Comparative study of the performance and safety of four Silicone-Hydrogel contact lens materials (Balafilcon A, Lotrafilcon A, Galyfilcon A and Senofilcon A)

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Study purpose

- Evaluation of performance and safety of 4 Silicone-Hydrogel CL materials
  - Balafilcon A
  - Lotrafilcon A
  - Galyfilcon A
  - Senofilcon A
Study design

- Retrospective study
- May 1, 2005 until April 30, 2006
- Patient pool of private CL practice (4395 active patients)
- 951 Silicone Hydrogel wearers
Study design

- Gradings: CCLRU scale was used for most categories

- For categories not represented by the CCLRU scale a grading pattern similar to the CCLRU scale was developed.
Results/Statistical Evaluation

- 438 patients were eligible to be included
  - 218 DW subjects
  - 220 EW subjects
- Gender distribution 60:40 (f:m)
- Age distribution represents „real world“ CL wearer population
- No statistically significant differences between spheric and toric version of Balafilcon A and Galyfilcon A
  - therefore no differentiation!
Results/Statistical Evaluation

• NO statistical significance \((p>0.05)\) for any CL material at any time:
  – Bulbar redness
  – Limbal redness
  – Corneal Staining
  – Infection (bacterial, viral)
  – Other corneal anomalies (SEAL, FB)
  – Infiltrates (AIK, SIK, CLPU, MK)
Results/Statistical Evaluation

• Statistical significance:
  
  – **Subjective discomfort**
    • Balafilcon A significantly higher than Galyfilcon A (p=0.013)
    • Galyfilcon A lower discomfort than Senofilcon A (p=0.002)

  – **Tarsal conjunctiva**
    • Galyfilcon A showed significantly higher tarsal changes than Balafilcon A (p=0.003) and Lotrafilcon A (p=0.010)
Results/Statistical Evaluation

- Category: Subjective Discomfort
Results/Statistical Evaluation

- Category: Tarsal Conjunctiva
Conclusion

• All 4 Si-Hy lenses performed well

• Good representation of „real world“ CL wearer population

• Incidence of adverse events very low / NO case of MK or vision loss

• Recurrent minor adverse events => consider switching to a different wearing mode!

• Possible criticism: retrospective vs. prospective studies?
Thank you for your attention!
References

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