

Sibbitt WL Jr., Michael AA, Bankhurst AD, Sibbitt RR. **Randomized Controlled Trial of the Reciprocating Procedure Device in Interventional Procedures.** *J Vasc Inter Radiol* 2007 Abstract 358 To be presented at Society for Interventional Radiology Annual Meeting, March 2007, Seattle, WA.

**Title: RANDOMIZED CONTROLLED TRIAL OF THE RECIPROCATING PROCEDURE DEVICE IN INTERVENTIONAL PROCEDURES**

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**Purpose:** The reciprocating procedure device (RPD) has been demonstrated to be clinically superior to the conventional syringe in interventional syringe procedures including deep aspiration of body fluids, fine needle aspiration biopsy, and precise anatomic injection of medications. We hypothesized that this clinical superiority was due to intrinsic design characteristics of the RPD that permitted one-handed operation and enhanced control of the device by the operating physician.

**Materials and Methods:** 20 physicians were tested for their ability to control a syringe and needle during a typical interventional syringe procedure with the RPD vs. the traditional syringe using the validated quantitative needle-based displacement procedure model. Outcomes included unintended forward penetration (loss of control of the needle in the forward direction measured in mm), unintended retraction (loss of control of the needle in the reverse direction), and the ability to generate vacuum. Physicians operated the RPD with one hand, and operated the traditional syringe alternatively with 1-hand and 2-hands. A non-operating observer recorded all outcomes and measurements.

**Results:** The traditional syringe demonstrated a significant unintended forward penetration of 13.9 ± 2.3 mm (one-handed) and 9.02 ± 3.11 mm (two-handed). The RPD reduced unintended forward penetration to 7.39 ± 1.83 mm (a reduction of 47% and 18% respectively,  $p < 0.001$ ). Similarly, the RPD reduced unintended retraction by 64% and 44% respectively ( $p < 0.001$ ). The RPD was superior the traditional syringe in terms of unintended forward penetration and retraction at all syringe sizes (1, 3, 5, 10, and 20 ml). The RPD at all sizes was also superior to the traditional syringe in generating vacuum ( $p < 0.001$ ).

**Conclusions:** The RPD with one hand generates vacuum more easily and is better controlled by physicians during typical interventional procedures than the conventional syringe with one or two hands. The RPD of all sizes are better controlled and superior to conventional syringes for typical interventional syringe procedures.