

City Research Online

City, University of London Institutional Repository

Citation: Wolffsohn, J., Dhirajlal, H., Vianya-Estopa, M., Nagra, M., Madden, L., Sweeney, L., Goodyear, A., Kerr, L., Terry, L., Sheikh, S., et al (2019). Fast versus gradual adaptation of soft daily disposable contact lenses in neophyte wearers. Contact Lens and Anterior Eye, 43(3), pp. 268-273. doi: 10.1016/j.clae.2019.08.011

This is the accepted version of the paper.

This version of the publication may differ from the final published version.

Permanent repository link: https://openaccess.city.ac.uk/id/eprint/23015/

Link to published version: https://doi.org/10.1016/j.clae.2019.08.011

Copyright: City Research Online aims to make research outputs of City, University of London available to a wider audience. Copyright and Moral Rights remain with the author(s) and/or copyright holders. URLs from City Research Online may be freely distributed and linked to.

Reuse: Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way. City Research Online: <u>http://openaccess.city.ac.uk/</u><u>publications@city.ac.uk</u>

Fast versus gradual adaptation of soft daily disposable contact lenses in neophyte wearers

¹James S Wolffsohn PhD j.s.w.wolffsohn@aston.ac.uk
¹Harshali Dhirajlal BSc <u>dhirajlh@aston.ac.uk</u>
²Marta Vianya-Estopa PhD <u>marta.vianya@anglia.ac.uk</u>
³Manbir Nagra PhD <u>manbir.nagra@port.ac.uk</u>
⁴Louise Madden PhD Louise.madedn@nes.scot.nhs.uk
⁴Laura Elaine Sweeney PhD laura.sweeney@gcu.ac.uk
⁴Anna Sarah Goodyear BSc agoody200@caledonian.ac.uk
⁴Lauren Victoria Kerr BSc lkerr209@caledonian.ac.uk
⁵Louise Terry PhD terryl1@cardiff.ac.uk
⁶Sabrina Sheikh BSc <u>sheikhsz@cardiff.ac.uk</u>
⁶Orla Murphy BSc <u>orla.murphy@dit.ie</u>
⁶Aoife Lloyd PhD <u>aoife.lloydmckernan@dit.ie</u>
⁷Carole Maldonado-Codina PhD <u>carole.m-codina@manchester.ac.uk</u>
and members of the British & Irish University & College Contact Lens Educators (BUCCLE) group

¹Ophthalmic Research Group, Aston University, Birmingham, UK
 ²Vision and Hearing Sciences, Anglia Ruskin University, Cambridge, UK
 ³School of Health Sciences and Social Work, University of Portsmouth, Portsmouth, UK
 ⁴School of Health and Life Sciences, Glasgow Caledonian University, G4 0BA
 ⁵School of Optometry and Vision Sciences, Cardiff University, Cardiff, CF24 4HQ, UK
 ⁶School of Physics & Clinical & Optometric Sciences, Technological University Dublin, Ireland.
 ⁷Faculty of Biology, Medicine and Health, The University of Manchester, Manchester, UK

Corresponding author

James S Wolffsohn, Aston University, Aston Triangle, Birmingham, B4 7ET, UK.Tel:+44(0)1212044140E-mail:j.s.w.wolffsohn@aston.ac.uk

Funding: BUCCLE's mission is to enhance optometry education in the UK and in this pursuit is funded by industry including Alcon, Bausch and Lomb, Coopervision, Johnson and Johnson Vision, No7 Contact Lenses and David Thomas/Menicon, but the research was designed and implemented independently. Other BUCCLE members include: Alison Alderson and Graham

Mouat (University of Bradford), Robert Conway (Anglia Ruskin University), Arnold Cochrane (University of Ulster), Claire McDonnell (TU Dublin), Byki Huntjens (City, University of London), Dean Dunning (Bradford College), Eilidh Martin and Laura Sweeney (Glasgow Caledonian University), Katherine Evans (Cardiff University), Shehzad Naroo (Aston University), Claire Mallon (The University of Manchester), Jo Underwood (Association of British Dispensing Opticians), Kishan Trivedy (University of Portsmouth), and Mahesh Joshi (University of Plymouth).

Abstract

Purpose: Despite the widespread practice of gradually adapting all new soft contact lens wearers (neophytes), there is little evidence-based research underpinning such practice. This work determined if a gradual adaptation period is necessary for neophytes when fitted with modern hydrogel or silicone-hydrogel daily disposable contact lenses.

Method: At four sites, neophytes (19-32 years) were randomly assigned to 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) and hydrogel (n=24 fast; n=21 gradual) or silicone-hydrogel (n=10 fast; n=10 gradual) contact lenses. Masked investigators graded ocular surface physiology and non-invasive tear breakup-time (NIBUT). A range of subjective scores (using 0-100 visual analogue scales) were recorded at the initial visit and after 10 hours of lens wear, 4-6 days and 12-14 days after initial fitting. Subjective scores were also repeated after 7 days.

Results: There was no difference (p>0.05) in ocular surface physiology between the fast and gradual adaptation groups at any time point in either lens type. NIBUT was similar at all time points for both adaptation groups in both lens types with the exception that the gradual adaptation silicone-hydrogel wearers had a slightly longer NIBUT (p=0.007) than the fast adaptation group. Subjective scores were also similar across the visits and lens types with the exception of 'lens awareness' and 'ease of lens removal' which were better (p<0.05) in the fast compared with the gradual adaptation hydrogel lens group at day 7. Additionally, 'end-of-day discomfort' was better (p=0.02) in the fast compared with the gradual adaptation hydrogel lens group at 12-14 days.

Conclusion: There appears to be no benefit in soft contact lens adaptation for neophytes with modern contact lens materials.

Keywords

soft contact lens; daily disposable; adaptation; neophyte; fast; gradual

Funding:

BUCCLE is funded by Alcon, Bausch and Lomb, Coopervision, Johnson and Johnson Vision, No7/Menicon, but the research was designed and implemented independently.

Highlights

- The conventional approach is to adapt new contact lens wearers by 'building-up' wearing time
- There is no underpinning scientific evidence for the need for this approach with modern soft contact lenses
- Fast versus gradual adaptation in new daily disposable hydrogel & silicon-hydrogel contact lens wearers were investigated
- No statistically or clinically significant differences were demonstrated between the adaptation schedules or lens materials
- The study demonstrated there is no need to recommend an adaptation schedule with modern daily disposable contact lenses

Introduction

Currently, most eye care practitioners (ECPs) commonly recommend that all new contact lens wearers (neophytes) should be 'eased' into lens wear in an attempt to maximise the clinical performance of their lenses over the first few days of wear.[1] The practice of constraining these initial wear times has been advocated by various authors in many of the key texts still used to train new ECPs (Table 1).[2-8] Typical proposed wear schedules vary from 2-4 hours on the first day followed by incremental increases of 1-2 hours daily until a maximum recommended wear time is achieved. A recent web-based survey of 186 ECPs from 26 countries gathered data on how silicone-hydrogel (daily disposable and re-useable) lenses were prescribed over the first week of wear [1] and found that there was no significant difference in how these two modalities were managed and that the majority of respondents advised wearing the lenses for 2-4 hours on the first day and gradually building-up to 'as long as comfortable' by the end of the first week.

Book	Recommendations on initial adaptation								
Contact Lens Practice Fetcher,	Individuals should start with 3 hours on the first day and add 1 hour each day.								
Lupelli and Rossi (1994) [5]	But neophytes with low Dk/t CLs are advised to go more slowly.								
Manual of Contact Lens	Neophytes should commence with 4 hours on the first day and increase by 1 hour every								
Prescribing and Fitting	day until 8-10 hours are reached. After first week, lenses can be worn for 12-15 hours.								
Hom and Bruce (1997) [7]									
Fitting Guide For Rigid And	Neophytes are advised to start with 4 hours a day and increase wear by 2 hours every								
Soft Contact Lenses	subsequent day until full-time wear is obtained.								
Stein et al (2002) [6]	A rapid wearing time suggestion is to wear CLs for 4 or more hours on the first day,								
	remove them for 1 hour and then wears lenses again for 4 or more hours. The wearing								
	time is increased by 2 hours daily with 1-hour break period.								
Clinical Contact Lens Practice	On the first day, neophytes should wear CLs for 4 hours followed by adding 2 hours every								
Bennett and Weissman (2005)	day until 12 hours is reached, by which, the patient should be able to wear CLs all waking								
[2]	hours.								
The Contact Lens Manual	Low WC CL wearers should start with 3 hours and add 1 hour every subsequent day until								
Gasson and Morris (2010) [8]	12 hours of wear is achieved (maximum).								
	High WC CLs neophytes are recommended start with 4 hours add 2 hours every day until								
	12 hours of wear is reached.								
	Silicone-hydrogel lens wearer should start with 6 hours and add 2 hours each day until								
	maximum wear time of all day (overnight) is achieved.								
Contact Lens Practice	Soft CL wearers should initially start with 4 hours and increase by 2 hours each day to 12								
Efron (2018) [4]	hours of wear per day (maximum).								
	Due to the improvements in soft CL this method is largely redundant now.								
Contact Lenses	Start with 4 hours a day as a minimum some neophytes may need as long as 2 weeks.								
Phillips and Speedwell (2019) [3]	Building up a wearing time is not required unless extended wear, continuous wear or RGP								
	lenses.								
	Soft CL wearers can start with 8 hours initially and then wear CLs for provided that they								
	are comfortable.								

Table 1:Recommended adaptation times for new soft contact lens (CL) wearers by
various authors.

Despite the widespread use and clinical acceptance of gradually adapting new lens wearers, there is remarkably little evidence-based research underpinning such practice, which instead seems to be based on clinical intuition. The underlying rationale appears to be based upon conventional wisdom, that a gradual increase in wear time allows the patient a period of acclimatisation with respect to comfort, vision and ocular physiology.[9-11] These first few days are crucial to the long-term success of a new wearer and there is no doubt that they must be carefully managed in order to avoid drop-out,[12.13] the most common reasons for which are: discomfort, visual and handling problems.[13-17]

Gradual adaptation is thought to be particularly important in high modulus rigid lens wear,[8] in order to allow a patient to become accustomed to the physical presence of the lens on-eye. However, soft lenses are significantly more comfortable than their rigid counterparts, which is thought to be due to the reduced interaction with the upper eyelid and a lower modulus.[8] In the past, soft lenses were manufactured from materials with low oxygen permeability, such as polyhydroxyethyl methacrylate,[9] which often resulted in hypoxia-related complications such as limbal hyperaemia, corneal epithelial microcysts and corneal stromal oedema. Longer-term effects such as thinning of the corneal epithelium, corneal endothelial polymegethism and stromal thinning have also been well documented.[9,10] It remains unclear, however, whether a gradual adaptation in the first week of wear with these lenses had any significant impact on the ocular physiology response.

Contemporary soft contact lenses have seen significant improvements compared to their predecessors in areas such as material biocompatibility (e.g. improved oxygen performance with silicone-hydrogel lenses), manufacturing quality and lens design, yet the practice of prescribing a gradual initial adaptation period persists. These lenses are associated with a lower incidence of adverse physiological reactions such as limbal and conjunctival redness,[9,18] and corneal swelling,[19] when compared to traditional hydrogels. With more and more lens wearers opting for the convenience of daily disposable lenses and many only wishing to wear them on an occasional basis, the notion of a gradual adaptation period may seem antiquated and conservative to many practitioners. Nevertheless, the increased risk of infiltrates in silicone-hydrogel daily wear remains a significant drawback, [20,21] being twice

as common as with hydrogel materials [22-24] It is unknown if the clinical requirements for any adaptation period differ with material type.

If the lack of a gradual adaptation phase was shown to be safe by any reasonable definition of the term and have no effect on ocular comfort, it would hold several advantages over a more gradual approach, such as: better patient compliance due to increased simplicity; less impact on the personal/work commitments of the wearer as a result of not needing to remove lenses part-way through the day; and to allow wearers who wish to wear their lenses infrequently to do so for a full day. Therefore, this work set out to investigate if there were differences in ocular surface physiology and subjective performance in contemporary daily disposable lens wearers subjected to a fast, versus a gradual, adaptation approach in the first few days of lens wear. The work also investigated if there were differences between these approaches for silicone-hydrogel and hydrogel contact lens wearers.

Methods

Study lenses

The two daily disposable lens types investigated in this work were the 1-DAY ACUVUE[®] MOIST and the ACUVUE[®] OASYS 1-DAY with HydraLuxe[™] (Johnson & Johnson Vision) and are outlined in Table 2. The lenses were chosen as representative examples of contemporary, commonly prescribed hydrogel and silicone-hydrogel lenses. Both had a similar design (i.e. edge shape and overall thickness profile) and the daily disposable modality was chosen, as it is the predominant modality consumer choice as well as mitigating any interactions from accompanying lens care solutions systems.

Lens Name	1-DAY ACUVUE® MOIST	ACUVUE [®] OASYS 1-DAY with HydraLuxe™
Manufacturer	Johnson & Johnson Vision	Johnson & Johnson Vision
Material	Etafilcon A	Senofilcon A
Oxygen permeability (ISO units)	21	77
Back optic zone radius (BOZR) (mm)	8.5, 9.0	8.5, 9.0
Total diameter (mm)	14.2	14.3
Equilibrium water content (%)	58	38
Back vertex power (BVP) (D)	+6.00 to -12.00	+8.00 to -12.00

Table 2: Study lenses

Subjects were fitted with one of the two lens types for a period of 12-14 days.

Study Design

This was a prospective, parallel group, randomised, investigator-masked, multi-site clinical investigation which was carried out at four academic institutions: Aston University (Birmingham, UK), Cardiff University (Cardiff, UK), Glasgow Caledonian University (Glasgow, UK) and the Technological University Dublin (Dublin, Ireland). All four institutions were given a favourable ethical opinion by their respective university research ethics committee. The study conformed to the tenets of the Declaration of Helsinki and all subjects provided written informed consent prior to enrolment. Inclusion criteria included being aged between 18 and 40 years, having astigmatism ≤0.75D, having healthy eyes and an ability to understand and full comply with the study procedures. Potential subjects were excluded if they were previous or current contact lens wearers, had had previous eye surgery, had an ocular or systemic condition or were on medication that could contraindicate contact lens wear, they had known hypersensitivity to saline or fluorescein, or they were pregnant or breast-feeding.

In order to determine the overall sample size, power analysis was undertaken. A sample size of 8 subjects in each adaptation/lens material group would give 80% power to detect a difference of 0.5 or more in Efron grading units in hyperaemia, based on a standard deviation of 0.2 grading units [25] and an alpha of 0.05 for a Mann-Whitney U test (G*Power). A sample size of 10 subjects in each adaptation / lens material group would have 80% power to detect a difference of at least 10 on a 100 point scale for subjective comfort scores using visual analogue scales, based on a standard deviation of 8-10 grading units [26,27] and an alpha of 0.05 for a Mann-Whitney U test (G*Power).

The 65 subjects attended three visits in total. At the initial visit, various clinical (baseline) investigations were performed. These included refraction, visual acuity and slit lamp biomicroscopy of the ocular surface; bulbar, limbal and palpebral conjunctival hyperaemia were graded to the nearest 0.1 unit using Efron 0-4 unit grading scales [25] (white light and 16X magnification). Following application of sodium fluorescein (1.5mg impregnated strips), corneal staining and palpebral redness and roughness were graded using the same grading scales. Non-invasive tear film breakup time (NIBUT) was assessed using the Tearscope Plus (Keeler, Windsor, UK) or keratometer mires (Bausch and Lomb, Rochester, NY, USA) prior to lid eversion and the average of three measurements were recorded for each eye.

Eligible subjects were assigned to one of the two lens types (Table 2), based on site (each site only fitted one lens type) and lens fit was assessed according to the criteria of Boychev et al.[28] After successful lens fitting, subjects were randomly assigned to one of the following two adaptation schedules: i) no build-up of wearing time (fast adaptation) where subjects wore lenses for 10 hours from the first day or ii) a more gradual build-up (gradual adaptation) where subjects wore subjects wore lenses for 4 hours on the first day and increased their wear time by 2 hours on each subsequent day until they had reached 10 hours. The investigator was masked to the subject's adaptation schedule. All subjects were carefully instructed on lens application and removal and given full information on how to care for their lenses as well as how to comply with their assigned wearing schedule.

Subjective scores were collected using visual analogue scales (0-100 where 0 indicated "very uncomfortable" and 100 "very comfortable") for comfort before lens application, comfort after lens application and overall clarity of vision.

Subjects were asked to return, once the lenses had been *in-situ* for 10 hours, for two further follow-up visits, one after 4-6 and the other 12-14 days from the initial visit. Similar slit lamp

biomicroscopy and TBUT investigations were undertaken at all visits. The same subjective scores were collected as at the initial visit but additionally 'lens awareness' (anchored by "very aware of lenses" to "completely unaware of lenses"), 'end-of-day comfort', 'ease of lens application' (anchored by "very difficult to handle" to "very easy to handle") and 'ease of lens removal' (anchored by "very difficult to remove" to "very easy to remove") were recorded using 0-100 visual analogue scales. The subjective visual analogue scales were also repeated after 7 days of lens wear by paper form returned at the final visit.

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.

Results

Subject demographics

The demographics of the study groups are shown in Table 3. All recruited subjects completed the study and no adverse events occurred. The lenses adequately fitted all subjects.

Lens	Experimental	Participants	Age	Male/Female	Refraction						
	Group		(years)	Ratio							
1-DAY ACUVUE®	Gradual	24	19 - 21	9 / 15	+1.25 to -1.75D						
MOIST	Fast	21	19 - 32	7 / 14	+1.00 to -4.75D						
ACUVUE [®] OASYS 1-	Gradual	10	19 - 22	3/7	+0.50 to -5.25D						
DAY with	Fast	10	19 - 24	4 / 6	+0.50 to -4.75D						
HydraLuxe™											
Table 3:	Demographics and refractive details of the study subjects										

There were no statistically significant differences in ocular surface physiology between the two adaptation schedule groups at baseline, or at the two follow-up visits for the hydrogel or silicone-hydrogel wearers (Tables 4 and 5). Similarly, there were no statistically significant differences in NIBUT at baseline or the follow-up visits, for both adaptation schedule groups for both lens types, with the exception that after 12-14 days of wear, the gradual adaptation silicone-hydrogel wearers had a significantly longer NIBUT than the fast adaptation group (p=0.007; table 5).

		E	Baseline	2	I	Day 4-6	5	Day 12-14			
		Mean	SD	р	Mean	SD	р	Mean	SD	р	
Bulbar	Fast	1.3	±0.6	0 202	1.1	±0.5	- 0.963 -	1.0	±0.6	0.936	
Hyperaemia	Gradual	1.1	±0.5	0.292	1.2	±0.6		1.0	±0.5		
Limbal	Fast	1.0	±0.4	0.205	0.8	±0.4	0.005	0.7	±0.5	0.972	
Hyperaemia	Gradual	0.8	±0.5	0.205	0.8	±0.4	0.665 -	0.7	±0.4		
Palpebral	Fast	0.8	±0.4	0.442	0.8	±0.3	0.797 -	0.7	±0.4	0.399	
Hyperaemia	Gradual	0.7	±0.3	0.443	0.8	±0.4		0.6	±0.4		
Palpebral	Fast	0.7	±0.4	0 227	0.6	±0.5	0.65	0.7	±0.5	0.198	
Roughness	Gradual	0.5	±0.4	0.227	0.7	±0.5	0.65	0.6	±0.4		
Corneal	Fast	0.3	±0.7	0 4 4 7	0.4	±0.7	0.000	0.4	±0.6	0.348	
Staining	Gradual	0.3	±0.6	0.447	0.2	±0.4	0.683 -	0.2	±0.4		
Non-invasive	Fast	13.3	±3.1	0.064	12.6	±4.0	0.671	12.6	±3.9	0.276	
breakup time (s)	Gradual	12.9	±5.4	0.964	11.4	±4.7	0.671 -	11.5	±4.5		

Table 4:Comparison of ocular physiology in fast and gradual adaptation of neophytes fittedwith hydrogel soft contact lenses. Efron scale grading between 0 and 4 units. SD = standarddeviation; p = significance value.

		E	Baseline	9	I	Day 4-6	5	Day 12-14			
		Mean	SD	Р	Mean	SD	р	Mean	SD	р	
Bulbar	Fast	0.9	±0.1	0.436	0.9	±0.3	0.105 -	1.1	±0.2	0.123	
Hyperaemia	Gradual	1.2	±0.5	0.430	1.1	±0.3		1.0	±0.4		
Limbal	Fast	0.9	±0.3	0.393	0.9	±0.3	0.853 -	0.9	±0.2	0.353	
Hyperaemia	Gradual	1.1	±0.5	0.393	0.9	±0.3	0.855	0.9	±0.5		
Palpebral	Fast	1.0	±0.8	0.529	1.0	±0.4	0.393 -	1.0	±0.4	0.165	
Hyperaemia	Gradual	1.1	±0.5		0.8	±0.3		0.8	±0.3		
Palpebral	Fast	1.1	±0.7	0.529	1.2	±0.6	- 0.604 -	1.0	±0.4	0.912	
Roughness	Gradual	1.2	±0.5	0.329	1.0	±0.6	0.004	0.9	±0.4		
Corneal	Fast	0.6	±0.8	0 7 2 0	0.2	±0.2		0.4	±0.3	0.570	
Staining	Gradual	0.6	±0.5	0.739	0.4	±0.3	0.447 -	0.5	±0.2	0.579	
Non-invasive	Fast	9.7	±4.1	0.010	8.8	±4.9	0.100	7.4	±1.3	0.007	
breakup time (s)	Gradual	10.5	±4.0	0.912	10.0	±3.2	- 0.190 -	10.2	±2.5		

Table 5:Comparison of ocular physiology in fast and gradual adaptation of neophytes fittedwith silicone-hydrogel soft contact lenses. Efron scale grading between 0 and 4 units. SD = standarddeviation; p = significance value (bold indicates level <0.05).</td>

At baseline there were no statistically significant differences in subjective scores between the two adaptation schedule groups in both the hydrogel (Table 6) and silicone-hydrogel (Table 7) wearers. This was also true at 4-6 days after lens wear commenced. After 7 days of lens wear, both 'lens awareness' (p=0.03) and 'ease of lens removal' (p=0.04) were significantly better in the fast compared with the gradual adaption group in the hydrogel lens wearers (Table 6). At both 4-6 days and 7 days after commencing lens wear, end of day comfort was on the 'cusp' of being significantly better in the fast compared to the gradual adaptation group wearing hydrogel material lenses, and this difference was significant by 2 weeks of wear (p=0.02).

		Baseline			Day -64			Day 7			Day 12-14		
		Mean	SD	р	Mean	SD	р	Mean	SD	р	Mean	SD	р
Comfort prior	Fast	96.6	±6.2	0.258	93.7	±8.7	0.784	95.3	±9.2	0.293	94.1	±13.6	0.342
to lens wear	Gradual	93.2	±10.3		94.6	±7.9		92.4	±11.8		93.2	±9.9	
Overall	Fast	78.9	±14.7	0.147	80.1	±17.4	0.576	79.4	±17.4	0.105	81.8	±14.9	0.177
comfort	Gradual	84.1	±14.0		79.4	±12.6		72.8	±14.5		77.0	±13.8	
Visual quality	Fast	83.0	±16.7	0.323	85.9	±15.7	0.141	82.5	±18.6	0.326	82.4	±17.2	0.493
	Gradual	88.7	±12.1		77.2	±18.5		77.3	±18.3		78.4	±18.2	
Lens	Fast				67.1	±21.2	0.828	72.5	±22.9	0.034	72.1	±26.4	0.206
Awareness	Gradual				65.8	±20.2	-	62.5	±15.5		66.9	±21.9	
End of Day	Fast				75.1	±18.4	0.053	71.5	±22.4	0.083	79.2	±18.9	0.019
Comfort	Gradual				64.7	±19.5	-	60.3	±20.4		66.4	±18.3	
Ease	Fast				77.6	±18.2	0.846	80.2	±22.2	0.629	80.6	±21.6	0.775
Insertion	Gradual				76.0	±20.7	_	81.5	±13.6		82.4	±12.3	
Ease	Fast				90.8	±12.6	0.338	94.1	±9.1	0.039	93.1	±11.0	0.162
Removal	Gradual				88.7	±11.9	-	89.5	±9.5		90.5	±9.4	
Table 6: Comparison of subjective ratings in fast and gradual adaptation of peophytes fitted													

Table 6:Comparison of subjective ratings in fast and gradual adaptation of neophytes fittedwith hydrogel soft contact lenses. SD = standard deviation; p = significance value (bold indicates level<0.05).</td>

		Baseline		Day 4-6			Day 7			Day 12-14			
		Mean	SD	р	Mean	SD	р	Mean	SD	р	Mean	SD	р
Comfort prior to lens wear	Fast	97.2	±3.9	0.739	98.5	±3.4	0.739	98.6	±2.3	- 0.739 -	98.5	±2.4	0.739
	Gradual	94.0	±8.8		95.2	±8.1	0.739	97.0	±6.7	0.739	95.0	±8.5	
Overall	Fast	92.3	±5.7	0.481	92.0	±8.2	0.436	89.0	±7.7	- 0.436 -	92.0	±8.6	0.436
comfort	Gradual	93.5	±8.5		89.5	±11.2	0.450	89.8	±13.4	0.430	89.2	±9.2	
Visual	Fast	95.5	±4.4	0.315	93.0	±7.1	0.912	90.8	±6.5	- 0.912 -	92.7	±8.4	0.912
quality	Gradual	91.2	±8.5		92.0	±7.5	0.912	88.2	±12.7	0.512	91.8	±10.4	0.312
Lens	Fast				84.5	±18.0	0.624	87.5	±17.2	0.215	92.5	±11.6	- 0.247
Awareness	Gradual				88.5	±14.3	0.631	84.5	±12.1	0.315 -	88.5	±9.4	
End of Day	Fast				87.7	±11.2	0.074	91.2	±15.8	0.052	93.0	±9.8	0.10
Comfort	Gradual				84.7	±19.7	0.971	81.0	±13.1	- 0.052 -	85.2	±12.0	0.19
Ease	Fast				83.0	±11.6	0.210	87.0	±13.6	0.004	90.5	±8.6	0.570
Insertion	Gradual				83.5	±27.0	0.218	85.0	±12.5	- 0.684 -	82.7	±19.2	0.579
Ease	Fast				95.5	±4.4	0.694	94.0	±9.4	0.700	94.0	±8.4	0.570
Removal	Gradual				90.1	±13.2	0.684	92.5	±9.2	- 0.796 -	89.8	±13.4	0.579

 Table 7:
 Comparison of fast and gradual adaptation of neophytes fitted with silicone

hydrogel soft contact lenses. SD = standard deviation; p = significance value.

Discussion

Gradual adaption to contact lens wear is thought to be particularly important in the initial management of new rigid contact lens wearers. However, these lenses are fitted to a minority of lens wearers. Only 11% of new wearers were fitted with rigid lenses in the latest international prescribing report.[29] In contrast, there has been a significant increase in daily disposable soft contact lens fittings over the past 20 years. In some markets, daily disposables are the most widely prescribed replacement modality, representing 63% of replacement fits in the UK and 74% in Denmark and Norway.[29] Hence, this study examined whether an adaption period was beneficial for modern soft daily disposable contact lenses.

Adaptation schedule (fast versus gradual) did not impact the short-term ocular surface physiologic response regardless of whether the neophyte was fitted with hydrogel or silicone-hydrogel lenses. This seems to indicate that, in the first few days of wear, the ocular surface responds in a similar way, regardless of how long the eye is exposed to lenses (up to 10 hours), at least for the material oxygen permeability values investigated here (21 and 77 ISO units). These findings are in line with recent work which has demonstrated that for some ocular surface parameters, silicone-hydrogel wear can be indistinguishable from that of non-lens wear [18]. The same work and that of others has shown that newer generation silicone-hydrogel lenses by showing a lower incidence of mechanically-related complications (papillary conjunctivitis and arcuate staining).[30] Additionally, no adverse events were reported at any of the sites which further supports the case that a gradual adaptation period is unnecessary in these lens wearers, although patient wearing months of exposure are low.

No differences were observed between the two adaptation schedules for NIBUT in either lens type, with the exception that NIBUT was longer at the 2 week follow-up visit in the gradual compared with the fast adaptation group in the silicone-hydrogel lens wearers only. There were however, no associated differences in subjective scores at this visit in these wearers. The fact that this difference was small, that it was not present 4-6 days after lens wear commencement and that no differences in subjective scores were present at the same visit lends weight to the proposal that tear film stability is unaltered as a result of the adaptation schedule. Faster adaptation is therefore unlikely to result in increased contact lens discontinuation as a result of tear-film related factors.[31-34]

The study evaluated subjective scores for comfort prior to lens wear, overall comfort with the lenses, visual quality with the lenses, lens awareness and end of day comfort over the two weeks post-fitting. In addition, subjective handling aspects relating to ease of application and

removal were assessed at each follow-up visit. Discomfort, handling problems and poor vision are among the biggest reasons for contact lens drop-out,[12], and the findings in this study show no increased risk if a fast adaptation approach is taken with the daily disposable lenses investigated. Perhaps counter-intuitively there were even some small benefits to the fast adaptation schedule in the hydrogel lens wearers since scores were significantly higher (better) in this group for 'lens awareness' and 'ease of removal' 4-6 days after lens commencement and 'end-of-day comfort' after 2 weeks wear.

There is no doubt that the first few days of lens wear require careful management and are critical to the success of contact lens wear but the results of this work suggest that gradual adaptation to modern daily disposable soft lenses is unnecessary. 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 (in the region of 10 hours). A survey carried out by Morgan (2013)[1] showed that the most commonly recommended strategy was to instruct patients to wear the lenses precisely in this manner i.e. 'as long as comfortable' in the long-term.

This approach is expected to bring additional benefits as it simplifies the instructions given to patients. A faster adaptation schedule is straightforward for ECPs to explain and for neophytes to remember. The proposed fast approach should be accompanied by comprehensive instruction on lens insertion and removal, as well as full and clear patient education on contact lens wear; an appointment for the first aftercare should be scheduled within the first two months,[35] although many ECPs are likely to opt to see these patients sooner. Further research should be carried out to determine the effects of different modalities and designs (e.g. re-useable, toric and multifocal lenses) on the need for gradual adaption in neophytes.

This work has shown for the first time that there appears to be no clinical benefit for a gradual adaptation period in new wearers fitted with soft daily disposable contact lenses. These findings have important ramifications for the clinical management of these patients in the initial lens wear period. The consistently high scores obtained for both hydrogel and silicone-hydrogel lenses regardless of adaptation schedule supports the adoption of a 'no need to adapt' approach for neophyte daily disposable lens wearers. Such management in the first few days of lens wear is likely to make compliance with instructions easier for these patients and allow their lens wear to fit in with their lifestyle requirements.

References

- [1] Morgan PB. Optimising contact lens wear for a lifetime of use. Optician 2013;245;6400: 32-37.
- [2] Fetcher R, Lupelli L, Rossi A. Contact lens Practice. 1st ed. 1994.
- [3] Hom M, Bruce A. Manual of contact lens prescribing and fitting. 3rd ed. Boston, Mass.: Butterworth-Heinemann, 1997.
- [4] Stein HA, Slatt BJ, Stein RM, Freeman ML. Fitting guide for rigid and soft contact lenses. A practical approach. St.Louis:Mosby, 2002.
- [5] Bennett E. Weissman B. Clinical contact lens practice. Philadelphia: Lippincott Williams and Wilkins, 2005.
- [6] Gasson A, Morris JA. The contact lens manual: a practical guide to fitting. Elsevier Health Sciences; 2010.
- [7] Efron N. Contact lens practice. 3rd ed. 2018.
- [8] Phillips A, Speedwell L. Contact lenses. 6th ed. 2019.
- [9] Jalbert I, Sweeney D, Stapleton F. The effect of long-term wear of soft lenses of low and high oxygen transmissibility on the corneal epithelium. Eye, 2009;23:1282-7.
- [10] Stapleton F, Stretton S, Papas E, Skotnitsky C, Sweeney DF. Silicone hydrogel contact lenses and the ocular surface. Ocular Surf 2006;4:24-43.
- [11] Millodot M. Effects of soft lenses on corneal sensitivity. Acta Ophthalmol 2009;52:603-8.
- [12] Pritchard N, Fonn D, Brazeau D. Discontinuation of contact lens wear: a survey. Int Contact Lens Clin 1999;26:157-162.
- [13] Sulley A, Young G, Hunt C. Factors in the success of new contact lens wearers. Contact Lens Ant Eye 2017;40:15-24.
- [14] Sulley A, Young G, Hunt C, McCready S, Targett MT, Craven R. Retention rates in new contact lens wearers. Eye Contact Lens 2017;44:S273-82.
- [15] Richdale K, Sinnott LT, Skadahl E, Nichols JJ. Frequency of and factors associated with contact lens dissatisfaction and discontinuation. Cornea 2007;26:168-74.
- [16] Dumbleton K, Woods CA, Jones LW, Fonn D. The impact of contemporary contact lenses on contact lens discontinuation. Eye Contact lens 2013;39:93-9.
- [17] Young G, Veys J, Pritchard N, Coleman S. A multi-centre study of lapsed contact lens wearers. Ophthalmic Physiol Opt 2002;22:516-27.
- [18] Maldonado-Codina C, Morgan PB, Schnider CM, Efron N. Short-term physiologic response in neophyte subjects fitted with hydrogel and silicone hydrogel contact lenses. Optom Vis Sci 2004;81:911-21.
- [19] Morgan PB, Brennan NA, Maldonado-Codina C, Quhill W, Rashid K, Efron N. Central and peripheral oxygen transmissibility thresholds to avoid corneal swelling during open eye soft contact lens wear. J Biomed Materials Res Pt B: Applied Biomaterials 2010;92:361-5.
- [20] Efron N. Contact lens wear is intrinsically inflammatory. Clin Exp Optom 2017;100:3-19.
- [21] Poyraz C, Irkec M, Mocan MC. Elevated tear interleukin-6 and interleukin-8 levels associated with silicone hydrogel and conventional hydrogel contact lens wear. Eye Contact Lens 2012;38:146-9.
- [22] Szczotka-Flynn LB, Diaz M. Risk of corneal inflammatory events with silicone hydrogel and low DK hydrogel extended contact lens wear: a meta-analysis. Optom Vis Sci 2007;84:247–56.
- [23] Radford CF, Minassian D, Dart JK, Stapleton F, Verma S. Risk factors for nonulcerative contact lens complications in an ophthalmic accident and emergency department: a casecontrol study. Ophthalmology 2009;116:385–92.
- [24] Chalmers RL, Keay LJ, McNally J, Kern J. Multicenter case-control study of the role of lens materials and care products on the development of corneal infiltrates. Optom Vis Sci 2012;89:316–25.
- [25] Wolffsohn JS, Mroczkowska S, Hunt OA, Bilkhu P, Drew T, Sheppard A. Crossover evaluation of silicone hydrogel daily disposable contact lenses. Optom Vis Sci 2015;92:1063-8.

- [26] Kollbaum PS, Jansen ME, Rickert ME. Comparison of patient-reported visual outcome methods to quantify the perceptual effects of defocus. Contact Lens Ant Eye 2012;35: 213-221.
- [27] Woods CA, Bentley SA, Fonn, D. Temporal changes in contact lens comfort over a day of wear. Ophthalmic Physiol Opt 2016;36:643-8.
- [28] Boychev N, Laughton D, Bharwani G, Ghuman H, Wolffsohn JS. How should initial fit inform soft contact lens prescribing. Contact Lens Ant Eye 2016;39:227-33.
- [29] Morgan PB, Woods CA, Tranoudis IG, Helland M, Efron N, Jones L, et al. International contact lens prescribing in 2017. Contact Lens Spectrum 2018;33:28-33.
- [30] Lin M, Yeh T. Mechanical complications induced by silicone hydrogel contact lenses. Eye Contact Lens 2013;39:114-23.
- [31] Schafer J, Mitchell GL, Chalmers RL, Long B, Dillehay S, Barr J, et al. The stability of dryness symptoms after refitting with silicone hydrogel contact lenses over 3 years. Eye Contact Lens 2007;33:247-252
- [32] Glasson MJ, Stapleton F, Keay L, Sweeney D, Willcox MDP. Differences in clinical parameters and tear film of tolerant and intolerant contact lens wearers. Invest Ophthalmol Vis Sci 2003;44:5116-24. doi:10.1167/iovs.03-0685
- [33] Best N, Drury L, Wolffsohn JS. Predicting success with silicone-hydrogel contact lenses in new wearers. Contact Lens Ant Eye 2013;36:232-7.
- [34] Pucker AD, Jones-Jordan LA, Marx S, Powell DR, Kwan JT, Srinivasan S, et al. Clinical factors associated with contact lens dropout. Contact Lens Ant Eye 2019;42:318-24.
- [35] Efron N, Morgan P. Rethinking contact lens aftercare. Clin Exp Optom 2017;100:411-31.