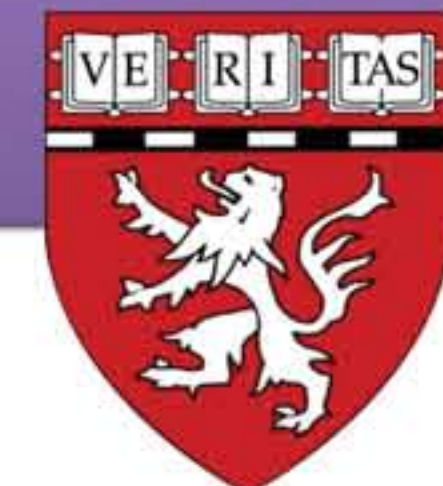


Safety and Effectiveness of SAF-R, a Novel Patient Positioning Device for Robot-assisted Pelvic Surgery in Trendelenburg Position

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INTRODUCTION

Robot-assisted pelvic surgery is commonly performed in steep T-burg position.

The position is associated with some risks, including:

- Cephalad shift (slippage) of the entire body on the operating table.
- Increased risk of nerve injury and joint damage.



The current position devices are:

- Not standardized
- Inadequately studied
- Time consuming to set up
- Provides limited access to the upper trunk, neck and arms

The SAF-R positioning device is developed to secure the patient quickly, easily, and reproducibly for such operations with minimal slippage on the operating table.

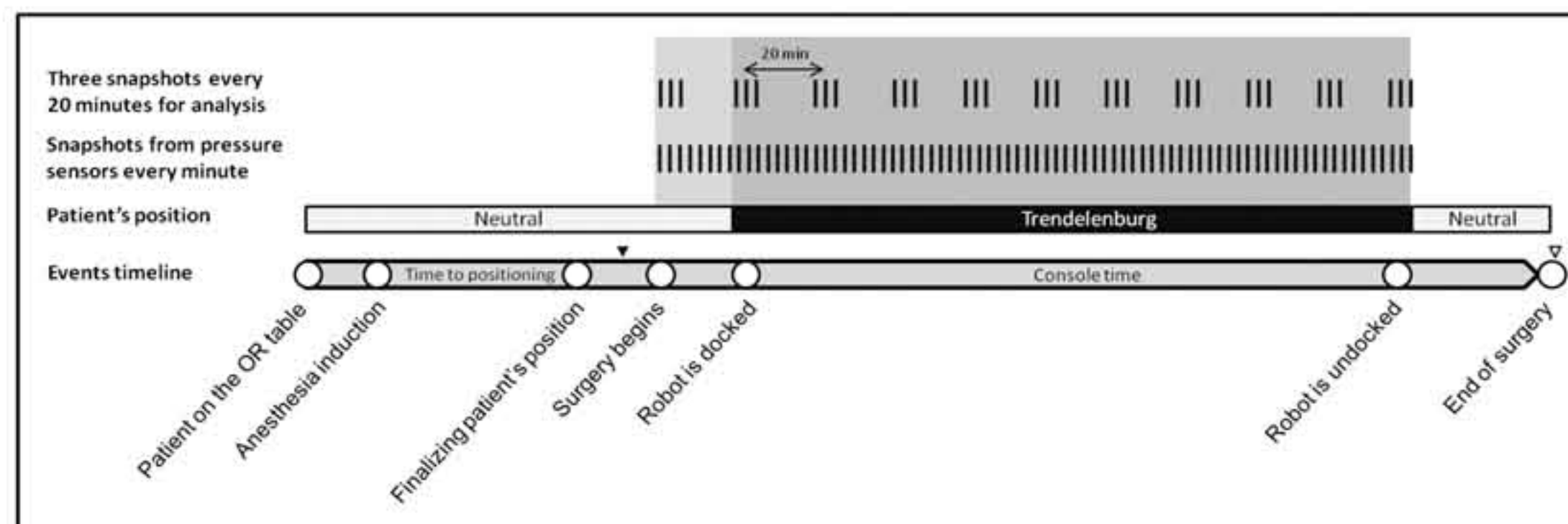
PATIENTS AND METHODS

In this prospective pilot study we aimed to test our hypothesis by investigating the safety and effectiveness of the SAF-R positioning device during robot-assisted pelvic surgery.

- Sixteen patients were positioned using SAF-R board.
- Pressure sensor mats were used for real-time monitoring of the contact pressures and contact area on the shoulders and calves throughout the surgery.
- The data collection included patients' BMI, time needed for positioning, total time in the T-burg position, contact pressure and contact area readings from the sensor mats and the patient shifting distance on the table.
- Patients were also followed for 1 month postoperatively for any position-related adverse event.

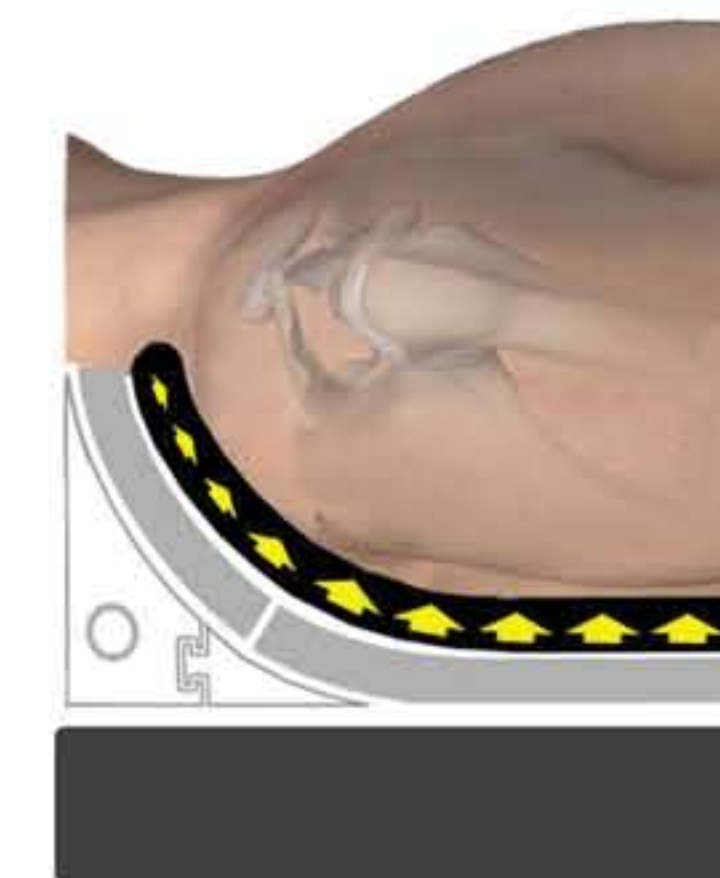


Figure 2. SAF-R Surgical board.



▼ Patients' position is marked with a straight line from the iliac crest down to the operating table. ▽ Patient shift in position is measured.

Figure 1. The timeline representing the events flow in OR



Gel mat
Plexiglass board
Operating table

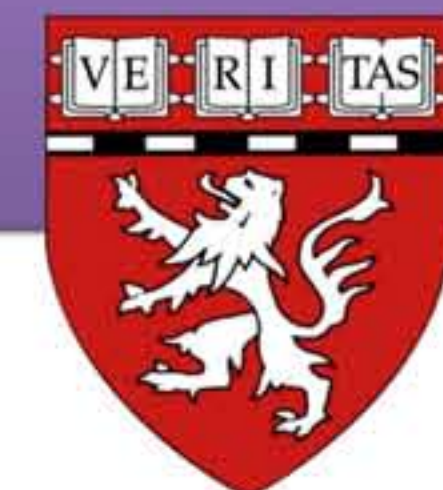
Figure 3. The upper back support follows the curve of the back over the patient's scapula; this helps to distribute the pressure from body weight over a larger area on both sides and prevents high focal pressures over the shoulders. The upper back supports cover all the way from tip of scapula to the acromion process but not the acromioclavicular joint, and that helps to prevent pressure transduction to the joint and subsequent compression of the nerve tracts traveling under it.

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RESULTS

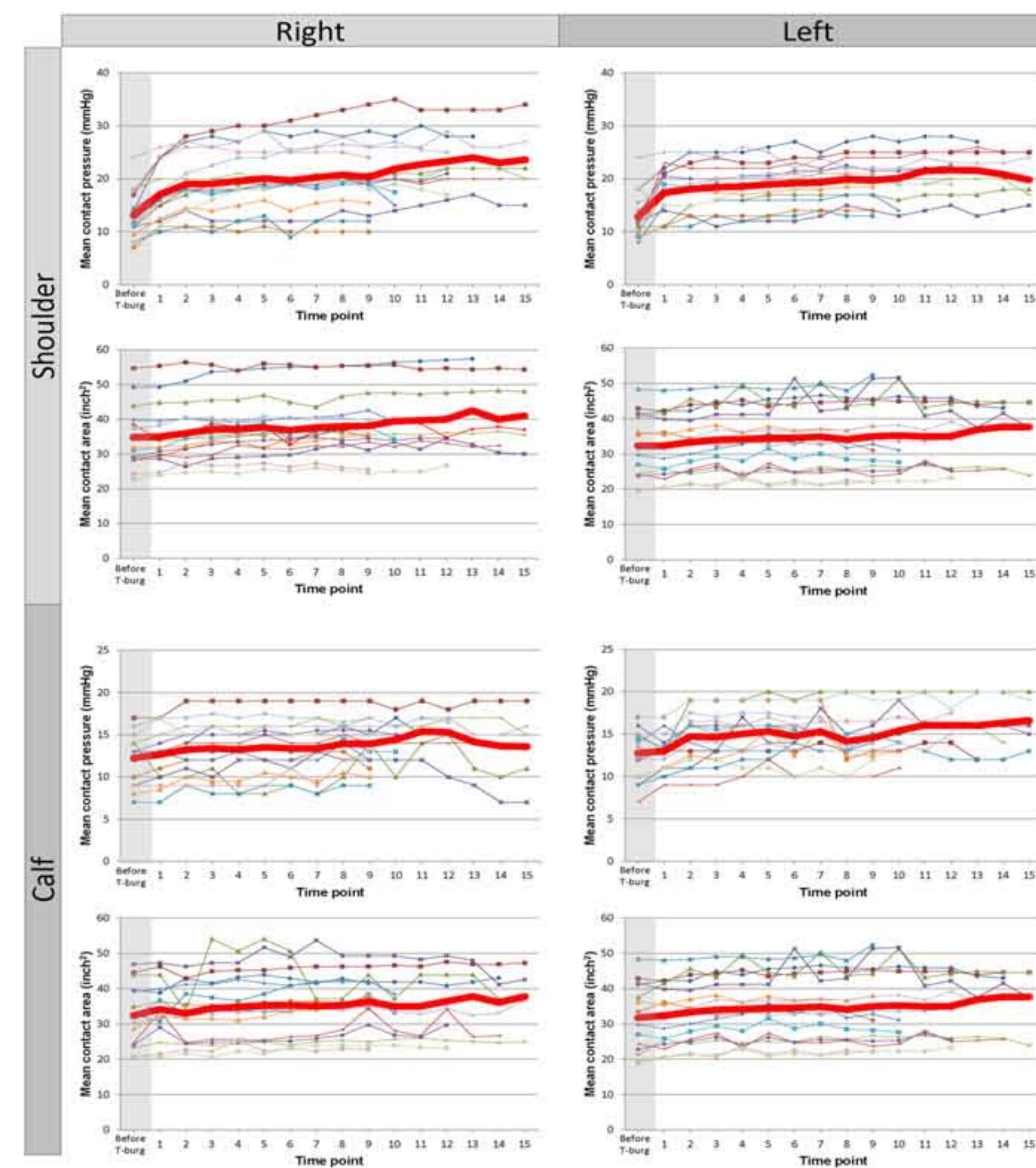
- Patient's shift was 1 cm on average
- Positioning took 6 minutes and it was concurrent with anesthesia induction
- There was an increase in shoulders' mean contact pressure when we shifted from neutral to T-Burg position and the last contact pressure measured in T-burg position (13.12±1.12 mmHg vs. 20.25±1.56 mmHg, p-value=0.001 for right shoulder and 12.84±1.05 mmHg vs. 19.60±1.09 mmHg, p-value=0.001, for left shoulder).
- The maximum changes in mean contact pressure was reported during the first 40 minutes after starting the T-burg positioning and this was calculated as 82% and 84.8% of the change of the mean contact pressure for right and left shoulders, respectively.
- The contact pressure remained relatively flat and in the safe range throughout the procedure.

There was no statistically significant association between patients' shift and either BMI, T-burg angle, duration of T-burg position, or change in mean contact pressure.

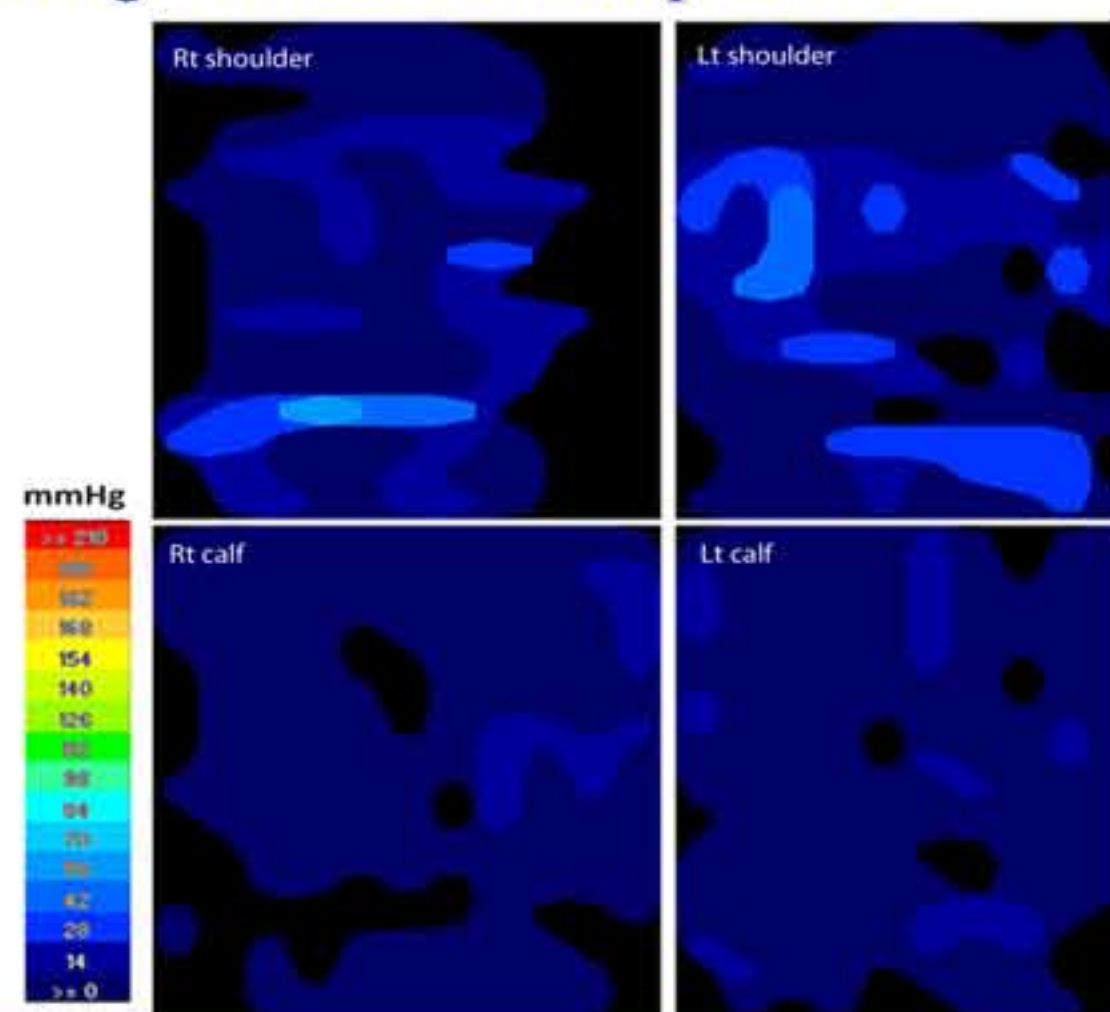
- The mean contact pressure before T-burg positioning and the last measurement during the T-burg position was 12.25±0.73 mmHg vs. 13.15±0.07 mmHg for right calf (p-value=0.066) and 12.75±0.76 mmHg vs. 14.25±0.78 mmHg for left calf (p-value=0.061), respectively. **The mean contact area of the calves did not change significantly during the operation in T-burg position** (p-value = 0.152 and 0.806 for right and left calves, respectively).
- There were no major post-operative complications related to the patients positioning. One patient complained of right shoulder pain 2 hours after her surgery. However, she had no pain or discomfort on 24 hrs and 30 days follow-up. There was no nerve injury, joint pain, skin abrasions or discoloration detected during post-operative follow-up.

Patients' demographic and perioperative characteristics

Variable	Number/Median	Range
Procedure		
Radical prostatectomy	8	-
Radical cystectomy	3	-
Bladder diverticulectomy	1	-
Distal ureterectomy	1	-
Hysterectomy	1	-
Myomectomy	2	-
Age (year)	56.5	35 - 74
Weight (kg)	86.8	54.1 - 113
Body mass index (kg/m²)	27.3	21.2 - 34.1
Time to positioning (min)	6	4 - 11
Duration of T-burg position (hr)	3.5	2.3 - 5.5
Degree of T-burg	20	16.7 - 26.4
Patient shift on the table (cm)	1	0.5 - 1.5



Mean contact pressure and mean contact area as is shown above, remained relatively flat during the surgery.



TekScan® pressure sensors systems for real-time monitoring and mapping of the contact pressures and contact area over the shoulders and posterior calves.

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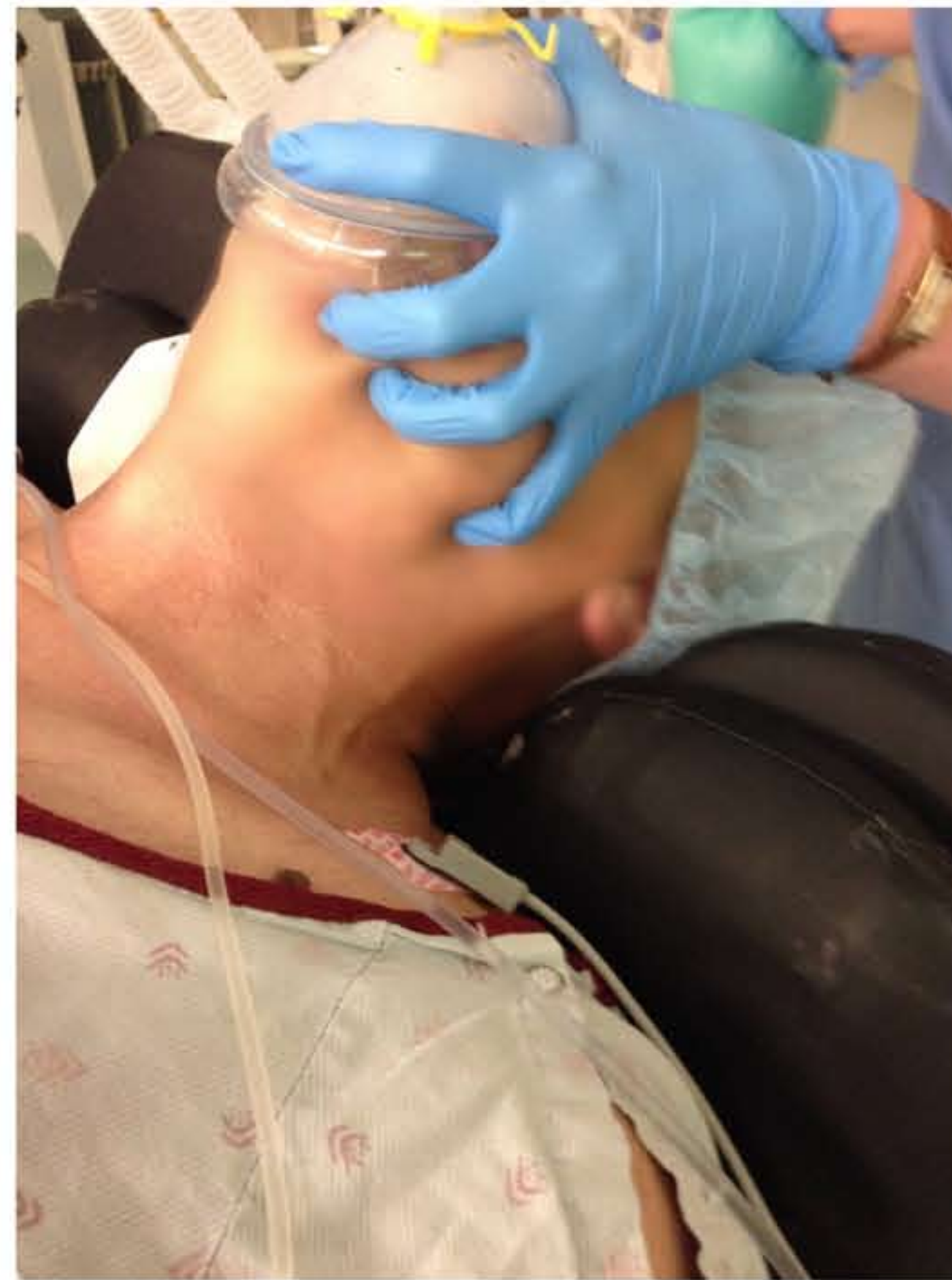
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CONCLUSION

- ❖ The board allows complete access to the patient's chest, neck and arms.
- ❖ Absence of chest harness, avoids any extra burden on ventilation pressure



- ❖ SAF-R surgical board is a safe, reliable, and time saving positioning device for patients undergoing robotic pelvic surgery in steep T-burg position.
- ❖ We believe this device will have a valuable place in the operating room, where such surgery is performed and will set a new standard in patient positioning safety for operations requiring steep T-burg positioning.