### Review



# How to evaluate a flexible ureterorenoscope? Systematic mapping of existing evaluation methods

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### **Objectives**

The objective of this study was to identify, map and review scope-related and user-related parameters used to evaluate the quality of flexible ureterorenoscopes. Thereby identifying key items and variability in grading systems.

### **Methods**

A literature search of four databases (MEDLINE [Ovid], EMBASE [Ovid], Web of Science, Google scholar and the Cochrane Library) was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines encompassing articles published up to August 2020. A total of 2386 articles were screened.

#### Results

A total of 48 articles were included in this systematic scoping review. All studies had a prospective design. Five key items in the assessment of flexible ureterorenoscopy were distinguished: 'Manoeuvrability' (87.5%), 'Optics' (64.6%), 'Irrigation' (56.3%), 'Handling' (39.6%) and 'Durability' (35.4%). After regrouping, every key item could be divided into specific subcategories. However, the quality assessment showed a wide variation in denomination, method of measurement, circumstances of measurement, tools used during measurements, number of measurements performed, number of observers, and units of outcomes.

#### Conclusion

The research field regarding quality assessment of ureterorenoscopes is heterogeneous. In this systematic scoping review we identified five key parameters: Manoeuvrability, Optics, Irrigation, Handling and Durability, used to grade flexible ureterorenoscopes. However, within these categories we found a wide variety in terms of method of measurements. A standardised, uniform grading tool is required to assess and compare the quality of flexible ureterorenoscopes in the future.

### **Keywords**

evaluation, ureterorenoscope, ureteroscope

#### Introduction

The first ureteroscopy was performed by Young in 1912 using a cystoscope in an infant with dilated ureters that advanced easily to the renal pelvis [1]. Marshall was the first to describe the use of a flexible fibre optic ureteroscope in 1964 and the first intended ureterorenoscopy (URS) was reported in 1977 [2]. This continuous evolution progressed rapidly in the 1980s, when flexible ureterorenoscopes were increasingly used to treat stones.

Since the introduction of flexible ureterorenoscopes in the 1970s, efforts have been made to reduce their size whilst optimising the working channel for irrigation flow and introducing numerous accessory instruments. Meanwhile, retaining optimal bidirectional deflecting properties and image quality [3,4]. Attempts to serve these seemingly conflicting interests resulted in flexible ureterorenoscopes which have become more fragile and prone to damage with loss of functionality [5]. Overcoming these problems of fragility, may result in ureterorenoscopes which are less

ergonomic or user-friendly. This loss of functionality could have an impact on procedure time, perioperative tissue damage, and surgical outcomes of URS.

Over the years, a wide range of flexible scopes have been introduced for clinical use. Functionality as well as characteristics related to the loss of functionality of these flexible ureterorenoscopes have been studied abundantly [5– 52]. Until now, studies used different approaches to evaluate the quality of flexible ureterorenoscopes. To objectively evaluate and compare parameters of different flexible ureterorenoscopes, a standardised way of assessment is needed to assess quality pre-, peri-, and postoperatively. The first step towards such an assessment tool is the identification of key parameters used to assess quality. Therefore, the aim of the present study was to systematically identify, map and review scope-related and user-related parameters used to evaluate flexible ureterorenoscopes in the current literature.

### **Evidence Acquisition**

This review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [53]. However, for this study we systematically reviewed the different evaluation methods and not the actual measurement outcomes of these studies. Therefore, a meta-analysis and a risk of bias was not performed.

#### Search Strategy

A literature search was performed in collaboration with a medical librarian in August 2020, covering four different databases: MEDLINE (Ovid), EMBASE (Ovid), Web of Science, Google scholar, and the Cochrane library. The Medical Subject Headings (MeSH) term 'Ureteroscope/ ureteroscopy' was used in combination (AND, OR) with 'flexible', 'evaluation', 'urolithiasis', 'equipment design', 'optic/ image', 'manoeuvrability' and 'durability'. In addition, derivatives and terms with no available MeSH terms were used. The search strategy for the four databases is shown in Appendix S1.

#### Inclusion Criteria

- 1. Peer-reviewed articles
- 2. Articles written in English
- 3. Studies evaluating scope-related parameters of flexible ureterorenoscopes
- Studies evaluating user parameters of flexible ureterorenoscopes

#### **Exclusion Criteria**

1. Editorials/Letters to the editor

- 2. Case reports/Abstracts
- 3. Reviews
- 4. Ongoing trials
- Studies outside the specialism of urology
- 6. Studies without any description on method of measurement (e.g. 'this scope is excellent')
- 7. Studies not assessing scope or user-related parameters

### Search Strategy and Outcome

A total of 2386 articles were left to screen after removing duplicates and screening the reference lists of the included articles for potentially relevant studies. All abstracts were reviewed by two independent reviewers (N.H. and M.H.), following pre-defined inclusion and exclusion criteria to retrieve relevant articles. Subsequently, full-text versions of the relevant articles were retrieved and screened for final inclusion. Any disagreement regarding the inclusion of an article was resolved based on consensus. If consensus could not be reached, a third reviewer (G.K.) was asked to make a final judgment. The results of the search strategy and the selection process are shown in a PRISMA flow chart (Figure 1). All articles screened for full text are appended in Appendix S3. A summary of the included articles is presented in Table 1 [5-52].

### Types of Study Designs Included

For this systematic review, all peer-reviewed articles describing original data (case series, cohort studies, randomised controlled trials [RCTs], quasi-RCTs, and nonrandomised studies) were eligible for inclusion. Additionally, all comparative and non-comparative studies were eligible for inclusion. As the aim of this study was to map all types of grading systems, in vivo clinical studies, ex vivo bench top evaluations as well as ex vivo simulations were included as presented in Table 1.

### Types of Ureterorenoscopes Included

The flexible scopes that were assessed in the included studies consisted of both single-use and re-usable flexible ureterorenoscopes.

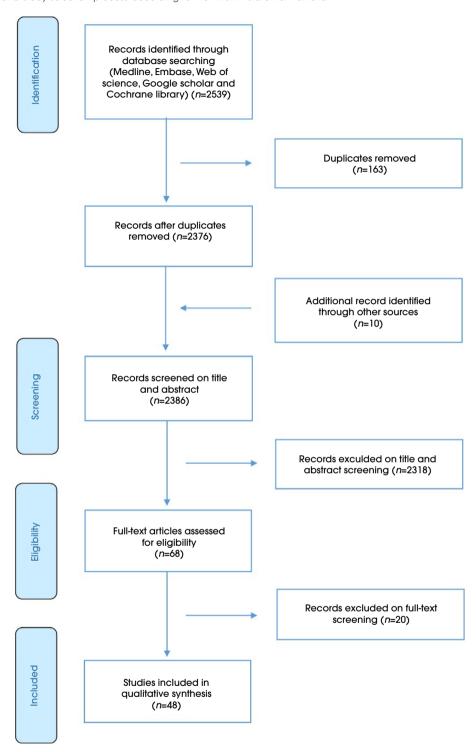
### **Evidence Synthesis**

#### Included Studies

A total of 48 articles were included in this review [5-52]. The main characteristics of these 48 articles are presented in Table 1. All studies had a prospective design and were published between 1997 and 2020.

Studies did not distinguish different methods of evaluation for different types of scopes (reusable vs single-use; fibre-optic vs digital etc.).

Fig. 1 Literature search and study selection process according to the PRISMA statement criteria.



The included articles evaluated different parameters of flexible ureterorenoscopes, which can be divided into five key parameters: 'Manoeuvrability', 'Optics', 'Irrigation', 'Handling', and 'Durability'.

Additionally, manufacturer's characteristics were specifically described in 42 papers as presented with an asterisk in Table 1. Expanded tables on type of manufacturer specification mentioned in articles are presented in Appendix S2.

Table 1 Summary of included articles.

| #   | Author   | Year | Journal  | Scope<br>types, n | Fibre optic<br>/digital, n | reusable/<br>single-use, n | Outcomes  | Ex vivo    | Simulation     | In<br>vivo | LOE      |
|-----|--|------|--|-------------------|----------------------------|----------------------------|---|------------|----------------|------------|----------|
| _   | Abdelshehid <i>et al.</i> [6]*                           | 2005 | Journal of Urology                               | 2                 | 2/0                        | 2/0                        | manoeuvrability, optics,                                    | Yes        | No<br>ON       | 8<br>8     | 2B       |
| 7   | Afane et al. [5]*  | 2000 | Journal of Urology                               | 4                 | 4/0                        | 4/0                        | manoeuvrability, optics, irrigation, durability,            | Yes        | <u>0</u>       | Yes        | 2B       |
| က   | Al Qahtani <i>et al.</i> [7]                             | 2020 | World Journal of Urology                         | _                 | 1/0                        | 1/0                        | manoeuvrability, optics,                                    | Yes        | o<br>N         | Yes        | 2B       |
| 4   | Al Qahtani <i>et al.</i> [8]                             | 2011 | Urology Annals                                   | _                 | 1/0                        | 1/0                        | manoeuvrability, optics,                                    | Yes        | 0<br>N         | Yes        | 2B       |
| 2   | Ames et al. [9]  | 2006 | Journal of Endourology                           | က                 | 3/0                        | 3/0                        | manoeuvrability, irrigation                                 | Yes        | o<br>Z         | 2          | 2B       |
| 9   | Andonian et al. [47]*                                    | 2008 | Journal of Endourology                           | _                 | 1/0                        | 1/0                        | optics  | Yes        | o<br>N         | <u>8</u>   | 4        |
| 8 7 | Bach <i>et al.</i> [10]*<br>Bader <i>et al.</i> [11]*    | 2008 | Journal of Endourology<br>Journal of Endourology | - 2               | 5/0<br>1/0                 | 5/0<br>0/1                 | manoeuvrability, irrigation<br>manoeuvrability, optics,     | Yes        | <u> </u>       | No<br>Yes  | 2B<br>2B |
| 0   | Rachdadi et al [19]                                      | 2017 | World In part of Urabay                          | α                 | 3/5                        | 1/7                        | irrigation, durability                                      | N<br>N     | S              | Z          | 2R       |
|     |  |      |  | Þ                 |                            |                            | irrigation, handling  | 3          | 2              | 2          | 7        |
| 10  | Bedke <i>et al.</i> [13]*                                | 2013 | Urolithiasis                                     | -                 | 1/0                        | 1/0                        | manoeuvrability,<br>irrigation, breaking<br>strenath basket | Yes        | <u>0</u>       | <u>0</u>   | 2B       |
| Ξ   | Binbay <i>et al.</i> [14]*                               | 2010 | Journal of Endourology                           | 2                 | 1/1                        | 2/0                        | manoeuvrability, irrigation                                 | Yes        | 02             | Yes        | 2B       |
| 12  | Boylu <i>et al.</i> [15]*                                | 2009 | Journal of Urology                               | 7                 | 1/9                        | 1/9                        | manoeuvrability, optics, irrication                         | Yes        | N <sub>O</sub> | <u>8</u>   | 28       |
| 13  | Cho <i>et al.</i> [16]                                   | 2018 | Scientific reports                               | _                 | 1/0                        | 1/0                        | magaranta magaranta irrigation, handling,                   | Yes        | o<br>Z         | Yes        | 4        |
| 14  | Dale <i>et al.</i> [17]*                                 | 2017 | Journal of Endourology                           | ო                 | 0/3                        | 2/1                        | manoeuvrability, optics,                                    | Yes        | No             | <u>8</u>   | 2B       |
| 15  | Deininger <i>et al.</i> [18]                             | 2018 | World Journal of Urology                         | က                 | 0/3                        | 1/2                        | irrigation<br>manoeuvrability, optics,                      | Yes        | Yes            | 9          | 2B       |
|     | ))   |      |  |                   |                            |                            | irrigation  |            |                |            |          |
| 9   | Doizi <i>et al.</i> [19]*                                | 2017 | World Journal of Urology                         | -                 | 1/0                        | 0/1                        | manoeuvrability, optics, irrigation, handling, durability   | Yes        | 0<br>Z         | Yes        | 2B       |
| 17  | Dragos <i>et al.</i> [20]*                               | 2017 | Journal of Endourology                           | 0                 | 4/5                        | 6/3                        | manoeuvrability   | 2          | Yes            | 8          | 2B       |
| 18  | Dragos <i>et al.</i> [21]*                               | 2019 | Translational Andrology and Urology              | ∞                 | 8/0                        | 4/4                        | manoeuvrability, optics, irrigation                         | Yes        | o<br>N         | <u>0</u>   | 28       |
| 19  | El-Husseiny <i>et al.</i> [22]*                          | 2009 | Future Medicin Ltd                               | -                 | 1/0                        | 1/0                        | manoeuvrability, optics, durability                         | Yes        | o<br>N         | <u>0</u>   | 28       |
| 20  | Emiliani <i>et al.</i> [23]*                             | 2018 | Central European Journal<br>of Urology           | -                 | 1/0                        | 1/0                        | manoeuvrability, optics, irrigation, handling, durability   | <u>8</u>   | <u>0</u>       | Yes        | 2B       |
| 21  | Emiliani <i>et al.</i> [48]*                             | 2017 | International Brazilian<br>Journal of Urology    | _                 | 1/0                        | 1/0                        | optics  | 2          | Yes            | <u>0</u>   | 28       |
| 22  | Hennessey <i>et al.</i> [24]*                            | 2018 | BJU International                                | _                 | 1/0                        | 1/0                        | manoeuvrability,<br>irrigation, costs                       | Yes        | o<br>N         | <u>0</u>   | 28       |
| 23  | Inoue <i>et al.</i> [25]*<br>Johnson and Grasso<br>[25]* | 2021 | World Journal of Urology<br>BJU International    | 4 0               | 3/1<br>NA                  | 3/1<br>NA                  | manoeuvrability<br>manoeuvrability                          | Yes<br>Yes | Yes            | No         | 2B<br>2B |
| 25  | Johnston <i>et al.</i> [27]*                             | 2018 | Central European Journal                         | _                 | 1/0                        | 1/0                        | manoeuvrability, optics,                                    | Yes        | o<br>N         | Yes        | 2B       |
| 56  | Kam <i>et al.</i> [28]*                                  | 2019 | International Journal of<br>Urology              | က                 | 0/3                        | 1/2                        | manoeuvrability, optics, durability                         | Yes        | o<br>Z         | Yes        | 2B       |
|     |  |      |  |                   |                            |                            |   |            |                |            |          |

OE 2B 2B 2B 2B 2B 28 2B 2B 28 28 28 28 28 2B 28 28 28 28 2B 2B 2B 2B Yes **9** € /es Yes /es § S 2 2 9 9 2222 9 2222 9 Yes Nes No Yes Yes Yes /es 2 2 9 9 ę 9 yes Nes % Ses Yes § S S § % es Ves Yes Yes Yes Yes 9 € 9 Yes 운 운 원 manoeuvrability, handling manoeuvrability, handling manoeuvrability, optics, manoeuvrability, optics irrigation, handling, handling, durability irrigation, handling irrigation, handling, irrigation, handling irrigation, durability irrigation, handling, irrigation, durability irrigation, durability manoeuvrability, manoeuvrability manoeuvrability, manoeuvrability durability durability handling durability irrigation handling irrigation Dandling handling rrigation 4/0 0/1 1/11 2/0 5/04/0/4/0 2/1 1/2 3/0 4/0 1/3 2/0 2/0 2/3 2 \_ 2/3 1/2 1/2 2/0 1/2 4/0 0/1 4/8 1/3 2/0 2/5 2/0 1/4 9/ 1/1 0/2 2/1 Scope types, n က 2 4 ω 4 က  $\alpha$ က 4 4 - 5 2 4 2729 2 2  $\alpha$ \*Mention of manufacturer specifications in article. LOE, Level of Evidence. Investigative and Clinical European Urology Focus Journal of Endourology Urological Research Journal of Urology Journal of Urology **BJU International** 1997 2016 2017 2017 2011 2017 2004 2018 2020 2017 2018 2018 2010 2013 2020 2019 2008 2020 Legemate et al. [30]\* Wendt-Nordahl et al. Multescu et al. [34]\* Schlager *et al.* [38]\* Marchini *et al.* [32]\* Multescu et al. [33] Schlager et al. [39] Winship et al. [46]\* Ludwig et al. [50]\* Tambo *et al.* [41]\* Tom *et al.* [42]\* Proietti et al. [37]\* Proietti et al. [51]\* Shvarts et al. [40]\* Paffen *et al.* [35]\* usch *et al.* [31]\* Traxer *et al.* [43]\* Kruck *et al.* [49]\* Talso et al. [52]\* Poon et al. [36]\* Villa et al. [44]\* Kim *et al.* [29]\* Author 27 28 30 32 33 34 35 35 37 38 39 40 45 44 48

(continued)

The following scopes were investigated in the included articles: ACMI DUR-8, ACMI DUR-8 Elite, ACMI DUR-8 prototype, ACMI Invicio DUR-D, Boston Scientific Lithovue, Circon-ACMI AUR-7, Circon-ACMI AUR-9, Cook Flexor Vue HF-EH, MaxiFlex SemiFlex Scope, Neoscope NeoFlex, Olympus URF-P3, Olympus URF-P5, Olympus URF-P6, Olympus URF-V, Olympus URF-Y0016, Olympus URF-V2, PolyScope, Pusen Uscope, Storz FlexX, Storz FlexX2, Storz FlexXc (SPIES), Storz 11274AA, Storz prototype, UscopePU3022, Wolf Cobra (Vision), Wolf 7331.001, Wolf

7325.076, Wolf7325.172, Wolf7330.072, Wolf 7331.001, Wolf BOA vision, Wolf Viper, YouCare ShaoGang, You Care YC-FR-A.

### **Key Parameters**

### Manoeuvrability

This parameter was evaluated in 42 of the 48 included studies [5-46]. Table 2 [5-52] shows an overview of the studies

Table 2 Manoeuvrability.

| #  | Author (year)                           | Manoeuvrability | Deflection     | Access  | Flexibility  |
|----|---|-----------------|----------------|---|--------------|
| 1  | Abdelshehid <i>et al.</i> (2005) [6]    | Yes             | Degrees        |   |              |
| 2  | Afane et al. (2000) [5]                 | Yes             | Degrees        |   |              |
| 3  | Al Qahtani <i>et al.</i> (2020) [7]     | Yes             | Degrees        |   | Likert scale |
| 4  | Al Qahtani <i>et al.</i> (2011) [8]     | Yes             | Degrees        |   | Likert scale |
| 5  | Ames et al. (2006) [9]                  | Yes             | Degrees        |   |              |
| 6  | Andonian <i>et al.</i> (2008) [47]      | No              |                |   |              |
| 7  | Bach <i>et al.</i> (2008) [10]          | Yes             | Degrees        |   |              |
| 8  | Bader <i>et al.</i> (2010) [11]         | Yes             | Degrees        |   |              |
| 9  | Baghdadi <i>et al.</i> (2017) [12]      | Yes             | Degrees        |   |              |
| 10 | Bedke <i>et al.</i> (2013) [13]         | Yes             | Degrees        |   |              |
| 11 | Binbay <i>et al.</i> (2010) [14]        | Yes             | Degrees        |   |              |
| 12 | Boylu <i>et al.</i> (2009) [15]         | Yes             | Degrees        |   |              |
| 13 | Cho <i>et al.</i> (2018) [16]           | Yes             | Degrees        |   | Likert scale |
| 14 | Dale <i>et al.</i> (2017) [17]          | Yes             | Degrees        |   |              |
| 15 | Deininger <i>et al.</i> (2018) [18]     | Yes             | Degrees        |   |              |
| 16 | Doizi <i>et al.</i> (2017) [19]         | Yes             | Degrees        |   | Likert scale |
| 17 | Dragos et al. (2017) [20]               | Yes             | Degrees        | Dichotomous   |              |
| 18 | Dragos et al. (2019) [21]               | Yes             | Degrees        |   |              |
| 19 | El-Husseiny et al. (2010) [22]          | Yes             | Degrees        |   |              |
| 20 | Emiliani et al. (2018) [23]             | Yes             | Likert scale   |   |              |
| 21 | Emiliani <i>et al.</i> (2017) [48]      | No              |                |   |              |
| 22 | Hennessey et al. (2018) [24]            | Yes             | Degrees        |   |              |
| 23 | Inoue et al. (2021) [25]                | Yes             |                | Degrees   |              |
| 24 | Johnson and Grasso (2004) [26]          | Yes             | Degrees        | Dichotomous   |              |
| 25 | Johnston <i>et al.</i> (2018) [27]      | Yes             | Degrees        |   | Likert scale |
| 26 | Kam <i>et al.</i> (2019) [28]           | Yes             | _              |   | Likert scale |
| 27 | Kim <i>et al.</i> (2018) [29]           | Yes             | Degrees        |   | VAS          |
| 28 | Kruck <i>et al.</i> (2011) [49]         | No              | <u> </u>       |   |              |
| 29 | Legemate <i>et al.</i> (2018) [30]      | Yes             | Likert scale   |   |              |
| 30 | Ludwig <i>et al.</i> (2017) [50]        | No              |                |   |              |
| 31 | Lusch et al. (2013) [31]                | Yes             | Degrees        |   |              |
| 32 | Marchini <i>et al.</i> (2018) [32]      | Yes             | mm             | Dichotomous   |              |
| 33 | Multescu et al. (2010) [33]             | Yes             | Degrees        | Dichotomous   | Likert scale |
| 34 | Multescu et al. (2013) [34]             | Yes             | Degrees        |   | Likert scale |
| 35 | Paffen <i>et al. (2008</i> ) [35]       | Yes             | Degrees and mm |   |              |
| 36 | Poon <i>et al.</i> (1997) [36]          | Yes             | Degrees        |   |              |
| 37 | Proietti <i>et al</i> . (2016) [37]     | Yes             | Degrees        | Dichotomous   | Frequencies  |
| 38 | Proietti <i>et al.</i> (2017) [51]      | No              | 3              |   |              |
| 39 | Schlager <i>et al.</i> (2017) [38]      | Yes             |                | Identification calices, Stone retrieval and time required |              |
| 40 | Schlager <i>et al.</i> (2020) [39]      | Yes             |                | Dichotomous   | Likert scale |
| 41 | Shvarts <i>et al.</i> (2004) [40]       | Yes             | Degrees        |   | 2            |
| 42 | Talso <i>et al.</i> (2018) [52]         | No              | D09.000        |   |              |
| 43 | Tambo <i>et al.</i> (2020) [41]         | Yes             |                | Time required   |              |
| 44 | Tom <i>et al.</i> (2017) [42]           | Yes             | Degrees        |   |              |
| 45 | Traxer <i>et al.</i> (2006) [43]        | Yes             | Degrees        |   | Likert scale |
| 46 | Villa <i>et al.</i> (2020) [44]         | Yes             | D09.000        | %   | LINOTI JOGIG |
| 47 | Wendt-Nordahl <i>et al.</i> (2007) [45] | Yes             | Degrees        | ,,  |              |
| 48 | Winship <i>et al.</i> (2019) [46]       | Yes             | Degrees        |   |              |
| 40 | Williamp 67 dr. (2017) [40]             | 163             | Deglees        |   |              |

assessing Manoeuvrability in three subcategories: 'Deflection', 'Access', and 'Flexibility'.

Deflection The subcategory deflection included studies that evaluated deflection defined as the maximum upward and/or downward deflection of the distal tip of the flexible ureterorenoscope; 35 studies met this definition (Table 2).

In all, 13 of these 35 papers, performed the deflection measurements on a photocopy or picture of the ureterorenoscope [5-9,19,26,27,31,32,35,40,46]. In the other 22 papers, deflection was directly measured from the ureterorenoscope in maximal deflection.

Measurements were performed with a protractor in 14/35 papers [6,10,12,19-22,27,31,34,36,43,45,46]. Dragos et al. [20], Johnson and Grasso [26], Tom et al. [42] and Deininger et al. [18] respectively used a ruler, a clockwork with degrees, SolidWorks angle measuring software and an Aristo goniometer to measure deflection. There was a broad range in the number of performed measurements (range 1–198 times), as well as in the number of observers evaluating access (range 1–7 observers).

The outcome measurement was described in degrees in 33/35 papers [5-22,24,26,27,29,31,33-37,40,42,43,45,46], and in two of the 35 papers using a Likert scale [23,30]. Two of the 35 studies described the radius of the curve of a scope in maximum deflection in millimetres [32,35]. Paffen et al. [35] described two measurement outcomes: maximal deflection in degrees and radius of the curve in millimetres.

In all, 25 of the 35 papers assessing deflection, evaluated maximum deflection with and without instruments inserted in the scope [6,9-15,17,18,21-24,26,31-37,40,42,45,46]. Three papers only evaluated deflection without instruments in the flexible ureterorenoscopes [7,8,43]. The remaining seven papers did not specifically describe whether they measured deflection with or without instruments inserted [5,16,19,20,27,29,30].

Access A total of 11 papers described the assessment of access in an ex vivo or simulated setting (K-Box, cadaver kidney or artificial kidney model) (Table 2). Access was defined as the feasibility of the flexible ureterorenoscope to access calices. Furthermore, Schlager et al. also [38,39] evaluated the extraction of artificial calculi in two studies.

There was a broad range in the number of performed measurements (range 1-115 times), as well as in the number of observers evaluating access (range 1-25 observers).

The measurement outcome within the access subcategory was scored as the success or failure (dichotomous) to access the calyces or extract artificial stones in seven of 11 studies [8,20,26,32,33,37,39]. Whereas degrees (range of reach within

a calyx), the number or percentage of correctly identified calvees, the number of stones extracted and the time needed to do so, was used as an outcome measurement in the remaining four studies [25,38,41,44].

Flexibility A total of 12 articles evaluated the flexibility of flexible ureterorenoscopes in an ex vivo or simulated setting (porcine kidney, cadaver kidney or artificial kidney model) (Table 2). This subcategory was defined as the ability of the scope to perform all necessary manoeuvres or movements.

In accordance with previous subcategories, there was a broad range in the number of performed measurements (range 1-150 times), as well as in the number of observers evaluating access (range 1-6 observers).

Kim et al. [29] used a visual analogue scale to assess flexibility. In the study of Proietti et al. [37] the surgeons' preference of one scope over other available scopes was used as subjective parameter reflecting flexibility. The remaining 10 papers used Likert scales scoring flexibility, almost all with a different rating system [7,8,16,19,27,28,33,34,39,43].

### **Optics**

Optics was studied in 31/48 articles as shown in Table 3 [5-52]. Six subcategories were assessed in the different papers: 'resolution', 'distortion', 'luminosity', 'colour/greyscale', 'view' (depth, direction, angle and field of view) and 'visibility' as assessed by the surgeon.

Resolution Resolution was defined as the potential detail of an image. Resolution was studied in 11 papers, all using the 1951 USAF pattern card in an ex vivo setting (Table 3). The outcome was defined as line pairs per millimetre in all studies. However, there was a variation in the distance between the flexible ureterorenoscope and the pattern card (3-50 mm), the number of repeated measurements (1-3 times) and the number of observers (2-4 observers).

Distortion Distortion, defined as the deviation from a rectilinear projection, was evaluated in seven papers using different types of distortion grid target cards and described in percentages in an ex vivo setting (Table 2). The distance to the test card varied between 3 and 10 mm. Measurements of distortion were performed one to three times by two to four observers.

Luminosity Six articles assessed luminosity or brightness, defined as the intensity of the light produced by the flexible ureterorenoscope. Five different types of outcomes (mV [oscilloscope], Lumen [photometer], Lux [Lux meter/Optical spectrometer], mW [power meter], and points [questionnaire]) in an ex vivo setting (Table 3). The intensity

Table 3 Optics.

| #          | Author (year)   | Optics        | Resolution     | Distortion | Luminosity            | Colour and grey scale | View           | Visibility        |
|------------|---|---------------|----------------|------------|-----------------------|-----------------------|----------------|-------------------|
| - 0        | Abdelshehid <i>et al.</i> (2005) [6]                                    | Yes           | LP/mm          | %          | /m/                   |                       |                |                   |
| <b>ν</b> ω | Arane <i>et al.</i> (2000) [3]<br>Al Qahtani <i>et al.</i> (2020) [7]   | Yes           |                |            | E                     |                       |                | Likert scale      |
| 4          | Al Qahtani <i>et al.</i> (2011) [8]                                     | Yes           |                |            |                       |                       |                | NR                |
| o 4        | Ames <i>et al.</i> (2006) [9]<br>Andonian <i>et al.</i> (2008) [47]     | 0 ŭ           | dN             |            |                       |                       |                |                   |
| ) <b>/</b> | Bach <i>et al.</i> (2008) [10]  | <u>2</u>      |                |            |                       |                       |                |                   |
| ∞          | Bader <i>et al.</i> (2010) [11]   | Yes           | LP/mm          | %          | wm                    |                       | Degrees        |                   |
| 6          | Baghdadi <i>et al.</i> (2017) [12]                                      | 2             |                |            |                       |                       |                |                   |
| 10         | Bedke <i>et al.</i> (2013) [13]   | 2 2           |                |            |                       |                       |                |                   |
| - 2        | Binbay <i>et al.</i> (2010) [14]<br>Bodin et al. (2000) [15]            | o %           |                |            |                       |                       | Dogroos        |                   |
| 3 5        | Cho <i>et al.</i> (2018) [16]   | Kes           |                |            |                       |                       | 5000           | NR                |
| 14         | Dale <i>et al.</i> (2017) [17]  | Yes           | LP/mm          | %          |                       | Reproducibility       | Degrees and mm |                   |
| 15         | Deininger <i>et al.</i> (2018) [18]                                     | Yes           |                |            | Lux and questionnaire | Questionnaire         |                | Questionnaire     |
| 9 :        | Doizi <i>et al.</i> (2017) [19]   | Yes           |                |            |                       | <u>(</u>              |                | Likert scale      |
| _ ;        | Dragos <i>et al.</i> (2017) [20]  | Yes           | -              | ò          |                       | NIS                   | •              |                   |
| <u> </u>   | Dragos <i>et al.</i> (2019) [21]<br>Et Hijsspiny of al. (2010) [22]     | Yes           | LF/mm          | %          | 2                     |                       | E              |                   |
| 2 - 2      | Ernasselly et al. (2010) [22]<br>Emiliani et al (2018) [23]             | ς α<br>Δ<br>Δ |                |            | Ĭ,                    |                       |                | Likert scale      |
| 22         | Emiliani <i>et al.</i> (2017) [48]                                      | Yes           |                |            |                       |                       |                | Likert scale      |
| 22         | Hennessey <i>et al.</i> (2018) [24]                                     | 2             |                |            |                       |                       |                |                   |
| 23         | Inoue <i>et al.</i> (2021) [25]   | 2             |                |            |                       |                       |                |                   |
| 24         | Johnson and Grasso (2004) [26]  | <u>0</u>      |                |            |                       |                       |                |                   |
| 25         | Johnston <i>et al.</i> (2018) [27]                                      | Yes           |                |            |                       |                       |                | Likert scale      |
| 56         | Kam <i>et al.</i> (2019) [28]   | Yes           |                | i          |                       |                       |                | Likert scale      |
| 27         | Kim <i>et al.</i> (2018) [29]   | Yes           | LP/mm          | %          |                       |                       |                | VAS               |
| 8 Z<br>Z   | Kruck <i>et al.</i> (2011) [49]   | 0 5           |                |            |                       |                       |                | - T T T T T T T T |
| 52 6       | Legemare <i>et al.</i> (2018) [30]                                      | Yes           |                |            |                       |                       |                | LIKert scale      |
| ر<br>د     | Luawig <i>el al.</i> (2017) [30]  | <u> </u>      | /U1            |            |                       | 9                     |                | ( C()             |
| - 6        | Luscri <i>ef di.</i> (2013) [31]<br>Marchini <i>et ci. (</i> 2018) [32] | S A           | IP/mm<br>IP/mm |            |                       |                       | Degrees        | LIKELI SCOIE      |
| 33         | Multescu <i>et al. (2</i> 010) [33]                                     | Yes           | :<br>:<br>:    |            |                       |                       |                | likert scale      |
| 34         | Multescu <i>et al.</i> (2013) [34]                                      | Yes           |                |            |                       |                       |                | Likert scale      |
| 35         | Paffen <i>et al.</i> (2008) [35]  | Yes           | LP/mm          | %          | Lux                   |                       | Degrees        |                   |
| 36         | Poon <i>et al.</i> (1997) [36]  | 9             |                |            |                       |                       |                |                   |
| 37         | Proietti <i>et al.</i> (2016) [37]                                      | Yes           |                |            |                       |                       |                | Frequencies       |
| 8 G        | Projetti <i>et al.</i> (2017) [51]                                      | o<br>Z ;      |                |            |                       |                       |                | -                 |
| ک<br>ک د   | Schidger <i>et al.</i> (2017) [38]                                      | Yes           |                |            |                       |                       |                | Questionnaire     |
| 04 5       | Schidger <i>et al.</i> (2020) [39]                                      | Yes           |                |            |                       |                       |                | LIKert scale      |
| - t<br>- c | Snydris <i>et di.</i> (2004) [40]<br>Talso et al (2018) [52]            | 0 %<br>2 >    |                |            |                       |                       |                | olpost social     |
| 43         | Tambo et al. (2020) [41]  | ?<br>- 2      |                |            |                       |                       |                |                   |
| 44         | Tom et al (2017) [42]   | Yes           | IP/mm          | %          |                       | <u>~</u> Z            | mm             |                   |
| 45         | Traxer <i>et al.</i> (2006) [43]  | 2             | 1              | 2          |                       |                       |                |                   |
| 46         | Villa <i>et al.</i> (2020) [44]   | 2             |                |            |                       |                       |                |                   |
| 47         | Wendt-Nordahl <i>et al.</i> (2007) [45]                                 | <u>0</u>      |                |            |                       |                       |                |                   |
| 48         | Winship <i>et al.</i> (2019) [46]                                       | Yes           | LP/mm          |            |                       |                       |                | Likert scale      |
|            |   |               |                |            |                       |                       |                |                   |

of the light source while measuring luminosity varied between 50% and 100%. Except for Deininger et al. [18], who described using seven observers, no specific number of observers was mentioned. Four studies mentioned the number of measurements that was performed (range 1-5) [11,18,22,35].

Colour/greyscale Colour assessment was done using a Gretag Macbeth colour checker target card or Greyscale camera contrast chart in an ex vivo setting in six studies (Table 3). Deininger et al. [18] used a questionnaire to assess colour/greyscale of high-quality pictures. All studies that reported the number of measurements (two of six), only performed the measurement once [17,21]. Similar to luminosity, Deininger et al. [18] were the only ones describing the number of observers (seven).

View Depth, direction, angle, and field of view were studied in an ex vivo setting in seven studies (Table 3). A protractor was used as a measurement-tool in two studies [11,32]. Two different test cards (a Multifrequency grid target card or the Edmund optics depth of field test target card) were used as a tool to perform measurements in three of the seven studies [17,21,42].

Outcomes were described in degrees or millimetres. None of the included studies described the number of observers. Four studies described the number of measurements performed (range 1–20 times) [11,17,21,35].

Visibility Visibility of the flexible ureterorenoscopes was assessed in 20 papers (Table 3). This subcategory was defined as the quality of the image as perceived by the surgeon.

A Likert scale was used most of the studies (14/20). A visual analogue scale, a questionnaire, and the frequency of which a scope was preferred over other scopes were used as an alternative in four studies as presented in Table 3.

Two studies did not mention which tool was used to evaluate visibility [8,16]. The Likert scales used differed between studies and all had different rating systems. Assessment of visibility was performed in an in vivo, simulated and ex vivo setting. Great diversity was observed in the number of observers (range 1-103) and the number of assessments performed (range 1-90 times).

#### Irrigation

Irrigation was studied in 27/48 articles. It was defined as the flow of fluid exiting the scope at the distal end. The outcome is presented in Table 4 [5-52].

Deininger et al. [18] also used intrapelvic pressure besides irrigation flow to describe irrigation. The majority of the studies (24/27) evaluating irrigation, performed their

measurements in an ex vivo setting [5,6,9-15,17,18,21,24,31-35,42,43,45,46,49].

Pressure during measurements of irrigation flow differed substantially (range 40-339.9 cmH<sub>2</sub>O). Measuring irrigation flow whilst applying a pressure of 100 cmH<sub>2</sub>O was mentioned most frequently (12/27) [9,10,13,14,17,18,24,32,33,42,43,49]. However, four articles did not describe the pressure used while measuring irrigation flow [16,19,23,29]. The unit used to describe pressure while measuring irrigation also differed between studies; 18 studies used cmH<sub>2</sub>O [9,10,12-14,17,18,21,24,32-35,42,43,45,46,49], five studies used mmHg as a unit for pressure [5,6,11,29,31].

In all, 23 of the 27 papers evaluated irrigation flow with and without instruments inserted in the scope [6,9-19,23,24,28,29,32-35,42,45,49]. Afane et al. [5] and Dragos et al. [21] only evaluated irrigation without inserted instruments. The remaining papers did not specifically describe whether irrigation measurements were performed with or without inserted instruments.

Overall, 10 papers measured irrigation with an undeflected and deflected ureterorenoscope [10,13,16,18,19,21,23,29,34,49]. The remaining 19 papers did not describe state of deflection while measuring irrigation.

A minority of papers (five of 27) reported flushing the scope for a certain amount of time before measurements were performed [6,13,18,46,49].

When described, irrigation flow was measured for a minimum of 30 s up to a maximum of 5 min [5,9,11-13,18,29,31,35,46,49]. The measurements were repeated between one and five times depending on the study. Furthermore, the number of observers varied between one and four.

Four studies used a Likert scale ranging from 0 to 5 to 0-10, all with different rating systems, to describe irrigation flow. All other studies (24/27) evaluating irrigation choose to use mL/min as a unit of measurement as shown in Table 4.

#### Handling

Handling was mentioned in 19 studies. The results for this key parameter are shown in Table 5 [5-52]. Handling was defined as the amount of gain or strain experienced by the surgeon when using the flexible ureterorenoscopes.

It was the most heterogeneous group with 26 subcategories after regrouping. Of the 19 studies describing a form of Handling, 15 defined two or more subcategories [16,19,23,27,29,30,32,34,35,38,39,41,43,50,51]. The subcategories included up to 12 items per study to define a form of Handling.

Table 4 Irrigation.

| #        | Author (year)   | Irrigation | Flow                  | Intrapelvic pressure |
|----------|---|------------|-----------------------|----------------------|
| 1        | Abdelshehid <i>et al.</i> (2005) [6]                                  | Yes        | mL/min                |                      |
| 2        | Afane <i>et al.</i> (2000) [5]  | Yes        | mL/min                |                      |
| 3        | Al Qahtani <i>et al.</i> (2020) [7]                                   | No         |                       |                      |
| 4        | Al Qahtani <i>et al.</i> (2011) [8]                                   | No         |                       |                      |
| 5        | Ames <i>et al.</i> (2006) [9]   | Yes        | mL/min                |                      |
| 6        | Andonian <i>et al.</i> (2008) [47]                                    | No         |                       |                      |
| 7        | Bach <i>et al.</i> (2008) [10]  | Yes        | mL/min                |                      |
| 8        | Bader <i>et al.</i> (2010) [11]                                       | Yes        | mL/min                |                      |
| 9        | Baghdadi <i>et al.</i> (2017) [12]                                    | Yes        | mL/min                |                      |
| 10       | Bedke <i>et al.</i> (2013) [13]                                       | Yes        | mL/min                |                      |
| 11       | Binbay <i>et al.</i> (2010) [14]                                      | Yes        | mL/min                |                      |
| 12       | Boylu <i>et al.</i> (2009) [15]                                       | Yes        | mL/min                |                      |
| 13       | Cho <i>et al.</i> (2018) [16]   | Yes        | Likert scale          |                      |
| 14       | Dale <i>et al.</i> (2017) [17]  | Yes        | mL/min                |                      |
| 15       | Deininger <i>et al.</i> (2018) [18]                                   | Yes        | mL/min                | mmHg                 |
| 16       | Doizi <i>et al.</i> (2017) [19]                                       | Yes        | Likert scale          |                      |
| 17       | Dragos <i>et al.</i> (2017) [20]                                      | No         |                       |                      |
| 18       | Dragos <i>et al.</i> (2019) [21]                                      | Yes        | mL/min                |                      |
| 19       | El-Husseiny <i>et al.</i> (2010) [22]                                 | No         |                       |                      |
| 20       | Emiliani <i>et al.</i> (2018) [23]                                    | Yes        | Likert scale          |                      |
| 21       | Emiliani <i>et al.</i> (2017) [48]                                    | No         |                       |                      |
| 22       | Hennessey et al. (2018) [24]  | Yes        | mL/min                |                      |
| 23       | Inoue <i>et al.</i> (2021) [25]                                       | No         |                       |                      |
| 24       | Johnson and Grasso (2004) [26]  | No         |                       |                      |
| 25       | Johnston <i>et al.</i> (2018) [27]                                    | No         |                       |                      |
| 26       | Kam <i>et al.</i> (2019) [28]   | No         | and frain O Bland and |                      |
| 27       | Kim et al. (2018) [29]  | Yes<br>Yes | mL/min & likert scale |                      |
| 28<br>29 | Kruck <i>et al.</i> (2011) [49]                                       | ves<br>No  | mL/min                |                      |
| 30       | Legemate <i>et al.</i> (2018) [30]                                    | No         |                       |                      |
| 31       | Ludwig <i>et al.</i> (2017) [50]                                      | Yes        | mL/min                |                      |
| 32       | Lusch <i>et al.</i> (2013) [31]<br>Marchini <i>et al.</i> (2018) [32] | Yes        | mL/min                |                      |
| 33       | Multescu <i>et al.</i> (2010) [33]                                    | Yes        | mL/min                |                      |
| 34       | Multescu <i>et al.</i> (2013) [34]                                    | Yes        | mL/min                |                      |
| 35       | Paffen <i>et al.</i> (2008) [35]                                      | Yes        | mL/min                |                      |
| 36       | Poon <i>et al.</i> (1997) [36]  | No No      | 11111/1111111         |                      |
| 37       | Proietti <i>et al.</i> (1997) [30]                                    | No         |                       |                      |
| 38       | Proietti <i>et al.</i> (2017) [57]                                    | No         |                       |                      |
| 39       | Schlager <i>et al.</i> (2017) [38]                                    | No         |                       |                      |
| 40       | Schlager <i>et al.</i> (2020) [39]                                    | No         |                       |                      |
| 41       | Shvarts <i>et al.</i> (2004) [40]                                     | No         |                       |                      |
| 42       | Talso <i>et al.</i> (2018) [52]                                       | No         |                       |                      |
| 43       | Tambo <i>et al.</i> (2020) [41]                                       | No         |                       |                      |
| 44       | Tom <i>et al.</i> (2017) [42]   | Yes        | mL/min                |                      |
| 45       | Traxer <i>et al.</i> (2006) [43]                                      | Yes        | mL/min                |                      |
| 46       | Villa <i>et al.</i> (2020) [44]                                       | No         |                       |                      |
| 47       | Wendt-Nordahl <i>et al.</i> (2007) [45]                               | Yes        | mL/min                |                      |
| 48       | Winship <i>et al.</i> (2019) [46]                                     | Yes        | mL/min                |                      |
|          | (2017) [10]   | . 55       | ,                     |                      |

After categorisation, the following groups were formed: 'Difficulty', 'Control', 'Ergonomics', and 'Satisfaction'. The vast majority (14/19) of all measurements were evaluated on a Likert scale or visual analogue scale [5,8,12,16,19,23,27,29,30,32,34,38,39,43]. Nonetheless, 17 different scales were used to estimate Handling.

Difficulty Difficulty was evaluated in 12 out of 19 papers describing Handling (Table 5). Difficulty was defined as the ease of insertion and handling of a flexible ureterorenoscope. This subcategory included the ease of insertion of a scope or instruments, ease of handling, rigidity of the flexible ureterorenoscopes, torsion stiffness of the flexible ureterorenoscopes, the workload on the surgeon to perform a task, and the difficulty of the procedure as experienced by the surgeon.

The ease of insertion was evaluated for the flexible ureterorenoscope, as well as for instruments in the flexible ureterorenoscope. All these measurements were assessed on different Likert scales or a visual analogue scale. Baghdadi et al. [12] additionally defined ease of insertion as a dichotomous variable (failure vs success). Attempts were

Table 5 Handling.

| #        | Author (year)   | Handling | Difficulty                                    | Control      | Ergonomics                                     | Satisfaction |
|----------|---|----------|---|--------------|--|--------------|
| 1        | Abdelshehid <i>et al.</i> (2005) [6]                                  | No       |   |              |  |              |
| 2        | Afane <i>et al.</i> (2000) [5]  | Yes      |   | Likert scale |  |              |
| 3        | Al Qahtani <i>et al.</i> (2020) [7]                                   | No       |   |              |  |              |
| 4        | Al Qahtani <i>et al.</i> (2011) [8]                                   | Yes      | Likert scale                                  |              |  |              |
| 5        | Ames <i>et al.</i> (2006) [9]   | No       |   |              |  |              |
| 6        | Andonian <i>et al.</i> (2008) [47]                                    | No       |   |              |  |              |
| 7        | Bach <i>et al.</i> (2008) [10]  | No       |   |              |  |              |
| 8        | Bader <i>et al.</i> (2010) [11]                                       | No       |   |              |  |              |
| 9        | Baghdadi <i>et al.</i> (2017) [12]                                    | Yes      | Dichotomous                                   |              |  |              |
| 10       | Bedke <i>et al.</i> (2013) [13]                                       | No       |   |              |  |              |
| 11       | Binbay <i>et al.</i> (2010) [14]                                      | No       |   |              |  |              |
| 12       | Boylu <i>et al.</i> (2009) [15]                                       | No       |   | Physics 1    | Physical Company                               |              |
| 13<br>14 | Cho et al. (2018) [16]  | Yes      |   | Likert scale | Likert scale                                   |              |
| 15       | Dale <i>et al.</i> (2017) [17]<br>Deininger <i>et al.</i> (2018) [18] | No<br>No |   |              |  |              |
| 16       | Doizi <i>et al.</i> (2017) [19]                                       | Yes      | Likert scale                                  | Likert scale |  | Likert scale |
| 17       | Dragos <i>et al.</i> (2017) [19]                                      | No       | Likeri scale                                  | Likeri scale |  | LIKEIT SCUIE |
| 18       | Dragos <i>et al.</i> (2017) [20]                                      | No       |   |              |  |              |
| 19       | El-Husseiny <i>et al.</i> (2010) [22]                                 | No       |   |              |  |              |
| 20       | Emiliani <i>et al.</i> (2018) [23]                                    | Yes      | Likert scale                                  | Likert scale |  | Likert scale |
| 21       | Emiliani <i>et al.</i> (2017) [48]                                    | No       | LIKOTI OGGIO                                  | LIKOTI GOGIO |  | LIKOTI GOGIO |
| 22       | Hennessey <i>et al.</i> (2018) [24]                                   | No       |   |              |  |              |
| 23       | Inoue <i>et al.</i> (2021) [25]                                       | No       |   |              |  |              |
| 24       | Johnson and Grasso (2004) [26]  | No       |   |              |  |              |
| 25       | Johnston <i>et al.</i> (2018) [27]                                    | Yes      | Likert scale                                  |              | Likert scale                                   | Likert scale |
| 26       | Kam <i>et al.</i> (2019) [28]   | No       |   |              |  |              |
| 27       | Kim <i>et al.</i> (2018) [29]   | Yes      | VAS   | VAS          |  | Likert scale |
| 28       | Kruck et al. (2011) [49]  | No       |   |              |  |              |
| 29       | Legemate <i>et al.</i> (2018) [30]                                    | Yes      | Likert scale                                  |              |  |              |
| 30       | Ludwig <i>et al.</i> (2017) [50]                                      | Yes      |   |              | Average and<br>cumulative muscular<br>workload |              |
| 31       | Lusch <i>et al.</i> (2013) [31]                                       | No       |   |              |  |              |
| 32       | Marchini <i>et al.</i> (2018) [32]                                    | Yes      | Likert scale                                  |              |  |              |
| 33       | Multescu <i>et al.</i> (2010) [33]                                    | No       |   |              |  |              |
| 34       | Multescu <i>et al.</i> (2013) [34]                                    | Yes      | Likert scale                                  | Likert scale |  |              |
| 35       | Paffen <i>et al.</i> (2008) [35]                                      | Yes      | T   |              |  |              |
| 36       | Poon <i>et al.</i> (1997) [36]  | Yes      | Torsion stiffness<br>meter and<br>dichotomous |              |  |              |
| 37       | Proietti <i>et al.</i> (2016) [37]                                    | No       |   |              |  |              |
| 38       | Proietti <i>et al.</i> (2017) [51]                                    | Yes      |   |              | Grammes and cm                                 |              |
| 39       | Schlager <i>et al.</i> (2017) [38]                                    | Yes      |   | Likert scale |  |              |
| 40       | Schlager <i>et al.</i> (2020) [39]                                    | Yes      | NASA TLX                                      | Likert scale |  |              |
| 41       | Shvarts <i>et al.</i> (2004) [40]                                     | No       |   |              |  |              |
| 42       | Talso <i>et al.</i> (2018) [52]                                       | No       |   |              |  |              |
| 43       | Tambo <i>et al.</i> (2020) [41]                                       | Yes      |   |              | Questionnaire                                  |              |
| 44       | Tom <i>et al.</i> (2017) [42]   | No       |   |              |  |              |
| 45       | Traxer <i>et al.</i> (2006) [43]                                      | Yes      | Likert scale                                  | Likert scale |  |              |
| 46       | Villa et al. (2020) [44]  | No       |   |              |  |              |
| 47<br>48 | Wendt-Nordahl <i>et al.</i> (2007) [45]                               | No<br>No |   |              |  |              |
| 40       | Winship <i>et al.</i> (2019) [46]                                     | INU      |   |              |  |              |

made to pass fibres at different states of deflection and irrigation. Kim et al. [29] assessed the rigidity of the flexible ureterorenoscope on a visual analogue scale. Legemate et al. [30] evaluated the ease of handling during URS on a Likert scale. Torsion stiffness was assessed by Paffen et al. [35] and defined as the resistance of the shaft to rotate at its longitudinal axis. It was measured with a torsion stiffness meter and expressed in Newton meter. Traxer et al. [43] assessed the difficulty of the procedure on a Likert scale. Finally, Schlager et al. [39] evaluated the workload during a

URS with the National Aeronautics and Space Administration Task Load Index (NASA-TLX).

Difficulty was assessed by one, two or three observers, depending on the study. Only Paffen et al. [35] assessed difficulty multiple times (eight). The other 10 studies performed one assessment.

Control This subcategory was assessed in nine of 19 papers evaluating this key parameter as found in Table 5. Control

was defined as the influence of the surgeon on the manoeuvrability of the flexible ureterorenoscope. However, all the studies used a slightly different definition. Emiliani et al. [23] for instance, mentioned torque: the degree to which movement in the handle was transmitted and precisely reproduced at the tip of the scope. As opposed to Kim et al. [29] who used the word control or Traxer et al. [43] who used manoeuvrability of the scope.

Furthermore, all studies used a different Likert scale or visual analogue scale to express control, leading to a great heterogeneity. There was no difference in the number of assessments, as all 19 studies only performed one evaluation of control. The number of observers, ranged from one to six observers.

Ergonomics Ergonomics was studied in five of 19 studies (Table 5). Ergonomics was defined as the physical comfort and efficiency in use of a flexible ureterorenoscope. It mostly concerned the extent to which a muscle group or body part was used, strained, or in pain [16,27,41,50]. One study focussed on the body mass index of the scope as an influencing factor on ergonomics [51]. All studies used different tools such as a Likert scale, a questionnaire or surface electromyography (EMG) electrodes to evaluate ergonomics. Likert scales and scales in questionnaires varied from 0-5, 1-5 to 1-10 all with different rating systems. Ludwig et al. [50] used surface EMG electrodes and expressed the outcome in average and cumulative workload.

Ludwig et al. [50] evaluated ergonomics three times. All other studies conducted measurements only once. With the exception of Tambo et al. [41] who asked 25 observers to assess ergonomics, all papers used one observer.

Satisfaction Satisfaction was described in four papers and was defined as overall satisfaction of the surgeon or convenience of use of the flexible ureterorenoscopes as assessed by the surgeon during a procedure as presented in Table 5. All four papers used a variation of a Likert scale to evaluate satisfaction.

Only Emiliani et al. [23] had more than one observer, namely two, to evaluate satisfaction. Furthermore, all four papers only performed one evaluation to assess overall satisfaction with the flexible ureterorenoscope.

#### **Durability**

Durability was defined as the property of the scope to withstand wear, pressure, or damage. Seventeen studies described the durability of flexible ureterorenoscopes, as presented in Table 6 [5-52]. All measurements were performed in an ex vivo setting. Emiliani et al. [23] and Legemate et al. [30] evaluated loss of deflection, visibility and image quality in an in vivo setting as well.

The interval of measurements varied substantially between studies. Wendt-Nordahl et al. [45] evaluated ureterorenoscopes in an ex vivo setting after the first and 100th procedure in a pig cadaver. Whereas Winship et al. [46] performed the evaluation on never-used single-use ureterorenoscopes and then repeated the same measurements after 200 cycles of maximum deflection. El-Husseiny et al. [22] evaluated durability after the first, tenth, 30th and 44th procedure. The remainder of studies evaluated durability before and after each procedure or did not report on the timing of evaluation.

Wear A total of 16 studies presented wear of functionality over a certain amount of time (Table 6). Wear was defined as the loss of quality of a specific characteristic (deflection, irrigation, luminosity, image quality, or visibility) over a period of time.

Of these 16 studies, 14 studies within the wear subcategory, focussed on loss of deflection [5,7,8,19,22,23,27,29,30,34,42,43,45,46]. Loss of deflection was mostly (13/14 papers) expressed in degrees (Table 6). Emiliani et al. [23] and Legemate et al. [30] expressed loss of deflection in the form of a Likert scale.

Three papers studied the loss of irrigation expressed in mL/ min as can be seen in Table 6. Afane et al. [5] and El-Husseiny et al. [22] assessed loss of luminosity measured by a photo- or spectrometer and expressed in lumen or lux. Three studies evaluated loss of image quality or visibility measured with a Likert scale (Table 6).

Except for Tom et al. [42], who performed the measurement three times, all other studies performed the measurement once [5,7,8,11,19,22,23,27-30,34,42,43,45,46]. The number of observers varied between one and five observers.

Damage Seven studies presented damage within the durability group (Table 6). Damage was defined as the breakdown of a characteristic of the flexible ureterorenoscope. The main topic of interest within the damage subcategory was broken optical fibres defined as the number of dark dots on the monitor. This type of damage was studies in four studies (Table 6). Leakage, damage to sheath and working channel and damage to the scope in general, were characteristics studied to evaluate damage in the remaining three papers. These characteristics were all scored as dichotomous variables.

Measurements were only performed once in all seven studies. Furthermore, six of the seven studies only used one observer.

Table 6 Durability.

| 1<br>2<br>3<br>4<br>5<br>6 | Abdelshehid <i>et al.</i> (2005) [6]<br>Afane <i>et al.</i> (2000) [5]<br>Al Qahtani <i>et al.</i> (2020) [7]<br>Al Qahtani <i>et al.</i> (2011) [8]<br>Ames <i>et al.</i> (2006) [9] | No<br>Yes<br>Yes | Degrees, mL/min and Lm   | # dark dots on monitor |
|----------------------------|---|------------------|--|------------------------|
| 3<br>4<br>5<br>6           | Al Qahtani <i>et al.</i> (2020) [7]<br>Al Qahtani <i>et al.</i> (2011) [8]  | Yes              | <u> </u>   | # dark date on manitar |
| 4<br>5<br>6                | Al Qahtani <i>et al.</i> (2011) [8]   |                  |  | " daik dois on monitor |
| 5<br>6                     |   | \/               | Degrees  | Dichotomous            |
| 6                          | Ames et al. (2006) [9]  | Yes              | Degrees  | Dichotomous            |
|                            |   | No               |  |                        |
| 7                          | Andonian <i>et al.</i> (2008) [47]  | No               |  |                        |
| /                          | Bach <i>et al.</i> (2008) [10]  | No               |  |                        |
| 8                          | Bader <i>et al.</i> (2010) [11]   | Yes              | mL/min   |                        |
| 9                          | Baghdadi <i>et al.</i> (2017) [12]  | No               |  |                        |
| 10                         | Bedke <i>et al.</i> (2013) [13]   | No               |  |                        |
| 11                         | Binbay <i>et al.</i> (2010) [14]  | No               |  |                        |
| 12                         | Boylu <i>et al.</i> (2009) [15]   | No               |  |                        |
| 13                         | Cho <i>et al.</i> (2018) [16]   | Yes              |  | Dichotomous            |
| 14                         | Dale <i>et al.</i> (2017) [17]  | No               |  |                        |
| 15                         | Deininger et al. (2018) [18]  | No               |  |                        |
| 16                         | Doizi <i>et al.</i> (2017) [19]   | Yes              | Degrees and Likert scale   |                        |
| 17                         | Dragos <i>et al.</i> (2017) [20]  | No               | <u> </u>   |                        |
| 18                         | Dragos <i>et al.</i> (2019) [21]  | No               |  |                        |
| 19                         | El-Husseiny <i>et al.</i> (2010) [22]   | Yes              | Degrees and Lux  |                        |
| 20                         | Emiliani <i>et al.</i> (2018) [23]  | Yes              | Likert scale   |                        |
| 21                         | Emiliani <i>et al.</i> (2017) [48]  | No               |  |                        |
| 22                         | Hennessey et al. (2018) [24]  | No               |  |                        |
| 23                         | Inoue <i>et al.</i> (2021)[25]  | No               |  |                        |
| 24                         | Johnson and Grasso (2004) [26]  | No               |  |                        |
| 25                         | Johnston <i>et al.</i> (2018) [27]  | Yes              | Degrees  |                        |
| 26                         | Kam <i>et al.</i> (2019) [28]   | Yes              | Dichotomous  |                        |
| 27                         | Kim <i>et al.</i> (2018) [29]   | Yes              | Degrees  |                        |
| 28                         | Kruck <i>et al.</i> (2011) [49]   | No               | <u> </u>   |                        |
| 29                         | Legemate <i>et al.</i> (2018) [30]  | Yes              | Degrees and Likert scale   |                        |
| 30                         | Ludwig <i>et al.</i> (2017) [50]  | No               | , and the second |                        |
| 31                         | Lusch et al. (2013) [31]  | No               |  |                        |
| 32                         | Marchini <i>et al.</i> (2018) [32]  | No               |  |                        |
| 33                         | Multescu et al. (2010) [33]   | No               |  |                        |
| 34                         | Multescu et al. (2013) [34]   | Yes              | Degrees  | # dark dots on monitor |
| 35                         | Paffen <i>et al.</i> (2008) [35]  | No               | 9  |                        |
| 36                         | Poon <i>et al.</i> (1997) [36]  | No               |  |                        |
| 37                         | Proietti <i>et al.</i> (2016) [37]  | No               |  |                        |
| 38                         | Proietti <i>et al.</i> (2017) [51]  | No               |  |                        |
| 39                         | Schlager <i>et al.</i> (2017) [38]  | No               |  |                        |
| 40                         | Schlager <i>et al.</i> (2020) [39]  | No               |  |                        |
| 41                         | Shvarts <i>et al.</i> (2004) [40]   | No               |  |                        |
| 42                         | Talso <i>et al.</i> (2018) [52]   | No               |  |                        |
| 43                         | Tambo <i>et al</i> . (2020) [41]  | No               |  |                        |
| 44                         | Tom et al. (2017) [42]  | Yes              | Degrees  |                        |
| 45                         | Traxer <i>et al.</i> (2006) [43]  | Yes              | Degrees and mL/min   | # dark dots on monitor |
| 46                         | Villa et al. (2020) [44]  | No               | ŭ  |                        |
| 47                         | Wendt-Nordahl <i>et al.</i> (2007) [45]   | Yes              | Degrees  | # dark dots on monitor |
| 48                         | Winship et al. (2019) [46]  | Yes              | Degrees  |                        |

Only Afane et al. [5] used four different observers to assess damage.

### Manufacturer's Specifications

A wide range of manufacturer's specifications was described in 42 of the 48 included papers (Table 1). There was a wide variety of specifications described in the different studies. Finally, a total of 29 different characteristics were mentioned in the included papers. A full overview of the specifications can be found in Appendix S2.

### **Discussion**

The evolution in flexible ureteroscopes have enabled urologists to expand the indication for endoscopic retrograde procedures. However, the instruments are fragile, and the purchase and repairs comes at high costs. Therefore, there is a great interest in evaluation and comparison of the quality of flexible ureterorenoscopes.

The present review systematically evaluated different approaches to assess the quality of flexible ureterorenoscopes. To the best of our knowledge, the present review is the first on this topic. The systematic literature search resulted in 48 articles [5-52]. Five key parameters were identified: Manoeuvrability (87.5%), Optics (64.6%), Irrigation (56.3%), Handling (39.6%) and Durability (35.4%). These parameters were partially described in previous systematic reviews, which focussed on comparing clinical results of different flexible ureterorenoscopes [54-57]. Within these parameters there is a great heterogeneity in terms of method of measurement, construct, definitions, and measurement outcomes. This variety makes it difficult to cluster or compare study results evaluating flexible ureterorenoscopes.

One explanation for this variety could be the range of year of publication of included articles (1997-2020) and the concomitant technological advances during this time frame. Although the importance of the evaluation of flexible ureterorenoscopes is illustrated by the number of included studies in the present review, uniformity in method of appraisal has yet to be reached.

### Grading Systems in Alternate Fields of Expertise

Originally, flexible ureterorenoscopes were derived from the first flexible endoscopic instrument used in the field of gastroenterology, the gastroscope. The gastroscope was developed in the 1950s, when a physics student and a gastroenterologist joined forces to develop this instrument [2]. The latter performed the first gastroscopy on himself and treated a stomach ulcer in a patient the next day. Although the gastroscope can be seen as a precursor of the first flexible URS (which had its first purposeful use in a patient in the 1970s), the gastroscope does not seem to be assessed in a uniform way as well.

Yet, in other fields such as physics and engineering, research is done to create uniform grading systems, for instance to compare images [58,59]. Moreover, institutions such as NASA, have found ways to systematically evaluate workload of certain tasks on a person in relation to the use of a tool (NASA-TLX) [60]. Finally, in the field of laparoscopy, validated questionnaires to estimate ergonomics are more common. As well as recommendations on improving ergonomics when performing laparoscopy, with the first articles on this subject already widely published in the 1990s [61]. As developments are made in different fields of expertise within medicine, as well as outside the working field of medicine, it is time to join forces and combine knowledge to create a reproducible and uniform assessment tool. A standardised assessment tool to evaluate the quality of flexible ureterorenoscopes is needed to structure outcomes and facilitate comparison in future studies. As the validity of a measurement can only accurately be graded if the characteristics measured and their applications are clearly defined [62].

### **Future Perspectives**

As we deem the heterogeneity of all aspects of analysed grading systems to be of too great an extent, we feel that it is not fitted to select preferred subcategories and methods based solely on our expertise. However, we do believe that with the present systematic scoping review, we identified main categories that should be used as a basis when creating a uniform assessment tool, namely: Manoeuvrability, Optics, Irrigation, Handling and Durability. Therefore, we will use these main categories to explore subcategories, measurement methods, construct, and measurement outcomes to establish consensus by means of a Delphi Consensus Project with active members in the research field of evaluation of ureterorenoscopes. In our opinion this is the only appropriate step after establishing such a vast non-uniformity. Finally, we would not like to venture possible influence on the results of such a project and therefor limit expressions of opinions on preferred methods.

#### Limitations

The major limitation of the present review is the possible publication bias, which is inherent to all non-randomised controlled cohort studies. However, we do believe, that even if there was a possible bias, this would have had an influence on the outcomes reported and not on the characteristics investigated. Thus, making it irrelevant for the present review. Furthermore, regrouping items in order to form categories is prone to be influenced by interpretation of the reviewers.

#### Conclusion

In the present systematic scoping review, we reviewed and identified parameters and methods used to evaluate flexible ureterorenoscopes. This review showed that there are five key parameters in the quality assessment of flexible ureterorenoscopes: Manoeuvrability, Optics, Irrigation, Handling, and Durability. Nevertheless, within the different studies there is great heterogeneity in terms of measurement methods, construct, definitions, and measurement outcomes, which complicates comparison of study outcomes. Therefore, a standardised assessment tool to evaluate the quality of flexible ureterorenoscopes is mandatory to structure outcomes and facilitate comparison in future studies.

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#### Conflict of Interest

G.M. Kamphuis received payment for the EMS Webinar on Endoscopic Combined Intrarenal Surgery, an online course for Boston scientific on decision making in Endourology and an online course for Olympus on the Thulium Fiber Laser usage in treatment of kidney stones. Furthermore he attends advisory board meetings for Olympus and Boston Scientific.

### **Author Contributions**

Both Nora Hendriks and Michaël M.E.L. Henderickx contributed equally and share first authorship. N. Hendriks: protocol/project development, data collection or management, data analysis, manuscript writing/editing. M.M.E.L. Henderickx: protocol/project development, data collection or management, data analysis, manuscript writing/editing. B.M.A. Schout: Protocol/project development, manuscript writing/editing. J. Baard: manuscript writing/editing. F.S. van Etten-Jamaludin: data collection or management, manuscript writing/editing. H.P. Beerlage: manuscript writing/editing. R.C.M. Pelger: manuscript writing/editing. G.M. Kamphuis: protocol/project development, data collection or management, manuscript writing/editing.

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Abbreviations: EMG, electromyography; MeSH, Medical Subject Headings; NASA(-TLX), National Aeronautics and Space Administration (Task Load Index); PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCT, randomised controlled trials; URS, ureterorenoscopy.

## Supporting Information

Additional Supporting Information may be found in the online version of this article:

**Appendix S1.** Literature searches.

**Appendix S2.** Manufacturer specifications 1.

**Appendix S3.** List of references screened for inclusion based on full text.