The Migraine Menders

How two doctors developed a protocol to quell migraine headaches

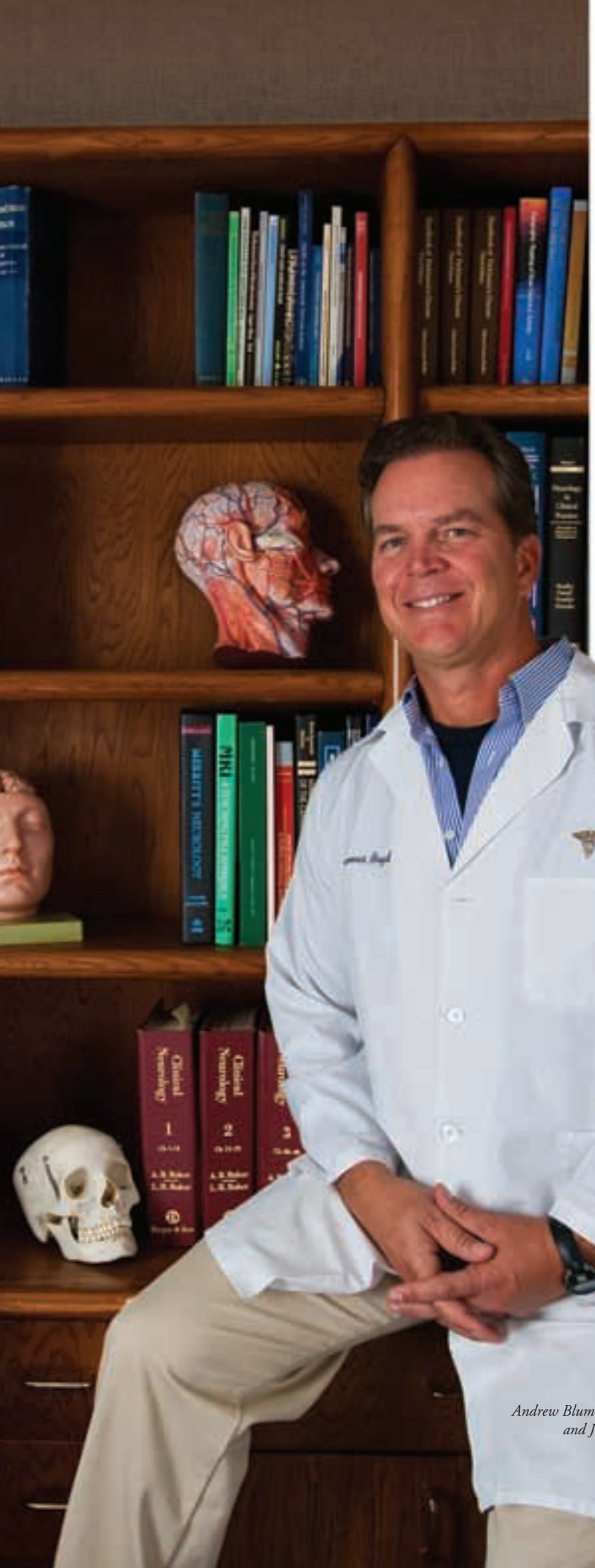
In 2005, neurologist Andrew Blumenfeld, MD, director of The Headache Center of Southern California, casually sat in on a lunch hour lecture presented by dentist James Boyd, who was describing the cause-and-effect connection between nocturnal parafunction and migraine. Blumenfeld, one of the country's leading authorities and researchers in migraine and its etiology, was skeptical.

"We are a tertiary clinic, with the majority of our patients having previously seen multiple practitioners, typically with little to no relief. I was expecting to hear Dr. Boyd try to convince me how someone's 'bite' could influence migraine," Blumenfeld says.

Probably more than any other chronic disease, migraine pain is commonly lumped in as a primary symptom of a variety of medical conditions treated by most every health-care provider. However, if you mention "occlusion" to a neurologist, especially to one whose practice is focused on migraine and its current research, you might get a cordial smile, and maybe even a roll of the eyes.

Instead, what Blumenfeld learned that day from Boyd not only added to his overall concepts of migraine etiology, it set the stage for future research and new insights into migraine.

"I evaluate things from a neurologic perspective, and what Dr. Boyd was talking about was excessive and dysfunctional trigeminal activity, which is at the heart of migraine. It wasn't so much the patient's bite or occlusion that mattered, but the intensity of *biting* (clenching) that was most influential. He also seemed to have a particular insight from a patient's perspective that I found most interesting," says Blumenfeld. What Blumenfeld didn't know was that Boyd used to suffer from chronic migraines; for a 12-year stretch he would awaken with a headache every morning. Drawing from his own therapeutic failures and independent study, Boyd had developed the therapeutic protocol for the NTI-tss (Nociceptive Trigeminal Inhibition tension suppression system), which had



Andrew Blumenfeld, MD (left), and James Boyd, DDS.

been approved by the U.S. FDA in 2001 for the prevention of medically diagnosed migraine pain.

"The phrase 'nocioceptive trigeminal inhibition' intrigued me, because in neurology, the therapeutic goal in migraine prevention is to limit the degree of trigeminal nociception," says Blumenfeld. "I thought maybe he was on to something." Following Boyd's presentation, Blumenfeld invited Boyd to visit his migraine clinic for a few days and provide NTI devices for their refractory patients.

"It didn't discourage me to be 'warned' that the patients I was about to see were 'the worst of the worst,'" says Boyd. "I just figured everything had already been ruled out, so management of intense nocturnal parafunction was probably the only thing left that could help," and he was right. More than half of the migraineurs provided with an NTI device reported considerable improvement in their condition.

"Prescribing an NTI to a patient became a refreshing option," says Blumenfeld. "I no longer had to routinely warn the patient of the considerable drug-related side effects our patients typically had to endure."

Over their five-year relationship, Blumenfeld has gone on to publish several research abstracts about the NTI in medical journals, and has presented his findings at symposiums in Los Angeles, London and Nice.

"As Dr. Blumenfeld and I talked over our observations of patients' responses to NTI therapy, I found myself wanting to analyze the third division of the trigeminal nerve on a deeper level," says Boyd. "The extent of my education had simply provided me with the knowledge of where to place anesthetic block injections. Here I had my own personal neurologist to interrogate, but Dr. Blumenfeld's response was a defining moment for me. He said, 'Jim, we're physicians. We ignore the third division. Our focus is the first division.' I knew right then that we were headed into uncharted territory.

"Over the course of multiple discussions, I started thinking from a completely different neurologic perspective. For example, what I once considered a 'posterior contact' now became the end result of a persisting motor innervation to the elevators. At one time, I had believed that a 'posterior interference' *caused* muscle hyperactivity, but obviously, the contact *doesn't even exist*

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until *after* the innervation has already initiated. What I began to see was that the scheme of the occluding teeth*facilitated* the escalation of motor hyperactivity, but not *caused* it. Suddenly, all of dentistry's occlusal philosophies made perfect sense to me. For example, the phrase, 'immediate posterior disclusion,' *stipulates* that the elevators are still being innervated as the lateral pterygoids work to disclude the teeth, but end up shifting the mandible excursively. Dentistry understands that if posterior teeth are still in contact during the persisting elevation, then excessive muscle hyperactivity can be facilitated, which is how pathologic strain and load can then be directed to the joint. Our acknowledging and preventing the posterior contact doesn't stop muscle hyperactivity, it reduces its potential. The active elevation activity persists, regardless of the scheme of the occluding teeth. Ultimately, the therapeutic goal in the management of occlusal parafunction has been to provide 'incisal guidance,' that is, incisor contact during the persisting innervation of the elevators, that is parafunction. Why? Because incisor contact facilitates far less motor innervation to the elevators (clenching) than canines or molars do. Essentially, that is what an NTI provides."

Not only has Boyd's perceptions about occlusal therapy been modified, so has his chairside practice.

"Seeing patients in a medical clinic is a completely different world. Initially, they were going to schedule patients in their typical 15-minute blocks, thinking nothing of 'double booking,' so they were puzzled as to why I required *a whole hour* to see a patient. Eventually, I could fabricate and deliver an NTI in around 30 minutes, but I was always pressing. What really slowed me down was the occasional patient with rather crooked teeth. The internal trimming and relining of the device with cold-cure acrylic had to be just right, otherwise the possible binding and tension on the patient's teeth might add to their nociceptive input (which is the opposite of migraine prevention). One afternoon, with three new patients still to be seen, I completely ran out of cold-cure acrylic. I had a jar of the NTI ThermoPlastic Beads that other dentists had begun using to reline and deliver NTI devices. I had never actually tried them… but I faked like I had and those last three deliveries were a breeze! I haven't used acrylic now for the last four years."

Using the thermoplastic material does have its drawbacks though. Although it is clear and colorless in its warmed manipulation stage, it cools to be stark opaque white.

"Many patients are quite familiar with splint therapy, and some prefer a less conspicuous device, even though it's only worn during sleep," says Boyd. "They love their NTI, but they don't like the way it looks. I don't hesitate to suggest they return to their regular dentist to have an NTI-Plus made through Keller Lab." An NTI-Plus is durable, clear and colorless, and minimizes the chairtime spent on insertion and adjustment to less than 10 minutes in most cases.

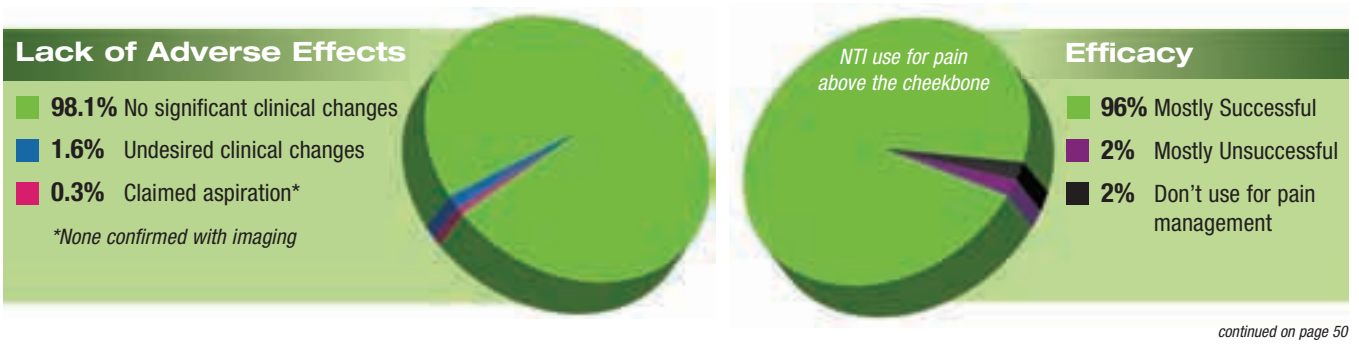
While enhancing chairside splint delivery protocol was a natural evolution for Boyd in the neurology clinic, it wasn't his primary goal in consulting with the group.

"The FDA approved the NTI for the prevention of medically diagnosed migraine pain based on the reported pain relief of migraineurs in the trials. The assumption followed that the NTI's method of action was to considerably reduce nocturnal clenching intensity of the chronic migraineurs, yet to this day, no study has actually identified nocturnal clenching as a complicating component of chronic migraine," says Boyd.

"My intent," Boyd continues, "was to simply have all-night temporalis EMG recordings on migraine patients; however, it became a considerable challenge to identify the ideal nocturnal EMG device. The device needed to record in microvolts during a patient's sleep over an eight-hour period, but all that were available were simple devices that could count the number of events that exceeded a predetermined threshold. I had previously become familiar with the sophisticated EMG recording equipment that BioRESEARCH provides, and knew that to truly add to the medical body of knowledge, that caliber of recording would be required to show specific diagnostic data."

"Just last year, our clinic completed a major addition of a multiple bed sleep lab, which now provides us with the facility to observe the migraineurs' sleep patterns in a controlled environment," says Blumenfeld.

"What was surprising was the lack of sophistication of the existing EMG software being used in the typical sleep lab setting. It was the same 'counting of events' set-up," says Boyd. "I called my colleagues at BioRESEARCH and described exactly what we needed, and without hesitation, they were on the case. So early next year we'll initiate another important study: a polysomnogram with temporalis EMG recordings of 100 consecutive chronic migraineurs. Each of those subjects will then use an NTI for eight weeks, and then have their sleep study repeated using



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their NTI. We believe this study will provide valuable information on the topics of sleep, pain and parafunction."

"This stands to be a very significant study," says Blumenfeld. "The medical community assumes that sleep is a significant factor in chronic headache, yet there has never been an objective evaluation of sleep of a large group of migraineurs. I am excited to see what we find. For the physician treating chronic migraine, it will be useful to advise the patient of what percentage responds well to NTI therapy, for example, or what percentage has evidence of sleep apnea."

Not all of the migraineurs that Blumenfeld treats are candidates for an NTI.

"The one problem that I felt we had with the NTI was its ease of use. With no other chairside options, a practitioner can be tempted to provide an NTI when another design, although more time consuming, may be indicated," says Blumenfeld.

"If the patient has a minimal or edge-to-edge incisal overlap, while an NTI may allow for a more optimal condylar positioning, it might result in an anterior open bite," says Boyd. "We needed to provide a method of splint therapy where the risk of that kind of revelation can be prevented if desired. Additionally, while an NTI is great for clenching patients, there are those, for example, with asymptomatic bruxism, that an NTI would not be indicated for. What we needed was an adaptable mouthpiece design that could be customized for the presenting diagnosis, without the concern of undesired effects."

"Obviously, with our sleep lab, we are prescribing CPAP regularly. Some of the patients who we've referred to a dentist for an apnea device have returned disappointed at the expense. So another challenge was to be able to provide a legitimate apnea device here in our facility, at a reasonable cost," says Blumenfeld.

"Essentially, our goal was to design the ideal mouthpiece system, one that could be delivered chairside in one appointment and be adapted to treat a variety of conditions, including asymptomatic bruxism, clenching-induced migraine and obstructive sleep apnea," said Boyd. "It needed to be 'provisionally permanent,' that is, sturdy enough to endure at least six months of vigorous use. While using cold-cure acrylic would be time-consuming and unpleasant for the patient, our use of the thermoplastic material would make it quick and easy, with no taste or smell, and would practically eliminate our limitations on design. What we came up with was the 'Total Splint System.'"

So what's next for Boyd and Blumenfeld?

"I've been in the position of wearing two hats for a long time now," says Boyd. "Twenty years ago, to treat my own chronic headache and migraine condition, I developed a therapeutic protocol which called for a specific splint design. My intent was never to try and create a marketable product for the dental industry, but ten years ago, that's what the NTI device became. While my passion has always been the research and development of therapeutic protocol and splint design, my obligation has been to oversee the small, privately held company that now distributes the NTI device throughout North America, Europe, the UK and parts of Asia, while licensing laboratory-fabrication rights to Keller Lab and its network. Through my association with Dr. Blumenfeld, I now have a greater understanding of the medical health care industry, and the legitimate need in the migraine field for a superior method of prevention. There is a large population of chronic migraineurs whose health-care providers, at this rate, might not consider nocturnal parafunctional control in their patient's lifetime, simply due to the lack of provided information and published research. I know my limitations, and I know that a little Internet mail-order company just can't make that happen all on its own.

"With our continuing research and development of the NTI, the Total Splint System and other therapeutic modalities that Dr. Blumenfeld has produced, I feel it's time to step away from the business side of things," continues Boyd. "I've been approached to license the NTI intellectual properties to a publicly held corporation, Therapeutic Solutions International, and remain in the research and development side of things. I think I'd better fasten my seatbelt for these next 10 years." ■