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STUDY OF MANUFACTURING OF TITANIUM KNEE IMPLANT BY USING ADDITIVE MANUFACTURING, POWDER METALLURGY, AND CONVENTIONAL MACHINING

Pankaj Patil[1], Mahendra Pawar[2], Chandrashekhar K. Patil[3]

[1,2] Assistant Professor, [3]Principal in BVCOE& RI Nashik (India)

ABSTRACT

The human implants are having enormous market. These implants are basically made by traditional manufacturing process, but for the custom-made implants which are manufactured by additive manufacturing process as well as powder metallurgy techniques. Additive Manufacturing process is a manufacturing process to form intricate, asymmetrical components. The conventional manufacturing processes are used for machining the surfaces of implant to achieve the surface quality as per requirement of implant. The Processes can be performed using conventional Computer Numerical Control (CNC) milling machine to achieve the dimensional accuracy and surface finish. Titanium (Ti) and its alloys manufactured by advanced manufacturing techniques such as additive manufacturing (or 3D printing).The Titanium and its alloys are majority attracted by various manufacturing sectors including the medical devices sector. It is possible that advanced manufacturing processes could replace the machining or casting of metal and its alloys in the manufacture of devices as well as implants because of several advantages that include flexibility of design, low processing costs, reduced scrap, and more easily manufacture difficult and complex or custom-shaped human implants. The additive manufacturing is used for manufacturing of implants because it avoids difficulties occurred in traditional implant fabrication techniques such as titanium casting. Using advanced additive manufacturing, it is also possible to produce more porous complex structures with improved mechanical properties, specifically matching the modulus of elasticity of local bone. While the engineering potential and economic of advanced manufacturing for the manufacture of muscular-knee implants is therefore clear. The review studies with Ti production for biomedical implants using powder metallurgy as well as additive manufacturing technique. Titanium typically is preferred for medical implants because of its light weight, high strength and biocompatibility. CNC machining gives improved surface finish for implants.

Keywords: CP-Ti; Ti6Al4V; titanium; biocompatibility; powder metallurgy; metal injection moulding; additive manufacturing; 3-D printing; cytotoxicity; implants

I. LITERATURE REVIEW

1.1 Titanium as Implant Material

Titanium and titanium alloys exhibit a high specific strength [2], which makes titanium an excellent choice for biomedical applications [3]. Furthermore, titanium is considered to be biocompatible because it has a low electrical conductivity which contributes to the electrochemical oxidation of titanium leading to the formation of a thin passive oxide layer [4]. The oxide layer in turn leads to a high resistance to corrosion. This protective passive layer is retained at pH values of the human body [5] due to titanium having an oxide isoelectric point of 5–6 [1]. In aqueous environments Ti and its oxides have low ion-formation tendency and low reactivity with macromolecules [9]. Titanium alloys are used in biomedical implant devices which replace damaged hard tissue. Some examples of Ti uses in biomedical applications are dental and orthopedic implants, artificial hearts, pacemakers, artificial knee joints, bone plates, cardiac valve prostheses, screws for fracture fixation, artificial hip joints [1] and cornea back plates [10]. Titanium and titanium alloys have therefore been used widely as biomedical implant materials since the early 1970s and the implants have been available as machined and cast components. The alloys that are preferred for the fabrication of titanium implants are commercially pure titanium (CP-Ti) and titanium alloy Ti6Al4V (Ti-64). CP-Ti has a higher resistance to corrosion and is widely regarded as the most biocompatible metal because of a stable and an inert oxide layer which spontaneously forms when its surface is exposed to oxidizing media [1]. Almost all commercially available per mucosal dental implants are made from CP-Ti as a result of the pioneering research of Braine mark and his co-workers [11].

The CP-Ti and Ti-64 manufactured via the traditional routes (such as strips, sheets, plates, bars, billets, forgings and wires) are specified according to the American Society for Testing and Materials (ASTM) as grades 1 to 5. Grades 1 to 4 are the unalloyed CP-Ti and grade 5 is the alloyed Ti-64. Table 1 summaries the mechanical properties of titanium according to the ASTM standards F67 [6] and F136 [7] for bars, billets and forgings. Grade 2 titanium is the main unalloyed Ti used in dental implant applications. Grade 2 Ti has a minimum yield strength of 275 MPa and this is the equivalent of yield strength in heat-treated austenitic stainless steels. Grade 5 Ti-64 is the most widely used titanium alloy in biomedical implants where high strength is required [1]. As it can be seen form Table 1, CP-Ti has lower strength whilst Ti-64 is an $\alpha + \beta$ alloy which offers a higher strength [8].

Tables A and B summarize the ALM and MIM processing methods and findings. The processing of titanium alloys manufactured via advanced powder manufacturing routes such as Additive manufacturing (or 3D printing) and metal injection moulding is clearly receiving increased attention and being adopted as alternative to machining and casting. The advance manufacturing process use creates advantages which include the design flexibility, reduced production costs, reduction in scrap, overall efficiency and improved product function. Therefore, the advanced manufacturing process opens a significant opportunity to transform its applications in the medical industry. On the other hand, whilst ALM offers design flexibility, the full scale adoption in implant manufacturing may be hindered by the current high cost of machines with metal 3-D printing capabilities and by costs associated with skills training. The advanced manufacturing process are developing rapidly, with new technologies and discoveries appearing almost endlessly and contributing to a very dynamic field. Furthermore, it has been shown that ALM can produce implants with customized rough surfaces, but in some implant cases such as in joints, a smooth surface is required and ALM and MIM are currently not capable of producing parts with very smooth surface finishes. This means that in some applications, ALM and MIM Ti implants may have to be post-processed or coated to achieve the adequately smooth surfaces. [27]

Table A-Summary of ALM processing methods and findings

. **Processing**	**Alloy**	**Biocompatibility test**	**Cell line/implantation**	**Other comments and references**
EBM	Ti6Al4V	In vitro	human fetal osteoblasts (hFOB 1.19)	Reduced cell proliferation in highly rough surfaces [12]
EBM	Ti6Al4V	In vivo	Frontal skull of domestic pig	More bone contact in more porous samples [9]
EBM	Ti6Al4V	In vivo	Rabbit femur and tibia	As-EBM implant response comparable to machined [13]
EBM	Ti6Al4V	In vitro	Human adipose-derived adult stem cells (hASC)	Increased proliferation on porous compared to polished and unpolished EBM discs [10]
EBM	Ti6Al4V	In vitro and in vivo	Osteoblasts extracted from Calvaria of rabbits, Calvaria of rabbits	Proliferation in porous EBM Ti-64 implants matched coated implants [14]
EBM	Ti6Al4V	In vivo	Sheep	High bone–implant contact in porous implant [15]
DMLS	Ti6Al4V	In vitro	human osteoblasts cells (HOB)	Cultured cells attached and proliferated on SLM substrates [16]
DMLS	Unspecified Ti	In vitro and in vivo	BMP-7 transduced human gingival Fibroblasts	In vitro and in vivo test data showing substantial bone ingrowth [17]
DMLS	Ti6Al4V	In vivo	Human anterior mandible, minipig mandibular	Peri-implant bone in close contact with the surface of the implant [18]
DMLS	Ti6Al4V	In vitro	Human osteoblasts	Osteoblasts well-spread and with multiple contact points [19]
LENS	CP-Ti	In vitro	human osteoblast cells (OPC1)	Cells well spread on porous Ti [24]
LENS	Ti6Al4V	In vivo	Male Sprague–Dawley rats	Increase in calcium (bone) within implant

				pores [25]
Modified FDM	CP-Ti	In vitro	L929 mouse fibroblast	Excellent bone cell attachment and proliferation [26]

Table B. Summary of MIM processing and findings.

Processing	**Alloy**	**Biocompatibility test**	**Cell line/implantation**	**Other comments and references**
MIM	Ti6Al4V	In vitro	L929 (ISO 10993)	Passing results for ISO10993 tests [20]
MIM	Ti6Al4V0.5B	In vitro	MG63 cell	Alloy satisfied requirements of a MIM implant [11]
MIM	CP-Ti and Ti6Al4V	In vitro	MC-3T3-E1 pre-osteoblasts	Cell adhesion much improved on the MIM-Ti, BIODIZE® and BIOCOAT® [21]
MIM	CP-Ti	In vitro	MC-3T3-E1 pre-osteoblasts	MIM-Ti and BIOCER® had enhanced cell proliferation, adhesion and differentiation [22]
MIM	Ti6Al4V	In vitro and in vivo	L929 fibroblast and mandible of Macacafascicularis	Cells proliferated with filopodia and attached to MIM Ti-64 [23]

II. METHODOLOGY

The three main major problems present in bulk titanium alloys used in implants are given below:

- High cost because the amount of processing energy and melting and casting difficulties
- Higher elastic modulus compared to bone
- Although the inert behavior of Ti is a good property, its bone attachment is difficult because it do not react with the human tissues

2.1 The Processing

A great problem of these new alloys is its fabrication processes because most beta titanium alloys contain considerable amounts of refractory elements with high melting temperatures. This results in heavily weight, difficult melting and solidification processing, low plastic deformability and high materials costs. The various refractory materials employed in casting are attacked by titanium with such severity that sounds castings, possessing good mechanical properties are difficult to obtain. So, conventional methods are not practical with titanium. The molten metal and the hot casting are susceptible to atmospheric contamination. Because Ti is very reactive with oxygen and other atmospheric gases, the melting and casting processes implies high temperature fusion and casting under vacuum or protective neutral atmospheres. Another casting problem is the maintenance of good flow over severe changes of dimensions or direction within the mold. Powder metallurgy (P/M) is an alternative method of fabrication in which metal powders are utilized by compacting and sintering to form useful products. This method is employed primarily to produce simple shapes with good dimensional stability, to form shapes with material of extremely high melting temperatures and to produce parts not feasible by other means. Production of cast titanium today takes 16 times more energy per ton than the production of steel. Instead of conventional melting, milling and machining, P/M techniques implies powders that remain in solid form during the entire procedure. This saves a tremendous amount of processing energy with a reduction of over 50% (Mehta, 2008).

2.2 The Elastic Modulus

As was said, the elastic moduli and strength of titanium and its alloys are much higher than those of human bones, which may result in stress shielding and the failure of implants. People have tried to develop new types of titanium alloys, such as □-Ti alloys, to reduce the modulus of the implants to the level approaching human bones. On the other hand, the mechanical properties of porous titanium can be adjusted by pore fraction and morphology, and the stress shielding effect will be reduced. Porous titanium with porosity in a wide range can be prepared with powder metallurgy methods (Zhiguang et al., 2009), from which other kinds of powders as second phase in green bodies would be removed during subsequent heat treatment.

2.3 The Inert Behavior

Despite the great progress achieved in orthopedic biomaterials, fixation of implants to the bone host remains a problem. As titanium has an inert behavior, the body tries to encapsulate the Ti-based implant. However, titanium does not bond directly to bone resulting in micro-movements and, eventually loosening of the implant. Undesirable movements at the implant-tissue interface results in failure cracks of the implant. As Osseo integration starts with the cellular stage and continues with the nucleation of mineral and the structuring of the new vital bone, the overall required time is varying in a broad range. A proposed solution for a better control of Osseo integration is the bioactive fixation. One approach to improving implant lifetime is to coat the metal surface with a bioactive material that can promote the formation and adhesion of hydroxy-apatite (Ca 10 (PO 4) 6 (OH) 2), the inorganic component of natural bone.

The methods used for manufacturing of titanium are given below

The additive manufacturing processes as well as powder metallurgy processes are given below

III. ADDITIVE LAYER MANUFACTURING

3.1.. Electron Beam Melting (EBM)

3.2. Direct Metal Laser Sintering (DMLS), Selective Laser Melting/Sintering

3.3 Direct Metal Injection Moulding

The major problem s of titanium machining are given below

Problems and solutions

3.4 CNC technology: - Bones made of titanium produces medical implants with the highest precision by using CNC technology. The idea for a new medical implant normally arises to meet a practical need. It is a long process before the implant can be produced in quantity: It takes approximately 12 to 18 months from the first drawing, including the design and job planning, through the completed, approved implant. Artificial bones made of titanium are mainly manufactured using the stock-removal process. At implant cast, for example, the production of knee implants runs on CNC turning-milling centers.

IV.TROUBLES WITH TITAMIUM MACHINING

Machining titanium alloys requires cutting forces only slightly higher than those needed to machine steels, but titanium alloys have metallurgical characteristics that make them more difficult to machine than steels of equivalent hardness.

Titanium has a work-hardening characteristic that eliminates the stationary mass of metal (built-up edge) ahead of the cutting tool. That makes for a high shear angle in machining that causes a thin chip to contact a relatively small area on the cutting-tool face. Because of this work-hardening characteristic, feeds should not be stopped while tools and work pieces are in moving contact. The high bearing forces produced by machining in this way, combine with the friction developed by the chip as it rushes over the bearing area to result in a great increase in heat on a localized portion of the cutting tool. Heat generated by cutting titanium does not dissipate quickly because it is a poor conductor. Therefore, most of the heat is concentrated on the cutting edge and the tool face. The combination of high bearing forces and heat produces cratering action close to the cutting edge, resulting in rapid tool breakdown. To make matters worse, titanium alloys have a strong tendency to alloy with or to react chemically with the materials in cutting tools at tool-operating temperatures, and they have a tendency to gall as chips weld to the cutting edges of tools. These difficulties multiply as tools start to wear, so tools used to machine titanium and its alloys should be watched carefully to make sure they are sharp, and they should be replaced before they dull. The rule-of-thumb in machining titanium and its alloys is that if you see any change in the machining process, you should change the tool immediately because it is likely that it is becoming dull. Another reason to keep tools sharp is that titanium can catch fire when cutting with worn or broken tools. The metal generates oxygen when it burns, so the fire can become self-sustaining. Therefore, many shops that machine titanium do not run "lights out," and they equip machines with fire-suppression systems.

With its relatively low modulus of elasticity, titanium has more "springiness" than steel, so work tends to move away from cutting tools unless heavy cuts are maintained or proper backup is employed. Slender parts tend to deflect under tool pressures, causing chatter, tool rubbing and tolerance problems. Consequently, rigidity of the entire system is very important, as is the use of sharp, properly shaped cutting tools.

V. DISADVANTAGES OF TITANIUM AS IMPLANT MATERIAL

Cobalt/chromium alloys are coming into use more often because they are stiffer, tighter grained and cleaner than titanium. Titanium material is difficult to machine by using conventional machining so it is very difficult to achieve close dimensions of implant part.

VI. CONCLUSION

Titanium and its alloys can be used as biomedical implants due to their excellent biocompatibility. The processing of titanium which uses advanced manufacturing technologies of ALM and MIM was until recently inhibited by relatively high production costs and the need to prove that the resulting surfaces have the equivalent biocompatibility of implants manufactured using old-style methods. This study has verified that advanced and additive manufacturing can be used successfully to manufacture safe, biocompatible titanium alloy structures for use as medical procedures in some applications. This conclusion done by conduction of various test of in vitro and in vivo studies.

REFERENCE

[1]. Elias, C.N.; Lima, J.H.C.; Valiev, R.; Meyers, M.A. Biomedical applications of titanium and its alloys. JOM **2008**, 60, 46–49.

[2]. Guo, S.; Qu, X.; He, X.; Zhou, T.; Duan, B. Powder injection molding of Ti-6Al-4V alloy. J. Mater. Process. Technol. **2006**, 173, 310–314.

[3]. Sidambe, A.T.; Figueroa, I.A.; Hamilton, H.G.C.; Todd, I. Metal injection moulding of CP-Ti components for biomedical applications. J. Mater. Process. Technol. **2012**, 212, 1591–1597.

[4]. Quinn, R.K.; Armstrong, N.R. Electrochemical and surface analytical characterization of titanium and titanium hydride thin-film electrode oxidation. J. Electrochem. Soc. **1978**, 125, 1790–1796.

[5]. Schiff, N.; Grosgogeat, B.; Lissac, M.; Dalard, F. Influence of fluoride content and pH on the corrosion resistance of titanium and its alloys. Biomaterials **2002**, 23, 1995–2002.

[6]. Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700); ASTM F67–13; American Society for Testing Materials: West Conshohocken, PA, USA, 2013.

[7]. Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401); ASTM F136–13; American Society for Testing Materials: West Conshohocken, PA, USA, 2013.

[8]. Sidambe, A.T.; Choong, W.L.; Hamilton, H.G.C.; Todd, I. Correlation of metal injection moulded Ti6Al4V yield strength with resonance frequency (PCRT) measurements. Mater. Sci. Eng. A Struct. **2013**, 568, 220–227.

[9]. Ponader, S.; von Wilmowsky, C.; Widenmayer, M.; Lutz, R.; Heinl, P.; Körner, C.; Singer, R.F.; Nkenke, E.; Neukam, F.W.; Schlegel, K.A. In vivo performance of selective electron beam-melted Ti-6Al-4V structures. J. Bio. Mater. Res. A **2009**, 92, 56–62.

[10]. Haslauer, C.M.; Springer, J.C.; Harrysson, O.L.A.; Loboa, E.G.; Monteiro-Riviere, N.A.; Marcellin-Little, D.J. In vitro biocompatibility of titanium alloy discs made using direct metal fabrication. Med. Eng. Phys. **2010**, 32, 645–652.

[11]. Ebel, T.; Blawert, C.; Willumeit, R.; Luthringer, B.J.C.; Ferri, O.M.; Feyerabend, F. Ti-6Al-4V-0.5B: A modified alloy for implants produced by injection molding. Adv. Eng. Mater. **2011**, 13, B440–B453.

[12]. Ponader, S.; Vairaktaris, E.; Heinl, P.; Wilmowsky, C.V.; Rottmair, A.; Körner, C.; Singer, R.F.; Holst, S.; Schlegel, K.A.; Neukam, F.W.; et al. Effects of topographical surface modifications of electron beam melted Ti-6Al-4V titanium on human fetal osteoblasts. J. Biomed. Mater. Res. A **2008**, 84A, 1111–1119.

[13]. Thomsen, P.; Malmström, J.; Emanuelsson, L.; René, M.; Snis, A. Electron beam-melted, free-form-fabricated titanium alloy implants: Material surface characterization and early bone response in rabbits. J. Biomed. Mater. Res. B **2009**, 90B, 35–44.

[14]. Li, X.; Feng, Y.F.; Wang, C.T.; Li, G.C.; Lei, W.; Zhang, Z.Y.; Wang, L. Evaluation of biological properties of electron beam melted Ti6Al4V implant with biomimetic coating in vitro and in vivo. PLos One **2012**, 7, e52049, doi:10.1371/journal.pone.0052049.

[15]. Palmquist, A.; Snis, A.; Emanuelsson, L.; Browne, M.; Thomsen, P. Long-term biocompatibility and osseointegration of electron beam melted, free-form-fabricated solid and porous titanium alloy: Experimental studies in sheep. J. BioMater. Appl. **2013**, 27, 1003–1016.

[16]. Hollander, D.A.; Wirtz, T.; Walter, M.V.; Linker, R.; Schultheis, A.; Paar, O. Development of individual three-dimensional bone substitutes using “selective laser melting”. Eur. J. Trauma **2003**, 4, 228–234.

[17]. Hollister, S.J.; Lin, C.Y.; Saito, E.; Lin, C.Y.; Schek, R.D.; Taboas, J.M.; Williams, J.M.; Partee, B.; Flanagan, C.L.; Diggs, A.; et al. Engineering craniofacial scaffolds. Orthod. Craniofac. Res. **2005**, 8, 162–173.

[18]. Mangano, C.; Piattelli, A.; d’Avila, S.; Iezzi, G.; Mangano, F.; Onuma, T.; Shibli, J.A. Early human bone response to laser metal sintering surface topography: A histologic report. J. Oral Implantol. **2010**, 36, 91–96.

[19]. Warnke, P.H.; Douglas, T.; Wollny, P.; Sherry, E.; Steiner, M.; Galonska, S.; Becker, S.T.; Springer, I.N.; Wiltfang, J.; Sivananthan, S. Rapid prototyping: Porous titanium alloy scaffolds produced by selective laser melting for bone tissue engineering. Tissue Eng. Part C Methods **2009**, 15, 115–124.

[20]. Sago, J.A.; Broadley, M.W.; Eckert, J.K.; Chen, H. Manufacturing of implantable biomedical devices by metal injection moulding. Adv. Powder Metall. Part Mater. **2010**, 4, 89–99.

[21]. Auzene, D.; Mallejac, C.; Demangel, C.; Lebel, F.; Duval, J.L.; Vigneron, P.; Puippe, J.C. Influence of surface aspects and properties of MIM titanium alloys for medical applications. PIM Int. 2012, 6, 57–61.

[22]. Demangel, C.; Auzène, D.; Vayssade, M.; Duval, J.-L.; Vigneron, P.; Nagel, M.-D.; Puippe, J.-C. Cytocompatibility of titanium metal injection molding with various anodic oxidation post-treatments. Mater Sci. Eng. C 2012, 32, 1919–1925.

[23]. Ibrahim, R.; Azmirruddin, M.; Jabir, M.; Muhamad, N.; Rafiq, M.; Hayaty, N.; Kasim, A.; Muhamad, S.; Hanada, K.; Shimizu, T.; et al. Pre-Clinical Study on the Oral Maxillofacial (OMF) Titanium Alloy Implants Produced By Metal Injection Molding (MIM) Using Palm Oil Based Binder System; Euro PM Congress and Exhibition and EPMA: Gothenburg, Sweden, 2013.

[24]. Xue, W.; Krishna, B.V.; Bandyopadhyay, A.; Bose, S. Processing and biocompatibility evaluation of laser processed porous titanium. ActaBiomater. **2007**, 3, 1007–1018.

[25]. Bandyopadhyay, A.; Espana, F.; Balla, V.K.; Bose, S.; Ohgami, Y.; Davies, N.M. Influence of porosity on mechanical properties and in vivo response of Ti6Al4V implants. ActaBiomater. **2010**, 6, 1640–1648.

[26]. Wiria, F.E.; Shyan, J.Y.M.; Lim, P.N.; Wen, F.G.C.; Yeo, J.F.; Cao, T. Printing of titanium implant prototype. Mater. Des. **2010**, 31, S101–S105.

[27]. Alfred T. SidambeBiocompatibility of Advanced Manufactured Titanium Implants—A Review materials ISSN 1996-1944 www.mdpi.com/journal/materials

[28]. Carlos Oldani and Alejandro Dominguez Titanium as a Biomaterial for Implants Department of Materials and Technology, Faculty of Exact,Physical and Natural Sciences, Universidad Nacional de Córdoba Argentina