Evaluation of a Novel Self-Refraction Device (USee) to Measure Refractive Error in Adults – A Pilot Study

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Introduction

Uncorrected refractive error is the leading cause of preventable visual impairment worldwide.[1]

- As of 2010, **108 million people were living with moderate to severe vision impairment caused by uncorrected refractive error alone.**[1]
- Vision impairment from uncorrected refractive error causes significant social (education and employment) and economic impact ($269 billion loss to global economy due to lost productivity).[2]
- 90% of this vision impairment occurs in low to middle-income countries and is due to a **lack of eye care providers and eye care resources.**[3]
- The World Health Organization (WHO) estimates **65,000 more eye care professionals** (OD, MD, opticians) for providing refractive correction to the **703 million people in need**, **costing up to $2.8 billion** in facilities and personnel training.[4]
- One alternative studied is the **use of self-adjusting spectacles.** Previously, two prototypes (**fluid-filled and Alvarez designs**) have proven to offer excellent visual acuity in adults and children.[3] The first type involves fluid being injected or removed to alter the power of the lens system. The other is a two-lens system where each lens moves relative to one another to change the power.[5]
- Although these designs were inexpensive, their disadvantages include poor cosmesis, heaviness of frame, and poor optical quality.[5,6] **The limitations with these spectacle options led to the creation of the USee device.**

How USee works:

- USee contains a refraction bar with refractive powers ranging from **+6 diopters (D) to -6D sphere**, fit into a trial frame with a small viewing aperture.
- As the user fixates monocularly on a distance target and rotates the dial, the image comes into focus as the refractive error is corrected.
- The prescription is determined based on the **spherical equivalent (SE)** in each eye

Image a. USee self refraction device

Image b. Subject doing monocular self-refraction with the USee device

Image c. Subject wearing USee pop-in spectacles

Image d. Frame and lens options for pop-in spectacles

Previous Self-Refraction Prototypes:

1. Fluid filled self-adjustable spectacles

Image from: http://www.bmj.com/content/343/bmj.d4767

2. Alvarez dual lens adjustable spectacles

Image from: https://sullens.com/product/adjustables/

Purpose

- The purpose of this pilot study is **to compare refractive error measurements from the USee device to those obtained by conventional refraction in adults.**
- Ultimately, it is hoped that the USee can be used to **refract and prescribe glasses for patients in developing countries where eye care resources are scarce.**

Methods

Subjects:

•**48 students** from the New England College of Optometry (mean age 25.2 years, 79.2% female) with:

- Uncorrected visual acuity of ≤20/40
- Known spherical equivalent (SE) refractive error of:
  - **≤6.00 diopters (D) myopia or hyperopia in both eyes or ≤2.00D astigmatism in both eyes**

Procedure:

1. Autorefraction
2. Monocular self-refraction by the USee device
3. Visual acuity (VA) through pop-in spectacles using the USee refraction
4. Vision through +0.50D over the pop-in spectacles
5. Clinical manifest refraction by the investigator
6. Exit survey on the USee device experience

Exclusion Criteria:

1.Eye surgery in the past 30 days
2.Significant ocular pathology including amblyopia and or strabismus.
3.Vision 20/30 or better WITHOUT correction in both eyes.

Results

Table 1. Characteristics of Study Population (N = 48)

Mean (SD) Age (in years)	25.5 (4.5)
Age range (in years)	22 – 42
Female, n (%)	38 (79.2%)
Handedness, n (%)	
Right	47 (97.9%)
Left	1 (2.1%)
Ambidextrous	0
Ethnicity, n (%)	
Non-Hispanic	46 (95.8%)
Hispanic	1 (2.1%)
Declined to answer	1 (2.1%)
Race, n (%)	
White/ Caucasian	21 (43.8%)
Asian	25 (52.1%)
Native American	1 (2.1%)
Declined to answer	1 (2.1%)

Table 2. Distribution of visual acuity (VA) after refraction.

	USee BCVA		Clinical BCVA	
Snellen VA (logMAR)	Better eye	Worse eye	Better eye	Worse eye
20/15 (-0.1)	28	16	24	21
20/20 (0)	16	22	21	24
20/25 (0.1)	3	9	1	1
20/32 (0.2)	1	1	0	0
Median VA in logMAR	-0.1	0	-0.1	0
Mean (SD) VA in logMAR	-0.1 (0.1)	0.0 (0.1)	-0.1 (0.1)	-0.1 (0.1)

BCVA = Best Corrected Visual Acuity

Table 3. Difference in Spherical Equivalent (SE) in Diopters

	Right eye	Left eye
Mean (SD)	0.16 (0.9)	0.18 (0.6)
Median	0.1875	0.1875
Range	-2.25, 3.125	-1.25, 1.375

Results - con't

Figure 1. Modified Bland Altman of difference in SE (MRx vs USee) for right eye.

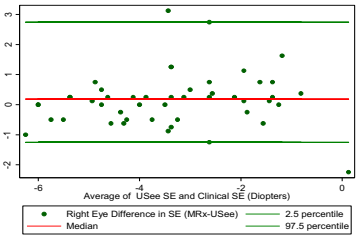
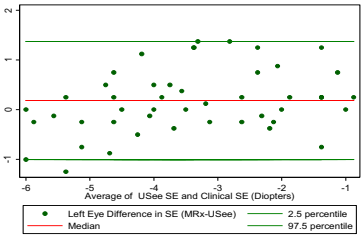


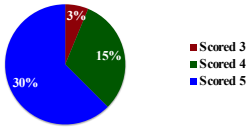
Figure 2. Modified Bland Altman of difference in SE (MRx vs USee) for left eye.



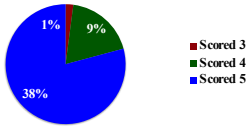
Exit Survey

Scoring Criteria:
1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree.

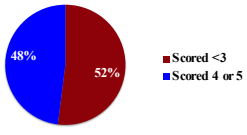
"The USee Was Easy To Use"



"Compared to No Correction, the Pop-in Glasses Made my Vision Better"

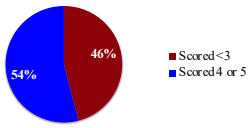


"The Pop-in Glasses Work as Well as my Current Correction"



Results - con't

"How Would You Rate Your Vision With the Pop-in Glasses?"



Scoring Criteria: 1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent

Discussion

- This *pilot study* compared the novel self-refraction device (USee) to conventional refraction in adults.
- **The mean BCVA was identical between USee refraction and manifest refraction in the better eye**. These results are comparable to previous studies with fluid-filled and Alvarez designs.
- One difference in this study was the inconsistency between the right and left eye. Clinical BCVA and USee BCVA were similar for the right eye, but more variable in the left. Such results may relate to the majority (97.9%) of our subjects being right-handed.
- **USee self-refraction is easy to use in adults.** The final vision with the device is better than no correction at all. No prior research has discussed subjective acceptance of self-adjustable spectacles. Future research will focus on overall visual function (stereopsis, contrast, glare) and self-esteem.
- The major limitation of this study was the **small sample size**. All subjects were also students at the New England College of Optometry with prior visual correction.

Conclusion

- Self-refraction with the USee device demonstrates comparable measures of SE and BCVA to that of manifest refraction and autorefraction for low to moderate refractive errors in young adult optometry students.
- Ultimately, it is hoped that the USee can be used to refract and prescribe glasses for patients in developing countries where eye care resources are scarce.
- Future studies will focus on the **usability of the USee device in a broader range of ages, including children.**

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