

Topoguided CXL trial

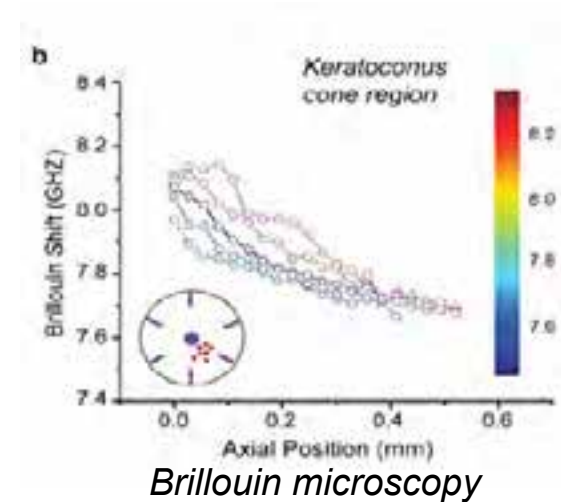
Clinical results

K. Pierné, M. Cassagne, P. Fournié, F. Malecaze

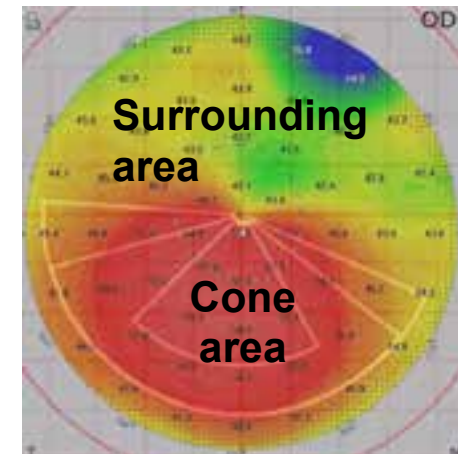


Two reasons for doing top-guided CXL

1. Biomechanics suggest pathology is centered on the cone



2. Should induce a local stiffening, flatten the cone and consequently improve visual function



Clinical study

Design

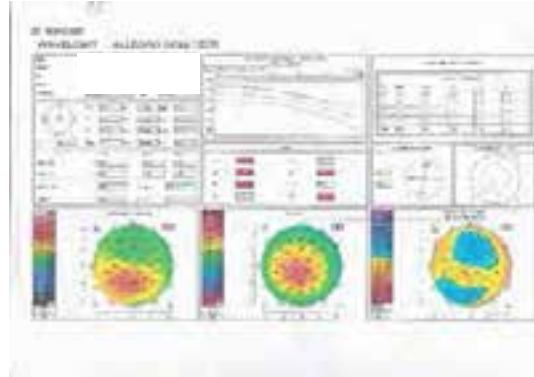
- **Monocentric study**
(National Reference Keratoconus Center Toulouse)
- Prospective, comparative, non-randomized
- **Conventional CXL (C-CXL)**
Vs topo guided CXL (TG-CXL)
- **60 patients with progressive keratoconus**
(progression > 1,5D Kmax)
 - C-CXL: 30
 - TG-CXL: 30
- **Follow up: M1, M3, M6, M12**



TG-CXL Method: Epi Off



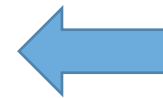
Topography



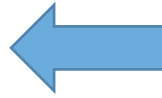
Map treatment



Epithelial removal **focused on the cone**



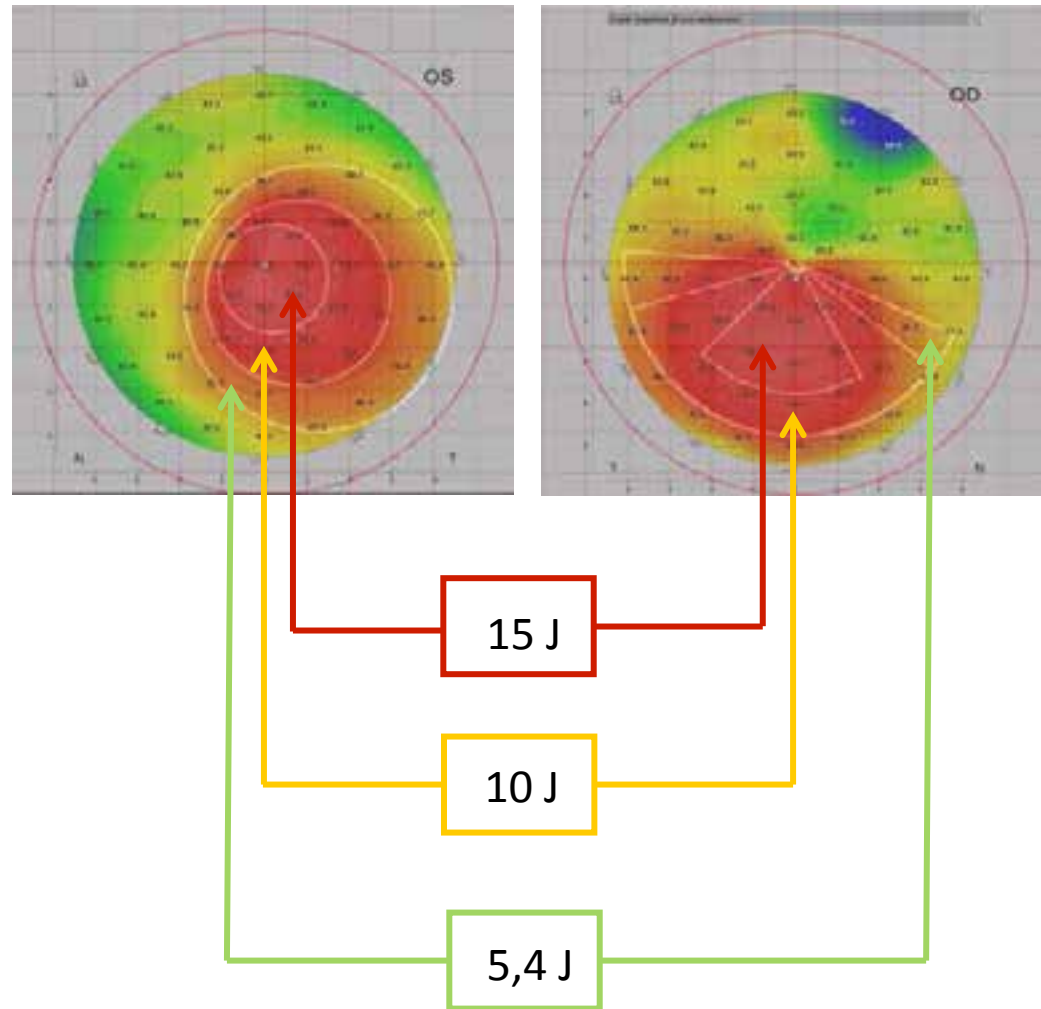
Riboflavine 0,1% VibeX rapid
1 drop every 2 min
During 10 min



Topo-guided **pulsed UVA**
(1sec on/1sec off) 16mn

TG-CXL Method

- UV treatment was **focused on the cone**
- « Multifocal treatment »
- Maximal dose 15 J/cm²

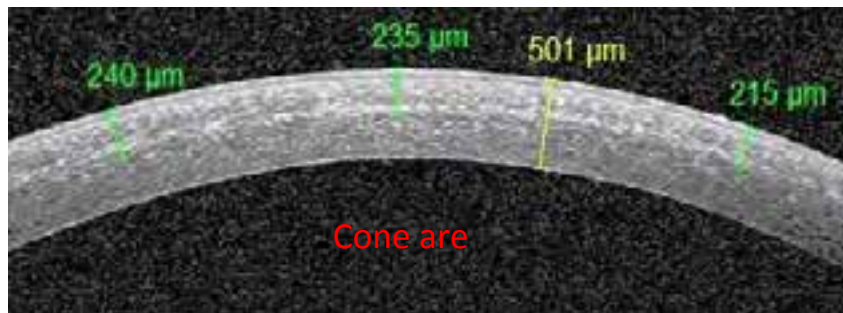
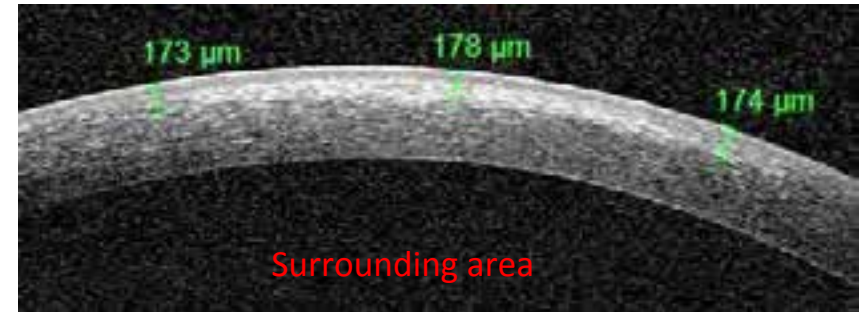
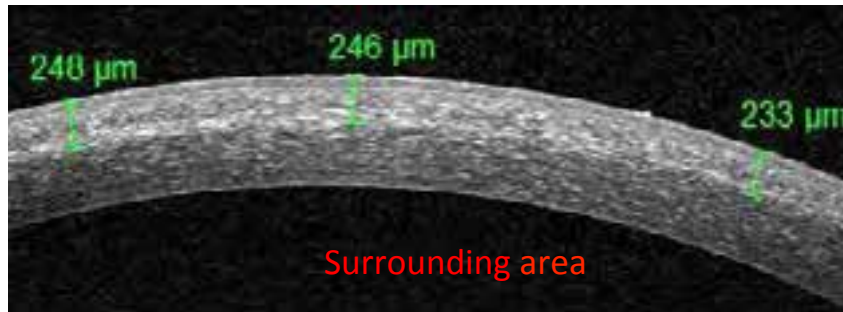


Results

OCT (1 month)

C-CXL

TG-CXL



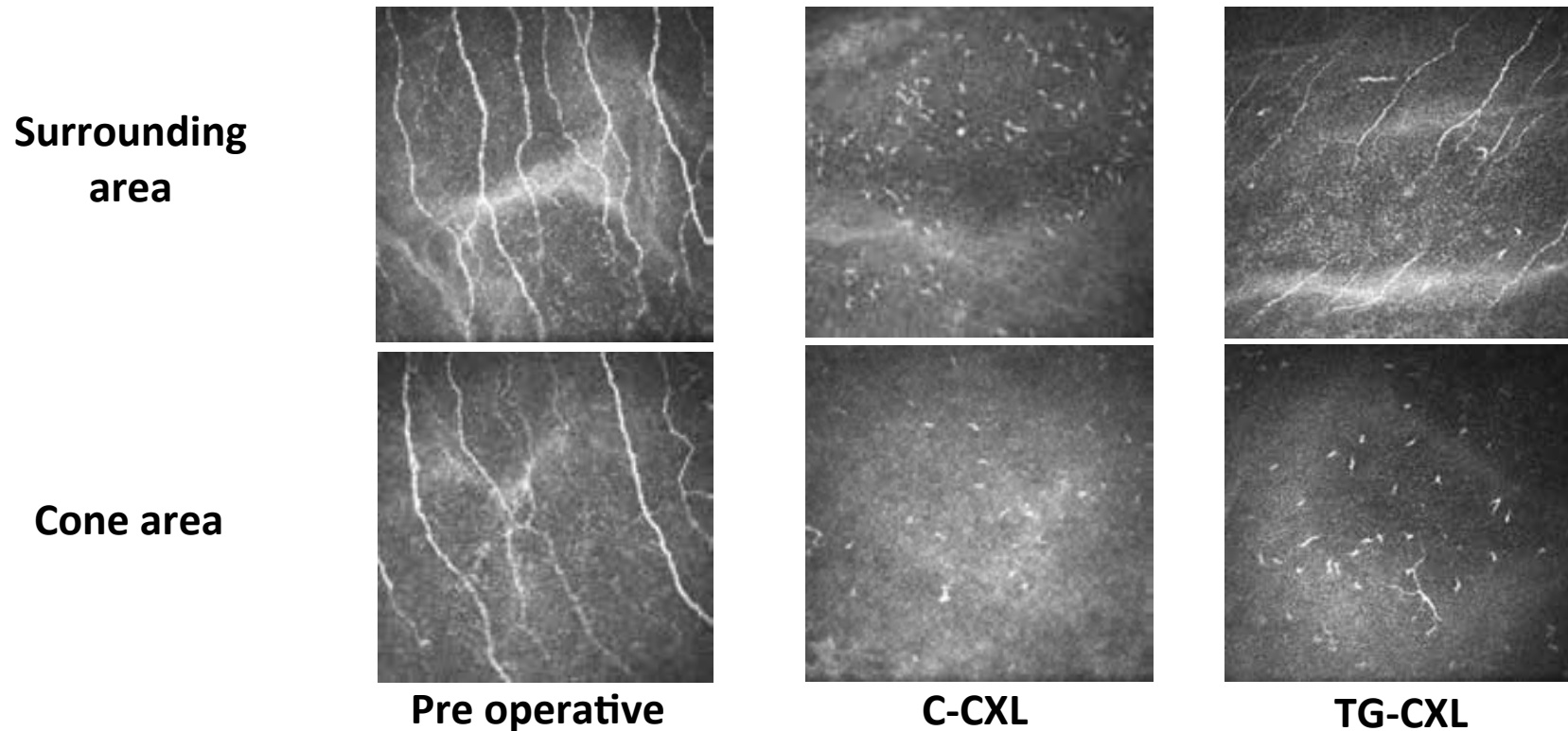
Demarcation line depth	C-CXL	TG-CXL
Surrounding area	245 ± 73 μm	182 ± 59 μm
Cone area	232 ± 43 μm	242 ± 46 μm

N.S. (between surrounding and cone areas for C-CXL)
p < 0.001 (between surrounding areas)
N.S. (between cone areas)

Results

Confocal Microscopy (1 month)

Nerve density

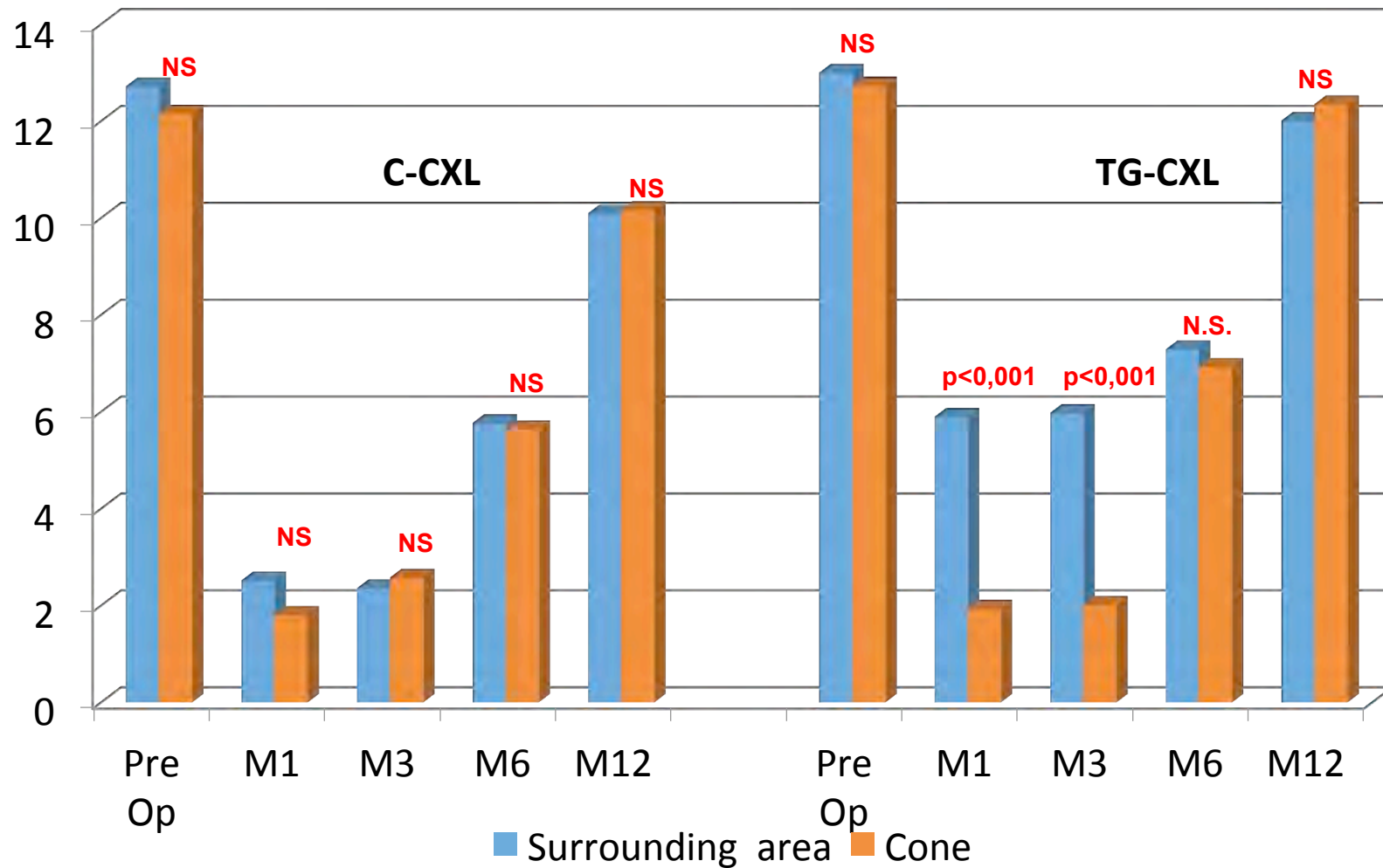


Counting Neuron J software	Surrounding area	Cone
C-CXL Nerve density	2,52 ± 1,61 nerves/mm ²	1,81 ± 1,10 nerves/mm ² <i>N.S.</i>
TG-CXL Nerve density	5,90 ± 5,04 nerves/mm ²	1,94 ± 3,45 nerves/mm ² <i>p<0.001</i>

Results

Confocal Microscopy

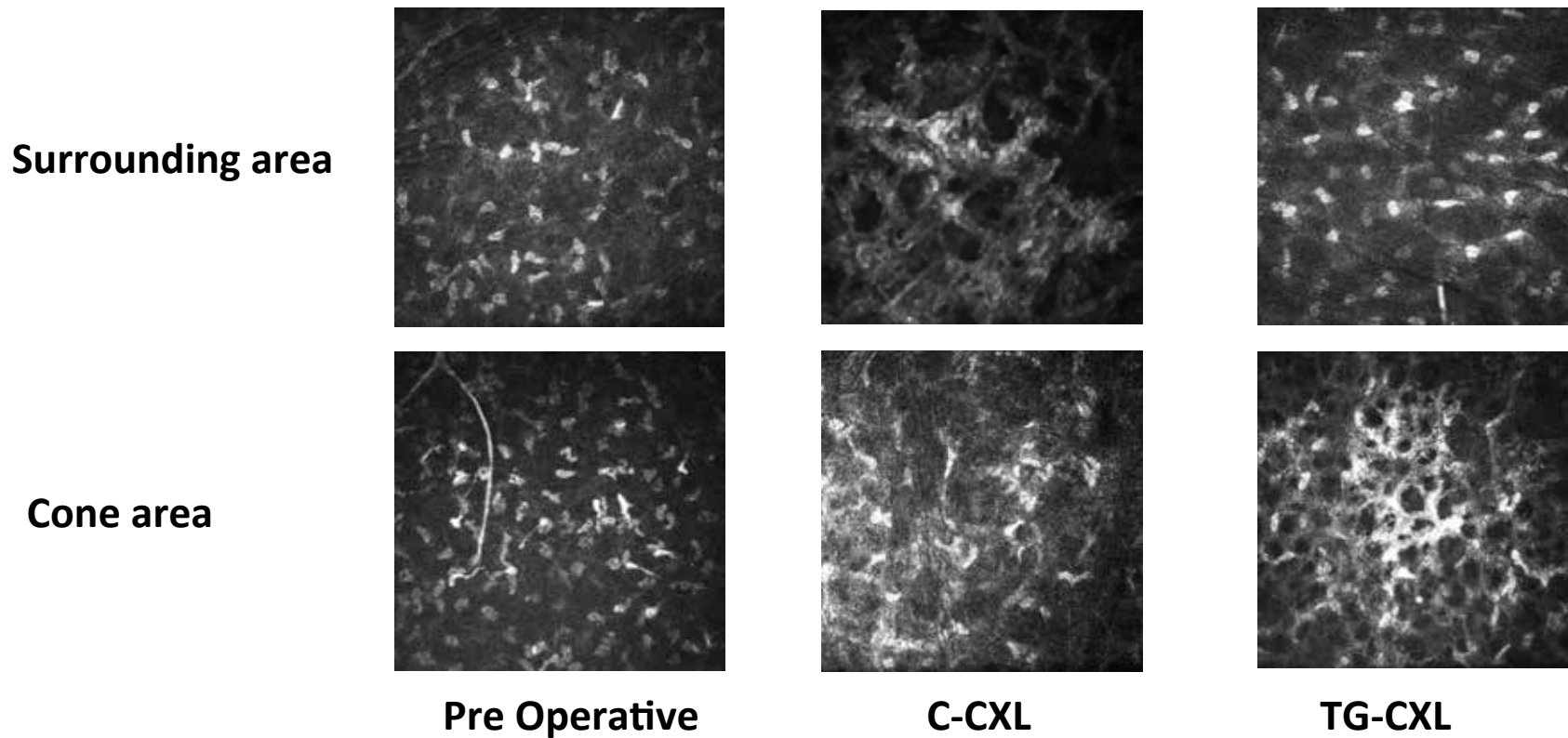
Nerve density evolution



Results

Confocal Microscopy (1 month)

Cell density

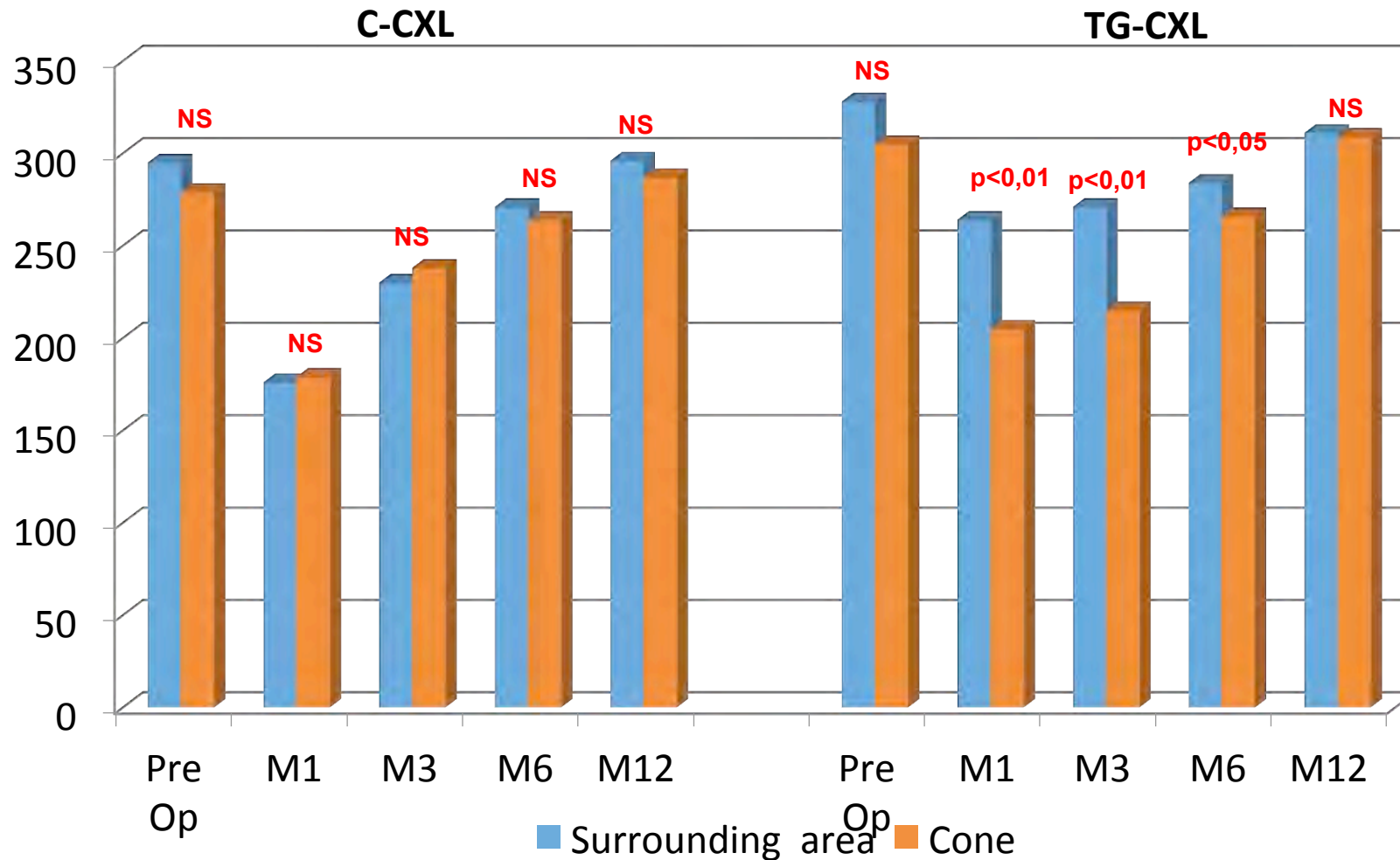


Counting Image J Software	Surrounding area		Cone area
C-CXL Cell density	176 ± 65 cells/mm ²	N.S.	179 ± 77 cells/mm ²
TG-CXL Cell density	264 ± 85 cells/mm ²	p<0,01	205 ± 70 cells/mm ²

Results

Confocal Microscopy

Cell density evolution

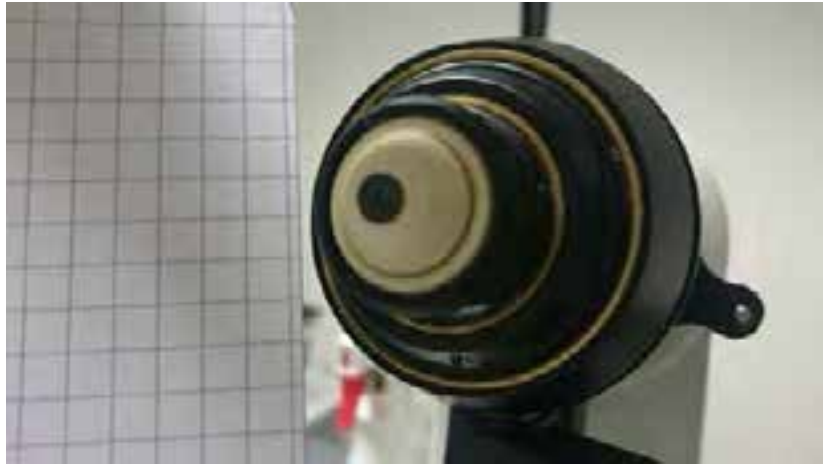


OCT and confocal studies

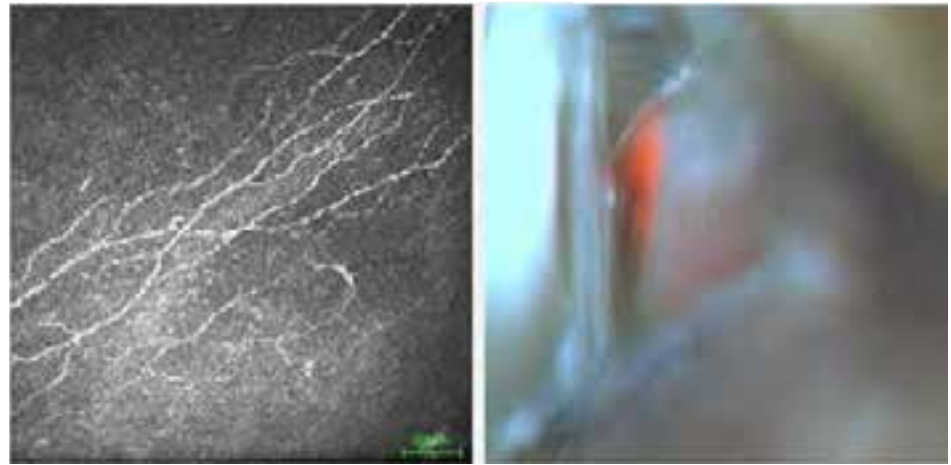
Summary

1. Topoguided treatment on top of the cone gives similar results to conventional epi off treatment (deep demarcation line , keratocyte activation)
2. Topoguided treatment also induces lower modifications on the surrounding area.



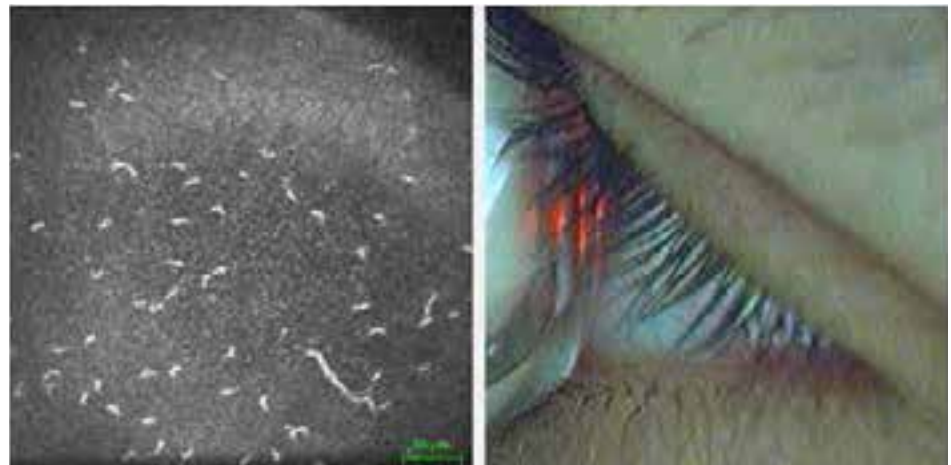


Optical head



Surrounding area

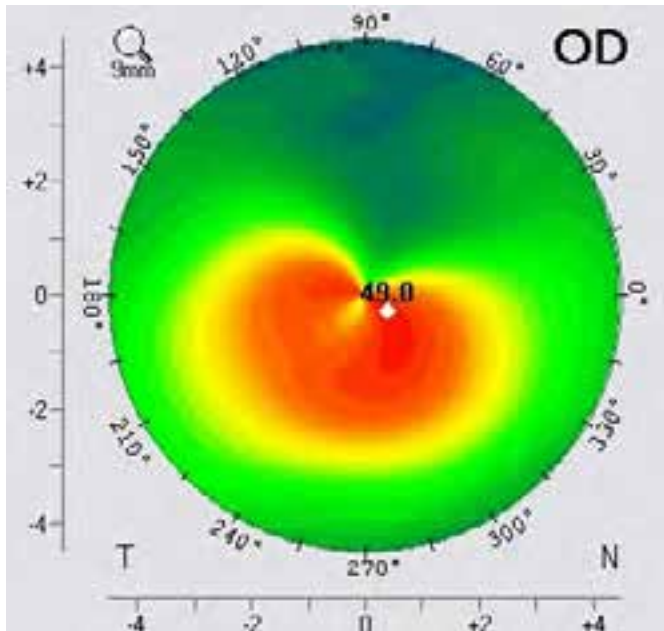
- Heidelberg Retina Tomograph II
avec Module Rostock Cornea
(Heidelberg Engineering GmbH, Heidelberg, Germany)



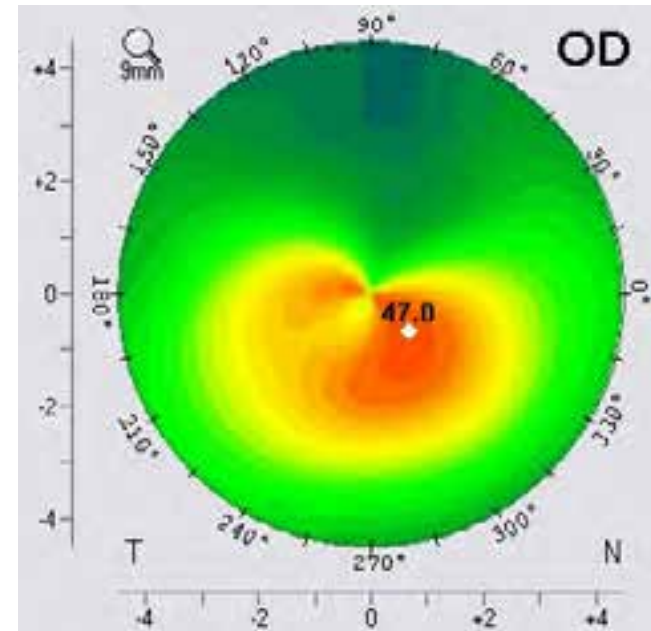
Cone area

Topography results 6 and 12 months

- Pentacam, WaveLight® Oculyzer™ II, (Alcon, U.S)



Pre Operative



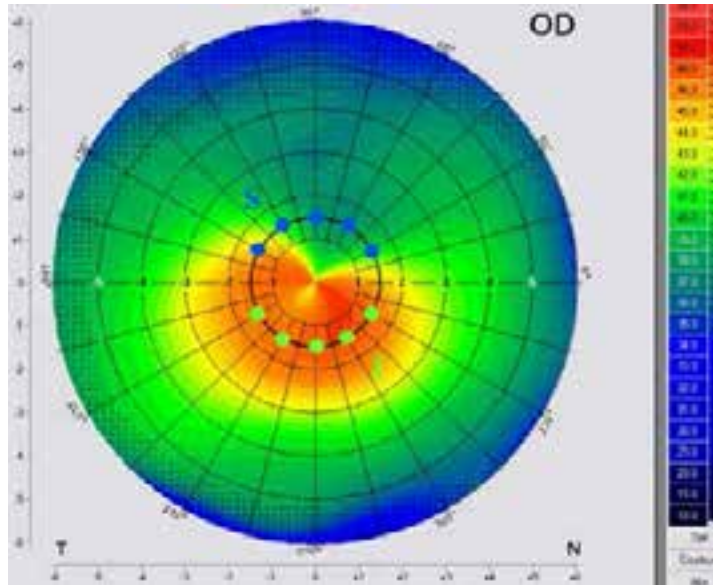
12 months post TG-CXL

K Max	TG-CXL		C-CXL
M6 - Pre Op	- 1,29 ± 2,44 $p < 0,01$	$p < 0,01$	0,44 ± 1,61 <i>N.S.</i>
M12 - Pre op	- 1,07 ± 1,70 $p < 0,001$	$p < 0,01$	0,4 ± 1,75 <i>N.S.</i>

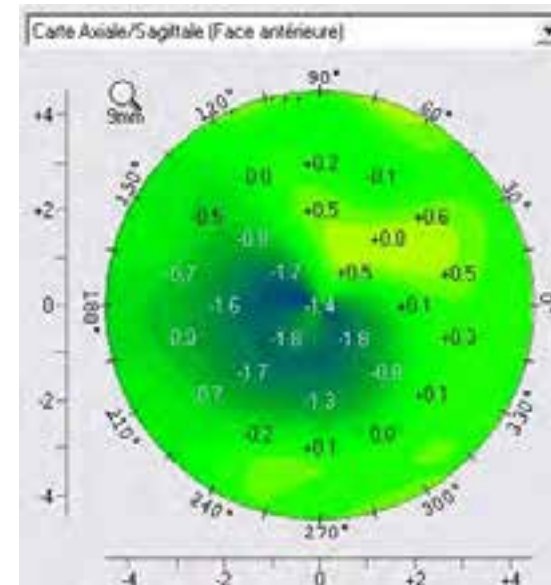
Topography results

Corneal reshaping : mean diopters (M12 – pre operative)

- Pentacam, WaveLight® Oculyzer™ II, (Alcon, U.S)



Mean diopters calculated with 5 points
on top and bottom on 3mm circle



Differential map M12-preop

M12 - preop	TG-CXL	C-CXL
On top (S)	0,645 ± 1,832 <i>N.S.</i>	0,636 ± 2,242 <i>N.S.</i>
On bottom (I)	-0,966 ± 1,204 <i>p<0,001</i>	0,5 ± 2,423 <i>N.S.</i>

p<0,01

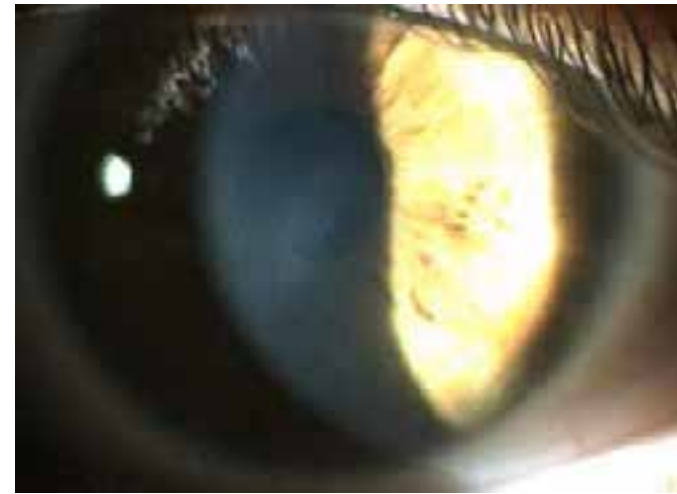
Best corrected visual acuity

Mean diopters (M12 – pre operative)

BCVA log(MAR)	TG-CXL	C-CXL
Preop	0,2996 ± 0,1907	0,3028 ± 0,2317
M12	0,2162 ± 0,2495	0,2648 ± 0,2574
M12 – Preop	-0,0898 ± 0,2108 $p < 0,05$	-0,0292 ± 0,1683 $N.S.$

Adverse events

- Side effects:
Pain, itching , haze



- Specular microscopy:

	TG-CXL	C-CXL
Pre Operative	2684 ± 276	2669 ± 233
12 months after surgery	2855 ± 497	2688 ± 281
(M12-Pre Op)	230,5 ± 534 N.S.	7,4 ± 248,4 N.S.

Conclusion

- On top of the cone, TG-CXL has **similar biological effects** as C-CXL (deep demarcation line, keratocytes activation, decrease of nerve density)
- TG-CXL induces a **biological gradient** between the cone and the surrounding area
- TG-CXL induces a **flattening effect** which is **more important than C-CXL**.
- TG-CXL **improves significantly best corrected visual acuity**.

**Thanks for your
attention**

