**Pilot study of the effect of vertical dimension bite plane therapy on nocturnal parafunction, sleep and respiration**

LETTER OF INFORMATION:

You are being asked to participate in a study looking at the effect of bite plane therapy in the treatment of nocturnal (grinding) and its associated symptoms. The purpose of this study is to determine how effective this treatment is in reducing bruxism (grinding) along with its effects on sleep and respiration. This study will also assess what effect bite plane therapy has on symptoms of myofascial pain dysfunction and quality of life.

If you agree to participate, the initial assessment will include measurement of your body weight, and blood pressure and these will be monitored on a regular basis. An intra and extra-oral examination will be done to assess tour teeth and jaws. You will have a bite plane (an intra-oral acrylic appliance) constructed for you to wear as instructed while you are participating in the study. You will be required to fill out a questionnaire answering questions about your sleep and breathing (i.e., snoring, excessive daytime sleepiness) and side effects and response to the treatment. You will be asked to fill out a questionnaire about quality of life as well as a questionnaire about the type and degree of facial pain you experience before and after splint therapy. This questionnaire will require about 20 to 30 minutes to complete.

Before the study is done you will undergo a cephalogram and a panorex x-ray. A cephalogram is an x-ray taken of the head and neck that provides an image of the upper airway and facial structure. The cephalogram is taken from the side while you hold your breath. A panorex is an x-ray of your upper and lower jaws and teeth. The panorex is a standard dental x-ray taken while you are seated. The x-ray machine rotates around your head to give a picture of the teeth and jaw. Your body will be shielded during the x-rays to decrease radiation exposure. There is a very small amount of radiation involved in these x-rays. You may refuse to have the cephalogram and/or panorex taken. Regular dental impressions will be taken of your upper and lower teeth in order to fabricate the bite plane appliance.

An overnight sleep study will be performed in the Sleep Laboratory at London Health Sciences Centre both before and after bite plane therapy. The overnight sleep study involves sleeping in the Laboratory while wearing numerous surface monitors. The monitors include electrodes on the scalp and face to measure brain wave activity and eye movement, electrodes on the chin, legs and jaw to measure muscle tone, and electrodes on the chest to measure heart rate. Bands will be placed around the chest and abdomen to measure breathing and a small tubing will be placed below the nose to measure airflow. An oxygen probe will be clipped to the finger or ear to measure oxygen saturation. This information allows us to determine if you are asleep., what type of sleep and quality of sleep you are having, whether you are grinding and whether the breathing is normal during sleep. This study is required to assess how effective the bite plane therapy has been in improving the grinding and in improving sleep quality. The final assessment will take place in the clinic following the overnight sleep study. This includes providing the sleep study results, assessing your response to the bite plane therapy, and repeating the questionnaires that were done at the baseline assessment. This will take approximately 30 minutes to 45 minutes.

Participation in the study is voluntary. You may refuse to participate or withdraw from the study at any time with no effect on your future care. The benefits or participating in this study include close supervision of your condition by a physician and a detailed assessment of the effectiveness of bite plane therapy in the treatment of parafunction (grinding) and its associated symptoms. All information obtained during the study will be held strictly confidential and you will not be identified by name or in any recognizable way in any reports of the completed study.

To cover any costs of participating in this study we will reimburse you up to $50.00 to cover parking, transportation or meals. London Health Sciences Centre charges for overnight parking in the Visitor’s Parking Lot. If you withdraw part way through the study we will provide partial compensation (i.e., $25.00 if half way through the study).

If you are involved with or are approached to participate in another study, please notify Dr. Diduch. Please contact Dr. Diduch at 661-3558 or Dr. Ferguson at 663-3606 at the University Campus of the London Health Sciences Centre, if you have any questions.