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## **The effectiveness of the use of mouth bites in radiotherapy**

### **Summary**

The tongue is a vital structure within the head and neck region and is possibly the most mobile structure in the region, yet studies looking at the immobilisation of the tongue appear to be extremely limited. With long term side effects which include loss of taste and a reduced quality of life for patients who undergo this treatment, ensuring the tongue does not receive too high a dose during treatment is of great importance. Anecdotal evidence points to the fact that mouth bite positioning and quality has a great deal to do with keeping the tongue immobilised during treatment, yet there is little solid evidence to show if and how the mouth bite position varies during a course of treatment, and in turn, what impact these changes may have on the overall treatment delivery. The purpose of this study, therefore, is to observe the variations in mouth bite and tongue position during a course of radiotherapy treatment for head and neck cancer patients, and to ascertain what this movement may be linked to.

### **Principal aims of the study**

- 1) To assess how the mouth bite and tongue position may vary over the course of treatment for head and neck cancer patients;
- 2) To explore what factors may impact upon mouth bite position during treatment

### **Primary Research Question**

- 1) Does the mouth bite move over the course of treatment, in relation to the original position at simulation?

### **Secondary research questions**

- 1) Does the tongue remain in its original position, as at simulation, throughout treatment?
- 2) Is there a trend in any movement over the course of a treatment regime i.e. is there more movement towards the end of a patient's treatment or at the beginning?
- 3) Is movement in the mouth bite linked to difficulties the patient may be experiencing in positioning the mouth bite because of the treatment side effects?

### **Literature review**

A literature review on this topic area has shown that the research seems to be extremely limited, and tends to focus more on stereotactic or IMRT treatment techniques, which tend to use a bite block system, rather than a mouth bite system (Baumert et al, 2005; Willner et al, 1997). The bite block system is a more rigid form of immobilisation, and is not used at NWCTC. There have been some published articles on movement of the mandible and cervical spine (Ahn et al, 2009; Suzuki et al, 2006; Zhang et al, 2006), but little on tongue or mouth bite movement. This lack of research will add more value to this research as it will be adding to the knowledge base of the profession.

## Method

This research will be conducted in the radiotherapy department at NWCTC. All head and neck patients requiring a mouth bite for radical radiotherapy treatment will be eligible for the study, providing that they have undergone simulator verification prior to the start of treatment. The simulator films will be used as the 'gold standard' on which to compare any variations in mouth bite position during treatment. Patients undergoing palliative treatment will be excluded, as these treatment regimes tend to be shorter with fewer images taken during treatment. As each patient referred to the department for radiotherapy will require some form of simulation, the pre-treatment radiographers will highlight any patients that will require a mouth bite for treatment to the investigator. The oncologists may also inform the investigator that a mouth bite has been requested for a particular patient. Patients will be approached at the simulation stage of treatment, which may be the patients first or second visit to the department, and they will be given an information sheet on the study. If they wish to take part in the study, a consent form will be issued prior to the first treatment, which will be signed, and a copy offered to the patient. As this study is taking part in Wales, the information sheet, consent form and questionnaires will be translated into Welsh, so as not to discriminate against Welsh speaking participants, and also to adhere to the trusts policy on Welsh language.

Patients will be recruited over an approximate time period of two to four months, with a minimum of 5 and a maximum of 10 patients. The recruitment time frame will need to be flexible, as the number of patients referred for radiotherapy who need a mouth bite may vary substantially on a monthly basis. After discussion with a statistician within the trust, it was felt that a small sample size of between 5 and 10 patients would be sufficient for this type of observational study. This sample size is also based on the fact that there are limited numbers of patients referred for radiotherapy that may require a mouth bite, and recent numbers have been in the region of 4 or 5 patients a month. It is hoped, therefore, that this study will be able to recruit approximately 10 patients, but there will be no upper limit, due to the small numbers of patients involved. Non-probability sampling will be used in this study, in which a target sample population is drawn with quotas for individuals with certain characteristics, in this case, head and neck cancer patients receiving radiotherapy and who will have a mouth bite. The advantage of using this sampling method is that it is inexpensive, but the disadvantage is that there may be selection bias introduced. In order to avoid this, the author will adhere strictly to the inclusion and exclusion criteria.

Questionnaires will be handed out to the patients once a week in an envelope, during a treatment session on which a portal image has been taken, for the duration of their treatment. During the first week of treatment, an initial questionnaire will be handed out to the patient which will ask the patient for some background information. On subsequent sessions, a shorter questionnaire will be handed out to patients. The questionnaires will be handed out by the chief investigator wherever possible, or a member of treatment staff when the investigator is unavailable. This will be done in a quiet location within the department where the patient will have the opportunity to complete the questionnaire and hand back to staff in a sealed envelope. If patients require assistance when completing the questionnaire, they may seek help and advice from the research radiographer, who will act as an independent point of contact for the participants, and will help to reduce bias. On a separate data collection sheet, using the portal images captured during treatment, it will be noted whether or not the mouth bite position has altered from the simulator image, and also whether or not the tongue is in its original position.

In some cases, due to the quality of portal images, it may not be possible to accurately measure discrepancies in tongue or mouth bite position. This will be noted on the data collection sheet. By recording this data over the course of a patient's treatment, it will hopefully eliminate the chances of any mouth bite movement being random. For completeness of the data, the mouth bites used by the patients will be weighed at the start of their treatment using simple scales. The volume of the mouth bites will also be measured. These measurements will be recorded on the data collection sheet, as they may have some bearing on the positioning of the mouth bite.

Using a software package such as SPSS, comparisons will be made between data collected from the questionnaires and the measurements taken from the images. Any trends in the data will also be identified to see if there is a pattern in the results over the course of the treatment.

There are various functions and tests that SPSS can perform in order to gain the most out of the raw data. These may include the Mann-Whitney test which can be used when the sample is small, or the Wilcoxon signed rank test, which involves comparisons of differences between measurements, and may be useful in identifying patterns over the course of the treatment in terms of any correlation between mouth bite position and patient comfort.

As with any study, the validity and reliability of the study method need to be assessed. From the literature review undertaken it appears that there has been no similar study done in this area before, and so there are no tried and tested questionnaires on what factors may be influencing the mouth bite movement. Therefore, the validity of the questionnaire used in this study may be called into question. However, the questionnaire has been reviewed by radiotherapy staff, who work closely with patients on a daily basis, and have an understanding of some of the issues encountered with the use of the mouth bites. The data collection sheet is an effective means of recording any shifts in the position of the mouth bite and tongue, and similar methods have been used in studies looking at isocentre movements (Baumert et al, 2005; Willner et al, 1997). In terms of reliability of this study, the area of concern will be in measuring the possible shifts of the mouth bite and tongue from the digital images. Measurements such as this are very subjective, so only the chief investigator will be reviewing the images to eliminate the possibility of inter-observer differences. This may mean that any systematic errors in the measuring technique are carried on throughout the study, however, measurements will be more consistent. Random errors in measuring shifts should be minimised by performing repeated measurements over the course of the patients' treatment. The investigator has had over 5 years' experience in performing portal imaging reviews, added to this the fact that the software used to review the images does have an auto-match function, which may improve the reliability of the results (Fritsch et al, 1995; Gilhuijs et al, 1993).

### **Ethical Considerations**

Taking part in this study should not have any negative impact on the individual patient, and apart from answering the short questionnaire on a weekly basis, the patient will not have to undergo any extra procedures. In answering the questionnaire, the patient may experience some distress, as it may make them focus more on negative aspects of the treatment.

Patients will be informed that the services of a clinical psychologist will be available to them should they require it. Patient confidentiality will be maintained throughout the study. Any identifying features from images that may be reproduced will be removed. Questionnaires will be identifiable only by the patient's hospital number, which will enable the investigator to link them to the portal images taken. However, when writing up the results, no identifiable patient data will be used. Questionnaires and data collection sheets will be kept in a locked filing cabinet in the research radiographer's office, which has a keypad access. This information will be kept for the duration of the study, and following successful completion of the study and MSc course, will be destroyed. The results of the study may be made available to the participants on request. This research complies with the principles outlined in the Declaration of Helsinki (1964).

### **Potential Impact of Study**

This evaluation may have implications for standardising mouth bite production within radiotherapy departments across the UK. As the head and neck guidelines from NICE (National Institute for Clinical Excellence) (2004) state, cancer centres should be committed to ongoing service development through the assessment of new diagnostic technology, new methods of treatment and support for patients.

### **Dissemination of Results**

This research will be highly relevant for all staff within the radiotherapy workplace, including mould room technicians, pre-treatment staff, and treatment staff. Radiation oncologists should be interested in the data, especially if they are working closely with head and neck patients on a daily basis. The information gained from this piece of research could be shared via publication in a radiotherapy journal, and possibly an article in a related magazine by the society of radiographers, such as Synergy. Presentations may also be given at conferences in order to add to the body of knowledge of the profession.

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