TITANIUM MIM: TECHNOLOGY FOR ORTHOPEDIC DEVICES

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ABSTRACT

Praxis Technology has developed MIM based technologies that offer design flexibility and cost savings for orthopedic devices. Material performance of TiRx™, our Ti-6Al-4V MIM material that meets the high cycle fatigue requirements of load bearing implants, will be discussed. Additionally, Praxis' novel 3DT technology provides for a variety of surfaces to be co-formed with TiRx; these include polymer anchoring surfaces, textured surfaces and three dimensional ingrowth surfaces. Characterization of these surfaces will be discussed.

INTRODUCTION

The use of metal injection molding (MIM) to form orthopedic implants has long been of interest to manufacturers desiring to reduce the manufacturing cost of their implantable products. Because of the multiple challenges of processing large geometries using reactive powder in an ISO 13485 environment, TiMIM has made few inroads into the orthopedic implant market. Praxis Technology has been steadily investing in developing technology for medical grade TiMIM. This paper will review how technology developed by Praxis helps TiMIM to overcome the fundamental barriers to entry of the orthopedic market, which are threefold:

1. The underlying MIM process needs to be robust enough to reliably produce Grade 5 material that consistently meets the chemical and mechanical specifications.
2. Integration surfaces must be able to be formed on the MIM article reliably and economically.
3. Grade 5 MIM titanium must demonstrate better fatigue performance than is possible with an as-sintered microstructure.

ROBUST TITANIUM MIM

In order to penetrate the orthopedic market, any TiMIM process needs to be robust enough to demonstrate that the product can consistently meet the chemical and mechanical performance requirements of the specifications that were used in the design of the device. Initially, this must be demonstrated in order to give the manufacturers the degree of comfort they need to make the substantial investment to convert to TiMIM. This investment includes not only the multiple sets of tooling required for a family of orthopedic parts but the functional testing of the device and the process validation. It could also potentially include costly in vivo testing. Once in production, a robust, statistically capable process is necessary so sampling plans can be instituted for the acceptance criteria that must be monitored by destructive testing, such as interstitial content.

The challenges of doing this are well understood within the industry.[i] Praxis Technology has been developing TiMIM technology for the last 10 years, and has become very familiar with these challenges. As a result of this commitment, Praxis has commercialized a validated TiMIM process for medical devices. During this validation, the consistency of the TiMIM process was evaluated at many points. This discussion will focus on testing the outputs of the process from the perspective of interstitial content and mechanical properties.

Medical devices undergo substantial functional testing to demonstrate that the device is effective and safe prior to the start of manufacturing. Notwithstanding this testing, it is important to have an understanding of the materials properties to benchmark the performance of the manufacturing process independent of specific device performance.

In 2011 ASTM adopted a standard for the metal injection molding of titanium (ASTM F2885-11). This standard contemplates two versions of the product. Type 1 is a densified version having higher ultimate and yield strength requirements and Type 2 is an as-sintered version having lower mechanical requirements. The interstitial requirements for both are the same. Praxis' development efforts have focused on Type 1 because the specification for Type 1 is more similar to other ASTM specifications used for titanium implantable devices and presents less adoption challenges to the device OEM's.

There has been some discussion in the community with regard to increasing the oxygen limit for the Grade 5 alloy. This should create some concern for manufacturers. With a properly controlled TiMIM process it is entirely possible to consistently meet the upper oxygen limit of 2000ppm. If a TiMIM producer cannot meet this requirement repeatably, they do not adequately understand their process and should refrain from representing their process as suitable for manufacturing Grade 5 titanium, let alone implantable devices.

Details of the capability studies, including sample size determination are discussed a concurrent paper, "Titanium MIM: Performance and Capability." Table 1 summarizes results of some of our capability studies. In order to provide a robust process, the capability objective was 1.33. This objective was met for all of the evaluated properties. Data for mechanical properties was collected at the upper and lower boundaries of the sintering window, the lesser of these values is presented. Data for the interstitial content was collected across three sequential furnace runs.

Table 1: Summary of Capability Data for Praxis' TiMIM process.

Property	ASTM F2885 Limit	Average	Std. Dev	Cpk/Ppk
UTS (MPa)	900	964	3.77	5.70
Yield Strength (MPa)	830	860	6.68	1.47
Elongation (%)	10	19.8	1.19	2.74
Oxygen (ppm)	2000	1720	6.5	1.42
Carbon (ppm)	800	361	5.6	2.61

Having a titanium MIM process with well understood and robust capability is the foundational step towards making the TiMIM process widely relevant to orthopedic devices. This allows the process to be monitored and quality assured via statistical sampling.

INTEGRATION SURFACES

Most orthopedic devices are manufactured with some type of integration surface. This surface may be a simple roughened "on-growth" surface or a more complex porous "ingrowth" surface. Ingrowth surfaces are increasingly becoming the standard of care on many orthopedic devices. By incorporating the formation of these surfaces into the MIM forming process, value is added to the TiMIM product.

Typically integration surfaces are added to an orthopedic implant in a step independent of the forming of the solid section of the implant. From a cost perspective it is desirable to reduce the number of manufacturing steps, so the possibility of simultaneously forming the integration layer and the substrate (co-forming) is alluring.

A typical integration layer may include one or more of the following regions: a fixation texture region which refers to the portion of an implant that provides for initial fixation of the device during surgery; the in-growth region which is the portion of implant that is intended to promote growth of tissue into the device for long-term fixation; and the substrate interface region which is the transitional area between the in-growth medium or fixation texture region and the dense portion of the implant. Figure 1 depicts each of these regions.

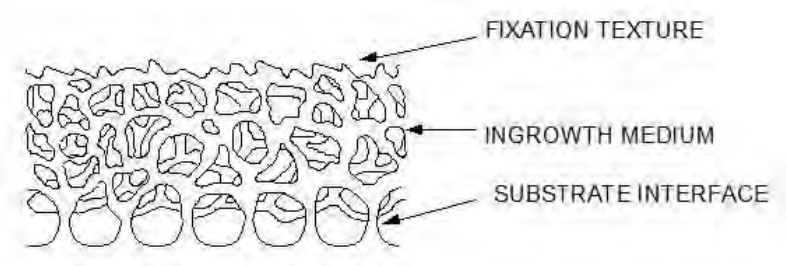

Figure 1: Schematic of an Integration Layer

These has been substantial activity in this area. There are several routes to approach forming a porous integration layer on a MIM article. This discussion addresses routes that incorporate the porous section

during the molding of the article prior to sintering. There are three fundamental approaches that can be used to add an ingrowth surface to a TiMIM article:

1. Co-forming with porous feedstock
2. Co-forming with a compacted preform
3. Co-forming with a sacrificial insert

Co-Forming with a Porous Feedstock

In this approach, a pore-former or space holder is incorporated into the MIM feedstock during compounding. The pore-former is a particulate material that can be removed from the feedstock after it is molded. The porous feedstock is used to form the porous section, and feedstock without pore former is used to create the solid portion of the article. In a typical approach, the porous section is molded and then used as an insert in a second molding operation.

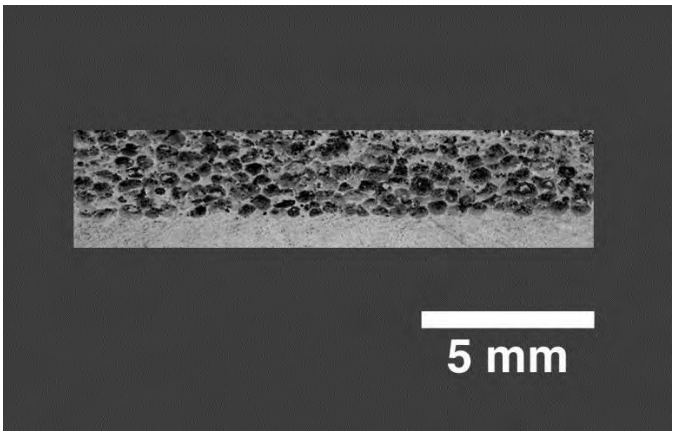

Figure 2: Cross-section of an article co-formed using porous feedstock

Figure 2 shows a cross-section of a specimen that was fabricated using this approach. While the porous section is well bonded to the solid substrate, the disadvantages of this approach are inherent and numerous. Among the challenges of using a feedstock-borne pore former are:

- Inability to form a net-shape texture on the surface of the porous section;
- Reduced porosity at surface;
- Difficulty achieve a highly interconnected porosity, (conflict of loading and flow);
- An irregular distribution of porosity, (separation of particles); and
- Low strength, (inherent limit of binder with pore former approach).

The challenges of net-shape texture and reduced porosity at the surface are related. The pore-formers are generally an order of magnitude larger in diameter than the metal powder in the feedstock. As the feedstock is molded, the pore formers along the outer edge of the part contact the wall of the mold. The balance of the feedstock system, being composed of finer metal powder and binder, flows around the pore-formers and obscures most of the pore-former from the mold surface. This can be overcome by removing some of the surface after molding, but it requires a secondary operation.

Along the same lines, it is difficult to impart texture to the molded article, not only because of the challenges of molding complex texture, but because the same problem discussed above precludes molding

of texture that has substantially open porosity. Again, overcoming this problem requires a secondary operation.

A problematic aspect of this approach is the conflicting need to create substantial interconnected porosity via contact between the pore-formers and to provide a highly loaded MIM feedstock with a usable viscosity. In addition to creating the porous metal matrix this feedstock needs to possess shrinkage compatible with the non-porous body of the implant.

A further challenge is related to separation of the pore-forming particles during injection. Larger particles are more prone to separation effects due to changes in directions encountered during filling of the mold. Not only does this create flow lines that would be undesirable from a cosmetic perspective, but it causes the porosity to be unevenly distributed and possibly not interconnected.

Co-Forming with a Compacted Preform

In this approach an insert comprised of a metal powder and a pore-former is created using a non-MIM method. This insert is placed in the mold and the MIM feedstock is molded around it, creating an article with a porous section and a solid section. This method has been successfully prototyped using porous sections formed by cold isostatically pressing a pore-former and titanium powder. After pressing, the compact is green machined into the desired shape, inserted in the mold cavity and the MIM feedstock is injected into and around the insert. Additional features or texture may be machined on the co-formed article after molding. Figure 3 schematically depicts this process.

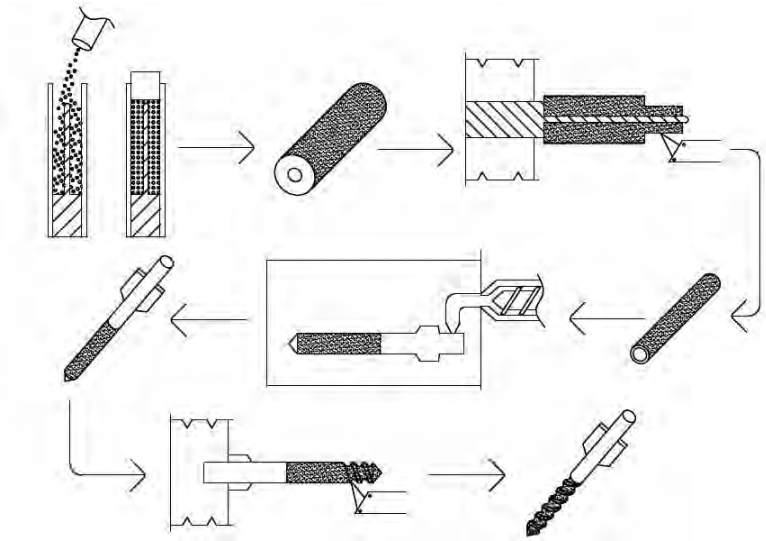

Figure 3: Process schematic of co-forming via insert molding.

This process overcomes several of the challenges of using a MIM feedstock containing pore formers. Because the blend of pore formers and metal powder is compacted, the pore formers can slightly deform into one another, ensuring interconnectivity. The hydrostatic nature of an injection molded article prevents any deformation of the pore-formers into one another. The issue of irregular distribution of porosity is overcome by incorporating homogenizing aids into the blend of metal powder and pore-formers, and stronger porous structures are formed because the porous section is formed without the need for an injection moldable powder/binder system, which allows for higher green densities.

The problem of reduced porosity at the surface is still present but is overcome because outermost layers are removed during machining of the inserts to fit into the injection molding tool. Similarly, the challenge of surface texture can be overcome by adding a texturing operation after the article has been co-formed with MIM feedstock. Texture can be imparted to a green surface via machining or abrasive blasting. Texture is difficult to apply to the insert prior to molding because the green strength of these compacts is quite low compared to typical injection pressure and the insert must have a close, well supported fit within the mold. Again this overcoming these challenges requires additional operations and creating aggressive fixation textures on green articles has its own set of unique challenges.

Photo 4 shows two types of threaded fasteners created using this approach. The upper screw has completely porous threads and a porous coating on the minor diameter. The lower screw has a porous section only at the tip of the threads. The porous sections are 67% porous. To demonstrate the strength of the completely porous threaded section, the upper device was tested in axial static tension and axial cyclic fatigue. In static tension the threads demonstrated a shear strength in excess of 40MPa. To test dynamic fatigue performance the threads were subjected to a cyclic axial load varying between 110kg tension and 110kg compression. The threads were undamaged after 10M cycles.

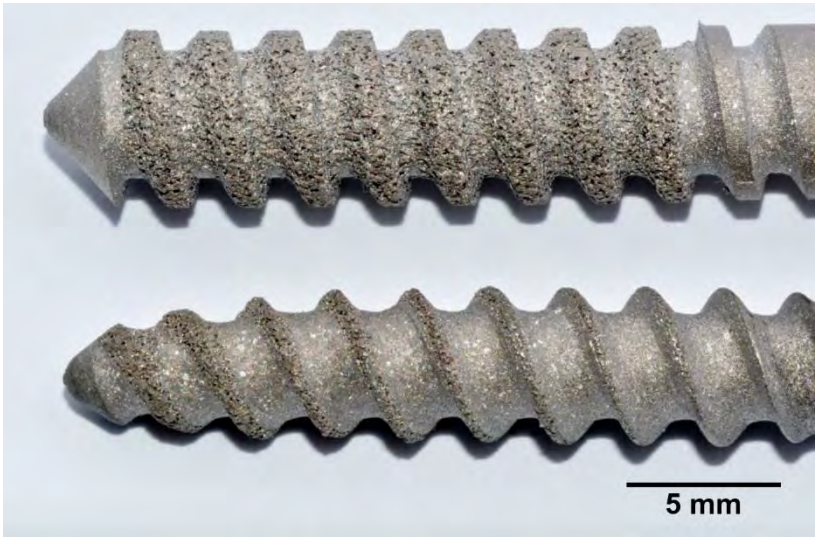

Figure 4: Pedicle screws with co-formed porous threads.

While this approach has been successfully demonstrated, it has significant limitations. The need to machine a precision insert adds cost to the process. Additionally, if the device requires texture, in most cases it will need to be added after the molding step. Finally engineering the shrinkage between two independently formed powder articles is challenging and becomes very difficult as the parts become larger, especially for large flat surfaces.

Co-Forming with a Sacrificial Insert

In order to overcome the issues described above, Praxis has developed a technology utilizing a sacrificial insert to form the integration layer (branded 3DT^{TM}) that enables the co-forming of complex surface during the molding process. The insert is typically comprised of a negative of the desired integration layer and a section to secure it in the mold. MIM feedstock is injected directly against the insert to form the elements of the integration layer. The insert is then removed during subsequent processing, preferably during first stage debinding. Due to the complex nature of these inserts the most practical way to manufacture them is additive manufacturing.

The use of sacrificial inserts with metal injection molding allows specific and simultaneous control over three critical aspects of the integration surface on implanted devices: control of the fixation texture, control of the ingrowth region, and control of the interface between the ingrowth region and the solid substrate. This is a significant advantage over using a porous preform or porous feedstock. While both of these previous methods can provide the porous portion of the integration surface, fixation texture must be formed during a secondary operation and control over the interface region is very limited. As an example, co-forming with a porous preform can overcome many of the challenges of the using a MIM feedstock containing pore-formers, but it cannot provide for netshape texture or control over the nature of the substrate interface.

In addition to unprecedented control over the nature of the various regions of the integration surface, this approach also enables the addition of these surfaces to geometries that are challenging to conventional approaches. Many conventional methods rely on the line-of-sight application of a coating. This can be difficult for geometries with inside surfaces such as a femoral knee or the inside of a monoblock acetabular cup.

When combined with additive manufacturing, this approach can provide for many different types of surfaces useful for orthopedic applications. The primary surfaces we have manufactured using this approach are ongrowth, ingrowth and polymer anchoring.

Ongrowth Surfaces:

Ongrowth surfaces provide an aggressive initial fixation texture without a porous ingrowth medium. There are many examples of this type of surface in the marketplace, most are deposited onto a substrate in a line-of-sight fashion. The 3DT™ technology not only consolidates the forming process into one molding step, but decouples this type for surface from line-of-sight limitations. Figure 5 show a close-up photograph of an ongrowth surface created using a sacrificial insert to form the surface.

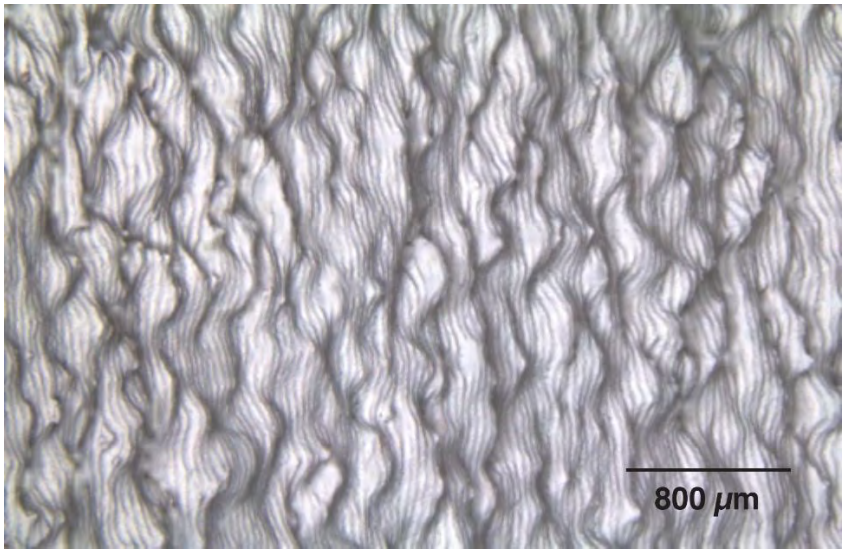

Figure 5: Ongrowth surface created using 3DT™ technology.

Conventional ongrowth surfaces are applied in a coating process and consequently delamination is always a concern. Because the 3DT™ surface is co-formed with the implant body, no interface exists between

the surface and the body, precluding delamination as a failure mode. Also, because the process is not a line-of-sight process, these aggressive textures can be applied to undercuts, inner diameter and other difficult to reach areas. Further, the process is highly repeatable and tailorable.

Ingrowth Surfaces:

Ingrowth surfaces currently provide the fullest expression of the potential of the 3DT™ technology. Fixation texture, ingrowth medium and the substrate interface are all defined precisely, repeatably and independently by different sections of the sacrificial insert. Further, these surfaces can be created on geometries without line-of-sight access. Figure 6 is a photo of a cross-section of an integration surface manufactured using a sacrificial insert.

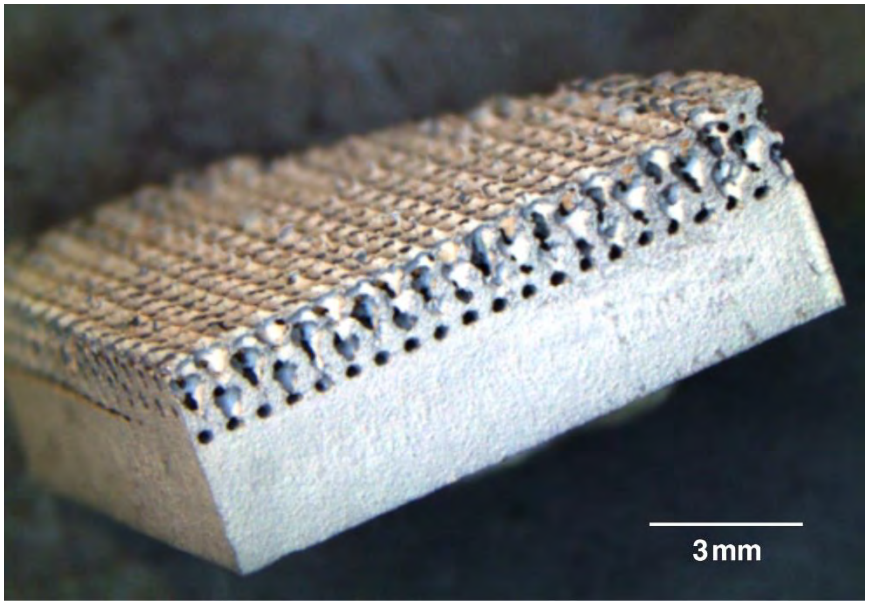

Figure 6: Three dimensional ingrowth surface manufactured using 3DT technology

Figure 7 is a close up of the cross-section in Figure 6. Area A indicates the aggressive net-shape fixation texture, area B indicates the highly interconnected ingrowth medium, area C indicates the tailored substrate interface and area D indicates the substrate.

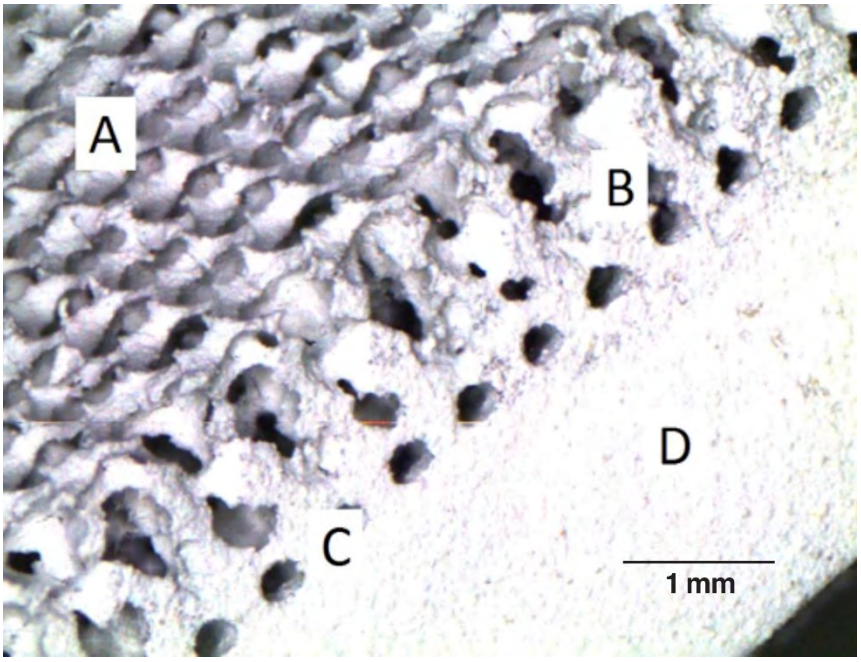

Figure 7: Cross-section of a titanium integration surface manufactured using 3DT™ technology.

Figure 8 is a close-up of a three-dimensional ingrowth surface made using this technology. The pores are highly interconnected and the struts are well formed. The ingrowth medium is 70 percent porous and the major pores have an average diameter of 500 microns and the minor pores have and average interconnecting pore size over 100 microns. Tensile testing performed on these surfaces yielded an average tensile strength of 64MPa.

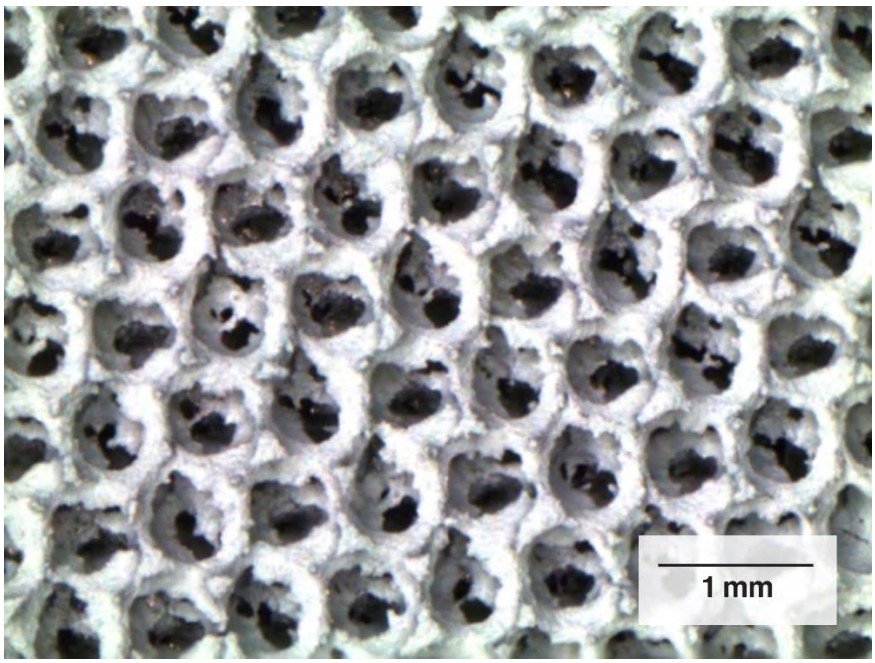

Figure 8: Close-up of highly interconnected ingrowth medium and fixation surface.

The surface depicted in Figure 8 is highly regular and repeating with respect to pore size and location. From a marketing perspective, it is often desired that three dimensional ingrowth surfaces have a less regular and more organic appearance. This can be accommodated by adjusting the program used to generate the sacrificial insert. Figure 9 shows a surface created in this manner; this surface has finer porosity and a much more organic appearance than the surface in Figure 8.

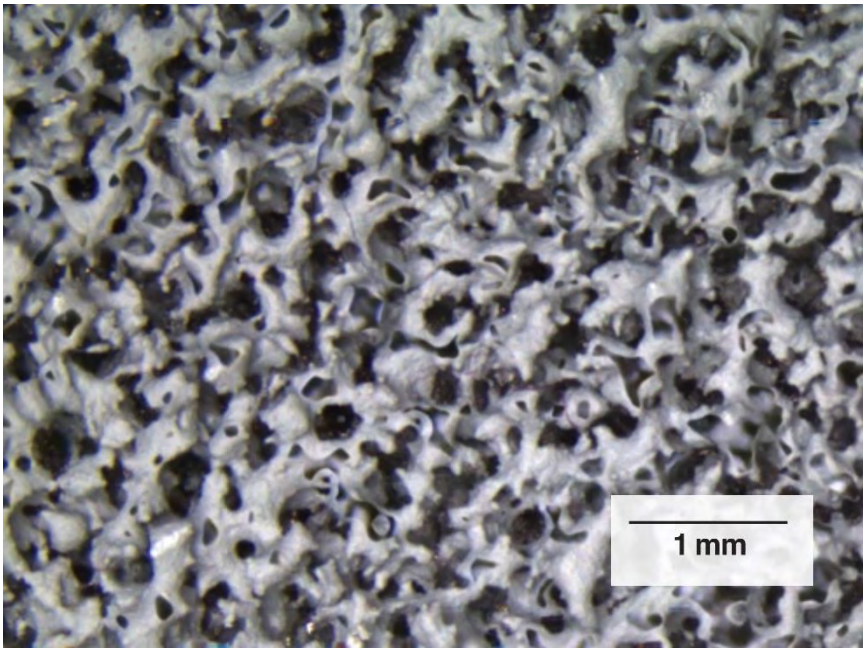

Figure 9:3DT™) surface with finer porosity and more organic appearance.

The 3DT technology has been demonstrated to enable conforming of ingrowth layers on large orthopedic devices. The Figure 10 shows three stages of the 3DT process. The left background shows a green molded part that has been co-molded with a sacrificial insert using an insert molding operation. The right background shows the green part after the sacrificial insert has been removed, and the foreground show the device after being debound and sintered.

Figure 10: TiMIM tibial tray with net-shaped 3DT™ ingrowth surface.

Polymer Anchoring Surfaces

In certain applications, it may be desirable to affix a polymeric wear material to a device. Devices such as these are often referred to as having a unitized or monoblock design. In these designs the polymeric bearing material is molded, formed or otherwise affixed directly against the metal implant body.

With this in mind it is desirable to create a surface on the metal body which the plastic bearing material can be formed against, thus allowing the plastic to form a strong mechanical bond between the molded plastic section and the metal. Typically rough or undercut surfaces are used to form these types of bonds. The 3DT technology is used to create a very complex, heavily interlocked surface on one or multiple sections of a MIM article.

These polymer anchoring layers can be tailored based on the requirements of the device. One variation is an interlocking layer that allows polymer bearing material to be molded into and around it. Figure 11 illustrates an example of this type of surface, where the interlocking layer is approximately 0.024 inches thick. The loops formed on the surface create a strong interlocking surface between the polymer material and the metal substrate.

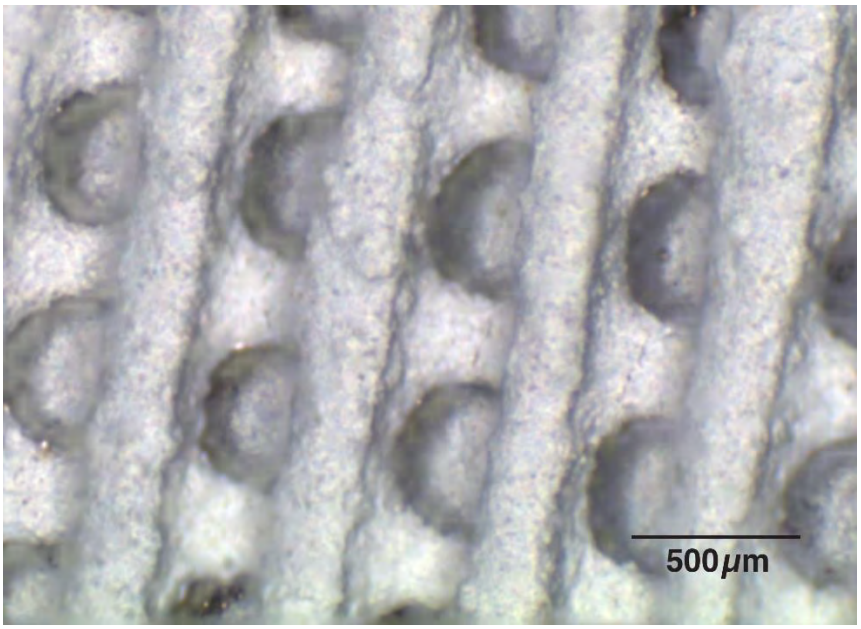

Figure 11- Close-up of an interlocking polymer anchoring surface.

Other types of surfaces can also be employed. Simple undercuts also interlock with the polymer material and are useful in reducing the overall thickness of the anchoring layer. Figure 12 shows a close up of an undercut layer. This layer is approximately 0.014 inches thick.

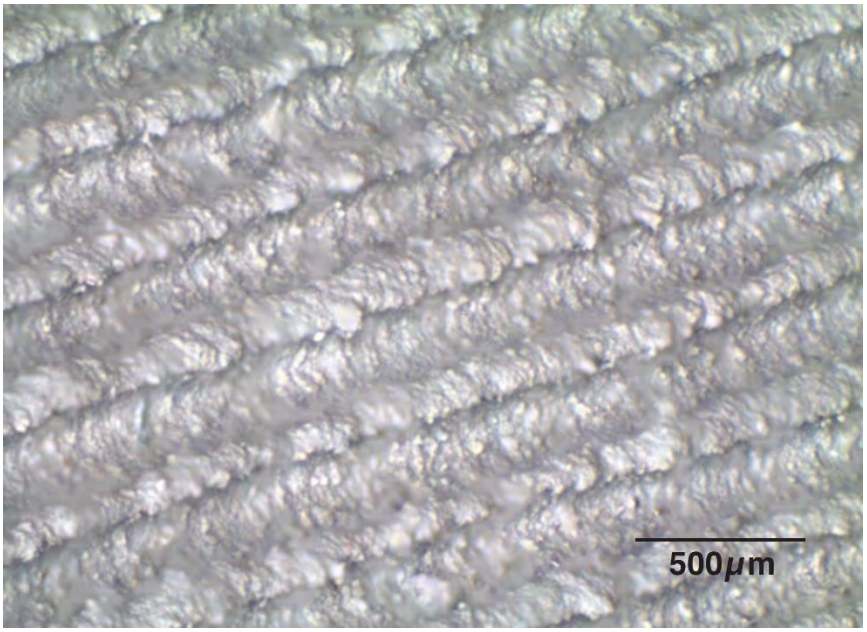

Figure 12- Undercut surface for polymer anchoring

The performance of these layers were demonstrated by compression molding UHMWPE against the surface and subjecting the molded article to tensile bond testing. A cross-section of the molded article

incorporating an interlocking style of anchoring surfaces is shown in Figure 13. This interlocking surface used was similar to the interlocking surface depicted in Figure 11.

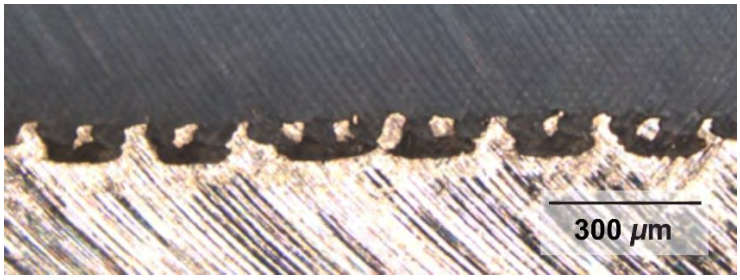

Figure 13- Cross-section of interlocking layer molded with UHMWPE

The mechanical properties of both interlocking surfaces and undercut surfaces were tested. The undercut surfaces had an average tensile strength of 14 MPa and the interlocking surfaces had an average tensile strength of 17MPa.

HIGH CYCLE FATIGUE PERFORMANCE

In addition to desire for complex surfaces, another major challenge to using TIMIM to manufacture orthopedic devices is that conventional TiMIM components do not have adequate fatigue strength for most load bearing applications. When measured by rotating beam fatigue testing, typical fatigue strengths are around 480 MPa (70ksi) at 10 million cycles. The commonly accepted minimum for load bearing applications is around about 620 MPa (90 ksi) at 10 million cycles. In order to overcome this limitation, Praxis developed a processing route to improve the final microstructure of the sintered titanium. This process, branded "TiRx™", provide fatigue strengths in excess of 620 MPa. TiRx achieves this performance while still meeting the chemical and mechanical requirement of ASTM F2885. Figure 14 compares the rotating beam fatigue life conventional TiMIM material and Praxis' TiRx material.

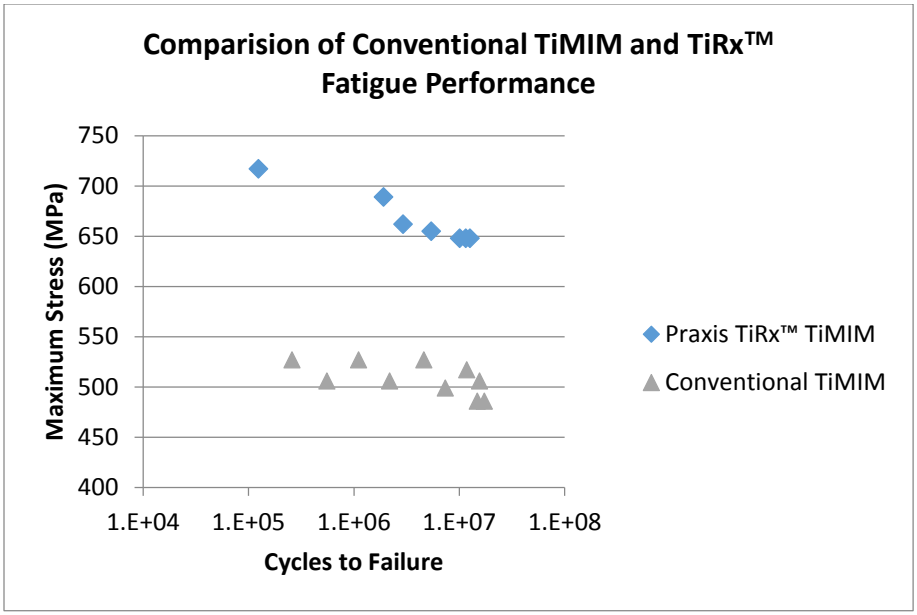

Figure 14: Comparison of high cycle fatigue performance for TiRx and conventional TiMIM.

CONCLUSIONS

In conclusion, implantable grade TiMIM has moved from an academic undertaking to a production capable process. In a validated process, robust capability has been demonstrated with both interstitial contamination and mechanical properties. Further the technology has been augmented to provide fatigue strengths suitable for load bearing implants and economical, net shape integration surfaces.

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1. [i] German, R.M. Progress in Titanium Metal Powder Injection Molding. In *Materials*, **2013**, 6, 3641-3662.