

## Tensile strength of sterilised surgical catgut

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THE test results for tensile strength obtained by us in a recent survey of currently available British-made surgical catgut showed all samples to have a comfortable margin over the B.P. requirements. In tests performed strictly in accordance with B.P. conditions, values ranged from 144% to 178% of the B.P. requirement. These same samples, moreover, had a performance of 92% to 123% of the U.S.P. strength requirement, and the U.S.P. standard therefore more closely reflects performance. No work has been published so far comparing the two test methods in detail, that reported herewith attempts to cover this ground.

### EXPERIMENTAL AND RESULTS

The experiment was designed to cover all the conditions specified in the two monographs and all possible combinations.

The testing machines were calibrated by dead weights. The 0-15 lb and 0-75 lb scales were used on the B.P. machine, and the 0-10 lb and 0-20 lb scales on the U.S.P. machine.

The temperature of the testing laboratory was maintained at 21°, and the relative humidity at 65% for testing under B.P. conditions and at 45% for testing under U.S.P. conditions.

After tying the surgeon's knot strictly in the manner specified, a length of rubber tube being used as a former in the U.S.P. test, two knot pull determinations were made on each string and, to balance results, 12 strings were submitted to each test although the U.S.P. calls for only 10. The material used consisted of 5 ft strings from a normal day's raw string production. Thus all the strings of any one gauge were produced from the same supply of sheep casings and from the same ply looping. Chromicised strings of normal manufacture in gauges 3/0, 0 and 2, covering the popular range, were examined. They were wound and sealed in foil packets containing approximately 3.5 ml of tubing fluid and sterilised by gamma irradiation from a <sup>60</sup>Co source with a dosage of 2.5 Mrad. The samples were aged for 5 months before testing.

The experiment was run in duplicate with two tubing fluids, 90% isopropanol or 95% industrial methylated spirits. The strings were distributed at random to ensure that no single section of the experiment was unduly biased.

A typical example of the data collected is given in Table 1. The results obtained by calculating the test results strictly in accordance with the respective monographs are abstracted and shown in Table 2.

We found that the U.S.P. machine usually gave a higher value than

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the B.P. machine, the advantage being about 10% at the lower end of the range and about 5% at the higher end of the range. The B.P. average, i.e., averaging the lower of each of the two pulls determined on each string, gives a value some 5% lower than that obtained by averaging all 24 readings made for each condition examined. The Relative

TABLE 1. GAUGE 0-90% ISOPROPANOL

R.H.	Wait	Knot on former	B.P. machine			U.S.P. machine		
			Diameter thou"	Av. 12 pulls (lb)*	Av. 24 pulls (lb)	Diameter thou"	Av. 12 pulls (lb)*	Av. 24 pulls (lb)
45%	No	No	18.9	7.7 (0.83)	7.8 (0.94)	18.9	8.1 (0.38)	8.5 (0.56)
		Yes	18.9	6.6 (0.42)	6.8 (0.51)	18.9	7.1 (0.50)	7.3U (0.65)
	10 min	No	18.5	8.9 (0.96)	9.5 (1.02)	18.4	8.1 (1.42)	8.7 (1.47)
		Yes	18.6	7.1 (0.64)	7.5 (0.76)	18.4	7.3 (0.93)	7.9 (1.02)
65%	No	No	18.8	7.4 (0.44)	7.7 (0.60)	18.9	7.8 (0.87)	7.7 (0.86)
		Yes	18.7	6.5 (0.31)	6.9 (0.57)	18.9	6.8 (0.43)	7.1 (0.52)
	10 min	No	18.4	8.5B (0.81)	8.9 (0.75)	18.5	8.7 (0.65)	9.1 (0.77)
		Yes	18.5	6.8 (0.63)	7.1 (0.66)	18.5	7.2 (0.49)	7.7 (0.71)

U—Signifies tested strictly in accordance with the U.S.P. XVI.

B—Signifies tested strictly in accordance with the B.P. 1963.

Note.—Figures in parentheses indicate the standard deviation.

\* i.e. Average of the lower pull on each of 12 strings.

Humidity, i.e., 45% or 65%, had practically no effect. The waiting time specified in the B.P. leads to a higher value of tensile strength—of about 10% overall.

Finally, the effect of tying the surgeon's knot on a former as in the U.S.P. test is to reduce the value obtained by about 10% although the effect was not so extreme with gut tubed in 95% industrial methylated spirits.

TABLE 2. RESULTS OBTAINED WHEN TESTS MADE STRICTLY IN ACCORDANCE WITH MONOGRAPHS

Sample	B.P. requirement (lb)	U.S.P. requirement (lb)	B.P. test			U.S.P. test	
			Actual (lb)	% B.P. Std.	% U.S.P. Std.	Actual (lb)	% U.S.P. Std.
Gauge 3/0 90% I.P.A.* 95% I.M.S.†	1.5	2.5	3.1	207	124	3.4	136
	1.5	2.5	3.6	240	144	3.2	128
Gauge 0 90% I.P.A.* 95% I.M.S.	3.5	5.5	8.5	243	155	7.3	133
	3.5	5.5	7.0	200	127	6.8	124
Gauge 2 90% I.P.A.* 95% I.M.S.	6.5	9.0	14.5	223	161	12.2	136
	6.5	9.0	14.0	215	156	12.3	137

\* Isopropanol. † Industrial methylated spirits.

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### DISCUSSION

The differences between the two tests tend to cancel themselves out. Thus the advantage in strength readings obtained on the Incline Plane Tester are compensated to a large extent by the tying of the surgeon's knot on a former (U.S.P.), and the stringency of the B.P. calculation is nullified by the advantage gained by allowing the material to "air off" before testing. Catgut is packaged with a slight excess of water to increase pliability and airing off the suture may reduce the moisture content to that giving peak tensile strength, or it may go beyond it, so giving a lower value of strength. The 10 min period at 60-80% R.H. specified in the B.P. does not achieve equilibrium, as can be demonstrated by the effect of differing tubing fluids on the strength. Furthermore, the residual moisture content may also be affected by the rate of air-flow over the material. The unstable condition is reflected in a larger standard deviation which is observed after waiting; this occurs particularly in the gauge 2 material.

It is obvious from these results that the current B.P. standards do not compare with those of the U.S.P., nor do they reflect the actual performance of British sterilised surgical catgut.

It is recommended that the B.P. raise the existing standards to equal numerically those required by the U.S.P. XVI. Since the Incline Plane Tester is not available in this country, the present method of test and calculation should be retained, although it would be more practical to carry out the test immediately after opening the container. It is then suggested that the atmospheric conditions be revised to a temperature of 18-22° and a relative humidity of not less than 40%.

Table 3 shows the effect of these modifications in relation to the proposed new standard.

TABLE 3. RESULTS OBTAINED WHEN TESTS MADE BY THE PROPOSED METHOD AND COMPARED WITH PROPOSED NEW STANDARD

Sample	Proposed B.P./U.S.P. requirement (lb)	Actual test result by proposed method (lb)	Result expressed as % of standard
Gauge 3/0 90% I.P.A. ... ..	2.5	3.3	132
95% I.M.S. ... ..	2.5	2.6	104
Gauge 0 90% I.P.A. ... ..	5.5	7.7	140
95% I.M.S. ... ..	5.5	6.0	109
Gauge 2 90% I.P.A. ... ..	9.0	11.4	127
95% I.M.S. ... ..	9.0	10.3	115

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