

PHASE I 14-DAY SAFETY AND ACCEPTABILITY STUDY OF 6% CELLULOSE SULFATE

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OBJECTIVES

Assess and compare the effect of twice-daily vaginal applications of 6% Cellulose Sulfate (CS) Gel or KY[®] Jelly:

- Symptoms and signs of genital irritation (baseline, after 7 and 14 days)
- Gram stain, pH, vaginal cultures and cytokine analyses (after 7 and 14 days)
- Acceptability of the study products (after 14 days)

METHODS

Design: Multi-center, phase I, placebo-controlled, randomized study

Study Sites: Eastern Virginia Medical School
University of Pittsburgh
Profamilia, Dominican Republic

Study Population:

	Sexually Abstinent Females	Sexually Active Females
CS	16	14
KY	14	16

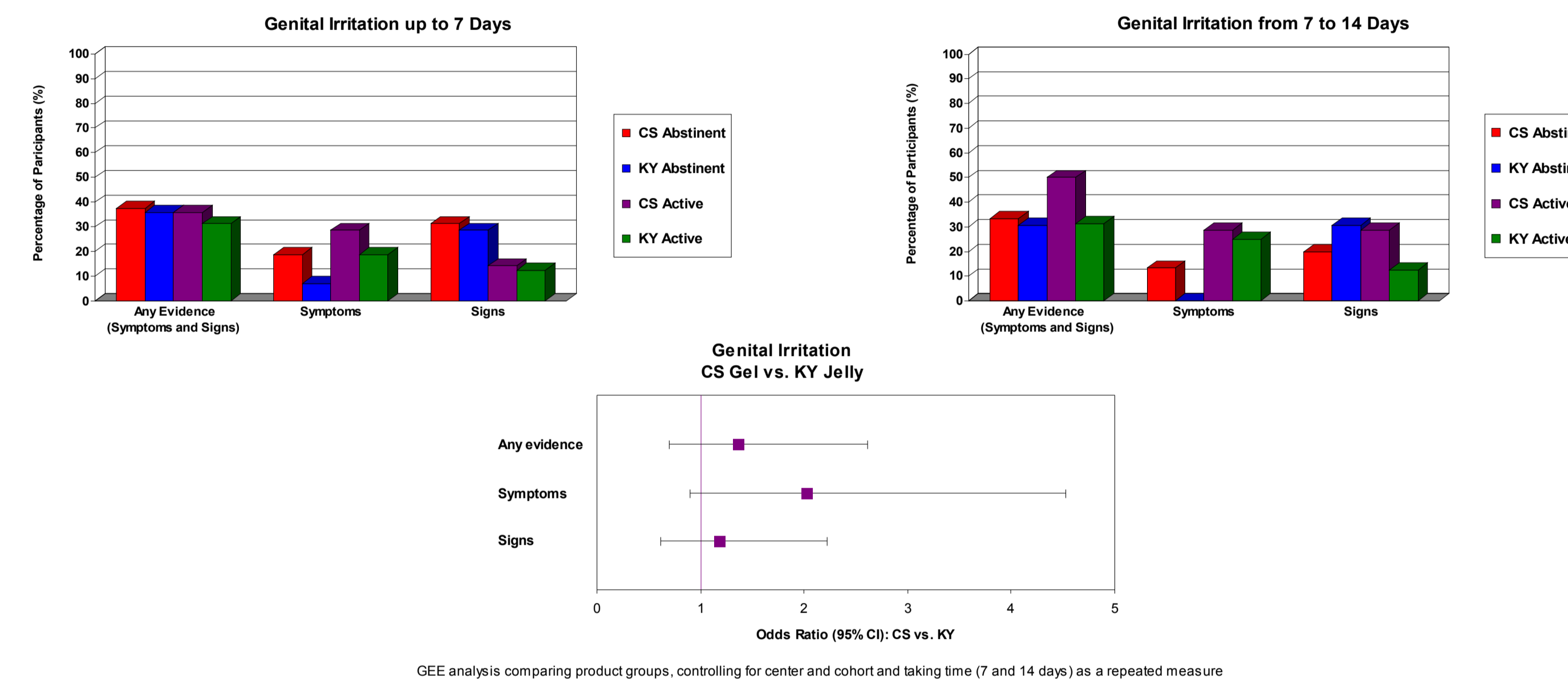
Study Visits: Screening, enrollment, after 7 days and 14 days

Treatment Regimen: Female participants applied 3.5ml of either 6% CS Gel or KY Jelly twice daily for 14 days

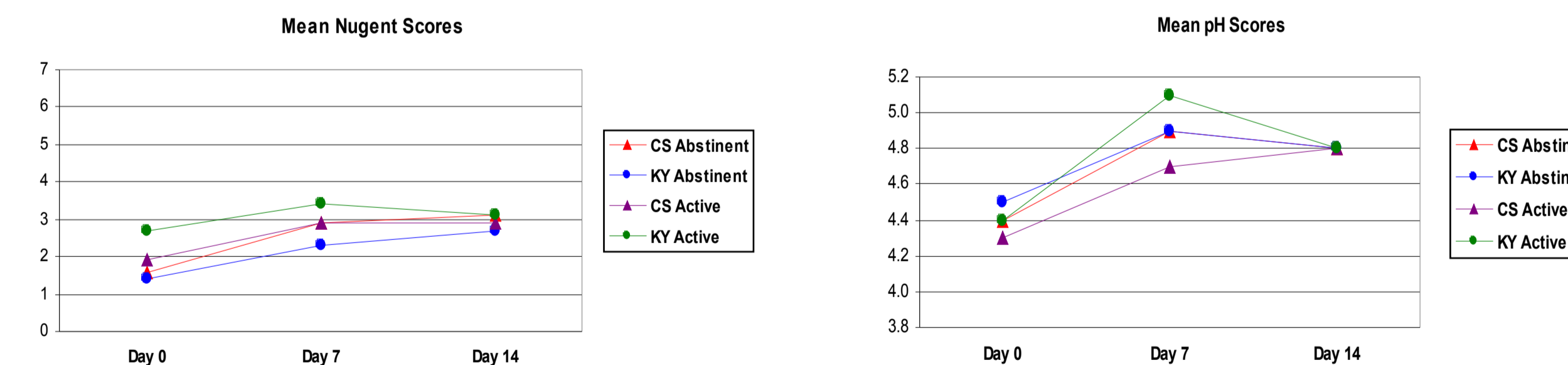
Procedures: Colposcopy, gram stain and wet mount, vaginal cultures and vaginal lavage, performed at baseline, after 7 and 14 days

RESULTS

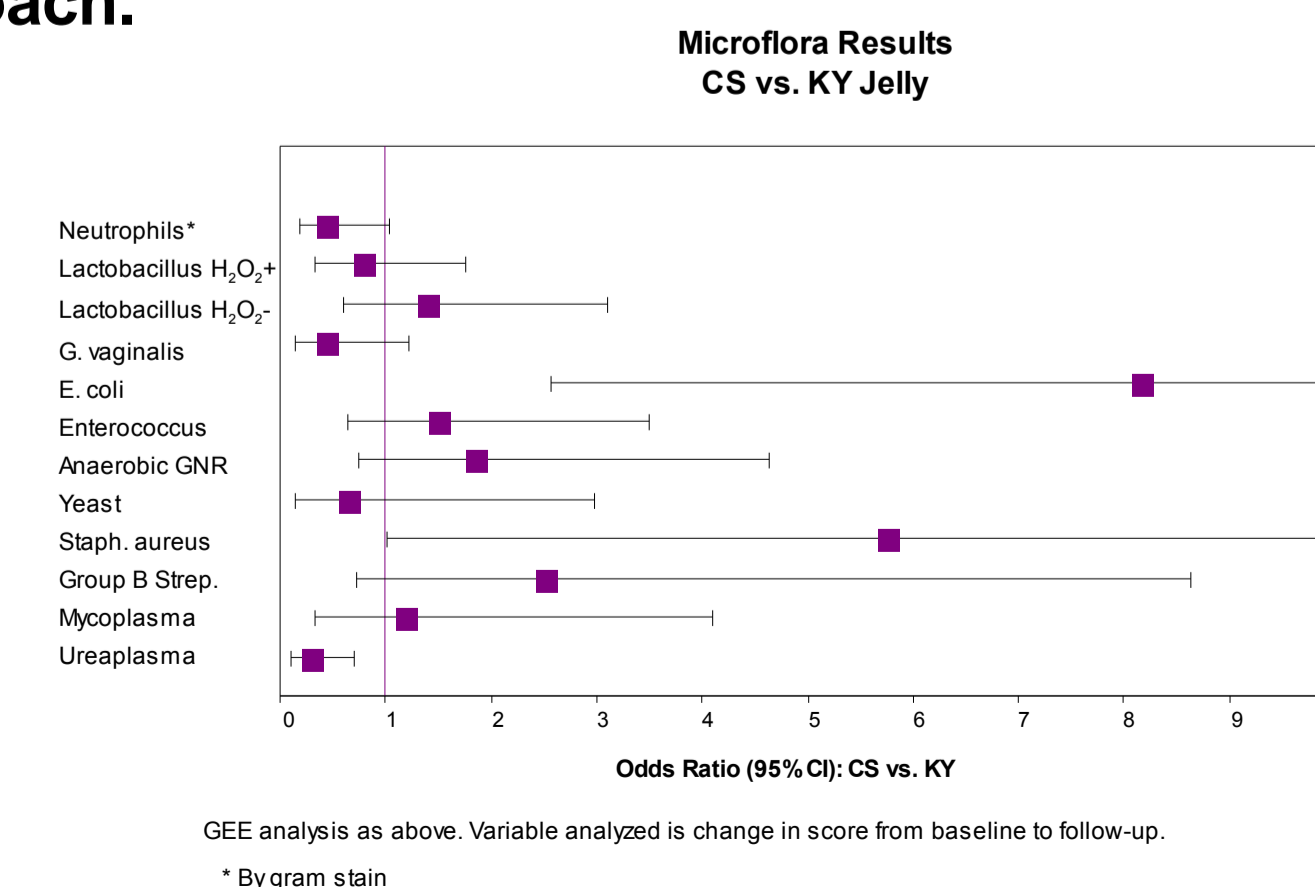
1. Minimal evidence of genital irritation in both treatment groups. No deep disruption of epithelium observed on colposcopy, and no severe adverse events reported.



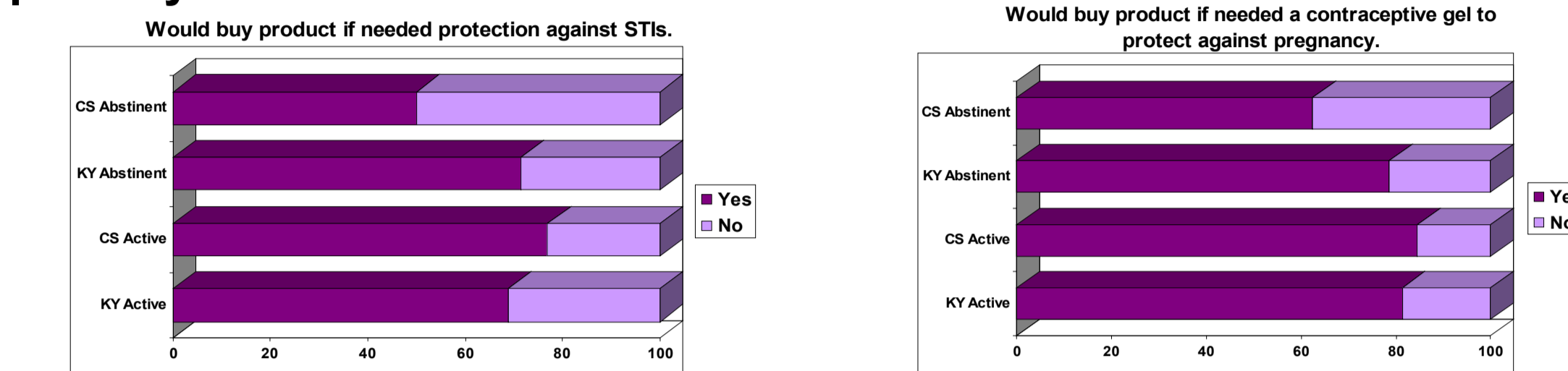
2. Minimal changes in Nugent and pH scores.



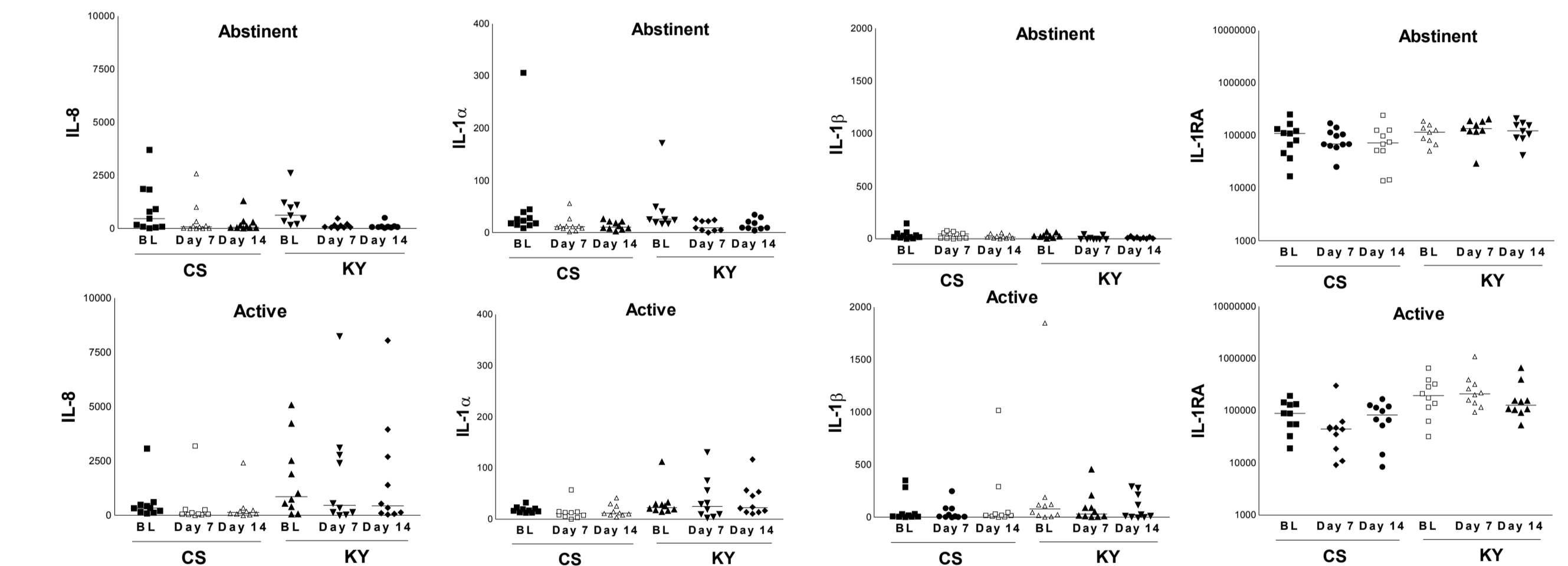
3. Some shifts in vaginal flora in the CS group were observed when compared with KY Jelly in the GEE approach.



4. Acceptability:



5. $TNF\alpha$ levels were <22 pg/ml in all cervicovaginal samples. High IL-8 values were recorded in a subset of subjects in both product groups at baseline and throughout product use. IL-1 α and IL-1 β were also elevated in a few of these subjects suggesting inflammatory conditions prior to product use. In the majority of subjects cytokine levels decreased or stayed the same during product use.



CONCLUSIONS

Cellulose Sulfate appears safe when used twice daily for 14 days.

Genital irritation: Minimal signs and symptoms of genital irritation were observed in both treatment groups.

Nugent and pH scores: Minimal changes in Nugent and pH scores were observed in both treatment groups.

Microflora: Some shifts in vaginal flora were observed in both treatment groups. Treatment with CS appears to increase the proportion of women with E. coli with a trend similar to that seen with BufferGel and N-9.

Acceptability: Both products appear to be acceptable.

Cytokines: Neither product appears to have proinflammatory effects.