Efficacy of Photorefractive Keratectomy for Military Pilot Recruitment in an Asian Air Force

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I have the following financial relationships to disclose:

- Employee of: Republic of Singapore Air Force (RSAF)

I will not discuss off-label use and/or investigational use in my presentation.

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Scope of Presentation

- Introduction
- Study details
  - Objectives
  - Design, subjects and methods
  - Results
- Discussion
• Introduction
• Study details
  – Objectives
  – Design, subjects and methods
  – Results
• Discussion
Myopia in Singapore

• Age-adjusted prevalence among adults
  – Chinese: 38.7%¹
  – Malay: 26.2%²
  – Indian: 28.0%³

• Increase in prevalence among SAF conscripts
  – 1987-1992⁴ to 1996-1997⁵: 19.9%
  – 1996-1997⁵ to 2009-2010⁶: 2.3%

RSAF CRS Program

- Implemented in end-2005 to enlarge the recruitment pool of potential military aviators
- Choice of CRS modality was PRK
  - Concerns over stability of LASIK corneal flap and risk of traumatic flap dislocation
    - Several case reports documented minor trauma causing late dislocation of flap¹-⁵
    - Histological studies in rabbits show that flap heals by epithelial adhesion at circumferential edge of wound only⁶-⁷

• Medical selection criteria for enrollment
  – Not worse than -5.00D spherical error
  – Not worse than -2.00D cylindrical error
• Rationale
  – High myopia (SE worse than -6 D) associated with increased risk of other ocular pathologies¹
    • Cataracts
    • Glaucoma
    • Retinal detachment

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Objectives

• To determine the efficacy and safety of Photorefractive Keratectomy (PRK) in young patients with low-moderate myopia (SE better than -6D)

• To review the efficacy and safety of the RSAF Corneal Refractive Surgery (CRS) Program
Design and Subjects

• Design
  – Retrospective, consecutive case series
  – Single-centre, multi-surgeon
  – Study period: 5 years (1 Jan 06 – 31 Dec 10)

• Subjects
  – 149 eyes of 76 consecutive patients who underwent PRK as part of the RSAF CRS Program during the study period
    • 3 patients underwent unilateral PRK
Methods

• The following were mined from paper-based medical records of all subjects and analysed:
  – Pre- and post-operative refraction, UDVA and CDVA
  – Post-operative corneal haze grading and retreatments

• For each outcome measure, the following were excluded from analysis:
  – Eyes that underwent retreatment at any point during the study period (except for cumulative incidences)
  – Eyes that had incomplete records for the outcome measure
Subject Characteristics

- **Age**
  - Median: 21 years (range, 18 – 26 years)
  - Mean: 20.9 ± 1.8 years

- **Sex**
  - Male: 73 (96.1%)
  - Female: 3 (3.9%)

- **Pre-op SE refraction**
  - Mean: -3.39D ± 1.19D
  - Range: -6.25D to +0.28D
Outcome Measures

- **Efficacy**
  - Post-operative uncorrected distant visual acuity (UDVA)
  - Spherical equivalent (SE) refractive accuracy
    - SE refraction was derived from the algebraic sum of the spherical error and half of the cylindrical error

- **Safety**
  - Change in corrected distant visual acuity (CDVA)
  - Retreatment rates

- **Others**
  - Stability of SE refraction
Efficacy: Post-operative UDVA

133 Eyes
12 months post-op

Cumulative UDVA (LogMAR)

- 36.8%
- 82.7%
- 98.5%
- 100%
- 100%

20/20 or better: 98.5%

Republic of Singapore Air Force Aeromedical Centre
Efficacy: SE Refractive Accuracy

137 Eyes
12 months post-op

Post-operative SE Refraction (D)

<table>
<thead>
<tr>
<th>Refraction Range</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; -1.00</td>
<td>0.0%</td>
</tr>
<tr>
<td>-1.00 to -0.51</td>
<td>10.2%</td>
</tr>
<tr>
<td>-0.50 to -0.14</td>
<td>81.8%</td>
</tr>
<tr>
<td>-0.13 to +0.13</td>
<td>8.0%</td>
</tr>
<tr>
<td>+0.14 to +0.50</td>
<td>0.0%</td>
</tr>
<tr>
<td>+0.51 to +1.00</td>
<td>0.0%</td>
</tr>
<tr>
<td>&gt; +1.00</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

±0.50D: 100%
Safety: Change in CDVA

128 Eyes
12 months post-op

Change in CDVA (LogMAR)

Loss of ≥ 2 lines: 2.3%
Safety: Retreatment Rates

- Retreatments: 10 eyes (cumulative incidence, 6.7%)
  - ≥ Grade 2 haze: 9 eyes (6.0%)
  - Unsatisfactory refraction: 1 eye (0.7%)
Stability: 6 to 12 Months Post-op

34 Eyes

Stability of SE Refraction

% changed > 0.50D
6-12 mo: 0%

Time after Surgery (Months)

Mean SE Refraction (D)

-6
-5
-4
-3
-2
-1
0
1
2

Sx 1 2 3 4 5 6 7 8 9 10 11 12

-3.75
+0.03
+0.13
+0.04
+0.02

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Stability: 4 to 12 Months Post-op

94 Eyes

Stability of SE Refraction

% changed > 0.50D
4-12 mo: 0%
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### Discussion: Efficacy

<table>
<thead>
<tr>
<th>Outcome Measure (at ≥ 12 months)</th>
<th>RSAF CRS Program</th>
<th>Murray, et al(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-op UDVA 20/20 or better</strong></td>
<td>98.5%</td>
<td>70.4% (range, 0.4% – 87.0%)&lt;br&gt;Low-moderate: 76.4% (range, 50.7% – 82.0%)</td>
</tr>
<tr>
<td><strong>Post-op UDVA 20/40 or better</strong></td>
<td>100.0%</td>
<td>92.3% (range, 37.6% – 98.8%)&lt;br&gt;Low-moderate: 96.3% (range, 78.2% – 97.0%)</td>
</tr>
<tr>
<td><strong>SE within ±0.50D of intended correction</strong></td>
<td>100.0%</td>
<td>68.0% (range, 56.5% – 87.4%)&lt;br&gt;Low-moderate: 86.6% (range, 39.1% – 95.8%)</td>
</tr>
<tr>
<td><strong>SE within ±1.00D of intended correction</strong></td>
<td>100.0%</td>
<td>71.6% (range, 65.0% – 88.7%)&lt;br&gt;Low-moderate: 90.4% (range, 78.3% – 98.8%)</td>
</tr>
</tbody>
</table>

### Discussion: Safety

<table>
<thead>
<tr>
<th>Outcome Measure (at last follow-up)</th>
<th>RSAF CRS Program</th>
<th>Murray, et al(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDVA (\geq 2) lines lost</td>
<td>2.3%</td>
<td>0.5% (range, 0% – 20.5%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low-moderate: 0.5% (range, 0% – 1.1%)</td>
</tr>
<tr>
<td>CDVA (\geq 1) line lost</td>
<td>11.7%</td>
<td>4.5% (range, 0.7% – 15.3%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low-moderate: 14.9%</td>
</tr>
<tr>
<td>Clinically significant corneal haze</td>
<td>Cumulative incidence, 6.0%</td>
<td>Cumulative incidence, 2% – 4%(^2)</td>
</tr>
</tbody>
</table>

Discussion: Stability of Refraction

- Post-op grounding period of military aviators shortened from 6 to 4 months in 2008
  - Study shows that there was no increase in % change in SE > 0.50 D from 6 – 12 months to 4 – 12 months
  - Possibility of further shortening of grounding period
    - Supported by other studies¹

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>6 – 12 Months (N=34)</th>
<th>4 – 12 Months (N=94)</th>
<th>3 – 12 Months (N=94)</th>
<th>1 – 12 Months (N=94)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Change in SE &gt; 0.50D</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>4.3%</td>
</tr>
</tbody>
</table>

Discussion: Limitations

• Case series design
  – Prone to bias (especially selection)

• Use of medical records retrospectively
  – Variable quality of clinical entries / incomplete records

• Last follow-up at post-op month 12
  – Unable to determine long-term efficacy and safety
Questions?

Thank you!

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LogMAR

- LogMAR: Logarithm of the Minimum Angle of Resolution
  - Advantages over Snellen chart
    - Equal no of letter per line
    - Regular progression
    - Final score based precisely on total of all letters read
  - Recommended for research

Corneal Refractive Surgery (CRS)

• PRK
  – Cornea epithelium removed with dilute alcohol
  – Anterior corneal surface reshaped by excimer laser
  – Re-epithelialisation generally occurs within 3-4 day
  – Complications:
    • Subjective symptoms
    • Refractive complications
    • Corneal haze
    • Microbial keratitis (rare)

Corneal Refractive Surgery (CRS)

• LASIK
  – Corneal flap created using microkeratome
  – Underlying corneal stroma reshaped by excimer laser
  – Corneal flap replaced over stroma, no sutures required
  – Complications:
    • Subjective symptoms
    • Refractive complications
    • Corneal haze and oedema
    • Flap-related complications (rare)
    • Microbial keratitis (rare)

Murray, et al; 2005

- Systematic review of 30 case series reports on PRK that met inclusion criteria:
  - Published from year 2000 onwards
  - Prospective studies: > 50 eyes, Retrospective studies: > 100 eyes
  - Assessed to be of good quality using 14-question questionnaire
Murray, et al; 2005: Efficacy

UDVA at ≥ 12 months

• 6/6 or better
  – Overall: 70.4% (range, 0.4% – 87.0%) [10 studies]
  – Low-moderate myopia: 76.4% (range, 50.7% – 82.0%) [3 studies]

• 6/12 or better
  – Overall: 92.3% (range, 37.6% – 98.8%) [9 studies]
  – Low-moderate myopia: 96.3% (range, 78.2% – 97.0%) [3 studies]
Murray, et al; 2005: Efficacy

Accuracy at ≥ 12 months

• SE within 0.50D of intended correction
  – Overall: 68.0% (range, 56.5% – 87.4%) [13 studies]
  – Low-moderate myopia: 86.6% (range, 39.1% – 95.8%) [4 studies]

• SE within 1.00D of intended correction
  – Overall: 71.6% (range, 65.0% – 88.7%) [13 studies]
  – Low-moderate myopia: 90.4% (range, 78.3% – 98.8%) [4 studies]
• Refractive complications at last follow-up
  – Loss of 1 line CDVA
    • Overall: 4.5% (range, 0.7% – 15.3%) [13 studies]
    • Low-moderate myopes: 14.9%\(^1\) [1 study]
  – Loss of ≥ 2 lines CDVA
    • Overall: 0.5% (range, 0% – 20.5%) [13 studies]
    • Low-moderate myopes: 0.5% (range, 0% – 1.1%)\(^{1-2}\) [3 studies]

• Corneal haze
  – Grade ≥ 2 at last follow-up: 0% (range, 0% – 16.3%) [8 studies]
Standardized graphs and terms for refractive surgery results