Clindoral® Periodontal Filler – A Summary of the "One More Step" Benefit Study

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As stated in the article "Go one step beyond in veterinary dental care",[i] the standard of care in companion animal dentistry includes a tooth-by-tooth examination with probes and intraoral radiographs and removal of plaque and tartar on the teeth above and below the gum line (closed root planing). This ability helps in diagnosing the severity of the periodontal condition/periodontitis. There are effective, evidence-based products such as Clindoral® (TriLogic Pharma)[ii] and Doxirobe® (Zoetis)[iii] to reduce pocket depths in early periodontitis, however, there is still some hesitancy in using these products amongst practitioners.

Periodontitis is a progressive condition and one of the major goals of periodontal care is to decrease pocket depth. While, neither product takes the place of thorough teeth cleaning and pocket debridement or periodontal surgery, both have proven to be effective in decreasing pocket depth.[i]

PERIODONTAL STUDY

Objective:
To assess the efficacy of the following periodontal care options in improving stage 2 (early) periodontal disease as evidenced by changes (improvement) in periodontal pocket depth in a blinded, randomized study.
- I.   Closed root planing (subgingival and gingival plaque removal, scaling and curettage and polishing) alone
- II.   Closed root planing with Doxirobe®
- III. Closed root planing with Clindoral®

Inclusion:
For a dog to be included in the study, it must be two to seven years old of any breed, sex, and weight and have early (stage 2) periodontal disease or periodontal pocket depth of 3 – 5 mm or attachment loss as evidenced by radiographs. Dogs must be healthy enough per investigator judgment to undergo multiple anesthesia procedures.

Exclusion:
A dog was excluded from the study, if it had a current history of cancer, uncontrolled metabolic disease like diabetes, autoimmune, or immunosuppressive disease, received oral or parenteral (a) antibiotics within the past 60 days, (b) short acting steroids within past 14 days, (c) long acting steroids within the last 30 days, an intact dog in estrus (female) within 30 days or with the findings such as (i) periodontal pockets of greater than 6 mm in no more than 3 teeth per quadrant, (ii) dental prophylaxis within the last 75 days, (iii) tooth Mobility Index of 2 to 3 for the treated tooth or (iv) requirement of oral antibiotics under anesthesia after an oral exam.

Summary of Procedures:
Day 0: Gather patient information and perform physical and oral examination for inclusion assessment. If all study requirements were met and the dog owner consented its participation in the study, the dog was randomly assigned to one of the options group.
Group I: Closed root planing and periodontal pocket depth measurement of the whole mouth under anesthesia. All teeth/pockets with a pocket depth measurement of > 3 but < 6 mm were noted.
Group II: Closed root planing and periodontal pocket depth measurement of the whole mouth under anesthesia. All teeth/pockets with a pocket depth measurement of > 3 but < 6 mm were noted, followed by the placement of Doxirobe® gel in those pockets.
Group III: Closed root planing and periodontal pocket depth measurement of the whole mouth under anesthesia. All teeth/pockets with a pocket depth measurement of > 3 but < 6 mm were noted, followed by the placement of Clindoral® periodontal filler in those pockets.

The study enrolled enough dogs in each options group so that each group had 25 treated sites to evaluate.

Day 90: The enrolled dogs were reexamined and whole mouth charting was done under anesthesia. The study ended on day 90.

The study was blinded by doctor A performing the day 0 charting and providing periodontal care and doctor B charting the pocket depths at day 90.

Plaque control methods (specialized dental diets, tooth brushing, wipes, dog chews, raw hides) were excluded once the periodontal care was provided on day 0 until the end of the study.

Periodontal Disease Classification:
The stage of the periodontal disease was determined based on the periodontal disease classification (Veterinary Dental Nomenclature adopted by the American Veterinary Dental College [AVDC]) and was based on two measurements, probing depth and percent attachment loss (PAL).
Probing depth was measured on day 0 (following closed root planing) and day 90 using a constant force electronic probe (Florida probe). The probe was gently inserted under the free gingival margin until resistance to take measurements. Six sites/surfaces (mesial-buccal, mid-buccal, distal-buccal, mesial-lingual, mid-lingual and distal-lingual) around the circumference of each tooth were measured. However, only the pockets with depths of > 3 but < 6 mm were considered for the study.
PAL was determined from radiographs (X-rays).

Efficacy of the periodontal care options was determined by improvement in the noted periodontal pocket depth at day 90 compared to its periodontal pocket depth at day 0.

Results:
Twenty-three (23) dogs were enrolled in this study, of which six (6) dogs did not complete the study (absent for recheck). Of the seventeen (17) dogs completing the study, eight (8) were female and nine (9) were male.

Table 1: Outcome of the Study

Group	Outcome (Mean ± standard deviation)				
	Age (yrs)	BW (lbs)	Pocket Depth (mm)		
			Day 0	Day 90	Improvement
I (Closed root planing alone)	4.0 ± 1.9	48.7 ± 15.3	4.217 ± 0.422	3.191 ± 0.715*	1.026 ± 0.696
II (Closed root planing + Doxirobe®)	4.7 ± 1.2	35.8 ± 22.2	4.226 ± 0.425	2.994 ± 0.879*	1.232 ± 0.903
III (Closed root planing + Clindoral®)	5.2 ± 1.6	30.8 ± 21.7	4.233 ± 0.430	2.453 ± 1.092*	1.780 ± 1.001**

*$p < 0.05$ when compared with the corresponding day 0 value (within group) using a paired, two-tail Student t-test.

**$p < 0.05$ when compared with group I and II improvement value (between groups) using a one-way ANOVA followed by Tukey-Kramer *post-hoc* test.

<u>Within group:</u>
Pocket depth at day 90 was significantly better than pocket depth at day 0 irrespective of the options, when compared within the group.

<u>Between groups:</u>
Improvement in pocket depth seen at day 90 with the addition of Clindoral® to closed root planing was significantly better when compared to the improvement in pocket depth seen at day 90 with closed root planing alone or closed root planing with Doxirobe®.

Conclusions:
It can be concluded from the above study that the addition of Clindoral® to closed root planing was significantly better in reducing pocket depth. The data from this study provides evidence that adopting just one more step in veterinary dental care is beneficial in periodontitis.

[i] Bellows J. Go one step beyond in veterinary dental care. *DVM360 Magazine* 2016;Jan 04.
[ii] Johnston TP, Mondal P, Pal D, et al. Canine periodontal disease control using a clindamycin hydrochloride gel. *J Vet Dent* 2011;28(4):224-229.
[iii] Zetner K, Rothmueller G. Treatment of periodontal pockets with doxycycline in beagles. *Vet Ther* 2002;3(4):441-452.

Clindoral® is a trademark of TriLogic Pharma LLC. Doxirobe® is a trademark of Zoetis Services LLC.