

temperature. The gingiva also may bleed upon gentle provocation such as toothbrushing or may bleed spontaneously. Gingivitis is usually not painful.

- *Oral Hygiene.* Self-administered processes aimed at controlling microbial and other deposits in the oral cavity.

- *Pellicle.* A thin, colorless, translucent film derived from bacterial products and saliva, which forms rapidly on tooth surfaces after natural cleansing or prophylaxis. A few hours after deposition, oral bacteria begin to adhere to the pellicle. These processes represent the earliest stages of plaque formation.

- *Periodontitis.* A disease condition of the periodontium characterized by inflammation of the gingiva, increasing probing depth, and destruction of the periodontal ligament and the adjacent supporting alveolar bone.

- *Tartar.* A synonymous term for calculus.

B. Background and General Discussion of Terms

1. Background

The Subcommittee was charged with the evaluation of the safety and effectiveness of ingredients or combinations of ingredients for the reduction or prevention of plaque and gingivitis as claimed in the labeling of OTC drug products in light of present-day knowledge and standards used in pharmacology, pharmacodynamics, therapeutics, and toxicology.

In making its evaluation, the Subcommittee relied upon factual data found in standard textbooks and scientific articles published by independent investigators in medical, dental, and other scientific journals. Manufacturers included some of these scientific articles in their submissions to FDA to provide a scientific basis for claims made for the safety and effectiveness of their ingredients. Data supplied by manufacturers in unpublished reports of studies performed by private laboratories under contract to the manufacturer or in manufacturers' laboratories were also used by the Subcommittee in making judgments. The Subcommittee also gave due consideration to data from marketing experience and widespread clinical usage when in agreement with basic data from controlled studies and scientific facts.

2. Plaque

Plaque, also known as dental plaque and/or microbial plaque, has been examined for several decades with most of the information explained in the past

25 years. Plaque has a critical etiological role in the development of dental caries, gingivitis, and periodontal disease. It is now clear that dental plaque is a variable biologic community made up of bacteria and a bacterially synthesized matrix. While dental plaque may be combined with other materials such as food particles and sloughed epithelial cells, the combination of these components is called *materia alba* and is no longer considered plaque.

The precise genera and species of microorganisms in each dental plaque may differ from individual to individual, site to site in the same individual, and within a specific site over time. Plaque from sites of similar clinical health within individual subjects tends to be more similar in composition than plaque from sites in different subjects. Even though there is considerable variation within dental plaques, the composition of plaque is influenced by several factors. The composition of dental plaques is currently known to be affected by plaque age, dietary intake of sucrose and other foods, and other factors (e.g., friction of mastication, oral health, and salivary flow).

Plaque composition is also affected by its location above or below the gingiva. Dental plaques are subdivided into supragingival plaque and subgingival plaque. The distinction resides in the location of dental plaque as either coronal (toward the crown) or apical (toward the root tip) to the soft tissue margin. The microbial populations may differ in plaque from the two locations.

The extracellular matrix synthesized by the bacteria is a significant component of plaque. Because the matrix provides plaque organisms with strong adhesive and cohesive properties, plaque is not easily removed. The tenacity of plaque to adhere to the surfaces of oral structures can be used to distinguish plaque from debris, in that plaque is not removed by flushing the mouth with water.

Plaques differ not only quantitatively but qualitatively in their bacterial composition. For example, microorganisms found in dental plaque include *Actinomyces* species, *Streptococcus sanguis*, *S. mutans*, and other *Streptococcus* species, *Spirochetes*, *Porphyromonas gingivalis*, *Bacteroides forsythus*, and other *Bacteroides* species, *Campylobacter recta*, *Peptostreptococcus micros*, *Eikenella corrodens*, *Actinobacillus actinomycetemcomitans*, *Eubacterium* species, *Fusobacterium* species, *Capnocytophaga* species, and *Prevotella* species. This difference in bacterial composition has a major effect on its

pathogenic potential both for periodontal diseases and caries. Some dental plaques are not pathogenic or associated with disease, whereas others are etiologic factors for caries and periodontal diseases. However, the two types of plaque cannot be distinguished visually. The pathogenic potential is dependent upon the microbial composition, including the metabolic products of microbes, dietary patterns, and the intrinsic resistance of the host. It may be prudent to treat all plaques as having pathogenic potential.

3. Calculus

Calculus is a hard concretion that forms on the teeth or dental prostheses through deposition of mineral salts in dental plaques. Human calculus is essentially mineralized dental plaque, which is almost always covered on its external surface by vital, tightly adherent, nonmineralized soft plaque. There may also be loosely held materials associated with calculus such as *materia alba*, shed bacteria, desquamated epithelial cells, and blood cells. In germ-free animals, calcified deposits may occur in the absence of bacterial accumulation (Ref. 1). However, in humans, virtually all calculus seen clinically likely results from the deposition of calcium and phosphates within bacterial plaques. Calculus formation occurs in an orderly fashion, beginning after 1 or 2 weeks of plaque formation and resulting in full calcification of plaque after 2 to 4 weeks. The process occurs more rapidly in some persons than in others.

Calculus may form subgingivally and is often stained and tenaciously attached to the crown and/or root of the tooth. Calculus may also form supragingivally, coronal (toward the crown) to the gingival margin. Supragingival calculus is found in greater amounts on tooth surfaces adjacent to the openings of the ducts of the major salivary glands. Both subgingival and supragingival calculus are often stained; supragingival calculus can be unsightly, particularly when formed in abundance on labial (facing the lips) surfaces. Although subgingival calculus is a contributing factor in the development of gingivitis, and can also be associated with the progression of gingivitis, periodontitis, and periodontal abscesses, the exact nature of the role of supragingival calculus in gingivitis is not clear. Supragingival calculus can accumulate plaque and act as a nidus (nest) for plaque formation, which can lead to gingivitis.

Calculus facilitates the retention of dental plaque in close proximity to the periodontal tissues. It reduces the