

Fifth Scientific Meeting of The TMJA

The Fifth Scientific Meeting of The TMJ Association is co-sponsored by Agencies of the National Institutes of Health.

Title:

Can Studies of Comorbidities with TMJDs Reveal Common Mechanisms of Disease?

When and Where:

June 1-3, 2008
Federation of American Societies for Experimental Biology (FASEB)
Bethesda, Maryland

Topics:

- Chronic Headache
- Generalized Pain Conditions
- Irritable Bowel Syndrome/ Endometriosis/Interstitial Cystitis/ Vulvodynia
- Fibromyalgia
- Chronic Fatigue Syndrome
- Rheumatoid Arthritis
- Temporomandibular Joint and Muscle Disorders

Who Should Attend:

Clinical and basic scientists, physicians, dentists and other healthcare professionals, federal agency officials, patients and loved ones, and patient advocates for the comorbid conditions are greatly encouraged to participate.

Meeting Details:

www.tmj.org/2008sciencemtg.asp or contact us at 262-432-0350

TMJDs and What Else is Wrong?

On behalf of all of us at The TMJ Association, I am pleased to invite you to attend our fifth scientific meeting. Over the years I have spoken with many of you and read thousands of letters and e-mails from patients. Often, you talked not only about your TMJ problems, but about other medical conditions that you were experiencing, such as chronic headache, fibromyalgia, irritable bowel syndrome, endometriosis, interstitial cystitis, chronic fatigue syndrome, rheumatoid arthritis, to name a few. As we have since learned, investigators studying these other conditions found that many of their patients were also experiencing Temporomandibular muscle and joint disorders (TMJDs). For that reason we have organized our upcoming meeting around some of the conditions that seem to go hand in hand with TMJDs. The goal of our meeting is to identify the common threads among these conditions and develop strategies for research that might reveal the mechanistic triggers that lead to the emergence of TMJDs as well as these other conditions.

Naturally, we invite scientists who care about TMJDs to our meeting, but since all our meetings are *about* patients and *for* patients, they have a special invitation. Having patients attend contributes valuable insights to discussions and provides a venue for interactions with scientists. This next meeting will be unique in that we have invited patient advocates and patients representing all the other medical conditions mentioned. If you are experiencing these other medical conditions, you will have an opportunity to meet the advocacy leaders.

Our meetings, co-sponsored by agencies of the National Institutes of Health, have been the catalyst for the directional change in TMJD research. We're proud of that and hope you are too. However, these meetings come at a price. If you're able to make a contribution at this time, it will be greatly appreciated and your name will be listed in the program. No contribution is too small or too large! Each gift is a reminder why we all are working so hard to "change the face of TMJ." ♦

*Terrie Cowley
President*

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The TMJ Communiqué

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The *TMJ Communiqué* is intended solely as an information guide and source of support for people with temporomandibular joint and muscle disorders (TMJDs). It does not constitute medical or dental advice, nor is it a substitute for medical or dental advice. Always consult your healthcare professional before starting treatment. The TMJ Association does not provide referrals.

The Association does not endorse any particular healthcare professional, specialty or organization, nor do the opinions of a healthcare professional or organization referred to in the *TMJ Communiqué* reflect the opinions of The TMJ Association.

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Latest Science Findings

In addition to the stem cell research on rebuilding TMJ cartilage (*Regenerating the TMJ Disc*, page 3), two articles of interest to TMJD patients were recently reported in peer-reviewed science journals:

Cortical Thickening in Migraine Sufferers¹

Using magnetic resonance imaging (MRI) scans, investigators at Massachusetts General Hospital, Harvard Medical School and Massachusetts Institute of Technology detected a thickening of the cortex of the brains of migraine headache patients, whether they experience a preceding aura or not, compared to normal controls. The thickening was found in the somatosensory cortex (SSC), an area of the brain surface that receives sensory signals (including pain) from all parts of the body. The SSC is arrayed like a map of the body and the thickened area corresponded to the head region served by the trigeminal nerve. In addition to the cortical thickening, patients with migraine headaches but without aura showed a subcortical thickening of trigeminal nerve pathways. The investigators conjecture that the cortical and subcortical thickening may be due to overstimulation of sensory fields by repeated headaches over many years or an innate hypersensitivity of the trigeminal system. They conclude that the brain changes "may be either the result or cause of repetitive migraine attacks, which may also affect other systems. This may explain the high comorbidity of migraine with other pain disorders, including back pain, temporomandibular disorders, and fibromyalgia."

Overactive Nerves May Trigger Tinnitus²

TMJD patients sometimes experience ringing in the ears, whooshing or wave-like noises, or other annoying and persistent sounds, called tinnitus. Now researchers studying guinea pigs with damaged hearing believe that the cause of the unwanted sounds may be extra activity of non-auditory nerve fibers that relay to the same brain center (the dorsal cochlear nucleus) that receives input from the auditory nerve. Susan E. Shore, Ph.D., and her team at U. Michigan Medical School's Department of Otolaryngology measured patterns of neuronal activity in the cochlear nucleus and found that diminished excitation of auditory neurons in guinea pigs with hearing loss was associated with hyperactivity of other neurons in the same nucleus. These other neurons respond to signals from nerve endings sensitive to touch, vibration, pain and skin temperature. The resulting "noise" generated by all these nerve cells firing in the brain may quite literally be sensed as noise in the ears, the researchers conclude. Something comparable may be occurring in people with temporomandibular disorders and tinnitus: a disruption in normal nerve input from the joint may lead to excessive activity in the cochlear nucleus, producing tinnitus.

References

¹DaSilva, A.F.M., Granziera A., Snyder J. & Hadjikhani, N. (2007, November 20). Thickening in the somatosensory cortex of patients with migraine. *Neurology*, 69, 1990-1995.

²Shore, S.E., Koehler, S., Oldakowski, M., Syed, S. & Hughes, L.F. (2008, January 1). Dorsal cochlear nucleus responses to somatosensory stimulation are enhanced after noise-induced hearing loss. *European Journal of Neuroscience*, 27(1), 155-168. ♦

Orthopaedic Research Society (ORS) Meeting Features TMJDs

The community of orthopaedic practitioners and researchers generally works on bones and joints below the head (knees, hips, elbows, wrists). This year, in connection with their annual meeting (March 2-5 in San Francisco), orthopaedic researchers had an opportunity to learn about the temporomandibular joint, thanks to the initiative of Dr. Stephen Gordon, a member of the TMJA's Scientific Advisory Board. Dr. Gordon chose pain in temporomandibular muscle and joint disorders (TMJDs) as a topic he proposed to the ORS, since it has been well studied in TMJ research and is of growing interest to Society members.

The workshop, *Pain as a Critical Component to Understanding Musculoskeletal Disorders—TMJDs as a Model*, featured talks by three experts in the field: Dr. Peter Grigg (U. Massachusetts Medical School) described the distribution of nerve endings in joints and other connective tissue sensitive to pain (nociceptors), and how individuals may experience increased sensitivity and severity of pain following tissue or nerve injury; Dr. Ronald Dubner (U. Maryland Dental School) and also a TMJA Scientific Advisory Board member, detailed how pain signals are processed and modulated at way stations in the spinal cord and brain; Dr. William Maixner (U. North Carolina) presented data on the genetic basis for differences in pain perception. Dr. Maixner is the principal investigator on a National Institute of Dental and Craniofacial Research grant studying risk factors for the development of TMJDs. The study is based on periodic examinations and samples of tissue collected from a group of adults who will be followed for seven years.

The organizers hope that the workshop will stimulate orthopaedic investigators to conduct more research on pain in musculoskeletal disorders, in particular, increasing the pool of researchers challenged by the complexities of TMJDs. ♦

Regenerating the TMJ Disc: Stem Cells to the Rescue

Like other joints in the body, the temporomandibular joint can become painful and dysfunctional when the disc that cushions the area where the skull and jaw bone meet is injured or degenerates as a result of arthritis. The disc is made up of fibrocartilage, a type of connective tissue that does not normally heal after injury. Now bioengineering scientists at Rice University in Houston, Texas have taken up the challenge hoping to capitalize on the regenerative powers of human stem cells. These cells, derived from early embryos and also found in some adult tissues can, given the right growth conditions, be nurtured into developing the characteristic cells of the body's organs, including cartilage.

While important progress has been made toward traditional engineering of replacement cartilages in the laboratory, questions remain concerning where a source of cells to generate new cartilage can be found. In addition, cartilage tissue engineering requires many cells to produce tissue of suitable size, and this requirement far exceeds current capability to obtain cartilage cells from an individual patient.

The Rice investigators believe that human embryonic stem cells (hESCs) may resolve these issues. Interestingly, little work has been done to investigate stem cell applications to cartilage studies. Toward that end, the investigators are addressing two questions: How can the stem cells be differentiated into cartilage-producing cells? and How can the cells then be used for tissue engineering of cartilage?

In a recent study published in the journal *Stem Cells*, the researchers, Eugene J. Koay, Gwen M.B. Hoben, and Kyriacos A. Athanasiou, cultured National Institutes of Health approved hESCs in regimens using growth factors known to have cartilage-inducing properties. The resulting cells were then used in a tissue engineering strategy called "self-assembly." This process deviates from traditional engineering approaches in not requiring the use of any scaffold material to direct the shape and size of the tissue.

The self-assembly approach with the hESC-derived cartilage cells resulted in uniform pieces of cartilage with cellular, biochemical, and biomechanical properties most similar to the TMJ disc and the knee meniscus, which are both fibrocartilages. Other joints use other types of cartilage. Interestingly, the cartilages developed from each distinct biochemical regimen the researchers used had a unique set of characteristics, suggesting that different types of cartilage can be generated from a single cell source in hESCs.

This study was the first demonstration of the ability of cartilage-differentiated hESCs to "self-assemble" and produce such robust cartilage, though there is still room for improvement. Additionally, the concept of producing multiple types of cartilage with this single cell source is new for the field, as the different cartilages of interest have diverse structures and biomechanical functions.

Following the success of their initial studies, the investigators will try to enhance the properties of the hESC-derived cartilage, direct their differentiation for specific cartilage applications, and determine the clinical applicability of these cells, including their safety. Their work was funded by an unrestricted fund from Rice University. ♦

Eugene J. Koay

Reference

Koay, E.J., Hoben, G.M.B., & Athanasiou, K.A. (2007, Sept.). Tissue engineering with chondrogenically differentiated human embryonic stem cells, *Stem Cells*, 25, 2183-2190.

Washington TMJ Update

Government Investigators Issue TMJ Implant Report

The findings of a long-anticipated government investigation into the process of approval of TMJ implants have been released. This is an important development for TMJD patients and one that The TMJ Association played a crucial role in initiating. The report—*Medical Devices: FDA’s Approval of Four TMJ Implants*—produced by the Government Accountability Office (GAO), the investigative arm of Congress, documents a series of serious shortcomings with the government’s oversight of TMJ implants. It is the first time in over a decade that Congress has shed light on problems associated with TMJ implants and could lead to more aggressive action by Congress and the Food and Drug Administration (FDA) to hold manufacturers accountable and improve the safety and quality of TMJ implants.

The GAO review was requested by three Senators with important roles in overseeing healthcare – Senator Edward Kennedy (D-MA), who is Ranking Member of the Senate Health, Education, Labor and Pensions Committee, Senator Tom Harkin (D-IA), Ranking Member of the Senate panel that funds most health programs, and Senator Herb Kohl (D-WI), who is Ranking Member of the Senate panel that funds the FDA. The TMJA is grateful to these members for their leadership and is working with them to press the GAO and the FDA for further action.

In their 2005 letter to the GAO requesting the investigation, the Senators stated bluntly, “Patients suffering advanced TMD lack treatment options that restore function and alleviate pain with an acceptable level of adverse events. These patients believe that the FDA is not requiring adequate design, adequate clinical trial evaluation, or adequate post-market surveillance of TMJ implants.”

The report was limited to a review of FDA’s approval of four TMJ implants since 1998: TMJ Concepts, TMJ Implants, Inc. total joint implant, TMJ Implants, Inc. partial joint implant; and the Walter Lorenz implant. The report lists the concerns raised by the FDA itself, how it addressed these concerns, and how the agency subsequently monitored the manufacturers’ compliance with FDA’s conditions for approval.

It appears that FDA officials raised similar concerns over all four devices. They questioned “the adequacy of the sponsors’ clinical trial protocols, patient follow-up, engineering, testing and other matters such as device labeling.” For example, the report notes that the, “FDA found that all the studies supporting the four applications

had deficient patient follow-up, which made it difficult to determine outcomes over time, such as improvements in patient symptoms.”

Staff objections overruled. Significantly, the GAO found that FDA staff charged with reviewing the devices recommended against approving two of the four implants: the TMJ Implants, Inc. partial and total joints. Nevertheless, FDA management overruled the staff experts and ordered the devices approved. The report states that “FDA management acknowledged that the concerns raised about the implants were legitimate. However, they ultimately concluded that the benefits provided by these two devices outweighed the concerns and approved both devices to help patients obtain relief from chronic pain.”

In its approval decision, FDA management acknowledged concerns about the quality and quantity of clinical data provided by the sponsor. However, the FDA stated that either good engineering data or good clinical data was acceptable to approve a device, not necessarily both, and that it deemed the engineering data to be satisfactory. The agency further indicated that the clinical data were not expected to be of high quality because the sponsor was a small manufacturer.

Inadequate reporting. In terms of monitoring and surveillance, the GAO found that only 13 of 18 annual reports required to document the compliance of the approval conditions set by the FDA had been submitted. Furthermore, seven of the 13 reports “did not provide FDA with sufficient information to assess compliance.” TMJ Concepts did not submit five of seven required annual reports.

In addition, one manufacturer, TMJ Implants, Inc, consistently “under-reported problems experienced by patients—known as adverse events—associated with the devices.” In response to the company’s repeated failure to address these concerns, the FDA filed a complaint for civil monetary penalties against it.

Next steps. The TMJ Association is now working with Senators Kennedy, Harkin, and Kohl on a follow-up request that the GAO provide Congress with additional information and analysis regarding the approval process. More detailed answers from the FDA are needed, as well as reform measures to assure that the serious shortcomings identified by the GAO are addressed and not repeated in the future. ♦

Peter Reinecke
TMJA Health Policy Advisor

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How You Can Help

Patients, friends, and loved ones can participate in the TMJA's on-line campaign, *Giving TMJ Patients A Voice*. Our goal is to empower you to share your story with your family, friends, and colleagues and, by doing so, raise much-needed public awareness of TMJDs and funding for scientific meetings.

Through this on-line campaign you will be able to:

- Create your own web page
- Share your story with your family, friends, colleagues
- Raise awareness of and funding for TMJA scientific meetings and research

Visit firstgiving.com/tmja to see our page.

Getting started is *easy* and *free*:

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TMJA in the Media

The TMJ Association received a \$1,000 award from the Milwaukee Journal Sentinel at the 2007 Building Partners for Humanity Award Ceremony. In 2007 the TMJA teamed with Stir, LLC, a local advertising and marketing firm, and created an advertisement to bring awareness of TMJDs to the Milwaukee community. The advertisement appeared in the Milwaukee Journal Sentinel and was judged as one of the top three ads submitted. Kudos to Stir for an award winning ad, helping us increase awareness of TMJDs, and their pro-bono services ♦



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Occlusal Splint Study

The Cochrane Collaboration recently published the study, *Occlusal splints for treating sleep bruxism (tooth grinding)*, by C.R. Macedo, A.B. Silva, M.A. Machado, H. Saconato, G.F. Prado. This study found that there was insufficient evidence to either support or refute the use of occlusal splints for treating patients with tooth grinding or clenching during sleep (sleep bruxism). Sleep bruxism is characterised by several signs and symptoms. Among them are abnormal tooth wear, fractured teeth, joint pain or tenderness, jaw muscle discomfort, and headaches. Treatments include odontological devices such as occlusal splints, pharmacotherapy, and psychotherapy. An occlusal splint is a removable appliance worn in the upper jaw (maxilla) or the lower jaw (mandible), with coverage of the dental surfaces. They are usually used to prevent tooth wear. ***The conclusion: There is not enough evidence in the scientific literature to show that occlusal splints can reduce sleep bruxism.***

The Cochrane Collaboration is an international organization that aims to help people make well-informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions. The main work of the Collaboration is done by approximately fifty Collaborative Review Groups, within which Cochrane Systematic Reviews are prepared and maintained. The Cochrane Oral Health Group aims to produce systematic reviews which primarily include all randomized control trials (RCTs) of oral health. Oral health is broadly conceived to include the prevention, treatment and rehabilitation of oral, dental and craniofacial diseases and disorders. ♦