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ORIGINAL RESEARCH ARTICLE

Manual morcellation (Resectr™ 9Fr) vs electromechanical morcellation (TruClear™) for hysteroscopic polypectomy: A randomized controlled non-inferiority trial

Steffi van Wessel[1] | Tjalina Hamerlynck[1] | Huib van Vliet[1,2] | Benedictus Schoot[1,2] | Steven Weyers[1]

[1]Women's Clinic, Ghent University Hospital, Ghent, Belgium

[2]Department of Obstetrics and Gynecology, Catharina Hospital, EJ Eindhoven, The Netherlands

Correspondence
Steffi van Wessel, Women's Clinic, Ghent University Hospital, Corneel Heymanslaan 10, 9000 Ghent, Belgium.
Email: steffi.vanwessel@uzgent.be

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Abstract

Introduction: Meta-analyses comparing hysteroscopic electromechanical morcellation with electrosurgical resection showed a shorter operating time for electromechanical morcellation, mainly for polypectomy. The Resectr™ 9Fr is a new hysteroscopic manual morcellator, designed to simplify this procedure. We aimed to compare manual with electromechanical morcellation for hysteroscopic polypectomy.

Material and methods: This two-center randomized controlled non-inferiority trial was performed from 2018 to 2021 in the Catharina Hospital and the Ghent University Hospital. The study was registered at the Dutch Trial Register (NL6922; ICTRP ID: NTR7118). One hundred and forty women with polyps (between 8 and 20 mm) scheduled for hysteroscopic removal were randomized between manual (Resectr™ 9Fr) or electromechanical (TruClear™) morcellation. The primary outcome was time (instrumentation set-up, resection, and total procedure time).

Results: The non-inferiority margin for the primary outcome time was 1.3. Mean instrumentation set-up time was 10% shorter with the manual compared with the electromechanical morcellator (estimated mean ratio manual/electromechanical = 0.9; 97.5% confidence interval [CI] 0.8–1.1). Mean resection time was 30% longer with the manual compared with the motor-driven system (estimated mean ratio manual/electromechanical = 1.3; 97.5% CI 0.9–1.9). Mean total procedure time was 10% longer with the manual compared with the electromechanical morcellator (estimated mean ratio manual/electromechanical = 1.1; 95% CI 0.91–1.298). The estimated odds (electromechanical/manual) of better surgeon's safety, effective and comfort scores were, respectively, 4.5 (95% CI 0.9–22.1), 7.0 (95% CI 1.5–31.9), and 5.9 (95% CI 1.1–30.3) times higher with the motor-driven compared with the manual morcellator. Conversion rates and incomplete resection rates were comparable in both groups (manual vs electromechanical) (7.6% [4/66] vs 2.9% [2/68] and 6.1% [4/66] vs

Abbreviations: CI, confidence interval; RCT, randomized controlled trials.

3.0% [2/66], respectively). No intraoperative and postoperative complications were registered.

Conclusions: The manual morcellator was non-inferior to the electromechanical morcellator for hysteroscopic polypectomy in terms of mean instrumentation set-up time and total procedure time. Results on resection time were inconclusive. Conversion and incomplete resection rates were within the range reported in the literature. Surgeon's reported rating for both devices was high, however, in favor of the motor-driven tissue removal system.

KEYWORDS
endometrial polyps, hand-driven hysteroscopic tissue removal system, hysteroscopic electromechanical morcellation, hysteroscopic manual morcellation, hysteroscopic morcellation, motor-driven hysteroscopic tissue removal system, operative hysteroscopy

1 | INTRODUCTION

The hysteroscopic electromechanical morcellator was introduced to facilitate the removal of intrauterine pathology: an optimal view and fewer complications (uterine perforation, gas embolism, and thermal damage) and shorter learning curve.[1,2] Different systems have been designed—TruClear™ (Medtronic), MyoSure (Hologic Inc.), and Intrauterine BIGATTI Shaver® (Karl Storz).

Three meta-analyses have been performed to compare the hysteroscopic electromechanical morcellator with electrosurgical resection for the removal of polyps and type 0 and 1 myomas.[3–5] Subgroup analysis of data derived from randomized controlled trials (RCTs) revealed a significantly shorter operating time for hysteroscopic electromechanical morcellation (mean difference 4.5 minutes). Subgroup analysis per pathology, however, showed only a benefit for the removal of polyps (mean difference 7.8 minutes). Overall, the complete removal rate was in favor of the hysteroscopic electromechanical morcellator, whereas the complication rate was not significantly different.

However, the development of devices continued and a new hysteroscopic manual morcellator, Resectr™ 9Fr (Minerva Surgical), was *Conformité Européene* (CE) marked in 2016 and US Food and Drug Administration approved in 2020. Its potential benefits are a simplified set-up, because of the replacement of the electrically powered control by a simple handgrip, and a larger working window (7.5 mm).

The aim of this RCT was to compare the manual morcellator (Resectr™ 9Fr) with the electromechanical morcellator (TruClear™) for hysteroscopic polypectomy in terms of procedure time, surgeon's convenience, safety, complications, conversion rate, and completeness of removal.

Key message

The manual morcellator is non-inferior to the electromechanical morcellator for polyp resection in terms of mean installation set-up and total procedure time.

2 | MATERIAL AND METHODS

This two-center, single-blinded RCT was performed from September 2018 to August 2021 in the Catharina Hospital and the Ghent University Hospital.

Women with endometrial polyps (largest diameter 8–20 mm) scheduled for hysteroscopic removal were eligible to participate. Diagnosis was made by transvaginal ultrasound, saline infusion sonography, and/or diagnostic hysteroscopy. Exclusion criteria were polyps with the largest diameter smaller than 8 mm or larger than 20 mm, myomas, visual or pathological evidence of malignancy, untreated cervical stenosis, or the presence of any contraindication for operative hysteroscopy.

After written informed consent, women were randomly assigned in a 1:1 ratio to manual or electromechanical morcellation. A computer-generated random allocation sequence (Research Manager) was used, with a block size of six. Randomization was stratified by center and polyp size (8 mm to <15 mm or 15 mm to 20 mm). Women were unaware of the treatment allocation. The Consolidated Standards of Reporting Trials 2010 statement for reporting of an RCT was followed.

Hysteroscopic polypectomy was performed in day surgery or office setting, according to local practices. Different types of anesthesia were used (none, cervical block, conscious sedation or spinal or general anesthesia). No cervical ripening agents or antibiotic prophylaxis were used. All procedures were performed using the TruClear™ 5C hysteroscope (5.6 mm, 17Fr), normal saline for distention and irrigation of the uterine cavity, and Hegar dilators up to 6 mm for cervical dilation if necessary. Fluid balance was closely monitored using the Hysteroscopic Fluid Management System (Medtronic; maximum pressure setting of 120 mm Hg and maximum flow setting of 700 mL/min).

The Resectr™ 9Fr (3 mm) was used in the intervention group (Figure 1). This new hand-driven tissue removal device consists of a

FIGURE 1 Resectr™ 9Fr device. Reprinted with permission of Dr. Skalnyi (Minerva Surgical).

35-cm long cannula, with a 7.5-mm cutting window and an internal rotating blade in an outer tube. The hand activation of the Resectr™ 9Fr replaces the electrically powered control unit in the existing motor-driven devices. Each squeeze on the handpiece initiates six turning movements of the inner blade. During each turn, the inner blade can cut tissue. The ENDOMAT® SELECT (Karl Storz; maximum flow setting of 300 mL/min), activated by a foot pedal, was used for controlled suction of the resected tissue, which is aspirated through the hollow lumen of the tissue removal device, collected in a pouch and available for pathology analysis. When the rotating inner blade and the ENDOMAT® SELECT are not activated, the window opening of the Resectr™ 9Fr is always closed to prevent fluid loss and loss of distension.

The TruClear™ incisor mini device (3 mm, 9Fr), currently renamed as soft-tissue shaver mini device, was used in the control group. The system has a 5-mm cutting window. The technique of hysteroscopic electromechanical morcellation has been described previously.[1]

The surgeons, experienced in operative hysteroscopy, had in vitro training.

The primary outcomes were instrumentation set-up time and resection time. The instrumentation set-up time was defined as the time to set up the hysteroscopic instrumentation ready for use, it included cervical dilatation (if necessary), assembly of the hysteroscopic morcellator, and was defined as ending when the hysteroscope was ready to be inserted. The resection time included only the removal of the largest polyp. Registration started when the hysteroscope was introduced through the external cervical ostium until the time at which the largest polyp was completely removed.

Secondary outcomes were total procedure time (the sum of the instrumentation set-up and resection time), fluid deficit, number of insertions, subjective surgeon-reported outcomes on a 5-point Likert scale immediately after the hysteroscopic procedure (safety [how safe did you feel with the instrument?], effective [how effective did you find the instrument to resect polyp tissue?] and comfort [how comfortable did you find the instrument?] scores), intraoperative and postoperative complications (including fluid deficit ≥2500 mL with clinical consequences, blood loss >500 mL, uterine perforation, and infection), conversion rate (an interruption of the hysteroscopic procedure to switch to another procedure or another device in order to complete the surgery), completeness of removal (removal of all visible polyp tissue from the uterine cavity), short-term effectiveness (persistence of symptoms at 6 weeks follow up), patient's satisfaction with the procedure on a 5-point Likert scale (at 6 weeks follow up), postoperative availability of tissue for pathology analysis, and pathology diagnosis.

2.1 | Statistical analyses

The sample size was calculated to test for non-inferiority of the hysteroscopic manual morcellator compared with the electromechanical system with respect to the geometric mean instrumentation set-up and resection times. In the paper of Hamerlynck et al, the mean instrumentation set-up and resection times with the electromechanical morcellator were 7.3 minutes (± standard deviation [SD] 2.5 minutes) and 6.6 minutes (± SD 3.3 minutes), corresponding to coefficients of variation of 0.3 and 0.5, respectively.[6] A mean ratio of 1.3 as non-inferiority margin for the manual vs electromechanical morcellator was chosen and would imply upper limits for mean instrumentation set-up and resection times with the manual morcellator of 9.5 minutes and 8.6 minutes, respectively. A non-inferiority test of lognormal geometric means using the confidence interval (CI) approach (97.5% CI constructed) on data from a balanced parallel-group design with sample sizes of 63 women in each group (126 women in total), will achieve at least 80% power when the true geometric mean ratio is 1, the common coefficient of variation is 0.5, and the non-inferiority limit is 1.3. To account for 10% drop-out, this sample size was increased to 140 women in total. The sample size was calculated in R version 4.1.1 using the PowerTOST package. Testing for superiority after non-inferiority can be demonstrated and will not impact the type I error rate, nor the sample size.

Data were collected and analyzed using the statistical program SPSS (version 27.0, IBM Corp.). Continuous variables were summarized with descriptive statistics (mean ± SD for data that were normally distributed, geometric mean and geometric SD factor for instrumentation set-up, resection, and total procedure times, and median and interquartile range otherwise). Categorical data were presented as absolute frequencies and percentages.

Linear mixed models of log-transformed instrumentation set-up, resection, and total procedure times on randomization group and stratification group were fitted with a random intercept for surgeon. The upper limit of the CI for the geometric mean ratio will be compared with the predefined non-inferiority margin of 1.3. Generalized estimating equations models with exchangeable working correlation matrix for women within surgeons were fitted for the ordinal 5-point Likert scales for safety, effective, and comfort scores (cumulative logit). Analyses for conversion rate and complete resection rate were kept descriptive because of quasi-complete separation.

For the two primary end points 97.5% CI are reported. Comparisons of other end points were not adjusted for multiple

testing (95% CIs are reported), because these analyses will only be interpreted if first non-inferiority on one of the primary end points can be demonstrated.

An intention-to-treat analysis was performed. A per-protocol analysis was also performed to assess the robustness of our findings, excluding women that did not receive the allocated treatment, had polyps that were too large (>20 mm), or had a conversion.

2.2 | Ethics statement

Approval was obtained from both ethical committees (Belgium: date of approval January 9, 2018, reference number 2017/1576; The Netherlands: date of approval April 25, 2019, reference number V.186069/R18.009/sr/ld). The study was registered on March 27, 2018 at the Dutch Trial Register (NL6922). However, this database is currently unavailable and registered studies were moved to the International Clinical Trial Registry Platform with ID: NTR7118 (https://trialsearch.who.int/Trial2.aspx?TrialID=NTR7118). Participant enrollment started in September 2018. Written informed consent was obtained from all participants.

3 | RESULTS

After informed consent, 140 women were randomized. A flowchart can be found in Figure 2. Forty-six percent (65/140) of women were treated in the Catharina Hospital and 54% (75/140) in the Ghent University Hospital. There was one drop out in each group. In the manual morcellation group, one woman was diagnosed with breast cancer and the hysteroscopic polypectomy, using a bipolar resectoscope, was performed concomitant with the breast surgery. In the electromechanical morcellation group, the procedure was canceled in one woman. There were two withdrawals of consent in the manual morcellation group. One for no specific reason, and the other because there would be no compensation in case of complications. In the manual morcellation group, the pathology was intraoperatively diagnosed as a myoma, the intervention was rescheduled as a procedure under conscious sedation.

Patients' demographics and polyp characteristics are shown in Tables 1 and 2, respectively. The estimated geometric mean instrumentation set-up time was 10% shorter with the manual morcellator compared with the electromechanical tissue system (estimated mean ratio manual/electromechanical = 0.9; 97.5% CI 0.8–1.1). The

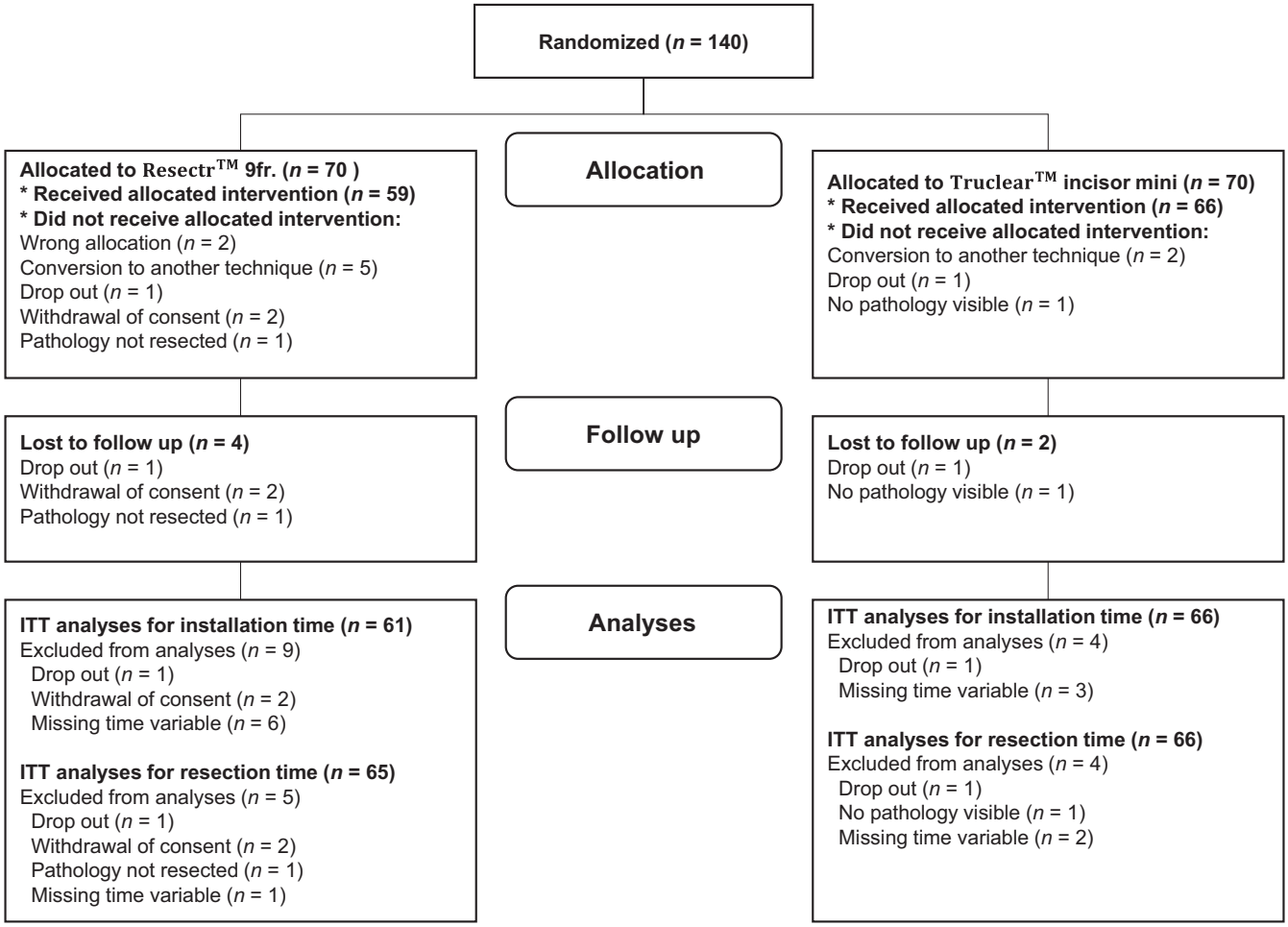

FIGURE 2 Consort flowchart.

TABLE 1 Patient demographics.

	Hand-driven hysteroscopic tissue removal		Motor-driven hysteroscopic tissue removal	
		N		*N*
Age (y)	53.0 ± 13.0	69	51.0 ± 11.0	70
Body mass index (kg/m^2)	25.7 (23.1–29.9)	65	26.2 (22.4–31.2)	68
Nulliparous	15 (22.4)	67	10 (14.5)	69
Menopausal	36 (52.2)	69	35 (50.0)	70
Smoker	3 (4.5)	67	5 (7.4)	68
Race				
White	64 (92.8)	69	63 (90.0)	70
Black	1 (1.6)		1 (1.4)	
Asian	3 (4.3)		4 (5.7)	
Hispanic	1 (1.6)		2 (2.8)	
ASA				
ASA I	42 (60.9)	69	39 (55.7)	70
ASA II	24 (34.8)		25 (35.7)	
ASA III	3 (4.3)		6 (8.6)	

Note: Data are mean ± standard deviation, median (interquartile range), or number (percentage). *p* values are from chi-squared tests, unless otherwise specified.

Abbreviation: ASA, American Society of Anesthesiologists.

upper limit of the 97.5% CI fell below the predefined non-inferiority limit of 1.3, hence we can conclude that the manual morcellator is non-inferior to the electromechanical morcellator with respect to the geometric mean instrumentation set-up time (3.3 ± 1.2 minutes vs 3.3 ± 1.2 minutes). Superiority however could not be demonstrated ($p = 0.13$).

The estimated geometric mean resection time was 30% longer with the manual morcellator compared with the electromechanical morcellator (estimated mean ratio manual/electromechanical = 1.3; 97.5% CI 0.9–1.9). The upper limit of the 97.5% CI fell above the predefined non-inferiority limit of 1.3, hence we are inconclusive about clinical non-inferiority of the manual morcellator compared with the electromechanical morcellator, with respect to the geometric mean resection time (3.7 ± 1.2 minutes vs 2.7 ± 1.2 minutes).

The estimated geometric mean total procedure time was 10% longer with the manual morcellator compared with the electromechanical morcellator (estimated mean ratio manual/electromechanical = 1.1; 95% CI 0.91–1.298). We can conclude that the manual morcellation is non-inferior to electromechanical morcellation, with respect to the geometric mean total procedure time (8.2 ± 3.7minutes vs 7.4 ± 3.7 minutes). Superiority however could not be demonstrated ($p = 0.37$). The per-protocol analysis led to similar conclusions.

Operative data are presented in Table 3. A congenital uterine malformation was present in two women in the hand-driven tissue removal system group (class U2 [partial septate uterus] and class 3Bb [complete bicorporal uterus]). A myoma was visualized in four women in the manual morcellation group (two concomitant to a polyp and left in situ, one intraoperatively diagnosed instead of a polyp and resected, and one intraoperatively diagnosed instead of a polyp and rescheduled for removal) and in two women of the electromechanical group (both intraoperatively diagnosed instead of a polyp and resected).

The conversion rate was 7.6% (5/66) and 2.9% (2/68) in the manual and electromechanical morcellation groups, respectively. In two cases, the Resectr™ 9Fr was converted to the resectoscope because of the intraoperative diagnosis of a myoma ($n = 1$) and in order to obtain a complete resection of hard tissue that turned out to be a myoma ($n = 1$). The Resectr™ 9Fr was converted to the TruClear™ incisor mini device because of device deficiency (defective inner blade $n = 1$), a large polyp ($n = 1$), and poor visibility due to blood loss ($n = 1$). Because of the intraoperative diagnosis of a myoma, the TruClear™ incisor mini device was converted to the resectoscope ($n = 1$) and to the TruClear™ ultra mini device, currently renamed as dense-tissue shaver mini device ($n = 1$).

Polyp resection was incomplete in 6.1% (4/66) of the cases in the manual morcellator group (one intraoperative diagnosis of a myoma, two fundal position, and one conversion to the resectoscope in order to obtain complete resection of hard tissue that turned out to be a myoma). In the electromechanical morcellation group, incomplete resection occurred in 3.0% (2/66) of the cases (one intraoperative myoma diagnosis and one fundal position). No complications were recorded and tissue was available for pathology analyses in all cases. It was necessary to reinsert the Resectr™ 9Fr once (the tissue was stuck in the working window).

TABLE 2 Polyp characteristics.

	Hand-driven hysteroscopic tissue removal		Motor-driven hysteroscopic tissue removal	
		N		*N*
Polyp number[a]	1 (1–2)	67	1 (1–1)	68
Largest diameter of the largest polyp (mm)	14 (11–18)	62	14 (12–18)	68
Symptoms	53 (76.8)	69	53 (75.7)	70
AUB	44 (83.0)	53	47 (88.7)	53
Abdominal pain		17 (32.1)	53	15 (28.3)
Dysmenorrhea	4 (12.1)	33	10 (28.6)	35
Infertility	4 (12.1)	33	5 (14.3)	35
Type of imaging				
US	2 (2.9)	69	3 (4.3)	70
US + SIS	7 (10.1)		5 (7.1)	
Diagnostic hysteroscopy	1 (1.4)		/	
US + diagnostic hysteroscopy	14 (20.3)		15 (21.4)	
US + SIS + diagnostic hysteroscopy	45 (65.2)		47 (67.1)	
Location of the largest polyp[a]				
Anterior	12 (18.5)	65	8 (12.3)	65
Posterior	18 (27.7)		23 (35.4)	
Side wall	22 (33.8)		19 (29.2)	
Fundal	12 (18.5)		14 (21.5)	
Cervical	1 (1.5)		1 (1.5)	

Note: Data are median (interquartile range), or number (percentage). *p* values are from chi-squared test, unless otherwise specified.
Abbreviations: AUB, abnormal uterine bleeding; SIS, saline infusion sonography; US, transvaginal ultrasound.
[a]As seen during operative hysteroscopy.

The estimated odds of better surgeon's safety, effective and comfort scores (above any fixed level) were, respectively, 4.5 (95% CI 0.9–22.1, $p = 0.06$), 7.0 (95% CI 1.5–31.9, $p = 0.01$), and 5.9 (95% CI 1.1–30.3, $p = 0.03$) times higher with the electromechanical morcellator than with the manual morcellator.

The postoperative data are presented in Table 4. An unscheduled postoperative visit with the gynecologist was recorded in 1.5% (1/66) of the manual morcellation group (pathology analyses revealed a carcinoma) and in 4.4% (3/68) of the electromechanical group (all three for bleeding and abdominal pain). An unscheduled postoperative visit with the general practitioner was recorded in 1.5% (1/66) of the manual morcellation group (abdominal pain) and 4.4% (3/68) of the electromechanical morcellation group (one for abdominal pain and fever, one for flu-like symptoms, and one for gastritis).

Tissue was insufficient for pathology analysis in 1.5% (1/68) of the electromechanical morcellator group.

4 | DISCUSSION

The manual morcellator (Resectr™ 9Fr.) was non-inferior to the electromechanical morcellator (TruClear™) in terms of mean instrumentation set-up and total procedure time. Our results were inconclusive regarding polyp resection time. Overall, instrumentation set-up, resection, and total procedure times for hysteroscopic polypectomy with both tissue removal systems were short.

To our knowledge, our RCT is the first to report on the clinical use of a new manual morcellator for hysteroscopic polypectomy and to compare this technique with electromechanical removal. We used unambiguous time definitions. Moreover, groups were comparable by measuring only the resection time of the largest polyp and by the stratified randomization.

Our trial has some limitations. The surgeon-reported outcomes are subjective; however, the trial was multicentric and different surgeons were involved. We did not analyze the cost-effectiveness. Nevertheless, as the procedure time and the hospitalization are similar, the difference between the two techniques can be based on the device and sterilization costs. Furthermore, the polyp size was limited to 2 cm in our trial, but in the existing literature it is rarely larger. Unfortunately, the primary outcome was missing in some cases, but this was less than 10%.

The simplified set-up of the Resectr™ 9Fr. was non-inferior to the TruClear™ incisor mini device regarding mean instrumentation set-up time, but we could not demonstrate its superiority. Replacement of the ENDOMAT® SELECT pump by a vacuum wall source, or an integrated vacuum system could further simplify the set-up. The reported instrumentation set-up times associated

TABLE 3 Operative data.

	Hand-driven hysteroscopic tissue removal		Motor-driven hysteroscopic tissue removal		
		N		*N*	*p*
Type of anesthesia					
None	13 (19.4)	67	15 (21.7)	69	0.93*
Cervical block	2 (3.0)		3 (4.3)		
Conscious sedation	14 (20.9)		15 (21.7)		
Spinal anesthesia	2 (3.0)		2 (2.9)		
General anesthesia	36 (53.7)		34 (49.3)		
Setting					
Day clinic	52 (77.6)	67	51 (73.9)	69	0.60*
Inpatient	/		1 (1.4)		
Office procedure	15 (22.4)		17 (24.6)		
Cervical dilatation					
None	18 (26.9)	67	25 (36.2)	69	0.19*
Easy	44 (65.7)		43 (61.3)		
Difficult	5 (7.5)		1 (1.4)		
Conversion	5 (7.6)	66	2 (2.9)	68	0.37
Complete resection	62 (93.3)	66	66 (97.1)	68	0.57*
Fluid deficit (mL)	181 (100–370)	46	55 (0–230)	54	0.03**
Surgeon's safety score (5-point Likert Scale)	5 (4–5)	64	5 (5–5)	68	<0.001**
Surgeon's practical score (5-point Likert Scale)	4 (3–5)	64	5 (4–5)	68	<0.001**
Surgeon's comfort score (5-point Likert Scale)	4 (3–5)	64	5 (5–5)	68	<0.001**

Note: Data are median (interquartile range), or number (percentage). *p* values are from chi-squared test, unless otherwise specified.

**p* value from Mann–Whitney *U* test.

***p* value from Fisher's Exact test.

with motor-driven hysteroscopic tissue removal systems (median 5.2 minutes) were higher.[7]

The Resectr™ 9Fr. is equipped with a larger working window (7.5 mm) than the TruClear™ incisor mini device (5 mm). This could have resulted in shorter resection times. Our results were inconclusive regarding non-inferiority and the mean resection time was shorter for the electromechanical morcellator. This might be explained by the inconsistent activation of the hand piece, resulting in variable resection speeds. Notwithstanding, the resection times were low. The reported resection times of electromechanical morcellators were not comparable to our measures because of heterogeneity in terms of polyp size and number.[8,9]

We could not observe a difference in conversion rates and incomplete resection rates between the two techniques in our sample but the study was not powered on these outcomes. The main reason for conversion to another technique in both groups was the presence of a myoma, which consists of dense tissue. The presence of a myoma and a fundal polyp were the main reasons for incomplete resection in both groups. The Resectr™ 9Fr. was not designed to remove myomas. The TruClear™ tissue removal system has specific devices developed for dense tissue (ultra mini and ultra plus devices). Fundal polyps may be hard to reach. The only two RCTs using the TruClear™ incisor mini device for hysteroscopic polypectomy did not report on conversion rates Their incomplete resection rates ranged from 2% to 8% and was mainly a result of inability to access the intrauterine cavity.

Manual morcellation was associated with higher fluid deficits than the electromechanical system for hysteroscopic polypectomy. Overall, these deficits were low and the maximum fluid deficit was 1620 mL. Pampalona et al and Smith et al did not calculate their fluid deficit.[8,9]

Surgeon's safety, effective and comfort scores were in favor of the electromechanical morcellator. Overall, these scores were high so one can question their clinical relevance. Surgeon's subjective scores were only reported by Tsuchiya et al, using the TruClear™ incisor plus device for polyp removal.[10] Maneuverability was scored on a Visual Analog Scale and was 7.7.

TABLE 4 Postoperative data.

	Hand-driven hysteroscopic tissue removal		Motor-driven hysteroscopic tissue removal		
	N		*N*		*p*
Unscheduled postoperative visit with the gynecologist	66	1 (1.5)	68	3 (4.4)	0.81
Unscheduled postoperative visit with the general practitioner	66	1 (1.5)	68	3 (4.4)	0.81
Postoperative bleeding (days)	63	3 (1–7)	65	3 (1–10)	0.80*
Persistent symptoms	53	4 (7.5)	53	7 (13.2)	0.85
Bleeding	44	4 (9.1)	47	5 (10.6)	
Pain	17	0 (0)	15	4 (26.7)	
Dysmenorrhea	4	0 (0)	10	1 (10)	
New symptoms	65	2 (3.1)	67	2 (3.0)	1.0
Pathology analyses					
Polyp	66	59 (89.4)	68	62 (91.2)	1.0
Myoma		3 (4.5)		4 (5.9)	
Atypical hyperplasia		0 (0)		1 (1.5)	
Carcinoma		2 (3.0)		0 (0)	
Endometrial tissue		2 (3.0)		0 (0)	
Patient's satisfaction	64	5 (4–5)	66	5 (5–5)	0.51*

Note: Data are median (interquartile range) or number (percentage). *p* values are from Fisher's Exact test, unless otherwise specified.

**p* value from Mann–Whitney *U* test.

A difference in patient satisfaction score could not be demonstrated. This was not reported before.

Tissue was insufficient for pathology analysis in one case of the motor-driven group. The TruClear™ tubing is long and it is necessary to flush it sufficiently in order to remove all the tissue. When removing small intrauterine pathologies, the resection time is brief, so we need to be aware that sufficient flushing does not automatically happen during the procedure. Apart from this, it has been shown that the TruClear™ tissue removal system provides an adequate specimen for pathology analysis.[11]

To our knowledge, there is only one other hysteroscopic manual morcellator, the MyoSure Manual (Hologic Inc.), which was CE marked in 2018. However, there are no studies available.

Future research should focus on the cost-effectiveness of hysteroscopic morcellators in general, the optimalization of the manual device (adaptation of the device tip to reach the fundal region, an integrated vacuum system, and a non-disposable variant) and other indications (smaller placental remnants).

5 | CONCLUSION

In our trial, the manual morcellator was non-inferior to the electromechanical morcellator for hysteroscopic polypectomy in terms of mean instrumentation set-up and total procedure time. Results on resection time were inconclusive. Conversion and incomplete resection rates were within the range reported in the literature. Surgeon's reported outcomes were high, but in favor of the electromechanical morcellator. Women were satisfied with both techniques.

AUTHOR CONTRIBUTIONS

All authors contributed to conception and design of study, data collection, data analysis and interpretation, being responsible surgeon or imager, manuscript preparation, and patient recruitment. SvW performed the statistical analysis.

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CONFLICT OF INTEREST

Huib van Vliet and Benedictus Schoot report personal fees from Medtronic for lectures and consulting on hysteroscopic morcellation, outside the submitted work. The other authors have nothing to disclose.

ORCID

Steffi van Wessel https://orcid.org/0000-0002-2725-7696

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