LASER WELDING OF CO-EXTRUDED TUBING

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Abstract

The use of infrared absorbers to laser weld plastics has been developed over the past few years. A challenging application for this joining technology is the welding of tubing, notably small diameter tubing. Recently, Natvar, a Tekni-Plex Company, and Gentex Corporation developed a production system in which extruded and co-extruded tubing can be laser welded. The weld strengths achieved by this technology exceed that produced by traditional joining techniques. In addition to providing improved product performance it opens the door to a “green technology” that provides solutions to environmental problems that are of concern to this market segment. This paper summarizes the development and test results of this new production system.

Introduction

Optically clear, plastic tubing is used extensively in medical devices, particularly in patient analysis and treatment systems. The demands of the specific application are important in determining which of the various FDA-approved plastics are used. Polyvinyl chloride (PVC) is typical material that is currently used to make tubing. It is a clear material that is usually formulated with suitable plasticizers necessary to enhance flexibility and other properties. Thermoplastic polyurethane (TPU) and thermoplastic elastomers (TPE) are also used in the manufacturing process for medical tubing.

But the choice of plastics is also limited by the ability to bond the tubing to end devices, such as luer connectors. Medical tube applications require clarity to allow for visual verification of fluids and or contaminants in the device. This requirement limits the bonding methods available to the medical device assembler. In addition, materials such as PVC, TPU and TPE are not suitable for bonding methods other than solvent or adhesive bonding. Therefore these are the currently accepted methods to bond tubes to luer connectors.

The typical bonding methods for joining a tube to a luer connection usually require surface preparation prior to solvent or adhesive applications. This surface preparation includes mechanical abrasion of the surface and chemical cleaning. Mechanical abrasion roughs up the smooth surface of the part by creating pits and imperfections. This surface preparation allows better entanglement for the solvent process. Chemical cleaning will remove any residue from processing or handling. This will ensure a good contact between the solvent and bonding part surface.

The standard bonding methods also have limitations such as drying or cure time and are labor intensive. Solvent bonding also requires that materials to be amorphous. Therefore semi-crystalline materials do not bond effectively with solvents. And finally, there is concern about the toxic effects of solvents typically used in such tube to luer applications. Typical solvents include acetone, toluene, methylene chloride, and methyl ethyl ketone.

It would be advantageous if alternative joining methods such as ultrasonic welding or hot plate welding could be used for this application. However alternative joining techniques have never provided bond strengths that were acceptable. A technique, which has shown promise, is infrared laser welding. But in order to absorb infrared energy in plastics a material such as carbon black is required as part of the tubing formulation (1). While the incorporation of colored absorbent materials into the medical tubing application would allow the use of laser welding technologies it is not preferred or accepted. The introduction of absorbent colors would require the tube to become opaque and not suitable for medical drug delivery applications.

Gentex Corporation has developed a series of infrared absorbers that meet the requirements as stated above (2). In laser welding operations, industrial lasers operate at specific wavelengths. Each type of infrared laser requires the use of an infrared absorber that absorbs energy strongly at the particular wavelength of the laser. The Clearweld® process incorporates a variety of absorbers into resins that match the wavelengths of these lasers.

Natvar is a leading manufacturer of medical components and has great expertise in the requirements of the medical industry. Natvar investigated laser welding of medical tubing devices and developed a laser welding system known as Sure Bond™. The concept used was that the laser energy absorbers could be extruded or co-extruded in the tubing. The extruded tubing would absorb the laser energy and convert it to heat. This would result in localized melting at the interface of tube and luer connector to form strong,
hermetically sealed welds. The welds would also exhibit minimal stress without forming particulates, making it ideal for medical tubing applications. This would eliminate the need for solvents or adhesives in assembly operations.

Clearweld® absorbers have the capability of absorbing infrared energy and converting that energy to a quantity of heat, which will cause a melting, and refusing of thermoplastic materials that are in the vicinity of the absorber. The selection of the absorber used in a process is dependent upon several factors (3,4). First the absorbing material must absorb infrared energy. Second the area in which the absorption occurs must coincide with the wavelength of the laser used in the welding process. In other words the absorber and laser must be matched insure the generation of a sufficient quantity of heat to cause the formation of a weld. Third the absorbing material can not degrade in the production of the tubing. That is the absorbing dye must be able to survive the temperatures and shear forces of typical extrusion processes as well as being chemically compatible with the thermoplastics that are commonly used in the manufacturing of tubing. Fourth the absorber must not impart coloration to the tubing to the degree that it creates a cosmetic problem that would be unacceptable to the end user of the tubing.

**Experimental**

In addition to the obvious goal of optimizing the bond strength of tubing to connectors, there were multiple questions that had to be answered in this experiment. What plastics and tube designs would be usable in laser welding? Did the infrared absorbers affect the normal compounding processes? Once the material was extruded would there be any adverse affects on the processing of the tubing. Would the tubing and welded products pass Class VI testing? How would gamma and ethylene oxide sterilization affect the product? Would there be any problems with extractable compounds? How would the interference fit be defined in the final product? How would the pre- and post-sterilization bond strengths compare to traditional bond strengths?

Based upon their knowledge of the market, Natvar opted to evaluate PVC, TPU and COPE materials. They then elected to investigate three tube geometries, which are illustrated in Figure 1. The first tube is tri-layered tubing comprised of an outer layer of PVC, TPU or COPE with an inner fluid-contact layer and an intermediate bonding layer. The outermost layer contains Clearweld LWA267 absorber. The second tube is dual-layer tubing with an outer layer of PVC, TPU or COPE and an inner contact layer of PVC, TPU, TPE or COPE. The third tube is a single layer tubing with an infrared absorber compounded directly into the material in order to make it reactive to laser energy.

The respective thickness of each layer of the multilayered tubing was controlled by the extrusion tooling utilized. Tubing manufactured in the tests utilized up to three extruders, which were configured to obtain the desired layer thickness and additive locations. This provides a uniform thickness of the layers in the tri-layer tubing and the dual-layer tubing. Master batches of infrared absorber were introduced into the compound using a PLC-based weight control system. All of the layers were combined in a crosshead and pushed out a die and core to form a tube to the required specification. In the tests, tubing with an inner diameter of 3.12mm, an outer diameter of 4.65mm and a length of 305mm were used.

Figure 2 illustrates a typical luer connector design. The luer design incorporates two critical features relating to bonding techniques. First, a taper is built in for compression fit of the tube to luer. A typical taper can range from 2 degrees to 10 degrees. The taper is designed to permit the filling of a void with an adhesive. Second, the pocket depth ranges from 6.35mm to 25mm. This provides a contact area that is necessary for adhesive or solvent bonding. Increased bond strength is achieved by increasing the length of the luer. This extra length is not necessary when laser welding is used to join the components. By using co-extruded, laser weldable tubing the two features are no longer critical. A redesigned luer connector would have permitted a larger weld area and significant improvement in the bond strength. However, the standard luer connections were used in this test since they were commercially available. In this test, standard polycarbonate (PC) luer connectors were used.

The welding was performed using a Rofin Sinar, 940nm, contour laser with a 4mm-beam width. The tubing and luer were held in place by the interference fit created by the taper in the luer connector. The energy density (Joules/mm²) was calculated for each of the resins used in the experiment. The optimum energy densities for various materials are shown in Table 1. The parts were welded by traversing the laser head across the luer-tube connection rather than rotating the connection. This single-pass of the laser was sufficient to create a quality weld. A quality weld was one that resulted in a visible bond around the entire perimeter of the tubing without the creation of entrapped bubbles in the weld joint. A typical weld is shown in Figure 3.

The results of the welding were evaluated by Natvar for pull strength. This was done by means of Instron Tensile Tester. The results of the welded samples were compared with those that were joined by solvent
bonding, temperature sensitive adhesives and ultraviolet cured adhesives. In addition, the tube and weld joints were evaluated for sterilization survivability, extractability of components and Class VI compatibility.

**Results**

Conventional bonding methods (tube to luer, tube to device) result in pull strengths of approximately 10 to 300 newtons. Pull strength is defined as the amount of force required to either pull the tube out of the luer or device or to destroy the tube prior to it pulling free from the luer or device. By utilizing laser welding, equivalent results can be obtained while eliminating solvents and adhesives. It can significantly reduce the luer size and permits the improvement of the design of the components.

In this experiment, the first material tested was a coextrusion of TPU with nylon core tubing. A masterbatch formulation of Gentex absorber LWA267 in TPU was prepared. In order to obtain quality welds with PC luer connectors, a let down ratio of 20 parts resin to 1 part masterbatch was required. The tubing was welded to the luer connectors and the results compared to solvent bonded and adhesive joined devices. Table 2 shows the average results of the Natvar pull tests. Laser welding was superior to solvent and non-ultraviolet cured adhesive bonding. The results of the laser welding and UV cured adhesives were equivalent. Typical test results are shown for an ultraviolet cured adhesive bond (Figure 4) and a Sure Bond™ joint (Figure 5).

The width of the laser weld joint was approximately 3.2 mm. By comparison, length of the bonding area for solvents and adhesives was 6.35mm. Even with a weld joint that was half that of a typical bond, the pull strength of the welds were equivalent to that achieved by ultraviolet curable adhesives. The test also indicated the large variability that is obtained by solvent bonding processes.

Subsequent tests were carried out using combinations of PVC, TPU, COPE and PC. The results of these tests were similar to those seen in the first series of experiments. Table 3 summarizes the pull strength results for these materials.

Process times for laser welding was a concern in the experiments. However, it was found that the samples could be welded by traversing the laser beam across the tubing rather than welding around the circumference of the tubing. This resulted in welding times of approximately one second.

In addition to the formation of a quality weld joint, the laser welding process required evaluation for sterilization survivability and Class VI compatibility. As a medical component, tube-to-connector assemblies must withstand sterilization techniques, notably gamma irradiation and ethylene oxide sterilization. For example, when exposed to cobalt 60 gamma rays, chemical bonds can be broken. The polymer can recombine into its original configuration or can be weakened. This may result in the plastic becoming brittle, change coloration or generate objectionable odors. No difference in the performance of the laser welded samples and control tubing was observed in any of the sterilization tests.

**Summary**

1. Laser welding can be successfully used to replace solvent and adhesive bonding of medical tubing.
2. Production speeds can be increased by using laser welding processes.
3. No inner diameter occlusions that can result from the use of solvents were detected in the laser welding tests.
4. The samples successfully passed Class VI compatibility testing as well as extraction testing of the components.
5. The welded components were not affected by gamma or ethylene oxide sterilization processes.
6. Laser absorbing materials can be compounded with engineered plastics to produce biodegradable “green systems” for use in the medical industry.

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**Key Words**

Clearweld, laser welding, Sure Bond, weldable resin

**References**


Figure 1 – Tube Designs

Figure 2 – Luer Connector Design

Figure 3 – Tubing to Connector Weld Joint

Figure 4 – Adhesive Pull Test Results

Figure 5 – Laser Weld Pull Test Results
### Table 1
**Energy Density Used to Weld Tubing**

<table>
<thead>
<tr>
<th>Tubing Material</th>
<th>Fitting Material</th>
<th>Optimum Energy Density (J/mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nylon/TPU</td>
<td>PC</td>
<td>1.3</td>
</tr>
<tr>
<td>Ecdel</td>
<td>PC</td>
<td>1.4</td>
</tr>
<tr>
<td>PVC</td>
<td>PVC</td>
<td>1.0</td>
</tr>
<tr>
<td>PVC</td>
<td>PC</td>
<td>1.2</td>
</tr>
<tr>
<td>PVC</td>
<td>Acrylic</td>
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</tr>
<tr>
<td>TPE</td>
<td>PC</td>
<td>1.4</td>
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### Table 2 - Weld Results – Test #1

<table>
<thead>
<tr>
<th>Joining Method</th>
<th>Pull Strength (N)</th>
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<tbody>
<tr>
<td>Solvent Bonding</td>
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<tr>
<td>Non-UV Adhesive</td>
<td>89</td>
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<tr>
<td>Clearweld</td>
<td>276</td>
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<tr>
<td>UV Cured Adhesive</td>
<td>285</td>
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### Table 3 – Weld Results - Test #2

<table>
<thead>
<tr>
<th>Materials</th>
<th>Solvent/Adhesive</th>
<th>Solvent/Adhesive Result (N)</th>
<th>Laser Weld Result (N)</th>
</tr>
</thead>
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<tr>
<td>PVC to PVC</td>
<td>Solvent</td>
<td>13 – 36</td>
<td>Tube Failure</td>
</tr>
<tr>
<td>PVC to PVC</td>
<td>Adhesive</td>
<td>45 – 67</td>
<td>Tube Failure</td>
</tr>
<tr>
<td>TPU to PC</td>
<td>Adhesive</td>
<td>267 – 289</td>
<td>329 to Failure</td>
</tr>
<tr>
<td>TPE to PC</td>
<td>Adhesive</td>
<td>133 – 200</td>
<td>320 to Failure</td>
</tr>
<tr>
<td>TPU to PVC</td>
<td>Solvent</td>
<td>27 – 54</td>
<td>Tube Failure</td>
</tr>
</tbody>
</table>