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Robert Earl, Richard L. Leask, Paul Fromme, "Nondestructive ultrasonic quality testing of endovascular devices," Proc. SPIE 12048, Health Monitoring of Structural and Biological Systems XVI, 120480R (19 April 2022); doi: 10.1117/12.2614511

Event: SPIE Smart Structures + Nondestructive Evaluation, 2022, Long Beach, California, United States

Nondestructive ultrasonic quality testing of endovascular devices

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ABSTRACT

Endovascular medical devices such as catheters are composed of multiple thermal plastic components joined by butt-welding. High quality joining of components is required to ensure patient safety. The current practice for assuring quality is limited to process validation and destructive testing. An ultrasonic system for endovascular weld inspection was developed to detect faults (porosity and contamination) post welding in polyamide (Pebax-72D). Results from angled ultrasonic measurements were compared to micro-CT and found to correlate well with weld quality as a potential non-destructive index for 100% in-line verification of the joining process.

Keywords: Catheter, Ultrasound, Polyamide Weld Inspection

1. INTRODUCTION

Medical device manufacturers develop minimally invasive endovascular devices to safely access patient target sites and deliver therapies. Endovascular devices such as catheters (Fig. 1) are often manufactured from multiple, welded plastic tubes [1]. The welding process for medical devices requires validation or verification to ensure weld performance and patient safety according to standards [2], e.g., sustaining a minimum tensile force depending on the cross section.

Current industry practice relies heavily on process validation, requiring destructive testing such as tensile, pressure, and overall performance testing. The small scale of endovascular devices makes non-destructive testing challenging as intravascular catheters typically have outer diameters in the ranges from 1 – 11.3 mm. Previous studies have examined the maximum tensile strength of polymer bonds and tried to optimize welding parameters [3-6].

Ultrasonic testing of plastic weld integrity in endovascular devices would be non-destructive and provide a cost-effective methodology with rapid through-put to identify any impedance changes or discontinuities (faults) hidden within a weld. Ultrasonic testing has previously been demonstrated to detect small tray seal faults [6]. The feasibility for the ultrasonic imaging and testing of plastic catheter welds with manufactured defects was investigated and compared to X-ray micro-CT high resolution imaging.

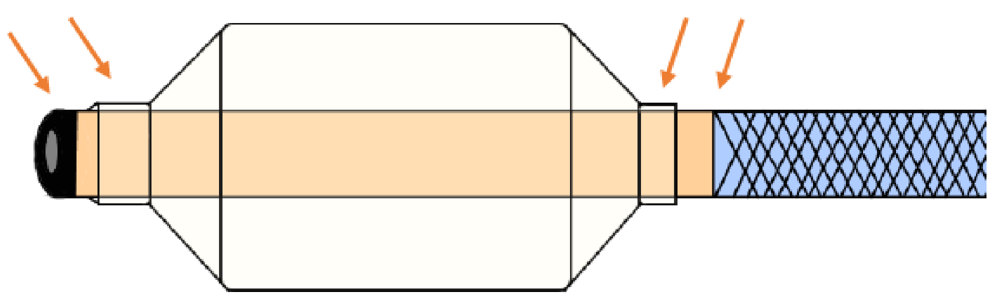

Figure 1. Schematic of distal end of balloon catheter, arrows indicate weld locations.

Health Monitoring of Structural and Biological Systems XVI, edited by Paul Fromme,
Zhongqing Su, Proc. of SPIE Vol. 12048, 120480R · © 2022 SPIE
0277-786X · doi: 10.1117/12.2614511

Figure 2. Butt welded Pebax control specimen (2.4 mm outer diameter).

2. EXPERIMENTAL METHODOLOGY

2.1 Polyamide weld specimens

Polyamide single lumen Pebax® 72D tubes (2.4 mm outer diameter, 1.5 mm inner diameter, 0.45 mm wall thickness) were butt welded using hot air with an outer jacket and internal mandrel (Fig. 2). In addition to a control group, porous and contaminated weld specimens were manufactured by wetting with alcohol or applying talcum powder to the weld surfaces. Six porous and contaminated specimens each were manufactured, with 5 control specimens.

2.2 X-ray micro-CT imaging

Using a Bruker Skyscan 1172 and SkyScan NRecon and CTAN, X-ray micro-CT images of all specimens were obtained, reconstructed, and thresholded. The voxel size was 3.99µm. Wall thickness and void and contamination content were obtained from 3D volumetric analysis of the reconstructed and thresholded images (Fig. 3).

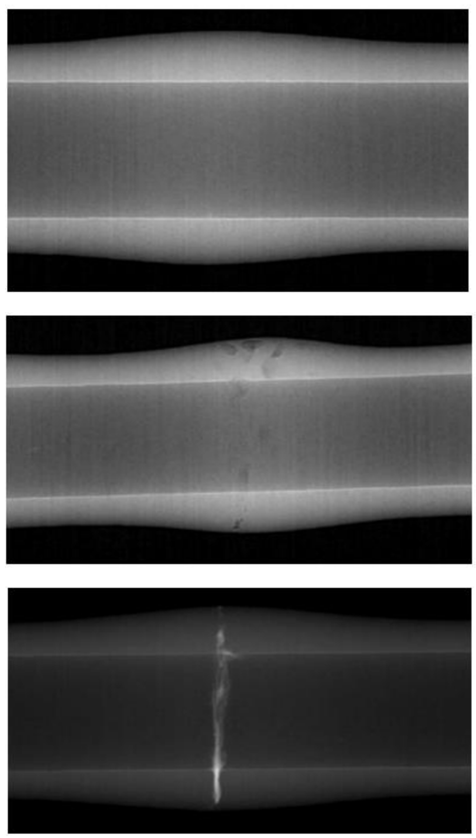

Figure 3. Cross sectional view of micro-CT image, butt welded Pebax specimens (2.4 mm outer diameter); top: control; center: porous; bottom: contaminated specimen.

Figure 4. Ultrasonic immersion setup for angled beam inspection.

2.3 Ultrasonic testing

The welded specimen and ultrasonic transducer (Olympus V3119, 15MHz, focussed) were submerged and positioned with the help of fixtures in a water tank (Fig. 4) for immersion ultrasonic scanning. The transducer could be moved horizontally and vertically by a scanning rig with 0.00635 mm resolution, and the specimen rotated with a resolution of 0.0879˚ steps. Angled ultrasonic inspection was performed with the transducer stationary and focused at 45˚ on the weld interface. The specimen was rotated in 15˚ steps, corresponding to a 0.157 mm outer arc length, which was less than the 0.2 mm focal spot diameter. Driving the transducer in pulse-echo (P/E) mode with a pulser-receiver, full time trace output at each angular location was recorded using an oscilloscope and averaged (32 averages, 7000 samples). Signals were bandpass filtered (2.5-30 MHz) using a 4^{th} order Butterworth filter. Data was transferred to a PC for offline processing using Matlab®. The signal energy was estimated through summation of the squared time signal amplitude for all angles and normalized with the energy from the end of the cylinder with no weld present.

2.4 Destructive tensile testing

Specimens were tensile tested to failure to quantify void and contamination influence on failure mode, elongation at break and ultimate tensile strength (Fig. 5). Specimens were held in mechanical grips with a gauge length of about 25mm on both sides of the weld and elongated in displacement control with a speed of 500mm/min.

2.5 Statistical analysis

The data was assumed to be normally distributed with a low sample size. One-way ANOVA with a Bonferroni post-test was used to assess difference between defect and control groups (significant differences for $p<0.05$). Linear regression curves are shown with 95% confidence bands. Cut-off values with an expected population coverage of approximately 99.9% were calculated using the mean of control group results plus 3 standard deviations.

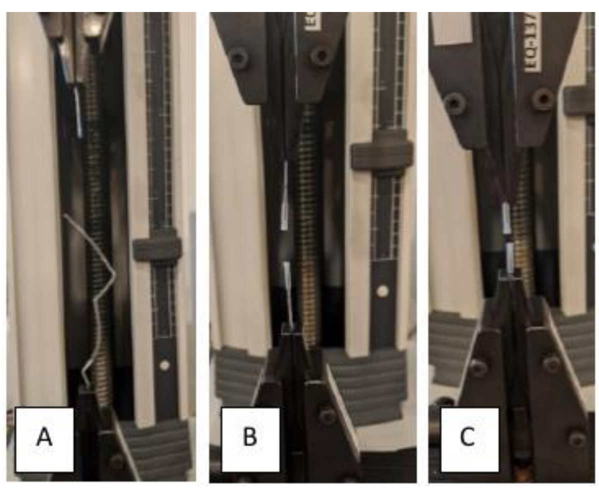

Figure 5. Mechanical testing with typical failure: a) control; b) porous; c) contaminated specimen.

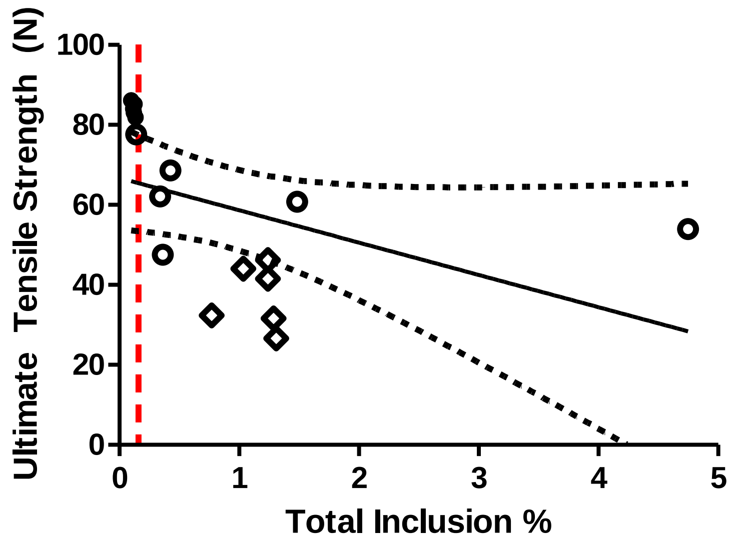

Figure 6: Correlation between total inclusion percentage and ultimate tensile strength (filled circles: control, open circles: pores, diamonds: contamination). Cut off (red dotted line) value at 0.16. Separation value of 0.87.

3. RESULTS AND DISCUSSION

Based on the micro-CT imaging of the weld region for each specimen, the percentage of inclusions was quantified as regions significantly above (contamination) or below (pores) the average density as seen in Figure 3. Figure 6 shows the correlation with the ultimate tensile strength across the 3 specimen groups. As expected, the low percentage of inclusions for the control group correlates with high and uniform tensile strength. The group with deliberate contamination of the weld shows approximately 1% inclusion and significantly lower ultimate tensile strength. The group with pores had a wide variation of inclusion percentage (one specimen close to 5%) and an average tensile strength between the other two groups. No statistically significant correlation was observed between the ultimate tensile strength and the total inclusion percentage combining all 3 groups. However, as the inclusion percentage was very small for the control group, it is possible to distinguish between control and defect samples based on the evaluation of the micro-CT imaging.

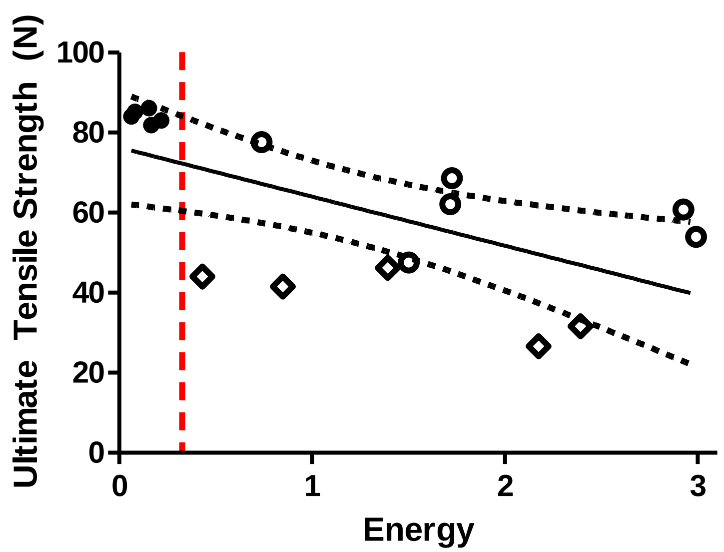

Figure 7: Correlation between total normalized ultrasonic signal energy and ultimate tensile strength (filled circles: control, open circles: pores, diamonds: contamination). P = 0.01, R^2 = 0.39. Control group average 0.14±0.06. Cut off (red dotted line) at 0.33. Separation value of 1.3.

The energy of the ultrasonic reflection signals was averaged and summed over the circumferential steps and correlated to the measured ultimate tensile strength, as shown in Figure 7. For the control group, uniformly low ultrasonic energy was measured, giving a dense spacing for the 5 specimens with the tensile strength above 80N. For both the pore and contaminated specimens, higher and more variable ultrasonic energy was observed due to the reflections at the inclusions and pores at the weld interface. Some, limited correlation of the ultimate tensile strength with ultrasonic energy was observed, combining all specimens. As the ultrasonic energy for the control group specimens was reasonably low and uniform, reasonable separation between control and defect specimens was possible. Future evaluation should investigate the variability of the different measured parameters and the correlation with weld quality.

4. CONCLUSIONS

High quality joining of plastic components is required to ensure patient safety of endovascular medical devices such as catheters. The feasibility of non-destructive ultrasonic inspection of butt-welds in polyamide (Pebax-72D) catheter components was investigated. Angled ultrasonic measurements of the weld circumference were conducted to detect artificial faults (porosity and contamination) introduced during the welding process. Results were compared to X-ray micro-CT imaging and found to correlate well with destructively measured weld quality (tensile strength). This demonstrates the potential of the immersion ultrasonic measurements for in-line verification during manufacture.

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