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COVER STORY

Comparing Tensile and Inflation Seal-Strength Tests for Medical Pouches

Clarifying the relationship between tensile and burst testing for the evaluation of package seals can help manufacturers establish more effective process control.

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A frequently used analytic tool, seal-strength testing provides quantitative seal-strength data for the medical package manufacturer. Such testing has become more prominent with the release of AAMI/ANSI/ISO 11607, "Packaging for Terminally Sterilized Medical Devices," and its adoption by FDA as an "FDA-recognized consensus standard."[1] Two readily available seal-strength testing methods are indicated for use in the ISO standard: tensile seal-strength testing and inflation seal-strength testing.

Tensile seal-strength testing uses a defined-width sample of a package perimeter seal. A moving jaw pulls the sample apart at a constant speed while measuring the resistance force during the seal separation. The inflation seal-strength test can be represented by either the "burst" or the "creep" test. The burst test—a method in which a whole package is inflated at a uniform rate until it ruptures—measures the peak pressure at rupture in order to determine seal strength and is the most commonly used inflation seal-strength test. Similarly, the creep test inflates a package to a constant pressure and holds the pressure either for a fixed time (a creep test) or until rupture occurs and the time to failure is measured (a creep-to-failure test). The creep test is similar to attaching a dead weight to a seal and waiting for the seal to shear or peel apart.

In cooperation with ASTM Committee F2.6 on flexible medical packaging methods, the authors have set out to investigate the nature of the relationship between the two seal-strength testing methods. Investigation of the relationship may shed light on the possibility of a universal correlation. Many device manufacturers as well as suppliers of medical pouches, package lids, trays, and materials have sought a universal correlation between the two methods—although none exists at this time.

A series of screening tests has been designed and run to determine whether the two methods can be compared, and, if so, on what basis. At issue is whether the inflation seal-strength tests can be configured to provide results that compare to the lowest tensile seal-strength area found in a medical package. An additional question is whether inflation seal-strength tests will provide the same level of sensitivity to process-change effects on seal strength as that seen with tensile testing.

BACKGROUND

When two packaging materials or webs are bonded together, the result is a seal. This seal can be either peelable or nonpeelable. Peelable seals are designed to separate upon application of a required separating force. Nonpeelable seals are intended to be stronger than the tensile or shear strength of the original materials. For medical packaging, peelable seals are designed to remain closed during processing and distribution, yet to be capable of being opened upon application of a reasonable separation force by the product user.

ANSI/AAMI/ISO 11607, "Packaging for Terminally Sterilized Medical Devices," states that "various methods can be used to determine seal strength, e.g., tensile strength testing and burst/creep pressure testing."[1] The standard goes on to state that "there is no general correlation between tensile strength and burst/creep testing. They are separate tests and the results obtained have entirely different implications regarding package seal strength."

Package validation is, among other things, a methodology for ensuring that the sealing process is under control, is consistent, and meets the design requirements established for the process and materials. An effective method for establishing design requirements is by using seal-strength measurements. The primary issue for the selection of a test method is its sensitivity. Does the test method have the capability to discriminate between minor variations in the process? Both tensile tests and the newer burst/creep tests are sufficiently sensitive. The tensile seal-strength test is sensitive to 0.01 lbf and the burst/creep tests have sensitivity to 0.02 psi.

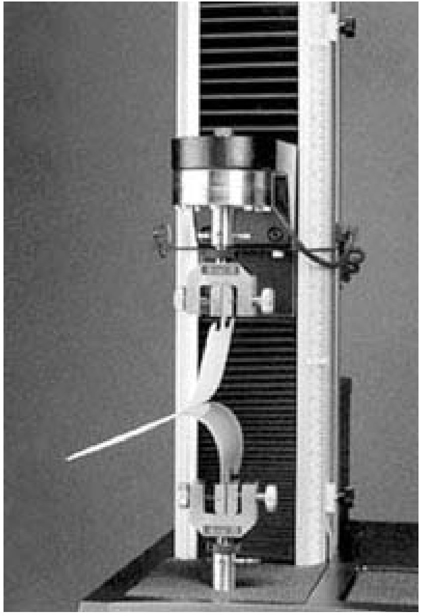

Figure 1. Tensile testing machine used in ASTM F 88 test method

The American Society for Testing and Materials (ASTM) has a test method designated as ASTM F 88, "Standard Test Method for Seal Strength for Flexible Barrier Materials."[2] This method is designed around using a tensile testing machine to measure the force required to separate the seal of a 1-in.-wide sealed sample (Figure 1). The rate of separation is usually fixed at 12 in./min, with output measurement in pounds of force per inch of seal width. However, the value chosen from a typical force plot can be peak value, average value, or force deformation. Though the current standard only discusses "peak values" of seal strength, a revision to the test method under review at ASTM includes the use of the force-deformation curve and average seal strength.

Because medical packages have seals all around the perimeter of the package, using F 88 requires sectioning the perimeter seal into 1-in.-wide samples at random locations or continuously around the seal. In the majority of cases, a perimeter seal is only sampled at several locations, leaving areas of the perimeter untested.

The inflation seal-strength tests—burst and creep—are discussed in ASTM standard method F 1140.[3] This method describes the apparatus and process used to automatically inflate a whole package and capture the peak rupture pressure (the burst pressure) or measure the hold pressure (creep pressure) over a defined time period. The measuring equipment is used along with either a clamp to seal an open-ended pouch (an open-package fixture, as in Figure 2) or a device for penetration of a completely closed package (a closed-package fixture, as in Figure 3).

Figure 2. Open-package test fixture.

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Figure 3. Closed-package test fixture

Because inflation tests use the whole package instead of a perimeter sample, they are well-suited for finding the weakest seal area. By monitoring this pressure-related value, the package supplier or device manufacturer can set minimum strength values and/or monitor the process of seal manufacture.

Each method has its inherent advantages. Inflation testing is obviously faster to execute since it requires little sample preparation and handling. Tensile testing offers a complete strength profile of the seal perimeter. Both provide a quantitative measure of the mechanical strength of the seal.

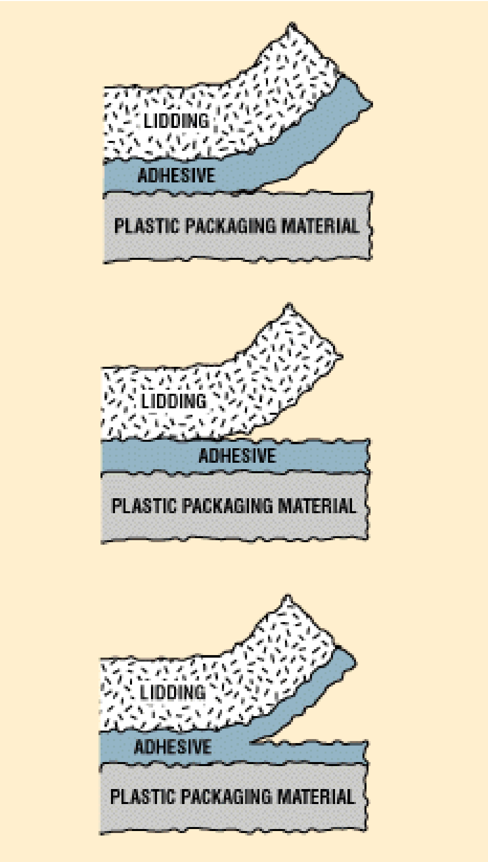

Figure 4. Failure mechanisms in seals: (top) normal opening; (middle) cohesive failure; (bottom) adhesive failure

Output data of the tensile seal-strength test can be better understood by examining peelable-seal failure mechanisms. Peelable seals are designed to fail adhesively or cohesively (Figure 4).[4] The applicable failure mechanism can be readily seen using the force-deformation-curve approach to tensile testing.[5,6]

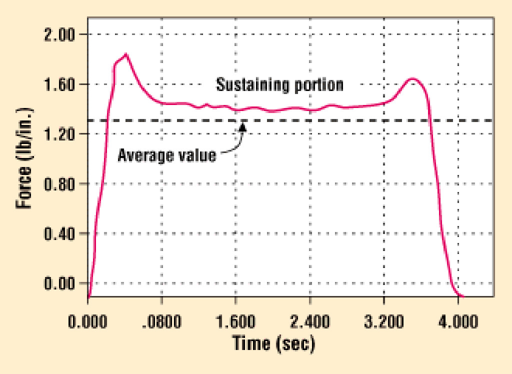

Figure 5. Typical force-deformation curve shown on a seal failure profile

Originally, the value used to determine the tensile strength of a seal was the maximum force required to separate the sealed webs. Although still in use, this concept is being replaced by the force-deformation-curve approach. Upon examining a seal failure profile, one generally sees peaks at the start and at the end of the curve (Figure 5). The starting peak, which is usually the maximum force, occurs for two reasons. First, the force required to start the peel separation or to overcome the static condition is greater that the force required to maintain motion. (This is similar to the physics of a static versus rolling coefficient of friction.) The second reason is that the edges of a seal are usually the result of higher seal pressures during the sealing process—which most likely also explains the second peak that occurs at the end of the curve.

The force-deformation curve makes it possible to determine the average separation force, either by averaging the forces along the curve or by integrating the area under the curve.

The visual characteristics or shape of the curve can be used to identify the sealing adhesive and sealing conditions, similar to a "fingerprint" identification of the materials and process.

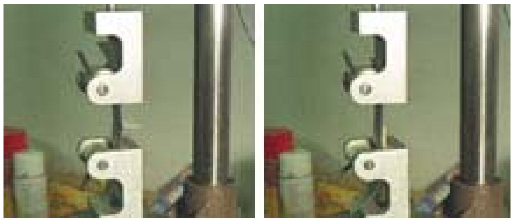

Figure 6. Test sample fixturing using (left) free-tail and (right) supported-tail methods

Consistent methodology in holding the test sample is required to ensure the best test results. There are several ways to fixture the test sample. For flexible samples, the choice is between the "free-tail" and "supported-tail" methods (shown in Figure 6). Both methods are acceptable, but it should be noted that the resultant force-deformation curves or results are not equivalent. In the free-tail method, the angle of peel is constantly varying from 90° to greater than 90°. In the supported-tail method, the sample tail is restrained by the use of a fixture to keep the angle of peel at 180°. While the choice of fixturing method is one of individual preference, many believe that the free-tail alternative more closely emulates real-world conditions. It is important to note that use of the supported-tail method will result in higher numerical values of seal strength.

Historically, attempts have been made to calculate the relationship between tensile seal-strength and inflation burst tests based on a force balance. As noted by Wachala, an empirical relationship is the preferred means of relating the outcomes of the two tests.[7] An analytical correlation can be derived, but—because of the complex nature of stresses applied to medical-pouch seals—usually results in errors that can exceed 30%. Futhermore, in today's market, the wide variety of sealing substrate materials adds more variables to the reaction of seal bonds to applied forces.

Chevron-style medical pouches were used to look at the relationship between tensile and inflation tests. This product geometry is very familiar to both suppliers andmanufacturers, and can be used to examine both porous and nonporous package configurations as well as the effect of various length-to-width ratios on the burst pressure of a pouch. (The width dimension is the distance across the chevron feature of the pouch.) For example, limitations of unrestrained burst testing have been noted for packages with large length-to-width ratios. One limitation is finding the weakest seal area. Packages usually show a consistent rupture along the longest seal feature. In fact, this burst area may not always be the weakest seal in the pouch perimeter related to tensile seal-strength data.

Properly conducted, unrestrained burst-strength testing of a pouch will result in a consistent burst-pressure value and a consistent burst area. This fact allows the unrestrained method to be useful as a process control tool. However, correlating tensile and inflation seal-strength testing requires additional control of the stresses on the package seals during the burst test. By restraining the pouch along its walls, the effect of material membrane stresses (so-called hoop stresses) can be minimized (Figure 7). In this way, the nature and direction of the forces needed to separate the seal can be examined, and it might be possible to develop equations to relate these forces.

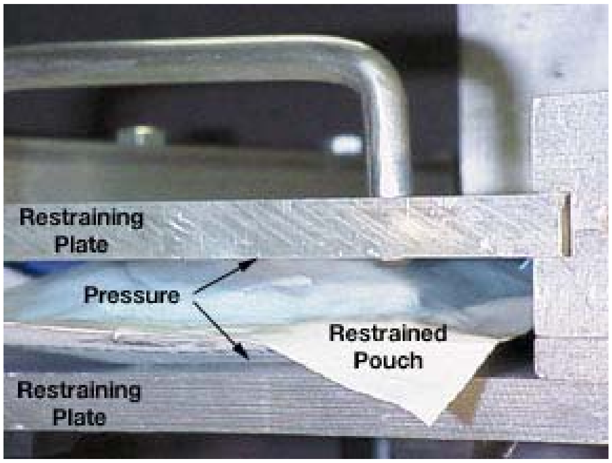

Figure 7. Pouch-restraining fixture.

The experience of some users indicates that under controlled conditions with the use of restraining plates, a predictable relationship can be developed between tensile and burst test results on a particular package.[8] Accordingly, a screening experiment was developed to examine the nature of the variables that may affect burst pressure. An additional experiment was proposed in which the sealing parameters of temperature, pressure, and dwell time were varied for a specific pouch, and the change in burst pressure related to the change in average tensile strength. If this relationship can be established, then the restrained burst test would have the added advantage of not only relating the lowest seal-strength area to tensile seal strength but also of setting up a numeric relationship between the two tests.

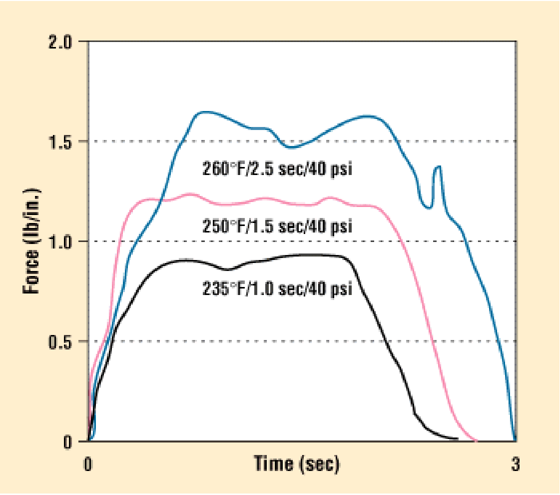

Figure 8. Force-deformation curves showing relationship of different process

One of the significant advantages of the tensile seal-strength method is its sensitivity, in that the force-deformation curve can discriminate changes in processing parameters. The graph in Figure 8 is an example of the differing results when the same materials were sealed at different processing parameters. These effects can be further enhanced depending on the type of peelable adhesive used. In this case, the adhesive was from a coextruded blend. The graph clearly shows that tensile seal strength and time increase directly as the sealing heat energy increases.

By relating burst and tensile tests, the faster burst-test technique will be available to provide tensile-related information directly to production or quality control personnel. In this way, corrective action can be taken almost immediately to prevent out-of-specification products from being manufactured.

EXPERIMENTAL DESIGN

The purpose of the initial experiments was to perform a screening of the possible relationships of variables in the inflation burst test. The initial tests were not meant to provide a rigorous statistical analysis, but only to indicate trends of the relationship. Statistical methods were applied to segregate significant differences.

Table I. Test factors for burst tests with medical packages.

Test Factor	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**
Restraining condition	Unrestrained	1/4 in.	1/2 in.	3/4 in.	1 in.
Geometry (L/W)[a]	A (2:1)	B (1:1)	C (1:2)		
Flow rate (time to burst)	Low	Medium	High		
Pouch type	Open	Closed			
Materials	Nonporous	Porous			
Package size	Small	Medium	Large		
Package style	Pouch	Tray	Strip bag		
Adhesive material	Peelable	Heat weld			

[a] Area is approximately the same.

The screening tests were designed to determine the effect on burst pressure (Pb) of an limited number of variables. Table I shows the possible test factors. Some factors were excluded from the initial test in order to provide the most effective test control. For example, the test materials were limited to nonporous films to exclude the variation in porosity of porous barrier films. As mentioned previously, package types were limited to peelable pouches, and package sizes kept to a common area while the length-to-width ratio was varied. The package bonding system was configured as a peelable, coextruded material to provide a more consistent medical peel pouch.

The screening tests were primarily designed to examine burst pressure with respect to restrained plate gap, to examine the effect of various length-to-width ratios, to discover if the burst area in restrained testing was in the lowest seal-strength area of the pouch, and to determine whether a significant difference in consistency exists between restrained and unrestrained burst tests. It should be noted that care in the design of the restraining plate fixture is required for both safety and fixture rigidity. Fixtures should be made of metals having a sufficient strength to resist the applied loads.[9]

A second test was designed to determine whether the restrained burst test would be sensitive enough to detect process changes in the seal manufacture. The pouch seals would be prepared at different conditions of temperature, pressure, or dwell time and then measured by both tensile and burst seal-strength test procedures.

The apparatus used for the tests was as follows:

- Automatic package tester (T.M. Electronics Model BT-1000).
- Open and closed package fixtures (T.M. Electronics).
- Variable-gap restrained plate fixture (T.M. Electronics).
- Pouches of coextruded film (#PLK-201 from Rexam Medical Packaging).
- Motorized test stand (Chatillon) with force gauge (Mark-10) and analysis software.

TEST RESULTS

The primary effect on burst pressure (Pb) found in these tests was the influence of gap distance between the restraining plates. Significant differences (P>0.05) were seen at gaps of 1/4, 1/2, 3/4, and 1 in. These data are shown in Figure 9. The influence of length-to-width ratio is shown in Figure 10. When pouches were tested in an open-ended or totally closed configuration at different gaps, no significant differences were noted.

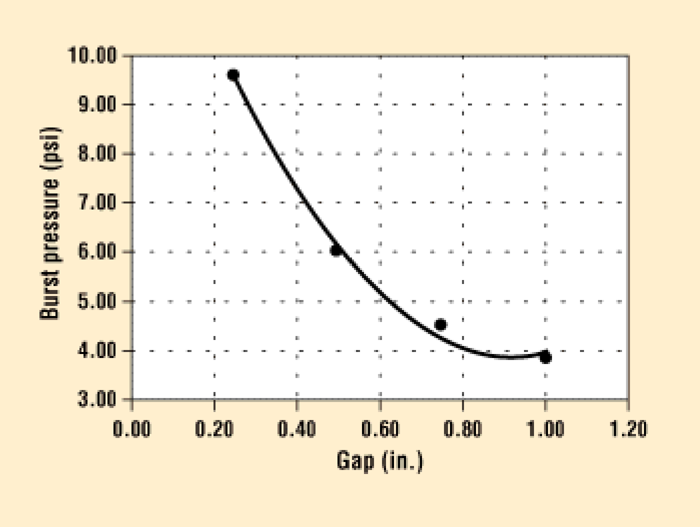

Figure 9. Average burst pressure versus plate gap size. Bags were nonporous B-bags (Rexam PLK-201) with a time-to-burst of 2.5 seconds. Correlation coefficient (R^2) = 0.9971.

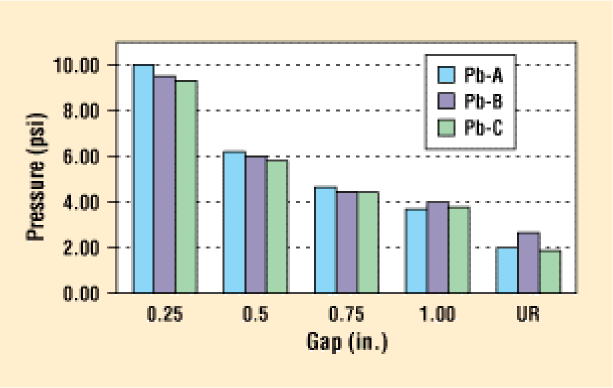

Figure 10. Effect of package length-to-width ratio (A, B, or C) on burst pressure (UR = unrestrained).

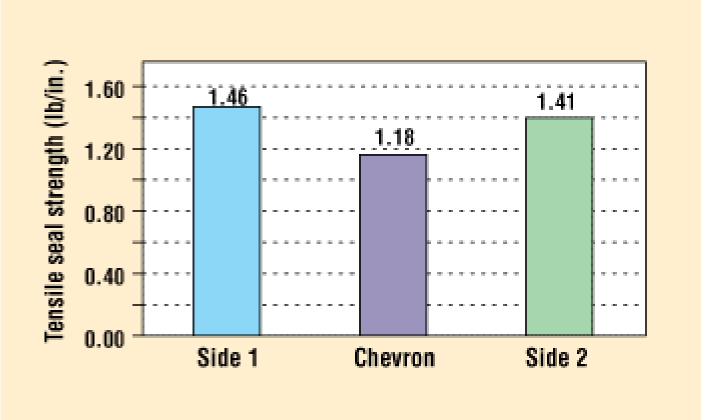

Figure 11. Tensile seal strength of pouches (separation speed = 12 in./min).

An examination of the burst area was conducted to distinguish between chevron- and side-seal rupture. Tests of tensile seal strength on all pouches showed that the chevron seal of the pouch contained the lowest tensile seal strength compared with the side seals (Figure 11). The data in Table II show that, depending on the length-to-width ratio, a plate gap could be found at which consistent bursting takes place in the lowest seal-strength area, which was identified as the chevron.

Table II. Bag burst locations, showing relation to package length-to-width ratios.

Test Method	**Chevron Seal**			**Side Seal**		
	L/W=2:1	**L/W=1:1**	**L/W=1:2**	**L/W=2:1**	**L/W=1:1**	**L/W=1:2**
1/4-in. gap	8	37	5	0	0	0
1/2-in. gap	9	45	15	19	0	0
3/4-in. gap	0	21	5	5	0	0
1-in. gap	0	119	5	10	4	0
Unrestrained	0	35	5	12	11	0

A test for significance was conducted to examine the hypothesis that restrained-plate burst tests were more consistent—that is, less variable—than unrestrained tests. The *F* test on variance from the tests at different gaps versus unrestrained testing is shown in Table III. These tests generally show no significant difference in variation between the unrestrained and restrained methods ($p<0.05$).

Table III. Variance analysis of tests at different plate gaps versus unrestrained tests.

Gap	n	Variance (s^2)	Unrestrained/Restrained s^2 Ratio	$F_{crit\ (0.05)}$	$F_{crit\ (0.01)}$
Unrestrained	5	0.0016			
1/4 in.	5	0.0064	4.0	6.39	15.98
1/2 in.	5	0.0004	4.0	6.39	15.98
3/4 in.	5	0.0016	1.0	6.39	15.98
1 in.	5	0.0016	1.0	6.39	15.98

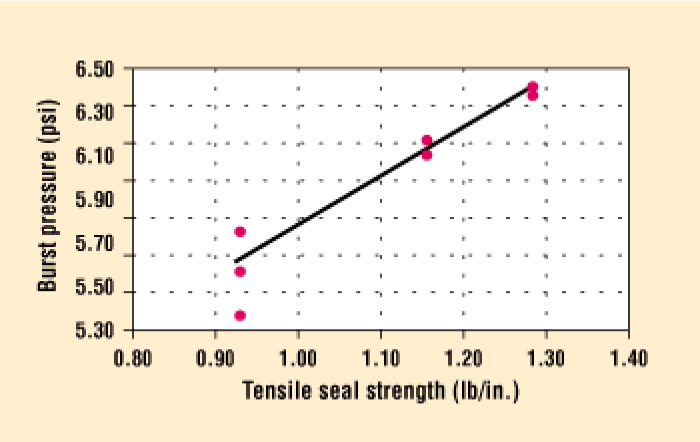

Figure 12. Linear regression of changes in burst and tensile seal strength related to changes in temperature. Correlation coefficient (R^2) = 0.9422.

The test to relate burst-test sensitivity to process variation was conducted by manufacturing the fourth seal on the premade pouches at various temperatures and dwell times. The two seal-strength test methods compared by producing the fourth seal of the open-ended pouch at higher and lower tensile seal strengths than the chevron and side seals. To affect the tensile seal strength for the selected material, a temperature range of ±10°F and dwell time of 1.5 seconds was required. Pressure was held constant. These variations produced seals with the tensile and burst seal strengths shown in Table IV, with a linear regression of the results shown in Figure 12. The results clearly show a direct relationship between the two tests and a comparable level of sensitivity in monitoring process changes for this material.

Table IV. Values for temperature tests.

Temp./Dwell/Press.	T_{ss} @ End Seal (lb-in.)	Burst Pressure (psi)	Area of Burst @ 1/2-in. Gap
260/2.5/40	1.283	6.42	Chevron
250/1.5/40	1.156	6.15	End
235/1.5/40	0.929	5.62	End

DISCUSSION

The relationship between increasing burst pressure and decreasing plate gap, shown in Figure 9, can be deduced according to the following arguments. The average or sustaining force required to separate the package seal is relatively constant when viewed by the tensile seal-strength test (Figure 5). Separation forces are applied to the seal by internal pressure of the package, created by the adjacent material walls that have pressure action along their surfaces. Extraneous forces or stresses from membrane- or hoop-stress transmission are minimized by counteracting forces on the walls in contact with the restraining plates (Figure 7). Only the unrestrained portion of the package wall is exerting force to separate the seal. Since $F = P \times A$ and the force is constant, then as the gap decreases, the area on which the pressure is applied decreases also. Thus, for a constant force, P must increase to compensate for decreasing area.

The influence of wall stresses may not be completely eliminated, as demonstrated by the effect of package length-to-width ratio shown in Figure 10, in which burst seal strength is seen to vary in the three ratios chosen (2:1, 1:1, and 1:2). Each package style follows the general pattern indicated in Figure 9. However, the longer length of the chevron seal in the 1:2 ratio package ruptures at a lower pressure. While the burst pressures are significantly different, each of the pouches has a surface area of 50 sq in. and approximately the same perimeter length. Therefore, the expectation, based on perimeter length, that the burst seal strength would be equal is shown to be valid only in an approximate sense. Differences do exist, based on package geometry.

In an initial effort to correlate the burst and tensile tests, packages were examined to relate the lowest tensile seal- strength area to the area of rupture along the perimeter in the burst test. When the data in Table II are reviewed, it is evident that the restrained packages would rupture in the chevron area. However, again depending on the length-to-width ratio of the pouch, the gap of the restraining plate might need to be reduced in order to achieve a consistent result. These data indicate that other mechanical stresses related to relative seal lengths and end constraints are acting during the seal rupture.

From a practical standpoint, the restrained-plate method shows that a configuration of plate gap can be found to achieve consistent rupture of seals in the lowest seal-strength area. These results will produce seal failures that correlate with the tensile seal-strength result.

A comparison of burst test results to determine the variability of unrestrained and restrained modes showed no significant differences. An *F* test ($p<0.05$) of the variance from each plate gap was performed relative to the unrestrained mode. The data show, in general, that both methods perform equally well. The materials, operator, and equipment controls can be construed to provide the consistency of both of these methods.

A more significant relationship between the inflation burst and tensile seal strengths was found when process sealing parameters were varied. The results of these tests are shown in Table IV and Figure 12, in which the data clearly indicate a change in tensile seal strength related to changes in temperature of 10–15°F (5–8°C) and dwell times from 0.5 to 1.0 seconds. These particular process changes were chosen relative to the test materials used. Because the tested pouch was premanufactured, the test seal applied (the fourth seal) was targeted for tensile seal strength above, below, and approximately equal to the chevron seal at 1.18 lb-in. The applied seal, however, was only 1/4-in. wide, as opposed to the 3/8-in.-wide premanufactured seals. The data show that the applied seal (end seal) failed consistently when weaker (0.93 lb-in.) than the chevron and did not fail when stronger than the chevron (1.5 lb-in.). When both seals had approximately the same tensile seal strength, the end seal ruptured first because it was narrower (1/4 in. versus 3/8 in.). Visual examination of the chevron seal clearly demonstrated that it was significantly opened and in process of failing when the seals were approximately the same strength.

A linear-regression plot of the burst and tensile seal strengths shows a high degree of correlation ($R>0.94$) (Figure 12). However, caution must be used in drawing conclusions from the data, since the relationship shown is only applicable to a particular material and test configuration. This result does not necessarily represent a universal algorithm.

CONCLUSION

It is well known that, when properly applied, tensile and inflation burst seal-strength tests are valuables tools for evaluating medical package seals. Both tensile and burst tests offer quantitative methods to gauge the strength of package seals relative to the design and validation requirements.

Inflation burst tests using restraining plates offer the advantage of identifying the lowest-seal-strength area of packages. This mode of testing provides a more uniform distribution of stresses on the package seals than other tests do.

Most importantly, for the materials and methods used in these tests, a significant correlation was seen between the tensile and burst seal-strength values when they were used in a variable process environment. Henceforth, manufacturers can confidently develop the relationship between these tests and apply the tests for process control.

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Top Photo by Jerry Davidson