**Hysteroscopic septum resection and reproductive medicine: A SWOT analysis**

**BIOGRAPHY**

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**KEY MESSAGE**

No solid published evidence supports uterine resection in women with septate uterus; however, clinical studies suggest improved reproductive outcomes after uterine septum resection. Data in favour of the intervention are based on studies with important methodological limitations. Clinicians and patients should make treatment decisions together.

**ABSTRACT**

Hysteroscopic septum resection in women with unfavourable reproductive and clinical outcomes has become common practice worldwide to improve reproductive results. No clear evidence on the possible advantages and drawbacks of this procedure has been published. In this opinion paper, based on a SWOT (strengths, weaknesses, opportunities, threats) analysis, the different aspects of this strategy are evaluated. Currently, no level 1 published evidence supports uterine resection in women with septate uterus. Clinical evidence from the studies analysed matches the more recent guidelines and suggests an improvement in reproductive outcomes after hysteroscopic resection of the septum, particularly in infertile women and women who have experienced recurrent miscarriages. In a patient with no history of infertility or prior pregnancy loss, it may be reasonable to consider septum incision after counselling about the potential risks and benefits of the procedure. Published clinical data in favour of the intervention, however, are based on studies with important methodological limitations. In this situation, the clinician and patient should reach an agreement together, based on the pros and cons of this intervention. Well-designed randomized controlled trials are required to confirm the clinical benefits and cost-effectiveness of this procedure.

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**KEYWORDS**

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Spontaneous abortion
INTRODUCTION

Septate uterus is the most common congenital uterine anomaly, accounting for 35% of all identified uterine anomalies (Chan et al., 2011). According to the new European Society of Human Reproduction and Embryology (ESHRE) and European Society for Gynaecological Endoscopy (ESGE) classification system of female genital anomalies, a septate uterus is defined as a uterus with a normal outline and an internal indentation (septum), at the fundal midline, exceeding 50% of the uterine wall thickness (Grimbizis et al., 2013).

Septate uterus has been associated with reduced fertility, increased miscarriage rates, increased preterm births, malpresentation at delivery and intrauterine growth retardation (Chan et al., 2011; Venetis et al., 2014). The pathophysiology of these poor reproductive outcomes is unknown, and it is unclear whether restoring normal anatomy also restores normal function, thereby improving fertility outcomes in women who wish to conceive.

Initially, the uterine septum was resected by a laparotomic hysterotomy (Paridisi et al., 2014); however, since the introduction of hysteroscopic septum resection in 1970 (Edström et al., 1970), this approach is considered first-line therapy. Despite some possible complications of a hysteroscopic septum resection, such as perforation of the uterus, bleeding, postoperative intrauterine adhesions and uterine rupture in subsequent pregnancies (Valle et al., 2013), it is common practice worldwide to improve reproductive outcomes (Paridisi et al., 2014).

Nevertheless, this procedure is assumed to be effective based only on non-randomized and mainly retrospective cohort studies (Rikken et al., 2017). Most of these studies have a high risk of bias owing to their before and after design, with the same group of women serving as trial and control, given that before and after comparison studies will always favour the intervention (Mostenbroek et al., 2006) and the prognosis without the surgical procedure is usually good (Christiansen et al., 2005).

Moreover, a publication bias seems to exist, as studies with positive pregnancy outcomes are more frequently published. Consequently, we are currently unaware of whether a septum resection may increase the chances of a live birth and whether this outweighs the possible complications of the procedure. Second, data comparing the costs of metroplasty versus expectant management are scarce, and different aspects related to the application of this procedure need to be assessed (Table 1) to shed light on the current role of septate uterus resection in reproductive performance.

Therefore, as no solid medical evidence exists, we conducted the following SWOT (strengths, weaknesses, opportunities, threats) analysis to assess the available published evidence on the possible recommendation of septum resection for women of reproductive age with a septate uterus.

STRENGTHS

Septum resection improves fertility

Most studies suggest that a uterine septum resection leads to improved spontaneous pregnancy rates in infertile women (Saygili-Yilmaz et al., 2003; Mollo et al., 2009; Shokeir et al., 2011; Bendifallah et al., 2013; Esmacizadeh et al., 2014) and in women who have experienced recurrent spontaneous miscarriage (Karnayos et al., 2006; Pang et al., 2011). Specifically, Mollo et al. (2009) conducted a prospective controlled trial that stratified their population into women affected by septate uterus and otherwise unexplained infertility and women with unexplained infertility (control group). They showed that the probability of a pregnancy was significantly higher in patients who had undergone metroplasty than in those with unexplained infertility. When the potential benefit of a hysteroscopic treatment of uterine septa on pregnancy rates is evaluated by analysing only parallel comparative studies, a small improvement that was not statistically significant was found, particularly in the group of infertile patients (Venetis et al., 2014). For patients with septate uterus with no history of adverse reproductive outcomes, some investigators support the use of hysteroscopic resection (Grimbizis et al., 1998; Jurkovic et al., 2007), whereas others do not (Corson et al., 1992).

Two systematic reviews (with a pooled analysis) and a meta-analysis (Hommer et al., 2000; Noun et al., 2010; Valle et al., 2013) assessed the effect of septum resection on pregnancy and live birth rates in women with infertility, in women who have miscarried, in women who have experienced recurrent pregnancy loss, or all three, and estimated a pregnancy rate of 60–80% and a live birth rate of 45–54%. With the effect of septum resection on unexplained infertility, a higher pregnancy rate (38.6% versus 20.4%, P < 0.05) has also been observed in these women (Mollo et al., 2009).

<table>
<thead>
<tr>
<th>TABLE 1 SWOT ANALYSIS: HYSTEROSCOPIC SEPTUM RESECTION AND REPRODUCTIVE MEDICINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengths</td>
</tr>
<tr>
<td>Septum resection improves obstetrical outcomes</td>
</tr>
<tr>
<td>Increases pregnancy rates</td>
</tr>
<tr>
<td>Decreases abortion rates</td>
</tr>
<tr>
<td>Decreases preterm delivery</td>
</tr>
<tr>
<td>Increases term births and live births</td>
</tr>
<tr>
<td>It does not delay assisted reproductive technology</td>
</tr>
<tr>
<td>Surgery is simple and safe with reduced morbidity</td>
</tr>
<tr>
<td>It improves obstetrical outcomes regardless of septum size</td>
</tr>
<tr>
<td>Opportunities</td>
</tr>
<tr>
<td>Predisposition to interventionism</td>
</tr>
<tr>
<td>Generalized reduction in the fear of surgical side-effects</td>
</tr>
<tr>
<td>Demand from women (society)</td>
</tr>
<tr>
<td>Patient confidence</td>
</tr>
</tbody>
</table>

Under-treating a situation that is causing infertility

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and, after surgery, 41% of the patients conceived with a median time to conception of 2.6 to 7.5 months (Shokeir et al., 2011).

Septate uterus has been associated with a high prevalence of repeated assisted reproductive technology (ART) failure (Raga et al., 1997) and early pregnancy loss after ART (Dicker et al., 1996). In these situations, resection of the septum seems to be useful in improving IVF pregnancy rates (Ozgur et al., 2007; Tomazevik et al., 2010; Abuzeid et al., 2014).

**Septum resection decreases miscarriage rate**

Numerous studies have found that septum resection reduces the rate of miscarriage (Kormányos et al., 2006; Colacurci et al., 2007; Wang et al., 2009; Bendifallah et al., 2013; Gundabattula et al., 2014; Freud et al., 2015). In a meta-analysis, Venetis et al. (2014) showed that women who underwent septum resection had a significantly decreased probability of spontaneous miscarriage compared with women who did not undergo treatment (RR 0.37, 95% CI 0.25 to 0.55). Moreover, in women with a history of miscarriages, the miscarriage rate decreased significantly after septum resection (Saygili-Yilmaz et al., 2003). This decrease in the miscarriage rate has also been observed in IVF clinical practice (Ozgur et al., 2007; Bano-Frangez et al., 2009). Several theories have been offered to explain why repetitive miscarriages occur in women with uterine septum with the most generally accepted cause being that of decreased vascularization of the septal area, as demonstrated during surgical division of the septum when the uterus is distended, therefore affecting blastocyst implantation and nutrition of the implanted embryo (Fedele et al., 1989).

**Septum resection decreases preterm delivery and increases term births and live births**

Hysteroscopic septum resection is associated with a reduction in preterm labour rates (Kormányos et al., 2006; Bendifallah et al., 2013; Crane et al., 2014; Gundabattula et al., 2014; Freud et al., 2015) and a meta-analysis confirmed this decrease in the probability of preterm labour (<37 weeks), yet not significant, in women who had been treated with hysteroscopic resection of the septum compared with women who had not been treated (RR 0.66, 95% CI 0.29 to 1.49) (Venetis et al., 2014). Improvement in live birth rate and full-term labour in women with infertility or prior pregnancy loss (Saygili-Yilmaz et al., 2003; Gundabattula et al., 2014) has also been reported.

Research on the effect of septum resection on live birth rates in women with primary infertility who underwent IVF suggests that this procedure is beneficial before IVF and embryo transfer based on the results of full term, preterm and severe preterm birth rates as well as on mean gestational age in pregnancy (Abuzeid et al., 2014).

**Septum resection does not delay time to assisted reproductive treatment**

Nowadays, many fertility centres recommend removal of the septum before ART to reduce the possibility of miscarriage (Raga et al., 1997) and to improve pregnancy outcome (Ozgur et al., 2007). Although hysteroscopic excision of uterine septum leaves an injured area within the endometrial cavity, it is rapidly covered by nearby healthy endometrium. Therefore, starting an IVF and intracytoplasmic sperm injection embryo transfer cycle immediately after the hysteroscopic procedure does not impair the implantation rate or pregnancy rate compared with those started 10 or more weeks after the procedure (Berkkanoglu et al., 2008).

**Septum resection surgery is simple, safe and with reduced morbidity**

Hysteroscopic septum resection is a simple, safe and effective procedure for achieving normal uterine shape (Jansen et al., 2008). According to most studies, few complications have been observed in hysteroscopic septum resection (Homer et al., 2000; Wang et al., 2013; Esmaielzadeh et al., 2014; Roy et al., 2015) as post-uterine septum resection rupture, fluid and electrolyte imbalance and thermal injury or perforation have been reported infrequently (Conturso et al., 2003). Nevertheless, the fact that the retrospective design of these studies could introduce reporting bias must be kept in mind when analysing these data. In addition, the side-effects of surgery, which include the risk of pelvic adhesions and caesarean delivery, are reduced with hysteroscopy. Therefore, it has been recognized as a favourable and safer therapeutic procedure for uterine septum removal (Ignatov et al., 2008), and some investigators have argued in favour of prophylactic hysteroscopic metroplasty in women with unexplained infertility, before assisted reproductive treatment (Homer et al., 2000).

**Improves obstetric outcomes regardless of septum size**

Evidence to conclude that obstetric outcomes are different when comparing the size, as defined by length or width of uterine septa, is insufficient (Gergolet et al., 2012). Similar to a large uterine septum, a small uterine septum has been reported as an important hysteroscopically preventable risk variable for preterm birth (Kormányos et al., 2006), in women with subseptate or septate uterus and in women with arcuate uterus, the pregnancy and live birth rates before surgery seem to be lower compared with controls (Tomasevič et al., 2010). A study conducted by Paradisi et al. (2014b) in 132 women showed that hysteroscopic metroplasty in cases of partial uterine septum and infertility significantly improves the reproductive performance irrespectively of septum size, and that reproductive performance is independent from previous obstetric history.

**Weaknesses**

Lack of evidence in randomized trials showing septum resection improves obstetrical outcomes

Despite the potential advantages of hysteroscopic septum resection, a recently published Cochrane review (Rikken et al., 2017) concluded that no solid evidence supports this procedure for women as a means of improving reproductive outcomes, because no randomized controlled trials (RCTs) comparing hysteroscopic septum resection with expectant management have been published. In this regard, high-quality RCTs are urgently needed, and two trials are currently under way (NCT00830401 and NCT02404454).

Not recommended in women without poor reproductive outcomes

The debate on whether operative hysteroscopy should be carried out to repair septate uterus in women who have not experienced adverse reproductive outcomes is ongoing. Although some studies suggest that hysteroscopic resection should be carried out once a woman is diagnosed with septate uterus to reduce the...
possibility of spontaneous miscarriage (Lin et al., 2009; Tonguc et al., 2011), a prospective study has suggested no significant difference in pregnancy outcomes between women with no history of poor reproductive outcomes who underwent surgery and those who underwent a conservative approach (Pang et al., 2011). Hence, it is not yet clear if patients with septate uterus who have no history of poor reproductive outcome may need to undergo surgery before pregnancy.

May affect peri-implantation and perinatal outcomes
Surgical technologies have improved greatly, however, the procedures may still induce unintentional inflammatory reactions that may positively or negatively affect placentation, and therefore the peri-implantation and perinatal outcomes of subsequent conceptions (Pundir et al., 2014). Data from intracytoplasmic sperm injection treatments (Ozgur et al., 2015) showed that some patients who underwent hysteroscopic surgery for intrauterine septa were still susceptible to a greater risk of fetal loss, possibly owing to intrauterine factors that are non-correctable (Taylor et al., 2008), such as altered intrauterine pressure dynamics, cervical incompetence (Homer et al., 2000; Crane et al., 2015), or both. Moreover, the effect of Asherman syndrome, which could be associated in some situations with septum resection in pregnancy, may increase the rate of infertility, miscarriage, poor implantation after IVF and abnormal placentation.

Surgical risks associated with septum resection
As with any surgical procedures, hysteroscopic septum resection may have its complications, some associated with the surgical technique used, e.g. uterine perforation, haemorrhage, infections and others, with possible damage to the endometrium, e.g. inflammation, Asherman syndrome, abnormal placentation and cervical insufficiency. The risks of surgery are minimal, and the perinatal outcomes of the patients who delivered after metroplasty are favourable, with no significant difference in the rate of complications compared with the control group, however, some complications described are life threatening, such as uterine perforation or uterine rupture in subsequent pregnancies, excessive haemorrhage or infection (Kenda et al., 2016). Other reported risks of surgery are abnormal anatomic results, such as a residual septum at the uterine fundus and isolated intrauterine adhesions in other locations (Ludwin et al., 2014). A high risk of bias, however, exists because of the subjective assessment of surgeons on the completeness of resection and a lack of standardized postoperative evaluation of the uterine cavity.

Non-standardized procedure
An important limitation of this procedure is no standardized technique exists for hysteroscopic septum resection, and insufficient evidence is available to recommend a specific method. One RCT (Colacurci et al., 2007) and some retrospective studies (Cararach et al., 1994, Litta et al., 2008) have evaluated efficacy or complications by comparing the different hysteroscopic techniques with each other. Currently, hysteroscopic septum resection with Versapoint carried out in an office setting is considered the procedure of choice given that the possible complications that may arise from the anaesthesia are avoided and costs are reduced; furthermore, use of the resectoscope and glycine are associated with a greater number of complications. Mechanical incision with scissors and incision with bipolar resectoscope using normal saline are also safe and minimally traumatic options.

Direct and indirect costs
A significant limitation of extending the use of this technique is that no cost-effectiveness studies have been published to date. Nevertheless, septoplasty is considered a relatively expensive procedure and its cost varies widely and depends on several variables. Outpatient procedure offers many benefits over its traditional counterpart, including lower staff costs, sterilizing costs and avoidance of general anaesthesia, speedier recovery, less time away from work and home, and cost savings for the woman, her employer and the National Health Service (Marsh et al., 2004). Moreover, according to published research, the application of a routine hysteroscopy before IVF may be cost-effective in women with intrauterine anomalies. Nevertheless, additional data on this subject are crucial to recommend the most cost-effective strategy for daily practice (Kasius et al., 2013).

OCCUPATIONAL RISK
Predisposition to interventionism
Currently, social and cultural values favour a greater predisposition to medical interventionism (McAra-Couper et al., 2010), and the confidence in the intervention by the patients shows greater satisfaction and quality of life (Kuppermann et al., 2013). In the case of hysteroscopic techniques, a high level of patient satisfaction and a trend towards outpatient intervention has been observed. In the study by Wortman et al. (2013), 98.8% of respondents were either ‘very satisfied’ or ‘satisfied; 97.6% preferred the office to a hospital setting (Wortman et al., 2013).

Generalized reduction in the fear of side-effects of surgery
Good anatomical and functional results, as well as a generalized reduction in the fear of side-effects of surgery, have favoured the diffusion of varied surgical procedures. This is because each time surgical procedures are made simpler, they become less risky and guarantee faster recovery rates for patients (Marsh et al., 2008). In the specific case of hysteroscopic resection of the septum, the introduction of small-diameter operative hysteroscopes has enabled physicians to carry out operative hysteroscopy in an office-based surgical setting with the possibility of diagnosing and treating lesions in a single session without parenterally administered analgesia or sedation (Lindheim et al., 2000, Wortman et al., 2013).

Demand from women and society to solve their problems, such as those related to infertility
An increasing number of studies have indicated increasing involvement of patients taking an active part in the decision-making and resolution of their medical problems, including those related to infertility. In a Cochrane review, Aarts et al. (2015) analysed the effectiveness and safety of different surgical options for hysterectomy in women with benign gynaecological processes and concluded that the surgical approach should preferably be decided by the patient after discussing the options with her surgeon. In this situation, a woman’s right to self-determination may favourably increase the hysteroscopic resection of the
uterine septum as an option to increase the probability of ongoing pregnancy.

Patient confidence
Septate uterus has been associated with a higher rate of early and recurrent miscarriages, reproductive failure and obstetric complications, although it has not been clearly related to infertility. Hysteroscopic resection may improve all these problems: it is a simple intervention, has a low complication rate (Zabok et al., 2001) and could increase patient confidence and provide peace of mind to those attempting to achieve pregnancy, spontaneously or by assisted conception.

Improved endometrial assessment after septoplasty
Finally, a better assessment of the factors on which treatment success depends is an important parameter in assisted reproduction. After septoplasty, the appearance and quality of the endometrium can be better evaluated when a reproductive treatment is indicated (Pace et al., 2013).

THREATS
Risk of over diagnosis
The regular use of ultrasound in the gynaecology clinic and the higher resolution of the equipment used together with the addition of three-dimensional technology in the diagnostic work-up for sterility contributes to the over diagnosis of uterine septum, although, in most cases, it has no clinical implications (Ludwin et al., 2013). It is still not clear what length of subseptation should be considered for correction: different opinions have been offered (Ludwin et al., 2014; 2015; 2017), with the more recent one recommending 5.9 mm (Detti et al., 2017). Although over-diagnosis is a risk (Ludwin et al., 2013), the ESHRE/ESGE classification offers an opportunity to evaluate the anatomical defect and treatment results objectively (Grimbizis et al., 2014), but without any therapeutic recommendation. This situation also makes it difficult to evaluate the residual septum after hysteroscopic septoplasty, sometimes leading to unnecessary reinterventions.

Risk of over-treating a situation that is not actually causing infertility
Sterility can be a result of multiple factors, and this makes it difficult to determine whether the diagnosis of a uterine septum is one of the main causes. For this reason, when a sterile couple is offered assisted reproductive techniques, assuming that the rate of success is uncertain (pregnancy rates are not 100%), it would be difficult to stop acting on a problem that could affect them, especially when the treatment is accessible, and its risks are reduced (Mairos and Di Martino, 2016). This, however, generates the general belief that the uterine septum should always be operated on and lead to unnecessary surgeries in situations that do not cause sterility or poor obstetric outcome (Maneschi et al., 1995).

Under-treating a situation that is causing infertility
When the clinician adopts a conservative stance (Rikken et al., 2017) to avoid the risks of overtreatment of the uterine septum based on scientific evidence, the risks of not treating will have to be assumed. We cannot forget that many studies associate uterine septum with an increase in reproductive pathology (Tomazevic et al., 2010; Practice Committee of ASRM, 2016) and that not treating uterine septum could force subsequent septoplasty after miscarriage, preterm delivery or simply no conception, either spontaneous or after assisted reproduction techniques, with the consequent economic, emotional cost, or both, as well as a loss of time that could be fundamental in older patients.

Easy access to information on the Internet overriding medical criteria
Nowadays, the internet offers a variety of medical information resources that are frequently used by patients (Bratucu et al., 2014) as well as by women attempting to become pregnant (Kraschnowski et al., 2014). The information, however, is not always in agreement with the information received directly in consultation, and could cause conflict within the medical–patient relationship if not re-discussed between the two parties as reflected by some systematic reviews of internet use in different pathologies (Tan et Goonawardene, 2017) or specifically by pregnant women (Sayakhot et al., 2016). Given the predisposition to medical intervention in society, previously analysed in the Opportunities section, the professional advice of not carrying out a septoplasty could lead the patient to seek additional information that would lead her to institutions in which advertising would have more weight than that of scientific information (Huang et al., 2005; Abusief et al., 2007).

CONCLUSIONS
Currently, no level 1 published evidence supports uterine resection in women with septate uterus. Clinical evidence from the studies analysed matches the more recent guidelines (NICE guidelines 2015; ASRM guidelines, 2016) and suggests an improvement in reproductive outcomes after hysteroscopic resection of the septum, particularly in infertile women and women who have experienced recurrent miscarriages. In a patient with no history of infertility or prior pregnancy loss, it may be reasonable to consider septum incision after counselling about the potential risks and benefits of the procedure (ASRM guidelines, 2016). Published clinical data in favour of the intervention, however, are based on studies with important methodological limitations and a possible publication bias. This could be associated with the lack of uniformity in the definition of the anomaly; the difficulty in setting up an RCT when information is so readily available online; and the fact that no women would accept participation in a randomization surgery study, particularly after years of infertility or two or more miscarriages. Other factors support the trend towards this approach, even if the evidence is questionable. These include current technical advancements that make it a safe and simple procedure without need for hospitalization; the predisposition to interventionism; and the societal demand by infertile women to solve any contributing factor that interferes in the possibility of pregnancy. In this situation, the clinician and patient could agree to make decisions together, based on the pros and cons of this intervention. Confirmation of the clinical benefits and cost-effectiveness of this procedure through well-designed RCTs still remains increasingly necessary.
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