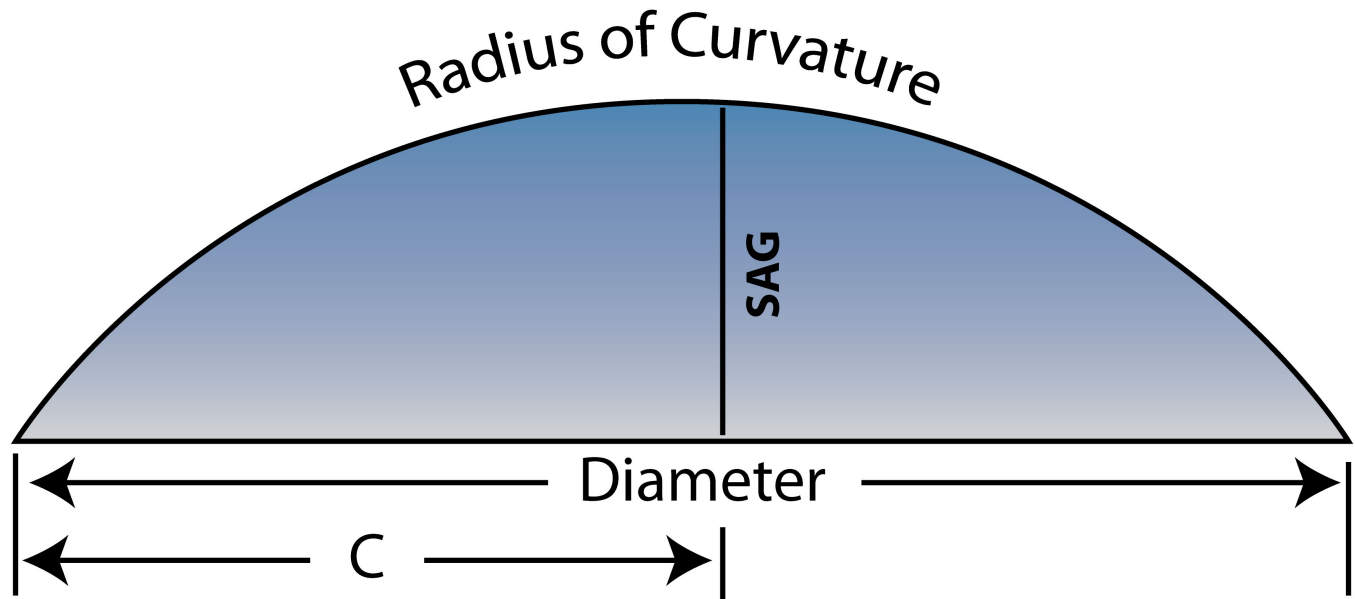


Predicting scleral lens trial with the use of two devices

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INTRODUCTION

- Scleral lenses are large gas permeable contact lenses fitted with the goal of vaulting over the ocular surface. To achieve this result it is necessary to use trial lenses and to evaluate the lens behavior to determine the optimal parameters of the lens to order.
- The first challenge is to evaluate accurately the ocular surface sagittal height. This can be done with the use of several devices, by extrapolation (topographers) direct measurements (eye profiler), or by scanning a mold made from the ocular surface imprint.
- The second challenge is to select a lens with a sagittal depth corresponding to the sagittal height of the ocular surface plus a certain amount of clearance, varying from 200 to 350 microns. There is no consensus, among manufacturers, on how to estimate the sagittal depth of a lens. Some will report the value based on the total lens diameter, others will estimate a chord where the lens lands on the ocular surface, a few will average these two numbers. For practitioners, it becomes difficult then to select the first trial lens, as close as possible from the optimal one to be fitted on a given eye.



OBJECTIVES

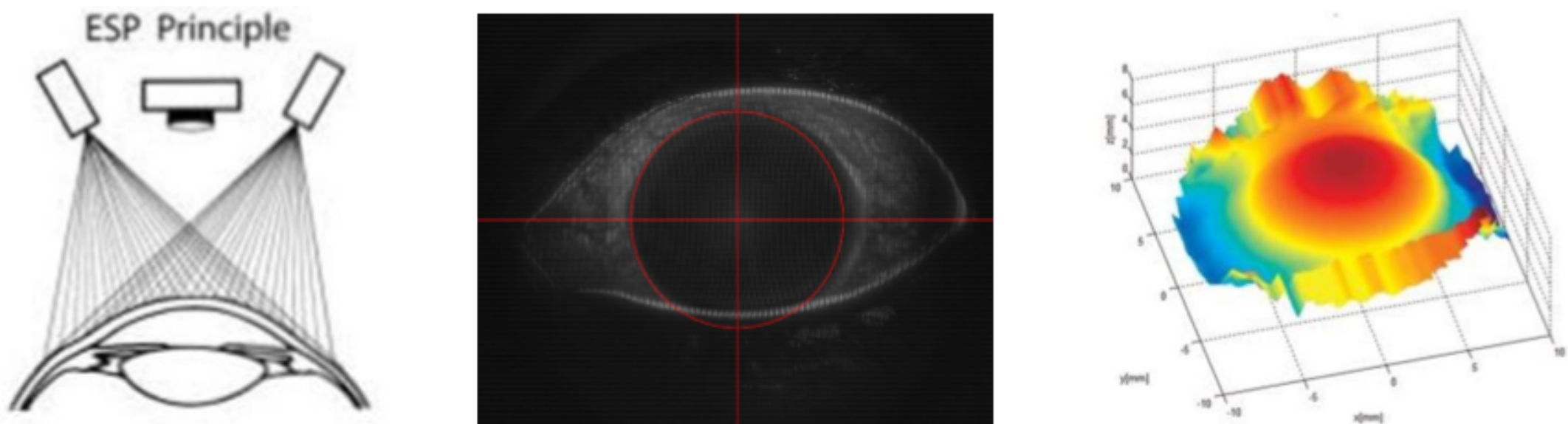
- This study aims to predict which parameter of a mini-scleral lens may be considered as optimal, based on the ocular profile derived from a topographer and an eye profiler, in order to ease the trial process and make it more efficient.

METHODS

- This is a prospective, randomized, non-dispensing study. Subjects are enrolled for a single session of testing lasting for 2h00.

INCLUSION CRITERIA :

- Being aged 18-45 years old
- Having a normal anterior segment ocular health
- To do not wear contact lenses or to had been washed out for lens wear in the last 48h00
- Be able to provide an informed consent
- One eye (R or L) was randomly selected for being assessed and fitted with a mini-scleral lens. Study began with topography measurement (Medmont Topographer, Precision Optics, Vancouver). Four different images were taken and saved if their quality was over 95%. A composite eye map was then generated. The following parameters were extracted from this file :
 - Sagittal height @ 11 mm
 - Sim K readings
 - Visible diameter of the cornea
- A second measurement was made with an eye profilometer (Eaglet SP, The Netherlands). This allows to scan the anterior ocular surface over 20 mm once the eye is dyed with fluoresceine.

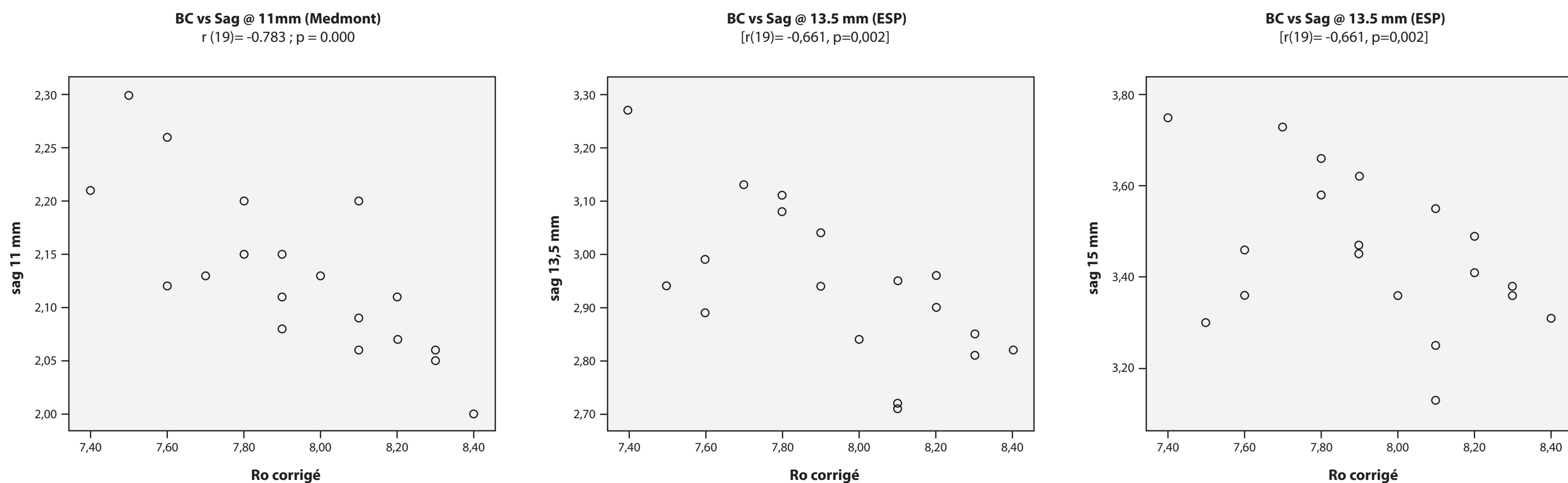


- The following parameters evaluated with this measurement were kept for analysis:
 - Ocular sag height (360 degree) @ 13.5 and 15 mm
 - Sim K – central cornea
 - Corneal diameter
- The One Fit mini-scleral lens (Laboratoires Blanchard, Sherbrooke, Qc) was fitted following manufacturer's recommendations: BC = Sim K(flat) + 0.3 mm. Diameter was kept standard at 14.9 mm. Lenses were filled with non preserved saline solution (Merck, Canada).
- After 30 minutes of stabilization on the surface of the eye, lens clearance was assessed with an anterior segment OCT (Optovue, Clarion Technologies, Texas, US). The clearance target was set up between 200 to 225 microns. If needed, the base curve of the lens was designed steeper (to increase clearance, ratio 50 um/ 0.1 mm BC change) or flatter (to reduce clearance).

RESULTS

- 19 subjects (14F; 5 M)
- Average Age : 27 y.o ± 4.42 y.o.

	N	Minimum	Maximum	Average	Std Dev
Sim K Med	19	7.23	8.30	7.7684	0.22918
IS Index	19	-0.83	0.93	0.2142	0.51400
SRI	19	0.11	0.70	0.2742	0.12487
SAI	19	0.30	1.24	0.6389	0.24081
Sag @ 11	19	2.00	2.30	2.1305	0.07619
Sag @ 13.5	19	2.71	3.27	2.9416	0.14167
Sag @ 15	19	3.13	3.75	3.4537	0.16422
Sim K ESP	19	7.35	9.50	8.3658	0.46535
BC initial	19	7.50	8.60	8.0579	0.23170
Clearance	19	0.00	261.00	147.1053	66.84966
BC final	19	7.40	8.40	7.9368	0.28908



- A linear regression allows to determine the relationship for each instrumentation
- Sag 11mm = -0,206(Rc) + 3,768 [F=26,910; p=0.000] ; (95%IC -0,290 à -0,122) - Medmont
- Sag 13,5 mm = -0,324(Rc) + 5,512 [F=13,176; p=0,002]; (95%IC, -0,512 à -0,136) - ESP

DISCUSSION

- It was possible to evaluate the sag value of the ocular surface with both devices. With the Medmont, the chord is limited to the topography map, up to 11 mm, but the sag height may be extrapolated by adding 200 um for every 0.5mm of chord.
- At 15 mm, the sag height is evaluated at 3,731 (+ 0,076) mm (Medmont) vs 3,547 (+ 0,164) (ESP). The latter value was evaluated for 360 deg and Medmont estimated the sag along the principal horizontal meridian, which explains the difference, which is not considered statistically significant (p=0.078)
- Using measured sag, it is possible to predict the initial lens to be fitted on the eye, as established with the formula. We compared this theoretical value to the final base curve selected, on patients, and found a fair agreement. However, there is a huge inter-individual variability.
- Sag @ 13.5 mm measured with ESP seems to be more accurate, taking in account that the lens is landing on the conjunctiva at this chord length, despite an overall diameter of 14.9.

SUBJECTS	Measured Base Curve	Estimated BC	Difference
		Sag 13,5	
1	8.1	8.6	-0.5
2	8.3	8.3	0.0
3	7.4	6.9	0.5
4	8	8.2	-0.2
5	8.1	8.6	-0.5
6	7.6	8.1	-0.5
7	7.7	7.4	0.3
8	7.9	7.9	0.0
9	7.8	7.4	0.4
10	7.6	7.8	-0.2
11	8.3	8.2	0.1
12	7.5	7.9	-0.4
13	8.1	7.9	0.2
14	8.2	7.9	0.3
15	7.8	7.5	0.3
16	7,9	7.9	0.0
17	8,2	8.1	0.1
18	8.4	8.3	0.1
19	7,9	7.6	0.3
Average	7,9	7.9	0.0
Median value	8.0	7.9	0.1

CONCLUSION

- It is possible to predict and select the initial trial mini-scleral lens using these 2 devices.

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