

# LASER Deposited Engineered Surfaces For Orthopedic Implants for Increased Device Longevity

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## Abstract

Increasing the lifespan of orthopedic and dental implants will serve to increase patient health and decrease medical costs by reducing the need for multiple surgeries for a single health issue. Device longevity can be extended by improving the method of fixation to bone tissue by increasing osteointegration. An engineered structured surface was deposited on a Ti-6Al-4V substrate with a Nd:YAG laser with finely screened Ti-6Al-4V or Ti-15Mo powder in an inert atmosphere. The surface, which currently has approximately an 800 $\mu$ m pore size, shows a complete metallurgical bond with the substrate while maintaining a wrought microstructure in the bulk material for higher overall strength without blind pores. The structured surfaces were cleaned and treated for passivation and cultured with osteoblasts. Cell growth was shown to be abundant on the structured surface as well as on the bare Ti-6Al-4V substrate and bone tissue was seen growing in the structured surface after 3 weeks *in vitro*. We have demonstrated that laser deposition is a valid method for creating osteogenic surfaces.

## Introduction

The major joints of the body are prone to damage and wear, and are comprised of tissues that have little regenerative ability. When these joints degenerate to a degree that an individual suffer from pain and loss of mobility, modern medicine now has the ability to replace these worn parts with prosthetic devices restoring comfort and function. However, the capacity of current technologies, as advanced as they may be compared to the first-generation arthroplastic devices, is still insufficient for all patient applications. To that end continuing research in the design of arthroplastic prosthesis is necessary to utilize this technology to its maximum potential. Key to the success of this effort is design of an optimal interface between bone and prosthesis.

It is necessary to take into consideration a number of biological and engineering factors in the design and improvement of arthroplastic prosthesis. Foremost is the issue of biocompatibility which is defined as “the ability of a material to elicit an appropriate biological response in a given application in the body.”<sup>1</sup>

The elastic (Young’s) modulus is a property comparable to biocompatibility in importance for use in orthopedics. The modulus of elasticity is material property quantifying the relationship between an applied stress and the resulting strain and can be qualitatively described as the stiffness of the material. Wolff’s law states “the form being given, tissue adapts to best fulfill its mechanical function.”<sup>1</sup> In orthopedics this may not be accurate and is more properly stated: tissue will adapt to stress to be most efficient in its consumption of resources. A severe difference in elastic modulus between bone and an implanted prosthesis, the modulus of cortical bone is approximately 20 GPa where as the modulus of Co-Cr-Mo alloys is over 200 GPa,<sup>1, 4</sup> can cause some tissue to not be regularly stressed, causing it resorbed by the body. By improving the fixation methodology of the initial device it will prevent resorption and prosthesis loosening.

The alloy most predominate for usage in arthroplastic devices is Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) which has the highest yield and fatigue strength in the as forged condition.<sup>6</sup> There are a few predominate manufacturing methods currently used in production for the creation of porous implant coatings: sintered bead (Fig. 1), fiber metal, and plasma spray. The methods of attaching sintered beads and fibre metal use fine beads or wire mesh that are sintered or diffusion bonded to the device. Plasma spray uses an electric arc and inert gas to create a high temperature plasma which melts a feedstock metal into a jet stream that adheres to the surface of the device.

The limits of these aforementioned technologies are twofold. The diffusion bonding and sintering processes impart such a high heat flux into the device as to anneal the substrate to a

weaker almost cast microstructure. Also, destructive testing has revealed as although these methods can produce as high as 50% porosity with sintered beads and fibre metal, the random orientation of the beads produces a low effective porosity. Many of the pores are blind, being partially or completely blocked by other beads or fibers preventing entrance of osteoblasts into the pores.

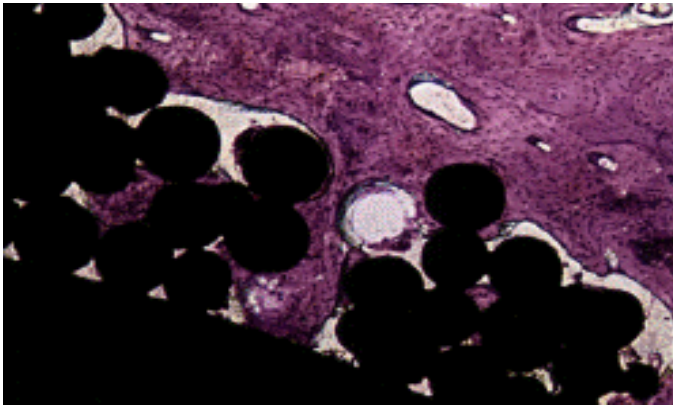


Figure 1: Cut through image of blind porosity and limited osteointegration.<sup>2</sup>

The latest research in developing porous implant coatings is an engineered or structured surface. An engineered surface is deposited on implant which has no blind porosity, a pore size of 50–200 microns, and an anisotropic structure matching the directionality of cortical bone.<sup>4,5</sup> By using a tightly focused laser and a stream of fine pneumatically focused powder in an inert atmosphere, an engineered surface can be successfully deposited.<sup>3</sup> Figure 2 is a graphical illustration of the LASER deposition process showing the 90° offset in subsequent layer buildup and width and thickness of individual beads. Figure 3 is an image of the first generation LASER deposition head and substrate mounting system with the LASER at a power of 300 watts.

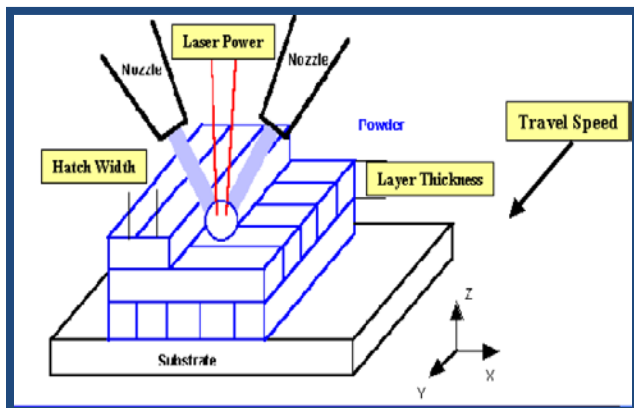


Figure 2: Illustration of LASER deposition process.

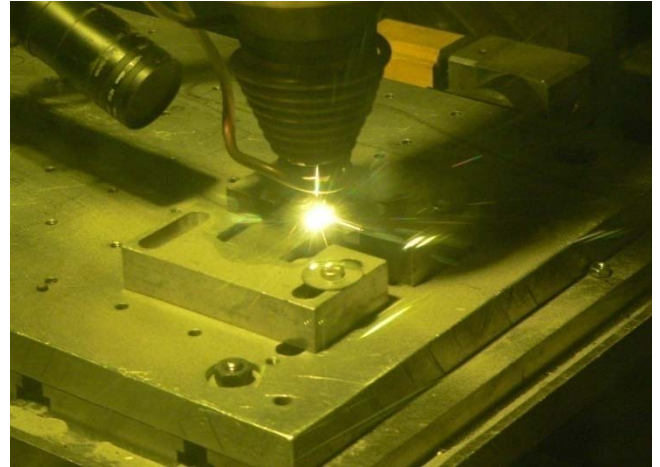


Figure 3: Head and mounting table of the LASER deposition system..

The use of laser technology can create a spot temperature high enough to bond the powder and substrate but with an overall flux low enough as to prevent overall substrate annealing and leave only a thin heat affected zone. This retains the as-forged microstructure throughout the device maintains better properties and performance of the implant.

### Procedure

First generation laser deposition used the following protocols. The initial stage of the study was conducted using Ti-6Al-4V powder screened to -100 +325 mesh (0.152 mm - 0.044 mm diameter), deposited onto a plate of Ti-6Al-4V substrate in an argon atmosphere with an oxygen level less than 50 ppm (averaging 15 ppm). The system used a Nd:YAG laser piped through a 600nm fibre, collimated and focused such that the focal point was 1mm into the substrate onto which the powder was deposited.

To determine the necessary parameters for the deposition of Ti-6Al-4V, the powder was deposited in a simple cross hatch pattern. The spacing between individual beads was set to 1.14mm. Each additional layer was deposited in a direction 90° to the previous layer with a total deposition thickness of 5.1mm. The LASER power was 600 watts.

The spacing of the beads was adjusted to 1.5mm and the power output set to 300 watts. Deposits were continued with the trend of increasing bead spacing and decreasing beam output. To increase the fineness of the features, the laser focus was readjusted from 1mm into the substrate to the surface of the substrate.

The powder was screened to -140+325 mesh (0.104 mm - 0.044 mm diameter). The spacing was increased to 2.0 mm with a 1.8 mm vertical build height. The power output of the first layer was set to 350 watts to insure a good bond to the substrate, with subsequent build up layers deposited at 200 watts.

Second generation testing used the following protocols in the newly created M-LAM (micro-Laser Additive Manufacturing) system. The was conducted using 316 stainless steel powder screened to -100 +325 mesh (0.152 mm - 0.044 mm diameter) and deposited onto a stainless steel plate substrate in an argon atmosphere with an oxygen level less than 200 ppm (averaging 100 ppm). The system used a Nd:YAG laser piped through a 60nm fibre, collimated, and focused to a focal point on the surface of the substrate.

To determine the parameters for the second generation system, multiple lines were deposited at a specific laser power from 85 watts to 285 watts with only a single layer of buildup.

During the secondary testing powder was deposited in a simple cross hatch pattern with spacing of the individual beads adjusted to 0.1 mm with a single layer of deposition and a laser power of 85 watts. The powder was then screened to -200 +325 mesh (0.074 mm – 0.044 mm) and deposited at 85 watts in three separate cross hatch patterns of one, three, and five layers of deposition build up.

Samples from these specimens were mounted in Bakelite, polished to 0.01 micron diamond suspension, etched with Kroll's reagent (2%HF/10%HNO<sub>3</sub>) and observed with optical microscopy.

Samples intended for cell culturing were wire brushed, cleaned and passivated in a 4%HF/40% HNO<sub>3</sub> solution, neutralized in a saturated NaHCO<sub>3</sub> solution, rinsed with water, and then acetone.<sup>7</sup>

The culture methods of first generation samples are as follows. MC3T3-E1 Preosteoblast cells were obtained from American Type Culture Collection, (Manassas, VA), and grown in Alpha MEM medium supplemented with 10% fetal bovine serum. Cells were further processed with *in vitro* Osteogenesis Assay Kit (Chemicon, Temecula, CA) according to supplier's protocol.

## Results

For the first generation samples, the width of the center pores was roughly measured to be slightly less than 1 mm with all pores open to the surface, indicating approximately 50% porosity (Fig 4). Bonding between the beads and the substrate was observed to be good and with a very thin heat affected zone (Fig 5 & 6). Furthermore, the high cooling rate of the

bead produced a very fine cast microstructure in the deposit build up.

Support of osteogenic activity on laser deposition substrates was demonstrated by attachment and growth of MC3T3-E1 cells. Osteogenic activity was demonstrated by Alizarin red-staining of calcified matrix deposited by cells. As was evident by casual observation, abundant bone deposition was seen throughout deposited matrix, especially within wells and on sloping surfaces of the build up.

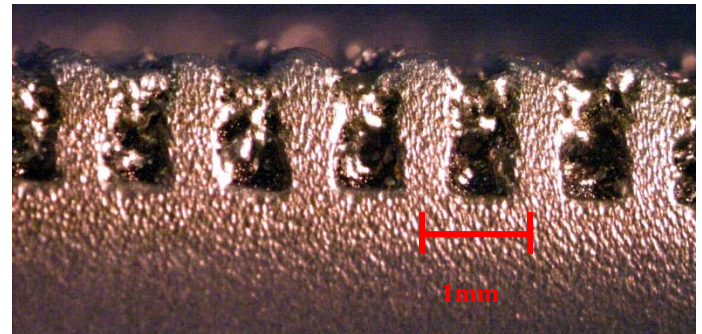


Figure 4: Cross sectional view of first generation sample showing porosity

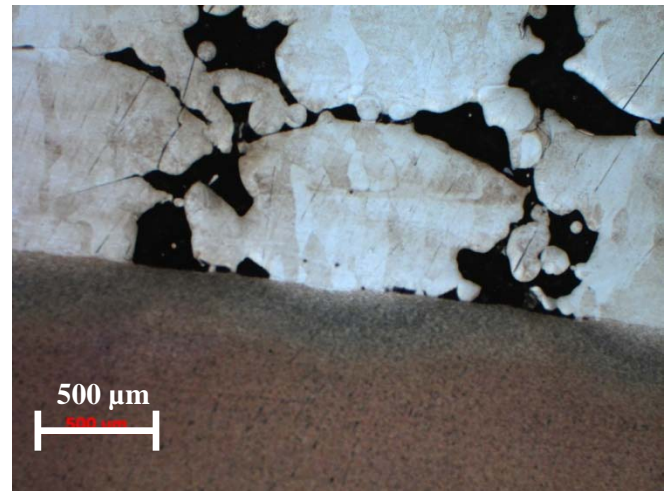


Figure 5: Metallographic image showing narrow heat affected zone

Figure 6 is a brightfield image of a first generation sample after wire brushing, cleaning and chemical passivation prior to cell culturing.

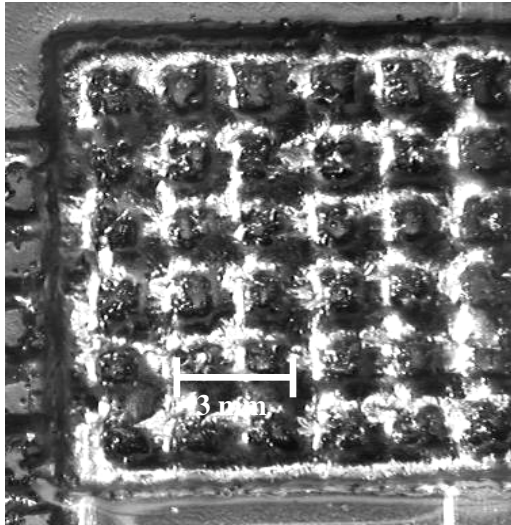


Figure 6: Brightfield top view image of first generation sample using finer screened power after cleaning and passivation

The samples used for testing osteointegration showed positive cell growth. Alizarin red-stained template displays calcified matrix deposited by osteogenic cells after 17 days in culture. As shown in Fig. 7 the heaviest deposits are evident around the periphery, within “wells”, and on sloping surfaces.

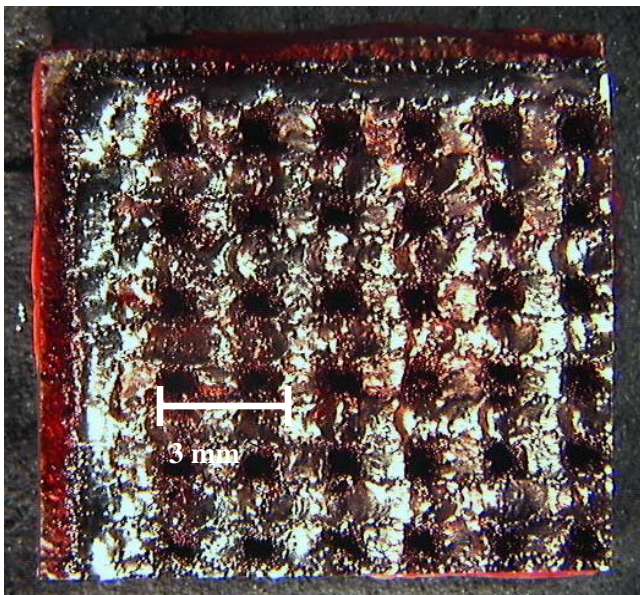


Figure 7: Alizarin Red-stained sample showing cell growth

After three weeks *in vitro*, culturing with osteogenic cells resulted in the growth of calcified bone tissue on the surface of the deposition build up as shown in Fig 8. The cells showed prevalence on the deposited surface and more growth on the edges and in the corners engineered structure than on the exposed substrate around the deposition or in the bottoms of the pores.

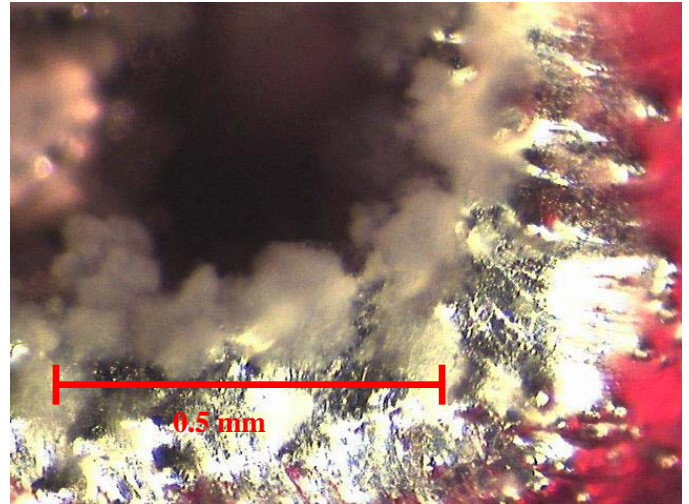


Figure 8: Close up of pore showing calcified bone tissue produced by cells on sloping sides of wells in matrix

Second generation samples showed highly improved resolution and fine pore size by nearly an order of magnitude (Fig 9).

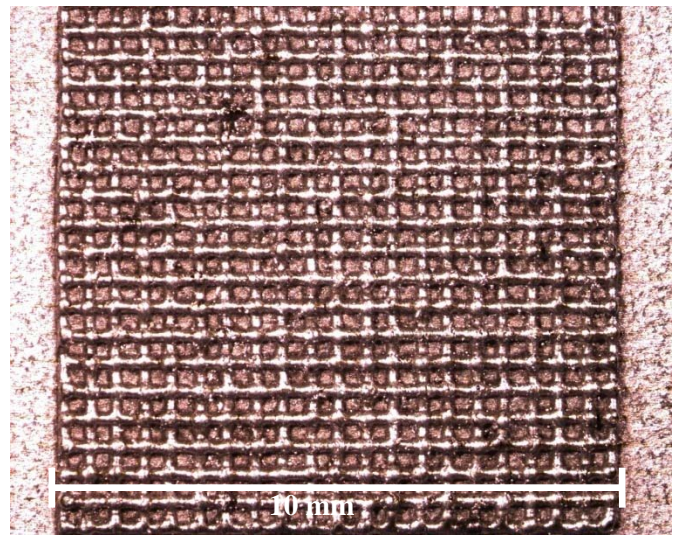
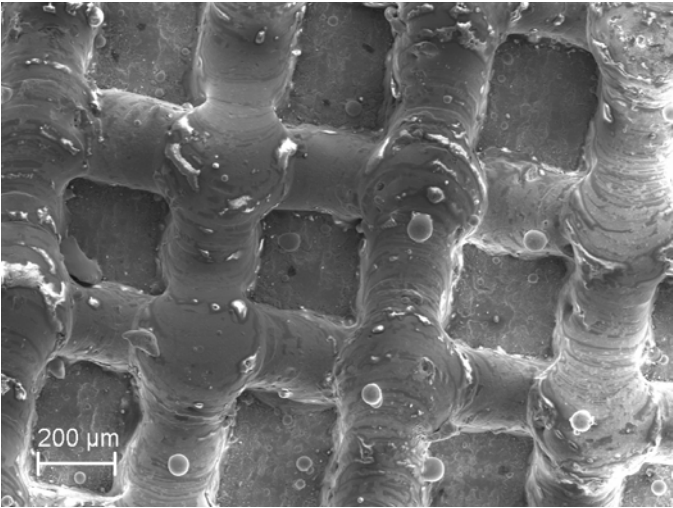


Figure 9: Second generation sample showing a finer pore size compared to Fig. 6.

Scanning electron microscopy of the second generation samples shows consistency in pore size and shape as well as minimal retained powder after build up. The pore size and bead width are approximately 200  $\mu\text{m}$  and consistent in both deposited directions as shown in Fig. 10. The surfaces of the second generation samples show only a little debris and scale, which should be removed, resulting in an improved surface for cell adhesion, by acid cleaning and passivation step.<sup>8</sup>



*Figure 10: SEM image of second generation sample with 200 μm pore.*

### **Summary and Conclusion**

It has been demonstrated that laser deposition provides potential advantages for the creation of osteointegrative surfaces. The feature resolution and consistency capable by M-LAM system is within the optimal pore size for osteointegration. The post cleaned and passivated structure showed a biocompatible surface with the engineered features having preferential growth to the Ti-6Al-4V plate. The heat flux of the LASER deposition process resulted in only a slight change in the substrate microstructure in only the near surface, so that the mechanical properties of the bulk of the substrate remain unchanged. Application of this technology should be researched and developed for orthopedic and dental applications.

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