A NOVEL RADIAL-DILATING BALLOON-EXPANDABLE URETERAL ACCESS SHEATH: THE INITIAL HUMAN EXPERIENCE *Glenn M. Preminger, Durham, NC; Tekisha U. Lindler*, Loma Linda, CA; Greg R. Lamberton, Loma Linda, CA; Brian K. Auge, San Diego, CA; D. Duane Baldwin, Loma Linda, CA; David M. Albala, Durham, NC*

INTRODUCTION AND OBJECTIVE: The ureteral access sheaths (UAS) currently on the market rely upon tapered dilators and the Dotter principle of axial force for insertion. This type of dilation creates sheering forces upon the urothelium. Due to this reliance upon axial dilation, the current UAS may not be inserted in up to 30% of patients. The purpose of this study is to report the initial experience with a novel balloon expandable ureteral access sheath that employs the less traumatic radial dilation for placement.

METHODS: The novel UAS consists of a folded ureteral access sheath wrapped around a high-pressure balloon. It is inserted into the ureter in a 9.5 Fr configuration. The device also has a lubricious coating facilitating ease of insertion. The tip of the device contains two radio-opaque markers that allow placement using fluoroscopy to the appropriate level in the ureter. Once positioned in the ureter a high pressure syringe is used to inflate the 20 atm balloon expanding the sheath to its full 12 Fr inner / 14 Fr outer diameter.

The initial 10 patients treated with this novel ureteral access sheath at Loma Linda University and Duke University are reported in this study. All patients underwent ureteroscopy combined with either holmium laser lithotripsy or intact extraction of stone fragments. A retrospective chart review was performed to determine a variety of preoperative, perioperative and postoperative parameters including operative time, blood loss, residual stone burden and complications.

RESULTS: The average patient age was 46 years (range 25-66). The mean stone size was large at 1.6 cm (range 1-2.5 cm). Mean operative time was 67.9 minutes (range 45-106). All patients were rendered stone free at short postoperative follow-up. Device insertion and removal was easy with all devices. There were no complications reported with the device and each instance the device allowed successful completion of the procedure. There were no ureteral abrasions, or lacerations in any patient. In a single patient mild difficulty to insert the ureteroscope was encountered.

CONCLUSION: The experience with the novel balloon expandable ureteral access sheath demonstrates that it is safe and effective. It was easily inserted in each patient with no complications. Its reliance upon radial dilation, which is less traumatic to the urothelium, makes this a promising new option for ureteral access.