Fast versus gradual adaptation of soft monthly contact lenses in neophyte wearers

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Abstract

Aim: To determine if a gradual adaptation period is necessary for neophytes when fitted with modern hydrogel or silicone hydrogel reusable disposable contact lenses.

Method: Across four sites, 74 neophytes (18-28 years) were randomly assigned to a reusable lens: Proclear® (hydrogel) or Biofinity® (silicone hydrogel) and an adaptation schedule: fast (10 hours wear from the first day) or gradual (4 hours on the first day, increasing their wear time by 2 hours on each subsequent day until they had reached 10 hours). Masked investigators graded ocular surface physiology and non-invasive tear breakup time (NIBUT) and a range of comfort, vision and lens handling subjective ratings (0-100 visual analogue scales) were recorded at the baseline visit and after 10 hours of lens wear, 4-6 days and 12-14 days after lens fitting. Subjective scores were also repeated after 7 days.

Results: There was no difference ($p>0.05$) in ocular surface physiology or NIBUT between fast and gradual adaptation groups at any time point in either lens type with the exception of increased corneal staining ($p=0.019$) in the silicone hydrogel fast adaptation group after 4-6 days. Subjective scores were also similar across the visits and lens types with the exception of 'lens awareness' ($p=0.019$) which was less in the gradual versus the fast adaptation silicone hydrogel lens group at 12-14 days.

Conclusion: There seems to be no clinical benefit for recommending a gradual adaptation period in new wearers fitted with modern soft reusable disposable contact lenses. The findings of this work add to a growing body of evidence suggesting that such advice is unnecessary in regular soft contact lens wear, which has important ramifications for the initial clinical management of these patients.

Key words: Soft contact lens, reusable, adaptation, neophyte, fast, gradual

1. Introduction

Currently, conventional practice advocates a cautious ‘easing-in’ approach for adapting new contact lens wearers (neophytes)[1]. In daily lens wear, this usually involves wear schedules of 2 to 4 hours on the first day followed by increases of 1-2 hours daily until the desired wear time is achieved. Whilst this is likely to be beneficial for newly-adapting rigid lens wearers, it is less likely to be important for wearers of soft contact lenses. Soft lenses have a much lower modulus than rigid lenses [2, 3] and have less interaction with the upper eyelid due to a larger diameter and reduced lens movement, which makes them significantly more comfortable from the very first application. For this reason, many patients use soft lenses on an occasional basis and the concept of building-up of wear time in the traditional sense seems redundant under these circumstances.

Previous work from this group [4] comparing fast to gradual adaptation in neophyte daily disposable lens wearers showed no significant differences in ocular physiology over the first two weeks of lens wear. Limbal, bulbar and palpebral conjunctival redness as well as corneal staining were found to be similar for the two groups with both contemporary hydrogel and silicone hydrogel daily disposable lenses. This finding lends weight to the hypothesis that the oxygen transmissibility of a lens is not relevant in deciding if a gradual adaptation period is required in a soft lens. Furthermore, the work showed that subjective comfort, vision and lens handling were not negatively impacted by a fast adaptation schedule; in fact, lens awareness and ease of lens removal were *improved* in the fast compared to the gradual adapters in the hydrogel lens wearers.

The report was the first to provide evidence that eye care practitioners could eliminate gradual adaptation periods in soft lenses – at least for daily disposable wearers. However, it remains unknown whether the same principle can be applied to reusable daily wear soft contact lenses which remain the most widely prescribed lens category across the world, currently making-up up 44% of lens fits globally [5]. There are additional complexities which could influence comfort and adaptation with reusable lenses compared with daily disposable lenses, such as the interaction of the care regimen with the ocular surface [6, 7] as well as the potential for increased levels of deposition and its effect on ocular physiology [8].

This work set out to build upon the findings of previous work[4] and sought to gain a better understanding of whether the recommendation of gradual adaptation was supported for reusable daily wear hydrogel and silicone hydrogel contact lenses. Specifically, the work aimed to investigate if there were differences in ocular surface physiology and subjective performance in contact lens neophytes prescribed reusable lenses who underwent a fast versus a gradual adaptation schedule in the first two weeks of lens wear.

2. Methods

2.1 Study lenses and care regimen

The two monthly reusable lenses investigated in this work were Proclear® and Biofinity® (CooperVision Inc.) (Table 1). These lenses were selected based on the similarity of their design (e.g. lens edge shape) and as representative examples of commonly prescribed hydrogel and silicone hydrogel monthly reusable lenses. Participants were fitted with one of the two lens types and worn bilaterally (as a matching lens pair) on a daily wear, reusable basis for a period of 12-14 days.

All participants used Opti-Free® Puremoist® multi-purpose contact lens solution (Alcon Laboratories Inc.) throughout the study together with the manufacturer-provided flat lens case. The care regimen is described as a buffered solution containing the dual disinfectants/preservatives POLYQUAD® (polyquartanium-1) 0.001% and ALDOX® (myristamidopropyl dimethylamine) 0.0006%[9] . Two wetting agents; Tetronic 1304 (BASF Corporation) and a proprietary linear diblock copolymer composed of poly(oxyethylene)-poly-(oxybutylene) named EOBO, HydraGlyde® Moisture Matrix are present as well as sodium citrate, sodium chloride, boric acid, sorbitol, aminomethylpropanol and disodium EDTA. Participants were instructed to use the solution following the manufacturer guidelines which also included a rub-and-rinse step.

2.2 Study Design

This was a prospective, parallel-group, randomised, investigator-masked, multi-site study based at four academic institutions: Aston University (Birmingham, UK), University of Bradford (Bradford, UK), Cardiff University (Cardiff, UK), and Glasgow

Caledonian University (Glasgow, UK). All four sites received human ethics approval from their respective institutional research ethics committee. The study conformed to the tenets of the Declaration of Helsinki and all participants provided written informed consent prior to enrolment.

Inclusion criteria included being aged between 18-40 years with astigmatism ≤0.75DC, being deemed suitable for contact lens wear following anterior eye assessment and being in possession of an in-date spectacle prescription. Participants were excluded if they had a history of contact lens wear within the previous six months, were pregnant or breast-feeding, had had recent refractive surgery, had a known hypersensitivity to saline or sodium fluorescein, took medications known to affect contact lens wear or had a systemic or ocular condition that could affect lens wear. The sample size of participants required for the study was estimated using power calculations from a previous study using daily disposable lenses[4]: 10 participants in each adaptation/lens material group would have 80% power to detect a difference of at least 10 points on a 0-100 grading scale for subjective scores.

Participants attended three visits. At the initial visit, baseline investigations included refraction, visual acuity, non-invasive tear breakup time (NIBUT) using either a Tearscope Plus (Keeler, Windsor, UK) or keratometry mires (Bausch and Lomb Rochester NY, USA) and slit lamp examination of the ocular surface: bulbar, limbal and palpebral conjunctival hyperaemia, palpebral roughness, and corneal staining were graded to the nearest 0.1 units using Efron grading scales[10]. The assessment was performed using 16x magnification under white light with the addition of sodium fluorescein (1.5 mg impregnated strips) for the observation of corneal staining using blue light together with a yellow enhancement filter in front of the observation system[11].

All eligible participants at each site were assigned to one of the two lenses for the investigation, with each site only fitting one of the lens types. Lens fit was assessed using the simplified approach proposed by Wolffsohn and colleagues[12]. An unacceptable fit was identified by the presence of limbal excursion or if there were two or more minus grading values for the fitting parameters. Subjective responses were reported using 0-100 visual analogue scales where 0 indicated a very poor or negative

experience and 100 indicated a very positive experience. At initial lens dispensing the following were recorded: ‘comfort before lens application’, ‘overall comfort’ and ‘visual quality’.

Participants were then randomly allocated to one of two adaptation schedules; i) no build-up of wearing time (fast adaptation) where participants would wear lenses for 10 hours from the first day or ii) a more gradual build-up (gradual adaptation) where participants would wear lenses for 4 hours on the first day and increase their wear time by 2 hours on each subsequent each day until they reached 10 hours. Investigators collecting data were masked to the adaptation schedule group. All participants were instructed fully on contact lens application and removal and given full instructions on how to care for their lenses, including the use of the care regimen.

Participants returned to the clinic for two further follow-up visits once they had reached 10 hours of lens wear: i) 4-6 days and ii) 12-14 days after fitting. Slit lamp biomicroscopy and NIBUT assessments were carried out at both visits similarly to the initial baseline visit. The following subjective scores were recorded using 0-100 visual analogue scales: ‘comfort prior to lens application’, ‘overall comfort’, ‘vision quality’, ‘lens awareness throughout the day’, ‘end-of-day comfort’, ‘ease of lens application’ and ‘ease of lens removal’. Participants were also asked to record these same parameters after wearing the lenses for 7 days and to return the completed questionnaire at the final visit.

2.3 Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics (v23 IBM Corp. Chicago, Illinois, USA). The data were not found to be normally distributed (Kolmogorov-Smirnov Test $p<0.05$) therefore Mann-Whitney U tests were used to investigate the differences between the gradual and fast adaptation groups at each visit. The statistical significance level was set at $p<0.05$.

3. Results

Seventy-four participants were enrolled and the demographics of the study groups are shown in Table 2. Overall the age range of all the study cohorts remained similar between 18-28 years, and the range of refractive error (spherical equivalent) was between +0.25 and -6.50 DS. All recruited participants completed the study and no adverse events occurred. No lens fits were deemed 'unacceptable'.

3.1 Ocular surface physiology and tear film stability

There were no statistically significant differences ($p>0.05$) in ocular surface physiology or NIBUT measurements between the two adaptation schedule groups at baseline, or at the two follow-up visits for the hydrogel or silicone-hydrogel wearers (Tables 3 and 4); the only exception was after 4-6 days of wear, when the gradual adaptation silicone hydrogel wearers demonstrated significantly lower scores for corneal staining compared to the fast adaptation group ($p=0.019$; Table 4), but this difference was not sustained after 12-14 days of lens wear.

3.2 Subjective assessments

At baseline there were no statistically significant differences ($p>0.05$) in subjective scores between the two adaptation schedule groups for both the hydrogel (Table 5) and silicone hydrogel (Table 6) wearers. This was also true at 4-6 days and day 7 after lens wear commenced. After 12-14 days of silicone hydrogel lens wear, 'lens awareness' ($p=0.02$) was significantly better in the gradual compared to the fast adaptors, but there were no other differences between the adaptation schedules (Table 5 and Table 6).

4. Discussion

This study built upon the knowledge gained from the first investigation on this topic which compared the effect of a fast compared to a more traditional gradual adaptation schedule on ocular surface physiology and subjective acceptance in neophyte daily disposable lens wearers[4]. As far as possible the same methodology and statistical analyses were repeated for the current second sister study, this time, using reusable daily wear contact lenses. Overall, the results from the present work are similar to those found in the previous study. Neither a fast nor a gradual adaptation schedule

had any major impact on the short-term ocular surface physiology or tear film stability with modern hydrogel or silicone hydrogel reusable contact lenses.

In hydrogel lens wear there were no differences between adaptation groups for bulbar, limbal or palpebral hyperaemia across time points and this was also the case for palpebral roughness and corneal staining. Similar results were seen in the silicone hydrogel lens wearers except that the gradual adaptation group demonstrated reduced levels of corneal staining after 4-6 days compared with the fast group. Given that the corneal staining scores were 0.3 versus 0.1 Efron grading units (fast vs. gradual adaptation groups, respectively), it seems reasonable to conclude that these differences are not clinically significant since their magnitude lies within the 'normal' range on this grading scale[13]. Any differences between the two groups in this parameter had disappeared by 12-14 days.

Contact lens wear causes disruption to the normal tear film structure and function [14-16] which is thought to be a significant factor in negatively impacting ocular discomfort despite the lack of conclusive evidence linking the two. No differences were observed between the two adaptation schedules for NIBUT in either lens type at either visit which suggests that tear film stability is not adversely affected as a result of how quickly the wearing time in built up in reusable lenses. Overall, these results are very similar to earlier findings investigating adaptation schedule in daily disposable wearers[4] with the exception that in the daily disposable work a longer NIBUT was found in those undergoing a gradual adaptation in silicone hydrogel lenses at the 12-14 day visit.

In terms of subjective comfort-related responses, there were no statistically significant differences between the two adaptation groups in the hydrogel lens wearers. Interestingly, in hydrogel daily disposable wearers 'lens awareness' and 'end-of-day' comfort were shown to be better in the fast versus the gradual adaptation group after 7 and 12-14 days, respectively[4]. No such differences have been demonstrated in the current work which could be as a result of the particular hydrogel lens design chosen, lens deposition differences or factors related to the lens/solution combination. This lack of comfort-related symptoms difference between the two adaptation groups is in

line with no differences being observed in ocular physiology and NIBUT in this lens type.

In the silicone hydrogel wearers, 'lens awareness' scores were better (i.e. scores were higher which corresponded to reduced lens awareness) in the gradual adaptation versus the fast adaptation group at the 12-14 day visit and this difference (86 vs. 71) is quite marked. The gradual adaptors also presented with significantly reduced corneal staining at the 4-6 day time point and it is not clear if this could have contributed to the subsequent lens awareness increases in this group at the following visit. Previous work has shown a link between comfort and levels of SICS staining[17-19], yet it is unlikely that the use of other lens care solutions such as hydrogen peroxide would have reduced the level of corneal staining observed or changed the study outcome as the frequency of cleaning was the same between the fast and gradual adaptation groups. It would be interesting to investigate whether or not this 'lens awareness' difference persists longer-term, but the difference between the two adaptation groups in this lens type is somewhat offset by there being no other differences in subjective comfort scores over the two-week study period.

Visual quality was similar for the adaptation groups in both lens types at all time points across the two-week period, which is in line with previous findings for daily disposable lenses. This study also evaluated subjective handling aspects relating to 'ease of application' and 'ease of removal' at each follow-up visit; as with the daily disposable lens study, no significant differences were found between the fast and gradual adaptation groups at any of the time points or for either lens type. This result is not unexpected given that the total amount of handling time is the same whichever adaptation schedule is followed i.e. participants would be applying and removing the lenses once per day.

Overall, the results from this work suggest that gradual adaptation to modern spherical reusable disposable soft lenses is unnecessary, regardless of the oxygen permeability of the material. As has been previously stated, this does not mean that wearers should be instructed to wear their lenses for 10 hours from the start regardless, but rather a sensible approach would be to instruct patients to wear them for as long as they are comfortable up to a suggested maximum. The first few weeks of lens wear are very

important in terms of the long-term success of a new contact lens wearer so the patient should be followed up to determine whether they have any issues that need addressing[20].

This work with reusable soft contact lenses has added to the growing body of evidence showing that gradual adaptation in neophytes has little clinical benefit compared to a fast adaptation approach in both hydrogel and silicone hydrogel lenses. These findings have important ramifications for the clinical management of these patients in the initial lens wear period.

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Lens name	Biofinity®	Proclear®
Manufacturer	CooperVision Inc.	CooperVision Inc.
Material	Comfilcon A	Omafilcon B
Base Curve (mm)	8.6	8.6
Total Diameter (mm)	14.0	14.2
Water content (%)	48	62
Oxygen permeability (ISO units)	96	20
Back vertex power range (BVP)	+8.00 to -12.00D	+6.50 to -20.00D

Table 1: Study lenses (parameters from the ACLM Yearbook)[21]

Lens	Experimental Group	Participants	Age (years)	Male/Female Ratio	Refraction (Spherical equivalent in dioptres)
Biofinity®	Gradual	17	18 - 23	4 / 13	+0.25 to -6.50D
	Fast	18	18 - 28	1 / 17	+0.25 to -4.50D
Proclear®	Gradual	20	18 - 27	3 / 17	+0.50 to -5.25D
	Fast	19	18 - 28	6 / 13	+0.50 to -6.50D

Table 2: Demographic and refractive details of the study participants.

		Baseline			Day 4-6			Day 12-14		
		Mean	**SD**	**p**	**Mean**	**SD**	**p**	**Mean**	**SD**	**p**
Bulbar Hyperaemia	Fast	0.8	±0.6	0.879	0.7	±0.7	0.365	1.0	±0.7	0.351
	Gradual	0.8	±0.8		0.9	±0.6		0.7	±0.8	
Limbal Hyperaemia	Fast	0.6	±0.4	0.945	0.8	±0.4	0.322	0.7	±0.6	0.322
	Gradual	0.6	±0.6		0.6	±0.6		0.5	±0.6	
Palpebral Hyperaemia	Fast	0.8	±0.5	0.728	0.8	±0.7	0.771	0.8	±0.6	0.513
	Gradual	0.7	±0.6		0.8	±0.6		0.7	±0.7	
Palpebral Roughness	Fast	0.7	±0.5	0.444	0.6	±0.6	0.879	0.6	±0.7	0.513
	Gradual	0.6	±0.5		0.6	±0.5		0.4	±0.5	
Corneal Staining	Fast	0.3	±0.4	0.771	0.5	±0.5	0.559	0.5	±0.4	0.708
	Gradual	0.1	±0.2		0.3	±0.4		0.5	±0.4	
Non-invasive breakup time (s)	Fast	9.1	±1.4	0.999	8.2	±1.1	0.270	7.6	±1.3	0.351
	Gradual	9.0	±1.6		8.7	±1.2		8.1	±1.6	

Table 3: Comparison of ocular physiology in fast and gradual adaptation of neophytes fitted with reusable hydrogel soft contact lenses. Efron scale grading between 0 and 4 units, using 0.1 increments. SD = standard deviation; p = significance value. (bold indicates level <0.05).

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		Baseline			Day 4-6			Day 12-14		
		Mean	**SD**	**p**	**Mean**	**SD**	**p**	**Mean**	**SD**	**p**
Bulbar Hyperaemia	Fast	0.6	±0.4	0.335	0.8	±0.4	0.173	0.9	±0.4	0.883
	Gradual	0.7	±0.4		0.8	±0.4		0.9	±0.4	
Limbal Hyperaemia	Fast	0.5	±0.4	0.636	0.6	±0.4	0.883	0.7	±0.3	0.660
	Gradual	0.5	±0.4		0.5	±0.3		0.8	±0.4	
Palpebral Hyperaemia	Fast	0.4	±0.3	0.590	0.4	±0.4	0.393	0.5	±0.5	0.405
	Gradual	0.5	±0.4		0.5	±0.4		0.6	±0.5	
Palpebral Roughness	Fast	0.4	±0.2	0.732	0.4	±0.2	0.463	0.5	±0.3	0.935
	Gradual	0.3	±0.2		0.5	±0.4		0.5	±0.4	
Corneal Staining	Fast	0.2	±0.3	0.999	0.3	±0.3	**0.019**	0.3	±0.4	0.351
	Gradual	0.1	±0.2		0.1	±0.2		0.2	±0.3	
Non-invasive breakup time (s)	Fast	11.1	±3.2	0.590	10.1	±2.0	0.270	9.6	±2.9	0.613
	Gradual	11.1	±2.3		10.4	±2.6		10.1	±4.2	

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409 **Table 4:** Comparison of ocular physiology in fast and gradual adaptation of
410 neophytes fitted with reusable silicone hydrogel soft contact lenses. Efron scale
411 grading between 0 and 4 units, using 0.1 increments. SD = standard deviation; p =
412 significance value. (bold indicates level <0.05).

		Baseline			Day 4-6			Day 7			Day 12-14		
		Mean	**SD**	**p**	**Mean**	**SD**	**p**	**Mean**	**SD**	**p**	**Mean**	**SD**	**p**
Comfort prior to lens wear	Fast	97.9	±4.2	0.428	96.1	±7.6	0.411	97.1	±5.6	0.923	98.7	±3.3	0.749
	Gradual	99.0	±4.5		97.5	±7.3		96.8	±7.8		96.3	±8.7	
Overall comfort	Fast	85.5	±9.1	0.708	81.1	±15.4	0.461	78.7	±17.5	0478	82.4	±13.3	0.351
	Gradual	86.0	±11.4		85.0	±13.2		83.0	±16.2		86.0	±12.3	
Visual quality	Fast	93.2	±8.0	0.687	94.2	±7.9	0.127	91.6	±10.5	0.336	95.3	±6.3	0.283
	Gradual	91.5	±15.2		85.5	±17.5		86.5	±14.5		88.8	±16.7	
Lens Awareness	Fast				77.9	±16.3	0.627	76.7	±18.8	0.478	76.6	±22.1	0.513
	Gradual				75.0	±18.9		73.6	±17.4		74.5	±18.3	
End of Day Comfort	Fast				72.9	±22.6	0.835	70.3	±24.4	0.945	70.8	±22.7	0.967
	Gradual				75.0	±22.9		73.5	±20.7		72.8	±17.3	
Ease Application	Fast				84.7	±12.9	0.846	85.8	±15.2	0.989	88.9	±14.4	0.687
	Gradual				90.5	±11.0		87.8	±10.2		88.3	±12.2	
Ease Removal	Fast				89.7	±11.0	0.270	92.6	±11.9	0.967	91.8	±10.3	0.569
	Gradual				94.3	±8.5		92.5	±12.0		94.8	±7.7	

Table 5: Comparison of subjective ratings in fast and gradual adaptation of neophytes fitted with reusable hydrogel soft contact lenses using visual analogue scales (0-100). SD = standard deviation; p = significance value (bold indicates level <0.05).

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		Baseline		p	Day 4-6		p	Day 7		p	Day 12-14		p
		Mean	**SD**		**Mean**	**SD**		**Mean**	**SD**		**Mean**	**SD**	
Comfort prior to lens wear	Fast	92.0	±9.9	0.660	88.9	±13.7	0.832	93.1	±9.0	0.961	93.6	±7.7	0.546
	Gradual	93.7	±9.3		91.7	±9.0		93.2	±8.8		95.3	±7.3	
Overall comfort	Fast	77.5	±20.9	0.613	74.4	±21.4	0.525	81.5	±15.8	0.832	79.8	±17.9	0.318
	Gradual	80.8	±20.4		80.6	±13.8		84.6	±9.8		87.5	±10.0	
Visual quality	Fast	88.8	±11.0	0.546	79.4	±18.8	0.503	87.9	±6.5	0.909	89.1	±9.1	0.708
	Gradual	83.2	±17.4		82.2	±20.0		84.6	±16.3		88.3	±13.4	
Lens Awareness	Fast				74.7	±28.1	0.618	78.0	±21.7	0.732	71.0	±21.3	**0.019**
	Gradual				74.7	±19.5		76.1	±22.1		86.1	±11.5	
End of Day Comfort	Fast				70.6	±26.4	0.987	73.4	±20.5	0.961	76.1	±17.1	0.369
	Gradual				74.3	±18.1		72.7	±19.3		81.3	±17.3	
Ease Application	Fast				81.3	±15.2	0.163	82.9	±14.9	0.999	90.3	±9.8	0.732
	Gradual				69.6	±21.5		81.8	±15.9		87.4	±13.2	
Ease Removal	Fast				83.0	±17.4	0.525	87.7	±13.4	0.935	93.6	±8.8	0.613
	Gradual				80.7	±15.3		87.5	±13.6		90.4	±13.3	

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424 **Table 6:** Comparison of fast and gradual adaptation of neophytes fitted with
425 reusable silicone hydrogel soft contact lenses using visual analogue scales (0-100).
426 SD = standard deviation; p = significance value. (bold indicates level <0.05).