# Combining Myoma Coagulation with Endometrial Ablation/Resection Reduces Subsequent Surgery Rates

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#### ABSTRACT

**Background:** This study compares results of endometrial ablation alone and in combination with myoma coagulation. Subsequent surgery rates were 38% for ablation alone and 12% for combined therapy.

**Objective:** The purpose of this study was to compare hysterectomy rates following various surgical procedures to treat profuse uterine bleeding as well as myomatous uteri.

**Study Design:** This is a descriptive study of women who underwent endometrial ablation alone, endometrial ablation with myoma coagulation, or endometrial resection with myoma coagulation to treat profuse uterine bleeding as well as myomatous uterus. From 1986 to 1995, the author performed 52 endometrial ablation procedures; 88 myoma coagulation and endometrial ablation procedures; and 28 myoma coagulations with resection of submucous myomas in patients who were subsequently available for follow-up. Patients were followed up for up to ten years.

**Results:** Of the patients undergoing ablation alone, 20 (38%) of 52 required a second surgery for continued symptoms during a mean follow-up of 47 months. Five of these patients (9.6%) underwent hysterectomy. Of the patients who underwent endometrial ablation plus myoma coagulation (myolysis), 11 (12.5%) of 88 required a repeat surgical procedure during a mean follow-up of 25 months. Five of these patients (5.7%) underwent hysterectomy. Volumetric measurements revealed an average reduction in fibroid volume of 54.5% in this patient group following treatment with a gonadotropin-releasing

hormone (GnRH) agonist and combined myoma coagulation and endometrial ablation surgery. Of the 28 patients who underwent myoma coagulation plus resection, five (18%) required a repeat procedure. Of these five, one (4%) required hysterectomy. Fibroid volume in this group was reduced by a mean of 72.6% following administration of a GnRH agonist and combined laparoscopic and hysteroscopic surgery as described. The rate of reoperation was significantly lower among patients receiving endometrial ablation with myoma lysis with or without resection compared with those undergoing endometrial ablation alone (P<0.01).

**Conclusions:** Myoma coagulation (myolysis), when combined with endometrial ablation among women with symptomatic fibroids and bleeding, reduces all subsequent surgery rates compared with endometrial ablation alone. Myolysis with endometrial resection also results in a reduced need for hysterectomy.

**Key Words:** Fibroids, Uterine bleeding, Endometrial ablation, Myoma coagulation, Endometrial resection, Hysterectomy.

#### INTRODUCTION

Approximately 750,000 hysterectomies are performed in the United States each year, with a mortality rate of about 12 per every 10,000 hysterectomies performed.<sup>1</sup> Costs to consumers and insurers have been estimated at approximately \$1.7 billion per year.<sup>2</sup> Thus, alternative procedures that are safer and less invasive, preserve the uterus, and have less of an economic cost are increasingly in demand. In recent years, several such techniques have been introduced.

Endometrial ablation was first performed in 1981 by Goldrath and colleagues using the Nd:YAG laser.<sup>3</sup> Vancaille subsequently published a report of rollerball ablation in 1989.<sup>4</sup> Amenorrhea rates following ablation have been 25% to 84%,<sup>3,5-14</sup> with patient satisfaction rates up to 80% at one year.<sup>6,7,15</sup> However, a recent study by Unger and Meeks<sup>16</sup> indicates that as many as 34% of women require hysterectomy within five years of abla-

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Table 1.     Comparison of outcomes following three procedures.						
	Ablation alone ( <i>n</i> =52)	Ablation + Myolysis ( <i>n</i> =88)	Resection + Myolysis ( <i>n</i> =29)			
Mean follow-up	about 4 years	about 2 years	nearly 3 years			
Menstrual outcome Amenorrhea Continued heavy bleed	36.5% ling 38%	57% 6.8%	18% 14%			
% who underwent 2nd procedures for any reason	38%	12.5%	18%			
% hysterectomies	9.6%	5.7%	3.5%			

tion, and that this number increases with time. Multiple procedures are likely to increase, rather than decrease, morbidity and costs associated with hysterectomy.

In 1990, Goldfarb first reported the technique of myoma coagulation (myolysis) in the United States.<sup>17</sup> Myoma coagulation was first performed with the Nd:YAG laser.<sup>18</sup> In 1992, the technique was altered by the use of a 5 cm modified bipolar needle (manufactured by B. Resnick & Company, Skokee, IL, and J.E.M.D. Medical, Hicksville, Long Island, NY) to pierce myomas using bipolar current at 50 to 75 watts.<sup>19</sup>

Since the introduction of myolysis in 1990, the procedure has been combined with endometrial ablation in patients with symptomatic fibroids who also exhibit persistent recurrent uterine bleeding refractory to medical therapy. It was hypothesized that this combination procedure would further reduce rates of subsequent hysterectomy or other surgeries.

This study compares subsequent reoperation rates in a cohort of three patient groups: 1) those who underwent endometrial ablation alone prior to 1990, 2) patients who underwent endometrial ablation with myoma coagulation, and 3) women who underwent endometrial resection for submucosal myomas with myoma coagulation. After 1990, all of the women in the latter two groups were treated for profuse uterine bleeding with fibroids. Prior to 1990, only endometrial ablation was available as a treatment modality; the majority of the women treated with ablation alone at this time had fibroid uterus as well as severe uterine bleeding. Subsequent rates of hys-

terectomy as well as repeat surgical procedures for these three patient groups are evaluated, and menstrual outcome and surgical complications are also tabulated.

# **MATERIAL AND METHODS**

All patients who presented between 1986 and 1990 with complaints of profuse uterine bleeding and wishing to preserve their uterus were considered for endometrial ablation. Most of these patients also had uterine fibroids. Between 1990 and 1995, patients with both profuse uterine bleeding and fibroids and no desire for future childbearing were considered for myoma coagulation with endometrial resection or ablation, depending upon the location of myomas. (Patients with submucosal myomas underwent resection; all others underwent ablation.)

All patients received a preoperative evaluation consisting of medical history, physical, and pelvic examination, as well as abdominal and vaginal ultrasound scan, endometrial biopsy, and hysteroscopy to determine uterine pathology.<sup>20</sup> Patients were considered possible surgical candidates if the endometrial biopsy revealed no hyperplastic tissue, they had fibroids measuring no more than 10 cm, and they had active menstrual function.

Patients meeting these criteria and providing informed consent were given a trial of gonadotropin-releasing hormone (GnRH) agonist in depot form 10 to 14 weeks prior to surgery as a therapeutic test. Surgery was conducted only in patients who had a good response to the GnRH agonist (ie, the symptoms disappeared and myoma volume was reduced 30% to 40%).

The incidence	e of subsequent hysterect ablatio	omies for women who had u n alone, myolysis-ablation, or	indergone one of three surgica myolysis-resection.	l procedures initially
Outcome	Ablation only	Myolisis + ablation	Myolisis + resection	Combined
Subsequent				
hysterectomy	5 (9.6%)	5 (5.7%)	1 (3.6%)	11 (6.5%)
No subsequent				
hysterectomy	47 (90.4%)	83 (94.3%)	27 (96.4%)	157 (93.5%)
Combined	52	88	28	168
x <sup>2</sup> (2,N=168).				

Various endometrial ablation techniques were employed, including the Nd:YAG laser and resectoscope techniques. These techniques have been described elsewhere.<sup>6,21</sup> Myoma coagulation was performed using either the Nd:YAG laser or bipolar needles, as previously described.<sup>19,22,23</sup> Resection was also performed as previously described.<sup>10</sup>

To maintain postoperative cavity patency, an endocervical and uterine endosuction was performed one month after surgery. In addition, amenorrheic patients were encouraged to return bi-yearly for vaginal ultrasounds to ensure that hematometra was not present. Patients who did not return for at least one postoperative follow-up visit after the initial one-month visit for endosuction were considered lost to follow-up.

The primary end point of this study was the requirement for subsequent surgery related to inadequate relief of symptoms following the initial procedure. In addition, menstrual outcome and complication rates were assessed in all groups.

Data on fibroid volume were obtained in select patients who underwent the combination procedures. In these patients, fibroids were measured pre- and postoperatively in three dimensions transvaginally and abdominally via ultrasound. To determine the volume of the leiomyoma, the following equation was used: 0.523(dimension 1)x(dimension 2)x(dimension 3).<sup>24</sup> A total of all the measured volumes was calculated for each group, and an average volume was obtained for the initial and postoperative ultrasounds. Based on these figures, an average percent reduction was computed for each group.

## RESULTS

### Ablation Alone Group

Of 72 patients who underwent endometrial ablation alone, 20 (28%) were lost to follow-up. The remaining 52 patients were followed up for an average of 47 months (range, 2 months to 105 months). Mean age at the time of surgery was 44 years, and mean parity was 1.87 children.

Nineteen patients (36.5%) became amenorrheic following the initial endometrial ablation. Twelve patients (23%) had subsequent bleeding within the normal range. Thus, approximately 59% experienced improvement in bleeding severity. Twenty women (38%) had continued heavy bleeding requiring subsequent surgery. Two patients (3.8% of the total group) required more than one subsequent surgery. Five patients (9.6%) underwent hysterectomy.

Complications of endometrial ablation were as follows: Twelve patients (16.6%) developed urinary tract infections. One patient (1.4%) became pregnant 17 months after the surgery. This patient subsequently underwent termination of pregnancy and tubal sterilization with no subsequent bleeding problem. Back and pelvic pain were experienced by one patient each (1.4% for each). Serious complications were experienced by four patients (5.5%) and included pulmonary congestion, hyponatremia, and degenerating myoma; fever, endometritis, and bleeding at one month postablation; uterine and intestinal perforation secondary to attempted fundal submucosal resection early in the series (repaired by laparotomy); and peritonitis, hyponatremia, fluid overload and pleural effusion.

Outcome	Ablation only	Myolisis + ablation	Myolisis + resection	Combined
Subsequent surgery of some kind	20 (38.5%)	11 (12.5%)	3 (10.7%)	36 (21.4%)
No subsequent surgery	32 (61.5%)	83 (87.5%)	25 (89.3%)	132 (78.6%)
Combined	52	88	28	168

#### Table 3.

The incidence of any surgery, including hysterectomy, subsequent to one of three procedures initially: ablation only, myolysis-ablation, or myolysis-resection.

## Myolysis and Ablation Group

Of the 119 patients who underwent myolysis and endometrial ablation, 31 (26%) were lost to follow-up, and the remaining 88 women were followed up for a mean of 25 months (range, 4 to 65 months). Mean age at the time of surgery was 45 years, and mean parity was 1.35 children.

Following surgery, 50 patients (57%) became amenorrheic, and 32 (36%) patients had normal levels of menstrual bleeding following surgery. Six patients (7%) had continued heavy bleeding. Eleven (12.5%) patients elected to undergo subsequent procedures due to inadequate control of symptoms with myoma coagulation plus endometrial ablation. Five of these patients (5.7% of the total evaluable group) underwent hysterectomy. The other procedures included laparoscopic myomectomy (1 patient); repeat ablation due to pain, hematometria and/or fibroid growth (4 patients); and myomectomy performed hysteroscopically to remove a prolapsed fibroid (1 patient).

Volumetric analysis was performed in 30 patients (34%). In 30 patients, preoperative fibroid size ranged from 12 to 630 cm<sup>3</sup>, with a mean of 230 cm<sup>3</sup> and a median of 205 cm<sup>3</sup>. Following treatment with the GnRH agonist and surgery, fibroids ranged in size from 3 to 483 cm<sup>3</sup>, with a mean and median of 103 and 81 cm<sup>3</sup>, respectively. The 30 patients experienced an average 54.5% reduction in fibroid size, with half the group experiencing reduction in fibroid volume of at least 68%.

Complications occurred in 14 of the 88 evaluable patients (15.9%), and included hematometra (5 patients, 5.7%); fever (4 patients, 4.5%); urinary tract infection (2 patients, 2.3%); perforated bladder (1 patient, 1.1%); bacteremia (1 patient, 1.1%); and fibroid prolapse (1 patient, 1.1%).

#### **Resection plus Myolysis Group**

Forty-five patients with submucosal myomas underwent resection and myolysis, of whom 17 (37%) were lost to follow-up; endometrial ablation by the remaining 28 were followed for a mean of 33 months (range, 3 to 77 months). Mean age at the time of surgery was 43 years, and the women had a mean of 2.0 children.

Following the surgery, four women (14%) experienced continued heavy bleeding. Five (18%) developed amenorrhea. The remaining 19 (68%) had normal menstrual bleeding postoperatively. Five patients (18%) underwent subsequent surgery due to inadequate symptom relief. One of these patients (3.5%) underwent hysterectomy. Of the other four patients, one underwent a repeat ablation and coagulation for hematometra; another received hysteroscopy and lysis of adhesions; the third required repeat resection, laparoscopic myomectomy, and bilateral salpingectomy for myoma degeneration and continued heavy bleeding; and the fourth patient required repeat endometrial coagulation and hysteroscopic resection of a submucosal leiomyoma.

Volumetric analysis of fibroid volume was conducted in 13 patients (46%). Preoperative fibroid volumes ranged from 30 to  $363 \text{ cm}^3$ , with a median of 111 cm<sup>3</sup> and a

Table 4.A survival analysis on the yearly incidence of subsequent hysterectomy for womenwho had undergone one of three procedures initially: ablation only, myolysis-ablation, or myolysis-resection.												
Yearly proportions of subsequent hysterectomies Number of years after initial surgery												
Initial surgical procedure	n	1	2	3	4	5	6	7	8	9	10	
Ablation alone	52	.043	.029	.036	.043	.000	.000	.000	.000	.000	.000	
Myolysis-ablation	88	.025	.033	.000	.044	.000	.000					
Myolysis-resection	28	.000	.000	.000	.000	.000	.333					

Note: The differences among the survival rates for the three surgical procedures were not statistically significant using the Wilcoxon-Gehan statistic.

Note: Since the two procedures involving myolysis were not used until 1990, the maximum time for follow-up data for these procedures was six years.

mean of 152 cm<sup>3</sup>. Following treatment with the GnRH agonist and surgery, all patients experienced a reduction in fibroid size. Postoperative fibroid volumes ranged from 1 to 73 cm<sup>3</sup>, with a median and mean of 36 and 35 cm<sup>3</sup>, respectively. Half of the patients experienced a reduction in fibroid volume of at least 83%. The entire group experienced an average reduction of 72.6%.

Of the 28 evaluable patients in this group, only two (7%) experienced surgical complications. One patient developed a pelvic infection and the other experienced uterine perforation during surgery.

#### **Comparing the Three Groups**

The incidence of hysterectomy was rather infrequent when the three procedures were combined (11 of 168 = 6.5%). The incidence in the ablation alone group (5 of 52 = 9.6%) was slightly higher compared with the two myolysis groups (6 of 116 = 5.2%). When all subsequent surgical procedures including hysterectomy were evaluated, the incidence in the ablation group (20 of 52 = 38.5%) was significantly higher than in the myolysis-ablation group (11 of 88 = 12.5%) or myolysis and resection group (5 of 28 = 17.9%) (X<sup>2</sup> N = 168 = 13.34 p <0.01). These outcomes are shown in **Tables 1-3**.

Survival analyses were carried out for both possible end points [hysterectomies **(Table 4)** and subsequent surgical procedures **(Table 5)**, in order to observe the yearly incidence rates for the different surgical procedures and to determine if there were differences between them. The incidence of hysterectomies in the ablation-only group appeared to be fairly uniform over the first four years, at roughly 4% yearly. The rates in the myolysisablation group also appeared fairly uniform; roughly 2.5% yearly. (The difference between these two rates is not statistically significant.) There were insufficient data from the myolysis-resection group to allow them to be meaningfully included in the survival analysis, since only one in 28 women in this condition required a hysterectomy. This hysterectomy was performed during the patient's fifth year.

When Life Table analysis was carried out using all subsequent surgical procedures as the end point (**Table 5**), the difference between ablation alone and the myolysisablation was striking. For ablation only, the yearly rate was roughly 10% for at least nine years, whereas for myolysis ablation the yearly rate was only 3% for the first three years. These analyses correct for length of participation and confirm that the difference between ablation only and myolysis and ablation is significant (p<0.05).

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Yearly proportions of subsequent hysterectomies Number of years after initial surgery												
Initial surgical procedure	n	1	2	3	4	5	6	7	8	9	10	
Ablation alone	52	.124	.110	.070	.122	.051	.069	.095	.133	.222	.000	
Myolysis-ablation	88	.037	.033	.026	.167	.000	.250					
Myolysis-resection	28	.071	.044	.000	.111	.000	.333					

Note: The differences among the survival rates for the ablation only procedure vs myolysis-resection was statistically significant using the Wilcoxon-Gehan statistic, P<0.05.

Note: Since the two procedures involving myolysis were not used until 1990, the maximum time for follow-up data for these procedures was six years.

## COMMENT

In a series of 52 evaluable patients who underwent ablation alone, 38% required at least one repeat surgery. Two of these patients had more than one subsequent surgery. The hysterectomy rate was 9.6%. If follow-up data for the past six years only is considered, (the length of follow-up available for the myolysis group also), only three of the women in the ablation-only group had hysterectomy beyond the sixth year. The chi square analysis remains unchanged, however, with the significance still <0.05.

In a similar series of patients treated with rollerball endometrial ablation by Unger and Meeks,<sup>16</sup> 14 of 41 women (34%) underwent hysterectomy within 5 years of the surgery. (No other types of repeat surgeries were permitted according to their study protocol.) They reported that the decision to undergo hysterectomy following ablation was associated with continued abnormal bleeding and menstrual pain as well as gross abnormalities such as uterine myomas. Seven (70%) of ten women with severe menstrual pain and probable adenomyosis underwent hysterectomy. In addition, 14 of the women who had hysterectomy had significant pelvic disease: ten had myomas, adenomyosis, or endometriosis. Unger and Meeks also reported a linear relationship between hysterectomy and time, projecting that all of their ablation

patients would undergo hysterectomy within 13 years of the initial procedure.

A comparison of the current data with those of Unger and Meeks is provided in **Table 6**. In the current series, the majority of patients undergoing ablation and all patients in the myolysis group had uterine fibroids. Resection was performed when submucosal myomas required significant resculpturing of the endometrial cavity.

An important point to consider is the motivation of patients and physician. Those patients with continued symptoms (bleeding) most often had migration of intramural myomas or submucosal myomas to the uterine or submucosal areas. In the current study, these patients were offered repeat ablation or resection and even myomectomy as an alternative to hysterectomy and were encouraged to choose their most desired solution. This contrasts with the series by Unger and Meeks in which only hysterectomy was offered as a second procedure.

Unger and Meeks also noted that because the uterine cavity may be scarred by the procedure and no longer patent with the vagina, any subsequent menstrual flow may be forced into the fallopian tubes causing pain and endometriosis. In this study, cavity patency was maintained by performing an endometrial endosuction one month after surgery; also, amenorrheic patients were fol-

Table 6.   Comparison of ablation data.						
	Goldfarb	Unger & Meeks				
n	72	42				
Diagnosis	Severe menorrhagia with or without fibroids	Severe menorrhagia with no other gynecologic abnormality				
Mean age	43.5 years	40 years				
Mean parity	1.87 children	2.5 children				
Geographic demographic	New Jersey	Wisconsin				
Ablation technique	Various	Rollerball				
Lost to follow-up	28%	2.3%				
Subsequent procedures* of any type	38% (w/in mean app. 4 years)	34% (within 5 years)				
hysterectomies*	9.6% (w/in mean app. 4 yrs)					
Amenorrhea	36.5%	not reported				
Continued heavy bleeding	20/52 (38%)	8/41 (19.5%)				
Serious complications	5.5%	None				

\*In Goldfarb, subsequent procedures included repeat ablation, curettage, myoma coagulation, hysterectomy, and others. In Unger, second-line surgical strategies were limited to hysterectomy.

lowed with bi-yearly vaginal ultrasound examination to ensure that hematometra had not developed.

A comparison of our data across patient groups reveals that the addition of myolysis to endometrial ablation increases the rate of postsurgical amenorrhea from 36.5% to 57% and reduces the rate of continued heavy bleeding from 38% to 6.8%. **(Table 2)**. Second procedures including hysterectomies were reduced from 38% to 12.5%, and the hysterectomy rate was reduced from 9.6% to under 5.7% by the combination of myolysis and ablation versus ablation alone. In patients who underwent resection and myolysis, rates of repeat procedures and hysterectomies were 21% and 3.5%, respectively.

Although the ablation as a single procedure was performed several years earlier than the combination surgical procedures, patients appeared to be fairly well matched with regards to demographic variables. It should be noted that a variety of techniques was used in performing ablation and that two different techniques were used in performing myoma coagulation. In addition, duration of follow-up varied across the three patient groups. Volumetric data were not collected on the earliest patient group (those who received ablation alone), so comparison of reduction of fibroid volumes across procedures is not possible. It is also not clear to what extent the reductions in fibroid volume seen in the combination-procedure groups were attributable to the surgery versus the administration of the GnRH agonist.

The literature has shown subsequent regrowth of myomas once GnRH agonist-therapy concluded; therefore, the long-term size reduction attributed to agonist therapy followed by myolysis and ablation can be accepted as real.

This article represents the author's experience with several recently developed surgical techniques that are successful in relieving symptoms related to leiomyomas and menorrhagia while leaving the uterus in place and reducing recovery time. Physicians should note that myolysis performed on an extremely enlarged uterus (fibroids >10 cm or 14 week gestation) is unlikely to succeed. Similarly, myolysis is unlikely to have a satisfactory outcome in women with disseminated leiomyomatosis. Endometrial ablation alone should be reserved for those women with persistent abnormal bleeding refractory to medical therapy without significant fibroids or adenomyosis; submucosal and intrauterine myomas must be identified and resected. The addition of myolysis in patients with fibroid tumors to endometrial ablation or resection markedly improves the success rate of these minimally invasive alternatives to hysterectomy.

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