Measurements of Human Tolerance to Horizontal Rotation within an MRI Scanner: Towards Gantry-Free Radiation Therapy

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Running title: Tolerability of patient rotation within an MRI

Abstract

Introduction: Recent advances in image-guidance and adaptive radiotherapy could enable gantry-free radiotherapy using patient rotation. Gantry-free radiotherapy could substantially reduce the cost of radiotherapy systems and facilities. MRI guidance complements a gantry-free approach because of its ability to visualise soft tissue deformation during rotation. A potential barrier to gantry-free radiotherapy is patient acceptability, especially when combined with MRI. This study investigates human experiences of horizontal rotation within an MRI scanner.

Methods: Ten healthy human participants and nine participants previously treated with radiotherapy were rotated within an MRI scanner. Participants' anxiety and motion sickness was assessed before being rotated in 45-degree increments and paused, representing a multi-field intensity modulated radiotherapy treatment. An MR image was acquired at each 45-degree angle. Following imaging, anxiety and motion sickness were re-assessed, followed by a comfort questionnaire and exit interview. The significance of the differences in anxiety and motion sickness pre- versus post-imaging was assessed using Wilcoxon signed rank tests. Content analysis was performed on exit interview transcripts.

Results: Eight of ten healthy and eight of nine patient participants completed the imaging session. Mean anxiety scores before and after imaging were 7.9/100 and 11.8/100 respectively ($p = 0.26$) and mean motion sickness scores were 5.3/100 and 13.7/100 respectively ($p = 0.02$). Most participants indicated likely acceptance of rotation if MRI were to be used in a hypothetical treatment. Physical discomfort was reported to be the biggest concern.

Conclusions: Horizontal rotation within an MRI scanner was acceptable for most (17/19) participants.

Key Words: Patient Comfort, Patient Positioning, Radiation Oncology, Radiotherapy, Rotation

Introduction

Approximately 50% of all cancer patients are indicated for external beam radiotherapy (EBRT) at least once during the course of their treatment[1]. Conventional EBRT involves rotation of an x-ray source around the patient in order to intersect the tumour to maximise therapeutic dose while minimising dose to healthy tissue. Recent advances of on-line image guided adaptive therapy[2] such as MRI-guidance[3] for soft-tissue visualisation, real-time tracking of the tumour[4] and on-line adaption of the treatment plan[5] now make it possible to identify and account for large inter and intra-fraction changes in anatomy during a treatment.

These technological advances have renewed interest in utilisation of patient rotation with a fixed radiation source, or gantry-free radiation therapy [6-10]. Gantry-free systems could greatly reduce costs and design complexity of x-ray therapy systems, and proton and heavy-ion therapy where large gantries contribute to significant capital costs. Theoretically, removing rotating gantries could allow proton systems to be installed within 1-2 conventional x-ray therapy bunkers, making more widespread clinical uptake of protons viable[11]. Several studies have demonstrated that it is theoretically possible to deliver image-guided treatments with a fixed radiation source and rotation of a patient using a conventional treatment machine[12,13].

A perceived limitation to implementing gantry-free therapy is the acceptance of patients to translation and rotation during treatment. It has been shown that cancer patients can tolerate translations of the treatment couch for motion-compensated beam delivery[14,15]. Whelan et al. conducted a study with 15 cancer patients and found most could tolerate horizontal and vertical rotations within a balance disorder rotation device[7]. In these studies, the participants, while immobilised, were in relatively open space with a clear field of view. Given the scale of anatomical deformation under rotation[9,16], the combination of MRI for soft tissue visualisation with patient rotation is advantageous. Since anxiety and claustrophobia associated with MRI is already of concern[17,18], patient immobilisation and rotation combined with MRI could increase distress on a patient, particularly during long imaging times.

This study evaluates the experiences of human participants during horizontal rotation within an MRI scanner. More specifically, the following questions are addressed: (i) does immobilisation within a patient rotation system (PRS) at different couch rotations (rolls) during an MRI scan lead to increased anxiety or motion sickness? (ii) To what extent would a patient experience discomfort during rotation?

Method

An ethics-approved study was undertaken with a cohort of 10 healthy participants (healthy volunteers - HV) followed by 9 patient participants previously treated for prostate cancer at one centre (patient volunteers - PV). HV's comprised current staff or students affiliated with the hospital where the study was conducted. A combination of healthy and patient participants was selected to capture any potential differences in the perspectives of providers of cancer therapy and those who have received radiotherapy. Participant demographic information is summarised in table 1.

Eligibility criteria included (i) no contraindication to MRI, (ii) >18 years of age (iii) not pregnant (iv) able to read and understand English (v) no clinical diagnosis of severe claustrophobia. For PV's (vi) cancer diagnosis of any stage (vii) current or previous treatment with radiotherapy. Participants had to meet the geometric restrictions of the patient rotation system (PRS) by not exceeding: weight 100 kg, height 190 cm, total anterior-posterior width 32 cm and a total lateral width 46 cm where the PRS covers the participant anteriorly. A summary workflow of the study procedure is shown in figure 1 and described below.

Pre-Imaging

Prior to imaging, participants completed psychometrically validated questionnaires assessing anxiety and motion sickness. The short form state sub-scale of the State Trait Anxiety Inventory Test (STAI)[19] was used to determine the current anxiety level of each participant. The STAI comprises 6 items: three anxiety present items, i.e. '*I feel tense'* and three anxiety absent items, i.e. '*I feel calm'*, each scored between 1 (Not at all) – 4 (Very much). Anxiety absent items were reverse scored and then items were summed to give a total score between 6 (lowest anxiety) and 24 (highest anxiety). Motion sickness was assessed with the Fast Motion Sickness Survey (FMS)[20]. Each participant would rate their current level of sickness on a visual analogue scale between 0 (no sickness) and 20 (very sick). To aid in the interpretation of results, all questionnaire scores were normalised for a final score of 0-100 consistent with the approach of Whelan et al.[7]. Each participant was provided with a patient information sheet as part of the consent process, which explained the procedure and the study objectives. Prior to imaging, the PRS device and MRI scan times were explained to the participant by an investigator.

Imaging

Participants were imaged on a 64-channel, closed, wide-bore 3 Tesla (MAGNETOM Skyra, Siemens, Erlangen, Germany) radiation therapy dedicated MRI scanner in a previously described bespoke patient rotation system (PRS)[6,9]. Participants were secured within the PRS using polyester straps and three airbags. Once secure, participants were rotated outside of the MRI scanner to ensure clearance during rotation and to familiarise participants with rotation prior to imaging (figure 2). Nine MRI scans were acquired in 45-degree incremental horizontal rotations from 0-degrees through to 360-degrees, representing a multi-field intensity modulated radiation therapy treatment. An initial 6-minute high-quality isotropic T2-weighed turbo spin echo (TSE) isotropic scan was acquired at the zero-degree (supine) position, with remaining T2-weighed scans taking 1 minute each.

Initially, participants' arms were positioned above the shoulders (figure 2) as it kept the hands out of the imaging volume and prevented compression of the arms during rotation. If a participant could not hold their arms in this position, or it was decided by investigators that attempting arm positioning above the shoulders would not be appropriate, the arms were placed by the participants side under the airbags and supporting structure (canopy). Arm positioning for each healthy and patient volunteer is shown in table 1.

Post-Imaging

Following the imaging session, participants completed the STAI and FMS questionnaires again to assess changes in anxiety and motion sickness. A two-tailed Wilcoxon signed rank test was used to determine if a significant change in mean anxiety or motion sickness was present following imaging. A p-value of less than 0.05 was considered statistically significant. The sample size was pragmatically chosen to obtain sufficient information but not expose human subjects to unnecessary scans. All analysis was conducted in Matlab version 2019a (MathWorks Inc., Natick, MA).

An additional purpose-designed questionnaire was administered to evaluate participants' comfort within the PRS. Participants answered five questions relating to overall comfort, change in comfort over time and dependence of comfort on the angle the PRS was positioned. For each question, the participant selected a response of 'Not at all' 'somewhat' 'moderately' or 'very much'. Each participant was then asked to rate the couch positions from 5 (most comfortable) to 1 (least comfortable) where couch positions were defined as 'lying on my back' (supine), 'lying on my stomach' (prone), 'lying on my right side' (90 degrees), 'lying on my left side' (270 degrees) and 'other positions' (45, 135, 225, 315 degrees). Finally, the participant was asked if they would hypothetically be prepared to undergo radiation therapy if it required use of the PRS. Comfort analysis did not include participants who did not complete the imaging session.

Following the imaging session, an exit interview was conducted with participants to gain a more in-depth understanding of the quantitative data. The exit interview consisted of six open ended questions covering overall experience, positive and negative aspects, potential areas of improvement and feelings regarding the hypothetical use of the PRS for radiation therapy. Content analysis[21] was carried out on the interview transcripts. A sub-set of transcripts were double coded to confirm that identified themes were consistent between investigators.

Results

Eight of ten HV's and eight of nine PV's completed the imaging session. HV01 was removed from the PRS after three couch rotations due to neck discomfort. HV02 was not able to be rotated beyond the 70-degree position due to their shoulder width exceeding PRS limits (which led to an amendment in the study selection criteria to include a shoulder width restriction). PV08 was removed prior to any imaging due to feelings of compression on the upper thoracic region when secured within the PRS.

Column graphs of the STAI and FMS responses from HV and PV cohorts are shown in figure 3 and figure 4, respectively. Boxplots of STAI and FMS scores pre and post imaging for HV and PV cohorts are shown in figure 5. Based on the standard deviation of measured STAI data (12), we had an 80% power to detect differences in mean STAI of 15 or more. Across the 19 participants the mean STAI score increased from 7.9/100 to 11.8/100 ($p = 0.26$). The median STAI score increased from 6.0/100 to 7.0/100. The mean FMS score increased from 5.3/100 to 13.7/100 ($p = 0.02$). The median FMS score remained 0 pre and post imaging.

The supine position was the preferred position across both HV and PV cohorts. Regarding other couch angles, HV's generally proffered the prone couch position over other rotations, while there was no preference for the PV's. The dependence of PRS angle and comfort was reflected in the comfort questionnaire responses shown in figure 6. Both cohorts reported that comfort depended on couch position, ranging from somewhat to very much. Both cohorts reported low to moderate levels of discomfort, with one PV reporting they were *very much* in discomfort. Deterioration of comfort over time was reported more by PV's than HV's, but in either case was no more than moderate. Both cohorts found the PRS to be moderately tolerable, and moderately better than expected, with the PV's reporting the system as slightly more tolerable than the HV's.

Asked if they hypothetically would be accepting of rotation as part of their treatment, 8 of 10 HV's would accept rotation, and two would not. In the exit interview, two HV's who would accept rotation added "(Would accept the rotation) *if it improved (treatment) outcome*" (HV06) and "*I would do anything the doctor told me essentially*" (HV07). HV03 commented that they felt the rotation would be acceptable for short treatment durations, but not for longer treatments. The two responders who would not accept rotation cited comfort (HV01) and nausea (HV03) as their primary reasons. All PV's said they would accept rotation if it was required for their treatment.

Content analysis of post-imaging interview transcripts showed participants' most significant concern was discomfort, particularly when the arms were positioned above the shoulders, with most of these participants reporting discomfort in the neck, arms or shoulders. One participant reported 'pins and needles' down their arms, while another reported shoulder pain and numbness in their hands. Participants positioned with their arms below the canopy did not report any discomfort in the neck, shoulders or arms, but two reported some discomfort during translation of the PRS between angles.

Some participants reported discomfort at certain angles, however there was no consensus as to which angles were worst - HV01 reported worse comfort on their right hand side (90-degrees) while HV03 felt most discomfort lying on their stomach (180-degrees) due to the feeling of blood rushing to their face. HV08 noted angles between 90-degree increments (45, 135, 225, 315-degrees) were most uncomfortable.

Another theme identified was that most participants felt the experience was acceptable overall, with some remarking that the experience was better than what they were expecting. HV08, for example, when asked if anything positive or negative stood out from their imaging session, remarked "It wasn't as bad as I thought it would be".

No participants reported feeling anxious or unwell during the study, though some felt unsure prior to imaging and that they would need to get used to the feeling of being rotated first. One PV reported feeling tense waiting for the MRI scanner to begin, adding *"I think it would be handy to know when it (the MRI scanner) would start working, and if you were just given a bit of notice*" and *"I think that (given a warning prior to scanning) would be a bonus, then you could relax in between."*

Discussion

In this study we present the first reported measurements of the acceptance of human rotation within an MRI scanner for a cohort of healthy human participants (HV) and cancer survivors' who received radiation therapy (PV). Acceptance of rotation is critical if gantry-free therapy incorporating MR-guidance is implemented clinically. Such systems could substantially reduce the size and cost of proton and heavy-ion treatment facilities, and more affordable x-ray therapy systems.

No significant pre- to post-imaging change in mean STAI was observed in HV's or PV's (7.9 to 11.8). For context, a 144-patient study from Harris et al. showed that patients with a high anxiety returned a normalised STAI score of 40 compared with 23 for low anxiety patients prior to undergoing an MRI exam[22]. There was a statistically significant increase in FMS score post-imaging ($p = 0.02$), however the median FMS score was zero for pre- and post-imaging, suggesting that motion sickness was not a concern for most participants. In their validation of the FMS, Keshavarz et al. separated participants who were considered at low or high susceptibility to motion sickness by FMS scores of less than or greater than 30 (normalised to 0-100)[20]. Of the participants in this study, HV04 would be considered susceptible but did not record any change in FMS before and after imaging. These results support previous studies assessing acceptance of patient motion which found patients generally tolerated translation[14,15] and rotation[7]. It does not appear that, at least for the cohort studied here, that the addition of MRI increased anxiety, or motion sickness. It was however noted that the distribution of STAI and FMS scores increased post imaging, which indicates acceptance of MRI and rotation does depend to an extent on each specific participant, which was reflected in post imaging interviews. HV03, who reported an increase in FMS score of greater than 30 (10 to 80), explaining "*for example if I go to amusement parks, I'm really bad with rides, so I did feel a bit more nauseous afterwards"* as their reasoning that they would not be willing to have rotation as part of a hypothetical cancer treatment. If patient rotation were to be introduced clinically, patients should be forewarned of that motion sickness may be experienced in susceptible individuals and patient suitability would likely need be assessed on a case by case basis.

Comfort of the device was clearly the biggest concern for study participants, especially those who were positioned with their arms above their shoulders. None of the participants with their arms inside the canopy reported discomfort in the upper body, with only some commenting that re-positioning of the PRS to different angles was uncomfortable in general. Since the arm positioning above the head was clearly identified as the biggest source of discomfort amongst healthy participants, and was reported to be a source of discomfort for the first two patient participants, a decision was made by the research team not to attempt the arms above the head for the remaining patient participants. This decision also considered that the age of the patient participants was higher than the healthy participant demographic, and thus were likely to be more susceptible to difficulties with shoulder mobility. Positioning the arms above the head is common practice in radiation therapy for certain treatment sites to keep the hands and arms out of the treatment fields. When designing future patient rotation systems, considerations will need to be taken for comfortable arm positioning, while keeping external limbs out of the treatment field for any site. This is not trivial if a patient rotation device must also fit within geometric constraints of an MRI scanner, and joining of the arms or hands, for instance in an arms crossed fashion, is avoided to reduce the risk of gradient-induced currents within the patient. Alternatively, considerations for a PRS could inform the design of the MRI scanner to increase comfort, which would need to be weighed against a decrease in imaging performance. Open MRI designs are of potential interest[23-25] and may also reduce feelings of claustrophobia among some patients[17].

Comfort depended on the angle of the PRS, with the supine position considered most comfortable for most participants. While HV's showed a clearer order of preference for other couch angles, PV responses were less conclusive. In a gantry-free scenario including on-line adaption, a patient may be at certain angles for several minutes and prolonged tolerability of certain angles could become an important consideration. Since, for the patient cohort, there was no clear consensus on which angles were harder to tolerate, the angles a patient could sustain for prolonged periods of time may need to be considered on a case-by-case basis, and treatment plans tailored accordingly.

PV08 was unable to complete the study due to a feeling of pressure across the thorax when secured within the PRS at the 0-degree (supine) position. Adjustments were made to remove as much pressure as possible, but the participant continued to report discomfort and began to breath rapidly once secured, so was removed from the PRS. This demonstrates that, for some patient's rotation may not be feasible, particularly older patients, patients with poor ECOG status, or toxicities associated with treatment. Additionally, patients with high levels of baseline claustrophobia would not be suitable.

There are several limitations of this study. Firstly, only a small sample was recruited and was restricted by geometric limitations of the PRS and MRI scanner, which did not allow some potential subjects to participate. The majority of HV's were recruited from the cancer therapy centre, and all PV's were recruited from a single clinic comprising prostate cancer patients in follow up. Since geometric restrictions of the PRS resulted in predominantly smaller participants, their responses may not represent tolerability more broadly. For the PV cohort, it is possible that the addition of female patients, patients with varying disease sites, and inclusion of patients currently receiving treatment would have affected the results. It is however worth noting that Whelan et al. considered patients of multiple gender, disease site, and time since treatment, and found that rotation was well tolerated across all participants[7].

Secondly, in this study participants were only in each couch position for the duration of MR imaging (approximately 1 minute per couch angle). A gantry-free workflow would almost certainly require image guidance prior to and during treatment delivery, which would increase the time a patient would be positioned at each couch angle. More significantly, an on-line adaption workflow would likely require images to be deformably registered to a planning image and potentially require re-contouring and plan re-optimisation for each couch angle. These steps would add significant time to the treatment workflow, and hence the time a patient was within the PRS. Some participants in our study reported comfort to worsen over time, and it is unclear if patients who were able to tolerate this study would be able to tolerate a full image-guided treatment using patient rotation. Furthermore, this process would need to be repeated during every fraction of radiation therapy.

When considering gantry-free radiation therapy, there are two ways to rotate the patient, in the horizontal direction, as performed here, or in the upright direction, as has been studied elsewhere[7,26,27]. The advantages of horizontal rotation are that existing imaging devices used for treatment planning and image-guided delivery can be more easily integrated with a horizontal approach, while vertical rotation would require dedicated upright imaging systems and new approaches to treatment planning[28]. Conversely, upright rotation does not introduce anatomical deformations during rotation which compromise treatments[9] and the upright position is generally more tolerable for patients[7]. Additionally, upright positioning can provide dosimetric benefits in the treatment of thoracic cancers due to a reduction in breathing motion and increased lung volume[29]. However, when combining MRI with horizontal rotation, the MRI can be used for adaptive radiation therapy[30], overcoming some of the advantages of upright rotation.

It would be advantageous to conduct a larger study in future, ideally with a PRS that could facilitate a more diverse range of participants, and to include more disease sites, patients currently receiving treatment, variable ECOG status, gender, age and concurrent treatments such as chemotherapy. Such a study would give a clearer indication which, if any, variables impact how accepting a patient would be to rotation based on their specific demographics and treatment. The study should also simulate a gantry-free treatment delivery scenario where participants are positioned at angles likely to be used for a treatment and kept at each couch angle for the expected time required for imaging, adaption and delivery of each beam. Finally, this should be repeated over several sessions to simulate a course of fractionated treatment delivery. A future study would also benefit from a baseline measurement of patient pain prior to imaging to help contextualise reported discomfort, which was observed for some participants. It would also be useful to record if each participant had previously received an MRI scan, and how those experiences compared with this study.

Conclusion

19 human participants (10 healthy and 9 former cancer patients) were rotated within a horizontal patient rotation system and concurrently imaged within an MRI scanner. Horizontal rotation within an MRI scanner was acceptable for most (17/19) participants. No substantial increase in anxiety or motion sickness was observed. Comfort was the largest area of concern and depended heavily on the participants' set-up position. While this study provides initial evidence for the acceptance of rotation within an MRI scanner, further research is required to assess the tolerability across patients with varying demographics, disease sites and comorbidities. Establishing the broader feasibility of patient rotation will support clinical implementation of this technology, which could globally impact the practice of radiation oncology.

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This study was carried out as part of a clinical trial registered with the Australian New Zealand Clinical Trials Registry: ACTRN12618000676213. The study was approved by the South Western Sydney Local Health District Human Research Ethics Committee (HREC/17/LPOOL/561).

Conflicts of Interest

JB, AS, MS, JD, RR, PM, GL have no conflicts to declare. LC acknowledges that Liverpool Hospital, where this research was undertaken, has a master research agreement with Siemens in regard to the MRI scanner used for this study. PK reports grants from Australian Government National Health and Medical Research Council, grants from Australian Cancer Research Foundation, grants from Australian Research Council, during the conduct of the study; grants and non-financial support from Conflicts updated and publicly disclosed at https://image-x.sydney.edu.au/home/disclosures/, outside the submitted work; In addition, Dr. Keall has a patent US 8,331,531 issued.

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Figure Legends

Figure 1: Study workflow. STAI – State-Trait Anxiety Inventory Test. FMS -Fast Motion Sickness Survey

Figure 2: Patient Rotation System (PRS) and the 3T MRI scanner with a participant in the ‘Above Shoulder’ position. The participant is positioned in the 0 (supine) and rotated 360-degrees in 45-degree increments.

Figure 3: Normalised State Trait Anxiety Inventory Test (STAI) score before and after rotation for healthy and patient volunteers. An asterisk (*) indicates participants which did not complete the rotation.

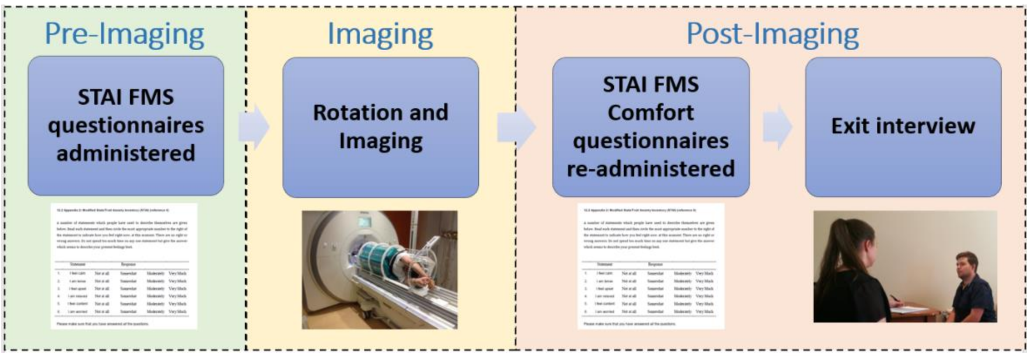
Figure 4: Normalised Fast Motion Sickness Survey (FMS) score before and after rotation for healthy and patient volunteers. An asterisk (*) indicates participants who did not complete the rotation.

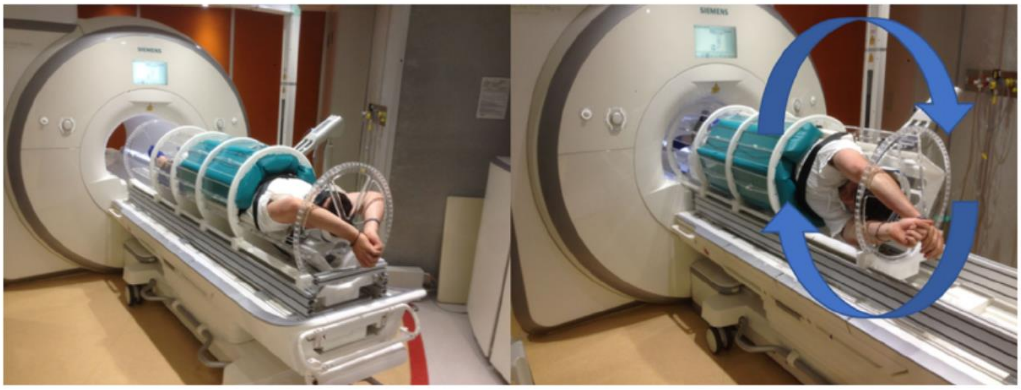
Figure 5: Normalised State Trait Anxiety Inventory Test (STAI) score and Normalised Fast Motion Sickness Survey (FMS) boxplots before and after imaging for healthy and patient volunteer cohorts.

Figure 6: Participant responses to the comfort questionnaire.

Table Legends

Table 1: Participant demographics and arm position during rotation.


Pre-Imaging
STAI FMS questionnaires administered
Imaging
Rotation and Imaging
Post-Imaging
STAI FMS Comfort questionnaires re-administered
Exit interview




Normalised STAI Healthy Volunteers
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Volunteer ID
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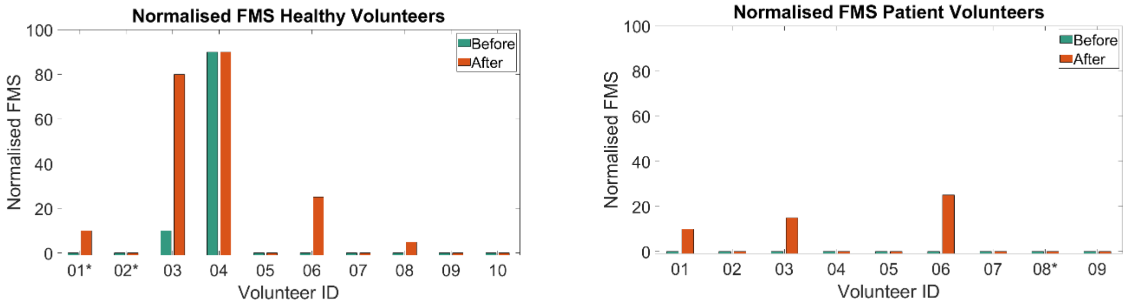
Normalised FMS Healthy Volunteers
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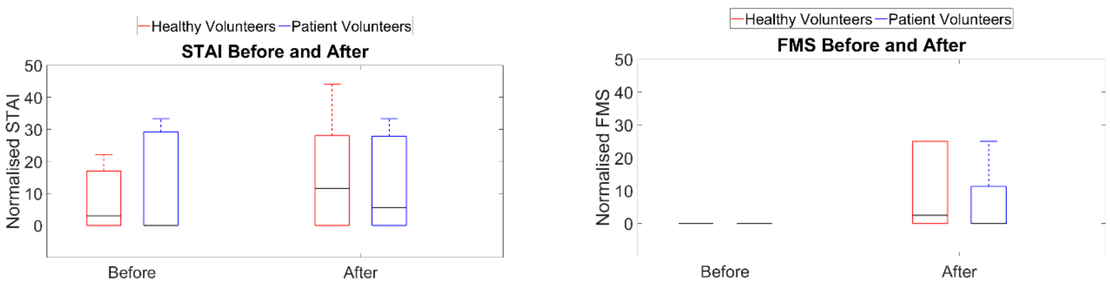
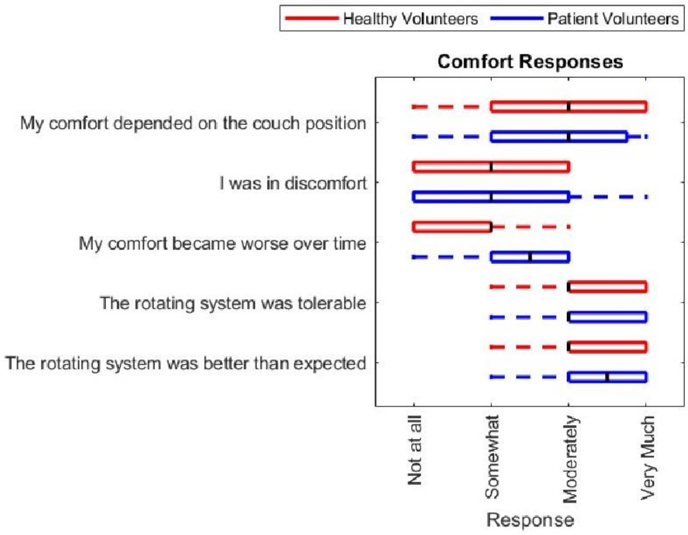

Healthy Volunteers
Patient Volunteers
STAI Before and After
Normalised STAI
Before
After
FMS Before and After
Normalised FMS



Volunteer (HV) ID	Age	Gender	Height (cm)	Weight (kg)	Arm Position
HV01	34	F	170	69	Above shoulders
HV02	57	F	160	75	Below canopy
HV03	26	F	154	52	Below canopy
HV04	26	F	160	56	Above shoulders
HV05	25	F	158	57	Above shoulders
HV06	27	F	155	41	Above shoulders
HV07	40	F	162	59	Above shoulders
HV08	30	M	175	70	Above shoulders
HV09	35	F	178	75	Above shoulders
HV10	46	F	167	76	Above shoulders
PV01	73	M	167	90	Above shoulders
PV02	68	M	159	74	Above shoulders
PV03	67	M	170	75	Below canopy
PV04	80	M	168	71	Below canopy
PV05	60	M	180	77	Below canopy
PV06	77	M	163	80	Below canopy
PV07	78	M	160	65	Below canopy
PV08	83	M	165	68	Below canopy
PV09	64	M	169	65	Below canopy