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Microwave Radiometry for Non-Invasive Detection of Vesicoureteral Reflux (VUR) Following Bladder Warming

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Abstract

Background—Vesicoureteral reflux (VUR) is a serious health problem leading to renal scarring in children. Current VUR detection involves traumatic x-ray imaging of kidneys following injection of contrast agent into bladder via invasive Foley catheter. We present an alternative non-invasive approach for detecting VUR by radiometric monitoring of kidney temperature while gently warming the bladder.

Methods—We report the design and testing of: i) 915MHz square slot antenna array for heating bladder, ii) EMI-shielded log spiral microstrip receive antenna, iii) high-sensitivity 1.375GHz total power radiometer, iv) power modulation approach to increase urine temperature relative to overlying perfused tissues, and v) *in vivo* porcine experiments characterizing bladder heating and radiometric temperature of saline filled 30mL balloon “kidney” implanted 3–4cm deep in thorax and varied 2–6°C from core temperature.

Results—SAR distributions are presented for two novel antennas designed to heat bladder and monitor deep kidney temperatures radiometrically. We demonstrate the ability to heat 180mL saline in *in vivo* porcine bladder to 40–44°C while maintaining overlying tissues <38°C using time-modulated square slot antennas coupled to the abdomen with room temperature water pad. Pathologic evaluations confirmed lack of acute thermal damage in pelvic tissues for up to three 20min bladder heat exposures. The radiometer clearly recorded 2–6°C changes of 30mL “kidney” targets at depth in 34°C *in vivo* pig thorax.

Conclusion—A 915MHz antenna array can gently warm *in vivo* pig bladder without toxicity while a 1.375GHz radiometer with log spiral receive antenna detects 2°C rise in 30mL “urine” located 3–4cm deep in thorax, demonstrating more than sufficient sensitivity to detect Grade 4–5 reflux of warmed urine for non-invasive detection of VUR.

Keywords

Radiometry; microwave heating; bladder; non-invasive thermometry; vesicoureteral reflux detection

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1. INTRODUCTION

Vesicoureteral reflux (VUR) is a potentially serious condition involving improper function of the valves separating the ureters from the bladder, allowing leakage of urine from the bladder back up the ureters into the kidneys. While this condition spontaneously resolves in many patients, high grade VUR in combination with urinary tract infections can lead to serious renal scarring in children and is one of the three most important factors contributing to kidney damage¹. VUR is a significant worldwide problem with the incidence of reflux following urinary tract infection estimated at up to 30% of the general population. Although approximately 2.5 million new cases of VUR are diagnosed annually², many cases go undetected due to the reluctance of physicians to order VUR detection procedures in the most susceptible population of 0–5 year old children. The two most common methods of assessing VUR are imaging with a voiding cystourethrogram (VCUG) or radionuclide cystogram. Both these methods involve significant trauma to young children in that they require catheterization of the urethra, ionizing radiation exposure, and often sedation. All these procedures are undesirable, including physically restraining young patients under a fluoroscope for up to 20 min after urethral injection of radioactive contrast agent into the bladder, and serve as motivation for introducing a new non-invasive and non-toxic procedure for detecting VUR to supplement the current standard approaches. Figure 1 depicts the involved anatomy and VCUG images of two patients with different grade VUR. The need for surgical correction in patients that routinely reflux as shown at right is clear.

This paper summarizes the current status of development and pre-clinical testing of an entirely non-invasive and non-toxic two step procedure for diagnosing pediatric VUR. The patients are anticipated to be 0–5 years of age and have bladders with a capacity of approximately 75 mL to 180 mL of urine. At this young age, the patients are often restless or non-compliant, so the equipment will be mounted within the support structure of a customized child seat that should offer familiar and acceptable restraint for the 20–30 min procedure. The procedure involves: 1) painless gentle warming of urine inside the bladder with a thin room temperature waterpad-coupled microwave antenna that is positioned over the lower abdomen inside the elastic strap of a child seat, and 2) non-invasive monitoring of both kidney temperatures with two miniature microwave radiometers mounted on the back of two deep penetrating directional beam microwave antennas. The goal of this intervention is to raise the temperature of urine from 37°C to approximately $42\pm 2^\circ\text{C}$ to provide a reservoir of fluid inside the patient at a safe and comfortable temperature higher than normal body temperature. This heated urine would be maintained at approximately $42\pm 2^\circ\text{C}$ for 20–30 min or less, as necessary to check for VUR. In patients with advanced disease, a reflux event will cause the pre-warmed urine to back up the ureters and enter the kidneys, which will then increase the volume-averaged kidney temperature above the normal $\sim 37^\circ\text{C}$ baseline. Temperature of the kidneys will be monitored continuously with microwave radiometers that are connected to radiometric receive antennas in the back of the child seat, which are held comfortably in place over the respective kidneys within a second elastic strap around the patient thorax. The following sections describe the design and pre-clinical testing of technology for: 1) safe and painless warming of 75–180mL urine in 6 cm maximum dimension bladder located from 0.5–4 cm depth below the skin surface with 915 MHz conformal microwave applicator, and 2) radiometric monitoring of a 2–6°C temperature rise of 30mL urine/saline inside a “kidney” located 3–4 cm below the skin using a 550 MHz bandwidth radiometer with center frequency of 1.375 GHz.

2. METHODS

2.1 Antenna design for heating pediatric bladder

Our primary design goals for an applicator to heat pediatric bladder were to: i) elevate the temperature of 75–180 mL of non-perfused (stagnant) urine located in a 6 cm maximum dimension bladder approximately 0.5–4 cm below the surface while maintaining the skin cool for patient tolerance, ii) use a 915 MHz (ISM band) heat system for power deposition into lossy urine with no special shielding requirements, and iii) use a thin and lightweight patient conforming antenna that can be secured comfortably to the lower abdomen of small children for a 20–30min heating period. Since small children may not be compliant with a complex treatment setup, the antenna must fit into a harness or elastic strap that crosses the lower abdomen and holds the patient and applicator in alignment. The authors have long experience with low profile flexible printed circuit board (PCB) microwave antennas used in large arrays for heating diffuse chestwall recurrence of breast carcinoma^{3–8}. With equal phase and amplitude excitation of each side of the square slot aperture, a broad radiation pattern covering the entire aperture face is achieved but the effective depth of penetration is restricted to approximately 1.5 cm. This is due to phase cancelation of fields originating from opposing slots as they radiate into tissue under the center of the aperture. In order to deposit more energy into a bladder located 0.5–4 cm below the surface, the DCC antenna feedline network was redesigned to produce phase addition centrally under each aperture^{9, 10}. The modified DCC antenna design is shown in Figure 2. While still based on a square slot aperture, the new antenna includes serpentine microstrip half-wave phase shift sections feeding two of the four side slots. This provides a phase reversal of radiation from opposing slots to provide phase-coherent addition of fields at depth under the center of each aperture. Power deposition or specific absorption rate (SAR) was measured at 915 MHz for the phase-rotated DCC antenna in a computer controlled 3 axis scanning system that steps a calibrated SAR probe (Model ALS-E010 Aprel Laboratories, Ottawa Canada) in 5 mm increments through a liquid muscle-equivalent phantom. Details of this scanning procedure have been published elsewhere^{11, 12}.

2.2 Antenna design for radiometric monitoring of kidneys

For radiometric sensing of kidney temperature, the design goal for the receive antenna was to produce a small and lightweight antenna (4–8 cm diameter depending on patient age) that could be incorporated into an elastic strap and secured comfortably to the patient surface for 20–30 min without discomfort to the pediatric patient. Several PCB microstrip spiral configurations were investigated using HFSS (Ansys Corp, Cannonsburg PA) electromagnetic simulations with the goal to maximize on axis beam penetration and minimize sidelobes. A 7 cm dia tapered log spiral designed for use in monitoring deep kidney temperature rise is shown in Figure 3, with the PCB antenna mounted inside the aluminum shieldcup at right. Theoretical optimization and performance of the tapered log spiral are presented in detail elsewhere¹³.

SAR patterns were measured in a scan tank filled with liquid muscle phantom intended to be tissue-equivalent at 1.3 GHz. Antenna receive patterns were measured at 1.1, 1.3 and 1.6 GHz to characterize response across the radiometer receive band, and were repeated with and without the surrounding EMI shield cup.

2.3 *In vivo* pig bladder heating experiments

Under an IACUC approved protocol, female pigs (14–17 kg) were anesthetized and prepared for *in vivo* characterization of the proposed bladder heating approach. A typical probe monitoring setup is shown in Figure 4 with #18g Celcon catheters (Flexi-needle, Best Medical Intl. Springfield VA) extending 12 cm across the face of the heating arrays in and

around bladder. Catheters were located on the skin surface, at a depth of 2–4 mm in subcutaneous fat/muscle, and crossing through the bladder at 2–4 cm depth. Ultrasound scanner measurements confirmed the depth and position of the implanted catheters relative to the pig bladder which was completely drained and refilled with a known quantity (180 mL) of urine substitute immediately prior to heating. The urine substitute consisted of distilled water with 2% by weight NaCl prewarmed to 37°C. Temperatures were measured during heating with 0.56 mm OD fiberoptic sensors (Luxtron 3100, Lumasense Corp, Santa Clara CA) which were scanned in 1 cm increments through the #18g catheters with 5s dwell time at each position, using a computer controlled mapping device. Temperatures were recorded at 13 positions along each catheter, to document temperatures inside, above, below and around the bladder. Additionally, temperatures were recorded with stationary sensors located in the inferior rectum (core) and tip of Foley catheter inside the bladder.

Six pigs were implanted with temperature probes and used for preliminary investigation of different antennas (including the two and four antenna phase rotated DCC arrays of Figure 2) and power modulation protocols. Once the appropriate array and timing of power on/off cycling was established for minimum heating of overlying fat and muscle tissue relative to urine inside the bladder, three additional “pathology pigs” were treated using the selected power modulation scheme to assess the repeatable safety of bladder warming with up to three times the required 20 min heating interval. In one pathology pig, a 20 min heat treatment was delivered according to the protocol identified below and the animal sacrificed for subsequent pathological examination of the bladder, overlying skin and muscle, and surrounding pelvic tissues. A second pathology pig was treated with the identical heating protocol, but then the 20 min heat treatment was repeated a second time after a 15 min power-off rest, before sacrificing the animal for pathological examination. Table 1 gives the power modulation protocol used to deliver two ~20 min heat treatments separated by 15 min rest to this subject. In a third pathology pig, the same 20 min heat protocol was repeated three times, with 15 min breaks for tissue to return to normal temperature between heat treatments. In all cases, the PCB antennas were coupled to the abdomen with a 1 cm thick waterbolus pad with circulating room temperature water.

2.4 1.375 GHz total power radiometer

A 1.375 GHz total power radiometer was constructed with first stage providing amplification of signal directly from a short 1 m length coaxial cable connected to the log spiral receive antenna. Short term stability was adequate for this temperature rise detection application without using a leading Dicke switch or temperature reference. Considerations of using Dicke switch compensation or matched front end amplification (to minimize losses preceding the critical first stage) are discussed in a related radiometer development¹⁴. Details of the 550 MHz bandwidth 1.375 GHz radiometer tested in the experiments of this effort will be described subsequently.

2.5 Radiometric thermal sensing of deep targets *in vivo*

Experiments were performed to assess the ability of our 1.375 GHz center frequency 550 MHz bandwidth total power radiometer to sense temperature differentials at depth in heterogeneous living tissue. The first set of experiments used the 7 cm diameter log spiral receive antenna inside a metal shielding cup (Figure 3) coupled to the skin surface of a living pig with 250 μ m thick $\epsilon_r = 20$ dielectric matching layer to achieve an S_{11} better than –15 db. The directional receive antenna was aimed through the abdominal wall at an implanted target of known volume and temperature that was varied during the experiment. The buried target shown in Figure 5 consists of a multiport 20 Fr Foley catheter modified by the addition of an inflatable latex balloon sealed around the tip and surgically implanted into the thorax of a living pig -immediately adjacent to the right kidney at a depth of 3–4 cm

from the surface. For these experiments, the balloon was filled with 30 mL of urine-equivalent saline to represent the overfilled calyces of a kidney after a serious Grade 4–5 reflux event. A peristaltic pump was connected to two channels of the Foley catheter to circulate temperature controlled saline into the balloon. The temperature of the deep tissue target was determined as the average of temperatures measured with fiberoptic sensors in the input and output ports of the Foley. Absolute power received by the radiometer from the spiral antenna over the frequency bandwidth of 1–1.6 GHz was recorded continuously as the temperature of circulating saline was varied, and the radiometer response was compared with temperatures measured in the deep tissue target.

3. PRE-CLINICAL TEST RESULTS

3.1 Heating Antenna

Figure 6 gives the SAR measured 1 cm deep in muscle tissue equivalent phantom for one 915 MHz square slot 180° phase-rotated Dual Concentric Conductor (DCC) antenna of the antenna arrays shown in Figure 2. The SAR is normalized to the peak in the 1 cm deep plane. Note the skewing and asymmetry of heating from the phase-rotated square slot aperture which is significantly different than the equal phase excited DCC aperture designed for uniform heating of large superficial tissue regions^{4–6, 8–10, 12, 15–18}. Due to improved phase coherence of fields from opposing slots adding in the center of the antenna, heating extends deeper into the tissue than is possible with square slot radiators excited with equal phase. With 2 cm spacing of 3 cm square apertures, arrays with two or four adjacent phase-rotated DCC apertures driven non-coherently produce separate SAR peaks centered under each antenna. With no additional heating of the surface tissue directly under each aperture, the SAR from multiple antennas combines additively to heat the bladder at depth. By cycling power off to one of the array antennas sequentially, the surface tissue directly under each antenna gets a cyclic rest period to cool while the bladder contents continue to receive power deposition at all times from one or more other powered antennas. Along with the lack of blood perfusion cooling of urine inside the bladder, this cyclic modulation of antenna power increases the differential heating of bladder relative to overlying tissue.

3.2 Radiometric receive antenna

The SAR measured 1 cm deep in 1.375 GHz muscle-equivalent phantom for the 7 cm dia tapered log spiral of Figure 3 is shown in Figure 7, with 100% SAR normalized to the peak at 5 mm depth. The field pattern radiated/received from tissue in front of the antenna is affected very little by surrounding the microstrip spiral with an RF shielded enclosure, which provides attenuation of outside EMI from behind the antenna. Also shown in Figure 7 is a plot of return loss for the antenna when coupled to the 1.375 GHz layered fat-muscle tissue phantom with four different dielectric constant Eccostock® (Emerson and Cummings) matching layer disks in front of the Mylar window. The data show effective matching better than –10 dB across the radiometric band with just the Mylar window dielectric, though other matching layers may be useful to accommodate the large range of tissue impedance seen in pediatric population.

3.3 In vivo pig bladder heating experiments

Figure 8 gives the temperatures recorded at 1 cm increments along three implanted catheters in *in vivo* pig as shown in the middle setup of Figure 4. Close examination of catheter locations in and around the bladder after surgical excision of tissues following all heat treatments identified specific locations of the thermal maps that were inside bladder, while other positions were located in the pelvis outside the 180 mL saline filled bladder. Sensor positions 2 – 5 of laterally directed Probe 1 and tip positions 0 – 1 of perineum Probe 3 recorded temperatures inside bladder, as marked on Figure 8. Intra-abdominal temperatures

dropped off rapidly with distance away from bladder. The data show that heating with the 1×2 DCC array of Figure 2a produced an average of 40 – 44°C in bladder, <38°C in subcutaneous tissue overlying bladder, <38°C on skin surface overlying bladder, and <36°C core temperature throughout the multiple heat treatments. Followup pathologic examinations in three pigs treated with one, two or three 20 min heat exposures showed no evidence of acute thermal damage to the skin, subcutaneous fat, muscle, anterior or posterior bladder wall, peritoneum, ovaries, uterus, vagina or rectum.

The data from the protocol treatment regimen of Table 1 is presented in Figure 9 plotting only the maximum temperatures in each probe to emphasize the difference in heating between non-perfused bladder contents (lossy urine/saline) and overlying surface tissues under the antenna.

3.4 Radiometric thermal sensing of deep targets in vivo

Figure 10 shows the absolute power collected by the 1.3 GHz radiometer from the 7 cm log spiral receive antenna directed through skin towards a 30 mL saline phantom target located adjacent to the right kidney 3–4 cm deep in *in vivo* pig thorax. The total power collected over the 550 MHz band is plotted in red and displayed on the right-hand scale. Note that stability of the radiometer is at the sub milli-dBm level. The signal produced by the radiometer is plotted on the same time base as the temperature of circulating saline in the Foley balloon target, as the heat exchanger in the saline pump circuit was plunged into three different temperature reservoirs as indicated in the bottom band. The radiometer response in Figure 10 is in excellent agreement with the corresponding saline target temperature (average of Foley input and output ports) though there is a delay in registering the change in temperature by the radiometer. This delay is expected since it takes time for the change in temperature of the small 30mL target to thermally stabilize with surrounding tissues – all of which are volumetrically averaged in the radiometer received power signal at right.

4. SUMMARY

This work demonstrates the feasibility of non-invasive warming of urine in the largest size bladder anticipated in young children (180 mL) with no damage to skin or surrounding tissues. Repeated heat treatments in live porcine subjects showed it was possible to maintain temperatures of 40–44°C in urine while restricting temperatures in the overlying skin, fat and muscle tissues to less than 38–40°C. Three pigs were treated with one, two or three successive 20 min heat exposures prior to pathologic examinations which showed no significant acute toxicity to bladder or surrounding normal tissues. The differential heating of bladder contents was enhanced by modulating power to the microwave antenna, allowing time for perfused superficial tissues to cool while non-perfused urine/saline maintained an elevated temperature. This differential heating effect was further enhanced using an array applicator with one or more apertures depositing power into urine at all times while apertures were sequentially turned off for 15–30s periods each to allow cooling of perfused superficial tissues. These studies demonstrate the suitability of using a room temperature waterpad-coupled 180° phase-rotated DCC array integrated within a child restraining seat setup to safely warm urine to the desired fever temperature range.

This work also describes the performance of a thin and lightweight 7 cm dia tapered log spiral optimized for increased penetration along the beam axis. Measurements confirm that a kidney calyx located 3–4 cm deep is within the 5% field contour of the antenna. Impedance matching of the receive antenna to skin was improved by using a correct thickness dielectric matching layer which produced an S_{11} better than –10 dB in phantom and –15 dB in the *in vivo* pig subjects. Mounting the microstrip antenna in an EMI shieldcup provided essential reduction of background noise pickup. A 1.375 GHz total power radiometer with 550 MHz

bandwidth worked well for sensing $>2^{\circ}\text{C}$ rise in 30 mL “bladder” at a depth of 3–4 cm in living tissue.

In conclusion, combination bladder warming with 915 MHz surface antennas and non-invasive radiometric monitoring of temperature rise in 30 mL target volumes at the depth of kidneys has been shown feasible in *in vivo* pig subjects that model the size and anatomic complexity of the intended pediatric patient population. The proposed method of radiometric monitoring of kidneys appears to be a promising new approach for non-invasive detection of VUR, and investigation in human subjects appears warranted.

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Figure 1.

a) Simplified anatomy showing relationship of bladder and kidneys; b) VCUG image showing mild reflux with moderate dilation of the ureter and renal pelvis but normal calyces; c) high grade reflux with severe dilation of ureter and renal pelvis, and blunting of the calyces.

Figure 2.

Printed circuit board microstrip antenna arrays for heating pediatric bladder. a) 1×2 array of 3 cm square slot radiators fed at the center of each side at 915 MHz with 180° phase delay to two adjacent sides. Top photo shows back side feedline network and bottom photo shows radiating apertures (skin side); b) Two 2×2 antenna array designs both with 3 cm DCC antennas and 180° phase shifts to two sides. The configuration at top right shows RF connectors mounted in the center of each aperture, whereas the bottom design has connectors in one outside corner of each aperture.

Figure 3.
7 cm dia. tapered log spiral antenna with directional on-axis beam profile.

Figure 4.

Typical temperature monitoring setups for *in vivo* pig studies. Heat treatments were performed in nine female pigs while investigating 1, 2 and 4 antenna heating arrays and different power-time modulation protocols.

Figure 5.

Multiport Foley catheter modified by adding a latex 30 mL balloon sealed around the tip and connected to an external circuit that circulates temperature regulated urine-equivalent liquid (saline). When surgically implanted at the depth of a kidney inside the thorax of a living pig, the catheter shown at right simulated a urine-filled renal pelvis of kidney with Grade 4–5 reflux – at known variable temperature.

Figure 6.

Measured SAR pattern in the plane 1 cm deep in muscle-equivalent phantom from a single 915 MHz DCC antenna of the arrays shown in Figure 2. The 180° phase shift to two adjacent sides of the square slot aperture produces a noticeable asymmetry of heating, but allows deeper penetration due to improved phase coherence centrally under the aperture.

Figure 7.

Measured SAR pattern in 1.375 GHz muscle-equivalent phantom from 7cm dia tapered log spiral of Figure 3. Note reduced side lobes and deep penetration centrally, covering calyx region of 3–5 cm deep kidney with 5% of maximum field. Antenna return loss shown at lower right for four 1 mm thick Eccostock® dielectric matching disks of varying permittivity between the antenna and tissue load in addition to the Mylar window.

Figure 8.

Temperatures measured at 1 cm increments along two catheters that cross inside the bladder approximately 2 cm deep and one catheter crossing the antenna array in subcutaneous fat/muscle tissue approximately 3–4 mm below the skin surface. Temperatures were measured as a function of time during a 20 min heating of bladder with duty cycle modulated power to the two element DCC array of Figure 2a. Note that core temperature of the anesthetized pig measured in the inferior urethra remained relatively cool throughout.

Figure 9.

Peak temperatures measured in two crossing bladder probes, abdominal surface under antenna, and core temperature as a function of time during the two 20 min heat exposure Pathology Pig experiment, using the power modulation protocol of Table 1.

Figure 10.

Total power measured with a 1.375 GHz radiometer from a surface mounted log spiral microstrip antenna as a function of fiberoptic temperature inside a Foley balloon with 30 mL of circulating saline surgically buried 3–4 cm deep in 34°C *in vivo* pig thorax. The radiometer response to transient changes in circulating saline temperature is shown in red with the scale at right. The average temperature measured with fiberoptic sensors in the Foley input and output ports is shown in blue on the scale at left. The 5–10 min time delay in peak radiometer readings is due to thermal conduction redistribution of volume-average tissue temperature following transient changes in circulating saline temperature indicated along bottom bar.

Power modulation protocol for two aperture phase rotated DCC array of Figure 2, driven with 30–35W at 915MHz, as delivered to the pathology pig with two sequential heat treatments.

Table 1

Heat Exposure 1 ----→ 15 min power off ----→ Heat Exposure 2					
Time	Power	Duty Cycle	Time	Power	Duty Cycle
First 3 min:	30W × 2	45s on – 15s off	First 3 min:	30W × 2	45s on – 15s off
Next 10 min:	30W × 2	15s on – 45s off	Next 20 min:	30W × 2	15s on – 45s off
Next 6 min:	35W × 2	15s on – 45s off			
Next 3 min:	30W × 2	15s on – 45s off			
Total heating duration = 22 minutes			Total heating duration = 23 minutes		