Evaluating the efficacy of two footbath concentrates to control digital dermatitis in free-stall dairy cows using a non-inferiority study

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Introduction
Digital dermatitis (DD), an infectious hoof lesion, is prevalent in U.S. dairies and compromises cow health, welfare and profitability. Footbaths are the main form of DD prevention and control. Understanding the comparative efficacies among commercial footbath products in preventing and controlling DD cases within a herd is necessary to provide farms with the information required when selecting a product for use. Digital dermatitis (DD), an infectious hoof lesion, is prevalent in U.S. dairies and can rapidly become endemic to a herd if not proactively controlled, compromising cow health, welfare and profitability. Footbaths are the main form of DD prevention and control. Understanding the comparative efficacies among commercial footbath products in preventing and controlling DD cases within a herd is necessary to provide farms with the information required when selecting a product for use. Our primary objective was to determine if a commercial footbath concentrate (Healmax®) was non-inferior to a copper sulfate concentrate in the prevention of new cases of digital dermatitis (DD). As a secondary objective, we sought to investigate the comparative efficacies of the 2 products in the control of chronic DD cases.

Materials and methods
Five Holstein and Holstein-cross herds ranging from 1323-2292 cows/herd were enrolled in the study starting December 2021. Treatments were allocated randomly at the pen level to the test product (HM; 2.5% concentration) or to a copper sulfate (CS; 5% concentration) footbath solution. Footbaths are run 4d/wk, once per day, for a 4-month time period, with footbaths changed after every 200-400 cows. All lactating cows were scored in the milking parlor every 2 weeks for DD by trained observers, including baseline evaluations prior to the study start. Using the M-based scoring system, a score of 0 denotes no lesion being present and 4, 4P, 2 and 2P being lesion categories of increasing severity. Herd-level data was extracted during each farm visit from farm DairyComp 305 software. Outcomes for DD score were measured at the leg level (rear legs only). For the study sample size calculations, a 5% incidence risk of new DD infections and a 25% non-inferiority margin has been used. A preliminary analysis was conducted to compare the number of new cases of DD after 10 weeks of treatment application for HM and CS cows. Preliminary data was analyzed by comparing means and using a linear mixed model, accounting for fixed effects of treatment, farm, pen, parity.

Results
The total proportion of legs scored as 0 at baseline (CS: 75.7%, 95%CI: 66.2, 85.2; HM: 76.2%, 95%CI: 66.3-86.2) was similar to the total scored as 0 after 10 weeks of treatment application (wk 10) for both treatment groups (CS: 77.6%, 95%CI: 70.0-85.2; HM: 78.0%, 70.5-85.6). A total of 78% of legs were scored as 0 at baseline and, of these, 28% developed a lesion between baseline and wk 10. For legs that had no lesions present at baseline (score 0), the number of legs that remained lesion-free at wk 10 was not statistically different between treatments (The total proportion of legs scored as 0 at baseline (CS: 75.7%, 95%CI: 66.2, 85.2; HM: 76.2%, 95%CI: 66.3-86.2) was similar to the total scored as 0 after 10 weeks of treatment application (wk 10) for both treatment groups (CS: 77.6%, 95%CI: 70.0-85.2; HM: 78.0%, 70.5-85.6). A total of 78% of legs were scored as 0 at baseline and, of these, 28% developed a lesion between baseline and wk 10. For legs that had no lesions present at baseline (score 0), the number of legs that remained lesion-free at wk 10 was not statistically different between treatments (The total proportion of legs scored as 0 at baseline (CS: 75.7%, 95%CI: 66.2, 85.2; HM: 76.2%, 95%CI: 66.3-86.2) was similar to the total scored as 0 after 10 weeks of treatment application (wk 10) for both treatment groups (CS: 77.6%, 95%CI: 70.0-85.2; HM: 78.0%, 70.5-85.6). A total of 78% of legs were scored as 0 at baseline and, of these, 28% developed a lesion between baseline and wk 10. For legs that had no lesions present at baseline (score 0), the number of legs that remained lesion-free at wk 10 was not statistically different between treatments (The total proportion of legs scored as 0 at baseline (CS: 75.7%, 95%CI: 66.2, 85.2; HM: 76.2%, 95%CI: 66.3-86.2) was similar to the total scored as 0 after 10 weeks of treatment application (wk 10) for both treatment groups (CS: 77.6%, 95%CI: 70.0-85.2; HM: 78.0%, 70.5-85.6). A total of 78% of legs were scored as 0 at baseline and, of these, 28% developed a lesion between baseline and wk 10. For legs that had no lesions present at baseline (score 0), the number of legs that remained lesion-free at wk 10 was not statistically different between treatments (The total proportion of legs scored as 0 at baseline (CS: 75.7%, 95%CI: 66.2, 85.2; HM: 76.2%, 95%CI: 66.3-86.2) was similar to the total scored as 0 after 10 weeks of treatment application (wk 10) for both treatment groups (CS: 77.6%, 95%CI: 70.0-85.2; HM: 78.0%, 70.5-85.6).
Significance
Preliminary results from our analysis suggest that the commercial footbath concentrate is performing at a level that is comparable to that of copper sulfate in the prevention of new cases of DD on commercial dairy farms. Further analysis cure rate and time-to-cure for chronic lesion cases is currently underway to confirm the non-inferiority of HM to CS.