

VOHC Policy on Trials Involving Use of Brushes or Similar Mechanical Devices

There is increasing interest in potential use of the VOHC product recognition system for brushes and dentifrices, gels or rinses.

The following recommendation from VOHC Council was approved by the AVDC Board in May 2011.

VOHC Trials of Brushes or Trials Requiring Use of a Brush to Apply a Chemical Agent (e.g. Dentifrice or Oral Gel or Rinse)

For VOHC trials in dogs, the following protocol has been adopted to ensure standardization of testing methodology in VOHC trials:

Teeth to be scored: Teeth to be scored in a VOHC trial are the standard VOHC teeth set: Maxillary I3, C, P3, P4, M1; mandibular C, P3, P4, M1.

Furcation Defects: The dogs used in the VOHC trial cannot have any complete furcation defects in the multi-rooted teeth that are scored (maxillary and mandibular P3, P4, M1). 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.

Safety Testing: All VOHC trials involving brushes or other devices with mechanical effect are to include VOHC safety and injury-monitoring observations (gingival inflammation scores and inspection for non-gingival inflammation, ulceration or laceration at day 0 and at the time of the final scoring for plaque and tartar [calculus]).

Brush: For medium and large size dogs, the ‘**VOHC standard brush**’ is a flat profile, soft bristle brush, compliant with American Dental Association standard ISO 20126:2005, Dentistry - Manual toothbrushes (http://www.ada.org/sections/scienceAndResearch/pdfs/iso_catalog.pdf). In a flat profile brush, the bristles are all of the same length when viewed from the side.

- For a VOHC trial involving use of a brush, an “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”.
- For a novel veterinary brush or other mechanical device, the product sponsor will be required to demonstrate as part of the VOHC submission that the brush meets or exceeds the ADA standard in ISO 20126:2005 for bristle length, shape and stiffness, or provide justification for use of a novel device that has not been or cannot be tested using the ADA standard.

- If the brush is the subject of the trial (i.e. it is to be applied without including a dentifrice, gel or liquid as the test article), the head of the brush is to be wetted with water before being applied to the teeth at the start of the brushing sequence.
- 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 for that dog throughout the trial.

Brushing Strokes: For VOHC trials, the following sequence is to be used, to ensure consistency between trials.

- 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.
- The brush is pressed gently against the buccal surface of the tooth during the brush stroke - if the bristles visibly deflect (curve), the pressure applied is too high.
- 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.
- The dog's mouth should be gently held slightly open to ensure that the strokes for the maxillary premolar and molar teeth do not also provide additional brush strokes to the mandibular premolar and molar teeth.
- To make the brushing process as comfortable as possible for the dog and as simple as possible for the person brushing the teeth, and depending on the size of the teeth and the size of the head of the brush, the number of teeth included in each horizontal stroke can be varied, provided that each tooth receives only three back-and-forth horizontal strokes and a final vertical stroke.
- In a medium- to large-size dog and using a human tooth brush with a small or medium head, a typical set of teeth for brushing will consist of:

Upper jaw 'sets':

- All six incisors;
- Left side canine + premolars 1-3;
- Left side premolar 4, molars 1,2;
- Right side canine + premolars 1-3;
- Right side premolar 4, molars 1,2.

Lower jaw 'sets':

- All six incisors + both canines;
- Left side premolars 1-4;
- Left side molars 1-3;
- Right side premolars 1-4;
- Right side molars 1-3.

Total 10 sets x four strokes = 40 strokes per mouth.

- 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 (see below), additional brushers can be used provided that each brusher is assigned the same number of dogs in each group as the other brushers.
- 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.

Frequency of Brushing:

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

Recommendation on 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.
- As per the requirement for all VOHC trials, the dogs in a trial involving use of a brush are to be presented for scoring in random order. VOHC recognizes that, 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 of presentation for scoring can be ‘blocked’ by treatment group, 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.

Recommendation for VOHC Trials of a Novel Brush or Similar Device:

- If a VOHC trial is of a brush or similar previously untested device, the trial does not have to include a non-brushed control group – it can consist only of a ‘VOHC standard brush’ group and a ‘test brush or device’ group. To be awarded the VOHC Accepted Seal, the results from the ‘test device’ group are to be statistically ‘at least as good as’ the results in the ‘standard brush’ group, and there is to be no evidence of mechanical injury to the mouth, as shown by pre- and post-trial gingivitis scores or inspection for oral inflammation, ulceration or laceration. VOHC recommends that commercial sponsors of a product that may be suitable for consideration by VOHC as

- a VOHC Accepted product contact VOHC early in the process of determining methodology for the required VOHC trials via VOHC@AVDC.org.
- VOHC requires that when a chemical anti-plaque or anti-tartar (calculus) product is tested and its recommended use by consumers includes application by a brush or other device or finger that is pressed against the teeth, a ‘positive control’ group (consisting of the application of the brush, device or finger without the chemical agent or by using a placebo agent) is to be included in the trial.

The information above applies to brushing during VOHC trials. The brush and brushing technique described above are recommended by AVDC for clinical use, with the following additional comments:

- As standard practice in companion animals, all teeth (and ideally all surfaces of all teeth) should be brushed daily. While the specific brushing technique described above is to be used in cooperative dogs in VOHC protocol trials, AVDC and VOHC recognize that some companion animal dogs will not cooperate with daily application of the full set of brush strokes. Any brushing activity, used regularly, is better than no brushing activity.
- Some periodontal pathology may require use of a different type of brush or different brushing technique, such as when there is a complete furcation defect. AVDC recommends that you ask your veterinarian whether the ‘standard’ brushing technique described above is appropriate for your dog.
- Dental plaque and tartar accumulate most rapidly on the buccal (cheek) surfaces of the teeth of dogs and cats, and these areas are included in the VOHC brushing set described above. AVDC recognizes that, when practical in clinical use, brushing of the teeth of pet dogs should also include additional strokes on the palatal/lingual (“inside”) surfaces of the teeth. The palatal/lingual surfaces are not to be brushed in VOHC trials only because doing so would risk inadvertent strokes on the buccal surface of the teeth in this standardized testing model.