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A randomised comparison of three different immobilisation devices for thoracic and abdominal cancers

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Abstract

Introduction: Patient immobilisation is critically important for both highly conformal conventionally fractionated radiotherapy and for stereotactic body radiotherapy. Different immobilisation devices are available to maintain patient position for radiotherapy but the most suitable one remains unknown. **Methods:** Forty-five patients were randomly allocated to one of three immobilisation devices; the Q fix arm shuttle, BodyFIX without wrap or BodyFIX with wrap. Patients were imaged before and after treatment to ascertain intra-fraction and inter-fraction motion. Bony anatomy was used for matching to determine the positional accuracy of each device. Treatments were timed using a standard method. Patient comfort and staff satisfaction questionnaires were also issued to determine comfort, ease of use and preferences for each device. **Results:** The BodyFIX without wrap was the more accurate device; however, the differences between the devices were not statistically significant. The BodyFIX with wrap was found to take significantly longer to set up and set down compared to the arm shuttle and the BodyFIX without wrap (all $P < 0.001$). Patients (37%) marginally preferred the BodyFIX with wrap. Most (81%) staff preferred the BodyFIX without wrap. **Conclusion:** Immobilisation using the BodyFIX without wrap was deemed to be suitable for clinical use. It was a clinically accurate device, the more efficient in terms of set up and set down time, the most preferred by staff and was accepted by patients.

Introduction

Patient immobilisation is important for conventionally fractionated radiotherapy and stereotactic body radiotherapy (SBRT).[1–6] The risk of a geographical miss or positioning error for hypo-fractionated techniques can be greater than with conventional fractionation.[1,7–13] There are a number of immobilisation devices available, with most research being for SBRT, however, even for this indication unknowns remain. In a survey of Japanese centres delivering SBRT, rigid immobilisation is used in most centres, with 11% using the BodyFIX system, 69% the Elekta stereotactic body frame and 20% using a combination of other devices, yet they did not compare the effectiveness of these devices.[14,15] Han et al.[7] compared the use of the BodyFIX system with wrap, the BodyFIX Blubag alone and with the abdominal compression plate (ACP). The results showed a decrease in motion in all three directions when applying vacuum pressure using the BodyFIX system, reducing tumour motion in the superior-to-inferior direction from 6.1 mm with free breathing to 5.3 mm with the vacuum pressure.

Winnie et al.[4] investigated the effect of performance status and immobilisation on intra-fraction motion and treatment time, finding that the evacuated cushion with abdominal compression was the most consistent, with 73% mid-treatment and 68% post-treatment still being within a 3 mm tolerance, whereas the chest board alone had only 58% mid-treatment and 46% post-treatment. The evacuated cushion with abdominal compression had the longest treatment time of 32.54 ± 8.07 min. The authors did not state how this time was achieved, however, for an SBRT patient this difference is small, but when using conventional fractionation, additional time could reduce efficiency when treating a longer course and may influence the decision to use the device or not.[4] Siva et al.[16] compared the BodyFIX system versus no BodyFIX system on the volume of tumour motion, finding that the immobilisation reduced the volume of tumour displacement by a mean of 83% ($P = 0.021$). Dahele et al.[17] were the only group to investigate the immobilisation of the patient without a rigid device for SBRT, looking at bony anatomy matching. They stated that when matching to bone, they managed to achieve 84% of fractions being within 1 mm translation and 1.5° rotation.[17] There is little literature available investigating patient and staff perspective on comfort and ease of use of the different immobilisation devices.

We examined patients having conventionally fractionated treatment, with a view to use the most suitable immobilisation device for both conventionally fractionated treatments and the implementation of SBRT. We undertook a comparison of the three indexed immobilisation devices including a range of relevant endpoints, to determine which immobilisation device: minimises inter-fraction and intra-fraction patient motion; is the most efficient and suitable to use; patients find acceptable (in terms of comfort and positional security); staff prefer in terms of reproducibility and ease of use.

Methods

The research proposal was approved by the Department of Health WA Human Research Ethics committee and Sheffield Hallam University Dissertation Management Group. The additional imaging doses delivered were approved by the Radiological Council of WA. All study participants gave written informed consent prior to participation.

The study was conducted between April 2013 and November 2014, with patients selected according to the inclusion and exclusion criteria shown in Table 1. Patients receiving either thoracic or abdominal radiotherapy were included as they use the same immobilisation and both encounter respiratory-associated tumour motion. Based on previous imaging data, a sample size of 45 was adequately powered to detect clinically important differences with 5% significance and 80% power. Forty-eight patients were entered into the study, although three patients were later removed from the study due to patient request or a change in treatment. Forty-five patients were evenly randomised into three study groups using the ‘sealed envelope’ method. This method removed sampling bias as the staff were not aware of the study arms at allocation as these were sealed blindly in an envelope, prior to booking their treatment.[18]

Table 1. Inclusion and exclusion criteria.

Inclusion:	Exclusion:
Patients only allocated to Varian OBI/ Varian Exactrac treatment linacs	Paediatric patients (less than 18 years old)
Any thoracic or abdominal tumour, treated with radical intent	Patients with intellectual disability or cognitive impairment
	Patients unable to maintain their position throughout treatment
	Patients weighing 150 kg or more

The patients were immobilised supine according to randomisation: (1) The Q Fix arm shuttle (the department’s standard immobilisation device for lung and upper abdomen patients); (2) BodyFIX blubag and (3) BodyFIX blubag with vacuum wrap. These devices are shown in Figure 1. The Q Fix arm shuttle is an indexed chest board system with winged sides to support the arms, moveable head rest and hand poles. The BodyFIX is an evacuated vacbag system that shapes to the contour of the patient. The blubag can also be formed with a vacuum wrap sealing the patient’s body within the system under an allocated vacuum pressure up to a maximum of 100 mbar.

All patients were scheduled for 20–36, 1.8–2 Gray fractions on a 6/18 megavoltage (MV) linear accelerator with a kilovoltage (kV) imaging system. Orthogonal images were scheduled daily before and after treatment, with all isocentre shifts being performed online by the treating radiation therapists (RTs), assessing spine, carina, chest wall and ribs for guidance. The images were re-matched by five suitably trained RTs to examine the differences between the pre-treatment computed tomography (CT) to treatment positional changes for inter-fraction motion and the post-treatment images for intra-fraction motion.

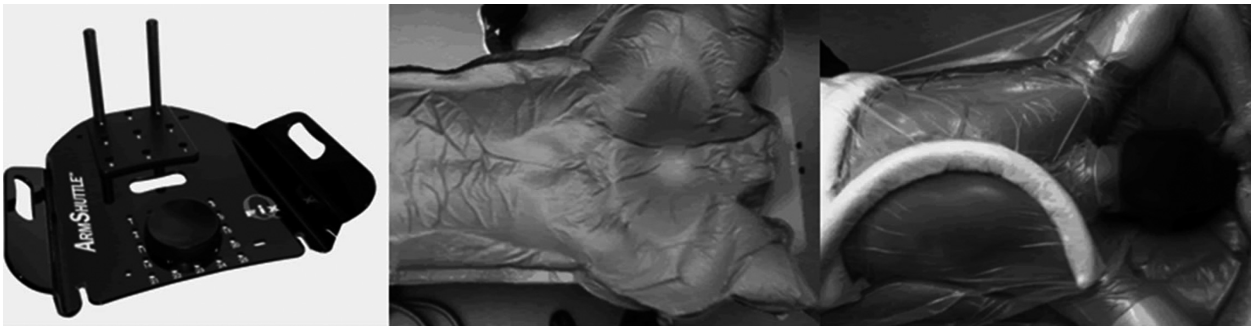

Figure 1. Photographs of the three devices (from Left to right): Q-Fix Arm shuttle, BodyFIX without vacuum wrap and BodyFIX with vacuum wrap.

Overall distance was calculated from the co-ordinates in each direction, using the three-dimensional (3D) vector (Pythagorean formula for the Euclidean distance in a 3D space).[9,11,19] The effect of distance moved during treatment was investigated using repeated measures analysis with linear mixed models. Fixed effects of time, device and device by time were included in the model as well as random effect of individual within device. The response, overall distance, was log transformed for analysis purposes. All treatments were timed by the RTs for set up duration (from the time the patient got onto the bed, into treatment position, until the RTs left the treatment room) and set down (beam-off time to the patient getting off the treatment couch). These times were analysed with a one-way analysis of variance (ANOVA) to determine whether set up and set down durations differed across the devices. Summaries of overall distance are reported as median (and inter-quartile range (IQR)) while times are reported as mean (and standard deviation).

The patients received a pre-treatment questionnaire at the CT appointment and a post-treatment questionnaire on the last fraction to assess how comfortable and secure they felt in the allocated immobilisation device. These were given to the researcher anonymously. Staff were allowed 1 month to complete an anonymous online satisfaction questionnaire on completion of the study to gauge their opinions. Both questionnaires had been assessed for content and validity in a pilot study undertaken by the BodyFIX-trained team.

Results

Image data analysis

The image data were analysed for 41 of the 45 patients in this study. Patients 34, 37, 41 and 42 (two from BodyFIX without wrap and two from BodyFIX with wrap groups) were removed from analysis due to incomplete data, as no post-treatment images were taken for these patients due to differing matching requirements. A summary of the absolute translations in each direction and overall distance moved from the planned isocentre to the treatment isocentre is provided in Table 2. The smallest overall distance moved was the BodyFIX without wrap with a median of 4.4 mm (IQR 2.14), whereas the BodyFIX with wrap had the largest median of 6.6 mm (IQR 2.27). The absolute translations in each direction were similar across all devices. The IQR of overall distance was smaller for the BodyFIX without wrap suggesting more reliable stabilisation. In comparison, there were relatively large maximum values for the left-to-right direction for the arm shuttle and the superior-to-inferior direction for the BodyFIX with wrap, indicating some weakness in these devices for these directions.

Differences in overall distance were investigated by assessing the linear mixed effects model pairwise

Table 2. Summary statistics for absolute translations (mm) and overall distance (mm) by device.

Device	Variable	*N*	Median	IQR	Min	Max
Arm shuttle	Left–right	15	2.18	2.16	0.16	16.34
	Superior–inferior		2.31	2.65	1.33	9.77
	Anterior–posterior		2.01	2.57	0.95	5.15
	Overall distance		5.25	5.52	2.01	16.49
BodyFIX without wrap	Left–right	13	1.87	1.25	0.12	6.27
	Superior–inferior		2.55	1.8	0.02	6.6
	Anterior–posterior		2.05	2.34	0.26	4.13
	Overall distance		4.38	2.14	2.25	9.21
BodyFIX with vacuum wrap	Left–right	13	2.01	1.45	0.31	5.55
	Superior–inferior		4.90	5.39	0.3	13.55
	Anterior–posterior		1.95	2.37	0.21	7.51
	Overall distance		6.61	2.27	3.09	14.05

IQR, inter-quartile range; Min, minimum; Max, maximum.

comparisons of device by time point. There were no significant differences in overall distance for any comparison of devices within intra-fraction images (all $P > 0.05$). However, for inter-fraction motion, the BodyFIX with wrap was significantly larger in terms of overall distance moved than both the arm shuttle (median 8.7 vs. 6.2 mm; $P = 0.021$) and BodyFIX without wrap (8.7 vs. 6.0 mm; $P = 0.002$). Similarly, for the same comparison within intra-fraction images, there was no significant difference in inter-fraction overall distance between the arm shuttle and BodyFIX without wrap (6.3 vs. 6.0 mm; $P = 0.340$).

Treatment timings

Summary statistics for set up and set down durations for each device are provided in Tables 3 and 4. Overall differences in devices for set up and set down times were compared using one-way ANOVAs. The BodyFIX with wrap took significantly longer than both the BodyFIX without wrap (mean 7.92 vs. 2.23 min; $P < 0.001$) and the arm shuttle (7.92 vs. 2.80 min; $P < 0.001$). Furthermore, it took significantly longer to set down the BodyFIX with wrap compared to both the BodyFIX without wrap (1.51 vs. 0.60 min; $P < 0.001$) and arm shuttle (1.51 vs. 0.60 min; $P < 0.001$). Conversely, there was no significant difference between the BodyFIX without the wrap and the arm shuttle for set up (2.23 vs. 2.80 min; $P = 0.185$) or set down (0.60 vs. 0.60 min; $P = 0.962$).

Patient preferences

The response rate for the pre-treatment questionnaire was 98% (47/48) of patients, with a reduction in the post-treatment questionnaire response rate to 80% (36/45). From the pre-treatment questionnaire, the patients were asked to choose their preferred device, based on the descriptions in the participant information leaflet. The results showed that 38% (18/47) would choose the BodyFIX with wrap.

Table 3. Summary statistics of overall distance (mm) from mid-point separated by device and time point.

Time point	Group	Median	IQR	Min	Max
Pre	Arm shuttle	6.25	4.70	3.65	16.20
	BodyFIX without wrap	5.96	2.00	4.31	11.28
	BodyFIX with wrap	8.72	1.80	6.24	15.01
Post	Arm shuttle	1.60	0.70	1.01	2.54
	BodyFIX without wrap	1.53	0.60	0.85	2.10
	BodyFIX with wrap	1.64	0.30	1.36	2.41

Pre-treatment images equate to inter-fraction motion (from planning CT to treatment setup), whereas post-treatment images equate to intra-fraction motion (motion during treatment.). IQR, inter-quartile range; Min, minimum; Max, maximum.

Table 4. Summary of the set up and set down durations (minutes) separated by device.

Duration	Device	*N*	Mean	Standard deviation
Set up	Arm shuttle	15	2.80	0.95
	BodyFIX without wrap	13	2.23	0.49
	BodyFIX with wrap	13	7.92	1.32
Set down	Arm shuttle	15	0.60	0.22
	BodyFIX without wrap	13	0.60	0.30
	BodyFIX with wrap	13	1.51	0.36

Staff preferences

The staff questionnaire had a response rate of 63% (42/67). Eighty one per cent (34/42) of RTs preferred the use of the BodyFIX without the vacuum wrap. When asked 'how they would rate their confidence levels using the bodyFIX without wrap', 93% (39/42) reported being confident or very confident. Conversely, only 50% (21/42) reported being confident or very confident using the BodyFIX with the vacuum wrap, with a further 26% (11/42) not being confident or not very confident. Overall, the RTs preferred the BodyFIX system's ability to maintain the patient position with 69% (29/42) describing the system as good or excellent, whereas the current immobilisation (arm shuttle) only had 14% (6/42).

Discussion

We assessed the three candidate immobilisation devices using several different endpoints. While the devices were similar for some endpoints, there was a clearly preferred device overall.

Inter-fraction/intra-fraction stability

The data suggest that the BodyFIX without wrap is the most effective, and the BodyFIX with wrap the least effective, device for maintaining patient position. Although not statistically significant, small differences in the range of motion and stability of a device might be clinically important when treating with tighter margins and hypo-fractionated treatment. The BodyFIX with wrap had large inter-fraction variations in the superior-to-inferior direction (see Table 2), which the literature agrees with this worsening during treatment.[4] The BodyFIX without wrap had the smallest range of movement and overall maintains the patient position to millimetre accuracy which is a requirement for SBRT.[16,20,21]

The results are comparable by Han et al.[7] with the mean movement being less than 1 mm across all BodyFIX devices and Wang et al.[22] reporting the majority of intra-fraction errors being less than 3 mm and overall motion of 1.4 mm using the alpha cradle. These studies both assessed tumour motion, achieving a high level of immobilisation, and cannot be directly compared to this study, but highlight the effectiveness of rigid immobilization, including the BodyFIX system.[7,22]

In this study, the post-treatment image results show that there is minimal intra-fraction movement of the patient. These differences could have been influenced by the online shifts performed by the RT matching the images online, highlighting some minor differences between treating staff and the five trained image reviewers. There is no statistical difference between the three devices, which correlates with the results from other studies, having mean intra-fraction differences of less than 1 mm for bony anatomy matching and 3 mm for tumour matching.[4,5,16,17,19]

Treatment times

The BodyFIX without wrap was the most efficient in terms of set up duration, but not significantly different from the arm shuttle. However, when compared to the BodyFIX with wrap, this difference in set up time is clinically important, as it is more beneficial to patient comfort. As prolonged treatment times can increase patient discomfort, reducing the treatment duration can result in less intra-fractional movement.[4,12] The literature notes a similar pattern with treatment times from verification to post-treatment cone beam CT (CBCT), with the vacuum fixation time of 29.40 ± 5.57 min as opposed to 24.17 ± 5.54 for the evacuated cushion only group.[5] Winnie et al.[4] demonstrated similar efficiency to this study, with the evacuated cushion with abdominal compression taking the longest time of 32.54 ± 8.07 min, the evacuated cushion time of 29.33 ± 8.20 min and chest board time of 30.17 ± 5.56 min. They also demonstrated higher accuracy in the evacuated cushion and abdominal compression over the chest board and evacuated cushion groups, however, as per this study, was not statistically significant.[4] The set up times in our study were a lot shorter than those of Han et al.[7] who used the BodyFIX with vacuum wrap, taking between 21 and 40 min, however, it was not clearly stated how these times were measured.

Patient preferences

Patient preference regarding the device they would choose appears to have been influenced by the immobilisation device that they were allocated to despite the question asking ‘from reading the descriptions, which device do you feel would be most comfortable for you?’. Although potentially biased it does suggest that patients tolerated a range of devices. From the responses, there could be a lack of understanding or lack of reading the participant information. As the preferences of device were not statistically significant, it would have been beneficial to assess the patients’ opinions at pre-treatment, improving patient understanding and reducing potential bias from the patients’ options by immobilising them on each device before their CT appointment, as Han et al.[7] did. In a study by Han et al.,[7] 21% of patients preferred the vacuum wrap; however, in this study 30% (14/46) patients on the study or 88% (14/16) in the BodyFIX with wrap arm found the BodyFIX with wrap to be comfortable or very comfortable at the pre-treatment questionnaire and 33% (13/39) at post-treatment. One patient (3%) described being uncomfortable in the BodyFIX with wrap at the post-treatment questionnaire, which could suggest this patient did not tolerate the abdominal pressure.[7,9] The devices that patients thought were the most secure and prevented movement tended to be the BodyFIX without wrap and BodyFIX with vacuum wrap which in conjunction with the literature, staff opinions and imaging results suggest that these are strong accurate immobilisation devices.[3,8,23]

As patients who were identified as unlikely to maintain their position during treatment were excluded from entry on the study, factors including co-morbidities and difficulty in breathing were not taken into account. One patient resigned early from the BodyFIX with vacuum wrap study arm after 20 fractions as they could not tolerate the vacuum pressure. This could be a problem for patients with breathing difficulties receiving radiotherapy for lung cancer.[7,9]

All devices were accepted by patients and the clinical benefits of stable immobilisation and the potential to reduce tumour motion are more likely to outweigh these small preferences. In our study, any delays in treatment from day of immobilisation device preparation due to chemotherapy reduced the effectiveness of the BodyFIX system as the patient size had changed slightly with weight loss. Although this may influence the imaging results, these changes did not require a re-simulation. Poorly fitting immobilisation, large variations in treatment verification images and separation changes would warrant re-simulation. Removing data for four patients due to lack of post-treatment image data reduced the effectiveness of the sample size calculation for the inter- and intra-fraction motion slightly.

Staff preferences

Little literature exists on staff preference, but is worth consideration when implementing a new immobilisation device. The staff questionnaires had a high response rate, with 81% of staff preferring the use of the BodyFIX without wrap. The reduced treatment time could influence the RT's opinion on the most effective immobilisation device, in addition to the ease of using this device. The lower confidence levels of staff when using the BodyFIX with wrap could have influenced the decision to choose the BodyFIX without wrap as staff were more comfortable using this and more confident. As the study progressed, staff became more familiar with the different devices and this was highlighted as staff who had treated more patients had higher confidence levels than those who had only seen a few. Although training was given to all staff in the use of the BodyFIX system, confidence was still low when using the vacuum wrap. This could have influenced the ability to use the device to its optimum and therefore decreased the accuracy of the device.

A key strength of this study was that it was randomised with a clear method described, which other studies comparing immobilisation systems did not report, therefore reducing the risk of bias within the results.[8,13] There were also good response rates on questionnaires from both patients and staff. Further studies could investigate which device best restricts internal organ motion and tumour motion, comparing the BodyFIX blubag alone, BodyFIX system with the vacuum wrap and the BodyFIX blubag with ACP.

This study was conducted with patients receiving conventional radiotherapy fractionation rather than hypo-fractionated SBRT. Daily kV imaging alone, however, is insufficient to adequately localise a tumour for SBRT.[3,7,24] At the time of this study, daily cone-beam imaging and other methods to account for respiratory-induced tumour motion could not be assessed due to limited resources and staff training. However, with rapid changes in technology, a drive for staff training and additional resources, this imaging modality could be introduced, meeting the Australian and New Zealand Guidelines for safe practice of SBRT.[24] In addition, higher doses per fraction with SBRT could mean longer treatment times, which might in turn influence intra-fraction motion. The ideal immobilisation device for SBRT remains uncertain.

Conclusion

The BodyFIX without wrap was the device chosen for clinical implementation as it is a suitable immobilisation device, is the most efficient in terms of set up time and was most preferred by staff in terms of accuracy, efficiency and staff confidence**.**

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Conflict of Interest

The authors declare no conflict of interest.

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