

# <u>VOHC Policy on Trials Involving Use of Toothbrushes or</u> Similar Mechanical Devices in Dogs

This file describes the standardized VOHC Brushing Technique for use in VOHC trials in dogs. A separate file describes the standardized VOHC Brushing Technique for use in VOHC trials in cats.

Before conducting a VOHC trial involving a new brush or similar device, read the Protocol information available on the <u>Protocol</u> page of the VOHC web site.

#### **VOHC 'Standard' Brush:**

For medium and large size dogs, a human adult flat profile, soft bristle brush, compliant with ADA standard ISO 20126:2005, Dentistry - Manual toothbrushes (<a href="http://www.ada.org/sections/scienceAndResearch/pdfs/iso\_catalog.pdf">http://www.ada.org/sections/scienceAndResearch/pdfs/iso\_catalog.pdf</a>) is to be used. For a VOHC trial involving use of a brush, any "ADA Accepted" flat profile brush will be deemed to have met the ADA standard without need for additional testing of the specifications of the brush. For example: The Oral B Indicator flat profile brush is ADA Accepted. In a flat profile brush, viewed from the side, the bristles are all of the same length.

For a VOHC trial using this brushing protocol, the dogs used in the trial cannot have any complete furcation defects in the teeth that are scored in the VOHC trial. A complete furcation defect is present when a blunt periodontal probe can be passed completely through the space between the roots of a multi-rooted tooth.

If the brush is to be applied without including a dentifrice or liquid as the test article, the head of the brush is to be dipped into water before being applied to the teeth at the start of the brushing sequence.

The brush is to be applied to the surfaces of the teeth at a 45° angle, with the tips of the bristles pointed towards the gingival tissue. Three horizontal strokes, each consisting of a back and forth movement, are made, covering a specific 'set' of several teeth at a time in each stroke, and a fourth stroke is made, directing the brush away from the gingiva towards the tip of the crowns of the teeth in that set

The brush is pressed gently against the buccal surface of the tooth during the brush stoke - if the bristles visibly deflect (curve), the pressure applied is too high.

Maxillary (upper) jaw 'sets':

- a. All six incisors;
- b. Left side canine + premolars 1-3;
- c. Left side premolar 4, molars 1,2;
- d. Right side canine + premolars 1-3;
- e. Right side premolar 4, molars 1,2.

Mandibular (lower) jaw 'sets':

- a. All six incisors + both canines;
- b. Left side premolars 1-4;
- c. Left side molars 1-3;
- d. Right side premolars 1-4;
- e. Right side molars 1-3.

Total 10 sets of four strokes = 40 strokes per mouth. Note that the 'sets' can be combined to make the brushing strokes as comfortable as possible for the dogs, but each tooth must receive four strokes, for example a single horizontal (i.e. both back and forth) stoke that covers all left side maxillary premolars and molar teeth will be considered to be two strokes of the 40 required strokes, because it covers two 'sets' of teeth.

When this protocol is used in a trial for potential VOHC submission, all brushing is to be performed by the same person (the 'brusher') in all dogs, to minimize variability in application pressure; except that, when a large number of dogs are to be brushed during a trial, which would make it impractical for all teeth in all dogs to be brushed by the same person and still follow the 'time-since-previous-brushing' requirement for scoring at the end of the trial, additional brushers can be used provided that each brusher is assigned the same number of dogs in each group as the other brushers.

When this protocol is used in a trial for a potential VOHC submission, each dog is to have a separate brush assigned to it; the brush is to be new at the start of the trial, and the same brush is to be used in that dog throughout the trial.

Note that, for VOHC trials, brushing is to be limited to the buccal surfaces, to ensure that the specified number of strokes is used and that attempts to brush the lingual/palatal surfaces do not result in unstructured strokes on the buccal surfaces.

For a trial in dogs designed to produce data for a potential VOHC submission, the teeth to be scored are: Maxilla (upper jaw): Third incisor, canine, third and fourth premolar, and first molar. Mandible (lower jaw): Canine, third and fourth premolar, and first molar.

For a novel veterinary product, the sponsor would be required to demonstrate as part of the VOHC submission that the brush reaches the ADA standard in ISO 20126:2005 for bristle

length, shape and stiffness, or to provide justification for use of a novel device that has not been or cannot be tested using the ADA standard. All VOHC trials involving brushes or other devices with mechanical effect are to include VOHC safety and injury-monitoring scores.

A child-size ADA Accepted, ISO compliant brush can be used as the standard brush in small dogs.

#### Frequency of Brushing:

The AVDC standard is daily brushing; therefore, a VOHC trial to establish effectiveness of a brush or similar device must include a "brushed daily" group.

## **Timing of Scoring in Brushing Trials:**

Scoring at the end of a trial involving use of a brush or other mechanical device is to be done no earlier than within one hour of the time when the next brushing episode (or similar activity) would have been scheduled. For example, for a brush used daily and assuming the teeth during the trial were brushed at 4 pm, the final scoring episode is to be scheduled no earlier than 3 pm on the final day of the trial. The same timing for scoring is to be applied to diets and treats that are given once daily. The dogs are to be presented for scoring in random order. Because using a randomization table for all dogs in large trials would result in some dogs that were brushed early in the day being presented for scoring late in the day, the randomization for order for presentation for scoring can be 'blocked': One dog from each group is randomly assigned to a series of "score order cells", and the actual order of presentation for dogs in that score order cell is then randomized among the dogs in that score order cell. The blocking for score order can be used to determine order for brushing, so that the order for brushing and the order for scoring minimize variability among times since last brushing at the time of scoring at the end of the trial.

### **VOHC Trials of a Novel Brush or Similar Device**

If a VOHC trial is of a brush or similar device, the trial does not have to include a non-brushed control group – it need consist only of a 'standard brush' group and a 'test brush or device' group. To be awarded the VOHC Accepted Seal, the data from test device group result are to be statistically at least as good as the VOHC control brush in dental efficacy and provided that the trial demonstrates that the test brush does not injure oral soft tissues (no evidence of mechanical injury to the mouth, as shown by pre- and post-trial inspection for oral inflammation, ulceration or laceration).