Software

An Ounce of Prevention

Space algorithms that came down to Earth are now preventing a major cancer.

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*M*ost people have bitten the inside of their cheek, or burned the roof of their mouth eating pizza, and thus most people have experience with seeing a fair number of red or white spots in their mouth. Small white or red oral spots are extremely common and are typically harmless; however, they sometimes contain cells that may become cancerous if they are not removed.

Oral cancer is a major source of morbidity and mortality in the United States and virtually all other developed countries. It is one of the largest sources of cancer death throughout Asia and is the single largest cause of cancer death in India. In the United States, oral cancer kills more people than either melanoma (skin cancer) or cervical cancer and is as common as all forms of leukemia combined. In both the United States and Europe, oral cancer is rising sharply among women, young people, and nonsmokers. More than 25 percent of U.S. oral cancer victims have no identifiable risk factors and do not use tobacco or abuse alcohol.

OralCDx—a technology that had its roots in DOD's Strategic Defense Initiative and is now being used by over 30,000 U.S. dentists—has made oral cancer a potentially preventable disease.

OralCDx can prevent oral cancer by facilitating routine painless testing of the common, small white and red areas in the mouth that appear in about 10 percent of the adult population. Several years before oral cancer can start, the patient develops a very small, painless, white or red spot that appears identical to a common benign oral spot but that contains precancerous cells. While most oral spots are harmless, up to 4 percent may contain pre-cancerous (dysplastic) cells. When these pre-cancerous cells are detected by OralCDx, the spot can then be easily removed, thus preventing the development of oral cancer years before it can even start.

From Research to Application

In the early 1980s, Mark Rutenberg, CEO and founder of CDx Laboratories (Suffern, NY), was a pioneering neural network researcher in the nascent field of missile defense. The algorithms developed in the course of this research, originally meant for identifying objects embedded in mystifying clutter, eventually proved invaluable for medical diagnostic applications. The first such successful application of Rutenberg's work resulted in the widely used computer-

aided test called PAPNET, which added greater accuracy to the common Papanicolau or "Pap" test for cervical cancer. Derivative systems now marketed as FocalPoint™ by TriPath Imaging continue to be valuable adjunct tools in women's health. CDx Laboratories has combined these imaging algorithms with a new tool in this latest technology, the OralCDx computer-assisted brush biopsy.

The patented OralCDx brush biopsy instrument quickly and painlessly extracts a complete tissue sample from the full thickness of the epithelium underlying the oral spot being tested. This unique tissue specimen is then analyzed by CDx Laboratories. It is at the computer interface at CDx labs where the "Star Wars" imaging algorithms perform their computations and quickly yield a result. The accuracy of OralCDx testing was successfully demonstrated in one of the largest clinical trials ever conducted in oral medicine. The results were published as a cover article in the Journal of the American Dental Association and have since been duplicated in numerous independent U.S. and European studies.
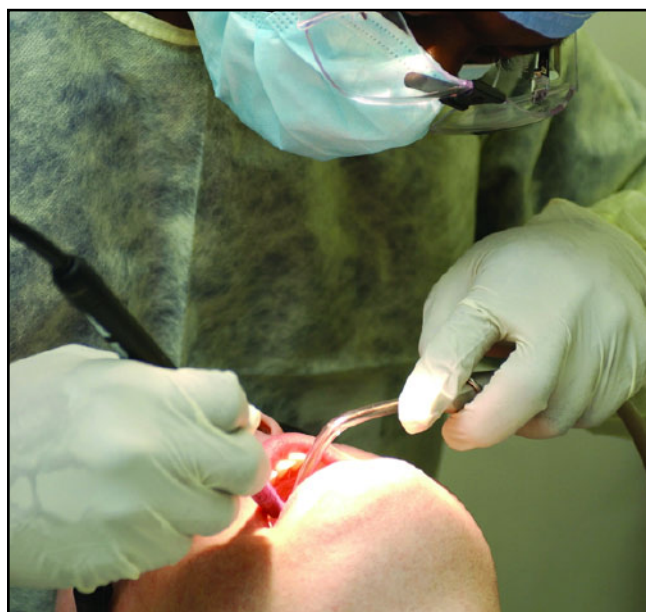
▲ CDx Laboratories is marketing an oral-cancer-detection biopsy brush that can be used during routine dental visits. Dentists can use the brush to collect tissue samples for testing.

OralCDx is now taught as standard practice in the majority of U.S. dental schools. By detecting oral lesions that were about to become cancerous, OralCDx has already been credited with saving thousands of lives.

Gaining Acceptance

All necessary FDA, EU, and other regulatory approvals required to provide OralCDx worldwide have been received. OralCDx testing is a covered benefit by Delta Dental, Cigna Dental, many other dental insurance plans, Medicare, Medicaid, and virtually all other government and private medical health insurance in the United States and abroad.

CDx Laboratories is also in the process of extending this technology's reach into the larynx and esophagus to detect cancers of the upper airway and digestive tract. The same principles underlying OralCDx (sampling by biopsy brush and computer-aided diagnosis) can be applied to these areas. In this application, the product is called EndoCDx and is designed for use in endoscopic examinations for the diagnosis of esophageal cancers, Barrett's esophagus (a pre-cancerous condition), and cancerous and pre-cancerous lesions of the upper airway.

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The latest special report from the MDA Technology Applications program is available online and in print.

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Defining Moments

1980 1985 1990 1995 2000 2005