MEDICAL & DENTAL CLINICAL STUDIES

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Temple University School of Dentistry
A Clinical Study of the Effects of Facial-Flex® in Patients with TMD
By Zarrinnia K, Braun RJ, Straja SR, Temple University School of Dentistry

BACKGROUND
The disorder of temporomandibular joint syndrome has probably existed since the dawn of man.

The diversity of symptoms and therapeutic techniques can make the proper choice of TMD treatment a frustrating experience.

There are numerous types of treatment modalities for TMD, ranging from simple facial muscle exercises to more involved surgical procedures for treatment of patients with TMD.

FACIAL-FLEX®
This device is designed to fit into the corners of the lips to improve facial muscle tone. Facial-Flex® operates on the principle of dynamic resistance.

PURPOSE

This pilot study examined the effects of the use of Facial-Flex® to treat TMD.

The control and experimental groups have been examined prior to initiation of the experiment. In addition, they have been examined approximately sixty (60) days after the initial clinical examination.

The dysfunction* and palpation** indexes individually do not show any improvement as a result of the treatment. But the craniomandibular index alone shows a statistically significant difference concerning the "improvements"; this index is a combination of the palpation and dysfunction indexes. For the craniomandibular index, the general trend is for a positive "improvement" for the treatment group and virtually no improvement for the control group.

METHODS AND MATERIAL
This pilot study has been conducted in an attempt to evaluate the effect of Facial-Flex® in patients with TMD.

Seventeen female subjects participated in this pilot study. The subjects were divided into two groups: (a) the control group and (b) the experimental group (treatment group). The control group consisted of eight (8) subjects and the experimental group consisted of nine (9) subjects. Subjects were randomly assigned to either group (a) or (b).

In this pilot study the Friction and Schiffman Craniomandibular index was used to evaluate the effects of the use of Facial-Flex® in relieving the symptoms of TMD.

Future investigations should include a larger sample and imaging of TMJ. Until additional investigations have been carried out, one cannot recommend the use of Facial-Flex® for patients with TMD.

** Dysfunction index is obtained by clinical examination of the 1) mandibular movement 2) TMJ noise and 3) TMJ capsule palpation*

*** Palpation index is obtained by clinical examination of the 1) extraoral palpation 2) intraoral palpation and 3) neck muscle palpation*

Temple University School of Dentistry
A Clinical Study of the Effects of Facial-Flex® in Patients with TMD
By Drs. R. Braun and K. Zarrinnia

The authors tested two groups of female patients with TMD to evaluate the benefits of using the Facial-Flex® exerciser over a 60-day period. One group used the device twice a day and a control group did not use it.

Two tests were used to evaluate the patients' condition: one, the Dysfunction Index, DI, obtained by clinical examination of mandibular movement, TMJ noise and TMJ capsule palpation, and the other, the Palpation Index, PI, obtained by clinical examination/palpation of the extraoral and intraoral muscles. The Craniomandibular Index, CMI, combines the Dysfunction and Palpation Indexes by the formula CMI=DI+PI/2.

The report lists individual DI and PI figures for all patients before and after the 60-day test period. However, the Craniomandibular CMI figures have not been calculated and tabulated even though the authors conclude, "the CMI alone shows a statistically significant difference concerning the improvements exhibited by the two groups as a result of the treatment." The tables that follow include both individual and average Craniomandibular Index figures. The average CMI figures are compared below for both groups before and after the 60-day test.

Improvement as measured by change in average CMI showed the control group improved by 11.8% while the experimental group improved by 41.8%.

	Control Group	Experimental Group
Initial Exam	7.37	9.31
Final Exam	6.50	5.42
CMI change	.87 (11.8%)	3.89 (41.8%)

Post-Evaluation by:

James B. Godshalk, B.S.

Chemical Engineering

University of Pennsylvania

January 11, 2000

Plastic and Reconstructive Surgery Journal
Lip Service for the Stiff Upper Lip
By Barry M. Zide, M.D., James P. Bradley, M.D., Michael T. Longaker, M.D.

ABSTRACT
Lip augmentation procedures can restore volume and shape to the aging, thin upper lip, but some patients may develop problematic lip tightness. This stiff upper lip is manifested by a restricted smile and a dynamic central upper lip. We have had success in treating post-reconstruction and post-augmentation stiff upper lip with a therapeutic device and treatment regimen. This therapy alleviated tightness and inability to smile. Also, the change in lip commissure-to-commissure distance in repose and when smiling improved after treatment.

University of Maryland
Interim Report for Facial-Flex® Corporation

By Edward G. Grace, D.D.S., M.A.
University of Maryland
February 11, 2001

INTRODUCTION
A study of the Facial-Flex® device called the Bite Assist Exerciser or BAE was begun in late June 2000 and the last data collection was performed in January of 2001. The purpose of the study was to evaluate the clinical performance of the BAE and validate that it performs as intended, which is to reduce muscle tension and increase muscle strength and muscle tone in patients with muscle dysfunction and/or muscle pain, associated with specific Temporomandibular Joint Disorders (TMD). The muscles usually affected adversely in most TMD patients are the muscles of mastication, which include the ptyergoids, masseters and temporalis muscles. These are the same muscles that have been shown in earlier studies to be positively affected by the use of the BAE exercise device.

CONCLUSIONS
The BAE was shown to be a safe, simple and efficient method of muscular exercise for TMD patients with a variety of diagnoses which included some form of muscular dysfunction.

DISCUSSION
The BAE was found to be a clinically useful device by both patients and dentists. Statistically no difference could be found between the groups, but trends toward efficacy of the BAE were detected. It may be useful in future studies to use a larger number of patients in order to be able to detect statistical significance. The clinical staff also felt that although it was recommended to use the appliance twice a day for 1 minute at a time, a better schedule would be to use it 3 times a day for 1 minute at a time or twice a day for 2 minutes at a time, depending on patient needs. The utilization of the combination of the BAE device with the original Facial-Flex® device may also help in the alleviation of muscular problems. The combination of horizontal and vertical programmed exercise with a measured amount of resistance could prove to be more helpful than the BAE alone.

COMMENTS FROM PATIENTS AND INVESTIGATORS
No patients had any adverse comments about the BAE. The original green exerciser was too “strong” for most patients but the newly designed one is very complimentary to the blue and yellow. There were no adverse outcomes from use of the BAE and no patients became worse with the use of the BAE. No patient was unable to understand the instructions for use and all were able to use the BAE properly.

The principal investigator likes the BAE as part of a good physical therapy home exercise and thermomodality regimen. Other dentists who have seen the BAE in use

also plan to use it as a part of routine muscular TMD therapy. Further data analysis is being performed and follow-up of patients who have not responded is continuing.

Parkinson's Disease
By Dr. Joseph R. Spiegel, M.D.

The patient is an 85-year-old male with idiopathic Parkinsonism. The patient had generalized oral-neurological weakness with hypomimmia and dysarthria. Subjective speech-language pathology judged intelligibility at 60%. During the establishment of baseline strength, the patient performed 3 repetitions with Facial-Flex®, with a severe oral action tremor.

At the end of the 3-week exercise period, the patient was able to perform 20 repetitions. Significantly, the action tremor had completely resolved. Speech-language pathology's subjective intelligibility evaluation had increased to 90%.