Femtosecond Lenticule Extraction (FLEEx) and Other Exciting Applications of Femtosecond Lasers - New Approaches to Cornea and Lens Laser Surgery

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Walter Sekundo, Markus Blum

San Francisco, 2008
Outline

Cornea – clinical results:
• Introduction to the surgical method (FLEX)
• Prospective FLEX study (ethic commission, clinical investigation plan)
• FLEX study results of 45 eligible eyes
• Detailed case report

Lens – experimental investigations:
• Fs-laser-therapy of presbyopia – SOMIT research project
• Diagnosis of accommodation
• Experimental investigations for a potential therapy
Introduction of the new surgical approach

- FLEX: Femtosecond Lenticule Extraction
- New approach for corneal refractive surgery
- Intracorneal lenticule removal to adjust the refractive properties of the eye
- Tissue removal instead of tissue ablation
- Precision of cutting determines predictability of the procedure
FLEX - Femtosecond Lenticule Extraction

1. Femtosecond laser pulse
   Laser processing of the lenticule back side

2. 

3. 
   Laser processing of the flap side cut

4. Lenticule removal after flap opening
FLEX study design

- prospective multicenter clinical study in Germany (Mainz, Prof. Walter Sekundo / Erfurt, PD Marcus Blum)
- controlled by ethics commission
- Femtosecond system provided by Carl Zeiss Meditec as final prototype version
VisuMax

Femtosecond lasersystem by Carl Zeiss Meditec
FLEX - Femtosecond Lenticule Extraction
FLEX - Femtosecond Lenticule Extraction

- 45 eyes in this interim report

- Lenticule diameters: 6.0 mm to 7.3 mm adapted to mesopic pupil size

- Remaining stromal bed > 300 µm

- Myopia < 8 D (mean SEQ -4.43 D ± 1.07 D)

- Myopic astigmatism < 6.0 D cyl

- Target refraction between 0.0 to -0.75 D
Subject demographics

- 45 eligible eyes (22 OS, 23 OD)
- 12 males, 13 females

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>36.6 y</td>
<td>21 y to 62 y</td>
</tr>
<tr>
<td>MR SEQ</td>
<td>-4.43 D ± 1.07 D</td>
<td>-2.63 D to -7.38 D</td>
</tr>
<tr>
<td>MR Sphere</td>
<td>-4.13 D ± 1.25 D</td>
<td>-0.00 D to -7.00 D</td>
</tr>
<tr>
<td>MR Cylinder</td>
<td>-0.56 D ± 1.09 D</td>
<td>-0.00 D to -6.00 D</td>
</tr>
</tbody>
</table>
FLEX – Femtosecond Lenticule Extraction
Safety – Change in BSCVA

<table>
<thead>
<tr>
<th>Change in BSCVA</th>
<th>3 m (45)</th>
<th>6 m (42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>lost &gt; 2</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>lost 2</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>lost 1</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>unchanged</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>gained 1</td>
<td>40%</td>
<td>40%</td>
</tr>
<tr>
<td>gained 2</td>
<td>42%</td>
<td>42%</td>
</tr>
<tr>
<td>gained &gt; 2</td>
<td>42%</td>
<td>42%</td>
</tr>
</tbody>
</table>

Percentage [%]
FLEX – Femtosecond Lenticule Extraction
Refractive outcome

Refractive outcome - Percentage within Attempted

- 5 to -2: 3 m (45) 6 m (42)
- -1.01 to -2: 2% 4%
- -0.5 to -1: 2% 4%
- +0.5: 78% 66%
- +0.51 to +1: 13% 29%
- +1.01 to +2: 4% 4%
- +2 to +5: 4% 4%
FLEX – Femtosecond Lenticule Extraction
Refractive Outcome → Learning curve

![Graph showing refractive outcome and learning curve](image)

- Early FLEX: 6 m (20)
- Today’s FLEX: 6 m (22)

(month (eyes))

Refractive outcome - Percentage within Attempted
FLEX – Femtosecond Lenticule Extraction

Stability

![Graph showing stability over time for FLEX FEMTO surgery. The x-axis represents time (45, 45, 45, 42 months), and the y-axis represents achieved correction SEQ [D]. Points marked at 1 month, 3 months, and 6 months showing stability at various levels.]
FLEX – Femtosecond Lenticule Extraction
Predictability

Achieved [D]

Overcorrected

Attempted delta SR equiv. [D]

Undercorrected

y = 0.82x + 0.94
R² = 0.79

Wavefront Congress 2008
FLEX – Femtosecond Lenticule Extraction
Efficacy - UCVA

Percentage [%]

month
(eyes)
- 3 m (45)
- 6 m (42)

UCVA

0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

1.6 or better
1.2
1.0
0.8
0.6
0.5
0.4 or worse
<table>
<thead>
<tr>
<th>Adverse events – 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>No adverse events and complications</td>
</tr>
<tr>
<td>No DLK</td>
</tr>
<tr>
<td>No TLSS</td>
</tr>
<tr>
<td>1 case of mild Haze (6 month post OP)</td>
</tr>
<tr>
<td>Some eyes with microstriae</td>
</tr>
</tbody>
</table>
4 cases of suction loss

- re-treated
- Femto-Lasik
- Lasek
### FLEX Case #1
Pre-Op data and therapy parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Data</strong></td>
<td></td>
</tr>
<tr>
<td>Patient ID</td>
<td>E1.9-OD</td>
</tr>
<tr>
<td>Age</td>
<td>33 years</td>
</tr>
<tr>
<td>MR</td>
<td>-5.50 D / -0.50 D / 15° (OD)</td>
</tr>
<tr>
<td>UCVA pre OP</td>
<td>&lt;20/200</td>
</tr>
<tr>
<td>BSCVA pre OP</td>
<td>20/20</td>
</tr>
<tr>
<td><strong>Therapy Parameters</strong></td>
<td></td>
</tr>
<tr>
<td>Flap diameter</td>
<td>7.8 mm</td>
</tr>
<tr>
<td>Flap thickness</td>
<td>150 μm</td>
</tr>
<tr>
<td>Optical zone diameter</td>
<td>6.5 mm</td>
</tr>
</tbody>
</table>
FLEX Case #1
Refractive outcome

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-Op</th>
<th>Post-Op (6 Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR</td>
<td>-5.50 D / -0.50 D / 15°</td>
<td>+0.25 D / -0.25D / 25°</td>
</tr>
<tr>
<td>UCVA</td>
<td>&lt;20/200</td>
<td>20/20</td>
</tr>
<tr>
<td>BSCVA</td>
<td>20/20</td>
<td>20/20</td>
</tr>
</tbody>
</table>

Target sphere: **-0.75 D**

Result: about 1 D sphere over correction
FLEX Case #1
Stability

Result: stable refraction despite overcorrection
FLEX Case #1
Corneal Topography (axial power)

Stable and slightly prolate shape
Intended optical zone size was achieved
FLEX Case #1
Ocular wavefront evolution (1 µm scale!)

Pre-OP
RMS = 0.34 µm
ED < 0.07 D

Post-1m
RMS = 0.36 µm
ED < 0.07 D

Post-6m
RMS = 0.39 µm
ED < 0.08 D

Very small overall changes, i.e. „neutral“ and very stable
FLEX Case #1
Change in Spherical Aberration pre/post-Op

Result: only very slight induction of SA within the OZ
FLEX – Femtosecond Lenticule Extraction

Summary

- Prospective clinical data show FLEEx to be safe and effective for treatment of myopia
- Refractive outcome is acceptable for all patients
- Predictability shows moderate over corrections for lower myopic cases
- FLEX shows the potential for a new way to achieve aberration neutral myopic treatments
Principle of potential fs-lasertherapy of presbyopia

BMBF Research Initiative SOMIT
Joint Project „fs-Lasertherapie der Presbyopie“
FKZ: 13N8829
WASCA with binocular accommodation target and a DSA-Software for dynamic data acquisition
Visante OCT - Diagnosis of accommodation

ACCOMMODATION
10 y.  10 D. = 314μ

ACCOMMODATION
55 y.  1.75 D. = 14 μ

Prof. Baikoff, MD
Visante OCT - Diagnosis of accommodation

ACCOMMODATION
10 y. 10 D. = 314μ

ACCOMMODATION
55 y. 1.75 D. = 14 μ

Prof. Baikoff, MD
FEM-results: influence of core hardness

Deformation at different core hardness (elongation 0.3 mm)

- $E_{\text{core}}$: 1 kPa
- 4 kPa
- 16 kPa
Experimental setup for lens structuring

Lasersystem

Scanner

Auge
Fs-Laser structured lens materials

Pig eyes: young, soft core, bubbles
Sheep eyes: old (10yr.), hard core, cracks

Nearly same threshold for observed effects

Optimized Laserparameters
– no bubbles or cracks

…therapeutic cuts to create gliding planes inside a lens are possible
Thank you for your kind attention!
Visante OCT - Diagnosis of accommodation

THICKNESS OF THE CRYSTALLINE LENS INCREASES DURING 10 D. ACCOMMODATION IN AN ALBINO EYE (19 y.)/Prof. Baikoff, MD
Visante OCT - Diagnosis of accommodation

THICKNESS OF THE CRYSTALLINE LENS INCREASES DURING 10 D. ACCOMMODATION IN AN ALBINO EYE (19 y.)/Prof. Baikoff, MD