UNIVERSIDAD SAN FRANCISCO DE QUITO USFQ

Colegio de Ciencias e Ingenierías

Manufacturing of Orthopedic Plates and Screws for the Internal Fixation of Bone Fractures

Propuesta tecnológica

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Manufacturing of orthopedic plates and screws for the internal fixation of bone fractures

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Abstract

Metal implants are widely used worldwide for the fixation of fractured bones. Orthopedic plates and screws are used by doctors to restore the bone to its natural position and propitiate healing. These medical devices can be expensive and are not produced in Ecuador. There is interest for the local production of this parts to lower the prices and improve availability. However, bone plates and screws must meet very strict safety standards and functional requirements. Using modern CAD/CAM technologies and medical grade stainless steel, 3D models were designed, and CNC machined using custom tooling and fixtures. Various methods to obtain the required surface finish and corrosion resistance were tested on the prototypes. Alternative techniques for manufacturing and treatment were also analyzed. Based on the study of the manufacturing of medical devices, a proposed industrial setup is included. Additionally, a simple estimation of manufacturing costs was made. The design and local manufacturing proved to be technically viable, but a very controlled system would be necessary to pass the testing requirements. Economic viability, on the other hand, needs further analysis, even though the high retail prices of the products make them highly attractive for the industry.

Keywords: Orthopedic implants, CAD/CAM, Medical grade materials, 316L stainless steel, osteosynthesis.

Resumen

Implantes metálicos se usan comúnmente en todo el mundo para remediar fracturas óseas. Médicos traumatólogos y cirujanos utilizan placas y tornillos ortopédicos para regresar el hueso a su posición natural y fomentar la sanación. Estos elementos de uso médico pueden ser muy costosos y no se fabrican en Ecuador. Existe interés en la producción local de estas partes para disminuir los costos y mejorar disponibilidad. No obstante, las placas y los tornillos de hueso deben cumplir muy estrictos estándares de seguridad y varios requerimientos funcionales. Usando modernas tecnologías CAD/CAM y acero inoxidable de grado médico, se diseñaron modelos 3D y se los mecanizó utilizando máquinas CNC, y, herramientas y sistemas de sujeción personalizados. Varios métodos para obtener el acabado superficial y la resistencia a la corrosión requeridos fueron probados en los prototipos. Otras alternativas para la fabricación y el tratamiento de las piezas también fueron analizadas. Basándose en este estudio de la manufactura de elementos de uso médico, se incluye una configuración propuesta para su industrialización. Adicionalmente, se hizo una estimación simple de los costos de producción. Se determina que el diseño y la producción local son técnicamente viables. Sin embargo, se recalca que se necesita un sistema altamente controlado para pasar las pruebas estandarizadas. Por otro lado, la viabilidad económica debe ser estudiada más a fondo, incluso tomando en cuenta que los altos precios de venta de estos productos hacen que esta industria sea muy atractiva

Palabras clave: Implantes ortopédicos, CAD/CAM, Materiales de grado médico, Acero inoxidable 316L, Osteosíntesis.

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INTRODUCTION

Metal implants have been used for years to treat various kinds of bone fractures. A surgical procedure known as osteosynthesis, whose goal is to restore the bone to the correct alignment and to propitiate the healing of the fracture, is the preferred treatment option for the stabilization of long bones. Some of its advantages include the preservation of bone perfusion and micromotion at the fracture gap (Sonderegger, Grob, & Kuster, 2010). Orthopedic plates, screws, nails and other fasteners are implanted by surgeons, in order to secure and support the broken bone. Orthopedic implants can be selected within an ever-growing variety of standard shapes and sizes, to be used for different techniques of osteosynthesis, throughout the skeleton (Colton & Orson, 2013a). Years of research and development on the topic of orthotics, and osteosynthesis in particular, have produced a variety of different plates and fasteners with their own characteristics and applications. In 1886, Carl Hansmann presented the first plate which protruded through the skin, but modern plate osteosynthesis began in the 1960s when the implants and the fixation methods evolved to provide for improved healing (Theodore Miclau & Martin, 1997).

The overall shape of orthopedic plates has evolved considerably during the last decades; a process which has been led by the AO (*Arbeitsgemeinschaft für Osteosynthesefragen)* Foundation. Round-holed plates, reconstruction plates, DCP, LC-DCP and LCP, are the most common modern plates for the internal fixation of bone fractures. The *AO Round-holed plate* is the most primitive and is rarely used nowadays due to its inability to produce compression, which means that it has to be used with an external compression device (Colton & Orson, 2013a). Needless to say, the healing process is neither very convenient, nor very secure. However, this form is still in use for procedures that require very small plates.

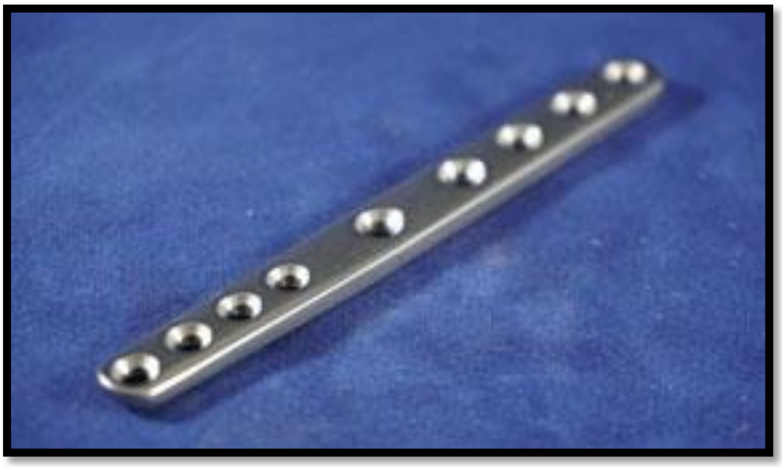

Figure 1 – Round holed flat plate

A simple modification to the round-holed plate produced the *dynamic compression plate* (DCP), a great improvement for the implantation and healing processes. The DCP plate includes a self-compressing hole that allows the screw to move relative to the plate on tightening. This relative motion compresses the bone fragments into position providing a more secure fixation. This illustration shows how a DCP plate works:

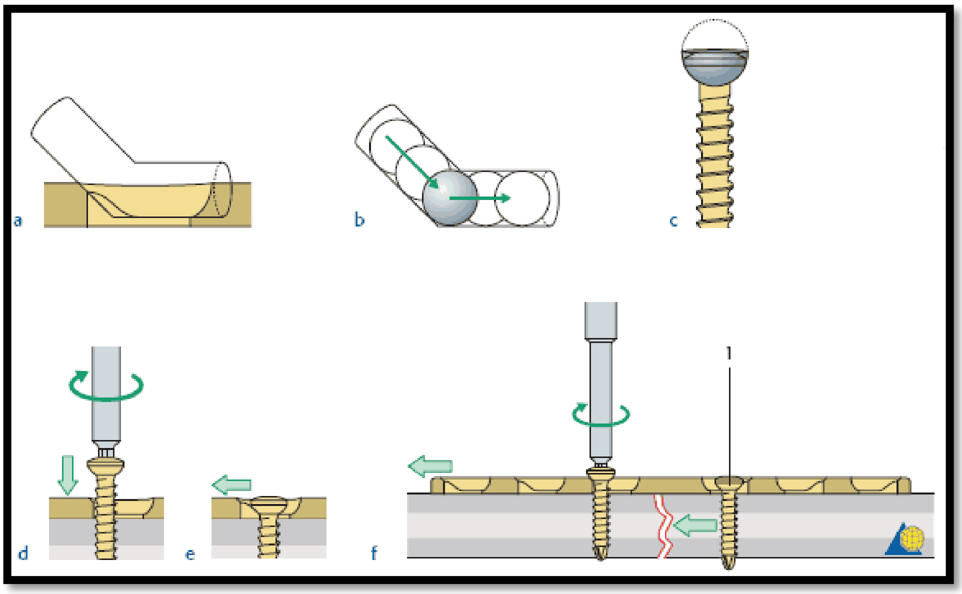

Figure 2 – DCP plate surgery reference by the AO Foundation. Arrows show the relative motion between the plate, bone and screw under tightening.

Although the DCP plate provided a secure reduction thanks to the compression hole, it does not produce a biological osteosynthesis because it blocks the bone perfusion[1]. As a response to this problem, the *limited contact dynamic compression plate* (LC-DCP) was designed with a reduced footprint which has the added benefit of an improved contour-ability. This characteristics, together with the screw hole design that allows for axial compression by eccentric screw insertion, make the LC-DCP plate the gold standard for plate fixation (AO Foundation, n.d.). The most common sizes, defined by the diameter of the cortex screws used together with plate, are the 3.5mm small fragment plates and the 4.5mm large fragment plates.

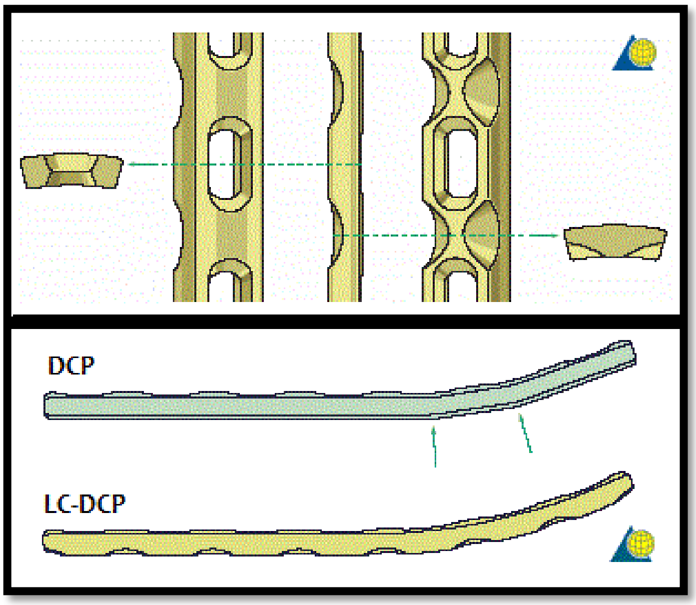

Figure 3 – Above, an LC-DCP plate. Below, the uniform bending of an LC-DCP plate vs. the "kinking" of a DCP plate.

The *locking compression plate* (LCP) is the last evolution of the LC-DCP plate that incorporates a *combi* hole which permits the insertion of standard bone screws and threaded locking head screws. The LCP plate can be used for standard bone reductions,

[1] Blood supply to the bone tissues

as a dynamic compression plate, or for angularly stable reductions, when used together with locking head screws (Colton & Orson, 2013a).

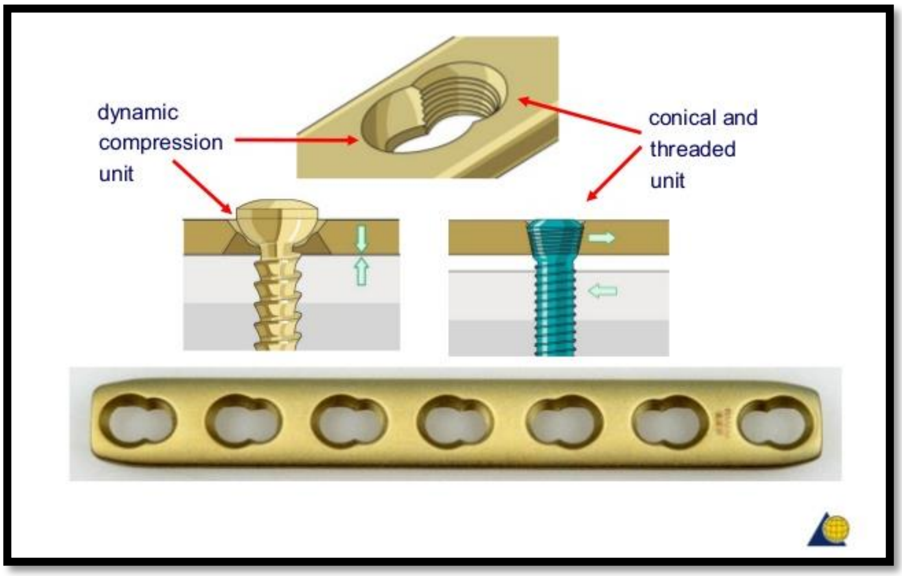

Figure 4 – Locking compression plate

To be used for complex anatomical reductions, reconstruction plates allow for bending on two different planes, due to its notched edges (Colton & Orson, 2013a). The contourable implant is bent by the surgeon to conform to the bone's shape.

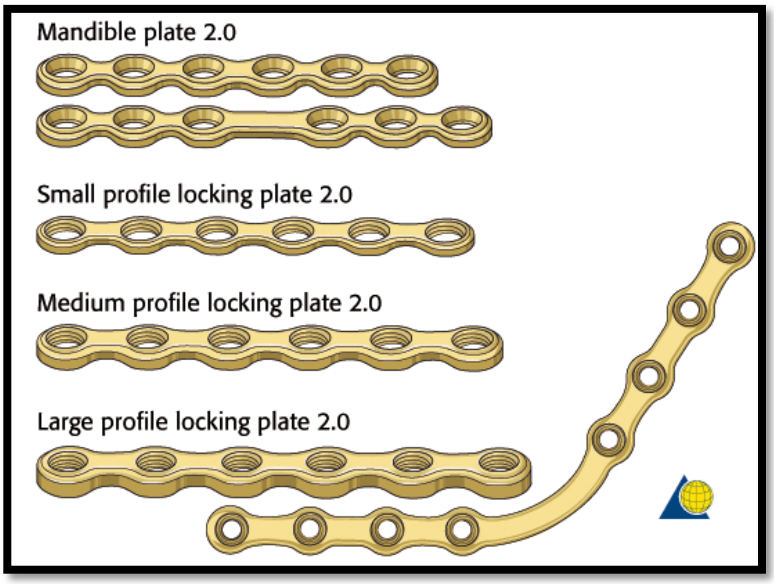

Figure 5 – Some kinds of reconstruction plates

Bone screws are available in different shapes, and sizes for different uses. Each kind of screw is defined by a specific thread, head, core and tip that suits its application.

Most commonly, bone screws are used for one of the following purposes: 1) to produce interfragmentary compression, 2) to attach implants to the bone by compressing them onto the bone surface, 3) to attach implants to the bone producing angular stability, to hold to bones in correct relationship or 4) to lock an intramedullary nail to the bone or its fragments (Colton & Orson, 2012). The main types of bone screws include: cortical bone screws, cancellous bone screws and locking head screws. Cortex screws are conventional screws with shallow threads and a rounded head that matches the compression holes of DCP and LC-DCP plates. Their dimensions and tolerances are specified by the ISO 5835 standard which refers to cortical bone screws as HA screws. Cortex screws are generally used together with any of the modern compression plates, or by its own to compress fracture fragments together, applying the lag screw technique (Messmer, Perren, & Suhm, n.d.).

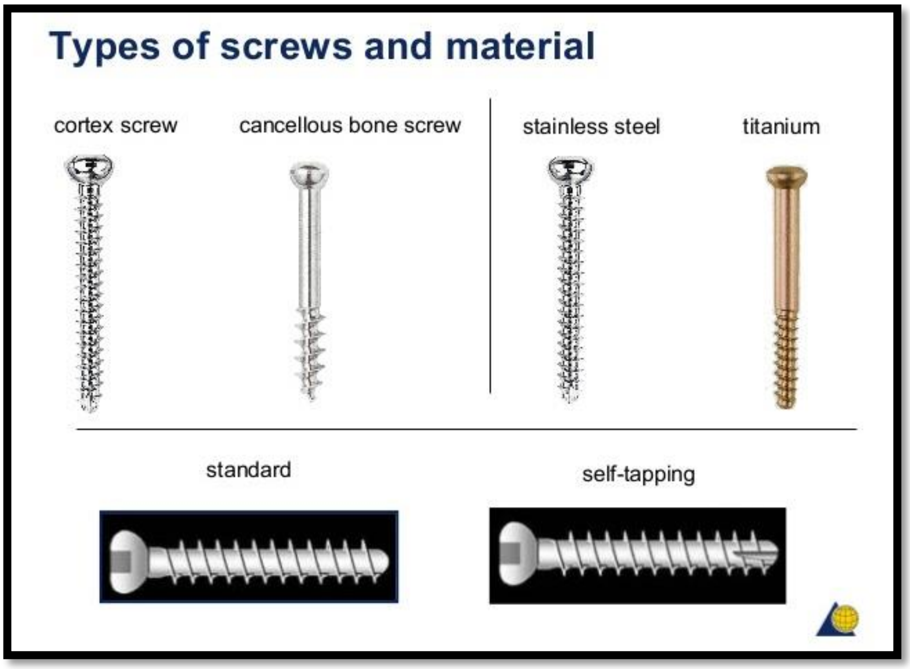

Figure 6 – General classification of bone screws

Cancellous screws are very similar in shape to cortex screws. However, a coarser deeper thread and larger diameters are necessary to be used in the softer tissue of spongy cancellous bone. Their dimensions and tolerances are also defined by the ISO 5835 in which they are called HB screws (ISO/TC 150, 1991). Cancellous screws have similar applications to those of cortex screws but are used where the cortex of the bone is insufficient or inadequate to tighten and support the screw.

Locking screws have a conical threaded head that matches the threaded hole of LCP plates. This feature locks the screw in place and creates an angularly stable construct that impedes the relative angular motion of plate and bone (Colton & Orson, 2012). Locking screws do not create a significant axial compression and act only as simple fixators.

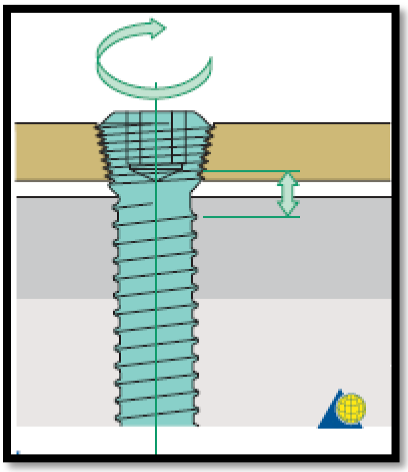

Figure 7 – Locking head screw

In Ecuador, surgeons use these implants and screws for osteosynthesis on a daily basis. However, these medical supplies must be imported, and the cost is very high. In some cases, privately insured patients and public hospitals spend thousands of dollars on implants for a single reduction procedure. There is interest in producing osteosynthesis plates and screws locally to lower the price and supply the constant demand of the national health care system. Establishing a local industry of high quality medical devices would be beneficial for the citizens and a great achievement for the industry.

The main objective of this project is to design and manufacture prototypes of orthopedic plates and screws for the internal fixation of bone fractures. The designed products must comply with the international standards for inter-compatibility, the requirements of the medical staff and with every regulation which aims to guarantee the patients' health and safety. The technical resources of the local industry and the manufacturing costs of the plates and screws as fully functional consumer products will be analyzed, to evaluate the possibility of growing this idea from engineering project to business. To be considered a viable industry, it should be able to provide an adequate supply of, at least, the most commonly used kinds of implants, at reasonable prices and with excellent quality control.

As a first approach to this industry, this project will focus on the plates that surgeons had pointed out as the most demanded: the 3.5mm LC-DCP plate for small fragments and the 4.5mm LC-DCP plate for large fragments. These two plates and their complementary screws will be designed and manufactured, complying with all the medical and mechanical requirements. The LC-DCP compression plates are regarded as the gold standard for osteosynthesis of long bones by the AO Foundation and manufacturers (AO Foundation, n.d.; Synthes (USA), 2010). It offers a good combination of ease of manufacturing and medical advantages and is a good compromise between the older DCP and the more expensive LCP. The appropriate screws for each of the selected plates is clearly specified by the AO Foundation: "The LC-DCP 4.5 is used with 4.5 mm cortex screws and 6.5 mm cancellous bone screws. The LC-DCP 3.5 is used with 3.5 mm cortex screws and 4.0 mm cancellous bone screws" (AO Foundation, n.d.). These screws will be manufactured together with their matching plates.

Considering that this is a design and manufacturing project, the usual engineering design process was followed. Several medical publications were reviewed to gather the design requirements and characteristics of the desired product (Colton & Orson, 2013b; T Miclau, Remiger, Tepic, Lindsey, & Mclff, 1995; Sonderegger et al., 2010; Synthes (USA), 2010). Applicable standards (ASTM International, 2017a, 2017b; ISO/TC 150, 1991) were analyzed for compliance and the end user was consulted to get valuable feedback. For plates, the AO Foundation handouts and surgery reference journals (AO Foundation, n.d.; Colton & Orson, 2012, 2013a; Messmer et al., n.d.) were used to understand the form and function of the chosen implants. Similarly, the ISO 5835 standard for bone screws was extremely useful to design the fasteners (ISO/TC 150, 1991). This information was used to design 3D CAD models which meet the ISO requirements and work with industrial standard tools.

Once the design of plates and screws was finished, the manufacturing and material selection procedures were very similar to those used for any mechanical part. However, special human safety requirements were especially considered. Orthopedic implants must be biocompatible, sterile and long-lasting to be safe. In this regard, surface finish, corrosion resistance, chemical stability, mechanical toughness and asepticism are crucial. Commercially pure titanium (cp-Ti) and 316L stainless steel are the materials of choice for most orthopedic implants, due to its excellent corrosion resistance, passivation capacity and biocompatibility (Textor, Sittig, Frauchiger, Tosatti, & Brunette, 2001). Manual trimming, machining, polishing, cleaning, anodizing and mechanical testing are some of the necessary techniques to produce safe implants (Xu et al., 2014).

Upon analysis of cost and technical complexity, surgical grade 316L stainless steel was the material of choice for plates and screws. CNC milling was used to shape the metal, to match the complex design of the plate, whereas CNC turning with custom made threading tools and spark erosion machining were used to machine the screws. Mechanical and electropolishing were used to improve the surface finish. Finally, the citric acid method described by the ASTM 967 Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts was used for passivation (ASTM

International, 2017b). These series of techniques form a complete process which can be used to produce the orthopedic implants. A proposed industrial setup is further described in the final part of this document. Testing procedures which are necessary to be able to commercialize the plates and screws were not performed and are just mentioned in each corresponding section of the suggested production line, as vital information for future projects in this subject.

METHODS

Design Requirements

The plates and screws for osteosynthesis work together as a system and their requirements and characteristics are correlated. That being said, screws are standardized and are already dimensioned and designed, so they are presented first.

Screws

The ISO 5835 standard for metal bone screws defines two different types of screws: the HA screw with shallow threads (for cortical bone) and the HB screw with deep threads (for cancellous bone) (ISO/TC 150/SC 5, 1991). The standard clearly defines the dimensions and tolerances for the screws, with spherical under-surface of head and asymmetrical thread, which are used to secure LC-DCP plates. Annex A and Annex B are extracts of the standard that define the design of cortical and cancellous screws respectively.

Plates

The requirements for LC-DCP plates are more elaborated and exact dimensions are not standardized. To begin with, the name of the plates gives some information. DCP stands for dynamic compression plate and refers to the dynamic compression holes the plate has. The hole must generate compression on the fracture when the screws are tightened. The older DCP plates used an asymmetrical hole shaped as an inclined cylinder which guided the screw head towards the center of the plate. However, LC-DCP plates feature a symmetrical hole shaped as half an ellipsoid. The central area of the hole is used for neutral screws (no compression generated) and has a slightly bigger radius of

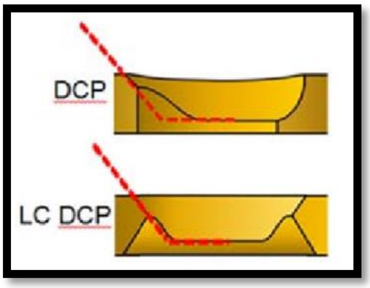

Figure 8 – Cross section of DCP and LC-DCP holes.

curvature than the screw head. In contrast, the sides of the hole have a smaller radius, so they can guide an eccentrically installed screw towards the center.

The prefix LC stands for limited contact and refers to footprint of the plate, or the surface area of the plate in contact with the bone. Whereas DCP plates had a flat bottom, LC-DCP have notches and fillets that reduce the contact with the bone and have the added benefit of producing a more uniform bending, as explained previously. Additionally, LC-DCP plates have slightly curved bottom faces to better conform to the surface of bones.

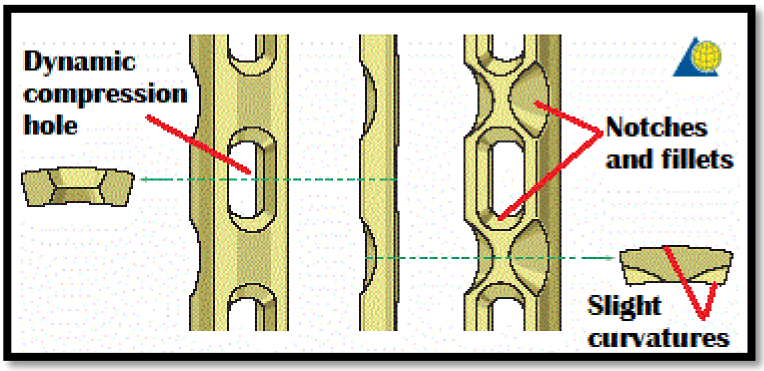

Figure 9 – Features of LC-DCP plates

The last requirement for plates is related to the screw geometry. The curvature of the hole must match the curvature of the ball shaped cup under the surface of the screw. For example, 3.5mm plates are used with 3.5mm cortex screws and 4.0mm cancellous screws which have heads with a 3mm radius. In consequence the radius of curvature of the neutral position of the holes must be marginally higher than 3mm.

3D Modelling

The manufacturing of 3D geometries with curvatures and small details requires the use of CAD software to create a digital blueprint that a CAM software can use to create the instructions for CNC machining. Autodesk Inventor Professional 2017-Student Version was the CAD software used for 3D modelling. Based on the design requirements and the information provided by the public catalogues of the leading orthotics manufacturer (DePuy Synthes), some basic dimensions were established in order to model the shapes and characteristics of both plates and screws. It is important to note that these implants are sold in many different lengths and with different number of holes, but the overall shapes are not size specific. The general dimensions for LC-DCP plates are included in Table 1. The specifications of the screws can be consulted in annexes A and B.

Table 1 - LC-DCP plates dimensions ("n" represents number of holes)

	LC-DCP 3.5mm	LC-DCP 4.5mm
Length	$(n \times 14)$ mm	$(n \times 18.5)$ mm
Width	12 mm	16 mm
Thickness	4 mm	5.5 mm
Holes separation	14 mm	18.5 mm
Holes curvature (min.)	r = 3 mm	r = 4 mm

CAD models of the selected plates and screws are shown in figures 10 and 11.

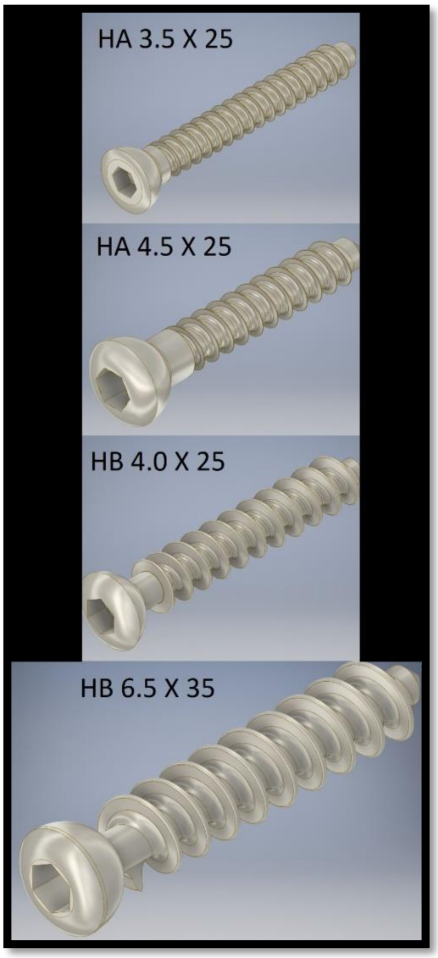

Figure 10 - CAD models of HA and HB screws based on the ISO 5835 standard

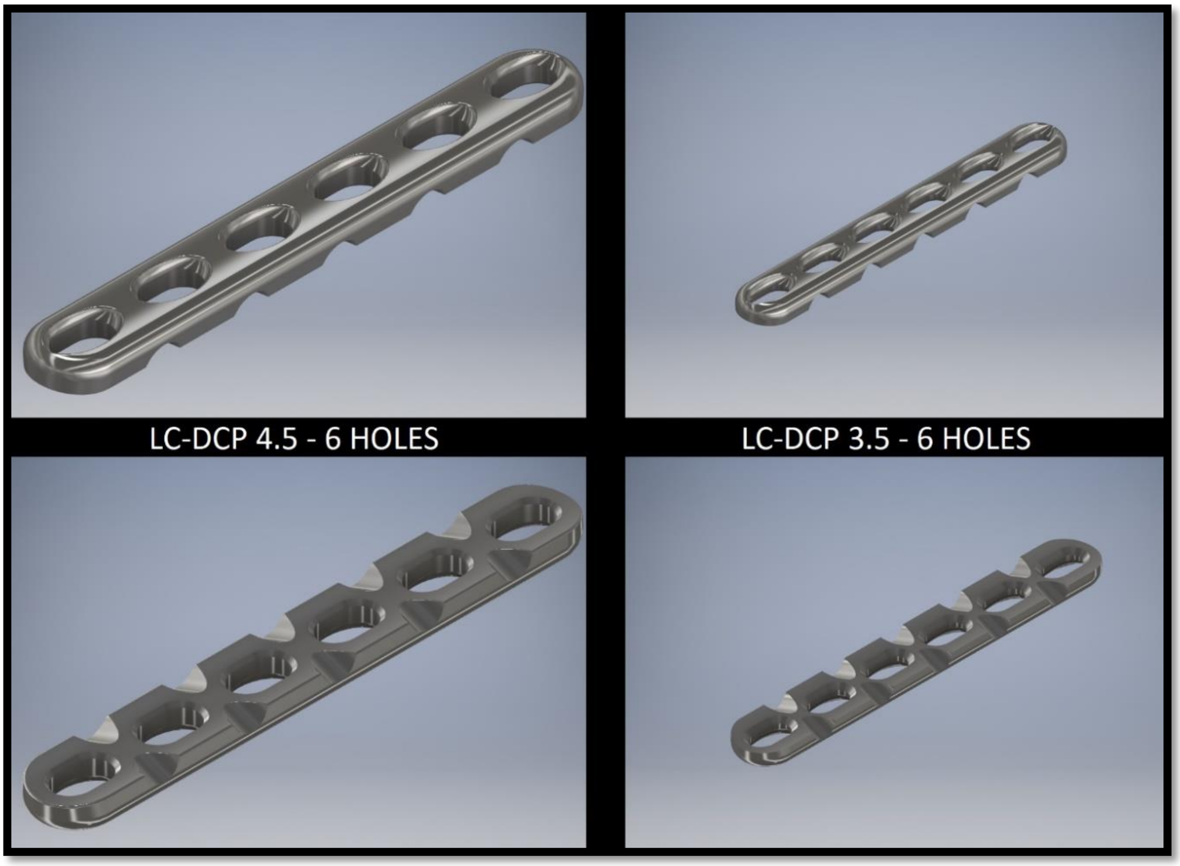

Figure 11 - CAD models of LC-DCP plates - front and back sides

Every characteristic given by the AO Foundation Surgery Reference was considered for the design of the plates. This includes the dynamic compression symmetrical holes, the reduced footprint in contact with the bone and the improved contour-ability. The first was achieved preforming a revolve operation to produce an ellipsoid shape.

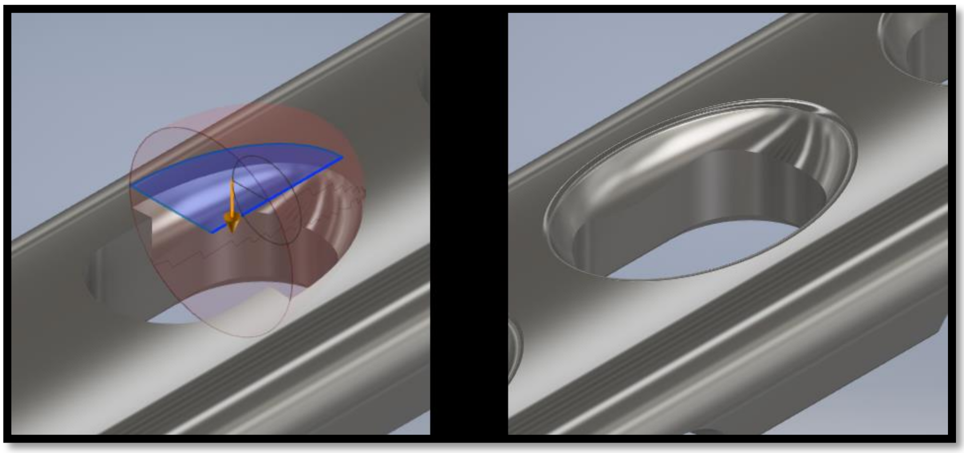

Figure 12 - Dynamic compression hole

The reduced surface area of the bottom face and the improved bendability are both a product of the grooves which are positioned where the cross section is normally bigger, far from the holes. This improvements of the LC-DCP plate over the DCP can be measured and are shown in the next figures. For example, the biggest to lowest cross section ratio of the 4.5mm plate goes from 1.87 to 1.56 thanks to the material removal in those areas. Considering that a ratio of 1 represent a constant cross section which would make for a perfectly contourable plate, the design is effective. Likewise, the surface contact with the bone is reduced from 10 cm^2 to 7.3 cm^2.

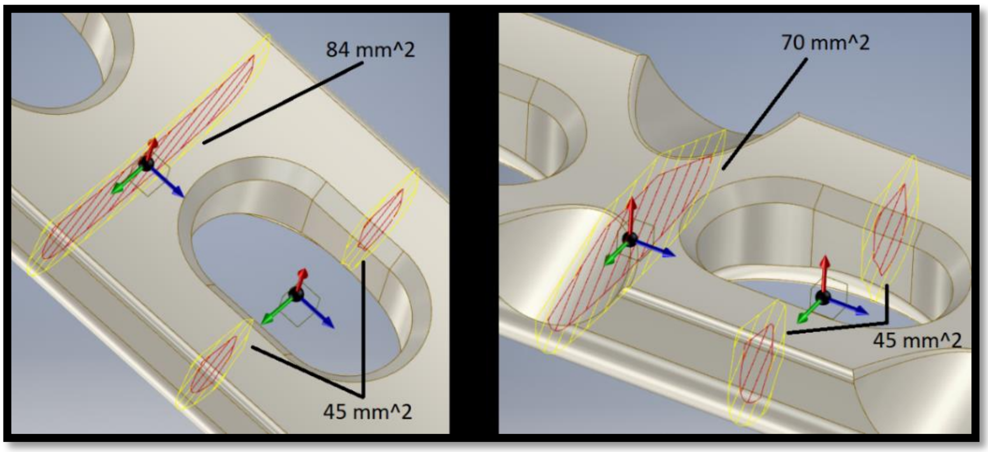

Figure 13 - Design analysis of the cross sections

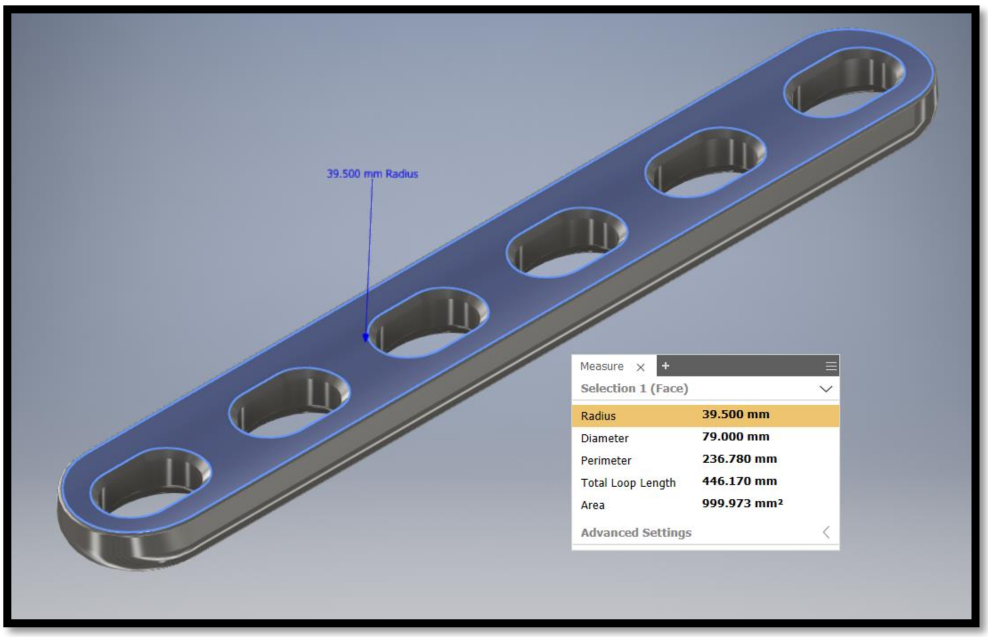

Figure 14 - Undersurface of a DCP shaped plate

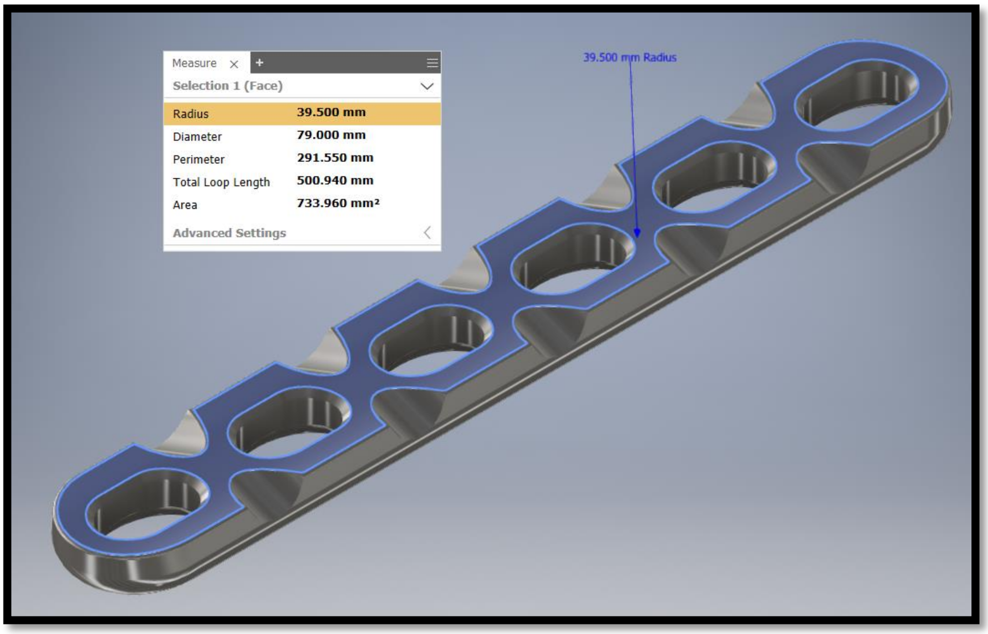

Figure 15 - Reduced undersurface (contact area) of the LC-DCP plate

Materials selection

There are three main requirements for the materials used for orthopedic implants: corrosion resistance, ductility, and mechanical strength. Additionally, price, availability and machinability should be considered. Three main metal alloys are used for orthopedic implants due to their high resistance to corrosion: stainless steel based alloys, cobalt alloys and titanium alloys (Sansone, Pagani, & Melato, 2013). LC-DCP plates and their corresponding screws are commonly made from 316L stainless steel, commercially pure titanium (grade 4) or Ti-6Al-4V titanium alloy. Table 2 summarizes the advantages and disadvantages of each of those materials.

Table 2 - Advantages and disadvantages of commonly used biocompatible materials

	316L SS	cp-Ti Grade 4	Ti-6Al-4V
Corrosion resistance	Biocompatible	Biocompatible	Biocompatible
Ultimate tensile strength	85 ksi	80 ksi	170 ksi
Machinability	Fair	Good	Fair
Price	Lower	Highest	Higher
Necessary surface finish	Mirror-like Polishing	Anodizing	Anodizing
Elongation at break	45%	15%	10%

For this project, 316L stainless steel was the material of choice due to its combination of availability, affordability, strength and ductility. Although it is harder to machine than cp-Ti, stainless steel does not need anodizing which is a process not available at this moment. As an added benefit, there is more information about 316L steel machining and tools are easier to find.

Machining

Screws

Manufacturing screws might seem trivial at first glance, but this particular kind of screws presents a series of challenges. Given that they have custom threads and heads, custom tooling is necessary. Also, the low production rates make CNC turning the only choice for manufacturing. Lastly, the small dimensions and the material poor machinability result in a highly difficult machining process. Parts breakage and dimensional inaccuracy due to bending are hard to avoid. Summarizing, the turning setup and the programming must be thoroughly controlled to obtain satisfactory results.

The first step of the turning process consists in making a center-drilled hole on the end of the stock material to accommodate the tailstock which is necessary to avoid the fracture or bending of the screws. After this manual operation, the rest of the process is CNC controlled. The approximate profile of the screw is turned first to remove most of the material rapidly. Then, the profile of the part is machined to its final dimensions with shallower step-overs to reduce stress on the material and improve surface finish.

Figure 16 - Turning process: profile roughing, profile finishing, thread roughing and thread finishing

The next step is threading, done with custom made Electric discharge machining (EDM) wire cut tools to match the dimensions given by the ISO 5835 standard. Threading generates the highest stress in the screws because it must cut deep and very slowly. In this case, the process is even more difficult because the threading tools have round edges (see figure) and the HB screws have extremely deep threads. After several failed attempts to machine the threads, a pointier threading tool was used to open the path before the final threading with the ISO 5835 based tool.

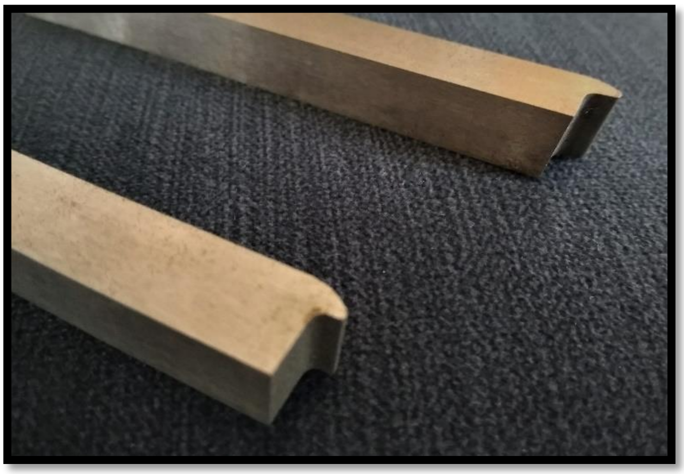

Figure 17 - Custom made HSS-Co threading tools

After threading, the screw was cut out of the stock material and both ends (head and tip) were machined using plastic bushings to hold the screw without damaging the threads. Turning times until this stage ranged from 12 to 20 minutes per screw.

Table 3 - Turning parameters used for all the screws

	Profile roughing	Profile finishing	Threading
Spindle speed	2500 RPM	2500 RPM	500 RPM
Feed per revolution	0.2 mm	0.1 mm	Thread pitch
Step-over	0.2 mm	0.1 mm	0.05 mm
Repeat finishing pass	No	Yes	Repeat whole cycle

Finally, a small hexagonal socket was machined in the head of each screw. There are two ways to machine polygonal sockets: rotary broaching and EDM by penetration.

The first uses a cutting tool (the broach) and a special holder to perform a drill-like operation using controlled wobble and a cutting angle relative to the work piece. This method is extremely precise and fast, so it is the ideal one for these parts. Unfortunately, rotary broaches are not available in the Ecuadorian market, leaving EDM by penetration as the only option.

EDM by penetration plunges an electrode with the desired shape of the socket into the workpiece using electric discharges to erode the material. This process has two main disadvantages: it is very slow (approx. 30 minutes per screw) and there can be contamination due to the use of diesel fuel as a dielectric between the copper electrode and the stainless steel part. The eroded surface finish left by the electric discharges needs a thorough cleaning and a subsequent electropolishing to ensure the adequate passivation of the part. EDM can be observed in Fig 18. The electrode is smaller than the desired socket to account for the process tolerances; a 0.1mm (approx..) gap is left between the eroded part and the electrode. The electrode was fabricated from copper.

Figure 18 - Hexagonal socket EDM by penetration

The result after every machining process is a screw with the shape and dimensions specified by the standard, but still far from the desired surface finish and cleanliness.

Figure 19 - Bone screws in post-machined condition

Plates

A desktop 3-axis CNC mill was used to machine the plates completely. A two-sided machining process was needed to form all the design features. The biggest challenges were the secure fixation of the material to the machine, the alignment after flipping the part and setting the machine and tools zeroes.

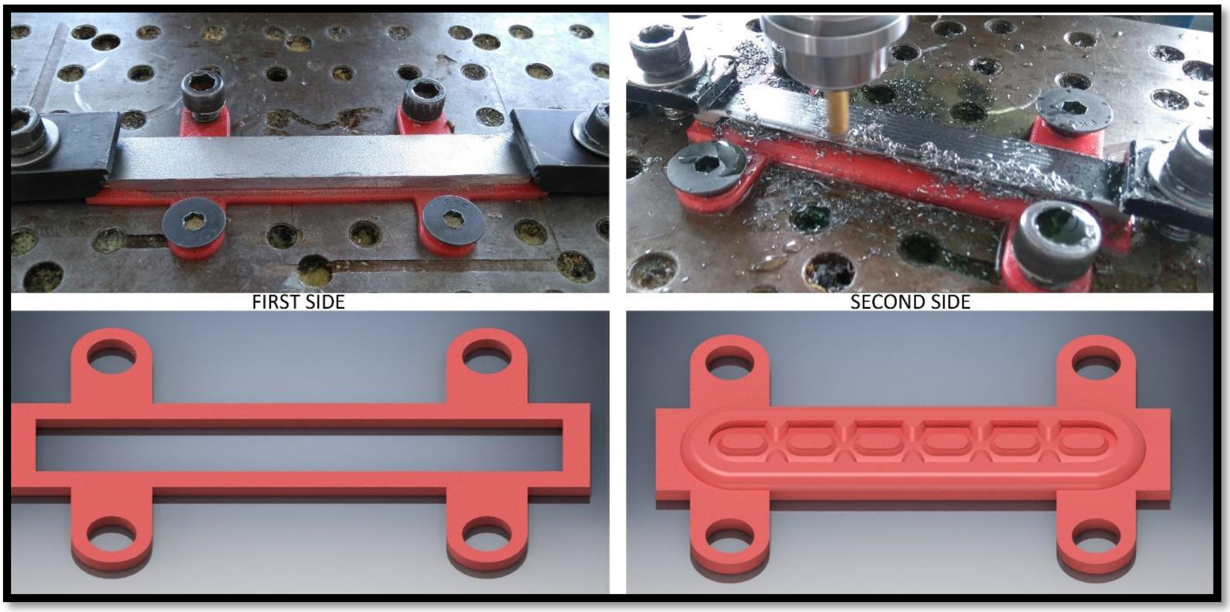

Figure 20 - Above, custom fixtures set up on the machine. Below, 3D renders of the fixtures design.

To address these inconveniences, custom fixtures were 3D printed to facilitate the alignment and improve the positional stability of the material. Additional metallic fasteners were used to ensure the tightness of the fixation. This system helped to minimize wasted material and machining time because it was possible to use smaller stock material. Additionally, it allows to move the fasteners to machine different sections of the part without misalignments.

On a different note, there are various factors that can limit or make stainless steel milling inviable. These include spindle power and torque, cooling and axis motion strength. Fortunately, the parts that had to be milled were small and small tools could be used, diminishing the required machining power and torque. The largest tool was a Niagara Cutter 4 flute AlTiN coated solid carbide 6mm ball endmill. The manufacturer recommends a speed of 160 SFM[2] and a feed of 0.0005 inch/tooth for 316L stainless steel. The maximum depth of cut was set to 1.2 mm because the maximum difference between the thicknesses of the stock material and the plate was 3.4 mm, which was split into a 1.2 mm roughing pass and a 0.5 mm finishing pass per side. The maximum width of cut was half the diameter of the tool. The specific cutting force K_c of 316L stainless steel was estimated to be 3500 MPa from tables. The following equation can be used to calculate the required spindle power (Tönshoff, 2013):

$$P_c = \frac{a_p \times a_e \times f_z \times z \times n \times K_c}{60 \times 10^6 \times \eta}$$

P_c is spindle power, a_p is depth of cut, a_e is width of cut, f_z is feed per tooth, z is the number of flutes, n is spindle speed, η is spindle efficiency and units are mm, MPa and kW. With a 90% efficiency, the maximum required power is 0.032 kW or 0.043 hp. The

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[2] Surface feet per minute

intelitek PROLIGHT 1000 milling machine used for the project is a 1 hp machine, so it has power to spare.

The spindle power is relatively low, but it can get transformed mostly into heat. 32 W can heat up a 30 gram piece of metal very fast. This can be problematic because high temperatures might affect the material properties, requiring subsequent heat treatment, and reduce tool life. The PROLIGHT 1000 did not have a coolant system, so manual cooling was necessary. Automotive engine coolant (without antifreeze) was used because it contains rust inhibitors and it is easily available. Engine oil was used when lubrication was required. This combination was found to be adequate. However, a machining specific coolant should be used for mass production.

Once fixation, power and cooling were taken care, the last step was to program the machine. Autodesk Inventor HSM 2017 Ultimate Student Version was the CAM program of choice due to its seamless integration with the CAD software. Modern CAM software automatically generate toolpaths based on the CAD model and the input machining parameters. The user just need to determine the ideal operation for each part of the model and the appropriate feeds and speeds. Additionally, the machining operations can be simulated to find any errors, avoid crashes and estimate runtime.

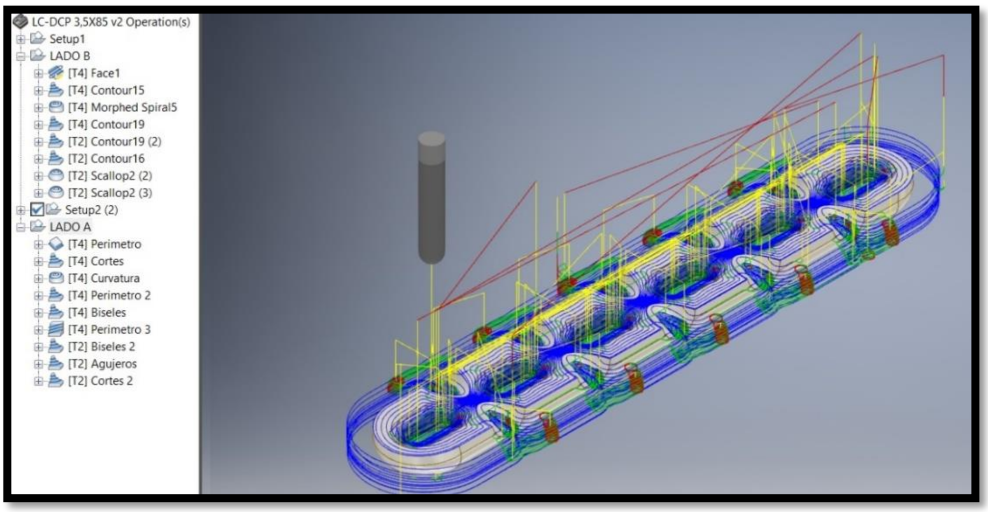


Figure 21 - Toolpaths for the LC-DCP 3.5 plate CNC machining

Calculated speeds and feeds were used to make the CAM programs and were sent to the machine. However, spindle speed and feed overrides were used to adjust chip load using vibration, noise and material removal as references. The sweet spot is characterized by small chips that do not stick to the tool or the part, and lack of high pitched sounds. Tool deflection was also considered when small tools were used. With this machine and tooling, the machining time was 5 hours for the 3.5 mm plate and 8 hours for the 4.5 mm plate. Three stages of the milling process are shown in Figure 22. Chips had adequate size and shape along the entire process.

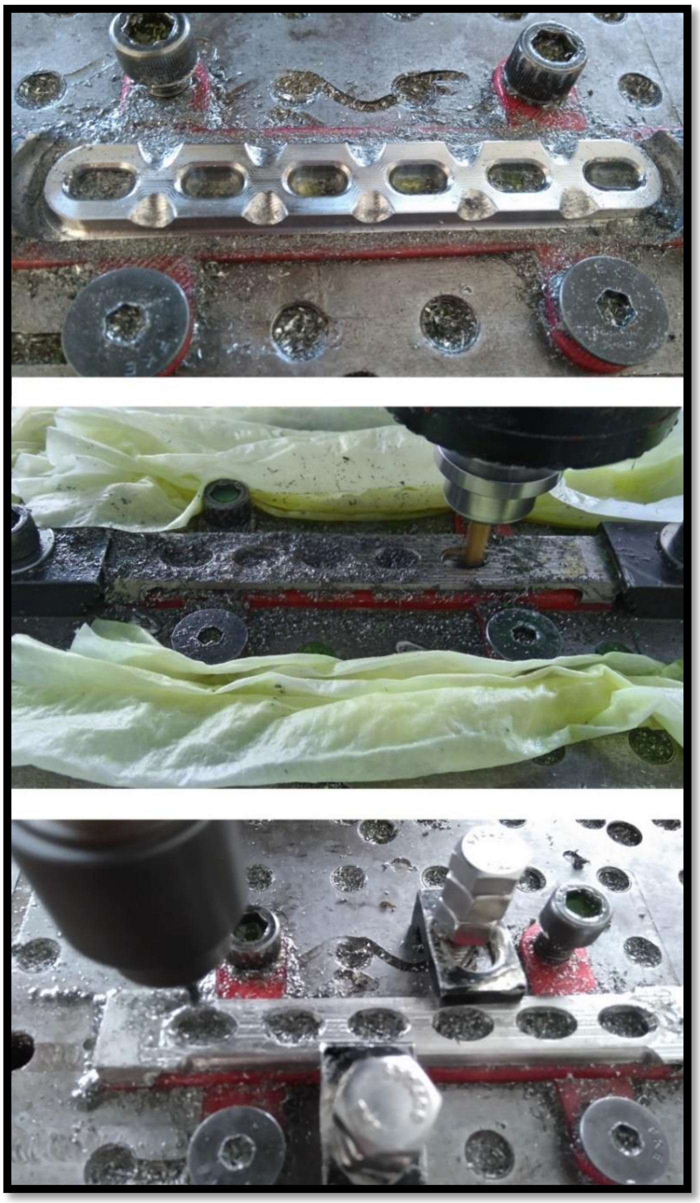


Figure 22 - Three stages of the milling process. Chips had adequate size and shape along the entire process.

Figure 23 shows the condition of the plates immediately after the machining process.

Figure 23 - LC-DCP plate in post-machining condition

The parts had a rough surface finish and marks from toolpaths. Also, the area which was last cut to remove the part from the leftover material had a ridge because the tool did not go all the way down to produce a smooth surface. Some grinding and sanding was necessary to remove burrs and imperfections. Afterwards, tumble polishing (with ceramic media composed by kaolinite, feldspar and silica) and buffing were applied to the plates to get a mirror like surface quality, suitable for medical use. After sanding the parts are rough but uniform; tumble polishing leaves a smooth but dull surface; finally, buffing produces a shiny finish. The surface quality after the last two steps is shown in Figure 24.

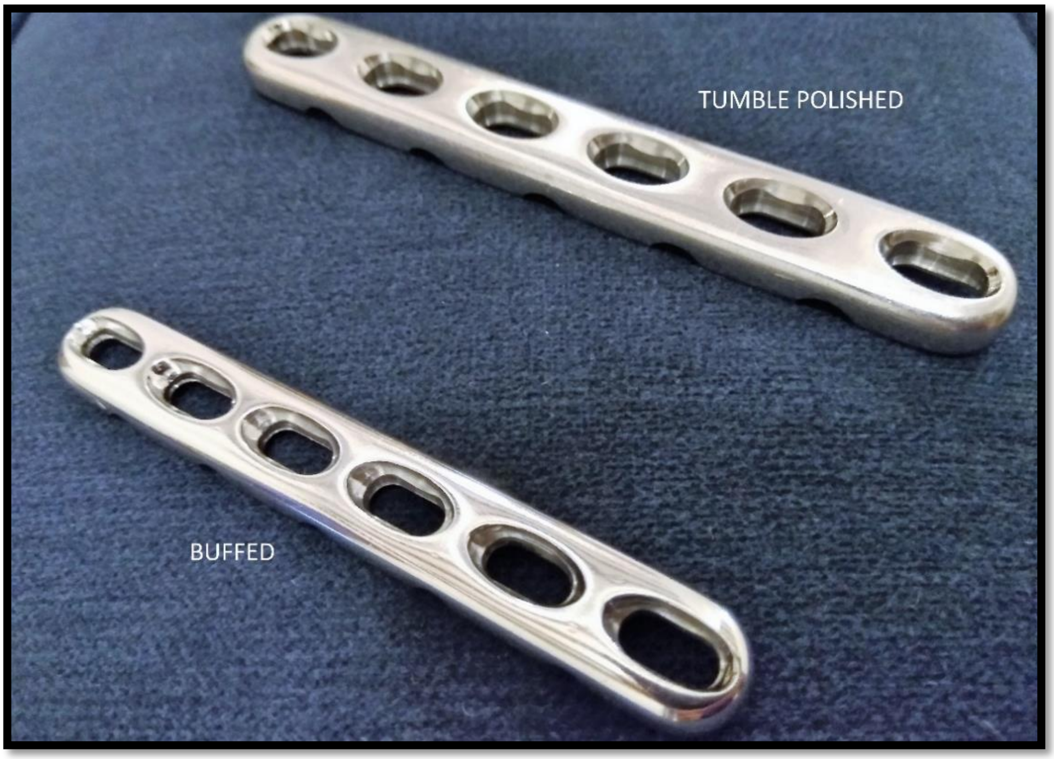


Figure 24 - Difference of surface finish between polished and buffed plates

Surface treatments

316L stainless steel is one of the most corrosion resistant metals. Under most circumstances the surface forms a protective oxide layer that prevents the attack of corrosive substances. Nonetheless, during manufacturing ferrous particles and other impurities can be deposited on the parts. To obtain the best possible corrosion resistance, parts must be passivated. Passivation removes most contaminants on the metal surface, but more importantly creates a continuous layer of chromium oxide which impedes the attack of oxygen in the air. The ASTM Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts is the industry's reference for stainless steel passivation and has guidelines for the three main methods: immersion treatments using nitric acid solutions, immersion treatments using citric acid solutions and electrochemical treatment.

Whichever treatment is selected for passivation, parts must be thoroughly cleaned and degreased to remove oil, grease, rust, coolant or any other form of contamination. Dirty spots might cause pitting when the acid bath reacts with any exogenous substance. The A967 standard (ASTM International, 2017b) refers to the A380 standard (ASTM International, 2017a) for information about pretreatment cleaning. The latter states: Degreasing and general cleaning shall be accomplished by immersion in, swabbing with, or spraying with alkaline, emulsion, chelate, acid, solvent, or detergent cleaners or a combination of these; by vapor degreasing; by ultrasonics using various cleaners; by steam, with or without a cleaner; or by high-pressure water-jetting. To select a cleaning method the sources of contamination were considered. Plates were mechanically polished, so the main contaminant was polishing compound. On screws there was diesel contamination due to the EDM process. A combination of immersion in citrus degreaser and swabbing was used to remove contaminants from every area of the parts, leaving a clean surface, suitable for passivation treatment. Figure 25 shows the parts soaking in degreaser.

Figure 25 - Pre-passivation cleaning process

After cleaning, different passivation treatments were selected for plates and screws, considering the surface condition produced by their corresponding manufacturing methods.

Plates

Thanks to their mostly accessible and naturally smooth surface, plates could be polished and buffed using traditional methods that produce a shiny finish. This means that they only needed either a nitric acid or a citric acid bath treatment. There are four suitable treatments for 316L steel passivation, as per the A967 standard (ASTM International, 2017b), as described in Table 4:

Table 4 - Passivation processes for 316L stainless steel

	Nitric 2	Nitric 3	Citric 1	Citric 2
Chemistry	20 to 45 volume percent of nitric acid	20 to 25 volume percent of nitric acid	4 to 10 weight percent of citric acid	4 to 10 weight percent of citric acid
Time	>30 minutes	>20 minutes	>4 minutes	>10 minutes
Temperature	21 to 32°C	49 to 60°C	60 to 71°C	49 to 60°C

Nitric acid passivation is the chosen method for many grades of stainless steel because of its effectiveness, but it is considered more hazardous and contaminant than citric acid passivation. 316L is a good candidate for citric acid passivation because it has an inherent high resistance to corrosion and does not require an aggressive treatment. Both citric acid methods were used, one on each plate. To finish the surface treatment, parts were rinsed with clean water and dried. Also, they were visually inspected to detect any possible damage due to improper acid bath treatment. No noticeable difference was found between the two combinations of time and temperature and neither caused evident flash attack[3]. The 3.5 mm plate was passivated using the *Citric 1* method, whereas the *Citric 2* method was used for the 4.5 mm plate, as shown in Figure 26.

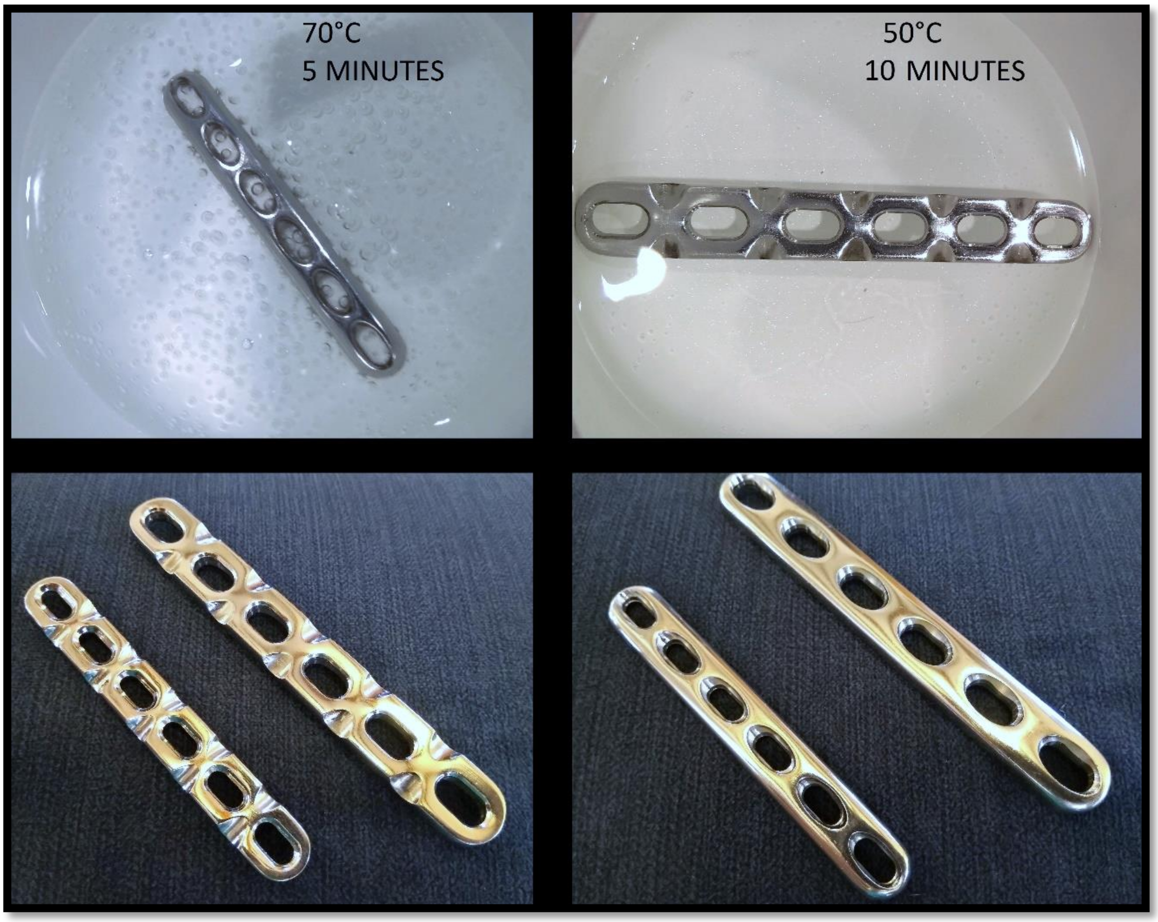


Figure 26 - LC-DCP plates acid-bath passivation and results

Screws

Screws have areas that are hard to reach with mechanical polishing methods: threads and sockets. In consequence, electropolishing is the only way to produce a smooth and shiny surface. Moreover, according to the A967 standard (ASTM International, 2017b), the surface resulting of electrochemical treatments does not require a separate treatment for passivation. This means that electropolishing is an all-

[3] Surface degradation on parts, characterized by a dull gray finish, due to improper acid concentration, chlorine contamination, temperature or immersion time.

in-one treatment to condition the parts for use in medical application because it achieves smoothness and corrosion resistance. Having said that, the complexity of the process is much higher than that of acid bath passivation. Finding the right parameters is not as simple as looking for an international standard. Few organizations publish their electropolishing setups and in the end some experimentation is inevitable to get good results. Figure 27 is a diagram of a basic electropolishing system: a power source is used to generate electric current between the part and metallic cathodes. Metal ions are removed from the part surface and flow through the electrolyte towards the cathodes.

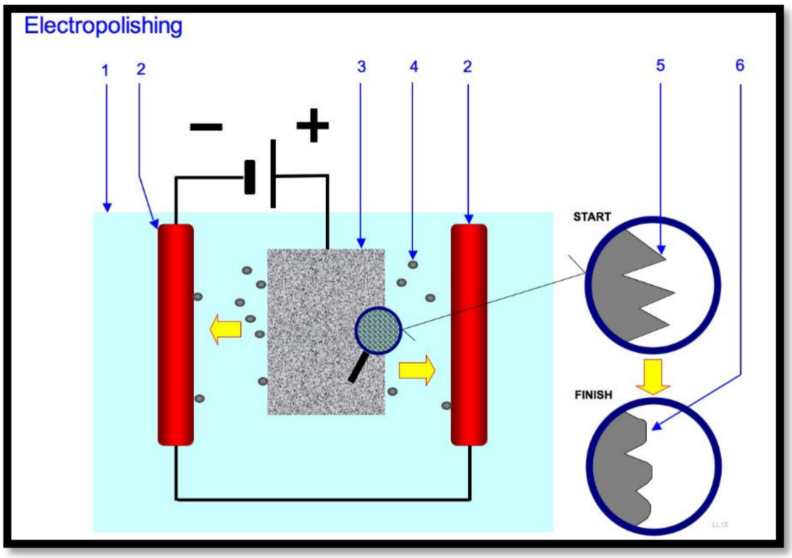


Figure 27 - Electropolishing setup: 1. Electrolyte 2. Cathode 3. Work-piece (anode) 4. Metal particles removed from work-piece 5. Surface before polishing 6. Surface after polishing.

A recommended system for stainless steel electropolishing consists of an equal volume mixture of 96% mass fraction sulphuric acid and 85% orthophosphoric acid electrolyte diluted with 20% of water, a current density between 5 and 25 A/dm^2, a temperature between 40 and 75°C and 2 to 20 minutes of polishing time (Kosmac, 2010). To simplify the process current was set to 1A, temperature to 45°C and time to three minutes for all the screws. With the set current, current density ranges from 11.3 to 24.6 A/dm^2. Figure 28 is a picture of the laboratory setup used to test the electropolishing process. Copper wiring, stainless steel cathodes and glass containers were used considering the acid electrolyte compatible materials.

Figure 28 - Electropolishing of bone screws

After polishing, the parts were rinsed with water and cleaned with degreaser to remove the electrolyte and any by-product of the process. Different results were obtained for each part, ranging from shiny and smooth to no-improvement. Current density differences produced different surface finishes and, probably, varying passivation effectiveness. However, parts did not have any visual signs of flash attack such as etched, dark or rough spots; not even the control sample which was submerged without electric current. Unfortunately, it was also evident that that the electropolishing process could not remove all the eroded material in the socket area. The electropolished screws are depicted by Figure 29.

Figure 29 - Electropolished bone screws

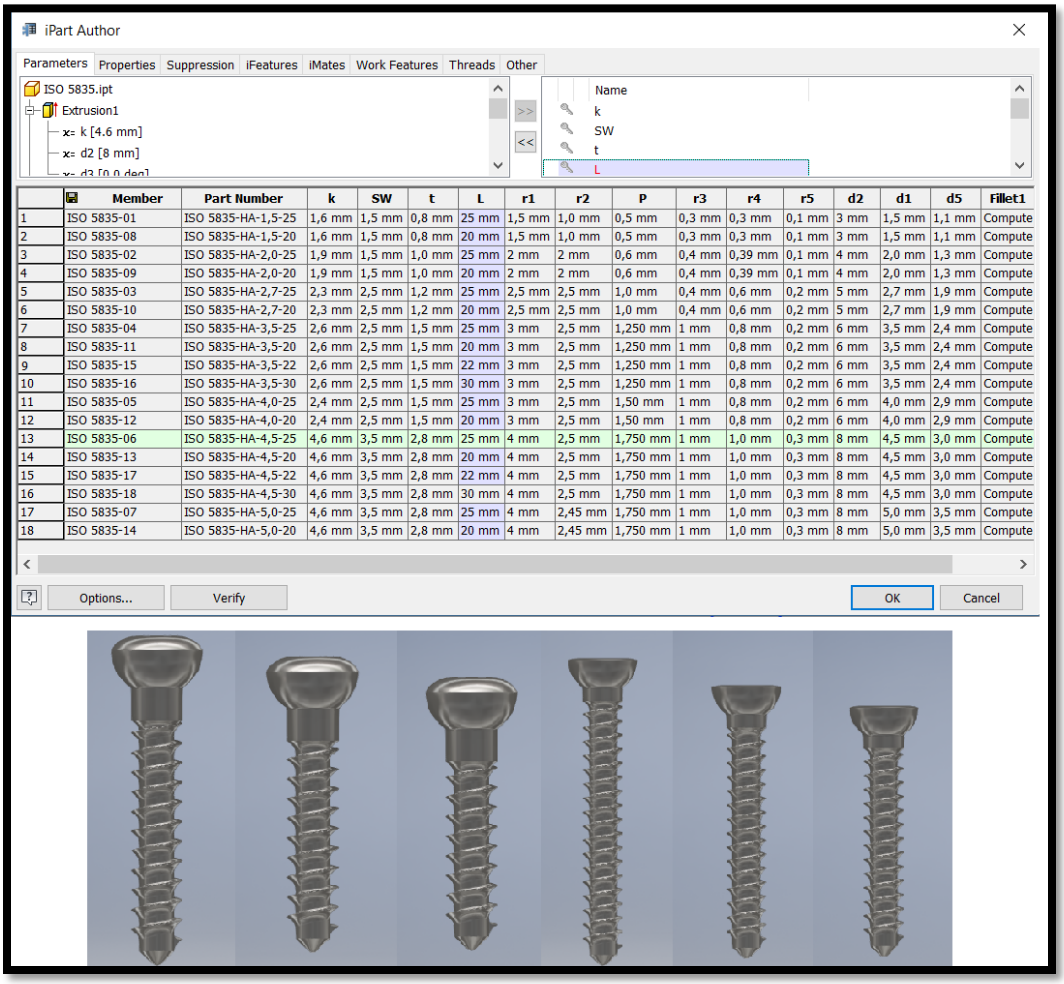
The results of the electropolishing process varied from part to part. Screw shown as *1* in the figure was treated with the highest current density and the surface finish was very smooth and shiny. The lowest current density was applied to screw number *2* and it got a shiny finish, but some machining imperfections were not smoothened. Screws *3* and *4* polishing was not satisfactory for unknown reasons. In all cases, electropolishing was not enough to remove all the eroded material from the socket area, although in screw *1* the improvement in this area was significant. In summary, the process can improve the surface finish, but parameters must be optimized to get adequate results.

RESULTS AND DISCUSSION

The general objective of the project was to gather all the theoretical and practical information needed to industrially produce LC-DCP plates and bone screws. This includes the designs, manufacturing processes, testing requirements, production times, and costs. One prototype of each kind of screw and plate was manufactured to apply and test fabrication techniques. The prototypes were manufactured considering every requirement of the final product and the end results are not mock-ups. Although standardized testing was out of the scope of this project, the plates and screws that were developed are technically very similar to commercial functional counterparts, materials and overall quality. Nonetheless, the prototypes by themselves are not the end result of the project; they were means to study manufacturing techniques and treatments for this kind of medical products. This section presents the outcomes of the research and development.

Design process

Screw and plates are available in various sizes. Each kind of screw and plate has particular geometric characteristics and some dimensions that remain constant. Autodesk Inventor has a feature called *iPart* which allows to generate CAD models with different dimensions based on a single design. With this, the models for every size of plate and screw were created by filling the varying parameters in a simple table. A very wide catalogue of parts is one of the results of this project. If necessary, other sizes can easily be created by anyone adding rows to the table. This means that no further CAD modelling would be necessary for the industrial manufacturing of the products. However, modifications and improvements can be done to the design and the program would automatically update all the models. The parametric nature of modern CAD design was used to create models which meet the design requirements in each size and version, maintaining factors like socket size and interface curvature while varying other parameters like length and number of holes. iParts are also linked to CAM setups and programs, which are easily modified for each part size. Figures 30 and 31 show a table of parameters that Autodesk Inventor uses to generate *iPart* models and some of resulting CAD models.



	Member	Part Number	k	SW	t	L	r1	r2	P	r3	r4	r5	d2	d1	d5	Fillet1
1	ISO 5835-01	ISO 5835-HA-1,5-25	1,6 mm	1,5 mm	0,8 mm	25 mm	1,5 mm	1,0 mm	0,5 mm	0,3 mm	0,3 mm	0,1 mm	3 mm	1,5 mm	1,1 mm	Compute
2	ISO 5835-08	ISO 5835-HA-1,5-20	1,6 mm	1,5 mm	0,8 mm	20 mm	1,5 mm	1,0 mm	0,5 mm	0,3 mm	0,3 mm	0,1 mm	3 mm	1,5 mm	1,1 mm	Compute
3	ISO 5835-02	ISO 5835-HA-2,0-25	1,9 mm	1,5 mm	1,0 mm	25 mm	2 mm	2 mm	0,6 mm	0,4 mm	0,39 mm	0,1 mm	4 mm	2,0 mm	1,3 mm	Compute
4	ISO 5835-09	ISO 5835-HA-2,0-20	1,9 mm	1,5 mm	1,0 mm	20 mm	2 mm	2 mm	0,6 mm	0,4 mm	0,39 mm	0,1 mm	4 mm	2,0 mm	1,3 mm	Compute
5	ISO 5835-03	ISO 5835-HA-2,7-25	2,3 mm	2,5 mm	1,2 mm	25 mm	2,5 mm	2,5 mm	1,0 mm	0,4 mm	0,6 mm	0,2 mm	5 mm	2,7 mm	1,9 mm	Compute
6	ISO 5835-10	ISO 5835-HA-2,7-20	2,3 mm	2,5 mm	1,2 mm	20 mm	2,5 mm	2,5 mm	1,0 mm	0,4 mm	0,6 mm	0,2 mm	5 mm	2,7 mm	1,9 mm	Compute
7	ISO 5835-04	ISO 5835-HA-3,5-25	2,6 mm	2,5 mm	1,5 mm	25 mm	3 mm	2,5 mm	1,250 mm	1 mm	0,8 mm	0,2 mm	6 mm	3,5 mm	2,4 mm	Compute
8	ISO 5835-11	ISO 5835-HA-3,5-20	2,6 mm	2,5 mm	1,5 mm	20 mm	3 mm	2,5 mm	1,250 mm	1 mm	0,8 mm	0,2 mm	6 mm	3,5 mm	2,4 mm	Compute
9	ISO 5835-15	ISO 5835-HA-3,5-22	2,6 mm	2,5 mm	1,5 mm	22 mm	3 mm	2,5 mm	1,250 mm	1 mm	0,8 mm	0,2 mm	6 mm	3,5 mm	2,4 mm	Compute
10	ISO 5835-16	ISO 5835-HA-3,5-30	2,6 mm	2,5 mm	1,5 mm	30 mm	3 mm	2,5 mm	1,250 mm	1 mm	0,8 mm	0,2 mm	6 mm	3,5 mm	2,4 mm	Compute
11	ISO 5835-05	ISO 5835-HA-4,0-25	2,4 mm	2,5 mm	1,5 mm	25 mm	3 mm	2,5 mm	1,50 mm	1 mm	0,8 mm	0,2 mm	6 mm	4,0 mm	2,9 mm	Compute
12	ISO 5835-12	ISO 5835-HA-4,0-20	2,4 mm	2,5 mm	1,5 mm	20 mm	3 mm	2,5 mm	1,50 mm	1 mm	0,8 mm	0,2 mm	6 mm	4,0 mm	2,9 mm	Compute
13	ISO 5835-06	ISO 5835-HA-4,5-25	4,6 mm	3,5 mm	2,8 mm	25 mm	4 mm	2,5 mm	1,750 mm	1 mm	1,0 mm	0,3 mm	8 mm	4,5 mm	3,0 mm	Compute
14	ISO 5835-13	ISO 5835-HA-4,5-20	4,6 mm	3,5 mm	2,8 mm	20 mm	4 mm	2,5 mm	1,750 mm	1 mm	1,0 mm	0,3 mm	8 mm	4,5 mm	3,0 mm	Compute
15	ISO 5835-17	ISO 5835-HA-4,5-22	4,6 mm	3,5 mm	2,8 mm	22 mm	4 mm	2,5 mm	1,750 mm	1 mm	1,0 mm	0,3 mm	8 mm	4,5 mm	3,0 mm	Compute
16	ISO 5835-18	ISO 5835-HA-4,5-30	4,6 mm	3,5 mm	2,8 mm	30 mm	4 mm	2,5 mm	1,750 mm	1 mm	1,0 mm	0,3 mm	8 mm	4,5 mm	3,0 mm	Compute
17	ISO 5835-07	ISO 5835-HA-5,0-25	4,6 mm	3,5 mm	2,8 mm	25 mm	4 mm	2,45 mm	1,750 mm	1 mm	1,0 mm	0,3 mm	8 mm	5,0 mm	3,5 mm	Compute
18	ISO 5835-14	ISO 5835-HA-5,0-20	4,6 mm	3,5 mm	2,8 mm	20 mm	4 mm	2,45 mm	1,750 mm	1 mm	1,0 mm	0,3 mm	8 mm	5,0 mm	3,5 mm	Compute

Figure 30 - Above, iPart table including multiple HA screws. Below, some of the generated 3D models.

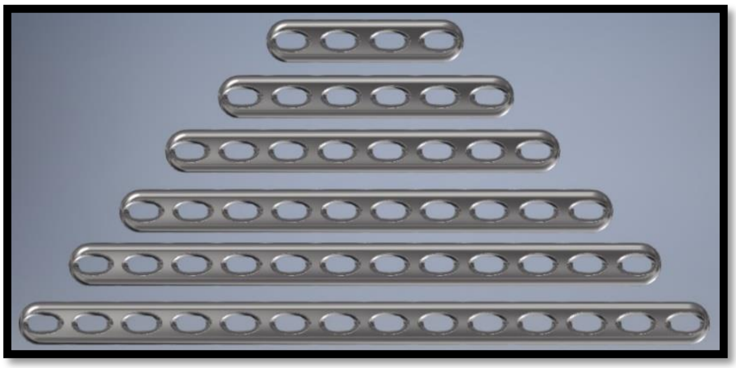


Figure 31 - Different sizes of LC-DCP 3.5 plates, generated by the iPart function

Manufacturing process

Manufacturing was a learning process which allowed to identify what is possible, what is correct and what is ideal for the production of bone plates and screws. Resources and services that are available in the Ecuadorian industry were used and evaluated. Parallelly, other (currently unavailable) systems and tools were studied and compared to determine if they are more suitable for this application. Medical grade products require specialized materials, treatments and tests that must be imported, implemented or industrialized to develop this kind of industry in Ecuador. Lessons learned along this process constitute a first approach to a highly scientific field of product development.

The first and most time-consuming part of the manufacturing process is machining. For plates, 3-axis milling was found to be perfectly adequate, although high torque and power would be necessary to use bigger tools and reduce the machining time. Also, programs and fixtures designed to mill multiple plates in a single run would be useful to reduce setup times and overall cutting distances. For mass production, speed and feeds would also need to be optimized, finding a balance between productivity and tool life. All things considered, machining LC-DCP plates locally would be perfectly viable.

In contrast, for bone screws, turning in a lathe is challenging for various reasons. The combination of material poor machinability, high length-to-diameter ratio, small diameters and high stress threading operations produced part breakages or low dimensional accuracy and less than ideal surface finish. With common CNC lathes, very low speeds and feeds are required to get acceptable results. This translates into long machining times and high costs. Swiss style lathes are a much better option for bone screws because they use a guide bushing system to hold the part near the cutting tool. The part can move in and out of the bushing to expose the area that is being cut. The bushing system provides rigidity to the part and reduces chatter improving tolerances, especially for small diameter parts. Additionally, standardized threading inserts would need to be imported to meet the required dimensions and tolerances. For sockets, EDM by penetration results were geometrically correct but the eroded finish was problematic considering the end use of the screws. Rotary broaching requires imported tools but would produce significantly better results in much shorter time.

Surface treatment needs further study and testing to determine the effectiveness of different methods. Nevertheless, mechanical polishing proved to be very effective on plates, but time consuming and inapplicable for screws. Apart from that, it does not passivate the surface, needing subsequent acid bath passivation. This combination takes time but has the advantage of a reduced probability of failure because of its simplicity, making it a viable alternative for plates. On the other hand, electropolishing needs precise control of electrolyte composition, current density, temperature and time making it more prone to failure, but can produce a smooth and shiny fully passivated surface. Electropolishing is the industry standard for surface treatment of medical implants due to its all-in-one nature and is suitable for both plates and screws. Developing an electropolishing setup, including custom electrodes and racks for plates and screws would be worth the effort for industrial production.

Metrology Control

Some dimensions are critical for the functionality of the LC-DCP plating system. In the case of screws, dimensions of the socket, head and thread are important for compatibility with plates, taps and tightening tools. As explained before, the turning process was problematic due to vibrations and bending of the screws, so it is necessary to verify the accuracy of the parts. The following table compares the standardized dimensions and the actual measurements for each screw.

Table 5 - Metrology control of bone screws based on the ISO 5835 standard (ISO/TC 150/SC 5, 1991).

	HA 3.5 x 25		HA 4.5 x 25		HB 4.0 x 25		HB 6.5 x 35	
	Target	Measured	Target	Measured	Target	Measured	Target	Measured
d_1	3.35 – 3.50	**3.57**	4.35 – 4.50	**4.68**	3.85 – 4.00	**3.62 – 3.88**	6.35 – 6.50	**6.60**
d_2	5.85 – 6.00	**5.98**	7.85 – 8.00	**8.02**	5.85 – 6.00	**6.03**	7.85 – 8.00	**8.04**
d_4	---	---	---	---	2.25 – 2.40	**2.34**	4.35 – 4.50	**4.52**
P	1.18 – 1.32	**1.26**	1.68 – 1.82	**1.71**	1.68 – 1.82	**1.76**	2.68 – 2.82	**2.75**
SW	2.51 – 2.55	**2.58**	3.51 – 3.56	**3.55**	2.51 – 2.55	**2.61**	3.51 – 3.56	**3.54**

Table 5 includes the dimensions that could be measured, including thread outer diameter and pitch, head maximum diameter and socket width (see Annexes A and B for definitions). These measurements give an idea of the accuracy of the turning process, but other dimensions are lacking. Most dimensions are within tolerance or not too far off and accuracy can be improved by adjusting some machining parameters. However, threads are an exception; the major diameter d_1 is totally out of tolerance in all cases which means that the threading process is inadequate for this application. Moreover, the HB 4.0 screw had an inconsistent diameter throughout its length. This suggests that single point threading should be replaced by a more adequate process such as thread whirling in which the cutter surrounds the screw avoiding wobble and bending.

For plates, there are no standardized dimensions and tolerances to meet and functionality is the criteria to judge the geometry. Cross sectional area is important to meet bending tests, but that is out of the scope of the project. Length and hole separation is relevant because doctors are used to industry standard dimensions, but even a seemingly large variation (±1mm per hole) would not be problematic. Unfortunately, the most critical geometric feature is the dynamic compression hole and it is very hard to do a dimensional control with standard tools. Nevertheless, the interface and mobility between the screws and the plates can be checked visually. Both plates exceeded the minimum required angular freedom of the screws: 25° inclination of the screws in the longitudinal plane, and 7° inclination in the transversal plane (AO Foundation, n.d.). Table 6 lists the basic dimensions of the plates, simply as a reference.

Table 6 - Measured dimensions of LC-DCP plates

	LC-DCP 3.5mm	LC-DCP 4.5mm
Length	84.7 mm	110.4 mm
Width	12.4 mm	16.6 mm
Thickness	4.2 mm	5.6 mm
Holes separation	14.1 mm	18.4 mm

Proposed Industrial Setup

In general, the mass production of bone plates and screws would not be exceedingly difficult but would require a considerable investment to acquire resources that are not available locally, to finance the required research and development process and to implement processing and testing systems. The following flow diagram (Figure 32) summarizes a suitable production line based on the information obtained during the project, including machinery, tooling and applicable standards.

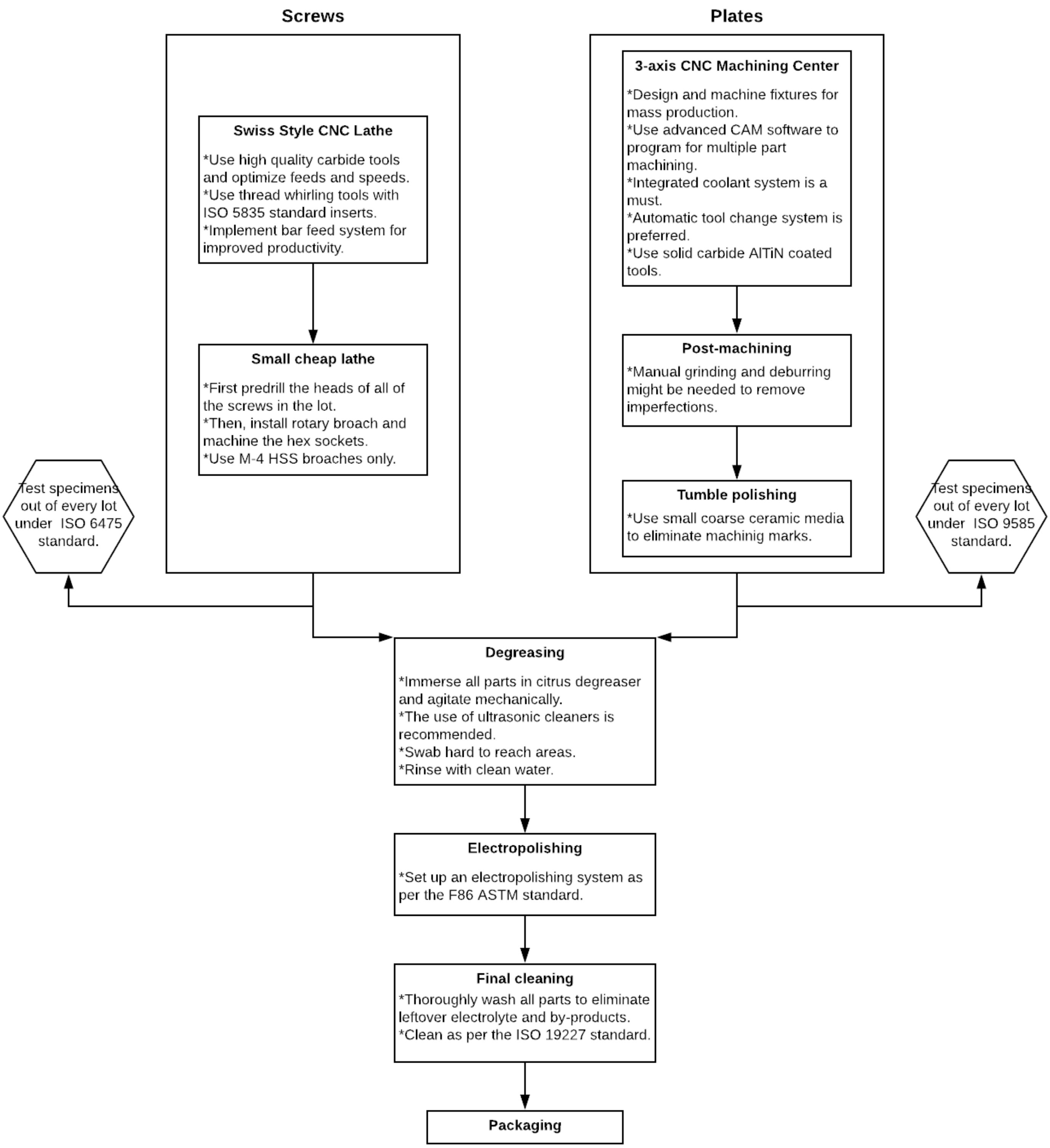


Figure 32 - Industrial setup for mass production of orthopedic implants for bone fractures (ASTM International, 2013; ISO/TC 150/SC 5, 1989, 1990, 2018).

As shown in Figure 32, there are many things needed for mass production, including but not limited to:

- A swiss style CNC lathe.
- A simple lathe for the broaching process.
- A 3-axis machining center capable of machining stainless steel continuously, with coolant system and ATC system.
- A tumble polishing system and ceramic media.
- An electropolishing system with custom racks for plates and screws.
- Custom fixtures for plate machining.
- Solid carbide AlTiN coated endmills in various shapes (ball, flat, drill bit) and sizes.
- Thread whirling tools and ISO 5835 inserts for each kind of thread.
- M-4 HSS rotary broaches and holders for 2.5 mm and 3.5 mm hex sockets.
- 316L stainless steel ¼" thick sheets.
- 316L stainless steel ⅜" diameter rods.
- Adequate metrology equipment.

Cost analysis

The production costs of these products are hard to estimate due to the complexity of the process. Each step would have to be valued based on time, materials, labor, machine depreciation and other factors. Moreover, production time and the use of resources is vastly different in mass production. To try and estimate the potential cost of plates and screws, strong simplifications and assumptions were made: significant tool life increase due to low material removal rates; a $5 hourly cost for labor; a 60% increase after import of the raw material and tools; a 50% additional cost over materials and manufacturing to account for managing, sales, rent and miscellaneous.

Using data from tool manufacturers, CAM software, standardized treatments and the experience from this project, rough estimations were done for the duration of each stage of the production process. The results are shown in Table 7. This is the most important data for the cost analysis, considering that even mass production of these parts takes a long time.

Table 7 - Estimated manufacturing times

	LC-DCP 3.5 6 holes	LC-DCP 4.5 6 holes	HA 3.5x25	HA 4.5x25	HB 4.0x25	HB 6.5x35
Machining	2 hrs.	3 hrs.	0.2 hrs.	0.2 hrs.	0.3 hrs.	0.3 hrs.
Deburring	0.2 hrs.	0.25 hrs.	0	0	0	0
Degreasing	0.25 hrs.	0.25 hrs.	0.15 hrs.	0.15 hrs.	0.15 hrs.	0.15 hrs.
Electropolishing	0.2 hrs.	0.2 hrs.	0.05 hrs.	0.05 hrs.	0.05 hrs.	0.05 hrs.
Cleaning	0.1 hrs.	0.1 hrs.	0.05 hrs.	0.05 hrs.	0.05 hrs.	0.05 hrs.
Total	**2.75 hrs.**	**3.8 hrs.**	**0.45 hrs.**	**0.45 hrs.**	**0.55 hrs.**	**0.55 hrs.**

After time was considered, an average hourly cost was necessary to get part manufacturing costs. The total hourly cost is the sum of various factors including tooling, machine depreciation, maintenance and labor. This is specific for each process, but machining is the most critical for two reasons: it is the longest step and parts are machined one by one, although batch production reduces setup time, labor requirements, tool changes and optimizes some cutting operations. In contrast, processes such as cleaning and electropolishing can treat many parts at a time, so they are much more cost efficient. For this reason, the cost of machining will be used as the average cost of manufacturing for estimations.

Machine depreciation

CNC machines can be costly and probably the biggest necessary investment for this business. Annexes C and D include quotes for a suitable mill and lathes. The selected mill is a small machine that is capable of machining eight 4.5mm LC-DCP plates with 12 holes or sixteen 4.5mm LC-DCP plates with 10 or less holes in a single run. Including all applicable automation systems (ATC, flood coolant system, probing systems), the milling machine would cost $26000 approximately, considering that duties and taxes for CNC machinery are less than 20%. For turning, two suitable Swiss style lathes were found: a new Chinese lathe and a used Japanese lathe. The approximate costs would be $45000 for the first and $85000 for the latter. With a 5 year depreciation term, 2000 working hours and a 20% of inactivity (for maintenance and setup), the hourly costs would be $3.25 for milling and $5.60-$10.60 for turning.

Tooling costs

Tools used for CNC machining can be expensive and must be replaced. Tool life can not be accurately calculated for complex cutting operations, but it is clear that it is highly dependent on cutting speed. Additionally, tool life is affected by tool chatter, work hardening and heat. Modern coated solid carbide tools are designed for very high material removal rates and long life. At high speeds and feeds these tools last 30 to 180 minutes before the surface finish is affected. However, the milling of LC-DCP plates has some particularities that might positively affect tool life. Most importantly, the prevalent cutting operations do not allow for high material removal rates, so stress on tools is low and heat generation is moderate. Nevertheless, cutting depths and widths must be controlled to maximize tool life. Also, adequate tools should be selected for each operation, with tool wear being one of the most important factors. For example, modular face milling tools with round carbide inserts have lower hourly costs because inserts can be rotated multiple times when edges lose sharpness. Table 8 includes examples of tools which can be used for the machining of LC-DCP plates and their estimated hourly costs.

Table 8 - Tooling hourly cost based on expected tool life

	Tormach modular toroidal 16 mm cutter	**Lakeshore ¼" flat end mill**	**Niagara Cutter 6mm ball end mill**	**Niagara Cutter 3mm ball end mill**
Operation	Facing	Roughing	3D Contours	Finishing
Max. material removal rate	7.6 $^{cm^3}/_{min}$	6.4 $^{cm^3}/_{min}$	3 $^{cm^3}/_{min}$	0.75 $^{cm^3}/_{min}$
Est. material removal rate	4 $^{cm^3}/_{min}$	0.5 $^{cm^3}/_{min}$	0.02 $^{cm^3}/_{min}$	0.01 $^{cm^3}/_{min}$
Expected tool life	2 hrs.	5 hrs.	10 hrs.	10 hrs.
Tool cost	$33	$32	$34	$29
Hourly cost	**$16.5/h**	**$6.4/h**	**$3.4/h**	**$2.9/h**

To get the average cost of tooling, the cutting time of each tool is considered. Facing and finishing take approximately 10% of the cutting time each, whereas Roughing and 3D contouring take 30% and 50% of the time respectively. The resulting hourly cost of tooling is $5.60/h (weighted average).

Tooling cost for bone screws turning is less complex. Speeds and feeds can be optimized for fast production and tool life can be set at one hour. Common carbide inserts have two to four edges, so an average life of three hours per insert can be expected. Inserts costs can vary between $20 to $40 (including import fees). With these assumptions, the average hourly cost of tooling would be $10.

Maintenance and labor costs

Although normal servicing and random break outs depend heavily on machine quality and use (or abuse), a conservative estimation for maintenance cost would be half of the machine depreciation. This translates to $1.65/h for milling and $2.80-$5.30 for turning. As stated earlier, labor cost is set to $5/h, but human involvement is limited in CNC machining, so workers can multitask. This means that $2/h of labor per machine is plenty.

Total machining cost

Table 9 summarizes the hourly costs of CNC milling LC-DCP plates and CNC turning bone screws.

Table 9 - Hourly cost of machining

	CNC milling	CNC turning
Machine depreciation	$3.25	$5.60-$10.60
Tooling	$5.60	$10
Maintenance	$1.65	$2.80-$5.30
Labor	$2.00	$2.00
Electricity	$0.20	$0.40
Total hourly cost	**$12.70**	**$20.80-$28.30**

Based on these results, it is fair to say that the machining cost of plates should be around $15/h and the machining cost of screws should be around $25/h.

Materials costs

The material cost estimation for plates is based on 24" x 24" sheets with an expected cost of $700 (listed on McMASTER-CARR for $447.24). More than 200 LC-DCP 3.5 6-hole plates can be machined out of 1 sheet, including spaces between plates and holding areas, so the unit cost would be $3.50. The unit cost of LC-DCP 4.5 6-hole plates would be $5.30 (132 pieces per sheet). For screws, a 6 ft. rod would cost approximately $80 (listed for $51.28). The unit cost for 25 mm and 35 mm long screws would be $1.35 and $1.80 respectively.

Other manufacturing costs

Machining is the most important process to produce plates and screws. Nonetheless, other steps listed in Table 5 have a cost too. Necessary information to make a thorough analysis of each stage is unavailable but a $20/hour rate will be used for processes other than machining.

Cost per part

The total cost for each part is shown in Table 10. Prices of a US-based online supplier (eSutures) are included for comparison.

Table 10 - Estimated costs

	LC-DCP 3.5 6 holes	LC-DCP 4.5 6 holes	HA 3.5x25	HA 4.5x25	HB 4.0x25	HB 6.5x35
Manufacturing	$45	$61	$10	$10	$12.50	$12.50
Material	$3.50	$5.30	$1.35	$1.35	$1.35	$1.80
Miscellaneous	$24.25	$33.15	$5.68	$5.68	$6.93	$7.15
Total cost	**$72.75**	**$99.45**	**$17.03**	**$17.03**	**$20.78**	**$21.45**
US price	**$125.30**	**$156.10**	**$16.28**	**$15.93**	**$17.33**	**$32.55**

The total cost of production is an estimate for the local manufacturing, once the industry is up and running and does not include R&D, testing and certification costs. On the other hand, taxes, duties, insurance, brokerage and the importer's profit must be added to the US prices to get local market prices of imported plates and screws. For example, an imported LC-DCP 3.5 plate with 6 holes could easily have a price of over $180 including a 20% import cost and a 30% gross profit. The locally produced plate could have a 100% gross profit and still be competitive at $145. Under the same logic, an imported HB 4.0x25 screw, which is the least attractive part to produce locally, would cost more than $26. At that same price, the local product would have a 25% gross profit which is too low to say beyond doubt that there could be any net profit. Anyhow, business efficiency and frugality could reduce the non-productive costs (Miscellaneous), which amount to one third of the estimated cost of each part, especially if the manufacturing volume was high enough.

Conclusions

- This research and development project covered various aspects of the design and manufacturing of LC-DCP orthopedic plates and cortical and cancellous bone screws for the internal fixation of bone fractures. CAD designs of the most common forms of these medical devices were modelled, based on the characteristics and requirements established by the AO Foundation literature and the applicable standards. Design requirements were analyzed and applied to ensure performance and compatibility with other commercial products and tools. 316L stainless steel was the material of choice after a thorough comparison with other common surgery grade metals. Machining tooling and parameters were selected for this particular material. Different methods to obtain the necessary surface finish and adequate passivation were also analyzed. In the end, prototypes of each of the selected plates and screws were produced to usable condition using the available resources. This whole process allowed to have an insider view to the requirements for medical device manufacturing, locally.
- After in-depth analysis, each method used to create the prototypes was determined to be either usable or not for mass manufacturing. For every unsuitable method, an alternative was proposed. For example, the time consuming and contaminating EDM process for socket machining should be replaced by rotary broaching. The manufacturing of implantable parts requires a very controlled process and can be complicated. However, the required technology, tools and materials are available to the general public. Ecuador has the human resources to develop this industry and there is a market for the products. Machines, tools and materials must be imported but that should not be

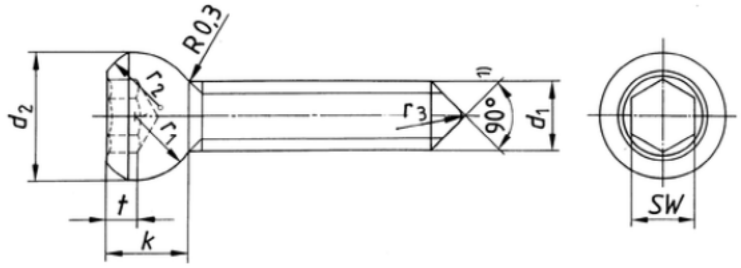
a limiting factor. Scientific and industrial research are a necessity in this field, considering that it can beneficial for society

- Finally, it is important to remember that medical products must be profitable to make the industry viable. According to doctors, the prices of this devices are extremely high in Ecuador. Even in the US they can be quite expensive. Estimations show that plates can be made with moderate costs, leaving a margin for profit. In contrast, screws are hard to machine and that makes them expensive, but it should be noted that plates and screws are a system. The profit made by plates could offset the small loses on screws. Further economic analysis is necessary to determine the viability of the business, but at a technical level the local production of this parts is totally viable.

ANNEXES

Annex A – Design requirements of cortical bones

Figure 1 — Screw with shallow thread (HA)



1) This may be 60° for self-cutting screws.

Table 1 — Dimensions of HA series screws

Code and diameter of thread	Nominal diameter d_1	d_2	d_2 tol.	k ≃	r_1 $^{+0,25}_{0}$	r_2 ≃	r_3 ≃	SW F10[1)]	t min.
HA 1,5	1,5	3	$^{0}_{-0,10}$	1,6	1,5	1,5	0,3	1,5	0,8
HA 2,0	2	4		1,9	2	2	0,4	1,5	1,0
HA 2,7	2,7	5	$^{0}_{-0,15}$	2,3	2,5	2,5	0,4	2,5	1,2
HA 3,5	3,5	6		2,6	3	2,5	1	2,5	1,5
HA 4	4	6		2,4	3	2,5	1	2,5	1,5
HA 4,5	4,5	8		4,6	4	2,5	1	3,5	2,8
HA 5	5	8		4,6	4	2,5	1	3,5	2,8

1) F10 = $\left\{ \begin{matrix} +0,047 \\ +0,007 \end{matrix} \right.$ for $SW \leqslant 3$ mm

F10 = $\left\{ \begin{matrix} +0,058 \\ +0,010 \end{matrix} \right.$ for $SW > 3$ mm

Figure 33 – HA screw body (ISO/TC 150/SC 5, 1991)

Figure 2 — Shallow thread (HA)

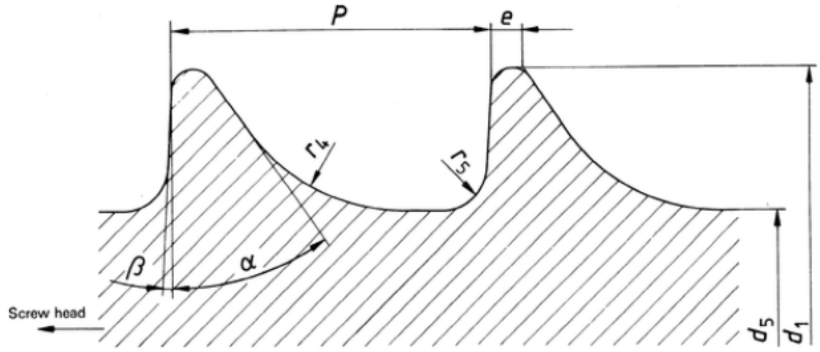


Table 2 — Dimensions of HA thread

Code and diameter of thread	d_1 $^{0}_{-0,15}$	d_5	d_5 tol.	e ≃	P	r_4 ≃	r_5 ≃	α ≃	β ≃
HA 1,5	1,5	1,1	$^{0}_{-0,10}$	0,1	0,5	0,3	0,1	35°	3°
HA 2,0	2	1,3		0,1	0,6	0,4	0,1	35°	3°
HA 2,7	2,7	1,9	$^{0}_{-0,15}$	0,1	1	0,6	0,2	35°	3°
HA 3,5	3,5	2,4		0,1	1,25	0,8	0,2	35°	3°
HA 4	4	2,9		0,1	1,5[1) 2)]	0,8	0,2	35°	3°
HA 4,5	4,5	3		0,1	1,75	1	0,3	35°	3°
HA 5	5	3,5		0,1	1,75	1	0,3	35°	3°

Figure 34 – HA screw thread (ISO/TC 150/SC 5, 1991)

Annex B – Design requirements for cancellous bone

Figure 3 — Screw with deep thread (HB)

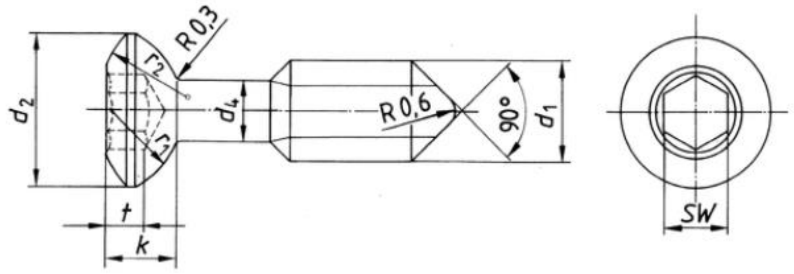


Table 3 — Dimensions of HB series screws

Code and diameter of thread	Nominal diameter d_1	d_2 $^{0}_{-0,15}$	d_4 $^{0}_{-0,15}$	k ≃	r_1 $^{+0,25}_{0}$	r_2 ≃	SW F10[1]	t min.
HB 4	4	6	2,4	2,9	3	2,5	2,5	1,5
HB 6,5	6,5	8	4,5	4,6	4	2,5	3,5	2,8

1) F10 = $\left\{ \begin{matrix} +0,047 \\ +0,007 \end{matrix} \right.$ for $SW \leq 3$ mm

F10 = $\left\{ \begin{matrix} +0,058 \\ +0,010 \end{matrix} \right.$ for $SW > 3$ mm

Figure 35 – HB screw body (ISO/TC 150/SC 5, 1991)

Figure 4 — Deep thread (HB)

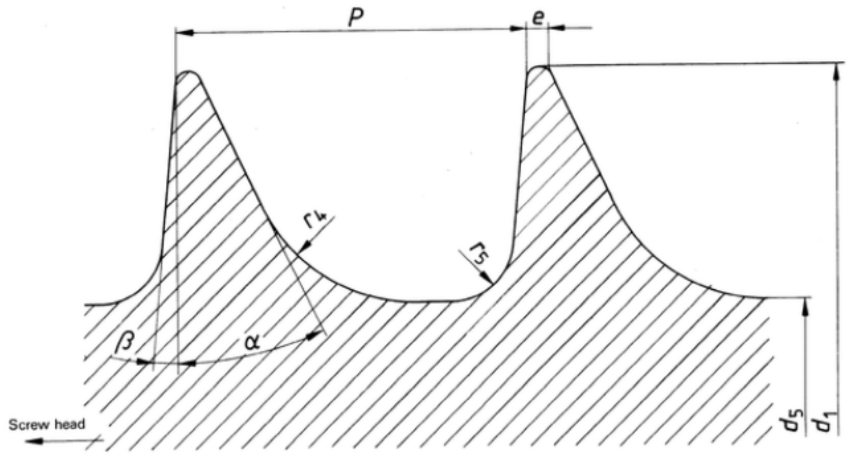


Table 4 — Dimensions of HB thread

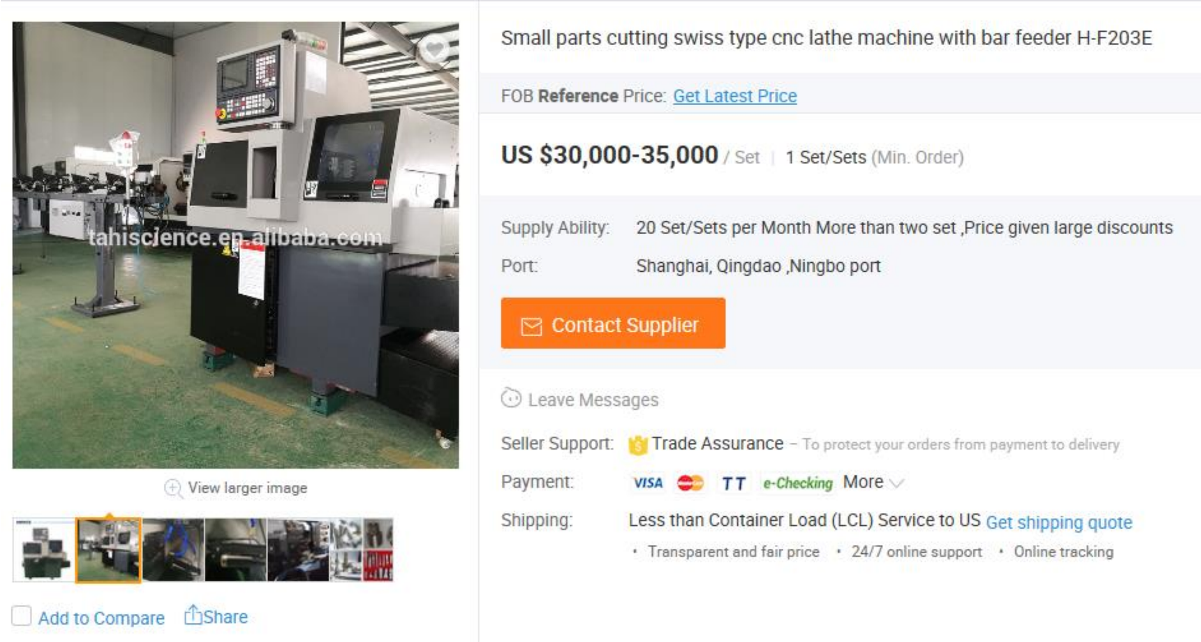
Code and diameter of thread	d_1 $^{0}_{-0,15}$	d_5 $^{0}_{-0,15}$	e ≃	P	r_4 ≃	r_5 ≃	α ≃	β ≃
HB 4	4	1,9	0,1	1,75[1) 2)]	0,8	0,3	25°	5°
HB 6,5	6,5	3	0,2	2,75	1,2	0,8	25°	5°

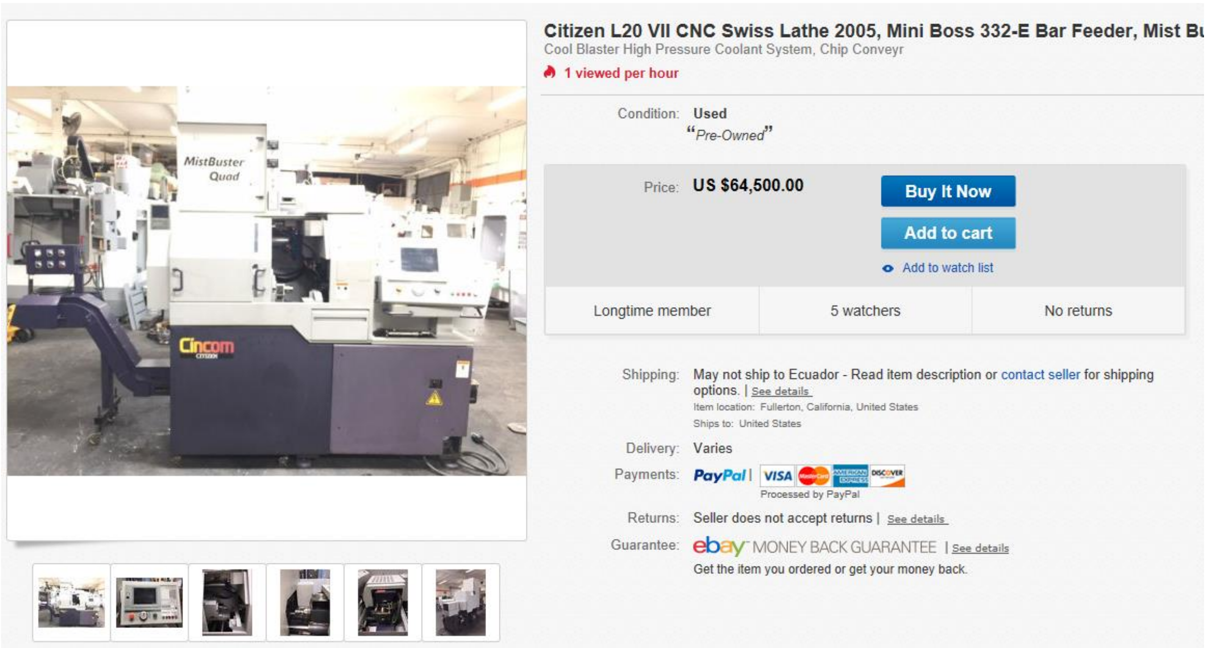
Figure 36 – HB screw thread (ISO/TC 150/SC 5, 1991)

Annex C – CNC mill quote

Item	Price	Quantity
32084 - PCNC 770 Series 3 PCNC 770 Oiler: 31302 - Manual Oiler PCNC 770 Owner's Kit: 31748 - PCNC 770 Owner's Kit	$6,850.00	1
34442 - Full Enclosure Kit for PCNC 770	$2,460.00	1
34668 - Machine Arm for Tormach PCNC 1100/PCNC 770 with Full Enclosure	$195.00	1
31367 - PCNC 770 Flood Coolant Kit	$185.35	1
34437 - Cable Kit for Tormach PCNC Mills	$39.95	1
31446 - Lifting Bar	$93.21	1
35286 - PathPilot Controller	$715.00	1
38207 - Wireless Network Adapter for PathPilot Controller	$13.95	1
30616 - Jog Shuttle	$84.02	1
30615 - Standard LCD Monitor	$162.80	1
37759 - Waterproof Mini Keyboard	$39.50	1
31289 - USB Bulkhead Port Assembly	$32.88	1
31947 - Basic 3 Piece Indicator Set	$75.16	1
32570 - Automatic Tool Changer for PCNC 770 Series 3	$4,300.00	1
32329 - ATC Pressure Sensor	$126.50	1
32436-PKG - PCNC 770 Power Drawbar	$1,193.50	1
31728 - Power Drawbar Foot Pedal Kit	$68.45	1
31945 - California Air Tools 4610S Air Compressor	$248.00	1
31991 - Pneumatic Hose Kit for Power Drawbar/ATC/Fogbuster	$16.23	1
32457 - FRL Filter-Regulator-Lubricator	$89.00	1
30553 - 5" Machinist Vise	$495.00	1
31687 - 2pc Vise Alignment Keys with Screws for 5" Machinist Vise	$14.03	1
32580 - Clamp Kit for 5/8" T-Slots (58 Pcs.)	$64.63	1
32284 - TTS CNC Operator Set with Tormach Tool Assistant	$795.00	1
31829 - TTS ER Collet Holder: ER20	$34.75	1
30584 - ER20 Collet Set (30 Pcs.)	$372.00	1
34086 - ER20/ER16 Deluxe TTS Wrench Set	$29.95	1
31875 - Tool Setter	$862.40	1
31925 - Floating Tramp Oil Collection Pillow	$10.35	1
31386 - Machine Oil	$34.50	1
31750 - Full Synthetic Coolant - 1 Gal.	$29.95	1
Total	**$19,731.06**	Update Quantities

Annex D – CNC Swiss style lathe quotes





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