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Thinking small

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Fabrication technology inspired by computer chips aims to turn complex designs into tiny medical devices, without the need for assembly. Siobhan Wagner reports.

With surgical and interventional procedures becoming increasingly less invasive, medical devices need to be be reduced in size to fit through smaller incisions.

And while engineers have the know-how to design such small instruments, the ability to manufacture them — especially those with multiple moving parts — can be difficult.

One US company, California-based Microfabrica, hopes to turn complex designs into working devices using EFAB fabrication technology inspired by computer chips.

The technique, the company claims, can produce tiny mechanisms with dozens of moving parts — without the need for assembly.

It works by forming and stacking sets of thin metal layers in the same way a loaf of bread might be assembled from individual slices.

'There really isn't a technology like ours,' said Adam Cohen, Microfabrica's chief technology officer. 'We have aspects that are comparable to precision metal working and to micro electro-mechanical systems (MEMS) technology. We're in some ways a hybrid.'

EFAB is a volume production process that uses tooling to create thousands of functional metal devices with micron-scale features.

The process is driven by a 3D CAD design of the desired fully-assembled device. Almost any suitable software package, such as SolidWorks or Pro/ENGINEER, can be used to create the 3D model.

Once the design has been finalised, the model geometry is exported in an industry-standard STL file format. Then a Microfabrica software program reads the file and generates 2D cross-sections for every layer to be fabricated.

The software then exports the files and uses them to create a set of photomasks, chrome-coated glass plates that allow light to shine through in a defined pattern.

These are used to define the locations of material deposition in each layer of the device. In combination, the layers produce a device that reconstructs the original CAD geometry.

Cohen explained that the EFAB manufacturing process begins with a blank substrate, typically a ceramic wafer, and grows devices layer-by-layer by depositing at least two metals in a clean room environment.

'One metal is structural, forming the features of the finished device,' he said. 'The other is sacrificial, supporting the device like scaffolding during its fabrication.'

It is this layered, two-material process that makes the geometrical complexities of the devices possible. Cohen added that it also allows pre-assembled sets of separate, independent components to be created.

The layering process involves three key steps.

First is deposition of the sacrificial metal which is electroplated on to the substrate in areas defined by the photomask. The pattern corresponds to the first cross-section of the device.

Second, the structural metal is blanket deposited and covers the first metal, filling in areas in which the first metal was not deposited.

Third, the two metals are flattened with a proprietary planarisation process to form a two-material layer of controlled thickness, flatness and surface finish.

All three steps are then repeated until all layers (as many as 50) have been formed and the desired device has been completed and encapsulated within a block of sacrificial metal.

The device inside this block can have multiple parts each of which is suspended within sacrificial metal. The spaces between parts are filled by sacrificial metal. Once all layers are formed, the sacrificial metal — including that filling the spaces between separate parts — is completely removed by an etching process. The device is then ready for use.

Cohen said the process behind EFAB technology is comparable to precision metal working and MEMS technology, but it can be much better for making small precision parts and devices.

This, he said, is because MEMS is typically silicon based, while EFAB is metal based.

'In terms of making instruments that would be used for a minimally invasive procedure, neither silicon nor glass — used for microfluidic devices — do the job satisfactorily,' said Cohen. 'The last thing you want are brittle materials going into your body.

'Furthermore', he pointed out, 'the geometries available to MEMS devices are very simple, typically produced by three to five layers'.

He added that EFAB technology is often better than traditional metal-working for making small metal devices because it is difficult to manufacture them economically.

Also, EFAB can produce internal features, almost like a ship in a bottle, and often avoid the need for assembly.

Some examples of instruments the company has created include water-powered turbines just over 1mm in diameter that spin at 120,000 revs/min and millimetre-scale 'car jack'-like expanders.

Cohen is particularly proud of one device — a multiple biopsy/continuous tissue resection 'chainsaw.' Measuring just 3mm wide, it has 40 to 50 moving parts and is used to continuously remove tissue from a patient's body.

Yet the technique has its limitations. While the layered process can make features that are smooth in the X/Y plane, they are not so smooth in the Z plane.

'If you imagine looking down at a sphere, it would be perfectly round, but viewed from the side it would be stair-stepped,' said Cohen. 'We could reduce the size of those stair steps at the top and bottom to as little as 0.004 mm, but nevertheless they would never go away.'

There are also material limitations. 'With machining you can machine any material you want because it's a subtractive process,' he said. 'We grow our devices and deposit a more limited array of materials.'

Yet Cohen said the material pallet will broaden over time. 'It will never be as broad as machining or any subtractive process where you typically start off with something that is formulated by melting it in an ingot and then removing what you don't want,' he said. 'There will always be limitations on what can be deposited in this process.'

EFAB technology has been available for applications such as testing computer chips since the early 2000s, but it wasn't until last year that Microfabrica introduced it for medical applications.

The company has been receiving steady interest from the US and Asia, but is now looking to expand further.

An upbeat Cohen said that Europe is the next frontier.

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