10MHz ultrasound linear array catheter for endobronchial imaging

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Abstract-
This paper presents the acoustical design, manufacture and evaluation of an ultrasound catheter array for endobronchial imaging. In order to be used in an existing bronchofiberscope, the 64 elements transducer is included in a 7 French (2.3 mm Outer Diameter) catheter, using a ribbon-based cabling technology. The ultrasound array has a 200 µm pitch, a 1.5 mm elevation, and operates at 10 MHz center frequency. The piezoelectric material is based on 1-3 piezo-composite technology and the front layer (optimized multilayer stack of passive materials) is selected to act both as a matching and protection layer. The probe is integrated into the 7 French catheter and interfaced to a commercial ultrasound system. Besides the manufacturing process of the whole transducer, the paper reviews electro-acoustical characteristics including sensitivity, frequency, bandwidth and homogeneity performances. The aim of this probe is the detection of epithelial abnormalities, transparietal extension of lesions and detection of lymph nodes related to local cancer. Finally, *in vivo* images obtained through a bronchofiberscope are presented and discussed from a clinical point of view.

I. INTRODUCTION

Recent advances in ultrasound transducers [1] in term of miniaturization and frequency increase currently open the way to new medical applications. Nowadays, exploration of several body parts is limited by inaccessibility or acoustical limits linked with air interposition.

Development of high frequency array transducers has enabled to image such structure as skin [2]. The possibility of including such array transducers in small diameter catheters encourages their use in body parts as bronchial tubes, ureters or uterine cavity.

External ultrasound imaging of bronchial tubes is limited due to air barrier between skin and tubes. Applying endoscopic ultrasound from bronchial tubes is of great interest and complementary with other imaging techniques. Bronchofiberscopy is well adapted to fine study of bronchial wall and biopsy guidance but does not allow transparietal tumors extension detection. CT Scan is effective for finding tumor but limited in term of exact tumor localization. A catheter-based ultrasound array transducer is therefore highly expected for the detection of epithelial abnormalities, transparietal extension of lesions and detection of lymph nodes related to local cancer.

Ultrasound images of bronchial tubes (endobronchial ultrasonography) are already performed with mechanical single element probe [3]. Possibility of using array probe would be of great interest for easiness of implementation and quality of images.

This work relates the design, manufacturing and evaluation of a 10MHz ultrasound array included in a 7 French outer diameter catheter for endobronchial imaging. We will first describe the acoustical design of the probe with regards to specifications and targeted performances, especially element size and frequency. Complete electroaoustical performances of the 64 elements array are disclosed. The main challenge for the complete miniaturized probe assembly is to have all the 64 elements connected and fully operating. Finally, we present *in vivo* endobronchial images that were obtained on available imaging system with the catheter transducer introduced through the working channel of an existing bronchofiberscope.

II. ACOUSTICAL DESIGN

In order to achieve sufficiently high resolution and adequate penetration, dimensions of the elements and frequency were set as follows, taking into account limited volume requirements. In term of pitch and frequency, this configuration will enable us to evaluate the probe on a commercial imaging system. The 64 elements probe will display an image length of 12.8mm.

Center frequency (MHz)	10
Number of elements	64
Type of array	linear
Pitch (mm)	0.2
Elevation (mm)	1.5

Several challenges have to be overcome in acoustical design:

-small dimensions of the elements (0.2x1.5mm)
-high frequency (10MHz)
-volume limitation (7 French diameter).

Active material of the transducer is a dice-and-fill 1-3 ceramic-polymer piezocomposite.
Both frequency level and element surface limitation lead us to select high dielectric permittivity ceramic to better match electrical impedance of the probe with impedance of driving system [2]. Moreover ceramic volume fraction is set to 59% which is a good trade-off between bulk damping and piezocomposite dielectric permittivity.
Second concern in composite design is the frequency position and amplitude of the lateral mode. This spurious mode within the piezo-composite 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. In our case the lateral mode is over 20 MHz. Final thickness of the piezocomposite is 145µm.

The piezoelectric is damped with a low impedance backing layer: Z= 1.5 MRayls. This backing provides sufficient damping for the piezocomposite structure and contributes to the high sensitivity of the transducer. As volume inside the 7 French tube is limited, thickness of the backing has to be reduced so requiring a high attenuation backing material.
The matching layer exhibits an impedance gradient designed to optimize the matching between the piezocomposite and the propagating medium acoustic impedances [4][5]. Matching layer and backing material are made by mixing epoxy resins and inorganic or metallic powders. By selecting volume fraction and nature of constituents, materials expected acoustic impedances are defined, tested and finally qualified.

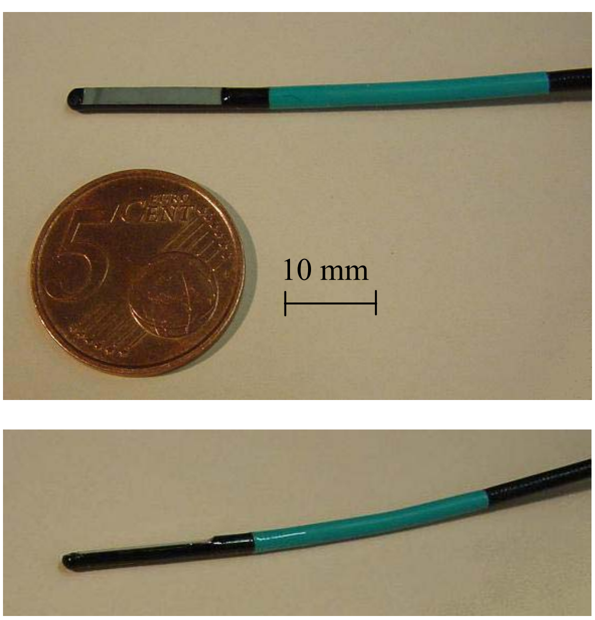

Figure 1: Acoustical face of transducer integrated in a 7 French diameter tube

III. COMPLETE PROBE ASSEMBLY

Several issues are to be taken into account in complete probe design work to adapt it to its final clinical application.
Main challenge to overcome is the miniaturization. To be inserted through the working channel of a regular bronchofiberscope the 64 elements array, interconnection and cable have to fit inside a 7 french (2,3 mm diameter) housing and catheter tube. Interconnection of each element is made through a flexible circuit which is then soldered on miniaturized flexible cable.
The catheter tubing length is set to 70 cm in order to provide the handle at the vicinity of the working channel output of the bronchoscope during examination. The cable length of the probe is 2 m and an ITT Cannon standard connector is mounted on the cable for interconnecting with the imaging system. Picture 2 shows the complete probe with cable.

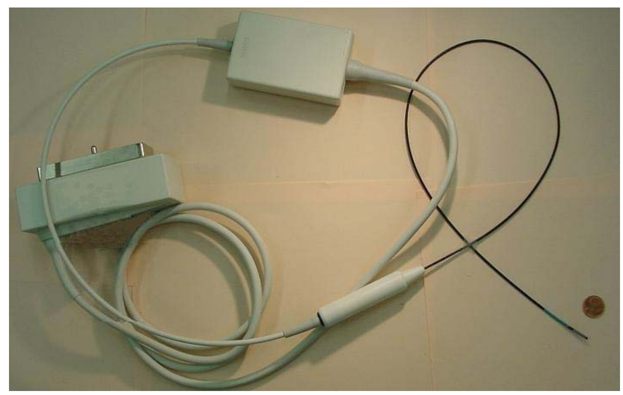

Figure 2: Final catheter probe

The catheter tube was selected to proper handiness of the probe when inserted in the working channel of the bronchoscope. To maintain a good contact between active face of the transducer and bronchial wall, the catheter tube is more flexible a few centimeters before the active part. Good torqueability of the tube is also needed to transmit a torque applied on the handle to the end of the probe.
At least, a challenging issue is dielectric strength to assess the suitability of the transducer to medical applications. With regards to safety consideration, dielectric tests were conducted on a final probe: a 41µA leakage current was measured at 1500V.

IV. ELECTRO-ACOUSTICAL 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 electrical source (damping 50 Ohms/ energy 1/ gain 20dB/ filter none). The array is positioned and geometrically aligned in front of flat stainless steel target. Then all 64 pulse-echo signals are acquired and stored. From these measurements fundamentals electroacoustic parameters (center frequency, high and low cutoff frequency, fractional bandwidth and pulse duration) are extracted for each element. Typical measured pulse and frequency spectrum of a single element are displayed in figure 3.

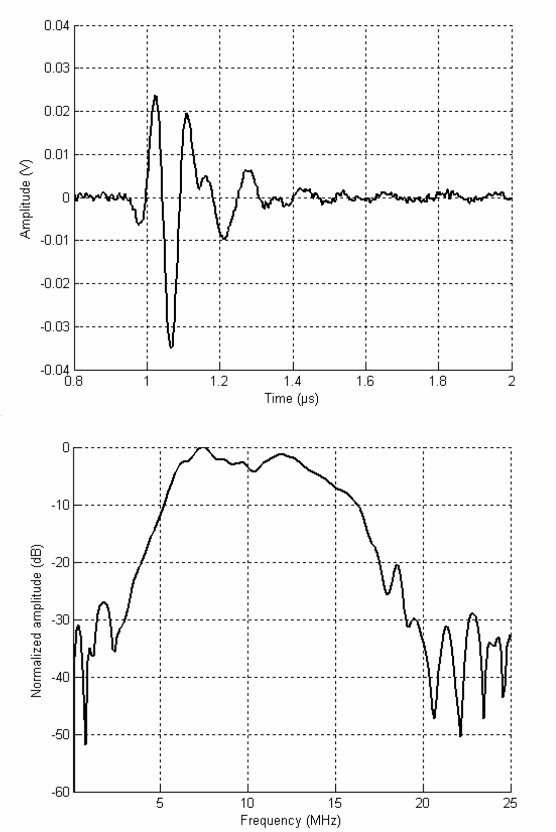

Figure 3: Pulse (a) and spectrum (b) response for a single element of the transducer
Fc= 10.1MHz; LCF(@-6dB)=5.7MHz;HCF(@-6dB)=14.5MHz; BW(@-6dB)=87%; AxR(@-20dB)=350ns

Three probes were manufactured for clinical use. Among them, two have all their 64 elements operating (homogeneity in sensitivity 4.3 and 5.9dB) and one has 2 non-operating elements (3%).

Main electro-acoustical measurements are summarized in the following table (Table 1) that details the average values of the parameters.

Average Sensitivity	**92 mV**
Average Frequency @-6dB	10.9MHz
Average Low Cut-off frequency @-6dB	6.7MHz
Average High Cut-off frequency@-6dB	15.1MHz
Average Bandwidth @-6dB	79 %
AverageAxR@-20dB	436 ns

Table 1: Average performances values for one of the complete probes

The average center frequency is in agreement with the targeted 10MHz with an average bandwidth @-6dB of 79%.

V. IMAGE EVALUATION

The complete probe was connected to a commercial imaging system. *In vivo* images were performed on several patients during conventional bronchofiberscopic examination of the patient. The probe was inserted through the working channel of a regular bronchofiberscope. This ultrasound examination required an additional 10 minutes time with no reported inconvenient. In term of handiness of the probe, contact improvement of the acoustic face of the probe with bronchial wall was achieved by modifying catheter tube mechanical properties (flexibility).

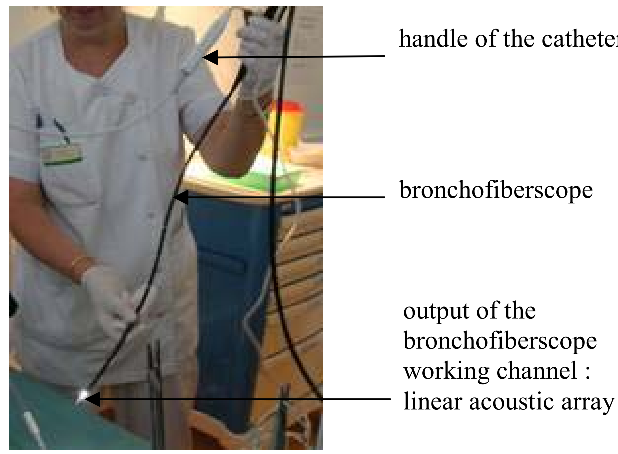

Figure 4 : Picture of the probe inserted in the bronchofiberscope

The probe enabled to explore external part of bronchial tube and peripherical vessels. Three *in vivo* images are displayed in following figures. Figure 5 shows a vascular structure. It was also possible to visualize a peribronchial tumor (figure 6) as well as a lymph node (figure 7) and its echogenic structure. Those first clinical results demonstrate feasibility and interest of such type of exploration.

Figure 5: *In vivo* image of peribronchial structures (depth 21mm): vascular structure

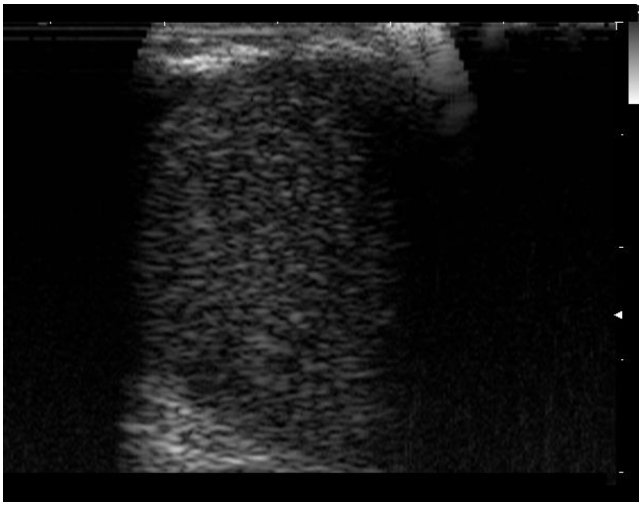

Figure 6: ***In vivo*** **image of peribronchial structures (depth 21mm): tumor**

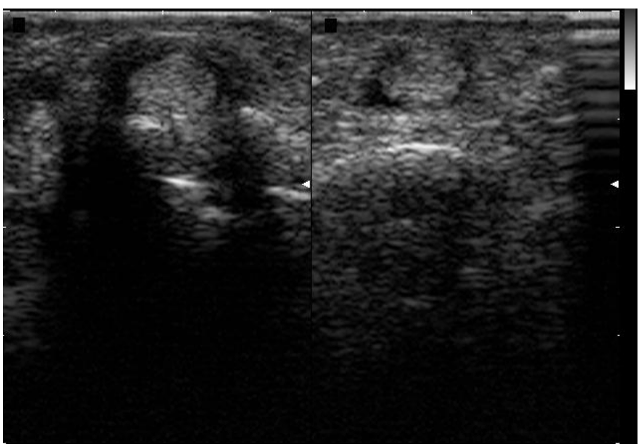

Figure 7 : I*n vivo* image of peribronchial structures (depth 21mm) : lymph node

VI.CONCLUSION

A 64 elements catheter-based ultrasound linear array included in a 7 French catheter was presented. Targets in miniaturization and frequency were achieved enabling us to manufacture fully operating 64 elements miniaturized probes working at 10MHz central frequency.
Performances of the complete probe were described from pulse-echo characteristics to image.
In vivo images evaluation has begun and first images were obtained, showing feasibility of endobronchial ultrasound imaging with such a probe, in combination with a regular bronchofiberscopic exploration.
Clinical evaluations of this 10MHz catheter-based ultrasound array will be further continued in view of these first promising results.

VII. ACKNOWLEDGMENTS

The authors would like to thank the French Ministère de la Jeunesse, de l'Education et de l'Industrie which funded this work under the ENDO project (N°02 B 0669).
Clinical evaluation has begun in CIT (Centre d'Innovation Technologique), University Hospital, Tours, France within Ultrasound Department and in collaboration with Endoscopy Department.

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