Burst Strength Testing of
DOW CORNING® brand Pharma Tubings

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About the Authors

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Gina received her doctorate in Biological Chemistry from the University of Michigan in 1982. After postdoctoral research at Michigan Molecular Institute in carcinogenic transformation processes, she joined Dow Corning in 1984. She has held various positions in Personal Care, Health and Environmental Sciences and Healthcare. Besides developing sensory methods for skin, hair and fragrance, and leading an extractables program, she has also monitored and performed many basic toxicology and biocompatibility tests on silicones. She is active in ASTM and the Society for Biomaterials and has also been involved in the Society of Cosmetic Chemists

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Bill received a Bachelors of Science degree from Saginaw Valley State University in 2000. Most of his ten years at Dow Corning has been spent working on the development and performance of various analytical methodologies and techniques to better characterize both silicone and organic extractants from silicone and biological matrices. Currently Bill is currently a technical service representative, primarily assisting fabrication customers with their understanding and processing of Dow Corning Healthcare materials. He has been involved with the American Society for Quality and is a current member of the American Chemical Society.

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Brent received a Bachelor's Degree in Chemistry with a Biology minor from Saginaw Valley State University in 2001. He first started at Dow Corning in 1986 in the Process Aids and Emulsions group, and became an extrusion operator at the Healthcare Industries Materials Site in 1994. He joined technical service in 1997 and has responsibility for pharmaceutical processing and large medical device customers.

Introduction

Silicone tubing is known for its flexibility and versatility. Tubing used for the pharmaceutical industry must meet special process requirements for purity, consistency, and in some cases for burst strength where pressure variations can be significant. DOW CORNING® Pharma tubings with and without reinforcement have been tested for burst strength by procedures similar to those described in published guidelines. The results indicate that lot-to-lot variation may be greater at smaller sizes and that room temperature burst strength, within a tubing type, is best predicted by an equation used to relate maximum internal pressure to inner and outer radii or diameters (hoop stress).

Platinum-catalyzed silicone tubing is highly flexible and tear-resistant, and as a result it will expand with increased intraluminal pressure. In the pharmaceutical industry, extremes of pressure can be encountered between vacuum operations and high pressure processes involving viscous mixtures, as well as in areas where foot traffic or short bend radii make kinking a concern. With worker safety and conservation of expensive product paramount, knowledge of tubing burst pressures can be used to optimize process design.

Stresses on a "thick" cylinder (where wall thickness/internal radius > 0.1) are in radial as well as circumferential directions. What is called "hoop stress" for the simple case of thin-walled cylinders is approximated by a more complex equation for tubings of the dimensions in typical pharmaceutical use[1]

Maximum internal stress =

$$\textbf{Internal pressure} \times \frac{(OR^2 + IR^2)}{(OR^2 - IR^2)}$$

where IR=internal radius, and OR= outside radius (diameters can also be used, instead of radius values) The value in brackets will be called the "hoop stress quotient" for ease of reference.

Materials and Methods

Basic room temperature (RT) procedure for nonreinforced tubing

Tubing samples of Pharma 50,65, 80 and Advanced Pump Tubing were tested. The procedure used was based on those described by ASTM[2] and ISO,[3] except the pressure change rate was about 95 psi/min (the maximum allowed by the apparatus using laboratory air supply) rather than 1000 psi/min.

Silicone properties are strain rate-dependent, and hence burst properties may be affected by the pressure change rate. The higher ASTM-prescribed rate would have made the observation of burst more difficult, as it would have occurred very rapidly in some cases.

Eighteen to 20 inches of tubing were cut to fit between two sets of barb fittings within a 36" × 13" polycarbonate box. One set of fittings within the box (farthest from the water intake) was connected to a Noshok 0-300 PSIG pressure gauge with a follow-arm. This gauge placement was found to allow the most accurate monitoring of the pressure changes that occurred during the test. At the end closest to the water intake, two barb fittings were available; one for larger bores, one for smaller. Tubing connected to these fittings connected with lab water supply. The polycarbonate box was set at an angle (down) from the intake end to the other; holes at the low end allow the draining of water that is released during the burst process.

To perform a test, a sample was connected to the proper fittings and secured in place using either standard metal hose screw clamps, or GB Gardner Bender[4] Cable ties (such as #46-303). The water was then turned on to maximum (flow rate: 4.93 L/min), and air bubbles were eliminated from the tubing. The water continued to flow into the tubing, but flow-through was blocked off after the pressure gauge. Leaking of water from either fitting should be eliminated or the trial repeated. The pump (SC Hydraulic Engineering Corporation; Brea, CA; Model #10-5000W018) was then started, and pressure was allowed to build until the tubing burst. The follow arm recorded the maximum pressure encountered.

The procedure was typically repeated 5 to 10 times on a given type of sample by a single operator on a single day.

Validation of RT burst procedure for nonreinforced tubing

A small study was designed to test the reproducibility and operator bias of the room temperature procedure. Two operators tested two different tubings, five replicates each, on two different days. This resulted in a total of 40 data points, which were evaluated by the "EMP" method.[5]

In addition to formal validation, lot-to-lot variation was also evaluated. Involved in this comparison were: two lots of APT ⅜ × ⅝", three lots of APT ⅛ × ¼", three lots of Pharma 50 ⅜ × ⅝" and four lots of Pharma 50, ⅛ × ¼".

RT testing of reinforced tubing

Pharma Reinforced Tubing (65 durometer silicone containing a Dacron® braid) of all standard sizes was tested. A 30:1 pneumatic pump (30,000 PSIG max.) was connected to an instrument-quality air supply line (½" nominal pipe size, 100 PSIG). An ARO-brand regulator (0-100 PSIG, ¼" NPT in/out) was installed on the air line at the pump and was used to vary the air pressure. Manual adjustment of the pressure resulted in increase rates of about 780 to 1200 psi/min, with minimal observed effect on results.

Tap water was supplied to the pump using a ½" flex hose. All discharge piping was ¼" nominal pipe size, high-pressure rated, with maximum allowable working pressure (MAWP) of 1000 PSI and higher.

The test sample (14-19 inches, depending on tubing diameter and the adapters needed) was fitted with off-the-shelf hose barbs and secured using Oetiker® brand 2-ear zinc-plated clamps over 0.004" stainless steel shims. The water supply line was connected to one end of the test hose. An air-bleed valve and maximum-indicating glycerin-filled brass-case gauge ±1.5% full-scale (not graded), 0-1000 PSIG were installed at the far end of the test hose.

Burst testing occurred in a polycarbonate box with hinged lid, 3/8" thick walls with drain holes drilled in the bottom. Burst strength averages were calculated from at least three replicates.

Results and Discussion

General findings

Overall, the room temperature burst strengths of the nonreinforced tubings tested range from approximately 30 to over 250 psi.

The burst strengths of reinforced tubings were at least five-fold higher than those for the corresponding sizes of nonreinforced tubing.

Validation testing

A Basic EMP study revealed that our RT burst measurements of nonreinforced tubing have a resolution of 1 psi, and the estimated test-retest variation is 0.0203. The procedure is easily able to discriminate between samples, and there is no operator-to-operator bias. Day-to-day biases can be seen with low durometer samples, and may be due to slight changes in maximum flow rates of the lab water supply. The biases encountered are also very small—less than 2 psi. The method described is therefore reliable and reproducible.

Lot-to-lot variation was greatest for the smaller Pharma 50 samples. An outlier test of the data failed to identify results for any lot as an outlier, so all results have been averaged. Table 1 shows the results of the lot comparisons.

Table 1

Lot-to-lot Comparisons of RT Tubing Burst Strengths

Tubing/Size	*Lot 1*	*Lot 2*	*Lot 3*	*Lot 4*
Pharma 50 1/8 x ¼"	96 (19)	67 (10)	72 (5)	54 (5)
Pharma 50 3/8 x 5/8"	61 (10)	55 (10)	62 (10)	
APT 1/8 x ¼"	77 (11)	82 (10)	78 (10)	
APT 3/8 x 5/8"	46 (10)	54 (10)		

Number in parentheses is number of replicates

Data trends

RT nonreinforced data show a linear relationship between durometer and burst strength for each size of tubing (see Figure 1). The slope increases as the inner diameter decreases. The relationships noted may allow for prediction of burst strength for tubings with durometers other than those tested (50, 65 and 80).

Within a durometer or type of nonreinforced Pharma tubing, burst strength also appears to be related to hoop stress by an exponential equation. This is shown in Figure 2. Slopes decrease with decreasing durometer.

Reinforced tubing behaves similarly to standard tubing, in that an exponential equation relates the hoop stress quotient to burst strength with high confidence (Figure 3). Burst strengths range from five to over seven times higher for reinforced tubing compared to nonreinforced counterparts (Figure 4).

Acknowledgements

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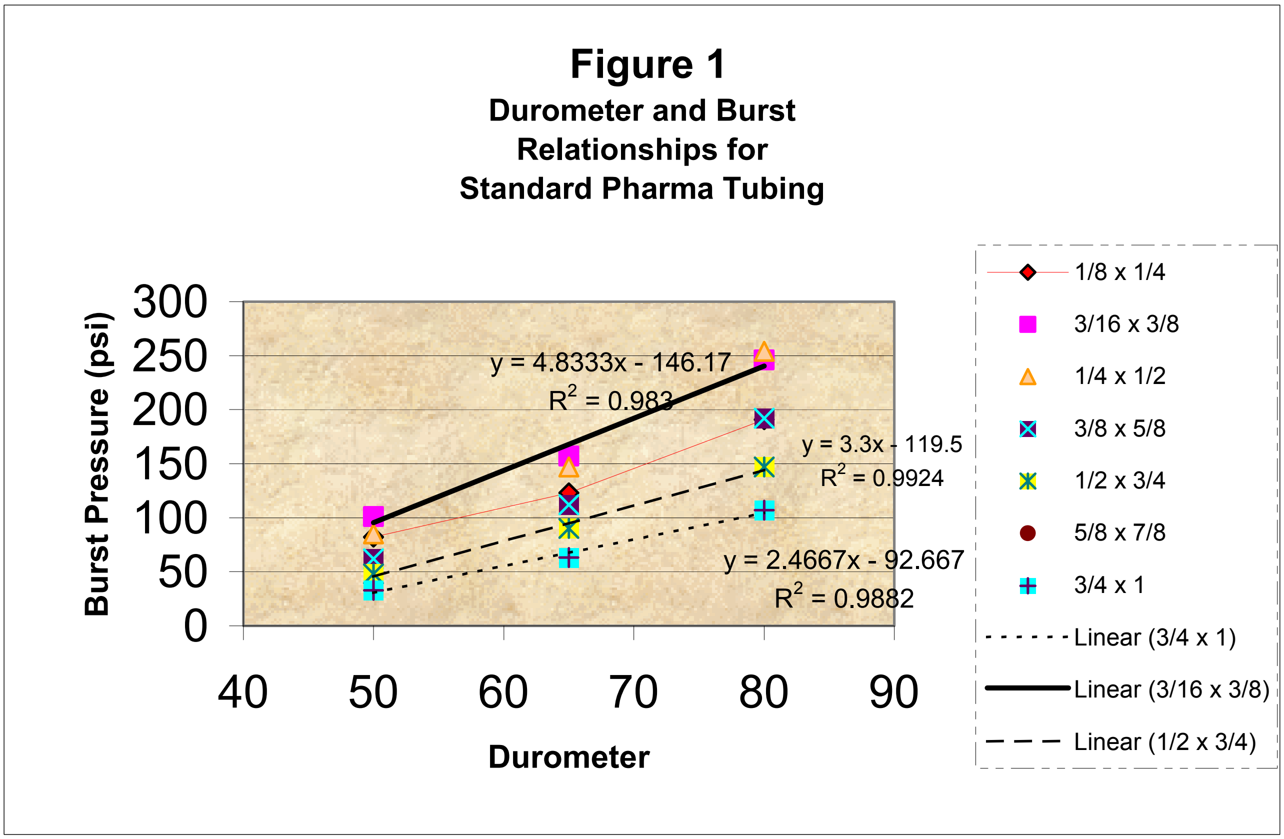

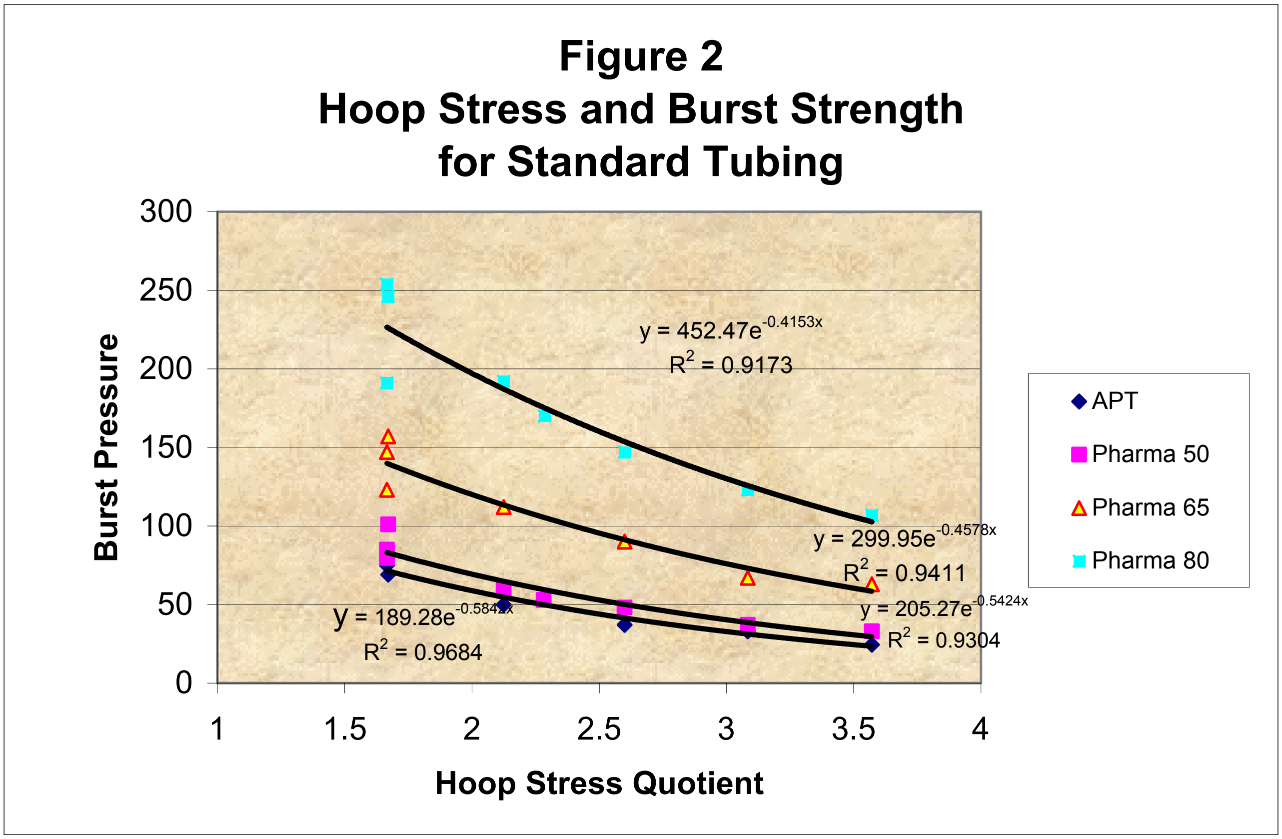
Figure 2
Hoop Stress and Burst Strength
for Standard Tubing
Burst Pressure
300
250
200
150
100
50
0
1
1.5
2
2.5
3
3.5
4
Hoop Stress Quotient
y = 452.47e^-0.4153x
R^2 = 0.9173
y = 299.95e^-0.4578x
R^2 = 0.9411
y = 205.27e^-0.5424x
R^2 = 0.9304
y = 189.28e^-0.5842x
R^2 = 0.9684
APT
Pharma 50
Pharma 65
Pharma 80

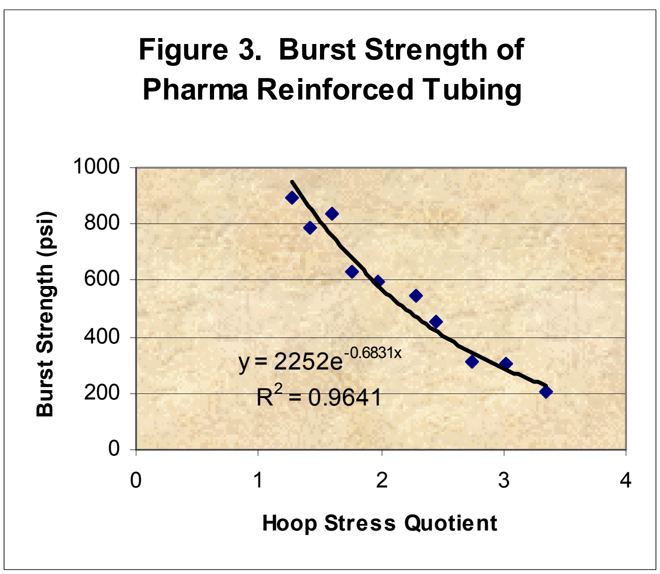
Figure 3. Burst Strength of
Pharma Reinforced Tubing
Burst Strength (psi)
1000
800
600
400
200
0
0
1
2
3
4
Hoop Stress Quotient
y = 2252e^-0.6831x
R^2 = 0.9641

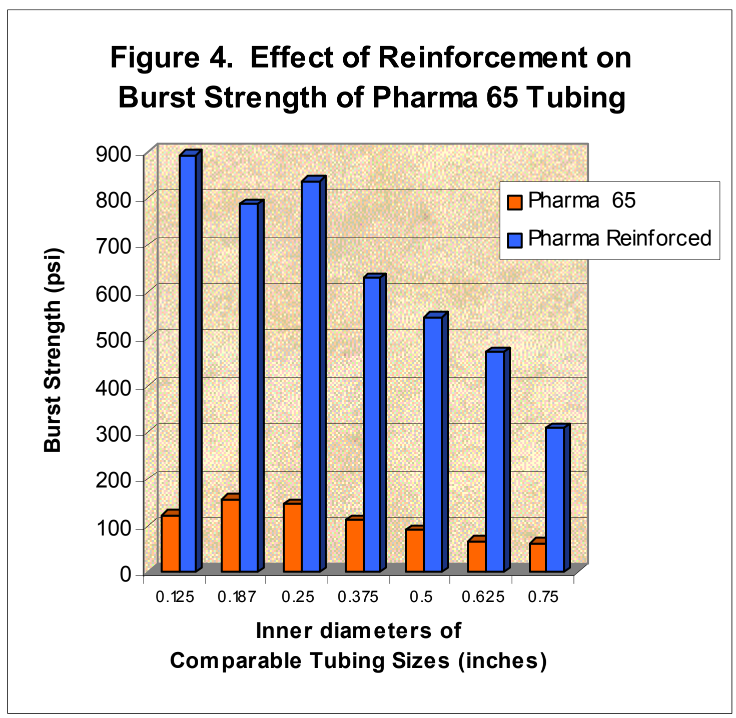
Figure 4. Effect of Reinforcement on
Burst Strength of Pharma 65 Tubing
Burst Strength (psi)
900
800
700
600
500
400
300
200
100
0
0.125
0.187
0.25
0.375
0.5
0.625
0.75
Inner diameters of
Comparable Tubing Sizes (inches)
Pharma 65
Pharma Reinforced

References

[1] R.C. Dorf, ed., The Engineering Handbook, CRC Press, Inc. Boca Raton, FL; 1996, pg. 1771

[2] ASTM Vol 09.01, D380-94; "Standard Test Methods for Rubber Hose"

[3] ISO 1402:1994(E); "Rubber Hoses and Hose Assemblies—Hydrostatic Testing"

[4] A division of APW Tools and Supplies; Milwaukee, WI

[5] Evaluating the Measurement Process, 2nd ed., D.J. Wheeler and R.W Lyday, SPC Press, Inc., Knoxville, TN, 1989

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