Efficient Thermobonding Process Forming a Polyurethane Based Diagnostic Catheter with Liquid Crystal Polymer*

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Abstract— **Diagnostic and therapeutic catheters play an inevitable role in minimal invasive medical procedures. Unfortunately, standard catheters show a limited transducer density and high production efforts. We propose a novel catheter design and manufacturing method using a liquid crystal polymer (LCP)-based flexible printed circuit board (FPCB) and a thermoplastic polyurethane (TPU) elastomer tube. Both components are bond together with a low cost, additive free lamination process at a re-flow temperature of 250° C. The lamination process is improved with a laser welding seam and LCP-integrated microholes preventing delamination. Standardized Mechanical tests were conducted to characterize the bonding. A Peel strength of up to 8.5 N in the radial direction and a non plastic elongation in the axial direction of 10% provide evidence that the thermobonding process is suitable for the production of flexible and mechanically durable medical catheters featuring high electrode densities.**

I. INTRODUCTION

The increasing prevalence of patients with cardiovascular diseases has enforced the number and complexity of minimally invasive medical procedures recently. Advanced diagnostic catheters play an important role for such interventions. The trend goes towards catheter that integrate multiple transducers and manifest flexibility and steerability at the same time. However, design and manufacturing of high-density catheters is cumbersome due to soft material properties and low dimensions. Design extensions and process automation are often limited. The resulting manual manufacturing is labor intensive and concurrently raises the costs similarly for the medical device supplier and the healthcare society.

To facilitate an easier manufacturing of high-density catheters, we present a process to laminate a FPCB based on LCP onto a TPU tubular body using laser welding and lamination in combination with LCP-integrated microholes. LCP, i.e. the core catheter material, has been used as dielectricum in FPCB's since many years [1]. Due to its biocompatible nature and water impermeability, LCP is well suited for medical devices such as neuroprosthetic implants [2], as well.

Current technologies for attaching a FPCB onto a polymer body rely on bonding, ultrasonic welding or other mechanical means [3], [4], [5]. Some of these processes result in catheters featuring high stiffness because the edges have been glued or welded together in order to establish a tubular structure. Such catheters are limited to specific applications where almost no bendability is required.

The majority of the bonding processes promote additives as key element to adhere the FPCB, which are generally sensitive to environmental conditions and additive dosage. Furthermore, the presence of adhesives is undesirable in clean room manufacturing. In some cases, the surface of the catheter undergoes a laser etching to improve adhesion of the bonding [6]. Other designs consider the insertion of a FPCB in a single- or multi-lumen tube and it's expansion at the distal end of the catheter [7].

The catheter resulting from the herein proposed design and manufacturing method is configured to be used as a esophageal diagnostic device for the detection of paroxysmal arrhythmia's as demonstrated in [8]. A more in depth look on the applicability of contemporary esophageal catheters can be found in [9].

II. METHODS

A. Components and Design

The FPCB that is adhered to the catheter tube has a single signal layer with a dielectricum based on LCP and the stack layout given in Table. II-A. The design shown in Fig.2 has 14 electrodes arranged in a distance of 10 up to 15 mm. Between each electrode there is a flexible element, which follows a meander shaped pattern. The width of these meanders get progressively smaller proportional to the number of traces in order render the catheter more flexible towards its distal end. Various designs were investigated including an alternating and straight spiral, with the goal to examine different bending characteristics during nasal or oral insertion. Segments of the FPCB tail can be bended in a 180 ° degree way as shown in [10] to form a straight line having a total length of 800 mm.

On the proxmial end of the catheter tube a molex zero insertion force (ZIF) connector with a pitch of 200 μm (Fig.2) is placed. Out of the 17 pads the three innermost pads have been left unconnected allowing the ZIF connector to be fully foldeable in the center section. The ZIF connector is supported by a polyamid plate with a thickness of 100 μm in order to fit in the corresponding female counterpart. The holes in the two possible connectors are used to be knoted to an insertion wire, which is pulled trough the catheter together with a laser etched PTFE liner used to guide a catheter stiffening wire.

To increase peel strength between LCP and TPU and prevent LCP delamination, a series of microholes are placed on the edges of the FPCB. The holes are intended to fill with the TPU tube material during lamination. The average diameter of holes is 120 μm with 300 μm interhole distance.

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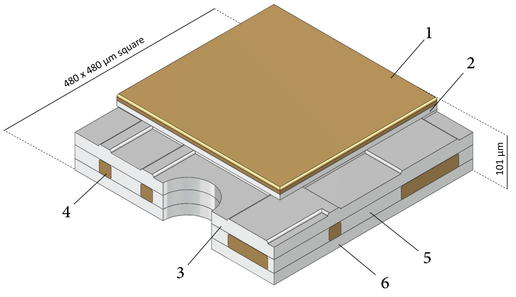

Layer No.	Layer type	Material	Thickness [μm]
1	Surface finish	ENIG-Au-Ni	2
2	Plated copper	ED type	12
3	Flex layer	Ultralam 3850 HT	25
4	Base copper	ED type	12
5	Bonding film	Ultralam 3809	25
6	Flex layer	Ultralam 3850 HT	25
Overall Thickness: 101 μm			

Fig. 1. Stack layout of the FPCB based on LCP.

The holes were laser cut during manufacturing of the LCP and they cover the contour for a segment with the length of 120 mm. A PUR 85 Pellethane 2363 80A extrusion is used as tubular body. The extruded tube has an outher diameter of 3 mm and a wall thickness of about 250 μm.

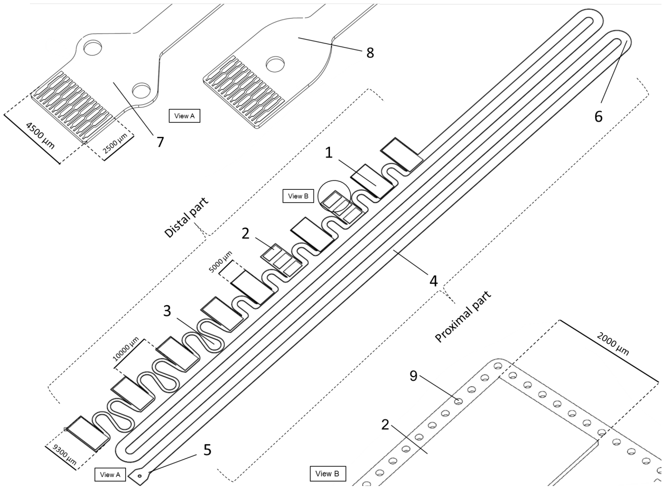

Fig. 2. FPCB design in planar form containing ring electrodes (1), split electrodes (2), omega shapes (3), tail (4), single hole connector (5), bending segments (6), double hole connector (7), single hole connector (8) and micro hole structure (9).

B. Lamination Process

The LCP was laminated onto the TPU applying heat and pressure. The heat was generated with a commercially available heat gun and the pressure was applied with the help of a peelable shrinktube (FluoroPEELZ, a product of ZEUS), which has a shrink ratio of 1.4 and an inner diameter of 3.32 mm. The catheter lumen was supported by a PTFE mandrel with an inner diameter of 1.45 mm and a wall thickness of 300 μm. The whole lamination process is subdivided into two phases. First, a PTFE mandrel is inserted in a single lumen catheter, whereby the outer diameter of the PTFE mandrel matches the inner diameter of the catheter tube. A second heating cycle is applied in which the melting temperature of the catheter tube is exceeded. The process requires a catheter material that has a lower melting point than the FPCB. The melting temperature of the catheter tube should be preferably in the range between 150 °C and 250 °C. The FPCB has to be made out of a material with a melting point above 280 °C. The electrode base material, i.e. Cu has a high ductility and malleability and, thus, can be easily shaped into a cylindrical form.

C. Laser Welding Process

Instead or in combination with lamination and the LCP microhole structure, a laser welding process can be used. This process was examined with a 3-axis CO_2 laser (Model BWTec type 1410) having a wavelength between 10570 and 10630 nm. A stainless steel mandrel is inserted inside a PTFE mandrel, which is placed in the lumen of the catheter, whereby the end of the catheter tube is held in place by an adhesive tape. The steel mandrel can then be clamped in the chuck of the laser machine. The FPCB is bent with the radius of 1.5 mm and placed on the catheter tube. The shrinktube with an inner diameter of 3.32 mm is moved over the assembly and subsequently heated by the Laser using a 360° turn. After this process step, the edges of the FPCB are welded onto the TPU tube by placing the laser welding seam on a space with the width of 1.3 mm. Various laser parameters were examined in combination with axial and rotary motion. After the full contour of the FPCB is laser welded, the stainless steel mandrel and the shrinktube are removed from the catheter. An subsequent reflow process step is applied to smoothen the surface of the catheter .

D. Mechanical Catheter Testing

To investigate the adhesion strength of the LCP-TPU bond, a peel and a tensile strength test was conduced. All test samples were submerged according to ISO standard EN1618:1997 in water at 37 °C for a duration of 2 hours in order to mimic the conditions that are encountered in a human body. The peel and tensile strength tests were done on a calibrated test machine (Zwick Roell Zwicki Z2.5) until delamination of the samples was reached as illustrated in Fig.3. Multiple samples varying the coverage of the catheter tube circumference were laminated, starting with a width of 1 mm (10% coverage) up to the full circumference of 9.4 mm (100% coverage), which corresponds to a ring electrode. The laminated parts were cut to stripes with the length of 60 mm, an adhesion surface of 20 mm and a width ranging from 1 mm to 9.4 mm. Similar adhesion surfaces were laser welded with an other sample set that subsequently underwent peel testing. Finally, a laser welded and laminated sample set was tested the same way. To test the tensile strength of the adhesion surface in the direction of the x-axis of the catheter, a force applied orthogonal to the direction of the peel force was applied to three test samples. The test samples were first clamped on the TPU tube and second on the latch of the LCP in the corresponding clamping mechanism as shown in Fig.3. The clampling was achieved by inserting a stainless steel cylinder into the first electrode of the design. A orthogonal pulling motion was applied until delamination of the LCP from the TPU took place. One sample was pulled to about 10 % of the total elongation, retracted and checked for traces of delamination.

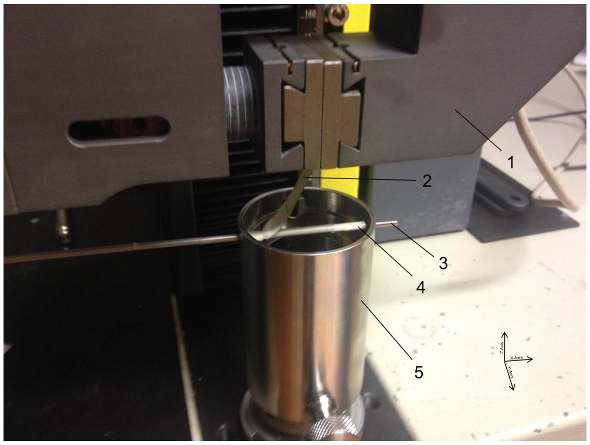

Fig. 3. Peel strength test setup containing vice (1), sample LCP sheet (2), moveable stainless steel mandrel (3), sample TPU tube (4) and base holder (5).

The microholes were examined for the quality of reflow with the help of a microscope (Nikon Eclipse LC150). Therefore, catheter samples were cut in order to inspect it's cross section. After the laser welding and the lamination had concluded, the samples were examined for electrical connectivity with the help of a multimeter. The FPCB's were pulled trough the catheter tube with the help of a tool consisting of a stainless steel rod and a surgical wire. The catheter connector shown in Fig. 2 was pulled trough the hole in the tube until the proximal end of the catheter tube was reached. To test compliance of the catheter during insertion in to the nasal cavity, all test samples underwent a bending test inside a gauge shown in Fig.4.

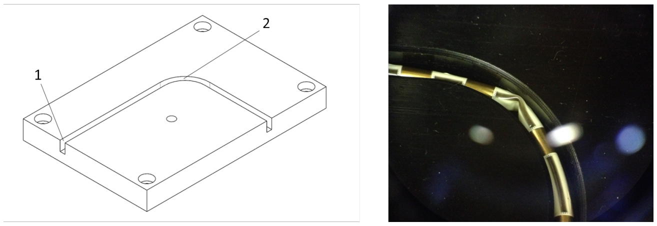

Fig. 4. Schematic view (left) and magnified image of characteristic kinking catheter in test gauge (right) with a 5x10 mm wide guidance channel (1) and a bending radius of 20mm (2).

III. RESULTS

The lamination and laser welding results in peel strengths in the range from 1 to 11 N. The finished catheter could be elastically deformed to up to 10% without being mechanically degraded. Furthermore, none of the processes impaired the electrical connectivity of the FPCB's. All test samples could be inserted into the nasal insertion test gauge without delaminating. In some cases a characteristic kinking could be observed that is shown in Fig. 4. The total time to manufacture one single catheter was about 30 minutes for the lamination process and exceeded 50 minutes when laser welding was applied.

A. Lamination

The peel tests of the laminated samples show adhesion strengths of up to 12 N in cases were the LCP covered 95% of the catheter circumference as shown in Fig. 5. When the laminate is exposed to heated solvent the maximum peel strength is decreased to 5 N for a 95% coverage. None of the samples delaminated on its own inside the heated solvent. However overall peel strength degradation due to solution exposure achieved 60%.

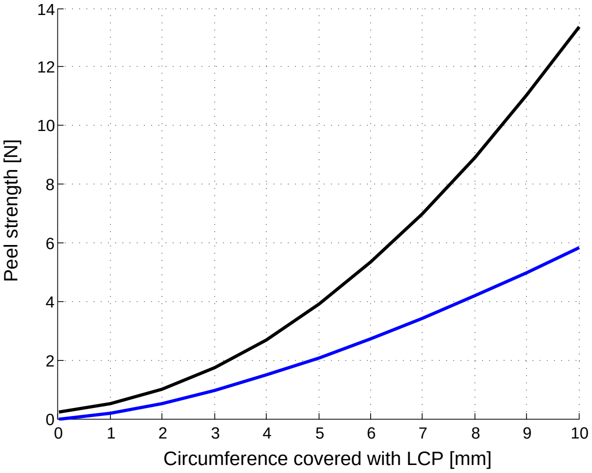

Fig. 5. Result of peel strength test in solvent (blue) and dry (black).

The hole in the catheter could be successfully closed with lamination. Visual inspection confirmed that the seal was intact and free of ruptures. Tests with the nasal insertion test gauge have shown that the catheter tends to kink when strongly bent. However no delamination is obserevd after the guide wire was retracted and inserted multiple times. None of the 14 leads of the connector were affected trough the lamination and resistances of traces below 1 Ω were observed. After haptically testing the catheter no issues concerning surface smoothness were determined. The examination of the crossection in Fig. 6 yielded that the TPU has become level with the FPCB, no air pockets or other inclusions could be observed in the adhesion zone. The visual inspection of the catheter revealed that the micro hole structure has reflowed with the TPU as depicted in Fig.6.

B. Laser welding

The peel test of the laser welded samples is summarized in Fig.7. A maximum force of 3.6 N with 95% LCP coverage for laser welding and 9 N in combination with lamination is attained. An average increase of 40% of peel strength

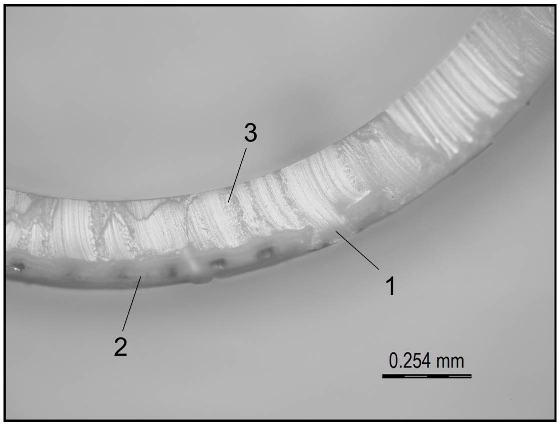

Fig. 6. Cross section trough a laminated sample with microholes (1), FPCB (2) and catheter tube (3).

can be measured for the instance were laser welding was combined with lamination. All 14 connections of the FPCB stayed intact even when the laser was hitting electrodes or traces directly. However, the welding seam altered the smoothness of the catheter such that surface irregularities were haptically noticeable. The introduction of the catheter in the nasal insertion test gauge resulted in a slight kinking of the tube with no FPCB delamination or other issues. The insertion wire was introduced into the catheter multiple times without any noticeable resistance.

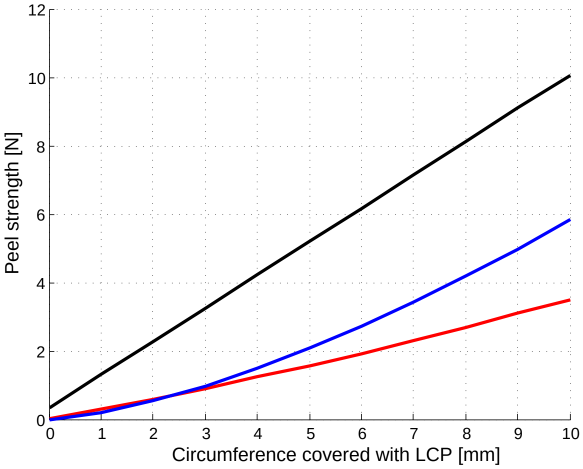

Fig. 7. Peel strength of the laser welded laminate. Laser welded (red), laminated (blue) and laser welding and lamination combined (black).

IV. DISCUSSION

We designed and manufactured esophageal catheter prototypes with a novel thermobonding process including lamination and laser welding. Peel strength tests have shown that the resulting thermobond between LCP and TPU is strong and durable in accordance with accepted standards for intravascular catheters [11]. A maximal peel strength of 9 N achieved for the lamination process indicates that a natural adhesion surface between LCP and TPU is created. The reason for the degradation of the peel strength by 60% under wet conditions can most probably be attributed to the fact that thermoplastic polymers like TPU absorb liquids and are temporarily deformed during heat exposure. The TPU is expanded, which alters the LCP to TPU adhesion boundary. As a consequence, a small amount of water may flow under the LCP and degrade the adhesion. A peel strength of 9 N even under wet conditions can be achieved with the combination of laser welding and lamination. This supports that the welding seam placed on the edge of the LCP mitigates the partial delamination by creating a tighter physical barrier against inflow of liquid. A similar effect can be observed with the LCP design integrating microholes as illustrated in Fig.2. Overall, a combination of all three design and manufacturing features can be considered as the most promising approach. The closure of the LCP insertion hole is achieved during the lamination process, whereby the placement, thickness and shape of the TPU cutout plays a key role for the quality of the resulting seal. The insertion test has not generated enough shearing force to damage the LCP or the TPU tube.

CONCLUSION

The present catheter design and corresponding thermobonding process, that have been filed as patent [12], enable the production of mechanically strong, flexible catheters that feature a high electrode density. Automated and efficient manufacturing of advanced diagnostic and therapeutic catheters might become possible.

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