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Concept and First Assembly Steps

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Intravascular Ultrasound at the tip of a guidewire: Concept and first assembly steps

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Abstract

Minimally invasive surgery of the most lethal disease worldwide, coronary artery disease, benefits from better diagnostic tools during the treatment. With this in mind, a novel concept is introduced for intravascular ultrasound on a 360 µm diameter guidewire. The complex manufacture of this medical instrument, and other devices that require extreme miniaturization, will benefit from our previously presented Flex-to-Rigid assembly platform. However, currently the scalability of this technology is limited by etch-dependent effects. But with an innovation on the process flow presented here, the required smaller, well-defined, arbitrary shaped rigid islands with flexible interconnects between them were fabricated, therefore making it possible to manufacture this device.

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Keywords: Intravascular Ultrasound; Assembly; Microfabrication; Platform Technology; Flex-to-Rigid

1. Introduction

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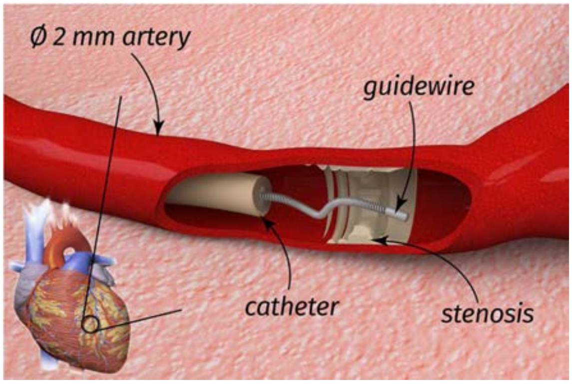

Fig. 1: During the minimally invasive procedure to treat coronary artery disease, first a guidewire is inserted and navigated to the location of the stenosis. The treatment catheter is slid over the guidewire.

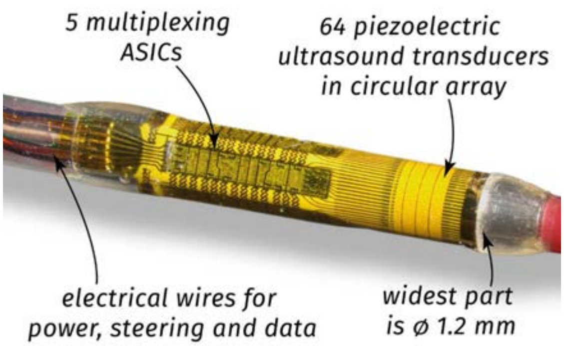

Fig. 2: State-of-the-Art intravascular ultrasound catheter Eagle Eye Platinum from Volcano/Philips. The components are assembled on a flat flexible interconnecting substrate before being wrapped.

With over 7 million deaths per year coronary artery disease is the leading cause of death worldwide [1]. In some cases this disease can be treated with medicine, but in other cases minimally invasive surgery is required. As the first step in this interventional procedure, a Ø 360 µm guidewire is inserted and navigated through the arteries. This device will later be used to steer either the diagnostic catheter or treatment catheter to the stenosis (Fig. 1). Intravascular ultrasound (IVUS) imaging on a catheter is a well-known and often used imaging modality for this procedure [2]. However, interchanging between the two types of catheters require extra steps during the procedure and the use of ultrasound imaging is, therefore, often minimized. It would be more efficient to include diagnostic ultrasound capabilities on the already present guidewire. In this paper, we present a concept that can be used to manufacture such an ultrasound device.

Our ambition to reduce the size of an ultrasound probe to fit on the tip of a guidewire comes, obviously, with challenges in miniaturization and integration. An approach suggested in literature is to use four phased 1D ultrasound arrays, which would be easy to integrate [3]. However, the resulting ultrasound image is likely inferior to a circular 2D ultrasound array, as used in the state-of-the-art IVUS catheter Eagle Eye Platinum, by Philips Volcano (Fig. 2). To manufacture this ultrasound catheter, standard flex-foil technology is used [4]. But, this technology has been stretched to its limits in miniaturization and will, consequently, not be suitable for the high level of miniaturization required for a guidewire. As an alternative to flex-foils we previously proposed the silicon processing based Flex-to-Rigid (F2R) assembly platform [5]. However, currently the scalability of this technology is limited by etch-dependent effects. In this paper, we present an intravascular ultrasound on guidewire concept and the required innovations to F2R to enable the extreme miniaturization. Furthermore, examples of the first assembly steps using this improved version of F2R are shown.

2. Theory and Concept

Our proposed concept makes optimal use of the limited volume available by wrapping the ultrasound transducer array around the required ASIC (Fig. 3). For the transducer array, a suitable choice was for capacitive micro-machined ultrasound transducers (CMUTs) because they can be wafer-scale fabricated, and therefore are compatible with the F2R technology. The transducers on the rigid silicon islands are interconnected through flexible bridges with the ASIC.

The data connection from the ASIC to the proximal side of the guidewire is a challenge by itself. The ASIC will multiplex the signals from 64 transducer elements, which implies that a communication speed of approximately 500 Mbps is required. However, a coaxial cable with well-defined characteristic impedance does not fit in the 360 µm diameter guidewire. As an alternative solution, we previously successfully demonstrated a high-speed optical data connection to an F2R substrate [6]. An 80 µm optical fiber was inserted in a 100 µm through-hole, and therewith passive aligned to a vertical cavity surface-emitting (VCSEL) laser (Fig. 4).

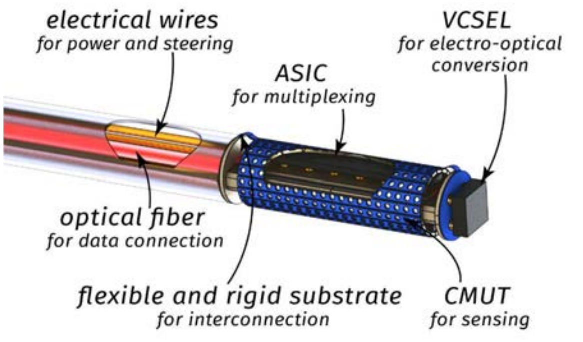

Fig. 3: Conceptual design for a Ø 360 µm ultrasound guidewire tip utilizing F2R technology. With this limited cable diameter and a high data rate, an optical data connection is more favourable.

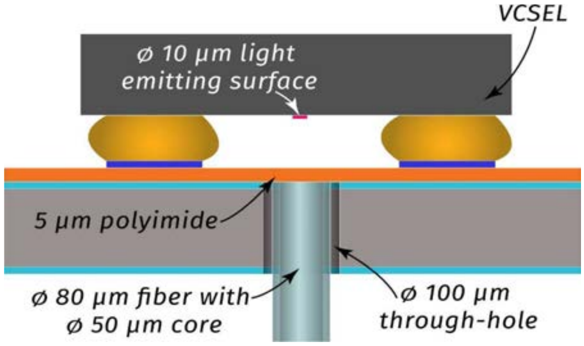

Fig. 4: Schematic cross-section of the optical coupling method. The wafer layout is defined by lithography. The VCSEL is positioned by solder self-alignment and the optical fiber by passive alignment.

However, the original F2R process flow is not suitable for the fabrication of well-defined silicon islands. In the standard F2R process, the islands need to be patterned on the back-side and subsequently that pattern is projected to the front-side by etching through the wafer. Because of through-wafer etch-effects occurring during this projection, it is difficult to create well-defined islands with a precisely defined opening for the optical fiber, as well as the very small islands required for the CMUT array. In the next section, an improved process flow with patterning of the front-side of the silicon wafer is discussed, resulting in High Definition Flex-to-Rigid (HD-F2R) islands.

3. Experimental

The process flow for the new HD-F2R explained in this section is based on the previously presented F2R technology [5]. The process started out with a 400 µm double-side polished wafer (Fig.5).

A low-stress PECVD SiO_2 layer with a thickness of 1 µm was deposited on the front-side of the wafer and a 4 µm thick layer was deposited on the back-side (Fig.5a). Defining the island outlines, trenches of 3 µm wide and several tens of microns deep were etched. On the back-side a two-step etch mask was created in the 4 µm SiO2 layer

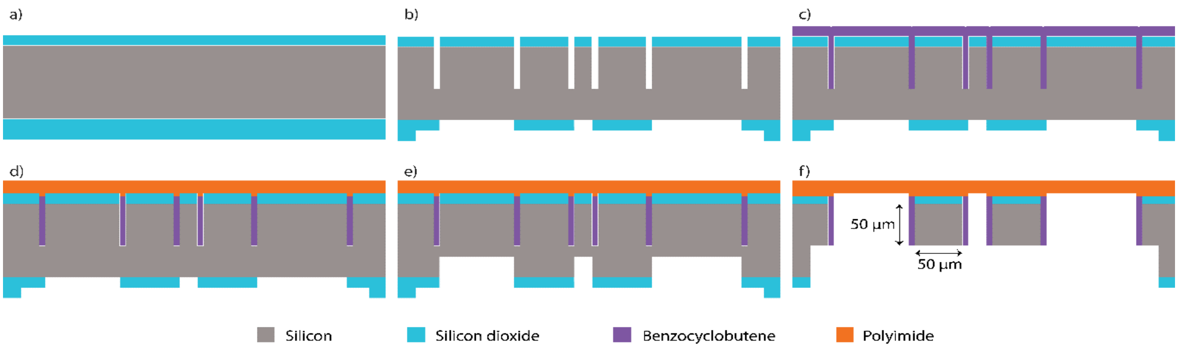

Fig. 5: Simplified BCB implementation in F2R process flow. a) On a 400 µm double-side polished wafer, 1 µm and 4µm PECVD SiO2 was deposited on respectively the front and back side. b) To define the lateral etch stops trenches 3 µm wide and tens of microns deep were etched on the front side. On the backside a two-step etch masked was created in the SiO2. c) BCB was spun 2.6 µm thick on the front side, filling the trenches. d) The BCB was etched back and subsequently a 5 µm polyimide layer was spun on the wafer. e) The wafer was selectively thinned down by two steps. First, an advance was deep etched into the silicon with the first SiO2 mask. Thinning the mask down by dry etching opened the second part in the SiO2 mask. f) With rest of the mask opened the second step in the silicon was etched. In the final step the SiO2 underneath the polyimide is removed by dry etching from the back.

(Fig.5b). To enable subsequent front-side processing over the trenches, a 2.6 µm thick benzocyclobutene (BCB) layer was first spun, filling the trenches (Fig.5c). Next, after curing the BCB was etched back and a 5 µm polyimide layer was spun on the wafer (Fig.5d). In the polyimide layer, aluminum interconnects (not drawn) were fabricated as demonstrated before.

During the next part of the process, the silicon was selectively bulk etched back in two steps. First, an advance was deep etched into the silicon with the first SiO2 mask (Fig.5e). After opening the larger window in the SiO2 mask, the second step in the silicon was deep etched (Fig.5f). In the final step the SiO2 underneath the polyimide is removed by dry etching from the back side as was demonstrated before [5].

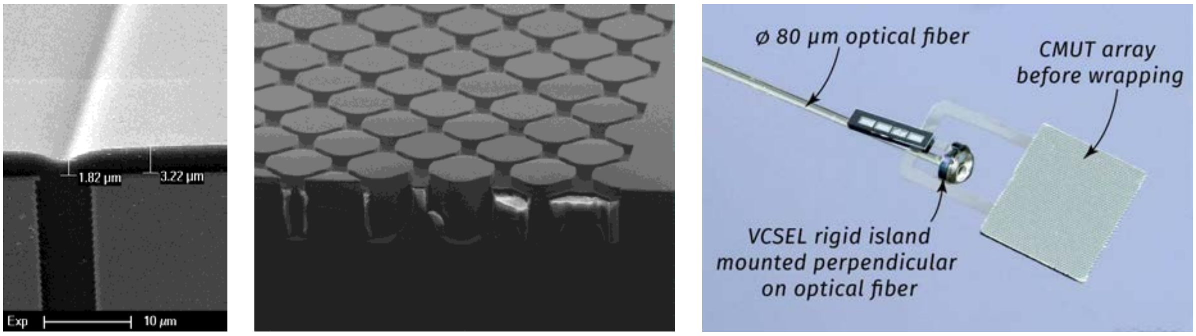

Fig 6. Fabrication results of the demonstration wafer. a) Filling of trenches with BCB. b) Filling of a large array of trenches with BCB. The volume flown into the trenches is too large, creating a local depletion of BCB. c) Stacked micrograph of a device released from the wafer by lasercutting and mounted at the time of an optical fiber. Subsequently, the rectangular island was glued parallel on the fiber.

4. Results and Discussion

A wafer with several designs, of which some can be seen in Fig 6, was fabricated for demonstration purposes. The BCB filling of the trenches was successful in most cases. As a result, the sidewalls of the rigid islands were still sharply defined after the final steps. If necessary, the BCB layer can be removed in a final etch.

However, large arrays of small islands still proved to be a problem (Fig. 6b). Due to a large volume of BCB required to fill the trenches around the islands in a large array, a local depletion of the material occurred. Therefore, planarization of the surface for subsequent processing becomes impossible. Furthermore, it appears some warpage of the wafer occurs, indicating an undesired level of stress in the BCB layer. The local depletion of the BCB in large arrays can possibly be solved by improving the spin parameters or the fluidity of the polymer. However, large arrays of silicon islands are still limited by design rules to minimize the stress in the BCB layer.

A device with a VCSEL island was mounted on the tip of an 80 µm optical fiber and the ASIC island bent 90 degrees and glued to the side of the fiber (Fig. 6c). In this case, the CMUT array is located on a single silicon island.

4. Conclusion

The improved process flow resulted in the successful fabrication of interconnected silicon islands of varying sizes while retaining the correct dimensions during the back-side etching. HD-F2R is shown to be a promising alternative to traditional flexible circuit boards, as an assembly platform. However, there is still room for improvement in the filling of the trenches. Of course, the utility of HD-F2R is not only limited to IVUS catheters. It can enable further miniaturization of any device where the same requirements are placed, particularly on- or in-body applications.

Acknowledgements

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