**Overall Summary**

Jeremy Mao, DDS (specialist in orthodontics), PhD (multidisciplinary engineering) is the inventor of the concept behind vibrating force to enhance and accelerate tooth movement. He based his idea on literature from long-bones indicating vibration improved bone density. Dr. Mao investigated the theory in a series of animal models predictive of tooth movement that indicated the idea had merit. Subsequently, a separate laboratory out of Japan (Nishimura) confirmed that vibration accelerated tooth movement in a rat model, and could be done safely (the vibration group showed a trend for less root resorption than the standard orthodontic “static load” group). Dr. Mao’s data led to the formation of OrthoAccel Technologies (OA) to develop a device (a small extraoral activator attached to a mouthpiece, used 20 minutes per day), and a study was subsequently initiated and completed at UT-Houston in Texas, US. CE Mark approval and ISO registration for the device was granted in early 2009; commercial launch in the United Kingdom is planned for Q4/end 2009.

**About the Device**

OA uses the application of pulsing forces to enhance standard braces or aligners and moves teeth faster through accelerated bone remodeling. This science has been applied in other parts of the body, for example increasing the rate of fracture healing and bone density in long bones. The OA appliance is a removable device (pictured below), similar to a retainer with a small motor, into which the patient bites. The science has been validated in animals with published results and in a recent human study. The premise is simple. Rather than using only constant pressure, the device applies very light vibrations to the dentition. The patient places and activates the device daily for twenty minutes of gentle pulsing. Users can carry out most routine daily tasks during the activation period; the device is rechargeable via a docking station (which also captures and displays compliance data). Most importantly, it is intended to work with all existing fixed appliance (bracket) systems and Invisalign.
Summary of Data

Why even consider vibration in the oral cavity?

Mechanical modulation of bone architecture has been studied since the mid-1980s for effects on skeletal diseases and problems such as fracture healing, osteoporosis, and other developmental deformities. Clint Rubin’s laboratory in particular has assessed mechanical loading and effects on bone density and bone mass. The attached articles discuss improved bone density in both animals and humans, as well as review articles discussing pathways mediating mechanical signaling in bone and reviewing various studies. They give a good basis for why someone might want to explore vibration for effects in various bones. Based on Dr. Rubin’s experiments, a device has been developed - the Juvent 1000 vibrating plate – which is an approved device used to address bone and muscle loss (www.juvent.com). This device vibrates the whole body – including the head and teeth - at approximately 30 Hz. at an acceleration unit of 0.3 G (force of gravity) and is used for 20 to 30 minutes a day.

There is also observational data that indicates that vibration is a reasonable and safe approach for enhanced tooth movement. People vibrate their teeth every day by chewing gum. Chewing typically occurs at a somewhat lower frequency (1 to 2 Hz. vs. up to 30 Hz. provided by the device) but at a much higher force (50N to 400N chewing vs. 20g device [0.2N device]). Also, typical forces used by orthodontic wires range from 50g to 400g – which again, are much higher forces than used by the OrthoAccel vibrating device. Additionally, a somewhat similar device – that vibrates at a higher frequency (between 100 Hz. and 250 Hz.) and at a higher force (approximately 1N or 100g) – has been commercially distributed and used in humans for reducing pain associated with orthodontic adjustment. Ste. Marie, et. al. report on 48 patients who experienced significant reduction in pain; no adverse events were reported. Shapiro also used a pulsating force device to enhance tooth movement in the 1970’s.

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Lastly, electronically powered toothbrushes are used in thousands of individuals. They provide a similar force at a higher frequency (200 to 300 Hz.) directly to the teeth. Although duration of use is somewhat less in this instance (2 minutes once or twice a day vs. 10 minutes twice a day), no safety issues have been reported by the large number of users.

Even though there is significant evidence for mechanical vibration’s impact on long-bones, very little information was available in the oral cavity until Dr. Jeremy Mao studied vibration in various animal models of tooth movement.

What data is available on vibration in the oral cavity and tooth vibration?

Cranial Suture / Tooth Movement Models

Cranial sutures are an accepted model for predicting orthodontic tooth movement. Meikle et. al. (1978) developed organ culture systems in which mechanical force could be applied to rabbit cranial sutures under controlled conditions. This simple experimental model mimics the forces to which the periodontal ligament and other sutural articulations of the craniofacial skeleton are exposed during orthodontic treatment. This is the model that Dr. Jeremy Mao studied to investigate vibratory forces and the associated impact on tooth movement.

Kopher and Mao\(^7\) assessed cyclic forces of 5N peak magnitude at 1 Hz. in rabbits, while Peptan and Mao\(^8\) assessed cyclic forces of 1N at 8 Hz. in rabbits, and Vij and Mao\(^9\) assessed cyclic forces of 300 mN at 4 Hz. in rats. In aggregate, the data from these three studies indicate that cyclic forces between 1 Hz. and 8 Hz., with forces ranging from 0.3N to 5N, increase bone remodeling. Rates depended on different methodologies, but increases of 2.5x with vibration were common. These studies are the basis for the OrthoAccel device.

Since Dr. Mao’s experiments, an independent study out of Japan has confirmed and strengthened the idea of vibration for speeding orthodontic tooth movement. Nishimura et. al.\(^10\) studied 60 Hz. vibration in a direct tooth movement model in rats. Rats received “standard orthodontics” through application of a spring that applied a force between the rat molars.


Vibration to the molars, at a 60 Hz. frequency, was added through a separate apparatus. The group that received vibration had a statistically significant increase in tooth movement when compared to the spring-force (static force) only group. Interestingly, the vibration group had a trend toward less root-resorption as compared to the static force-only group. Additionally, although taking a slightly different approach using magnets for vibration, Darendeliler\textsuperscript{11} also found evidence for faster tooth movement with vibration.

These studies provide a basis for both possible efficacy and likely safety for using vibration in humans to assist orthodontic tooth movement.