A novel immobilization device dedicated to precise intracranial radiation treatments: clinical application and accuracy assessment

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Abstract

**Background:** Immobilization devices are crucial to minimize patient positioning uncertainties in radiotherapy (RT) treatments. Recently, a new immobilization device has been developed specifically for the radiation treatment of intracranial malignancies (Solstice ™ SRS Immobilization System, CIVCO Radiotherapy). To date, no data are available on the use of this device in daily clinical practice. The aim of this study is to investigate the intra and interfraction variations, patient comfort and radiographer confidence of the Solstice system from two distinct institutions.

This report includes data from HagaZiekenhuis, Den Haag, Netherlands and IRCCS Ospedale Sacro Cuore Don Calaria, Negrar, Italy. From both institutions, the inclusion criteria were: a) age > 18 years, (b) diagnosis of oncological brain disease eligible to RT, (c) informed consent. Exclusion criteria were: (a) patients not eligible to RT, (b) claustrophobic patients. Focusing on dose prescription, IRCCS Ospedale Sacro Cuore Don Calabria included patients eligible to standard fractionation or moderate hypofractionated, while HagaZiekenhuis enrolled only stereotactic radiation treatments. In all patients, the immobilization device was assembled during CT simulation. A short interview to the patient regarding the comfort of the device was conducted at the end of the simulation procedure. Additionally, simulation setup time and radiographers (RTT) procedures (i.e. mask preparation) were evaluated. Prior to the radiation treatment at least one pre-RT cone beam CT (CBCT) was performed to verify the position of the patients. Additional CBCT was acquired after the treatment in order to verify any possible variation in patient position during the treatment.

**Results:** A total number of 126 CBCT were analyzed from the match data of 16 patients treated in IRCCS Ospedale Sacro Cuore Don Calaria (10 diagnosed with brain metastases and 6 with primary central nervous systemic tumor) and 17 patients (all diagnosed with brain metastases tumor) treated in HagaZiekenhuis.

The median target volume was 436 cc (range 3.2-1628 cc) and 4.58cc (range 0.4-27.19cc) for IRCCS and Haga, respectively. For patients treated in IRCCS Sacro Cuore Don Calabria, the median dose prescription was 30 Gy (range 27-60 Gy) and median number of fractions 10 (range 3-30). In Haga the median dose prescription was 21 Gy (range 8-21 Gy) and the median number of fraction was 1 (range
All patients responded positive to the comfort of the mask. Median time request to RTT to perform with Solstice™ SRS Immobilization System was 9 minutes (range 6-12 minutes). In terms of comfort, all patients reported a good-to high level of satisfaction. Results of positioning uncertainties were comparable between the two institutes. The mean interfraction motion for all translational and rotational directions were <1mm (SD <4mm) and <0.5°(SD < 1.5°), respectively, while the mean intrafraction motions were <0.2mm (SD < 0.6mm) and 0.5° (SD < 0.6°).

**Conclusions:** This study demonstrates the efficacy and feasibility of the Solstice™ SRS Immobilization System, CIVCO Radiotherapy immobilization device in the intracranial radiation treatment. Both patient comfort and preparation time by radiographers are considered adequate. In combination with online daily imaging procedure, this device can achieve submillimeter accuracy required for stereotactic intracranial treatments.

**Introduction**

Accuracy in radiation treatment is considered one of the most relevant issues in modern radiotherapy (RT) [1]. This concept included two distinct aspects, the delivery of high radiation doses (e.g. stereotactic cranial and extracranial RT and hypofractionation) and the decrease in normal tissue irradiation. The chance to obtain this balance includes several aspects: i) the implementation in the definition and verification of the oncological target, supported by radiological and metabolic images (Image guided radiotherapy therapy – IGRT), ii) employing modern planning techniques (Intensity Modulated Radiotherapy – IMRT and volumetric modulated arc therapy – VMAT) and finally, during radiation delivery, iii) reducing the inter- and intrafraction motion with suitable immobilization devices (and, if available, real-time monitoring system such surface guided systems).

All immobilization systems designed for radiation treatment should meet several conditions. The capability of reducing positioning errors and the limiting patient movements alone are not considered sufficient. In fact, during radiation planning and delivery, the immobilization device should not obstruct the path of the beam or alter the surface dose. Additionally, a good comfort for the patient, short time for the construction of the device by radiographers and limited economical cost are also of utmost importance. One of the most relevant aspects recently explored in the literature was the role
of immobilization devices, focusing on intracranial stereotactic treatments [2–3]. Recently, a new immobilization device (Solstice™ SRS Immobilization System, CIVCO Radiotherapy) has been developed by CIVCO Radiotherapy (Kalona, USA), dedicated to the treatment of intracranial disease. To date, there are not data about its clinical application. The aim of this study is to evaluate the intrafraction and interfraction variations in patients treated with this immobilization system and to explore its potential future role in stereotactic brain treatments.

Material And Methods
In this observational study, we investigated the inter- and intrafraction variations of the Solstice immobilization device for precise intracranial radiation treatments. Moreover, we evaluated patient comfort and the time required for preparation by radiographers. Data collected from 2 different institutes, HagaZiekenhuis (Haga), Den Haag, Netherlands and IRCCS Ospedale Sacro Cuore Don Calaria, Negrar, Italy, was analyzed. From both institutions, the inclusion criteria were: a) age > 18 years, (b) diagnosis of oncological brain disease eligible to RT, (c) informed consent. Exclusion criteria were: (a) patients not eligible to RT, (b) claustrophobic patients. Focusing on dose prescription, IRCCS Ospedale Sacro Cuore Don Calabria included patients eligible to standard fractionation or moderate hypofractionated, while HagaZiekenhuis enrolled only radiosurgical patients.

Immobilization device and CT simulation
The Solstice system comprised of a carbon fiber head support, customizable accuform cushion, thermoplastic mask and, optionally, a thermoplastic Precise Bite™ mouth-bite (Figure. 1). The head support allows manual pitch setup errors correction by rotating the screw located at the back of the system. Two radiographers were responsible for the construction of the thermoplastic mask and customizable cushion for each patient. The total set up time was calculated from the recline patient position on the CT simulation couch up until the acquisition of CT images. Three distinct landmarks were positioned to the mask (1 frontal and 2 laterals). CT simulation was performed without contrast media and the scan length included the whole brain. Slice thickness varied between 1 to 3 mm, according to different treatment protocols.

At the end of each procedure radiographers reported in a specific form, any limitation or problem
recorded during the procedure (e.g. ease of mask use, lock stability and mask clips)). In both institutes, all patients were treated without the thermoplastic precise bite. After CT simulation, a radiation oncologist interviewed the patient in order to collect information about comfort. Radiation volumes, dose prescription and fractionation were chosen according to internal clinical protocols.

Positioning workflow

The general procedure for intracranial radiation treatment consisted of different phases: i) mask fixation; ii) landmark alignment to the laser; iii) automatic shift to the isocenter (delta movement); iv) acquisition of a cone-beam CT (CBCT); v) online correction of detected setup error; vi) RT delivery; vii) acquisition of post-treatment CBCT. In IRCCS Ospedale Sacro Cuore Don Calabria, all patients were treated with a TrueBeam™ (Varian Medical System) v. 2.0 Perfect Pitch configuration, due to the high precision in the definition of movement variation in all directions (6D positioning system). In Haga, all patients were treated with using Elekta Synergy Agility linear accelerator in combination with the pitch-rotational functionality available with the Solstice system.

The online imaging procedure were slightly different between the 2 institutes. In IRCCS, a CBCT was acquired before the radiation treatment. If the shifts in translational and rotational directions were ≤ 7 mm and 3°, respectively, a 6D correction was executed. If the tolerance was exceeded, the patient was repositioned and the entire procedure was repeated. In Haga, at least 2 CBCT’s were acquired before the radiation treatment. The first CBCT were acquired and setup errors in all translational directions were corrected. If a pitch rotational error of > 1° was detected, this would be manually corrected with the Solstice system. The accuracy of this adjustment was verified with a second CBCT. If all translational and rotational setup errors were smaller than 1 mm/3°, treatment fields will be delivered. In both institutes, a post-treatment CBCT was acquired with the aim to identify patient movements during the delivery. Rigid registration was performed on all scans based on bony anatomy and validated by experienced radiation oncologist or radiographer.

Set-up error, inter and intrafraction data collection

A standardized off-line procedure has been used to collect data, with the support of ARIA® version 15.1 – Varian™ (IRCCS) and Elekta XVI version 5.0 (Haga). Match values of all three translational axes
(x, y, z) and three rotational axes (roll, pitch and yaw) from the very first CBCT were recorded in order to establish the daily pre-treatment setup errors (interfraction variation). Similar procedure was used to match the post-treatment CBCT to the CBCT acquired right before treatment delivery (intrafraction variation). Additionally, in order to quantify the deviations in 3D space, a “displacement vector” (D vector) was defined from 3 axes data.

Results
Patients
Between January 2018 and August 2019, a total number of 126 pre and post treatment CBCTs were analyzed, from 16 and 17 patients with a diagnosis of intracranial oncological disease tumor treated at IRCCS and Haga, respectively. In IRCCS, ten (62.5%) patients had a diagnosis of brain metastases, while 6 (37.5%) reported a primary central nervous systemic tumor. All patient treated in Haga were diagnosed with brain metastases tumor. Median target volume was 436 cc (range 3.2–1628 cc) and 4.58 cc (range 0.4-27.19 cc) for IRCCS and Haga, respectively.

The median dose prescription was 30 Gy (range 27–60 Gy), and 21 Gy (range 8 Gy – 21 Gy) for IRCCS and Haga, respectively. The median number of fractions was 10 (range 3–30), and 1 (range 1–3) for IRCCS Calabria and Haga, respectively. The comfort while immobilized with the Solstice system was reported as excellent in 62% of the cases and good in the other 38%. The median setup time required was 8 minutes (range 6–12 minutes). The details of patient characteristics and dose prescriptions are listed in Table 1.

| Patient characteristics and dose prescriptions in IRCCS Sacro Cuore Don Calabria and HagaZiekenhuis |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| Number of patients (%) | 16 (100%) | 17 (100%) |
| Male (%) and female (%) | 7 (43.8%) and 9 (56.2%) | 10 (58.8%) and 7 (41.2%) |
| Brain metastases cases (%) | 10 (62.5%) | 17 (100%) |
| Primary CNS tumor cases (%) | 6 (37.5%) | 0 |
| Median target volume (cc) (range) | 436 (3.2–1628 cc) | 4.58 (0.40–27.19 cc) |
| Median dose prescription (range) | 30 Gy (27–60 Gy) | 21 Gy (8–21 Gy) |
| Number of fraction (range) | 3 (3–10) | 1 (1–3) |

CNS: central nervous system

Interfraction Variability

The interfraction variability was obtained by matching the first CBCT with planning-CT. The same radiation oncologist reviewed off-line the images to confirm the quality of the match, focusing on bone structures and air cavities matching. If the fusion was evaluated uncertain in terms of quality, a
second radiation oncologist completed a double check.

Mean and Standard deviation (SD) of the interfraction motion for both institutes for all translational and rotational directions are presented in Fig. 2. The mean 3D-vector displacement of the interfraction variability for IRCCS and Haga were 0.23 and 1.18 mm, respectively.

Intrafraction Variability
The intrafraction mean values were obtained by the match between pre-treatment CBCT and post-treatment CBCT. The mean and SD of the interfraction motion for both institutes for all translational and rotational directions are presented in Fig. 3. The mean 3D-vector displacement of the intrafraction variability for IRCCS and Haga were 0.13 and 0.26 mm, respectively.

Discussion
New technical planning improvements, including intracranial and extracranial stereotactic ablative treatment and IMRT, are significantly allowing the delivery of high radiation dose to the target, reducing significantly normal tissue exposure. These innovations could be perceived ineffective, if adequate immobilization devices are inapplicable.

Over the years, several non-invasive stereotactic immobilization system [4–8] and bite blocks [9–10] were introduced. Recently, a new open immobilization device has been developed by (Solstice™ SRS Immobilization System, CIVCO Radiotherapy), to support the treatment of central nervous system disease. Up to date, there are still no data about its clinical application.

For this reason, we conducted this multicentric study to analyze the intra and interfraction accuracy of the Solstice immobilization system during conventional and stereotactic treatment.

At first, we evaluated patient tolerability and radiographer comfort in the use of this immobilization device. The results of our experience reported that radiographers felt confident with the mask, observing a fast learning curve and a progressive decrease in time for mask preparation. In terms of comfort, all patients reported a good-to high level of satisfaction.

The results of inter and intrafraction variations of both institutes were comparable. For translational and rotational directions, the mean interfraction motion was < 1 mm (SD < 4 mm) and < 0.5° (SD < 1.5°), respectively. Daily IGRT procedure, using CBCT, is able to detect patient positioning errors.
Hence, these errors are usually corrected before treatment delivery. In terms of treatment accuracy, intrafraction motions play a more important role. In both institutes, the mean intrafraction motions for all translational and rotational direction were < 0.2 mm (SD < 0.6 mm) and 0.5° (SD < 0.6°), respectively. This is within the 1 mm PTV margin commonly used for stereotactic radiation treatment. Our results are comparable to current literature on non-invasive stereotactic immobilization systems, despite different measuring and statistical methods were applied [11–19]. One strength point of our approach was the comparison between pre- and post-treatment CBCT. As supported by the literature [11], the use of 6D couch allowed a high precision in detecting positioning variations. In particular, Guckenberger et al. demonstrated that the integration of image guidance significantly affects reducing set-up error from 3.9 ± 1.7 mm to 0.9 ± 0.6 mm [12]. In our experience, the set-up errors were 0.23 mm at IRCCS Ospedale Sacro Cuore Don Calabria and 1.18 mm (3D vector) HagaZiekenhuis respectively, confirming the CBCT accuracy for the isocenter identification.

Analyzing intrafraction motion, the current literature reported heterogenous results, due to the use of different immobilization system. Intrafraction 3D vector varied between 0.5 mm to 3.9 mm [13–17]. Our report shows superior intrafraction 3D vector displacement of 0.13 and 0.26 mm for IRCCS and Haga, respectively.

The interfraction positioning based on stereotactic coordinates is heterogeneous. Accuracy and reproducibility data about patient repositioning varied according to the immobilization system used (with or without bite block). Isocenter deviation varied between 0.5 mm ± 0.7 mm in the experience published by Minniti et al. [17] and 3.7 mm when mask immobilization was used alone [18]. Nevertheless, a more recent article published by Ramakrishna et al. [19] did not record any significant intrafraction variation in patients treated with radiosurgery using a frame-based versus a frameless image-guided system. Analyzing our data, the use of frameless radiotherapy supported by CBCT was associated with comparable results published in these literatures. We underline that a standard deviation of 10.9 mm in a single measure was documented to the “y axis”. This values was observed at the last radiation dose delivery in a patient with a lose weight during the radiation treatment, while the treatment mask consistency was preserved.
Conclusions
This report showed that Solstice TM SRS Immobilization System, CIVCO Radiotherapy is feasible and efficient for treating patients with intrafraction lesion. Additional good feedback has been reported by both patients and radiographers. In combination with daily CBCT, the Solstice system could achieve submillimeter positioning accuracy, which is required for high precision stereotactic treatment.

Abbreviations
RT: radiotherapy
SD: standard deviation
IGRT: imaged guided radiotherapy
IMRT: intensity modulated radiotherapy
VMAT: volumetric modulated arc therapy
RTT: radiographers
CBCT: cone beam computed tomography

Declarations
Ethics approval and consent to participate
All patients signed an informed consent for the treatment

Consent for publication
Not applicable.

Availability of data and materials
The patient information may be shared under ‘IRCCS Sacro cuore – Don Calabria’ hospital and HagaZiekenhuis, Den Haag, Netherlands. IRB approval of amendment on a case by case base. The Solstice™ SRS Immobilization System is proprietary CIVCO Radiotherapy due to patent protection.

Competing interests
Not applicable

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Authors’ contributions
OLC, NGL, FA conceived the study, analyzed and interpreted data and wrote manuscript;
LN, VF: collected data, review and revision of manuscript

DT: collected data

EMF: analyzed and interpreted data, review and revision of manuscript

All authors approved the final version of the manuscript.

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Figures

Figure 1

Solstice (TM) SRS Immobilization System, CIVCO Radiotherapy
Figure 2
Interfraction variability for patients treated in IRCCS and Haga

Figure 3
Interfraction variability for patients treated in IRCCS and Haga