

ABDO Contact Lens Uncorrected Cylinder (CLUC) Trial

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It has long been a conundrum facing a contact lens prescriber, when assessing a patient with low cylinder corrections, whether to select a best sphere or a toric lens initially. This small scale in practice clinical trial may offer an insight into the positive and negative outcomes of the selection process and therefore enable the ECP to make a more rational decision. It may also point to areas where progress can be made to enable a daily disposable toric soft contact lens to become the lens of first choice.

Objective

The primary objective was to determine if statistically significant improvements in objective and subjective vision can be found among new and existing contact lens wearers with toric soft contact lenses (SCLs) compared with an uncorrected low cylinder when they were trialed with daily disposable (DD) spherical lenses. The secondary objective was to determine if a combination of clinical and subjective vision data could be correlated with whether subjects would change their modality at any price point.

Methods

This was a prospective, randomised, subject masked, single group trial. Subjects were masked to lens brands, lens type, and the trial sponsor. Eighteen subjects were enrolled and completed the trial.

Potential subjects were screened for their interest in this trial by contacting them by telephone, mail, or during practice visits. A guideline script with a description of the trial and visit schedule was used to standardise the information for recruiting and to reduce bias for the outcome of the trial. Potential subjects completed an informed consent before any in-practice trial procedures took place.

Inclusion criteria

- Subjects with axes 0 to 30, axes 30 to 60, or axes 60 to 90 and cylinders between -0.50 and -1.00 inclusive.
- Manifest refraction indicating correction needed in both eyes with the trial lenses.
- Agree to the trial protocol.
- Agree to the trial visit schedule

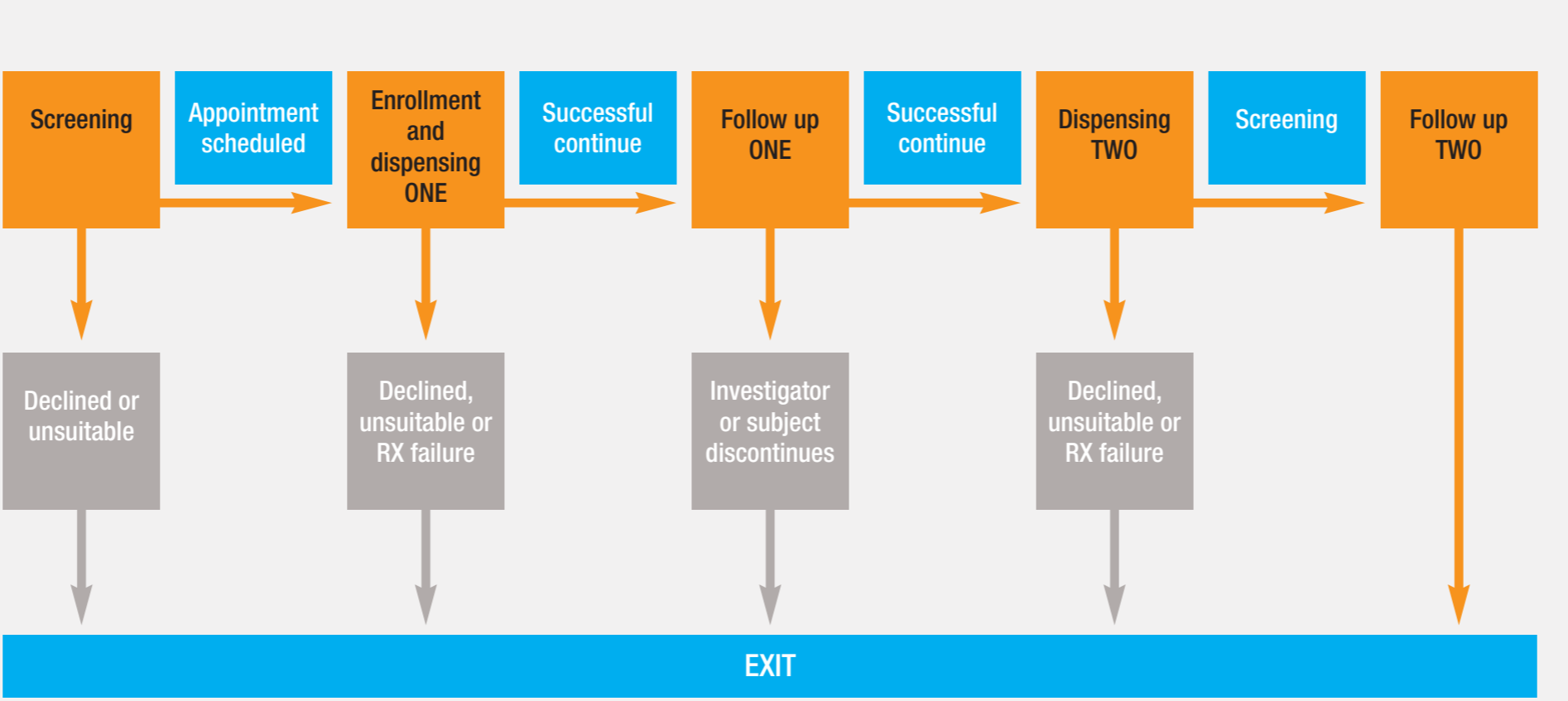
Exclusion criteria

- Ocular surgery or disease within six months of enrollment that contraindicates wearing DD SCLs.
- Under 18 years of age.
- Potential subjects who will accept treatment in only one eye.
- Rigid gas permeable (RGP) wearers.

Subject profile

	Average ± SD (min - max), n	
Age	40.5 ± 18.2 (18 - 70), 18	
Sex	Number	(%)
Female	14	(78%)
Male	4	(22%)
Grand total	18	(100%)
Habitual sphere		
Myopic	14	(78%)
Hyperopic	4	(22%)
Total	18	(100%)
Habitual modality		
None	1	(6%)
SCLs	3	(17%)
Spectacles	14	(78%)
Grand total	18	(100%)
Days / Week		
SCL wearers	Average ± SD (min - max) n	
Spectacles wearers	5.3 ± 2.1 (3 - 7), 3	
Total wearers	6.5 ± 0.9 (5 - 7), 14	
Hours/Day		
SCL wearers	6.3 ± 1.2 (3 - 7), 17	
Spectacles wearers	Average ± SD (min - max) n	
Total wearers	11.0 ± 3.6 (8 - 15), 3	
	12.6 ± 3.8 (2 - 18), 14	
	12.3 ± 3.7 (2 - 18), 17	

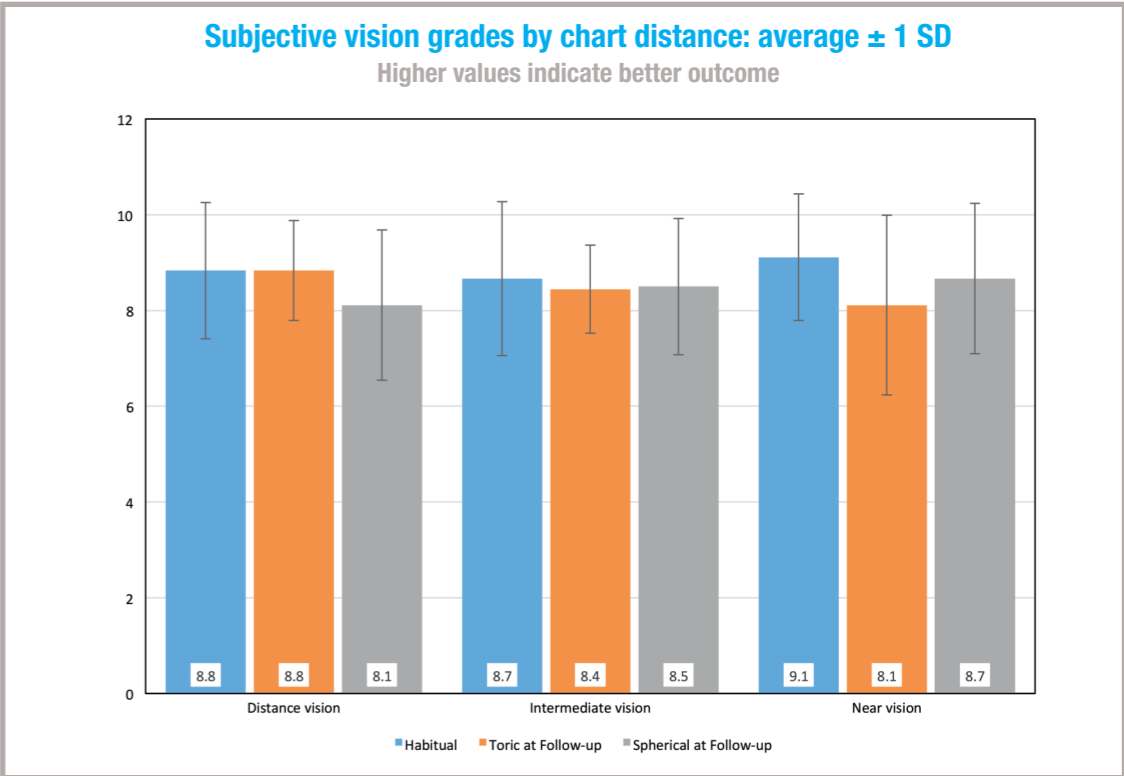
Trial procedure flow chart



Baseline refraction and test lens Rx Average ± SD (min - max) n

	Baseline	Spherical Rx	Toric Rx
OD Sphere	-2.10 ± 2.71 (-7.00 - 3.25) 18	-2.44 ± 2.61 (-7.00 - 3.00) 18	-2.08 ± 2.61 (-7.00 - 3.25) 18
Cylinder	-0.72 ± 0.23 (-1.25 - -0.50) 18		-0.81 ± 0.16 (-1.25 - -0.75) 18
Axis	108 ± 63 (10 - 180) 18		104 ± 63 (10 - 180) 18
OD Sphere	-1.94 ± 2.49 (-7.75 - 1.75) 18	-2.36 ± 2.30 (-7.50 - 1.00) 18	-1.96 ± 2.31 (-7.00 - 1.25) 18
Cylinder	-0.83 ± 0.27 (-1.50 - -0.50) 18		-0.82 ± 0.17 (-1.25 - -0.75) 18
Axis	103 ± 68 (2 - 180) 18		112 ± 66 (10 - 180) 18

Subjective vision



Statistical Results

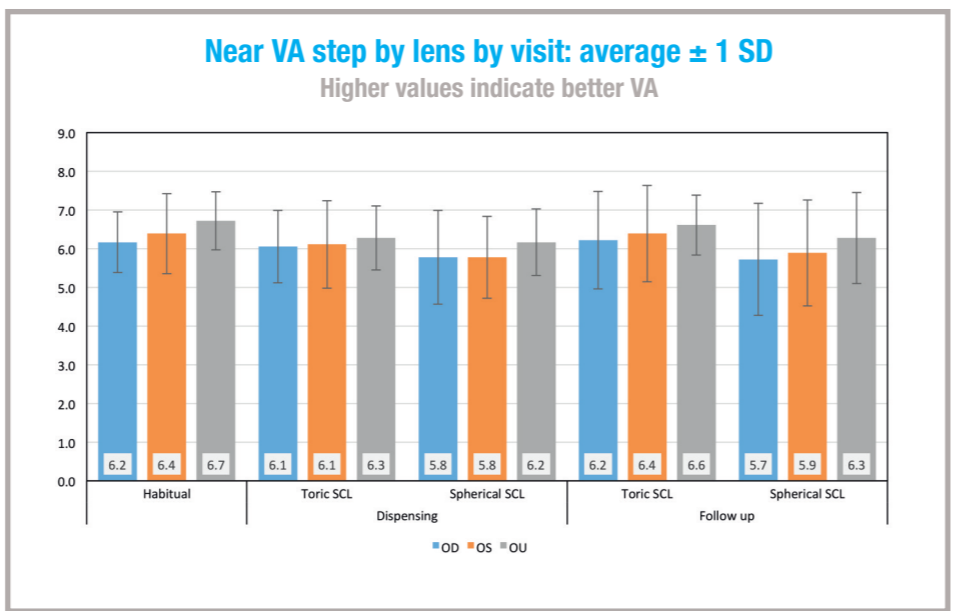
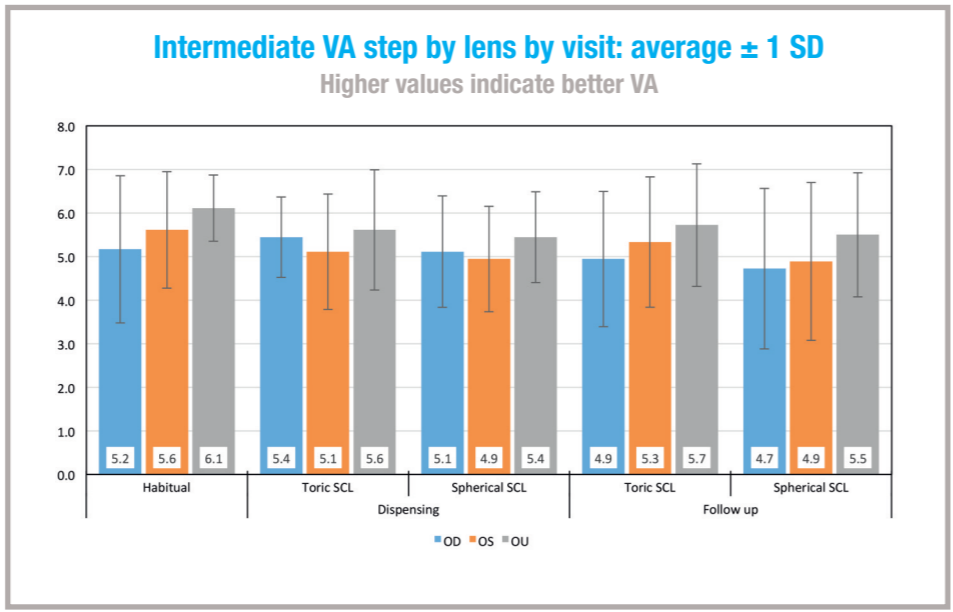
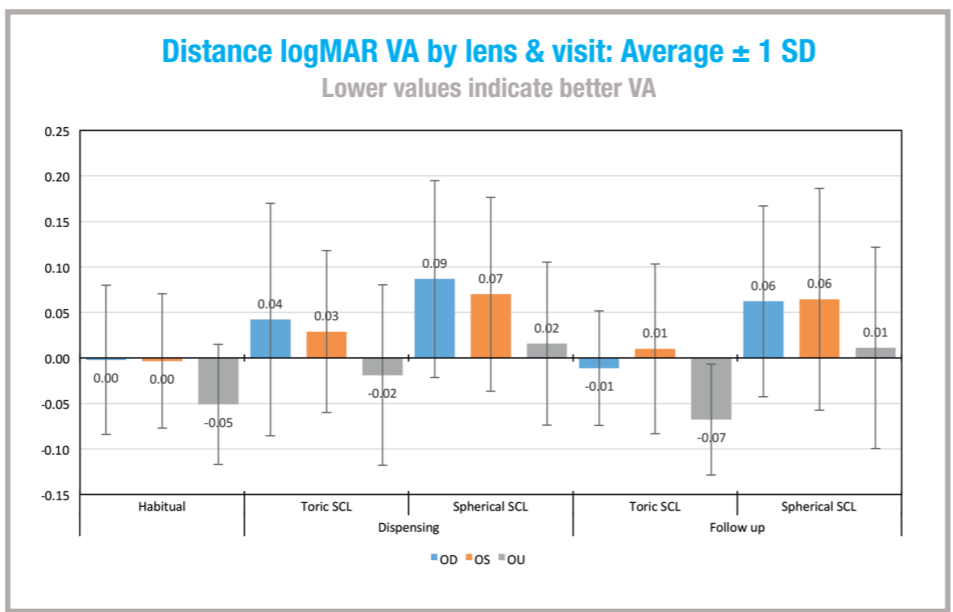
Paired T-tests, 2 sided comparing toric & sphere	P-values* Dispensing	Follow up
Dispensing HC distance logMAR VA OD	0.1921	0.0069
Dispensing HC distance logMAR VA OS	0.2479	0.0063
Dispensing HC distance logMAR VA OU	0.1996	0.0038
Dispensing HC intermediate logMAR VA OD	0.2687	0.2980
Dispensing HC intermediate logMAR VA OS	0.5282	0.0722
Dispensing HC intermediate logMAR VA OU	0.4827	0.2596
Dispensing HC near logMAR VA OD	0.2878	0.0081
Dispensing HC near logMAR VA OS	0.1631	0.0346
Dispensing HC near logMAR VA OU	0.6073	0.1872
Follow up overall satisfaction		0.4619
Follow up subjective distance vision		0.1202
Follow up subjective intermediate vision		0.8675
Follow up Subjective Near Vision		0.3051
Follow up Likelihood to Recommend		0.7119
Critical Value	0.05	0.05

*Values < 0.05 indicate statistically significant differences.

VA & Toric Rotation

- Binocular objective distance visual acuity (DVA)** was better with DD toric SCLs than DD spherical SCLs at dispensing and better still at the two to three hour follow-up, as shown in the graph opposite.
- Binocular objective DVA** was better at follow-up with DD toric SCLs than habitual correction (none 6%, SCLs 17%, spectacles 78%). Binocular subjective DV vision grade was equal for both corrections.
- Binocular objective DVA and subjective vision grade** was worse at follow-up with DD spherical SCLs than both DD toric SCLs and habitual correction.
- Binocular objective intermediate visual acuity (IVA)** was marginally better with DD toric SCLs than spherical DD SCLs at dispensing and follow up. Both were worse at follow up than the habitual correction, but toric less so as shown in the graph opposite.
- Subjective intermediate vision grade** was marginally worse at follow up with both toric and spherical DD SCLs than habitual correction.
- Binocular objective near visual acuity (NVA)** was very similar with both habitual and DD Toric SCLs at follow up but down with spherical DD SCLs, as shown in the graph opposite.
- Subjective near vision grade** was worse at follow up with toric DD SCLs and also but less so with spherical DD SCLs than habitual correction.
- There was a large range of 'away from intended' orientations at dispensing (20 minutes). Some orientations were recorded at up to 40, 45 and even 80 degrees.

RESULTS



Toric Rotation (away from intended)

Subject	Eye	Dispensing	Follow up
001	OD	0	0
002	OD	5	0
003	OD	0	0
004	OD	0	0
005	OD	25	5
006	OD	0	0
007	OD	0	0
009	OD	10	5
008	OD	0	0
010	OD	10	0
013	OD	5	0
011	OD	0	0
012	OD	20	10
014	OD	0	5
015	OD	45	9
016	OD	10	0
017	OD	0	0
018	OD	10	0
001	OS	0	0
002	OS	5	5
003	OS	5	0
004	OS	0	0
005	OS	25	10
006	OS	0	0
007	OS	5	0
009	OS	10	10
008	OS	10	10
010	OS	20	10
013	OS	15	10
011	OS	10	10
012	OS	80	0
014	OS	0	0
015	OS	40	10
016	OS	10	5
017	OS	0	0
018	OS	20	5
Average		11.6	3.3
Standard deviation		16.5	4.3
Minimum		0	0
Maximum		80	10
% ≥ 20		24%	0%
% paired (n=17)			
Count		34	36

Conclusions

- Toric DD SCLs** gave better objective and subjective vision for distance. However for **intermediate and near vision** the overall conclusions were less clear cut. It is interesting to hypothesize that the toric cyl axis may, in some cases, be influenced by the eyes' convergence and inferior gaze and hence vision adversely affected.
- Objective distance and near VAs** improved at follow up at two to three hours compared with dispensing at 20 minutes for the toric SCLs, whereas for the spherical SCL it hardly changed at all. This points to toric SCL assessments would be more accurately assessed at a longer time period.

- Generally in preference, although toric lenses scored better (**DVA**) or at least equal (**IVA & NVA**) than spherical prescriptions, when it came to comfort, for a number of subjects, it was reversed. This should point to attention being given to improving comfort of toric lens design by manufacturers.
- Just as **objective distance and near VAs** improved at follow up at **two to three hours** compared with dispensing at **20 minutes** for the toric SCLs, the rotation 'away from intended' reduced dramatically in some subjects. This again points to toric SCL assessments being more accurately assessed at a longer time period than has been historically. If initial assessments are carried out at 20 minutes then it should be expected that more patients will be found not suitable than if assessed later.

Declarations

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