Micro Moulding and Nano-Structuring for Medical and Biotech Devices

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The continuing industrial interest in micro-components and micro/nano structuring of devices is being driven by increasing needs for point of care diagnosis, portability, minimally invasive surgery, and other factors outside the medical device industry that require miniaturisation. In addition to the established know-how in production micro-moulding, there is a technology push from research & development as methods are developed to design at the nano-level and to achieve specific component functionalities.

Moulding Processes

Micro-moulding has now been established as a specialised injection moulding process for several years. Whereas conventional plastic injection moulding machines are adequate for producing many small plastic medical parts, a dedicated micro-moulding machine offers a degree of control and repeatability for the moulding of very small components down to less than 0.005g part weight, that can not be achieved with a conventional machine.

Current commercially available micro-injection moulding machines inject the material into the mould using a plunger of 3-5mm diameter, and they are designed specifically to make miniature parts as small as 0.005g in weight.

Advantages of using a dedicated micro-moulding machine include:

- Much smaller feed & gating system resulting in less pressure drop to the mould cavities and less wastage of expensive medical-grade moulding materials.
- Injection of small quantities of material with precise position and speed control via the miniature injection plunger which is driven by a servo electric drive.

Other advantages can include an integrated clean room cell, integrated handling and camera inspection & packaging system in a very small envelope, and higher dosage repeatability due to the metering and injection system design.

Mould design & manufacture

Design of micro moulds requires attention to be given to factors such as precise alignment of mould components, support of the mould under high injection pressure, gate size and degating, venting of the mould, reliable ejection system, and part handling on ejection. If any of these factors are not correctly designed, and the parts are not made with the correct tolerances and materials, the process will fail. Mould alignment may be necessary to less than 5 micrometers, and gate diameters are typically from 60 to 200 micrometres. Venting is typically assisted by vacuum in order to avoid air traps when the part is filled. Filling of the cavities can often take place in less than 0.1sec.

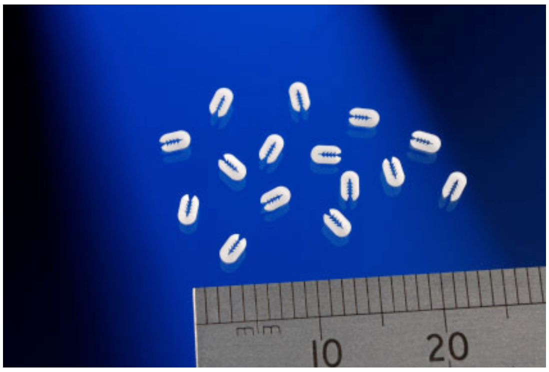

Fig 1: Micro-moulded part for a medical staple. The pitch of the teeth is 0.3mm.

The processes used to make micro-moulds are a combination of refined traditional toolmaking processes and more specialised processes. Traditional toolmaking processes would include high speed milling, electro-discharge maching (EDM) and wire-erosion. The equipment for these processes can now be highly controlled and precise especially when used in a temperature controlled environment. More specialised processes would include diamond cutting and a range of nano-manufacturing processes described below.

Nano-structured inserts and replication in plastic

Sub-micrometer structures on surfaces have interest in the medical field in areas where components are in contact with fluids, or where optical functions are needed. Structured surfaces of this type also have bio-technology applications when used in contact with cells, and in other fields such as anti-counterfeiting and unique identification.

The table summarises different nano-manufacturing processes and their typical capabilities in terms of mechanical feature size. These processes can be used to structure metallic surfaces that can be used directly or can be replicated in plastic by a moulding method.

The features on the surface of a compact disc (CD) or digital video disc (DVD) are sub-micrometer in size and have been made for many years by injection moulding. The master pattern is created by laser structuring, this is replicated by nickel electroforming, and the nickel 'shim' is used as the face of a mould insert. Features in the order of 200 nanometres in size can be replicated effectively via injection moulding (1).

The equipment used for the processes in the table is highly specialised and mostly exists only in research establishments or other specialised laboratories. To utilise it, companies need to develop working relationships with such establishments and develop ways to make use of surfaces made by these methods on engineering components. For example, to take a nickel electroformed shell from an electron-beam machined silicon master, machine this to size, and fit it into an injection mould tool to mould plastic parts requires engineering development and expertise.

Nickel has a limited lifetime in a mould tool compared to hardened tool steel. For this reason, hardened steel is always preferred by moulders and recent efforts in some centres have developed methods to etch optically diffractive elements into steel.

Table 1: Special processes for sub-micron structuring.

Process	**Capability**
Diamond cutting	Features >5µm size with Ra range 3-30nm.
Direct laser machining	Holes and line features >10µm diameter/width.
Laser Interference Lithography	Lines & interference patterns >1µm size.
LIGA	High aspect ratio features >5µm footprint
Electron beam machining & lithography	Feature sizes 25nm - 1µm.
Focussed ion-beam	Features down to 2.5nm size.
Nickel electroforming	Used for replicating master patterns cut by the above processes.

Applications

Devices for treatment and surgery

Micro machining and micro moulding capabilities enable the manufacture of micro devices for many applications including certain types of cancer treatment, small moulded catheter tips, micro-needles, and small surgical instruments. Another application is in dental surgery, where a new type of filling and infection control has been developed for root canal treatment, using a micro-moulded x-ray opaque material with a hygroscopic coating (2).

Small slots or radii in metal parts or mould inserts can be cut to <0.050mm width, and plastic parts can be micro injection moulded in mould tools using steel ejector pins <0.20mm diameter for part ejection. Holes <0.1mm diameter can be moulded, and when holes too small for moulding are required, hole sizes <0.030mm diameter can be produced by laser machining.

Figure 1 shows a development part for a medical staple. This is micro-moulded in a 4 cavity mould with a cycle time of about 6 seconds. The pitch of the teeth is 0.3mm.

Fluids and optics

Design and structuring of specific surface features at the nano-level (below 1 micrometre in size) can modify the wettability of a surface to help control the movement of fluid, a phenomenon widely seen when studying nature. This type of effect requires a combination of the correct surface chemistry and mechanical micro/nano structure.

The structuring processes highlighted in the table can also be used to manufacture diffractive optics, for example, to shape the beam of light emitted from a laser or light emitting diode (LED) needed for analysis work. The use of diffractive optics allows flatter, thinner lenses to be used and can achieve results not possible using refractive optical systems.

Figure 2 shows a diffractive optical structure used for beam shaping. This was produced by a combination of processes and employed in plastic injection moulding.

A relatively new application is the interaction of cells with synthetic nanostructured surfaces which is the subject of current research. An example is cell contact guidance to differentiate stem cells. (3)

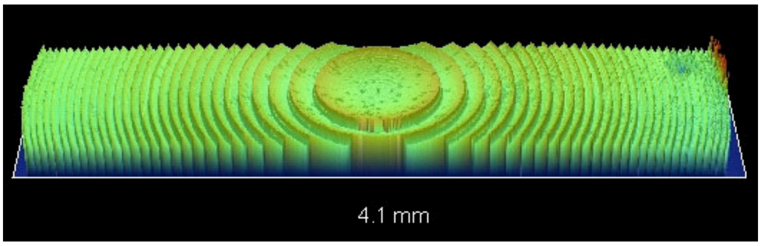

Fig 2: Diffractive optical structure used as part of a mould for beam-shaping optics.

Implanted devices

Some treatments require bio-resorbable devices to be used, or structural components to be permanently implanted. The scale of parts that are possible with micro-moulding, ie. parts <1mm in size with features much smaller than this, opens up new possibilities. At this scale, the problem can become more one of handling than of manufacturing. However, micro-moulding also opens up opportunities for slightly larger scale parts with micro/nano surface features or holes. These could be types of clips or staples, devices for drug delivery, bone-replacement implants, or possibly components used in neuro-surgery.

Other applications are starting to be found. The key to manufacturing success in these areas is the know-how to design at the micro/nano-scale, and to integrate the necessary cutting-edge technologies to bring a final product to production. In parallel with this, there is an ongoing need for designers of devices to be educated with respect to the capabilities of these processes.

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