## CLINICAL AND EXPERIMENTAL OPTOMETRY



# Using clinical optical coherence tomography to characterise contact lens edge shape and base curve radius

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Keywords:	contact lenses, OCT, contact lens edge, back optic zone radius
Abstract:	Clinical relevance: Clinical optical coherence tomography devices are widely used in optometry and ophthalmology and may be used to measure contact lens base curvature radius and visualise contact lens edge shape.  Background: Knowledge of contact lens geometry facilitates fitting, while optical coherence tomography provides a powerful means of measuring geometrical form. This study evaluates the performance of a clinical optical coherence tomography device (3D OCT-1000) in characterising contact lens edge shape and measuring the back optic zone radius of rigid gas-permeable contact lenses in vitro.  Methods: First, an opto-mechanical optical coherence tomography contact lens adaptor was designed and 3D-printed to facilitate a contact lens being imaged using a commercial optical coherence tomography device. Second, several image-processing algorithms and a simple calibration method were developed to measure back optic zone radius in optical coherence tomography B-scans. Finally, based on the findings of two experiments, B-scan performance was evaluated in terms of 1) capacity to differentiate between contact lens edge geometries, and 2) capacity to obtain accurate and repeatable back optic zone radius measurements. Statistical and graphical analyses were performed to characterise reliability and reproducibility.  Results: The 3D OCT-1000 and adaptor combination was capable of acquiring images of sufficient quality to discriminate between soft and rigid contact lens edge geometries. Additionally, statistical analysis of the rigid contact lens measurements demonstrated satisfactory back optic zone radius measurement accuracy and reproducibility.  Conclusion: This study demonstrates that a 3D OCT-1000 fitted with an opto-mechanical adaptor combination can be used to assess contact lens edges in vitro and that this clinical optical coherence tomography device, combined with image processing and linear calibration of the B-scans, is capable of obtaining back optic zone radius measurements of rigid gas-permeable cont

manufacturing tolerance range (±0.05 mm).

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1	CEOptom-23-164-OP
2 3 4	RESEARCH
5	Using clinical optical coherence tomography to characterise contact lens edge shape and base curve radius
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22	Abstract
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- 23 Clinical relevance: Clinical optical coherence tomography devices are widely used in
- 24 optometry and ophthalmology and may be used to measure contact lens base curvature
- 25 radius and visualise contact lens edge shape.
- 26 **Background:** Knowledge of contact lens geometry facilitates fitting, while optical
- 27 coherence tomography provides a powerful means of measuring geometrical form. This
- study evaluates the performance of a clinical optical coherence tomography device (3D
- OCT-1000) in characterising contact lens edge shape and measuring the back optic zone
- radius of rigid gas-permeable contact lenses in vitro.
- 31 **Methods:** First, an opto-mechanical optical coherence tomography contact lens adaptor
- 32 was designed and 3D-printed to facilitate a contact lens being imaged using a commercial
- optical coherence tomography device. Second, several image-processing algorithms and a
- 34 simple calibration method were developed to measure back optic zone radius in optical
- coherence tomography B-scans. Finally, based on the findings of two experiments, B-
- 36 scan performance was evaluated in terms of 1) capacity to differentiate between contact
- lens edge geometries, and 2) capacity to obtain accurate and repeatable back optic zone
- 38 radius measurements. Statistical and graphical analyses were performed to characterise
- 39 reliability and reproducibility.
- 40 **Results:** The 3D OCT-1000 and adaptor combination was capable of acquiring images of
- 41 sufficient quality to discriminate between soft and rigid contact lens edge geometries.
- 42 Additionally, statistical analysis of the rigid contact lens measurements demonstrated
- 43 satisfactory back optic zone radius measurement accuracy and reproducibility.
- Conclusion: This study demonstrates that a 3D OCT-1000 fitted with an opto-
- 45 mechanical adaptor combination can be used to assess contact lens edges in vitro and that
- 46 this clinical optical coherence tomography device, combined with image processing and
- 47 linear calibration of the B-scans, is capable of obtaining back optic zone radius
- 48 measurements of rigid gas-permeable contact lenses that are close to the ISO 18369-
- 49 2:2018 manufacturing tolerance range (±0.05 mm).

### [Introduction]

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02	Optical conference tomography (OC1) devices are widely used in optometry and
53	ophthalmology clinics to diagnose and study eye health <sup>2,3</sup> and/or to observe and evaluate contact
54	lens fitting. 4,5,6 Alternatively, some researchers are also using the high-accuracy interferometric
55	capabilities of OCT to measure the mechanical properties of soft contact lenses <sup>7</sup> and the
56	geometric shape of eye surfaces in vivo.8-12 Since OCT devices can achieve very accurate
57	geometric measurements when used appropriately, several researchers have successfully
58	demonstrated the application of specific lab-built spectral domain OCT devices in measuring
59	the topographic surface and central thickness of intraocular lenses 13,14 and rigid and/or soft
60	contact lenses in vitro, 15-17 achieving sufficient sensitivity to discriminate changes in soft contact
51	lenses after use. 18,19
62	Recently, an OCT device designed to measure contact and intraocular lenses achieved
63	consistent results within the ISO 18369-3:201820 tolerance ranges for curvature radius and
54	central thickness. <sup>21,22</sup> This technology could help practitioners monitor the geometry of contact
65	lenses fitted in patients. For instance, it could assist in determining contact lens edge shape
66	profile, which is difficult to assess non-destructively. <sup>23,24</sup> Unfortunately, OCT devices marketed
67	for in vivo ocular examination cannot easily measure contact lenses in vitro for two main
68	reasons: 1) device design does not permit proper positioning of the lenses, and 2) clinical OCT
59	device manufacturers do not usually provide information about the spatial geometric
70	transformations performed on B-scan data. Therefore, any spatial information recovered from
71	B-scan data in a clinical OCT device should always be treated with caution.
72	In this study, a specific opto-mechanical adaptor was developed to measure contact lenses using
73	an OCT device marketed for clinical application (Topcon 3D OCT-1000). In addition, a linear
74	calibration model and image-processing methods were developed to retrieve accurate geometric
75	measurements from B-scan data provided by this clinical OCT device.
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77	Methods
78	Two experiments were conducted to test the ability of the OCT device to monitor contact lens

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geometry. In the first experiment, B-scans of the edges of various rigid and soft contact lenses

were acquired with the OCT device and an opto-mechanical adaptor. The second experiment

measured the back optic zone radius (BOZR) of a rigid contact lens sample. To achieve this, the

posterior radius measurements of the device were calibrated against reference values obtained

using an optical radiuscope. Next, repeatability between sessions and operators was tested.

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84 Finally, statistical analysis was performed on two independent series of measurements taken in 85 different sessions to compare the accuracy of the OCT measurements with those of the 86 radiuscope. 87 Contact lenses 88 The edge assessment experiment employed a set of 8 soft and rigid contact lenses (corneal and 89 scleral; see Table 1). The set was chosen as a representative sample of the contact lenses found 90 at accessible research and teaching laboratories. 91 For the BOZR experiment, 18 monofocal (-3.00 D) rigid gas-permeable spherical contact lenses 92 with a 6.00 mm optical zone diameter and central BOZRs from 7.30–8.40 mm were used. These 93 lenses were manufactured by Lenticon Pharmaceutical SA (Madrid, Spain) from Polycon II 94 copolymer (Silafocon A). 95 Instrumentation 96 A Neitz CG-X optical radiuscope (Sterling Ultra Precision, AMETEK, USA) was used to 97 measure the vertex radii of curvature of the back surface of the contact lenses at a resolution of 98 0.01 mm 99 OCT device and contact lens adaptor 100 A 3D OCT-1000 clinical spectral domain OCT device was used (Topcon Co.; central 101 wavelength: 840 nm; bandwidth at half maximum: 50 nm). Maximum in-air axial resolution can 102 therefore be estimated from the coherence length formula of the standard light source<sup>1</sup> for a 103 Gaussian spectrum as  $\Delta z = 2 \times \ln(2) / \text{pi} \times \lambda \text{c}^2 / \Delta \lambda \text{FWHM} = 6.23 \, \mu\text{m.} [\Delta z = \text{maximum in-air}]$ 104 axial resolution,  $\lambda c = central$  wavelength,  $\Delta \lambda FWHM = bandwidth$  at half-maximum of the 105 spectrum]. 106 Maximum light exposure power at the corneal plane position was less than 0.65 mW and 107 maximum lateral resolution was better than 20 µm. In anterior segment scanning mode, the 108 device acquires B-scans with a lateral scanning range of 6 mm and an axial range of 2 mm. An 109 opto-mechanical OCT contact lens adaptor was designed using Inventor® Software (AutoDesk 110 Inc. USA) and fabricated from polylactic acid using a commercial fused deposition modelling 111 printer. The adaptor included a movable holder for positioning a tilted flat mirror. This mirror 112 was employed to redirect the probe beam toward the contact lens surface and to collect and 113 redirect the backscattered beam toward the pupil entrance of the OCT device (Figure 1). In its

current form, the adaptor is not designed to measure soft lenses immersed in saline solution.

This capability can be achieved, however, using a cuvette with planar transparent walls.

116	B-scan to assess contact lens edge geometry
117	The contact lens adaptor was used to capture 6-mm-wide B-scans with the ability to perform
118	transverse movements. Trained operators acquired and exported the B-scans as $1143 \times 617$ 24-
119	bit colour images. As the images were only taken to show the image quality that this clinical
120	OCT device can achieve for edge lens geometry analysis, there was no attempt to locate the
121	azimuthal meridian position of each sample.
122	Optical distortion caused by different curves and refractive indices or by distortion of the OCT
123	cross-scan was not corrected since the edge B-scans were only for qualitative observation.
124	BOZR measurements using the optical radiuscope
125	The radiuscope, calibrated as per ISO 18369-3:2018, <sup>20</sup> served as the reference standard for
126	measuring BOZR after confirming the surface regularity of the contact lenses using the above-
127	mentioned surface microscope. A trained operator repeated 5 measurements on each lens to
128	increase precision and the average was calculated. The contact lens was removed and reinserted
129	into the holder before each measurement to simulate real measurement conditions.
130	B-Scan of the posterior curve of rigid contact lenses
131	The measurement procedure was as follows:
132	(1) The contact lens was placed on the OCT device contact lens adaptor in a stabilised
133	horizontal position with the concave side facing up.
134	(2) The contact lens was transversely aligned with the optical axis of the OCT device.
135	(3) The axial position of the OCT device was adjusted to position the image profile within
136	the reference axial interval on the B-scan live video display.
137	(4) 6-mm-wide horizontal B-scans were acquired in anterior chamber measurement mode
138	and exported as portable network graphics files.
139	To research inter-session repeatability, Operator1 repeated the same measurements in a different
140	session. Under this procedure, two data sets - Operator1-Session1 and Operator1-Session2 -
141	were generated. To research inter-operator repeatability, Operator2 repeated the entire
142	procedure for all contact lenses, obtaining an image set named Operator2-Session1.
143	BOZR calculation from B-scans
144	To estimate the BOZR from B-scans, image processing and curve fitting are required. A
145	program was written (Matlab R2019b, Mathworks Inc) to perform the operations in the flow-
146	chart shown in Figure 2. These operations included colour-to-intensity conversion, noise

147	filtering to increase B-scan signal-to-noise ratio, automatic intensity thresholding to avoid
148	background noise <sup>25</sup> and image segmentation to pre-process the exported B-scan data before
149	analysis.
150	Once the region corresponding to the posterior curve was segmented, local centroid
151	calculations <sup>26</sup> were performed to estimate, with subpixel precision, the axial position of each
152	scattering point of the posterior curve of the contact lens. Finally, least squares were used to fit
153	pairs of XZ centroid coordinates to a general circle profile to estimate the BOZR. <sup>27</sup>
154	Prior to conducting experiments, the curvature radius estimation algorithm was evaluated using
155	noise-free synthetic B-scans. The results confirmed that the described procedure accurately
156	estimates the curvature radius from noise-free synthetic B-scans of circle curves with nominal
157	radii ranging from 7.30-8.40 mm. The absolute value of the maximum error and the standard
158	deviation of the difference between the estimated radii and the nominal ones were 0.006 mm
159	and 0.0013 mm, respectively.
160	Moreover, to estimate the limit of precision for curvature radius measurements due to spatial
161	random noise, a simulation was conducted using the same set of synthetic concave coordinate
162	profiles corrupted with additive Gaussian noise with a standard deviation of 6.23 µm. The
163	simulation, for nominal curvature radii ranging from 7.30-8.40 mm, resulted in a maximum
164	error of 0.065 mm and a standard deviation of the difference of 0.018 mm (i.e. an order of
165	magnitude higher than in the noise-free case).
166	BOZR linear calibration from an initial measurement sample
167	As the processes before image export, scanning distortion and the reference refractive index are
168	unknown for this clinical OCT device, simple linear calibration was performed using a set of
169	radiuscope reference values. Starting with an initial pixel size of $5.25\ \mu m$ , the radiuscope
170	measurements were used to calculate the parameters (aa and bb) for a linear calibration
171	function, which minimised the average squared error between the Operator1 and radiuscope
172	measurements (optical radiuscope = $aa \times BOZRestimation + bb$ ). The results of this process
173	were aa = $0.695106$ , bb = $0.047948$ mm and r-squared = $0.981469$ . The slope of the linear fit
174	(aa) accounted for the pixel calibration and reference refractive index, while the z-intercept (bb)
175	accounted for systematic errors caused by fan-scanning distortion.
176	Statistical analysis
177	To assess the precision and accuracy of the OCT BOZR measurements, statistical analyses were
178	performed using IBM SPSS Statistics V.20. The absolute maximum differences between OCT
179	and radiuscope BOZR measurements were evaluated along with the standard deviation of the

180	difference. The variation coefficient was calculated for each sample as the ratio 100 × standard
181	deviation of difference / <radiuscope bozr="" measurements="">, where <radiuscope bozr<="" td=""></radiuscope></radiuscope>
182	measurements> is the average of the radiuscope BOZR values of the whole sample, providing a
183	measure of the relative error of each measurement versus the reference values.
184	Normal data distribution was analysed using the Shapiro-Wilk test and parametric tests for
185	contrast data analysis. Inter-observer and inter-session repeatability were assessed using <i>t</i> -tests
186	for paired samples between measurements taken by different operators (BOZROperator1-
187	Session1 vs BOZROperator2-Session1) and the same operator in two different sessions
188	(BOZROperator1-Session1 vs BOZROperator1-Session2).
189	A p-value < 0.05 was considered statistically significant. Bland-Altman plots were used to
190	explore systematic differences between measurements taken by different operators and sessions.
191	The limits of agreement were calculated as the mean $\pm 1.96$ standard deviation.
192	Finally, to evaluate the accuracy of OCT-based BOZR measurements (BOZROperator1-
193	Session1, BOZROperator2-Session1) versus the radiuscope, Student's <i>t</i> -test for paired samples
194	and the intra-class correlation coefficient were used. Bland-Altman plots were also used to
195	explore systematic differences between BOZR radiuscope and OCT-based measurements.
196	
197	Results  B-scans of contact lens edges
198	B-scans of contact lens edges
199	Figure 3 shows B-scans (454 × 170 pixels) of contact lens edges that have been cropped and
200	presented in 24-bit colour without additional image processing. The images were taken to
201	demonstrate the ability to discriminate between different edge geometries (rigid gas-permeable
202	contact lens edges (blue) and soft contact lens edges (red)). The same cropping and scaling sizes
203	(see scale marking in Figure 3(f)) were used for all sub-images.
204	BOZR of a rigid gas-permeable contact lens set
205	One hundred sixty-two B-scan profiles were acquired and processed to estimate the BOZR for
206	all the samples in the contact lens set. Table A (Appendix A) displays the mean and standard
207	deviation of BOZR values obtained from processed B-scans (BOZROperator1-Session1,
208	BOZROperator1-Session2, BOZROperator2-Session1) along with nominal BOZR and mean
209	radiuscope BOZR measurements. BOZROperator1-Session1 represents the mean and standard
210	deviation of BOZR values obtained from Operator1-Session1 measurements; BOZROperator1-
211	Session? corresponds to the mean and standard deviation of BOZR values estimated by

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manufacturing tolerance limits ( $\pm 0.05$  mm)<sup>28</sup>.

[Figure 4 near here].

212	Operator1 during Session2; BOZROperator2-Session1 shows the mean and standard deviation
213	of BOZR values estimated from Operator2 B-scans.
214	The top of Table 2 shows the standard deviation, maximum BOZR error and variation
215	coefficient values versus the average values of the radiuscope BOZR measurements for each
216	OCT measurement series. For the sake of completeness, the results equivalent to those
217	described in the preliminary numerical simulations testing the image-processing algorithm are
218	presented in the same table in dark red italic font. As can be seen, the BOZR measurements
219	based on B-scan data show much higher standard deviations (standard deviation of the
220	Operator1-Session1 difference = 0.059 mm, standard deviation of Operator1-Session2
221	difference = 0.039 mm, standard deviation of Operator2-Session1 difference = 0.059 mm) and
222	maximum absolute errors (Operator1-Session1 = 0.110 mm, Operator1-Session2 = 0.104 mm,
223	Operator2-Session1 = 0.130 mm) than those obtained in noise-free conditions (standard
224	deviation of no noise difference = 0.0013 mm, maximum absolute error of no
225	noise = 0.006 mm). They are also higher than the errors estimated by minimum spatial noise
226	simulation (minimum = 0.018 mm, maximum = 0.065 mm).
227	The paired <i>t</i> -test results and the intra-class correlation coefficient analysis to assess intra-
228	operator and intra-session repeatability are shown at the bottom of Table 2. The measurements
229	taken by the OCT operators do not present significant statistical differences: p-value = 0.660
230	and p-value = 0.997 for BOZROperator1-Session1 vs BOZROperator2-Session1 and
231	BOZROperator1-Session2 vs BOZROperator2-Session1, respectively. Moreover, testing
232	BOZROperator1-Session1 vs BOZROperator1-Session2 resulted in p-value = 0.666, indicating
233	that good intra-operator repeatability is achievable.
234	Finally, the results of comparison between BOZR with radiuscope and BOZR OCT-based
235	measurements are also shown in Table 2, which shows Student's t-test results for
236	BOZROperator1-Session1 vs radiuscope BOZR (p-value = 0.661), BOZROperator2-Session1
237	vs radiuscope BOZR (p-value = 0.996) and intra-class correlation coefficients between the
238	radiuscope measurement and BOZR obtained for Operator1 (0.992(p $<$ 0.001)) and Operator2
239	(0.991(p < 0.001)).
240	Bland-Altmann plot
241	Intra-session agreement is shown in Figure 4(a), while inter-observer agreement is illustrated in
242	Figure 4(b). Mean difference is represented by a solid red line; dashed red lines show the 95%
243	confidence intervals for the mean difference; grey-shaded regions indicate ISO 18369-2:2018

246	The differences between radiuscope measurements and OCT-based measurements for two
247	different operators in the sessions that were not used for the linear calibration (Operator1-
248	Session1 and Operator2-Session1) are shown in Figure 5(a) and Figure 5(b).
249	
250	Discussion
251	An opto-mechanical adaptor was created for clinical use and fitted to an OCT device to acquire
252	B-scans of light scattering from contact lens surfaces. The system qualitatively assessed the
253	edge geometry of different contact lens models and measured BOZRs of 3D spherical rigid gas-
254	permeable contact lenses.
255	Qualitative assessment of edge geometry
256	The findings confirm the validity of using acquired B-scans to discriminate between the
257	rounded edges of rigid gas-permeable contact lenses and the more peaked edges of soft contact
258	lenses (Figure 3). This finding is significant because it provides a non-destructive way of
259	differentiating between contact lens characteristics. OCT-based edge imaging has only
260	previously been achieved using lab-built instruments <sup>5,23,29,30</sup> or by fitting contact lenses on real
261	eyes, 31,32,33,34,35 making these results particularly noteworthy.
262	Figure 3(c,d) shows the greater peripheral thickness with which scleral lenses are manufactured
263	versus other contact lenses. Consequently, as clearly shown, the slopes of both sides of the
264	scleral contact lenses need to change quickly to form the edge of the lens. The acquired B-scans
265	also enabled estimation of the depth of the engraving mark of a rigid gas-permeable torical
266	contact lens (Figure 3(b)). This subtle finding suggests that the combination of the adapter and
267	OCT could be used to monitor the damage that appears on the edges and surface of contact
268	lenses due to use.
269	Finally, in the images in Figure 3, and unlike other studies using specific lab-built OCT
270	devices, <sup>36-38</sup> optical geometrical distortion and refraction index path-length modulation were not
271	corrected. Geometrical information extracted from these images must therefore be treated with
272	caution.
273	BOZR measurements
274	Several researchers have successfully used lab-built OCT devices to measure the geometry of
275	optical refractive surfaces from OCT B-scans and have noted that the key to success at this task
276	differs between the first exposed surface and subsequent posterior surfaces. Measurement of
277	surfaces placed after the refraction caused by preceding ones requires correction of the

270	distortion innerent to the OCT transverse scan, knowledge of the preceding refractive indexes
279	and surface geometries and application of an optimal estimation technique that efficiently uses
280	all available information. <sup>37-39</sup> Conversely, measurement of the geometry of a first exposed
281	surface only requires correction of the distortion due to transversal scanning or, alternatively,
282	use of scanning methods that do not introduce geometrical distortions caused by non-telecentric
283	lateral scanning. <sup>13</sup>
284	The lack of technical information about the spatial distortion correction algorithms used by the
285	clinical OCT device led this study to explore the feasibility of employing straightforward linear
286	calibration to obtain an accurate BOZR estimation from a spherical rigid contact lens sample.
287	Using B-scans for BOZR measurement also meant developing image-processing algorithms
288	capable of estimating the BOZR value for a rigid gas-permeable contact lens sample.
289	The results corroborate previous findings made with a prototype Optimec is830 device
290	developed specifically for contact lens inspection; <sup>23</sup> there were no statistically significant
291	differences between the OCT-based BOZR measurements and those measured by an optical
292	radiuscope (see Table 2). Figure 5(a,b) shows that almost all OCT-based BOZR measurements
293	(26/36) were within the ISO tolerance range. The repeatability findings are also consistent with
294	those obtained by Huang et al. <sup>13</sup> when measuring an intraocular lens using a lab-built OCT
295	device free of geometric scanning distortion, as well as with those obtained by Karnowski et
296	al.15 when measuring soft contact lenses using a spectral domain OCT device developed in-
297	house. In both studies, BOZR measurement repeatability is in the order of 0.08 mm (0.065 mm
298	for the Optimec is 830, and an estimated 0.1085 mm for the 36 D intraocular lens, assuming an
299	equiconvex geometry), similar to the 0.059 mm obtained for Operator1-Session1 and
300	Operator1-Session2 in relation to the radiuscope measurements.
301	The fact that the experimental standard deviations for the OCT-based measurements triple the
302	ones obtained by numerical simulation with minimum spatial random noise (0.018 mm)
303	suggests that placing and removing the contact lenses for each measurement may constitute an
304	additional noise input in BOZR measurement. To test this hypothesis, additional series of 30
305	consecutive BOZR measurements were performed on the three rigid contact lenses with
306	nominal BOZR = [7.30, 7.80, 8.40] mm, keeping them in the same transversal position
307	throughout the procedure. This latter experiment produced smaller standard deviations
308	(0.023 mm, 0.035 mm, 0.028 mm) in each case.
309	It could therefore be argued that, due to image-processing artefacts, the system is not operating
310	at the physical limit of axial resolution or that the spatial noise is higher than that calculated
311	from the coherence length of the optical source of the OCT device <sup>1</sup> . It is nonetheless noteworth

313	needed to further understand and potentially improve system precision.
314	Bland-Altmann plots
315 316	Figure 5(a) shows a weak correlation between the difference in radiuscope reference values,  Operator 1 OCT measurements and average curvature radius. This trend is also visible in the
317 318	intra-session repeatability shown in the Bland–Altmann plot (Figure 4(b)), indicating that linear
319	calibration may be insufficient. However, this trend is not present in the Operator2 measurements (Figure 5(b)) or in the intra-observer Bland–Altmann plot (Figure 4(b)),
320	indicating that a more complex calibration model may not be necessary. In fact, almost all the
321	measurements are within the ISO 18369-2:2018 manufacturing tolerance range <sup>28</sup> ( $\pm 0.05$ mm)
322	for rigid gas-permeable contact lenses. Nevertheless, the BOZR measurement reproducibility
323	reported in this paper was generally worse than stipulated in ISO 18369-3:2018 <sup>20</sup> (±0.015 mm).
324	
325	Limitations
326	It is important to note that clinical OCT devices present several limitations versus laboratory-
327	developed instruments specifically designed for lens shape measurement. <sup>15</sup> Firstly, clinical OCT
328	devices are not optimised to measure soft contact lenses suspended in fluid. In contrast, both the
329	Optimec is 830 and the in-house OCT device developed by Karnowski et al. 15 were specifically
330	optimised to obtain B-scans of soft contact lenses with sufficient contrast for processing.
331	Secondly, the lateral range is limited to 6 mm, meaning the lens must be laterally shifted to scan
332	its most extreme lateral ranges (>14 mm diameter). Newer clinical spectral domain OCT
333	devices, such as the Revo NX (Optopol Technology SA), <sup>40</sup> produce larger ultra-high-resolution
334	cross-sectional B-scans (ranging from 3–18 mm), meaning this limitation only applies to older
335	clinical OCT devices like the one in this study. Moreover, due to its relevance to rigid contact
336	lens fitting, this paper focused on measuring the BOZR of a rigid spherical contact lens. The
337	methods presented here can also be used to measure the curvature radius of the front curve
338	surface of a spherical contact lens if the lens is flipped. Measurement of non-spherical surfaces
339	(e.g. multifocal lenses) is potentially possible after modifying the last step of <i>BOZR calculation</i>
340	from B-scans to perform the corresponding optimal numerical fitting. However, the reliability
341 342	of this clinical OCT device as a profilometer cannot be extrapolated from the results of this
342 343	study.  In summary, this paper has demonstrated the feasibility of using a clinical OCT device (3D)
343 344	OCT-1000) to visually inspect the morphology (including edges) of commercial contact lenses
J <b>++</b>	OC1-1000) to visually inspect the morphology (including edges) of commercial contact lenses

- and measure the radius of curvature of the posterior face to a precision compatible with the ISO
- standard. Although the clinical OCT device cannot replace a radiuscope for ISO 18369-3:2018-
- 347 compliant<sup>20</sup> quality-control BOZR measurements, the findings of this study suggest that clinical
- OCT devices may play a valuable role in contact lens research and clinical practice. It is hoped
- that these results will encourage further studies using newer clinical OCT devices and to
- motivate manufacturers to develop the necessary opto-mechanical adaptors, methods, and
- 351 software to take measurements like those presented here.

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#### 456 APPENDIX

457 Appendix A – Measurement data

The table below provides the mean and standard deviation of the different measurements taken in this study.

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Table A. BOZR values obtained by optical radiuscope and by OCT image processing, taken in different sessions and by different operators.

CLs	Procedures, sessions and operators				
Nominal base curve [mm]  Nominal_BOZR	Radiuscope base curve (mm) Radiuscope BOZR Mean ±SD	OCT base curve (mm) BOZR_O1S1 Mean ±SD	OCT base curve (mm) BOZR_O1S2 Mean ±SD	OCT base curve (mm) BOZR_O2S1 Mean ±SD	
7.30	$7.26 \pm 0.01$	$7.27 \pm 0.03$	$7.26 \pm 0.01$	$7.31 \pm 0.06$	
7.40	$7.39 \pm 0.01$	$7.46 \pm 0.01$	$7.42 \pm 0.05$	$7.33 \pm 0.02$	
7.50	$7.48 \pm 0.01$	$7.57 \pm 0.04$	$7.48 \pm 0.04$	$7.51 \pm 0.09$	
7.55	$7.55 \pm 0.01$	$7.56 \pm 0.01$	$7.56 \pm 0.07$	$7.59 \pm 0.04$	
7.60	$7.57 \pm 0.01$	$7.66 \pm 0.09$	$7.57 \pm 0.03$	$7.62 \pm 0.12$	
7.65	$7.61 \pm 0.01$	$7.65 \pm 0.03$	$7.67 \pm 0.02$	$7.61 \pm 0.06$	
7.70	$7.69 \pm 0.01$	$7.66 \pm 0.10$	$7.67 \pm 0.03$	$7.71 \pm 0.08$	
7.75	$7.78 \pm 0.00$	$7.73 \pm 0.05$	$7.72 \pm 0.07$	$7.71 \pm 0.04$	
7.80	$7.81 \pm 0.01$	$7.78 \pm 0.01$	$7.77 \pm 0.01$	$7.82 \pm 0.05$	
7.85	$7.83 \pm 0.01$	$7.81 \pm 0.02$	$7.84 \pm 0.03$	$7.88 \pm 0.11$	
7.90	$7.88 \pm 0.01$	$7.86 \pm 0.01$	$7.88 \pm 0.01$	$7.85 \pm 0.03$	
7.95	$7.93 \pm 0.01$	$7.90 \pm 0.04$	$7.90 \pm 0.01$	$7.87 \pm 0.03$	
8.00	$7.99 \pm 0.01$	$7.94 \pm 0.05$	$7.97 \pm 0.01$	$8.03 \pm 0.10$	
8.05	$8.03 \pm 0.00$	$8.03 \pm 0.03$	$8.07 \pm 0.08$	$8.06 \pm 0.11$	
8.10	$8.13 \pm 0.00$	$8.11 \pm 0.13$	$8.07 \pm 0.01$	$8.14 \pm 0.11$	
8.15	$8.17 \pm 0.00$	$8.10 \pm 0.05$	$8.22 \pm 0.01$	$8.10 \pm 0.01$	
8.30	$8.29 \pm 0.01$	$8.20 \pm 0.03$	$8.29 \pm 0.03$	$8.25 \pm 0.06$	
8.40	$8.35 \pm 0.01$	$8.30 \pm 0.03$	$8.35 \pm 0.03$	$8.32 \pm 0.10$	

CLs: contact lenses; O1s1: Operator1-Session1; O1s2: Operator1-Session2; O2s1: Operator2-Session1; SD: standard deviation.

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#### Table 1. Technical specifications of the contact lens sample used in edge assessment. 466

	Brand	Manufacturer	Lens type	Material / RI	Power (D)	BOZR (mm) / S_depth (µm)	TD (mm)	DK
a)	Alexa 20 Aspherica	Tiedra	Spherical RL	Pasifocon A / 1.4373	+3.50 Sph	8.15/-	9.60	16
b)	Torica GP Polycon II	Lenticon	Back Torical SL	Silafocon A / 1.473	-3.00 Sph	7.30_7.80/-	9.60	10
c)	ICD™ Mini	Lenticon	Spherical SRGPL	Paflufocon D / 1.442	-7.00 Sph	-/3700	14.50	100
d)	$ICD^{TM}$	Lenticon	Spherical SRGPL	Paflufocon D / 1.442	-2.00 Sph	-/4200	16.50	100

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	Brand	Manufacturer	Lens type	Material / RI	Power (D)	Axis (Degree)	BCR (mm)	TD (mm)	% Water
e)	Gold Medalist <sup>TM</sup> Toric	Bausch & Lomb	Torical SCL	Hefilcon C / 1.410	-2.00 Sph -1.75 Cyl	180	8.60	14.20	57
f)	Acuvue® 1-Day	Johnson & Jonhson	Spherical SCL	Etafilcon A / 1.405	-4.50 Sph	-	8.50	14.20	58
g)	Air Optix <sup>TM</sup> for astigmatism	CIBA Vision GmbH (Alcon)	Torical SCL	Lotrafilcon B / 1.421	-2.00 Sph -2.25 Cyl	70	8.70	14.50	33
h)	Toric 55	Aspect Vision Care	Torical SCL	Methafilcon A / 1.420	-2.00 Sph -1.25 Cyl	180	8.70	14.40	55

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RI: refraction index; D: Dioptre; BOZR: back optic zone radius; BCR: base curve radius; S depth: sagittal depth; TD: total diameter; Dk: contact lens oxygen permeability in barrers; RL: rigid lens; SRGPL: scleral rigid gas-permeable lens; SCL: soft contact lens.

### Table 2. Variability, intra-class correlation coefficient and Student's *t*-test results.

Dataset	VC	Sd_Diff(mm)	max_Diff Absolute Error (mm)
O1s1	0.75%	0.0590	0.110
O1s2	0.50%	0.0390	0.104
O2s1	0.75%	0.0590	0.130
Sim noise-free	0.016%	0.0013	0.006
Sim minimum spatial noise	0.23%	0.0180	0.065

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Comparison	Student's t-test	CCI
•	p-value	
BOZR_O1s1 vs BOZR_O1s2	0.666	0.991 (p < 0.001)
BOZR_O1s2 vs BOZR_O2s1	0.997	0.984 (p < 0.001)
BOZR_O1s1 vs BOZR_O2s1	0.660	0.986 (p < 0.001)
BOZR_O1s1 vs radiuscope BOZR	0.661	0.992 (p < 0.001)
BOZR_O2s1 vs radiuscope BOZR	0.996	$0.991 \ (p < 0.001)$

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478 479 480 VC: variation coefficient; Sd\_Diff: standard deviation of the difference; max\_Diff: absolute value of the maximum error of the difference; CCI: intra-class correlation coefficient. O1s1: Operator1-Session1; O1s2: Operator1-Session2; O2s1: Operator2-Session1.

481	[Figure legends]
482	Figure 1. Contact lens adaptor placed in front of a 3D OCT-1000 with a tilted flat mirror.
483	
484	Figure 2. Image processing and OCT B-scan analysis flow-chart.
485	
486	Figure 3. Original in vitro cropped B-scans of different lens edges of several commercial
487	rigid gas-permeable contact lenses and soft contact lenses. (a) Spherical RGP ("Alexa 20
488	Aspherica"; Tiedra), (b) torical RGP ("Torica GP Polycon II"; Lenticon), (c) rigid scleral
489	lens ("ICDTM), (d) rigid scleral lens ("ICDTM; Paragon), (e) torical SCL ("Gold
490	$Medalist^{TM}\ Toric";\ Bausch\ \&\ Lomb),\ (f)\ spherical\ SCL\ ("Acuvue\ 1-Day";\ Johnson\ \&\ 1-Day";\ Johnson\ &\ 1-Day";\ Johnson\$
491	Jonhson), (g) torical SCL ("Air $Optix^{TM}$ for astigmatism"; CIBA Vision, Alcon) and (h)
492	torical SCL ("Toric 55"; Aspect Vision Care). The scale shown in Figure 3(f) is the same
493	for all sub-images. A torical marking is surrounded by a white dashed circle in Figure
494	3(b).
495	
496	Figure 4: (a) Bland-Altman plot of intra-session (BOZR Operator1-Session1 and BOZR
497	Operator1-Session2) differences, and (b) intra-operator (BOZR Operator1-Session1 and
498	BOZR Operator2-Session1) differences.
499	
500	Figure 5: Bland-Altman plots for BOZR measurement differences between radiuscope
501	measurements and two different operators. (a) Differences between radiuscope BOZR
502	$values \ and \ the \ measurements \ taken \ by \ Operator 1-Session 1 \ (BOZR \ Operator 1-Session 1).$
503	(b) Differences between radiuscope BOZR values and the measurements taken by
504	Operator2 (BOZR Operator2-Session1).
505	

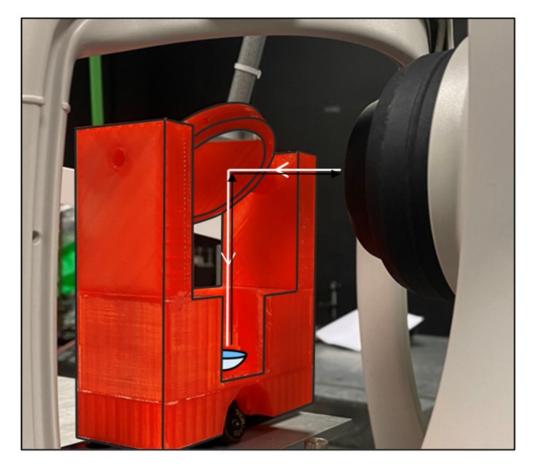
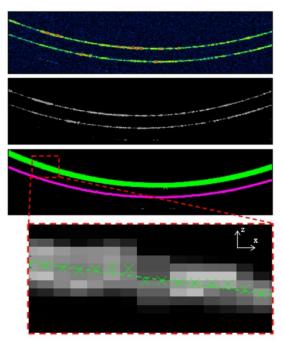


Figure 1. Contact lenses adaptor emplaced in front of 3-D OCT-1000 with a tilted flat-mirror. 317x279mm~(400~x~400~DPI)



- 1) OCT image reading and Region of Interest (ROI) selection.
- 2) RGB to intensity image conversion.
- 3) Image noise removal.
- 4) Automatic image thresholding.
- 5) Image segmentation for the first and second reflection curve.
- Centroid calculation for each vertical profile of the first reflection curve.
- 7) Least squares circle fitting of the centroid data.

Figure 2. Flow chart of image processing and analysis of the B-scan OCT image.

381x255mm (400 x 400 DPI)

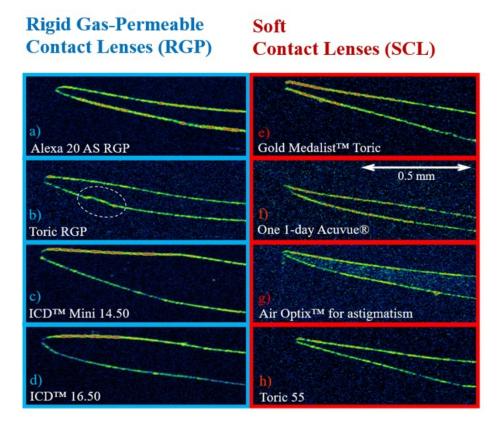


Figure 3. Original in-vitro cropped B-scan images of different lens edges for some commercial rigid gaspermeable contact lenses and soft contact lenses. (a) Spherical RGP "Alexa 20 Aspherica" (Tiedra), (b) toric RGP "Torica GP Polycon II" (Lenticon), (c) rigid scleral lens "ICD™, (d) rigid Scleral lens "ICD™ (Paragon), (e) toric SCL "Gold Medalist™ Toric" (Bausch & Lomb), (f) spheric SCL "Acuvue® 1-Day" (Johnson & Jonhson), (g) toric SCL "Air Optix™ for astigmatism" (CIBA Vision, Alcon) and (h) Toric SCL "Toric 55" (Aspect Vision Care). The scale size shown at subFigure (f) is the same for all sub-images. A toric marking is surrounded with a white dashed circle at subFigure (b).

381x314mm (400 x 400 DPI)

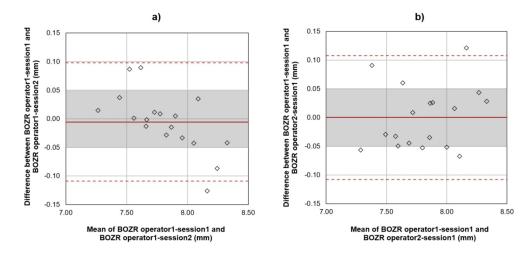


Figure 4: (a) Bland-Altman plot of intra-session (BOZR operator1-session1 and BOZR operator1-session2) and (b) intra-operator (BOZR operator1-session1 and BOZR operator2-session1) differences.

381x189mm (399 x 399 DPI)

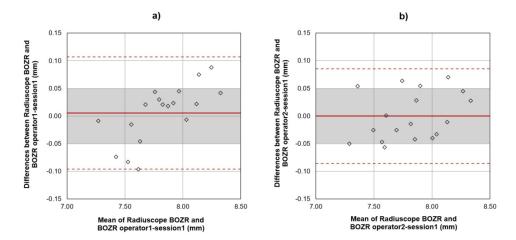


Figure 5: Bland-Altman plots for BOZR measurement differences between Radiuscope measurements and two different operators. (a) Differences between Radiuscope BOZR values and the measurements taken by operator1-session1 (BOZR operator1-session1). (b) Differences between Radiuscope BOZR values and the measurements taken by operator 2 (BOZR operator2-session1).

382x175mm (398 x 398 DPI)