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Analysis of shearing stress in the limited durability of bovine pericardium used as a biomaterial

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The objective of the study was to determine the shearing stress exerted by the suture thread under conditions of normal working stress. Thirty-six samples of calf pericardium, similar to that employed in the manufacture of bioprosthetic cardiac valve leaflets, were subjected to tensile testing. Prior to the trial, a continuous suture was sewn in the central zone of each sample, at a 45° angle to the longest axis of the sample, using commercially-available threads (silk, Gore-Tex, Surgilene and nylon). Application of the Mohr circle for combined wear revealed that the shearing stress ranged between 2.68-fold greater (for samples sewn with silk) and 5.48-fold greater (for samples sewn with nylon) than the working tensile stress in the region of the suture. It is concluded that the shearing stress is responsible for the limited durability of sutured samples of calf pericardium prepared to simulate bioprosthetic cardiac valve leaflets. © *1998 Chapman & Hall*

1. Introduction

The limited durability of cardiac bioprostheses made of calf pericardium is attributed to the calcification of the material [1–3] and to the mechanical wear of the tissue [4, 5]. In 1990, our research team presented an hypothesis according to which cutting or shearing stress would largely be responsible for the mechanical wear of the biomaterial [6]. The basis for this proposal was the differing elastic behaviour of the valve leaflet made of calf pericardium and the suture thread used to sew it [7–11].

It has been estimated that 60% of valve leaflets explanted after failure present calcifications [12]. Our questions are whether the said calcification is a primary phenomenon that can be prevented by chemical treatment, as appears to be the case with porcine bioprostheses [13, 14], or whether the calcification is also promoted by an intolerable mechanical force. Many tissues undergo calcification at the biological level as they age or when subjected to anomalous working conditions. Could it be that calcium is more readily deposited at the sites of greater mechanical wear [15]?

The objective of this report is to determine the true role of the mechanical force produced by the shearing stress in the early failure of cardiac bioprostheses made of calf pericardium. For this purpose, we have designed a trial with samples of pericardium sewn with different suture threads (silk, Gore-Tex, Surgilene and nylon). The suture was sewn at a 45° angle with respect to the longest axis in order to quantify the shearing stress imposed on the pericardium sample by the suture thread when the biomaterial was subjected to stretch exerted at each end. The quantification of this force for a normal working stress would, by analogy, provide us with a precise idea of the true role of this stress in the failure of the valve leaflets of cardiac bioprostheses.

2. Materials and methods

Thirty-six samples of calf pericardium, sewn with commercial sutures made of silk, Gore-Tex, Surgilene and nylon (Tables I and II) were subjected to tensile–shearing stress. The sutures, which were continuous, were sewn in the central part of the sample at a 45° angle to the longest axis of the sample. All the samples were subjected to constant stretching in opposite directions from each end of the longest axis until they tore.

Calf pericardial sacs from young calves (six–eight months old) were taken randomly and transported from the abattoir in ice-cold isotonic saline (0.9% sodium chloride). The pericardium was stripped of fat manually and fixed with 0.625% glutaraldehyde in 0.1 M potassium phosphate buffer at pH 7.4 for 24 h. After selection of the pericardial sacs on the basis of their physical aspect, and once the tissue had been manually cleaned and freed of fat, each sac was mounted loosely on a 150 mm diameter ring, with the diaphragmatic attachment in the centre and the sternopericardial ligament on the circumference. For sample

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TABLE I Series of sutured calf pericardium assayed

Series	Type of suture	Region B (No.)	Region C (No.)	Total
SB–SC[a,b]	Silk	5	4	9
TB–TC[c]	Gore-Tex	5	4	9
SGB–SGC[d]	Surgilene	5	4	9
NB–NC[e]	Nylon	5	4	9
Total		20	16	36

[a] B and C: regions of the pericardium (see text).
[b] SB and SC: samples of pericardium from regions B and C, respectively, sutured with silk.
[c] TB and TC: samples of pericardium from regions B and C, respectively, sutured with Gore-Tex.
[d] SGB and SGC: samples of pericardium from regions B and C, respectively, sutured with Surgilene.
[e] NB and NC: samples of pericardium from regions B and C, respectively, sutured with nylon.

selection and cutting, the pericardial membrane was divided into three regions according to Purinya's design [16]: region A, that occupying the V-shaped area in the upper portion of the superior pericardial ligaments; region B, immediately below region A and the superior pericardial ligaments and immediately above the pericardial sternal ligament; and region C, symmetrical and contralateral to region B. Regions B and C were the source of the trial samples ($n = 5$ and 4, respectively, for each type of suture thread), cut from the root to the apex. Region A was not used for technical reasons (difficulty in obtaining samples of the proper length for the trial). The samples were cut into strips measuring 20 mm wide and 120 mm long, and a slit was made in the centre of each at a 45° angle and sewn with a continuous suture using the above-mentioned threads (Table II). The samples were then clamped at each end leaving a length of 60 mm free, guaranteeing a secure anchorage without sample slippage once the trial started (Fig. 1). The thickness of the pericardium was measured using a Mitutoyo micrometer with a precision at 20 °C of ± 3 μm. Serial measurements were made at 0.5 cm intervals.

This trial involved the use of an Instron TTG4 tensile tester that registered strain and tensile stress under varying rates of load. The stretch rate was maintained constant at 5 mm min^{-1}. The results were recorded graphically, showing the load–stretch diagram that enabled the calculation of the functions that

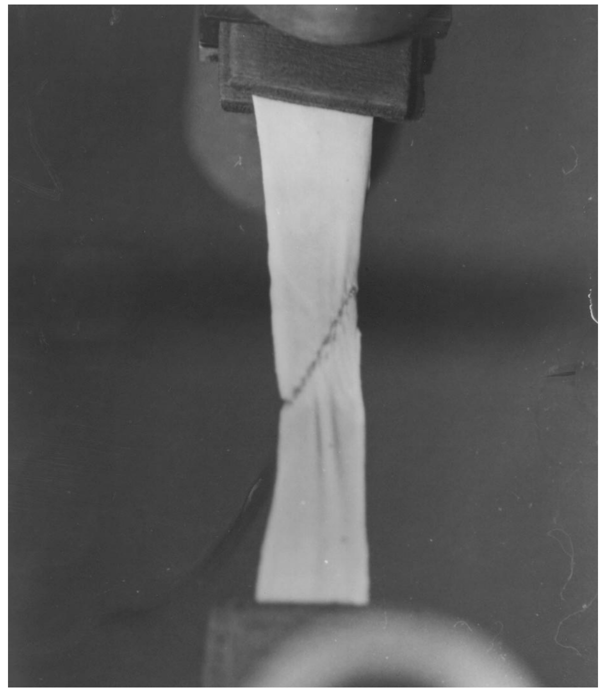

Figure 1 Placement of the samples for tensile testing.

expressed the stress–strain curve with the best mathematical fit. To calculate the shearing stress, the wear circle or Mohr's circle for combined wear was used [17]. To calculate the shearing stress exerted on the pericardial wall by the suture thread, the mean sample thickness, the thread diameter and the number of stitches in the suture were taken into account (see the appendix).

The results were subjected to mathematical and statistical studies (comparison of the means and the chi-squared test).

3. Results

3.1. Breaking point

There were no statistically significant differences among the various types of sutures with respect to the mean values at breaking point (Table III). Nor were significant differences observed between regions B and C for each series. The mean values ranged between 7.39 MPa for samples sutured with silk and 6.67 MPa for those sewn with nylon. The range for the set of values was approximately between 5 and 9 MPa (Table III).

TABLE II Suture materials

Series	Suture[R][e]	Gauge	Composition	Structure	Manufacturer
SB–SC[a]	Silk	4/0	Silk	Multifilament	Lorca Marin, Inc.
TB–TC[b]	Gore-Tex	6/0	Polytetrafluoroethylene (PTFE)	Monofilament	Gore, Inc.
SBG–SGC[c]	Surgilene	5/0	Polypropylene	Monofilament	B. Braun-Dexon, Inc.
NB–NC[d]	Nylon	5/0	Polyamide	Multifilament	Lorca Marin, Inc.

[a] SB and SC: samples of pericardium from regions B and C, respectively, sutured with silk.
[b] TB and TC: samples of pericardium from regions B and C, respectively, sutured with Gore-Tex.
[c] SGB and SGC: samples of pericardium from regions B and C, respectively, sutured with Surgilene.
[d] NB and NC: samples of pericardium from regions B and C, respectively, sutured with nylon.
[e] *R*: determinant coefficient.

TABLE III Breaking stress (MPa) for the different sutures

Suture	Mean breaking stress (MPa)	Standard deviation	Range
Silk	7.39	1.27	5.50–9.12
Gore-Tex	7.26	0.99	5.94–9.24
Surgilene	7.04	1.22	5.56–8.29
Nylon	6.67	1.21	4.91–7.83

3.2. Mathematical analysis

The mathematical analysis of the stress–strain curves demonstrated that when the tensile strength of the samples was tested, the functions with the best fit were quadratic parabolas corresponding to the equation $y = ax^2 + bx$, incident at their origin ($c = 0$), as demanded moreover by the biomechanical interpretation of the results (y representing the stress in MPa and x is the per unit stretch). Good significance was obtained for the coefficients and the overall fit. Table IV shows the values for coefficients "a" and "b" and for the determination coefficient R^2 for the different series and regions. A different fit can be observed for regions B and C in each series. These results appear in Figs 2 and 3.

3.3. Analysis of shearing stress

The shearing stress to which the pericardium was subjected by the suture was analysed in each series under a working stress of 0.25 MPa. Table V presents the means and ranges of these results, calculated according to the procedure described in Section 2. It was found that the highest shearing stress, 1.37 MPa, was produced by the nylon thread (ranging from 1.16 to 1.52 MPa) and the lowest, 0.67 MPa, by the silk suture (ranging from 0.57 to 0.76 MPa).

TABLE IV Constants a and b of the equation $y = ax^2 + bx$ and the resulting determination coefficient, R^2

Series	a	b	R^2
SB[a]	30.03	6.63	0·849
SC[a]	10.81	7.10	0.872
TB[b]	42.66	6.53	0.894
TC[b]	22.04	4.57	0.894
SGB[c]	19.09	5.54	0.920
SGC[c]	7.73	6.98	0.767
NB[d]	9.79	4.53	0.763
NC[d]	11.40	2.04	0.837

[a] SB and SC: samples of pericardium from regions B and C, respectively, sutured with silk.
[b] TB and TC: samples of pericardium from regions B and C, respectively, sutured with Gore-Tex.
[c] SGB and SGC: samples of pericardium from regions B and C, respectively, sutured with Surgilene.
[d] NB and NC: samples of pericardium from regions B and C, respectively, sutured with nylon.

4. Discussion

The results of the trial to breaking point have provided no findings of interest. At breaking point, the type of suture employed makes no difference, even when different regions of pericardium are compared [16], thus confirming previous data proving that sutured samples are less resistant and durable than those tested without suturing [18]. Breakage occurs after periods of permanent deformation and fluency of the biomaterial, as Hooke reported for elastic materials in his classical study [19]. Once the elastic period is surpassed, permanent deformations make any replacement device in the human organism barely tolerable. The data obtained demonstrate that the different levels of breaking stress obtained (Table III) are of no help in selecting a given suture thread or design [7, 8].

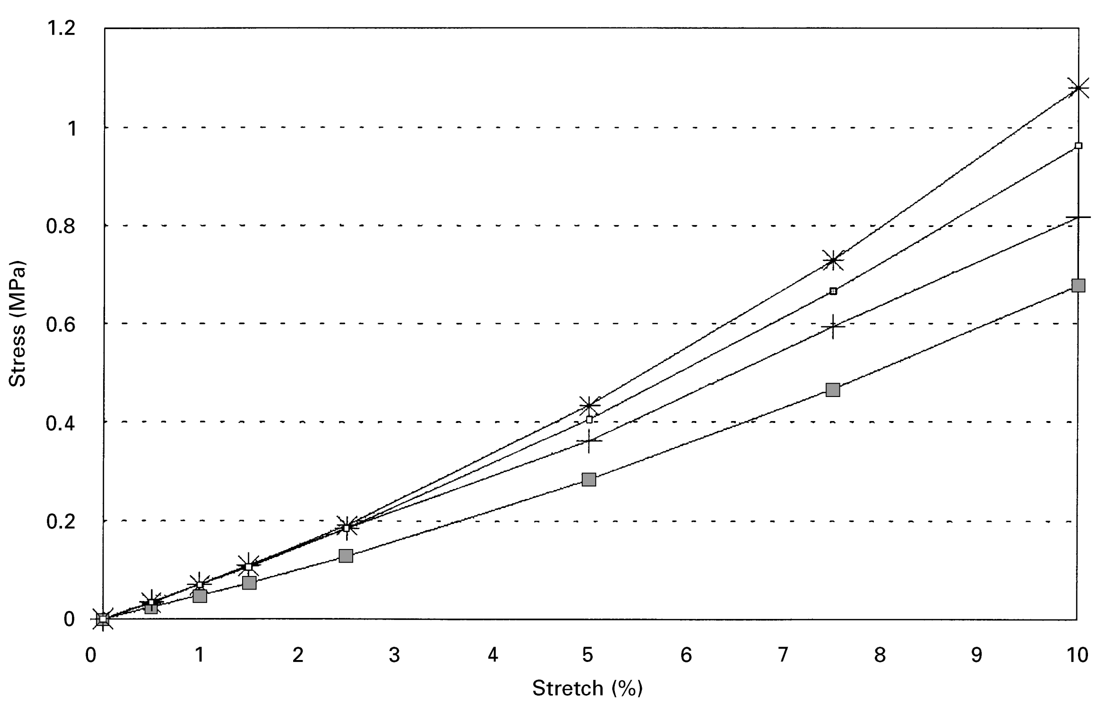

Figure 2 Per cent of stretch that samples of pericardium from regions B and C sewn with silk and Gore-Tex undergo when subjected to different stresses (MPa). Region B: (–□–) silk, (∗) Gore-Tex. Region C: (+) silk, (–■–) Gore-Tex.

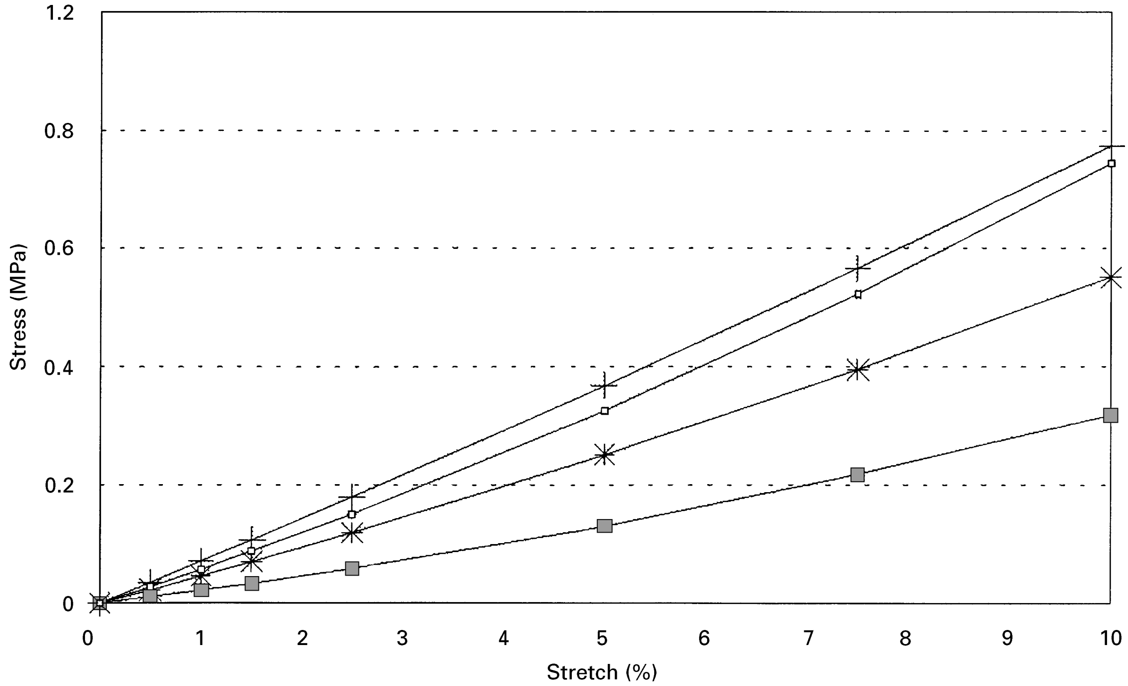

Figure 3 Per cent of stretch that samples of pericardium from regions B and C sewn with Surgilene and nylon undergo when subjected to different stresses (MPa). Region B: (–□–) Surgilene, (∗) nylon. Region C: (+) Surgilene, (–■–) nylon.

TABLE V Shearing stress (means and ranges) produced by the different threads in regions near the suture (regions B and C) for a working stress of 0.25 MPa

Suture	Mean shearing stress (MPa)	Range (MPa)
Silk	0.67	0.57–0.76
Gore-Tex	0.75	0.65–0.88
Surgilene	0.95	0.83–1.08
Nylon	1.37	1.16–1.52

TABLE VI Per cent of deformation of the sutured samples from regions B and C when subjected to a working stress of 0.25 MPa

Suture	Region B (% deformation)	Region C (% deformation)
Silk	3.28	3.35
Gore-Tex	3.17	4.50
Surgilene	3.97	3.45
Nylon	4.98	5.85

The selection of pericardium from specific regions according to a previous report [16] allowed us to demonstrate that the two regions being considered (B and C) behave differently (Table IV and Figs 2 and 3). In general, region C allows a greater degree of deformation when sewn with silk, Gore-Tex or nylon; but not with Surgilene, where the results obtained with samples from the two regions are similar. A poorer correlation of the functions obtained ($R^2 = 0.767$) together with a relatively small number of samples may explain this result. We have studied the behaviour of sutured pericardium simulating a stress of 0.25 MPa, similar to the stress to which a spherical valve leaflet is subjected [20, 21] (Table VI and Figs 2 and 3). The samples obtained from region B and sutured with silk or Gore-Tex show the least amount of deformation: 3.28 and 3.17%, respectively, for the working stress exerted (0.25 MPa), calculated on the basis of the functions obtained in these assays (Table IV). Does this difference in behaviour justify selecting tissue from this region and using these sutures?

The final part of our study may respond to our initial hypothesis concerning the role of shearing stress in the durability of a valve leaflet [6]. We

Figure 4 Illustration of how cutting stress is produced (breaking point).

analysed the shearing or cutting stress generated in the regions adjacent to the sutures. Fig. 4 shows how this stress is produced. To quantify it, if we suppose that the samples are subjected to a tensile stress of 0.25 MPa, similar to the working stress of a valve leaflet [20, 21], the shearing stress exerted on the sample will be 0.125 MPa according to the Mohr circle. When we analyse this suture-induced shearing stress, taking into account the calculation referred to in the appendix, the value ranges between 0.7 MPa for samples sewn with silk and 1.37 MPa for those sutured with nylon (Table V). This stress, in which the suture thread compresses one wall and exerts tension and shearing on the opposite wall, is 2.68 times greater than the working stress when silk is used and up to 5.48 times greater when nylon is used, making the latter the least suitable, at least on the theoretical level. Our results with samples sewn with nylon subjected to real wear testing [22] demonstrate a substantial loss of durability with this suture thread.

The values reached in the portions of the pericardium adjacent to the sutures are dangerously near the elastic limit (2.04 $\pm$ 0.82 MPa) [23] beyond which recovery is impossible; the permanent deformation leads to poor function and a progressive deterioration that probably facilitates calcium accumulation [15] and finally breakage. Nevertheless, real wear trials [22] must be performed with samples obtained from region B sewn with silk and with Gore-Tex because the results are notably better, encouraging distant hopes of introducing newly designed and prepared bioprostheses made from this biomaterial years after its being reported a failure [24–26]. The challenge will be to design constructive systems capable of radically reducing deleterious forces of this kind.

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Appendix
Calculation of the shearing stress exerted by the suture thread on the orifice created by the stitch and the surrounding region

If S_t is the estimated working tensile stress, applying Mohr's wear circle, the shearing stress exerted on the sample will be $\sigma_t/2$. The load in kilograms, F_i, applied to the sample by shearing will be $\sigma_t/2/10.19/S_i$, where S_i is the sample section. If the sample has n_i sutures and a thickness of e_i, and d_i represents the diameter of the suture thread, then we can establish the following equation

$$\sigma_{CS} = F_i/e_i \times d_i \times n_i$$

where σ_{CS} is the shearing stress exerted by the suture thread on the pericardium adjacent to the orifice produced by the stitch, expressed in kilograms per centimetre squared. If this amount is divided by 10.19, we obtain the same value in mega pascals.

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