# Development and clinical evaluation of a 10MHz ultrasound linear array catheter for endobronchial imaging

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***Abstract-***

**Applying endoscopic ultrasound to image external part of bronchial tubes is of great interest and complementary with other imaging methods.**

**In continuation with our previous work [1], this paper presents the design and acoustical testing of a catheter array for endobronchial imaging completed by results of the clinical study performed with this probe. The transducer is a 64 elements ultrasound array included in a 7 Fr (2.3 mm Outer Diameter) catheter in order to be used in an existing bronchofiberscope. The 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 is selected to act both as a matching and barrier layer. The probe is interfaced to a commercial ultrasound system. It was used in 25 patients without any inconvenience for the patient (in terms of discomfort and time duration which is limited to 10 minutes at the maximum) or the clinicians (easy use, perfect visualization of the area of interest). The only limitation encountered concerns the presence of air bubbles on bronchial walls which could limit the visualization of structures. This allowed the characterization of chest tumors (hypoechoic tissue) with possible adjacent lymph nodes (minimal size of 3 mm) which were not described on CT-scan. This identified clearly some underlying vessels to be spared during biopsy. This helps in identifying some regions of tumours which appeared as vascularized to guide the site of biopsy. In conclusion this specific probe is of great value to better image bronchial structures, to depict extension of tumours as well as possible sentinel lymph nodes for a more complete initial diagnosis and guidance of biopsies. This will be used to improve diagnosis and safety of biopsy.**

## I. INTRODUCTION

Recent advances in ultrasound transducers [2] in term of miniaturization and frequency increase currently open the way to new medical applications, such as exploration of several body parts that was limited by inaccessibility or acoustical limits related to air interposition. Development of high frequency array transducers has enabled to image such structures as skin [3]. The possibility of including these array transducers in small diameter catheters encourages their use in body parts as bronchial tubes, ureters or uterine cavity.

External ultrasound bronchial imaging 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 but does not allow transparietal tumors extension detection. CT Scan is effective for finding tumor but limited in term of exact tumor localization and small nodes visualization. A catheter-based ultrasound array transducer is therefore highly expected for the detection of epithelial abnormalities, transparietal extension of lesions and lymph nodes related to local cancer. It is also expected to improve biopsy guidance and safety by clearly identifying underlying vessels to be spared.

Ultrasound images of bronchial tubes (endobronchial ultrasonography) are already performed with mechanical single element probe [4]. Using array probe includes several advantages: implementation easiness, images quality and doppler modality.

In our previous publication [1] we described acoustical design and first images obtained with a 10MHz ultrasound array included in a 7 French outer diameter catheter for endobronchial imaging. This article focuses on the construction and clinical evaluation of the probe. We will describe the re-usable catheter with regards to the specific application requirements. Acoustical design and complete electroaoustical performances of the 64 elements array are disclosed. Finally, we present typical *in vivo* endobronchial images obtained during clinical evaluation and explained their significant contribution for diagnosis improvement.

## II. CATHETER CONSTRUCTION

The 7F endobronchial catheter was designed to be easily used with commercial ultrasound imaging system and regular bronchofiberscope as shown in Fig. 1.

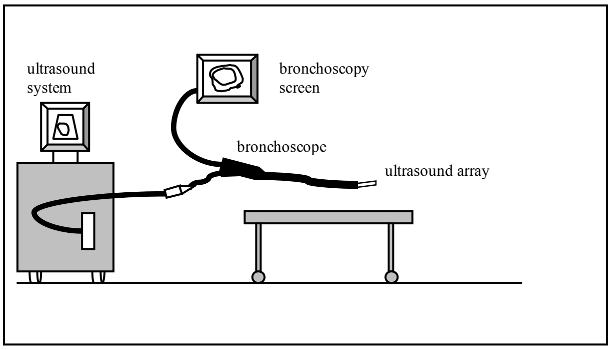



**Figure 1:** ultrasound probe is inserted through the working channel of a regular bronchofiberscope allowing combined bronchoscopy and ultrasound imaging.

The 64 elements imaging transducer array is placed at the end of the catheter to form an image plane in line with the tip (see Fig. 2).

The active imaging aperture is 1.5mm in elevation and 12.8mm in length with an element pitch of 200µm. Center frequency is set to 10 MHz to achieve good resolution and be compatible with the imaging system.

There are several challenges in designing an efficient and re-usable ultrasound catheter [5], suitable to endobronchial applications: miniaturized fully populated interconnection, proper handiness of the probe, electrical safety and reliability. To enable use inside the working channel of a regular bronchofiberscope, the 64 elements array, interconnection and cable have to fit inside a 7 Fr (2,33 mm diameter) housing and catheter shaft. Interconnection of each element is made through a flexible circuit which is then soldered on miniaturized flexible cable. Three probes were manufactured for clinical use. Among them, two have all their 64 elements operating and one has 2 non-operating elements (3%).

The catheter tube was selected to ensure proper handiness of the probe when inserted in the working channel of the bronchoscope. To maintain a good contact between the active face of the transducer and the bronchial wall, the catheter tube is more flexible a few centimeters before the active part (see Fig. 2). The catheter shaft torque-ability enables fine adjustment of image plane positioning. 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 is 2 m length and an ITT Cannon standard connector is mounted on the cable for interconnecting with the imaging system. Fig. 3 shows the complete probe assembly.

Tip encapsulation material is chosen to act as a protective, biocompatible and acoustical layer. Its thickness is set close to λ/4 to optimize front face acoustical matching for a better sensitivity of the probe. Dielectric tests were conducted on the three final probes: leakage currents were measured at 260V AC, with values of 11, 12 and 14 µA.

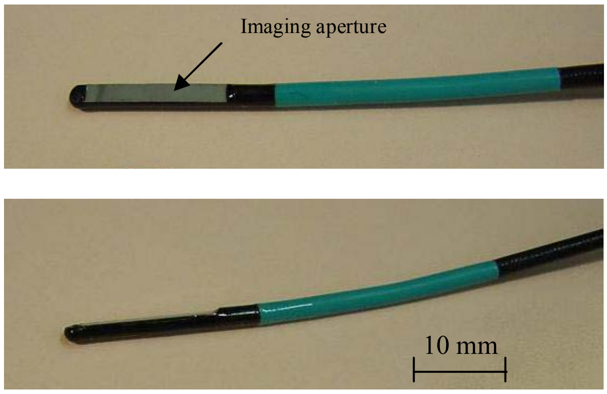



**Figure 2: Catheter tip**

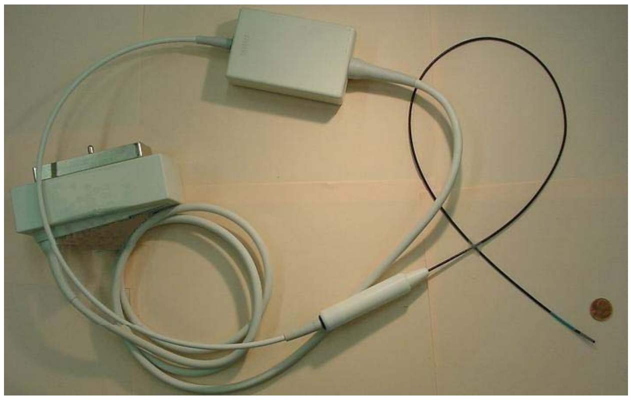


**Figure 3: Final catheter probe**

During clinical evaluation, probe was disinfected using high-level liquid disinfection. It was re-used in more than 25 patients without performance deterioration.

## III. Acoustic design and performances

### *A. Array Design*

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 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 [3]. 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 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. 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. The matching layer exhibits an impedance gradient designed to optimize the matching between the piezocomposite and the propagating medium acoustic impedances [1].

*B. 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/ no filter). All 64 pulse-echo signals are acquired and stored. Measured pulse and frequency response of a typical element are displayed in Fig.4 as well as homogeneity in sensitivity of one of the three probes manufactured.

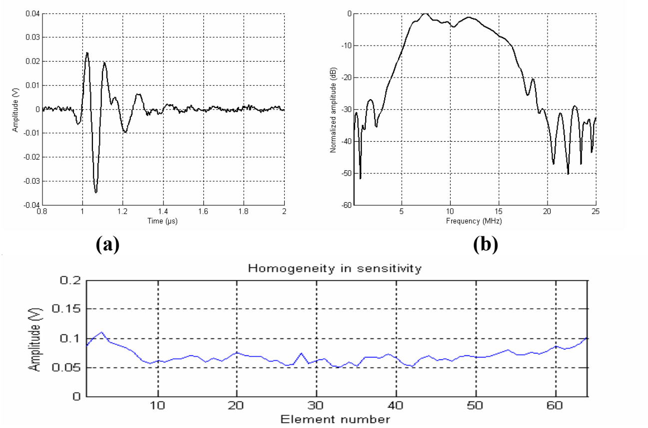



**Figure 4 : Pulse (a) and spectrum (b) response for a typical element of the transducer. Homogeneity in sensitivity (c) for all transducer**
Typical element : Fc= 10.1MHz; LCF(@-6dB)=5.7MHz; HCF(@-6dB)=14.5MHz; BW(@-6dB)=87%; AxR(@-20dB)=350ns
Homogeneity value: 6.7dB

Main electro-acoustical measurements are summarized in the following table (Table I) that details the average values of the parameters. The average center frequency is in agreement with the targeted 10MHz with an average bandwidth @-6dB of 80%.

TABLE I
AVERAGE PERFORMANCES VALUES FOR ONE OF THE COMPLETE PROBE

| | |
|---|---|
| Average Sensitivity | 70 mV |
| Average Frequency @-6dB | 10.3MHz |
| Average Low Cut-off frequency @-6dB | 6.2MHz |
| Average High Cut-off frequency@-6dB | 14.3MHz |
| Average Bandwidth @-6dB | 80 % |
| AverageAxR@-20dB | 455 ns |

The directivity angle was also evaluated for this configuration. The experimental value is an angle of 25° (at –6dB).

## V. CLINICAL EVALUATION

*In vivo* images were performed on 25 patients during conventional bronchofiberscopic examination of the patient. The probe was inserted through the working channel of a regular bronchofiberscope (see Fig. 5). This ultrasound examination required an additional 10 minutes time with no reported inconvenience for the patient or the clinicians (easy use, perfect visualization of the area of interest). The only limitation encountered concerns the presence of air bubbles on bronchial walls which could limit the visualization of structures.

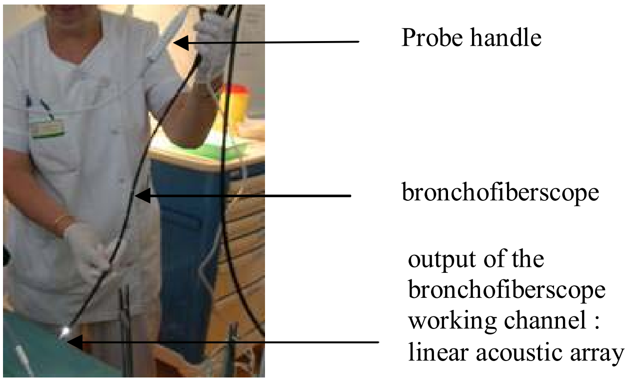



**Figure 5 : Picture of the probe inserted in the bronchofiberscope**

*In vivo* images are displayed in Fig. 6, 7, 8 and 9, with 21 mm imaging depth. They show representative results obtained for four different patients.

In Fig. 6 one can see a tumor that affects bronchial wall (top of image) which allows to detect a bronchial tumor. In Fig. 8 bronchial wall is clearly distinct from the tumor: it is an extrabronchial tumor.

Fig. 7 allows to characterize a tumor and to identify adjacent lymph nodes (located between tumor and bronchial wall) which were not visible on CT scan because of their small size (3-5 mm). Nodes are indeed hardly depictable on CT scans if their diameter is below 7 mm

Presence of fluid is clearly visible on Fig.8(a) and Fig.8(b) (Doppler image) as well as in Fig.9 (vascular structure). Ultrasound allows to distinguish tissue and liquid whereas CT scan does not do it. This helps greatly in identifying some region of tumors which appeared as vascularized to guide the site of biopsy and to identify some vessels to be spared during biopsy.

In conclusion, this first clinical study demonstrates significant contribution of ultrasound for diagnosis improvement:

-confirmation of CT scan diagnosis (improved reliability)

-characterization of chest tumor and their relation to bronchial wall (seen on 5 patients)

-visualization of adjacent lymph nodes not visible on CT-scan (seen on 3 patients)

-significant help to guide biopsy when bronchoscopy image was not enough to determine if a biopsy would be safe (for 3 patients)

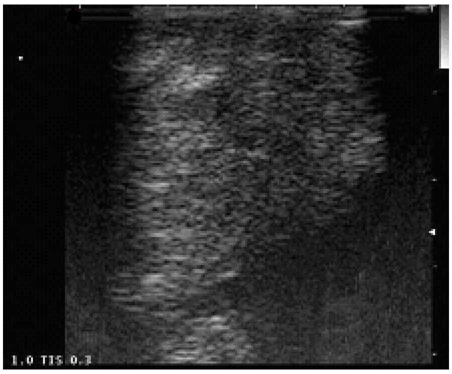
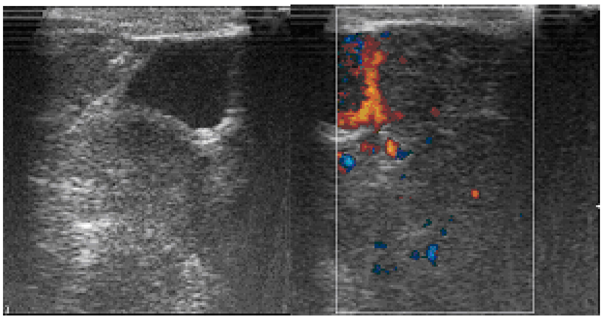


**Figure 6 : bronchial tumor (depth 21mm)**



**(a) (b)**

**Figure 8: (a) extra-bronchial tumor and presence of liquid**
**(b) Doppler image, extra-bronchial tumor**
**(depth 21mm)**

## VI. Conclusion

Development of a 64 elements catheter-based ultrasound linear array included in a 7 French catheter was presented. Targets in miniaturization, frequency and medical application requirements were achieved enabling us to manufacture fully operating, miniaturized and re-usable probes working at 10MHz central frequency for endobronchial imaging.

First clinical evaluation demonstrates:

-feasibility of endobronchial ultrasound imaging with such a probe, in combination with a regular bronchofiberscopic exploration.

-significant contribution of ultrasound images to diagnosis and biopsy safety improvement

Clinical evaluation of endobronchial imaging with this ultrasound catheter will be further continued in view of these valuable results.

## Acknowledgments

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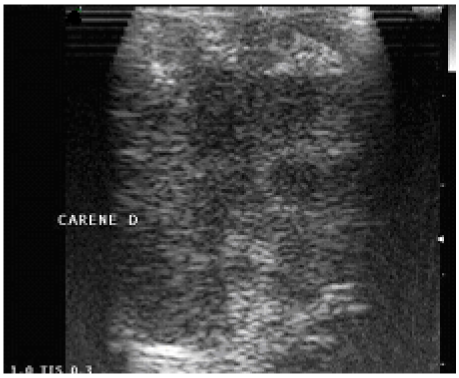


**Figure 7 : tumor with peripherical lymph nodes (depth 21mm)**

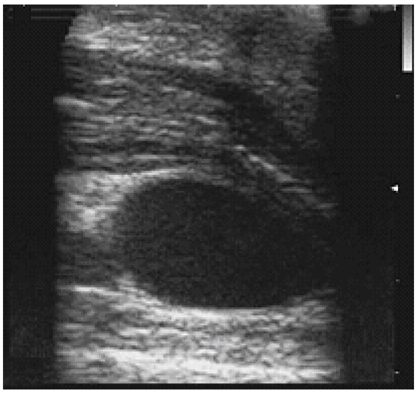

**Figure 9: vascular structure (depth 21mm)**

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