Intra-examiner repeatability and inter-examiner reproducibility of subjective refraction

Authors : *Kelly Woog, PhD ; Jérôme Perderiset Msc ; Damien Gatinel, MD, PhD ; Laure Pichereau, Msc*

Objectifs :

- Literature review on repeatability and reproducibility of subjective refraction to examine the allowable range of dispersion between two measurements,
- Bibliographical study on the parameters which can be at the origin of refraction errors between two measurements.
- Clinical study comparing a classic subjective refraction performed by an expert to that obtained by a new device allowing the automation of the eye examination process (SiVIEW Solution).

I. Bibliographical study

Factors that may cause refraction errors

- Fluctuations in the optical quality of the retinal image (unstable tear film or floating bodies),
- The measuring step.
- Low VA: lower sensitivity: higher measurement uncertainty,
- The examiner's method of questioning, the patient's answers, and how the answers are interpreted by the examiner,
- Accommodative physiological fluctuations and accommodative spasms,
- The size of the pupil, conditioning the depth of field of the eye,
- Pathologies (diabetes, some drugs...).

Intra-examiner repeatability

	Freemann and Hodd 1955	Zadnik et al., 1992	Rosenfield and Chiu 1995	Smith et al 2006	Goss & Grosvenor 1996
N patients	17	40	12	Nc	Literary Review
Âge	19-38 y	20-43 y	23-60 y	Nc	Literary Review
Ametropia	Emmetrope to hypermetrope	-10D à +2 D Cyl 0 to -1.50D	Mean Sph = -1.79D Mean Cyl = -0.45D	Nc	Literary Review
Conclusions	Mean difference in absolute value : ▪ **0.13D (S)** ▪ **0.080 (C)** ▪ **4° (Axis)**	Cycloplegic-free95% LoA : • **± 0,63 D** <u>Note:</u> Confusion between repeatability and reproducibility	95% LoA : • **± 0,30 D for ES** • **± 0,27 D for S** • **± 0,16 D for C** • **± 17.1° for A** (attention: mean of the SDs and not of the variances: values lower than those actually obtained)	95% LoA : **0.6 D**	**80%** LoA : • **0.25D** min **95%** LoA : • **0.50D** min (S, ES, C)

Inter-examiner reproducibility

	MacKenzie, 2008	Pesudovs et al., 2007	Grein et al., 2014	Goss & Grosvenor 1996	Leinonen et al., 2006	Sloane et al., 1954	French and Jennings, 1974	Perrigin et al., 1982	Bullimore 1998
N patients	1	16	20	Literary Review	22 healthy patients (T=99)	21	12	32	86
N examiners	40	4	6	Literary Review	8	3	12	3	2
Âge	29 y	Nc	28-72 y	Literary Review	26-89 y	14-18 y	Students	Students	11-60 y
Ametropia	Small myopia	Nc	SE between - 6.19 and +1.98 D Cyl between 0.08 and 4.32 D	Literary Review	-6.1 D à +3.8D	Myopic and weak or no astigmatism	Nc	Nc	SE between -7.50 and +2.50D Cyl max : 4.00D
Conclusions	**<u>95% LoA</u>** (sur SD) : • **±0,549 D (SE)** • **±0,47 D (C)** **<u>Limit of reproductibility</u>** – ($\sqrt{2}$ x 1.96 x SD) : **±0,78 D (SE)**	**<u>95% LoA</u>** : • **± 0,484 D** (SE) • **0,345 D** (Cyl) • **0,611 D** (total vector) <u>Note:</u> no calculation details	**<u>95% LoA</u>** : • **±0,2 D à ±0,65 D** for ES and cylinder	**80%** LoA : • **0.25D** min **95%** LoA : • **0.50D** min (S, ES, C)	**<u>95% LoA</u>** (on T) : • **± 0.74D (ES)** • **± 0.34D (C)** **<u>95% LoA</u>** (0,3<VA<0,45) : • **± 1.14D** (SE) **<u>95% LoA</u>** (VA ≥ 0.7) : • **± 0.51D** (ES) <u>Note:</u> confusion between repeatability and reproducibility	**<u>Difference ≤ 0.25D</u>** In 73% (SE) In 79% (S) In 81% (C) **<u>Difference ≤ 0.50D</u>** In 97% (SE) In 90% (S) In 99% (C)	**<u>Difference ≤ 0.25D</u>** In 68% (S) In 85% (C) Best repeatability when ref between -2.00 and +0.50	**<u>Difference ≤ 0.25D</u>** In 78% (ES) In 88% (S) In 92% (C) **<u>Difference ≤ 0.50D</u>** In 95% (ES) In 98% (S) In 98% (C) **<u>Axe</u> :** 65% dans les 5° 87% dans les 10°	**<u>95% LoA</u>** : SE • **-0.90 à +0.65 D** • bias between the 2 clinicians (-0.12D) **<u>95% LoA</u>** : Cyl • **-0.37D à +0.39D** • No bias

Conclusion : Limit of agreement (**LoA =** 1.96 x SD) in 95% of cases : **+/-0.50D** for the ES, the sphere and the cylinder. **Limit of reproductibility** = √2*LoA ≈ **0.71D** (0,78D for MacKenzie).

II. Clinical Study

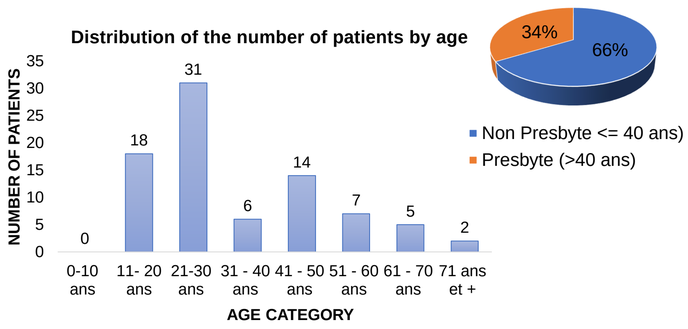
<u>Purpose</u>: Comparing a new automated eye examination device to a classical subjective refraction

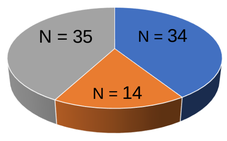
METHOD

- **83** patients (LE)
- from **15 to 78 y** (mean 34 y)

- 1 **traditional** subjective refraction
  - **Examiner 1**
- 1 automated refraction by **SIVIEW**
  - **Examiner 2**

- Sphere between -7.75D and +9.50D
- Cylinder between 0 and - 4,00D
- ES between -8.50D and +8.75D

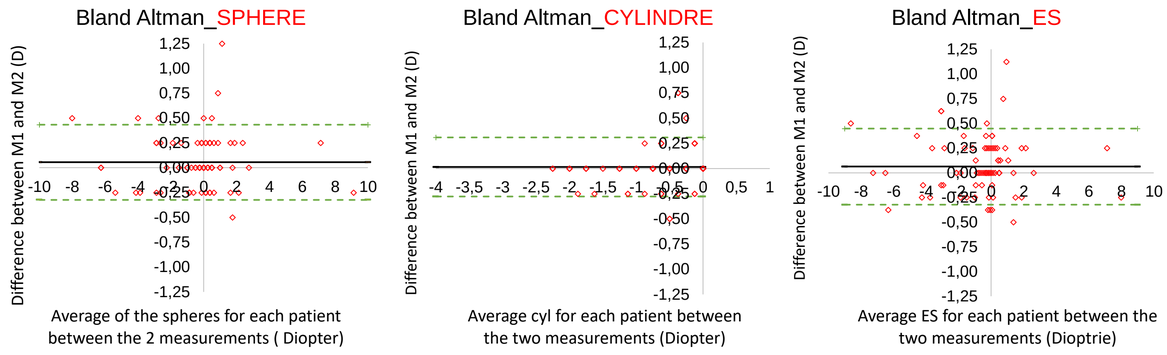




Description of SiVIEW solution

- Connected and **automated** eye examination solutionPlug & Play
- **Easy, intuitive, fast and accurate**
- Possibility of **delegating** tasks while leaving the practitioner at the heart of the final decision thanks to a **detailed report**

RESULTS



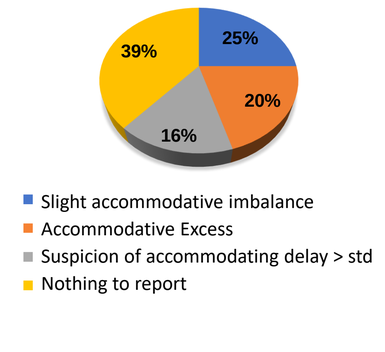
—— = Average of differences
- - - = Average +/- LoA (mean +/- 1,96xSD)

	S	C	SE
LoA	0,38	0,29	0,39
Repro limit	**0,54**	**0,42**	**0,55**

NEAR VISION :

- Tested on 44 people including 31 with a NV recommended by SiVIEW, according to case study and DV refraction.
- Age : mean 23 y (min 17 y - max 31 y)
- **95% of the additions have been confirmed by the expert and accepted by the patient.**
- For only 1 person, the addition was not confirmed by the expert.

Accommodating behaviour (NV)



CONCLUSION

- ✓ **No clinical difference** between the two measurement methods
- ✓ **LoA** between **0.29** and **0.39D** for sphere, cylinder and SE
- ✓ **Reproducibility limit** between **0.42** and **0.55D**

⇒ **Lower than the results found in the literature**

⇒ **Reliable, precise and reproducible**

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