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Research Article

A Novel Intraoral Vibratory Device for treatment of Myofascial Pain Dysfunction Syndrome
Running Title: Novel Intraoral Vibratory Device

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Abstract

Myofascial Pain Dysfunction Syndrome is a distressing condition wherein a patient experiences pain in certain areas of orofacial muscles. An array of treatment modalities exists to deal with the ailment however these have a short-term reversible action. This necessitates the development of modalities that the patient can readily utilize at their residence without needing to visit a physician multiple times. Overall, the development of such a modality would increase patient compliance and result in a regular reinforcement of the therapeutic intervention. Mechanical vibration has been used in physiotherapy for disorders and ailments involving bones, muscles, and tendons. The authors have designed a novel device that can be easily maneuvered within the oral cavity and apply mechanical vibrations to the trigger points on the muscles of mastication intraorally. The ease of operation of the device enables it to be safely utilized by the patients without the need of a physician or apprehension of adverse effects.

Keywords: Vibration therapy; Musculoskeletal pain; Stress

Introduction

Myofascial Pain Dysfunction Syndrome (MPDS) is a painful condition involving the masticatory muscles that subsequently result from limitation of jaw movement such as deviation in closing and opening the mouth and sensitivity on stimulation of certain areas. These areas, referred to as 'Myofascial Trigger Points', (MTrP) are highly localized and hyperirritable spots in a palpable taut of skeletal muscle fibers which cause the restricted range of stretch and tightness of the involved muscles ^[1]. Muscular involvement in MPDS has been reported to be present in almost

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82.5% (n=200) of the cases comprising of the muscles of mastication – medial pterygoid, lateral pterygoid, masseter, and temporalis^[2].

A multitude of treatment modalities has been utilized with a varying degree of success in the treatment of MPDS which include various medications, appliances, relaxation training, mock equilibration, transcutaneous nerve stimulation, vibration treatment, and psychologic counseling^[3]. These treatment modalities follow a common trajectory wherein they aim at objectively alleviating the pain in the involved muscles, however, their resultant beneficial actions are reversible and involved some degree of compliance on the part of patients to be effective. Considering their ephemeral effect on the improvement of the condition, it is, thus, preferable treatment modalities that are readily accessible to the patients and can be easily utilized by them without inflicting any harm to themselves. This would help reproduce the beneficial effects of the treatment modality at the patient's residence without needing to visit the physician multiple times thereby facilitating a more compliant, timely, and regular intervention.

Vibrators have been widely used for treatment, as physiotherapeutic interventions or rehabilitation purposes in delayed onset muscle soreness (DOMS), cerebral palsy, post-stroke, and orthopedic patients, and other diseases^[4]. Segmental vibration therapy (SVT) is a more site-specific type of vibration therapy wherein low-magnitude, high-intensity vibrations are applied to specific focal areas^[5]. Previous work has suggested positive results with the use of vibratory stimulation for the relief of pain from the dental origin^[6] and in a more recent pilot study, gloved fingers have been used to deliver vibration to the medial pterygoid muscle^[7]. These findings point towards the potential of vibration therapy in MPDS wherein MTrPs could serve as a guide determining the areas of treatment.

Presently, segmental vibration therapy is widely practiced in physiotherapy clinics, however, a device for the provision of mechanical vibrations intraorally is unavailable. In this context, the authors have designed a device that could provide mechanical vibration on the intraoral MTrPs which could be easily and effectively be utilized by patients suffering from MPDS at their residence.

Methods

Concept of the Intraoral Vibratory Device

Mechanical vibratory stimulation is a more selective modality for activating predominantly large diameter afferent fibers that are rapidly adapting as well as primary muscle spindles subsequently causing an elevation in the subjective threshold for detection of pain^[6]. An additional factor supporting the effectiveness of vibration therapy in the reduction of pain is the resultant reduction of inflammatory cytokines associated with the perception of pain such as Interleukin-6, C- reactive protein, and histamine^[8]. A frequency of 50 Hz has been demonstrated to elevate the pain threshold which may vary as per the patient's tolerance level^[9]. Thus, the selection of motor was carried out such that it would be able to provide vibrations in the frequency range 20 Hz – 130 Hz with an amplitude of 2 mm.

A provision for modulating the current provided to the motor and subsequent vibrations produced was incorporated by means of a knob. Rotation of the knob would step down or step up the resistance to current reaching the motor, resulting in the corresponding modulation of the frequency of vibrations produced. The importance of frequency modulation cannot be overlooked especially when the device is to be used in an area such as the oral cavity which is relatively more

sensitive to external stimuli owing to a relatively thinner epithelium with less keratin, rich nerve supply, and hydrated environment.

Novelty in the design of Intraoral Vibratory Device

The eccentric rotating mass coin-type motor and associated Pulse width generation circuit were encased within a 3D printed biocompatible Polylactic acid plastic which is designed to facilitate maneuvering of the vibration within the oral cavity for effective application on the MTrPs present on the muscles of mastication. The device is divided into four parts for ease of illustration – head, neck, handle and base as depicted in Figure 1.

Figure 1: Perspective view of the device. Division of the device into four compartments for ease of illustration.

The vibratory motor of 10 mm diameter and 2.7 mm thickness embedded into the core of the head portion of the device. The head was designed to be of a disc shape corresponding to that of the ‘flat coin’ motor such that its working face could readily be applied to the muscles and its rounded periphery could easily be adapted to the intraoral vestibular regions to gain access to pterygoid and temporalis muscles intraorally. Biocompatible foam-coated padding was provided on the working face of the head that was to be applied to the mucosal surface so that the application of the device during the procedure did not produce any discomfort to the patient.

The neck portion of the device was incorporated between the handle and the working head such that the device could easily be held outside the patient’s mouth while the head was applied to any of the muscles of mastication intraorally. The neck was designed to be of relatively fewer dimensions to avoid the contact of the device with the teeth thereby focusing all the vibrations on the target muscles yet of sufficient bulk that would maintain rigidity and avoid subsequent bending or distortion of the device. The handle portion of the device was designed such that the operator could hold the device with ease while the vibration was applied to the target muscles.

The base of the device comprises a controller switch for turning the device on or off and a socket for charging the batteries supplying to the motor [Figure 2]. The battery utilized is 3.3 V which makes it possible to utilize the device for 5 minutes per muscle of mastication throughout the session of SVT which would be of at least 20-minute duration with ease. The knob to modulate the frequency of vibrations was also incorporated at the junction of the handle and basal compartments. This would facilitate modulation of frequency accordingly with the patient’s level of comfort while the device was in the target area. Although currently the knob manually indicates the frequency of vibrations being provided by the motor, future incorporation of a digital indicator for the purpose would make it easier to precisely modulate the vibrations provided.

Results

The device was pilot tested on five patients following the procurement of ethical approval from the institutional ethical review board [Figure 3]. It was perceived to be greater in effectivity as compared to the existing ultrasonography therapy regimen. Patients adapted easily to the use of the device after a brief training session and found it beneficial that they could themselves guide the device to the intraoral painful areas rather than depending on a clinician which often fails to pinpoint the painful areas. The benefits of the device could be elicited almost immediately after its application in function and lasted for varying amounts of time suggestive of multiple factors involved in their longevity.

Advantages and Limitations

The device was found to be advantageous owing to the following reasons:

- The novelty of the device lies in its design which enabled it to be used to effectively provide mechanical vibrations on MTrPs present on muscles of mastication intraorally as well as extra orally.
- The shape of the head ensured maximal contact with all the muscles of mastication, especially medial pterygoid and temporalis which would otherwise be difficult to reach by an intraoral approach.
- The compact size and lightweight enabled the device to be easily maneuvered by the patients to the areas of pain.
- The rounded periphery and foam-cushioned head rendered the device comfortable for the patient while delivering adequate vibrations to the painful areas for the duration of therapy.
- The biocompatible materials used for the fabrication of the device and the absence of any external wires rendered it safe to be used in the sensitive and humid oral cavity.
- The device had an added advantage wherein it could be used wirelessly operating on batteries resulting making it easier, safer, and more comfortable for the operator.

The use of the device in patients presents itself with certain limitations since the optimal regimen for therapy has yet to be determined and standardized through clinical trials. Secondly, a patient using the device at their residence cannot be monitored for the correctness of technique and compliance with the prescribed schedule by the clinician.

Additional details regarding the use of the device:

The design of the device has been registered as of the number 326797-001 underclass 24-02 of the Designs Act, 2000 in the Indian Patent Office.

Conclusion

Thus, the novel device that is compactly designed can be effectively used to selectively target MTrPs of muscles of mastication in patients suffering from MPDS. The specifics of its design impart its unique ability to provide SVT to the muscles intraorally with ease of operation such that the patient could use it at their residence with adequate training from the medical personnel. A standardized protocol could be developed and then subsequently evaluated using evidence-based methods for the inclusion of this novel device as a routine treatment modality for MPDS.

Conflict of Interest: None

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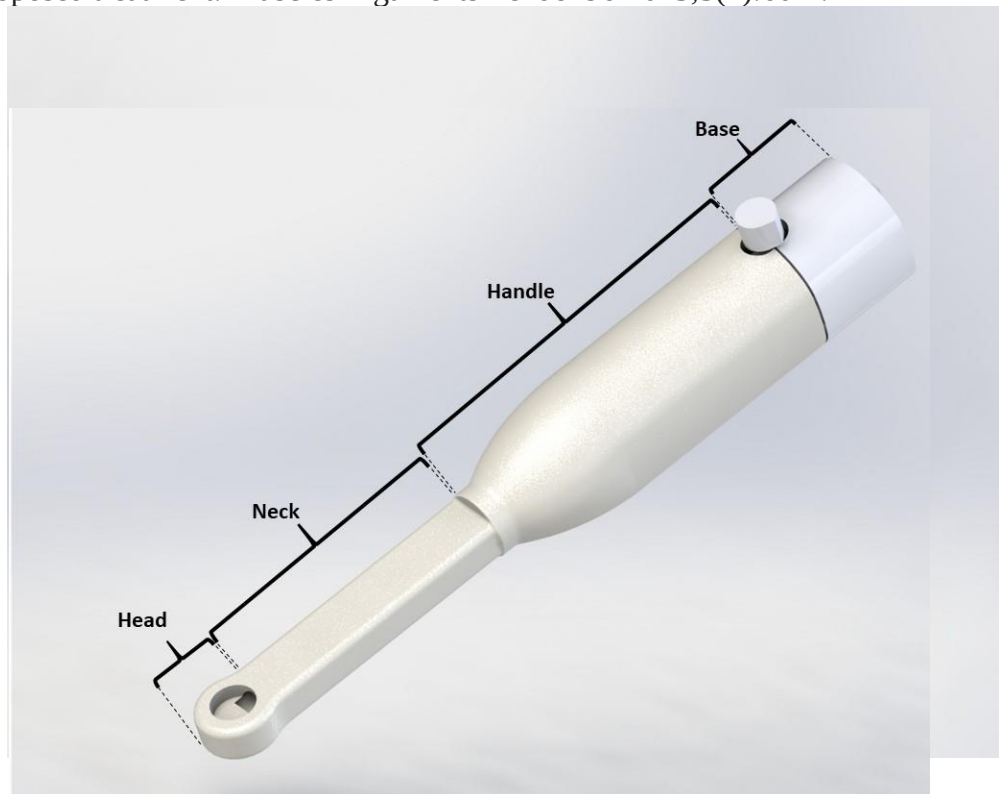


Figure 1: Perspective view of the device. Division of the device into four compartments for ease of illustration.

Figure 2: Bottom view of the device illustrating components present in the basal compartment

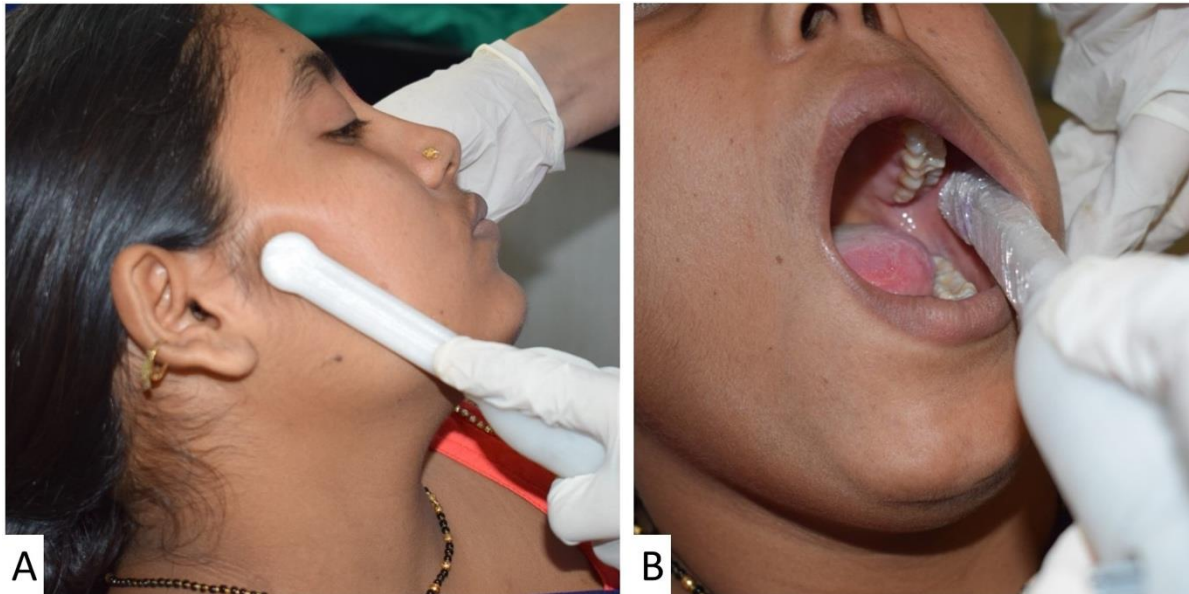


Figure 3: The device is used for the treatment of the patient applied on trigger points of Masseter muscle A) Extraorally and B) Intraorally