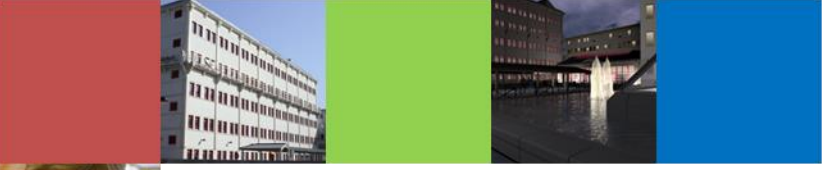
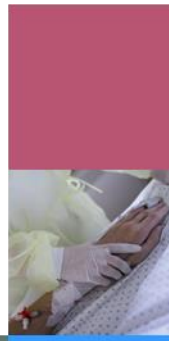


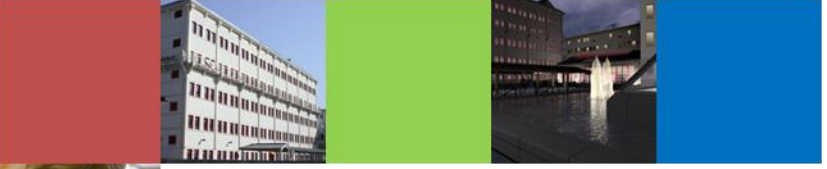
Centre Hospitalier Universitaire et
Psychiatrique de Mons-Borinage

B-Flex Multifocal

Dr Emmanuel Van Acker
Belgium



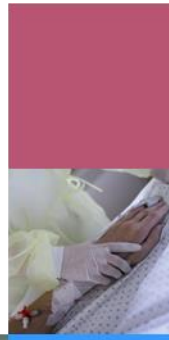
CHU AMBROISE PARÉ



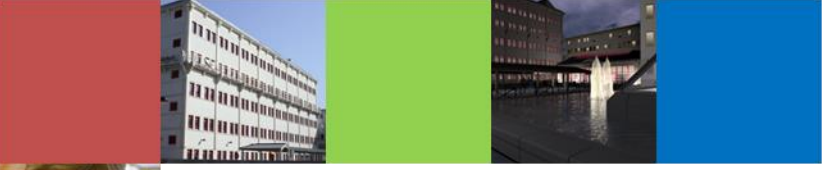
Comparison of clinical outcomes and patient satisfaction after implantation of two different types of diffractive apodized IOLs:

Bi-Flex M (based on PAD technology)
FineVision (Micro F) trifocal diffractive IOL

Prospective, randomized, observational study

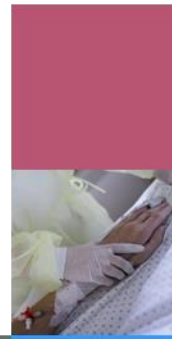



CHU AMBROISE PARÉ



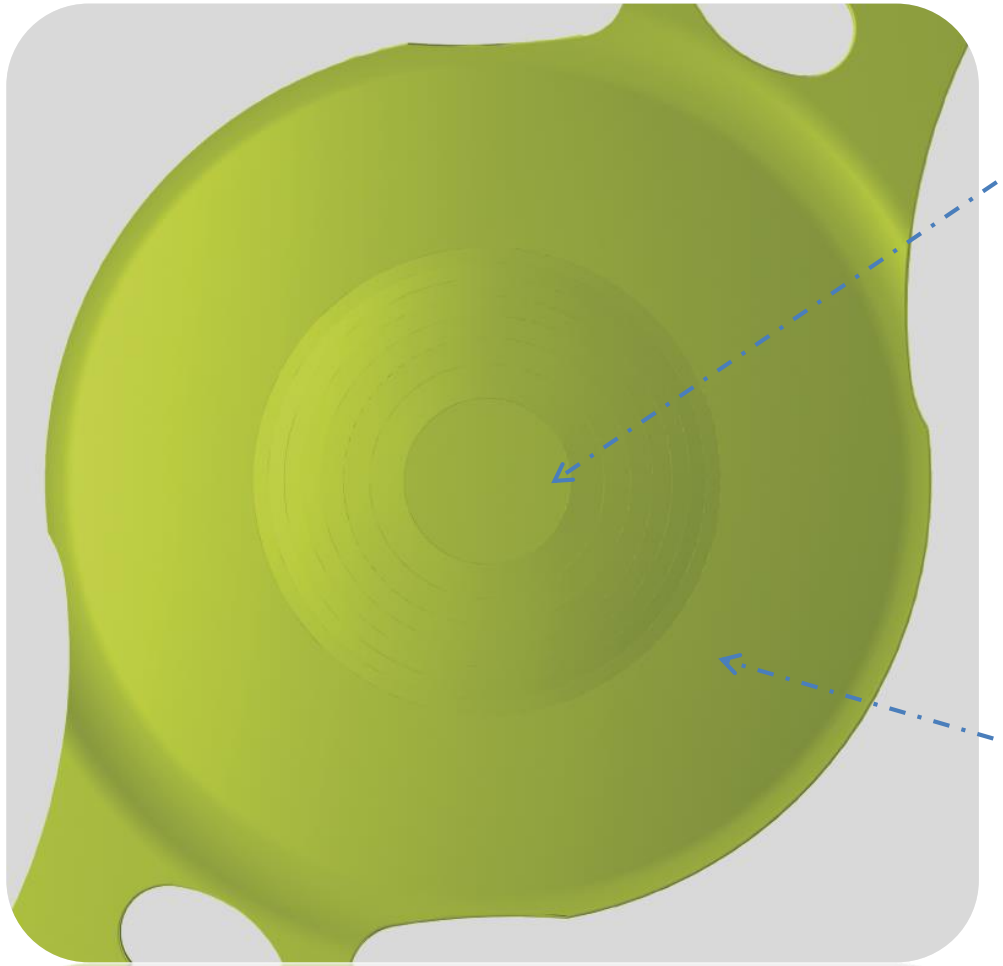
Description *	Value	
	Bi Flex M (677MY) 	**FineVision (MicroF)** 
Optic & haptics material	Hydrophilic acrylic (copolymer formed of 2-HEMA and OEMA) => 25% water content UV filter; Blue light filter (390-440 nm)	
Refractive index	1.46 (when hydrated)	
Optic diameter	6 mm	6.15mm
Overall diameter	13 mm	10.75 mm
IOL	Single piece	Single piece
Technology	Aspheric; Refractive/diffractive apodized; PAD technology	Aspheric; trifocal; diffractive (2 diffractive arrays); apodized
Type of haptics	Double (Z-loop modified)	Four loops haptics
Haptic angulation	0° (posterior voltage)	5°
Available power	+10D to +35D	+10 to + 35D
Addition	+1.75, +3.5	+1.75, +3.5
Estimated Incision	1.8-2.2 mm	1.8
A-Constant SRK II		119.1
A-constant SRK-T	118.9	118.9

*Data of FineVision IOL are taken from official scientific material (brochure; website) from company Physiol




CHU AMBROISE PARÉ

Bi Flex M Technology



Central 3.0 mm apodized diffractive structure

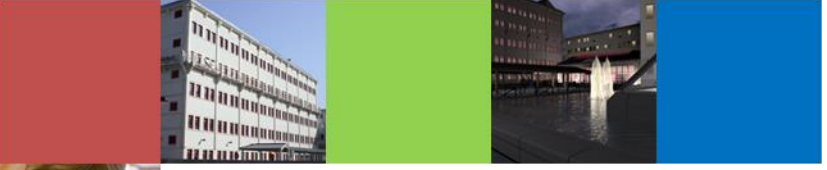
Step heights decrease peripherally from 2.2 – 1.4 microns

+3.5D at lens plane equalling +2.7D at spectacle plane

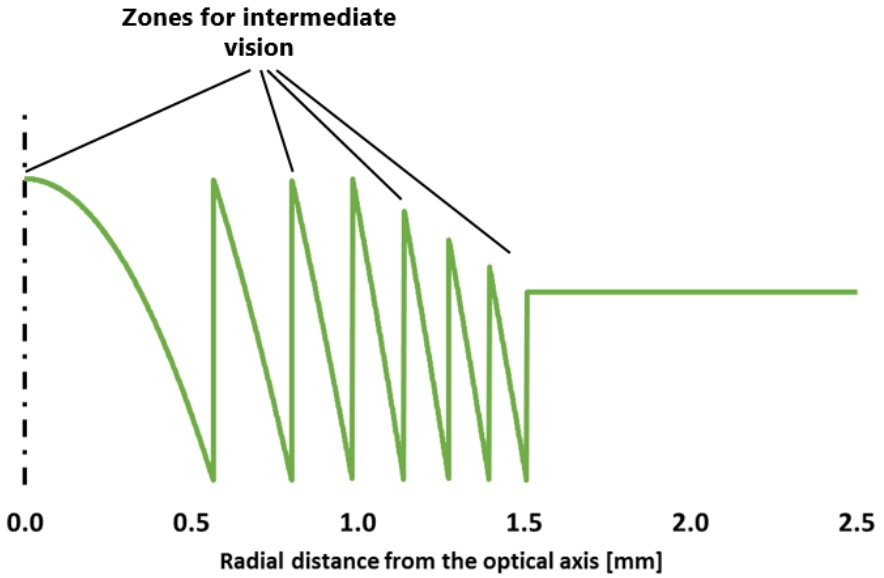
Outer refractive zone

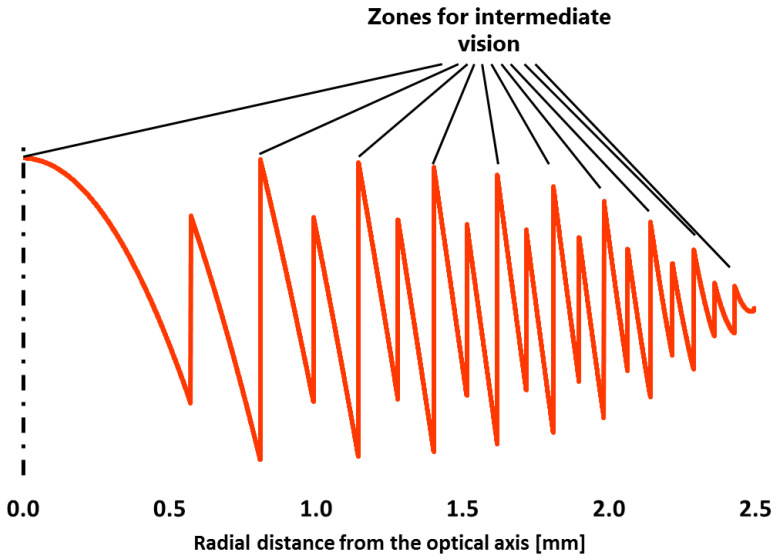
Aspheric (neutral approach)

CHU AMBROISE PARÉ



Bi-Flex M (677MY)	FineVision

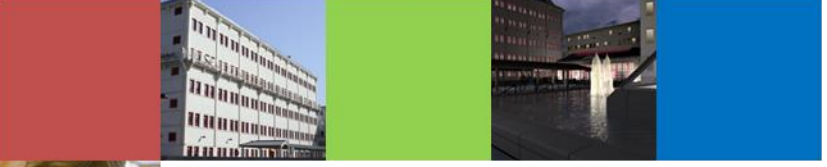




- 7 rings
- Diffractive zone diameter: 3 mm

- 20 rings
- Diffractive zone diameter: full optic

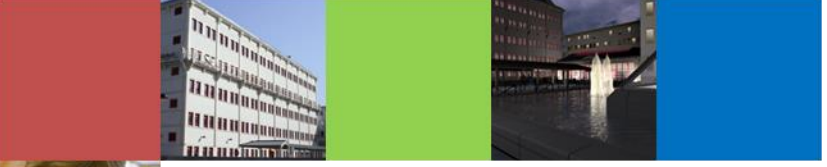
CHU AMBROISE PARÉ



STUDY DESIGN

- Prospective
- Randomly chosen IOL type for each patient
- Consent form
- Tenets of Declaration of Helsinki – international Ethical committee (FEKI)
- Statistical analysis: Mann-Whitney-U test and independent t-test.
  - Significance level was set up to 0,05.
  - Analysis performed by IBM SPSS Statistics version 24.


CHU AMBROISE PARÉ



MEASUREMENTS

Metrovision

Glare test

Contrast sensitivity

Pupillometry

Standard tests

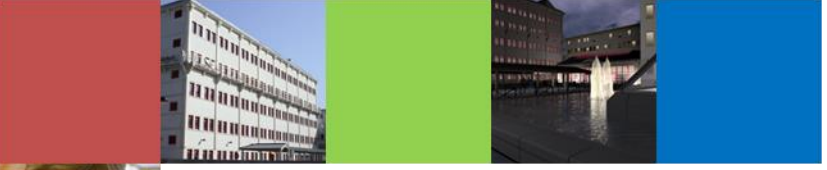
Visual acuity (ETDRS)

Biomicroscopy

Defocus curves

Visual Fct Questionnaire


CHU AMBROISE PARÉ



Examination Test Protocol of the Study

Randomly included patients
Discussion, explanations

Medical history
Pre-operative examination
biometry

Implantation of the IOL bilateral
(interval min. 24 hours)

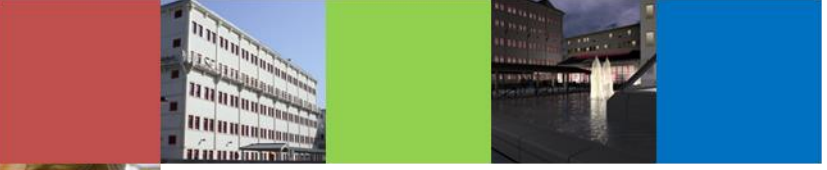
Follow-up
12 months
D1 D7 M1 M3 M6 M12

UCDVA, UCIVA, UVNVA
(monocular, binocular)
ETDRS table (Decimal)

Refraction, intraocular pressure
Contrast sensitivity (Metrovision)
Defocus curves

Subjective satisfaction
Spectacle independency
Optic phenomena's (glare, halo..)
Validated quality of vision questionnaire

CHU AMBROISE PARÉ

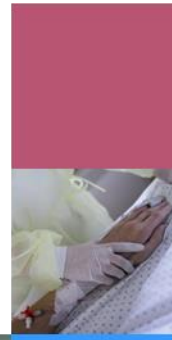


Consecutive patients included

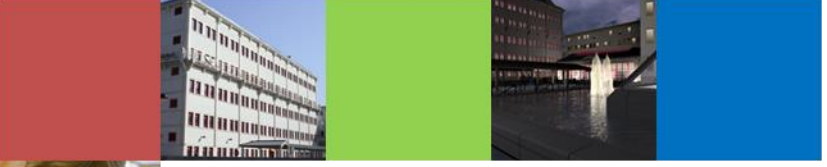
39 patients / 78 eyes

20 patients/ 40 eyes

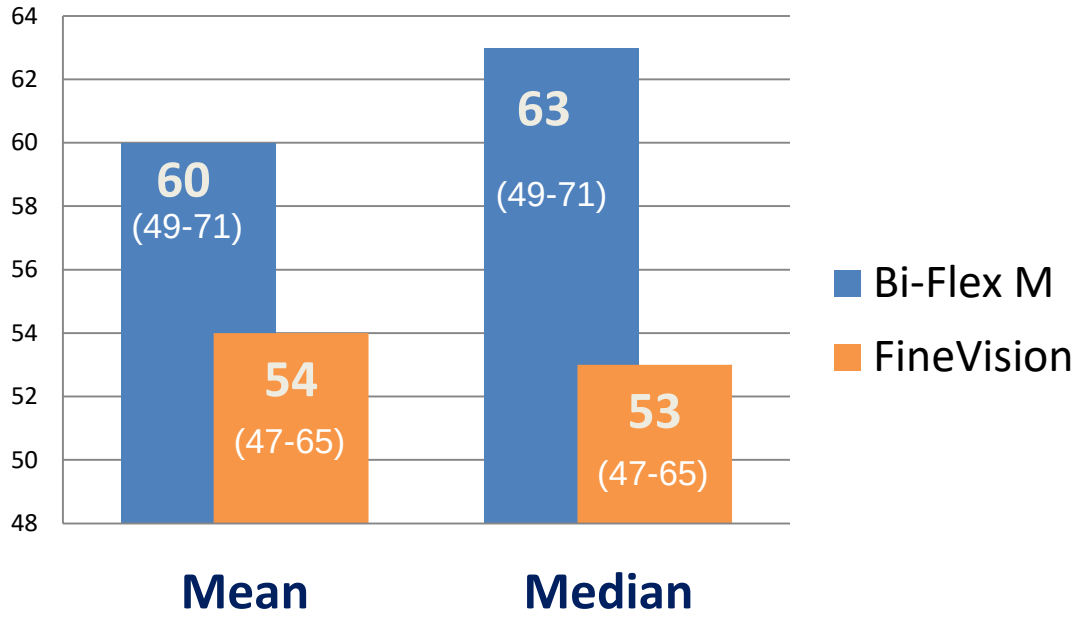
19 patients / 38 eyes



CHU AMBROISE PARÉ

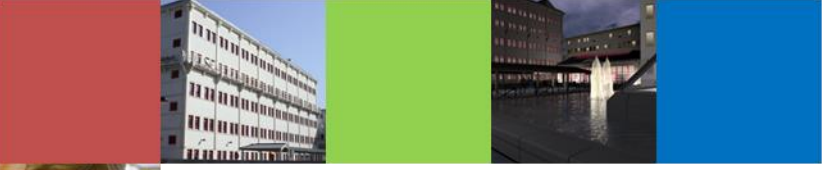


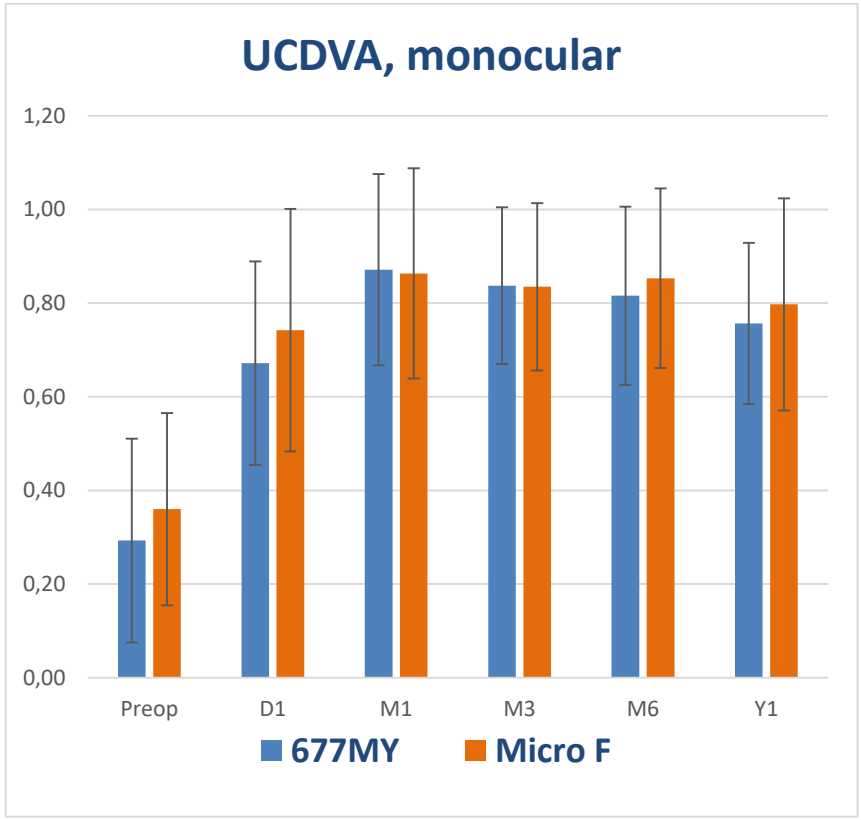
Age of patients

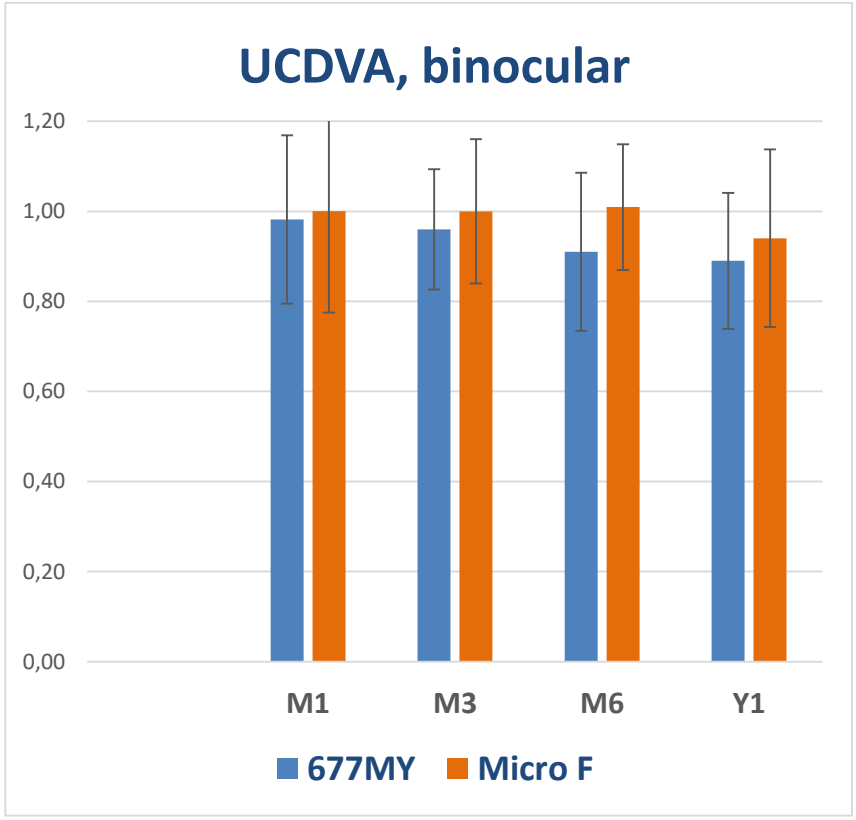


There WERE STATISTICALLY SIGNIFICANT DIFFERENCES IN AGE of patients in between both groups

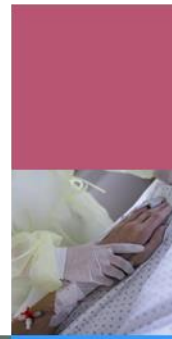

CHU AMBROISE PARÉ



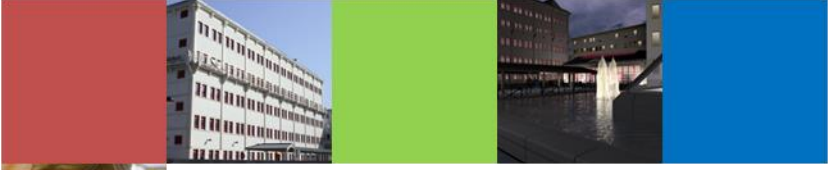


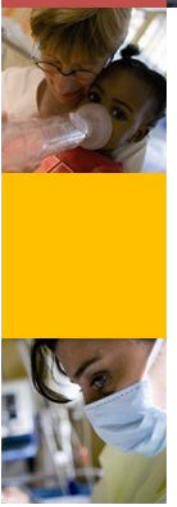


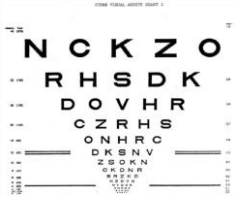
There were NOT STATISTICALLY SIGNIFICANT DIFFERENCES IN BINOCULAR VA

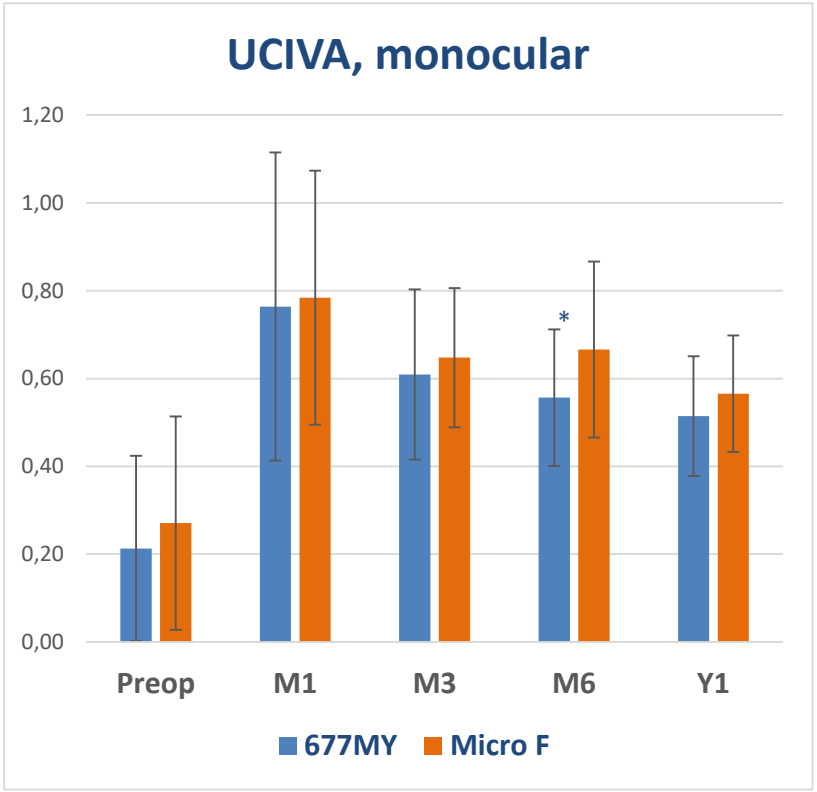


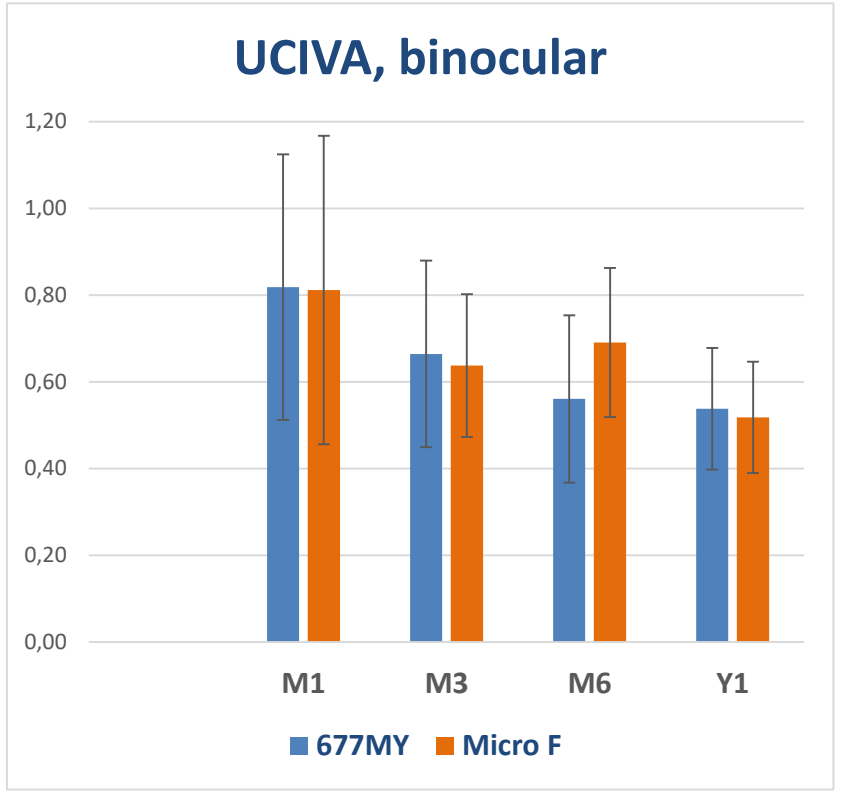
CHU AMBROISE PARÉ





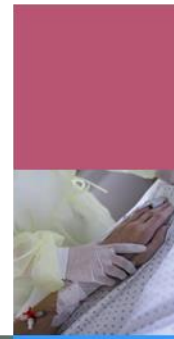




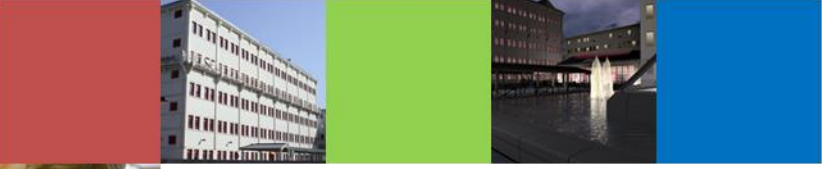


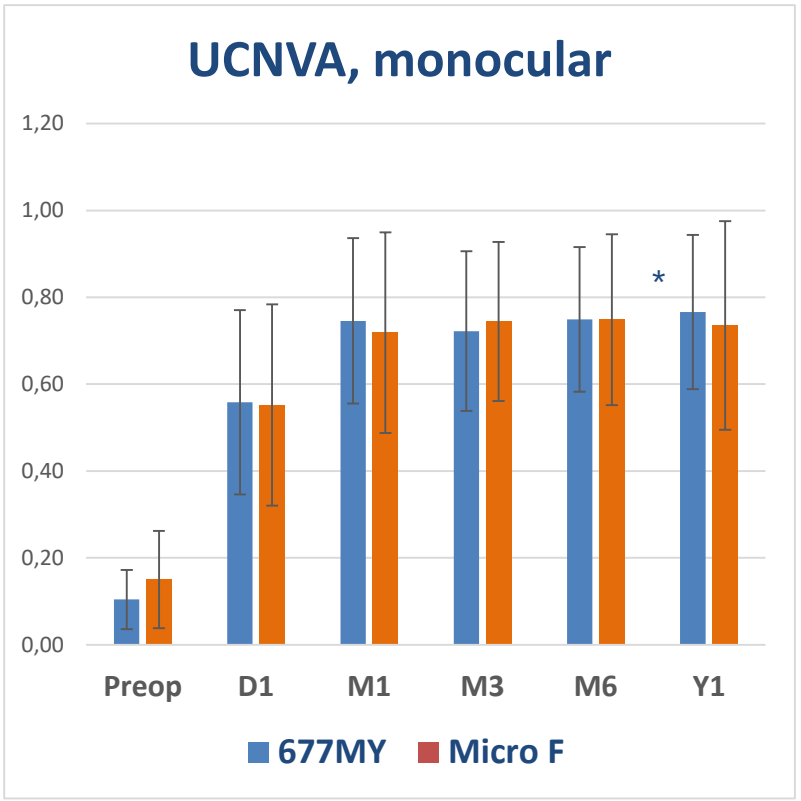
- *UCIVA at M6 - statistically significant differences;
- All other UCIVA during other follow up periods – NO STATISTIC DIFFERENCEs

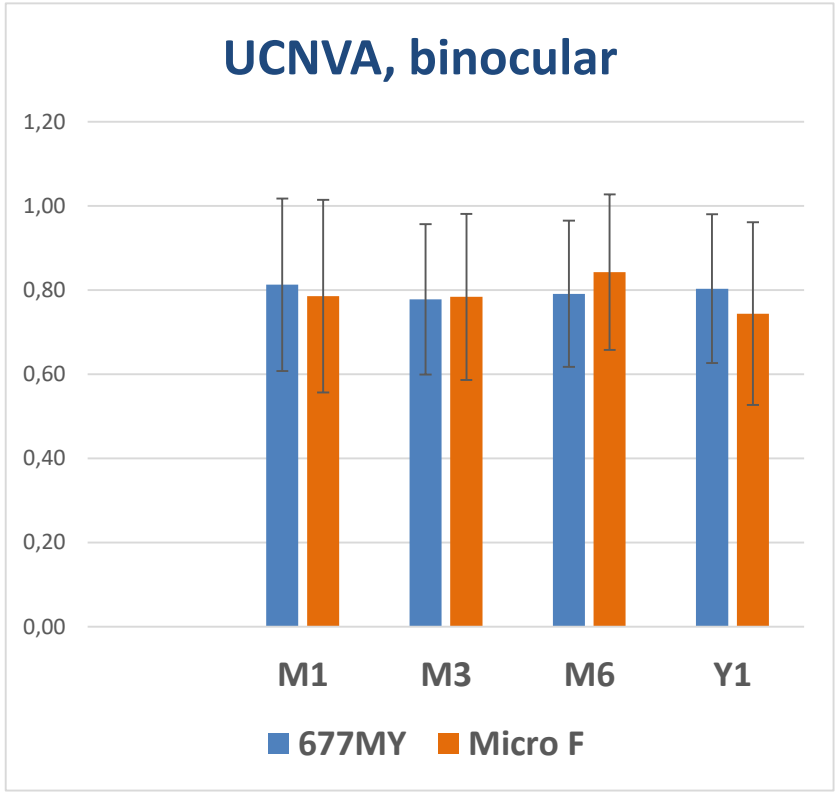
There were NOT STATISTICALLY SIGNIFICANT DIFFERENCES IN BINOCULAR VA



CHU AMBROISE PARÉ

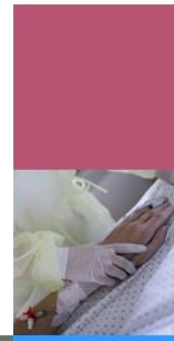




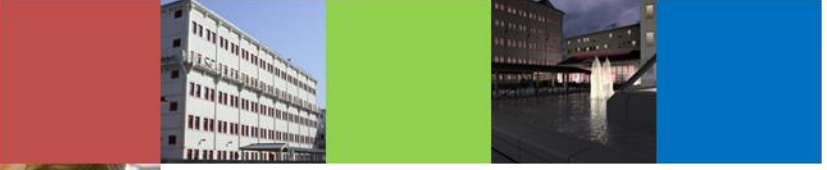


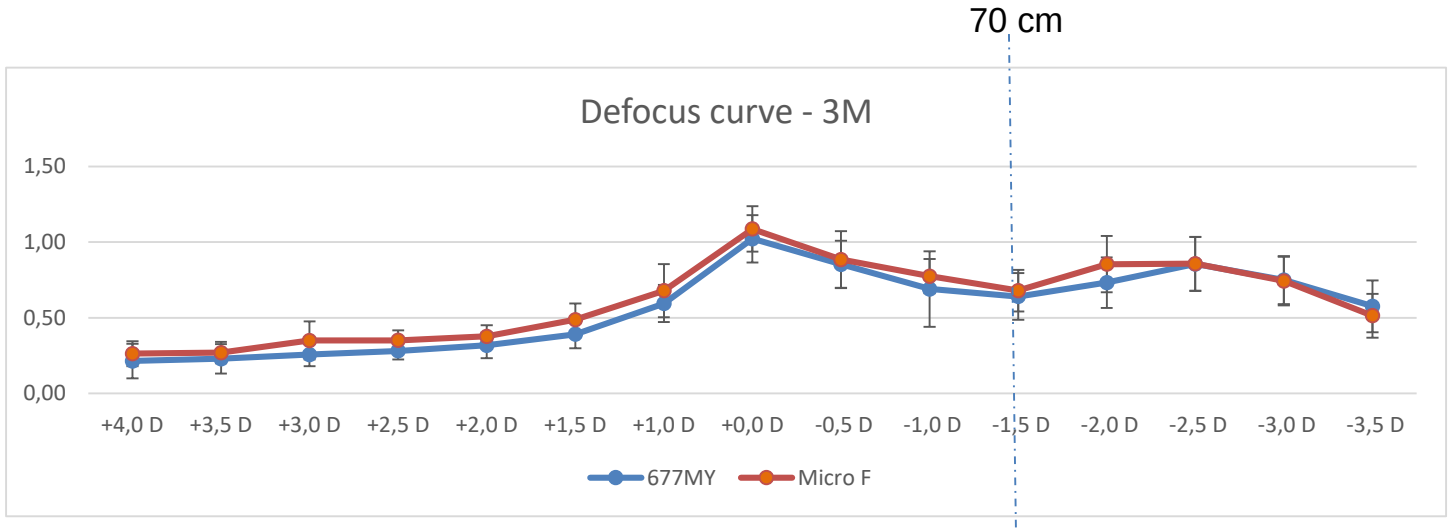
- *UCIVA at Y1 - statistically significant differences;
- All other UCIVA during other follow up periods – NO STATISTIC DIFFERENCEs

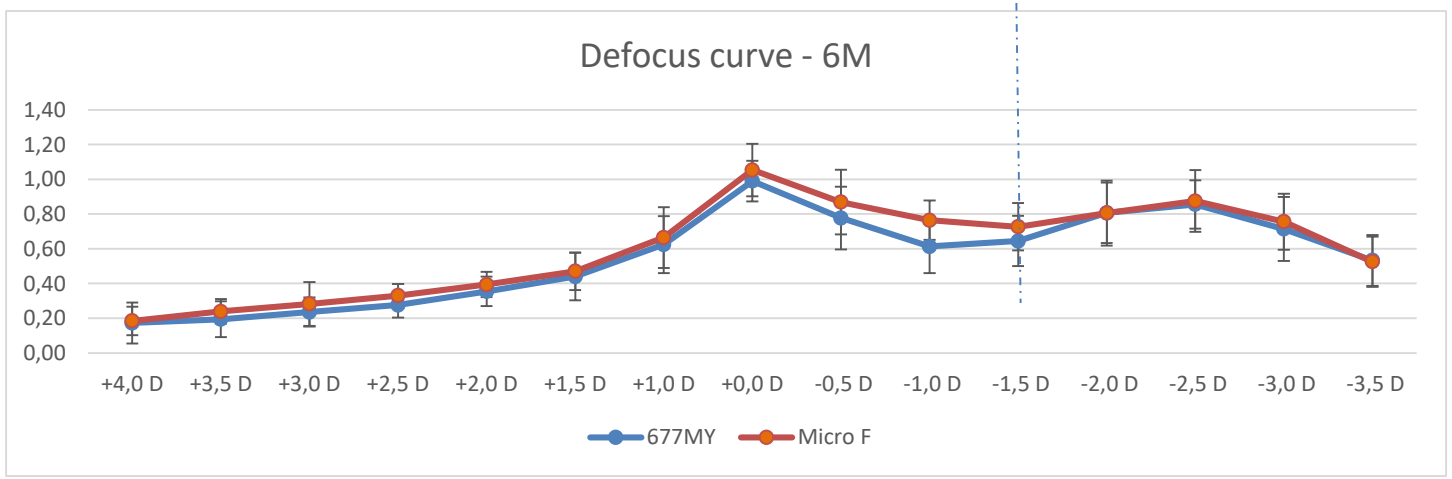
There were NOT STATISTICALLY SIGNIFICANT DIFFERENCES IN BINOCULAR VA

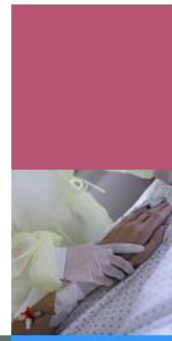


CHU AMBROISE PARÉ

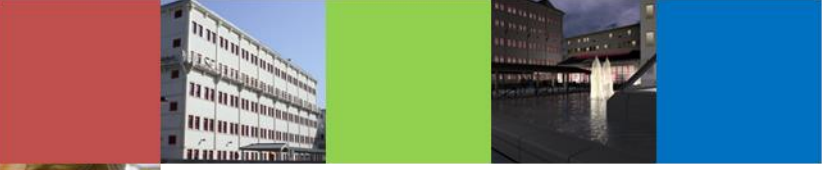


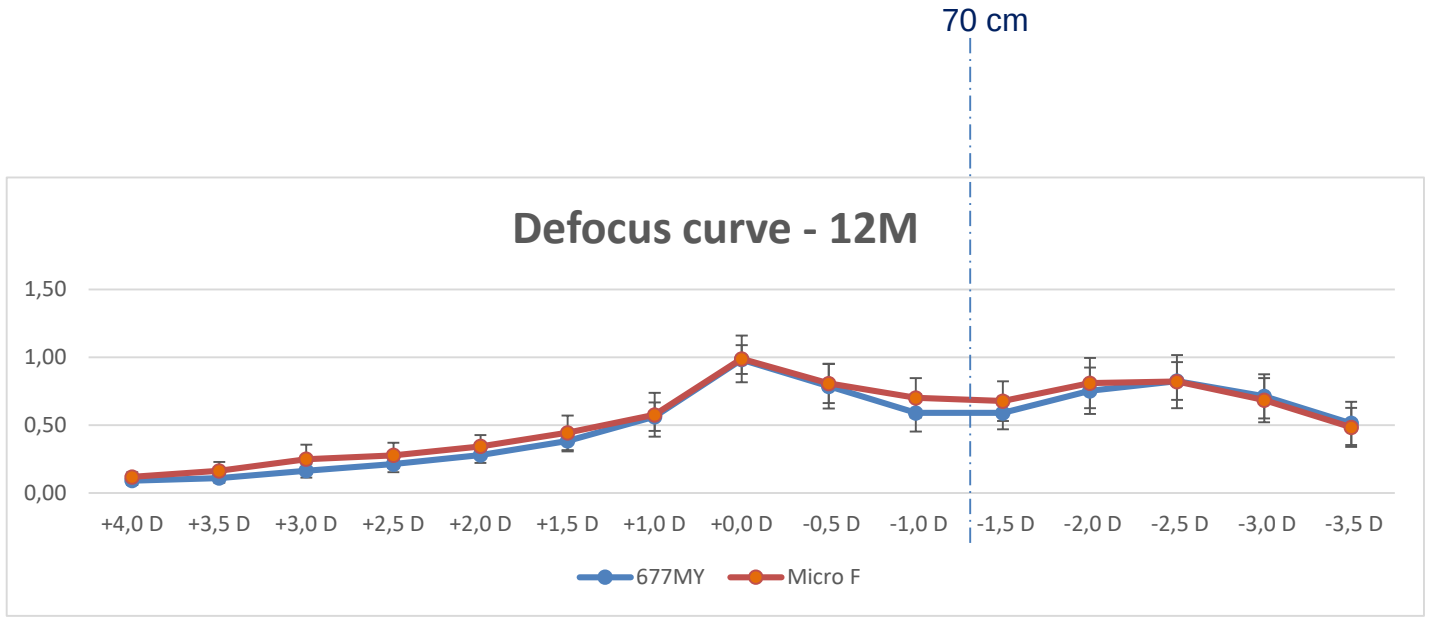






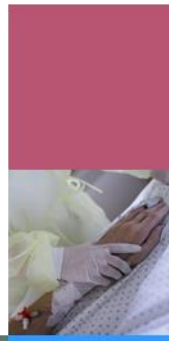
CHU AMBROISE PARÉ



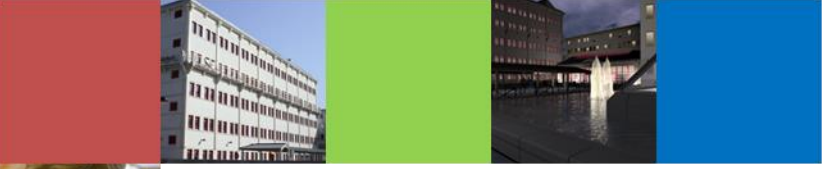


There were NOT STATISTICALLY SIGNIFICANT DIFFERENCES

- in any points of the defocus curves during follow-up period
- In the area underneath the defocus curves during follow-up period

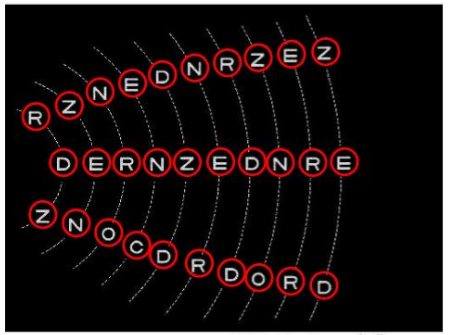


CHU AMBROISE PARÉ

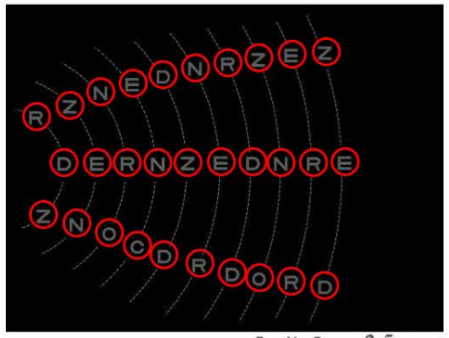


Emmétrope – 1998

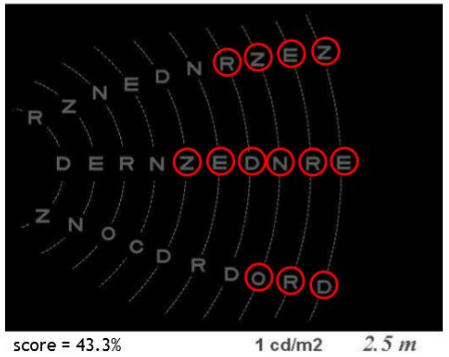
GLARE TEST
BI stimulated

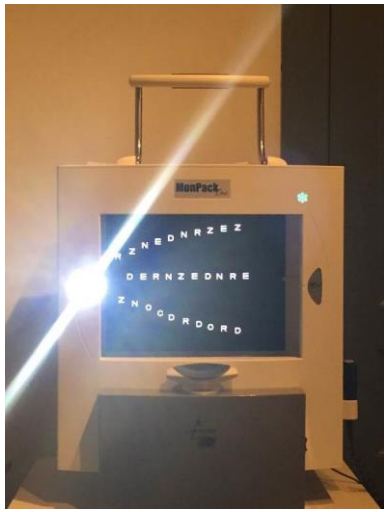


GLARE TEST
BI stimulated

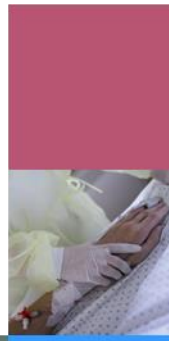


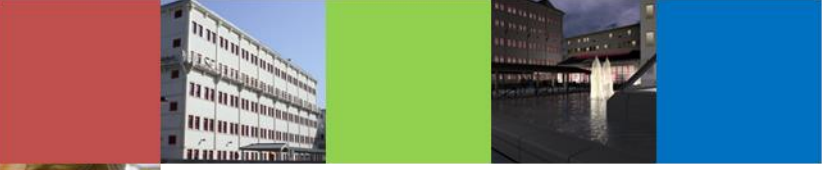
GLARE TEST
BI stimulated



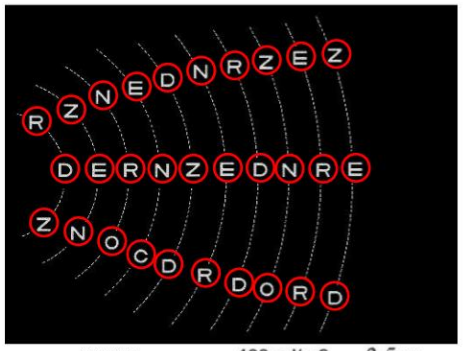


CHU AMBROISE PARÉ



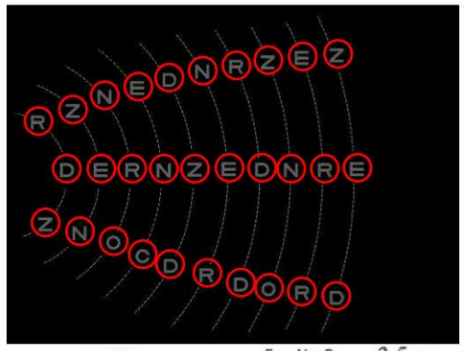


GLARE TEST
BI stimulated

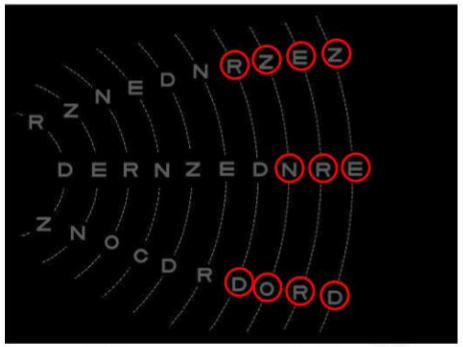


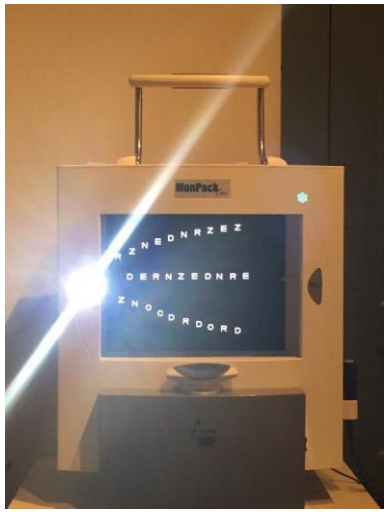
GLARE TEST
BI stimulated

Emmétrope – née 2000

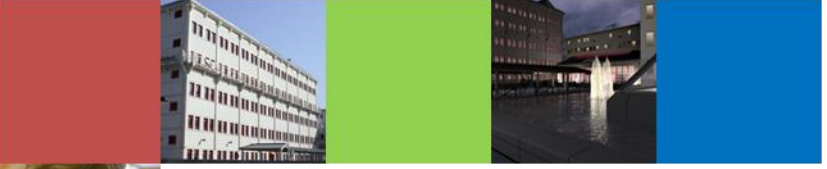


GLARE TEST
BI stimulated



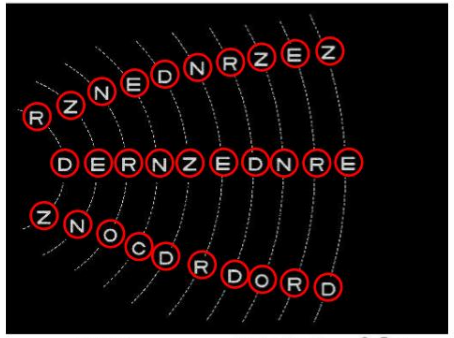


CHU AMBROISE PARÉ



GLARE TEST

BI stimulé

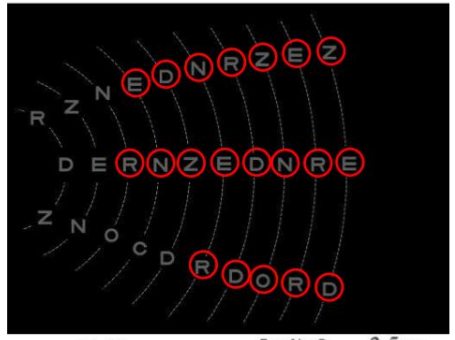


score = 100,0% 100 cd/m2 2.5 m

GLARE TEST

BI stimulé

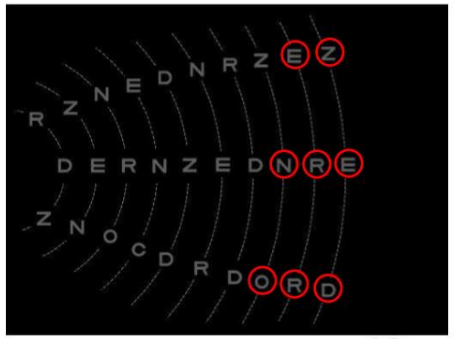
B-Flex M



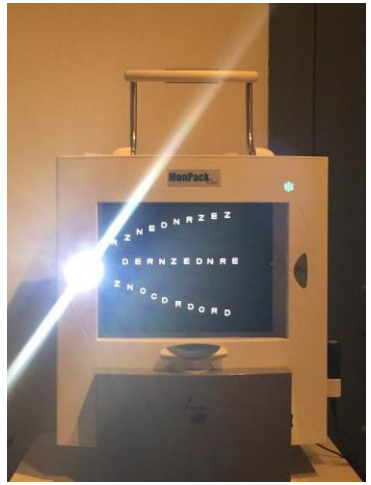
score = 66,7% 5 cd/m2 2.5 m

GLARE TEST

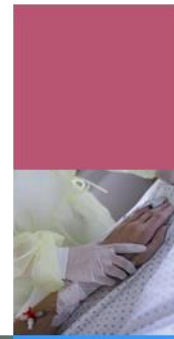
BI stimulé

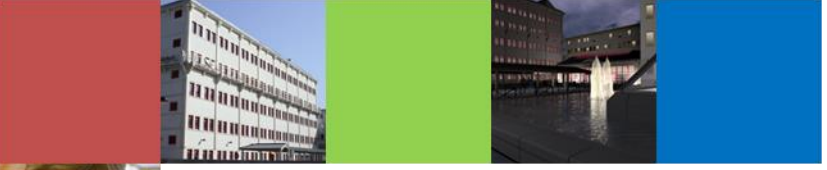


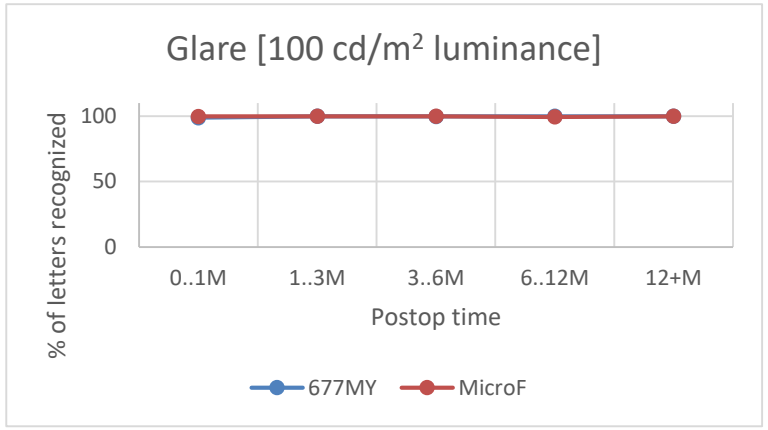
score = 26,7% 1 cd/m2 2.5 m

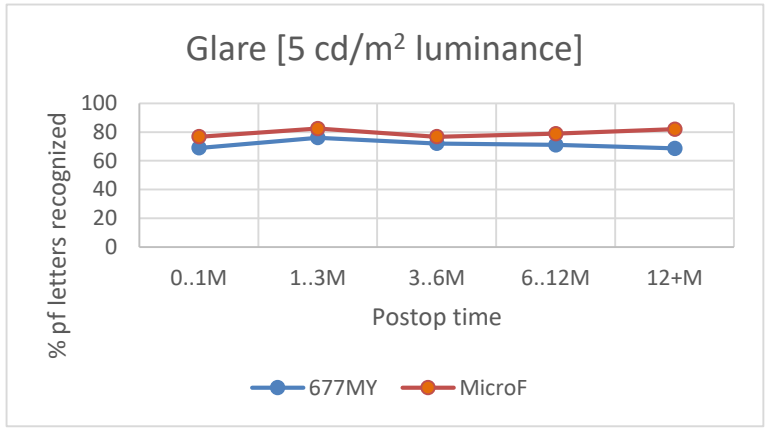


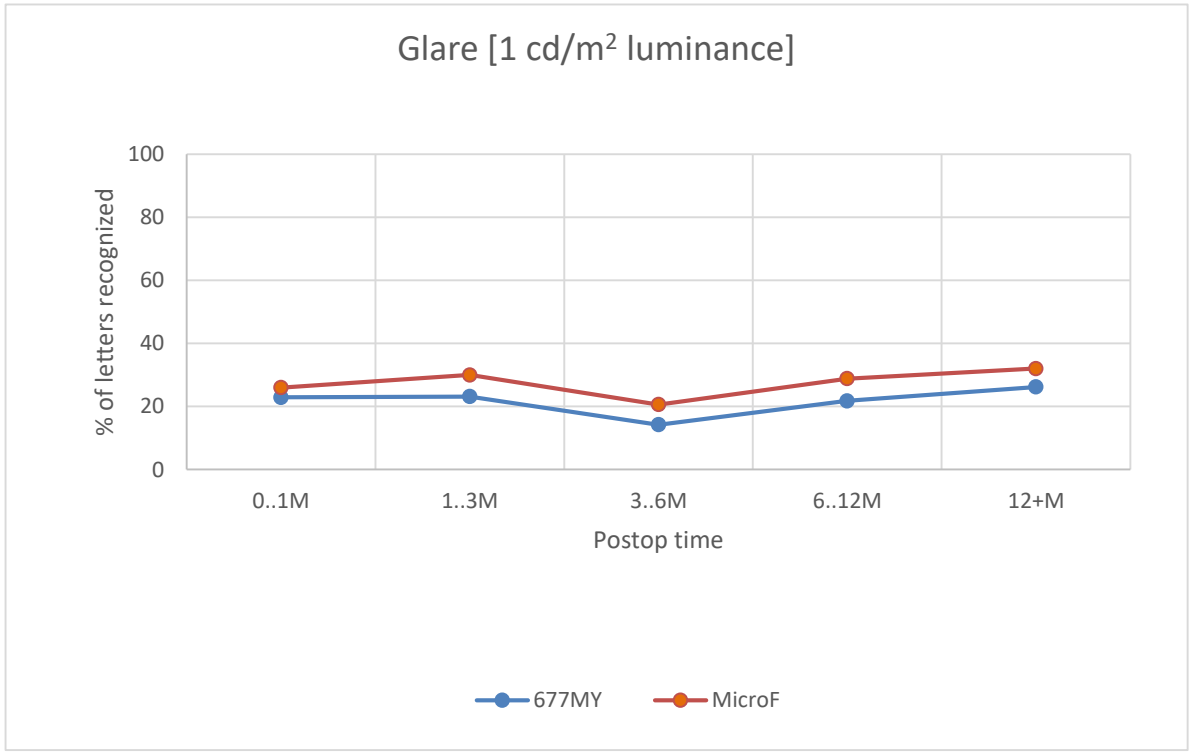
CHU AMBROISE PARÉ



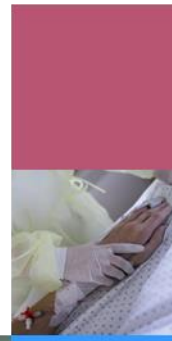


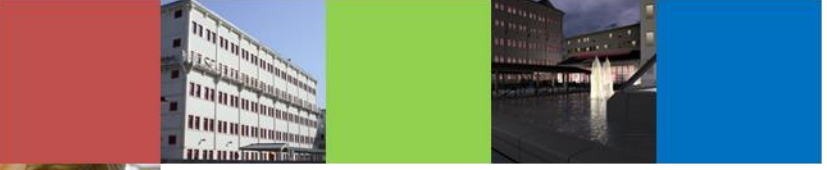






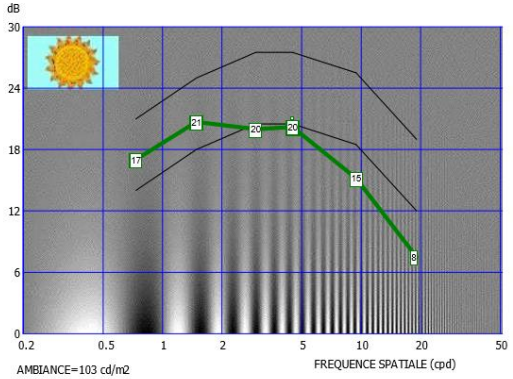
CHU AMBROISE PARÉ





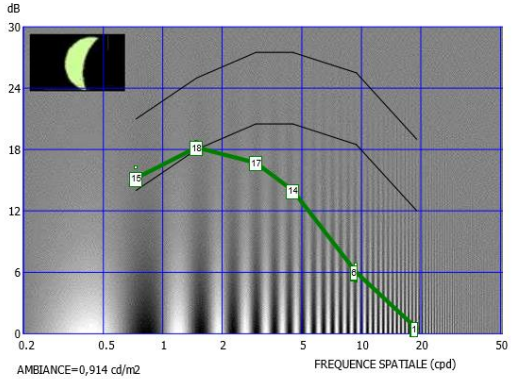
Contraste statique

OD stimulé



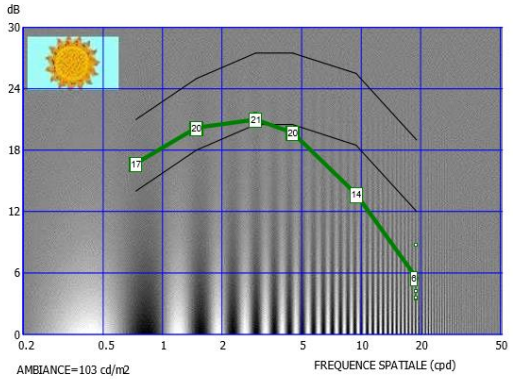
Mesopic

OD stimulé



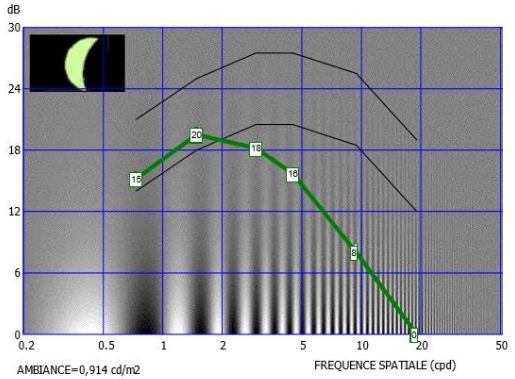
Contraste statique

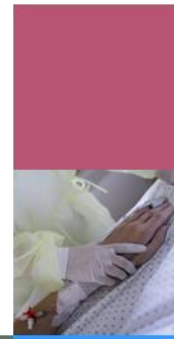
OD stimulé



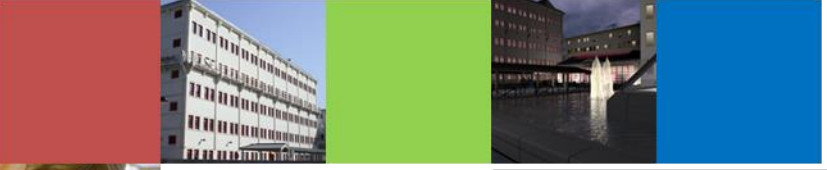
Mesopic

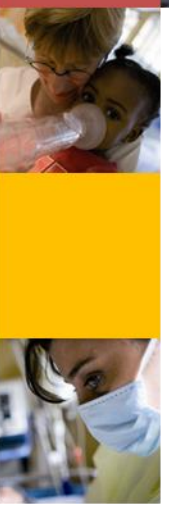
OG stimulé

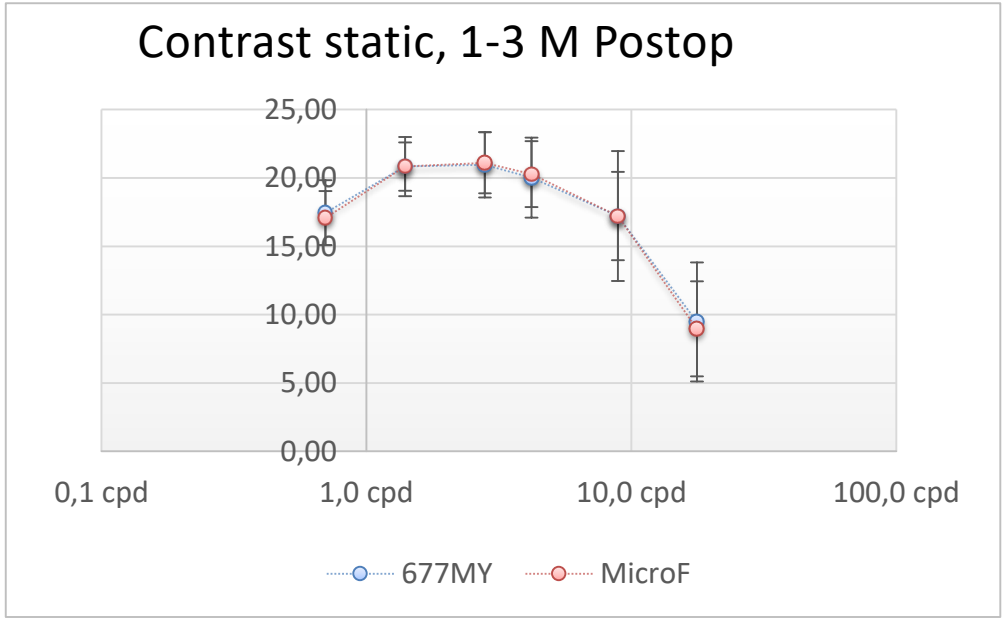




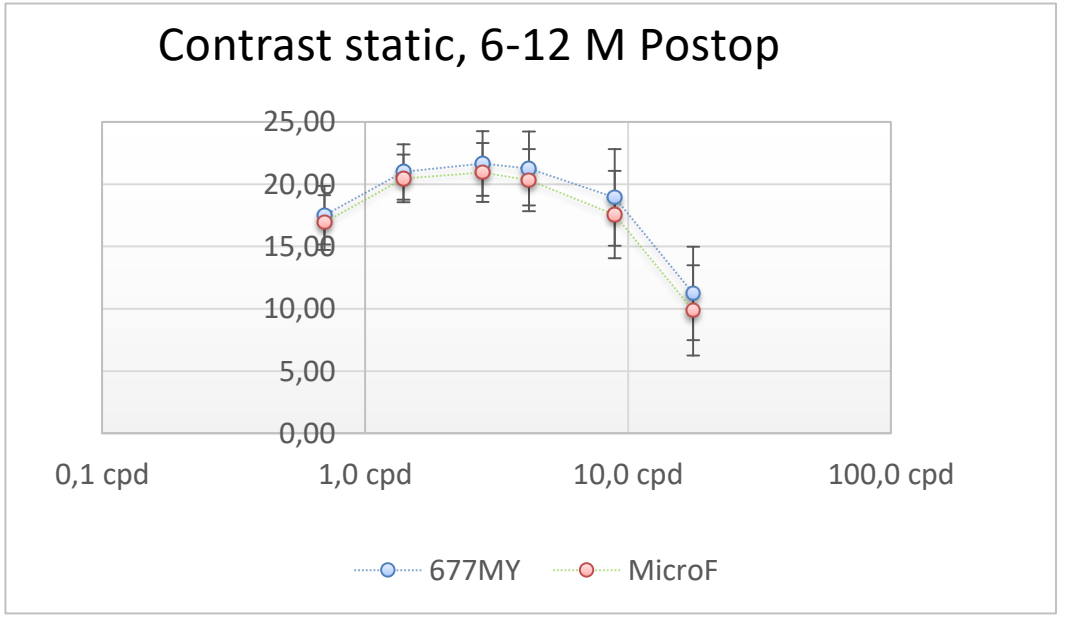
CHU AMBROISE PARÉ



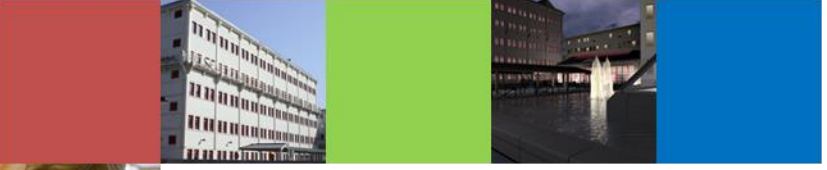


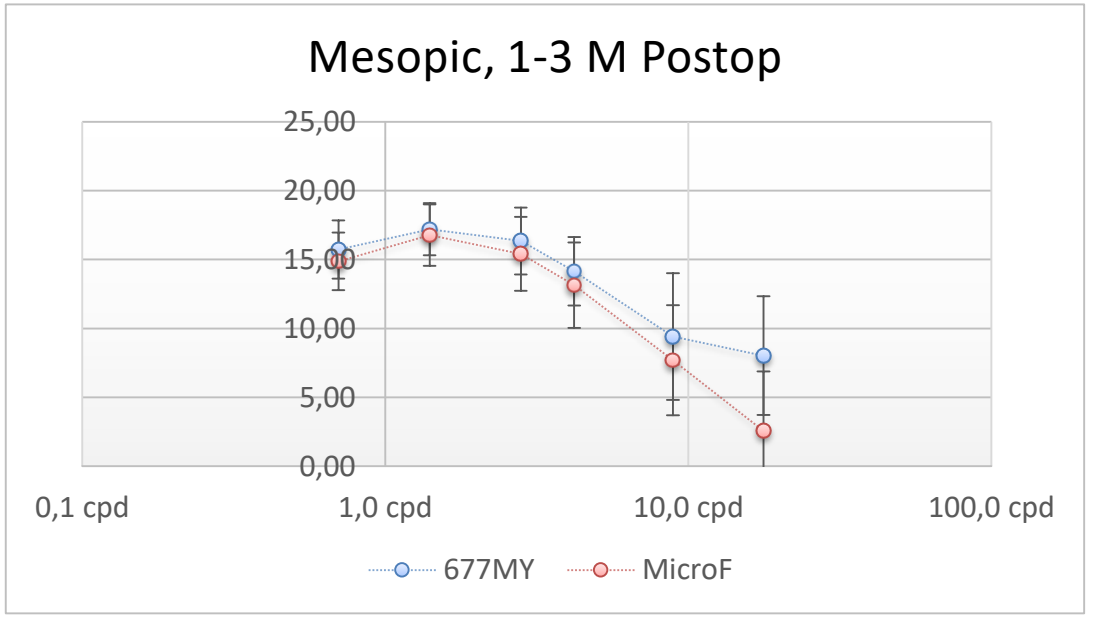


CONTRAST SENSITIVITY **PHOTOPIC**

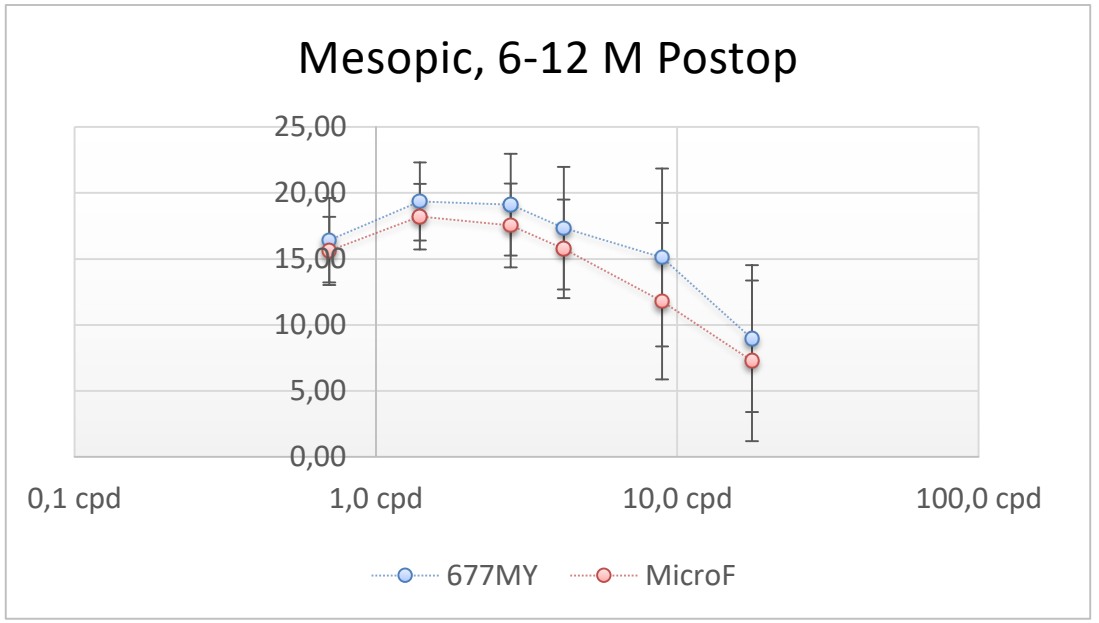


CHU AMBROISE PARÉ

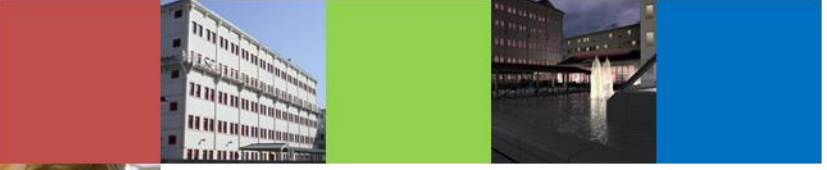




CONTRAST SENSITIVITY **MESOPIC**



CHU AMBROISE PARÉ

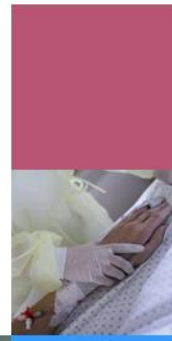


QUALITY OF VISION QUESTIONNAIRE

		677MY	MicroF
Glare/Flare		1,9	2,2
	Color	1,0	1,2
	Halo	2,6	2,9
	Depth	1,1	1,0
	Distort near	1,2	1,0
	Distort far	1,2	1,0
	Blurred near	1,2	1,1
	Blurred far	1,1	1,1
	Double vision	1,0	1,0
VISUAL LIFESTYLE ACTIVITIES (1-6 worse)	TV/movies	1,1	1,1
	Play O/S	1,0	1,1
	Play w/children	1,0	1,0
	Reading time on alarm clock	1,1	1,0
	See clearly after wakeup	1,2	1,1
	Reading time on wall clock	1,0	1,0
	Performing job/hobbies	1,0	1,0
	Sports/recreation	1,0	1,0
	Social events	1,0	1,1
	Reading/near work	1,1	1,2
	Drive at night	2,3	2,6
	Drive when raining	1,3	1,3
	Using a computer	1,2	1,3
	Cooking	1,0	1,0
	Shopping	1,1	1,1
	Using cellular	1,0	1,0
	Shaving/Make up	1,1	1,0

Overall satisfaction: 9.3/10

1	no difficulty
2	minor difficulties
3	moderate difficulties
4	major difficulties
5	cannot accomplish
6	not applicable

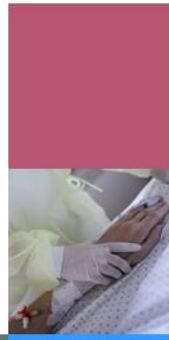


CHU AMBROISE PARÉ

CONCLUSION

- The study showed similar clinical performance of trifocal Fine Vision IOL (Physiol) and PAD Bi-Flex M (Medicontur) IOLs.
  - Contrast sensitivity, glare tests
  - Refractive results & stability
  - Visual acuities
  - Satisfaction of the patients
  - Defocus curves

- The study confirmed **clinical trifocal performance of PAD Bi-Flex M**
- Both IOLs were accepted by patients with high satisfaction
- **All patients in both examined groups were glass independent**



CHU AMBROISE PARÉ