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Manufacturing and effectiveness evaluation of effective breast suit for breast radiotherapy

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ABSTRACT

Background: Various techniques and devices are used to immobilize the breast satisfactorily during radiation therapy for breast cancer, and they are adopted and utilized in treatment centers according to their preferences.

Objectives: In this study, a breast suit was manufactured using the advantages of thermoplastics used in breast cancer and thoracic radiotherapy, and the breast suit was validated by analyzing the reproducibility of setup errors.

Materials and methods: A computed tomography simulator and phantom were used to acquire reference images of a breast suit and a commercial bra, respectively. After acquiring the images in the CBCT system, the setup error reproducibility was analyzed using a Volume View™ 3D image acquisition tool. The image analysis method used automated mode and manual mode, and the validity was evaluated by analyzing the change of setup error reproducibility in the X, Y, and Z axis directions and pitch, roll, and yaw rotation directions of each matched image.

Results: The reproducibility of setup errors between the breast suit and the commercial bra ranged from 0.4 mm to 5.6 mm on the X-axis and from 0.3 mm to 5.8 mm on the Y-axis. In contrast, the Z-axis exhibited larger variations, ranging from 0.8 mm to 16.2 mm. Rotational setup errors were all less than 1°, indicating no significant differences. While the breast suit showed comparable setup errors to the commercial bra in the X and Y directions, it demonstrated improved reproducibility along the Z-axis ($p = 0.09$) and significantly lower rotational errors ($p < 0.05$).

Conclusions: The validity of the reproducibility change of setup errors was confirmed in the X, Y, and Z directions for the breast suit, and valid results were obtained for more stable reproducibility change in the Z-axis direction. Therefore, it is inferred that the breast suit can be used as a fixation device to reduce setup error reproducibility by limiting breast movement.

Introduction

According to national cancer screenings from 2004 to 2018, stomach, liver, colon, breast, and cervical cancers were the top five cancers among Koreans. The incidence of breast cancer has increased among women, accounting for 20.6% of all female cancers according to the National Cancer Registry Project of the Ministry of Health and Welfare.[1] Breast cancer is a disease in which malignant cells form in the breast organ. The most common type of breast cancer is ductal carcinoma *in situ* (DCIS), which starts from cells

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in the ducts. Cancer that starts in the lobes or lobules is called lobular carcinoma and occurs more often in both breasts than other types of breast cancer.[2]

The standard treatment for breast cancer is mastectomy and partial mastectomy for DCIS. In addition, there is a method to improve the local control rate (up to 95%) with radiation therapy, which is expected to be as effective as mastectomy.[3] In general, radiotherapy for breast cancer is treated using the tangential technique of three-dimensional conformal radiation therapy (3D-CRT). However, in complex radiotherapy involving axillary nodes and internal mammary nodes (IMNs), high doses are delivered to surrounding organs at risk (OARs) and the heart to distribute the maximum dose to the planning target volume (PTV). Previous studies have shown that volume modulated arc therapy (VMAT) and helical tomotherapy techniques with Intensity-modulated radiation therapy (IMRT) can improve dose distribution to the PTV and OARs, and show more uniformity dose distribution compared to 3D-CRT.[4] As more sophisticated treatment delivery techniques than 3D CRT are used to treat breast cancer, additional means of immobilization are needed to properly align the patient during treatment. Thermoplastic immobilization systems can reduce chest wall motion in lung cancer patients under extreme breathing conditions, and thermoplastic immobilization that extends from the top of the breast to the upper torso can effectively reduce intra-fraction and inter-fraction motion under normal breathing conditions in patients undergoing breast or chest wall radiation therapy.[5]

As radiation therapy for breast cancer transitions from 3D-CRT to IMRT, VMAT, and helical tomotherapy, the Monitor Units (MUs) increase by 2 to 3 times, leading to increased scatter and leakage radiation doses, as well as increased exposure to the surrounding tissue, which can elevate the risk of secondary malignancies. Overall, IMRT may increase the risk of secondary malignancy occurrence by nearly doubling, from approximately 1% to 1.75%, compared to conventional radiation therapy over a 10-year survival period.[6,7] IMRT also requires high accuracy in treatment setup reproducibility due to the presence of steep intervals where the radiation dose changes rapidly. When the accuracy of positional reproducibility is not high, high doses of radiation can be delivered to surrounding normal organs. Therefore, to deliver uniform doses and high doses of radiation to the target volume, reliable image guidance devices and accurate patient positioning devices within the treatment room are necessary.[8]

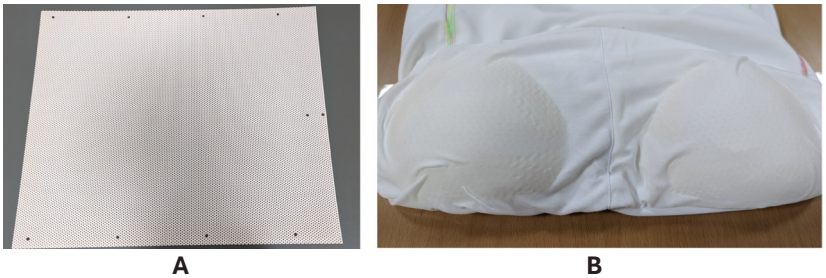
Various techniques and devices are used to immobilize the breast satisfactorily during radiation therapy for breast cancer, and they are adopted and utilized in treatment centers according to their preferences. These immobilization devices include; 1) prone breast board, 2) supine breast board, 3) thermoplastic shells, 4) wireless bra, 5) breast ring, 6) breast cup, and 7) vacuum bags, etc. Several previous studies, such as Strydhorst JH *et al.*, and Kovac *et al.*, have published data on the accuracy and reproducibility of patient setup using different thermoplastic materials or validated setup errors across different breast immobilization techniques.[9-12]

In this study, we fabricated a breast suit using the advantages of thermoplastic materials, a fixation technique used in breast cancer radiotherapy. The reproducibility and validity of setup errors in radiation therapy were verified by comparing the fabricated breast suit with a commercial bra. This study was based on the premise that the reproducibility of setup errors, which is an advantage of thermoplastic materials, is excellent, but it may cause skin side effects due to thermoplastic materials.

Materials and methods

Materials

Radiation therapy for breast cancer involves the use of several different fixation devices. Different fixation devices are used depending on the preference of the radiotherapy center. In this study, we used thermoplastic materials that are effective for fixation of the head & neck, and chest among various fixation devices. Use of a standard-sized thermoplastic sheet (approx. 550×450 mm) heated at 70°C. Application of elastic, breathable polyethylene fabric to enhance comfort and fit. Molding procedure directly over the breast pad. a breast suit was made by combining light, breathable, and elastic polyethylene materials that are quick to absorb and dry (Figure 1).



A B

Figure 1. Breast suit made using thermoplastic in breast radiotherapy. A: thermoplastic plate, B: breast suit.

To evaluate the reproducibility of setup errors in the breast suit, a thorax phantom (Radiology Support Devices; RSD, USA) and a water bag were fabricated and attached between the 2nd and 6th rib to create a custom-made breast phantom (Figure 2).



A B

Figure 2. Breast phantom made using a thorax phantom and a water bag. A: thorax phantom, B: brest phantom.

Methods

A breast board commonly used in breast cancer radiotherapy was used, and a breast suit and a commercial bra (Chabner XRT® Radiation Bra, USA) were worn on the breast phantom, respectively. Four Region of Interest (ROI) points were marked on the breast of the breast phantom to acquire baseline images, which were acquired using a 16-channel CT simulator (Somatom Definition AS CT, Siemens, Germany) at 120 kV, 87 Eff. mAs, 5 mm thickness, and 16.69 scan time. Images of each breast suit and commercial bra were acquired using the Volume View™ 3D image acquisition tool on a cone-beam computed tomography (CBCT) system (XVI, Elekta Infinity™, UK) with a linear accelerator (Elekta Infinity™, UK). The Volume View™ 3D image acquisition was performed using a 360° counterclockwise (CCW) rotation with a tube voltage of 120 kV and a tube current of 40 mA, and a volumetric image was acquired using 1040 mAs, 740 frames, field size medium(M20), and F1(filter), (Figure 3).



A B

Figure 3. Acquisition of breast suit and commercial bra. A: acquisition setup error evaluation, B: acquisition setup error evaluation for commercial bra for breast suit.

To evaluate the validity of the reproducibility of the setup error of the breast suit, the reference images of the breast suit and commercial bra acquired from the computed tomography simulator were registered with the CBCT system, an image guidance device. Using a Volume View™ 3D image acquisition tool, the reference images of the breast suit and commercial bra were compared and analyzed with the CBCT acquired images. The image analysis method used a manual method and an automated method of bone registration and gray value registration in the Volume View™ 3D image acquisition tool. Each matched image was validated by analyzing the change in reproducibility of six-dimensional setup errors in the X, Y, and Z axis directions and pitch, roll, and yaw rotation directions. Data were collected in Microsoft Excel sheets and statistically analyzed using SPSS version 20.0 for Windows (SPSS Inc., Chicago). Continuous variables were expressed as mean ± standard deviation (SD). A *P* value of < .05 was considered to reject the null hypothesis.

Results

Changes in reproducibility of setup errors in X, Y, and Z coordinate systems

The images acquired using a breast suit and a commercial bra in the 3D image acquisition mode of the CBCT system were compared and evaluated. The acquired images were analyzed by setting the region of interest using the 3D imaging tool and checking the change in reproducibility of setup errors in the X, Y, and Z axis coordinate system using manual and automated methods. In the manual method for the breast suit, the change was 0.4 mm in the X-axis, 0.3 mm in the Y-axis, and 0.35 mm in the Z-axis. For the Bone automation method, the change was 2.3 mm in the X-axis, 2.1 mm in the Y-axis, and 5.1 mm in the Z-axis. For the Gray automation method, the change was 3.7 mm in the X-axis, 0.2 mm in the Y-axis, and 3.9 mm in the Z-axis.

In the manual method of Commercial bra, the variation was 5.6 mm in the X-axis, 1.5 mm in the Y-axis, and 0.8 mm in the Z-axis. In the automated method of bone, the variation was 1.8 mm in the X-axis, 3.3 mm

in the Y-axis, and 16.2 mm in the Z-axis. For the Gray automation method, the change was 1.0 mm in the X-axis, 5.8 mm in the Y-axis, and 13.6 mm in the Z-axis.

The paired t-test analysis of translational setup errors showed no statistically significant differences between the breast suit and the commercial bra along the X-axis and Y-axis. However, along the Z-axis, the breast suit exhibited a lower mean error than the commercial bra, with a p=0.0881. Although this result did not meet the threshold for statistical significance, it indicates a clinically relevant trend, suggesting that the breast suit may provide improved reproducibility in the superior-inferior direction (Table 1 and 2, Figure 4).

Table 1. Setup error reproducibility results in the coordinate system (mm).

Axis	Breast suit			Commercial breast bra		
	Manual	Auto		Manual	Auto	
		Bone	Gray		Bone	Gray
X	0.4	2.3	3.7	5.6	1.8	1.0
Y	0.3	2.1	0.2	1.5	3.3	5.8
Z	0.3	5.1	3.9	0.8	16.2	13.6

Table 2. Setup error of mean absolute shift between breast suit and commercial bra (mm).

Axis	Breast suit	Commercial bra	*p* value
	Mean±SD (mm)	Mean±SD (mm)	
X	1.81±1.32	2.90±1.68	0.98
Y	1.11±0.78	3.10±1.62	0.29
Z	2.74±1.87	7.21±6.48	0.09

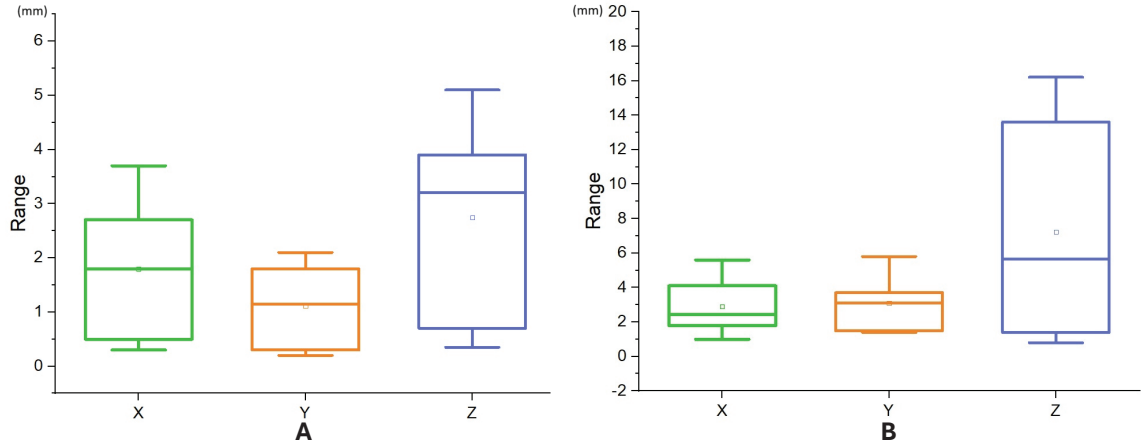


Figure 4. Setup error evaluation of breast suit and commercial bra. A: breast suit, B: commercial bra.

Changes in the reproducibility of setup errors in pitch, roll, and yaw rotation directions

The change in rotation setup error reproducibility of the breast suit and commercial bra was analyzed using the 3D image acquisition mode of the CBCT System, setting the same region of interest as the previous analysis method, and checking the change in pitch, roll, and yaw using the manual and automated methods. For the Breast suit, the change in the manual method was 0.28° for Pitch, 0.07° for Roll, and 0° for Yaw, while the change in the bone automation method was 0.19° for Pitch, 0° for Roll, and 0° for Yaw. For the Gray automation, the change was 0.19° for Pitch, 0.16° for Roll, and 0° for Yaw.

For the manual method of Commercial bra, the variation was 0° for pitch, 0.01° for roll, and 0.24° for yaw. For the automated method of bone, the variation was 0.74° for pitch, 0.1° for roll, and 0.1° for yaw. For the gray automation method, the variation was 0.64° for Pitch, 0.1° for Roll, and 0.1° for Yaw.

Paired t-test analysis of rotational setup errors revealed statistically significant differences between the breast suit and the commercial bra in all rotational directions. In the pitch direction, the breast suit showed an average error of 0.23±0.07°, compared to 0.29±0.39° for the commercial bra (p<0.05). In the roll direction, the breast suit exhibited a significantly higher stability with an error of 1.10±0.07°, while the

commercial bra showed 0.14±0.12° (p<0.05). For yaw, the breast suit and commercial bra recorded 0.03±0.04° and 0.16±0.09°, respectively (p<0.05). These results indicate that the breast suit provides superior reproducibility in rotational setup accuracy across all axes (Table 3 and 4, Figure 5).

Table 3. Setup error reproducibility results in rotation direction (°).

Axis	Breast suit			Commercial breast bra		
	Manual	Auto		Manual	Auto	
		Bone	Gray		Bone	Gray
Pitch	0.28	0.19	0.19	0	0.74	0.64
Roll	0.07	0	0.16	0.01	0.10	0.10
Yaw	0	0	0.24	0.24	0.10	0.10

Table 4. Rotation setup error of mean absolute shift between breast suit and commercial bra.

Axis	Breast suit	Commercial bra	*p* value
	Mean±SD (mm)	Mean±SD (mm)	
Pitch	0.23±0.07	0.29±0.39	0
Roll	1.10±0.07	3.10±1.62	0
Yaw	0.03±0.04	7.21±6.48	0

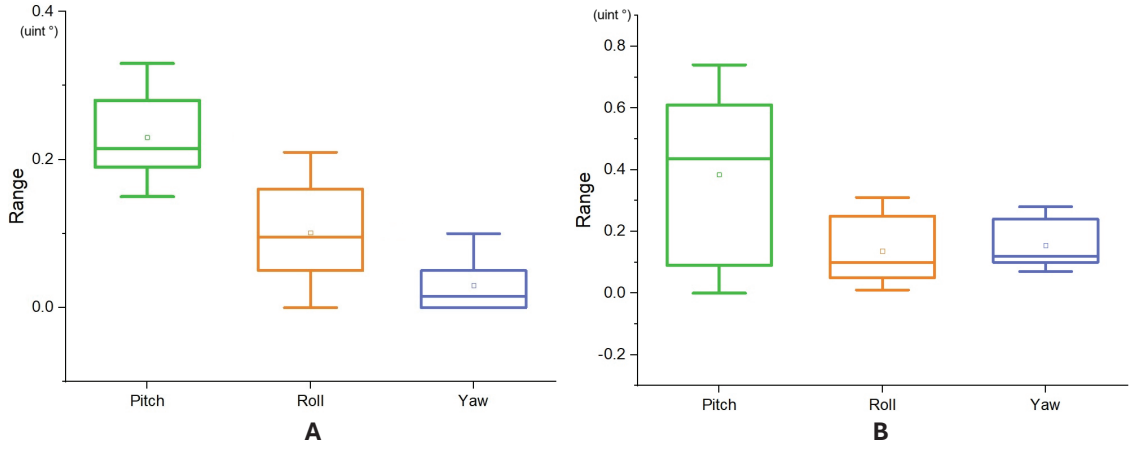


Figure 5. Rotation setup error of breast suit and commercial bra. A: breast suit, B: commercial bra.

Discussion

With the use of sophisticated radiotherapy techniques, proper alignment of patient posture is an important factor. Thermoplastic immobilization devices can effectively reduce intra-fraction and inter-fraction motion during normal breathing in patients undergoing radiotherapy to the breast or chest wall and chest.[13]

In this study, a breast suit was fabricated using thermoplastic fixtures to effectively reduce movement, and the reproducibility of setup errors in breast cancer radiotherapy was verified.

The setup error reproducibility of the breast suit showed variation of minimum 0.4 mm to maximum 5.6 mm in all directions in the X, Y, and Z axes. The setup error reproducibility of the commercial bra did not show a significant difference when comparing the changes in the breast suit with the changes in the X and Y axes, ranging from minimum 0.8 mm to maximum 5.8 mm. However, the Z axis showed a significant result with a minimum of 0.8 mm and a maximum of 16 mm.

Like the studies of Kubo *et al.*, and Kataria T *et al.*, that it is necessary to limit the setup error with significant vertical movement in chest radiotherapy, the breast suit showed better setup error reproducibility changes in the z-direction than the commercial bra.[14,15] These results demonstrate the validity of setup error reproducibility in the X, Y, and Z axes, and are expected to help improve setup error reproducibility by restricting breast movement in radiation therapy for breast cancer.

Breast suit rotation setup error reproducibility was no more than 1° at most in all directions of pitch, roll, and yaw for the breast suit and commercial bra, and did not show significant differences. Matthias

Guckenberger *et al*. showed in a study on the clinical relevance of size and rotation setup errors that the influence of weight and size on rotation errors is small.[16] However, it is believed that changes in the X, Y, and Z axes and corresponding changes in rotation can reduce setup error reproducibility as much as possible in radiation therapy for breast cancer.

Statistical analysis of the setup error reproducibility between the breast suit and the commercial bra showed no significant differences along the X- and Y-axes. However, in the Z-axis, the breast suit demonstrated a lower mean error, indicating a tendency to more effectively suppress gravitational sagging (p=0.09).

In terms of rotational directions, the breast suit demonstrated significantly lower setup errors in pitch, roll, and yaw, all of which reached statistical significance. These findings suggest that the breast suit provides superior stability in both translational and rotational positioning, supporting its clinical applicability in advanced radiotherapy techniques such as IMRT and VMAT. As this study was conducted using a phantom, the results may differ from those observed in actual clinical settings. Furthermore, no patient data were used in this study.

Conclusion

In this study, we analyzed the reproducibility of setup errors in breast cancer radiotherapy, which is a critical factor influencing treatment outcomes. A breast suit was fabricated in-house and evaluated by examining changes in setup error reproducibility. The breast suit showed no significant changes along the X and Y axes; however, in the Z-axis, it demonstrated smaller variations (2-5 mm) compared to the commercial bra (8-16 mm). No significant differences were observed in rotational setup error reproducibility. Overall, the breast suit exhibited greater stability, particularly in the Z-axis direction, and may serve as an effective fixation device in breast cancer radiotherapy by minimizing breast movement and gravitational sagging.

Ethical approval

Our study didn't involve humans or animals and didn't require ethics approval

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This study received no research funding.

Conflict of interest

The authors declare no conflict of interest.

CRediT authorship contribution statement

Yi-Seong Lee: conceptualization, investigation, resources, validation, and writing: original draft; **Jeong-Koo Kim**: conceptualization, methodology development, supervision, statistical analysis, and writing: review and editing.

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