Original Article

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Comparison of Two Different Immobilization Devices for Pelvic Region Radiotherapy in Tomotherapy

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The purpose of this study was to compare the patient setup errors of two different immobilization devices (Feet Fix: FF and Leg Fix: LF) for pelvic region radiotherapy in Tomotherapy. Thirty six-patients previously treated with IMRT technique were selected, and divided into two groups based on applied immobilization devices (FF versus LF). We performed a retrospective clinical analysis including the mean, systematic, random variation, 3D-error, and calculated the planning target volume (PTV) margin. In addition, a rotational error (angles, ^{o}) for each patient was analyzed using the automatic image registration. The 3D-errors for the FF and the LF groups were 3.70 mm and 4.26 mm, respectively; the LF group value was 15.1% higher than in the FF group. The treatment margin in the ML, SI, and AP directions were 5.23 mm (6.08 mm), 4.64 mm (6.29 mm), 5.83 mm (8.69 mm) in the FF group (and the LF group), respectively, that the FF group was lower than in the LF group. The percentage in treatment fractions for the FF group (ant the LF group) in greater than 5 mm at ML, SI, and AP direction was 1.7% (3.6%), 3.3% (10.7%), and 5.0% (16.1%), respectively. Two different immobilization devices were affected the patient setup errors due to different fixed location in low extremity. The radiotherapy for the pelvic region by Tomotherapy should be considering variation for the rotational angles including Yaw and Pitch direction that incorrect setup error during the treatment. In addition the choice of an appropriate immobilization device is important because an unalterable rotation angle affects the setup error.

Key Words: Tomotherapy, Immobilization, Setup error, MVCT

Introduction

It is important that highly radiation delivered to the tumor include reduced the normal tissues in order to achieve highly the therapeutic ratio (TR). The intensity modulated radiation therapy (IMRT) with the image guided radiotherapy (IGRT) have a key part to precisely delivery targeting.[1] Especially, verification of the targeting error and correct to the residual errors has demanded in IMRT due to highly dose gradient to target area or the organ at risks (OARs) during the treatment. Target miss according to patient setup uncertainty gave rise to the complication of normal organs and decrease TR factor after treatment. However, verifying of patient setup uncertainty before treatment is important to accuracy delivery and increase treatment effects.[2]

Tomotherapy (Accuray Inc, Sunnyvale, CA, USA) is a special modality that consists of the computed tomography (CT) platform and a linear accelerator (LINAC) with continuously helical rotational delivery include IGRT by the megavoltage-

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CT (MVCT).[3] MVCT images are acquired by the nominal energy of the incident electron beam to 3.5 MeV and detecting the transmitted photon through a panel consisting of Xenon detectors, and although MVCT images are not used for diagnostic purposes, it is sufficient to patient setup verification and correct target miss in treatment.[1,4] For correction directions, translational directions (medio-lateral; ML, superior-inferior; SI, anterior-posterior; AP) and the rotational angle (axis of SI; Roll) could be possible the adjustment during the treatment. However, two rotational directions for the Pitch (axis of ML) and Yaw (axis of AP) are impossible due to specific feature for the couch type with similar properties like CT platform.[5,6)]

The accuracy tumor targeting while reducing critical organ dose was essential in use the IMRT technique.[7] In particular, the region of pelvic has to be accurately patient setup because that OARs such as the small bowel, bladder, and rectum could be occurring the accurate or late complication from the radiation.[8] A pelvic region has sensitively setup uncertainty compared to another treatment site.[9] Li et al.[10] has evaluated 152 patients with various treatment sites (skull, brain, head and neck, chest, abdomen, pelvis, and extremities) for the setup uncertainty, and reported that maximal shift observed at pelvis site was greater than another site as 20.3 mm, and also required 8.3 mm of target volume margin. Therefore, the immobilization devices are important to accuracy tumor targeting and highly reproducibility in the treatment of pelvic regions and considering the rotational variation in the clinic. For the immobilization devices of pelvic regions, Lee et al.[11] evaluated the patient setup errors for 19 prostate case by using the cone beam-CT (CBCT), and reported that the group by using the thermoplastic mold was smaller than no used the immobilization device. In addition, Martine et al.[12] reported that different for the treatment accuracy and reproducibility depend on using the immobilization devices with different types, such as alpha-cradle mattress and Orifit cast. Consequently, the appropriate immobilization device could be changing the treatment accuracy and reproducibility for the pelvic region by the IMRT treatment.

In clinical, the immobilization devices with various types can be applying to patients with pelvic region due to essentially reducing targeting errors while patients comfort and safety and, should be used before the treatment. A few of study reported for the patient setup uncertainty depends on using the different immobilization devices.[13-16] It is possible that the pelvic region has applied to use proper immobilization devices include various types than another site, such as the brain, head and neck, thorax, and abdomen. Malone et al.[13] was compared between leg cushion consist of the rubber, alpha-cradle and thermoplastic Hipfix for setup errors, and reported that the Hipfix has smaller than other devices. White et al.[14] was evaluated forty patients with the prostate cancers, and reported that the difference in cranial-caudal (CC) axis contributed most to the results, and the current CC margin for the Hipfix system might be considered as inadequate. Therefore, using properly immobilization devices could give rise to reducing the deviation of targeting errors as well as assuring the treatment accuracy and reproducibility during the treatment.

The purpose of this study was to evaluation the patient setup errors according to applied two different immobilization devices for pelvic region radiotherapy in Tomotherapy.

Materials and Methods

1. CT simulation and treatment planning

We selected a total of 36 patients who treated with pelvic regions by using the Tomotherapy in from 2014 to 2016. This study received approval from our institutional ethics review board (IRB approval 2016-11-009). Each patient was randomly used two immobilization devices that either the Feet Fix (FF) (R634-L-3E, Klarity, USA) or the Leg Fix (LF) (R516-16LEG, Klarity, USA) during the treatment simulation (Fig. 1). Table 1 shows the characteristics of patients and eighteen patients were immobilized by using the FF and remain patients used the LF. For IMRT planning, kVCT images were acquired by CT-simulator (Somatom Emotion, Siemens, Munich, Germany) with a slice thickness of 3 mm and a field of view (FOV) of 500 mm. Acquired planning kVCT images were exported to a treatment planning system (Pinnacle, Philips Healthcare, Amsterdam, The Netherlands) to contour the gross target volume (GTV) and the region of interests (ROIs), and planned by using a Tomotherapy planning system.

2. Setup verification and calculation

All patients were positioned with the similar same position

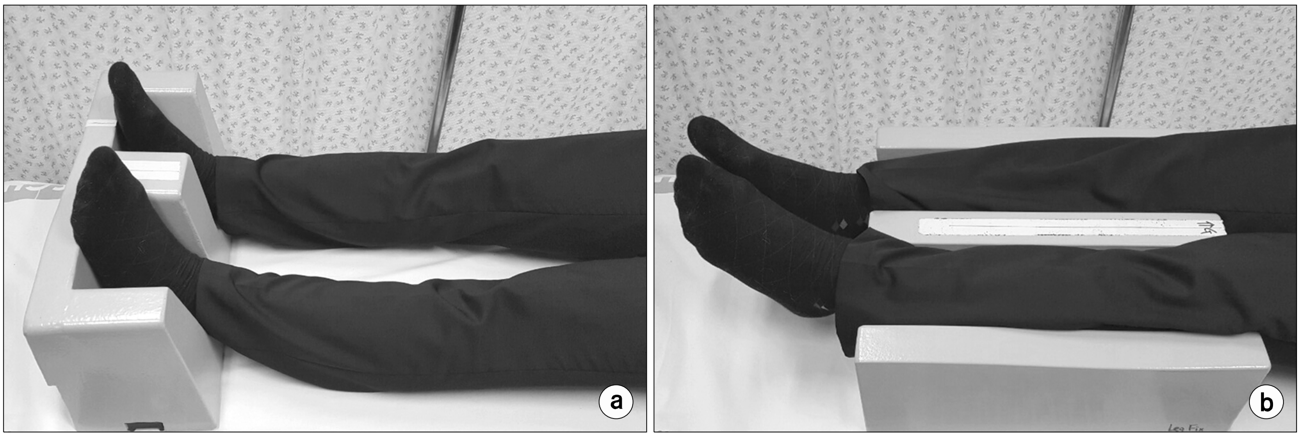

Fig. 1. Patient positioning with supine by using the Feet Fix (a) or Leg Fix (b) for the immobilization of the leg area.

Table 1. Patient characteristics of each group (FF group and LF group) in this study.

Parameter	Value (range or number)	
	FF	LF
Age (year)	56 (31∼76)	59 (33∼76)
Site		
Bladder	1	4
Cervix	7	4
Endometrium	1	2
Prostate	1	6
Rectum	5	1
Other	3	1
Total dose (cGy)	4,930 (4,000∼5,400)	4,891 (4,000∼6,600)
Fraction dose (cGy)	182 (180∼200)	192 (154∼230)
Number of fractions (number)	27 (20∼30)	26 (20∼33)
Treatment time (sec)	203 (125∼323)	237 (156∼354)

FF: Feet Fix device, LF: Leg Fix device.

in CT-simulation process, and the patient setup was performed by using the skin marker of each patient and a red laser in the room during the treatment. The verification and correction of the patient setup were performed by the image registration process through MVCT scanning before the treatment in Tomotherapy operation software. The MVCT scanning could be used three modes as the fine, normal, and coarse depend on the image resolution with slice thickness. In our institution, MVCT images were obtained using coarse mode to reduce the total treatment time and patient dose. To correct between planning kVCT and daily MVCT images, the image registration was performed by applying bone and tissue, and the standard resolution.[17)]

A total of 108 MVCT images sets were acquired before start treatment, and retrospectively analyzed (i.e., the Feet Fix and Leg Fix). Final correction of the daily setup errors was applied in process that first is the automatic image registration and second is manual correction by a radiation oncologist, and recorded of each patient setup error data. The MVCT datasets were divided into two groups based on the different immobilization devices. The translational directions (ML, SI, and AP) and the rotational angle (Roll) were recorded, and calculated a mean (M) for each patient. Moreover, the systematic (Σ) and random errors (σ) for the population patients were calculated based on the methodology introduced by van Herk[18] Here, the systematic error is equal to the standard deviation of the patient specific systematic errors, and the random was calculated by the root-mean-squire (RMS) for all patients.[18] In addition, we applied the margin (mm) of setup errors for the planning target volume (PTV) from calculated the systematic and random error. The following equation was used;

$$\text{Margin}=2.5\Sigma+0.7\sigma \quad (1)$$

The three dimensional (3D) displacement errors used to determine the magnitude of setup uncertainty for the ML, SI, and AP direction as follows;

$$\text{3D-error}=\sqrt{\text{ML}^2+\text{SI}^2+\text{AP}^2} \quad (2)$$

We also analyzed the rotational directions (Roll, Pitch, and Yaw) by using the automatic image registration that a combination of the full image and standard resolution function as well as the translational directions.[17]

3. Statistical analysis

The independent t-test was conducted to find the setup uncertainty with statistically significant difference between applied two different immobilization devices (the Feet Fix versus Leg Fix) at a level of $p<0.05$, and also analyzed the coefficient of correlation between the translational and rotational adjustments by using the Pearson's product-moment coefficient from recorded data.

Results

Table 1 shows the patient characteristics. The median age of patients in the FF group and LF group were 56 (range: 31～76) years and 59 (33～76) years, respectively. Treatment regions were the bladder (n=5), cervix (n=11), endometrium (n=3), prostate (n=7), rectum (n=6), and other (n=4). Average of the total dose was 4,930 cGy (4,891 cGy) in the FF group (and the LF group). Average of the fraction dose was 182 cGy (192 cGy) in the FF group (and the LF group). Mean of treatment fractions were 27 and 26 in the FF and LF group, respectively. Lastly, average of the treatment time was 203 sec (237 sec) in the FF group (and the LF group).

Table 2 shows the patient setup uncertainty including the mean, systematic, random error, and the setup margin for two different immobilization devices. In the ML direction, the mean value of the Feet Fix group (FF) and the Leg Fix group (LF) were −0.51 mm and −0.88 mm, respectively. In the SI direction, the FF and LF were −0.82 mm and 0.22 mm, respectively. In the AP direction, the FF and LF were 1.13 mm and 0.15 mm, respectively. Lastly, the rotational errors (roll angle) were 0.25° and 0.54° for the FF and LF, respectively.

The systematic errors (Σ) in the ML, SI, AP directions and the roll angle for the FF group (and the LF group) were 1.61 mm (1.71 mm), 1.37 mm (2.06 mm), 1.73 mm (2.83 mm), and 0.31° (0.7°), respectively. The random errors (σ) in the ML, SI, AP directions and the roll angle for the FF group (and the LF group) were 1.73 mm (2.57 mm), 1.72 mm (1.61 mm), 2.16 mm (2.32 mm), and 0.35° (0.71°), respectively. Lastly the

Table 2. Patients' setup uncertainty compared with the Feet Fix (FF) and Leg Fix (LF) devices.

Direction	Immobilization device								p-value
	FF	LF	FF	LF	FF	LF	FF	LF	
	Mean (M)		Systematic (Σ)		Random (σ)		Margin		
ML (mm)	−0.51	−0.88	1.61	1.71	1.73	2.57	5.23	6.08	0.358
SI (mm)	−0.82	0.22	1.37	2.06	1.72	1.61	4.64	6.29	0.019*
AP (mm)	1.13	0.15	1.73	2.83	2.16	2.32	5.83	8.69	0.099
Roll (°)	0.25	0.54	0.31	0.70	0.35	0.71	N/A	N/A	0.03*
3D-error (mm)	3.70	4.26	2.73	3.90	3.26	3.82	N/A	N/A	0.081

*Significant of these differences ($p<0.05$).

3D-errors for the FF and the LF groups were 3.70 mm and 4.26 mm, respectively; the LF group value was 15.1% higher than the FF group value (Table 2). No statistically significant difference in the 3D-error was noted between the FF and the LF groups, as shown in Table 2 ($p=0.081$, $p>0.05$).

The calculated PTV margins in the ML, SI, AP directions and the roll angle for the FF group (and the LF group) were 5.23 mm (6.08 mm), 4.64 mm (6.29 mm), and 5.83 mm (8.69 mm), respectively. The FF group was higher than the LF group in the ML, SI, and AP directions as 14.0%, 26.0%, and 33.0%, respectively. Overall, value of the LF group was higher than the FF group, as shown in Table 2. Lastly, there was statistically significant difference between the FF and the LF group in SI direction ($p=0.019$, $p<0.05$) and the roll angle ($p=0.03$, $p<0.05$) exclusion with ML ($p=0.358$, $p>0.05$), and AP direction ($p=0.099$, $p>0.05$), as well as the 3D-errors ($p=0.081$, $p>0.05$).

Table 3 and 4 shows the correlation between translational directions and the roll angle from measured data set of the set-up errors for two immobilization devices of all patients. Table 3 shows correlation for the FF group that statistically significantly correlation for the ML-SI directions (0.276, $p<0.05$), the ML-Pitch directions (0.291, $p<0.05$), and SI-Yaw directions (−0.262, $p<0.05$). For the LF group, there was statistically significantly correlation for the ML-AP directions (−0.464, $p<0.001$), SI-Yaw directions (−0.315, $p<0.05$), and Pitch-Yaw directions (0.420, $p<0.001$), as shown in Table 4.

Table 5 shows the translational and rotational variations of patient setup compared with between the FF and the LF groups performed by the automatic image registration. Statistically significant different in the AP direction were noted between two groups ($p=0.014$, $p<0.05$). Moreover, the rotational variations in the Pitch, Roll, and Yaw directions for the FF group (and the LF group) were 0.12 ± 0.66^{o} (0.33 ± 1.08^{o}), 0.35 ± 0.41^{o} (0.55 ± 0.72^{o}), and 0.00 ± 0.68^{o} (0.16 ± 0.89^{o}), respectively.

Fig. 2 shows the distributions of the magnitudes of setup variations for two groups. For the FF groups, case with ML, SI, and AP directions with 0∼1 mm accounted for 26.7%,

Table 3. Correlation analysis of directional setup displacement in the Feet Fix immobilization device (FF).

Direction	Direction					
	ML	SI	AP	Pitch	Roll	Yaw
ML	1					
SI	0.276*	1				
AP	−0.198	−0.087	1			
Pitch	0.291*	0.178	0.048	1		
Roll	−0.145	0.063	0.037	0.097	1	
Yaw	0.141	−0.262*	−0.237	−0.120	−0.096	1

*Significant of these differences ($p<0.05$).

Table 4. Correlation analysis of directional setup displacement in the Leg Fix immobilization device (LF).

Direction	Direction					
	ML	SI	AP	Pitch	Roll	Yaw
ML	1					
SI	−0.177	1				
AP	−0.464**	0.122	1			
Pitch	0.82	0.183	−0.55	1		
Roll	−0.222	0.212	0.095	0.024	1	
Yaw	0.109	−0.315*	−0.145	0.420**	−0.188	1

*Significant of these differences ($p<0.05$) and **Significant differences ($p<0.01$).

Table 5. Patients' setup uncertainty compared with the Feet Fix (FF) and Leg Fix (LF) in automatic image registration.

Direction	Immobilization device				p-value
	FF	LF	FF	LF	
	M		SD		
ML (mm)	−0.41	−0.91	2.07	2.95	0.296
SI (mm)	−0.61	0.03	1.85	2.60	0.136
AP (mm)	1.32	−0.04	2.62	3.21	0.014*
Pitch (°)	0.12	0.33	0.66	1.08	0.197
Roll (°)	0.35	0.55	0.41	0.72	0.07
Yaw (°)	0.00	0.16	0.68	0.89	0.268

*Significant of these differences ($p<0.05$), M: value of mean, and SD: standard deviation.

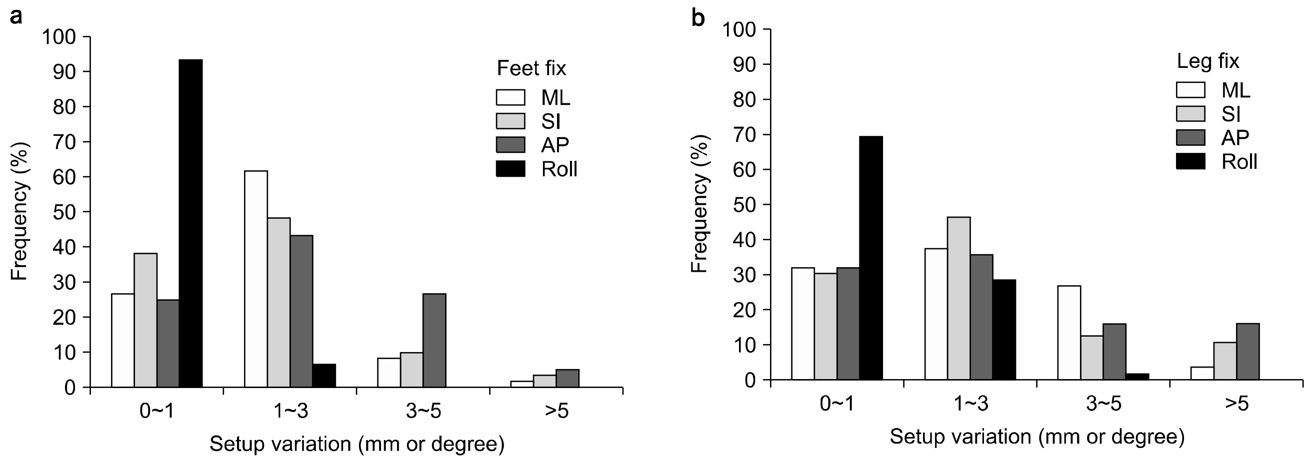

Fig. 2. Percentage of distribution in the treatment fractions of the patient setup variations, the FF group (a) and the LF group (b), in overall patients that the ML, SI, AP directions, and Roll rotational angles.

38.3%, and 25.0% of the group; case 1∼3 mm accounted for 61.7%, 48.3%, and 43.3% of the group; case 3∼5 mm accounted for 8.3%, 10.0%, and 26.7% of the group; and cases with >5 mm accounted for 1.7%, 3.3%, and 5.0% of the group. Furthermore, the roll angle was within $0\sim1^{o}$ for 93.9% of the cases and $1\sim3^{o}$ for 6.7% of the cases. For the LF groups, case with ML, SI, and AP directions with 0∼1 mm accounted for 32.1%, 30.4%, and 32.1% of the group; case 1∼3 mm accounted for 37.5%, 46.4%, and 35.7% of the group; cases with 3∼5 mm accounted for 26.8%, 12.5%, and 16.1% of the group; and cases with >5 mm accounted for 3.6%, 10.7%, and 16.1% of the group. Furthermore, the roll angle was within $0\sim1^{o}$ for 69.6% of the cases, $1\sim3^{o}$ accounted for 28.6% of the cases, and $3\sim5^{o}$ accounted for 1.8% of the cases.

Discussion

In IMRT for the pelvic region, sparing of the normal tissue, such as cervix, rectal, and prostate is always desirable.[8,12,19] The IMRT technique can be more available to decrease the side-effect of urogenital organs, upper/lower gastrointestinal, and the dose of the small bowel, bladder, and rectum than the conventional conformal therapy.[19,20] Decreasing the dose on the critical organs is essential not only a steep dose fall-off by IMRT technique but positioning accuracy during the treatment.[19] Reducing the patient setup errors is essential that increasing tumor control while decreasing normal organs dose in using the IMRT techniques.

The immobilization device which allows minimizing the movement of the patient is important to maintain the patient's positioning during the treatment. The immobilization devices affect directly the accuracy and reproducibility. The evaluation of these devices has to be verified with a quantitative value, such as the patient setup error including the systematic and random error as well as PTV margin.[18] Many researchers have studied the immobilization devices with various types in the clinic.[11,12] Lee et al.[11] have compared with a thermoplastic mold immobilization devices and without of the setup uncertainty for 19 prostate cancer. The value of 3D-error (overall mean error＋SD of the systematic error) with the thermoplastic mold (and without) was 4.05±3.02 mm (8.90±4.79 mm). In our study, the value of 3D-error of FF and the LF group were 3.70±2.73 mm and 4.26±3.90 mm, respectively; the FF group was lower than the thermoplastic mold, however, the LF group was higher than by comparing with Lee et al.[11] This study shows that using un immobilization device can reduce the setup error.

The pelvic region, especially, has using various immobilization devices due to the large area (from the leg to the pelvis or abdomen).[13-16] Malone et al.[13] assessed three immobilization devices which was rubber leg cushion, alpha cradle, and Hipfix and reported that Hipfix has lower total vector error (TVE) than others (i.e., leg cushion and alpha cradle). Contrariwise, White et al.[14] reported that the TVE for an alpha cradle and Hipfix were 2.8±0.8 mm and 5.1±1.9 mm, respectively. In other words, previous studies have shown conflicting results. It seems that these results can be cause according to the difference materials and production of the immobilization, and also lead the setup error during the CT-simulation and/or treatment.[21] In general, the pelvic immobilization devices are generally divided into a single anatomical region (i.e., the leg, pelvic, and etc.) or a bundle (i.e., the both leg and pelvis). Melancon et al.[15] studied that the leg immobilization could be reduced the femoral rotation and translation in prostate case. Moreover, Fiorino et al.[22] tested the immobilization device using alpha cradle device, and compared between in pelvis level and legs level. They reported that the immobilization in legs level showed a better accuracy and reproducibility than the pelvis level with reducing the margin around the CTV (range: from 10 mm to 8 mm) in the AP direction. In our study, FF and LF devices includes fixation at legs level, consequently, setup error of the LF group was higher than the FF group. Fig. 2 shows the percentage in treatment fractions for the FF group (ant the LF group) in greater than 5 mm at the ML, SI, and AP direction were 1.7% (3.6%), 3.3% (10.7%), and 5.0% (16.1%), respectively. The LF group was higher than the FF group in all directions, especially, there was high in the AP direction.

In addition, Table 5 shows the variation of the translational directions and rotational angles such as the Pitch, Roll, and Yaw degree by using the automatic image registration in Tomotherapy operation system. Setup deviation of the LF group was higher in all directions. There was statistically significant difference ($p<0.05$) in the AP direction. With regards to the setup deviation in AP direction, there should be maintain same positioning at the treatment simulation with keeping the reference marking and reducing device setting in daily. We verified that 3D-error variation in the LF group was 15.1% more than in the FF group. Particularly, the setup margin in the SI direction of the FF and the LF group was 4.64 mm, 6.29 mm, respectively ($p<0.05$). Also, the average rotational variation of pelvis was 0.25 ± 0.31^{o} and 0.54 ± 0.70^{o} ($p<0.05$). Only using the LF device could be taking rotational uncertainty such as the ankle rotation with no fixation. In contrast, the FF device could be unstable positioning in the leg. Therefore, it is considered that the combined use with the FF and LF devices is more effective for stable position of the patient.

Conclusion

We evaluated the setup uncertainty of two immobilization devices for the pelvic region by IMRT technique. The setup error can be yielded due to the different fixed (i.e., immobilization) regions, such as the foot, leg, and knee. Two different immobilization devices were affected the patient setup errors due to different fixed location in the low extremity. The radiotherapy for the pelvic region by Tomotherapy should be considering the rotational variations including the Yaw and Pitch rotational angles that incorrect setup error during the treatment in Tomotherapy. In addition the choice of an appropriate immobilization device is important because an unalterable rotation angle affects the setup error.

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