Development and evaluation of a 20MHz array for ultrasonic detection of middle ear effusion

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Abstract-
This paper presents the design and acoustical testing of a 20 MHz 2D array for non-invasive detection and characterization of middle ear effusion, as well as results of the clinical study performed with this probe. The transducer is a 3x3 element, 400µm pitch array and operates at 20 MHz center frequency. It is shaped with a 3mm radius spherical convex surface. The piezoelectric material is based on 1-3 piezo-composite technology and front layer is optimized. The probe is placed on the tip of 3 mm outer diameter tubing and interfaced to a pulsing system. The challenging manufacturing process of the whole transducer is here reviewed, as well as the electro-acoustical characteristics including sensitivity, frequency range and homogeneity. Clinical exams were performed by non-invasively introducing the probe into the external auditory canal. The condition of the middle ear was determined by the analysis of ultrasonic echoes collected from the tympanic membrane and middle ear cavity. The spherical geometry of the probe allowed easy positioning of one element of the array perpendicular to the reflecting surface (tympanic membrane) and thus obtain optimal ultrasonic echoes. The clinical results achieved with the probe show the significant value of this technique for detection and characterization of middle ear effusion in children.

I. INTRODUCTION

Otitis Media is a common inflammatory process of the middle ear, especially in children. It may be associated with the development of a fluid effusion in the middle ear and is one of the most common indications for outpatient antibiotics use in children. The gravity of the complications of undiagnosed Otitis Media combined with unsatisfactory, non-invasive diagnostic techniques often lead to the unnecessary over-medication of a child with antibiotics, which is only warranted in the presence of a bacterial infection in the effusion. The only reasonably accurate methods for diagnosing the state of the effusion are invasive, painful and require anesthesia. A non-invasive, office-based method to aid the diagnosis would thus be of great interest.

Ultrasound has been used in the past to detect middle ear effusion. A preliminary study was also done to characterize the type of effusion [1][2]. A single-element probe was used in A-mode and demonstrated the potentiality of ultrasound to be an accurate method for determining the presence and characteristics of middle ear effusion in children. Refinement in probe design was necessary to improve probe placement and stability within the external auditory canal.

We present here this refined new design leading to a 20MHz 3x3 element probe with a radius 3mm convex surface. The acoustic stack is defined to achieve a high resolution level. The spherical geometry allows easy positioning of one element of the 3x3 array perpendicular to the reflecting surface (tympanic membrane) and thus to obtain optimal ultrasonic echoes.

In this paper we will first describe the acoustical design and the complete probe with regards to the specific application requirements. Complete electroacoustical performances of the 20MHz 2D array are displayed. Finally we present in vivo results obtained during clinical studies and explain the significant interest of this non-invasive method for detection and characterization of middle ear effusion.

II. ACOUSTICAL DESIGN

High resolution and adequate penetration through the tympanic membrane are needed for this application, resulting in the following element dimensions and frequency. Limited volume requirements are also taken into account. The front face of the transducer is curved in a spherical convex shape.

Center frequency (MHz)	20
Number of elements	9
Type of array	2D
Element geometry (mm)	0.4x0.4
Front face convex radius (mm)	3

Several challenges have to be overcome in the acoustical design. The small dimensions of the elements ($0.16mm^2$) and need for high frequency require the choice of high performances materials and an accurate and reproducible process.

The transducer is designed to be placed on the tip of a 9 French (3mm) tubing, as shown in Fig. 1.

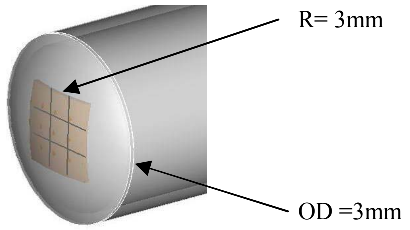


Figure 1: acoustic geometry

The active material of the transducer is a 1-3 ceramic-polymer piezocomposite. The flexibility of piezocomposite materials is necessary to achieve the final 3 mm radius of curvature [4].

Both frequency level and element surface limitations lead us to select a high dielectric permittivity ceramic to better match the electrical impedance of the probe with the impedance of a driving pulser/receiver. Moreover ceramic volume fraction is set to 56% which provides a good trade-off between bulk damping and piezocomposite dielectric permittivity.

The second concern in composite design is the frequency position and amplitude of the lateral mode. This spurious mode within the piezocomposite is a consequence of the periodic structure of the composite. Both polymer phase and piezocomposite kerf widths are chosen in order to push the lateral mode far away from the operating bandwidth.

We have reported in Fig. 2 the real and the imaginary parts of the electrical impedance measured on the piezocomposite alone. The lateral mode is over 30 MHz, thickness coupling coefficient is 0.50 and anti-resonance frequency is 22.9 MHz. Therefore, this composite is suitable for 20MHz application.

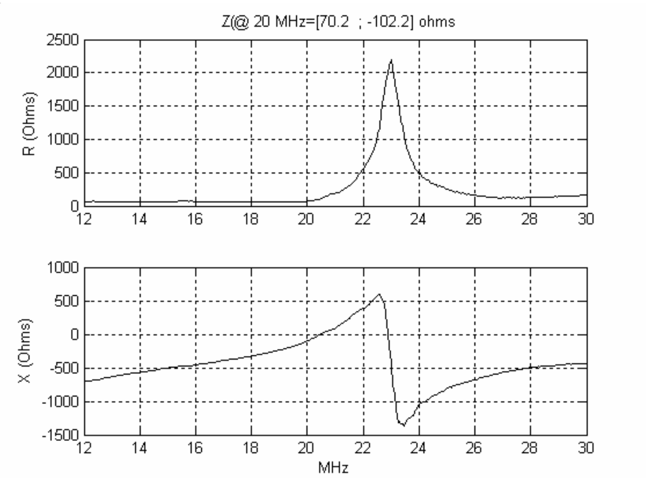


Figure 2: real and imaginary part of the electrical impedance of the piezocomposite (0.4x0.4 mm^2)

The matching layer exhibits an impedance gradient designed to optimize the matching between the piezocomposite and the propagating medium acoustic impedances [5]. Matching layer and backing material are made by mixing epoxy resins and inorganic or metallic powders. By selecting the volume fraction and nature of the constituent materials, the expected acoustic impedances are defined, tested and finally qualified.

III. Probe construction

There are several challenges in designing an efficient and re-usable high frequency 3x3 array suitable for middle ear applications. The main one is the 2D interconnection of each element through a miniaturized circuit.

Probe ergonomics were designed for proper application of the device near the tympanic membrane. To enable use inside the external auditory canal of children, the array, interconnection and cable have to fit inside 9 French (3 mm diameter) tubing shaped with an appropriate angle. The probe is mounted on a handle and interconnected to a 2m length coaxial cable. A standard 25 pin AMP connector is mounted on the cable for interconnection with the electronic pulser/receiver system.

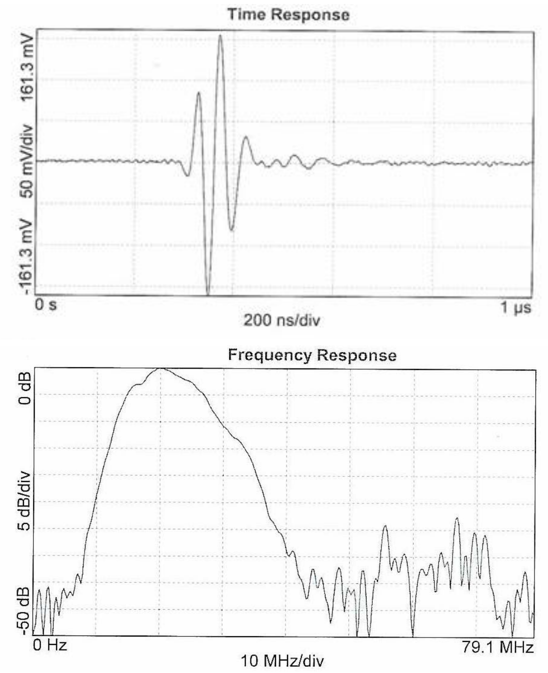
Two series of probes were manufactured for clinical study.

Figure 3: handle and probe tip

Figure 4: complete probe

IV. Electroacoustical characterization

Electro-acoustical measurements were performed on the transducer immersed in water and handled by a tilting – translating mechanical system. A Panametrics 5073PR pulser-receiver is used as the electrical source (damping 50 Ohms/ energy 1/ gain 20dB/ no filter). The array is positioned and geometrically aligned in front of a stainless steel target. All 9 pulse-echo signals are acquired and stored, and the measured pulse and frequency response of a typical element are displayed in Fig. 5.



(a)

(b)

Figure 5: Pulse (a) and spectrum (b) response for a single element of the transducer
Fc= 20.6MHz; LCF(@-6dB)=14.1MHz;HCF(@-6dB)=27.2MHz; BW(@-6dB)=63%; AxR(@-20dB)=155ns

The main electro-acoustical measurements are summarized in the following table (Table I) that details the average values of the measured parameters. The average axial resolution is 155ns or 3.2λ (wavelength in water). The average center frequency is in agreement with the targeted 20MHz with an average bandwidth @-6dB of 63%.

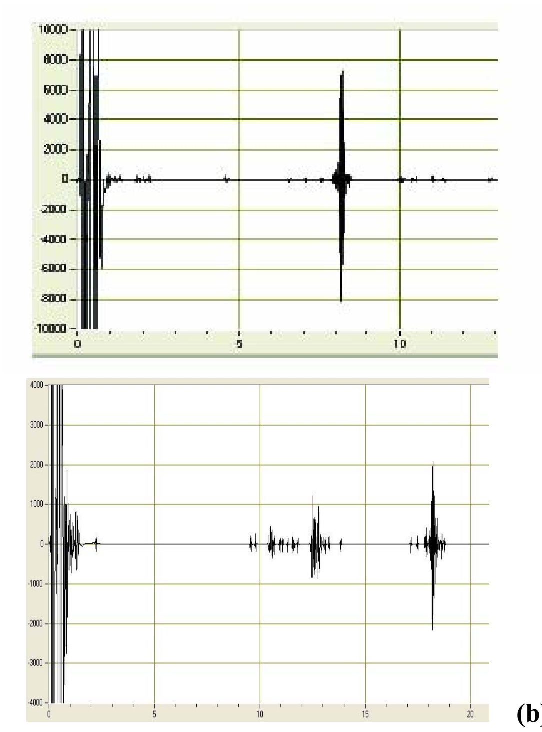
TABLE I
AVERAGE PERFORMANCE VALUES FOR ONE OF THE COMPLETE PROBE

Average Sensitivity	253 mV
AverageAxR@-20dB	155 ns
Average Frequency @-6dB	20.6MHz
Average Low Cut-off frequency @-6dB	14.1 MHz
Average High Cut-off frequency@-6dB	27.2 MHz
Average Bandwidth @-6dB	63 %

The directivity angle was also evaluated for this configuration. Due to the low signal level of the transducer element, we emitted with the element and received on a miniature hydrophone (Precision Acoustic hydrophone with 75µm active part diameter). Both elevation and azimuthal 1D scanning were performed. The experimental aperture angle in both directions is 15° (at –6dB), while the theoretical value for a plane element is 13.5°. A slightly higher experimental aperture angle is obtained due to convex shape of the element.

V. Clinical evaluation

During clinical test a high frequency wideband ultrasonic pulse is directed toward the tympanic membrane. When air is present behind the tympanic membrane (normal ear), the acoustic impedance mismatch between the membrane and the air is high, thus a large single reflection is received by the transducer. Reflections within the finite thickness of the membrane provide a very characteristic frequency signature of the reflected signal from the tympanic membrane. When fluid is present behind the membrane, a large portion of the energy is conducted into the inner ear. In this case, reflections from bones in the back of the inner ear cavity will be detected after the tympanic membrane reflections. The relative amplitude and frequency characteristic of these reflections can be used to determine the viscosity of the effusion which will provide an indirect determination of the presence of bacterial infection. Typical scans recorded from actual patient testing are shown in Fig.6, demonstrating a dry ear and an ear containing a serous or thin effusion.



(a)

(b)

Figure 6: (a) signal from dry ear (single tympanic membrane peak at 8µs) (b) signal from thin fluid ear (tympanic membrane peak at 12µs, second larger peak from inner ear at 18µs)

The clinical study was performed on patients scheduled for myringotomy pressure-equalizing tube placement surgery due to recurring middle ear problems. For the purposes of the ultrasound study, 0.5-1.0 ml of sterile water was placed into the external ear canal using a dropper to serve as a medium for ultrasound transmission. Next, the ultrasonic probe was placed into the external ear canal under direct visualization and positioned about 5 mm from the tympanic membrane. The convex shape of the transducer is such that each of the elements is directed in a slightly different direction. The BIOMEC proprietary software algorithm automatically detects which element(s) was optimally aligned with the tympanic membrane. During myringotomy samples of the effusion fluid were collected, when possible, and viscosity measured.

86 ears were processed with the ultrasound system and a proprietary algorithm was then applied on the A-mode data to discriminate the results into three categories: dry, serous (thin) and mucoid (thick). Of the 86 ears tested, an overall accuracy rate of greater than 90% was achieved.

In addition, viscosity measurements were compared to the results of bacterial cultures, demonstrating a high correlation between thick effusions and the absence of a bacterial infection. This study is ongoing to achieve a higher statistical certainty. This correlation is of great interest to the physician in determining the suitability of antibiotic treatment.

VI. Conclusion

A 20MHz convex shaped ultrasound 3x3 array was presented. Targets in miniaturization, interconnection, frequency and resolution were achieved enabling us to manufacture fully operating 9 element miniaturized probes included in 3mm diameter tubing. Complete electroacoustical characterization of the probe was conducted.

The device is suitable for use by all front line physicians. Clinical tests performed with the hand held probe demonstrated an accuracy of greater than 90% in detecting and characterizing middle ear effusions in pediatric patients. Further work will include the use of a positioning sleeve for better placement of the probe and thus improved accuracy of diagnostic results.

Acknowledgments

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