PresbyMAX® multicenter study:
3 Months Results

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Sir Harold Ridley implanted the first intraocular lens (IOL) in a human eye at St Thomas' Hospital in London.
Various treatment strategies for presbyopia have been brought forward using the excimer lasers.

Besides monovision, creation of a multifocal cornea represents an attractive option, called PresbyLasik.

PresbyLASIK is a technique which currently is still in an optimizing process.

The first published studies have shown that PresbyLASIK and MIOL implantation provide similar outcomes.
PresbyLASIK: General principle

• **PresbyLASIK** treatment creates a **multifocal corneal surface** and aims at **good uncorrected near- and distance vision** outcomes.

• **Different ablation profiles** are being currently practiced by manufacturing companies and scientific groups.

Exclusion Criteria

• As exclusion criteria for PresbyLASIK are valid the general contraindications that also apply for the refractive surgery using excimer laser!
PresbyMAX® - Principle

• In comparison to the other methods creates Presbymax ® a bi-biaspheric multifocal ablation profile, each zone is multifocal with a transition zone for the intermediate vision.

• The term “bi-aspheric” refers to the aspheric optimization of the central corneal area for near vision and the midperipheral cornea for far vision.
PresbyMAX® : Principle

Bi-aspheric profiles: The PresbyMAX® procedure

- Cornea
- Transition Zone
- Distance corrected area
- Intermediate corrected area
- Near corrected area
Pupil dependency

Relative Pupil Diameter

- Multi-Zonal for DE+NDE
**PresbyMAX® - Principle**

- **Binocular vision**
  - Both eyes are treated in order to achieve an optimum binocular vision at all distances.

- Presbymax increases the „depth of focus“.

- **Light distribution**
  - Near: ~ 35 - 40%
  - Intermediate: ~ 15%
  - Distance: ~ 45 – 50%
PresbyMAX® - Presbyopia compensation

- **PresbyMAX®** Software suggests automatically an addition in the patients based on their age.

- For younger patients, **PresbyMAX®** suggests a higher addition as normally required so as to profit them longer from the treatment.

- In the elderly patients, **PresbyMAX®** offers an undercorrection of near addition, as not to affect the distance visual acuity.

- The higher the near addition the stronger would be the visual distance acuity affected.
PresbyMAX® - the Presbyopia compensation

- SCHWIND PresbyMAX® permits a patient age-based compensation of presbyopia.
What offers PresbyMax®?

- Creates a pseudoaccommodation.
- Decreases the dependency on reading glasses.
- Delays the dependency on reading glasses while presbyopia progresses.
- Reversible, can be repeated, central near zone can be reversed.
- Simultaneous correction of refractive error!
**PRESBYMAX®-Study**

- **Participants**: Spain, Egypt, Brasil and Kiel.

- **15 Patients** were recruited from each country.

- **3 groups**: 5 Myopes, 5 Hyperopes und 5 Emmetropes.
PresbyMAX®: The Multicenter Study Team

Prof. Alio, Spain

Prof. Uthoff, Germany

Dr. Tarek, Egypt

Dr. Martines, Brasil

Jens Flügge

Tobias Ewering

Samuel Arba Mosquera
Inclusion Criteria

- Manifest Refraction from - 4.0 to + 4.0 D
- Manifest Astigmatism \( \approx \) 2.5 D
- Near addition \( \approx \) 2.5 D
- Others, e.g. pachymetry
- No ocular pathology
Patients

• **Mean age:** 50 years

  – **Myopes:** 47-55 years

  – **Hyperopes:** 39-64 years

  – **Emmetropes:** 48-51 years
Methods

• All Patients were operated by the one surgeon.

• Flap was created by Femto Laser (Ziemer’s FEMTO LDV™).

• Follow-up:
  - 30 min. postop
  - 1 day postop
  - 7 days postop
  - 3 and 6 months postop
### Results: Distance refraction

#### HYPEROPES [10 eyes]

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>Post-op [3 Mo.]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spherical equivalent</td>
<td>1.75 ± 0.65</td>
<td>0.18 ± 0.52</td>
</tr>
<tr>
<td>Sphere</td>
<td>1.93 ± 0.55</td>
<td>0.40 ± 0.57</td>
</tr>
<tr>
<td>Cylinder</td>
<td>- 0.35 ± 0.29</td>
<td>- 0.45 ± 0.20</td>
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#### MYOPES [10 eyes]

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>Post-op [3 Mo.]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spherical equivalent</td>
<td>- 2.48 ± 0.68</td>
<td>- 0.49 ± 0.39</td>
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<tr>
<td>Sphere</td>
<td>- 2.13 ± 0.78</td>
<td>- 0.30 ± 0.42</td>
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<tr>
<td>Cylinder</td>
<td>- 0.70 ± 0.39</td>
<td>- 0.38 ± 0.32</td>
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</tbody>
</table>

#### EMMETROPES [10 eyes]

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>Post-op [3 Mo.]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spherical equivalent</td>
<td>0.38 ± 0.45</td>
<td>- 0.04 ± 0.29</td>
</tr>
<tr>
<td>Sphere</td>
<td>0.53 ± 0.49</td>
<td>0.10 ± 0.34</td>
</tr>
<tr>
<td>Cylinder</td>
<td>- 0.30 ± 0.16</td>
<td>- 0.28 ± 0.22</td>
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Refractive Outcome:
Distance Refraction

![Bar chart showing refractive outcomes for different diopter ranges.](chart.png)
At tempted versus achieved Defocus

\[ y = 0.88x - 0.18 \]
\[ R^2 = 0.93 \]
Visual Outcome
Distance and Near Uncorrected Binocular Visual Acuity Before Surgery
Visual Outcome
Distance and Near Uncorrected Binocular Visual Acuity After Surgery

![Graph showing visual outcome](image)
Cumulative uncorrected visual acuities: distance uncorrected visual acuity
Cumulative uncorrected visual acuities: Near uncorrected visual acuity
Achieved multifocality (D) correlated to planned addition (D). Achieved multifocality was obtained from the radial symmetric terms of the Corneal Wavefront Analyzer @ 6 mm diameter.
Subjective indications of our patients

<table>
<thead>
<tr>
<th>Hyperopia</th>
<th>Myopia</th>
<th>Emmetropia</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Near vision significantly better in bright light</td>
<td>• Near Vision: good (with rest Myopia)</td>
<td>• Near and distance Vision: improved significantly</td>
</tr>
<tr>
<td>• Distance vision: satisfactory following surgery</td>
<td>• Distance vision: increased</td>
<td>• Only for reading very small letters spectacles are needed</td>
</tr>
<tr>
<td>• Reading: very good; distance vision very good;</td>
<td>• Reading in the accustomed distance not satisfactory</td>
<td>• Even during cloudy weather the sunglasses bring an improvement</td>
</tr>
<tr>
<td>• Needs spectacles only for doing Handwork</td>
<td>• Reading newspaper at 50 cm without any difficulty</td>
<td>• Daily routine: Spectacle free life</td>
</tr>
<tr>
<td>• Very happy</td>
<td>• For reading: Requires bright light</td>
<td>• Glare from the headlights of oncoming cars, partially hazy at distance</td>
</tr>
<tr>
<td></td>
<td>• Distance Vision: Blurred (specially during bright sunshine)</td>
<td></td>
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Patient satisfaction

- Only **one patient** would retrospectively not like be treated again.
- **All other patients** were willing to **undergo surgery** again.
Conclusions: Our preliminary results

- The **preliminary results** of the ongoing clinical Presbymax-Study with the AMARIS Laser are **encouraging, especially for hyperopes**.

- The **hyperopic patients** seem to be the most confident group after presbymax treatment for distance and near refractive correction.

- Uncorrected **near vision** improved in the hyperopic and emmetropic group.

- Postoperative **stability** was achieved within 1 months of the surgery.

- 6 months results are comparable to 3 months results

- **No patient** required retreatment till now.
Thank you for your interest!