

A small-scale open-label study of the treatment of canine flea allergy dermatitis with fluralaner

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Background – Fluralaner is an isoxazoline systemic insecticide and acaricide that provides persistent flea-killing activity on dogs for 12 weeks. European and US field studies have shown that fluralaner treatment alleviates the signs of flea allergy dermatitis (FAD) in client-owned dogs.

Hypothesis/Objective – To assess the clinical response in FAD affected dogs over the 12-week period following a single oral fluralaner treatment.

Animals – Twenty client-owned dogs were diagnosed with FAD on the basis of compatible clinical signs and a positive response in flea antigen tests, using intradermal and/or serological methods.

Methods – An open-label small-scale study with all dogs receiving a single oral fluralaner treatment. All enrolled dogs were diagnosed with FAD and then clinically monitored at 4-week intervals for 12 weeks. Twenty dogs completed the study.

Results – All dogs were flea-free at all post-treatment assessments except for one dog that had a single flea at the first post-enrollment assessment at 4 weeks. At the 4-week post-treatment assessment active FAD signs had resolved in all dogs; at 8 weeks post-treatment, two dogs showed mild signs. All clinical signs of FAD had resolved at the final assessment of 12 weeks after treatment.

Conclusions and clinical importance – A single administration of fluralaner alleviated or resolved signs associated with FAD in all treated dogs over the recommended 12-week treatment period.

Introduction

Flea allergy dermatitis (FAD) is a common skin disease of dogs in which affected individuals experience a hypersensitivity response induced by salivary antigens that are injected intradermally during flea feeding. Affected dogs develop skin lesions that tend to be more prevalent over the back and dorsal lumbosacral area, and are associated with moderate to intense pruritus. The isoxazoline compound fluralaner is widely commercially available for the treatment of flea infestations of dogs. Fluralaner acts by antagonising the arthropod ligand-gated chloride channels and is available as a 13.64% w/w flavoured chewable tablet (Bravecto®, MSD Animal Health; Madison, NJ, USA). Fluralaner is administered to fed dogs, achieving peak blood levels within 1 day. The apparent half-life of 12–15 days and mean residence time of 15–20 days are associated with a high level of flea-killing activity maintained for 12 weeks after treatment.^{1,2}

Field studies in several European countries and the United States have reported on the effectiveness of

fluralaner treatment in client-owned dogs to provide flea control for three consecutive months.^{3,4} In both studies it was noted that fluralaner-treated dogs showed substantial improvements in clinical signs of flea allergy dermatitis (FAD), although this was not a primary outcome measure of either study.^{3,4}

The demonstration of improvement in clinical signs of FAD can be difficult to quantify because of the confounding effects of other dermatoses.⁵ The aim of this study was to assess the response to fluralaner treatment of client-owned dogs with clinical signs of FAD.

Materials and methods

The protocol and study procedures complied with Australian Animal Welfare guidelines and was conducted with the approval of the Queensland Department of Primary Industries and Fisheries: Community Access Animal Ethics Committee.⁶

Inclusion/exclusion criteria

The enrollment procedure was initiated during the weeks prior to the active flea season and consisted of a preliminary screening telephone call, a screening home visit by the study investigator (SI) and a visit to a local veterinary referral clinic. The home visit verified that all dogs in enrolling households were at least 8 weeks of age and that at least one dog, which had a temperament that would allow for completion of study procedures, was showing clinical signs consistent with FAD.⁷ Animals showing aggression towards the investigators were excluded from the study. To avoid introduction of potentially confounding factors, enrolled dogs had to be in good health with no

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obvious disease processes that would preclude assessments and be neither lactating nor pregnant. Households were excluded if any dogs spent significant periods away from the residence, if other animals visited the residence, or if a cat shared living quarters with any of the canine residents. Exclusion criteria resulted in no households with cats being enrolled.

Dogs were included in the study if previous flea treatments had not been used within a period prior to enrollment of twice the claimed duration of effectiveness or re-treatment interval. Alternatively, a dog with signs of FAD could be included if previous flea treatments had been used according to a consistent, label-compliant treatment regimen for a minimum of the previous 3 months, thus demonstrating that the flea population was not being controlled.

In order to complete the provisional enrollment, owners of qualifying dogs signed a detailed Owner Consent and Agreement Form. This form indicated that all dogs resident within the household would receive the study treatment and that neither household dogs nor their bedding and living areas would be treated with any insecticides during the study.

At this and subsequent visits by the SI, flea counts were performed using a modification of the Dryden thumb count method.⁸ For study assessments the operator counted fleas for exactly 1 minute at each of six specified areas of the dog's body. If no fleas were found the operator spent two more minutes examining other areas on the dog. It was assumed that where very low-level infestations were present, they would be difficult to detect and could still be the cause of FAD signs in sensitive dogs. Therefore, dogs were not required to have a positive flea count at enrollment.⁹ Dogs meeting all inclusion criteria were then clinically evaluated to establish a diagnosis of FAD.

Clinical assessment

The FAD diagnosis was initially established on the basis of the clinical presentation. When examining the dog the veterinarian followed a published description of the regional distribution and lesion appearance of FAD.⁷ The severity of the signs of FAD was graded on the following unvalidated scale: very mild – mild – moderate – severe – very severe. The veterinarian also had to determine that any non-FAD related skin disease was minor in severity and unlikely to affect either the resolution or interpretation of the signs of FAD.⁵

Intradermal injection of a commercial flea antigen (Greer Laboratories, Greer Veterinary; Lenoir, NC, USA) was performed for each study subject. An immediate hypersensitivity reaction was defined as wheal formation at the flea antigen injection site within 5–10 minutes following injection. Dogs without immediate reactivity were monitored for up to 24 hours for delayed hypersensitivity reactions. Responses to the flea antigen were compared to a negative control (saline; standard wheal grade 0), a positive control (histamine; standard wheal grade 4+) and an irritant control (maize; standard wheal grade 2+). A wheal which developed at the flea antigen injection site and was graded between 2+ and 4+ was classified as consistent with FAD.

Dogs that were negative for both immediate and delayed skin test site reactions had serum samples submitted to a commercial laboratory (Allercept®, Heska, Gribbles Veterinary Pathology Laboratory; Clayton, VIC, Australia) for flea antigen-specific IgE antibody testing. A positive result for one, or more, of these three tests (immediate or delayed IDT, or serology) was required for enrollment. Dogs were provisionally enrolled and treated with fluralaner pending receipt of test results. One provisionally enrolled dog was withdrawn when the serology result was negative.

At the clinic visit, owners were asked to mark a validated pruritus visual analog scale (PVAS)¹⁰ using a score from 0 to 100. The extent of the skin disease was recorded for each dog using the canine atopic dermatitis extent and severity (CADESI-03) index; the index is not validated for the assessment of dogs with signs of FAD.¹¹ Tape impression smears and skin scraping samples were assessed for evidence of secondary infection and ectoparasitic mites, respectively. Plucked hairs were submitted for dermatophyte culture.

Treatment

As soon as possible after provisional enrollment, the SI visited the household to administer oral fluralaner at a minimum dose of 25 mg/kg. Immediately after treatment dogs were offered a meal, observed for 5 min post-dosing and confined for 1 h for further owner observation. Treatment for each dog was administered once, on Day 0, and all dogs were assessed over the following 12 weeks (range 82–90 d). All household animals were to be maintained as usual, with respect to diet, housing and other management. Cohabiting dogs were not enrolled but were treated with the fluralaner formulation to avoid a potential flea population reservoir. Participants received no concomitant treatment with any other flea-control products or with any drug having antipruritic or anti-inflammatory activity, including glucocorticoids, antihistamines and nonsteroidal anti-inflammatory agents, throughout the 12-week study; bathing was permitted. Owners maintained a daily observation log noting any changes in the health or behaviour of the dog (positive or negative). They also recorded other information including any concomitant treatments administered, any deviations from routine management, bathing or swimming, and any animal incursions or excursions.

Assessments and follow-up visits

For clinical assessment and CADESI scoring, follow-up visits to the clinic were scheduled for weeks 4, 8 and 12. Clinical FAD presentation was categorized as being either active or inactive based on the presence of signs including erythema and acute excoriations for active FAD. Secondary effects of self-trauma including alopecia, chronic excoriations, lichenification and salivary staining may take longer to resolve; these were classified as inactive FAD lesions. Other observed skin lesions that were inconsistent with a description of FAD⁷ were classified as non-FAD dermatitis. Owners recorded their evaluation of the dog's pruritus using the PVAS each month during the follow up visits. All monthly SI visits to the households were performed at similar intervals as the clinic visits and were for flea thumb counts, verification of protocol compliance and owner responses to questions about their perceptions of efficacy, health issues and adverse events.

Statistical analysis

The CADESI data were log-transformed for analysis. A value of one was added to all observations to make log-transformation applicable. The log-transformed data were analysed by a mixed linear model with repeated measures including fixed effect Week and repeated subject Animal. Kenward–Roger correction was used to determine the denominator degrees of freedom. Akaike information criterion (AIC) was used as the criterion to select the covariance structure for repeated measures. Least-squares means were used for treatment comparisons and were back-transformed to obtain the estimates for the geometric mean at each week. The flea count data were analysed using the same model, whereas the PVAS data were analysed using the same model without log-transformation. Statistical significance was declared when $P \leq 0.05$. Two-tailed tests were used for the comparison among time points. The primary software was SAS® Language: Reference, v9.3, (SAS Institute Inc., Cary, NC, USA).

Results

This study was conducted in south-east Queensland, Australia, during the summer to early autumn season. This is a region and time period known to be highly favourable to flea infestation on pets.

Twenty two dogs from 18 households were provisionally enrolled at the initial SI visit. The enrolled dogs were of mixed breeds or purebreds ranging

between 3 and 18 years of age and weighing from 3.40 to 40.65 kg. There were 15 males (seven castrated) and five females (two spayed) enrolled in the study. Twelve households contained a single dog whereas four households had two dogs enrolled. One dog was eliminated at the initial clinic visit because other clinical signs observed on the dog were not considered to be typical of FAD and were sufficiently serious to potentially confound FAD interpretation. The results of the cytology, fungal and skin scraping tests were either negative or deemed unlikely to invalidate enrollments. Therefore, 21 provisionally enrolled FAD dogs were successfully treated with fluralaner (between 1 February and 1 March 2013). All dogs ate their meal within an hour of dosing and none of the animals vomited within 24 h post treatment. No dog exhibited any treatment-related adverse event. One dog was removed because of three negative FAD immunological tests (as noted above) and the remaining 20 dogs from 16 households completed the study and were included in the analysis.

All dogs with skin lesions consistent with active FAD, observed at the clinic enrollment visit, were found to be free of active FAD lesions at Week 4 (Table 1). At the Week 8 visit two dogs showed skin lesions consistent with active FAD; these were graded as mild or very mild; by Week 12 these had resolved and no dog showed signs of active FAD at Week 12 (100% resolution).

The CADESI, PVAS and flea count scores declined steadily over the 12-week treatment period with the most rapid decrease observed in the initial 4 weeks after treatment (Figure 1).

The geometric mean of the CADESI scores on Day 0 was 68.4 and this decreased to 21.4 at Week 4, 8.4 at Week 8 and 2.2 at Week 12. In the pairwise comparisons, the CADESI scores were highly significantly different between any two time points (P -values <0.0001 for all pairs of time points).

The PVAS mean score was 71.4 on Day 0, this decreased to 20.9 at Week 4, 9.9 at Week 8 and 4.0 at Week 12. In the pairwise comparisons, the PVAS scores were highly significant between any two time points (P -value ≤ 0.0270).

The geometric flea count mean was 5.7 on Day 0; this decreased to 0.0 at Week 4 and remained at 0.0 at weeks

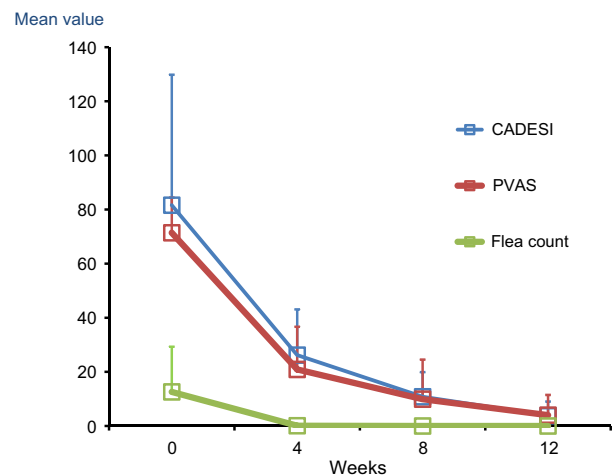


Figure 1. Mean and standard deviation for flea counts (green line), Canine Atopic Dermatitis Extent and Severity Index (CADESI) scores (blue line) and owner-assessed Pruritus Visual Analog Scale (PVAS) scores (red line) for 20 flea allergy dermatitis (FAD)-affected dogs before treatment and during the 12 weeks following administration of oral fluralaner. Y-axis units are: CADESI – mean numerical value; PVAS – mean percentage, owner assessed PVAS score; Flea count – mean total count.

8 and 12. In the pairwise comparisons, the flea count at Week 0 was significantly higher to the flea counts at weeks 4, 8 and 12 (P -value <0.0001).

The complete absence at Week 12 of any FAD-related signs, either active or inactive, indicated that there was 100% resolution of FAD lesions in all dogs.

Discussion

A single fluralaner treatment eliminated flea burdens on treated dogs, reduced skin lesions as measured with CADESI scoring and reduced owner assessments of pruritus; there were no treatment-related adverse effects. All FAD-associated lesions in all of the dogs resolved over the 12-week post-treatment period. Therefore, fluralaner was successfully used as a treatment for FAD-associated skin lesions in dogs.

The study protocol was aligned with a previous study on the impact of indoxacarb treatment on FAD in dogs.⁵ In both studies the combination of examination by a referral clinician, negative results on test for other infectious causes and positive intradermal flea-antigen and serology testing, was used to establish that enrolled dogs were suffering from FAD. Follow-up assessments with clinical examination, flea counts, owner-assessed PVAS scoring and evaluation using a CADESI scoring system, allowed comparison of changes in the clinical status with comparison to baseline values. It is important to acknowledge that the CADESI-03 scoring system is only validated for canine atopic dermatitis and not for dogs with FAD. In this study CADESI-03 scores provided a measure of the severity of clinical signs; this index cannot be used to classify the clinical signs as being definitively caused by flea bite allergy.⁵ The authors are not aware of a validated clinical assessment tool for scoring the signs of FAD in dogs.

Table 1. Clinical assessment of skin lesions

Number of dogs (% of total)	Day 0	Week 4	Week 8	Week 12
Presence of active* FAD lesions	20 (100%)	0	2 (10%)	0
Presence of only inactive* FAD lesions	0	17 (85%)	1 (5%)	0
Non-FAD lesions	4 (20%)	5 (25%)	9 (45%)	3 (15%)
No lesions	0	1 (5%)	11 (55%)	17 (85%)

*Active lesions were erythema and acute excoriation; inactive lesions of FAD were alopecia, chronic excoriations, lichenification and salivary staining.

A major weakness of this small study is that there was no comparator flea control agent used as a control group, and therefore the assessment of response to treatment was not blinded to the owner or the veterinarians assessing the cases.

Resolution of FAD clinical signs subsequent to fluralaner treatment was seen in field studies in client-owned dogs in Europe and the United States.^{3,4} The degree of recovery from FAD in the field studies was less than the 100% seen in this study. The diagnosis of FAD in the field study protocols was based on the observation of characteristic FAD lesions by first-opinion veterinarians; it did not include examination by a clinician working in a referral setting and did not include intradermal and serological tests that can be used to support a diagnosis of FAD, as required in this study. The diagnostic criteria used in this study may explain the greater resolution of clinical signs seen, because causes other than flea allergy may have contributed to the dermatological lesions observed in field trial dogs.

Animals in this study were enrolled even if they were showing mild signs of other skin conditions so long as these signs were not severe and did not interfere with the FAD assessments. As the signs of FAD in the study animals improved after fluralaner treatment, some mild non-FAD conditions that had been concealed by the severity of the FAD signs at the start of the study became apparent. At Week 12, three dogs showed non-FAD skin conditions; one had mild atopic dermatitis, the second had bacterial pyoderma (confirmed by cytology and not associated with the clinical signs of FAD), and the third had a patch of alopecia on its nose caused by trauma. In all three cases the skin condition was considered to be clearly not associated with FAD.

The occurrence of clinical signs of FAD in two dogs at the Week 8 re-examination (Table 1) may have been associated with a low level of exposure to adult fleas emerging from pupae in the home environment. Fluralaner treatment eliminates all flea life stages in the home environment over the 12-week treatment period;² however, there may be continued emergence of adults in a heavily infested home during the earlier portion of this interval. Dogs can also become re-infested with fleas during their usual routine exercise such as walking in a park frequented by other animals.

The apparent improvement in assessment parameters during a 12-week open trial of a single dose of fluralaner

may offer a high level of flea control and help in the management of dogs with signs of FAD.¹²

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Résumé

Contexte – Le fluralaner est un insecticide et acaricide systémique de la famille de l'isoxazoline qui fournit aux chiens une activité antipuce persistante pendant 12 semaines. Les études de terrain en Europe et aux US ont montré que le traitement au fluralaner soulage les signes de dermatites par allergie aux piqûres de puces (FAD) chez des chiens de propriétaires.

Hypothèses/Objectifs – Déterminer la réponse clinique des chiens atteints de FAD sur une période de 12 semaines à la suite d'une prise orale unique de fluralaner.

Sujets – Vingt chiens de propriétaires ont été diagnostiqués avec une FAD sur la base de signes cliniques compatibles et une réponse positive aux tests antigéniques contre les puces, à l'aide de tests intradermiques ou sérologiques.

Méthodes – Une étude ouverte à petite échelle, sur tous les chiens recevant un traitement unique de flu-

ralaner par voie orale. Tous les chiens enrôlés étaient diagnostiqués FAD et suivis cliniquement toutes les 4 semaines pendant 12 semaines. Vingt chiens ont terminé l'étude.

Résultats – Tous les chiens étaient indemnes de puce à tous les moments post-traitement sauf un chien ayant une seule puce au contrôle post-traitement à 4 semaines. Au contrôle, 4 semaines post-traitement, les signes actifs de FAD étaient résolus pour tous les chiens; huit semaines après le traitement, deux chiens présentaient des signes modérés. Tous les signes cliniques de FAD se sont résolus au contrôle final, 12 semaines post-traitement.

Conclusion et importance clinique – Une seule administration de fluralaner améliore ou résout les signes associés à la FAD pour tous les chiens traités sur la période recommandée de 12 semaines.

Resumen

Introducción – Fluralaner es un insecticida y acaricida sistémico de tipo isoxazolina que aporta actividad persistente frente a las pulgas en perros durante 12 semanas. Estudios europeos y americanos de campo han demostrado que Fluralaner alivia los signos de la dermatitis alérgica por pulgas (FAD) en perros de propietarios privados.

Hipótesis/Objetivos – evaluar la respuesta clínica en perros con dermatitis alérgica por pulgas durante las doce semanas posteriores a un tratamiento único oral con Fluralaner.

Animales – 20 perros de propietarios privados se diagnosticaron con dermatitis alérgica por pulgas en base a signos clínicos compatibles y respuesta positiva a las pruebas de antígenos de pulgas utilizando métodos intradermales y/o serológicos.

Métodos – un estudio a pequeña escala abierto con todos los perros recibiendo una sola dosis oral de Fluralaner. Todos los perros incluidos en el estudio se diagnosticaron con dermatitis alérgica por pulgas y se controlaron clínicamente a intervalos de cuatro semanas durante 12 semanas. 20 perros completaron el estudio.

Resultados – todos los perros estaban libres de pulgas en todos los puntos posttratamiento evaluados salvo un perro que tenía una sola pulga en la primera evaluación a las cuatro semanas. A las cuatro semanas tras el primer tratamiento todos los perros con dermatitis alérgica por pulgas presentaron resolución de las lesiones; a las 8 semanas posttratamiento dos perros mostraron ligeros signos clínicos. Todos los signos clínicos de dermatitis alérgica por pulgas se habían resuelto al final del período de evaluación a las 12 semanas tras el tratamiento.

Conclusiones e importancia clínica – una sola administración de Fluralaner alivia o resuelve los signos clínicos de dermatitis alérgica por pulgas en todos los perros tratados en el periodo recomendado de 12 semanas.

Zusammenfassung

Hintergrund – Fluralaner ist ein Isoxazolin, ein systemisches Insektizid und Akarizid, welches eine langwirksame Flohtötungsaktivität bei Hunden für die Dauer von 12 Wochen bietet. Europäische und US Feldstudien haben gezeigt, dass eine Behandlung mit Fluralaner die Symptome einer Floh-allergischen Dermatitis (FAD) bei Privathunden lindert.

Hypothese/Ziele – Eine Beurteilung der klinischen Reaktion bei an FAD erkrankten Hunden über eine 12-wöchige Periode nach einer einzigen Behandlung mit Fluralaner *per os*.

Tiere – Zwanzig Hunde in Privatbesitz wurden basierend auf vergleichbaren klinischen Anzeichen und einer positiven Reaktion beim Flohallergentest, mittels intradermalen oder serologischen Methoden mit FAD diagnostiziert.

Methoden – Eine offene Studie in kleinem Format bei der alle Hunde eine einzige Fluralanerbehandlung *per os* erhielten. Alle teilnehmenden Hunde wurden mit FAD diagnostiziert und dann klinisch über ein Intervall von 4 Wochen 12 Wochen lang beobachtet. Zwanzig Hunde beendeten die Studie.

Ergebnisse – Alle Hunde waren bei allen Beurteilungen nach der Behandlung Floh-frei außer einem Hund, der bei der ersten Untersuchung nach 4 Wochen einen einzigen Floh hatte. Bei der Untersuchung 4 Wochen nach der Behandlung waren bei allen Hunden die aktiven FAD Symptome abgeklungen; bei der Untersuchung 8 Wochen nach der Behandlung zeigten 2 Hunde geringgradige Anzeichen. Alle klinischen Anzeichen von FAD waren bei der letzten Untersuchung 12 Wochen nach der Behandlung verschwunden.

Schlussfolgerungen und klinische Bedeutung – Eine einzige Behandlung mit Fluralaner erleichterte oder heilte die Anzeichen, die mit FAD einhergehen, bei allen behandelten Hunden über die empfohlene 12 wöchige Behandlungsperiode.

要約

背景 – フルラネルはイヌにおいて12週間のバ殺虫効果の持続をもたらすイソキサゾリン全身性殺虫剤およびダニ駆除剤である。ヨーロッパおよびUSの実地検査ではフルラネル治療が飼育犬のバアレルギー性皮膚炎(FAD)の症状を緩和することを示していた。

仮説/目的 – FAD罹患犬において単回の経口フルラネル治療後、12週間の期間にわたり臨床反応を評価すること。

供与動物 — 矛盾のない臨床症状および皮内反応試験あるいは血清学的方法を用いたノミ抗原試験において陽性反応であることを基にFADと診断された20頭の飼い犬。

方法 — すべてのイヌに経口フルラネルの単回投与を行う非盲検小規模試験。組み入れたすべてのイヌはFADと診断され、4週間隔で12週間、病院で観察を行った。20頭のイヌが試験を終了した。

結果 — すべてのイヌは組み入れ後、4週目の時点で1匹のノミがみられた1頭のイヌを除き、すべての治療後評価時にノミがいなかった。4週目の治療後評価にて、アクティブなFAD症状はすべてのイヌで消失しており、8週目の治療後評価にて、2頭が軽い症状を示した。FADのすべての臨床症状は治療後12週での最終評価で消失していた。

結論および臨床的な重要性 — フルラネルの単回投与は治療したすべてのイヌにおいて、奨励されている治療期間の12週間の間、FADと関連する症状を軽減あるいは消失した。

摘要

背景 — Fluralaner是一种全身性杀虫剂和杀螨剂,其成分为异恶唑啉,用于犬能够持续灭蚤12周。研究显示,对欧美地区的家养犬,fluralaner治疗能够减轻跳蚤叮咬过敏性皮炎(FAD)的症状。

假设/目的 — 给予FAD患犬单次口服fluralaner,观察超过12周,评估其对FAD患犬的临床效果。

动物 — 20只来自于动物主人的犬,基于临床症状,及皮内和或血清学检测跳蚤抗原阳性,诊断为FAD。

方法 — 采取非盲小规模实验,所有犬均单次口服fluralaner。所有犬均为FAD,随后在12周内,每隔4周进行临床监测。20只犬均完成了这项实验。

结果 — 除了一只犬在服药后4周的第一次评估中发现跳蚤外,其他所有犬在治疗后评估中均无跳蚤感染。在第4周的评估中,所有犬明显的FAD症状均消失;在八周后的评估中,2只犬表现出轻度症状。在治疗后12周的最后一次评估中,所有犬均没有FAD的临床症状。

总结和临床意义 — 所有治疗犬单次fluralaner给药后,在建议的12周治疗周期内,其相关FAD症状均有所减轻或消除。