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Integration of a capacitive pressure sensing system into the outer catheter wall for coronary artery FFR measurements

Frank Stam[a], Heikki Kuisma[b], Feng Gao[c], Jaakko Saarilahti[c], David Gomes Martins[c], Anu Kärkkäinen[c], Brendan Marrinan[d], Sebastian Pintal[d],

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ABSTRACT

The deadliest disease in the world is coronary artery disease (CAD), which is related to a narrowing (stenosis) of blood vessels due to fatty deposits, plaque, on the arterial walls. The level of stenosis in the coronary arteries can be assessed by Fractional Flow Reserve (FFR) measurements. This involves determining the ratio between the maximum achievable blood flow in a diseased coronary artery and the theoretical maximum flow in a normal coronary artery. The blood flow is represented by a pressure drop, thus a pressure wire or pressure sensor integrated in a catheter can be used to calculate the ratio between the coronary pressure distal to the stenosis and the normal coronary pressure. A 2 Fr (0.67mm) outer diameter catheter was used, which required a high level of microelectronics miniaturisation to fit a pressure sensing system into the outer wall. The catheter has an eccentric guidewire lumen with a diameter of 0.43mm, which implies that the thickest catheter wall section provides less than 210 microns height for flex assembly integration consisting of two dies, a capacitive MEMS pressure sensor and an ASIC. In order to achieve this a very thin circuit flex was used, and the two chips were thinned down to 75 microns and flip chip mounted face down on the flex. Many challenges were involved in obtaining a flex layout that could wrap into a small tube without getting the dies damaged, while still maintaining enough flexibility for the catheter to navigate the arterial system.

Keywords: Fractional Flow Reserve (FFR), catheter integration, flexible circuit, capacitive pressure sensor, chip bumping & coining, die thinning, flip chip interconnect, solder laser jetting

1. INTRODUCTION

Cardiovascular diseases are the number one cause of death globally[1]. In 2012 17.5 million people world-wide died from cardiovascular disease, about 42% of these are from coronary heart disease (e.g. atherosclerosis when an inside arterial wall thickness increase can lead to a narrowing of the blood vessel (stenosis)). A situation exacerbating by an ageing population. The blood flow restriction, or rupture of the plaque can sometimes be treated by performing a percutaneous transluminal coronary angioplasty (PTCA). This involves bringing in a catheter with a balloon to the stenosis and inflating the balloon across the blockage to widen the vessel and increase the blood flow. The procedure then could be completed by placing a stent which could mechanically enhance the dilation of the vessel. As visualisation of the vessel narrowing has been limiting, blood pressure measurements have been introduced to assess the flow conditions before, and after the PTCA procedure. Initially this required the use of two guidewires, one with a balloon and one with a pressure sensor. While more accuracy about the stenosis could be obtained, it still wouldn't give the cardiologist much information to decide on an overall treatment strategy. However, in 1993 the concept of FFR (Fractional Flow Reserve) was invented[2], which offered a better solution. It involved determining the ratio between the maximum achievable blood flow in a diseased coronary artery and the theoretical maximum flow in a normal coronary artery. The blood flow is represented by a pressure drop, thus a pressure sensor integrated in the catheter or a guidewire can be used to calculate the ratio between the coronary pressure distal to the stenosis and the normal coronary pressure (Figure 1). Results showed better clinical outcome, decreased number of stents used per patients and a better cost effectiveness. An FFR-guided revascularization strategy has now been classified as a Class IA recommendation in the 2010 European Guidelines on myocardial revascularization. FFR can be considered for the following patient population, single-vessel

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coronary artery disease, multi-vessel coronary artery disease, equivocal left main coronary artery lesions, or bifurcation lesions. It has also been validated for patients with acute myocardial infarction (MI) or unstable angina.

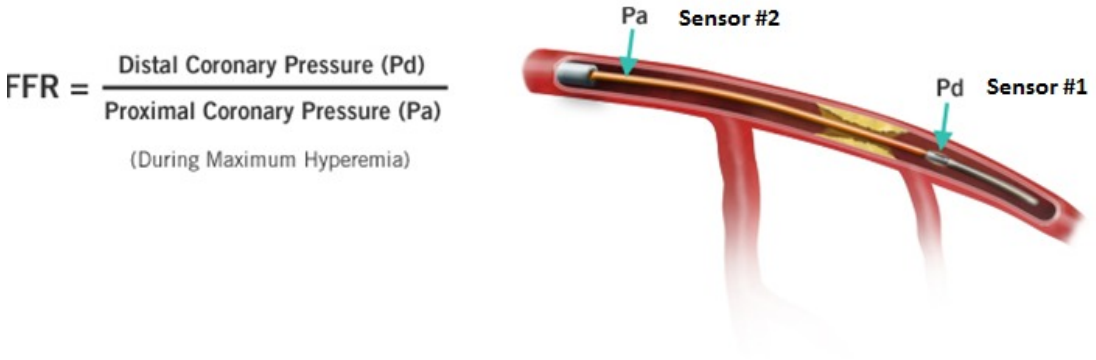


Figure 1. Principle of FFR measurement in a coronary artery

The objective of the reported work was to develop an FFR solution for a 2 Fr (0.67mm) outer diameter catheter with a pressure sensor integrated in the outer catheter wall. This is different from so far reported approaches with the pressure sensor integrated in a guidewire[5]. The catheter has an eccentric guidewire lumen with a diameter of 0.43mm. Figure 2 illustrates the envisaged concept. With this novel approach the physician can use his standard guidewires, particularly in difficult to access cases.

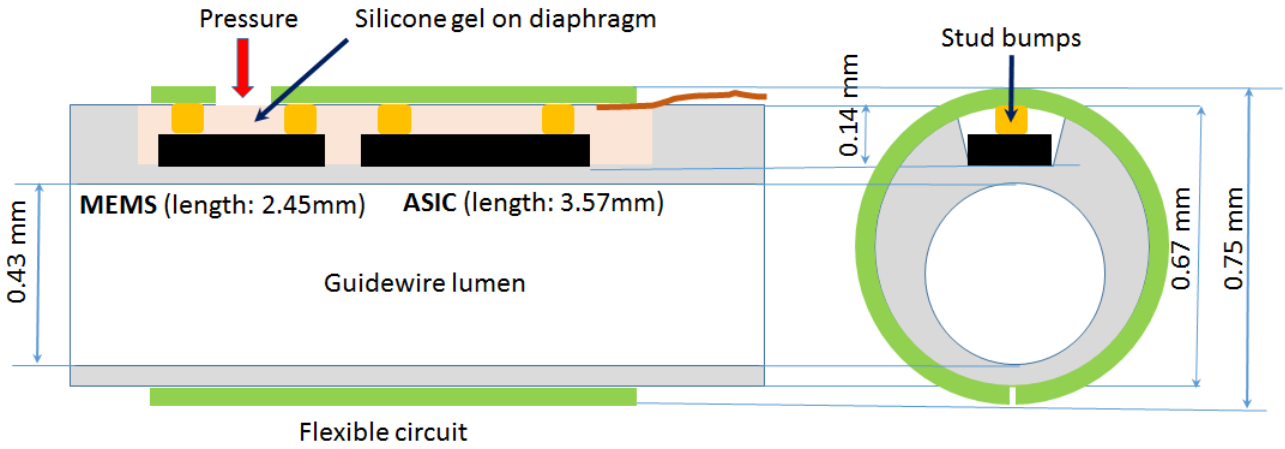


Figure 2. Integration of pressure sensor and ASIC dies in a 2 Fr FFR catheter

Commercial FFR solutions are based on guidewire integration using an optical sensor or silicon piezo-resistive technology[3]. Optical sensors offer many benefits: small size, insensitivity to environmental effects such as electrical or magnetic signals. However, the system becomes more complex at the optical back-end and could be more sensitive to fibre bending. The piezo-resistive compared to capacitive technology[4] is not as thermally stable and mechanically stress insensitive. Silicon capacitive technology on the other hand requires interface electronics nearby, compensation of parasitics and protection from the environment. The capacitive MEMS device[5] used here was designed in collaboration between Murata Electronics Oy and VTT Technical Research Centre Ltd., based on surface micromachining of SOI (Silicon On Insulator) wafers from Okmetic, and post-fabrication processing by VTT Technical Research Centre Ltd..

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2. PRESSURE SENSING SYSTEM

2.1 System overview

In Figure 3 an overview of the FFR catheter system is shown. The soft atraumatic tip and flexible circuit with the MEMS pressure sensing device and the control ASIC (Application Specific Integrated Circuit) are 15mm long, while the overall distal section of the catheter is 250mm long. It further contains a marker band and the 6 Multifilar® wires soldered to the flex circuit and wrapped as a ribbon around the outer extrusion under 45 degree angle. The distal section is connected to a stainless steel hypo tube section via a transition section including a grind wire welded to the hypo tube which improves the pushability of the catheter and prevents kinking between the soft distal section and the relatively stiff proximal section. It also facilitates an RX (Rapid eXchange) guidewire port. The total length of the catheter is 1.4 m, and at the wiring conversion point the wires are doubled in thickness from 48 AWG (American Wire Gauge) - 31 µm to 26 AWG – 60 µm via a fanout flex. Via standard male/ female connectors the wires are connected to an MCU-Arduino microcontroller board which can provide supply /current for the sensor and Asic, do a digital ASIC readout, and perform sensor calibration. Via an MCU Arduino USB link and a Graphical User Interface (GUI) the sensor signal can be displayed on a laptop or other display device. Further sensor data processing is done via a Matlab/ Python software development environment.

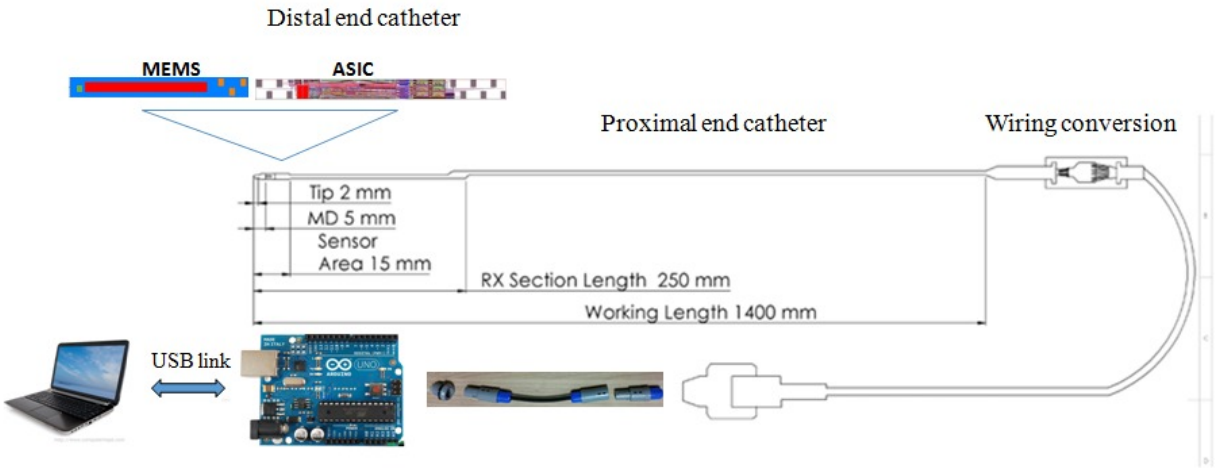


Figure 3. FFR pressure sensor catheter system overview

2.2 MEMS capacitive pressure sensor die

The sensor die for this application has a peculiar oblong shape (i.e. long and narrow), which doubles the sensitivity over more traditional circular membrane sensors with equal area and deflection and improves the robustness of the sensor under external forces. The MEMS pressure sensor is specified for -30 – 300 mmHg relative blood pressure. With a barometric range of 600-825 mmHg, the absolute blood pressure sensing range is: 570 – 1125 mm Hg. Figure 4 shows the initial layout, which was based on wirebonding interconnect using 4 Aluminium contact pads. However, with a height budget of only 140 µm for die and interconnect, the dies would have to be thinned and flip chip bonded. It would involve mounting the MEMS device face down on the circuit flex and in order for the blood pressure to affect the diaphragm, a window over the diaphragm area would need to be cut in the flex. For flip chip assembly the ideal bond pad metallisation would be gold. So in order to make the Aluminium bond pads solderable, gold stud bumps were required on the bond pads. The stud bumps would typically be 40-50 µm high, so allowing for a 20 µm interconnect interface layer, the thinning target was set to 75 µm. Despite these MEMS devices getting very small, it still is very difficult to integrate them in the catheter. Other sensor technologies are appearing like a very thin piezoelectric PVDF-TrFE co-polymer film[6] used as a smart catheter pressure sensor, but there seems to be no static pressure response. Also the average pressure, which is used for FFR, fluctuates quite a bit without a reason.

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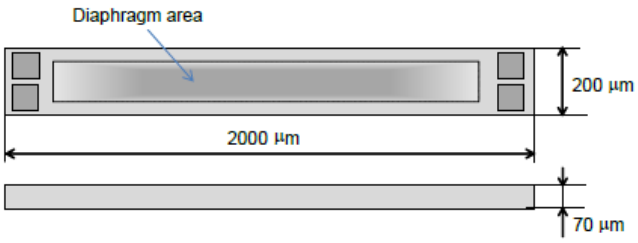


Figure 4. Initial layout of MEMS die

The flip chip revision of the MEMS die also required a leveling of the contact pads in one plane to obtain a uniform stand-off height between chip and circuit flex. Figure 5 shows the new design schematic and a wafer section with 10 MEMS dies. The number of functional contact pads has been reduced to 3, but on the right hand side a mechanical support pad is put in place to avoid tiling of the die during assembly. The 3 bond pads on the left are slightly staggered so that the die won't be mechanically unstable across its width. A consequence of the new layout is that the die has become almost 25% longer, which increases the risk of diaphragm damage. A USA company Silicon Microstructures Incorporated, has reported on a similar sized, 240x900x70 µm, piezoresistive, pressure sensor, but which was integrated in a 355 µm diameter guidewire[3].

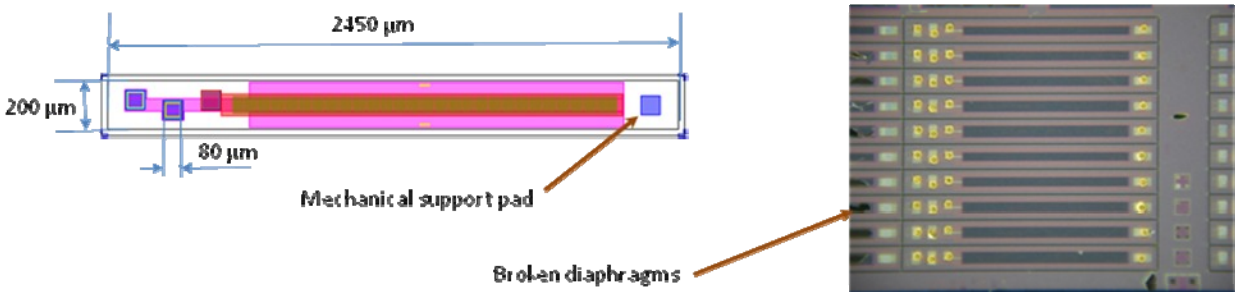


Figure 5. Flip chip layout of the MEMS die

2.3 ASIC die

The process technology selection was based on the interface ASIC's specification requirements. The most suitable process technology was found to be the 0.35µm CMOS by Austria Microsystems (AMS) which complies with the speed and size requirements. It also covers well modelled analogue and digital libraries. A Multiple Project Wafer (MPW) run had a short turn-around time at low cost. Based on prior experience with pressure sensor front-ends and systematic comparison of different architectures, a dual slope converter with integrated counters and switchable capacitors was chosen. The selection was justifiable since the design fitted the really challenging area target and still could fulfil all the performance requirements. Tests done on the ASIC showed that it performed similarly to simulations without any detected bugs.

Like the MEMS die, the ASIC die was also modified for flip chip assembly (see figure 6), and the ten 80x80 μm^2 bond pads were staggered similarly as the MEMS bond pads for mechanical stability sideways. Lengthwise the chip is also balanced with 4 bond pads on one end and 6 on the other end for the catheter wiring (inc. data in; data out; ground; voltage source; clock in; latch). It required the ASIC to lengthen more than the MEMS die and with an outline of 3570µm x 200µm is more vulnerable to bending stresses. The ASIC was also thinned down to 75 µm.

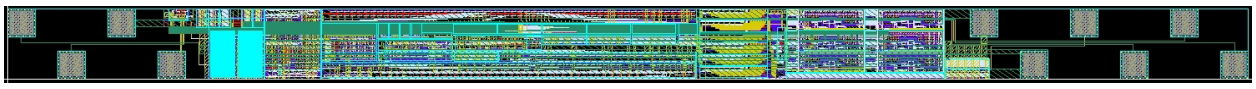


Figure 6. Flip chip layout of the ASIC die

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2.4 Stud bumping & coining

For the stud bumping 25 µm diameter gold wire was used. A single bump process was developed with minimum ball size and tail length. Small unthinned wafer pieces were used, and ESD (Electrostatic discharge) control was applied for all processing. The MEMS pieces (8x8, 8x16 or 16x16 mm) were larger than the ASIC pieces (~ 2x3.5mm), and different chuck fixturing was required. The MEMS pieces could be held by vacuum, but the ASIC pieces were held down by adhesive tape.

For the stud bumping a Finetech® Lambda flip chip bonder was used. For the ASIC pieces consisting of 5 chips two coining steps were used. Maximum load of 40N was applied to the 30 stud bumps on one side, this equates to 1.33 N/bump. To obtain the same amount of deformation for the 20 bumps on the other side 1.33x20= 26.60N was used. Figure 7 shows that the coining of the ASIC results in about 85 µm diameter stud bump surface areas. The height was estimated at 40 µm. For the MEMS pieces, lower coining forces had to be used as diaphragms broke at the loads used for the ASICs. A save coining force for the MEMS bumps was 0.87 N/bump.

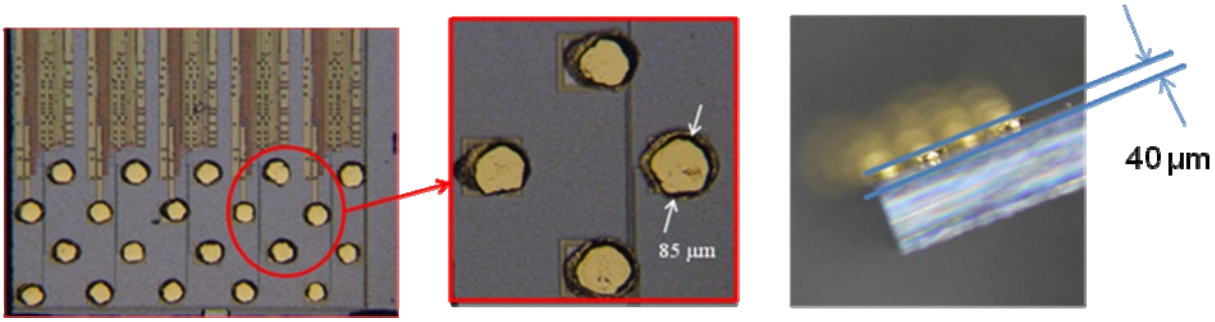


Figure 7. Stud bumped ASICs from above and from the side

2.5 Die thinning & dicing

The MEMS dies were fabricated with a surface micromachining technique on a SOI substrate with a 75 µm thick device layer on top of a buried oxide layer. 75 µm cuts were made in the active surface to avoid device damage later in the process[7]. Then the back of the wafer was etched with a 30-50 µm thick silicon layer left underneath the buried oxide layer as a frame support for the stud bumping. After the bumping, the remaining silicon was etched from the back as depicted in Figure 8 on the right. At this point the MEMS dies are only held in place by the oxide layer.

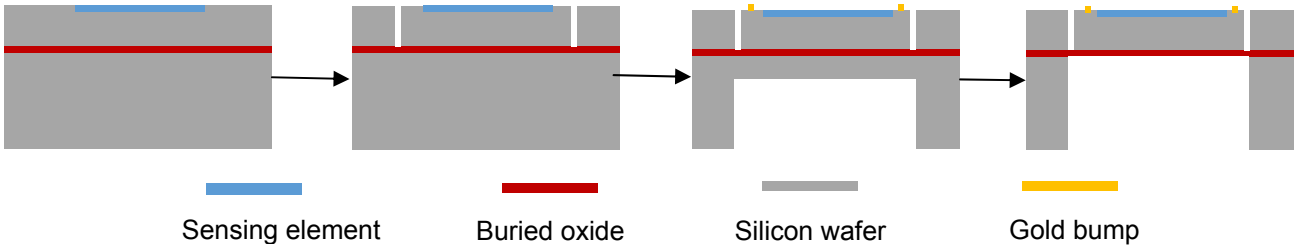


Figure 8. MEMS wafer thinning & dicing process

The thinning and dicing of the ASIC dies were both realised with a dicing saw. After the bumping step the ASICs were pre-diced with a narrow sawing blade (from the top) to be able to singulate them easier afterwards. The dicing grooves were about 75 µm deep so that the final die thickness would be the same as the MEMS dies. The remainder of the silicon was removed from the bottom side with a wider sawing blade and overlapping cuts (Figure 9).

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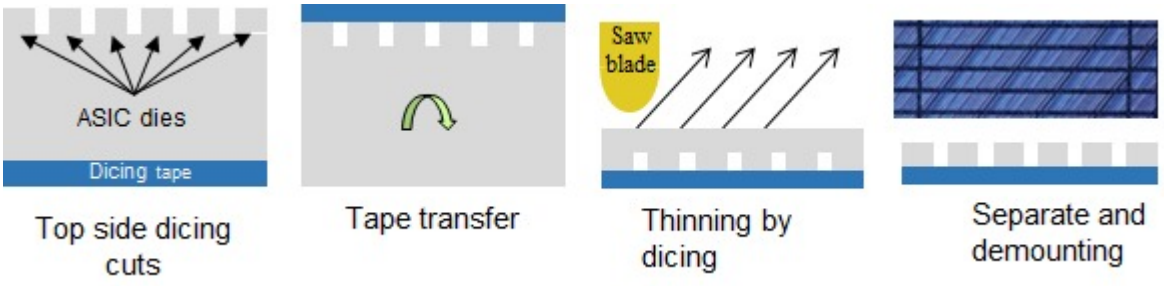


Figure 9. ASIC wafer thinning & dicing process

2.6 Circuit flex

A flexible circuit was required for keeping the MEMS pressure sensor and ASIC close together and provide connections between them and the catheter wiring. It had to be positioned near the tip of the catheter and in order to comply with the required 2Fr or 0.67mm catheter diameter (see figure 2), the maximum width of the flex could be 2.07mm. The length needed to be as short as possible, but is dictated by the length of the two dies, and space needed for catheter wiring soldering pads. The sensor area can be about 15mm long, which limits the flex length. 18 µm thick Polyimide (PI) flex material was used with 12.5 µm thick Copper and 4 µm ENEPIG (electroless Nickel, electroless Palladium and immersion Gold). Initial flex shaping, torquing & kinking trials showed metal delamination and cracking (also in PI). Figure 10 shows initial circuit design with ground plane area. Stress relief laser cuts were applied to the back of the flex and improved bendability, but this process was not commercially available. Another issue that had to be considered was the adding on of a cover or solder mask layer to isolate the flip chip and catheter wiring contact pads to avoid shorting between them during assembly. It was not possible to obtain accurate enough resolution in the chip interconnect areas, while the added thickness of the flex would increase the stiffness. Figure 10c shows an alternative with all flex covered in solder mask except for the full chip areas. There were no real benefits so a solder mask layer was discarded. Consequence was that assembly methods based on isotropic conductive adhesive and solder dispensing and dipping could not be used.

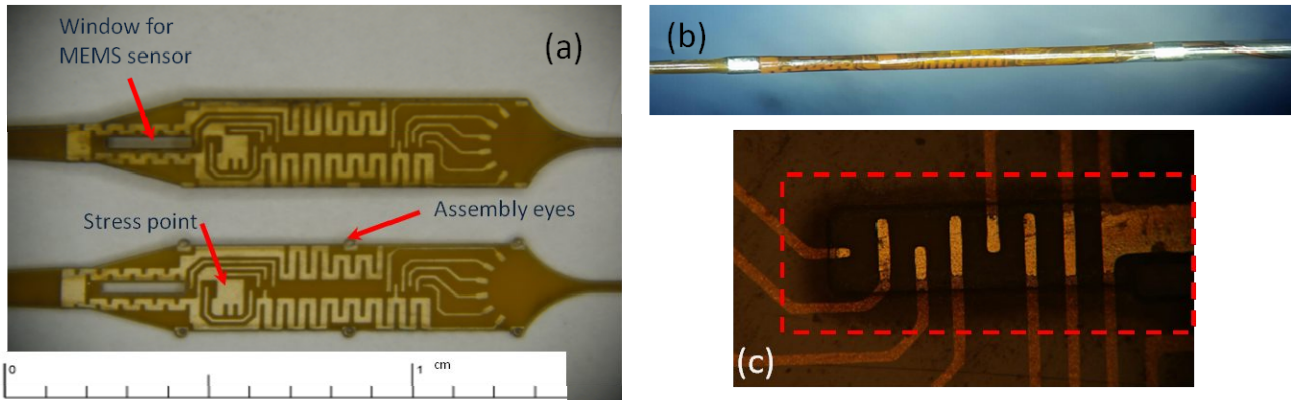


Figure 10. (a) Initial flex circuit layout, (b) flex wrapped with required diameter, without dies, (c) Flex partially covered with solder mask

The next circuit design iteration was based on 6 µm thinner PI and the track widths and large ground plane areas were avoided while also stress friendly rounded track corners were used. Good wrapping results were obtained! The assembly eyes shown in figure 10a didn't help much with securing the flex into a tubular shape, so 6/8 side strips were added instead which could be removed afterwards. Also longer front and back sections with cut-outs were used for better securing the flex in place. Experience from some early catheter steering trials, with dummy chips attached to the flex, showed that there was a tendency to "kinking" between the two "in-line" chips, so an alternative "side-by-side" layout was developed as shown in figure 11. The "side-by-side" layout is shorter, but the flip-chip assembly appeared more difficult, so the in-line option is still preferred.

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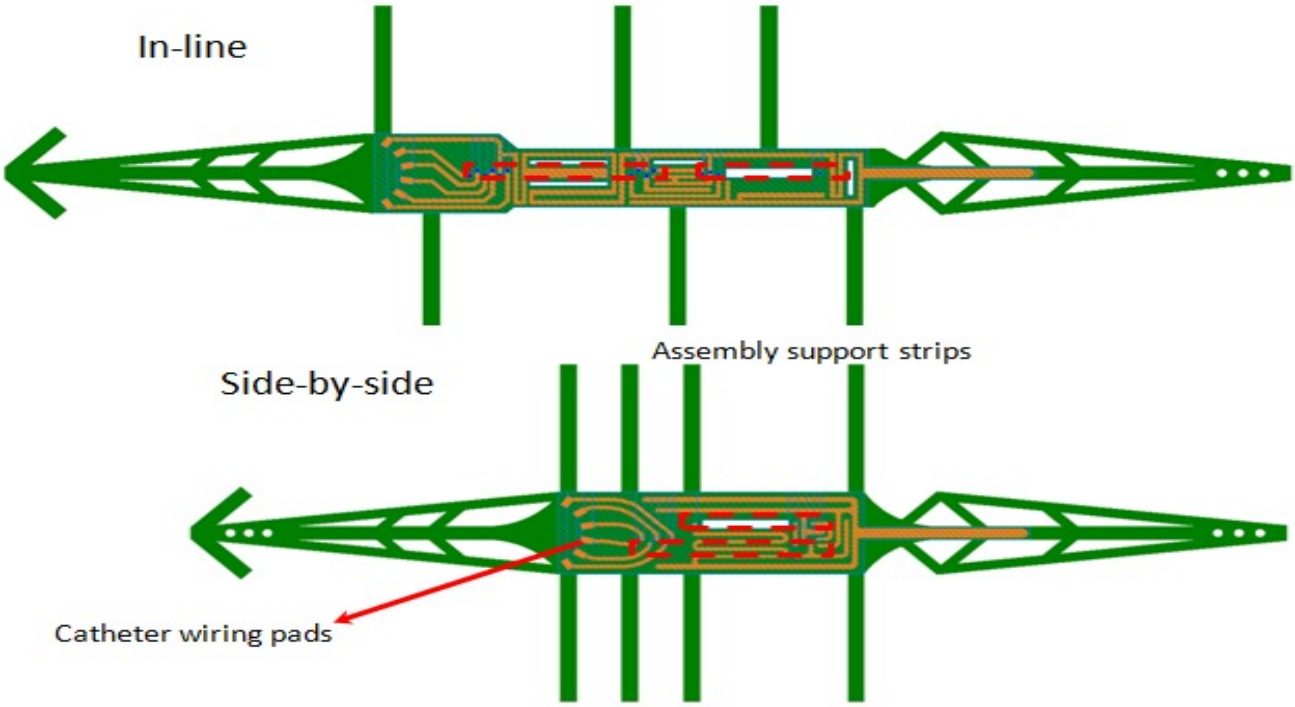


Figure 11. "In-line and "side-by-side" die configurations

2.7 Flip chip assembly

Two flip chip assembly methods were/are investigated: flip chip using dispensed *Anisotropic Conductive Paste* (Henkel, ACP 3122 – with silver filler particles) on the flex and flip chip based on *solder jetted spheres on gold stud bumps* (EFD Norton Sn96.5Ag3.5Cu0.5 lead free eutectic with Tm= 217 deg. C; no clean flux; particles 5-15µm).

The ACP was dispensed with using a Nordson EV2 system. For the ASIC a line under the die area was dispensed and for the MEMS two dots on both ends of the die. A Finetech® Lambda flip chip bonder was used to pick & place the dies. For the curing a steep ramp-up to 160 deg. C was used for both bottom hot plate and top chip holder for duration of 5 seconds and forced air cooling. During the curing a force of 3 N/ sq. mm^2 was applied from the top[8,9]. Chips were placed and bonded after each other. The flex pieces are taped down at their ends, but there is still a springiness in the flex which could cause some placement inaccuracies. Also the bonding tool is the exact same width as the dies (200 µm), so there is a chance that some ACP could cure on the tool. To check for electrical functionality, a special probe setup is needed for which samples need to be shipped to other project partners. Alignment and bond line thickness can also be assessed by microsectioning and other visualization techniques, but is very time consuming.

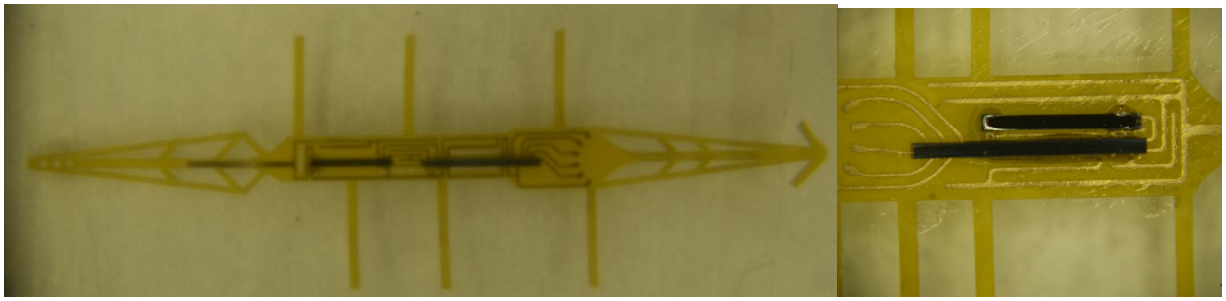


Figure 12. "In-line" and "side-by-side" flex assemblies made with ACP thermal compression bonding

Laser solder jetting was used to make the gold stud bumps solderable. In figure 13 the result of solder jetting on a MEMS device stud bumps is shown. The system used was a Pachtech SB^2-SM which can shoot molten solder spheres onto the targeted studs. One

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concern for the flip chip assembly afterwards is that the solder could reflow onto the gold tracks and an insufficient joint could form. An underfill process step to enhance the bonding strength between chip and flex will be needed for this assembly method.

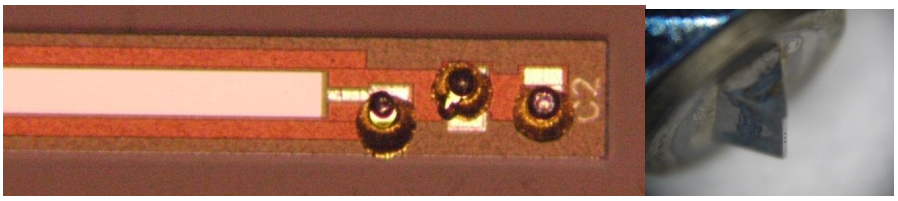


Figure 13. Laser solder jetted (SnAgCu eutectic) solder balls onto coined gold stud bumps and the flip chip pickup & bonding tool

2.8 Catheter integration

There are many detailed steps involved in integrating the electronics into the catheter, so just a subset will be described. Often designers start with the sensor or implant[10] and then develop the delivery device for it, but the other way around might avoid a few obstacles on the way. Assuming the flex assembly has passed the electrical test, then the first step is soldering 6 wires to the flex. The wire ends need to be stripped bare and the wires singulated, while the two chips need to be protected during the manual soldering. The catheter system will incorporate some custom made parts such as the soft tip, a strain relief hub, marker bands, a wire size conversion box, a rapid exchange port, and a heat shrink wire protector. The primary focus has been to design a catheter that integrates the sensor with limited impact to catheter profile and mechanical performance, comparable to existing devices accessing coronary arteries. The sensor housing consists of a slot in the thicker wall section of the distal catheter shaft extrusion (see figure 2). The flex will be wrapped around the shaft with the two chips facing down into this slot, and secured/glued in place. Wires need to be routed through the catheter and wrapped and also secured in place. A window needs to be cut in the surrounding heat shrink over the sensor area. Silicone (medical grade MED-66340) is put over the diaphragm to seal the circuitry from blood access. The catheter concept and in particular the distal shaft extrusion segment design has been adapted for improved assembly and to limit the heat effect during assembly, taking into account the delicate handling requirements for the dies; and stiffness/flexibility requirements. The discrete housing concept design allows for the sensor with wires attached to be loaded into the housing before assembly, eliminating the need for extra handling and heat being required to place a jacket over the sensor.

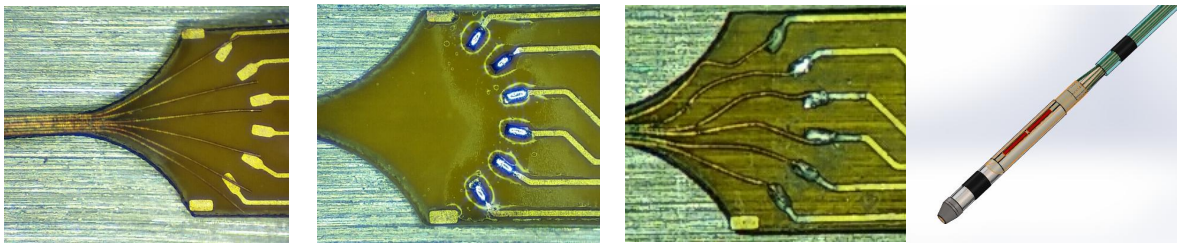


Figure 14. Hand soldering steps for catheter wiring and assembled distal end of the catheter

3. CATHETER TESTING

A test plan was incorporated to allow for continuous evaluation of catheter functionality during development. There are two primary catheter tests that can be done after assembly that will give an indication to what extent the manufactured catheter fulfils the required qualification criteria. In each instance the product is tested against comparable products currently on the market. In addition *in vivo* testing within a pig model is to be completed to confirm the benchtop performance.

Track Test

The catheter with the latest “in line” flex wrapped around was successfully tested in the track test on a coronary 2-D track model (see figure 15) with a 6Fr Introducer Sheath and a 0.014’’ guidewire. This is a standard coronary track model used to test comparable PTCA balloon catheters and the accessory devices used are typical devices used in these procedures for access to the coronary arteries.

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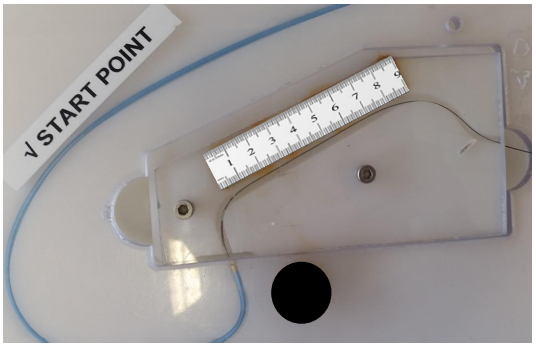


Figure 15. Catheter track test

Kink Test

Kink testing has been identified as a critical test for this sensor catheter, in that from a patient safety perspective it is important that the risk of device kinking and potentially breaking due to the sensor size and rigidity is fully considered. Again a standard kink test appropriate for devices accessing coronary arteries was selected. In the kink test the "in line" assembly passed 15 mm and 12.5 mm radius tests but failed at 7.5 mm radius due to kinking between the silicon devices. This limits the current iteration to be used in particularly tortuous coronary vessels.

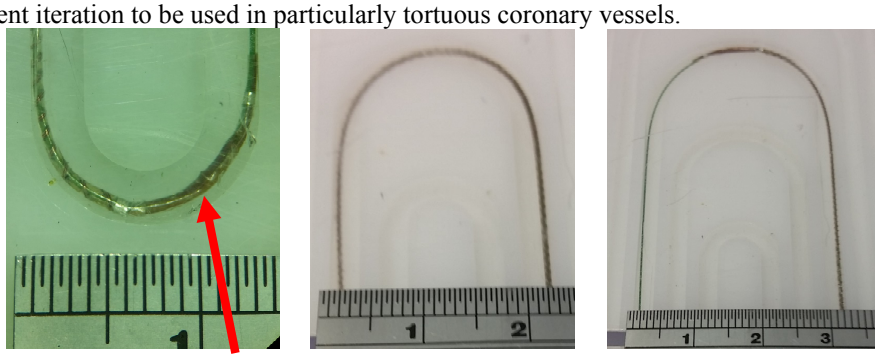


Figure 16. The assembly kinks at 7.5 mm bending radius but passes 12.5 and 15 mm tests.

Tensile Testing

The distal tip section, the rapid exchange port joint, the distal polymer extrusion shaft to the proximal hypo tube and strain relief hub to the hypo tube joints were all tensile tested according to the ISO 1055 procedure. Acceptable criteria were achieved for all parts.

CONCLUSION

At the outset of the project there were many unknowns, but the thought was that if you set yourself challenging tasks you will learn more than when you aim to achieve safe targets. Targeting a 2 Fr catheter set the bar high, as it dictates the maximum sizes for the dies, and it will demand advanced specs for the circuit flex. Microassembly traditionally is carried out on a flat platform, but more and more 3D integration is required. Flip chip interconnect is a typical flat to flat surface assembly process, how reliable will these interconnections be when brought into a curved configuration consisting of thin flexible dies and a thin flexible circuit flex? The reported work has progressed to the point that some mechanical testing was carried out, and the next phase will consist of electrically assessment of the sensor sub-assembly and subsequent catheter integration.

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