



Introduction

We have reported previously that approximately half of soft contact lens (CL) wearers could be regarded as 'problem' patients¹. These patients experience dryness, discomfort, reduced comfortable wearing time (CWT) and compromised ocular physiology, although they are often regarded as 'clinically normal' by eye care practitioners. Understanding the nature of this population and investigating new CL options is of great importance. Replacement schedule and CL material are parameters that are often taken into consideration by eye care practitioners, as they are known to affect ocular surface symptoms¹⁻².

Purpose

- To estimate the prevalence of 'problem' patients in Reusable CL wearers.
- To investigate the effect of refitting these patients with daily disposable (DD) CLs of two different materials, etafilcon A and nelfilcon A.

Methods

Design:

Part I: The prevalence of key symptoms and signs was measured in 364 Reusable CL wearers: dryness, irritation, reduced CWT and clinically relevant bulbar or limbal hyperaemia and corneal staining (Table 1).

Part II: 235 'problem' patients were fitted with etafilcon A (n=107) or nelfilcon A (n=128) DD-CLs and assessed 1-2 weeks later. The 'problem' Reusable CL wearers fitted with DD-CLs included 154 patients identified in Part I and 81 patients with objective signs of dry eye recruited in separate trials.

Patients were between 18 and 45 years of age with a spherical refractive CL prescription between -1.00 and -6.00D. Patients were enrolled in sites in the UK and North America.

- Lenses:** Etafilcon A: 1•DAY ACUVUE® and 1•DAY ACUVUE® MOIST® were dispensed to 93 and 14 patients, respectively. Nelfilcon A: Focus® DAILIES® Aqua Release, Focus® DAILIES® Aqua Comfort plus and Focus® DAILIES® were dispensed to 46, 11 and 71 patients, respectively.

- Statistical Analysis:** Baseline vs. follow-up results and etafilcon A vs. nelfilcon A data were compared using the SPSS software (v19, IBM). A P value of less than or equal to 0.05 was considered a significant difference.

Symptom	Grading	Qualifying criteria
Dryness or Irritation	"How frequently do you experience dryness or irritation with your habitual lenses?" Possible answers: 'Constantly', 'Frequently', 'Seldom' and 'Never'	Frequently or constantly
Reduced Comfortable Wearing Time	Average Wearing Time (AWT) and CWT were measured in hours.	Difference between AWT and CWT > 2 hours
Bulbar or Limbal hyperaemia	Scale 0-4	≥2
Corneal staining	Scale 0-15 (NEI: 0-3, 5 corneal areas) or 0-9 (0=none and 9=severe patch >4mm)	Sum of all areas ≥3 if NEI scale or ≥ 4 on a 0-9 scale

Table 1: Qualifying criteria for 'problem' patients. CL wearers qualifying for at least one of the above criteria were classified as 'problem' patients.

REFERENCES

- Riley C, Young G and Chalmers R. 2006. Prevalence of ocular surface symptoms, signs and uncomfortable hours of wear in contact lens wearers: The effect of refitting with daily-wear silicone hydrogel lenses (senofilcon A). *Eye & Contact Lens*,36(6):281-286
- Jones L, Jones D and Simpson T. 1999. The impact of replacement frequency and care regime on subjective satisfaction with disposable/frequent replacement lenses. *Optom Vis Sci.* 76:12s 172

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Results

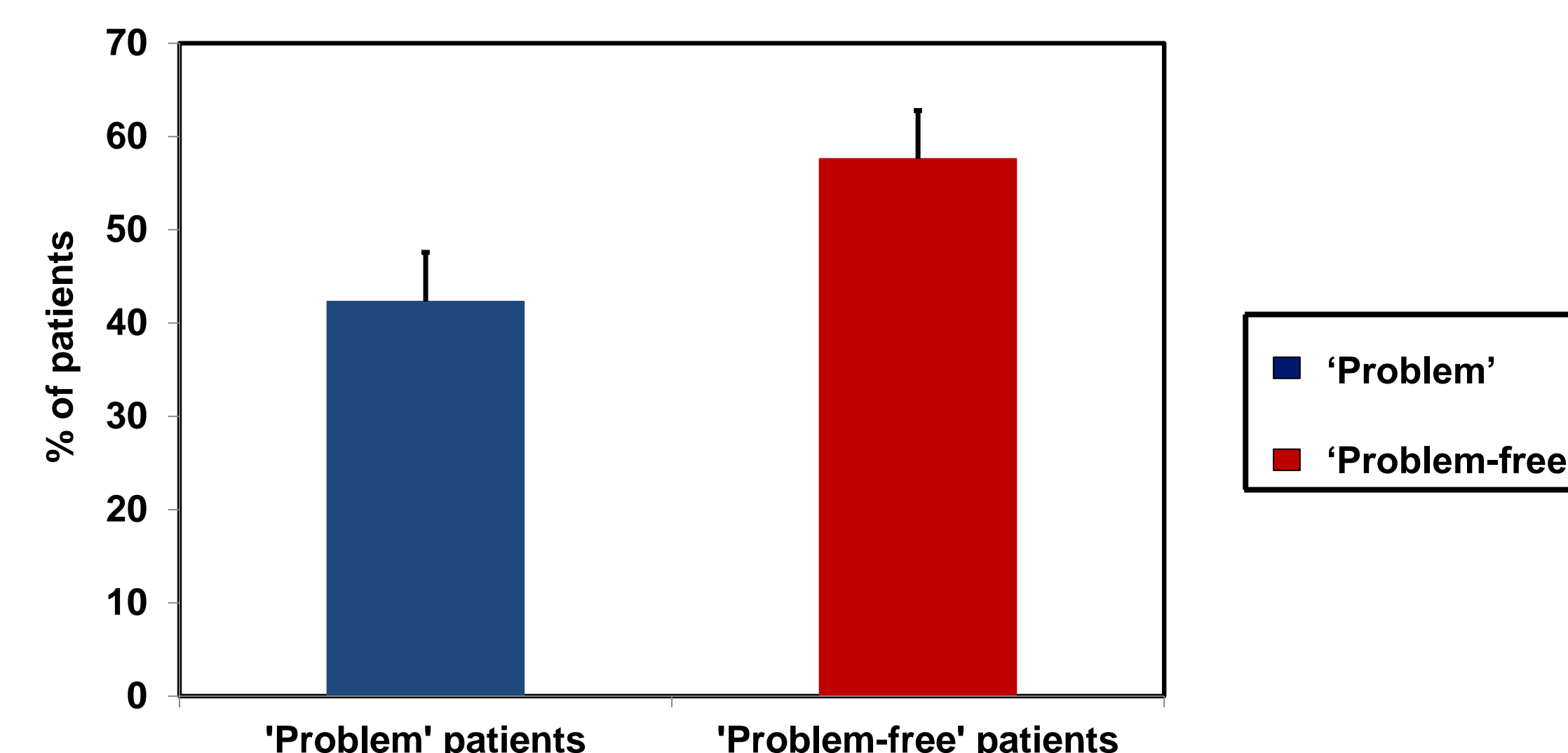


Figure 1: Prevalence of 'problem' patients in soft Reusable CL wearers. Reusable CL wearers (N=364) were classified as 'problem' or 'problem-free' patients based on the criteria described in Table 1. Error bars = 95% confidence intervals (CI).

Prevalence of 'problem' Reusable CL:

- 42% (154 of 364) of Reusable CL wearers could be regarded as 'problem' patients (Fig. 1).

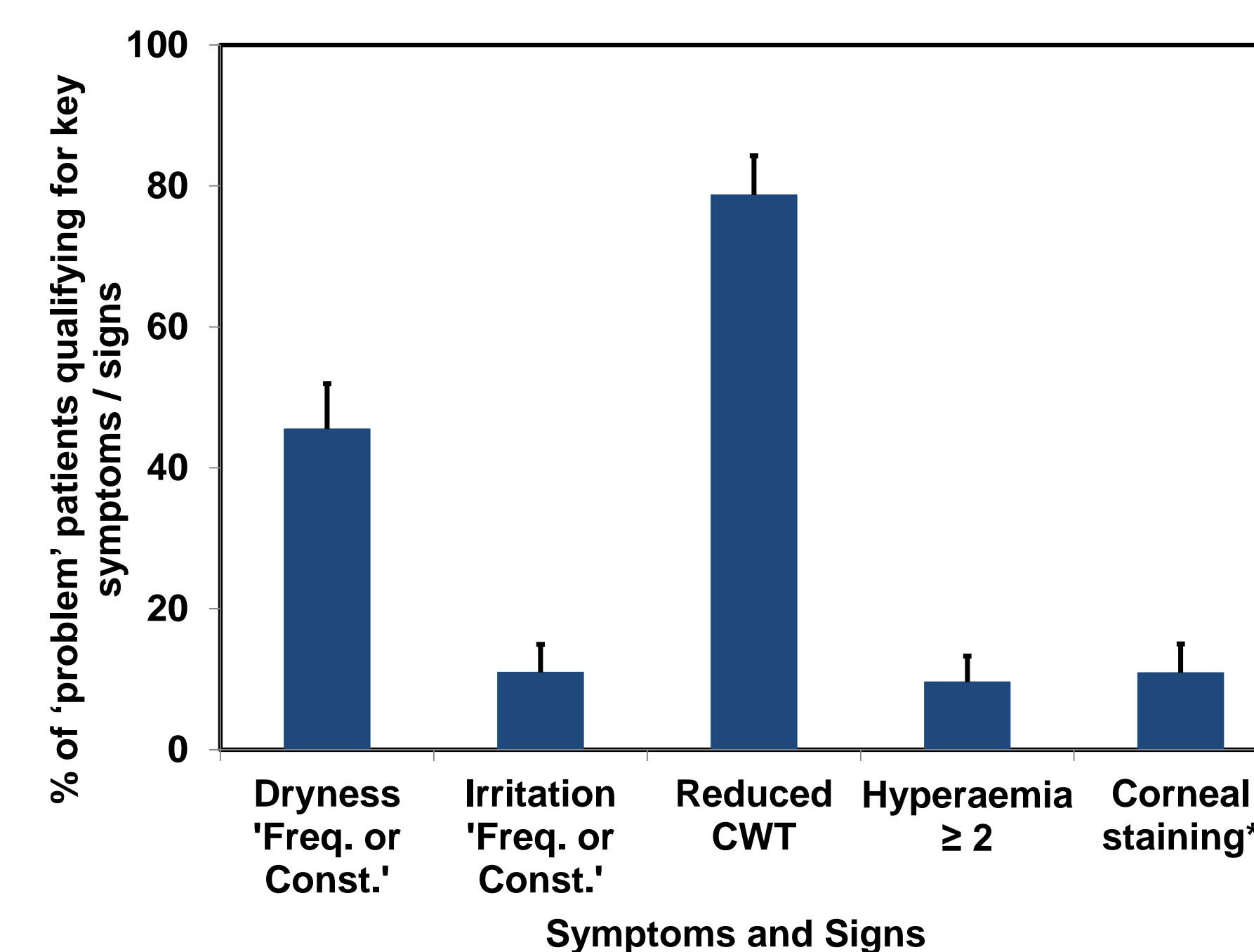


Figure 2: Prevalence of key symptoms and signs in 'problem' patients. N=154, error bars=95%CI, * sum of all areas ≥3 if NEI scale or ≥ 4 on a 0-9 scale.

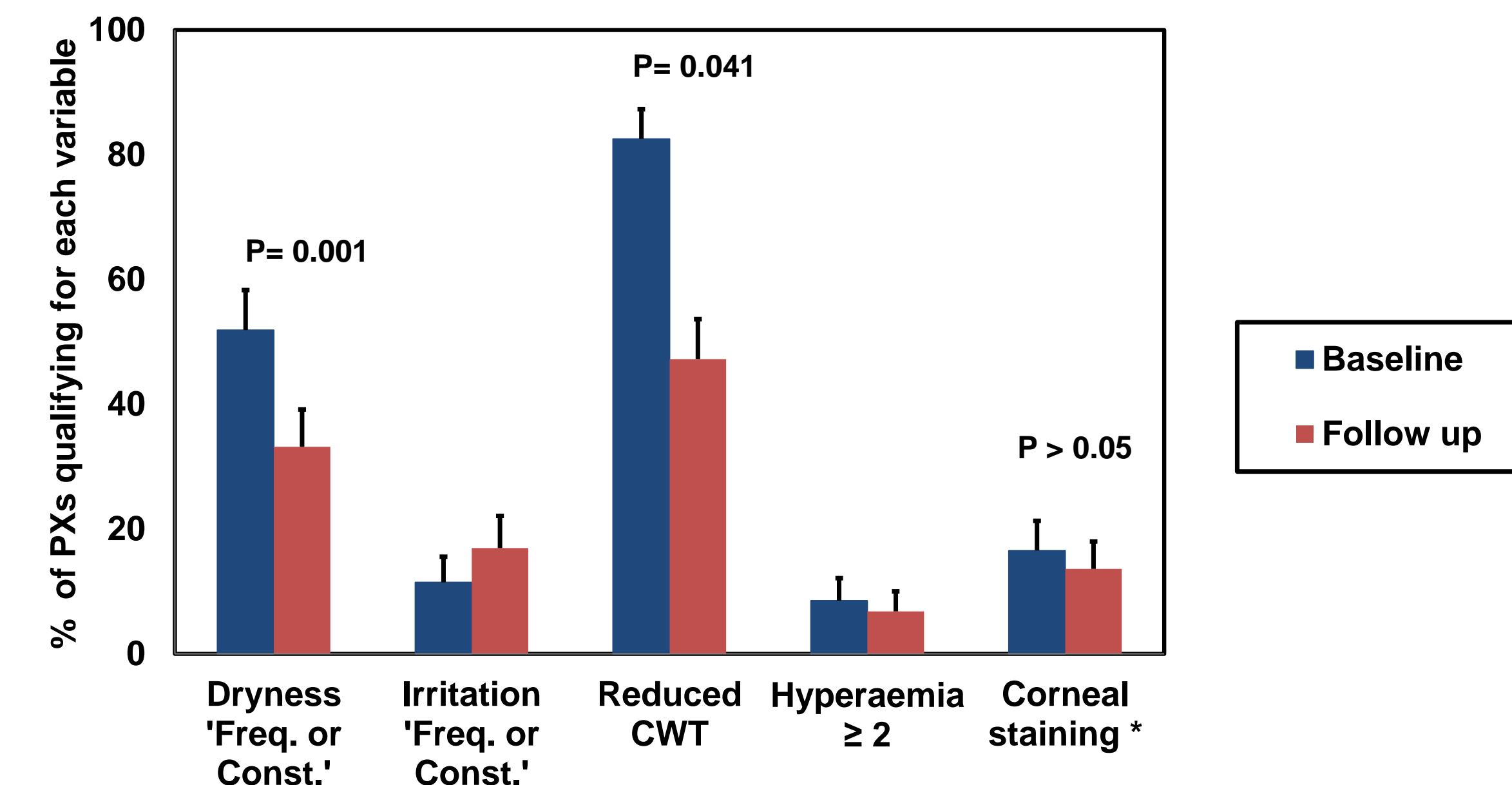


Figure 3: The effect of fitting 'problem' Reusable CL wearers with DD CLs. Problem Reusable CL wearers (N=235) were fitted with DD CLs (n=107 etafilcon A, n=128 nelfilcon A) and the prevalence of symptoms and signs was reassessed at a follow-up visit. Error bars = 95%, P values= McNemar's test, * sum of all areas ≥3 if NEI scale or ≥ 4 on a 0-9 scale.

Effect of DD lenses as a replacement schedule:

- Refitting with DD-CLs reduced the prevalence of dryness and uncomfortable WT from 51.9% to 33.2% (P=0.001) and from 88.6% to 47.2% (P=0.041), respectively (Fig. 3).
- No significant effect on irritation, hyperaemia or corneal staining (Fig. 3).

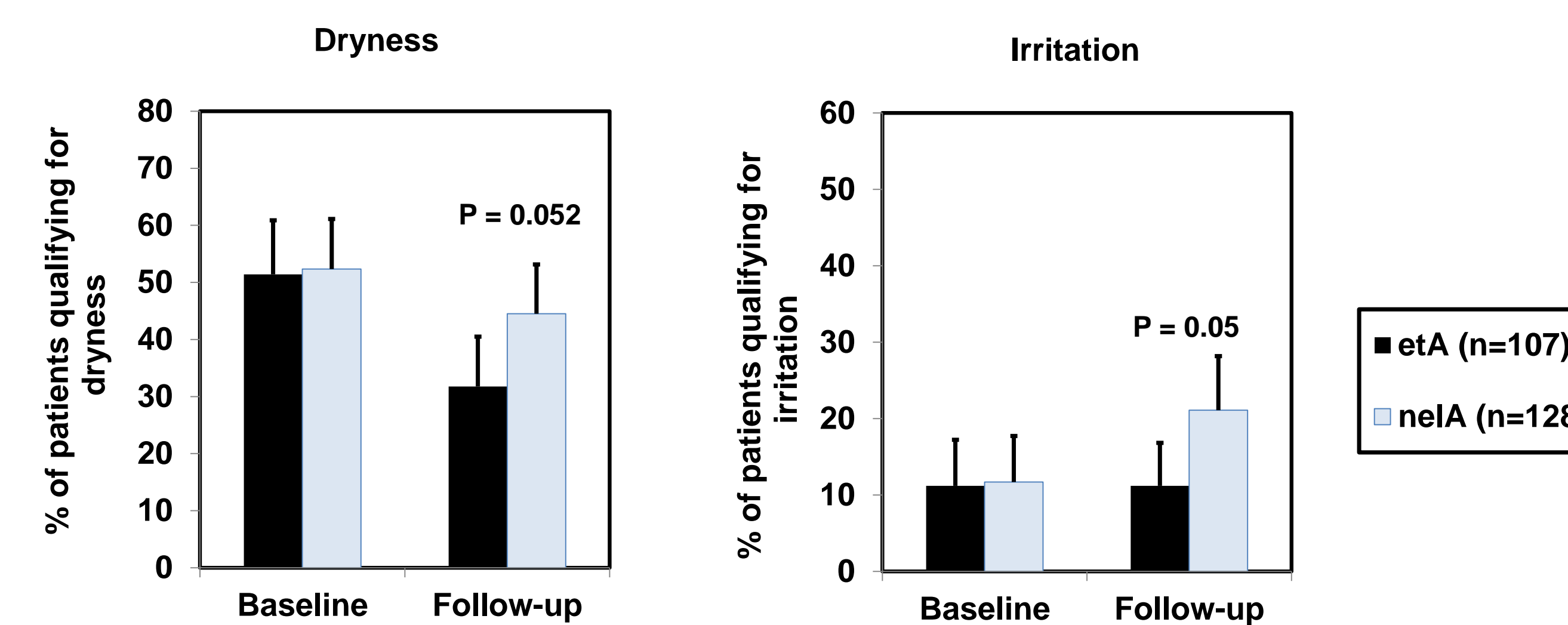


Figure 4: Etafilcon A vs. nelfilcon A: Effect on symptoms. Problem Reusable CL wearers (N=235) were fitted with either etafilcon A (n=107) or nelfilcon A (n=128) and the prevalence of symptoms was reassessed at a follow-up visit. Data from etafilcon-A fitted patients were compared with data from nelfilcon A-fitted patients for baseline and follow-up visits. Error bars = 95%, * P values = Chi-squared test (Chi).

Effect of DD lens material on symptoms and signs:

- The prevalence of irritation was significantly lower in patients fitted with etafilcon A in comparison to nelfilcon A lenses (11.7% vs. 21.9%, P=0.05). The prevalence of dryness also trended lower with etafilcon A lenses (31.7% vs. 44.5%, P=0.052), although the difference between the two materials did not reach significance. (Fig. 4).
- Etafilcon A was significantly more effective in reducing the numbers of patients with 'clinically relevant' hyperaemia (1.8% vs. 10.9%, P=0.003) (Fig. 5).
- Reduction in corneal staining was noticed with both lens materials, but the difference between the lens materials did not reach significance (Fig. 5).
- Reduced CWT was significantly lower (more hours of comfort) in etafilcon A-fitted patients (37.3% vs. 55.4%) (Fig. 6).

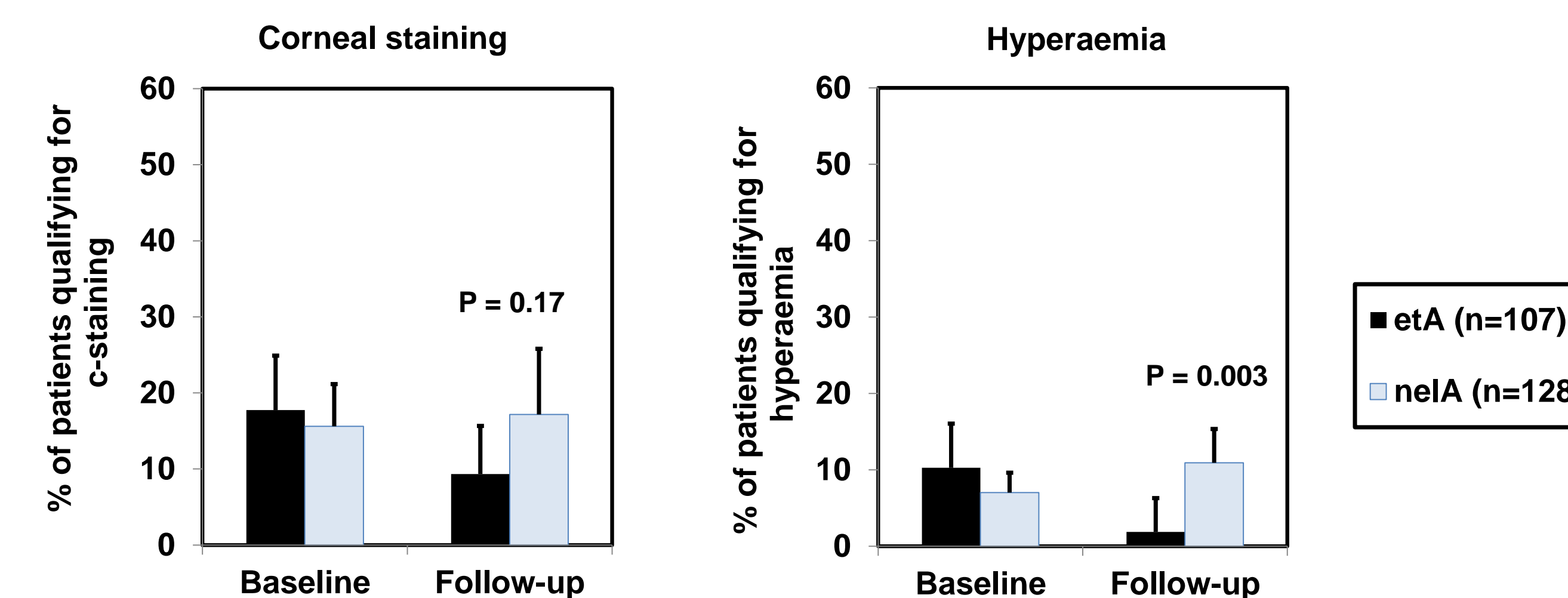


Figure 5: Etafilcon A vs. nelfilcon A: Effect on signs. Problem Reusable CL wearers (N=235) were fitted with either etafilcon A (n=107) or nelfilcon A (n=128) and the prevalence of signs was reassessed at a follow-up visit. Data from etafilcon-A fitted patients were compared with data from nelfilcon A-fitted patients for baseline and follow-up visits. Error bars = 95% CI, P values = Chi Squared test.

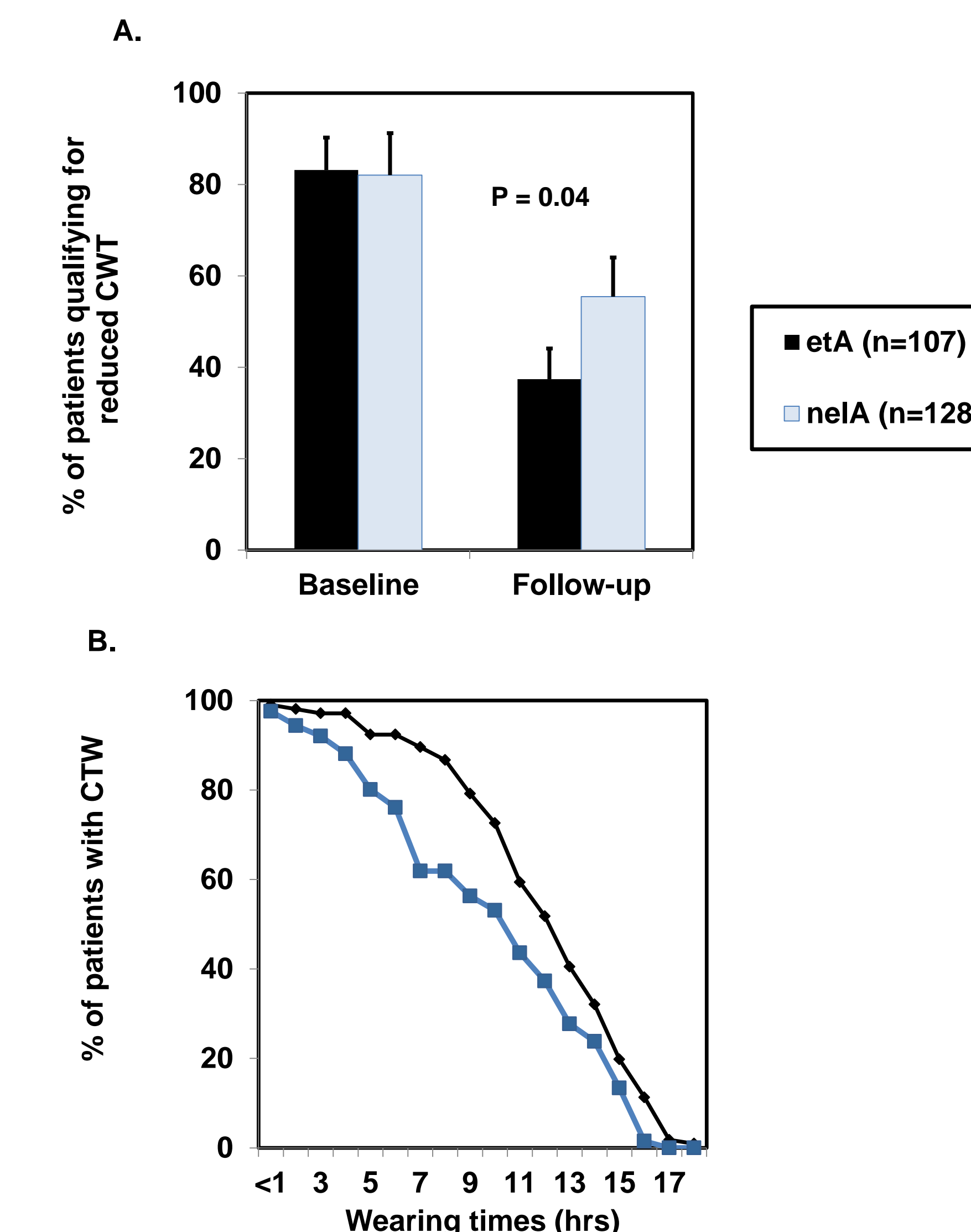


Figure 6: Etafilcon A vs. nelfilcon A: Effect on comfortable wearing time. A. Comparison of the prevalence of reduced comfortable wearing time between etafilcon A and nelfilcon A-fitted patients. B. Cumulative frequency graph of comfortable wearing time at the follow-up visit., Error bars = 95% CI, P values=Chi Squared test.

Discussion & Conclusions

- A high proportion of current soft Reusable CL wearers can be regarded as 'problematic' or 'marginally successful' based on specified criteria.
- Changing from Reusable to DD lenses, improved dryness and increased comfortable wearing time, indicating that DD lenses could be used as an alternative regime in order to alleviate these symptoms.
- The type of material and lens design was found to further affect lens performance.
- Etafilcon A lenses were more efficient in reducing symptoms of dryness and irritation in comparison to nelfilcon A lenses.
- The number of patients with clinically relevant hyperaemia was lower in the etafilcon A group compared to nelfilcon A-fitted patients, while no significant differences in the number of patients with corneal staining were noticed between the two groups.
- Patients fitted with etafilcon A lenses wore their lenses comfortably for longer during a period of time representing an average work day (8-12 hours of comfort) in comparison to nelfilcon A-fitted patients.