Uhmwpe Processing
Techniques and Problems

by Mark Allen

Ultra High Molecular Weight (Uhmwpe) is used in a lot of applications, but a very important use is in the orthopaedic field. In this paper all processing techniques for this material are examined and discussed.

The conception and development of polyethylene in its various forms is well documented, however the Ultra High Molecular Weight (Uhmwpe) species was not selected as a potential material for orthopaedic use until 1962. Charnley early comparisons with Ptfe displayed encouraging results that eventually led to the commercial implantation during 1962. The use of Uhmwpe for this application was because of the characteristic properties:

- low coefficient of friction;
- high wear resistance;
- good chemical resistance;
- resistance to environmental stress cracking;
- dimensional stability over a wide temperature range;
- high notched impact strength;
- high energy absorption at high stress rates.

Since the first successful use of polyethylene over 40 years ago the market growth has been phenomenal with in excess of 1.6 million joint replacement procedures performed each year, on average over 90% of the components will perform in excess of 10 years. This successful clinical performance has enabled the development of a multitude of designs incorporating combinations of Uhmwpe, metals and ceramics.

Ultra High Molecular Weight (Uhmwpe)

This simple supermolecular polymer consisting of mainly hydrogen and carbon molecules has an extremely complex structure, which undergoes complex transformations during processing. The molecular weight of materials used in orthopaedic applications is dependant upon the grade of material selected, however in most cases there are in excess of 400,000 carbon atoms on the molecular chain (this has been described as a piece of spaghetti 1 km in length). The orientation of these molecules into an ordered structure via segmental rotation and chain folding leads to the formation of crystalline lamellae which are embedded in areas or disorder known as the amorphous regions. The nature of the folded surface within a crystal has been the subject of controversy over the years, the following have both been proposed as likely models (Figure 1). The mass of crystalline lamellae within a semi-crystalline solid are commonly viewed as merely contiguous, however the interspherulitic boundaries are

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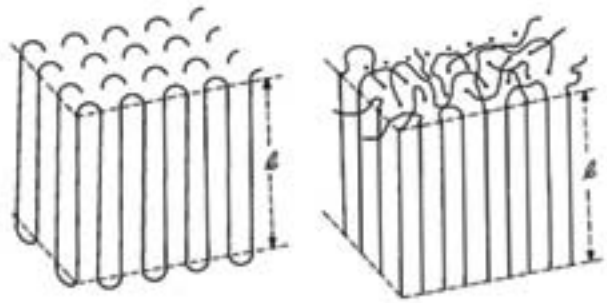

Figure 1 - Models of chain morphology in a single crystal

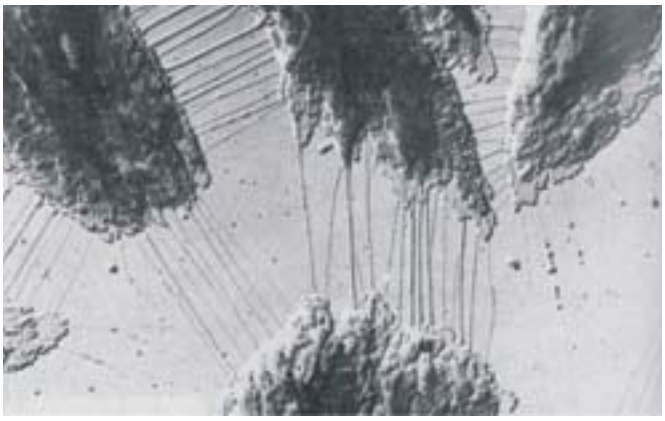

Figure 2 - Intercrystalline links between the lateral edges of the lamellae

held together by molecular ties embedded in neighbouring lamellae (Figure 2). The commercially available polymer is supplied in a powder form, the individual grain of Uhmwpe has a complex morphology where high orientation/crystallinity within the core (values as high as 80%) have been noted (Figure 3). Ticona (formally Hoechst) and Himont/Montell/Basel (1900H manufactured until recently and still in use) currently supply the powder form of Uhmwpe for medical applications, both suppliers offer a variety of grades with different molecular weights, all grades available conform to Iso 5834/1 and Astm F648. Within the context of the standard the following material properties are required.

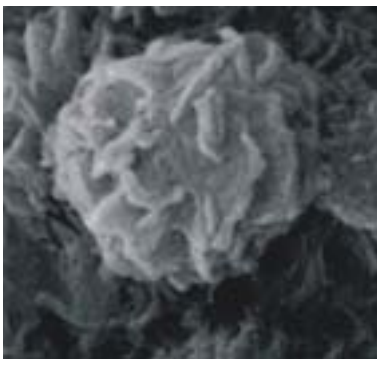

Figure 3 - Sem of typical Uhmwpe prior to consolidation

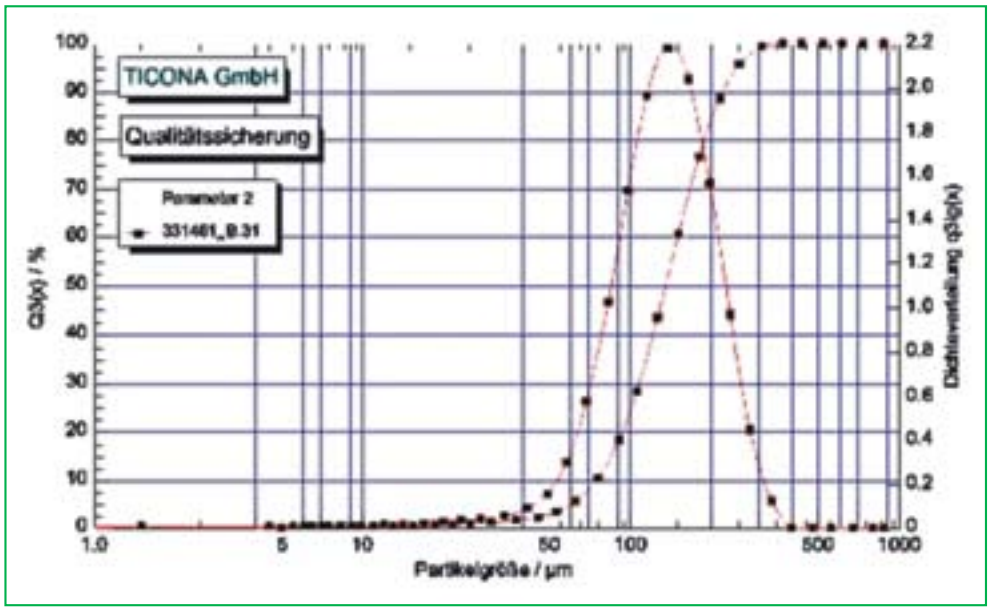

Figure 4 - Powder particle size distribution data

Elongational stress (Iso 11542-2)
and viscosity number (Iso 1628-3)

Both of these tests are an indication of the molecular weight distribution of the material.

Trace element analysis

Determines the level of trace elements within the polymerised material, this is an indication of polymerisation residues (i.e catalyst) and possible contamination which has a detrimental effect on the performance of the material.

Ash content

Quantitative determination of any contamination and residues still present in excess of 700 °C.

Particulate matter

Determination of the number of particulates present as visible defects. The powder form supplied is an irregular form with a specific particle size distribution in each case (Figure 4). The data currently available for the commercial Ticona grades indicate powder particle sizes ranging from 0-500 µm, with an average size in the region 135-150 µm (Figure 5). The original materials supplied by Ticona in the early orthopaedic implants contained levels of calcium stearate, this was primarily used as a process lubricant/release agent, however it was also believed to react with any catalyst residue present. The addition of calcium stearate was considered to have a detrimental effect on both fusion characteristics and oxidation of the polymer. Due to advances in the catalyst technology, the use of the controversial calcium stearate additive was stopped in the late 1990's by Ticona. The 1900H material never contained calcium stearate.

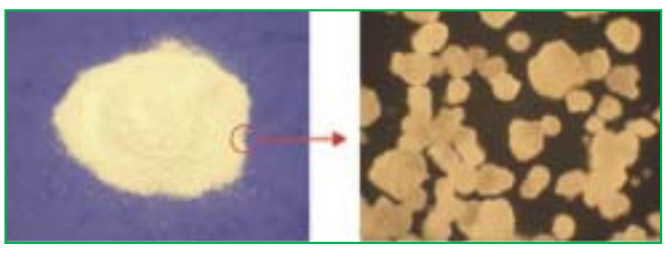

Figure 5

Polymer storage and transfer

Polymers from the major manufacturers are available in a variety of packaging from 25 kg sacks to 1,000 kg Octobins, the form supplied is dependent upon the processors handling capabilities. The transfer of the material from the supplied form to the process equipment is obviously a complex and critical operation. In the case of extrusion transfer would be to storage feed silo, however in the compression moulding the material is transferred directly to the mould. Control of the environment during this process is paramount in reducing the inclusion of contamination.

Processing

Due to the extremely high molecular weight of Uhmwpe affecting the melt viscosity to a point where conventional thermoplastic processing equipment cannot be used, the material must be consolidated using controlled pressure, temperature and time. The combination of these parameters allows the conformation change within the intergranular boundaries and reptation (De Gennes compared the model to a snake moving through grass). Previously we have considered the crystalline regions of the structure, however the amorphous region is best envisaged as a bowl of spaghetti, within this action of reptation on the movement of the chain within the three dimensional network contained within a hypothetical tube. This motion is characterised by a reptation time or more accurately relaxation time, which is a measure of the time required for the chain to escape (Figure 6). The theoretical models of relaxation show the dependence of the molecular diffusion/frictional coefficient on chain length, therefore overcoming the restraining influence of the entanglements within the grain boundaries extremely critical in the processing of Uhmwpe. Visualising these grain boundaries is undertaken using an optical microscope in accordance with Astm F648, however the grain boundaries present in consolidated material are very difficult to detect (Figure 7).

Extrusion

Conventional screw extrusion techniques cannot be used with Uhmwpe due to the high melt viscosity, during the 1970's in the United States a process called ram extrusion was devel-

oped. Although the early systems have been significantly modified to manufacture medical grade product, the fundamentals remain the same (Figure 8).

- virgin Uhmwpe powder is transferred to the extruder hopper from the storage silos;
- the extrusion equipment is commonly situated in a clean controlled environment;
- the hopper is mounted on the extrusion die and semi-continuously feeds the powder into the heated die chamber;
- the extrusion die consists of a heated die with a horizontal reciprocating ram at the rear, during the reverse ram cycle the powder is accepted into the die;
- the forward motion of the ram applies pressure to the Uhmwpe powder, which forces the material through the die section where temperature is applied;
- back pressure within the die is a direct result of the frictional forces of the molten resin against the heated die wall;
- the molten extrudate manufactured at very low production rates (mm/min.) is supported and cooled within the clean environment.

Using this technique Uhmwpe can be extruded up to 350 mm in diameter, however medical grade product is commercially manufactured up to 115 mm diameter.

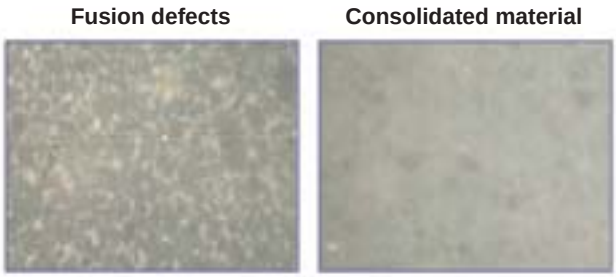

Figure 7

Compression moulding

This manufacturing technique originated in Germany in the 1950's, several manufacturers use derivatives of these early hydraulic presses to manufacture medical grade Uhmwpe product. The fundamentals apply to the compression moulding of Uhmwpe where the consolidation of the materials is a direct result of the heat, pressure and time combination used by the processors, this however is dependant upon the size of hydraulic presses/mould dimensions used (Figure 9). In some cases multi-daylight compression moulding equipment can be utilised to improve productivity:

- the equipment is commonly situated in a clean and controlled environment;
- virgin powder is loaded into the clean reciprocating mould used in the press;
- the mould is retracted into the press housing;
- once situated pressure is applied to the mould at a controlled rate;
- a temperature profile is applied to the mould using electric or fluid heated systems;
- the mould is opened and the compression moulded product removed from the mould, which is cleaned and the process repeated.

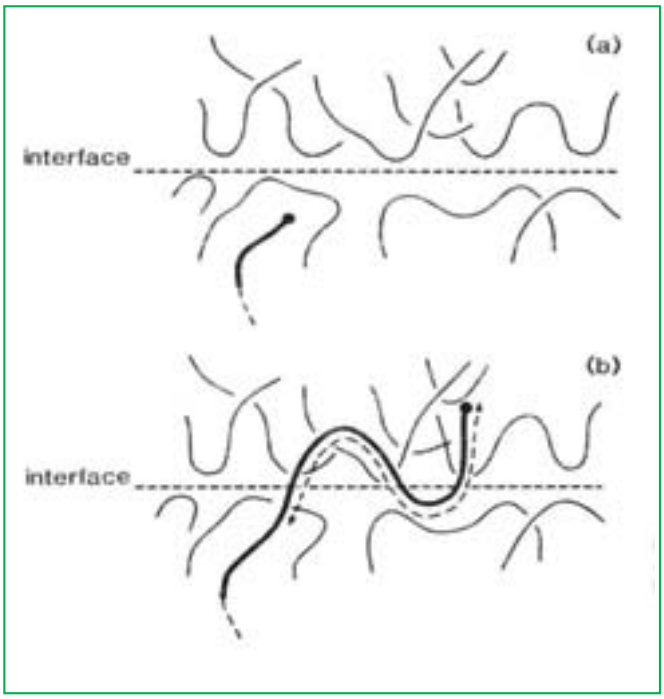

Figure 6

Direct compression moulding (Dcm)

Utilising a similar principle to the large-scale compression mould method, this uses a small-scale operation to mould the orthopaedic implant directly, thus enabling the manufacture of a component with a highly polished direct moulded surface therefore removing the machining surface definition present on conventionally machined products articulating surface.
By undertaking the compression moulding operation over a smaller projected area it was possible to attain greater control over the pressure and temperature cycles than simple bulk compression moulded, thus in theory improving the properties of the product although micro testing evaluation is only possible due to the sample size.

Annealing

During the manufacture of Uhmwpe product through any of the processes described above orientation of the molecules

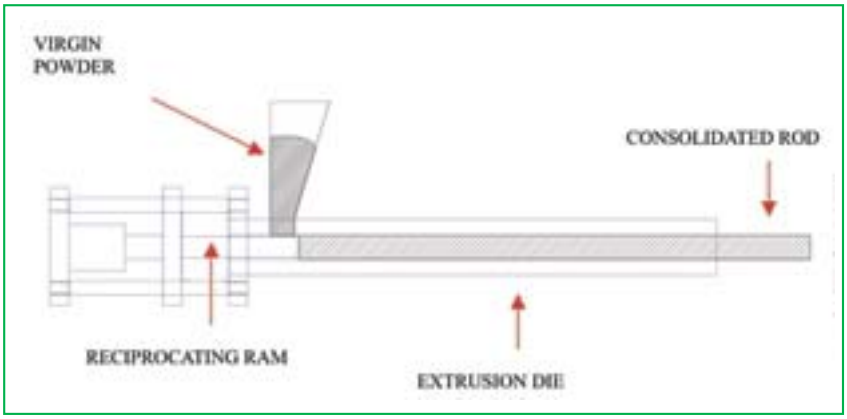

Figure 8

occurs. Often the temperature sensitive crystalline and amorphous regions develop morphological boundaries, at these boundaries the different physical characteristics develop complex stress distributions. Recovery of the associated strain (stretched spring) is only possible at elevated temperature were the load removed, therefore allowing molecular motion and recoiling of the molecules to occur which would otherwise be time dependant on creep. Consolidated product is heat treated in air circulating (fan assisted) ovens under controlled conditions, thus compensating for thermal dwell through the otherwise insulating layers of the product to the core region.

Physical/mechanical testing

In accordance with historical and existing standards and specification the following testing is completed on all medical grade polymer batches produced:

- Tensile Testing (Ultimate Tensile Strength/Elongation at Break/Yield)
- Izod Impact Testing
- Charpy Impact Testing
- Density
- Hardness
- Microscopy (Light Patch/Fusion Defects)
- Particle Count

Other tests include:

- Fourier Transform Infrared (Oxidation Index/Trans Vinyl Index)
- Swell Ratio
- Oxidative Ageing
- Deformation Under Load.

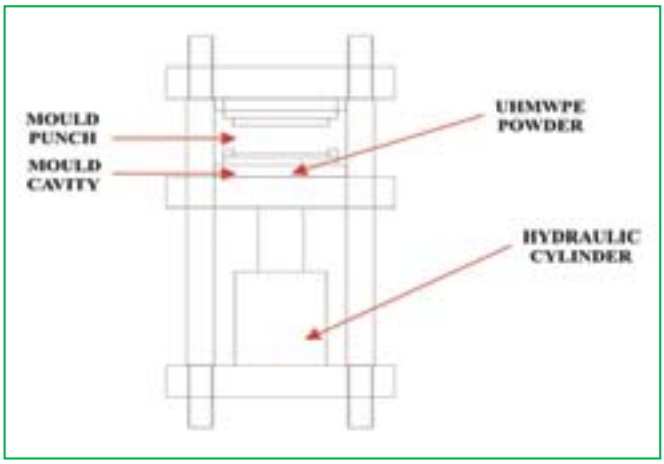

Figure 9 - Simple schematic of compression moulding process

Quality control

All processes used in the manufacture of medical grade products are validated with all data stored for a minimum of 30 years. Typical quality standards are also applied such as Iso 9001, Iso 13488 and Iso 14001. Full product trace-ability techniques are employed during the manufacture of all medical grade material. Visual inspection techniques are employed to determine the product quality along with non-destructive ultrasonic testing. Product batch testing is completed in accordance with Iso 5834-2, Astm F648 and Customer specifications. Certification of conformance is supplied with every shipment of product in accordance with standard requirements or customer specifications.