A Message from Our Guest Editor …

Nada Naaman, DDS, PhD
Professor, Department of Periodontology
Dean, Faculty of Dental Medicine
Saint-Joseph University
Beirut, Lebanon

Dear Reader …

I hope you will find this new issue of Gingival Health Dialogue as interesting as I did. The papers enclosed summarize recent discoveries in the field of periodontology, but reach the global dental profession and demonstrate the array of approaches available for maintaining healthy periodontal tissues.

The issue begins with a brilliant review by Dr. Panos Papapanou on gene expression and disease classification. Based on earlier studies published by his group, he suggests a new pathobiology-based classification of periodontal disease that will implement future approaches.

The next paper, written by the Distinguished Professor Sebastian Ciancio, is a review on the clinical efficacy of triclosan/copolymer-containing fluoride toothpastes. The author offers the latest information on this subject.

The third paper, by Christine Hovliaras, presents a methodological view of tooth brushing and ergonomics, showing how an electric toothbrush can be an added value for improving oral hygiene.

Next, Emily Boge presents novel and important data on an oral rinse and its active ingredients for controlling gingival inflammation.

Dr. S.G. Damle then introduces the readers to the field of Ayurveda medicine, and shows how the application of this different medical approach can be effective in treating some diseases. The author then developed the data regarding oil pulling and oral health.

Finally, we present the updated Second Edition of the textbook Periodontal Disease and Overall Health: A Clinician’s Guide (R.J. Genco and R.C. Williams, Editors), which is now available.

On behalf of the program sponsor – the Colgate-Palmolive Company – I thank you for your readership. I am confident this important work is an added value for spreading scientific data to our profession.

Sincerely,

[Signature]

A New Approach to the Classification of Periodontal Diseases

Panos N. Papapanou, DDS, PhD

For the past decade, our research group at the Division of Periodontics, Columbia University College of Dental Medicine, has focused on the study of gene expression signatures in gingival tissues, having as overall aims to (1) gain a better understanding of the pathobiology of periodontal diseases, and (2) provide the foundation for the development of a new classification of periodontitis based on pathobiology rather than on clinical symptomatology.

Gene Expression Profiling

Gene expression profiling refers to the systematic cataloguing of messenger-RNA (mRNA) molecules in a cell or tissue sample. As the readers of the Gingival Health Dialogue certainly recall from their basic biology courses, DNA in the nucleus is first transcribed into mRNA, before ultimately translated into protein. Protein expression is what decides the cells or the organ's phenotype, i.e., it determines its characteristics and behavior. It is important to realize that although all cells in our body share the same genetic information, they produce vastly different proteins depending on their specific functions. By examining which particular mRNAs are being transcribed at a given time point in a specific cell population, we can get a rough idea of which particular proteins are about to be translated in these cells and, thereby, an estimate of their expected phenotype. One way that this can be studied in the lab is as follows: First, total RNA is extracted by a cell or tissue sample and is then transcribed in vitro to recombinant DNA and also labeled with specific tracer molecules. These labeled fragments are then allowed to hybridize (i.e., to bind according to DNA-base complementarity) with specific probes (i.e., nucleotide sequences) that have been immobilized on a slide, a so-called “gene chip.” Gene chips that are commercially available today carry probes that correspond to all known genes in our body. The intensity of the hybridization signal provides us with an estimate of gene expression, i.e., the amount of mRNA that corresponds to each particular gene that is being transcribed in the sample. By studying the expression of thousands of genes simultaneously, the transcriptional profile, alternatively termed “gene expression signature,” of the particular cell or tissue sample is obtained.

Class Validation

Gene expression profiling studies generate large amounts of data and have required the development of specific bioinformatics techniques in order to be successfully analyzed. Two principal analytic approaches are being used in this context. The first is termed “class validation,” and is used when a given classification scheme that is based on a traditional diagnostic method (e.g., “healthy” and “diseased” tissue, histological type 1 versus histological type 2 tumor) is explored at the level of gene expression. These studies can provide support for, or refute, the biological relevance of the original diagnostic
Application of Gene Expression in Classifying Periodontal Disease

Inspired by the publications above, our group initiated similar studies targeting periodontal diseases. We hypothesized that the study of gene expression in gingival tissues would identify the molecular underpinnings of periodontal homeostasis and pathology, and would ultimately facilitate the development of a novel classification of periodontitis based on pathobiology. In this project, we recruited a sample of 120 periodontitis patients, including men and women with either chronic or aggressive periodontitis (63 and 57 patients, respectively). From each of these individuals, we harvested at least two interproximal gingival papillae from areas with deep pockets, attachment loss, and bleeding on probing, as well as one control healthy tissue sample (with no signs of clinical inflammation, pocketing, or attachment loss), if available. Prior to harvesting these tissue samples, we also obtained samples of subgingival plaque from both the mesial and distal aspect of the harvested interproximal gingival papilla. In all, our completed database consisted of 311 tissue samples (240 from diseased and 71 from healthy sites) that were analyzed with respect to the level of expression of > 38,500 well-characterized genes. The database also included the corresponding subgingival plaque samples that were analyzed with respect to the level of each of 11 bacterial species, as well a sample of peripheral blood from each participant that was analyzed with respect to the presence of IgG antibodies to each of the 11 bacterial species.

Our first publication originating from this database provided the first comprehensive description of gene expression signatures in the gingival tissues in states of periodontal health and disease, and identified those genes and molecular pathways that are differentially expressed between the two conditions. The full listings of these genes and pathways are available online and provide a valuable resource to researchers in the scientific community.

Our next aim was to explore whether the bacterial content of the periodontal pocket facing the gingival tissues was a significant determinant of gene expression. This work demonstrated that the levels of certain bacteria, including *Campylobacter rectus*, *Porphyromonas gingivalis*, and *Tannerella forsythia* are strong regulators of gene expression in the adjacent gingiva, while levels of other bacteria were only weakly associated with differential gene expression in the tissues. Subsequently, we proceeded with a formal class validation step, and compared expression patterns in gingival tissue lesions originating from patients with either chronic or aggressive periodontitis. This work demonstrated that the differences in the transcriptomes of the two main forms of periodontitis are relatively limited, and did not provide any support for the commonly believed notion that there are fundamental differences in the molecular makeup of lesion-form chronic and aggressive periodontitis. In other words, the gingival tissues forming a deep pocket obtained from a chronic periodontitis patient expressed largely similar mRNA patterns as gingival tissues from a pocket of an aggressive periodontitis patient with similar clinical characteristics.

However, when we proceeded with a class discovery approach, i.e., first pooled together all chronic and aggressive periodontitis patients and asked the transcriptomes to identify novel groups based on common gene expression patterns, we identified two robust clusters based on the molecular patterns (Figure 1). Interestingly, these two clusters also displayed significant phenotypic differences. Thus, patients in
Cluster #2 showed higher extent and severity of periodontitis than their Cluster #1 counterparts, as indicated by statistically significantly higher mean probing depth (PD), mean clinical attachment loss (CAL), and mean number of sites with PD ≥ 5 mm or CAL ≥ 5 mm. In addition, patients in Cluster #2 showed a higher frequency of sites with bleeding on probing, despite comparable levels of dental plaque. With respect to bacterial profiles, patients in Cluster #2 were more heavily colonized by most “red” and “orange complex” species examined, while colonization levels by health-associated bacteria were significantly higher in Cluster #1. Furthermore, patients in Cluster #2 showed approximately five-fold higher mean serum IgG antibody levels to Campylobacter rectus, significantly higher IgG levels to T. denticola and Actinomyces naeslundii, and a tendency for higher IgG to P. gingivalis.

Lastly, when assessing the host responsiveness to periodontal colonization by using the ratio of antibody titer over the mean level of colonization by the homologous species (“infection ratio,”14 Cluster #2 patients showed significantly more robust responses to C. rectus and A. naeslundii. These findings demonstrate that gingival tissue transcriptomes can indeed identify clusters of patients with distinct periodontal phenotypes, and thus suggest that, after further development and appropriate external validation, this approach can provide the foundation for a novel, pathobiology-based classification of periodontitis.

Application to the Study of Gingival Inflammation

Our laboratory has used a similar approach in the study of the development of gingival inflammation using an experimental gingivitis model. In this study,15 ten periodontally healthy volunteers abstained from plaque control over a period of three weeks and donated gingival tissues at baseline, 7, 14, and 21 days of plaque accumulation (“induction group”). A second group comprising another 10 individuals developed experimental gingivitis over 21 days, after which they received prophylaxis and reinstituted oral hygiene measures; they donated gingival tissues at days 21, 25, 30, and 35 (“resolution group”). By serially examining the activation of genes over time, we were able to study the molecular dynamics in the gingival tissues during the induction and resolution of experimentally induced inflammation. As shown in Figure 2, the most eventful period in terms of gene activation in the gingival tissues was the second week of gingivitis induction and the first five days after prophylaxis and reinstatement of oral hygiene. In the same volunteers, we used a high throughput proteomic approach to identify proteins secreted in the gingival crevicular fluid during the course of experimental gingivitis.16 Using liquid chromatography-tandem mass spectrometry (LC-MS/MS), we identified a total of 254 human, 14 bacterial, 12 fungal, and 7 yeast proteins, several of which were reported for the first time in gingival inflammation.

The Future of Pathobiological Approaches to Periodontal Disease

Our research group is continuing to develop an integrated systems biology approach in the study of the pathobiology of periodontal diseases. We expect that the use of the high throughput technologies described above will shed new light into our understanding of the complex molecular interactions that occur in the gingival tissues.

References


Figure 2. Number of differentially expressed genes during the induction and resolution phases. Red color indicates upregulated genes, green color indicates downregulated genes.
Clinical Efficacy of a Triclosan/Copolymer Dentifrice

Sebastian G. Ciancio, DDS

In 1992, the Colgate-Palmolive Company introduced Colgate® Total® Toothpaste, containing 0.3% triclosan — a broad spectrum antibacterial — 2.0% polyvinylmethyl ether maleic acid (PVMA) copolymer, and 0.243% sodium fluoride in a silica base. The addition of the copolymer to the dentifrice formulation allowed for greater uptake and retention of the triclosan to the enamel and buccal epithelial cells, providing long-lasting antimicrobial effects that are well documented. Colgate® Total® is accepted as safe and effective by the American Dental Association and by dental associations in over 40 countries around the world.

Efficacy of Colgate® Total® Toothpaste

Review of Clinical Benefits by an Independent Organisation

Colgate® Total® Toothpaste was the subject of a recently published review by the prestigious Cochrane Collaboration. They designed a meta-analysis that included 30 studies, published between 1990 and 2012, involving 14,835 participants. The objective of the review was to assess the effect of triclosan/copolymer-containing fluoride toothpastes, compared with other fluoride toothpastes, for the long-term control of caries, plaque, and gingivitis in children and adults. The findings clearly support the beneficial oral health effects of daily use of Colgate® Total® Toothpaste on reduction of plaque, gingivitis, caries, and calculus. These effects were greater than those seen with non-triclosan-containing toothpaste use. Further, the review found no indication of adverse effects associated with the use of this dentifrice.

Table 1. Plaque and Gingivitis Efficacy of Triclosan/Copolymer Dentifrice Long-Term Clinical Studies

<table>
<thead>
<tr>
<th>Investigators</th>
<th># Subjects</th>
<th>Duration (Mo)</th>
<th>Plaque Efficacy vs. Placebo</th>
<th>Gingivitis Efficacy vs. Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mankodi, et al.11</td>
<td>294</td>
<td>6</td>
<td>-11.9</td>
<td>-19.7</td>
</tr>
<tr>
<td>Bolden, et al.4</td>
<td>306</td>
<td>6</td>
<td>-17.9</td>
<td>-29.0</td>
</tr>
<tr>
<td>Garcia-Godoy, et al.3</td>
<td>108</td>
<td>7</td>
<td>-58.9</td>
<td>-30.1</td>
</tr>
<tr>
<td>Cubells, et al.5</td>
<td>108</td>
<td>6</td>
<td>-24.9</td>
<td>-19.7</td>
</tr>
<tr>
<td>Deasy, et al.9</td>
<td>121</td>
<td>6</td>
<td>-32.3</td>
<td>-25.6</td>
</tr>
<tr>
<td>Denepitiya, et al.7</td>
<td>145</td>
<td>6</td>
<td>-18.4</td>
<td>-31.5</td>
</tr>
<tr>
<td>Palomo, et al.12</td>
<td>98</td>
<td>6</td>
<td>-12.7</td>
<td>-24.1</td>
</tr>
<tr>
<td>Triratana, et al.23</td>
<td>120</td>
<td>6</td>
<td>-32.9</td>
<td>-18.8</td>
</tr>
<tr>
<td>Lindhe, et al.10</td>
<td>110</td>
<td>6</td>
<td>-31.2</td>
<td>-26.6</td>
</tr>
<tr>
<td>Renvert and Birkhed13</td>
<td>114</td>
<td>6</td>
<td>-25.0</td>
<td>-41.9</td>
</tr>
<tr>
<td>Svatun, et al.11</td>
<td>220</td>
<td>7</td>
<td>-16.1</td>
<td>-24.3</td>
</tr>
<tr>
<td>Hu, et al.9</td>
<td>183</td>
<td>6</td>
<td>-29.9</td>
<td>-33.2</td>
</tr>
</tbody>
</table>

Plaque and Gingivitis

The clinical efficacy and safety of triclosan/copolymer was demonstrated in over 2,000 subjects who participated in 13 six-month, independent, double-blind clinical studies which followed a similar study design.13-15 The triclosan/copolymer dentifrice reduced plaque and gingivitis up to 58.9% and up to 41.9%, respectively, as compared to a placebo dentifrice. These studies are summarized in Table 1.

Oral Malodor

Clinical studies also demonstrate that a triclosan/copolymer/fluoride dentifrice provides long-lasting fresh breath protection,16-18 and specifically inhibits volatile sulfur compound (VSC)-producing bacteria.19 In addition, there were no significant local or systemic adverse effects observed following triclosan/copolymer/fluoride dentifrice use, including lack of development of bacterial resistance. This is not surprising since triclosan has a nearly four-decade history of safe use in soaps and deodorants.20

Periodontitis

Four separate long-term clinical studies, one of which was five years in duration, were conducted on over 1,200 subjects to assess the effect of the daily use of a triclosan/copolymer/fluoride dentifrice on periodontitis.21-24 Results from these studies showed reductions in attachment loss and pocket depth, and gains in clinical attachment levels. These data suggest that a triclosan/copolymer/fluoride dentifrice may be of benefit in stabilizing patients after periodontal therapy.

Calculus

In addition to benefits on periodontal health, four studies demonstrated significant differences in supragingival calculus levels in patients who
used the triclosan/copolymer/fluoride dentifrice as compared to a placebo dentifrice (p < 0.01), with an average reduction of 34%.25-28

Anti-Inflammatory Effects of Colgate® Total® Toothpaste

Since excessive or chronic inflammation can cause tissue damage and has been associated with systemic diseases, control of inflammation is important for both gingival and general health. Research suggests that the anti-gingivitis effect of a triclosan/copolymer/fluoride dentifrice results from its combined antimicrobial and anti-inflammatory properties.

As early as 1993, it was suggested that triclosan could reduce inflammation. Since then, a number of investigators have conducted studies to assess the anti-inflammatory action of triclosan.29-33 These studies demonstrated that triclosan inhibited the production of two inflammatory cytokines — interleukin-1 beta (IL-1β) and tumor necrosis factor alpha (TNF-α). These cytokines stimulate robust inflammatory responses that often result in both soft and hard tissue destruction. In addition, IL-1β and TNF-α can induce production of prostaglandin E2 (PGE₂), a potent inflammatory mediator, during the early stages of inflammation. PGE₂ causes collagen breakdown and bone resorption, and exhibits a broad range of inflammatory effects. Importantly, triclosan inhibits both IL-1β and TNF-α-induced PGE₂ production for up to 24 hours, likely due to the inhibition of PGE₂ biosynthesis.

Finally, recent work indicates that triclosan can support the stability of collagen by inhibiting matrix metalloproteinase (MMP) production in fibroblasts and osteoblasts that were stimulated with inflammatory cytokines. This dual action is demonstrated in Figure 1.

It is noteworthy that Colgate® Total® is the only FDA-approved toothpaste that has gone through the rigorous NDA process — the same process used to review the safety of prescription drugs.

The reviews showed that no studies documented adverse human health outcomes from the use of triclosan in toothpaste. The levels of triclosan used in toothpaste and other consumer products have been determined by these regulatory agencies to be safe, efficacious for oral health, and not harmful to human health.

Additionally, as part of a company’s approval under the U.S. Food and Drug Administration (FDA) New Drug Application (NDA) process, if the company becomes aware of any serious adverse event, they are required to immediately report it to the FDA. All adverse events must be monitored for trends as part of a signal detection process. In the nearly 18 years that Colgate® Total® Toothpaste has been on the market in the United States, there has been no signal of a safety issue from adverse event reports. It is noteworthy that Colgate® Total® is the only FDA-approved toothpaste that has gone through the rigorous NDA process — the same process used to review the safety of prescription drugs.

Triclosan Does Not Induce Local or Systemic Bacterial Resistance

Resistance of oral microorganisms to triclosan has not been demonstrated clinically. It is hypothesized that microorganisms fail to develop resistance because triclosan exerts its antibacterial properties through multiple, dose-dependent mechanisms. Further, several publications document the existence of multiple sites/modes of action of triclosan.40 Its primary site of action is thought to be at the cytoplasmic membrane, resulting in interference with uptake of amino acids, uracil, and other nutrients. At higher concentrations (more typical of those associated with toothpaste use), membrane lesions and leakage of cell contents are observed leading to cell death.41 Thus, triclosan exerts its effects through multiple mechanisms, and this is thought to explain the lack of microbial resistance observed.

The development of microbial resistance in patients using a triclosan-containing toothpaste has been carefully studied. Six long-term clinical studies (6–60 months) in approximately 1,000 patients concluded that there was no significant adverse shift in flora comprising the normal plaque, nor the periodontopathogenic, cariogenic, or opportunistic microbes. Moreover, no resistant strains emerged over the experimental period of 6–60 months after dentifrice usage.

The results of these earlier studies are supported by findings from a five-year clinical study in over 500 patients using Colgate® Total® Toothpaste.32 This study evaluated both clinical and microbiologic endpoints in the active group compared to the controls. Results showed

Safety of Colgate Total

Safety of Long-Term Use of Colgate® Total® Toothpaste in Humans

Government agencies and health officials around the world support the use of triclosan where efficacy and safety has been demonstrated, as is the case with Colgate® Total® Toothpaste.34-36 These agency reviews include:
- U.S. Food and Drug Administration;35
- U.S. Environmental Protection Agency, Cancer Assessment Review Committee (2005);34
- Health Canada;36
- Commission, Scientific Committee on Consumer Products (2009);37 and
- Australian Industrial Chemicals Notification and Assessment Scheme (2009).38

The reviews showed that no studies documented adverse human health outcomes from the use of triclosan in toothpaste. The levels of triclosan used in toothpaste and other consumer products have been determined by these regulatory agencies to be safe, efficacious for oral health, and not harmful to human health.

Additionally, as part of a company’s approval under the U.S. Food and Drug Administration (FDA) New Drug Application (NDA) process, if the company becomes aware of any serious adverse event, they are required to immediately report it to the FDA. All adverse events must be monitored for trends as part of a signal detection process. In the nearly 18 years that Colgate® Total® Toothpaste has been on the market in the United States, there has been no signal of a safety issue from adverse event reports. It is noteworthy that Colgate® Total® is the only FDA-approved toothpaste that has gone through the rigorous NDA process — the same process used to review the safety of prescription drugs.

Triclosan Does Not Induce Local or Systemic Bacterial Resistance

Resistance of oral microorganisms to triclosan has not been demonstrated clinically. It is hypothesized that microorganisms fail to develop resistance because triclosan exerts its antibacterial properties through multiple, dose-dependent mechanisms. Further, several publications document the existence of multiple sites/modes of action of triclosan.40 Its primary site of action is thought to be at the cytoplasmic membrane, resulting in interference with uptake of amino acids, uracil, and other nutrients. At higher concentrations (more typical of those associated with toothpaste use), membrane lesions and leakage of cell contents are observed leading to cell death.41 Thus, triclosan exerts its effects through multiple mechanisms, and this is thought to explain the lack of microbial resistance observed.

The development of microbial resistance in patients using a triclosan-containing toothpaste has been carefully studied. Six long-term clinical studies (6–60 months) in approximately 1,000 patients concluded that there was no significant adverse shift in flora comprising the normal plaque, nor the periodontopathogenic, cariogenic, or opportunistic microbes. Moreover, no resistant strains emerged over the experimental period of 6–60 months after dentifrice usage.

The results of these earlier studies are supported by findings from a five-year clinical study in over 500 patients using Colgate® Total® Toothpaste.32 This study evaluated both clinical and microbiologic endpoints in the active group compared to the controls. Results showed...
that clinical efficacy was maintained for the five-year period. Measurements of dental plaque bacteria (*P. gingivalis*, *P. intermedia*, and *A. actinomycetemcomitans*) showed results consistent with the lack of development of resistance by any of the organisms studied over the five years. These studies are summarized in Table 2.

Most recently, a 2014 study analyzed dental plaque samples collected at eleven different times over 19 years from 58 adults using a 0.3% triclosan, 2.0% copolymer, and 0.243% sodium fluoride toothpaste. The study also included plaque samples from 97 adults using toothpaste without triclosan. In addition, the susceptibility of supragingival dental plaque collected from subjects who used the triclosan dentifrice for 5–13 years was compared to subjects who used a dentifrice without triclosan. Each sample contained supragingival dental plaque collected from the entire dentition. The samples were cultured in media alone, or in media with 7.5 or 25 g/ml of triclosan. The concentrations of triclosan used in this study were selected based on the MICs (Minimal Inhibitory Concentration) for strains of oral bacteria.

Results showed that the growth inhibition averaged 99.451% (91.200%–99.830%) on media containing 7.5 g/ml triclosan and 99.989% (99.670%–100%) on media containing 25 g/ml triclosan. There was no discernable change in microbial susceptibility to triclosan over time in plaque samples taken over 19 years, including samples from subjects using a triclosan-containing dentifrice for at least five years.

For the susceptibility testing, supragingival plaque samples from both groups demonstrated susceptibility to both concentrations of triclosan. There was no significant difference in triclosan susceptibility between those who regularly used triclosan dentifrice and those who did not (p < 0.05). From this study the authors concluded that the data generated from carefully controlled clinical trials of up to 25 years of daily use around the world fully support the microbiologic safety of Colgate® Total® Toothpaste. 34-38

**Lack of Relevance of Animal Studies**

There have been some questions raised by articles in the public media relative to the safety of triclosan based on data from animal studies. Studies in rats have suggested it causes an alteration of hormones associated with the thyroid gland and reproductive organs, as well as carcinogenic effects in mice. However, it is important to note that animal studies are used during drug development to establish the safety of a product and evaluate its pharmacological effects. To determine drug safety, these experiments rely on high levels of triclosan; in some instances injected directly into the abdomen and at levels thousands of times greater than from exposure through the use of consumer products. Also, the safety evaluation of triclosan includes lifetime exposure studies in laboratory animals such as rats, hamsters, and mice.41

In addition, the potential endocrine effect of triclosan in toothpaste has been assessed in two human clinical studies and neither study showed any adverse effect. In fact, not a single study has documented adverse endocrine health outcomes from the use of triclosan in consumer products. A comprehensive, independent analysis of the scientific literature regarding triclosan-containing toothpaste and endocrine effects was conducted. It was published in the peer-reviewed journal *Critical Reviews in Toxicology*, and affirms the safety of Colgate® Total® Toothpaste relative to endocrine function.45,46

Finally, there is no indication that lifetime exposure to triclosan resulted in an increase in tumor development in rats and hamsters. Tumors found in mice were due to a well-recognized mechanism specific to the species that is not relevant in humans. This non-relevance has been affirmed by regulatory agencies.35-39 Every regulatory agency that has reviewed the safety of triclosan, including its use in Colgate® Total® Toothpaste, has concluded, based on evidence, that triclosan is not carcinogenic in humans.

**Conclusion**

Triclosan in a dentifrice formulation has been used since 1992, with billions of doses applied by consumers. It is remarkable that with such broad use, adverse events reported have been minimal (less than 1/100,000) and are the same as for non-triclosan-containing dentifrices. These users have also had no reports of clinical conditions suggesting the development of opportunistic, pathogenic, or resistant microorganisms, or significant adverse effects on body organs and tissues or oral tissues in studies ranging from six months to five years.

It is noteworthy that 90 clinical studies over 20 years among 20,000 subjects support the safety and efficacy of Colgate® Total® Toothpaste. It comes as no surprise, therefore, that the American Dental Association,
on August 15, 2014, reaffirmed its acceptance of Colgate® Total® Toothpaste for its Seal.

Acknowledgment: The author would like to thank Dr. Srinivas Rao Myneni for his editorial and content assistance.

References

32. (www.epa.gov) USEPA.
33. (www.fda.gov) USFDA.
34. (www.dec.ca.gov) IIDC.
Toothbrushing and Ergonomics

Christine A. Hovliaras, RDH, BS, MBA, CDE

Introduction

As dental professionals in the twenty-first century, we acknowledge that one of the most essential components for optimal oral hygiene care is utilizing the toothbrush to effectively remove acquired pellicle and dental plaque biofilm, thus helping prevent dental caries, gingivitis, and periodontitis. This article will discuss the important role ergonomics plays in tooth brushing, and how we as dental professionals need to select the right toothbrush for our patients based upon their oral care needs and level of manual dexterity, and encourage them through professional recommendation and instruction to brush for at least a two-minute period of time at least twice daily to effectively reach the gumline and tooth surfaces for improved oral health.

The Importance of Ergonomics

Ergonomics refers to the application of scientific knowledge from the fields of anatomy, physiology, mechanics, and psychology to utilize human energy most effectively. Examples of ergonomically developed items include furniture that consumers use in their homes and at the workplaces that are designed to fit a lifestyle by being comfortable and easy to use; as well as toothbrushes that a person can grip and utilize to effectively clean their teeth and gums. Ergonomics should provide a safe and non-threatening environment for continued use of these items on both a daily and long-term basis.

Ergonomics plays a vital role in assisting patients to comply with oral hygiene care at home after they have visited their dental professional for a six-month professional cleaning and oral examination.

When we look at the effect of ergonomics on tooth brushing with a manual or electric toothbrush, there is not an abundance of published research that offers insights in this area. Ergonomics plays a vital role in assisting patients to comply with oral hygiene care at home after they have visited their dental professional for a six-month professional cleaning and oral examination.

Today’s Toothbrushes

The toothbrushes that are offered to consumers in both manual and electric (which includes sonic) options today have evolved with regard to the shape of the toothbrush head, the length of the toothbrush handle, and the length of the bristles. Additionally, flat-trimmed brush heads have progressed to multi-leveled bristle configurations, bristle configuration has also advanced to include polishing cups, handle grip has improved for comfort during tooth brushing, timers have been added to electric toothbrushes to assist consumers in brushing quadrants longer, and thousands of vibrating strokes provided per minute help consumers brush more thoroughly around teeth and the gingival margin to remove plaque biofilm.

Consumers’ Tooth Brushing Times

Consumer studies show that most people will brush their teeth for less than a minute, versus the two minutes that the American Dental Association advises. I would like to highlight two separate studies that review the length of consumer brushing time. The first study, which included two global studies in Zurich conducted by Saxer, et al., reported that consumers’ estimated time they brushed was higher than the actual brushing time; 134.1 to 148.1 seconds and 83.5 to 72.8 seconds, respectively. Gallagher, et al. reported that brushing for two minutes removed 26 percent more plaque than brushing for 45 seconds, thus oral healthcare professionals should reinforce efforts to persuade patients to brush for longer periods of time in order to provide clinically significant oral health benefits.

Another study highlighted the use of powered toothbrushes vs. manual toothbrushes in reducing plaque and calculus levels without formal instruction. The use of powered toothbrushes equipped with timing devices improved overall time spent tooth brushing as compared to using a manual toothbrush. Dentino, et al. reported that 17 percent of manual toothbrush users met the two-minute brushing time as compared to 66 percent of powered toothbrush users. The increased efficacy of the powered toothbrush is related to the small head design, as well as the presence of the timing device to encourage longer brushing times. This study also showed that if subjects were instructed on proper oral hygiene there would be even greater oral care benefits.

Manual and Electric Toothbrushes

When ergonomics is explored in the manual toothbrush category, we can consider the handle and grip design, angulation of the toothbrush head, the design of the toothbrush head to reach posterior teeth, and toothbrush bristles being able to reach the gumline and interproximal spaces to remove dental plaque biofilm and food debris.

With electric toothbrushes, we observe these same elements as mentioned above for manual toothbrushes. In addition, we need to consider if the device is easy to turn on and off, what are the brushing speeds offered to the user, if changes in brushing speeds provide feedback (audible or tactile), what these brushing speeds mean during toothbrushing, rechargeability of the toothbrush device, and the size of the toothbrush and holder, relative to storage and use in the bathroom at home.

The New Colgate® ProClinical™ A1500 Electric Toothbrush

In the fall of 2012, the Colgate-Palmolive Company launched its first electric toothbrush, the Colgate® ProClinical™ A1500 Electric Toothbrush (Figure 1). This sonic toothbrush provides high frequency brush strokes with an audibility range to the human ear as being roughly 20Hz to 20kHz. Three brushing modes are offered (Auto, Optimum, and Deep Clean) and operate at a frequency range between 20,000 – 32,500 strokes per minute.

This engineered sonic-powered toothbrush provides the latest technology in the Auto mode, which allows the brush to adjust its audible speed while the user moves the handle in any direction in the oral cavity without having to change speed manually. This is a desirable option; the toothbrush does the work of brushing for the user, allowing
the experience to be more pleasant and enjoyable. In low-speed, the Colgate ProClinical A1500 toothbrush head will perform a back and forth sweeping motion to brush the buccal and lingual surfaces of the teeth.

The Optimum mode operates at mid-speed at a frequency of 27,000 strokes per minute and moves in up-down and side-to-side strokes to clean the gumline at a 45° angle. This electric toothbrush utilizes an LED display that lights up on the handle when the consumer is brushing at a 45° angle along the gumline (Figure 2a).

The Deep Clean mode operates at a frequency of 32,500 strokes per minute, with up-down strokes that clean deep in between and behind teeth and the occlusal surfaces of teeth (Figure 2b).

Figure 1. The Colgate ProClinical A1500 electric toothbrush.

Figure 2. Visual photograph of the Optimum Mode brush head movement operating with up-down and side-to-side strokes. a. Visual photograph of the Deep Clean Mode brush head movement operating with up-down strokes. (From: J Clin Dent 2012;23[Spec Iss A]:A1-4. Reprinted with permission.)

This electric toothbrush contains accelerometers, which are electric sensors that adjust speed and motion to assist in measuring acceleration forces based upon the location of the toothbrush head in three dimensions. The accelerometer will adjust the speed and action of the toothbrush head based upon its location in the mouth.

Ergonomic Evaluation of the Colgate ProClinical A1500 Electric Toothbrush

This is the first electric toothbrush to be evaluated by the Metaphase Design Group, considered the ergonomic experts in the field. Two separate studies evaluated the ergonomic elements of the Colgate ProClinical A1500 electric toothbrush and consumer usability. The first study compared the Colgate ProClinical A1500 electric toothbrush to the Sonicare FlexCare and Oral-B Smart Series electric toothbrushes. Ergonomic experts evaluated the three brushes for one week and assessed the following ergonomic principles: grip design; handle length; use of controls; and sound audibility.

The investigators concluded that each of the three electric toothbrushes had adequate grip controls to properly handle the toothbrush, and provided easy access to the on/off control button. The Colgate ProClinical A1500 had the most distinct feature with the longitudinal shape of the handle, and that the handle angled downward from the top, which provided additional control when gripping the toothbrush and improved ability to see the brushing area in the mouth while the brush was in use (Figure 3). The Colgate ProClinical A1500 provides ease of use with its changing speeds when used while tooth brushing; brush movements and sound change occur during changes in brushing speeds.

The second study was a usability study with 14 participants, each instructed to use the Colgate ProClinical A1500 electric toothbrush twice daily for 3 weeks. Four toothbrush trials were conducted and videotaped during weekly visits to the study site. Participants also videotaped themselves brushing with their manual toothbrush at home, which was the baseline evaluation for this study.

Participants who were included in this usability study for a 3-week period did increase the length of the tooth brushing with the Colgate ProClinical A1500 electric toothbrush, due largely to the sensing and control technologies built into the product. When participants brushed with their manual toothbrush in this study, they brushed for only 54 seconds. When they brushed with the Colgate ProClinical A1500 electric toothbrush, their brushing time averaged from 99 to 107 seconds during Trials 1, 2, and 3. The users had a positive brushing experience being able to manipulate this electric toothbrush in their mouths and brushing in the recommended angle. Participants commented that their teeth were cleaner after using the brush and the handle was lightweight and easy to clean back teeth.

Toothbrush Handle and Head Design, Interchangeable Heads, and Portability

The Colgate ProClinical electric toothbrush has a cylindrical-shaped handle to allow the user to easily manipulate and rotate it in their hand. The handle angles downward at the top and provides a notch for the
index finger to hold the brush securely and keep the brush head in line with the handle to position and place the toothbrush in the mouth. The on-off button is easy to access with the thumb, and the brushing modes are easy to observe and operate (Figure 4). The toothbrush head is smaller than other commercially available power toothbrushes and able to clean hard-to-reach areas in the posterior of the mouth. The tapered outside bristles clean deep along the gingival margin.19–20

The Colgate ProClinical A1500 requires a 16-hour charge before it can be used the first time; after that it will not need to be recharged for 4 to 5 days.

Figure 4. Colgate ProClinical A1500 Electric Toothbrush controls and user interface. (From: J Clin Dent 2012;23(Spec Iss A):A26-30.)

Conclusion

Ergonomics plays a vital role in the development of manual and electric toothbrushes to assist patients in complying with the oral health recommendations of dental professionals. The Colgate ProClinical A1500 provides the important ergonomic features, such as grip design, handle length to reach posterior teeth, ease of use, and differentiating sounds to identify the angle of toothbrush. The brush guides the user to the area and angle they should be brushing, and reach a 45° angle to brush the gumline as well as interproximal and occlusal surfaces to effectively clean the teeth. Study participants have brushed longer with the Colgate ProClinical A1500 electric toothbrush and have had cleaner teeth and a positive tooth brushing experience for improved patient compliance and optimal oral health.

References

The Benefits of Incorporating a Therapeutic Rinse for Gingival Health

Emily Boge, RDH, BS, MPAc

The dental community recognizes that oral health means much more than a dazzling set of white teeth. To us, oral health includes the stability of hard tissues, the strength of the chewing muscles, the productivity of the salivary glands, and the health of the oral soft tissues and lips. Maintaining the condition of the entire oral cavity is vital for maintaining the strength of the dentition. Without any of the key pieces, the health of the oral cavity is incomplete. Unfortunately, many patients do not understand this concept, so we must bridge this disconnect on a worldwide scale and help establish a healthy preventive knowledge base. By assisting patients in finding an effective home care regimen, we will improve the health of the oral cavity. In this article, we will discuss the importance of including an oral rinse as an integral part of a daily care regimen to build a foundation for gingival health.

The burden of oral disease is a global concern. As the percentage of older adults continues to grow worldwide, chronic disease is a major concern, and these chronic oral conditions include gingival inflammation and periodontal disease. Poor oral health is not only found in this mature category of people, but across all age groups. The incidence of oral inflammation must be addressed as these conditions continue to be associated to other chronic diseases affecting international populations. The challenge of educating populations on the topic of gingival inflammation and periodontitis lies in establishing programs and products that will address these concerns into the future. During this time of emerging research, science is available to identify products that are effective and to recommend them to those who will benefit from their use.

Compliance with effective techniques such as e-wrap flossing, sucrilic tooth brushing, and the use of interproximal dental aids can present a challenge to patients. Using a mouthrinse can assist patients in the removal of food particles, plaque, and plaque acids. Choosing an effective oral rinse can be challenging, as the combinations of oral microflora vary from patient to patient. In addition, each patient presents with extenuating medical conditions that might also vary their level of saliva, immunocompromisation level, and susceptibility to bacterial adherence. Multiple antiseptic mouthrinses are on the market today, both over-the-counter and by prescription. These oral rinse formulas are used for both their therapeautic and prophylactic qualities, and clinicians must educate themselves on both oral rinse composition and indications for use.

In addition to basic ingredients such as cleansers, water, flavors, colors, and alcohol, manufacturers often use scientific research to add medicaments for patient benefit. Fluoride is often added for remineralization and antimicrobial benefits, depending on which type of fluoride is chosen. Manufacturers add antimicrobial agents to target bacteria that contribute to gingival inflammation, and to assist in the reduction of dental caries, periodontitis, and halitosis. Herbal formulations and cultural oil rinsing techniques are also emerging with a high level of patient popularity. These formulations, however, have limited scientific research or support. The formulation for each individual rinse determines the health value of the rinse to the patient. Since there are many health requests made by patients, there are numerous rinses on the market today, generally falling into one of three categories: cosmetic, tooth decay prevention, and periodontal inflammation reducing.

While tooth decay is certainly one of the most predominant oral diseases affecting the human population worldwide, inflammatory periodontal disease is the focus of this discussion. Despite large strides made in the field of oral disease prevention, the incidence of gingival inflammation continues to grow. As clinicians, it is imperative that we have a clear understanding of various medicaments available to assist our patients in using these agents as an adjunct to the treatment received in-office. Rinses vary in composition, with the most effective power to reduce biofilm-induced gingival inflammation found in one of three categories: chlorhexidine gluconate, cetylpyridinium chloride, or essential oil compounds. Each of these compounds can effectively reduce the growth of various species of plaque bacteria.

Essential oil (EO) compound rinses have been available over the counter in the United States for over 100 years. EO rinses effectively reduce aerobic bacteria with a low incidence of staining.

Chlorhexidine gluconate (CIX) oral rinse (0.12%) continues to be considered the “gold standard” in antimicrobial rinses, and is available by prescription only in the United States. Colgate® PeriGard® Rinse is a brand name of CIX rinse, and has been shown, in a five-week study, to reduce both anaerobic and aerobic bacteria without changes in bacterial resistance, causing overgrowth of potentially opportunistic bacteria or adverse changes in oral microflora. Chlorhexidine gluconate is generally used between professional visits as part of a periodontal maintenance program for treating gingival inflammation and swelling, often measured by bleeding upon periodontal probing. CIX has been linked to an increased amount of supragingival calculus and staining, but for those who are battling chronic periodontitis, CIX can be an effective medicament in a rinse solution.

Cetylpyridinium chloride (0.05 to 0.075%) is a compound with powerful antiseptic properties that can be found over the counter globally in rinses with and without alcohol. Cetylpyridinium chloride rinse (CPC) inhibits aerobic and anaerobic micro-organisms associated with dental caries, gingival inflammation, periodontitis, and halitosis. Some formulations of CPC may cause brown staining of the teeth and tongue due to the method of action of the medicament, yet the over-the-counter effectiveness in the reduction of gingival inflammation offsets the presence of stain in terms of overall oral health. Colgate-produced rinses which contain 0.075% CPC are sold under the Colgate® Total® Rinse brand in the United States, the United Kingdom, and Canada, and under the Colgate® Plax Rinse brand outside the United States.
The challenge faced by dental professionals is the acceptance and compliance by patients with the inclusion of a daily therapeutic rinse during oral hygiene. It is well known that patients do not brush for the recommended amount of time, and most do not floss, so asking them to add another step is very demanding. However, as professionals we must advise our patients regarding the beneficial effects that adding a therapeutic rinse can have, both in treating existing disease and preventing future disease. Balancing the normal oral flora while eliminating pathogenic bacteria is a challenging act for patients and their clinicians. Yet the addition of an oral rinse to the daily homecare routine can help a patient reduce the chances of gingival inflammation. The addition of a rinse, such as Colgate Total or Colgate Plax, to a twice-daily regimen of tooth brushing, can improve the control of plaque and the diseases it causes. It is an easy step that will have both therapeutic, as well as cosmetic benefits.

*Emily Boge, RDH, BS, MPAc is currently a health sciences public administration master’s degree candidate at Upper Iowa University. She has practiced dental hygiene since 2003 in Manchester, Iowa, USA. Emily is also the owner of Think Big Dental, a consulting and writing firm specializing in educating professionals on the role of a dental hygienist.*

References

Oil Pulling and Oral Health: A Myth or a Reality?

S.G. Damle, PhD, MDS, FDS, RCS, FAMS

Introduction

Ayurveda is a holistic system of medicine that evolved in India some 3000–5000 years ago. It is a system of traditional medicine native to the Indian subcontinent, now practiced in other parts of the world as a form of consequent medicine. Ayurvedic medicine is one of the world’s oldest whole body remedial systems. The concept of healing is based on the association of the body with mind and spirit. The best analogy is that of a tree whose roots are nourished so that it becomes strong and able to fight off stress and disease.1 Today, health is becoming more of an article of trade to be purchased, whereas in Ayurveda it is held that health is a way of life, to be inculcated as a culture.

The earliest inscription on Indian medical systems appeared during the Vedic period in India; the Sūruta Sāṃhitā and the Cāraka Sāṃhitā are its earliest trustworthy texts. Over the centuries, Ayurvedic practitioners formulated an extensive array of medicinal compounds for the treatment of various ailments and diseases. In recent years, harmonizing and unconventional medicine are gaining popularity over conventional allopathic medicine as the products and practices used are natural and safe.2 There is a provision of self treatment with an added advantage of cost effectiveness.

Oil Pulling

Oil pulling is a powerful detoxifying Ayurvedic technique that has gained statutory rank as a complementary and alternative remedy.3 Oil works wonders as a natural cleaner for oral health. The therapy is preventive and, at the same time, curative. With its use, surgery and its possible complications can be prevented for a number of chronic illnesses. The vitalizing aspect of this healing method lies in its simplicity.

Oil pulling is a procedure that involves swishing oil in the mouth for oral and systemic health benefits. It has its mention in the Ayurvedic text Cāraka Sāṃhitā where it was called Kavala or Gandusha, and is claimed to alleviate about 30 systemic diseases ranging from headache and migraine to diabetes and asthma. Oil pulling has been used extensively as a traditional Indian folk remedy for many years to prevent oral malodor, bleeding gums, dryness of throat, and cracked lips, and for strengthening teeth, gums, and the jaw, as well as preventing tooth decay.4 However, there are very few clinical trials evaluating the effect of oil pulling therapy on oral health.

Oil Pulling Therapy

Oil pulling therapy can be done using oils like sunflower oil or sesame oil. The Sesamum indicum of the Pedaliaceae family has been considered a gift of nature to mankind for its nutritional qualities and desirable health effects. Sesame oil is considered to be the king of oil due to its beneficial effects.5 A tablespoon of sesame seed oil is taken in the mouth, sipped, sucked, and swished between the teeth for 10 to 15 minutes until the oil loses its thickness and becomes milky white in color. Then it is expectorated and the mouth is rinsed thoroughly with water several times. It is preferably practiced during early morning on an empty stomach and can be done for a maximum of three times in a day in case of acute diseases.6 There is no contraindication for the practice of oil pulling except for use in children below the age of 5 years, as they find difficulty in swishing and there is a chance of aspiration and swallowing.

Since the world has become so widely dispersed in ethnicity, the likelihood of encountering a patient who practices oil pulling is very possible.

Oil pulling is simple to practice, cost effective, and does not cause any staining of teeth, persistent taste, or known allergic reactions. Oil pulling is an interesting theory without any stated negative effects. Since the world has become so widely dispersed in ethnicity, the likelihood of encountering a patient who practices oil pulling is very possible.7

How Does It Work?

How can swishing oil provide these therapeutic benefits? Two schools of thought have been put forth to explain the mechanism.

Some researchers claim that swishing of oil in the mouth activates enzymes and draws toxins out of the blood. Sesame seed oil has a high concentration of polyunsaturated fatty acids and is a good source of vitamins.8 The antioxidants present in sesame seed oil include sesamin, sesamolin, and sesaminol. These ligands act as detoxificants, antioxidants, are able to potentiate the action of vitamin E, and prevent lipid peroxidation; its antibiotic effect helps in the control of microorganisms. Sesamin has been found to inhibit the absorption of cholesterol as well as its production in the liver, reduce lipogenesis, and exhibit an antihypertensive action. However, the exact mechanism of the action of oil pulling therapy is still not fully understood.

The second hypothesis is based on simple biology. Most of the microorganisms that are part of oral ecology in the mouth consist of a single cell with a fatty membrane making up the outer wall of the cell. When the oil pulling is done, these fatty membranes are attracted to the oil while the oil is pulled or swished. During swishing of the oil around teeth and gums, bacteria hiding in the crevicular space of the gingival tissue and exposed tubules within the teeth are sucked out of their “hiding places” and become a part of the thick foam that is formed during oil pulling. This is the reason one needs to pull oil in the mouth for a sufficient duration of time to pull all the microbes from the mouth.9 The saliva and oil together can attract and pull all the food particles, and cleans and frees an individual’s mouth from harmful substances and maintains overall health and the body’s capacity to self heal. However, as with the first hypothesis regarding mechanism of action, there is little research to support the second hypothesis.

Oil pulling appears to work by removing all types of microorganisms and reducing the number of potentially harmful ones. But clinical research needs to be carried out to prove its effectiveness on positively altering the bacterial load in the mouth, as well its effects on the soft tissue. Researchers have tried various ways to alter the bacterial micropopulations in people’s mouths. These populations can be altered by mechanically cleaning the teeth, using antisepic toothpastes or mouthwashes, and even taking antibiotics. However, the ordinary
inhabitants and their relative proportions reestablish, on their own, in due course of time. Killing oral bacteria helps to reduce their numbers, but it does not change the types of organisms that thrive in mouth. So-called “friendly organisms” can inhibit or even kill the more troublesome ones. Oil pulling is very unlikely to cause any such damage with routine use.³ Some researchers have suggested that after oil pulling in the mouth, the mouth should be swished with warm water to remove the biofilm, whereas another school of thought recommends the use of salt water which will act as an antimicrobial and reduce tissue inflammation. Amith, et al.⁴ reported significant improvement in plaque scores, while Asokan, et al.⁵ demonstrated its effectiveness in inhibiting microorganisms.

In the very near future, it is possible that oil pulling will open new avenues in oral healthcare. A 2009 study was conducted by Asokan, et al.⁶ to evaluate the effect of oil pulling with sesame oil on plaque-induced gingivitis, and to compare its efficacy with chlorhexidine mouthwash. A total of 20 age-matched adolescent boys with plaque-induced gingivitis were selected randomly into the study to be in the oil pulling group, a control group, or a chlorhexidine group. Plaque index and modified gingival scores were recorded and baseline plaque samples collected. At the conclusion of the study, there was a statistically significant reduction of the pre- and post-values of the plaque and modified gingival index scores in both the study and control groups. Oil pulling therapy showed a reduction in the plaque index, modified gingival scores, and total colony count of aerobic microorganisms in the plaque of adolescents with plaque-induced gingivitis.

Thaweboon, et al.⁷ in 2011, conducted a study to investigate the effect of oil pulling using coconut oil, corn oil, rice bran oil, palm oil, sesame oil, sunflower oil, and soy bean oil on biofilm models formed by Streptococcus mutans KPSK2, Lactobacillus casei ATCC 6363, and Candida albicans ATCC 13803 on salivary-coated microtiter plates. Saline solution and 0.2% chlorhexidine gluconate solution were used as negative and positive controls, respectively. The investigators found that coconut oil exhibited antimicrobial activity against S. mutans and C. albicans. Sesame oil had antibacterial activity against S. mutans, whereas sunflower oil had antifungal activity against C. albicans. However, L. casei was found to be resistant to all tested oils. Thus, they concluded that oil pulling therapy could probably be used as a preventive home therapy to maintain oral hygiene against dental caries, especially in developing countries.

Conclusions

Ayurveda is the science of healing and rejuvenation based upon universal principles. Oil pulling is a form of Ayurveda. It should be noted that sufficient scientific research has not been carried out to evaluate the effect of oil pulling therapy on oral health, and this needs to be addressed.

In the very near future, it is possible that oil pulling will open new avenues in oral healthcare, but the current evidence-based data is inadequate and unconvincing. Nonetheless, it might be considered of some value when used as an adjunct to preventive home therapy in developing countries.

Professor Danle is Vice Chancellor, Maharishi Markandeswara University, Mullana (Ambala) Haryana (India), and Professor of Pediatric and Preventive Dentistry in Maharishi Markandeswara College of Dental Sciences & Research, Mullana.

References


The newly expanded 370-page edition contains updated findings in the study of the relationship between oral and systemic health. Chapter authors include 32 scientists from dentistry and medicine, each on the cutting edge of global research in this growing field. It is a must read for medical and dental practitioners.

In the words of Editors Robert J. Genco and Ray C. Williams, “The integration of medicine and dentistry grows daily, and a common resource such as this textbook can serve as a constructive tool to help the two disciplines work collaboratively. We are hopeful that this textbook will find broad readership and will be useful to the dental and medical communities and—most important—that it will result in better general health as well as oral health.”

The complete textbook will be freely accessible at www.colgateprofessional.com, as well as on the Colgate Oral Health Network (http://www.colgateoralhealthnetwork.com). An e-book version is planned and hard copies will be available on a limited basis.