



DEVELOPING SCIENCE INTRODUCING TECHNOLOGIES

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A Quarterly Publication
from
You First Services, Inc.

You First Services Updates

Since its inception, You First Services, Inc. has been making steady and continuous progress following the benchmarks of a successful corporation. YFS knows its core competencies and follow the best management practices adopting strict regulatory requirements in governance and acquiring the necessary technology to



implement it. Under its corporate umbrella different companies are bringing new healthcare applications to the market impacting the western New York economy and employment opportunities. In a short period of time YFS grew significantly providing substantial contribution to the local economy. The company continues to pursue local, state and federal collaborations and support for its ongoing innovative research endeavors. The company seeks scientific collaborations from various national and international agencies for projects in health care related research. The company has successfully launched

subsidiaries following development of the technologies. With a team of world class scientific researchers, YFS is committed to bring in solutions to many medical issues of concern.

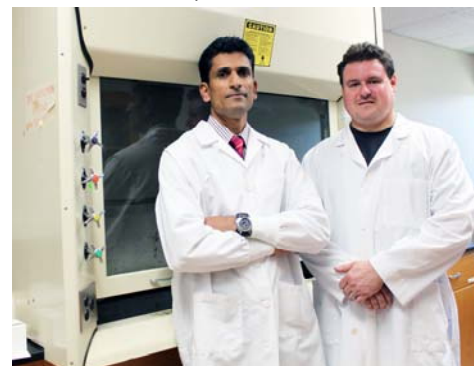
Exploring Clinical and Applied Research

Applied research is critical in device and drug development. YFS considers clinical research is very important and strive to have productive, meaningful research collaboration with the researchers in academia. We will support promising research where the public funding is nonexistent or getting scarce. Societal interests are significantly affected if the research enterprise is impeded or is less robust. Innovative solutions come from research done in a diversified field. YFS is involved in multifaceted research in oral care, infection control, joint pain management, environmental diagnostics etc. to mostly



benefit the suffering population. Another aim of the company is to provide these solutions

to the developing countries who cannot afford it otherwise. Medical research can have an enormous impact on human health and



longevity which in turn contributes hugely to the national economy by increasing the productivity of a healthy population. Introducing these technologies to general population is another major challenge that has to be met with innovative strategies and human resources.

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Obstructive Sleep Apnea and Oral Dryness

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Pulmonary & Critical Care, Sleep Medicine, VA WNY Healthcare System



Obstructive sleep apnea (OSA) is an underdiagnosed silent killer that is characterized by stopping or slowing down of breathing numerous times, while the unaware victim sleeps.[1] The relaxation of the pharyngeal and tongue muscles during sleep, in predisposed individuals, causes the upper airway to collapse, resulting in repetitive apneas and hypopneas causing hypoxic stress to the body. These repeated cyclic oxygen desaturations lead to sympathetic overdrive, which affects almost every system in the body, resulting in an increased incidence of hypertension, cardiovascular disease, stroke, pulmonary hypertension, cardiac arrhythmias, metabolic dysfunction, increased insulin resistance, neurocognitive impairment, mood disorders and altered immune function[2-5]. It also increases the risk of having an accident as a result of excessive daytime somnolence resulting from sleep fragmentation.[6] Studies have also shown OSA to be an independent risk factor for all-cause mortality. [7]

As patients with OSA spend most of their sleep time desperately seeking for air, it is not surprising that they wake up with a dry mouth, as the instinctive physiological response is to open the mouth to allow as much air in as possible. Saliva has important functions in protecting the hard and soft tissues of the oral cavity from acids and pathogenic microbes. Also contributory to the oral dryness may be the circadian rhythmicity in the amount of saliva production that is maximum in the morning and diminishes dramatically during sleep. However, dry mouth upon awakening is not classically included in the key diagnostic signs and symptoms of OSA that are loud snoring, excessive daytime

sleepiness, and witnessed apnea. Although these key features are easily recognizable, they can be largely underreported. Patients may be unaware of their snoring or deny it due to social embarrassment, and they are unlikely to be aware apneic episodes unless reported by a witness/bed partner. Instead of reporting daytime sleepiness many patients feel they are simply tired, fatigued, or lack energy. Dry mouth is a symptom of OSA that is perhaps more readily recognized and reported by patients. Kales et al., reported complaints of dry throat on awakening in 74% of patients with severe OSA. In another study by Oksenberg et al., its prevalence and severity in OSA patients was systematically investigated in adults referred for polysomnographic evaluation (PSG) because of snoring and suspected OSA. Data were obtained from self-administered questionnaires and PSG evaluation. The prevalence of dry mouth upon awakening was twofold higher in patients with OSA (31.4%) than in primary snorers (16.4%, $P < 0.001$), and increased linearly from 22.4%, to 34.5%, and 40.7% in mild, moderate, and severe OSA respectively ($P < 0.001$). The prevalence of dry mouth upon awakening in the control group was 3.2%. Dry mouth upon awakening is undoubtedly a significant symptom of OSA.

Treatment options for sleep apnea include weight loss, positional therapy, oral devices, continuous positive airway pressure (CPAP), and upper airway surgery. CPAP is the

gold standard in the treatment of OSA, and is effective when used regularly and properly. Mouth dryness resulting from leakage of air around the mouth during CPAP is the most frequent side effect reported by patients, even after using humidified air and regardless of the type of mask used. Poor compliance resulting from oral dryness represents a serious challenge to effective treatment and increases the risk of related long term comorbidity when CPAP treatment is discontinued.

We are undertaking a study to address this important issue by trying a novel therapy to address the symptom of oral dryness in patients with OSA.

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[4] A.K. Medeiros, R.Q. Coutinho, I.M. Barros, L.O. Costa, A.P. Leite, M.S. Bittencourt, T.C. Lustosa, M.M. Carvalho, M.P. Lira, M.N. Ferreira, G. Lorenzi-Filho, L.F. Drager, R.P. Pedrosa, Obstructive sleep apnea is independently associated with subclinical coronary atherosclerosis among middle-aged women, *Sleep Breath*, (2016).

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Metallic Taste or Dysgeusia

Bindukumar Nair, Ph.D.



- Glaucoma medications, such as methazolamide
- Osteoporosis medications

Chemotherapy and Radiation

According to the American Cancer Society, certain types of chemotherapy and radiation can cause a metallic taste. This side effect is sometimes called “chemo mouth.” Studies suggest that certain vitamin supplements, such as vitamin D or zinc, can help prevent taste distortion in people undergoing radiation therapy or chemotherapy. This suggests that certain vitamin deficiencies may be a contributor to taste distortion.

Sinus Issues

Sense of taste is closely related to the sense of smell. When sense of smell is distorted, it can have an impact on the sense of taste. Sinus issues are a common cause of metallic taste in the mouth. Sinus issues can be caused by:

- allergies
- the common cold
- sinus infections
- other upper respiratory infections

Central Nervous System (CNS) Disorders

CNS sends messages to the rest of the body, including messages about taste. A CNS disorder or injury, such as stroke or Bell’s palsy, can distort these messages. This can result in impaired or distorted taste.

Pregnancy

Some pregnant women report a metallic taste, especially early in their pregnancy. The cause is unknown, but some believe it’s caused by the

change in hormones experienced during early pregnancy. Others have attributed an increase in the sense of smell, a symptom commonly associated with pregnancy, as the cause.

Food Allergies

Metallic taste has been identified as a symptom of some food allergies. If one experience distorted taste after eating a type of food, such as shellfish or tree nuts, they may have a food allergy.

Middle Ear Surgery

Middle ear and ear tube surgery is often performed due to chronic ear infections, or otitis media. Occasionally, chorda tympani, a structure close to the inner ear that controls taste in the rear two-thirds of the tongue, may be damaged during surgery. This can result in distorted taste or dysgeusia. One case study showed significant improvement in taste with medication management [3].

Oral Health

Poor oral and dental health can contribute to taste dysfunction. Regular dental cleanings and cavity filling can reduce the risk of developing taste changes.

Chemical exposures

Long term inhaling of mercury or lead substances often can lead to a metallic taste.

Dysgeusia is variably defined as an abnormal or impaired sense of taste, an unpleasant alteration of taste sensation, or a distortion or perversion of the sense of taste. Dysgeusia can be described as a bitter, metallic, salty, or unpleasant taste. Dysgeusia is closely linked to changes in olfaction as both taste and smell are involved in producing the sense of flavor. Taste and olfaction provide sensory information and sensory pleasure and it is known that cancer therapies affect both [1]. These alterations affect the daily quality of life of these patients and may lead to patient malnutrition, weight loss and, in severe cases, significant morbidity [2].

Dysgeusia is assessed clinically by measuring the detection or recognition threshold values for the five basic tastes: sweetness, bitterness, sourness, saltiness, and umami (the savoriness of protein-rich foods), either by applying filter- paper taste strips impregnated with various concentrations of a basic taste or, in the laboratory setting, with the use of an instrument called an electrogustometer. However, these methods do not provide qualitative information on taste acuity such as which basic taste perception is most influenced by cancer or its treatment. Qualitative changes are, instead, reported through patient complaints, interviews, and clinical observations [4].

CAUSES

Medication

Distorted taste is a common side effect of certain medications. These medications include:

- Antibiotics, such as clarithromycin or metronidazole
- Blood pressure medications, such as captopril

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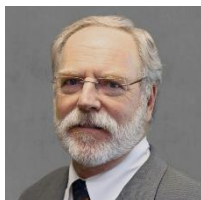
[2] M.Y. Halyard, Taste and smell alterations in cancer patients—real problems with few solutions, *J Support Oncol*, 7 (2009) 68-69

[3] V. Makler, N.S. Litofsky, Successful treatment of dysgeusia after middle-ear surgery with amitriptyline: Case report, *American journal of otolaryngology*, 36 (2015) 456-459.

The Leap from R&D to Commercialization

John M. Barrett,

Chief Executive Officer, You First Services, Inc



So, you have conducted some laboratory research and have found successful outcomes to one or more of your initial hypotheses. Now what do you do? This is the dilemma that confronts researchers on a daily basis. You may have a product or process that has the potential to ‘make a difference’, however, without an experienced team or game plan to move forward, most of the research conducted will end only with a thesis presentation or published paper.

The process to commercialize laboratory research can be long and frustrating. Some early steps in this process, as supported by the National Science Foundation, include identifying and/or developing:

- Key Partners
- Key Activities
- Key Resources
- A Value Proposition
- Customer Relationships
- Channels of Distribution
- Customer Segments/Vertical Markets
- Cost Structure
- Revenue Streams

Additional considerations, if a decision is made by the researcher to work directly on commercialization include the development and related costs needed for:

- Putting together an experienced team to ‘get down the learning curve’ as soon as possible
- Conducting safety and other testing

- Institutional Review Board (IRB) submissions and approvals for Clinical Trials
- Locating medical specialists and/or institutions willing to implement the IRB’s, etc.
- Development of manufacturing protocols, processes and related scale up of production to meet FDA Guidelines
- Development and implementation of a Quality Management System to meet FDA Management Guidelines
- The long & costly process, particularly if FDA submissions and approvals are required

There have been researchers that have followed this model and have had varying degrees of success, based on the length of time needed to address the above issues and the opportunity cost of getting through the entire process. There are also many more researchers that have licensed their intellectual property and/or technology to organizations that are much better positioned to take their work to the next level. For the researcher willing to take the next step, either of these decisions can be difficult, but none the less a decision that only the researcher can make based on their own cost/benefit analysis.

Our Success

New Products

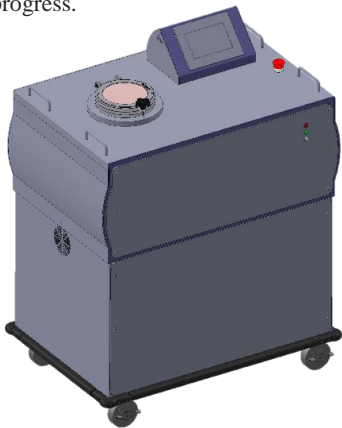
You First Services has successfully developed research based technologies introduced under Independent Companies.



The latest in the series is MetaQil™ (www.metaqil.com), an oral spray which can alleviate metallic taste in the mouth caused by treatment of cancer or various prescription drugs. YFS Inc. continues to carry on multiple research projects in the field of oral health.



Lubricity® is widely appreciated by people suffering from dry mouth and is being evaluated for its efficacy in dry mouth caused by various conditions through clinical studies. The studies are at different stages in the progress.



The plasma cleaner/etcher/Disinfector, GloTran®, successfully undergone electronic safety testing per IEC61010 and is now undergoing further efficacy testing as per the regulatory requirements.

Sterilized Surgical Space

The present sterilization methods are simply inadequate or highly hazardous. Antimicrobial agents dispensed using vapor generators are available for use to disinfect large room enclosures, but typically these types of products are limited for use inside controlled environments due to the toxicity of the concentrated microbial agent. Atmospheric plasmas are also effective at killing micro-organisms bound to solid surfaces, but lack the ability to be effective over long distances and large spaces. Scientists and engineers at You First Services, Inc., focusing on preventing the spread of infectious pathogens in medical equipment re-processing and in other healthcare applications, recognize the importance of clean and germ-free environments and healthcare products not only in the clinic but also in other common and specialty areas and are actively pursuing the development of an innovative and unique product, which will combine different sterilization techniques to sterilize areas most difficult to treat with conventional technologies.

You First Services, Inc. Awarded CAT Grant

You First Services, Inc. has been awarded “University at Buffalo Center for Advanced Biomedical and Bioengineering Technology (UB CAT) Grant, third in a row. The project, “Fabrication of an enduring temporomandibular joint with lubricated fibrous tissue to reduce wear,” is developed in collaboration with the Center for Bio-surfaces and Biomaterials Grad. Program at the State University of New York (SUNY) at Buffalo.

You First Services, Inc. Expansion

In order to expand its operations and accommodate new employees, You First Services, Inc. is pleased to announce that it has moved to a new building with an area of 8000 sq.ft. at 485 Cayuga Rd near Buffalo Niagara International Airport, while keeping the lab space at the Baird Research Park.

Clinical Studies

XEROSTOMIA TREATMENT

A number of patients suffer from xerostomia. Xerostomia may be caused by medications, or various conditions which affect the salivary glands, including Sjogren’s syndrome. These individuals have difficulty in eating, have irritated oral tissues, and a poor quality of life because of this. The clinical study by Dr. Sebastian G. Ciancio, School of Dental Medicine, University at Buffalo, to evaluate the efficacy of Lubricity in reducing the discomfort caused by dry mouth is successfully completed and the data is being analyzed.

IRB Approvals

VAGINAL DRYNESS

Estrogen levels decline during the menopause transition and after menopause. One of the consequences of this normal decline in estrogen is vaginal atrophy, which in many women causes symptoms of dryness, lack of lubrication and dyspareunia. In this study we propose to test a novel lubricating solution for treatment and tolerability in women with symptomatic vaginal dryness.

DRY MOUTH IN SLEEP APNEA

Dry mouth or xerostomia, happens when the mouth doesn’t produce enough saliva for proper lubrication or the saliva produced dries up due to some medical conditions. During routine clinical practice, it is observed that patients with suspected obstructive sleep apnea (OSA) often reported waking up with a dry mouth during the night or in the morning and impacts quality of life. There is an urgent need for an oral care product to make these patients more comfortable

DRY SKIN TREATMENT

Dry skin can be caused by hereditary factors and age-related decrease in naturally moisturizing factors in the skin in addition to the disturbance of the skin barrier by extrinsic stimuli such as weather and chemical agents. This randomized study will investigate the tolerability of a novel lubricating solution in patients with symptomatic skin dryness and its efficacy in minimizing the symptoms associated with dry skin.

WELCOME NEW EMPLOYEES

Daniel Judge



Manager

Sales and Market Development

Brittany Grimmer



Communication Specialist

Collaborators

Vanessa M. Barnabei, MD, PhD

Vanessa M. Barnabei MD PhD is the Professor and Chair of Department of Obstetrics and Gynecology, University at Buffalo. As Chair of the Department she is very involved with health care partners at the University at Buffalo and in the community, focusing on improving the quality and safety of women’s health care. Dr. Barnabei’s long-time clinical focus is the care of women with menopausal and peri-menopausal problems. Menopause and hormone therapy have also been a large part of Dr. Barnabei’s research activities, and she has been an investigator with several of the large clinical trials on the impact of hormone therapy on symptoms and disease, including the Women’s Health Initiative.



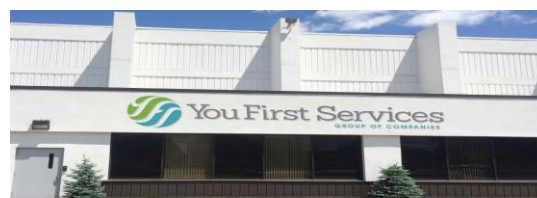
Sawsan Tabbaa, DDS

Dr. Sawsan Tabbaa, is an Associate Professor, School of Orthodontics, Brooks Rehabilitation College of Healthcare Sciences, Jacksonville University, FL. Dr. Tabbaa has earned several awards in recognition of her abilities as a researcher,, an accomplished educator and a caring clinician. In addition to her experience in conventional children and adolescents orthodontic treatment, Dr. Tabbaa’s clinical interest is focused on treating adult/ senior population, fast orthodontics and Invisalign.



YFS Foundation is excited to announce that it has signed a Memorandum of Understanding to collaborate with IIMPACT (www.iimpact.org) a non-governmental organization in India whose primary focus is the education of girl children from socially and economically disadvantaged sections of society. YFS Foundation will sponsor 61 female children between ages 6-14 in Sherpur Village of Alwar district, Rajasthan, India for one whole year in their education.

The YFS Foundation launching and fundraising dinner took place on March 18th at Salvatore’s Italian Gardens Restaurant. During the event YFS Foundation awarded scholarships to two students from schools in the Buffalo School district. Ben Lue was nominated by McKinley High School for his excellent performance in his studies. Abida Tasnim was awarded a scholarship as well due to her nomination by the Buffalo Academy of Science Charter School.



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