ACCURATE LOCATION OF TUMOR IN HEAD AND NECK CANCER RADIOTHERAPY TREATMENT WITH RESPECT TO MACHINE ISOCENTRE

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To the almighty and my family.

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ABBREVIATIONS

IMRT	Intensity Modulated Radiation Therapy
RT	Radiotherapy
HNC	Head and Neck Cancer
CT	Computed Tomography
LINAC	Linear Accelerator
3D	Three Dimensional
PTSD	Post-Traumatic Stress Disorder
ART	Adaptive Radiation Therapy
IGRT	Image Guidance Radiotherapy
VAMC	Veterans Affairs Medical Center
SRS	Stereotactic Radio Surgery
DOF	Degree of Freedom
PEEK	polyetheretherketone
MRI	Magnetic Resonance Imaging
SFOV	Scan Field of View
LCS	Local Coordinate System
GCS	Global Coordinate System
GPa	Giga Pascal
TPS	Treatment Planning System
LR	Left-Right
AP	Anterior-Posterior
SI	Superior-Inferioir

ABSTRACT

Tangirala, Deepak Kumar M.S.M.E, Purdue University, May 2017. Accurate Location of Tumor in Head and Neck Cancer Radiotherapy Treatment With Respect To Machine Isocentre. Major Professor: Ali Razban.

Radiation Therapy has been one of the most common techniques to treat various types of cancers in particular is Head and Neck Cancer (HNC) which accounts for three percent of all cancers in the United States. During the treatment procedure, the patient is immobilized using immobilization devices such as the full head face mask, bite blocks, stereotactic frame, etc. to get accurate location of tumor. The disadvantage of these devices is that they are very uncomfortable to the patient especially people suffering from Post-Traumatic Stress Disorder (PTSD) and claustrophobia who cannot wear any confined masked system such as the full head mask or bite block during the treatment procedure. To mitigate this problem, there has been a lot of research in modifying such immobilizing devices without neglecting the accurate location of tumor.

To this end, the research presented in this thesis focuses on developing a mask less system with accurately locating the position of tumor using the technique of coordinate transformation at the same time fulfilling the three important characteristics:

- Comfort
- Accuracy
- Low Price

Such a system is comfortable to the patient because no confining mask system is used and we choose minimal contact points on the patient for fixing the patient. Traditionally, such type of cancer treatment is carried out in two stages: Diagnosis

stage, which identifies the location of the tumor and the external markers and the Treatment stage where the tumor is treated with immobilization device being common in both the stages. In the new system, the immobilization devices vary at the two stages. The head position is monitored by using pressure sensor assembly where spring and pressure sensor setup detects the amount and direction of head deviation. We also prepare a customized 3D printed nose bridge part for extra referencing in the treatment room. Also, it is important that we use material for our immobilization devices which does not contain any metal and also MRI compatible. Once the patient lies down on the treatment couch and is immobilized using the immobilization devices then tumor location is calculated using the theory of coordinate transformation and transformation matrix in the Diagnosis and Treatment Stage.

To validate the system, simulation of immobilization devices used in the new design was carried out using ANSYS Workbench 15.0 and LS-Dyna softwares Explicit Dynamics method. The simulation for the head fixing device showed a deflection of ±0.1974 mm with respect to machine isocentre with a load of 60 N which is lower than the customer requirement of ±3 mm of head deviation with respect to machine isocentre. The material used for the external markers for patient positioning was selected to be polyetheretherketone (PEEK) which is a radiolucent and widely used MRI compatible material. The system also takes into consideration the effect of weight loss which is one of the drawbacks of the current systems.

Although still in the development stage, this mask less system holds to be the next new variety of immobilization devices which are comfortable to the patient and also less expensive to be implemented in future cancer treatment practices.

1. INTRODUCTION

Accurate tumor location is very important in radiation therapy of HNC patients because there are multiple critical organs around the tumor target area. These critical organs need to be separated from the cancerous organs so as not to overdose them with radiation. The cure for HNC involves radiotherapy where the cancerous tumor is killed by bombarding high-energy x-ray beams to the desired tumor location. For successful head and neck tumor treatment the design requirements for any system are:

- **Comfortable Immobilization System:** The setup for radiotherapy involves many immobilization devices that hold the patient rigidly on the treatment couch such as custom made thermoplastic mask or the camera tracking system. The immobilization devices should be such that they accurately locate the position of the tumor even if the patient makes little movements. The system should correct itself for minute patient deviations during the treatment procedure but at the same time make the patient feel comfortable.

- **Accuracy of Tumor Location:** The patient positioning setup should ensure that the accuracy of the tumor location is not altered during the treatment and diagnosis stage.

- **Durability of the Setup:** The whole patient positioning setup should be durable enough to accommodate for the anatomical changes in the patient that occur during the course of the treatment

- **Quick and Easy Setup:** The patient positioning system should also be very easy to setup and understand by the radiation therapist. For example, the entire preparation time for the thermoplastic facemask is about 3-4 minutes, which includes heating the mask and then cooling down to take the shape of patients face. The procedure for preparing the mask is also very easy.

In common clinical practice and at VA Medical Centre (VAMC) in Indianapolis, Indiana in particular, large number of patient population suffers from PTSD and other psychiatric conditions and therefore cannot easily tolerate wearing a confining mask or having surface markers tattooed on their body for their daily treatments. For these patients, there is a need to either medicate them prior to therapy and/or disrupt the integrity of the mask by cutting portions of the facemask so that they can be comfortable enough to receive daily treatment. In current clinical practice, the confining mask system is used to immobilize patient that consists of a reusable positioning head frame and a custom formed thermoplastic facemask that attaches to the radiation treatment couch. These masks have the advantage of being relatively inexpensive (∼$105) and can be quickly formed by therapists for the patient at the time of the initial planning CT scan. At present, VAMC treats about 10-12 patients with HNC a month, only a fraction of whom cannot tolerate the confining facemask. There are some head frames (e.g. Gamma Knife frame) that incorporate titanium into the device but it is positioned on the patient in such a way that the metal does not interfere with the beam path.

The following section will explain the current clinical practice to cure HNC. This is followed by a detailed explanation of the current patient positioning systems and patient immobilization systems used. At the end of this chapter different types of radiation therapy treatment procedures used in current practice will be explained.

1.1 Head and Neck Cancer Treatment Process: Current Practice

HNC region is anatomically diverse area of the human body that effects variety of glands and organs including the throat, larynx, nose, sinuses, and mouth. Most HNCs are squamous cell carcinomas that begin in the flat squamous cells that form the inner lining in many parts of the human body. Many cancers of head and neck can be cured especially if they are found early. For radiologists, the primary goal of the treatment is to kill the cancer but preserving nearby healthy nerves, organs and tissues. The current cancer treatment process is shown as a flowchart in Figure 1.1. The treatment of HNC is divided into three Stages-Diagnosis using CT scanning machine, Simulation using Eclipse™ Treatment Planning Software and Treatment using Linear Accelerator (LINAC). In the Diagnosis and Treatment stage, following are the steps required to follow to accurately locate tumor and to treat it in respective stages:

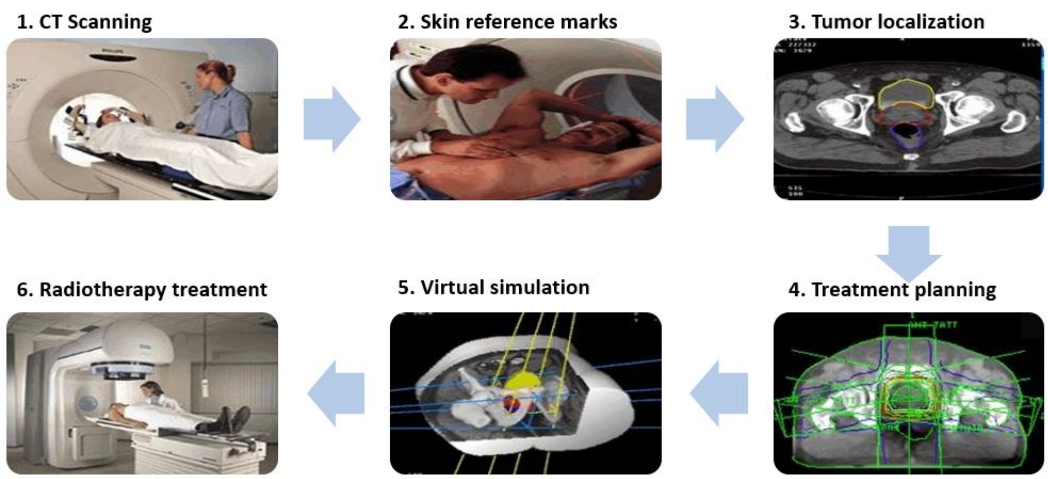

Fig. 1.1. Flowchart of current Radiation Therapy Treatment Process explaining each of the cancer treatment stages

- **Patient Positioning:** The first step is to position the patient accurately to get the correct position of the tumor. To position the patient, the x, y and z coordinates of the patient with respect to the machine isocenter are required which are given by CT machines Exact Treatment Planning software.

- **Patient Immobilization:** Patient immobilization systems are used such as the full head face mask to fix the patient in a particular position and use the same system to position the patient in the treatment room. These devices also need to be placed at the same position every time the patient comes in for treatment, thus the radiotherapist records the positions of these devices in an instruction sheet.

- **Type of Treatment Plan:** Once the patient has been positioned and the immobilization devices rigidly fix the patient in one particular position, the next step is to decide on what treatment plan to be used to cure the cancerous tumor.

1.1.1 Diagnosis Stage

The Diagnosis is the first step for head and neck cancer treatment where the right diagnosis technique and determining how much the cancer has spread in the target region. This is carried out using CT scanning machine similar to the one shown in Figure 1.2(a) where the patient is positioned accurately using immobilization devices and markers for repeatability as shown in stage 1 (CT Scanning) and stage 2 (Skin reference marks) in Figure 1.1, then the couch is made to go inside the donut shape of the machine. Once inside, a continuous rotation of beams is bombarded on the target area to locate for tumor location shown in stage 3 i.e. tumor localization stage in Figure 1.1. After scanning, the patient is released and called for the treatment stage if necessary. To immobilize the patient at VA Hospital a full head mask is being used. This mask is a thermoplastic mask which is dipped in a hot water bath set at 148°F to 158°F for 3-4 minutes to get soft. Once the mask becomes soft then it is taken out of the how water bath and then the excess water is washed out using a towel for 10-15 seconds so as to reach room temperature. Next, the mask is taken and placed on the patients face and tightly pressed against patients face. Now the mask is locked to the treatment couch using the screws provided on the mask and remains there for 10-15 minutes for the mask to cool down and harden to take the shape of patients face. Special attention is required during this cooling time so that the patient does not move their head inside the mask for reproducible immobilization. Once the mask has cooled down and taken the shape of patients face, the next step is to place an external marker to localize the isocentre on the patients face. The CT machine has lasers as shown in Figure 1.2(b) to align the patient exactly at the same position for subsequent treatments. Isolines are drawn on the facemask coincident to the machine lasers. The markers are aligned along these lasers and the position is recorded to be used for patient reproducibility in the treatment room.

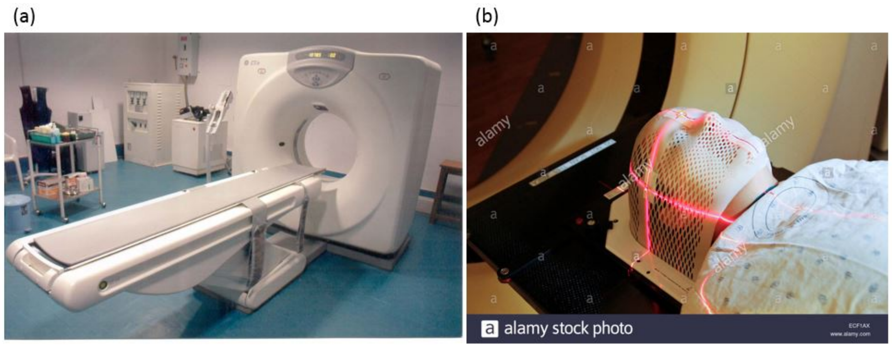

Fig. 1.2. (a)CT Scanning Machine used to scan location of tumor[1], (b) CT Machine lasers lines (in red) used to position a patient in the CT room[2]

1.1.2 Simulation Stage

In this stage all the CT scan data and patient positioning data is taken offline by the radiologist and then accurate location of tumor and the right amount of x-ray dosage to be given to the patient for cancer treatment is decided. This is the planning stage for the radiologist where using Exact^{TM} Treatment Planning software they plan the region of interest for cancer treatment as shown by stage 4 i.e. Treatment Planning stage in Figure 1.1. In this stage the safe non-cancerous organs are alienated so that they are not affected by the radiation but only target the tumor. The location of the external markers is also used to position the patient in the treatment room and get the accurate location of tumor. This is shown in stage 5 i.e. Virtual Simulation stage in Figure 1.1.

1.1.3 Treatment Stage

Once the extent of cancer spread in the body is determined or the type and location of the cancer has been identified then comes the treatment stage. In this stage, depending on the severity of the cancer the patient is made to go through radiotherapy and chemotherapy over a set period of time. The goal of this treatment is to destroy cancer cells and slow tumor growth without harming the surrounding healthy tissues or organs. This stage is shown in Figure 1.1 in stage 6 i.e. radiotherapy treatment stage. At weekly imaging sessions, an orthogonal pair of kilo voltage radiographs (usually A-P and lateral) is recorded using LINAC machine similar to the one shown in Figure 1.3 for patient setup accuracy. A kV Cone Beam CT (CBCT) was acquired to position the patient in the exact same location as in the Diagnosis stage. multi-leaf collimators (present inside the LINAC) take the shape of the tumor defined in the simulation stage and are targeted to the tumor location[3]. Radiologist also direct the beams to target the tumor while avoiding the healthy surrounding tissues or organs. The gantry of the LINAC also rotates 360 degrees to get 3D image of the malignant tumor. After the process is over either the patient is instructed to come back again for further treatment in the same procedure or the cancer cells have been killed and the patient is ready for discharge.

1.2 Patient Positioning System

Patient positioning is the first step in the treatment of HNC because if the head is mobile then we cannot get consistent results for the position of the tumor. For accurate patient positioning the setup requirements are:

- Same patient positioning setup and treatment couch to be used in the diagnosis and treatment stage for identical patient setup in both the CT room and Treatment room

Fig. 1.3. Linear Accelerator (LINAC) Treatment Machine used in VAMC, Indianapolis, Indiana, USA to treat the cancerous tumor cells (Courtesy of Varian Medical Systems Inc.$^{\text{TM}}$)

- Indexed immobilization system to be used which will enhance treatment effectiveness and maximize clinical efficiency. Indexed immobilization system means that the immobilization devices contain index marks so that the position of the devices can be recorded and facilitate precise repeatable patient positioning both in the treatment room and the CT room

At Richard L. Roudebush VAMC, Indianapolis this is done using imaging techniques such as CT scanning where the exact location and extent of cancer causing tumor is identified [4]. Digital image processing is used to generate the three dimensional image of the tumor from a series of images taken around a single axis of rotation. Firstly, the patient is immobilized on the treatment couch using immobilization devices and then patient positioning is carried out using the CT scanning machine and the LINAC. For this, the patient is aligned along the laser lines as shown in Figure 1.2(b) of the imaging machine using skin markers or external markers for positional accuracy. Next, the machine isocenter is defined and the tumor is aligned along this imaginary point. Isocenter is defined as the imaginary point of intersection of the gantry, treatment couch and collimator rotation axis. Due to the continuous rotation of the CT scanning machine, the geometric positioning of the isocentre can vary and thus The American Association of Physicists in Medicine (AAPM) group report recommends that up to ±3 mm deviation between the radiation and mechanical isocentre is acceptable for Stereotactic Radio Surgery (SRS) treatments [5]. Once this stage is complete, the same immobilization device like the full head mask can be reused in the Treatment stage for reproducibility and positional accuracy.

1.3 Patient Immobilization System

Once the patient positioning has been setup the next step is to immobilize the patients head rigidly on the treatment couch to get accurate position of the tumor. Although there are other means to immobilize the patients head like strapping the head to the treatment bed, but it is generally advised to use immobilization device due to their accuracy and repeatability. The amount of patient movement called as couch movement in radiotherapy varies according to the device being used [6-8]. Typically, the couch correction in all directions varies between ±2 mm to ±3 mm. The importance of immobilizing patients head for HNC Radiotherapy (RT) is well known in the radiology community and many such immobilization devices have been developed in the past. A few notable immobilization devices are the stereotactic frame bolted to patients head [9], bite blocks that include dental mold so that the patient bites this mold to fix the head [10-12], thermoplastic masks [13-15] or stereotactic devices [16] or a combination of both.

Stereotactic devices as shown in Figure 1.4(a) were the earliest immobilization devices used made out of acrylic plastic suitable for use under a CT scanning machine. Probes protruding out of the frame in numerous directions is made to fit on patients cranium and fastened by means of screw devices. Such devices cause a lot of discomfort to the patient and thus discontinued in medical practice but this provides a very rigid immobilization of patients head. Bite blocks as shown in Figure 1.4(b)

Fig. 1.4. Various Immobilization devices used to fix the patient rigidly on the treatment couch(a)Stereotactic Frame, (b) Bite Block and (c) Full Head Face Mask

have also been used for patient immobilization that consists of dental mold fitted on a stereotactic frame for rigidity. The dental mold is then placed inside patients mouth with instructions given to tightly press the mold with their teeth. This device though is an improvement on the stereotactic frame but it causes discomfort to the patient. This is so because patient has to hold on to the dental mold until the scanning is done which typically lasts for 4-5 min. Improvement to the bite block was the thermoplastic facemask as shown in Figure 1.4(c) and is the most widely used immobilization device at present. The first facemask that was developed covered the entire face, which reported a repositionable accuracy of ± 3 mm. The preparation of this type of mask has been explained in chapter 5.6.1. As the mask is prepared separately for each patient, this type of a mask can be used repeatedly over a long period. It also holds the patients head very rigidly and restricts head movement to less than ± 2 mm [15]. The disadvantage registered with such a device is that patients feel uncomfortable and claustrophobic wearing it as many of the patients that come for head and neck cancer treatment suffer from PTSD and thus there is a need to design a system where they feel comfortable during the duration of the treatment. To ease off the claustrophobia, the full head mask can be given cuts at the mouth and eye region to create another type of thermoplastic mask called open facemask. The method to prepare the mask for radiosurgery is same as that of a full head mask but when the mask is hardened then it produces sharp corners and irregular cutting which can be discomfort to the patient.

1.4 Types of Radiation Therapy Treatment

Previously there have been many techniques developed to treat the cancer like IMRT, Adaptive Radiation Therapy (ART) and image guidance technique [17-19]. All these techniques use a full facemask or an open face mask to immobilize the head which is uncomfortable for the patient. The common equipment used for patient head positioning in the techniques discussed below are a full head mask and a standard head rest affixed to the base plate which is further placed on the treatment couch. This whole setup is aligned along the isocentre of the LINAC and the process can be repeated in the treatment room too with the same equipment. IMRT is the technique currently used by physicians to treat cancer patients. IMRT uses linear accelerators to precisely deliver the doses to the target volume without harming the surrounding at risk organs. The problem with the IMRT technique is that, it does not account for positional change of the tumor and changes to normal anatomy during the treatment stage leading to exposure to critical at risk organs and increase in the overall dosage. There have been studies which show that IMRT causes severe pharyngeal and oral side effects for head and neck cancer patients [10,11,20]. IMRT also does not consider weight loss which is one of the most major side effects of cancer [21].

To overcome the drawbacks of IMRT and to prevent over dosage and exposure to at risk organs one of the most notable therapies available right now is ART [22]. ART is defined as changing the radiation treatment plan due to changes in the anatomy during the treatment stage. ART involves changing the treatment plan based on the most up to date biological information of the target. ART can be used offline between fractions, online immediately prior to a fraction and in real time during a fraction. Although ART provides for so many advantages the method has major drawbacks too. As ART involves an updated biological information during each treatment stage, it involves a lot of documentation and expert guidance during the treatment planning which in turn involves lot of money and training for teaching the software. Although this method has been proven to be beneficial but the time and training that has to be given to physicians is difficult keeping in mind the number of treatments carried out in a single day [19,23]. Also during CT scanning, patients are made to put on the immobilized face mask for immobilizing the head which is as discussed above one of the major points of discomfort to the patient.

Image Guidance Radiotherapy (IGRT) is another type of technique which has been proven to be successful in patient positioning and delineating the tumor from the at risk organs while deciding the amount of dose to be delivered in the target area. This technique uses portal imaging, CT scanners and ultra sound devices for image guidance. If anatomy of the patient has been altered, then deformable registration algorithm can be employed to calculate the amount of dose to be delivered in the target area during planning stage.

2. PREVIOUS WORK

There have been many studies done in the past to immobilize the head and get the correct position of the tumor and they have either used a full face mask or an open face mask or mask less system to immobilize the head. The following section will describe a few of the studies done in this field. Firstly, a system with full or open face mask is described and then mask less system for immobilizing the head for head and neck cancer radiotherapy is explained.

2.1 Masked Immobilization of the Head for Head and Neck Cancer Radiotherapy

One of the most earlier studies to solve the immobilization of the head and analyze the head motion was carried out by researchers from Loma Linda University of Medical Sciences, California using proton beam radiotherapy where the treatment typically lasts for 1-5 days with 2-6 daily fields (Figure 2.1) [12]. In this study, the patients were made to lie on the treatment couch in supine position and the head was immobilized via a thermoplastic facemask. Two x-ray tubes projecting orthogonally to the proton beam and one in the beam direction were installed to get the patients position. 16 patients (8 males, 8 female) were chosen with mean age group of 49 years (range 15-70 years). The mean time from patient placement to the end of the treatment was 30.6 mins (range 10-68 mins). The patient motion was detected by placing two LED displacement sensors (Omron Z4W-V) connected to a PLC unit. Each sensor was placed on an adjustable extension arm affixed to a magnetic base, which was further affixed to the proton beam machine. The axis of one sensor was placed along the anterior-posterior patient axis and the second sensor was placed along the lateral or longitudinal patient axis. A touch screen device was placed adjacent to the treatment couch for manually adjusting the couch motion or patient motion by the operator so that the patient is aligned along the isocentre of the proton beam machine. It was concluded that the mean deviation of the patient was ±0.18 mm and the maximum deviation was ±0.46 mm with respect to isocentre is within the threshold value of ±1 mm. However, the drawback of this method is that it uses a thermoplastic facemask to immobilize the head, which is very uncomfortable for the patients. This method cannot be applied for IMRT where the treatment lasts for a minimum of 6 weeks during which there can be weight loss to the patient. Due to weight loss, the mask will get loose and patient can move their head freely giving inconsistent results.

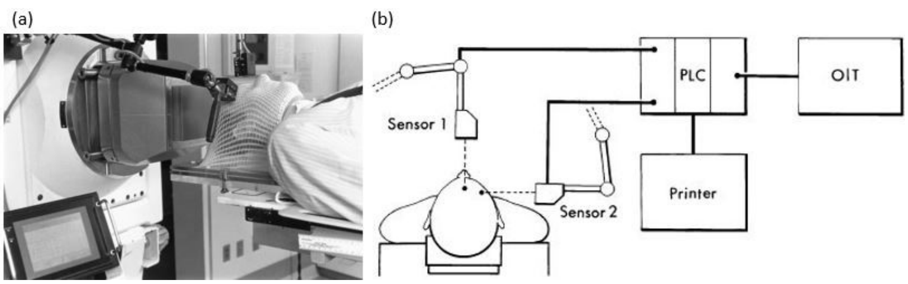

Fig. 2.1. (a) View of the patient motion monitoring system in the proton treatment room. The sensors are placed in AP and LAT direction. The OIT in the front displays the patient's motion data, (b) Schematic diagram of the patient motion monitoring system.

Another research was conducted by a team from Memorial Sloan Kettering Cancer Centre in New York, USA using 2D and 3D image guidance [23]. According to this research, the researchers state that daily manual 2D-2D image registration of the radiographs reduces positioning errors and conclude that thermoplastic masks are effective for patients. The experiment was conducted on nine patients with daily imaging sessions making it 54 sessions throughout the course of the treatment. Patients were made to lie on the treatment couch and the head was placed on a standard headrest, which is affixed to the couch. Each patient had an individual custom-made thermoplastic facemask prepared at the simulation stage and affixed to the base plate.

The treatment isocentre was determined based on the CT scan, tattoos were put on the patients chest, and isolines were drawn on the facemask for alignment with the room laser at the treatment stage. Two types of immobilization devices were used: Aktina Pin Point system (head mold and mouthpiece) shown in Figure 2.2(a) and the CDR Freedom (head mold and open face mask) as shown in Figure 2.2(b) and cone beam CT (CBCT) was used in both cases for initial head alignment and intra-fractional motion monitoring. 25 patients were selected for the Pinpoint system and 8 patients were selected for Freedom system. The time spent for rotation corrections was 5.0±4.1 min for the Pinpoint system and 2.7±1.3 min for Freedom system [23]. For forced head movement both systems could restrict head movement to ±1.5 mm which is less than the threshold limit of ±3 mm. The disadvantage of such a system is discomfort because both systems use confined mask systems to immobilize the patient.

There has been another study from Memorial Sloan Kettering Cancer Centre in New York, USA where they have compared two frameless stereotactic radiosurgery (fSRS) systems for immobilizing the head under same clinical conditions using Cone Beam CT [18]. The first stereotactic device was PinPoint developed by Aktina Medical and the other was called Freedom developed by CDR Systems. The comparison of the two systems was based on residual head motion of the patients during the scanning stage, head restricting capacity of the device and the patient setup time. The Pin Point system consists of a head mold and mouthpiece to immobilize the head. This system locks the head in 6 degrees of freedom where the head mold restricts head movement in posterior-superior and left-right direction while the mouth piece restricts in anterior-inferior motion. The mouth piece consists of a customized dental mold and vacuum suction between the mold and upper palate. This mouthpiece setup is prepared prior to the CT simulation. Three tattoos were placed on patients face, one each on the eyebrows and third on the lateral hairline. For simulation, the patient is aligned along the three body tattoos using room lasers and the head is locked with the mouthpiece. The entire anterior-superior facial region from forehead

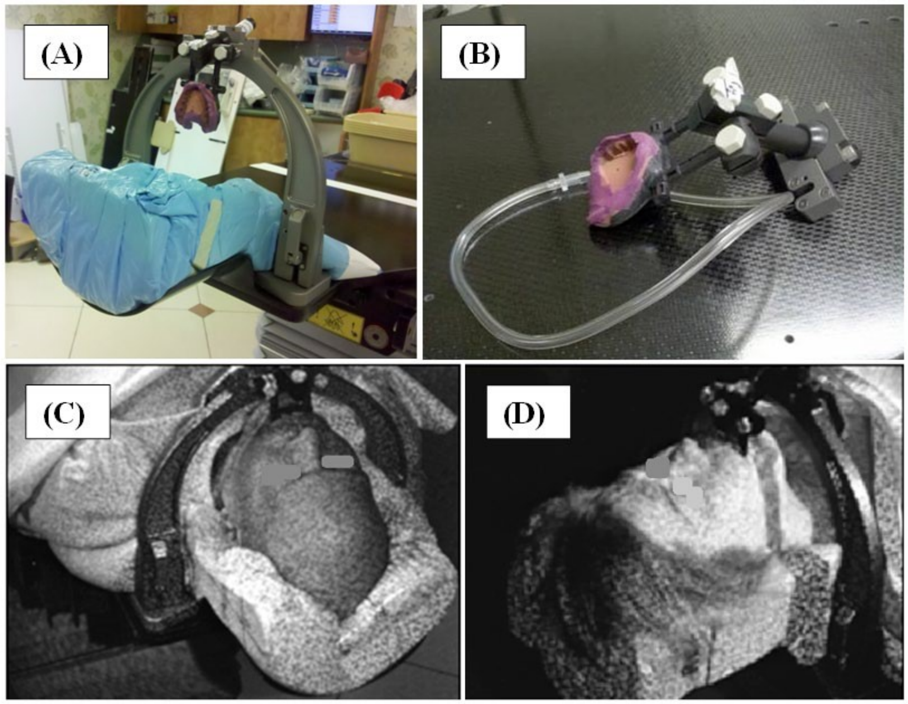

Fig. 2.2. Equipment used by Memorial Sloan Kettering Cancer Center to design a masked immobilization device(a) Aktina Pin Point Immobilization device, (b) Vacuum suction mouthpiece, (c) and (d) Patients immobilized with these systems

hairline to philtrum is considered as the region of interest. AlignRT camera system is used to assess six degree of freedom alignment of head rotation. Rotation exceeding 1 degree in any direction was corrected manually followed by reassessment using AlignRT camera system. The Freedom stereotactic device prepared by CDR Systems consists of the head mold and open face mask to immobilize the head. The head mold prevents posterior-superior and left-right movement and the open face mask restricts anterior-inferior movement. Similar to the Pin Point system, three markers are placed on the face. For the experiment the head and shoulders are supported using and the patient is aligned along the markers using room lasers available on the couch extension board. The results for both the system showed that the Pin Point system was less accurate in patient positioning than Freedom stereotactic device. Freedom device showed rotation restriction of about 0.5 ± 0.2 degrees as compared to the Pin Point system which showed a rotation restriction of 1.1 ± 0.5 degrees. The setup time for the Freedom system was faster, 2.7 ± 1.0 minutes as compared to Pin Points setup time to be 5.0 ± 4.1 minutes. The reason for such long setup time in the Pin point system is because the patient is made to rotate if there is more than 1degree deviation from reference point whereas the Freedom system uses AlignRT to reorient the patient. The translational deviation for the Freedom system was 1.5 ± 0.7 mm as compared to Pin Point systems translational movement to be 2.4 ± 1.3 mm. Also it was found that the patient was feeling more discomfort using the mouthpiece than Freedom system because when the patient was manually adjusted for reorientation during CT scanning, the mouthpiece had to be moved along with the patient. With these results it was concluded that the open face mask was the best frameless stereotactic device to be used for patient positioning and immobilizing patients head. The disadvantage with using the open face mask is that it does not take into consideration the effect of weight loss which is one of the side effects of cancer. The above experiment was carried out for 35 fractions during which the mask can get loose and give inconsistent results.

Another study to get the correct position of patients head was done in 2012 by a team from Italy [24]. According to this paper, a patient setup verification device called Sentinel was used for patients head positional accuracy. Sentinel unit consists of a scanner unit, containing the laser and the camera and surface matching registration software. For the registration software both the CT image and the Sentinel camera image were used as reference. Tests were performed on phantoms and the results showed that reproducibility of surface acquisition and setup procedure was better than 0.5 mm and 0.5 degree and 1mm and 0.4 degree respectively. The problem with this study was that the team performed experiment on phantoms and did not consider the anatomical changes that occur in the body during the treatment stage thus it is not an exact representation of the actual test results.

A correctional device in 4 Degree of Freedom (DOF) has been developed to correct translational and rotational head deviations [25]. Patient is made to lie on the treatment couch in supine position and the correctional device is placed below patients head. The base plate along with the head rest mold is placed on the top plate of the correctional device. So when the patients head moves in 6 DOF then the correctional device brings the head back to the original position. The setup consisted of IR tracking sensor that was placed above patient couch on LINAC and tracked four markers on the forehead block frame with spatial accuracy of 0.25 mm and temporal resolution of 12-30Hz [26]. So if the tracking system senses a shift in the position above 0.25 mm of the reference markers then the correctional device will bring back the marker to the original reference position thereby maintaining patients head position accuracy. The advantage of this type of a system is that it can correct the deviations even after extreme cases such as coughing and respiration during the treatment stage unlike other methods where a respiratory motion detecting device has to be placed on the patients chest for respiration. Though this method looks to be very promising but the main disadvantage of this study is that commercially available correctional devices are available in the market but they are very costly (∼$30000). The correctional device has to be placed below patients head which might obstruct with the LINAC when the patient goes into the machine for scanning so the device has to be removed once the patients setup is confirmed.

2.2 Mask Less Immobilization of Head for Head and Neck Cancer Radiotherapy

Many methods have been developed to solve the problem of claustrophobia by eliminating the face mask but the problem with such methods is that reference marker is placed on the patients body to align the patient in a particular direction and detect the movement. Once the treatment is done then the patient goes home and washes the marker. The next time the patient comes for treatment then new markers are placed and it is not guaranteed that will be placed in the same position accurately and thus giving inconsistent results.

One such study was carried out by a team from University of Florida College of medicine [27]. In this study instead of the traditional face mask a standard head mold is used for immobilizing patients head. Commercially available stereotactic infrared ExacTrac camera system (Brain Lab, Illinois) is used for patient setup accuracy. The head mold is placed on a standard head rest and the patient is made to lie on this setup to get the shape of the mold and in a few minutes the mold gets head. A frame with IR markers and camera system attached is fabricated. A bite tray is also attached to the frame. The movement of the markers with respect to the bite tray is monitored for head movement. If the patients head motion exceeds a predefined threshold value, then the patient is requested to reorient back. The advantage if this type of a system is that it takes into account the effect of weight loss during the treatment stage and also provides sub millimeter accuracy of patients head movement. The disadvantage of this type of a system is that there are frequent beam delivery interruptions in the camera system which hampers the accurate location of tumor in the CT scan when the radiologist is calculating the size and shape of tumor. Also the use of a bite tray makes it uncomfortable for some patients.

Another study that was conducted on defining the patients head position accurately was done by Department of Radiation Technology at University of Virginia in 2015 by developing a remote controlled and self-contained audio visual aided interactive system for immobilizing claustrophobic patients [19]. For this particular experiment no face mask was used and it involved developing a remote controlled system with audio visual aided interactive system with iPad Mini for sensing the motion of the head during the treatment stage for claustrophobic patients. The system involved the use of 2 iPad Mini tablets one which is held via a stand and placed around 20 cm anterior-inferiorly away from the patients head inside the room and the other is with the technician who stands outside the room and controls unit1. Unit1 is used as the interactive medium to the patient and Unit2 is used to remotely control Unit1. A colored marker is marked on the patients nose tip for interactive guidance and also as a reference point. Unit1 continuously captures the image of this marker and tracks this colored marker using the front camera of the tablet [28]. Unit1 has a reference marker setup and can be adjusted by the remote tablet, so when the reference marker and the marker on the patients nose match, then the reference markers(Unit1) color will change its color depending on the amount of deviation from a pre-defined value. If the reference marker image matches the patients marker and lies within a tolerance value, then the marker will change to green and if the deviation is greater than this tolerance value then it will change to red indicating by beep sounds to the patient that he/she has to match the tolerance value. This is a very interesting way of defining the head position without using the facemask and also very cheap as the equipment is very cheap and readily available. The advantage of this experiment is that it does not use any face mask to immobilize the head thereby making the patient very comfortable. Also the audio-visual interactive concept is very easy to understand by the patient and physicians. On the other hand, this has disadvantages too. The biggest disadvantage is that this method fails for patients with audio and visual impairment. Also the colored circular marker is placed on the nose tip assuming that it provides a fixed frame of reference which is not true because the tip of the nose contains skin which can move and thereby giving inconsistent results. The experiment considers 2D tracking only, the anterior-inferior position of the head is not tracked.

The most recent research work in this area was carried out by a team from MIT, Massachusetts using 3D mapping of the face to track the head movement [19]. According to this paper an image guided soft robot patient positioning system was developed using a Kinect Xbox 360 camera for 3D mapping the face. Soft robots are polymer based deformable enclosures with fluid filled chamber that can be used for measuring the change in the motion by varying the pressure of the fluid inside the chambers. The experiment was performed on a mannequin head with a hollow base. A proportional flow control valve was attached to this hollow base which was further connected to a 1 HP air compressor. Inlet air to the mannequin head was fixed at 30 psi. The Kinect camera was placed on a stand at 710 cm above the mannequins head and the pressure change was monitored by National Instruments myRio embedded system. It is mentioned that in real applications the Kinect camera will be replaced by Align RT vision camera. The tip of the nose was used to determine the patients position with respect to the origin of the camera frame. First the patient is made to lie on the treatment couch in supine position and then the face of the patient was 3D mapped by the Kinect Vision camera and then the position of the tip of the nose was determined from the previous step. The face was constantly tracked and change in the motion of the mannequin head was monitored by changing the pressure in the pressure regulator. The results showed that the soft robot can track a desired step reference trajectory with 2 mm precision after a lag time of 15 seconds. Though this method looks to be the best methods for monitoring head movement but it has certain drawbacks. The first drawback is that they use Align RT vision camera system in the treatment room which is expensive costing around $32000. Also, not all hospitals are equipped with such camera system. Another drawback of this method is that the experiment was carried out on a mannequin head but not extended to real human head.

3. CUSTOMER REQUIREMENTS

Following are the customer requirements for developing a new system for accurate patient positioning and immobilization with repeatable immobilization devices:

- Comfort for the patient
- Fast and reproducible devices for immobilizing the patient on a daily basis
- The system should be accurate enough to get the correct position of the tumor. At present, VAMC demands an accuracy of ±3 mm for tumor location
- The system should be compact enough not to interfere with machines gantry while it is rotating around to take 3D images of the patient
- The system should be inexpensive as compared to the current system
- Quickly produced so as not to delay the treatment planning or start
- The system should incorporate the effect of weight loss without changing the equipment during the course of the treatment
- Weight loss is one of the major side effects of cancer treatment which is caused due to changes in the immune system or metabolism. This is because there is constant bombarding of radiation to the body during treatment process
- At VAMC, there are a few cases where a new device is prepared during treatment course if a patients anatomy changes. This leads to extra time spent on preparing the device and cost. Thus, a system has to be developed which will adapt to the anatomical changes during the treatment course

- The material used for the device must be radiolucent for the MV x-ray beam coming out of the CT scanning machine or the LINAC. This means that the device should not contain any metal deposits
- The device should also be MRI compatible without creating image artifact

4. ENGINEERING SPECIFICATIONS

For the success of the design the system should be validated for the following engineering specifications:

- Head movement should be less than 3 mm in all directions with respect to machine isocentre
- MRI Compatible material
- Comfortable System
- Account for weight loss
- Minimal patient contact points
- System should lie within SFOV (60 cm)
- Spring selection

4.1 Head Movement

To detect the head movement we will be using the pressure sensor assembly and the amount of head deviation will be restricted by the head fixing devices. As shown in chapter 6.3, in ideal case using the input parameters mentioned, the head deviation was restricted to ± 0.1974 mm in anterior-posterior direction because the maximum deviation was observed in the nose bridge part. This value is less than the current value of 3 mm using the masked system.

4.2 MRI Compatible Material

As mentioned before there should not be any metallic material in the current setup so as not to form artifacts during CT scanning. Thus we have used materials that are MRI compatible and widely used in current practice. Table 4.1 shows the material used in the entire setup and a detailed Bill of Materials with vendor information is mentioned in Table D.1 in Appendix D.

Table 4.1.
MRI Compatible Materials used in the New Design

Sl. No.	Part Description	Material	MRI Compatible
1.	Treatment Couch	Carbon Fiber	Yes
2.	Extendible Headrest	Carbon Fiber	Yes
3.	Locking Assembly	PEEK	Yes
4.	Nose Bridge Part	Acetal	Yes
5.	Spherical Markers	PEEK	Yes
6.	Constraining Pins	Carbon Fiber	Yes
7.	Shoulder Retractors	Carbon Fiber	Yes
8.	Pressure Sensors	Polyester	Yes
9.	Pressure Sensor Tubes	PEEK	Yes
10.	Pressure Sensor Holder	PEK	Yes
11.	Springs	PEEK	Yes

4.3 Comfortable System

Patient comfort is defined with respect to the number of contact points on the patient for immobilization and the type of immobilization devices used. The new design does not use any masked system to immobilize the patient thus making it comfortable for patients suffering from PTSD and claustrophobia. In addition, the new design has only four patient contact points-left and right head fixing device, marker near patients nose bridge and the pressure sensor assembly on the occipital bone area. This is less than the current masked system where the mask completely touches the face thereby making it uncomfortable. To prove how comfortable the new system is, we will have to build a physical prototype.

4.4 Account for Weight Loss

The new system uses immobilization devices that are indexed to the treatment couch for reproducibility. This indexing is used to account for the effect of weight loss by just adjusting the positions of the immobilization devices. This is one of the advantages of the new design as compared to other system currently used in clinical practice.

4.5 Minimal Patient Contact Points

The new design does not use any mask less system to immobilize patients head. Patient contact points are necessary to get a reference point for locating and tracking tumor during radiotherapy treatment. The new design uses three patient contact points for referencing as explained in chapter 5.4.2.

4.6 Spring Selection

For the pressure sensor assembly to work properly a proper spring has to be selected. The selection criteria for the spring are as follows:

- Allowable head movement to less than the current value of 3 mm
- Material has to be MRI compatible

To calculate the spring constant, the sensor assembly was run for analysis in LS-Dyna using Explicit Dynamics method to get the Force-Deflection curve. The slope of this curve (Figure 4.2) will define the spring constant. The input parameters for analysis are:

- Material of system: PEEK

- Mesh size: 3 mm
- Density of material: 1.32 g/cm3
- Tensile Modulus: 91.7 MPa
- Load applied in Y axis: 50 N (Mass of human head=5 kg*10 m/sec2)

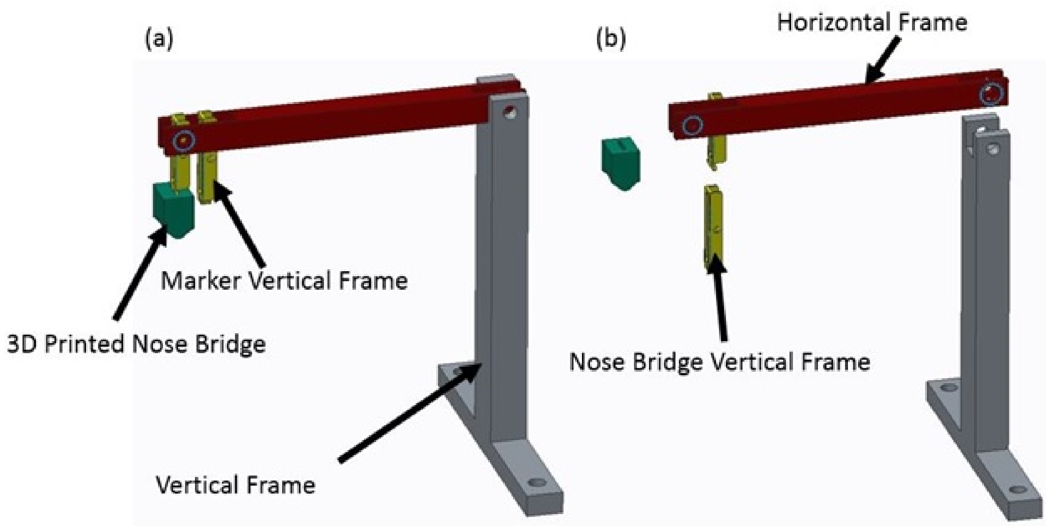

Fig. 4.1. (a) Assembly view of Stereotactic Frame, (b) Exploded View of Stereotactic Frame

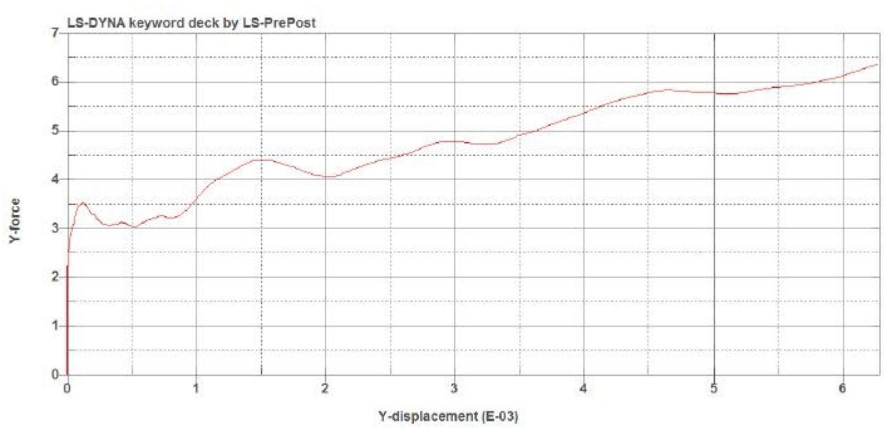

Fig. 4.2. Force-Deflection Curve. Slope=Spring constant=1.78 N/mm

Keeping all the criterias in mind I have selected the spring with the following properties:

- Part No.: PKSP6-10-50
- Material: PEEK
- Outside diameter: 10 mm
- Wire diameter: 3 mm
- Overall Length: 50 mm
- Spring constant: 1.78 N/mm

5. NEW DESIGN

The current clinical practice has certain shortcomings the major ones being comfort to the patient and tumor location inaccuracy. Thermoplastic facemask is used to fix the patient on the treatment couch, which is uncomfortable to patients especially suffering from PTSD and claustrophobia. The current practice also does not take into account the effect of weight loss due to which the mask becomes loose and the tumor location accuracy is altered. To eradicate these shortcomings, it is necessary to design a new mask less system, which is comfortable to the patient and improves the accuracy of tumor location. The following sections explain how the new design will fulfill these parameters by defining the new technique used to locate tumor accurately and the working procedure to be followed to treat HNC. Also, new immobilization systems have been created for this new design. Pressure sensor assembly and the nose bridge part will be used to maintain the heads position, which will be explained in detail. Chapter 5.5 explains the entire cancer treatment process with the new design by taking a case study of a patient as provided by VAMC.

5.1 New Design Objectives

Main Design Objectives Explanation:

- **Accurate Tumor Location:** The main objective of this research is to develop a new system that will accurately locate the position of the tumor both in the CT room and in the Treatment room with minimal patient contact points and minimum immobilization devices. Using the new theory of coordinate transformation, theoretically we need to prove that the system will detect head deviation of ± 3 mm (an ideal case). A prototype has to be prepared to validate this system, which is out of the scope of this study. Another subset of accuracy is the

Fig. 5.1. Weight loss a factor for reducing system accuracy. Steve jobs in Jan 2007 before diagnosed with cancer and in Sept 2009 after diagnosed with cancer and the effect of weight loss

effect of weight loss. The new system also takes into account the effect of weight loss (Figure 5.1) which is one of the side effects of cancer treatment unlike the full head face mask or the bite block.

- **Comfortable System:** The previous research work and the current radiotherapy treatment procedure neglects this very important point. Typically the diagnosis and the treatment stage lasts for about 30-45 minutes. It is important to use a system which is comfortable for the patient during this interval. The thermoplastic mask even though is accurate in terms of tumor location but the setup is uncomfortable as explained in previous sections. Also the bite block has to be held by the patient during the whole stage which is uncomfortable to the patient. Keeping these points in mind we have developed a system which is more comfortable to the patient. To ensure comfort we have developed a system which has minimal patient contact points. Earlier the face mask had many patient contact points because once the hot thermoplastic cools down it takes the shape of the patients face.

Fig. 5.2. A mask less system to immobilize patient. Here a head mold is created that takes the patients head shape [29]

- **Mask Less System:** The new system includes a mask less device similar to one shown in Figure 5.2 to immobilize the patient where tumor location is identified using coordinate transformation technique. The mask less system includes immobilization devices (explained in section 5.4) which completely fix patients head/shoulder and location of three spherical markers as taken from the CT scanning image are used to reference the detect tumor location. To detect small head deviation, we use pressure sensors where the force mapping shows direction of greater head movement. In the treatment room a customized nose bridge part is used for repeatability and extra referencing for locating the tumor accurately.

5.2 New Design Specifications

The criterions to keep in mind while designing the system were:

- **Scan Field of View (SFOV):** This is defined as the diameter of the area being examined. For a CT machine, this is defined as the actual area of interest scanned by the CT scanning machine (Figure 5.3(a)). It varies as per each CT machine and the value of SFOV for the CT scanning machine and the treatment machine is 60 cm. This is the actual area of interest selected by the radiologist before the CT scan begins. It can also be defined as the area within the gantry of the treatment machine from which the raw data of the patient is acquired. Our new setup thus should lie within this SFOV (Figure 5.3(b) and Figure 5.3(c)) for successful results or else the setup will clash with the rotating gantry and the scan will be out of range.

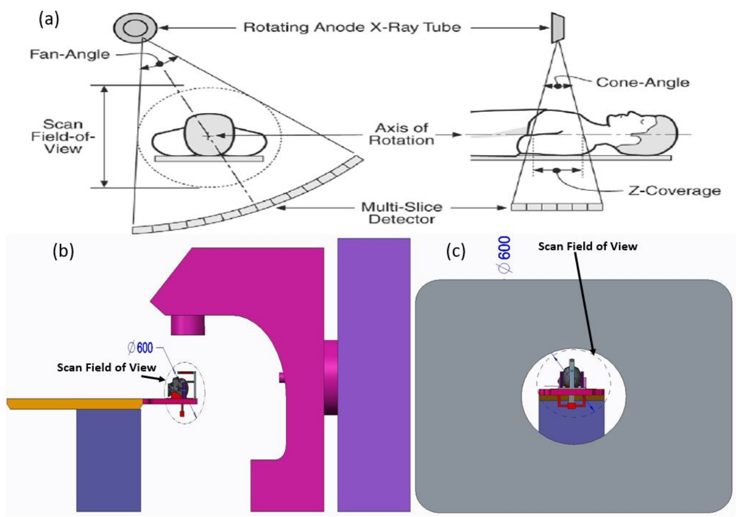

Fig. 5.3. Scan Field of View that defines the actual area of interest to scan the tumor (a) Detailed drawing, (b) SFOV (dotted line) in Treatment Room=600 mm and (c) SFOV (dotted line) in Scanning Room=600 mm

- **Pressure Sensor Sensitivity:** The pressure sensor assembly has been used to detect small head deviations that occur during the scanning or treatment stage. The sensor assembly is placed below the extendible headrest and the patients head rests on this assembly with the patients occipital bone in contact with the pressure sensor surface. The pressure distribution map of the pressure sensors indicates the direction of head movement and used to bring back the patients head in neutral position. For this, the pressure sensor assembly should be sensitive enough to detect very small head deviation or head movement thus the spring has to be stiff enough to detect these small head deviations. Average adult human head weighs about 5 kg or 50 N [30]. As per our calculations (Section 4.6), the spring constant that we selected was 1.78 N/mm that is stiff for the 50 N load that the head puts on the device in actual practice.

- **No Surface Markers:** As explained in previous section, patient comfort is one of the main objectives of creating a mask less system for accurately locating the tumor. Currently, radiologists use surface markers such as tattoos or ink dots for accurate patient positioning. The tattoos are permanent inks made out of India ink that are put on the patients face which are uncomfortable to the patient because the ink will be shown permanently on the patients face. The ink dots are small pricks of ink that are put on the patient. This ink can be washed away but then the repeatability of placing the ink again at the same spot during subsequent fractions of cancer treatment is hampered. To mitigate this problem and to accurately reproduce the same position of the markers every time the patient comes for treatment, the new system will use spherical markers fixed using a bio-adhesive glue (Figure 5.4(a)) to locate the position of the tumor.

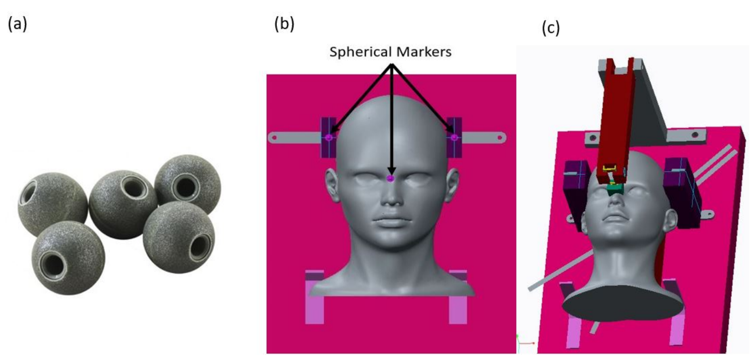

Fig. 5.4. Devices used for Tumor tracking in the new design (a) Spherical Markers, (b) Markers positioned in the new design, (c) Customized 3D printed nose bridge part(Green)

- **Comfortable Stereotactic Frame:** As explained in previous section, the stereotactic frame is used to fix the markers in the CT room and the treatment room. The location of these devices should be such that it does not cause any discomfort to the patient. The positioning of this device is shown in Figure 5.4(c) where it placed behind the patients field of view. Such a location is comfortable to the patient because it is away from the field of view of the patient and also the system can be easily adjusted or removed without disturbing the patient.

- **No Metallic Material:** As the setup will be inside the CT scanning or LINAC machine, it is important that the material for the new setup be MRI compatible. If there are any metal parts, then the CT image will show artifacts in the C scan which can hamper the treatment. A MRI compatible material is a special type of nonferromagnetic material.

5.3 New Design Equipment Required

5.3.1 CT Room

Figure 5.5 shows the assembly of various devices used for CT scanning stage. The equipment required at this stage is mentioned below (These equipments remain common both in the CT room and Treatment room):

- **CT Machine:** To take CT scan of tumor

- **Extendible Headrest (Part No: PortraitTM MR Head and Neck Device, RT-4552MRI, Qfix positioning):** Attached to the CT machine treatment couch and holds the patient and entire new design setup.

- **Pressure Sensor Assembly:** To detect head deviation
  - Pressure Sensors (Part No: FlexiForce B201, Tekscan)
  - Pressure sensor holder

  - Pressure Sensor Holder
  - Spring (Part No: PKSP6-10-50, SolidSpot)

- **Silverman Head Rest (Part No: MTSILVER2, CIVCO):** For patient head support
- **Vacuum Bag (Part No: MTACL 1520, CIVCO):** For patient comfort
- **Head Fixing device:** Immobilizes patients head in left-right direction
- **Shoulder retractable device (Part No: MTCFHN006SUB6, CIVCO):** Immobilizes patients shoulders
- **Constraining Pins (Part No: MT2504, CIVCO):** Immobilizes patients arm pit region
- **Stereotactic Frame:** Holds the markers in a fixed position and this position can be repeated for subsequent fractions of cancer treatment
- **Spherical Markers (BTS Bio engineering):** For patient positioning and locating tumor

The system was designed using actual dimensions of the CT scanning machine (2565 mm X 2057 mm X 1040 mm) as shown in Figure 5.6 and the LINAC (2566 mm X 2642 mm X 1067 mm) as shown in Figure 5.7 so that the system can be proved without fail when building a prototype [31].

5.3.2 Treatment Room

The basic patient positioning equipment required at this stage remains the same as in CT scanning stage (Figure 5.8) but there are two additions as follows:

- **Nose bridge Stereotactic Frame:** Used for holding the nose bridge part and marker in a fixed position

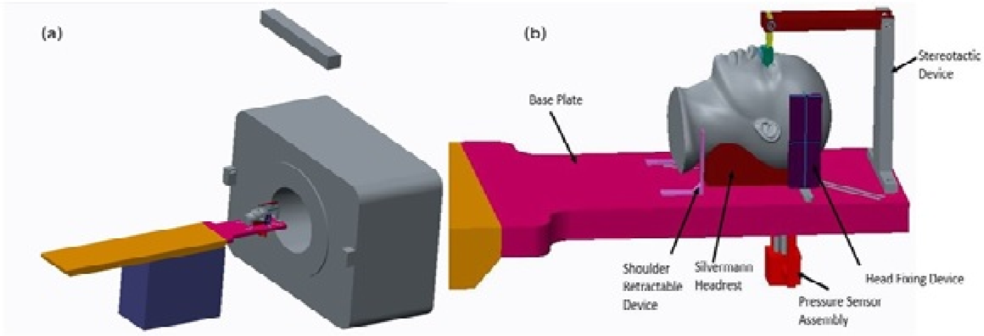

Fig. 5.5. Equipment required in the CT room for the new design (a) Complete Setup of the equipment in the CT scanning stage, (b) Description of various devices required to fix the patient rigidly in the CT scanning room

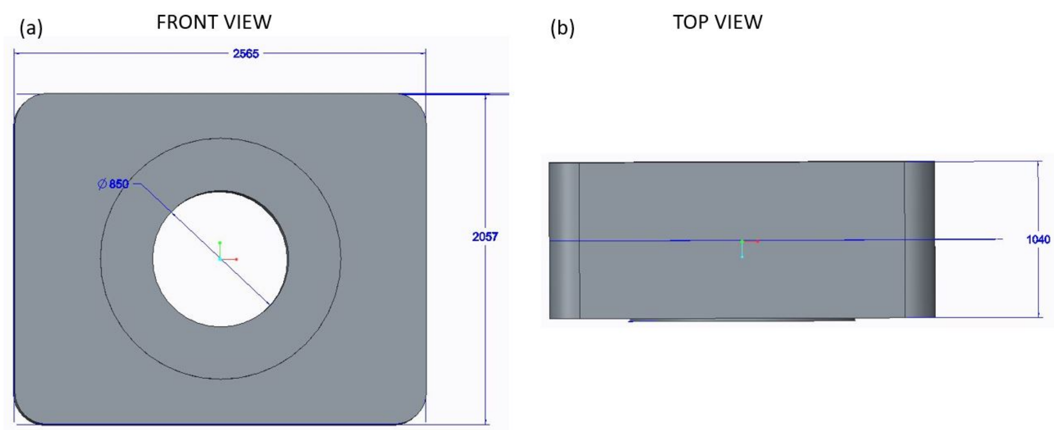

Fig. 5.6. CT Machine dimensions (a) Front View, (b) Top View

- **Patient customized 3D printed nose bridge part (Figure 5.9):** Used for patient referencing and patient immobilization

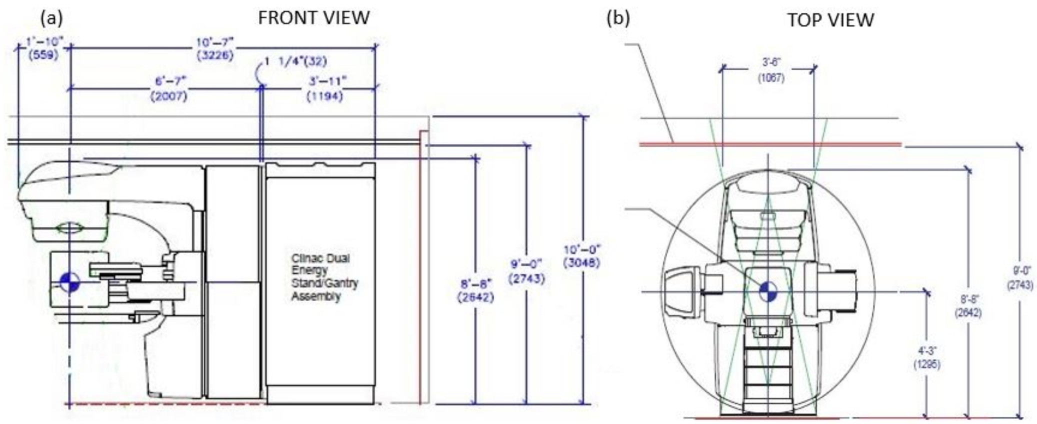

Fig. 5.7. LINAC Dimensions (a) Front View, (b) Top View

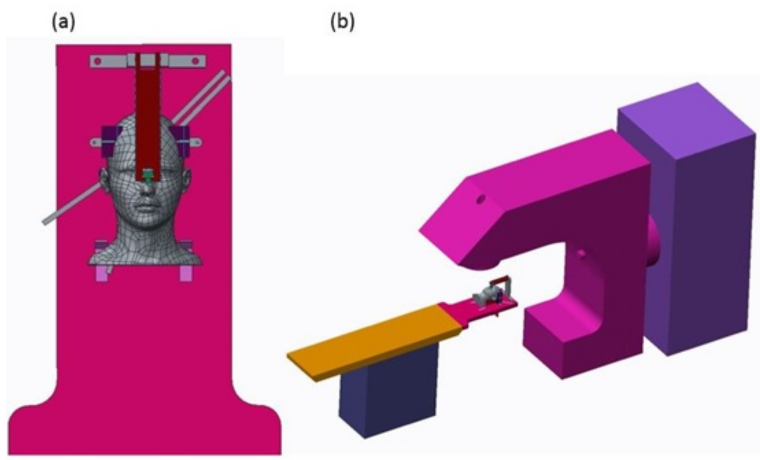

Fig. 5.8. Treatment Stage Assembly

Fig. 5.9. 3D Printed Nose Bridge Part

5.4 New Patient Immobilization System

The new design includes immobilization devices that are used for two different applications:

- Immobilizing patient's head and shoulder
- Accurate location and tracking of tumor

The following section explains the various devices used for each of the above mentioned applications and how each of them fulfill the design objectives mentioned in chapter 5.1.

5.4.1 Immobilization of Patient's Head and Shoulder

Immobilization is the most crucial step for head and neck radiotherapy because of the many critical structures in the area. It is also important the setup be reproducible for precise dose delivery to the tumor. Figure 5.10 shows the positioning of various immobilization devices in the new design. These devices will remain the same in the CT room and the treatment room to immobilize patients head and shoulder region.

- **Immobilizing patient's shoulder:** To immobilize patients shoulder the new design will use constraining pins (Figure 5.11(a)) and shoulder retractable devices (Figure 5.11(b)). The shoulder retractable device is a standard product commercially available in the market and consists of a carbon fiber frame and rubber pads for comfort reasons that is attached to the treatment couch. This is a common equipment used during the entire cancer treatment procedure. The location and position of this device is indexed using indexing marks mentioned on the device for repeatability and accuracy of test results. As shown in Figure 5.10 (pads for immobilizing shoulders) this will immobilize the patient in left-right and inferior-superior direction of patients shoulder but the patient can still move in anterior-posterior direction. To fix this direction we use the

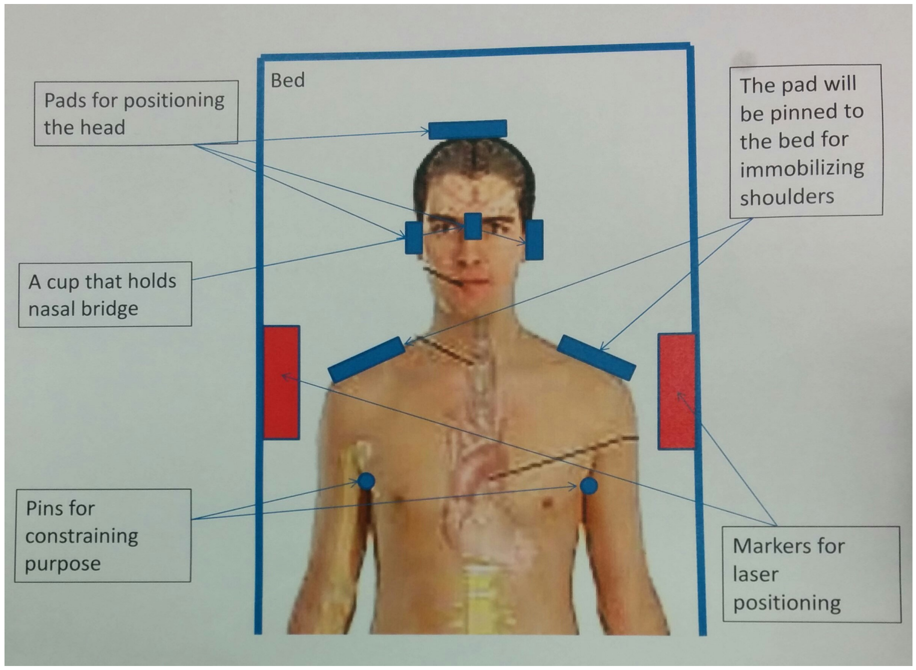

Fig. 5.10. Location of patient positioning and immobilization devices used in the new design

constraining pins (Figure 5.11(a)) which are also commercially available products. These are positioned near the patients arm pit region as shown in Figure 5.10 and attached to the treatment couch and positioned accurately using index marks on the device. The constraining pins are a common equipment used in the diagnosis and treatment stage.

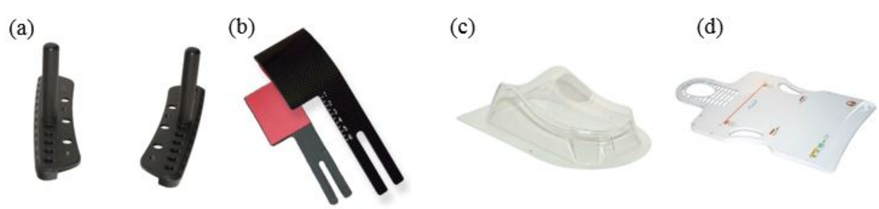

Fig. 5.11. New designs equipment required for patient immobilization in CT scanning stage: (a) Constraining Pins, (b) Shoulder retractable device, (c) Silverman Headrest and (d) Extendible Headrest

- **Immobilizing patient's head:** To fix the patients head, we use the Silverman headrest for head support (Figure 5.11(c)) and the specially designed side head fixing device (Figure 5.12) to fix the temporal bone area. These devices are fixed to the extendible headrest (Figure 5.11(d)) which is a commercially available device used as an extension to the treatment couch. These devices remain common in the diagnosis and treatment stage. This device is made of MRI compatible material PEEK so that there are no metallic artifacts shown in the CT scan. This device is also attached to the treatment couch and has indentations on it for positioning and repeatability of results. Once the patient lies down on the treatment couch these devices are attached to the treatment couch and hold patients head rigidly (Figure 5.10). The Silverman headrest is a commercially available product that is used to support patients head when he/she is in supine position for radiotherapy treatment. It is made out of transparent durable polyurethane foam material - a MRI compatible.

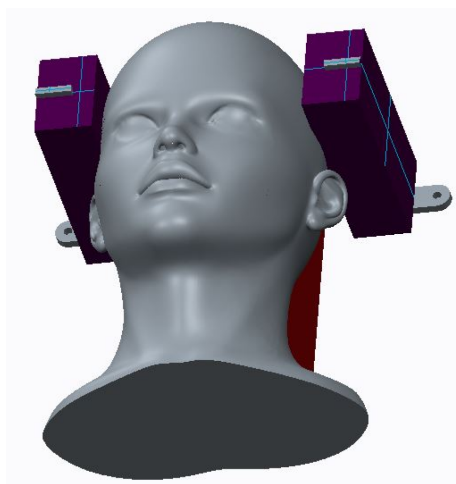

Fig. 5.12. Head Fixing Device (purple) to fix the head specially prepared in the new design

5.4.2 Immobilization Devices For Tracking Tumor

In the CT room for tracking the location of tumor, we use three spherical markers (Figure 5.13(a)). These are commercially available products made of radiopaque material containing metallic material so that the location of these markers is seen in the CT image [32]. These markers are attached to the head fixing devices and the nose bridge by a bio-adhesive hypoallergenic tape as shown in Figure 5.13(b). The nose bridge marker is further attached to a stereotactic frame for accuracy and repeatability of placing the marker in the same location over subsequent fractions of cancer treatment procedure. The CT machine and the LINAC machine using image-processing technique locate the markers images automatically. The coordinate points of the markers are defined by this imaging technique and utilized to calculate the accurate location of tumor.

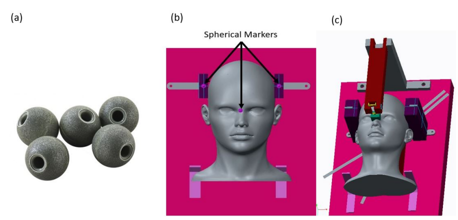

Fig. 5.13. Devices used for Tumor tracking in the new design (a) Spherical Markers, (b) Markers positioned in the new design, (c) Customized 3D printed nose bridge part(Green)

In the treatment room, the nose bridge spherical marker gets replaced by the customized 3D printed nose bridge part (Green part in Figure 5.13(c)) that is prepared before the treatment procedure. The procedure for preparing this nose bridge part will be explained in chapter 5.8.

For tracking the location of the tumor, in both stages it is very important to maintain the relative position between the head and shoulder fixing device because this relationship is a prerequisite for calculating the relationship between the immobilization devices and tumor.

5.5 Finding Tumor Location: A Case Study

The new design uses the technique of coordinate transformation to get the accurate location of the tumor. This section explains this theory in detail for each stage of cancer treatment by taking a case study of one of the patients provided by VAMC Hospital, Indianapolis, Indiana. The patient details has been kept anonymous for patient identity security reasons. A detailed explanation of the process is mentioned in Appendix B.

5.5.1 Diagnosis Stage

As explained in chapter 1.1, this is the first step for cancer treatment where the patient lies down on the treatment couch, aligned along CT scanning machines isocentre and then sent inside the donut shape of the machine where the tumor is identified and scanned for the radiotherapist to do the diagnosis.

In the new design, the patient comes into the CT room and the Qfix extendible headrest is attached to the CT machine table top. Then, the pressure sensor assembly is prepared as per steps mentioned in chapter 5.7 and attached to the bottom of the Qfix headrest. Then the Silverman headrest is placed at the top of the table. Here you will see that the pressure sensor tubes are protruding out of the Qfix headrest. The position of the pressure sensor tubes is marked on the transparent Silverman headrest surface. Now holes are drilled into this headrest for the entry of the pressure sensor assembly with diameter equal to the diameter of the pressure sensor tubes. The Silverman headrest is again attached to the tabletop with the pressure sensor tubes protruding out of the drilled holes. Now a vacuum bag is placed on the Silverman headrest for making the patient comfortable when they lie down on the table top. The patient is brought into the CT room and made to lie down on the table top in supine position with their head resting on the vacuum bag. Now the immobilization devices mentioned in chapter 5.4 are attached to the table top to fix the patient in a particular position.

The constraining pins are attached first to fix the patients shoulder, then the shoulder retractable devices are used to further fix the shoulder. Next, the side head fixing devices are attached to the table top to fix the patients head. All these immobilization devices are indexed and their positions are recorded in an instruction sheet to be used in the treatment room and for reproducibility. Now two of the three spherical markers are glued to the side head fixing device using the bio-adhesive tape as shown in Figure 5.13(b). The third spherical marker is placed on patients nose bridge part using the stereotactic frame as shown in Figure 5.13(b). The frame is also fixed to the table top using screws provided. Once the patient has been positioned, the table top is aligned along machines isocenter using room laser lines. Now the head movement is also checked by the pressure mapping of the pressure sensors. The feedback from the pressure sensors is sent to the computer for recording the pressure distribution corresponding to the current head position. Figure 5.23 is a screenshot of the patients CT image with position of markers as taken from Eclipse Treatment Planning software (TPS). Next, the patient is sent inside the machine for scanning and location of tumor.

5.5.2 CT Stage

In this stage, the patients CT scan is available to the radiotherapist to decide how much dosage of x-rays has to be given to patient for treatment. Now that the patient has been positioned and rigidly immobilized, the radiation therapist exits out of the room and goes to the simulation room. Here the pressure mapping is checked again for any adjustments to be made to the patients head and bring the head to the neutral position. When the head has been adjusted to the neutral position, the table top goes inside the donut shape of the CT machine and a scan of patients head is taken with the location of the markers recorded using the Exact Treatment Planning software. The coordinate points of the three markers as recorded by the Exact TPS

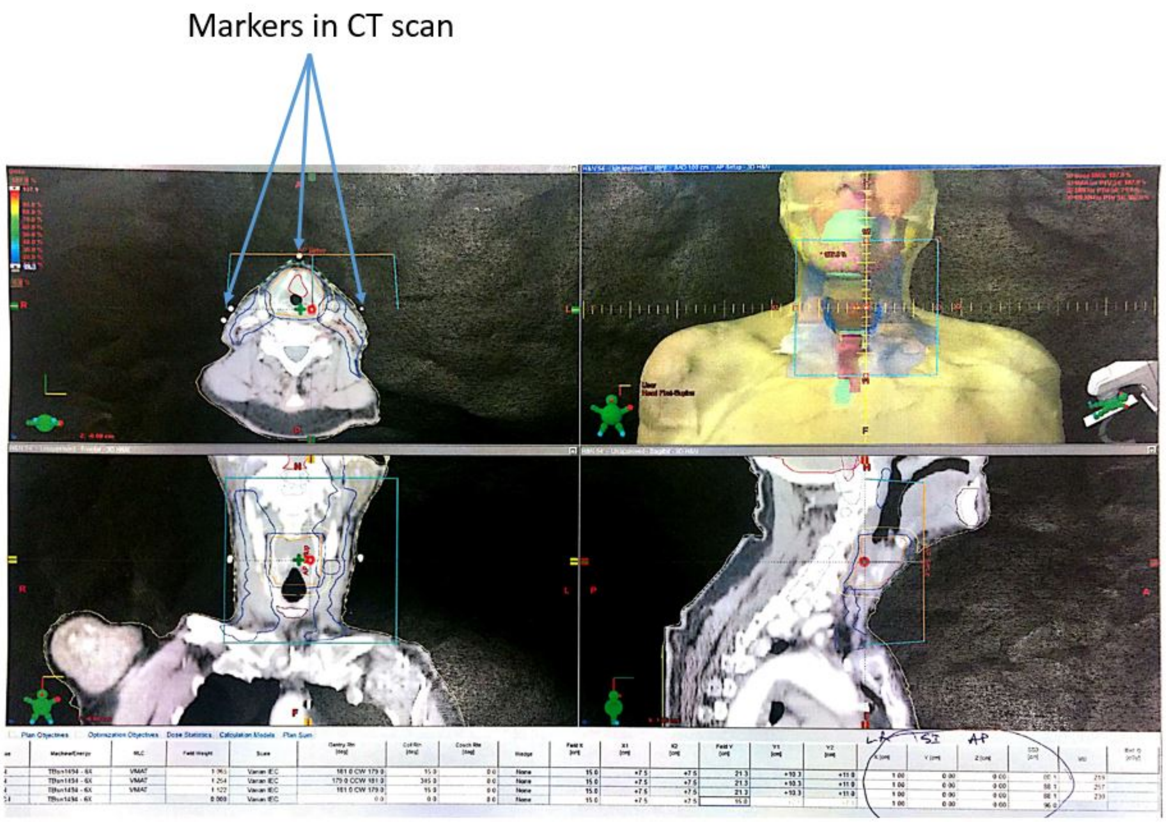

Fig. 5.14. Marker (white dots) location in CT scan with the circled part in the table shows the coordinates of the three markers with respect to machine isocentre (shown in red cross hair)

are shown in tabular form at the bottom of Figure 5.23 (circled). Table 5.1 shows the coordinates of the markers as shown in Figure 5.23.

Table 5.1.
Coordinate points of markers as shown in Figure 5.23

Markers	**X [cm]**	**Y [cm]**	**Z [cm]**
Marker1	-6.15	-7.84	-19.95
Marker2	-6.15	7.84	-19.95
Marker3	8.15	0	20

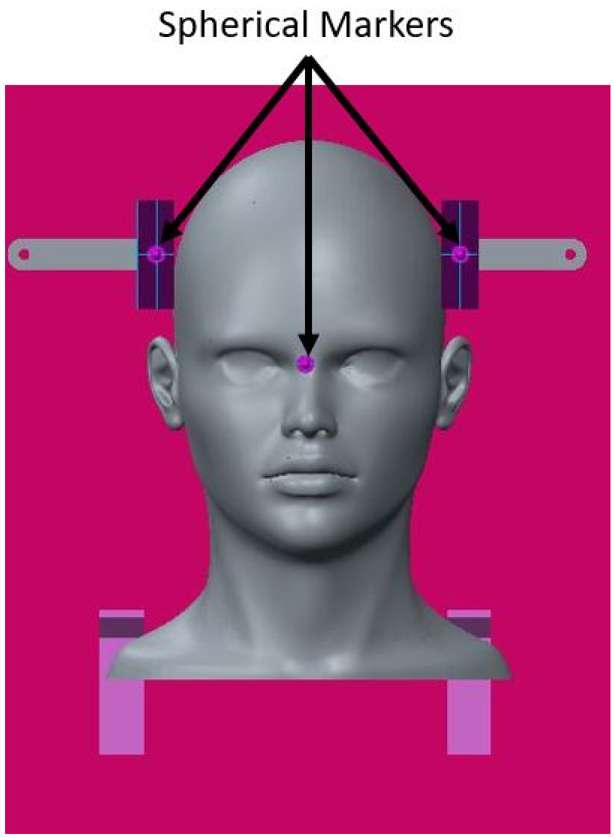

Fig. 5.15. Marker positioning in CT scan and Treatment Room

The coordinates of the markers with respect to CT room coordinate system are:

$$\overrightarrow{\textbf{Marker1}} = \begin{bmatrix} -6.15 \\ -7.84 \\ -19.95 \end{bmatrix} = \begin{bmatrix} X1 \\ Y1 \\ Z1 \end{bmatrix} \tag{5.1}$$

$$\overrightarrow{\textbf{Marker2}} = \begin{bmatrix} -6.15 \\ 7.84 \\ -19.95 \end{bmatrix} = \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} \tag{5.2}$$

$$\overrightarrow{\textbf{Marker3}} = \begin{bmatrix} 8.15 \\ 0 \\ 20 \end{bmatrix} = \begin{bmatrix} X3 \\ Y3 \\ Z3 \end{bmatrix} \tag{5.3}$$

Let the coordinate points of the tumor be:

$$\overrightarrow{\textbf{Tumor}} = \begin{bmatrix} -0.15 \\ -5.84 \\ -19.95 \end{bmatrix} = \begin{bmatrix} Xt \\ Yt \\ Zt \end{bmatrix} \tag{5.4}$$

The coordinate axes for GCS are X, Y and Z and the corresponding unit vectors along these axes is $\hat{I}$, $\hat{J}$ and $\hat{K}$.

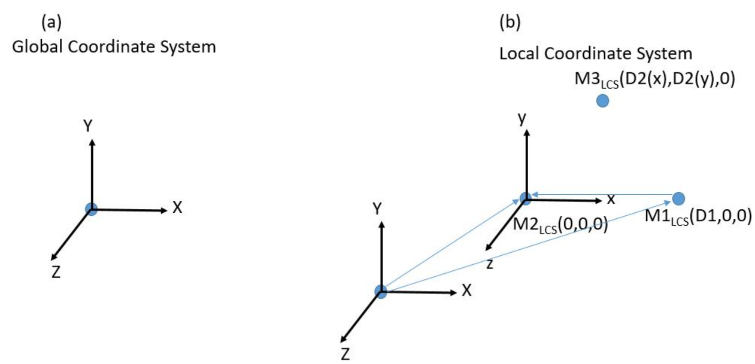

Fig. 5.16. Coordinate Transformation (a) Global Coordinate System (GCS) with coordinate axes X, Y and Z, (b) Local Coordinate System (LCS) with coordinate axes x, y, z and location of new markers M1, M2 and M3 with respect to GCS

Now a coordinate system is defined which will be fixed throughout the simulation and treatment stage and is termed as the Global or Fixed Coordinate System and represented by GCS. The coordinate points of any of the marker is taken as the origin for this GCS, say Marker2. Taking Marker2 as origin, we will define the coordinate axes for GCS. The x axis (represented as $\overrightarrow{X}$) is calculated by taking a vector from Marker2 to Marker3. We need an orthogonal axis to $\overrightarrow{X}$, thus we will first define a vector $\overrightarrow{A}$ from Marker2 to Marker3 and then take cross product of this vector with $\overrightarrow{X}$ to get $\overrightarrow{Y}$. The third orthogonal axis $\overrightarrow{Z}$ will be a cross product of the $\overrightarrow{X}$ and $\overrightarrow{Y}$. The mathematical representation of the three axes in GCS are:

$$\overrightarrow{\mathbf{X}} = [Marker2 - Marker1] = \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} - \begin{bmatrix} X1 \\ Y1 \\ Z1 \end{bmatrix} \tag{5.5}$$

$$\overrightarrow{\mathbf{A}} = [Marker2 - Marker3] = \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} - \begin{bmatrix} X3 \\ Y3 \\ Z3 \end{bmatrix} \tag{5.6}$$

$$\overrightarrow{\mathbf{Y}} = \overrightarrow{X} \times \overrightarrow{A} = \begin{bmatrix} i & j & k \\ X(x) & X(y) & X(z) \\ A(x) & A(y) & A(z) \end{bmatrix} \tag{5.7}$$

$$\overrightarrow{\mathbf{Y}} = \begin{vmatrix} X(y) & X(z) \\ A(y) & A(z) \end{vmatrix} i - \begin{vmatrix} X(x) & X(z) \\ A(x) & A(z) \end{vmatrix} j + \begin{vmatrix} X(x) & X(y) \\ A(x) & A(y) \end{vmatrix} k \tag{5.8}$$

$$\overrightarrow{\mathbf{Z}} = \overrightarrow{X} \times \overrightarrow{Y} = \begin{vmatrix} i & j & k \\ X(x) & X(y) & X(z) \\ Y(x) & Y(y) & Y(z) \end{vmatrix} \tag{5.9}$$

$$\overrightarrow{\mathbf{Z}} = \begin{vmatrix} X(y) & X(z) \\ Y(y) & Y(z) \end{vmatrix} i - \begin{vmatrix} X(x) & X(z) \\ Y(x) & Y(z) \end{vmatrix} j + \begin{vmatrix} X(x) & X(y) \\ Y(x) & Y(y) \end{vmatrix} k \tag{5.10}$$

Next, we calculate the unit vectors-$\hat{I}$, $\hat{J}$ and $\hat{K}$ along these coordinate axes. Unit vectors are defined as the normalized vectors of the coordinate axes.

$$\hat{I} = \frac{X}{\|X\|}, \hat{J} = \frac{Y}{\|Y\|}, \hat{k} = \frac{Z}{\|Z\|} \tag{5.11}$$

where $\|\|$ represents the magnitude of the vector. Figure 5.17 shows the flowchart on the steps to follow in the diagnosis stage.

In the meantime, in this stage, the size of the tumor and amount of radiation dosage to be given is also calculated by the therapist and dosimetrist respectively. A 3D part of the nose bridge is prepared using Mimics software (explained in chapter 5.8) and sent to the manufacturer to get prepared. The simulation stage is complete and in the final stage of cancer treatment, the patient comes to the treatment room.

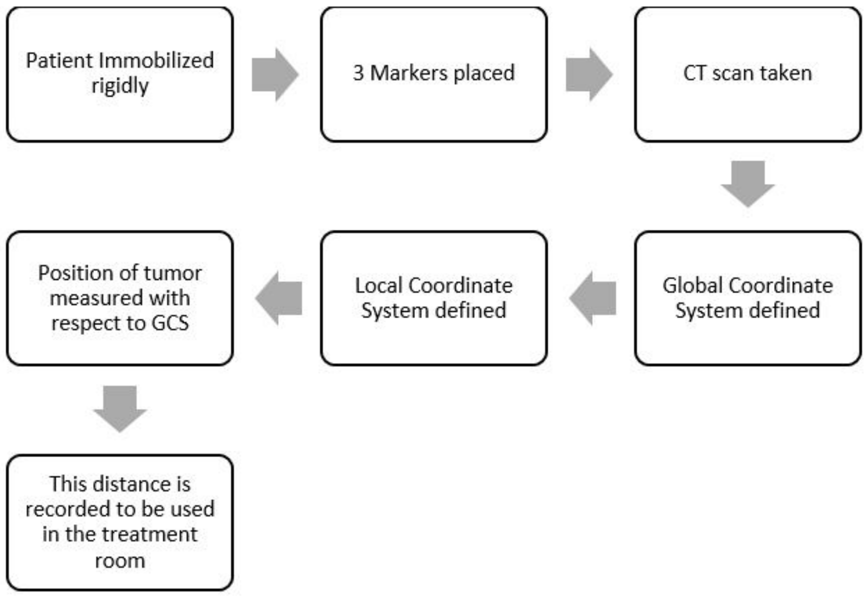

Fig. 5.17. Flowchart of tumor location in Simulation Stage

In the meantime, in this stage, the size of the tumor and amount of radiation dosage to be given is also calculated by the therapist and dosimetrist respectively. A 3D part of the nose bridge is prepared using Mimics software (explained in chapter 4.8) and sent to the manufacturer to get prepared. The simulation stage is complete and in the final stage of cancer treatment, the patient comes to the treatment room.

5.5.3 Treatment Stage

From the treatment planning stage, we know the coordinates of the markers, which have the fixed relations to the tumor. In the treatment room, the coordinate points of the marker are fed into the LINAC machine. Next, the extendible headrest is attached to the treatment couch and then the pressure sensor assembly is attached to the bottom of the couch. Previously used Silverman headrest is attached to the top of the couch and then vacuum bag is placed on it. The patient lies down on the couch with their head resting on the vacuum bag. The same immobilization devices as used in the CT room are used here. The instruction sheet s prepared in the CT room is used to place the devices in the same position. The patient is fixed and the new position of the immobilization devices are recorded in the same instruction sheet. Markers are placed on the devices and the customized nose bridge part is attached to the stereotactic frame. Radiation therapist now exists out of the room. The patient position is adjusted using the pressure sensor assembly and the pressure mapping data. Using audio signals the therapist instructs the patient to adjust their head to come to the neutral position. Over here we will define a new coordinate system called the Local Coordinate System (LCS) which will move with respect to GCS such that if one of the markers move during the simulation or treatment stage the system is not altered (Figure 5.16). The coordinate axes x, y and z for LCS are defined in the following way:

To define the X axis i.e. $\overrightarrow{x}$ we will define a vector going from Marker2 to Marker1, the direction of which is from left to right.

$$\overrightarrow{\mathbf{V1}} = < \overrightarrow{M1} - \overrightarrow{M2} > = \begin{bmatrix} X1 \\ Y1 \\ Z1 \end{bmatrix} - \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} \tag{5.12}$$

$$\tag{5.13}$$

The Y axis i.e. $\overrightarrow{y}$ has to be perpendicular to $\overrightarrow{x}$. This is achieved by first defining a vector $\overrightarrow{V2}$ from Marker2 to Marker3 and then taking a cross product of $\overrightarrow{x}$ and $\overrightarrow{V2}$.

As per Right Hand Thumb Rule for vectors the direction of this vector will be outside of the paper (shown in Figure 5.18).

$$\overrightarrow{\mathbf{V2}} = < \overrightarrow{M3} - \overrightarrow{M2} > = \begin{bmatrix} X3 \\ Y3 \\ Z3 \end{bmatrix} - \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} \tag{5.14}$$

$$\overrightarrow{y} = \overrightarrow{x} X \overrightarrow{V2} = \begin{vmatrix} i & j & k \\ x(x) & x(y) & x(z) \\ V2(x) & V2(y) & V2(z) \end{vmatrix} \tag{5.15}$$

Lastly, the Z axis i.e. $\overrightarrow{z}$ has to be a vector that is perpendicular to both $\overrightarrow{x}$ and $\overrightarrow{y}$.

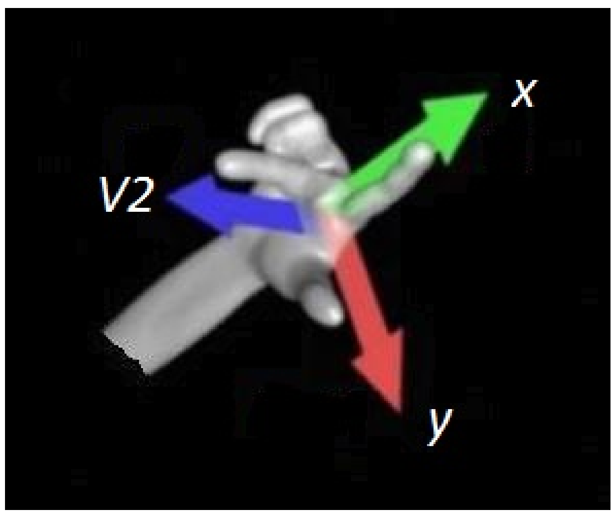

Fig. 5.18. Direction of y axis as per Right Hand Thumb Rule

Thus, we take a cross product of $\overrightarrow{y}$ with $\overrightarrow{x}$ and as per Right Hand Thumb Rule for vectors $\overrightarrow{z}$ will be pointing in upward direction (Figure 5.19).

$$\overrightarrow{z} = \overrightarrow{y} X \overrightarrow{x} = \begin{vmatrix} i & j & k \\ y(x) & y(y) & y(z) \\ x(x) & x(y) & x(z) \end{vmatrix} \tag{5.16}$$

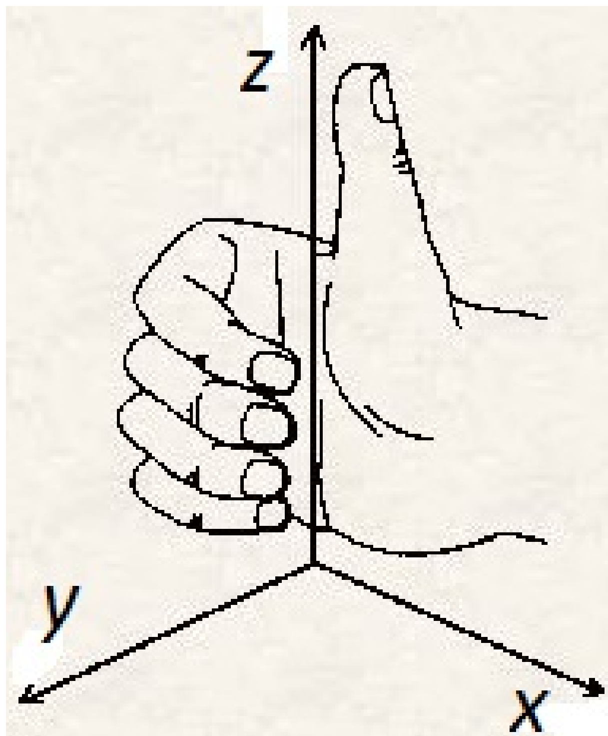

Fig. 5.19. Direction of z axis as per Right Hand Thumb Rule

Now that the coordinate axes for the new coordinate system i.e. LCS have been defined, the next step is to define the location of the markers with respect to LCS. The new position of the markers as recorded by the LINAC machine are:

$$\overrightarrow{M2} = \begin{bmatrix} 0 \\ 0 \\ 0 \end{bmatrix} = \begin{bmatrix} x2 \\ y2 \\ z2 \end{bmatrix} \tag{5.17}$$

$$\overrightarrow{M1} = \begin{bmatrix} D1 \\ 0 \\ 0 \end{bmatrix} = \begin{bmatrix} x1 \\ y1 \\ z1 \end{bmatrix} \tag{5.18}$$

$$\overrightarrow{M3} = \begin{bmatrix} D2(x) \\ D2(y) \\ 0 \end{bmatrix} = \begin{bmatrix} x3 \\ y3 \\ z3 \end{bmatrix} \tag{5.19}$$

where D1 is the distance between Marker2 and Marker1 in GCS

$$D1 = \sqrt{(X2 - X1)^2 + (Y2 - Y1)^2 - (Z2 - Z1)^2} \tag{5.20}$$

D2(x) is the x coordinate distance between Marker3 and y

$$D2(x) = \sqrt{(y(x) - X3)^2 + (y(y) - Y3)^2 - (y(z) - Z3)^2} \tag{5.21}$$

D2(y) is the y coordinate distance between Marker3 and x

$$D2(y) = \sqrt{(x(x) - X3)^2 + (x(y) - Y3)^2 - (x(z) - Z3)^2} \tag{5.22}$$

Unit vectors $\hat{i}$, $\hat{j}$ and $\hat{k}$ along LCS:

$$\hat{i} = \frac{X}{||X||}, \hat{j} = \frac{Y}{||Y||}, \hat{k} = \frac{Z}{||Z||} \tag{5.23}$$

This location of the markers takes into consideration the effect of rotational and translational changes that happen when transforming coordinate points from one coordinate system to the other. Until now we have defined a fixed coordinate system and then new location of the markers with respect to this fixed system.

Now the selected points must be transformed from one room to the other for which we require a transformation matrix. The transformation matrix is a matrix notation of coordinate points transferred from one coordinate system to the other. The transformation matrix is written as:

$$[T] = \begin{bmatrix} 1 & 0 & 0 & 0 \\ X2 & l1 & m1 & n1 \\ Y2 & l2 & m2 & n2 \\ Z2 & l3 & m3 & n3 \end{bmatrix} \tag{5.24}$$

Where the submatrix $[R_0]^T$ = [X2,Y2,Z2] represents the position of the origin of Marker2 in GCS. The submatrix [R] also called as the rotation matrix is:

$$[R] = \begin{bmatrix} l1 & m1 & n1 \\ l2 & m2 & n2 \\ l3 & m3 & n3 \end{bmatrix} \tag{5.25}$$

has its columns the scalar direction cosines of the axes of LCS with respect to GCS. The direction cosines are calculated using the unit vectors from the LCS with respect to GCS. Using these unit vectors, the direction cosines are calculated as:

$$l1 = \hat{I}.\hat{i}, m1 = \hat{I}.\hat{j}, n1 = \hat{I}.\hat{k} \tag{5.26}$$

$$l2 = \hat{J}.\hat{i}, m2 = \hat{J}.\hat{j}, n2 = \hat{J}.\hat{k} \tag{5.27}$$

$$l3 = \hat{K}.\hat{i}, m2 = \hat{K}.\hat{j}, n3 = \hat{K}.\hat{k} \tag{5.28}$$

where $\hat{i}$, $\hat{j}$, $\hat{k}$ represent the components of unit vectors in LCS and $\hat{I}$, $\hat{J}$, $\hat{K}$ the components of unit vectors of GCS. Substituting the values of l, m and n in the transformation matrix T will give us the matrix to transform any set of points from one coordinate system to another. To get the location of markers after transformation from one room to the other, we use the formula:

$$\overrightarrow{\mathbf{M}}_{new} = [T]^{-1} \times \overrightarrow{\mathbf{M}}_{GCS} \tag{5.29}$$

Where $\overrightarrow{\mathbf{M}}_{new}$ is the location of the markers after transformation, $\overrightarrow{\mathbf{M}}_{GCS}$ is the location of the markers in the GCS and T is the transformation matrix.

Now that the transformation matrix has been calculated, we will place the markers and the immobilization devices at the exact same spot as kept in the simulation room. This is easy to do because in the simulation room, the location of the immobilization devices has been recorded on the instruction sheet and the CT scan of the markers also includes the location of the markers with respect to room coordinate system. The same location points and coordinate location can be replicated in the treatment room. In the treatment room, we will introduce the 3D printed nose bridge part and place it on the patients nose bridge area. This device acts as a rigid part and holds the nose bridge rigidly so that there can be no motion of patients face during the treatment stage. Using the above transformation of markers formula, the new location of the tumor with respect to GCS can be calculated and checked if it is same or not. If the location is same, then the system is good otherwise the position of the markers or the immobilization devices must be altered or adjusted. A MATLAB code was generated to test this theory and is shown in Appendix C and Figure 5.20 shows a flowchart of the process to go through in the treatment room.

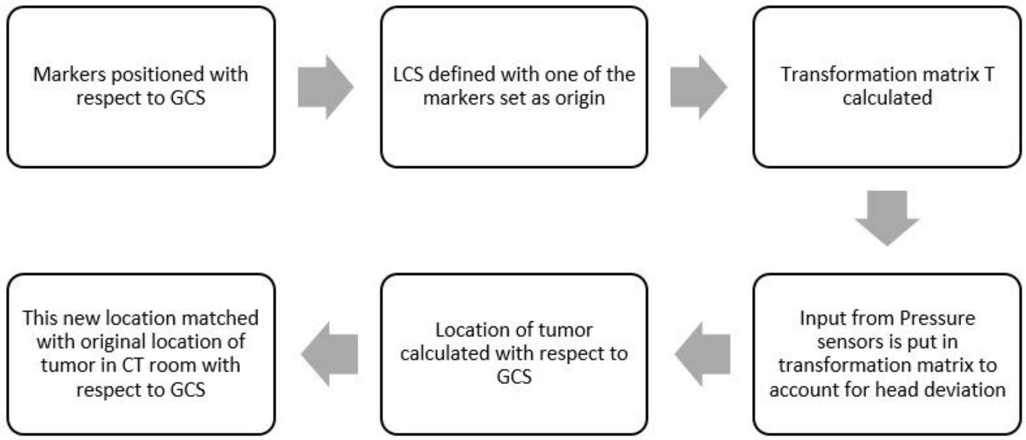

Fig. 5.20. Flowchart for locating tumor in Treatment Room

5.6 New Design Working Procedure

The system was designed using actual dimensions of the CT scanning machine and the LINAC (chapter 5.3.1) so that the system can be proved without fail when building a prototype [31]. The current practice uses the face mask to rigidly immobilize patients head and restrict head deviation while being locked to the treatment table but as explained in previous sections, is uncomfortable to the patient. In the new design, we have used the immobilization device mentioned in Section 5 to fix patients head and used a specially prepared pressure sensor assembly to detect the patient head deviation. The following section explains the working procedure to be followed to get accurate location of the tumor in each of the three stages of cancer treatment.

5.6.1 Diagnosis Stage

As explained before this stage involves locating the tumor by taking patients CT scan. Figure 5.21 shows a flowchart of this procedure in the CT room. The first step is to prepare the pressure sensor assembly (chapter 5.7). Next, we take the extendible

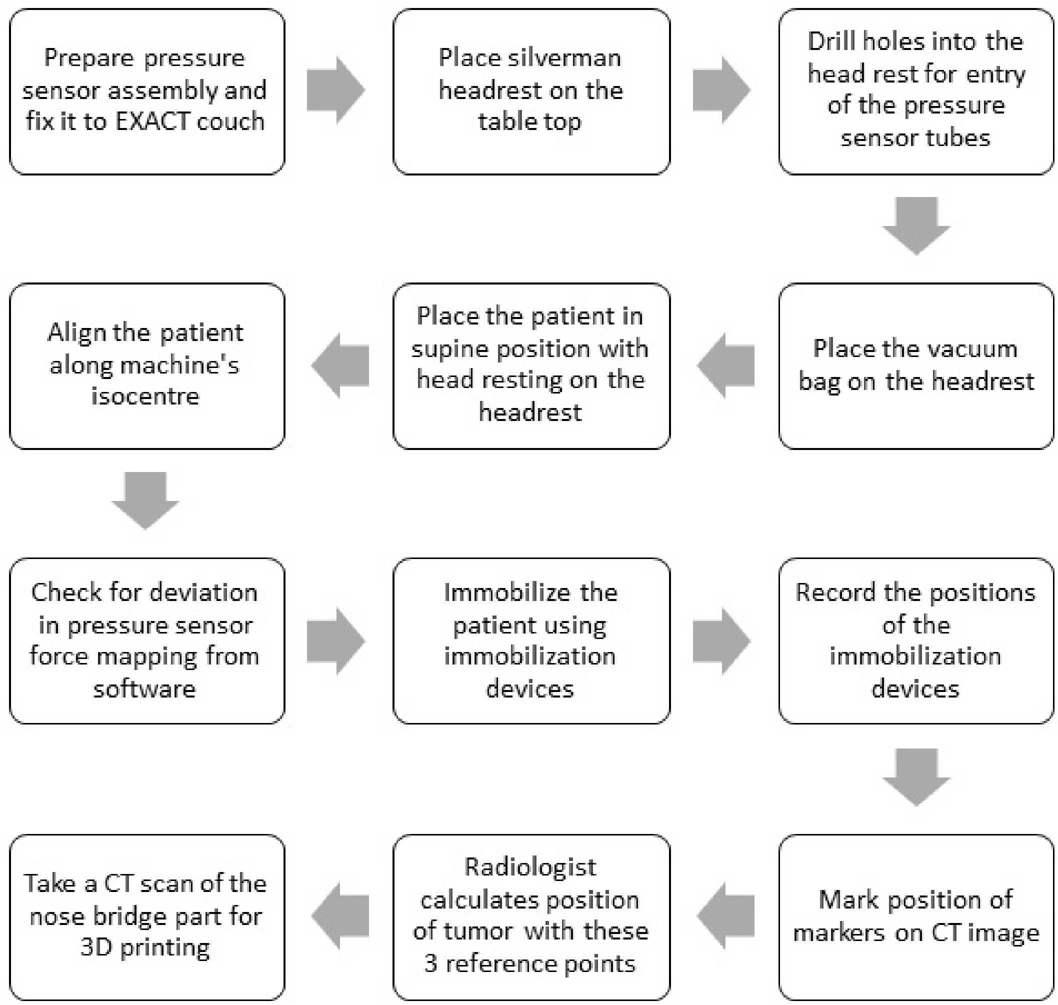

Fig. 5.21. Flowchart for working procedure of new design in Diagnosis Stage

headrest and attach it to the EXACT table top. After attaching the extendible headrest we will mount the pressure sensor assembly to the bottom of the headrest as shown in Figure 5.5(b). Then place the Silverman headrest to the table top as shown in Figure 5.5(b). Now mark the position of the pressure sensor tubes and then drill holes equal in diameter to the plastic sensor tubes into the Silverman headrest for the smooth entry of the sensor assembly. This also ensures a rigid support to the head rest. Once the holes are drilled and sensor assembly is mounted, the sensor tubes would be poking out of the Silverman headrest and when the patient lies down would be uncomfortable to the patient. To get rid of this discomfort we will place

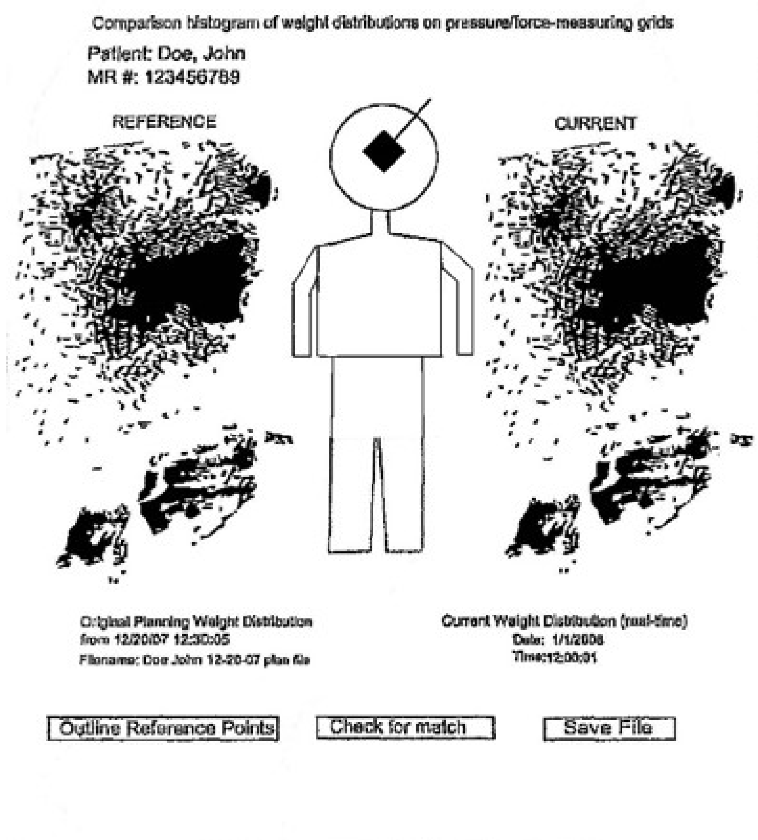

Fig. 5.22. Pressure Sensor Mapping using WELF2 software

the vacuum bag on the Silverman headrest and now request the patient to lie down in supine position with their head resting on the Silverman headrest and vacuum bag assembly. Using room lasers and machines isocentre, align the patient along this isocentre and then check for patient head deviation using the force mapping from the sensor software. The sensor software will show the area where there is more pressure as shown in Figure 5.22. The value of pressure in the map depicts the direction of head movement based on which the patient is instructed to adjust the head position in a particular direction.

Once the patients head has been properly aligned along machines isocentre, the patients head is immobilized using the head fixing device and the shoulders are immobilized using the shoulder retractors and constraining pins in the arm pit region.

The position of all the immobilization devices is recorded in an instruction sheet for repeatability. Next, two spherical markers are attached using the adhesive tape on the head fixing devices. The third markers is attached to a stereotactic frame and then aligned above patients nose bridge area (Figure 5.23) for repeatability and accuracy of marker positioning. The position of the stereotactic frame arms is also recorded in the instruction sheet. Now the patient is fixed and sent into the donut shape of the CT scanning machine where a CT scan of the patients head is taken. In the CT scan it is to be made sure that the three markers are also visible. In addition to the markers and the tumor, a CT scan of the nose bridge is also taken to prepare the customized nose bridge part for patient positioning in the treatment room.

5.6.2 Simulation Stage

As mentioned in previous section, in this stage all the CT scan data is taken offline and then used to calculate the amount of x-ray dosage to be given to the patient for cancer treatment. In addition to this, the new design involves locating the tumor using the technique of coordinate transformation. With the location of markers shown in CT image, the radiologist calculates the position of the tumor with respect to the LCS defined in the theory. In addition, radiologist also prepares the 3D nose bridge part by taking the DICOM CT scan file and then using Mimics software, converts it into 3D printable STL file format.

5.6.3 Treatment Stage

The basic patient positioning equipment required at this stage remains the same as in CT scanning stage but there are two additions as follows:

- Stereotactic Frame
- 3D printed nose bridge part

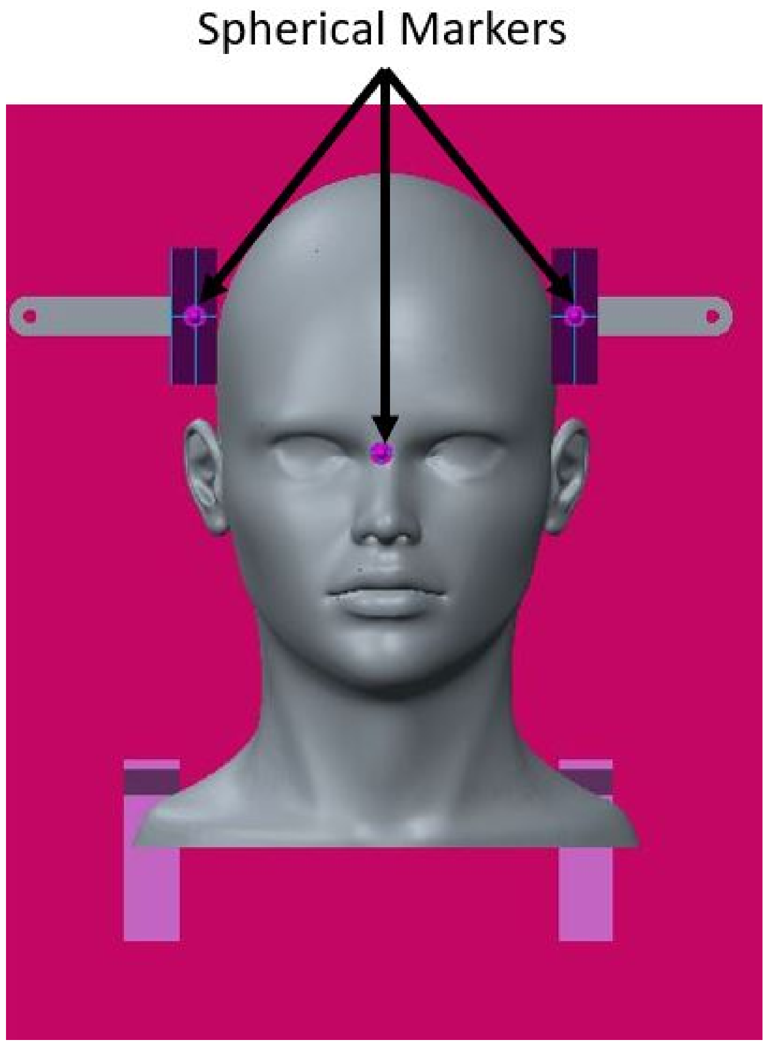

Fig. 5.23. Positioning of spherical markers when patient is in supine position in CT Room

The patient is immobilized in the same position as in the CT room using the recorded position of the immobilization devices. In addition to these devices we use customized nose bridge 3D printed part (prepared in the previous stage) and the stereotactic frame for immobilizing the patient. Nose bridge part will act as extra reference point and the stereotactic frame will hold the nose bridge part rigidly. The position of the part is recorded in the instruction sheet using indexed arms of the frame.

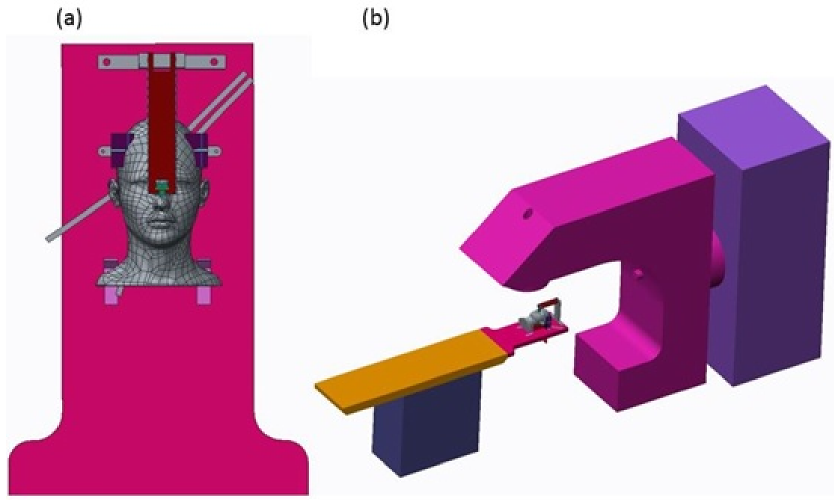

Fig. 5.24. Treatment Stage Assembly (a) Head position, (b) Overall Assembly

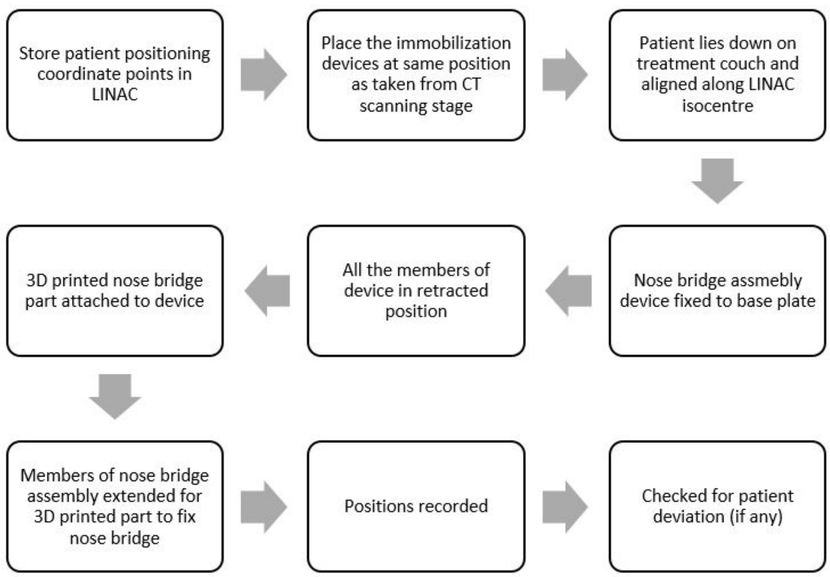

Fig. 5.25. Flowchart for Treatment Stage

Once the patient has been immobilized, then the radiologist calculates the location of the tumor in the treatment room using the theory as explained before. This location of the tumor should be the same as the location of the tumor in the CT room.

5.7 Preparing Pressure Sensor Assembly

The purpose of using a pressure sensor assembly is to detect patients head deviation during the diagnosis and treatment procedure the input of which is used to calculate the transformation matrix. The system should be compact enough to lie within the SFOV of 60 cm. The range of head movement allowed in all directions is ±3 mm in all directions. The following section describes the design of the assembly and the detailed assembly is shown in Figure 5.25. The equipment required to build this system are:

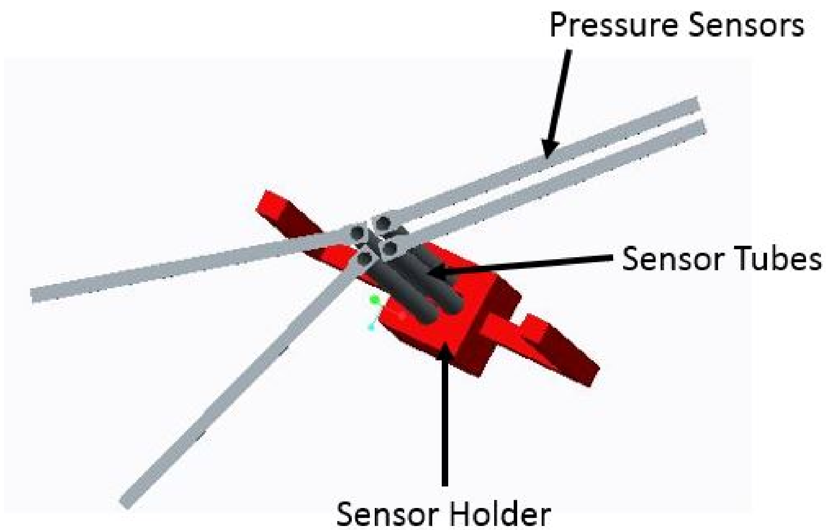

Fig. 5.26. Pressure Sensor Assembly

- **Sensor Holder:** The sensor holder is the base product for the entire assembly. It has holes in diamond shape with diameter of 16 mm that is greater that sensor outer diameter of 14 mm for easy entry of the plastic sensor tubes. The sensors are placed in each of the vertices of the diamond shape. The reason for choosing diamond shape is that this shape acts as contact points for pressure sensing over very small area. The area of interest is the occipital bone and the contact area is 25.4 mm × 25.4 mm (Figure 5.26). Keeping in mind the size of the sensors (outer diameter of 14 mm) and the area of interest we were able to incorporate four sensors. The sensor holes in the base part were placed 25 mm apart.

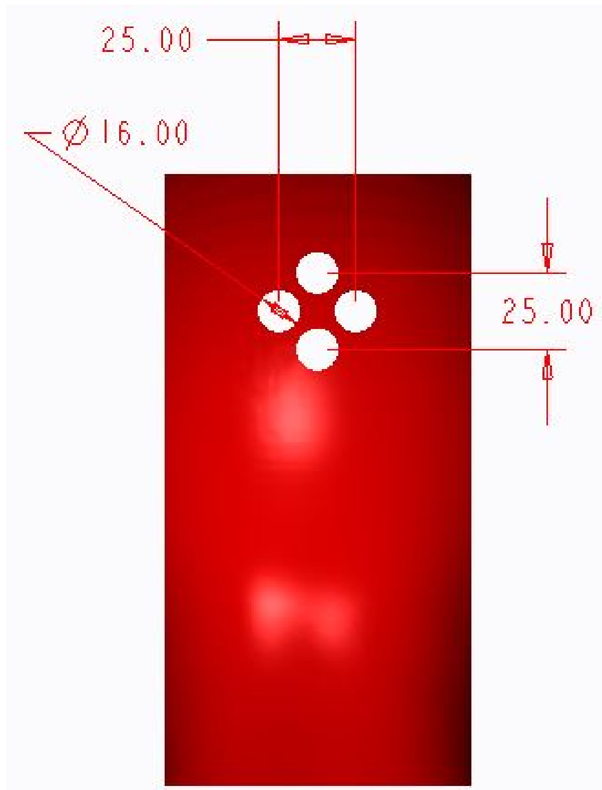

Fig. 5.27. Pressure Sensor positioning in diamond shape with dimensions

- **Plastic Sensor Tubes:** These incorporate the spring and the pressure sensors. The outer diameter of the tube is 14 mm equal to the outer diameter of the pressure sensor.

- **Springs:** The springs are used to detect the head deflection when in supine position. The spring constant should be stiff enough to detect very small deflections.

- **Pressure Sensors:** These show the value of pressure input by patients head for patient positioning purpose. We will be using FlexiForce B201 (Figure 5.28(b)) type force sensors from Tekscan Inc.® which can withstand a maximum load of

111 N. The sensors are a flat type sensor with circular sensing area of diameter 9 mm on one end and the other end consisting of the terminals connecting to the wireless transmitter.

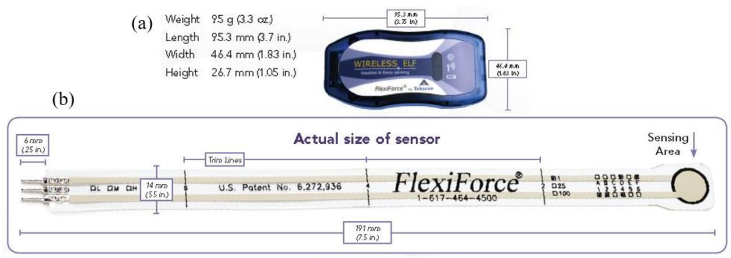

Fig. 5.28. Force Measurement Sensor (a) WELF Wireless device and (b) FlexiForce B201 Sensor (Courtesy of Tekscan Inc.®)

Four pressure sensor tubes are attached to the sensor holder. Springs are inserted into these tubes with the pressure sensors placed on these springs for readings. The wires for the sensors are passed through the tubes which are further connected to the transmitter. The force measurement system is a wireless based system-FlexiForce WELF 2 system (Figure 5.28(a)) which uses Wi-Fi to get connected and transmit readings from the transmitter to the receiver i.e. the computer. The Wi-Fi connection setup has ad hoc and access point (unsecured router) network capability and has force measurement software that is compatible with Windows 2000, XP and Windows 7 and above. When force is applied to the sensors then the readings can be observed by the radiologist using a remote computer and depending on the force distribution can instruct the patient to make slight adjustments to the head. Screen display consists of real time force measurement the properties of which can be changed according to the application. Every patient has a different shape of the occipital bone due to which the position of the sensor tubes can be customized and recorded using the instruction sheet. This instruction sheet consists of the positions of all the immobilization devices used for each patient so that it can be repeated in the treatment stage. The flowchart is shown in Figure 5.29 to prepare pressure sensor assembly.

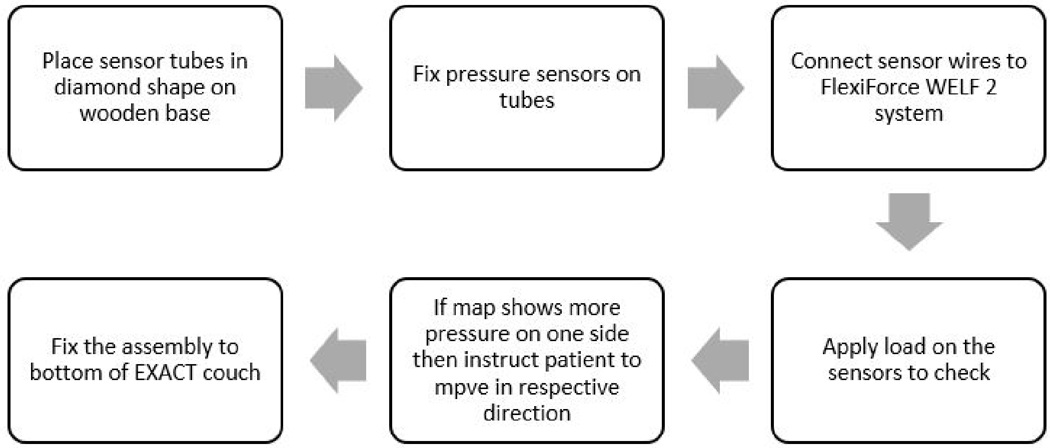

Fig. 5.29. Flowchart for preparing pressure sensor assembly

5.8 Preparing 3D Printed Nose Bridge Part

The main objective of preparing this part is to immobilize the patients head in the Treatment Room only. This part is customized to each patient and costs around $20 to be 3D printed. The design requirements to build this part are:

- The part should be customized to each patient
- Material should be MRI compatible
- Designed in a way that rigidly fixes patients nose bridge
- Design should be comfortable to the patient
- Quick preparation

Keeping in mind all the above mentioned requirements, the following section explains the working procedure for preparing this part. Firstly, from the CT scan of patients head we get a Digital Imaging and Communications in Medicine (DICOM) file. A DICOM file is a standard file format for handling, storing, printing and transmitting information in medical imaging [33]. For 3D printing we use Materialise Mimics® software [34]. The advantage of using this software from other similar image analysis softwares like 3D Slicer® [35] or Visualization Tool Kit (VTK) [36]or SimVascular 2.0 [37] is the diverse functionality and the ability to convert a DICOM file format into 3D printable Stereolithography (STL) file format [38]. Another advantage of this particular software is that there is an inbuilt 3D viewer software where the 3D printed part can be edited for its properties like mesh size, 3D printable material, etc. In other softwares the STL file has to be viewed using another software. The DICOM file is input in the Mimics software (Figure 5.30(a)) and then using Image segmentation and thresholding tools a 3D part of the nose bridge part is created. During the thresholding process it has to be made sure that the patients skin is also taken into consideration. Once the thresholding is done then a 3D mask of the nose bridge is created and then cropped to the area of interest (blue part in Figure 5.30(b)). Now that the mask has been created we can create a STL file using the inbuilt STL tool. Now we have a STL file for 3D printing. If we want to change the properties then we can open the STL file in the inbuilt 3D viewer. To print the 3D printed part the material was chosen to be Acetal-MRI safe material. A final 3D printed part is as shown in Figure 5.30(c). This part is comfortable to the patient because it is not too tight as the patients skin was taken into consideration.

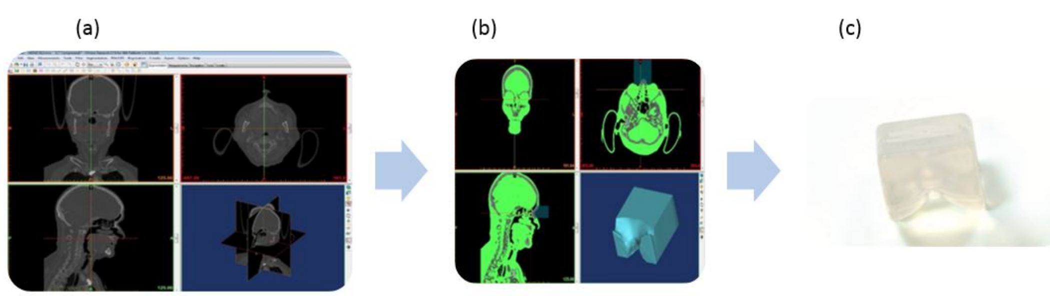

Fig. 5.30. Procedure to 3D print Nose bridge part using Materialise Mimics software (a) DICOM file of patient's CT scan, (b) 3D printed part after thresholding and cropping of 3D mask, (c) Finished product

5.9 Stereotactic Frame

The main objective of designing this product was to rigidly fix the immobilization devices. The design requirements are:

- Design should lie within SFOV
- Material to be MRI compatible
- Design to be reproducible for subsequent fractions of cancer treatment
- Durable design

The frame consists of arms and levers with proper indexing. The material chosen was Acetal which is a widely used MRI compatible material. The base frame is a vertical frame of length 225 mm and height 250 mm which is within the SFOV and is fixed to the extendible headrest. Attached to this vertical frame is a horizontal frame that can slide back and forth. This part is properly indexed as shown in Figure 3.28 in blue marks. Screwed to the front of the horizontal frame is the Nose Bridge vertical frame. The vertical position can be adjusted as per each patient. Fixed to the nose marker vertical part is the 3D printed nose bridge part and the marker. Behind the Nose Bridge vertical frame is the Marker vertical frame the position of which can be adjusted as per the positioning of the marker. All the positions of the frame members is recorded in an instruction sheet for repeatability.

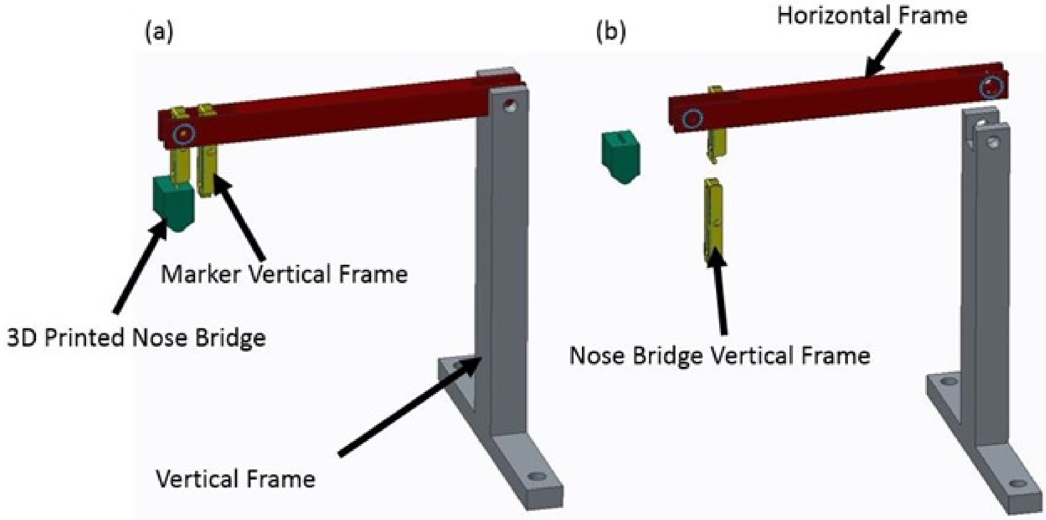

Fig. 5.31. (a) Assembly view of Stereotactic Frame, (b) Exploded View of Stereotactic Frame

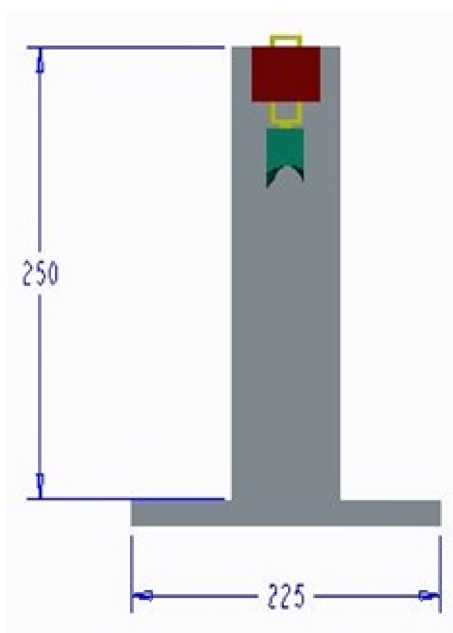

Fig. 5.32. Overall Dimensions of Stereotactic Frame

6. RESULTS AND DISCUSSION

This chapter gives the results for the analysis carried out in the previous chapter. To run the analysis ANSYS software was done to calculate the deflection of the immobilization devices under applied load from the patient. Further LS-Dyna software was used to calculate the value for spring constant. The method of explicit dynamics was used to get the force-deflection curve. In this method first the force vs time graph is generated and then deflection vs time graph is generated. From these two graphs the new graph for force vs deflection can be calculated.

Firstly, the amount of load that the patient puts on the immobilization devices will be experimentally calculated. Next, this value of load is used as input parameter to get the value of deflection for the immobilization devices and the stereotactic frame. Then a case study is done on one of the patients from VA Hospital Indianapolis, Indiana to get the accurate location of the tumor using the new design. Finally, the new design is compared with the current clinical practices in terms of accuracy of head movement, comfort, ease of setting up the equipment and price for the system.

6.1 Failure Mode

For validating our new system, the failure modes encountered during the design stage are deflection of the device and the strain acting on the device due to the load applied. Table 6.1 shows the failure modes in various parts with the corrective measure to be taken to avoid it:

Table 6.1.
Failure Mode Analysis of engineered parts

Failure Mode Analysis					
Part Name	**Function**	**Potential Failure Modes**	**Potential Effects of Failure**	**Potential Causes of Failure**	**Action Taken**
Stereotactic Frame	Fix patient's nose bridge area rigidly	Patient forcefully tries to move the device with a force greater than 20 N	Bending of the horizontal stereotactic frame	Patient not communicated with instructions during treatment stage	Proper instructions given to the patient before going into the room for treatment
		Nose bridge part not attached properly	Irregular patient positioning readings	Imperfections on the 3D printed nose bridge part	Inspection of 3D printed nose bridge part carried out before placing on the frame
		Indexing of horizontal and vertical stereotactic frame members	Inaccurate tumor location readings	Indexing positions of the frame members not recorded prior to the treatment	Indexing positions of the frame members recorded on the instruction sheet provided to the radiotherapists
Head Fixing Device	Patient's head rigidly fixed on the treatment couch	Patient moves their head with a force greater than 60 N	Inaccurate readings for tumor location	Device not indexed properly	Device indexed and position recorded on the instruction sheet
Pressure Sensor Assembly	Detects amount of patient's head deviation	Indexing of sensor tubes	Sensor tubes not indexed to the proper position	Inaccurate head deviation readings which will further effect the tumor location readings	Sensor tubes indexed as per patient head position and recorded in the instruction sheet
		Sensor selection	Wrong patient head deviation readings	Improper sensor wire connections and wrong sensor selection	Wireless connectivity checked before treatment stage and WB201 sensor used
Spherical Markers	Calculating coordinate points for patient immobilization	Indexing of spherical markers	Inaccurate tumor location readings	Indexing of markers not recorded on instruction sheet	Position of markers recorded on the instruction sheet
Shoulder Retractable Device	Rigidly fixing patient's shoulder	Indexing of the shoulder retractable device	Patient can move and thus inaccurate test results	Device not indexed properly	Patient instructed not to move during treatment and position of device recorded on the instruction sheet

6.2 Load Calculation

The design of the whole system was done using PTC Creo Parametric 2.0 software as shown in Figure 6.1(b).

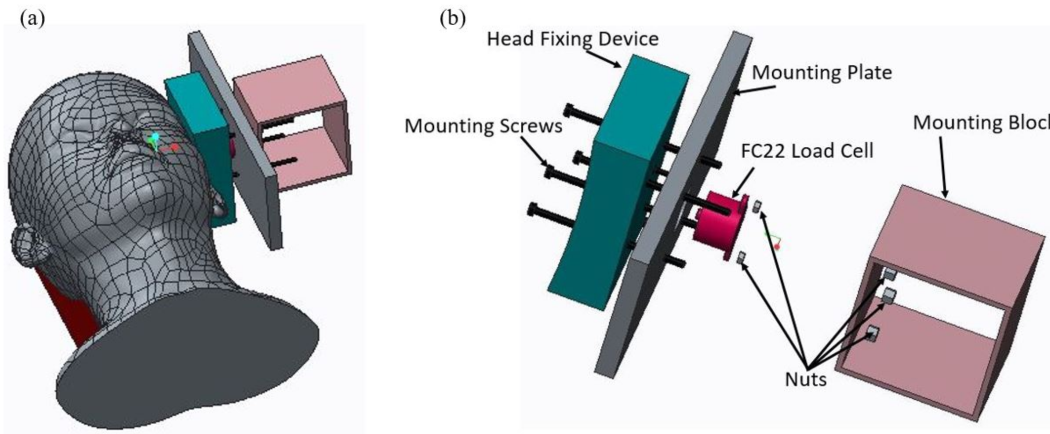

Fig. 6.1. Experimental setup to calculate amount of load patient exerts on the immobilization devices for doing the analysis on ANSYS software(a) Experimental Setup with 3D printed part touching patients face for load calculation and (b) Exploded view of the assembly

The engineering analysis of various immobilization devices for durability was done using ANSYS Workbench 15.0 software with static analysis method. To start the engineering analysis, the amount of force experiencing on patients head was calculated using a simple experimental setup. As shown in Figure 6.1(a), the setup consists of FC22 compression load cell with a full scale force range from 0-100 N or 0-22.5 lbf with an accuracy of ±1 N bolted on a 200 mm x 76 mm x 10 mm rectangular stainless steel plate [39].

A 3D printed PEEK (Table 6.1) plastic part was fixed on this plate that experiences the load of the head for measurement purpose. The coding (Appendix 10.1) of the experiment was done using Arduino UNO kit that consists of the Arduino UNO circuit board (as shown in Figure 6.2(a)) and the Arduino Software (IDE). This hardware is an open source hardware where the students can build their own board using the files provided by Arduino and the software is compatible with Windows operating system. The software was installed in Lenovo Y50-70 Windows 10 laptop. The UNO board can be powered via the USB connection or with an external power supply where the power source is selected automatically. The wire connections for the setup to run is shown in Figure 6.2(b). The power pins include 5 V pin which is connected to the load cell assembly and the GND pin to ground the board. UNO has six analog inputs labeled through A0 to A5 each of which provides 10 bits of resolution (i.e. 1024 different values) and measures default values ranging from ground to 5 volts. A1 pin was chosen as the input pin. Similar connections were also made in breadboard as shown in Figure 6.2(b) for communication purpose from the load cell to UNO board. To complete the connections one end of the USB connector was connected to the UNO board and the other was connected to Lenovo Y50-70 laptop running on Windows 10 operating system. For rigidity a 76 mm × 76 mm × 63 mm stainless steel mounting

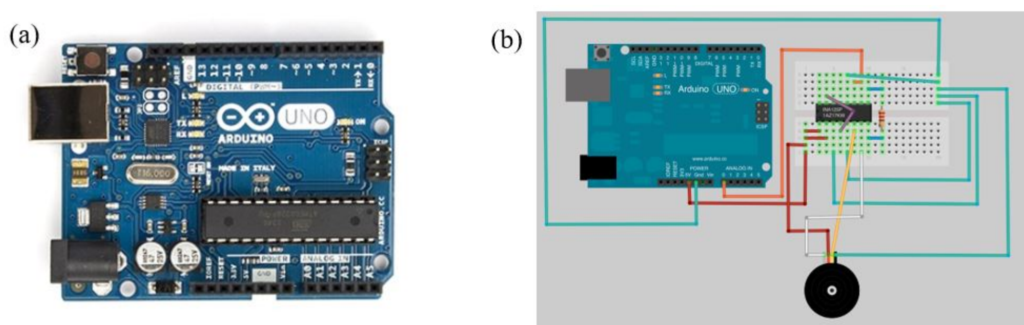

Fig. 6.2. Arduino Uno kit used to generate the code for load calculation (a) Arduino Uno circuit board (*Courtesy of Arduino*®), (b) Arduino Uno breadboard connections[40]

block was attached to this assembly and further the setup was fixed to the table and then a volunteer was made to lie on the table with the side of the head touching the 3D printed part as shown in Figure 6.1(a).

The volunteer was instructed to put the maximum amount of force on the 3D printed part to get the maximum force experienced by the load cell. The load cell recorded consistently a maximum load of 60 N, which was taken as the maximum load for engineering analysis on the immobilization devices. Similar setup was prepared to calculate the force experienced on the nose bridge region and a maximum load of 20 N was recorded. The nose bridge contact area had a surface are of 762.44 mm^2. In ANSYS Workbench software the vertical bar for the nose bridge assembly was fixed and a pressure of 0.02 MPa was applied on the nose bridge contact point. With ABS plastic as the material chosen for the setup a deflection of 0.972 mm was observed which is below the threshold limit as doctors require a minimum deflection of less than 3 mm.

Simulation of various immobilization devices was carried out using ANSYS Workbench software. As explained above a force of 60 N was taken as the reference load for doing the analysis. Firstly, the stereotactic device is selected for analysis and a radiopaque material like PEEK was chosen [41]. PEEK is a semi-crystalline high temperature colorless thermoplastic material that has a unique property of being radiopaque. Radiolucent materials are special variety of materials that are transparent to x-rays. Currently PEEK is the most widely used and FDA approved MRI compatible material for making medical immobilization equipment especially CT/MRI scanning because of its radiolucent property. Table 6.2 below shows the chemical and physical properties of PEEK.

Table 6.2.
PEEK Material Physical Properties (Source: [41,42])

Property/Material	**PEEK**
Density	1320 kg/m^3
Young's Modulus	1.103 GPa
Tensile Strength	91.7 MPa
Poisson's Ratio	0.4

Because of these unique properties PEEK was chosen to be the standard material for analysis purpose. For simulation purpose various immobilization devices like the nose bridge assembly, stereotactic device, head fixing device, shoulder retractable device, etc. were put under loading conditions and the amount of deflection was calculated.

6.3 Head Fixing Device

The device is made of carbon fiber base and the head pads are made of thermoplastic material like PEEK for comfort purpose. Firstly, for engineering analysis, the material was defined to be PEEK with the properties as mentioned in Table 6.2 input in the software. The device was fixed at the base and a point load of 60 N was given on the front flat side of the device in Z direction because this is the part which will experience the pressure. A total deformation was selected from the solution drop down menu. The results of the problem are shown in Figure 6.3.

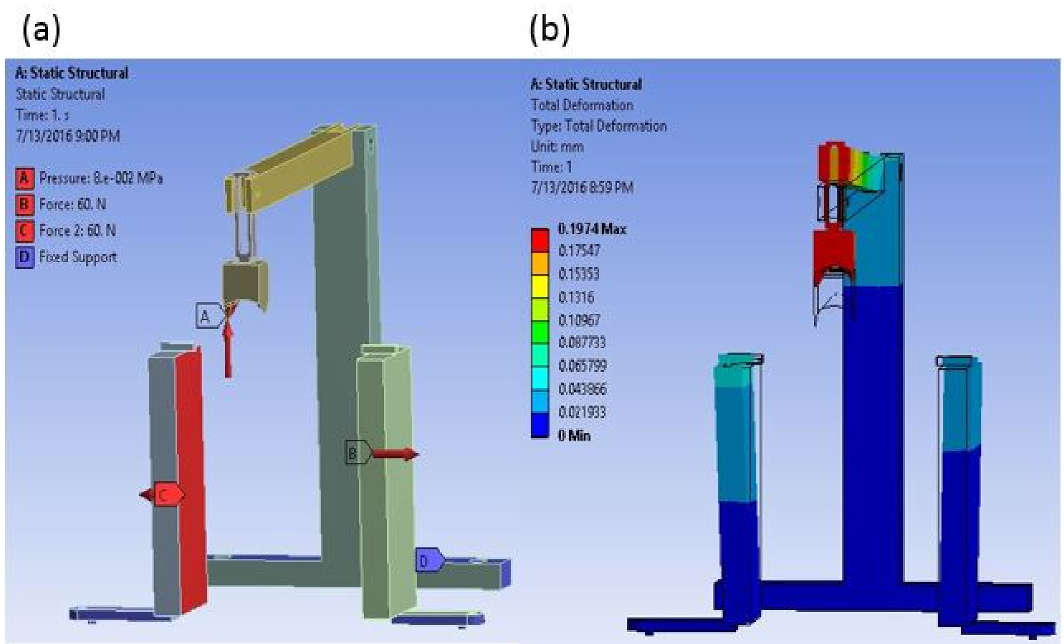

Fig. 6.3. Engineering analysis of Head fixing device (a) Input values and direction of loads, (b) Value of Deformation=0.1974 mm

6.4 Stereotactic Device

The material chosen for this was PEEK because this has to allow the x rays to pass from the source. As shown in Figure 6.4(a) the vertical member is fixed and pressure is applied on the nose bridge region. A pressure of 0.0787 MPa is applied on the nose bridge surface because the force acting on the member as explained in previous section is 60 N and the surface area of the contact region is 762.244 mm^2. The results for total deformation is as shown below.

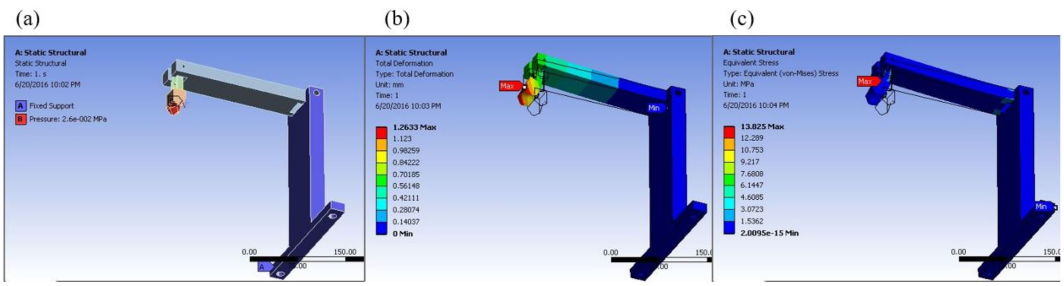

Fig. 6.4. Engineering Analysis of Stereotactic Device (a) Fixed support and Pressure location, (b) Deformation=1.2633 mm and (c) Stress=13.825 MPa

6.5 Tumor Location

In CT Room:

$$\overrightarrow{M1} = \begin{bmatrix} 6.15 \\ -7.84 \\ -19.95 \end{bmatrix} \text{; Left immobilization device}$$

$$\overrightarrow{M2} = \begin{bmatrix} 7.15 \\ 7.84 \\ -19.95 \end{bmatrix} \text{; Right immobilization device}$$

$$\overrightarrow{M3} = \begin{bmatrix} 8.15 \\ 0 \\ 20 \end{bmatrix} \text{; Nose Bridge}$$

$$\overrightarrow{Tumor} = \begin{bmatrix} -3.25 \\ -4.54 \\ -10.25 \end{bmatrix}$$

Unit vectors along GCS using equation (B.5):

$$\hat{I} = \frac{X}{||X||} = \begin{bmatrix} 1 \\ 0 \\ 0 \end{bmatrix}$$

$$\hat{J} = \frac{Y}{||Y||} = \begin{bmatrix} 0 \\ 1 \\ 0 \end{bmatrix}$$

$$\hat{K} = \frac{Z}{||Z||} = \begin{bmatrix} 0 \\ 0 \\ 1 \end{bmatrix}$$

Defining the new coordinate system LCS using equations (B.6)-(B.11):

$$\overrightarrow{V1} =< \overrightarrow{M2} - \overrightarrow{M1} >= \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} - \begin{bmatrix} X1 \\ Y1 \\ Z1 \end{bmatrix} = \begin{bmatrix} 1 \\ 15.68 \\ 0 \end{bmatrix}$$

$$\overrightarrow{V2} =< \overrightarrow{M2} - \overrightarrow{M3} >= \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} - \begin{bmatrix} X3 \\ Y3 \\ Z3 \end{bmatrix} = \begin{bmatrix} -1 \\ 7.84 \\ -39.95 \end{bmatrix}$$

Coordinate axes in LCS $\overrightarrow{x}$:

$$\overrightarrow{x} = \overrightarrow{V1} = \begin{bmatrix} 1 \\ 15.68 \\ 0 \end{bmatrix}$$

$$\overrightarrow{y} = \overrightarrow{x} \times \overrightarrow{V2} = \begin{vmatrix} i & j & k \\ x(x) & x(y) & x(z) \\ V2(x) & V2(y) & V2(z) \end{vmatrix} = \begin{bmatrix} 626.4160 \\ -39.95 \\ -23.52 \end{bmatrix}$$

$$\overrightarrow{z} = \begin{vmatrix} i & j & k \\ x(x) & x(y) & x(z) \\ y(x) & y(y) & y(z) \end{vmatrix} = \begin{bmatrix} -368.7936 \\ 23.52 \\ -9.8622e+03 \end{bmatrix}$$

New marker location with respect LCS using equations

$$\overrightarrow{M2}_{LCS} = \begin{bmatrix} 0 \\ 0 \\ 0 \end{bmatrix}$$

$$\overrightarrow{M1}_{LCS} = \begin{bmatrix} D1 \\ 0 \\ 0 \end{bmatrix} = \begin{bmatrix} 15.7119 \\ 0 \\ 0 \end{bmatrix}$$

$$\overrightarrow{M3}_{LCS} = \begin{bmatrix} D2(x) \\ D2(y) \\ 0 \end{bmatrix} = \begin{bmatrix} 9.8894e+03 \\ 26.4005 \\ 0 \end{bmatrix}$$

Unit vectors $\hat{i}$, $\hat{j}$ and $\hat{k}$ along LCS:

$$\hat{i} = \frac{x}{||x||} = \begin{bmatrix} 0.0636 \\ 0.9980 \\ 0 \end{bmatrix}$$

$$\hat{j} = \frac{y}{||y||} = \begin{bmatrix} 0.9973 \\ -0.0636 \\ -0.0374 \end{bmatrix}$$

$$\hat{k} = \frac{z}{||z||} = \begin{bmatrix} -0.0374 \\ 0.0024 \\ -0.9993 \end{bmatrix}$$

Direction cosines for the transformation matrix can be represented in the rotation matrix as (using equations (B.20)and (B.22)):

$$[R] = \begin{bmatrix} I.i & I.j & I.k \\ J.i & J.j & J.k \\ K.i & K.j & K.k \end{bmatrix} = \begin{bmatrix} 0.0636 & 0.9980 & 0 \\ 0.9973 & -0.0636 & -0.0374 \\ -0.0374 & 0.0024 & -0.9993 \end{bmatrix}$$

The transformation matrix T which includes the above calculated rotation matrix R as per equation (B.25):

$$[T] = \begin{bmatrix} 1 & 0 & 0 & 0 \\ 7.15 & 0.0636 & 0.9980 & 0 \\ 7.84 & 0.9973 & -0.0636 & -0.0374 \\ -19.95 & -0.0374 & 0.0024 & -0.9993 \end{bmatrix}$$

New location of markers after transformation from GCS to LCS as per equations (B.27)-(B.29):

$$\overrightarrow{m1} = [T]^{-1} \times \overrightarrow{M1}_{GCS} = \begin{bmatrix} 15.7119 \\ 0 \\ 0 \end{bmatrix}$$

$$\overrightarrow{m2} = [T]^{-1} \times \overrightarrow{M2}_{GCS} = \begin{bmatrix} 0 \\ 0 \\ 0 \end{bmatrix}$$

$$\overrightarrow{m3} = [T]^{-1} \times \overrightarrow{M3}_{GCS} = \begin{bmatrix} 9.8894e+03 \\ 26.4005 \\ 0 \end{bmatrix}$$

6.6 Comparison of Current and New System

Table 6.3 shows the comparison between systems used in current practice with a masked immobilization system and the new mask less system developed which is described in this project. The table clearly proves that the new system is satisfying all the criteria of an immobilization device where comfort and accuracy are the key points during the treatment procedure. The new system is comfortable to the patient and also easy to setup by the therapist. Once the holes for the pressure sensor assembly has been drilled for subsequent fractions of treatment the setup time of the equipment is also quicker than the previous system.

Table 6.4 shows the comparison of the Mask less 3D mapping system as mentioned in chapter 3.2 and the new mask less system developed which is described in this

Table 6.3.
Comparison between masked system and the New Mask Less System

	PinPoint Immobilization System	**Mask Less New System**
Accuracy	±1.7 mm	±0.1974 mm
Comfort	Masked system is uncomfortable to the patient	No mask and thus comfortable to the patient
Ease of setup	The head mold must be specially prepared for each patient	Nose bridge part is custom made for each patient
Price	Setup with immobilization device = $32,000	3D printed part = $20 each Mimics software = $8,000 Sensor setup with software = $1,500 Total = $10,000

project. The table shows that the new system is more accurate than the current mask less system used in current practice. The new system is also inexpensive because it does not use expensive equipment like the camera system to detect head movement. The disadvantage of the camera system is that the cameras have to be mounted in the treatment room that requires time for installing and setting up the system. Such a system can only be used when the treatment room is being renovated or else the machines have to shut down until installation of the system is compete which is inconvenience to the patient and the therapist. To run the camera system, the therapist has to understand the working of the system that requires training and thus more time and cost.

Table 6.4.
Comparison between Masked 3D mapping system and the new system

	3D Mapping of the Head Mask Less System	**Mask Less New System**
Accuracy	±2 mm	±0.1974 mm
Comfort	No mask used thus comfortable	No mask and thus comfortable to the patient
Ease of setup	The camera system must be properly understood to run the system	Nose bridge part is custom made for each patient
Price	Infrared Camera system = $10,000 Setup = $3,000 Total = $13,000	3D printed part = $20 each Mimics software = $8,000 Sensor setup with software = $1,500 Total = $10,000

7. CONCLUSION

In the current techniques for patient positioning and immobilization, the devices used make the patient uncomfortable which is the most important factor during the treatment stage. The development of new devices to make the patient more comfortable during treatment is thus very important but at the same time it should be inexpensive, repeatable and easy to setup by the radio therapist. Keeping all these factors in mind we developed a new system where the patient is immobilized without using any confining mask but at the same time give accurate patient positioning. To accomplish this, we developed an immobilization system which is different at the CT scanning and treatment stage as compared to the traditional method where they use a confining thermoplastic mask. At the CT scanning stage, the patient is immobilized using pressure sensor assembly, immobilization devices and head rest to fix the patient. While the CT scanning is being done, an image of the external markers is also taken to be used in the treatment stage. Next, at the treatment stage, the coordinate points of the patient from the CT scanning stage are replicated over here by inputting the values in the LINAC. For further referencing, a stereotactic device that includes the 3D printed nose bridge part is used. The nose bridge part is fixed to patients nose bridge part which is properly indexed. After designing the system, we validated it using ANSYS Workbench software and we concluded that the deflection of the system is ± 1.6 mm that is lower than the customer requirement of ± 3 mm. This system takes into consideration the effect of weight loss because our device is referenced to patients nose bridge part that is a bony region and there are no anatomical changes during the course of the treatment. Another objective of the system was to design a system that is comfortable for the patient without using any confining masks or bite block to immobilize. This system was also approved by VAMC and concluded that it is more comfortable than the present systems available.

Although still more research has to go into building a prototype of the system and experimenting it on live patients, but after online simulation it has been concluded that the system is comfortable and easy to use by the therapists.

8. FUTURE WORK

Although the new design has been proven to be comfortable and ideal values of patient head movement have been calculated, a physical prototype has to be built to prove this design. Currently, due to lack of funds a physical prototype was not prepared. Following are the future works:

- Building a physical prototype for testing and design validation
- Quantifying patient comfort through product testing
- Preparing algorithm to translate the sensor value from the pressure sensor assembly to corrected head deviations for calculations. For this the pressure mapping software has to be bought and tested.
- Using the current algorithm the head deviation was ± 0.1974 mm. The physical prototype will have to test if this value can be achieved. If not ± 0.1974 mm the head deviation should be less than ± 1.7 mm which is the head deviation encountered in mask less system as mentioned in Table 5.3.

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APPENDICES

A. ARDUINO CODE FOR LOAD CALCULATION

Arduino Code for Load Calculation using FC-22 Load cell

```
// Arduino with load cell

// Put two known loads on the sensor and take readings. Put those
// values here.
float aReading = 142;
float aLoad = 100; // gm.
float bReading = 156.0;
float bLoad = 200; // gm.

long time = 0;
int interval = 1000; // Take a reading every 500 ms
float g = 0.98;
float force =0;

void setup() {
  Serial.begin(9600);
}

void loop() {
  float newReading = analogRead(0);

  // Calculate load based on A and B readings above
  float load =
```

```
 ((bLoad - aLoad)/(bReading - aReading)) * (newReading - aReading)
 + aLoad;

  // millis returns the number of milliseconds since the board
  started the current program
  if(millis() > time + interval) {
    if(newReading < 103)
    {

      Serial.print("\t Load (gms)");
      Serial.println(0);
    }
      else
      {
    Serial.print(" Reading: ");
    Serial.print(newReading,1); // 1 decimal place
    Serial.print("  \t Load(gms)");
    Serial.println(load+178.6,1);  // 1 decimal place, println
    adds a carriage return

    force = load *g ;
   Serial.print("                         \t force (N): ");
   Serial.println(force/100,2);
   time = millis();
      }
  }
}
```

B. COORDINATE TRANSFORMATION FROM CT ROOM TO TREATMENT ROOM

To calculate the coordinate transformation, special care is taken to fix the immobilization devices rigidly because the coordinate points of the markers will change if the immobilization devices are oscillating. So the assumption that we have taken is that the position of the immobilization devices is fixed and does not move during the whole treatment process. As explained in previous sections, the three markers are placed on the immobilization devices.

First, the 3 external markers-M1, M2 and M3 are attached to the side head resting devices and the nose bridge area. Then, a CT scan of the patients head is taken and in addition these 3 marker locations are also imprinted in the scan. In the simulation stage, the location of the markers is defined with respect to the simulation room coordinate system and is shown by the Eclipse Treatment planning software. This coordinate system is termed as the Global or Fixed Coordinate System (GCS). The coordinates of the markers in GCS is defined as:

$$\overrightarrow{Marker1} =< X1, Y1, Z1 > \tag{B.1}$$

$$\overrightarrow{Marker2} =< X2, Y2, Z2 >= \overrightarrow{M2} \tag{B.2}$$

$$\overrightarrow{Marker3} =< X3, Y3, Z3 >= \overrightarrow{M3} \tag{B.3}$$

$$\overrightarrow{Tumor} =< Xt, Yt, Zt >= \overrightarrow{Mt} \tag{B.4}$$

The location of the markers is shown in Figure B.1. The GCS has coordinate axes defined as X, Y and Z with the origin set as [0,0,0]. We will now define unit vectors-$\hat{I}$, $\hat{J}$ and $\hat{K}$, along these coordinate axes. The normalized vector of the coordinate axes

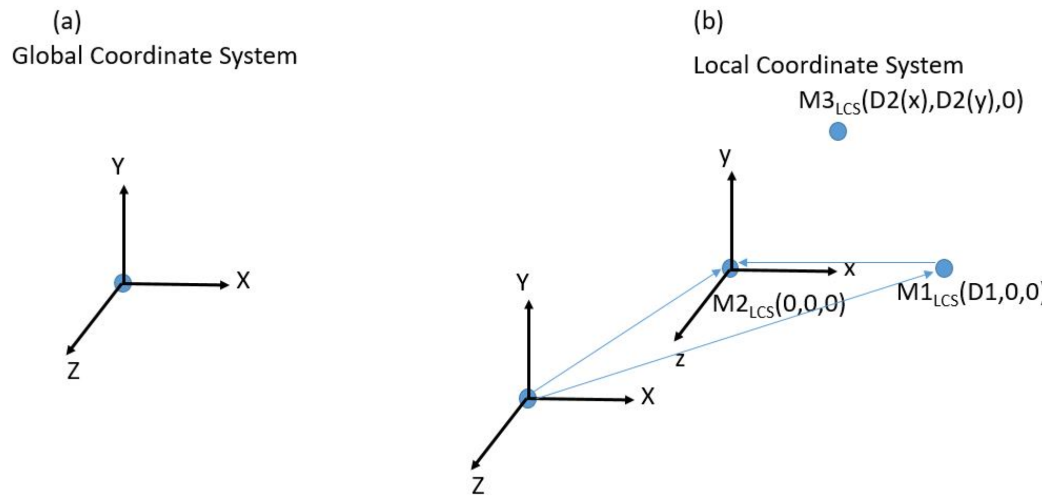

Fig. B.1. Transformation Technique with marker location in GCS and LCS

defines the unit vectors.

$$\hat{I} = \frac{X}{||X||}; \hat{J} = \frac{Y}{||Y||}; \hat{K} = \frac{Z}{||Z||} \tag{B.5}$$

where |||| represents the magnitude of the desired vector.

The GCS defines a fixed position of the markers and the tumor in the room coordinate system. Next, we will have defined a new coordinate system because we are shifting from the room coordinate system to the treatment room coordinate system keeping the position of the markers same. When we are changing rooms then there can be a possibility of markers shifting their position or rotating. To take this problem into consideration, we will be defining a new coordinate system called as the Local Coordinate System (LCS). To define the new coordinate system, we need a origin point along which all other future measurements will be done. We will select an of the positions of the markers as origin because these positions are fixed and not moving during the treatment stage as the patient is immobilized during the whole duration of the treatment. We have selected Marker2 as the origin. To define the X axis of this new coordinate system, we must define the magnitude and direction of this vector. This vector termed as $\overrightarrow{V1}$ is defined as a vector going from Marker2 to Marker1 in the horizontal direction.

$$\overrightarrow{V1} = < \overrightarrow{M1} - \overrightarrow{M2} > = \begin{bmatrix} X1 \\ Y1 \\ Z1 \end{bmatrix} - \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} \tag{B.6}$$

The standard convention to follow in defining coordinate axes is the Right Hand Thumb Rule (Figure B.2). As per B.6 the direction of the vector is from right to left (reference Figure B.1) and is the -X direction. To get the +X direction we will reverse the vector to get the vector from left to right and this is termed as x_{LCS}.

To get the next orthogonal vector $\overrightarrow{y}$ we must define a vector from Marker 2 to

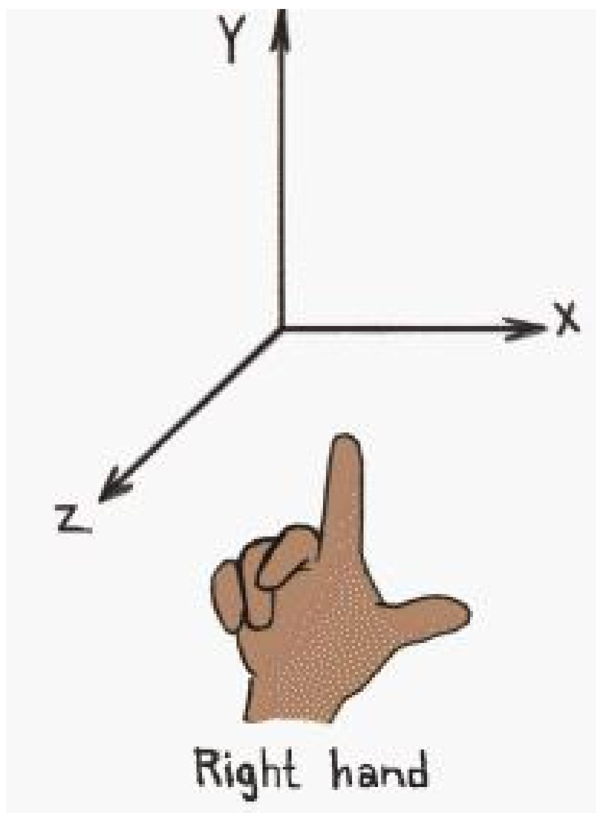

Fig. B.2. Right Hand Rule for selecting the direction of coordinate axes[43]

Marker3 and then take a cross product with $\overrightarrow{x}$

$$\overrightarrow{V2} =< \overrightarrow{M3} - \overrightarrow{M2} >= \begin{bmatrix} X3 \\ Y3 \\ Z3 \end{bmatrix} - \begin{bmatrix} X2 \\ Y2 \\ Z2 \end{bmatrix} \tag{B.7}$$

With this we have defined a vector that is coming from Marker3 to Marker2 which will be -Y direction. To get the +Y direction, we will take the reverse of this vector. As per the right-hand thumb rule, when we curl our fingers from the $\overrightarrow{x}$ to +Y direction of the $\overrightarrow{V2}$ we will get a orthogonal vector in upward direction and is termed as $\overrightarrow{y}$ as shown in Figure B.1.

$$\overrightarrow{y} = \overrightarrow{x} \times \overrightarrow{V2} = \begin{vmatrix} i & j & k \\ x(x) & x(y) & x(z) \\ V2(x) & V2(y) & V2(z) \end{vmatrix} \tag{B.8}$$

$$\overrightarrow{y} = \overrightarrow{x} \times \overrightarrow{V2} = \begin{vmatrix} x(y) & x(z) \\ V2(y) & V2(z) \end{vmatrix} i - \begin{vmatrix} x_{LCS}(x) & x_{LCS}(z) \\ V2(x) & V2(z) \end{vmatrix} j - \begin{vmatrix} x(x) & x(y) \\ V2(x) & V2(y) \end{vmatrix} k \tag{B.9}$$

The z axis as per the right-hand rule will now be pointing out of the paper and is denoted as $\overrightarrow{z}$ (Figure B.1). To get this third orthogonal axes we will be taking a cross product of $\overrightarrow{x}$ with $\overrightarrow{y}$.

$$\overrightarrow{z} = \begin{vmatrix} i & j & k \\ x(x) & x(y) & x(z) \\ y(x) & y(y) & y(z) \end{vmatrix} \tag{B.10}$$

$$\overrightarrow{z} = \begin{vmatrix} x(y) & x(z) \\ y(y) & y(z) \end{vmatrix} i - \begin{vmatrix} x(x) & x(z) \\ y(x) & y(z) \end{vmatrix} j - \begin{vmatrix} x(x) & x(y) \\ y(x) & y(y) \end{vmatrix} k \tag{B.11}$$

Now that the new coordinate system LCS is defined, we can measure the location of the markers with respect to this system. The coordinates of each of the three markers in LCS are defined as:

$$\overrightarrow{M2}_{LCS} = \begin{bmatrix} 0 \\ 0 \\ 0 \end{bmatrix} \tag{B.12}$$

$$\overrightarrow{M1}_{LCS} = \begin{bmatrix} D1 \\ 0 \\ 0 \end{bmatrix} \tag{B.13}$$

$$\overrightarrow{M3}_{LCS} = \begin{bmatrix} D2(x) \\ D2(y) \\ 0 \end{bmatrix} \tag{B.14}$$

where D1 is the distance between Marker2 and Marker1 in GCS:

$$D1 = \sqrt{(X2 - X1)^2 + (Y2 - Y1)^2 + (Z2 - Z1)^2} \tag{B.15}$$

D2(x) is the x coordinate distance between Marker3 and $\overrightarrow{x}$

$$D2(x) = \sqrt{(z(x) - X3)^2 + (z(y) - Y3)^2 + (z(z) - Z3)^2} \tag{B.16}$$

D2(y) is the y coordinate distance between Marker3 and $\overrightarrow{y}$

$$D2(y) = \sqrt{(x(x) - X3)^2 + (x(y) - Y3)^2 + (x(z) - Z3)^2} \tag{B.17}$$

Next step is to calculate the unit vectors - $\hat{i}$, $\hat{j}$ and $\hat{k}$ along the new coordinate axes in similar fashion as in equation (B.5). The new unit vectors are:

$$\hat{i} = \frac{x}{||x||}; \hat{j} = \frac{y}{||y||}; \hat{k} = \frac{z}{||z||} \tag{B.18}$$

The relationship between the components in one coordinate system and the components in a second coordinate system are called the transformation equations. These transformation equations are derived and discussed in what follows.

B.1 Rotations and Translations

Any change of Cartesian coordinate system will be due to a translation of the base vectors and a rotation of the base vectors. A translation of the base vectors does not change the components of a vector. Mathematically, this can be expressed by saying that the components of a vector a are a.$\hat{i}$ and these three quantities do not change under a translation of base vectors. Rotation of the base vectors is thus what one is concerned with in what follows.

B.2 Components of Vector in Different Coordinate Systems

Consider the cartesian coordinate system GCS with base vectors $\hat{I}$, $\hat{J}$ and $\hat{K}$ and origin as GCS. Any vector $\overrightarrow{a}$ can be written as $\overrightarrow{a}_{GCS} = a_{GCS}(x).\hat{I} + a_{GCS}(y).\hat{J} + a_{GCS}(z).\hat{K}$ and a(x), a(y), a(z) are its components. Now a second coordinate system with base vectors $\hat{i}$, $\hat{j}$ and $\hat{k}$ and origin set as LCS can be written as $\overrightarrow{a}_{LCS} = a_{LCS}(x).\hat{i} + a_{LCS}(y).\hat{j} + a_{LCS}(z).\hat{k}$. The components of a vector in new coordinate system can be expressed with respect to the old coordinate system as:

$$\begin{bmatrix} a_{LCS}(x) \\ a_{LCS}(y) \\ a_{LCS}(z) \end{bmatrix} = \begin{bmatrix} l1 & m1 & n1 \\ l2 & m2 & n2 \\ l3 & m3 & n3 \end{bmatrix} \cdot \begin{bmatrix} a_{GCS}(x) \\ a_{GCS}(y) \\ a_{GCS}(z) \end{bmatrix} \tag{B.19}$$

where l,m and n are called the direction cosines of the vector and are measure of the angle between two vectors. The direction cosines are calculated as:

$$l1 = \cos(I, i), m1 = \cos(I, j), n1 = \cos(I.k) \tag{B.20}$$

$$l2 = \cos(J, i), m2 = \cos(J, j), n2 = \cos(J.k) \tag{B.21}$$

$$l3 = \cos(K, i), m3 = \cos(K, j), n3 = \cos(K.k) \tag{B.22}$$

To calculate the values of direction cosines, we use the formula of dot product of two vectors to get the angle between two vectors

$$\overrightarrow{u}.\overrightarrow{v} = ||\overrightarrow{u}||||\overrightarrow{v}|| \cos\theta \tag{B.23}$$

$$\cos\theta = \frac{\overrightarrow{u}.\overrightarrow{v}}{||\overrightarrow{u}||||\overrightarrow{v}||} \tag{B.24}$$

The transformation matrix T related to this coordinate transformation is defined as:

$$[T] = \begin{bmatrix} 1 & 0 & 0 & 0 \\ X_2 & l1 & m1 & n1 \\ Y_2 & l2 & m2 & n2 \\ Z_2 & l3 & m3 & n3 \end{bmatrix} \tag{B.25}$$

where X2,Y2 and Z2 are the coordinates of Marker2 in GCS and the submatrix [R]= $\begin{bmatrix} l1 & m1 & n1 \\ l2 & m2 & n2 \\ l3 & m3 & n3 \end{bmatrix}$ is called the rotation matrix with direction cosines as explained using equations (B.20-B.22). Now we have a transformation matrix that defines the transformation of points from one coordinate system to the other. To get the location of markers in the new coordinate system we use the following formula:

$$A_{new} = [T]^{-1} \times A_{old} \tag{B.26}$$

where A_{new} is the coordinates of a point in the new coordinate system, T is the transformation matrix and A_{old} are the coordinates of the same point in old coordinate system. Using B.26 we can define the new location of the markers in LCS as:

$$\overrightarrow{M1}_{LCS} = [T]^{-1} \times \overrightarrow{M1}_{GCS} \tag{B.27}$$

$$\overrightarrow{M2}_{LCS} = [T]^{-1} \times \overrightarrow{M2}_{GCS} \tag{B.28}$$

$$\overrightarrow{M3}_{LCS} = [T]^{-1} \times \overrightarrow{M3}_{GCS} \tag{B.29}$$

$$\overrightarrow{Tumor}_{LCS} = [T]^{-1} \times \overrightarrow{Tumor}_{GCS} \tag{B.30}$$

C. MATLAB CODE FOR COORDINATE TRANSFORMATION

```
clc
clear all

%Location of Markers in Room(Global/Fixed) Coordinate System GCS
X1 = 6.15; Y1 = -7.84; Z1 = -19.95; M1 = [X1,Y1,Z1]'
X2 = 7.15; Y2 = 7.84; Z2 = -19.95; M2 = [X2,Y2,Z2]'
X3 = 8.15; Y3 = 0; Z3 = 20; M3 = [X3,Y3,Z3]'
Xt = -3.25; Yt = -4.54; Zt = -10.25; Tumor = [Xt,Yt,Zt]'
%GCS
X = [1,0,0];
Y = [0,1,0];
Z = [0,0,1];
%Unit vector along GCS
I = X/norm(X);
J = Y/norm(Y);
K = Z/norm(Z);
%Defining LCS
V1 = [M2 - M1];
V2 = [M2 - M3];
%Defining the coordinate axes for LCS
xlcs = V1
ylcs = cross(V2,xlcs)
zlcs = cross(xlcs,ylcs)
```

```
%New marker location
M2lcs = [0,0,0]
D1 = norm(M2 - M1);
M1lcs = [D1,0,0]
D2x = norm(zlcs - M3);
D2y = norm(xlcs - M3);
M3lcs = [D2x,D2y,0]
%Unit vectors along LCS
i=xlcs/norm(xlcs)
j=ylcs/norm(ylcs)
k=zlcs/norm(zlcs)
%Direction cosines
l1 = dot(I,i)/(norm(I)*norm(i));
m1 = dot(I,j)/(norm(I)*norm(j));
n1 = dot(I,k)/(norm(I)*norm(k));
l2 = dot(J,i)/(norm(J)*norm(i));
m2 = dot(J,j)/(norm(J)*norm(j));
n2 = dot(J,k)/(norm(J)*norm(k));
l3 = dot(K,i)/(norm(K)*norm(i));
m3 = dot(K,j)/(norm(K)*norm(j));
n3 = dot(K,k)/(norm(K)*norm(k));
A = l1*l3+m1*m3+n1*n3
% Transformation matrix TR
TR = [1 0 0 0;
      X2 l1 m1 n1;
      Y2 l2 m2 n2;
      Z2 l3 m3 n3]
BR = inv(TR)*TR
M1new = inv(TR)*[1;M1]
```

```
M2new = inv(TR)*[1;M2]
M3new = inv(TR)*[1;M3]
```

D. BILL OF MATERIALS

Table D.1 shows the BOM for the various equipments required for the successful operation of the project. The table also shows the total cost of the project along with the quantity of items required. The softwares mentioned are one-time costs and the extendible head rest is also a one-time cost because it not customized to each patient.

Table D.1.
Bill of Materials with Vendor information

Bill of Materials						
Part Name	**Description**	**Part No.**	**Quantity**	**Unit Cost (in USD)**	**Material**	**Vendor**
Extendible headrest	Extendible Headrest	RT-4552MRI	1	6355	Carbon Fiber	Qfix
Locking Assembly	Stereotactic Frame Assembly	Manufactured part	1			
Standard Headrest	Silverman Headrest	MTSILVER2	1	181	Acetal	CIVCO
Head Support	Support to fix head	Manufactured part	2	100	PEEK	
Shoulder Device	Shoulder Retractable Device	MTCFHN006SUB6	2	926	Carbon Fiber	CIVCO
Accuform Cushions	Vacuum Bag	MTACL 1520	1	36	Porous resin beads	CIVCO
Sensor Holder Assembly	**Pressure Sensor Assembly**					
Sensor Holder	Base Frame	Manufactured part	1	100	PEEK	
Sensor Tube	Plastic Sensor Tube	Manufactured part	4	100	PEEK	
Sensor	Pressure Sensors	FlexiForce WB201	4	117	Polyester	Tekscan
Sensor software	Software to run the wireless sensors	WLF2-STD	1	1099		Tekscan
Sensor cable	Cable to connect the sensors	ZFLEX-FSEC-60	4	70		Tekscan
Sensor power supply	Flexiforce Wireless ELF power supply	WLF-A-PS	1	49		Tekscan
Spring	Spring	PKSP6-10-50	4	80	PEEK	SolidSpot
Marker	Spherical Markers		10	100	PEEK	Qualisys
Mimics Software	Image segmentation software	Materialise Mimics	1	8000		Materialise
Nose bridge	3D printed nose bridge part	Manufactured part	1	20	Ceramic	Sculpteo
Delrin Hand Grips	Constraining Pins	MT2504	2	200	Delrin	CIVCO
Total				**17533**		