WAFER-SCALE, SOLID FREEFORM FABRICATION OF FULLY-ASSEMBLED METAL MICRO-MECHANISMS FOR MINIMALLY-INVASIVE MEDICAL DEVICES

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Abstract

The EFAB process was first presented at the SFF Symposium in 1998, at a very early stage of its development. Currently, the technology is able to produce complex 3-D devices—including mechanisms built pre-assembled—in production volumes, using a three-step process of selective electrodeposition of one metal, blanket electrodeposition of another metal, and planarization. Layer thickness is as small as 4 µm, minimum feature size is down to 10 µm, and linear tolerances are ~2 µm. Metals are biocompatible materials with mechanical properties similar to stainless steel. The technology enables new instruments for minimally-invasive surgical and interventional procedures.

Introduction

The popularity of minimally-invasive medical procedures has grown rapidly in recent decades, yet some minimally-invasive procedures are still quite invasive, and many surgical procedures remain open, since a less invasive alternative is not available. One reason for this is instrumentation: minimally-invasive procedures often require miniaturized, highly-functional tools and a means of manufacturing them. Despite the wide range of manufacturing processes available, limitations on what can be produced, or produced affordably, remain. Thus, new production technologies for miniature instruments can have a significant impact on minimally-invasive medicine.

Figure 1: Double-acting micro-forceps 0.7 mm in diameter, produced without assembly using EFAB technology (material: Ni-Co).

EFAB Technology

EFAB technology was invented in the mid-1990s at the University of Southern California with funding from DARPA, and has been commercialized by Microfabrica Inc. (formerly MEMGen Corporation), a venture-funded company based in Van Nuys, California. The technology was first described at the Solid Freeform Fabrication Symposium in 1998 [1]; later publications [2-7] documented the development of the process and its eventual application to medical devices and other areas.

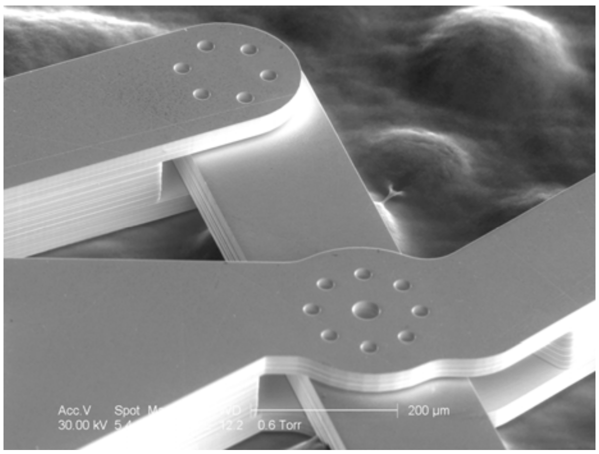

Figure 2: Detail of single-acting micro-forceps illustrating feature quality (material: Ni-Co).

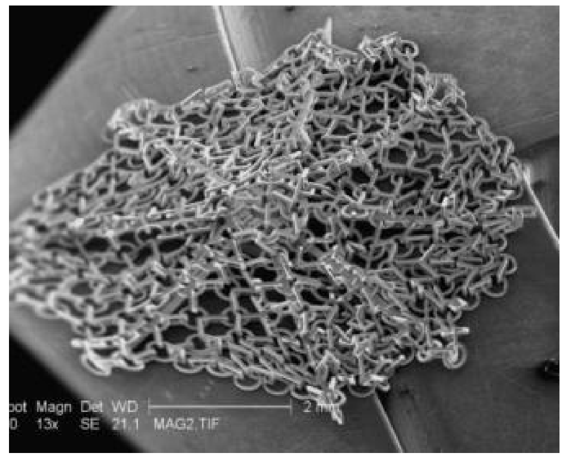

Figure 3: Micro-chainmail "umbrella" (material: Ni-Co).

The EFAB process enables flexible, cost-effective, highly-repeatable production of intricate metal devices measuring millimeters to centimeters in overall size with features measured in microns or tens of microns. Devices made with EFAB are produced at a wafer scale, typically in batches of 100s to 1000s, using a solid freeform fabrication process that is both additive and subtractive in nature. Metal is deposited through electroplating, yielding fully-dense material with excellent mechanical properties and demonstrated biocompatibility for many applications. The process involves three steps: selective electrodeposition of one metal, blanket electrodeposition of a second metal, and planarization. Layer thickness is as small as 4 µm, minimum feature size is down to 10 µm, and linear tolerances are ~2 µm.

Figure 1 shows over a U.S. penny a double-acting forceps Ni-Co instrument ~0.7 mm diameter, in which all moving parts are co-fabricated together. Figure 2 is an SEM detail of a single-acting Ni-Co forceps, while Figure 3 is an SEM image of a chainmail "umbrella" for retrieval of foreign bodies or capture of emboli, featuring hundreds of individual links and measuring about 7 mm in diameter. Both devices are fabricated without assembly.

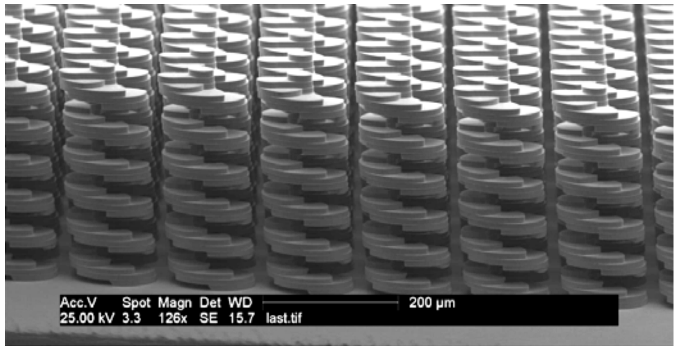

Figure 4: Array of helical micro-springs developed for use in semiconductor probing (material: Ni-Co).

EFAB technology makes possible an unprecedented level of device complexity at the sub-millimeter to millimeter scale, including the creation of fully-assembled mechanisms with independently-moving parts, often obviating the need for costly micro-assembly. EFAB provides a versatile, freeform process for producing metal structures at a small scale, freeing medical device and other designers from the constraints of standard shapes and conventional processes (e.g., slotting a tube, bending a wire). The process enables new types of devices previously impossible to make, and can also significantly lower the cost of devices now difficult to manufacture. EFAB technology has found use in medical devices, semiconductor testing (spring-like probes such as in Figure 4 for probing wafers), microwave/millimeter-wave devices (e.g., the hybrid coupler shown in Figure 5) and military safing/arming and fuzing devices relying on watch-like mechanisms similar to those in Figure 6.

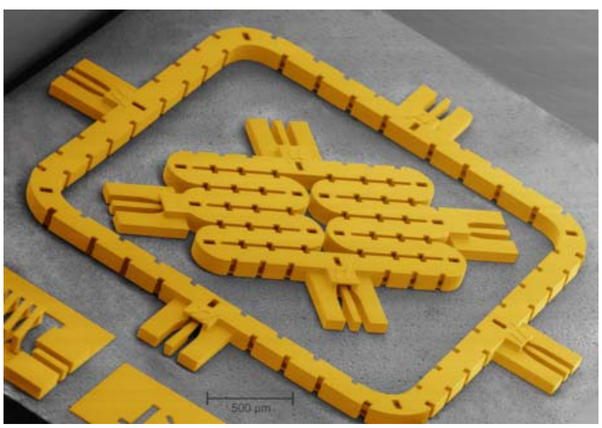

Figure 5: Folded and unfolded versions of a millimeter-wave hybrid coupler based on highly-miniaturized coax (material: Ni).

Figure 6: Mechanical energy-harvesting device ~5 mm diameter incorporating a spiral spring and moving mass (material: Ni-Co).

As with all SFF processes, EFAB produces devices by forming and stacking a series of thin layers, according to 3-D CAD designs. But there are important differences with EFAB other than its smaller scale:

- EFAB is a volume production process that may be used to make prototypes, rather than a prototyping process per se.
- It yields functional metal devices in the final production materials.
- It is performed at present in a cleanroom by technicians, rather than in a single automated machine.
- It uses tooling, rather than being a direct-write process driven by CAD data.
- Devices are typically built using tens, vs. hundreds, of layers.

Process Flow

The EFAB process is driven by a 3-D CAD model of the desired final device. The model is often of an assembly having multiple, independent parts. The model geometry is exported as an STL file and imported into a specialized software package developed by Microfabrica called Layerize which generates 2-D cross-sections for every layer that is to be fabricated. Layerize exports files in GDSII format; these are then used to drive an e-beam or laser-based pattern generator, yielding a set of photomask tools that define each cross section with sub-micron resolution. The photomasks are used in the EFAB process to define the locations of selective material deposition on each layer of the device.

The EFAB manufacturing process beings with a blank substrate (typically alumina) and grows devices layer-by-layer by depositing and planarizing at least two metals. One metal is structural, forming the features of the finished device. The other metal is sacrificial, providing support during the layering process and eventually removed.

Figure 7 depicts the layering process, involving three key steps. In Step 1, a first metal (e.g., the sacrificial metal as shown) is selectively electrodeposited onto the substrate in areas defined by the photomask, in a pattern corresponding to the first cross-section of the device. In Step 2, a second metal (e.g., the structural metal) is blanket deposited (typically by electrodeposition). The second metal covers the first metal and fills in the region where the first metal was not deposited. In Step 3, the two metals are planarized via a proprietary process to form a two-material layer of precisely-controlled thickness, flatness, and surface finish. These three steps are then repeated again and again until all layers have been formed and the desired device has been fully generated. Lastly, the sacrificial metal is completely removed by a selective etching process, freeing the device for use.

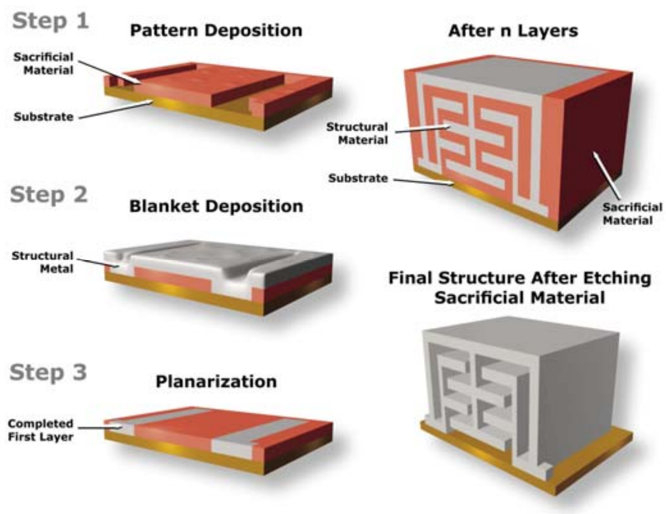

Figure 7: The EFAB process. A 3-step process is performed on each layer using two materials. Eventually one material is etched to release the structure.

If the first layer is entirely sacrificial metal, then devices will be completely released from the substrate; this method is typically used for medical devices. However, electrically-interfaced devices such as those shown in Figure 5 can also be built directly on the substrate and remain attached to it; dicing the substrate then singulates the individual 'chips' for use.

Development History

The EFAB process was originally practiced using a selective electrodeposition technique invented at USC called "Instant Masking". Instant Masking allows metal to be electrodeposited through the apertures patterned in a compliant mask that is pressed against the surface to be patterned (e.g., the substrate or previous layer). The poorly-defined yet monolithically-built chain presented in Figure 8 at the 1998 SFF Symposium [1] was made with this process, as were many later devices of greatly-improved quality, such as the transformer of Figure 9.

Figure 8: Early (c. 1998) chain produced using EFAB technology through Instant Masking (material: Ni).

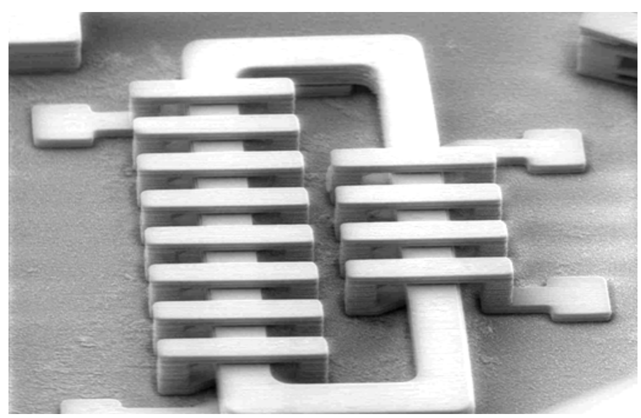

Figure 9: Micro-transformer produced using EFAB through Instant Masking (material: Ni).

Instant Masking was conceived as a means of bypassing the complex and time-consuming steps required by photolithography through the use of pre-fabricated masks, thus allowing selective deposition and the other EFAB process steps to be performed within a single, automated machine, according to the classic SFF paradigm. Several such machines (Figure 10) were developed by Microfabrica capable of producing small quantities of prototype devices on 25-mm diameter substrates. When the time came to to scale EFAB technology to production-capable (e.g., 100 mm diameter) substrates, a more conventional pholithography-based approach was adopted over Instant Masking, as it was determined that scaling the latter to larger substrates would require considerable time and resources.

Figure 10: Automated EFAB machine .

EFAB for Medical Devices

EFAB technology found its first applications in electronics and defense, but some of the most exciting applications for the technology are in medicine, especially those which enable minimally-invasive procedures. Several devices are described as follows, all of which are monolithically fabricated without assembly.

Figure 11: EFAB-produced hydraulically-operated forceps (material: Ni-Co).

Figure 12: Tissue approximation device (current material: Ni-Co).

Figure 11 shows a hydraulic forceps in which a piston is moved within a curved cylinder using water, forcing the moving jaw to pivot around a hinge. When the pressure is released, a return spring opens the jaw. The device has been shown to grip small objects. Hydraulic devices are useful, for example, in interventional or diagnostic procedures performed through tortuous anatomy where motion of a rotating or sliding wire can be problematic due to friction or fatigue. Figure 12 depicts a tissue approximation device under development for such applications as closing a congenital heart defect known as patent foramen ovale. Inspired by drywall toggles at a much larger scale, this device is delivered through tissue inside a needle. Withdrawing the needle allows spring-loaded wings to pop open at both the distal and proximal ends; pulling on a wire then ratchets the two sets of wings together, approximating the tissue. The device is removable if desired.

Figure 13: Reciprocating tissue saw (material: Ni-Co).

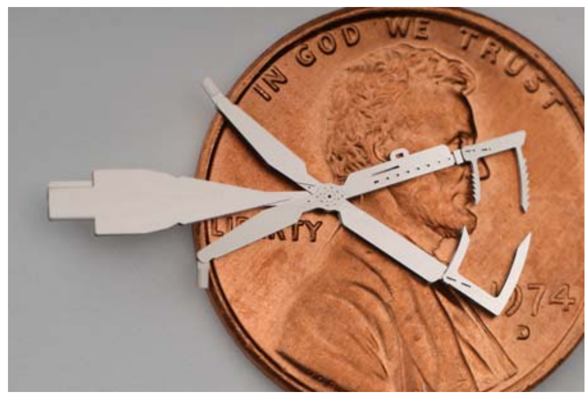

Figure 14: Tissue approximation clip (material: Ni-Co).

Figure 13 is a photograph of a reciprocating endoscopic saw—essentially a powered scalpel—that cuts through soft tissue with little pressure and without the need to draw the device across the tissue. It comprises two external blades and an inner blade that is mechanically vibrated to and fro along the longitudinal axis. Figure 14 shows a ratcheting, two-piece surgical clip deployed at the end of a forceps-like delivery device. The clip is intended to approximate tissue in lieu of a suture, but requiring much less motion and procedural time than suturing.

From the perspective of a medical device developer, EFAB offers a number of key benefits that complement those of conventional manufacturing processes. Parts and devices 1 mm or more in height, and millimeters-centimeters in width and breadth, can be produced with complex 3-D geometries, including those with internal features that would not be amenable to machining. Devices with features as small as 4 µm can be fabricated with tolerances of just a few microns. The high cost of fabricating complex small parts and then assembling them into devices can be dramatically reduced by using EFAB to batch-fabricate complex ‘assemblies’ with multiple independent, moving parts. Unlike many manufacturing processes, the cost of EFAB is not heavily influenced by complexity, and in general the process is net shape, with no post-processing required. Finally, features such as threads (Figure 15), micro-textures (Figure 16), part numbers, and logos can be added to devices at virtually no additional cost.

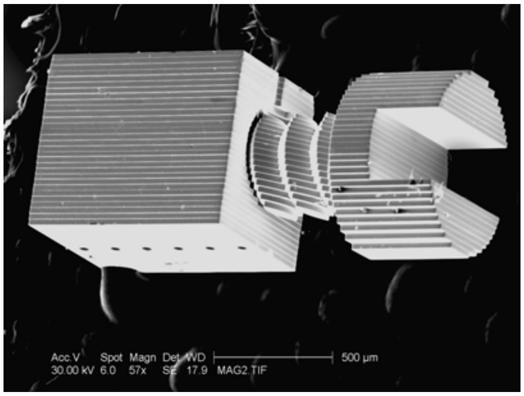

Figure 15: Functional threads produced with using EFAB technology.

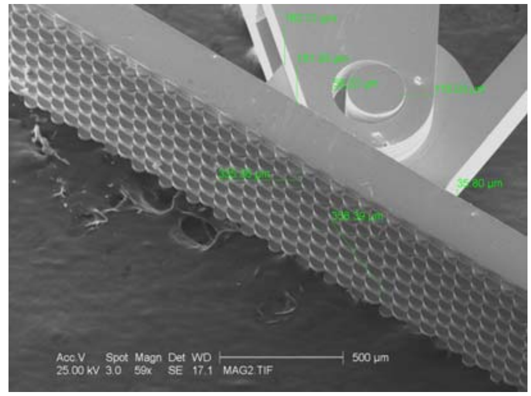

Figure 16: Built-in micro-textures.

EFAB technology is highly repeatable, thanks largely to the use of photolithography to define layer geometry. In addition, bypassing the need for assembly can significantly boost quality: Assembly processes relying on welding, adhesives, fasteners, and the like may fail, risking disintegration of devices during a medical procedure. In contrast, most EFAB-built devices are monolithic. Obviating the need for assembly also avoids the risk of the wrong part being used, a part being forgotten, or assembly of parts occurring in the wrong order.

Process Details

A typical device produced using EFAB is relatively small, intricate, tightly-toleranced, and quite frequently is a pre-assembled mechanism with multiple independentl components. Using EFAB, devices may be fabricated with undercuts, internal features, narrow and deep holes and slots, curved and non-circular holes and channels, tall yet thin walls, and reasonably sharp corners are all possible. Also, since material is added as the process progresses, devices may be made from more than a single material: either on different layers or within a single layer. The primary geometrical limitation of EFAB technology is related to release of the sacrificial metal. It is not possible, for example, to produce a completely closed, hollow box, since there would be no way to etch the sacrificial metal inside; at least one release hole is needed. In general, devices made with EFAB may require the addition of release holes (e.g., the holes on the surface of the device in Figure 6) to ensure complete release. With proper hole design complete release of sacrificial material can be assured.

EFAB is currently limited to making devices just over 1 mm in the Z axis, but Microfabrica is working to increase this height significantly. The practical limit, assuming the use of layers thicker than 25 µm, will probably be 2-3 mm. Along the X and Y axes, there is no such limit other than wafer size (now 100 mm with a planned transition to 150 mm) and cost (fewer large devices can be made per wafer)). On the other extreme, devices can be made that are very small (e.g., 4 x 25 x 25 µm with a mass of ~ 0.02 µg. A typical device is 0.5-1.0 mm in height and up to several millimeters in width and breadth, weighing a few mg or tens of mg. Devices with up to 50 layers have been fabricated to date, and those with two-three dozen layers are routinely made. While this layer count is much lower than those commonly found with SFF processes, it is still about an order of magnitude larger than the layer count typically found with microfabrication processes such as surface micromachining commonly used to make small-scale devices such as microelectromechanical systems (MEMS). The primary limitation on layer count is cost and lead time.

Along the layer stacking (Z) axis, features can be as small as the layer thickness (4 µm or thicker at present). In the plane of the layers, features at currently are as small as 10-20 µm, but in principle can be less than 5 µm. Design techniques based on staggering features from one layer to the next can be used to achieve holes, slots, and clearances that are effectively smaller, typically down to 5 µm. EFAB processing is accurate, repeatable, and free of many distortions. The control of dimensions along the Z axis is currently +/- 2 µm. In the X/Y (i.e., layer) plane, dimensions are typically controlled to within +/- 2 µm. Inter-layer alignment is now +/- 1.5 µm; if tighter alignment tolerances are needed, these are achievable with better equipment. These tight tolerances are attributable to the use of sub-micron resolution photomasks to define the layer geometry, and a precise planarization process. EFAB is typically a net-shape process, producing no burrs and only a small amount of distortion due to residual stress (normally not noticeable except on very thin, cantilevered features).

The surface finish of the top and bottom of layers is typically about 0.15 µm; optical quality surfaces are possible if desired. The most significant source of surface roughness for some devices is the ‘stair steps’ along the layer-stacking (Z) axis due to the layered nature of EFAB. Conversely, in the X/Y plane the steps associated with the rastered nature of the photomask are submicron and normally not noticeable. At present, layer thickness can be specified on a layer-by-layer basis over the range of 4-25 µm. In order to minimize any objectionable surface roughness associated with stair steps, layer thickness can be optimized. For example, a cylinder built with its axis parallel to the X/Y plane may be built with thinner layers near the top and bottom.

Materials for EFAB Technology

At present there are two commercialized EFAB materials suitable for medical devices: Valloy™-120 metal (a proprietary fine-grain nickel-cobalt alloy) and Edura™-180 metal (rhodium). A third metal is currently in development for implantable medical devices, and for those used in MRI-guided procedures.

Table 1. Properties of commercial EFAB materials..

Property	**Valloy-120**	**Edura-180**
Ultimate tensile strength, MPa	1,100	Not available
Yield strength, MPa	900	Not available
Hardness, Rc	~40	~68
Modulus of elasticity, GPa	180	Not available

The primary structural material used is Valloy-120, an electrodeposited, fully-dense, ductile, corrosion-resistant alloy with very good mechanical properties and demonstrated biocompatibility. Edura-180 is not used to make entire devices but is used selectively for features needing extreme hardness or wear resistance; devices incorporating more than one material (e.g., Valloy-120 and Edura-180) are routinely fabricated.

The properties of Valloy-120 and Edura-180 metals are summarized in Table 1. Both materials achieve their mechanical properties as-deposited, with no heat treatment needed. The adhesion between layers in a device made by EFAB is a large fraction of bulk ultimate tensile strength. Thus for many devices, EFAB devices can be considered to be nearly monolithic even though formed from discrete layers.

Extensive third-party laboratory tests of Valloy-120's biocompatibility demonstrate its suitability for medical devices intended for < 24 hours exposure to tissue and circulating blood. The material is however, not suitable for long-term implantation. Tests have shown that Valloy-120 has very good corrosion resistance and is of high purity.

Edura-180 metal is an electroplated rhodium material. Edura-180's hardness exceeds the ~57 Rockwell C hardness of hardened 440C stainless, making if attractive for portions of devices in abrasive contact with hard materials.

Process Limitations and Cost

As noted earlier, an important limitation of EFAB technology is that devices cannot be too large. Another consideration is that the range of materials is presently quite limited and may not meet all requirements. The layered nature of the process creates stair steps on some part surfaces and gives rise to inter-layer misalignment. In addition, all dimensions along the layer stacking axis are quantized to the local layer thickness. The unique ability of the EFAB process to produce devices with internal features and multiple components may require adding release holes to the design; sometimes these are undesirable. Not all devices can be made fully pre-assembled using EFAB due to issues with stairsteps or minimum clearance between moving components (though design "tricks" may sometimes be used to overcome the latter). For example, due to stair steps, vertical and horizontal shafts which rotate smoothly are difficult to include in one monolithically-fabricated device.

In production quantities (e.g., 10,000s-1,000,000s of units) EFAB technology can be very cost-effective and in many cases—particularly for small, complex, or tightly-toleranced devices—significant cost-savings can be realized. The ability to batch produce sophisticated, net or near-net shape parts and devices, combined with the ability to reduce or eliminating small-scale assembly of mechanisms are key factors making EFAB economically attractive. The primary cost driver for EFAB-built devices is overall device size and the number of layers needed to produce it. Device complexity only has a small impact on cost. Since EFAB requires tooling, prototyping can be costly, but this can be amortized by simultaneously prototyping multiple device variations and even unrelated devices (dozens have been combined on a single wafer), subject to the need for a common set of layer thicknesses.

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