USING AN INNOVATIVE ATTACHABLE RADIATION REDUCTION EXTENSION SUPPORT SHEATH REDUCES STERILITY BREAKS AND ENHANCES SURGICAL PROFICIENCY

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INTRODUCTION

A number of factors are driving endovascular intervention (versus traditional vascular surgery), including decreased recovery times, infection rates, bleeding, and hospital stays. Endovascular procedures access patient vessels through a vascular sheath. Endovascular procedures are performed through image guidance with X-rays or computed tomography, or both, placed directly over the patient on the area of interest. Vascular access sheaths are typically 4-10 centimeters in length, with the hub of the sheath just external to the external surface of patient skin. This design of vascular access sheaths puts the hands of the interventional radiologist close to, or even within, the primary radiation beam throughout the duration of the procedure[1-3]. Thus, it is important to minimize these occupational health hazards to preserve highly trained physicians and allow optimal completion of each procedure. An innovative attachable radiation reduction extension support sheath (ARRESS sheath) could address this need. The purpose of this study was to quantitatively and qualitatively compare surgical proficiency and sterility performance of the standard sheath with the ARRESS sheath during antegrade common femoral artery access and intervention.

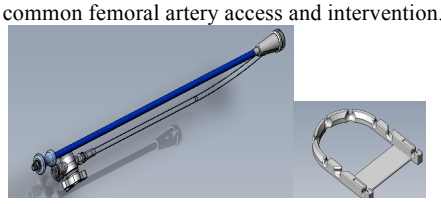


Figure 1. Attachable radiation reduction extension support sheath (ARRESS sheath)

METHODS

The current developed ARRESS extension sheath incorporates a novel design: a universal sheath adaptor attached to a bendable, malleable extension sheath and a separate adhesive multichannel, securement clasp. (Figure 1). Seven physician operators familiar with endovascular procedures were selected.

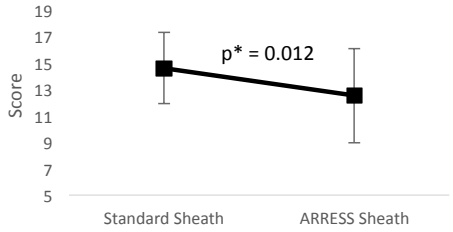
A swine model with critical limb ischemia was selected. Bilateral anterograde common femoral artery access was obtained (with and without ARRESS sheath; total of four procedures per physician) along with balloon angioplasty of the runoff vessel, followed by balloon angioplasty and stent deployment of the superficial femoral artery equivalent. Procedure sterility breaks of the physicians and nurse assistants were monitored by filming the procedure with two video cameras placed at orthogonal angles. Custom Matlab code (R2011a; Mathworks, Natick, MA) was used to automatically track the sterility breaks via the Kanade-Lucas-Tomasi algorithm. The sterile field was defined as the area between the shoulders and belt line and anterior axillary line. Two dependent variables were measured; occurrences of sterility breaks and total duration of sterility breaks (time normalized to total procedure time). Surgical proficiency was assessed using a questionnaire that was given after each procedure. The nine-item questionnaire captured procedure difficulty, lubricous level of the sheath, and procedure performance. Higher scores indicated greater difficulty (range from 1-25), the sheath being more lubricous (range from 1-5), and better surgical performance during the procedure (range from 1-15). The value of each dependent variable was averaged across both sides of the procedure. Paired t-tests were performed to compare the effect of ARRESS sheath ($p=0.05$).

RESULTS

The occurrences of sterility breaks and the duration of sterility breaks decreased 17% while using ARRESS sheath compared with using the standard sheath (Table 1). Regarding the surgical proficiency results, the questionnaire scores were 14.58 ± 2.68 and 12.5 ±

3.56 for procedure difficulty (p = 0.012), 3.29 ± 1.11 and 3.57 ± 1.27 for lubricous level (p = 0.178), and 11.36 ± 2.73 and 12.89 ± 1.53 for surgical performance (p = 0.046) (Figure 2). These results indicate that while using the ARRESS sheath, physicians felt that the procedure was less difficult, the sheath was as lubricous as expected, and that their surgical performance was better compared with using the standard sheath.

a) Procedure Difficulty



b) Surgical Performance

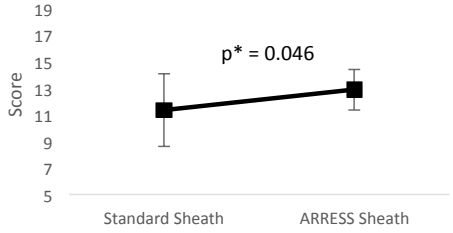


Figure 2. Physician rating of 1) procedure difficulty, and 2) surgical performance via questionnaires. Higher scores indicate less procedure difficulty and better surgical performance.

CONCLUSIONS

Despite the increasing popularity of endovascular surgeries, little work has been done to advance surgical technologies, including vascular access sheaths. Therefore, the goal of this study was to develop a novel sheath that would improve workflow to evaluate surgical proficiency of this new sheath compared to the current standard. Our results demonstrate the ARRESS sheath benefits for both workflow and surgical proficiency. Specifically, using the ARRESS sheath decreased the number of occurrences and overall time spent outside the sterile field. These decreases make the likelihood of an infection to the patient less likely and save costs by using fewer supplies during the procedure. Qualitative analysis further using data obtained from operators' questionnaires demonstrated a significant improvement in surgical proficiency while performing antegrade common femoral artery intervention using ARRESS versus standard sheath. Improved surgical proficiency can make procedures more efficient and save health care workers and facilities time and money. Overall, using the ARRESS sheath resulted in improved workflow and surgical proficiencies and further research should be conducted to determine whether the device should be used in a clinical setting.

REFERENCES

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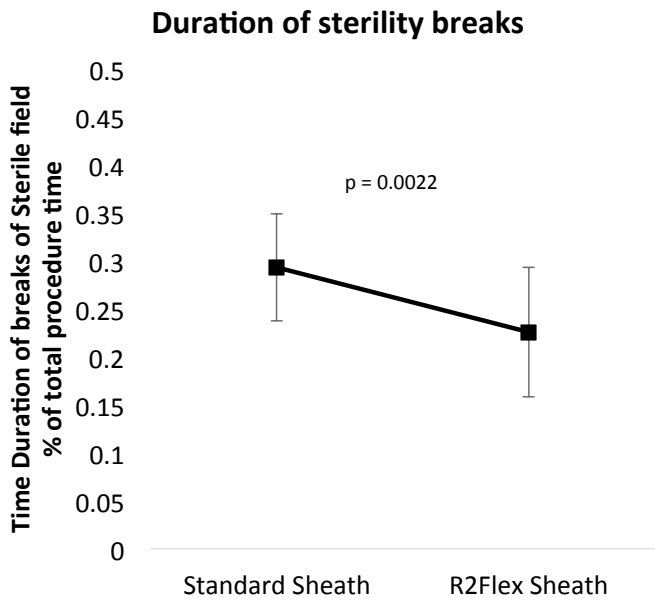
Table 1: Occurrence of sterility breaks and duration of sterility breaks

	Standard Sheath	ARRESS Sheath	
Occurrences of sterility breaks	29.57±6.60	24.43±7.68	p = 0.24
Duration of sterility breaks	0.27±0.08	0.22±0.133	p = 0.13



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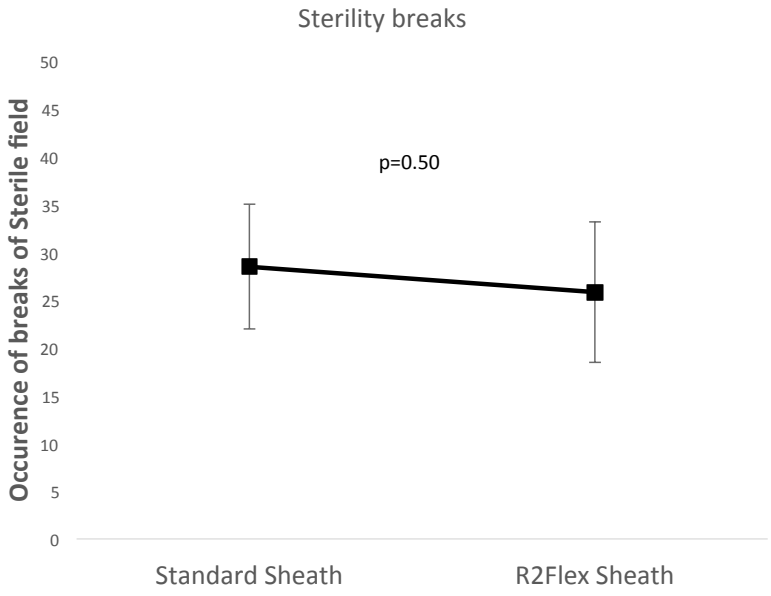

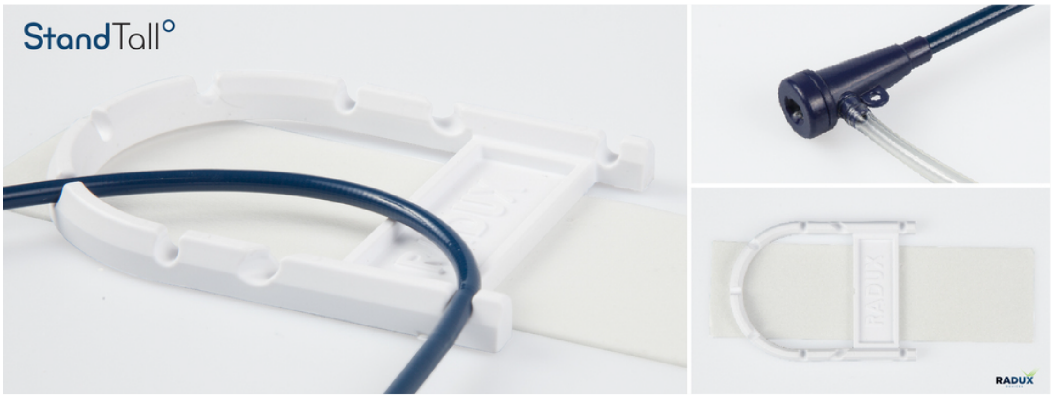
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