Prospective Comparison of Flexible Fiberoptic and Digital Cystoscopes

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OBJECTIVES To compare the optics, performance, and durability of digital (DC) and fiberoptic (FC) cystoscopes.

METHODS In an office setting, we randomly assigned staff urologists to 1 of the 4 cystoscopes, the Gyrus-ACMI ICN-0564 (AD), Gyrus-ACMI ACN-2 (AF), Olympus CYF-V2 EndoEYE Cysto-Nephro Videoscope (OD), Olympus CYF-5 Cysto-Fiberscope (OF), to perform diagnostic or surveillance cystoscopy and stent removal. The documented metrics included a subjective surgeon assessment of cystoscope optics and function characteristics on a 10-point scale (1, poor to 10, excellent). The measurement of the upward and downward cystoscope deflection and damage and repairs were all documented.

RESULTS A total of 1022 cases were performed. The DC and FC were used 690 and 332 times, respectively. Two repairs (0.2%) were documented (1 AF and 1 AD); both resulted directly from incorrect cystoscope handling/cleaning. The mean operative time per case for the DC and FC was 4.5 and 4.6 minutes, respectively ($P = .66$). The mean surgeon optical ranking for the DC and FC was 8.4 and 7.8, respectively ($P = .0076$). The mean surgeon deflection ranking for the DC and FC was 8.6 and 8.0, respectively ($P = .0001$). The mean surgeon retroflex deflection ranking for the DC and FC was 8.4 and 7.8, respectively ($P = .001$). The mean overall cystoscope score surgeon ranking for the DC and FC was 8.6 and 7.9, respectively ($P = .0001$).

CONCLUSIONS In the office setting, with proper care, FCs and DCs are durable for office applications. Overall, surgeons significantly preferred the DCs as demonstrated by discrepancies in both use and differences in the subjective metrics. UROLOGY 74: 427–430, 2009.

Since the development of the flexible cystoscope in 1973, these instruments have become an important component of the urologist's armamentarium. Office-based flexible cystoscopy remains the reference standard procedure for outpatient lower urinary tract imaging, providing easy access and valuable diagnostic information that can be difficult to obtain with any other technique.[1] Evolving technical advances such as active deflection, incorporation of working/irrigation channels, secondary passive deflection, smaller endoscopes, and improved optics have resulted in the rapid evolution of flexible cystoscopy for diagnostic and therapeutic applications.

The latest innovation in cystoscope technology has been the introduction of distal sensor video chips. Distal sensor cystoscopes were introduced in an effort to provide urologists with better optical resolution, contrast, color differentiation, and improved durability compared with the fiberoptic counterparts. In vitro evaluation has demonstrated that distal sensor cystoscopes are superior to fiberoptic cystoscopes (FCs) in terms of resolution, contrast discrimination, and red color differentiation.[2] Reports comparing the optical resolution of the distal sensor and standard FCs in an in vitro model have also demonstrated that distal sensor technology improves visibility in a simulated challenging work environment compared with standard FCs.[3] Another important consideration in choosing surgical technologies is the cost and durability. The durability of contemporary FCs must also be considered.[4]

As part of an effort to determine which technology to purchase for our outpatient office practice, we performed a prospective randomized evaluation of the currently available cystoscopes. Both currently available distal sensor cystoscopes and their fiberoptic counterparts were compared in the present study.

MATERIAL AND METHODS

The institutional review board of our institution granted permission for the present study. The study was conducted from September 2006 to November 2007 during which time the 2 manufacturers agreed to allow an extended equipment loan of

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new cystoscopes and towers for evaluation. During this period, 13 surgeons performed a total of 1022 cystoscopic procedures in an outpatient setting. The number of cystoscope evaluations was therefore not determined on the basis of power calculations, but rather as a part of a time-based equipment trial. The inclusion criteria included all patients undergoing office-based flexible cystoscopy by the faculty of the Columbia University Department of Urology.

The cystoscopes evaluated included the Gyrus-ACMI ICN-0564 (AD), Gyrus-ACMI ACN-2 (AF), Olympus CYF-V2 EndoEYE Cysto-Nephro Videoscope (OD), and Olympus CYF-5 Cysto-Fiberscope (OF). For each cystoscopy, all attending urologists were randomly assigned 1 of the 4 available cystoscopes. Because this study was part of an equipment trial, each urologist was given the opportunity to breach the randomization protocol and defer the assigned cystoscope to move to the next randomized cystoscope in the line until they were given what they considered was an acceptable option.

During each procedure, the type of cystoscope used, purpose of the procedure, interventions performed, instruments used, total time used, problems during the procedure, damage during processing, and gross inspection of the cystoscope after the procedure were recorded. Attending surgeons were asked to subjectively rate the visibility and maneuverability (cystoscope optics, deflection, visibility of bladder neck inspection on retroflexion [if done], and overall cystoscope performance) of the instrument. Documented metrics with each use included repairs and surgeon assessments on a 1-point scale (1, poor to 10, excellent). Each cystoscope was used until it required repair. The reason for repair was recorded, and the device was sent to the manufacturer for repair.

After each week of use, the maximal upward and downward deflection angles of each cystoscope were measured by photocopying the device in maximal active deflection and measuring the angle between the deflection tip and the remainder of the shaft using a protractor. Each cystoscope was tested for deflection without any instruments in the working channels and then with a 3.0F grasping forceps (Cook, Spencer, IN).

Careful cystoscope cleaning and sterilization were performed after the each procedure by experienced trained personnel. The cleaning method consisted of full immersion in a detergent agent (Cidex, Irvine, CA) for 30 minutes after appropriate cleaning of the working channels.

The results for all cystoscopes were organized into 2 comparison groups: digital (DC) and fiberoptic (FC) cystoscopes. All results were averaged for the 2 groups, and the data were stratified only by image mechanism type (fiberoptic vs distal sensor) as a condition of the extended equipment loan with the 2 manufacturers. Statistical comparisons for the continuous variables were analyzed using the Student *t* test. All subjective rankings were compared with the Mann-Whitney rank sum statistical test. All analyses were performed with Stata statistical software (StataCorp, College Station, TX).

RESULTS

From September 2006 to November 2007, 1022 cystoscopy cases were performed. The AD, AF, OD, and OF were used 320, 195, 370, and 137 times, respectively. The mean patient age was 66 years. A total of 13 attending urologists participated in this study. Table 1 lists the number and types of cases performed for the FCs and DCs.

Table 1. Type of intervention

	Cystoscope Type (n)		
Intervention	Digital	Fiberoptic	Total (n)
No intervention	558	280	838
Stent removal	89	30	119
Biopsy and fulguration	11	10	21
Biopsy	7	1	8
Ureteral catheterization	6	1	7
Fulguration	1	3	4
Other	18	7	24
Total	690	332	1022

Table 2. Tabulated comments

Cystoscope	Surgeons (n)	Comment
Fiberoptic	5	Preferred digital cystoscopes
	4	Thought pink/red discoloration present
	5	Complained about light source
	9	Thought cystoscope was adequate
	1	Could not finish case because of cystoscope
Digital	9	Cystoscope was outstanding
	1	Complained about light source
	2	Cystoscope performed well in bloody conditions
	10	Pink/red discoloration present
	12	Excessive glare or brightness
	13	Cystoscope was adequate

During the study period, 2 repairs (0.2%) were documented. Both the AF and the AD cystoscopes needed repair because of incorrect cystoscope handling/cleaning. The distal segment of the insertion tube of both cystoscopes was damaged.

The mean operative time per case for the DCs and FCs was 4.4 and 4.5 minutes, respectively ($P = .66$). The mean surgeon optical ranking for the DC and FC was 8.3 and 7.8, respectively ($P = .0076$). The corresponding mean surgeon deflection rankings were 8.6 and 8.0 ($P = .0001$). The corresponding mean surgeon retroflex deflection rankings were 8.4 and 7.8 ($P = .001$). The mean overall cystoscope evaluation surgeon ranking for the DCs and FCs was 8.6 and 8.0, respectively ($P = .0001$). Additionally, surgeons were asked for a general comment about the DC and FC (Table 2).

Active deflection and retroflexion varied with time. Table 3 lists the manufacturer's maximal deflection and retroflection angles compared with our initial, middle, and ending angle measurements. As anticipated, the deflection angles diminished when an instrument was introduced into the working channel of the cystoscope. The AD, OD, AF, and OF experienced a 31.7%, 11.15%, 11.2%, and 11.05% decrease in deflection angle, respectively.

Table 3. Upward and downward deflection angles of all cystoscopes studied

Deflection	Manufacturers' Measurements	Our Measurements		
		Initial	Middle	End
Upward				
AD	200°	175°	184°	186°
AF	180°	163°	162°	163°
OD	210°	198°	200°	198°
OF	210°	204°	197°	193°
Downward				
AD	180°	146°	146°	143°
AF	170°	155°	161°	159°
OD	120°	104°	104°	102°
OF	120°	105°	104°	105°

AD, Gyrus-ACMI ICN-0564; AF, Gyrus-ACMI ACN-2; OD, Olympus CYF-V2 EndoEYE Cysto-Nephro Videoscope; OF, Olympus CYF-5 Cysto-Fiberscope.

COMMENT

Flexible cystoscopes have undergone substantial improvements since 1973 when Tsuchida and Sagawara[5] reported on the first dedicated flexible cystoscope that incorporated into its design a rigid insertion tube. Flexible cystoscopy has evolved to become an important component of urologic practice owing to its diagnostic and treatment capabilities.[6,7]

Recently, the incorporation of solid-state camera chips (distal sensor optics) has offered the potential for improved optical resolution and color depth with endoscopic technologies.[3] Charged couple device (CCD) distal chip sensor technology was first developed in the 1970s. During the past 30 years, the fabrication of CCD sensors has been optimized to yield a very high-quality image-producing sensor. The CCD sensor is composed of small photo sites that incorporate a photodiode to convert light (photons) to charge (electrons). The charge is then transferred to charge transfer cells and then to a charge transfer register. Charge packets of each column are then shifted out of the CCD sensor by row, and each pixel's charge is converted to a voltage. These individual pixel voltages then undergo further electronic modification by other chips that are not part of the CCD sensor. The information is then transferred to a controller box (the box to which the endoscope is attached).

The latest generation of distal sensors incorporates a 1.3 million pixel complementary metal-oxide-semiconductor sensor and dual light-emitting diode lights. Two important features of complementary metal-oxide-semiconductor devices are the high-noise immunity and low-static power consumption. This enables minimal energy loss to heat production while maintaining an extremely precise measurement, advanced image clarity, and accurate color reproduction. The capabilities and potential of this new technology have been described in published reports.[8] Distal sensor cystoscopes currently exist as simple plug-and-play devices. Compared with FCs, the distal sensor equivalents are much lighter and easier to handle during procedures. Additionally, distal sensor cystoscopes do not require white balancing and camera focusing.[9] A disadvantage of all contemporary distal sensor endoscopes is the inability to level the field (previously done by orienting the camera head on fiberoptic instruments).

Distal sensor endoscopes have been demonstrated to provide a number of advantages.[10,11] Even first-generation distal sensor flexible cystoscopes provided superior ability to discern objects in a simulated challenging working environment compared with the most advanced FCs available.[3] As such, it has been suggested that superior optics will result in superior surgical performance, particularly during challenging cases. However, this has yet to be clinically demonstrated. As research on distal sensor chip technologies and their related computer software progresses, we can expect improvements in this already superior visual diagnostic performance. Distal sensor video imaging also allows rapid and high-quality image capture that can be stored and transferred with standard computer memory technologies.

During the 1-year study period, we recorded 2 repairs in the FCs. The distal segment of the cystoscope was damaged as a direct cause of incorrect cystoscope handling, and needed repair in both cases. The insertion tube was damaged when the cystoscopes were put in a storage case in both cases. The low occurrence of repairs across all groups, a 0.2% incidence rate, suggests that the fragility is not increased with the DCs. This finding is consistent with that of Canales et al.[12] who reported that the distal sensor technology decreases maintenance cost by requiring <1 repair every 2 years. Additionally, the findings of the present study are consistent with those of McDougall et al.,[13] who reported that 72% of damages occur because of incorrect handling, cleaning, and storage, for which surgeons are not involved. Although the cleaning methods are known to affect the durability of endoscopes, the present study did not evaluate this parameter, because all cystoscopes were processed in the same manner.

Substantial differences were found with cystoscope deflection when the instruments were placed in the working channel. Although this was clearly a function of the cystoscopes' design, it is interesting that the surgeons evaluated did not believe that a diminishment in function occurred with the AD cystoscopes despite the substantially less deflection under these conditions.

The present study had several limitations. First, no power analysis was performed to establish the number of cases required to adequately compare the cystoscopic technologies. Because the study period was limited by the nature of the equipment loans from the manufacturer, we used a time-based endpoint for termination of patient accrual. Additionally, because the primary purpose of this trial was to determine which type of equipment was preferred by the practicing urologists in our department, the urologists were allowed to breach the randomization protocol to use equipment with which they were comfortable to provide an optimal patient outcome. Although compromising randomization, the application of this study protocol did result in substantial differences in individual cystoscope use, suggestive of surgeon preferences for specific equipment.

Overall, in this prospective office-based trial, the distal sensor cystoscopes were considered by the practicing urologists to provide superior optics and deflection without compromising durability.

CONCLUSIONS

Our experience with flexible cystoscopes has indicated that, with proper care, FCs and DCs are durable for office applications. Overall, surgeons significantly preferred DCs as demonstrated by the discrepancies in usage (DCs 690 cases vs FCs 332 cases) and significant differences in subjective optical and functional metrics.

References

1. Patel AR, Jones JS, Angie S, et al. Office based flexible cystoscopy may be less painful for men allowed to view the procedure. *J Urol.* 2007;177:1843-1845.
2. Borin JF, Abdelshehid CS, Clayman RV. Comparison of resolution, contrast, and color differentiation among fiberoptic and digital flexible cystoscopes. *J Endourol.* 2006;20:54-58.
3. Quayle SS, Ames CD, Lieber D, et al. Comparison of optical resolution with digital and standard fiberoptic cystoscopes in an in-vitro model. *Urology.* 2005;66:489-493.
4. Parkin J, Keeley FX Jr, Timoney AG. Flexible ureteroscopes: a user's guide. *BJU Int.* 2002;90:640-643.
5. Tsuchida S, Sugawara H. A new flexible fibercystoscope for visualization of the bladder neck. *J Urol.* 1973;109:830-831.
6. Witjes JA, Moonen PM, van der Heijden AG. Comparison of hexaminolevulinate based flexible and rigid fluorescence cystoscopy with rigid white light cystoscopy in bladder cancer: results of a prospective phase II study. *Eur Urol.* 2005;47:319-322.
7. Kawakami M, Ishikawa M, Kontani K, et al. Flexible video cystoscope with built-in high-frequency cauterizing element for transurethral resection of bladder tumor. *Int J Urol.* 2001;8:713-714.
8. Kanne U. Digital CMOS sensor chips for media-isolated liquid flow sensing. *Med Device Technol.* 2003;14:16-18.
9. Andonian S, Okeke Z, Smith AD, et al. Digital ureteroscopy: the next step. *J Endourol.* 2008;22:603-606.
10. Abdelshehid C, Ahlering MT, Chou D, et al. Comparison of flexible ureteroscopes: deflection, irrigant flow and optical characteristics. *J Urol.* 2005;173:2017-2021.
11. Traxer O, Dubosq F, Jamali K, et al. New-generation flexible ureterorenoscopes are more durable than previous ones. *Urology.* 2006;68:276-281.
12. Canales BK, Gleason JM, Hicks N, et al. An independent analysis of flexible cystoscope repairs and cost. *J Urol.* 2007;178:2098-2102.
13. McDougall EM, Alberts G, Deal KJ, et al. Does the cleaning technique influence the durability of the <9F flexible ureteroscope? *J Endourol.* 2001;15:615-618.