

2022-09

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<http://hdl.handle.net/10026.1/18818>

10.1177/11206721211069737

European Journal of Ophthalmology

SAGE Publications

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One-year post-operative comparison of visual function and patient satisfaction with trifocal and extended depth of focus intraocular lenses

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Abstract

Purpose: To evaluate visual performance with trifocal and extended depth of focus IOL at 1 year post-operatively. **Setting :** BMI Southend Hospital. **Design:** Cohort study. **Methods:** An age-matched cohort of forty subjects bilaterally implanted with the AT LISA 839MP trifocal IOL (20 patients, 40 eyes) and the Tecnis Symphony extended depth of focus IOL (20 patients, 40 eyes) were assessed at 3–6 months and 12–18 months post-operatively. Primary outcome measures were distance (6 m), intermediate (70 cm), near visual acuity (40 cm), and analysis of defocus profiles. Secondary outcomes included contrast sensitivity, Radner reading performance, quality of vision and assessment of halos. **Results:** Distance visual acuity (VA) and defocus areas were similar ($p = 0.07$). No significant difference in intermediate VA was noted but the intermediate area of focus was greater in the EDoF ($0.31 \pm 0.12 \text{ LogMAR} \cdot \text{m}^{-1}$) compared to the trifocal ($0.22 \pm 0.08 \text{ LogMAR} \cdot \text{m}^{-1}$) ($p = 0.02$). However, all near metrics were significantly better in the trifocal group. 80% of trifocal subjects were spectacle independent compared to 50% EDoF subjects. Quality of vision questionnaire found no significant differences between groups, however halo scores were greater at 3–6 months in the trifocal group ($p < 0.01$) but no differences were noted at 12–18 months. **Conclusions:** Near vision is significantly better for the trifocal, thus greater levels of spectacle independence. The range of intermediate vision was greater for the EDoF but no difference in intermediate VA. In the early period, differences in contrast sensitivity and halo size/intensity were noted, however, by one-year these measures were not significantly different.

In an era, where computer use is commonplace, good intermediate vision is desirable to patients considering refractive surgery. In this regard, despite being linked to increased photopic phenomena both in vitro^{1,2} and in vivo, trifocal multifocal intraocular lenses (MIOL) improve greater intermediate vision resulting relative to a traditional bifocal MIOL^{3–5} More recently, extended depth of focus (EDoF) IOLs have been marketed as alternatives to MIOLs and promise high quality intermediate vision with minimal dysphotopsia.⁶ Comparative studies have shown unaided near vision to be inferior in EDoF IOLs compared to a MIOL but intermediate and distance vision to be at least equivocal.^{7–11} The definition of an EDOF is relatively inclusive and hence there is a diverse assortment of optical principles for which these lenses are based including; diffractive optics, small aperture designs, bioanalogic hydrogels, and asphericity.^{6,12,13}

A number of comparative studies have been published investigating trifocal and EDoF IOLs,¹³ however our literature search revealed there are only three which directly compare clinical outcomes of the AT LISA 839MP trifocal MIOL and the Tecnis Symphony EDoF IOL.^{8,11,14} Two of the studies assessed clinical outcomes following a short post-operative interval^{8,11} and the final study assessed subjects at, 1 year post-operatively.¹⁴ In addition one of the studies targeted micromonovision in the EDoF group.¹¹

This study aims to examine the visual outcomes of the AT LISA 839MP trifocal MIOL and the Tecnis Symphony EDoF IOL at both 3–6 months and 12–18 months post implantation using both clinical measures and patient reported quality of vision outcomes.

Methods

This study was a retrospective cohort study. The protocol adheres to the tenets of the Declaration of Helsinki and ethical approval was obtained prior to commencement of the study. Written consent was obtained from all subjects. No modification to the protocol or outcome measures were made during the study.

Patient selection

Forty subjects (80 eyes) attending the BMI Southend Hospital for refractive lens exchange and who were bilaterally implanted with either the Tecnis Symphony (subjects = 20, eyes = 40) or the AT LISA 839MP Trifocal (subjects = 20, eyes = 40) were recruited within a 9-month period. The subjects were best matched according to age, IOL power and gender and had no existing ocular pathology as is our standard practice. nor pre-operative corneal astigmatism $>0.75D$.

One of two experienced consultant ophthalmic surgeons, operated on all subjects, using small incision phacoemulsification. The same surgeon implanted both lenses for an individual subject. In each case, a 2.2 mm clear corneal incision was located on the steepest corneal meridian. There were no surgical, nor post-operative complications. All subjects used topical steroids and antibiotics for 24 days post-operatively as is our standard practice. Second eye surgery was within 4 weeks of initial surgery in all cases.

Primary outcome measures

A clinician who was independent of the selection process but not masked to the IOL type conducted all post-operative visits. Subjects were reviewed at two study visits, Visit1 (3–6 months post-operatively) and Visit 2 (12–18 months post-operatively). At each visit, monocular and binocular logarithm of the minimum angle of resolu-

tion (logMAR) acuities for uncorrected and corrected distance visual acuities were measured using computerized test charts (Thomson Software Solutions Ltd) at 6 m following the Bailey-Lovie principles and using Sloan letters consistent with testing methods established by the Early Treatment Diabetic Retinopathy Study (ETDRS). Subjective refraction was conducted at 6 m with a distance fixation target. The assessment of uncorrected (UNVA) and distance-corrected (DCNVA) near visual acuities, distance corrected intermediate visual acuity used ETDRS charts for near (40 cm), and intermediate (70 cm) (Precision Vision) working distances, respectively. To further assess intermediate and near vision at a range of distances, defocus profiles were plotted from $-5.00 D$ to $1.50 D$ in $0.50 D$ steps.¹⁵ The letters and defocus lenses were randomized between measures, and subjects were prompted once using the phrase “can you read any more letters?”.¹⁶

Secondary outcome measures

CS was assessed binocularly with the CSV-1000 (Precision Vision) calibrated to 2.4 m and both monocularly and binocularly using Pelli-Robson charts at 6 m (Thomson Software). Radner reading charts were used to assess reading speed at 40 cm following the method outlined by Radner using a digital stopwatch.¹⁷ The subjective perception of vision was assessed using a quality of vision questionnaire¹⁸ and NAVQ.¹⁹ Glare simulator (Carl Zeiss AU5 Meditec AG) was used to quantify the appearance of halos and glare. All secondary measures were assessed at visits 1 and 2. The same

assessment room was used throughout the study, and all primary and secondary outcome measures were performed by a single investigator in photopic conditions (illuminance 120 cd/m²; luminance 95 lux).

Statistical analysis

Statistical analysis was performed using SPSS software, version 24 (IBM). All data were tested for normality. In all instances a p value of <0.05 was considered statistically significant. In order to evaluate the effect size, Hedges' g was calculated. A repeated measures ANOVA was used to establish similarity between right and left eyes in both IOL groups. No significant differences were found, thus only right eye data is presented. One-way and two-way ANOVA tests were used to compare differences between IOL groups for VA and contrast sensitivity measures and where differences were found, further pairwise post hoc analysis was performed. Independent t tests were used to assess IOL group difference for all other primary and secondary measures.

The Radner reading data was fitted with a non-linear regression (exponential rise to a maximum) curve. Maximum reading speed (MRS) was defined as the asymptote of this curve and critical print size (CPS) was calculated as the value for x (print size) when the reading speed was 95% of the MRS.

Results

The mean age of subjects was 63.5 ± 12.6 years in the EDoF group and 64.5 ± 7.1 in the Trifocal group (Table 1). The pre-operative refractive error (p = 0.45) and visual acuity (p = 0.37) were similar as was the power of the IOLs implanted (p = 0.47).

Visual acuity

Significant differences were found between groups $F_{1,213} = 16.51$, $p < 0.01$. Further pairwise testing revealed measures of distance and intermediate acuity were similar but UNVA (monocular $p < 0.01$, binocular $p < 0.01$) and DCNVA (monocular $p < 0.01$, binocular $p < 0.01$) was better in the trifocal group at both V1 and V2 (Figure 1). In addition, both reading acuity and critical print size was significantly better in the trifocal cohort at both V1 and V2 (Figure 2).

Refraction

Post-operative refractive error was similar (p = 0.79) for the two cohorts, Manifest Spherical Equivalent was

-0.09 ± 0.52 (EDoF) and -0.05 ± 0.31 (Trifocal).

Defocus

Direct comparison of binocular defocus curves found the trifocal group to have better visual acuity from defocus

-2.50 to -5.00 at both visits. The EDoF group had better VA at -0.50 defocus (p = 0.03) at Visit 1 only and at -1.50 defocus at Visit 2 (p = 0.02) (Figure 3(a)).

No significant difference was identified for the distance area of defocus region (0.5 to -0.5D); within the intermediate range (-0.5 to -2.00) the EDoF cohort had a larger area (p = 0.02), whilst the trifocal IOL performed better (p < 0.01) in the near range (-2.00 to -4.00D) with a notably large effect size (g = 2.69) (Figure 3(b)). The range of focus metrics revealed a greater range for the trifocal cohort (p < 0.01) (Figure 3(c)).

Contrast sensitivity

There was no significant difference in Pelli-Robson contrast sensitivity between groups. Furthermore, the two cohorts achieved similar contrast sensitivity values in photopic conditions for 3, 6 and 12 cpd measured with the CSV-1000. At 18 cpd the EDoF group had significantly better contrast sensitivity at Visit 1 ($p = 0.03$) but not Visit 2 ($p = 0.09$).

Questionnaire

Overall satisfaction was high in both groups for distance and intermediate tasks (>95%). 70% of the EDoF IOL group reported satisfaction with their unaided near vision, whilst 100% of the trifocal cohort were satisfied. (Figure 4(a)). Difficulty scores for near and everyday tasks were similar in both groups (Figure 4(c) and 4(d)). However the NAVQ scores were better in the trifocal cohort at both Visit 1 ($p < 0.01$) and visit 2 ($p < 0.01$) (Figure 4(e)).

The Halo-Glare simulator scores for both halo size ($p < 0.01$) and brightness ($p < 0.01$), were significantly greater in the trifocal group at V1 but were similar by visit 2 (Figure 5(b)). The subjective perceptions of vision difficulty at night were similar for the two lenses (Figure 5(a)),

Discussion

Trifocal MIOLs are designed to reduce spectacle dependence by providing good distance, intermediate and near vision. EDoF IOLs are based on the ethos that distance and intermediate vision are prioritised to minimise the effect on contrast and dysphotopsia. As such, it is

important to evaluate clinically the effects of these design differences over time to evaluate the effect on vision. This study evaluates the visual outcomes of these lenses over a one-year post-operative period and highlights the effect this longer adaption period has on vision.

Distance visual acuity was excellent in both groups and all subjects were satisfied with their distance vision at visit 1 and visit 2. The only difference observed in contrast sensitivity occurred in the 3–6 month visit at 18 cpd where the EDoF cohort performed better. This result is supported Mencucci and colleagues⁸ who also found a significant difference at 18cpd at a three-month timeline. Interestingly by the one-year post-operative visit, this observation was no longer present and contrast sensitivity was similar even at this high spatial frequency, consistent with Lubinski's study.¹⁴ Similarly, at 3–6 months, both halo size and brightness were significantly greater in the trifocal group; however, by the one-year visit these values were similar between cohorts. These striking changes for CS and halo between visit 1 and visit 2 are compelling evidence for an increasing occurrence of neural adaptation in the trifocal cohort over a one-year post-operative period. Lubinski also suggested their contrast sensitivity findings were indicative of adaptation.¹⁴

Previous bench studies have shown contradictory evidence of halo characteristics: Gatinel et al.²⁰ found that halo characteristics were similar in EDoF and bifocal and trifocal IOLs, yet Yoo et al.²¹ suggested that the halo pattern of these EDoF IOLs is actually comparable to monofocal IOLs. Clinically, Monaco et al.¹⁰ found no difference in photic phenomena between an EDoF and a trifocal group, yet Rodov et al.²² found increased levels in trifocals. Lubinski found that halos/glare were more apparent in their trifocal group, yet despite this, the trifocal group reported less difficulty with night driving than the EDoF group.¹⁴ To date, there is no firm agreement in the literature that the dysphotopsia experienced in trifocals is more likely to be symptomatic than in EDoF IOLs. This variability could be related to testing methods, direct questions are more likely to result in a report of glare/ halos than indirect questions and a patient's personality traits and expectations will influence how they cope with such visual disturbances. Within the current study, there was no significant difference in the perceived difficulty in night vision described by subjects.

The present study demonstrated improved Intermediate vision in the EDoF cohort when examining the results of the defocus curves: Both the intermediate area of focus (between -0.5 and $-2.00D$) and vision with $-1.50D$ of defocus (according to the direct comparison method) were better when compared to the Trifocal cohort. Intermediate visual acuity testing failed to illicit such differences with both cohorts demonstrating similar values. In comparison Weber's¹¹ tested intermediate VA at 66 cm, Mencucci used 80 cm⁸ and this study tested at 70 cm. Mencucci also found that intermediate vision was similar whilst Weber's¹¹ found UIVA to be better in the Symphony group, however they themselves questioned whether their finding of a 0.03 LogMAR difference, was clinically relevant, despite being statistically significant. In contrast, Lubinski found better VA in the trifocal group at 70 cms.¹⁴ This discrepancy in findings highlights the inadequacy of VA testing as an isolated measure as it only affords the clinician a snapshot of visual performance at a fixed distance, which may differ between studies, thus direct comparison is rendered impossible.

Both unaided and best corrected near VA was significantly better with the trifocal group and this finding was confirmed by direct comparison of the defocus range and the near area of focus metric. Further affirmation of the heightened near performance is the better NAVQ score achieved in the trifocal group and greater spectacle independence. However, 50% of the EDoF group still achieved complete spectacle independence suggesting that they achieved adequate near vision for their particular lifestyle. This finding is perhaps not unexpected as this was not a randomised trial, thus subjects who chose to have an EDoF IOL were those best suited to its characteristics and likely to benefit from the intermediate VA rather than near. Higher levels of spectacle independence have

been reported in other studies where a micro-monovision approach has been used with EDoF lenses.^{11,23,24}

The defocus profiles illustrated differences in the groups from -2.50D onwards only, thus IOLs performed similarly at -2.00D of defocus (50 cm), and it is likely this is why many subjects do not require spectacles for reading. Webers¹¹ also found differences, in favour of the trifocal, in the defocus curve from -2.50D to -4.00 despite their micromonovision approach. Other studies comparing the defocus curves of these IOLs, have not explored such a wide range and thus cannot be compared adequately.^{23,25} Reading performance assessed with the Radner tests, highlighted improved performance in the trifocal group at all visits. This is an expected finding as this test was performed at 40 cm in photopic conditions, as was visual acuity testing. Both previous studies, reported no differences in CPS, RA or MRS, this is expected when micromonovision has been targeted,¹¹ yet somewhat incongruous in Mencucci's study as it is in direct contrast to their own UNVA and DCNVA finding.⁸

The present study is somewhat limited in its evaluation of these lenses as it was not randomised and did not involve the masking of both subject and assessor. However, it does evaluate the lenses without additional modifications such as micromonovision and includes both short and long term post-operative visits.

Near vision is significantly better for the AT LISA 839MP leading to greater levels of spectacle independence whilst the range of intermediate vision was greater for the EDoF IOL. In the early period (3–6 months) there was a difference in contrast sensitivity and halo size and intensity, with the EDoF performing better however, by one-year post-operatively these measures are similar, suggesting an neuro-adaptive response in the Trifocal group. Overall satisfaction of distance vision is high in both groups.

Meeting presentations:

Nil

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship and/or publication of this article.

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Table 1. Patient demographics.

	EDoF	Trifocal	<i>p</i>
Number of subjects	20 (40 eyes)	20 (40 eyes)	0.48
Male/Female	35% / 65%	30% / 70%	
Mean age (yrs)	63.5 ± 12.6	64.5 ± 7.1	
Range (yrs)	53-74 years	51 -75 years	
Pre-Op Refractive	-8.00 to + 1.83	-9.13 to + 3.60	0.45
Error (DS)	-0.70 ± 3.05	0.10 ± 3.56	
Spherical			
Equivalent Range			
MSE			
Pre-Op visual acuity	0.17 ± 0.14	0.12 ± 0.17	0.37
(logMAR)			
RE CDVA			
IOL Power (D)	10 to 25	12 to 25	0.47
Range	20.4 ± 3.0	20.5 ± 3.7	
Mean			

Data are mean ± Standard deviation ; RE: right eye; CDVA = Corrected distance visual acuity, IOL = Intraocular lens, J0 = cylindrical effect at 180°, J45 = cylindrical effect at 45°, MSE = Manifest spherical equivalent.

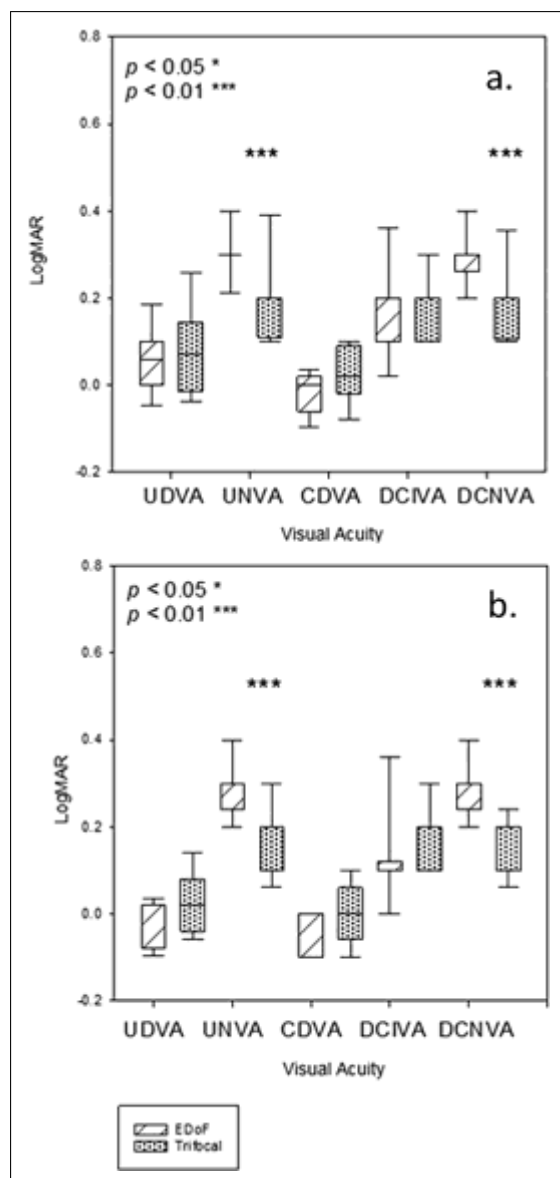


Figure 1. a) V2 monocular visual acuity b) V2 binocular visual acuity.

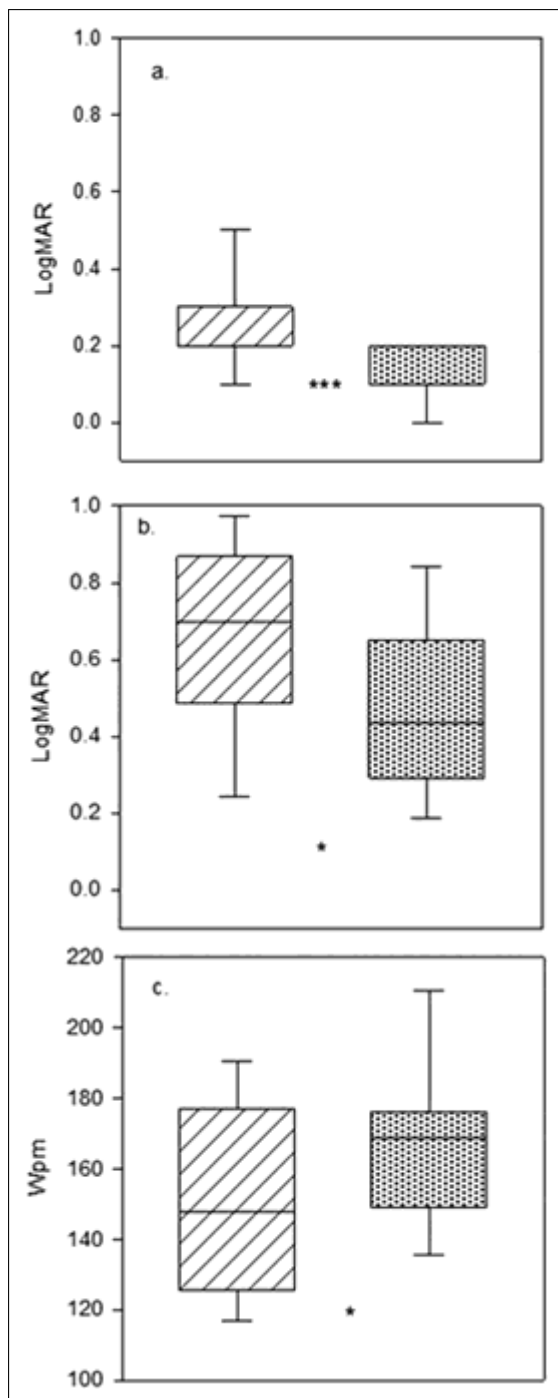


Figure 2. a) V2 radner acuity b) V2 95% critical print size c) V2Maximum reading speed.

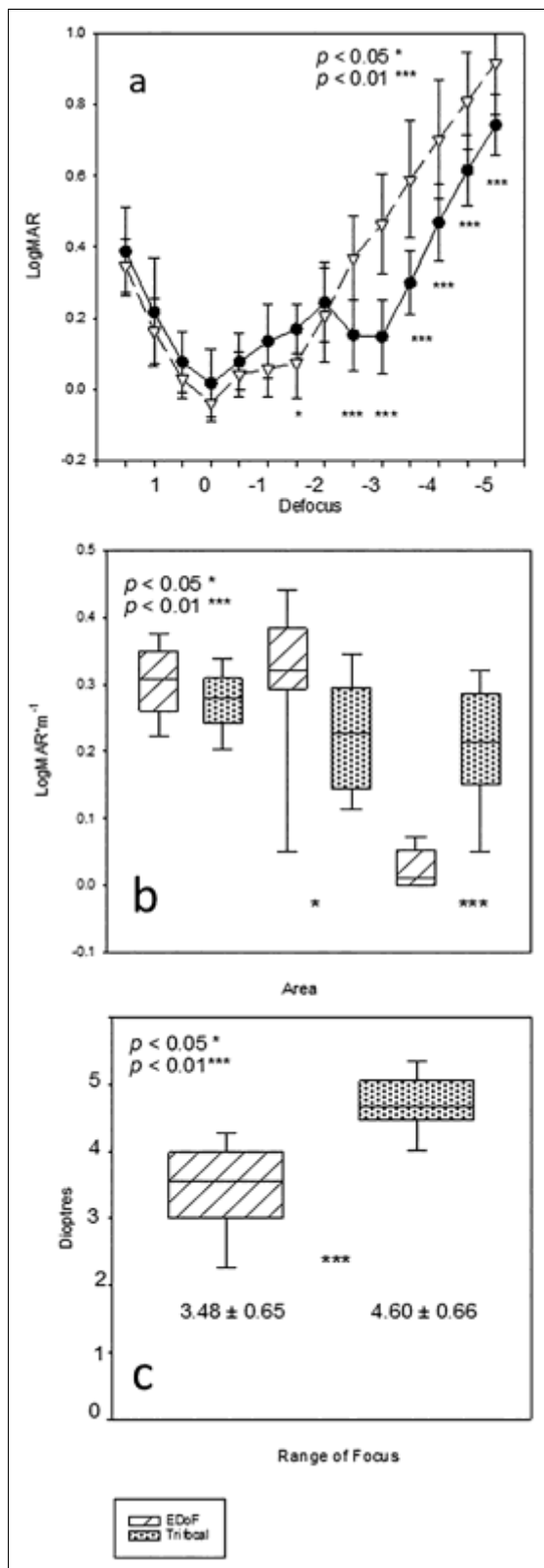


Figure 3. a) V2 defocus profile b) area under defocus curve c) range of focus.

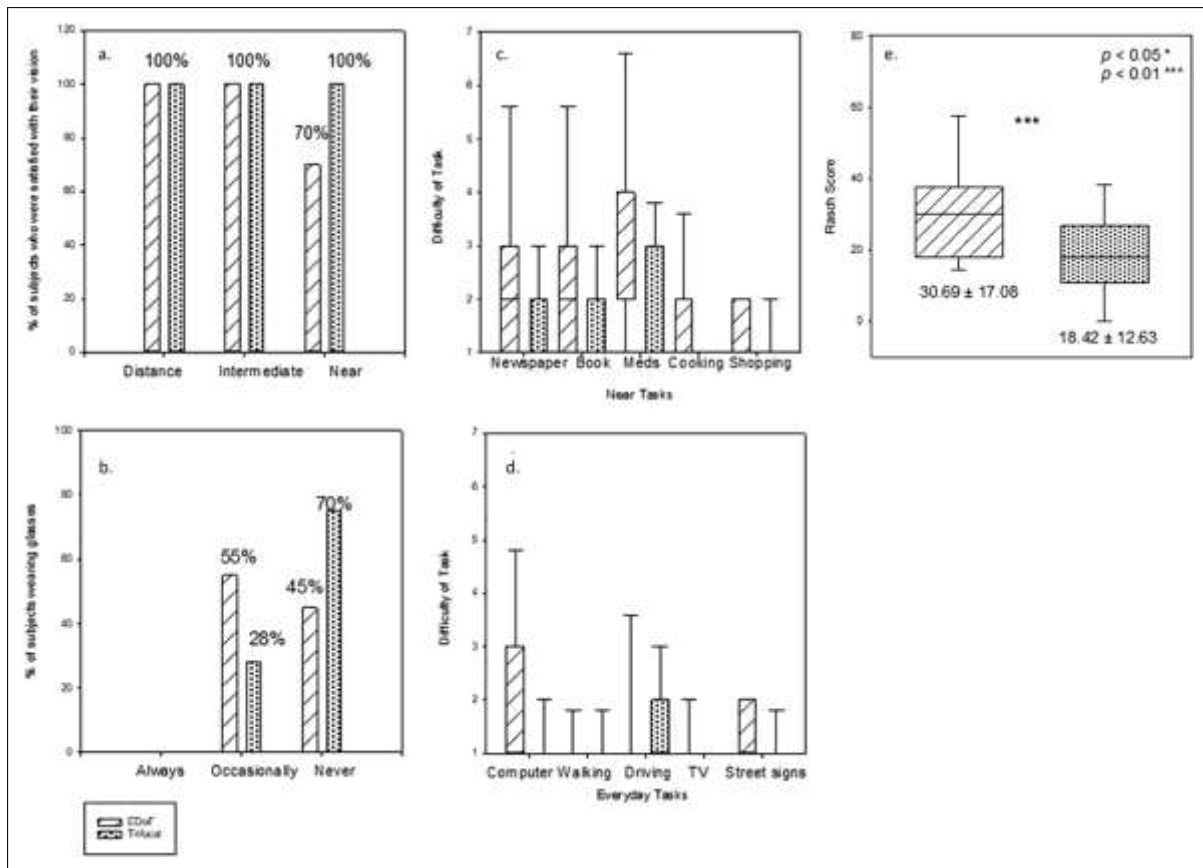


Figure 4. a) satisfaction V2; b) spectacle wear V2; c) near tasks V2; d) everyday tasks V2; e) V2 NAVQ scores.

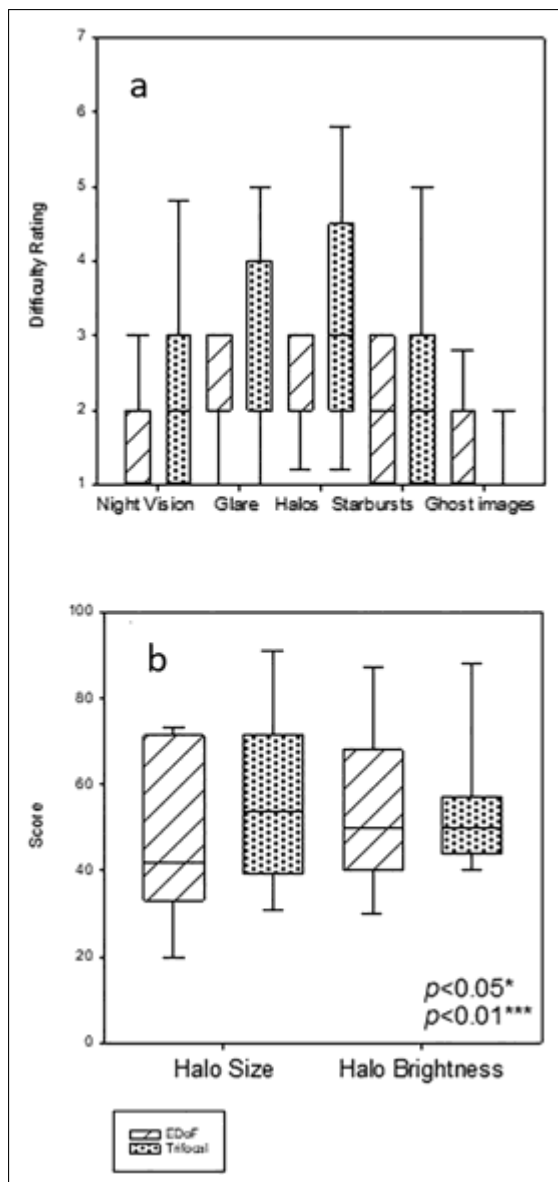


Figure 5. a) Night vision V2 b) Halo V2.