A 9.2GHz MICROWAVE APPLICATOR FOR THE TREATMENT OF MENORRHAGIA

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ABSTRACT

We report on the design, analysis and clinical use of a 9.2GHz medical applicator specifically developed for the purpose of endometrial ablation in the treatment of menorrhagia. The technique of endometrial ablation is introduced. Experimental and clinical trials are summarised.

INTRODUCTION

Menorrhagia is generally defined as excessive menstrual bleeding in the absence of organic pathology where the blood loss in each menstrual cycle exceeds 80ml[1]. Menorrhagia is now considered to be one of the most frequently encountered gynaecological problems. For many years, total abdominal and vaginal hysterectomies have been the standard treatments for intractable menorrhagia. In 1980 there were 625000 hysterectomies in the USA, (65 cases per 10000 women aged 14-60), at a cost of $1700 million.[2] Of all hysterectomies, 30-45% are performed on women who suffer from menorrhagia[3], yet this operation is known to be associated with significant morbidity, expense and a prolonged inpatient stay[4].

Since the 1940's various methods have been employed to destroy the regenerative capacity of the endometrium, (the glandular lining of the uterine cavity, which generates the menstrual flow), to effect an alternative to hysterectomy in the treatment of menorrhagia. Treatment methods, often termed endometrial ablation, have been diverse yet only a few techniques have met with some degree of success. These methods have included cryosurgery[5], laser ablation[6], electroresection using RF driven diathermy loops and roller-balls[7,8], RF ablation at 27.12MHz[9], and thermal balloons[10]. All of these techniques have been evaluated; however, complications[11,12,13] have driven surgeons and scientists to continue the search for an ablation procedure that is rapid, simple and safe to perform, and has predictable outcomes.

An entirely new approach to the problem has resulted in the development of a microwave applicator specifically designed for the purpose of endometrial ablation.

ENDOMETRIAL ABLATION

The regenerative nature of the endometrium is well known[14] so to achieve an effective result using endometrial ablation the basal layer of the endometrium must be completely destroyed. This has become the primary objective for all endometrial ablation techniques.

The endometrium, diagrammatically shown in Figure 1, with basal layer consisting of epithelial cells extruding up from glandular tufts, is set in the muscular walls of the myometrium.

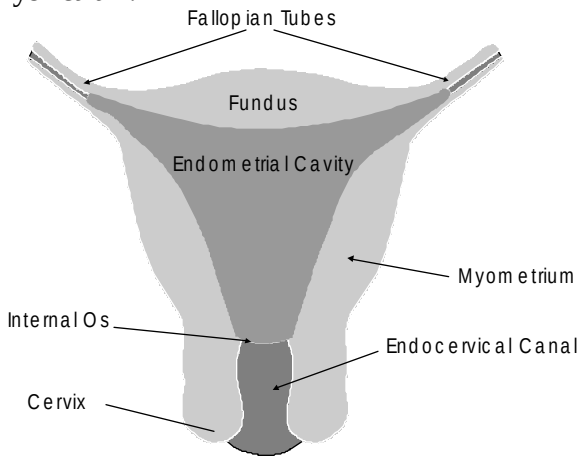

Figure 1: The Uterus

Considering that endometrial glandular elements will almost invariably be present deeper in the myometrium, it is necessary to destroy tissue to a depth of at least 5mm where this depth should include 2.5mm to 3mm of

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myometrium to prevent isolated regeneration of endometrium.[15]

Entry to the endometrial cavity is made via the cervix, which can be dilated, to a maximum diameter of about 10mm. It is imperative that the endocervical canal is not heated as a result of the ablation treatment as this can result in cervical stenosis and resultant hematometra. Achieving full coverage of the endometrial cavity and consistent depth of necrosis is essential if amenorrhea (no more periods) or patient satisfaction (light periods) is to occur as a result of an endometrial ablation procedure. It is therefore, essential to design an applicator that can destroy tissue in a hemispherical zone in order to access endometrium set in the fundus (ceiling) of the uterus, in the corners leading to the fallopian tubes, and in the side walls throughout the uterine cavity.

APPLICATOR DESIGN

A 9.2GHz microwave frequency was chosen to produce the 5mm depth of necrosis required to completely destroy the basal layer of the endometrium.

The delivery of microwave energy at 9.2GHz to the uterine cavity presents several difficult design problems which have all been overcome. The diameter of the applicator must be less than 10mm to enter the uterine cavity via the cervix and to prevent postoperative infection the applicator shaft must remain cool. Heat generated by losses in the applicator shaft and conduction from the heated tissue adjacent to the radiating portion of the applicator must be efficiently sunk to protect the surrounding endocervical tissue from damage.

The design approach taken was to use circular metal pipe waveguide to propagate microwave energy at 9.2GHz into the uterine cavity. At this frequency the internal diameter of an air filled circular waveguide should be about 20mm and this dimension would make the applicator line too large to gain entry to the uterine cavity via the cervix. To reduce this diameter a high permittivity ceramic is used to load the waveguide[16]. This dielectric is then extended beyond the metal pipe to form the radiating tip. A photograph of the applicator is shown in Figure 2.

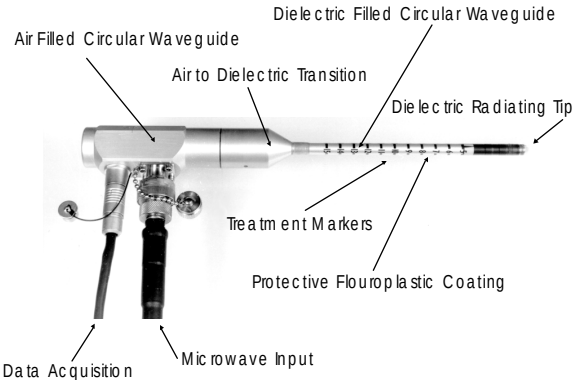

Figure 2: The Microwave Applicator

The combination of a metal pipe dielectric filled waveguide and dielectric radiating tip gives this applicator excellent power handling and heat-sinking capabilities. Furthermore, the dielectric applicator tip produces a hemispherical field of heating in tissue that has proven to be efficient at treating the difficult to reach fundus and corners of the uterine cavity.

APPLICATOR MODELLING

The applicator has been modelled using HFSS Version 4. The model shows that the reflection coefficient (S11) from the radiating tip in endometrial tissue is -10.5dB at 9.2GHz. This result correlates well with measurements made on a vector network analyser and confirms that the structure couples well into endometrium without the need for additional tuning elements. The model also yields information about the nature of the electromagnetic field generated in the tissue around the tip.

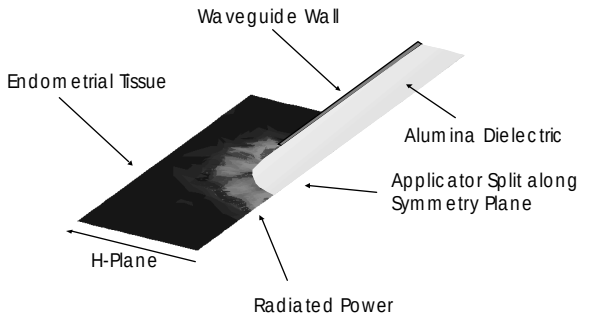

Figure 3: HFSS Model

Figure 3 shows a greyscale picture indicating the electric field pattern around the applicator tip in the H-Plane. For the purpose of the model a value equal to

45+j36 was used for the dielectric constant of endometrium. This value was measured using the resonant perturbation method on a small sample of endometrium tissue placed in a purpose built cavity.[17] In this picture the contrast has been enhanced to increase the visibility of the pattern. The figure shows that the field is distributed quite uniformly over the surface of the radiating tip and, in particular, significant power is transmitted to the tissue in the forward direction. This aspect of the applicator design is key to the effectiveness of treatment in endometrial ablation.

EXPERIMENTAL TRIALS

Early empirical tests involved checking the applicator field pattern in tissue phantoms. Figure 4 shows a simple test where the applicator tip is immersed in egg white.

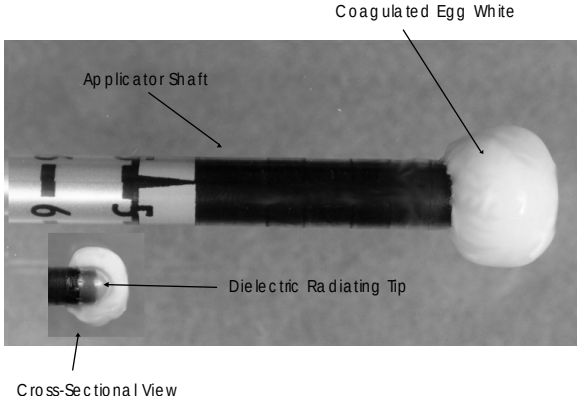

Figure 4: Egg White Tests

With normal power levels (30W) the egg white quickly hardens showing a clear representation of the hemispherical field pattern emanating from the dielectric tip. The coagulated egg white can also be removed and sectioned to observe the depth and symmetry of the field pattern.

The applicator has been extensively tested in animal tissue, excised uteri, perfused excised uteri, and finally in vivo prior to hysterectomy. In the latter experiments the specimens were stained with a tissue stain[18] (Figure 5) which stains vital tissue an intense blue while devitalised areas (necrosed tissue) fail to stain and remain pale.

Using the information obtained during these experimental trials it is now possible to consistently achieve a depth of necrosis of 5-6mm in vivo.

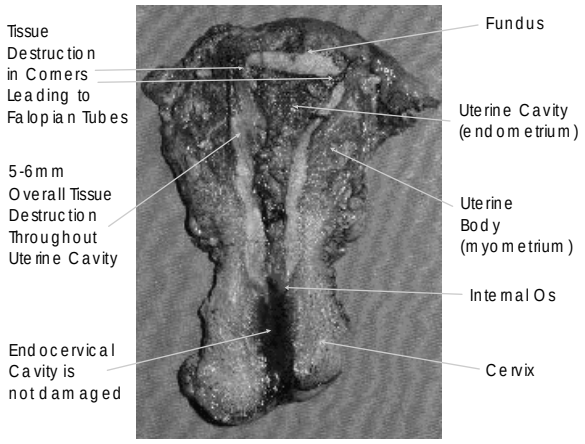

Figure 5: In Vivo Test

TREATMENT DYNAMICS

Uterine tissue has a very high water content so the microwave field amplitude will be reduced by 90% approximately 3mm from the surface of the applicator tip. Beyond this zone of intense microwave heating, further tissue destruction occurs by thermal conduction from the heated region. The total depth of necrosis, therefore depends upon the power level used and the length of time for which this power is applied. The pattern of heating in tissue resulting from this applicator tip is hemispherical and monitoring the temperature of heated tissue adjacent to the applicator tip surface controls the overall depth of necrosis. A thermocouple on the applicator tip measures the temperature at the surface of the endometrium. This temperature is displayed graphically in real-time, enabling the surgeon to monitor the progress of heating. The microwaves coming out of the applicator tip heat the endometrium, causing the temperature to rise. Likewise, when the applicator tip is moved to untreated endometrium the temperature will fall. Figure 6 shows a diagrammatic representation of the treatment process. The surgeon uses this graphical temperature response to control absolute depth and coverage of heating during the MEA treatment. The system LCD screen provides the surgeon with a proven treatment temperature band and warning tones are activated if treatment temperatures are allowed to exceed pre-set lower limits.

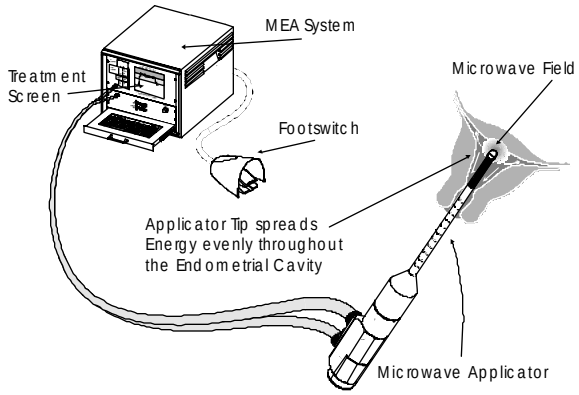

Figure 6: Treatment Process

CLINICAL TRIALS

Clinical trials using prototypes commenced in October 1994 and the initial results were published in the Lancet[19]. In September 1996 the first commercial MEA system was installed in a UK hospital. There have been more than 500 patients treated to date. The technique is easy to learn and the average 30W treatment will take less than 3 minutes. There have been no complications reported and the clinical data suggests that the treatment success rate is better than 90% with two and three year follow-up.

CONCLUSIONS

Following extensive experimental and clinical trials we have been able to show that Menorrhagia can be treated through surgical destruction of the endometrium by microwave heating. The use of an applicator based upon a dielectric loaded circular metal pipe waveguide allows the endometrium to be totally destroyed to a depth of 5-6mm without damage to the endocervical canal. The system uses temperature as a parameter by which the surgeon can confidently control the movement of the applicator within the endometrial cavity to produce a uniform layer of tissue destruction. The microwave power level used is 30 watts and the duration of the treatment is typically 2-3 minutes. Over 500 patients have been treated to date with a 90% satisfaction rate. There have been no complications reported.

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