September 2002

MEDICAL DEVICE & DIAGNOSTIC INDUSTRY

THE MAGAZINE OF MEDICAL PRODUCT DESIGN, MANUFACTURING, AND MARKETING

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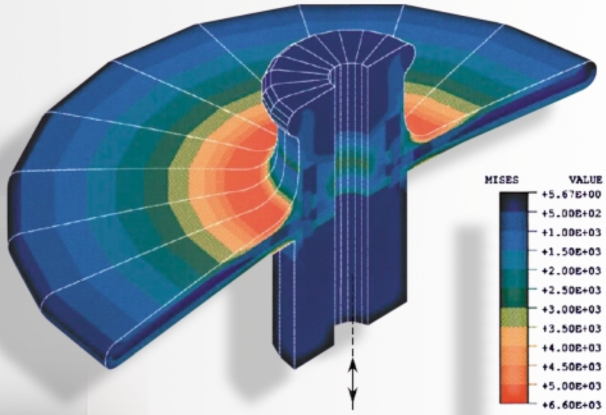

Design and Development

Learning from Failure: How to Profit from Prototyping Setbacks

Improve Product Development with Innovation Mapping

Understanding Sterilization Options, p. 52

The Ins and Outs of Welding Polyurethane, p. 62

A Canon Communications LLC Publication

Polyurethane Thin-Film Welding for Medical Device Applications

Manufacturers seeking to replace PVC or latex must understand how bonding processes affect materials.

Tilak Shah

THERMOPLASTIC FILMS have been used in flexible medical product applications since the 1960s, when plasticized polyvinyl chloride (PVC) blood storage bags replaced glass bottles.[1] In the 1970s, PVC became the material of choice for Band-Aids, and a decade later the use of polymeric film patches in surgical draping became popular, replacing latex films. In the 1990s, the use of organ bags, drug-delivery patches, and breathable films for wound care increased dramatically, making films much in demand in the medical industry. However, health and environmental concerns about PVC and latex films have driven the development of alternative materials for these applications (see sidebar on p. 65).

Nearly all thermoplastics can be used in film form as thin, soft, flexible, elastomeric materials that can be folded or creased without damage. In selecting films for medical devices, designers must consider a variety of factors, including cost, biocompatibility, sterilizability, mechanical toughness, elasticity, optical clarity, leachability, barrier properties, drug interaction, and sealing and assembly characteristics.

Health and environmental concerns are prompting manufacturers to seek out new applications for materials such as polyurethane. To make effective use of this material, however, designers must understand how it responds to various bonding processes.

In selecting films for medical devices, designers must consider several factors.

Photo courtesy of POLYZEN INC.

WELDABILITY OF THERMOPLASTICS

Films most commonly used in the medical industry include high- and low-density polyethylene and polypropylenes from the polyolefin family, plasticized PVC, polyurethane elastomers, and breathable specialty films such as polyester. Designers need a clear understanding not only of a material's properties, but also of how a particular welding process will affect it.

The weldability of plastics is affected by various factors, including type of polymer; resin grade; presence of plasticizers, lubricants, and other additives; and moisture content. Thermal properties, molecular characteristics, and crystallinity of a polymer affect processing and film properties; additives influence extrusion and orientation processes and improve film properties; and reductions in the thickness of a film can lower costs and increase the area obtained from a given weight of polymer yield per square meter.[2]

Amorphous polymers respond better to welding than crystalline polymers do because they soften, melt, and resolidify gradually. However, some amorphous resins with high melting points, such as polycarbonate and polysulfones, are difficult to weld.[3] Crystalline polymers, which have high, more defined melting points, tend to melt and resolidify quickly, making them challenging to weld. Among the crystalline polymers are polyethylene, polypropylene, nylon, thermoplastic polyesters, acetal, and polyphenylene sulfide.

Thermoplastic polyurethane, an aromatic or aliphatic polymer, is well suited for use in flexible medical products such as storage and collection bags and many other types of flexible containers and similar articles.

Polyurethane films offer some important advantages over other films, including PVC. They have similar welding characteristics to PVC, provide strength equal to PVC in a thinner film, contain no plasticizers, are sterilizable by either EtO or gamma radiation, and have good alcohol resistance. Polyurethane films also can be readily sealed using radio frequency (RF) welding techniques.

Process	Mechanism	Special Features	Suitable Materials
Flame bonding	Natural gas flame	Continuous web application	PVC to foam lamination
Hot air gun	Hot air or nitrogen	Plastic welding rods	Low melting plastic, PE
Hot knife welding	Heat from metal surface	Bond in one plane	Thermoplastic rubbers
Hot plate welding	Hot tool/die	Draft angle of bar	High temperature plastics
Induction/impulse	Resistance wire	Straight line seal	Olefins, low temperature films
Dielectric – RF	Loss in alternative electrostatic field	Quick bonding	Polar or amorphous elastomer
Ultrasonic welding	High-frequency compressive loading	Sonic conductor	Rigid plastics
Solvent bonding	Material swell/dissolve	Chemical fusion	Amorphous resin

Table I: Fusion welding processes. Adapted from* Encyclopedia of Polymer Science and Engineering *(New York: Wiley).

FILM-JOINING METHODS

Welding processes commonly used in assembling medical devices from thermoplastic films include RF welding, also known as dielectric sealing; ultrasonic welding; direct thermal sealing; induction welding or sealing, and solvent bonding (see Table I). Selecting the best process for bonding thin-film materials in the assembly of medical products involves a number of considerations. The material itself is the primary factor. Size of the product, volume, process capability, cycle time, and cost are other critical variables.

In each welding process, controlled heat is applied to the materials, causing the plastic to melt in a narrow zone at the joint interface. Pressure is applied and, once the heat is cut off, the material cools and resolidifies, forming a weld bond. The amount of compression used is important, since too little or too much can result in a weak seal. A smooth, uniform bead along the weld line is ideal.

RF Welding. RF welding, a form of dielectric heating, is one of the most widely used methods for assembling medical devices. The process offers consistent quality; thin, strong weld lines; short sealing cycles for high output; minimal thermal distortion of the film or substrate; and the ability to produce weld-edge tear seals. Of these, the most important advantage is extremely thin weld seams. Impulse welding and hot-bar sealing produce a seal area that is about 1/8 in. wide—too wide for some medical applications. For applications such as containers, the width of the seam is not significant, but for implantable medical devices, a thinner seam is preferred.

Material	Loss Index	Response (G=good, F=fair, P=poor, N=none)
ABS polymers	0.025	F–P
Acetal resin	0.025	F–P
Cellulose acetate	0.15	F
DAP	0.04	F
Epoxy	0.12	F
Melamine	0.2	G
Phenal formaldehyde	0.2	G
Polyamide	0.16	F
Polycarbonate	0.03	F–P
PVDF	0.04	F
Polyester	0.05	F
Polyethylene	0.0008	N
Polyimide	0.013	P
PMMA	0.09	F
Polypropylene	0.001	N
Polystyrene	0.001	N
PTFE	0.0004	N
FEP	0.001	P
PVDF	0.05	F
PU film/foam	0.4	G
PVC film, flexible	0.4	G
TPE	0.13	F
Silicone	0.009	P–N
Urea formaldehyde	0.2	G

Table II. Response of polymers to dielectric heating. Adapted from JD Ferry,* Viscoelastic Properties of Polymers *(New York: Wiley, 1970), and S Saito and T Narajiman* Journal of Applied Polymer Science *2:1959, 93.

The materials to be joined by RF welding must be poor conductors of electricity, since a good conductor would act as a short circuit, weakening the field near the conductor. Polyethylene, polypropylene, polystyrene, silicone, and rubber are among the materials that are not responsive to the process. Polymers with strong dipoles respond best to RF welding. The

POLYURETHANE FILM AS AN ALTERNATIVE TO PVC AND LATEX

MATERIAL CHOICES

PVC. The most commonly used material in the manufacture of flexible medical devices, PVC has come under fire owing to concerns about the use of phthalates as plasticizers and environmental problems with disposal. The softness, flexibility, and low-temperature characteristics of PVC are determined by the type and amount of plasticizer used in the compound. The most widely used plasticizer, di-ethylhexyl phthalate (DEHP), has been linked to toxic effluents produced during manufacturing and to the generation of hydrogen chloride during incineration. Environmentalists have raised concerns that the disposal of PVC by incineration may be a source of dioxin contamination.

PVC devices, such as IV bags and blood bags, typically contain 30–40% DEHP by weight. Other devices, such as medical tubing, may contain as much as 80% DEHP by weight. Because DEHP is not chemically bound to the polymer in a PVC device, it can be released when the device is heated, or it can leach out when the device comes into contact with certain media, such as blood, drugs, saline, or water. As a result, several pharmaceutical manufacturers are providing warning labels that advise against the use of DEHP-plasticized PVC for administration of specific products.[6]

These findings have encouraged the medical industry to welcome alternatives to PVC that can provide the same or better performance characteristics at comparable costs.

Polyolefin-based systems are being used successfully for barrier covers or sleeves, machine covers, and similar products.

Metallocene polyethylene film is being used as a PVC replacement for medical applications, but it is not suitable for RF welding unless it is blended with other polyolefins or specialty polymers.

Ethylene-vinyl acetate polymer, another alternative to PVC, is RF weldable. Devices made from this material are easily abraded, however. The material also has poor strength and flex-fatigue resistance.

Natural Rubber Latex (NRL). A desire for safer alternatives to NRL arose more than a decade ago, when the number of reported cases of allergic reactions to latex started increasing dramatically. Healthcare personnel, such as nurses and lab technicians, are particularly at risk for latex sensitivity because of their high exposure to the material.[7] NRL alternatives include nitrile rubber, synthetic latex, styrenic elastomers, polyurethane, and silicone.

Thermoplastic Polyurethanes. Thermoplastic polyurethanes contain no plasticizer and have a lower density than PVC, producing a higher film yield. The films offer toughness and strength, and high water-vapor permeability. They can be sealed using RF welding. Soft formulations can be dip molded into gloves, although the process is more expensive than welding

Polyurethanes are thermoplastic rubbers made from isocyanates and are designated aromatic or aliphatic on the basis of the chemical nature of the diisocyanate component in their formulation. Aromatic and aliphatic polyurethanes share the following properties that make them suitable for use in medical devices:

- High tensile strength (4000–10,000 psi).
- High ultimate elongation (250–700%).
- Wide range of durometer (72 Shore A to 84 Shore D).
- Good biocompatibility.
- High abrasion resistance.
- Good hydrolytic stability.
- Ability to be sterilized via EtO or gamma irradiation.
- Ability to retain elastomeric properties at low temperature.
- Resistance to chemicals, oil, and UV light.

Newly developed low-durometer, high-elongation formulations of thermoplastic polyurethanes are attractive alternatives to PVC and latex in medical applications.[8] Products assembled from polyurethanes have passed toxicological, biological, and physiological testing procedures. They are environmentally sound and can be recycled or safely incinerated.

A thorough understanding of processing conditions is required when working with polyurethane resins, however, due to their hygroscopic nature. Polyurethanes absorb and react with moisture in the air very rapidly. Extreme care must be taken when processing a polyurethane. Otherwise the material can be degraded and defects can result in the finished products.

For example, successful RF welding of polyurethanes requires special die designs, modifications to conventional equipment, and adjustments to the parameters of the welding process. The die determines the width of the seam. A typical die design incorporates an insulated knife that cuts and seals the film in one step. Using conventional RF welding equipment with thin films produces excessive arcing and weak seams. It is a technology that requires high-level skills.

CONCERNS ABOUT PVC

Human exposure to DEHP can occur in the ambient environment and in the medical setting. DEHP exposures occurring in the medical setting are of particular concern because the amount of exposure can be substantial and because those exposed, such as premature infants and adults with life-threatening illnesses, may be particularly vulnerable to the effect of toxic chemicals. Adverse health effects such as respiratory distress, cholestasis, and histoloical abnormalities of the liver have been found in subjects having documented exposure to DEHP.

Researchers have concluded that humans are exposed to substantial levels of DEHP through medical devices.[6] Certain populations, such as hemophiliacs, kidney dialysis patients, and high-risk newborns are particularly heavily exposed. Given the human exposure to DEHP from medical uses and the potential for adverse health effects, it is prudent to investigate alternative materials for use in medical environments.

An organization known as Health Care without Harm petitioned FDA to issue a warning to medical professionals, institutions, and consumers about the potential hazards posed by phthalate leaching from PVC medical products. [9]

Also, three studies published in 2000 by the European Commission confirmed serious environmental and economic problems with PVC waste disposal, including findings that incineration of 1 kg of PVC leads in most cases to more than 1 kg of hazardous wastes.[10] Furthermore, landfilling of PVC releases hazardous phthalate softeners, such as DEHP, and contributes to the formation of dioxins and furans in accidental landfill fires.[11]

process has been used to join flexible PVC for many years. Its use with polyurethane film, however, is a relatively new development.

The RF process generates radio-wave power, which produces enough heat to melt plastic materials and produce a free exchange of molecules, thereby bonding materials. Ac power is converted to a high-voltage Dc current, which an oscillator or resonator outputs as an alternating current. Although dielectric heating can be performed at frequencies ranging from 10 to 100 MHz, the radio frequency most commonly used in the United States is 27.12 MHz.

An interchangeable electrode, or die, machined in the shape of the part to be welded, is used to apply power to the workpiece. Such electrodes are commonly made of brass, since the metal transfers heat evenly. The electrode is pressed against the part, and a high-intensity alternating field is directed through the material. The degree of polarization and the energy required to achieve it control the loss factor or dissipation factor of a material. A material that is readily polarized by a small electric field has a high loss factor and is easy to heat (see Table II). If the polarizing field changes direction at a high frequency, a considerable amount of energy, in the form of heat, can be imparted to each molecule of the material.

During the RF process, molecules within the material are agitated and move rapidly in a lateral direction, trying to align with the changing electric field. As a result, heat is generated within the material, allowing for excellent uniformity and remarkable speed of heating. The heat produced is highest at the interface of the two components being joined. With other methods, such as thermal sealing and impulse welding, the outside layers of the plastic that touch the dies are the hottest areas, which can result in degradation of film surfaces.

When the power to the RF-energy generator is shut off, the melted plastic resolidifies, resulting in a uniform weld that is as strong or stronger than the materials being bonded together. The entire process can take from a fraction of a second to several seconds, depending on the polymer, film thickness, and size of the welding zone.

Tooling for the RF welding process consists of an upper die mounted to an aluminum tool and jig plate and a bottom die or nest, typically made of aluminum. However, any metal that conducts electricity will work. Tooling with rounded weld lines provides a stronger seal than straight lines. Sharp edges and corners are not desirable since voltage rises when it is applied to corners and sharp edges. This can increase the likelihood of arcing, which can damage the film as well as the die.

Ultrasonic Welding. Ultrasonic welding directs ultrasonic vibratory energy through thermoplastic workpieces, causing them to melt at the interface and form a bond. Electrical energy is transformed into high-frequency (20 to 40 kHz) vibrations, which are directed into the workpieces in a holding fixture through an ultrasonic horn. The most important variable affecting the ultrasonic process is vibrational amplitude, the peak-to-peak displacement, or excursion, of the horn. Controllers can improve weld integrity by varying the amplitude to meet the changing requirements during each cycle. Once melted, the plastic is pressed together and held until cool.

The RF welding process generates radio-wave power, which produces enough heat to melt plastics.

The ultrasonic energy requirements of thermoplastic materials are determined primarily by the material's melt temperature, modulus of elasticity, and structure. Soft plastics with a low modulus of elasticity are difficult to weld with this process because they attenuate the ultrasonic vibrations. Rigid plastics are more responsive to the vibratory energy; they typically melt in less than two seconds, producing a strong, uniform molecular bond.

Direct Thermal Sealing. Direct thermal sealing methods are well suited for joining soft plastics such as polypropylene, polyethylene, and thermoplastic polyimides. In hot-tool welding, one or more electrically heated platens or bars are pressed against the surfaces of the films until they melt and bond together at the point of contact. A nonstick coating on the tool facilitates its removal.

Temperature, time, and pressure are the primary variables. Platens for temperatures up to 500°F are made of aluminum. For higher temperatures, bronze and steel are used. Cycle time is typically less than 20 seconds. Using heated platens on each side of the parts can reduce the welding time of a thermoplastic to 1–3 seconds. Since heat must be conducted to the joint interface, the thickness of the materials being welded is also an important consideration. Thickness is generally limited to about 1 mm.

Impulse Sealing. Impulse sealing is an advanced form of hot-tool welding, in which the heating and cooling cycles are controlled while the joint is held under pressure. Impulse-type sealers use a metal wire or bar that is heated intermittently to avoid overheating the plastic material. Hot-bar and impulse welding processes are commonly used in the packaging industry to seal plastic bags and join thermoplastic films of 0.5 mm or less.

Hot-Plate Welding. Hot-plate welding is another variation of direct thermal sealing. The layers of thermoplastic film to be joined are pressed against the sides of a heated platen, which is removed when the plastic melts. The joined film is pressed together and held at the interface until the material cools, forming a molecular bond. Most thin thermoplastic films can be welded with this process.

Induction Welding. A form of electromagnetic heating, induction welding uses a metal element in the shape of the weld line to bond thermoplastic materials. The metal vibrates rapidly when subjected to a magnetic field, producing heat. When film is pressed against it, the molecules in the plastic melt and fuse together.

Solvent Bonding. In this method, a solvent, such as methylene chloride, is applied along the joint interface.The thermoplastic films are then held together in a fixture. As the solvent evaporates, polymer chains move about freely and become entangled with other chains. The result is a solid mass of entangled polymer chains that produce a weld. The main limitation of this technique is in the handling of the solvent. The pressure and time required for the process depends on the thermoplastic material, the solvent, and the joint design.[5] Amorphous thermoplastics are more suitable for the process than are crystalline materials.

CONCLUSION

The very thin seams that are now possible with RF welding of polyurethane film have opened up a whole new area of applications of the material for medical products. It is possible to produce multipart welded devices that look, feel, and perform like seamless products. In the future, we can expect to see thin polyurethane film replacing PVC film and latex in medical products as the medical industry continues to move away from these materials.

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