.3 Schematic representation of the anatomy of the conjunctiva.

The conjunctiva may be affected by contact lens wear. Lid parallel conjunctival folds (LIPCOF) are subclinical folds that form in the lower lateral quadrant of the bulbar conjunctiva, parallel to the lower lid margin. LIFCOF show a 73% sensitivity and 91% specificity for the comfort of contact lenses[8,77].

1.7The Lid Margin

The eyelid margin, located between the anterior and posterior lid border, can be differentiated into three distinct areas (Figure 1.4; the posterior extension of the free lid margin skin epidermis which surrounds the meibomian orifices, the transition between the conjunctiva and epidermis, and the lid wiper zone (marginal conjunctiva)[78, 79,80].

The lid wiper zone extends from the tarsal conjunctiva to the crest of the upper lid border and is a thickened epithelial lip with conjunctival mucosal morphology; it wipes over the bulbar surface during blink[81]. It contains goblet cells arranged as single cells and in clusters or groups. These can produced soluble mucins that are secreted onto the lid wiper surface and provide lubrication[81]. This area has the highest neural sensitivity out of all the lid and conjunctival regions[8,82]

The meibomian glands are large sebaceous glands found in the tarsal plates of the eyelids. They produce the lipid part of the tear film[83, 84]. They are less numerous in the lower tarsal plate than in the upper plate[85]. The glands of Zeiss open into the hair follicles and are modified sebaceous glands. The glands of Moll are modified sweat glands and are parallel to and in contact with the eyelash follicles[85].Human meibum is 30-45mol% cholesterol esters with long acyl chains (C22:1-C34;1)[83]. The Meibomian lipid film is extremely tolerant to seeding with other lipids[83.88]. The eyelid margin is a key contact zone with contact lenses.

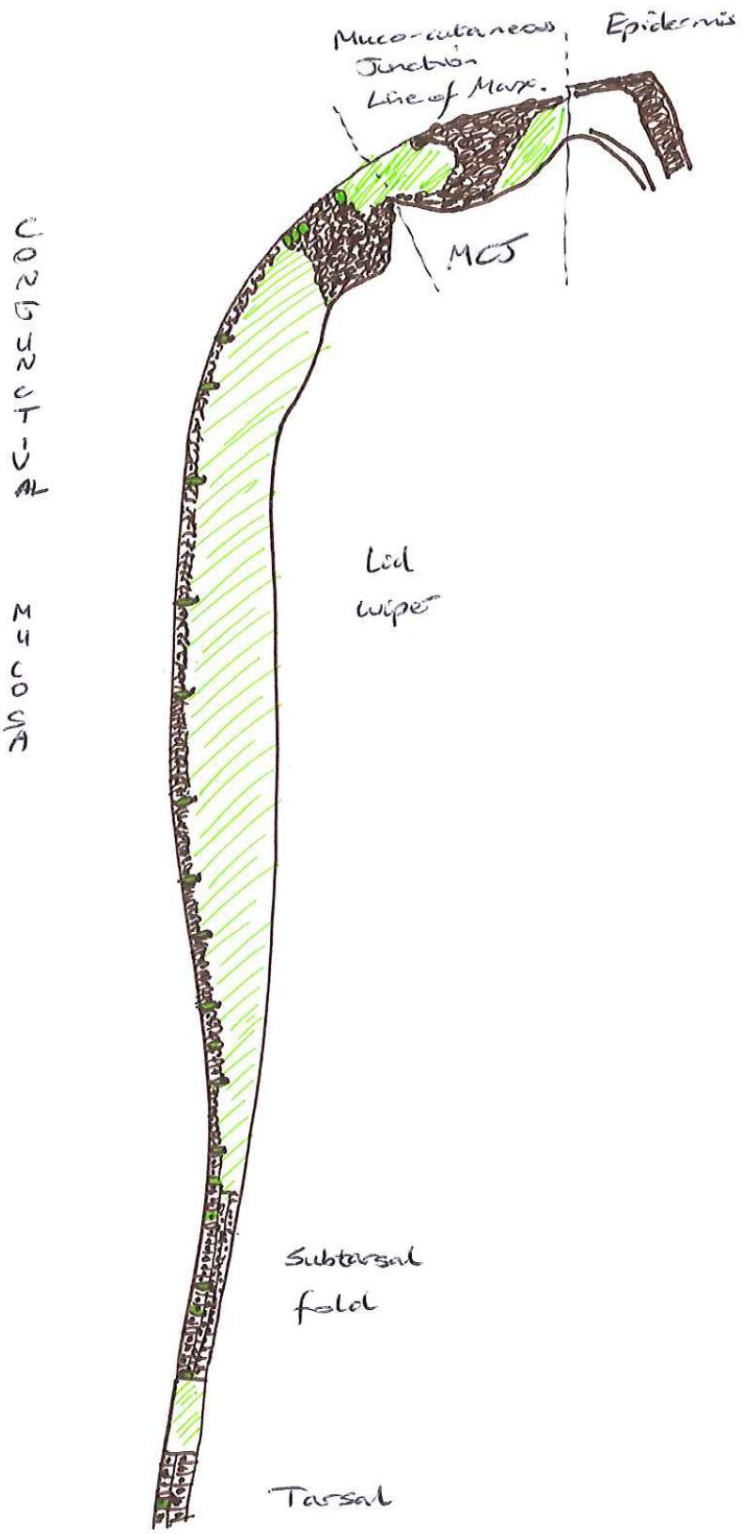

FIGURE 1.4 Tissue zones at the posterior eye lid margin

Lid wiper epitheliopathy (LWE) is potential consequence of contact lens wear[77]. It was first described by Don Korb and his associates in 2002. They found that 80% of subjects with dry eye symptoms (assessed using the ODSI questionnaire), showed staining of the portion of the upper eyelid that is in contact with the globe, when fluorescein and rose bengal were installed[86]. These results were confirmed by others[87]. It occurs where the marginal conjunctiva of the upper lid wipes the surface and spreads the tear film over the contact lens. When the tear film is insufficient, this area is traumatized during repeated blinks; 61% of contact lens wearers who have dry eye have LWE versus 13% of those who do not have dry eye[75,77].

1.8 The Innervation of the Eye

The eye is one of the most richly innervated areas of the body, estimated at 7000 nerve terminals per square millimetre in the central cornea[82]. The sensory (afferent) nerves come from the ophthalmic and maxillary parts of the trigeminal ganglion (Figure 1.5). They give rise to numerous intraepithelial terminals which may reach to within a few micrometers of the ocular surface[82]. They originate from a few hundred neurones in the ophthalmic and maxillary regions of the trigeminal ganglion. The nerves reach the cornea and adjacent bulbar conjunctiva by travelling via the two long ciliary nerves and a communicating branch to the ciliary ganglion)[82]. Whilst in transit the fibres branch and anastomose repeatedly to give rise to multiple nerve bundles that approach the anterior segment at equidistant intervals around the limbal circumference. Sensory nerves exit the anterior port of the plexus to supply the limbal conjunctiva and cornea whilst additional fibres exit the posterior part of the plexus to supply the ciliary body and iris[82].

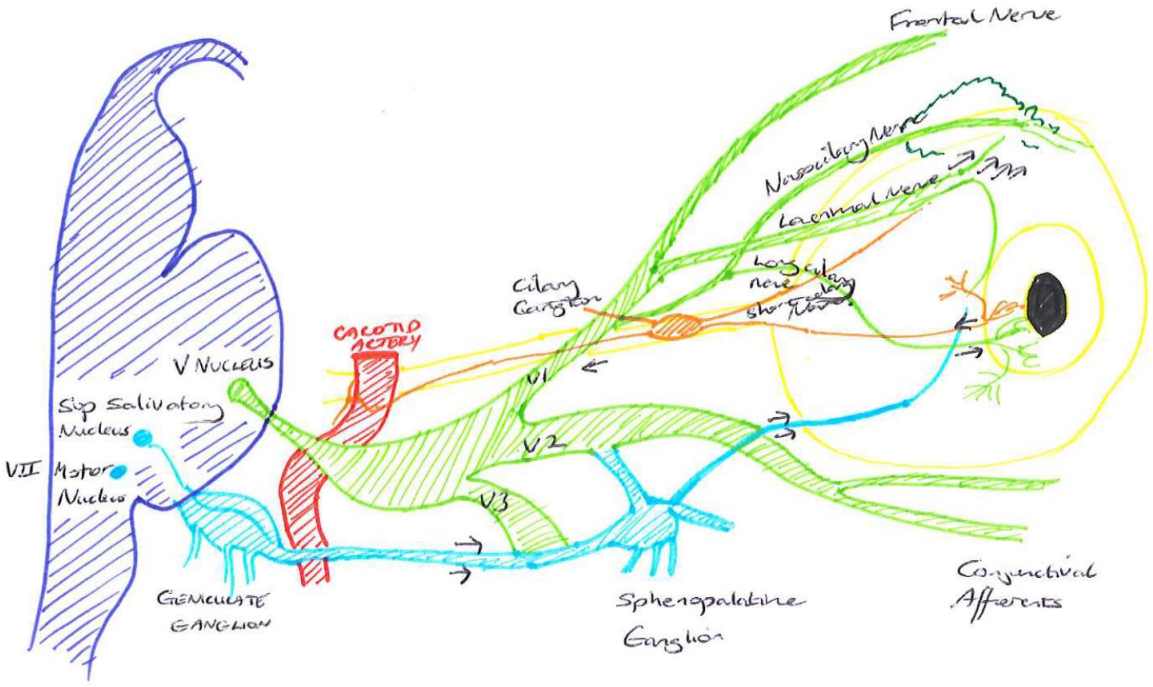

FIGURE 1.5. The innervation of the eye

The Lacrimal Functional Unit is an integrated system comprising the lacrimal glands, ocular surface (cornea, conjunctiva, Meibomian glands, goblet cells, and lids), and the sensory and motor nerves that connect them[82]. Trigeminal sensory fibres arising from the ocular surface, particularly the cornea, run to the superior salivary nucleus in the pons, from where efferent fibres pass, in the nervus intermedius, to the sphenopalatine ganglion. Here, postganglionic fibres arise that terminate in the lacrimal gland, nasopharynx, and vessels of the orbit. Another neural pathway controls the blink reflex, via trigeminal afferents and the somatic efferent fibres of the seventh cranial nerve[82]. Higher centres feed into the brainstem nuclei and there is a rich sympathetic supply to the epithelia and vasculature of the glands and ocular surface[82]. The stromal nerves enter from the limbus in 60 to 80 evenly

spaced, prominent, radially direct, midstromal nerve bundles. At the point of entry 70 to 80% of the nerves are unmyelinated, the rest are finely myelinated which lose their sheath within a millimetre of entering the cornea[82].

Between 200 and 500 stromal nerve fibres penetrate Bowman's layer, mostly in the intermediate and peripheral cornea, to supply the corneal epithelium[82]. These sensory corneal nerves are made up of polymodal receptors, mechano-nociceptors (they respond to mechanical forces of a magnitude close to that needed to damage corneal epithelial cells), and cold-sensitive thermoreceptors (these react to decreases in temperature caused by the evaporation of tears at the corneal surface, or the instillation of cold and hyperosmolar solutions)[75]. The activation of these nociceptors is via specific ion channels, but there seems to be no relationship between channel activation and contact lens discomfort.

Postreceptor sensory nerve signal propogation goes from the source through the trigeminal ganglion to and in multiple discrete zones along the rostrocaudal axis of the trigeminal brainstem sensory complex of the central nervous system[82]. Here sensory nerves end in the ventral part of the transition region between caudalis interpolaris of the spinal trigeminal nucleus and caudalis of the same region or the spinomedullary junctions. Sensory innervation to the bulbar and palpebral conjunctiva and eyelid margins are via branches of the supratrochlear, supraorbital, infratrochlear and lacrimal nerves (all of which are branches of the ophthalmic nerve) and the infraorbital nerve (a branch of the maxillary nerve)[82]. It consists of mostly unmyelinated, but some finely myelinated axons that end as unencapsulated free nerve endings in the stroma, along the surfaces of blood vessels and in the epithelium[82].

The lacrimal and meibomian glands receive parasympathetic and sympathetic nerve supply[8]. The input and output from these and the ocular surface are the basis of a reflex arc between the ocular surface, brainstem and lacrimal glands, which alters the tear secretion to meet daily requirements.

It is possible that contact lens wear might affect nerve fibre density, tortuosity, branching, beading, thickness or reflectivity. Changes that occur with orthokeratology to the morphology of the subbasal nerve plexus increase the threshold to sensitivity[8,82]. Changes in corneal sensitivity with contact lens wear has been widely reported, though the mechanism is not known[82]. It is also possible that stimulation of subacute inflammation of the ocular surface may happen during contact lens wear and nerves might respond to the production of a variety of inflammatory mediators such as cytokines and arachidonic acid metabolites. Neurotrophin nerve growth factor (NGF) seems to be upregulated in contact lens discomfort[75,82]. It is involved in the survival and maintenance of sensory and sympathetic neurones, suggesting that nerves are either being damaged or altered in other ways with contact lens discomfort[75].

1.9 Ocular Defence Mechanisms

The eye has a complex and effective defence mechanism. The first line of defence is the blink reflex. This is stimulated by visual, aural, chemical and mechanical stimuli[15]. The eye closes within a fraction of a second, with a latent period often less than 200 msec[15]. In a normal healthy eye, the eyelids seal the eye during sleep and during exposure to continued adverse conditions. It has been suggested that a decreased corneal sensitivity affects the blinking mechanism and the feedback loop to the lacrimal gland. This results in decreased tear secretion and increased tear evaporation, which leads to dry eye symptoms[82,89].

The cornea is composed of an extraordinary array of epithelial cells which undergo a set process of differentiation and cell death to maintain an effective barrier. The initial phase of corneal wound healing is the migration of existing epithelial basal cells at the wound edge within 4 to 6 hours of the incident. The next phase involves the migration of the epithelial cells over the area before mitosis begins, resulting in a linear type of cell 'healing', which involves the formation of temporary adhesions[90]. When the migration of a monocellular layer is complete it becomes more firmly anchored to the basement membrane and Bowman's layer. The last stage is the proliferation of the epithelial cells until normal epithelial thickness is restored[90].

The conjunctiva does not seem to have the complex organization of the cornea. It presents a different type of barrier. Any form of insult causes a mucous discharge from the goblet cells which are found in large numbers through the bulbar and palpebral conjunctiva[68]. The epithelial cells produce several peptides that have antibacterial properties [11]. Mucins trap and clear allergens and pollutants[11].

The conjunctiva has been shown to be more closely associated with contact lens discomfort (CLD). Bulbar conjunctival staining has been shown to be associated with CLD, although bulbar hyperaemia has not[75]. The leading edge of the palpebral conjunctiva, as a contact lens moves across the meibomian glands, has been shown to be associated with CLD[75].

At any point in time it is possible to culture potential pathogens from 5% of eyes[91]. The incidence of eye infections is much less that this, due to the ocular defence mechanisms which resist infection and are superior to the ability of microorganisms to invade the eye. However, with contact lens wear this balance is altered significantly. Contact lens wearers are about 60 times more likely to have a corneal infection than non wearers[52,92]. Alongside this, different types of contact lens care and handling have been shown to alter the type and increase the number of bacteria on the ocular

surface as well as some of the defence mechanisms becoming inhibited, such as blinking and tearing. There is some evidence that some of the anti-microbial factors (human beta-defensin-2) released by the epithelium to resist Pseudomonas aeruginosa infection are diminished with contact lens wear[92, 93].

1.10 Dry Eye and Contact Lens Discomfort (CLD)

CLD is characterised by persistent or episodic adverse ocular sensation related to contact lens wear (with or without visual disturbance) resulting from reduced capacity between the contact lens and the ocular environment. This may result in reduced wearing time and discontinuation of lens wear[94]. It is reported by symptomatology primarily rather than by the observation of clinical signs[75].

Contact lens discomfort (CLD) is experienced by most contact lens wearers at least occasionally, some so severely that they alter their wearing pattern, some discontinuing lens wear. Indeed CLD is the primary factor associated with permanent discontinued wear of lenses[75,95,96] with studies showing a dropout rate of between 12% and 51% due to CLD[75,95, 96].

It is a condition that occurs after adaptation to contact lens wear and is not related to lens insertion. It may be accompanied by signs including conjunctival hyperaemia, meibomian gland changes, conjunctival and or corneal staining. Modifiable factors that affect CLD include care compliance[94]. Allergens and pollutants which might affect the ocular environment are also associated with CLD[94].Dry eye and CLD may intertwine. However, there are those who suffer irritation when wearing their lenses (CLD) who have no signs or symptoms of dry eye (23% in one report)[17]

Dry is defined by the TFOS 2007 Dry Eye Workshop as 'a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability with potential damage to the ocular surface. It is accompanied by an increased osmolarity of the tear film and inflammation of the ocular surface'

Dry eye is cited as one of the most common reasons for contact lens drop out, 53% in the UK[75]: 20 to 50% of contact lens wearers experience discomfort with their lens wear. Known contributory factors to dry eye with contact lens wear include air conditioning, central heating and draughts[96]. The effect of makeup has not been reported or investigated.

Both practitioners and the industry show that the drop out rate for contact lens wear is highest in the first 3 to 6 months of lens wear, with daily disposable lenses having the highest retention rate of 60%[94]. The most common reason cited is comfort[94]. In the USA 72% and in the UK 53% gave the primary reason of ceasing lens wear to be lens discomfort[77,97]. Symptoms of CLD include tired eyes, itchiness, watery eyes, pain, aching, excessive blinking and burning[17].

Increased tear osmolarity can lead to the sensation of dry eye[12,13,77]. There are various methods of measuring tear quantity – tear meniscus height, Schirmer test, phenol thread test. Tear quality can also be measured by measuring the tear break up time (both invasively using fluorescein dye and non-invasively using keratometry mires or a tearscope). Bulbar conjunctival and corneal staining with fluorescein, plus other dyes such as rose Bengal and lissamine green give an indication of the amount of dry eye[98].

Contact lenses divide the tear film into a pre- and post lens tear film[16,21,75]. This results in a less stable tear film on the front lens surface and some post lens tear film changes also, but these are less well defined. No relationship has been found between CLD and total tear protein, lactoferrin and lysozyme[75].

The link between contact lens deposits and contact lens discomfort is closely associated to the disturbance of the pre lens tear film and its associated lack of wettability[96,98]. Poor lens wetting has been reported in 40% and 39% who had a rapid pre-lens noninvasive tear break up time and prefluorescein breakup time[17]. There are mixed results for gender affecting CLD, though it has been shown not to be a factor in lens discontinuation[17,96]. Age has sometimes been shown to be associated with CLD[17]. While expert clinical evidence suggests that the use of soaps, lotions and cosmetics may contribute to CLD, there is little scientific evidence to support their role in CLD[17].

1.11 Assessment of Ocular Comfort

Different validated questionnaires have been developed to give a subjective evaluation of dry eye. The two most widely used are the McMonnies Dry Eye Index (CLDEQ-8) and The Ocular Surface Disease Index (OSDI). The McMonnies is a screening test using yes/no answers, it takes into account epidemiological risk factors, frequency of symptoms and sensitivity to environmental triggers.

OSDI was developed to grade the severity of dry eye syndrome, to provide a rapid assessment of the symptoms of ocular irritation consistent with dry eye. It assesses the frequency of ocular symptoms, difficulty with vision-related function and discomfort due to environmental factors. It has undergone psychometric testing and has been found to be valid , effectively discriminating between normal, mild, moderate and severe dry eye [99,100,101] and has been accepted by the U.S. Food and Drug Administration for use in clinical trials. This test was used to help subjectively differentiate any difference between the modes of contact lens insertion in both the questionnaire and the detailed eye examination part of the study.

Contact lens dry eye differs from non contact lens dry eye in that it differs significantly throughout the day. The OSDI attempts to estimate the disease severity as well as reflecting the range of dry eye symptoms in one index which is easy for patients to handle[77].

ODSI has been used in other studies – Ng et al[47] found that 83% of respondents used eye cosmetics regularly. They used the ODSI score and found that the ODSI scores of cosmetic users were similar to that of non users, but perceived comfort was greater when cosmetics were not used. They found that the frequency and type of cosmetics used did not influence the OSDI, though they found that the median scores suggested a trend towards reduced comfort in those who wore eyeliner. Korb et al[86] also used the OSDI in their study of patients with dry eye and described lid wiper epitheliopathy for the first time.

1.12 Thesis Aims

The review of the academic literature confirms that while make up has the potential to deposit on a contact lens and be an irritant to the eye, exacerbated by contact lens wear, there is little know about how common an issue this may be and whether strategies such as the order of make-up application and lens insertion, or the use of eyelid primer, may improve subjective comfort.

The current advice is to insert lenses then apply makeup; this advice has been given for many years. However, the literature review uncovered no studies that provided an evidence base for this advice. There appear to have been no studies into the effect of wearing a product that could help makeup remain on the eyelid, an eyelid primer / foundation[46]. There are also no published papers on the effects of tear contamination by makeup on the normal physiology of the tear film[46].

Several of the major contact lens companies (Sauflon, Coopervision, Acuvue) were contacted and they knew of no such studies, nor did the College of Optometrists. There is advice published by the contact lens manufacturers[102, 103, 104, 105, 106, 107, 108] and the College of Optometrists which states that the reason for inserting contact lenses before applying makeup is self-evident, 'due to what we know about the dangers of debris getting under a contact lens. Thus, the main reason that makeup should be applied after a contact lens is inserted, is to ensure that makeup debris does not become trapped under the lens during application. This also applies to hair products such as hairspray.'

There are two other reasons stated that makeup should be applied after a contact lens is inserted:

'1. For patients who are long sighted, inserting their lenses first will help them to see what they are doing while applying their makeup.

2. If makeup is applied before inserting contact lenses, you run the risk of smudging your makeup if you have issues with inserting the lenses.'

For presbyopes and hyperopes, who may have difficulty focusing at near without their lenses in, the advice to insert lenses first may well be the most appropriate for logistical reasons. However, many myopes see better at near without their lenses, so the current advice may not be the most appropriate in these cases.

In the case of RGP wearers, they may have the additional discomfort of pressing on the eyelid during application of eye makeup as well as the risk of debris under the lenses due to the movement of tears under the lenses if the lenses are inserted first'. [personal communication: 27.2.09 from Peter Rolfe, 27.3.09 from John Rogers and Karl Aberdeen, 26.2.08 from Annette Latham Jackson}.

The American Optometric Association advice [56] is to insert soft lenses before applying makeup, but to insert RGP lenses after applying makeup. However, there appears to be no evidence based research for their advice.

Whilst reviewing contact lens advice literature recently, colleagues were asked what they themselves did regarding lens insertion and make up. The answers were that some inserted lenses after the application of makeup, despite knowing what the official advice was, as they found it improved lens comfort.

Hence the hypotheses investigated in this study were:

- The use of make-up is common in the female community, regardless of demographic
- That's that subjective comfort and wearing time would increase when soft contact lenses are inserted before, rather than after, the application of makeup in habitual contact lens and makeup wearers
- That the use of eyelid primer would increase comfort and decrease ocular hyperaemia induced by the application of make-up while wearing contact lenses
- That myopes and prepresbyopic emmetropes would be better at applying make-up without impacting the ocular surface than hypermetropes and presbyopic emmetropes

The aim of this study was to look at the wearing patterns of patients who wore both contact lenses and makeup. It was also to see if there was any advice that could be given to lens wearers who also wore makeup, with regard to the sequence of lens insertion and to application of makeup, in order to improve lens comfort and compliance.

The general use of contact lenses in the population was firstly investigated, along with the length of time the lenses were worn, length of comfortable wearing time, the use of makeup and the type of

makeup worn. This was then further broken down by modality of contact lens wear – soft daily disposable, weekly disposable, monthly disposable, extended wear and rigid gas permeable (RGP) contact lenses.

A second study, cross over in design, was carried out by volunteers with healthy eyes who regularly wore contact lenses and makeup to see whether there was any difference in the level of comfort and wearing time when lenses were inserted before and after makeup was applied. This group was investigated in more detail regarding the modality of lens wear – soft daily, weekly, monthly disposable lenses, extended wear and RGPs, to determine if the results varied with lens type.

The third study involved the use and non-use of an eye shadow primer to limit the amount of debris in the eye was carried out on a group of hyperopes, myopes and presbyopes, who regularly used makeup and contact lenses, to investigate if its use should be advised and if there should be a difference in the advice given with the type of refractive correction worn. The results were also compared with when no makeup was worn.

This thesis contributes to the current understanding and advice given to contact lens wearers who also wear makeup.

Chapter 2

Population survey

2.1 Introduction

In 2014 the UK incidence of contact lens wear was 7.2% of the population (the same as in 2009)[109]. The national demographics in 2009 in the UK were as follows: – the average age for new contact lens fits was 31.3years ± 14.1 years, the average age for refits 37.5 years ±12.8 years, 49% were refits, 64% were females[110]. In 2014 the UK prescribing trend for new fits was 97% soft lenses and 92% soft lenses for refits[111]. Silicone hydrogels made up 80% of refits and 71% of new fits. For new fittings 45% were daily disposable, 2% 1 to 2 weekly disposable and 53% monthly disposable lenses. For the refits 42% were daily disposables, 8% 1 to 2 weekly and 49% monthly disposable lenses[111]. This has changed with time; in the UK, one study showed the majority of lens wearers use soft lenses (approx 90%)[112]. Of these 38% were daily disposable lens wearers [113]. Sully[114] in 2005 identified that in the UK 40.67% were daily disposable wearers, 14.69% wore RGPs 32.50% soft daily wearers, 11.88% soft extended wearers and 2.81% traditional soft wearers. This will continue to change with time with the introduction of new lens types and cost.

The effect of wearing makeup and contact lenses together has been studied little[46, 47]. Cosmetics contain a wide range of ingredients such as oils, waxes, pigments and preservatives and their application may bring them into close proximity to the eye and its surrounding tissues. Despite this there has been little understood or studied about the impact of makeup on contact lenses and the best way to combine the use of both.

It is thought that makeup can cause a problem in contact lens wear due to contamination of the tear film and contact lenses, but there is little evidence[46]. It is known that the patients profile for those that wear contact lenses fits well with those applying makeup[46]. However, it is not clear what advice they are given on applying makeup when wearing contact lenses, but we do know that compliance to contact lens wear is generally poor[89,112, 113, 115] .

Therefore, the aims of this study were to investigate the contact lens wearer and makeup wearing habits and experience of two groups of people. One was made up from group of the general public that attended Optometric practices in South Wales and the other group was made up from the Optometry department at Aston University.

2.2 Method

A survey of two population groups was carried out. Both groups were asked the same questions:- their age and gender, whether they wore make up, whether they wore contact lenses. If they wore makeup they were asked whether they wore foundation, powder, blusher, lipstick, eye shadow, eye shadow primer, mascara, and eye liner.

If they wore contact lenses they were asked which type – daily disposable, weekly or monthly disposable, extended wear, or RGP lenses. They were asked to rate the comfort of their lenses out of 10 (10 being perfect) at the start and at the end of their wearing time, the average wearing time and length of time the lenses were comfortable

One group consisted of patients who attended branches of The Optic Shop over a 2 week period and were asked to fill in the short questionnaire by members of staff.The other group consisted of students from Aston University Optometry department were contacted by email and asked to take part in a quick survey run by survey monkey, plus reminded at lectures.

For this type of study the questionnaire needs to be quick and easy to fill in, without asking too many personal details, in order to have a high and truthful response rate[99, 115,116, 117, 118].

The research followed the tenets of the Declaration of Helsinki and had the approval of the Audiology and Optometry Ethics Committee

SURVEY

1) Age __yrs gender: male / female

2) Do you habitually wear makeup yes/no

If yes do you wear

Foundation face powder blusher lipstick

Eyeshadow eyeshadow primer mascara eyeliner

3)Do you wear contact lenses no/

Daily disposable weekly disposable monthly disposable extended wear rgp

If yes, how comfortable are your lenses:

at the start of your wearing time (1 being painful, 10 not knowing they are there)

at the end of your wearing time (1 being painful, 10 not knowing they are there)

What is your wearing time: average __hrs/day time lenses are comfortable __hrs/day

2.3 Statistics

The data was first analysed to see if it was normally distributed or not using a Kolmogorov-Smirnov test. As it was not normally distributed, the data was analysed using an Independent Samples Mann Whitney U test using IBM SPSS package v 20

Optic Shop

The population values were not known but a retrospective sample size analysis was conducted with Statistical Solutions LRC using the means and standard deviations found in the study.

TABLE 2.1 Optic Shop Data

CL wearers	Age (years)		Comfort at start		Comfort at end		Average wearing time (hours)		Time Comfortable (hours)	
	Mean	S.D.	Mean	S.D	Mean	S.D.	Mean	S.D	Mean	S.D
Non makeup wearer Total n=18	38.83	14.03	5.82	4.53	4.37	3.52	6.03	5.46	4.69	3.79
Makeup wearers Total (n= 43)	43.67	13.34	9.00	1.10	6.97	1.65	9.22	2.66	7.31	2.98

For a 2 sided test with an α value of 0.05, a power of 80% the sample size required to detect the difference found in the comfort at the start in makeup v non-makeup wearers was 9 subjects and for comfort at the end of the day was 13 subjects.

As there was a minimum of 18 subjects in each group they were sufficiently powered to detect the difference should one be present. For the average wearing time the minimum number of subjects was 18 and for the comfortable wearing time 25 subjects.

It was powered to determine a 1.7 difference in average wearing time or comfortable wearing time in the group that wore makeup with 13 subjects in the monthly disposable group

Aston University Group

The population values were not known but a retrospective sample size analysis was conducted with Statistical Solutions LRC using the means and standard deviations found in the study.

TABLE 2.2 Aston University data

Cl wearers	Age (years)		Comfort at Start		Comfort at End		Wearing Time (hours)		Time Comfortable (hours)	
	Mean	S.D.	Mean	S.D	Mean	S.D.	Mean	S.D.	Mean	S.D.
Non makeup wearers Total (n=18)	19.17	2.68	9.17	2.92	7.00	1.37	9.03	2.74	7.53	2.85
Makeup wearers Total (n=64)	20.68	7.12	5.82	4.53	4.37	3.52	6.03	5.46	4.69	3.79

For a 2 sided test with an α value of 0.05, a power of 80% the sample size required to detect the difference found in the comfort at the start in makeup v non-makeup wearers was 9 subjects and for comfort at the end was 13 subjects.

As there was a minimum of 18 subjects in each group they were sufficiently powered to detect the difference should one be present. For the average wearing time, the minimum number of subjects was 28 and for the comfortable wearing time 20 subjects.

2.4Results

2.4.1The Optic Shop

TABLE 2.3 The Optic Shop Overall Data

Gender	Female	Male
Number	134	84
Makeup wearer	104	3
Foundation	93 (89.4%)	2 (66.7%)
Face Powder	90(86.5%)	2 (66.7%)
Blusher	86 (82.7%)	2 (66.7%)
Lipstick	94 (90.4%)	0
Eye Shadow	80 (76.9%)	0
Eye Shadow Primer	12 (11.5%)	0
Mascara	97 (93.3%)	1 (33.3%)
Eyeliner	77 (74.0%)	0
Contact Lens Wearer	37	19

TABLE 2.4 Non makeup wearers

Cl wearers	Age (years)		Comfort at start		Comfort at end		Average wearing time (hours)		Time Comfortable (hours)	
	Median	Interquartile %	Medain	IQ %	Median	IQ %	Median	IQ %	Median	IQ%
Total n=18	38	24.5 65.5	9	8 10	7	6 7.5	10	10 10.5	8	7 8.5
Daily Disposable (n=9)	39	24.5 47.5	8	8 10	7	6 8.5	10	10 12	8.00	8 12
Weekly Disposable (n=0)	-	-	-	-	-	-	-	-	-	-
Monthly Disposable (n=6)	41	30.5 50.75	8.5	8 9.75	6.5	6 7	10	8.5 10	7	4.75 7.75
Extended Wear (n=3)	25	21.5 36.5	9	9 9.5	8	7 8.5	24	22 24	22	19 23
RGP (n=0)	-	-	-	-	-	-	-	-	-	-

TABLE 2.5 Data by Contact Lens Type

Cl Type	Makeup wearer	Non Makeup wearer	Combined
Daily Disposable	21 (41.1%)	9 (17.0%)	30 (54.6%)
Weekly Disposable	0	0	0
Monthly Disposable	13 (23.2%)	6 (10.7%)	19 (33.9%)
Extended Wear	0	3 (5.36%)	3 (5.36%)
RGP	1 (1.8%)	0	1 (1.8%)

TABLE 2.6 Makeup wearers

	Age (years)		Comfort at Start		Comfort at End		Wearing Time (hours)		Time Comfortable (hours)	
	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
Total (n= 43)	41	20 51	9	8 10	7	6 8	8.5	8 10	7	5.75 9
Daily Disposable (n=21)	44	34 55	9	1 10	6	1 8	8	1 9	6	1 7
Weekly Disposable (n=0)	-	-	-	-	-	-	-	-	-	-
Monthly Disposable (n=13)	36	23 49	9	8 10	8	6 8	10	10 11	8	7 10
Extended Wear (n=0)	-	-	-	-	-	-	-	-	-	-
RGP (n=1)	37	0	8	0	8	0	16	0	15	0

There were 218 participants 134 (61.5%) female and 84 (38.5%) male. Of these 104 females (77.6%) and 3 (3.6%) of the males regularly wore makeup (Table 2.3). The median age was 49.5 years (30 - 67 interquartile percentage(IQ%)). The median age of those who wore makeup was 41 years (20 – 51 IQ%) and those who did not wear makeup was 38 years (24.5 – 65.5IQ%). 25.7% of the participants wore contact lenses, 27% of the females and 22.6% of the males.

Of those who wore make up 93 females (89.4%) and 2 males (66.7%) wore foundation, 90 females (86.5%) and 2 males (66.7%) wore face powder, 86 females (82.7%) and 2 males (66.7%) wore blusher, 94 females (82.7%) wore lipstick, 80 females (76.9%) wore eyeshadow, 12 wore (11.5%) eyeshadow primer, 97 females (93.3%) and 1 male(33.3%) wore mascara, 77 females (74.0%) wore eyeliner.

37 (27.6%) of the females wore contact lenses and 19(22.6%) of the males. For those that wore contact lenses, 70.5% wore makeup and 29.5% did not (Table 2.5).Of those who wore contact lenses, 21 (31.8%) wore daily disposable lenses and makeup, 9 (13.6%) wore daily disposable lenses and no makeup. There were no weekly disposable lens wearers. There were 13 (19.7%) monthly disposable lens wearers who wore makeup and 6 (9.1%) who did not wear makeup.There were 3 (4.6%) extended lens wearers who did not wear makeup and 1 (1.5%) rgp wearer who wore makeup.

Analysis was carried out to look at the differences between those who wore contact lenses with and without makeup. There was no significant difference with age between the two groups ($p=0.346$) nor was there a significant difference between the comfort at the start ($p=0.303$) or the end of the wearing time ($p=0.907$). Nor was there a significant difference in the comfortable wearing time ($p=0.067$). There was a significant difference in the average wearing time ($p=0.04$), with non-makeup wearers having a longer average wearing time. See Figure 2.7.

For those who wore makeup and contact lenses, here was no significant difference with age (p=0.889), comfort at the start (p=0.420), comfort at the end (p=0.362) or the average wearing time (p=0.065). There was a significant difference with comfortable wearing time (p=0.01), with monthly wearers having a longer wearing time.

The non-makeup wearer groups by lens type were too small to analyse (Table 2.4)

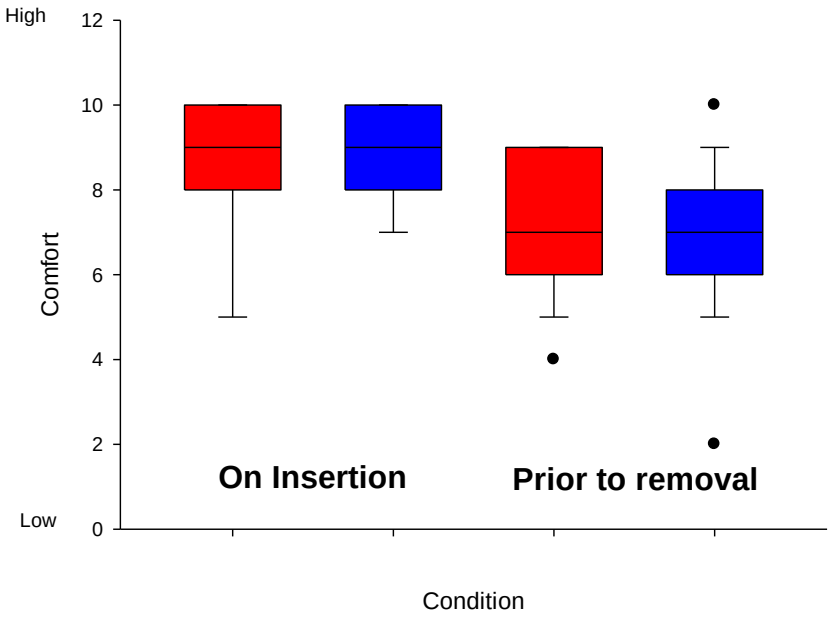

FIGURE 2.1 Optic Shop comfort scores (red – those who did not wear make up, blue – those who did wear makeup). Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

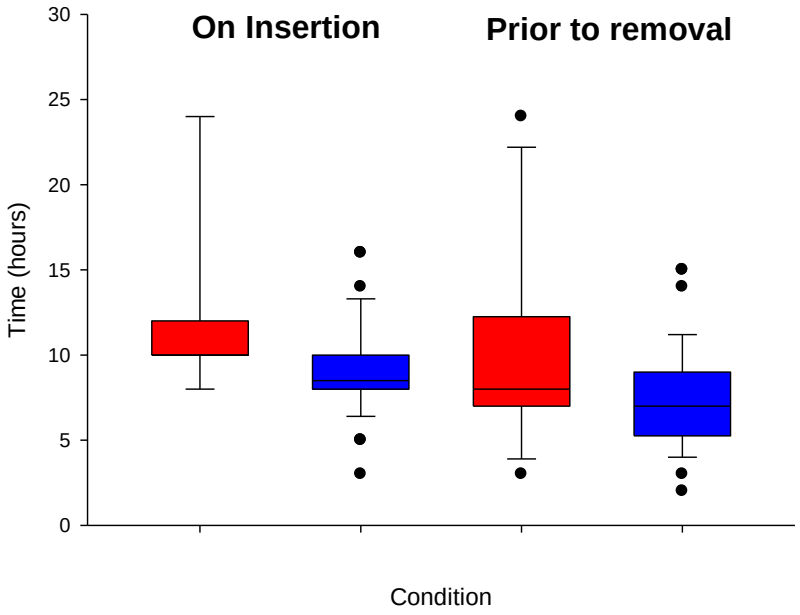

FIGURE 2.2 Average and comfortable wearing times (red – those who did not wear make up, blue – those who wore makeup). Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

For the non makeup wearers the median comfortable wearing time was 8 hours (7 – 8.5 hours IQ%) and the median wearing time was 10 hours (10 – 10.5 hours IQ%). Within this group for the daily disposable lens wearers the median wearing time was 10 hours (10 - 12 hours IQ%), and the median comfortable wearing time was 8 hours (7 - 12 hours IQ%). For the monthly disposable lens wearers the median comfortable wearing time was 7 hours (4.75 – 7.75 hours IQ%) and the median wearing time was 10 hours (8.5 - 10 hours IQ%). For the extended lens wearers the median wearing time was 22 hours (19- 23 hours IQ%) and the median comfortable wearing time was 24 hours (22 – 24 hours IQ%).

For the makeup wearers the median comfortable wearing time was 7 hours (5.75 - 9 hours) and the median wearing time was 8.5 hours (8 – 10 hours IQ%). Within this group for the daily disposable lens wearers the median wearing time was 8 hours (1 - 9 hoursIQ%), and the median comfortable wearing time was 6 hours (1 - 7 hours IQ%). For the monthly disposable lens wearers the median comfortable wearing time was 8 hours (7 - 10 hours IQ%) and the median wearing time was 10 hours (10 - 11 hours IQ%). For the rgp wearer the median wearing time was 16 hours (±14.8 hours) and the mean comfortable wearing time was 15 hours.

2.4.2 Aston University Population

There were 99 participants, 80 females and 19 males. Of these, 68 females (85%) and 2 males (10.5%) wore makeup, 53 (66.3%) of the females and 13 (68.4%) of the males wore contact lenses – 66.7% of the total participants wore contact lenses. The median age was 18 years (18 – 21.5 IQ%)

TABLE 2.7 Aston University Overall Data

Gender	Female	Male
Number	80	19
Makeup wearer	68	2
Foundation	48	1
Face Powder	21	1
Blusher	39	0
Lipstick	34	0
Eye Shadow	27	0
Eye Shadow Primer	5	0
Mascara	60	2
Eye Liner	60	2
Contact Lenses	53	13

TABLE 2.8 Contact Lens Wearers who did not wear makeup

CL wearers who not do wear makeup	Age (years)		Comfort at Start		Comfort at End		Wearing Time (hours)		Time Comfortable (hours)	
	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
Total (n=18)	18	18 18	9	7.25 10	7	6 8	9	7.25 11.5	7.75	6 8.75
Daily Disposable (n=14)	18	18 18	9	0 10	7.5	0 8	8	0 10	6.5	0 8
Weekly Disposable (n=1)	18	18 18	10	10 10	9	9 9	12	12 12	12	12 12
Monthly Disposable (n=3)	18	18 18	10	9 10	7	6.5 7	12	10.5 12	8	8 8.5
Extended Wear (n=0)	-	-	-	-	-	-	-	-	-	-
RGP (n=0)	-	-	-	-	-	-	-	-	-	-

TABLE 2.9 Contact Lens wearers who also wear makeup

	Age (years)		Comfort at Start		Comfort at End		Wearing Time (hours)		Time Comfortable (hours)	
	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
Total (n=48)	18	18 18	9	8 10	7	5 8	8.5	7 10	6.75	5.5 8
Daily Disposable (n=33)	18	18 18	9	8 10	6	4.75 8	8	6 10	6	3.75 8
Weekly Disposable (n=2)	31.50	24.75 38.25	7.50	7.25 7.75	7	7 8	8.00	7.5 8.5	6.75	5.63 7.88
Monthly Disposable (n=10)	18	18 18	9.5	8.25 10	8	7.25 8	9.5	7.63 11	7.75	6.13 9
Extended Wear (n=3)	18	18 19.75	9	7.75 10	6	5 6.5	10.25	8 18	7.5	6.38 8.63
RGP (n=0)	-	-	-	-	-	-	-	-	-	-

TABLE 2.10 Data by Contact lens Type

	Makeup Wearer	Non makeup Wearer	Total
Daily Disposable	32 (66.7%)	14 (77.8%)	46 ((68.7%)
Weekly Disposable	3 (6.3%)	1 (5.6%)	4 (6.1%)
Monthly Disposable	10 (20.8%)	3 (16.7%)	13 (19.7%)
Extended Wear	3 (6.3%)	0	3 (4.5%)
RGP	0	0	0

Out of those who wore makeup, the different types of makeup worn were as follows:- 48 females (70.6%) and 1 (50%) male wore foundation, 21 females (30.9%) and 1 male (50%) wore face powder, 39 females (57.4%) wore blusher, 34 (50%) wore lipstick, 27 (39.7%) wore eyeshadow, 5 (7.4%) wore eyeshadow primer, 60 females (88.2%) wore mascara and 2 males (100%), 60 females (88.2%) and 2 males (100%) wore eyeliner.

Out of the total population 53 females (66.4%) and 13 males (68.4%) wore contact lenses. Out of the population who wore contact lenses 35 females (66.0%) and 11 males (84.6%) wore daily disposable lenses, 4 females (7.6%) wore weekly disposable lenses, 11 females (20.8%) and 2 males (15.4%) wore monthly disposable lenses, 3 females (5.7%) wore extended wear lenses and none wore rgp lenses.

Of those who wore makeup and or contact lenses; 18 (27.3%) wore no makeup, 48 (72.7%) wore makeup. 14 daily disposable lens wearers did not wear makeup and 32 did, 1 weekly disposable lens wearer did not wear makeup and 3 did, 3 monthly disposable lens wearers did not wear makeup and 10 did, and all 3 extended wearers wore makeup.

Analysis was carried out to look at the differences between those who wore contact lenses with and without makeup. There was no significant difference with age between the two groups (p=0.272) nor was there a significant difference between the comfort at the start (p=0.451) or the end of the wearing time (p=0.715). Nor was were a significant difference in the comfortable wearing time (p=0.895) or with the average wearing time (p=0.647).

The data for those who did not wear makeup and contact lenses was not analysed by lens type there were 14 daily and only 3 monthly lens wearers. Of the 70 makeup wearers there were 32 daily and 9 monthly lens wearers so again the could not be compared.

For the non-makeup wearers the median comfortable wearing time was 7.75 hours (6 -8.75 hours IQ%) and the median wearing time was 9 hours (7.25 – 11.5 hours IQ%). Within this group for the daily disposable lens wearers the median wearing time was 8 hours (0 - 10 hours IQ%), and the median comfortable wearing time was 6.5 hours (0 - 8 hours). For the monthly disposable lens wearers the median comfortable wearing time was 8 hours (8 – 8.5 hours IQ%), the median wearing time was 12 hours (10.5 - 12 hours IQ%).

For the makeup wearers the median comfortable wearing time was 6.75 hours (5.5 - 8 hours IQ%) and the median wearing time was 8.5 hours (7 - 10 hours). Within this group for the daily disposable lens wearers the median wearing time was 8 hours (6 - 10 hours IQ%), and the median comfortable wearing time was 6 hours (3.75 - 8 hours IQ%). For the weekly disposable lens wearers the median comfortable wearing time was 6.75 hours (5.63 – 7.88 hours IQ%) and the median wearing time was 8 hours (7.5 – 8.5 hours IQ%). For the monthly disposable lens wearers, the median comfortable wearing time was 7.75 hours (6.13 - 9 hours IQ%) and the median wearing time was 9.5hours (7.63 - 11 hours IQ%). For the extended lens wearers, the median wearing time was 10.25 hours (8 - 18 hours IQ%) and the median comfortable wearing time was 7.5 hours (6.38 – 8.63 hours IQ%).

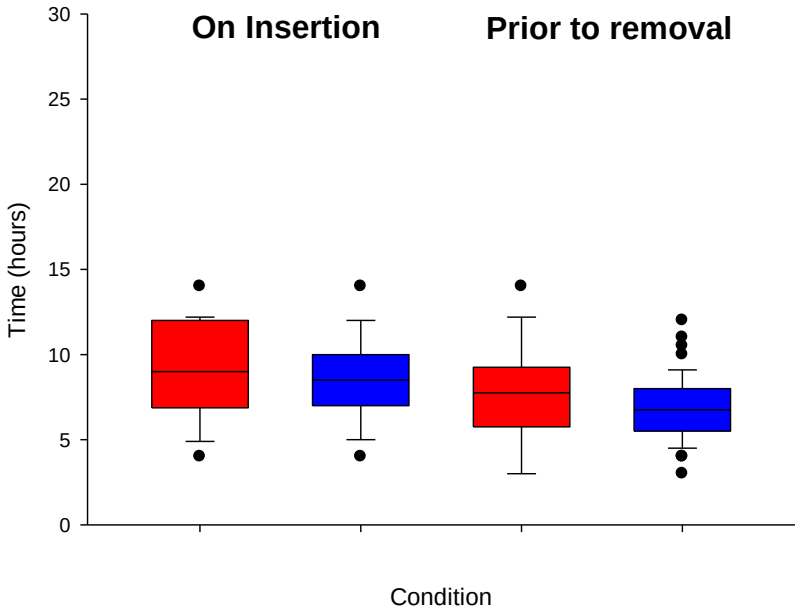

FIGURE 2.3 Aston University average and comfortable wearing times (red – those who did not wear make up, blue – those who wore makeup). Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

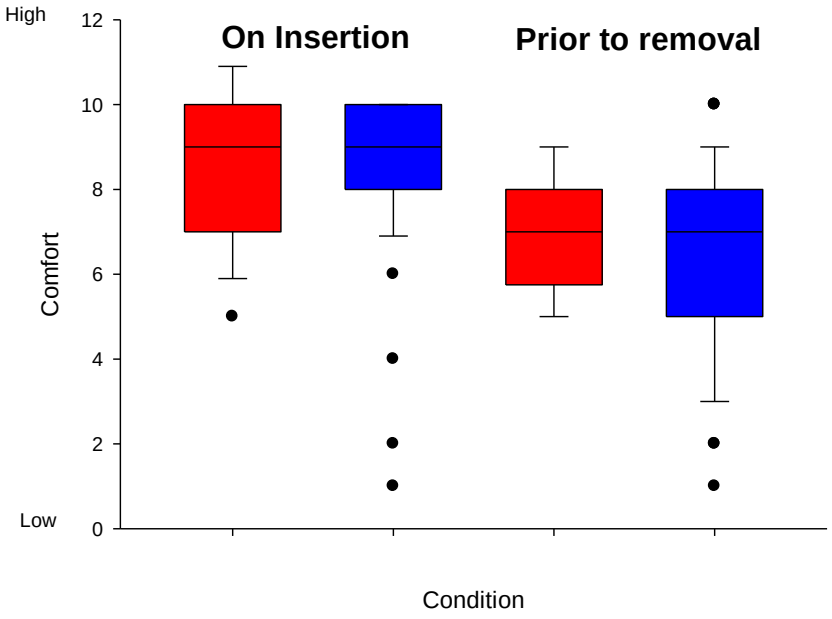

FIGURE 2.4 Aston University comfort scores (red – those who did not wear make up, blue – those who wore makeup). Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

2.5 Discussion

The two groups consisted of very different populations so the two groups could not be combined and the results merged. The Aston University group had a much higher proportion of female respondents(80%) then The Optic Shop (61.5%). This would be due to there being a higher proportion of female students in the department (about 70%).There was also a difference in the median age and IQ% with Aston University having a lower age 18 years (18 – 21.5 IQ%) than the Optic Shop 49.5 years (30 – 67 IQ%), again because it was a student population. There was also a higher percentage of Aston males who wore makeup, 10.5% versus 3.6% in the Optic shop population. This might also be due to the age difference.

The percentage that wore the different types of makeup worn was similar for foundation, eye shadow primer, mascara and eyeliner. For face powder, blusher, lipstick and eye shadow more of the Optic shop population wore these than the Aston population. Again, this difference is probably due to the age difference.

One aspect that was not investigated was ethnicity.

At Aston University the latest published demographics give 35% as Asian/ Asian British throughout the entire student population (Student Equalities Report 2012/13). In the latest census in 2011 7.5% of those in Wales recorded their ethnicity as Asian/ Asian British [119]

Several studies have shown that Asian ethnicity is associated with contact lens discomfort and dryness [121, 122]

Both groups, the Optic shop and Aston participants, had a higher percentage of contact lens wearers than found in the general public. The national demographics in 2009 were – the age for new contact lens fits 31.3+- 14.1 years, age for refits 37.5+-12.8 years, 49% refits, 64% females[110].In 2014 the UK prescribing trend was for 7.2% of the population to wear contact lenses (the same as

in 2009[109]). For the Optic shop group this would be because for contact lens wearers, the recall time is usually 6 to 12 months as opposed to 12 to 24 months for spectacle wearers. For the Aston group this would probably be because of the offer of free contact lenses that the Aston Optometry students receive as well as a shorter recall time for contact lens wearers. However, the published data is for new fits and does include those who already wear contact lenses and so may not reflect the incidence of contact lens wear in the general population.

Contact lens modality of wear profile – there was a higher proportion of contact lens wearers in the Aston university group (66%), versus the Optic Shop group (25.7%). This is probably due to the age difference and the fact the optometry students are given vouchers for free contact lenses by the contact lens companies (this is for use within the department so that their colleagues can practice fitting lenses). The split by gender was similar in both groups. When this is compared with the two groups, the Optic shop groups had 53.6% daily disposable wearers, no weekly disposable wearers, 33.9% monthly disposable wearers, 5.4% extended wear and 1.8% RGP lens wearers.

The Aston group had 69.7% daily disposable wearers, 6.1% weekly disposable wearers, 19.7% monthly disposable wearers, 4.5% extended wearers and no RGP wearers. The main differences are that more of the Aston group wore daily disposable and less monthly disposable lenses. This may also be due to the fact that the Aston group were in receipt of vouchers for free lenses when fitted by their student colleagues, therefore finances were not a constraint in their choice of lens modality. In the UK, one study showed the majority of lens wearers use soft lenses (approximately 90%)[75]. Of these 38% were daily disposable lens wearers[113]. Sully[114] in 2005 showed in the UK out of 320, 122 were daily disposable wearers (40.7%), 47 SGP (14.7%), 104 soft daily wearers (32.5%), 38 soft extended wearers(11.9%), traditional soft wearer 9 (2.1%).In 2014, the trend in the UK was for new fits 97% soft lenses and 92% soft lenses for refits[102]. Silicone hydrogels made up 80% of refits and 71% of new fits. For new fittings 45% were daily disposable, 2% 1 to 2 weekly

disposable and 53% monthly disposable lenses. For the refits 42% were daily disposables, 8% 1 to 2 weekly and 49% monthly disposable lenses[111].

The question arises - how is the lens wear modality affected by other factors such as dry eye, contact lens discomfort, the required wearing time for specific occupations or hobbies, financial constraints. The effect that these and other factors have on the results is an unknown quantity.

The Aston population have additional factors to take into consideration – the population consists of students who have less money, so may be affected by financial constraints, but have the offer of free lenses and the motivation to help their fellow students. This may result in there being a higher proportion who started contact lens wear. This will also affect their level of motivation to wear lenses.

Within the Optic Shop population, the only significantly different parameter between those who did and did not wear makeup and contact lenses was the average wearing time, with non makeup wearers having a longer average wearing time. This may be due to effects of makeup on the tear film and hence lens comfort. It could also be affected by the motivation to wear contact lenses – the reason for their use. It may be that those who wear makeup wear lenses for vanity and those who do not wear makeup wear contact lenses for their optical benefits in their occupation or hobbies.

Within the Optic Shop the monthly disposable contact lens wearers had a significantly longer comfortable wearing time than the daily disposable contact lens wearers. This may be due to an element of selection – those who wear daily lenses may do so rather than monthly lenses due to problems with monthly lenses such as dry eye and contact lens discomfort.

For the Aston population there was no significant difference between those who did and did not wear makeup and contact lenses. This difference may be due to the age difference – the Aston group being younger and having better quality and quantity of tears and less dry eye.

There was a between the total wearing time and comfortable wearing time that was similar between the two groups plus across all modes of lens wear. This was between 2 and 3 hours. This has been the case in other studies, where the difference between the total wearing time and comfortable wearing time had an average of 2.5 hours[113].

This does beg the question – why do people wear uncomfortable lenses? There may be many reasons for this - to fit in with their lifestyle, the inconvenience of removing their lenses earlier - vanity.

The amount of time that lenses had been worn in total was not asked and would be an interesting factor to take into account - the drop out rate for contact lens weardecreases after the first 6 months of lens wear (when the drop out rate is at its highest)[18,75,,95]. It is likely that the Aston population had more people who had worn lenses for 6 months or less due to the student vouchers scheme. Therefore, the drop out rate with time would be expected to be higher and the proportion of those who wore lenses whilst they were uncomfortable to be higher.

The numbers for the weekly disposable, extended wear and rgp lens wearers are too small in both the Optic Shop and Aston group to be independently analysed statistically but they contribute to the overall picture.

Having obtained a profile of lens and makeup wearing habits, the next element of the research was to look in more detail at the difference in the level of comfort when lenses were inserted before and after the application of makeup, to see if there was any significant difference.

CHAPTER 3

Subjective Benefit of inserting lenses before / after makeup

3.1Introduction

In the previous study it was found that in a general optometric population that 61.5% were female, 38.5% were male. Of these 77.6% of the females and 3.6% of the males regularly wore makeup, 27% of the females wore contact lenses and 22.6% of the males. Having examined two general populations – one of optometry students, the other from an optometric practice, the next stage was to investigate in more detail the insertion of lens habits and preferences of a group of contact lens wearers who habitually wore makeup.

The aim was to determine the most appropriate advice to give contact lens wearers who also wear makeup, with regard to lens insertion. This was achieved using the following objectives

- measuring the length of time the lenses were worn, the length of time until the lenses were comfortable, the comfortable wearing time on a daily basis, when both lenses and makeup were worn. This was done when lenses were inserted before and after the application of makeup.

- comparing the level of burning and foreign body sensation on insertion and removal, when lenses were inserted before or after the application of makeup with the same patients to see if there was a statistically significant difference using a non- parametric paired analysis technique.

- comparing the OSDI scores for when lenses were inserted before and after the application of makeup

- dividing the patients in groups regarding lens wear modality:- soft daily and monthly disposable lenses and RGP lenses) and analysing the results within each group by the order of lens insertion, to see which order results in better lens comfort.

3.2 Method

This part of this study consisted of a survey of contact lens wearers with healthy eyes who also wear makeup on a regular basis (two or more days a week) and their wearing time, type of lenses worn and type of makeup worn.The participants were recruited from contact lens patients attending six branches of The Optic Shop throughout south Wales and at Aston University. The populations from the Optic Shop and Aston University were combined for this part of the study – there were only 3 participants for Aston University so it made no sense to analyse them separately. The inclusion criteria were that they regularly wear makeup (at least two days per week), be over the age of 18 years, be an established contact lens wearer i.e. not at their first aftercare, and have healthy external eyes.

Potential subjects were excluded if they were: under 18 years of age, had an abnormality of the external eye that would affect contact lens wear such as keratoconus, were a new contact lens wearer, did not wear makeup on a regular basis or their eyes were found not to be healthy at the aftercare visit e.g. had infiltrates or a significant corneal staining pattern that required a contact lens refit.

The potential participants were asked, at their routine contact lens aftercare appointment, by their optometrist / contact lens practitioner if they would be interested in taking part. There was no incentive for the optometrists to recruit reluctant patients. There was no indication made on the record card about whether the patient was going to participate or not. The participants from Aston University were members of the Optometry department and were contacted by email.

The participants were given the information sheet to read and discuss and the consent form to sign if they agreed to take part (see appendix 1). It was made clear to the participants that this was on a

voluntary basis, that they were free to withdraw at any time. There were no consequences of their non-participation.

Participants were given a questionnaire to fill in regarding contact lens comfort for up to 4+ weeks to start on the next 5 days that they intended to wear contact lenses and makeup. The questionnaires were put in a random order before they were handed out. In one group the participants were asked to apply makeup before lens insertion while the other group of participants were asked to apply makeup after lens insertion, for the next 5 times that they intended to wear both makeup and contact lenses. After this there was a one day break from either lens wear or make up or both (a wash out period). The groups were then reserved – a cross over design study. The results were analysed to identify which method resulted in better lens comfort. The data was further analysed to see if there was any difference with the modality of lens wear - daily vs monthly disposable vs extended wear vs RGP.

The questionnaires did not ask for the participant's name and these results were anonymous at source. The results of the questionnaire were put onto a data base and the patient's details were not included on this.

The participants were asked to grade the level of burning/ stinging and foreign body/ grittiness sensation on lens insertion and when the lenses were removed on a scale to 1 – 10 (with 10 being completely comfortable and 1 being so uncomfortable they had to remove the lens). The participants were also asked how long the lenses were worn and how long it took to achieve the maximum level of comfort and how long this comfort lasted. The participants were asked what type of makeup they use – foundation, powder, blusher, eye shadow, eye shadow foundation/ primer, eyeliner, mascara. The participants were also asked to fill in an OSDI (ocular surface

disease index) form at the end of the 5 days to grade the level of dry eye that they experienced with each method of contact lens insertion.

The wearing of contact lenses during the study carried the normal risks involved with contact lens wear, along with the risks involved with wearing makeup. Participants were not required to insert lenses more frequently or apply more make up than they would normally do. The only difference was the order in which lenses were inserted versus application of makeup. Participants could expect no direct benefit from participation, though increased lens comfort was possible due to a change in habit. They were advised that this study might be of benefit to future contact lens wearers.

The primary ethical issue was the risk of contact lens wear and makeup. The information gained was important in order to be able to give current and future wearers of contact lenses the most appropriate advice regarding lens wear and makeup. The participants were not being asked to wear lenses or makeup more frequently that they would otherwise do, so there was no increase in risk. The participants were asked to remove the lenses immediately if they feel as if there was something under the lens. The participants had access to their normal aftercare practitioners and had an emergency phone number in case of any problems. This minimized the risk of corneal trauma.

The research followed the tenets of the Declaration of Helsinki and had the approval of the Audiology and Optometry Ethics Committee(see appendix 1 for a copy of the consent form and patient information sheet handed out).The difficulty with this type of survey is that it takes time and commitment from the participants without offering a reward. This resulted in a low participation and completion rate[102, 103,104,110].

Thank you for agreeing to take part in this study.

You are being asked to insert your contact lenses as normal before and after applying your makeup in the usual way.
Please follow the instructions given as to whether you insert your lenses before applying makeup or after; this is very important to the outcome and analysis of this study.

The next 5 times that you are going to wear your contact lenses and makeup you are to insert your lenses before applying your makeup (do wash your hands before handling your lenses).

Please grade any degree of burning/stinging of your lenses on insertion on a scale of 1 to 10 (10 being completely comfortable and 1 being so uncomfortable that you had to remove your lenses). Also grade any degree of foreign body/grittiness from 1 to 10 (10 being completely comfortable and 1 being so uncomfortable that you had to remove your lenses.

At the end of the day please also grade the degree of burning/stinging and foreign body/grittiness

Day 1

Burning/stinging on insertion	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on insertion	1	2	3	4	5	6	7	8	9	10
Burning/stinging on removal	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on removal	1	2	3	4	5	6	7	8	9	10

length of times lenses were worn…….. how long till lenses felt their most comfortable……..how long did this last……

Day 2

Burning/stinging on insertion	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on insertion	1	2	3	4	5	6	7	8	9	10
Burning/stinging on removal	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on removal	1	2	3	4	5	6	7	8	9	10

length of times lenses were worn…….. how long till lenses felt their most comfortable……..how long did this last……

Day 3

Burning/stinging on insertion	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on insertion	1	2	3	4	5	6	7	8	9	10
Burning/stinging on removal	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on removal	1	2	3	4	5	6	7	8	9	10

length of times lenses were worn…….. how long till lenses felt their most comfortable……..how long did this last……

Day 4

Burning/stinging on insertion	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on insertion	1	2	3	4	5	6	7	8	9	10
Burning/stinging on removal	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on removal	1	2	3	4	5	6	7	8	9	10

length of times lenses were worn…….. how long till lenses felt their most comfortable……..how long did this last……

Day 5

Burning/stinging on insertion	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on insertion	1	2	3	4	5	6	7	8	9	10
Burning/stinging on removal	1	2	3	4	5	6	7	8	9	10
foreign body/grittiness on removal	1	2	3	4	5	6	7	8	9	10

length of times lenses were worn…….. how long till lenses felt their most comfortable……..how long did this last……

Please go to the next page and fill in the Ocular Surface Disease Index questionnaire

You are now to take a break from this study and have a day either without wearing contact lenses or without wearing makeup.

Ocular Surface Disease Index© (OSDI©)[2]

Please answer the following 12 questions, and circle the number in the box that best represents each answer.

Have you experienced any of the following *during the last week?*	**All of the Time**	**Most of the time**	**Half of the time**	**Some of the time**	**None of the time**
1. Eyes that are sensitive to light? . .	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Have problems with your eyes limited you in performing any of the following *during the last week?*	**All of the time**	**Most of the time**	**Half of the time**	**Some of the time**	**None of the time**	
6. Reading?.	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?.	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Have your eyes felt uncomfortable in any of the following situations *during the last week?*	**All of the time**	**Most of the time**	**Half of the time**	**Some of the time**	**None of the time**	
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned?. .	4	3	2	1	0	N/A

3.3 Statistics

The study employed a repeated measures design and Armstrong and colleagues advise at least 15 degrees of freedom for repeated measure type statistics[123] which was achieved in all metrics for the daily and monthly disposable groups, but not those wearing RGPs. A sample size of more than 4 was required. The data was non parametric due to the subjective data collected.

3.4 Results

41 participants were recruited (out of more than 400 contacted by email and 500 via optometric practice). All of the participants were female. 2 subjects did not complete the study or state what type of makeup was worn, including the only weekly disposable lens wearer and the other did not state what type of lens was worn. There were another 3 who did not state what type of lenses they wore; their results were included in the totals.

TABLE 3.1 Contact Lenses inserted before makeup

CL inserted before makeup	Age (years)		Burning on insertion		Foreign body on insertion		Burning on Removal		Foreign Body on Removal	
	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
Total (n=41)	34.5	24 46.75	1	1 2	1	1 2	1	1 2	1	1 2
Daily Disposable (n=23, 56.10%)	29	24 44.25	1	1	1	1 2	1	1 1	1	1 2
Weekly Disposable (n=1, 2.44%)	55	0								
Monthly Disposable (n=10, 24.39%)	34.5	30 49.5	1	1 2	1	1 3	1	1 3	1	1 3
RGP (n=2, 4.83%)	50.5	48.75 52.25	2	1.25 2	3	3 3	1.5	1 2.75	1.5	1.2 2.7

TABLE 3.2 Contact lenses inserted before makeup

CL inserted before makeup	Wearing Time (hours)		Time till Comfortable (mins)		Length of Time Comfortable (hours)		OSDI	
	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
Total (n=41)	11	8 13.5	3	0.5 30	10	7 12.5	3	1 5
Daily Disposable (n=26)	11.00	8 13.5	3	1 18.75	10	7 12.5	3	1 4
Weekly Disposable (n=0)	-	-	-	-	-	-	-	-
Monthly Disposable (n=10)	11	8 14	5	0.25 30	10	6.13 12	2.5	1.25 4.75
RGP (n=2)	12.50	9.25 15	22.5	10 30	10	7 13.75	3.5	2.75 4.25

TABLE 3.3 Type of makeup worn

	Foundation	Face Powder	Blusher	Lipstick	Eye Shadow	Eye Shadow Primer	Mascara	Eye Liner
Total n=36	24 66.7%	24 66.7%	19 52.8%	17 47.2%	22 61.1%	30 83.3%	15 41.7%	35 97.2%
Daily Disposable (N=23)	14 60.9%	13 56.5%	13 56.5%	9 39.1%	15 65.2%	19 82.6%	9 39.1%	22 95.7%
Weekly Disposable (N=1)	1 100%	1 100%	0 0%	1 100%	1 100%	1 100%	0 0%	1 100%
Monthly Disposable (N=10)	7 70%	8 80%	5 50%	6 60%	6 60%	9 90%	5 50%	10 100%
RGP (N=2)	2 100%	2 100%	1 50%	1 50%	0 0%	1 50%	1 50%	2 100%

TABLE 3.4 Contact lenses inserted after makeup

CL inserted after Make up	Burning on Insertion		Foreign body on Insertion		Burning on Removal		Foreign body on Removal	
	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
Total (n=41)	1	1 3	1	1 3	1	1 2.75	1	1 3
Daily Disposable (n=26)	1	1 2	1	1 2	1	1 2	1	1 2
Weekly disposable (n=1)	2	2 2	2	2 2	2	2 2	2	2 2
Monthly Disposable (n=10)	1	1 4	2	1 3.75	1	1 3	1	1 3
RGP (n=2)	3	3 3.75	4	3 35	2	1 3	2.5	2.3 3

TABLE 3.5 Contact lenses inserted after makeup

CL inserted after makeup	Wearing Time (hours)		Time Till Comfortable (mins)		Length of Time comfortable (hours)		OSDI	
	Mean	S.D	Mean	S.D.	Mean	S.D	Mean	S.D
Total (n=41)	10	8 13	5	1 25	10	6 13	3	0.75 6.25
Daily Disposable (n=26)	12	9 14	2	1 25	10	6.5 13	3	0 5
Weekly Disposable							2	2 5
Monthly Disposable (n=10)	9	5 11.75	5	0.63 15	8.25	5 12	2	2 5
RGP (n=2)	12.50	10 15	32.5	10 60	9	6 13	6.5	6.25 12

The data was first analysed using a Related Samples Wilcoxon Signed Rank Test to see if there was a difference in any of the measures between contact lenses inserted before and after the application of makeup. For 3 measures there was a significant difference

- Burning on insertion $p=0.031$
- Foreign body sensation on insertion $p<0.01$

- Burning on removal p=0.011

For all the other measures there was no significant difference

- Foreign body sensation on removal p=0.177
- Length of time lenses were worn p=0.158
- Length of time till lenses felt comfortable p=0.916
- Length of time that lenses felt comfortable p=0.109
- OSDI score p=0.416

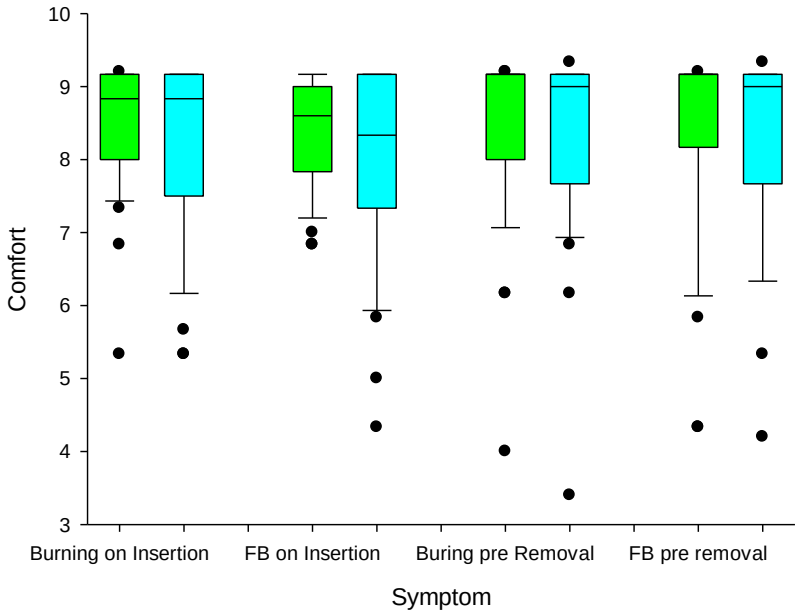

FIGURE 3.1 Level of comfort (green – lenses inserted before makeup. Blue – lenses inserted after makeup). Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this

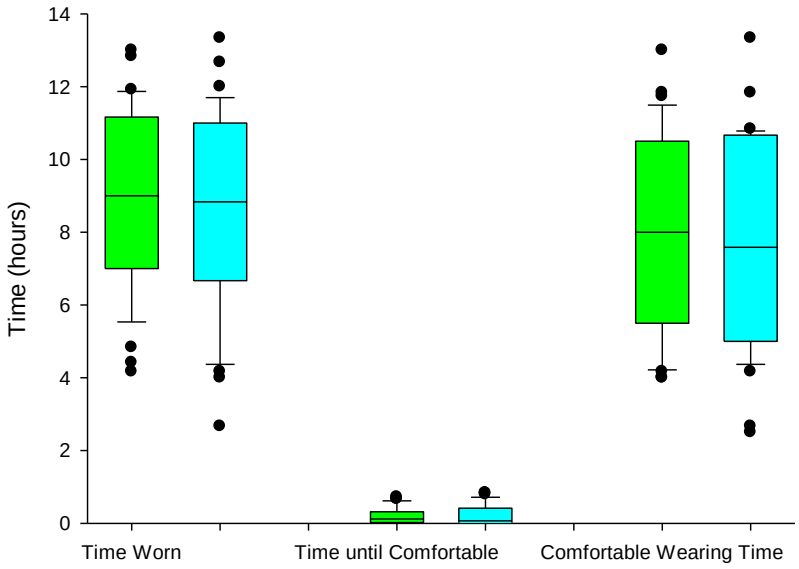

FIGURE 3.2 Wearing times (green – lenses inserted before makeup. Blue – lenses inserted after makeup). Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

The difference over the 5 day period was analysed for each scenario. When the lenses were inserted before makeup was applied there were no significant differences with any measure:

- Burning on insertion p=0.207
- Foreign body sensation on insertion p=0.966
- Burning on removal p=0.900
- Foreign body sensation on removal p=0.865
- Length of time lenses were worn p=0.879
- Length of time till the lenses were comfortable p=0.287
- Length of time that the lenses felt comfortable p=0.555

Nor was there any significant difference with any measure when the lenses were inserted after makeup was applied:

- Burning on insertion p=0.972
- Foreign body sensation on insertion p=0.737
- Burning on removal p=0.184
- Foreign body sensation on removal p=0.820
- Length of time lenses were worn p=0.062
- Length of time till the lenses were comfortable p=0.326
- Length of time that the lenses felt comfortable p=0.246

The average value for the 5 days was analysed for each scenario to see what associations there were with the method preferred – contact lenses inserted before or after the application of makeup.

For those who preferred contact lenses inserted before makeup the method preferred was related to the foreign body sensation on insertion (p=0.024) and the burning on removal (p=0.42).For those who preferred to insert their lenses after their makeup up the only significant association was with the length of comfortable wearing time (p=0.036).All the other measures were p>0.05. The different types of makeup used were analysed and there was no significant difference with any type of makeup p>0.05.

A Spearman's Rank Correlation Test was carried out to see if there was a relationship to age. There was a positive relationship with the OSDI score both when lenses were inserted before makeup (r=+0.367, p==0.046) and when lenses were inserted after makeup (r=+0.424, p=0.020). There was also a relationship with age for the length of time till the lenses were comfortable for both scenarios. When lenses were inserted before makeup r=+0.394, p=0.03. When lenses were

inserted after makeup r=+0.496, p=0.05. There was a relationship for foreign body sensation on removal and burning on insertion when lenses were inserted after makeup (r=+0.400, p=0.029 and r=+0.431, p=0.017 respectively).

The OSDI score when the contact lenses were inserted before makeup was applied had a median of 3(1 – 5 IQ%). The ODSI when the lenses were inserted after makeup was applied was 3 (0 - 5 IQ%).

The proportion who wore different types of makeup used was similar across all types of lens wear. Of those participating, 66.7% wore foundation - 60.9% of the daily disposable wearers, 70% of the monthly disposable wearers, both the RGP wearers and the weekly disposable wearer. For face powder 61.7% of all the lens wearers wore face powder, 56.5% of the daily disposable lens wearers, 80 of the monthly lens wearers and again both of the RGP and the weekly disposable lens wearer. 52.8% of the participants wore blusher, 56.5% of the daily disposable lens wearers, 50% of the monthly disposable wearers, one of the RGP wearers and not the weekly disposable lens wearer. Out of all of the participants, 47.2% wore lipstick, 39.1% of the daily disposable lens wearers, 60% of the monthly lens wearers, one RGPs and one weekly contact lens wearer. Eyeshadow was worn by 61.1% of the participants, 65.2% of the weekly disposable lens wearers, 60% of the weekly disposable lens wearers and the weekly disposable lens wearer. Eyeshadow primer was used by 83.3% of those who participated, 82.6% of the weekly disposable lens wearers, 90% of the monthly disposable lens wearers, one RGP wearers and one weekly disposable lens wearer. Mascara was worn by 41.7% of the participants, 39.1% of the daily disposable lens wearers and 50% of the monthly and RGP wearers. Eyeliner was worn by 97.2% of the participants, 95.7% of the daily disposable wearers, all the monthly, weekly and RGP wearers.

The participants were asked which order they preferred after they had completed the study. Of those who answered 23 (63.9%) preferred to insert their lenses then apply their makeup, 7 (19.4%) preferred to apply their makeup then insert their lenses and 6 (16.7%) had no preference.

3.5 Discussion

The aim of this study was to see if there was a difference in lens comfort when lenses were inserted before and after the application of makeup. It was surprising that overall there was very little difference in the results measured between inserting lenses before or after applying makeup. There were only three parameters that were significantly different between inserting the lenses before or after applying makeup – the level of burning on insertion and interestingly that was worse when makeup was applied before inserting the lenses; the level of foreign body sensation on insertion which was also worse when makeup was applied after contact lenses and the level of burning on removal which was also worse when lenses were inserted after makeup. If anything, based on the current advice to contact lens wearers, it would be expected to be the other way around. For every other parameter measured there was no significant difference.

There were results that varied with age; there was a positive relationship between age and foreign body sensation when lenses inserted before and after makeup. The eye is drier with age[20,23] and comfortable had a positive relationship with age for lenses inserted after makeup as well as for foreign body sensation on removal and burning on insertion. The numbers for the weekly disposable (n=1) and RGP wearers (n=2) are too small to do meaningful statistical analysis on their own. However, they contribute to the group profile.

Not all the participants stated what type of modality of lens wear they used and so the total number does not equal the number that wore the individual lens types. Their results are still valid and contribute to the overall analysis, though could not be included in the modality of lens wear analysis.

There was an association with the preferred order of contact lens insertion and makeup application; preference to insertion of contact lenses before makeup was related to the level of foreign body sensation on insertion and the level of burning on removal. Those who preferred to

insert contact lenses after makeup had an association only with the length of comfortable wearing time.

Of those who stated what modality was worn, 56.1% wore daily disposable lenses, 2.4% wore weekly disposable lenses, 24.4% wore monthly disposable lenses and 4.9% wore RGP lenses.

This is a different wearer profile compared to studies published on UK contact lens wearers. One study showed the majority of lens wearers used soft lenses (approximately 90%)[75]; of these 38% were daily disposable lens wearers[113]. Sully[114] in 2005 showed in the UK out of 320, 122 were daily disposable wearers (40.67%), 47 RGP (14.69%), 104 soft daily wearers (32.50%), 38 soft extended wearers(11.88%) and9 traditional soft lens wearer (2.81%). In 2014 the UK prescribing trend was that 7.2% of the population wore contact lenses (the same as in 2009[109]. New fits 97% soft lenses and 92% soft lenses for refits[111]. Silicone hydrogels made up 80% of refits and 71% of new fits. For new fittings 45% were daily disposable, 2% 1 to 2 weekly disposable and 53% monthly disposable lenses. For the refits 42% were daily disposables, 8% 1 to 2 weekly and 49% monthly disposable lenses[111]. However, these studies do not take into account drop out rates and existing wearers, so they do not represent the current modality of lens wear across the population. This may explain some of the differences found between the studies and this participant population.

The type of makeup used was similar in proportion across all of the lens modality types. The percentage who wore foundation, blusher and eyeliner was closer to the previously sampled Aston group than the Optic shop group. For face powder it was between the Aston and Optic shop groups; for eyeshadow it was closer to the Optic shop group. Eyeshadow primer use was a lot higher than either the Optic shop or Aston group. Mascara was a lot less used than either the Optic shop or Aston group.

Further questioning as to why certain types of makeup were or were not worn would be interesting.This was a group of contact lens wearers who habitually wore both makeup and contact

lenses. Therefore, they were experienced at applying both. Whether the results would be different for new lens wearers or for those who have not worn makeup before is an interesting question. It would not be reasonable or ethical to carry out a study with such participants as they would be put at risk of corneal trauma due to inexperience. However, the new contact lens wearers are those that need the most advice. It may be that the advice should be to do whatever feels most comfortable for them. If they are presbyopes or hyperopes who might struggle to see to apply their makeup without their lenses then maybe they should insert the lenses first. It they are myopes who can see well at near with and without their lenses the order of application does not matter.

These results were not easy to obtain – approximately 1000 people were invited to take part and followed up. This does mean that this group of participants may not reflect the general population. They carried out a minimum 11 day trial and recorded their results on a daily basis. This asks the question as to how they differ to those who did not take part. More information about how makeup affects the eye and the tear film itself would be useful as well as if there was a difference depending on the refractive error (myope, hyperope and presbyope). Hence the next chapter examines these issues.

CHAPTER 4

Objective Analysis of inserting contact lenses before/ after makeup

4.1 Introduction

Having obtained the data from the group of volunteers who applied their makeup before and after they inserted their lenses, and then assessed the comfort of their lenses and found no significant difference between the two methods; the next stage was to examine a smaller group objectively as well as subjectively.

The aim of this study was to carry out a more detailed analysis at the objective as well as the subjective effect of inserting contact lenses before and after the application of makeup, the effect of the use of an eyelid primer/foundation when lenses were inserted before and after makeup, and also compare these with the effect of wearing no makeup.

The aim was also to see the effect of an eyelid primer - did it have any benefit, in reducing the amount of debris in the eye or affect ocular redness, staining or comfort. To investigate whether the application of an eyelid primer is something that should be advised to contact lens patients who also wear eyeshadow

This was carried out on a group of myopes, hyperopes and presbyopes to see if refractive error affected the results and any subsequent advice that could be given. One of the reasons stated for advising the insertion of lenses before the application of makeup by The College of Optometrists was that for those with presbypia and hypermetropia, the ability to see close up would be beneficial. Another aim of this part of the study was to see the advice given should be different with refractive error.

4.2 Method

Participants were recruited from those involved in the previous study. They were asked by their contact lens practitioner / optometrist if they were willing to participate in a further in-depth study. The participants were recruited from contact lens patients attending six branches of The Optic Shop throughout south Wales and at Aston University.

The inclusion criteria were that they regularly wear makeup (at least two days per week), be over the age of 18 years; be an established contact lens wearer i.e. not at their first aftercare, and have healthy external eyes.

Subjects were excluded if they were: under 18 years of age, had an abnormality of the external eye that would affect contact lens wear such as keratoconus, were a new contact lens wearer, did not wear makeup on a regular basis, or their eyes were found not to be healthy at the aftercare visit e.g. had infiltrates or significant corneal staining pattern that requires a contact lens refit.

The participants were given the information sheet to read and discuss and the consent form to sign if they agreed to take part. It was made clear to the participants that this was on a voluntary basis, that they were free to withdraw at any time. There were no consequences of their non-participation.The research followed the tenets of the Declaration of Helsinki and had the approval of the Audiology and Optometry Ethics Committee.

Participants were asked to attend their branch of The Optic Shop or Aston University Eye Clinicon multiple occasions to have their eyes examined by Una Whitcombe. Each session lasted approximately 10 minutes. On one occasion they were asked to attend wearing their lenses and no makeup and at this session to apply their makeup after lens insertion. On the other occasions they were asked to attend having inserted their lenses after applying makeup. On the other 2 occasions they were to attend having used an eyelid primer/foundation called Touchbase for Eyes by

Clinique, and inserted their lenses before and after applying their makeup. The order of the visits was randomised and they were not to tell the researcher which order they inserted their lenses/applied makeup or whether they used an eyelid primer until the end of the visit. They were told to apply the Touch Base cream by gently rubbing the cream in the container with the tip of their index finger and then gently apply it to their upper eye lid with a gentle rubbing action.

At each of these visits the participants were asked to fill in an OSDI form to measure the level of dry eye that they might be experiencing at that time. Dry eye may be due to a lack of tear volume and or poor tear quality.

Measuring tear volume with contact lenses in situ was not feasible in clinical practice. A Tearscope (Keeler, Windsor, UK) was not available in all of the practices so the non-invasive tear break up time (TBUT) with contact lenses in situ was measured using a 2 position keratometer.At these visits the participant were asked to place their head in position on a keratometer. The noninvasive tear break up time (TBUT) was measured to the nearest second using the reflected keratometry mires over the contact lenses. The participant was asked to blink three times and then to keep their eyes open as long as possible whilst the observer looked at the eye through the keratometer. The observer recorded the amount of time taken for the reflected mires to distort and break up. This measure was repeated three times and the average taken. The measurement was taken for each eye. This was a measurement of the tear break up time; there is no standard test for the tear break up time with contact lenses in situ and this test mimics the standard non-invasive tear break up time test without contact lenses in situ[16]. There are no cut off values for clinical dry eye with contact lenses in situ.

At these visits the external eye was examined using a slit lamp. The degree of conjunctival redness was graded usingan Efron grading scale (Figure 4.1) to 1 decimal place using 10x magnification(this amount of magnification was chosen as it was the one available at all the practice locations). The

amount of debris in the tear film was counted and recorded as the number of fragments seen using 10x magnification.

FIGURE 4.1 Efron grading scale for conjunctival redness

The participant then removed their contact lenses and fluorescein was inserted into each eye using a moistened fluoret and the amount of corneal and conjunctival staining wasgraded using Efron grading scales to 1 decimal place using 10 x magnification. Fluorescein seemed to offer the best clinical means of diagnosing the presence of corneal epithelial surface defects (Matheson). Fluorets were also readily available at all the sites used.

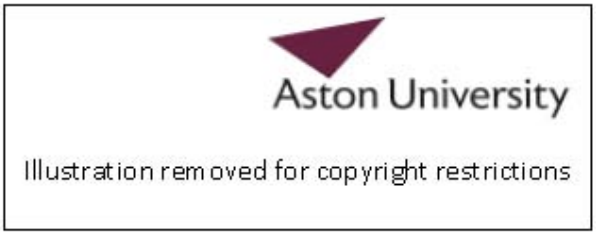

FIGURE 4.2 Efron grading scale for corneal and conjunctival staining

After this the eye was rinsed with a minim of sterile saline 0.9% if the participant wished to insert their contact lenses. The participants were advised to bring their spectacles to wear after the visit.

4.2.1Touch Base for Eyes

Touch base for eyes by Clinique was used as an eyelid primer. Its ingredients are:- cyclopentasiloxane, aluminium distearate, ceresin, zinc stearate, dimethicone, microcrystalline wax/cera microcrystallina/cira microcrystalline, hydrated silica, +/- bismuth oxychloride (CI 77163), titanium dioxide (CI 7891), mica, iron oxides (CI 77491, CI 77492, CI 77499), manganese violet (CI 77742), chromium oxide greens (CI 77288), ultramarines (CI 77007), ferric ferrocyanide (CI 77510), chromium hydroxide green (CI 77289), carmine (CI 75470) (LN28976).

FIGURE 4.3 Touchbase for eyes

4.2.2 Fluorescein

Fluorescein cannot penetrate intact cell membranes. It diffuses into the intercellular spaces for example defects in the tight junctions of basal epithelial cells. Once it gains entry it can freely diffuse to the interior of surrounding cells by passing through junctional surfaces[19,124]. There is some controversy as to whether the dye is staining damaged cells or areas where cells are missing or intracellular junctions are weak.

The intensity of the fluorescence of Fluorescein in an aqueous solution increases with increasing concentration to a maximum at about 0.001 to 0.004% and then decreases. The use of a moistened fluoret results in a rapid useful level of fluoresce which lasts a longer time than using a drenched fluoret or minims[19].

4.3 Statistics

For this part of the study the aim was to recruit 30 participants; 10 myopes, 10 hyperopes and 10 presbyopes who wore soft contact lenses and makeup.

A Kolmogorov-Smirnov test was carried out to see if the data was normally distributed. It was normally distributed for Tear Break Up Time (TBUT) but for no other measure.

Armstrong and colleagues advise at least 15 degrees of freedom for repeated measure type statistics[116] which was achieved for all of these measures; a minimal sample size of more than 4 was required

4.4 Results

There were 23 participants, 8 hyperopes, 10 myopes and 5 presbyopes; they were all female and wore silicone hydrogel, daily disposable lenses.The median age of the hyperopes was 28.4 years (±12.2 years S.D.), the mean age for the myopes was 27.8 years (±7.6) and the mean age for the presbyopes was 53.8 years (±14.5).

The data for the right eye only was analysed to avoid the problems associated with pooling non-independent data.

TABLE 4.1 Data for all participants

All participants	TBUT (secs)		Conjunctival Injection		Debris		Corneal Staining		Conjunctival Staining		OSDI	
N=23	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
CL After makeup, no primer	10	8 14.75	0.4	0.25 0.65	5	2 7.5	0.2	0.1 0.3	0.3	0.2 0.35	6	2.5 9.5
CL before makeup, no primer	12	8 16	0.3	0.2 0.4	3	3 5	0.2	0.15 0.35	0.3	0..2 0.3	7	2 9.5
No makeup	16	12 20	0.3	0.2 0.45	0	0 0	0.1	0 0.2	0.2	0.15 0.2	3	1 7
CL After makeup, with primer	13	10 17	0.3	02. 0.3	7	2 10	0.2	0.1 0.2	0.2	0.2 0.3	4	0.5 10
CL before make up with primer	13	8 17	0.3	0.2 0.35	5	2.5 15	0.1	0.05 0.2	0.2	0.2 0.3	4	1 8

TABLE 4.2 Hyperopes

Hyperopes	Tear Break up Time (secs)		Conjunctival redness		Debris		Conjunctival staining		Corneal Staining		OSDI	
N=8	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
CL after, no primer	8.5	6 12.75	0.3	0.28 0.43	3	2 5	0.25	0.18 0.53	0.3	0.28 0.43	7.5	2.75 9.25
CL before no primer	9	7 12.75	0.3	0.2 0.4	3	1.5 4	0.25	0.2 0.35	0.3	0.28 0.3	6	3.5 9.25
No makeup	17	8 24	0.3	0.18 0.33	0	0 0	0.2	0 0.28	0.2	0 0.23	4	1 6.5
CL after with makeup	12	5 20	0.3	0.28 0.3	6.5	3 9.75	0.15	0.1 0.2	0.3	0.2 0.33	6.5	0.75 10.25
CL before with primer	8	4.5 15.75	0.3	0.2 0.3	3	2 8.5	0.15	0.08 0.2	0.2	0.18 0.23	6.5	2.25 10.75

TABLE 4.3 Myopes

Myopes	Tear Break up time (secs)		Conjunctival Redness		Debris		Conjunctival Staining		Corneal Staining		OSDI	
N=10	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
CL after, no primer	12	9.25 15	0.6	0.35 0.78	7.5	4.25 18.75	0.2	0.1 0.28	0.25	0.2 0.45	7	3.25 8.75
CL before, no primer	14.5	10 16.75	0.4	0.2 0.68	5	3.25 18.5	0.2	0.05 0.43	0.25	0.2 0.3	7.5	2.5 8
No makeup	15.5	12 20	0.4	0.23 0.5	0	0 1.5	0.05	0 0.1	0.2	0.2 0.2	4	2 5.5
CL after, with primer	14.5	12 17	0.25	0.2 0.38	8.5	1.25 10	0.15	0.03 0.2	0.2	01. 0.3	4.5	2.5 6
CL before with primer	15	12 18.75	0.25	0.2 0.4	12.5	5 20	0.10	0 0.18	0.2	0.13 0.28	4.5	2.25 6

TABLE 4.4 Presbyopes

Presbyopes	Tear Break up time (secs)		Conjunctival redness		Debris		Corneal Staining		Conjunctival Staining		OSDI	
N=5	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%	Median	IQ%
CL after, no primer	10	8.25 10	0.3	0.2 0.4	2	2 5	0.1	0.1 0.1	0.3	0.2 0.3	3	1 15
Cl before, no primer	10	8 13.5	0.2	0.2 0.3	3	3 3	0.2	0.1 0.2	0.3	0.3 0.3	3	0 14
No makeup	15	12.5 18	0.20	0.2 0.2	0	0 0	0.10	0.1 0.1	0.2	0.2 0.2	3	0 11
CL after with primer	12	10 14	0.2	0.2 0.3	5	2 10	0.2	0.1 0.2	0.2	0.2 0.3	3	0 11
CL before with primer	11	10 13.75	0.3	0.2 0.3	3	2 15	0.2	0.2 0.2	0.3	0.2 0.3	3	0 8

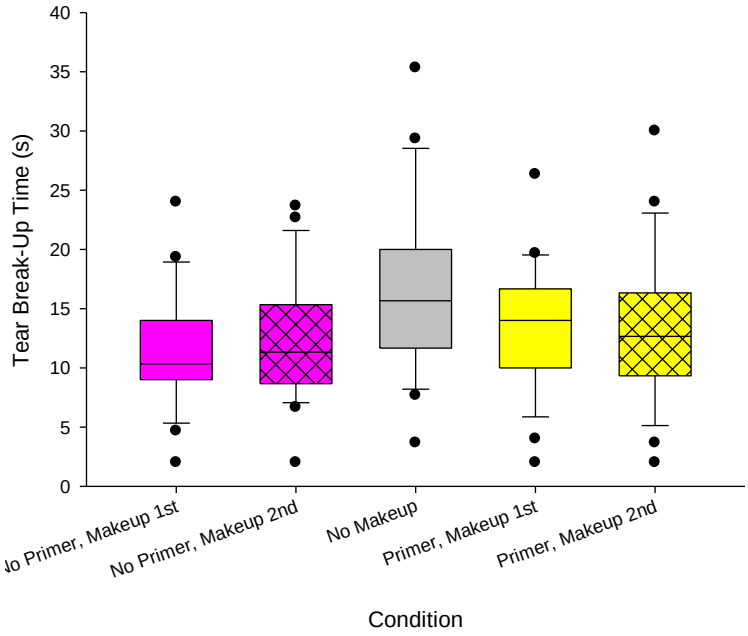

FIGURE 4.4 Tear break up time analysis - comparing no make-up, both with and without primer applied before and after contact lens insertion. Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

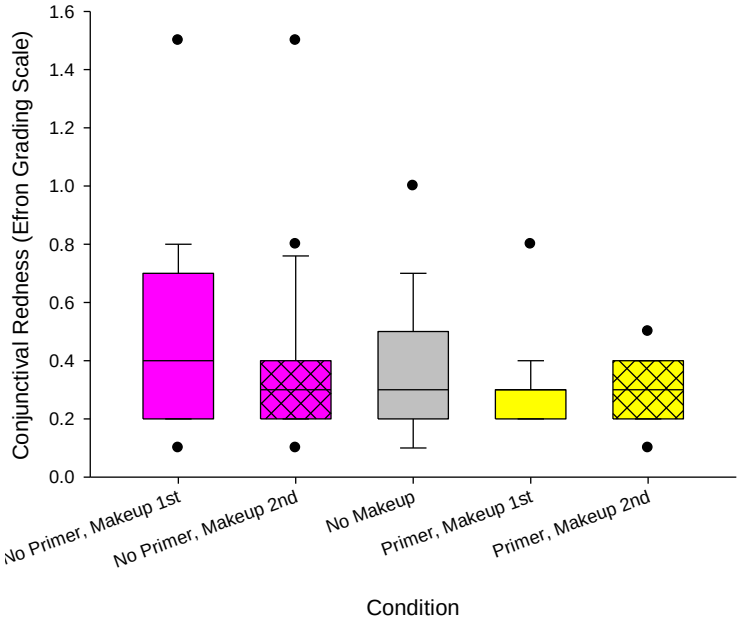

FIGURE 4.5 Conjunctival injection - comparing no make-up, both with and without primer applied before and after contact lens insertion. Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

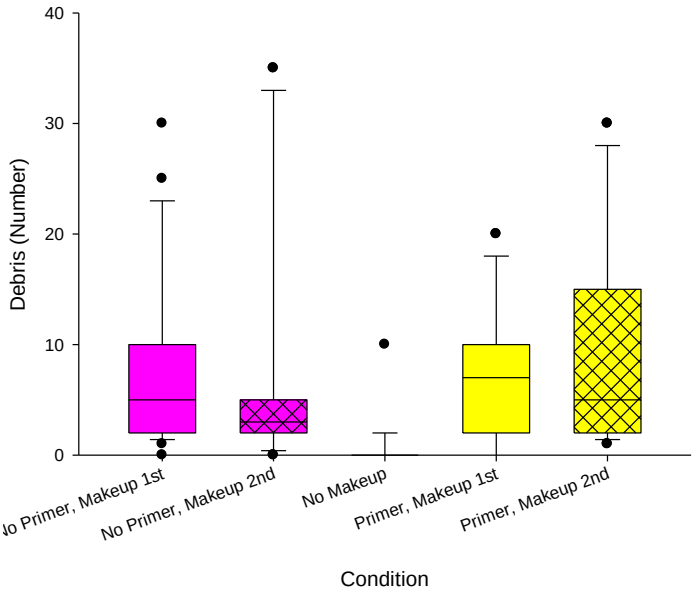

FIGURE 4.6 Debris - comparing no make-up, both with and without primer applied before and after contact lens insertion. Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

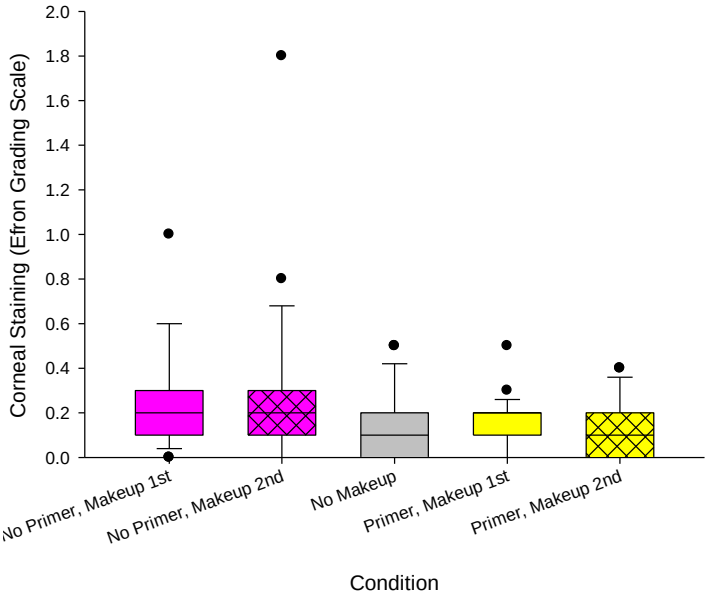

FIGURE 4.7 Corneal staining - comparing no make-up, both with and without primer applied before and after contact lens insertion. Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

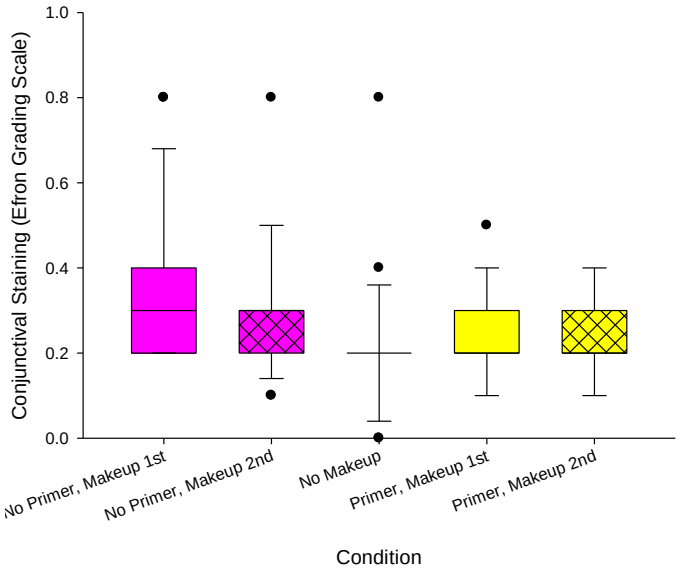

FIGURE 4.8 Conjunctival staining - comparing no make-up, both with and without primer applied before and after contact lens insertion. Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

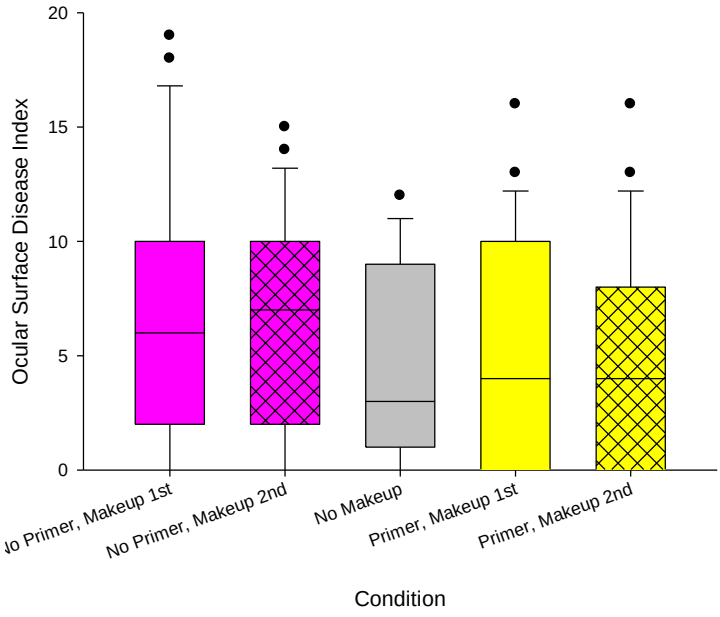

FIGURE 4.9 OSDI Scores - comparing no make-up, both with and without primer applied before and after contact lens insertion. Box indicates ±1 S.D., line within the box is the median, whiskers indicate the extent of the 95% confidence interval and dots data beyond this.

For the total group a Related Samples Friedman's 2 Way Analysis of Variance by Rank was carried out for each of the 5 scenarios to determine if they were significantly different. This was found to be the case for each measure:

- TBUT $p<0.001$
- Conjunctival redness $p=0.002$
- Debris $p<0.001$
- Corneal Staining $p<0.001$
- Conjunctival staining $p=0.001$
- OSDI $p=0.006$

The different scenarios were analysed by type of refractive error for the 5 scenarios using a Related Samples Silcoxon Signed Rank Test. There was no significant difference for any measure:

- TBUT $F=0.4612$, $p=0.637$
- Conjunctival Redness $p=0.098$
- Debris $p=0.176$
- Corneal Staining $p=0.547$
- Conjunctival staining $p=0.954$
- OSDI $p=0.877$

The difference that the use of a primer made when makeup was applied before contact lenses was analysed in the same manner. There was a significant difference for each measure, except the amount of debris:

- TBUT $p=0.013$
- Conjunctival Redness $p<0.001$
- Debris $p=0.605$

- Corneal Staining p=0.001
- Conjunctival staining p<0.001
- OSDI p=0.0.25

The same type of analysis was applied to see if there was a significant difference between the use of a primer and makeup applied before or after the insertion of lenses. There was no significant difference for each measure:

- TBUT p=0.0731
- Conjunctival Redness p=0.273
- Debris p=0.207
- Corneal Staining p=0.944
- Conjunctival staining p=0.137
- OSDI p=0.225

4.5 Discussion

There was a significant difference for every parameter between all of the 5 scenarios, which was to be expected. There was no significant difference with refractive error for any parameter. This indicated that the possible inability or difficulty to see close for the hyperopes and presbyopes did not affect the outcome. This was one of the criteria that this study set out to investigate. It had been anticipated that the results would be different when makeup was applied before and after the insertion of the lenses for these groups, but it was not the case. This unexpected result may be because the participants were habitual users of makeup and contact lenses. It would be interesting to see if the results were similar with new lens wearers or those who were new to wearing makeup. However, it would be unethical to carry out such a study as in both cases the participants would be at a higher risk of corneal trauma.

No makeup resulted in a significantly higher tear break up time for all the groups. This was expected as it is known that makeup affects the tear film[47,49,50]. It also resulted in a significantly lower amount of debris in the eye – also expected as there was no makeup to contribute to the level of debris. The use of no makeup also resulted in the lowest amount of corneal and conjunctival staining, again to be expected[47, 49, 50].

Interestingly there was no significant effect on the OSDI for no makeup, and the use of makeup with and without primer. This could be because these were one off events and not the average score over a week (which the test was designed to measure). However, it was not possible to do this in this study.

The use of a primer with the insertion of contact lenses after makeup had a significant effect on all parameters except the amount of debris. The use of a primer resulted in better values, which was expected; the amount of debris was not expected to be affected. The use of a primer had no significant difference for any parameter between contact lenses inserted before and after makeup.

Thus, the difference is due to the use of a primer not the effect of inserting lenses before or after the application of makeup. The significantly optimal results for all parameters were when no makeup was worn. This would suggest that the use of a primer should be advised to lens wearers, whatever their refractive error to improve lens comfort.

However, the questions need to be asked - are these patients representative of the general population? They were all were daily disposable lens wearers and all wore silicone hydrogel lenses. They were all highly motivated as agreeing to take part meant they had to attend 5 times which is a high level of commitment. Can these results be extrapolated to all modalities of lens wear? These were all daily disposable silicone hydrogel lens wearers, what would be the difference with monthly disposables lenses, extended wear lenses, traditional HEMA type lenses?

Ideally the time from makeup application and investigation would be the same in all scenarios, this was not possible as this took place in general practice. It is not known what impact this has on the results. Palpebral aperture may be another factor to take into consideration. Those with a large aperture may not need to hold their lids open to insert their lenses and so do not smudge or affect their makeup. This is another factor that could be worth measuring and considering.

Chapter 5

CONCLUSIONS

There were several research questions investigated in this study;-

- What is the incidence of makeup and contact lens wear in the general and student population?

The incidence of both contact lens wear and makeup was found to be 70.5% in a general optometric population and 72.7% in an optometric student population. These values have not been investigated before in the UK[46] and show the importance of considering the lifestyle of patients who wear contact lenses and the potential effects that the use of makeup might have on their contact lens wear.

The study also showed that non makeup wearers had a significantly longer average wearing time for the general optometric population and that monthly contact lens wearers had a significantly longer comfortable wearing time. This could be because there is an element of self selection with daily disposable lens wearers – those with any problems tend to use these lenses rather than monthly disposable ones.

There was a difference in the experience of contact lens wear between a student population and a general optometric practice population in that there were no significant differences with the student population.

It would be interesting to find out the difference between a general student population versus the optometric student group. The optometric students are offered free lenses so that their colleagues can practice fitting and carrying out aftercares. It would be also interesting to know what proportion wore lenses before they started at the department, the drop out rate for contact lens wear over their time at University and once they started having to pay for their lenses. This would have an impact on the interpretation of their results. It would be interesting to investigate these population groups further, for example carry out a dry eye survey such as ODSI scores to see if that

is different, also to find out why these people wear contact lenses, why do they wear makeup? It may be some wear contact lenses in order to see better, to play sports, for hobbies or work where spectacles are inconvenient and not just for cosmesis; it may be that there are more of the former in the non makeup wearing group. It may also be that those with less allergies are in the makeup wearing group. This is another factor that would be worth asking and analysing.

There was a difference between the total wearing time and comfortable wearing time of 2 and 3 hours, similar to that found in other studies. This introduces the question why do people continue to wear lenses even when they are not comfortable, what is their level of tolerance, what do they do about it and have they sought advice about it? These are questions that would provide more information and insight into lens wear habits.

- What is the difference in comfort and wearing time when lenses are inserted before and after the application of makeup in habitual contact lens and makeup wearers?

For the group who did the cross over study in Chapter 3 – all were habitual wearers of contact lenses and makeup. The level of burning on insertion, interestingly, was worse when makeup was applied before inserting the lenses; the level of foreign body sensation on insertion which was worse when makeup was applied after contact lenses and the level of burning on removal which was worse when lenses were inserted after makeup. If anything, based on the current advice to contact lens wearers, it would be expected to be the other way around. This has not been studied before and gives some factual evidence for advice regarding the insertion on lenses and the application of makeup.

One factor that could be worth investigation is what was the time delay between applying makeup and inserting the lenses? Does this have any effect on the results and should there be a

recommended time delay? The question then arises for new lens wearers -would the results be different? It would be unethical to carry out a trial as there would be an increased risk or corneal trauma due to their inexperience at lens handling. However, this would be useful as it would lead to being able to give general advice to new lens wearers. It would be beneficial to the analysis to have a larger group, but this was difficult to recruit participants due to the level of commitment and time involved.

- Is there any advice that could be given to wearers of makeup and contact lenses that could improve comfort? Is there any difference with refractive error?

The aim of this study was to look at the wearing patterns of patients who wore both contact lenses and makeup. It was also to see if there was any advice that could be given to lens wearers who also wore makeup, regarding the sequence of lens insertion and to application of makeup, in order to improve lens comfort and compliance. For the detailed study (chapter 4), the refractive error did not affect the result. This was surprising as it would be expected that presbyopes and hyperopes would have worse results when inserting their lenses after makeup due to their inability to see close. During the study no participants used special spectacles to apply their makeup. It may be that these participants were experienced at applying makeup and lens handling, so neither were an issue. It may be different with new contact lens wearers the results might be different, so it is difficult to extrapolate and give advice to new wearers of contact lenses who wish to wear makeup.

The amount of time between contact lens insertion, makeup application and the objective analysis was not recorded. Ideally this would be the same in every scenario, but that was not possible in this study. This is a factor that could be investigated in further studies and warrants investigation as it could potentially help with advice that is given to lens and makeup wearers.

The use of makeup affected all of the parameters measured – this is the first time that these results have been compared in the same eyes and shows the effect of wearing makeup. The use of a primer improved all the parameters measured; maybe this should be advised for all contact lens wearers who also wear makeup.

This could be repeated with weekly, monthly, extended wear and rgp lens wearers for hyperopes, myopes and presbyopes. It would be difficult to recruit such a group in practice due to the level of commitment required. Another measure that may have some significance is the palpebral aperture. Should the advice be the same for those with a narrow aperture? This is a measurement that would be worth knowing. The age of this group was not analysed, the presbyopes were probably older and thus the question arises;- did this affect their results? The myopes had the longer tear break up times for all the scenarios, but between the hyperopes and presbyopes the results were similar. It would be expected that the presbyopes had a shorter tear break up time due to their age. However, the ODSI scores were not significantly different and this is a measure of how dry the eyes are. In conclusion, this study shows that for people who are habitual users of makeup and contact lenses, there is no benefit in applying their makeup before or after their lenses. The advice that could be given to improve lens comfort is to use and eyelid primer before the application of eye makeup.

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Abbreviations

CLD	Contact Lens Discomfort
ODSI	Ocular Disease Surface Index
MUSAC	mucin secreting goblet cells
LIPCOF	lid parallel conjunctival folds
LWE	lid wiper epitheliopathy
TFOS	Tear film and Ocular surface society
RGP	rigid gas permeable
IQ%	interquartile percentage
S.D.	standard deviation
TBUT	tear break up time
CL	contact lens
HEMA	2-hydroxyethyl methacrylate

Appendix 1

CONSENT FORM - QUESTIONNAIRE

Research workers, school and subject area responsible

Prof J Wolffsohn, Life and Health Sciences, Aston University, Mrs Una Whitcombe, Life and Health Sciences, Vision Sciences, Aston University, Dr Olivia Hunt, Life and Health Sciences, Vision Sciences, Aston University

Project Title

Does the insertion of contact lenses before the application of makeup result in better lens comfort in habitual make up wearers over the age of 18 years rather than insertion after the application of make up?

Invitation

You are invited to take part in a research project. It is important for you to understand what is being done and why before you agree to take part. Please take the time to read the following information carefully.

What is the purpose of the study?

The purpose is to determine what advice should be given to contact lens wearers who also wear makeup. Should they be advised to insert their lenses before or after applying their make up?

This is an important part of compliance with contact lens wear and hygiene and as a consequence lens comfort. We want to analyse which leads to better comfort and hence compliance. Is this affected by the type and power of lenses that you wear?

Why have I been chosen?

You have been chosen as you are a contact lens wearer over the age of 18 years and that you wear makeup on at least 2 days a week.

All contact lens wearers, 18 years of age and over, who are habitual wearers of makeup and are members of the optometry department at Aston University are being asked to participate.

What will happen to me if I take part?

You will be asked to fill in a questionnaire regarding contact lens comfort over the next few weeks.

You will be asked to insert your lenses either before or after applying your make up for the next 5 times that you intend to wear both makeup and contact lenses. You will then take a break for a day and either not wear your contact lenses or not wear makeup. The following 5 times you intend to wear contact lenses and make up you are to fill in the same questionnaire but doing the opposite regarding which is applied first - lenses or makeup. You will be asked about what types of makeup you wear and to fill in an ocular surface disease index questionnaire about each method of insertion of your lenses.

Are there any potential risks in taking part in the study?

The only risks involved are those that are associated with contact lens wear and wearing makeup, which you do anyway. You are not being asked to apply more make up or use it more frequently than you do at present or to wear your lenses more frequently.

If you suffer any redness, stickiness or discharge from your eyes you are requested to contact the Eye Clinic as soon as possible, as is the normal advice. Your normal emergency contact telephone number is still the same .

If you feel that you have any contaminant on the lens and suffer any pain, you are to remove the lens and indicate this on the questionnaire.

Do I have to take part?

This is voluntary and you are under no obligation. Your contact lens care regimen will be carried out as usual by the Eye Clinic whether you take part or not. There will be no sanctions taken against you. There will be no indication on your record card about whether you have participated or not.

If you wish to stop part way through, you are completely free to do so without any obligation. However, we would request that you please send in the questionnaire to that date with your reason for ceasing as it may aid our research.

Expenses and payments

There are no foreseen expenses or payments.

All completed forms will be entered into a prize draw to win either a pair of Rayban Wayfarer sunglasses, or 6 months supply of your monthly disposable lenses or 2 months supply of your daily lenses (or the equivalent).

Will my taking part in this study be kept confidential?

The results will be kept fully confidential. There will be no way to link any research data to an individual participant.

What will happen to the results of this research study?

We aim to publish the results of study. There will be no research data published about any individual participant

There will be a copy of any published articles kept at the department.

Who is organizing and funding the research?

There is no funding of this research project.

It is organized by the Life and Health Sciences, Vision Sciences Department at Aston University.

Who has reviewed the study?

This research has been submitted for approval to Aston University's Ethics Committee.

Who do I contact if something goes wrong or if I need further information?

Please feel free to contact Prof James Wolffsohn – 01212044143 regarding the study.

Your normal emergency contact telephone number for contact lens problems still applies

Who do I contact if I wish to make a complaint about the way in which the research is conducted?

If you have any concerns about how this research is carried out please contact the secretary of Aston University Ethics Committee on j.g.walter@aston.ac.uk or 01212044665