Research Square

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Impact of lokivetmab for Canine Atopic Dermatitis on Owner and Canine Health-Related Quality of Life and Owner Treatment Satisfaction

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Abstract

Background

Lokivetmab is a caninised monoclonal antibody that neutralises circulating interleukin-31 (IL-31), a cytokine implicated in the pathogenesis of canine atopic dermatitis (AD). The objectives are to evaluate changes in quality of life (QOL) for atopic dogs and their owners, owner treatment satisfaction (TS), and pruritus (PVAS) over 91 days following initiation of lokivetmab into multi-modal managed cases. A prospective, open-label, multi-centre, practice-based outcomes study in 10 U.S. general veterinary practices. Lokivetmab was administered per label on Days 0, 28, 63 and 91; visits targeted ± 2–3-day windows. Seventy-five dogs with AD and their owners were enrolled; 68 dogs contributed evaluable data. At each visit, veterinarians assessed dermatitis severity; owners completed the Pruritus Visual Analog Scale (PVAS) and the Canine Dermatitis Quality of Life and Treatment Satisfaction Questionnaire (CDQOL-TSQ). Primary endpoints were Dog QOL, Owner QOL, TS and PVAS. A linear mixed model for repeated measures estimated least-squares means (LSMeans) over time with veterinarian as a random effect; covariance structure was selected by the Akaike Information Criterion (AIC). The protocol specified a minimum of 2 mg/kg per label at each dosing visit. Concomitant medications were recorded on day 0 and 91. Previously published minimally important change (MIC) thresholds were ≥ 12.5 for Dog QOL and ≥ 18.8 for Owner QOL.

Results

Dog QOL, Owner QOL and TS improved significantly from baseline at all timepoints (overall time effect $P < 0.0001$ by mixed model); for each outcome, every post-baseline timepoint differed from Day 0 ($P \leq 0.001$) in pairwise LSMeans comparisons. PVAS decreased at every timepoint; mean PVAS ≤ 20 ("normal itch") was reached by Day 63. Owner QOL gains were maximal by Day 42, with numerically highest mean scores observed at Day 91; Dog QOL and Treatment Satisfaction were numerically highest at Day 91, whereas PVAS and veterinarian-assessed dermatitis severity were lowest at Day 91. PVAS declined 57% from Day 0 (78.16) to Day 7 (33.39, $P \leq 0.001$), indicating an early treatment-associated improvement prior to subsequent doses. The veterinarian-assessed dermatitis severity score (0 = normal to 6 = extremely severe) decreased from 5.02 at Day 0 to 2.24 at Day 91 (~ 55% decrease). MIC responder proportions for Dog and Owner QOL increased over time. By Day 28, 34/71 (47.9%) exceeded the Dog QOL MIC; by Day 42, 46/55 (83.6%) exceeded the Owner QOL MIC; PVAS ≤ 20 was achieved by 47/67 (70.1%) at Day 63 and 52/65 (80.0%) at Day 91. Moderate positive Owner–Dog QOL correlations and inverse Owner QOL–PVAS correlations were statistically significant across timepoints ($P \leq 0.01$).

Conclusions

In routine practice, initiating lokivetmab within multimodal management was associated with rapid reductions in pruritus and clinically meaningful improvements in canine and owner QOL and owner TS.

Background

Canine atopic dermatitis (AD) is a common, chronic, pruritic, inflammatory skin disease with complex genetic and environmental underpinnings [1]. Pruritus in AD is driven by multiple mediators, notably interleukin-31 (IL-31), a type-2 cytokine that activates neuronal pathways mediating itch and contributes to skin inflammation [2]. Lokivetmab (Cytopoint®, Zoetis Inc., Parsippany, NJ, USA) is a caninised monoclonal antibody that neutralises circulating IL-31 and has demonstrated clinical benefit for allergic and atopic dermatitis in client-owned dogs across trial and practice settings [3–6].

Across randomised and practice-based studies, adverse-event (AE) rates with lokivetmab are generally low and comparable to placebo or favourable versus ciclosporin for common gastrointestinal signs. In a double-blind, placebo-controlled field study (N = 245), no immediate hypersensitivity was observed; injection-site discomfort occurred in ~ 5% of dogs and treatment-induced immunogenicity in ~ 2.5%, with frequently reported AEs (e.g., otitis externa, dermatitis, bacterial skin infection, vomiting/diarrhoea) occurring at rates similar to placebo [7]. In a 3-month randomised head-to-head trial versus ciclosporin followed by a 6-month lokivetmab continuation phase, gastrointestinal AEs were lower with lokivetmab during the comparative phase (overall digestive disorders ~ 26% vs ~ 55%; vomiting 15.5% vs 37.1%; diarrhoea 13.4% vs 35.6%), and no immediate hypersensitivity was reported; GI AE frequencies declined further during continuation [8]. Retrospective cohorts report ~ 8% of dogs with any AE, typically mild and self-limited [9, 10]. Post-marketing information and EU/UK product characteristics list hypersensitivity reactions (including anaphylaxis, facial oedema, urticaria) as **rare**, with very uncommon neurological signs reported in spontaneous reports; clinicians should treat promptly if suspected [11].

Owner- and patient-centered outcomes are increasingly emphasized in veterinary dermatology, where owner observations complement clinical examination to index day-to-day symptom impact. Validated owner instruments—including the Pruritus Visual Analog Scale (PVAS) with interpretable thresholds (e.g., ≤ 20 denoting “normal itch”)—permit consistent measurement of pruritus severity over time. Likewise, the Canine Dermatitis Quality of Life and Treatment Satisfaction Questionnaire (CDQOL-TSQ) quantify dog and owner quality of life (QOL) and owner treatment satisfaction, with minimally important change (MIC) thresholds established in validation work (Dog QOL ≥ 12.5; Owner QOL ≥ 18.8). In this prospective, practice-based study, we evaluated trajectories of owner-reported pruritus (PVAS), Dog QOL, Owner QOL and owner Treatment Satisfaction (TS) across 91 days following initiation of lokivetmab administered per label. We hypothesized that lokivetmab initiation would be associated with reductions in PVAS and clinically meaningful improvements in QOL domains exceeding MIC thresholds; secondary objectives examined correlations between Owner and Dog QOL and between Owner QOL and PVAS.

Materials and methods

This study was designed to evaluate owner- and dog-centered quality of life with lokivetmab as an anchor therapy under routine general-practice conditions; because AD care is inherently multimodal, quality-of-life outcomes cannot be evaluated in isolation from clinician-directed co-interventions.

Eligibility, Ethics, informed consent and sites. Prospective, longitudinal, practice-based outcomes study conducted from August 2017 to February 2018 in 10 U.S. general practices. Dogs had PVAS ≥36/100 at Day 0 and met ≥5/8 Favrot criteria; stable concurrent treatments were allowed; exclusions per protocol. Owners provided written informed consent.

The practice-based observational protocol, owner consent forms, and data-handling plan were reviewed and approved by the Zoetis Ethical Review Board study number (17SORDER-01-01). The study was conducted in accordance with applicable animal-welfare regulations and institutional policies. All owners provided digital informed consent, and clinic participation agreements were executed before study initiation. No procedures beyond standard-of-care diagnosis and treatment were mandated by the protocol.

Lokivetmab was administered subcutaneously per authorized label (≥2 mg/kg) on Days 0, 28, 63 and 91 at the attending veterinarian's discretion. Exact per-visit mg/kg doses were recorded locally at clinics but were not centrally aggregated; therefore, a cohort mean mg/kg by timepoint cannot be reported. No response-based dose escalation was planned or implemented. Primary outcomes were owner- and dog-centered quality-of-life measures (Dog QOL, Owner QOL), owner Treatment Satisfaction (TS), and PVAS; the study was not designed to estimate dose–response.

Other primary AD treatments (oclacitinib, corticosteroids, ciclosporin, antihistamines) were intended to be discontinued ≥2 weeks depending on the drug before the first lokivetmab injection; subsequent case management remained at clinician discretion under standard of care. Systemic antipruritic could be used short-term as rescue for flares at the veterinarian's discretion starting at day 0. Lokivetmab was administered subcutaneously at ≥2 mg/kg per label on Days 0, 28, 63 and 91. Exact per-visit mg/kg doses were recorded locally but were not centrally aggregated; a cohort mean mg/kg by timepoint cannot be reported.

Dogs were evaluated on Days 0, 28, 63 and 91; owners completed PVAS and the CDQOL-TSQ on Days 0, 7, 28, 42, 63 and 91. Veterinarians scored dermatitis severity on a 7-point visual scale (0 = normal to 6 = extremely severe).

Concomitant therapies were recorded at each scheduled visit (Days 0, 28, 63, and 91) but not centrally captured. For the prespecified reduction summary, we compared cohort-level counts of distinct therapy classes/agents at baseline (Day 0) versus the last study visit (Day 91). These counts are population-level (presence/absence across the cohort) and do not reflect per-dog totals, dose, or duration. Because inter-visit dose and duration were not centrally captured, medication-intensity scores were not computed. Short-term systemic rescue for flares was permitted at clinician discretion under standard of care.

The primary outcomes assessed were Dog Quality of Life (QOL), Owner QOL, systemic Treatment Satisfaction (TS), and the Pruritus Visual Analog Scale (PVAS). To determine minimally important change (MIC), thresholds were set as follows: Dog QOL ≥12.5 and Owner QOL ≥18.8, based on CDQOL-TSQ validation.

For statistical analysis, a mixed model for repeated measures was employed, with time treated as a fixed effect and veterinarian as a random effect. Pairwise LSMeans comparisons versus Day 0 were performed at a significance level of $\alpha=0.05$. In addition, Pearson correlations were calculated with two-sided P-values to assess relationships between variables. Descriptive statistics included MIC responder proportions.

Furthermore, correlation analyses were conducted using SAS PROC CORR to compute Pearson product-moment coefficients, accompanied by two-sided P-values. The interpretive thresholds for correlation strength were defined as follows: Perfect (≈±1), Strong (±0.50 to ±1), Moderate (±0.30 to ±0.49), Low (<±0.29), and None (0).

Statistical analysis details. Mixed-model repeated measures were fit with time as a fixed effect and veterinarian as a random effect, repeated time within dog. Degrees of freedom and covariance structure were specified as a priori; missing observations were handled under the mixed-model missing at random (MAR) assumption without imputation (available-case denominators shown in Results). Pairwise LSMeans vs Day 0 were two-sided at $\alpha=0.05$; no multiplicity adjustment was applied. Pearson correlations (Owner QOL vs Dog QOL; Owner QOL vs PVAS) were calculated per timepoint with two-sided P-values.

Results

Of the 75 enrolled dogs, up to 73 contributed baseline assessments, while 68 provided evaluable post-baseline data (comprising 33 females and 35 males, with a mean age of 6.8 years and a mean weight of 22.4 kg). For a detailed breakdown of demographics, please refer to Supplementary Table 1.

Regarding the available-case numbers of dogs with data at each planned study day (Days 0, 7, 28, 42, 63, and 91), the following sample sizes (number of dogs contributing data at each time point) were recorded: Dog QOL—73, 62, 72, 55, 72, 70; Owner QOL—73, 62, 72, 55, 72, 70; Treatment Satisfaction—67, 61, 71, 54, 72, 69; PVAS—72, 71, 71, 67, 67, 65; and Veterinarian-assessed dermatitis severity—68, 68, 66, and 65.

Over the course of the study, primary outcomes were monitored longitudinally. In accordance with the study design, lokivetmab was administered at a dosage of ≥2 mg/kg per label at each dosing visit; exact per-visit mg/kg doses were recorded locally and were not centrally aggregated. Dog QOL, Owner QOL, and Treatment Satisfaction scores all showed significant improvement from baseline at every timepoint (overall time effect, $P < 0.0001$). For each of these outcomes, every post-baseline timepoint differed significantly from Day 0 ($P \leq 0.001$).

Moreover, PVAS scores decreased at every timepoint, with a 57% reduction observed from Day 0 (78.16) to Day 7 (33.39; $P \leq 0.001$), ultimately reaching a cohort mean of ≤20 (“normal itch”) by Day 63 (Figure 1). Similarly, the veterinarian-assessed dermatitis severity score dropped from 5.02 at Day 0 to 2.24 at Day 91, representing an approximate 55% decrease (Table 1).

Timing of Maximal Change

The timing of maximal change varied across outcomes. Dog QOL and Treatment Satisfaction scores were numerically highest on Day 91, indicating sustained improvement throughout the study period. In contrast, Owner QOL exhibited its largest early gain by Day 42, followed by smaller subsequent increases that culminated in a numerical maximum at Day 91. Both PVAS and veterinarian-assessed dermatitis severity reached their lowest mean values at Day 91, reflecting notable reductions in pruritus and skin severity over time.

Correlations

Examining the relationships between outcomes, Owner QOL demonstrated a positive correlation with Dog QOL and an inverse correlation with PVAS across timepoints. For example, on Day 42, the correlation between Owner QOL and Dog QOL was strong ($r \approx 0.71$, $P < 0.0001$), while at Day 91, the correlation remained significant ($r \approx 0.52$, $P < 0.001$). Similarly, Owner QOL and PVAS showed moderate inverse correlations at Day 63 ($r \approx -0.49$, $P < 0.001$) and Day 91 ($r \approx -0.53$, $P < 0.001$). For a detailed summary of correlation coefficients, P-values, and sample sizes at each timepoint, refer to Table 2 and Supplementary Table 3.

Concomitant Therapies

As a secondary, qualitative cohort-level variable, the number of distinct concomitant therapy categories/agents recorded at Day 0 versus Day 91 declined, indicating a simplification of regimens at the population level. Inter-visit dose and duration were not centrally captured, and per-dog medication scores were not computed. Cohort-level counts (Day 0 vs Day 91) are provided in Supplementary Table 2.

Because inter-visit dosing and treatment duration were not centrally recorded, individual medication scores could not be computed. Throughout the study, case management was left to the discretion of the clinician and followed standard of care practices. For further details, please refer to Supplementary Table 2.

Responder Analyses

Responder analyses further illustrate the progression of improvement over time. MIC responder proportions increased steadily; for instance, by Day 28, 34 out of 71 dogs (47.9%) exceeded the Dog QOL MIC threshold, and by Day 42, 46 out of 55 owners (83.6%) exceeded the Owner QOL MIC. Additionally, the proportion of dogs achieving PVAS ≤20 rose from 47 out of 67 (70.1%) at Day 63 to 52 out of 65 (80.0%) at Day 91. Notably, Owner–Dog QOL correlations were moderate to strong after Day 0 ($r \geq 0.40$), and Owner QOL–PVAS correlations remained moderate and inverse at later timepoints (Supplementary Table 3).

Discussion

Canine AD management in general practice is inherently multimodal. In this practice-based outcomes study, initiating lokivetmab as an anchor therapy was associated with rapid reductions in owner-reported pruritus and clinically meaningful improvements in dog and owner quality of life (QOL) and owner treatment satisfaction (TS). Improvements were evident within 7 days, with PVAS ≤ 20 reached by Day 63 for 70.1% (47/67) and by Day 91 for 80.0% (52/65), and MIC responders accumulating over time (Dog QOL Day 28: 47.9% [34/71]; Owner QOL Day 42: 83.6% [46/55]).

Randomized clinical trials have shown that lokivetmab reduces pruritus and is generally well tolerated, with early onset of effect and favorable tolerability compared with ciclosporin [6–8]. Our time-course (large PVAS decrease by Day 7; cohort mean PVAS ≤ 20 by Day 63) is directionally consistent with these reports and with proactive maintenance observations in AD [5]. Safety findings in controlled settings and post-marketing information (rare hypersensitivity; lower rates of common gastrointestinal events than ciclosporin) align with our pragmatic, practice-based observations [7, 8, 11]. Real-world cohorts also report low adverse-event rates over longer-term use, further supporting generalizability to routine practice [9, 10]. Numerically, Dog QOL and Treatment Satisfaction peaked at Day 91; Owner QOL showed its largest early gain by Day 42 with smaller subsequent increases to a numerical maximum at Day 91; PVAS and veterinarian-assessed dermatitis severity reached their lowest means at Day 91.

Correlations between Owner QOL and Dog QOL, and inverse correlations with PVAS, reinforce the conceptual linkage between pruritus control and caregiver well-being. The reduction in the number of distinct concomitant therapies from baseline to Day 91 suggests a simplification of management burden; however, because dose and duration of interim concomitants were not captured, we refrain from attributing outcomes solely to lokivetmab across all individuals. Some dogs presenting at Day 0 were in tapering windows from prior regimens. These cohort-level counts do not quantify dose or duration and were not used to attribute effects to lokivetmab at an individual level.

The PVAS instrument and its interpretive thresholds have been validated for owner-observed pruritus in dogs [12, 13]. Our descriptive responder thresholds for QOL (Dog QOL ≥ 12.5; Owner QOL ≥ 18.8) reflect CDQOL-TSQ validation work and facilitate interpretation of clinically meaningful change from the owner's perspective [14]. The observed moderate positive correlations between Owner and Dog QOL and inverse correlations between Owner QOL and PVAS are concordant with prior literature linking disease severity, pruritus control, and caregiver experience in dermatologic conditions [15, 16].

Chronic pruritus is associated with sleep disruption and caregiver burden; improving symptom control can mitigate these effects and support the human–animal bond [15, 16, 17]. The early pruritus reduction and rapid Owner QOL and TS improvements we observed are consistent with this literature and may promote adherence to ongoing care plans.

These findings have immediate relevance for general practice. Initiating lokivetmab can be associated with rapid, owner-perceived improvements in pruritus and QOL, with high Treatment Satisfaction and a trajectory toward "normal itch." Embedding validated owner-reported measures (PVAS; CDQOL-TSQ) into routine care provides actionable feedback for shared decision-making about response and ongoing

control. In many clinics, lokivetmab is also used adjunctively during allergen-specific immunotherapy (ASIT) induction to maintain patient comfort; duration is individualized, with tapering or discontinuation once durable control is achieved with ASIT or other modalities.

Because systemic antipruritics could be used short-term as rescue and inter-visit dose/duration were not centrally captured, medication-intensity scoring and dose–response analyses were not feasible. Outcomes should therefore be interpreted as practice-based effects of initiating lokivetmab within multimodal care—not as isolated efficacy of a single agent. Nonetheless, the population-level reduction in distinct concomitant therapy classes/agents from baseline to Day 91 (− 60.7%) suggests a simplification of treatment burden at the cohort level. In another long term study with lokivetmab many pet owners also reported that they were able to reduce use of other products.[18] Future studies that prospectively capture medication intensity and dosing would allow per-dog causal attribution A recent study glucocorticoids, ciclosporin and antihistamines was prohibited but lokivetmab with topical treatment with glucocorticoid-free, moisturizing or antimicrobial treatments was permitted. The authors still highlighted the negative impact of canine AD on the QoL of dogs and their owners, and the positive benefit of lokivetmab therapy.[19]

Because systemic antipruritics could be used short-term as rescue and inter-visit dose/duration were not centrally captured, medication-intensity scoring and dose–response analyses were not feasible. Outcomes should therefore be interpreted as practice-based associations after initiating lokivetmab within multimodal care—not as isolated efficacy of a single agent. In this pragmatic design, individual regimens were not standardized and varied by case; under such real-world conditions, a two-timepoint, cohort-level snapshot of concomitant therapy categories (Day 0 vs Day 91) provides context but does not quantify individual exposure.

In routine GP settings, lokivetmab can be deployed as an anchor for symptom control while diagnostic clarification and long-term strategies (e.g., allergen-specific immunotherapy) are pursued. Proactive use to maintain control is consistent with prior reports [5] and with guideline-supported multimodal management of AD [2]. Duration of lokivetmab should be individualized; many dogs and owners perceive substantial benefit by 4–6 weeks, with incremental improvements through 3 months in our cohort.

Limitations

This was an open-label, practice-based study without a control group, with dogs effectively serving as their own controls over time. Although this reflects real-world use, it limits the ability to separate treatment effects from natural disease variation, regression to the mean, or placebo effects. Owner-reported outcomes may also be influenced by expectation or reporting bias in an unblinded setting, and the veterinarian-assessed dermatitis severity scale was not formally validated, which may introduce variability and limit comparability with other studies.

External validity is further constrained by limited breed and geographic diversity. The provision of lokivetmab could have positively biased owner treatment satisfaction ratings. In addition, interim concomitant medication dose and duration were not systematically captured, precluding calculation of medication scores and limiting assessment of changes in overall treatment burden. Finally, administered lokivetmab volumes were not centrally collated, preventing calculation of mean mg/kg doses by timepoint; although dosing followed the product label and a prespecified schedule without response-based escalation, this precludes evaluation of dose–response relationships in this dataset. The authors of the study were employed by the manufacturer of lokivetmab and oclacitinib and some authors were on the validation publication for the CDQOL-TSQ). None of the authors were involved with data collection or the decision to prescribe medications in real world practice-based study.

Conclusion

Under general-practice conditions, lokivetmab initiation was associated with rapid and sustained improvements in pruritus, Dog and Owner QOL, and Owner TS across 91 days. While concomitant therapy burden decreased, incomplete medication-dose data limit formal medication-score analyses. These practice-based findings complement controlled-trial evidence and support routine monitoring of owner- and patient-centered outcomes in AD management. In practice, lokivetmab may be continued as needed.

Declarations

Ethics approval and consent to participate

The practice-based observational protocol, owner consent forms, and data-handling plan were reviewed and approved by the Zoetis Ethical Review Board study number (17SORDER-01-01). The study was conducted in accordance with applicable animal-welfare regulations and institutional policies. All owners provided digital informed consent, and clinic participation agreements were executed before study initiation. No procedures beyond standard-of-care diagnosis and treatment were mandated by the protocol.

Consent for publication

All data presented is anonymized and consent to publish was included in the owner and veterinary consent forms and study agreements.

Availability of data and materials

Prospective, practice-based observational study conducted in 10 U.S. general practices. De-identified, per-dog, per-visit records including study day/visit; owner-reported PVAS; CDQOL-TSQ domain totals (Dog QOL, Owner QOL, systemic Treatment Satisfaction); veterinarian dermatitis severity (0–6);

disposition; and baseline demographics (age, sex, neuter status, breed, weight). These data underpin all results and supplementary analyses.

Interim concomitant medication dose and duration between visits were not collected in a timepoint-resolved manner across sites; administered lokivetmab volumes (mg) at dosing visits were recorded locally at clinics but not centrally aggregated, so cohort-level mg/kg by timepoint cannot be computed; and site-level source documents (e.g., dosing forms/logs) were retained at clinics and are not part of the central analytical dataset. The de-identified analytical dataset and analysis code are available from the corresponding author upon reasonable request, subject to internal ethical review and clinic agreements. Any shared files will exclude personal identifiers and mask site identifiers. Clinic-level source documents (e.g., dosing forms/logs) are not available for central sharing.

Competing Interest: KM, AH, MR, DA, TS and AW were employees of Zoetis Inc., the manufacturer of oclacitinib and lokivetmab at the time of this study, and data was analyzed.

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Authors 'Contributions: Conceptualization: KM, AH, AW. Methodology: KM, AW. Investigation: KM. Data curation: KM, DA. Formal analysis: DA, KM. Visualization: KM. Writing—original draft: KM, TS, MR. Writing—review & editing: TS, AH, KM, AW, MR. Supervision: KM. All authors approved the final manuscript.

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Tables

Table 1 Veterinarian Assessed Dermatitis Severity Score

Study day	Mean ± standard deviation	Improvement over baseline, %
0	5.02 ± 0.99	NA*
28	4.77 ± 1.05	5.0
63	4.31 ± 0.93	9.3
91	2.24 ± 0.99	55.4

*NA = not applicable.

Table 2. Correlations between canine QOL, owner QOL and owner PVAS scores

Study day	**Correlation of owner QOL score compared with:**			
	Dog QOL		**PVAS**	
	r	**Strength**	**r**	**Strength**
0	0.3099	**Moderate**	-0.2538	**Low**
7	0.4376	**Moderate**	-0.4700	**Moderate**
28	0.4625	**Moderate**	-0.4885	**Moderate**
42	0.7090	**Strong**	-0.4688	**Moderate**
63	0.4898	**Moderate**	-0.5807	**Strong**
91	0.6417	**Strong**	-0.5463	**Strong**

Figures

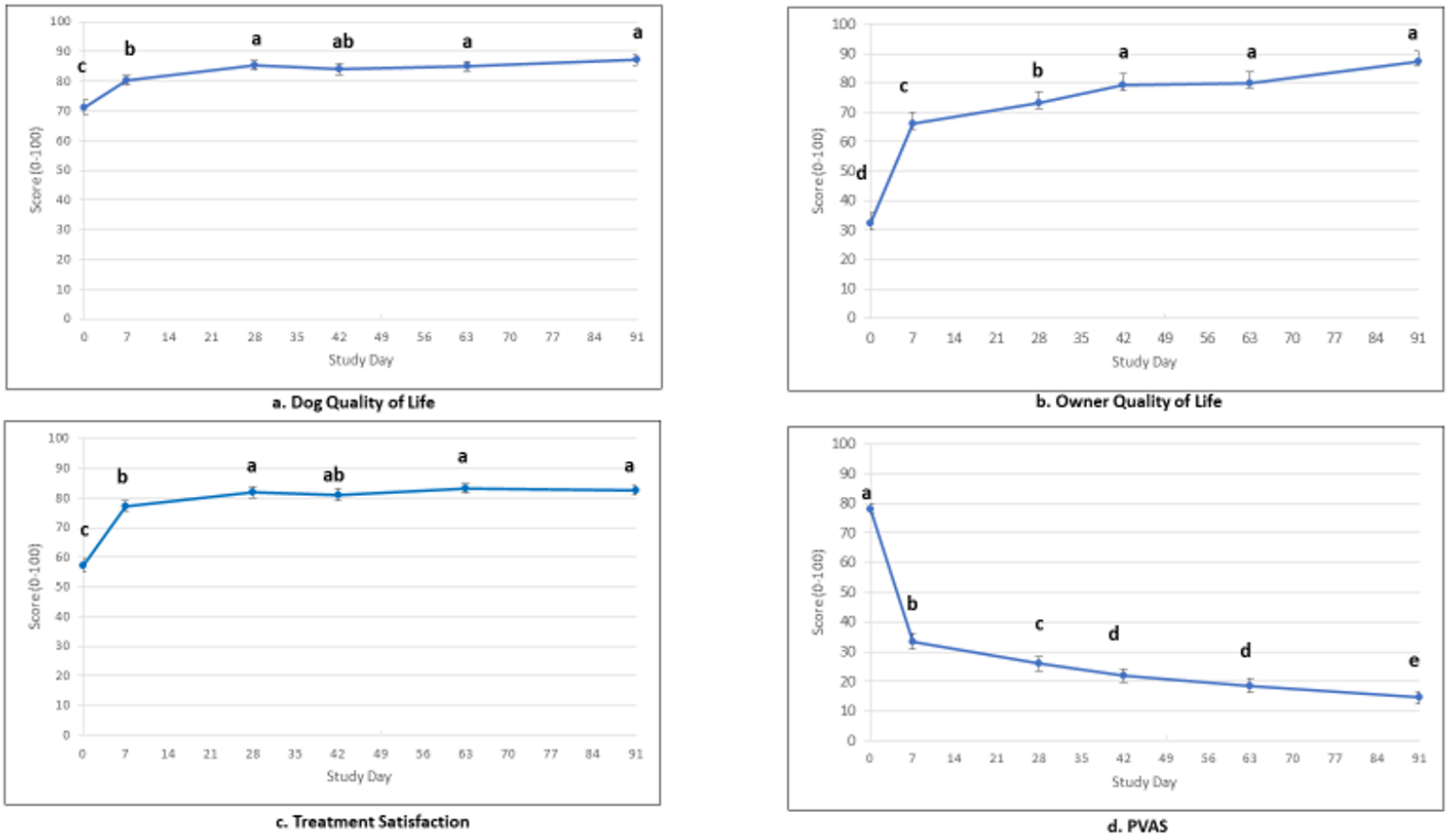


Figure 1

CDQOL-TSQ and Pruritus VAS score results over time: α=0.05; LSMeans are represented by letter grouping (a,b,c,d and e). The same letter at each time point in each graph means those time points are not statistically different. Different letters at each time point denotes a statistical difference.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryTableS1Demographics.docx
- SupplementaryTableS2ConcomitantTherapies.docx
- CDQLTS.pdf