Gynecol Surg (2014) 11:9–18
DOI 10.1007/s10397-013-0827-z

ORIGINAL ARTICLE

# Hysteroscopic myomectomy with the IBS® Integrated Bigatti Shaver versus conventional bipolar resectoscope: a retrospective comparative study

**G. Bigatti · S. Franchetti · M. Rosales · A. Baglioni · S. Bianchi**

Received: 2 September 2013 / Accepted: 18 December 2013 / Published online: 9 January 2014


**Abstract** From June 2011 to June 2013, all hysteroscopic myoma resections at the Ospedale San Giuseppe of Milan were performed using either the IBS® or the Versapoint® bipolar resectoscope. Dilatation time of the cervical canal, resection time, fluid balance, and complete single-stage removal of the myoma have been studied. The outcome was stratified for groups of myomas larger and smaller than 3 cm. Seventy-six myomectomies were performed with the IBS® and 51 with the Versapoint®. Both groups had a similar distribution of difficult cases like G2 and larger than 3 cm myomas. The results show no difference in terms of cervical dilatation, resection time, and fluid deficit between the two groups, but, for myomas less than 3 cm and G2 myomas, the IBS® has been able to treat respectively 93.5 % ($p$=0.3753) and 62.5 % ($p$=0.5491) of cases in a single step procedure. The overall number of necessary second procedures has been statistically significantly less in the IBS® Group than in the Versapoint® Group ($p$=0.0067). Although no significative difference in terms of time of resection, the IBS® has proven to be able to approach all kind of submucosal myomas in a single-step procedure and in a very precise and easy way. The IBS® can be considered a valid alternative to the conventional resectoscope.

**Keywords** IBS® · Hysteroscopy · Resectoscopy · Shaver · Myomectomy

G. Bigatti (✉) · S. Franchetti · M. Rosales · A. Baglioni
U.O. di Ostetricia e Ginecologia, Ospedale Classificato San Giuseppe Via San Vittore, 12, 20123 Milan, Italy
e-mail: g.big@tiscalinet.it

S. Bianchi
Direttore dell'Unità Opertiva di Ostetricia e Ginecologia Ospedale Classificato San Giuseppe Via San Vittore, Università degli Studi di Milano, 12, 20123 Milan, Italy

## Background

The incidence of submucosal myomas in women during their reproductive age ranges from 20 to 25 % [1–3].

Most of submucosal myomas may induce severe clinical symptoms such as abnormal uterine bleeding and menorrhagia with an incidence ranging from 60 to 84 % [3], dysmenorrehea , and infertility [1, 2, 4, 5]. The hysteroscopic treatment of this pathology has shown to be effective in relieving symptoms and in improving on the patients' fertility [6].

Presently, the double-flow bipolar resectoscope is considered the gold standard technique to perform hysteroscopical myomectomy [7, 8]. Unfortunately, the use of a bipolar resectoscope does not prevent overload syndrome and water intoxication [9]. The use of isotonic solutions like 0.9 % sodium chloride prevents dilution hyponatremia and hypocalcaemia [10], but the risk of fluid overload is still present. In addition, the massive absorption of normal saline solution can result in severe hyperchloremic metabolic acidosis and dilution coagulopathy that must be resolved with diuretic therapy [11, 12]. The use of high-frequency current during resection may lead to complications such as uterine perforation with bowel injury and internal and external burns caused by the uncontrolled leakage of current [13–15]. The most important limit of bipolar technique is that, during resection of large myomas, the tissue chips that remain inside the uterine cavity impair the surgeon's visual field, thus increasing the risk of perforation. Tissue pieces must be removed from the uterine cavity in order to complete the procedure under visual control. This makes the operation tiring and increases the overall resection time, thus 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 conventional resectoscope's large diameter [16].

Due to the above-mentioned features, the Versapoint® resectoscopy has a long learning curve, explaining why, even today, only a few surgeons perform operative hysteroscopy [17, 18]. By removing the tissue chips at the same time as their resection, the Integrated Bigatti Shaver (IBS®) has shown to improve on results of conventional resectoscopy, reducing the complications rate and improving the learning curve time [19]. Our previous study about polypectomy had shown that both resection time and fluid deficit were statistically better when using the IBS®, also because of a much faster learning curve [20]. Unfortunately, randomization has been related only to major pathologies groups and not to each single minor pathological group. Therefore, since myomectomies were unequally randomized, a comparative analysis was not possible. Our study shows that the IBS® is much superior to the Versapoint® in the polypectomy cases, but it is not indicative as to myomectomy.

The present study has been designed to compare 76 myomectomies performed with the IBS® with 51 with the Versapoint®, in order to evaluate whether this new technique offers real advantages.

## Materials and methods

### Equipment

We have performed all operations using either the IBS® or the conventional bipolar resectoscope (Versapoint® by Gynecare). The choice between one of the two devices was depending on the availability of the IBS®. We could use the IBS® for a 3-month period continuously with a 3-month pause during which the instrument had to be tested by the producing company. During this period of time, we have used only the IBS®. The reseptoscope was alternatively used during the pause period, when the IBS® was not available. The IBS® is made of 90° angulated 6° optics (Karl Storz GmbH of Tuttlingen) provided with a continuous flow sheath and an extra operative channel, into which a rigid shaving system has been inserted (Fig. 1). The continuous flow sheath is connected to a peristaltic pump (Endomat® Karl Storz GmbH of Tuttlingen) to maintain optimal distension and visualization inside the uterine cavity. Two separate stopcocks regulate inflow and outflow. The diameter of the outer sheath is 24 Fr (8 mm). The rigid shaving system consists of two hollow reusable metal tubes fitting into each other. The inner tube rotates within the outer tube, and it is connected to a handheld (Drill cut-x® Karl Storz GmbH of Tuttlingen) motor drive unit (Unidrive® S III Karl Storz GmbH of Tuttlingen) and to a roller pump (Endomat® LC Karl Storz GmbH of Tuttlingen) controlled by a foot pedal (Fig. 2). These two latter units are connected to each other and synchronized. The foot pedal activates simultaneously the shaver tip and the roller pump

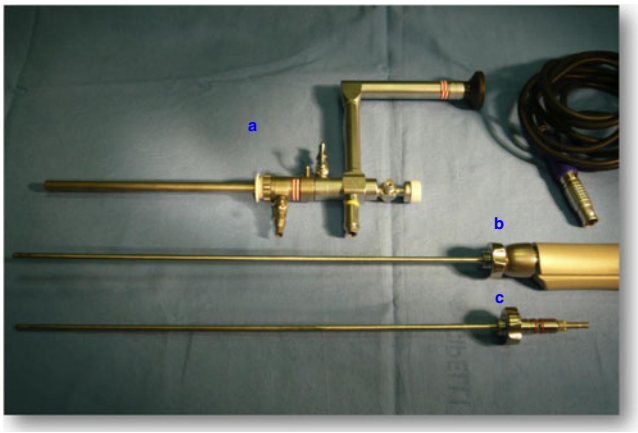


**Fig. 1** Integrated Bigatti Shaver (IBS®). **a** 90° angulated 6° optics (Karl Storz GmbH of Tuttlingen) with a double flow sheath and an extra channel for the insertion of a **b** Rigid shaving system, **c** reusable blade

to maintain a continuous suction power on the window tip during the procedure. The first pedal switch activates the roller pump in order to aspirate the pathological site into the window, while the second switch activates the engine of the blades, in order to dissect the pathological tissue. The IBS®


**Fig. 2** Integrated Bigatti Shaver (IBS®): **a** Endomat® LC, **b** Unidrive® S III, **c** foot pedal (Karl Storz GmbH of Tuttlingen)

shaver tip is specifically designed in order to be aggressive for any kind of tissue. The inner rotating tube has a double window blade provided with a row of very sharp teeth. At the edge of the outer tube, there is a 25 $mm^2$ large window provided with teeth, too.

We have used two different shapes of blade: n°6=25 $mm^2$ flute beak shape and n.7=25 $mm^2$ elliptically open, similar to shark jaws (Fig. 3).

A power up to 5,000 oscillating rotation power per minute and a 200 to 1,000 ml/min aspiration flow are offered by these units. After dilatation of the uterine cervix internal ostium up to Hegar number 8.5, the panoramic optics (with the in- and outflow channels connected to the Endomat® pump) is inserted into the uterine cavity. A normal isotonic solution, like 0.9 % sodium chloride, is used for the irrigation. The maximum flow setting is 450 ml/min with a <95 mmHg intrauterine pressure. After visualizing the pathological site, the rigid shaving system (connected to the motor drive unit and to the roller pump) is inserted into the operative channel, and the procedure can start. The aspiration is activated only by pressing the roller pump pedal, in order to prevent the massive outflow-related collapse of uterine cavity. The rotating and oscillating movements of the shaving system inner blade cut the tissue. The resected tissue is then aspirated directly into a glass bottle connected to the roller pump (Endomat LC® Karl Storz GMBH of Tuttlingen), in order to be used as histologycal specimens.

Correct fluid balance is calculated by checking the total amount of the fluid aspirated by the Endomat® in addition to the fluid aspirated by the shaving system connected roller pump and to the fluid collected in an underlying graduated plastic bag.

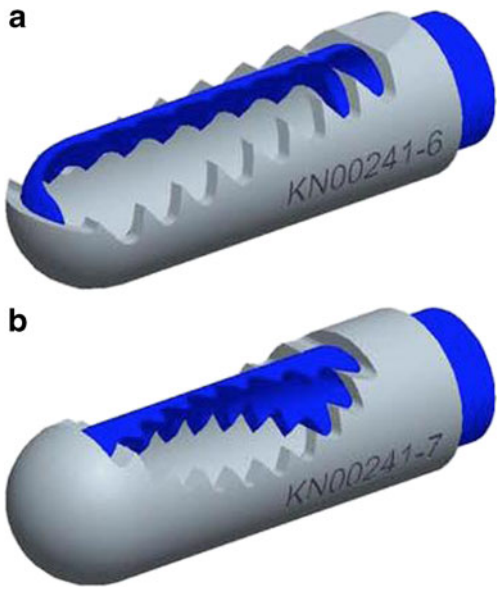


**Fig. 3** Integrated Bigatti Shaver (IBS®) blades: **a** flute beak shape **b** shark jaws shape

The conventional bipolar resectoscope (Versapoint® by Gynecare) consists of a 4-mm wire loop electrode mounted on a working element with hand piece and of a 12° operative optics endoscope. The loop electrode is connected to a Versapoint® unit, automatically supplying a 170 and 80 W bipolar current respectively for cutting and coagulation. The Versapoint® unit is set to VC1 [21]. The operative endoscope has a continuous flow sheath with separate in- and outflow stopcocks connected to a peristaltic pump (Endomat® Karl Storz GmbH of Tuttlingen), to maintain optimal distension and visibility. The continuous flow sheath is rotation-free and has a 27 Fr (9 mm) external diameter.

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

## Source population

The source population includes 238 women undergoing operative hysteroscopy with the IBS® versus 230 women with the Versapoint® over a 2-year period, from June 2011 to June 2013, in our center: Ospedale San Giuseppe of Milan—Italy, a University teaching Hospital. With the IBS®, we have performed 76 myomectomies, 138 polypectomies, 10 mixed pathologies (myomectomies+polypectomies+sinechiolysis), 11 endometrial ablations, and 3 septum resections.

With the Versapoint®, we have performed 51 myomectomies; 157 polypectomies, 6 mixed pathologies (myomectomies+polypectomies+sinechiolysis), 15 endometrial ablations, and 1 septum resection (Table 1).

Oncological cases were excluded from our trial.

## Study population

The study population has been selected from the source population (Table 2). Seventy-six patients, of whom 66 (86.8 %) patients with 1 myoma and 10 patients (13.2 %) with more than 1 myoma, undergoing a myomectomy with the IBS® have been included in Group A whereas 51 women, of whom 46 (90.2 %) patients with 1 myoma and 5 patients (9.8 %) with more than 1 myoma, undergoing a myomectomy with the Versapoint® have been included in Group B.

In Group A, a total amount of 88 myomas have been treated, of which 28 (31.8 %) were G0 type myomas, 28 (31.8 %) G1 type, and 32 (36.4 %) G2 type.

**Table 1** Source population: IBS® and Versapoint® personal series of a 2-year period, June 2011–June 2013, Ospedale San Giuseppe, Milano, Italy

| IBS® and Versapoint® personal series June 2011–June 2013 | | |
|---|---|---|
| Indication | IBS® N° of cases | Versapoint® N° of cases |
| Myomectomies | 76 | 51 |
| • G0 | 28 | 18 |
| • G1 | 28 | 18 |
| • G2 | 32 | 20 |
| Polypectomies | 138 | 157 |
| Myomectomies+polypectomies+ sinechiolysis | 10 | 6 |
| Endometrial ablation | 11 | 15 |
| Septum resection | 3 | 1 |
| Total | 238 | 230 |

In Group B, a total amount of 56 myomas have been treated, of which 18 (32.1 %) were G0 type myomas, 18 (32.1 %) G1 type, and 20 (35.8 %) G2 type.

Sixty-one (69.3 %) IBS®-treated myomas with a diameter less than 3 cm have been included in Subgroup A1 and 27 (30.7 %) IBS®-treated myomas with a diameter larger than 3 cm have been included in Subgroup A2.

Thirty-five (62.5 %) Versapoint®-treated myomas with a diameter less than 3 cm have been included in Subgroup B1, and 21 (37.5 %) Versapoint®-treated myomas with a diameter larger than 3 cmhave been included in Subgroup B2.

Myomas with a diameter larger than 5 cm, classified according to the Wamsteker classification [22, 23], have been excluded from this study. Both groups, A and B, were similar as to patients' age, parity, and symptoms (Tables 3, 4, and 5).

**Table 2** Study population: N° of myomas per patient, total N° of myomas per group, type, and size of myomas at myomectomy in Group A (IBS®) and in Group B (Versapoint®) during a 2-year period June 2011–June 2013

| N° Myomectomies: June 2011–June 2013 | | |
|---|---|---|
| | Group A IBS® (*n*=76) | Group B Versapoint® (*n*=51) |
| N° of myomas per patient | | |
| 1 | 66 (86.8 %) | 46 (90.2 %) |
| >1 | 10 (13.2 %) | 5 (9.8 %) |
| N° total of myomas | 88 | 56 |
| Type | | |
| G0 | 28/88 (31.8 %) | 18/56 (32.1 %) |
| G1 | 28/88 (31.8 %) | 18/56 (32.1 %) |
| G2 | 32/88 (36.4 %) | 20/56 (35.8 %) |
| Size (mm) | | |
| <30 | 61/88 (69.3 %) Group A1 | 35/56 (62.5 %) Group B1 |
| >=30 | 27/88 (30.7 %) Group A2 | 21/56 (37.5 %) Group B2 |

## Measurement methods

All patients have undergone a general or a regional anaesthesia, and a standard gynaecological set up has been adopted in the operating room. Three skilled surgeons performed all the operations.

The myoma size, type, and position were assessed by vaginal ultrasound and confirmed by diagnostic hysteroscopy.

The time of the cervical canal dilatation, resection time, and the fluid balance have been recorded. The resection time has been measured from the moment the active shaver tip or the resectoscope loop was visible inside the uterine cavity, till resection completion.

The number of second step procedures and device conversions in the two groups has also been evaluated.

Second-step procedures have been referred to those cases, in which, given the fluid deficit or the time limit of the operation, we have had to plan a second procedure, 2 months later, in order to completely remove the myoma. Limits have been referred to a 2,000 ml fluid deficit and to an hour time duration for the whole hysteroscopic procedure.

For conversions, we have considered those operations that started with the IBS® had to be completed with the Versapoint®, for two reasons. The first occurred when the myoma consistency combined with the size was preventing its fast resection with the IBS® [24], the second when, upon reaching of the fluid limit, has made it necessary to remove a

**Table 3** Demographic characteristics of the two groups of patients: Group A (IBS®) and Group B (Versapoint®)

| | Group A IBS® (*n*=76) | Group B Versapoint® (*n*=51) | *P* value |
|---|---|---|---|
| Age | 47.55 | 48.04 | 0.8011[a] |
| Premenopausal age (%) | 42 (55.3) | 29 (56.9) | 0.9966 [b] |
| Postmenopausal age (%) | 34 (44.7) | 22 (43.1) | |
| Symptoms | | | |
| None | 38 | 27 | 0.985806 [b] |
| Menorrhagia | 18 | 12 | |
| Pelvic pain | 10 | 6 | |
| Infertility | 10 | 6 | |
| Parity | 0.84 | 0.94 | 0.5551 [a] |
| Myoma size (mm) | 23.12 | 25.18 | 0.3567 [a] |

Normally distributed variables are summarized as mean (95 % confidence interval, SD); non-normally distributed variables are given as median and interquartile range or number (%)

[a] T Student test

[b] Yates corrected chi-square test

**Table 4** Group A (IBS®) demographic characteristics, type, and size of myomas, and associated hysteroscopic findings and symptoms

| No. of patients | 76 |
|---|---|
| No. of myomas | 88 |
| Age, mean±SD (95 % CI), years | 47.3±10.1 (43.7; 50.9) |
| Parity, no. (%) | |
| Nulliparous | 36 (47.4) |
| Pluriparous | 40(52.6) |
| Submucous myomas, no. (%) | |
| 1 | 66 (86.8) |
| >1 | 10 (13.2) |
| Myomas' size, mm | |
| Principal myoma, mean±SD (95 % CI) | 21.9±10.1 (18.6–25.3) |
| Second myoma, mean±SD (95 % CI) | 23.5±11.4 (12.6–34.4) |
| Type of principal myomas, no. (%) | |
| Wamsteker classification | |
| G0 28 (31.8) | |
| G1 28 (31.8) | |
| G2 32 (36.4) | |
| Associated hysteroscopic findings, no. (%) | |
| None | 66/76 (86.9) |
| Polyp | 9/76 (11.8) |
| Synechiae | 1/76 (1.3) |
| Symptoms, no. (%)[a] | |
| None | 44/76 (57.9) |
| Menorrhagia | 18/76 (23.6) |
| Infertility | 10/76 (13.1) |
| Pelvic pain | 10/76 (13.1) |

Normally distributed variables are summarized as mean and lower and upper quartiles computed at 0.05; non-normally distributed variables are given as median and interquartile range

*SD* standard deviation, *CI* confidence interval 95 %

[a] Patient may have more than one symptom

**Table 5** Group B (Versapoint®) demographic characteristics, type and size of myomas, and associated hysteroscopic findings and symptoms

| No. of patients | 51 |
|---|---|
| No. of myomas | 56 |
| Age, mean±SD (95 % CI), years | 48.04±11.4 (44.8–51.3) |
| Parity, no. (%) | |
| Nulliparous | 23. (45.1) |
| Pluriparous | 28 (54.9) |
| Sub mucous myomas, no. (%) | |
| 1 | 46 (90.2 %) |
| >1 | 5 (9.8 %) |
| Myoma size, mm | |
| Principal myoma, mean±SD (95 % CI) | 25.2±14.6 (21.1–29.3) |
| Second myoma, mean±SD (95 % CI) | 20.8±12.1 (18.7–24.9) |
| Type of principal myoma, no. (%) | |
| Wamsteker classification | |
| G0 18 (32.1) | |
| G1 18 (32.1) | |
| G2 20 (35.8) | |
| Associated hysteroscopic findings, no. (%) | |
| None | 45 (88.2) |
| Polyp | 6 (11.8) |
| Synechiae | 0 (0) |
| Symptoms, no. (%)[a] | |
| None | 27 (52.9) |
| Menorrhagia | 12 (23.5) |
| Infertility | 6 (11.7) |
| Pelvic pain | 6 (11.7) |

Normally distributed variables are summarized as mean and lower and upper quartiles computed at 0.05; non-normally distributed variables are given as median and interquartile range

*SD* standard deviation, *CI* confidence interval 95 %

[a] Patient may have more than one symptom

small portion of a very hard myoma being left in the uterine cavity during the same procedure.

### Statistical analyses

No preoperative therapy statistical analysis has been planned.

Statistical analysis has been based on the Student's *t*test and the Yates corrected chi-square test. Differences between groups have been considered as statistically significant at $p<0.05$. IBM SPSS Statistics 19 (©IBM Corporation 2010, IBM Corporation, Route 100 Somers, NY 1058, USA) statistical software package has been used.

### Ethical approval

The institutional ethical committee has approved this research, and all the patients have been provided with informed consent.

## Findings

### Second-step procedures

Concerning the overall number of second-step procedures (Table 6), there has been a statistically significant difference

**Table 6** Comparison of second-step procedures between Group A (IBS®) and Group B (Versapoint®) during a 2-year period June 2011–June 2013

| Operative II step procedures | | | |
|---|---|---|---|
| | Group A IBS® (*n*=76) | Group B Versapoint® (*n*=51) | *P* value[a] |
| N° of II step procedures | 7/76 (9.2 %) | 15/51 (29.4 %) | 0.0067 |

[a] Yates corrected chi-square test

**Table 7** Comparison of second-step procedures and conversions in Group A (IBS®) and second-step procedures in Group B (Versapoint®) during a 2-year period June 2011–June 2013

| Operative II step procedures+conversions | | | |
|---|---|---|---|
| | Group A IBS® (*n*=76) | Group B Versapoint® (*n*=51) | *P* value [a] |
| Operative II step procedures+ conversions | 16/76 (21.1 %) | 15/51 (29.4 %) | 0.6766 |

[a] Yates corrected chi-square test

between those recorded in the IBS® Group (Group A; 7; 9.2 %) and those recorded in the Versapoint® Group (Group B; 15; 29.4 %; $p$=0.0067).

## Second-step procedures and conversions

No statistically significant difference has been shown comparing the overall number of second-step procedures and conversions altogether recorded in the IBS® Group (Group A; 16; 21.1 %) with the number of second-step procedures recorded in the Versapoint® Group (Group B; 15; 29.4 % $p$= 0.6766, Table 7).

## N°, type, and size of myomas in the case of second-step procedures and conversions

Four (6.7 %) and six (10 %) patients with one IBS®-treated myoma have, respectively, undergone a second-step procedure and a conversion procedure (Group A; total 10; 16.7 %) against 13 (28.3 %) patients with one Versapoint®-treated myoma (Group B) who have undergone a second-step procedure ($p$=0.2311).

Three (18.8 %) and three (18.8 %) patients with more than one IBS®-treated myoma have respectively undergone a second step and a conversion procedure (Group A; total 6; 37.6 %) against two (40 %) patients with Versapoint®-treated myomas (Group B) who have undergone a second-step procedure ($p$=0.6694).

Two (7.1 %) and four (14.4 %) G0 type myomas have been found in the IBS®-treated Group of patients who have respectively undergone a second step and a conversion procedure (Group A; total 6; 21.5 %), against two (11.1 %) G0 type myomas found in the Versapoint®-treated Group of patients (Group B) who have undergone a second-step procedure ($p$= 0.6153).

Two (7.1 %) and one (14.3 %) G1-type myomas have been found in the IBS®-treated Group of patients who have respectively undergone a second-step and a conversion procedure (Group A; total 3; 21.4 %), against n.3 (16.7 %) G1 type myomas found in the Versapoint®-treated Group of patients (Group B), who have undergone a second-step procedure ($p$= 0.8914).

Five (15.6 %) and seven (21.9 %) G2 type myomas have been found in the IBS®-treated Group of patients who have respectively undergone a second step and a conversion procedure (Group A; total 12; 37.5 %) against 10 (50 %) G2 type myomas found in the Versapoint®-treated Group of patients (Group B) undergoing a second-step procedure ($p$=0.5491).

Three (4.9 %) and one (1.6 %) IBS®-treated myomas with a diameter less than 3 cm(Group A1; tot.4; 6.5 %) have respectively undergone a second-step and a conversion procedure against five (10.52 %) Versapoint®-treated myomas with a diameter less than 3 cm(Group B1) who have undergone a second-step procedure ($p$=0.3753; Odds ratio, 2.38).

**Table 8** Comparison of N°, type, and size of myomas in second-step procedures and conversions in Group A (IBS®) and second-step procedures in Group B (Versapoint®) at myomectomy during a 2-year period June 2011–June 2013

| Operative II step procedures+conversions | | | | | |
|---|---|---|---|---|---|
| | Group A IBS® II Step P. (no. total=7/76) | Group A IBS® Conversions (no. total=9/76) | Tot. | Group B Versapoint II step P (no. total=15/51) | *P* value [a] |
| N° of myomas per patient | | | | | |
| 1 | 4/60 (6.7 %) | 6/60 (10 %) | 10(16.7 %) | 13/46 (28.3 %) | 0.2311 |
| >1 | 3/16 (18.8 %) | 3/16(18.8 %) | 6 (37.6 %) | 2/5 (40 %) | 0.6694 |
| Type | | | | | |
| G0 | 2/28 (7.1 %) | 4/28 (14.4 %) | 6(21.5 %) | 2/18 (11.1 %) | 0.6153 |
| G1 | 2/28 (7.1 %) | 1/28 (14.3 %) | 3(21.4 %) | 3/18 (16.7 %) | 0.8914 |
| G2 | 5/32 (15.6 %) | 7/32 (21.9 %) | 12(37.5 %) | 10/20 (50 %) | 0.5491 |
| Size (mm) | | | | | |
| <30 | 3/61 (4.9 %) | 1/61 (1.6 %) | 4(6,5 %)A1 | 5/35 (10.52 %) B1 | 0.3753 |
| >/=30 | 4/27 (14.8 %) | 8/27 (29.6 %) | 12(44.4 %)A2 | 10/21 (43.75 %)B2 | 0.9418 |
| N° total of myomas | 88 | | | 56 | |

[a] Yates corrected chi-square test

Four (14.8 %) and eight (29.6 %) IBS®-treated myomas with a diameter larger than 3 cm, (Group A2; tot.12; 44.4 %) have respectively undergone a second-step and a conversion procedure against ten (43.75 %) Versapoint®—treated myomas with a diameter larger than 3 cm(Group B2) who have undergone a second step procedure ($p$=0.9418; Odds ratio, 1.14; Table 8).

## Resection time, fluid balance, and dilatation time of the cervical canal regarding myomas with a diameter less than 3 cm

As to resection time, fluid used, fluid deficit, and dilatation time of the cervical canal reported during the treatment of myomas with a diameter less than 3 cm, no statistically significant difference has been reported between the IBS® Group (Group A1) and the Versapoint® Group (Group B1) (Table 9).

## Resection time, fluid balance, and dilatation time of the cervical canal regarding myomas with a diameter larger than 3 cm

As to the resection time, fluid deficit, and time of dilatation of the cervical canal reported during the treatment of myomas larger than 3 cm no statistically significant difference between the IBS® (Group A2) and the Versapoint® (Group B2) groups have been reported.

For the Versapoint®-treated myomas (Group B2; mean, 5,885 ml; median; 5,100 ml; range, 1,000–17.000 ml; SD, 3,957.84 ml), we have used a statistically significantly smaller fluid volume in comparison with what used for the IBS®-treated myomas (Group A2; mean, 11.583 ml; median, 12.500 min; range, 400–20.000 ml; SD, 4,663.92 ml; $p$=0.0001, Table 10).

**Table 9** Resection time, fluid used, fluid deficit, and cervical dilatation time comparison between Group A (IBS®) and Group B (Versapoint®) in≤3 cm myomas

| Outcomes myomas <3 cm | Group A1 IBS® ($n$=61) | Group B1 Versapoint® ($n$=35) | $P$ value[a] |
|---|---|---|---|
| Resection time (min) | | | |
| Mean (min) | 21.12 | 21.13 | 0.8715 |
| Median | 15 | 16 | |
| Standard deviation | 14.38755 | 12.3146 | |
| Range | 3–60 | 10–45 | |
| IC 95 % | 16.35–25,28 | 17.12–26.04 | |
| Fluid used (ml) | | | |
| Mean (min) | 3,765 | 2,655 | 0.0998 |
| Median | 3,000 | 1,500 | |
| Standard deviation | 3,114.041 | 2,425.811 | |
| Range | 800–15,000 | 500–10,000 | |
| IC 95 | 2,843–4,688 | 1,766–3,544 | |
| Fluid deficit (ml) | | | |
| Mean (min) | 342 | 240 | 0.1486 |
| Median | 300 | 100 | |
| Standard deviation | 327.2728 | 256.3914 | |
| Range | 0–1500 | 0–600 | |
| IC 95 | 245–439 | 146–334 | |
| Cervical dilatation (min) | | | |
| Mean (min) | 1.59 | 1.60 | 0.9320 |
| Median | 1.5 | 1.5 | |
| Standard deviation | 1.09 | 0.93 | |
| Range | 0–5 | 0.5–5 | |
| IC 95 | 1.26–1.91 | 1.26–1.94 | |

Normally distributed variables are summarized as mean (95 % confidence interval, SD); non-normally distributed variables are given as median and interquartile range or number (%)

[a] T Student test

**Table 10** Resection time, fluid used, fluid deficit, and cervical dilatation time comparison between Group A (IBS®) and Group B (Versapoint®) in ≥3 cm myomas

| Outcomes myomas >3 cm | Group A2 IBS® ($n$=27) | Group B2 Versapoint® ($n$=21) | $P$ value [a] |
|---|---|---|---|
| Resection time (min) | | | |
| Mean (min) | 47.19 | 42.25 | 0.4333 |
| Median | 45 | 35 | |
| Standard deviation | 23.85 | 17.35 | |
| Range | 15–109 | 25–85 | |
| IC 95 % | 38.1–56.26 | 34.14–50.36 | |
| Fluid used (ml) | | | |
| Mean (min) | 11,583 | 5,885 | 0.0001 |
| Median | 12,500 | 5,100 | |
| Standard deviation | 4,663.925 | 3,957.84 | |
| Range | 400–20,000 | 1,000–17,000 | |
| IC 95 | 9,807–13,358 | 4,035–7,735 | |
| Fluid deficit (ml) | | | |
| Mean (min) | 907 | 685 | 0.2352 |
| Median | 800 | 600 | |
| Standard deviation | 740.1404 | 435.6181 | |
| Range | 0–1,500 | 100–1500 | |
| IC 95 | 625–1189 | 481–889 | |
| Cervical dilatation (min) | | | |
| Mean (min) | 1.56 | 1.57 | 0.9674 |
| Median | 1.5 | 1.25 | |
| Standard Deviation | 0.90 | 1.08 | |
| Range | 0.5–5 | 0.5–5 | |
| IC 95 | 1.21–1.90 | 1.06–1.07 | |

Normally distributed variables are summarized as mean (95 % confidence interval, SD); non-normally distributed variables are given as median and interquartile range or number (%)

[a] T Student test

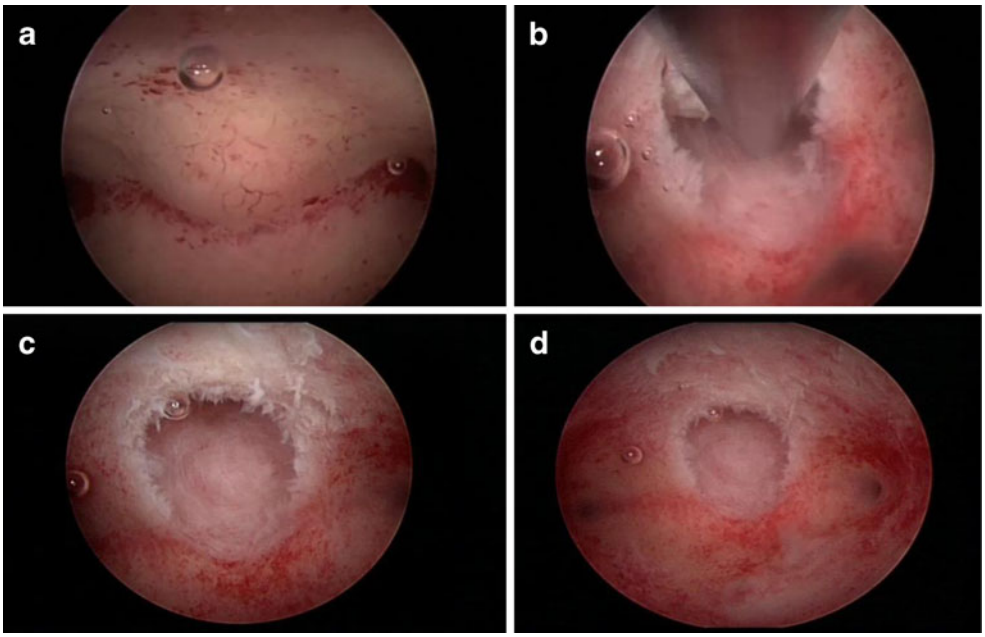


**Fig. 4** **a** G2 1,5 cm myoma. **b** Integrated Bigatti Shaver (IBS®) in action. **c** With the Integrated Bigatti Shaver (IBS®) myomas are effectively enucleated from their fovea and the myoma intramural site of insertion is removed. **d** The surrounding healthy endometrium is avoided without any thermal injury occurring

## Discussion and conclusion

This study shows that myomectomy performed with the IBS® can be a very easy and precise procedure. It has several well-documented advantages especially for the treatment of myomas up to 3 cm.

First of all, any type of submucosal myoma, including G2 myomas, which had been excluded from similar studies about morcellators, has been included in this study [18]. In addition, one of the main advantages of the IBS® is that it enables the effective enucleation of myomas from their fovea and the removal of its intramural site of insertion (Fig. 4). The surrounding healthy endometrium is protected against any thermal injury; no coagulation is needed, and there are no excessive bleeding problems.

It is worth highlighting that complications like major bleeding, fluid overload, but even more significant postoperative adhesions formation have been reported during myomectomies with the conventional bipolar resectoscope.

Deans and Abbott have reported 31.3 % and 45.5 % adhesions formation after the removal of respectively single and multiple myomas [25].

The continuous cutting capacity always performed under direct visual control together with the immediate removal of the tissue chips at the same time as resection result in a more efficient and safer reduction of the tumor's volume. No bleeding or major complication has been observed in the IBS® group procedures.

Our results show that there is no statistically significative difference in terms of cervical dilatation, resection time, and fluid deficit between the IBS®- and the Versapoint®-treated myomas.

Even if myomas with a less than 3 cm diameter are slightly more represented in the IBS® group compared to the Versapoint® group (69.3 % vs. 62.5 %), this difference is not shown to be significatively in favor of the former group of patients.

However, the data shown in the present study are very promising because they confirm the IBS® ability to treat 93.5 % of myomas with a diameter less than 3 cm and 62.5 % of myomas G2 type ®, in a single procedure without the resectoscope.

With the IBS®, we have reported an overall number of significantly less second step procedures compared to those reported in the Versapoint® Group.

These data are not confirmed when comparing the overall number of second-step procedures and conversions of the IBS ® altogether, with the second-step procedures of the Versapoint®.

On the other hand, a statistically significantly bigger volume of fluid has been used in the IBS® Group, even though the fluid deficit has been the same in both groups.

This is probably due to the double aspiration enabled by the IBS®. One aspiration stopcock is placed in the optical channel while the second aspiration is placed at the back of the drill cut handler and is activated during the resection. With the IBS®, we have used more fluid, but we have also recovered a larger amount of it.

As discussed by Emanuel et al., the diameter of an intrauterine pathology is strongly related to the operation time and to the complication rate [26]. Considering the tissue volume to be removed according to the $4/34/3\pi r^3$ formula, the conventional monopolar loop-based resection of Ø 2, 3, and 4 cm-sized myomas has respectively taken 8.4, 28.2, and 67.0 min, at a resection speed of 0.5 $cm^3$/min.

Also in our study, we have reported a 50 % need of second-step procedures in the Versapoint ® group due to the G2 type and to the large diameter of myomas interested by the resection.

Certainly also, the IBS® effectiveness is presently affected by the size rather than the type of myomas, but we think that the IBS® efficacy should be assessed according to the myomas consistency [24].

Regarding the approach of very large myomas some improvements are likely needed to improve our blade system in order to prevent the occurrence of possible drawbacks. Compared with other blind intrauterine applications, the IBS® allows us to perform procedures under visual control and to remove the tissue chips in an automated and straightforward way. As it has been proven in randomized controlled trials [27], the reduction of the instrument diameter improves the accessibility of ambulatory diagnostic hysteroscopy. The absence of complications during the cervical dilatation time enabled by the IBS® indicates that its small size enhances its usability. Although further modifications of the IBS® are necessary, this technique has shown so far very interesting and promising features for the future operative hysteroscopy that can be carried out in a faster and easier way, avoiding major complications.

In conclusion, the IBS® proves to be a promising innovative new instrument for the removal of myomas. This instrument is smaller, thus easier to use than the conventional resectoscope. The fact that surgery is not interrupted by tissue chips removal will likely shorten the total operating time in the future. It is further postulated that electrical current-free resection of myomas could significantly reduce the postoperative adhesions formation and that the IBS® system should preferentially be used in the case of young women, during their reproductive age.

Prospective randomized comparative study should be planned to prove this advantage in the treatment of infertile patients.

**Acknowledgments** This paper is dedicated to my wife Daniela. Special thanks go to Karl Storz GmbH & Co employees, Storz Italia, for their technical support, and in particular, to Dr. h.c. mult. Sybill Storz and Helmut Wehrstein, who have believed in this project from its beginning. Special thanks are addressed to Prof. Ivo Brosens, Dr. Rudi Campo, Dr. Yves Van Belle, and Prof. Berndt Rudelstorfer maestro di vita.

Translation by Ettore Claudio Iannelli.

**Declaration of interest** The contracts with Dr. Bigatti and the mutually provided benefits concerning the development and the consultancy on the IBS® are in no way affiliated with any other service or procurement decisions on the part of the contractual parties, including studies like the present one. Therefore, Dr. Bigatti has received no financial compensation for this study.

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