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Applicability evaluation of direct metal tooling-based additive manufacturing for reducing ceramic liner fracture in total hip arthroplasty

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ABSTRACT

Recently, the combination of a press-fit acetabular cup and ceramic articulation has been widely used for implanting cementless acetabular components and has been shown to provide good initial stability. However, this combination may lead to the failure of ceramic liners by their non-concentric seating due to acetabular cup deformation. To reduce the risk of this, we applied direct metal tooling (DMT)-based additive manufacturing (AM) with the hypothesis that DMT-based AM would minimize the deformation of the acetabular cup by increasing its strength, which would ultimately prevent the ceramic liner from fracturing. To confirm this, we performed post-fatigue tests simulating a press-fit situation for the acetabular cups subjected to DMT-based AM and compared them with the cups treated with titanium plasma spray (TPS). The post-fatigue tests were then performed under a maximum load of 14 kN for 20×10^7 cycles. The roundness and inner diameter of the cups and liners were measured in all testing phases. The results revealed no differences between the acetabular cups subjected to DMT-based AM and TPS. However, when comparing only the mean values directly, the results for the acetabular cup subjected to DMT-based AM indicated that it might have increased the strength of the acetabular cup, compared with those treated with TPS, thereby minimizing the possibility of fracture of the ceramic liner. In conclusion, DMT-based AM was shown to be at least equivalent to TPS, or could possibly supersede it. Additionally, via DMT-based AM, it is possible to control the porous structure freely, so this approach allows a greater range of applications and potential for further improvement than TPS.

1. Introduction

Ceramic-on-ceramic (COC) bearings were first introduced by Boutin in 1970 in total hip arthroplasty (THA). Currently, COC bearings are widely used worldwide with metal-on-polyethylene (MOP) and metal-on-metal (MOM) bearings and are known to be associated with excellent clinical results [1–3]. These COC bearings are known to have many advantages. Among them, the ceramic material has an advantage of a very low wear rate compared with other bearings because of its wettability, low roughness ($R_a = 0.02\,\mu m$), and high surface hardness, which is reported to be a very important factor in the successful prognosis of THA [4]. In clinical practice, COC bearings are known to exhibit linear wear rates of 0.016–0.025 mm/year, which is about 1/4000 of that of MOP bearings [5–7]. Additionally, wear particles generated from COC bearings are reported to have superior biocompatibility to those of other bearings [3,7]. For example, Nizard et al. [8] measured the production of tumor necrosis factor alpha (TNF-α) and cytokines, which are known to be responsible for osteolysis, in this context; they found that when the macrophage responses to alumina and microparticulate debris (microparticle debris) were compared, the alumina microparticulate debris was associated with the release of 8–10 times more TNF-α than the polyethylene microparticulate debris. These results are supported by many long-term clinical studies, which have reported far fewer osteolysis-related problems in THA when COC bearings are used [4,6,8–10]. However, despite these numerous advantages, problems with COC bearings are still being reported, such as

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fracture [1,4,10–12], squeaking [13–15], and dislocation [3]. Fracture of the ceramic liner is the greatest disadvantage of COC bearings; the main causes of this have been reported to be the brittleness inherent to the ceramic, incorrect seating of the liner during taper locking inside the cup, and non-concentric seating of the liner due to acetabular cup deformation [3]. Among these factors, it is known that the non-concentric seating of the ceramic liner occurs when the liner is inserted into an elliptically deformed acetabular cup and is due to the acetabular cup press-fitting occurring when the acetabular cup is inserted into a relatively bony rigid acetabulum [16]. This non-concentric seating due to acetabular cup deformation may result in high stresses in the dome and taper areas of the ceramic liner, possibly resulting in fracture of the ceramic liner and chipping or fragmentation at the liner rim area [16].

The mono-block type, which provides a pre-combined acetabular cup and ceramic liner, is thus far the only proposed approach for reducing acetabular cup deformity [17]; however, to date, only short-term clinical results for this method have been published, while long-term clinical results require continuous observation [18]. Recently, Shin et al. [19,20] applied additive manufacturing (AM) based on the direct metal tooling (DMT) to the surface of an acetabular cup, as a potential replacement of the existing porous coating technology such as titanium plasma spray (TPS). The DMT-based AM similar with laser-engineered net shaping (LENS™) is a technology in which a titanium alloy base material of an acetabular cup is irradiated with a laser to make a molten paste, while at the same time pure titanium powder is injected into a molten pool or melted into a molten pool by direct irradiation with a laser; as a result, this method can induce bonding of the acetabular base material and titanium powder, as if they had been welded together [19–26]. This technology is expected not only to reduce the elliptical deformation of the acetabular cup by increasing its strength, but also to reduce the decrease in the diameter in the acetabular cup rim area, which occurs due to the melting and fusing of the base metal and titanium powder. However, few quantitative studies have investigated on the possibility of preventing ceramic liner fracture by minimizing the deformation of the acetabular cup by increasing the actual acetabular cup strength.

This study was established with the goal of verifying the hypothesis that DMT-based AM would minimize the deformation of the acetabular cup by increasing its strength, which would ultimately prevent the ceramic liner from fracturing. For this purpose, we attempted to verify the hypothesis proposed in this study by analyzing and comparing the changes in roundness and inner diameter before and after the application of a fatigue load to ceramic liners inserted into an acetabular cup to which the commonly used TPS or DMT-based AM had been applied.

2. Materials and methods

2.1. Specimens

A total of 12 acetabular cups to be used in this study were prepared using Ti6AL4V ELI, in accordance with ASTM F136. Acetabular cups with a diameter of 52 mm (rim thickness: 3.4 mm and pole thickness: 3.5 mm), which had the thinnest wall, were selected for use here. For the ceramic liner and ball head, a 36/44 liner and a 36-mm-diameter ball head were used, which are the specifications combinable with the selected acetabular cup.

2.2. Applications of titanium plasma spray (TPS) and direct metal tooling (DMT)-based additive manufacturing (AM)

Six of the 12 acetabular cups were coated with TPS, while the remaining six were coated by applying DMT-based AM. The thickness of the coating on the acetabular cup surface was 0.5 ± 0.127 mm ($p > 0.05$) (Fig. 1).

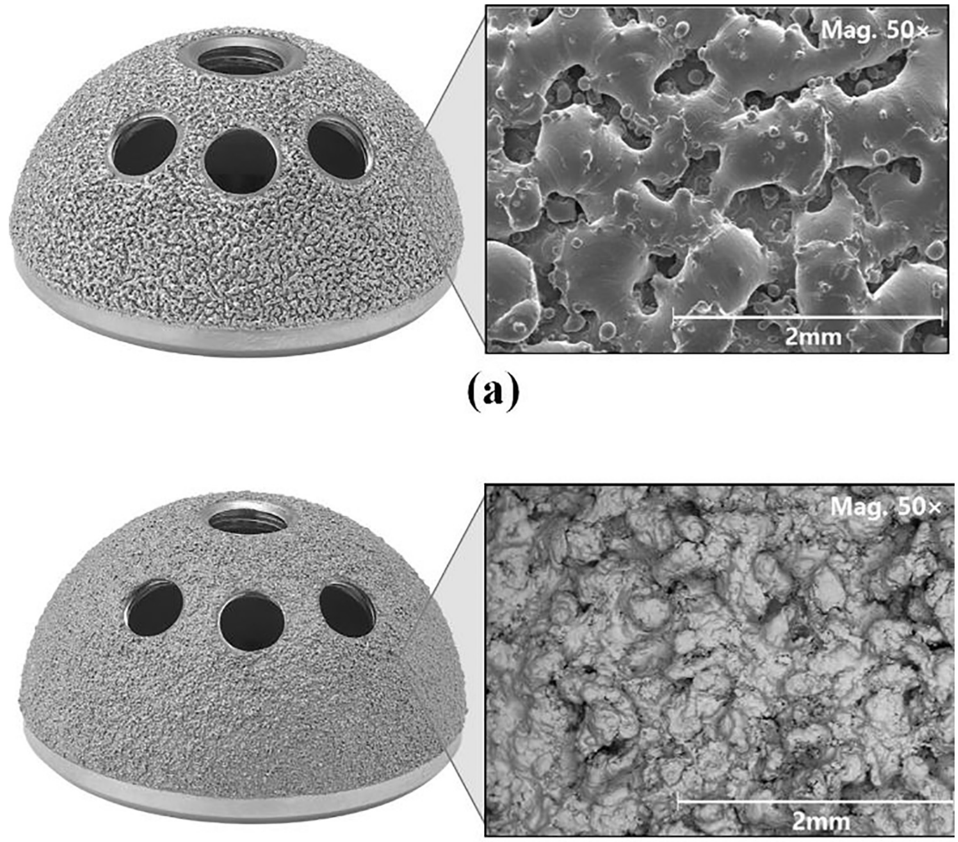
In the case of TPS, pure Ti (grade 4, ASTM F1580) metal powder was melted using a high-temperature, high-speed ionized plasma gas and attached to the acetabular cup. For DMT-based AM, we melted and laminated pure Ti (grade 2, ASTM F1580) metal powder using the beam of a relatively inexpensive high-powered medical laser on the metal surface of an artificial joint (Fig. 2). The porous structure was then manufactured using a 3D computer-assisted design 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, which formed a melted pool. Next, metal powder was sprayed and laminated onto the artificial joint surface.

2.3. Evaluation of acetabular cup deformation following fatigue loading

To reproduce the deformation of the acetabular cup, the acetabulum of the pelvis where the acetabular cup can be fixed was modeled using polyurethane (PU) foam blocks (ASTM F1839 Grade 30, Sawbones; Pacific Research Laboratories, Vashon, WA, USA) [27]. At this time, to reproduce the worst-case scenario of acetabular cup deformity, hemispherical holes in which the acetabular cup could be seated in the PU foam block were made smaller than the external diameter of the acetabular cup. For the difference in dimensions from the acetabular cup, the acetabular cup was used by applying the largest difference of 2 mm in general surgical technology. Additionally, a final worst-case scenario for acetabular cup deformation was achieved by further reaming of the PU foam block in the superior and inferior directions of the acetabular cup. This was performed to simulate the compression being applied to the acetabular cup by high-density bone in the ischial and ilium directions when the actual acetabular cup is inserted into the acetabular cup (Fig. 3) [28].

Before the fatigue test, an acetabular cup and a liner were sequentially inserted into a PU foam block to simulate the insertion of an acetabular cup and a ceramic liner into the acetabulum of an actual patient. The roundness and inner diameter of all of the acetabular cups and ceramic liners were measured primarily using a 3D coordinate measuring machine (CONTURA G2 RDS; Carl Zeiss, Jena, Germany) before the insertion of the acetabular cup and the ceramic liner. The roundness and inner diameter were measured at the following locations: two levels (E1, E5) for the acetabular cup and three levels (E2, E3, E4) for the ceramic liner (Fig. 4). After the initial measurements of the roundness and inner diameter of the acetabular cup and ceramic liner, the acetabular cup was inserted into the prepared PU foam block using 5–10 strokes with a mallet, as in an actual operation. The degree of deformation of the acetabular cup due to its insertion was confirmed by measuring the roundness and inner diameter a second time at the same locations as in the primary measurement. As the last step, the ceramic liner was lightly pushed into the acetabular cup and placed in the same position as in an actual operation, lightly striking it with a mallet. After the insertion was completed, the roundness and inner diameter of the ceramic liner were again measured at the same position as in the primary measurement, and the degree of deformation of the ceramic liner due to its insertion was confirmed.

A fatigue test was performed to evaluate the deformation of the acetabular cup and ceramic liner: the weight of a human body was applied for a long time after they were inserted into the PU foam block. At this time, a poly(methyl methacrylate) resin (Vertex Dental, Zeist, Netherlands) was placed inside a jig made of stainless steel to fix a PU foam block on which an acetabular cup and a ceramic liner were seated to the lower part of a universal material testing machine (Instron 8872; Instron System Corp., MN, UK). Additionally, a ceramic ball head for applying the load to the ceramic liner was fixed to the upper part of the testing machine and other areas, but the axis to which the load was applied was allowed to move freely, so that no load except for the axial load was added (Fig. 5). With regard to the conditions of fatigue loading, a cyclic loading of 0.5–14 kN was applied in accordance with FDA guidelines and 20 million cycles were applied, which corresponded to the gait cycle for about 20 years following the insertion of an



(a)

(b)

Fig. 1. Test specimens of the acetabular cups treated with (a) DMT-based AM and (b) TPS and their scanning electron microscopy (SEM; model TM3030, HITACHI, Japan) images.

artificial hip joint into a human body [29]. Finally, after the final fatigue test was completed, the roundness and inner diameter of the ceramic liner were measured at the same position as in the primary and secondary measurements and compared with the results before the fatigue test (results of the primary and secondary measurements).

2.4. Statistical analysis

To identify significant differences between TPS and DMT-based AM with regard to coating thickness and dimensional deformation, we conducted paired *t*-tests using SPSS software (SPSS version 24.0; SPSS Inc., Chicago, IL, USA). A *p*-value < 0.05 was taken to indicate statistical significance.

3. Results

The roundness of the acetabular cup and ceramic liner was measured before and after insertion of the acetabular cup and ceramic liner into the PU foam block, as well as after the fatigue test, as shown in Fig. 6. Before insertion of the acetabular cup into the PU foam block, the mean roundness of the acetabular cup subjected to DMT-based AM was slightly higher than that of the acetabular cup treated with TPS, by about 4–8 μm based on measurement position ($p < 0.05$), whereas the roundness of the ceramic liner measured before insertion into the acetabular cup did not differ significantly at any measurement position ($p > 0.05$). Immediately after the insertion of the acetabular cup into the PU foam block, there was no significant difference between the roundness of the acetabular cup treated with DMT-based AM and that of the acetabular cup treated with TPS ($p > 0.05$). The roundness of the ceramic liner measured after being inserted into the acetabular cup treated with DMT-based AM was lower than that of the liner treated with TPS, but this difference was not significant ($p > 0.05$). Even after insertion of the acetabular cup into the PU foam block and application of the fatigue load, the roundness of the ceramic liner inserted into the acetabular cup treated with DMT-based AM was lower than that of the ceramic liner inserted into the acetabular cup treated with TPS, but the difference was not significant ($p > 0.05$). After applying the fatigue load, because the ceramic liner was inserted into the acetabular cup, it was not possible to measure the roundness of the acetabular cup.

Fig. 7 shows the inner diameters of the acetabular cup and ceramic liner measured before and immediately after the insertion of the acetabular cup and ceramic liner into the PU foam block, as well as after the fatigue test. Before the insertion of the acetabular cup into the PU foam block, the inner diameter of the acetabular cup treated with DMT-based AM did not differ significantly from that of the acetabular cup treated with TPS, at all measurement points ($p > 0.05$). The inner diameter of the ceramic liner measured before insertion into the acetabular cup also did not differ significantly at any measurement position ($p > 0.05$). Immediately after insertion of the acetabular cup into the PU foam block, the inner diameter of the acetabular cup treated with DMT-based AM and the inner diameter of the acetabular cup treated with TPS did not differ significantly ($p > 0.05$). Furthermore, the inner diameter of the ceramic liner inserted into the acetabular cup did not differ significantly ($p > 0.05$). Even after the acetabular cup had been inserted into the PU foam block and the fatigue load had been applied, the inner diameter of the ceramic liner inserted into the acetabular cup treated with DMT-based AM did not differ significantly from its TPS-treated equivalent ($p > 0.05$). After applying the fatigue load, because the

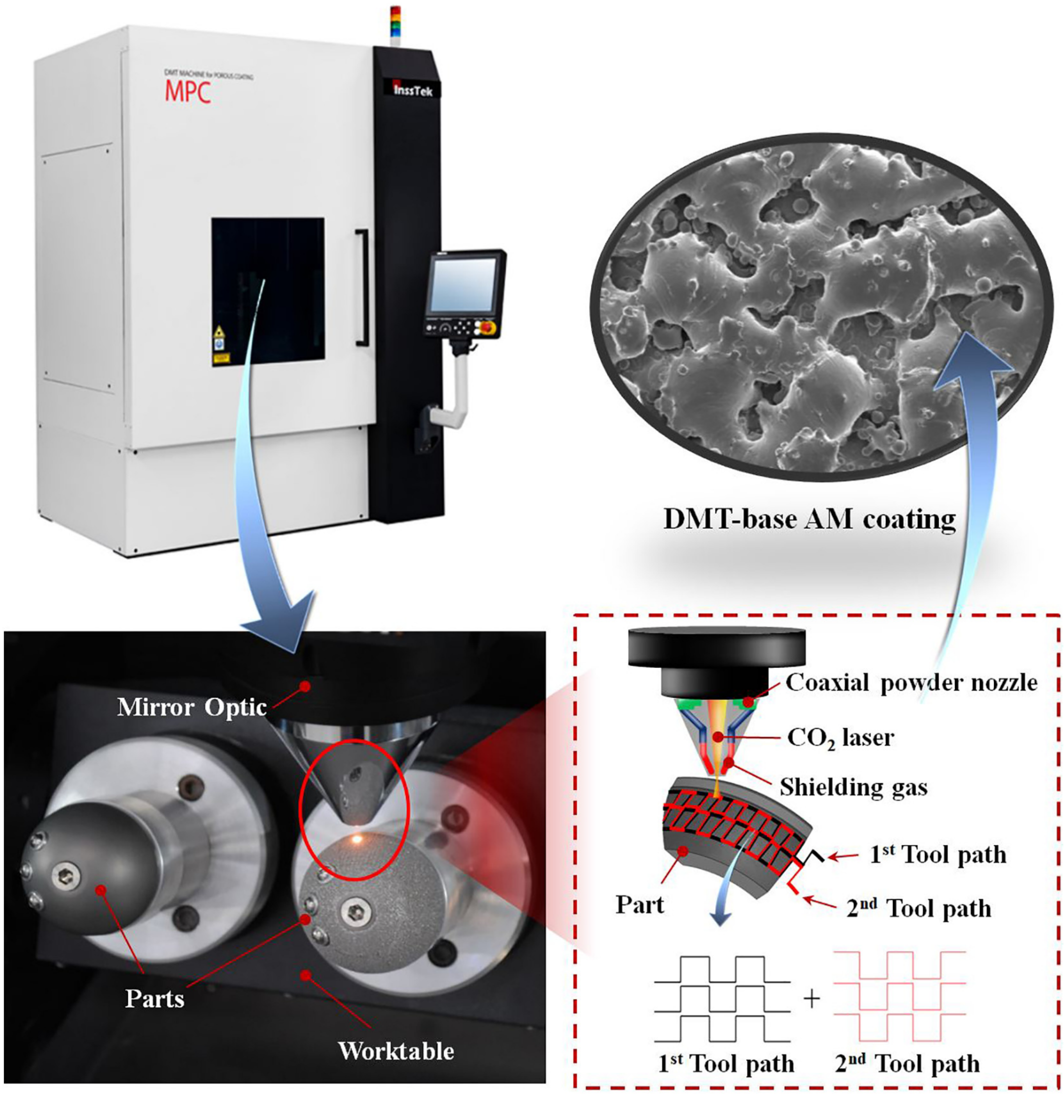


Fig. 2. Schematic and actual images of the laser-aided DMT to melt and laminate pure Ti (grade 2, ASTM F1580) metal powder on the metal surface of the acetabular cup.

ceramic liner had been inserted into the acetabular cup in the same manner as in the measurement of roundness, it was not possible to measure the inner diameter of the acetabular cup.

4. Discussion

Measurements of roundness before insertion revealed that the roundness of the acetabular cup treated with DMT-based AM was higher than that of its TPS-treated equivalent. This difference was likely caused by thermal deformation due to the characteristics of DMT, which involves local irradiation of the base material with a laser and temporarily generates a high level of heat. However, the roundness still satisfied the inner diameter and roundness requirements of a general acetabular cup for assembling it with a ceramic liner; the difference was also extremely small compared with the roundness value immediately after insertion into the PU foam block. Therefore, the difference should have a minimal effect on fracture of the ceramic liner.

Immediately after the insertion, the roundness of the acetabular cup was approximately 100 and 600 μm at levels E1 and E5, respectively. From these values, the roundness at the rim area can be estimated to be approximately 130 to 140 μm. Because the roundness is determined by the difference between the minimized portion and the maximally extended portion, it can be assumed to represent the reduced value of the acetabular cup. Squire et al. [30] reported that deformation of the acetabular cup is highly likely to increase bearing abrasion and chipping of the ceramic liner; they measured how much deformation of the acetabular cup inserted into a patient actually occurred and confirmed that the average deformation of the acetabular cup was 160 μm. The acetabular cup deformation in this study was similar to the results of that previous study; the in vitro test to achieve acetabular cup deformation was thus considered to be highly reliable.

Immediately after inserting the acetabular cups into the PU foam block, the roundness and inner diameter were measured. The results revealed that the acetabular cups treated with DMT-based AM had a level of roundness similar to that of their TPS-treated equivalents. The mean inner diameter of the acetabular cup treated with DMT-based AM was smaller than that of its TPS-treated equivalent, but the difference was not significant. Additionally, measurements of the roundness and inner diameter after the acetabular cups had been inserted into the PU foam block and the fatigue load had been applied revealed that the acetabular cups treated with DMT-based AM had a lower mean roundness at the rim area than that of their TPS-treated equivalents, but the difference was not significant. Moreover, they had similar inner diameters. Excessive deformation of the acetabular cup rim is known to cause a concentration of stress in the liner rim due to non-concentric seating of the ceramic liner assembled into the acetabular cup;

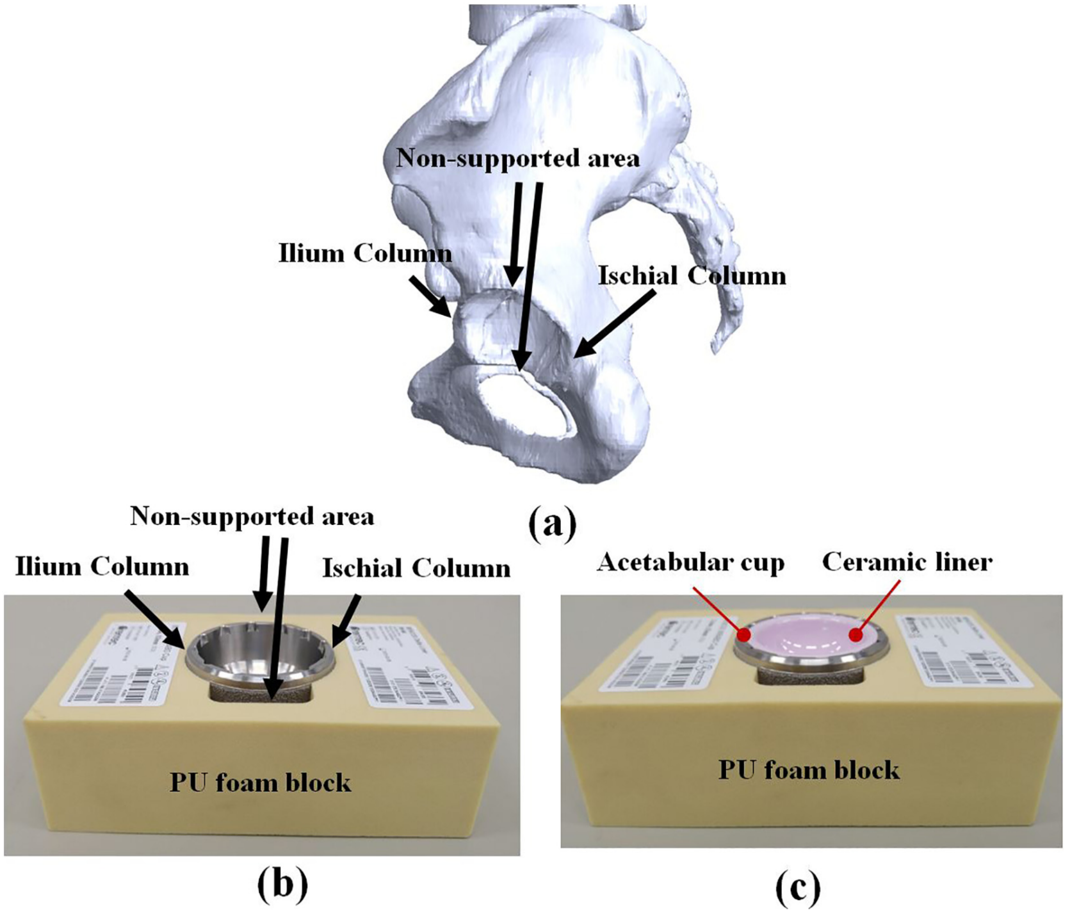


Fig. 3. (a) Medial view of pelvis with location of ischial column, ilium column, and non-supported area noted; (b) acetabular cup into the polyurethane foam block with supported and non-supported areas to simulate the compression being applied to the acetabular cup by high-density bone in the ischial and ilium directions; and (c) ceramic liner into the acetabular cup compressed in the polyurethane foam block.

deformation of the acetabular cup rim should thus be minimized [3]. Based on the results of this study, the deformed rim of the acetabular cup treated with DMT-based AM had a similar roundness to that of the acetabular cup treated with TPS: the two had similar elliptical shapes. Although statistical significance was not reached because the inner diameter of the acetabular cup treated with DMT-based AM has a larger value on average, it is likely that the contraction deformation will be smaller. Ultimately, this may minimize the possibility of fracture of the ceramic liner. This possibility can be explained by the methodological differences between DMT-based AM and TPS. Specifically, TPS does not significantly affect the strength of the acetabular cup via the molten titanium powder being injected at high speed into the base material and combining with the base material. In contrast, DMT-based AM is likely to increase the strength of the acetabular cup due to the base material and titanium powder being melted by the projected laser, which are completely fused and combined into a single mass. In conclusion, although we were not able to confirm via statistically significant results that the strength of the acetabular cup treated with DMT-based AM was increased, thus minimizing its deformation and the likelihood of fracture of the ceramic liner, a simple comparison of the mean values suggested that this is a possibility. Even if there is actually no difference in the strength of the acetabular cups between those treated with DMT-based AM and TPS, the acetabular cups treated with the former approach have the advantages of being more easily combined with the constituent base materials and allowing better control of the porous structure of the surface coating. Therefore, DMT-based AM is at least comparable to TPS or could possibly supersede it for use in artificial joint surface coating.

This study had some limitations. First, our sample size was relatively small. Second, because all specimens were inserted manually

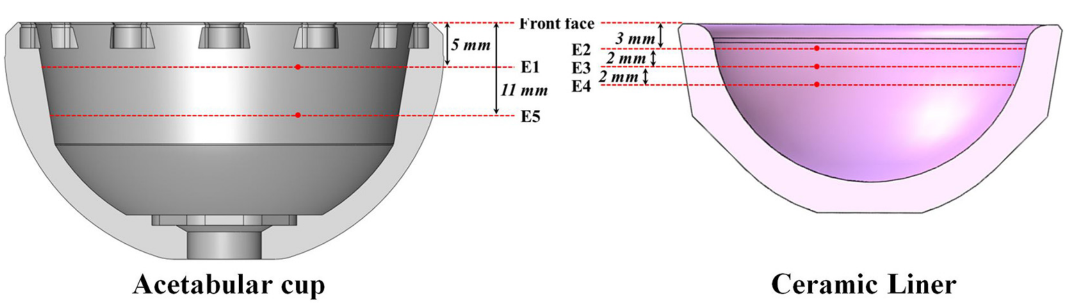


Fig. 4. (a) Locations to measure the roundness and inner diameter for the acetabular cup and ceramic liner.

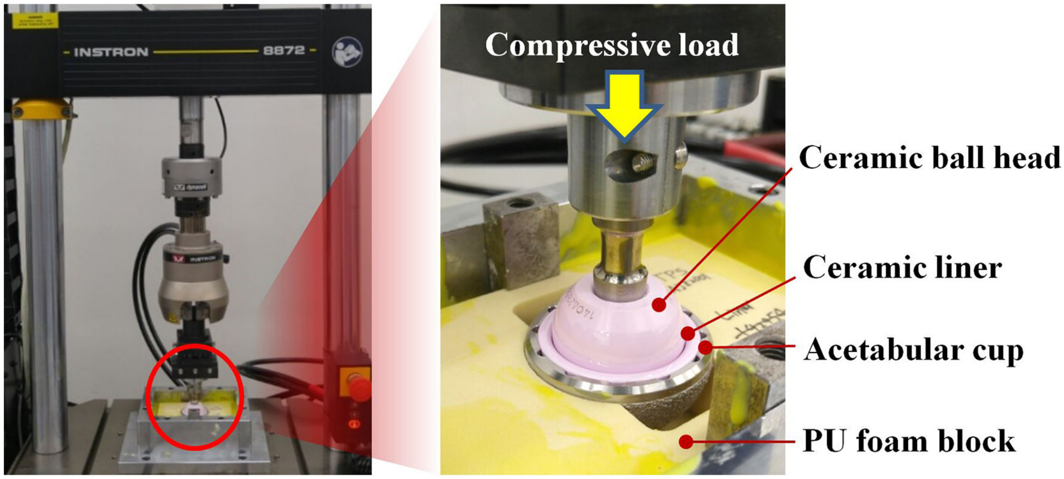


Fig. 5. Fatigue test configuration for the evaluation of the deformation of the acetabular cup and ceramic liner.

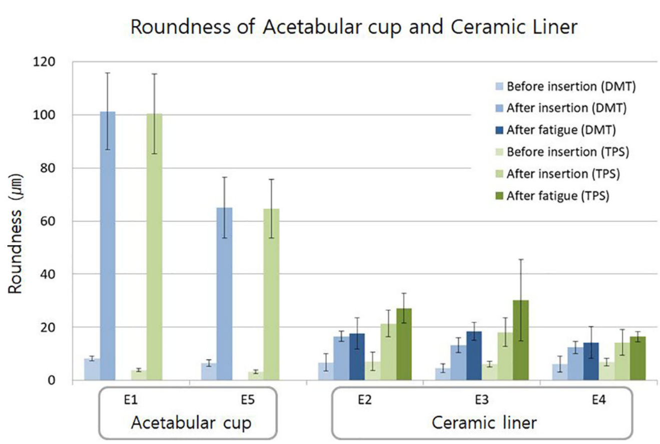


Fig. 6. Results of the roundness of the acetabular cup and ceramic liner measured before and after insertion of the acetabular cup and ceramic liner into the PU foam block and after the fatigue test following the insertion.

using a dedicated impactor, the same impact direction and load were not applied, which may have affected the statistical significance in the comparisons of roundness and inner diameter. The results would be more meaningful if the specimens were inserted using the same axis and load, which should be performed in future work. Third, in the fatigue test, the composite load of the human body was assessed by applying a simple compressive load in only one axis. The actual human weight is a complex load that is dynamically and irregularly applied. Therefore, additional fatigue tests using more realistic human body loading conditions should be performed in the future. Additionally, the in vitro test results for coatings applied by DMT-based AM as obtained in this study should be verified after application in actual clinical practice through short- and long-term follow-up studies. However, a previous study evaluated the possibility of DMT-based AM-treated acetabular cups being applied in a clinical setting in the development of artificial joints, via evaluations of the mechanical performance and biological response of such cups [19,20]. Based on those findings and the current results, the present work has great significance in being the first to verify the possibility that acetabular cups treated with this technique can overcome the problems related to ceramic liner fracture of existing acetabular cups.

5. Conclusions

In an acetabular cup treated with DMT-based AM, the roundness and inner diameter of the acetabular cup itself and the roundness and

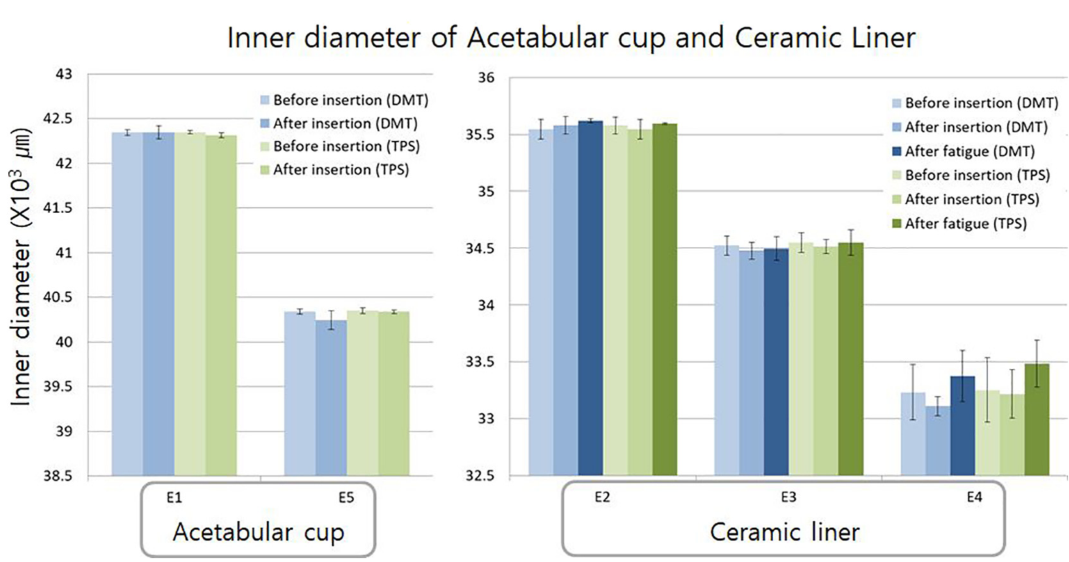


Fig. 7. Results of the inner diameters of the acetabular cup and ceramic liner measured before and after insertion of the acetabular cup and ceramic liner into the PU foam block and after the fatigue test following the insertion.

inner diameter of the ceramic liner were similar to those of its conventional TPS-treated equivalent. Therefore, the DMT-based AM has no effects that would reduce the possibility of fracture of the ceramic liner. However, when comparing only the mean values directly, the acetabular cup treated with DMT-based AM exhibited increased strength compared with its TPS-treated equivalent, which minimized the deformation of the acetabular cup itself and thereby minimized the possibility of fracture of the ceramic liner. Thus, this study revealed that DMT-based AM is at least comparable to TPS or could possibly supersede it. Additionally, when acetabular cups are treated with DMT-based AM, it is possible to control the porous shape of the acetabular cup surface coating freely, in contrast to the acetabular cups treated with TPS. As a result, DMT-based AM might allow greater applicability and extendibility than TPS, in terms of developing artificial joint surface coating technology.

Data availability

All data generated or analyzed during this study are included in this published article.

Competing financial interests

The authors declare no competing financial interests.

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