

**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

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Study design

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

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Study design

- Gratings: 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.

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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!*

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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)

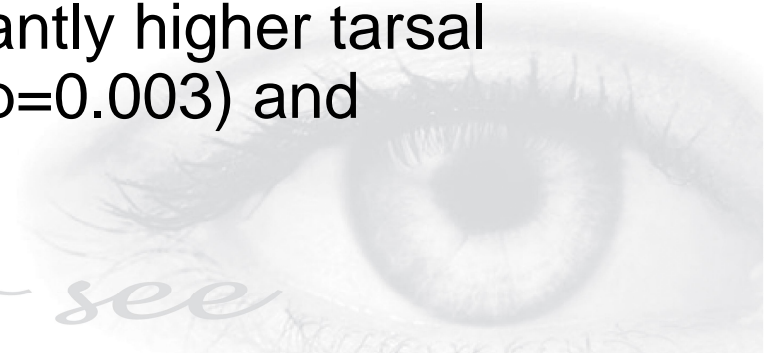
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Results/Statistical Evaluation

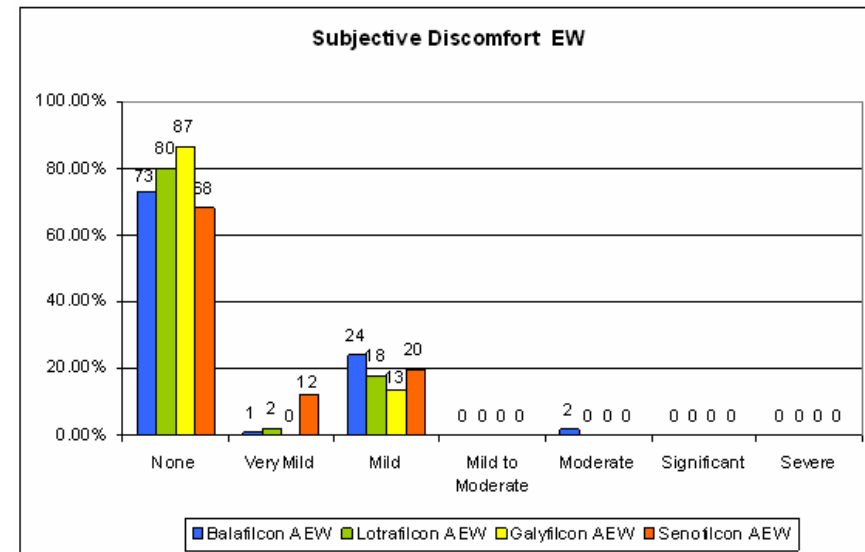
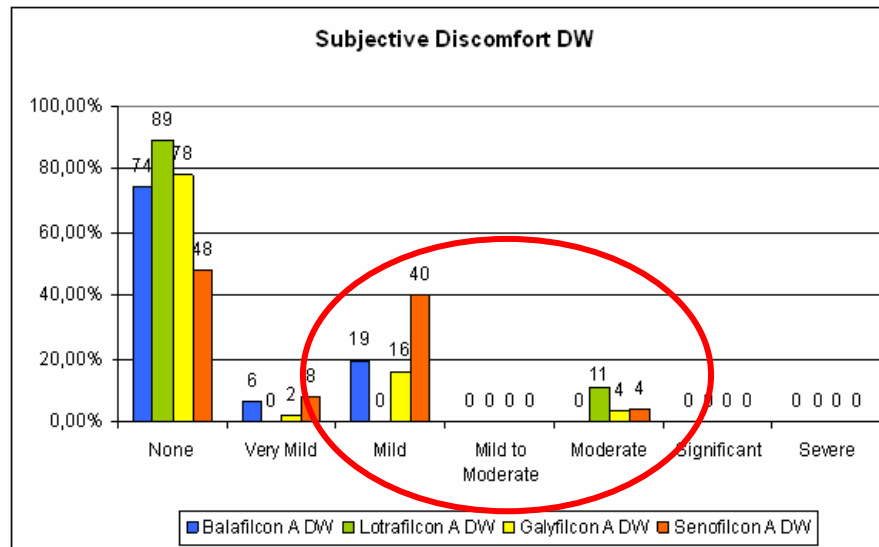
- **Statistical significance:**
 - **Subjective discomfort**
 - Balafilcon A significantly higher than Galyfilcon A ($p=0.013$)
 - Galyfilcon A lower discomfort than Senofilcon A ($p=0.002$)
 - **Tarsal conjunctiva**
 - Galyfilcon A showed significantly higher tarsal changes than Balafilcon A ($p=0.003$) and Lotrafilcon A ($p=0.010$)

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Results/Statistical Evaluation

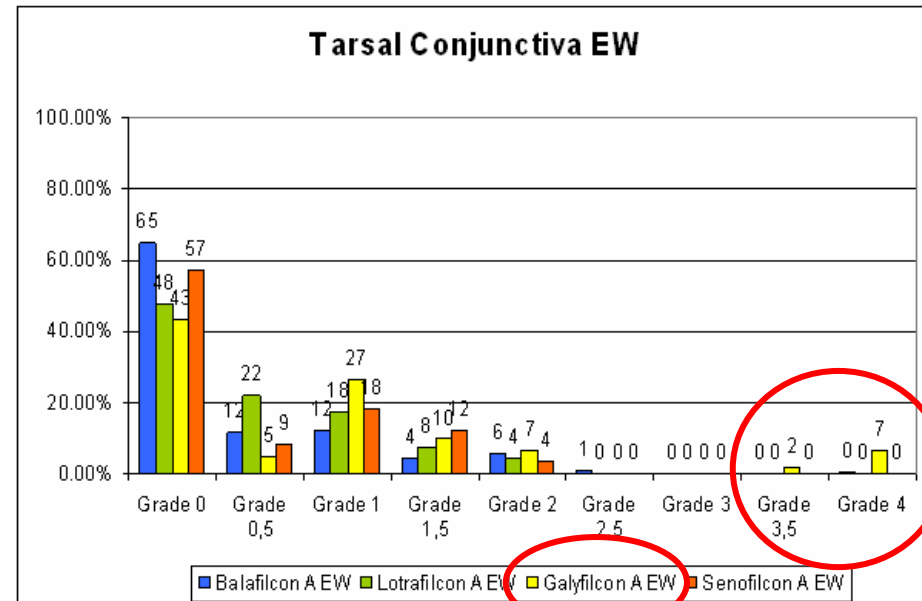
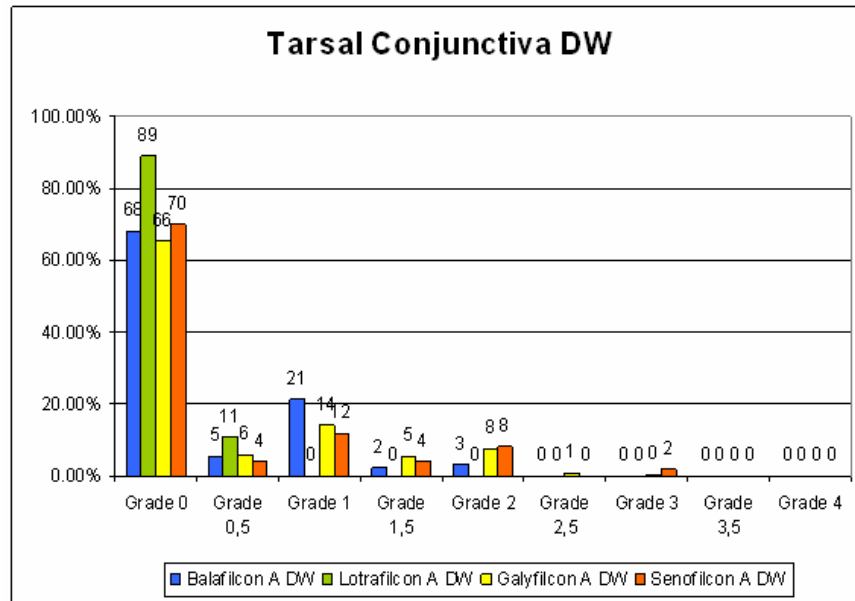
- Category: Subjective Discomfort



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Results/Statistical Evaluation

- Category: Tarsal Conjunctiva

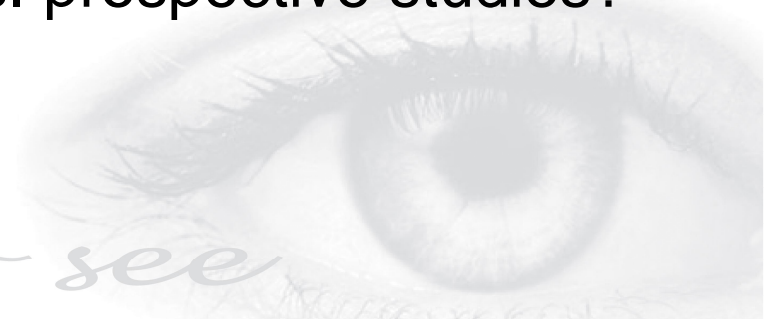


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Conclusion

- 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?

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Thank you for your attention!

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