The Clinical Implementation of Salivary Diagnostic Testing for Risk Assessment in Periodontal Disease

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Periodontal disease is an inflammatory disease of the supporting tissues of the teeth, which is caused by specific microorganisms or groups of microorganisms living in a biofilm, on and around the teeth. Microorganisms initiate an immune response, and in some cases the result is progressive destruction of gingival tissues, the periodontal ligament and alveolar bone. Disease progression is characterized by increased pocket formation, recession, tooth mobility, and in some cases, the eventual loss of teeth.\(^1\)

For many practitioners, the traditional standard of recording bleeding, pocket depths, and bone loss seems to simply provide historical information about a patient’s periodontal disease progression. What has been missing is a reliable way to determine the pathogens present and the current microbial makeup of a patient’s specific disease.

Traditional subjective observations fail to provide information about the specific causative agents, their identity and concentration. As well, they do not quantify the change in the microbial profile after therapy. Add to this, the patient’s individual immune response, and we can certainly see the need to consider utilizing technology to facilitate an ideal outcome. This paper will describe a novel approach to optimize diagnosis and treatment of periodontal disease for a more predictable outcome.

SALIVARY TESTING IN DENTISTRY

With the availability of saliva testing today, we can collect microbial data, determine genetic predisposition and monitor the elimination or suppression of disease causing agents during therapy.

OralDNA® Labs is a specialty diagnostics company that offers saliva screening by three DNA-polymerase chain-reaction (DNA-PCR) tests based on bacteria, genomics and viral load. Two of these tests will be discussed below.

The first is a bacterial test, MyPerioPath®, which is used to detect periodontal disease, specifically pathogenic bacteria (Fig. 1). This helps guide therapy based on causative agents and not on subjective observation. Additionally, the results of the test will identify tissue invasive bacteria and suggest adjunct oral and locally applied antibiotic protocols if needed (Fig. 2). After therapy is completed, a follow-up sample will help monitor the efficacy of treatment and determine if additional measures are required.

The second test is based on the individual’s genetic response to inflammation (Fig. 3). MyPerioID® is a genetic susceptibility test which needs to be performed only once in a patient’s lifetime. The Interleukin-6 (IL-6) gene variance in a patient’s DNA is an indication of a predisposition
for over-expression of inflammatory mediators. Over-expression of inflammatory mediators can increase the risk for attachment loss or periodontal disease activity. This test result will either be positive or negative. Knowing this information will help determine genetic risk prior to extensive therapy and can help guide therapeutic decisions. Knowing their genetic susceptibility can also help patients understand the severity of their disease and why they might struggle in controlling it. This is additionally helpful for patients with therapy resistant periodontitis or aggressive infections where host modulation therapy is needed.

In summary, both MyPerioPath® and MyPerioID® enable early identification of risk, and therefore, an opportunity to further personalize care. Without personalized therapy, the patient may continue to experience unresolved infection after therapy and the further spiral of periodontal breakdown.

Saliva as a diagnostic tool offers numerous advantages when used to monitor health or to detect disease. First and foremost, it is safer, easier, more accessible and less expensive than blood tests. For the patients, it is non-invasive, meaning that there is no pain from injections and no need to go to a laboratory for blood draw or a finger pricking. Patients also appreciate the concept that this new technology results in a personalized periodontal therapy approach, based on their individual risks and that is not a one-size-fits all protocol.

In fact, Dr. M. Hughes, Deputy Director for Human Genome Research, NIH, stated “Molecular diagnostics based on DNA-PCR technology is the most important new scientific technology to come along in the last one hundred years”.

We have often heard that the saliva is “the mirror of the body”. In 2002, Dr. David Satcher, former Surgeon General, stated that the mouth is “a sentinel of disease and it is critical to overall health and wellbeing”. In fact, salivary bio-fluid has been used for years as a diagnostic medium in nutritional and metabolic assays, endocrinology, immunology, hormonal status and many other indices to easily mirror the entire spectrum of normal and disease states. The ability to explore specific biomarkers associated with health or disease of an individual is of tremendous benefit to patient care.

The ability to now recognize the onset and progression of disease, monitor health status, and evaluate treatment outcomes through non-invasive means, such as salivary testing, is a huge step in health care advancement and patient care.

**ORAL SYSTEMIC LINK**

One hundred million Americans are infected with periodontal disease. It is recognized to increase risk for diabetes, heart disease, stroke and other systemic diseases. One out of every two American adults over age 30 has gum disease, according to the Center for Disease Control and Prevention (CDC). The findings, published in the Journal of Den-
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The findings are based on data collected as part of the CDC's 2009-2010 National Health and Nutrition Examination Survey (NHANES), a program of studies designed to assess the health and nutritional status of adults and children in the United States.

Current scientific evidence links periodontal disease to a myriad of health problems, such as pneumonia, chronic respiratory disease, heart disease, preterm and low-birth weight babies. One study published in Cardiovascular (1999) reported that among Canadians aged 36 to 69, individuals with severe gum disease have a three to seven times higher risk of fatal heart disease. Researchers also found that those with poor oral health may be up to three times more likely to have a stroke.4

You may be asking yourself what these findings have to do with salivary bacterial DNA testing and dentistry? Bacterial DNA is the key to finding out if the patient is at risk from a microbial burden or genetically predisposed to an exaggerated response to inflammation. Both are contributory and put the patient at risk for treatment failure. Other risk factors include smoking, diabetes, alcohol consumption, hypertension, physical inactivity, obesity and other metabolic syndromes5. These factors increase the risk of periodontitis and should be identified as red flags during the initial data collection appointment.

The lab results will provide clarity as to the microbial etiology of inflammation and the basis of antimicrobial consideration

The OraRisk HPV® is the third screening tool that identifies HPV status, now recognized as a separate risk factor for oral cancer.

All three tests consist of a sterile saline ampule, funneled collection tube with screw cap, two barcode labels (including one for the patient chart), and a plastic specimen bag (Fig. 4). To begin the testing process, the patient’s name and date of birth are recorded on the barcode label. The label is then affixed lengthwise to the collection tube.

Saliva collection must be done prior to any therapeutic debridement, polishing, rinsing, or other disturbance of the oral environment. The procedure is as simple as swishing vigorously with a sterile saline solution and expectorating in the carrier. A prepaid postage label is generated after manually inputting the patient’s information on the test acquisition page.

Within five to six days, the MyPerioPath® report is delivered via email for review. The report includes laboratory confirmation of the presence of high, moderate and low-risk pathogens and the appropriate antibiotics for treatment, as well as other treatment recommendations. The MyPerioID® report states whether the patient is positive or negative for Interleukin-6 with the genetic predisposition for a heightened inflammatory response.

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treatment of perio infections and maintenance therapy.6

Directing therapy against known organisms with known antibiotic concentrations produces a better disease management outcome.7

Let’s take a look at an example of treatment and management of periodontal disease using salivary diagnostics (courtesy of Dr. Douglas Thompson, Bloomfield Hills, MI).

**CASE REPORT AND CLINICAL RISK ASSESSMENT:**
- Past history of SRP in selected areas (2005 repeated 2007)
- Periodontal pockets 2mm-4mm
- Generalized Recession
- Clinical attachment loss up to 5mm
- Increased bleeding charted at re-care visits
- <20 percent prior bone loss

**MEDICAL RISK ASSESSMENT:**
- Smoking (1/2 pack daily for 30 years)

In late 2008, active disease was diagnosed, represented by nine bleeding sites during periodontal charting. However, the clinical presentation did not show obvious inflammation under visual inspection. Radiographs represented bone loss of < 30 percent, Class I furcation involvement, and generalized moderate to clinically severe attachment loss (a combination of pocket depths and prior recession).

**TREATMENT**
Upon detection of inflammation represented by bleeding, the office collected saliva for the initial MyPerioPath® assay. The test results indicated the presence of pathogenic bacteria with a large pathogen load over threshold (Fig. 5).

Four quadrants of SRP were initiated using a combination of ultrasonic and hand scaling, followed by chemotherapeutic irrigation with chlorhexidine. No other treatment modalities were used.

At the 7-week disease reevaluation, periodontal charting showed improvement in pocket depths and reduction in bleeding sites to five. A post treatment test using MyPerioPath® was administered. The clinical results after conventional SRP produced improvement in bleeding and pocket depth. However, the post treatment microbial test (Fig. 6) showed little to no effect on the pathogen profile. Realizing that conventional treatment did not affect the microbial profile, it was evident that there was a need to take a more comprehensive approach. This approach to disease treatment employs a total mouth disinfection methodology and includes other microbial control agents.

**An outline of the total mouth disinfection protocol is as follows:**
1. Occlusal analysis to identify and remove any fremitus in chewing.
2. Attack the bacteria in the pockets mechanically using scaling and root planing.

**FIGURE 5**—Clinical Study—Initial lab results, indicating initial pathogenic bacteria load
**FIGURE 6**—Clinical Study—Lab results after total mouth disinfection indicating the need for a more comprehensive approach to therapy.
**FIGURE 7**—Clinical Study—Lab results after two-month re-evaluation with clinical establishment of zero bleeding. Microbial profile was altered through eradication, suppression or alteration of bacterial load.
4. Deposition of a locally applied time-release antibiotic, Arestin® (OraPharma, Inc., www.orapharma.com) in all pockets equal to or greater than 5mm.
4. Attack the bacteria in the bloodstream with the antibiotic regimen suggested on the OralDNA report.
5. Attack the bacteria in the rest of the oral cavity with CariFree Treatment Rinse, ProFresh (ProFresh International Corp., www.profresh.com) or other chlorine dioxide rinse to control microbial load. The rinse protocol is to swish for one minute, twice daily.
6. Prescribe home care adjuncts such as a mechanical toothbrush, Waterpik® (Water Pik, Inc., www.waterpik.com) or Hydroflosser (Shazzam Tsunami™, Bling Dental Products, www.blingdentalproducts.com) and interproximal aids, etc., for enhanced bacteria load control.
7. Maintain two-month re-evaluation appointments until stability (zero bleeding on periodontal chart) has been achieved.

After formulating a more comprehensive method of a total mouth disinfection to address the unresolved infection in this patient, treatment was reinitiated.

In order to achieve a predictable and successful long-term stabilization of the patient’s periodontal condition, specific home hygiene management protocols were also discussed and followed.

Here is the specific total mouth disinfection protocol followed:
- Full mouth mechanical debridement with ultrasonic scaling and root planning followed by hand scaling.
- Full mouth in office irrigation with CariFree Treatment Rinse.
- Locally applied Arestin antibiotic placement in all pockets 5mm and above.
- Systemic antibiotic as suggested from the OralDNA report – Amoxicillin 500 mg tid for eight days in combination with Metronidazole 500 mg bid for eight days.
- Oral hygiene instructions were reviewed with specific instructions on the use of an electric toothbrush and an oral irrigator.
- CariFree Treatment Rinse was initiated for one minute twice daily for two months to control biofilm on the tongue, cheeks, and areas not supported by the teeth.
• A tight two-month re-evaluation schedule was planned until zero bleeding was established.

Two months after the total mouth disinfection approach was applied, the patient was retested using MyPerioPath®. With the use of total-mouth disinfection, the microbial profile was positively affected through eradication, suppression, or alteration of the bacterial load as evidenced in Figure 7. It is important to note this profile was measured when there was zero bleeding, suggesting gingival stability.

Without the specific baseline data of the initial salivary test, subsequent reevaluation treatment for this patient would not have been modified. Salivary diagnostics provided the information and direction to assist the clinician, and the patient, in achieving optimal health based on individual microbial risk.

CONCLUSION
As the future of dental medicine collaborates with the medical model, we must open our eyes to the power of personalized therapies. The art of stabilizing disease with treatment, based on bacterial and genetic information obtained from the saliva, will eliminate one size fits all programs. Simply using traditional therapy like SRP, oral biofilm and microbial levels return to their pretreatment levels within three to seven days, rendering traditional care ineffective. In order to enhance the effectiveness of our SRP, we should consider antimicrobial therapy and adjunctive methods of microbial control more often. In the authors view, this can be accomplished by offering a simple salivary test, personalizing therapies based on the test results and targeting periodontal pathogens with specific bactericidal agents. This approach produces healthier patients through greater compliance and a greater understanding of the disease process. Understanding the microbial profile empowers the dental team and the patient to collaborate in optimizing therapeutic modalities with the goal of stabilizing disease using personalized protocols.

Debra Z. Sabatini is the founder of the OralED Institute, an educator and author. Her focus is Oral Systemic Health, Oral Cancer Prevention, Oral HPV, Effective Communication, Technologies for Risk Assessment and Personalized Medicine for Optimal Therapy Outcomes. Oral Health welcomes this original article.