とうちんのｴｯｾｲ **2001**

# 米国知的財産権（特許権）その後

佐藤　透

思いがけない e-mail が届いた。米国カリフォルニア大学サンフランシスコ校（UCSF）の技術管理部門会計担当者からだった。留学中に発明した脳腫瘍などの温熱療法に用いる組織内留置型マイクロ波アンテナの特許料(royalty)支払いのため、住所確認の問い合わせだった。もう、かれこれ帰国して 15 年、開業して 10 年になるのに、よくぞ分け前を教えてくれたもんだ、と米国の正義に素直に感謝した。事情の詳細は分らないけれど、機嫌を損ねてもいけないので、直ちに現住所を返信 mail した。3 週間後の平成 12 年 11 月 30 日に、UCSF 振出しの額面 TWO THOUSAND FIVE HUNDRED FORTY-EIGHT AND 86/100 US DOLLAR ($2,548.86***)の小切手（チェック）が届いた。うーん、30 万円か。

そういえば、“留学を終えて帰国して 2 年後の 1989 年、We have a patent、米国特許取得の連絡があった。確か、大学出入りの温熱治療機器会社 Clinitherm 社と特許ライセンス契約するはずだった。そういやぁ、はよぅ医者やめて、ひだり団扇のはずじゃったな。”（当時の事情は第 23 回岡山大学脳神経外科同門会誌、pp48-53、1990（平成 2 年 2 月 17 日）に既報、この際ご一読ください）。早速、当時のボス、UCSF Radiation Oncology の Paul R Stauffer 准教授(現)に事の次第を尋ねてみた。と言うのも、彼が first name(^！)で、小生との連名で登録された“われわれの”米国特許に対する royalty であった。彼曰く、C 社はいわゆるひとつのベンチャー企業であって、とうの昔に倒産してしまった。その後特許の買い手がなくて大学の不良財産となっていた。UCSF では、悪性脳腫瘍の温熱療法の臨床研究は、もはやしていないけど、乳癌、皮膚癌の温熱放射線療法は続いている。最近では、癌の温熱療法は形を変えて、前立腺肥大に対する温熱治療、肝細胞癌の電磁波焼灼治療、頻脈性不整脈での経カテーテル房室結節アブレーション治療が広く行われ、それらにマイクロ波アンテナが用いられている。このたび、世界 No1 の温熱治療機器会社 BSD 社が、われわれの特許を購入することとなり契約が成立した。ただ、現時点では新案のアンテナを製造して全世界で販売す

るというよりも、競合する他社にライセンスがわたり、BSD 社の類似したアンテナが製造できなくなるのを防止する意味合いから特許購入となった。1989 年 5 月 2 日公開の特許権で、米国特許の有効期限は 17 年だから、2005 年まであと 5 年、あと 5 回支払いがあるかどうか、契約内容の詳細は大学と会社とのビジネスなので立ち入れない。でも、小額だけど、今回はお小遣いができてよかった。小切手に同封された大学からの支払いの明細は、7/1/99 から 6/30/00 までの royalty が＄12,000.00、大学の特許管理費が 15％、＄1,800.00 など差引いて残額＄10,195.43、これを UC（カリフォルニア州）が 50％、発明者が 50％で、結局のところ、小生の取分は 25％の＄2,548.86 となった。

特許とはなんたるか？早速 Yahoo で特許の項目で検索して、日本の特許庁のホームページ（*http://www.jpo.go.jp/indexj.htm*）を開いてみた。最近は、特許を含めて知的財産権（通称、知財あるいは知的所有権というらしい）に対する社会的認知がいろいろな分野で進み、各企業、国家の競争力を高める戦略的手段として知的所有権が保護強化されている。これがマイクロソフトや理化学研究所などをはじめとした最近の行過ぎた訴訟問題の背景だな、フムフムと妙に感心した。知的財産権は、人間の幅広い知的創造活動について、その創作者に権利保護を与える。独創的なアイデアである「発明」は特許法で、新しい「考案」には実用新案法で、ユニークなデザインである「意匠」は意匠法で、音楽や小説、絵画などの「著作物」は著作権法で保護される。また、事業活動を行う時の名前である「商号」は商法で、自己の商品やサービスを示すためのブランド「商標」は商標法で保護される。さらに、バイオテクノロジーや情報通信などのハイテク分野では、コンピュータ・プログラムや、半導体集積回路なども保護の対象とされる。知的財産権のなかで、物または方法の技術面で新しいアイデアでかつ高度に独創的なもの、実用新案と比べて長ライフサイクルのものは、特許権として認められ、日本ではその知財が出願から 20 年間保護される。（ただし、医薬品と農薬については5年が限度とされ、先発品のあとすぐにゾロゾロと出てくるお馴染みの後発医薬品は皆さんご存知のとおり。）

このなかに、ノーベル賞と特許のコラムがあり、日本人ノーベル賞受賞者の特許出願状況が分析してある。1949 年物理学賞の湯川秀樹博士、1965 年物理学賞の朝永振一郎博士は特許出願がゼロ。1973 年物理学賞の江崎玲於奈博士以降、1981 年化学賞の福井謙一博士、1987 年医学・生理学賞の利根川進博士、2000 年化学賞の白川英樹博士、そして本年 2001 年の化学賞を受賞した野依良治博士は、いずれも特許

出願を行っている。なかでも、白川博士が、日本 32,米国 8,欧州 3、野依博士は、日本 166,米国 35,欧州 69 と研究成果についてとてつもなく多くの特許出願をしていることを特筆し、大学･公的研究機関や企業における研究成果の効果的な社会還元を得るうえで、特許取得の大切さを指摘している。日本の 10 大発明家として、人力織機の豊田佐吉、養殖真珠の御木本幸吉、アドレナリンの高峰譲吉、グルタミン酸ソーダの池田菊苗、ビタミン B1 の鈴木梅太郎、邦文タイプライターの杉本京太、KS 鋼の本多光太郎、八木アンテナの八木秀次、写真電送の丹波保次郎、MK 鋼の三島徳七が紹介され、いずれの場合も研究成果として得られた発明の特許取得が契機となり、その当時の産業技術が著しく発展したことから、特許の重要性を喚起している。

最近の情報公開により、各国特許庁の database（ *http://www.246.ne.jp/~yasuon/* ）がインターネットで簡単に覗けるようになった。ちなみに、米国特許貿易庁のホームページ（ *http://www.uspto.gov/patft/index.html* ）を開くと、Patent Grants の項目から、われわれの米国特許 4825880: Implantable helical coil microwave antenna (June 19, 1987 Filed, May 2, 1989 Patented)が full-text で閲覧できる( http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=4825880.PN.&OS=PN/4825880&RS=PN/4825880 )。Patent claim は、延々 9 頁にアンテナ図譜付きで、通常の科学論文 2 倍強のボリュームである。画面で見るには忍耐がいるので、直ちにプリントアウトして、15 年ぶりに特許論文を熟読してみた。この中で科学論文の impact factor にも相当するわれわれの特許論文の引用が、2000 年までの 10 年間で 48 回にのぼっていた。われわれが特許申請時に引用した論文はわずか 4 編であった。これに対し、われわれ以降に特許申請でわれわれの特許内容を参照した関連案件がその後 48 件あることになり、この 10 年間の microwave antenna 関連特許の発展を伺う 1 つの指標と思われる。Quick search で最近 5 年間の microwave antenna に関する新規特許を探してみると 535 件にものぼる。最新のものは米国特許 6,289,249: Transcatheter microwave antenna で、前立腺肥大の温熱治療用に開発した経尿道カテーテル内に留置可能なマイクロ波アンテナが公開されている。特許出願･特許取得は科学研究や日常臨床におけるアイデアとして、米国では、もっと気軽に自由に挑戦される環境が出来ているようだ。しかし、単に特許が得られても、特許権が誰かにどこかでライセンス化され、その特許が社会で活用されて、はじめてアイデアと一連の研究が社会に還元

されたと言える。

今回の朗報は、直ちに、医局長（田宮隆講師）にご相談申し上げ、早速、全額を医局研究奨学資金として寄付させていただいた。（そういえば、感謝状がまだ届いてねえなあ。!~）これで米国知的財産権である特許権がライセンス化され、長年お待ちいただいた特許申請に伴う弁理士手数料が相殺されたこと、カリフォルニア大学の知的財産の不良債権にならずに済んだこと、社会還元とまではいかなかったけど、第 60 回日本脳神経外科学会総会（大本堯教授会長）を控えた医局に小額ながら還元できたこと、そして、なによりも、思いつきではじめた場当たりの研究アイデアが、米国特許としてやっと陽の目を見たことに充分満足し、いま感慨を新たにしている。

Patent の詳細は、論文並みの記述にある。お時間のあるお方、ご興味のある方は、以下、ご一読くだされたし。

UNITED STATES PATENT AND TRADEMARK OFFICE
An Agency Of The United States Department Of Commerce
Patent Full-Text and Full-Page Image Databases

**United States Patent** **4,825,880**

**Stauffer , et al.** **May 2, 1989**

**Implantable helical coil microwave antenna**


**Abstract**

An implantable helical coil microwave antenna, particularly adapted for interstitial hyperthermia therapy of cancer, comprises a coaxial cable having a distal end of its outer conductor removed and a helical coil mounted on the exposed inner conductor insulator. A proximal end of the helical coil is separated axially from the distal end of the outer conductor and the distal end of the helical coil is connected to the inner conductor of the coaxial cable feed line. The antenna functions to confine heat to the area immediately surrounding the coil and thus induces substantially identical thermal profiles at varying antenna insertion depths in tissue when the antenna is energized with microwave energy.

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Assignee: **The Regents of the University of California** (Berkeley, CA)

Appl. No.: **07/084,334**

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|---|---|
| **Current U.S. Class:** | **607/156** |
| **Current International Class:** | A61B 18/18 (20060101); A61N 005/02 () |
| **Field of Search:** | 128/804,784,401 |

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*Primary Examiner:* Cohen; Lee S.

*Attorney, Agent or Firm:* Phillips, Moore, Lempio & Finley

## *Government Interests*

This invention was made with Government support under Grant Contract No. CA-39428 and CA-13525 awarded by the National Institute of Health. The Government has certain rights in this invention.

## *Claims*

We claim:

1. An implantable helical coil microwave antenna for improving localization of interstitial hyperthermia comprising

an inner conductor,

a dielectric insulator covering said inner conductor,

an outer conductor covering only a proximal portion of said insulator to form a coaxial cable thereat and to leave a distal portion of said insulator uncovered, and

a helical coil means surrounding the distal portion of said insulator and having a proximal end spaced axially from a distal end of said outer conductor to form a separation gap therebetween and a distal end of said coil means connected to a distal end of said inner conductor for confining heat to immediate areas surrounding said coil means and for inducing substantially identical thermal profiles at varying depths of insertion of said antenna into an organic subject when said antenna is energized with microwave energy.

2. The antenna of claim 1 wherein the axial length and turn density of said helical coil means provide an impedance match of a microwave generator to said organic subject at a microwave frequency within the range of 0.1 to 3.0 GHz.

3. The antenna of claim 1 wherein the outside diameter of of said helical coil means is constant.

4. The antenna of claim 3 wherein the outside diameter of said outer conductor approximates 0.095 cm for close insertion within a 16-gauge catheter.

5. The antenna of claim 3 wherein the outside diameter of said coil means approximates 0.12 cm.

6. The antenna of claim 1 or 5 wherein said helical coil means has a length selected from the approximate range of from 1.0 to 20.0 cm and has turns in the approximate range of from 7 to 16 turns per cm of said length.

7. The antenna of claim 1 or 5 wherein the separation gap between the proximal end of said helical coil means and the distal end of said outer conductor has a length in the approximate range of from 0.1 cm to 5.0 cm.

8. The antenna of claim 7 wherein said helical coil means comprises a metallic wire coiled to have at least seven turns per cm of axial length thereof.

9. The antenna of claim 8 wherein said wire has ten turns per cm of axial length thereof.

10. The antenna of claim 8 wherein the outside diameter of said wire is selected from the approximate range of from 0.02 to 0.04 cm.

11. The antenna of claim 10 wherein said wire is composed of nichrome, bare copper, varnish insulated copper or silver-plated copper.

12. The antenna of claim 1 wherein the outside diameter of said helical coil means varies.

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***Description***

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TECHNICAL FIELD

This invention relates generally to a microwave antenna and more particularly to an implantable helical coil microwave antenna for improved localization of interstitial hyperthermia.

BACKGROUND ART

Hyperthermia constitutes an effective adjuvant treatment for malignant tumors which are refractory to conventional therapy with surgery, radiation or chemotherapy. Hyperthermia can be administered to a patient either by an externally applied electromagnetic or ultrasound source, or internally by an interstitial heating technique. Implantable microwave antenna heating has proven the most popular of the three present interstitial heating modalities.

However, major problems arise with the use of conventional half-wavelength dipole antennas which severely limit the applicability and effectiveness of interstitial microwave hyperthermia. Such problems include: variability of heating profiles when the antenna is inserted to different depths in the tissue to be treated, restricted range of possible heating lengths for a given microwave frequency, and the presence of a so-called "cold region" or "dead length" occurring at the tip of the antenna. Attempts have been made to solve one or more of the above problems by providing implantable radiating antennas having improved performance characteristics.

For example, two-node and three-node microwave antennas have been proposed to expand the heating volume to as much as twice that provided by a single-node dipole antenna. However, such antennas have exhibited an inhomogenous heating pattern with three or four peaks along the antenna axis and a failure to heat effectively out of the antenna tip. A variable diameter dipole antenna has also been proposed to force the heating current into larger diameter sections of the antenna which fit snugly within the biocompatible plastic catheter. The larger diameter section at the tip of the antenna appears to provide more effective tip heating, but the antenna still exhibits considerable dependence of heating on insertion depth and periodic excessive surface tissue heating.

Other types of dipole antennas, such as the sleeved coaxial slot and balun-fed folded dipole, have been proposed for shifting the heating field out to the antenna tip. The concept of multiple breaks in the coax outer conductor of the antenna with each section being driven by a separate microwave source has held some promise for closer control of the depth heating profile, but at the expense of greatly increased equipment complexity. Although often accomplishing an expansion of the effective heating length for a given frequency and/or a reduction in dead length at the tip, the above types of antennas are commonly plagued with the same critical problem as that of the linearly polarized simple dipole antenna, namely, a critical dependence of the heating pattern on the depth of insertion.

Another proposed technique employs an "over-ride" reciprocated motion system for linearly translating the dipole antenna during treatment. Although this technique may potentially solve at least part of the axial heating pattern problem, predictability and real time control of the overall heating pattern would likely prove difficult due to power deposition pattern changes at different positions within the range of antenna movement.

A similar development of antenna designs has occurred for intracavitary heating applications. Antennas of this type having somewhat larger diameters (e.g., 1-1.5 cm v. 0.1-0.15 cm) have been used in the treatment of tissues surrounding body cavities. An antenna of the latter type has been constructed with a 1.0 cm diameter coax cable outer conductor cut in a helical manner and pulled apart axially to form a helical extenson of the antenna feedline outer conductor having ten turns extending 14 cm in length. Thermal profiles of the antenna were found to be quite variable for the different conditions studied and the antenna exhibited a strong dependence on both source frequency and insertion depth. Most tests were performed using insertion depths less than the 14 cm length coil.

A so-called "flexible leakage type" antenna has also been proposed for use at 2450 MHz. This type of antenna consists of a helical structure composed of 1.0 mm wide copper foil tape interconnected between the inner and outer conductors of a 2.0 mm diameter flexible coaxial cable.

## DISCLOSURE OF THE INVENTION

The improved microwave antenna of this invention is comprised of an inner conductor, a dielectric insulator covering the inner conductor and an outer conductor covering only a proximal portion of the insulator to form a coaxial cable thereat and to leave a distal portion of the insulator uncovered. A helical coil surrounds the distal portion of the insulator and has its proximal end spaced axially from a distal end of the outer conductor and its distal end connected to a distal end of the inner conductor.

The antenna will function to confine heat to the immediate area surrounding the helical coil and to produce substantially identical thermal profiles at varying depths of insertion of the antenna into the treatment volume tissue when the antenna is energized with microwave energy. In addition, the antenna of this invention exhibits other advantages over existing implantable microwave antenna designs. For example, the size of the heated volume for a given frequency can be adjusted readily by simply changing the length of the coil (within a preselected range). The dead length (cold portion at the end of the implanted antenna) is eliminated which minimizes the need for implanting antennas deeper than the lower extent of the target region. Undesirable tissue heating along the antenna feedline is eliminated with deep insertions, as well as overheating of the tissue surface for shallow depth insertions of the antenna.

The antenna of this invention will thus provide well focused and controlled interstitial hyperthermia to a given volume of tissue, regardless of location within a larger structure without undesirable and uncontrollable hot spots along the antenna feedline. Multiple antenna arrays may be used to expand the effective heating volume laterally, using either coherently or incoherently phased microwave sources. Use of the antenna is compatible with existing radioactive seed brachytherapy for combination interstitial hyperthermia and radiation therapy of malignant tumors. Although the antenna is particularly adapted for improved heating uniformity in interstitial hyperthermia therapy of cancer, the antenna is useful for a variety of other applications wherein heat must be applied uniformly to the interior of large lossy dielectric volumes. New applications in food warming, material quick-thawing and tissue therapy are expected with reduced pricing of antennas and microwave sources.

## BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of this invention will become apparent from the following description and accompanying drawings wherein:

FIG. 1 is a longitudinal cross-sectional view of a microwave antenna embodying this invention;

FIG. 2 graphically illustrates the effect of varying insertion depths on the axial thermal profiles of a 2450 MHz, L=1 cm. helical coil antenna in a tissue equivalent homogenous phantom;

FIG. 3 is a longitudinal cross-sectional view of a commonly used style of implantable dipole antenna;

FIG. 4 is a graph, similar to FIG. 2, showing the effect of varying insertion depth on the axial thermal profiles of a 2450 MHz, L=1 cm simple dipole antenna (FIG. 3) for comparison with the antenna of this invention;

FIG. 5 is a comparison in dog thigh muscle in vivo of the radial temperature fall-off from the antenna of this invention to that of the standard dipole antenna, and to that of thermal conduction heating only; and

FIG. 6 is a graph showing the essentially constant shape of the induced temperature distribution for three different 915 MHz helical coil antenna insertion depths in dog thigh muscle in vivo.

## BEST MODE OF CARRYING OUT THE INVENTION

### General Description

FIG. 1 illustrates an implantable helical coil microwave antenna 10 embodying the present invention. The antenna was constructed from a miniature coaxial cable comprising a metallic inner conductor 11 surrounded by a tubular dielectric insulator 12 fully covering the inner conductor. A distal section of a tubular metallic outer conductor 13 was removed so that the outer conductor only covered a proximal portion of insulator 12 to form a coaxial cable portion thereat and to leave a distal portion of the insulator uncovered.

A metallic wire helical coil 14 was constructed to surround the distal portion of insulator 12 and to have its proximal end spaced axially from a distal end of outer conductor 13 to form a separation gap G therebetween. A distal end of the helical coil was soldered and connected at 15 to a distal end of inner conductor 11. As more fully explained hereinafter, antenna 10 was found to confine heat to the immediate area surrounding helical coil 14 and to induce substantially identical thermal profiles at varying depths of insertion of the antenna into an organic subject when the antenna was energized with microwave energy.

In use, antenna 10 is adapted to slip within a standard 16-gauge plastic catheter 16, as is, commonly used for brachyradiotherapy treatments. In use, the catheter entirely covers the implanted antenna and is closed at is distal end. Antenna design parameters, such as the axial coil length L, coil turn density and specific wire material composing helical coil 14, are predetermined for proper impedance match to biological tissue at a given microwave frequency.

The exact number of coil turns and separation distance of gap G are predetermined for each antenna application, along with the coil turn density and connection configuration of the coil to the coax feed line which are essential determinates of the radiated field. In addition to the ability of antenna 10 to effectively confine heat to the region immediately surrounding helical coil 14 and to efficiently radiate such heat independently of implanted depth, the size of the heated voluem can be readily adjusted by adding more such antennas to the array, by changing frequency and/or by changing length L of the helical coil for a given coil turn density. Additional adjustments to the heating field may be accomplished by using variable spacing and variable diameter of the coil turns to shape the power deposition pattern along the antenna length. Since the dead length (cold portion at the end of the implanted antenna) is eliminated, the need for implanting the antenna deeper than the lower extent of the target region is minimized. Also, undesirable tissue heating along the antenna feedline is eliminated along with overheating of the tissue surface for shallow depth insertions.

Comparative testing of antenna 10 against the simple dipole antenna 17 (FIG. 3) showed that the power deposition characteristic of the standard antenna varied significantly for varying insertion depth (FIG. 4) in contrast to the power deposition pattern of antenna 10 which remained essentially constant regardless of insertion depth (FIG. 2). In use, implanted antenna 17 is also entirely covered with a plastic catheter 16 (FIG. 1), closed at its distal end. The ordinates "% maximum temperature rise" in FIGS. 2 and 4 also depict "relative specific absorption rate."

DETAILED DESCRIPTION

The specific antenna embodiment 10 used for comparative testing purposes described below constituted a 0.095 cm OD semi-rigid coaxial cable sized to slip within plastic catheter 16 (FIG. 1). The outer diameters of inner conductor 11, insulator 12 and outer conductor 13 were 0.02 cm, 0.061 cm and 0.095 cm, respectively. Gap G, between the distal end of outer conductor 13 and the proximal end of helical coil 14, was 0.1 cm whereas length L of the helical coil was 1.0 cm. The distal end of the helical coil was soldered to the distal end of the inner conductor at 15. The inner and outer conductors were composed of a standard copper based alloy having high electromagnetic wave energy transmission properties whereas insulator 12 was composed of a standard Teflon (polytetraflouroethylene) material.

Helical coil 14 was also composed of a metallic conductor having high microwave energy transmission properties. For example, antennas constructed with 0.032 cm nichrome, 0.032 cm varnish insulated copper, and 0.0203 cm silver-plated copper wire all have been used successfully. The outside diameter of the helical coil closely approximated 0.12 cm to facilitate insertion of antenna 10 into standard 16-gauge plastic catheter 16.

Helical coil 14 was formed by wrapping a wire tightly around a stainless steel wire form, dimensioned to provide the desired diameter, length and turn density of helical coil 14. After extracting the wire form from the formed helical coil, the helical coil was installed carefully over the bare dielectric insulator portion of insulator 12, as shown in FIG. 1, and soldered at 15. Gap G was set at 0.1 cm.

In the preferred embodiments of this invention, axial length L and the turn density of helical coil 14 provide an impedance match of a microwave generator to an organic subject (e.g., tissue to be treated) at a microwave frequency ranging from approximately 0.1 to 3.0 GHz. Helical coil 14 preferably has a length L selected from the approximate range of from 1.0-10.0 cm and has equally spaced turns in the approximate range of 7 to 16 turns per cm. More sophisticated applications of this invention are anticipated with variable turn density along the coil to customize the heating field shape.

## SURGICAL PROCEDURE

The following discussion briefly summarizes a typical surgical procedure using the above-described helical coil microwave antenna 10 for improving the localization of interstitial hyperthermia. An appropriate length antenna is first chosen to provide the desired heating pattern in accordance with the above discussions. For 915 MHz operation, a nichrome or copper wire coil with axial length L in the range of 1.0-10.0 cm may be selected for proper heat localization to the coil tip. Depending on target size, multiple-antenna array operation is possible to expand the effective heating volume.

A parallel array of 16-gauge plastic catheters 16 are inserted into the target region of a patient with the aid of a .ltoreq.1.0 cm grid template or stereotactic surgical frame. Metal needles or stainless steel stylets are normally used to guide the catheters in place. A standard CT scan or simple X-ray will verify proper location of the catheters relative to the tumor or other tissue to be treated.

Antennas 10 are inserted into the desired catheters 16 and extended to the appropriate insertion depth. Standard temperature sensing probes are inserted into other plastic catheters to monitor and control the temperature distribution. If it is found that one or more of the antennas are not well matched electrically to the tissue load, minor adjustments can be made to the helical coil turn spacing or a double stub tuner can be used to obtain the best match of antenna to generator. Each antenna is connected to a microwave generator via a flexible coaxial cable in a conventional manner.

Microwave power can be controlled either manually or automatically by a computer feedback system to maintain the desired minimum tissue temperature (typically 43.degree. C. for one hour, or equivalent). The temperature probes are manually translated inside the respective plastic catheters to monitor temperatures at approximately 1 cm increments within the heated tissue volume several times during the treatment to provide information on the internal temperature distribution of the tumor volume. At the end of treatment, microwave power is terminated and all antennas and sensors are removed from the catheters. Interstitial hyperthermia therapy induced via the implanted antennas can be repeated before and after radioactive seed brachyradiotherapy without additional surgery, using the same implanted plastic catheters 16.

COMPARATIVE EVALUATION WITH EXISTING TECHNOLOGY

Standard dipole antenna 17 of FIG. 3 was constructed from a 0.095 cm semi-rigid coaxial cable having an inner conductor 18 covered by an insulator 19. An outer conductor 20 was cut circumferentially at 21 to form an axial separation gap of 0.1 cm between the cut portions of the outer insulator. A metallic connector 22 was soldered between the distal ends of the inner and outer conductors. Previous tests have shown this simple "Dipole" type structure operates identically to other dipole styles having a soldered connection (not shown in FIG. 3) of inner conductor 18 to outer conductor 20, adjacent to gap 21.

The specific polarization pattern of HCS style antennas is highly dependent on the source frequency, length of helix, spacing and diameter of coil turns 14.

Antenna 10 with a coil turn density of 10 turns/cm, a gap G of 0.1 cm, a coil diameter of 0.12 cm and a coil length of .lambda./4 of 1.0 cm (3.5 cm) was found to generate apparently circularly polarized electromagnetic waves which effectively localized the heating to the region surrounding the coil when driven at 2450 MHz (915 MHz). Other similar helical coil antennas with lengths L ranging from 1-5 cm, turn densities of 7-16 turns/cm and gap G from 0.1-5 cm also have been tested successfully at the two frequencies.

For comparative dosimetry study purposes and to match heating efficiencies of the antennas, each antenna was tuned to the coaxial feedline with a double stub tuner. The tuners were capable of precisely matching the antennas to the source frequency and feedline characteristics. This procedure enabled a direct comparison of antenna performance under optimum matched conditions, regardless of tissue properties or antenna insertion depth.

In order to study the antenna heating characteristics in a reproducible, homogenous tissue medium, soft tissue phantom was used initially to obtain the relative heating profiles of the different antenna configurations as a function of insertion depth. The phantom was composed of a mixture of distilled water (75.2%, base), TX-150 (15.4%, gelling agent), sodium chloride (1.0%, to adjust electrical conductivity), and polyethylene powder (8.4%, to lower dielectric constant). The mixture is known to have approximately the same electrical properties as those of human soft tissue at 915 MHz. A similarly appropriate phantom mixture was used for studies at 2450 MHz.

The material was contained in an 8.times.8.times.11 cm plexiglass box transversed by a 0.5 cm array of 16-gauge Teflon catheters for holding the antennas and multi-sensor temperature probes. Five phantom models were constructed during the course of the experiments and the reproducibility of thermal profiles in each phantom was verified, using both antennas 10 and 17. To evaluate the difference in axial thermal profiles (FIG. 2 vs. FIG. 4) produced by each antenna type, single antennas were inserted into a catheter which was immersed in the phantom so that gap G (FIG. 1) or gap 21 (FIG. 3) was located 1.0 cm below the phantom surface. The total insertion depth of 2.1 cm (approximately .lambda./2 in tissue) was considered near optimum for the standard dipole antenna 17.

Axial power deposition profiles of antennas 10 and 17 were compared for total insertion depths of 1.35 cm, 2.1 cm and 3.1 cm in phantom, as illustrated by each of the three curves in FIGS. 2 and 4. These tests were intended to model the three clinically relevant conditions of antenna use: too shallow, optimum implant depth, and too deep. Radial power deposition profiles in several planes perpendicular to the antennas were obtained for a single insertion depth of 2.1 cm. These profiles were then compared to the radial temperature fall-off obtained using a heated water circuit of similar dimensions as a control for strictly thermal conduction heating.

The antennas were both driven at either 915 MHz or 2450 MHz using a continuous wave microwave power source (Model CA 2450, manufactured by Cheung Laboratory, Inc., Lanham-Seabrook, Md. Power fed to each antenna was tuned with a double stub tuner (Model 1729, Maury Microwave, Cucamonga, Calif.) for optimum impedance match to the generator, since no attempt was made to trim each antenna to exactly 50 ohms. Since the phantom material had no cooling effect from circulating blood, all experiments consisted of short 30 sec. heat trials during which the rate of change of temperature was determined at all internally monitored points to represent the power deposition characteristics of the antennas.

The thermal profile information was obtained using a multiple-sensor optical fiber probe with four sensors spaced 0.25 cm apart with each inserted in a catheter parallel to and 0.5 cm away from the antenna axis. Using a separate stationary single sensor probe located mid-depth in a second parallel catheter as control between trials, longer axial heating profiles were measured by moving the multi-sensor probe 1 cm and repeating the heat trial after cool-down of the phantom to initial conditions.

All temperatures were recorded every 10 seconds by a computerized fiber optic thermometry system and displayed in tabular and graphic forms on a color monitor. The increase in temperature above baseline [.DELTA.T was calculated for each point and the measure of power deposition (Specific

Absorption Rate or SAR) was determined from the time rate of change of temperature following power on as SAR=c.multidot.d.DELTA.T/dt, wherein c=specific heat of phantom tissue].

The axial thermal power deposition profile of each antenna was determined independently at four different sites within the phantom box for each experiment. The antennas were tested in more than one phantom to minimize erroneous conclusions that might arise from slight catheter placement variations at depth in the phantom or other systematic test errors. Axial profiles from corresponding trials were averaged together by first selecting the maximum SAR of each linear distribution as 100% SAR and normalizing the profile to a percentage of the peak (Relative SAR).

FIGS. 2 and 4 compare the effects of varying insertion depth on the axial power deposition profiles of antennas 10 and 17. As noted in FIG. 4, the thermal profile of standard antenna 17 varied significantly, depending on insertion depth. With a 3.1 cm total insertion depth, the thermal profile was almost symmetrical with the peak located 1.5 cm below the surface and a 50% HL and Dead Length of 2.04 and 0.68 cm, respectively. With a shorter insertion of 1.35 cm (gap 21 depth of 0.25 cm), the 50% HL and Dead Lengths were both drastically reduced to 1.21 cm and 0.17 cm, respectively, but the antenna entrance point was overheated with 78% of the peak SAR obtained near the surface.

In contrast, the power deposition profiles induced by antenna 10 were essentially identical regardless of insertion depth. The heat peak moved correspondingly deeper with increasing insertion, remaining 0.5 cm proximal to the antenna tip midway along the axis of helical coil 14 (FIG. 1). The 50% HL for 1.35, 2.1, and 3.1 cm insertion depths was a constant 1.2 cm and the Dead Length remained essentially 0.0. Studies on the reproducibility of profiles for antennas 10 and 17 tested identically in five different phantoms disclosed no significant variation in the location of Peak Depth, 50% HL, or Dead Length.

Relative radial power deposition profiles perpendicular to the axes of antennas 10 and 17 were also obtained and compared with the radial temperature fall-off from a heated water circuit of similar dimensions. The corresponding comparative radial temperature distributions for L=3.5 cm antennas

10 and 17 driven at 915 MHz in dog thigh muscle tissue in vivo are shown in FIG. 5. FIG. 6 gives the absolute temperature distributions in dog thigh muscle along the axial length of antenna 10 (at R=0.5 cm distance) for three different clinically relevant antenna insertion depths. Note the very similar 50% HL's and slopes of the individual temperature distributions for the three different implant conditions.

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