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The Effect of the Spray and Stretch Technique on the Silent Period Duration of the Masseter Muscle

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The Effect of the Spray and Stretch Technique on the Silent Period Duration of the Masseter Muscle

By

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ABSTRACT

THE EFFECT OF THE SPRAY AND STRETCH TECHNIQUE ON THE SILENT PERIOD DURATION OF THE MASSETER MUSCLE

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The purpose of this study was to evaluate the effectiveness of Fluori-Methane vapocoolant spray, as used in the spray and stretch technique, on decreasing a prolonged silent period duration in the masseter muscle. Ten subjects were selected, all of whom were identified as having masseter muscle dysfunction and/or spasm. The population consisted of two males and eight females, whose ages ranged from 24-58. The silent period duration of the masseter was measured following elicitation of the jaw-jerk reflex. Five readings were taken and the mean silent period duration was calculated. All means longer than 35 milliseconds were considered prolonged. An EDX 1000 electromyograph and Beckman standard size silver surface electrodes were used in recording the data. The amount of mandibular depression available was also measured. Once these measurements were completed, each subject was treated using Fluori-Methane vapocoolant spray, as used in the spray and stretch technique. The silent period duration and amount of mandibular depression were then remeasured in the same manner as was done prior to treatment. The

pre and post-treatment data was then analyzed using the t-test for related measures. The effectiveness of Fluroi-Methane on decreasing a prolonged masseter silent period duration was significant at the .005 level of significance for directional tests. The effectiveness of Fluori-Methane on increasing mandibular opening was significant at the .0005 level of significance for directional tests.

These results are consistent with the expected outcome and reinforce previous studies that have found Fluori-Methane to be effective in reducing muscle spasms. This study also provides a means for objectively measuring the progress of a patient with masseter spasms who is undergoing physical therapy management.

CHAPTER I

INTRODUCTION

Description of the Problem

With regard to patients suffering from temporomandibular joint (TMJ) dysfunction, it has been well documented that masticatory muscle dysfunction is one of the predominant presenting signs. (Bell, 1969; Gelb & Arnold, 1959; Laskin, 1969; Schwartz & Chayes, 1968; Trott & Goss, 1978). Specifically, dysfunction of the masseter muscle is present in most cases of TMJ dysfunction (Gelb & Tarte, 1975; Atkinson, Vossler & Hart, 1982). In addition, the patient with TMJ dysfunction may have a decreased ability to open the mouth to normal parameters, (Bessette, Bishop & Mohl, 1971) which may be secondary to the masseter muscle dysfunction. To obtain an objective assessment of the masseter muscle dysfunction, investigators have used electromyography to measure the silent period duration (Bessette, Bishop & Mohl, 1971; McNamara, Crane, McCall & Ash, 1977; Widmalm, 1976). The silent period duration of the masseter muscle is a period of electrically quiet activity in the muscle, immediately following an elicitation of the masseteric or jaw jerk reflex. It has been determined that a silent period duration of greater the thrity-five milliseconds is abnormally long (Bessette & Shatkin, 1979).

A number of treatment approaches for TMJ dysfunction have been utilized. Among these is the use of vapocoolant sprays, which have been used for a number of years to treat myofascial pain resulting

from trigger points and muscle spasms (Mennell, 1975; Nielsen, 1978; Travell, 1976; Travell & Rinzler, 1952; Rubin, 1981). They have specifically been shown to be of benefit in treating TMJ dysfunction, secondary to muscle dysfunction (Schwartz, 1959; Travell, 1960).

Purpose of the Study

The primary goal of this study was to determine the effectiveness of Fluori-Methane vapocoolant spray in decreasing a prolonged silent period duration of the masseter muscle, through use of the spray and stretch technique. A secondary goal was to determine if a limitation of mandibular depression might be related to an abnormal silent period duration of the masseter.

CHAPTER II

REVIEW OF LITERATURE

The electromyographic determination of the silent period duration, has been used in the past to evaluate patients with TMJ dysfunction (Bessette, Bishop & Mohl, 1971). In this study, twenty-seven individuals were used, ten of whom had no history of pain in the TMJ area, and seventeen of whom were randomly selected from a group that demonstrated any or all of the following complaints: 1) pain in one or both temporomandibular joints; 2) deviation or limitation in opening the mouth; 3) presence of TMJ sounds during movement. With each subject mandibular opening was determined by measuring the widest interincisor distance, and pantographic and TMJ X-rays were taken to rule out gross pathology of the TMJ as well as pathology of the teeth and jaws as possible etiologic factors.

In order to elicit the masseter, or jaw jerk reflex, a solenoid driven plunger was used to deliver a tap to the mandibular symphysis. This tap simultaneously triggered the beam on an ocilliscope, which was used to store the response. Bipolar silver disc surface electrodes were used over the masseter in order to record the response. Prior to applying the tap, the subject was asked to clench his teeth as strongly as possible. The procedure was repeated twice on each subject to determine reproducibility of the electromyograph (EMG) readings.

At the conclusion of their study the authors found that the mean silent period duration for the ten normals was 24.0 milliseconds

on the right and 24.7 milliseconds on the left. The range for this group was 20 to 30 milliseconds. For the group with TMJ symptoms, the mean silent period duration was 59.7 milliseconds on the right and 53.8 milliseconds on the left. The range for this group was from 23 to 150 milliseconds.

A brief discussion was included on the mechanism for production of the jaw jerk in normals and the mechanism for a normal silent period duration. Unlike the silent period in the peripheral limb reflexes, the silent period of the masseter cannot be abolished by voluntary effort, which indicates a source of persistent active inhibition or a marked disfacilitation of the masseteric motorneuron pool. Several possible sources of active inhibition were mentioned and discussed. Among these sources were included the periodontal ligament, the Golgi tendon organs in the masticatory muscles, or recurrent inhibition, via the motor axon collaterals, which could lead to disfacilitation of the motorneurons, which may result from the silencing of the muscle spindles during the muscle twitch of the jaw jerk.

In the patient with a prolonged silent period duration, the authors felt that there must be present a persistent source, either of active inhibition or disfacilitation to the masseteric motorneuron pool. It was proposed that since the TMJ patient generally has muscle spasms present, that perhaps the Golgi tendon organs in these muscles have a prolonged discharge, which could provide a source of active inhibition leading to a prolonged silent period duration.

The significance of the study by Bessette et al. (1971), is that it established normal parameters for the silent period duration, which

were shown, for this group, to be between 20 to 30 milliseconds. It also established the presence of a prolonged silent period duration in patients diagnosed as having TMJ dysfunction with concomitant masseter muscle dysfunction. Clinically, this now allows for the objective measurement of masseter muscle dysfunction.

Subsequent to the study discussed above, investigators have used the silent period duration as an indication of treatment effectiveness (Beemsterboer, McNamara, Holden & Ash, 1976; Bessette & Shatkin, 1979). In each of these studies, an alteration was made in the occlusion of the patient. Occlusion as defined by Steadman's (1976), is "the relationship between the occlusal surfaces of the maxillary and mandibular teeth when they are in contact." (p. 971).

Beemsterboer et al.(1976) measured the silent period duration, of ten patients, and then for each patient fabricated a heat cured acrylic maxillary occlusal splint which was worn for periods ranging from 3 to 8 weeks. The silent period duration was measured again following treatment. Before treatment the mean silent period duration was 44 milliseconds bilaterally. After wearing the splint, the mean silent period was 25 milliseconds on the right and 26 milliseconds on the left. Their conclusion was that the duration of the silent period may serve as a useful diagnostic aid and assist in the diagnosis and treatment of tempormandibular joint dysfunction. In addition, use of the bite splint also resulted in a significant decrease of post-treatment mean duration values for the EMG silent period.

Bessette and Shatkin (1979), used the silent period duration of the masseter to predict the results of nonsurgical treatment of TMJ dysfunction. 308 patients who complained of pain and limitation of

mandibular opening, were seen for diagnosis and treatment. Of the 308 patients evaluated, 161 had a lengthened masseteric silent period duration, of greater than 35 milliseconds. Of these 161 patients 64% experienced muscle tenderness of palpation, and 50% demonstrated limitation of mandibular opening. 96 of the 161 patients were treated using a maxillary occlusal splint and occlusal adjustments. The splint was worn for a four week period. 90 of the 96 patients were asymptomatic within four weeks of treatment, and demonstrated a shortened silent period. However, no mean duration was given for the silent period following treatment. Success in this study was defined as freedom from symptoms immediately after therapy, and also at a subsequent evaluation six months later. The success rate was stated as being 93% for this group.

The authors felt that in the past the lack of definitive diagnostic test for TMJ dysfunction syndrome, has made the clinician dependent upon subjective clinical impressions. The utilization of electromyography to measure the silent period, now makes the differential diagnosis easier to determine in terms of differentiating pain due to muscle spasm versus pain due to some other factor.

In published literature to this time, treatment aimed primarily at altering the silent period duration has been of a dental nature. Published studies have appeared, however, that dealt with treating muscle spasms and limitation of mandibular movement by other means. The use of vapocoolant sprays has been one of the treatment approaches to appear in the literature.

Schwartz (1954) addressed the issue of treating painful limitation of mandibular movement with a vapocoolant spray, which in this instance

was ethyl chloride. His study involved 256 patients, 27 of whom gave limitation of mandibular movement as their chief complaint. In 20 of the 27 patients, muscle spasm was felt to be the cause of limitation. In addition to this group of 27, limitation of movement was found in 199 patients whose chief complaint was pain. The author went on to point out that the appearance of limitation of mandibular movement, especially in the absence of a history of trauma of sufficient severity to cause fracture, always suggests the possibility of muscle spasm. In cases of limitation, spasms are generally present in the masseter and internal pterygoid muscle. A discussion of the physiology of mandibular movement ensued, which included a discussion of the the function of the masticatory musculature and its importance to mandibular movement. It is relevant to note, that if a muscle is in a state of spasm, and is unable to assume its normal resting length, then it will limit whatever movement requires the lengthening of that muscle. If the masseter is in spasm, then the mandible will be unable to reach full depression. In his study, Schwartz used a group of ten patients with limited mandibular movement secondary to muscle spasm. Each of these patients was treated with ethyl chloride spray using the procedure that is advocated by Travell (1952). The duration of treatments were: Three required one treatment, one required two treatments, two required treatment of one week, three required treatment for four weeks, and one required treatment for two months on a daily basis. Out of the ten patients, seven recovered, two obtained temporary improvement, and one received no benefit. Of those who did gain benefit from the treatment, it appeared that the longer they had been symptomatic, the greater the treatment time needed.

In conclusion, Schwartz stated that "Ethyl chloride spray has been found to be effective in the treatment of limited, painful mandibular movement caused by muscle spasm, and offers a promising field for further investigation." (p. 507)

Janet Travell, who has published numerous articles on the use of vapocoolant sprays, also has advocated their use in treating TMJ dysfunction (1960). A substantial portion of this article deals with causes of muscle spasms, the pathophysiologic effects of long term spasming, and areas of referred pain secondary to specific muscle spasms in the head and neck. However, she does address the treatment of muscle spasms through the use of procaine injections or a vapocoolant spray. The procedure for applying the spray is given in detail as well as precautions to be observed. She feels the mechanism by which the vapocoolant spray works is as follows.

> The cold shock and rapidly changing temperature gradient are thought to induce an afferent barrage which modifies the central excitatory state and so blocks the stream of noxious impulses from the muscles. Pain and cold sensations both travel in spinothalamic tracts and terminate in the same higher centers; nerve impulses traveling over a given pathway may either initiate a response or block it.
>
> It seems certain that brief refrigeration anesthesia of cutaneous receptors and counter irritation, that is, a strong input of stimuli, both enter into the neurophysiologic mechanism by which the vapocoolant sprays terminate painful muscle spasm and referred myofascial pain. (p. 760-761)

In conclusion, Travel states "... application of a vapocoolant spray with gentle stretching of the muscles in spasm offers an effective method for terminating pathophysiologic stress disorders of the skeletal muscles ..." (p. 761)

Mennell (1975) advocates the use of Fluori-Methane spray instead of ethyl chloride, because of the latter's "... explosive, flammable, highly toxic, and fast acting properties." (p. 1149) Fluori-Methane is less cold during application than ethyl chloride, and he stresses that muscle chilling must be avoided in treatment. Lowering the intramuscular temperature of a muscle in spasm can exacerbate the spasm and increase pain. Fluori-Methane is used " ... to promote the restoration of the normal resting length of muscle by substitution of sensory input --touch and cold-- and not by cooling the muscle itself." (p. 1149) He goes on to explain the mechanism by which this substitution of sensory input works.

> Clinically, it appears that the effectiveness of cold in the relief of pain probably is based on the difference in speed of conduction of the epicritic cold and touch sensation via anatomically larger nerve fibers, and of the protopathic muscle sensation via the smaller gamma afferents of the muscle pain-receptor organs. Every muscle seems to have a specific representation in the overlying skin.
>
> By the reaction of the senory receptor organs transmitted via the local cord reflex arc or via the long central nervous system, it seems that the faster moving epicritic sensory impulses arrive at their centers before the slower moving protopathic sensory impulses. It is plausible that the impulses

> arriving first make the centers refractory to the slower impulses, which temporarily block the reception to protopathic pain impulses. During the refractory period in which the muscle pain -- muscle spasm -- is relieved momentarily. The muscle then can relax and the normal resting length of muscle, and, consequently, the normal tonic reflex patterns, can be restored. In this manner the abnormal noxious conditioned reflex maintaining spasm is overcome. In treatment, however, the normal resting length of muscle is not achieved unless the muscle is mechanically stretched during the period in which reception of the noxious stimulus is blocked. (p. 1147-1148).

Summary of Findings

Based on the articles by Schwartz (1954), Travell (1960), and Mennell (1975), it is readily apparent that Fluori-Methane spray can be generally effective in reducing muscle spasms and increasing mandibular opening when applied using the spray and stretch technique. According to the conclusions drawn by Bessette, Bishop, and Mohl (1971), the presence of a prolonged masseteric silent period duration is generally indicative of muscle spasms in the masseter. Beemsterboer, McNamara, Holden and Ash (1976) and Bessette and Shatkin (1970), showed that it was possible to reduce the duration of a prolonged silent period by appropriate treatment. In both instances, an occlusal splint and/or occlusal adjustment was utilized to normalize occlusal discrepancies that were present.

Significance of Findings

Given that Fluori-Methane is an effective treatment modality for reducing muscle spasms in the masseter and increasing mandibular

opening, and that a prolonged masseteric silent period duration is indicative of the presence of muscle spasms in the masseter, then it would seem logical that Fluori-Methane would be effective in reducing a prolonged masseteric silent period duration.

To this date in the published literature, there has been no data presented conerning the use of vapocoolant sprays to decrease a prolonged masseteric silent period duration.

CHAPTER III

METHODS AND PROCEDURES

Description of Subject Population

Ten subjects participated in this study. They were recruited on a voluntary basis from patients seen for Physical Therapy treatment at the William B. Irby Craniofacial Pain Center, in Charleston, South Carolina. The subject population consisted of eight females and two males. The range of their ages was 24-58. Two of the subjects were suffering from masseter muscle spasms following the removal of third molars; three of the subjects seen had undergone orthognathic surgery and were in mandibular fixation for six to eight weeks following surgery; four of the subjects had undergone a surgical repair of the meniscus in the TMJ; and one subject was suffering masseter spasms of undertermined origin.

Inclusion Criteria

Criteria for subject participation included:

1) History of dysfunction of the temporomandibular joint or the masseter muscle. This was determined by the subjects diagnosis, evaluation for tenderness in the masseter muscle, and evaluation of the amount mandibular depression available in order to ascertain if it was limited.

2) A masseteric silent period duration of greater than thirty-five milliseconds, as measured using an eletromyograph.

Description of Procedures

Initially, the amount of mandibular depression that was available was measured using a clear plastic ruler that was graduated in millimeters. This amount was determined by measuring the distance between the upper and lower incisors upon maximum active opening. This amount was then recorded. Through questioning the subject and palpation of the masseter muscles for tenderness, it was determined which side had the greater involvement. The skin overlying the masseter on this side was then cleaned using 70% isopropyl alcohol to remove any makeup, body oil, or other residue from the surface. Two surface electrodes were prepared and placed over the previously prepared surface area. The posterior edge of the superior electrode was placed five millimeters anteroinferior to the tragus of the ear on a line running toward the corner of the mouth. The superior edge of the inferior electrode was placed five millimeters from the inferior edge of the superior electrode in a posteroinferior direction. This placement was parallel to and in line with the orientation of the muscle fibers of the masseter. A standard ground electrode was prepared and placed over the styloid process of the ulna on the ipsilateral side. These electrodes were then attached to the pre-amplifier of an EMG.

The investigator then placed the medial aspect of the second phalanx of the third digit of his left hand, on the symphysis menti of the mandible of the subject, just superior to the mental protuberance. The medial surface of the second digit of the left hand was then placed in contact with the lateral surface of the third digit. The subject was asked to close his eyes and clench his teeth

in order to achieve maximum intercuspidation. A rubber reflex testing hammer held in the investigators right hand was then used to deliver a firm tap to the lateral portion of the investigators second digit. The purpose of this tap was to elicit the masseteric reflex. Immediately following the tap, the investigator tripped a foot switch that was connected to the EMG. This stored, on the ocilliscope screen of the EMG, information about the motor activity of the masseter that was occurring immediately prior to when the foot switch was tripped. The duration of the silent period was then recorded. This process of eliciting the masseteric reflex with its silent period was repeated four more times. The mean of these five readings was then computed. If the silent period duration was less than 35 milliseconds, the subject was not used for this study. If the duration was greater than 35 milliseconds, the subject was included in the study, and treatment utilizing Fluori-Methane spray was rendered.

The spray and stretch technique using the Fluori-Methane was performed in the following manner. Each subject was asked to open his mouth to the point of limitation, and a cardboard cylinder 32 millimeters in diameter and fifty-five millimeters in length was inserted sideways between the subjects upper and lower teeth. Some of the subjects were unable to open their mouths a sufficient amount to completely insert the cylinder, therefore they were asked only to insert as much of the cylinder as was possible. The subject was then asked to close his eyes in order to avoid the accidental introduction of Fluori-Methane into the eyes. A stream of Fluori-Methane was then sprayed over the area of the masseter muscle. The bottle of Fluori-Methane comes equipped with a calibrated nozzle,

so the application was with a fine stream rather than a mist. The application was parallel to the muscle fibers of the masseter and was applied from inferior to superior. There was an overlap of about ten centimeters superior and inferior to the area treated. The stream of Fluori-Methane was applied five to six times, beginning at the posterior portion of the area and moving anteriorly, so that each stream of spray was adjacent to the last. This was then repeated. Care was taken so as not to frost the skin. The speed of application was about ten centimeters per second. Following the application of the spray, the cardboard cylinder was removed from the subjects mouth, and each was asked to open his mouth as widely as possible within a pain free range, and to hold that position for ten seconds. Each subject was then asked to close the mouth and relax for five seconds. This sequence was repeated twice more, followed by the application of a warm, moist towel to the area treated for one minute. This application of heat was used to rewarm the skin, and was not of sufficient dosage to cause an increase in intramuscular temperature. The towel was then removed, and the spray and stretch sequence was repeated again.

Once the treatment portion of the study was concluded, the amount of mandibular depression was again measured in the same manner as was done prior to treatment. In addition, the silent period duration of the masseter was again measured in the same manner as was carried out prior to treatment. The amount of mandibular depression available, and the length of the silent period duration were recorded following the reevaluation.

Description of Data Gathering Instruments

In order to measure and record the silent period duration of the masseter, an EDX 1000 electromyograph was used. This unit contained a Tektronix Op 76 ocilliscope with storage capabilities. Attached to the preamplifier of the EDX 1000, were two Beckman silver chloride surface electrodes, which measured 15 millimeters in diameter. These electrodes were used to pickup the electrical activity from the masseter. A standard rubberized ground electrode was also used.

In order to record the amount of mandibular depression present. a clear plastic ruler, graduated in millimeters, was utilized.

Statistical Procedures Used

The t-test for related measures was utilized to compare the pre and post-treatment means of the masseteric silent period duration and the pre and post-treatment values for mandibular depression, in order to determine the significance of the Fluori-Methane application. In this study, each subject served as his own control.

The t-test for related measures is generally employed to determine the significance of a difference between two correlated means. It is most commonly used this way when two values or scores are recorded for the same individual when some sort of special training or treatment takes place during the interval between the determination of the two values. (Bruning & Kintz, 1968)

The Pearson product-moment correlation was used to determine if there was a relationship that existed between the two variables being tested. In this instance this correlation was between the pre and

post-treatment means of the silent period duration, and the pre and post-treatment values for mandibular depression.

CHAPTER IV

RESULTS

The individual pre and post-treatment means for silent period duration, as well as the difference between those means, are given in Table 1. As a group, the pre and post-treatment mean difference in silent period duration is 12.68 milliseconds.

The t-test for related measures for determination of significance of treatment is computed to be 4.367 with nine degrees of freedom. The effect of this treatment on decreasing silent period duration is significant at the .005 level of significance for directional (one-tailed) tests. The standard deviation is 9.181.

The individual pre and post-treatment measurements for mandibular depression, as well as the difference between these measurements, are given in Table 2. As a group the pre and post-treatment mean difference in mandibular depression is 6 millimeters.

The t-test for related measures for determination of significance of treatment is computed to be 7.614 with nine degrees of freedom. The effect of this treatment on increasing mandibular depression is significant at the .0005 level of significance for directional tests. The standard deviation is 2.494.

The Pearson product-moment correlation was used to determine if a relationship exists between the pre and post-treatment silent period duration and the pre and post-treatment measurements of mandibular depression. This value is computed to be -.359, which is not considered significant.

TABLE 1

Silent Period Duration

Subject Number	Pre-Treatment Mean*	Post-Treatment Mean*	Difference*
1	83.6	65.2	18.4
2	81.6	59.6	22
3	56	49.2	6.8
4	43.2	41.2	2
5	78	45.2	32.8
6	55.2	46.8	8.4
7	68	58.8	9.2
8	67.2	55.6	11.6
9	60	54	6
10	77.6	68	9.6
Group Mean	67.04	54.36	12.68

*measured in milliseconds

TABLE 2

Amount of Mandibular Depression

Subject Number	Pre-Treatment*	Post-Treatment*	Difference*
1	16	24	8
2	28	34	6
3	32	37	5
4	38	47	9
5	29	34	5
6	18	26	8
7	26	28	2
8	25	33	8
9	17	24	7
10	15	17	2
Group Mean	24.4	30.4	6

*interincisoral difference measured in millimeters

CHAPTER V

DISCUSSION, RECOMMENDATIONS AND CONCLUSIONS

Interpretation of Results

The main finding in this investigation is the statistically significant decrease in the masseteric silent period duration following treatment with Fluori-Methane spray. This supports the original hypothesis that Fluori-Methane would decrease the silent period duration, and is not surprising since in the literature review it was noted that a prolonged masseteric silent period duration had been related to muscle spasms in the masseter, and clinically Fluori-Methane is known to relieve muscle spasms. The second finding, that Fluori-Methane caused an increase in the amount of mandibular opening when this opening was limited by masseter muscle spasms, was the expected outcome, as this has been previously documented in literature, as was pointed out earlier.

Because of the limited number of participants in this study, the statistical correlation between a decreased silent period duration causing an increase in mandibular opening was not significant.

Relationship to Studies in Literature

Based on the information gathered in this investigation and on the literature review, there was no new information gained regarding possible mechanisms for the cause of a prolonged silent period or the reason the Fluori-Methane causes a decrease in the silent period duration.

Implications

Clinically, masseter muscle spasms are usually identified through palpation for tenderness within the muscle, which is somewhat subjective. The establishment of a prolonged silent period duration in patients with masseter muscle spasms (Bessett et al., 1971) allowed for the objective assessment of these patients. The findings of this investigation will allow for the objective assessment of patient progress during the physical therapy management of their problems. This objective assessment is not limited just to the application of Fluori-Methane spray, but has applications to any treatment mechanism that is utilized.

Recommendations for Future Research

There were recognized shortcomings in this investigation and the following are ways which could improve the project:

1) An increase in the sample size would lend more validity to the study.

2) In this investigation, the principle investigator measured and recorded the silent period duration and the amount of mandibular depression present both pre and post-treatment. While there was no intentional bias on the part of the principle investigator, using an individual uninvolved in the study to take those readings would eliminate this possibility.

3) The stimulus for eliciting the jaw jerk response was provided manually, which allowed for some variation in the amount of force applied each time. A mechanically driven device would allow for consistency in application of force applied.

4) Each subject was instructed to clench the teeth as hard as

possible while remaining pain free. There was most probably variation in the amount of force used to clench. A pressure sensitive transducer placed between the teeth would allow for each subject to clench with the same amount of pressure.

5) Each subject served as his own control, which is a very valid mechanism. Another possibility however, might involve a control group, each of whom would go through the exact procedure as the experimental group, except for the application of Fluori-Methane.

Conclusions

The conclusions drawn from this study are: the application of Fluori-Methane vapocoolant spray is an effective method of reducing a prolonged masseteric silent period duration, resulting in a decrease in muscle spasms in the masseter. Fluori-Methane is also effective when used to increase the amount of mandibular depression available when it is limited secondary to masseter muscle spasms. These findings are consistent with all literature reviewed that pertained to this investigation.

APPENDIX

INFORMED CONSENT AGREEMENT

INFORMED CONSENT AGREEMENT

I, _____, do hereby consent to being a subject in the study that Mr. Aaron has explained to me, as described below, and I fully understand the following:

A) Two surface pickup electrodes will be placed on the side of my face and held in place with an adhesive collar. These electrodes will then be attached to an electromyograph (EMG). Mr. Aaron will then place two of his fingers on my chin and I will be asked to clench my teeth. Once I have clenched my teeth, he will tap his two fingers that are on my chin with a rubber hammer. Following this tap, I will be able to relax my jaw while Mr. Aaron records the measurements from the EMG. He will repeat this same process four more times. The electrodes will be removed, and treatment will then be given. This will consist of having Fluori-Methane vapocoolant spray applied to the side of my face overlying the area of the masseter muscle. After the spray is applied, a warm towel will be placed over the area that was sprayed for one minute. This treatment will then be repeated. Then the same pickup electrodes that were used previously, will be placed on my face again, and the same procedure that was done prior to treatment will be repeated. The entire process will take about forty-five minutes.

B) There is a remote possibility that Fluori-Methane may inadvertently be sprayed into my eye during treatment. However, this is unlikely, because I will have my eye closed during treatment, and Mr. Aaron will have his thumb placed over the corner of my eye to provide further protection. If for some reason, some of the Fluori-Methane is sprayed into my eye, I understand there

will be a slight burning sensation, but no damage to my eye will occur.

C) The benefits I can expect from this treatment are that the muscle spasms I am experiencing in my face will be decreased and consequently I will be able to open my mouth further with less pain. The measurements taken during this study will allow the objective measurement of my progress.

Mr. Aaron has agreed to answer any inquiries that I may have concerning the procedure and has informed me that I might also contact the Medical University of South Carolina Institutional Review Board for Human Research (803/792-4148) directly. This board administers the agreement with the United States Department of Health and Human Services covering the protection for human subject.

I understand that in the event of physical injury resulting from the research procedures to the participant, reasonable medical treatment is available free through the Medical University of South Carolina; financial compensation is not available for medical treatment elsewhere, loss of work or other expenses.

I understand that my records of participation in this study are not accessible to the general public and confidentiality will be maintained. Information that may be gained from this study will be used only for research and educational purposes. Information may be published with permission of the principal investigator in medical journals, but my identity will not be revealed. However, identifying information will be available to monitors from the M.U.S.C. I.R.B. for Human Research, and upon proper judicial order, the U.S. Food and Drug Administration.

I also understand that I am free to withdraw my consent and discontinue participation at any time. Discontinuation will in no way jeopardize my ability to receive treatment now or in the future at this institution.

WITNESS	SIGNATURE OF PARTICIPANT
SIGNATURE OF PERSON OBTAINING CONSENT	DATE
WITNESS	

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