MMC in ASA; Clinical Results

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Financial Disclosure

- I do not have any financial interests or relationships to disclose.
MMC in ASA; Clinical Results

- LASEK+MMC:
  - Compare to LASIK in the treatment of high myopia
  - Compare to FSBK
  - Evaluate efficacy and safety in thin corneas
  - Analyze when to perform an enhancement after MMC-LASEK
  - Evaluate efficacy and safety in special situations; post-LASIK
Patients: high myopia

- LASEK+MMC vs LASIK in high myopia:
  - Prospective
  - 228 consec eyes (114 LASEK, 114 LASIK)
  - Esf ≥ -7.00 D
  - Cyl ≤ -3.50 D
  - MMC 0.02 % x 60"
  - Planned undercorrection of 10 % in LASEK+MMC
  - Refractive error-matched:
    - Preop SE: from -7.00 to -13.75 D
      - -8.72 ± 1.2 LASEK
      - -8.74 ± 1.2 LASIK

Results: high myopia

- LASEK+MMC vs LASIK in high myopia:
Results: high myopia

- LASEK+MMC vs LASIK in high myopia:
  - No dif BSCVA, safety and efficacy ind. ($P > 0.05$)
  - Loss $\geq 2$ lines: 0 LASEK+MMC, 7 LASIK
  - Gain $\geq 2$ lines: 8 LASEK+MMC, 1 LASIK
Results: high myopia

- LASEK+MMC vs LASIK in high myopia:

<table>
<thead>
<tr>
<th></th>
<th>LASEK</th>
<th>LASIK</th>
<th>P = 0.0001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sph 3m postop</td>
<td>+0.25 ± 0.6</td>
<td>-0.06 ± 0.5</td>
<td></td>
</tr>
<tr>
<td>± 0.50 D</td>
<td>68 %</td>
<td>79 %</td>
<td></td>
</tr>
</tbody>
</table>

Equivalente esférico (D) (% de ojos)

![Bar chart showing equivalente esférico for LASEK and LASIK](chart.png)
Discussion: high myopia

- LASEK+MMC vs LASIK in high myopia:
  - No other studies using MMC
  - ASA without MMC vs LASIK:
    - Scerrati: Better BSCVA and contrast sens
    - Kim et al.: Worse visual and refractive results
    - Hersh et al.: More loss of BSCVA, similar predict
  - Overcorrection after LASEK+MMC
  - Patients with a calculated RSB thinner than 250-300 µm benefit from LASEK with MMC, with similar visual results.
  - The upper limit of myopia is the same in ASA than LASIK.

LASEK + MMC vs FSBK

- Rationale: Comparison of LASEK (with MMC if needed) vs the most modern “flap-approach” (femtosecond, aiming for a 100 micron flap).
- Purpose: compare the efficacy and safety of these two (competing) procedures.
- Outcome: VA
- Follow-up: 6 months (3 months if VA results are OK)

## LASEK + MMC vs FSBK

### Baseline

<table>
<thead>
<tr>
<th></th>
<th>LASEK</th>
<th>FSBK</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>1036</td>
<td>1072</td>
<td></td>
</tr>
<tr>
<td>Sph</td>
<td>-3.93 (0-11.75)</td>
<td>-3.87 (0-12)</td>
<td>P=0.8</td>
</tr>
<tr>
<td>BSCVA</td>
<td>1.12</td>
<td>1.12</td>
<td>P=0.9</td>
</tr>
<tr>
<td>Age</td>
<td>31.03 (18-40)</td>
<td>30.5 (18-40)</td>
<td>P=0.07</td>
</tr>
<tr>
<td>OZ</td>
<td>6.36</td>
<td>6.30</td>
<td>P=0.09</td>
</tr>
</tbody>
</table>
LASEK + MMC vs FSBK

Post-op UCVA ($p < 0.05$ in all visits)
LASEK + MMC vs FSBK

Sph Eq. 3 months

- ± 0.50 D
  - FSBK: 89.45%
  - LASEK: 83.65%

Bar chart showing the percentage of eyes with spherical equivalent (D) ranges:
- -3 to -2.1: 0.28%
- -2 to -1.1: 1.77%
- -1 to -0.51: 8.70%
- -0.5 to 0: 71.37%
- +0.1 to +0.5: 9.14%
- +0.51 to +1: 12.28%
- +1.1 to +2: 4.01%
- +2.1 to +3: 2.7%
- 0 to +0.1: 0.37%
LASEK + MMC vs FSBK

Change in lines of BSCVA 3 months
## LASEK + MMC vs FSBK

Loss of BSCVA lines. 6 month follow up

<table>
<thead>
<tr>
<th></th>
<th>LASEK</th>
<th>FSBK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3m. 2&gt;</strong></td>
<td>20 (1.93%)</td>
<td>9 (0.84%)</td>
</tr>
<tr>
<td><strong>6m =</strong></td>
<td>6 (0.58%)</td>
<td>1 (0.09%)</td>
</tr>
<tr>
<td><strong>6m 1 line</strong></td>
<td>8 (0.77%)</td>
<td>4 (0.37%)</td>
</tr>
<tr>
<td><strong>6m 2&gt;</strong></td>
<td>2 (0.19%)</td>
<td>3 (0.28%)</td>
</tr>
<tr>
<td><strong>6 m gaining lines</strong></td>
<td>4 (0.37%)</td>
<td>1 (0.09%)</td>
</tr>
</tbody>
</table>
LASEK + MMC vs FSBK

Conclusions

- LASEK (MMC) and FSBK
  - Similar in terms of safety
  - Similar in terms of predictability (from a clinical point of view, slightly better results with FSBK)
  - Much faster visual recovery in FSBK (lack of re-epithelization time in FSBK and refractive stability achieved sooner in this procedure)
  - Don’t need to go deeper than 100 with FS (“the thicker the flap the better VA” dogma not true
  - Caution; these conclusions may apply only if MMC is used in ASA, and FSBK with the Intralase FS device
LASEK + MMC in Thin Corneas

Rationale;
- Thin corneas may be more prone to develop ectasia after corneal refractive surgery
- MMC-induced decrease in the keratocyte proliferation may increase the risk of ectasia

Objective; evaluate the safety of LASEK+MMC in corneas with a CCT < 500 microns, but normal topography

Main outcomes; VA, Sph, Topography

Follow-Up; 15 months

De Benito-Llopis L, Teus MA et al. AJO 2008; 145: 807-812
LASEK + MMC in Thin Corneas

- 136 consecutive eyes
- Preop sph: -3.49 ± 2.10 D (0 to -11 D)
- Preop CCT; 484.4 ± 11.8 (440 to 499)
- 3 month post-op CCT; 417.9 ± 32.1 (339 to 473)

<table>
<thead>
<tr>
<th></th>
<th>3 m postop</th>
<th>15 m postop</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>136</td>
<td>136</td>
<td></td>
</tr>
<tr>
<td>UCVA</td>
<td>0.97 ± 0.1</td>
<td>1.01 ± 0.2</td>
<td>$P=0.08$</td>
</tr>
<tr>
<td>BSCVA</td>
<td>1.02 ± 0.1</td>
<td>1.11 ± 0.1</td>
<td>$P=0.0001$</td>
</tr>
<tr>
<td>Sph</td>
<td>+0.27 ± 0.50</td>
<td>+0.06 ± 0.4</td>
<td>$P=0.01$</td>
</tr>
<tr>
<td>Cyl</td>
<td>-0.20 ± 0.40</td>
<td>-0.25 ± 0.40</td>
<td>$P=0.1$</td>
</tr>
</tbody>
</table>
LASEK + MMC in Thin Corneas
- Visual results at 15 months. MMC vs no-MMC

<table>
<thead>
<tr>
<th></th>
<th>MMC</th>
<th>No MMC</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>49 (36%)</td>
<td>87 (64%)</td>
<td></td>
</tr>
<tr>
<td>UCVA</td>
<td>1.01 ± 0.2</td>
<td>1.06 ± 0.2</td>
<td>P=0.2</td>
</tr>
<tr>
<td>BSCVA</td>
<td>1.11 ± 0.1</td>
<td>1.10 ± 0.1</td>
<td>P=0.7</td>
</tr>
<tr>
<td>Sph</td>
<td>+0.06 ± 0.40</td>
<td>+0.14 ± 0.60</td>
<td>P=0.2</td>
</tr>
<tr>
<td>Cyl</td>
<td>-0.31 ± 0.40</td>
<td>-0.18 ± 0.60</td>
<td>P=0.2</td>
</tr>
</tbody>
</table>
LASEK + MMC in Thin Corneas

- Conclusions:
  - ASA safe in Thin corneas (with normal topography)
  - MMC makes ASA achieve the same visual results than LASIK (either MLASIK or FSBK) in deeper ablations in these eyes (prevents haze)
  - VA results are stable in thin corneas, at 15 month post-op
  - MMC use does seem to be safe (in terms of ectasia and VA stability) in these corneas
Enhancements after MMC LASEK

- When to retreat after myopic LASEK+MMC:
  - Prospective study
  - Myopic LASEK+MMC
  - 3 months postop:
    - Low residual refractive error
    - Suboptimal UCVA or BSCVA
  - Compared the 3-m and 6-m postop visits:
    - In the whole group
    - In 4 subgroups: myopic sph, hyperopic sph, myopic cyl, hyperopic cyl

De Benito-Llopis L, Teus MA et al. AJO 2009;147:71-6
Results: rettt after LASEK

- When to retreat after myopic LASEK+MMC:
  - 178 consecutive eyes
  - Preop sph: -4.37 ± 2.90 D (0 to -12 D)
  - Preop cyl: -1.50 ± 1.20 D (0 to -6.50 D)

<table>
<thead>
<tr>
<th></th>
<th>3 m postop</th>
<th>6 m postop</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>178</td>
<td>178</td>
<td></td>
</tr>
<tr>
<td>UCVA</td>
<td>0.83 ± 0.2</td>
<td>0.87 ± 0.2</td>
<td>P=0.0001</td>
</tr>
<tr>
<td>BSCVA</td>
<td>0.98 ± 0.1</td>
<td>1.04 ± 0.1</td>
<td>P=0.0001</td>
</tr>
<tr>
<td>Sph</td>
<td>+0.37 ± 0.80</td>
<td>+0.27 ± 0.80</td>
<td>P=0.001</td>
</tr>
<tr>
<td>Cyl</td>
<td>-0.58 ± 0.60</td>
<td>-0.60 ± 0.60</td>
<td>P=0.1</td>
</tr>
</tbody>
</table>
## Results: rettt after LASEK

<table>
<thead>
<tr>
<th>Subgroup with residual hyperopic sphere</th>
<th>3 m postop</th>
<th>6 m postop</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCVA</td>
<td>0.92 ± 0.2</td>
<td>1.0 ± 0.2</td>
<td>0.001</td>
</tr>
</tbody>
</table>

| Sphere                                  | +0.8 ± 0.4 | +0.44 ± 0.4 | 0.0001       |

<table>
<thead>
<tr>
<th>Subgroup with residual hyperopic cylinder</th>
<th>3 m postop</th>
<th>6 m postop</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCVA</td>
<td>0.77 ± 0.1</td>
<td>0.85 ± 0.2</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

| Cyl                                      | +1.09 ± 0.5 | +0.9 ± 0.7 | 0.002        |
Discussion: rettt after LASEK

• Optimal moment for retreatment after myopic LASEK+MMC, based on the residual refraction 3 m postop:
  – Myopic: no need to wait until 6 months, you can go ahead at 3 months post-op
  – Hyperopic: must wait at least 6 months after the procedure
Use of MMC in enhancements after previous LASEK+MMC

- 88 eyes
- Pre-op UCVA = 0.59±0.2
- Post-op UCVA= 0.93±0.1
- Safety index = 1.01±0.1
- Efficacy index = 0.96±0.1
- No MMC related complications

De Benito L, Teus M. AJO 2010; 150: 376-380
Patients and results: post-LASIK LASEK

- LASEK to treat post-LASIK regression:
  - 4 eyes with mild myopic regression after LASIK (SE from -0.50 to -1.25 D)
  - MMC 0.02% x 30”
  - Planned undercorrection of 10%
  - No eye developed haze, but the refractive results 3 months postop very unpredictable, showing a great tendency to overcorrection (postop SE from -0.5 to +2.75 D)

Teus MA, de Benito-Llopis L. JCRS 2007;33:1674-5
Discussion: post-LASIK ASA

LASEK to treat post-LASIK regression:
- In-the-bed enhancement: limited by the RSB thickness.
- ASA without MMC after LASIK:
  - Associated with dense haze even when treating low refractive errors
  - (-2 D or ablation depth >50 microns)
  - Poor results treating hyperopic errors or myopic refractions ≥-2 D
- ASA+MMC after LASIK:
  - Avoids haze
  - Srinivasan et al.: treating a max of 42 microns report good refractive results, although they do not report the range of the residual SE
  - Alió et al.: at 6 months, 16.6% of the eyes had a residual sph >+1.50 D.
  - Teus MA, de Benito-Llopis L: great tendency to overcorrection.

Saeed A et al. JCRS 2008;34:1736-41.
Srinivasan S et al. JRS 2008;24:S64-7.
Alió JL et al. JCRS 2008;34:1727-35.
Teus MA, de Benito-Llopis L. JCRS 2007;33:1674-5