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ORIGINAL ARTICLE

IBS® Integrated Bigatti Shaver, an alternative approach to operative hysteroscopy

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Abstract At present, conventional resectoscopy can be considered the gold standard procedure for major hysteroscopic operations [1]. Despite well-recognized advantages of resectoscopy, several problems, such as fluid overload, uterine perforation due to monopolar or bipolar current, lack of visualization resulting in a time-consuming procedure, and long learning curve, remain still unsolved. We have made, in cooperation with Karl Storz GmbH & Co., a new shaving system that, introduced through a straight operative channel of a panoramic 90° optic, allows to perform all kinds of major operative procedures such as polypectomy, G0, G1, and G2, submucosal myomectomy, and endometrial ablation. We have performed 44 operative hysteroscopy, including 24 polyps, 15 submucosal myomas, two polyps + submucosal myomas, three endometrial ablations. The polyps' size ranged from 5 to 40 mm, and all procedures were performed with the IBS®. The mean time for polyps' resection was 3′28″. Ten cases of myoma's resection were performed exclusively with the IBS® of which four Type 0, two Type 1, four Type 2, the size ranged from 10 to 30 mm and the mean resection time was 14′. For five cases of myoma's resection, we started the operation with the IBS®, and we ended the procedure with the conventional monopolar resectoscope. The myomas' size ranged from 20 to 40 mm of which three Type 0, two Type 2, and the mean resection time was 32′. When the IBS® was used, the dilatation number reached 8.5 Hegar size that increased to 9.5 when we switched to conventional resectoscopy. We used sorbitol–mannitol at the beginning of the study and in all cases that we suspected the possibility of conversion to conventional monopolar resectoscope. As our learning curve improved, we switched to normal saline. No coagulation was needed when the IBS® was used. Two overload complications occurred: one was not depending on the method but to a malfunctioning of the Endomat® system. The second complication occurred during a G2—3 cm myoma's resection. This preliminary study is intended to evaluate the feasibility of this new technique that offers considerable advantages such as reduced dilatation of the cervix, better visualization during the procedure as tissue chips are removed at the same time of resection, no coagulation or cutting current is needed, the use of normal saline instead of sorbitol and mannitol, and a much faster learning curve.

Keywords Hysteroscopy · New instrumentation · Shaver

Introduction

The first resectoscope as we know today dates back 1926 and was used by Stern to remove three chips of prostatic tissue. The resectoscope Stern-McCarthy, made a few years later and that used optics with different angles 0°–30°, must be considered the precursor of the tool that we use today [2]. At present, the continuous flow monopolar or bipolar resectoscope is still considered the first-choice instrument to perform major operative hysteroscopical and urological procedures. Despite its versatility, many problems, technique-related, remain still unsolved. In case of monopolar technique, the absorption of large volumes of electrolyte-free, low viscosity fluid such as sorbitol–mannitol may result in volume overload with water intoxication [3]. Volume overload may

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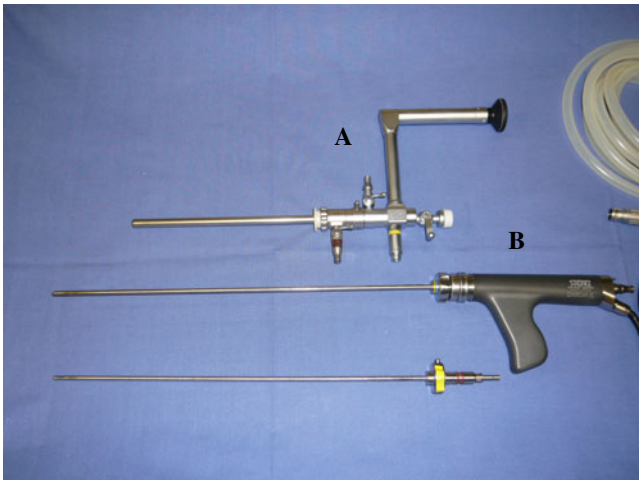

Fig. 1 IBS®: **a** 90° angulated 0°optic (Karl Storz gmbh of Tuttlingen) with a continuous flow sheath and an extra channel for the insertion of a **b** rigid shaving system

cause pulmonary edema, and water intoxication may lead to hyponatremia, hypo-osmolarity, and cerebral edema. Also, the use of bipolar technique does not prevent from these complications. If the use of isotonic solutions such as 0.9% sodium chloride prevents from dilution hyponatriemia, the risk of fluid overload is still maintained. In addition, several case reports have shown that massive fluid absorption during hysteroscopic myomectomy with normal saline solution resulted in severe hyperchloremic metabolic acidosis and dilution coagulopathy resolved with diuretic therapy [4, 5]. Another big concern is related to the use of high-frequency monopolar or bipolar current during resection. Uterine perforation with bowel injury can be caused by the loop of the resectoscope and oblige the surgeon to perform laparoscopy or laparotomy in order to repair the lesion [6]. In addition, during large polyps' or myomas' resection, the visual field of the surgeon is reduced by the tissue chips that stay inside the uterine cavity, increasing the risk of perforation. The procedure becomes time consuming, as the tissue pieces must be removed from the uterine cavity in order to continue the procedure under visual control. This tiring procedure exposes the patient to intravasation and cervical laceration. Another minor but not secondary problem is that more than half of the uterine perforations are entry related, due to the large diameter of the conventional resectoscopes [7].

All these observations explain why this technique has such a long learning curve and why only a few surgeons perform operative hysteroscopy [8].

In order to reduce the complications rate abovementioned and make this technique easier, we have made in cooperation with Karl Storz Gmbh of Tuttlingen a prototype of a new instrument.

The Integrated Bigatti Shaver (IBS®) with a double windows blade has been studied to improve the results of conventional resectoscopy. The IBS® is able to remove the tissue chips at the same time of resection so that the procedure, always done under visual control, becomes faster, and with less complications. In addition with the IBS®, there is a considerable reduction of the learning curve. The present study reports the first 44 cases made with the IBS® and debates about the feasibility of this technique.

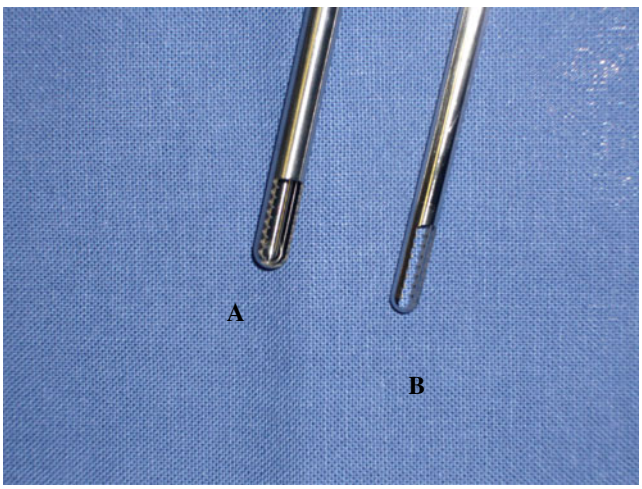

Fig. 2 **a** IBS® 25 mm^2 shaver tip with a **b** double window blade provided with a row of very sharp teeth

Table 1 Number of cases

	No. of cases	Percentage
Polyps	24	54.5
Myomas	15	34.1
Polyp +Myoma	2	4.5
Endometrial Hyperplasia	3	6.8
Total	44	

Table 2 Polyps

No. of cases (%)	24 (54.5)
Size (mm)	5–40
IBS® Average time of resection	3′28″
Average negative fluid balance (ml)	170
Average amount of fluid used (ml)	1,195
Complications	–

Table 3 Myomas

	IBS®	IBS® + resectoscope
N° CASES (%OF MYOMAS)	10 (66,6)	5 (33.3%)
SIZE (mm)	10–30	20–40
TYPE(G)	4G0-2G1-4G2	3G0-2G2
Average Time Of Resection	14′	32′
Average negative fluid balance (ml)	540	940
Average amount of fluid used (ml)	3,910	9,300
Complications	1[a]	1[b]

[a] Malfunctioning of the Endomat® pump

[b] Rupture of the blade of the IBS®

Materials and methods

The IBS® is made of 90° angulated 0°optic (Karl Storz Gmbh of Tuttlingen) with a continuous flow sheath and an extra channel into which a rigid shaving system is introduced—Fig. 1. The continuous flow sheath is connected to a peristaltic pump (Endomat® Karl Storz gmbh of Tuttlingen) in order to maintain distension and visualization inside the uterine cavity. The outer sheath diameter is of 24 Fr (8 mm). The rigid shaving system consists of two hollow reusable metal tubes fitting to each other. The inner tube rotates within the outer tube and is connected to a handheld (Drill® cut-x Karl Storz gmbh of Tuttlingen) motor drive unit (Unidrive® eco Karl Storz gmbh of Tuttlingen) and to a roller pump (Endomat® LC Karl Storz gmbh of Tuttlingen) controlled by a foot pedal.

The foot pedal activates at the same time the movements of shaver tip and the roller pump's aspiration in order to maintain a continuous suction power on the window tip during the procedure.

The shaver tip of the IBS® has been specifically designed in order to be aggressive on any kind of tissue. The inner rotating tube has a double window blade provided with a row of very sharp teeth—Fig. 2. At the outer tube's edge there is a window, provided of teeth too, of different sizes: 10, 17, 20, and 25 mm^2.

We used a 300 to 450 oscillating rotation power per minute and a flow pressure of suction 1,000 ml/min.

After dilatation of the internal ostium of the uterine cervix up to number 8.5 of Hegar, the panoramic optic with inflow and outflow channels connected to the Endomat pump was inserted into the uterine cavity. For irrigation, we used both sorbitol–mannitol and normal physiologic saline solution according to the type of procedure. The maximal flow setting was 450 ml/min with an intrauterine pressure lower than 95 mm/Hg. Once visualized the pathological site we introduced the rigid shaving system connected to the motor drive unit and to the roller pump into the operative channel and started the procedure. Aspiration starts only when the pedal of the roller pump is pressed, this prevents from the collapse of the uterine cavity due to the massive outflow. The rotating and oscillating movement of the inner blade of the shaving system cuts the tissue and allows aspiration of specimens for histology that are collected into a glass bottle directly connected to the roller pump.

A correct fluid balance is calculated by checking the fluid aspirated by the Endomat pump and by the rollerpump connected to the shaving system plus the fluid collected into a graduated plastic bag placed under the patient.

From June 2009 to February 2010, we have performed 44 operative hysteroscopy with the IBS®. All patients underwent a diagnostic hysteroscopy before the operation.

The institutional ethical committee approved the research, and all patients gave their informed consent. All patients underwent general or regional anesthesia, and standard gynecological setup was used in the operating room.

As listed in Table 1, 24 endometrial polyps, 15 submucosal myomas, two endometrial polyps + myomas, and three endometrial abnormalities requiring endometrial ablation were included in the study. The polyps' size ranged from 5 to 40 mm, while the myomas' size was from 10 to 40 mm. All types of submucosal myomas, G0, G1, G2 classified according to the ESGE guidelines, were included in the study [9, 10]. Seven patients before myomectomy underwent a preoperative GnRH agonist

Table 4 Polyp + Myoma

N° of cases (%)	2(4,5)
Size (mm)	Polyp 10–30—Myoma 15–20(G0–G1/2)
IBS® Average time of resection	24′
Average negative fluid balance (ml)	500
Average amount of fluid used (ml)	5,750
Complications	–

therapy. Recordings were made of fluid balance, time of dilatation of the cervical canal, total operating time, time of resection, type of distension media used, and complications. For total operating time, we have considered the time of the procedure without the dilatation time. For time of resection, we have considered the time that goes from the view in the cavity of the shaver tip to the end of resection.

Results

We have analyzed the behavior of the IBS® with the different intrauterine pathologies.

The size of the polyps was between 5 mm and 4 cm with a mean time of resection of 3′28″. We use an average of 1,195 ml of saline with a negative fluid loss of 170 ml. All procedures were performed exclusively with the IBS® and no complications occurred (Table 2).

Ten cases of myoma resection were performed exclusively with the IBS®, the size ranged from 10 to 30 mm of which four Type 0, two Type 1, four Type 2, and the mean resection time was 14′. We used an average of 3,910 ml of sorbitol–mannitol with a negative fluid loss of 540 ml. For five cases of myoma resection, we started the operation with the IBS®, and we ended the procedure with the conventional monopolar resectoscope. The myomas' size ranged from 20 to 40 mm of which three Type 0, two Type 2, and the mean resection time was 32′ (Table 3). We used an average of 9,300 ml of sorbitol–mannitol with a negative fluid loss of 940 ml. We decided to switch to conventional resectoscopy when the negative fluid balance compared with the remaining tissue to resect was too high. Approximately with a negative fluid balance of more than 750 ml of sorbitol–mannitol, we decided to use the conventional monopolar resectoscope in order to end the procedure in one step. The average negative fluid balance increased according to the length of the operation e showed to be higher when the conventional resectoscope was used in combination with the IBS®.

Two overload complications occurred during myomectomy performed with the use of sorbitol–mannitol as distension media.

The first happened during a procedure performed exclusively with the IBS® and was due to a malfunctioning of the Endomat pump. In this case, the tubing system set was placed in the wrong position and, despite the fact that the whole procedure lasted only 20 min, we used 10,000 ml with a negative fluid loss of 1,500 ml. The second complication occurred during a G2—3 cm myoma resection done with the combination of the IBS® and the conventional resectoscope. In this case, one of the blades broke down, and we had to change it. Due to this operation, we did not properly check the fluid balance and the time of the whole operation. As a consequence, we used 12,500 ml with a negative fluid loss between 1,000 and 1,500 ml. Both cases were uneventful.

With the IBS®, we also performed two cases with the contemporary presence of a myoma and a polyp in the same patient, and the average time of resection was 24′. We used an average of 5,750 ml of sorbitol–mannitol with a negative fluid loss of 500 ml (Table 4).

Table 5 Endometrial hyperplasia

No. of cases (%)	3(6.8%)
Endometrial Thickness (mm)	>5
IBS® Average time of resection	12′10″
Average negative fluid balance (ml)	330
Average amount of fluid used (ml)	2,500
Complications	–

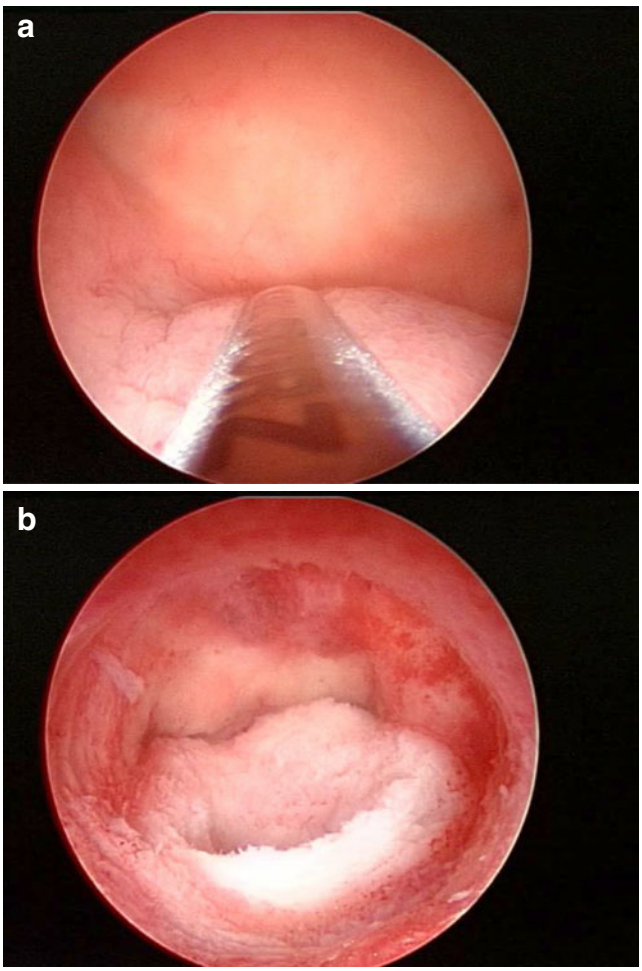

Fig. 3 IBS® resection of a G2, 2.5 cm large, submucosal myoma. **a** Before and **b** after the IBS® treatment. The Myoma is completely enucleated and the surrounding healthy endometrium is respected

We have also made three cases of endometrial ablation with an average time of resection of 12′10″. We used an average of 2,500 ml of sorbitol–mannitol with a negative fluid loss of 330 ml (Table 5). The mean dilatation time of the cervical canal was 2′.

Discussion

Polipectomy with the IBS® showed to be a very fast, clean, safe, and precise procedure. We started to remove the polyp from its top until we reached the base of the pedicle without affecting the surrounding endometrium. No bleeding was observed. Regarding myomectomy, the first remark is that we approached all types of submucosal myomas including G2 myomas. In 10 cases where the size was between 1 and 3 cm, we showed that the procedure was possible in an adequate lapse of time. When the size was approximately 4 cm, the time of the procedure became double, and conventional resectoscopy or a two-step procedure with the IBS® should be considered. What is really remarkable is that in the 10 cases done exclusively with the IBS®, the myoma was effectively enucleated, and only the intramural site of insertion of the myoma was interested by the procedure—Fig. 3. The surrounding healthy endometrium was respected without any thermal injury, compared with a less precise behavior of conventional resectoscopy. No coagulation was needed, and we had no extra bleeding problems. As our learning curve improved, only normal saline was used with less problems of fluid overload. With this paper, we want to assess the feasibility of this new technique. We believe that we should continue to work in this direction in order to reduce the time of myoma's resection that is still our major concern. To reach this goal, probably disposable and more aggressive tips are needed. At present, we have an ongoing randomized study to compare the IBS® with conventional bipolar resectoscopy. At the same time, further modifications to the IBS® are studied, in order to successfully perform all kind of hysteroscopic procedures in shorter time avoiding all major complications.

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Declaration of interest The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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