RESORBABLE LACTIDE BASED POLYMERS

History

Lactide-based polymers are the most commonly used polymers in resorbable medical device manufacturing. They include synthetic polyesters such as polylactide and copolymers with glycolide and ε-caprolactone.

Commercially available products based on lactide- and glycolide-based polymers have been on the market for more than 40 years. The technology was originally introduced in wound closure products as resorbable surgical sutures and was first introduced for use in orthopedic implants in the 1980s. They have an established track record of safe and effective use in numerous applications including wound closure, orthopedic treatments, controlled drug-delivery systems, and vascular closure devices with a proven in vivo biocompatibility and biological safety.

FIGURE 1: Interference/ACL-screw

Numerous products have been developed and commercialized for a range of orthopedic applications since the 1980s, including within sports medicine, trauma, and spinal implants. Currently available resorbable devices for orthopedic applications amongst others include implants for soft tissue fixation (ACL interference screws as for example in figure 1, suture anchors, tacks), for

bone fracture fixation (plates, screws, pins) as well as bone graft implants.

Function

The objective of placing a resorbable implant is to temporarily fulfill the functionality of the defective tissue. During the healing phase, the tissue restores its initial functionality while the functionality of the implant gradually decreases. The strength of the device and its degradation must be coordinated precisely with the healing process. The implant needs to retain its strength for the minimum required length of the healing process. The degradation time of the implant must be finely adapted to the tissue type and the individual clinical application.

Tunable properties, such as mechanical strength and degradation time, make lactide-based polymers remarkably versatile in these applications. However, an in-depth knowledge of their structure, properties, and the process of their degradation in vivo is required to select the best suited material for the specific clinical use.

Main advantages are:

- No secondary surgery required.
- No image-interference with MRI/CT.
- Eventually no foreign body material left.

FIGURE 2: Resorbable polymer granulate

Properties

Degradation of the polymers is based on hydrolysis. Within the body, the implant first absorbs water from the surrounding tissue. This process allows the polymers to gradually break down into smaller fragments, which are consequently broken down into lactic acid and eventually released from the body via the Krebs cycle.

The rate at which the polymers degrade is related to their hydrophilicity, the more hydrophilic, the quicker it will degrade. For example, polyglycolide degrades faster compared to polylactide.

Another factor that influences the rate of degradation is the molecular weight of the original polymer: the longer the chain length, the more time it takes to degrade.

Finally, the crystallinity of the polymer influences the degradation rate. Semi-crystalline polymers (such as poly(L-lactide)) degrade more slowly than amorphous polymers. Semi-crystalline polymers are preferred for the manufacture of a device that must fulfill a mechanical property, whereas amorphous polymers allow faster degradation and are the polymer of choice for drug-release systems.

The mechanical properties of lactide-based polymers, such as the strength of an implant and the degradation properties, can be modified by using various monomer building blocks. A range of polymers, from rigid to very flexible are commercially available, and some examples of properties are provided in table 1.

PURASORB grade	T_g (°C)	T_m (°C)	E (GPa)	σ_m (MPa)	ε_{-break} (%)	Degradation* (months)
PL 38	60	180 - 190	3.1 - 3.7	65	2 - 6	> 24
PDL 20	55	-	3.1 - 3.7	50	2 - 6	12 - 16
PG 20	40	215 - 225	6.5 - 7.0	100	1 - 2	6 - 12
PC 12	-60	55 - 65	0.2 - 0.3	30	> 300	> 24
PLC 7015	20	105 - 115	0.02 - 0.04	3	> 300	12 - 24
PLG 8531	60	140 - 150	3.3 - 3.5	65	2 - 6	12 - 18

TABLE 1 : Properties of selected PURASORB polymers

** Time to complete mass loss. This depends a/o on processing method, device geometry and implantation site.*

Processing & testing

The composition of the resorbable polymer plays a vital role in the performance of the finished device. However, additional factors are of equal importance like processing and manufacturing methods including sterilization, device design, and the site of implantation. These factors are interconnected in developing and controlling the performance of a resorbable device.

Typical processing methods are injection or compression molding and extrusion. All melt processing methods should be performed under a strict quality regime with special care for the moisture content of the polymer in order to minimize hydrolytic degradation.

End products can be tested and analyzed according to various procedures. In vitro degradation test methods are described in ASTM F1635, whereas a standard specification and test methods for bioresorbable plates and screws used in internal fixation implants are described in ASTM F2502.

Partner

For over 35 years Purac Biomaterials has developed, manufactured and marketed lactide based polymers with large scale technology under the PURASORB brand name. Purasorb polymers supplied for orthopedic applications comply with ASTM F1925. Purac Biomaterials facilitates successful development of resorbable devices with its polymer expertise through interaction with product designers and manufacturers as well as end users. It offers off-the-shelf polymers of various types of lactide based resorbable polymers as well as custom-made compositions and contract manufacturing.

www.puracbiomaterials.com

purac
pure by nature