BME 410 – FDA and ISO Requirements for the Development and Manufacturing of Medical Devices
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Standard Revision Report

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Summary of ASTM BME410(24)

The standard ASTM BME410(24) discusses the test methods covering procedures that are used to evaluate tensile properties of vulcanized thermoset rubbers and thermoplastic elastomers [1]. The test begins with test pieces that are taken from the sample material; these specimens can be in the shape of dumbbells [1]. Five test specimens are prepared for testing. In order to determine the elastic modulus of the given material, it is important to measure the thickness of the dumbbells by taking three measurements, one at the center and one each at the end of the reduced section of the dumbbell; these three measurements are taken as a median and then used as the thickness of the dumbbell. The width of the dumbbells are also taken as the distance between the cutting edges of the dumbbell in the reduced section [1]. These values can be used in order to calculate the cross-sectional area in Equation 1, where M is the mass of the specimen, D is the density of the specimen, and L is the length of the specimen.

$$A = \frac{MD}{L} \tag{1}$$

Once the initial measurements of the specimens have been completed, the testing of the specimens is able to be performed. The specimens were carefully loaded onto the device to ensure that only the elongated portion of the dumbbells were visible and that the dumbbells were symmetrically placed in order to ensure that the tension that was to be applied to the dumbbells would be distributed uniformly over the cross-section [1]. The elongation of the material and device's spring was measured before and after stretching to find the displacement of the material and spring [1]. Three trials were completed and the displacement of the material and spring was recorded at consistent intervals [1]. As testing was finished and data collection was completed, calculations were made in order to determine the elastic modulus of the material. Calculations involved, the force applied to the spring, material stress and strain, as well as the elastic modulus [1].

Results from the In-Class Activity

In conducting the testing to determine the elastic modulus of polyurethane, we were given five different samples of dumbbell die to test, labeled A through E. These dumbbell dies were polyurethane and had different gauge lengths, thicknesses, and widths. These findings can be shown in Table 1 below.

Sample	Material Source	Gauge Length (mm)	Thickness (mm)	Width (mm)
A	polyurethane	36	1.5	6
B	polyurethane	37	1.6	6.1
C	polyurethane	36.9	2	5.9
D	polyurethane	37.2	2	5.8

E	polyurethane	36.5	1.8	6.1

Table 1. *Dimensions of Each Dumbbell Die.*

As shown in Table 1, we used the caliber to measure everything instead of the markings on the device, so all of the measurements are shown in millimeters instead of inches. Therefore, our measurements must either be converted to inches or have our elastic modulus converted at the end.

Next, we followed the instructions in the standard and collected the material displacement, calculated based on the values in Table 1, and the spring displacement with a starting length of 85 mm and a spring constant of 1.5 lbs/in. After we collected the data, we were able to calculate the applied force using the following Equation 2.

$$F = kx \tag{2}$$

Where F is the force, k is the spring constant, and x is the spring displacement. We calculated the material stress by dividing the force by the area. We then calculated the material strain by dividing the material displacement by the original length of the material. The elastic modulus is then calculated by dividing the material stress by the material strain. We did this for three trials for each sample and took the average of all the trials. After that, we concluded that the elastic modulus of our material is 81.899 PSI. Our data can be shown in Table 2 below.

	Measured		Calculated			
Sample Trial	Material Displacement (in)	Spring Displacement (in)	Applied Force (spring)	Material Stress	Material Strain	Elastic Modulus
	Change in length	Change in length	Delta Spring*K	Force / Area	delta material / length	stress / strain
A 1	0.3937007874	0.0787401574	0.118110236	8.466666667	5	1.693333333
A 2	2.244094488	1.456692913	2.18503937	156.6333333	1.540540541	101.674269
A 3	3.503937008	1.653543307	2.480314961	177.8	2.119047619	83.90561798
B 1	0.905511811	0.3937007874	0.590551181	39.03688525	2.3	16.9725588
B 2	1.496062992	0.6692913386	1.003937008	66.36270492	2.235294118	29.68857852
B 3	2.598425197	1.338582677	2.007874016	132.7254098	1.941176471	68.37369598
C 1	1.106299213	0.9448818898	1.417322835	77.49152542	1.170833333	66.18493275
C 2	2.326771654	1.417322835	2.125984252	116.2372881	1.641666667	70.80443947
C 3	3.232283465	1.850393701	2.775590551	151.7542373	1.746808511	86.87514193

D 1	0.5039370079	0.8267716535	1.24015748	68.97413793	0.609523809	113.160695
D 2	1.645669291	1.496062992	2.244094488	124.8103448	1.1	113.4639498
D 3	3.25984252	2.007874016	3.011811024	167.5086207	1.623529412	103.1755997
E 1	1.279527559	1.299212598	1.948818898	114.5081967	0.984848484	116.2698613
E 2	2.618110236	2.047244094	3.070866142	180.4371585	1.278846154	141.0937179
E 3	3.720472441	2.204724409	3.307086614	194.3169399	1.6875	115.1507792
Average	2.055643045	1.312335958	1.968503937	118.4708966	1.798641008	81.89914472

Table 2. *Measured and Calculated Data*

However, the elastic modulus calculated in class was not the same as the correct elastic modulus. Every type of polyurethane has a different elastic modulus, so we cannot determine the exact value without further specifying what type of polyurethane was being used. The elastic modulus of polyurethane ranges from 90 to 797 ksi [2], which is roughly a thousand times larger than the value we calculated.

Sources of Error

In conducting round robin testing to determine the elastic modulus of polyurethane, our class observed significant discrepancies across the calculated values reported by different groups. After averaging the results from each group's five polyurethane dogbones, it became evident that severe inconsistencies were present across the calculated elastic modulus. Following discussions in class on October 17th and thorough inspection, we identified that six of the eight stations had improperly set up equipment, with three distinct issues distributed across these stations. These setup irregularities significantly influenced the accuracy of the tensile testing results, as each setup flaw introduced a unique source of error likely affecting the relevant teams calculated elastic modulus.

One primary source of error was related to the measurement apparatus at stations 3 and 4, which employed less precise tools compared to the other stations. These measurement devices featured fewer lines and lacked the consistent specificity of the other 6 devices needed for accurate and cohesive elongation tracking. This lack of precision is critical, as the tensile modulus calculation depends heavily on accurate strain data, which is derived from measuring how much a sample and the spring it is in series with stretches. When strain measurements lack the required precision, the stress-strain relationship, and thus the elastic modulus, can deviate substantially from the true values. With fewer measurement lines, these stations likely recorded less accurate elongation data, leading to discrepancies in their modulus values.

The second issue we observed arose from the properties of the springs used in the stretching apparatus at stations 5 and 6. These stations employed springs that were notably shorter than those utilized by the other machine set ups. Upon physical inspection, we felt that they were easier to stretch than the other springs likely implying a reduced spring constant. The spring constant affects the force exerted on a sample at a given extension, with a lower constant leading to less force being applied for the same amount of stretch. This ultimately results in a lower measured tensile stress. Since the elastic modulus calculation relies on an accurate ratio of stress to strain, any reduction in measured tensile stress directly reduces the calculated modulus. Therefore, the improperly calibrated springs at these stations likely contributed to inaccurately low modulus values.

Lastly, and directly relevant to our team, an error was identified in the grain orientation of the dogbone specimens tested. While most stations used dogbones cut along a vertical grain, our station, along with station 8, we discovered had tested samples cut with a diagonal grain orientation. For polyurethane, which can exhibit anisotropic or direction-dependent properties due to its molecular alignment, the grain direction significantly impacts tensile characteristics. When samples are cut at a diagonal grain, the material's resistance to stretching may be higher, as the force is applied at an angle that goes against the material's natural structural orientation. This mismatch likely led to higher tensile strength and elasticity in our samples, resulting in an inaccurately high modulus for our team's reported values.

Improving consistency across these parameters—ensuring a standard for precision of measurement tools is utilized, standardizing spring geometry as well as constants, and verifying uniform specimen preparation—would enhance the reliability of elastic modulus testing. By addressing these sources of error, future experiments could yield results that more accurately reflect the true mechanical properties of polyurethane, reducing variability and fostering greater confidence in the reported modulus values.

Proposed Changes to Standard

To address the issue identified in the BME410(24) standard and in class tensile testing protocol, several modifications are proposed to improve the measurement consistency, control grain orientation, and standardize force applications across testing stations. These adjustments are essential to achieving accurate and reliable data on the tensile properties of materials like polyethylene, which exhibit anisotropic behavior influenced by their molecular alignment. By implementing these changes, the standard will provide a more robust framework for testing, enhancing the reproducibility and validity of the results.

Improving Measurement Consistency

One key problem with tensile testing is that the measurement precision is inconsistent, with inconsistent tools across the stations. All the stations should be fitted with digital calipers calibrated to ±0.01 mm to ensure that the thickness, gauge length, and width are consistently measured. Minor deviations in the dimensions of width and thickness make large variations in the calculation for cross-sectional area and tensile stress. Additionally, it is recommended that all the calipers should go through calibration checks before each class session of testing to maintain the accuracy of measurements. This will ensure standardization and reduce variability of the measurements, hence giving reliable and comparable calculations of tensile properties between different test groups. Higher precision in measurement would prevent modulus value errors caused by slight differences in specimen dimensions.

Spring Calibration

Finally, for tensile testing to be reliably carried out, consistency in force application is imperative. All stations should have springs of the same spring constant, set at 1.5 lbs/in, as specified in the protocol. Before each experiment, all springs should be calibrated to ensure that they possess the same force-extension properties across all testing stations. Standardization of spring constants will ensure that reliability in force application is maintained, reducing the dispersion in the calculation of stress due to station dissimilarities with respect to the application of force.

Second, there should be consistency in the geometry of all the specimens, especially in thickness, gauge length, and width, as even small variations in any of these can lead to differences in computation for tensile properties. In fact, when we follow strict geometry, we will be able to obtain more comparable test results-reliably, thus obtaining a much closer calculation of material properties to the real characteristics of the material being tested.

Proposed Addition to ASTM BME410(24)

New Section 5.5: Standardized Calibration of Measurement Instruments

All measuring apparatus that is to be used in the measuring of specimen dimensions, thickness, gage length, and width shall be calibrated to an accuracy of ± 0.01 mm before each test session. The measuring activity shall be done with digital calipers or other high precision measuring apparatus to obtain consistent results. Calibration records shall be kept for each instrument, and each instrument shall be checked against a reference measurement standardized for that particular testing station to ensure consistency between all testing stations.

This addition speaks to the issue of variability in measurement associated with the need for fine tuning in the measurement tools. Small variations in the dimensions of the specimens result in large differences in calculated tensile properties. By standardizing this requirement, this revision will improve consistency and accuracy in measurements so that calculated modulus and stress values are derived from accurate consistent input for all stations.

Revised Section of the ASTM BME 410(24) Standard

(Section 6.1: Testing Machine):

"The Testing machine shall have both a suitable dynamometer and an indicating or recording system for measuring the applied force within 10%".

Revised Text (Section 6.1: Testing Machine):

The testing machine shall be equipped with a suitable dynamometer and an indicating or recording system to measure the applied force within ±2%. Force-measuring devices, including springs, must be calibrated to ensure identical force-extension properties. If springs are used, it is desirable that a spring constant of 1.5 lbs/in be maintained for all test stations to assure consistent force measurement. Calibration verification and documentation shall be performed before each testing session.

This will help eliminate any problems in the consistent measurement of force, since different spring constants yield different measured forces. Calculations of stress are expected to be more consistent, as are the modulus values, in return.

References

[1] Standard Test Methods for Biomedical Engineering Class 410 Thermoplastics – Tension, ASTM BME410 (2024), ASTM International, Mar. 1, 2024.

[2] "MatWeb - The Online Materials Information Resource," *matweb.com*. https://matweb.com/search/DataSheet.aspx?MatGUID=2fe782a31c4b4bed984b49651762b086