CHAPTER 2

THE NEED FOR A MONOFILAMENT ABSORBABLE SUTURE

During the last two decades, the use of synthetic absorbable sutures has gained wide acceptance by the surgical community. At present, two braided materials are available; these are Polyglactin 910 ('Vicryl') and Poly(glycolic acid) ('Dexon') sutures. These polyester sutures degrade by simple hydrolysis and are absorbed by the body with minimal tissue reaction. Their biological behavior in terms of breaking strength retention, tissue reaction and absorption is more uniform and predictable than natural, collagen-based absorbable surgical gut sutures.

Because of the inherent rigidity of the polymers, monofilament sutures produced from 'Dexon' and 'Vicryl' are too stiff for general surgical use. These polymers can be used as monofilament sutures only in the very finest sizes. Their surgical usefulness as monofilaments is primarily in opthalmic and microsurgical procedures.

2.1 The Rationale for a Synthethic, Monofilament, Absorbable Suture

2.1.1 Synthetic Materials

A synthetic material produces a suture which is consistent and predictable in its properties and performance. This is in contrast to a suture manufactured from a naturally occurring material like catgut.

A synthetic suture has consistent

- tensile strength
- 'in vivo' profile (tensile strength retention and absorption)
- handling characteristics and
- suture diameter

The precise specification of a synthetic suture allows a predictable period of support during wound healing.

2.1.2 Monofilament Sutures

A monofilament suture has definite advantages when compared with a multifilament:

- reduced risk of infection
- decreased tissue drag
- more likely to produce leak-proof anastomoses (e.g. in the biliary or urinary tract)

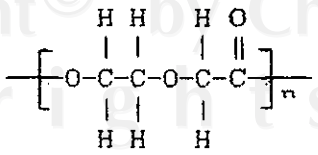
2.1.3 Absorbable Sutures

An absorbable synthetic suture has less tissue reaction than a non-absorbable suture because:

- it is biodegradable and thus evokes less local reaction
- an absorbable suture reduces the foreign body effect in the tissue, thus making it a more biocompatible material

2.2 Polydioxanone 'PDS' Sutures

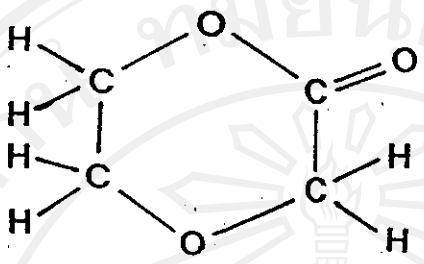
An extensive research program led to the discovery in 1978 of a novel polymer which could be converted into a uniquely flexible monofilament suture of all sizes. It is known as polydioxanone ('PDS') suture. Recently, 'PDS II' has appeared on the market as an improved version of 'PDS'. It is apparently still the same polymer, polydioxanone, made by the same company, Ethicon, but with slightly improved flexibility. The reasons for this improvement remain undisclosed. Polydioxanone has the chemical structure:



poly-p-dioxanone

('PDS' or 'PDS II')

It is prepared by polymerizing the monomer, para-dioxanone, in the presence of a suitable catalyst:



para-dioxanone

Polydioxanone is a colorless, crystalline polymer. As a suture material, it is usually violet-colored by adding Drug and Cosmetic Violet No. 2 dye.

The polymer, either dyed or natural, is processed into small granules, dried and melt-extruded through appropriate dies into monofilaments of any desired suture size. The extruded fibers are oriented and heat-treated to obtain optimum physical and biological properties. In the dyed sutures, the dye is uniformly distributed. The visual appearance of the undyed suture is clear and shiny.

After cutting the strands to the required lengths, needles are attached. The sutures are then wound, put into folders and placed in aluminium foil-laminated packages. The sutures are sterilized with ethylene oxide, are thoroughly degassed, and finally sealed in a dry atmosphere. The physical properties of a typical size 2-0 polydioxanone monofilament are summarized in Table 2.1.

Table 2.1: Properties of polydioxanone ('PDS') monofilament suture, size 2-0 [5].

Physical Properties	Value
Diameter	13 mils
Straight tensile strength	80,000 p.s.i.
Knot-pull strength	50,000 p.s.i.
Elongation to break *	30 per cent
Young's Modulus #	250,000 p.s.i.

* Percent increase in suture length at breaking point.

\# A measure of filament flexibility or pliability derived from stress-strain characteristics; inversely proportional to flexibility.

p.s.i. = pounds per square inch

Young's Modulus is a measure of flexibility; the lower the number, the greater the flexibility. Monofilament 'Dexon' and 'Vicryl' sutures have a Young's Modulus in excess of 1 million pounds per square inch, compared with 250 thousand pounds per square inch for monofilament 'PDS'. This desirable flexibility is achieved by incorporating an ether oxygen linkage into the backbone structure of the polymer [5].

Like 'Dexon' and 'Vicryl' sutures, 'PDS' is also a polyester which degrades by simple hydrolysis in the body. In contrast, surgical gut degrades in the body as a result of enzymatic processes. The 'in vivo' performance of 'PDS' monofilament sutures, as determined by breaking strength retention, absorption and tissue reaction studies, has been described [12]. These parameters, as well as relevant 'in vitro' data, are considered to be the most important to surgical performance.

Breaking Strength Retention

A suture must maintain sufficient strength to ensure adequate apposition of tissues until the wound can withstand stress without mechanical support. The initial strength of the suture should be equal to, or greater than, the normal tissue through which it passes. Further, the reduction of suture strength during the healing period should be no more than proportional to the gain in wound strength. The breaking strength retention of the suture is commonly evaluated by implanting the suture in laboratory animals, usually subcutaneously. At various periods of 'in vivo' residence, the suture strands are recovered, and their breaking strength is determined using an appropriate tensometer. It is important to note that the reduction of breaking strength and absorption 'in vivo' are separate phenomena. In all patients, absorbable sutures lose their strength before being completely absorbed.

A comparison of the 'in vivo' (rat) breaking strength retention of 'PDS' and the two multifilaments, 'Dexon' and 'Vicryl', is shown in Fig. 2.1.

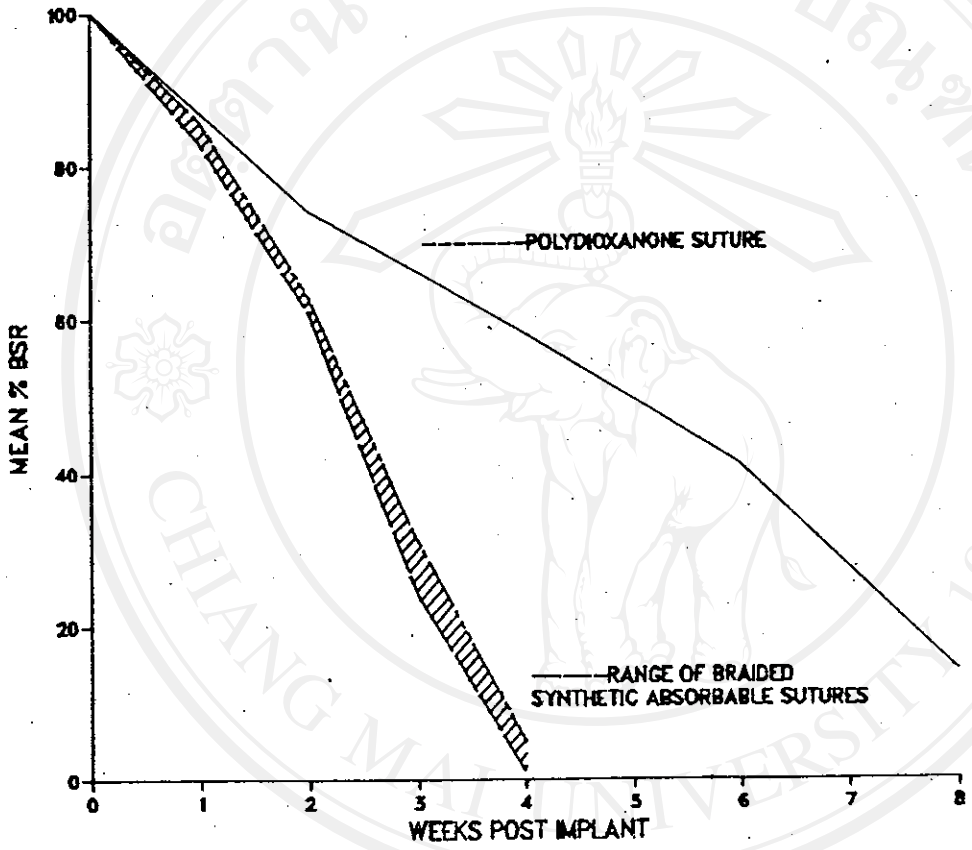


Fig. 2.1 : Average breaking strength retention, BSR, of monofilament polydioxanone ('PDS') suture following implantation in the subcutis of rats compared with the range of similarly derived data for multifilament ('Dexon' and 'Vicryl') sutures. Data expressed as average percentage of original, unimplanted strength [15].

Absorption

The term "absorbable suture" implies that absorption (eventual disappearance of the suture from the site of implantation) will take place, thereby limiting the duration of the tissue response. Absorption of synthetic absorbable sutures occurs following hydrolytic breakdown of the polymer chain and resultant molecular weight reduction. This proceeds in a regular and predictable manner in tissue. Like breaking strength, the rate of absorption is assessed following implantation, often intramuscularly, of suture strands in laboratory animals. It is judged by weight reduction, by recovery of radiolabel from labeled suture or, commonly, by histologic assessment. An example of the type of data which can be obtained is shown in Fig. 2.2 for the 'in vivo' (rat) absorption of 'PDS'.

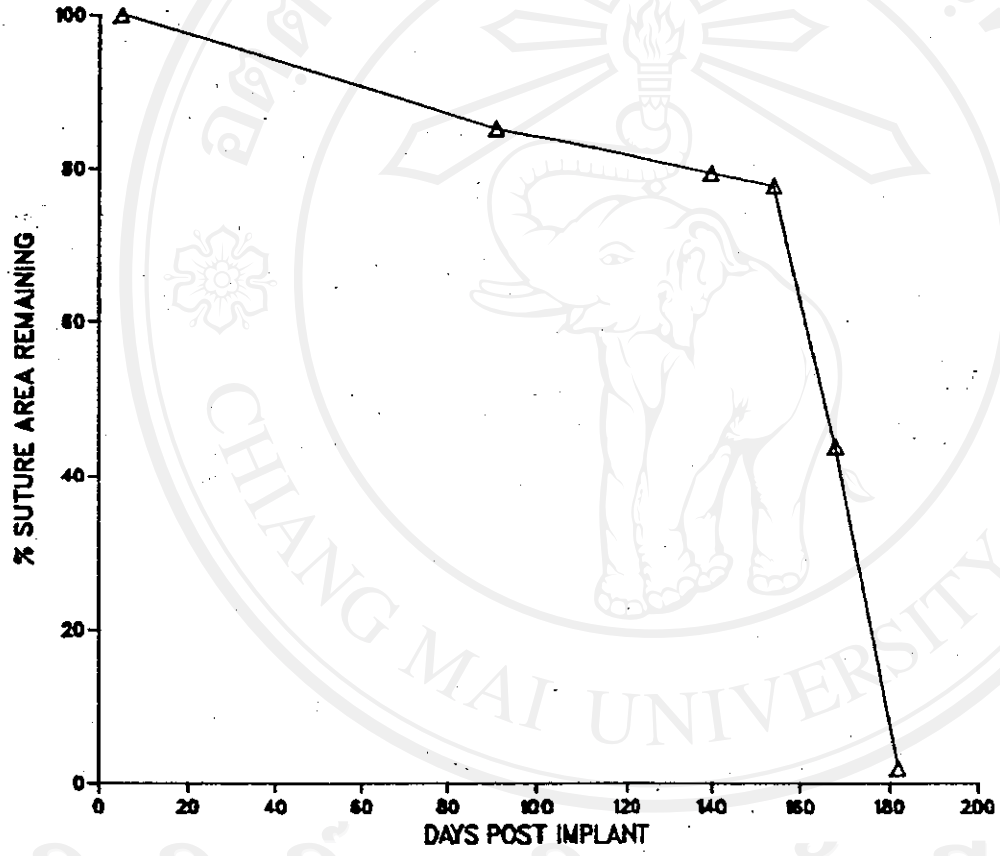


Fig. 2.2: Absorption of monofilament polydioxanone ('PDS') suture as a function of time 'in vivo' (rat), expressed as average percentage of suture area remaining [5].

Tissue Reaction

Absorbable sutures are replaced by healthy tissue during the healing period. In general, the tissue response to synthetic absorbable sutures is foreign body in nature. Further, the inflammatory response has been reported by Blomstedt [13] to be less pronounced around suture materials with low capillarity, for example, monofilament sutures, than around those with higher capillarity such as braided multifilaments.

'PDS' synthetic absorbable monofilament suture has been formulated to provide wound support through an extended healing period as well as to minimize the variability of breaking strength retention and absorption and to invoke minimal tissue reaction. These features are particularly beneficial in critical applications such as those involving slowly healing tissues.

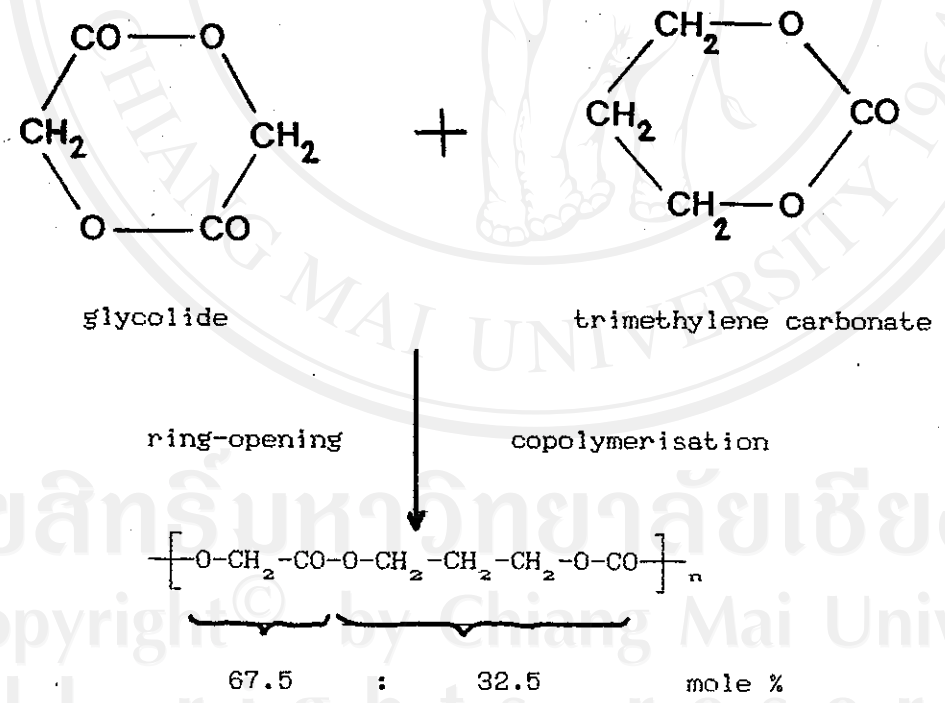
2.3 Polyglyconate ('Maxon') Sutures

'Maxon' (polyglyconate) is a recently developed synthetic, monofilament, absorbable suture. It is a copolymer of glycolide and trimethylene carbonate which is usually absorbed over a period of about six months.

Chemical Properties

The chemical composition of 'Maxon' determines its physical characteristics and the nature of the biological interaction which takes place 'in vivo'. This in turn determines the efficacy, safety and biocompatibility of the suture in the clinical situation.

'Maxon' is derived from the simple organic substance glycolic acid, naturally occurring in animal and some plant tissues, and trimethylene carbonate. The two constituents are combined in the ratio of approximately 2:1 in a random copolymer type structure, as shown below:



poly(glycolic acid-co-trimethylene carbonate)

('Maxon')

Physical Properties

The physical properties of the suture material determine its performance during the various stages of wound healing and its handling characteristics during the operative procedure.

The parameters commonly used to assess these physical properties are strength (straight pull tensile strength, knot pull tensile strength), knot security, loop capacity and handling.

Biological Properties

The interaction of a suture with the tissues in which it is used is an important feature of wound healing. This interaction consists of both the effect of the suture on the tissues (local and systemic) and conversely that of the tissues on the suture.

(1) Tissue Reaction

The process of absorption is by non-enzymatic hydrolysis. The end-products of breakdown are carbon dioxide, β-hydroxybutyric acid and glycolic acid which are excreted in the urine.

The effect of 'Maxon' on tissue can be local or systemic.

Local - Being a synthetic non-protein-containing material which is absorbed by non-enzymatic hydrolysis, 'Maxon' evokes very little tissue reaction unlike natuarally occurring materials such as catgut.

Systemic - 'Maxon' has been extensively studied in animal laboratories for any evidence of systemic effects. It has been shown that is not antigenic, pyrogenic, or carcinogenic.

(2) Period of Absorption

Absorption of 'Maxon' sutures is essentially complete in tissue, as shown by 'in vivo' animal studies, after between 26 and 30 weeks. An 'in vivo' absorption profile is shown in Fig. 2.3.

(3) Tensile Strength Retention

'Maxon' gradually loses its tensile strength over a period of about eight weeks. It retains more than 70 % at two weeks, and more than 55 % at three weeks. A comparison of the 'in vivo' (rat) tensile strength profiles of 'Maxon', a synthetic monofilament, and catgut, a naturally occurring monofilament, is shown in Fig. 2.4.

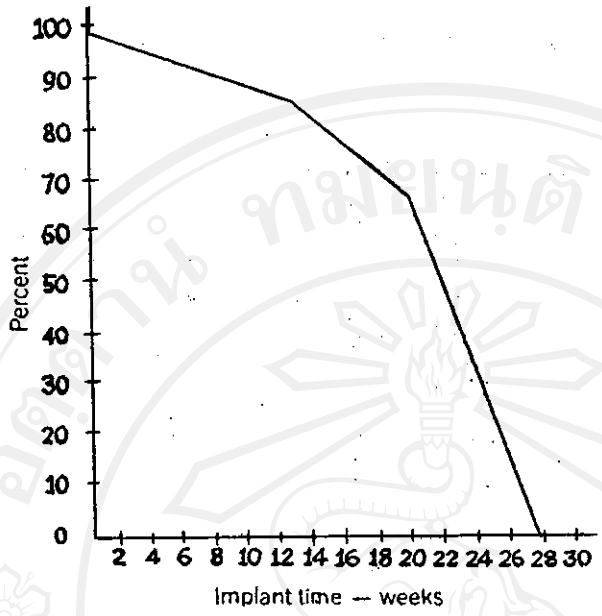


Fig. 2.3: 'In vivo' absorption profile of 'Maxon' (size 2-0) in animals [14].

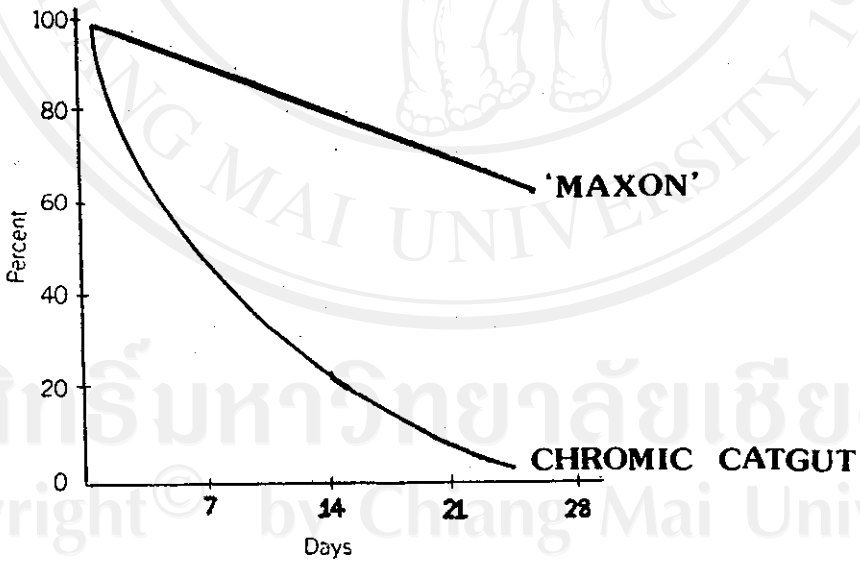


Fig. 2.4: 'In vivo' (rat) tensile strength profile of 'Maxon' compared with chromic catgut [14].