

# **NovaSure™ Impedance Controlled Endometrial Ablation System. Long-term Follow-up Results**

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## **Introduction**

According to the American College of Obstetrics and Gynecology, the strict definition of menorrhagia is menstrual bleeding lasting for longer than seven days or a menstrual blood loss (MBL) exceeding 80 ml from normal secretory endometrium after normal ovulation (1982). This condition is most often found among women over 35 years of age and often leads to iron deficiency anemia due to decreased hemoglobin, hematocrit, and serum iron levels.

Moreover, menorrhagia frequently contributes to an upheaval of social, occupational, and sexual activities. These combined conditions oftentimes lead to underlying psychological depression. The prevalence rate of menorrhagia has been estimated to be 9-14% among otherwise healthy women (Valle, 1994).

Current treatment modalities include hysterectomy, drug therapy, D&C and a wide variety of endometrial ablation modalities. Because of a lower mortality and morbidity rate and significantly lower procedure costs<sup>1</sup>, endometrial ablation is increasingly becoming popular amongst the gynecological community worldwide<sup>2</sup>.

For a number of years now the hot balloon systems have been available, representing the second generation of Endometrial Ablation technologies. Due to the fact that these technologies could not provide high levels of procedure success, a number of new technologies have been developed.

## Description of the NovaSure System

The NovaSure Impedance Controlled Endometrial Ablation System (Novacept, Inc., Palo Alto, California, USA) consists of a single use ablation device (Picture 1) and RF Controller (Picture 2). It allows for a customized, controlled and contoured endometrial ablation in an average of 90 seconds treatment time. No hysteroscopic visualization or endometrial pre-treatment is required when using the NovaSure system<sup>3</sup>.



Picture 1 – NovaSure single-use ablation device



Picture 2 – NovaSure RF Controller

- *NovaSure RF Controller*

The NovaSure RF Controller is specifically designed for the endometrial ablation procedure and is a constant power output generator with a maximum power delivery of 180 Watts. The RF Controller automatically calculates the output power based on the uterine cavity length and width. Length of the uterine cavity is assessed during the uterine sounding and dilation, and a component of the handheld endometrial ablation device, measures the uterine cavity width (cornu-to-cornu distance).

A vacuum pump is built into the Controller. The pump generates continuous suction during the ablations cycle. Suction allows for a removal of liquid components that may be present in the uterine cavity (i.e. blood, saline), therefore active bleeding during the time of the operative visit is not a limiting factor when NovaSure system is used. Suction also maintains a close apposition of the uterine walls to the bi-polar electrode.

The Cavity Integrity Assessment System (CIA) is a built-in safety feature that is designed to detect uterine perforations and prevent energy delivery to the organs of the abdominal cavity. Operation of the CIA System is based on monitoring CO<sub>2</sub> pressure within the uterine cavity. After the device is inserted and then deployed in the uterine cavity, CO<sub>2</sub> is delivered into the cavity at a safe flow rate and pressure. If the pressure of 50-mm Hg can be maintained for a period of 4 seconds – the RF Controller will proceed with the ablation.

- *NovaSure Endometrial Ablation Device*

The NovaSure device consists of a single use, bipolar electrode gold-plated mesh, mounted on an expandable and flexible frame. The electrode mesh is stored in a thin sheath during the device insertion, and after being deployed, conforms to the shape of the uterine cavity. It can be used in a uterus with a maximum sounding length of 12 cm. The NovaSure system is using the tissue impedance (electrical resistance) as a modality to control the depth of ablation. During the ablation of the endometrium, the impedance of the tissue is low due to a high concentration of saline in endometrial tissue. Endometrium therefore is vaporized and evacuated from the uterine cavity by suction. As soon as the ablation front progresses into the myometrium (tissue with a much lower concentration of saline), the impedance rises rapidly. The ablation cycle automatically stops when the impedance of the tissue reaches 50 Ohms. This approach allows for a very safe, reproducible and controlled ablation.

Due to a specific configuration of the electrode, the ablation depth in the cornua and lower uterine segment will not exceed 2mm, and will reach 5-7 mm in the mid-body of the uterus.

## **Study Design**

This clinical study represents a single-center, prospective, single-arm, non-randomized design and was conducted at St. Imre Teaching Hospital, Budapest, Hungary.

## **Study Objective**

The primary objective of this study was to evaluate the safety and effectiveness of the NovaSure system in treating patients suffering from excessive menstrual bleeding due to benign causes.

## **Subjects and Methods**

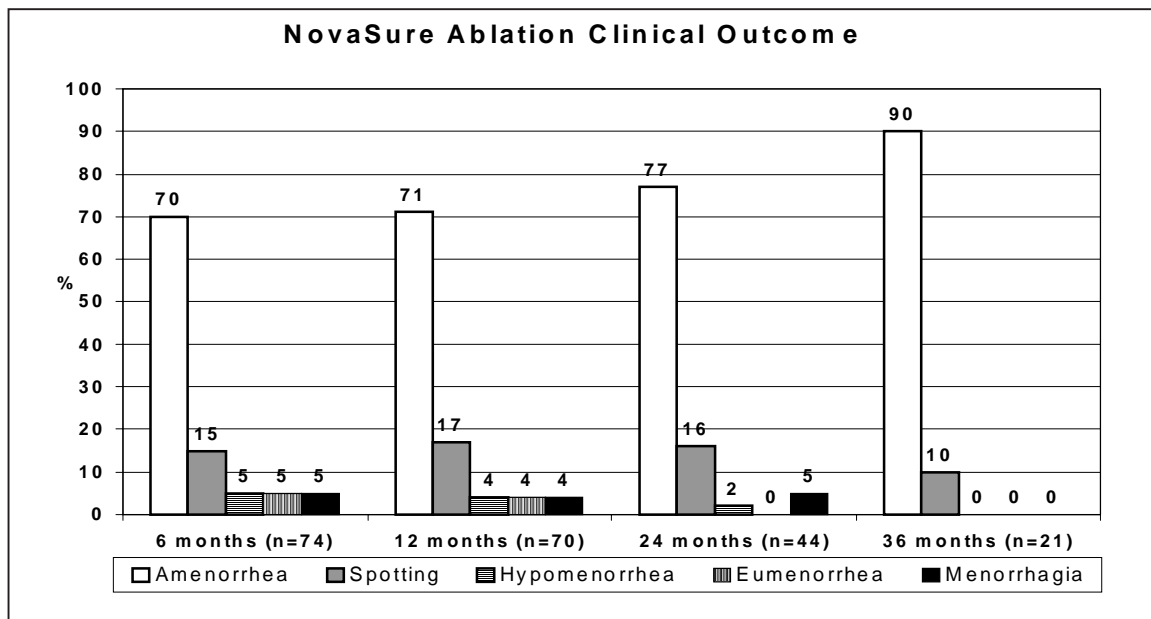
A total of 75 pre-menopausal patients unresponsive to drug therapy were included in the study between December 1997 and June 2000. The average age was 44 years and all patients had completed childbearing at the time of the procedure. The average number of pregnancies before ablation was 3.3 and average number of deliveries was 1.8. Menstrual blood loss was assessed using a pictorial blood assessment chart<sup>4</sup> (PBAC). The mean PBAC score in patients treated in this study was 936. With respect to the uterine position, the distribution within this patient population was as follows: anteverted – 86%, retroverted – 9%, and mid-position – 5%. The uterine cavity was evaluated by means of hysteroscopy or sonohysteroscopy to exclude patients with submucous fibroids or polyps that would distort the uterine cavity. Hereditary malformations of the uterine cavity, as well as a history of classical Cesarean section or conservative myomectomy were exclusion criteria in this study. Uterine cavity size averaged 8 cm. The average cornu-to-cornu distance was 3.45 cm, ranging from 2.8 – 5.3 cm. All patients had FSH levels determined prior to the procedure and at each follow-up interval, to assure their pre-menopausal status. Further diagnostic evaluation of the patient was similar to that which is standard for women deemed to be candidates for endometrial ablation.

Patients received no hormonal or surgical (i.e. D&C) endometrial pre-treatment and the procedure was not timed to a particular menstrual cycle day. The ablation procedure was performed in some patients who were actively bleeding during the time of the operative visit. All of the procedures were performed under local anesthesia with or without intravenous sedation.

## **Results**

All patients were treated in a hospital OR setting. Of the 75 women

treated in this clinical trial, there were no intra-operative complications. Average treatment time was 90 seconds, ranging from 40-120 seconds. All patients were discharged in 1-2 hours following treatment. The intra- and post-operative pain associated with the ablation performed using the NovaSure system appeared to be minimal and was tolerated by patients very well. No additional analgesics were required in the post-operative period. One patient was removed from the study follow-up phase at 12 months due to an elevated FSH result. At 6 months follow-up she reported complete amenorrhea. Two patients underwent hysterectomy due to pelvic pain and adenomyosis was confirmed during the pathological examination. There were no other medical/surgical interventions (i.e. D&C, endometrial re-ablation, drug therapy). The mean pre-operative PBAC score of 936 dropped to 7 at 6 months follow-up, 8 at 12 months, 1.2 at 24 months and was reported to be 0.7 at 36 months following the procedure. Graph 1 below represents complete data results available at the time of the manuscript submission.



Graph 1

## Discussion

The authors of this paper agree that the procedure does not require extensive technical skill. Nevertheless, the procedure should be performed by a physician comfortable with intrauterine manipulations (i.e. D&C, IUD insertion). The NovaSure System is found to be very safe due a number of safety features employed. Presence of the CIA System is a unique, pro-active safety feature that will ultimately not allow for RF energy being delivered if a perforation of the uterine wall remained

undetected by the operator. The Device Position Feedback System allows the operator to monitor the device position in the uterine cavity and prevent RF energy delivery if the NovaSure device is placed into a false passage. Since no distension media is required and the treatment is very quick (90 seconds) it is tolerated by patients very well and can be easily performed under PCB  $\pm$  IV sedation.

One of the major benefits of the NovaSure system we consider to be the feature that the ablation will be equally effective without endometrial preparation of any kind (i.e. D&C, drugs, timing)<sup>5</sup>. The procedure can be performed during menses.

Perhaps the most important aspect that is applicable not only to NovaSure, but to any endometrial ablation system is patient counseling. It is very important that we (physicians) set correct expectations for our patients with regards of the procedure outcome. We believe that under no circumstances we should promise amenorrhea to our patients. It is imperative for patients to understand that the purpose of the endometrial ablation procedure is reduction in menstrual bleeding to normal levels. And if amenorrhea is achieved, it should be treated as a bonus.

## Conclusions

1. Long-term clinical results indicate that the NovaSure System is a safe and effective treatment modality for women with menorrhagia secondary to DUB.

2. NovaSure ablation system is the only system that does not require endometrial pre-treatment.

3. The system was found to be very easy to use.

4. Because of a number of safety features employed, NovaSure system should be considered a system of choice in treatment of menorrhagia due to benign causes.

5. Long-term results obtained in this study are consistent with the results published in the literature<sup>5,6</sup> and seem to be quite durable.

## References

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