

# Prospective Case History Study using Systane® Lubricant Eye Drops to Help Reduce Symptoms of Dry Eye Associated with Contact Lens Wear

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## ABSTRACT

### PURPOSE:

To evaluate the use of Systane® Lubricant Eye Drops before and after contact lens wear in improving patients daily lens wearing experience.

### METHODS:

75 patients experiencing dryness or discomfort during lens wear were enrolled in this 2-week prospective non-controlled clinical evaluation. Patients using any brand of soft or RGP lenses or any pre-study lens care regimen were eligible to participate as long as they experienced discomfort due to dryness while wearing their lenses. Patients that met enrollment criteria were asked to dose with Systane 10-15 minutes prior to lens insertion and again after lens removal in the evening. Patients were instructed not to dose with Systane while wearing lenses. Baseline average lens wear time and comfortable wear time were determined. At Day 7 and Day 14 patients were contacted by telephone and asked questions about lens wear time and asked a series of 5-point Likert questions designed to determine if using Systane pre/post lens wear improved their lens wearing comfort.

### RESULTS:

As expected, total average wear time did not change. There was a significant increase in comfortable wear time (2 hrs by Day 7 and 3.1 hrs by Day 14). The percent of patients that marked Agree or Strongly Agree to specific Likert questions concerning how the drops improved lens comfort are as follows: Drops made CL more comfortable upon insertion (Day 7 = 72%; Day 14 = 89.3%); CL more comfortable all day (Day 7 = 61.3%; Day 14 = 80%); CL more comfortable at end-of-day (Day 7 = 46.7%; Day 14 = 69.3%); CL less dry all day (Day 7 = 74.7%; Day 14 = 80%); eyes less dry at end of day (Day 7 = 69.3%; Day 14 = 78.7%); longer lens wear time (Day 7 = 42.7%; Day 14 = 58.7%).

### CONCLUSION:

This non-controlled case history study demonstrated that patients using Systane before and after lens wear improved patients daily lens wear experience. This study was sponsored and conducted by Alcon Research Ltd, Fort Worth, TX.

## INTRODUCTION

Contact lens related dry eye is a common problem and has contributed a significant number of patients discontinuing lens wear. In 1991, Efron, et al., found that rewetting drops (currently on the market, at that time) were not significantly better than saline for providing relief from contact lens related ocular dryness and did not reduce lens dehydration. It was suggested that symptomatic re-

lief of contact lens induced dry eye may be accomplished by wetting of the bulbar conjunctiva or reduced tear film evaporation. Thus far, attempts at improving comfort of contact lenses by improved rewetting drops or lens materials have not had a visible effect on the number of contact lens dropouts seen annually.

Systane® Lubricant Eye Drops has been shown to significantly reduce both signs and symptoms in dry eye patients versus an active control (Refresh Tears® Lubricant Eye Drops) and has been shown to significantly increase tear film break up time vs competing artificial tears (Refresh Tears, Refresh Endura) through 20 minutes. No artificial tear on the market is approved for use while wearing contact lenses, but doctors have been reported seeing significant enhancement of patients' contact lens wearing experience by using Systane pre and post lens wear.

The purpose of this prospective case history study was to evaluate if Systane Lubricant Eye Drop would have significant effects on lens wearing comfort when used prior to lens insertion and after lens removal on patients who reported discomfort while wearing their contact lenses.

## MATERIALS AND METHODS

75 patients experiencing dryness or discomfort during lens wear were enrolled in this 2-week prospective non-controlled clinical evaluation. Patients using any brand of soft or RGP lenses or any pre-study lens care regimen (MPS to Peroxide) were eligible to participate as long as they answered Agree or Strongly Agree to the statement: "I experience discomfort when wearing my contact lenses".

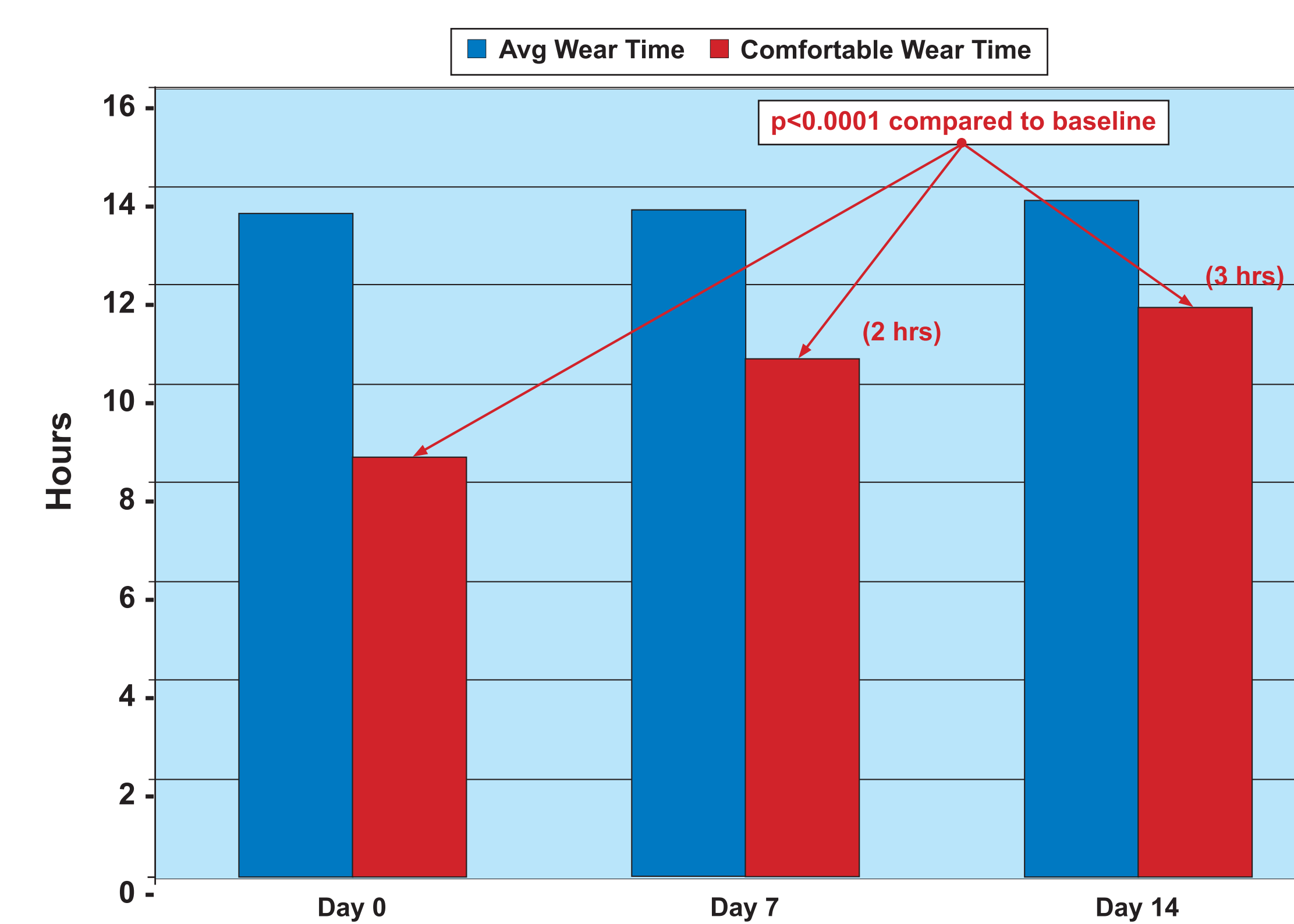
Patients who met enrollment criteria were asked to dose with Systane 10-15 minutes prior to lens insertion and again after lens removal in the evening. Patients were instructed not to dose with Systane while wearing lenses. Baseline average lens wearing time and comfortable wearing time was determined.

At Day 7 and Day 14 patients were contacted by telephone and asked about their average and comfortable lens wear time and they were also asked a series of 5-point Likert questions designed to determine if using Systane pre/post lens wear improved their lens wearing experience. Likert ranking included 1- Strongly Disagree, 2- Disagree, 3- Undecided, 4- Agree and 5- Strongly Agree. Analysis of wear time was performed by Paired t-tests. Chi-Square analysis was used to compare patients responding with Agree and Strongly Agree to those responding with Strongly Disagree, Disagree or Undecided for each question at each time point. The McNemar test is a test for categorical related samples and was used to determine if Day 14 was significantly greater than day 7.

## RESULTS

As expected, total wear time did not change over the course of the study. The average daily lens wear time found in this study (13.5 hrs) is common among lens wearers. Comfortable wear time significantly increased by 2 hrs on Day 7 ( $p < 0.0001$ ) and by 3.1 hrs on Day 14 ( $p < 0.0001$ ) compared to baseline (Fig. 1).

Figure 1: A comparison of average and comfortable wear time per visit.



The following figures are the result of the Likert questions asked at Day 7 and Day 14 concerning lens and ocular comfort.

Figure 2: "This drop makes my contact lenses more comfortable on insertion".

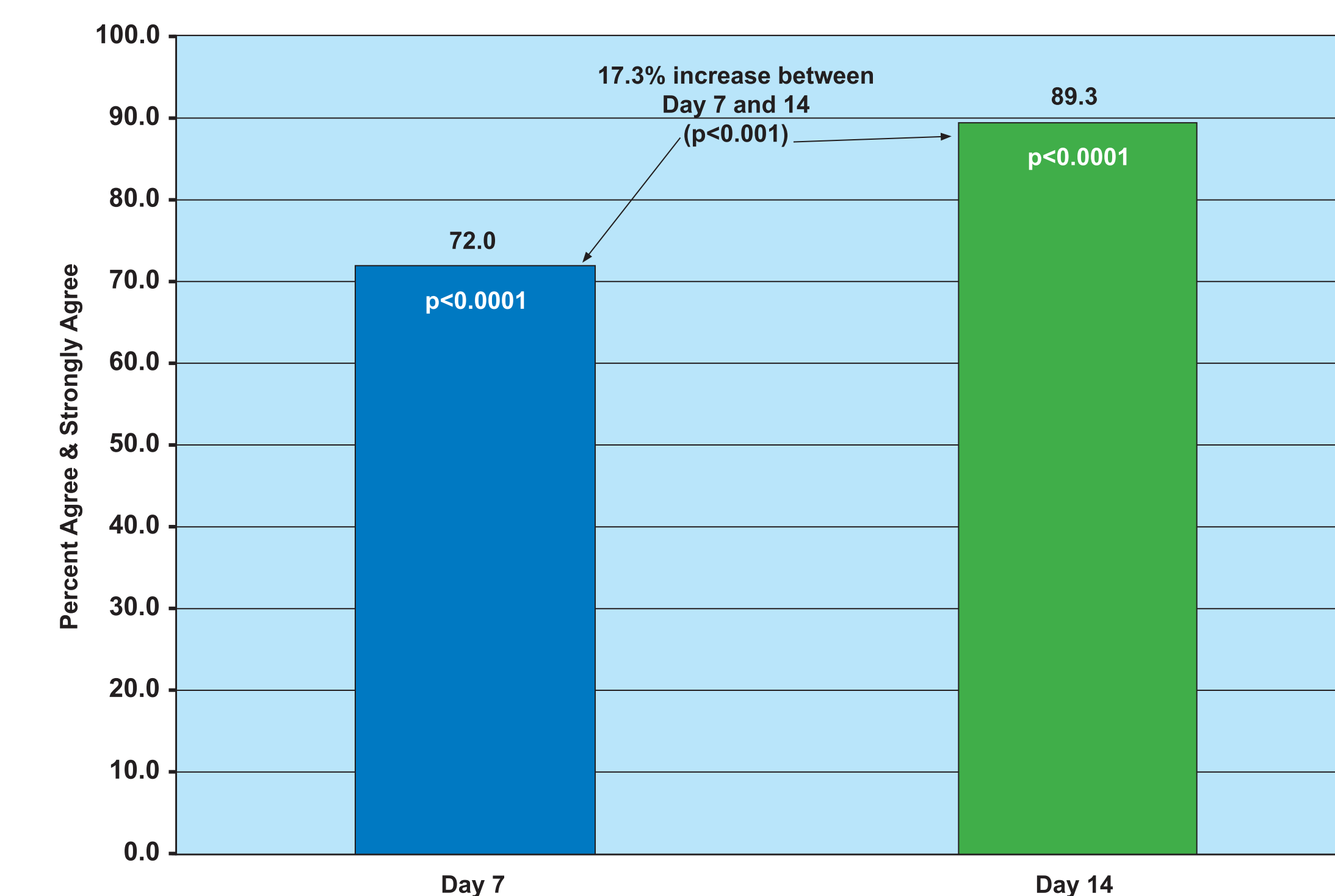


Figure 3: "This drop makes my contact lenses more comfortable all day long".

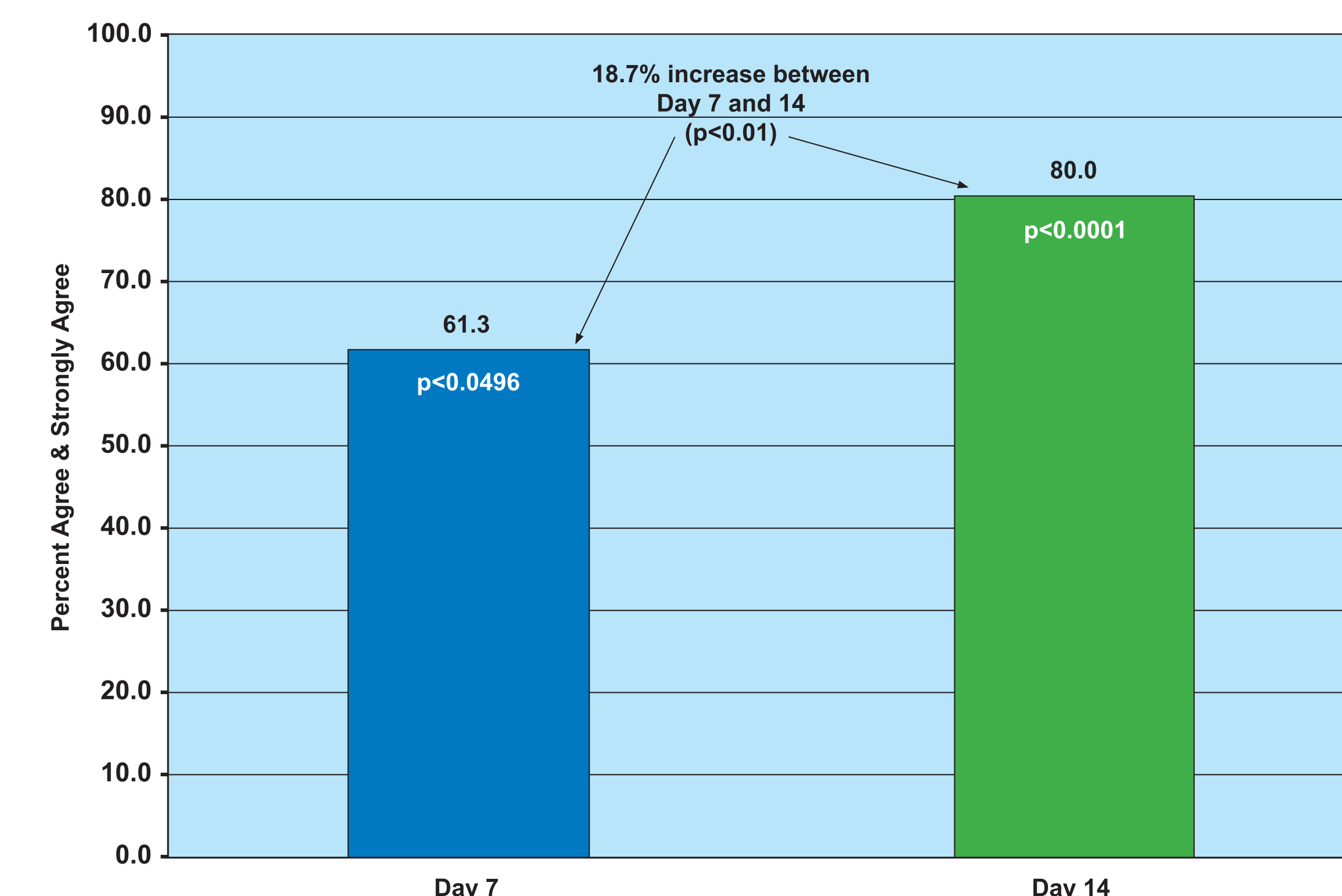


Figure 4: "This drop makes my contact lenses more comfortable at the end of the day".

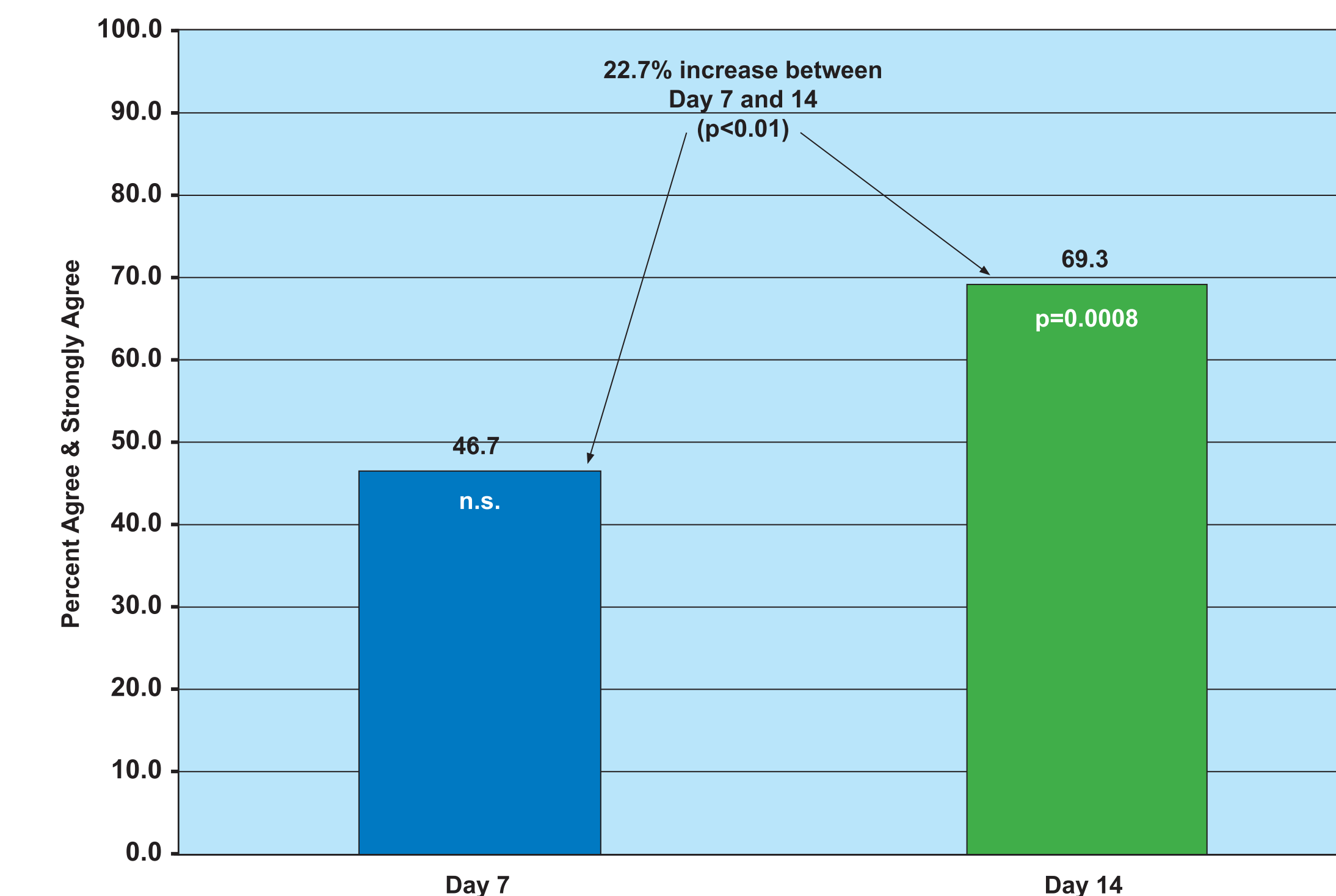


Figure 5: "This drop makes my contact lenses less dry all day".

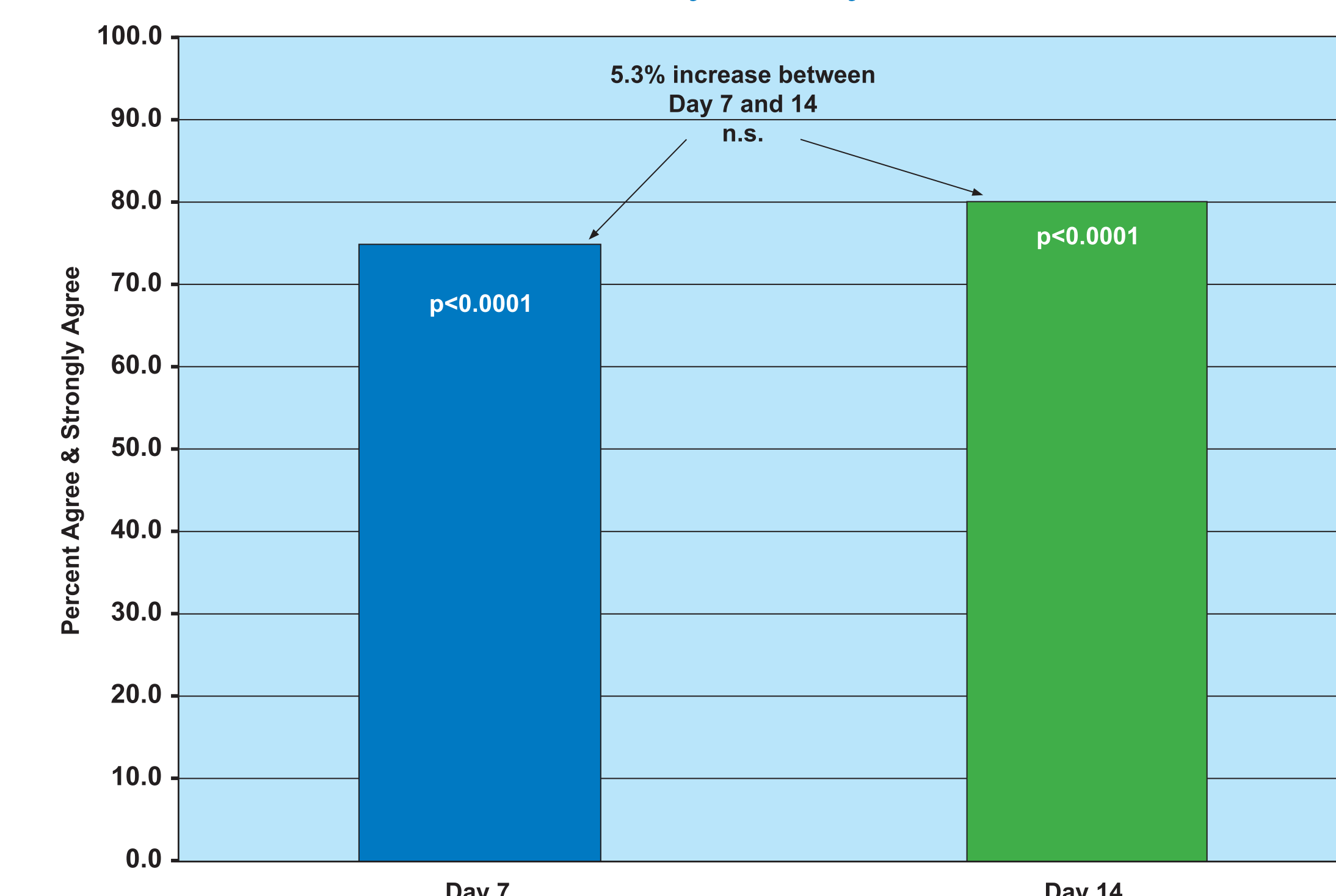


Figure 6: "My eyes feel less dry at the end of the day when I use this drop".

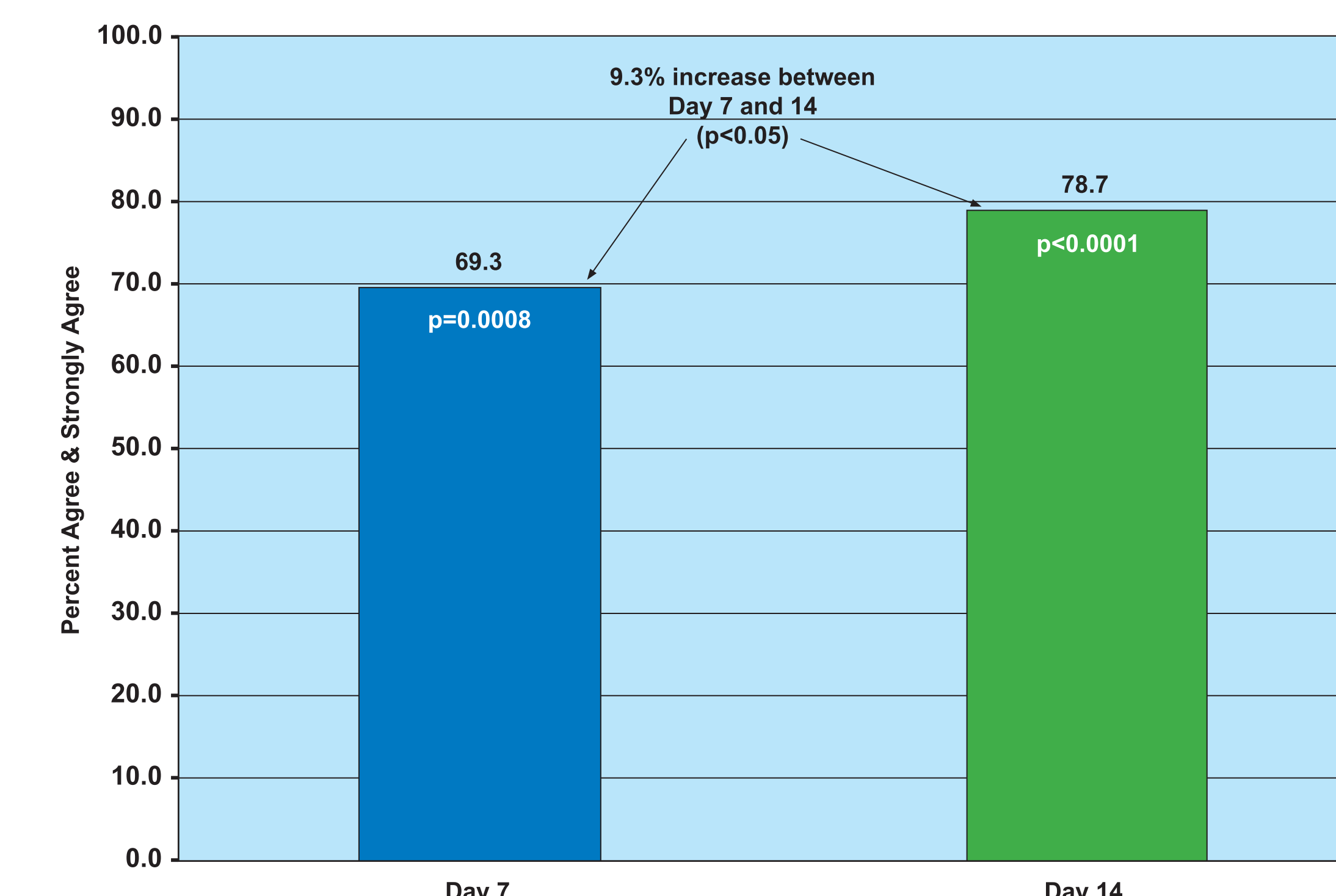
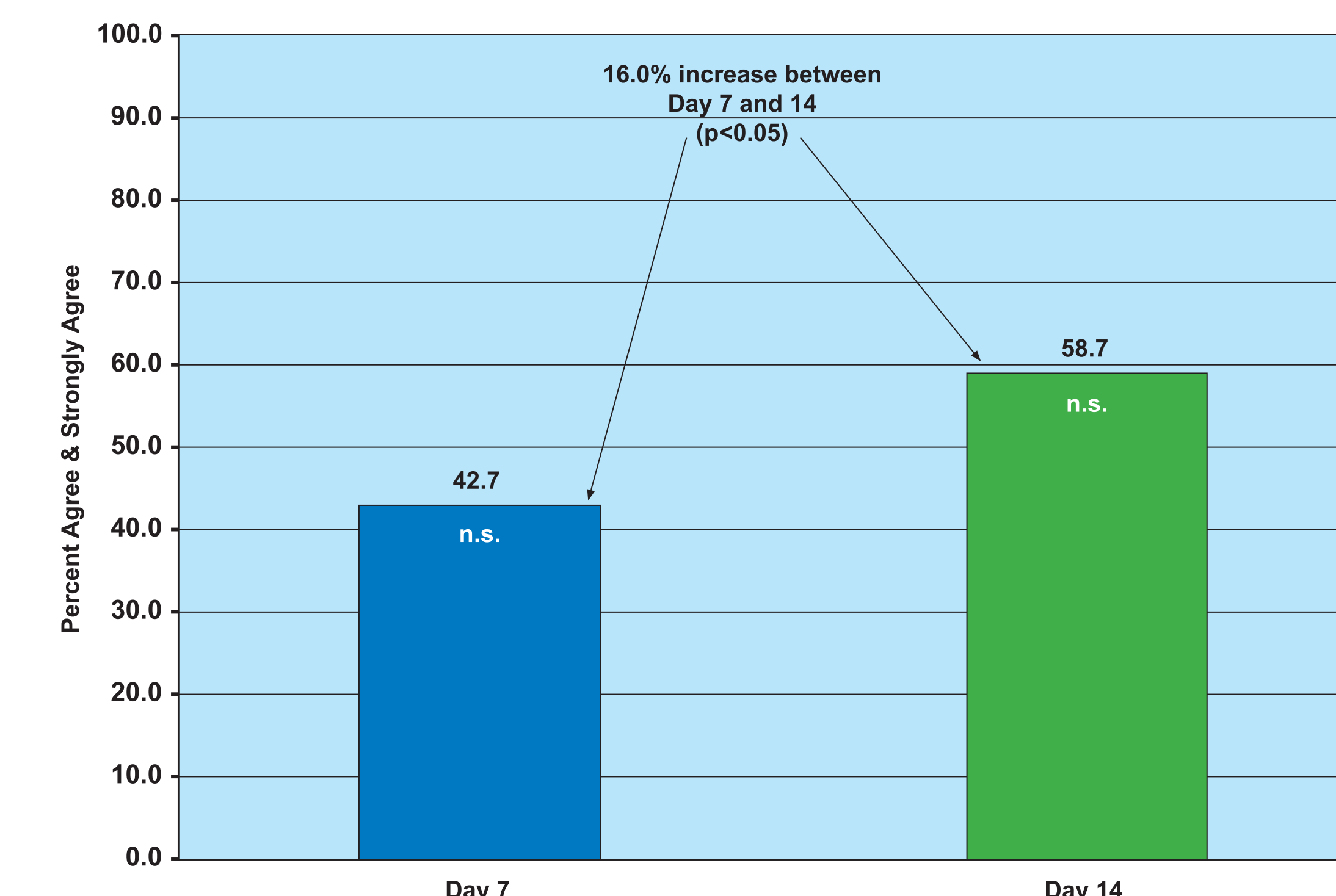


Figure 7: "I can wear my contact lenses longer when I use this drop".



## DISCUSSION

Use of Systane Lubricant Eye Drops significantly improved comfortable wear time and also improved the overall lens wearing experience of patients as shown in the above charts.

It may be important to not only consider the kind of lens care regimen or lens brand that is prescribed to our patients that suffer from contact lens related dry eye, but to also consider a dry eye relief regimen (pre/post lens wear) as a means of helping patients wear their lenses more comfortably longer. This could also potentially help reduce contact lens dropout. Many of the patients commented when they exited the study that the use of Systane significantly helped them and made their lenses and eye more comfortable. Many also indicated that they planned to continue with the Systane regimen as outlined above.

## CONCLUSIONS

Using Systane Lubricant Eye Drops pre and post lens wear resulted in:

- Significant improvement in contact lens comfort over the course of the day.
- Significant improvement in comfortable lens wear time compared to baseline.
- Significant improvement continued throughout the two weeks of the study.

Many patients indicated their desire to continue with the Systane regimen after the study was completed. Use of Systane pre and post lens wear resulted in a significant increase in comfortable wear time and contributed to an overall improvement in patient's lens wearing experience.

## REFERENCES

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- <sup>iii</sup> Efron N, Golding TR, Brennan N. The Effect of Soft Lens Lubricants on Symptoms and Lens Dehydration. *CLAO J.* 1991;17(2):114-119.
- <sup>iv</sup> Christensen MT, et al. Clinical Evaluation of an HP-guar Gellable lubricant eye drop for the relief of dryness of the eye. *Cur Eye Res.* 2004;28(1):55-62.
- <sup>v</sup> Christensen MT, Stein J, Stone R, Meadows D. Evaluation of Tear Film Break-up Time Extension by Artificial Tears in Dry Eye Patients. *Abst. Opt Vis Sci.* 2003;80(12s):106.