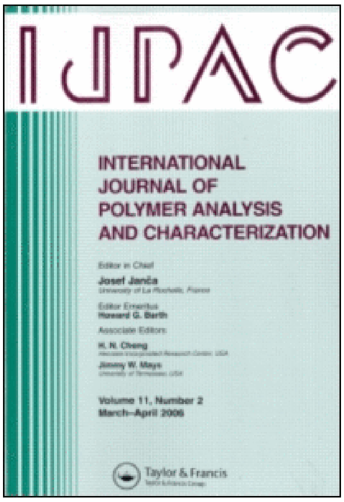

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Density Determination of Medical Sutures by Pycnometry

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In this study, we evaluated the density of medical sutures using a Micromeritics pycnometer. The types of sutures, their size, and experimental conditions were investigated to determine their effects on density measurement. Based on the results of two types of suture materials and six suture sizes, the pycnometer is a relatively fast method for density determinations for biomaterials and medical devices with small sizes, such as for sutures. The instrument yields repeatable and precise results; however, the measurement error increases when the sample weight becomes very small.

Keywords: Polypropylene; Biodegradable; Suture; Density; Biomaterials; Wound closure

INTRODUCTION

Sutures are the oldest implants and the most important wound closure medical devices at the present time. In past century, we have seen dramatic changes in suture biomaterials, from naturally occurring materials to synthetic polymers, from permanent nondegradable materials to transition biodegradable polymers. Although small, sutures have wide,

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irreplaceable applications in surgery. Polypropylene sutures, for example, are used in general, cardiovascular, plastic, and orthopedic surgery, and in securing implants, such as intraocular lenses and heart valves. For many years, research activities in the field of sutures have focused on mechanical and chemical properties, in vitro and in vivo studies. However, one under-explored area is the density of these materials, particularly in the form of medical devices.

Density determination of sutures is important as it is related to their performance. The analysis of density may also provide information on percent crystallinity, orientation, and homogeneity of the suture. There are few detailed studies in the area of density measurements and the reported data in open literature indicates a large variation in density experimental results for suture materials. It was reported, for example, that the density of polypropylene sutures is between 0.8162 and 0.9874 g/cm^3[1]. Such a large range is probably due to different measurement methods and the relatively small size of sutures, which may result in difficulty in measuring density. To try to close the gap and explore density measurements of sutures, we have conducted a series of experiments on two types of sutures using a Micromeritics pycnometer. In this article, density measurements of two suture materials are presented and the data are compared to those in the literature.

MATERIALS AND METHODS

Two types of medical sutures were selected: polypropylene (PP) and polyglactin-910, a 90:10 copolymer of glycolide and lactide, representing general suture types. PP is nondegradable, while polyglactin-910 is biodegradable. The PP sutures are monofilament and polyglactin-910 sutures are braided. The specific blue-dyed PP sutures used in this study were PROLENE polypropylene sutures (Ethicon, Inc., USA). Polyglactin-910 sutures were coated VICRYL sutures (Ethicon); the coating is a combination of equal parts of a lactide and glycolide copolymer, plus calcium stearate. PP resins (Ethicon) in extruded pellets were also included in this study for comparison.

The instrument used for density analysis was a 1 cm^3 AccuPyc 1330 Pycnometer (Micromeritics Instrument Corp., USA). The instrument is a fully automatic gas displacement pycnometer, in which density and volume are measured from the pressure change of gas in a calibrated volume. The instrument measures a sample volume, from which its density is derived if the sample weight is known. In this study, a 0.1 cm^3 sample insert was used because of the relatively small volume of the medical sutures. The instrument was calibrated and operated according to the manufacturer's recommendations. All experiments were conducted under helium purge at ambient conditions with temperature variations of less than 3°C. A Sartorius BP 211D analytical balance with an accuracy of 0.01 mg was used to measure sample weight.

DENSITY CALCULATIONS

To analyze the density of a sample, the pycnometer needs to be calibrated first. Equations (1) and (2) are used for calibration, which yield V_e, the volume of the expansion chamber, and V_c, the volume of the sample cell with cup.

$$V_e = \frac{V_s}{\frac{P_1}{P_2} - \frac{P_3}{P_4}} \tag{1}$$

and

$$V_c = V_e\left(\frac{P_1}{P_2} - 1\right) \tag{2}$$

where V_s is the volume of calibration standard, P_1 is the equilibrated charge pressure with the sample cup empty, P_2 is the equilibrated pressure with the sample cup empty after expansion, P_3 is the equilibrated charge pressure with the calibration standard in the sample cup, and P_4 is the equilibrated pressure with the calibration standard in the sample cup after expansion.

After V_e and V_c values are obtained from the calibration, the sample volume V_m is then calculated using the following equation:

$$V_m = V_c - V_e\left(\frac{P_1'}{P_2'} - 1\right) \tag{3}$$

where P_1' is the equilibrated charge pressure with the sample in the sample cup and P_2' is the equilibrated pressure with the sample in sample cup after expansion.

Finally, after V_m is determined, the sample density d_s is calculated by

$$d_s = \frac{w_s}{V_m} \tag{4}$$

In Equation (4), the sample weight w_s is entered into the instrument prior to the start of the procedure. The Micromeritics pycnometer performs all of the above calculations automatically.

RESULTS AND DISCUSSION

The instrument was first calibrated using a stainless steel standard according to the manufacturer's recommendation[2]. In this report, all the experimental data are presented as the average of at least three runs. The pycnometer measures volume and density by determining the pressure change of helium in a calibrated volume. It uses a fairly small amount of sample, yet yields repeatable and precise results. Each experiment takes about 30 min to perform three density measurements on a sample. Table I shows the results of density measurements from two suture materials investigated in this study. The data were the average of three measurements, with a standard deviation of 0.0002 to 0.0022 g/cm^3. Eleven sutures and two PP resins were used. It is obvious from Table I that PP sutures had essentially the same density for six different sizes, with a maximum difference of less than 5%. The highest density of 0.9147 g/cm^3 was found for size 2-0 PROLENE sutures. The lowest density of 0.8753 g/cm^3 was from size 5-0 PROLENE sutures. The last row in Table I shows the density of two PP resins. Comparison of the density data of PROLENE sutures from the corresponding PP resins indicates that the suture manufacturing process (extrusion and drawing) tends to increase the density of PP. This may suggest further crystallization and molecular orientation in the PP filament during processing. The overall results show that the densities for PP suture materials are very close to the reported data[3] for this polymer, which are 0.900 to 0.905 g/cm^3. The data for the coated VICRYL sutures show that the density of the sutures stays fairly constant with suture size. The maximum difference in the density measured for this suture is less than 3%. The averaged density of VICRYL sutures from this study is about 1.49 g/cm^3 and the results are close to the reported value of 1.54 g/cm^3 determined by a density gradient column[4].

TABLE I Density of suture materials (g/cm^3)

Size	1	0	2-0	3-0	4-0	5-0
PROLENE[a] suture	0.8963	0.8838	0.9147	0.8771	0.8739	0.8753
Coated VICRYL[a] sutures	1.4972		1.5113	1.4928	1.4911	1.4690
PP resin	0.8854 (dyed)	0.8831 (undyed)				

Experimental conditions: 25° to 28°C; sample weight = 20.9 to 21.7 mg for PP sutures, 27.1 to 27.7 mg for coated VICRYL sutures, and 27.4 to 37.6 mg for PP resins.

[a]Trademarks of Ethicon, Inc.

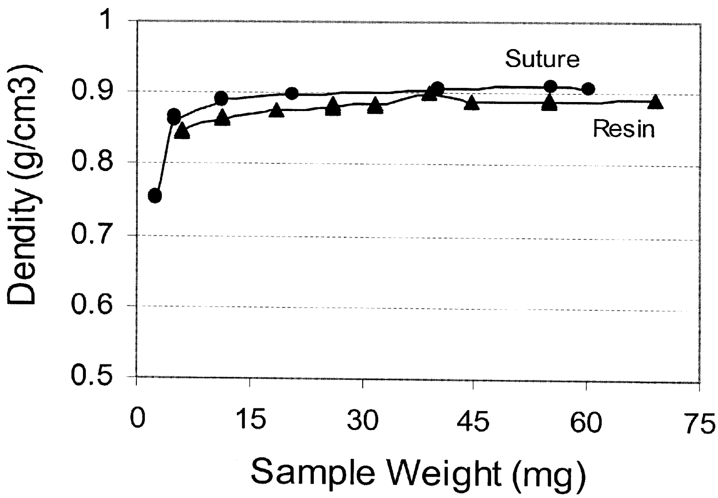

FIGURE 1 Effects of sample weight on density of size-1 PROLENE suture and dyed PP resin.

It is well known that experimental results are strongly dependent on testing condition, and two important factors are temperature and sample weight. Effects of sample weight on density measurement were investigated for PROLENE sutures and PP resins at room temperature. Three runs were performed on each sample weight, which are displayed in Figure 1. It is shown that the density of the materials exhibits little change except for the sample weight below 15 mg. Above 15 mg, the material density approached a constant value. This figure also shows that the suture has slightly higher density than the resin, as previously discussed.

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