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Comparative study on biocompatibility and absorption times of three absorbable monofilament suture materials (Polydioxanone, Poliglecaprone 25, Glycomer 631)

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SUMMARY. Monofilament synthetic absorbable suture materials offer excellent glide characteristics and cause minimal tissue trauma as a result of their smooth monofilament structure and gradual bio-absorption. An investigation was conducted on 72 rats to compare three types of monofilament absorbable suture material (Polydioxanone, Poliglecaprone 25, Glycomer 631), with respect to their clinical characteristics, tissue inflammatory reaction and suture absorption times. The results identified different qualities for each suture: Poliglecaprone 25 and Glycomer 631 suture materials were found to be less reactive than Polydioxanone in rat skin. However, because of their extremely low tissue reaction values, all three materials were deemed particularly suitable for use as intracuticular sutures. Absorption times in rat skin were less than 3 months for Poliglecaprone 25, between 3 and 6 months for Glycomer 631 and 6 months for Polydioxanone. The differences in suture characteristics which were detected in our study can help in the surgical selection of the most appropriate suture material. © 2000 Harcourt Publishers Ltd

Keywords: absorbable suture, Polydioxanone, Poliglecaprone 25, Glycomer 631, inflammation, absorption, handling, rat model.

Enormous advances have been made in the last 50 years in the development of better suture materials. Improved understanding of applied molecular biology and continued technological advances have enabled us to obtain synthetic sutures with programmed absorption times, optimised tensile strength and minimal tissue reactivity. Recently developed absorbable monofilament materials offer the benefits of easy glide and low tissue trauma as a result of their monofilament structure, and also have the capacity for gradual absorption within the healing tissues.[1–4]

The biological characteristics of such materials need to be investigated in order that the surgeon can select the most appropriate for each surgical application.

This study compares three commonly used absorbable monofilament suture materials: Polydioxanone (PDS, Ethicon), Poliglecaprone 25 (Monocryl, Ethicon) and Glycomer 631 (Biosyn, USSC), to assess their clinical and histologic characteristics and their possible use in intradermal skin suture.

Materials and methods

This study was performed in accordance with the prevailing regulations about protection of animals used in experiments. Seventy-two Winstar male rats of between 275 and 320 g in weight were employed in this study. Animals were housed in individual cages under standard laboratory environment conditions. For inducement and maintenance of anaesthesia, intraperitoneal sodium pentobarbital (40 mg/kg) was used. Using aseptic conditions, a full thickness midline abdominal skin incision of 3 cm in length was made down to the level of the fascia of the rectus muscles. The wound edges were apposed with six buried vertical intradermal suture stitches,[5–7] placed 0.4 cm apart, closed with five simple flat knots.

The animals were allocated in random manner to three experimental groups. For each group a different suture was used (Polydioxanone, Poliglecaprone 25 and Glycomer 631) of the same gauge (5/0) mounted on the same type of needle (3/8 of circle, 13 mm long, triangular section). Clinical evaluation of the suture characteristics at the time of wound closure was carried out on the basis of five parameters: absence of memory effect, flexibility, gliding capacity, knotting ability and knot hold. Each parameter was scored from 0 (nil) to 5 (excellent). The average of all the scores for each suture provided the final value.

The clinical evaluation was performed by three different surgeons (GM, FS, GB). It was not possible to carry out blinded observation because each suture material had easily identifiable characteristics. All experimental animals were examined daily, any complications at the wound site were noted. For each experimental group, rats were selected randomly for excision biopsies of the surgical scars at 15 days, 1 month, 3 months and 6 months after the initial wound closure.

Excised tissue was immediately fixed in 10% formalin solution overnight. Longitudinal and transverse sections of the sample tissue were taken at the suture level and mounted in paraffin. Two cross-sections of 5 μm in thickness were produced and stained for light microscopy using haematoxylin and eosin (Figs 1–3).

The histologic evaluation of biocompatibility was performed using the Sewell method. This is a method of quantifying the microscopic tissue reaction to allow

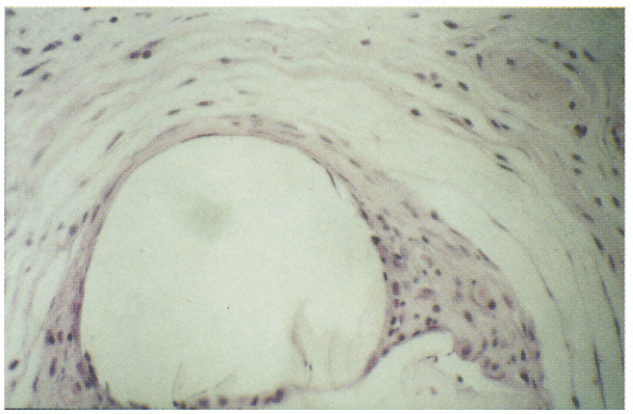

Figure 1—Poliglecaprone 25 5/0 suture thread at 1 month post-implantation into rat skin. Tissue reaction was graded as slight (S = 20). Thread diameter was 0.13 mm.

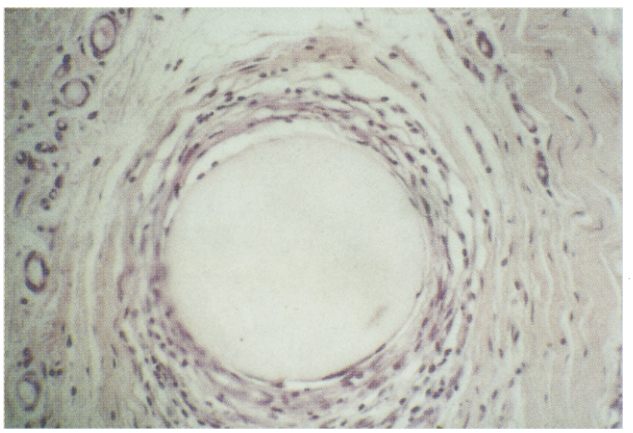

Figure 2—Photomicrograph showing the suture track of Glycomer 631 detectable 3 months after implantation into rat skin. Tissue reaction was graded as slight (S = 20). Diameter was 0.08 mm.

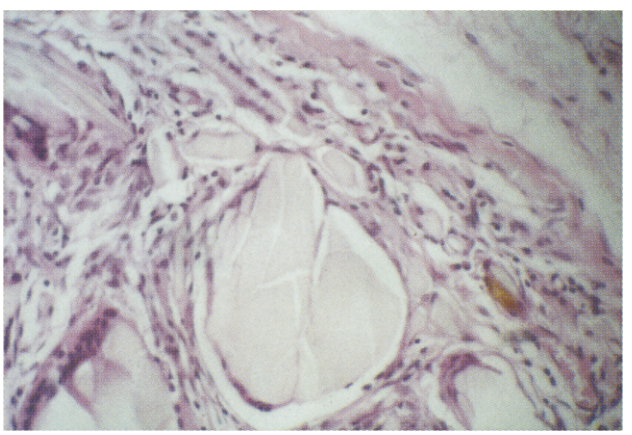

Figure 3—Small remaining fragments of Polydioxanone still detectable 6 months after implantation into rat skin. Tissue reaction was graded as slight (S = 20). Thread diameter was 0.02 mm.

objective comparison of surgical materials. It takes account of the dimensional characteristics of the inflammatory response and the qualitative and quantitative characters of cell infiltration around the suture thread. Sewell assigned empirically different weighting factors to the various cell types and to the overall cellular density since they were not considered of equal importance in interpreting the inflammatory

Table 1 Tissue reaction diameter grading

Inflammatory reaction diameter	*Grade*
0.01–0.25	1
0.26–0.35	2
0.36–0.50	3
0.51–1	4
1.1–2.0	5
2.1–3.0	6
3.1–4.0	7
Over 4.1	8

Table 2 Cellularity grading

Cells per immersion field	*Grade*
1–5	1
6–15	2
16–20	3
21–35	4
36–50	5
51–100	6
101–150	7
Over 150	8

Table 3 Histologic parameters and weighting factors

Cell type	*Weighting factor*
Diameter of inflammatory reaction	5
Neutrophils	6
Eosinophils	2
Lymphocytes	2
Giant cells	2
Fibroblasts	1
Histiocytes	1
Overall cell density	3

cellular response.[8] We preferred this method to others previously described[9–11] because it is still the most complete and accurate despite being dated (1955).

The protocol we used is described below:

1. With an ocular micrometer the size of the inflammatory response around the suture thread was evaluated, in order to provide measure of the relative tissue irritation. The inflammatory reaction diameter was determined by measuring the distance from the edge of the suture thread to the neovascularisation 'vallum'. The average measurement for each thread was calculated. These diameters were assigned a grade from 1 to 8 (Table 1).
2. The predominant cell type involved in the inflammatory response as recognised by light microscopy was considered for each tissue specimen. The average count per immersion field was determined for each type (neutrophil, eosinophil, histiocyte, giant cell, lymphocyte, fibroblast). Ten fields of observation were considered and the average of the values obtained was then calculated for each cell type. A grade from 1 to 8 was assigned based on the average number of cells per field for each material (Table 2).
3. The total cell density was evaluated in 10 fields of observation around the suture with a high

Table 4 Tissue reaction rating

Score (S)	*Tissue reaction*
0–16	Very slight
17–32	Slight
33–48	Slight to moderate
49–64	Moderate
65–80	Moderate to marked
81–96	Marked
97–112	Marked to extensive
Over 113	Extensive

Table 5 Clinical evaluation

	Polydioxanone	*Poliglecaprone 25*	*Glycomer 631*
Absence of memory effect	2.25	4.5	4.4
Flexibility	2.5	4.25	4.25
Gliding capacity	4.75	4	4.25
Knotting ability	4	5	4.5
Knot hold	4	4.75	3.75

Table 6 Tissue reaction to Polydioxanone

	Inflammatory reaction diameter	*Cell density*	*Cell type*						
			H	*F*	*L*	*GC*	*N*	*E*	*Total*
15 days	10	13	4	4	4	2	6	2	45
1 month	5	11	5	2	4	2	6	2	37
3 months	5	9	4	2	2	0	6	0	28
6 months	5	9	1	1	4	0	0	0	20

H = Histiocytes; F = Fibroblasts; L = Lymphocytes; GC = Giant cells; N = Neutrophils; E = Eosinophils.

Table 7 Tissue reaction to Poliglecaprone 25

	Inflammatory reaction diameter	*Cell density*	*Cell type*						
			H	*F*	*L*	*GC*	*N*	*E*	*Total*
15 days	5	9	5	3	2	2	0	2	28
1 month	5	3	4	2	4	2	–	–	20
3 months	0	4	1	1	2	0	0	0	8
6 months	0	3	1	1	0	0	0	0	5

H = Histiocytes; F = Fibroblasts; L = Lymphocytes; GC = Giant cells; N = Neutrophils; E = Eosinophils.

magnification lens (430×) and average values ascribed a grade from 1 to 8.

The inflammatory reaction diameter, the various cell types and the total cell density were then given a weighting factor (Table 3).[8]

These factors were multiplied by the grades assigned to each parameter. The values obtained were added up, giving a final score (S) indicating the tissue reaction relative to each suture. Relative ratings were assigned to the reaction scores (S) within the limits reported in Table 4.

Suture absorption was assessed by a direct measurement of the cross-sectional diameter (in mm) of the suture material present in the tissue samples.

Results

Clinical evaluation

At the time of the original surgery, Poliglecaprone 25 and Glycomer 631 proved to be the suture threads with optimum flexibility.

Polydioxanone retained more packaging memory than the other two monofilaments; this material did however show an optimum capacity to pass through tissue.

Poliglecaprone 25 had a better knotting ability and a higher knot hold than the other two materials.

The average results of the surgical evaluation are given in Table 5.

During the clinical follow-up no major complications were observed in any animal. In no case were abscess formations or any fluid collections detected in the wound. All rats survived up to the time of biopsy.

Histologic evaluation

For Polydioxanone: at 15 days and 1 month from execution of the suture there was a slight to moderate tissue reaction (S = 45 and S = 37 respectively), while at 3 months and 6 months the tissue reaction was slight (S = 28, S = 20) (Table 6).

For Poliglecaprone 25: there was a slight tissue reaction at 15 days and 1 month from execution of the suture (S = 28, S = 20) and it was very slight at 3 months and 6 months (S = 8, S = 5) (Table 7).

For Glycomer 631: there was a slight to moderate tissue reaction at 15 days and 1 month from execution of the suture (S = 36, S = 34), slight at 3 months (S = 20) and very slight at 6 months (S = 7) (Table 8).

Tissue reaction to the three materials over time is shown in Figure 4.

Table 8 Tissue reaction to Glycomer 631

	Inflammatory reaction diameter	*Cell density*	*Cell type*						
			H	*F*	*L*	*GC*	*N*	*E*	*Total*
15 days	5	11	4	2	4	2	6	2	36
1 month	5	12	3	2	2	2	6	2	34
3 months	5	9	2	2	2	0	0	0	20
6 months	0	3	1	3	0	0	0	0	7

H = Histiocytes; F = Fibroblasts; L = Lymphocytes; GC = Giant cells; N = Neutrophils; E = Eosinophils.

Table 9 Quantitative evaluation of absorption (thread diameters in mm)

	Thread diameter Polydioxanone	*Thread diameter Poliglecaprone 25*	*Thread diameter Glycomer 631*
15 days	0.16	0.2	0.18
1 month	0.15	0.13	0.17
3 months	0.14	–	0.08
6 months	0.02	–	–

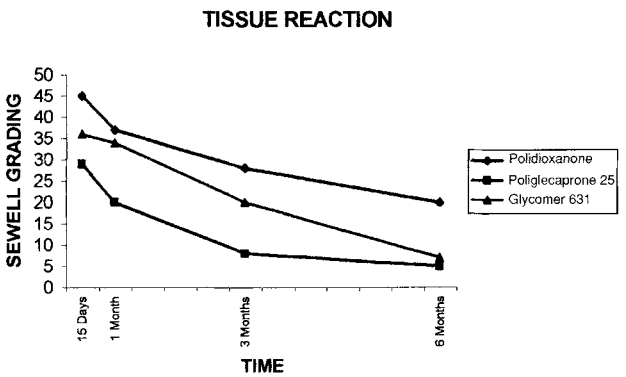

Figure 4—Tissue reaction/time correlation.

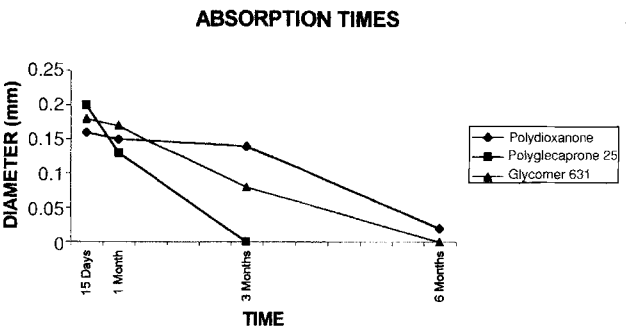

Figure 5—Absorption/time correlation.

The quantitative examination of the suture material present in the biopsies revealed: complete absorption of Poliglecaprone 25 at 3 months from execution of the suture; presence of traces of Glycomer 631 at 3 months, while at 6 months this material was completely absorbed; presence of traces of Polydioxanone in the 6-month histologic preparations (Table 9).

Absorption of the three materials over time is shown in Figure 5.

Discussion

Clinical examination of the scars from all experimental groups showed a linear course and absence of irregularity at any point. It can be concluded that all three suture materials gave highly satisfactory results.

Polydioxanone proved to have little flexibility and ease of handling in keeping with previously published data.[12] This material however showed the best glide through the tissues. Poliglecaprone 25 showed a high flexibility and low memory effect which influenced its knotting ability. These characteristics agree with previously reported experiences.[1,2,4] Glycomer 631 showed physical characteristics similar to those of Poliglecaprone 25; in particular, the capacity to pass through tissue was a little greater, while the knot hold was slightly inferior.

The results of the histologic examination of the samples allow the following conclusions to be made: the three sutures showed optimum biocompatibility, giving extremely low tissue reaction values. Poliglecaprone 25 presented a consistently lower tissue reaction than the other two materials examined. The biopsies carried out at 1 month from execution of the suture showed, in the samples for Poliglecaprone 25, a near total absence of acute inflammatory reaction cells, although these were present in the Polydioxanone and Glycomer 631 samples. In the biopsies for Poliglecaprone 25, the presence of chronic inflammatory reaction cells was low by as early as 3 months. This can be probably attributed to the complete absorption of the material in that time. Glycomer 631 causes greater fibrous reaction than Poliglecaprone 25 at both 3 months and 6 months.

From the data on material absorption, it emerged that Polydioxanone presented a slow absorption in the first 3 months and more accelerated thereafter. At 6 months there were still traces of the material in the tissues.

Poliglecaprone 25 showed a faster absorption rate, being absent in the biopsy at 3 months. This aspect differs from the previously published data according to which this material is completely absorbed in vivo between the 90th and 120th day.[1,2]

Glycomer 631 was completely absorbed 6 months post-implantation.

The data obtained from this study correspond with the modality of absorption and biocompatibility of the three absorbable monofilament sutures examined. The relevance of these findings in rats is debatable. Since the metabolic rate and body temperature are higher in the rat than in the human, Sewell stated that the rate of absorption and the tissue reaction would be smaller in the human than in the rat.[8] This is the reason that rat models have been widely used in the experimental testing of new synthetic surgical materials.[1,8,12,13] Experimental comparative evaluation of the tensile strength of single strands of suture, in the same animal population, should surely add valuable information.

All three materials were deemed to be suitable for use as intracuticular sutures, both running or buried vertical interrupted. The clinical relevance of this study is in helping surgeons to select the appropriate suture material for use in different anatomical regions and particular surgical applications. We would not recommend the use of Polydioxanone as an intracuticular suture on the face because of the high absorption time; the other two materials have the potential capacity to be well tolerated and early dissolved.

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