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ANALYSIS AND EVALUATION OF BURST TEST METHODS USING RESTRAINING FIXTURES

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Hugh E. Lockhart
Major professor

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ANALYSIS AND EVALUATION OF BURST TEST METHODS USING RESTRAINING FIXTURES

By

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ABSTRACT

ANALYSIS AND EVALUATION OF BURST TEST METHODS USING RESTRAINING FIXTURES

By

Rosamari Feliú-Báez

Three restrained burst tests were performed: two for blisters and one for pouches. For both, blisters and pouches, four basic behaviors were found. First, burst pressure varies inversely with package size. Second, unrestrained burst pressures are lower than the restrained burst pressures. Third, burst pressure is inversely proportional to plate separation. Fourth, restraining fixtures do not necessarily reduce variability or improve repeatability. In fact, different patterns were found for raw variance and coefficients of variation for unrestrained and restrained burst tests results for blisters and pouches.

Another experiment was performed with the purpose of correlating burst peel strength and tensile peel strength for Tyvek/Plastic chevron seal pouches. Correlation between burst peel strength and tensile peel strength could not be confirmed even though burst peeling times and tensile peeling times were controlled to be the same.

To my husband, Ruben

ACKNOWLEDGMENTS

I want to express my gratitude to my major professor, Dr. Hugh Lockhart for all his advice, support and help in the development of this research project. I would like also to thank Dr. Gary Burgess and Dr. Dennis Gilliland for being part of my committee and for all their contribution to this project. Their assistance was of great value.

I also want to thank my friends and the packaging graduate students for their support. Special thanks to my parents, grandparents, my two brothers, my sister, and other family members for all their love and encouraging words during the hard days. I want to express my sincere gratitude to my husband Ruben for his love, support, patience, and encouragement. Finally, I want to thank God for giving me the strength to finish this project.

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CHAPTER 1. INTRODUCTION

The assurance of the seal integrity of any package, but especially of packages for medical and food products, is one of the most critical steps of any quality control program. There are different ways to measure the seal strength of a package. The most commonly used tests for this purpose are the tensile or peel test, and the burst or gas pressurization test. Although the tensile test has been used through the years in industry, it has some inconveniences: it is a time consuming test because many strips have to be cut from a package in order to get a "true measure" of the seal strength. In cases in which only some sample strips are tested, there is a possibility that some of the weak areas may be overlooked. The burst test, on the other hand, has gained acceptance in industry because it does not require as much time and it is easier to perform. Also, it provides an evaluation of the entire package system not only of the seal. Burst testing of packages subjects the entire sterile package system to some of the stresses that packages encounter in the manufacturing, distribution and use environment [5].

This research project focused its investigation on the burst test. Burst testing consists of increasingly pressurizing a package until it breaks. The pressure required to break the package is recorded as a measure of the seal strength. Since most packages for medical purposes are made with at least one flexible side the internal pressure tends to deform the package during the test. In the case of pouches, it deforms both sides; while in the case of blisters or trays, which are packages formed by a preformed plastic sheet with flexible, semi-rigid, or rigid cover, it tends to deform only the lid or the lid material. This deformation of the package may direct the force of the pressure to specific areas depending on the package geometry and on the type of seal. In doing so, it may influence the resulting burst values. It is also known that the package size, seal peel strength, and material thickness, among other factors, affect the burst values.

In recent years, the idea of using restraining fixtures in the burst test has been developed by engineers, researchers, and people from industry in general. A standard method of restrained burst test has been proposed to the American Society for Testing and Materials (ASTM). Members of leader companies like Carleton Technologies, Medtronic, Rexam Medical Packaging, and TM Electronics have been providing reasons for using restraining fixtures in the burst test.

One of these reasons is that with restraining plates there is a greater chance to find the weakest point. As said before, when the package is inflated in an unrestrained burst test it tends to deform. This deformation creates stress concentrators in some areas of the package causing them to break at the point of stress concentration. The main concern is that the package does not deform in the same way each time and that it does not necessarily break on the weakest point but as a result of the stress concentration caused by the deformation. Restraining plates are thought to limit the extent and variation of deformation. Because all seal surfaces are exposed to the same forces with restraining plates then there is a greater chance of finding the weakest point. A second reason these people believe, is that restraining fixtures will provide more consistent test results, and that the use of the restraining plates will help reduce or eliminate the effect of other variables like package size and geometry. The possibility that the repeatability of the burst test can be improved by using restraining plates is the main reason why people in industry nowadays are proposing a new standard.

The purpose of this thesis project is to provide an analysis of the burst test method using restraining plates, to study its advantages and disadvantages, and to evaluate the applicability of this type of test in different situations. This analysis will include the package size and package geometry effects on restrained burst tests results. Since the restrained burst pressure is known to vary with the restraining plate separation, an analysis of plate separation (gap) effect will be provided and the theoretical relationship between the restrained burst pressure and plate separation will be analyzed. Also an overall comparison between the unrestrained burst test results and the restrained test results will be performed.

CHAPTER 2. LITERATURE REVIEW

RESTRAINED BURST TEST METHODS FOR BLISTERS

In 1994, David Bohn, from Medtronic, Inc., wrote in his article *"Using Burst Testing to Evaluate Sterile Blister Packaging"* about research being planned for totally restricted burst testing [5]. It was not until 1996, that John Spitzley, from Medtronic, Inc., wrote and designed a test plan (PTP9609121) in order to define the tests and procedures required to determine the effect of a restraining fixture on the burst values of packages of widely varying sizes and geometries [18]. They decided to do this because blisters have one flexible side and they think that one of the effects of the internal pressure in an unrestrained burst test is a "doming" of the lid which can alter the shape of the package. This may direct the force of the pressure to specific areas depending on package geometry thus influencing the resulting burst values. Medtronic's theory was that if the lid of the package were prevented from "doming" by a restraining fixture, the result may be to minimize the effects of package size and geometry on the resultant burst values. This test plan was put in practice in the School of Packaging. The results will be shown later on in this report.

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RESTRAINED BURST TEST METHODS FOR POUCHES

In January 1992, the use of restraining plates for food flexible pouches was mentioned in section 4.3.4 of the MIL-P-44073 D - *Military Specification Packaging and Thermoprocessing of Foods in Flexible Pouches* [13]. Its revised edition, from February 1996, MIL-PRF-44073E - *Performance Specification for Packaging of Food in Flexible Pouches,* mentions in section 4.3.7 the use of restraining fixtures [14]. It says that the internal pressure resistance shall be determined by pressurizing the pouches while they are restrained between two rigid plates spaced 1/2 inch +/- 1/16 inch apart. It mentions the use of the plates for open package (three-seal tester) and for closed package (four-seal tester). Also, it specifies the parameters to be used in the test, how the pouches should be examined and the criteria that should be used to consider a test failure.

Professor Kit Yam, from Rutgers University, published in 1993 an article *"Relationship between Seal Strength and Burst Pressure for Pouches"*, in which he mentioned the use of restraining plates [22]. The purpose of his study was to find the relationship between peel and burst tests. The burst test was performed using restraining fixtures. The article explained, based on force analysis, that the seal strength (S) obtained from the peel test is equivalent to the product of the burst pressure (P) and half of the plate separation (D) used for the burst test ($S = P*(D/2)$). Yam wrote the equation as ($S = (P*R)$), where $R = D/2$. He emphasized in his article that the validity of this equation is based on the assumption that the peeling times for the peel test and the burst test should be the same.

Thomas Wachala, from Carleton Technologies, in 1994, published a study *"Restrained Vs Unrestrained Pressure Testing"*, in which he compared both burst test methods [20]. He explained in his article how the package is not the only factor affecting the burst test results. He thinks that the method of holding the package during the test can also have a big effect. Wachala also says that some of the advantages of the restrained burst test method are: that it helps to test the packages more uniformly by exposing all surfaces to the same forces and that this test provides a greater chance to find the weakest point of the package. Also he mentioned as an advantage that the restraining fixture would minimize the effects of package geometry and that the plate separation could be standardized for use for specific packages at multiple locations. He thinks that the unrestrained test, if done at multiple locations, has greater potential for large differences in burst values. The disadvantages for using restraining fixtures, he says, include higher burst values, and the need for a variety of plates to accommodate various package sizes.

On January 21 1997, Committee F 2.6 of the American Society for Testing and Materials (ASTM), presented a draft proposal for a *Standard Test Method for Burst Test Seal Strength Testing of Flexible Packages using Internal Air Pressurization within Restraining Plates* [4]. This standard method in particular is to be applicable to packages with seals that are intended to have a peelable seal feature. In this proposed standard method, the restraining plate burst method is described as a rapid means of evaluating minimum seal strength and tendencies for package seal failure when the package is exposed to an internal pressure. The use of the restraining fixtures is recommended in order to maintain dimensional stability while the package is pressurized.

Also, Neil Lorimer, from Rexam Medical Packaging made a presentation *"Understanding Restrained Burst Testing"*, on April, 1997 to the ASTM F02 Subcommittee on Medical Packaging, in which he explained reasons for performing restrained burst testing [12]. One of the reasons he provided was that restrained burst testing provides a rapid means of evaluating minimum seal strength (burst strength). The other reason is that this test is more efficient and economical to perform than force gage testing of peel strength. He also mentioned in his presentation that restrained burst testing can reliably detect the weakest area of a package seal placed around the perimeter of a flexible package and that this is very important when developing correlation between peel and burst test. It is important to recognize that tests values for burst strength are correlated only to the weakest areas of the pouch seal and not to the entire distribution of seal strength values. He thinks that in order to find correlation between burst and force gage peel tests it is better to use restrained burst testing results than the unrestrained burst test results. Pouches, when tested in an unrestrained mode, tend to burst in the middle of the bag in spite of where the weakest point is really located. This appears to be because a crease appears there, which concentrates stress.

Appendix D, at the end of this report, provides a detailed list of reasons why members of leader companies are suggesting the use of restraining fixture in the burst test.

RESTRAINED BURST TEST STUDIES PERFORMED AT MICHIGAN STATE UNIVERSITY - SCHOOL OF PACKAGING

During fall 1996 we started working with restrained burst test methods for blisters and pouches. Dr. Hugh E. Lockhart, Professor at Michigan State University School of Packaging is in charge of this project. We have worked together on the design of all the tests, the design of test fixtures, the experimental designs, and in the analysis and interpretation of the results. We learned from our experiments three basic behaviors that hold for both pouches and blisters. The first one is that in burst testing, the burst pressure required to break a package decreases as the package size increases. The second one is that unrestrained burst pressures are lower than restrained burst pressures. The third one is that as the plate separation decrease, the burst pressure required to break a package increase [9, 10, and 11]. These three behaviors were observed while testing pouches and blisters and the results will be discussed in this report.

The literature review presented above demonstrates that there is some work that has been done in order to explain burst test methods using restraining fixtures. There is certainly an effect of package size and of plate separation distance on the burst test results. There is also a difference between the unrestrained burst test method and the restrained method. The intent of this thesis project is to study and analyze these effects on the burst test results, and to understand the main differences between restrained and unrestrained burst test methods.

CHAPTER 3. THEORY

RELATIONSHIP BETWEEN PEEL TEST AND BURST TEST

As mentioned in the literature review section, Professor Kit Yam, from Rutgers University has worked on correlating peel test with restrained burst test results. In his article [22], he explained that the seal strength (S) obtained from the peel test is equivalent to the product of the burst pressure (P) and half of the plate separation (D) used in the burst test (S = P*(D/2)). He derived this equation based on the assumption that the walls of the pouch take approximately a circular shape when the air pressure exerts a tensile force on the seal to peel it apart. The Y component of forces (tensile peel) around the seal area can be represented by:

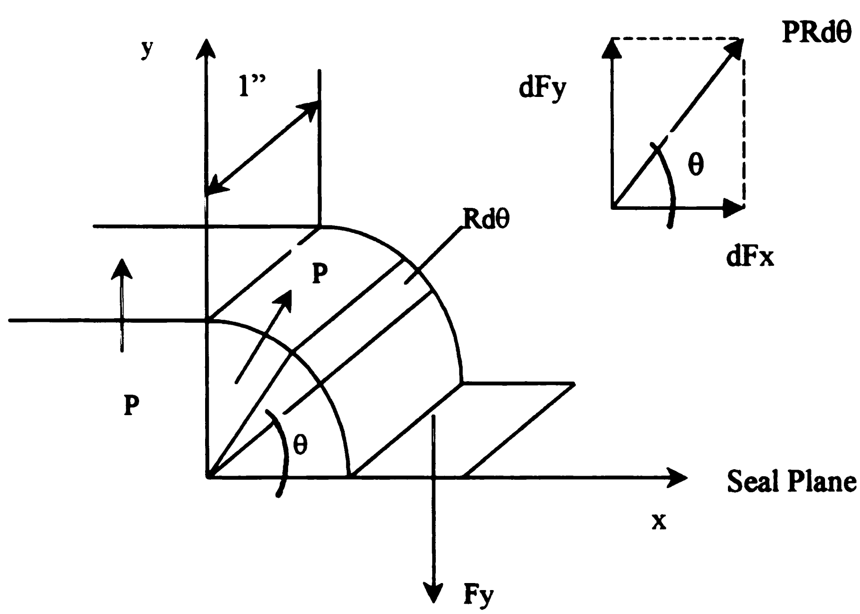


Figure 1. Force Diagram in Seal Area

$dFy = P\,R \sin\theta\, d\theta$

Fy = force peeling a one inch width of the seal

P = internal pressure

R = half plate separation

$$Fy = \int_0^{\pi/2} PR \sin\theta\, d\theta$$

$Fy = P\,R$; Fy can be substituted by S (lb./in) at rupture

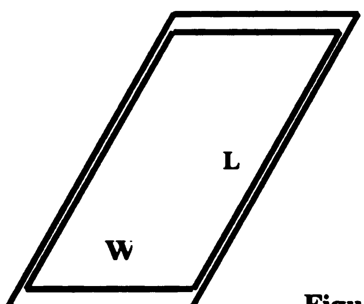
S = P R

He emphasized in his article that the validity of this equation is based on the assumption that the peeling times for the peel test and the burst test should be the same. The tensile peeling time is a function of gauge length, crosshead speed and strain-stress properties of the pouch material and the seal. The burst peeling time is a function of plate separation, rate of pressurization and stress-strain properties of the pouch material and the seal. Professor Yam presented data in his article to support his theory.

BURST TEST THEORY - UNRESTRAINED & RESTRAINED CASES

During summer 1997, Dr. Gary Burgess, Professor at Michigan State University, got involved in the development of this project. He developed theoretical equations, based on force diagrams, in order to explain the pouch behavior during an unrestrained and a restrained burst test. The following equations and diagrams were provided by Dr. Burgess.

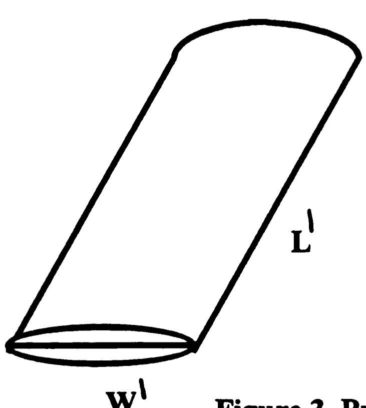
Pouch Burst Testing:



L, W are the internal dimensions of the flat pouch before pressurization

Figure 2. Pouch in its Flat Configuration

When the package is pressurized the center section of the pouch tries to become circular. The pouch "shrinks".



The internal dimensions are now **L'** and **W'** and are smaller than L and W, respectively.

$(L' < L)$ and $(W' < W)$

Figure 3. Pressurized Pouch - Unrestrained Case

Unrestrained Case:

The force diagram, in Figure 4, represents a half center section strip of width h in an unrestrained burst test at failure. The work needed to peel the seals apart can be described by the vector component of the force in Y direction, perpendicular to the plane of the seal.

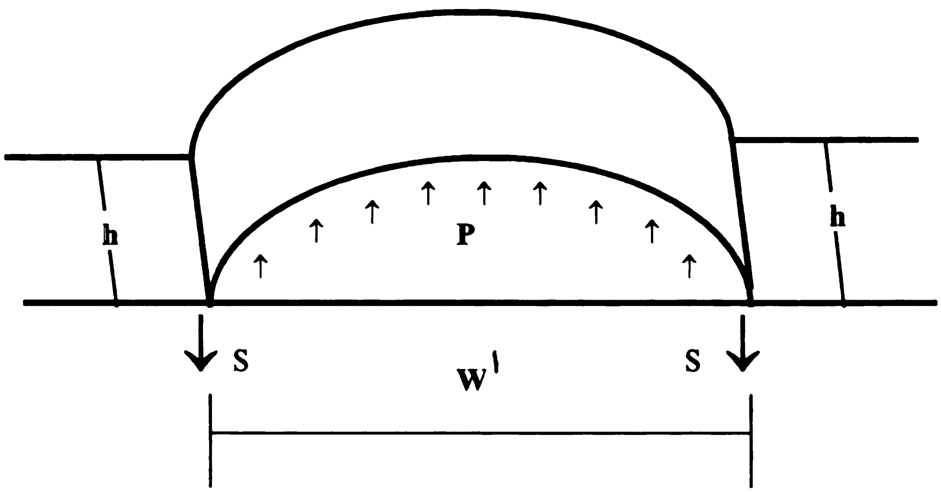


Figure 4. Force Diagram of Half-Center Section Strip - Unrestrained Case

the vertical component = $\Sigma Fy = P\, W^{I}\, h = 2\, S\, h$;

$$P = [(2\ S) / W^{I}] \qquad (1)$$

where P = pressure

h = width of the strip

S = seal strength (lb./inch) in a 180 ° degree peel test

(force required to peel seal apart / the width of the strip)

W^{I} = diameter of the pouch (See Figure 5, next page)

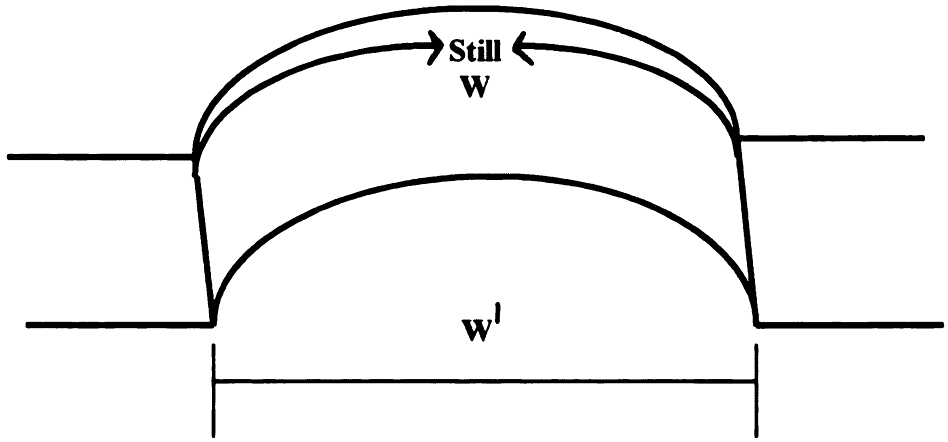


Figure 5. Diagram of Half-Center Section Strip - Inflated Pouch

If the center section is approximated as a circle, assuming that the strip does not stretch much along its perimeter, then;

$\pi W' = 2 W$ (π * diameter = circumference)

$W' = [(2 W) / \pi]$; $W' = .636 W$ (it shrinks about 1/3) (2)

Substitute equation (2) in (1);

$p_{critical} = [(\pi S) / W)]$; $p_{critical}$ = Burst Pressure (3)

So, for the **unrestrained case** the burst pressure is a function of seal strength and pouch size. With this equation, some predictions can be made:

1. The burst pressure increases as the seal strength increases
2. The burst pressure decreases as the width of the package increases. Therefore, bigger pouches are weaker in burst, even when seal strength is the same.
3. Dimension "L" has no effect on $P_{critical}$. The burst pressure depends only on the smaller dimension (W); so lengthening of the pouch while keeping the width the same should not affect the burst strength.

Restrained case:

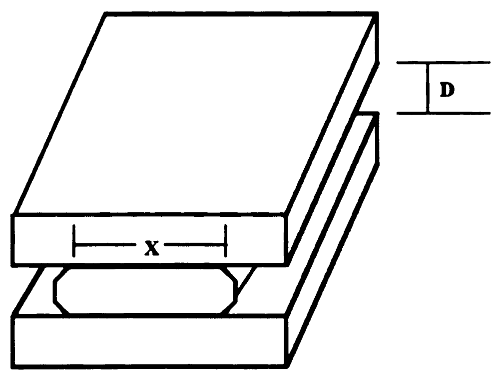


Figure 6. Pressurized Pouch - Restrained Case

The restraining plates apply force over the contact length x. This force is equal and opposite to the air pressure P inside and so these forces cancel and do not enter the force balance. The vertical components of the pressure along the curved parts are balanced by the seal tension, assuming the material does not stretch

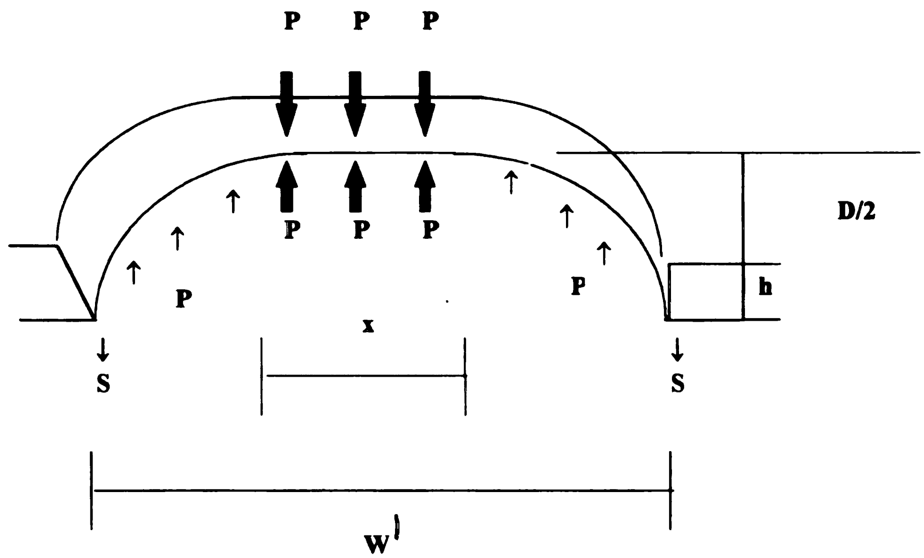


Figure 7. Force Diagram of Half-Center Section Strip - Restrained Case

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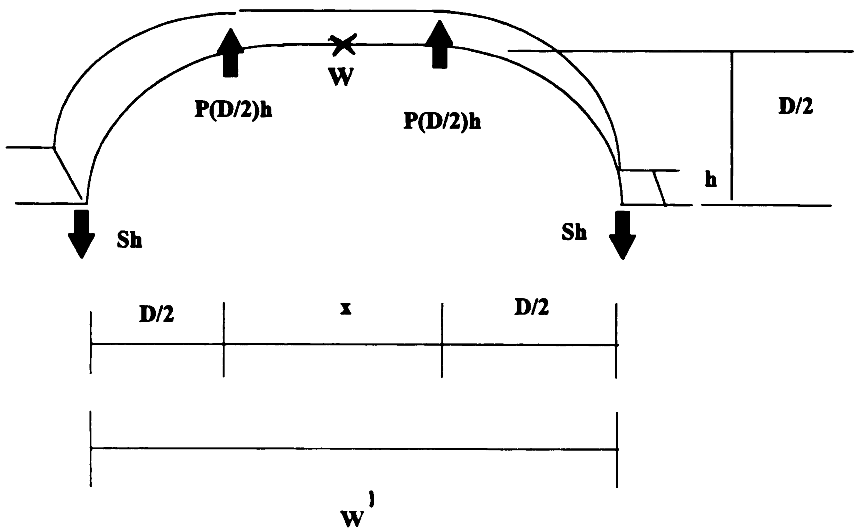

Figure 8. Force Diagram of Half-Center Section Strip - Restrained Case

From the figure above;

$$x + [\pi/2 * (D/2)] + [\pi/2 * (D/2)] = W \qquad x = W - [\pi * D/2] \qquad (4)$$

$$\sum Fy = 2\, S\, h = 2 * (p\, D\, h / 2)\,; \qquad p = [(2\, S) / D] \qquad (5)$$

So $p_{critical} = [(2\,S) / D]$

So, for the **restrained case** the burst pressure is a function of seal strength and plate separation. With this equation, some predictions can be made:

1. The burst pressure increases as the seal strength increases.
2. The burst pressure increases as the distance between the plates decreases.

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It is important to notice that the unrestrained case is a special case of the restrained case. If D gets bigger and bigger, then eventually it will be unrestrained. This happens when $x = 0$; which from equation (4) above happens when $D = [(2\,W) / \pi]$. When this D value is substituted into equation (5), the following can be obtained;

$P_{critical} = \{(2\,S) / [(2\,W) / \pi]\}$; $\quad$ $P_{critical} = [(\pi\,S) / W]$

which is the burst pressure obtained for the unrestrained case. See equation (3)

Both cases can be put in a single graph.

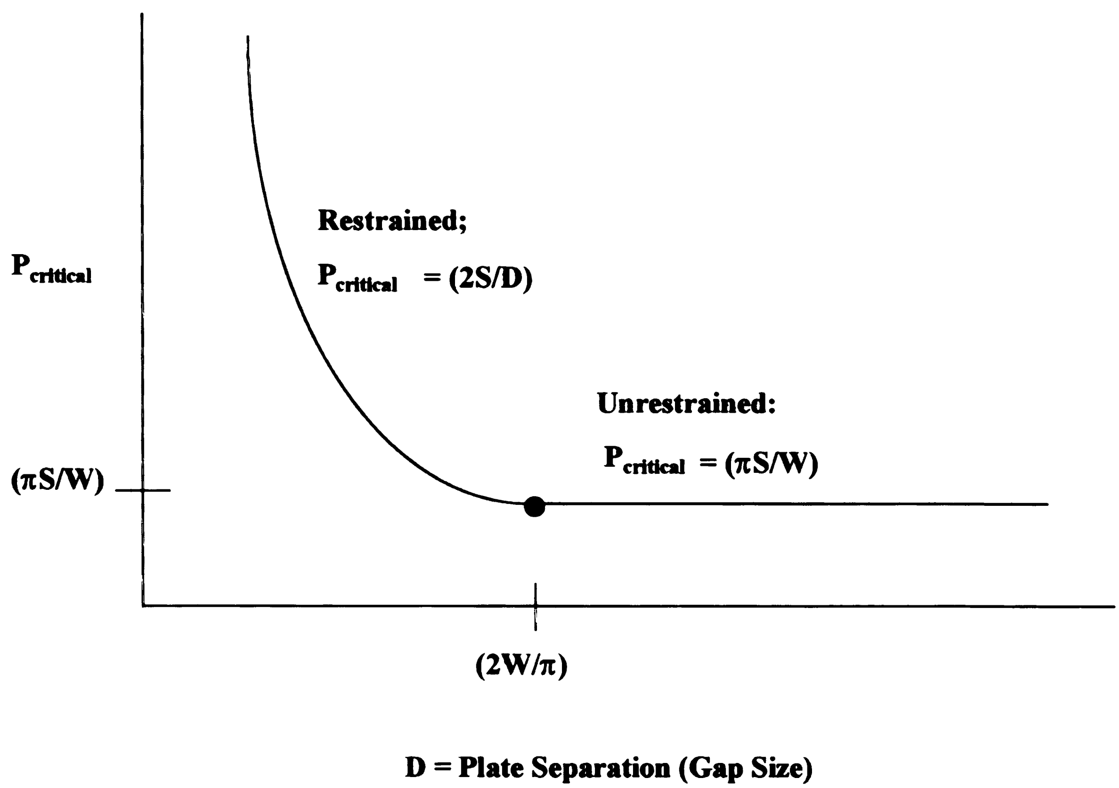

Figure 9. Relationship between Critical Burst Pressure and Plate Separation

It can be seen from the graph that the restrained results could be represented theoretically as a hyperbolic function. Beyond a certain D (plate separation) value, there is no contact between the package and the plates and the test is similar to an unrestrained one. In this case $P_{critical}$ is independent of D and the data cannot be represented with a hyperbolic function anymore. The results provided by Dr. Burgess agree with the results provided by Dr. Kit Yam in his article *"Relationship between Seal Strength and Burst Pressure for Pouches"*[22].

CHAPTER 4. MATERIALS AND METHODS

PART A - BLISTERS:

I. UNRESTRAINED VS RESTRAINED BURST TEST RESULTS

Materials Tested:

1. Medtronic Accessories Package (P/N 119401-001)

   Seal Perimeter (13.5")

2. Medtronic Thera Small Outer IPG Package (P/N 119679-001)

   Seal Perimeter (20.0")

3. Medtronic Standard Leads Outer Package (P/N 119421-001)

   Seal Perimeter (27.5")

4. Medtronic Myocardial Leads Outer Package (P/N 119553-001)

   Seal Perimeter (33.0")

Test Methods Used:

1. ARO 2600 Burst and Creep Tester - Medtronic's Operating Procedure PE026
2. Medtronic's Test Plan PTP9609121

   "Effect of a Restraining Fixture on the Burst Values of Sterile Packages"

Equipment:

1. Test-A-Pack 2600 Burst Tester - Carleton Technologies with closed fixture
2. Burst Test Restraining Fixture (14.5" x 11.5" x 3/8") – Medtronic's design and construction. See Figure 10, next page.

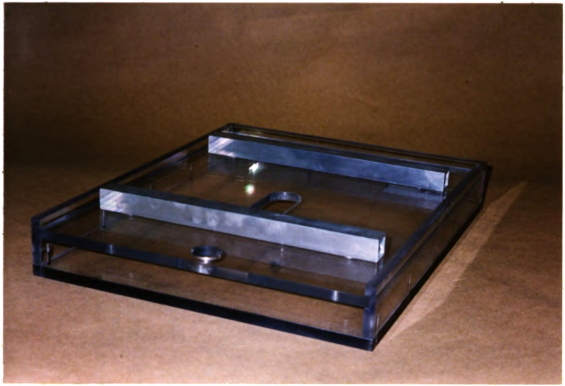

Figure 10. Burst Test Restraining Fixture for Blisters (14.5" x 11.5" x 3/8") at Plate Separation = 1.0" – Medtronic's Design

Procedure:

One half (50) of the packages of each kind were burst tested in an unrestrained mode, and the other half (50) were burst tested using Medtronic's restraining fixture. Each group of (50) packages was tested on two days, 25 each day. This allowed evaluation of day effect as a result of starting and stopping the test sequence.

The blisters were placed with or without the restraining plates in the closed package fixture; depending if restrained or unrestrained burst test, respectively, was being performed. A needle punctured the lid of the blister. The package was pressurized until it broke. The pressure required to break the package was recorded.

Experimental Design:

See Table 1. Sampling Procedure for Blisters - Unrestrained Vs Restrained Burst Test Results, next page.

Data Analysis:

Test results were analyzed statistically for significant difference between the means using one-way and two-way analysis of variance, and t-tests as appropriate. The results were further analyzed to determine if there were differences in variation between the two test methods.

EXPERIMENTAL DESIGN

Table 1. Sampling Procedure for Blisters - Unrestrained Vs Restrained Burst Test Results

Package Type	Day Start Time	Temperature & Relative Humidity	Unrestrained Test Parameters	Restrained Test Parameters	Total Number of Samples Tested
Accessory Package P/N 119401-001 **PKG. #1**	10/22/96 2:20 p.m.	T = 22 ° C RH = 43 %	25 samples Fixture Setup = 13 Flow Rate = 5 Sensitivity = 9	25 samples Flow Rate = 5 Sensitivity = 5 Gap = 0.14”	50
Accessory Package P/N 119401-001 **PKG. #1**	10/23/96 5:30 p.m.	T = 20 ° C RH = 43 %	25 samples Fixture Setup = 13 Flow Rate = 5 Sensitivity = 9	25 samples Flow Rate = 5 Sensitivity = 5 Gap = 0.14”	50
Thera Small Outer Package P/N 119679-001 **PKG. #2**	10/23/96 6:30 p.m.	T = 21 ° C RH = 43 %	25 samples Fixture Setup = 7 Flow Rate = 5 Sensitivity = 9	25 samples Flow Rate = 5 Sensitivity = 5 Gap = 0.20”	50
Thera Small Outer Package P/N 119679-001 **PKG. #2**	10/24/96 5:00 p.m.	T = 22 ° C RH = 43 %	25 samples Fixture Setup = 7 Flow Rate = 5 Sensitivity = 9	25 samples Flow Rate = 5 Sensitivity = 5 Gap 0.20”	50

EXPERIMENTAL DESIGN - CONTINUATION

Table 1. Sampling Procedure for Blisters - Unrestrained Vs Restrained Burst Test Results

Package Type	Day Start Time	Temperature & Relative Humidity	Unrestrained Test Parameters	Restrained Test Parameters	Total Number of Samples Tested
Outer Standard Leads Package P/N 119421-001 **PKG. #3**	10/28/96 10:30 a.m.	T = 21 ° C RH = 43 %	25 samples Fixture Setup = 1 Flow Rate = 5 Sensitivity = 5	25 samples Flow Rate = 5 Sensitivity = 5 Gap = 0.15"	50
Outer Standard Leads Package P/N 119421-001 **PKG. #3**	10/29/96 8:00 a.m.	T = 20 ° C RH = 43 %	25 samples Fixture Setup = 1 Flow Rate = 5 Sensitivity = 5	25 samples Flow Rate = 5 Sensitivity = 5 Gap = 0.15"	50
Outer Standard Myocardial Package P/N 119553-001 **PKG. #4**	11/12/96 8:20 a.m.	T = 20 ° C RH = 43 %	25 samples Fixture Setup = 9 Flow Rate = 5 Sensitivity = 5	25 samples Flow Rate = 5 Sensitivity = 5 Gap = 0.01"	50
Outer Standard Myocardial Package P/N 119553-001 **PKG. #4**	11/15/96 10:30 a.m.	T = 21 ° C RH = 43 %	25 samples Fixture Setup = 9 Flow Rate = 5 Sensitivity = 5	25 samples Flow Rate = 5 Sensitivity = 5 Gap = 0.01"	50

II. PACKAGE SIZE AND GAP SIZE EFFECT

Materials Tested:

1. Medtronic Accessories Package (P/N 119401-001)

   Seal perimeter = 13.5"

2. Medtronic Thera Small Outer Package (P/N 119679-001)

   Seal perimeter = 20.0"

Test Methods Used:

1. ARO 2600 Burst and Creep Tester - Medtronic's Operating Procedure PE026
2. Medtronic's Test Plan PTP9609121

   "Effect of a Restraining Fixture on the Burst Values of Sterile Packages".

Equipment:

1. Test-A-Pack 2600 Burst Tester - Carleton Technologies with close package fixture.
2. Medtronic's Burst Test Restraining Fixtures (See Figure 10)

   Box #1, #2, #3, #4, & #5 - the difference in boxes is the plate separation

Procedure:

All the packages were burst tested in the restraining fixture. Each group of 24 packages, at 3 different gaps, was tested on 2 days, 12 each day. This allowed evaluation of day effects .

The blisters were placed within the restraining fixture. A needle punctured the lid of the blister. The package was pressurized until it broke. The pressure required to break the package was recorded. The same procedure was repeated for the three gaps.

EXPERIMENTAL DESIGN

Table 2. Sampling Procedure for Blisters - Package Size and Gap Size Effects

Package Type	Day Start Time	Temperature & Relative Humidity	Test Parameters	Box Number Gap Size			Total number of samples tested		
Accessory Package P/N 119401-001 **PKG. #1**	3/19/97 11:30 a.m.	T = 21 ° C RH = 43 %	Flow Rate = 5 Sensitivity = 5	Box #3 Gap = .20"	Box #1 Gap = .10"	Box #4 Gap = .01"	12	12	12
Thera Small Outer Package P/N 119679-001 **PKG. #2**	3/19/97 2:30 p.m.	T = 21 ° C RH = 43 %	Flow Rate = 5 Sensitivity = 5	Box #1 Gap = .20"	Box #5 Gap = .10"	Box #2 Gap = .01"	12	12	12
Accessory Package P/N 119401-001 **PKG. #1**	3/24/97 1:30 p.m.	T = 22 ° C RH = 40 %	Flow Rate = 5 Sensitivity = 5	Box #3 Gap = .20"	Box #1 Gap = .10"	Box #4 Gap = .01"	12	12	12
Thera Small Outer Package P/N 119679-001 **PKG. #2**	3/24/97 2:30 p.m.	T = 22 ° C RH = 40 %	Flow Rate = 5 Sensitivity = 5	Box #1 Gap = .20"	Box #5 Gap = .10"	Box #2 Gap = .01"	12	12	12

Data Analysis:

The results were analyzed statistically for significant differences between means using one-way and two-way analysis of variance. The results were further analyzed to test the effect of gap size on variance.

PART B – POUCHES:

I. UNRESTRAINED VS RESTRAINED BURST TEST RESULTS

II. PACKAGE SIZE AND GAP SIZE EFFECT

A single test was conducted to compare unrestrained vs. restrained burst test results and also to analyze the effects of package and gap size on the burst test results.

Materials Tested:

1. Package #1 - Oliver Products Company
   (5" x 10") Chevron Seal Pouch
   Pouch Raw 1073 B/Tyvek Pouch W/48 Gage PET
   Plastic (2.6 mil) / Tyvek (7.0 mil)
   Basis Weight (76.83 g/m^2 or 2.26 oz/yd^2)
   Average Peel Strength (2.1 lb./in.)
   Seal Perimeter (16.5")
   Seal Width (3/8")

2. Package #2 - Oliver Products Company
   (7" x 11") Chevron Seal Pouch
   Pouch Raw 1073 B/Tyvek Pouch W/48 Gage PET
   Plastic (2.6 mil) / Tyvek (7.2 mil)
   Basis Weight (75.10 g/m^2 or 2.21 oz/yd^2)
   Average Peel Strength (2.2 lb./in.)
   Seal Perimeter (19.0")
   Seal Width (3/8")

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3. Package #3 - Oliver Products Company

(9" x 12") Chevron Seal Pouch

Pouch Raw 1073 B/Tyvek Pouch W/48 Gage PET

Plastic (2.6 mil) / Tyvek (7.1 mil)

Basis Weight (74.85 g/m^2 or 2.21 oz/yd^2)

Average Peel Strength (2.0 lb./in.)

Seal Perimeter (21.5")

Seal Width (3/8")

Test Methods Used:

1. ARO 2600 Burst and Creep Tester Operating Procedure
2. INSTRON Tensile Tester (Model 4201) Operating Procedure

Equipment:

1. Test-A-Pack 2600 Burst Tester - Carleton Technologies with open package fixture.
2. Burst Test Aluminum Restraining Fixture (12" x 12" x ¾").

   See Figure 11, next page.
3. INSTRON Tensile Tester Machine – Model 4201

Figure 11. Burst Test Aluminum Restraining Fixture for Pouches (12" x 12" x ¾") at gap = 1.0"

Procedure:

A group of 30 packages were peel tested. There were 3 package sizes, 5 pouches each, in 2 days. Four (4) locations (A, B, D, and E) were tested from each pouch. See figure below.

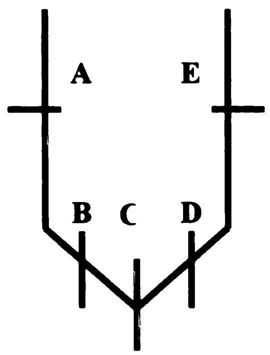

Figure 12. Pouch Seal Locations

The peel strength of the sides (A and E) was compared with the peel strength of the chevron area (B and D) to see if they were statistically different.

A group of 420 packages were burst tested. There were 3 package sizes, at 7 different modes, 10 samples each, in 2 days. The testing modes consisted of two (2) types of unrestrained modes: chevron up or chevron down and five (5) types of restrained modes: gap heights of 0.25", 0.50", 0.625", 0.75", and 1.0", were used. Chevron up means that the pouch was placed with the plastic side looking up and chevron down means that it was placed with the Tyvek side looking up. So, in general, there were 3 sizes * 7 modes * 10 samples * 2 days = 420 packages. The size of the three different packages was determined by measuring the seal perimeter. The seal perimeter values really represent the inner border of the sealed area.

The pouches were placed with or without the restraining plates in the open package fixture; depending if restrained or unrestrained burst test, respectively, was being

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performed. The pouches were slid over the test fixture's inflation port until its top portion touched the metal stops. The actuator was pressed down to clamp the pouch in place. The package was pressurized until it broke. The pressure required to break the package was recorded. The same procedure was repeated for the seven different modes.

Experimental Design:

See Tables 3 and 4, next page. Sampling Procedure for Pouches – Peel Test and Burst Test, respectively.

Data Analysis:

The results were analyzed statistically for significant differences between the means using one-way and two-way analysis of variance. The results were further analyzed to determine if there were differences in variation between the three different package sizes and the seven different modes.

EXPERIMENTAL DESIGN
Table 3. Sampling Procedure for Pouches - PEEL TEST

Package Type	Day Start Time	INSTRON Parameters	Location Number of Samples			
PKG. #1 (5" x 10")	10/25/97 3:00 p.m.	Gauge Length = 2.0" Speed = 12 in/min	A 5	B 5	D 5	E 5
PKG. #2 (7" x 12")	10/25/97 3:00 p.m.	Gauge Length = 2.0" Speed = 12 in/min	A 5	B 5	D 5	E 5
PKG. #3 (9" x 12")	10/25/97 3:00 p.m.	Gauge Length = 2.0" Speed = 12 in/min	A 5	B 5	D 5	E 5
PKG. #1 (5" x 10")	10/26/97 11:00 p.m.	Gauge Length = 2.0" Speed = 12 in/min	A 5	B 5	D 5	E 5
PKG. #2 (7" x 12")	10/26/97 11:00 p.m.	Gauge Length = 2.0" Speed = 12 in/min	A 5	B 5	D 5	E 5
PKG. #3 (9" x 12")	10/26/97 11:00 p.m.	Gauge Length = 2.0" Speed = 12 in/min	A 5	B 5	D 5	E 5

EXPERIMENTAL DESIGN

Table 4. Sampling Procedure for Pouches - BURST TEST

Package Type	Day Start Time	Temperature & Relative Humidity	Test Parameters	Test Mode Number of Samples Tested						
PKG. #1 (5" x 10")	10/25/97 10:00 a.m.	T = 21 ° C RH = 42 %	Flow Rate = 5 Sensitivity = 1 Prefill = N	URCU 10	URCD 10	R-1.0" 10	R-0.75" 10	R-.625" 10	R-0.50" 10	R-0.25" 10
PKG. #2 (7" x 12")	10/25/97 10:00 a.m.	T = 21 ° C RH = 42 %	Flow Rate = 5 Sensitivity = 1 Prefill = N	URCU 10	URCD 10	R-1.0" 10	R-0.75" 10	R-.625" 10	R-0.50" 10	R-0.25" 10
PKG. #3 (9" x 12")	10/25/97 10:00 a.m.	T = 21 ° C RH = 42 %	Flow Rate = 5 Sensitivity = 1 Prefill = N	URCU 10	URCD 10	R-1.0" 10	R-0.75" 10	R-.625" 10	R-0.50" 10	R-0.25" 10
PKG. #1 (5" x 10")	10/26/97 6:00 p.m.	T = 20 ° C RH = 41 %	Flow Rate = 5 Sensitivity = 1 Prefill = N	URCU 10	URCD 10	R-1.0" 10	R-0.75" 10	R-.625" 10	R-0.50" 10	R-0.25" 10
PKG. #2 (7" x 12")	10/26/97 6:00 p.m.	T = 20 ° C RH = 41 %	Flow Rate = 5 Sensitivity = 1 Prefill = N	URCU 10	URCD 10	R-1.0" 10	R-0.75" 10	R-.625" 10	R-0.50" 10	R-0.25" 10
PKG. #3 (9" x 12")	10/26/97 6:00 p.m.	T = 20 ° C RH = 41 %	Flow Rate = 5 Sensitivity = 1 Prefill = N	URCU 10	URCD 10	R-1.0" 10	R-0.75" 10	R-.625" 10	R-0.50" 10	R-0.25" 10

Note: URCU = Unrestrained Chevron UP; URCD = Unrestrained Chevron Down; R = Restrained

Part C - CORRELATION BETWEEN BURST TEST AND PEEL TEST FOR POUCHES

Materials Tested:

1. Package #4 - Ethicon Endo Surgery
   (6" x 10") Plastic/Tyvek and Chevron Seal Pouch
   Plastic (2.5 mil) / Tyvek (6.8 mil)
   Seal Widths (A= 3.5/8", B and D = ½", E=3/8")

Test Methods:

1. ARO 2600 Burst and Creep Tester Operating Procedure
3. INSTRON Tensile Tester (Model 4201) Operating Procedure
4. ASTM F-88 – 94 *Standard Test Method for Seal Strength of Flexible Barrier Materials*

Equipment:

1. INSTRON Tensile Tester Machine - Model 4201
2. Test-A-Pack 2600 Burst Tester - Carleton Technologies - with the open package fixture.
3. Burst Test Aluminum Restraining Fixture (12" x 12" x ¾").
   (See Figure 11)
4. Stopwatch CASIO with sensitivity of .01 minute.

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Procedure:

According to Yam [22], the validity of the equation relating burst pressure and seal strength is based on the assumption that the peeling times for the peel test and the burst test are the same. He explained that the tensile peeling time is proportional to the elongation and inversely proportional to the crosshead speed; $t_p = (60 * \Delta L) / v$. t_p is the tensile peeling time, ΔL (in) is the elongation, v is the crosshead speed (in/min), and 60 is the factor used to convert from minutes to seconds. The tensile peeling time (t_p) changes as the crosshead speed in the INSTRON machine changes.

In order to find a crosshead speed to make the tensile peeling time equal to burst peeling time ($t_b = t_p$) the following equation was used: $t_b = t_p = (60 * \Delta L) / v$ in the form $v = (60 * \Delta L) / t_b$. The burst peeling time (t_b) was obtained from the burst test and ΔL is taken as 2w, twice the seal width, so it was possible to solve for v.

The assumption that $\Delta L = 2w$ was made because the elongation of the materials (Tyvek and plastic) was negligible when compared to the elongation of the seal at peak load. ΔL, is the elongation of the specimen during the peel test and w is the seal width. In order to verify that assumption, a tensile test for the Tyvek and plastic materials of the pouch and a peel test for the seal were performed and compared.

As described by Professor Kit Yam in his article [22], a restrained burst test was performed for all pouches. Three different gaps were used: 0.25", 0.50", and 1.0". The flow rate, which is the speed at which the air enters the package, was set at 1, 5, and 9 when testing the packages at each gap. The other two parameters were set at a specific value and kept constant (sensitivity = 1 and prefill = N). The time between initial pressurization and pouch bursting (t_b = burst peeling time), changed as the flow rate was d

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changed. The burst peeling time (t_b), burst pressure values, and the location of failure were recorded for each sample. The burst peeling time was measured using a stopwatch.

One-inch wide specimens were cut, according to ASTM F88 - 94, from four different pouch locations. See figure below.

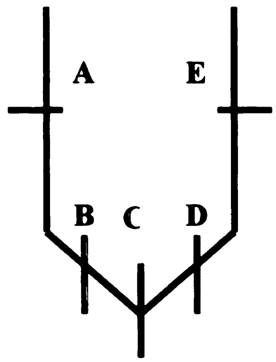


Figure 13. Pouch Seal Locations

The gauge length in the INSTRON machine was set to πR (R = plate separation divided by two) so that the area of the specimen acted upon by the tensile peel test was the same as the area acted upon by the burst test [22]. Since the gaps tested in this experiment were 0.25", 0.50", and 1.0", the gauge length used were 0.40", 0.80", and 1.60", respectively. The tensile peeling time (t_p), and the seal strength at peak (S) were recorded for each sample. The tensile peeling time was measured using a stopwatch.

The predicted burst pressure was calculated using the equation $P = (S/R)$ or $P = (2S/D)$; where P is the predicted burst pressure, S is the seal strength at peak obtained from the peel test, D is the plate separation, and R is half of the plate separation. The predicted burst pressure was compared with the experimental burst pressure.

Experimental Design:

See Table 5. Sampling Procedure for Pouches - Correlation Between Burst Test and Peel Test, next page.

Data Analysis:

The predicted values were calculated with the minimum and total seal strength. The predicted and observed results were plotted to see their agreement.

EXPERIMENTAL DESIGN

Table 5. Sampling Procedure for Pouches - Correlation Between Burst Test and Peel Test

BURST TEST

Gap Size	Day Start Time	Temperature & Relative Humidity	Carleton Test Parameters	Total Number of Samples Tested		
				Flow = 1	Flow = 5	Flow = 9
Gap = 1.0"	10/21/97 8:30 a.m.	T = 21 ° C RH = 43 %	Sensitivity = 1 Prefill = N	15	15	15
Gap = 0.50"	10/14/97 10:30 a.m.	T = 20 ° C RH = 41 %	Sensitivity = 1 Prefill = N	15	15	15
Gap = 0.25"	10/22/97 8:30 a.m.	T = 20.8 ° C RH = 42 %	Sensitivity = 1 Prefill = N	15	15	15

PEEL TEST

Gap Size	Day Time	INSTRON Gauge Length (inch)	Crosshead Speed (in/min) Total Number of Samples Tested		
			Corresponding to Flow = 1	Corresponding to Flow = 5	Corresponding to Flow = 9
Gap = 1.0"	10/21/97 3:00 p.m.	1.60"	v = .74 to .99 32 samples	v = 6.44 to 8.58 32 samples	v = 13.13 to 17.51 32 samples
Gap = 0.50"	10/16/97 4:00 p.m.	.80"	v = .66 to .88 32 samples	v = 5.47 to 7.29 32 samples	v = 11.74 to 15.65 32 samples
Gap = 0.25"	10/23/97 5:00 p.m.	.40"	v = .58 to .67 32 samples	v = 5.5 to 7.0 32 samples	v = 9.55 to 12.60 32 samples

Note: Eight (8) pouches were tested at four (4) locations each, for each gap size and flow parameter. So, (8 * 4) 32 samples in total.

CHAPTER 5. RESULTS & DISCUSSION

Even though blisters and pouches are different types of packages and required different fixtures to perform the tests, the obtained results were similar. As mentioned, in the literature review chapter, three behaviors were observed while testing blisters and pouches. Part A and Part B of this chapter are intended to discuss these three behaviors for the blisters and pouches, respectively.

Part A (for blisters) and Part B (for pouches) are both divided in three sections. In the first section the results show that unrestrained burst pressures are lower than restrained burst pressures. The second section will show results that demonstrate the package size effects and the plate separation or gap effects on the burst values. It was observed that the burst pressure required to break a package is inversely proportional to package size and plate separation (gap size). The third section of both parts provides a summary of the results obtained for the blisters and pouches, respectively.

Part C, show the results of an experiment that was performed with a different pouch than the one used in Part B. The purpose of this experiment was to correlate burst and peel test. The formulas used and the procedure followed were based on Professor Kit Yam's research, published in 1993 [22]. A summary of the results obtained in this experiment is provided at the end of Part C.

The results were analyzed statistically for significant differences between the means using one-way and two-way analysis of variance (ANOVA). Generally a log transformation of the data helps to stabilize the variances. The ANOVAs were run for both, the raw data and for the logged data. The analysis of residuals for each ANOVA showed somewhat improved conformance to normality for the logged data. The ANOVA results were essentially the same in regard to significance and we report only the results of ANOVAs performed on the raw data. A comparison between the variances and the coefficients of variation of the raw data was performed for each experiment. These results are reported following the ANOVA results on each section. Statistical significance is determined at the $\alpha = 0.05$ level unless otherwise noted.

PART A - BLISTERS:

I. UNRESTRAINED VS RESTRAINED BURST TEST RESULTS

The main purpose of this section is to compare unrestrained with restrained burst test results and to show how unrestrained burst pressures are lower than the burst pressures obtained when using a restraining fixture. Even though the package size effects will be discussed in section II, the results in this section also point out how the burst values within the unrestrained mode and within the restrained mode vary inversely proportional with package size.

UNRESTRAINED RESULTS:

Table 6. Unrestrained Results for Blisters

PKG #	n	Avg. (in. H_2O)	Std Dev	C. of Var (%)	Min	Max	Range	Burst/Perimeter (Burst/inch)
1	50	121.4	10.21	8.41	95.0	147.4	52.4	9.0
2	50	73.1	3.63	4.97	64.1	82.1	18.0	3.7
3	50	39.0	2.68	6.87	31.2	44.3	13.1	1.4
4	50	38.4	1.91	4.97	33.9	42.4	8.5	1.2

One (1) variable: Package Configuration
Seal Perimeter Package #1 = 13.5"
Seal Perimeter Package #2 = 20.0"
Seal Perimeter Package #3 = 27.5"
Seal Perimeter Package #4 = 33.0"

It can be seen from the table above that the average burst values vary inversely with the package size. The smaller package has a higher burst value than the bigger package.

Table 7. Unrestrained Burst Test for Blisters
ANOVA One-way analysis - Package Size Effect

Source Of Variation	Degrees of Freedom	Sum of Squares	Mean Square	$F_{calculated}$	$F_{critical}$	p_{value}	Conclusion
PKG Size	3	229432	76477	2386.46	2.6507	0.000	PKG Size Effect
Error	196	6281.1	32	---	---	---	---
Total	199	235713	---	---	---	---	---

The one-way analysis of variance in the table above shows statistically significant differences between package size. So, **package size affects the unrestrained average burst test values.**

The *t*-test comparison of PKG #3 and PKG #4 resulted in a p value = 0.20. Therefore, packages 3 and 4 are not statistically different from each other in an unrestrained burst test. All other *t*-test results showed significant differences, so packages 1 and 2 are different from each other and from packages 3 and 4. Differences in shape and angles in the four types of blisters or trays could be responsible for these results.

RESTRAINED RESULTS:

Table 8. Restrained Results for Blisters

PKG #	n	Avg. (in. H_2O)	Std Dev	C. of Var (%)	Min	Max	Range	Burst / Perimeter (Burst/inch)	Gap (in)
1	50	153.7	10.72	6.97	128.4	190.7	62.3	11.4	.14
2	50	113.2	8.37	7.39	84.1	135.0	50.9	5.7	.20
3	50	114.5	7.40	6.46	98.6	131.9	33.3	4.2	.15
4	50	86.8	3.56	4.10	76.5	94.0	17.5	2.6	.01

Two variables: Package Configuration and Gap Height. The variables cannot be separated for statistical analysis because the experiment design does not allow it.
Seal Perimeter Package #1 = 13.5"
Seal Perimeter Package #2 = 20.0"
Seal Perimeter Package #3 = 27.5"
Seal Perimeter Package #4 = 33.0"

In this case it is not possible to estimate the package effect and the gap effect individually because the two variables are changing at the same time.

The *t*-test comparison of PKG #2 and PKG #3 resulted in a p value = 0.41. Therefore, packages 2 and 3 are not statistically different from each other in a restrained burst test. All other *t*-test results showed significant differences. Because the gap and package size were confounded, valid analysis for gap and size was impossible. Therefore, another experiment was designed, and the analysis of this one is reported on page 55.

COMPARISON BETWEEN UNRESTRAINED & RESTRAINED RESULTS:

A two-way analysis of variance was performed for each package configuration to see the effect of test method (unrestrained Vs restrained) and day on the results. We found statistical evidence of differences between test methods and no statistical evidence that days affected the burst test values. For all reported analyses we pool the samples from the separate days for each package.

Table 9. Restrained Vs Unrestrained Results for Blisters

PKG Configuration	n	Unrestrained Average (in. H_2O)	Restrained Average (in. H_2O)	Ratio
PKG #1 Accessories	50	121.4	153.7	1.3
PKG #2 Thera Small Outer IPG	50	73.1	113.2	1.6
PKG #3 Standard Leads Outer	50	39.0	114.5	2.9
PKG #4 Myocardial Leads Outer	50	38.4	86.8	2.3

Table 9, above, shows that, at each package configuration, restrained average burst pressures are higher than unrestrained average burst pressures.

Table 10. Overall Package Size and Test Method Effect on Burst Test Results for Blisters - ANOVA Two-way Analysis

Source of Variation	Degrees of Freedom	Sum of Squares	Mean Square	$F_{calculated}$	$F_{critical}$	p value	Conclusion
PKG Size	3	317044	105681	2229.6	2.63	0.000	PKG Size Effect
Test Method	1	240850	240850	5081.2	3.87	0.000	Test Method Effect
Interaction	3	26384	8794.6	185.54	2.63	0.000	Interaction Effect
Error	392	18576	47.4	---	---	---	---
Total	399	602854	---	---	---	---	---

The two-way analysis of variance in the table above shows strong statistical evidence of differences between packages and test methods. **So, in general, test methods and package size, both affect the average burst test results.** This analysis also demonstrated an interaction between package and test method, but interaction accounted for a relatively small percentage of the variation.

Figure 14, next page, shows the relationship between average unrestrained and restrained burst test values Vs package seal perimeter (package size). It can be seen from this figure that within the restrained testing mode, the burst pressure decreases as the seal perimeter increases. The same behavior was observed when the package was tested in an unrestrained mode. This figure also shows that restrained burst pressure was higher than the unrestrained burst pressure for all package sizes.

Figures 15 and 16, in the following pages, present box plots of the burst pressure for four different package sizes for unrestrained and restrained burst test, respectively. These plots indicate that an increase in package seal perimeter produce a lower unrestrained burst pressure. These box plot also shows the variability of the unrestrained burst pressure within each package size (seal perimeter) as well as the variability between different package sizes. It can be seen in both figures that the distribution of unrestrained burst pressure at a particular package size is reasonably symmetrical, and the variability in unrestrained burst pressure appears to be higher for the smaller packages than for the bigger ones. Also, variability seems to be greater for restrained than for unrestrained. Tables 11 and 12 summarize the analysis for variances and coefficients of variation.

Figure 14. Average Unrestrained and Restrained Burst Pressure Vs. Package Seal Perimeter for Blisters

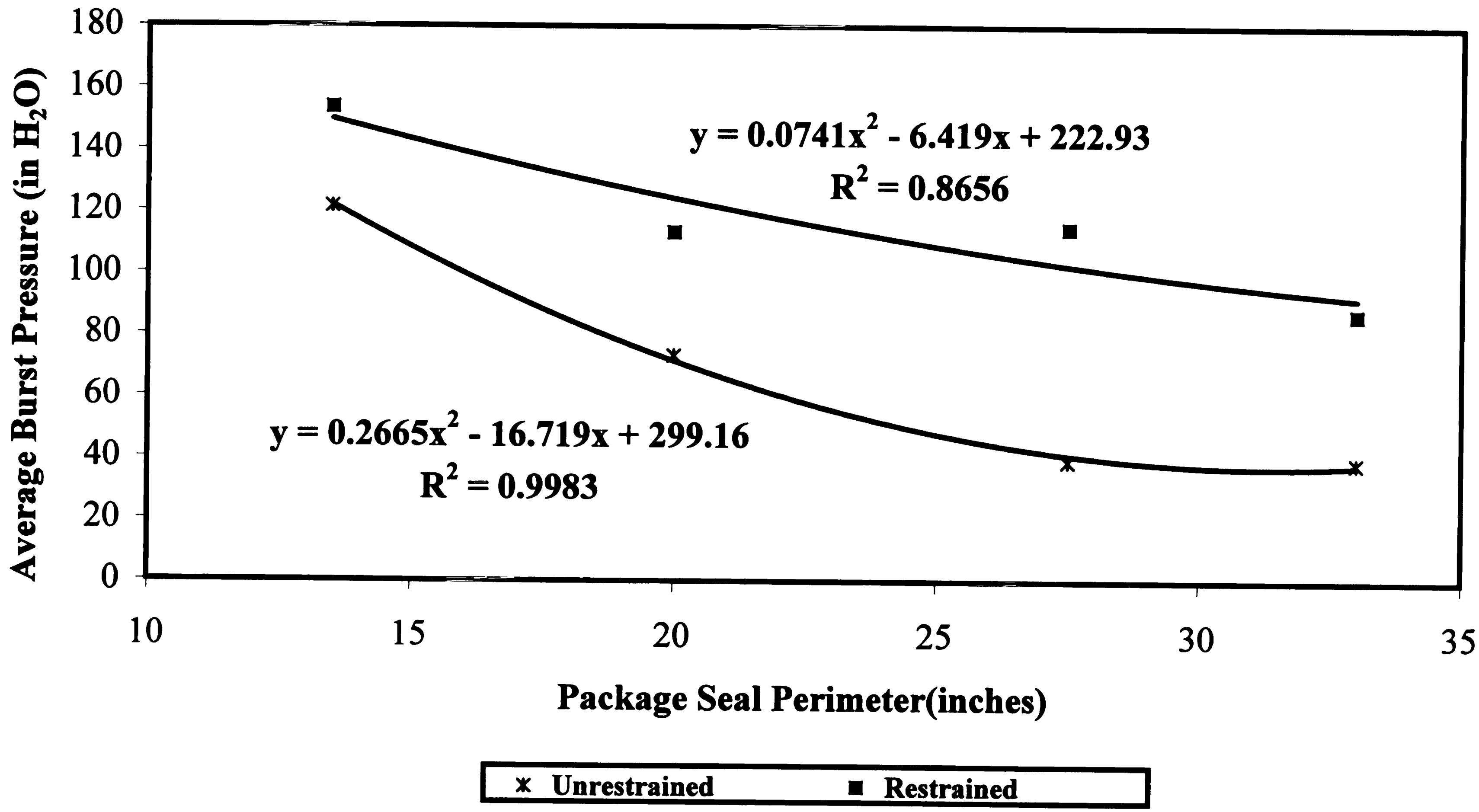


Figure 15. Unrestrai

Figure 15. Unrestrained Burst Pressure Vs. Package Seal Perimeter for Blisters

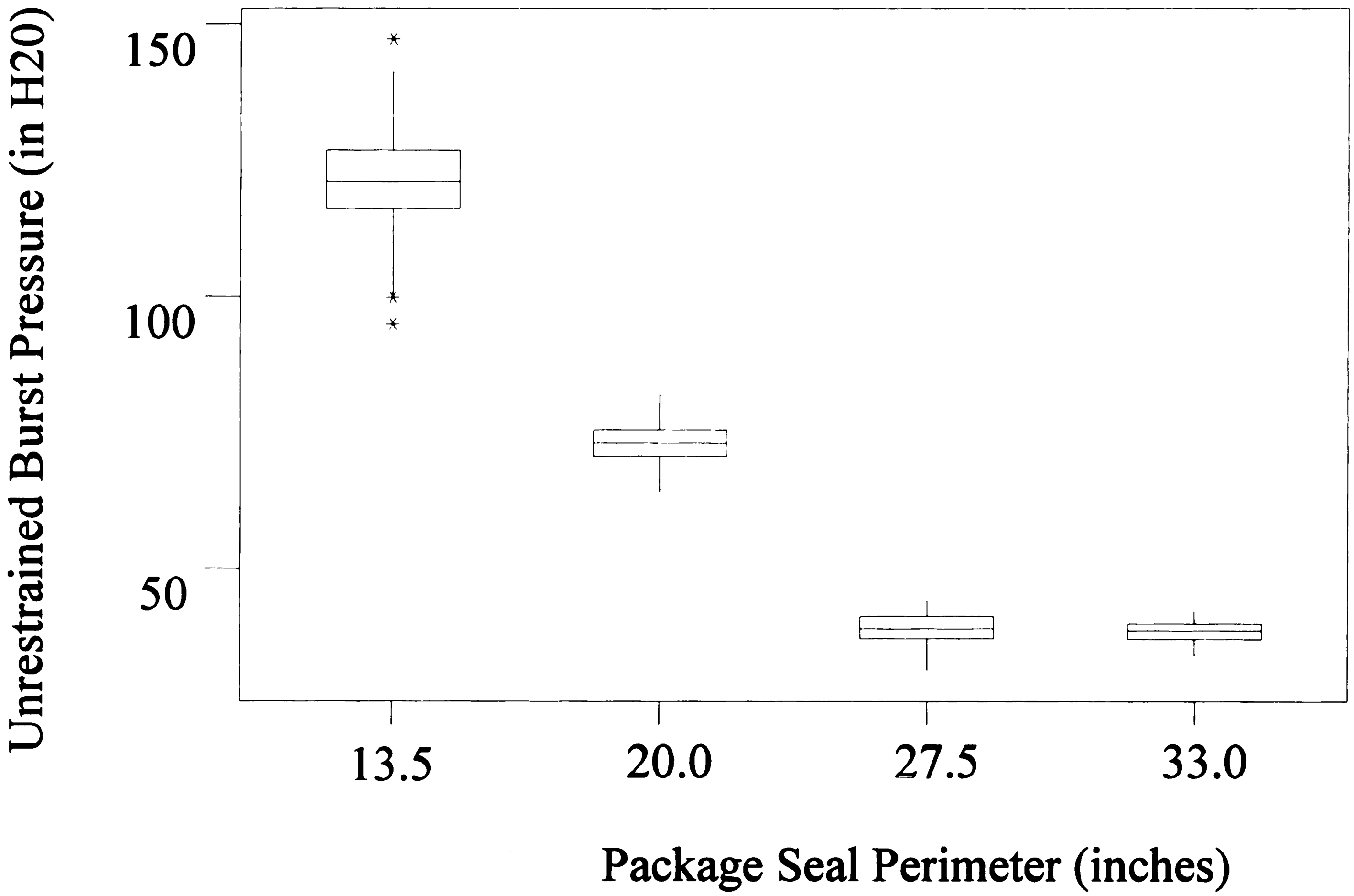
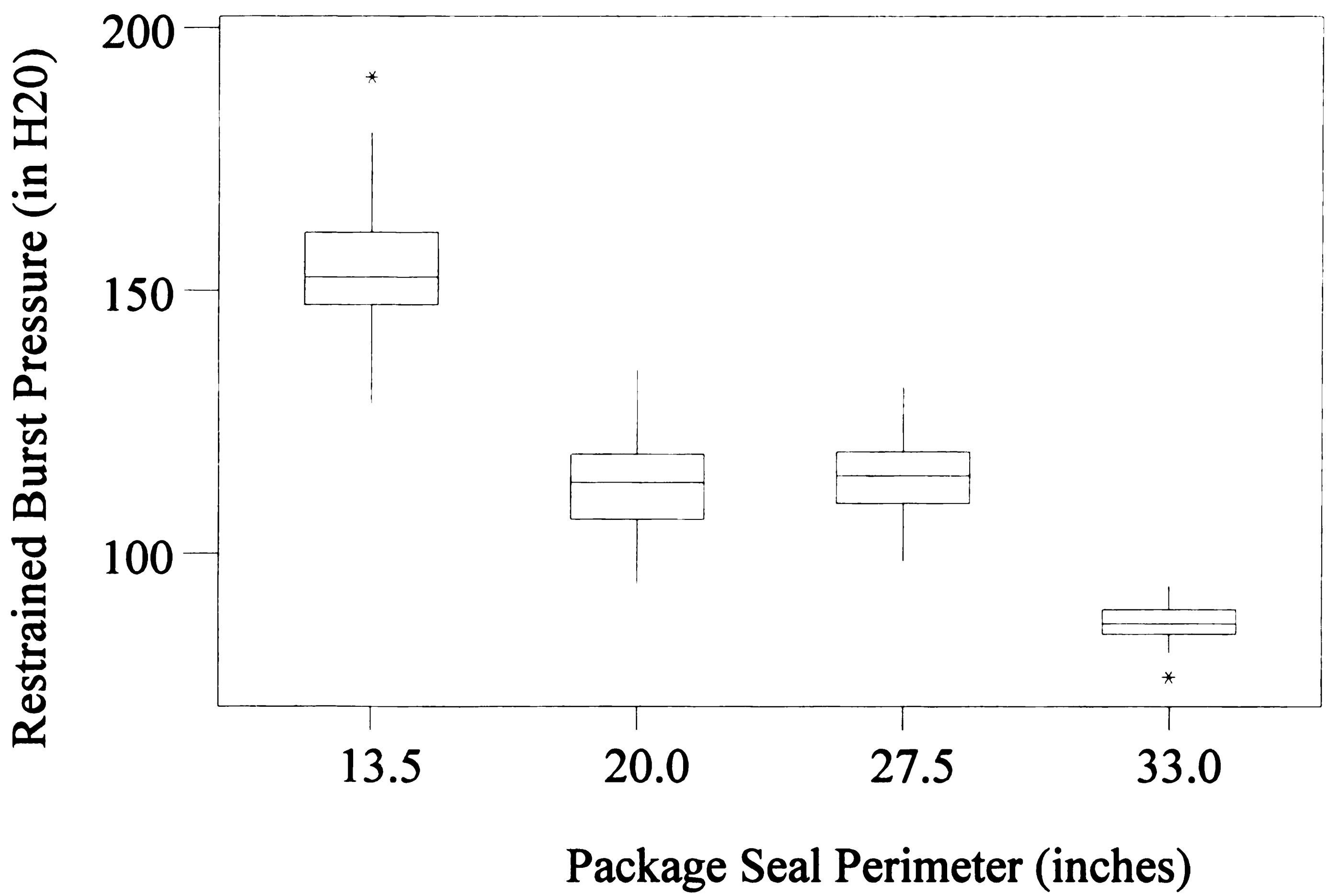


Figure 16. Restrained Burst Pressure Vs. Package Seal Perimeter for Blisters



COMPARISON BETWEEN VARIANCES:

Table 11. Test for equality of two variances for Blisters (F- test for Unrestrained Vs Restrained)

Package	Unrestrained (Variance)	Restrained (Variance)	F-Ratio	p-value
1	104.24	114.92	1.10	7.34E-01
2	13.18	70.06	5.32	3.28E-08
3	7.18	54.76	7.62	4.76E-11
4	3.65	12.67	3.47	2.58E-05

The F-ratio was calculated dividing the higher variance over the lower variance. The calculated two-sided p values were compared against 0.05. It can be seen in the table above that the variances for packages #2, #3, and #4 are statistically different. For all cases, the restrained variances are higher than the unrestrained variances.

COMPARISON BETWEEN COEFFICIENTS OF VARIATION:

Table 12. Comparison between Coefficients of Variation for Blisters (Unrestrained Vs. Restrained)

Package #1

Test Mode	Standard Deviation	Average (in. H_2O)	Coeff. Of Variation	Standard Error (CV)
Unrestrained	10.21	121.40	8.41	0.8469
Restrained	10.72	153.70	6.97	0.7008
Comparing	**Difference in CVs**	**Std Error (Difference)**	**Z-ratio**	**p-value**
UR & R	1.44	1.10	1.31	0.19

Package #2

Test Mode	Standard Deviation	Average (in. H_2O)	Coeff. Of Variation	Standard Error (CV)
Unrestrained	3.63	73.10	4.97	0.4978
Restrained	8.37	113.20	7.39	0.7434
Comparing	**Difference in CVs**	**Std Error (Difference)**	**Ratio**	**p-value**
UR & R	2.43	0.89	2.71	0.01

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Table 12. Comparison between Coefficients of Variation for Blisters (Unrestrained Vs. Restrained) Continuation

Package #3

Test Mode	Standard Deviation	Average (in. H_2O)	Coeff. Of Variation	Standard Error (CV)
Unrestrained	2.68	39.00	6.87	0.6904
Restrained	7.40	114.50	6.46	0.6490
Comparing	**Difference in CVs**	**Std Error (Difference)**	**Ratio**	**p-value**
UR & R	0.41	0.95	0.43	0.67

Package #4

Test Mode	Standard Deviation	Average (in. H_2O)	Coeff. Of Variation	Standard Error (CV)
Unrestrained	1.91	38.40	4.97	0.4986
Restrained	3.56	86.80	4.10	0.4108
Comparing	**Difference in CVs**	**Std Error (Difference)**	**Ratio**	**p-value**
UR & R	0.87	0.65	1.35	0.18

In order to compare coefficients of variation we used the standard errors of each coefficient of variation [16] and the root mean square formula to determine the standard error of the difference. The difference in coefficients of variation was calculated as the higher coefficient of variation minus the lower coefficient of variation. The statistical significance was determined using the standardized difference called the Z-ratio and standard normal distribution. The obtained two-sided p values were compared against 0.05. It can be seen from the table above that package #2 was the only one that shows statistical difference between the coefficients of variation. The coefficient of variation for package #2 for the restrained case is higher than the coefficient of variation for the unrestrained case.

II. PACKAGE SIZE AND GAP SIZE EFFECT

The results that will be shown in this section will demonstrate the effects of changing the package (blister) and gap size on the burst pressure. It will be seen that both, package size and gap size, vary inversely proportionally with burst pressure.

GENERAL RESULTS:

Table 13. Restrained Results for Blisters – Package Size and Gap Size Effects

Package #1 Accessories Package (P/N 119401-001)

Gap Size (in.)	n	Avg. (in.H_2O)	Std Dev	Coeff. of Var. (%)	Min	Max	Range	Burst per Perimeter (Burst/Inch)
0.20	24	124.10	8.41	6.78	109.30	139.90	30.60	9.19
0.10	24	151.93	11.16	7.34	125.00	170.70	45.70	11.25
0.01	24	235.70	13.56	5.75	214.20	265.20	51.00	17.46

Seal Perimeter = 13.5 inch

Package #2 Thera Small Outer Package (P/N 119679-001)

Gap Size (in.)	n	Avg. (in.H_2O)	Std Dev	Coeff. Of Var (%)	Min	Max	Range	Burst per Perimeter (Burst/Inch)
0.20	24	104.07	8.00	7.65	85.50	116.90	31.40	5.24
0.10	24	130.63	5.19	3.97	120.20	139.70	19.50	6.53
0.01	24	157.77	4.55	2.88	150.60	164.70	14.10	7.89

Seal Perimeter = 20.0 inch

It can be seen from Table 13 that average burst values vary inversely with the gap size. Smaller gaps produce higher burst values. Also, it can be noticed that the average burst value at any gap size is different for different package geometries. The smaller package (seal perimeter) has a higher average burst value than the bigger package.

STATISTICAL RESULTS:

A two-way analysis of variance was performed for each package configuration to see the effect of gap and day on the results. We found statistical evidence of differences between the gap sizes. On the other hand we found no statistical evidence that days affected the burst test values. For all reported analyses we pool the samples from the separate days for each package.

Overall Package and Size Effects

Table 14. Overall Package Size and Gap size Effect on Burst Test Results For Blisters - ANOVA Two way Analysis

Source of Variation	Degrees of Freedom	Sum of Squares	Mean Square	$F_{calculated}$	$F_{critical}$	p value	Conclusion
PKG Size	1	56894	56894.2	695.53	3.91	0.000	PKG Size Effect
Gap Size	2	170359	85179.3	1041.3	3.06	0.000	Gap Size Effect
Interaction	2	26236	13118.0	160.37	3.06	0.000	Interaction Effect
Error	138	11292	81.8	---	---		---
Total	143	264781	---	---	---		---

This two-way analysis of variance shows strong **statistical evidence of difference in average burst value between packages and among gap sizes.** This analysis also shows an interaction between package and gap sizes.

Figure 17, next page, shows the relationship between burst pressure and gap size. It can be seen from this figure that for both packages the burst pressure decreased as the gap size increased. This figure also shows that package #1 with a seal perimeter of 13.5 inches required higher burst pressure to break than package #2, which has a seal perimeter of 20.0 inches. So, burst pressure varies inversely proportionally with package and gap size.

Figures 18 and 19, on the following pages, presents box plots of the burst pressure at three different gaps for packages #1 and #2, respectively. These plots indicate than an increase in gap size produces lower burst pressures. These box plots also show information about the variability within and between gap sizes. The distribution of burst pressure at a particular gap, for package #1, was reasonably symmetrical for gaps 0.10" and 0.20". Also, the variability that was found at each gap was very similar. For package #2, the distribution of burst pressure at a particular gap was reasonably symmetrical for gaps 0.01" and 0.10". The variability that was found at gap = 0.20" was greater than for the other two gaps. Also see Tables 15, 16 and 17.

Figures 20, 21, and 22 are also box plots but presented in a different way: burst pressure Vs. package seal perimeter at gaps 0.20", 0.10", and 0.10", respectively. These plots provide information about variability within and between different package sizes. The three figures show that, for the three gaps, the distribution of burst pressure within a certain package size was reasonably symmetrical. The variability between package sizes differed more at gaps 0.10" and 0.01". Also see Tables 15, 16 and 17.

Figure 17. Average Burst Pressure Vs. Gap Size for Blisters

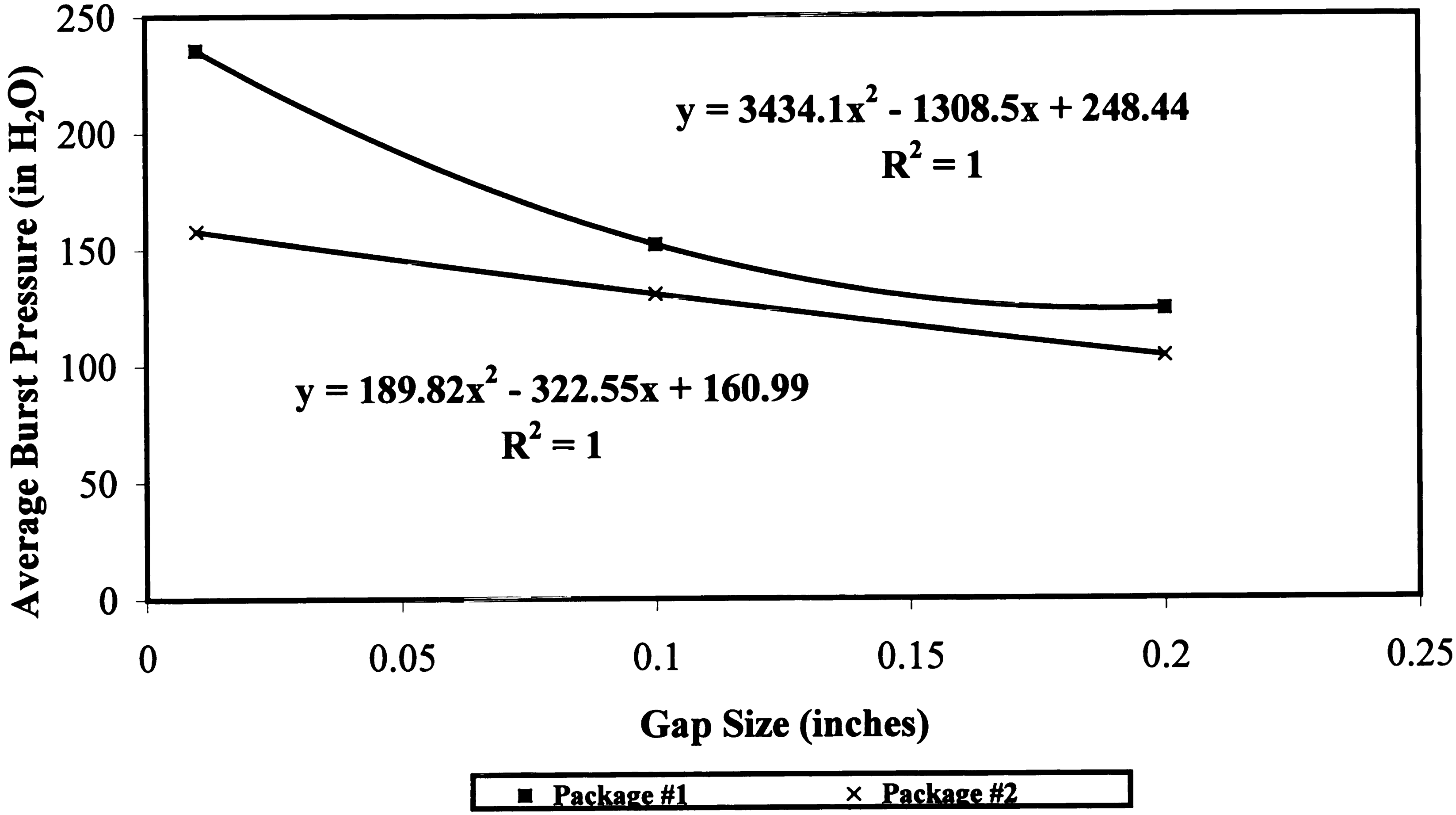


Figure 18.Burst Pressure Vs. Gap Size for Blisters - Package #1

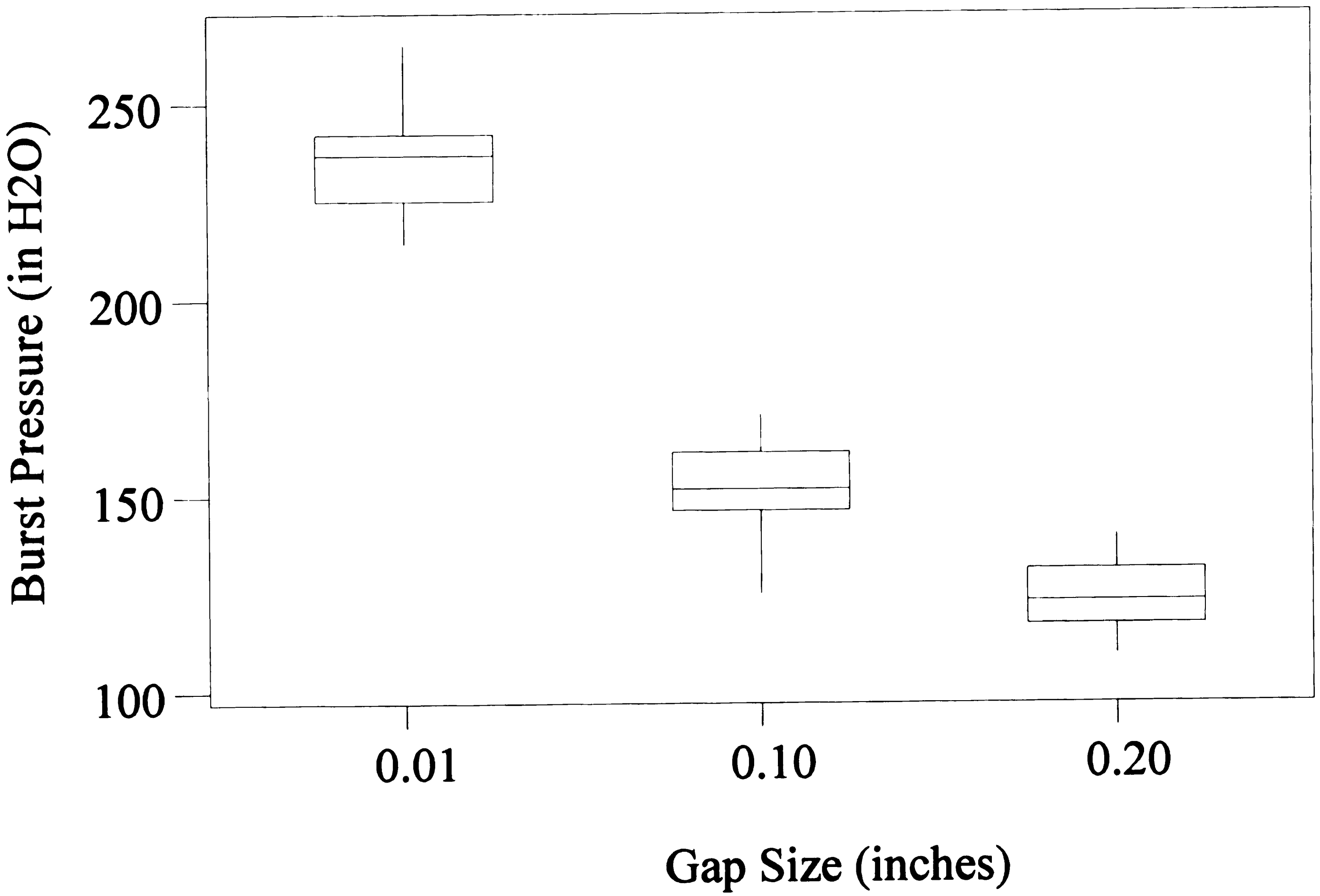


Figure 19. Burst Pressure Vs. Gap Size for Blisters - Package #2

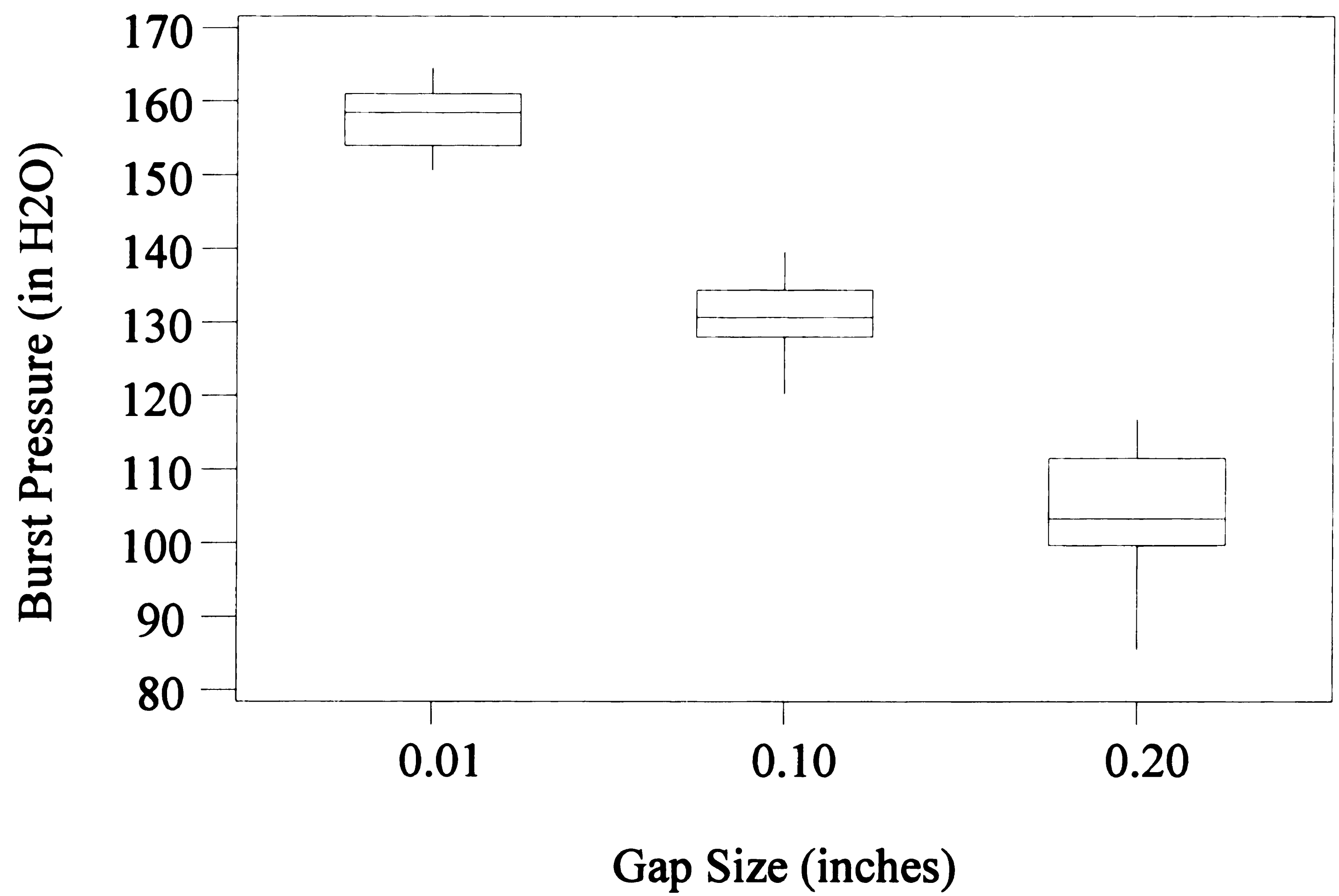


Figure 20. Burst Pressure Vs. Package Seal Perimeter for Blisters - Gap = 0.20"

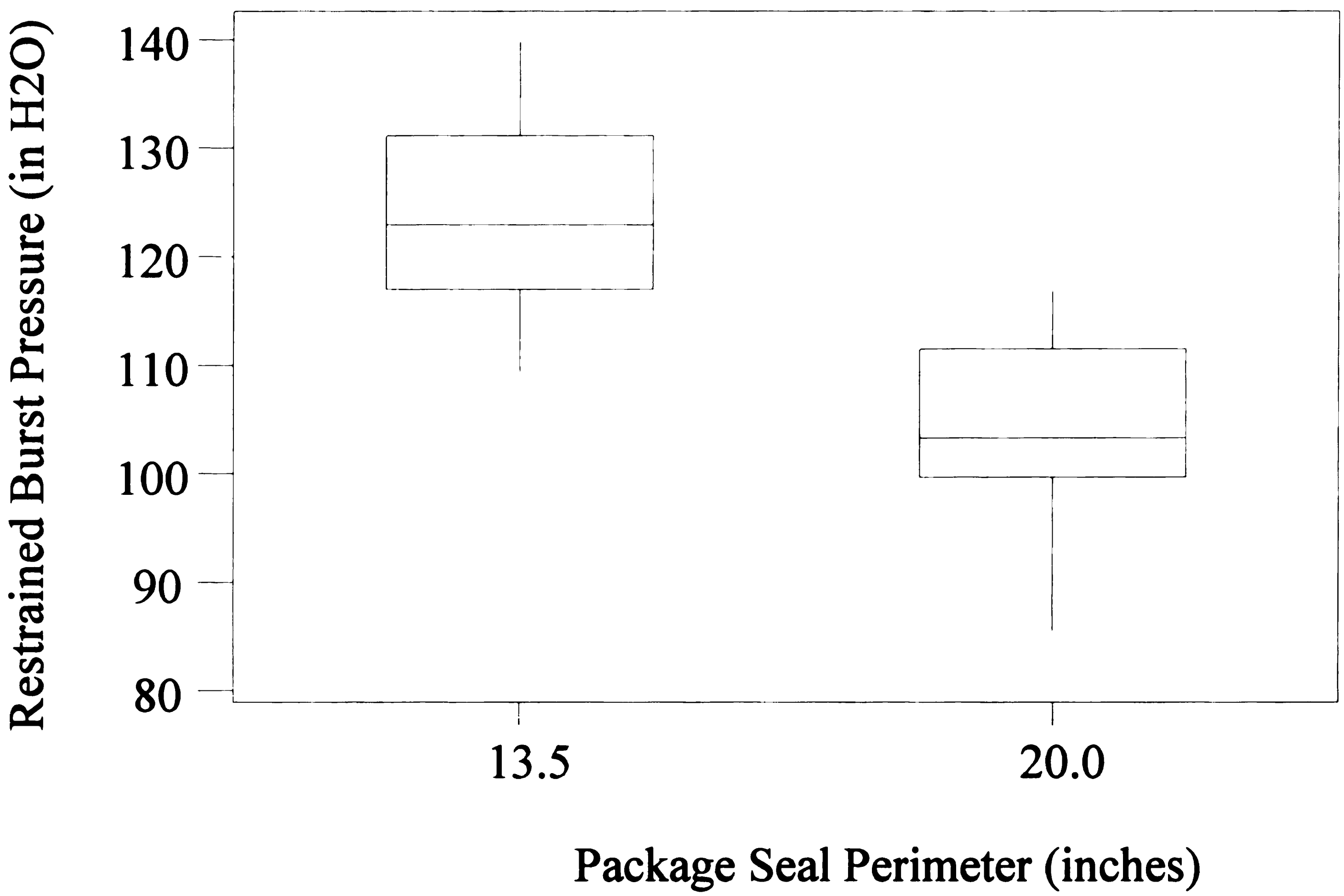


Figure 21. Burst Pressure Vs. Package Seal Perimeter - Gap = 0.10"

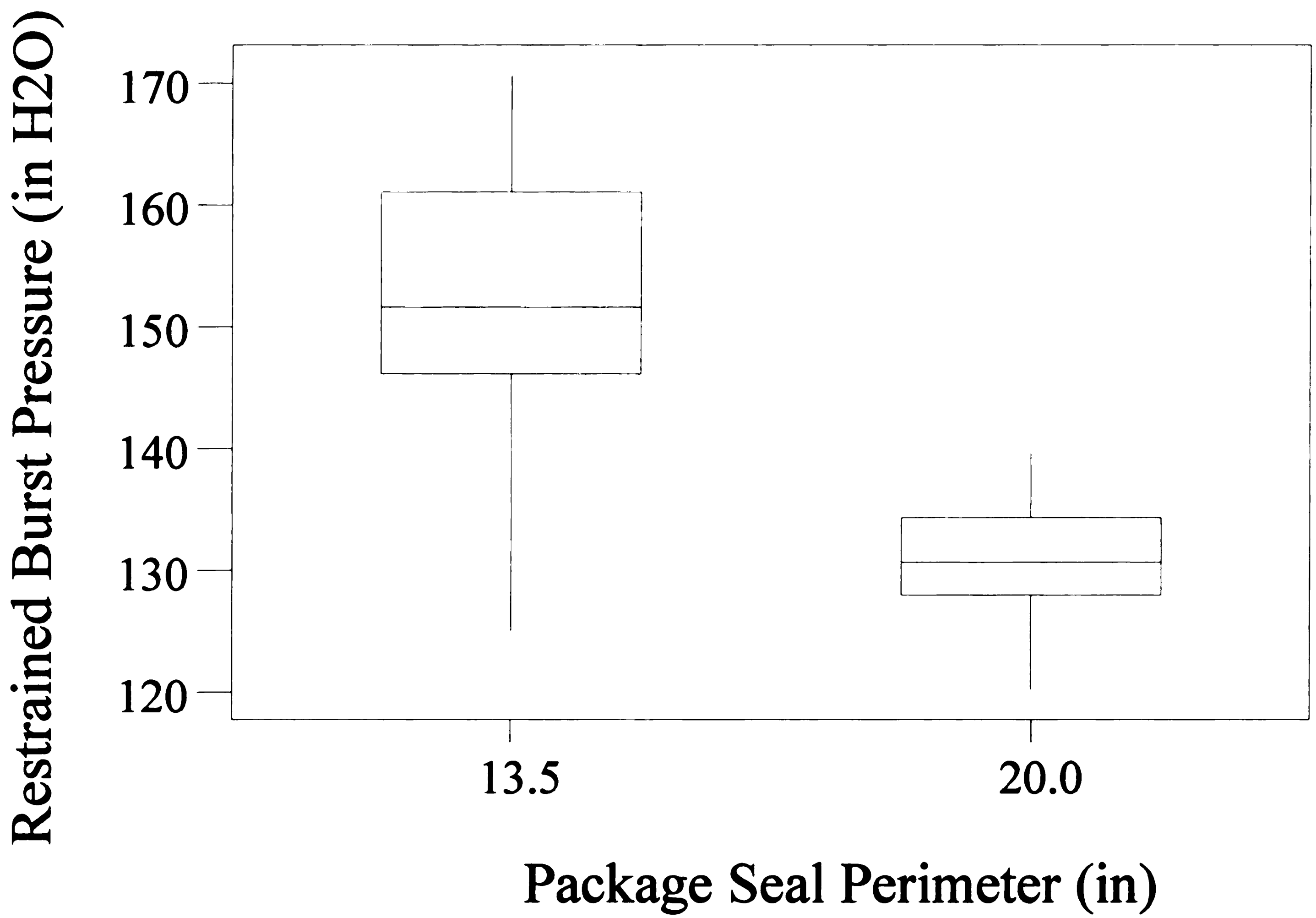
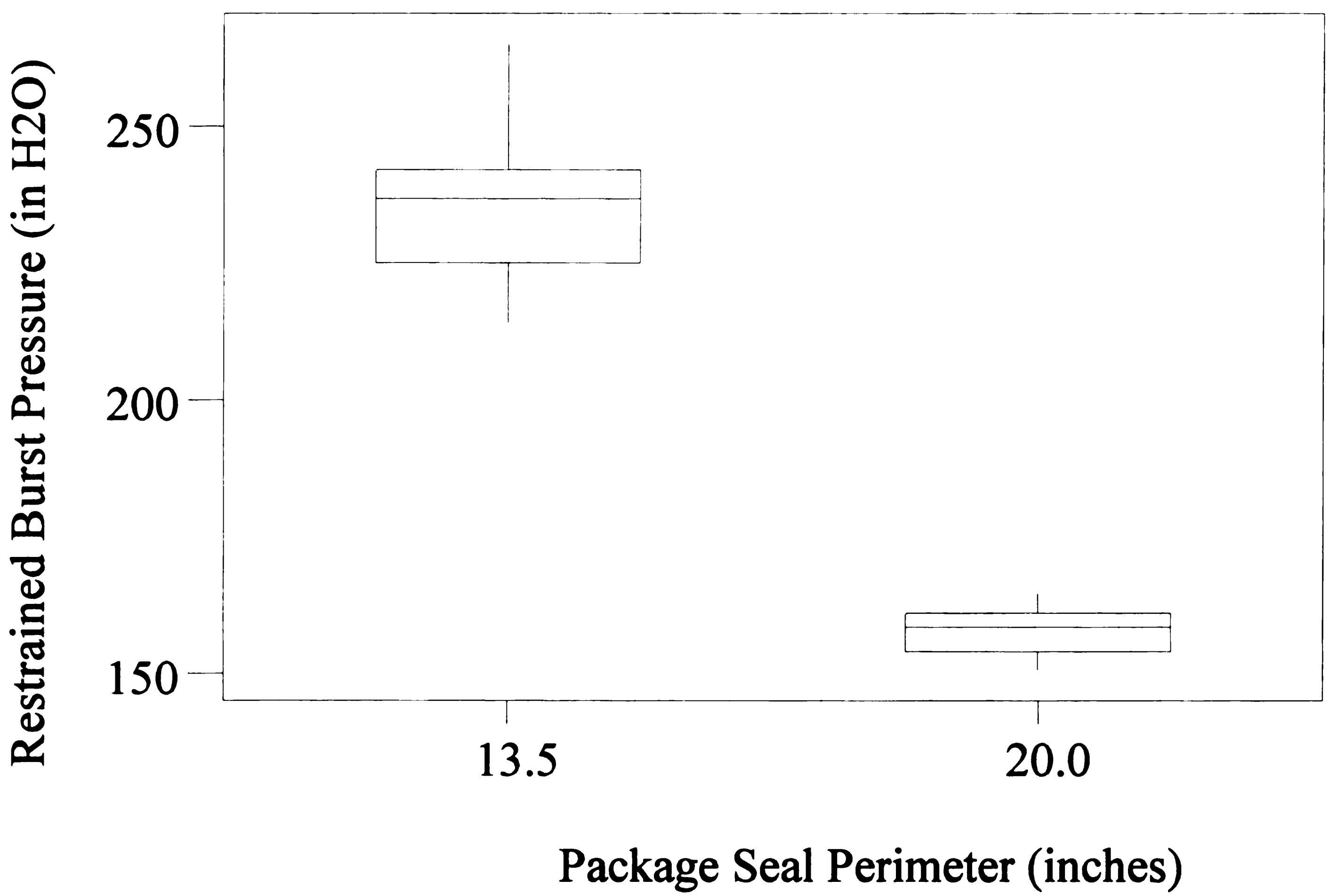


Figure 22. Burst Pressure Vs. Package Seal Perimeter for Blisters - Gap = 0.01"



COMPARISON BETWEEN VARIANCES:

Table 15. Comparison between Variances for Blisters Package Size and Gap Size Effects (Bartlett's Test for Homogeneity of Variances)

Package #1

Gap (inches)	Standard Deviation	Variance	ln (Variance)	Chi-Square	p-value
0.20	8.41	70.73	4.26	5.06	7.95E-02
0.10	11.16	124.55	4.82		
0.01	13.56	183.87	5.21		
	Average	**126.38**	**4.77**		

Package #2

Gap (inches)	Standard Deviation	Variance	ln (Variance)	Chi-Square	p-value
0.20	8.00	64.00	4.16	8.45	1.46E-02
0.10	5.19	26.94	3.29		
0.01	4.55	20.70	3.03		
	Average	**37.21**	**3.49**		

The Bartlett's test for homogeneity of variances [16] is suggested when there are more than two groups of variances to be compared. With this test an overall comparison between the variances can be done. When comparing the obtained p value with 0.05 it can be seen that there is no statistical difference between the variances coming from different gaps for package #1. On the other hand, there are statistical differences between variances for package #2.

Table 16. Pairwise Comparisons of Variances for Blisters (Package Size and Gap Size Effects)

Package #1

Variance at Gap = 0.20"	**Variance at Gap = 0.10"**	**Variance at Gap = 0.1"**
70.73	124.55	183.87
Pairwise Comparisons	**F-Ratio**	**p-value**
0.20 & 0.10	1.76	0.18
0.20 & 0.01	2.60	0.03
0.10 & 0.01	1.48	0.36

Package #2

Variance at Gap = 0.20"	**Variance at Gap = 0.10"**	**Variance at Gap = 0.1"**
64.00	26.94	20.70
Pairwise Comparisons	**F-Ratio**	**p-value**
0.20 & 0.10	2.38	0.04
0.20 & 0.01	3.09	0.01
0.10 & 0.01	1.30	0.53

The F-ratio was calculated dividing the higher variance over the lower variance. For multiple pairwise comparisons of k treatments, p values less than [0.05/(k*(k-1)/2)] were regarded as significant, the Bonferroni approach to multiple comparisons. For our application k = 3 so the critical p value is .05/3 = 0.017. The obtained p value was compared against 0.017. It can be seen in the table above that in package #2 the comparison between gap 0.20" and gap 0.01" show a p value lower than the critical value (0.017).

COMPARISON BETWEEN COEFFICIENTS OF VARIATION:

Table 17. Pairwise Comparisons of Coefficients of Variation for Blisters (Package Size and Gap Size Effects)

Package #1

Gap (inches)	Standard Deviation	Average (in. H_2O)	Coeff. Of Variation	Standard Error (CV)
0.20	8.41	124.10	6.78	0.9826
0.10	11.16	151.93	7.35	1.0659
0.01	13.56	235.70	5.75	0.8331
Comparing Pairs	**Difference in CVs**	**Std Error (Difference)**	**Z-ratio**	**p-value**
0.20 & 0.10	0.57	1.45	0.39	0.6949
0.20 & 0.01	1.02	1.29	0.79	0.4268
0.10 & 0.01	1.59	1.35	1.18	0.2392

Package #2

Gap (inches)	Standard Deviation	Average (in. H_2O)	Coeff. Of Variation	Standard Error (CV)
0.20	8.00	104.07	7.69	1.1161
0.10	5.19	130.63	3.97	0.5744
0.01	4.55	157.77	2.88	0.4166
Comparing	**Difference in CVs**	**Std Error (Difference)**	**Z-ratio**	**p-value**
0.20 & 0.10	3.71	1.26	2.96	0.0031
0.20 & 0.01	4.80	1.19	4.03	0.0001
0.10 & 0.01	1.09	0.71	1.53	0.1248

In order to compare coefficients of variation we used the standard errors of each coefficient of variation [16] and the root mean square formula to determine the standard error of the difference. The differences in coefficients of variation were calculated as the higher coefficient of variation minus the lower coefficient of variation. The statistical significance was determined using the standardized difference called the Z-ratio and standard normal distribution.

For multiple comparisons of k = 3 treatments p-values less than 0.017 were regarded as significant, the Bonferroni approach to multiple comparisons. For package #2, the pair comparison between gap 0.20" and 0.10", and between 0.20" and 0.01" show a p value lower than 0.017.

III. SUMMARY OF THE RESULTS FOR BLISTERS:

1. Restrained burst test pressures are higher than unrestrained burst test pressures.
2. The burst value varies inversely with the gap size. Smaller gaps produce higher burst values.
3. In general, the package with smaller seal perimeter produces higher burst pressures than the bigger packages. This behavior is also true for the restrained burst test method. The burst value at any gap size is higher for smaller packages than for bigger packages.
4. There was no pattern in the difference in variation between restrained and unrestrained burst tests:
   a. There is statistical difference in raw variances between restrained and unrestrained burst test for packages #2, #3, and #4. For all cases the restrained variances are higher than the unrestrained variances.
   b. There is no statistical difference in coefficients of variation between restrained and unrestrained burst test for packages #1, #3, and #4. Package #2 was the only one that shows statistically significant difference between coefficients of variation. For package #2 the restrained coefficient of variation is higher than the coefficient of variation for the unrestrained case.
5. There was no pattern in the difference in variation between gaps:
   a. There is statistically significant difference in raw variance and coefficients of variation between gaps for package #2. No statistical difference, in raw variance and coefficients of variation, between gaps was found for package #1. Differences in shape and geometry can explain this gap effect on variation.

PART B – POUCHES:

As mentioned before, the first section of Part B is intended to compare unrestrained and restrained burst test results. In section II package size and gap size effects will be studied. The last section of this chapter consists of a summary of the results obtained for pouches.

I. UNRESTRAINED VS RESTRAINED BURST TEST RESULTS

UNRESTRAINED RESULTS:

Table 18. Unrestrained Results for Pouches

Unrestrained Chevron Up

PKG #	n	Average (in. H_2O)	Std Dev	C. of Var (%)	Min	Max	Range	Burst per Perimeter (Burst/inch)
1	20	59.69	9.73	16.30	43.00	77.30	34.30	3.62
2	20	45.65	11.51	25.21	31.40	65.60	34.20	2.40
3	20	41.55	6.85	16.49	26.20	49.90	23.70	1.93

Unrestrained Chevron Down

PKG #	n	Average (in. H_2O)	Std Dev	C. of Var (%)	Min	Max	Range	Burst per Perimeter (Burst/inch)
1	20	48.74	10.49	21.52	38.30	69.80	31.50	2.95
2	20	45.77	14.15	30.92	29.80	65.70	35.90	2.41
3	20	43.32	5.52	12.74	33.80	50.80	17.00	2.01

Seal Perimeter Package #1 = 16.5"
Seal Perimeter Package #2 = 19.0"
Seal Perimeter Package #3 = 21.5"

It can be seen from the table above that the average burst values vary inversely with the package size. The smaller package has a higher burst value than the bigger package.

Table 19. Overall Package Size and Chevron Effect in Unrestrained Burst Test Results for Pouches - ANOVA Two-way Analysis

Source of Variation	Degrees of Freedom	Sum of Squares	Mean Square	$F_{calculated}$	$F_{critical}$	p value	Conclusion
PKG Size	2	2957	1479	14.50	3.08	0.000	PKG Size Effect
Chevron Effect	1	274	274	2.69	3.92	0.104	No Chevron Effect
Interaction	2	958	479	4.70	3.08	0.011	Interaction Effect
Error	114	11681	102	---	---	---	---
Total	119	15871	---	---	---	---	---

The two-way analysis of variance in the table above shows strong statistical evidence of differences between packages. On the other hand, no statistical evidence of difference between chevron up and chevron down was found. **So, in general, package size affects the average burst test results and the way the chevron is positioned does not.** This analysis also demonstrated a weak interaction between package and chevron position but interaction accounted for a relatively small percentage of the variation.

Figure 23, shows the relationship between unrestrained burst test values Vs package seal perimeter. This figure shows that as the package seal perimeter increases the unrestrained burst pressure decreases. It also shows that for package #1, with seal perimeter 16.5", there was a difference in burst pressure between chevron up and chevron down. On the other hand, no difference was found between chevron up and chevron down for packages #2 and #3. A possible reason for the difference in results could be because packages, when tested unrestrained, do not deform in the same way each time. It is possible that during this test package #1 varied more in deformation than the other two packages. This could be the source of the weak interaction effect found in the analysis of variance

Figures 24 and 25, on the following pages, are box plots which present unrestrained burst pressure Vs. package seal perimeter for chevron up and chevron down, respectively. In both cases it can be seen that as the package seal perimeter increased the unrestrained burst pressure decreased. Both plots show that package #2 (seal perimeter = 19.0") was the one with higher variability and package #3 (seal perimeter 21.5") the one with lower variability. When comparing both figures it can be seen that there is not much difference between the two, meaning that there is not much difference in variability due to chevron effects. Tables 23 to 26 summarize the analyses for the variances and coefficients of variation.

Figure 23. Average Unrestrained Burst Pressure Vs. Package Seal Perimeter for Pouches

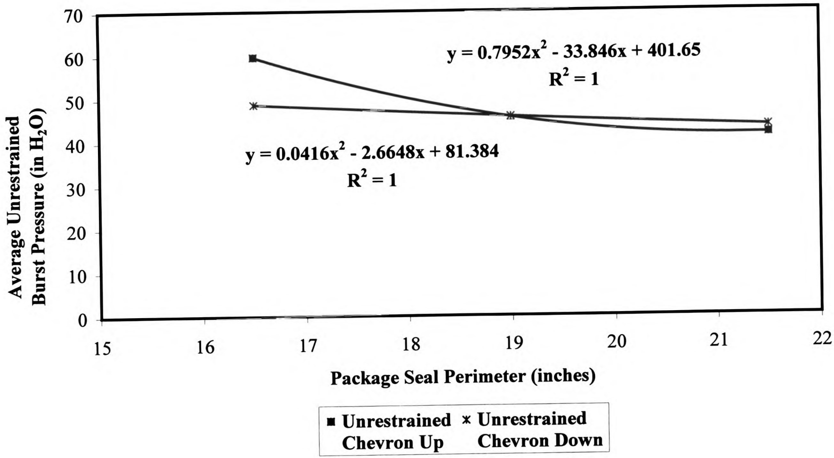


Figure 24. UR Burst Pressure Vs. Package Seal Perimeter for Pouches - Chevron Up

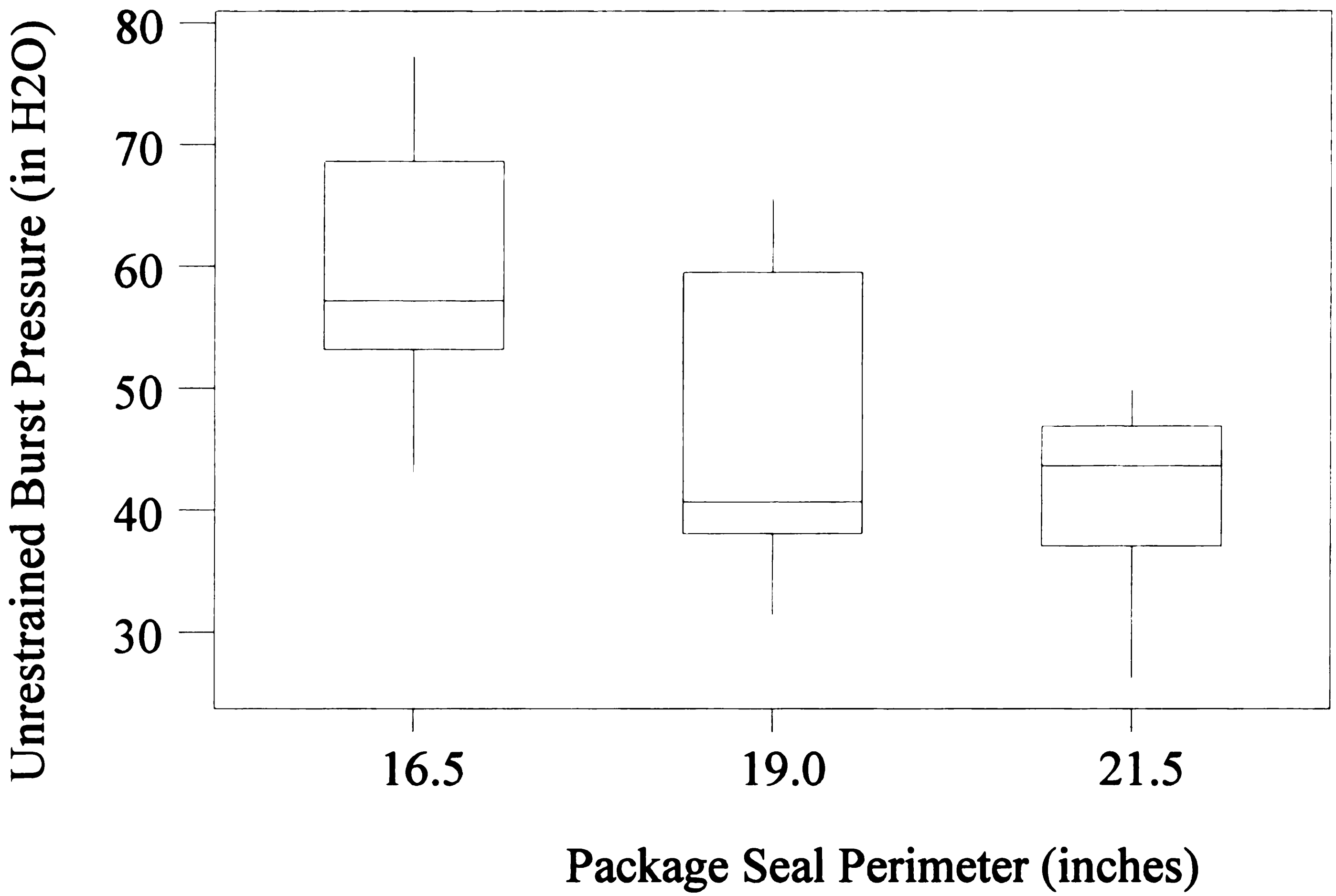
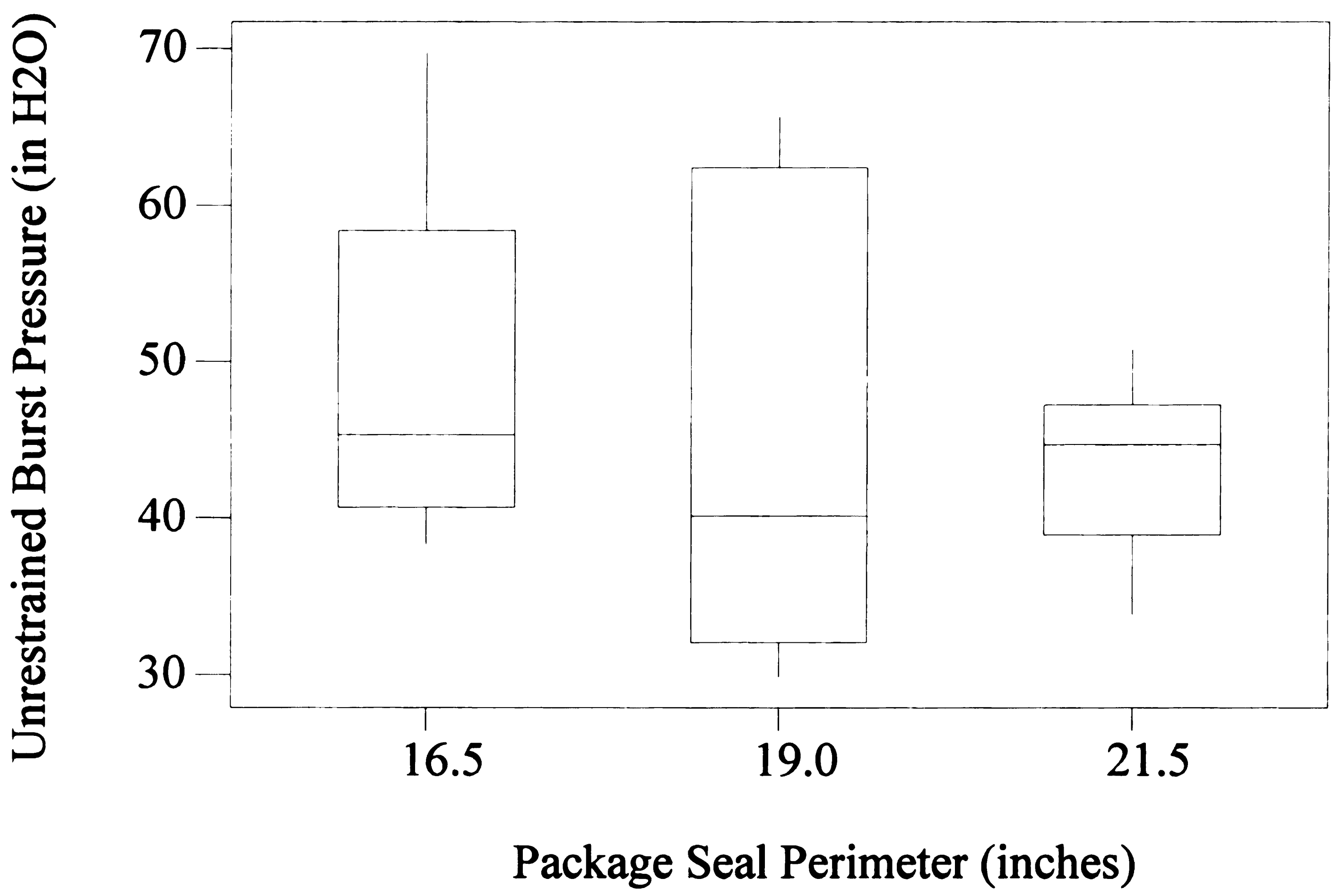


Figure 25. UR Burst Pressure Vs. Package Seal Perimeter for Pouches - Chevron Down



RESTRAINED RESULTS:

Table 20. Restrained Results for Pouches - per Gap Size

Gap = 1.0"

PKG #	n	Average (in. H_2O)	Std Dev	Coeff. Var (%)	Min	Max	Range	Burst per Perimeter (Burst/inch)
1	20	84.18	12.94	15.37	66.90	113.20	46.30	5.10
2	20	73.24	6.81	9.30	62.80	86.70	23.90	3.85
3	20	64.85	9.12	14.06	48.10	81.00	32.90	3.02

Gap = 0.75"

PKG #	n	Average (in. H_2O)	Std Dev	Coeff. Var (%)	Min	Max	Range	Burst per Perimeter (Burst/inch)
1	20	102.22	13.63	13.33	73.20	128.70	55.50	6.20
2	20	91.40	13.82	15.12	65.90	114.90	49.00	4.81
3	20	76.72	9.48	12.36	58.90	90.70	31.80	3.57

Gap = 0.625"

PKG #	n	Average (in. H_2O)	Std Dev	Coeff. Var (%)	Min	Max	Range	Burst per Perimeter (Burst/inch)
1	20	111.05	11.90	10.72	87.60	128.10	40.50	6.73
2	20	107.97	9.89	9.16	84.70	125.70	41.00	5.68
3	20	89.38	8.94	10.00	69.40	104.90	35.50	4.16

Gap = 0.50"

PKG #	n	Average (in. H_2O)	Std Dev	Coeff. Var (%)	Min	Max	Range	Burst per Perimeter (Burst/inch)
1	20	124.37	10.17	8.18	105.7	143.7	38.00	7.54
2	20	122.33	6.59	5.39	105.5	133.6	28.10	6.44
3	20	102.54	7.65	7.46	85.30	116.3	31.00	4.77

Gap = 0.25"

PKG #	n	Average (in. H_2O)	Std Dev	Coeff. Var (%)	Min	Max	Range	Burst per Perimeter (Burst/inch)
1	20	196.42	15.72	8.00	166.9	224.2	57.30	11.90
2	20	195.89	18.38	9.38	147.1	224.7	77.60	10.31
3	20	175.25	22.11	12.62	144.7	221.0	76.30	8.15

Seal Perimeter Package #1 = 16.5"
Seal Perimeter Package #2 = 19.0"
Seal Perimeter Package #3 = 21.5"

It can be seen from the table above that the average burst values vary inversely with the gap size. Smaller gaps produce higher burst values. The average burst value is also different, at any gap size, for different package sizes. The smaller package has a higher average burst test value than the bigger package.

COMPARISON BETWEEN UNRESTRAINED & RESTRAINED RESULTS:

A two-way analysis of variance was performed for each package size to see the effect of test method (unrestrained Vs restrained) and day on the results. We found statistical evidence of differences between test methods and no statistical evidence that days affected the burst test values. For all reported analyses we pool the samples from the separate days for each package.

Table 21. Overall Unrestrained Vs Restrained Burst Test Results for Pouches

Package #1 (5" x 10") - ANOVA One-way analysis

Source Of Variation	Degrees of Freedom	Sum Of Squares	Mean Square	$F_{calculated}$	$F_{.05,1,138}$	p_{value}	Conclusion
Test Method	1	137747	137747	111.43	3.9097	0.000	Test Method Effect
Error	138	170596	1236	---	---	---	---
Total	139	308343	---	---	---	---	---

Package #2 (7" x 11") - ANOVA One-way analysis

Source Of Variation	Degrees of Freedom	Sum Of Squares	Mean Square	$F_{calculated}$	$F_{.05,1,138}$	p_{value}	Conclusion
Test Method	1	149984	149984	104.60	3.9097	0.000	Test Method Effect
Error	138	197871	1434	---	---	---	---
Total	139	347855	---	---	---	---	---

Package #3 (9" x 12") - ANOVA One-way analysis

Source of Variation	Degrees of Freedom	Sum Of Squares	Mean Square	$F_{calculated}$	$F_{.05,1,138}$	p_{value}	Conclusion
Test Method	1	100510	100510	82.76	3.9097	0.000	Test Method Effect
Error	138	167600	1214	---	---	---	---
Total	139	268110	---	---	---	---	---

The one-way analysis of variance in the table above shows evidence of statistical difference between unrestrained and restrained test methods on each package configuration. So, **the test method does affect the average burst values.**

Another one-way analysis of variance was performed in order to compare the unrestrained method with the biggest gap. See the table below.

Table 22. Overall Unrestrained Vs Gap = 1.0" Burst Test Results for Pouches ANOVA One-way analysis

Package #1 (5" x 10")

Source Of Variation	Degrees of Freedom	Sum Of Squares	Mean Square	$F_{calculated}$	$F_{.05,1,58}$	p_{value}	Conclusion
Test Method	1	11970	11970	83.96	4.0069	0.000	Test Method Effect
Error	58	8269	143	---	---	---	---
Total	59	20239	---	---	---	---	---

Package #2 (7" x 11")

Source Of Variation	Degrees of Freedom	Sum Of Squares	Mean Square	$F_{calculated}$	$F_{.05,1,58}$	p_{value}	Conclusion
Test Method	1	10102	10102	81.32	4.0069	0.000	Test Method Effect
Error	58	7205	124	---	---	---	---

Package #3 (9" x 12")

Source Of Variation	Degrees of Freedom	Sum Of Squares	Mean Square	$F_{calculated}$	$F_{.05,1,58}$	p_{value}	Conclusion
Test Method	1	6697.6	6697.6	126.14	4.0069	0.000	Test Method Effect
Error	58	3079.7	53.1	---	---	---	---
Total	59	9777.3	---	---	---	---	---

The results in the table above show that the average unrestrained burst values, even when compared with the highest gap, are statistically different from the average restrained test results. In general, average restrained burst test results are higher than average unrestrained burst test results.

Figures 26 to 30, on the following pages, show the relationship between unrestrained and restrained burst pressure Vs package seal perimeters, for gaps = 1.0", 0.75", 0.625", 0.50", 0.25", respectively. These five figures show that the unrestrained and restrained burst pressures vary inversely proportional with package seal perimeter. It is also shown that at each package size, restrained burst pressure was always higher than the unrestrained burst pressure. Figure 31, shows all testing modes together in one graph. The line on the top represents the restrained burst pressure for the smallest gap (0.25") for three different packages. The lines on the bottom represent the unrestrained burst pressure (chevron up and down) for the three packages. This figure shows that gap 0.25" is a lot higher than the other gaps. This is evidence that this gap represents a special situation.

Figures 32 to 36, present box plots of burst pressure vs. package seal perimeter for gaps 1.0", 0.75", 0.625", 0.50", and 0.25", respectively. These plots show that the variability at each package size tend to be similar in the first four gap but increases at gap 0.25". The variability between package sizes and within gaps did not follow a specific pattern. Tables 23 to 26 summarize the analyses for the variances and coefficients of variation.

Figure 26. Average Burst Pressure Vs. Package Seal Perimeter for Pouches Unrestrained and Restrained (Gap = 1.0")

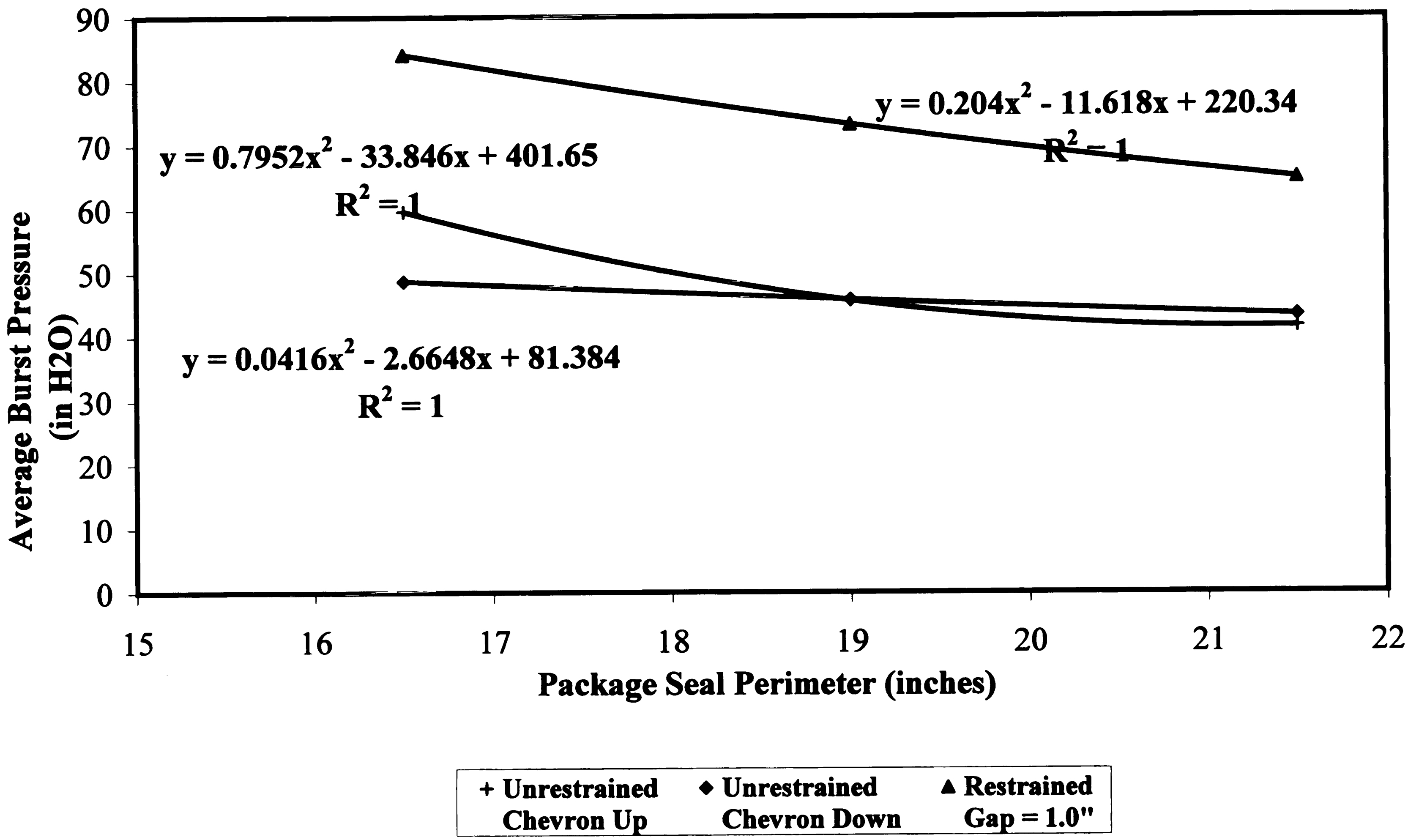


Figure 27. Average Burst Pressure Vs. Package Seal Perimeter for Pouches Unrestrained and Restrained (Gap = 0.75")

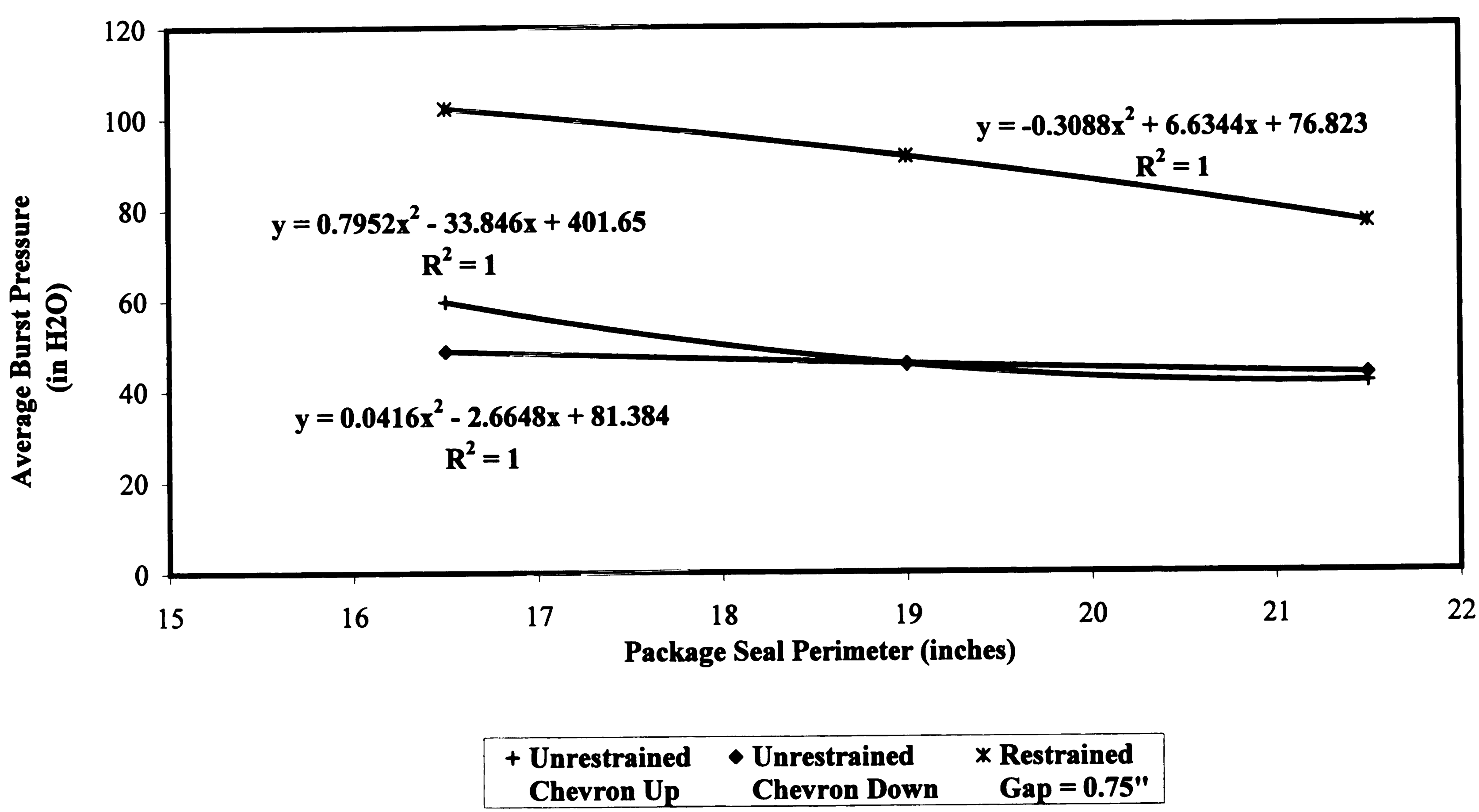


Figure 28. Average Burst Pressure Vs. Package Seal Perimeter for Pouches Unrestrained and Restrained (Gap = 0.625")

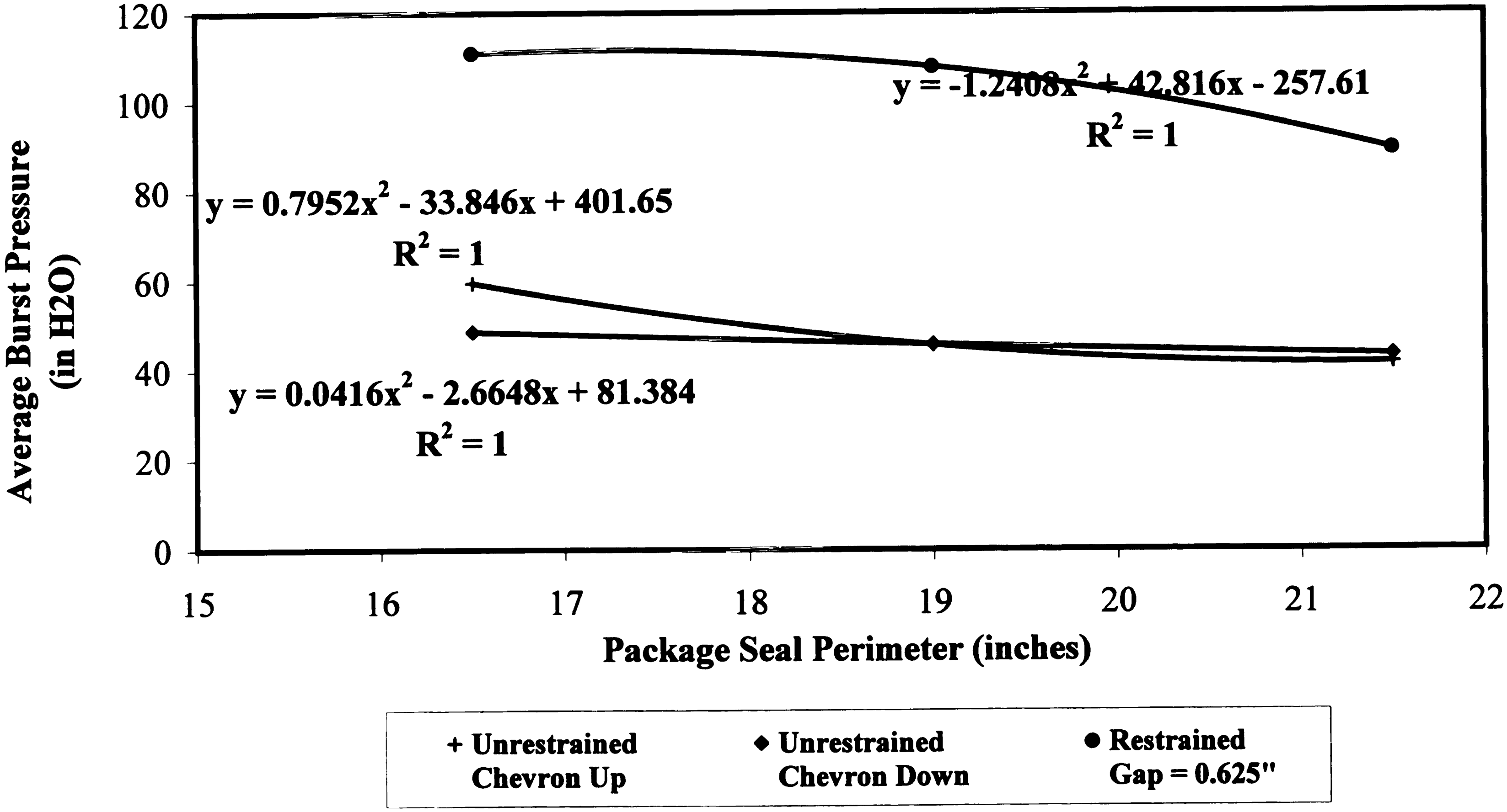


Figure 29. Average Burst Pressure Vs. Package Seal Regions for

Figure 29. Average Burst Pressure Vs. Package Seal Perimeter for Pouches Unrestrained and Restrained (Gap = 0.50")

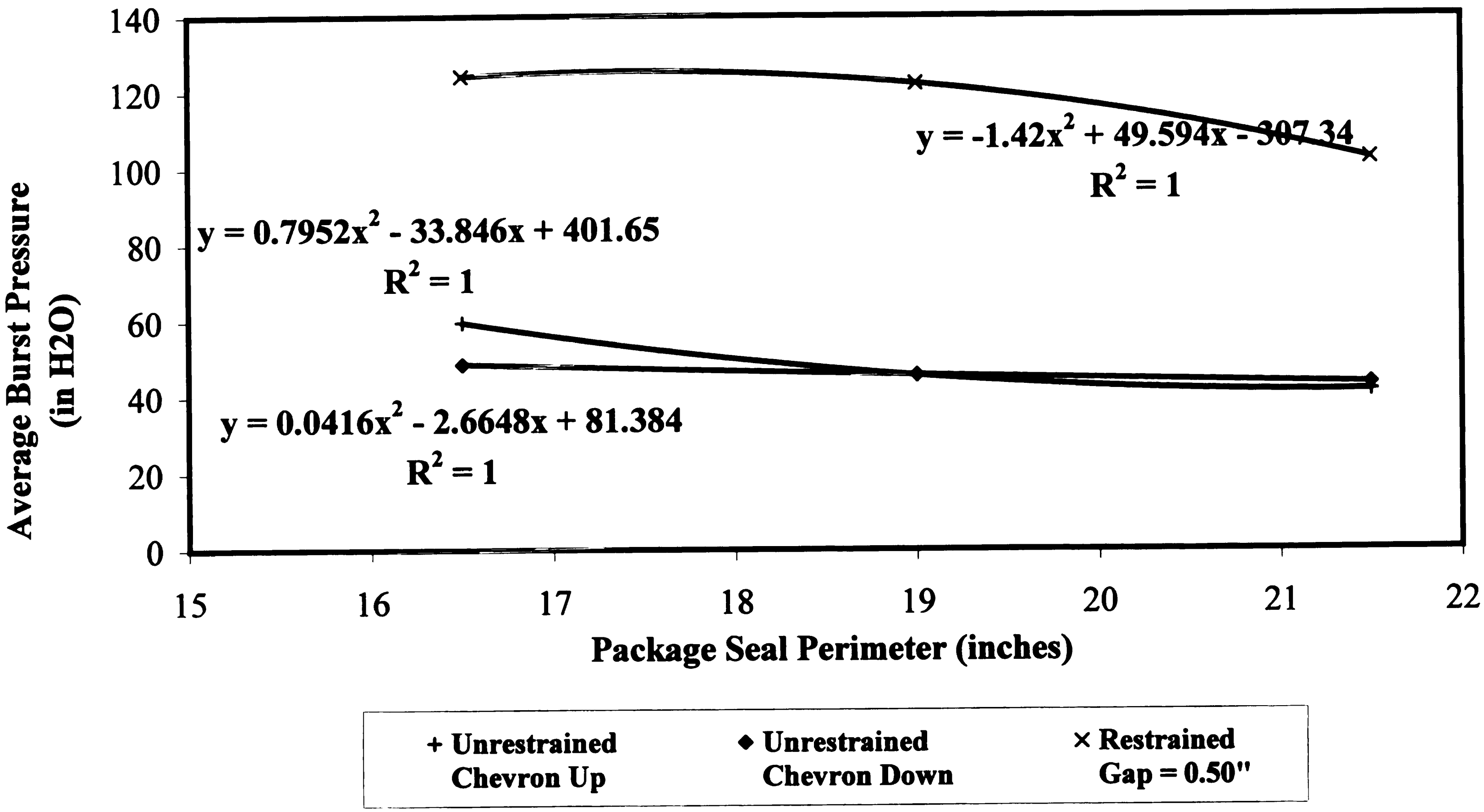


Figure 30. Average Burst Pressure Vs. Package Seal Perimeter for Pouches

Figure 30. Average Burst Pressure Vs. Package Seal Perimeter for Pouches Unrestrained and Restrained (Gap = 0.25")

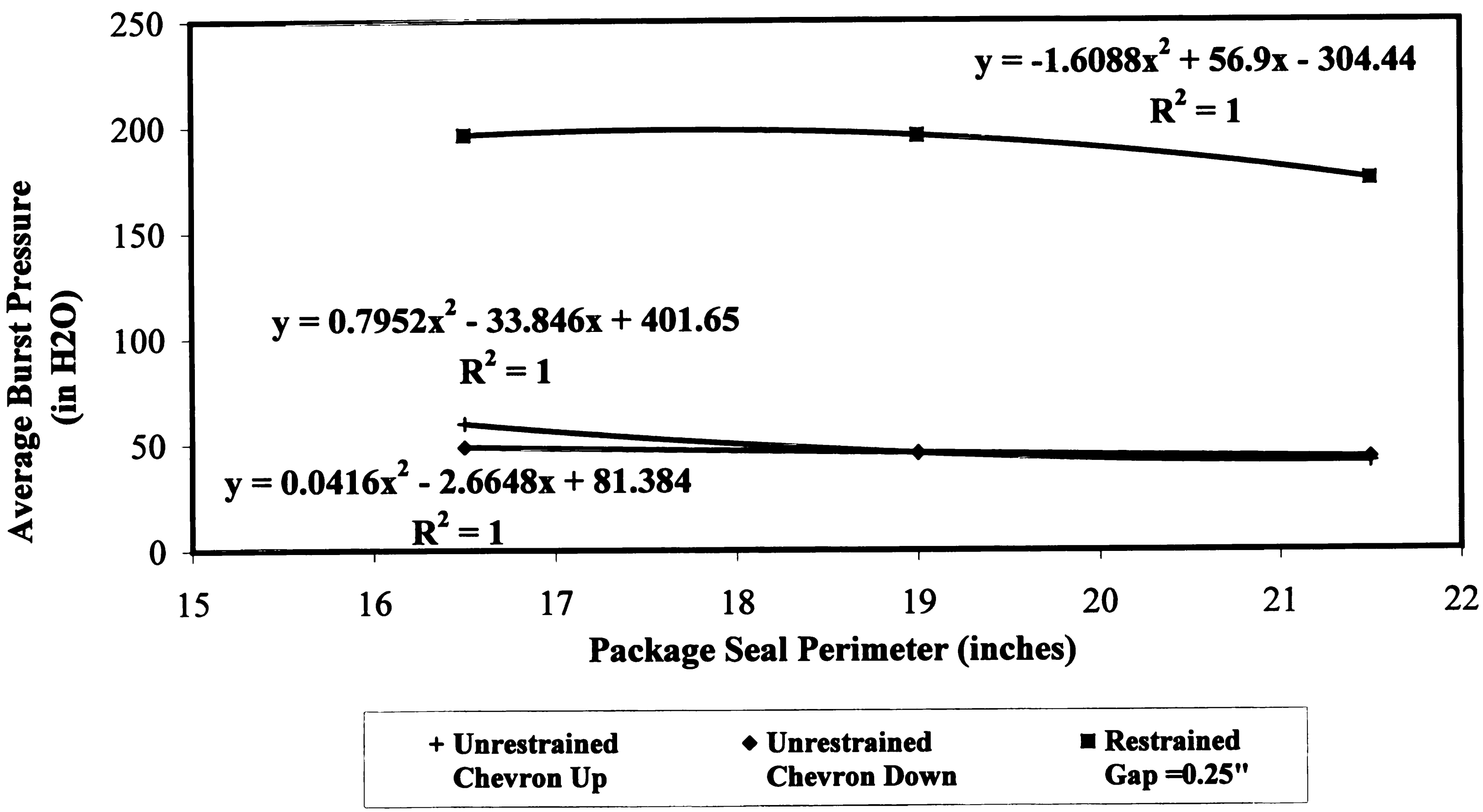


Figure 31. Average Burst Pressure Vs. Package Seal Perimeter for Pouches
Unrestrained and Restrained Results

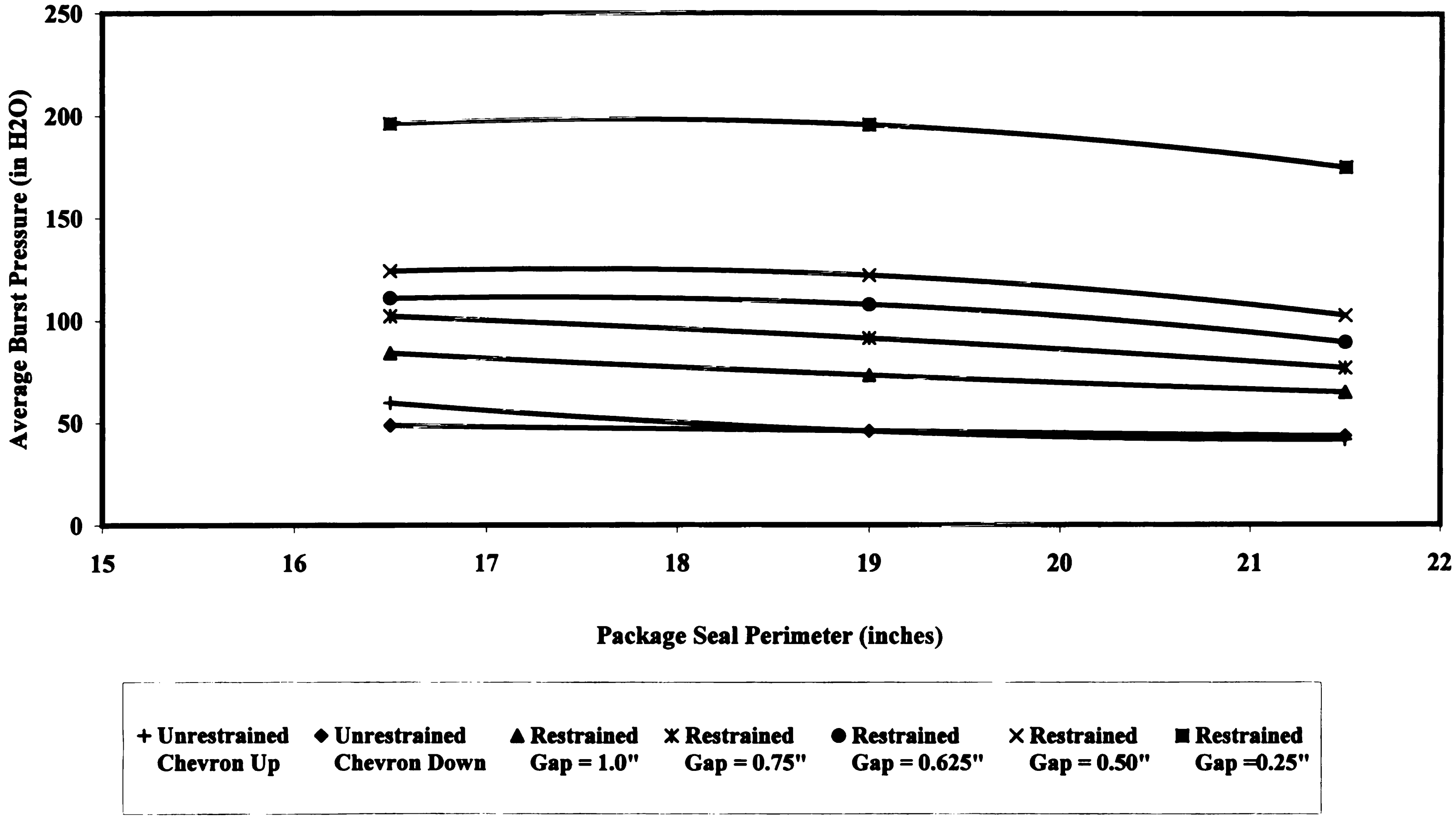


Figure 32. Burst Pressure Vs. Package Seal Perimeter for Pouches - Gap = 1.0"

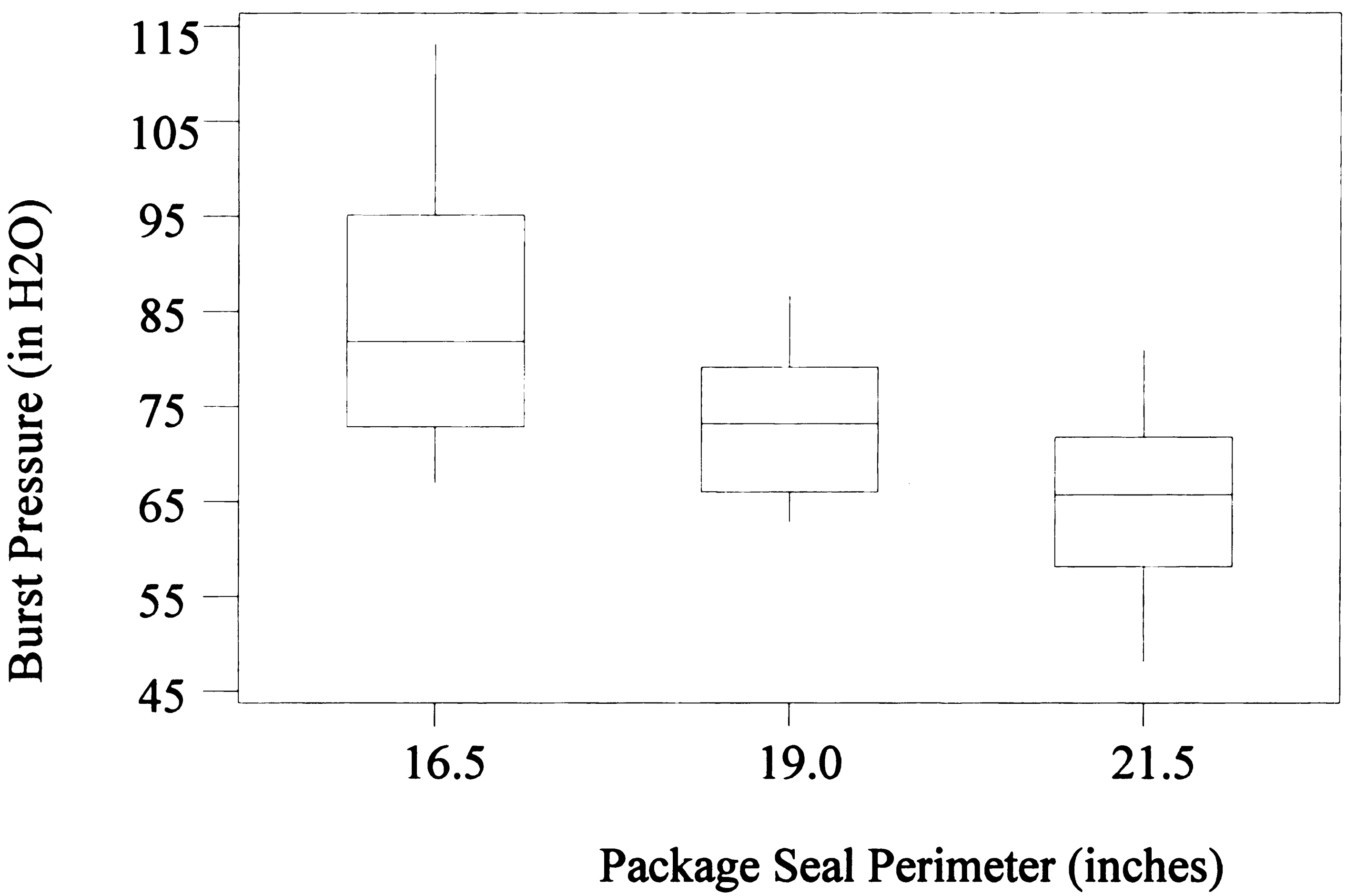


Figure 33. Burst Pressure Vs. Package Seal Perimeter for Pouches - Gap = 0.75"

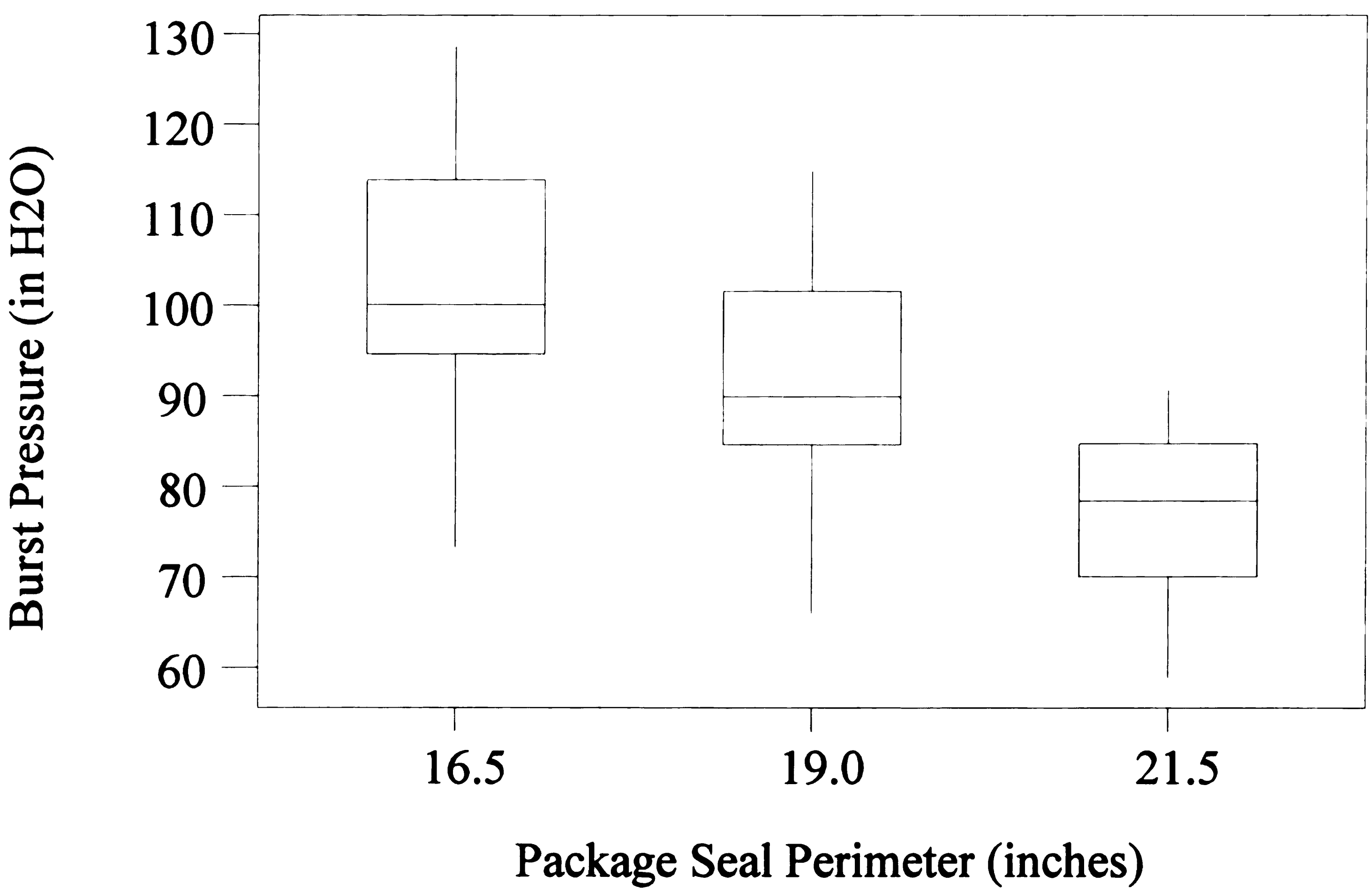


Figure 34. Burst Pressure Vs. Package Seal Perimeter for Pouches - Gap = 0.625"

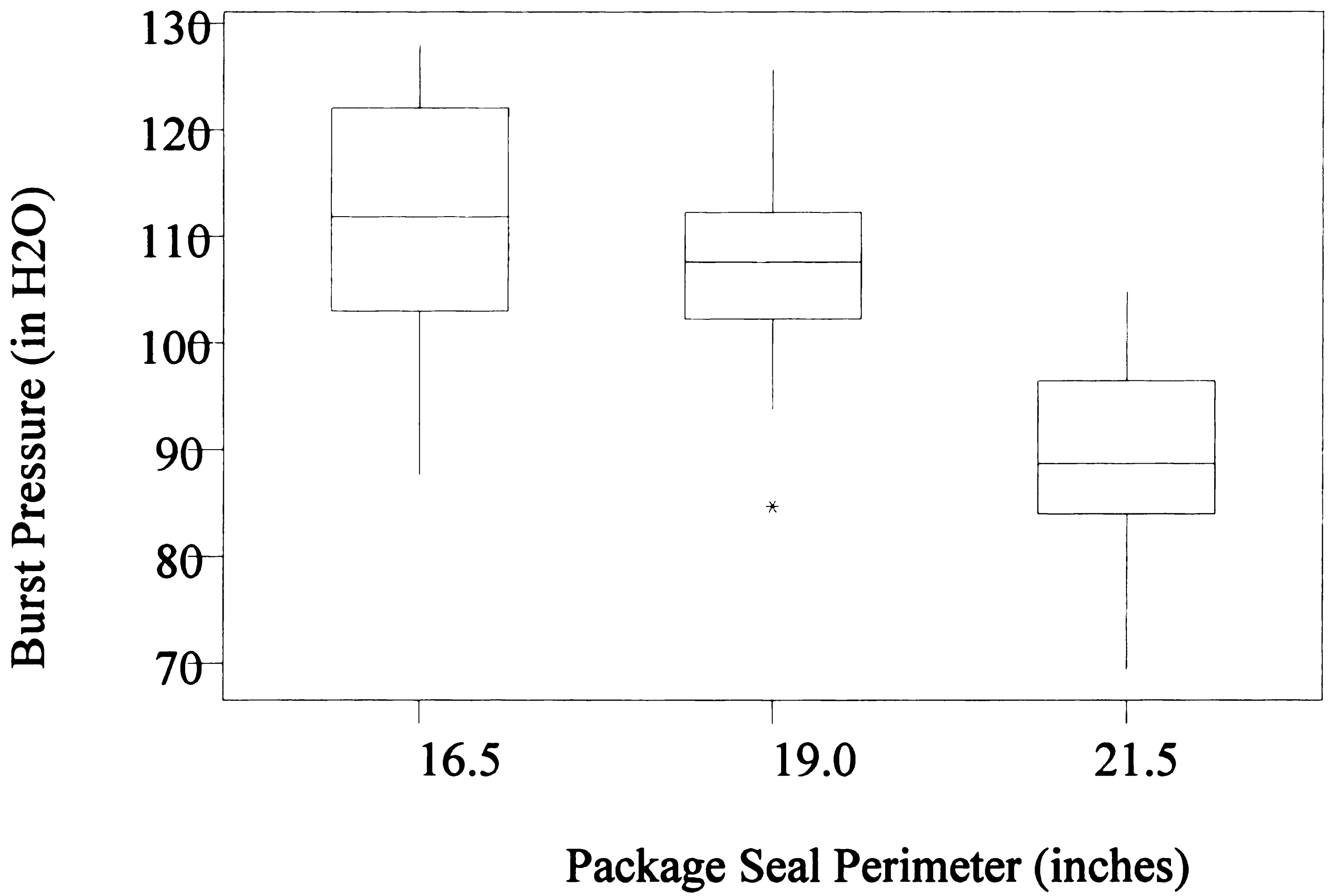


Figure 35. Burst Pressure Vs. Package Seal Perimeter for Pouches - Gap = 0.50"

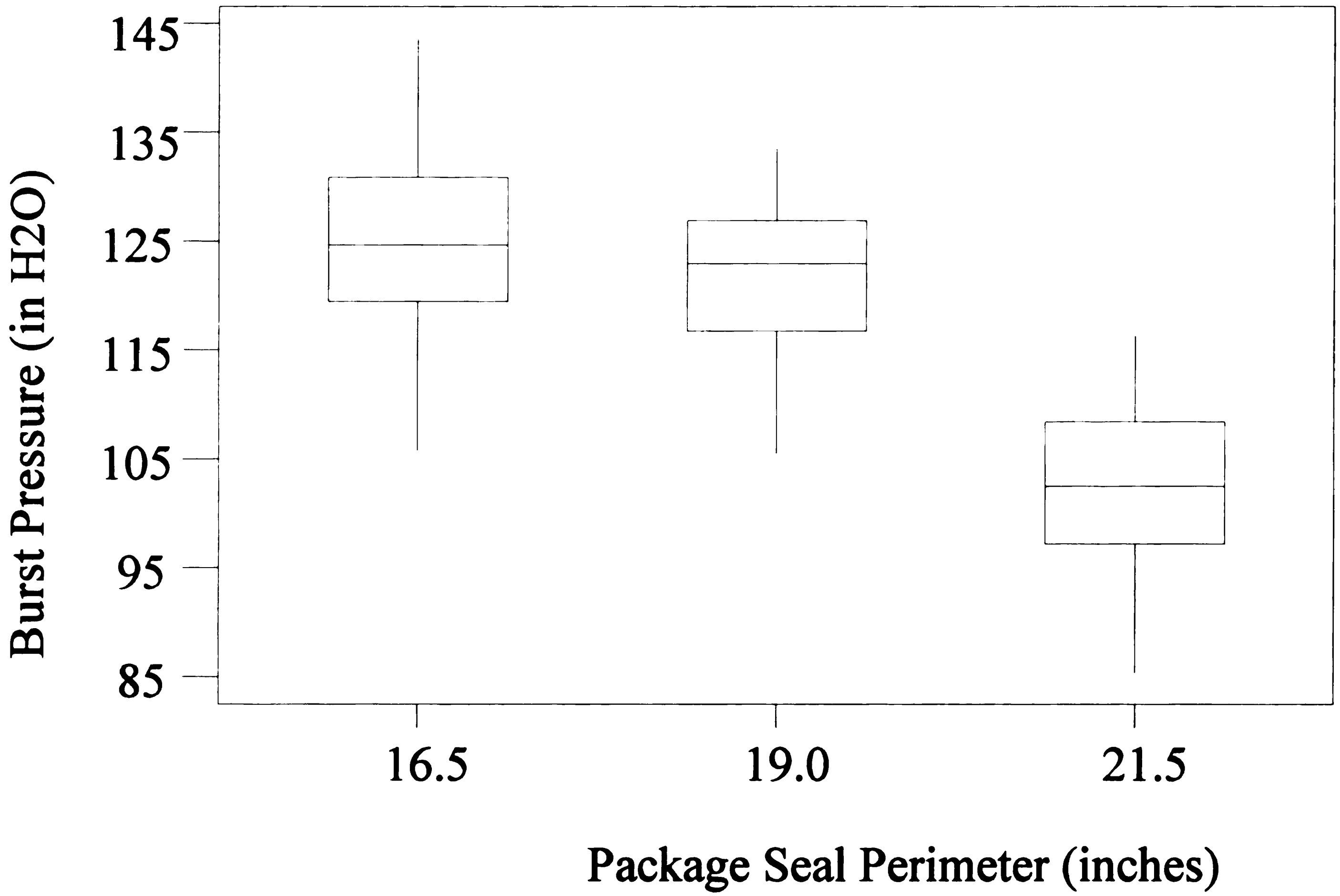
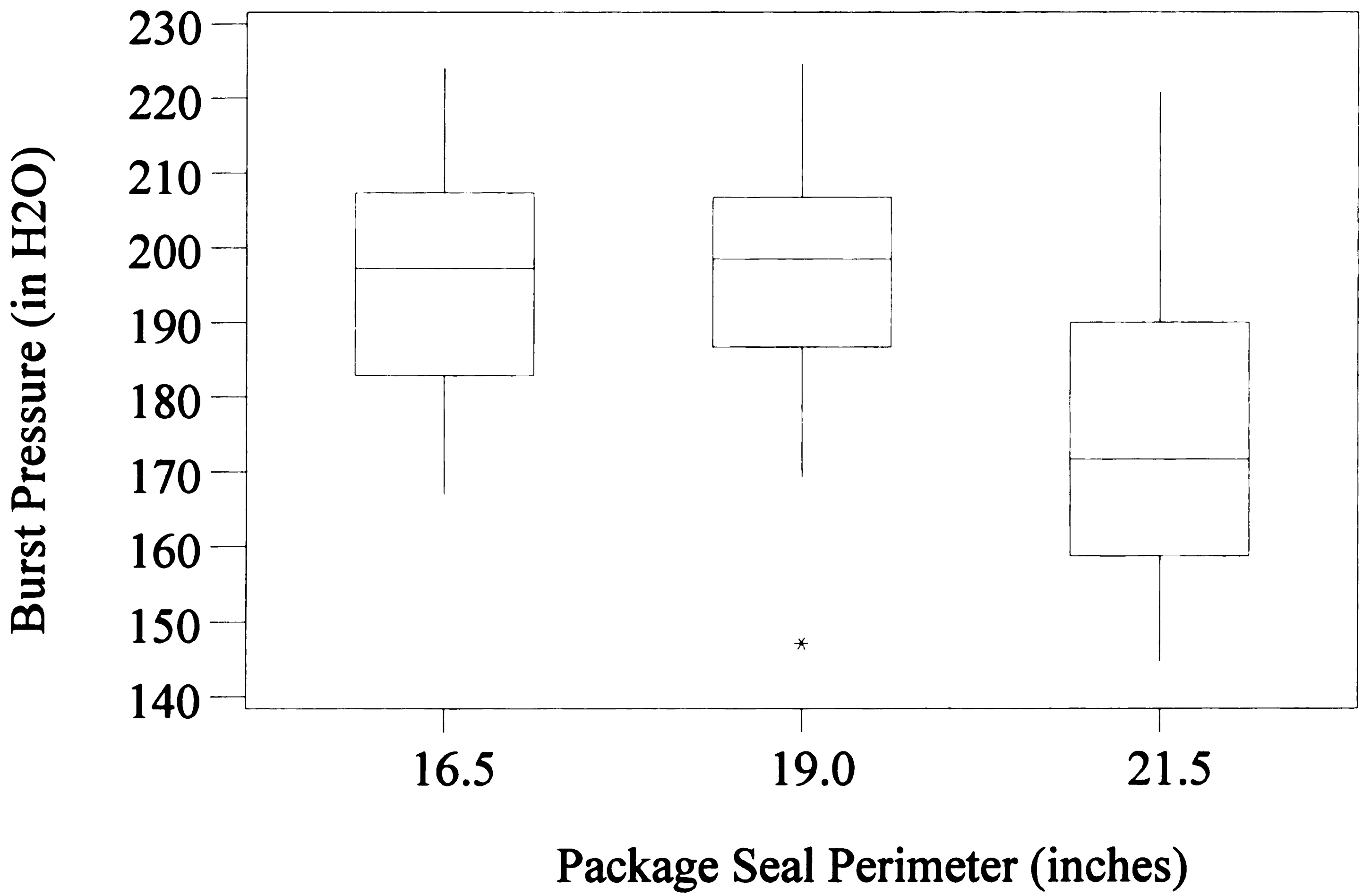


Figure 36. Burst Pressure Vs. Package Seal Perimeter for Pouches - Gap = 0.25"



COMPARISON BETWEEN THE VARIANCES:

Table 23. Comparison between Variances for Pouches (Bartlett's Test for Homogeneity of Variances)

Package #1

Test Mode	Standard Deviation	Variance	ln (Variance)	Chi-Square	p-value
URCU	9.73	94.67	4.55	7.16	3.06E-01
URCD	10.49	110.04	4.70		
1.0"	12.94	167.44	5.12		
0.75"	13.63	185.78	5.22		
0.625"	11.90	141.61	4.95		
0.50"	10.17	103.43	4.64		
0.25"	15.72	247.12	5.51		
	Average	**150.01**	**4.96**		

Package #2

Test Mode	Standard Deviation	Variance	ln (Variance)	Chi-Square	p-value
URCU	11.51	132.48	4.89	30.73	2.86E-05
URCD	14.15	200.22	5.30		
1.0"	6.81	46.38	3.84		
0.75"	13.82	190.99	5.25		
0.625"	9.89	97.81	4.58		
0.50"	6.59	43.43	3.77		
0.25"	18.38	337.82	5.82		
	Average	**149.88**	**4.78**		

Package #3

Test Mode	Standard Deviation	Variance	ln (Variance)	Chi-Square	p-value
URCU	6.85	46.92	3.85	56.87	1.94E-10
URCD	5.52	30.47	3.42		
1.0"	9.12	83.17	4.42		
0.75"	9.48	89.87	4.50		
0.625"	8.94	79.92	4.38		
0.50"	7.65	58.52	4.07		
0.25"	22.11	488.85	6.19		
	Average	**125.39**	**4.40**		

The Bartlett's test for homogeneity of variances [16] was used to make an overall comparison between the variances of different testing modes. This test was performed for each package. When comparing the obtained p values with the critical p value (0.05) it can be seen that package #2 and package #3 show statistical difference between the variances. When looking at the data closely we realized that the variance obtained for gap = 0.25" was a lot higher than the variance obtained for the other gaps. Since we thought that this gap was being responsible for the difference between the variances, we ran a Bartlett's test excluding gap 0.25" data.

Table 24. Comparison between Variances for Pouches (Bartlett's Test for Homogeneity of Variances w/o gap = 0.25")

Package #1

Test Mode	Standard Deviation	Variance	Ln (Variance)	Chi-Square	p-value
URCU	9.73	94.67	4.55	3.63	0.60
URCD	10.49	110.04	4.70		
1.0"	12.94	167.44	5.12		
0.75"	13.63	185.78	5.22		
0.625"	11.90	141.61	4.95		
0.50"	10.17	103.43	4.64		
	Average	**133.83**	**4.86**		

Package #2

Test Mode	Standard Deviation	Variance	Ln (Variance)	Chi-Square	p-value
URCU	11.51	132.48	4.89	19.44	0.0016
URCD	14.15	200.22	5.30		
1.0"	6.81	46.38	3.84		
0.75"	13.82	190.99	5.25		
0.625"	9.89	97.81	4.58		
0.50"	6.59	43.43	3.77		
	Average	**118.55**	**4.60**		

Table 24. Comparison between Variances for Pouches - Continuation (Bartlett's Test for Homogeneity of Variances w/o gap = 0.25")

Package #3

Test Mode	Standard Deviation	Variance	Ln (Variance)	Chi-Square	p-value
URCU	6.85	46.92	3.85	7.49	0.1868
URCD	5.52	30.47	3.42		
1.0"	9.12	83.17	4.42		
0.75"	9.48	89.87	4.50		
0.625"	8.94	79.92	4.38		
0.50"	7.65	58.52	4.07		
	Average	**64.81**	**4.11**		

The results on the table above show that gap 0.25" was being responsible for the differences in variance for package #3. This was not the case for package #2. We found statistical difference between the variances for package #2. In order to follow up our Bartlett's test results for package #2 we ran an F-test for individual comparisons between pairs of variances.

Table 25. Pairwise Comparisons of Variances for Pouches – Package #2

Test Mode	Standard Deviation	Variances
URCU	11.51	132.48
URCD	14.15	200.22
1.0"	6.81	46.38
0.75"	13.82	190.99
0.625"	9.89	97.81
0.50"	6.59	43.43
0.25"	18.38	337.82

Table 25. Pairwise Comparisons of Variances for Pouches – Package #2 Continuation

Comparisons	F-ratio	p-value
URCU & URCD	1.51	0.3760
URCU & 1.0"	2.86	0.0271
URCU & 0.75"	1.44	0.4326
URCU & 0.625"	1.35	0.5148
URCU & 0.50"	3.05	0.0192
URCU & 0.25"	2.55	0.0478
URCD & 1.0"	4.32	0.0025
URCD & 0.75"	1.05	0.9191
URCD & 0.625"	2.05	0.1272
URCD & 0.50"	**4.61**	**0.0016**
URCD & 0.25"	1.69	0.2632
1.0" & 0.75"	4.12	0.0034
1.0" & 0.625"	2.11	0.1124
1.0" & 0.50"	1.07	0.8877
1.0" & 0.25"	**7.28**	**0.0001**
0.75" & 0.625"	1.95	0.1537
0.75" & 0.50"	4.40	**0.0022**
0.75" & 0.25"	**1.77**	0.2230
0.625" & 0.50"	2.25	0.0848
0.625" & 0.25"	3.45	0.0096
0.50" & 0.25"	**7.78**	**0.0000**

The F-ratio was calculated by dividing the higher variance over the lower variance. For multiple comparisons of k treatments, p values less than [0.05/(k*(k-1)/2)] were regarded as significant, the Bonferroni approach to multiple comparisons. For our application k=7 so the critical p value is .05/21= 0.0024. When comparing the obtained p values with the critical p value (0.0024) it can be seen that what is causing the difference in variance in package #2, besides gap 0.25”, is the difference in variation between unrestrained chevron down mode and gap 0.50”. The reason for that is not explained. It may be an artifact of the experiment. Further experimentation will be required to determine the cause.

COMPARISON BETWEEN COEFFICIENTS OF VARIATION:

Table 26. Pairwise Comparisons of Coefficients of Variation for Pouches

Package #1

Test Mode	Standard Deviation	Average (in. H_2O)	Coefficient of Variation	Std Error (CVar)
URCU	9.73	59.69	16.30	2.64
URCD	10.49	48.74	21.52	3.56
1.0"	12.94	84.18	15.37	2.49
0.75"	13.63	102.22	13.33	2.15
0.625"	11.90	111.05	10.72	1.71
0.50"	10.17	124.37	8.18	1.30
0.25"	15.72	196.42	8.00	1.27

Package #1-Pairwise Comparisons

Pairwise Comparisons	Difference in CVar	Std Error (Diff)	Z-ratio	p-value
URCU & URCD	5.22	4.43	1.18	0.2388
URCU & 1.0"	0.93	3.63	0.26	0.7980
URCU & 0.75"	2.97	3.41	0.87	0.3837
URCU & 0.625"	5.58	3.15	1.77	0.0764
URCU & 0.50"	8.12	2.95	2.76	0.0059
URCU & 0.25"	8.30	2.94	2.83	0.0047
URCD & 1.0"	6.15	4.34	1.42	0.1565
URCD & 0.75"	8.19	4.15	1.97	0.0487
URCD & 0.625"	10.81	3.95	2.74	0.0062
URCD & 0.50"	**13.35**	**3.79**	**3.52**	**0.0004**
URCD & 0.25"	**13.52**	**3.78**	**3.58**	**0.0003**
1.0" & 0.75"	2.04	3.28	0.62	0.5350
1.0" & 0.625"	4.66	3.02	1.54	0.1232
1.0" & 0.50"	7.19	2.81	2.56	0.0104
1.0" & 0.25"	7.37	2.79	2.64	0.0084
0.75" & 0.625"	2.62	2.75	0.95	0.3403
0.75" & 0.50"	5.16	2.51	2.06	0.0399
0.75" & 0.25"	5.33	2.49	2.14	0.0326
0.625" & 0.50"	2.54	2.15	1.18	0.2381
0.625" & 0.25"	2.71	2.14	1.27	0.2039
0.50" & 0.25"	0.17	1.82	0.10	0.9239

Table 26. Pairwise Comparisons of Coefficients of Variation for Pouches Continuation

Package #2

Test Mode	Standard Deviation	Average (in. H_2O)	Coefficient of Variation	Std Error (CVar)
URCU	11.51	45.65	25.21	4.23
URCD	14.15	45.77	30.92	5.33
1.0"	6.81	73.24	9.30	1.48
0.75"	13.82	91.40	15.12	2.44
0.625"	9.89	107.97	9.16	1.46
0.50"	6.59	122.33	5.39	0.85
0.25"	18.38	195.89	9.38	1.50

Package #2-Pairwise Comparisons

Pairwise Comparisons	Difference in CVar	Std Error (Diff)	Z-ratio	p-value
URCU & URCD	5.70	6.81	0.84	0.4024
URCU & 1.0"	**15.92**	**4.48**	**3.55**	**0.0004**
URCU & 0.75"	10.09	4.89	2.06	0.0389
URCU & 0.625"	**16.05**	**4.48**	**3.59**	**0.0003**
URCU & 0.50"	**19.83**	**4.32**	**4.59**	**0.0000**
URCU & 0.25"	**15.83**	**4.49**	**3.53**	**0.0004**
URCD & 1.0"	**21.62**	**5.54**	**3.90**	**0.0001**
URCD & 0.75"	15.80	5.87	2.69	0.0071
URCD & 0.625"	**21.76**	**5.53**	**3.93**	**0.0001**
URCD & 0.50"	**25.53**	**5.40**	**4.72**	**0.0000**
URCD & 0.25"	**21.53**	**5.54**	**3.89**	**0.0001**
1.0" & 0.75"	5.82	2.86	2.04	0.0417
1.0" & 0.625"	0.14	2.08	0.07	0.9470
1.0" & 0.50"	3.91	1.71	2.29	0.0223
1.0" & 0.25"	0.08	2.11	0.04	0.9680
0.75" & 0.625"	5.96	2.85	2.09	0.0363
0.75" & 0.50"	**9.73**	**2.59**	**3.76**	**0.0002**
0.75" & 0.25"	5.74	2.87	2.00	0.0453
0.625" & 0.50"	3.77	1.69	2.23	0.0257
0.625" & 0.25"	0.22	2.09	0.11	0.9151
0.50" & 0.25"	4.00	1.72	2.32	0.0204

Table 26. Pairwise Comparisons of Coefficients of Variation for Pouches Continuation

Package #3

Test Mode	Standard Deviation	Average (in. H_2O)	Coefficient of Variation	Std Error (CVar)
URCU	6.85	41.55	16.49	2.68
URCD	5.52	43.32	12.74	2.05
1.0"	9.12	64.85	14.06	2.27
0.75"	9.48	76.72	12.36	1.98
0.625"	8.94	89.38	10.00	1.60
0.50"	7.65	102.54	7.46	1.19
0.25"	22.11	175.25	12.62	2.03

Package #3-Pairwise Comparisons

Pairwise Comparisons	Difference in CVar	Std Error (Diff)	Z-ratio	p-value
URCU & URCD	3.74	3.37	1.11	0.2666
URCU & 1.0"	2.42	3.51	0.69	0.4897
URCU & 0.75"	4.13	3.33	1.24	0.2151
URCU & 0.625"	6.48	3.12	2.08	0.0375
URCU & 0.50"	**9.03**	**2.93**	**3.08**	**0.0021**
URCU & 0.25"	3.87	3.36	1.15	0.2490
URCD & 1.0"	1.32	3.05	0.43	0.6654
URCD & 0.75"	0.39	2.85	0.14	0.8923
URCD & 0.625"	2.74	2.60	1.06	0.2913
URCD & 0.50"	5.28	2.37	2.23	0.0256
URCD & 0.25"	0.13	2.88	0.04	0.9651
1.0" & 0.75"	1.71	3.01	0.57	0.5710
1.0" & 0.625"	4.06	2.77	1.46	0.1431
1.0" & 0.50"	6.60	2.56	2.58	0.0099
1.0" & 0.25"	1.45	3.04	0.48	0.6342
0.75" & 0.625"	2.35	2.55	0.92	0.3552
0.75" & 0.50"	4.90	2.31	2.12	0.0341
0.75" & 0.25"	0.26	2.84	0.09	0.9270
0.625" & 0.50"	2.54	1.99	1.28	0.2014
0.625" & 0.25"	2.61	2.58	1.01	0.3110
0.50" & 0.25"	5.16	2.35	2.20	0.0281

In order to compare coefficients of variation we used the standard errors of each coefficient of variation [16] and the root mean square formula to determine the standard error of the difference. The differences in coefficients of variation were calculated as the higher coefficient of variation minus the lower coefficient of variation. The statistical significance was determined using the standardized difference called the Z-ratio and standard normal distribution.

For multiple comparisons of k=7 treatments p-values less than 0.0024 were regarded as significant, the Bonferroni approach to multiple comparisons. For package #1, two pairs were different. For packages #2 and #3, nine pairs and one pair were statistically different, respectively. Results of previous tests (not reported here) have yielded a different response in pattern for variation.

II. PACKAGE SIZE AND GAP SIZE EFFECT

The results shown in this section are the same restrained burst test results that were shown in the previous section. These results are arranged in a way that it is easier to see, just by looking at Table 27, the effects of changing the gap size and package size on the restrained burst pressure. The statistical results show evidence of difference between the burst values coming from different package and gap sizes. It will be seen that both, package size and gap size, vary inversely proportional with burst pressure.

GENERAL RESULTS:

Table 27. Restrained Results for Pouches - per Package

Package #1 (5" x 10" Pouch) - Seal Perimeter = 16.50"

Gap Size (in.)	n	Average ($in.H_2O$)	Std Dev	Coeff. Var (%)	Min	Max	Range	Burst per Perimeter (Burst/Inch)
1.0	20	84.18	12.94	15.37	66.90	113.20	46.30	5.10
0.75	20	102.22	13.63	13.33	73.20	128.70	55.50	6.20
0.625	20	111.05	11.90	10.72	87.60	128.10	40.50	6.73
0.50	20	124.37	10.17	8.18	105.70	143.70	38.00	7.54
0.25	20	196.42	15.72	8.00	166.90	224.20	57.30	11.90

Package #2 (7" x 11" Pouch) - Seal Perimeter = 19.00"

Gap Size (in.)	n	Average ($in.H_2O$)	Std Dev	Coeff. Var (%)	Min	Max	Range	Burst per Perimeter (Burst/Inch)
1.0	20	73.24	6.81	9.30	62.80	86.70	23.90	3.85
0.75	20	91.40	13.82	15.12	65.90	114.90	49.00	4.81
0.625	20	107.97	9.89	9.16	84.70	125.70	41.00	5.68
0.50	20	122.33	6.59	5.39	105.50	133.60	28.10	6.44
0.25	20	195.89	18.38	9.38	147.10	224.70	77.60	10.31

Package #3 (9" x 12" Pouch) - Seal Perimeter = 21.50"

Gap Size (in.)	n	Average ($in.H_2O$)	Std Dev	Coeff. Var (%)	Min	Max	Range	Burst per Perimeter (Burst/Inch)
1.0	20	64.85	9.12	14.06	48.10	81.00	32.90	3.02
0.75	20	76.72	9.48	12.36	58.90	90.70	31.80	3.57
0.625	20	89.38	8.94	10.00	69.40	104.90	35.50	4.16
0.50	20	102.54	7.65	7.46	85.30	116.30	31.00	4.77
0.25	20	175.25	22.11	12.62	144.70	221.00	76.30	8.15

Table 27, shows that the average burst values vary inversely with the gap size and package size. Smaller gaps and smaller packages produce higher burst values.

STATISTICAL RESULTS:

Table 28. Overall Package Size and Gap size Effect on Burst Test Results for Pouches - ANOVA Two way Analysis

Source of Variation	Degrees of Freedom	Sum of Squares	Mean Square	$F_{calculated}$	$F_{critical}$	p value	Conclusion
PKG Size	2	25980	12990	82.74	3.03	0.000	PKG Size Effect
Gap Size	4	476795	119199	759.23	2.40	0.000	Gap Size Effect
Interaction	8	1479	185	1.18	1.97	0.311	No Interaction Effect
Error	285	44880	157	---	---		---
Total	299	549134	---	---	---		---

This two-way analysis of variance shows strong **statistical evidence of differences in average burst value between packages and among gap sizes**.

Figure 37, next page, shows the relationship between burst pressure and gap size. It can be seen from that figure that as the gap size increases the burst pressure decreases. Also it is shown that within a certain gap size the burst pressure varies inversely with the package size.

Figures 38 to 40, which are box plots, besides showing that burst pressure varies inversely with gap size, show the variability within and between gaps for each package. These plots show that the variability at gap 0.25" was higher than the variability obtained from other gaps for the three packages. Also see Tables 23 to 26.

Figure 37. Average Restrained Burst Pressure Vs. Gap Size for Pouches

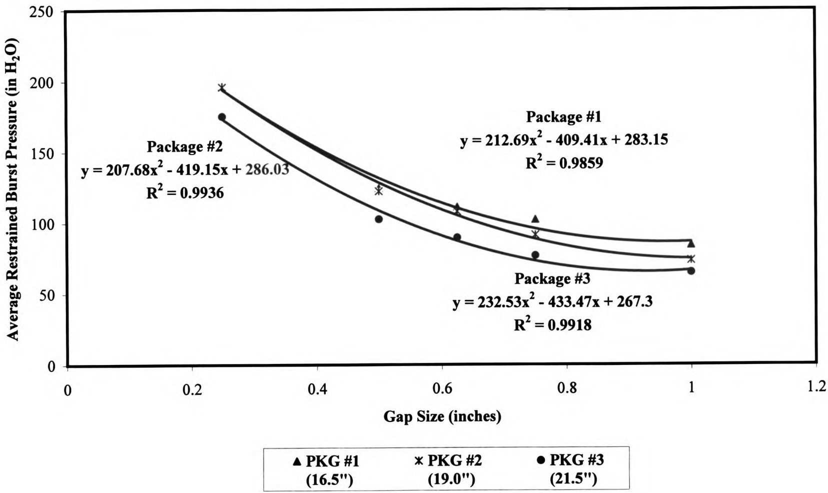


Figure 38. Restrained Burst Pressure Vs. Gap Size for Pouches - Package #1

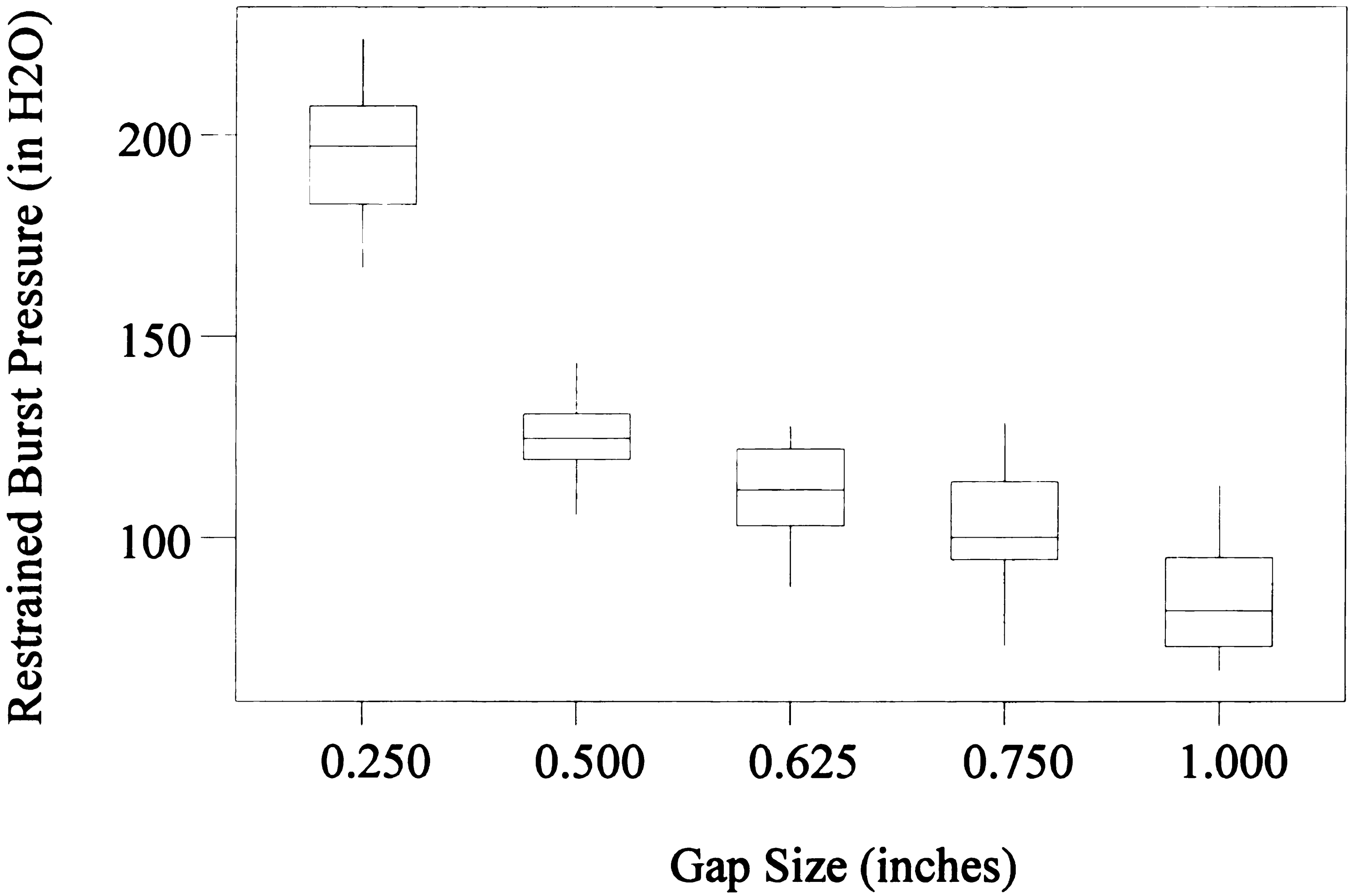


Figure 39. Restrained Burst Pressure Vs. Gap Size for Pouches - Package #2

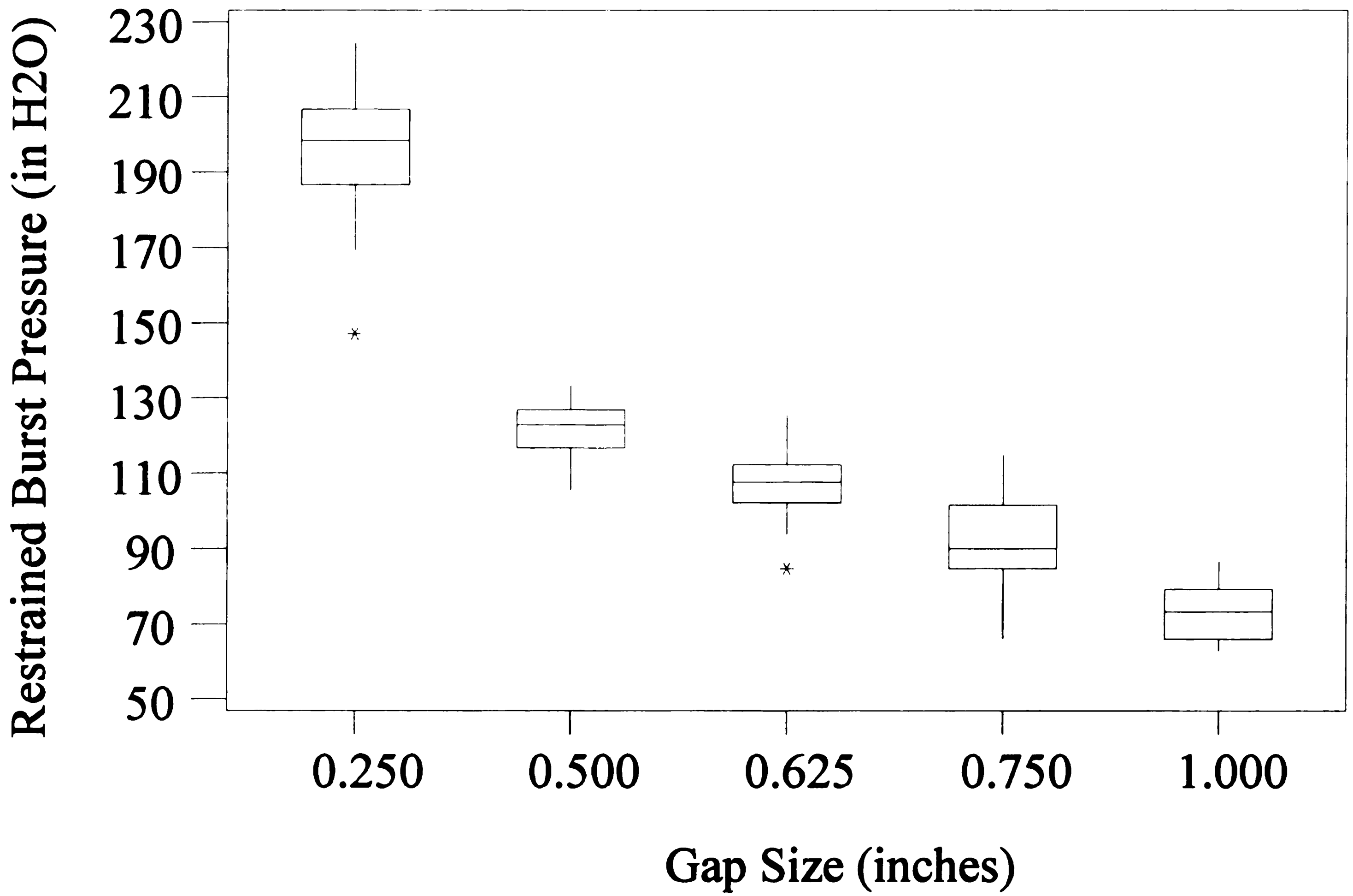
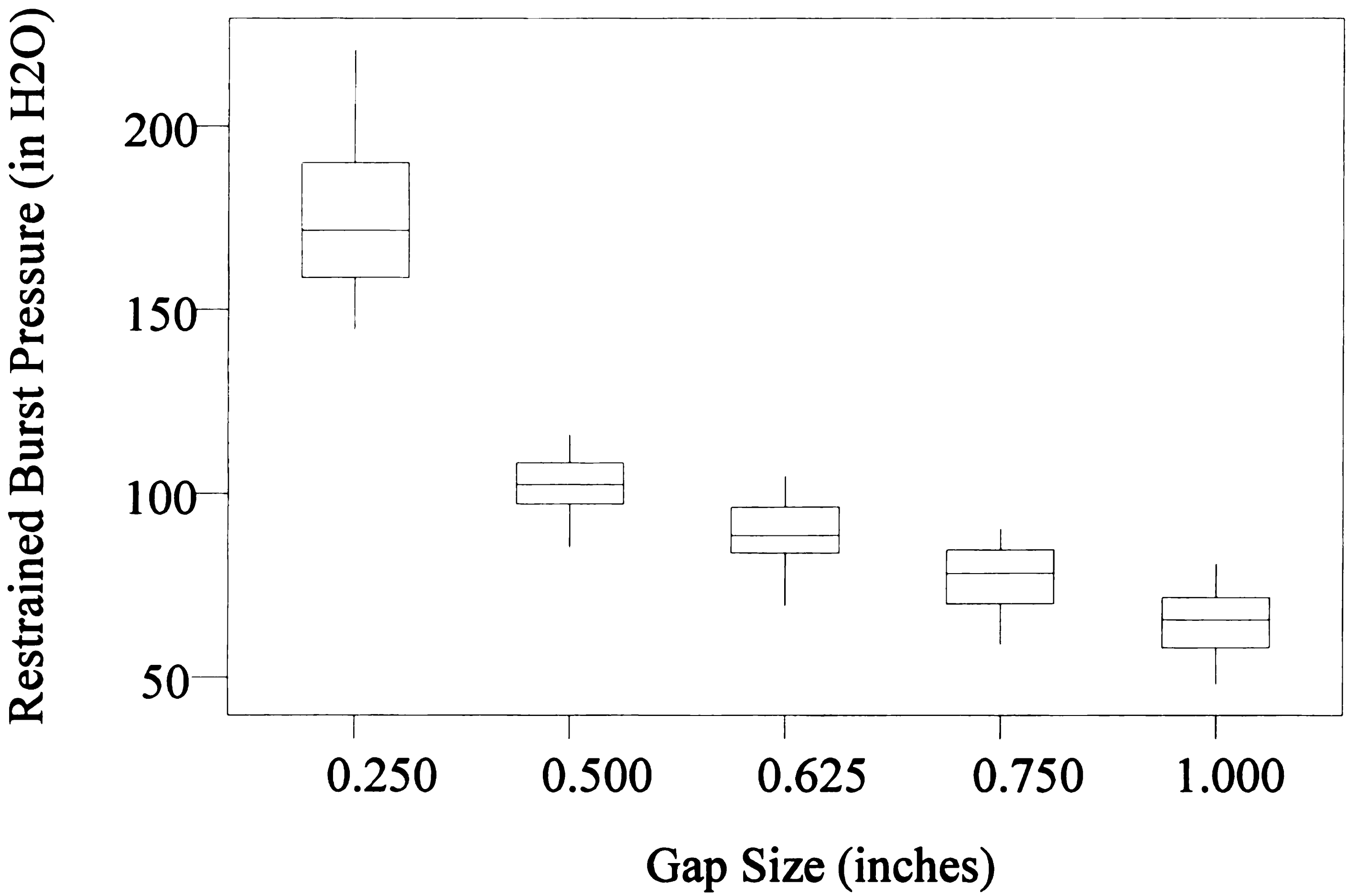


Figure 40. Restrained Burst Pressure Vs. Gap Size for Pouches - Package #3



ANALYSIS OF FAILURE PATTERN FOR DIFFERENT PACKAGE SIZES:

As part of this experiment a peel test was performed for the three different packages. The results show no difference in seal strength between the sides and the chevron. However, the pattern of burst failures showed more failures on the chevron than on the sides when the pouches were tested in a restrained mode. A possible explanation for that behavior is that the side seals of the pouch experience more pressure than the chevron seal when it is tested in an unrestrained test mode. In a restrained burst test, the restraining fixture makes the force to be more uniformly distributed around the seal perimeter. This will make the chevron seal receive more stresses than it would receive in an unrestrained burst test. This fact plus the fact that the chevron has corners which will act as stress concentrators make the chevron more prone to have a failure, when testing with a restraining fixture. Table 29, next page provides information about the location of failures obtained when the three pouches were tested in a restrained and unrestrained test mode.

Table 29. Location of Failures for Pouches

Package #1 (5" x 10")

	Location of Failures							
Mode	**A**	**B**	**BC**	**C**	**BCD**	**CD**	**D**	**E**
URCU	5	4	0	0	0	1	6	4
URCD	1	5	0	0	2	2	9	1
Gap = 1.0"	1	5	2	1	2	3	5	1
Gap = 0.75"	1	4	3	0	5	1	5	1
Gap = 0.625"	0	8	6	0	3	0	2	1
Gap = 0.50"	0	6	6	0	5	1	2	0
Gap = 0.25"	1	14	1	0	0	0	4	0

Package #2 (7" x 11")

	Location of Failures							
Mode	**A**	**B**	**BC**	**C**	**BCD**	**CD**	**D**	**E**
URCU	6	6	2	0	0	0	6	0
URCD	5	6	1	0	2	2	4	0
Gap = 1.0"	0	8	1	0	0	1	10	0
Gap = 0.75"	0	11	0	0	1	3	5	0
Gap = 0.625"	1	9	0	0	1	0	9	0
Gap = 0.50"	0	12	0	0	0	0	8	0
Gap = 0.25"	0	10	0	0	0	0	9	1

Package #3 (9" x 12")

	Location of Failures							
Mode	**A**	**B**	**BC**	**C**	**BCD**	**CD**	**D**	**E**
URCU	2	7	1	0	0	2	8	0
URCD	5	6	1	0	1	0	6	1
Gap = 1.0"	0	11	1	0	3	0	5	0
Gap = 0.75"	0	11	0	0	0	0	9	0
Gap = 0.625"	0	12	0	0	0	0	8	0
Gap = 0.50"	0	13	0	0	0	0	7	0
Gap = 0.25"	0	9	0	0	0	0	11	0

NOTE: URCU = Unrestrained Chevron Up
URCD = Unrestrained Chevron Down.

Table 30. Summary Location of Failures for Pouches

Package #1 (5" x 10")

Mode	Number of Failures on the Sides (Out of 20 samples)	Number of Failures on the Chevron (Out of 20 samples)
URCU	9	11
URCD	2	18
Gap = 1.0"	2	18
Gap = 0.75"	2	18
Gap = 0.625"	1	19
Gap = 0.50"	0	20
Gap = 0.25"	1	19

Package #2 (7" x 11")

Mode	Number of Failures on the Sides (Out of 20 samples)	Number of Failures on the Chevron (Out of 20 samples)
URCU	6	14
URCD	5	15
Gap = 1.0"	0	20
Gap = 0.75"	0	20
Gap = 0.625"	1	19
Gap = 0.50"	0	20
Gap = 0.25"	1	19

Package #3 (9" x 12")

Mode	Number of Failures on the Sides (Out of 20 samples)	Number of Failures on the Chevron (Out of 20 samples)
URCU	2	18
URCD	6	14
Gap = 1.0"	0	20
Gap = 0.75"	0	20
Gap = 0.625"	0	20
Gap = 0.50"	0	20
Gap = 0.25"	0	20

As it can be seen from Tables 29 and 30, the pattern of failures showed in general more failures on the chevron than on the sides when tested using the restraining fixture.

III. SUMMARY OF RESULTS FOR POUCHES:

1. Restrained burst test pressures are higher than unrestrained burst test pressures.
2. No statistical difference was found for burst value between chevron up and chevron down in the unrestrained test.
3. The burst values vary inversely with the gap size. Smaller gaps produce higher burst values.
4. In general burst values decrease with an increase in package size. This behavior is true for both restrained and unrestrained burst test methods. The burst value at any gap size is lower for bigger packages than for smaller packages.
5. Since there was no pattern in the overall difference in raw variances and coefficients of variation between restrained and unrestrained burst tests, there is no evidence that restraining fixtures reduce variation.
   a. There is statistical difference in raw variances between restrained and unrestrained burst test for packages #2. No statistical difference in raw variances was found for packages #1 and #3.
   b. There is no pattern in the difference in coefficients of variation between restrained and unrestrained burst test for the three packages.
6. A small gap (0.25" in this experiment) contributes to an increase in variation.
7. Even though the results showed no difference in seal strength between the sides and the chevron, the pattern of failures showed more failures on the chevron seal than on the side seal when the pouches were tested in a restrained mode.

PART C - CORRELATION BETWEEN BURST TEST AND PEEL TEST – POUCHES

The main purpose of this section is to study and analyze the theoretical formulas developed by Professor Kit Yam [22] that correlate burst test with peel test. It was found that for the package under study, which is a Tyvek/plastic chevron seal pouch, the results obtained from burst and peel tests did not correlate.

GENERAL RESULTS:

Table 31. Burst Test Results for Pouches
Correlation between Burst and Peel Tests

Gap = 0.25 inches

Flow	Average Burst Peeling Time – tb (sec)	Burst Peeling Time Standard Deviation	Average Burst Pressure (in. H_2O)	Burst Pressure Standard Deviation
1	78.37	3.43	197.03	11.88
5	8.78	0.23	200.42	8.44
9	4.86	0.27	223.21	21.32

Gap = 0.50 inches

Flow	Average Burst Peeling Time – tb (sec)	Burst Peeling Time Standard Deviation	Average Burst Pressure (in. H_2O)	Burst Pressure Standard Deviation
1	68.53	2.75	132.22	10.94
5	8.23	0.19	147.45	8.67
9	3.83	0.25	148.38	7.35

Gap = 1.0 inches

Flow	Average Burst Peeling Time – tb (sec)	Burst Peeling Time Standard Deviation	Average Burst Pressure (in. H_2O)	Burst Pressure Standard Deviation
1	60.89	2.38	76.65	4.76
5	6.99	0.23	84.79	6.06
9	3.43	0.12	86.61	5.33

Note: Setting for other parameters - Sensitivity = 1 and Prefill = N
The burst peeling time (tb) was measured using a stopwatch

Table 32. Peel Test Results using "Average Seal Strength" Value (S_{avg}) Correlation between Burst and Peel Tests

Gauge Length = 0.40" (Corresponding to a gap = 0.25")

Velocity (in/min)	Average (S_{avg}) (lb./in)	Standard Deviation (S_{avg}) (lb./in)	Average tp (sec)	Standard Deviation tp (sec)
0.58 – 0.78	1.515	0.24	82.76	3.38
5.50 – 7.00	1.813	0.24	9.15	0.29
9.55 – 12.60	1.779	0.29	5.15	0.18

Gauge Length = 0.80" (Corresponding to a gap = 0.50")

Velocity (in/min)	Average (S_{avg}) (lb./in)	Standard Deviation (S_{avg}) (lb./in)	Average tp (sec)	Standard Deviation tp (sec)
0.66 – 0.88	1.776	0.24	69.02	6.63
5.47 – 7.29	1.891	0.28	8.63	0.27
11.74–15.75	1.987	0.24	4.15	0.18

Gauge Length = 1.60" (Corresponding to a gap = 1.0")

Velocity (in/min)	Average (S_{avg}) (lb./in)	Standard Deviation (S_{avg}) (lb./in)	Average tp (sec)	Standard Deviation tp (sec)
0.74 –0.98	1.776	0.21	62.58	1.50
6.44 – 8.58	1.928	0.30	7.34	0.18
13.13-17.51	2.000	0.27	3.61	0.09

Note: The tensile peeling time (tp) shown in this table was measured using a stopwatch and it represent the average time it took for all samples to peel.

A peel test was performed on eight (8) pouches in four (4) locations each, so there are 32 samples in total. The "average seal strength" value (S_{avg}) is the average of the peel strength values obtained from all 32 specimens. This "average seal strength" value was substituted as the S, in the (P = 2S / D) formula, to get the predicted burst pressure. In the formula, S is the seal strength, D is the plate separation or gap, and P is the predicted burst pressure.

Table 33. Peel Test Results using "Minimum Seal Strength" Value (S_{min}) Correlation between Burst and Peel Tests

Gauge Length = 0.40" (Corresponding to a gap = 0.25")

Velocity (in/min)	Average (S_{min}) (lb./in)	Standard Deviation (S_{min}) (lb./in)	Average tp (sec)	Standard Deviation tp (sec)
0.58 – 0.78	1.282	0.16	82.50	3.18
5.50 – 7.00	1.601	0.19	9.17	0.28
9.55 – 12.60	1.462	0.16	5.03	0.14

Gauge Length = 0.80" (Corresponding to a gap = 0.50")

Velocity (in/min)	Average (S_{min}) (lb./in)	Standard Deviation (S_{min}) (lb./in)	Average tp (sec)	Standard Deviation tp (sec)
0.66 – 0.88	1.486	0.20	66.4	1.03
5.47 – 7.29	1.617	0.23	8.69	0.42
11.74–15.75	1.732	0.22	4.15	0.19

Gauge Length = 1.60" (Corresponding to a gap = 1.0")

Velocity (in/min)	Average (S_{min}) (lb./in)	Standard Deviation (S_{min}) (lb./in)	Average tp (sec)	Standard Deviation tp (sec)
0.74 –0.98	1.566	0.17	62.15	1.76
6.44 – 8.58	1.553	0.29	7.26	0.21
13.13-17.51	1.709	0.23	3.64	0.09

Note: The tensile peeling time (tp) shown in this table was monitored using a stopwatch and it represent the average time it took for the samples with minimum peel strength to break.

A peel test was performed on eight (8) pouches in four (4) locations each, so there are 32 samples in total. The "minimum seal strength" value (S_{min}) is the average of what could be the "weakest point" or the lowest peel strength value from each pouch. S_{min} is the average of the minimum value of the 8 pouches. This "minimum" value was substituted as the S, in the ($P = 2S / D$) formula, to get the predicted burst pressure. Table 34, next pages, shows the predicted Vs observed burst values obtained at each gap, using the "average" and "minimum" seal strength values.

Table 34. Relationship Between Seal Strength and Burst Pressure

Gap 0.25" – "Average Seal Strength" Value (S_{avg})

Tensile Peeling Time tp (sec)	Velocity v (in/min)	Burst Peeling Time tb (sec)	Flow	Predicted Burst Pressure $P_{predicted}$ (in. H_2O)	Observed Burst Pressure $P_{observed}$ (in. H_2O)	Overestimate (%)
82.76 +/- 3.38	(.58 to .78)	78.37 +/- 3.43	1	**335.36 +/- 54.03**	197.03 +/- 11.88	70.21
9.15 +/- 0.29	(5.50 to 7.00)	8.78 +/- 0.23	5	**401.33 +/- 53.47**	200.42 +/- 8.44	100.24
5.15 +/- 0.18	(9.55 to 12.60)	4.86 +/- 0.27	9	**393.80 +/- 63.11**	223.21 +/- 21.32	76.43

Gap 0.25" – "Minimum Seal Strength" Value (S_{min})

Tensile Peeling Time tp (sec)	Velocity v (in/min)	Burst Peeling Time tb (sec)	Flow	Predicted Burst Pressure $P_{predicted}$ (in. H_2O)	Observed Burst Pressure $P_{observed}$ (in. H_2O)	Overestimate (%)
82.50 +/- 3.18	(.58 to .78)	78.37 +/- 3.43	1	**283.78 +/- 34.51**	197.03 +/- 11.88	44.03
9.17 +/- 0.28	(5.50 to 7.00)	8.78 +/- 0.23	5	**354.40 +/- 41.11**	200.42 +/- 8.44	76.83
5.03 +/- 0.14	(9.55 to 12.60)	4.86 +/- 0.27	9	**323.63 +/- 35.31**	223.21 +/- 21.32	44.99

Table 34. Relationship Between Seal Strength and Burst Pressure – Continuation

Gap 0.50" – "Average Seal Strength" Value (S_{avg})

Tensile Peeling Time tp (sec)	Velocity v (in/min)	Burst Peeling Time tb (sec)	Flow	Predicted Burst Pressure $P_{predicted}$ (in. H_2O)	Observed Burst Pressure $P_{observed}$ (in. H_2O)	Overestimate (%)
69.02 +/- 6.63	(.66 to .88)	68.53 +/- 2.75	1	**196.57 +/- 26.36**	132.22 +/- 10.94	48.67
8.63 +/- 0.27	(5.47 to 7.29)	8.23 +/- 0.19	5	**209.30 +/- 31.18**	147.45 +/- 8.67	41.95
4.15 +/- 0.18	(11.74 to 15.65)	3.83 +/- 0.25	9	**219.92 +/- 26.34**	148.38 +/- 7.35	48.21

Gap 0.50" – "Minimum Seal Strength" Value (S_{min})

Tensile Peeling Time tp (sec)	Velocity v (in/min)	Burst Peeling Time tb (sec)	Flow	Predicted Burst Pressure $P_{predicted}$ (in. H_2O)	Observed Burst Pressure $P_{observed}$ (in. H_2O)	Overestimate (%)
66.40 +/- 1.03	(.66 to .88)	68.53 +/- 2.75	1	**164.47 +/- 21.98**	132.22 +/- 10.94	24.39
8.69 +/- 0.42	(5.47 to 7.29)	8.23 +/- 0.19	5	**178.97 +/- 25.71**	147.45 +/- 8.67	21.38
4.15 +/- 0.19	(11.74 to 15.65)	3.83 +/- 0.25	9	**191.70 +/- 24.80**	148.38 +/- 7.35	29.20

Table 34. Relationship Between Seal Strength and Burst Pressure – Continuation

Gap 1.0" – "Average Seal Strength" Value (S_{avg})

Tensile Peeling Time tp (sec)	Velocity v (in/min)	Burst Peeling Time tb (sec)	Flow	Predicted Burst Pressure $P_{predicted}$ (in. H_2O)	Observed Burst Pressure $P_{observed}$ (in. H_2O)	Overestimate (%)
62.58 +/- 1.50	(.74 to .98)	60.89 +/- 2.38	1	**98.28 +/- 11.71**	76.65 +/- 4.76	28.22
7.34 +/- 0.18	(6.44 to 8.58)	6.99 +/ 0.23	5	**106.70 +/- 16.39**	84.79 +/- 6.06	25.84
3.61 +/- 0.09	(13.13 to 17.51)	3.43 +/- 0.12	9	**110.68 +/- 14.69**	86.61 +/- 5.33	27.80

Gap 1.0" – "Minimum Seal Strength" Value (S_{min})

Tensile Peeling Time tp (sec)	Velocity v (in/min)	Burst Peeling Time tb (sec)	Flow	Predicted Burst Pressure $P_{predicted}$ (in. H_2O)	Observed Burst Pressure $P_{observed}$ (in. H_2O)	Overestimate (%)
62.15 +/- 1.76	(.74 to .98)	60.89 +/- 2.38	1	**86.66 +/- 9.65**	76.65 +/- 4.76	13.06
7.26 +/- 0.21	(6.44 to 8.58)	6.99 +/ .23	5	**85.94 +/- 16.07**	84.79 +/- 6.06	1.36
3.64 +/- .09	(13.13 to 17.51)	3.43 +/- .12	9	**94.57 +/- 12.81**	86.61 +/- 5.33	9.19

It can be seen from Table 34 that when S_{avg} is used the predicted burst pressure deviates more form the observed burst pressure than when S_{min} is used. S_{avg} and S_{min}, when substituted in the formula P=2S/D, overestimate the burst pressure. The last column of Table 34 shows the percentage by which $P_{predicted}$ is higher than $P_{observed}$, when using S_{avg} and S_{min}..

Figures 41 and 42, on the following pages, show the relationship between burst pressure and plate separation (gap) and it plots both, the predicted and the observed burst pressures, using S_{avg} and S_{min} values, respectively. Both figures show how the formula P = 2S/D tends to overestimate the burst pressure.

Another analysis was performed with this data. A linear fit was tried, using the natural logarithm of burst pressures and burst separation. The equation P = 2S/D, can be expressed as ln P = ln 2S – ln D. A plot was made using the natural logarithm of the gaps and the predicted and observed burst pressures. These plots affirm that the equation P = 2S/D overestimates the burst pressure at every gap size. Figures 43 and 44 show these results.

Figure 41. Average Burst Pressure Vs. Plate Separation with "Average Seal Strength" Values - S_{avg}

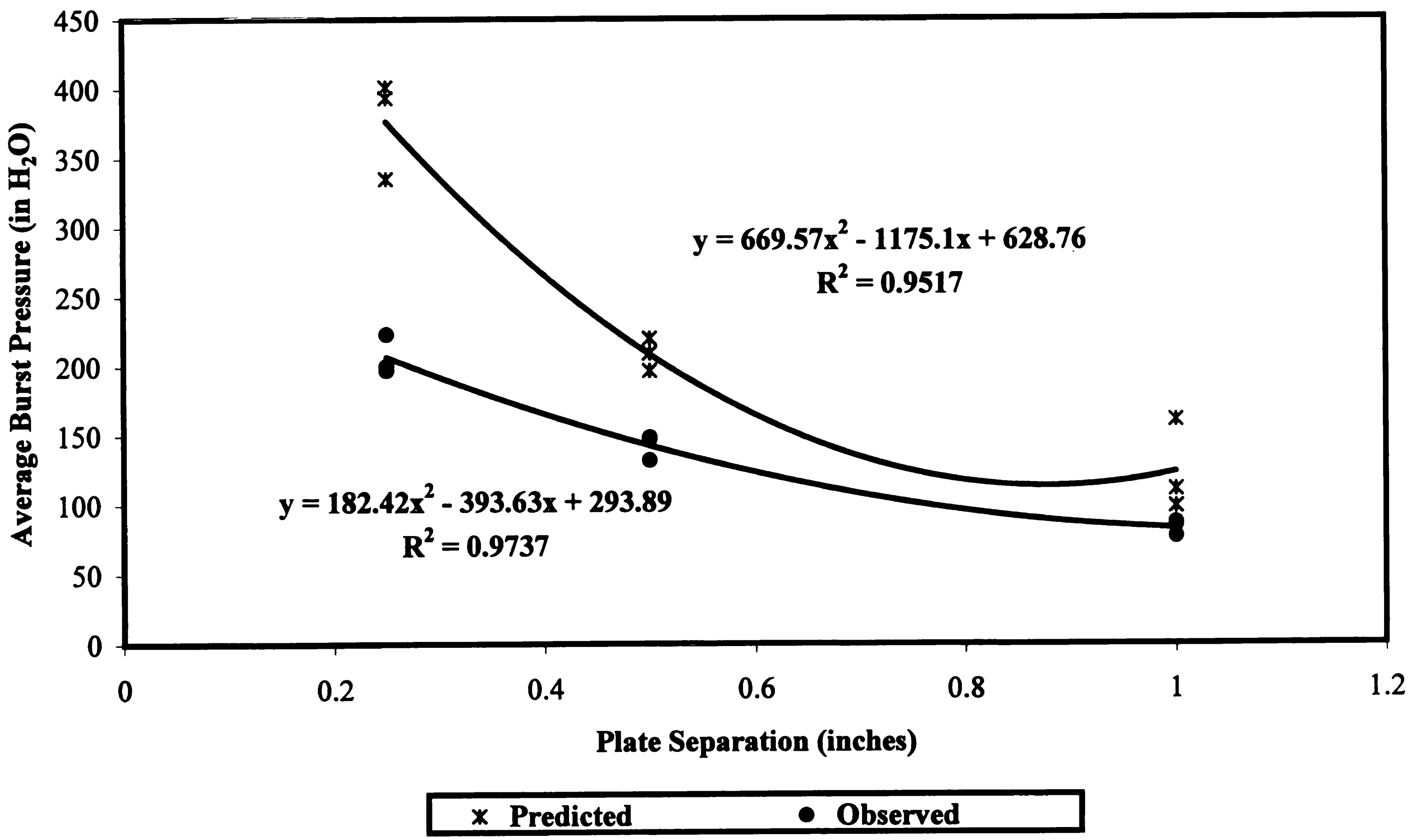


Figure 42. Average Burst Pressure Vs. Plate Separation with "Minimum Seal Strength" Value - S_{min}

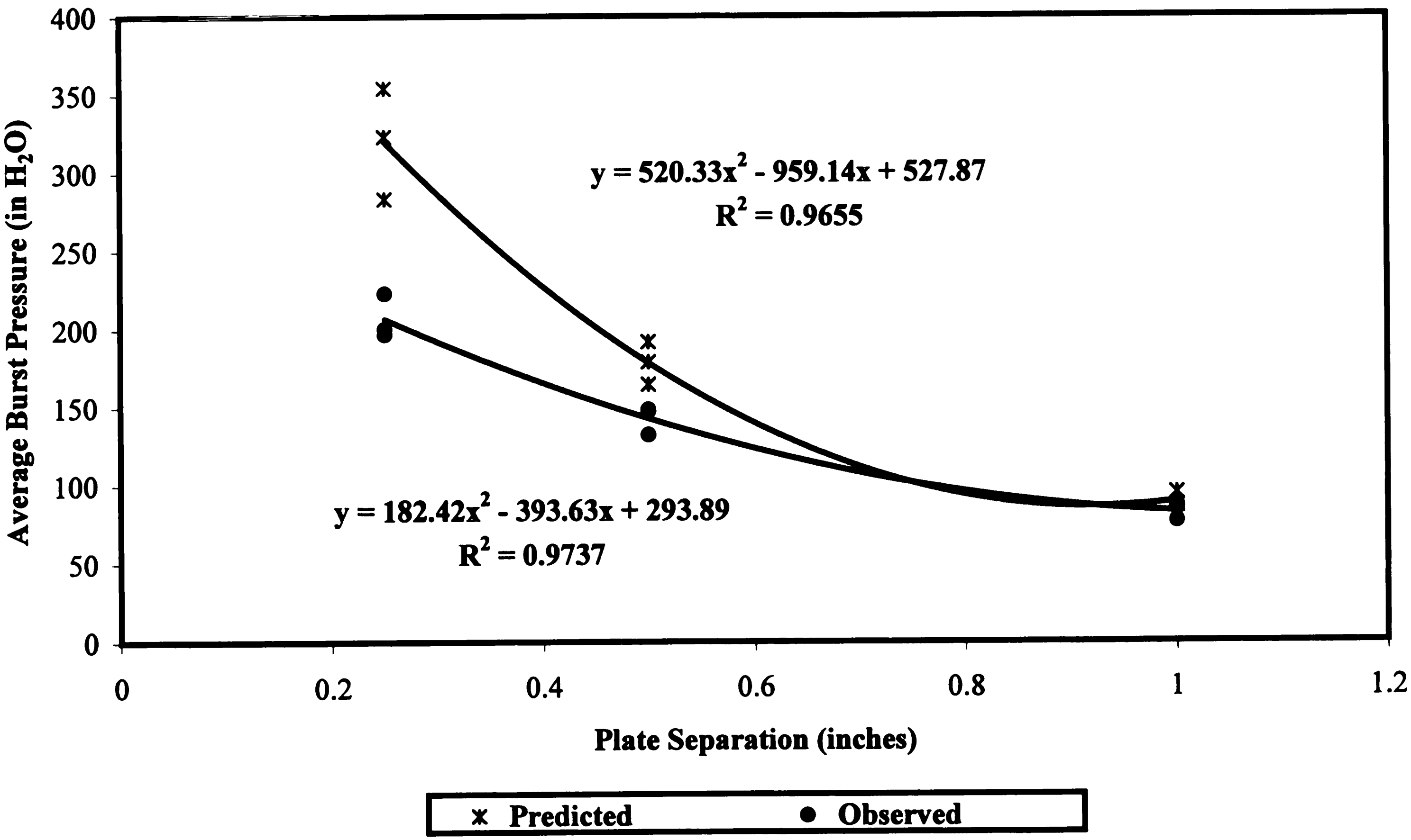


Figure 43. ln [Average Burst Pressure] Vs. ln [Plate Separation] with "Average Seal Strength" Value - S_{avg}

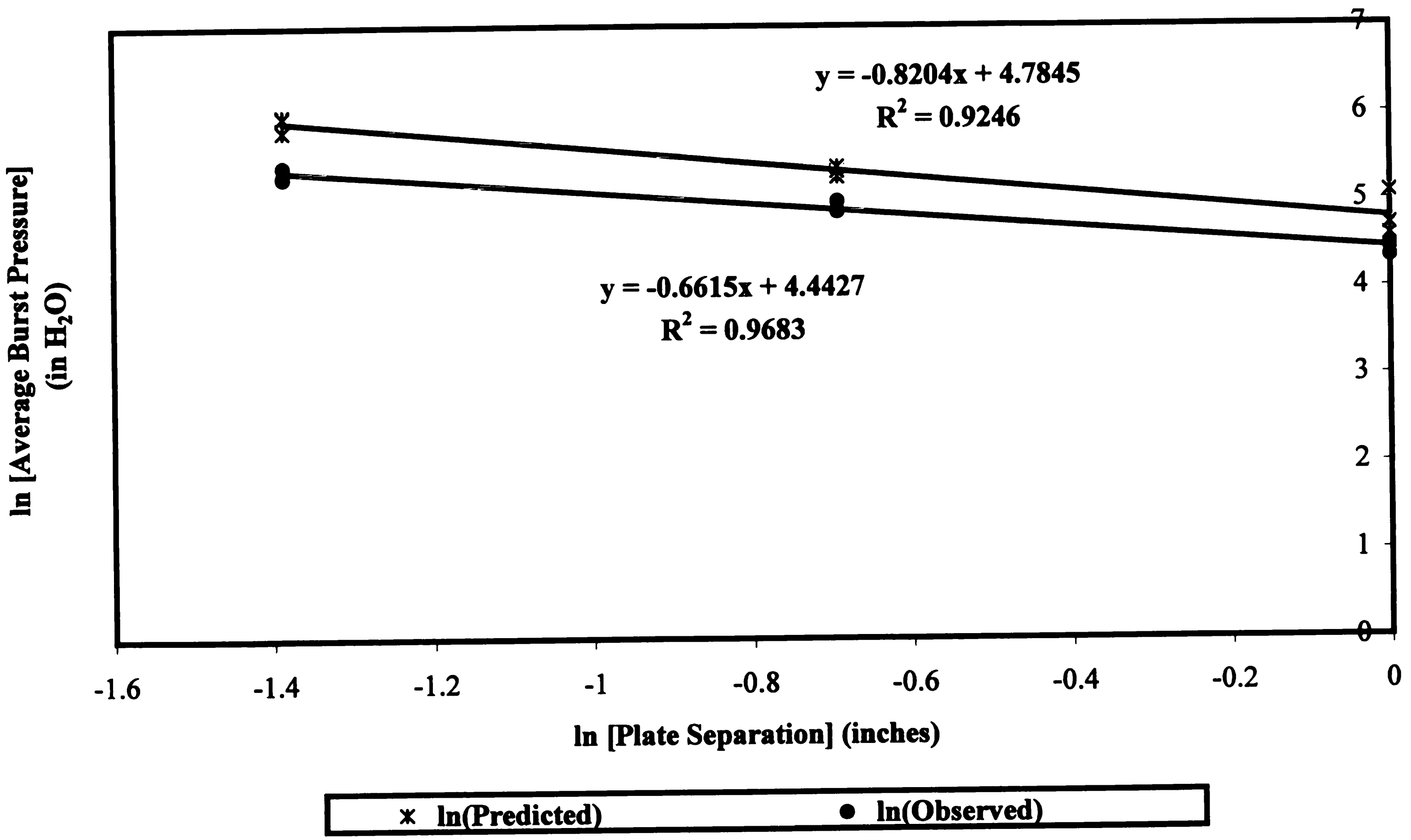
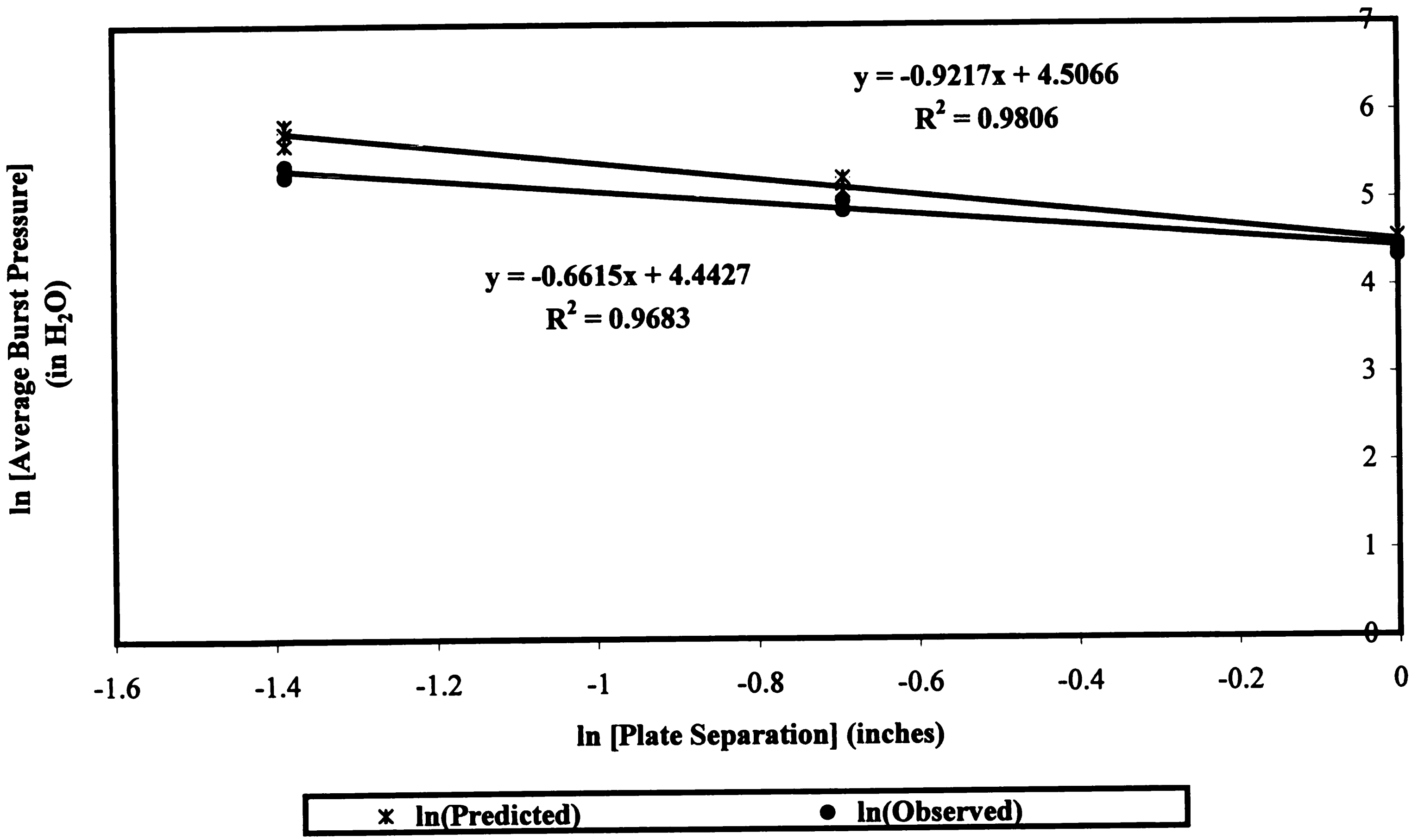


Figure 44. ln [Average Burst Pressure] Vs. ln [Plate Separation] with "Minimum Seal Strength" Value - S_{min}



SUMMARY OF RESULTS

CORRELATION BETWEEN BURST TEST AND PEEL TEST - POUCHES:

1. The formula P = 2S/D tends to overestimate the burst pressure. The overestimation of burst pressure increases at smaller gaps. See Table 34 and Figures 41 & 42.
2. The correlation between peel and burst test does not seem to work well, at least for the pouches that were tested, which are Tyvek/plastic chevron seal pouches. There are some reasons that can explain why this correlation does not work:
   a. The burst test and the peel test are two different types of test. In the burst test, the force applied results in deformation of the package. On the other hand, in the tensile peel test, deformation is being applied and it results in some force. In the peel test, deformation is applied to a one-inch wide strip of material or seal. In the burst test when the package is pressurized the seal perimeter does not take the same load at all points because it deforms differently around the seal perimeter. For example, the areas that have wrinkles are loose and slack, so they do not take any force. It is only the perimeter of the stressed part that takes the force. Also, corners, curves and straight line seals take force differently.
   b. In the burst test, not only the seal perimeter affects the burst pressure. There are other factors like sharp edges, corners, and angles that can act as stress concentrators and therefore affect the results.
   c. The variation of the seal strength around the seal perimeter of the pouch makes the correlation harder. The area from which a strip is cut to be peel tested may not necessarily represent the point in which the pouch would break in a burst test.

d. The time that it takes for a sample to peel or burst can affect the results. If the strip or seal is being stressed slowly it will elongate and then break at a lower value than if it is stressed quickly due to the nature of the material [7]. According to Professor Kit Yam [22], if the tensile peeling time and the burst peeling times are controlled to be the same, a correlation between burst test and peel test is possible. The percent difference between burst and peeling times obtained in this experiment was approximately 5%, not much different from the percent difference obtained by Yam. The obtained results on this thesis project show that the correlation between the two tests was not possible to achieve for Tyvek/plastic chevron seal pouches, even when the tensile and burst peeling time were controlled to be the same. Professor Yam used a different type of package. He used PET/aluminum/PP MRE pouches. Yam's research results show higher tensile and peeling times and higher burst values than the ones obtained in this experiment. The difference in type of package, seal and material could explain the differences in the obtained results.

DISCUSSION

Wachala, Bohn, Spitzley, Franks, Lorimer, and ASTM Committee F2.6, all give reasons for using restraining fixtures in the burst test (see Appendix D). When these reasons are compared with the results of this experiment, some agree and some do not. It is true that when using the restraining fixture, all seal surfaces are exposed to the same forces. The forces are distributed more uniformly around the seal than when the package is unrestrained. This gives the entire seal area a more equal opportunity to burst. It was also observed that when the package was pressurized within restraining plates, the dimensional stability of the package was maintained and the tendencies to deform were minimized. Also it is true that the restrained burst test results will provide a better way to correlate burst and peel test than unrestrained burst test results. But even when using restrained burst testing there are still some difficulties in trying to find that correlation for Tyvek/plastic chevron seal pouches. The predicted burst pressure obtained with the formula described by Kit Yam [22] overestimated the observed burst values.

Some of the reasons provided do not agree with the obtained results. For example, the use of restraining plates to get more consistent results. It was seen that in the case of the pouches a gap of 0.25" contributed to an increase in variation. In general, the results for blisters and pouches showed no specific pattern in the variation.

Another common reason why the use of restraining fixtures is being proposed is that it may reduce or eliminate the influence of package geometry and package size effects on the burst values. The results of this project show that burst pressure varies inversely with package size for both, unrestrained and restrained burst test. For both, blisters and pouches, the package size effect was not reduced or eliminated with the use of restraining plates, but stayed almost the same or even increased. See Tables 6 & 8, for blisters and Tables 18 & 20, for pouches.

It is believed by some of the researchers mentioned above, that there is a greater chance to find the weakest area when using restraining fixtures. The design of this experiment does not allow to prove or disprove this because the pouches that were tested have the same seal strength around the seal perimeter (sides and chevron). It is true that when the pouches were tested in a restrained mode, they showed more failures on the chevron than on the sides. It is not clear why this happened. There are some factors that could explain this behavior. They are the following: first, the chevron is receiving more stress when the pouch is restrained than when it is unrestrained. This is because when tested unrestrained the pressure entering the package make the flexible membranes of the pouch to form a "pillow" shape which pulls more on the side seal than on the chevron seal. When using the restraining plates, they prevent these flexible membranes from forming that "pillow" shape and allow testing the seal more uniformly. Second, the peak and corners on the chevron act as stress concentrators, which would make it more likely to break in a restrained test than the sides. It was observed that the pouch still deforms a little bit on the chevron area while tested between the restraining plates; this can create stress concentrators along the seal depending on how it deforms. Another test should be conducted in the future using pouches with a chevron seal made weaker than the sides. In that way, it will be possible to see if the restraining fixture helps to find the weakest area or not.

Another reason why the use of restraining fixtures is being suggested is that it provides a way of measuring the minimum seal strength of the package. I think this really depends on the way "minimum seal strength" is interpreted and what is the intended purpose of the burst test being conducted. The obtained results showed that for blisters and pouches the restrained burst pressures are higher than the ones obtained in the unrestrained test. When the pouches are tested in an unrestrained mode they break at a lower value. There was a lot more deformation of the package when it was tested unrestrained than when it was tested restrained. This deformation can fold the seal area and create wrinkles. This will make the package easier to break in some places than in others. This burst value can be seen as the "minimum seal strength" that a package will show. This will represent the worst case even though it does not necessarily represent the real strength of the seal. When the package is tested in a restrained mode, because there is less deformation and fewer stress concentrators, the package breaks at higher values. In this case the deformations are smaller, therefore the stress concentrators must be lower, so the package seal remains secure until the air pressure is higher. The "minimum seal strength" in this case represents more the strength of the seal.

CHAPTER 6. CONCLUSIONS & RECOMMEDATIONS

CONCLUSIONS

The use of restraining plates in the burst test is currently being proposed in industry. Members of leader companies have provided reasons for using restraining fixtures in the burst test. Some of these reasons are not in accordance with the results obtained in this experiment. Other experiments that have been performed previous to this one have shown similar results. Therefore, some of these reasons need to be reconsidered.

The use of a restraining fixture in the burst test has its advantages and disadvantages. Some of the advantages are:

1. The tendency for package deformation (pouches) and doming of the lid (blisters) is minimized
2. The dimensional stability of the package (pouches) and lid (blisters) is maintained
3. Package seals are tested more uniformly.

Some of the disadvantages are:

1. There is no conclusive evidence that restraining fixtures reduce variation. The data analysis shows that the raw variance and coefficients of variation give different answers with respect to variation.
2. It requires higher pressure to break the package and longer time to complete the test.

3. Restraining fixtures of different sizes are needed to test packages of different sizes. Pouches that are extremely large or wide will probably need a bigger restraining fixture than the rest of the pouches.
4. Gap heights needs to be specified depending of the package size and type. A gap that is too big for a certain pouch will not minimize the effects of folding and creasing of the flexible membranes. For blisters, choosing a gap height is more complicated because the height of the tray needs to be taken into consideration. Also, it is hard to determine which gap size will provide the best results for a certain package and to determine if testing more than one gap will be useful or not.
5. A restrained burst test does not necessarily represent what the most of the packages will encounter in reality. If the package in reality will behave like in an unrestrained situation, and the restrained burst test results are being used as an indicator of what is the pressure that the package can withstand, then the results will indicate that the package is stronger than what it is in reality. That is because restrained burst pressure is higher than the unrestrained burst pressure.

The burst test provides a means for measuring the overall strength of the package, and determines the weakest point of the entire seal [15]. The internal burst pressure is considered to be a good overall measure of the ability of a pouch to withstand transport and handling [22]. It subjects the entire package to some of the stresses that packages encounter in the manufacturing, distribution and use environments [5].

If the goal of the burst test being conducted is to provide a measure of the package integrity in the use environments then the unrestrained test should be used since most of the packages behave like that in reality. It does not matter if deformation lowers the burst pressure if in reality that is what is happening to the package. All packages, during their useful life, can experience a series of different situations that are difficult to predict. It is hard to predict how the package will deform or behave in those situations. The unrestrained burst test will provide information about the lowest burst pressure that a package can withstand. I think it is important to reconsider the reasons why restraining plates should be used; if it is going to be used instead of the unrestrained burst test or if it is going to be used in addition to it.

RECOMMENDATIONS

After completing the experiments and the data analysis, there are some things that were learned and should be considered before repeating a future test.

1. If a restraining fixture will be used;
   a. Define and specify the purpose of using it because:
      1. There is no conclusive evidence that restraining fixtures reduce variation.
      2. It was demonstrated that the use of restraining plates does not reduce or eliminate the package geometry and size effects.
   b. Find a way of estimating the best gap height to use for a specific pouch. For example, we know that for a future test we should avoid using narrow gaps, for example 0.25" (¼") or lower, for packages of the size range used in this research project. The variation for gap 0.25" was actually higher than for the other gaps.
   c. Since the raw variance (σ^2) and coefficients of variation (CV) give different patterns of response, it is essential that reports of repeatability or variation and discussions make clear whether raw variance or coefficients of variation is being reported.
2. When testing pouches in an unrestrained mode, it could be done either with the chevron facing up or the chevron facing down. It was demonstrated that there is no statistical difference between the unrestrained burst test results performed with the pouch at this two different chevron orientations.

Even though we have accomplished some of our goals in terms of explaining the basic behavior of the packages when tested in a restrained mode there is still more research that needs to be done. Some of the recommendations for future research are:

1. Determine why the restrained burst test is used
    a. To predict real life performance?
    b. As a quality control test to detect changes in seal integrity and quality during production?
    c. Other?
2. Study, analyze, reconsider, and formulate reasons why restraining plates should be used.
3. Conduct two restrained and unrestrained burst tests for Tyvek/plastic pouches. In the first test, pouches that have a chevron seal weaker than the sides will be tested. In the second, the same test will be performed using a package with the same size and material, but with the side seals weaker than the chevron. The main purpose of these tests is to see if the restraining fixture really help to find the weakest point. If the pouches break mostly on the chevron in the first test and on the side seals in the second test, then that will be a good indication that the restraining plates help to find the weakest point. On the other hand, if the pouches break mostly on the chevron during both tests, then it means that there is something else that is causing breakage in that specific area. It could be the way the pouch is held in the fixture, the deformation experienced while testing, and others.

4. Use pouches made of different types of material (for example aluminum pouches) to conduct:
    a. An unrestrained burst test to study the chevron orientation effect
    b. A restrained test to study the gap size effect
    c. A peel and restrained burst test to see if a correlation between the two will work or not
5. Conduct a restrained and unrestrained burst test with different types of blister configurations.
    a. Additional gap sizes should be included in the experiment.
    b. Differences in tray shape and geometry and differences in angles and radii at the corners should also be considered
6. Investigate if a correlation between peel test and burst test will work for blisters.

APPENDICES

APPENDIX A

APPENDIX A

BLISTERS -RAW DATA

I. UNRESTRAINED VS RESTRAINED BURST TEST RESULTS

Table 35. Unrestrained and Restrained Results – Blisters Raw Data

Package #1 and Package #2

	PKG #1 Accessory Package				PKG #2 Thera IPG outer Package			
	P/N 119401-001				P/N 119679-001			
Sample	**UR**	**Location**	**R**	**Location**	**UR**	**Location**	**R**	**Location**
1	117.5	C	154.2	A	68.2	A	116.6	AC
2	132.7	A	157.0	B	73.4	C	100.2	A
3	125.3	D	146.9	A	75.6	A	94.1	A
4	119.6	D	152.4	AB	80.7	C	118.9	A
5	123.0	D	150.3	B	75.1	A	102.1	A
6	118.0	D	163.7	CD	75.6	B	112.6	A
7	126.9	A	147.6	B	72.6	B	102.4	AB
8	126.3	A	149.8	D	73.5	B	114.9	mf
9	127.9	C	156.5	B	70.9	C	121.5	A
10	125.1	A	147.4	A	72.7	C	116.1	C
11	125.3	D	152.6	CD	75.4	B	119.1	B
12	130.1	C	162.2	B	71.8	A	111.5	A
13	109.7	A	154.2	B	72.0	A	115.7	B
14	117.7	A	154.4	D	72.8	A	111.4	A
15	123.0	C	146.9	CD	73.6	C	129.9	B
16	129.6	D	151.8	B	64.1	A	112.8	B
17	99.8	D	152.2	B	72.9	A	113.6	B
18	118.2	C	141.4	CD	74.9	C	104.7	A
19	116.3	C	137.3	CD	73.3	B	113.4	A
20	128.2	C	144.5	CD	76.9	C	115.3	AC
21	115.9	C	154.4	A	69.0	A	107.6	AB
22	95.0	C	152.1	CD	80.2	C	118.1	C
23	115.0	D	150.5	D	76.9	A	119.0	A
24	100.2	C	151.2	AB	68.0	A	115.5	A
25	118.2	D	149.8	A	71.7	A	121.0	C

Note: mf = material failure; nb = non break

Table 35. Unrestrained and Restrained Results – Blisters Raw Data Continuation

Package #1 and Package #2

	PKG #1 Accessory Package				PKG #2 Thera IPG outer Package			
	P/N 119401-001				P/N 119679-001			
Sample	**UR**	**Location**	**R**	**Location**	**UR**	**Location**	**R**	**Location**
26	120.3	C	145.2	C	69.3	C	105.2	A
27	124.2	A	149.2	C	69.9	A	115.3	A
28	116.6	C	128.4	D	74.6	B	106.7	A
29	121.3	C	162.0	C	69.4	A	116.0	A
30	121.0	D	151.1	C	73.5	A	100.7	A
31	114.6	A	180.3	A	74.5	A	105.0	B
32	122.5	C	144.8	C	75.7	A	119.5	CD
33	108.8	D	166.6	D	69.6	A	127.6	AC
34	112.3	D	153.4	C	76.0	B	110.9	AB
35	117.0	A	135.8	Nb	72.5	A	105.8	A
36	124.9	A	162.9	D	71.9	A	120.5	A
37	136.7	B	155.6	C	80.1	A	114.2	C
38	120.7	C	153.6	D	72.5	B	125.3	A
39	126.9	D	164.8	D	67.5	mf	113.3	A
40	141.7	C	190.7	C	66.9	A	107.2	A
41	125.7	D	163.6	C	70.0	A	101.2	CD
42	141.7	C	165.5	AC	82.1	B	125.3	D
43	147.4	C	153.0	D	72.2	B	135.0	C
44	135.2	C	160.7	A	71.3	A	112.2	A
45	124.9	D	162.2	D	73.5	A	109.2	A
46	112.9	D	168.7	Nb	70.0	C	101.8	A
47	112.9	C	143.4	AB	73.7	A	122.3	C
48	108.5	C	159.8	B	77.1	B	111.9	A
49	128.8	A	138.2	AB	76.4	B	104.4	B
50	116.4	D	145.7	D	74.7	C	116.8	B
Average (in. H_2O)	**121.4**	**N/A**	**153.7**	**N/A**	**73.1**	**N/A**	**113.2**	**N/A**
Std Dev	**10.2**	**N/A**	**10.7**	**N/A**	**3.6**	**N/A**	**8.4**	**N/A**

Note: mf = material failure; nb = non break

Table 35. Unrestrained and Restrained Results – Blisters Raw Data Continuation

Package #3 and Package #4

	PKG #3 Standard Leads Outer				PKG #4 Myocardial Leads Outer			
	P/N 119421-001				P/N 119553-001			
Sample	**UR**	**Location**	**R**	**Location**	**UR**	**Location**	**R**	**Location**
1	40.3	C	123.2	D	38.1	mf	85.3	BC
2	41.2	C	103.4	A	42.0	B	89.5	BC
3	35.2	C	119.6	B	41.0	AB	89.5	BC
4	40.1	C	101.5	B	40.0	B	84.0	BC
5	41.4	A	104.4	B	36.6	mf	86.8	BC
6	33.5	C	120.9	C	38.7	B	84.9	BC
7	43.2	C	124.6	AD	34.9	mf	88.1	BC
8	42.1	C	115.4	B	36.8	AB	84.8	BC
9	43.3	C	109.5	B	39.9	B	83.9	BC
10	41.5	C	114.4	D	38.0	B	87.2	BC
11	39.8	C	122.2	B	40.0	B	85.8	BC
12	34.2	mf	122.7	D	37.3	AB	93.5	BC
13	39.5	C	119.7	B	36.7	B	83.3	BC
14	38.6	mf	112.9	A	40.0	B	82.0	BC
15	40.1	C	115.0	B	36.8	B	81.7	BC
16	38.9	C	119.2	C	40.1	AB	84.7	BC
17	41.2	C	131.9	D	35.9	mf	81.9	BC
18	37.0	mf	105.8	B	38.7	B	88.7	BC
19	42.9	C	118.3	D	36.9	A	86.2	BC
20	40.9	C	125.3	AD	38.9	AB	86.6	BC
21	40.5	C	108.2	B	38.3	A	88.6	BC
22	38.3	C	113.3	B	40.7	AB	92.2	BC
23	38.3	C	112.0	B	37.7	B	85.0	BC
24	44.3	C	101.9	B	38.1	mf	83.0	BC
25	39.2	mf	106.2	B	39.1	B	89.3	BC

Note: mf = material failure; nb = non break

Table 35. Unrestrained and Restrained Results – Blisters Raw Data Continuation

Package #3 and Package #4

	PKG #3 Standard Leads Outer				PKG #4 Myocardial Leads Outer			
	P/N 119421-001				P/N 119553-001			
Sample	**UR**	**Location**	**R**	**Location**	**UR**	**Location**	**R**	**Location**
26	36.8	C	106.5	A	38.0	B	89.0	BC
27	38.3	C	117.2	D	34.0	AB	82.9	BC
28	38.0	C	106.4	B	39.9	AB	92.6	AD
29	37.0	C	131.6	CD	42.4	A	85.8	BC
30	37.2	C	115.4	D	39.9	AB	89.3	BC
31	35.9	C	111.9	D	38.6	AB	85.0	BC
32	39.8	C	117.5	B	39.3	AB	83.9	BC
33	39.9	C	121.4	D	40.6	AB	81.1	BC
34	42.2	C	119.1	A	36.5	B	91.0	BC
35	36.7	C	115.4	D	39.4	AB	90.4	BC
36	38.2	C	98.6	B	38.8	AB	90.9	BC
37	36.5	C	116.3	B	33.9	AB	86.7	BC
38	43.3	C	111.2	AB	37.3	A	86.1	BC
39	38.2	C	109.5	AB	37.1	AB	90.9	BC
40	37.1	mf	111.0	A	38.2	AB	86.5	BC
41	38.9	C	114.4	A	39.6	AB	89.0	BC
42	41.6	C	120.9	D	35.4	AB	90.8	BC
43	31.2	mf	105.4	B	36.0	A	86.8	BC
44	37.8	C	111.4	B	39.3	AB	94.0	AD
45	36.9	C	114.7	CD	39.5	AB	84.9	BC
46	38.0	C	117.0	A	37.1	AB	76.5	BC
47	38.6	C	114.2	B	41.0	B	86.6	BC
48	39.1	C	118.6	D	38.1	AB	91.5	BC
49	37.0	mf	115.2	A	39.0	B	84.5	BC
50	42.2	C	111.4	B	40.6	A	88.3	BC
Average (in. H_2O)	**39.0**	**N/A**	**114.5**	**N/A**	**38.4**	**N/A**	**86.8**	**N/A**
Std Dev	**2.7**	**N/A**	**7.3**	**N/A**	**1.9**	**N/A**	**3.6**	**N/A**

Note: mf = material failure; nb = non break

BLISTERS -RAW DATA

II. PACKAGE SIZE AND GAP SIZE EFFECT

Table 36. Package and Gap Size Effects – Restrained Burst Test Results Blisters Raw Data

Package #1 - Accessories Package -

	Gap = .20"		Gap = .10"		Gap = .01"	
Sample	Burst Value (in. H2O)	Location of Failure	Burst Value (in. H2O)	Location of Failure	Burst Value (in. H2O)	Location of Failure
1	117.8	D	166.9	B	265.2	C
2	115.9	D	150.8	C - D	235.3	C
3	136.1	A	166.4	D	227.7	C
4	122.9	D	141.6	D	216.6	D
5	119.0	C	149.8	D	249.6	A - C
6	122.2	C	159.5	D	264.0	D
7	123.9	D	150.8	C - D	240.9	B - D
8	121.1	D	162.3	C - D	238.4	B - D
9	139.8	B	128.4	D	237.4	D
10	114.1	C	125.0	C - D	246.3	C
11	131.3	B	146.5	C - D	241.3	C
12	114.0	C	147.5	D	246.4	C
13	114.6	D	162.0	D	242.4	D
14	130.7	C	141.8	C	241.0	C
15	128.5	C	147.1	D	239.4	A - C
16	132.2	C	146.0	C	230.2	B - D
17	139.9	C	155.9	D	236.4	C
18	125.6	C	157.6	A	220.5	C
19	126.1	C	161.6	D	220.5	D
20	109.3	C	145.5	D	215.4	C
21	120.8	D	170.7	C	235.2	A - C
22	123.0	C	153.3	A - B	224.2	A - C
23	132.8	D	157.0	D	228.3	B - D
24	116.7	D	152.4	D	214.2	D
Average	**124.10**	**N/A**	**151.93**	**N/A**	**235.70**	**N/A**
Std Dev	**8.4123**	**N/A**	**11.1619**	**N/A**	**13.5612**	**N/A**

Table 36. Package and Gap Size Effects - Restrained Burst Test Results Blisters Raw Data - Continuation

Package #2 - Thera Small Outer Package

	Gap = .20"		Gap = .10"		Gap = .01"	
Sample	**Burst Value (in. H2O)**	**Location of Failure**	**Burst Value (in. H2O)**	**Location of Failure**	**Burst Value (in. H2O)**	**Location of Failure**
1	116.9	B	135.3	B - D	151.3	A - C
2	98.8	A	139.7	B - D	157.9	A - C
3	100.6	B	130.9	B - D	164.7	B - D
4	96.8	A	129.5	A - C	156.6	B - D
5	112.5	A - C	129.4	A - C	155.0	A - C
6	99.6	A	134.1	C	159.1	A - C
7	116.0	A	132.2	A - C	160.2	D
8	100.4	B	137.4	C	162.6	C - D
9	112.4	D	128.4	A - C	161.1	A - C
10	108.7	A	137.1	B - D	164.3	A - C
11	108.6	A	121.8	A - C	150.6	A - C
12	99.8	B	136.0	C	159.7	B - D
13	101.8	B	133.7	B - D	150.6	B - D
14	90.3	A	134.4	A - C	156.4	B - D
15	107.8	A	129.4	A - C	151.3	A - C
16	105.4	B	130.4	B - D	153.7	B - D
17	103.1	B - D	132.5	D	159.3	B - D
18	114.1	D	127.0	A - C	151.9	A - C
19	100.6	A	120.2	B - D	159.9	A - C
20	85.5	B	127.8	B - D	163.7	B - D
21	113.2	A	133.5	A - C	163.3	A - C
22	103.5	B	128.7	B - D	160.9	A - C
23	95.0	A	121.1	A - C	154.8	A - C
24	106.2	B	124.5	A - C	157.7	A - C
Average	**104.07**	**N/A**	**130.63**	**N/A**	**157.78**	**N/A**
Std Dev	**8.0029**	**N/A**	**5.1917**	**N/A**	**4.5503**	**N/A**

APPENDIX B

APPENDIX B

POUCHES -RAW DATA

I. UNRESTRAINED VS RESTRAINED BURST TEST RESULTS

II. PACKAGE SIZE AND GAP SIZE EFFECTS

Table 37. Unrestrained Burst Test Results – Pouches Raw Data

Package #1 (5" X 10")

	Unrestrained Chevron Up		Unrestrained Chevron Down	
Sample	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**
1	50.7	B	46.7	D
2	66.7	E	41.3	CD
3	43.0	CD	46.9	BCD
4	45.1	D	46.1	D
5	54.1	B	39.7	D
6	62.9	A	39.4	CD
7	56.7	D	41.4	D
8	77.3	D	60.4	D
9	50.9	E	38.3	D
10	52.9	B	49.7	BCD
11	64.4	D	69.8	B
12	76.0	A	57.1	E
13	59.4	B	68.9	B
14	55.5	E	64.0	A
15	69.3	A	41.3	B
16	71.5	D	41.1	D
17	54.0	A	38.8	B
18	57.6	D	40.5	D
19	69.9	A	58.8	B
20	55.9	E	44.5	D
Average	**59.69**	**N/A**	**48.74**	**N/A**
Std Dev	**9.7289**	**N/A**	**10.4903**	**N/A**
C Var (%)	**16.2990**	**N/A**	**21.5252**	**N/A**

Table 37. Unrestrained Burst Test Results – Pouches Raw Data Continuation

Package #2 (7" X 11")

	Unrestrained Chevron Up		Unrestrained Chevron Down	
Sample	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**
1	40.2	B	31.5	CD
2	39.4	B	64.8	A
3	41.9	BC	30.2	B
4	32.7	BC	65.7	B
5	38.5	D	32.9	D
6	52.7	D	31.9	BCD
7	38.0	B	40.3	D
8	41.3	D	32.5	D
9	61.3	A	30.4	B
10	36.0	D	29.8	BCD
11	40.7	D	63.0	A
12	31.4	D	63.8	A
13	32.7	B	39.9	CD
14	60.4	A	54.0	B
15	40.6	B	63.4	A
16	59.5	A	50.4	BC
17	62.3	A	35.9	B
18	38.3	B	60.7	A
19	65.6	A	38.1	D
20	59.5	A	56.2	B
Average	**45.65**	**N/A**	**45.77**	**N/A**
Std Dev	**11.5122**	**N/A**	**14.1515**	**N/A**
C Var (%)	**25.2183**	**N/A**	**30.9188**	**N/A**

Table 37. Unrestrained Burst Test Results – Pouches Raw Data Continuation

Package #3 (9" X 12")

	Unrestrained Chevron Up		Unrestrained Chevron Down	
Sample	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**
1	45.3	D	49.8	A
2	32.9	D	44.6	B
3	44.4	B	45.9	A
4	48.1	A	47.3	BC
5	36.2	D	33.8	D
6	41.9	B	46.1	BCD
7	47.4	B	42.9	E
8	45.6	B	34.6	B
9	44.6	A	42.6	D
10	41.2	D	44.8	A
11	49.9	B	34.4	B
12	39.6	D	41.4	D
13	47.2	BC	50.8	B
14	46.0	CD	46.3	A
15	28.4	D	39.8	D
16	26.2	B	36.0	B
17	41.8	B	38.6	D
18	48.6	CD	50.1	D
19	32.8	D	47.0	B
20	42.8	D	49.6	A
Average	**41.55**	**N/A**	**43.32**	**N/A**
Std Dev	**6.8456**	**N/A**	**5.5199**	**N/A**
C Var (%)	**16.4776**	**N/A**	**12.7416**	**N/A**

Table 38. Restrained Burst Test Results – Pouches Raw Data – Package #1 (5" x 10")

	Gap = 1.0"		Gap = 0.75"		Gap = 0.625"		Gap = 0.50"		Gap = 0.25"	
Sample	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**
1	71.8	B	94.6	BCD	115.0	BCD	129.4	BC	178.1	B
2	102.5	CD	114.2	A	111.7	BC	125.0	BC	182.3	A
3	81.6	D	83.8	D	121.0	BC	118.6	BCD	199.6	B
4	72.2	D	101.3	B	124.6	B	124.0	BCD	179.1	B
5	76.0	D	92.5	BCD	107.4	BCD	110.3	CD	192.9	B
6	87.2	BC	114.2	BC	113.6	BC	136.0	BC	189.3	B
7	70.7	D	88.8	BCD	112.0	B	130.5	B	185.5	B
8	95.9	BCD	97.1	BCD	102.7	BCD	124.3	B	216.5	D
9	73.1	B	73.2	D	87.6	B	111.8	D	202.9	B
10	85.6	B	101.4	D	99.1	BC	106.0	D	221.0	BC
11	72.8	E	112.9	B	117.1	B	122.5	BC	207.9	D
12	103.6	B	100.9	BC	89.9	D	122.1	B	166.9	B
13	86.2	BCD	98.9	E	99.4	E	125.0	BC	224.2	B
14	82.1	C	99.3	CD	104.0	BC	138.5	B	211.7	D
15	80.0	BC	107.1	D	104.0	B	131.1	B	205.7	B
16	96.4	A	128.7	B	108.8	B	143.7	BCD	203.9	B
17	66.9	D	120.6	BCD	127.2	BC	128.6	BC	184.7	B
18	113.2	CD	94.6	D	128.1	B	131.0	BCD	179.2	B
19	73.0	B	122.8	BC	122.4	B	105.7	B	202.0	D
20	92.7	CD	97.5	B	125.4	D	123.3	BCD	195.0	B
Average	**84.18**	**N/A**	**102.22**	**N/A**	**111.05**	**N/A**	**124.37**	**N/A**	**196.42**	**N/A**
Std Dev	**12.9353**	**N/A**	**13.6323**	**N/A**	**11.9035**	**N/A**	**10.1686**	**N/A**	**15.7185**	**N/A**

Table 38. Restrained Burst Test Results – Pouches Raw Data – Continuation - Package #2 (7" x 11")

	Gap = 1.0"		Gap = 0.75"		Gap = 0.625"		Gap = 0.50"		Gap = 0.25"	
Sample	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**
1	79.8	B	102.9	B	113.8	B	105.5	B	204.1	B
2	71.7	D	66.9	B	93.8	B	122.6	B	217.0	B
3	62.8	D	97.0	B	109.3	D	122.6	B	207.0	D
4	77.1	BC	85.7	D	105.1	B	126.9	B	184.9	E
5	72.4	D	88.1	B	99.0	A	120.1	D	169.4	D
6	81.5	B	84.8	D	112.3	D	114.9	D	190.1	B
7	66.2	B	97.7	BCD	124.0	D	123.3	B	206.1	D
8	86.7	D	97.0	B	101.4	B	120.5	D	205.4	B
9	65.5	B	112.1	B	84.7	B	116.1	D	190.8	B
10	82.2	D	96.0	D	101.0	B	117.2	B	147.1	B
11	75.4	B	84.5	B	112.2	D	126.3	B	174.8	D
12	64.5	B	86.8	B	125.7	D	116.6	D	186.4	D
13	73.4	B	86.6	B	107.5	D	128.7	B	224.7	B
14	72.9	D	108.8	CD	109.9	B	115.3	B	197.8	D
15	64.8	D	106.6	CD	106.6	B	133.6	D	199.3	B
16	65.9	D	65.9	B	111.8	BCD	126.8	D	211.1	D
14	80.7	D	74.8	D	104.9	D	128.7	B	219.9	D
18	71.5	B	79.1	B	104.8	D	126.6	D	191.1	D
19	73.7	CD	114.9	CD	123.9	B	128.1	B	202.9	B
20	76.0	D	91.8	D	107.7	D	126.1	B	187.8	B
Average	**73.24**	**N/A**	**91.40**	**N/A**	**107.97**	**N/A**	**122.33**	**N/A**	**195.89**	**N/A**
Std Dev	**6.8132**	**N/A**	**13.8157**	**N/A**	**9.8948**	**N/A**	**6.5926**	**N/A**	**18.3805**	**N/A**

Table 38. Restrained Burst Test Results – Pouches Raw Data – Continuation - Package #3 (9” x 12”)

	Gap = 1.0"		Gap = 0.75"		Gap = 0.625"		Gap = 0.50"		Gap = 0.25"	
Sample	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**	**BP (in. H2O)**	**Location**
1	54.1	B	70.8	B	88.0	B	107.8	B	157.7	B
2	72.4	B	77.8	D	84.6	D	112.1	B	175.3	D
3	76.0	BC	69.7	B	83.8	D	102.7	B	148.0	D
4	69.9	B	72.6	B	93.4	D	102.8	B	168.8	B
5	61.0	B	60.2	D	95.2	D	85.3	B	174.7	D
6	69.0	BCD	79.9	B	96.9	B	96.7	D	162.3	B
7	51.1	D	69.8	B	89.1	B	102.3	D	188.4	B
8	65.7	B	82.1	B	69.4	B	93.3	B	177.0	B
9	65.2	D	79.0	B	77.7	D	102.9	B	211.0	D
10	51.0	B	75.4	D	96.3	B	113.5	B	182.6	B
11	64.4	B	58.9	B	77.6	B	98.6	D	162.0	B
12	76.7	B	90.7	B	92.0	D	93.7	D	196.9	B
13	65.7	D	61.4	D	88.3	D	116.3	D	221.0	D
14	72.6	D	75.0	D	98.7	B	105.3	B	209.7	B
15	59.4	D	84.0	D	81.1	B	102.0	B	167.2	D
16	81.0	BCD	85.0	D	104.9	D	108.6	B	144.7	D
17	57.7	B	86.7	D	101.9	B	102.2	D	149.7	D
18	68.2	BCD	89.2	D	86.6	B	109.0	D	190.6	D
19	67.7	B	79.2	B	96.5	B	102.3	B	167.7	D
20	48.1	B	86.9	B	85.5	B	93.3	B	149.7	D
Average	**64.85**	**N/A**	**76.72**	**N/A**	**89.38**	**N/A**	**102.54**	**N/A**	**175.25**	**N/A**
Std Dev	**9.1166**	**N/A**	**9.4774**	**N/A**	**8.9424**	**N/A**	**7.6471**	**N/A**	**22.1106**	**N/A**

Table 39. Peel Strength Results for Package #1 (5" x 10")

		Pouch Locations				Results per pouch		
	Sample	**A**	**B**	**D**	**E**	**Average**	**Std Dev**	**C Var. (%)**
	1	2.459	2.228	1.949	1.938	**2.14**	**0.2495**	**11.64**
	2	2.432	2.464	2.158	2.309	**2.34**	**0.1390**	**5.94**
	3	2.378	2.099	2.158	2.132	**2.19**	**0.1265**	**5.77**
	4	1.579	1.573	1.718	2.475	**1.84**	**0.4311**	**23.48**
	5	1.584	1.970	2.169	2.529	**2.06**	**0.3943**	**19.11**
	6	2.013	2.448	1.621	2.260	**2.09**	**0.3572**	**17.13**
	7	1.702	2.250	2.448	2.609	**2.25**	**0.3951**	**17.54**
	8	2.679	2.078	1.656	2.336	**2.19**	**0.4313**	**19.72**
	9	2.298	2.115	2.062	2.126	**2.15**	**0.1024**	**4.76**
	10	2.099	1.342	1.809	1.863	**1.78**	**0.3169**	**17.82**
Results	**Average**	**2.12**	**2.06**	**1.97**	**2.26**			
per	**Std Dev**	**0.3929**	**0.3565**	**0.2702**	**0.2459**			
Location	**C Var. (%)**	**18.51**	**17.33**	**13.68**	**10.89**			

Table 39. Peel Strength Results for Package #2 (7" x 11") - Continuation

		Pouch Locations				Results per pouch		
	Sample	A	B	D	E	Average	Std Dev	C Var. (%)
	1	2.491	1.954	2.094	2.110	2.16	0.2301	10.64
	2	2.244	2.153	1.938	2.540	2.22	0.2497	11.25
	3	2.405	2.137	1.616	2.620	2.19	0.4333	19.75
	4	2.314	1.868	2.346	2.470	2.25	0.2631	11.70
	5	2.314	1.976	2.030	2.260	2.15	0.1669	7.78
	6	2.309	1.938	1.605	2.126	1.99	0.3006	15.07
	7	2.427	1.552	2.137	2.212	2.08	0.3741	17.97
	8	2.035	1.702	1.648	2.819	2.05	0.5398	26.32
	9	2.577	2.121	2.078	2.905	2.42	0.3942	16.29
	10	2.121	2.056	2.282	2.717	2.29	0.2976	12.97
Results	Average	2.32	1.95	1.98	2.48			
per	Std Dev	0.1635	0.1955	0.2708	0.2901			
Location	C Var. (%)	7.04	10.05	13.69	11.71			

Table 39. Peel Strength Results for Package #3 (9" x 12") - Continuation

		Pouch Locations				Results per pouch		
	Sample	A	B	D	E	Average	Std Dev	C Var. (%)
	1	2.148	1.369	1.761	2.733	2.00	0.5815	29.04
	2	2.105	1.681	1.815	2.491	2.02	0.3587	17.73
	3	2.309	1.412	1.895	1.949	1.89	0.3686	19.49
	4	2.577	1.804	1.310	2.421	2.03	0.5835	28.77
	5	2.389	2.072	1.852	2.561	2.22	0.3174	14.31
	6	1.987	1.621	1.498	1.487	1.65	0.2339	14.19
	7	2.599	2.040	1.557	2.523	2.18	0.4834	22.18
	8	1.756	2.132	1.525	1.865	1.82	0.2520	13.85
	9	2.142	1.906	2.013	1.911	1.99	0.1109	5.56
	10	2.395	1.648	1.922	2.276	2.06	0.3404	16.52
Results per Location	Average	2.24	1.77	1.71	2.22			
	Std Dev	0.2642	0.2685	0.2278	0.3973			
	C Var. (%)	11.79	15.18	13.29	17.88			

APPENDIX C

APPENDIX C

CORRELATION BETWEEN PEEL TEST AND BURST TEST – POUCHES RAW DATA

Table 40. RESTRAINED BURST TEST – Results for Correlation

Gap = 0.25" ; Flow = 1

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	74.1	191.2	D
2	83.1	194.0	D
3	79.0	211.4	B
4	85.7	213.2	E
5	80.7	190.3	E
6	80.7	187.0	A
7	77.8	204.5	D
8	75.3	190.5	D
9	78.8	183.8	A
10	76.3	210.2	B
11	80.7	221.5	A
12	77.9	186.1	D
13	77.5	186.3	D
14	73.7	193.8	B
15	74.3	191.6	A
Avg.	**78.37**	**197.03**	**N/A**
Std Dev	**3.4288**	**11.8841**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 40. RESTRAINED BURST TEST – Results for Correlation Continuation

Gap = 0.25"; Flow = 5

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	9.2	217.5	B
2	8.9	198.7	D
3	9.0	202.9	B
4	8.6	197.3	B
5	8.4	191.5	D
6	8.8	207.0	D
7	8.7	209.3	B
8	8.7	189.6	B
9	8.9	201.0	D
10	8.9	209.7	B
11	8.7	196.6	D
12	8.6	190.2	D
13	9.1	202.8	B
14	8.8	203.8	B
15	8.4	188.4	D
Avg.	**8.78**	**200.42**	**N/A**
Std Dev	**0.2305**	**8.4364**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 40. RESTRAINED BURST TEST – Results for Correlation Continuation

Gap = 0.25"; Flow = 9

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	4.5	197.8	B
2	5.1	213.2	D
3	5.3	238.8	B
4	4.5	196.3	D
5	4.8	216.0	D
6	4.8	228.3	D
7	4.9	222.5	E
8	5.0	236.5	D
9	5.1	244.8	D
10	5.1	261.4	D
11	4.8	213.5	B
12	4.8	224.8	D
13	5.1	249.9	B
14	4.8	221.9	B
15	4.3	182.5	D
Avg.	**4.86**	**223.21**	**N/A**
Std Dev	**0.2720**	**21.3154**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 41. RESTRAINED BURST TEST – Results for Correlation

Gap = 0.50"; Flow = 1

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	63.0	129.9	B
2	72.0	136.9	D
3	68.0	117.9	D
4	71.0	131.1	D
5	70.0	134.6	D
6	69.0	123.9	D
7	72.0	155.3	D
8	72.0	144.9	B
9	67.0	125.4	D
10	70.0	146.3	A
11	67.0	126.1	D
12	68.0	133.0	D
13	64.0	113.8	B
14	67.0	127.0	E
15	68.0	137.2	B
Avg.	**68.53**	**132.22**	**N/A**
Std Dev	**2.7482**	**10.9418**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 41. RESTRAINED BURST TEST – Results for Correlation Continuation

Gap = 0.50"; Flow = 5

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	8.3	150.1	B
2	8.4	148.4	B
3	8.2	153.0	D
4	8.0	139.9	D
5	8.3	151.2	D
6	8.0	138.4	B
7	8.3	141.8	B
8	8.5	156.5	D
9	8.4	143.6	B
10	8.4	158.0	B
11	8.3	161.8	D
12	7.8	127.9	D
13	8.1	142.4	D
14	8.2	149.7	B
15	8.2	149.0	D
Avg.	**8.23**	**147.45**	**N/A**
Std Dev	**0.1870**	**8.6715**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 41. RESTRAINED BURST TEST – Results for Correlation Continuation

Gap = 0.50"; Flow = 9

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	3.8	146.8	D
2	3.6	137.4	D
3	3.9	139.7	D
4	3.8	145.0	D
5	3.6	142.3	D
6	4.2	151.6	BC
7	4.1	154.9	CD
8	3.9	147.6	A
9	3.6	141.6	D
10	4.3	158.4	B
11	3.9	157.1	D
12	3.4	157.7	D
13	3.7	139.4	B
14	4.0	156.4	B
15	3.7	149.8	D
Avg.	**3.83**	**148.38**	**N/A**
Std Dev	**0.2469**	**7.3510**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 42. RESTRAINED BURST TEST – Results for Correlation

Gap = 1.0"; Flow = 1

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	56.7	70.2	B
2	64.2	82.7	B
3	63.1	77.2	B
4	63.2	83.1	D
5	60.4	72.7	B
6	62.3	74.8	B
7	60.3	74.8	B
8	63.3	79.9	B
9	62.0	80.9	D
10	59.2	76.9	B
11	62.2	77.8	B
12	60.9	79.1	D
13	61.0	81.5	E
14	57.3	69.7	D
15	57.2	68.5	A
Avg.	**60.89**	**76.65**	**N/A**
Std Dev	**2.3820**	**4.7571**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 42. RESTRAINED BURST TEST – Results for Correlation Continuation

Gap = 1.0"; Flow = 5

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	6.8	79.0	A
2	7.3	90.8	A
3	7.2	92.5	B
4	7.2	95.7	B
5	7.0	85.3	B
6	7.0	80.5	D
7	7.1	84.1	D
8	6.9	83.9	D
9	6.9	86.6	CD
10	6.9	76.8	A
11	6.8	88.1	CD
12	7.3	90.9	D
13	6.5	75.2	D
14	7.2	83.9	D
15	6.8	78.6	E
Avg.	**6.99**	**84.79**	**N/A**
Std Dev	**0.2251**	**6.0624**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 42. RESTRAINED BURST TEST – Results for Correlation Continuation

Gap = 1.0"; Flow = 9

Sample	Burst Peeling Time (sec)	Burst Pressure (in. H20)	Location
1	3.5	95.3	D
2	3.3	83.5	A
3	3.3	84.1	D
4	3.3	84.4	D
5	3.5	83.1	B
6	3.4	78.6	E
7	3.7	93.5	E
8	3.5	90.6	B
9	3.3	87.0	D
10	3.5	86.6	D
11	3.3	88.0	CD
12	3.4	79.4	E
13	3.4	83.4	A
14	3.5	96.4	B
15	3.5	85.3	D
Avg.	**3.43**	**86.61**	**N/A**
Std Dev	**0.1163**	**5.3330**	**N/A**

Other parameters: Sensitivity = 1; Prefill = N

Table 43. PEEL TEST Results for Correlation - Gap = 0.25" and Flow = 1

	Location							
	A		B		D		E	
Sample	S (lb./in)	Tensile Peeling Time (sec)	S (lb./in)	Tensile Peeling Time (sec)	S (lb./in)	Tensile Peeling Time (sec)	S (lb./in)	Tensile Peeling Time (sec)
1	1.256	80.80	1.600	87.90	1.380	81.30	**1.165**	**85.60**
2	**1.621**	**84.90**	1.863	82.80	1.664	78.10	1.681	81.80
3	1.503	81.80	1.332	79.30	**1.101**	**80.50**	1.734	84.80
4	1.949	87.00	1.460	76.40	**1.246**	**82.10**	1.305	87.40
5	**1.240**	**87.50**	1.407	81.40	1.756	83.00	1.965	79.50
6	1.855	83.50	1.906	88.80	**1.342**	**81.40**	1.584	84.00
7	1.745	86.30	1.353	76.20	**1.240**	**78.40**	1.589	85.80
8	1.385	80.90	**1.299**	**79.60**	1.401	83.40	1.552	86.00
Avg.	**1.569**	**84.09**	**1.528**	**81.55**	**1.391**	**81.03**	**1.572**	**84.36**
Std Dev	**0.2684**	**2.7315**	**0.2394**	**4.7582**	**0.2198**	**1.9506**	**0.2479**	**2.5646**

Note: Parameters used: Gauge length = 0.40", Velocities = 0.67, 0.78, and 0.58 in/min for A, B & D, and E, respectively.

Table 43. PEEL TEST Results for Correlation – Continuation - Gap = 0.25" and Flow = 5

	Location							
	A		B		D		E	
Sample	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**
1	2.035	9.5	1.938	8.7	**1.713**	**9.1**	1.965	8.7
2	1.970	9.4	1.697	9.5	**1.514**	**9.4**	1.809	9.3
3	1.976	8.8	1.718	9.0	**1.611**	**8.7**	1.960	9.0
4	1.707	9.2	1.530	9.5	**1.374**	**9.4**	1.759	9.2
5	1.815	9.0	1.777	9.4	**1.396**	**9.1**	1.659	8.7
6	2.132	8.9	2.089	9.4	**1.885**	**9.0**	2.309	8.6
7	2.260	9.5	2.067	9.1	**1.713**	**9.5**	1.809	8.9
8	2.056	9.3	**1.364**	**9.1**	1.627	9.5	1.793	9.5
Avg.	**1.994**	**9.20**	**1.773**	**9.21**	**1.604**	**9.21**	**1.883**	**8.99**
Std Dev	**0.1735**	**0.2726**	**0.2532**	**0.2850**	**0.1722**	**0.2850**	**0.1995**	**0.3227**

Note: Parameters used: Gauge length = 0.40", Velocities = 6.25, 7.00, and 5.50 in/min for A, B & D, and E, respectively.

Table 43. PEEL TEST Results for Correlation – Continuation - Gap = 0.25" and Flow = 9

	Location							
	A		B		D		E	
Sample	S (lb./in)	Tensile Peeling Time (sec)	S (lb./in)	Tensile Peeling Time (sec)	S (lb./in)	Tensile Peeling Time (sec)	S (lb./in)	Tensile Peeling Time (sec)
1	1.605	5.3	1.906	5.0	**1.557**	**5.0**	1.702	5.5
2	2.132	5.0	**1.187**	**4.9**	1.885	5.3	1.611	5.1
3	2.234	5.3	1.659	4.9	**1.595**	**5.0**	2.572	5.0
4	1.911	5.3	1.847	5.0	**1.616**	**5.1**	1.890	5.2
5	2.158	5.1	2.046	5.1	**1.450**	**5.3**	1.493	5.5
6	1.799	5.0	**1.310**	**5.0**	1.756	5.1	2.046	5.2
7	1.847	5.1	**1.519**	**4.9**	2.099	5.3	1.675	5.5
8	1.756	5.1	**1.519**	**5.2**	1.707	5.0	1.831	5.5
Avg.	**1.930**	**5.15**	**1.624**	**5.00**	**1.708**	**5.14**	**1.853**	**5.31**
Std Dev	**0.2222**	**0.1309**	**0.2977**	**0.1069**	**0.2060**	**0.1408**	**0.3378**	**0.2100**

Note: Parameters used: Gauge length = 0.40", Velocities = 11.10, 12.60, and 9.55 in/min for A, B & D, and E, respectively.

Table 44. PEEL TEST Results for Correlation - Gap = 0.50" and Flow = 1

	Location							
	A		B		D		E	
Sample	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**
1	1.783	84.50	**1.573**	68.10	1.815	73.40	2.180	69.10
2	1.825	82.00	1.890	66.00	**1.471**	65.10	1.992	67.40
3	1.944	84.10	1.879	67.30	**1.272**	65.60	1.799	65.80
4	1.992	83.40	1.734	65.30	**1.514**	65.60	1.938	64.00
5	1.691	83.50	**1.670**	65.80	1.691	66.50	1.766	65.60
6	1.997	66.20	2.056	65.60	**1.664**	67.30	2.126	65.30
7	2.121	69.00	**1.111**	66.80	1.702	64.40	1.573	63.40
8	1.793	65.20	1.702	62.40	1.954	67.90	**1.611**	66.90
Avg.	**1.893**	**77.24**	**1.702**	**65.91**	**1.635**	**66.98**	**1.873**	**65.94**
Std Dev	**0.1428**	**8.7366**	**0.2828**	**1.7041**	**0.2124**	**2.8384**	**0.2243**	**1.8439**

Note: Parameters used: Gauge length = 0.80", Velocities = 0.77, 0.88, and 0.66 in/min for A, B & D, and E, respectively.

Table 44. PEEL TEST Results for Correlation – Continuation - Gap = 0.50" and Flow = 5

	Location							
	A		B		D		E	
Sample	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**
1	1.842	8.5	1.568	8.3	**1.385**	8.3	2.309	8.6
2	**1.944**	9.2	2.089	8.6	1.981	8.5	2.260	8.5
3	2.051	8.7	2.201	8.6	1.874	8.3	**1.654**	8.4
4	2.180	8.8	1.981	9.0	**1.428**	8.3	1.960	8.5
5	2.099	8.7	**1.847**	8.4	1.954	8.6	2.368	8.3
6	1.917	8.7	**1.498**	9.0	1.691	8.3	2.105	8.6
7	2.078	8.8	1.874	8.9	2.132	8.6	**1.825**	9.3
8	1.401	9.0	**1.353**	8.6	2.046	8.4	1.611	8.7
Avg.	**1.939**	**8.80**	**1.801**	**8.68**	**1.811**	**8.41**	**2.012**	**8.61**
Std Dev	**0.2435**	**0.2138**	**0.2999**	**0.2659**	**0.2814**	**0.1356**	**0.2956**	**0.3044**

Note: Parameters used: Gauge length = 0.80", Velocities = 6.38, 7.29, and 5.47 in/min for A, B & D, and E, respectively.

Table 44. PEEL TEST Results for Correlation – Continuation - Gap = 0.50" and Flow = 9

	Location							
	A		B		D		E	
Sample	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**
1	2.352	4.4	2.094	4.1	**1.895**	3.9	1.944	4.5
2	1.825	4.3	1.804	4.3	2.234	3.9	**1.396**	4.3
3	**1.530**	4.3	2.164	4.0	2.099	4.0	2.062	4.1
4	**1.949**	4.1	2.266	3.9	2.094	4.3	2.169	4.0
5	2.072	4.0	**1.600**	3.9	1.885	3.9	2.341	4.0
6	1.927	4.3	2.078	4.2	**1.916**	4.4	2.196	4.0
7	1.981	4.5	2.072	4.1	**1.969**	4.1	1.992	4.2
8	1.675	4.3	2.035	4.2	**1.603**	4.2	2.362	4.1
Avg.	**1.914**	**4.28**	**2.014**	**4.09**	**1.962**	**4.09**	**2.058**	**4.15**
Std Dev	**0.2493**	**0.1581**	**0.2124**	**0.1458**	**0.1896**	**0.1959**	**0.3069**	**0.1773**

Note: Parameters used: Gauge length = 0.80", Velocities = 13.70, 15.65, and 11.74 in/min for A, B & D, and E, respectively.

Table 45. PEEL TEST Results for Correlation - Gap = 1.0" and Flow = 1

	Location							
	A		B		D		E	
Sample	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**
1	1.954	62.60	1.868	64.10	**1.804**	64.00	1.874	63.20
2	1.756	63.60	1.793	64.50	**1.568**	64.50	1.997	61.70
3	1.976	61.60	1.863	63.00	**1.745**	61.90	1.911	62.70
4	**1.686**	61.10	1.784	63.30	2.056	60.90	1.842	61.20
5	**1.482**	63.50	1.686	65.90	1.766	63.40	1.895	64.60
6	2.035	64.30	**1.557**	62.30	1.632	61.50	1.965	63.40
7	2.207	62.00	1.691	62.40	1.342	61.30	**1.310**	60.20
8	1.917	62.40	**1.374**	59.70	1.858	62.10	1.638	59.60
Avg.	**1.877**	**62.64**	**1.702**	**63.15**	**1.721**	**62.45**	**1.804**	**62.08**
Std Dev	**0.2263**	**1.0914**	**0.1680**	**1.8330**	**0.2123**	**1.3395**	**0.2270**	**1.7044**

Note: Parameters used: Gauge length = 1.60", Velocities = 0.86, 0.98, and 0.74 in/min for A, B & D, and E, respectively.

Table 45. PEEL TEST Results for Correlation – Continuation - Gap = 1.0” and Flow = 5

	Location							
	A		B		D		E	
Sample	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**
1	**1.353**	7.6	1.847	7.5	1.960	7.2	1.890	7.3
2	1.895	7.5	2.153	7.2	**1.740**	7.0	2.180	7.2
3	2.212	7.3	**1.638**	7.3	2.158	7.5	2.051	7.5
4	2.099	7.5	1.976	7.1	**1.434**	7.1	1.783	7.0
5	2.250	7.7	**1.944**	7.1	2.207	7.5	1.949	7.3
6	2.003	7.5	2.078	7.3	1.783	7.5	**1.020**	7.3
7	**1.788**	7.5	2.067	7.5	2.008	7.5	2.067	7.5
8	1.954	7.3	**1.509**	7.2	2.223	7.1	2.491	7.4
Avg.	**1.944**	**7.49**	**1.902**	**7.28**	**1.939**	**7.30**	**1.929**	**7.31**
Std Dev	**0.2851**	**0.1356**	**0.2254**	**0.1581**	**0.2738**	**0.2204**	**0.4246**	**0.1642**

Note: Parameters used: Gauge length = 1.60”, Velocities = 7.50, 8.58, and 6.44 in/min for A, B & D, and E, respectively.

Table 45. PEEL TEST Results for Correlation – Continuation - Gap = 1.0" and Flow = 9

	Location							
	A		B		D		E	
Sample	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**	**S (lb./in)**	**Tensile Peeling Time (sec)**
1	2.336	3.5	**1.691**	3.6	2.244	3.6	2.389	3.4
2	2.255	3.7	2.094	3.6	2.325	3.6	**2.067**	3.6
3	1.750	3.5	2.013	3.7	1.985	3.6	**1.691**	3.5
4	2.400	3.7	1.981	3.7	**1.911**	3.6	2.046	3.6
5	**1.595**	3.6	2.158	3.6	1.917	3.7	1.976	3.5
6	1.836	3.6	**1.600**	3.8	2.024	3.5	1.643	3.6
7	2.019	3.5	2.191	3.8	2.212	3.7	**1.820**	3.7
8	2.126	3.5	2.051	3.6	**1.299**	3.7	2.341	3.6
Avg.	**2.040**	**3.58**	**1.972**	**3.68**	**1.990**	**3.63**	**1.997**	**3.56**
Std Dev	**0.2916**	**0.0886**	**0.2147**	**0.0886**	**0.3199**	**0.0707**	**0.2752**	**0.0916**

Note: Parameters used: Gauge length = 1.60", Velocities = 15.32, 17.51, and 13.13 in/min for A, B & D, and E, respectively.

APPENDIX D

APPENDIX D

REASONS WHY RESTRAINING FIXTURES SHOULD BE USED

As mentioned before in this report, members of leader companies like Carleton Technologies, Medtronic, Rexam Medical Packaging, and TM Electronics have provided reasons for using restraining fixtures in the burst test. Also, Committee F 2.6 on Medical Packaging of the American Society for Testing and Materials (ASTM), pointed out in its proposed standard method [4], some of the reasons and situations in which restraining fixtures should be used in a burst test. The following paragraphs show these reasons.

Thomas Wachala - CARLETON TECHNOLOGIES – [19]

1. "In an unrestrained test there is no guarantee that under pressure, each package will fold and deform the same way. The test can not be considered statistically fair if one or more tests are biased because of the lack of consistency in fixturing and holding the package under test. This lack of consistency may adjust the mean burst value to a point where a degree of uncertainty may develop concerning the acceptability of a perfectly acceptable lot from the production floor."
2. "If testing (referring to the unrestrained test) is being done at multiple locations, or if the end user or customer verifies product supplied by the manufacturer, the potential exists for large differences in burst values."
3. "The unrestrained testing does not necessarily identify the weakest part of the seal".
4. "The use of properly sized restraining plates will minimize the deformation of the package during a burst test"

5. "By maximizing the effect of restraining plates, the working surfaces around the perimeter of the package can be equalized, but not entirely. The surfaces at and near corners and curves will not respond equally, and will remain as a localized area of incongruity".
6. "Restraining plates give the operator the opportunity to test the package seals more uniformly with a greater chance of finding weak areas."
7. "The effects of package geometry and tendencies to deform during a test are minimized."
8. "The plate separation gap can be standardized, for use with a specific package, at multiple locations."
9. "This increases the likelihood that the test procedure and package geometry will remain consistent, thus reducing the variables that prevent repeatable test performance".
10. "Restraining plates are yet another tool for quantifying and qualifying the performance of package seals. If used safely and properly, the information they provide can help control the manufacturing process and give the manufacturer the ability to design and control the strength of specific seal areas."

David Bohn/John Spitzley – MEDTRONIC-[5]

1. "Additional research may yield to improved methods that will remove more variables from the burst tests and increase its sensitivity to variation within the process."

2. "Restricting the lid from ballooning may reduce or eliminate the influence of package shape on the burst test and give the entire seal area a more equal opportunity to burst. This will make monitoring of package burst zones more sensitive to material, tooling and other processing variation."

Stephen Franks - TM ELECTRONICS-[8]

1. "With restraining burst test it is possible to get more consistent results."
2. "It helps to get a more accurate picture of where the weakest area of the seal is."
3. "With restraining plates a more uniform loading is being applied."
4. "It provides a way of measuring the minimum seal strength of the package."
5. "Do not have to deal as much with the geometry problem."

Neil Lorimer – REXAM MEDICAL PACKAGING-[12]

1. "Restrained burst testing provides a rapid means of evaluating minimum seal strength (burst strength)."
2. "Restrained burst testing is more efficient and economical to perform than force gage testing of peel strength."
3. "By restraining the pouch to maintain dimensional stability the stress is more uniformly applied to the sealed perimeter of the pouch."
4. "Restrained burst testing can reliably detect the weakest area of a package seal placed around the perimeter of a flexible package."
5. "Studies using 1" gap on restraining plates have shown correlation coefficients of 0.92 or greater between peel test and burst test results. Burst test results compared to peel test values for areas of pouches where the lowest seal strength were observed (burst in that location)."

6. "Burst testing with restraining plates cannot test for general package integrity, it is a test of seal strength, not package integrity."
7. "Burst testing cannot be used to evaluate the strength characteristics of the entire sealed area since it provides a measure only of the weakest area of the seal. It should be combined with other methods of seal evaluation to determine uniformity of seal or other potential peel defects (i.e. bearding, fracturing, etc.)"

ATSM Standard- Draft proposal – [4]

1. "This test provides a rapid means of evaluating tendencies for package seal failure and minimum seal strength when the package is exposed to a pressure differential."
2. "This test provides an indicator of the minimum strength of a seal area around the perimeter of a package. An indicator of the minimum seal strength may be of importance to the package manufacturer and end user in ensuring package integrity and conversely that the seal strength is not so high as to limit opening (peelable seals) by end users."
3. "This test cannot provide a measure of the uniformity of seal strength above that minimum seal strength detected by this test method. This test methods of evaluating uniformity of seal strength or opening functionality or opening functionality."
4. "Restraining plates maintain dimensional stability while the package is being pressurized and more uniformly direct the stresses of pressurization to the perimeter of the package."
5. "In particular this test is intended as applicable to packages with seals that are intended to have a peelable seal feature (peeled open by end user to remove contents of package)."

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