Evaluating the acceptability of an online patient decision aid for the surgical management of lower urinary tract symptoms secondary to benign prostatic hyperplasia

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Appendices available at cuaj.ca

Abstract

Introduction: The growing number of surgical options available to treat benign prostatic hyperplasia (BPH), may overwhelm patients and urologists when deciding on an optimal treatment. Therefore, we developed an online patient decision aid (PtDA) that includes all guideline-approved surgical modalities. The objective of this study was to assess the acceptability of the PtDA among former BPH surgery patients and urologists that treat BPH surgically.

Methods: The International Patient Decision Aids Standards were used to develop a PtDA that includes monopolar transurethral resection of the prostate (TURP), bipolar TURP, GreenLight photovaporization, endoscopic enucleation of the prostate, Rezum, Urolift, Aquablation, open retropubic prostatectomy, and robotic simple prostatectomy as management options. Eleven urologists that regularly treat BPH and 19 patients who received BPH surgery were recruited. Alpha-testing was performed using a validated acceptability scoring system.

Results: For all sections of the PtDA, most urologists agreed that the language used was easy to follow (91.9%), that the amount of information provided was adequate (63.6%), that the length of the PtDA was appropriate (63.6%), and that the outcomes reported were correct (81.8%). All 19 patient participants agreed that the length of the PtDA was appropriate (84.2%), and that the outcomes reported were well-explained (89.5%).

Conclusions: Our PtDA was found to be acceptable among urologists and patients. These results demonstrate that most of the participants either recommend the use of this tool or plan to incorporate it in their clinical practice.

Introduction

Benign prostatic hyperplasia (BPH) affects up to 50% of men over the age of 50, with a prevalence that increases with age.¹ Associated lower urinary tract symptoms (LUTS) can significantly worsen health-related quality of life (HRQoL).² First-line therapy usually consists of lifestyle changes or medical therapy. However, if patients’ symptoms worsen following conservative management or medical therapy, surgical intervention is often recommended.³ Currently, several surgical options to treat LUTS secondary to BPH exist. These treatments vary in their intensity, need for anesthesia, risk of morbidity, functional outcomes, durability, effect on patient’s HRQoL, and accessibility.²

The growing armamentarium available for the surgical management of LUTS may overwhelm both patients and urologists when selecting a treatment. This makes it challenging and time-consuming for both patients and urologists to ensure that patients are well-informed of their available options and have the opportunity to share their personal values and preferences when selecting an optimal treatment. Adopting a shared decision-making approach enables patients and physicians to mutually agree on a solution that incorporates both physician clinical expertise and patient preferences.⁴ Patient decision aids (PtDA) can be used to facilitate shared decision-making among patients facing challenging clinical decisions.⁵ PtDAs promote informed shared decision-making by explaining the background information related to the decision at hand, presenting the available risks and benefits of the available treatment options, and providing patients with the possibility to communicate their personal values and preferences.⁶⁻⁷ In comparison to standard counselling, PtDAs have been shown to improve patient knowledge, improve patient activation, provide realistic expectations, and reduce decisional conflict.⁵

Conclusion
Existing PtDAs for the treatment of BPH do not focus on the surgical management of the condition, are outdated, and/or are pay-for-use. Therefore, we developed an interactive, online PtDA that includes all BPH guideline-approved surgical modalities and techniques. In this study, we report the development of our BPH PtDA and findings related to its acceptability testing among patients and urologists prior to its implementation in clinical practice.

Methods

Development

Using the Ottawa Decision Support Framework, the International Patient Decision Aid Standards, and the steps outlined by McAlpine et al, a PtDA that includes monopolar transurethral resection of the prostate (TURP), bipolar TURP, GreenLight photovaporization, endoscopic enucleation of the prostate, Rezum, Urolift, Aquablation, open retropubic prostatectomy (ORP), and robotic simple prostatectomy (RSP) as management options was developed. Decision Aid standards were followed to ensure the development of a high-quality, evidence-based PtDA. A steering committee including content and methodological experts, as well as patient advisors, was assembled to develop the PtDA. The PtDA was stratified according to patients’ prostate volumes following society guidelines. The three prespecified volume cutoffs used were: small-to-moderate prostates (30–80 mL), moderate-to-large prostates (80–150 mL), and large prostates (>150 mL). A detailed overview of the development process specific to this PtDA has been previously published.

Alpha-testing

Once the prototype of the online PtDA was complete, we evaluated its acceptability among former BPH surgery patients that previously selected and received a surgical treatment for their BPH and urologists that treat BPH surgically. A convenient sampling method was used to recruit both patients and urologists. Alpha-testing ensures that the developed tool is easy to read, comprehensive, of appropriate length, and unbiased when describing the available management options. Alpha-testing was achieved through the use of a validated scoring system that is routinely used when evaluating the acceptability of a PtDA. This scoring system was translated into a brief online survey that was completed by both patients and urologists once they had reviewed the PtDA. The survey consisted of Likert scale and open-ended questions (Appendices A, B; available at cuaj.ca).

Since the PtDA consisted of three sections that presented an ensemble of different treatment modalities, each section of the PtDA was assessed independently with a survey. Urologists were tasked with completing the surveys related to all three sections of the aid, whereas patients were responsible for completing the survey related to their estimated preoperative prostate volume, which was provided by their treating urologist. Upon completion of the survey, all participants had the opportunity to provide additional narrative feedback related to each question in the survey. Institutional ethics board approval was obtained at the University of Montreal Hospital Centre.

Statistical analysis

The survey results were analyzed with descriptive analyses. Feedback provided during alpha-testing was reviewed by the steering committee and used to update the prototype to create a finalized version of the PtDA.

Results

Alpha-testing was completed by 11 urologists in both academic and community settings, and 19 patients. None of the steering committee members were considered as alpha-testing participants. The detailed demographic data for the urologist participants can be found in Table 1. Among the 19 patients, 11 were from the small-to-moderate prostate volume group (30–80 mL), five were from the moderate-to-large prostate volume group (80–150 mL), and three were from the large prostate volume group (>150 mL).

Urologist results

Urologist participants assessed all three sections of the PtDA when evaluating its acceptability. For all sections of the PtDA, 91.9% agreed that the language used was easy to follow, 63.6% agreed that the amount of information provided was adequate, 63.6% agreed that the length of the PtDA was appropriate, and 81.8% agreed with the outcomes reported. Overall, 81.8% of urologists anticipate using this PtDA once complete and 91.9% were satisfied with the overall quality of the PtDA. The detailed urologist results specific to each section of the PtDA can be found in Table 2.

| Location, n (%) |
|----------------|
| Montreal       7 (63.6%) |
| Toronto        3 (27.3%) |
| Sudbury        1 (9.1%)  |

| Practice, n (%) |
|----------------|
| Academic       8 (72.7%) |
| Community      3 (27.3%) |
All 11 urologist participants found that the description of the treatments within the moderate-to-large section of the PtDA was well-balanced. For both the small-to-moderate and large prostate sections, 90.9% (10/11) of participants found treatment descriptions were well-balanced. Within the small-to-moderate section, one participant believed that the description of Rezum was favored. Regarding the large prostate volume section of the PtDA, one urologist believed that the description of both RSP and ORP were favored (Table 3).

In the open-ended survey questions, clinicians highlighted the strengths and weaknesses of the PtDA and were able to provide suggestions that would improve the tool. Regarding the strengths of the aid, urologists reinforced the idea that this is a user-friendly tool that provides thorough information that can be easily understood. Additionally, urologist participants supported the need for the creation of this tool and felt the PtDA would inform patients of other options that their own urologist may not offer. In this section, the urologist population also provided suggestions that mainly consisted of: changes related to the reported outcomes, reducing the amount of information in the aid, and adding more media to alleviate the text. Additionally, there were multiple sugges-

| Table 2. Detailed description of quantitative clinician alpha-testing results specific to each section of the patient decision aid (n=11) |

| Questions | Small to moderate prostate volumes (<80 ml) | Moderate to large prostate volumes (80–150 ml) | Large prostate volumes (>150 ml) |
|-----------|--------------------------------------------|-----------------------------------------------|---------------------------------|
| 1         | The amount of information provided was:    |                                               |                                 |
|           | Much less than wanted                      |                                               |                                 |
|           | A little less than wanted                  |                                               |                                 |
|           | About right                                |                                               |                                 |
|           | A little more than wanted                  |                                               |                                 |
|           | Much more than wanted                      |                                               |                                 |
| 2         | The length of the PtDA was:                |                                               |                                 |
|           | Too short                                  |                                               |                                 |
|           | Just right                                 |                                               |                                 |
|           | Too long                                   |                                               |                                 |
| 3         | The language used was easy to follow:      |                                               |                                 |
|           | Strongly disagree                          |                                               |                                 |
|           | Disagree                                   |                                               |                                 |
|           | Neutral                                    |                                               |                                 |
|           | Agree                                      |                                               |                                 |
|           | Strongly agree                             |                                               |                                 |
| 4         | I agree with the outcomes reported:        |                                               |                                 |
|           | Strongly disagree                          |                                               |                                 |
|           | Disagree                                   |                                               |                                 |
|           | Neutral                                    |                                               |                                 |
|           | Agree                                      |                                               |                                 |
|           | Strongly agree                             |                                               |                                 |

Section for all prostate volumes

| Questions | n (%) |
|-----------|-------|
| 5         | I believe the PtDA would be a useful tool when counseling a new patient with BPH: |       |
|           | Strongly disagree                        |       |
|           | Disagree                                 |       |
|           | Neutral                                  |       |
|           | Agree                                    |       |
|           | Strongly agree                           |       |
| 6         | I anticipate using this PtDA in my practice once it is complete: |       |
|           | Strongly disagree                        |       |
|           | Disagree                                 |       |
|           | Neutral                                  |       |
|           | Agree                                    |       |
|           | Strongly agree                           |       |
| 7         | I am satisfied with the overall quality of this PtDA: |       |
|           | Strongly disagree                        |       |
|           | Disagree                                 |       |
|           | Neutral                                  |       |
|           | Agree                                    |       |
|           | Strongly agree                           |       |

BPH: benign prostatic hyperplasia; PtDA: patient decision aid.
tions to create a French version of the tool. Detailed narrative feedback results from open-ended survey questions for the urologist population can be found in Table 4.

**Patient results**

For the three sections of the PtDA, all 19 patients agreed that the language used was easy to follow, and most agreed that the amount of information provided was adequate (84.2%), that the length of the PtDA was appropriate (84.2%), and that the outcomes reported were easy to understand (89.4%). Overall, 100% of patients were satisfied with the quality of the PtDA and indicated that they would recommend it to new BPH patients. The detailed quantitative patient results specific to each section of the tool can be found in Table 5.

The three patient participants within the large prostate volume subgroup found that the description of the treatments within this section was well-balanced. Regarding the small-to-moderate prostate volume sections, 36.3% (4/11) of participants found treatment descriptions were well-balanced. Among the small-to-moderate prostate volume section, 36.3% (4/11), 27.2% (3/11), and 18.2% (2/11) of participants believed that the description of monopolar TURP, GreenLight photovaporization, and Rezum were favored, respectively. Regarding the moderate-to-large prostate volume section of the PtDA, one participant (20%) believed that the description of GreenLight photovaporization was favored; all other participants (80%) believed that the description of the treatments were well-balanced (Table 6).

Narrative feedback from the patient population highlighted several important strengths of the PtDA. For one, patients indicated that it helped present the outcomes in a much more efficient manner, allowing patients to explore all their options equally. Nevertheless, the patients did emphasize that despite being very informative, the PtDA does not replace the role of the physician in the decision-making process. Other reported strengths included the logical flow, thoroughness, readability, and clarity of the tool. Detailed narrative feedback results from open-ended survey questions for the patient population can be found in Table 4.

**Updating the patient decision aid and dissemination**

The alpha-testing survey results will be reviewed by the steering committee and used to update the PtDA. The latest version of the PtDA can be found using the following link: https://cua-bph-decision-aid.web.app/?fbclid=IwAR3aXpk oAOkf9TZctvyM8GweC118_4llgK2nCLMn7lW6ACD7TnPljg_ L0gKbU. Once the changes are made, the finalized version of the PtDA will be offered free-of-charge on the Canadian Urological Association's (CUA) website. This will allow the tool to be easily distributed and readily used internationally.

**Discussion**

Patients opting for the surgical management of LUTS secondary to BPH can be faced with an overwhelming amount of information related to the available treatments and the potential risks and benefits they entail. We developed an interactive, online, evidence-based PtDA that includes all BPH guideline-approved surgical modalities and techniques to facilitate shared decision-making for these patients. In this study, we sought to assess the acceptability of our PtDA among patients and urologists. Our alpha-testing results demonstrated that this PtDA is an acceptable and valued clinical tool among urologists and patients that have previously faced the target decision. Most patient responders recommend this tool to future patients facing this decision and most urologist responders anticipate using this tool in their practice.

PtDAs improve patient knowledge related to the decision at hand, decrease decisional conflict, and facilitate shared decision-making.\(^5,19\) Additionally, PtDAs help clinicians provide an evidence-based and standardized education, minimizing the risk of treatment inequity among patients.\(^5,8,21\) This allows patients to explore the available treatments and limits the bias that may arise when surgeons exclusively present treatments that they are more comfortable with or that are available at their institution. A fundamental aspect of PtDAs is their ability to help patients clarify and communicate their personal values and preferences related to their management. Thus, the use of a PtDA for men with LUTS due to BPH is a feasible solution that can allow for high-quality and informed decisions to be made efficiently.

Among the four previously developed PtDAs related to the treatment of BPH, the one developed by the Dutch Society for Urology is the only one that can be accessed free-of-charge and allows patients to select a surgical treatment that aligns best with their preferences.\(^12\) It is important to mention that the Dutch PtDA presents limitations. For

**Table 3. Number of participants identifying which treatment was favored in each section of the patient decision aid (n=11).**

| Prostate volume | TURP | B-TURP | GL-PVP | EEP | Rezum | Urolift | Aquablation | ORP | RSP | Well-balanced |
|-----------------|------|-------|--------|-----|-------|--------|------------|-----|-----|--------------|
| Small to moderate (<80 ml) | 0    | 0     | 0      | 0   | 1     | 0      | 0          | 0   | 0   | 10           |
| Moderate to large (80–150 ml) | –    | –     | 0      | 0   | 0     | –      | 0          | –   | –   | 11           |
| Large (>150 ml) | –    | –     | 0      | 0   | 0     | –      | –          | 1   | 1   | 10           |

B-TURP: bipolar transurethral resection of the prostate; EEP: endoscopic enucleation of the prostate; GL-PVP: GreenLight photovaporization; ORP: open retropubic prostatectomy; RSP: robotic simple prostatectomy; TURP: transurethral resection of the prostate.
one, there are important PtDA requirements that are not included in the Dutch PtDA, such as a validated screening tool to assess patients’ decisional conflict, and knowledge questions that verify patients’ understanding of the presented information. Additionally, the Dutch PtDA lacks generalizability, as the information it provides only discusses treatments that are most commonly performed within the Netherlands (TURP, OSP, GreenLight photovaporization, and Urolift), and the majority of the recommendations are solely based on an old version of the European Urological Association (EAU) guidelines. In comparison, our PtDA was developed according to the most updated version of the CUA, EAU, and American Urological Association (AUA) guidelines; thus, promoting the international adoption of our newly developed PtDA.

PtDAs can be used to facilitate shared decision-making, however, they are not designed to replace the need for patient-physician consultation. Indeed, this was further emphasized within both urologist and patient findings. Patients furthered this idea and demonstrated that physician expertise is of crucial importance in the decision-making process.

### Table 4. Detailed narrative feedback results from open-ended survey questions for the urologist and patient population

| Theme | Quote | Participant type |
|-------|-------|------------------|
| Strengths of the PtDA | “Gives a good overview of the possible treatment options for the patients.” | Urologist |
| | “Very organized, easy to navigate through, easy language for patients, gives all options available in the market even if they are not provided by the patient’s urologist.” | Urologist |
| | “Well-organized, well-expressed, easy to follow.” | Urologist |
| | “The information provided for each option will help patients understand and reinforce what was (hopefully) explained to them in clinic.” | Urologist |
| | “Nice flow and good language used.” | Urologist |
| | “This is a good source of information that is concise and visually appealing.” | Urologist |
| | “It was clear and simple enough to be understood coming from a non-science background.” | Patient |
| | “I believe this decision aid will be very helpful in future decisions for patients. It contains the info required to help make a best treatment decision.” | Patient |
| | “Was relatively easy to follow, and by narrowing the volume group to 1, 2, or 3, it narrowed the variables to factor in the decision-making.” | Patient |
| | “Did not take a lot of time and was explained well.” | Patient |
| | “Clear and concise. Easy to follow and understand.” | Patient |
| | “It gave a good general overview of what to expect and, importantly, information in regard to OHIP coverage — or not.” | Patient |
| | “Responded to all the questions that I was concerned about easily and understandably.” | Patient |
| | “It is informative, but I believe the doctor’s help is always needed to finalize the end result.” | Patient |
| | “Doctor did an excellent job verbally explaining my options, but this aid allows it to be presented much more efficiently. As well, it lessens any biases that the doctor may have towards which is the best procedure and allows the patient to impartially see all the options.” | Patient |

| Weaknesses/suggestions | “Video links could be an interesting addition. Example of a short video: A urologist explaining a technique with an animated clip of how the technique is performed.” | Urologist |
| | “Maybe you can add figures next to the text to improve patient understanding, e.g., introduction to BPH.” | Urologist |
| | “Very important detail that is not presented is that most hospitals in the province offer only MTURP, BTURP and open simple prostatectomy. In the advantages and disadvantages, it SHOULD be included that the treatment (HoLEP, for example) is only offered in a tertiary center.” | Urologist |
| | “I think in the picture where you are highlighting risk of complications and the faces represent the chance out of 100 that some complication will happen you should not use the color green. Green is typically reserved for good outcomes. Also, it might be linked to “GreenLight” for some readers. I would use some other color.” | Urologist |
| | “Often use the phrase ‘a lot’ to describe reduction in the prostate after procedure. The phrase is open to interpretation. Can use ‘significantly’ or ‘moderately’ instead?” | Patient |
| | “This decision aid may make patients feel that with this knowledge they can make the best decision for themselves. It should state that the overall decision is with the recommendation and advice of their doctor.” | Patient |
| | “More information with regards to anesthesia options and postoperative care.” | Patient |
| | “Felt for very large prostate options, more info was necessary about the possible sexual consequences of GreenLight and open prostate. Was left a little unclear as to why one would choose open prostate over GreenLight.” | Patient |
| | “I believe two additional factors are relevant for many candidates: 1) how long will it take to have a particular procedure performed; and 2) bearing of out-of-pocket cost on patient’s decision.” | Patient |
### Table 5. Detailed description of quantitative patient alpha-testing results specific to each section of the patient decision aid (n=19)

| Questions                                                                 | Small to moderate prostate volumes (<80 ml) (n=11) | Moderate to large prostate volumes (80–150 ml) (n=5) | Large prostate volumes (>150 ml) (n=3) |
|---------------------------------------------------------------------------|-----------------------------------------------------|-------------------------------------------------|-------------------------------------|
|                                                                           | n (%)                                               | n (%)                                           | n (%)                                |
| 1 The amount of information provided was:                                |                                                     |                                                 |                                      |
| Much less than wanted                                                    | –                                                   | –                                               | –                                    |
| A little less than wanted                                                | –                                                   | 2 (40.0%)                                       | 1 (33.33%)                           |
| About right                                                              | 11 (100%)                                          | 3 (60.0%)                                       | 2 (66.67%)                           |
| A little more than wanted                                                | –                                                   | –                                               | –                                    |
| Much more than wanted                                                    | –                                                   | –                                               | –                                    |
| 2 The length of the PtDA was:                                            |                                                     |                                                 |                                      |
| Too short                                                                | –                                                   | –                                               | 1 (33.33%)                           |
| Just right                                                               | 9 (81.82%)                                         | 5 (100.0%)                                      | 2 (66.67%)                           |
| Too long                                                                 | 2 (18.18%)                                         | –                                               | –                                    |
| 3 The language used was easy to follow:                                  |                                                     |                                                 |                                      |
| Strongly disagree                                                        | –                                                   | –                                               | –                                    |
| Disagree                                                                 | –                                                   | –                                               | –                                    |
| Neutral                                                                  | –                                                   | –                                               | –                                    |
| Agree                                                                    | 3 (27.27%)                                         | 1 (20.0%)                                       | 2 (66.67%)                           |
| Strongly agree                                                           | 8 (72.73%)                                         | 4 (80.0%)                                       | 1 (33.33%)                           |
| 4 The outcomes reported were easy to follow:                             |                                                     |                                                 |                                      |
| Strongly disagree                                                        | –                                                   | –                                               | –                                    |
| Disagree                                                                 | –                                                   | –                                               | –                                    |
| Neutral                                                                  | 2 (18.18%)                                         | –                                               | –                                    |
| Agree                                                                    | 6 (54.55%)                                         | 3 (60.0%)                                       | 2 (66.67%)                           |
| Strongly agree                                                           | 3 (27.27%)                                         | 2 (40.0%)                                       | 1 (33.33%)                           |

#### Section for all prostate volumes

| Questions                                                                 | n (%)                                               | n (%)                                           | n (%)                                |
|                                                                           |                                                     |                                                 |                                      |
| 5 This decision aid would have been helpful during my treatment decision-making: |                                                     |                                                 |                                      |
| Strongly disagree                                                        | –                                                   | –                                               | –                                    |
| Disagree                                                                 | –                                                   | –                                               | –                                    |
| Neutral                                                                  | 1 (9.09%)                                          | –                                               | 1 (33.33%)                           |
| Agree                                                                    | 4 (36.37%)                                         | 4 (80.0%)                                       | –                                    |
| Strongly agree                                                           | 6 (54.54%)                                         | 1 (20.0%)                                       | 2 (66.67%)                           |
| 6 I would recommend this decision aid for new patients with BPH:          |                                                     |                                                 |                                      |
| Strongly disagree                                                        | –                                                   | –                                               | –                                    |
| Disagree                                                                 | –                                                   | –                                               | –                                    |
| Neutral                                                                  | –                                                   | –                                               | –                                    |
| Agree                                                                    | 3 (27.27%)                                         | 2 (40.0%)                                       | –                                    |
| Strongly agree                                                           | 8 (72.73%)                                         | 3 (60.0%)                                       | 3 (100%)                             |
| 7 I am satisfied with the overall quality of this PtDA:                   |                                                     |                                                 |                                      |
| Strongly disagree                                                        | –                                                   | –                                               | –                                    |
| Disagree                                                                 | –                                                   | –                                               | –                                    |
| Neutral                                                                  | –                                                   | –                                               | –                                    |
| Agree                                                                    | 3 (27.27%)                                         | 2 (40.0%)                                       | 2 (66.67%)                           |
| Strongly agree                                                           | 8 (72.73%)                                         | 3 (60.0%)                                       | 1 (33.33%)                           |

BPH: benign prostatic hyperplasia; PtDA: patient decision aid.

### Table 6. Number of patient participants identifying which treatment was favored in each section of the patient decision aid (n=19)

| Prostate volume          | TURP | B-TURP | GL-PVP | EEP | Rezum | Urolift | Aquablation | ORP | RSP | Well-balanced |
|--------------------------|------|--------|--------|-----|-------|---------|-------------|-----|-----|--------------|
| Small to moderate (<80 ml)| 4    | 0      | 3      | 1   | 0     | 0       | 0           | 0   | 0   | 4            |
| Moderate to large (80–150 ml)| –   | –      | 1      | 0   | –     | –       | –           | 0   | 0   | 4            |
| Large (>150 ml)          | –    | –      | 0      | 0   | –     | –       | –           | 0   | 0   | 3            |

TURP: bipolar transurethral resection of the prostate; EEP: endoscopic enucleation of the prostate; GL-PVP: GreenLight photovaporization; ORP: open retropubic prostatectomy; RSP: robotic simple prostatectomy; TURP: transurethral resection of the prostate.
surgical treatments for BPH. Therefore, it can be argued that the sample size used in our study may be representative of real-world prostate volume distributions.

Conclusions

Our PtDA was found to be acceptable among urologists and patients. These results demonstrate that most of the participants were satisfied with the quality of this PtDA. Patient participants in this study recommend the use of this tool for future patients and participating urologists plan to incorporate the PtDA in their clinical practice. Once the tool is updated and finalized, it will be made available through the CUA’s website.

Competing interests: Dr. Chughtai is a consultant for Boston Scientific, Ferring, Medense Bio, Olympus, and Urovant. Dr. Elterman, Dr. Zorn, and Dr. Bhogani are consultants and investigators for Boston Scientific, Olympus, and PROCEPT Biorobotics. Dr. Razvi receives royalties from Cook Urological for a medical device and fellowship support from Cook Urological and Karl Storz Lithotripsy. No other author reports any competing personal or financial interests related to this work.

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