New structures for resorbable polymers

New meltblown processes have been developed successfully and demonstrate the ability to produce narrow webs made from standard resorbable polymers suitable for a wide range of biomedical applications, especially implantable devices. The plant, designed and built by FET, have the correct scale and output rates for products made from special bioresorbable polymers. Both the manufacturers of these biomedical products and the suppliers of resorbable polymers are interested in these developments.

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Nonwovens can be readily made from resorbable polymers following a new development by FET. The new processing technology is an adaptation of the meltblowing process and makes it possible to convert existing medical grade, resorbable polymers into nonwovens in a single processing stage. The new process is versatile and capable of producing nonwoven structures with a very wide range of properties. The high porosity and high internal surface area of these materials gives properties that are of potential benefit to the clinical repair of defective tissues. In particular they could be used to provide the following functions:

- scaffold for cell migration and growth
- temporary mechanical support or separation
- delivery of bioactives.

Combinations of the nonwovens with other materials such as knits or films can provide additional functionality and enhanced mechanical properties. Possible areas of application include wound care, adhesion barriers, staple line reinforcement, hernia repair, orthopedics including ligament and tendon repair, plus repair of other soft tissues.
Suitable polymers are those used already for medical resorbable sutures such as PGA, PLA and their copolymers. But these have been hitherto difficult to process using the standard meltblown process because of their high molecular weight and low melt mass flow rate (MFR).
New developments in the design and manufacture of meltblowing equipment by FET have enabled a single stage process from polymer to web to be used successfully to manufacture webs with a wide range of structures and properties from standard resorbable polymers.

Research and development

An intensive R&D project was embarked to develop a method of producing nonwovens, especially targeted at processing resorbable polymers such as those used in sutures. The objective was to produce a new range of materials for use in medical devices.
For the initial stages of the project an earlier meltblowing line was re-engineered and processing trials carried out with PGA. Once the key design principals had been established, a purpose made pilot line was designed and built (Fig. 1).
After further refinement of the equipment and processing conditions, the range of materials was extended to include all the common resorbable polymers such as PGA, PLA and their copolymers to be processed. These medical grade polymers are of high value and efficient procurement would be assisted if existing grades could be used, hence avoiding the need to specify a special grades of polymer solely for the meltblown process. The work was therefore concentrated on polymers with MFR in the range 3.4–16.0 g/10 min (PGA). This is in contrast with the special grades with higher flow rates and therefore lower viscosities offered by some polymer suppliers for the meltblown process. The work was successfully concluded and the result is a very versatile process from which a wide range of structures and properties can be achieved from materials that are not considered conventionally to be suitable for meltblowing.

Meltblowing process

Meltblowing is a process for producing fibrous webs or articles directly from polymers or resins using high velocity air to attenuate the filaments [1].
The meltblowing process is shown schematically in Fig. 2. The polymer melt is delivered to a linear spinneret and extruded through an array of fine holes. The emerging filaments are carried away immediately by the hot, high speed, primary airflow. This airflow quickly becomes turbulent, stretching and fragmenting the filaments. Cooler, secondary air is drawn in to the airstream and the filaments are partially quenched by the time

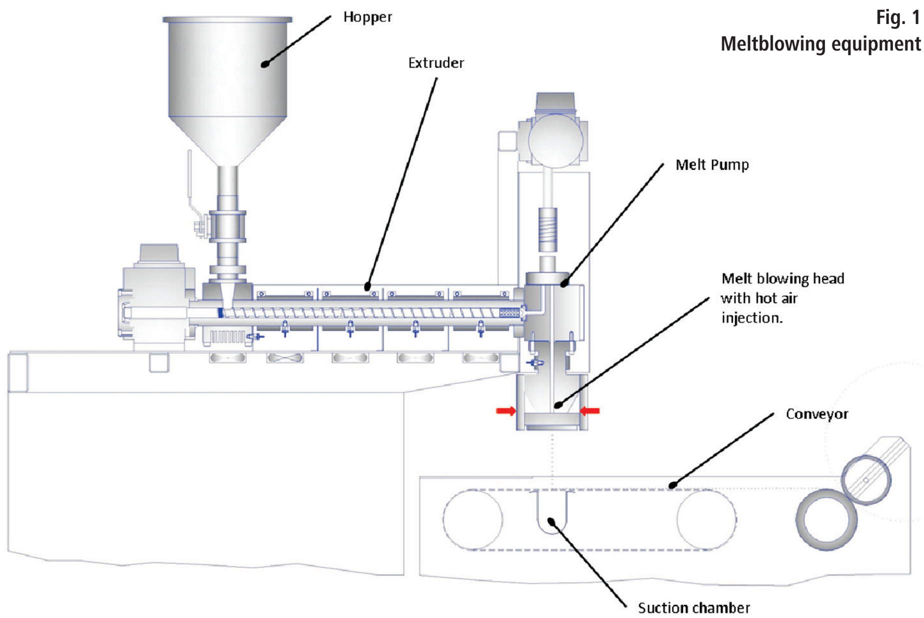

Fig. 1
Meltblowing equipment

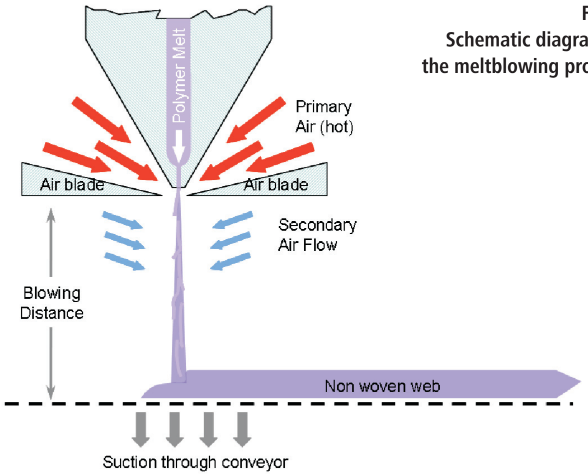

Fig. 2
Schematic diagram of the meltblowing process

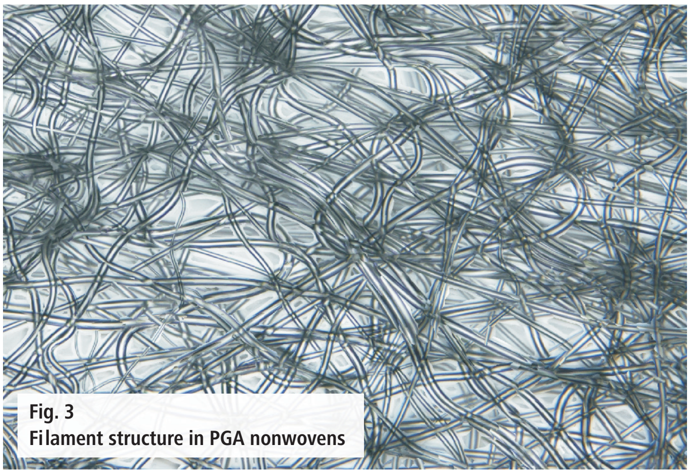

Fig. 3
Filament structure in PGA nonwovens

they land on the conveyor forming a continuous web. The filaments intermingle and fuse to each other to give the web integrity. Downstream processing such as calendaring, point bonding or laminating can be used to further develop the material properties. The random structure of resorbable nonwovens is shown in Fig. 3.
The meltblowing process is much younger than the spunbonding process and the achievement of uniform drawing and the minimizing of waste at the edges of the web are still issues today. FET has shown that correct design and control of the air flow can significantly reduce edge wastage. However, when considering the production of comparatively narrow fibrous webs from high value polymers, the reduction of polymer waste especially at the start and end of the production run is much more important.

Properties and applications

The range of resorbable polymers includes PGA, PLA and copolymers PLLA and PGLA. These polymers are made from lactides (lactic acid) and glycolides (glycolic acid). These ingredients are made from natural materials such as starch and glucose. Provided care is taken during their manufacture, these materials are not rejected by the human body – on the contrary they are absorbed as a result of hydrolysis. The time taken for this absorption to occur depends upon many factors including: the initial molecular weight of the polymer and the inevitable losses during processing, conversion and sterilization. An advantage of the meltblowing process is that it produces the nonwoven direct from the polymer granules in a single operation. This minimizes opportunity for the materials to degrade during manufacture and is in stark contrast to other nonwoven processes such as needle felt where many more processing steps are required to achieve the same result.
The processing of these resorbable polymers shows similarities to that for polyester although at lower temperatures. Polymers have to be dried before melting and the resulting textile materials have to be kept cool and above all dry to minimize degradation before use. Sterilization is a further process stage before use in or near the human body.
Narrow webs made from these resorbable polymers can be produced typically with properties within the ranges shown in the table below. Within these ranges, it is possible to select materials that are appropriate for the applications listed in the introduction.

Property	Lower end of range	Higher end of range
Filament size [μ]	2	30
Density [mg/ml]	20	250
Web thickness [mm]	0.2	10

The distribution filament sizes in meltblown nonwovens can be controlled by selection of processing conditions. Filament diameters can be as fine as 2 microns, which for PGA is equivalent to 0.04 denier. A selection of typical filament size distributions are shown in Fig. 4.

New materials are being discovered and developed all the time with outstanding abilities to improve medical care both during surgery and in cases where after care is even more important.

FET Profile

FET is a good solution for the plant required to produce webs made from available resorbable polymers using the meltblown process. The in-house pilot R&D facilities reduce the cost of misplaced investment and these facilities enable the customer to ensure that the available polymers can be spun to form a web with the target properties before the plant is purchased and the polymer supplier is contracted.
Much of the experience with resorbable polymers has been gained already while supplying both mono- and multifilament plants for making sutures. All such plants are custom-engineered to meet the requirements, both of the customer and the end-use application.

Reference

[1] Artul Dahiya et al., web.utk.edu., April 2004

Fig. 4
Examples of filament size distributions for melt blow webs