NATIONAL JOURNAL OF CLINICAL ORTHOPAEDICS

ISSN (P): 2521-3466
ISSN (E): 2521-3474

www.orthoresearchjournal.com
2022; 6(4): 22-27
Received: 21-08-2022
Accepted: 27-09-2022

Luciano Bertolotti
MBA, Department of Engineering, Patient-Specific Designs, Paragon 28, Buenos Aires, Argentina

Akhil Sharma
MD, Department of Orthopaedic Surgery, St. Luke's University Health Network, Bethlehem, PA, USA

Selene G Parekh
MD MBA, Duke University Medical Center, Durham, NC, USA

Corresponding Author:
Akhil Sharma, MD
Department of Orthopaedic Surgery, St. Luke's University Health Network 801 Ostrum Street Bethlehem, PA, USA

Electron beam manufacturing 3D printed titanium with titanium nitride coating shows favorable overall performance when compared to selective laser sintering cobalt chrome in patient specific talus implants

Luciano Bertolotti, Akhil Sharma and Selene G Parekh

DOI: https://doi.org/10.33545/orthor.2022.v6.i4a.378

Abstract
Background: Selective Laser Sintering (SLS) Cobalt Chrome (CoCr) has been utilized extensively in medical implants. However, Electron Beam Manufacturing (EBM) 3D Printed Titanium-6 Aluminum-4 Vanadium Extra Low Interstitial (Ti6Al4V ELI) is increasingly being utilized due to its higher strength to weight ratio, biocompatibility, resistance to corrosion, and capacity for osseointegration. More recently, Titanium Nitride (TiN) coatings have been applied to Ti6Al4V ELI to improve its long-term durability. While durability and tribology are a critical measure of an implant's overall performance, no studies comparatively examine these properties in Ti6Al4V ELI TiN and CoCr talar implants.
Methods: As a result, two independent laboratories were engaged to test these properties using: ASTM F1978-18 "Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser", and ISO 22622:2019 "Implants for surgery-Wear of total ankle-joint prostheses".
Results: Testing using method ASTM F1978-18, Ti6Al4V ELI TiN performed 34x more favorably than mirror polished CoCr. Using method ISO 22622:2019, Ti6Al4V ELI TiN and SLS performed similarly, showing only slight wear when tested against Ultra High Molecular Weight Polyethylene (UHMWPE) over 5 million cycles.
Conclusion: With density, durability, tribology and ingrowth potential as a combined measure of overall performance, results support Ti6Al4V ELI TiN being favorable to CoCr in certain talar implants.
Clinical Relevance: In addition to offering superior abrasion performance and slightly better wear resistance, 3D printed Ti6Al4V ELI TiN coated implants offer physicians and patients a highly customizable implant with a lower strength to weight ratio than existing CoCr SLS implants.
Level of Evidence: V.

Keywords: Electron beam manufacturing, cobalt chrome, titanium nitride, talus implants, taber abrasion

Introduction
Selective Laser Sintering (SLS) Cobalt Chrome (CoCr) has a broad history of extensive utilization in medical implants [3, 6, 16]. Titanium-6 Aluminum-4 Vanadium (Ti6Al4V) has been used in the aerospace industry due to its high strength to weight ratio and is increasingly being incorporated into medical implants [3]. Consequently, a growing number of bench and patient studies have been carried out exploring Ti6Al4V's high biocompatibility, resistance to corrosion and capacity for osseointegration. Additionally, research shows that a physical vapor deposition (PVD) applied TiN coating on Ti6Al4V provides improved wear resistance in load bearing implant applications. [16] Studies have examined a variety of CoCr and Ti6Al4V performance characteristics including material density, 3D printability, biocompatibility and capacity for Osseo integration [6, 11]. Although seen as critical measures of a medical implant's overall performance, no studies have comparatively examined the durability and tribology of Titanium-6 Aluminum-4 Vanadium Extra Low Interstitial Titanium Nitride (Ti6Al4V ELI TiN) and CoCr. Further, no studies directly compare the overall performance of 3D printed CoCr and Ti6Al4V ELI TiN in a talar implant to obtain a more complete understanding of comparative implant performance including durability and tribology, these properties were identified as essential for further biomaterials testing.

It was imperative to examine four key material characteristics to achieve a combined measure of “overall performance

Density: A material’s strength-to-weight ratio and 3D printable densities.

In growth Potential: Biocompatibility and capacity for osseointegration.

Durability: Abrasion resistance and corrosion resistance.

Tribology: Friction and wear while the surface is in motion.

It is important to note that while Ti6Al4V is regularly utilized in biomedical applications, the material has a variety of grades each with use-specific benefits. This study specifically focuses on Ti6Al4V ELI (Grade 23 or ASTM F3001), which contains reduced levels of oxygen, nitrogen, carbon and iron, and where maximum oxygen content is only 0.13%. Reducing the presence of these elements results in improved ductility and fracture toughness.

Materials and Methods

An extensive analysis of existing studies was carried out to develop an understanding of known performance characteristics of SLS CoCr and EBM Ti6Al4V ELI TiN in medical implants. Specifically, studies analyzing material density, bearing and articulation, biocompatibility, corrosion resistance, 3D printability and capacity for osseointegration were reviewed. Prior to this paper, a six month clinical postoperative patient study to examine in growth potential on EBM Ti6Al4V ELI implants was conducted by the senior author.

To gather data on durability and tribology, two independent laboratories were engaged to conduct tests using two internationally recognized standards to analyze the durability of 3D printed Ti6Al4V ELI TiN in a medical implant. The first, ASTM F1978-18, carried out by Taber® Industries in March 2020, analyzed abrasion resistance of 4 inch round coupons over 100 cycles using the Taber Abrasion method. The second, ISO 22622:2019, carried out by Endo Lab® from March-June 2020, analyzed the wear of articulating talar component surfaces against an ultrahigh molecular weight polyethylene (UHMWPE) tibial insert over 5 million cycles.

Method for ASTM F1978-18 “Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser”:

Instrument: Taber Rotary Abraser-Model 5155, *Abrasive Wheels*: H-22, *Load*: 250 grams, *Vac. Nozzle Gap*: 3 mm, *Total Cycles*: 100 cumulative cycles (2, 3, 5, 90), *Environment*: 72±3°F, 50±5% RH

- Fresh cleaning solution of deionized water and reagent grade NaCl was prepared
- Specimens were places in the ultrasonic cleaner with the testing side facing down
- After 10 minute cleaning (20 min for group 3), specimens were placed in a 100 Degree C oven for 10 minutes
- All H-22 wheel sets were refaced using the diamond tool reface prior to testing. Once a specimen run was initiated no other specimen was tested using the same wheel until the specimen run was finished

After removing from the oven, specimens were cooled to room temperature until a stable reading could be obtained on the balance (40 min for Group 1 and 2, 60 min for group 3). The Taber Rotary Abraser setup with tested coupons can be seen in Figure 1. The ultrasonic cleaner setup with tested coupons are shown in Figure 2.

Fig 1: The Taber Rotary Abraser setup with tested coupons can be seen

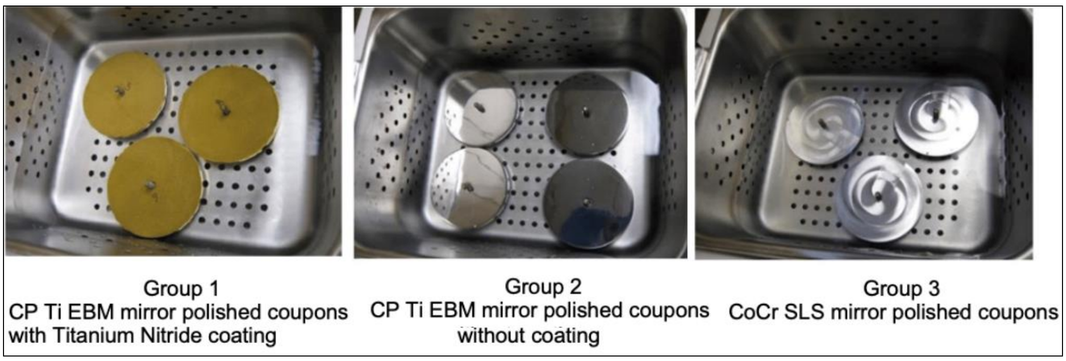

Fig 2: The ultrasonic cleaner setup with tested coupons are shown

Method for ISO 22622:2019 "Implants for surgery-Wear of total ankle-joint prostheses-Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding

Talar Component Group 1: Ti6Al4V ELI with TiN Coating (applied with PVD). Components can be seen in **Figure 3**.

Fig 3: Ti6Al4V ELI with TiN Coating (applied with PVD). Components can be seen

Talar Component Group 2: CoCr F75 (fine resolution direct metal, build in 20 micron layers). Components can be seen in Figure 4.

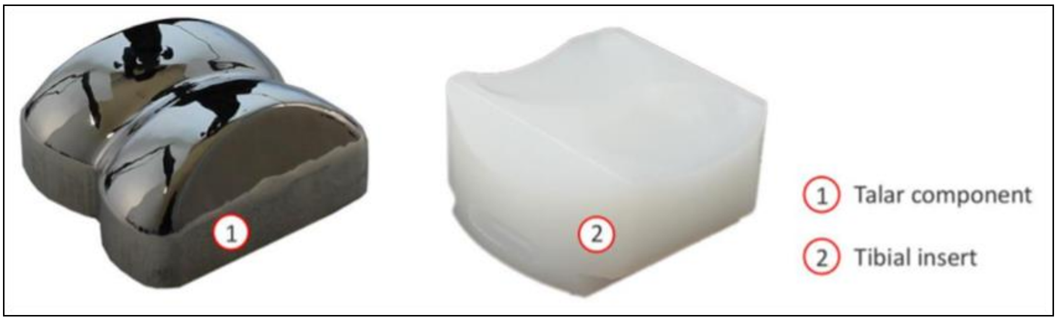

Fig 4: CoCr F75 (fine resolution direct metal, build in 20 micron layers). Components can be seen

Tibial Insert: Total Ankle Replacement System, Size 5+, 16mm All test equipment was compliant with Endo Lab® internal calibration standards. The UHMWPE tibial inserts were not pre-soaked. The Endo Lab joint simulator features three simultaneously running stations emulating the left ankle joint. In neutral position, the TAR components were oriented at a zero degrees flexion and tested in an inverted position (talar component in a superior position). The axial load axis was centered between both condyles for all angles. Figure 5 shows a single test chamber mounted on the test rig. The applied loads were axial force, tibial AP force and tibial rotational torque. The plantar/dorsiflexion angular movement (-15° to +15°) was applied to the talar component, whereas the axial force (192N - 2366N), anterior posterior force (-124N to 257N) as well as the rotational torque (-5.83Nm - 0.25Nm) was applied to the tibial component. The tibial component was free to move relative to the talar component under the influence of the applied forces. The specimen assembly was conducted within a laminar flow unit to prevent contamination of the cleaned test chambers. The encapsulated test chambers were then mounted on the joint similar and filled with approximately 500 ml of test fluid (calf serum diluted with deionized water). Fluid was replaced every 0.5 million cycles. Macroscopic analysis of the bearing surface of all talar components were performed after 0.5, 1.0, 2.0, 3.0, 4.0 and 5.0 million cycles. Photographs of the talar bearing surfaces were taken at each inspection (Figure 6). After 5.0 million cycles the bearing surfaces of the talar components were inspected using a light microscope. The results of these tests as well as a synthesis of existing studies on Density and Ingrowth Potential are elaborated below.

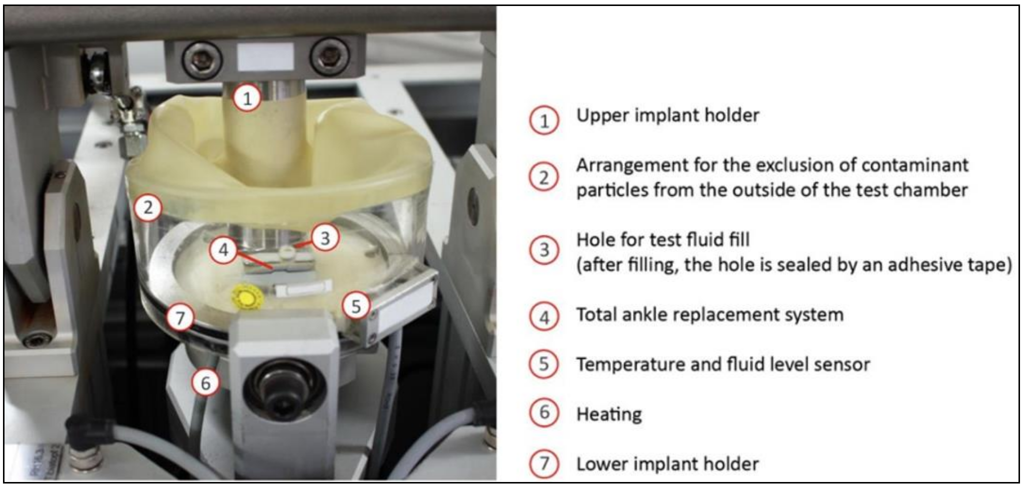

Fig 5: Shows a single test chamber mounted on the test rig.

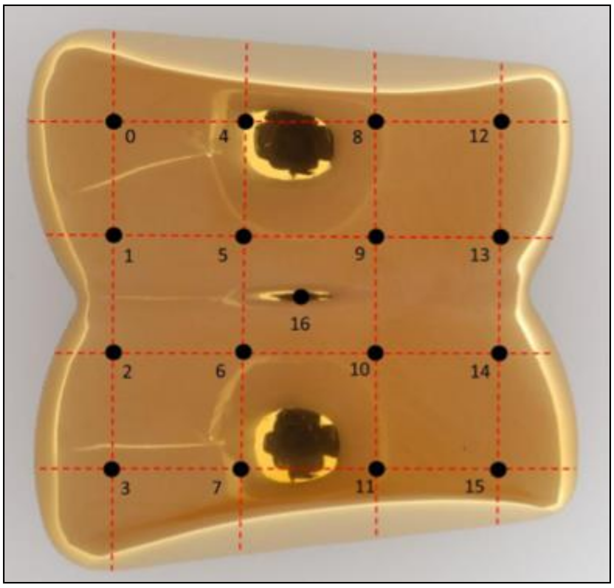

Fig 6: Macroscopic analysis of the bearing surface of all talar components were performed after 0.5, 1.0, 2.0, 3.0, 4.0 and 5.0 million cycles. Photographs of the talar bearing surfaces were taken at each inspection

Results

Density

An examination of implant manufacturer data shows that CoCr has a Rockwell Hardness of 47 HRC, Ultimate Tensile Strength of 960 MPa, Elongation at Break of 20%, Reduction of Area of 20% and Modulus of Elasticity of 210 GPa. Meanwhile, Ti6Al4V ELI has a Rockwell Hardness of 32 HRC, Ultimate Tensile Strength of 970 MPa, and Elongation at Break of 16%, Reduction of Area of 50% and Modulus of Elasticity of 120 GPa[1, 2, 11]. Due to the specific requirements of talar implants, the lower modulus of elasticity and higher strength to weight ratio of Ti6Al4V ELI are preferential given the specific load bearing and tribologic requirements of talar implant [9]. The modulus of elasticity of Ti6Al4V ELI is much closer to that of bone than CoCr, which reduces the chance of repetitive stress fractures.

In growth Potential

Based on the postoperative patient study to examine ingrowth potential on EBM Ti6Al4V ELI implants conducted by the senior author, the 3D printed EBM titanium Evans and Cotton wedges show a 73.1% bone ingrowth at six months postoperative, whereas the competitive wedges show a 41.5% bone ingrowth at twelve months postoperative. The results of this clinical study are supported by existing research demonstrating that larger implant surface area, increased surface porosity and increased surface roughness in EBM Ti6Al4V ELI implants show more enhanced osteogenic differentiation and Osseo integration than traditional implants [7, 11]. Studies also show higher total bone-implant contact with Ti6Al4V ELI than with CoCr[15]. This characteristic is particularly relevant for certain procedures with non-articulating elements where bone ingrowth and fusion is critical.

Durability

Results from the ASTM F1978-18 method show that Ti6Al4V ELI TiN (Group 1) performed an order of magnitude better than uncoated Ti6Al4V ELI (Group 2), and more than 34x better than mirror polished CoCr SLS (Group 3) as indicated below:

- **Group 1:** Average loss after abrasion was 0.0002 g across 6 coupons. Blank coupon showed a weight gain of (0.0004) g. Standard deviation was 0.0002.
- **Group 2:** Average loss after abrasion was 0.0020 g across 6 coupons. Blank coupon showed a weight gain of (0.0004) g. Standard deviation was 0.0012.
- **Group 3:** Average loss after abrasion was 0.0069 g across 6 coupons. Blank coupon shows a 0.0009 g weight loss. Standard deviation was 0.0011.

Tribology

Results from the ISO 22622:2019 method show that Ti6Al4V ELI TiN outperformed CoCr SLS over 5 million cycles (Figure 7). Both Ti6Al4V ELI TiN and CoCr SLS were only slightly duller on the medial and lateral side after 2M cycles. While the extent of areas with a duller appearance increased from 2M - 5M cycles, there was no debris or coating removal during the 5M cycles. All talar components showed slight scratch marks in the plantar/dorsiflexion direction, however these marks were more distinct for the uncoated CoCr SLS talar component. All UHMWPE inserts showed a polished surface and onset of striations of 5.0 million cycles (Figure 8).

Fig 7: Results from the ISO 22622:2019 method show that Ti6Al4V ELI TiN outperformed CoCr SLS over 5 million cycles (**Figure 7**).

Fig 8: All talar components showed slight scratch marks in the plantar/dorsiflexion direction, however these marks were more distinct for the uncoated CoCr SLS talar component. All UHMWPE inserts showed a polished surface and onset of striations of 5.0 million cycles (Figure 8).

Discussion

A review of the current landscape of total talus replacement reveals the most commonly used implant materials include alumina ceramic, cobalt chrome, and titanium [14]. The greatest advantage of a ceramic prosthesis is that it does not contain any metallic components which may lead to the release of allergenic ions and subsequent inflammation, allowing them to be more biocompatible with soft tissue. Ceramic implants also have very low wear rates, and this enables them to have a long life expectancy when compared to some metallic prostheses [8]. However, metal implants generally have greater hardness and tensile strength, and are able to sustain greater impact forces. To mitigate the adverse effect of corrosion and possible freeing of metal ions into the body, metal implants are often coated with a polymer. Although the total talus replacement is relatively young, more longstanding procedures such as the total hip or total knee arthroplasty have seen success with materials such as titanium nitride coating on metal implants, such as we have discussed in this study with total talus prostheses [5].

Titanium nitride coatings in arthroplasty have been used for many decades. However, there is very limited empiric data in regard to performance of TiN compared to CoCr coated prosthetics; especially in the case of talus implants [4]. A 2016 publication in retrieval analysis of TiN coated prosthetic femoral heads articulating with polyethylene discovered that modern TiN heads are characterized by resistance to in vivo roughening which is better than seen in some Co Cr Mo components [10]. Results of the study indicate that currently manufactured femoral heads with titanium nitride coatings are less susceptible to wear than older generations of implants analyzed in previous studies [10]. Another relevant publication from 2018 investigated the use of a titanium rather than cobalt-chromium femoral prosthesis and remelted rather than triple-annealed polyethylene in hip resurfacing procedures. This study sought to determine the functional outcome and complications implant survivorship, bone conservation and biomechanics, and incidence of osteolysis and polyethylene wear [13]. The postoperative functional results as assessed by the Harris Hip Score, WOMAC, SF-12, and UCLA activity scores all improved significantly. The implant survivorship, wear results, and biomechanics of TiN coated hip resurfacing systems using crossed linked polyethylene lining on the acetabular component were also improved compared to previous studies using CoCr [12,13]. Although biomechanics of the hip joint are vastly different from the ankle joint, current literature in total knee and hip arthroplasty suggest that TiN coated implants are superior to CoCr, which may entail that such outcomes will be consistent when applied to talar implants as well. In conclusion, EBM Ti6Al4V ELI with TiN coated talar implants show favorable overall performance compared to SLS CoCr talar implants as supported by both the ASTM and ISO methods. In addition to offering superior abrasion performance and slightly better wear resistance, 3D printed Ti6Al4V ELI TiN coated implants offer physicians and patients a highly customizable implant with a lower strength to weight ratio than existing CoCr SLS implants.

Limitations

The design of this study is subject to limitations which can be addressed in future clinical studies. Specific limitations include:

Laboratory Environment

This experiment was performed in a laboratory without consideration of the influences and impacts that a human body may have on medical implants. The laboratory that performed these experiments did so in a highly controlled environment using an internationally recognized standard to compare the abrasion resistance of metallic thermal spray coatings" using the Taber Abraser. Postoperative studies need to be carried out to more accurately determine long term abrasion impacts on the selected materials.

Sample Size

Given the small sample size of this study, the results of this study should not be considered representative of a larger data set. Future studies with larger sample sizes are required to develop a statistically significant model.

Conflict of Interest

Not available

Financial Support

Not available

References

1. Arcam. ASTM F75 CoCr Alloy. Retrieved from http://www.arcam.com/wp-content/uploads/Arcam-ASTM-F75-Cobalt-Chrome.pdf; c2020.
2. Arcam. Ti6Al4V ELI ELI Titanium Alloy. Retrieved from https://s3.amazonaws.com/3diligent-docs/Arcam+AB/Arcam-Ti6Al4VELI-ELI-Titanium-Alloy.pdf
3. Balla VK, Bhat A, Bose S, Bandyopadhyay A. Laser processed TiN reinforced Ti6Al4V composite coatings. J Mech Behav Biomed Mater. 2012 Feb;6:9-20. Doi: 10.1016/j.jmbbm.2011.09.007. Epub 2011 Sep 21. PMID: 22301169; PMCID: PMC3272254.
4. Breugem SJM, Linnartz J, Sierevelt I, Bruijn JD, Driessen MJM. Evaluation of 1031 primary titanium nitride coated mobile bearing total knee arthroplasties in an orthopedic clinic. World J Orthop. 2017 Dec 18;8(12):922-928. doi: 10.5312/wjo.v8.i12.922. PMID: 29312851; PMCID: PMC5745435.
5. Ghosh S, Abanteriba S. Status of surface modification techniques for artificial hip implants. Sci Technol Adv Mater. 2016 Nov 25;17(1):715-735. doi: 10.1080/14686996.2016.1240575. Erratum in: Sci

Technol Adv Mater. 2017 Jun 19;18(1):436. PMID: 28228866; PMCID: PMC5278906.
6. Hamid KS, Parekh SG, Adams SB. Salvage of Severe Foot and Ankle Trauma with a 3D Printed Scaffold. Foot Ankle Int. 2016 Apr;37(4):433-9. doi: 10.1177/1071100715620895. Epub 2016 Jan 13. PMID: 26764314.
7. Hara D, Nakashima Y, Sato T, *et al*. Bone bonding strength of diamond-structured porous titanium-alloy implants manufactured using the electron beam-melting technique. Materials Science and Engineering: C. 2016;59:1047-52.
8. Jazrawi LM, Bogner E, Della Valle CJ, *et al*. Wear rates of ceramic-on-ceramic bearing surfaces in total hip implants: a 12-year follow-up study. J Arthroplasty. 1999 Oct;14(7):781-7. doi: 10.1016/s0883-5403(99)90025-6. PMID: 10537250.
9. Jin Z, Zheng J, Li W, Zhou Z. Tribology of medical devices. Biosurface and Biotribology. 2016; 2(4):173-192. doi: 10.1016/j.bsbt.2016.12.001.
10. Łapaj Ł, Wendland J, Markuszewski J, Mróz A, Wiśniewski T. Retrieval analysis of titanium nitride (TiN) coated prosthetic femoral heads articulating with polyethylene. J Mech Behav Biomed Mater. 2015 Mar;55:127-139. doi: 10.1016/j.jmbbm.2015.10.012. Epub 2015 Oct 30. PMID: 26584076.
11. Ogawa M, Tohma Y, Ohgushi H, Takakura Y, Tanaka Y. Early fixation of cobalt-chromium based alloy surgical implants to bone using a tissue-engineering approach. Int J Mol Sci. 2012;13(5):5528-41. doi: 10.3390/ijms13055528. Epub 2012 May 9. PMID: 22754313; PMCID: PMC3382757.
12. Pritchett JW. Hip Resurfacing Using Highly Cross-linked Polyethylene: Prospective Study Results at 8.5 Years. J Arthroplasty. 2016 Oct;31(10):2203-8. doi: 10.1016/j.arth.2016.03.013. Epub 2016 Mar 15. PMID: 27067469.
13. Pritchett JW. Hip resurfacing with a highly cross-linked polyethylene acetabular liner and a titanium nitride-coated femoral component. Hip Int. 2018 Jul;28(4):422-428. doi: 10.1177/1120700017752334. Epub 2018 May 7. PMID: 29734816.
14. Regauer M, Lange M, Soldan K, *et al*. Development of an internally braced prosthesis for total talus replacement. World J Orthop. 2017 Mar 18;8(3):221-228. doi: 10.5312/wjo.v8.i3.221. PMID: 28361015; PMCID: PMC5359758.
15. Shah FA, Omar O, Suska F, *et al*. Long-term osseointegration of 3D printed CoCr constructs with an interconnected open-pore architecture prepared by electron beam melting. Acta Biomater. 2016 May;36:296-309. doi: 10.1016/j.actbio.2016.03.033. Epub 2016 Mar 18. PMID: 27000553.
16. Sovak G, Gotman I, Weiss A. Osseointegration of Ti-6Al-4V alloy implants with a titanium nitride coating produced by a PIRAC nitriding technique: a long-term time course study in the rat. Microsc Microanal. 2015 Feb;21(1):179-89. Doi: 10.1017/S1431927614013634. Epub 2014 Dec 8. PMID: 25482093.

How to Cite This Article
L. Bertolotti, Akhil S. Selene G Parekh. Electron beam manufacturing 3D printed titanium with titanium nitride coating shows favorable overall performance when compared to selective laser sintering cobalt chrome in patient specific talus implants. National Journal of Clinical Orthopaedics**.** 2022; 6(4): 22-27.