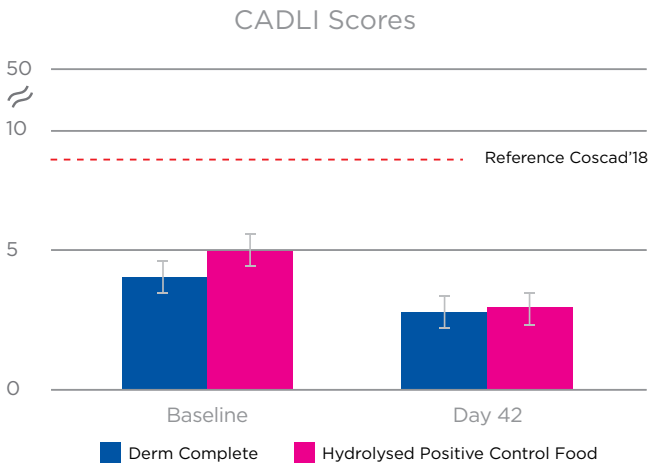
CLINICAL EVIDENCE REPORT

In a multi-centre, blinded, controlled, longitudinal study, client-owned dogs with well-controlled food allergies fed **Hill's Prescription Diet Derm Complete** demonstrated continued control of clinical signs.

Hill's Pet Nutrition, Inc. Data on file

Results:

Veterinarian-Reported Canine Atopic Dermatitis Lesion Index (CADLI) Scores Were No Different from Baseline = Continued Control*



*Veterinarian assessments over times were not significantly different vs baseline or compared with control food (P>0.05)
**CADLI (Figure 1) score less than or equal to 8 (dotted line above) is normal (COSCAD, 2018).
Error bars: standard error

These results demonstrate that **Prescription Diet Derm Complete** maintained control of clinical signs of adverse food reaction in dogs previously well controlled on a dietetic novel or hydrolysed food and was as effective as a hydrolysed protein dietetic food when fed to food-allergic dogs in a 21-day study.

Additional Significant Findings:

- Dogs with dermatological clinical signs noted, once transitioned from original novel or hydrolysed protein dietetic foods were few and similar in number between groups.
- There were no significant differences between foods or over time in the activity data collected from Hill's wearable collars, including no significant increases in scratching, shaking or worsening of sleep quality behaviours.
- There were no differences in owner-reported control of scratching using the Pruritus Visual Analog Scale (PVAS, Figure 2), sleep and stool quality when food-allergic dogs were fed Derm Complete compared with a dietetic hydrolysed protein food.
- There was a significant improvement in veterinarian-reported skin healing scores in the United Kingdom study dogs fed Derm Complete after 21 days compared with dogs fed the hydrolysed protein dietetic positive control food ($P<0.05$).

Implications for Practice

These results demonstrate that Derm Complete provides excellent control of clinical signs of adverse food reaction in dogs and therefore is an excellent first choice for dogs with suspected food or environmental allergies. Additionally, Derm Complete was associated with significant skin healing in food-allergic dogs in as little as 21 days.

Supplementary Study Information

Subjects

- 57 client-owned dogs
- Mean age 6 years
- Previously diagnosed with food allergy, well-controlled on a dietetic novel or hydrolysed protein dietetic food

Methods

Dogs with a food allergy were recruited for two identical, randomised, double-blinded, controlled studies in the United States and United Kingdom to evaluate the effect of a test food (Prescription Diet Derm Complete), on food allergy-related signs over a 42-day period compared with a positive control food. The results of the two studies were similar and have been combined for analysis. The test food contained egg, omega-3, 6 and 9 fatty acids, and the control food a hydrolysed animal protein. Dogs had been diagnosed by a food elimination trial, managed in general veterinary practice and were consuming a novel or hydrolysed protein dietetic food at the time of enrollment. Veterinary-reported canine atopic dermatitis lesion index (CADLI) scores (Figure 1) and owner pruritus visual analog scale (PVAS, Figure 2) values were performed at study entry to assess dermatologic clinical signs and conformed with the 2018 COSCAD (Core Outcome Set for Canine Atopic Dermatitis trials) guidelines outlined by the veterinary dermatology profession (Olivry, 2018). Dogs consumed their usual diet for the 21-day study and then CADLI and PVAS values were repeated. Dogs wore a collar-mounted activity monitor throughout the study. Machine learning-based behaviour recognition algorithms quantified the total duration of scratching (sec/day), shaking (sec/day), resting (hrs/day) and sleeping (hrs/day); sleep quality was evaluated with an algorithm based on the absence of night-time disturbance (0: highly disturbed sleep, 100: undisturbed sleep). The validated scratching and shaking algorithms have an accuracy >99%. Behaviours, CADLI and PVAS values were analysed in SAS using linear mixed-models with diet, time, and diet x time as fixed-effects and a significance threshold of $P<0.05$. On Day 22 (end of baseline), dogs were randomly assigned to either Test Food (Prescription Diet Derm Complete dry food) or a positive control hydrolysed protein dietetic food (Royal Canin Anallergenic canine dry food) until study day 42. Upon study completion, veterinarian-reported CADLI, owner-reported PVAS and behavioural assessments collected by the activity monitors were evaluated and compared with baseline. Analysis was linear mixed-models with diet, time, and diet x time as fixed-effects in SAS and was appropriately powered to detect significant differences between groups ($P<0.05$) with 80% power if any differences were to have existed. There were no significant differences between groups for all relevant measures.

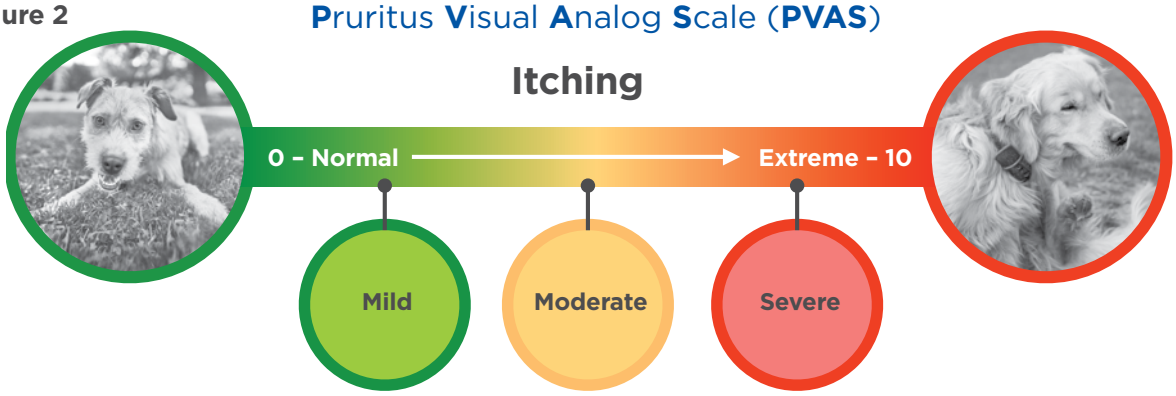
Figure 1

Veterinary Evaluations:
The Canine Atopic Dermatitis Lesion Index (CADLI)

Body Region	Erythema Excoriation Erosion 0-5	Alopecia Lichenification Hyperpigmentation 0-5
Head & Pinnae		
Forefeet		
Hind Feet		
Ventral Thorax & Axillae		
Ventral Abdomen & Inguinal		
Sub-totals 0-25		
Totals 0-50		

Figure 2

Pruritus Visual Analog Scale (PVAS)



Key Conclusions

Prescription Diet Derm Complete is as effective as a dietetic hydrolysed protein food in maintaining control of clinical signs of adverse food reaction in a 42-day study in food-allergic dogs as assessed by veterinarians, owners and use of objective wearable data.

Olivry, T, Bensignor, E, Favrot, C. *et al*. Development of a core outcome set for therapeutic clinical trials enrolling dogs with atopic dermatitis (COSCAD'18). *BMC Vet Res.* 2018(14):238.

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