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Evaluation of a self-imaging OCT for remote diagnosis and monitoring of retinal diseases

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4 **Evaluation of a self-imaging OCT for remote diagnosis and monitoring of**
5 **retinal diseases**

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28
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31 **Synopsis**

32 This study validates the accuracy and feasibility of a self-imaging OCT in measuring
33 central subfield thickness and identifying retinal lesions, showing the potential for
34 home monitoring or screening of retinal diseases.

35 **Abstract**

36 **Objectives** To evaluate the feasibility and accuracy of a portable, self-imaging
37 optical coherence tomography (OCT) for measuring central subfield thickness (CST)
38 and achieving diagnostic concordance for retinal lesions compared to clinic-based
39 spectral-domain OCT (SD-OCT).

40 **Methods** This comparative, cross-sectional study was conducted between August
41 2020 and February 2021. Two groups of adult participants were recruited: (1) a
42 selected cohort of 160 participants with confirmed diagnosis, and (2) a consecutive
43 cohort of 315 participants recruited randomly. All participants underwent self-imaging
44 OCT examination, as well as standard OCT examination. CST was automatically
45 calculated for comparisons between the two OCT devices. Diagnostic concordance
46 for retinal lesions and the success rate of self-imaging were assessed within the
47 consecutive cohort.

48 **Results** In the selected cohort, self-imaging OCT images yielded consistent CST
49 with SD-OCT, with a mean difference of $0.1 \pm 7.7 \mu\text{m}$ for normal eyes, $4.9 \pm 10.6 \mu\text{m}$
50 for macular edema, $-1.3 \pm 9.5 \mu\text{m}$ for choroidal neovascularization, $5.0 \pm 7.8 \mu\text{m}$ for
51 epiretinal membrane. The self-imaging OCT also demonstrated good repeatability,
52 with a mean test-retest difference in CST of $0.7 \pm 3.9 \mu\text{m}$ and limits of agreement
53 (LOA) ranging from -6.9 to $8.3 \mu\text{m}$. Additionally, within the consecutive cohort, inter-
54 device κ values ranged for detecting various retinal lesions ranged from 0.8 to 1.0,
55 except in the cases of retinal detachment ($\kappa = 0.5$). All eyes (100%) in the selected
56 cohort and 242 eyes (76.8%) in the consecutive cohort successfully completed self-
57 imaging. Participants spent less time on self-imaging compared to SD-OCT operated
58 by a technician (66 vs. 73 seconds, $p < 0.01$). A majority of participants (90%) found
59 the self-imaging process "easy" and "comfortable".

60 **Conclusions and Relevance** The present study demonstrates that our self-imaging
61 OCT and clinic-used SD-OCT are highly consistent not only in measuring the central
62 subfield thickness but also in identifying most retinal lesions.

63

64 **Key Messages**

65 **What is already known on this topic?**

66 OCT plays a crucial role in screening, diagnosing, and routine monitoring of retinal
67 diseases. However, the accessibility of OCT machines is often restricted to hospitals
68 or clinics, which requires patients frequently visit for these facilities. Moreover, the
69 reliance on human operation poses a burden on the healthcare system for screening
70 and diagnosis. To address these limitations, we have developed a lightweight,
71 portable, and self-imaging OCT machine, but it is important to validate its accuracy
72 and feasibility.

73

74 **What this study adds?**

75 In this comparative cross-sectional study including patients with retinal diseases, our
76 self-testing OCT device demonstrated strong agreement with the standard SD-OCT
77 in both measuring central subfield thickness and diagnosing retinal lesions.
78 Furthermore, the self-imaging process exhibited an acceptable completion rate.

79

80 **How this study might affect research, practice or policy?**

81 With the added convenience of door-to-door delivery service, our self-imaging OCT
82 device will significantly enhance the availability and accessibility of OCT for routine
83 monitoring of central subfield thickness in conditions such as diabetic macular
84 edema (DME), as well as facilitate remote imaging of retinal diseases in the comfort
85 of patients' homes.

86

87 **Introduction**

88 Optical Coherence Tomography (OCT) is the primary imaging modality used for
89 screening, diagnosing, and routine monitoring of vision-threatening retinal
90 diseases,(1) including age-related macular degeneration (AMD)(2) and diabetic
91 macular edema (DME).(3) Regular evaluation of central subfield thickness (CST)
92 using OCT is imperative, especially for patients necessitating frequent intravitreal
93 anti-vascular endothelial growth factor (anti-VEGF) injections,(2, 4) to optimize
94 treatment outcomes. CST in OCT images primarily determines the response to
95 treatment and the need for extra injections.(4, 5) Furthermore, the integration of OCT
96 shows the potential to enhance the remote screening and diagnosis of retinal
97 diseases.(6, 7)

98

99 Despite their important role in retinal diseases management, OCT machines are
100 typically bulky desktop instruments only available in dedicated rooms within eye
101 centers, hospitals or clinics, involving trained ophthalmic technicians for their
102 operation.(1) These limitations inevitably resulting in patients being required for
103 frequent hospital/clinic visit to undergo OCT imaging, thereby exerting a substantial
104 burden on them, including the time and indirect expenses associated with
105 transportation and caregiver availability, as well as the inconvenience of numerous
106 visits.(2, 8) Such challenges can easily lead to non-adherence or non-persistence
107 with follow-up visits and treatment regimen.(9, 10)

108

109 Rather than requiring patients to frequently visit hospital/clinic, we proposed a home-
110 based eye care model called "Express Medicine," which involves sending OCT
111 machines to patients' residences via established courier networks.(11) Such a model
112 has the potential to overcome the barriers of hospital visits in terms of space and
113 time, bringing significant benefits to patients, including greater access to under-
114 served populations and reduced travel time and cost burdens. The primary
115 prerequisite is to overcome the limitations of workspace and operation for OCT. We

116 have developed a lightweight, portable, and self-imaging OCT device (**Figure 1**),
117 equipped with scanning parameters comparable to those in commercial desktop
118 OCT machines. This self-imaging OCT enables patients to capture high-resolution
119 retinal OCT images from the comfort of their homes, subsequently transmitting these
120 images to healthcare providers in remote settings. With door-to-door delivery
121 service, our self-imaging OCT will expand the role of OCT in routine monitoring of
122 CST and remote imaging of retinal diseases at home.

123

124 The aim of this pilot study was to evaluate the accuracy, repeatability, and feasibility
125 of our self-imaging OCT device in two possible application scenarios: remote
126 measurement of CST, and remote diagnosis of various retinal lesions. We used the
127 commercially available Spectral Domain Optical Coherence Tomography (SD-OCT),
128 which is a widely accepted and established imaging technique in clinical practice, as
129 the reference standard.

130

131 **Methods**

132 **Ethical approval**

133 This study was approved by the Ethical Review Committee of the Zhongshan
134 Ophthalmic Center (approval ID: 2020KYPJ201) and was conducted in accordance
135 with the tenets of the Declaration of Helsinki. Written informed consent was obtained
136 from all participants who were enrolled between August 2, 2020, and February 13,
137 2021.

138

139 **Study design and setting**

140 We conducted a comparative, cross-sectional study at the Zhongshan Ophthalmic
141 Center (ZOC), Sun Yat-sen University, China. We recruited two cohorts of patients
142 from the Retina Clinic, including the selected and the consecutive cohorts (**Figure 2**).
143 The selected cohort comprised patients with confirmed retinal disease to assess the
144 accuracy and repeatability of our device in quantifying CST. The consecutive cohort
145 consisted of patients randomly recruited from the retinal clinic to evaluate the
146 feasibility and diagnostic accuracy of our device in detecting retinal lesions.

147

148 In the selected cohort, eligible participants were 18 years of age or older and had a
149 confirmed diagnosis of choroidal neovascularization (CNV), macular edema
150 (intraretinal fluid, ME) or epiretinal membrane (ERM) in one or both eyes, as
151 determined by two retina specialists (S.C. and Z.L.). Normal participants were also
152 included in the selected cohort, with best corrected visual acuity (BCVA) $\geq 20/40$ and
153 no signs of ocular disease. Exclusion criteria were BCVA $< 20/200$ in the better eye
154 (to prevent fixation failure), spherical equivalents ≤ -12 diopter (D), or Lens Opacities
155 Classification System III posterior subcapsular opalescence grade ≥ 3.0 .(12) In the
156 consecutive cohort, we randomly enrolled patients who needed OCT examinations,
157 diagnosed by the two retina specialists through review of their ophthalmic records.
158 Complicated cases (e.g., those with low vision, severe cataract, or high myopia)
159 were also recruited. Exclusion criteria were any severe diseases or conditions

160 preventing participants from participating and providing informed consent (e.g.,
161 cognitive diseases).

162

163 **OCT examination and participant survey**

164 All participants underwent OCT imaging with both the self-imaging OCT and the SD-
165 OCT (Spectralis, Heidelberg Engineering, Germany) on the same day.

166

167 Our self-imaging OCT is a prototype device with a smaller size (L362 × W425 ×
168 H438 mm) and a lighter weight (20 kg) compared to the desktop SD-OCT (**Figure 1**).

169 The self-imaging OCT employed an infrared light source with a wavelength of 840

170 nm, an axial resolution of 5 μm, an imaging area of 12 × 8 mm and a scan speed

171 exceeding 80,000 A-scans per second. The self-imaging was conducted in a

172 separate examination room within the clinic to simulate a home environment. Before

173 imaging, each participant read the instruction manual and viewed a 2-minute video

174 tutorial. Subsequently, practical instructions on device usage were provided to help

175 participants develop the proficiency with self-imaging. After the initial training,

176 participants were then left alone in the room to undergo the self-imaging. Guided by

177 step-by-step voice instructions from the device, they were asked to position their

178 head on the headrest properly, focus directly on the internal fixation target generated

179 by the self-adjusting sensor and avoid blinking during imaging. The default scanning

180 pattern consisted of 6 radial, concentric, and 6-mm-long B-scans centered on the

181 fovea. In instances where participants failed to comply, the equipment prompted

182 them to repeat the imaging process, affording them up to three attempts. Both eyes

183 were imaged, and we recorded the outcome (success or failure), the underlying

184 reasons for failure, and the duration of the self-imaging process. A subset of 20

185 normal participants was invited to repeat the self-imaging OCT after a 10-minute

186 interval to assess the repeatability.

187

188 The standard SD-OCT examination was performed by an experienced technician.

189 The scanning pattern comprised a raster of 19 horizontal line scans with a scan
190 density of 512 A-scans per line, averaging 9 iterations, and 9-mm-long B-scans
191 centered on the fovea. Imaging was performed for both eyes, and the duration was
192 recorded.

193

194 To further assess the feasibility, all participants in the consecutive cohort were invited
195 to survey about their perceptions and preferences regarding to self-imaging. The
196 non-validated questionnaire consisted of four statements, using a 5-point scale, with
197 1 indicating strongly agree; 3, uncertain; and 5, strongly agree (Supplemental Table
198 3).

199

200 **Image Grading**

201 Representative images from both OCT devices are shown in **Figure 1**. All OCT
202 images were deidentified and independently graded by the two retina specialists
203 (S.C and Z.L.). The final grading was achieved by consensus, and a third senior
204 specialist (X.L.) was consulted if disagreement arose. Separate grading was
205 performed for SD-OCT and self-imaging OCT images of the same eye. OCT images
206 were considered uninterpretable if the macula could not be clearly identified or if they
207 exhibited extremely poor quality. OCT images were graded according to the
208 presence of various lesions including ERM, ME, CNV, retinal detachment, macular
209 holes, and any other abnormal retinal findings.⁽¹³⁾ Some images might have more
210 than one kind of retinal lesion. Only eyes that have interpretable images from both
211 types of OCT devices were included in the statistical analysis.

212

213 **Measurement of the Central Subfield Thickness (CST)**

214 Automated image segmentation for both SD-OCT and the self-imaging OCT was
215 executed using the SD-OCT software (Heidelberg Eye Explorer version 6.0.9.0) and
216 the proprietary software for the self-imaging OCT, respectively. Software-generated
217 CST, defined as the distance between the inner limiting membrane and the lower

218 border of the retinal pigment epithelium, was assessed. No manual adjustments
219 were applied to the automated image segmentation process. The automated
220 annotation of retinal boundaries was further reviewed by the two retina specialists.
221 Images displaying segmentation failure and eyes with macular holes were excluded
222 from the analysis of CST.

223

224 **Statistical analysis**

225 For the comparison in the agreement of CST, a sample size of 30 eyes for each
226 group of retinal lesion would yield a two-sided 95% confidence interval (CI) with a
227 width of 0.08 when the Pearson's product-moment correlation estimate is 0.950.
228 Continuous variables were described as means and standard deviations (SDs), while
229 categorical variables were presented as counts and percentages. Only the right eye
230 was chosen for statistical analysis for normal participants and patients with retinal
231 diseases in both eyes, otherwise the only affected eye was selected. We used
232 Bland-Altman analysis and Pearson's correlation analysis to evaluate the agreement
233 of CST measurements between the two OCT devices, as well as the repeatability.
234 The mean difference was calculated by subtracting the mean thickness of the SD-
235 OCT measurements from those of the self-imaging OCT, while the limits of
236 agreement (LOA) were determined as the mean differences plus or minus 1.96 times
237 the standard deviations. All results were reported with 95% CIs. From a clinical
238 perspective, acceptable LOA values were predefined as $\pm 20 \mu\text{m}$ in the selected
239 cohort and $\pm 30 \mu\text{m}$ in the consecutive cohort. The test-retest reliability (TRR) of the
240 self-imaging OCT was also calculated.

241

242 Cohen's κ test was used to evaluate the diagnostic concordance between the two
243 OCT devices, following the grading system of Landis and Koch.(14) Paired t-tests
244 were employed to compare the time required for examination completion using the
245 two OCT devices. We performed all statistical analyses using Stata Statistical
246 Software 16 (StataCorp., TX, USA), and findings were considered significant at $p <$

247 0.05.

248

249 **Results**

250 This study included 160 eyes from 160 participants in the selected cohort and 315
251 eyes from 315 participants in the consecutive cohort. For the selected cohort, the
252 mean (SD) age was 58.3 (12.6) years and 93 participants (58.1%) were female. For
253 the consecutive cohort, the mean (SD) age was 56.5 (13.3) years and 179
254 participants (56.8%) were female. The detailed demographic information is shown in
255 **Supplemental Table 1**.

256

257 In the selected cohort, we aimed to assess the accuracy and repeatability of
258 measuring CST. All the 160 participants (100%) successfully completed self-imaging
259 and yielded interpretable images from both OCT devices. **Table 1** shows the
260 comparison results in CST measurement. The mean (SD) difference in CST between
261 the two OCT devices was 0.1 (7.7) μm (95% LOA, -15.0 to 15.1 μm) for normal eyes,
262 4.9 (10.6) μm (95% LOA, -15.9 to 25.6 μm) for eyes with ME, 5.0 (7.8) μm (95%
263 LOA, -19.9 to 17.4 μm) for eyes with ERM, -1.3 (9.5) μm (95% LOA, -10.3 to 20.2
264 μm) for eyes with CNV.

265

266 In the consecutive cohort, we aimed to evaluate the feasibility of implementing self-
267 imaging OCT in a real-world clinic setting (**Supplemental Table 2**). Among the 315
268 participants, 45 out of them (14.3%) failed self-imaging. The main reasons for
269 unsuccessful self-imaging included an inability to maintain fixation on the internal
270 target (36 out of 315, 11.4%) and an inability to operate the self-imaging OCT device
271 by themselves (9 out of 315, 2.9%). Among those who completed the self-imaging
272 process, 10.4% of them (28 of 270) obtained images classified as uninterpretable.
273 This was primarily due to issues related to image quality (20 out of 28, 71.4%) and
274 macular region not captured in the image (8 out of 28, 28.6%). Out of the remaining
275 270 eyes, 242 (89.6%) yielded interpretable images from both the reference SD-
276 OCT and the self-imaging OCT for the identification of retinal lesions, and 213 of
277 these (78.9%) provided valid CST measurements.

278

279 For the 213 eyes in the consecutive cohort, the self-imaging OCT and the SD-OCT
280 showed a mean (SD) difference of 2.0 (9.4) μm (95% LOA, -16.4 to 20.4 μm) in CST
281 measurements. Correlation coefficients ranging from 0.948 to 0.999 indicated a
282 strong and consistent correlation in CST measurements across both OCT devices in
283 both cohorts. Regarding the self-imaging OCT, the TRR in CST measurement
284 exhibited a mean (SD) of 0.7 (3.9) μm , with a range from -7 to 7 μm and the 95%
285 LOA from -6.9 to 8.3 μm . **Figure 3** illustrates the Bland Altman plots for the
286 agreement between both OCT devices in measuring CST for both cohorts and the
287 TRR.

288

289 Substantial agreement was observed in identifying most retinal lesions between the
290 standard SD-OCT and the self-imaging OCT (**Table 2**), including ERM ($\kappa = 0.9$),
291 macular edema ($\kappa = 0.9$), CNV ($\kappa = 0.9$), macular holes ($\kappa = 1.0$), atrophy of choroid
292 ($\kappa = 0.96$), subretinal fluid ($\kappa = 0.86$) and atrophy of retinal out layer ($\kappa = 0.93$).
293 However, the diagnostic agreement for retinal detachment was just moderate ($\kappa =$
294 0.50).

295

296 Overall, participants were satisfied with the self-imaging OCT. The questionnaire
297 received responses from 270 participants (86.0%). Of the respondents,
298 89% “strongly agree” or “agree” with statements about the simplicity and comfort of
299 operating the self-imaging device. Additionally, 73% were willing to choose this
300 instrument for future monitoring, while 69% found it faster than the commercial SD-
301 OCT device. The questionnaire response about the self-imaging OCT is shown in
302 **Supplemental Table 3**. The mean (SD) scanning time of the self-imaging OCT was
303 66.7 (20.1) seconds per eye, which was significantly faster than that of the SD-OCT
304 (73.3 [32.5] seconds per eye, $p < 0.05$).

305

306 **Discussion**

307 The aim of this proof-of-concept study was to evaluate the accuracy, repeatability,
308 and feasibility of a self-imaging OCT device in quantifying central subfield thickness
309 and identifying abnormal retinal lesions. Firstly, our results demonstrated that most
310 patients were able to operate the self-imaging OCT device and successfully capture
311 high-quality images of their own eyes. Secondly, the self-imaging OCT provided
312 accurate and repeatable measurements of CST. Thirdly, substantial agreement was
313 observed between both types of OCT in identifying most retinal lesions. These
314 findings support the potential of the self-imaging OCT to facilitate home-based
315 management and screening of retinal diseases.

316

317 Our self-imaging OCT device is designed to serve as a portable and automated
318 home OCT for self-imaging. Maloca et al. reported on a sparse OCT prototype for
319 home-based monitoring, which was tested in only a limited group of patients with
320 AMD.(15) This early prototype, with its limited imaging capabilities, necessitates
321 operators and lacks automatic analysis software. Kim et al. introduced another novel
322 home OCT device, the Notal Vision Home OCT (NVHO), which exhibits improved
323 imaging capabilities and automation.(16) However, the application of NVHO or other
324 home OCT devices is confined due to their relatively small imaging area and low
325 scanning speed, limiting their utility in the detection and measurement of macular
326 fluid.(16-18) In contrast, our self-imaging OCT device is equipped with scanning
327 parameters comparable to those of the commercial desktop SD-OCT, conferring
328 great advantages not only in the monitoring macular thickness but also in the
329 screening and diagnosis of most retinal diseases.

330

331 One of the most promising applications of this self-imaging OCT device lies in its
332 ability to facilitate home-based monitoring of CST in patients receiving anti-VEGF
333 therapy.(19) When compared to the commercial SD-OCT, our self-imaging OCT
334 achieved excellent agreement in CST measurements. The mean difference in groups

335 of eyes affected by common retinal diseases remained within $\pm 5 \mu\text{m}$ (SD $\pm 11 \mu\text{m}$),
336 with the range of difference within $\pm 30 \mu\text{m}$. These results were superior to the
337 previous study about the sparse OCT (SD $\pm 20 \mu\text{m}$; the range, 65.6 to 41.5 μm).⁽¹⁵⁾
338 Moreover, the robust correlation coefficients also suggested the high consistency
339 and reproducibility of CST measurements for our self-imaging OCT. The growing
340 number of patients with DME or AMD who are required to be closely monitored after
341 injection poses an increasing burden on healthcare systems, warranting automated
342 solutions to alleviate monitoring burdens.^(20, 21) Our self-imaging OCT holds the
343 potential not only to integrate into home-based eye care programs, but also to be
344 incorporated into the proposed 'Express Medicine' eye care model.

345

346 Our self-imaging OCT offers a distinctive advantage by providing OCT images with a
347 larger field of view and higher resolution when compared to other home OCT
348 devices. This study demonstrated that substantial agreement in identifying most
349 retinal lesions using our self-imaging OCT, supporting its application in remote
350 retinopathy screening or diagnosis in communities or homes. Pivotal studies have
351 demonstrated that incorporating OCT for DME screening could reduce false
352 positives, improve sensitivity, and exhibit cost-effectiveness when compared to sole
353 fundus photography.⁽⁶⁾ Combining fundus photography and OCT for remote retinal
354 diagnosis imaging has been shown to be comparable to traditional dilated eye
355 examinations performed by retinal specialists in clinics.⁽⁷⁾ Additionally, OCT shows
356 potential for early glaucoma detection⁽²²⁾ or progression monitoring.⁽²³⁾ However,
357 all the previous studies proposed to use the heavy, expensive, and desktop OCT
358 devices that require trained operators for screening or remote diagnosis, which
359 significantly raises the direct medical cost and imposes a burden on healthcare
360 systems. Our portable, low-cost, self-imaging OCT provides an automated solution
361 to alleviate the screening task and enhance the screening efficacy for retinopathy
362 and even glaucoma.

363

364 Assessing the self-operability of our self-imaging OCT device in patients with retinal
365 disease is a critical step in planning its clinical application. A previous study
366 demonstrated that 80-90% of AMD patients (with VA \geq 20/400) completed self-
367 imaging using NVHO 2.5 and 3.0 in clinic.(16) In our study, all eyes of AMD or DME
368 participants (VA \geq 20/200) successfully completed self-imaging and obtained
369 interpretable images using our self-imaging OCT device. Moreover, our study is the
370 first study to evaluate the feasibility of applying self-imaging OCT device in the real-
371 world clinic setting, where patients often present with more complicated conditions.
372 Our survey received positive feedback from patients regarding the device's usability,
373 with a majority finding it easy to use and comfortable during testing.

374

375 **Limitations and strengths**

376 The main limitation of this study lies in the absence of field testing the device in
377 patients' own homes. Despite the self-imaging OCT device's intended robustness
378 and lightweight design to ensure autonomous service provision to patients without
379 supervision, and although it was tested in a separate room simulating a home
380 environment, further investigations at home are still needed. Moreover, it is important
381 to note that the self-imaging OCT and SD-OCT devices use different scanning
382 patterns, which may have contributed to the divergence in retinal thickness
383 measurements.

384

385 **Conclusions**

386 Our findings suggest that the self-imaging OCT device performs comparably to
387 conventional SD-OCT in detecting pathological findings and measuring macular
388 thickness. However, it is important to note that further research is warranted to
389 determine the feasibility of using self-imaging OCT outside of clinical settings,
390 including real home monitoring.

391

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402

403 **Author Contributions:** Drs Y.Z. Liu and S.D. Chen had full access to all data in the
404 study and are responsible for the integrity of the data and the accuracy of the data
405 analysis. Concept and design: Y.Z. Liu, Zheng, and Chen. Acquisition, analysis, or
406 interpretation of data: All authors. Drafting of the manuscript: Chen, Z.T. Liu, Zheng.
407 Critical revision of the manuscript for important intellectual content: All authors.
408 Statistical analysis: Z.T. Liu, Chen, Jin, Zheng. Administrative, technical, or material
409 support: W.Y. Huang. Supervision: Y.Z. Liu.

410

411 **Conflict of Interest Disclosures:** Drs. Y.Z. Liu and Zheng reported that they hold
412 patents on the self-imaging device used in this study, and on the automated imaging
413 analysis system associated with the imaging software used in this study. No other
414 disclosures were reported.

415

416 **Data and Materials Availability:** All data necessary to assess the conclusions of the
417 paper are present in the paper or in the Supplemental Materials.

418

419

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479 **Table 1. Mean difference, SD and LOA for Bland-Altman analyses and Pearson's correlation analysis results of central subfield thickness**
 480 **(CST) for the selected cohort.**

481

Cohorts	No.	SD-OCT (Mean [SD])	Self-imaging OCT (Mean [SD])	Mean Difference (95% CI)	SD (95% CI)	LOA (95% CI)		Range	Correlation Coefficient (95% CI)
						Lower	Upper		
The selected cohort									
Normal	50	218.2 (24.0)	218.3 (23.5)	0.1 (-2.1, 2.3)	7.7 (6.4, 9.6)	-15.0 (-18.7, -11.2)	15.1 (11.4, 18.9)	(-14, 19)	0.948 (0.910, 0.970)
Macular edema	40	361.3 (177.4)	366.2 (180.4)	4.9 (1.5, 8.3)	10.6 (8.7, 13.6)	-15.9 (-21.7, -10.0)	25.6 (19.8, 31.5)	(-19, 23)	0.998 (0.997, 0.999)
CNV	30	330.7 (188.2)	329.5 (183.7)	-1.3 (-4.8, 2.3)	9.5 (7.6, 12.8)	-19.9 (-26.1, -13.8)	17.4 (11.3, 23.5)	(-18, 26)	0.999 (0.998, 1.000)
ERM	40	359.1 (126.5)	364.1 (127.4)	5.0 (2.5, 7.5)	7.8 (6.4, 10.0)	-10.3 (-14.5, -6.0)	20.2 (15.9, 24.5)	(-9, 22)	0.998 (0.996, 0.999)
The consecutive cohort	213	283.9 (142.9)	285.9 (144.4)	2.0 (0.8, 3.3)	9.4 (8.6, 10.4)	-16.4 (-18.5, -14.2)	20.4 (18.3, 22.6)	(-19, 26)	0.998 (0.997, 0.998)

482 **Abbreviations: CNV: choroidal neovascularization; ERM: Epiretinal membrane; SD: standard deviation; LOA: limits of agreement; CI: confidence interval; SD:**
 483 **standard deviation; SD-OCT: spectral-domain optical coherence tomography; no, number.**

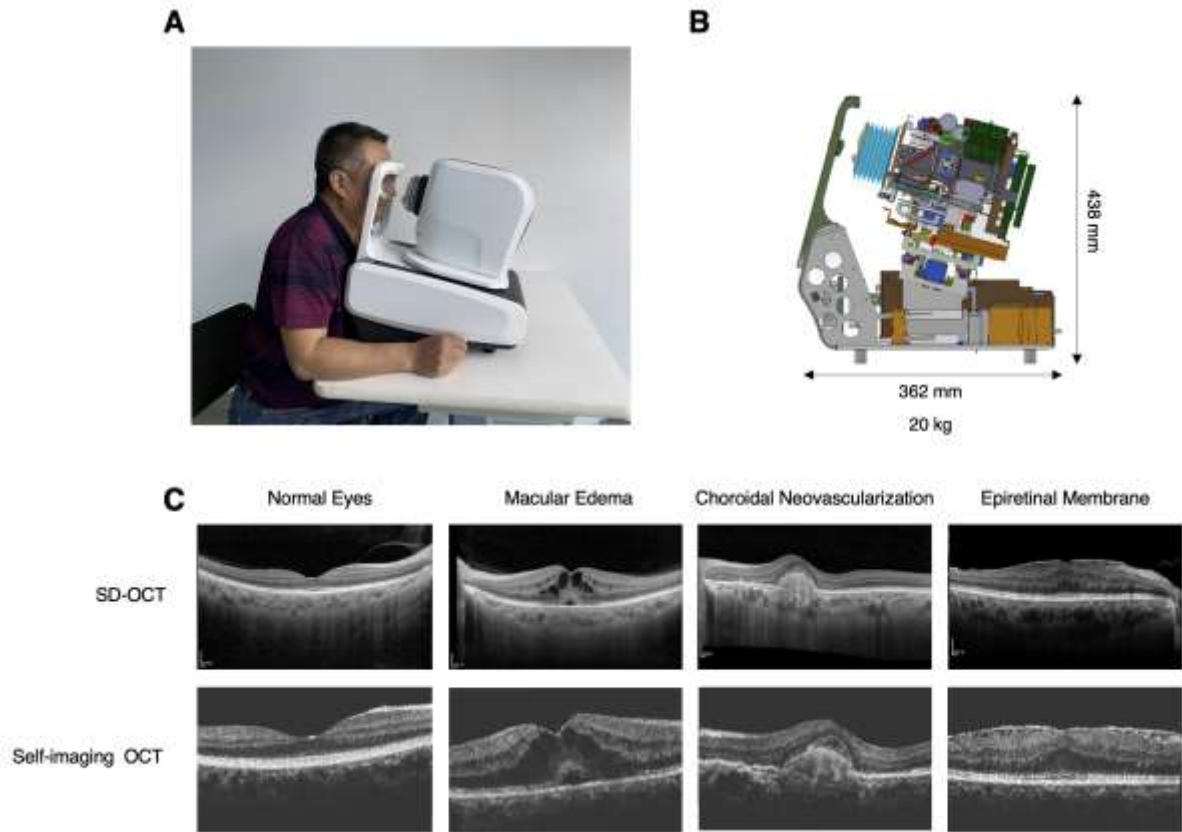
484 **Table 2. Diagnostic concordance between the SD-OCT and self-imaging OCT images from**
 485 **the consecutive cohort**

	SD-OCT	Self-imaging OCT	Rate	Kappa value
Normal	84	81	96.4%	0.9
Epiretinal membranes (ERM)	56	50	89.3%	0.9
Macular edema (intraretinal fluid, ME)	50	43	86.0%	0.85
Choroidal neovascularization (CNV)	23	21	91.3%	0.90
Macular hole (MH)	17	17	100.0%	1
Atrophy of choroid (AC)	15	14	93.3%	0.96
Subretinal fluid (SF)	11	10	90.9%	0.86
Atrophy of retinal out layer (ARO)	8	7	87.5%	0.93
Abnormal of IS/OS (AS)	7	7	100.0%	0.82
Retinoschisis (RS)	2	2	100.0%	0.80
Retinal detachment (RD)	2	1	50.0%	0.50

498 **Abbreviations: SD-OCT: spectral-domain optical coherence tomography.**

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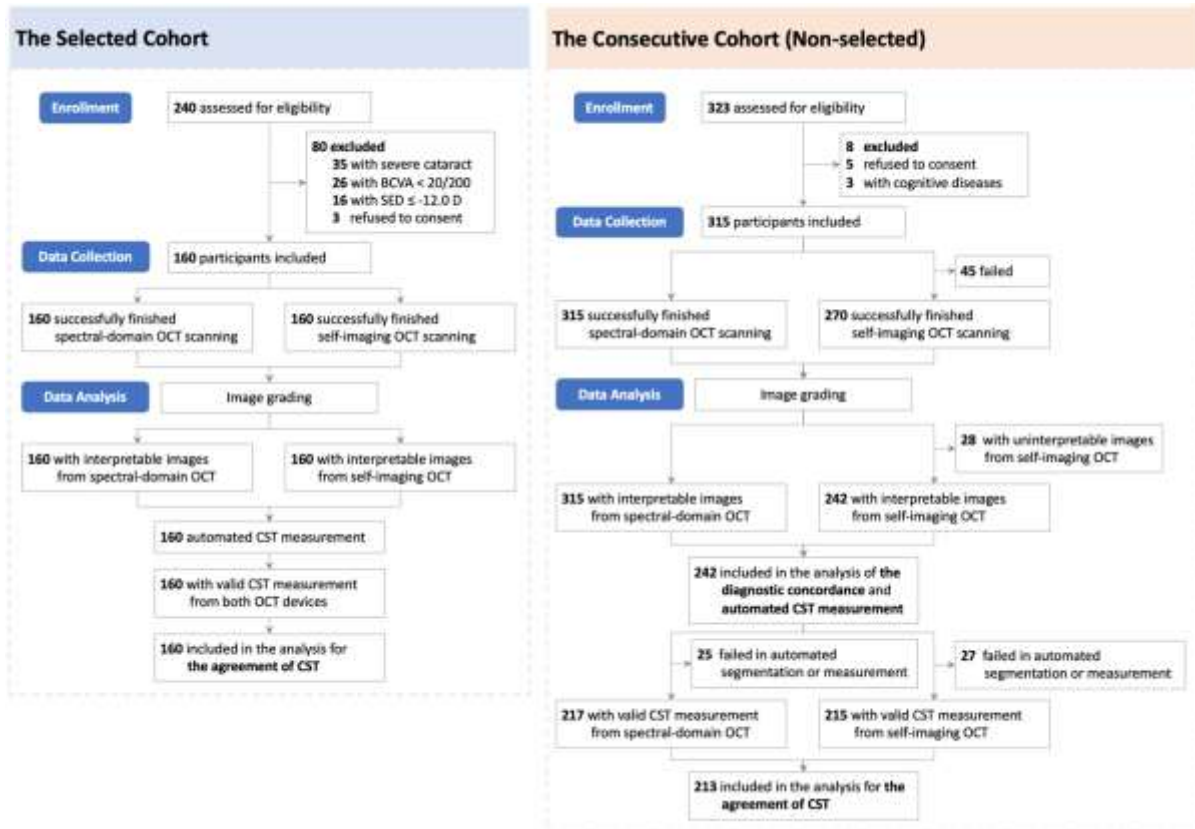
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502 **Figure 1.** Illustration and performance of the self-imaging optical coherence
 503 tomography (OCT) device. **(A, B)** Illustration of the compact design. **(C)** Comparison
 504 of OCT images from the spectral-domain OCT (SD-OCT) and self-imaging OCT (the
 505 same eye for each column). OCT images of normal eyes and eyes with macular
 506 edema, choroidal neovascularization, or epiretinal membrane.

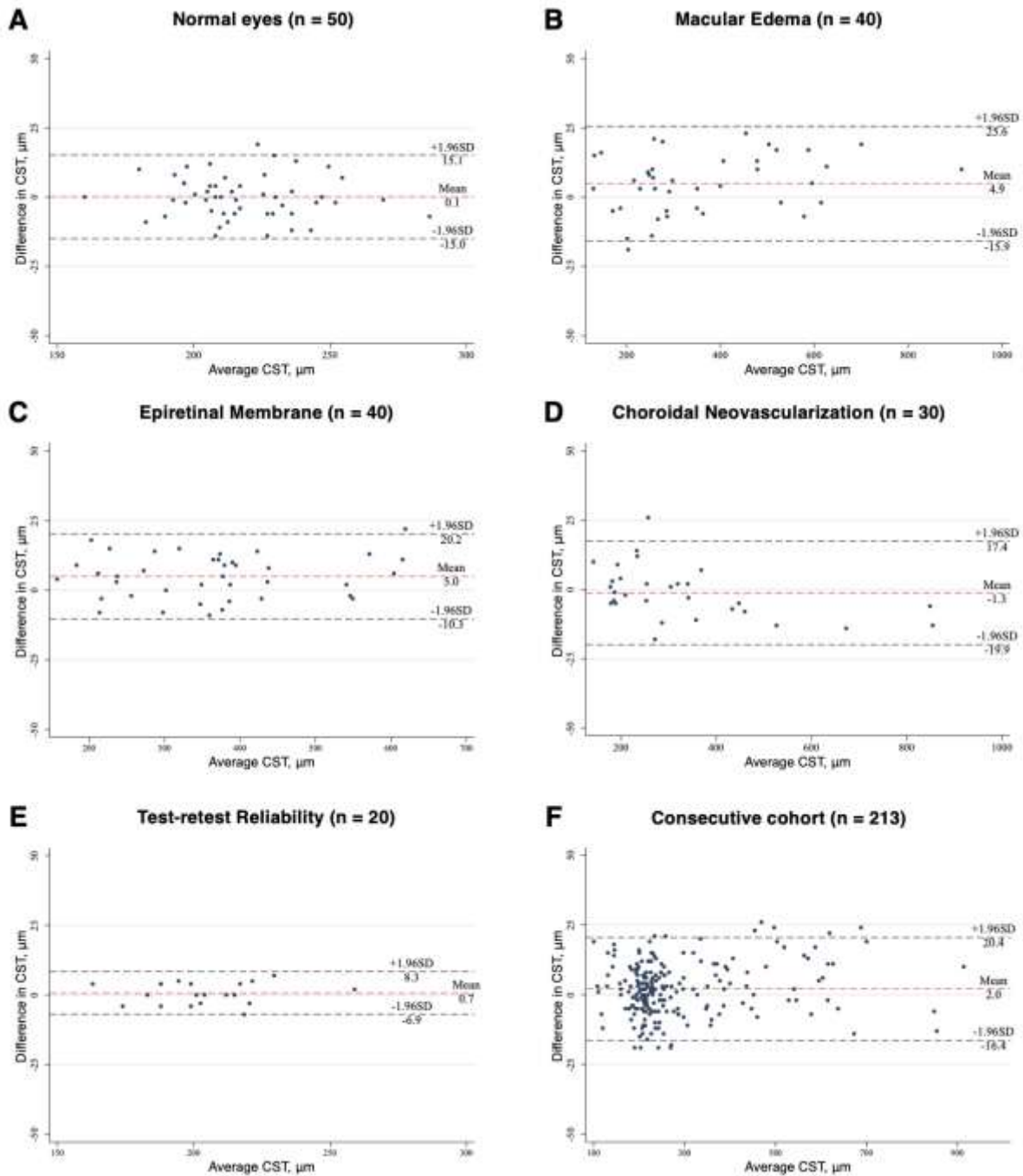
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508 **Figure 2.** Flow chart of the selected and the consecutive (non-selected) cohorts in
 509 this study.

510 Abbreviations: SD-OCT: spectral-domain optical coherence tomography; CST,
 511 central subfield thickness.

512



513 **Figure 3.** Bland Altman plot of central subfield thickness (CST) measurements. **(A-**
 514 **D)** CST measurements by spectral-domain optical coherence tomography (SD-OCT)
 515 and self-imaging OCT in participants of the selected cohort in normal eyes, eyes with
 516 macular edema, choroidal neovascularization (CNV) or epiretinal membrane,
 517 respectively. **(E)** Test-retest reliability in 20 normal eyes. **(F)** CST measurements by
 518 the two types of OCT in eyes with valid CST in the consecutive cohort. Black dashed
 519 horizontal lines: 95% limits of agreement (LOA). Red dashed horizontal lines: mean

520 differences between measurements.

521 **Supplemental Materials**

522

523 **Supplemental Table 1. Baseline characteristics of the participants in the two**
524 **cohorts.**

525

Cohorts	No.	Age (mean [SD])	Sex, (female, no [%])
The selected cohort			
Normal	50	56.9 (14.5)	32 (64.0%)
Macular edema*	40	55.0 (10.9)	20 (50.0%)
CNV [#]	30	61.8 (13.8)	17 (56.7%)
Epiretinal membrane	40	60.8 (11.2)	24 (60.0%)
The consecutive cohort	315	57.0(13.1)	181 (57.5%)

526 *Macular edema: secondary to diabetic retinopathy or retinal vein occlusion

527 [#]CNV: choroidal neovascularization secondary to age related macular degeneration, myopic macular
528 neovascularization or idiopathic

529

530

531 **Supplemental Table 2. Performance of the two OCT devices in the consecutive**
532 **cohort.**

533

Categories	No. (n / N [%])	
	Self-imaging OCT	SD-OCT
Total participants	315	
Failed the self-imaging	45 / 315 (14.3%)	N/A
Not able to operate the device by themselves	9 / 315 (2.9%)	N/A
Not able to fixate on the target	36 / 315 (11.4%)	N/A
Completed the self-imaging	270 / 315 (85.7%)	N/A
Included in the image grading	270	
With uninterpretable images	28 / 270 (10.4%)	N/A
Images with poor quality	20 / 270 (7.4%)	N/A
Macular region not captured	8 / 270 (3.0%)	N/A
With interpretable images	242 / 270 (89.6%)	315 / 315 (100%)
Included in the diagnosis concordance analysis and segmentation	242	
Failed in the automated segmentation	10 / 242 (4.1%)	8 / 242 (3.3%)
Segmentation error	1 / 242 (0.4%)	1 / 242 (0.4%)
No segmentation	9 / 242 (3.7%)	7 / 242 (2.9%)
Excluded due to macular holes	17 / 242 (7.0%)	17 / 242 (7.0%)
With valid CST	215 / 242 (88.8%)	217 / 242 (89.7%)
With valid CST from both devices	213	

534 **Abbreviations:** SD-OCT: spectral-domain optical coherence tomography; CST: central subfield
535 thickness; N/A, not applicable

536

537 **Supplemental Table 3. Subjective assessments of self-imaging OCT in the**
 538 **consecutive cohort.**

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
The tasks to scan my eye using the self-testing OCT were easy to perform.	67%	22%	5%	6%	0%
I felt comfortable during the self-imaging.	72%	17%	5%	5%	1%
The time for self-testing was shorter than the one for conventional OCT.	35%	34%	8%	18%	5%
I prefer to use self-testing OCT to scan my eye when needed next time.	43%	30%	8%	16%	3%

539 Abbreviations: OCT, optical coherence tomography.