JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICINE 14 (2003) 411–417

Sutured calf pericardium: influence of the type and angle of the suture on mechanical behavior

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Careful selection of the biological tissue to be used in cardiac bioprostheses and a thorough knowledge of its mechanical behavior, facilitating both the prediction of this behavior and the interactions between the tissue and the other materials employed, is the best approach to designing a durable implant. For this purpose, a study involving uniaxial tensile testing of calf pericardium was carried out. Two sets of three contiguous strips of tissue were obtained from each pericardial membrane, to perform a total of 144 trials. Two samples were sewn with one of four commercially available suture materials: Gore-Tex, nylon, Prolene and silk. In each set of three samples, the center strip remained intact and unsutured to serve as a control, while the left-hand strip was sutured at a 45° angle with respect to the longitudinal axis and the right-hand strip was sewn at a 90° angle. All the samples were tested until rupture. The results demonstrated a significant loss of mean load ($p < 0.01$) in the sutured samples at rupture. The angle of the suture had no influence on these results, although the stress/strain curves showed that, as the tensile stress increased, the mechanical behaviors were less uniform. The rupture of the collagen fibers could explain this phenomenon. The pericardium sutured with Gore-Tex presented a greater strain, or deformation (elongation), at lower levels of stress, regardless of the angle of the suture. The tissue selection criteria, based on the use of paired samples, enabled a correct prediction of the mechanical behavior of the tissue, with excellent correlation coefficients (> 0.98) and a high degree of homogeneity in the results.
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1. Introduction

Calf pericardium has been employed in the manufacture of the valve leaflets of cardiac bioprostheses since the 1970s [1, 2]. The excellent initial expectations in view of its good hemodynamic behavior and low rate of hematogenous complications (thrombosis, hemorrhage, etc.) have been lowered by their limited durability. Primary tissue failure, with early tears in the valve leaflets [3], or medium-term calcium deposition, with hardening and loss of physiological function, are the main reasons for the clinical failure of bioprostheses [4, 5]. The limited and unpredictable durability of these devices on some occasions has reduced their role in favor of mechanical prostheses [2].

At the present time, bioprostheses made of calf pericardium or total bioprostheses made of native pig valves are only the replacements of choice for implantation in tricuspid position, in women of child-bearing age who wish to have children and could be compromised by anticoagulation therapy, and in aortic position in elderly patients [6–9]. The use of bioprostheses which, in contrast to mechanical prostheses, require only initial, short-term anticoagulation, is much more feasible for most patients living in underdeveloped countries, but the handicap is their limited durability [10–13].

Among the causes of bioprosthetic valve failure, aside from the biochemical changes derived from the chemical treatments and tissue-related factors, are the interactions among the different biomaterials used in their construction to give them their functional structure [14]. Suture materials play an important role in these interactions,

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producing shear stress that can cause the leaflets to tear in the region of the suture line [14–18]. The mechanism responsible for the shear stress would be the combination of the limited elasticity of the threads used to sew the calf pericardium, which behaves like a viscoelastic material [14]. This difference in behavior generates internal stresses that must be absorbed by the biomaterial [16]. Over the course of time, the repetitive work of the valve leaflet affects the capacity of the biomaterial to absorb these stresses, ultimately leading to valve failure [10–13].

In the attempt to better understand the possible deleterious effects of the interaction between the suture thread, which secures and gives form to the cardiac valve leaflet, and the calf pericardium of which the valve leaflet is made, we designed an *in vitro* assay to test their mechanical behavior.

We subjected samples of calf pericardium, cut and sutured, to axial tensile testing. The suture materials were four commercially available threads, which were used to perform running sutures at angles of 45° or 90° with respect to the direction in which the load was to be applied. The aim was to assess their mechanical behavior, comparing the findings corresponding to the different suture materials, and to examine the influence of the angle of the suture line. A series of unsutured control samples of calf pericardium was also tested to aid in the correct evaluation of the results.

2. Material and methods

2.1. Tissue preparation

Calf pericardium obtained directly from a local abattoir was employed. The animals had been bred and raised in Spain, and were sacrificed at the age of 9–12 months. The tissue was transported to the laboratory in isotonic saline (0.9% sodium chloride) in HEPES buffer (pH 7.4) at 4 °C. There it was properly cleaned by hand to remove any remains of fat tissue.

The anterior portion of parietal pericardium protecting one third of the heart between right and left ventricle was employed. The pericardial sacs, once opened, measured nearly 15 cm from root to apex and were approximately 10 cm wide. To prepare the tissue for the cutting of samples in the desired direction, the sacs were opened in such a way as to leave the diaphragmatic ligament in the center and the sternopericardial ligaments on the circumference. The manner by which they were procured ensured that all the calf pericardium specimens had a similar morphology (Fig. 1).

Two sets of three adjacent strips measuring 12 × 2 cm were obtained from each pericardial membrane (Fig. 1), for a total of 144 samples. The tissue was cut longitudinally, from root to apex (Fig. 1). The pericardium was treated for 24 h with 0.625% glutaraldehyde (pH 7.4), prepared from a commercially available solution of 25% glutaraldehyde (Merck) at a ratio of 1/50 (w/v), in 0.1 M sodium phosphate buffer.

In each set of three samples, the center strip remained intact and unsutured to serve as a control. In the left-hand strip, an incision was made at a 45° angle with respect to the longitudinal axis, which was to be the axis of loading in all the trials, and was then sewn with one of the four suture materials. These samples will be referred to as left. The right-hand strip was cut and sewn, with the same suture material, at a 90° angle with respect to the longitudinal axis, and will be referred to as right. The samples were repaired with a running suture that was knotted at the end.

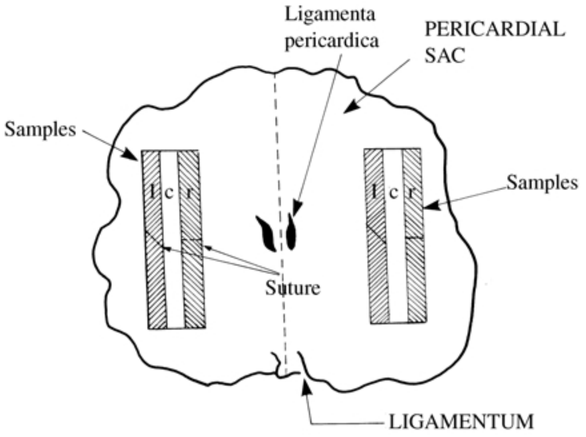

Figure 1 Diagram of the open calf pericardial sac. Samples: *l*: left (sutured at a 45° angle), *c*: center (unsutured), *r*: right (sutured at a 90° angle).

The following suture materials were employed: 6-0 monofilament Gore-Tex (polytetrafluoroethylene) from Gore, Inc. (USA), 5-0 braided nylon (polyamide) from Lorca-Marín, Inc. (Spain), 5-0 monofilament Prolene (polypropylene) from Braun-Dexon, Inc. (UK) and 4-0 braided silk from Lorca-Marín, Inc. (Spain).

The 144 trials were distributed as follows: 36 samples, 12 unsutured controls and 12 each from the left and right of the control, sutured with Gore-tex; 36 samples, 12 unsutured controls and 12 each from the left and right of the control, sutured with nylon; 36 samples, 12 unsutured controls and 12 each from the left and right of the control, sutured with Prolene; and 36 samples, 12 unsutured controls and 12 each from the left and right of the control, sutured with silk.

The thicknesses of the samples were determined by taking the measurement at 10 different points using a Mitutoyo micrometer (Elecount series E/A33/8), which has a precision at 20 °C of ± 3 μm.

2.2. Assay method

Each sample was subjected to uniaxial tensile testing, from root to apex, until rupture. These assays were carried out on an Instron TTG4 tensile tester (Instron Ltd., High Wycombe, Bucks, England), which determines the strain, or elongation, produced at each level of stress. The samples were firmly clamped in such a way as to leave a free lumen of 60 mm. Rupture was confirmed by the loss of load and the morphological evidence of tears in the tissue. The tearing of the tissue resulted in the separation of the edges of the sutured samples, leading to the failure of the suture. The maximum load reached was considered to be the rupture load.

The results were recorded graphically, showing the load/elongation diagram necessary to allow the calculation of the stress/strain (elongation) curve. The tensile stress in the pericardium was calculated taking into account the mean cross-sectional area.

2.3. Statistical study

2.3.1. Comparison of mean values at rupture

The mean values at rupture for the different series of samples and those corresponding to each zone (left, center, right) were compared by means of analysis of variance (ANOVA), using as factors the zone and type of suture material, and the Newman–Keuls test for multiple comparisons. The Shapiro–Wilk test was employed to verify the normal distribution.

2.3.2. Mathematical fit of the tensile stress/strain (elongation) ratio

The tensile stress (MPa)/strain (per unit elongation) ratio was studied using the least squares method. The best fit corresponded to a third-order polynomial, the shape of which is expressed as $y = a_1x + a_2x^2 + a_3x^3$, where y is the tensile stress in MPa and x is the per unit elongation (strain or deformation). The value of the constant a_0 was made to equal zero since, due to biological considerations, the equation must pass through the origin; at zero tensile stress, there would be no deformation. For these same considerations, the analysis was done for $x < 1$. The behavior of the function when the membrane had surpassed its elastic limit, entering the realm of irreversible elongation, that is deformation, was not considered to be of interest.

2.3.3. Selection criteria

Selection criteria were established to ensure greater homogeneity of the samples. The purpose of these statistical criteria was to determine the probability that each membrane tested actually belonged to the zone to which it was assigned in the initial selection. Thus, those membranes with a minimum thickness greater than the mean value for the corresponding series plus one standard deviation or less than the mean value minus one standard deviation were excluded, as were those membranes in which the difference between the mean thickness in a given series and the minimum thickness of the sample was greater than the mean value for this difference as determined in the series, plus one standard deviation, indicating a lack of homogeneity. The pairs of samples (left/center and right/center) in which the stress (MPa) for $x = 0.15$ in the center strip (control) was above or below the mean, plus or minus one standard deviation for the series to which they pertained, were also excluded.

The values for samples from left and right zones are considered unknown since the objective is to predict them on the basis of the results in the previously assayed center strip or control. Thus, the value for each left or right sample, respectively, would be the dependent variable, and that of its paired control sample the independent variable.

2.3.4. Mean overall fit in the selected zones

On the basis of the aforementioned criteria, the following 36 pairs were selected, representing 50% of all the samples assayed.

1. Pericardium sutured with Gore-Tex: left/center, samples nos. 1, 4 and 8; right/center, nos. 1, 4, 8 and 10.
2. Pericardium sutured with nylon: left/center, samples nos. 3, 9, 10, 11 and 12; right/center, nos. 3, 9, 10 and 11.
3. Pericardium sutured with Prolene: left/center, samples nos. 5, 6, 9, 10 and 11; right/center, nos. 5, 6, 9 and 12.
4. Pericardium sutured with silk: left/center, samples nos. 3, 5, 9, 11 and 12; right/center, nos. 3, 5, 9, 10, 11 and 12.

2.3.5. Predictive study

A predictive study of the values for the left zone and for the right zone was performed after the selection process had been carried out and the values for the equivalent center strips were known. This determination involved the mathematical calculation of the values in the samples selected according to the aforementioned criteria, using linear regression analysis, where the values for the center strip were known independent variables in each case and those of either the left zone or the right zone were predicted, dependent variables. For each set of samples, the tensile strength (MPa) y_{left} or y_{right} was estimated on the basis of that of the central zone (y_{center}), and the 95% confidence intervals were calculated. The estimated values for y_{left} and y_{right} were compared with the known values for y_{left} and y_{right}, respectively, and the behavior of each type of suture material was also studied.

2.3.6. Comparison of the mechanical behavior of the left and right samples sewn with the different suture materials

The mechanical behavior, or stress expressed in MPa (y), of the pairs of sutured samples (left/right) was studied for different per unit elongation values, between 0 and 0.5, taken at intervals of 0.05. These pairs of stress values were used to obtain a best-fit linear regression equation. The correlation coefficient for each fit was determined.

3. Results

3.1. Rupture

The tensile stresses at rupture are shown in Table I.

All of the sutured series presented a statistically significant loss of resistance ($p < 0.01$), when compared with the corresponding unsutured controls, regardless of the type of suture material and the angle of the suture line (45° or 90°).

The mean values in the sutured samples ranged between 4.01 MPa for pericardium sewn with nylon at a 45° angle (left) and 8.27 MPa for that sewn with Prolene at a 90° angle (right). In the samples from the right, the mean values at rupture were 7.16, 6.23, 8.27 and 7.35 MPa for samples sutured with Gore-Tex, nylon, Prolene and silk, respectively. In the samples from the

TABLE I Mean tensile stress at rupture (MPa)

Assay series	No.	Tensile stress (MPa)	Standard deviation	Range
Gore-Tex				
Left	12	6.48	2.34	2.86, 10.60
Right	12	7.16	2.97	3.56, 13.22
Center	12	11.49	4.64	5.72, 23.94
Nylon				
Left	12	4.01	1.50	1.84, 6.30
Right	12	6.23	1.59	4.42, 9.87
Center	12	7.88	2.25	3.03, 10.41
Prolene				
Left	12	7.07	2.43	3.47, 6.30
Right	12	8.27	3.18	5.02 14.17
Center	12	10.41	2.67	5.48, 15.51
Silk				
Left	12	5.71	2.02	2.64, 10.01
Right	12	7.35	1.97	4.75, 12.49
Center	12	13.44	4.29	6.67, 19.09

Left series: sutured at a 45° angle with respect to the longitudinal axis of the sample. Right series: sutured at a 90° angle with respect to the longitudinal axis of the sample. Center series: unsutured control samples.

left, the mean values at rupture were 6.68, 4.01, 7.07 and 5.71 MPa, respectively.

In the unsutured pericardium, the mean tensile stresses at rupture ranged between 7.88 and 13.44 MPa.

3.2. Mathematical fit of the tensile strength or stress/strain (elongation) ratio

Table II shows the fit of the stress/strain curve when the sample selection criteria were not applied. The coefficients of determination (R^2) ranged between 0.739 and 0.953. After application of the selection criteria described in the material and methods section, the coefficients of determination (R^2) improved, ranging from 0.841 to 0.991, as shown in Table III. Figs. 2–5 show these results for the four types of suture thread graphically.

TABLE II Mathematical fit of the tensile stress/strain (elongation) curve when selection criteria were not applied (see text)

Series	a_1	a_2	a_3	R^2
Gore-Tex				
Left	– 2.79	110.75	– 177.90	0.739
Right	– 2.46	114.76	– 140.05	0.819
Center	– 9.79	242.01	– 345.72	0.898
Nylon				
Left	– 2.78	156.34	– 320.37	0.872
Right	– 5.11	146.76	– 176.59	0.936
Center	– 10.76	304.88	– 600.40	0.953
Prolene				
Left	2.17	111.29	– 172.16	0.798
Right	2.06	87.86	– 114.96	0.780
Center	– 14.46	331.72	– 578.57	0.944
Silk				
Left	– 2.15	144.41	– 44.05	0.926
Right	– 13.74	231.56	– 401.18	0.878
Center	– 18.47	296.67	– 257.99	0.942

Left series: sutured at a 45° angle with respect to the longitudinal axis of the sample. Right series: sutured at a 90° angle with respect to the longitudinal axis of the sample. Center series: unsutured control samples. R^2: coefficient of determination.

TABLE III Mathematical fit of the tensile stress/strain (elongation) curve after selection criteria were applied (see text)

Series	a_1	a_2	a_3	R^2
Gore-Tex				
Left	– 3.15	57.69	– 47.66	0.841
Center	– 11.26	199.37	– 145.52	0.998
Right	– 0.65	96.04	– 131.51	0.855
Center	– 6.89	217.76	– 299.38	0.910
Nylon				
Left	– 8.66	279.61	– 893.39	0.885
Center	5.30	44.07	281.04	0.951
Right	– 12.13	210.27	– 317.33	0.959
Center	5.59	28.71	364.05	0.948
Prolene				
Left	– 9.24	202.31	– 243.11	0.887
Center	– 11.89	313.48	– 520.40	0.959
Right	– 1.32	– 6.88	272.42	0.925
Center	– 11.30	254.33	– 310.93	0.991
Silk				
Left	– 4.90	162.39	– 40.10	0.910
Center	– 5.91	113.03	380.17	0.964
Right	– 10.75	209.50	– 284.41	0.941
Center	– 5.91	113.03	380.17	0.964

Left series: sutured at a 45° angle with respect to the longitudinal axis of the sample. Right series: sutured at a 90° angle with respect to the longitudinal axis of the sample. Center series: unsutured control samples after applying the selection criteria to the left and right series, respectively (see text). R^2: coefficient of determination.

3.3. Predictive study

The results of the predictive study appear in Table IV, which shows the coefficients of the regression curves, a (constant) and b (slope), and the correlation coefficient (r), which was always greater than 0.96. These regression curves establish the relationship between the known values of the control (center) series, the independent variable (x), and the predicted values of

TABLE IV Results of the predictive study. Comparison of the coefficients of the regression curves of the sutured series (left and right) (y) and their corresponding center control series (x)

Type of suture	Constant a (95% CI)	Slope b (95% CI)	r
Gore-Tex			
Left	0.31 (0.15, 0.46)	0.35 (0.30, 0.39)	0.984
Right	0.10 (0.05, 0.15)	0.52 (0.50, 0.53)	0.999
Nylon			
Left	0.17 (– 0.07, 0.39)	0.59 (0.53, 0.65)	0.991
Right	– 0.12 (– 0.36, 0.12)	0.64 (0.58, 0.70)	0.992
Prolene			
Left	– 0.15 (– 0.29, – 0.01)	0.76 (0.72, 0.79)	0.998
Right	0.07 (0.04, 0.11)	0.61 (0.60, 0.62)	1.000
Silk			
Left	0.32 (0.06, 0.57)	0.73 (0.68, 0.78)	0.995
Right	0.27 (– 0.14, 0.67)	0.42 (0.34, 0.51)	0.967

Left series: sutured at a 45° angle with respect to the longitudinal axis of the sample. Right series: sutured at a 90° angle with respect to the longitudinal axis of the sample. 95% CI: 95% confidence interval. r: correlation coefficient.

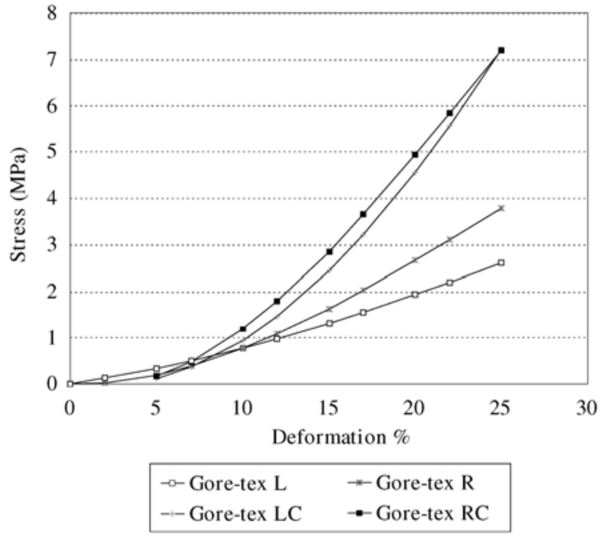

Figure 2 Tensile stress/strain (elongation) curve for pericardium sutured with Gore-Tex. Comparison of the left sample series, sutured at 45° (l), and the right sample series, sutured at 90° (r), with their control, unsutured center series (cl and cr, respectively) after application of the selection criteria.

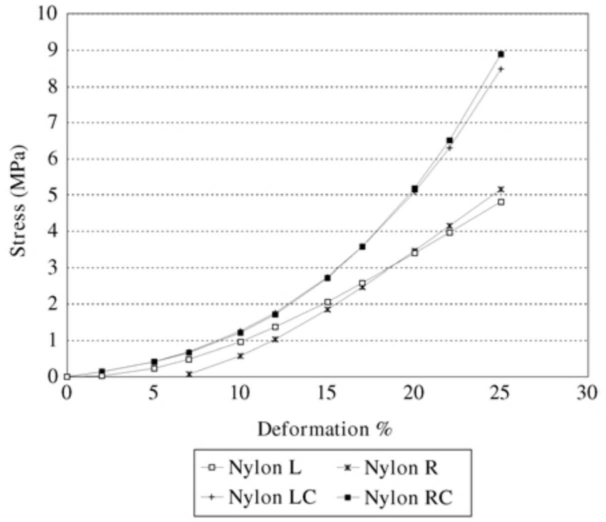

Figure 3 Tensile stress/strain (elongation) curve for pericardium sutured with nylon. Comparison of the left sample series, sutured at 45° (l), and the right sample series, sutured at 90° (r), with their control, unsutured center series (cl and cr, respectively) after application of the selection criteria.

the right and left samples, respectively, which are the dependent variables (y) for each type of suture.

3.4. Comparison of the different series studied in terms of mechanical behavior

The findings with the different suture materials were compared in samples from the left and from the right in Table V which show the results of linear regression analysis. The correlation coefficients (r) were over 0.98 in every case.

4. Discussion

The main problems with biological prostheses are derived from their limited durability when compared with metallic replacements. Calcification and primary tissue failure are both consequences of the biochemical composition of the tissue itself and of the chemical treatments to which it is subjected. On the other hand, there are also drawbacks due to design and the lack of knowledge of the interactions between the different materials used in the construction of bioprostheses [1, 2, 19–21]. The average durability of these devices is known, but it is difficult to guarantee it on an individual basis [11–14].

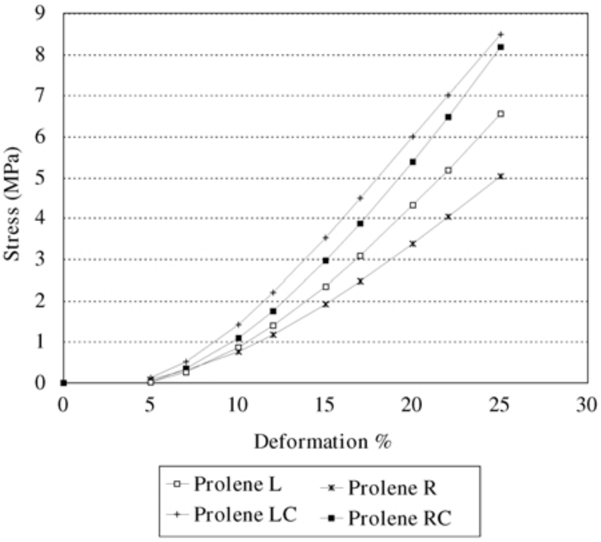

Figure 4 Tensile stress/strain (elongation) curve for pericardium sutured with Prolene. Comparison of the left sample series, sutured at 45° (l), and the right sample series, sutured at 90° (r), with their control, unsutured center series (cl and cr, respectively) after application of the selection criteria.

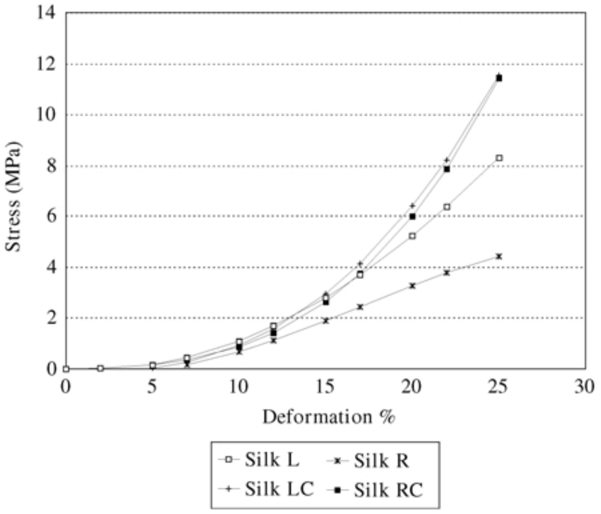

Figure 5 Tensile stress/strain (elongation) curve for pericardium sutured with silk. Comparison of the left sample series, sutured at 45° (l), and the right sample series, sutured at 90° (r), with their control, unsutured center series (cl and cr, respectively) after application of the selection criteria.

In this report, we study four commercially available suture materials, Gore-Tex, nylon, Prolene and silk, used to repair incisions made at different angles (45° and 90° with respect to the longitudinal axis) in strips of calf pericardium. The trio of contiguous samples is completed by a center control strip that remains intact and unsutured.

TABLE V Comparison of the coefficients of the regression curves of the samples from the left and right series sewn with the different suture materials

Dependent variable (y)	Independent variable (x)	Constant a (95% CI)		Slope b (95% CI)		R	
		Left	Right	Left	Right	Left	Right
Gore-Tex	Prolene	0.31 (0.16, 0.45)	0.13 (0.006, 0.20)	0.37 (0.32, 0.42)	0.74 (0.71, 0.79)	0.986	0.999
Gore-Tex	Silk	0.30 (0.14, 0.47)	0.16 (0.007, 0.20)	0.30 (0.26, 0.35)	0.79 (0.76, 0.83)	0.983	0.998
Gore-Tex	Nylon	0.18 (0.09, 0.26)	0.25 (0.14, 0.36)	0.52 (0.48, 0.56)	0.70 (0.65, 0.74)	0.996	0.997
Prolene	Silk	– 0.17 (– 0.11, 0.08)	0.004 (– 0.09, 0.17)	0.74 (0.79–0.83)	1.07 (1.01, 1.13)	0.999	0.997
Prolene	Nylon	– 0.32 (– 0.51, – 0.13)	0.16 (0.009, 0.22)	1.38 (1.30–1.46)	0.94 (0.91, 0.97)	0.997	0.999
Silk	Nylon	– 0.36 (– 0.68, – 0.04)	0.12 (– 0.01, 0.24)	1.69 (1.56, 1.83)	0.88 (0.83, 0.93)	0.995	0.997

95% CI: 95% confidence interval. r: correlation coefficient.

The mean tensile stresses at rupture demonstrate the statistically significant loss of load ($p < 0.01$) in the sutured series (range: 4.01–8.27 MPa), when compared with the corresponding unsutured controls (range: 7.88–13.44 MPa). Another finding was the negligible influence of the angle of the suture on these results (ranges: 4.01–7.07 MPa for 45° suture angles versus 6.23–8.27 MPa for 90° angles) (Table I).

The resistance to rupture is only an indirect index of durability. However, the decrease in resistance of the sutured series indicates the presence of internal stresses within the pericardium that can facilitate its early rupture [15, 16].

The development of tears in a valve leaflet of a cardiac bioprosthesis is a sign of valve failure. Initially, the tear impairs the correct function of the device due to the loss of coaptation between the leaflets, leakage and valve insufficiency, which can lead to heart failure. When the tear is considerable, death may be imminent if emergency replacement of the valve is not performed. In any case, the bioprosthesis will have to be replaced.

More important than the resistance to rupture is the analysis of the mechanical behavior according to the stress/strain (elongation) curves. Figs. 2–5 illustrate these behaviors. The curves corresponding to sutured pericardium present lower slopes than the controls, showing that the equivalent elongation, or deformation, is produced at lower levels of stress and that the resistance to rupture is also reduced by suturing. These findings also indicate, indirectly, the existence of internal tensions within the biomaterial when subjected to suture.

The suture angle (45° or 90°) appears to have little influence on the pericardium sewn with nylon (Fig. 3), and somewhat greater when silk is used (Fig. 5); the latter is also the suture material most resistant to deformation. These differences are more clearly observed when the stress is increased, as illustrated in these two figures. The rupture of collagen fibers, the main contributor to the resistance of the biomaterial [22], may explain this behavior.

The pericardium sutured with Gore-Tex, independently of the suture angle, permits a greater degree of deformation at a lower level of stress. That is to say that the pericardium/suture unit is more elastic or that the internal stresses generated within the unit are lower, thus allowing greater elasticity [16–18].

Biological tissues present great intraspecies and interspecies variability. This lack of homogeneity can even occur among the different zones of a given sample of pericardium. Despite this problem, a totally satisfactory tissue selection process had not been devised [23–26]. The selection criteria described in this report, involving the use of paired samples [27], achieved precise mathematical fits (Table III), clearly improving on the manual selection of the tissue (Table II) and enabling the predictive study of the results.

Once the tensile strength of an unsutured sample is known, the application of the aforementioned criteria makes it possible to foresee the tensile stress that the sample with which it is paired will withstand. Table IV shows the regression curves corresponding to the predictive study. After applying the selection criteria, only 50% of the samples were selected, but these presented a high degree of homogeneity and permitted the prediction of the results, opening a new approach to the selection of biological samples [23–27].

We also compare, by means of linear regression analysis, the different stresses associated with the types of suture material in samples sewn at 45° and 90° (Table V). With the application of the selection criteria, these comparisons resulted in excellent correlation coefficients (r), higher than 0.995, making it possible to predict the mechanical behavior of one member of the sample pairs on the basis of that observed in the other sample.

The selection method involving paired samples has been useful in achieving the homogeneity of the results and allowing their prediction. In order for implants and bioprostheses to be acceptable, it must be possible to estimate their durability with a very small margin of error. Although this study is inconclusive with respect to the choice of the ideal suture material for use in combination with calf pericardium, it does demonstrate that, to achieve a high degree of predictability, the proper selection of the tissue is of the utmost importance.

Acknowledgment

The authors wish to thank Martha Messman for the translation of this manuscript and Dr. Nicolás Lopez de Medina, director of the abattoir Norte in San Agustín de Guadalix, Madrid, for his collaboration.

This work was financed with grant no. MAT2000-0292 from the Spanish Ministry of Science and Technology.

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Received 14 March
and accepted 20 August 2002