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UP6-1 - Avoiding a Lemon: Performance Consistency of Single-Use Ureteroscopes

Sun, Sep 23
8:30 AM - 5:00 PM

Introduction & Objective :

Single-use flexible ureteroscopes are increasingly popular due to recent focus on repair costs and adequacy of sterilization of reusable scopes. The Boston Scientific LithoVue is the most widely used single-use scope in the US. However, as additional single-use scopes enter the market, concern has arisen regarding the consistency of performance of these newer devices. Our objective was to compare two digital single-use ureteroscopes: the Pusen PU3022a (Zhuhai Pusen Medical Technology Co) and the LithoVue (Boston Scientific) with emphasis on the consistency of performance between scopes regarding tip deflection, optical resolution, and working channel flow rate.

Methods :

10 LithoVue and 10 Pusen scopes were evaluated in new, never-used condition. The following parameters were recorded: Maximal tip deflection in both directions with an empty working channel and with a 200 μ m laser fiber; best achievable image resolution by viewing a 1951 USAF test pattern card; and irrigation flow rate at a pressure of 50cmH₂O with an empty working channel. Mean values for each parameter were compared using T-tests. The variance for each tested parameter was calculated and an F-test performed to evaluate the equivalency of the variances.

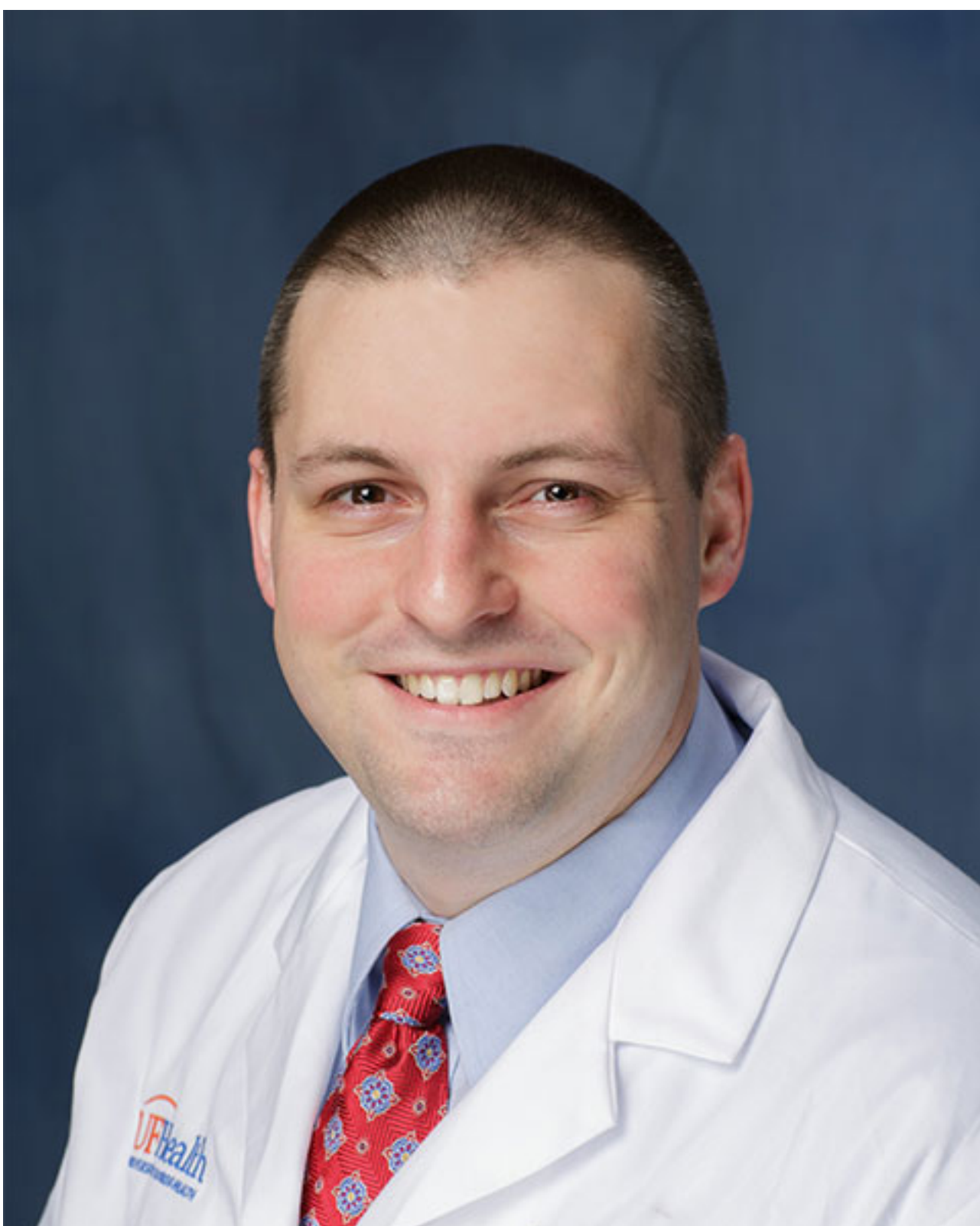
Results :

Both scopes provided an average maximum deflection of over 270 $^{\circ}$ in both directions. There was no difference in upward maximum deflection between scopes. The Pusen scope flexed to a significantly greater degree in the downward direction relative to Lithovue (302.7 $^{\circ}$ vs 284.5 $^{\circ}$ p<0.005). However, the Pusen scope lost a significantly greater degree of mean maximum deflection with a laser fiber in the working channel (15.5 vs 8.2 $^{\circ}$, p=0.0006). The Pusen scope had significantly higher resolution than Lithovue (18.9 vs 16.1 lp/mm, p=0.0001). Irrigation flow through an empty channel was significantly higher with the Pusen scope (18.2 vs 16.4ml/min, p<0.005). Variability between scopes was minimal and not statistically significant between manufacturers at all measured parameters.

Conclusions :

Lithovue and the newer PU3022a have similar "out-of-the-box" performance characteristics and, despite concerns over quality control, perform consistently regardless of manufacturer. Future research will test the durability of these performance characteristics as the different ureteroscopes are subjected to use.

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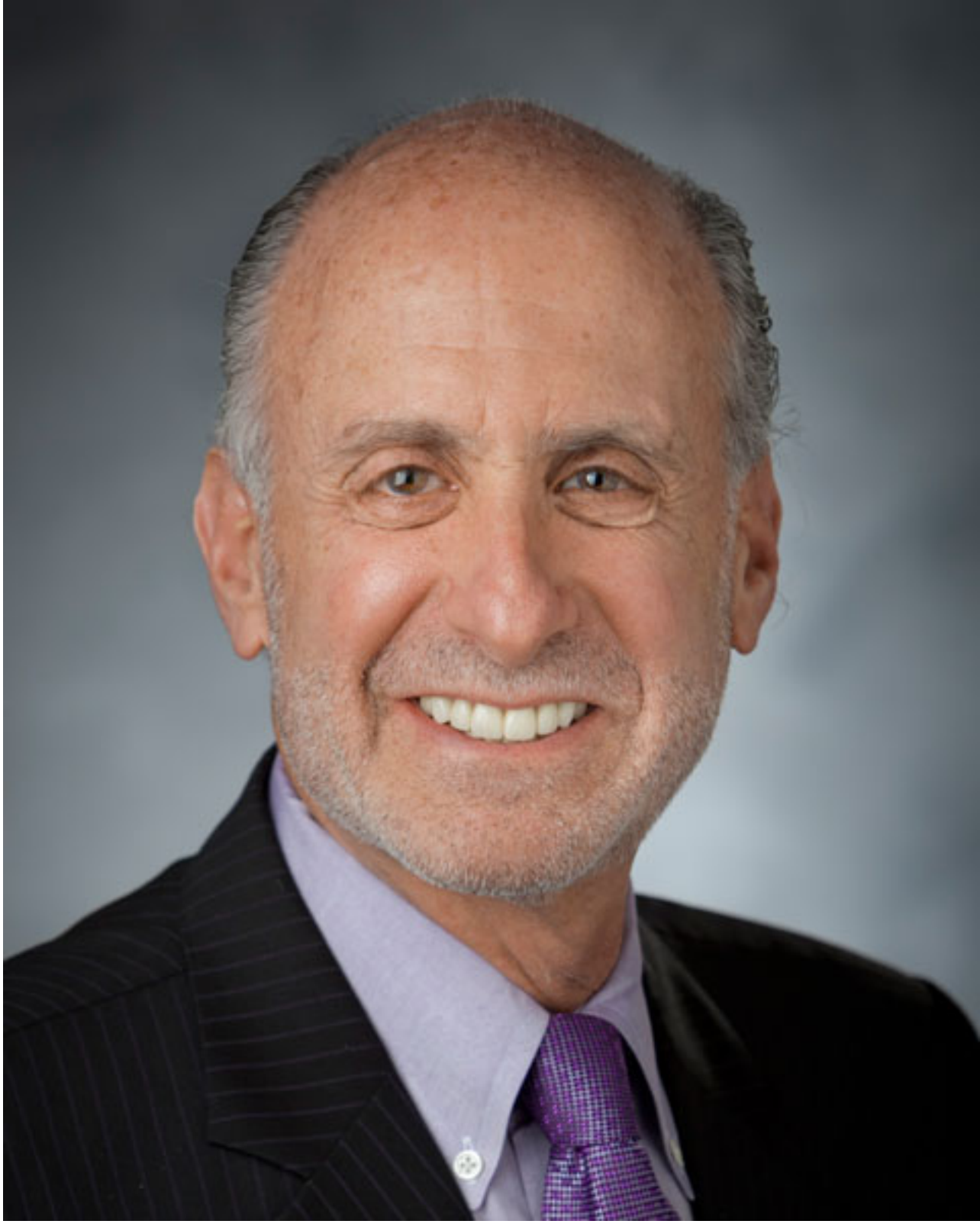
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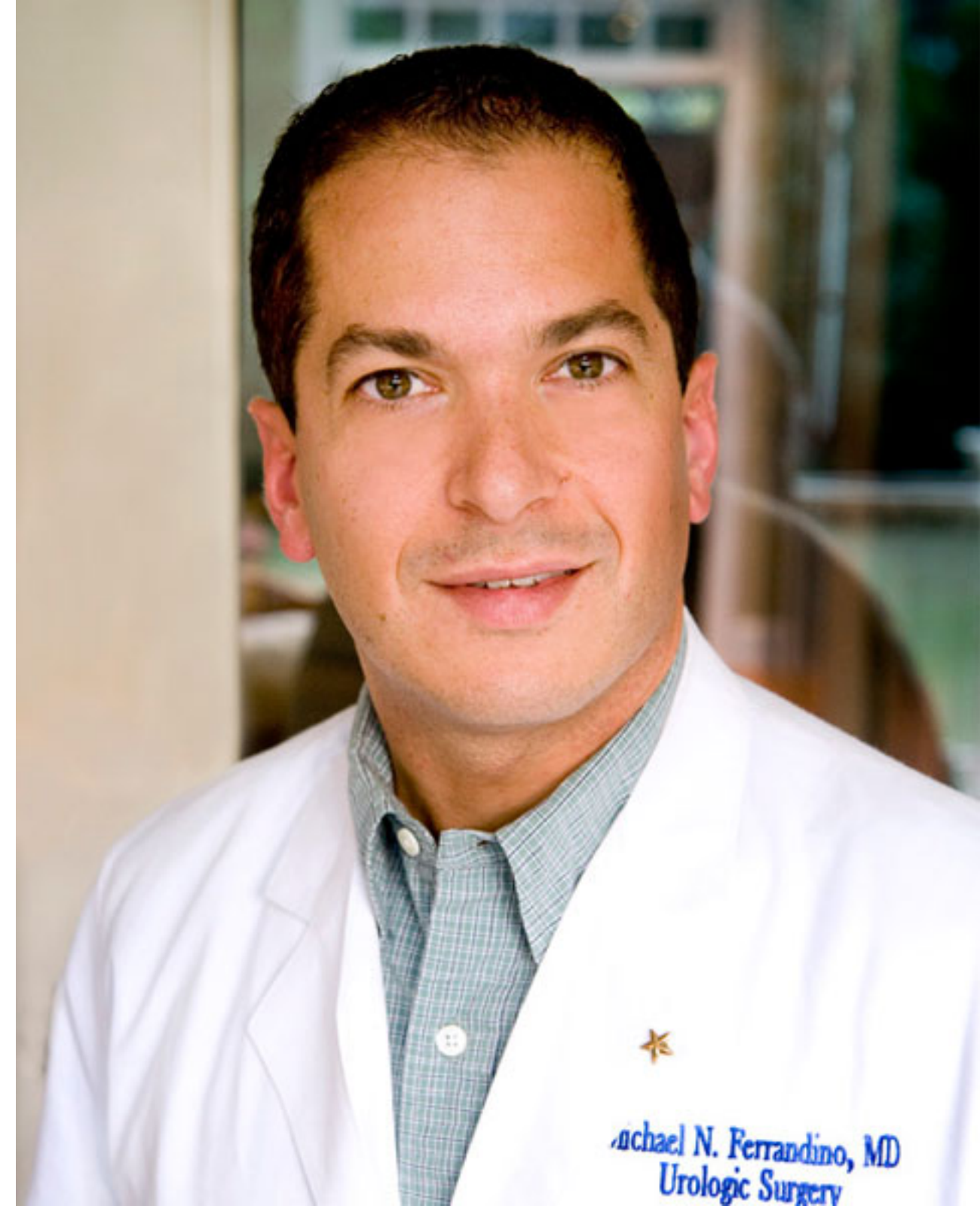
Charles D. Scales, Jr., MD MSHS is Associate Professor of Surgery (Urology) and Population Health at Duke University School of Medicine and Vice Chief for Quality Improvement and Patient Safety in the Division of Urologic Surgery. He completed medical school and residency training in urology at Duke University Medical Center. After residency, Dr. Scales completed the Robert Wood Johnson Foundation Clinical Scholars Program at UCLA, where he received advanced training in health services research, health policy, and quality of care.

Dr. Scales has a strong interest in education, having previously served on the ACGME Review Committee for Urology and as a member of the ACGME Board of Directors. He currently leads a course in quality improvement and data analytics in the Masters of Management in Clinical Informatics program at the Duke University School of Medicine.

From the research perspective, Dr. Scales has a longstanding interest in the epidemiology of and patient care for urinary stone disease. Recent studies have redefined the burden of urinary stone disease in the United States, compared the effectiveness of dominant stone removal technologies, and identified new opportunities for improving patient-centered and policy-relevant outcomes, such as unplanned care after procedural interventions. His research and perspective on urinary stone disease has been highlighted in U.S. News & World Report, Reuters, NPR, and the Wall Street Journal, among other media outlets.

As a result of these investigations, he has an appointment at the Duke Clinical Research Institute where he leads a diverse health services and clinical research program. He has received research support from the National Institute of Aging, the American Geriatrics Society, and philanthropic funding, among other sources. Currently, Dr. Scales is the Principal Investigator for the Scientific Data and Research Center for the NIDDK Urinary Stone Disease Research Network (U01).

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Dr. Michael Ferrandino is Director of Minimally Invasive Surgery for the Division of Urology at Duke University Medical Center in Durham, NC. He is an Associate Professor of Urologic Surgery. His area of expertise and is minimally invasive surgical approaches to benign and malignant urologic disease. He received his medical degree in 2001 from NYU School of Medicine. In 2007 he completed his urology residency at SUNY Downstate Medical Center and went on to an Endourologic Fellowship at Duke University Medical Center. He joined the faculty after fellowship and has continued to grow the field of minimally invasive surgery throughout his tenure. He serves as the Associate Residency Program Director and the Vice Chief of Education for the Division of Urology.

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