A NEW, NONINVASIVE APPROACH FOR SUCCESSFULLY TREATING THE PAIN AND INFLAMMATION OF TMJ DISORDERS

Milton Hodosh, DMD; Steven H. Hodosh, DMD; Alex J. Hodosh, DMD

This article introduces a new topical gel and method for rapidly relieving temporomandibular joint (TMJ), muscles of mastication, and myofacial pain while uniquely inhibiting the associated destructive chronic inflammation. The gel (composed of 18% potassium complex, 10% dimethylisosorbide, and 72% aqueous hydroxyethyl cellulose gel) was applied and gently rubbed onto the facial skin over the painful TMJs, muscles of mastication, and myofacial areas. The gel was applied as soon as clinicians identified the TMJ disorder, as the authors have found that the gel routinely and predictably provides rapid pain relief and patient comfort and speeds restoration of the jaw’s functional abilities, usually within 5 minutes after it is applied. The relief is attributable to the combined ability of potassium and dimethylisosorbide to inhibit inflammation and pain. These dynamic results have led the authors to recommend that the gel be applied as a first-step procedure before trying to definitively diagnose and treat the cause(s) of the patients’ pain and dysfunction. Once the pain had been eliminated as a complicating factor, a diagnosis and treatment plan concerning the jaw’s biomechanical problems may be identified and dealt with. The ability to remove pain and inflammation as a first measure before making a definitive diagnosis and treatment plan minimizes patient anxiety, depression, and psychological concerns. Subsequent diagnosis and treatment of the biomechanical disorder(s) related to TMJ are then more easily and effectively accomplished.

Key Words: TMJ disorders; pain; inflammation

INTRODUCTION

Temporal mandibular joint (TMJ) disorder has many causes, including muscular imbalance, TMJ dysfunction, malocclusion, parafunctions, and postural alterations.1,2 Pain is the patient’s most frequent complaint, and it is certainly the most pressing problem for patients with TMJ disorders. Clinicians who treat TMJ disorder usually try to discover the specific cause of their patients’ pain and dysfunction in order to correct it.

The hypothesis presented in this article is that this goal, although seemingly logical, should be temporarily deferred as it will certainly be easier to discover the specific cause of the TMJ disorder when the pain associated with the dysfunction is relieved; pain and muscle spasm(s) frequently create a confusing overlay of biomechanical and psychological signs and symptoms that obscure the original cause of the problem.3 For this reason, it is very important that the first phase of treatment should be to relieve the patient’s pain.4,5 Once this has been achieved, it will be easier for the clinician and the patient to diagnose and treat the dysfunctional phase of the TMJ disorder.

The authors have developed a very effective, noninvasive, rapid acting, predictable, and reproducible topically applied gel that rapidly alleviates and
eliminates TMJ, muscles of mastication, and myofacial pain, while inhibiting the associated inflammation (see Table 1).

This discovery has evolved from continued extensive research with other uses for potassium compounds following our development of potassium nitrate as a superior tooth desensitizer. This article introduces a new technology for the rapid inhibition of TMJ disorder’s pain and associated inflammation.

**METHODS AND MATERIALS**

Study subjects were 54 volunteer patients with the chief complaint of TMJ pain along with varying degrees of dysfunction and myofacial pain. Using a table of random numbers, subjects were randomly chosen from the practice of Hodosh Dental Associates clinical practice to participate in the study.

The aim of the study was to see if the pain and associated inflammation of patients with TMJ pain and dysfunction could be inhibited by applying a gel composed of 18% potassium complex, 10% dimethylisosorbide (Dmi), and 72% aqueous hydroxyethyl cellulose (HEC) topically and gently rubbing it onto the preauricular and other facial areas from which the pain originated. Each patient met the following inclusion/exclusion criteria.

**Inclusion criteria**

For each patient, the diagnosis of TMJ disorder was professionally confirmed by exhibiting pain in the TMJ(s) area upon digital palpation (with or without myofacial pain). Patients had to agree to use the assigned gel twice a day as directed for 2 additional days after the initial day office application and to keep the necessary check-up appointments.

**Exclusion criteria**

Patients were excluded from the study if they had a history of sensitivity to the ingredients in the gels (potassium nitrate, potassium citrate, potassium chloride, Dmi, or HEC).

**Gel**

Test gel No. 1 (placebo) contained aqueous hydroxyethyl cellulose.

Test gel No. 2 (Active) contained 18% potassium complex (6% potassium chloride, 6% potassium citrate, 6% potassium nitrate), 10% Dmi, 72% aqueous HEC.

**Clinical examination**

A clinical examination, including palpation of the TMJs with the mouth closed and open was performed for all patients to determine the severity of the patients’ TMJ pain and the presence of a TMJ disorder. If light finger palpation pressure applied over the TMJs produced a sharp painful reaction and patient pull back from the clinician’s fingers, the pain was considered to be very severe. If only heavy finger palpation pressure applied over the TMJs caused pain, then it was considered to be more moderate. This pretreatment procedure helped establish the presence of a TMJ disorder and served as a baseline standard to be used for comparison by each patient to better self-evaluate his or her degree of pain relief, if any, by comparing

---

**Table 1**

Summary statistics of the raw visual analog scale scores for each time pain was assessed

<table>
<thead>
<tr>
<th>Time point</th>
<th>No. of patients</th>
<th>Mean</th>
<th>SE</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>54</td>
<td>81.57</td>
<td>1.64</td>
<td>85</td>
</tr>
<tr>
<td>Placebo</td>
<td>54</td>
<td>81.57</td>
<td>1.64</td>
<td>85</td>
</tr>
<tr>
<td>Day 1</td>
<td>54</td>
<td>1.52</td>
<td>0.48</td>
<td>0</td>
</tr>
<tr>
<td>Day 2</td>
<td>54</td>
<td>4.65</td>
<td>1.00</td>
<td>0</td>
</tr>
<tr>
<td>Day 3</td>
<td>54</td>
<td>0.33</td>
<td>0.33</td>
<td>0</td>
</tr>
</tbody>
</table>

**Table 2**

Change from baseline after placebo gel was applied

<table>
<thead>
<tr>
<th>Location</th>
<th>Variability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>0</td>
</tr>
<tr>
<td>Median</td>
<td>0</td>
</tr>
<tr>
<td>Mode</td>
<td>0</td>
</tr>
<tr>
<td>Range</td>
<td>0</td>
</tr>
<tr>
<td>Interquartile range</td>
<td>0</td>
</tr>
</tbody>
</table>

**Figure 1.** The course of each patient’s pain measurements over the time of the study. Note the dramatic lessening of pain using the active gel No. 2.
their initial pain experience with any pain experienced after the treatment gel was applied (see Figure 1).

The patient’s pain assessment was based on the use of a visual analog scale (VAS) ranging from 0 mm to 100 mm. The VAS was used by each patient to establish the degree of pain present before receiving the gel treatment (baseline) and during treatment. The VAS scores were as follows: 0 mm = no pain, 25 mm = slight pain, 50 mm = moderate pain, 75 mm = severe pain, and 100 mm = very severe pain, pain as bad as one can stand. A comparison of visual analog scores was used to measure the effects of the treatment gels.

Before treatment patients were also asked to fully open and then close their mouths so that baseline measurements could be taken to determine the distance between the incisal edges of the maxillary and mandibular anterior teeth (central incisors were preferred) at maximal opening. Measurements were recorded in millimeters. Opening and closing ability was retested 5 minutes after each office gel application treatment. Results were recorded and compared with the initial baseline reading at each check-up. These procedures were duplicated, and the results were compared.

**Technique**

Gel No. 1 was first applied to and gently rubbed into the painful preauricular and other painful areas of each patient’s face or neck. After waiting for 5 minutes for gel No. 1 to permeate into and penetrate through the skin to the deeper targeted painful tissues, the TMJs were palpated to determine if there was a change in the patient’s pain status (see Table 2). Previous unpublished pilot studies indicated that notable pain relief routinely began to occur within 5 minutes following the application of the active medication (#2). If significant pain relief with gel No. 1 (placebo) did not occur within 5 minutes of its application, and the pain was still present without improvement washout time, gel No. 2 was applied as described to the same area(s) in the same order and way as gel No. 1 was applied. After 5 minutes the same areas were repalpated to see if the pain had disappeared, lessened, remained the same, or exacerbated. Using the baseline VAS it was possible for each patient to recognize any change in pain. Each patient served as his or her own control in this way. The study was designed so that all patients enrolled would receive the best chance for rapid pain relief.

No patient failed to receive the active gel treatment (gel No. 2). In this way all patients were provided with the opportunity to receive the benefits that the active gel could provide, while still receiving the placebo for comparative pain evaluation purposes. This approach was used to lessen the patients’ pain and anxiety as efficaciously as possible (see Tables 3 and 4 and Figure 2).

Patients did not know which gel was the active gel or the placebo because both were identical in appearance. All patients were given a 1-oz bottle of gel No. 2 (the active) to apply to the affected painful areas twice a day for 2 additional days at home (thus, each patient received 3 days of treatment in all). Patients were then reexamined in the office and

**TABLE 3**

<table>
<thead>
<tr>
<th>Location</th>
<th>Variability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>80.06</td>
</tr>
<tr>
<td>SD</td>
<td>11.72</td>
</tr>
<tr>
<td>Median</td>
<td>80.00</td>
</tr>
<tr>
<td>Variance</td>
<td>137.45</td>
</tr>
<tr>
<td>Range</td>
<td>52.00</td>
</tr>
<tr>
<td>Interquartile range</td>
<td>16.00</td>
</tr>
</tbody>
</table>

*For this analysis, the following variable was created where VAS = visual analog scale: Baseline VAS – Day 1 VAS.

**TABLE 4**

<table>
<thead>
<tr>
<th>Test</th>
<th>Statistic (</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student $t$ t</td>
<td>50.18</td>
<td>$&lt;.0001$</td>
</tr>
<tr>
<td>Signed rank S</td>
<td>742.5</td>
<td>$&lt;.0001$</td>
</tr>
</tbody>
</table>

*Tests for the lasting effect of the gel comparing the visual analog scale score for days 2 and 3 yielded similar results; all had $P$ values $<.0001$.
scheduled for treatment of their biomechanical jaw problems.

When the TMJ, muscles of mastication, and myofacial pain was relieved and the functional abilities were assessed, the clinician(s) turned to establishing a definitive diagnosis and treatment for the causative factors of the jaws’ biomechanical problems. At this time each patient was examined for muscular disorders, TMJ dysfunction, malocclusal problems, parafunctional habits, and/or poor postural conditions. These disorders and other problems were addressed. The authors have not described the specific biomechanical problems and treatments rendered, as they are not within the scope of this article. The intent of this article is to describe an important, new, noninvasive approach for successfully treating the pain and inflammation of TMJ disorders.

## Results

### Placebo

None of the 54 patients were helped by gel No. 1 (placebo). Application of gel No. 1 did not relieve or diminish pain within 5 minutes after an in-office application to the patients’ TMJs and other associated painful facial muscle areas, nor were functional jaw opening or closing movements enhanced.

### Active gel

All 54 patients obtained relief of their pain by the end of day 3. Specific findings were as follows:

- Forty-five patients had complete pain relief from an initial office application of the active gel within 5 minutes after the first application of gel No. 2.
- Nine patients had notable, but not complete pain relief from an initial office application of gel No. 2. These patients had slight pain (VAS < 25 mm).
- After the second day of twice-a-day application of gel No. 2, 35 patients had freedom of pain and 19 patients had slight pain. In 13 of the 45 patients that had freedom of pain after a single office application, slight pain returned the next day (slight pain = a VAS < 25 mm).
- After the third day of twice-a-day application of gel No. 2, all 54 patients were free of pain.

Patients treated with gel No. 2 who had slight pain at one time or another emphasized that the pain was “slight” and that they welcomed the dramatic pain relief attained so rapidly. They also appreciated having the gel to use at home. Patients returned to the office after the third day of treatment for a check-up and treatment for the biomechanical aspects of their TMJ disorder.

### Inflammation

After the application of the active gel No. 2, the tissues became cooler to the touch, swelling diminished or disappeared, and the preauricular areas were no longer painful or tender to palpation. In addition, all patients reported less jaw difficulty with eating, speaking, and opening and closing the mouth. With solid pain (and twitching) relief, there was a general improvement in each patient’s ability to more freely open and close his or her mouth with less difficulty or stiffness. All the patients exhibited considerably less anxiety.6 These improvements took place before treatment for the biomechanical jaw problems. The authors attribute these findings to the attained freedom of pain and the unique inhibition of inflammation by potassium/Dmi.

### Discussion

When treating TMJ disorders, it is recommended that clinicians should first try to relieve the patient’s pain as quickly as possible, as this pain is most often very severe and debilitating. Pain relief should be given top priority before seeking to discover the causes of the pain and dysfunction of the TMJ and jaw biomechanical problems. Patients generally presented with varying degrees of physical and emotional problems.7,8 They were in pain and therefore were frequently upset, afraid, and stressed. These distressing symptoms were significantly alleviated with pain cessation.

Before discovering this technology, genuine pain relief was extremely difficult to accomplish. Methods...
of pain relief included acupuncture, pharmacopathy, biofeedback, oral and intramuscular injections of narcotics, nonsteroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants, dry needling, vapor coolant spray, muscle massage, occlusal adjustments of gross prematurities, bite stabilizers, intraoral appliances, stretching exercises, and other methods. Injectable local anesthetics have also been used to temporarily relieve pain. It is interesting that this invasive technique provides only transient pain relief and does not have a therapeutic effect, is often frightening to patients, and can only be used infrequently. It is also associated with a numbing feeling and does not inhibit the signaling of the mast cells by the sympathetic nerves of the autonomic nervous system to initiate and/or maintain a targeted inflammatory response to the involved tissues. Inflammation that lasts for 1 or 2 days to 2 or 3 weeks becomes chronic and destructive and causes the condition to linger and exacerbate.

Our studies indicate that potassium in combination with Dmi applied to the painful skin over the TMJ areas, muscles of mastication, and myofacial areas penetrates and permeates these painful tissues in a targeted, noninvasive manner and inactivates both the nerves of the central nervous system (CNS) and autonomic nervous system (ANS) thereby inhibiting pain, inflammation, and untoward muscle spasms. Pain-inducing substances can be produced and released from cell membranes by trauma to the soft tissues and bone, infection, and allergenic reactions. Therefore, a large part of the successful management of pain requires blocking or inhibiting the inflammation.

The potassium/Dmi/aqueous HEC gel has the advantage of being able to be directly target the affected tissues without having to enter any of the usual pharmokinetic pathways that use intramuscular, intravenous, or subcutaneous injections of corticosteroids, sedatives, local anesthetics, muscle relaxants, NSAIDs, narcotics, and other medications given via oral, rectal, or vaginal routes of drug delivery. The ability to target the delivery of this very effective noninvasive gel directly into the involved tissues diminishes the possibility of producing untoward side effects, thereby avoiding serious and even life-threatening complications, especially for patients who suffer from debilitating illnesses such as heart failure, diabetes, and blood dyscrasia.

When patients have more than a brief episode of severe pain that is not quickly relieved, depression may occur, requiring psychotherapeutic and other drugs. Family, occupational, and interpersonal relationship problems can often result as a sequela to a severe prolonged experience of pain.

These findings indicate that potassium/Dmi/aqueous HEC gel can routinely, predictably, effectively, and rapidly (usually within 5 minutes after application) diminish the pain and inflammation of TMJ-related disorders.

Rationale for treatment of TMJ pain and inflammation

We have pioneered the use of water-soluble potassium salts for a number of uses, and the current application is another important extension of that technology. Use of potassium/Dmi to inhibit the pain and inflammation of dysfunctional TMJs, muscles of mastication, and myofacial areas is associated with the modification of the nerves’ electrical potential. Potassium alters the electrical potential of the nerves of the CNS and the ANS. Its mode of action is based on sound physiologic science.

Nerves and other tissues are bathed in electrolytes that polarize within and without their membranes. Electrolytes within the nerve’s membranes have a net negative charge from a contained preponderance of anions, whereas electrolytes located outside the nerve’s membranes have a net positive charge. The charges are not balanced, and the difference between these 2 charges provide for a resting membrane potential (RMP) of approximately 85 mV. Nerves of the CNS and ANS can only conduct an impulse at their RMP. A gel rich in potassium ions can penetrate and permeate these painful tissues, and this is readily accomplished by the combined action of potassium and Dmi; Dmi is a safe water- and lipid-soluble nontoxic osmotic that draws water from cells and other membranous tissues, shrinking them in volume. This process creates spaces between the cells. The intercellular spaces thus established provide a pathway for potassium to readily penetrate and permeate the targeted painful tissues. These are very vital, normal physiologic processes for nerves and other cells. Nerves possess the ability to function physiologically within a range from RMP to their acting potential, and all cells have the ability to shrink and swell in volume.

By the mechanisms described, potassium in combination with Dmi inhibits nerve conduction and pain from the CNS. Nerves from the ANS (sympathetic division) are also inhibited by the same mechanism and are unable to conduct the necessary signals to the Mast cells to initiate and/or maintain the targeted inflammatory responses to the painful dysfunctional tissues. The special ability of potassium in combination with Dmi to inhibit inflammation is not
only important for the treatment of temporomandibular joint disease but it also is remarkable in alleviating other painful inflammatory conditions, including craniofacial and muscular/joint pain. Every disease or condition has an associated inflammatory component, and inflammation is an important defense mechanism that protects human beings and animals from invading microorganisms and other harmful causes. However, when it has essentially done its job and has remained too long (2 or 3 days to 2 or 3 weeks), it turns chronic and becomes “the enemy,” adding to the severity by compounding, prolonging, and aggravating the condition. This is true for TMJ disorder with and without muscles of mastication and myofacial involvement. When chronic inflammation is inhibited, the body’s healing capacity improves as it no longer is opposed and impeded by the destructive chronic inflammatory phase of the condition. This leads to better tissue health and improved restoration of functional capabilities.

CONCLUSION

This manuscript highlights the discovery that applying potassium/Dmi/aqueous HEC topical gel, specifically onto the face in front of the tragus of the ear or the muscles of mastication and onto other myofacial painful areas, rapidly begins to eliminate the pain and inflammation associated with this difficult-to-treat condition, often within minutes. The gel can be reapplied by the patient as needed, safely providing self-help for comfort control and aiding in the successful treatment of this troublesome condition. The gel treatment is topically applied and directly targeted. It is also painless, odorless, noninvasive, and routinely and predictably very effective. The ability to rapidly inhibit pain and inflammation as a first measure makes the TMJ biomechanical problems easier to diagnose and treat. Relieving pain minimizes patient anxiety and psychological concerns and shortens the course of treatment.

REFERENCES