Gynecol Surg (2012) 9:63–72
DOI 10.1007/s10397-011-0701-9

ORIGINAL ARTICLE

IBS® Integrated Bigatti Shaver versus conventional bipolar resectoscopy: a randomised comparative study

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Received: 8 June 2011 / Accepted: 17 August 2011 / Published online: 6 September 2011

Abstract Conventional bipolar resectoscopy is widely recognized as the first choice for major hysteroscopic operations. We recently proposed an alternative approach to operative hysteroscopy called Integrated Bigatti Shaver (IBS®) that improves visualization during the procedure, reducing several problems of conventional resectoscopy such as fluid overload, water intoxication, uterine perforation and long surgeon's learning curve. In cooperation with Karl Storz GmbH & Co., we created a new shaving system that, when introduced through the straight operative channel of a panoramic 90° optic, allows performance of many major hysteroscopic operations. The present randomised comparative study was designed to compare 50 cases performed with conventional bipolar resectoscope with 50 cases performed with the IBS®. Several types of major intrauterine pathologies such as polyps and submucosal myomas (according to ESGE classification) were included in the study. Two cases of via falsa were reported. In one case, the procedure was immediately stopped with no further complication for the patient, whereas in the second patient, the complication did not compromise the operative course. Dilatation time, overall procedure time, resection time and fluid balance were carefully monitored during each procedure in the two groups. The aim of the study was to compare the two techniques to confirm several advantages offered by the IBS® such as reduced dilatation of the cervix, better visualization during the procedure because tissue chips are removed at the same time as the resection, no need for coagulation or cutting current, utilization of normal saline and a much faster learning curve.

Keywords IBS® · Hysteroscopy · Resectoscopy · Shaver

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Background

Presently, the double-flow bipolar resectoscope is considered the gold standard for performing major operative hysteroscopical procedures [1, 2]. The resectoscope Stern-McCarthy built in the 1920s must be considered the precursor of the tool that we use today [3–5]. Despite its versatility, many technique-related problems remain unsolved. The use of a bipolar technique does not prevent overload syndrome with water intoxication. Although the use of isotonic solutions like 0.9% sodium chloride prevents dilution hyponatriemia and hypocalcaemia [6], the risk of fluid overload is still present. In addition, several case reports have shown that massive absorption of normal saline solution results in severe hyperchloremic metabolic acidosis and dilution coagulopathy that must be resolved with diuretic therapy [7, 8]. Additionally, because a high-frequency electric current is used during resection, uterine perforation with bowel injury and internal and external burns caused by uncontrolled leakage of current can occur [9–11]. Finally, during resection of large polyps or myomas, the surgeon's visual field is impaired by the tissue chips that remain inside the uterine cavity, increasing the risk of perforation. Tissue pieces must be removed from the uterine cavity in order to continue the procedure under visual control, making the operation tiring and increasing the overall resection time, resulting in a higher risk of intravasation and cervical laceration. Another minor problem is that more than half of the uterine perforations are entry related because of the large diameter of the conventional resectoscopes [12].

Resectoscopy with the conventional bipolar technique has a long learning curve for surgeons, explaining why even today, only a few surgeons perform operative hysteroscopy [13, 14]. The Integrated Bigatti Shaver (IBS®), with a double-window blade, has been shown to improve on the results of conventional resectoscopy, reducing the complication rate and improving the learning curve time [15]. The IBS® can remove the tissue chips at the time of the resection so that the procedure, always done under visual control, becomes faster and easier. The present study compares 50 cases performed with the IBS® with 50 cases performed with the conventional bipolar resectoscope.

Materials and methods

We performed all operations using either the IBS® or the conventional bipolar resectoscope (Versapoint ® by Gynecare). The IBS® is made of 90° angulated 0° optic (Karl Storz GmbH of Tuttlingen) with a continuous flow sheath and an extra-operative channel into which a rigid shaving system was introduced (Fig. 1). The continuous flow sheath was connected to a peristaltic pump (Endomat® Karl Storz GmbH of Tuttlingen) to maintain optimal distension and visualization inside the uterine cavity. Two separate stopcocks regulated inflow and outflow. The outer sheath diameter was of 24 Fr (8 mm). The rigid shaving system consisted of two hollow reusable metal tubes fitting into each other. The inner tube rotated within the outer tube and was connected to a handheld (Drill cut-x Karl Storz GmbH of Tuttlingen) motor drive unit (Unidrive® eco Karl Storz GmbH of Tuttlingen) and a roller pump (Endomat® LC Karl Storz GmbH of Tuttlingen) controlled by a foot pedal.

The foot pedal is activated at the same time as the shaver tip and the roller pump to maintain a continuous suction power on the window tip during the procedure. The shaver tip of the IBS® was specifically designed 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. At the outer tube's edge, there is a window, 17, 20, 25 and 25 mm^2 wider radial large openings (Fig. 2), also provided with teeth.

We used 300 to 450 oscillating rotation power per minute and a flow pressure of suction of 500 ml/min. After dilatation of the internal ostium of the uterine cervix up to Hegar number 8.5, the panoramic optic with inflow and outflow channels connected to the Endomat pump was inserted into the uterine cavity. For irrigation, we used a normal isotonic solution like 0.9% sodium chloride. The maximum flow setting was 450 ml/min with an intrauterine pressure less than 95 mmHg. Once the pathological site was visualized, we introduced the rigid shaving system connected to the motor drive unit and the roller pump into the operative channel and started the procedure. Aspiration started only when the pedal of the roller pump was pressed; this prevented the collapse of the uterine cavity due to massive outflow. The rotating and oscillating movements of the inner blade of the shaving system cut the tissue and allowed aspiration of specimens for histology directly into a glass bottle connected to the roller pump (Endomat® LC Karl Storz GMBH of Tuttlingen).

Correct fluid balance was calculated by checking the fluid aspirated by the Endomat and roller pump connected to the shaving system plus the fluid collected in a graduated plastic bag placed under the patient.

The conventional bipolar resectoscope (Versapoint ® by Gynecare) consists of a 4-mm wire loop electrode mounted on a working element with hand piece, and a 12° operative

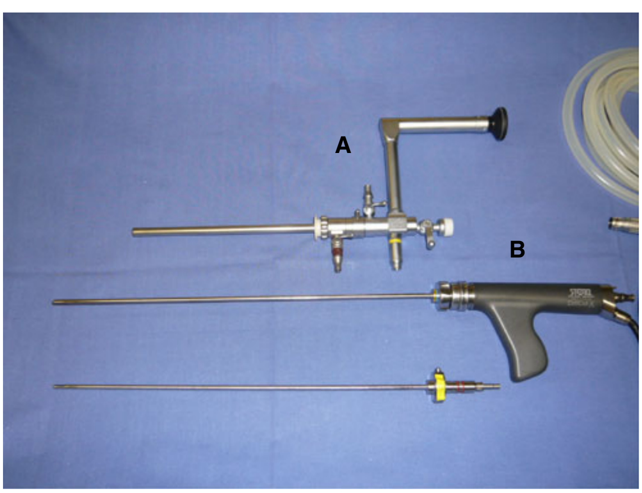

Fig. 1 Integrated Bigatti Shaver (IBS®). **a** 90° angulated 0°optic (Karl Storz GmbH of Tuttlingen) with a double flow sheath and an extra channel for the insertion of a **b** rigid shaving system

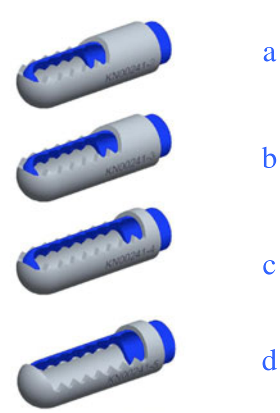

Fig. 2 Integrated Bigatti Shaver (IBS®) shaver tips: **a** 17 mm^2, **b** 20 mm^2, **c** 25 mm^2 and **d** 25 mm^2 wider radial opening

Table 1 Demographic and clinical data for Group A using Integrated Bigatti Shaver (IBS®)

	Polypectomy	Myomectomty	Polypectomy + Myomectomy	Endometrial Ablation
n (%)	31 (62)	12 (24)	5 (10)	2 (4)
Size (mm)[a]	15 (3–60), 17.5 (12.6)	20 (8–30), 20 (8.32)	Polyp 12.5 (10–40),17.5 (10.7) Myoma 20 (10–25), 18 (5.09)	
Age (years) [b]	44 (84–31)	45 (35–74)	58 (46–64)	41 (36–46)
Parity(%)				
Nulliparous	16 (51.6)	5 (41.7)	2 (40)	2 (100)
Multiparous	15 (48.4)	7 (58.3)	3 (60)	0 (0)
Menopause (%)	14 (45.2)	4 (33.3)	3 (60)	0 (0)
Symptoms (%)				
None	9 (29)	1 (8.3)	3 (60)	0 (0)
Menorrhagia	9 (29)	11 (91.6)	1 (20)	2 (100)
Anaemia	0 (0)	3 (24.9)	0 (0)	1 (50)
Post Menop. AUB	3 (9.7)	0 (0)	1 (20)	0 (0)
Pelvic Pain	0 (0)	1 (8.3)	0 (0)	0 (0)
Infertility	4 (12.9)	1 (8.3)	0 (0)	0 (0)
Complications (%)	0 (0)	0 (0)	0 (0)	0 (0)

[a] Median (range); mean (SD)

[b] Median (range)

optic endoscope. The loop electrode is connected to a Versapoint® unit automatically supplying bipolar current of 170 W for cutting and 80 W for coagulation. The Versapoint® unit was set to VC1 [16]. The operative endoscope had a continuous flow sheath with separate inflow and outflow stopcocks connected to a peristaltic pump (Endomat® Karl Storz GmbH of Tuttlingen) to maintain optimal distension and visibility. The continuous

Table 2 Demographic and clinical data for Group B using the bipolar resectoscope (Versapoint®)

	Polypectomy	Myomectomty	Polypectomy + Myomectomy	Endometrial Ablation
n (%)	42 (85.7)	3 (6.1)	2 (4.1)	2 (41)
Size (mm)[a]	15 (4–55) 15.60 (9.35)	20 (10–20) 17.5 (4.33)	Polyp 8 (6–15) 9.67 (3.85) Myoma 8 (8–8) 8 (0)	
Age (years) [b]	52 (29–82)	48 (43–52)	38 (37–39)	50 (39–61)
Parity (%)				
Nulliparous	16 (38.1)	1 (33.3)	2 (100)	1 (50)
Multiparous	26 (61.9)	2 (66.6)	0 (0)	1 (50)
Menopause (%)	22 (52.4)	1 (33.3)	0 (0)	1 (50)
Symptoms (%)				
None	13 (31.3)	2 (66.6)	1 (50)	0 (0)
Menorrhagia	15 (36)	1 (33.3)	1 (50)	1 (50)
Anaemia	0 (0)	1 (33.3)	0 (0)	1 (50)
Post Menop. AUB	12 (28.7)	0 (0)	0 (0)	1 (50)
Pelvic Pain	0 (0)	0 (0)	0 (0)	0 (0)
Infertility	6 (14)	0 (0)	0 (0)	0 (0)
Complications (%) [c]	2 (4.76)	0 (0)	0 (0)	0 (0)

[a] Median (range); mean (SD)

[b] Median (range)

[c] Complete perforation of the fundus (*n*=1) and a 5 to 10 mm false root of the fundus (*n*=1)

Table 3 Dilatation time

Dilatation	Group A (IBS®)				Group B (Versapoint®)				*p* Value
	Median	Range	Mean	DS	Median	Range	Mean	DS	
Dilatation (min)	1.5	1–18	2.14	2.7	2	1–14	2.65	2.53	0.3371

flow sheath was rotation free and had an external diameter of 27 Fr (9 mm).

After dilatation of the internal ostium of the uterine cervix up to Hegar number 9.5, the resectoscope connected to the peristaltic pump was inserted into the uterine cavity. Conventional resection technique was used. For irrigation, we used normal isotonic solutions like 0.9% sodium chloride. The maximal flow setting was 450 ml/min with an intrauterine pressure lower than 95 mmHg. Correct fluid balance was calculated by checking the fluid aspirated by the Endomat pump and by the fluid collected in a graduated plastic bag placed under the patient.

From March 2010 to February 2011, we performed 100 equally randomised either for the IBS® in Group A or the Versapoint ® Group B. The institutional ethical committee approved the research and all patients provided informed consent. Patients with several major intrauterine pathologies such as polyps as large as 6 cm, and G0, G1 and G2 submucosal myomas (classified according to the ESGE guidelines) that were up to 3 cm in diameter were included in the study [17, 18]. Uterine malformations such as partial or complete septum ablations and oncological cases were excluded from our trial. Both groups were similar with regard to age, parity and symptoms. All patients underwent general or regional anaesthesia, and a standard gynaecological setup was used in the operating room. All operations were performed by one expert surgeon and by one resident to evaluate the improvement in the surgeon's learning curve.

No statistical analysis was planned regarding preoperative therapy. Times of dilatation of the cervical canal, total operating time, resection time, fluid balance and complications were recorded. We considered the time for the procedure, without the dilatation time, as the total operative time. The time from the view of the cavity with the shaver tip or the resectoscope loop to the end of the resection was considered the resection time. Statistical analysis was performed using the Student's *t* test. Differences between groups were considered statistically significant at $p<0.05$. IBM SPSS Statistics 19 (©IBM Corporation 2010, IBM Corporation, Route 100 Somers, NY) statistical software package was used.

Findings

Patient collective

With the IBS®, we performed 31 (62%) polypectomies, 12 (24%) myomectomies, 5 (10%) polypectomies and myomectomies and 2 (4%) endometrial ablations (Table 1).

With the Versapoint®, 42 (85.7%) polypectomies, 3 (6.1%) myometomies, 2 (4.1%) polypectomies and myomectomies and 2 (4.1%) endometrial ablations were performed (Table 2).

The study design only randomised for major pathology but not within one group of pathology; for this reason, the myomectomies that are unequally randomised do not permit a comparative analysis.

Cervical dilatation time

As shown in Table 3, there was no statistically significant difference in the overall dilatation time between Groups A and B ($p=0.3371$). There was a statistically significantly shorter time of dilatation in the IBS® group (Group A) during myoma resection (median, 1.5 min; range, 1–2.5 min; mean, 1.37 min; DS, 0.42 min) compared with

Table 4 Polyp resection

Polyp resection	Group A (IBS®)				Group B (Versapoint®)				*p* Value
	Median	Range	Mean	DS	Median	Range	Mean	DS	
Dilatation (min)	1.5	1–18	2.51	3.51	2	1–14	2.5	2.33	1.0000
Operating Time (min)	5	3–13	6.76	5.21	9.75	4–21	10.5	4.51	0.0016
Resection Time (min)	2	0.16–12	2.95	3.23	5	0.33–16	5.56	3.57	0.0020
Fluid used (ml)	1500	400–5000	1845	1276.8	1550	500–5000	1697	874.9	0.5598
Fluid deficit (ml)	100	0–800	124.2	143.6	200	0–700	208.33	166.87	0.0271

Table 5 Myoma resection

Myoma resection	Group A(IBS®)				Group B (Versapoint®)				*p* Value
	Median	Range	Mean	DS	Median	Range	Mean	DS	
Dilatation (min)	1.5	1–2.5	1.37	0.42	1.5	1–12	4.83	5.66	0.0202
Operating Time (min)	23.25	6.5–66	27.41	18.95	8	8–13	9.66	2.34	0.1392
Resection Time (min)	15.08	0.9–50	19.92	15.29	5	2.5–9	5.34	2.7	0.1333
Fluid used (ml)	9250	2000–20.000	9925	5351.6	1700	1000–2000	1566.6	418.99	0.0208
Fluid deficit (ml)	550	100–2000	666.66	488.76	200	200–300	233.33	47.140	0.1596

Group B (median, 1.5 min; range, 1–12 min; mean, 4.83 min; DS, 5.66 min; $p=0.0202$) (Table 5).

Polyp resection

We performed 31 (62%) polypectomies in Group A (IBS®; Table 1) compared with 42 (85.7%) in Group B (Versapoint®; Table 2). The size of the polyps was similar in both groups. The median size of the polyps was 15 mm (range 3–60 mm) in Group A (Table 1) and 15 mm (range 4–55 mm; Table 2) in Group B. The median total operating time in Group A was 5 min (range 3–13 min) and 9.75 min in (range 4–21 min) Group B ($p=0.0016$) (Table 4). The median resection time in Group A was 2 min (range 0.16–12 min) and 5 min (range 0.33–16 min) in Group B ($p=0.0020$) (Table 4). In Group A, a mean of 1,845 ml of fluid was used compared with 1,697 ml in Group B ($p=0.5598$) (Table 4). The mean fluid deficit was 124.2 ml in Group A compared with 208.33 ml in Group B ($p=0.0271$) (Table 4). Our data indicate that both the operating time and resection time were statistically significantly in favour of the IBS® group. In addition, the lower fluid deficit, when the IBS® was used, was also an advantage.

Myoma resection

We performed 12 (24%) myomectomies in Group A (IBS®; Table 1) and 3 (6.1%) in Group B (Versapoint®; Table 2).

In Group A, the median size of the myomas was 20 mm (range 8–30 mm; Table 1) and the median size was 20 mm (range 10–20 mm) in Group B (Table 2). In Group A, one myoma was G0, five were G1 and six were G2, whereas all myomas in Group B were G1 (Table 6). The median total operating time in Group A was 23.25 min (range 6.5–66 min) and 8 min (range 8–13 min) in Group B ($p=0.1392$) (Table 5). The median resection time in Group A was 15.08 min (range 0.9–50 min) and 5 min (range 2.5–9 min) in Group B ($p=0.1333$) (Table 5).

A mean of 9,925 ml of fluid was used in Group A compared with 1,566.6 ml in Group B ($p=0.0208$) (Table 5). The mean fluid deficit was 666.66 ml in Group A compared with 233.33 ml in Group B ($p=0.1596$) (Table 5).

In Group A, seven procedures were single step, two required a second operation and only the intra cavitary portion of the myoma was removed in three cases without need for a second treatment, whereas in Group B, all procedures were completed in one step (Table 6).

Apart from the total amount of fluid used, there was no statistically significant difference in favour of either of the two techniques, despite a disproportion between the number cases performed with the IBS® compared with those that underwent conventional bipolar resection (12 with the IBS® vs. three cases with Versapoint®). In addition, the longer operating and resection times, higher volumes of fluid used and the fluid deficit could be explained by the different sizes of the myomas treated: up to 3 cm in the IBS group compared with 2 cm or smaller in the bipolar group.

When myomas of 2 cm or less were considered and divided into two subgroups, Group A1 for the IBS® and Group B1 for conventional bipolar resection group (Versapoint®), the median size of the myomas in Group A1 was 15 mm (range 10–20 mm) and 20 mm (range 10–20 mm) in Group B1 (Table 8). Also, four myomas were G1 and three were G2 in Group A1 whereas three myomas were G1 in Group B1 (Table 8). The median total operating time in the

Table 6 Myoma resection by myoma type, according ESGE guidelines, and number of procedures

	Group A(IBS®)	Group B (Versapoint®)
	Myoma type	
G0	1	0
G1	5	3
G2	6	0
	Number of procedures (%)	
Single step	7 (58.3)	3 (100)
Two steps	2 (16.6)	0 (0)
Residual myoma	3 (25)	0 (0)

Table 7 Myoma resection, ≤20 mm

Myoma resection	Sub Group A1 (IBS®)				Sub Group B1 (Versapoint®)				*p* Value
	Median	Range	Mean	DS	Median	Range	Mean	DS	
Dilatation (min)	1	1–1.5	1.2	0.245	1.5	1–12	4.83	5.66	0.1009
Operating time (min)	8	6.5–13	9.1	2.49	8	8–13	9.66	2.34	0.7493
Resection time (min)	5	0.9–9	5.34	2.92	5	2.5–9	5.34	2.7	1.0000
Fluid used (ml)	2700	2000–5000	2940	1101.9	1700	1000–2000	1566.6	418.99	0.2236
Fluid deficit (ml)	300	200–400	300	89.44	200	200–300	233.33	47.140	0.2859

Group A1 was 8 min (range 6.5–13 min) and 8 min (range 8–13 min) in Group B1 ($p=0.7493$) (Table 7). The median resection time in Group A1 was 5 min (range 0.9–9 min) and 5 min (range 2.5–9 min) in Group B1 ($p=1.0000$) (Table 7). In Group A1, we used a mean of 2,940 ml of fluid compared with 1,566.6 ml in Group B1 ($p=0.2236$) (Table 7). The mean fluid deficit was 300 ml in Group A1 compared with 233.33 ml in Group B1 ($p=0.2859$) (Table 7). All procedures in the two subgroups were completed in a single step (Table 8). There was no statistically significant difference in favour of either method.

Polyp and myoma resection

We performed five (10%) polypectomies plus myomectomies (contemporary resection of endometrial polyps with submucosal myomas) in Group A (IBS®; Table 1) and two (4.1%) in Group B (Versapoint®; Table 2). The median size of the polyps in Group A was 12.5 mm (range 10–40 mm) (Table 1) and 8 mm (range 6–15 mm) in Group B (Table 2).

The median size of the myomas was 20 mm (range 10–25 mm) in Group A (Table 1) and 8 mm (range 8–8 mm) in Group B (Table 2). Three myomas in Group A

Table 8 Demographic and clinical data for patients with myomas ≤20 mm

	Sub Group A1 (IBS®)	Sub Group B1 (Versapoint®)
n (%)	7 (14)	3 (6.1)
Size (mm)[a]	15 (10–20) 15 (4.47)	20 (10–20) 17.5 (4.33)
Age (years)[b]	51 (44–74)	48 (43–52)
Parity (%)		
Nulliparous	3 (42.8)	1 (33.3)
Multiparous	4 (57.2)	2 (66.6)
Menopause (%)	2 (28.6)	1 (33.3)
Symptoms (%)		
None	1 (14.3)	2 (66.6)
Menorrhagia	4 (57.2)	1 (33.3)
Anaemia	1 (14.3)	1 (33.3)
Post Menop. AUB	1 (14.3)	0 (0)
Pelvic Pain	0 (0)	0 (0)
Infertility	0 (0)	0 (0)
	Myomas' Type	
G0	0	0
G1	4	3
G2	3	0
	Number of procedures (%)	
Single step	7 (100)	3 (100)
Two steps	(0)	0 (0)
Residual Myoma	(0)	0 (0)
Complications (%)	(0)	0 (0)

[a] Median (range); mean (SD)

[b] Median (range)

Table 9 Polyp + myoma resection

Polyps + myoma resection	Group A (IBS®)				Group B (Versapoint®)				*p* Value
	Median	Range	Mean	DS	Median	Range	Mean	DS	
Dilatation (min)	1.5	1–2	1.6	0.37	2	2–2	2	0	0.2082
Operating time (min)	17	5.33–32	19.86	9.93	12	11–13	12	1	0.3388
Polyp res. time (min)	0.5	0.16–1	0.55	0.27	4	3–5	4	1	0.0000
Myoma res. time (min)	6.89	0.16–22	8.93	8.25	5	5–5	5	0	0.5460
Fluid used (ml)	5200	1500–7500	5100	2038.6	1800	1600–2000	1800	200	0.0831
Fluid deficit (ml)	500	200–100	500	275.68	150	100–200	150	50	0.1519

were G0, one was G1 and one was G2, whereas all myomas were G1 in Group B (Table 10). The median total operating time in Group A was 17 min (range 5.33–32 min) and 12 min (range 11–13 min) in Group B (p= 0.3388) (Table 9). The median resection time for polyps in Group A was 0.5 min (range 0.16–1 min) and 4 min (range 3–5 min) in Group B (p=0.0000) (Table 9). The median resection time for myomas in Group A was 6.89 min (range 0.16–22 min) and 5 min (range 5–5 min) in Group B (p= 0.5460; Table 9).

In Group A, a mean of 5,200 ml of fluid was used compared with 1,800 ml in Group B (p=0.0831) (Table 9). The mean fluid deficit was 500 ml in Group A compared with 150 ml in Group B (p=0.1519) (Table 9). All procedures in both groups were completed in one step (Table 10). IBS® showed a clear superiority in terms of polyp resection time, but the time difference was not statistically significant for myomectomy.

Endometrial ablation

We performed two (4%) endometrial ablations in Group A (IBS®; Table 1) and two (4.1%) in Group B (Versapoint®; Table 2). The median total operating time in Group A was 11.5 min (range 10–13 min) and 24.5 min (range 24–25 min) in Group B (p=0.0073) (Table 11). The median resection time in Group A was 7.5 min (range 5–10 min) and 17.5 min (range 15–20 min) in Group B (p= 0.0572) (Table 11). In Group A, a mean of 1,750 ml of fluid was used compared with 2,750 ml in Group B (p= 0.2473) (Table 11). The mean fluid deficit was 200 ml in Group A compared with150 ml in Group B (p=0.2929) (Table 11). The operating time was shorter with IBS, probably because the tissue chips were removed at the time of resection.

Table 10 Polyp + myoma resection by myoma type, according ESGE guidelines, and number of procedures

	Group A (IBS®)	Group B (Versapoint®)
	Myoma type	
G0	3	0
G1	1	2
G2	1	0
	Number of procedures (%)	
Single step	5 (100)	2 (100)
Two steps	0 (0)	0 (0)
Residual Myoma	0 (0)	0 (0)

Complications

Two perforations were reported during the dilatation process in Group B (Versapoint®). In Group A, no complications were reported. Both lesions were in the fundus. The first was a complete perforation, and the second was a 5- to 10-mm false root. In the first case, the procedure was immediately stopped with no further complications for the patient. In the second case, the procedure was safely completed with complete removal of the polyp without problems for the woman. The mean complication rate in Group A was 4.76% vs. 0% in Group B. Considering that only two complications occurred during the dilatation process in Group B (Versapoint®) and no complications were reported in Group A (IBS®), it is suggested that reduction of dilatation diameter could improve patient safety.

Learning curve

Polyp resection was used to evaluate the learning curve because the number of cases was sufficiently large to reach a conclusion. We analyzed 12 cases performed by an expert surgeon and compared them with 11 cases performed by a resident in Group B (Versapoint®) and 12 cases performed by an expert surgeon and 9 cases performed by a resident in Group A (IBS®) (Table 12).

Table 11 Endometrial ablation

Endometrial ablation	Group A (IBS®)				Group B (Versapoint®)				*p* Value
	Median	Range	Mean	DS	Median	Range	Mean	DS	
Dilatation (min)	1.5	1.5–1.5	1.5	0	1.75	1–2.5	1.75	0.75	0.6838
Operating Time (min)	11.5	10–13	11.5	1.5	24.5	24–25	24.5	0.5	0.0073
Resection Time (min)	7.5	5–10	7.5	2.5	17.5	15–20	17.5	2.5	0.0572
Fluid used (ml)	1750	1000–2500	1750	750	2750	2300–3200	2750	450	0.2473
Fluid deficit (ml)	200	200–200	200	0	150	100–200	150	50	0.2929

In Group B, the median size of the polyps removed by the expert surgeon was 10 mm (range, 8–40 mm; mean, 15.7 mm; DS, 8.4 mm) whereas the median size of polyps removed by the resident was 15 mm (range, 7–55 mm; mean, 17.5 mm; DS, 12.7 mm) (Table 13). The median operating time for the expert surgeon was 8 min (range 5–16 min), whereas the median operating time for the resident was 14 min (range 10–20 min) ($p=0.0010$) (Table 13). The median resection time for the expert surgeon was 3.5 min (range 1–10.5 min), whereas the median resection time for the resident was 9 min (range 0.5–13.5 min) ($p=0.0371$) (Table 13).

In Group A, the median size of the polyps removed by the expert surgeon was 12.5 mm (range, 8–30 mm; mean, 15.1 mm; DS, 7.23 mm), whereas median the size of the polyps removed by the resident was 20 mm (range, 10–40 mm; mean, 21.4 mm; DS, 10.2 mm) (Table 14). The median operating time for the expert surgeon was 3.5 min (range, 2–8 min), whereas the median operating time for the resident was 5 min (range, 3–12 min) ($p=0.2167$) (Table 14). The median resection time for the expert surgeon was 1.5 min (range, 0.2–5.5 min) whereas the median resection time for the resident was 2.25 min (range, 0.5–10 min) ($p=0.2446$) (Table 14).

There was a statistically significant difference in both the operating and resection times of cases performed with conventional bipolar resectoscope, but no statistically significant difference in the cases performed with the IBS® between the expert surgeon and the resident, suggesting that the experience of the surgeon was most important when the conventional bipolar resectoscope was used. A higher number of procedures are necessary with the resectoscope compared with the IBS® for the surgeon to gain the same level of skill. In addition, larger-sized polyps were removed by the resident in the IBS® group than those removed by the expert surgeon, indicating that the new technique is much easier to use, even in more complicated cases.

Table 12 Number of polyp resection cases: expert surgeon vs. resident

	Expert surgeon	Resident
Group A	12	9
Group B	12	11

Discussion and conclusion

This study shows that major hysteroscopic surgical procedures can be performed with the IBS® in a very easy, fast, precise and safe way. Especially for the treatment of large polyps and myomas up to 2 cm, it has several well-described advantages. As discussed by Emanuel et al., the diameter of an intrauterine pathology is strongly related to the operation time and to the complication rate [19]. Considering the volume calculation of the tissue to remove by the formula $4/3\pi r^3$, we need 8.4 min to resect 2 cm, 28.2 min for 3 cm and 67.0 min for 4 cm at a resection speed of 0.5 cm^3/min for a conventional monopolar loop. The bipolar loops are smaller and resection time should increase accordingly. In this resection time, we do not calculate the time necessary to remove the chips, a major hurdle in resection of large myomas. The first generation bipolar resectoscopes loop is even smaller than the conventional monopolar or the second generation of bipolar resectoscope resulting in a challenging situation for all pathology over 2 cm. The IBS® seems to be much faster than the Versapoint®. Probably, this is due to the fact that the continuous cutting capacity performed always under direct visual control, with immediate removal of the chips at time of resection, results in a more efficient reduction of the tumour volume. Differences in both operating and resection times were statistically significant in favour of the IBS®. No bleeding or major complication was observed in the IBS® group. Not only operation time but also total fluid loss seems to be better with the IBS® system. In fact, this study demonstrates that using the IBS®for myoma resection,

Table 13 Group B (Versapoint®)—polyp resection, expert surgeon vs. resident

Group B	Expert surgeon				Resident				*p* Value
	Median	Range	Mean	DS	Median	Range	Mean	DS	
Size (mm)	10	8–40	15.7	8.4	15	7–55	17.5	12.7	–
Operation Time (min)	8	5–16	9	3.59	14	10–20	15.4	3.6	0.0010
Resection Time (min)	3.5	1–10.5	4.37	2.85	9	0.5 –13.5	7.87	4.08	0.0371

the median total operating time was 23.25 min (range 6.5–66 min) with a medium resection time of 15.08 min (range 0.9–50 min). The fluid deficit was limited to 666.66 ml despite a mean of total fluid used of 9,925 ml. We could explain the better fluid deficit with a very limited bleeding we had with the use of the IBS®. While this has been proven for polyp resection, for myoma, the current study cannot make a comparative statement. Unfortunately, not enough myoma resections where allocated into the resectoscope group, and the larger myomas (>2 cm) were all treated by the IBS®. It is clear that due to the different consistency of myomas and their possible intramural location, the results of polypectomy cannot be extrapolated to the myoma resection. Anyway, all types of submucosal myomas, including G2 myomas that were excluded from similar studies with morcellators, were included in our study [14]. In addition, the main advantage of the IBS® was that the myomas were effectively enucleated from their fovea and the intramural site of insertion of the myoma was removed (Fig. 3). The surrounding healthy endometrium was avoided without any thermal injury occurring compared with the less precise behaviour of conventional resectoscopy. No coagulation was needed, and there were no excess bleeding problems. We bear in mind that myoma surgery with the resectoscope has reported complications like, major bleeding, fluid overload, two-step surgery, but even more significant postoperative adhesion formation. Deans R and Abbott J reported a 31.3% adhesion formation in a single myoma and 45.5% in multiple myoma removal [20]. Especially for the treatment of large and multiple myomas, an alternative to the conventional resectoscope could be interesting and in benefit of the patient. For very large myomas, we will possibly need to improve our blade system because the IBS® had some drawbacks also here. One of the most important finding in this study is the difference in the learning curves between the IBS® and the resectoscope. The IBS® was statistically significantly easier to learn than the resectoscope. This improvement opens a window for very common gynaecological interventions like polypectomy into the hands of less experienced hysteroscopist. Compared to other blind intrauterine applications, the IBS® has the major advantage that surgeons always perform the procedure under visual control, with automated and easy removal of tissue chips. As it has been proven in randomised control trials [21], reducing the diameter of the instrument improves the accessibility of ambulatory diagnostic hysteroscopy; the IBS® broadens the accessibility in major hysteroscopic operations. In addition, there were no complications reported in the IBS group, even if both polyps and myomas were larger than in the Versapoint ® group. The complication rate in the Versapoint ® group, although it was only related to the cervical dilatation, indicates that smaller is probably easier. Although further modifications of the IBS® will be necessary, at present, this technique has very interesting and promising features for future operative hysteroscopy, making the procedure faster, easier and with significantly fewer major complications. In conclusion, we can say that the IBS® is a very promising new instrument for the removal of polyps and myomas. This smaller instrument is easier to apply than the conventional resectoscope. For the treatment of large polyps, the IBS® seems to be superior as it works faster and at a lower risk

Table 14 Group A (IBS®)—Polyp resection, expert surgeon vs. resident

Group A	Expert surgeon				Resident				*p* Value
	Median	Range	Mean	DS	Median	Range	Mean	DS	
Size (mm)	12.5	8–30	15.1	7.23	20	10–40	21.4	10.2	–
Operation Time (min)	3.5	2–8	4.15	1.93	5	3–12	5.8	2.9	0.2167
Resection Time (min)	1.5	0.2–5.5	1.51	1.63	2.25	0.5–10	3.1	3.17	0.2446

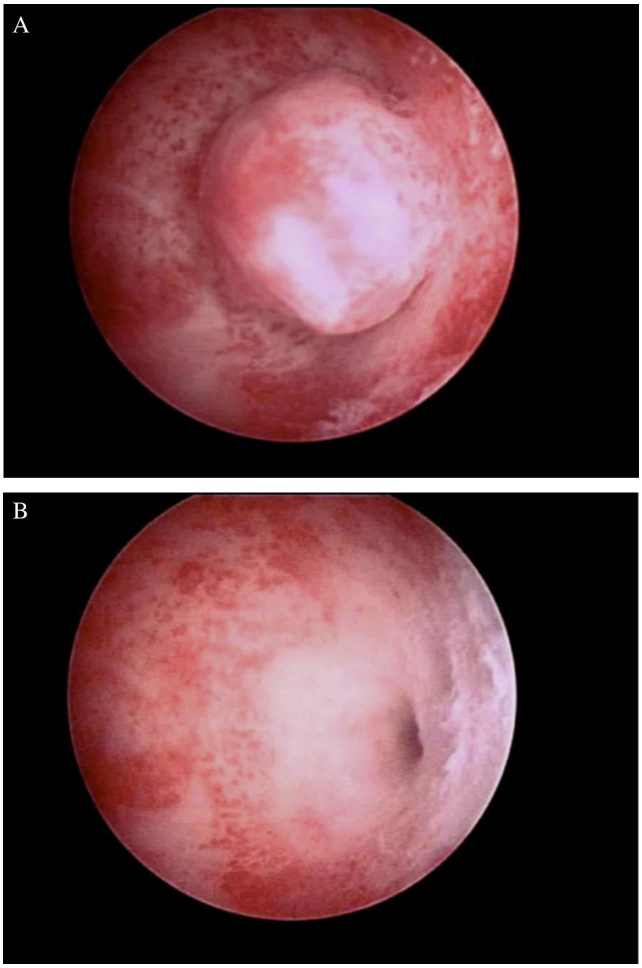

Fig. 3 Integrated Bigatti Shaver (IBS®) resection of a 2-cm G0 submucosal myoma. (**a**) Before and (**b**) after the IBS® treatment. The myoma was completely removed without damaging the surrounding healthy endometrium

profile. Very interesting is that the IBS® is able to resect also myomatous tissue, making this a very promising alternative to the resectoscope. In fact, surgery is not interrupted by tissue chips removal making total operating time shorter. It is further postulated that resection of myomas without the use of electrical current could significantly reduce the postoperative adhaesion formation and that the IBS® should preferentially be used in younger women in their reproductive age. Further studies will have to be performed to tailor the indication potential of this exiting approach.

Acknowledgment This paper is dedicated to my parents for their support throughout the years. Special thanks to Karl Storz GmbH & Co employees, Storz Italia for technical support and in particular, to Dr. H.C. Mult. Sybill Storz and Helmut Wehrstein, who believed in this project from the beginning. Special thanks go to Rudi Campo.

Declaration of interest Dr. Giuseppe Bigatti was involved in the concept and design of the IBS® with Karl Storz GmbH of Tuttlingen but received no financial compensation for this study.

References

1. Di Spezio SA, Mazzon I, Bramante S, Bettocchi S, Bifulco G, Guida M, Nappi C (2008) Hysteroscopic myomectomy: a comprehensive review of surgical techniques. Hum Reprod Updat 14(2):101–119
2. Oona Hamerlynck TW, Dietz V, Schoot BC (2011) Clinical implementation of the Hysteroscopic morcellator for removal of intrauterine myomas and polyps. A retrospective descriptive study. Gynecol Surg 8:193–196
3. Associazione Italiana di Endourologia-Da Lichtleiter ai Nostri Giorni-Segreteria Via Porrettana 76/2-40033-Casalecchio di Reno (Bo) www.ieanet.it/italiano/endourologia.php
4. Witz CA, Silverberg KM, Burns WN, Schenken RS, Olive DL (1993) Complications associated with absorption of hysteroscopic fluid media. Fertil Steril 60(5):745–756
5. Mencaglia L, Lugo E, Consigli S, Barbosa C (2009) Bipolar resectoscope: the future perspective of hysteroscopic surgery. Gynecol Surg 6(1):15–20
6. Yong Lee G, In Han J, Joo Heo H (2009) Severe Hypocalcemia caused by absorption of sorbitol - mannitol during Hysteroscopy. J Korean Med 24:532–534
7. Shaafer M, Von Ungern-Sternberg BS, Wight E, Schneider MC (2005) Isotonic fluid absorption during Hysteroscopy resulting in severe Hyperchloremic Acidosis. Anesthesiology 103:203–204
8. Van Kruchten PM, Vermelis JM, Herold I, Van Zundert AA (2010) Hypotonic and isotonic fluid overload as a complication of hysteroscopic procedures: two case reports. Minerva Anestesiol 76(5):373–377
9. Pasini A, Belloni C (2001) Intraoperative complications of 697 consecutive operative hysteroscopies. Minerva Ginecol 53(1):13–20
10. Sutton CJG, Mc Donald R (1993) Endometrial Resection. In: Lewis BV, Magos AL (eds) Endometrial ablation. Churchill Livingstone, Edinburgh, pp 131–140
11. Odell R (1993) Eletrosurgery. In: Sutton CJG, Diamond MP (eds) Endoscopic Surgery for Gynaecology. Saunders, London, pp 51–59
12. Jansen FW, Vredevoogd CB, Van Ulzen K, Hermans J, Trimbos JB, Trimbos-Kemper TC (2000) Complication of hysteroscopy: a prospective, multicenter study. Obstet Gynecol 96(2):266–270
13. Emanuel MH, Wamsteker K (2005) The intrauterine morcellator: a new hysteroscopic operating technique to remove intrauterine polyps and myomas. J Minim Invasive Gynecol 12(1):65–66
14. Van Dongen H et al (2008) Hysteroscopic morcellator for removal of intrauterine polyps and myomas: a randomized controlled pilot study among residents in training. J Minim Invasive Gynecol 15:466–471
15. Bigatti G (2011) IBS® Integrated Bigatti Shaver, an alternative approach to operative hysteroscopy. Gynecol Surg 8(2):187
16. Instruction for Use Versapoint. Official Notification 2001. Gynecare. A division of Ethicon. www.ethicon.com
17. Wamsteker K, Emanuel MH, de Kruif JH (1993) Transcervical hysteroscopic resection of submucous fibroids for abnormal uterine bleeding: result regarding the degree of intramural extension. Obstet Gynecol 82:736–740
18. Salim R, Lee C, Davies A, Jolaoso B, Ofuasia E, Jurkovic D (2005) A comparative study of three-dimensional saline infusion sonohysterography and diagnostic hysteroscopy for the classification of submucous fibroids. Hum Reprod 20:253–257
19. Emanuel MH, Hart A, Wamsteker K, Lammes F (1997) An analysis of fluid loss during transcervical resection of submucous myomas. Fertil Steril 68(5):881–886
20. Deans R, Abbott J (2010) Review of intrauterine adhesions. J Minim Invasive Gynecol 17(5):555–569
21. Campo R, Molinas CR, Rombauts L, Mestdagh G, Lauwers M, Braekmans P, Brosens I, Van Belle Y, Gordts S (2005) Prospective multicentre randomized controlled trial to evaluate factors influencing the success rate of office diagnostic hysteroscopy. Hum Reprod 20(1):258–263