Information Sheet on pH of Home Oral Care Products

What is pH?

pH is a measure of the activity of hydrogen ions in solution. In aqueous solutions, pH is measured using a logarithmic scale known as the pH scale, which is used to express the acidity or alkalinity of the solution. A pH less than 7 indicates an acidic solution, and one with pH greater than 7 is alkaline. Because pH values are logarithmic, each change of one pH unit is equivalent to a ten-fold change in the concentration of hydrogen ions.

Numerous oral care products are sold over-the-counter (OTC) for oral hygiene or cosmetic purposes, including toothpastes, mouthrinses, whitening gels/strips and oral moisturizers. Such products are manufactured with formulations that include variable concentrations of therapeutic (active) and inactive ingredients. They are also marketed for various accepted indications (e.g., reducing caries or gingivitis), and are formulated at specific pH levels to accommodate specific ingredients and intended purpose.[1, 2] Questions have been raised about the overall safety and effectiveness of the pH in various oral care product formulations.[3-5]

Intra-oral pH

Intra-oral pH refers to a pH level or measurement (or range of measurements) taken within the oral environment. Numerous studies have measured pH in various intraoral locations, including tooth surfaces, mucosa, tongue, palate, floor of the mouth as well as in oral fluids (e.g., unstimulated or stimulated whole saliva; gingival crevicular fluid).[6-10]

Not surprisingly, saliva has a primary role in maintaining intra-oral pH and oral homeostasis.[11, 12] Saliva is the clear, viscous, protein-rich biofluid continuously secreted by salivary glands. Although composed primarily of water (about 99 percent), saliva is also comprised of protective ions, glycoproteins, amylase, enzymes, mucins and other components.

Overall, intra-oral pH levels typically range between pH 6.5-7.8, although higher (more alkaline) pH occurs in stimulated saliva and lower pH in unstimulated saliva.[8, 11, 13] Saliva pH may also vary depending on adequate salivary composition/flow, time of day, or the location where saliva pH is measured,[6-8, 14-18] as well as variation in dietary exposures, bacterial metabolism, and antibacterial components in saliva itself.[19-22]

Saliva serves several protective functions, including cleansing the oral cavity, facilitating oral processing and swallowing food or drink, protecting oral tissues against physical and microbial insults, maintaining a neutral pH and helping to prevent demineralization.[19] Through these functions, saliva provides protection against the primary forms of enamel demineralization (caries and dental erosion), which are both modifiable by the buffering protection provided by saliva and the salivary pellicle. [23]

Caries is the localized destruction of dental hard tissues that arises from exposure to organic acids generated by bacteria within the plaque biofilm.[24] Decreased or impaired salivary secretion is a known risk factor for caries, as well as candidiasis and other mucosal complications.[19, 25-27] Dental erosion (or erosive tooth wear) is the second-most common form of enamel demineralization, and occurs from chemical dissolution of dental hard surfaces by exposure to acids not produced by bacteria in the mouth.

One primary risk factor for dental erosion is frequent exposure to low pH acids in beverages (e.g., soft drinks), juices and food products (e.g., lemon) with acidic pH.[28] The buffering systems present in saliva help with neutralizing the pH of potentially erosive acids, both extrinsic (e.g., soft drinks, fruit juice, energy drinks) and intrinsic (e.g., gastric acid).[28, 29]

One essential function of human saliva is its bicarbonate buffering system, which serves a primary role in neutralizing intra-oral acids. Salivary pH is modulated by the ratio of the bicarbonate/carbonic acid concentrations within the saliva,[30, 31] where increased bicarbonate concentrations can elevate pH and assist with neutralizing exposure to plaque acid.[10] In general terms, when an individual's salivary flow increases, the bicarbonate concentration in saliva tends to increase, raising intra-oral pH.

Since the 1940s, researchers have investigated what's known as the "critical pH" of saliva, which is the salivary pH level below which dissolution of enamel can occur.[9, 25, 32, 33] The critical pH value for enamel dissolution is about pH 5.5,[10, 34, 35] although the actual pH for demineralization varies based on other factors including the concentrations of calcium and phosphate in saliva in contact with enamel.[32, 36] When intra-oral pH rises above 5.5 (in tandem with adequate salivary composition and flow), conditions within the oral environment help promote enamel remineralization.

Mature human enamel is the hardest mineralized material in the body and is primarily composed of complex arrays of hydroxyapatite crystallites (formed through matrix-mediated biomineralization).[37, 38] To support oral homeostasis, saliva's complex mixture of calcium and phosphate ions help maintain a stable environment on enamel surfaces.[11, 12] Other salivary constituents, such as mucins, assist in forming the the enamel pellicle, which provides protective coatings for hard and soft tissues.[10, 11]

pH of Toothpaste

American National Standards Institute/American Dental Association (ANSI/ADA) Standard 130 specifies that the pH of dentifrice be less than 10.5.[39] Studies have demonstrated that acidulated (i.e., lower) pH in fluoride-containing toothpaste improves fluoride uptake in human enamel and in plaque.[40-43] Toothpastes with stannous fluoride salts are commonly formulated at lower pH to assist with product stability.[1]

Manufacturers' safety data sheets for fluoride-containing toothpastes are available in the Household Products Database, and many include information on pH. A review, in 2019, of toothpaste safety data sheets in the Household Products Database found pH levels in the OTC toothpaste products ranged from about pH 4.0 to 9.68. A Brazilian study of pH in seven fluoride toothpastes with calcium carbonate, a common abrasive, found that product pH levels were primarily alkaline, ranging from pH 8.67 to 10.03.[44]

Additionally, people can use OTC toothpastes that contain sodium bicarbonate (baking soda), which typically have more alkaline pH levels and can assist with neutralizing plaque pH after sucrose exposure.[45, 46] More information on active and inactive ingredients in OTC toothpastes may be found on ADA.org Oral Health Topic page on Toothpastes.

pH of Mouthrinse

The ANSI/ADA Standard 116[47] stipulates that the pH of oral rinses be between 3.0 and 10.5. For oral rinses with a pH below 5.5, ANSI/ADA Standard 116 calls for further demonstration of product safety, either through a demineralization test or erosion test or other appropriate methods.[47]

OTC mouthrinses are generally grouped within three product categories: therapeutic mouthrinses that contain fluoride to reduce caries risk; therapeutic mouthrinses to reduce plaque/gingivitis risk; and mouthrinses that make cosmetic claims (e.g. reduce bad breath). There are, in addition, therapeutic mouthrinses available by prescription that typically deliver an active ingredient in concentrations greater than in OTC products or an ingredient (e.g. chlorhexidine) that is not available without a prescription.

Active ingredients in mouthrinses can be delivered at specific pH values within the oral cavity because dilution with saliva is minimal.[5] Review of the manufacturers' safety data sheets for ten widely available OTC mouthrinse products (included in the Household Products Database) found that their pH levels ranged from 3.43 to 7.05.

pH of Home-Use Whitening Products

Several types of consumer whitening products are available for home use, including gels, rinses, chewing gums, toothpastes, paint-on films and hydrogen peroxide whitening strips. These whitening products (by group/category) differ in terms of application times and durations of treatment.

In the United States, most, if not all, extracoronal bleaching products available OTC for whitening of vital teeth contain either carbamide peroxide and/or hydrogen peroxide. Peroxide-based materials are used in home-use tooth whitening products because dental hard tissues are permeable to fluids, which allows for diffusion of peroxide-based materials inside the tooth (within dentin and enamel).[48, 49] The whitening process also includes pH-mediated interaction of hydrogen peroxide with the tooth structure, which can also be influenced by temperature or light.[50]

The pH of home-use whitening products is primarily related to the concentration of hydrogen peroxide.[51] Overall, tooth whitening products with hydrogen peroxide tend to be more acidic, and they are generally manufactured as lower pH formulations to improve product stability, primarily because hydrogen peroxide is less stable at higher pH.[52]

When used according to manufacturer instructions, home-use whitening products are typically well tolerated and have demonstrated a good safety profile.[50] Examples of reported adverse events include tooth sensitivity and oral soft tissue irritation.[48, 50]

Information on Specific Products

Clinicians and patients interested in the pH level of specific home oral care products can find information about many products through the Household Products Database, which is searchable by product name or manufacturer.

Reporting Problems

Clinicians and individuals can report adverse effects related to oral care products (or any medication or medical device) to the U.S. Food and Drug Administration's MedWatch Program.

Conclusions

- **The pH of Oral Care Products Depends Primarily on Product Formulation and Composition:** Products are specifically formulated to accommodate ingredients and purpose, and to provide therapeutic and cosmetic functions. Incorporation of fluoride into hard tissues, for example, is maximized at lower pH, thereby enhancing caries prevention.[41, 53, 54] Tartar control toothpaste may have an alkaline formulation to facilitate the delivery of active ingredients.[1] Some OTC toothpastes are manufactured with small amounts of sodium hydroxide to adjust formulation pH. Oral rinses may have an acidic formulation to facilitate better dissociation of active ingredients within the oral cavity.

The safety of many OTC toothpastes, mouthrinses and other products has been evaluated through a wide range of clinical testing, safety evaluations and post-marketing surveillance.[2] On occasion, using an oral care product may result in an allergic reaction or contact dermatitis, but such cases are not common, usually not severe, and usually unrelated to pH. Allergic reactions may arise from the presence of specific ingredients (e.g., flavoring agents, sodium lauryl sulfate) to which the individual reacts.[1, 55, 56]

- **Frequency of Oral Care Product Use:** To support at-home oral hygiene, the American Dental Association (ADA) issued recommendations for Home Oral Care, which advise people to perform:

  - twice-daily brushing with fluoride toothpaste;
  - daily cleaning between teeth; and
  - for those with increased risk of caries or periodontal disease, follow the personalized recommendation from their dentist regarding use of fluoridated mouthrinse, and/or use of mouthrinse or toothpaste with antimicrobial activity.

- **Safety Profile:** Over-the-counter oral care products have a strong track record of safety. Adverse events (e.g., dry mouth, gingival irritation, allergic reaction) may arise, especially when product instructions about amount and frequency of use are disregarded. Within the complex environment of the oral cavity, buffering by saliva helps protect teeth and mucosal surfaces following changes in pH, returning and maintaining intraoral pH near neutral (i.e., pH 7.0).

Disclaimer

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