Patients Front and Center at the 2018 TMJ Patient-Led RoundTable

Article by Sophia Stone, TMJA contributing author

It is still all too fresh in the minds of many patients. Fifty years ago, between the 1970s and 1980s, some 10,000 TMJ patients received Vitek jaw implant devices. Over time, these would shatter into microscopic Teflon particles, "cannibalizing" through the skull and even implanting in brain tissue. The result was a major inflammatory response and years of unrelenting pain. What's worse is that Vitek implants were approved by the Food and Drug Administration (FDA) in the absence of any human clinical trials demonstrating their safety.

In total, Vitek, Inc. sold about 26,000 TMJ implant devices, of which about 10,000 were implanted into patients. When patients returned complaining of debilitating pain, Vitek initially issued safety warnings, and two years later withdrew its device from the market. After yet another two years, the FDA recalled the device and issued its own safety alert. Meanwhile, Vitek filed for bankruptcy and its founder, Charles Homsy, fled to Switzerland to seek legal immunity from a tidal wave of lawsuits. But a $22 million settlement fund won't reverse the skull degeneration, facial deformity, and devastating pain surviving patients continue to suffer. The Vitek device is one example of implant devices TMJ patients have received over the years.

By contrast, consider the situation today: the average medical device racks up a bill of over $30 million before FDA approval. How is it even conceivable that, despite presumably millions of dollars and years of development, a device like the Vitek implant would get through this pipeline, a device that would be implanted at a critical joint in a sensitive region of the face, mere millimeters of bone separating it from the skull? So who's to take the heat for the Vitek implant disaster? The inventors at Vitek? The FDA staff that pushed for its approval? The oral surgeons who implanted the device in thousands of patients? One might well imagine considerable friction, if not downright animosity, between the device industry, dental and medical practitioners and TMJ implant patients.

A RoundTable of Former Adversaries
But, incredibly, this has not been enough to keep them from coming together, united in the fight to improve the plight of TMJ patients. On May 11, 2018, this diverse group of interested parties met for the second TMJ Patient RoundTable at FDA headquarters. Their initial meeting took place on June 16, 2016, at which time they established three objectives:

- Listen to patients' perspectives;
- Discuss methods for collecting patient-reported outcomes; and
Establish Working Groups to meet these goals.

Two years later, this cohort of FDA administrators, National Institute of Health directors, scientists, healthcare professionals, clinicians, device manufacturers, and, most importantly, TMJ patients met to review progress on these aims.

As a TMJ patient with a science background, I found the most striking takeaway from this meeting was the gap between the emerging science on temporomandibular disorders (TMD) and the critical needs of actual, living patients today—patients sitting, quite literally, elbow-to-elbow with the scientists who’ve spent their careers studying the problem. From a purely scientific perspective, the dizzyingly technical discussions about genome-wide association studies, bioinformatics, the human microbiome, artificial intelligence, and stem cell models were fascinating. It inspired hope to think that top scientists in leading fields are deploying our biggest and baddest technologies against a condition that, according to some estimates, affects the lives of millions of Americans. But from a patient’s perspective, it’s impossible to disentangle scientific inquiries into TMD from the very real, everyday experiences of patients. They are mutually interdependent.

Yet this separation was very much my experience working in a research lab years ago. There it was impossibly easy to disassociate what we were doing from the painful reality of the disease we were studying. That’s actually okay—science demands cool objectivity in the lab, and I wouldn’t wish the psychological burden of TMD to fall upon any clinician or researcher. But one of the patient advocates at the RoundTable, Tricia Kalinowski reminded the group that she had undergone 12 jaw surgeries over 35 years. She said she’s “watched the dentists and others who got to move on with their lives and mine got stuck, and in fact has gotten much worse. I lost my career and so much more.”

More Basic Science...
As RoundTable participants noted, temporomandibular joint disorders represent a complex family of conditions, and research should match that complexity. The RoundTable discussion focused to a significant extent on the extensive needs of TMD science, including:

- A greater understanding of genetic and environmental risk factors, including gender and sex differences;
- Identification of biomarkers for diagnosis and treatment;
- Genetic information and analytics, including from other chronic and pain conditions;
- Molecular and animal studies as disease models; and
- Improved clinical studies with longitudinal cohorts and follow-up.

That is, we need more—and more rigorous—science on the TMJ itself, as well as on medical devices like TMJ implants before they go to market, and frankly, into patients' skulls. Others at the meeting remarked upon the challenge of balancing such regulation with innovation so that we can get new, cutting-edge therapies to the patients who need them, but safely. It’s a commandment of Medical Ethics 101 to only offer patients evidence-backed treatments that have been proven safe. But for that to happen, significant scientific groundwork must be laid—from exhaustive genetic and molecular models to animal studies to all stages of human clinical trials. In short, we need the basic knowledge just to understand the disorder, let alone develop effective treatments. The kind of patience this requires can be frustrating, as perhaps is best expressed by a patient advocate at the meeting. She reacted to someone’s "comment that 'we needed to temper patients’ expectations' regarding jaw replacement surgery by questioning why were we even there."

...And Clinical Studies Too
RoundTable participants emphasized clinical needs, stressing patient-centeredness:
A registry to track outcomes of patients with acute and chronic TMD;  
The need to define meaningful and successful outcomes according to patients;  
Tools to measure meaningful and successful patient outcomes;  
Efforts to bridge medicine and dentistry and apply the medical model of care to TMD;  
Evaluation and adoption of other models, such as those used in the United Kingdom; and  
Standardization of educational requirements and TMD care standards.

**Limited Practice Guidelines and a Failure to Educate**

One of the Working Groups was tasked with evaluating the TMD practice guidelines of professional dental/medical organizations. They found there are scientific statements and parameters of care, but no formal guidelines for TMD treatment formulated by professional groups for the management of TMD. Of 24 organizations, only 5 had published directives on TMD care. Almost no mentions of patient-centeredness were found. The American Dental Association (ADA) does not publish any standards of care. This is unfortunately consistent with the Working Group's report on the lack of educational standards for dentists. That's not an exaggeration: the Council on Dental Accreditation (CODA) does not require that TMD or orofacial pain be taught in dental schools. Dental graduates who want to develop expertise in this area can choose between only 12 CODA-approved orofacial pain training programs. Tracy Jones, a patient advocate at the meeting, has seen over 20 dentists during her 25 years with TMD. She recalled that when "one dentist examined me, he told me that he 'knew just enough about jaws to be dangerous' and suggested I go to the dental school." Turns out the punch line is on the patient.

RoundTable participants who had personal experience with TMD were particularly enthusiastic about a registry to track patient outcomes. According to Kalinowski, "Vitek [implant] patients were promised a registry. We got one for a year and then the funding ran out. We were also told they would do research on the effects the Vitek truly had on patients and that we should be followed medically...That didn't happen. There isn't any test that exists that shows them where in my body the Teflon might be or what conditions to follow me for." Clearly such uncertainty would be unnerving.

**From My Perspective**

It's understandable that the collaborative spirit of the RoundTable was not necessarily felt by all. Some participants felt that the dental community has failed to "step up to the plate" and take sufficient responsibility for TMD care. "It takes everything I've got to sit in these meetings and not scream," Kalinowski explained. "The anger I recently experience over what happened to me because of the failure of [the FDA] to do its job caught me by surprise. I tried to tell myself that nobody here would have done that and pretended like it never happened."

The TMJ Patient RoundTable was fundamentally organized to explore ways to improve TMJ implant treatment outcomes and bring all stakeholders to the table with a patient-led focus. I cannot and do not claim to speak on behalf of the dozen or so other patient advocates who traveled hundreds or thousands of miles to be present at the RoundTable. The physical distance traveled fails to speak to the days of recovery that would be followed for many just to be present for a few hours at this meeting. And the money spent by patients who are treatment poor. But we're not just TMJ patients. We're programmers and teachers and medical device testers. We laughed and gossiped and swapped stories over our soups and smoothies during the lunch break.

The outrage felt in the TMJ community—at negligent practices, at a failure of regulatory systems, or at the genetic lottery—is very real, and it would be a waste of our shared human experience not to use this raw emotion for good. We need to protect the next generation of patients from these preventable tragedies. Trust needs to be rebuilt from within the medical and dental communities, starting with a patient-centered approach to care.
treatment. Kalinowski, who left the RoundTable early because she was feeling very sick, questioned how well her needs were heard. The science is essential and necessary, but so too should the patient's needs be held at the forefront.

While a TMD cure may not reveal itself overnight, consider what the committed patient advocates at The TMJ Association has (almost) single-handedly accomplished over the last 30 years, and continues to accomplish. If anyone's going to crack this puzzle, it is going to be a collaborative unit that doggedly persists in the goal of giving TMJ patients what they need. Hope.

Face Caddy Donation

The TMJA is grateful for a donation of 10 Face Caddy wraps from owner John Lucas. These cold/hot packs were distributed to TMJ patients who attended our May 2018 meeting.

If you'd like to give the Face Caddy a try, Mr. Lucas has offered to provide our readers 10% off your order. Be sure to enter "TMJA" when ordering online in the coupon code area. The TMJA does not benefit financially from the company or your sales. We thought you might like to know about this tailor made product for TMD discomfort.

Brain Fog

We thank Michele Kaseta for sharing her perspective as a TMJ patient about the topic of brain fog with author Claire Altschuler which recently appeared in Practical Pain Management. We encourage you to read this article at: https://www.practicalpainmanagement.com/patient/treatments/mental-and-emotional-therapy/tackling-brain-fog-expert-advice-clearer-thinking

TMJ Researcher Spotlight

Duke University School of Medicine's website recently featured an article on Yong Chen, PhD, who is currently working in the Neurology Department. He discusses his research discover of the Trpv4 in trigeminal ganglion sensory neurons which is critical for the masticatory pain of TMD. Dr. Chen is one of the young investigators who attended the TMJA's past scientific meetings.

Click her to view the article: https://neurology.duke.edu/about/news/faculty-spotlight-yong-chen-phd

Changes of TM Joint in Patients With and Without TMD Complaints

The results from this study confirm that TMJ imaging with cone beam computed tomography (CBCT) is not generally diagnostic for most patients with TMD, due to the common finding of various structural "abnormalities" on these sophisticated images. Since the explanations for joint pain are not generally based on such morphologic findings, we need to concentrate on the other biologic reasons for people to develop such pains.

Comparison of the Bony Changes of TMJ in Patients With and Without TMD Complaints Using CBCT
Abstract

Statement of the Problem: Temporomandibular joint disorders (TMD) may show a poor correlation between their clinical findings and radiological characteristics.

Purpose: The aim of this study was to assess the osseous alterations of temporomandibular joint (TMJ) in symptomatic and asymptomatic subjects by employing cone beam computed tomography (CBCT) images.

Materials and Method: In this study, CBCT images of 120 temporomandibular joints in 30 patients with TMJ disorder and 30 age- and sex-matched individuals without TMJ complaints were evaluated. Osteoarticular derangements of the joint were assessed by two experienced examiners. Data was statistically analyzed with SPSS software using chi-square test ($p <0.05$).

Results: Out of 120 CBCT images (60 in each group), at least one osseous change was observed in 90% and 86.7% joints in symptomatic and asymptomatic subjects, respectively. There were no significant differences between symptomatic and asymptomatic subjects regarding frequency of osteoarticular changes including flattening (73.3% vs. 75%), irregularity (36.7% vs. 48.3%), sclerosis (20% vs. 8.3%), cyst (3.3% vs. 3.3%), erosion (13.3% vs. 21.7%), hypoplasia (3.3% vs. 5%), ankylosis (1.7% vs. Zero), osteophyte (43.3% vs. 40%), decrease joint space (3.3% vs. 3.3%), and increase joint space (5% vs. 5%). ($p > 0.05$)

Conclusion: By employing CBCT as a modern diagnostic imaging tool, findings of this study revealed that the frequency of various temporomandibular joint alterations on CBCT images is comparable in patients with and without TMD complaints, suggesting that some people with TMJ structural damage may not display clinical manifestations. Moreover, CBCT imaging might not be necessary for TMD patients and more attention should be given to clinical examination.

Tissue Engineering the TM Joint

Researchers at the University of California, Irvine (UCI) and others have recently tested the first-ever tissue implant to treat TMD in animals. UCI Distinguished Professor of biomedical engineering Kyriacos Athanasiou, senior author on the study, published in Science Translational Medicine. He has spent nearly two decades researching the condition and potential cures.

"This is the first time that cogent healing has been shown in the TMJ area and, I dare say, the first time anyone has shown successful biomechanical healing in any joint. It's key that we can achieve regeneration of an ailing tissue with our engineered implant, one that's mechanically suited to withstand stresses," Athanasiou said. "So we believe this represents an important first in all joint healing studies."

Click here to read the full article: https://news.uci.edu/2018/06/20/joint-venture-uci-others-create-breakthrough-treatment-for-crippling-jaw-disease/

A Small Cause of Big Pain

Neurologist Anne Louise Oaklander investigates a cause of chronic pain that is treatable without opioids.
For many patients and their physicians, opioids still seem to be the most effective way to relieve chronic pain. But what if an opioid prescription—and its risks of addiction—could be sidestepped by finding a more precise diagnosis and treatment?

Anne Louise Oaklander, director of the Nerve Unit and neurodiagnostic skin biopsy lab at Massachusetts General Hospital, looks at a common condition called small-fiber polyneuropathy (SFPN), which is characterized by several unexplained, unprompted symptoms, including chronic pain. By diagnosing and treating SFPN directly, says Oaklander, physicians could reduce the need for addictive opioids that only temporarily dampen pain.

Read the full interview at: Proto

Dr. Oaklander also participated in the TMJA’s 2015 scientific meeting and a summary of her talk is found in our TMJ Science on page 14.

**FDA Approved Devices and the Patient Perspective**

**A Netflix Documentary**

The new Netflix documentary, *The Bleeding Edge*, provides an investigative look at how medical devices enter the marketplace. Although temporomandibular joint devices are not discussed specifically in this film, our patient stories are very similar to those presented. We encourage you to watch this documentary to learn not only about the process a device goes through in getting on the market but also the devastating impact device failures have on the lives of patients and their loved ones. [https://www.netflix.com/title/80170862](https://www.netflix.com/title/80170862)

The TMJ Association was founded by two TMJ implant patients who were harmed by devices that were approved and placed on the market in the early 1980s. To this day your TMJ Association continues to advocate on behalf of patients and safe and effective devices as well as all other TMJ treatments. [We can’t continue our work without the support of individuals like you!](https://www.tmaj.org) The TMJA is a 501(c)3 nonprofit organization dedicated to improving the quality of health care and lives of everyone affected by temporomandibular disorders.

**Meet George**

I have been living with chronic TMD for the last seven years where I would experience constant migraines, a stiff neck, discomfort in the throat, swollen masseters, backaches, a misaligned spine, tight shoulders, chipped teeth from nighttime grinding, and poor memory on a daily basis. The anguish is so debilitating that sometimes I have trouble studying and doing ordinary tasks.

To cope with the intense pain and not let it further interfere with my life, I receive acupuncture treatments every week to temporarily alleviate the symptoms. When I first noticed the condition, I did not know what was wrong or why I felt so much pain. Initially, I thought the pain was caused by excessive academic stress because at the time, I felt overwhelmed with adjusting to my new life in college. However, I saw that this was not the case because I still experienced the same amount of pain even during summer vacations and Christmas break. I saw several specialists hoping that they could figure out what was going on. They noticed my TMJ muscles were inflamed and prescribed some muscle relaxants for me to take. However, the medication did not work and during the follow-up appointments, they injected me with Botox, but that did not help either. The doctors then suggested I do some physical therapy and ultrasound treatments, but those methods also proved ineffective.
Since no one knew how to completely cure my TMD, I felt completely lost and defeated. I thought I would have to live in agony and rely on acupuncture for the rest of my life. After graduating from university, I took some time to fully investigate the root cause of my chronic disease. After reading several scientific articles and doing some reflective thinking, I deduced that my TMD was unarguably caused by prior orthodontic treatment. I vividly recalled I was perfectly fine before I got braces and that the TMJ pain started during the last stage of the teeth straightening process. I also remembered that the pain got markedly worse when I was fitted for a retainer after my braces were removed.

Since I have finally discovered the main culprit, I am currently going through additional TMD treatments. So far, it's helped me eliminate a few of my chronic symptoms. I am optimistic that with continued medical attention, I can fully recover and live life fully to the greatest extent possible. I hope my personal journey serves as a guide for those struggling through similar difficulties.

### Future NIH Research Initiative for TMD

Concepts represent early planning stages for initiatives in which the National Institute of Dental and Craniofacial Research (NIDCR) seeks to support research in an understudied and significant area of science. Council approval does not guarantee that a concept will become a program announcement, request for applications, or request for proposals. NIDCR bases this determination on scientific and programmatic priorities balanced with the amount of funds available.

The following new concept clearance was presented by Dr. Yolanda Vallejo and approved by Council at the **218th NIDCR Council Meeting: May 2018**:

#### TMD: Identifying Pathways Involved in Chronic Pain and Endogenous Resolution

**Goals:**
- Catalyze multi-disciplinary research addressing central and peripheral plasticity mechanisms that promote chronic TMD and its endogenous resolution.
- Delineate brain changes in human and animal models that can be correlated with molecular changes in animal and human craniofacial tissue.
- Evaluate TMD animal models to identify those that best recapitulate human pathophysiology to preclinical studies.

**Gaps and Opportunities:**
- Precision Medicine approaches to pain management necessitate:
  - Determination of the mechanisms that sustain or promote resolution of chronic TMD pain.
  - Elucidation of strategies to intrinsically and extrinsically modulate these mechanisms.
- Recent technological advances and resources developed through the NIH BRAIN, Blueprint, and SPARC Initiatives are poised to enable significant advances.

**Specific Areas of Interest:**
- Determine underlying mechanisms that mediate maladaptive and/or adaptive plasticity changes in modulatory circuits that either promote chronic TMD pain or facilitate endogenous resolution.
- Adaptation/utilization of new technologies to assess brain-wide connectivity changes in TMD animal models that can parallel human imaging studies.
- Development of new lines of research that leverage the availability of human tissue banks with advancing technology.
- Elucidation of interactions of the skeletal, muscular, cartilage, nervous, immune and circulatory systems in TMD.
Strategies to address sex-based differences/influences.


The TMJA will stay abreast of this new development and will report updates in future issues of TMJ News Bites.

**NIH Funding Opportunities**

Basic and Clinical Research

In an effort to promote greater understanding of TMD, and to develop safe and effective evidence-based diagnostics and treatments, The TMJ Association promotes and encourages basic and clinical research on Temporomandibular Disorders. Click here to view the latest National Institutes of Health (NIH) funding opportunities for scientists interested in advancing TMJ research. The following NIH research opportunities are currently available:

- Clinical Coordination Center for Common Fund Acute to Chronic Pain Signatures (A2CPS) Program (U24 Clinical Trial Optional)
- Multisite Clinical Center Common Fund Acute to Chronic Pain Signatures Program: Acute Peri-operative Pain (UM1 Clinical Trial Optional)
- Multisite Clinical Center Common Fund Acute to Chronic Pain Signatures Program: Acute Pain from Musculoskeletal Trauma (UM1 Clinical Trial Optional)
- Omics Data Generation Centers (ODGCs) for Common Fund Acute to Chronic Pain Signatures Program (U54 Clinical Trial Optional)
- Data Integration and Resource Center (DIRC) for Common Fund Acute to Chronic Pain Signatures Program (U54 Clinical Trial Optional)
- Biologic Factors Underlying Dental, Oral, and Craniofacial Health Disparities (R01 & R21 - Clinical Trial Not Allowed)
- Discovery of Biomarkers, Biomarker Signatures, and Endpoints for Pain (R61/R33 Clinical Trial Optional)
- Expanding the Human Genome Engineering Repertoire (U01 Clinical Trial Not Allowed) Discovery of Biomarkers, Biomarker Signatures, and Endpoints for Pain (R61/R33 Clinical Trial Optional)
- Regenerative Medicine Innovation Project (RMIP) Investigator-Initiated Studies (U01 - Clinical Trial Not Allowed)
- Clinical Validation of Candidate Biomarkers for Neurological Diseases (U01 Clinical Trial Optional)
- Factors Underlying Differences in Female and Male Presentation for Dental, Oral, and Craniofacial Diseases and Conditions (RO1) (R21)
- NIDCR Small Research Grants for Secondary Analysis of FaceBase Data (RO3)
- Tailoring Dental Treatment for Individuals with Systemic Diseases that Compromise Oral Health (R01) (R21)
- Personalized Strategies to Manage Symptoms of Chronic Illness (R15) (RO1) (R21)
- Research on the Mechanisms and/or Behavioral Outcomes of Multisensory Processing (R01)
- Blueprint Neurotherapeutics Network (BPN): Small Molecule Drug Discovery and Development for Disorders of the Nervous System (UH2/UH3) (U44)
- Population Health Interventions: Integrating Individual and Group Level Evidence (R01)
- Family-Centered Self-Management of Chronic Conditions (R21) (R01)
- mHealth Tools for Individuals with Chronic Conditions to Promote Effective Patient-Provider Communication, Adherence to Treatment and Self-Management (R01) (R21)
- The Biomarkers Consortium
“Sometimes a TMJ patient needs inspiration just to get through each day.”

- The TMJ Association, Ltd.

Connect with others who understand in the new TMJ Cafe Support Community

Visit TMJ.Inspire.com

Research E-Newsletter

*Cutting Edge - COPCs Research Advances*, is an electronic newsletter published by the Chronic Pain Research Alliance, an initiative of The TMJ Association. Developed to keep the medical-scientific community abreast of recent research advances, this publication contains abstracts of recently published studies on the epidemiology, pathophysiology and clinical management of Chronic Overlapping Pain Conditions. These conditions include temporomandibular disorders, chronic low back pain, chronic migraine and tension-type headache, endometriosis, myalgic encephalomyelitis/chronic fatigue syndrome, fibromyalgia, vulvodynia, irritable bowel syndrome and interstitial cystitis/painful bladder syndrome.
The most current issues are now available for your review at: http://www.cpralliance.org/New_Findings. If you would like to receive future issues of COPCs Research Advances, click here to register.

Educational Brochures on Chronic Overlapping Pain Conditions

This brochure addresses Chronic Overlapping Pain Conditions (COPCs), how COPCs are diagnosed, the complexity of the chronic pain experience, and how to work with your health care provider to develop a treatment plan. It is available by postal mail or as a PDF on our website.

Educational Brochures on TMD

Your Guides for Temporomandibular Disorders - This brochure written by the TMJA is a straightforward, easy-to-read booklet that guides patients in how to make health care decisions. It is available by mail or as a PDF on our website and we encourage you to share it with your friends, health care professionals and family members.

TMJ Disorders - This brochure is produced and distributed by the National Institute of Dental and Craniofacial Research in partnership with the Office of Research on Women's Health, components of the National Institutes of Health (NIH) in Bethesda, Maryland. Part of the U.S. Department of Health and Human Services, NIH is one of the world's foremost medical research centers and the federal focal point for medical research in the United States. This booklet is available in English and Spanish at: https://www.nidcr.nih.gov/OralHealth/Topics/TMJ/TMJDisorders.htm.

Dental Care Guide

Temporomandibular Disorders, Dental Care and You

The TMJ Association developed this guide to provide you with oral hygiene self-care tips that you can do at home, as well as suggestions for future dental appointments. Routine maintenance of your teeth and gums should reduce the risk of dental disease and the need for invasive dental treatments. Click here to view on our website.

TMJ Science Journal

Our latest issue of TMJ Science, which includes the summary and recommendations from our 8th scientific meeting-How Can Precision Medicine Be Applied to Temporomandibular Disorders and Its Comorbidities---is now available. We hope you're impressed with how far the science of Temporomandibular Disorders has come. We invite you to read this new publication which is available in the publication section of our website as a pdf file.

Update on our Privacy Policy

We want you to know how we protect your privacy. We do not sell, rent, or exchange your information with anyone! You can read more about our privacy policy here.
Support Our Work

The TMJ Association (TMJA) is the only patient advocacy organization fighting for the best science that will lead to a greater understanding of Temporomandibular and related disorders, as well as safe and effective treatments. We cannot change the face of TMJ without YOU.

[Click HERE to make a tax-deductible online contribution today!]

About The TMJ Association

Changing the Face of TMJ

The TMJ Association, Ltd. is a nonprofit, patient advocacy organization whose mission is to improve the quality of health care and lives of everyone affected by Temporomandibular Disorders (TMD). For over 25 years, we have shared reliable information on TMD with people like you. We invite you to visit our website, [www.tmj.org](http://www.tmj.org).

- If you’re not currently receiving *TMJ News Bites* and would like to be on our mailing list, [sign up here.](http://www.tmj.org)
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