A randomized non-inferiority study evaluating the efficacy of two commercially available teat sealants in dairy cows

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Introduction
The primary objective of this study was to compare the efficacy of a new internal teat sealant (ShutOut™, Merck Animal Health, Madison, NJ) (SO) to the current U.S. industry leader (Orbeseal®, Zoetis, Parsippany, NJ) (ORB). This comparison was based on a non-inferiority evaluation of quarter-level new infection risk during the dry period, with secondary comparisons of cure risk, incidence of clinical mastitis at the cow level during the first 120 days in milk, as well as cow-level performance in early lactation based on milk production, somatic cell count (SCC), and risk for removal from the herd.

Materials and methods
This study was conducted on 6 commercial dairy farms (2 in Iowa and 4 in Minnesota) and 1 university dairy (Iowa State University). On all farms, cows were randomly assigned to treatment groups, blocked by farm on the day of enrollment. Eligibility criteria included an expected dry period of 30-90 days, at least 3 functional quarters, body condition score > 2.0 out of 5, and a lameness score < 4 out of 5. Cows designated to be culled early in the subsequent lactation were also ineligible. Cows were excluded from enrollment if they had received any antimicrobial treatment within 14 days of dry off.

Study personnel collected aseptic, quarter-level, duplicate samples for routine aerobic culture immediately prior final milking and treatment at dry-off, and again within 14 days of calving, to evaluate risk of new intramammary infection (NIMI) and cure of existing intramammary infection (CIMI). Following milking machine detachment, all quarters received 500 mg of cloxacillin benzathine (Orbenin® DC, Merck, Madison, NJ) followed by their assigned sealant. Post-milking procedures and dry-period care were executed per individual farm protocols. Animal performance was also monitored for 120 days post-calving using Dairy Herd Improvement Association (DHIA) electronic records and owner-captured clinical mastitis events as well as culling and death loss. Effect of treatment on dry-period CIMI and NIMI in the first 14 DIM were evaluated using generalized linear mixed models.

Results
Crude prevalence of IMI at Dry-off was 32.0% (931/2909). During the dry period, the new infection risk was 10.7% with 11.1% of ORB quarters affected (CI 0.080, 0.146) and 10.4% of SO quarters (CI 0.060, 0.116) with no difference identified between treatment groups ($P = 0.126$). In post-fresh samples, cure risk was also not different between treatment groups with 93.5% of ORB cows attaining a cure during the dry period (CI 0.934, 0.978) and 94.1% of SO cows attaining a cure (CI 0.925, 0.974) ($P = 0.676$). When evaluating cow-level events within the first 120 days, there was no difference in clinical mastitis risk between treatment groups with a 12.3% incidence in ORB cows and 11.2% for SO cows ($P = 0.619$). Risk of culling was also similar between treatment groups with 11.0% of ORB cows affected and 7.4% of SO ($P = 0.076$). Finally, death rate did not differ between treatment groups with 2.2% of ORB cows affected vs 2.3% of SO cows ($P = 0.932$).

Significance
No difference was identified in quarter-level new infection and cure risks during the dry period in our comparison of 2 commercially available internal teat sealants. Cow-level events including culling, clinical mastitis and death within the first 120 DIM also showed no differences between treatment groups. ShutOut provides a non-inferior alternative as an internal teat sealant to the current industry leader, Orbeseal.