Technical Innovations & Patient Support in Radiation Oncology 24 (2022) 48–53

Contents lists available at ScienceDirect

Technical Innovations & Patient Support in Radiation Oncology

journal homepage: www.sciencedirect.com/journal/technical-innovations-and-patient-support-in-radiation-oncology

Short communications and technical notes

Standard Operating Procedure (SOP) for mould room practices and simulation of head neck cancer patients undergoing proton therapy

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ARTICLE INFO

Keywords:
Proton
HN Cancer
Immobilization
SOP

ABSTRACT

Head Neck cancer patients treated with modern proton therapy need special attention during mould room procedures. In addition to usual mould room practices, patients undergoing Intensity Modulated Proton Therapy (IMPT) require attention to the special characteristics of protons viz., sensitivity to beam path and its alteration, sharp dose fall off and end of range. In this article, we discuss the Standard Operating Procedure (SOP) for HNC immobilization and simulation for IMPT, developed and practiced at our centre. The SOP details each step during the immobilization and simulation process, with nuances specific to IMPT.

Introduction

In the recent few years, modern proton therapy installations have increased worldwide, with >95 functional centers and >45 upcoming centers [1]. In the treatment of HNCs, Intensity Modulated Proton Therapy (IMPT) based on the pencil beam scanning technique (PBST), has emerged as a radiotherapy modality that improves the therapeutic radio over Intensity Modulated Radiotherapy (IMRT) [2–4].

We initiated modern proton therapy (PT) i.e., IMPT, with on-board image guidance (both kilovoltage_X-rays and Cone-Beam_CT) in January 2019, and have treated >90 HNC patients till date.

Immobilization and planning CT image acquisition play a crucial role in radiotherapy for HNCs [5]. Similar to IMRT, immobilization should be acceptable, comfortable and reproducible with ease for efficient planned daily treatment [6]. In addition to the standard practice of immobilization for HNC, there are important considerations specific to PT, due to sharp dose fall-off, end range uncertainties and sensitivity to beam path changes. In this article, we document and discuss the Standard Operating Procedure (SOP) followed at our centre for immobilization and simulation of HNC patients undergoing IMPT.

SOP for proton for head neck cancer

This SOP is divided into four major steps, discussed in detail below and summarized in Fig. 1.

Step 1 – Patient selection and assessment

All patients are registered with a Unique Health Identification (UHID) number and undergo detailed clinical assessment, collection of all previous reports and documentation in the Oncology Information System.

Following this, the clinical details are discussed in the MDT (multi-disciplinary-tumor-board). Patients advised PT undergo counselling by the treating physician; a schedule is prepared for immobilization and simulation. Informed consent is obtained, with the help of an interpreter if required, from the patient and family, documenting intent of proposed treatment, side effects, both acute and late. A dental review is carried out by a dental surgeon prior to simulation [7]. Metal caps, if present, are replaced by acrylic caps; exact details of material non-replaceable dental caps/implants are obtained.

Step 2 – Preplanning audit

The preplanning audit (PPA) is a discussion of case history, proposed treatment, immobilization devices to be used, planning image acquisition, and use of additional/multi-modality imaging. The discussion is held by a team of primary radiation oncologists, medical physicists and radiotherapy-technologists (RTT). Additional imaging like MVCT, KV_X-ray is planned in case of Metal/Dental implants in the treatment site or beam direction, to determine exact dimensions. Similarly, the need for a

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https://doi.org/10.1016/j.tipsro.2022.09.003
Received 10 July 2022; Received in revised form 27 August 2022; Accepted 14 September 2022
Available online 30 September 2022

mouth-bite, MRI, PET-CT, and or gaze fixation is discussed, as per diagnosis. A good PPA is important for both: smooth efficient workflow and prevention of errors [8].

Step 3 – Immobilization

Materials in use

- Specifically designed carbon fiber BoS (QFix, Avondale USA), (Fig. 2 (A)) inserts (Short or Long) are used as a base plate as per site of treatment and patient characteristics, to meet the requirements of proton beam transmission.
- Mold_care_cushion (MCC), (QFix, Avondale USA) (Fig. 2(B-i)), is customized to patient's HN region. This comprises a soft fabric bag, containing expandable polystyrene beads coated in a moisture-cured resin, the former packed in sealed moisture free aluminum bag. When activated with sprinkled water/ambient humidity, the pillow becomes rigid, conforming to the contours of the patient's body. Different MCC are available for head alone (Fig. 2(B-ii)) and head-neck-shoulder region (Fig. 2(B-iii)), respectively.
- Thermoplastic headframes (Fibreplast BoS) (QFix, Avondale USA), are used to immobilize the face. Head & Neck and Head & Shoulder headframes (Fig. 3-Ia-IVb) are used.
- Customized mouth-bites (Fig. 4-IIa, IIb, IIc) are fabricated using thermoplastic pellets (Fig. 4-Ia).
- Aids such as couch top pads (SofTouch), knee rest, multi-indexing handgrip for patient's comfort and proper positioning may be used during procedure.

Patient positioning and immobilization

Patients are positioned and immobilized in a dedicated mould-room with a wall mounted longitudinal laser (MICRO+, Gammex, Sun Nuclear Limited) by a team of RTTs. An RTT confirms the patient's identity, diagnosis, treatment site and key inputs discussed in PPA such as particular neck position for likely beam arrangement or use of accessories e.g., mouth-bite.

- The patient is photographed for identification.
- Detailed complete explanation of procedure with demo devices, is given to the patient, for their education and co-operation, by the designated RTT. The components of this explanation are:
  - o Steps of immobilization and its importance.
  - o The co-operation required from the patient.
  - o The safety and efficacy of the procedure.
  - o How the patient may alert the RTT if they have difficulties during the procedure.
- Removable denture, hearing aids, toupees, jewelry and any kind of foreign body in the region to be immobilized are removed.
- The patient is asked to undress the pertinent site or upper hemi-body and change into a hospital gown which can be easily removed once the procedure commences.
- The patient is positioned on the mould-room-procedure couch in a comfortable position which is reproducible for daily treatment.
- All immobilization devices are indexed to the couch to reduce errors.
- Skin folds in the neck region are minimized by retracting the shoulders, elevating the neck; while prioritising the patient's comfort.
- If the patient has long hair, the hair is tied together with a cotton ribbon or small hairband preferably to vertex either in the midline or lateralised, as per proposed beam arrangement (Fig. 3-Va, Vb).
- Documentation and labelling of all devices and their indexed positions including setup photos is performed by one RTT and confirmed by a fellow RTT.
- Special attention is taken in tracheostomised patients to avoid airway obstruction by making an appropriate opening in the mask to clear the tracheostomy site. The same is done for nasogastric tubes (Fig. 3-Vc),
- Patients with additional issues such as PEG, colostomy bag, urinary catheter etc. require special care while handling and positioning.

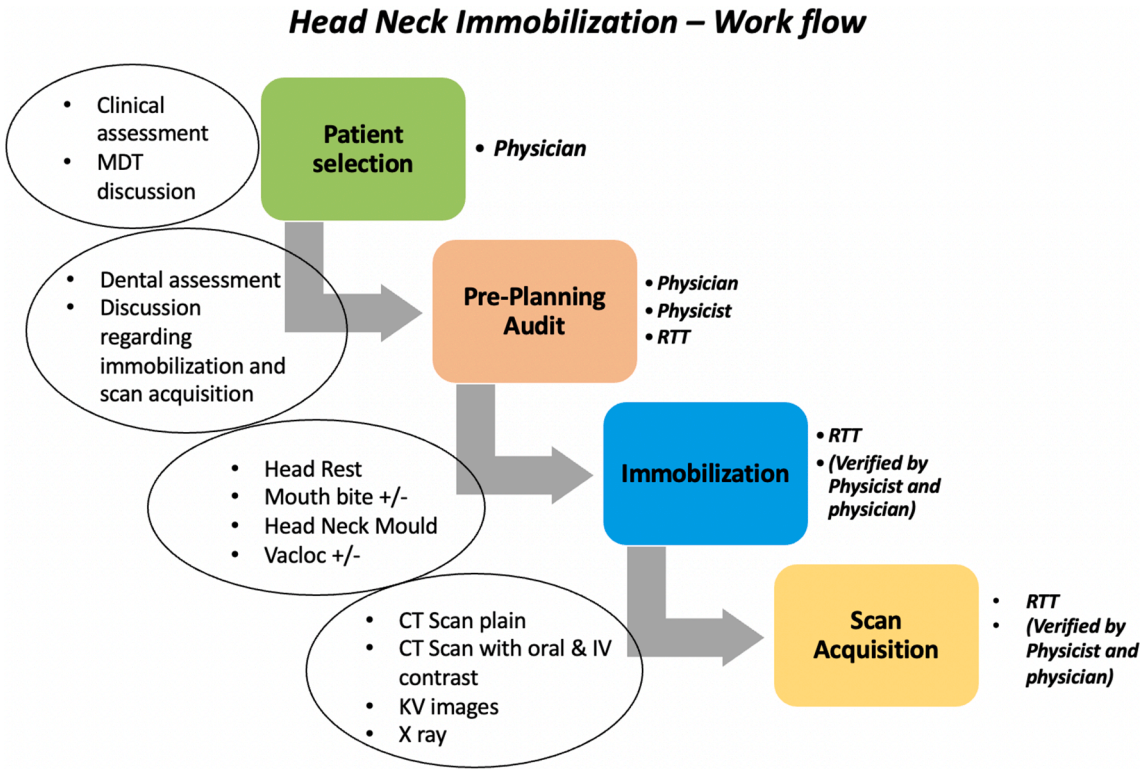

Fig. 1. Head neck immobilization work flow schematic representation RTT – Radiotherapy technologist, CT – Compute Tomography, IV – Intravenous.

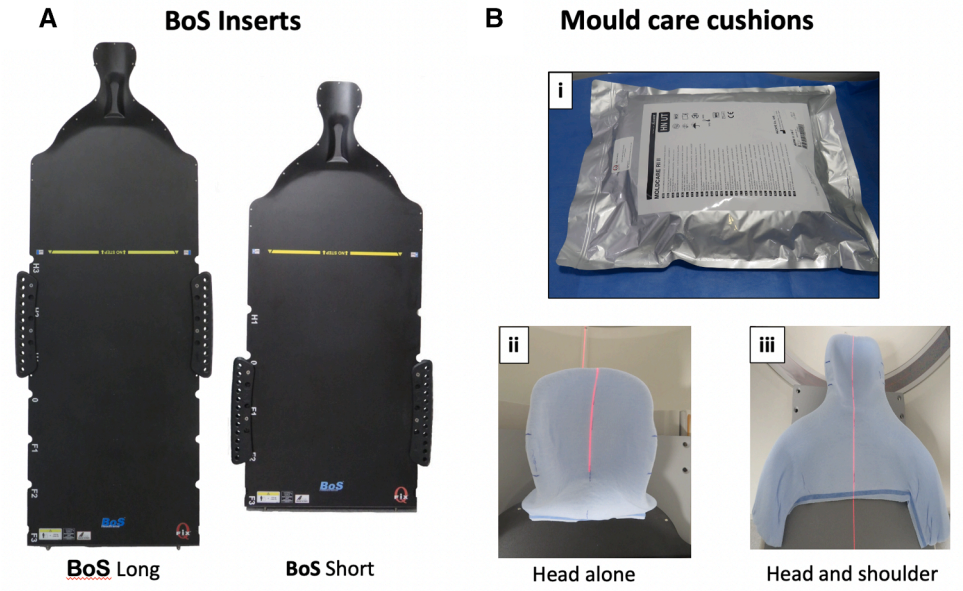

Fig. 2. (A) Carbon fibre BoS inserts, long and short. (B) Mould Care cushions (MCC), i – Packed MCC, ii – Fabricated head alone MCC, iii – Fabricated head and shoulder MCC.

- The procedure is started with construction of mouth-bite, if any, followed by fabrication of a customised mould care cushion and followed by fibreplast mask, respectively.
- The reproducibility of positioning is ensured repeatedly.

Construction of mouth-bite (Fig. 4)

- At the outset, jaw opening, depth and teeth implants are checked.
- The mouth-bite is chosen according to patient's breathing pattern and dental status. A Guedle airway is used as the stem for mouth-breathers and edentulous patients while a wooden spatula for patients who do not have nasal obstruction.
- Thermoplastic acrylic beads are melted in a thick polythene bag in hot water (temperature $> 70\ ^{\circ}C$) to form a clay like consistency and then wrapped around the main stem of the mouth-bite to the required length, width, and thickness.
- When temperature reduces to that of tepid warm water, the mouth-bite is inserted into patient's mouth by positioning tongue as discussed in PPA, pushing laterally or down.
- The patient is asked to bite gently and then firmly, once, for a minute or two to obtain an impression of the bite on the mouth-bite, for reproducibility.
- The estimated procedure time is 15–20 min.
- Usual thickness of the mouth-bite is 1–3 cm depending on jaw opening. Occasionally, in patients with poor mouth opening, mouth-bites as slim as 0.7 cm may be constructed.
- Reproducibility is confirmed after fabrication.
- The whole process may have to be repeated to obtain the desired mouth-bite.

Customizing head & neck Mold care (Fig. 2B)

- The patient is positioned on BoS table.
- The cushion is unpacked, flattened and the beads rationed primarily towards the vertex, neck and shoulders, to facilitate building the neck bridge, shoulder and vertex caps, respectively, in <1 min.
- Following this, the cushion is placed under patient's HN region without disturbing the position of patient but instead by helping the patient to lift shoulders and head up.
- Customization helps support the cranium and cervical spine posteriorly and keep them straight with the chin elevated.
- Care is taken to keep the pinna in or out of the Mold care as per patient's comfort and reproducibility.
- The shoulders and vertex region caps are molded sufficiently to avoid longitudinal displacement.
- The cushion gradually hardens and conforms to the body contours, creating an impression on the device.
- The estimated preparation time is 15–20 min.
- The first 3 min are crucial while customizing, because of the softness of the material. Following this, fine molding can be done by applying gentle pressure, while keeping the patient immobilized, to avoid the sagging of the material at the edges of the BoS. This prevents difficulties subsequently, in clamping the face-mask.
- It is important to avoid any air gaps in neck and upper back region which, if not reproducible, can result in beam path changes and proton dose perturbation.
- Three RTTs are required for the fabrication, one addressing the vertex and neck, and one on each side to address the shoulders.
- We avoid sprinkling water over the material due to the ambient humidity of our location, average 75 %. Spraying water may cause the formation of lumps in the cushion due to uneven density of the material (Fig. 3-VIa).

Fabrication of fibreplast mask (Fig. 3)

- Once the mouth-bite and cushion are made, the patient is placed afresh on the couch, to confirm reproducibility and note uncertainties, if any.
- We use a moisture free heating system as it is more hygienic and hassle free; however, a water bath can be used instead.
- The precut fibreplast mask is placed in Rapid Heat Hot Air Oven for 7 min, the oven having been preheated to $75\ ^{\circ}C$.
- The temperature tolerance is tested, on patient's forehead or over the dorsum of the hand before starting fabrication.
- The mask is stretched slightly out for the ease of fabrication, keeping the patient position as it is.
- The thermoplastic mask is fabricated with no/minimal air gap between the skin and the mask. Attention is paid for at least 3–4 min

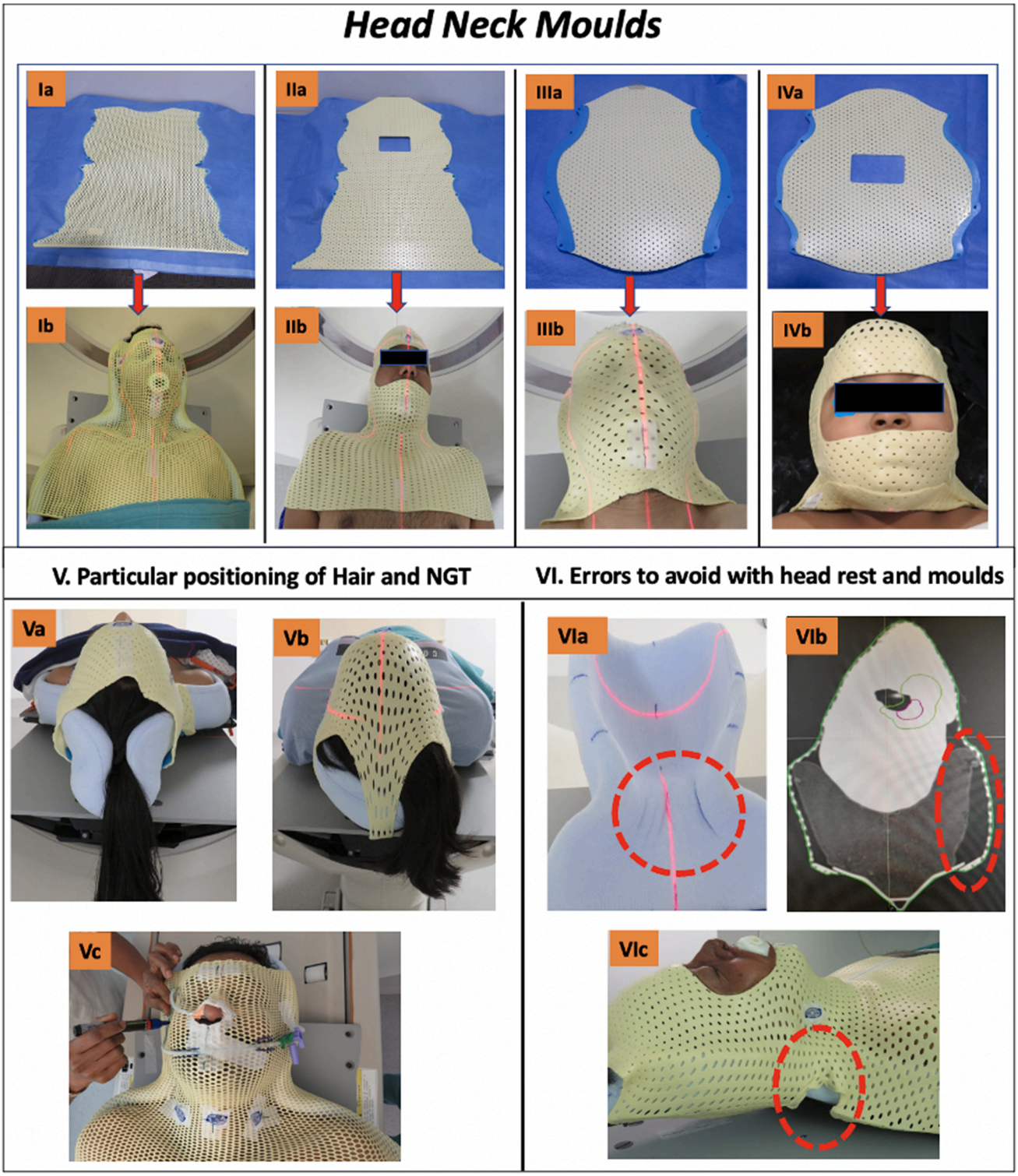

Fig. 3. Head Neck Moulds Ia – Head Neck mould sheet, Ib – Fabricated Head Neck mould sheet IIa – Head Neck open face mould sheet, IIb – Fabricated Head Neck open face mould sheet IIIa – Head mould sheet, Ib- Fabricated Head mould sheet IVa – Head open face mould sheet, IVb – Fabricated Head open face mould sheet V – Particular positioning of hair and nasogastric tube (NGT) Va – Hair pulled together and positioned straight at vertex Vb – Hair pulled together and positioned laterally at vertex Vc – NGT positioned and position marked for daily reproducibility VI – Examples of common errors must be avoided with MCC an HN moulds VIa – Folds lumps in MCC (highlighted with dotted red circle) VIb – Gap between body. MCC and mould (highlighted with dotted red circle) VIc – Folds in Head neck mould (highlighted with dotted red circle).

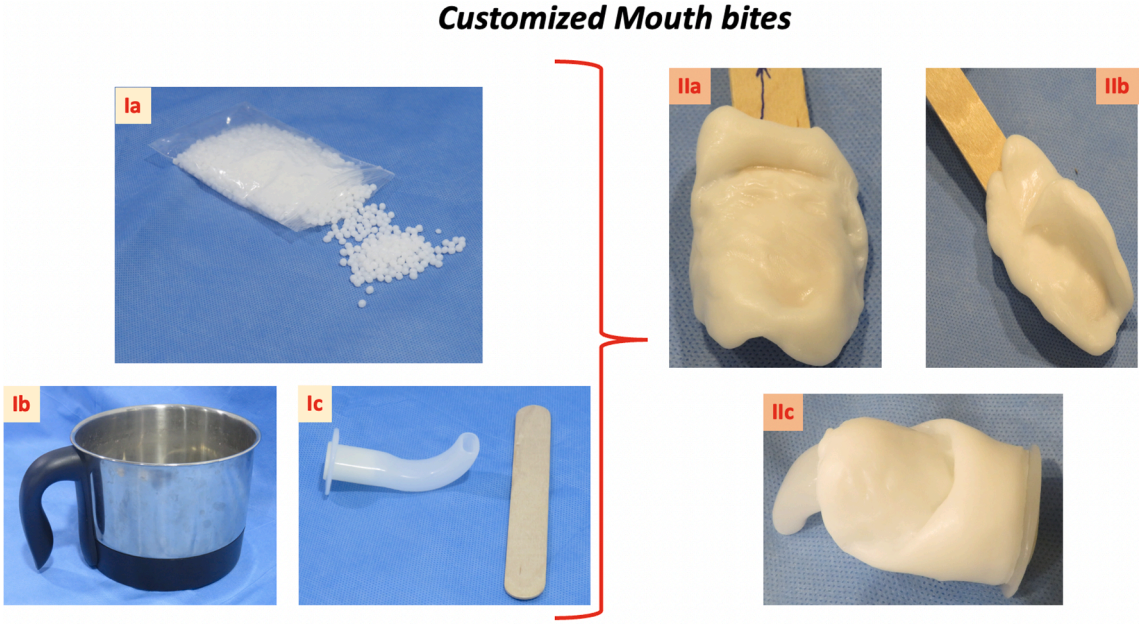

Fig. 4. Customized mouth-bites Ia – Thermoplastic pellets Ib – Electric kettle to heat water Ic – Guedle airway and wooden spatula IIa – Mouth-bite using wooden spatula to push tongue down IIb – Mouth-bite using wooden spatula to push tongue laterally IIc – Mouth-bite using Guedle airway to push tongue down.

over the forehead, nasal bridge, and the chin for the correct construction of mask.
- The estimated total time for fabrication of mask is 15–20 min.
- Three RTTs are required for the process one for the vertex and one on each side of the patient.
- Irregularities and fold are to be avoided (Fig. 3-VIb, VIc).
- Additional jaw thrust can be used in edentulous elderly patients to avoid jaw drop.

Step 4 – CT scan acquisition

- Following immobilization procedures, the patient is shifted for a planning CT scan acquisition; slice thickness, area of interest and use of contrast is as per PPA.
- The patient is shifted accompanied by trained hospital staff, either walking or using a wheelchair, depending on their general condition.
- Before commencing the procedure, the patient's details are reconfirmed.
- Canon_Aquilion_LB CT Scanner (Canon Medical Systems, Singapore) is used in our centre for planning image acquisition.
- The patient is positioned for scan with the customized immobilization devices on the BoS insert placed on CT couch.
- The reference markings with fiducials are made on the immobilization devices with the help of in-built CT drum lasers.
- Antero-posterior and lateral topograms are acquired and reviewed for non-reproducible uncertainties if any, before performing the scan.
- Field of View for the scan must include the entire immobilization.
- The planning scan is acquired without contrast at a pre-discussed axial thickness and SEMAR (Single_Energy_Metal_Artifact_Reduction) algorithm.
- Following the plain scan, the mask is removed, without moving the patient, and the body mid line laser and external auditory meatus position marked quickly on the Mold care.
- A second scan is performed for scar and mouth-bite delineation using radio-opaque wire and thin oral contrast respectively and intravenous contrast, if required.
- All relevant reference makings and measurements are made and site-setup photos captured for documentation, treatment reproducibility and verification.
- Following procedure, the patients is kept under observation in the designated wait area to check for side effects or discomfort, if any.
- The acquired images are sent to the treatment planning system for further activities.
- Additional images such as MVCT, KV_X-rays and MRI are acquired as per PPA.

Discussion

This SOP was developed and implemented for HNC patients undergoing PT. The SOP is in concordance with published SOPs for HN IMRT, and in addition, contains specific measures for IMPT [5]. This has helped simulate HNC patients with ease, in minimal time and cost effectively with limited re-simulation due to immobilization errors.

Conclusion

We have summarized the workflow pertaining to preparation of immobilization device for PT for HNC, emphasizing basic steps as well as vital nuances gained from our experience. With the increasing availability of PT and wider application in HNC, we believe, this SOP will be a resource for both existing and upcoming centres.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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