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HYSTEROSCOPY Editorial teaM

Dear Friends and Colleagues,

Medicine and especially surgery is a field in constant evolution characterized by innovation-seeking for a safer and more efficient result for our patients.

Hysteroscopy and the surgery of the uterine cavity are an example of an unstoppable evolution in the last 20 years but more markedly during the last decade.

In contrast to this fact, blind procedures of the uterine cavity are still widely used, dilation and curettage (D&C) is a procedure that is still performed in the same way as the first time, in 1846. No evolution, no improvement, and the repercussion to women's health are also the same.

In the GCH, we believe that it is time for a change thanks to the available technology, the time to evolve from "blind" intrauterine procedures to safer "under direct vision" procedures has arrived.

This is the main reason for this meeting organized by GCH under the title of "HTRS: Technological Revolution in Hysteroscopy. First steps for the end of blind procedures", where we will be able to finally meet again.

We invite you to be part of this historic event, to witness the beginning of a revolution led by the best surgeons and speakers, with surgery techniques explained by the most experienced. You will see new technology "in action" where traditional "blind procedures" used to be the norm.

This is going to be a game-changing revolutionary event that will conclude with the signature by our organization along with members of the AAGL and ESGE of a Consensus Statement of Intentions against blind procedures and a new beginning for Hysteroscopy becoming THE standard in Gynaecology.

Looking forward to seeing you soon!

Luis Alonso Pacheco, Sergio Haimovich, Tony Carugno, Attilio Di Spiezio Sardo, Miguel Ángel Bigozzi

GCH Executive Board

If you are interested in sharing your cases or have a hysteroscopy image that you consider unique and want to share, send it to hysteronews@gmail.com

HTRs: first steps to the end of blind intrauterine procedures. key aspects of an epic congress

Dr. José Hidalgo López. Hospital Universitario de Cabueñes. Spain

Hysteroscopy Newsletter Vol 8 Issue 3

The Global Community of Hysteroscopy (GCH) organized this past month of May in Malaga a special congress on the "revolution" that hysteroscopic mechanical morcellation systems represent, which are also called HTRS (Hysteroscopy Tissue Removal System).

The common theme of the congress was the comparison of classical dilation and curettage with the use of these systems, which represents a paradigm shift. During the last decade of the 20th century, another important advance was introduced with the "see and treat" philosophy allowing to use a variety of instruments and energies through small diameter hysteroscopes. The most recent innovation in the field of intrauterine surgery was the introduction of mechanical morcellation systems (HTRS). This technology is designed to extract tissue from the intrauterine cavity under direct visualization in an efficient and reliable way. The speakers showed their great gratitude to Dr. Mark Hans Emanuel, creator of the first hysteroscopic morcellator.



Málaga | Thu & Fri 26-27 May 2022 International Congress including the signature of a Consensus Statement of Intentions

Blind intrauterine uterine procedures, both for diagnosis and treatment of uterine pathology, have been the "gold standard" until the last decade of the 20th century. Although ultrasound guidance has introduced some improvements in the safety of blind procedures, it is not a substitute for direct visualization. Dilation and curettage is a blind procedure introduced in 1846 with little improvement or modification since then. It continues to be used routinely for both diagnosis and treatment of intrauterine pathology. Since the introduction of the diagnostic hysteroscope in 1980, we have seen rapid advances in optics producing very small diameter instruments, offering excellent resolution.

The initial presentations compared the advantage of working under direct vision for diagnostic purposes (endometrial biopsy), which provides greater precision than curettage. Curettage can lead to insufficient sample collection, or obtaining the sample from an inappropriate location, having lower diagnostic sensitivity. The role that the miniresectoscope or the HTRS can play for this purpose was presented.

But the topic that occupied most of the presentations was the role of HTRS in the treatment of placental remnants (Products of conception) and, to a lesser extent, miscarriage below 10 weeks of gestation.



RPOCs consist of the retention of chorionic tissue in the uterine cavity after an abortion or childbirth. RPOC can occur in up to 1% of deliveries and 6% of abortions, reaching up to 15% when are pharmacological. The classic treatment of RPOC has been uterine curettage once diagnosed. Uterine curettage is a blind procedure that can potentially damage the basal membrane of the endometrium and expose the uterus to unnecessary trauma, increasing the risk of intrauterine adhesions formation or other complications such as bleeding or uterina perforation. The incidence of adhesions after blind sharp curettage is 15%, which increases to 40% in the case of repeated curettage. The progressive decrease in endometrial thickness is also described, with an additive effect. The appearance of such adhesions frequently compromises the future fertility of the patient.

`The treatment of RPOC by means of HTRS has a series of advantages when compared to curettage. On the one hand, it prevents endometrial damage and the formation of intrauterine adhesions. It also ensures complete evacuation, since ROPs are often focal. On the o ther hand, it allows diagnosis

of coexisting pathologies (polyps, cavity anomalies, etc.), and provides better sample quality. But the one great advantage of morcellation systems, due to their small diameter, is that dilation is not required, which facilitates their use on an outpatient basis in most cases. This avoids the need for general anesthesia and the associated risks, as well as minimize length of stay in outpatient surgery units. All of this results in less trauma on the patient and in better management of resources.

It is also interesting to compare the treatment of RPOC using HTRS and the other available technology, which is the classic resectoscope. The evidence shows that the hysteroscopic treatment of RPOC should be performed with a mechanical morcellator rather than with a resectoscope. This is because with the HTRS it only requires a single entry into the uterine cavity, there is no thermal/electrical damage, there are no loose fragments or bubbles that can impair the visualization, and as we have said, it does not require dilation and allows its use in the outpatient setting. The widespread use of HTRS is leading to a progressive use of hysteroscopic decline in the resectoscope, which is already becoming a striking fact in the United States, as highlighted by Dr. Linda Bradley ("the resectoscope is dying in the U.S. ").



There are two factors that must be taken into account when evaluating the treatment of RPOC: Size and vascularization. Special emphasis was placed on vascularization. A pre-procedure evaluation must always be performed using Doppler US and classify the case according to the Gutenberg Classification. This classification correlates the different ultrasound patterns with the hysteroscopic appearance of the ROP, also allowing anticipation of the complexity that we may encounter at the time of its evacuation. The type of vascularization will largely condition our management. In the presence of a type 2 or 3 case, it is advisable to wait whenever possible, since time will reduce vascularization, making the resection easier. The waiting period recommended by the speakers ranges between 6 and 8 weeks from the end of pregnancy. When we are faced with a persistent type 3 case, that is, with significant vascularization at the myometrial level, uterine artery embolization before the procedure can be considered.



Gutenberg classification for Retained Products of Conception (RPOC):

- Type 0: Avascular hyperechoic intracavitary mass
- Type 1: Intracavitary mass of mixed echogenicity with minimal or no vascularization.
- Type 2: Mass confined to the highly vascularized uterine cavity

• Type 3: Highly vascularized mass with highly vascularized myometrium

Once the presence of ROPC is diagnosed, the management can be expectant, medical or surgical. The clinical situation of the patient will determine the recommended management. The only case in which Sharp/suction curettage should be performed is in cases of acute heavy bleeding. It should be done with ultrasound guide and limiting "scratching" to as possible. lf the patient little as is asymptomatic, the recommendation is to wait 6 weeks from the end of pregnancy, since the mayority of cases will resolve spontaneously. As for patients who have mild or moderate bleeding, an individualized assessment must be performed, taking into account the patient's desire, since it is very common for patients to desire to finish the process as soon as possible. If watchful waiting is not effective or the clinical situation requires it, surgical removal of the remains products of conception by hysteroscopy would be indicated as the technique of first option. There is no consensus on the need for antibiotic treatment.

Of great interest were the "practical" symposiums where each speaker shared their experience using HTRS in the treatment of RPOC. The keys to the RPOC morcellation technique were described, the most important being to start the morcellation in the area opposite to the base, so that bleeding interferes as little as possible. The bleeding that occurs is self-limited and stops when the resection of the remains is completed. The three leading companies were represented at these symposiums: Medtronic, Hologic and Storz with their respective Truclear, Myosure and Bigatti systems, all showing a great result. It can be said that the Truclear, being a morcellator for low-density tissue, offers great safety but may have limitations if the RPOCs are larger or vascularized. As for the Myosure, it has great morcellation capacity and speed that will be very useful in the case of larger and vascularization RPOC, but due to its dense tissue morcellation capacity, it is necessary to be cautious during the learning curve. As for the Bigatti, it is the only one that has a reusable blade, also allowing the use of mini laparoscopic instruments (3 mm) through the operative channel.

Regarding the management of missed abortions of less than 10 weeks of gestational age, it was commented that curettage is frequently performed despite the possibility of expectant management or medical treatment, with the result of unnecessary curettage, and that if curettage is performed, it is advisable to do it under ultrasound guide, avoiding to "scratching". Regarding uterine perform evacuation in first-trimester abortions using HTRS, it seems to be a safe and feasible option in selected cases, such as patients with previous uterine surgery (myomectomy, metroplasty) or patients with repeated abortions. The hysteroscopic approach makes it possible to precisely locate the insertion of the gestational sac and evaluate possible anomalies in the implantation area (uterine malformation, adenomyosis, endometritis) in patients with recurrent miscarriages. Finally, approach the endoscopic allows hysteroembryoscopy to be performed before uterine evacuation and more accurately than curettage to study the fetal karyotype with low maternal contamination.

In the conclusions section, it was highlighted that despite the existing technology, training and evidence supporting the use of intrauterine surgical procedures under direct vision, blind procedures are still widely used.

Recommendations for the use of instruments "under direct visualization", when the technology is available, are shown below:

1. Level of evidence "I" with Grade of recommendation B => Endometrial biopsy

2. Level of evidence "I" with Grade of recommendation A => Treatment of RPOC

3. Level of evidence "II" with Grade of recommendation B => Diagnosis and treatment of MAS

4. Level of evidence "I" with Grade of recommendation A => Diagnosis and treatment of polyps

5. Level of evidence "II" with Grade of recommendation B => Diagnosis of thickened endometrium

6. Slight evidence "V" with Grade of recommendation D => Missed abortion until 10 weeks of gestational age. More studies are necessary

7. No evidence for pregnancy termination of pregnancy during the first trimester



For this reason, members of the three societies that lead the field of intrauterine endoscopic surgery (GCH, AAGL and ESGE), based on the existing levels of evidence, wish to promulgate a declaration of intent document in favor of performing procedures under direct visualization when the evidence supports it.

These members commit to continue working to achieve a unified consensus document with the clinical practice guidelines and to publish it.

Declaration of Intentions Document:

As members of the GCH, AAGL and ESGE:

We believe that when:

1. the level of published evidence shows superiority of the use of procedures under direct visualization and

2. the technology is available,

blind intrauterine procedures, both for diagnosis and treatment, should be avoided.

"The Beginning to the End of Blind Intrauterine Evaluation" A Manifesto for Change

Prof. Linda D. Bradley, Cleveland Clinic. USA

Hysteroscopy Newsletter Vol 8 Issue 3



What can I say about the Global Congress of Hysteroscopy, held in sunny Malaga, Spain in May 2022? It was pure "edutainment"--educational and entertaining, but packed with dozens of evidence-based lectures, debates, award winning videos, and robust discussions. Conversations lingered into the exhibit halls and over glasses of wine.

My keynote lecture was entitled, "My Hysteroscope Is My Stethoscope for Evaluating Intrauterine Health." However, after attending the meeting and listening to myriad evidence-based lectures from astute gynecologists globally, who deftly decried and urged the audience to radically change their techniques and include hysteroscopy when indicated --I would more aptly entitle my lecture, "The Beginning to the End of Blind Intrauterine Evaluation"---A Manifesto for Change." This was the theme of the entire meeting.

It has been more than 153 years since Pantaleoni performed the first diagnostic hysteroscopy in 1869. For the past century, blind dilation and curettage (D&C) has been the mainstay of endometrial cavity evaluation and surgery. Despite the low sensitivity for detecting focal pathology, lack of confirmation that lesions are completely excised, and risk of uterine perforation without visualization, D&C remains widely used for diagnostic and therapeutic purposes. It has under-treated women, many missed pathology. and overwhelmingly misleads our patients understanding of what is wrong with them.

It is incredulous that practicing gynecologists still evaluate intrauterine health blindly. We have been miseducated for so long. It is incredibly cruel to perform a dilation and curettage to "scrape the endometrial cavity until it cries." Today, there is no justification for blind sampling or blind surgical acrobatic techniques for removing intracavitary pathology. In a single glance, our eyes can focus light and send visual information to our brain. We can see depth, color, movement thus adding exceptional benefits to evaluate intrauterine health. Surgeons aren't blind.



Let's use our eyes. Let's use our hysteroscope. Looking within the uterine cavity is imperative to accurate and timely diagnosis and improving patient outcomes.

Modern hysteroscopic technology has patient comfort, improved safety, and miniaturized hysteroscopes permit both diagnostic and small operative procedures in the office to evaluate endometrial health. Additionally, hysteroscopy improves patient care by minimizing financial and logistical barriers, aiding in streamlining diagnosis and treatment planning, and importantly averting unnecessary operative procedures in the operating room under anesthesia.

Office hysteroscopy is a simple, safe, and cost-effective modality for optimizing gynecologic care for our patients.

We boldly proclaim that performing hysteroscopy is a radical act. An act that needs to be disseminated is worldwide. Less blind sampling—more direct visualize must be our goal.

Our three societies, ESGE, AAGL and GCH announced our intention to eradicate blind evaluation of the endometrial cavity by signing a consensus document to end blind sampling. Our lofty goal is to provide an evidencebased guideline document to assist gynecologists in evaluating the intrauterine cavity.

With fervor, we look forward to further study and publications as well as new applications for diagnostic and operative hysteroscopy. We zealously embrace direct inspection and uninterrupted visualization via hysteroscopy and visually directed curettage should be our goal. Join us, as we wholeheartedly embrace, panoramic views, and myriad colors by peering into the miraculous and ever-changing vistas of the uterine cavity.

As gynecologists, our hysteroscope is our stethoscope for evaluating intrauterine health. We, the members of the GCH advocate for universal education in the safe and effective use of office and operative hysteroscopy. Training and education are also essential components of maintaining and increasing access.

As my favorite poet Maya Angelou poignantly says, "When you know better, you do better."

Hysteroscopy is better than blind sampling and better than blind intrauterine surgery. Seeing is believing. Let's start doing better for the women we evaluate and treat.

Hysteroscopic endometrial biopsy:

when and how?

Prof. Grigoris Grimbizis, Aristotle University of Thessaloniki, Greece

Hysteroscopy Newsletter Vol 8 Issue 3



Hysteroscopy revolutionize our approach of the previously "unknown" endometrial cavity giving us the opportunity of its visual estimation as well as guided treatment interventions. It became obvious that, with its introduction, new treatment modalities like hysteroscopic removal of submucous myomas, septum resection and lysis of intrauterine adhesions added in our armentarium.

It is quite strange that despite the obvious advantage of hysteroscopic visualization and the office setting of the procedure, blind biopsy of the endometrium is still in practice. In this transition period, evidence-based proofs of the comparative advantages of hysteroscopic endometrial biopsy are important; when and how it should be applied? Looking to the indications, it seems that there are three distinct groups of patients that potentially might benefit from hysteroscopic endometrial biopsy: (1) infertile, (2) women with abnormal uterine bleeding and (3) those suspected or having endometrial hyperplasia and / or endometrial cancer.

Although ultrasound is quite useful in the evaluation of endometrial environment of infertile patients, especially in experts hands, it is generally accepted that ultrasound examination has an accuracy of <98%; thus, there is always a minority of patients with a missing pathology compared to hysteroscopy. Furthermore, treatment of patients with infertility, recurrent implantation failures or pregnancy losses, having chronic endometritis hysteroscopic guided in endometrial specimens, is associated with higher live birth rates. Patients with recurrent implantation be benefitted failures might also by hysteroscopic scratching, although further evidence is needed. It seems, therefore, that represents one of the main infertility indications of hysteroscopic endometrial evaluation and biopsy, although its routine application was questioned in some prospective studies.

Patients with abnormal uterine bleeding are "classic" candidates for endometrial biopsy being, even today, one of the main indications for curettage. The introduction of ultrasound made possible the non-invasive diagnosis of endometrial lesions related to abnormal uterine bleeding like polyps and submucous myomas. However, their treatment and final histological diagnosis as well as differential diagnosis between polypoid adenomyomas and polyps is only feasible only after their hysteroscopic treatment; it should be noted that atypical polypoid adenomyomas are related to endometrial cancer and deserves special hysteroscopic management. Exclusion of premalignant and malignant endometrial lesions is also very important in patients with abnormal uterine bleeding and, although, their prevalence is higher in postmenopausal women, there is no actual age cut-of. It seems, therefore, that abnormal uterine bleeding is an absolute indication for visual hysteroscopic biopsy.

Coming more specifically to endometrial hyperplasia and cancer, the sensitivity of blind endometrial sampling is lower than previously thought. On the other hand, as hysteroscopy alone is a subjective diagnostic test and its result depends on the experience, the knowledge and the capability of the performing physician, endometrial hysteroscopic biopsies in all the women for whom the hysteroscopic vision suspects such pathologies seems to be necessary. Thus, suspicion of hyperplasia and / or cancer seems to be an indication for visual endometrial exploration and biopsy.



Advances in the field of instrumentation provide, nowadays, various minimally invasive options, most of them giving the opportunity to perform hysteroscopy in an outpatient setting. Actually, three different types of instruments are available: (1) mechanical energy forceps and scissors, (2) bipolar energy instruments, and (3) mechanical tissue removing systems.

Concerning the mechanical energy instruments, snake and alligator hysteroscopic forceps may be considered the first choice to perform an endometrial biopsy. Furthermore, preoperative hysteroscopic quided endometrial biopsy with alligator forceps provides a more accurate diagnosis of endometrial cancer histology type and tumor grade for endometrioid types compared to blind endometrial biopsy with the Novak curette.

Chip biopsy is feasible with the use of bipolar needle. Hysteroscopic resection with bipolar resectoscope in cases of early stages endometrial cancer might place a crucial role in the conservative management of patients wishing to preserve their fertility potential: the NEMos (neoplasia endometrium myometrium organized sections) hysteroscopic resection technique seems to represent a promising approach in those cases. However, apart from the conservative treatment of early stages endometrial cancer, a potential future application might be the staging of those patients to examine the infiltration of the myometrium and extend of the lesion. addition hysteroscopic Furthermore, of resectoscope directed biopsy might improve diagnosis when preoperative outpatient endometrial sampling identifies atypical hyperplasia or is insufficient for explicit diagnosis of tumor type and grade.

Mechanical tissue removal instruments seem to simplify the visual hysteroscopic treatment of endometrial lesions; and obvious advantage of these systems is that they reduce the skills needed by the operator to perform the lesion excision.

Thus, it is noteworthy to conclude that hysteroscopic guided endometrial biopsy has, nowadays, a clear evidence-based place in the investigation of women with infertility, abnormal uterine bleeding as well as endometrial hyperplasia and cancer. Blind techniques are of significantly lower accuracy and should be abandoned. Hysteroscopic guided endometrial biopsy could be done by different options. Mechanical energy instruments might be used; grasping and snake forceps seems to be more accurate. Bipolar energy instruments are another alternative; resectoscopic chips using the NEMos technique are indicated for management of cases with endometrial hyperplasia and cancer. Mechanical tissue removal instruments seem to simplify significantly the treatment of endometrial lesions.

Tissue Removal Systems for Biopsy

Dr. Attilio di Spiezio Sardo & Alessandra Gallo, University of Naples Federico II, Italy



Blind Dilatation and Curettage (D&C) has long been considered the gold standard procedure for obtaining endometrial samples for histologic analysis, although its wellrecognized deficiencies. Extensive literature support that performing blind procedures does not ensure adequate, representative sampling of the endometrial cavity, missing nearly 10% of endometrial cancer, resulting in falsenegative diagnoses. Hysteroscopic endometrial sampling with direct visualization of the endometrial cavity, represents an alternative to replace blind D&C, allowing direct visualization of the lesions allowing the collection of targeted biopsies. In case of endometrial malignancy, this technique has shown to achieve a high concordance of Hysteroscopy Newsletter Vol 8 Issue 3

histologic type and tumor grade, especially in presence of an endometrioid-type tumor ^[1].

With the increased availability of miniaturized instruments, hysteroscopic targeted biopsy has several features that have made it the new gold standard technique for the evaluation and management of patients with intrauterine pathology, replacing D&C. blind Hysteroscopy, being able to be performed in an office setting as a "Walk-In/Walk-Out" procedure, avoids the need of the operating use of medication and/or room. the anesthesia, allows direct visualization of lesions with targeted biopsies using 5Fr. instruments. Moreover, endometrial biopsy using the "grasp" technique has replaced the traditional hysteroscopic "punch" biopsy, as it allows a larger portion of endometrial tissue to be excised; it also allows to perform a biopsy in case of presence of Intra Uterine System (IUS), that can remain in place during the procedure^[2].

Where the area to be biopsied is noted to be hypo/atrophic, 5-Fr scissors can be used to collect adequate tissue samples that are then removed with the grasping forceps. But 5-Fr instruments have some weaknesses, such as their fragility that cause them to easily break, the need of surgical skills to get adequate sample and the need of "in and out of the uterus" movements to retrieve the tissue. 15 Fr bipolar office resectoscope, with a cutting loop, overcome these limitations to some extent. It provides large amount of tissue even from atrophic endometrium, from the subendometrial layer or from the endocervical canal, when needed; thanks to its diameter it doesn't require cervical dilatation and, owing to its ergonomic design and the optimally angle loop electrode, it is well-suited for tissue cutting with bipolar energy. However, it also requires surgical skills, it may cause pain and it has the disadvantages linked to use of



electrosurgery. Limits related to hysteroscopic use of electrosurgery include issues related to gas bubbles, thermal damage of healthy endometrium or myometrium, or even of the quality of the histologic specimen due to thermal damage.

But limits need to be overcome and innovation comes from going beyond the Hysteroscopic Tissue limits. Removal Systems (HTRS) have emerged as a new tool for mechanically collect targeted and larger amount of endometrial tissue. HTRS have several advantages such as reduce operating time, simultaneously cutting and suctioning tissue fragments, avoiding the need for multiple removal and insertions of the device into the uterine cavity and maintaining continuous clear view. As their purely mechanic cut. TRS allow complete pathological analysis of aspirated tissue, with adequate quality and without damaging the surrounding healthy endometrium; low risk of perforation and/or of adhesions also come from not using electrosurgery.

Given these characteristics, a new technique named "visual D&C" has been proposed, as a type of atraumatic curettage performed under direct visualization, which obviates the need for using electric energy while offering the added benefit of direct vision of the uterine cavity. Visual D&C combines the advantages of the old D&C technique with the new technology of HTRS.

Most of HTRS have a similar structural design consisting of a power control unit with dedicated software, footswitch, hand piece,

hysteroscope and cutting blades ^[3]. The prerequisite for office use is an outer diameter of not larger than 6 mm, which avoids the need of cervical dilatation and anesthesia or analgesia. Miniaturized scopes such as the TruClear5C hysteroscope of 5.25 mm, the TruClearTM Elite Mini hysteroscope of 6.15 mm, the Omni hysteroscope of 5.5 mm and the mini Bigatti shaver (IBS) of 6.3 mm, are suitable for an office setting use and have shown to be less painful and more acceptable to women for the removal of endometrial lesions in an office setting ^[4].

"Visual D&C" with target sampling could represent a safe and effective technique in case of homogeneously or heterogeneous thickened endometrium, or to provide a diagnosis when neoplasia is suspected. It also represents an alternative for conservative treatment of young patients diagnosed with atypical endometrial hyperplasia/cancer who want to preserve their fertility, although further studies are needed to confirm the feasibility of this indication.

Whether hysteroscopy might increase the dissemination of tumor cells into the peritoneal cavity is an old debate; however, the potential spread of malignant endometrial cells into the peritoneal cavity following diagnostic hysteroscopy has been shown not to alter tumor staging and has not been shown to adversely affect the patient's prognosis ^[5]. Tissue removal devices also do not result in increased dissemination of malignant cells into the peritoneal cavity when used as an initial biopsy method in the diagnosis of endometrial cancer and are not associated with surgical surgical upstaging of patients compared with conventional endometrial biopsy methods ^[6]. It is important to highlight that the FIGO staging system states that the confirmed diagnosis of a positive peritoneal washing does not alter the tumor stage and is recorded separately from the report issued on the staging itself ^[7].



Based on the current data, all commercially available HTRS offer a fast, precise, safe, and cost-effective alternative to conventional hysteroscopic surgery ^[8-11]. HTRS are easy to learn, as they require a shorter and faster learning curve, when compared with bipolar electrical instrumentation. Life-threatening complications such as fluid overload, uterine perforation and bleeding seem to occur less frequently with use of intrauterine morcellation devices. compared with electrocautery resection, although they cannot be eliminated completely^[12].

In our opinion, Visual D&C is gaining an important diagnostic role in collecting endometrial biopsy, overcoming the limits of previously available endometrial biopsy techniques.

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Management of Missed Abortion up to 11 weeks of gestational age

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INTRODUCTION

Spontaneous abortion occurs in approximately 10 to 15% of all pregnancies and is due to multiple factors such as endocrine abnormalities, infectious conditions, metabolic, immunologic, and chromosomal abnormalities (1). Pregnancy loss in infertile patients requires further investigation aiming to determine the cause, allowing appropriate counseling regarding risk of recurrence. Because chromosomal abnormalities account for almost 50% of all miscarriages, obtaining an accurate fetal chromosomal analysis is mandatory for future pregnancy planning.

Transcervical embryofetoscopy involves introducing a hysteroscope into the uterine cavity to identify and enter the gestational sac, enabling visualization of the fetus through the amnion for investigation of anatomic malformations to explain a developmental reason for the pregnancy loss (1, 2). Direct sampling can be performed after anatomic surveillance with the hysteroscope to provide accurate chromosomal analysis of the fetus. The use of suction curettage creates mechanical damage to the tissue as it is removed, and thus anatomic evaluation is compromised without the use of hysteroscopy.

MISSED ABORTION. THE CURRENT APPROACH

EARLY PREGNANCY LOSS (EPL)

Early pregnancy loss (EPL) is defined as a nonviable intrauterine pregnancy diagnosed up to 13 weeks of gestational age. The incidence of EPL is unclear because some losses may occur before the patient knows she is pregnant. In a 1988 study, the incidence of EPL was estimated at 31% and included clinically recognized and unrecognized (identified clinical pregnancies before diagnosis) (3). More recent publications report an incidence of 12.8% to 13.5%; however, this is based on losses in clinically recognized pregnancies only (4, 5). With the avail ability of highly sensitive over-the-counter urine pregnancy tests that allow pregnancy detection before formal clinical diagnosis, the incidence of EPL is likely higher than that published clinically recognized for pregnancies.

Cholkeri-Singh et al (6) reported that the use of hysteroscopy to directly biopsy chorionic villi allowed for significantly improved fetal karyotyping with reduced maternal cell contamination compared with the standard suction dilation and curettage (D&C)



technique. This finding was also reported in previous studies published on incorporating embryofetoscopy for evaluation of fetal demise (7, 8). Fetal karyotyping is important in women experiencing recurrent miscarriage as well as those involved in extensive fertility treatment, because it allows for appropriate genetic counseling and evaluation before pursuing a future pregnancy. Table 1 reports list the incidence of common chromosomal abnormalities seen in patients wirh early pregnancy loss.

Chromosomal	Incidence
Abnormality	
Single autosomal trisomy	64.6
Triploidy	13.1
Monosomy X	10.4
Chromosomal	5.2
rearrangement	
Combination of	4.2
chromosomal abnormalities	
Tetraploidy	1.4
Autosomal monosomy	0.8

With the rise of assisted reproductive technology, the American Society for Reproductive Medicine guideline states that genetic screening may be used for some patients with severe male factor infertility, advanced reproductive age, or recurrent in vitro fertilization failures.

Table 2. Potential complications of blindintrauterine procedures

- Risks of anesthesia (When performed in the operating room under general anesthesia)
- Pain during and after the procedure
- Incomplete procedure. Retained Products of Conception (RPOC)
- Uterine perforation
- Cervical trauma
- Infection
- Intrauterine adhesion formation

Suction curettage evolved by incorporating careful visual separation of the chorionic villi from maternal decidua to reduce maternal cell contamination. However, the incorporation of operative hysteroscopy significantly increases the rate of fetal chromosome detection without significantly increasing surgical complication rates. Ferro et al in 2003 (7) and

Robberecht et al in 2012 (2) had already publish a study highlighting the benefits of incorporating hysteroscopy in the management of patients with EPL. Ferro et al published a case series of 68 women who underwent operative hysteroscopy with direct biopsy of the chorion and amnion, followed immediately by suction curettage. The authors separated the chorionic villi from the curettage specimen sent for analysis independent of direct biopsies.



Total maternal contamination occurred in 1 in 4.5 curettage materials, resulting in possible misdiagnosis in 22.2% of patients if direct biopsy was not performed. The study concluded that direct biopsy is reliable and suitable for analyzing the full karyotype (7). Robberecht et al (2) reported similar findings in 51 women undergoing hysteroscopic directed biopsy of the chorionic villi. The authors concluded that a strength of embryoscopy is its ability to directly biopsy products of conception with fetal origin to reduce maternal contamination.

The greatest debate is over whether chromosomal analysis via conventional karyotype will remain the gold standard approach. Typically, a recently demised embryo or chorionic villi tend to culture well. However, if normal female karyotype is detected, chromosomal microarray analysis can be performed, because it does not require dividing cells and thus is more favorable with demise. Unfortunately, microarray is not readily available or affordable worldwide. The cost for microarray analysis is around \$7000, and it is usually performed only in those cases in which maternal cell contamination may have been the cause of a normal female karyotype result on conventional chromosomal analysis.

Another benefit of embryofetosocpy is the capacity to document embryo morphology. Table 3 list potential benefits of embryofetoscopy.

Table 3. Embryoscopy benefits

- Embryo/fetal anatomy survey
- Patients can see the fetus helping to provide closure
- Selective tissue biopsy
- Selectively oriented suction curettage (only the uterine wall of placental implantation)
- Evaluation of the endometrium/ decidua
- Minimal endometrial trauma

CONCLUSION

Fetal loss can be devastating to couples that are trying to conceive. Patients who suffer the devastating consequences of a pregnancy loss frequently look for answers of the cause of their miscarriages. Early pregnancy loss should be evaluated with embryofetoscopy with direct biopsy of the chorionic villi and/or fetus before suction curettage. This procedure will provide an opportunity for genetic counseling if an abnormal fetal karyotype is found, reducing the risk of a recurrent miscarriage due to the same condition.

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Hysteroscopic Tissue Removal Systems (HTRS) for Missed abortions till 10 weeks

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There is no doubt that Mankind has made amazing strides over the last few decades. We have reached the moon and Mars, the internet superhighway and the smartphone have connected the world in unprecedented ways, surgical robots have been invented, while millions of women continue to receive blind intra-uterine procedures for miscarriage and retained products of conception (RPOC), without any significant improvements since blind Dilation & Curettage (D&C) was first described in the 1840s!

The evidence is abundant that blind D&C provides inadequate assessment of the uterine cavity, leads to Incomplete removal of RPOC, hence leading to reoperations,

increasing the risk of complications, such as uterine perforation and Intra-uterine Adhesions (IUAs) with further detrimental impact on fertility.

Performing these procedures under hysteroscopic visualization offers many advantages over blind evacuation, namely ensuring complete evacuation and avoiding further procedures, hence shortening the time to future conception. Decreasing the rate of IUAs preserves fertility and minimizes the need for subsequent unnecessary procedures to treat the iatrogenic adhesions.

Other benefits of hysteroscopic management of SAB & RPOC is diagnosis of mullerian anomalies such as uterine septum & intrauterine pathology such as polyps, fibroids and adhesions that may have contributed to the miscarriage in the first place, and Their treatment can decrease the risk of future miscarriages.

Hysteroscopy has also been shown to improve the ability to obtain fetal chromosomes for genetic testing, with less maternal chromosomal contamination.



Embryofetoscopy also provides a valuable tool for assessment of morphologic characteristics of genetic disorders that may have contributed to the miscarriage.

It's time to end blind intra-uterine procedures and raise the bar for the millions of women worldwide suffering from miscarriages every year. Hysteroscopic Tissue Removal Systems have revolutionized our ability to treat RPOCs under hysteroscopic guidance.

The hysteroscopy community has gathered in Malaga, Spain to discuss the evidence, and the Global Community of Hysteroscopy (GCH) joined hands with the American Association of Gynecologic Laparoscopists (AAGL) and the European Society of Gynecologic Endoscopy (ESGE) with a strong unified voice, supported by evidence, and signed the "Malaga Document" with an Intention Consensus agreement, aiming to eliminate blind intrauterine procedures. I urge every GYN surgeon to consider hysteroscopy as an option the next time you are caring for a patient with miscarriage or RPOC. Our patients look up to us and entrust us with their care, and it's our obligation to provide them with the best, safest and most effective care we possibly can.

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Retained Products of Conception (RPOC): Indications & Methods

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RPOC is defined as the presence of placental and/or fetal tissue that remains inside the uterus after a spontaneous pregnancy loss (miscarriage), planned pregnancy termination or delivery and it is estimated that it's incidence is approximately 0.5% after first trimester abortions, increasing its incidence as the gestational age of the termination of pregnancy advances.

The symptoms can vary between patients related to the amount of tissue retained, the vascularization of the products and the length of time that has been retained. The main symptom is vaginal bleeding, other frequent symptoms are uterine tenderness, pelvic pain and in cases of infection, fever. As a general rule, the presence of RPOC should be suspected in any case presenting with excessive bleeding that occurs after an abortion, miscarriage or delivery (both vaginal and by cesarean section).

The accurate diagnosis of RPOC represents a challenge since it is considered normal to have some bleeding and discomfort or pain after the termination of a pregnancy, regardless of the week of gestation at which the termination occurs.

Without a doubt, ultrasound is the main imaging modality for the diagnosis of RPOC. The visualization of a mass inside the endometrial cavity is the most important finding in the ultrasonographic diagnosis of RPOC and the absence of debris inside the uterine cavity with the visualization of a thin endometrial stripe excludes this pathology with a predictive value of 100%.

After the delivery of a viable fetus or an abortion, the endometrium undergoes a series of changes that are part of the mechanism of evacuation of the uterus, after this initial period of bleeding, the absence of an intracavitary mass after 8 weeks postpartum or 2 weeks post-abortion, rules out the presence of RPOC while an endometrial thickness greater than 13 mm, is considered as a pathognomonic diagnostic criterion for the ecographic diagnosis of this entity.

Occasionally, the retained products have high vascularization, with the use of Doppler technology this vascularization can be appreciated not only in the retained material but also affecting the implantation area. Some authors argue that the implantation area remains highly vascularized during the postpartum and post-abortion period of uterine involution.

Hysteroscopy is considered the gold standard for the diagnosis of intrauterine pathology including gestational retained products.



The hysteroscopic appearance of this pathology varies depending on the involution, vascularization and the degree of necrosis of the trophoblastic retained tissue, which results in no single hysteroscopic pattern. This is because the retained tisue undergoes a process of involution over time that makes changes in their macroscopic appearance, so it is important to know the different macroscopic aspects that this pathology presents.

The Gutenberg classification correlates the different ultrasound patterns with the hysteroscopic appearance of RPOC, which allows to anticipate the complexity and degree of difficulty that may be encountered at the time of uterine evacuation.

This classification differentiates four ultrasound patterns that are based on retained tissue echogenicity as well as vascularization at both the intracavitary and the myometrial levels. The tissue sonographic appearance can undergo variations over time due to degenerative tissue modifications.

The echographic patterns above referred have а direct correlation with the hysteroscopic view. Thus, the Gutenberg classification also distinguishes 4 hysteroscopic patterns. The hysteroscopic patterns are very diverse and have been classified in 4 types that vary according to the process of involution experienced by the retained products. Except in type 0, in which no known structures are identified, the rest of the types show the presence of identified chorionic villi with different degrees of vascularization.

The definitive diagnosis is established by the identification of chorionic villi in the pathology study of the retained tissue material. These chorionic villi can have a normal structure or present hyaline or necrotic degeneration giving place to the so-called "ghost villi".

The treatment is generally dictated by the patient's hemodynamic condition, the gestational age that resulted in RPOC, the amount of product retained and the experience of the physician dealing with the condition.

Expectant management could be considered in women with RPOC clinically stable with no evidence of infection. The reported success rates range from 50 to 85 percent at one to two weeks of follow-up, and up to 90 percent when subjects are followed for six weeks



Different medical treatments have been described to facilitate the evacuation of RPOC. Misoprostol is one of the most widely used medications and has been shown to be effective in more than 90% of incomplete first trimester abortions. It is reasonable to consider medical management in any stable patient with RPOC.



The physical evacuation of RPOC through the technique of dilatation of the cervical canal and uterine curettage, either with fenestrated sharp curette or by suction with aspiration cannula, continues to be the most widely evacuation method used in clinical practice. Due to the focal nature of the pathology and that uterine curettage is a blind technique, there is risk of incomplete uterine evacuation, which has been reported as high as 20.8% after performing conventional curettage [8] Moreover, this technique, when performed blindly, can produce not only an incomplete evacuation but increases the possibility of injury to surrounding healthy endometrial tissue, performing a uterine curettage can damage the basal layer of the endometrium favoring the development of intrauterine adhesions or even Asherman's syndrome. The incidence of uterine adhesions in women who undergo repeated curettage for the evacuation of RPOC is reported at 40%,

Hysteroscopic evacuation of RPOC is a feasible, safe, and effective technique that prevents injury to surrounding healthv endometrium, which clearly reduces the of complications possibility such as intrauterine adhesion formation or incomplete evacuation of products of conception. There are different tools and techniques for removal of RPOC, their use depends on the availability and physician's experience. Anv hysteroscopic technique is useful for the extraction of intrauterine retained products of conception, although in cases where there is high vascularization, we recommend the use of the resectoscope provided with energy that allows to selectively cauterize the blood vessels when needed. Special care should be taken with Type III RPOC cases, since bleeding can be profuse, increasing the chance of severe complications.

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The Role of Tissue Removal Systems (TRS) in the Treatment of RPOC

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I was very pleased to talk about RPOC in HTRS Malaga as it is currently a hot topic. My personal view is that we should move forward to implicate hysteroscopic operation for retained product of conception instead of blind D&C. Tissue removal systems are revolutionary in the treatment of the RPOC and greatly facilitate RPOC removal. During our recent congress I have presented valuable ideas to consider hysteroscopic approach and the use of the shaver for RPOC treatment.

Further I will explain the way that I manage RPOC and I would like to leave you with one thought, to consider the use of the shaver technique in your clinics in the future. Retained products of conception is a wellknown and common condition where placental or fetal tissue remains inside the uterine cavity after an abortion or termination of pregnancy

It can lead to continuous bleeding, infection and late complications including intra uterine adhesions (IUA's) and infertility

There are certain factors that increase the risk of RPOC, such as uterine anomalies (in 10% of patients with RPOC), the reason being difficulty in evacuating uterine cavity after D+C or abnormal uterine contractility. Previous operations on the uterus including septal resection, intracavitary myomectomies, synechia removal and D+C may all cause abnormal placentation.

Traditionally, D&C is the surgical treatment of choice for RPOC with the associated risks including bleeding, perforation and sequels including IUA's and infertility.

The risk of intra uterine adhesion after D+C is about 30% and the risk increases to around 40% in cases of repeated D+C

Compared to D&C where metal curette is used, hysteroscopic resection seems to be associated with a lower rate of IUA's and a higher pregnancy rate for patients with desire of further pregnancy.



Nowadays a combination of grayscale and color Doppler Ultrasound has become the first line modality for the diagnosis of retained products of conception, allowing assessment of the uterine structures and blood flow with high sensitivity and specificity(Figure 1,2)

Aya Kamaya et al. categorized RPOC into four subtypes from 0 to 3. The degree of vascularity of the endometrial component can be compared with the myometrial vascularity in the same image section to differentiate these 4 sub-types.



Treatment of RPOC can be different depending on the condition of the patient. Such factors as gestational age, the size of retained products of conception, heavy bleeding, asymptomatic or a wish for further pregnancies should be considered.

Expectant management is the first approach for the treatment of RPOC.

The second conservative approach will be the use of uterotonic agents such as misoprostol, usually at a dose of 600 micrograms. The success rate of misoprostol in the first trimester is 84%, compared to 97% for vacuum aspiration.

Almost 80% of patients will respond to the above methods but if they do not, the next step will be surgery.

The most widely used surgical treatment for RPOC is D&C or suction curettage with the associated risks

In most parts of the world, including in developed countries, D&C is the most common procedure for retained products of conception with the associated risks, such as uterine perforation, incomplete removal, infection and intra-uterine adhesions. Intrauterine adhesion is the worst consequence for women who desire further pregnancy.

It is well known that blind procedures such as too aggressive curettage may damage the basal layer of the endometrium which is the regenerative reservoir of the endometrium. During the healing process after D+C there may be fusion between the injured opposing endometrial or myometrial layers and as a consequence partial or complete obliteration of the uterine cavity may result.

The advantages of the hysteroscopic approach in general are well recognized, and also because of direct visualization of the placental remnants, complete removal without damaging the surrounding healthy endometrium, and availability of a specimen for pathologic analysis, this approach is preferable to blind D&C.

Tissue removal systems have been introduced more recently for the management of RPOC.

They come in three types: Truclear, Myosure and IBS. Of these, Myosure and Truclear have disposable blades whereas intra uterine Bigatti shaver (IBS) is totally reusable.

From December 2013 to April 2022, we had 257 patients treated with shaver in our clinic from type 0 to type 3. (Figure 3 to11) Results: The median interval between surgery and the end of pregnancy was 56 days (a range of 15-90 days). The size of placental remnants was between 15 and 30mm. Median fluid deficit [saline solution] was 240 ml. No perforation or postoperative complications occurred. Shaver seems to be an effective and safe instrument for the removal of placental remnants. It allows for short operation time with a high success and low complication rate.



The time period between the end of pregnancy and the removal of RPOC helps with devascularization of RPOC and the implementation area. This is why it is better to wait for 6 to 8 weeks for the hysteroscopic removal of type 2 or 3..

The main advantage of hysteroscopy for RPOC is visualization of the whole cavity and locating the exact place of RPOC, as it is always focal. This method avoids the possible damage to the healthy surrounding endometrium as it always happens with D&C.

Hysteroscopy is a targeted procedure.

Compared with resectoscope, Tissue Removal Systems are much easier to apply and have the same efficiency and efficacy.

The current low level of surgeons' preference for hysteroscopy versus the traditional D+C for RPOC reflects some disadvantages with the current approach, namely resectoscope. Some of these are listed below:

1. Resectoscopy requires skill and has a long learning curve.

2. Abundant bleeding may impair the sight, making the procedure very difficult. In such cases a good irrigation system is crucial to maintain a clear sight of the uterine cavity.

3. In some cases, the resectoscope loop may bend.

4. Before the introduction of the bipolar resectoscope, there had always been concern for fluid overload and water intoxication with hypernatremia.

In order to increase surgeons' adoption of hysteroscopy for RPOC, the new Shaver technique addresses these challenges. method the following advantages are observed:

1. A good visualization of the uterine cavity and the relative intrauterine pathology, through the removal of tissue chips at the same time as the resection. When the resectoscope is used, tissue chips may impair vision. This requires the surgeon to perform repeated in-and-out movements, with a higher risk of perforation and cervical laceration. Once inserted into the uterine cavity, the Shaver is left in place for the entire duration of the procedure.

2. A reduced risk of intravasation due to the use of saline solution, the brevity of the procedure, and a very low fluid deficit.

3. A much more precise and clean surgery due to the good visualization and direct action of the shaver over the pathological tissue. Moreover, the gentle mechanical technique and the blunt tip of the Shaver limits the damage to the healthy surrounding endometrium, leading to a reduced risk of uterine perforation, formation of intrauterine adhesions, and Asherman Syndrome.

4. The possibility to collect all tissues for pathologic examination.

5. A very short learning curve for the Shaver procedure may encourage gynecologists to choose operative hysteroscopy instead of D&C for removing RPOC.

Tissue removal systems are the newer generation of operative hysteroscopy and have the same efficiency and efficacy as the resectoscope for managing RPOC.

In our clinic we employ shaver, as it is totally reusable and affordable for both the hospital and the patients. Different studies have shown that all Tissue Removal Systems are efficient and effective for managing RPOC. However, it is hoped that with the aid of morcellators D&C is abandoned altogether in the near future.

Hysteroscopic Tissue Removal Systems (HTRS) From an Idea to a Reality

Prof. Dr. Mark Hans Emanuel. University Medical Center Utrecht. Nederland



When I was writing my PhD thesis (Abnormal Uterine Bleeding and Submucous Myomas; epidemiology, diagnosis and treatment), which I defended in 1998 at the University of Amsterdam (picture A1 + A2), I realized that something was missing in hysteroscopic surgery. No not a fancy robot, but a more elegant and safer for the patient technology that had to be, easy to handle, easy to use and easy to learn.

At that time we organized 3-day international courses for the Hysteroscopy Training Center in the Spaarne Hospital in Haarlem The Netherlands, directed by the late Kees Wamsteker (our classification of submucous myomas was the basis for the later FIGO PALM-COEIN classification ¹).

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I met many novices in hysteroscopy who were all complaining about the fact that resectoscopy (designed for urology and not for gynecology) was too complicated and too difficult to learn. Nevertheless, there was no alternative at that time, so our courses were welcomed and attracted colleagues from all over the world.

The idea about an alternative for resectoscopy kept me busy and I started to orientate into fields other of endoscopic surgery (ophthalmology, orthopedic surgery, ENT etc.). The idea of mechanical cutting and fragmentation with aspiration and collection of tissue fragments, with the use of saline irrigation and distention of the uterine cavity, was born. At that time just monopolar highfrequency electrodes were available that could only be used with non-conducting electrolyte free fluids which could potentially be harmful the patient in case of extensive to intravasation. Therefore the use of saline for irrigation and distention in major hysteroscopic surgery was very welcome after it had already been introduced in diagnostic hysteroscopy and minimal hysteroscopic surgery with conventional instruments. Furthermore it was



obvious that, as in the latter techniques, the new technique had to be continuous flow at all time.



After building a prototype (picture B) and protecting the intellectual property in a worldwide patent (picture C) Smith and Nephew Endoscopy Inc. in Andover Mass (S&N) was contacted as they were marked leader at that time for similar techniques in orthopedic ENT and surgery. The representatives of the company were very enthousiastic about the ideas, especially when the first patients were treated successfully in Haarlem. At the beginning of this millennium in January 2000 the patent rights were assigned.





to S&N. From that moment on it took a few more years before a full range of versatile instruments (for soft and hard tissue) were developed, FDA approved and launched into the market in 2006

In the meantime the technique was presented at several international scientific meetings, for the first time in Bologna in 2002 at the Annual ESHRE Meeting. A press conference was organized by ESHRE and the technique was revealed to the general public through many articles in public journals (picture D).

The first scientific manuscript was published in 2005 ² (picture E). The products under the brandname TRUCLEAR found their way to the gynecologists especially in the USA but also in the rest of the world. Many more scientific studies were published and presented at international conferences. In 2013 the AAGL rewarded the Birmingham Womens Hospital gynecology team the Golden Hysteroscope Award for their MERT study, a randomized comparison between office use of Truclear and electrosurgery.



After the successful introduction of Truclear the first competitive device with similar technology came on the market in 2011 (Myosure by Hologic Inc.) and in 2012 (IBS by Storz GmbH, not available in the USA). Some people "The interest of other stated: companies has affirmed that this technique is the way of the future ... ". Because of the FDA warning against laparoscopic morcellation in 2014 the technique is called no longer hysteroscopic morcellation but Tissue Removal (Systems or Technology) thereafter. In 2016 Medtronic Inc. acquired the Truclear brand and products. In the last fifteen years it became apparent that the technique has further stimulated and introduced hysteroscopic surgery into the general gynecological practice of minimal access surgery and this is in the interest of all our patients. I am very happy that the GCH organized the first world congress about HTRS that took place in the wonderful atmosphere of Malaga in Spain last month.



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An insight on the Tissue Removal Systems Technology

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In last years, scientific evidence provided that mechanical hysteroscopic tissue removal (mHTR) systems are a safe and effective alternative to conventional resectoscopy to treat endometrial polyp, uterine myomas, removal of placental remnants and to perform targeted endometrial biopsy under direct visualization (visual D&C).

In 1998, Dr Mark Hans Emanuel, a gynecologist from Utrecht, Netherland, created, with the support of Smith and Nephew, Andover Ma, the first generation of this innovative technology that uses mechanical energy to simultaneously cut and remove the tissue.

Since then, additional mHTR systems have become available: TruClear[®] (Medtronic, Dublin, Ireland), MyoSure[®] (Hologic, Marlborough, Ma, USA) and Integrated Bigatti Shaver[®] (Karl Storz, Tüttlingen, Germany. An Hysteroscopy Newsletter Vol 8 Issue 3

innovative hybrid system the Symphion[™] (Minerva Surgical Inc, Santa Clara, CA, USA) which offers automatic aspiration of tissue fragments resected with bipolar radiofrequency through a self-contained, recirculating fluid management system has also become available. Lastly, a new disposable system Aveta[®] (Meditrina, Inc., San José, CA, USA) with high-speed mechanical oscillation mechanism, received 510(k) premarket notification in May 2020.

Most of mHTR systems have a similar structural design consisting of a power control unit with dedicated software, footswitch, hand piece, hysteroscope and cutting blades.

Power Control Unit

Power Control Unit (PCU) provides an appropriate speed for cutting based on a preset program or modifiable by the operator. The PCU, is connected to the blade via a flexible drive cable, having the capacity to rotate and reciprocate the blade at an adjustable speed that is measured in revolution per minute (rpm). A digital display of the Control Unit shows the function mode (oscillation and reciprocation), speed (rpm) and surgical time corresponding to the blade working time. An electric motor is located inside the PCU or in the hand-piece . A foot pedal activates the motor that drives the blade inside the hysteroscope.

Footswitch

The foot pedal controls activation and deactivation of the motor which powers the cutting action of the blade. Depending on the different model, the footswitch allows presetting the mode of function of the blade (oscillation, rotation, rotation or with reciprocation) automatically or with а dedicated button.

Moreover, the foot pedal actives the aspiration

from the window blade or helps to set, before starting the procedure, the blade window in the closed position (window lock): pressing a dedicated button, the inner blade slowly turns until the window is closed.

Hand-piece

The hand-piece drives surgical blades and provides, in some system, manual control of the suction flow. Since the blade is placed in the operative channel of the dedicated hysteroscope, it is recommended that the handpiece should be held with the dominant hand ("pistol grip"). The connecting suction device is used to simultaneously retrieve the chips out of uterine cavity during the procedure.

Hysteroscope

There actually a wide range size of rigid hysteroscopes with a straight working channel for blades and with rod lenses for visualization, only the smallest size one utilizes fibers. The majority of hysteroscopes are with a continuous flow or with a hybrid system because the outflow drains through the window only when the blade is activated. Inflow comes around the device through the working channel or there is dedicated inflow channel

The scopes are compatible with a customdesigned or generic fluid management systems.

Shaver blades

Different diameter motorized reusable or disposable blades with wide range of windows sizes have been developed by the different companies. All blades access the uterine cavity through a straight working channel of the dedicated hysteroscope. The blade consists of an outer hollow sheath and an inner hollow rotating/cannula with corresponding windows for simultaneous suction and cutting. The inner tubes create negative pressure and absorb the tissue in proximity to the windows.

Therefore, the blade cutting capacity is linked to a vacuum source which grips the pathology towards the window and aspirates resected tissue and to the speed that needs to leave enough time for tissue fragments to enter. The blade is connected to the hand-



piece and also to a vacuum source which aspirates resected tissue through a sidefacing cutting window in the device's outer tube. Distension fluid and resected tissue are transported from the blade window to a tissue trap and vacuum canister via a tube protruding from the proximal end of hand piece.

Recently, two manual HTR devices MyoSure Manual[®] (Hologic, Marlborough, Ma, USA) and ResectrTM Tissue Resection (Boston Scientific, USA) have become available. Manual control enables physicians to perform tissue resection by squeezing and releasing the handle with their finger.

Irrigation and suction system

Normal saline solution is the most commonly used distension media with mHTR systems. Since an accurate control of intracavitary pressure and fluid balance is crucial to minimize the risk of fluid intravasation syndrome and to allow an adequate visualization of the intrauterine cavity during the procedure, the saline solution must be delivered using an electronically controlled irrigation pump and suction device system.

Therefore, common to every mHTR systems is the use of automated fluid management systems that continuously measure the distending media input and output, the intrauterine pressure, and the fluid deficit volume.

Moreover, an integrated vacuum suction provides a negative pressure through the central cylinder of the blade and brings the tissue fragments into the cutting window. As the blade rotates, the tissue is cut, and is instantly aspirated through the central tube and is collected in a suction trap.

Hysteroscopic Tissue Retrieval Systems (HTRS) Are all the Needs Covered?

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Hysteroscopy Newsletter Vol 8 Issue 3



The importance of performing intrauterine procedures under direct visualization makes sense and it is easy to understand, the evidence that accumulates demonstrates its superiority over blind intrauterine procedures. The tissue retrieval systems or intrauterine morcellators are here to stay and with them a great enthusiasm of the gynaecologic community.

The question to ask would be: has current technology managed to meet our needs as surgeons of the uterine cavity?

In November 2021, the annual congress of the AAGL took place in Austin, Texas. During the conference, Linda Bradley (AAGL Medical Director) told me "Resectoscopy is dying in America". Impressive and disconcerting phrase but when entering the exhibition area of the companies what is striking is the number of companies that offer devices designed for the extraction of tissues from the uterine cavity, I could see at least 6 different companies offering these devices.

Then I understood what Linda meant when she said, resectoscopy is disappearing in the US, since compared to HTRS the learning curve is longer, the required skill level to use it safely is higher and they have a higher rate of complications.

Along with this technological issue, another event changed the landscape of hysteroscopy in the United States. In 2017 the medical realized companies insurance that procedure performed outside the operating room (in the office setting) is cheaper and change the reimbursement of hysteroscopic procedures performed in office increasing by 237%. Currently, physician reimbursement of an in office hysteroscopic procedure is 4 times higher than a myomectomy and 5 times more than an endometrial ablation performed in the operative room. This financial incentive, along with other factors caused that in 2018 more than half a million procedures were performed in office. But the USA does not have a tradition of in office hysteroscopy or "see & treat" hence there is a great demand for training but little capacity to train.



HTRS are a legacy of orthopaedics shavers, publications of their use date back to the 80s. In 1999, Mark Hans Emanuel filed a

	Truclear™ 8.0 System FDA 2005	Integrated Bigatti Shaver (IBS) FDA 2012 2018	Myosure System FDA 2009	Truclear 5C System FDA 2012	Synphion System FDA 2014	TruClear Elite FDA 2008	Omni Hysteroscope FDA 2018
Manufacturer	Smith &Nephew (Medtronic)	Storz	Hologic	Medtronic	Boston Scien- tific Minerva Sur- gical	Medtronic	Hologic
Hysteroscope							
Diameter (mm)	9.0	6.3	7.25 6.25	5.25	6.3	7.25 6.0	6.0 5.5
w/o outflow sheet (mm)	8.0		7.25 6.25	5.6		7.25 6.0	6.0 5.5
Optic Size (mm)	3.5	6.3	2.0	0.8	6.3	1.9	2.0
Optic System	ROD Lens	ROD Lens	ROD Lens	Fiberoptic	ROD Lens	ROD Lens	ROD Lens
Optic Device	0°	6°	0°	0°	0°	0°	0°
Cutting Device							
Outer Diameter (mm)	4.0 Disposable	4.5 Reusable	3.0 4.0 Disposable	2.9 Disposable	3.6 Disposable	4.0 2.9 Disposable	3.0 4.0 Disposable
Action	Rot/Recip	Rotation	Simoul- taneous Rot/Recip	Rot/Recip	RF bipolar plasma resec- tion	Rot/Recip	Simoul- taneous Rot/Recip
Window closure	Operator to set	Automatic	Automatic	Operator to set	Automatic	Operator to set	Automatic
Mm: Millimeters; w/o: without; Rot: Rotation; Recip: Reciprocation; RF: radiofrequency							

patent for a shaver adapted for use in hysteroscopy, the first HTRS, which was launched on the market in in 2005. Since then, in addition to the Truclear, the Myosure and the Bigatti shaver others such as Symphion or Aveta have come out.

The design is such that an optic is created around the HTRS, increasing the external diameter. In this way, the system has an external diameter that varies between 5.5mm and 8mm with a working window of 2.9 to 4.5mm.

The working "window" is at times too small for certain pathologies, limiting the use of these systems. It is possible that the design required is that of a system that meets the needs of surgeons and create an optical system adapted to it. There are currently available 1mm diameter optical fibers with a viewing depth of 3cm that could be utilized in these systems. The characteristics of the current HTRS make them limited in cases such as:

Endometrial biopsy – HTRSs have a very high cost to perform an endometrial biopsy, which is the most common procedure performed by gynecologists. Even the current systems adapted to the 5Fr working channel of our hysteroscope, such as the Myosure Manual is costly. It is necessary to create a low-cost device designed for biopsies as part of the diagnosis of intrauterine pathology.

High-consistency tissue such as fibroids, especially G2 – the current HTRS have limitations in this type of pathology, with the disadvantage of needing a long time to excise the pathology, generating the risk of fluid overload.

Missed abortion – the works carried out to date express difficulty to obtain an adequate visualization due to bleeding and the long time required to complete the procedure. A different HTRS design is needed that is adapted to the needs of this procedure, since the alternative is to perform a sharp curettage with all that this entails in terms of complications and the possible deleterious impact on future fertility.



The impression that a "short learning curve" is needed to safely use HTRS- this message is dangerous as it confers a false sense of security. In expert hysteroscopic hands it really is a short curve but in inexperienced hands it could be a dangerous tool. The FDA database of reported complications MAUDE reports these complications. (See table) Another consequence of the adoption of HTRS is that resectoscopic surgical skills are neglected, and little by little, surgeons will no longer have resectoscopic skills needed to treat more complex problems such as a dysmorphic uterus that cannot by treated with HTRS.

Journal of Minimally Invasive Gynecology, Vol 22, No 1, January 2015





Original Article

Hysteroscopic Morcellation: Review of the Manufacturer and User Facility Device Experience (MAUDE) Database

Karina Haber, MD*, Eleanor Hawkins, MD, Mark Levie, MD, and Scott Chudnoff, MD

Table 2

Adverse events by complication and manufacturer

	TRUCLEAR	MyoSure
Major complications	6	31
Death	0	2
Bowel injury	3	9
Intensive care unit admission	1	13
Hysterectomy	1	5
Unknown cause of admission	1	2
Minor complications	17	65
Uncomplicated fluid overload	1	18
Pelvic infection	0	4
Uterine perforation	6	22
Postoperative bleeding, controlled	1	5
Device failure	9	16

The cost of the procedure - this represents a huge barrier depending on the country and the reimbursement per procedure. It limits the expansion of a necessary technology that is currently being used only in the US and in some European countries that represent less than 10% of the world's population.

In conclusion, HTRSs still have limitations due to design and cost, but they are here to stay, and their use will become popular in the future. These systems simplify the treatment of intrauterine pathology, especially in office procedures due to the ease of use and the speed of action. But even so, there is still room for design improvements and lower cost to make them a global phenomenon.

Consensus Intentions Document on Blind Intrauterine Procedures

GCH, AAGL and ESGE

Hysteroscopy Newsletter Vol 8 Issue 3

INTRODUCTION

1- The blind access to the uterine cavity for diagnosis and treatment of intrauterine pathologies has been the gold standard till the last decade of the 20th century

2- Although ultrasound guidance introduced some improvements in the safety of blind procedures, it is not a substitute for direct visualization

3- Dilation and Curettage (D&C) is a blind procedure introduced in 1846 with little improvement and/or modifications since then. It still being use both for diagnosis and treatment of intrauterine pathologies

4- Blind biopsies of the endometrium are still widely use globally for diagnosis of endometrial pathologies. Pippelle, Novak and other systems are being use for that purpose

5- Since the introduction of the diagnostic hysteroscope in 1980, we have witnessed rapid advances in the optics, producing diagnostic hysteroscopy devices with very small diameters, offering excellent resolution and magnification

6- During the last decade of the 20th century another major improvement was introduce with the "See & Treat" philosophy, thanks to the possibility of using various types of devices/energies through small diameter hysteroscopes; this concept allowed visuallyguided endometrial biopsies and the ability to treat various pathologies under direct visualization, both in the OR and the Office settings

7- The most recent innovation in the field of the Intrauterine surgery was the introduction of Hysteroscopic Tissue Removal Systems (HTRS). This technology is design to extract tissue from the intrauterine cavity under direct visualization in a efficient and reliable manner

RATIONALE

In spite of the widely available technology, education, and evidence supporting the performance of intrauterine surgical procedures under direct, blind procedures are still being performed widely, the same regarding endometrial biopsies

The procedures that are still being carried out by Dilation and Curettage (D&C) are:

- a. Endometrial Biopsies in cases of thick endometrium or Post-Menopausal Bleeding
- b. Treatment of Retained Products of Conception
- c. Evacuation of first trimester missed abortions
- d. First trimester termination of pregnancy
- e. Diagnosis and treatment of heavy menstrual bleeding
- f. Treatment of endometrial polyps
- g. Diagnosis in cases of Thick Endometrium

There is strong evidence in favour of performing the procedures under direct visualization in some of the cases, promising results in some and a lack of evidence in others.

Members of the 3 leading societies in the field of Intrauterine Endoscopy Surgery (GCH, AAGL and ESGE), based on the existing levels of evidence would like the signed Intentions Documents to support the performance of procedures under direct visualization when supported by the evidence



CURRENT RECOMENDATIONS

- 1- Endometrial Biopsies should be performed under direct visualization Level of evidence: I / Level of recommendation: Grade B
- 2- Treatment of **Retained Products of Conception** (RPOC) should be performed under direct visualization

Level of evidence: I / Level of recommendation: Grade A

3- Diagnosis and treatment of **heavy menstrual bleeding** should be performed under direct visualization

Level of evidence: II / Level of recommendation: Grade B

- 4- Diagnosis and treatment of **endometrial polyps** should be performed under direct visualization Level of evidence: I / Level of recommendation: Grade A
- 5- Diagnosis and treatment of **thick endometrium** should be performed under direct visualization Level of evidence: II / Level of recommendation: Grade B
- 6- Treatment **missed abortions till 10 weeks** under direct visualization is only supported by low quality data showing some promising results, more well-designed studies are needed in order to conclude whether direct visualization is superior to traditional blind procedures *Level of evidence: V / Level of recommendation: Grade D*
- 7- There is no evidence regarding the use of direct visualization systems in cases of first trimester termination of pregnancies

GCH, AAGL and ESGE:

We believed that when:

- 1. the level of published evidence shows the superiority of direct visualization procedures and
 - 2. technology is available,

blind intrauterine procedures, both for diagnostic and therapeutic purposes, should be avoided.

HTRS: TECHNOLOGICAL REVOLUTION IN HYSTEROSCOPY FIRST STEPS FOR THE END OF BLIND PROCEDURES



SPAIN 2022

Málaga | Thu & Fri 26-27 May 2022 International Congress including the signature of a Consensus Statement of Intentions