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Manufacturing of human knee by cryogenic machining: Walking towards cleaner processes

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Abstract

Nowadays, medical manufacturing sector has to deal not only with economic and environmental issues but also with providing cleaner processes in comparison with other sectors such as aeronautical or automotive. In case of prosthesis manufacturing, this issue is critical due to afterwards they are introduced inside human bodies and it is needed avoiding pathogenic transmission related with dirty coming from oil emulsions used to assist machining processes. It should be noted that in Spain the rejection cases are stablished in 350-450 times only in knee and hip substitutions. Besides, the use of oil emulsions supposes expenses from 17% to 30% of the part cost and its disposal is not efficient at 100% due to almost 8% of oil emulsions are lost as leakages. Therefore, it is needed suppress its use to reduce the number of prosthesis rejections, economic expenses and environmental footprint. In line with this, CO2 cryogenic machining is presented as ECO2 coolant (ecological+economic) and is used as cleaner fluid in other sectors. Then, the joining of these two features to medical manufacturing sector can open a new line of researching in which obtain clean workpieces without the needed of subsequent aggressive cleaning processes. Consequently, in this work a knee manufacturing processes with CO2 cryogenic machining is presented in order to evaluate the suitableness of this technology in this type of components.

Keywords: Cryogenic machining; Ti6Al4V milling; knee prosthesis manufacturing; green-manufacturing

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1. Introduction

In recent years, worldwide competitiveness is a fact which have to be taken into account. Nevertheless, environmental matters have become in a hot topic which have to be dealt before thinking in increasing that competitiveness [1]. In machining industry both issues have taken into account through the use of environmentally friendly lubricooling alternatives. Among them, only a few imply a balance between environmental and technical processes optimization. These techniques are minimum quantity lubrication (MQL), CO2 cryogenic machining and the combination of both (CryoMQL). Each alternative presents advantages and disadvantages which were studied by the authors widely in previous researches [2, 3].

The use of these alternatives implies which the expenses and disadvantages related to conventional oil emulsions are eliminated. It should be noted that only in European Union 320.000 Tm/year were used in 2012 – in the midst of the last crisis – [4] and its treatment after its useful life costs upon 2 and 4 times its purchase price [5]. Besides, 30% of the total amount of oil emulsions are lost during its useful life through leakages, cleaning processes, etc. [6] and its prolonged use has negative effect on human health causing respiratory and skin diseases [7,8]. Then, its use is benefit from an environmental, economical and health point view at the same time.

However, biomedical manufacturing sector – besides these issues – also has to take into account another factor to obtain successful processes. The key is the total aseptic environment which guarantee the complete cleanness of the prosthesis workpieces machined. For achieving this goal, nowadays the finished prosthesis workpieces are wrapped with several plastic protective layers and sterilized by radiation techniques [9]. However, despite this sterilization process, the prosthesis replacements carried out due to infections are around 10% [10]. This amount supposes more than 350-400 rejections annually only in Spain [11]. Then, the radiation techniques used does not eliminate the dirt steamed from machining processes completely and reaching a solution is mandatory.

A way of reducing the rejections is improving the cleanness of machining processes with the aim of becoming the radiation processes more efficient. For this, suppress any cutting fluid would be a solution due to the oil which workpieces have is the main dirt focus on machines and workshops. However, prosthesis workpieces are manufactured of biocompatible alloys. These alloys are mainly Ti6Al4V Grade 23, that is, a difficult to cut material [12, 13]. The use of this alloy implies the need of maintaining low cutting temperature to avoid chemical reactions with the tool materials and protect the surface integrity [14]. Then, cutting fluids are needed but without oil.

In this line, and preserving the environmental and competitiveness, from the three lubricooling techniques mentioned above, CO2 cryogenic machining is presented as the solution for dealing with this biocompatible alloy. From an environmental point of view, this technique uses recycled CO2, that is, it is captured from a primary process, liquified and used as cutting fluid [15]. From competitiveness, the recent techniques allow using CO2 as internal coolant, as is shown in Figure 1. This implies economical savings. Finally, CO2 is used as cleaning technique in other medical applications with autoclave's similarities [16].

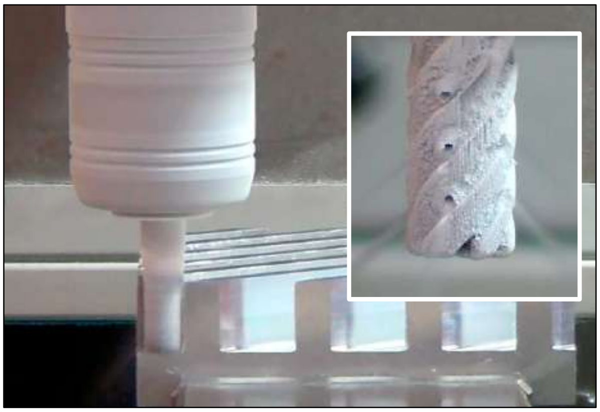


Fig. 1. CO2 used as internal coolant through the milling tool [17].

Therefore, in this work a novel technique of prosthesis manufacturing with cryogenic CO2 is presented with the aim of improving the current process based on oil emulsions. In particular, a knee prosthesis was manufactured by computer assisted manufacturing software (CAM) using CO2 as internal coolant without any type of oil used as cutting fluid. The results show that with CO2 a new cleaner performance is possible in which oils are suppressed completely from the process.

2. Experimental setup

The knee prosthesis was carried in a Kondia HS1000 5-axis machining center. The material for carrying out the performance was Ti6Al4V grade 23 (Titanium grade ELI). This alloy is considered the higher purity version of Ti6Al4V alloys. In comparison with Ti6Al4V grade 5, used in aeronautics, the grade 23 is characterized by having higher tensile strength and higher yield strength. Mechanical properties of this alloy are shown in Table 1.

Table 1. An example of a table.

Tensile strength	Creep limit (0,2%)	4D Elongation	Reduction area
MPa	MPa	% min.	% min.
860	795	10	25

Regarding the technique used for injecting CO2 during the machining process, a BeCold® system was used. This system is characterized by allowing to handle CO2 with pressures below 20 bars without dry-ice formation during its flow. On the other hand, the CO2 injected presents 99.9% of purity with the aim of not introducing any external pathogen during the machining process. For introducing CO2 throw the tool a special toolholder was used. In particular, this toolholder is provided with dry bearings which avoid any danger of freezing it and thus, seizing it. Finally, with the aim of verifying the viability of the process from a technical point of view, surface roughness of the knee prosthesis manufactured was analyzed with a confocal microscope Alicona with a resolution of 0.1 nm. The performance is shown in Figure 2.

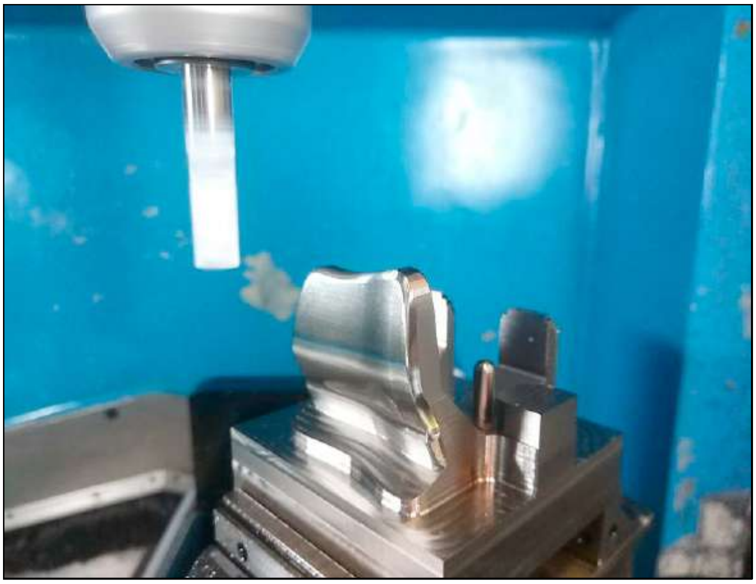
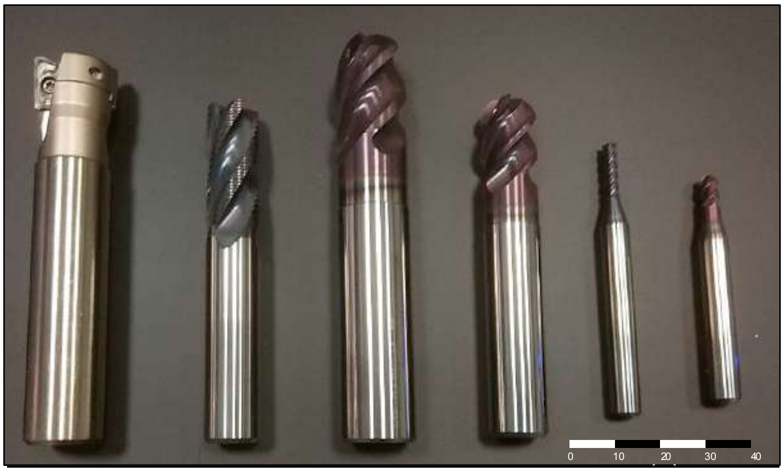


Fig 2. The performance carried out

3. Manufacturing process and results

Cutting tools used for manufacturing process were carbide tools coated with TiAlN for all operations with the exception of the first roughness. In this case, indexed tool with carbide inserts were chosen with the aim of using an economical option. On the other hand, carbide entire tools were provided with an internal channel carried out with EDM with the aim of reducing CO2 consumption and becoming the tool in a heat exchanger for controlling cutting temperature during the machining. Cutting conditions were chosen based on industrial experiences with the aim of maintaining similar chip removal rates. Tools used and cutting conditions are summed in Figure 3.



	Roughing	Finishing
Cutting speed	40 m/s	40 m/s
Feed per tooth	0.03 mm/z	0.03 mm/z
Axial depth	1 mm	0.1 mm
Radial depth	12 mm	3 mm

Fig. 3. Tools and cutting conditions used during manufacturing process

Due to the fact that knee prosthesis is considered a complex geometry and , as mentioned before, the material to be cut is considered a difficult-to-cut material, machining strategies optimal definition are crucial to fulfill manufacturing requirements in terms of surface integrity and dimensional deviation. Defined strategies for this knee prosthesis are defined into 3 different stages: roughing, semifinishing and finishing. Figure 4 shows the different strategies performed inside each stage and the surface finishing estimation after each stage.

For roughing stage, strategies performed with a 3+1/2 axis machine configuration were selected. As it is observed in the surface estimation, some surfaces presented big leaps derived from the adaptability of a simple strategy to a complex curved surface; these operations matched with machining timing and cost expectations in terms of machine movements and tool wear. Nevertheless, these leaps need to be considered for the definition of semifinishing strategies, avoiding the wrong interaction of the tool with the workpiece and controlling cutting parameters to prevent tool breakage. In this case, the main objective of semifinishing stage consisted of removing that extra material, obtaining a more regular surface near to final tolerances. Semifinishing strategies are more closed to finishing strategies, performed with 5 interpolated axis machine configurations, what leads to a more difficult operations programming. Finally, the finishing stage is performed with ball-end mill tools, using the single point milling operation, implying the highest machining time; on the contrast, this technique obtains tight tolerance requirements.

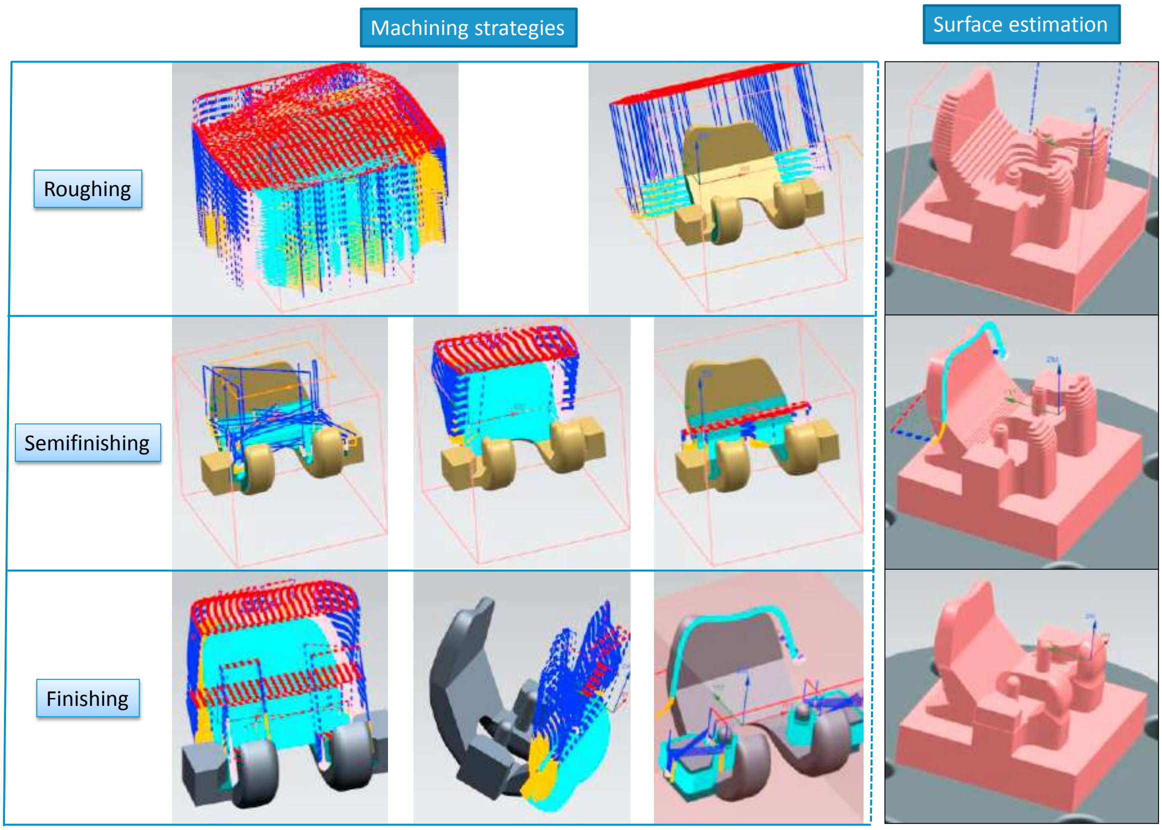


Fig. 4. Machining strategies programmed by a CAD/CAM/CAE software (a) and estimation of surface finishing (b)

During the machining of complex geometries it is common to use a virtual verification to consider all machine components and avoid collisions between machine components, tools and part. In this case, Figure 5 shows prosthesis definition and the extra material needed for the blank design; additionally it was performed a clamping fixture to facilitate the turnover of the part. Moreover, machine axes are defined according to real machine limitations.

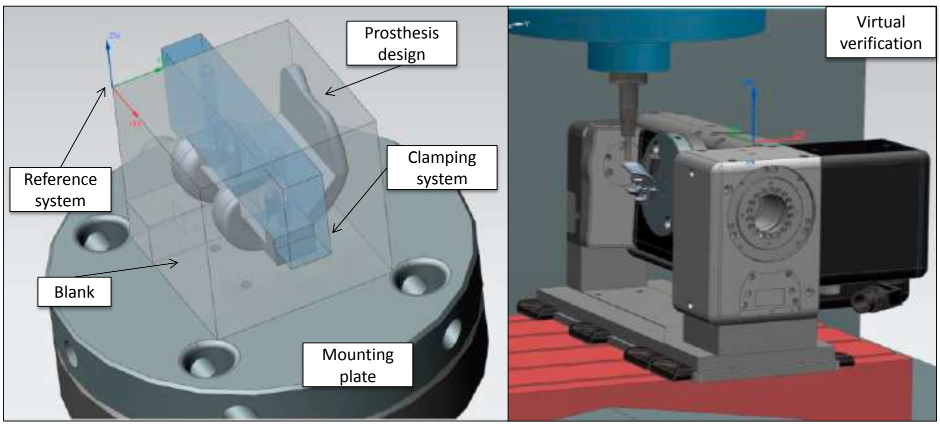


Fig. 5. Knee prosthesis design and machining components definition (a) Virtual verification (b)

Regarding surface integrity, the joint zone was measured. The cut-off-length chosen was 0.8 mm and an evaluation length of 4 mm were used according to the standard ISO 4288 with Gaussian filter [18]. Figure 6 shows the results obtained.

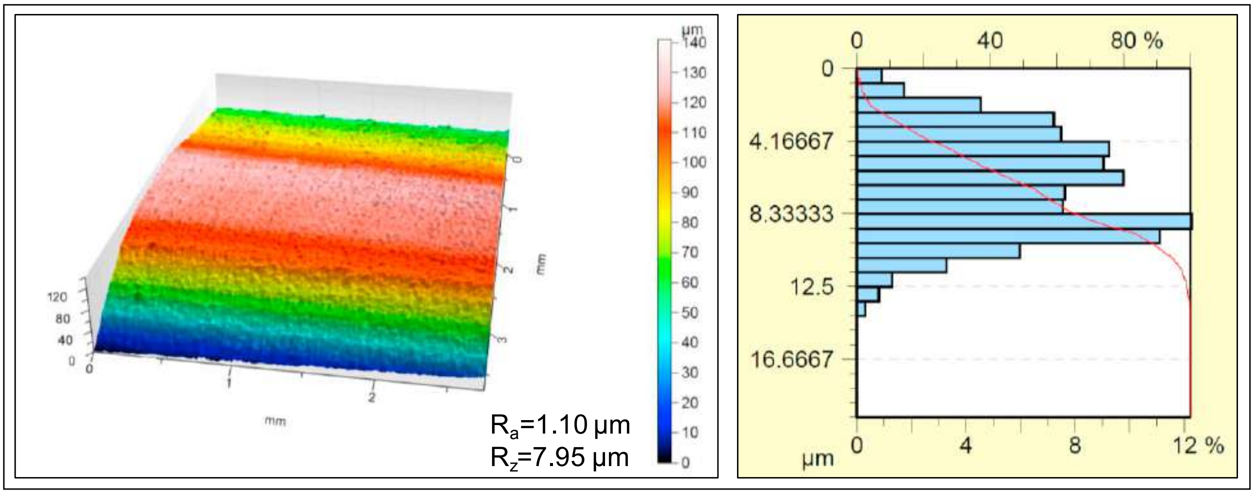


Fig. 6. Surface roughness obtained

The pattern obtained is characteristic of the milling processes, that is, the process was controlled. The values obtained are 1.10 µm for average roughness (Ra) and 7.95 µm for the mean values of five consecutive maximum heights between peak-valley (Rz). This supposes values which make possible finishing processes by abrasive machining assisted by cryogenics to preserve the cleanness achieved with this performance. Therefore, the use of CO2 as fluid coolant applied to biomedical sector is presented as a solution which allows to improve the process from the three points of view which an industrial process need to be applied, that is, deals with the economic, environmental and cleanliness point of view at the same time.

4. Conclusions

In this paper a new prosthesis manufacturing technique based on CO2 cryogenic machining is presented. The advantage of this setup is which not only combines the benefits of environmental and economical issues but also implies a cleaner method in which cutting fluid based on oils are suppressed.

For achieving this performance, CO2 was used as coolant throw internal channels manufactured by EDM on WC conventional tools. This performance was used for roughing, semifinishing and finishing operations.

Surface roughness values obtained are homogeneous in the different knee prosthesis faces. In particular, the values measured were 1.10 µm for average roughness and 7.95 µm for the mean values of five consecutive maximum heights between peak-valleys on top and bottom surfaces, respectively.

Therefore, based on these values – which are the expected by a conventional milling process – internal cryogenic machining with CO2 is presented as a suitable alternative to be used during the entire milling processes in which environmental, economical and cleanliness issues are taken into account and improved in comparison with conventional oil emulsions.

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