Advanced solutions for measuring contact pressure decrease defects in medical packaging, molding, and tooling

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ARTICLE FOCUS

- Technologies for contact surface pressure measurement
- Uses for tactile sensors pressure indicating sensor film
- Importance of advanced systems for precision pressure measurement

Precise contact measurement is more critical to the success of the medical device industry than to most other industries. The reason for this is simple. When human lives are at stake, the margin of error for defective products is minimal. Which is why medical device designers and manufacturers have been exploring advances in contact surface pressure measurement.

Until the 1990s, technology had not advanced sufficiently to precisely measure contact pressure between two surfaces. Force between contacting surfaces was measured using load cells, which were large and often difficult to interface. Pressure was obtained by averaging the measured load over the entire surface. A pressure distribution could not be obtained from the load cell data.

What was needed for exacting, medical device applications was access to easily performed surface pressure measurement at high resolution. Now with the advent of new technologies, such as pressure indicating film and electronic tactile sensors, the pressure distribution between contacting and impacting surfaces can be measured to a micron resolution. This article discusses these technologies for static and dynamic contact surface pressure measurement.

Detecting contact pressure variations in heat sealing equipment

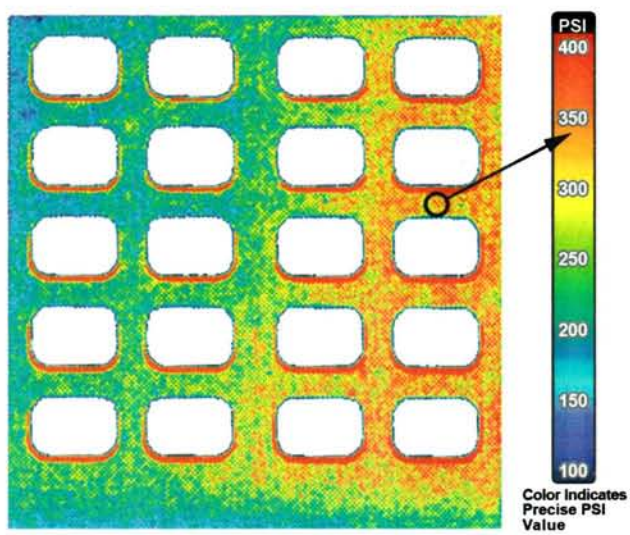
An important advance in contact pressure measurement was achieved with the introduction of FujiFilm Prescale (formerly referred to as Fuji Prescale film). This tactile pressure indicating sensor film, distributed by **Sensor Products Inc** (SPI), provides quick and convenient static surface pressure measurement. With a spatial resolution of 5 to 15 microns, it revolutionizes contact surface pressure measurement and ends sole reliance on load cells and strain gauges. For researchers and designers, it provides a method to confirm finite element analysis model predictions.

Fujifilm Prescale is a tactile Mylar film that maps and measures pressure distribution between a heat sealer's contacting platens and rollers. When placed between any two contacting surfaces and force is applied, it instantaneously and permanently changes color. The color intensity is directly proportional to the actual pressure. As a result of this force, tiny microcapsules of dye on the top layer of the film rupture to create a permanent high resolution image of pressure magnitude and distribution across the contact area. This pressure map then can be visually examined and compared to a color calibration chart. SPI has also developed an optical analysis system called Topaq to provide quantitative assessment of pressure. Below is a color coded pressure image of a blister pack seal, which would also include 3D images, line scans of pressure, and histograms among other features.

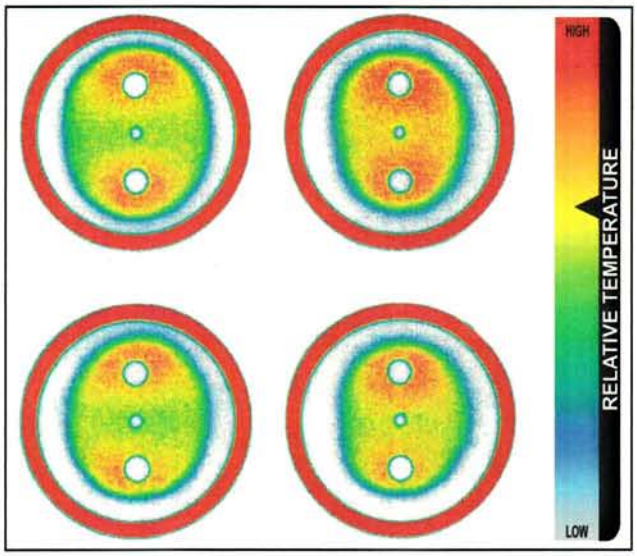
Temperature measurement at the interface of heat sealing equipment

Medical device and pharmaceutical packaging require uniform temperature distribution as well as uniform pressure distribution. Traditional methods of thermal management do not reveal whether uniform temperature at the interface of the heat seal has been achieved.

An economical, thin sen-



Topaq imaging from Sensor Products Inc shows heat seal surface pressure variations.



Thermex temperature distribution paper enhanced by Topay Analysis.

sor material is offered by SPI that is placed at the interface of heated contacting platens or rollers to quickly diagnose the temperature. Thermex reveals critical temperatures for heat sealing of plastics ranging from 200° to 300°F (93° to 149°C). Thermoplastics, such as polyethylene and polypropylene are heat sealed within this temperature range.

Thermex changes color instantaneously upon exposure to heat to reveal relative temperature distribution. The intensity of the color change relates to the temperature to which it was exposed. This material reveals spot high or low temperature zones and minute surface variations. These fluctuations cause improper sealing and need to be corrected to ensure quality control. Thermex may be used alone or in combination with Fuji Prescale film. The Topaq Analysis system is also compatible.

Dynamic pressure measurement of heat sealing equipment

Dynamic electronic sensor systems have also been developed for pressure mapping of heat sealing in real time so the user can make adjustments to the platens as pressure readings are displayed as color-coded pressure images on a computer screen.

The Tactilus system includes sensor pad, electronics controller and Windows-based proprietary software. Viewing options include isobar and region-of-interest, graphical displays of data in bar charts, line scans and histograms, statistical analysis of average/minimum/maximum pressures, total force over any selected area, pressure vs. time and more. For a video demonstration, visit *sensorprod.com/heat-seal*.

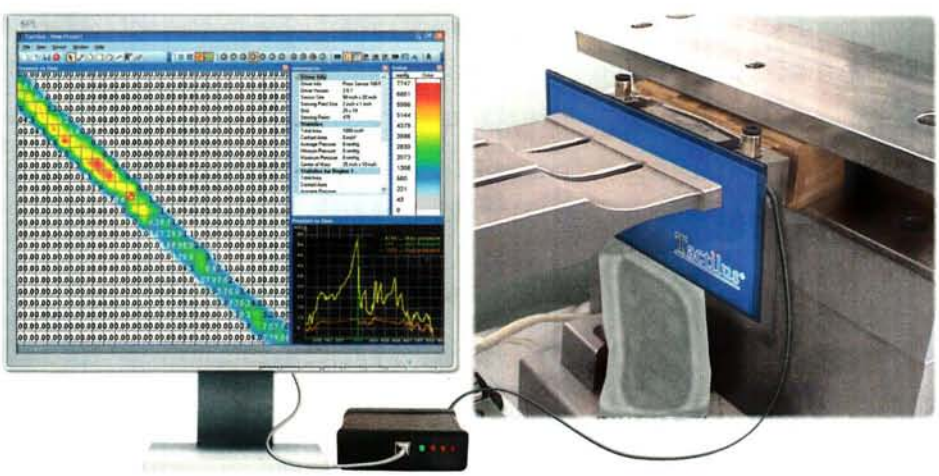
Contact pressure measurement of surgical clamps, retractors, and spreaders

Most tooling, including clamps, connectors, and fasteners, as well as bolted joints and gasket seals, depend on uniform pressure for effective operation. Yet the actual pressure at the tool's contacting surfaces may contain undetected pressure variations that can result in sub par products or expensive defects if not revealed and corrected prior to production. Such variations can occur due to surface irregularities of the tooling, misalignment, warpage, and nonparallel surfaces.

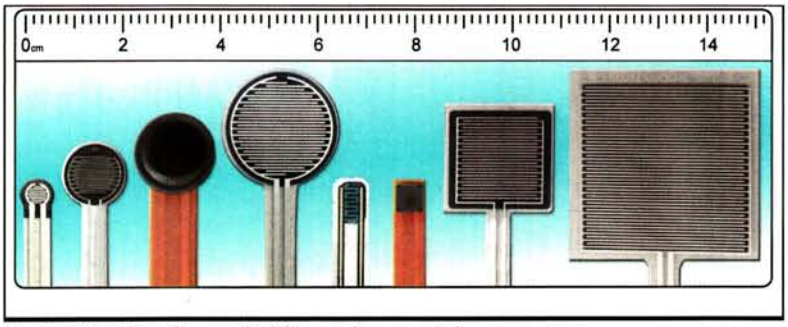
Both film and electronic tactile sensors are being used to monitor the magnitude and uniformity of contact pressure of surgical clamps, as well as retractors and spreaders. Attention is being paid to amount of contact pressure being applied by these instruments during surgeries. The calibration and recalibration of these instruments is important. For instance jaw clamps used to pinch arteries can become uneven. Excessive or nonuniform pressure on the human anatomy during operations can bruise patients unnecessarily. The outcome of the surgery, as well as the comfort and the postoperative condition of the patient, vitally depends on both design of the instrument and its pressure in operation.

Tactilus tactile surface sensors in various configurations are used by instrument manufacturers to record pressure distribution and magnitude in mock-up surgical experiments. Each Tactilus free form sensor element is individually calibrated, sequentially serialized and quality tested to ensure the highest repeatability and accuracy. Should sensors require recalibration, a calibration jig can be supplied by Sensor Products or the sensor can be returned for adjustment.

Pressures indicating films and electronic sensor systems also have been used to research biomechanics and to characterize the contact pressures of joints and bones for clinical and surgical procedures. Tactilus Free Form sensors enable the user to select the precise locations where data collection is required. Data can be collected and assimilated from up to 32 separate sensor elements simultaneously. Pressures from 0 to 250 PSI (0 - 14.1 kg/cm^2) can be accommodated. The



Tactilus measures pressure distribution across a heat seal.



Tactilus Free Form Sensors in different shapes and sizes.

free form system can also be designed for surface temperature measurement in the 68°-158° F (20°-70°C) range.

Prostheses, orthotics, and orthopedic medical devices for the knees, hips, and shoulders have been researched and designed with the aid of tactile sensors. A new field of body mapping has developed over the past decade to help ensure the comfort of patients. SPI has worked with design engineers to develop new surgical tables, which maximize the patient's blood circulation and comfort.

Contact pressures in the molding of medical devices

In the medical device industry, where stringent performance and tolerance criteria must be followed, it is especially important that the two parts of the mold are perfectly aligned and sealed. According to ScientificMolding.com owner John Bozzelli, who teaches injection molding seminars, "Pressure indicating film is a great troubleshooting tool that can save molders and mold makers thousands of dollars by documenting and preventing problems when utilized to check a new or used mold." Potential parting line defects such as flash, burns, short shots, and splay can be averted and the vents checked to allow for proper filling of the mold cavity.

Christian Fuentes, director of testing at REP International, uses Sensor Product's new relative pressure indicator film Mold-Align to test new mold designs. REP manufactures injection molding machines and supplies solutions for the thermoplastic and polymer industries.

"Mold-align works very well and shows us exactly what we need," says Fuentes. "In the first photo (below) the problem is flash in center. For our test we need a perfect mold closing to be sure that the spiral length has the exact flow compound characteristics. From the pressure marks on the Mold-Align film, we know that the mold had to be remachined in the center. In the second photo, Mold-Align reveals a mold with a perfect closing and runners." A complimentary sample of this new film is available to *Medical Design* readers for testing. Contact info@sensorprod.com or www.sensorprod.com/pr/meddesign .

Contact pressures in ultrasonic welding of medical devices

Pressure indicating film is also used in the RF and ultrasonic welding of medical devices to reveal the pressure being applied by the horn and anvil that are critically compressed during the manufacturing process. Machinery for ultrasonic welding (USW) can be adjusted through manual checks with the pressure indicating film. This joining technique uses high-frequency ultrasonic acoustic vibrations to create solid-state welds. It is used in the medical device industry because it does not introduce contaminants into the weld and it creates strong hermetic bonds without any need for adhesives, mechanical fasteners, or solders. Items such as dry-powder inhalers arterial, blood and anesthesia filters, IV catheters, face masks, pouches, and blister and clam shell packaging are assembled with ultrasonic welding.

To optimize the weld and prevent defects in USW, the horn and anvil must be precisely aligned during setup so that the horn exerts uniform pressure across the entire weld area. Routine use of pressure indicating film during the set up of ultrasonic welders provides an economical method to ensure proper contact pressure and alignment between the horn and the anvil. This, in turn, results in welds of greater bond strength, lower rejected product, and lower base factory cost.

Summary

The past two decades have brought unheralded advances in the field of contact surface pressure measurement. Tactile pressure measurement film has transformed the way contact pressure measurement can be conducted. Electronic sensor systems are being deployed with greater frequency for real time pressure measurement. These electronic sensor systems will be discussed in greater detail in a future article we are writing for *Medical Design*. Stay tuned.

Mold-Align reveals flash in the center of the spiral mold.

Mold-Align reveals a mold with a perfect closing and runners.