The new Invisio® DUR-D 'chip-on-the-tip' digital flexible ureterorenoscopes: evaluation of changes in physical properties over time

Background & purpose: Flexible ureterorenoscopes (fURSs) have become an essential tool in endourological practice. In 2006, a new generation of digital fURSs (Invisio® DUR-D, ACMI, USA) with new optical technology was introduced. We have compared both light intensity and deflection angles, with and without indwelling instruments, between identical scopes of different number of uses to evaluate changes in physical properties over time. **Materials & methods:** On three identical Invisio DUR-D digital flexible ureteroscopes of different usages we measured and compared the light intensity. Measurements were taken three times each with the ureteroscopes in straight position and maximum upwards and downwards deflection, respectively. The first scope was brand new; the second had been used 30 times while the third had been used 44 times. We also measured and compared the deflection angles without and with widely used accessory instruments inside the working channel in four identical scopes after 0, 10, 30 and 44 uses, respectively. **Results:** Light intensity for each scope showed slight differences in relation to deflection angles, but it remained stable after many uses. By contrast, the deflection angle is shown to deteriorate with instruments inside the working channel. This is relatively independent of the type of microinstrument used, but the decrease is directly proportional with advanced age of the scope in terms of uses. **Conclusions:** As an advantage over earlier generation scopes, light output remains constant due to the absence of the fragile low-resolution fiberoptics. Similarly to the earlier generation scopes, there remains a decrease in deflection capability over time with the new Invisio DUR-D digital fURSs.

KEYWORDS: deflection angle ■ digital flexible ureteroscopes ■ light intensity

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Since the initial description of passive diagnostic flexible ureteroscopy in 1960, the technology has advanced significantly [1]. Flexible ureterorenoscopy is standard for diagnosing and treating upper urinary tract diseases such as urolithiasis, transitional cell carcinoma and ureteral strictures [2]. This has expanded the usefulness and clinical applications of flexible ureteroscopes and thus a passive diagnostic tool has evolved to an active therapeutic instrument [3–7].

Over the last few years, technology has allowed miniaturization of flexible ureteroscopes, laser fibers and wire devices raising important questions regarding fragility, breakage, repair costs and proper utilization.

Despite these new developments with increased deflection and smaller ureterorenoscope calibers, durability has not been compromised. Recent reports have even shown that the latest generation of flexible ureterorenoscopes (fURSs) were more durable than the previous generation [8,9].

The new Invisio® DUR-D digital fURSs (Gyrus, ACMI, USA) was the first 'chip-on-the-tip' flexible ureteroscope to be marketed. It was introduced into urological practice in late 2006. It was claimed that not only should this ureteroscope provide a superior quality image, but also make the instruments more durable in the whole.

Physical properties of flexible ureteroscopes are known to change over time. Therefore, the aim of this study was to compare both light intensity and deflection angles, with and without indwelling instruments, between identical scopes of different number of uses.

Materials & methods

We measured some of the physical properties that are widely considered as good characteristics of durability of flexible ureteroscopes on identical Invisio DUR-D digital flexible ureteroscopes of different usages.

The study was carried out in an *in vitro* setting, where the scopes were fixed on a straight workbench and the deflection angles of empty and loaded scopes were measured using a protractor. The light intensity measurements were taken at a given setting of the light source using an Ocean Optics™ optical spectrometer at a 20-mm fixed distance from the tip of the scope. To minimize measurement errors, all measurements were taken three times and mean values were calculated.

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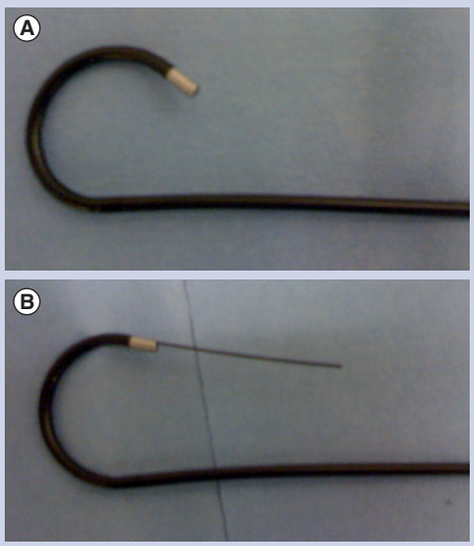

Figure 1. (A) Deflection angle without guidewire and (B) deterioration in deflection angle after introduction of a 0.035" Guidewire (Cook™ Medical).

Therefore, we measured and compared the deflection angles without and with instruments – a 0.035" Guidewire (Cook™ Medical), a disposable 200 µm laser fiber and a 3F Zero-Tip Nitinol Basket (Boston Scientific™) – inside the working channel of four identical different scopes after 0, 10, 30 and 44 uses, respectively, as the above instruments are some of the widely used instruments in routine endourological practice (Figure 1).

In addition, we measured and compared the light intensity at a given setting of the light source. Measurements were taken three times each with the ureteroscopes in straight position and upwards/downwards active deflection, respectively. The first scope was brand new; the second had been used 30 times while the third had been used 44 times (Figure 2).

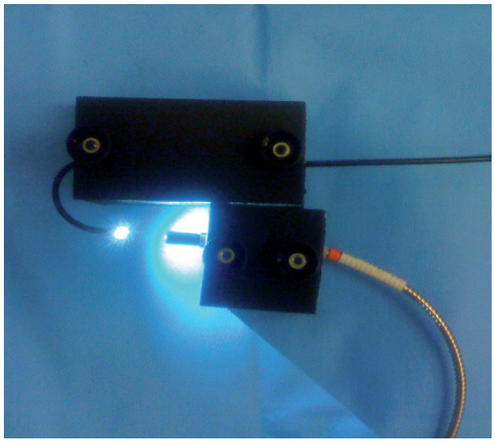

Figure 2. The ureteroscope in deflection, placed at a distance of 20 mm from an Ocean Optics™ optical spectrometer.

Results

Statistical analysis was carried out on the results using 'Analyse-it' statistical software program (Version 2.21) and the appropriate statistical test was used according to the type of data. The level of statistical significance was defined as $p < 0.05$.

Light intensity output for each scope showed a slight difference in relation to deflection angles, which was within the experimental error and was not statistically significant (Table 1).

On the other hand, all scopes showed more deflection angle with an empty working channel, while the deflection angle is shown to deteriorate with instruments inside the working channel. Results from this study showed that this is relatively independent of the type of microinstrument used, but the decrease is directly proportional with advanced age of the scope. This deterioration was statistically significant in both upward deflection ($p = <0.0001$) and downward deflection ($p = 0.0100$) (Table 2).

Expert commentary

Flexible ureteroscopy has become the standard and most frequent upper tract endourological procedure for the diagnosis and the treatment of numerous urinary tract conditions such as stones, transitional cell carcinoma, ureteric strictures and extrinsic compression. The fact that the flexible scopes can virtually reach every part of the collecting system ensures that patients usually have a successful diagnostic or therapeutic procedure. As it is a minimally invasive procedure, patients can usually be discharged the same day and hence the technique has gained popularity with surgeons and patients.

Over the last decade several innovations have improved the performance of flexible ureteroscopes; for example their miniaturization, improved manoeuvrability and optimization of the accessory instrumentation.

The ongoing attempts to improve the optical characteristics of the fURSs resulted in a significant advancement when in 2006 the first digital fURS was introduced. The Invisio DUR-D was the first commercial digital flexible ureteroscope that dramatically improved image quality and is considered the current gold standard image quality [10].

The Invisio DUR-D digital fURS integrates the endoscope, digital camera and light source in a simple plug-and-play device. It has a 3.6F

Table 1. Light intensity in different deflection (unit: Lux × 10^3)

Uses	Straight	Upwards	Downwards
0	5.5	4.36	4.84
30	6.19	6.30	6.25
44	5.05	5.25	5.15

working channel and is capable of dual 250° of deflection. The shaft's diameter is 9.3F, while the distal tip's diameter is 8.7F; the distal tip houses dual light-emitting diode (LED)-driven light carriers. At the tip, there is also a tiny 1-mm digital camera 'chip-on-the-tip' (Figure 3), which eliminates the need for fragile, low-resolution fiberoptics. These two technological advances reduce the weight of the ureteroscope and eliminate the risk of fires since there are no external cameras or light source [11]. The Invisio DUR-D weighs 505 g compared with the conventional fiberoptic ureteroscope (e.g., DUR-8 Elite) with external camera and light cord that weighs 1012 g. This represents a 50% reduction in weight [11].

Deflection angle

Most current new-generation ureteroscopes allow active deflection up to 250°. The Invisio® DUR-D was the first to offer dual active primary and passive secondary tip deflection that totals 250°, offering access to almost every point in the collecting system.

The loss of deflection capacity once a tool is used in the working channel is a critical point that might limit the surgeon's ability to reach certain points within the collecting system.

Our results show that there is no significant difference in loss of deflection between the use of guidewire, laser fiber or stone basket; there is no significant difference between the upwards or downwards deflection of the scope but the deflection angles are directly proportional to the number of uses of the scope. Hence, in this regard, these new digital ureteroscopes have no real advantage over the standard fiberoptic ureteroscopes as both lose some deflection with increased use. This loss appears proportional to the number of uses of the ureteroscope.

In our opinion, combining primary active deflection and strategic passive secondary deflection provides unrestricted access to virtually all calyces in the vast majority of patients. The added cost and complexity of these dual-deflection ureteroscopes might not justify their routine inclusion in the ureteroscopic armamentarium in all urological institutions as yet, although they will play an important role in the often complex case mix found in tertiary referral centers such as our unit. The experienced endourologist can often overcome the limitations of the older potentially inferior fiberoptic ureteroscopes and hence the added cost of these new digital flexible instruments may not be routinely justified.

Light intensity

The Invisio DUR-D digital fURS provides excellent image quality, zoom capability and digital image enhancement, thus achieving a remarkable improvement in comparison with fiberoptic technology. The instrument requires no separate light source; illumination is provided by two LEDs instead of the conventional fiberoptics. This LED light lasts up to 10,000 h, which is 10–20-times longer than the expensive xenon lights [11]. Consequently, there is a decrease in weight and fragility of the endoscope, materialized in the lower repair costs and increased lifespan [12].

Results from this study have shown that the light intensity output from the Invisio DUR-D fURSs remains constant over time, which can be attributed to the elimination of use of the

Table 2. Deflection angles with different instruments.

Uses	No instruments	0.035'' guidewire	200-µm laser fiber	3F nitinol basket
0 upwards	218°	196°	205°	204°
10 upwards	216°	194°	203°	203°
30 upwards	197°	173°	174°	174°
44 upwards	163°	148°	155°	152°
0 downwards	216°	194°	209°	191°
10 downwards	199°	191°	192°	190°
30 downwards	230°	139°	151°	147°
44 downwards	170°	123°	141°	158°

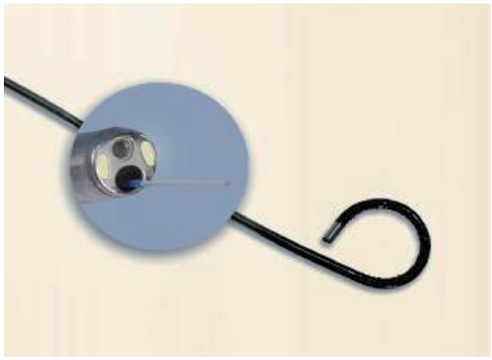

Figure 3. The tip of the Invisio® DUR-D houses a dual light-emitting diode, a 12 o'clock digital camera and a 6 o'clock 3.6F working channel.

fragile low-resolution fiberoptics and the digital enhancement achieved by the instrument. This constancy in one of the most important physical properties of flexible ureteroscopes is a great advantage over earlier generation scopes.

Future perspective

Flexible ureteroscopes have evolved from purely diagnostic tools to key instruments in the management of stone disease and other pathology of the upper urinary tract. Despite these advances, problems related to visibility and manoeuvrability can hinder the goals of surgical intervention. The ongoing efforts and innovations have resulted in the first digital fURS, the Invisio DUR-D. The Cobra Dual-Channel Flexible Ureteroscope has dual channels, which allow for better flow of irrigation while simultaneously using microinstruments, but this is at the expense of the scope being larger in diameter and depending on older fiberoptic technology. We believe that the ideal future flexible ureteroscope should incorporate 'chip-on-the-tip' technology, dual channels and, above all, have a smaller diameter.

Conclusion

The Invisio DUR-D fURS has an advantage over earlier generation scopes in that the light output remains constant. However, as with earlier generation scopes, there remains a decrease in deflection capability over time.

Only a few studies have been conducted up to now relating to the overall durability and manoeuvrability of this instrument after use for clinical purposes, which is probably due to its recent introduction to the market. This study was carried out in a cross-sectional manner, where measurements and calculations were performed on identical scopes of different number of uses at a certain point of time. Although performing this study in a longitudinal-sectional manner might be more bias free, this was not applicable at our unit owing to instrumental availabilities.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Executive summary

- Flexible ureterorenoscopy is now the standard for diagnosing and treating upper urinary tract diseases such as urolithiasis, transitional cell carcinoma and ureteral strictures.
- The new Invisio DUR-D® digital flexible ureterorenoscopes (Gyrus, ACMI, USA) was the first 'chip-on-the-tip' flexible ureterorenoscope to be marketed in late 2006.
- We compared both light intensity and deflection angles, with and without indwelling instruments, between identical scopes of different number of uses to evaluate changes in physical properties over time.
- As an advantage over earlier generation scopes, light output remains constant.
- Similarly to the earlier generation scopes, there remains a decrease in deflection capability over time.

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