SEVERANCE

International CXL Experts' Meeting

Changes in Biomechanically corrected IOP a nd Dynamic Corneal Response Parameters M easured with the Corvis ST before and after l aser vision surgery

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EYEREUM OPHTHALMIC CLINIC

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Corneal biomechanics

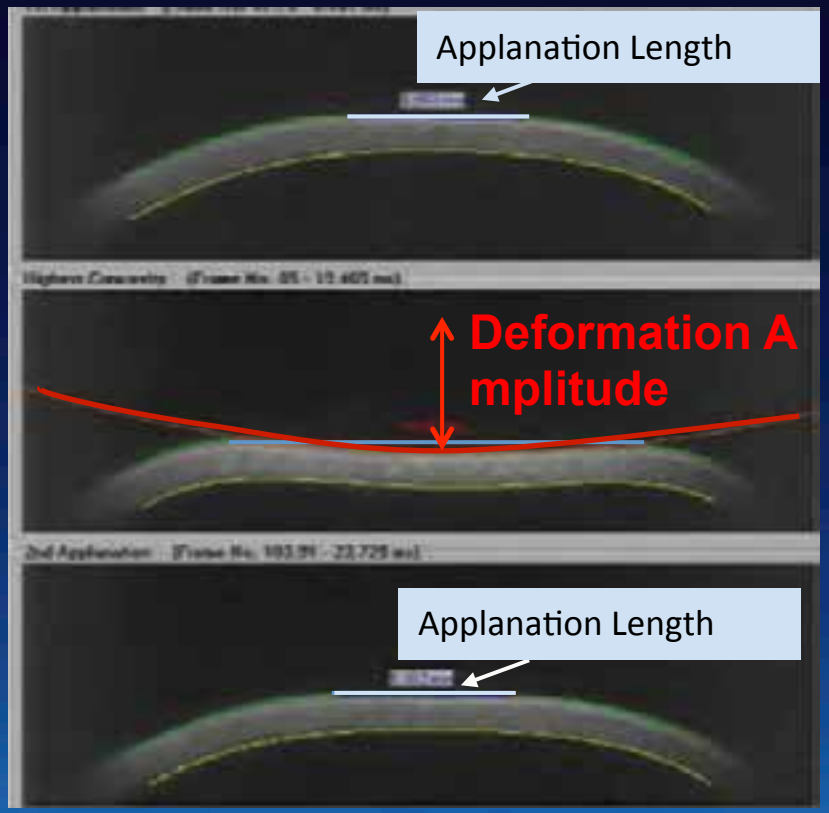
- Response of corneal tissue to an applied force
  - interactions between the externally applied force, the intrinsic viscoel astic properties of the cornea, as well as the intraocular pressure
  - Elasticity = capability of a strained body to recover its size and shape a fter deformation, Viscosity = resistance of material to flow or permane nt deformation
- Influence the measurement of IOP alongside the central corneal thickness
- Useful clinically for many purposes
  - susceptibility to the development of glaucomatous damage
  - identification of corneal disease
  - characterization of susceptibility to ectasia progression

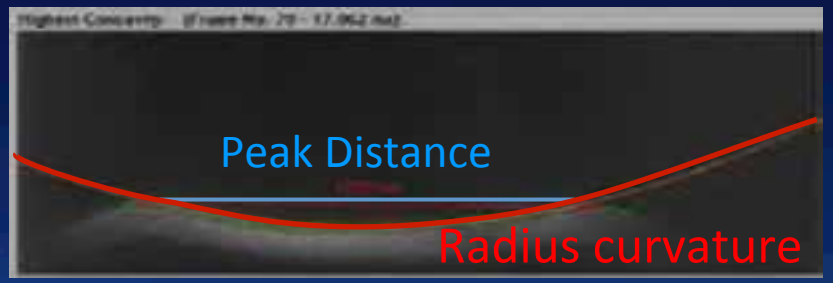
CorVis® ST (Oculus, Germany)

- in vivo characterization of corneal biomechanical deformation response to an applied air puff (constant metered collimated air pulse)
- Ultra High-Speed Scheimpflug Technology
  - 4,330 frames/secwith 8mm horizontal coverage
  - Captures 140 images in 31 ms after air pulse
- Currently FDA approved for tonometry and pachymetry

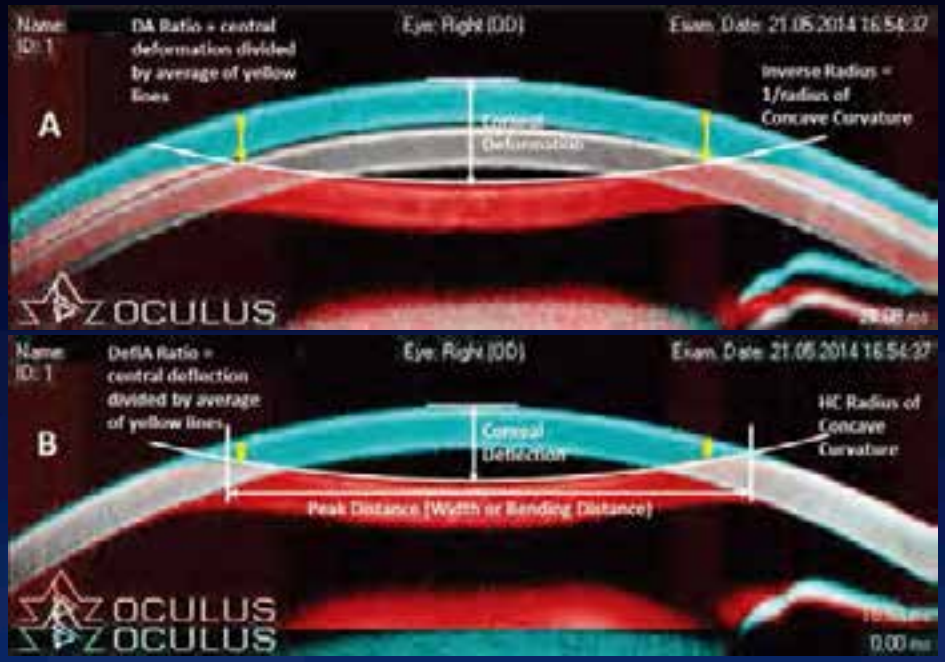
CorVis® ST

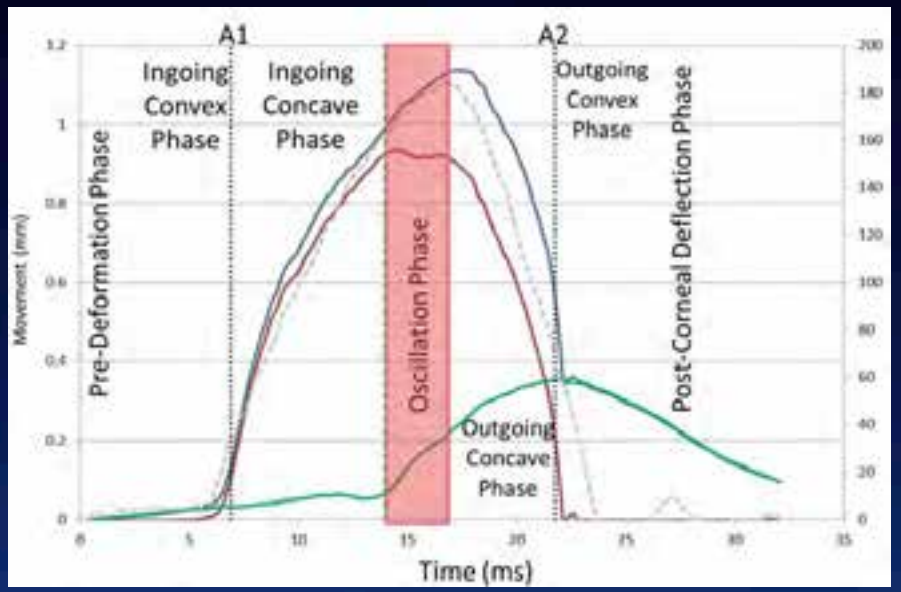
- A variety of dynamic corneal response parameters by analyzing patterns of deformation at highest concavity (HC) and applanation both during inwar d deformation (loading) and during outward recovery (unloading)





Deformation phases



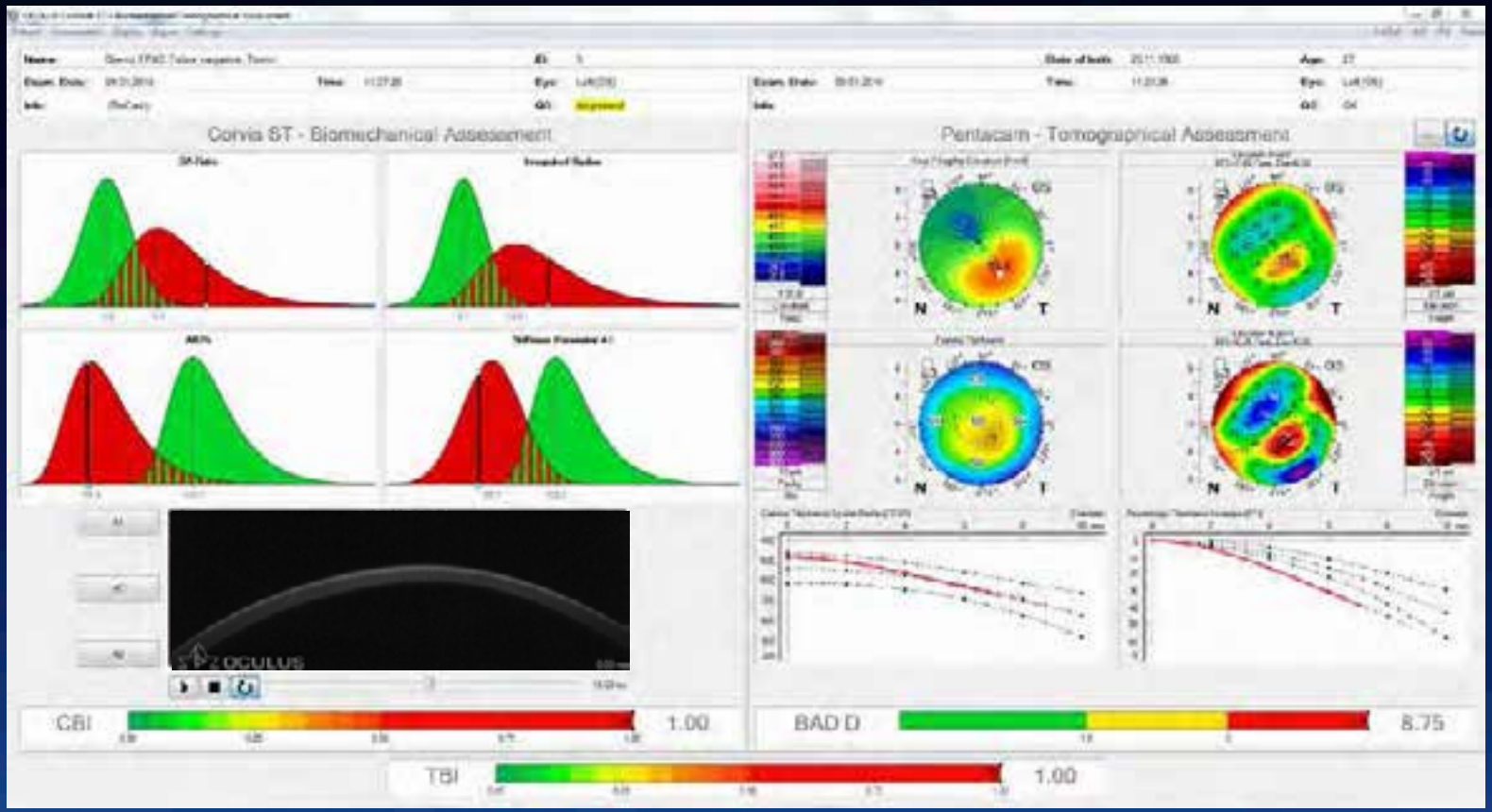


A. Cornea in the Predeformation phase (pseudocolo red blue), at maximal corneal deflection (pseudocol ored red), and at maximal whole eye movement (ps eudocolored white), B. Correction for whole eye mo tion by aligning all corneal images in the periphery t o that at predeformation♪

Courtesy from PhD. Cynthia Roberts

Highest Concavity
Max Peak Distance
Radius HC
Max Inverse Radius
Max Deflection Amplitude
Max Deformation Amplitude♪

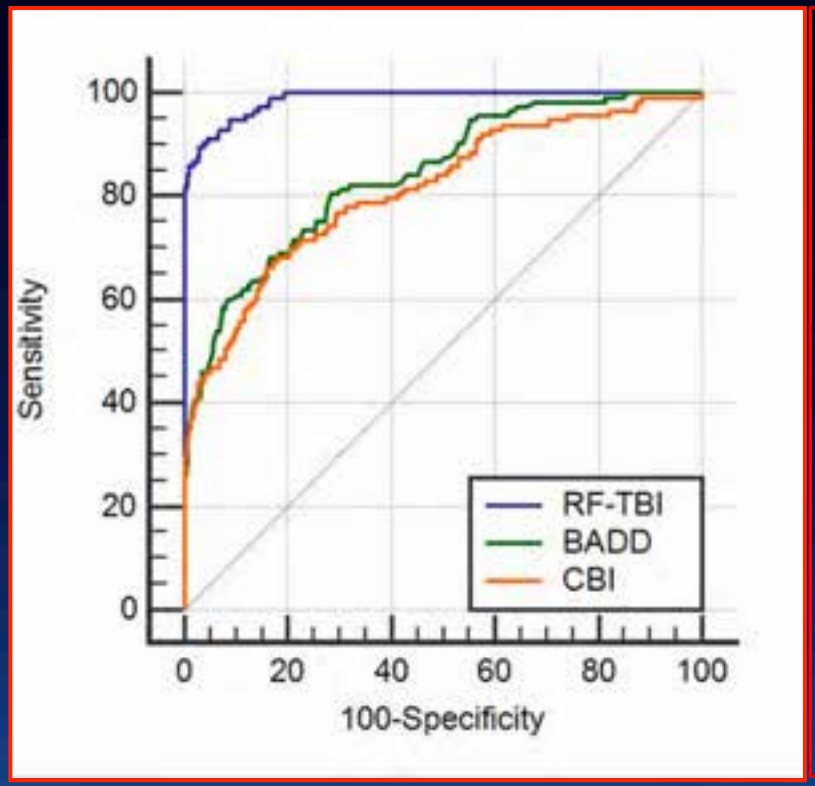
Integration of Scheimpflug Tomography and Biomechanics



ARV: *Ambrosio-Roberts & Vinciguerra Tomography and Biomechanics Report*

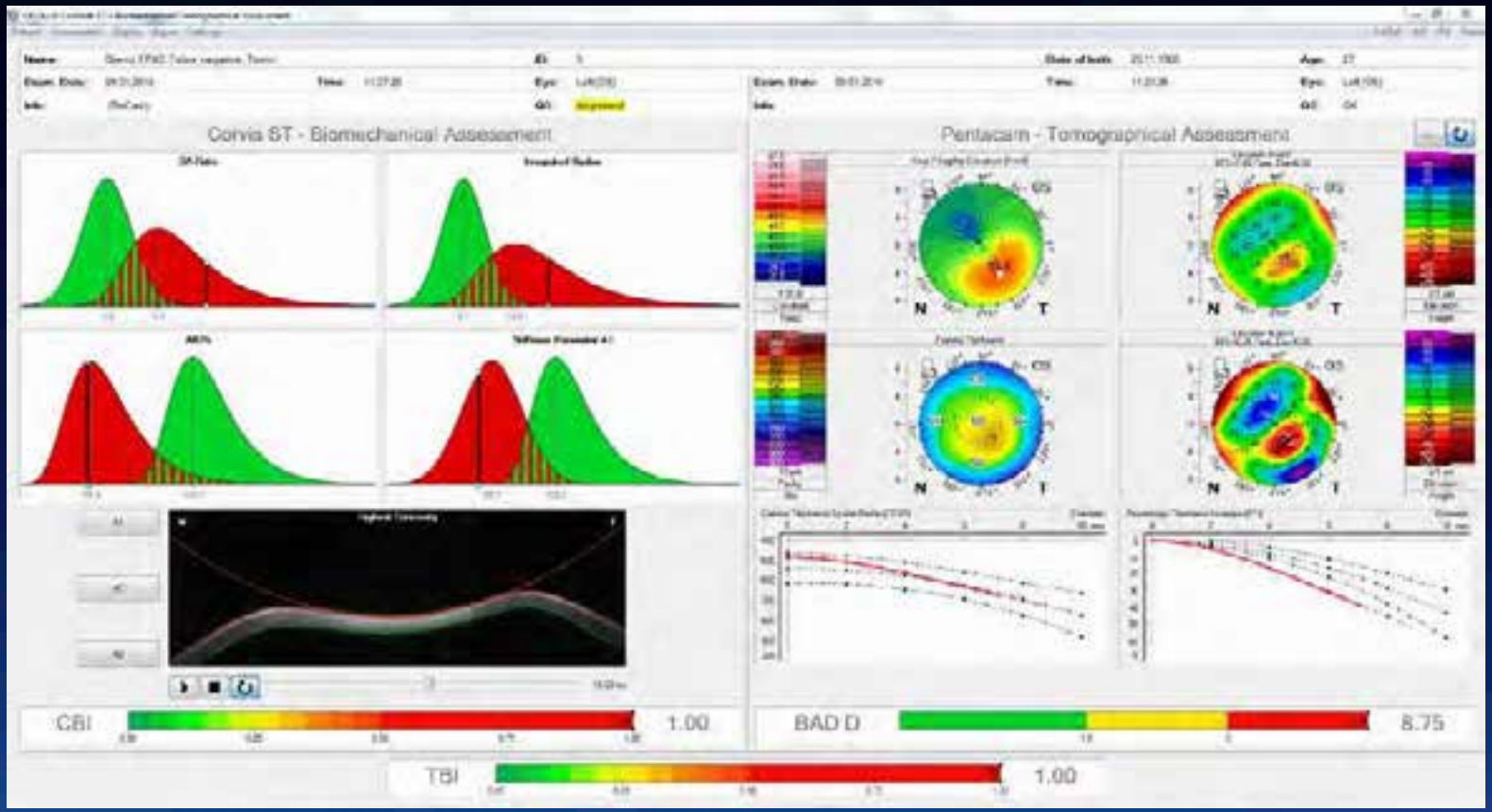
TBI x CBI x BADDv3

ROC curves



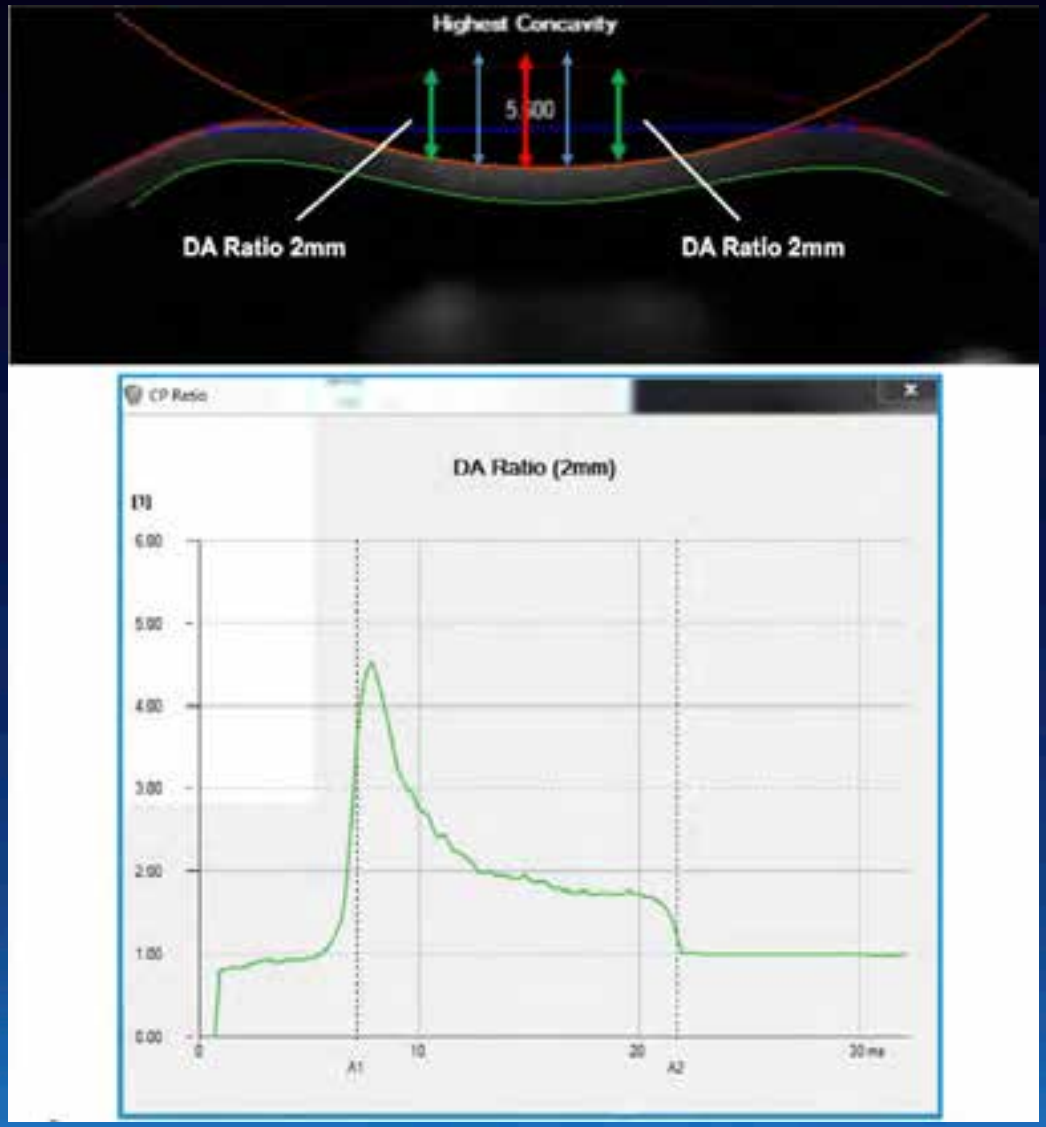
Area under the curves

Significant improvement in accuracy of TBI for FFKC cases (DeLong, $p<0.001$)


Corvis ST - Biomechanical Assessment
Pentacam - Tomographical Assessment
CBI
1.00
BAD D
8.75
TSI
1.00

DCR new parameters

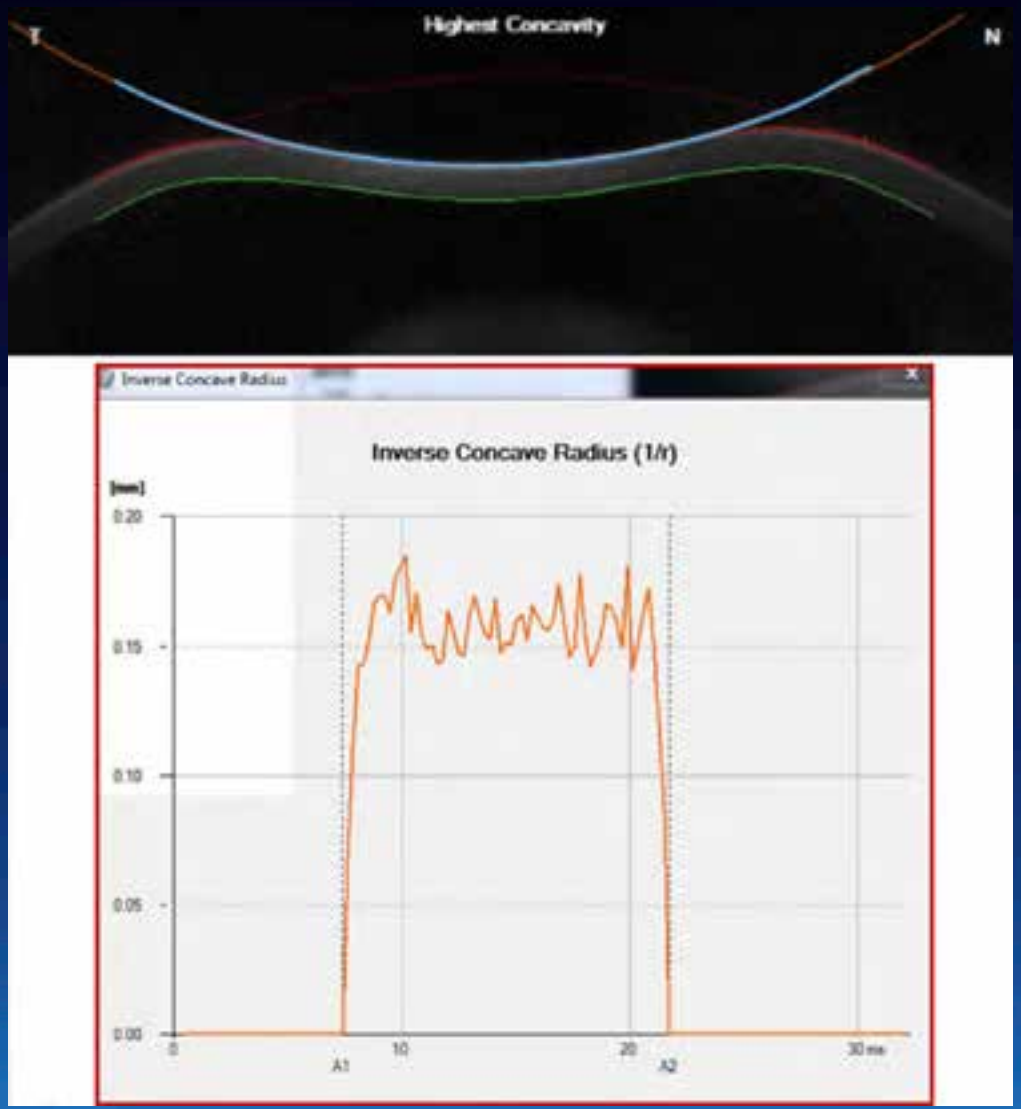
DA ratio 1 mm & 2 mm



- DA ratio 1 mm and DA ratio 2 mm demonstrate the ratios between the DA of the apex and the average of two points located 1 mm and 2 mm, respectively, on either side of the apex
- The higher the value of either of these parameters, the softer is the cornea and the lower is its resistance to deformation

DCR new parameters

Integrated radius



- The inverse radius is the reciprocal of radius during the concave state of the cornea.
- A greater concave radius is associated with greater resistance to deformation or a stiffer cornea.
- The greater integrated inverse radius and maximum inverse radius, the less resistance to deformation and the lower the corneal stiffness.

DCR new parameters

Stiffness parameter at first applanati on

3-Point Loading

Stiffness = Load/Displacement

Load : Air Pressure - IOP♪

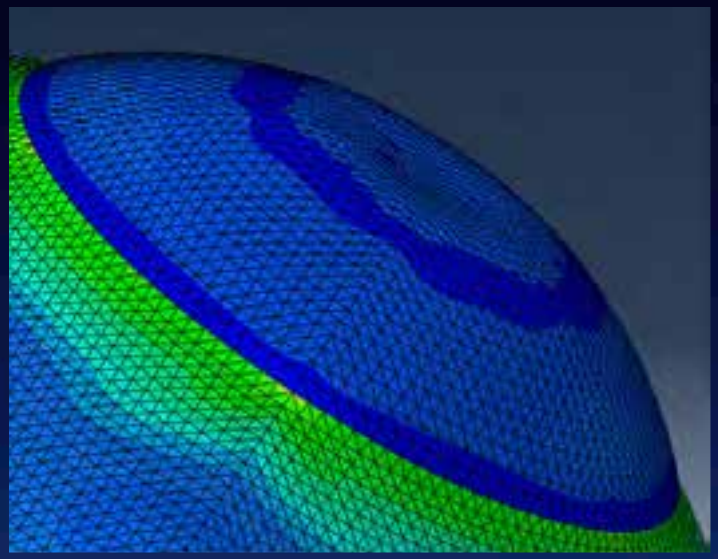
- New stiffness parameters (SP) are defin ed as the resultant pressure at inward a pplanation, divided by corneal displace ment.
- SP-A1 uses displacement from the unde formed state to A1;
  - ✓ SP-A1 = (Air Pressure –bIOP-FEM)/ (A1DeflAmp)
  - ✓ higher SP-A1, the greater the stiffn ess
- Clinically useful in screening for keratoc onus with the highest sensitivity and sp ecificity of any single parameter value

Courtesy from PhD. Cynthia Roberts

DCR new parameters

biomechanically-corrected IOP

Based on Finite Element Modeling



numerical model of a human eye subjected to pre-set IOP and air pressure generated by the Corvis procedure

$$bIOP = C_{CCT1} * C_{AP1} * C_{age1} + C_{CCT2} * C_{age2} + C_{DCR} + a19$$

- C_{CCT1} = (a1*CCT3+a2*CCT2+a3*CCT+a4)
- C_{AP1} = (a5*AP1+a6)
- C_{age1} = (a7*[Ln(Beta)]2+a8*[Ln(Beta)]+a9)
- C_{CCT2} = (a10*CCT3+a11*CCT2+a12*CCT+a13)
- C_{age2} =(a14*[Ln(Beta)]2+a15*[Ln(Beta)]+a16)
- Beta = 0.5852*EXP(0.0111*Age[year])
- C_{DCR} = a17*highest concavity radius + a18

The bIOP is an estimate of true IOP, which considers the biomechanical response of the cornea, effects of variation in CCT and material behavior

Computer Methods in Biomechanics and Biomedical Engineering 2015;1-11
J Refract Surg 2016;32(8):550-561

Clinical application

Study I

New DCR parameters and bIOP among trans epithelial PRK, SMILE, and FS-LASIK

Collaborated with Cynthia J. Roberts (The Ohio State University), Renato Ambrósio Jr. (Rio de Janeiro Corneal Tomography and Biomechanics Study Group, Rio de Janeiro, Brazil), Ahmed Elsheikh (University of Liverpool, United Kingdom), Tae-im Kim, Hun Lee

AJO review

Clinical application

Purpose

- ✓ To assess the stability of the recently introduced bIOP estimates, and evaluate the changes in the new DCR parameters obtained from the Corvis ST
  - – After transepithelial PRK (tPRK)
  - – small incision lenticule extraction (SMILE)
  - – femtosecond laser-assisted LASIK (FS-LASIK)

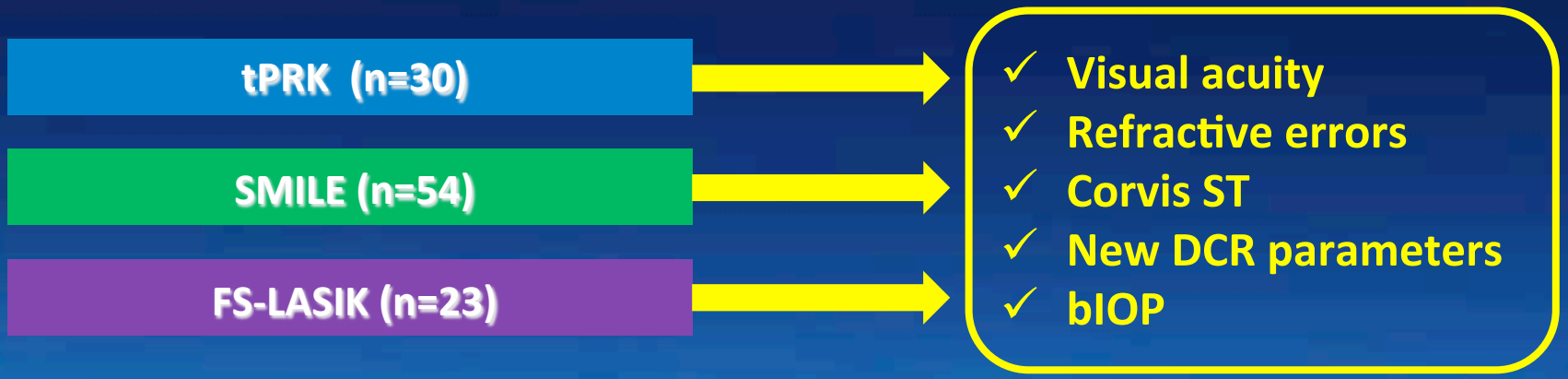
Collaborated with Cynthia J. Roberts (The Ohio State University), Renato Ambrósio Jr. (Rio de Janeiro Corneal Tomography and Biomechanics Study Group, Rio de Janeiro, Brazil), Ahmed Elsheikh (University of Liverpool, United Kingdom), Tae-im Kim, Hun Lee

AJO review

Clinical application

Methods

- ✓Retrospective, comparative, observational case series
  - 30 eyes underwent tPRK alone
  - 54 eyes underwent SMILE
  - 23 eyes underwent FS-LASIK
- ✓Before and 3 months after surgery
  - UDVA, CDVA, refractive errors, keratometry values, IOP
  - DCR parameters and bIOP
  - Only one randomly selected eye from each patient



Clinical application

Results

- Retrospective, comparative observational case series

Characteristics	Transepithelial PRK (n=30)	SMILE (n=54)	FS-LASIK (n=23)
Age, years old[a]	27.9 ± 4.8 (22 to 41)	28.4 ± 6.2 (20 to 45)	31.7 ± 6.8 (20 to 45)
Sex (% women)	66.7 %	55.6 %	47.8 %
Spherical	-4.10 ± 1.39 (-7.00 to -1.25)	-4.01 ± 1.21 (-6.50 to -1.75)	-3.68 ± 1.42 (-6.00 to -0.12)
Cylindrical	-0.69 ± 0.51 (-2.00 to 0.00)	-0.90 ± 0.64 (-3.00 to 0.00)	-0.72 ± 0.63 (-2.37 to 0.00)
SE	-4.45 ± 1.42 (-7.19 to -1.38)	-4.46 ± 1.29 (-7.25 to -1.81)	-4.04 ± 1.48 (-6.38 to -0.31)
Mean K reading (D)	43.27 ± 1.20 (40.5 to 46.2)	43.02 ± 1.45 (38.96 to 46.25)	43.60 ± 1.64 (40.23 to 46.72)
Corvis-CCT	548.6 ± 30.5 (501.0 to 631.0)	556.8 ± 27.9 (501.0 to 640.0)	552.3 ± 17.7 (525.0 to 596.0)
Optical zone (mm) [a]	6.75 ± 0.23 (6.40 to 7.26)	6.73 ± 0.26 (6.30 to 7.20)	6.83 ± 0.20 (6.50 to 7.26)
Total ablation zone (mm) [a]	8.27 ± 0.18 (7.86 to 8.56)	7.83 ± 0.26 (7.40 to 8.30)	7.89 ± 0.23 (7.45 to 8.24)
Ablation depth (µm)	87.0 ± 17.5	98.7 ± 23.0	84.8 ± 24.6

[a]Kruskal–Wallis test

Clinical application

Unchanged bIOP

	Trans- PRK (n=30)				SMILE (n=54)				FS-LASIK (n=23)				total (n=107)			
	Pre	Post	Δ	P	Pre	Post	Δ	P	Pre	Post	Δ	P	Pre	Post	Δ	P
uncorrected IOP (mmHg)	16.60 ± 1.62	14.35± 1.18	2.25 ± 1.31	<.001[a]	16.65± 2.08	13.82 ± 1.29	2.83 ± 1.67	<.001	16.94 ± 1.63	14.24 ± 1.26	2.70 ± 1.18	<.001	16.70 ± 1.86	14.06 ± 1.26	2.64 ± 1.49	<.001[a]
bIOP (mmHg)	16.27 ± 1.59	16.40 ± 1.00	-0.13 ± 1.21	.299[a]	16.08 ± 1.53	15.73 ± 1.13	0.36 ± 1.46	.079	16.41 ± 1.50	15.95 ± 1.44	0.46 ± 1.22	.084	16.21 ± 1.53	15.97 ± 1.19	0.24 ± 1.35	.067
Corvis-CCT (μM)	548.6 ± 30.5	449.3 ± 43.2	99.3 ± 28.1	<.001	556.8 ± 27.9	458.1 ± 33.1	98.7 ± 23.0	<.001	552.3 ± 17.7	469.3 ± 22.9	83.0 ± 29.0	<.001	553.5 ± 26.8	458.0 ± 34.9	95.5 ± 26.4	<.001

[a]Wilcoxon signed rank test.

Significantly smaller than those from uncorrected IOP (0.24 ± 1.35 mmHg versus 2.64 ± 1.49 mmHg, $P < 0.001$)

Clinical application

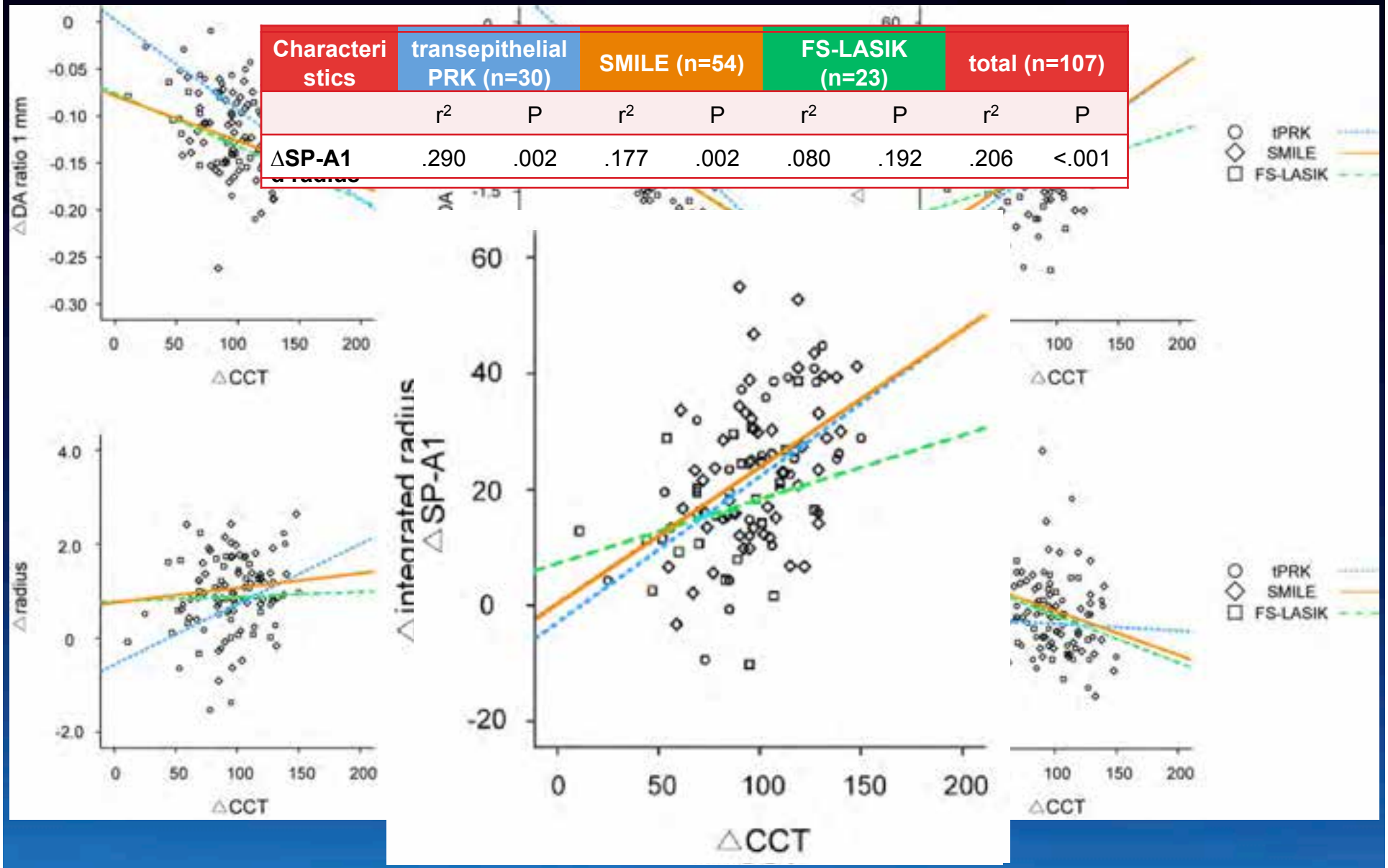
DCR parameters

	Trans-PRK (n=30)				SMILE (n=54)				FS-LASIK (n=23)				total (n=107)			
	Pre	Post	Δ	P	Pre	Post	Δ	P	Pre	Post	Δ	P	Pre	Post	Δ	P
DA ratio 1 mm	1.62 ± 0.06	1.71 ± 0.07	-0.09 ± 0.05	<.00	1.60 ± 0.05	1.73 ± 0.05	-0.13 ± 0.04	<.00	1.59 ± 0.03	1.71 ± 0.04	-0.12 ± 0.03	<.00	1.61 ± 0.05	1.72 ± 0.05	-0.12 ± 0.04	<.00
DA ratio 2 mm	4.42 ± 0.39	5.33 ± 0.70	-0.91 ± 0.52	<.00 1	4.32 ± 0.43	5.56 ± 0.52	-1.24 ± 0.37	<.00 1	4.25 ± 0.27	5.40 ± 0.44	-1.15 ± 0.34	<.00 1	4.33 ± 0.39	5.46 ± 0.57	-1.13 ± 0.43	<.00 1
SP-A1	126.6 ± 15.1	104.5 ± 13.2	22.0 ± 13.2	< 0	126.9 ± 15.9	103.3 ± 12.0	23.6 ± 12.8	< 0	111.5 ± 11.3	95.1 ± 7.9	16.4 ± 11.4	< 0	123.5 ± 16.0	101.9 ± 12.1	21.6 ± 12.8	< 0
Radius	6.79 ± 0.76	6.08 ± 1.06	0.71 ± 0.86	< 0	6.77 ± 0.72	5.71 ± 0.56	1.06 ± 0.76	< 0	6.81 ± 0.85	5.95 ± 0.65	0.86 ± 0.74	< 0	6.79 ± 0.76	5.87 ± 0.76	0.92 ± 0.79	< 0
integrated radius	8.38 ± 0.80	10.39 ± 1.48	-2.01 ± 1.08	0	8.33 ± 0.87	11.24 ± 1.18	-2.91 ± 0.77	0	8.32 ± 0.81	10.61 ± 0.98	-2.30 ± 0.73	0	8.34 ± 0.83	10.87 ± 1.28	-2.53 ± 0.94	0

[a]Wilcoxon signed rank test.

Clinical application

Characteristics	transepithelial PRK (n=30)		SMILE (n=54)		FS-LASIK (n=23)		total (n=107)	
	r^2	P	r^2	P	r^2	P	r^2	P
ΔSP-A1	.290	.002	.177	.002	.080	.192	.206	<.001



Characteristics	transepithelial PRK (n=30)		SMILE (n=54)		FS-LASIK (n=23)		total (n=107)	
	r^2	P	r^2	P	r^2	P	r^2	P
Δintegrated radius	.530	<.001	.359	<.001	.250	.015	.327	<.001
	r^2	P	r^2	P	r^2	P	r^2	P
ΔSP-A1	.290	.002	.177	.002	.080	.192	.206	<.001

Strongest relationships with ΔCCT, indicated by the r^2 values, was Δintegrated radius, with tPRK at the top (r^2 = 0.530), followed by SMILE (r^2 = 0.359) and finally FS-LASIK (r^2 = 0.250).

The ΔSP-A1 was the only parameter where tPRK and SMILE had similar relationships,whereas ΔSP-A1 in the FS-LASIK group had no relationship with ΔCCT.♪

♪

Clinical application

ANCOVA and ΔCCT as a covariate

	trans PRK (n=30)				SMILE (n=54)				FS-LASIK (n=23)				total (n=107)			
	Pre	Post	Δ	P	Pre	Post	Δ	P	Pre	Post	Δ	P	Pre	Post	Δ	P
DA ratio 1 mm	1.62 ± 0.06	1.71 ± 0.07	-0.09 ± 0.05	<.001	1.60 ± 0.05	1.73 ± 0.05	-0.13 ± 0.04	<.001	1.59 ± 0.03	1.71 ± 0.04	-0.12 ± 0.03	<.001[a]	1.61 ± 0.05	1.72 ± 0.05	-0.12 ± 0.04	<.001
DA ratio 2 mm	4.42 ± 0.39	5.33 ± 0.70	-0.91 ± 0.52	<.001	4.32 ± 0.43	5.56 ± 0.52	-1.24 ± 0.37	<.001	4.25 ± 0.27	5.40 ± 0.44	-1.15 ± 0.34	<.001	4.33 ± 0.39	5.46 ± 0.57	-1.13 ± 0.43	<.001
SP-A1	126.6 ± 15.1	104.5 ± 13.2	22.0 ± 13.2	<.001	126.9 ± 15.9	103.3 ± 12.0	23.6 ± 12.8	<.001	111.5 ± 11.3	95.1 ± 7.9	16.4 ± 11.4	<.001	123.5 ± 16.0	101.9 ± 12.1	21.6 ± 12.8	<.001
Radius	6.79 ± 0.76	6.08 ± 1.06	0.71 ± 0.86	<.001	6.77 ± 0.72	5.71 ± 0.56	1.06 ± 0.76	<.001	6.81 ± 0.85	5.95 ± 0.65	0.86 ± 0.74	<.001	6.79 ± 0.76	5.87 ± 0.76	0.92 ± 0.79	<.001
integrated radius	8.38 ± 0.80	10.39 ± 1.48	-2.01 ± 1.08	<.001	8.33 ± 0.87	11.24 ± 1.18	-2.91 ± 0.77	<.001	8.32 ± 0.81	10.61 ± 0.98	-2.30 ± 0.73	<.001	8.34 ± 0.83	10.87 ± 1.28	-2.53 ± 0.94	<.001

[a]Wilcoxon signed rank test.

Discussion

- ✓ Postoperative changes in DA ratio 1 mm, DA ratio 2 mm, and integrated radius after tPRK are significantly smaller than those for SMILE or FS-LASIK
- ✓ Surface ablation has the smallest additional effect on corneal biomechanics
- ✓ No significant differences in the changes of the DCR parameters were noted between SMILE and FS-LASIK
  - corneal wound healing patterns in SMILE and LASIK
  - creation of the anterior cap during SMILE
    - ✓ corrugated arrangement of the anterior lamellae, which originates from the difference in arch length between the anterior cap and profound stromal pocket

Conclusion

- ✓ We demonstrated the reliability of the bIOP estimates obtained by the Cor vis ST through the stability of its measurement following three common fo rms of laser vision surgery
- ✓ This result indicated the reduced effect of changes in corneal thickness an d material behavior on bIOP measurements, compared to uncorrected IOP estimates
- ✓ New DCR parameters, such as *DA ratio 1 mm, DA ratio 2 mm, integrated r adius, and SP-A1* can be helpful as reliable measures of the biomechanical changes in the cornea caused by laser vision surgery
- ✓ tPRK had a smaller change compared to lamellar procedures

Clinical application

Study II

New DCR parameters and bIOP bewteen transepithelial PRK and transepithelial PRK with accelerated CXL

Collaborated with Cynthia J. Roberts (The Ohio State University), Renato Ambrósio Jr. (Rio de Janeiro Corneal Tomography and Biomechanics Study Group, Rio de Janeiro, Brazil), Ahmed Elsheikh (University of Liverpool, United Kingdom), Tae-im Kim, Hun Lee

Unpublished

Clinical application

Purpose

- ✓ To assess the stability of the recently introduced bIOP estimates, and evaluate the changes in the new DCR parameters obtained from the Corvis ST
- ✓ After transepithelial PRK (tPRK) and tPRK with accelerated corneal collagen cross-linking (tPRK-CXL)

Collaborated with Cynthia J. Roberts (The Ohio State University), Renato Ambrósio Jr. (Rio de Janeiro Corneal Tomography and Biomechanics Study Group, Rio de Janeiro, Brazil), Ahmed Elsheikh (University of Liverpool, United Kingdom), Tae-im Kim, Hun Lee

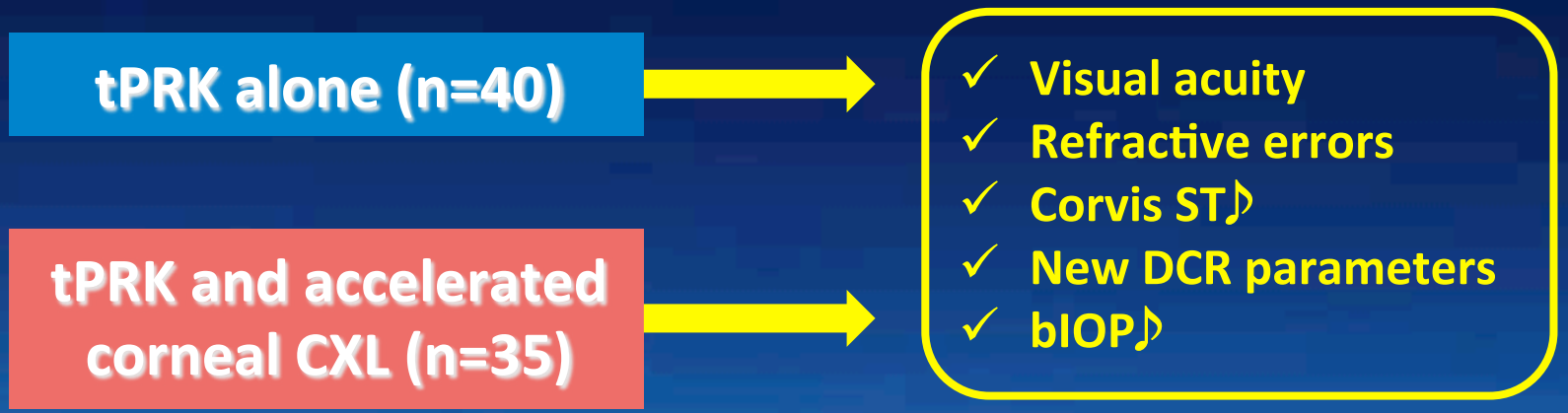
Unpublished

Clinical application

Methods

✓Retrospective, comparative, observational case series

- 40 eyes underwent tPRK alone, 35 eyes underwent tPRK with CXL
- Before and 3 months after surgery
  - UDVA, CDVA, refractive errors, keratometry values, IOP
  - DCR parameters and bIOP
  - Only one randomly selected eye from each patient



Clinical application

Results

- Retrospective, comparative observational case series

Characteristics	tPRK (n=40)	tPRK-CXL (n=35)	*P*
Age, years old	24.4 ± 4.9 (19 to 41)	25.5 ± 5.6 (19 to 40)	.371
Sex (% women)	72.5 %	74.3 %	.861
Spherical	-5.27 ± 1.07 (-7.87 to -3.00)	-5.20 ± 1.27 (-7.50 to -2.50)	.783
Cylindrical	-0.92 ± 0.63 (-2.62 to 0.00)	-1.21 ± 0.68 (-2.50 to 0.00)	.058
SE	-5.73 ± 1.07 (-8.12 to -3.69)	-5.80 ± 1.33 (-8.19 to -2.63)	.798
Mean K reading (D)	43.34 ± 1.05 (41.13 to 45.86)	43.33 ± 1.41 (40.34 to 46.68)	.982
CCT	544.80 ± 25.86 (508.0 to 596.0)	541.89 ± 29.07 (497.0 to 608.0)	.690
Optical zone (mm)	6.58 ± 0.17 (6.26 to 7.00)	6.57 ± 0.27 (6.00 to 7.26)	.919
Total ablation zone (mm)	8.35 ± 0.21 (8.04 to 8.97)	8.32 ± 0.22 (7.80 to 8.77)	.510
Ablation depth (µm)	103.79 ± 13.80 (70.73 to 136.60)	102.54 ± 17.18 (63.06 to 131.45)	.727
WTW	11.51 ± 0.40 (10.69 to 12.30)	11.61 ± 0.34 (10.84 to 12.26)	.321

Clinical application

Unchanged bIOP

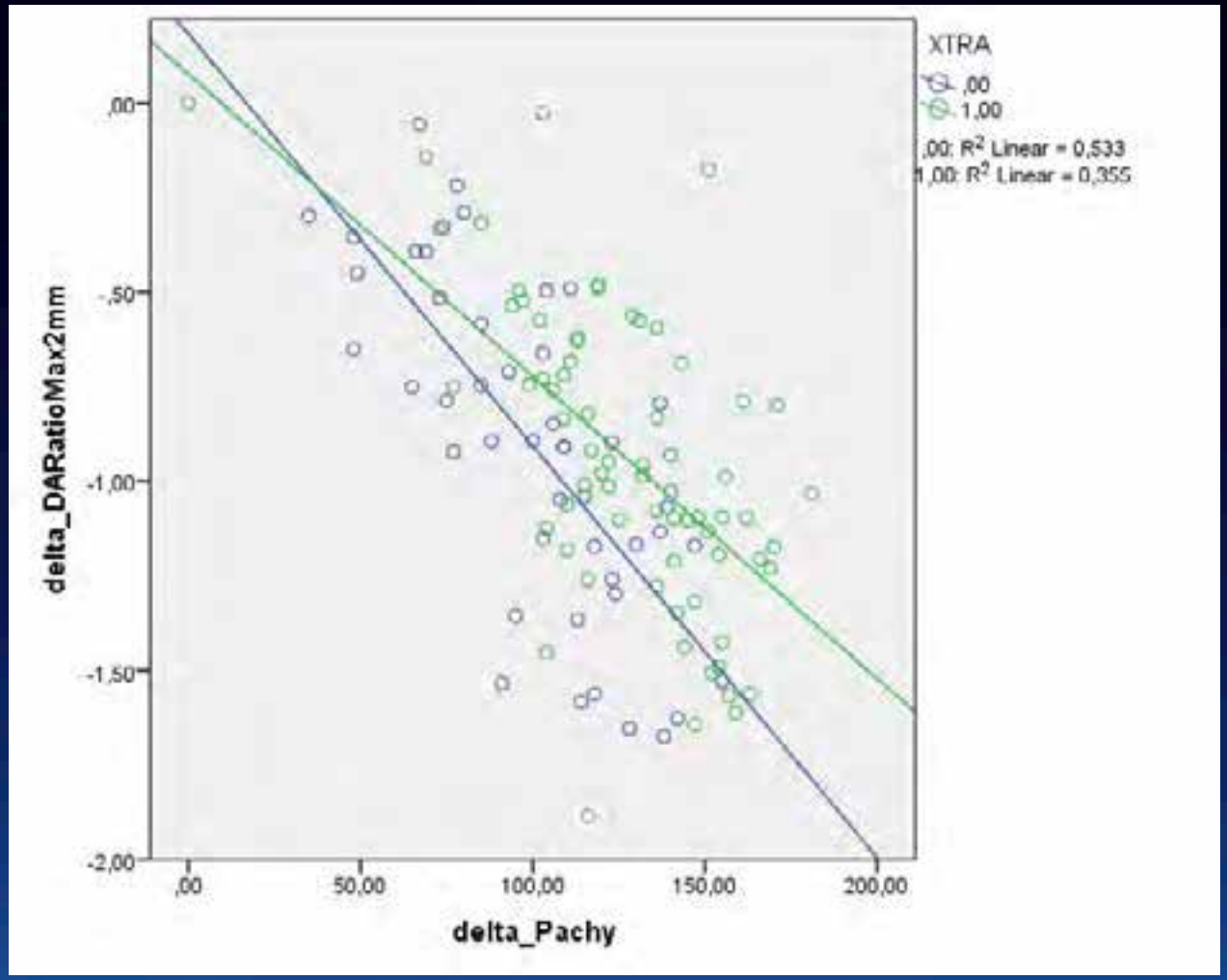
Characteristics	tPRK (n=40)				tPRK-CXL (n=35)					total (n=75)			
	Pre	Post	Δ	P[a]	Pre	Post	Δ	P[a]	P[b]	Pre	Post	Δ	P[a]
uncorrected IOP (mmHg)	17.00 ± 2.12	14.34 ± 1.45	-2.66 ± 1.84	<.001	17.06 ± 2.08	14.71 ± 1.34	-2.34 ± 1.83	<.001	.454	17.03 ± 2.09	14.51 ± 1.40	-2.51 ± 1.83	<.001
bIOP (mmHg)	16.58 ± 1.94	16.78 ± 1.38	0.21± 1.90	.499	16.91 ± 1.50	17.15 ± 1.10	0.24 ± 1.41	.326	.935	16.73 ± 1.74	16.95 ± 1.27	0.22 ± 1.68	.259
Corvis-CCT (μm)	552.2 ± 26.9	434.2 ± 31.7	- 118.0 ± 19.0	<.001	540.4 ± 32.1	428.5 ± 37.4	- 111.9 ± 27.5	<.001	.264	546.7. ± 29.9	431.6 ± 34.4	- 115.1 ± 23.4	<.001

[a]*P* value between preoperative and postoperative parameters.♪
[b]*P* value between the two groups regarding changes in parameters.♪

Clinical application

	tPRK (n=40)				tPRK-CXL (n=35)						
	Pre	Post	Δ	*P*[a]	Pre	Post	Δ	*P*[a]	*P*[b]	*P*[c]	*P*[d]
DA ratio 1 mm	1.62 ± 0.06	1.73 ± 0.06	0.11 ± 0.05	<.001	1.62 ± 0.05	1.71 ± 0.06	0.09 ± 0.06	<.001	.206	.157	.330
DA ratio 2 mm	4.35 ± 0.41	5.40 ± 0.57	1.05 ± 0.40	<.001	[illegible]	5.19 ± 0.55	0.81 ± 0.40	<.001	**.013**	**.005**	**.027**
SP-A1[e]	110.06 ± 24.93	76.13 ± 26.88	-33.93 ± 12.69	<.001	97.24 ± 19.35	64.57 ± 16.94	-32.67 ± 15.81	<.001	.704	.621	.871
Intregrated inverse radius	8.36 ± 0.97	10.74 ± 1.18	2.38 ± 0.83	<.001	[illegible]	10.64 ± 1.27	1.99 ± 0.86	<.001	.050	**.030**	.103
Max inverse radius	0.16 ± 0.02	0.20 ± 0.02	0.03 ± 0.01	<.001	0.17 ± 0.02	0.20 ± 0.02	0.03 ± 0.01	<.001	.561	.642	.932
bIOP (mmHg)	16.58 ± 1.94	16.78± 1.38	0.21 ± 1.90	.499	16.91 ± 1.50	17.15 ± 1.10	0.24 ± 1.41	.326	.935	.932	.797

[a]*P* value between preoperative and postoperative DCR parameters.♪
[b]*P* value between the two groups regarding changes in DCR parameters.♪
[c]*P* value between the two groups regarding changes in DCR parameters with ANCOVA with refractive error change as a covariate.♪
[d]*P* value between the two groups regarding changes in DCR parameters with ANCOVA with CCT change as a covariate.♪
[e]There were statistically significant differences in preoperative and postoperative SP-A1 between the two groups.♪


XTRA
,00
1,00
,00: R² Linear = 0,533
1,00: R² Linear = 0,355
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-1,00
-1,50
-2,00
delta_DARatioMax2mm
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150,00
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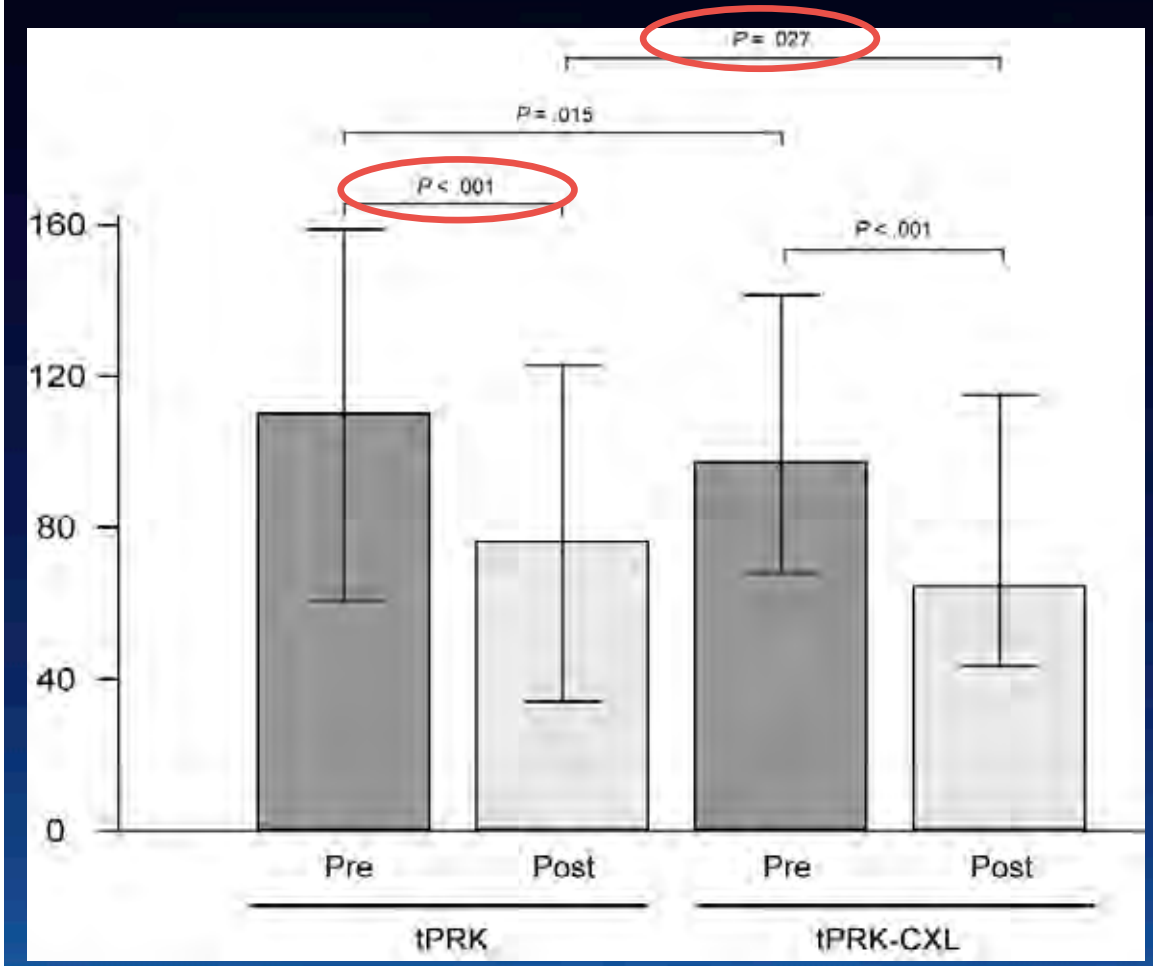
delta_Pachy

Clinical application

SP-A1



- There were significant difference in preoperative and postoperative SP-A1 between the two groups
- Corneas in tPRK-CXL group, although initially softer, were relatively more stiff after the CXL when compared to corneas of uncrosslinked tPRK♪

Conclusion

- ✓ We suggest that tPRK combined with a prophylactic CXL interventio n appears to have a role in causing a smaller reduction in stiffness o f the corneal tissue relative to the uncrosslinked tPRK
- ✓ Significantly smaller magnitude of changes in DA ratio 2 mm and int regrated inverse radius in tPRK-CXL group
- ✓ bIOP obtained from the Corvis ST can be helpful in assessing intraoc ular pressure before and after tPRK and tPRK with CXL

SEVERANCE

International CXL Experts' Meeting

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Thank you!

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