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Review

Powder Metallurgy: A New Path for Advanced Titanium Alloys in the EU Medical Device Supply Chain

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Abstract: New beta titanium alloys are expected to present high mechanical properties with good biocompatibility to meet the demands of next-generation implants. This paper presents an overview of the current European Union titanium supply chain and several metallurgical processes and technologies required to develop the beta-based titanium alloy industry. The thermomechanical process involves manufacturing advanced beta titanium alloys, where cost reduction must involve every step of the entire process. When synergistically combined, powder metallurgical technology, together with a set metallurgical process, can produce advanced materials for the biomedical industry with a low-cost ratio compared to current melting and forging manufacturing routes. We propose a new strategy to increase the role of advanced titanium alloys in the European Union medical device supply chain.

Keywords: titanium; supply chain; powder metallurgy; biomaterials

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1. Introduction

In the last 25 years, the healthcare system has been established in developed countries as a key economic sector. The workforce currently employed in health care surpasses 15% and contributes more than 10% to the Gross Domestic Product (GDP) in the most advanced European countries. The European Union (EU) study performed in 2002 reported that both life expectancies and health expenditures will increase in EU Member States because population aging will rise in the following decades, which will place burdens on health expenditure [1,2]. There is a clear indication that, in one way or another, health expenditure is related to treated patients' age and gender. This fact is observed in Spain, Germany and the USA, where health expenditure values in the GDP are represented together with average life expectancy according to pre-COVID-19 data (Figure 1). Longer life expectancy increases the number of people who require medical treatment, which, in turn, increases healthcare expenditure in the GDP. The number of patients needing professional health services is extremely likely to increase because longevity will allow more people to enter the age groups that are known for their high morbidity and intensive treatment needs (Figure 1).

One main condition that enables people to age "actively" is for them to be physically able to work for more years and to actively participate in the social community to which they belong. The main objective of medical implants (hip, knee, spine, dental, etc.) is to alleviate pain, recover mobility and functionality, and improve patients' quality of life. The development of new titanium alloys, and their manufacturing capabilities, is a key point for EU Member States to consider in the future to ensure that the population is in relatively good health and with sufficient capacities to autonomously move and behave. Therefore, industrial efforts to maintain people active for longer require new titanium alloys with not only higher osseointegration rates to prevent the stress shielding effect but also high corrosion resistance and mechanical properties. All these capabilities will improve patients' recovery periods and increase implant life expectancy. Joint replacement implants help people to remain active, prolong healthy life expectancy and improve quality of life or allow people to be physically able to continue to do their jobs. The appropriate development of new biomaterials can prevent, postpone and minimize dependence in old age and, thus, reduce costs in social protection services.

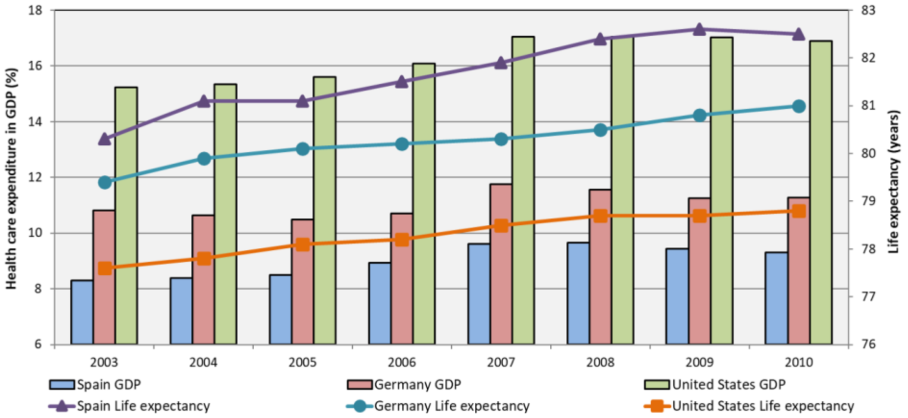

Figure 1. Relation between healthcare expenditure and life expectancy in some developed countries. Source: Eurostat.

The European medical industry is the second global medical market after the USA, with annual sales estimated in 2016 at EUR 110 billion [3]. The compound annual growth rate for the orthopedic sector was estimated at around 3.7% between 2017 and 2024. The top ten orthopedic companies are expected to surpass the USD 41.2 billion mark in sales. Innovation in new biomaterials is likely to increase according to the aforementioned factors, and advanced power metallurgy (PM) manufacturing routes will make new titanium alloys available, which are expected to outperform existing orthopedic implants, thanks mainly to their greater biocompatibility and quicker patient recovery periods.

EU Member States rely 100% on the intermediate product (titanium sponge) or final product imports (ingots, billet, bar or plate, etc.). Supply chain sources of titanium ores and concentrates comprise more than 20 countries. Titanium sponge is a semi-manufactured product required to produce titanium mill products in the form of ingots, bars or plates. The largest amount comes from Norway (25%), South Africa (18%) and Canada (16%) [4]. According to the 2019 US Geological Survey, the main countries that hold global titanium reserves are Australia, China, India and South Africa [4]. Titanium mill products are categorized as being critical from the Economic Importance (EI 2020: 4.66) perspective, with marked Supply Risk (SR 2020: 1.26) categorization because these materials have been employed in the military, energy, aerospace sectors and for implants in the medical industry by the European Commission (EC) since 2011 [4]. The major consumer of titanium alloys in Europe is employed to manufacture aircraft engines, parts for motor vehicles and medical implants (Eurostat, 2019). In fact, about two-thirds of all produced titanium metal is used in aircraft engines and frames [5]. After the global economic crisis of the 2010s, titanium prices have started to rise again due mainly to the growing demand for military and aerospace industries [6]. The USA Producer Price Index (PPI) for finished rolled titanium has changed over the 1971–2006 period to 350 PPI in 2006 (PPI 100 in 1982) and has continued to rise after this period [7].

Next-generation implants will require advanced titanium alloys, where advances in chemical composition and manufacturing technologies (thermo-mechanical process and surface treatments) will be necessary [8]. These new alloys will provide better mechanical properties and corrosion resistance than the Ti6Al4V ELI and Ti CP alloys used today in the medical sector. The EU is increasing its efforts to secure the supply of titanium sponges and other strategic minor elements (niobium, tantalum, vanadium, etc.) used in the special alloys that the aerospace and medical sectors require. The EU depends on imports of 13 of the 39 raw materials employed in the aerospace, energy and medical industry sectors, of which 22 are classified as critically rate material (CRM), and titanium and beta-stabilizer elements appear on the CRM list [5]. Therefore, the EU needs to secure the supply of these raw materials from international sources and to further develop the manufacturing of titanium alloy capabilities to improve its competitiveness in advanced materials production.

Europe's titanium alloy industry is represented by companies that mill ingots, bars or slabs to produce end parts. However, the EU lacks major titanium alloy manufacturers, especially after Brexit, which is needed for the aerospace or medical industry. Currently, they are produced mainly in countries such as China, Russia, Japan and the USA. This condition creates a potential supply chain bottleneck for the materials employed in the EU aerospace, automotive and medical industries, a situation that should be studied and addressed in forthcoming years to improve their resilience. Some global titanium metal producers are Allegheny Technologies Incorporated, TIMET, VSMPO, Perryman Co., Kobe Steel, Toho Titanium Co. and Baoji Titanium Industry [4]. The demand for advanced titanium alloys is expected to increase in European and North American markets, mainly due to their use in medical and aerospace applications. The advanced alloys employed for aerospace and medical applications require operating under extreme conditions and environments and, thus, require new technological thermo-mechanical processes to be incorporated into the supply chain to improve their material properties (fatigue, corrosion, creep, biocompatibility, etc.). Two of the weakest steps in the supply chain of these industry sectors are the supply of raw materials (titanium, niobium, tantalum, vanadium powders) and the consolidation process (VIM, VAR, EBM or other melting technology) due to lack of EU infrastructure [4].

The EU relies on other countries to supply raw materials, on which it very much depends. Global titanium alloy production is dominated by China, which supplies more than half the raw materials, while the other half is produced by other foreign countries (Russia, Kazakhstan or Ukraine) or small suppliers with minor shares in global production [9]. After the Ukraine conflict (2022), global production depends even more on China and other foreign countries (Figure 2). The EU industry should improve its production capabilities by considering the required number of investments and lead times to be made in the market. In this scenario, PM comes over as a completive advance compared to conventional melting technologies, which require very high capital investment and involve substantial energy use.

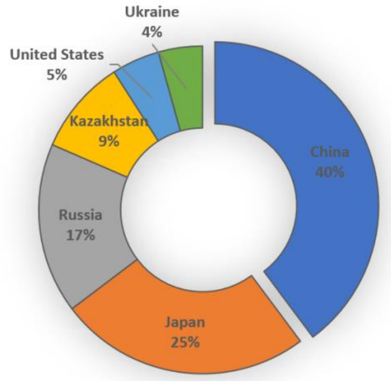

Figure 2. World Sponge Metal Production capacity. Source: Adapted from US Geological Survey, Mineral Commodity Summaries, 2011, data from [9].

2. The PM Path in the EU Titanium Alloy Supply Chain

The material supply chain of the aerospace and medical sectors is a complex multilevel network that starts with mining, refining, consolidations, mill manufacturers, distributors and retailers/wholesalers. PM metallurgy technology can efficiently improve the titanium supply chain by reducing the delivery lead times in the consolidation step and can offer competitive prices thanks to reducing the energy use and investments that equipment and facilities require. An advanced, resilient titanium alloy industry is essential for European countries' overall growth and competitiveness.

The future titanium market expectations need to be considered on the macro level market. Apart from the supply and demand trends of the titanium market, it is necessary to consider the impact of the technological innovations required to reduce the titanium production cost. PM techniques offer the competitive advantage of eliminating the vacuum melting and remelting process (VIM, VAR, EBM), which adds high production costs due to its very high energy use. However, we should bear in mind that in all the steps that need to be followed to manufacture an implant, the cost of raw material (titanium alloy) is only a small fraction of the total cost [10]. A high implant cost is the result of the high cost of machining, surface treatment, development, homologation or government agencies' certification (Figure 3).

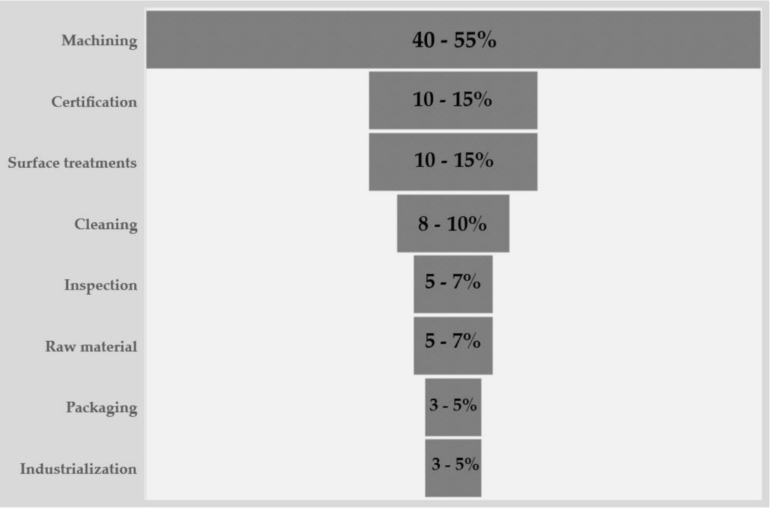

Figure 3. Relative cost of an implant device per operation or step.

At present, the most employed powder is hydrogenation dehydrogenation (HDH), which is produced from titanium sponges from Hunter or Kroll, with prices ranging from USD 15 to USD 40 per kg [11] compared to the pre-alloyed titanium powder employed in additive manufacturing, which usually ranges from USD 90 to USD 400 per kg depending on composition and mesh sizes [12]. HDH titanium powder is 2–3 higher than the titanium sponge employed on the melt and wrought processing route, according to the 2018 US Geological Survey, which indicated an average purchase titanium sponge price of USD 9 per kg [9]. The generally accepted cost of machining an orthopedic implant represents around 40–50% of the total cost. This reduces the influence that raw material has on the total manufacturing cost (around 5–10%) depending on the employed alloy (Figure 3). Other processes, such as design and development, cleaning, surface treatments, and homologation or certification, each increase the production cost by between 5% and 15% (Figure 3).

The difference in cost doubles when refractory elements (Nb, Ta, Mo, etc.) are added to stabilize the beta phase in titanium alloys. This fact is represented in Figure 4, where the cost of the different titanium alloys per chemical composition is represented according to the AISI 316LVM cost. It is relevant that the raw material cost doubles when titanium alloys replace stainless steel as the base material to manufacture orthopedic implants. The main reason for this change is titanium alloys' higher degree of biocompatibility. The same is observed (doubled raw material cost) when advanced beta titanium alloys (e.g., TNZT) replace current Ti CP or Ti6Al4V ELI alloys (Figure 4).

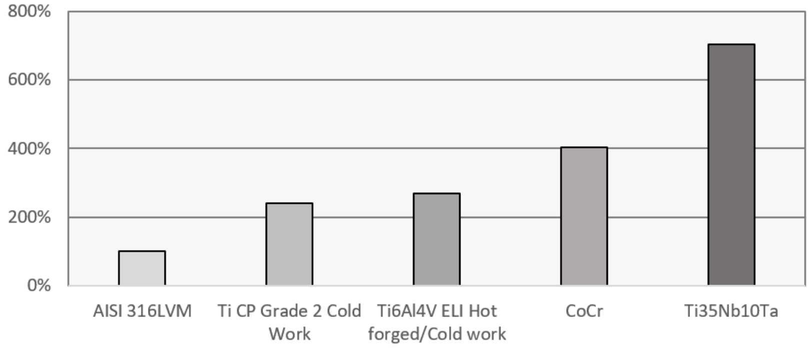

Figure 4. Raw material cost according to stainless steel AISI 316 LVM.

The impact on biocompatibility and long-term implant performance is directly related to the microstructure (chemical composition, phases, grain size) obtained in titanium alloy thermo-mechanical consolidation steps and on the surface treatments that modify the thickness, chemical composition and phases of oxides. Both these factors modulate the implant's corrosion resistance, ion release, cell differentiation and cytotoxicity [8]. Figure 5 summarizes the steps that need to be followed to transform bars or pellets into final medical devices and shows the different manufacturing steps and their impact on end-product properties. This means that the introduction of next-generation biomedical alloys will lead to a significant improvement in the medical field, with a total increase in the final cost of around 5–10%, but it would also add value as a competitive advantage compared to the current manufacturers that employ conventional materials. Although titanium prices have been volatile over time, the recent price peaks have been far more marked than previous price fluctuations.

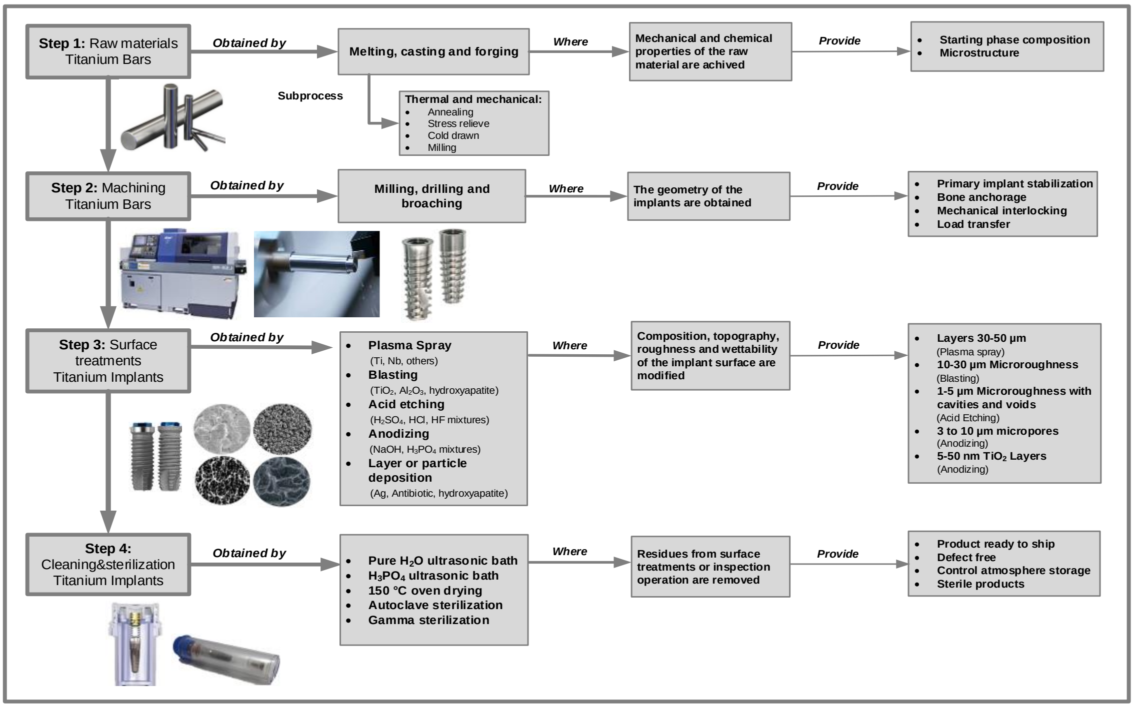

Figure 5. The conventional titanium implant manufacturing process from bars to medical devices.

The titanium production cost is at least five-fold higher than that of aluminum when considering the refining and melting manufacturing steps. If the next steps on the production route are included (ingots, forging, machining) to obtain end products, then the titanium cost can be up to 10-fold higher than it is for aluminum production [10–12]. The conventional melting steps required to consolidate titanium alloys involve 2–3 melting steps in a vacuum arc remelting (VAR) furnace, which has been a set standard in the metallurgy industry for at least 40 years. New technological advances in melting equipment have allowed new consolidation routes to be introduced, and only one melting step is required if electron beam melting (EBM) or plasma arc melting (PAM) equipment is used. Titanium parts are finished by rolling through the forging, extrusion, hot and cold forming, machining, casting and secondary production process (Figure 6).

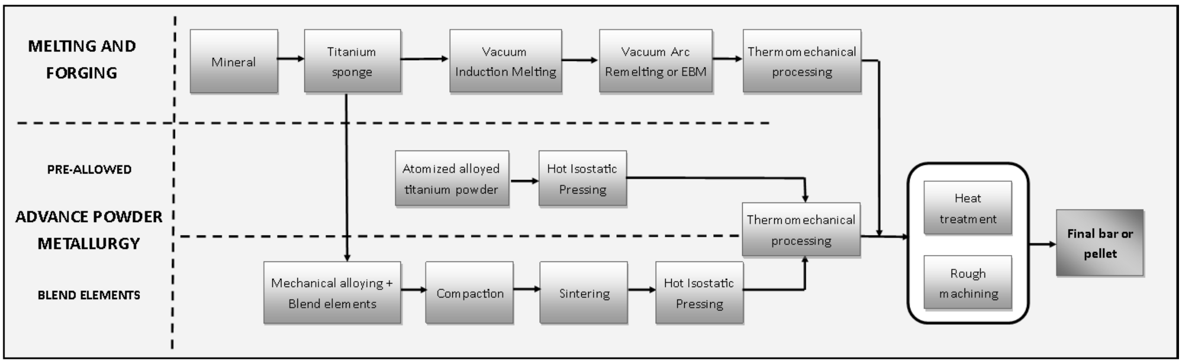

Figure 6. Differences between the melt/forge and PM titanium alloy manufacturing steps.

The EBM consolidation route improves production rates compared to the traditional VAR remelting process. The current EBM approach allows around 15 t of titanium to be produced in a 14-day lead time, compared to the 60 days required in the VAR remelting approach [12]. After ingot consolidation, the material has to follow several metallurgical processes (rolling, drawing, heat treatment, pickling and milling calibration) to obtain the bars needed to produce orthopedic implants (Figure 6).

Titanium powder metallurgical technology presents capabilities to overcome current melting technologies and to share a percentage of the titanium alloy market for specific applications. The PM technological approach does not employ melting steps (VAR, EBM, PAM) to consolidate titanium alloys and reduces the amount of energy and the high investment required for capital investments in facilities [10–12].

The advantages of PM are that small ingots, or even pellets, are produced by a one-time sintering method that is suitable for mass production. However, this process is also appropriate for small quantities for preparing special alloys (Figure 7). Sintered parts should be further processed in more thermo-mechanical steps to improve their mechanical properties. If these thermo-mechanical processes are successfully applied to the beta titanium alloys obtained by the PM approach, the market's production rate will extend titanium supply, which will considerably shorten delivery times. Moreover, energy and labor power savings will be made if titanium metal prices fall.

As the driving force to consolidate powders in PM, technology is diffusion in the sintering step instead of melting, and energy use can be drastically reduced compared to conventional manufacturing production, which employs VAR, EBM and PAM furnaces. Currently, conventional PM parts share a market niche for high-demand applications, and introducing advanced processes will improve their properties and make these processes more appealing. However, given the high titanium market price, the medical industry is extending its suppliers, and the PM approach is expected to become a new, widely used process for beta titanium alloys in the near future.

The competitive advantages that the advanced PM approach presents for advanced titanium alloy production are: making lower investments in the capital equipment required to consolidate alloys; much lower energy use due to shorter sintering cycles and lower working temperatures; and superior mechanical, chemical and biomedical properties. These new materials will create new implants with core competencies (good mechanical biocompatibility, less invasive, high osseointegration and excellent recovery rates) with a strategic advantage that will distinguish them from competitors.

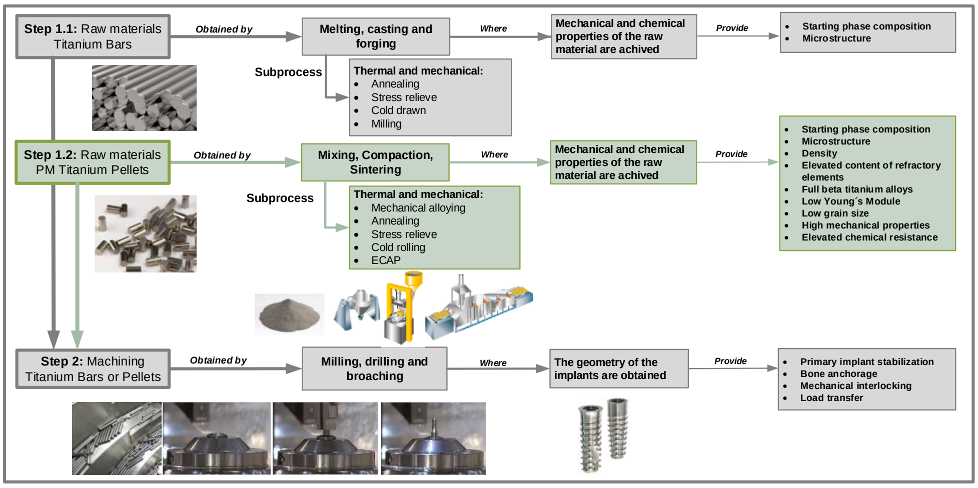

Figure 7. Advance PM technology to manufacture medical devices. A new manufacturing path.

A company that incorporates these new advanced titanium materials will provide new products with a higher perceived value than the competitors that currently employ Ti6Al4V ELI or Ti CP alloys, which implies a performance advantage that customers value. This was previously the case in the medical industry when stainless steel (316 or 307) was substituted for titanium. Although titanium is 2–3 times more expensive than stainless steel [13,14], its relative lightness, higher strength and good corrosion resistance confer it an advantage in the medical industry that favors material substitution [12].

3. Advance Titanium Alloys for Next-Generation Implants

Developing advanced biomaterials is necessary to boost patients' recovery periods and for use over longer periods without failing. To achieve these purposes, interdisciplinary efforts will be required in the full implant supply chain [15], along with the collaboration of all the impacted industries, which range from powder manufacturing, metallurgical manufactures and the biomedical industry to international homologation institutions such as the US Food and Drug Administration (FDA) or EU Medical Device Regulation (MDR).

The average implant longevity is estimated to last between 12 and 15 years. This means that patients under the age of 65 will require revision surgery at least once [14]. This fact increases the importance of developing new materials to be employed in next-generation orthopedic implants. Eurostat data show that the number of hip implant surgeries in Spain (per one hundred thousand inhabitants) has increased from 93 in 2008 to 106 in 2020 and is expected to increase in the next few decades (Figure 8). The data collected from National Center for Health Statistics estimate relate to cost per surgery type. They showed USD 17,538 for hip implants in 2014 and USD 16,370 for knee implants [2]. The total number of hip replacement surgeries performed in the EU in 2013 exceeded 660,000 operations, with an estimated cost of 11 billion. Knee arthroplasty replacements involved more than 370,000 surgical applications with an estimated economic impact of EUR 5 billion, which is expected to increase due to the EU population's longer life expectancy (Eurostat).

Traditionally, the medical industry has employed the available titanium alloys developed for aerospace industry applications (Ti6Al4V ELI or Ti CP) because of major equipment investment requirements instead of developing new material with the specific properties required for implants. Therefore, PM technology offers the opportunity to develop and produce the appropriate titanium phase and microstructure as an economical alternative to consolidation by the sintering approach and the proper selection of fabrication steps to produce next-generation raw materials for implants.

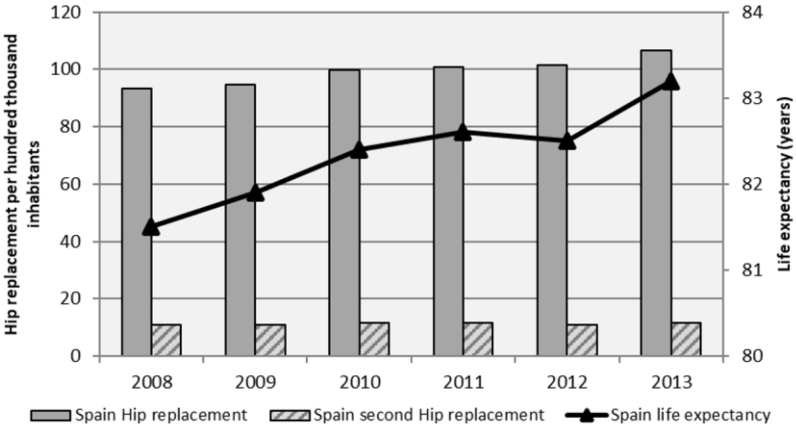

Figure 8. Hip replacement per one hundred thousand inhabitants in Spain correlates with life expectancy for the 2008–2013 period. Source: Eurostat.

4. High-Performance Titanium Materials Produced on the PM Route

Advanced beta titanium alloys with tailored properties would be difficult or expensive to produce by means of conventional ingot melting technologies. The PM route, a lower cost and shorter lead times will increase PM titanium alloys' competitive position compared to current melted alloys [16–18]. Recently, self-propagating high-temperature synthesis (SHS) has been an alternative route to reduce production lead times and energy consumption during titanium alloy consolidation, but this technology is more focused on the production of porous materials [19,20]. The synthesis of ultrafine-grained β-type Ti-based alloys and the required process are presented and discussed in this review. In the last decade, the orthopedics industry has considered β alloys to be the raw material used for next-generation implants, thanks mainly to greater bone mechanical compatibility, superior corrosion resistance and better biocompatibility [21–23]. The chemical composition of β alloys contains enough β-stabilizer elements to ensure β-phase retention while cooling to room temperature [14,24].

Titanium PM alloys can be obtained by the single compaction and sintering processing steps. This material meets the expected mechanical properties for most industrial applications [25]. However, high-performance implants require good fatigue and mechanical resistance. This material type should be processed in secondary operations to eliminate residual porosity and to obtain more homogeneous and suitable microstructures (Figure 9).

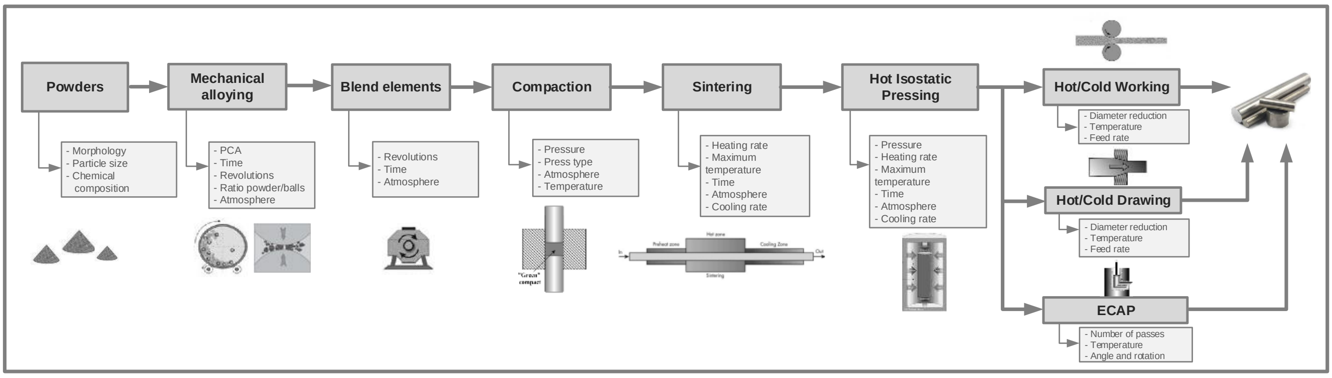

Figure 9. New path for advancing PM titanium alloys for the medical industry.

The material service capabilities for biomedical applications (tensile properties, fatigue strength, fracture toughness and corrosion resistance) are directly connected to the different manufacturing steps required to make titanium alloy billets or bars. The mechanical and electrochemical responses of titanium alloys are influenced by thermo-mechanical processing history, which determines microstructure, chemical and phase homogeneity. The new beta titanium alloys obtained by PM technology must present strength and fatigue properties that equal or improve current Ti6Al4V ELI or Ti CP obtained by the melting techniques and thermo-mechanical processes currently employed in the medical industry. These PM routes will permit fully consolidated materials to be obtained for non-static and high-demand applications. The typical high cycle fatigue (HCF) strength for Ti6Al4V ELI is around 700 MPa. Fatigue behavior decreases with pores and microstructural inhomogeneity, and these elements act as a crack initiators [26].

The definition and selection of appropriate processing conditions during different thermo-mechanical operations are key for defining the processing window to manufacture advanced beta titanium for the medical industry. The following sections attempt to explain the relationship between different metallurgical processing operations and microstructure/mechanical properties and corrosion resistance.

4.1. Mechanical Alloying

The mechanical alloying process allows pre-alloyed powders in a solid state to be obtained. This advanced metallurgical process consists of deforming powder repetitively and plastically to create new phases and/or microstructures [27]. During the process, each powder particle undergoes cold welding and further fracturing for continuous impacts.

Depending on the selected process parameters (processing temperature, atmosphere, milling energy, control agent, etc.), they can alter welding and fracturing processes, which results in the nature of the obtained powder being different (morphology, grain distribution, phases and microstructure) [28]. Attention should be paid to the process control agent to obtain advanced titanium powders because it is a source of undesirable or interstitial elements. The portion of contamination added by the process control agent (PCA) can create dispersoids, such as carbides, oxides or precipitates, which may diminish mechanical properties after consolidation. M. Zadra (2013) notes that when adding 0.25 wt% calcium PCA, the titanium alloy is able to withstand elongation of around 37%, and yield stress increases to 2500 MPa due to small grain size and low oxygen content [28]. Rare earth metals, magnesium and calcium, present low solubility in the titanium matrix and also have a higher affinity for oxygen and chlorine for refining powders and for improving their performance.

4.2. Hot Isostatic Pressing

Conventional powder pressing and the sintering processing route (P&S) present the lowest cost for manufacturing titanium alloys by PM technology. However, the presence of residual porosity in end parts reduces mechanical performance [29]. This drawback affects the material's long-term performance for biomedical applications but can be improved by employing post-thermo-mechanical treatment, such as hot isostatic pressing (HIP).

The development of HIP technology to manufacture titanium parts started in the 1970s with the production of jet and rocket engines. This technology advanced later in the 1990s thanks to computer modeling techniques applied by net shape technology. These innovations enable significant cost reductions with good cost-efficient ratios for several applications such as aerospace, oil, gas and power generation [30]. The majority of the metal injection molding (MIM) industry relies on the HIPing process to remove residual porosity and to meet specifications in the automotive and aerospace sectors [31].

With the introduction of additive manufacturing (AM) technologies, and like the manufacturing technology for metals in the past decade, which are based on laser or electron beam sources, the HIP post-process becomes more important because high thermal gradients are present in the consolidation step. These thermal gradients are produced by the high cooling rates reached during the fabrication process, which cause residual tensile stress that is detrimental to material fatigue resistance. As it is sometimes impossible to avoid thermal gradients during production, post-thermal treatments are required to consolidate fabricated parts, which is where HIP plays an important role by introducing these manufacturing technologies into several industries where high performance is mandatory [32,33].

HIP applies deformation by a combination of argon gas pressure and high temperature. The results are near fully dense material with comparable properties to casting and forging titanium alloys. Pore closure increases the ductility percentage, and the samples' ultimate tensile strength (UTS) was studied (Table 1) [16].

Table 1. Tensile properties of Ti6Al4V alloy. Adapted with permission from ref. [16]. Copyright 2011 Elsevier.

Manufacturing Route	UTS (MPa)	Yield Strength (MPa)	Elongation (%)	Relative Density (%)
AMS 4928 (Min.)	896	827	100	100
Wrought	965	896	14	100
PM CIP-Sintered	951	841	15	98
PM HIPed	965	854	16	10

HIP furnaces enable the HIP cycle to be combined with conventional heat treatment, where high cooling rates are required to stabilize the beta phase at room temperature. Modern HIP furnaces present cooling rates capabilities up to 10–50 $K{\cdot}s^{-1}$, which makes it possible to generate a beta phase and eliminate further heat treatment steps. Molaei et al. (2018) studied the effect of HIPing and annealing treatments on the ductility and fatigue strength of PM Ti6Al4V. These post-processing steps reduce porosity, improve elongation, and result in comparable axial fatigue strength values to conventionally melting and forging titanium alloys [34]. Table 2 summarizes the tensile properties of a Ti6Al4V alloy according to its manufacturing route [34].

Table 2. Tensile properties of Ti6Al4V alloy. Adapted with permission from ref. [16]. Copyright 2011 Elsevier.

Manufacturing Route	UTS (MPa)	Yield Strength (MPa)	Elongation (%)	Theorical Density (%)
Conventional BE	773	683	6	95
CIP + v.s. BE	830	740	6	95
CHIP BE	960	882	17	≈100
P&S + HT + HIP	921	1000	17	≈100

BE: blended elemental powder processing; CIP: cold isostatic pressing; VS: vacuum sintering; CHIP: cold and hot isostatic pressing; P&S: single pressing and sintering; HT: heat treatment; HIP: hot isostatic pressing.

4.3. Thermo-Mechanical Deformations

Titanium alloys can be formed by hot or cold plastic deformation. Working temperatures depend on the β-transus temperature, which is directly related to its chemical composition. Higher temperatures allow greater ductility and, therefore, increase formability in hot forming and may produce an alpha case that should be removed by a chemical or milling process. Titanium alloys' strength can increase without changing their chemical compositions. This is performed by applying a thermo-mechanical deformation process. Plastic deformation applied by forging, rolling or drawing allows residual porosity to minimize by collapsing pores and creating bonds between particles in short diffusion times [26]. These factors enhance the mass transfer rate by accelerating particle–particle contacts and are helpful wherever elevated refractory elements are employed in the chemical alloy composition of PM Ti alloys. These thermo-mechanical production steps are employed to apply microstructural refinement by static and dynamic recrystallization [35].

Grain refinement improves mechanical strength, corrosion resistance and hardness. The microstructure and phase evolution of the titanium alloys obtained by PM technology follow the same physical metallurgy principles as melt-wrought materials during thermomechanical processing if residual porosity has been removed in previous steps.

Liu et al. (2006) studied the influence of new PM TiFeMoAl alloys' porosity and elongation after forging and heat treatment, where the full density was obtained after being thermo-mechanically post-processed, and elongation values rose to 18–20% [25]. The grain refinement of TNTZ alloys was studied by K. Cho et al. (2013), where bars were subjected to cold swaging by reducing the diameter from 20 to 5.5 mm, followed by heat treatment at 923 K for 3.6 ks and, finally, quenched in water. These thermo-mechanical treatments reduce the starting grain size from 27 µm to 2 µm [36].

4.4. Equal Channel Angular Pressing

Equal channel angular pressing (ECAP) is a metallurgical technique employed to enhance the strength of bulk metallic materials. The hydrostatic pressure applied to rods forces the material to pass through a die at an abrupt angle, and shear strain accumulates in the billet, which introduces high lattice densities and ultimately leads to the formation of a submicron or nanoscale grain structure [37]. As the rod diameter remains unchanged after the ECAP step, pressings may repeatedly rotate the part to introduce shear strain in different directions and to increase grain refinement, which leads to high strength, hardness and ductility values [37–42]. The average grain size obtained in pure metals by several SPD techniques usually lies within the ~150–300 nm range but may be significantly smaller in alloys. ECAP processing is a thermo-mechanical step that is followed to fabricate PM beta titanium alloys with smaller ultrafine grain size (UFGS) than those that can be attained by conventional thermo-mechanical processing (forging, hot/cold rolling or hot/cold drawing) [38].

The mechanistic ECAP process involves introducing large quantities of dislocation that are arranged in low-energy configurations very close to the saturation level, and short annealing at low temperatures can increase ductility and have no strong impact on their strength [39]. Valiev et al. (2008) reported high-strength Ti CP materials processed by ECAP + Cold Rolling, yield strength of 1200 MPa and ultimate strength of 1240 MPa while retaining good ductility at 12.5% [40]. Table 3 shows that the fatigue strength of nanostructured CP titanium at 106 cycles almost doubles the melt and forge Ti Cp values and exceeds the conventional Ti-6Al-4V alloy. The corrosion resistance of ECAP Ti Cp is 10-fold greater than coarse-grained, mainly due to its rapid passivation and UFGS [41]. Z. Li et al. (2014) report the ECAP post-processing step on hot-extruded TiNbTaZr alloys (YS: 360 MPa, UTS: 498 MPa, EL: 32%). After three passes, mechanical strength increases by approximately 40% (YS: 692 MPa, UTS: 716 MPa), and elongation decreases by almost 18% [42]. The hardness of nanostructure titanium alloys is greater than that of their coarse-grained structures, so it is reasonable to anticipate increased wear resistance [37].

Table 3. Mechanical properties of titanium alloys according to metallurgical technique employed. Adapted from [43].

Manufacturing Route	UTS (MPa)	Yield Strength (MPa)	Elongation (%)	Fatigue Strength at 10^6 Cycles
Conventional Ti CP4	700	530	25	340
nTi ECAP + TMT	1240	1200	12	620
Annealed Ti6Al4V ELI	940	840	16	530

The current technology has a high potential to be employed in next-generation beta titanium alloys, where materials must operate in extreme environments. ECAP processing techniques provide nanostructured titanium alloys with enhanced mechanical and biomedical properties to develop medical devices with improved design and smaller dimensions [43].

4.5. Oxygen Content

Titanium alloys' phase stability is associated with the amount of alloying elements present (Al, Fe, V, Nb, Mo, Ta, etc.) and with the cooling rate from a predefined temperature [44–46]. Apart from these elements being intentionally added to the material's chemical composition, there are others that are considered interstitially (O, N, C, H). This depends on the manufacturing route and the quality of the employed raw material, where these sources can be considered contaminated. Oxygen is one of the most important interstitial elements and is a decisive factor in the mechanical properties of gum metal or TZNT because it acts as an effective solid solution by strengthening elements in contents between 0.7% and 3% [44–46]. As an interstitial impurity element, oxygen tends to segregate at grain boundaries and dislocations, which could hinder dislocation glide/creep and grain boundary migration [44].

H. Duan et al. (2012) report that oxygen suppresses α'' and ω generation and also lowers the martensite starting temperature [46]. Both these phases are considered the main factors for titanium alloy embrittlement. The oxygen content of beta titanium alloys can be controlled in PM technology by ensuring a controlled atmosphere in the blending, mechanical alloying, pressing and sintering steps. It can also be increased by adding titanium oxide powder to the starting composition and by stabilizing the β phase at room temperature because it affects phase transformation from β to α'' in the cooling step [45].

4.6. Heat Treatments

Titanium alloys' service capabilities in medical devices depend on several factors, such as mechanical properties, corrosion resistance and biocompatibility. An alloy's microstructure, which is directly linked with the historic thermo-mechanical process on the materials manufacturing route, is one of the important factors in controlling its tensile properties, fatigue strength and fracture toughness [43–52]. There are other factors in medical devices, such as surface treatments or geometrical design, which affect the aforementioned properties [49].

The beta titanium alloys that have mechanically deformed during previous operations require a heat treatment step to retain the beta phase and to improve ductility. The solution treatment consists of a heat treatment above β-transus, followed by quenching, and aging treatment can sometimes be included. The final grain size depends on the selected time and solution treatment temperature. K. Cho et al. (2013) studied the effect of time in an annealing treatment performed at 923 K on hot forged and rolled TNZT alloys. They found an increase from 1.7 to 4.0 μm and a heat treatment time from 3.6 to 10.8 ks [36]. Ahmed et al. (2012) reported the influence of the chemical composition and cooling rate on phase formation in Ti-Nb alloys. An increment in beta-stabilizing elements eliminates α'' phase precipitation [50].

If the intention is for a duplex microstructure to improve strength at a lower temperature, then around 400 °C to 600 °C should be selected. Increased strength is related to the precipitation of the isothermal ω phase and the α phase after heat treatment [47]. The UFG titanium alloys obtained after ECAP processing should be subjected to moderate annealing treatment to improve ductility and low-cycle fatigue properties without significantly sacrificing strength [37].

To consolidate materials, heat treatments can be employed on precursor powders, especially those that have been subjected to mechanical alloying. Mechanical alloying adds large amounts of work-hardening in powders, which is detrimental to further consolidation steps [50]. When short annealing times are applied, crystallization does not undergo excessive grain growth, powder work-hardening reduces, and the green density obtained after pressing operations improves [17].

5. New Path on the EU Industry through the Resilience PM Supply Chain

The manufacturing industry currently shares 15% of the EU GDP, represents 80% of EU exports and 25% of its employment [53]. The European medical industry should increase competitiveness by stimulating innovation and research and creating new materials with more added value. This approach could also help to reduce dependence on the critical raw materials employed in strategic sectors (aerospace, automotive and medical) that come from other countries. In order to boost European titanium alloy competitiveness, a balanced private and public research policy is needed to create the right conditions for investments and to promote stronger collaboration among all the medical supply chain stages. Financing the R&D of medical devices involves a very high-risk level and requires a long-term approach in profitability terms, which is why the market is often reluctant to take this risk.

In order to foster innovation for advanced titanium alloys produced by PM for orthopedic devices, the EC should encourage public-private partnerships and establish the right conditions to boost collaboration between universities and businesses. Investment in R&D is both an important and often necessary step to determine a manufacturer's overall competitiveness in the marketplace. Regardless of this R&D expenditure being internally funded or carried out through investments by customers, it often leads to new or improved medical implants, more efficient manufacturing techniques and the creation of new intellectual property. During the 4-year period from 2010 to 2013, aggregate capital expenditures for the titanium industry increased 86% from USD 792 million to nearly USD 1.5 billion in the USA [54]. To create economic value in the biomedical industry, innovations for beta titanium alloys have to be taken to the market. In order to reach this milestone, a collaborative approach between the private industry and a European policy is needed. EU Structural Funds can help to develop all the involved industries (powder manufacturers, powder metallurgy companies and medical device companies), which might be able to bring a competitive advantage to the EU. In order to address the challenges that Europe is currently facing, the EU industry remains over-fragmented and industrial growth should be based on implementing new technologies and innovating in the thermo-mechanical processes required to produce new alloys. Industries and universities should further collaborate and conclude innovation partnerships.

The deteriorated EU-Russian and China relationships will have a negative impact on EU milling industries because ingots or bars are supplied mainly by Russia and China. The sudden crisis of global supply chains being disrupted has shown our dependence and vulnerability. The EU has identified 137 products as vulnerable (a significant concentration of resources), and just under half of them come mainly from China [55]. Around 30 million European jobs depend on the availability of essential critical raw materials for manufacturing new and innovative products, such as batteries, microchips, medical devices and turbines [56].

The raw materials domestic supply policy should take industry, environment policy and raw materials diplomacy as an integrated approach. The impact of globalization on the international supply of minerals should be properly assessed by the EU and Member States whenever imports of raw materials from beyond the EU prevail. Access to raw materials required to manufacture advanced titanium alloys should be guaranteed for European users, and the EU's strategic dependence should be reduced [57]. Geopolitical competition in raw materials terms, which has been accelerated by the COVID-19 pandemic and the Ukraine conflict, has adversely impacted the titanium supply chains that support strategic sectors, such as medical, military, aerospace and energy generation. Other foreign sources for titanium sponge have proven unreliable due to today's geopolitical status. By way of example, China's titanium sponge exports to the USA have dropped from nearly USD 63 million in 2011 to less than USD 200 thousand in 2018. Ukraine's exports have dropped from more than USD 20 million in 2011 to barely USD 300 thousand in 2018. Russia's titanium sponge exports to the US have reduced from more than USD 11 million in 2012 to barely USD 100 thousand in 2018 [58]. A US-Europe free-trade area (TTIP) represents a major opportunity for EU Member States to acquire titanium sponges from trusted countries, which is necessary to further develop advanced PM titanium alloys. During the 2010–2013 period, exports of titanium-related items from US locations to commercial interests abroad increased 55% from USD 975 million to USD 1.5 billion [58]. Europe needs a strong competitive industrial base in both production and investment terms as a key driver for economic growth and jobs [59].

The resilience of the titanium supply chain, from powder to bars, should be made a political priority so that the EU industrial ecosystem can withstand the pressures of international competition and disrupted external supplies. Advanced titanium alloys are essential for manufacturing next-generation implants to cover our modern society's needs, where efforts made in innovation and supply chain resilience need to succeed.

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