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Are Urologists Getting French-Fried? Discrepancy between Advertised and Actual Sizes of Endourology Instruments

Pankaj M Joshi*, Devang J Desai, Craig Hunter, Walid Shahrour and Sanjay B Kulkarni

Department of Urology, Kulkarni Reconstructive Urology Centre, Rajpath Society, Pune, India

***Corresponding author:** Pankaj M Joshi, Department of Urology, Kulkarni Reconstructive Urology Centre, Rajpath Society, Opposite Vanaz Engineering, Paud Road, Pune, 411038, India

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Abstract

Introduction: In the 19th century, Joseph-Frédéric-Benoît Charrière developed a uniform, standard gauge for measuring catheters and endoscopic medical instruments. Urethral stricture disease was at heart, on inception of the modern French scale. Our aim was to study if we were to measure our endoscopic urologic equipment, would the actual measurements be equivalent to the advertised labeled sizes.

Methods: The French unit is equivalent to the circumference in millimeters. We analyzed three different instruments, 26Fr TURP sheath, elliptical 20 Fr cystoscopy sheath and 6/7.5 semi-rigid ureteroscope. Digital caliper was used to take 30 measurements of diameter and 30 of circumference at proximal, mid and distal part of the instruments. The measurement were accurate to 0.01 mm. Size of the instrument was derived by using diameter and circumference.

Results: The 26 Fr sheath actually measured 28 Fr on measurement of the diameter. The 20 Fr sheath at the narrow portion was 6.09mm/19.12 Fr and at the wide portion measured 7.96mm/24.99 Fr. The 6/7.5 semi-rigid ureteroscope, at the distal end was 7.06 to 9.22 Fr while at the proximal portion was 3.52 mm/11.05Fr. The 26 Fr sheath measured over 27 French, the 20 Fr sheath was close to 23 Fr while the 6/75 Ureteroscope was 9.33-12 French on circumferential measurement.

Conclusion: The sizes of our endoscopic instruments are larger than the labeled size. The circular 26 Fr TUR sheath measured to be 27 Fr. The 20 Fr sheath was more than 22 Fr, and the 6/7.5 Fr ureteroscope is actually 9/12 Fr. There are clinical implications of the sizes of instruments we use. Urologists would be wise to familiarize with the actual size prior to utilising these in the urethra or ureters to avoid injury.

Introduction

In the 19th century, Joseph-Frédéric-Benoît Charrière, a Parisian maker of surgical instruments, developed a uniform, standard gauge for catheters and medical instruments. Charrière's system has uniform increments between sizes of an object, such as a bladder catheter, endoscope or guide wire. A Charrière unit is now commonly known around the world as a "French" (Fr) unit of measurement which is well known to all urologists. Charrière was described as a perfectionist [1]. He had superior technical competence and he excelled at intricacy [2]. His goals of "simplicity, small size, and low cost," eventually led to worldwide adoption to his French catheter scale [3]. The principle of incremental predictable sizes of instruments was important in the development of urethral sounds for the treatment of urethral strictures. Surgeons ordering from catalogs wanted specific sizes of tools, especially for procedures like progressive dilation [3]. Urethral stricture disease was at the heart of inception of the modern French scale.

Was Charrière successful in his goal of simplicity, precision, and uniformity?

If we measure our endoscopic urologic equipment, would the actual measurements be equivalent to the labeled advertised sizes?

Our aim was to determine the accuracy in sizing of our endoscopic equipment.

Methods

What is a French unit? Is it a measurement of diameter or of circumference? BAUS website states that French unit is equivalent to the circumference in millimeters [4]. Literature review from Campbell's states that catheter size is measured in the Charrière or French scale, whereby one Fr or Ch is equal to 0.33 mm. This measurement indicates the total circumference of the catheter and not the lumen size [5] On review of the catalogue of endoscopic

manufacturers there is no discrepancy that French size is the outer circumference in millimeters. Thus, it is clear that French size is indicative of the outer circumference of the instrument in millimeters. However, in order to measure circumference, we need to apply the mathematical formula using the diameter. Circumference = 2 x Pi x radius. The irrational number pi (3.14159265359…) complicates the discrepancy between the diameter and circumference. This is because there is no suggestion in the literature if the value of Pi should be rounded off to 3 or should it be considered as 3.14. To make a precise sized instrument the manufacturers would have to apply this mathematical formula. If a circular object has a circumference of 30 mm, the diameter (divided by pi) is equal to 9.5492965… mm. Likewise a circular object of 10 mm would have a circumference of 31.4159265359… The circumference size in millimeters would actually be 4.72% larger if the value of pi was rounded to 3 rather than 3.14159265359.

Now, what about an elliptical or non-circular object? If the unit of measure is the diameter, what diameter is used for measurement?

Most of our current endoscopic equipment is elliptical. In the case of elliptical instruments, the circumference measurement would be preferred because of the ability to accommodate instruments that are not truly circular. The circumference is also clinically valuable, assuming physiologic tubes (urethra, ureter, etc.) are distensible. The discrepancy between pi, the diameter, and circumference was going to lead to inaccuracy. A solution was to contact the manufacturers of our equipment to find out their particular method of measurement. We attempted multiple times to contact 3 major instrument manufactures. Unfortunately, no endoscopic equipment manufacturer replied to our repeated requests for information. To achieve better accuracy and also accommodate elliptical instruments, we took circumference AND diameter measurements of our instruments. We segregated our results into diameter French measurement, and circumference French measurement to obtain the equivalent measurement in French units 3.14 multiplied the measured diameter in mm, according to the mathematical formula. Our circumference in mm was the second method of measurement. The French unit was equal to measured circumference in mm. This was particularly useful for elliptical instruments.

We analyzed three different instruments (Figure 1). In order to protect the academic nature of our evaluation, the manufacturers will remain anonymous. The first instrument was a circular "26 Fr" Transurethral Resection (TUR) sheath. The second was an elliptical "20 Fr" cystoscopy sheath. The third instrument was an elliptical "6.7.5 Charr." (Charrière or Fr) semi-rigid ureteroscope.

Figure 1: Ureteroscope, Cystoscope sheath and TURP sheath being considered for measurements.

For the 26 Fr TUR sheath, a total of 60 measurements were made (Figure 2). 30 were made of the outer diameter and 30 of the circumference. The diameter measurements were with digital calipers (Model Z22855, PowerFix, Neckarsulm Germany) measured to the nearest 0.01 mm. Ten diameter measurements were taken at 3 (distal, mid, and proximal) areas of the sheath. The circumference was measured with a white 4-0 polyglactin suture (Figure 3). With the aid of the 2.5 x loupe magnification and a sharp pencil the intersection was marked. The marked suture was measured with a digital caliper (Figure 4).

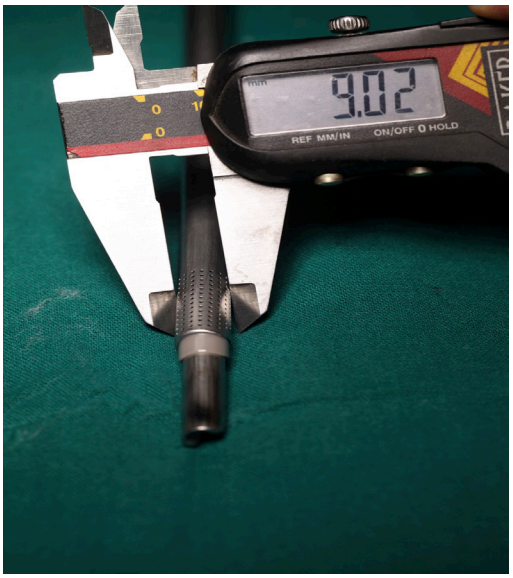

Figure 2: Measurement of outer diameter of TURP sheath at distal shaft by digital calipers. (9.02 x 3.14 = 28.32).

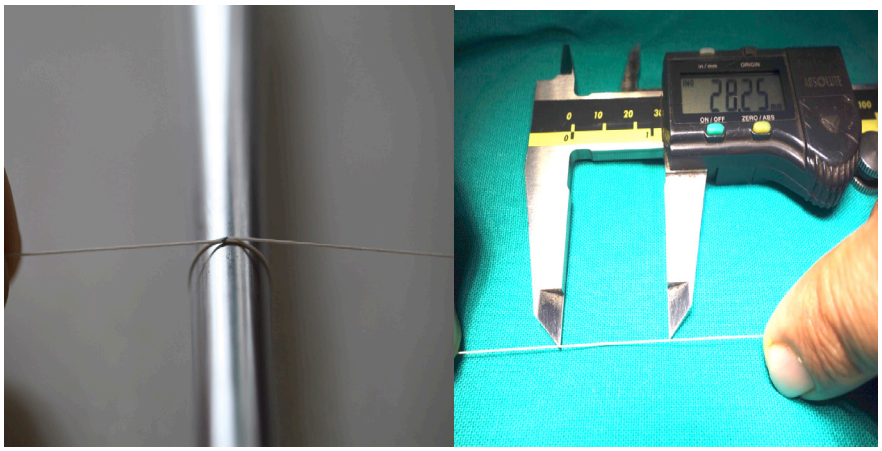

Figure 3: Measurement of outer circumference of TURP sheath at distal shaft by thread technique.

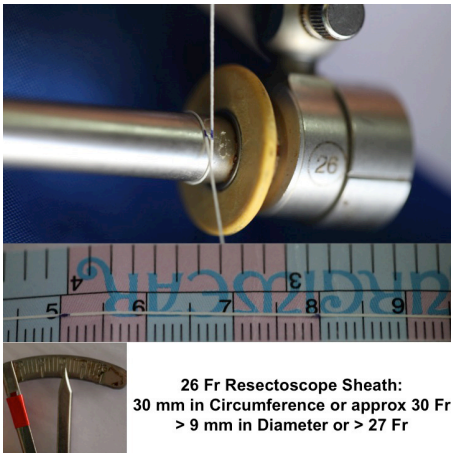

Figure 4: Measurement of distance marked on the thread by digital calipers, depicting the outer circumference of TURP sheath.

For the 20 Fr sheath, a total of 90 measurements were made (Figure 5). The 20 Fr sheath was an elliptical shape. The elliptical shaped required 60 diameter measurements. The method was the same as above but included 30 measurements of the wide diameter and 30 of the narrow diameters. The 30 circumference measurements were obtained by the same method.

Figure 5: Measurement of outer diameter of cystoscopy sheath at distal shaft by digital calipers.

For the 6/7.5 Charr (Fr) ureteroscope, a total of 60 measurements were taken (Figure 6,7). The semi rigid ureteroscope was also elliptical in shape. 20 circumference measurements were taken by the above stated method. 40 measurements of the diameter were also noted. 10 measurements each were taken at the narrow distal end, 10 were taken at the wide distal end, 10 were taken at the narrow proximal end, and 10 were made at the wide proximal end. 20 circumference measurements were taken, obtaining10 proximal and 10 distal measurements. Statistical analysis was performed with STATA software.

Figure 6: Measurement of outer diameter of ureteroscope at proximal shaft by digital calipers.

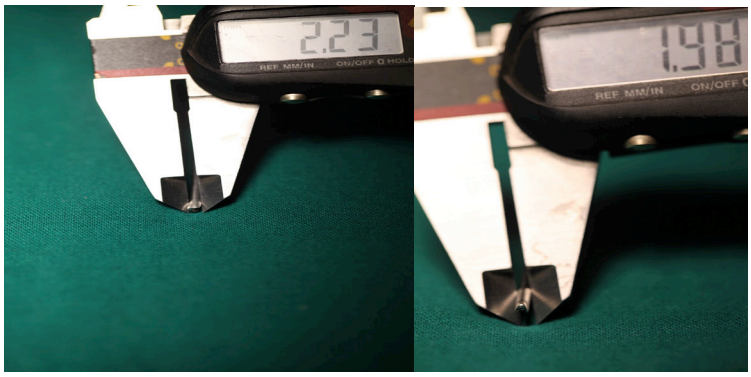

Figure 7: Measurement of outer diameter of ureteroscope at distal tip by digital calipers.

Results

Tables 1-3 outlines the mean actual measurements from each location on each instrument. Table 4 outlines the overall size discrepancy between the stated label size and measurements. The mean sizes of the different portions (distal, mid, lateral) of each instrument were averaged for the overall mean size of each instrument.

A: Diameter

26 Fr TUR Sheath Diameter Measurements	Proximal	Mid	Distal
Mean Diameter in mm (SD)	8.78 (0.01)	8.84 (0.04)	9.05 (0.10)
French measured by Diameter x 3.14 (SD)	26.75(0.04)	27.75 (0.12)	28.43 (0.33)
P – value	<0.001	<0.001	<0.001

B: Circumference

26 Fr TUR Sheath Circumference Measurements	Proximal	Mid	Distal
Mean Circumference in mm (SD)	27.13 (0.17)	27.35 (0.13)	27.52 (0.15)
P – value	<0.001	<0.001	<0.001

Table 1: Measurements taken from TURP sheath.

A: Diameter

20Fr Sheath Diameter Measurements	Proximal	Mid	Distal
Mean Diameter in mm (SD)	7.93 (0.02)	8.00 (0.03)	7.95 (0.04)
French measured by Diameter x 3.14 (SD)	24.91 (0.05)	25.13 (0.10)	24.98 (0.14)
P – value	< 0.001	<0.001	<0.001

B: Circumference

20 Fr Sheath Circumference	Proximal	Mid	Distal
Mean Circumference in mm (SD)	22.64 (0.19)	22.57 (0.17)	22.60 (0.20)
P-Value	<0.001	<0.001	<0.001

Table 2: Measurements taken from 20 Fr Cystoscopy sheath.

A: Diameter

Semi-rigid Ureteroscope	Distal	Proximal
Mean Diameter in mm (SD)	3.07 (0.01)	3.53 (0.05)
French measured by Diameter x 3.14 (SD)	9.65 (0.04)	11.09 (0.16)
P – value	< 0.001	<0.001

B: Circumference

Ureteroscope 6/7.5 Circumference	Distal (6 Charr.)	Proximal (7.5 Charr.)
Mean Circumference in mm (SD)	9.33 (0.12)	11.70 (0.16)
P-Value	<0.001	<0.001

Table 3: Measurements taken from 6-7.5 Ureteroscope.

Instrument	Mean French size by Diameter Calculation (% Discrepancy)	Mean French size by Circumference Calculation (% Discrepancy)
26 Fr TUR sheath	28 (7.6 % increase)	27.33 (5% increase)
20 Fr sheath	19.12-24.99 (25% increase)	22.60 (13% increase)
6 Fr (Distal) end of ureteroscope Narrow measurement	7.06(17.6% Increase)	9.33 (55% Increase)
6 Fr (Distal) end of ureteroscope Wide measurement	9.63(60% Increase)	9.33 (55% Increase)
7.5 (proximal) end of ureteroscope	11.05(46.6 % Increase)	11.7 (56% Increase)

Table 4: Overall size discrepancy comparison.

Diameter measurement for French calculation (mm multiplied by 3.14 = Fr)

The basis of our study was the accurate measure of the circumference of the instrument. This can be measured by 2 techniques. In the first technique we used precise markings on a string. The second method is to calculate exact diameter and apply mathematical formula for circumference, which is 2 x Pi x Radius. We used the value of Pi as 3.14. For convenience it has been suggested that diameter multiples by 3 is the size of instrument in French. However, mathematically it is multiplication by value of Pi (3.14). Consider an example of elliptical instrument. Which diameter do you consider for labeling? Longest or shortest? In this case circumference is of importance and our study, suggests that even the labeled circumference, is much less than actual circumference of the instrument.

If the measurement method is by diameter, the actual size of the 26 Fr sheath is closer to 28 Fr. For 20 Fr elliptical sheaths - when taking elliptical measurements, the mean diameter of the narrow portion was 6.09 mm (±0.05) or 19.12 Fr while that of the wide portion was 7.96 mm (±0.03) or 24.99 Fr. The semi rigid ureteroscope 6/7.5 Charrière (Fr) is also elliptical in shape. The narrow distal diameter had a mean of 2.25 mm (±0.03). The diameter of the distal narrow elliptical end would correspond to 7.06 fr. However, the distal wide diameter measured 3.07 mm (±0.01), or 9.63 Fr. The proximal portion of the ureteroscope was more circular and had a diameter of 3.52 mm (±0.03) or 11.05 Fr if the measurement was by diameter.

Circumference measurement for French calculation (Circumference in mm = Fr)

The 26 Fr sheath: If the measurement of the sheath is by circumference in mm, the mean circumference of the 26 Fr sheath is 27.33 or over 27 French. The 20 French sheath: If the measurement of the sheath is by circumference in mm, the overall mean circumference was 22.60 (±0.20). The 20 Fr would be more accurately stated as being at least 22 French, or closer to 23 Fr. If using the circumference method of measurement, 22.60 mm corresponds to an increase in size above the label of 13%. The 6/7.5 Ureteroscope: The circumference distally measured 9.33 mm (±0.12). This corresponds to an increase in the label size of 55%. The circumference proximally measured 11.70 mm (±0.16) or closer to 12 Fr. If the circumference was the method of French measurement, the size was 56% above that of the label 7.5 Fr.

Reporting the different narrow and wide dimensions became less valuable when we agree the useful French measurement for elliptical instruments is circumference. However, the narrow and wide measurements of the ureteroscope were included in our report because the results were found to be insightful. Recall that even the narrow portion of the elliptical ureteroscope, using the diameter measurement, was larger than the 6 Fr stated size. Theoretically, the narrow portion of an elliptical instrument should be much smaller than the labeled size, in order to accommodate the wider dimension of the ureteroscope – assuming to be able to stay true to the labeled size.

Discussion

Our instruments are larger than the labeled size. The diameter of our instruments has clinical implications. The male urethral size is 21-24 Fr at the meatus. It is 30-36 Fr at the fossa navicularis, 27-30 Fr at the penile urethra and 36 to 42 Fr at the bulbar urethra. The average measurement diameter of the male adult urethra is 31.5 Fr [5].

One example of clinical relevance is that of post TUR stricture. The rate of post TUR stricture can be as high as 10% [6]. The relationship between the size of resectoscope sheath during TUR procedures and development of urethral stricture has not been reported. Conceptually a larger scope increases the likelihood the development of such stricture. Appropriate knowledge of anatomy and our surgical instruments is important in making clinical decisions. It is surprising to note that a 26 Fr sheath of a resectoscope is closer to size 28 Fr. The 9 mm diameter is larger than the meatus and as large as the penile urethra. A transurethral resection of the prostate (TURP) with any sheath larger than 26 Fr sheath has have a larger diameter than the average male urethra. Accurate labeling will prevent urologists from having a false sense of security by using a 28 Fr resectoscope when the sheath maybe larger than the average male urethra. The discrepancy between the size of urethra and size of the sheath illustrates the large peg and a small hole concept.

Approximately 42-50% of iatrogenic ureteral injuries are caused by urologic intervention. Over 80% are caused by ureteroscopy [7,8]. Surprisingly, very little is written on the dimensions of the ureter. We commonly quote 3-4 mm as being the diameter or the ureter. Despite the abundance of ureteral stone papers in the literature, very little has been written on the size of the ureter. One 2004 radiology paper examined extraluminal diameter of the normal ureter on CT to be 1.8 mm with SD of 0.9 mm [9]. The intraluminal size of the ureter is likely smaller. The narrow distal diameter of our ureteroscope was 2.25 mm. The wide distal diameter was 3.07 mm. Most semi-rigid ureteroscopes used in practice today have a distal tip with a range of 6.9 to 8.6 Fr and are likely to be larger than our measured 6 Fr scope. Ureteroscopy and TUR provide two clinical illustrations that highlight the importance that a practitioner must be appropriately informed of the size of endourological instruments. This is not the first report of a manufacture mislabeling. A recent report by Kronenberg and Traxer outlined a median increase of 87.3% outer diameter size above the labeled advertised diameter of laser fibers [10]. They found significant lack of uniformity and precision among manufacturers. Mislabeling is a concern that the FDA is commonly enforcing [11,12]. The confusion is perpetuated when elliptical instruments are used. In order to maintain consistency

and clinical validity, the circumference in mm should be used to label instruments. Clinically, the urethra and ureter appear circular in endoscopic view however, there is no reference to suggest this. They are pliable and distensible. The shape of the urethra and ureter can adjust an ellipse without significant trauma. Elliptical instruments are not the problem. What appears to be lacking is a standardized and precise method to measure elliptical instruments.

Accurate information from the manufacturers would be appreciated. Our attempts at obtaining any information from them were futile. A representative who wished to remain anonymous stated the discrepancy is well known throughout the industry. If it is well known, (uncorroborated of course) it should be well known to the practitioner. If manufacturers are not aware of the discrepancy, perhaps this report will motivate appropriate labeling. Perhaps manufacturers warrant more quality controls, or periodically investigations to ensure correct labeling of the technical specifications of instruments. This will minimize risk to the patient. Manufactures have an obligation to properly label their equipment. The size of the instrument is labeled in French, and the practicing urologist assumes the label is correct and accurate. The greatest discrepancy was with our "6/7.5" Fr ureteroscope. The circumference measurement of the distal ureteroscope was over 9 Fr. The diameter measurement of the narrow distal end was even larger than 6 Fr. Regardless of the confusion between circumference/diameter and elliptical/circular, the narrow distal diameter was the most conservative measurement of all our instruments. This conservative measurement is still significantly larger than the labelled size!

Limitation of our evaluation was with the definition of a French unit. As was stated in the introduction, different sources state a different method of calculating a French unit. BAUS states on its website that size of instrument is the outer circumference in millimeters [4]. It is possible the manufacturers have an explanation for their methods – the explanation could have saved hours of preparation and production of this report. The confusion between whether the diameter or circumference was used is harmonized into our ultimate result. Our ultimate results demonstrate that regardless of the method of measurement, our instruments are larger than the labeled advertised size. The second limitation of the study is that may be the measured instrument sizes fall within the error of measurement. However, this seems to hold true only for the TURP sheath. The measurements of cystoscopy sheath and ureteroscope seems way beyond the error of measurements. Charriere, a perfectionist and a man who paid attention to detail would likely turn disappointed with the amount of discrepancy and variation between surgical instruments. He developed a uniform standard system for surgical instruments. Today our instruments do not appear to be uniform. Our instruments do not appear to be standardized. It is tragic that a man of such precision unfortunately has a legacy tainted by inconsistency [13-15].

Conclusion

The sizes of our endoscopic instruments are larger than the advertised labeled size. Of the instruments measured, the circular 26 Fr TUR sheath was close to size 27 Fr. The 20 Fr sheath is over 22 Fr, and the 6/7.5 Fr ureteroscope is actually 9/11 Fr. There are clinical implications on using an endourology instrument that has been mislabeled. Practicing urologists would be wise to be familiarize with the actual size of their instruments prior to making clinical decisions which may mitigate the risks to their patients.

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