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A Laser-Aided Direct Metal Tooling Technology for Artificial Joint Surface Coating

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Longevity of cementless arthroplasty is determined by the characteristics of the porous structure formed at the surface. However, currently used artificial joint surface coating technologies have several limitations. Therefore, the goal of this study was to investigate the use of an artificial surface coating technology to overcome the limitations of currently used technologies. An artificial joint surface coating that controls porosity of the porous structure formed at the surface of the artificial joint was developed based on laser-aided direct metal tooling (DMT) technology, which is a three-dimensional (3-D) additive manufacturing (AM) technology. The structural, mechanical, and physical properties of the DMT surface coating was measured in accordance with the international testing standards and compared to titanium plasma spray (TPS) surface coating, a commercially available artificial joint surface coating. DMT exhibited characteristics comparable, if not better, than the existing commercial TPS in terms of mechanical and physical properties. DMT may be useful for cementless artificial joint surface coating required the porosity control of the porous structure formed at the surface of the artificial joint and provides enhanced longevity and patient prognosis compared to the existing surface coating technologies.

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1. Introduction

Cementless arthroplasty is a surgical procedure that provides a biological fixation for joint repair. This procedure is widely known for its durability and enhanced bone preservation compared to cemented arthroplasty. Thus, it is a widely used treatment in young patients.[1–5] Since the stability of cementless arthroplasty is based on the porous structure formed at the surface of the artificial joint, this procedure requires an enough initial fixation force, an excellent adhesive force, and an effective enhancement of biological fixation.[6,7] Osteointegration refers to the process whereby bone grows directly onto or into the implant surface.[8] The design of surface coatings must satisfy several conditions; first, the coating must be biocompatible and not trigger significant immune or foreign-body response; second, it must be its promotion of osteoblasts to adhere to, proliferate and grow on the surface of the implant; third, the implant must be able to recruit various stem cells from surrounding tissue and circulation and induce differentiation into osteogenic cells. Finally, the coating must be have sufficient mechanical stability when under physiological stresses.[9] These can be achieved by offering an optimal porous structure for bone ingrowth by forming a pore shape at the artificial joint surface similar to that of cancellous bone.[6,7]

Commercially available artificial joint surface coatings utilized on cementless arthroplasty include fiber metal sintering, arc welding, and titanium plasma spray (TPS). Clinical and histological evidences from retrieved implants clearly demonstrated that these porous surfaces coatings enhance bone tissue ingrowth and are effective in supplementing the stability of the implant by biological fixation.[10,11] Particularly, TPS surface coating has been shown to perform better than other existing surface coatings. Thus, TPS surface coating is widely used as a surface coating of artificial joints recently.[11,12] This TPS surface coating generally forms a porous structure by the injection of pure titanium powders into high-speed ionized plasma gases under vacuum, which melts the titanium allowing it to rapidly adhere to the artificial joint applied surface.[11] TPS surface coating, however, has its own advantages and disadvantages that can influence long-term clinical results.[10,11]

In artificial joint surgery, osteolysis has been recognized as a major limitation to the long-term survival of artificial joint.[13] Osteolysis was initially referred to as cement disease because it was thought to be the result of cement fragments.[14] It is, however, currently recognized as an inflammatory response to polyethylene (PE) and metallic wear debris. These wear debris are dominantly formed by abrasion on prosthetic joint articulations and modular interfaces of artificial joint.[15] Additionally, when the surface coating on the artificial joint are detached, the detached surface coating fragments are also considered as wear debris on non-articulating interfaces of artificial joint. It is known that wear debris stimulate the production of various bone resorptive cytokines including tumor necrosis factor, interleukin-1, and interleukin-6.[16] These resorptive cytokines induce inflammation, resulting in either direct or indirect loosening of the implant of artificial joint due to osteolysis (bone resorption).[13] Furthermore, several studies[17,18] have reported that the porosity of conventional surface coatings (30~60%) are less than cancellous bones (50~90%).[19] Low porosity reduces the contact strength on the interface between the artificial joint surface and the bone,[20] because of the decreasing contact area. Therefore, a new biomimetic artificial joint surface coating that complements the limitations of available surface coating (e.g., detachment of coating material and low porosity) would be extremely useful.

Laser-engineered net shaping (LENS™) was introduced by Sandia National Laboratories in the late 1990's, generally known as solid freeform fabrication, which can be used to construct total hip arthroplasty by layered manufacturing processes.[21] This process is similar to our technology in that metal particles are fed into laser beams producing three-dimensional parts. However, we determined that our technology would be more economical method compared with LENS™ in relation to manufacturing atmosphere, metal powder retrieval, and capability of additive manufacturing based on substrate including conventional acetabular cup.

To complement the limitations of conventional surface coatings on artificial joint, in this study we proposed an artificial joint surface coating that utilizes laser-aided direct metal tooling (DMT), a three-dimensional (3-D) additive manufacturing (AM) technology, and evaluated the applicability of the use of DMT as a surface coating technology for artificial joint through comparing it with TPS, a commercially available artificial joint surface coating. The advantages of DMT include the ability to adjust porosity and increased surface roughness. Thus, we hypothesized that DMT, due to its advantages, would serve as an optimal or alternative artificial joint surface coating.

2. Materials and Methods

2.1 Artificial joint surface coating utilized laser-aided DMT

For the AM technology-based DMT method, we melted and laminated pure Ti (grade 2, ASTM F1580) metal powders using a relatively inexpensive medical high-powered laser beam on the metal surface of an artificial joint (Fig. 1). The porous structure was then manufactured using a 3-D computer-assisted design (CAD) program that created a sufficient fixation force by matching this material to the properties of cancellous bone from patients. A laser irradiated the surface of the artificial joint by following the path of a pre-programmed grid-shaped tool with 100W laser power, 1.5 m/min scan speed, and 2.2

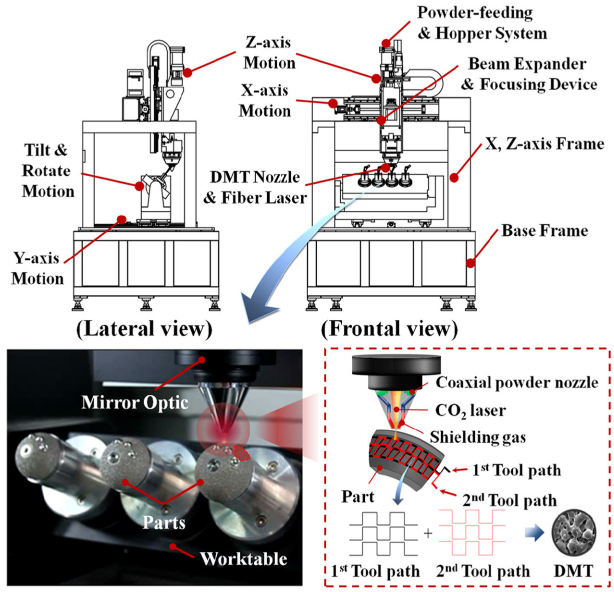

Fig. 1 Schematic drawings of the equipment used in the deposition of a surface layer using the laser-aided direct metal tooling method

g/min power delivery rate which formed a melted pool. Next, metal powders were sprayed and laminated onto the artificial joint surface, which is different from selective laser melting (SLM) and electron beam melting (EBM; an AM technology). In addition, the pre-programmed path allowed the laser to follow the grid-shape in increments of 0.7 mm to increase porosity and irregularity of the shape of the coating. Since metal powder (40~150 μm) was not sprayed uniformly on the path due to the law of inertia, the thickness and width of the formed laminate was irregular (Fig. 1). The above process was repeated twice to laminate the first and second layers using asymmetrical pre-programmed paths. The first coating layer was laminated with an average thickness of 300 μm, while the second layer had an average thickness of 500 μm. The different thicknesses further increased the irregularity of the coating shape.

2.2 Comparative evaluation

2.2.1 Specimen preparation

To investigate the use of DMT, its mechanical and physical properties were compared to TPS, a commercially available artificial joint surface coating. For plasma spray technique, an electric arc was generated between two electrodes in a gun. The arc was heated a gas up to 20,000°C. The gases are accelerated and passed through the jet-shaped anode at a high speed. The powder for the coating was injected into the plasma gas stream, melted and impacted onto the substrate with high kinetic energy. And then Porous coating with varying degrees of porosity can be constructed.[9] These properties were evaluated in accordance with international testing standards.[22-24] Specimens were fabricated using either DMT or TPS, and classified into groups according to the used technology (n = 5 in each group for the tensile test and shear test; n = 6 in each group for the abrasion test and roughness measurement). The substrate used for DMT was titanium alloy (Ti-6Al-4V ELI) and pure titanium (Pure Ti Grade 2, 50~150 μm, ASTM F1580) powders (Titanium Industries, Inc. New Taipei, Taiwan) were laminated

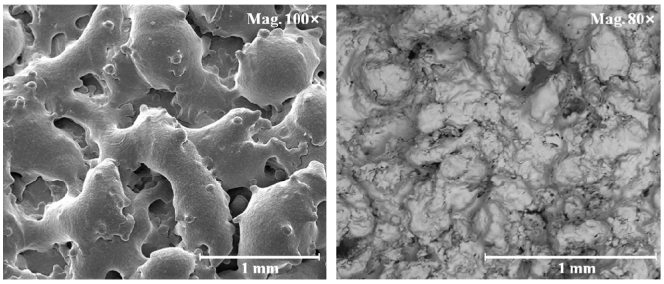

Fig. 2 Morphologies of a DMT coating (left) and TPS coating (right) on a Ti-6Al-4V alloy substrate

over the substrate as a surface coating treatment (average pore size in the coating layer: 200~500 µm, average porosity: 65 ± 5%, and coating thickness: 500 ± 100 µm) (Fig. 2). Here, the average porosity in DMT specimens was considered to create a biomimetic porous structure that is similar to human cancellous bone. We also used titanium alloy and pure titanium powders for surface coating treatment with TPS (average pore size: 50~200 µm, average porosity in the coating layer: 40 ± 5%, and coating thickness: 500 ± 127 µm) (Fig. 2). Here, the average porosity in TPS specimens was considered based on the fact that the porosity of TPS is commonly known as approximately 43%.[25] The mechanical and physical properties of the specimens were evaluated in accordance with international testing standards[22-24] (Fig. 2).

2.2.2 Measurement of mechanical properties

2.2.2.1 Static tensile test

Static tensile tests were conducted using a universal testing machine (Servohydraulic Test Frame, Endolab, Germany) in accordance with the international testing standard ASTM F1147[23] for both DMT and TPS specimens (n = 5 per group). For this test, DMT or TPS and non-coated specimens were bonded by adhesive, which had a minimum adhesive strength ≥ 34.5 MPa. Loads were applied at a constant speed of 0.25 cm/min, and static tensile tests were conducted until the coating layer was completely separated from the substrate.

2.2.2.2 Static shear test

Static shear tests were conducted using a universal testing machine (Servohydraulic Test Frame, Endolab, Germany) in accordance with the international testing standard ASTM F1044 [22] for DMT and TPS specimens (n = 5 per group). For this test, DMT or TPS and non-coated specimens were bonded by adhesive, which had a minimum adhesive strength ≥ 34.5 MPa. Loads were applied at a constant speed of 0.25 cm/min, and static shear tests were conducted until the coating layer was completely separated from the substrate.

2.2.2.3 Static abrasion test

Static abrasion tests were conducted using a wear measuring device (Taber® Rotary Platform Abraser Model 5135, Taber Industries, USA) in accordance with the international testing standard ASTM F1978[24] for DMT and TPS specimens (n = 6 per group). For the abrasion test, wear loss was calculated as the wear amount (Δw_n) that occurred during each rotation of the abrading wheel (2, 5, 10, and 100 cycles). After ultrasonic cleaning and drying for 30 min, Eq. (1) was used to calculate

Table 1 Results of the static tensile and shear tests for DMT and TPS specimens

	DMT coating	TPS coating	p
Tensile strength	60.5 ± 1.2 MPa	51.5 ± 11.6 MPa	0.12
Shear strength	46.3 ± 1.9 MPa	42.0 ± 0.6 MPa	0.0004
Roughness measure (Ra)	62.5 ± 1.8 µm	46.8 ± 7.9 µm	0.005
Roughness measure (Rz)	316.1 ± 7.2 µm	224.9 ± 25.8 µm	0.0001

the wear loss:

$$\Delta w_n = \langle w_o \rangle - \langle w_n \rangle \tag{1}$$

where n refers to the number of cumulative cycles, Δw_n refers to the cumulative wear during n cycles, $\langle w_o \rangle$ refers to the mean of three measurements of the specimen mass at the start of the test, and $\langle w_n \rangle$ refers to the mean of three measurements of the specimen mass during n cycles.

2.2.3 Roughness test for physical analysis

Roughness tests were conducted using a surface roughness measuring device (Surfcom 1400D, Accretech, Tokyo, Japan) in accordance with the international testing standards ISO 4288.[26] This involved ensuring that the acetabular cup was fixed and then the stylus of the device was scanned over the coating on the side of the cup except for the screw holes (measuring section length was 12.5 mm) for all specimens. Two surface roughness parameters were determined, namely Arithmetic average roughness, Ra and Maximum roughness depth, Rz. For more information, Ra refers to the arithmetic mean deviation of the absolute ordinate value from a mean line, and Rz refers to the difference between the maximum profile depth above and below a mean line. For each of the coatings, 7 specimens were used (n = 7).

2.3 Statistical analysis

To identify significant differences between DMT and TPS technologies with regard to structural, mechanical, and physical properties, we conducted paired t-tests using SPSS software (SPSS version 24.0, SPSS Inc., USA). A p-value < 0.05 was taken to indicate statistical significance.

3. Results

3.1 Mechanical characteristics (tensile, shear, and abrasion)

The average maximum tensile strength of the DMT specimen was 48.6 ± 4.3 MPa, which was approximately 6% lower than that of the TPS specimen (51.5 ± 11.6 MPa) ($p < 0.05$) (Table 1). In contrast, the static shear test results showed that the maximum shear strength of DMT and TPS specimens were 46.3 ± 1.9 MPa and 42.0 ± 0.6 MPa, respectively, which were not statistically different ($p > 0.05$) (Table 1). However, we verified that the average maximum tensile and shear strength of DMT and TPS specimens satisfied the minimum tensile strength (≥ 22 MPa) and shear strength (≥ 20 MPa) recommended by the international testing standards. In addition, from the failure mode, we verified that failures in DMT specimens occurred mainly at the adhesive interface between the coated specimens and non-coated specimens. However, failures in TPS

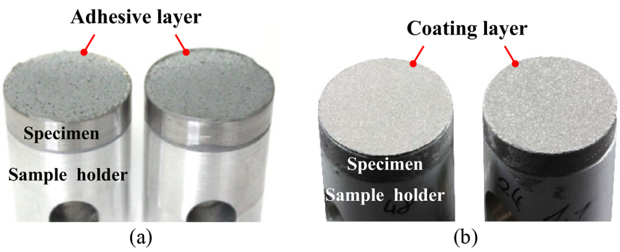

Fig. 3 Failure mode observed in DMT and TPS specimens. Failure at the adhesive interface between the coated specimens and non-coated specimens in DMT specimens (a) and failure at the coating layer rather than at the adhesive interface in TPS specimens (b)

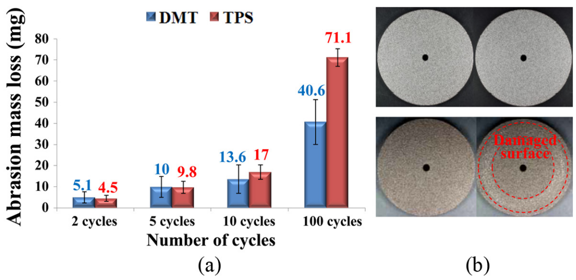

Fig. 4 Summary of the abrasion test results: mass loss (a) and state of the surface of DMT-coated (top) and TPS-coated specimens after 100 cycles (b)

specimens occurred at the coating layer and adhesive interface (Fig. 3).

The results from the wear test showed that DMT specimens (2 cycles, 5.1 ± 2.6 mg; 5 cycles, 10.0 ± 4.9 mg; 10 cycles, 13.6 ± 6.7 mg; 100 cycles, 40.6 ± 10.6 mg) had less wear than TPS specimens (2 cycles, 4.5 ± 1.4 mg; 5 cycles, 9.8 ± 2.8 mg; 10 cycles, 17.0 ± 3.4 mg; 100 cycles, 71.1 ± 4.2 mg) at 10 and 100 of the abrading wheel rotation cycle ($p < 0.05$) (Fig. 4(a)). UP to 10 cycles of the abrasion wear test, the difference in amount of abrasion wear when a DMT coating was used was not significantly different from that when a TPS coating was used; however, the difference was significant after 100 cycles of testing, we showed that after 100 cycles, the wear of the DMT specimen (40.6 ± 10.6 mg) was 42.9% lower than the TPS specimen (71.1 ± 4.2 mg) (Fig. 4(a)). Furthermore, at the end of the tests, surface damage was visually apparent on TPS coatings but not on DMT coatings (Fig. 4(b)).

3.2 Physical characteristics (roughness)

The results of the representative roughness profile is shown in Table 1. Our results indicate that both the Ra (77.1 ± 11.5 μm) and Rz (370.5 ± 56.5 μm) values for DMT specimens were higher than the Ra (48.9 ± 3.9 μm) and Rz (251.5 ± 20.6 μm) values for the TPS specimens, by approximately 57.7% and 47.3%, respectively ($p < 0.05$) (Table 1).

4. Discussions

Average porosity (65 ± 5%) of DMT specimens considered in this study was within the range of porosity for human cancellous bone (50~90%), but that (40 ± 5%) of TPS specimen was not a little. Also, in spite of weakness of mechanical and physical characteristics of coating structure that can be induced by approximately 1.6 times higher porosity of DMT specimens compared with that of TPS specimens, DMT specimens exhibited characteristics comparable, if not better, than the existing commercial TPS specimens in terms of mechanical and physical properties. These may indicate that DMT creates a more proper biomimetic porous structure with desirable mechanical and physical characteristics, compared with TPS. Therefore, DMT was regarded as a more appropriate surface coating technology for cementless arthroplasty than the existing TPS technology. Furthermore, since DMT can control porosity, it may be utilized to create a patient-specific porous structure on cementless arthroplasty.

Analysis of the mechanical characteristics showed that the maximum tensile and shear strengths of DMT specimens satisfied the criteria recommended by the international testing standards ASTM. Furthermore, the results of analysis using DMT coating were comparable that of TPS coating. In particular, we verified from the failure mode that failures in the DMT specimens occurred mainly at the adhesive interface between the coated specimens and non-coated specimens. However, failures in TPS specimens occurred at the coating layer rather than at the adhesive interface. These results indicate that using TPS on arthroplasty may increase the chance of failures at the coating layer itself rather than the adhesive interface between the substrate and coating layer compared to DMT. When fractures occur at the coating layer, debris separated from the coating layer forms, subsequently loosening the implant directly. In addition, the debris can cause inflammation inside the bones loosening the implant indirectly due to bone resorption.[13] The results from the wear test showed that the DMT specimen had reduced wear compared to the TPS specimen regardless of the rotation cycle of the abrading wheel. For example, when an abrading wheel was rotated for 100 cycles, there was approximately 40% less wear for the DMT specimen compared to the TPS specimen. Furthermore, when specimens were visually inspected following the test, no damage on the DMT specimen was observed, whereas we observed damage in the shape of a circular strap on the specimen. Thus, comparison of these results indicated that DMT may have increased resistance to abrasion compared to TPS. Conclusively, DMT may be more appropriate for implant surface coating than TPS with regard to mechanical performance; i.e., DMT used on arthroplasty may result in enhanced mechanical performance compared to TPS, ultimately resulting in an improved patient prognosis.

Analysis of the results of the physical properties showed that DMT specimens had increased roughness compared to TPS specimens. These results indicate that DMT technology may induce osseointegration with cancellous bones more efficiently when implanted in the human body.[27] Furthermore, the efficient induction of osseointegration may increase initial fixation after implantation, thereby increasing the longevity of arthroplasty. Thus, compared to existing TPS, DMT used on arthroplasty may be a more beneficial and effective approach.

This study had a few limitations. First, our sample size was relatively small. Second, our tests were limited to the evaluation of mechanical and physical properties, which lacked evaluation of biological characteristics. Finally, we believe it will be necessary to conduct follow-up studies evaluating this application in clinic. Thus, additional in-depth studies will be necessary in the future to address the abovementioned limitations. Currently, we are in the process of performing follow-up studies focused on a few of these limitations, such as the biological characteristics. Nonetheless, we believe the results from the current study are valuable for several reasons: first, we proposed an alternative artificial joint surface coating based on DMT technology to overcome the limitations of the existing commercial surface coating; and second, we investigated DMT technology by analyzing its mechanical and physical characteristics.

5. Conclusions

The essential features of an additive manufacturing, namely, direct metal tooling (DMT), used for depositing a porous surface coating on Ti-6Al-4V alloy substrates, was presented. Properties of this coating were compared to those of coatings deposited using plasma spraying in air (TPS), which is a popular method used to deposit surface coatings on parts of implants used in cementless arthroplasties. While the thicknesses of the DMT and TPS coatings were comparable, DMT coatings had larger pores, were more porous, were rougher, and more resistant to abrasion wear than TPS coatings.

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