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A randomised clinical feasibility trial of a breast immobilisation device: the SuPPORT 4 All (S4A) bra.

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Title:

A randomised clinical feasibility trial of a breast immobilisation device: The SuPPORT 4 All (S4A) bra.

Shortened Title: Breast cancer radiotherapy patient immobilisation bra.
Type of Manuscript: Full manuscript

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Ethics statement: Ethics approval for this clinical feasibility trial was provided by the Health Research Authority (Research ethics reference number 17/NW/0236), the study was reviewed and approved by the North West Research ethics committee. Approval to use the SuPPORT 4 All bra was also given by the Medicines and Healthcare Products Regulatory Agency (UK) reference

CI/2017/0016.
The trial was also registered with the Clinical Trials database reference number ISRCTN38272993. The full trial protocol can be found at https://www.isrctn.com/ISRCTN38272993?q=38272993&filters=&sort=&offset=1&totalResults=1&page=1&pageSize=10

Abstract

Background

Despite the breast being a mobile organ there is currently no standard suitable immobilisation device to optimise radiotherapy for women treated after a wide local excision with larger breasts. The SuPPORT 4 All bra (or S4A bra) was co-designed with patients and radiotherapy professionals. The purpose of this study was to test the feasibility of using the S4A bra in the existing breast cancer radiotherapy pathway.

Method

A randomised feasibility trial was conducted in a single institution; primary feasibility endpoint was recruitment of 50 participants. Efficacy endpoints were also tested including assessment of skin reactions, dose to organs at risk, and patient comfort. Fifty women were randomised to receive either standard radiotherapy with no immobilisation (control) or radiotherapy with the S4A bra (intervention). A separate planning study was undertaken on the cases randomised to receive the S4A bra. Participants in the intervention arm (S4A bra) underwent two planning CT scans, one with the bra on and one without the bra; allowing direct comparison of organs at risk data for S4A bra vs no bra.

Results

All women that started radiotherapy wearing the S4A bra completed treatment with the bra, and patient comfort did not change across the three weeks of treatment. Positional accuracy using the bra was comparable with existing published accuracy for methods without immobilisation. Mean ipsilateral lung doses showed some improvement when positioning with the S4A bra is compared with the no bra set-up (3.72Gy vs 4.85Gy for right sided cases, 3.23Gy vs 3.62Gy for left sided cases respectively).

Conclusions

The S4A bra is feasible to use in the radiotherapy pathway with good patient adherence. The S4A bra has potential to reduce dose to organs at risk (specifically ipsilateral lung dose) while maintaining good breast tissue coverage, and improved patient dignity, warranting further investigation on a larger scale.

Keywords

Breast radiotherapy, immobilisation device, support bra.

Background

Over 2.2 million people were diagnosed with breast cancer globally in 2020[1]. The incidence of breast cancer continues to rise, with a projected incidence of 3.19 million cases expected to be diagnosed globally by 2040[2]. However, breast cancer survival has also shown a significant increase over time, with five-year age standardised net survival increasing in the UK from 53% in 1971-1972 to 87% in 2010-2011[3]; with survival predicted to reach 1.7 million by 2040[4]. Globally significant variations exist in survival rates across countries with mortality rates 17% higher in low to middle Human Development Index (HDI) countries (compared with high/very high HDI countries)[5].

With improvements in breast cancer mortality, focus has turned towards quality of life after treatment and reducing long-term toxicity. External beam radiotherapy to the breast or chest wall is known to increase the risk of developing ischaemic heart disease[6], symptomatic pulmonary fibrosis, a second primary malignancy (particularly lung[7-9] and angiosarcoma[10]. Hence it is important to investigate methods that may reduce radiation doses to these critical organs at risk (OAR) with the aim of improving quality of life during survivorship.

Techniques such as 3D conformal and Intensity Modulated Radiotherapy (IMRT) along with voluntary deep inspiration breath hold (vDIBH) provide opportunity to spare sensitive structures that lie close to the breast [11]. However, with greater complexity the requirement for greater accuracy in patient alignment increases. Set up inaccuracies have dosimetric consequences that may increase the risk of a loco-regional recurrence[12] or the cosmetic outcome of treatment[13]. Furthermore, there is a proportion of patients who find vDIBH challenging (12% to 21% of patients)[14, 15].

Methods to immobilise the breast include the use of thermoplastic material, using the patient's own wireless bra, breast boards (supine and prone), adhesive tape, breast ring, breast cups, stocking, vacuum bags, and L-shaped breast plates. These methods show variable levels of reproducibility ranging from 1.8mm-6.1mm in the supine position (anteroposterior systematic error) depending on method of immobilisation[16]. In the prone position systematic errors appear to be higher (3.4mm-7.2mm AP direction) although intrafraction movement is low (0.1mm)[16].

In addition, women lie supine for breast irradiation, bare from the waist upwards, with up to four Therapeutic Radiographers (Radiation Therapists) including men, adjusting, and manipulating their thorax and breast in preparation for treatment. This can be distressing for women at a time when they may still be adjusting to an altered body image[17, 18].

Women with large or ptotic breasts can be difficult to position and often have worse skin reactions following radiotherapy[19, 20]. Specifically, overhang of the breast inferiorly produces a self-bolussing that leads to an increased skin dose in the infra-mammary fold. Moist desquamation of the skin is more common in this region. The use of a support bra to lift the breast could reduce this skin reaction, making cosmetic outcome and treatment experience for women with larger/ptotic breasts more comparable to that experienced by women with smaller breasts. We have developed a novel support bra (Support 4 All bra or S4A bra) using a co-design methodology to lift the breast upwards and away from the chest wall.

The aims of this single centre randomised feasibility trial were to test the feasibility, practicality, and acceptability of the study design and protocol, and to confirm safety of the device (see S1 for the feasibility trial research questions).

Method

Study Design.

The Medical Research Council framework[21] for evaluating complex interventions was adopted; this framework has recently been updated[22]. Stakeholder engagement in the early development phase of the framework[23] was supplemented with a review of the existing research evidence on available immobilisation devices[15] to facilitate the development of a prototype bra (S4A bra)[24] (Figure 1). Experimental testing on phantoms and healthy volunteers was undertaken to determine proof of concept and acceptability of the S4A bra prior to clinical testing. The randomised single centre feasibility trial was registered on the International Standard Randomised Controlled Trials Number database.

Eligibility Criteria

All patients included were required to fulfil the following eligibility: aged over 18 years, post breast conservative surgery, invasive carcinoma (pT1-3, pN0-1, M0), suitable for whole breast radiotherapy and bra cup size that fitted the S4A bra size 3 and above (see Table S1) for example those with a bra size of 32DD/34D/36C and above. All standard adjuvant systemic therapies were allowed. Particular exclusion criteria were patient with a previous ipsilateral or contralateral breast cancer (including Ductal Carcinoma In-Situ) a requirement for regional lymph node irradiation or a boost to the tumour bed. Inclusion criteria were designed to allow consistency in both arms, simplicity of evaluation, and ability to test the bra functionality appropriately.

Endpoints

Primary feasibility endpoint was recruitment of 50 participants at a single centre. Efficacy endpoints were also used to assess suitability for a subsequent larger trial. Treatment accuracy and reproducibility data were collected as the primary efficacy endpoint. We expected the S4A bra to either maintain or improve on existing levels of accuracy for the Host centre. However, data on reproducibility were planned to be viewed and balanced with improvements identified in the dose to OAR (mean lung and mean heart dose)(see S1 for secondary feasibility and efficacy endpoints).

Randomisation

Prior to randomisation an eligibility checklist was completed and signed informed consent was obtained. Allocation was through block randomisation (with blocks an integer multiple of four); stratified by bra cup size (S4A bra size 3-7 vs. S4A bra size 8-12). The trial statistician (SW) generated a randomisation schedule that was held remotely by the study-coordinator (JH) who was not directly involved in recruiting patients to the study. At the point of randomisation, the recruiting practitioners (GB,SH) contacted the study coordinator, and received a study number and treatment allocation in return. Patients were randomised 1:1 to receive the intervention (breast radiotherapy with S4A bra with one midline tattoo) or the control (existing radiotherapy set-up with no immobilisation with minimum of three tattoos). It was not possible to blind patients to the intervention or to blind physicists/dosimetrists undertaking dose planning or the TRs that analysed on-treatment images; the S4A bra was visible on imaging.

Fitting of the S4A Bra

To ensure appropriate and safe use of the Support 4 All bra HP led a formal training session with the radiography staff on how to fit and adjust the bra as well as use of the accessory equipment (inflation methods). A half-day programme was delivered (and repeated) covering the results of the experimental data to date, a step-by-step guide to the design and all the components, how to

measure a patient for the correct sized S4A bra. HP also attended the fitting sessions on site for the first cohort of patients recruited to the study to support staff until they felt confident about the measuring and fitting process.

Patients randomised to the S4A bra arm of the study were measured and fitted for the S4A bra at the CT planning session. The fitting process involved using the patient's own bra size as a starting point, reviewing how well the bra was fitting, and then standard measurements of the thorax were taken to confirm size. The standard measurements included a measure of the patient's chest circumference (using a standard dressmaker tape measure) at the point underneath the breasts and at the widest part of the breasts. This allowed calculation of the bra cup and bra band size. The difference between the band measure and the fullest breast measure determines the bra cup size. A series of Perspex, wipeable cups, one for each S4A bra size were also used to cross check the correct S4A size for each participant.

Dose Fractionation

All patients received 40Gy in 15 fractions over 3 weeks to the whole breast. No bolus was used.

Outcome Measures

Accuracy and reproducibility

Standard methods were used to calculate random and systematic errors [25] taken from on-treatment imaging on days 1-3, then weekly until treatment completion (see Table S4 and Figure S1 supplementary text for the baseline measures and explanation of measures taken).

Skin Toxicity and breast changes

Skin reactions were assessed using the Radiation Therapy and Oncology Group acute skin scoring assessment (RTOG)tool. RTOG scores were recorded at day 0 (at the planning visit) and once weekly until the end of treatment by a designated radiographer blind to the intervention group. Patients were also asked to self-report skin toxicity using a specifically created skin and breast assessment booklet. Patient representatives and healthcare practitioners designed both these patient self-scoring tools in the product development phase of this study[23]. The booklet included a lay version of the RTOG scoring system and a new SELF tool (SizE, Look, Feel), designed for patients to monitor and document breast swelling that may be indicative of breast lymphoedema. The aim of was to assess compliance, usefulness, and ability for patients to score skin and breast changes themselves, constituting the first part of the validation process for these tools.

Patient comfort, modesty, empowerment, and acceptability.

To assess patient comfort with the support bra a new comfort questionnaire was designed based on interviews with healthy volunteers that had previously worn the support bra in a pre-experimental phase. Patients were asked to complete the questionnaire after the first planning session and once weekly until the end of treatment.

Participants were asked to complete the 15-item patient empowerment scale[26] (Person separation index =0.78) at day 0 (Radiotherapy planning visit) and once weekly during treatment. Patient modesty and experience was measured by a specially designed storyboard incorporating questions from the patient modesty scale[27].

Participant and Therapeutic Radiographer (Therapist) views on acceptability of the intervention were assessed using a specially designed Technology Acceptance questionnaire based on the Technology Acceptance Model[28].

Dose to organs at risk

Dose to OAR was assessed at planning for all trial patients the following parameters were calculated for all patients:

- Mean ipsilateral lung dose,
- V12- Volume of ipsilateral lung receiving more than 12Gy total dose,
- Combined lungs total mean lung dose,
- Mean heart dose,
- Percentage of heart volume receiving >10Gy and 2Gy.

To allow a direct comparison of dose to OAR with and without the S4A bra all patients randomised to the intervention group underwent two CT scans (one with and one without the S4A bra). This allows a more accurate like for like comparison on the same internal anatomy.

Radiotherapy

Patients in both arms were positioned supine, inclined on a breast board (with both arms abducted above the head and gripping poles with cup rests to support the raised arms). A single anterior positional tattoo placed on the midline within the positional aperture of the S4A bra (point 9 in Figure 1), and side crosses marked on the support bra were used in the intervention arm to ensure patients were in a reproducible position. Patients in the control arm received three tattoos, one on mid-line and one on either side (replicating the side cross on the S4A bra in the intervention group). Patients in the intervention arm received two planning CT scans; one while wearing the S4A bra and one without the bra, to enable a direct comparison of OAR doses. To ensure appropriate set-up with the S4A bra on treatment sporadic fidelity checks were completed (see Supplementary text 2).

Radiotherapy Planning

The Planning target Volume (PTV) was planned using a pair of isocentric (SAD 100 cm) tangential fields with a non-divergent back edge. Use of multileaf collimators (MLC) and field-in-field (FiF) was permitted for optimisation of dose distributions as deemed necessary (Inverse-planned IMRT was not used). The final dose calculation was performed with correction for tissue heterogeneity, using a Type B algorithm. OAR were outlined and dose constraints used for planning can be found in Tables S2 and S3.

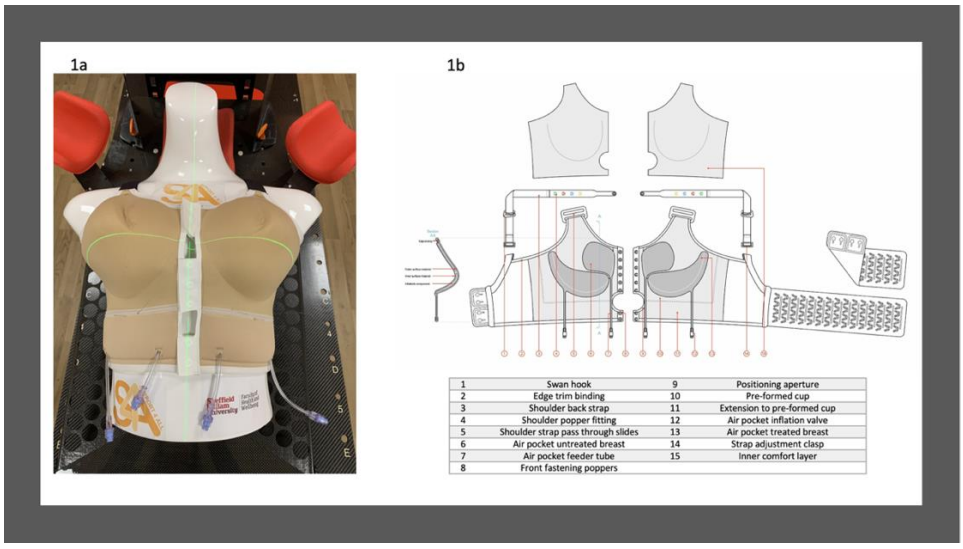

Figure 1. The Support 4 All bra positioned on a mannequin (1a) and a schematic of the Support 4 All Bra component parts (1b).

Statistical Analysis

Statistical analysis focussed on providing sufficient information to make a judgement about the appropriateness of the chosen outcome measures and to allow decision-making regarding any refinements needed to the S4A bra design ahead of a subsequent definitive trial.
As this was a feasibility study the analysis was mainly descriptive and concentrated on confidence interval estimation and not formal hypothesis testing.

Descriptive statistics have been used to describe the dose to OAR and skin reaction data; the skin reaction data providing additional safety data. The results presented are the Intention to Treat (ITT) analysis for the sample studied. All analyses were conducted in R version 3.6.0.

Results

Figure 2 demonstrates participant recruitment and attrition for the study.

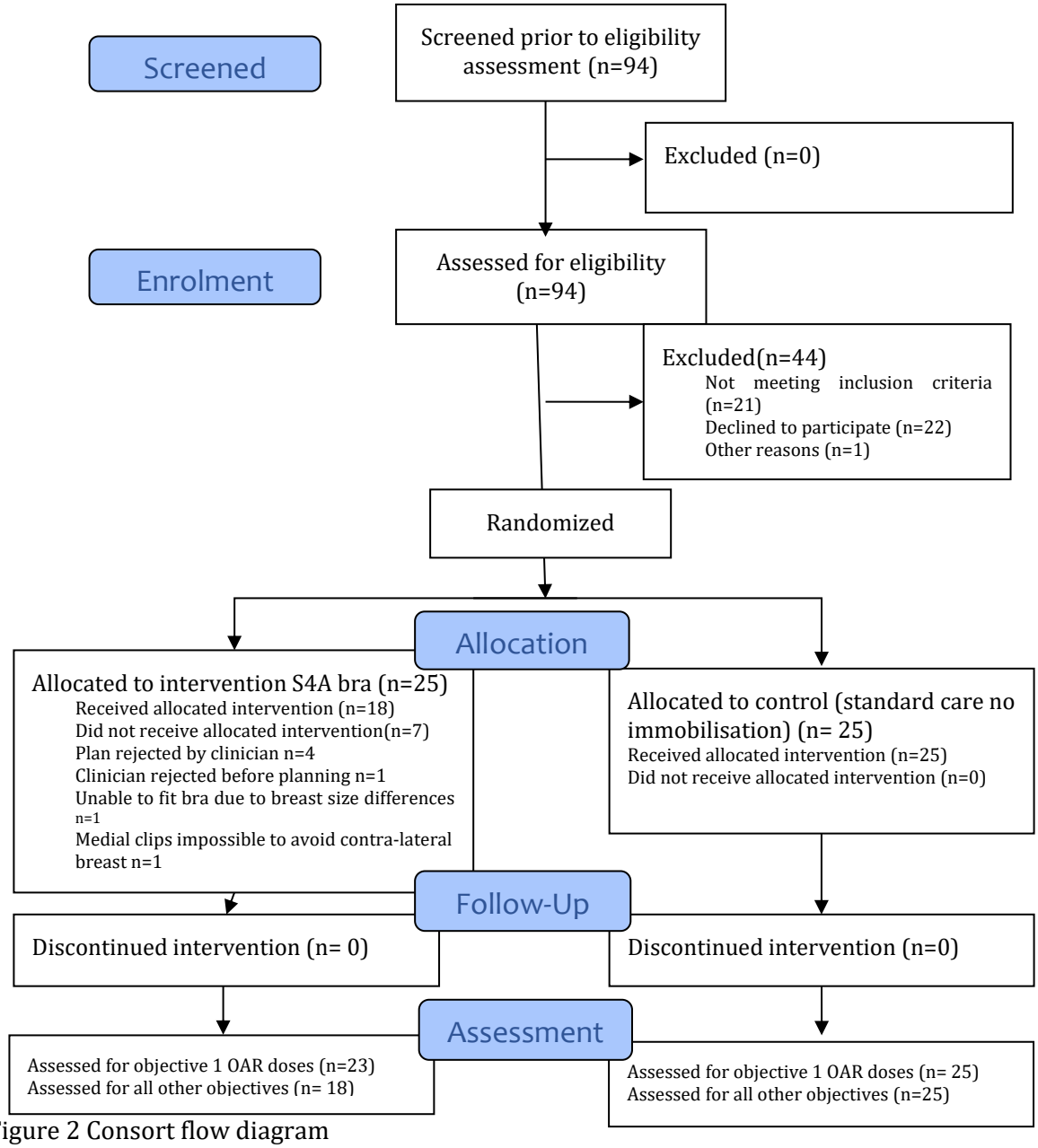

Figure 2 Consort flow diagram

Recruitment started October 2017 and finished January 2019. Of the 25 women randomised to the S4A bra 23 were fitted with the S4A bra and underwent two CT planning scans allowing a within subjects dose comparison to be undertaken. There were no dropouts in either arm following the start of radiotherapy. In the intervention arm (S4A bra arm) 7 women randomised to receive the bra did not proceed to have treatment in the bra; the radiotherapy plan was rejected because of poor bra fitting indicating a need for more in-depth staff training in the bra fitting process.

Basic Characteristics

Participants mean age was 60 years (S4A group A) and 59 years (control group B) (SD 7.4 and 5.9 respectively). Twenty-three of the participants were treated for a right breast cancer and 25 for a left breast cancer. Table 1 shows patient PTV (in cm^3) for the control and intervention arm; for the S4A group the PTV was measured with and without the bra.

Table 1. Planning Target Volume across the study participants.

	Allocation	Bra Status	Mean (cm^3)	SD	Median (cm^3)
1	A (n=23)	No Bra	1,416.3	417.6	1,335.7
2	A (n=23)	With S4A Bra	1,468.0	456.1	1,454.2
3	B (n=25)	No Bra	1,480.6	458.1	1,432.4

Group A= Randomised to S4A bra, scanned and planned twice, once with the S4A bra on and once with the bra off.

Group B= Randomised to no bra

Table 1 indicates that in the S4A bra group the mean PTV was marginally larger when the S4A bra was worn.

Set-Up Reproducibility

Systematic Error

Table 2 Summary of Population Mean Systematic Error (mm).

Measurement	Mean group A S4A bra	Mean group B No Bra	Difference in means (bra-no bra)	95% CI Lower limit	95% CI Upper Limit
CLD	0.9	-1.5	2.4*	0.9	3.9
CrLD	0.2	-1.5	1.7*	0.4	3.1
CBESD	-2.6	-2.0	-0.6	-2.3	1.2
CIW	2.3	1.3	1.0	-0.7	2.6
CCD	2.7	1.5	1.2	-0.6	3.1

Central Lung Depth (CLD), Cranial Lung Distance (CrLD), Central Beam Edge Skin Distance (CBESD), Central Irradiated Width (CIW), Caudo-Cephalic Distance (CCD) * indicates measures where the S4A appeared to showed improvements in systematic error over no bra set ups.

Population mean systematic errors are below 3mm for both groups (Table 2). Systematic error of lung positioning was lower in the S4A bra group compared with the control arm (CLD and CrLD measures in Table 2). The 95% CI estimates between the control and S4A bra groups for CLD and CrLD measures are compatible with a difference in mean systematic errors between the randomised groups. For the three other measures of breast positioning the control arm performed better with lower population mean systematic errors. For the measurements,

CBESD, CIW and CCD the differences in mean systematic errors between the S4A bra and No bra group were <1.2 mm and the 95% confidence interval estimates, for the difference in means, are compatible with no difference between the randomised groups. For CLD and CrLD the differences in mean systematic errors between the groups were larger (2.4 and 1.7 mm respectively) and the 95% CI estimates are compatible with a difference in mean systematic errors between the randomised groups.

Random Error

Table 3 Summary of Mean Random Population Set-Up errors (mm).

Measurement	Mean group A S4A bra	Mean group B No bra	Difference (Bra-No Bra)	95% CI Lower limit	95% CI Upper limit
CLD	2.8	2.1	0.7	0	1.4
CrLD	2.6	1.9	0.7	0	1.3
CBESD	3.2	2.7	0.5	-0.3	1.3
CIW	3.2	2.5	0.7	0	1.5
CCD	4.6	2.2	2.4*	1.2	3.7

Central Lung Depth (CLD), Cranial Lung Distance (CrLD), Central Beam Edge Skin Distance (CBESD), Central Irradiated Width (CIW), Caudo-Cephalic Distance (CCD) *indicates measure where the S4A appeared to showed worse random error over no bra set ups.

The control arm (no bra) had smaller random set up errors for all 5 measures assessed, although in 4 measures the difference was <1mm (Table 3).

The larger difference in random error seen for CCD indicates a potential bra fitting error, or a need for better staff training in bra fitting.

Dose to Organs at Risk

The planning data presented below (Table 4 and Table S5 in the supplementary text) is an analysis of 2 sets of data on the intervention arm cases only, providing a within subjects analysis of the S4A bra group (the intervention). Data set 1 is the planning data for all patients randomised to receive the S4A bra planned without the bra on (patients were not treated on this plan). Data set 2 is the planning data for patients randomised to receive the S4A bra planned with the bra on (this is the plan they were treated on). This analysis provides a more like for like comparison of breast volumes and anatomy. Data is presented for the side that is treated (i.e. left or right breast) as this can have an influence on the volume of lung and percentage of heart that is close to the target volume.

Heart Doses

All patients treated for a left breast cancer across control and S4A bra arms underwent vDIBH. No differences were seen in calculated mean heart doses when the S4A bra was worn for planning compared with the no bra plan (see Table S5 supplementary text). For left breast cases mean heart doses was 1.04Gy vs 0.98Gy (no bra vs S4A bra respectively n=13) and for right breast cases mean heart dose was 0.53Gy vs 0.55Gy (no bra vs S4A bra respectively n=10).

Lung Doses

Table 4 Analysis of lung doses (Gy) .

Allocation	With or Without Bra	Side treated	Ipsilateral V12(Gy)	Ipsilateral mean (Gy)	Combined lungs mean (Gy)	Number (n)
A	No bra	Right	0.10	4.85	2.64	10
A	With bra	Right	0.06	3.72	2.02	10
A	No bra	Left	0.06	3.62	1.70	13
A	With bra	Left	0.05	3.23	1.54	13

A= Allocated to the S4A group

Improvements in mean ipsilateral lung dose were observed in the S4A bra in both right and left sided cases (mean improvement 1.13Gy and 0.39Gy respectively Table 4). These reductions in lung dose are also seen when considering combined lung doses for both left and right sided cancers.

Skin Doses

No patient experienced a grade 3 toxicity in either group (see Table S6 and S7 for a breakdown of RTOG scores for both groups). There were no serious adverse events reported in the trial supporting the safety of the product in terms of skin reactions. All patients that started treatment wearing the S4A bra completed all 15 treatments in the bra. There was no change in the mean comfort score reported in the S4A bra group from planning to week 3 (mean comfort scores 53.3 at planning vs 53.1 at week 3) indicating that the S4A bra did not feel less comfortable as treatment progressed. For patient empowerment there was a small improvement in mean score of 3.8 from baseline (planning visit) to week 3 score for those wearing the S4A bra, compared with a mean improvement of 1.2 in the control arm. While these mean empowerment scores are promising they must be viewed with caution as the numbers completing the empowerment scales were low across the treatment course with only 10 completed questionnaires returned at week 3.

Discussion.

This study demonstrated encouraging data to indicate it is feasible to use the S4A bra as part of the current radiotherapy pathway for those patients with an intact breast. The RTOG skin scores indicate the bra material does not elevate skin reactions. Consistency in comfort scores from baseline to week 3, also confirm that the bra retains its comfort even as the normal radiation skin reaction develops.

For OAR, mean heart doses (left sided treatments) for both intervention and control arms were δ 1.0Gy (1.04Gy for no bra vs 0.98Gy for the S4A bra); mean heart dose for cases treated for a right breast cancer were 0.5Gy with or without the S4A bra. These mean heart doses are marginally higher than the mean heart dose references from the Heartspare studies[29,30] where mean heart doses of 0.6Gy (for vDIBH and ABC[29]) and 0.44Gy (0.38-0.51 vDIBH) and 0.66Gy (0.61-0.71 prone technique)[30] are reported. Using a plastic breast cup has been shown to reduce mean heart and lung doses (compared with no breast cup) without the use of breath hold techniques[31], and maybe particularly useful for patients unable to manage a breath hold. For left sided cases a reduction from 5.11Gy to 2.8Gy (mean heart dose no cup vs plastic cup respectively) and from 10Gy to 6.3Gy (mean ipsilateral lung dose no cup vs plastic cup respectively).For right sided cases mean lung dose with the cup was 5.87Gy[31], significantly larger than the 3.72Gy mean lung dose achieved using the S4A bra in this feasibility trial; mean heart dose achieved with the plastic breast cup (0.66Gy) was similar to the mean heart dose of

0.55Gy achieved with the S4A bra in right sided cases.

Comparing OAR doses across studies should also consider breast volume coverage; this is problematic as there is no agreed approach to recording breast size with CTV, PTV and bra cup size all used as breast volume measures. In Heartspare Stage 1B the mean contralateral breast volume is reported as 1002cm^3 (range 718-1784cm^3) [29] mean CTV (676-677cm^3[29]); slightly smaller than the mean PTV of this current study (1,416.3cm^3 no bra and 1,468cm^3 S4A bra).

Despite the limitations in comparing OAR doses across different study populations, the comparison does serve to highlight that when using the S4A bra in women with larger breasts it may be possible to keep mean heart doses low without compromising on breast tissue.

Mean lung doses using the S4A bra show a small reduction, particularly for right sided cases that warrants further analysis in a larger study. In a single Institution review of mean lung doses between 2014 and 2018 McKenzie et al (2020)[32] reported mean lung dose for hypofractionated regimens of 3.4Gy (including Left and Right sided cases, mean breast volume 1348cm^3). In the Heartspare studies mean lung doses (left sided cases only) of 3.73Gy[30] and 4.2Gy[29]are reported for vDIBH techniques compared with mean lung dose of 0.34Gy for the prone technique. In our study no bra (with vDIBH) the mean lung doses for left sided cases were comparable (3.62Gy) with other reported data for supine methods. The S4A bra improved mean lung doses with on average larger mean breast volumes.

Positional accuracy using the S4A bra appears consistent with existing set-up accuracy (within 1.2mm) for random and systematic errors across all measurement points apart from the caudo-cephalic direction where the S4A bra had greater mean random error (4.6mm S4A bra vs 2.2mm no bra). The larger difference in random error seen for CCD indicates a potential bra fitting error, or a need for better staff training in bra fitting.

Table 5 below shows how the S4A bra reproducibility compared with other published data without immobilisation.

When considering other immobilisation devices thermoplastic immobilisation has been reported to have higher inter-fraction random error of 4mm, 12 mm and 4.5mm (left/right, superior/inferior and anterior/posterior respectively)[33] or 4.1mm, and 3mm (superior/inferior, anterior/posterior respectively)[34].

Table 5 Comparison of reproducibility from the current study with published data.

	Random Error (mm)		
	Right-Left	Superior-inferior	Anterior-Posterior
ABC Breath Hold device[29]	3.8	3.3	2.6
vDIBH Heartspare I data (n=22)	2.4	4.1	2.7
vDIBH Heartspare Ib data (n=23)[30]	1.9	2.6	3.5
Prone Heartspare Ib	5.4	4.5	4.6
S4A Bra (n=18)	**-**	**4.6**	**2.8**
	Systematic Error (mm)		
	Right-Left	Superior-inferior	Anterior-Posterior
ABC Breath Hold device	4.4	4.9	3.3
vDIBH Heartspare I data (n=22)	2.5	3.9	2.8

vDIBH Heartspare Ib data (n=23)	1.8	3.0	1.8
Prone Heartspare Ib	1.8	3.0	5.2
S4A Bra (n=18)	**-**	**2.7**	**0.9**

Conclusions

This randomised feasibility trial demonstrated that the S4A bra could be used safely within the current radiotherapy pathway. All women that started radiotherapy wearing the S4A bra completed all treatments using the bra. The S4A bra provides much needed dignity and modesty as evidenced by patient reported outcomes, with modest costs per bra (estimated to be in the region of the cost of a high end commercially available bra). Importantly, there were no signals suggesting increased skin toxicity and ipsilateral lung doses were marginally reduced. Reproducibility measures were comparable with published data. This feasibility study provides important preliminary data to guide the design of future larger clinical trials. Further work is planned to improve the bra fitting process and the training of Therapeutic Radiographers (RTTs) in how to measure and fit patients with the bra.

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