Contact Lens Fitting after Corneal Collagen Crosslinking

Boris Severinsky, OD, FAAO, FBCLA, FSLS
Specialty Lens Service
Emory University
Atlanta, GA
Treatment of Keratoconus

► Started in late 90’s by Prof. Seiler, Germany
► Approved by US FDA advisory pannel, 2016
Avedro KXL system

Can corneal crosslinking stop progressive keratectasia in keratoconus?
Why Crosslinking

HALTS PROGRESSION OF:

• KERATOCONUS
• PMD (PELLUCID)
• POST LASIK KERATECTASIA

- INCREASE IN CORNEAL STEEPNESS AND ABERRATIONS
- LOSS OF BCVA !!!
- ABOUT 20 % OF KERATOCONUS CASES END UP HAVING KERATOPLASTY (Taft SJ. Ophthalmol. 1994)
- DRAMATICALLY REDUCE FURTHER NEED FOR SURGERY

• ANY INTERVENTION TO PREVENT PKP IS WELCOMED
KC Progression - Definitions

An increase of (over 12 months):

• Manifest refractive astigmatism >1.0 D or > 0.5 D of SE
• Or steepest keratometry (Kmax) > 1.0 D
• Stop soft CL 2-3, RGP 7 days pre examination !?

OD +1.75/-2.75x45, 20/40
OD +2.25/-3.25x60, 20/40+/
soft CL VA 20/25
OD -1.50/-5.75x77, 20/70
RGP CL VA20/20-

Mar 2014, Kmax 58.0
Mar 2015, Kmax 65.2
RGP CL 20/40
Stiffness of keratoconic cornea

Assumption:
• The stiffness of the keratoconus cornea is reduced
• Evident before changes in topographical pattern

• KC Cornea - reduced amount of crosslinks
• Age dependent

• Aim of CXL:
  • Compensation of this weakening

• Increase of biomechanical stiffness by a factor of 1.5!

\[ \sigma_{KC} = 8.1 \text{ N/mm}^2 \]
\[ \sigma_{nor} = 12.7 \text{ N/mm}^2 \]
64%
CORNEAL PACHYMETRY
Minimum 400 micron

• To avoid damage to endothelium
• In corneas thinner then 400 micron hypo-osmolar riboflavin required to inflate the cornea before UV application

• Decrease of UV intensity
• Effective crosslinking is achieved in the anterior 250-300 µm of corneal stroma
• **No endothelial damage!**
0.35 mW/cm² cytotoxic treshold level
Dresden Protocol

- Corneal abrasion 8mm
- 0.1% Riboflavin in 20% dextran until the anterior chamber is yellow colored (flare)
- 365 nm, 3mW/cm² for 30 minutes
  - Only the cornea is irradiated, sclera and limbus are not treated.
  - Due to the fluorescence the irradiated area is visible.
Demarcation Line

Due to change in refractive index

Standard CXL
3 mW/cm² for 30 min
CXL - Corneal Curvature Effect

- F/U - 1, 3, 7 days – epithelial healing
- F/U - 0.5, 1, 3, 6 months – topos, refraction, CL?
- Initial worsening (steepening) 1-2 months
  Reduction in epithelial layers and thickness
- Continuous flattening 2-12 months
  Stromal “compaction” effect
- Surface regularization and decrease in astigmatism
Corneal Steepening after CXL

Pretreatment: 29yo, male RGP intolerance, VAspec 0.3".

2 m. post CXL, Steepening, Hypertrophic (white) epithelium, haze, VA 0.5" (Soft KC lens).

4 m. post CXL
Base level topography VA ↑
Corneal Flattening after CXL

21 yo, f, Pre treatment
VA Spec 0.3; VA CL (soft) 0.5

1.5 m after CXL
Soft KC VA 0.7
Central Haze, Minor flattening

9 m after CXL VA↑ 0.9
>2 D of flattening
Central Corneal Regularization

- Improvement in UCVA and BCVA
- Decrease of corneal astigmatism
- Change of spherocylindrical refraction

Preop OS Plano/-5.50x70, BCVA 20/50

4 m. postop. OS -3.00/-1.25x110, 20/25
Keratoconus is a (non)-inflammatory disease

COMPROMISED OCULAR SURFACE

**Chronic Inflammation**¹

CL induced chronic epithelial micro-trauma, erosions
(Mechanical trauma associated with keratocytes apoptosis²)

Cell-toxicity by solutions with preservatives

Eye Rubbing

Dry eyes

Corneal hyposensitivity

Compromised corneal epithelium

**IMPORTANCE OF MINIMAL CL EFFECT ON RECOVERING CORNEA**

2. Wilson et al., 1996a; Helena et al., 1998
Types of contact lens correction

- (R)GP – rigid gas permeable – corneal 8-11 mm
- Corneo-scleral RGP’s – large diameter, 12-14 mm
- Hybrid lenses, 8 mm GP lens, SiHy skirt
- Hydrogel/SiHy lenses
- Scleral Lenses
Spherical Corneal Lens

• Sequence of continuous radial curves
• BC – (base curve), fits central or most protrusive corneal area
• OZD – (optic zone diameter), larger or equal to pupil size
• Back peripheral radii- alignment with corneal contour, landing over “normal” peripheral cornea
• Edge lift – tear exchange, pumping mechanism

Till recently → “Gold Standard” for KC visual rehabilitation?
RGP’s fitting approaches

- Separate fitting of central (OZ area) and peripheral cornea (secondary curves)
- Depend on corneal contour, cone location and size:
  - central, inferocentral – nipple cone
  - inferior – oval cone
  - marginal degeneration (PMD)
RGP’s fitting approaches

- Three point touch vs. apical clearance
- Even spreading of CL weight over “healthy” peripheral cornea
- Corneal scaring prevention
Spherical RGP’s Complications

• Central bearing/three point touch
• Better VA over scared/highly irregular corneas
• Higher rates of CL induced:
  • corneal erosions → stromal fibrosis
  • Corneal scaring – decreased VA (CLEK study)
• Rate of MK?
Keratoconus Spherical RGP’s

• **Minimum apical clearance:**
  - light ! fluorescein pooling in the center
  - “feather” touch in intermediate curve
  - sufficient edge lift to allow tear exchange
  - tight lens syndrome, corneal imprint
Large Diameters RGP’s

• Peripheral corneal degeneration, large inferior cones, post PKP
• Intralimbal, full corneal coverage
  TD: 11 – 13.5 mm
• Larger OZ relatively to microcorneal lenses
  ~8.50 – 9.20 mm
Asymmetric Corneal Periphery

• Limbal ATR astigmatism
• Spherical BC, Toric lens periphery
• Better corneal alignment => VA↑

b.c. 8.10, diam. 10.3

same b.c. toric per. 8.0D difference

VA 20/40

VA 20/30
Asymmetric Corneal Periphery

- KC - marked peripheral inferior steepening
- PMD, post LASIK ectasia
- The inferior quadrant of the lens is steeper
Piggyback Lens Systems

- Hybrid of RGP & thin soft CL
- Improved comfort!!!
- Reduce peripheral RGP complications (SPK’s, abrasion, 3&9 desiccation)
- Surface regularization (Improvement in regularity)

Cons
- Two lens per eye daily
- GP lens may dislodge
- Dual optics – increase in aberration
Piggyback Lens Systems

- Improve patient comfort
- **SCL Protects corneal epithelium**
- Manage peripheral RGP complications
  (No mechanical abrasion)
- Provide smoother fitting surface
  (Improvement in regularity)

Management
- Two lens per eye daily
- Dual optics - higher aberrations
- Centration depends on carrier’s shape (positive/negative Pow.)
Custom Piggyback Systems

Improves RGP’s centration
• Pocket lens
• Pillow lens
• Low oxygen passage - fenestrations
• Aberrations
Complexity of CL fitting post CXL – RGP’s

• Epithelial thinning and remodeling → months (Rocha KM, JRF2014)
• Decrease in basal epithelial cells & neural plexus density (Sehra SV, Br J Ophth., 2014)
• Corneal hypoesthesia - up to 3 month
• GP lens driven inflammatory response ↑ (Lema I. Cornea 2008)
• Mechanical trauma - risk of CL related microbial keratitis
• RGP’s after PRK - wait 3-4 m. (Zadnik K. Curr Opin Ophthalmol 1999)

Delayed epithelial healing
CLEFT Study and Corneal Scarring

Keratoconus and RGP Contact Lenses

- 5-year incidence of corneal scarring: 13.7%
- 38.0% incidence in eyes steeper than 52 D wearing RGP contact lenses
- **RGP contact lens wear - more than doubled risk of corneal scarring**

- Corneal scarring may be reduced by modifying contact lens fit:
  - Special Soft
  - Hybrid lenses
  - RGP or Soft scleral’s
RGP’s- It should be bearing surface somewhere

- First 3-6 mo. - No more the “Gold Standard”
- Corneal insult
- Neural plexus density ↓
- Central cones, thicker corneas, apical clearance
- Ex. Rose-K
Patients and Lenses

- 53 patients (68 eyes), 63 (93%) eyes epi-off CXL
- Study period 2014-2015
- **Soft Mini-Sclerals (SmS)** (coopervision, UK)
- **Hybrids**: UH, KC, Syn KC (Synergeyes, US)
- **Sclerals** (Microlens 18.50 mm and ICD 16.50)
- Success criteria > 10 h/day wearing time

<table>
<thead>
<tr>
<th>Lens Modality</th>
<th>Eyes, No</th>
<th>Mean Age, yr</th>
<th>Mean F/U time, months</th>
<th>Time after CXL, months</th>
</tr>
</thead>
<tbody>
<tr>
<td>SmS, n=22</td>
<td>30</td>
<td>27.2 ± 9.6</td>
<td>6.4 ± 2.7</td>
<td>2.5 ± 1.6</td>
</tr>
<tr>
<td>Hybrids, n=19</td>
<td>24</td>
<td>26.2 ± 7.1</td>
<td>5.6 ± 3.1</td>
<td>4.3 ± 2.2</td>
</tr>
<tr>
<td>Sclerals, n=12</td>
<td>14</td>
<td>28.5 ± 6.8</td>
<td>6.1 ± 2.8</td>
<td>4.7 ± 2.7</td>
</tr>
</tbody>
</table>
Soft Contact Lenses

• Bandage CL after CXL
• 7-14 days
• Ex. Acuvue Oasys 8.4, Pure Vision 2, Night&Day
• Use lowest modulus
• Large diameter BCL (16 - 20 mm)
  - Steep corneas, poor centration
  - Delayed healing

Ex. Kontur, David Thomas
“Regular Cornea” designs after CXL

- CXL leads to reduction in myopia, astigmatism and aberrations
- Corneal regularization, conventional may CL works well
- Better results with stiffer SiHy Ex. PureVision, AirOptix Aqua or Night&Day

Pre CXL -1.00/-3.25x150 20/40
Postop -0.50/-2.00x140 20/25
Soft Lenses for KC + CXL

- “Minimal apical touch"
- Rest over sclera and peri-limbal cornea
- No limbal compression
- Lens thickness and rigidity responsible for surface regularization effect → liquid lens effect

- Ex. Soft-K SiHy mini-scleral, NovaKone, Flexlens
Soft (SiHy) Scleral Lenses

- TD = 17 mm; CT = 0.5-0.6 mm
- Rests on sclera and peri-limbal cornea
- No limbal compression, minimal epithelial impact
- Minimal apical touch, PLTL (post lens tear layer)

CT = 0.6 mm
Oxygen Delivery

• Compensate for lens thickness

• **Definitive® - Latheable SiHy:**
  - Dk of 60, modulus of 0.39 MPa
  - Oxygen flux, five times greater than hydrogels¹

• Positive fluid ventilation

• **Fenestrations:**
  - Improved limbal oxygenation
  - Prevent lens adhesion

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Surface Regularization - Soft Sclerals

- **Lens material**: Definitive 65, Contamac, UK
- **Increased resistance to deformation**, Modulus of 1.0!
- Marked improvement in regularity
- Surface stability = ↑BCVA

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![Over CL Topography](image)

**Sim K 47.3 / 44.2**

**Sim K 40.0 / 39.0**
Modern Hybrid Lenses

- Absence of contact with central treated zone
- Rigid & Soft landing zones – provide excellent centration
- Work well for mild KCN and central cones
- VA similar to RGP, much improved comfort!

**Hybrid lenses evolution**

<table>
<thead>
<tr>
<th>Lens Type</th>
<th>Center, Dk</th>
<th>Skirt, Dk</th>
</tr>
</thead>
<tbody>
<tr>
<td>KC</td>
<td>100</td>
<td>9.3</td>
</tr>
<tr>
<td>ClearKone</td>
<td>100</td>
<td>9.3</td>
</tr>
<tr>
<td>UltraHealth &amp; Duette</td>
<td>130</td>
<td>84 !!!</td>
</tr>
</tbody>
</table>
Hybrid Lenses after CXL

- Clearance over the central cornea/treated zone!
- Lands on peripheral cornea
- CT=0.22 mm $\rightarrow$ 60 Dk/t
- Sealed cornea-lens system
Scleral Lenses after CXL

- Probably the best case scenario for:
  - Steep corneas, \(K_{\text{max}} > 55\)D
  - Compromised ocular surface

- Precautions:
  - Fluid ventilated, non sealed lens
  - Avoid any limbal touch - disrupts Epi. remodeling

Visser ES, et. al. Scleral Lens Tolerance after Corneal Cross-linking for Keratoconus. OVS 2015
Mini-Scleral Lenses for KC

- 14.0-17.0 mm diameter
- Ideal for central ectasia
- Adhesion, limbal compression and blanching
- Fenestrations - better oxygenation, break down adhesion
Mini-Scleral Lenses for KC

- Compromised fit on progressive cases - higher vaults
- Insufficient corneal vault, due to small size <15.0 mm
- Importance of minimal movement and fluid ingressions
Full Scleral Lenses after CXL

- Works for corneas steeper than 60 D, inferior cones
- No contact with treated zone
- Can be fitted on eyes with markedly irregular cornea
- Provide constant lens-cornea aqueous reservoir
- Drug delivery
Results

- 64 eyes (94%) BCVA CL of ≥ 20/40; Success rate ≈ 90%
- Soft Sclerals – 8 eyes Kmax ≥ 55 D, BCVA ≥ 20/40
- Sclerals: ↑ BCVA despite higher Kmax, thinner K’s
- 24 (42%) eyes exhibited ≥1.0 D flattening of Kmax

<table>
<thead>
<tr>
<th>Lens Modality, eyes</th>
<th>VA, Refr</th>
<th>VA, CL</th>
<th>Kmax, D</th>
<th>CCT, mic</th>
</tr>
</thead>
<tbody>
<tr>
<td>SmS, n=30</td>
<td>0.43 (20/50+)</td>
<td>0.69±0.17 (20/30)</td>
<td>49.5±3.9</td>
<td>445±34</td>
</tr>
<tr>
<td>Hybrids, n=24</td>
<td>0.41 (20/50)</td>
<td>0.74±0.14 (20/25-)</td>
<td>53.8±4.5</td>
<td>420±40</td>
</tr>
<tr>
<td>Sclerals, n=14</td>
<td>0.33 (20/70)</td>
<td>0.77±0.12 (20/25)</td>
<td>56.9±4.8</td>
<td>411±55</td>
</tr>
</tbody>
</table>
Results: Safety

- Mean wearing time 10.2, range 6-14 h/day
- Drop outs: 8 patients (15%)
  - SmS: 2 pt insufficient VA, 3 pt recurrent non-wetting
  - Hybrids: 2 pt epi. insult, 1 pt extreme corneal flattening
  - Sclerals: NON

3.50 D flattening, BCVA 20/25 (soft toric)

4 m. post CXL

- Sm K's:
  - 46.86 (7.20) @42° [e = 0.90]
  - 45.82 (7.37) @132° [e = 0.80]
- dk = 1.04 (0.17)
- KISA%: 25
Hybrid Lenses after CXL study - Complications

- 49 eyes of 35 pt. (9f/26m)
  ✓ KC - 24 eyes
  ✓ KC+CXL - 25 eyes
  • KC+CXL fitted 9.2 ± 5.3 m after CXL

<table>
<thead>
<tr>
<th>Group</th>
<th>Juncture erosion</th>
<th>Central erosion</th>
<th>SEI</th>
<th>Epithelial edema</th>
<th>GPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>KC</td>
<td>7</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>KC+CXL</td>
<td>2</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

2 weeks, 250/M Ring erosion
Skirt changed to F
Hybrid Lenses after CXL Complications

- **Juncture bearing**
  - Ring erosion, sterile infiltrates
  - Corneal tissue remodeling – BAD!
  - Epithelial hypertrophy

- **Wait >2 hours to evaluate**
- **Flatter the skirt** (increase vault to compensate)
- **Piggybacking**
  - Hyper Dk SiHy - N&D, Total-1 (off label use)

![2 mo post CXL](image1)
![2 weeks after fitting](image2)
Post CXL fitting - Proposed paradigm

- Wait for $\geq 6$ weeks (healing dependent)
- Start custom Soft mini-Scleral lenses:
  *Allow 3-4 mo. for Epi. remodeling* (Severinsky B et. al Clin Exp Optom, 2013)
- Refit with Scleral: Jupiter, Zen, your custom design...
Conclusions

• CXL: Continuous Biomechanical Changes
• Compromised ocular surface/delayed healing
• Steeper corneas may require longer recovery time
• Scleral contact lenses (Soft and GP) seem to be the best option available

The art of contact lens fitting after CXL is minimally interfere with normal corneal recovery
Scleral Lenses after CXL

• CXL and scleral contact lenses - first steps in treating keratoconus

• Corneal imaging for progression monitoring

• Side effects of scleral lens wear may bias CXL decisions
Importance of serial imaging for progression monitoring

• What considered progression?
• Serial anterior topographic analysis
• A steepening of the Anterior Corneal surface by >1.00D or an increase in Refractive Astigmatism of 1.00D over 6 months
Scleral Lenses for Keratoconus

- Gaining international popularity, became a mainstream in the US
- 78% of KC patients are Specialty Contact Lens dependent
- 2017 data >30 % using Scleral Lenses
- Often fitted as soon as 2-3 weeks after CXL

Potential complications of Scleral lens wear:
- Corneal warpage – never studied, since contradicts scleral lens principles
- Corneal Edema – studied and was found insignificant (<1.7%)

Progression monitoring in Scleral Lens Wearers

37 YOM, Moderate Progressive? KCN, Scleral CL wearer Came in for progression monitoring Exam: Well fitted SCL, good CL corrected vision (20/25+)
Topo → significant corneal flattening ( > 4 diopters)
• Good Fit - Scleral lens with no corneal contact or limbus compression
• No signs of corneal edema
• Flattening of K steep of 2.1 D
Cornea may fluctuate significantly under SCL

Same day Topo after lens removal

Lens discontinued for 2 weeks
K’s are back to pre SCL readings
SCL vs. CXL induced Flattening

• 15 yo, BM, Advanced KCN, OS - 6 mo s/p CXL
• Very dependent on SCL for school, Can’t take CL “holidays”
• Corneal regularization: Central flattening with mid-peripheral steepening
• Possible CXL effect?
Questions

• How do we follow up on progression/regression after CXL in Scleral Lens wearers?
• May SCL bias CXL treatment/Retreatment decisions?
• Does CXL prevent unwanted scleral lens effects?
KC progression monitoring following CL wear

• Recent documented topographic progression and accurate topography readings are essential for CXL decision and post CXL follow-up

• In most CXL studies, patients who wear corneal RGP lenses are requested to discontinue CL wear in order to avoid bias in corneal curvature determination.

• For scleral lenses, there is no defined consensus on this topic
Study Design

• To evaluate the influence of short time scleral lens wear on the anterior corneal topography
• Nine KC subjects (14 eyes)
• KC and CXL group – 7 eyes
• KC w/o CXL – 7 eyes, control group
• Corneal Topography at the base line and after 2 and 5 Hr
• All fitted with 18.50 mm lenses, Contamac Optimum Extra (Dk=100)
• All fitted lenses had the post settling clearance of 130 to 200 mic (Visante, Zeiss, inc)
Results

- Mean age 28.5 ± 6.8 years
- KC+CXL group – meant time after CXL 2.1± 1.3 months
- Mean cl BCVA 0.77±0.12 (20/25)
- Corneal flattening was observed in 12 (85.7%) of fitted eyes, (p<0.05)
  - Ksteep flattening of 0.4±0.6 (2 hours) and 0.7±0.6D after 5 hr
  - Kmax flattening of 0.6±0.6 D (2 hours) and 0.9±0.7 D after 5 hr
Results: KC+CXL vs KC Sim K’s and Kmax changes

- After 5 hours of the lens wear no statistically significant difference was found in the amount of Ksteep and Kmax flattening between CXL (0.6 and 0.75 D) and non-CXL (0.7 and 0.9 D) eyes.
Corneal flattening - Proposed Mechanisms

- **Epithelial thinning** - fluid forces or negative pressure under the lens, d/t over time reduction in post-lens corneal clearance
  
  Vincent et.al. CLAE, 2018 Thinning of 2.4% after 6 h of SCTL wear

- **Scleral lens induced corneal swelling**
  
  • Increased pachymetry associated with central corneal flattening
  
  Compan et. al. IOVS 2014 – Swelling of 1.5-4 %. **Our study swelling of 1.7%**

- **Blink forces** and upper eyelid pressure cause superior corneal flattening.
  
  Controversial [Vincent et. al. CLAE, 2014]
Conclusions

• Scleral lens wear causes flattening of the anterior corneal surface

• History of CXL treatment doesn't warrant for corneal shape stability following scleral lens wear.

• Practitioners should be aware of these changes since SCL wear may mask the signs of disease progression or regression following CXL, due to an artificial, temporary corneal flattening

• Discontinuation of lens use prior to evaluation is necessary for proper follow up on the ongoing corneal changes, however further studies are required to determine its duration.
Complications
Contact lens induced sub-epithelial infiltrates
BY, 18yo, male

BCL- Purevision, modulus of 1.5!
Pre-CXL
Irregular surface
Very steep cornea

4 d after RE CXL; cultures: negative

Kmax 67D
Custom Soft Lenses- Complications

• Fitted up to 1.0 mm flatter than Kmax
• Increased thickness (SiHy ↑stiffness )
• Erosions & demolding similar to RGP’s
• Limbal support = impingement (compression)
MGD and Surface Wettability of SiHy

- MGD and tear film compromise
- Alternation of the polymer structure
- Lipid accumulation and formation of the non-wetting areas

First treat the ocular surface!
Large Diameters RGP’s

• Better comfort: minimal lens movement and low edge lift, BUT:
• Higher risk of corneal hypoxia and edema
• High DK materials & fenestrations of the peripheral area?
ClearKone
50 µm apical clearance

After lens removal

SEI under the juncture area
6 m post-CXL, K max 64.6 D

Juncture area
Semi-circular SEI

Hybrid Lenses after CXL-Complications
Scleral Lenses
Importance of Physiological Fit

• Mild KC, s/p SXL, spec blur after lens removal
• Mini-SCTL 15.60 diam, 170 μm central vault
• Fluid reservoir depth of small-diameter lenses decreases ~ 50% after 2 hr of lens wear → **Possible Epithelial compression and thinning** (Schornack, ECL, March 2017)
• Refitted with 18.50 lens, 250 μm clearance, stable VA

Base, Kmax 56.32, Ast 7.1 D
5 hours Kmax 55.34, ast 6.5
CXL and Scleral Lenses for Keratoglobus

PKP contraindicated!!!

What about TEP CXL and Sclerals
Conclusions

• CXL - Continuous Biomechanical Changes
• Corneal Steepening – Epithelial Remodeling
• Corneal Flattening – Stromal Changes
• Regularization and fluctuations of refraction
• RGP’s no longer the “ONLY” option
• The art of contact lens fitting after CXL is minimally interfere with normal biological recovery of corneal surface
Conclusions

Contact Lenses for Keratoconus

- Time consuming procedure, multiple visits required
- Requires numerous lens/designs changes
- Variable vision and comfort
- Might be very expensive, compromised insurance coverage

Corneal Collagen Crosslinking

- As a primary eye care practitioners, we have an obligation to tell our patients with ectatic disease that there a procedure that could stop, slow or stabilize the progression of the disease... especially when treating early onset disease in young/pediatric patients. We have the ability and technology to stop a lifetime of bad vision, challenging contact lens fits, expensive optical devices and even corneal transplants.
Thank you for your attention!

borisseverinsky16@neco.edu