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Original article

Feasibility evaluation of prone breast irradiation with the Sagittilt© system including residual-intrafractional error assessment

Évaluation de la faisabilité de l'irradiation du sein en décubitus ventral avec le système Sagittilt© et de l'erreur résiduelle pendant les fractions

suppl. Informations

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ABSTRACT

Purpose. – Feasibility evaluation of the Sagittilt© prone breast board system (Orfit Industries, Wijnegem, Belgium) for radiotherapy focusing on patient and staff satisfaction, treatment time, treatment reproducibility with the assessment of residual-intrafractional errors.
Material and methods. – Thirty-six patients underwent whole-breast irradiation in prone position. Seventeen received a sequential boost (breast: 42.56 Gy in 16 fractions, boost: 10 Gy in five fractions), while 19 patients received a concomitant boost protocol (breast/boost: 45.57/55.86 Gy in 21 fractions). Treatment verification included a daily online cone-beam CT (CBCT). In order to assess the residual and residual-intrafractional errors post-treatment CBCTs were performed systematically at the first five treatment sessions. Treatment time, patient comfort, staff satisfaction were also evaluated.
Results. – The pretreatment CBCT resulted in a population systematic error of 4.5/3.9/3.3 mm in lateral/longitudinal/vertical directions, while the random error was 5.4/3.8/2.8 mm. Without correction these would correspond to a clinical to planning target volume margin of 15.0/12.3/10.3 mm. The population systematic and random residual-intrafractional errors were 1.5/0.9/1.7 mm and 1.7/1.9/1.6 mm. Patient and staffs' satisfaction were considered good and average. The mean treatment session time was 21 minutes (range: 13–40 min).
Conclusion. – The Sagittilt© system seems to be feasible for breast irradiation and well-tolerated by patients, acceptable to radiographers and reasonable in terms of treatment times. Set-up accuracy was comparable with other prone systems; residual errors need further investigations.

Mots clés :
Cancer du sein
Radiothérapie en décubitus ventral
Précision du placement
Tomographie conique

RÉSUMÉ

Objectif de l'étude. – Évaluation de la faisabilité de l'irradiation du sein en décubitus ventral avec le système Sagittilt© (Orfit Industries, Wijnegem, Belgique) en étudiant la satisfaction du patient et du personnel soignant, le temps de traitement et la reproductibilité du traitement avec une évaluation de l'erreur résiduelle pendant les fractions.
Méthodes. – Trente-six patientes ont bénéficié d'une irradiation de la totalité du sein en décubitus ventral, 17 ont reçu un *boost* séquentiel (sein : 42,56 Gy en 16 fractions ; *boost* : 10 Gy en cinq fractions) et 19 patientes un *boost* concomitant (sein/*boost* : 45,57/55,86 Gy en 21 fractions). La vérification quotidienne du placement a été faite par une tomographie conique (CBCT). Pour évaluer l'erreur résiduelle pendant les fractions, une tomographie conique a été effectuée systématiquement après les cinq premières fractions. Le temps de traitement, le confort du patient ainsi que du personnel soignant ont également été évalués.

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Résultats. – La tomographie conique avant le traitement a mis en évidence une erreur systématique de 4,5/3,9/3,3 mm dans les directions latérale/longitudinale/verticale, l'erreur aléatoire était de 5,4/3,8/2,8 mm. Sans correction, cela correspond à une marge du volume cible anatomoclinique (CTV) au volume cible prévisionnel (PTV) de 15,0/12,3/10,3 mm. L'erreur systématique et aléatoire pendant les fractions étaient respectivement de 1,5/0,9/1,7 mm et de 1,7/1,9/1,6 mm. La satisfaction du patient était considérée comme bonne et celle du personnel comme moyenne. Le temps moyen de traitement était de 21 minutes (13–40 min).
Conclusion. – Le système Sagittilt© est utilisable en routine et bien toléré par le patient, il est acceptable pour le personnel soignant avec des temps de traitement raisonnables. La précision de la mise en place est comparable avec d'autres systèmes de traitement en décubitus ventral. De plus amples investigations sont nécessaires afin d'évaluer les erreurs résiduelles.

1. Introduction

Radiotherapy in supine position is the generally used treatment for early breast cancer after breast-conserving surgery [1]. Concerning large breast volumes, some efforts should be made to reduce the dose to the organs at risk [2–4] and to avoid hot spots within the target to prevent cardiac failure, secondary lung cancer, acute toxicity and impaired cosmetics [5–7]. To achieve these requirements various solutions exist, including the use of advanced radiotherapy techniques with or without deep inspiration breath-hold [8–10] or changing treatment position [5,11] or both [9,12,13]. One promising all-in-one solution could be the prone position. Prone position significantly reduces respiratory motions, lung doses and acute radiotherapy side effects as compared to supine position [5,9,14–18]. Prone position has already been shown to be superior for heart-sparing mainly in patients with large breast volumes [5,18,19]. Moreover, prone deep inspiration breath-hold opened a new horizon to further reduce the heart dose, even with small cup sizes, while maintaining the drastic dose reduction to the lungs [12,20]. One major drawback of prone position is the higher set-up error [13,14,16,21–24].

To date, several prone system are used in clinical practice [5,25]. However, comprehensive feasibility analysis of a certain product is lacking and the available data are rather addressed to the prone position itself than to other factors such as the applied immobilization system. Furthermore, the frequently used custom-made devices were either completely replaced or suffered considerable design change with time and the results of a test session are rarely published. Therefore, our group decided to pursue for a dedicated board that will serve as a baseline product for future developments as well. This stepwise project has been conducted by a team at the University Hospital of Liège (Belgium) in cooperation with Aeriane Company (Gembloux, Belgium) and Orfit Industries (Wijnegem, Belgium). The end-product is called Sagittilt©. In this paper, we present the following feasibility benchmarks of Sagittilt©:

- patient and staff satisfaction;
- treatment time;
- treatment reproducibility including the assessment of residual-intrafractional errors.

To our knowledge this is the first report on residual-intrafractional errors in prone position.

2. Material and methods

This study was approved by the institutional ethics committee. Thirty-six women underwent breast-conserving surgery for T1–2 invasive ductal/lobular carcinomas were included. Axillary/parasternal tumour bed location, nodal irradiation, poor general condition (ECOG ≥ 2) and comorbidities preventing holding the position were exclusion criteria. Patient and tumour characteristics are presented in Table 1.

Table 1
Breast cancer radiotherapy in prone position using the Sagittilt© system: patient and tumour characteristics.
Irradiation du sein en décubitus ventral avec le système Sagittilt© : caractéristiques des patientes et des tumeurs.

Variables	Values
Number of patients	36
Age, mean (range)	59 years (43–72 years)
Weight, mean (range)	71 kg (51–110 kg)
T stage	
T1a–c	28 (78%)
T2	8 (22%)
Breast side	
Right	23 (64%)
Left	13 (36%)
Localisation of tumour bed	
Internal quadrants	7 (14%)
Central	9 (30%)
External quadrants	20 (56%)
Tumour histology	
Invasive ductal	31 (86%)
Invasive lobular	5 (14%)
Cup size (%)	
A–B	6 (17%)
C–D	22 (61%)
> D	8 (22%)

Fig. 1 shows prone positioning on the Sagittilt© system, which consists of three components:

- the cranial part immobilizes the head and arms. The head resting on a forehead–chin bracket, the arms are braced at the elbows, and the patient grips a pair of handlebars;
- on the thoracic portion the index breast hangs free through a cut-out while the contralateral thorax is supported by a horizontal board;
- the caudal portion was designed to support the pelvis and lower extremities, with thermoplastic mask fixation.

All elements except the chin support are adjustable and indexed. The system is clamped onto the scan or treatment table using two alignment bars at the cranial and thoracic portion. The system can be tilted along the longitudinal patient axis to a maximum of 10° on each side by using a metal shaft which connect the cranial and caudal part underneath the breast bridge. Detailed patient set-up and simulation procedure as used in our centre are available on the Orfit website (http://www.orfit.com).

The clinical target volume (CTV) was the palpable breast volume plus any additional breast tissue visualized on CT, limited by 5 mm from skin and chest wall/lung interfaces. The tumour bed

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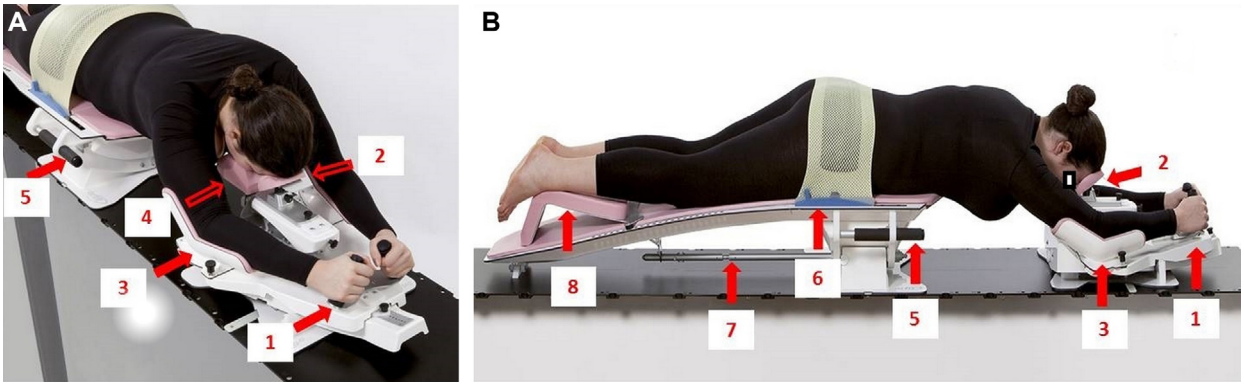

Fig. 1. Treatment set-up on Sagittilt© for prone breast irradiation (with permission of Orfit). A. Oblique view. B. Lateral view. 1: hand grips; 2: forehead support; 3: elbow support; 4: chin support; 5: lateral handle bar; 6: thermoplastic mask fixation; 7: metal shaft for tilting; 8: leg support.
Dispositif Sagittilt© pour l'irradiation du sein en décubitus ventral (avec la permission d'Orfit). A. Vue oblique. B. Vue latérale. 1 : poignées ; 2 : support front ; 3 : support coude ; 4 : support menton ; 5 : repose bras latéral ; 6 : fixation pour masque thermoplastique ; 7 : tige métallique d'inclinaison ; 8 : support jambes.

was defined by surgical clips, seroma and any architectural distortion. Planning target volumes were generated by the addition of 3D 5 mm margins to CTV, limited by 5 mm from skin surface. The boost was sequential for the first 17 patients and simultaneously integrated for the remaining 19 cases. The treatment planning system was Pinnacle V9.0–9.6 (Philips, Eindhoven, Netherlands). (Fig. S1, Suppl.) Fractionation schemes were the following: 42.56 Gy in 16 fractions for breast followed by a 10 Gy in 5 fractions boost, 45.57/55.86 Gy for breast/boost in 21 fractions [26].

Treatment verification included daily online kilovoltage cone-beam CT (CBCT; Elekta XVI system, Crawley, UK, [27]). (Fig. S2, Suppl.). Grey value registration with manual adaptation to the surgical clips was performed to the reference planning CT. The region of interest (clipbox) included the whole breast plus 2 cm using the centre of PTV as reference point. If necessary, afterwards manual adjustments were made to achieve optimal titanium-clip match. Only translational table shifts were applied. For the first five fractions, post-treatment CBCTs were acquired to evaluate residual-intrafractional errors.

Time span between patient entry and exit from the bunker were measured as well as the time slot between two CBCTs. The time taken to assemble the system was also registered. Patient comfort and staff satisfaction were evaluated by a 4-point score scale (1 – very poor, 5 – excellent) on the first and last week of the treatment.

CBCT registration results were analysed for each patient. Population systematic errors (P) and random (r) errors as well as CTV–PTV margins based on the van Herk formula ($2.5P + 0.7r$) were calculated [28]. For patient and staff satisfaction a radar representation was used to determine points where most improvements should be made.

3. Results

The pretreatment population systematic errors were 4.5/3.9/3.3 mm in lateral/longitudinal/vertical direction, while for the random errors the corresponding values were 5.4/3.8/2.8 mm. Without correction, these would correspond to a CTV–PTV margin of 15.0/12.3/10.3 mm. The population systematic and random residual-intrafractional errors were 1.5/0.9/1.7 mm and 1.7/1.9/1.6 mm, requiring a CTV–PTV margin of 5.0/3.6/5.4 mm, respectively (Table 2).

The mean overall patient comfort score was good, achieving 4.2 and 4.4 on the first and fourth week of the treatment (Fig. 2). There were slight differences between the different items. The lowest comfort score was achieved for the ribs (3.7) while the best score was reported for mask discomfort (4.8). The staff's scores were generally lower than patient comfort scores. The average difference was more than one point, reaching an overall average of 2.9 point (Fig. 2). Most frequent complaints were about set-up time, forehead position, reproducibility, head comfort (<2.6), while least with the use of thermoplastic mask (≥3). Radiographers complained about shoulder mobility as well, which resulted in difficulties in matching all tattoos in the reference plane.

Average time at which patients entered and left the treatment room was 21 minutes (range: 13–40 min). Time between two completed CBCTs varied between 7 min 15 s to 10 min 20 s (mean: 8 min). Assembling of the system took only 2 minutes on average.

4. Discussion

We aimed to present the feasibility of the Sagittilt© system, including residual-intrafractional errors.

In general, the system was comfortable for the patients (Fig. 2). As comparing to the UK group [14], we used a more detailed-point score scale to obtain not only a general impression but an exploration about the potential weak points of the system as well. During the preclinical phase pain in the forehead, chin, shoulder and rib were the most common symptoms. By changing the foam composition, these problems have almost disappeared, resulting in a comfortable final design for the patients (Fig. S3, Suppl.). Similarly to other group's observation [14], the staff was less satisfied with the system comparing with the conventional supine position practice. The main concerns were set-up/treatment time, shoulder mobility, forehead comfort and positioning. Treatment time has been reported to be significantly longer or equivalent for prone compared to supine positioning [13,14,16]. Our average time slot of 21 min is comparable to these findings (19–21.2 min). The lower staff satisfaction can be partially explained by the frequent turnover at the machines (one main campus, three satellites), compromising the individual learning curve. This likely contributed to larger set-up errors and relatively long treatment sessions as well. Supraclavicular nodal radiotherapy might also be feasible with Sagittilt© due to a large clearance at the ipsilateral upper thorax–shoulder region. On the other hand, this was leading to larger shoulder movements, as it was reported by our staff, however it was considerably reduced by enhancing the elbow support (Fig. 1). Altogether 7 of 43 patients were switched to supine during simulation. Two patients with fibromyalgia were not able to keep the position permanently. In two other cases, the clips were found in the parasternal region. The chin support is the only element which is not adjustable, thus it was difficult or even impossible to centralize the breast within the cut-out area for three patients with short neck. This part of the

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Table 2
Breast cancer radiotherapy: set-up accuracy in prone position assessed by cone-beam CT (literature review).
Radiothérapie du cancer du sein : reproductibilité du traitement en décubitus ventral évaluée par tomographie conique (revue de la littérature).

Studies	Whole or partial-breast irradiation	Number of patients	Method	Error (mm)						CTV–PTV margin (mm)		
				Population systematic			Population random					
				Right–left	Superior–inferior	Anterior–posterior	Right–left	Superior–inferior	Anterior–posterior	Right–left	Superior–inferior	Anterior–posterior
Veldeman et al., 2010 [23]	Whole	10	CBCT	3.6	5.6	3.6	3.6	2.6	3.2	11.5	15.8	11.2
Jozsef et al., 2011 [22]	Partial	70	CBCT	2.8	2.1	3.8	3.7	2.9	4.3	9.6	7.3	12.6
Kirby et al., 2011 [14]	Whole	25	CBCT	3.1	4.3	3.4	3.8	5.4	4.2	11.5	15.6	12.5
Ahunbay et al., 2012 [21]	Partial	10	CT							13.9[a]	–	–
Veldeman et al., 2012 [16]	Whole	10	CBCT	0.6	0.8	7.2	3.8	6.9	4.4	4.2	6.9	21.1
Bartlett et al., 2015 [13]	Whole	34	CBCT	5.9	6.5	5.2	5.4	4.5	4.6	–	–	–
Mulliez et al., 2016 [24]	Whole	139	CBCT	6.4	4.3	3.3	9.2	4.3	3.4	22.4	13.7	10.5
Present study, 2016	Whole	36	CBCT	4.5	3.9	3.3	5.4	3.8	2.8	15.0	12.3	10.3
			Residual-intrafractional error	1.5	0.9	1.7	1.7	1.9	1.6			

CBCT: cone-beam computed tomography; CTV: clinical target volume; PTV: planning target volume.
[a] No directional values were given.

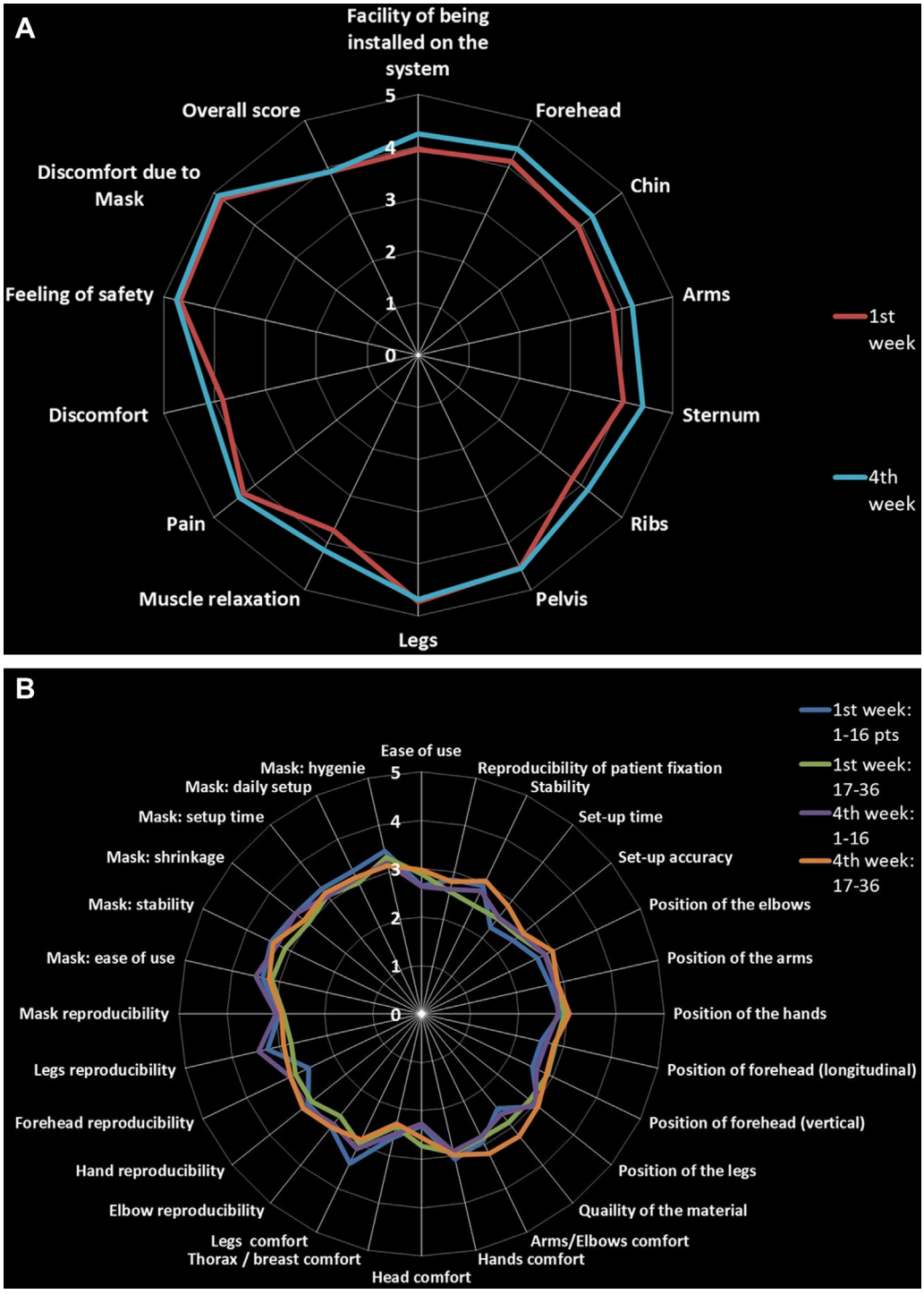

Fig. 2. Evaluation of the Sagittilt© system for prone breast irradiation: radar representation of patient comfort and radiographer satisfaction on the 1st and 4th week of treatment. A. Patient comfort. B. Radiographer satisfaction. Scores are presented separately for the first and second phase of the study.
Utilisation du système Sagittilt© pour l'irradiation du sein en décubitus ventral : représentation « radar » des scores mesurant le confort du patient et la satisfaction du personnel soignant pour la première et la quatrième semaine de traitement. A. Confort du patient. B. Satisfaction du personnel soignant. Les scores sont représentés séparément pour la première et seconde phase du traitement.

system needs further improvements, while parasternal clip localization, shoulder or back pain can be overcome by proper patient selection and tilted position.

The population systematic and random errors achieved by Sagittilt© were comparable to studies with daily CBCT verification [13,14,16,21–24] (Table 2). Notably, the direction of the largest margin varied across these published data. Our calculated CTV–PTV margins were 15.0/12.3/10.3 mm in right–left/superior–inferior/anterior–posterior directions, respectively. Prone treatments would require more than 10 mm CTV–PTV margin at least in one direction, while for supine it is consistently less than 10 mm in each direction [5,14,23]. Factors which may influence set-up errors included system type, platform design (flat/tilted), set-up technique (breast–torso-oriented), set-up verification (EPID/CBCT), CBCT registration method (clip and/or chest wall), learning curve, study design and patient related factors

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(body mass index) [14,16,21,23,24]. Despite the heterogeneity of the above mentioned factors in the previous studies, the achieved reproducibility remained more or less the same.

Pretreatment CBCT is meaningful in reducing the initial set-up error, while it is not able to determine which margin should be applied as residual-intrafractional errors may contribute to treatment accuracy. Cai et al. reported the magnitude of residual-intrafractional errors in CBCT-guided supine partial-breast irradiation [29]. They found that even with 3 mm action level, the residual-intrafractional errors were similar to the skin marker set-up errors detected by pretreatment CBCT. In prone position, where patients are positioned with a natural or artificial rolling along with a prolonged treatment time and larger set-up errors, such an investigation would be essential. To our knowledge this is the first publication on residual-intrafractional errors in prone position. In our analysis population systematic and random residual-intrafractional errors were 1.5/0.9/1.7 mm and 1.7/1.9/1.6 mm in right–left/superior–inferior/anterior–posterior directions, requiring a minimum of 5 mm CTV–PTV margin. The reduction of pretreatment set-up errors was about fifty percent in superior–inferior and right–left directions while remaining moderate in anterior–posterior direction. This latter is probably explained by the attributing effect of gravity. These errors could be partly linked to longer treatment time allowing more patient relaxation/movement. Moreover, the second CBCT prolongs the board on time by one minute. Larger set-up errors require larger couch shift movements and patients unavoidably react to the couch movement [16]. We did not acquire CBCT images immediately after correction thus we cannot quantify either the contribution of this factor or the accurate onset of residual-intrafractional errors.

Darby et al. found a relationship between the doses of radiation to which the heart is exposed and ischemic cardiac events, and Grantzau et al. found a relationship between the dose delivery to the lungs and secondary lung cancer [2,3]. Lung sparing effect is a clear advantage of prone position. However, cardiac protection is still a debatable question due to gravity-induced anterior heart displacement toward the irradiated region [13,30,31]. Dosimetric data showed that whole-breast irradiation is superior in prone position over supine position for heart-sparing, especially in patients with large breast volumes [18,19,32]. On the other hand, comparative dosimetric data are available, supine deep inspiration breath-hold treatment is better at heart-sparing than treatment using a free-breathing prone technique [13,30]. However, introduction of deep inspiration breath-hold in prone position showed comparable effect to supine deep inspiration breath-hold concerning heart dose while maintaining lung protective effect [12,20]. Dosimetry analysis did not form the part of our publication, however preliminary reports with acute toxicity have been already presented on international podium [33].

Another advantage of prone position would be that the influence of treatment techniques on treatment quality is less pronounced. Hardee et al. have questioned the need of intensity-modulated radiotherapy (IMRT) in prone [34]. They found that breast IMRT significantly improved dosimetry but provided only a modest benefit in terms of toxicity. Moreover, they concluded that if simultaneous integrated boost is not planned, 3D conformal radiotherapy can be an adequate approach for prone whole-breast irradiation. Similarly, Mulliez et al. found only rather small dosimetric differences between tangential-field and multibeam IMRT in prone position [9].

5. Conclusion

We reported a comprehensive feasibility assessment of the Sagittilt© system. It appears to be feasible and well-tolerated by patients, acceptable to radiographers and reasonable in terms of treatment times. Set-up errors were comparable with other prone systems. Residual errors need further investigations, this kind of evaluation is recommended for all available system.

Disclosure of interest

Professor Philippe Coucke declares that a patent request for Sagittilt© has been submitted (decision still pending) and there is a commercial agreement between the University hospital of Liège, the manufacturer and the distributor of the Sagittilt©. The other authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.canrad.2016.05.014.

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