ViTAL Keratoconus Classification, The AMART (or SECRET) & Gregory Lens Projects

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Purpose:

- To describe a classification system for keratoconus designed to address present and future therapeutic options for the individual keratoconus patient
  **ViTAL Classification**
- To present an Excimer Laser based technique to treat early, moderate and advanced keratoconus
  **The AMART (SECRET) Project**
- To present an idea for a novel iris supported phakic IOL
  **The Gregory lens Project**
Lateral thinking is solving problems through an indirect and creative approach, using reasoning that is not immediately obvious and involving ideas that may not be obtainable by using only traditional step-by-step logic. The term was coined in 1967 by Edward de Bono. [1]
CXL – Dresden protocol, C3R, TransCXL, Triple CXL, Reverse Bioptics CXL, Athens Protocol, accelerated CXL, KXL, KXL II, PRK-xtra, Lasik-xtra, PACK-CXL, PiXL......
Greek Tabloid 1/2014
“Myopia Terminated with Drops”

“This revolutionary application...invented in Greece.....is approved for clinical use in Europe (CE Mark)”
Avedro’s PiXL

- Novel myopic refractive correction with transepithelial very high-fluence collagen cross-linking applied in a customized pattern: early clinical results of a feasibility study

Published online Apr 7, 2014. doi: 10.2147/OPTH.S59934
PMCID: PMC3984063
It is possible to perform PKP/Open Sky Surgery without ever losing the IOP

>> the Eyelock KP system

It is possible to perform PKP surgery without sutures and without glues and still have the strongest attachment ever

>> the T-Kplasty system
2014: The EyeLOCK V.03 Device
• It is theoretically possible from a simple classification system to predict which keratoconic patient needs which specific (surgical) treatment option
• It is theoretically possible to perform up to -9.00 dpt of ablative excimer laser surgery in a “stable” patient with keratoconus without jeopardizing his recently crosslinked cornea.
• It is theoretically possible to manufacture and place a phakic iris enclavated lens
  – with micron 3D Accuracy in order to safely correct all higher order aberrations.
    • 100% LOS and XY alignment
    – <2mm incision size
    – Procedure accessible to the average surgeon
background

• Not long ago surgical options for keratoconus were limited to PKP or DALK
  – Curvature based classification systems for keratoconus were adequate
• With introduction of new techniques like corneal inlays, wavefront ablation/CXL & phakic IOL’s current curvature classification systems do not predict success/failure
Pt seen on Wednesday

BSCVA 20/80
RGP VA 20/20
AbVol 2400nl

BSCVA 20/32
RGP VA 20/20
AbVol 4400nl
Stage III Keratoconus
“I have only made this letter longer because I have not had the time to make it shorter.”

(Letter 16, 1657)”

— Blaise Pascal, The Provincial Letters
ViTAL Classification for keratoconus

Ablation Volume

Amount of tissue that needs to be removed in order to regularize keratoconic surface - corneal WF theory!

Derived from the curvature > elevation topographical disparity from "norm"

incorporates curvature abnormality + Refractive Error of eye of interest

Pierre Denoix (1912-1990) (1943-52)

T umor

N odes-(lymph-)

M etastasis
ViTAL

Vi  Vision (BSCVA)
T  min Thickness
A  Ablation (ORK-CAM)*
L  Length (AC Depth)

• Extra denominator

U / P / S  unknown / progressing / stable  Topography

*ablation volume in nL theoretically needed in CW module to regularize surface  (TAZ 8,30mm)
Vi: BSCVA

- $V_{i_1}$ 20/20-20/25
- $V_{i_2}$ 20/32-20/50
- $V_{i_3}$ 20/63-20/100
- $V_{i_4}$ <20/125
Thick not topography (min pachymetry)

- T1 >500min
- T2 >450min
- T3 >400min
- T4 <400min

Extra denominator

- U: unknown stability
- P: progressing topography
- S: Stable topography
- O: opaque – centrally scarred cornea

Eg T_{4SO} = thin & centrally scarred but stable topography
Length (AC Depth)

- $L_1 > 3.4 \text{mm}$
- $L_2 > 3.1 \text{mm}$
- $L_3 < 3.1 \text{mm}$
“Ablation”

• Derived from the predicted Volume to be **theoretically** ablated (in nL) from the CornealWF module of the Schwind-Amaris CAM in order to regularize the particular cornea towards **EMMETROPIA**
  – Total Ablation Zone (TAZ) limited to 8.3mm
  – Full Zernicke Fitting and max allowed refractive correction (eg A -8.00 cyl will be reduced to -6.00 or -5.00)
KC cornea with steep and flat areas

Principle of Ablation topography of the KC eye

62 steep cone

31 flat area

RED: the area that the laser needs to remove for complete removal of the cone

Targeting emmetropia (44 in this particular eye)

This is not possible in practical terms

Instead, we reduce the steep areas by ablating on the cone and steepen the flat areas by ablating distant

To the flat areas according to the OZ
Why “Ablation” is the single most valuable metric in our system:

• Ablation Volume for the irregularly shaped keratoconic cornea is an excellent metric of the topographic abnormality AND refractive status

• Ablation volume is a function of the P-V (Peak to Valley) value on the Schwind-Keratron Topographical unit.
An example......

- The same Keratoconic Cornea requires a totally different excimer laser treatment ablation profile if it belongs in a 20 or a 25mm (or 30mm)Eye and therefore in the ViTAL System they are classified differently!!
• In fact, Ablation Volume may be a better metric than refractive error dioptric values when it comes to considering Excimer Laser Candidancy for ALL refractive Errors TOGETHER (like in case of KC eyes)
ORK-CW Ablation Volume in KC is a metric of topography+refraction!

<table>
<thead>
<tr>
<th>12,0 vertex</th>
<th>Nominal OZ</th>
<th>Max Depth</th>
<th>Overall Ablation</th>
<th>Abl Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>-10.00 sph PRK</td>
<td>6.50</td>
<td>148</td>
<td>9.00</td>
<td>3360-90nl</td>
</tr>
<tr>
<td>-10.00sph Lasik</td>
<td>6.50</td>
<td>154</td>
<td>8.47</td>
<td>3242-65nl</td>
</tr>
<tr>
<td>Plano -5,50x90 (lasik)</td>
<td>6.50</td>
<td>99 (centr 88)</td>
<td>8.71</td>
<td>3291nl</td>
</tr>
<tr>
<td>Plano +5.50x90 (lasik)</td>
<td>6.50</td>
<td>105</td>
<td>8.82</td>
<td>1885nl</td>
</tr>
<tr>
<td>+5,50 sphere</td>
<td>6.50 (6.75)</td>
<td>107 (115)</td>
<td>9.00 (9.25)</td>
<td>3913 (4367)</td>
</tr>
</tbody>
</table>

Ablation volumes are easier appreciated and are more clinically relevant then pure numbers in orthogonic (routine) refractive Errors for the refractive surgeon.

In Higher order Refractive Errors the Ablation Volume describes the topographical abnormality for a given refraction (axial length etc..) therefore is much more suitable then topography staging or refraction alone for excimer laser prediction.
**ViTAL** Ablation (nL Volumes)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablation volume &lt; 550nl</td>
<td>$A_1$</td>
</tr>
<tr>
<td>Ablation volume &lt; 2500nl</td>
<td>$A_2$</td>
</tr>
<tr>
<td>Ablation volume &lt; 3500nl</td>
<td>$A_3$</td>
</tr>
<tr>
<td>Ablation volume &gt; 3500nl</td>
<td>$A_4$</td>
</tr>
</tbody>
</table>

75% of Stage III KC is classified as $A_3$ or less
**ViTAL** Ablation (nL Volumes)

<table>
<thead>
<tr>
<th>Ablation volume</th>
<th>A</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 550 nL</td>
<td>$A_1$</td>
<td>CW PRK</td>
</tr>
<tr>
<td>&lt; 2500 nL</td>
<td>$A_2$</td>
<td>AMART</td>
</tr>
<tr>
<td>&lt; 3500 nL</td>
<td>$A_3$</td>
<td>T-AMART xtra</td>
</tr>
<tr>
<td>&gt; 3500 nL</td>
<td>$A_4$</td>
<td>PALK</td>
</tr>
</tbody>
</table>
Definition of $A_1$ Keratoconus

A1 keratoconus  Keratoconus amenable to CW Ablation

Keratoconus amenable to CW Ablation with the Amaris Schwind laser is classified as $A_1$ Keratoconus.

Currently we define $A_1$ as ablation of less or equal to 550nl. This is roughly the equivalent AblVol of 2 dpt of myopia with a 6,50mm OZ.
It is theoretically possible to perform up to -9.00 dpt of ablative excimer laser surgery in a stable patient with keratoconus without jeopardizing his recently crosslinked cornea. We achieve this by (preferentially!) thickening out the “healthy” parts of the cornea.
• CAN WE ABLATE MORE TISSUE...let’s say the equivalent to -9 dpt of myopia in keratoconic eyes ??
• Can we ablate more then 5 dpt in the plus direction?
Athens Minimal Additive Refractive Treatment (AMART)
miniEpikeratophakia-mini EPI
Ablatable Epikeratophakia - AEP
Micrograft
Customized Collagen
Subepithelial Collagen Lens
Sub Epithelial Collagen Refractive Treatment (SECRET)
Schwind’s Minimal Additive Refractive Treatment (SMART)
There are over 30,000 DS(A)EK cases performed in the US/Europe yearly.

Nano/ Femto LaserFabrication of Refractive Neutral Lenticles with Planar Configuration
Addition of 7500nL of tissue
To thicken the cornea by 120μ
(lamellar 9,25mm planar graft)
Epikeratophakia

Werblin/Kaufman
- Thick
- Sutures
- Designed to change the curvature of the cornea

AMART/ micrograft
- Thin
- No sutures
- Designed to leave the cornea’s curvature (almost) unchanged
- Useless without corneal wavefront Excimer ablation
Xtra

Epi lens is placed and not lasered. It is lasered s/p 3 months transepithelially. Allows deeper ablation.

Lasik-like

Epi lens is secured in an artificial Hinge, is then lasered on the flip side preserving the graft’s Bowman.

Tucked in

Epi K lens is tucked in a previously prepared groove in order to secure lens on the surface.

Classic

EpiK lens is ablated 30min after placed on the cornea.

Planar 8.5 central 120μ zone

9,25mm

The AMART 7500nl Project
1/ Amaris PTK: 55\(\mu\) centrally and 65+\(\mu\) peripherally to 9.25mm
Planar 8.5 central 120μ zone

9,25mm

Classic AMART – Ablatable 7500μ EpiK

AMART lamellar graft
120μ thick
Diam 9,25mm
Classic AMART – Ablatable 7500μ EpiK
T-AMART

1/ Femto/nano lamellar preparation of the Recipient eye to tuck in the AMART graft
T-AMART

1/ Femto/nano lamellar preparation of the Recipient eye to tuck in the AMART graft: Pull the graft into the groove
2. Amaris PTK to 8.50 mm
AMART lamellar graft
>120μ thick
Diam 9,25mm
The 7500nano graft is tucked in the peripheral groove without sutures.
The lasik-like AMART
<table>
<thead>
<tr>
<th></th>
<th>Ablation Volume</th>
<th>Added Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>&lt;550nL</td>
<td>n.a.</td>
</tr>
<tr>
<td>A2</td>
<td>&lt;2500nL</td>
<td>&gt;5000nL</td>
</tr>
<tr>
<td>A3</td>
<td>&lt;3500nL</td>
<td>&gt;3500nL</td>
</tr>
<tr>
<td>A4</td>
<td>&gt;&gt;3500nL</td>
<td>&gt;25000nL</td>
</tr>
</tbody>
</table>
Vi₁₇₂₃ₐ₉₉₉₃

• This eye has excellent BSCVA, has a corneal minimum Thickness of more then 400μ (but less then 450μ) with a stable topography and the ablation volume needed to regularize the surface is less then 2500nl for a total ablation zone of 8.30mm and OZ >6mm. The AC length (depth) is short and no phakic lens may be implanted!

• This Eye is probably amenable to Ti-AMART since the graft will add over 7500nl of tissue and no ablation is going to take place on the patient’s own cornea
**ViTAL /AMART Weakpoints**

- BSCVA is a poor metric for Visual function in keratoconics
- Lower order refraction is unreliable in keratoconics but important in CW corrections
- CAM software limits for astigmatism/sphere
- A1 definition is arbitrary
- New ablation algorithm is necessary
- Optical index diversity between air/cornea vs aqueous/cornea
AON-eye
Seeing is believing

Wavefront Sensing
High-Density Sampling
Wavefront Scanner

HD Wavefront Sensor provides an Objective Characterization of the Eye's Optics

Vision Testing

OLED micro-display projects a variety of Vision Tests in one finger touch

Vision Correction

Adaptive Optics Proprietary Technology gives Full Control of the Ocular Wavefront

Personalization

Adaptive Optics to replicate & customize optical designs prior the implementation as Personalized Solutions for Vision

voptica – Smart Visual Optics
voptica.com
info@voptica.com

voptica smart visual optics

Athens Vision
• This eye has decreased BSCVA (less than 20/50), has a corneal minimum Thickness of more than 400μ (but less than 450μ) with a stable topography and the ablation volume needed to regularize the surface is more than 3500nl for a total ablation zone of 8.30mm. The AC length (depth) is actually very long and would certainly accommodate a phakic implant.

• CAN WE IMPLANT A PHAKIC IMPLANT IN AN EYE WITH A BSCVA of less than 20/50???
YES if we could fabricate the lens we designed!

The Gregory Lens System !!

The Gregory Lens

It consists of

**Element 1**: A frame (same for every patient)

**Element 2**: An individualized Optic (Constructed *after* the exact ELP is known)

Downside: It needs two surgical procedures (Wound <2mm and most likely <1.5mm possible in both)
Element 1: frame same for every patient
Element 2: individualized optic
Initial Version of the Gregory Lens

– V01.1-3

Versions had to have off centered OZ’s which is a real burden to produce!

The OZ size had be substantially decreased as well

V2 fixes all these issues
March 23, 1937 First silver clip for aneurysm in the neck – (Walter Dandy)

There are over 1,500,000 Yasargil clips that have been implanted since 1968

Why can’t we use “double” Yasargil-like clips, for the Gregory lens project?
designing the Individualized Optics ex Vivo
Based on the Two Pillars preplaced in the eye
2/ designing of the Individualized Optics ex Vivo
Marking of the Line of Sight

Photo can not be rotated!
3/” introducing” the Gregory ‘preCut” Lens “into” the image of the AC (the precut version of the lens NEVER actually enters the Eye)
3/” introducing” the Gregory ‘preCut” Lens “into” the image of the AC (the precut version of the lens NEVER actually enters the Eye)
Conclusions

1. The ViTAL system offers a novel approach in registering important clinical information in KC patients

2. It allows accurate description of four important denominators to guide specific treatment options & enhances communication among care providers

3. Ablation Volume: Is the most important Metric in our system that addresses both topographical abnormality and refraction. The ORK-CAM is a valuable tool in our staging system
4. The AMART project may allow deep ablations on keratoconic corneas of ~ 3500nl.

5. The design of best possible ablations for keratoconus is still evolving (SCHWIND R/D dept)
6. Correcting huge higher order aberrations is theoretically possible in the phakic young KC patient with a customized phakic IOL like the Gregory lens system we describe here.
Thank you for your kind attention!