

NOVEL METHOD FOR INSIDE DIAMETER DETERMINATION

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ABSTRACT

Molded component development and release procedures require that numerous dimensions be obtained. Outside dimensions of a part can often be easily measured, but inside dimensions can be difficult to measure especially on small pieces. A new method is described for the measurement of the inside diameter of small orifices. A negative copy of the orifice or cavity is made with a low-shrinkage, harden in place polyester resin. The inside dimensions of the orifice are then taken from the outside dimensions of the copy. The method is equally accurate compared to other methods of measurement, and is much easier to accomplish. The procedure was applied to the study of some critical dimensions of oral inhalers used with metered dose inhalation aerosols.

INTRODUCTION

Outside dimensions (OD) of a molded part can typically be measured easily with micrometer, caliper etc. However, accurate and reproducible inside dimension (ID) measurements are difficult to make. These measurements can be especially troublesome as the size of the orifice diminishes. For example, in parts such as an aerosol mouthpiece, the spray orifice is very fine and it requires careful measurement (1,2).

There are many methods of sizing available for the measurement of inside diameters, but they have limitations. Inside calipers, regular or telescoping are restricted to larger orifices, and often can not be applied to the small orifices encountered in molded parts. A hole gauge does not detect non-concentricity and is also limited by small orifice size.

Other methods for measuring inside diameters based on optical methods are quite accurate, and can detect non-concentricity. Most often optical comparators are used for fine orifice measurement. These devices are specialized pieces of equipment which combine sophisticated optics with micrometer accuracy. Optical methods can be used to measure tapered orifices, and both diameter and depth measurements can be taken. While methods based on optical devices are widely used, they can be very time consuming if multiple determinations are required. Optical methods also very often require that the part be sectioned prior to measurement, and would therefore be considered a destructive method of measurement. In

addition difficulties with optical methods such as a determination of the proper instrument focus can affect the variability and accuracy of the measurement. It is also necessary to carefully and reproducibly locate reference points where the measurements are taken to reduce operator variability.

Pin-sizing is a simpler method, but it may not provide the level of accuracy desired. The approximate size of the orifice is determined by attempting to fit a series of different sized pins into the orifice being measured. A pin that fits will have an outside diameter smaller than the inside diameter of the orifice (Figure 1). When the next larger pin in the series will not fit into the orifice, the inside diameter is between the dimensions of the two pins. The closer the two pins are in diameter, the more accurately the inside diameter will be approximated. The method is quick and simple to perform, and does not require any specialized equipment or training. Pin-sizing however, does not provide an actual dimension, but rather a size range for the orifice. In addition, this method will not detect non-concentricity (Figure 2), and can not be readily used to determine orifice depth. Since even an undersize pin will most certainly touch and abrade the orifice being measured, the method should be considered destructive testing.

In this paper we compared optical comparator techniques with the resin negative copy method. The amount of resin shrinkage that occurred was determined, and the effect of the resin to catalyst ratio on polyester shrinkage was measured. Orifices of

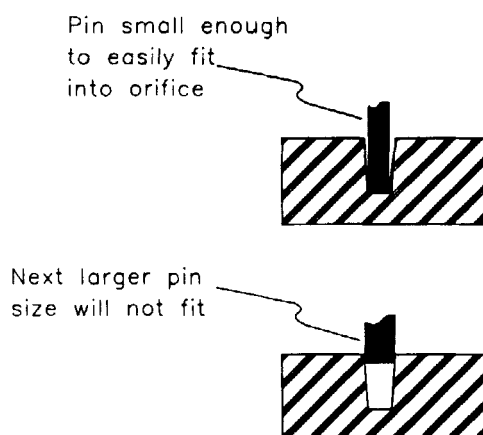


FIGURE 1 Pin-sizing; fit or no fit.

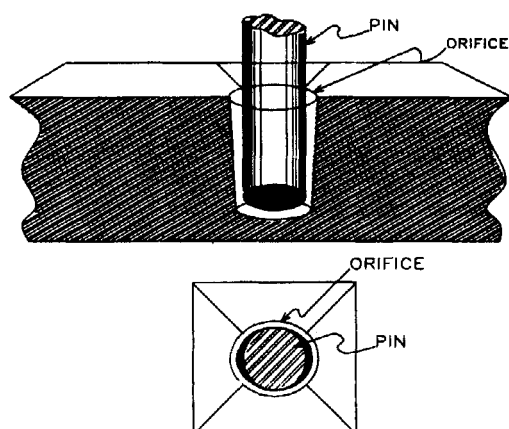


FIGURE 2 Pin-sizing; a round pin in a non-concentric orifice.

known dimension were measured by both the resin negative copy method and optical methods to demonstrate the accuracy of the new method. The resin method was then used to determine the critical dimensions of a series of aerosol oral inhalers.

EXPERIMENTAL

Both the optical and resin negative copy method of orifice measurement were used in this study to measure the inside diameter of several test orifices. After describing these methods it will be apparent why molding a negative copy or plug is a preferable method.

OPTICAL COMPARATOR METHOD

This procedure requires cross sections of the orifice to be prepared by making precise transverse or longitudinal cuts in multiple molded parts. Inside dimensions are then taken from the cross sections with the aid of specialized optical measuring equipment.

The molded orifice to be measured is removed with some of the surrounding polymer from the component or device. Before the cross section is cut, it is necessary to predetermine the point at which the section will be made. This insures that any replicates (other mold cavities, etc.) can be measured in an equivalent position. Parts molded from soft polymers such as polyethylenes can be cut with a scalpels or knife, but harder plastics require more elaborate cutting devices. Typically a minimum of three replicate cross sections per mold cavity are cut and perpendicular ID determinations on each cross section are measured. The orifice

cross sections must be oriented on the optical comparator such that the smallest ID of the orifice is closest to the optical comparator. This minimizes the distortion of the image due to diffraction of light when a transmitted source is used, and allows for precise focussing on the plane of the cross section if reflected light is used. When using a transmitted light source a standard should be used to correct for the effect of light diffraction. The use of reflected light avoids the diffraction problem but it can be difficult to determine the precise points to start and end the measurement.

The sample requirements are larger for the optical comparator method. For example to determine the dimensions of the stem receiving orifice for an oral inhaler, it would be necessary to have a minimum of three transverse cross sections, 1) at the opening or beginning of the stem travel, 2) at the mid-depth or middle of the stem travel and 3) at the bottom of the orifice. These dimensions would be required for each individual mold cavity to characterize diameter, concentricity and taper. An additional sample of each mold cavity may also be required to determine the orifice depth. To allow for a comparison between mold cavities, three replicates per measurement parameter per mold cavity would be required. A typical comparison would therefore require the measurement of twelve oral inhalers from each mold cavity. If the mold contained eight mold cavities, a total of 96 units would have to be destructively sampled and prepared for measurement.

To verify the accuracy of the method a series of holes were drilled in polyethylene sheet stock to simulate the prepared

orifice cross sections, and the dimensions determined by the optical comparator method. Focus, lighting and relative placement of the orifices were carefully controlled to insure reproducible measurement. Measurement of the orifices was done with an optical comparator in both the transmitted light and reflected light modes. Data from these measurements was used as a control to compare with the polyester resin method, and to verify its suitability.

POLYESTER RESIN COPY METHOD

The polyester resin copy method was developed to facilitate the routine measurement of fine orifices. The method is based on the use of a fast hardening resin, with a low degree of shrinkage and a reasonable cost. The bonding characteristics of the polyester resin allows it to conform to the orifice surface but the hardened polymer is easily removed from plastics such as polyethylene.

To determine the dimensions of an orifice (Figure 3), the resin was mixed with catalyst and injected with a disposable syringe into the orifice of the component being evaluated. After a 24 hour curing time, the hardened polyester plugs were easily removed from the molded component with the edge of a sharp blade. The bond of the hardened resin to the polyethylene surface is easily broken and under the right conditions an adhesion line can be observed detaching from the sample as the plug is pried away

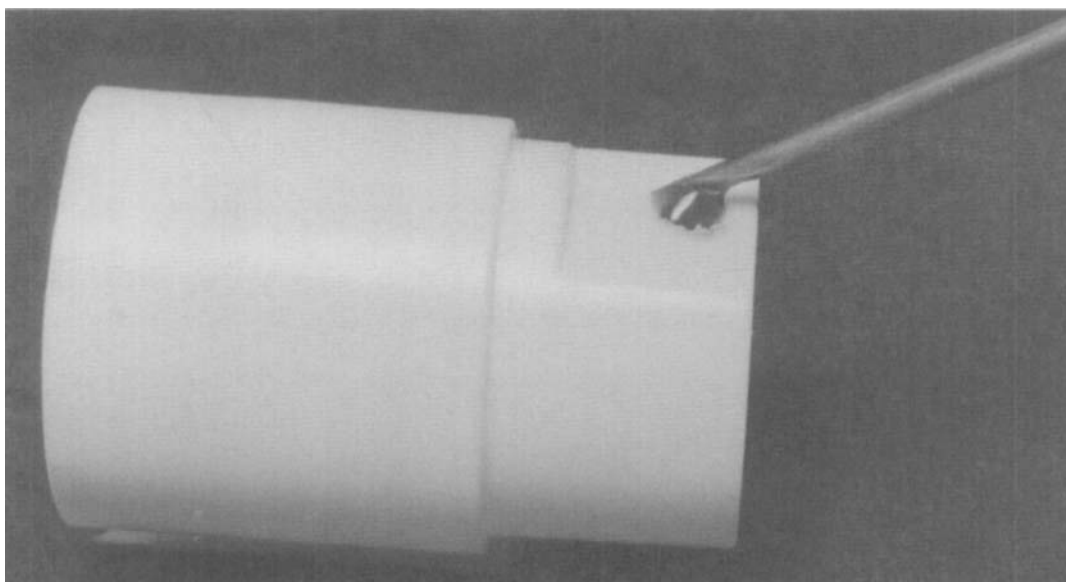


FIGURE 3A Inject liquid polyester resin catalyst mixture into orifice.

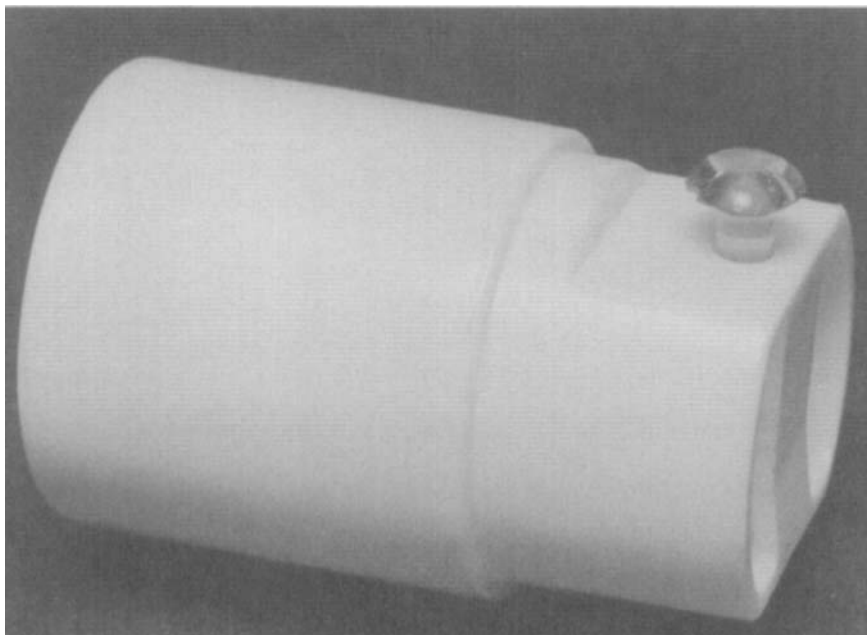


FIGURE 3B Remove hardened polyester resin copy from orifice.

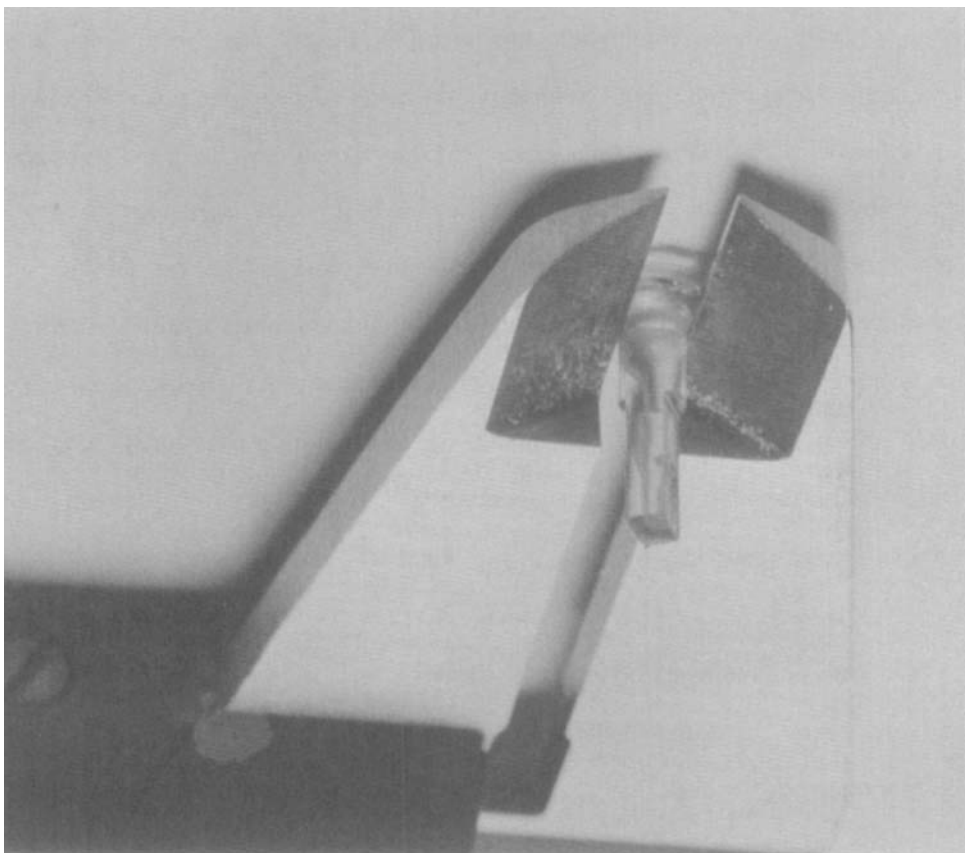


FIGURE 3C Measure inside dimension of orifice by determining outside dimension of polyester resin copy.

with the blade, which indicates a close fit with the component. The inside dimensions of the orifice were determined easily from the outside dimensions of the polyester resin plug with a set of calipers. The time necessary to prepare the polyester resin mix, to inject the polymer into the orifice, and to take dimensions from the copies was less than an hour.

The shrinkage of the polyester resin was small, but it was measured to allow for a correction of the data. The amount of shrinkage was also studied with various ratios of catalyst to resin, to determine the sensitivity of the method to resin composition and polymerization speed.

The inside dimensions of shallow polyethylene molds measuring 1 in.x 4 in. were measured with a set of calipers to the nearest 0.001 in. Catalyst to resin mix ratios of 24 drops:4 oz finished resin, 60 drops:4 oz finished resin, and 120 drops:4 oz finished resin were prepared. The recommended ratio of catalyst to resin was 30 drops per 4 oz. The mixtures of catalyst and resin were thoroughly mixed, poured into the molds and allowed to harden. After 24 hours curing time the polyester pieces were removed from the molds for measurement and comparison with the dimensions of the molds. From the shrinkage seen, a shrinkage factor was calculated, and the effect of resin composition on the polymer shrinkage was determined.

In a separate experiment, the mixture of catalyst and resin recommended by the manufacturer was prepared and injected into simulated cross section test orifices prepared in a polyethylene sheet. After the 24 hour curing time, the hardened polyester resin plugs were removed, and the outside dimensions of the resin plugs were determined with a set of calipers. This data was then compared to the dimensions of the orifices measured with the optical comparator methods as described above.

To determine the suitability of the method for the measurement of fine orifices in molded parts, the stem receiving orifices

TABLE 1**SHRINKAGE OF POLYESTER CONTROLS**

Concentration of Catalyst	% of Recommended Catalyst	% Shrinkage over 4.006"	% Shrinkage over 1.000"
0.2 drops/mL	80	1.42	1.30
~0.5 drops/mL	200	2.11	1.99
1.0 drops/mL	400	1.90	1.30

of three types of metered dose oral inhaler mouthpieces were measured. The recommended mixture of catalyst and resin was prepared and injected into the stem receiving orifice of each mouthpiece. After the 24 hour curing time, the hardened polyester resin plugs were removed, and the outside dimensions of the resin plugs were determined with a set of calipers.

RESULTS

Results of the studies conducted to determine the effect of the resin composition on shrinkage is shown in TABLE 1. The data shows that a small amount of shrinkage occurred with all ratios of catalyst to resin tested. However, there was no apparent trend in shrinkage over the catalyst concentrations studied, and all shrinkage was found to be approximately 2% or less. During these studies, it was observed that the polymerization time was affected

by the ratio of catalyst to resin. If less than the recommended concentration of catalyst was used, polymerization time is prolonged. In the mixture containing only 80% of the recommended catalyst, the polymerization time was significantly longer than that observed when mixtures of the recommended ratio were used. With these low catalyst content mixtures, soft spots were observed in the 1 in. x 4 in. pieces several weeks after pouring the resin mixtures into the molds. The use of a catalyst to resin mixture which contained 400% of the recommended concentration of catalyst produced excessive heat in the mold during curing. In addition to the excessive heat produced, the surface of the hardened polymer was slightly irregular with the high catalyst to resin ratio. Based on the result of this study, it appears that a catalyst to resin ratio of up to two times the recommended concentration can be used satisfactorily. These results indicate that the resin will cure satisfactorily, and provide stable dimensions over a range of resin to catalyst ratios. If less than the recommended ratio of accelerator to resin is used, it will, however, markedly increase the polymerization time. Based on the results of these studies, control mold studies should probably be conducted with each mixture of catalyst:resin mix to determine a shrinkage factor for the set of measurements being taken.

A comparison of the simulated cross section test orifice dimensions taken by the optical comparator method and the polyester resin copy method is shown in TABLE 2. These data show the very good agreement between the optical methods and the polyester

TABLE 2

DIMENSIONAL COMPARISON OF
OPTICAL AND DIRECT MEASUREMENT (in.)

OPTICAL COMPARATOR		DIRECT MEASUREMENT	
TRANSMITTED LIGHT	REFLECTED LIGHT	WITH CALIPERS	CORRECTED
0.095	0.093	0.092	0.094
0.168	0.166	0.165	0.168
0.084	0.083	0.082	0.084
0.096	0.095	0.092	0.094
0.109	0.108	0.107	0.109
0.276	-	0.272	0.277

resin plug method. For the dimensions taken with the reflected light and transmitted light optical methods, the data (columns 1 & 2) appear to be equivalent. Some variability was observed, however, it was not significant and most likely related to the inherent variability of the optical methods. A comparison of the optical method dimensions with the polyester resin plug method shows good agreement, but the dimensions taken from the polyester resin plugs were slightly less than the optical methods for all of the cross section test orifices studied. This difference is most likely the result of the shrinkage of polyester plugs while curing. If the correction factor of 2% is applied to the polyester resin plug data (column 4), the dimensions from the polyester resin plug method appear to be equivalent to the optical methods.

The data from the determination of the stem receiving orifices of the aerosol inhalers is shown in TABLE 3. The large

TABLE 3
STEM RECEIVING ORIFICE
 Perpendicular I.D. Dimensions

Inhaler 1	Cavity	Unit	Entry	Middle	Bottom
A	1		0.112 x 0.108	0.108 x 0.106	0.106 x 0.104
	2		0.111 x 0.110	0.107 x 0.107	0.106 x 0.105
B	1		0.111 x 0.110	0.107 x 0.105	0.106 x 0.104
	2		0.112 x 0.113	0.107 x 0.106	0.106 x 0.104
C	1		0.111 x 0.110	0.109 x 0.107	0.106 x 0.107
	2		0.112 x 0.110	0.108 x 0.107	0.106 x 0.104
D	1		0.112 x 0.110	0.108 x 0.107	0.106 x 0.104
	2		0.111 x 0.110	0.108 x 0.106	0.106 x 0.104
E	1		0.113 x 0.110	0.108 x 0.106	0.106 x 0.104
	2		0.110 x 0.109	0.107 x 0.106	0.106 x 0.104
F	1		0.110 x 0.110	0.107 x 0.106	0.106 x 0.104
	2		0.110 x 0.108	0.107 x 0.106	0.106 x 0.104
G	1		0.110 x 0.110	0.108 x 0.106	0.106 x 0.104
	2		0.110 x 0.109	0.108 x 0.107	0.106 x 0.105
H	1		0.110 x 0.110	0.106 x 0.106	0.106 x 0.104
	2		0.110 x 0.108	0.108 x 0.107	0.106 x 0.104
	Mean		0.111 x 0.110	0.108 x 0.106	0.106 x 0.104
Inhaler 2	A		0.108 x 0.107	0.106 x 0.103	0.105 x 0.102
	C		0.108 x 0.106	0.106 x 0.103	0.106 x 0.103
D	1		0.109 x 0.106	0.107 x 0.105	0.105 x 0.102
	2		0.106 x 0.106	0.106 x 0.104	0.106 x 0.104
G	-		0.106 x 0.107	0.106 x 0.104	0.105 x 0.103
H	-		0.107 x 0.107	0.105 x 0.105	0.105 x 0.105
	Mean		0.107 x 0.106	0.106 x 0.104	0.105 x 0.103
Inhaler 3	1	-	0.110 x 0.108	0.109 x 0.108	0.106 x 0.107
	2	-	0.109 x 0.108	0.108 x 0.108	0.107 x 0.107
3	-		0.110 x 0.108	0.109 x 0.108	0.107 x 0.107
4	-		0.110 x 0.109	0.108 x 0.108	0.106 x 0.107
6	-		0.109 x 0.108	0.108 x 0.107	0.106 x 0.106
8	-		0.109 x 0.109	0.108 x 0.108	0.106 x 0.106
	Mean		0.110 x 0.108	0.108 x 0.108	0.106 x 0.107

number of measurements shown in TABLE 3 would have been extremely time consuming and tedious to compile using the optical methods. In this study the total time necessary to determine the inside dimensions of the 28 pieces listed in TABLE 3 was less than 2.5 man-hours.

CONCLUSION

The use of a harden in place polyester resin polymer to measure small cavities or orifices appears superior to other methods of measurement. This method is accurate and significantly reduces the time necessary to measure the dimensions of a small orifice or cavity and may increase the accuracy of the dimensions taken. A non-shrinking polymer would seem ideal, but a small amount of shrinkage facilitates the removal of the polyester resin plug or negative copy from the orifice in question. A shrinkage correction factor can be determined for the polyester resin used and applied to the dimensions taken. The polyester resin plug method appears to have two major advantages, a reduction in the time required for measurement and improved accuracy. Additional benefits might be realized, depending on application. The method might be considered a non-destructive test method which could allow test pieces in some applications to be returned to inventory. In addition, the polyester resin plugs or negative copies are a permanent record of the component dimension, which could be referenced at a later date if necessary.

This procedure was developed for use with injection molded polyethylene aerosol components. However, it can be used with other components with orifices or cavities. If the polyester resin used in this study is not compatible with the plastic in the component, other materials such as an epoxy resin system might be substituted. If the resin system bonds to the component, a suitable mold release could be applied to the part. Alternatively, after the resin system had hardened in place, the plastic or other material containing the orifice or cavity could be dissolved, boiled or melted away leaving the polymer negative copy. An example of this application might be for the determination of orifice or cavities in animal or plant tissue samples.

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