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Tensile strength requirements for sutures

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The official requirements for sutures in Australia are those of British Pharmacopoeia (B.P.). The results of a survey conducted by this Laboratory indicate that the B.P. test and specifications for knot pull strength are no longer appropriate for sutures currently available in this country. It is suggested that tensile strength measurements on sutures should be carried out, without prior soaking, using the load cell type of constant rate of extension apparatus rather than the pendulum type tester specified in the B.P. Use of a simple knot is suitable for testing synthetic sutures, but the surgeon's knot is preferred for catgut. All products tested easily met both the B.P. and the United States Pharmacopeia (U.S.P.) requirements for tensile strength.

Official requirements for sutures in Australia are those of the British Pharmacopoeia (B.P.), which are essentially the relevant monographs of the 1973 edition of the British Pharmaceutical Codex (B.P.C.). Most sutures available in Australia are manufactured to the specifications of the United States Pharmacopeia (U.S.P.), which differ from those of the B.P. There are, therefore, potential difficulties in the application of official requirements to marketed products. The pharmacopoeial monographs specify tests for dimensions, identity, strength of needle attachment and knot pull strength. Tests for knot pull strength and strength of attachment to the needle are of particular importance in defining the quality of sutures. The knot pull test is intended to measure the tensile strength of the suture under conditions which simulate usage of the product. The test consists of tying the prescribed knot in the suture which is then broken under defined conditions. Dawson et al (1964) noted that the results of testing catgut sutures using the B.P. method for knot pull strength differed from those obtained using the U.S.P. procedures and did not reflect the actual performance of the commercially available products†. On the basis of the official testing performed in this Laboratory it is apparent that there is a need to rationalize the testing apparatus, the treatment of sutures before testing and the type of knot used in carrying out the knot pull test.

The work described here was undertaken with a view to developing official requirements for these products which would encompass appropriate pharmacopoeial requirements and include official test procedures that reflected current industrial practice, methodology and availability of apparatus.

Types of apparatus used for testing suture strength

The B.P. specifies the constant rate of traverse type of tensile tester for the knot pull and needle attachment tests. This type of instrument, which is generally known as the pendulum type, is no longer available in Australia. The textile industry in Australia has replaced the B.P. apparatus with the electronic load cell type of constant-rate-of extension tensile tester. This trend has followed the development of Australian Standard L54–1970, Determination of Breaking Load and Extension of Yarns and Threads, by the Standards Association of Australia (S.A.A.). The Foreword to the AS L54 comments on the 'constant-rate-of-traverse' type of machine as follows:

'The inherent sensitivity of this machine to the effect of small differences in design has led to nominally similar machines made by different manufacturers giving different results. Further, the inertia of the pendulum has raised doubts of the validity of static calibration in the dynamic operating condition of the machine during a test. These aspects influenced the committee not to approve of this type of machine as the basis of a standard test procedure'.

The U.S.P. has adopted the constant-rate-of-loading type of tensile tester (inclined plane tester) for the knot pull test. Although the inclined plane tester does not appear to suffer from the defects of the pendulum type of instrument it is not readily available in this country and is not recommended by the S.A.A. Consideration is now being given by the U.S.P. to the specification of a constant rate of

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† British Pharmacopoeia knot pull tensile strength specifications for catgut sutures were subsequently revised but the discrepancy between the B.P. limits and the commercially available sutures remains (S. Lee unpublished results).

extension type of tensile tester in future monographs for sutures (D. Banes, private communication). Manufacturing industry in this country and in the U.S.A. is beginning to use the load cell tensile tester for the knot pull test without altering the existing U.S.P. suture specifications. Assessment of the validity of this practice by comparing the performance of both test procedures on a range of samples was required, so that the use of these instruments and specifications could be placed on a sound experimental basis.

Comparison of tensile strength testers

The U.S.P. apparatus was compared with the load cell tester using five types of suture. The inclined plane tester was operated at a speed such that the sample broke within 20 s of test commencement and the load cell instrument was operated at 200 mm ± 20 mm min^{-1}. Previous work at this laboratory had established there was no significant difference in results obtained using the load cell tester at different speeds in the range 100 to 300 mm min^{-1}. The variation in tensile strength measurements between the instruments was investigated over a range of applied loads and the results are shown in Table 1. Wherever possible, a long length of suture (90 m) was used so that a series of tests could be carried out on the same reel. Both tensile testers gave similar mean results but the load cell instrument had better precision than the inclined plane device. This difference in precision is partly due to the pre-tensioning device on the load cell tester which enables suture samples to be handled and mounted in a reproducible fashion. The inclined plane tester tended to give a higher breaking force value than the load cell type. The differences in breaking force measurements between the two instruments was dependent on the load range in the case of non-absorbable sutures, and was not related to the material used. This trend is consistent with the data quoted by Booth (1964).

The results obtained from testing catgut sutures also showed increasing differences with increase in breaking load, but the load cell tester values were higher than those obtained using the inclined plane tester. The high coefficients of variation obtained reflect the lack of uniformity of the catgut sutures and additional tests would have to be performed before a reliable trend could be established.

Effects of soaking on tensile strength of sutures

The B.P. requires sutures that are packaged in the dry state to be soaked in ethanol (95%), or 2-propanol (90%) for 24 h before testing. For linen sutures, 30 min soaking in water at 16–21 °C immediately before testing is specified. These requirements are in contrast to those of the U.S.P. which do not specify prior conditioning of sutures before testing. The rationale for soaking sutures that are stored in the dry condition is unclear. The practice may have originated when this type of suture was sterilized in ethanol or boiling water immediately before use. Soaking of catgut sutures may also have rendered the strands supple and more readily manipulated, whereas currently available products are marketed as sterile goods in sealed containers which include an appropriate conditioning solution.

To determine the effect of soaking on the tensile strength of various sutures nylon, polyester and linen sutures were soaked according to the conditions of the B.P. The sutures, were then examined on the load cell tester by using the straight pull test (tensile strength without a knot in the suture) which gives more precise results than the knot pull test.

Table 1. Comparison of inclined plane and load cell tensile testers using straight pull test.

Type of suture	Metric size	Number tested	Breaking force (Kgf) Inclined plane	Load cell	Difference	*t* value	*P*
Silk, braided	0·3	15	0·05 (0·006)	0·04 (0·007)	0·01 ± 0·002	4·2	0·05
	0·5	20	0·216 (0·02)	0·203 (0·012)	0·013 ± 0·005	2·4	>0·05
	1·0	20	0·80 (0·026)	0·78 (0·016)	0·02 ± 0·007	2·9	>0·05
Steel, monofilament	1·0	15	1·44 (0·008)	1·25 (0)	0·19 ± 0·002	92·0	<0·001
	1·5	15	1·59 (0·01)	1·39 (0·019)	0·20 ± 0·006	36·1	<0·001
	2·0	15	3·75 (0·044)	3·55 (0)	0·20 ± 0·011	17·6	<0·001
Nylon, braided	3·0	20	4·67 (0·066)	4·39 (0·024)	0·28 ± 0·016	17·8	<0·001
	3·5	20	6·39 (0·180)	6·12 (0·049)	0·27 ± 0·042	6·4	=0·02
	5·0	20	14·47 (0·107)	13·33 (0·08)	1·14 ± 0·030	38·2	<0·001
Polyester, braided	5·0	20	13·95 (0·144)	12·80 (0·04)	1·15 ± 0·027	42·6	<0·001

Note: Percent coefficient of variation is given in parentheses after each tensile strength value.

Table 2. Effects of presoaking on tensile strength (Straight pull test).

Type of suture and metric size	Type of soaking	Tensile strength (kg) After soaking	Tensile strength (kg) Without soaking	(%)*
Linen (n = 30)				
2·0	Water, 21 °C, 30 min	2·44 (22·5)	1·87 (18·7)	31·0
3·0	Water, 21 °C, 30 min	5·87 (13·6)	4·57 (10·3)	29·0
Polyester (n = 20)				
4·0	Ethanol, 24 h	11·45 (6·47)	12·31 (1·30)	−7·5
5·0	Ethanol, 24 h	13·82 (2·02)	13·74 (0·41)	−1·01
5·0	90% 2-propanol, 24 h	13·98 (0·64)	13·74 (0·41)	−1·02
Nylon (n = 20)				
3·0	Ethanol, 24 h	3·98 (3·04)	4·54 (0·66)	−14·1
	90% 2-propanol, 24 h	3·97 (0·93)	4·54 (0·66)	−14·4
3·5	Ethanol, 24 h	5·33 (1·50)	6·15 (0·65)	−15·4
	90% 2-propanol,	5·43 (1·34)	6·15 (0·65)	−13·3

Percent coefficient of variation is given in parentheses after each tensile strength value.

* Difference (%) in tensile strength between soaked and unsoaked sutures.

The results obtained are given in Table 2 and show that soaking procedures cause significant changes in tensile strength for some types of suture. Linen sutures showed a marked increase in strength, while nylon sutures had reduced strength after soaking both in ethanol and 2-propanol. The polyester size 4 suture showed a 7·5% reduction in strength after soaking in ethanol for 24 h. Reproducible results could not be obtained after soaking certain polyester sutures in 90% 2-propanol owing to the sutures breaking, within 5 mm of the jaws of the instrument. It is apparent that the practice of soaking sutures before testing may lead to results for knot pull strength which are not consistent with the performance of the sutures under actual conditions of use where these products are used immediately after removal from the packet, and there seems to be no valid reason for the retention of this procedure in future official tests. In proposed N.B.S.L. standards for sutures, all the knot pull specifications are set for the sterile products, and the limit is increased by 25% if the product is non-sterile. The N.B.S.L. specifications are more realistic than the B.P. requirements and eliminate the soaking process which is cumbersome and imprecise.

Types of knots used in testing sutures

The B.P. requires the simple knot to be used in testing for tensile strength. The simple knot is formed by passing the end of a suture held in one hand over that held in the other and then drawing the free end through the loop and pulling it taut. The U.S.P. requires the use of the surgeon's knot. The surgeon's knot is a square knot, in which the free end if first wrapped around a rubber tube and passed twice through the loop and pulled taut. The free end is then passed once through a second loop and the ends are drawn taut so that a simple knot is superimposed upon a compound knot. The technique of the operator plays an important part in the performance of the test when the surgeon's knot is used as the correct tension must be applied at all stages during the tying of the knot.

Comparative results obtained on various types of sutures using the two types of knot are given in Table 3. For nylon and silk sutures, the precision obtained using the simple knot was better than that achieved with the surgeon's knot. The simple knot also seems preferable to the surgeon's knot in testing non-absorbable sutures because of its ease of tying. In

Table 3. Comparison of results obtained using the surgeon's knot and the simple knot.

Type of suture	Metric size	No. tested	Breaking force (Kgf) Surgeon's knot (U.S.P.)	Breaking force (Kgf) Simple knot (B.P.)	Difference	*t* value	*P*
Nylon, braided	3·0	30	2·70 (0·20)	2·74 (0·14)	0·04 ± 0·04	1·0	0·35
	4·0	30	5·97 (0·26)	6·50 (0·16)	0·53 ± 0 06	8·8	<0·001
	5·0	30	7·35 (0·48)	7·83 (0·36)	0·48 ± 0·11	4·4	<0·001
Silk, braided	2·0	30	1·29 (0·07)	1·28 (0·06)	−0·01 ± 0·02	0·5	0·60
	3·0	30	3·21 (0·14)	3·10 (0·13)	−0 11 ± 0·035	3·1	0·005
	4·0	30	5·46 (0·20)	5·76 (0·13)	0 30 ± 0·04	7·5	<0·001
Catgut, chromic	3·0	10	1·94 (0·12)	1·78 (0·21)	−0·16 ± 0·08	2·0	0·08
	4·0	10	3·36 (0·38)	4·19 (0·40)	0·83 ± 0·17	4·9	<0·001
	5·0	10	4·85 (0·29)	5·17 (0·75)	0·32 ± 0·25	1·3	0·20
	6·0	10	5·62 (0·57)	5·50 (0·64)	−0·12 ± 0·27	0·4	0·75
Catgut, plain	3·5	10	2·70 (0·15)	2·96 (0·33)	0·26 ± 0·11	2·4	0·05
	3·5	10	2·56 (0·20)	2·80 (0·25)	0·24 ± 0·10	2·4	0·05
	5·0	10	4·47 (0·39)	5·16 (0·16)	0·69 ± 0·23	3·0	0·015

Note: Percent coefficient of variation is given in parentheses after each tensile strength value.

contrast, the surgeon's knot generally gave better precision than the simple knot when catgut sutures were tested. The lower relative precision with the simple knot may be related to ease of slippage and the stiffness of the catgut and the surgeon's knot may be preferable for this type of suture.

Survey of suture performance

A total of 26 types of non-absorbable sutures were tested for knot pull strength using the load cell instrument and a simple knot. The samples included nylon, polyester, silk and polypropylene sutures of monofilament or braided construction and linen thread. All sutures complied with both U.S.P. and B.P. knot pull requirements, in most instances exceeding the pharmacopoeial specifications by a wide margin. On the basis of these results (Table 4) it would appear that the U.S.P. requirements more closely reflect the performance of commercially available non-absorbable sutures than do the corresponding B.P. specifications.

The B.P. has requirements for the knot pull strength of individual sutures (minimum individual values), in addition to specifications for the mean minimum knot pull strength. At least 80% of the sutures in the samples must exceed the mean minimum knot pull value and none has a knot pull strength less than the minimum individual value. The use of minimum individual values, which are not specified in the U.S.P., is considered to be important as a means of detecting weak spots which could develop during faulty manufacturing processes. The B.P. individual minimum values vary considerably between individual sizes of suture, with sizes greater than 2·5 having values of 50–60% of the minimum breaking load, and smaller diameter sutures generally having lower specified minima. For example, in the case of polyester suture, metric size 2, the U.S.P. specification for mean breaking load is 0·96 kg, the B.P. value for mean minimum breaking load is 0·80 kg, and the B.P. individual minimum value is 0·20 kg. The experience of this Laboratory has been that the minimum individual value, as a percentage of the mean breaking load, does not vary appreciably with the size of the suture, and that individual minima of between 80 and 95% of the mean breaking load are the norm regardless of size.

Minimum values of less than 50% seem unsatisfactory, particularly as the low minimum individual values specified by the B.P. relate to the commonly used medium diameter size sutures. Proper quality control during manufacture would avoid the need for such low permitted individual minimum values. The data in Table 4 show that the minimum individual values obtained for non-absorbable sutures ranged from 76·3 to 96·3% of the tested mean values with

Table 4. Knot pull breaking load data for non-absorbable sutures.

Type of suture	Metric size	Mean breaking load, kg	Mean as % of pharmacopoeial minimum: B.P.	Mean as % of pharmacopoeial minimum: U.S.P. (Class 1)	Minimum individual breaking load: kg	Minimum individual breaking load: As % of mean	Minimum individual breaking load: As % B.P. minimum	Minimum individual breaking load: B.P. requirement as B.P. minimum
Nylon, monofilament	0·7	0·29 (17·5)	242	145	0·24	82·8	200	41·7
	1·0	0·67 (10·8)	479	168	0·59	88·1	422	57·1
	5·0	4·85 (8·0)	180	138	4·20	86·6	156	61·1
Nylon, braided	1·5	1·03 (8·3)	294	172	0·90	87·4	257	34·3
	2·0	1·56 (8·2)	240	162·5	1·35	86·5	208	30·8
	3·0	2·42 (3·4)	173	168	2·25	93·0	161	46·4
Polyester,	1·0	0·63 (8·5)	315	158	0·55	87·5	276	50·0
	3·0	2·23 (4·2)	131	155	2·07	92·8	122	47·1
	3·5	3·97 (6·0)	178	184	3·50	88·2	157	53·8
Silk, braided	0·7	0·38 (6·3)	380	190	0·35	92·1	350	50·0
	1·5	0·96 (4·5)	259	160	0·90	93·8	243	27·0
	3·5	3·16 (3·9)	171	146	3·00	94·9	162	59·5
Polypropylene, monofilament	0·7	0·35 (5·2)	—	175	0·32	91·4	—	—
	1·0	0·64 (2·6)	—	160	0·62	96·9	—	—
	3·0	2·88 (2·9)	—	200	2·70	93·8	—	—
Linen thread	2·0	0·98 (16·7)	123	148	0·78	79·6	97·9	50·0
	3·0	2·35 (14·0)	181	230	1·88	80·0	144·8	61·5
	4·0	3·64 (12·7)	165	201	3·02	83·0	137·0	59·1

Note: Percent coefficient of variation is given in parentheses after each value for mean breaking load.

Table 5. Knot pull breaking load data for absorbable sutures.

Type of suture	Metric size	Mean breaking load, kg	Mean as % of pharmacopoeial minimum B.P.	Mean as % of pharmacopoeial minimum U.S.P. (Class 1)	Minimum individual breaking load kg	As % of mean	As % of B.P. minimum	B.P. requirement as % B.P. minimum
Catgut, plain	1	0·27 (7·4)	180	139	0·24	88·9	160·0	26·7
	3	2·50 (5·6)	200	200	2·35	94·0	188·0	52·0
	5	4·60 (11·1)	153	121	3·85	83·7	128·0	53·3
Catgut, chromic	1	0·32 (6·3)	213	178	0·29	90·6	193·0	26·7
	3	1·72 (10·5)	138	138	1·56	90·7	125·1	52·0
	5	4·33 (6·0)	152	114	4·10	94·7	143·9	53·3
Polyglycolic acid monofilament	1·0	0·87 (3·9)	—	—	0·83	95·4	—	—
	2·0	2·37 (6·4)	—	—	2·20	92·8	—	—
	4·0	6·5 (2·5)	—	—	6·2	95·4	—	—

Note: Percent coefficient of variation is given in parentheses after each value for mean breaking load.

the average of 88·3%. These figures are considerably higher than the minimum individual values specified in the B.P. and these figures represent a range of 422 to 156% of the B.P. minimum values with a mean 226%.

Synthetic absorbable sutures tested in this survey (Table 5) complied with U.S.P. requirements (there is no monograph for this type of product in the B.P. 1980). Knot pull strength values for catgut satures easily met the requirements of both the B.P. and U.S.P. Again, the U.S.P. specifications seemed more appropriate for the products tested than the current B.P. requirements. Minimum individual values for synthetic absorbable sutures ranged from 84·7 to 98·0% of the mean knot pull strength, while the corresponding range for catgut sutures was 84·8 to 94·7%.

On the basis of the results in Tables 4 and 5, a minimum individual value of not less than 70% of the mean knot pull breaking load would appear to be an appropriate specification for synthetic sutures. The catgut sutures tested in the survey would also comply with this specification. However, individual strands of catgut can show greater variation in knot pull strength than synthetic sutures. This may be due to differences between individual animals used for the production of the catgut. Consequently, a more lenient specification for minimum individual value is needed for catgut sutures.

In order to confirm that the products tested in the survey were made from standard grades of material, the tenacity values were determined for all the synthetic sutures using a straight pull test to determine breaking load. The results obtained indicated that the material in all the sutures tested was of normal commercial quality with tenacities within typical ranges (I.C.I. 1962).

Conclusions

The results obtained suggest that it would be desirable for present Australian requirements for knot pull strength of sutures to be modified to take account of current product performance and testing equipment. In particular, it is proposed that tensile strength testing should be carried out on load cell type apparatus, that dry packed sutures should not be soaked before testing and that minimum individual values should be specified as a constant percentage of the mean breaking load. The simple knot should be used for testing all non-absorbable sutures and all synthetic absorbable sutures with the use of the surgeon's knot being reserved for catgut sutures. In a number of instances, the knot pull test requirements of the U.S.P. appear to more closely reflect the performance of sutures on the Australian market than do the corresponding B.P. specifications. Adoption of U.S.P. values, modified where necessary to take account of the different test procedure, would appear to be the basis for more realistic requirements for sutures.

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