SOME ASPECTS OF THE STORAGE AND TESTING OF STERILISED CATGUT

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Results obtained during an examination of plain and chromicised surgical catgut stored in tubing fluids of differing water content, and the effect on diameter, tensile strength and flexibility are described. A fall in tensile strength and an increase in diameter which vary with water content and time of storage was observed, although gut does not deteriorate rapidly when immersed in water and several days elapse before significant changes occur. The official testing methods have been examined, and the results indicate that the surgeon's knot test gives a more reliable measurement of tensile strength than the straight pull. Also the present gauge method for measurement of diameter can lead to errors due to compression of the gut. The time of equilibration of the gut in air is important for the measurement of both tensile strength and diameter, particularly when tubing fluids contain a high water content. A relation has been shown between tensile strength, extensibility and softening, and it is suggested that this might provide an index of flexibility of the gut. The effect of some common disinfectant solutions on the gut has been investigated.

THE first monograph on surgical catgut in an official publication in the United Kingdom appeared in the B.P.C. Supplement VI (1944) and this monograph has remained substantially the same to the present day and now appears in the B.P. 1958.

The preparations are packed in a wide variety of "tubing fluids" of varying composition[1–10] for which advantageous properties, like enhancement of flexibility, are claimed.

Douglas[11] (1949) criticised the official methods of test on the grounds that the figures obtained for tensile strength were not realistic.

This paper reports the results obtained during a storage test on catgut and an examination of the testing methods and comments upon them.

EXPERIMENTAL

The number of variables was reduced to reasonable proportions by selecting the two most used grades of catgut, namely 2/0 Plain and 2/0 Chromicised Medium Hard.

Strands were selected so that their diameters were nearly uniform and were about the mean of the prescribed limits. These strands were subjected to dry sterilisation and subsequent tests showed them to be sterile.

Cut into lengths of 15 inches the gut was randomly distributed into fluids contained in 2 litre glass-stoppered cylinders so that the proportion of fluid per strand was about the same as when packed in tubes. Further samples were sealed in tubes containing similar fluids. The cylinders were stored at room temperature, to simulate normal storage and the sealed tubes at 37°, as an accelerated test to provide advance information of possible changes at room temperature.

TABLE I

COMPARISON OF OPTICAL AND MICROMETER METHODS FOR THE MEASUREMENT OF THE DIAMETER OF CATGUT

Water concentration, per cent	Chromic gut		Water concentration, per cent	Plain gut	
	Optical	Gauge		Optical	Gauge
Controls	36·12	35·29	Controls	38·25	36·98
5	38·12	36·60	5	36·50	34·77
25	38·56	38·04	10	36·96	35·58
50	36·88	35·58	50	43·21	35·17

B.P. Limits 31·8 to 40·6 mm./100

ANALYSIS OF VARIANCE (CHROMIC GUT)

Source	S.S.	d.f.	M.S.	F.	Significance
Between methods	101·0651	1	101·0651	22·98	S.
Between groups	391·82031	3	130·60677	29·69	H.S.
M × G	13·19532	3	4·39844	1·43	N.S.
Strands within groups	2665·61459	44	60·58214	16·88	V.H.S.
S × M	157·86458	44	3·58783	1·16	N.S.
Between strands	3329·5599	95			
Residual	888·25	288	3·0842		
Total	4217·8099	383			

TABLE II

CHANGE IN DIAMETER OF CATGUT DURING EQUILIBRATION PERIOD

	Optical		Gauge	
	Mean	s.e. Mean	Mean	s.e. Mean
Control chromic R.T. 11 months				
0 min.	36·54	1·810	37·38	1·991
5 min.	38·95	0·567	38·06	0·598
10 min.	35·39	0·652	34·25	0·637
15 min.	36·32	0·194	33·69	0·120
20 min.	36·99	1·480	35·94	0·409
100 per cent H_2O chromic R.T. 11 months				
0 min.	47·48	1·648	41·38	1·897
5 min.	38·72	0·532	36·31	0·187
10 min.	38·13	1·449	37·12	0·486
15 min.	31·53	0·541	31·62	0·681
20 min.	35·28	0·862	35·75	0·889
Control plain R.T. 11 months				
0 min.	43·64	0·174	40·19	0·360
5 min.	38·13	1·224	38·94	0·624
10 min.	37·69	1·949	37·38	1·615
15 min.	35·29	1·002	34·56	1·183
20 min.	37·47	0·391	34·50	0·685
100 per cent H_2O plain R.T. 11 months				
0 min.	52·34	1·586	32·75	1·237
5 min.	45·44	1·515	31·31	1·484
10 min.	34·25	1·611	30·88	1·379
15 min.	36·88	1·749	33·69	1·378
20 min.	35·18	0·922	35·19	0·832

The fluids had the following composition. (1) Potassium mercuri-iodide 0·2 per cent in industrial methylated spirit (96 per cent). (2) Fluid 1 with 5 per cent v/v added sterile distilled water. (3) Fluid 1 with 10 per cent v/v added sterile distilled water. (4) Fluid 1 with 25 per cent v/v added sterile distilled water. (5) Fluid 1 with 50 per cent v/v added sterile distilled water. (6) Potassium mercuri-iodide 0·2 per cent in sterile distilled water. (7) Sterile distilledwater.

Examinations were made before the test commenced ($t = 0$), after 3, 7, 30, 60, 90 and 180 days, and sufficient samples were retained at room temperature for examination at 360 days.

TABLE III

EFFECT OF EQUILIBRATION ON THE TENSILE STRENGTH AND EXTENSION OF CATGUT

			Time (min.) 0	15
Tensile strength S.P. (lb.) ..	Control	Mean	6·54	7·33
		s.e. mean	±0·726	±0·446)
		t	<1·812	
		P	>0·1	
		Significance	N.S.	
	100 per cent water	Mean	4·38	6·08
		s.e. mean	±0·248	±0·601
		t	2·628	
		P	0·05 > P > 0·02	
		Significance	S.	
Extension (in.	Control	Mean	1·46	1·46
		s.e. mean	±0·070	±0·053
		t	0	
		P	—	
		Significance	—	
	100 per cent water	Mean	1·40	1·33
		s.e. mean	±0·099	±0·095
		t	<1·812	
		P	>0·1	
		Significance	N.S.	

Plain gut after 11 months at room temperature was used throughout. The tensile strength was assessed by the straight pull test, and the extension was of 5 inch strands up to the break-point.

All measurements were made according to the B.P. 1958 monograph. On each 15-inch length one determination of tensile strength was made by a straight pull and a second over a surgeon's knot, and the results subjected to statistical analysis.

Diameters were determined at approximately equal intercepts along each 15-inch strand, in the early stages of the experiments by the micrometer method and later optically in addition, because contrary to expectations, there appeared to be a reduction in diameter.

Using the dial gauge micrometer of the type suggested in the pharmacopoeias, considerable pressure is found to be exerted on the gut. Although the pressure on the whole of the anvil averages only 200 g. (1·625 kg./sq.cm.), the pressure exerted by the pressor foot on the gut, assuming a line contact of about one-quarter of its diameter for the 2/0 gauge, is in excess of 160 kg./sq.cm. This high pressure is responsible for an apparently smaller diameter compared with the results obtained when pressure is not used and is variable according to the thickness of the gut and its softness.

The optical method used a microscope eyepiece micrometer calibrated against pieces of wire of different gauges about the range under consideration.

The gut when measured optically does not always conform to the B.P. specification for diameter, whereas when measured by the micrometer falls within these limits. Table I summarises the salient figures, which have been abstracted from the 180 days storage data and an analysis of variance for chromic gut is given.

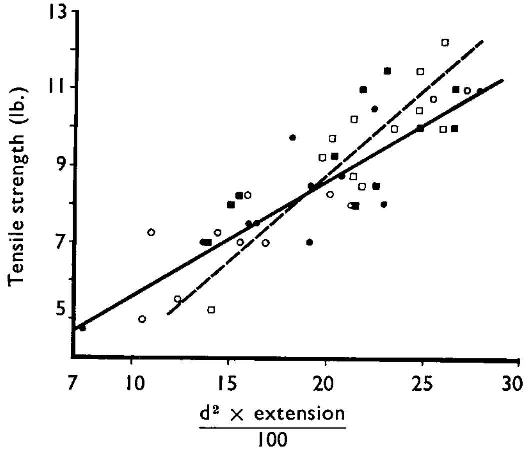

FIG. 1. The relation between extension, cross sectional area and tensile strength of surgical catgut stored at room temperature for 11 months. Tensile strengths were measured by the straight pull test. Extension was measured in inches up to the break-point. Diameters were measured optically.

○ = Plain gut in Fluid 1 (control).
● = „ „ 7 (100 per cent H_2O).
□ = Chromicised gut in Fluid 1 (control).
■ = „ „ „ 7 (100 per cent H_2O).
— Plain gut. — — Chromicised gut.

Owing to the implications of these differences a special test was introduced in which further comparisons were made, and these substantiated the findings particularly where swelling of the gut had occurred because of the high water-content of the fluid.

As an example, the diameter in hundredths of a millimetre of plain gut in fluid 6 (100 per cent water) were 33·31 (micrometer), 36·61 (optical) at 180 days and analysis of variance showed this difference to be highly significant.

A comparison between the B.P. and U.S.P. methods of test revealed a major difference in detail. The B.P. requires a time lapse of 10 to 15 minutes in free air between removal of the strand from the fluid and determination of the physical characteristics of the gut, whereas according to the U.S.P. the determinations are made immediately upon removal from the fluid. This feature has been examined by measuring the diameter of gut removed at 180 days from fluid 1 (control) and fluid 6 at times up to 20 minutes (Table II). This shows the differences between the results obtained by the two methods until the gut has dried sufficiently to resist the pressure applied to it in certain groups. These results are confirmed in other experiments.

Since modern tubing fluids may contain a proportion of water or other materials for the express purpose of keeping the suture in a flexible condition it is still possible even after 10 to 15 minutes drying for the gut to be sufficiently flexible to be distorted by pressure.

As different diameters were recorded according to the time of equilibration in air before measurement, the tensile strength was also determined at 0 and 15 minutes after removal from the fluid and the results are given in Table III, which gives figures for the straight pull tests during which extension was measured.

A significant increase in tensile strength was recorded for gut in fluid 6 after 15 minutes compared with time 0. With fluid 1 (control) the increase in tensile strength was not significant.

To examine the relation between the extension and the tensile strength of the gut an attempt was made to apply Young's Modulus and the plot of the results obtained for plain and chromicised gut stored for 11 months at room temperature is given in Figure 1. Good correlation ($r = 0{\cdot}86$) was obtained. Similar results were obtained with chromicised gut ($r = 0{\cdot}80$). There was a direct relation between the water content of the fluid and extensibility of chromic gut. Analysis of variance showed the relation to be quadratic and the line of best fit in Figure 2 has been calculated by the method of least squares.

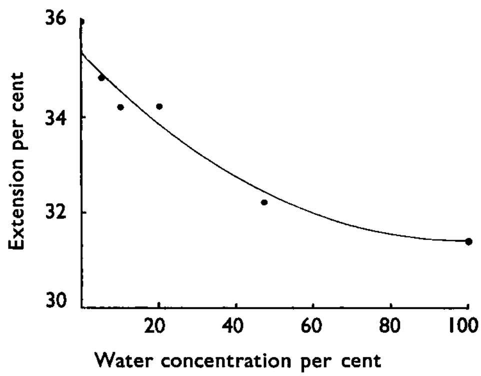

FIG. 2. Relation between extension measured to the straight-pull break-point and the water concentration of the tubing fluid.

An attempt was made to correlate extensibility and softening. As already mentioned, there was a significant difference in optical and gauge diameters when gut was measured immediately after removal from fluid which disappeared after 15 minutes equilibration.

DISCUSSION

The data presented largely confirms the belief that there is a deterioration in surgical catgut when stored for long periods in high concentrations of water but contrary to some opinion there is no rapid change even in 100 per cent water. In all concentrations of water chromicised gut is considerably more stable than plain and storage at 37° accelerates deterioration.

In tubing fluids of high water content where swelling occurs there can be a large difference between diameters measured by micrometer gauge and when pressure is not applied. The gauge can suggest a reduction in diameter due to softening, whereas in fact the gut has increased in diameter. This effect varies with the water content and with the type of gut, and disappears only after 15 minutes equilibration, so if the measurements are made in the B.P. and U.S.P. periods of less than 15 minutes erroneous results will be obtained.

In the analysis indicated in Table IV an attempt has been made to relate softness and flexibility. The ratio of optical to micrometer gauge measurement of diameter, a measure of softness, has been related with the extension of the gut up to the break-point. A high negative correlation exists when measurements are taken as soon as the gut is removed from the tubing fluid but since the optical to gauge ratio decreases to unity after 15 minutes equilibration the correlation becomes insignificant at this time. The correlation coefficient is larger in the gut stored in fluid 6 than in fluid 1 (control) both at time 0 and after 15 minutes. For

TABLE IV

THE EFFECT OF EQUILIBRATION ON RELATIONSHIP BETWEEN OPTICAL/GAUGE DIAMETER RATIO AND EXTENSION TO BREAK POINT

Control 11 months R.T.			
Time zero		15 minutes	
O/G	Extension (in.)	O/G	Extension (in.)
0·934	1·625	0·929	1·375
0·992	1·5	0·938	1·5
0·998	1·5	0·969	1·625
1·029	1·5	0·971	1·25
1·040	1·5	0·972	1·5
1·076	1·125	0·976	1·5
$r = -0·814$		$r = 0·156$	

100 per cent water 11 months R.T.			
Time zero		15 minutes	
O/G	Extension (in.)	O/G	Extension (in.)
1·308	1·75	0·932	1·75
1·340	1·625	0·978	1·25
1·385	1·375	0·987	1·125
1·404	1·25	0·989	1·125
1·420	1·25	1·004	1·375
1·491	1·125	1·100	1·375
$r = -0·953$		$r = 0·269$	

Plain gut was used throughout. Diameters were measured at 4 equal intercepts, and extension to the break-point, on each strand. O/G = Ratio of optical to micrometer gauge diameter.

measurement of tensile strength, the surgeon's knot test provides a more reliable indication of the quality of the gut than does the straight pull test. Furthermore, since the limits for the tensile strength by the surgeon's knot test given in the B.P. are exactly half for the straight pull and in the U.S.P., where the knot is tied round a $\frac{1}{4}$ inch diameter rubber tube, about 70 per cent, there appears little reason for inclusion of the straight pull test. As in an interrupted suture, which, according to Douglas[11], is the weakest kind, a knot is always tied, it appears logical for the gut to be thus tested.

The B.P. requires two determinations on a strand exceeding 30 inches in length, the lower reading to be taken as the breaking load, and for this figure to be considered in relation to stated acceptance limits. The U.S.P. takes the mean without attempting to consider variation within the batch. These are crude systems of quality control, the B.P. method being better than the U.S.P., as with the latter it is possible for figures as wide apart as 0·25 and 10 lb. on two strands to be averaged and to pass the test for 2/0 gut. By a consideration of all the figures, however, it is possible to obtain a measurement of variation within the batch and this could be used to provide a more rigorous quality control scheme.

The difference between the methods of testing in the U.S.P. and B.P. monographs concerning equilibration may have a considerable effect if tubing fluids of high water content are used (see Table III where the straight pull test is illustrated) but in the surgeon's knot test the effects are at a minimum.

We have also examined the ratio of "surgeon's knot strength/diameter^2" for each sample of control and purchased gut in an attempt to eliminate differences due to unequal matching of diameters and in all cases the control gut showed to advantage.

Since catgut in use may come into contact with some common disinfectants in which tubes of gut are stored in hospitals and which are used in the operating theatre, it is interesting to note that those of the phenolic type have no effect on the gut. This is important as it is well known that phenol, in particular, can seep through minute cracks in glass tubes.

There is no provision made in either the B.P. or the U.S.P. for a standard for flexibility, although from the surgeon's point of view this property ranks in importance with tensile strength.

It is suggested that the test for extensibility described provides an assessment of the flexibility of the gut.

Other workers[12] have shown that catgut under longitudinal stress has similar properties and behaves in a similar manner to metallic wires, an X-ray diffraction pattern indicating an amorphous structure in the resting state and re-orientation into crystalline micelles when under stress. We have shown that for a given type of gut extensibility and tensile strength both change on storage, but Figure 1 shows that Young's modulus remains constant; that is, the plot of tensile strength against cross-sectional area × extension is coincidental for gut stored in fluid 1 (control) and fluid 7.

Since it would appear that plain and chromicised gut have much the same physical characteristics, we fitted a common regression line to both sets of data and obtained $r = 0{\cdot}87$ for the correlation. Analysis of variance for the regression of tensile strength on the product of cross-sectional area and extension showed a very highly significant linear regression. This confirms that catgut however treated maintains a fundamentally characteristic relationship between its flexibility and its tensile strength.

The relationship between the surgeon's knot and straight pull was also examined but no relation was obtained between this ratio and water concentration, elongation or optical to gauge ratio. A limitation of the work is that gut of only one gauge was used to reduce the variation. This automatically reduced the diameter range but, nevertheless, within the working range there was sufficient variation for the more important relationships to be demonstrated. It is possible that other effects would have been found had a wider range of gut been used.

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After Mr. Wilkinson presented the paper there was a DISCUSSION. The following points were made.

Measurements were made using a microscope eyepiece micrometer without tension applied to the strings and with a check for roundness; as far as possible the dial guage was applied at the same point. The tensile strength and total extension to break point were measured using a B.P. type apparatus without studying the pattern of the extension. Tying a knot on a piece of rubber tubing apparently increases the strength. The effect of methanol on flexibility and diameter had not been overlooked, but water was the factor related to pliability, and measurements made during the first 72 hours' storage were without significant results.