

Brief Overview of VOHC Submission

Summary of Clinical Studies on Tartar Shield Soft Rawhide

Background

The requirements for obtaining the VOHC Seal include the need for clinical trials designed in compliance with the guidelines promulgated by the Veterinary Oral Health Council (VOHC) and, if the test product contains additives to enhance the oral health benefits, the dental benefits of the test product must be at least 20%. In addition, if the test product is available in more than one size the clinical trials must include at least two studies using one size of the product and one trial using a different size. Since Tartar Shield Soft Rawhide contains an anti-calculus agent (sodium tripolyphosphate) and an anti-microbial agent (cetyl pyridinium chloride) and is available in three different sizes, a total of three trials demonstrating at least a 20% benefit were required.

Overview of Procedures

All of the trials of Tartar Shield Soft Rawhide were designed as complete crossover studies with all dogs provided each of the regimens and they were conducted using the so-called “clean tooth model” in which all dogs receive a dental prophylaxis at the initiation of each test period. At the conclusion of each 4-week test period the dogs were anesthetized and examined in a random order using published and recognized criteria by experienced clinical examiners who had no knowledge of the group assignments or regimens. The resulting data were statistically analyzed using an analysis of variance model.

Summary of Clinical Studies on Tartar Shield Soft Rawhide Chews

<u>Study Number</u>	<u>Study Site</u>	<u>Study Design</u>	<u>Breed Of Dogs</u>	<u>No. Dogs Completing</u>	<u>Calculus* Reduction</u>	<u>Plaque* Reduction</u>	<u>Gingivitis* Reduction</u>
3012	Private Practice	Crossover	Chihuahua	7	54.3%	38.9%	28.4%
1353	I.U. School of Dentistry	Crossover	Beagle	19	34.0%	14.4%	6.6%(NS)
1434	I.U. School of Dentistry	Crossover	Beagle	14	28.20%	18.5%	45.7%
Average					38.3%	23.9%	26.9%

*Unless noted by (NS) all values are statistically significant

Summary of Results

From the foregoing table it is apparent that significant reductions in calculus formation were observed in each study and the magnitude of the benefit ranged from 28.2% to 54.3% with an average benefit for the three studies of 38.3%.

The reductions in dental plaque accumulations in the different studies ranged from 14.4% to 38.9% and the average benefit for the three studies was 23.9%.

Benefits with regard to gingivitis were more variable with a range from 6.6% to 45.7% and an overall average for the three studies of 26.9%.

Conclusion

In October 2007 the Veterinary Oral Health Council awarded Tartar Shield Soft Rawhide Chews the VOHC Seal for Calculus on the basis of the results of these three clinical studies.